EXHIBIT 23

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

QXMédical, LLC, *Plaintiff and Counterclaim Defendant*, v. Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc., *Defendants and Counterclaim Plaintiffs*.	**Case No. 0:17-cv-01969 (PJS/TNL)**

EXPERT REPORT OF PETER T. KEITH ON INFRINGEMENT, CLAIM COVERAGE, AND LACK OF ACCEPTABLE NONINFRINGING ALTERNATIVES

EXHIBIT 23

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I. INTRODUCTION

A. Assignment

1. My name is Peter T. Keith. I am an engineer, inventor, and independent consultant in the medical device industry. I have over 30 years of experience in research and development of medical devices, and in particular catheters for cardiovascular procedures.

2. I have been retained as an independent expert on behalf of Vascular Solutions LLC, Teleflex Innovations S.à.r.l., and Arrow International, Inc., whom I will refer to collectively in this report as Vascular Solutions or VSI.

3. I have been asked to provide my expert opinions and testimony in the patent dispute between Vascular Solutions and QXMédical, LLC. In particular, I have been asked to analyze whether QXMédical's Boosting Catheter infringes the following claims of Vascular Solutions' patents:

- Claims 3 and 8 of U.S. Patent No. 8,048,032 (the '032 Patent)
- Claim 9 of U.S. Patent No. 8,142,413 (the '413 Patent)
- Claims 1, 3, and 8 of U.S. Patent No. RE45,380 (the '380 Patent)
- Claims 25, 30, 31, 32, and 48 of U.S. Patent No. RE45,760 (the '760 Patent)
- Claims 25, 32, 36, 52, and 53 of U.S. Patent No. RE45,776 (the '776 Patent), and
- Claims 25, 34, and 53 of U.S. Patent No. RE46,116 (the '116 Patent).

I will refer to these claims throughout this report as the asserted claims.

4. In addition to analyzing whether QXMédical's Boosting Catheter infringes the asserted claims, I was asked to analyze whether the asserted claims cover Vascular Solutions' GuideLiner and TrapLiner devices and Boston Scientific Corporation's Guidezilla devices.

5. Finally, I was asked to analyze whether Terumo's Heartrail 5-in-6 device or the catheters described in U.S. Patent No. 5,527,292 to Adams et al. ("Adams"), U.S. Patent No.

5,290,247 to Crittenden ("Crittenden"), and U.S. Patent No. 5,439,445 to Kontos ("Kontos") would be acceptable noninfringing alternatives to the Boosting Catheter if made commercially available.

6. This report summarizes the opinion testimony I expect to offer if called to testify at trial. This report is based on the information currently available to me. If additional information becomes available, I reserve the right to supplement and/or amend my analysis and my opinions. In particular, I understand that QXMédical or one of its experts may offer opinions regarding the questions I have analyzed in this report and I reserve the right to review and respond to that testimony.

7. If I am called to testify at trial, at a deposition, or at another hearing or proceeding about this report, I may cite other documents or information similar to what I have specifically identified in this report. I may also use graphics, animations, pictures, demonstrations, and/or other audio/visual aids to explain my analysis and opinions. In particular, I may use product samples of the Boosting Catheter, GuideLiner, Guidezilla, and other related products discussed in this report.

B. Summary of Opinions

1. Infringement

8. In order to form my opinions on infringement, I reviewed the Vascular Solutions patents, the asserted claims, and various information produced during discovery in this case, including technical documents and deposition testimony. I personally attended the depositions of QXMédical's chief technical officer, Fernando Di Caprio. In addition, I manually inspected and performed various laboratory tests on samples of the Boosting Catheter device.

9. Based on my review of these materials relating to the Boosting Catheter, I have formed opinions about whether the Boosting Catheter meets the limitations of each of the

asserted claims. For claims to the device itself, I have also reached a conclusion about whether QXMédical infringes the claims by making, using, selling, or offering for sale the Boosting Catheter. For asserted claims covering methods of using the device or systems including the device and a guide catheter, I have not reached an ultimate conclusion about whether QXMédical infringes the claims. Instead, I have reached a conclusion about whether physicians (generally cardiologists) using the Boosting Catheter or combining it with a guide catheter infringe the method and system claims. I have also formed opinions about whether the Boosting Catheter constitutes a material part of the invention of the asserted claims, whether the Boosting Catheter is especially made or adapted for use in the method or system of the asserted claims, and whether the Boosting Catheter is a staple article or commodity of commerce suitable for substantial noninfringing use. I have not formed opinions regarding QXMédical's knowledge or intent, nor whether QXMédical has induced or contributed to physicians' infringement. Those questions are beyond the scope of my analysis.

10. **The '032 Patent:** It is my opinion that each model of the Boosting Catheter meets the limitations of claim 3 of the '032 Patent and that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claim 8 of the '032 Patent. It is my opinion that QXMédical infringes these claims when it makes, uses, sells, offers for sale, or imports one of these devices in or into the United States.

11. **The '413 Patent:** It is my opinion that each model of the Boosting Catheter meets the limitations of claim 9 of the '413 Patent when used for a coronary vascular procedure with a guidewire, standard guide catheter, and an interventional cardiology device (balloon catheter or stent), and that physicians infringe claim 9 of the '413 Patent when using the Boosting Catheter when performing such procedures. It is my opinion that the Boosting Catheter

constitutes a material part of the method of claim 9 of the ’413 Patent, that the Boosting Catheter is especially made or adapted for use in the method of claim 9 of the ’413 Patent, and that the Boosting Catheter is not a staple article or commodity suitable for substantial noninfringing use.

12. **The ’380 Patent:** It is my opinion that each model of the Boosting Catheter meets the limitations of claims 1 and 3 of the ’380 Patent when combined with a guide catheter and that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claim 8 of the ’380 Patent when combined with a guide catheter. It is my opinion that physicians infringe claims 1, 3, and 8 of the ’380 Patent when they assemble and use the combinations just described to perform vascular procedures. It is my opinion that each model of the Boosting Catheter constitutes a material part of the systems of claims 1 and 3 of the ’380 Patent, that each model of the Boosting Catheter is especially made or adapted for the systems of claims 1 and 3 of the ’380 Patent, and that no model of the Boosting Catheter is a staple article or commodity suitable for substantial noninfringing use. Further, it is my opinion that the six French Boosting Catheter constitutes a material part of the system of claim 8 of the ’380 Patent, that the six French Boosting Catheter is especially made or adapted for use in the system of claim 8 of the ’380 Patent, and that the six French Boosting Catheter is not a staple article or commodity suitable for substantial noninfringing use.

13. **The ’760 Patent:** It is my opinion that the six French model of the Boosting Catheter, Model No. BC57-150, meets the limitations of claims 25, 30, 31, 32, and 48 of the ’760 Patent when combined with a guide catheter, and that physicians infringe claims 25, 30, 31, 32, and 48 of the ’760 Patent when they assemble and use the combinations just described to perform vascular procedures. It is my opinion that the six French Boosting Catheter constitutes a material part of the systems of claims 25, 30, 31, 32, and 48 of the ’760 Patent, that the six

French Boosting Catheter is especially made or adapted for use in the systems of claims 25, 30, 31, 32, and 48 of the '760 Patent, and that the six French Boosting Catheter is not a staple article or commodity suitable for substantial noninfringing use.

14. **The '776 Patent:** It is my opinion that each model of the Boosting Catheter meets the limitations of claims 25, 36, and 52 of the '776 Patent and that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claims 32 and 53 of the '776 Patent. It is my opinion that QXMédical infringes these claims when it makes, uses, sells, offers for sale, or imports one of these devices in or into the United States.

15. **The '116 Patent:** It is my opinion that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claims 25 and 34 of the '116 Patent when used for a coronary vascular procedure with a guide catheter and a balloon catheter or stent and that each model of the Boosting Catheter meets the limitations of claim 53 of the '116 Patent in those circumstances. It is my opinion that physicians infringe claims 25, 34, and 53 of the '116 Patent when performing a procedure as just described. It is my opinion that the six French Boosting Catheter constitutes a material part of the methods of claims 25 and 34 of the '116 Patent, that the six French Boosting Catheter is especially made or adapted for the methods of claims 25 and 34 of the '116 Patent, and that the six French Boosting Catheter is not a staple article or commodity suitable for substantial noninfringing use. It is my opinion that each model of the Boosting Catheter constitutes a material part of the method of claim 53 of the '116 Patent, that each model of the Boosting Catheter is especially made or adapted for use in the method of claim 53 of the '116 Patent, and that no model of the Boosting Catheter is a staple article or commodity suitable for substantial noninfringing use.

2. GuideLiner, TrapLiner, and Guidezilla

16. Similar to my opinions on infringement, I have formed opinions regarding which of the asserted claims cover VSI's GuideLiner and TrapLiner catheters and Boston Scientific's Guidezilla catheters based on my review of the asserted patents and claims, information produced in discovery, and my manual inspection and testing of the products.

17. There are four models of the GuideLiner catheter: the first generation of the device, which I will call Version 1 or V1, the second generation of the device, Version 2 or V2, the third generation of the device, Version 3 or V3, and an extra-long version of the device, XL. Models V1, V2, and V3 come in different sizes, for example five French and six French. Model XL comes in six French size only. In summarizing and explaining my opinions in this report and the attached claim charts, I will use the phrase "all versions" to refer to all four versions of the GuideLiner and the phrase "all sizes" to refer to all sizes of those models. Where appropriate, I will specify which models and sizes I am indicating.

18. Similarly, there are two versions of the Guidezilla catheter: a first generation that I will call Version 1 or V1 and a second generation that I will call Version 2 or V2. Version 1 was available in a six French size only; Version 2 is available in several sizes. I will use the same conventions just described to refer to the various versions and sizes of the Guidezilla catheter.

19. **The '032 Patent:** It is my opinion that all versions and sizes of the GuideLiner and Guidezilla meet the limitations of claim 3 of the '032 Patent. It is my opinion that the six French size of each version of the GuideLiner and Guidezilla meets the limitations of claim 8 of the '032 Patent.

20. **The '413 Patent:** It is my opinion that all versions and sizes of the GuideLiner and Guidezilla meet the limitations of claim 9 of the '413 Patent when used for a coronary

vascular procedure with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent).

21. **The '380 Patent:** It is my opinion that all versions and sizes of the GuideLiner and Guidezilla meet the limitations of claims 1 and 3 of the '380 Patent when combined with a guide catheter. It is my opinion that the six French size of each version of the GuideLiner and Guidezilla meets the limitations of claim 8 of the '380 Patent when combined with a guide catheter.

22. **The '760 Patent:** It is my opinion that the six French size of each version of the GuideLiner, Guidezilla, and TrapLiner meets the limitations of claims 25, 30, 31, 32, and 48 of the '760 Patent when combined with a guide catheter, except that the GuideLiner V2 does not meet the limitations of claim 32 of the '760 Patent.

23. **The '776 Patent:** It is my opinion that all versions and sizes of the GuideLiner, Guidezilla, and TrapLiner catheters meet the limitations of claim 25 of the '776 Patent and that the six French sizes of those catheters meet the limitations of claim 32 of the '776 Patent. It is my opinion that all sizes of the GuideLiner V3 and the TrapLiner meet the limitations of claim 36 of the '776 Patent. It is my opinion that all versions and sizes of the GuideLiner, Guidezilla, and TrapLiner except GuideLiner V2 meet the limitations of claim 52 of the '776 Patent and that the six French sizes of those catheters meet the limitations of claim 53 of the '776 Patent.

24. **The '116 Patent:** It is my opinion that the six French size of each version of the GuideLiner, Guidezilla, and TrapLiner meets the limitations of claims 25 and 34 of the '116 Patent when used for a coronary vascular procedure with a guide catheter and that all versions and sizes of the GuideLiner, GuideZilla, and TrapLiner meet the limitations of claim 52 of the '116 Patent in those circumstances.

3. Acceptable noninfringing alternatives

25. It is my opinion that neither the Heartrail 5-in-6 catheter, Adams, Crittenden, nor Kontos embodies or describes a device that would be an acceptable noninfringing alternative to the Boosting Catheter if made commercially available in the United States. Although those devices would not infringe the asserted claims, they each suffer from a number of practical drawbacks that would make them unacceptable alternatives. I describe these drawbacks in greater detail in Part VI below.

C. Qualifications

26. I summarize my educational background and career history in the following paragraphs. My curriculum vitae is attached as Appendix A to this report.

27. I received a Bachelor of Science degree with High Distinction from the University of Minnesota in 1987.

28. During my undergraduate training, I began working as an engineering intern in the research and development (R&D) department at SCIMED, which was later acquired by Boston Scientific Corporation. I joined SCIMED full-time after graduation, and I remained with the company until 1996. During this time I rose from engineering intern to full-time R&D engineer to Director of R&D. Throughout my various roles at SCIMED, the focus of my work was on medical devices in the field of interventional cardiology, and particularly catheter design.

29. From 1997 through today, I have served as an independent consultant for early stage medical device companies in the areas of product design and intellectual property development. Several of my consulting clients have developed successful products that are on the market and in hospitals today. A number of the products have been in the field of interventional cardiology, and particularly catheters.

30. In addition to my work as an independent consultant, I have engaged in a number of entrepreneurial ventures in the field of medical devices since the year 2000. In many of these ventures, I held chief responsibility for product design and development. Several of these products have been in the area of interventional cardiology. I have also done considerable work outside the area of interventional cardiology, including in treatments for chronic sinusitis, orthopedics for extremities such as feet and ankles, and treatment of spinal disorders.

31. Between my work at SCIMED, my independent consulting, and my entrepreneurial ventures, I have been named as an inventor on over 100 issued U.S. patents, as well as many corresponding patents in foreign countries. Numerous patent applications on which I am a named inventor are still pending.

32. I have served as an expert witness in three prior patent litigations on behalf of Boston Scientific Corporation, my former employer. These litigations are described briefly in my curriculum vitae, Appendix A. I have not testified as an expert witness by deposition or at trial in the last four years.

D. Compensation

33. I am being compensated at my normal rate of $475 per hour for my time spent preparing this report. I am also being reimbursed for my reasonable expenses associated with my work on this case. My compensation in no way depends on my conclusions or the outcome of this case.

E. Materials Considered

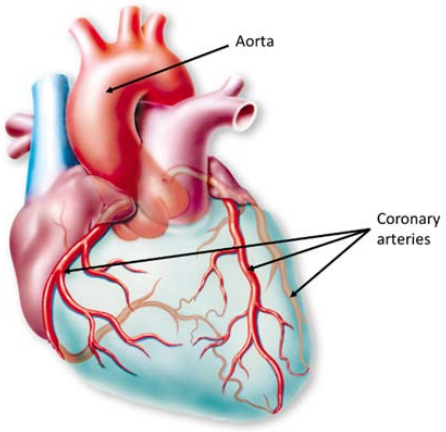
34. In preparing this report, I have relied on my years of experience and expertise in the relevant technology. I have also reviewed and relied upon the materials listed in Appendix B, as well as all other documents cited in this report and its attachments.

II. BACKGROUND ON THE TECHNOLOGY OF THIS CASE

A. Coronary Catheters and Heart Disease

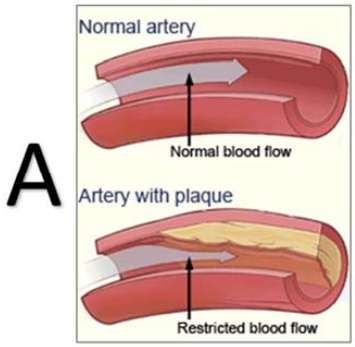
35. The technology involved in this case pertains to coronary catheter procedures. These are procedures for treating conditions in the blood vessels of the heart itself (coronary arteries). More specifically, this case pertains to a specialized catheter device used in some of the more challenging procedures, called a "guide extension catheter".

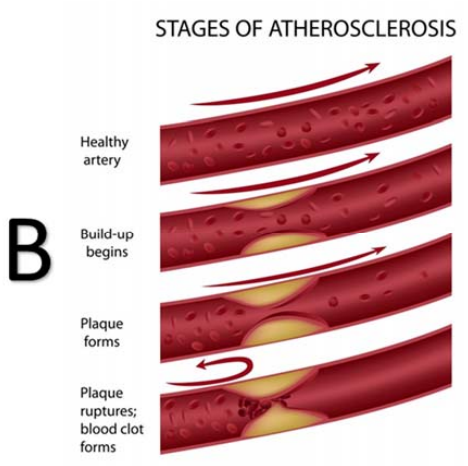
36. As the heart is essentially a large muscular pumping organ, it requires a lot of oxygenated blood to sustain itself. This blood circulates within the heart muscle via the coronary arteries (see diagram below). Over time, these blood vessels may become diseased (coronary artery disease, "CAD") resulting in regions of narrowing or clogging. Starting in the 1970s, advances were made in treating this disease with catheter devices advanced into the coronary arteries from relatively accessible arteries in the leg or arm, e.g., the femoral artery in the leg or the radial artery in the arm.



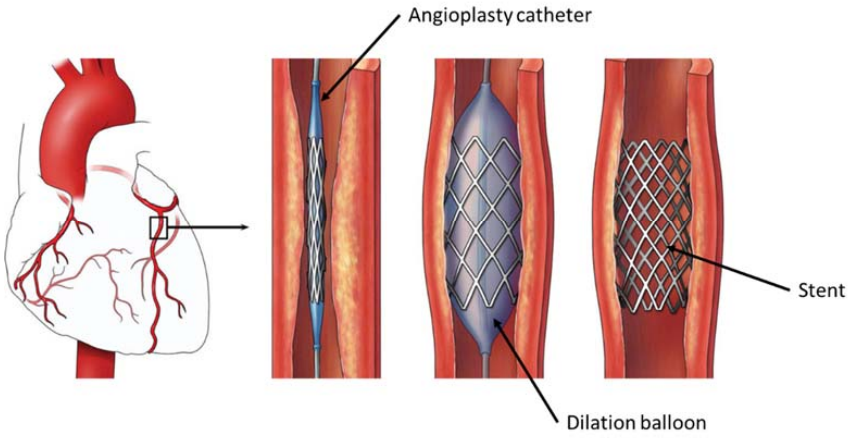
37. CAD (also called atherosclerosis or plaque buildup) results in narrowed regions (lesions or stenoses) that can restrict the flow of blood to regions of the heart muscle (see below—A). Severe lesions can dramatically restrict the blood flow, starving the muscle of oxygen (ischemia), which can create severe chest pain, and significantly limit a patient's activity

and quality of life. If the restriction completely blocks the flow of blood (typically from a subsequent blood clot within the lesion), this can lead to a heart attack (myocardial infarction). (See below—B). Severe lesions and complete blockages necessitate some sort of treatment to re-open the blocked region and re-establish normal blood flow. In the case of a complete blockage (myocardial infarction), the patient may die if the blocked vessel is not re-opened quickly, i.e., within hours of the blockage.

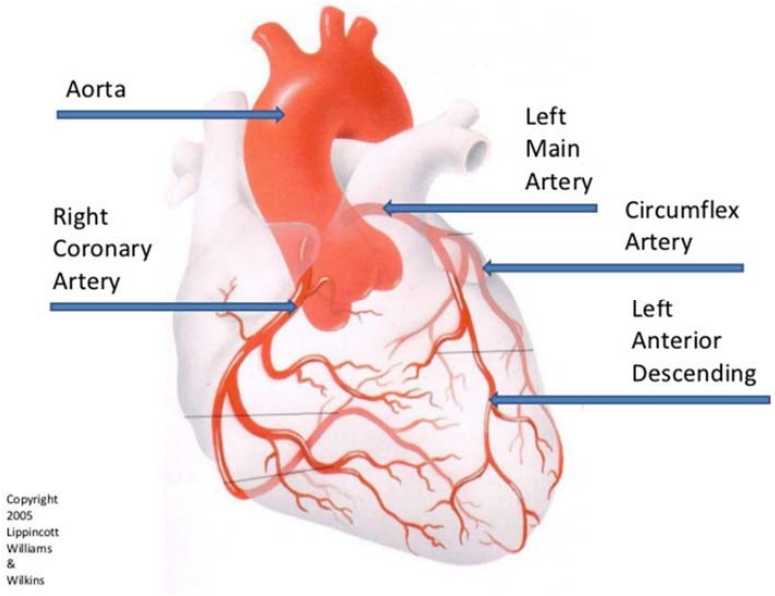




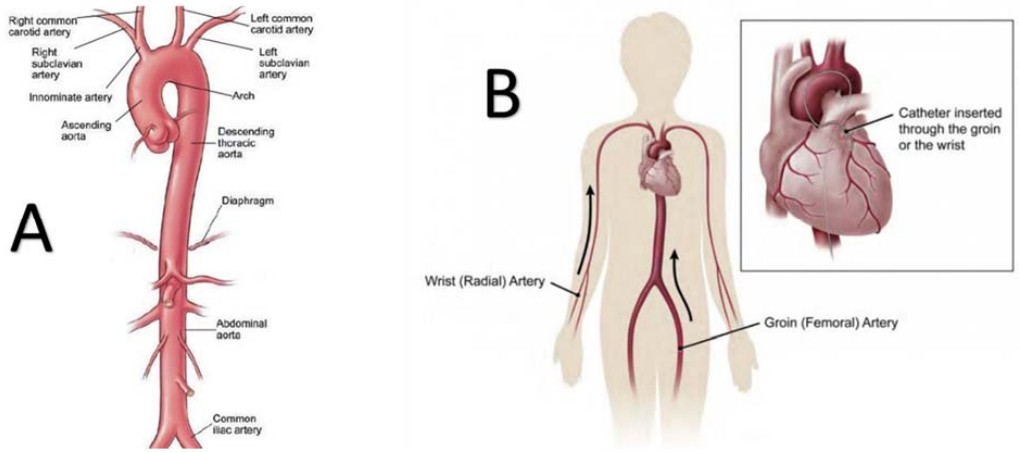
38. The most common treatment for CAD is with catheter devices that dilate the blockage from inside and place a support scaffold (stent) therein. The stent is inserted across the lesion in a collapsed state and then dilated with a balloon-tipped catheter called an angioplasty catheter (see below). It is therefore critical that these catheter devices are able to be positioned within the blockage, and positioned quickly, in order to successfully treat the patient.



39. One of the main pumping chambers of the heart is the left ventricle "LV". The LV receives the oxygenated blood from the lungs, and pumps it to the body via the aorta. The rest of the blood vessels that oxygenate the body are all branches and sub-branches off of the aorta. The very first branches, near the very beginning of the aorta, are the coronary arteries, the left main coronary artery "LM", and the right coronary artery "RCA". The openings of these arteries from the aorta are called ostia (singular: ostium). The LM runs for a short length before it branches into two longer arteries that run the rest of the way down the left and posterior sides of the heart: the left anterior descending "LAD" and left circumflex "LCX". The RCA extends down the right side of the heart. The RCA, LAD, and LCX are considered the three primary coronary arteries. Each of these arteries, in turn, has numerous side branches, which then further branch ultimately into the capillary beds where the actual transfer of oxygen to heart muscle tissue takes place (see figure below). Most lesions requiring treatment are within these three primary arteries, or occasionally a major branch stemming therefrom.



40. Beyond the coronary arteries, the aorta has numerous branches and sub-branches as it feeds oxygenated blood to the rest of the body (see diagram below—A). The aortic arch is where the aorta turns and heads inferiorly (descending aorta) towards the legs. One of the branches off the aorta that feeds the arm is the right subclavian artery. A sub-branch of this artery is the radial artery near the wrist. Another branch from the aorta is the iliac artery, which further sub-branches into the femoral artery near the groin. The femoral artery and radial arteries are relatively close to the skin surface, and one or the other are typically used as the access vessels to gain access to the aorta and the coronary arteries as will be described below (see diagram below—B).

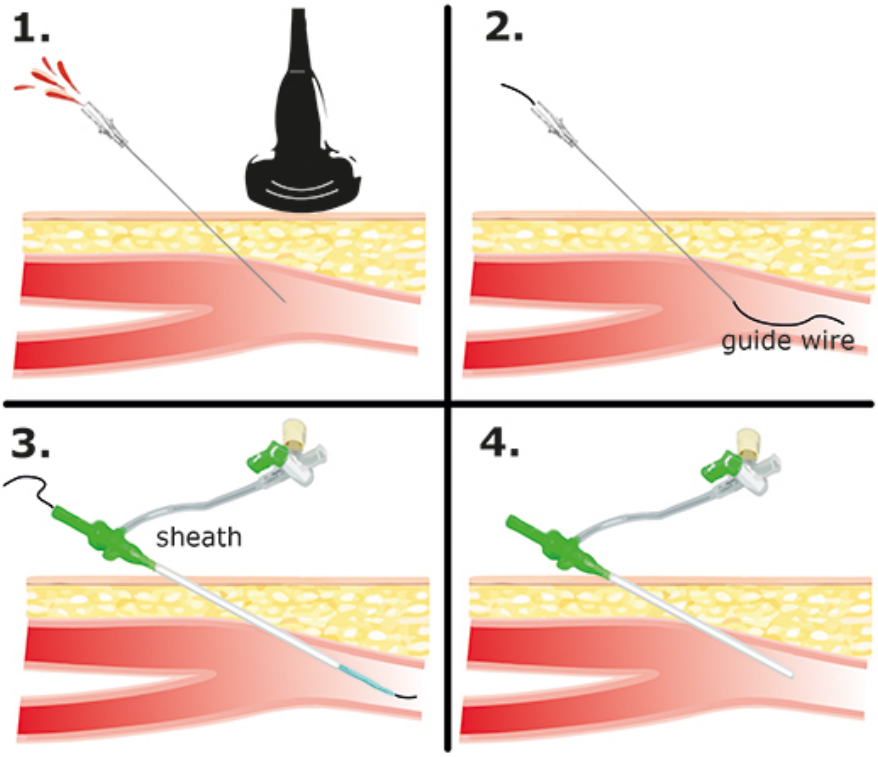


41. In the following paragraphs, I will describe a typical treatment procedure. Many variations of this exist, but this description of a typical and common procedure will serve to illustrate the issues pertinent to the technology in the case at issue.

42. The treatment of these lesions by catheter techniques involves accessing a remote blood vessel, e.g., the femoral artery, via a needle puncture from the skin into the vessel, known as percutaneous access. A series of devices and maneuvers (called the "Seldinger" technique) results in placement of an introducer sheath into this vessel (see below). The introducer sheath is a relatively short tubular access catheter, approximately 20 cm long. Its purpose is primarily to maintain an access pathway into the femoral artery to facilitate the rest of the procedure.[1] These sheaths have a fixed inner diameter of 5, 6, 7, or 8 French. (One French is 0.33mm). A slitted seal is provided on the back (proximal) end of the sheath to keep blood from exiting. The size is chosen by the interventionalist and depends on numerous factors, including the sizes of the planned devices to be inserted through the sheath and used for the coronary lesion.

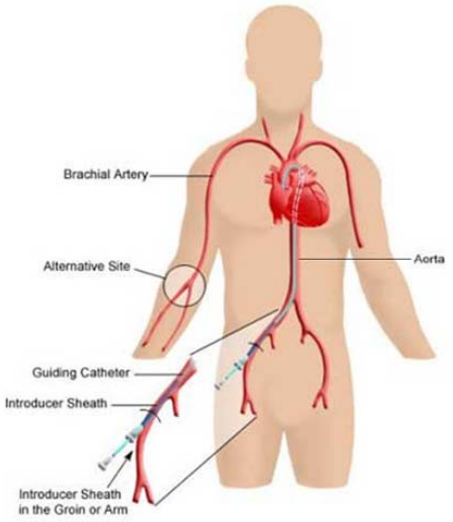
[1] In some angioplasty procedures, particularly those targeting sites in the peripheral vasculature, physicians use a long guiding sheath in lieu of a guide catheter. These guiding sheaths are different from the introducer sheaths I am now discussing.

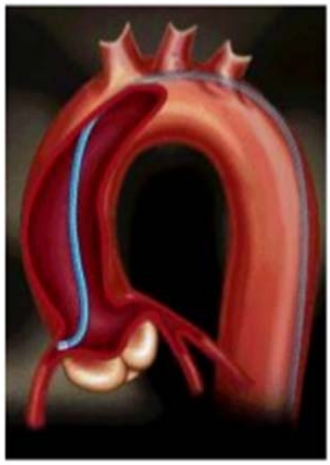
43. Once access is established to the remote artery, a catheter (hollow tube) is advanced through the aorta into the heart where a "diagnostic" catheterization procedure is performed. This entails injecting an x-ray visible contrast solution through the catheter into the main coronary vessels and one or more of the pumping chambers of the heart. This technique identifies the location of any blockages or narrowings that may require treatment with angioplasty catheters, as well as any defects in the valves that separate the chambers of the heart. Sometimes this diagnostic catheterization procedure is performed as a separate procedure.



44. After the sheath is placed and the diagnostic procedure is complete, in order to treat the lesion a device called a guide catheter "GC" (also called a guiding catheter, or sometimes just a "guide") is inserted into the sheath and advanced from the femoral artery, up

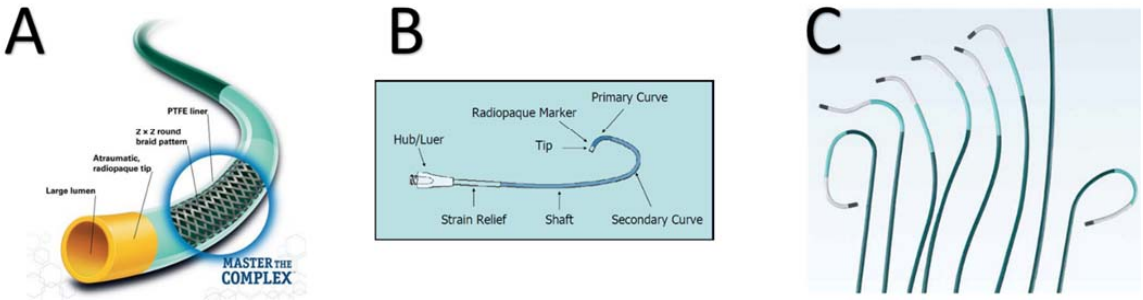
the aorta, around the aortic arch, with its tip next to or just into the coronary ostium of choice (see figure below). A stiffening wire, usually about 0.035 inches in diameter, is often placed inside the length of the guide catheter to keep some of the distal curves (described below) straight until the curve of the aortic arch is reached. This wire is then removed. The primary purpose of the GC is to provide a stable access route for coronary devices and a lumen for delivery of x-ray contrast fluid for visualizing the vessel and lesion.



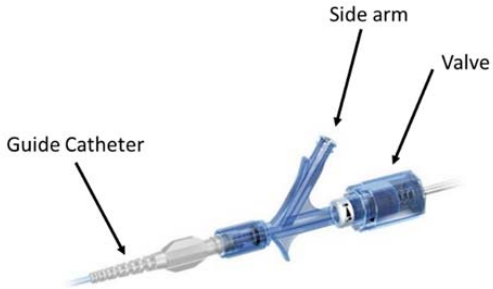


45. GC's are more complex than they may appear. They typically have multiple layers and multiple regions of flexibility, stiffer at the proximal end and progressively more flexible towards the distal end. A lubricous liner extends through the inside of the guide catheter. Embedded in the walls of the tube is a metallic wire braid which facilitates "torquability" by enhancing the torsional stiffness (see below—A). GC's also have pre-set curves near the distal tip, to aid in placement within the aortic arch and into the ostium (see below—B). There are numerous curve shapes offered by many manufacturers (see below—C). The combination of stiffness characteristics, torsional characteristics and curve shapes aids in the ability to

successfully intubate the ostium of the particular individual. Every person's arch and ostium anatomy is different. Therefore, accessing each ostium can be a challenge—thus the variety of guide catheters available. GC's are also available in a range of outer diameters, corresponding to the sheath inner diameters.

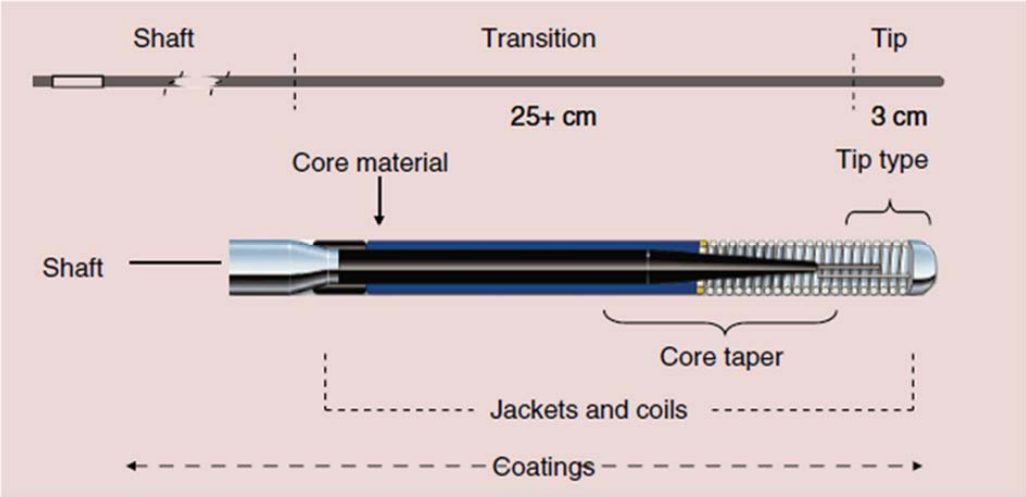


46. A device called a hemostasis valve (also called a Y-connector or Y-adaptor) is positioned on the proximal end of the GC to prevent bleeding from this catheter (see figure below). The valve can be temporarily opened when devices are passed into the guide catheter. A side arm allows for injection of fluids, such as contrast for periodic x-ray visualization.



47. Through the GC, a small wire called a guide wire "GW" (sometimes written as a single word, guidewire) is inserted into and through the guide catheter, into the coronary vessel and across the lesion. A GW used in coronary applications is typically 0.014 inches in diameter, and 175 cm long. The primary purpose of the guide wire is to cross the lesion and serve as a

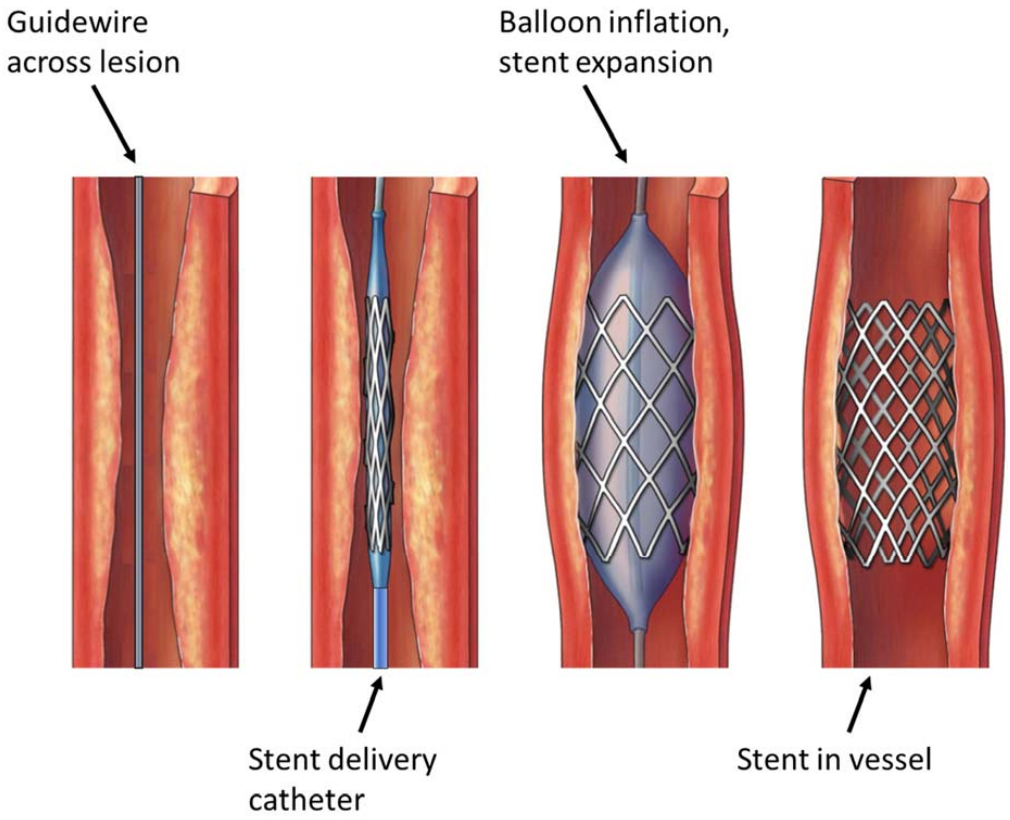
"track" over which other catheter devices are positioned into the coronary vessel and across the lesion. GW's are also more complex than they first appear. They are formed from a solid metal core wire, about 0.014 inch diameter, typically a springy stainless steel. Towards the distal end, the core wire diameter is ground down gradually until the diameter is around 0.001 inch diameter. This diameter transition zone is about 30 cm long. So the proximal part of the guide wire is significantly more rigid than the distal part. Stated differently, the distal end is significantly more flexible than the proximal end. With each of these GC and GW devices, each has relative stiffness/flexibility within the same device; these are not absolute terms. This is important, as the distal end needs to safely navigate the fragile coronary vessel, while the proximal end needs to accurately advance and rotate the distal end within the confines of the guide catheter. Much of the length of the reduced diameter portion is covered in a fine wire coil, which maintains the outer diameter of the GW at 0.014 inches (see diagram below).



48. To aid in navigating the wire through the coronary vasculature, a small "J" bend is often formed at the distal end (see below), and when the GW is rotated from the proximal end, the J bend is rotated. The combination of careful rotation and advancement of the GW allows it

to be steered through the coronary artery and through the lesion. The tip portion is usually advanced to a position several cm distal to the lesion, to allow for a more rigid portion of the guide wire to be within the lesion. The positioned guide wire now serves as the track to guide the subsequent dilation or stent delivery catheter to the lesion.

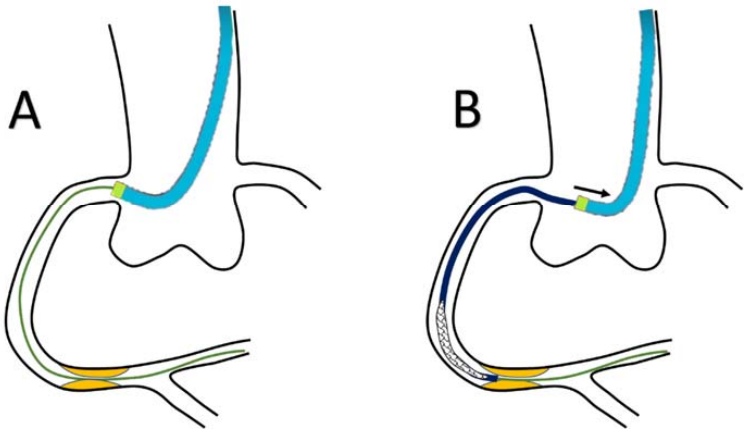
49. With the GW in place across the lesion, a stent delivery catheter can be advanced over the GW to position an unexpanded stent across the lesion. Somewhat similar to the guide wire, the distal portions of the stent delivery catheter need to safely navigate within the fragile coronary artery, and therefore its distal portions are relatively flexible. The proximal portions are relatively rigid to provide for responsive advancement of the distal portion. Stent delivery catheters are available in different diameters, to deliver an appropriately sized stent to the particular lesion. The stent is mounted over a dilation balloon, which, when inflated with fluid, expands the stent, deforming it to a larger diameter scaffold that dilates the lesion from the inside, and maintains the now expanded diameter of the blood vessel. Blood flow to the heart muscle distal to the lesion is thus restored (see figure below).



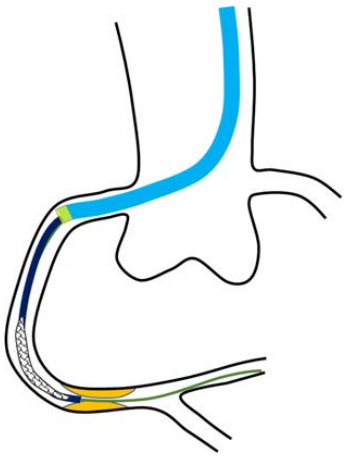
50. Once the dilated lesion is deemed successfully dilated (with confirmation from x-ray imaging using contrast injections into the artery), the catheter and guide wire devices are removed from the patient. Or, other lesions may be subsequently treated with either the same devices, or different devices, depending on the location and size of the other lesions.

51. Numerous variables can impact how easy or difficult it is to treat a particular patient's lesion. Many of these variables relate to the anatomical variation of a particular patient's aortic or coronary vascular anatomy. For example, if a lesion is particularly tight (small diameter residual lumen, or heavily calcified), after the lesion is crossed with the guide wire (see below—A) it may be difficult to advance the stent delivery catheter across the lesion. A tighter lesion will require a higher advancement force on the stent delivery catheter vs. a less tight

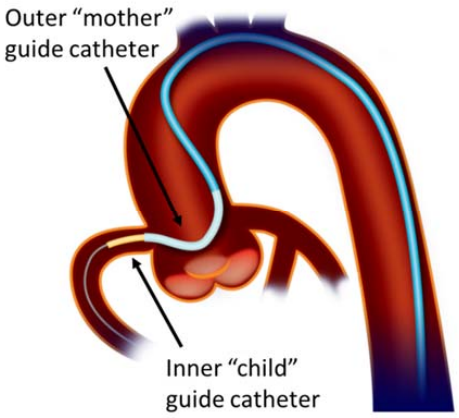
lesion. When the stent delivery catheter is pushed to cross the lesion, a reactive force is placed against the curve(s) at the distal end of the guide wire. If the reactive force is high enough, it will cause the GC to "back out" of the ostium (see diagram below—B). Continued advancement of the stent delivery catheter will merely move the tip of the GC further out, and allow for the stent delivery catheter to buckle. So, there is a limit to how much force can be used to advance the stent delivery catheter. In some instances, the lesion may be so tight or difficult to cross that attempted advancement of just the guide wire can cause the guide catheter to back out. In addition to the characteristics of the lesion, other anatomic variables influence the tendency toward guide back out, including the aorta anatomy, the tortuosity of the coronary vessel, calcification in the vessel, etc. Several device design factors can also impact how readily the guide catheter will back out, including the stiffness of the distal portion of the guide catheter, the shape of the distal portion of the guide catheter, the stiffness of the distal region of the guide wire, the diameter profile of the stent delivery catheter, etc. However, there are design trade-offs for all of these devices which limit just how much these variables can be altered. For example, the stiffness of the distal portion of the guide catheter cannot be so high as to inhibit its ability to be navigated around the aortic arch, or so high as to potentially damage the aorta or the coronary ostium. Perhaps a larger diameter (therefore stiffer) guide catheter would be more appropriate, but this would necessitate removal of the first guide catheter for another, which adds time and potential risks to the procedure.

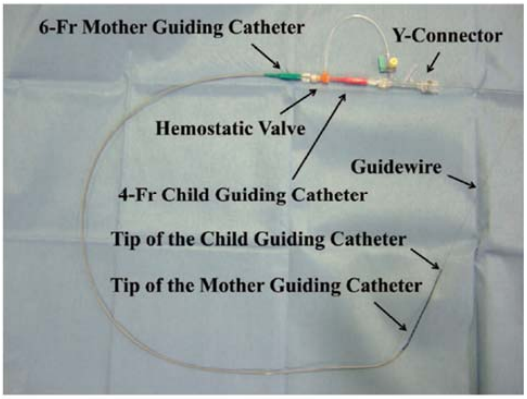


52. One approach that has been tried in this scenario where the guide catheter is prone to backing out is to "deep seat" the guide catheter, by advancing the tip more deeply into the coronary vessel (see figure below). While this maneuver can increase the anchoring force of the guide catheter, it risks causing damage to the proximal portion of the coronary artery. The high relative stiffness of the distal guide catheter (compared to, say, the stiffness of the distal portion of a guide wire or stent delivery catheter) can scrape or dissect the artery, both very serious complications. As a result, this technique is rarely performed.



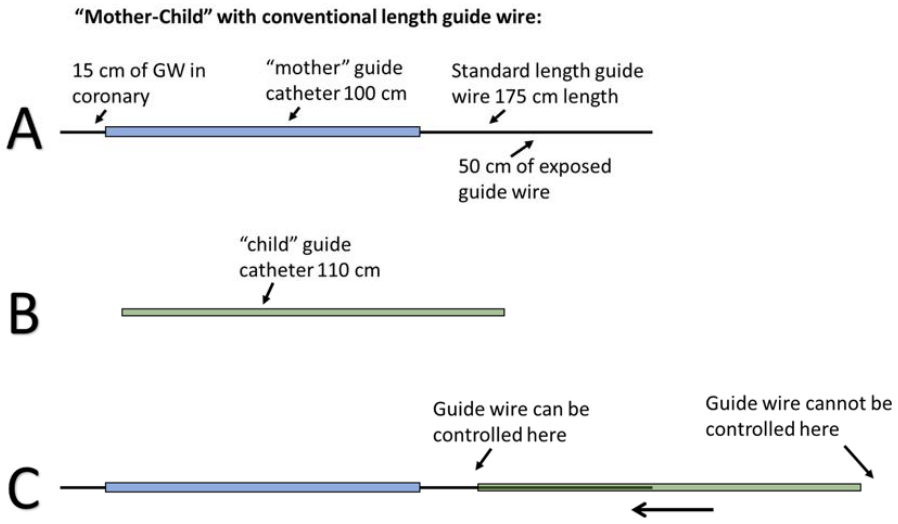
53. Another approach that has been tried incorporates the use of a smaller diameter and longer guide catheter inside the larger diameter conventionally positioned guide catheter. The inner guide catheter, being a smaller diameter, and typically without a pre-set bend on the tip, is more flexible than the larger guide catheter. Therefore it may be more safely inserted deeper into the coronary artery to a position closer to the lesion. This is referred to as the "mother and child" approach (see figure below). Once the inner guide catheter ("child") is positioned in the coronary artery, effectively "extending" the guide catheter, a stent delivery catheter is advanced across the lesion and the lesion dilated and stented. It should be noted that while the smaller diameter child catheter is smaller than the larger guide catheter, it still has a large enough inner diameter to allow various stent delivery catheters or other catheter devices to be advanced within it.





54. The "mother and child" approach described above is effective at improving the support required to allow for greater pushing forces to be applied to the stent delivery catheter, and is a much safer approach than the "deep seating" approach described above, as the "child" catheter, being smaller, is more flexible and less traumatic for advancing down the coronary

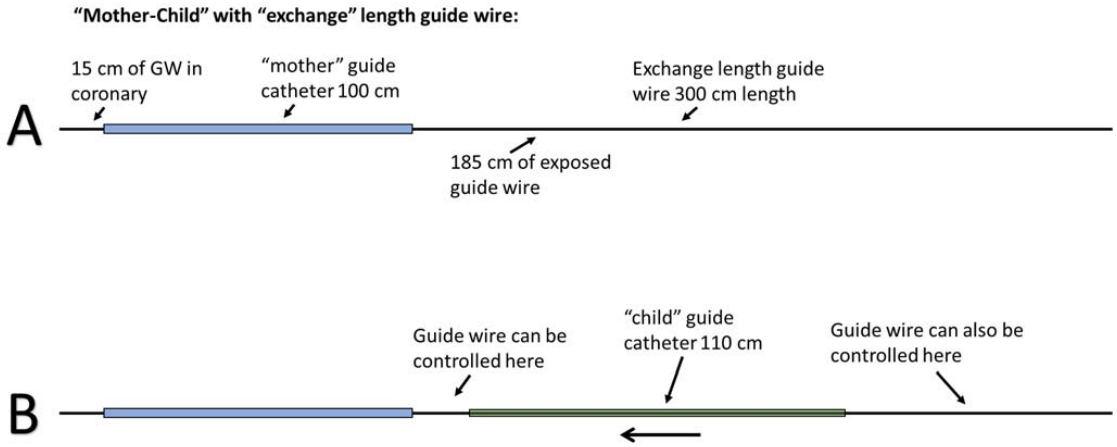
artery. However, there are some significant drawbacks. For example, this approach needs to be used with a specialized long "exchange length" guide wire, as will be now described. The "child" guide catheter has a fully extending lumen from its distal end to its proximal end, similar to the "mother" guide catheter. Devices such as guide catheters and stent delivery angioplasty catheters that have fully extending lumens for guide wires are called full length "over the wire" catheters. When the "child" catheter is inserted within the "mother" guide catheter, and over the prior positioned guide wire, there needs to be enough length of exposed guide wire proximal of the mother guide catheter to allow installation into the mother guide, while always having the ability for the guide wire to be grasped and controlled, either in front of (distal to) the child catheter, or back of (proximal to) the child catheter. Standard length guide wires cannot be used in this case because standard guide wires are about 175 cm while standard guide catheters (the "mother" catheter in this case) are about 100 cm long (see figures below). If, for example, 15cm of the guide wire is inserted into the coronary artery, only 50 cm of guide wire extends proximally from the mother guide catheter (less actually, when the length of the hemostatic valve is added in) (see below—A). The child guide catheter needs to be well over 100 cm to be able to further extend into the coronary artery, say 110 cm (see below—B). If this child catheter is positioned over the guide wire, the guide wire may be grasped and stabilized in front of the child guide catheter, but once the child guide catheter reaches the proximal end of the mother guide catheter, there is no exposed guide wire to grasp and stabilize any more (see below—C). If the child guide catheter were to continue to be advanced into the mother guide catheter without grasping and stabilizing the guide wire, the guide wire is likely to be dragged along and further inserted into the coronary artery. This is very dangerous as further uncontrolled advancement of the guide wire may perforate or otherwise damage the distal coronary artery that it is within.



55. To remedy this concern of loss of control of the guide wire, a longer guide wire may be used. Longer guide wires exist, called "exchange length" guide wires. These are typically 300 cm long. If the procedure is planned out ahead of time to involve the use of the "mother and child" approach, an exchange length guide wire will be used for the crossing of the lesion. Note that if the procedure is converted (vs. pre-planned) to a "mother and child" approach, the pre-existing standard length guide wire will need to be switched to the longer exchange length wire. This is highly undesirable as the lesion needs to be successfully re-crossed with the guide wire a second time, which may be difficult, time-consuming, and risky to the patient.

56. A 300 cm long guide wire is more difficult to manage in the operating room and typically requires the assistance of a second operator, as it must be advanced and steered all within the relatively small confines of the sterile area of the operating table. Regardless, once the lesion is crossed, there is now about 185 cm of available exposed guide wire exiting from the mother guide catheter (see figure below—A). Now, when the child guide catheter is installed over the guide wire, once the distal end of it gets to the proximal end of the mother guide

catheter, there will be exposed wire proximal of the child guide catheter, which may now be grasped to keep control of the guide wire while the child guide catheter is inserted into the mother guide catheter and into the coronary artery (see below—B).



57. While this "mother and child" approach to improving the backup support is workable, it has never gained much traction. There are many reasons for this. For example, the substantial challenges posed by the need to use an exchange length guide wire have limited this technique. Furthermore, the "child" guide catheters used were still primarily designed as guide catheters, and not optimized for deep vessel placement. For example, they included braid and other features which tend to make the distal portions still somewhat stiff and not ideal for safe advancement into a coronary artery.

58. The need for improving the support for delivery of interventional devices into coronary arteries and lesions has been substantial, and continues to become greater, as more and more challenging coronary procedures are performed. In addition to the example above, where a "tight" lesion requires a higher level of crossing support, many other factors can lead to a need for increasing the crossing support. High tortuosity (curvy) arteries, distal lesions, sharp side

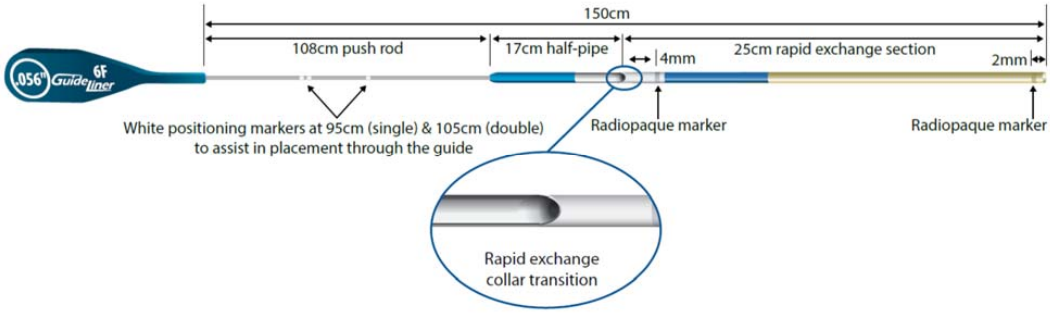
branch lesions, heavily calcified lesions, unfavorable aortic anatomy, small peripheral arteries, poor initial guide catheter selection, large profile interventional catheter devices, are but some of the situations that may benefit from a technology that can increase the level of crossing support from a guide catheter. However, a satisfactory solution to this need must not require the need for an exchange length guide wire, but be compatible with standard length guide wires, and incorporate design features which improve the safety and deliverability of the guide extension catheter itself into the coronary arteries, and provide for subsequent delivery of a wide range of interventional devices into the coronary arteries.

59. The rapid exchange guide extension catheters in this case do just that. And as will be evident in their descriptions below, they must also possess other important attributes.

B. VSI's GuideLiner Devices

60. The VSI GuideLiner devices are the first in a new class of devices referred to as "guide extension catheter" devices, and operate in some ways similar to the "mother-child" devices described above, but importantly allow for the use with a standard length guide wire. Devices that are used with standard length guide wires are often referred to as "monorail" or "rapid exchange" devices. This primarily refers to an attribute of the device, wherein the "over the wire" portion of the device is short enough to be advanced over the exposed portion of a prior placed standard length guide wire (e.g. approximately 175 cm for a standard length coronary guide wire). The "monorail" design for stent delivery angioplasty catheters has been in existence for some time. These catheters have a total length typically about 135 cm, but the guide wire lumen within them is typically only about 30 cm long. This is short enough that these devices can be loaded over a prior placed standard length guide wire. The guide wire has enough exposed length proximal of the guide catheter to allow for full control of the guide wire during insertion of the angioplasty device.

61. The VSI GuideLiner devices are monorail catheters, in that only the distal portion of the catheter rides over the guide wire when it is positioned.[2] The distal "over the wire" portion is between 25 and 40 cm (see below, version V3 shown—note this image is not to scale), depending on the model, which is short enough to be used with conventional length guide wires. Importantly, because it can be used with conventional length guide wires, use of the GuideLiner can be either pre-planned for the procedure, or used later in the procedure on an "as needed" basis, without necessitating removal of the already positioned guide wire and guide catheter.



62. In its simplest description, the GuideLiner consists of 3 sections or portions: the distal tubular section, the proximal shaft section, and the side opening section.

63. The distal tubular section in the V3 version described above is 25 cm long. It is somewhat longer, up to 40 cm, in other models. In all versions, the tubular section has a lumen that is configured both to ride over the guide wire during advancement/placement of the catheter, and to allow for subsequent catheter devices such as stent delivery catheters to be advanced through it. Important features of the distal tube include having a reinforcement (coil) to provide

[2] I use the term "monorail" or "rapid exchange" to refer to this type of device. However, these devices are still sometimes referred to as "mother and child" devices because there is a smaller catheter within a larger one. In this report, I use the term "mother and child" only to refer to a system with a full-length inner catheter lumen.

for a kink-resistant stable circular lumen as it is advanced into potentially tortuous (curved) vessels. Unlike standard guide catheters that have braid reinforcement, the coil reinforcement used in the GuideLiner is relatively more flexible so that it can safely be advanced deep into a coronary artery. As described above, standard guide catheters are relatively rigid in comparison, and therefore the risk of complications is higher when deep seating a conventional guide catheter. While smaller guide catheters may be more flexible than larger guide catheters (as in the "child" guide catheters described in the example above), the GuideLiner is optimized for flexibility to aid in its placement in a coronary artery. The distal tubular section further makes use of a flexibility transition from its proximal end to its distal end by incorporating polymers of differing rigidity. This further facilitates the "trackability" of the catheter into coronary vessels. The distal tubular section further makes use of a lubricious inner liner, a soft atraumatic tip, and a lubricious external coating. The construction of the distal tubular section allows for it to have a relatively thin wall thickness. Combined with a relatively "snug" fit of the outer diameter, the inner diameter can be relatively large compared to the guide catheter it is compatible with. The resulting inner diameter of the GuideLiner is approximately one "French" smaller (or less) than the inner diameter of the selected compatible guide catheter. This maximizes the number of various catheter devices that can fit within it and be used in the coronary vessels.

64. The proximal shaft section is formed of a metallic rod. Being formed of stainless steel, it is able to be both small in its cross-sectional dimensions and substantially rigid, allowing for positive advancement of the GuideLiner catheter down the guide catheter and into the coronary vessel. Once in the vessel, the proximal shaft section also maintains a stable position of the distal tubular section within the coronary vessel, while other devices such as a stent delivery catheter are advanced across the stenosis. It is important for the proximal shaft to be small in its

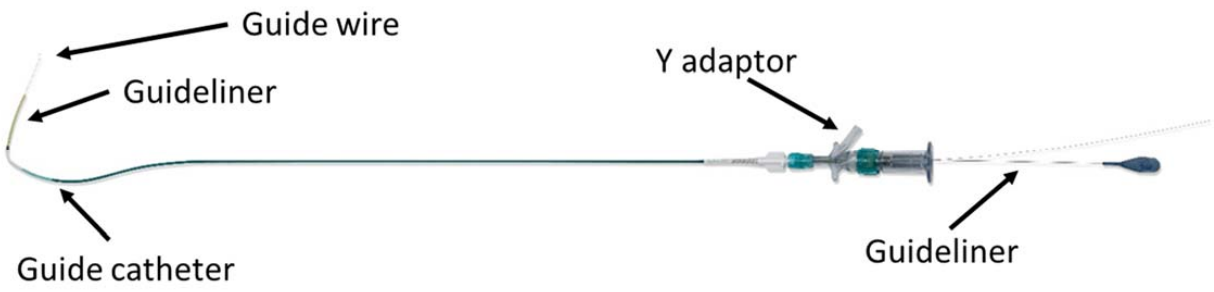
cross-sectional dimensions so as not to dimensionally interfere with the other devices that will be advanced alongside it in the guide catheter. Thus, a stiff metal such as stainless steel is suitable. The dimension of the proximal shaft is further reduced by fabricating it out of a flattened ribbon. The combination of the relatively more rigid proximal shaft with the relatively more flexible distal portion of the distal tube optimizes the pushability responsiveness of the GuideLiner with the trackability of the distal tube.

65. The side opening section is the part of the catheter where the proximal shaft is joined to the distal tube, and where the opening into the lumen of the distal tube is formed. An important consideration for this section of the GuideLiner is to have a secure connection between the two shafts, wherein potential for kinking and deformation of this section are minimized. A side opening that is more rigid than the tubular section helps to achieve this. Another important consideration is to have the side opening be angled or beveled relative to the axis of the catheter. This helps to facilitate smooth introduction of the subsequent coronary devices into the lumen of the distal tube.

66. The GuideLiner device is typically used as follows. Once the guide catheter is advanced to the coronary ostium (as was described above), a standard length guidewire can be advanced down the guide catheter and into the coronary vessel and across the lesion. The GuideLiner may be used at this stage ("pre-planned"). Alternately, it may be used only on an "as needed" basis, after attempts have been made with the interventional device(s) such as stent delivery catheters. If it is used after attempts have been made with other interventional device(s), those device(s) are removed from the guide wire, leaving the guide wire "alone" in the guide catheter. In either situation, the guide wire will be "alone" within the guide catheter and across

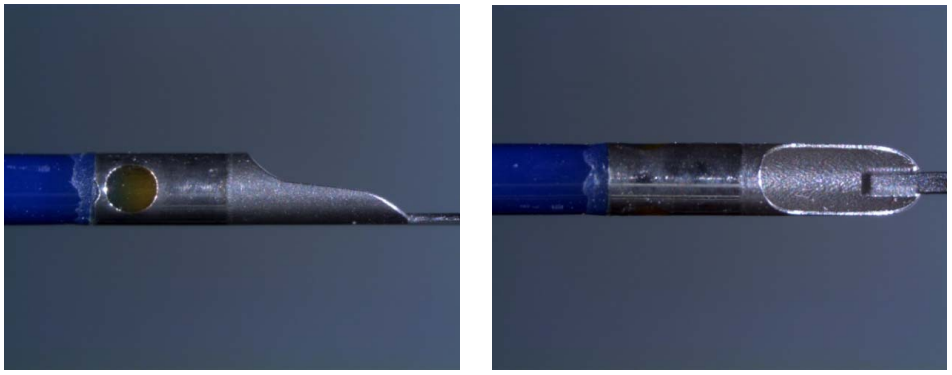
the lesion. The GuideLiner is then loaded over the back end (proximal end) of the exposed guide wire, and fed into the Y-adaptor on the back end of the guide catheter (see diagram below).

67. The GuideLiner is then advanced down the guide catheter, following the guide wire, until the tip emerges from the guide catheter and into the coronary vessel (see image below).

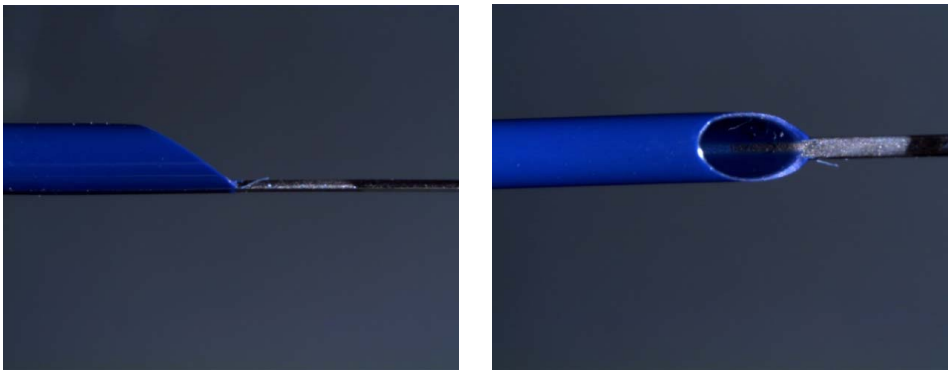


68. Next, an interventional device such as a stent delivery catheter is advanced over the proximal (back) end of the guide wire, and into the guide catheter, following over the guide wire. On the V3 version of the GuideLiner, a "half pipe" that extends for approximately 17 cm proximal of the fully tubular section aids in guiding the stent delivery catheter into the lumen of the distal tubular portion (see figure below). The stent delivery catheter is then advanced across the stenosis with the aid of the increased backup support provide by the GuideLiner.

69. The GuideLiner device has been available in four different versions, V1, V2, V3, and XL, with V3 and XL being the most current commercialized models. All are similar, with the main exception of certain details pertaining to the side opening portion (see figures below). As described already, the side opening portion of the V3 model includes the "half-pipe", and the angled entrance into the lumen is a polymer tube reinforced by the continuation of the metallic ribbon portion of the proximal shaft. The prior version, V2, incorporates the angled side opening and a continuation of the metallic ribbon, but no "half-pipe". The first commercial version, V1, has an angled metallic collar connected to the ribbon. The XL, which is longer than the other models by virtue of having a longer distal tube, is based on the V1 design. A reinforced polymer tube extends distally from the metallic collar. Each version of the GuideLiner except XL is or was available in several French sizes, compatible with various guide catheters French sizes.



GuideLiner V1



GuideLiner V2

GuideLiner V3

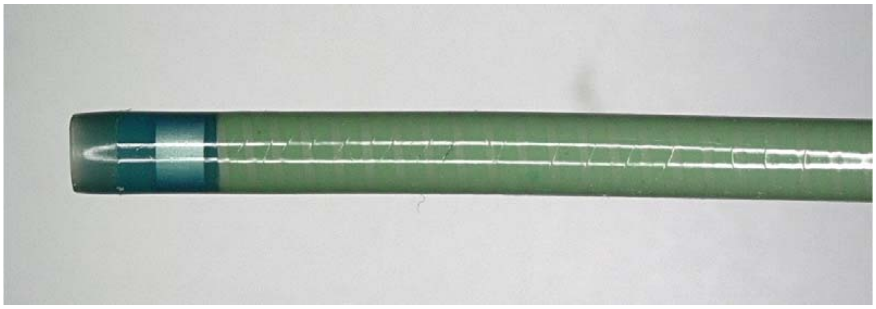
C. QXMédical's Boosting Catheter

70. The Boosting Catheter is very similar to the VSI GuideLiner. Like the GuideLiner, the Boosting Catheter is a guide extension catheter designed to be used within a guide catheter to aid in the delivery of various catheter devices into an artery. Like the

GuideLiner, the Boosting Catheter has 3 general sections or portions: a flexible tubular distal section, a rigid proximal shaft section, and a side opening section between them.

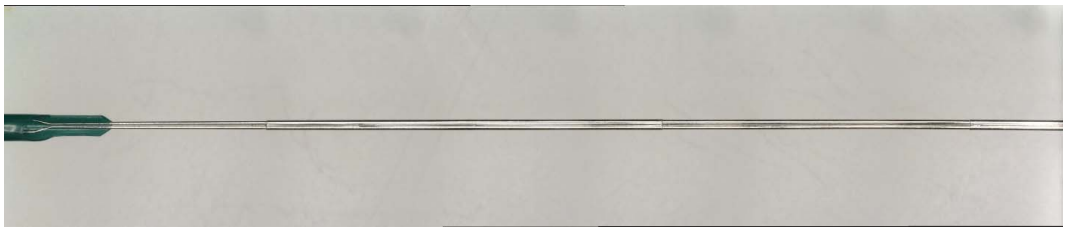
The Boosting Catheter

71. The distal tube portion is formed of multiple layers of polymer tube with an embedded metal coil for reinforcement, as in the GuideLiner. At the very tip of the distal tube is a tip portion that is not reinforced with the metal coil, so as to be more flexible as the leading end of the device.

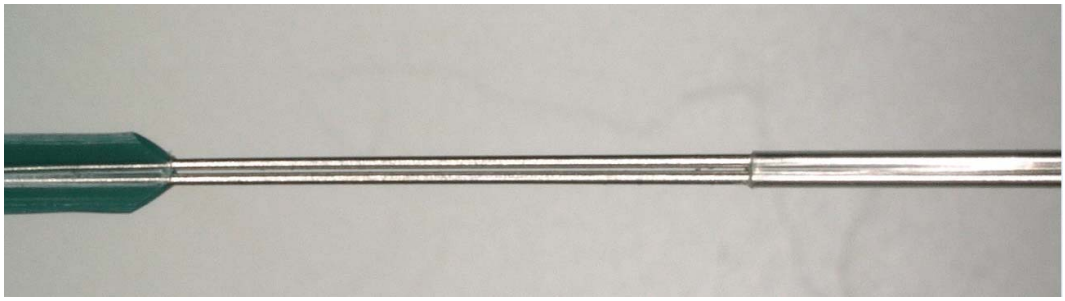


Distal tube of the Boosting Catheter

72. The proximal shaft portion is metallic, stainless steel, like the GuideLiner. It is formed of two solid wires encased by a polymer wrap. Near the distal end of the proximal shaft, the polymer wrap terminates, and the two wires are exposed. Further distal, a second portion of wrap encases a short length of the shaft wires, and this wrap terminates proximal of the side opening section.



Polymer wrap on proximal shaft



Closeup of proximal shaft, distal end

73. The proximal shaft and distal tube are connected together at the side opening section. The wires of the proximal shaft are encased in and terminated in the polymer of the distal tube to a point adjacent the reinforcement coil and proximal marker band. The polymer tubing is cut at an angle to give a bevel to the side opening. Proximal to this bevel, a section of semi-circular polymer tubing extends proximally, and this is, in turn, cut away at an angle to the exposed shaft.

Side opening section of the Boosting Catheter

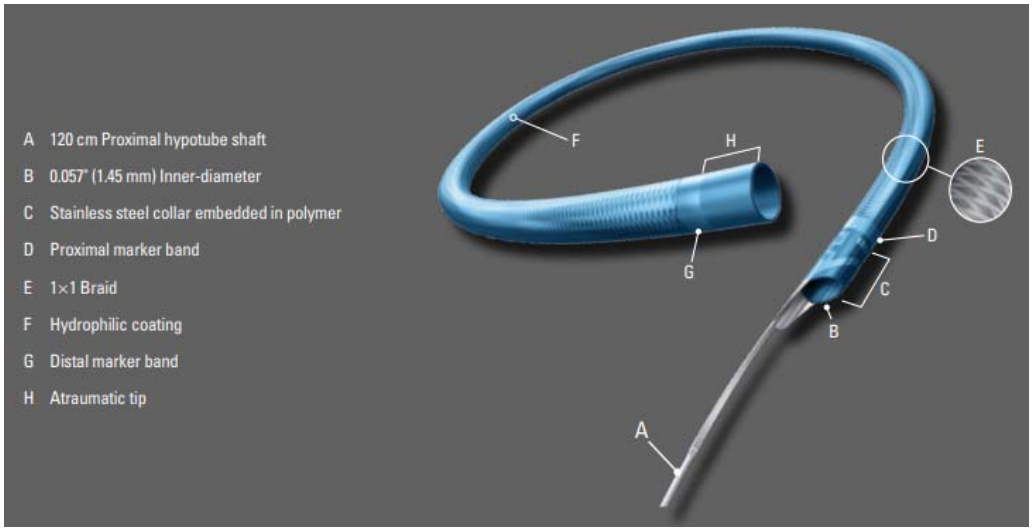
74. The QXMédical Boosting Catheter is used in substantially the same manner as the VSI GuideLiner, as I have described above. I discuss the use of the Boosting Catheter in greater detail below, in the detailed discussion of my opinions in this case.

75. I understand that QXMédical is the assignee of various patents and patent applications relating to the Boosting Catheter, including United States Patent Nos. 9,144,662 ("the '662 Patent") and 10,124,146 ("the '146 patent") and United States Patent Application Publication Nos. 2016/0096002 ("the '002 application") and 2017/0095646 ("the '646 publication"). Generally speaking, the '662 and '146 patents relate to the Boosting Catheter and methods for using the Boosting Catheter, including the Boosting Catheter's proximal shaft portion having two solid wires encased by a polymer wrap. The '002 application relates to the discontinuous polymer wrap used on the Boosting Catheter's substantially rigid portion, and to a folded-over bumper tip at the distal end of the Boosting Catheter's tubular portion. The '646 application relates to a support membrane at the Boosting Catheter's side opening section. As will become clear from my analysis on infringement, each of these items is a supposed improvement of one or more features that are claimed in the VSI patents—the substantially rigid portion, the distal tip of the device, and the rigidity of the side opening section.

D. Other Catheters—Guidezilla and TrapLiner

76. The Guidezilla catheter from Boston Scientific (BSC) is another commercially available guide extension catheter. There have been two versions, the V1 and V2, with the V2

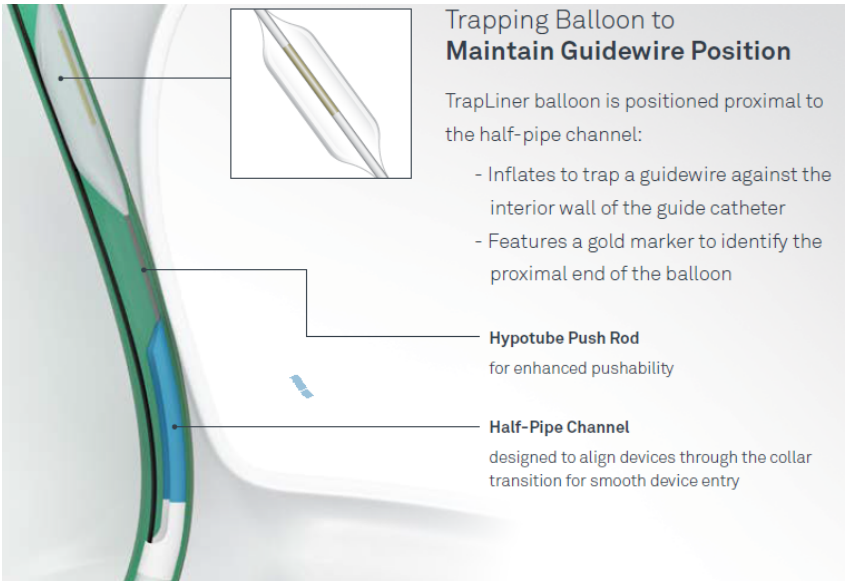
being the newer design. Both versions are also very similar to the GuideLiner, and similar to the Boosting Catheter as well. They have a distal tubular section configured to fit within various sized standard guide catheters, connected to a rigid proximal shaft. At the connection between the two shafts is a side opening section. The primary difference between the two versions is in the design particulars of the side opening section, although they both have an angled opening and a metallic collar. The collars have different cutout patterns. The distal tubular section is reinforced with a metallic braid. The proximal shaft is a hypodermic tube, sealed off at both ends.

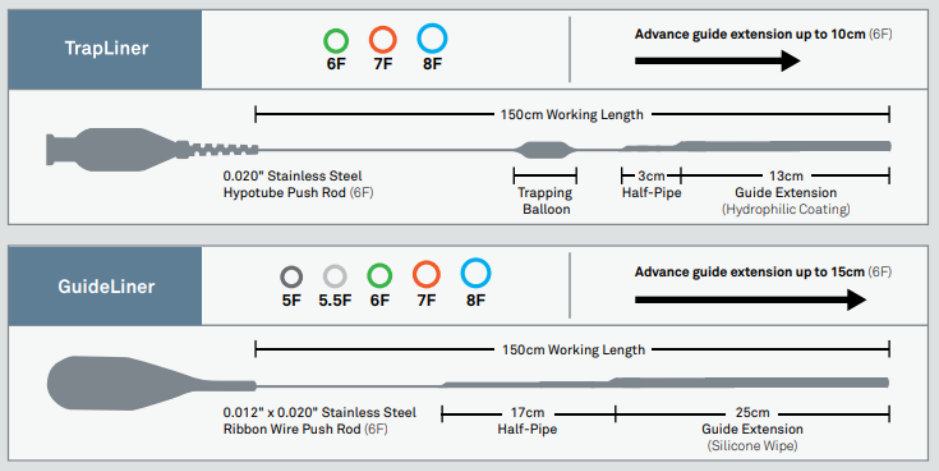


Guidezilla V1

Guidezilla V2

77. The TrapLiner from VSI is also very similar to the GuideLiner product, in that it is a guide extension catheter comprising a distal tube configured to fit within various sized standard guide catheters, connected to a rigid proximal shaft, with a side opening section therebetween. The primary difference between the TrapLiner and the GuideLiner is the presence of an inflatable anchoring balloon near the distal end of the proximal shaft. The anchoring balloon serves to temporarily lock a guide wire to the inside of the guide catheter in order to allow for catheter exchanges of full length over-the-wire interventional devices (as opposed to monorail interventional devices, where such a locking function is not necessary). In order to inflate the balloon, the shaft is made from a hollow hypotube, where the internal channel is used for conveying fluid from a proximal luer fitting to the balloon. The TrapLiner also has a shorter length distal tubular section, but otherwise is similar in construction to the GuideLiner V3.





TrapLiner vs GuideLiner

E. Overview of VSI's Patents

78. In this section, I will describe certain of the more prominent guide extension catheter features claimed in the asserted claims of the VSI patents. Described simply, the patented invention consists of a distal tubular section, a proximal shaft section, and a side opening section between these two sections, with other aspects relating to these sections.

79. The distal tubular section of the patented device is described by variations of patent claim language. Each asserted independent claim – i.e., claim 1 of the '032 patent, claim 1 of the '413 patent, claim 1 of the '380 patent, claims 25 and 48 of the '760 patent, claims 25, 52, and 53 of the '776 patent, and claims 25 and 52 of the '116 patent – recites "a tubular structure." It is to be understood that claims that depend from claims recited in this section have the limitations of the claims from which they depend.

80. The proximal shaft section of the patented device is described by variations of patent claim language. Each asserted independent claim – i.e., claim 1 of the '032 patent, claim 1 of the '413 patent, claim 1 of the '380 patent, claims 25 and 48 of the '760 patent, claims 25,

52, and 53 of the '776 patent, and claims 25 and 52 of the '116 patent – recites "a substantially rigid" portion or segment.

81. The side opening section of the patented device is described by variations of patent claim language. Specifically, claim 3 of the '032 patent, claim 9 of the '413 patent, and claim 3 of the '380 patent recite a "proximal side opening"; claims 25, 52, and 53 of the '776 patent recite a "partially cylindrical opening"; and claims 25 and 52 of the '116 patent and claims 25 and 48 of the '760 patent recite a "side opening."

82. The asserted VSI patents also contain claim language that requires a transition in rigidity from the more rigid proximal end to the more flexible distal end of the guide extension catheter. Some of the asserted claims require that the proximal shaft section be more rigid than the distal tubular section:

- "a substantially rigid portion … more rigid along a longitudinal axis than the flexible tip portion," as recited in claim 1 of the '032 patent, claim 1 of the '413 patent, and claim 1 of the '380 patent.

Some claims require that the flexible cylindrical distal tip portion be more flexible than the flexible cylindrical reinforced portion:

- "the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion," as recited in claim 1 of the '380 patent.

Other claims require that the side opening be more rigid than the distal tubular section:

- "a material forming the segment defining the side opening is more rigid than the tubular structure," as recited in claim 25 of the '760 patent;
- "the segment defining the partially cylindrical opening … formed from a material more rigid than a material or material combination forming the tubular structure," as recited in claim 25 of the '776 patent;
- "the segment defining the partially cylindrical opening … formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure," as recited in claim 52 of the '776 patent; and

- "the segment defining the side opening … is more rigid than the [a] distal end portion of the tubular structure," as recited in claim 52 of the '116 patent and claim 48 of the '760 patent.

83. Some claims of the asserted VSI patents expressly recite the purpose of the guide extension catheter, which is to provide backup support. For example, claim 2 of the '032 patent and claim 2 of the '380 patent recite, "the device assists in resisting axial and shear forces … that would otherwise tend to dislodge the guide catheter from the branch artery," and claim 1 of the '413 patent recites, "[a] method of providing backup support for an interventional cardiology device."

84. Several of the asserted VSI patent claims recite that the side opening and the distal tubular portion are adapted to receive and pass interventional cardiology devices, such as stents and balloon catheters. For example, the asserted claims recite:

- "the tubular structure is configured to receive a stent and a balloon catheter," as in claim 32 of the '776 patent;
- "the tubular structure configured to receive one or more stents or balloon catheters," as recited in claims 25 and 48 of the '760 patent;
- "the segment defining the partially cylindrical opening … configured to receive one or more interventional cardiology devices," as recited in claims 25, 52, and 53 of the '776 patent;
- "advancing the balloon catheter or stent … through the side opening, and through the tubular structure," as recited in claims 25 and 52 of the '116 patent;
- "a flexible tip portion … having a cross-sectional inner diameter through which interventional cardiology devices are insertable," as recited in claim 1 of the '032 patent and claim 1 of the '380 patent; and
- "advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion," as recited in claim 1 of the '413 patent.

85. Further, some of the asserted claims of the VSI patents require a minimal gap between the guide extension catheter and the guide catheter, by reciting that the inner diameter of

the guide extension catheter is not more than one French size smaller than the inner diameter of the guide catheter:

- "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter," as recited in claim 8 of the '032 patent;
- "the lumen of the tubular structure … having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter," as recited in claim 25 of the '760 patent and claim 48 of the '760 patent;
- "a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter," as recited in claim 30 of the '776 patent;
- "the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter," as recited in claim 25 of the '116 patent; and
- "a tubular structure … having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter," as recited in claim 53 of the '776 patent.

86. Generally speaking, the features claimed in VSI patents are the essential features of the GuideLiner devices (as well as the Guidezilla and Boosting Catheter) that distinguish them from previous devices and enable them to function as guide extension catheters with rapid exchange convenience.

III. LEGAL STANDARDS AND CLAIM CONSTRUCTION

87. Although I am not a lawyer, I have been asked to apply certain legal concepts in my expert opinions in this case. This section summarizes my understanding of the legal concepts I applied.

88. **Patent infringement in general:** I understand that infringement of a patent is assessed on a claim-by-claim basis. I understand that a patent claim is infringed if each and every limitation of the claim is met by the infringing product, method, or system.

89. **Doctrine of equivalents:** I understand that a claim limitation may be met literally or under the doctrine of equivalents. I understand that a claim limitation is met under the doctrine of equivalents if there are only insubstantial differences between the allegedly infringing product or method and the claim limitation. Similarly, I understand that a claim limitation is met under the doctrine of equivalents if the allegedly infringing product or method meets what is called the "function-way-result" test: it performs substantially the same function and works in substantially the same way to achieve substantially the same result as the requirement of the claimed invention.

90. **Direct and indirect infringement:** I understand that there are multiple types of infringement, including direct infringement, active inducement, and contributory infringement. I understand that a person directly infringes a patent claim if he or she makes, uses, sells, offers for sale, or imports the patented invention in or into the United States.

91. **Active inducement:** I understand that a person actively induces infringement of a patent when he or she knows of a patent, intentionally induces others to infringe the patent, and those others actually infringe the patent directly. I have not been asked to render any opinions on whether QXMédical has induced infringement of VSI's patents other than to opine on whether physicians using the Boosting Catheter infringe the VSI patents directly.

92. **Contributory infringement:** I understand that a person may contribute to infringement of a patent when he or she sells, offers to sell, or imports in or into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process. I understand that a person is liable for contributory infringement if (1) the component, material, or apparatus constitutes a material part of the invention, (2) the person knows that the component, material, or apparatus is

especially made or especially adapted for use in infringing the patent, and (3) the component, material, or apparatus is not a staple article or commodity of commerce suitable for substantial noninfringing use. I have not been asked to render any opinions on QXMédical's knowledge or intent.

93. **Contributory infringement for foreign activities:** I understand that a person is liable for patent infringement if he or she supplies in or from the United States any uncombined component of a patented invention that is especially made or adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, if the person (1) knows that the component is so made or adapted and (2) intends that the component will be combined with other components outside of the United States in a manner that would infringe the patent in the United States.

94. **Claim Construction.** Similar to the legal concepts just explained, I have been asked to apply certain claim constructions—definitions of terms in the asserted claims—that were either agreed to by Vascular Solutions and QXMédical or decided by the Court in its claim construction order. I have followed those directions and applied the following claim constructions:

"reinforced portion"	"portion made stronger by additional material or support"
"flexural modulus"	"a numeric, dimension-independent material property that captures the tendency of a material to bend"
"proximal"	"a position that is nearer to, or in a direction toward, the physician"
"distal"	"a position that is more distant from, or in a direction away from, the physician"
"substantially rigid"	"rigid enough to allow the device to be advanced within the guide catheter"
"flexible"	plain and ordinary meaning

"rail structure"	"structure . . . that facilitates monorail or sliding rail delivery"
"lumen"	"the cavity of a tube"
"side opening" / "partially cylindrical opening"	plain and ordinary meaning; not required to be in a section of the substantially rigid portion or segment
"wherein a material forming the segment defining the side opening is more rigid than the tubular structure"	"wherein the matter forming the segment defining the side opening is more rigid than the tubular structure"
"formed from a material more rigid than a material or material combination forming the tubular structure"	"formed from matter that is more rigid than the matter forming the tubular structure"
"formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure"	"formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure"

IV. OPINIONS ON INFRINGEMENT

A. Overview

95. I have been asked to analyze issues related to six Vascular Solutions patents: the '032 Patent, the '413 Patent, the '380 Patent, the '760 Patent, the '776 Patent, and the '116 Patent. The patents are all very similar in that they originated from a common patent application and have essentially the same written description. The claims differ, however, in that some of the asserted claims cover a guide extension catheter itself (the '032 and '776 Patents), others cover a method of using a guide extension catheter (the '413 and '116 Patents), and others cover a system including a guide extension catheter and a guide catheter (the '380 and '760 Patents).

96. As explained above in paragraph 9, the scope of my analysis depended on the type of claim asserted. For claims directed to the guide extension catheter itself, I analyzed whether the Boosting Catheter meets each limitation of the asserted claims. If so, I concluded that QXMédical infringes the asserted claims by making, using, selling, or offering for sale the Boosting Catheter. For claims directed to a method of using the guide extension catheter or a

system including the guide extension catheter and a guide catheter, I analyzed whether an interventionalist using the Boosting Catheter or combining it with a guide catheter would meet all the limitations of the asserted claims. I also analyzed whether the Boosting Catheter constitutes a material part of the invention of the asserted claims, whether the Boosting Catheter is especially made or adapted for use in the claimed method or system, and whether the Boosting Catheter is a staple article or commodity of commerce suitable for substantial noninfringing use. I did not reach any ultimate conclusions about whether QXMédical infringes the asserted claims indirectly (that is, by active inducement or contributory infringement) because that involves analysis of QXMédical's knowledge or intent, which are not technical questions and are thus beyond the scope of my analysis.

97. The bulk of my analysis is set forth in Appendix I, a set of claim charts in which I set forth my opinions regarding each element of the asserted claims. Those claim charts should be considered an extension of this report, and are incorporated by reference here. Although the charts differ somewhat in form from this written document, I do not intend for my statements there to be weighed differently than my statements here.

98. For some limitations of the asserted claims, I performed laboratory testing on samples of the Boosting Catheter to help determine whether the limitations of the asserted claims are met. I set forth my testing methods and results in Appendices C-H. Similar to my claim charts, the test results in Appendices C-H should be considered an extension of this report, and are incorporated by reference here. I do not intend for my statements there to be weighed differently than my statements here.

B. The '032 Patent

99. I understand that claims 3 and 8 of the '032 Patent are asserted in this case. Both of these claims depend from claim 1, and claim 3 also depends from claim 2. I have set forth the text of the claims below:

> [1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:
>
> a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and
>
> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,
>
> such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.
>
> 2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the

> guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.]
>
> **3.** The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.
>
> […]
>
> **8.** The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

100. It is my opinion that each model of the Boosting Catheter meets the limitations of claim 3 of the ’032 Patent and that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claim 8 of the ’032 Patent. I explain my analysis supporting these opinions in the claim charts in Appendix I.

101. Because the Boosting Catheter by itself meets each limitation of claims 3 and 8 of the ’032 Patent, it is my opinion that QXMédical infringes these claims when it makes, uses, sells, offers for sale, or imports one of these devices in or into the United States.

C. The ’413 Patent

102. I understand that only claim 9 of the ’413 Patent is asserted in this case. Claim 9 depends from claim 1. Together, the text of those claims reads:

> [1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end

adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:

inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,

further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;

advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and

inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.]

9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular

> structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.

103. It is my opinion that each model of the Boosting Catheter meets the limitations of claim 9 of the ’413 Patent when used with a guide catheter, guidewire, and interventional cardiology device (stent or balloon) for an interventional procedure in the coronary vasculature. I explain my analysis supporting this opinion in the claim charts in Appendix I.

104. Because claim 9 is directed to a method of using the device, it is my opinion that anyone who uses a Boosting Catheter as just described infringes claim 9 of the ’413 Patent.

105. It is my opinion that the Boosting Catheter constitutes a material part of the method of claim 9 of the ’413 Patent. The Boosting Catheter is the “coaxial guide catheter” described in three of the steps of the claimed method. These steps cannot be performed without the Boosting Catheter or an equivalent device. Moreover, the claim imposes several specific requirements on the coaxial guide catheter: it must have a “flexible tip portion . . . defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter”; it must have “a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion”; the substantially rigid portion must “defin[e] a rail structure without a lumen and hav[e] a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion”; and the device as a whole must be “longer than the length of the continuous lumen of the guide catheter.” Of the four devices required to perform the claimed method (the guide catheter, guidewire, coaxial guide catheter, and interventional cardiology device), the coaxial guide catheter is the most specifically described.

106. For all of these reasons, it is my opinion that the Boosting Catheter constitutes a material part of the claimed invention.

107. It is also my opinion that the Boosting Catheter is especially made or adapted for use in the method of claim 9 of the '413 Patent. As I explain in my claim charts, the Instructions for Use that QXMédical provides with the Boosting Catheter describe its suitability for use in procedures that generally follow the steps of the claimed method: "inserting the standard guide catheter into a first artery over a guidewire," "positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery," "inserting a flexible tip portion of a coaxial guide catheter . . .", "further inserting a substantially rigid portion . . .", "advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery," and "inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter . . . and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery."

108. In addition, as I explain in my claim charts, the Boosting Catheter meets all of the structural requirements listed in claim 9: the "flexible tip portion . . . defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter"; the "substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion"; and the device as a whole being "longer than the length of the continuous lumen of the guide catheter." The fact that the Boosting Catheter meets each of these requirements is a

product of the design and manufacturing specifications created by QXMédical. Each of those requirements helps the Boosting Catheter function as a guide extension catheter in the claimed method.

109. Finally, it is my opinion that the Boosting Catheter is not a staple article or commodity suitable for substantial noninfringing use with respect to the '413 Patent. The only substantial use of the Boosting Catheter I know of is using the device with a guide catheter, guidewire, and interventional cardiology device (stent or balloon) for an interventional procedure in the coronary vasculature.

110. I understand that QXMédical's Instructions for Use for the Boosting Catheter suggest that the device can be used to assist with the delivery of "procedural fluids" rather than interventional devices, that it can be used in the "peripheral vasculature" rather than in the coronary vasculature, and that it can be used with a "sheath" rather than a guide catheter. I do not believe any of these possible uses is substantial compared with the primary use of performing interventional procedures in the coronary vasculature using a guide catheter, guidewire, and interventional cardiology device.

111. At QXMédical's deposition, the company's chief technical officer, Fernando Di Caprio, testified that he was not aware of the Boosting Catheter ever being used in a peripheral case. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 40-41 ("Q. Are you aware of your Boosting Catheter being used in peripheral applications? A. It's indicated for peripheral applications. I don't believe I have ever witnessed a Boosting catheter being used in a peripheral application. . . . . Q. You are not aware of the Boosting Catheter being used in a specific case, peripheral case? A. I haven't seen that."). Mr. Di Caprio agreed that QXMédical's sales efforts thus far have been "directed at interventional cardiologists and cath

labs" and that the product would "typically" be used in a coronary catheterization procedure. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 292-93. When asked whether "the only use the Boosting Catheter has [been] put to so far is coronary catheterization," Mr. Di Caprio declined to give a "definitive answer," but did not name a single instance of the Boosting Catheter being used for anything else. *Id.* at 293-94. This testimony supports my view that the possible use of the Boosting Catheter for peripheral applications is not substantial.

112. For similar reasons, I do not believe the possible use of the Boosting Catheter with a sheath rather than a guide catheter is substantial. Mr. Di Caprio testified that a sheath could not be used for a coronary catheterization procedure because the shape of the sheath could not safely pass through the coronary vasculature. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 45-46.

113. I also do not believe the possible use of the Boosting Catheter to deliver procedural fluids alone is substantial. I am not aware of any cases of the Boosting Catheter being used for such purposes, and even if there are some, I doubt that they would be substantial compared to the primary use of delivering interventional devices such as balloon catheters and stents.

D. The '380 Patent

114. I understand that claims 1, 3, and 8 of the '380 Patent are asserted. The text of those claims and claim 2, from which claim 3 depends, reads as follows:

> **1**. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:
>
> a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional

cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;

wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.

[2. The system of claim 1, wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.]

> **3**. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.
>
> **8**. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

115. It is my opinion that each model of the Boosting Catheter meets the limitations of claims 1 and 3 of the ’380 Patent when combined with a guide catheter and that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claim 8 of the ’380 Patent when combined with a guide catheter. I explain my analysis supporting these opinions in the claim charts in Appendix I.

116. Because the claims are directed to a system including both the Boosting Catheter and a guide catheter, it is my opinion that physicians infringe claims 1, 3, and 8 of the ’380 Patent when combining the two as just described.

117. It is my opinion that each model of the Boosting Catheter constitutes a material part of the systems of claims 1 and 3 of the ’380 Patent and that the six French Boosting Catheter constitutes a material part of the system of claim 8 of the ’380 Patent. Each of the claims recites a system comprising two parts: “a guide catheter” and “a device.” The Boosting Catheter is the “device” described in the claims. It is clear from the language of the claims that the claimed “device” is a material part of the invention—in fact, the *principal* part of the invention, as it is defined with more detail and more limitations than the other component of the claimed system, the guide catheter. As I explain in my claim charts, the Boosting Catheter meets all of the structural requirements in claims 1 and 3, including the “flexible tip portion . . .”, the

"substantially rigid portion . . .", the "flexible cylindrical distal tip portion" and the "flexible cylindrical reinforced portion."

118. It is my opinion that each model of the Boosting Catheter is especially made or adapted for the systems of claims 1 and 3 of the '380 Patent and that the six French Boosting Catheter is especially made or adapted for use in the system of claim 8 of the '380 Patent. The Instructions for Use that QXMédical provides with the Boosting Catheter describe its suitability for combination with a guide catheter, laying out in a table which sizes of the Boosting Catheter are indicated for use with which sizes of guide catheter. The Instructions for Use also indicate that the Boosting Catheter is appropriate for use with interventional cardiology devices. The fact that the Boosting Catheter is suitable for such uses is a product of the design and manufacturing specifications created by QXMédical. In addition, as explained in the preceding paragraph, the Boosting Catheter also meets the general structural requirements of the claims. The fact that the Boosting Catheter meets each of these requirements is a product of the design and manufacturing specifications created by QXMédical. Each of those requirements helps the Boosting Catheter function in combination with a guide catheter for the delivery of interventional cardiology devices.

119. With regard to claim 8 of the '380 Patent, which requires that the inner diameter of the device be "not more than one French smaller" than the inner diameter of the guide catheter with which it is used, it is my opinion that the six French Boosting Catheter is especially made or adapted for this use. As I explain in my claim charts, combining the six French Boosting Catheter with a standard 0.070-inch guide catheter literally infringes claim 8 and combining the six French Boosting Catheter with a standard 0.071-inch guide catheter infringes claim 8 under

the doctrine of equivalents. It is my opinion that the Boosting Catheter is especially made or adapted for use with either of those guide catheter sizes.

120. QXMédical's process validation testing confirms that the six French Boosting Catheter is sized appropriately to pass through a smaller 0.070-inch guide catheter. I know this from my review of QXMédical's testing documentation as well as from the deposition testimony of its chief technical officer, Mr. Di Caprio. Defendants' Depo. Ex. 19 (Design Review Meeting Minutes, with Process Validation) at QXM 8641; August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 203-04.

121. In addition, QXMédical obtained FDA approval for the use of its six French Boosting Catheter with a 0.070-inch guide catheter. Defendants' Depo. Ex. 44 (FDA submission) at QXM 6315-16, 6327; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7372, 7391, 7398; *see also* August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 212-13. When QXMédical changed its Instructions for Use to say that the device is compatible with guide catheters of 0.071 inches or greater, it did not make any changes to the design of the device itself, nor did it notify the FDA.

122. Finally, it is my opinion that no model of the Boosting Catheter, six French or otherwise, is a staple article or commodity suitable for substantial noninfringing use with respect to the asserted claims of the '380 Patent. The only substantial use of the Boosting Catheter I know of is with a guide catheter.

123. I understand that QXMédical's Instructions for Use for the Boosting Catheter suggest that the device can be used with a "sheath" rather than a guide catheter. I do not believe that possible use is substantial compared to use with a guide catheter.

124. At QXMédical's deposition, the company's chief technical officer, Fernando Di Caprio, testified that a sheath could not be used for a coronary catheterization procedure because the shape of a sheath could not safely pass through the coronary vasculature. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 45-46. Mr. Di Caprio testified that a sheath "would be used primarily more in peripheral-type applications." August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 46.

125. Mr. Di Caprio testified that he was not aware of the Boosting Catheter ever being used in a peripheral case. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 40-41 ("Q. Are you aware of your Boosting Catheter being used in peripheral applications? A. It's indicated for peripheral applications. I don't believe I have ever witnessed a Boosting catheter being used in a peripheral application. . . . . Q. You are not aware of the Boosting Catheter being used in a specific case, peripheral case? A. I haven't seen that."). Mr. Di Caprio agreed that QXMédical's sales efforts thus far have been "directed at interventional cardiologists and cath labs" and that the product would "typically" be used in a coronary catheterization procedure. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 292-93. When asked whether "the only use the Boosting Catheter has put to so far is coronary catheterization," Mr. Di Caprio declined to give a "definitive answer," but did not name a single instance of the Boosting Catheter being used for anything else. *Id.* at 293-94. This testimony supports my view that the possible use of the Boosting Catheter with a sheath is not substantial.

126. With regard to claim 8, it is my opinion that use of the Boosting Catheter with a 0.071-inch guide catheter is not a substantial noninfringing use because that use infringes the claims under the doctrine of equivalents.

E. The '760 Patent

127. I understand that claims 25, 30, 31, 32, and 48 of the '760 Patent are asserted.

The text of these claims reads as follows:

> **25**. A system, comprising:
>
> a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and
>
> a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,
>
> the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;
>
> wherein a material forming the segment defining the side opening is more rigid than the tubular structure.

30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.

31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.

32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.

48. A system, comprising:

a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and

a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,

the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the

distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.

128. It is my opinion that the six French model of the Boosting Catheter, Model No. BC57-150, meets the limitations of claims 25, 30, 31, 32, and 48 of the '760 Patent when combined with a guide catheter. I explain my analysis supporting these opinions in the claim charts in Appendix I.

129. Because the claims are directed to a system including both the Boosting Catheter and a guide catheter, it is my opinion that physicians infringe claims 25, 30, 31, 32, and 48 of the '760 Patent when combining the two as just described.

130. It is my opinion that the six French Boosting Catheter constitutes a material part of the systems of claims 25, 30, 31, 32, and 48 of the '760 Patent. Each of the claims recites a system comprising two parts: "a guide catheter" and "a guide extension catheter." The Boosting Catheter is the "guide extension catheter" described in the claims. It is clear from the language of the claims that the claimed "guide extension catheter" is a material part of the invention—in fact, the *principal* part of the invention, as it is defined with more detail and more limitations than the other component of the claimed system, the guide catheter. As I explain in my claim charts, the Boosting Catheter meets all of the structural requirements in claims 25, 30, 31, 32, and 48 of the '760 Patent, including the "substantially rigid segment," the "segment defining a side opening," and the "tubular structure defining a lumen."

131. It is my opinion that the six French Boosting Catheter is especially made or adapted for use in the systems of claims 25, 30, 31, 32, and 48 of the '760 Patent. The Instructions for Use that QXMédical provides with the Boosting Catheter describe its suitability

for combination with a guide catheter and for use with interventional cardiology devices. The fact that the Boosting Catheter is suitable for such uses is a product of the design and manufacturing specifications created by QXMédical. In addition, as explained in the preceding paragraph, the Boosting Catheter also meets the general structural requirements of the claims. The fact that the Boosting Catheter meets each of these requirements is a product of the design and manufacturing specifications created by QXMédical. Each of those requirements helps the Boosting Catheter function in combination with a guide catheter for the delivery of interventional cardiology devices.

132. With regard to the claims' requirement that the inner diameter of the device be "not more than one French size smaller" than the inner diameter of the guide catheter with which it is used, it is my opinion that the six French Boosting Catheter is especially made or adapted for this use. As I explain in my claim charts, combining the six French Boosting Catheter with a standard 0.070-inch guide catheter literally infringes the claims and combining the six French Boosting Catheter with a standard 0.071-inch guide catheter infringes the claims under the doctrine of equivalents. It is my opinion that the Boosting Catheter is especially made or adapted for use with either of those guide catheter sizes.

133. QXMédical's process validation testing confirms that the six French Boosting Catheter is sized appropriately to pass through a smaller 0.070-inch guide catheter. I know this from my review of QXMédical's testing documentation as well as from the deposition testimony of its chief technical officer, Mr. Di Caprio. Defendants' Depo. Ex. 19 (Design Review Meeting Minutes, with Process Validation) at QXM 8641; August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 203-04.

134. In addition, QXMédical obtained FDA approval for the use of its six French Boosting Catheter with a 0.070-inch guide catheter. Defendants' Depo. Ex. 44 (FDA submission) at QXM 6315-16, 6327; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7372, 7391, 7398; *see also* August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 212-13. When QXMédical changed its Instructions for Use to say that the device is compatible with guide catheters of 0.071 inches or greater, it did not make any changes to the design of the device itself, nor did it notify the FDA.

135. Finally, it is my opinion that no model of the Boosting Catheter, six French or otherwise, is a staple article or commodity suitable for substantial noninfringing use with respect to the asserted claims of the '760 Patent. The only substantial use of the Boosting Catheter I know of is with a guide catheter.

136. I understand that QXMédical's Instructions for Use for the Boosting Catheter suggest that the device can be used with a "sheath" rather than a guide catheter. I do not believe that possible use is substantial compared to use with a guide catheter.

137. At QXMédical's deposition, the company's chief technical officer, Fernando Di Caprio, testified that a sheath could not be used for a coronary catheterization procedure because the shape of a sheath could not safely pass through the coronary vasculature. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 45-46. Mr. Di Caprio testified that a sheath "would be used primarily more in peripheral-type applications." August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 46.

138. Mr. Di Caprio testified that he was not aware of the Boosting Catheter ever being used in a peripheral case. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 40-41 ("Q. Are you aware of your Boosting Catheter being used in peripheral applications?

A. It's indicated for peripheral applications. I don't believe I have ever witnessed a Boosting catheter being used in a peripheral application. . . . . Q. You are not aware of the Boosting Catheter being used in a specific case, peripheral case? A. I haven't seen that."). Mr. Di Caprio agreed that QXMédical's sales efforts thus far have been "directed at interventional cardiologists and cath labs" and that the product would "typically" be used in a coronary catheterization procedure. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 292-93. When asked whether "the only use the Boosting Catheter has put to so far is coronary catheterization," Mr. Di Caprio declined to give a "definitive answer," but did not name a single instance of the Boosting Catheter being used for anything else. *Id.* at 293-94. This testimony supports my view that the possible use of the Boosting Catheter with a sheath is not substantial.

139. It is my opinion that use of the Boosting Catheter with a 0.071-inch guide catheter is not a substantial noninfringing use because that use infringes the claims under the doctrine of equivalents.

F. The '776 Patent

140. I understand that claims 25, 32, 36, 52, and 53 of the '776 Patent are asserted. The text of those claims plus claim 30, from which claim 32 depends, is:

> **25**. A guide extension catheter for use with a guide catheter, comprising:
>
> a substantially rigid segment;
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and
>
> a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology

devices therethrough when positioned within the guide catheter,

wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.

[30. The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.]

32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.

36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.

52. A guide extension catheter for use with a guide catheter, comprising:

a substantially rigid segment;

a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and

a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,

wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;

wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

> **53**. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:
>
> a substantially rigid segment;
>
> a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and
>
> a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;
>
> wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

141. It is my opinion that each model of the Boosting Catheter meets the limitations of claims 25, 36, and 52 of the ’776 Patent and that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claims 32 and 53 of the ’776 Patent. I explain my analysis supporting these opinions in the claim charts in Appendix I.

142. Because the Boosting Catheter by itself meets each limitation of claims 25, 32, 36, 52, and 53 of the ’776 Patent, it is my opinion that QXMédical infringes these claims when it makes, uses, sells, offers for sale, or imports one of these devices in or into the United States.

G. The ’116 Patent

143. I understand that claims 25, 34, and 53 of the ’116 Patent are asserted. The text of those claims plus claim 52, from which claim 53 depends, reads:

> **25**. A method, comprising:

advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;

advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and

while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.

34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.

[52. A method, comprising:

advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;

advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a

side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and

while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.]

53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.

144. It is my opinion that the six French Boosting Catheter, Model No. BC57-150, meets the limitations of claims 25 and 34 of the ’116 Patent when used for a coronary vascular procedure with a guide catheter and that each model of the Boosting Catheter meets the limitations of claim 53 of the ’116 Patent in those circumstances. I explain my analysis supporting these opinions in the claim charts in Appendix I.

145. Because claims 25, 34, and 53 are directed to a method of using the device, it is my opinion that, in the circumstances just described, the person who uses the Boosting Catheter infringes claims 25, 34, and 53 of the ’116 Patent.

146. It is my opinion that the six French Boosting Catheter constitutes a material part of the methods of claims 25 and 34 of the ’116 Patent and that each model of the Boosting Catheter constitutes a material part of the method of claim 53 of the ’116 Patent.

147. The Boosting Catheter is the "guide extension catheter" described in three of the steps of each of the claimed methods. These steps cannot be performed without the Boosting Catheter or an equivalent device. For example, the operator must be able to "advance[e] a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter," which means that the device must have a push rod or other means to control the device when the proximal end of the tubular structure disappears into the proximal end of the guide catheter, out of reach of the operator. The operator also must be able to "advance[e] the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure," which requires that the device have a push rod or other substantially rigid segment proximal to the side opening, and that the device allow passage of an interventional cardiology device along the push rod and into the tubular structure through the side opening. Having a device that enables these steps to occur is a critical part of performing the claimed method.

148. Moreover, of the three devices required to perform the claimed method (the guide catheter, guide extension catheter, and balloon catheter or stent), the guide extension catheter is the most specifically described. In addition to the structural requirements imposed by the method steps described above, claims 25 and 34 require that the side opening "extend[] for a distance along a longitudinal axis of the guide extension catheter" and be "accessible from a longitudinal side defined transverse to the longitudinal axis," and that the tubular structure "hav[e] a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter." Claim 53 requires that "the

segment defining the side opening comprise[] a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure." These additional limitations confirm that the guide extension catheter is a material part of the claimed invention.

149. It is my opinion that the six French Boosting Catheter is especially made or adapted for the methods of claims 25 and 34 of the '116 Patent, and that each model of the Boosting Catheter is especially made or adapted for use in the method of claim 53 of the '116 Patent. As I explain in my claim charts, the Instructions for Use that QXMédical provides with the Boosting Catheter describe its suitability for use in procedures that generally follow the steps of the claimed methods: "advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery," "advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter . . . while a segment defining a side opening of the guide extension catheter remains within the guide catheter," "maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter," and "advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery." In addition, as explained above in paragraph 147, the Boosting Catheter also meets the general structural requirements imposed by the method steps. The fact that the Boosting Catheter meets each of these requirements is a product of the design and manufacturing specifications created by QXMédical. Each of those requirements helps the Boosting Catheter function as a guide extension catheter in the claimed method.

150. With regard to claims 25 and 34 of the '116 Patent, which require that the inner diameter of the device be "not more than one French size smaller" than the inner diameter of the guide catheter through which it passes, it is my opinion that the six French Boosting Catheter is

especially made or adapted for this use. As I explain in my claim charts, use of the six French Boosting Catheter with a standard 0.070-inch guide catheter literally infringes the claims and use of the six French Boosting Catheter with a standard 0.071-inch guide catheter infringes the claims under the doctrine of equivalents. It is my opinion that the Boosting Catheter is especially made or adapted for use with either of those guide catheter sizes.

151. QXMédical's process validation testing confirms that the six French Boosting Catheter is sized appropriately to pass through a smaller 0.070-inch guide catheter. I know this from my review of QXMédical's testing documentation as well as from the deposition testimony of its chief technical officer, Mr. Di Caprio. Defendants' Depo. Ex. 19 (Design Review Meeting Minutes, with Process Validation) at QXM 8641; August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 203-04.

152. In addition, QXMédical obtained FDA approval for the use of its six French Boosting Catheter with a 0.070-inch guide catheter. Defendants' Depo. Ex. 44 (FDA submission) at QXM 6315-16, 6327; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7372, 7391, 7398; *see also* August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 212-13. When QXMédical changed its Instructions for Use to say that the device is compatible with guide catheters of 0.071 inches or greater, it did not make any changes to the design of the device itself, nor did it notify the FDA.

153. With regard to claim 53 of the '116 Patent, which requires that "the segment defining the side opening comprise[] a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure," it is my opinion that all models of the Boosting Catheter are especially made or adapted for that purpose. As I explain in my claim charts and further in my laboratory testing summary, the side opening portion of the Boosting

Catheter is more rigid than the distal end portion that protrudes from the end of the guide catheter during use. This is a result of several features of the Boosting Catheter's design, including the use of relatively high-durometer polymers in the side opening section, the embedding of the push rod's paddle ends into the polymer of the tubular structure, and the addition of a PTFE patch around the mouth of the device. These features combine to give the side opening more rigidity than the distal end portion of the tubular structure.

154. Finally, it is my opinion that no model of the Boosting Catheter, six French or otherwise, is a staple article or commodity suitable for substantial noninfringing use with respect to the '116 Patent. The only substantial use of the Boosting Catheter I know of is using the device with a guide catheter and interventional cardiology device (stent or balloon) for an interventional procedure in the coronary vasculature.

155. I understand that QXMédical's Instructions for Use for the Boosting Catheter suggest that the device can be used to assist with the delivery of "procedural fluids" rather than interventional devices, that it can be used in the "peripheral vasculature" rather than in the coronary vasculature, and that it can be used with a "sheath" rather than a guide catheter. I do not believe any of these possible uses is substantial compared with the primary use of performing interventional procedures in the coronary vasculature using a guide catheter, guidewire, and interventional cardiology device.

156. At QXMédical's deposition, the company's chief technical officer, Fernando Di Caprio, testified that he was not aware of the Boosting Catheter ever being used in a peripheral case. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 40-41 ("Q. Are you aware of your Boosting Catheter being used in peripheral applications? A. It's indicated for peripheral applications. I don't believe I have ever witnessed a Boosting catheter being used in a

peripheral application. . . . . Q. You are not aware of the Boosting Catheter being used in a specific case, peripheral case? A. I haven't seen that."). Mr. Di Caprio agreed that QXMédical's sales efforts thus far have been "directed at interventional cardiologists and cath labs" and that the product would "typically" be used in a coronary catheterization procedure. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 292-93. When asked whether "the only use the Boosting Catheter has put to so far is coronary catheterization," Mr. Di Caprio declined to give a "definitive answer," but did not name a single instance of the Boosting Catheter being used for anything else. *Id.* at 293-94. This testimony supports my view that the possible use of the Boosting Catheter for peripheral applications is not substantial.

157. For similar reasons, I do not believe the possible use of the Boosting Catheter with a sheath rather than a guide catheter is substantial. Mr. Di Caprio testified that a sheath could not be used for a coronary catheterization procedure because the shape of the sheath could not safely pass through the coronary vasculature. August 2, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 45-46.

158. I also do not believe the possible use of the Boosting Catheter to deliver procedural fluids alone is substantial. I am not aware of any cases of the Boosting Catheter being used for such purposes, and even if there are some, I doubt that they would be substantial compared to the primary use of delivering interventional devices such as balloon catheters and stents.

159. With regard to claims 25 and 34, it is my opinion that use of the Boosting Catheter with a 0.071-inch guide catheter is not a substantial noninfringing use because that use infringes the claims under the doctrine of equivalents (assuming the other requirements are met).

V. OPINIONS ON GUIDELINER, TRAPLINER, AND GUIDEZILLA

160. Similar to my opinions on infringement, I was asked to analyze whether the asserted claims cover VSI's GuideLiner and TrapLiner catheters and Boston Scientific's Guidezilla catheters. I based my analysis on my review of the asserted patents and claims, information produced in discovery, and my manual inspection and testing of the products.

161. I was asked only to analyze whether the claims cover the devices or their use in certain ways. For the '032 and '776 Patents, whose claims are directed to the guide extension catheter itself, I was asked to analyze whether the devices meet each limitation of the asserted claims. For the '413 and '116 Patents, whose claims cover methods of using the device, I was asked to analyze whether an interventionalist's use of the devices in combination with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) would meet each limitation of the claims. For the '380 and '760 Patents, which are directed to systems including a guide extension catheter and a guide catheter, I was asked to analyze whether an interventionalist's combining the devices with a guide catheter would meet each limitations of the asserted claims. Unlike my opinions on infringement, I was not asked to analyze any issues relating to active inducement or contributory infringement, such as whether the devices constitute a material part of the claimed inventions.

162. The bulk of my analysis is set forth in Appendices J-P, a set of claim charts in which I set forth my opinions regarding each element of the asserted claims. Those claim charts should be considered an extension of this report, and are incorporated by reference here. Although the charts differ somewhat in form from this written document, I do not intend for my statements there to be weighed differently than my statements here.

163. For some limitations of the asserted claims and for some devices, I performed laboratory testing on samples of the devices to help determine whether the limitations of the

asserted claims are met. I set forth my testing methods and results in Appendices C-H. Similar to my claim charts, the test results in Appendices C-H should be considered an extension of this report, and are incorporated by reference here. I do not intend for my statements there to be weighed differently than my statements here.

164. **The ’032 Patent:** It is my opinion that all versions and sizes of the GuideLiner and Guidezilla meet the limitations of claim 3 of the ’032 Patent. It is my opinion that the six French size of each version of the GuideLiner and Guidezilla meets the limitations of claim 8 of the ’032 Patent.

165. **The ’413 Patent:** It is my opinion that all versions and sizes of the GuideLiner and Guidezilla meet the limitations of claim 9 of the ’413 Patent when used for a coronary vascular procedure with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent).

166. **The ’380 Patent:** It is my opinion that all versions and sizes of the GuideLiner and Guidezilla meet the limitations of claims 1 and 3 of the ’380 Patent when combined with a guide catheter. It is my opinion that the six French size of each version of the GuideLiner and Guidezilla meets the limitations of claim 8 of the ’380 Patent when combined with a guide catheter.

167. **The ’760 Patent:** It is my opinion that the six French size of each version of the GuideLiner, Guidezilla, and TrapLiner meets the limitations of claims 25, 30, 31, 32, and 48 of the ’760 Patent when combined with a guide catheter, except that the GuideLiner V2 does not meet the limitations of claim 32 of the ’760 Patent.

168. **The ’776 Patent:** It is my opinion that all versions and sizes of the GuideLiner, Guidezilla, and TrapLiner catheters meet the limitations of claims 25 of the ’776 Patent and that

the six French sizes of those catheters meet the limitations of claim 32 of the '776 Patent. It is my opinion that all sizes of the GuideLiner V3 and the TrapLiner meet the limitations of claim 36 of the '776 Patent. It is my opinion that all versions and sizes of the GuideLiner, Guidezilla, and TrapLiner except GuideLiner V2 meet the limitations of claim 52 of the '776 Patent and that the six French sizes of those catheters meet the limitations of claim 53 of the '776 Patent.

169. **The '116 Patent:** It is my opinion that the six French size of each version of the GuideLiner, Guidezilla, and TrapLiner meets the limitations of claims 25 and 34 of the '116 Patent when used for a coronary vascular procedure with a guide catheter and interventional cardiology device (balloon catheter or stent) and that all versions and sizes of the GuideLiner, GuideZilla, and TrapLiner meet the limitations of claim 52 of the '116 Patent in those circumstances.

VI. LACK OF ACCEPTABLE NONINFRINGING ALTERNATIVES

170. **Heartrail 5-in-6 catheter.** The Heartrail 5-in-6 device is an example of the "mother and child" approach, in which a guide catheter is augmented with a longer, smaller-diameter guide catheter that is inserted through the primary guide catheter. As I explain in my technical background discussion above, *see* paragraphs 53-57, the "mother and child" approach can be effective at improving backup support and is safer than deep-seating an ordinary guide catheter in the coronary artery. However, the technique suffers from significant drawbacks compared with the inventions claimed in VSI's GuideLiner patents.

171. The first and probably greatest drawback is the need for a specialized, longer "exchange length" guidewire, as I explain in detail in paragraphs 54-56. Using an exchange length guidewire is cumbersome in the best of circumstances, ordinarily requiring a second operator to handle the excess guidewire, which may be several feet long. The need to use an exchange length guidewire is also cumbersome because, if the need for the "mother and child"

approach is only identified after the first guidewire is in place, the operator would need to withdraw the first guidewire, insert the exchange length guidewire, and cross the lesion for a second time. Crossing the lesion is one of the riskiest and most difficult steps in a catheterization procedure, and having to do it twice would be highly disfavored.

172. Another drawback of the Heartrail 5-in-6 (and the "mother and child" approach generally) is that a second hemostatic valve is needed to close off the child catheter from the outflow of blood, which is cumbersome and an additional expense. In addition, because the child catheter occupies much of the space within the mother catheter along its entire length, it would be more difficult to transmit procedural fluids through the system compared with the GuideLiner, whose full tubular section occupies only a small portion of the length of the guide catheter. Finally, because the child catheter must be longer than a typical guide catheter, using the "mother and child" approach may reduce the operable range of use for some interventional devices, depending on their length.

173. **Adams.** The Adams '292 patent describes three different devices that could theoretically substitute for a GuideLiner: one embodiment having a long tube with no push rod, similar to the Heartrail 5-in-6, and two embodiments having shorter tubes with push rods, more similar to the GuideLiner. Each of these embodiments suffers from a number of drawbacks compared to the GuideLiner.

174. Adams's long-tube embodiment, shown in Figure 8 and described in the text at lines 13:26-67, has three primary drawbacks: first, its slitted design would be cumbersome to use; second, like the Heartrail 5-in-6, it would necessitate the use of a second hemostatic valve; and third, also like the Heartrail 5-in-6, it would restrict fluid transmission more so than the GuideLiner. In order to eliminate the need for an exchange length guidewire, the Adams device

has a slit running the length of the tube, similar to the foam insulation tubes sometimes placed on hot and cold water pipes in homes. The slit allows the device to be fed over an guidewire that is already in place, without requiring a length of guidewire protruding from the body that is greater than the length of the device itself. Although this eliminates the exchange length guidewire problem, it would be cumbersome in practice. To function correctly, the Adams device's slit would need to be narrow and tight enough to close itself elastically once passed over the guidewire. That means that the operator would need to exert some force (perhaps squeezing the device between finger and thumb) to keep the slit open while threading the device over the guidewire and into the hemostatic valve of the guide catheter. This would be difficult to do, and if the slit closed inadvertently on the guidewire as the device was being threaded on, it could get caught and damage either the Adams device or the guidewire—or worse, harm the patient.

175. Another deficiency of the Adams full-tube device is that it would be difficult to incorporate a hemostatic valve given the presence of the slit running the entire length of the tube. The Adams patent does not describe any solution for this problem.

176. Adams's other embodiments suffer from other drawbacks. One of the embodiments, shown in Figures 3 and 5, has a perpendicular opening ringed by an inflatable balloon. The balloon is designed to be inflated around the lumen portion of the device to hold it in place at the end of the guide catheter. The balloon requires space between the outer walls of the device and the inner walls of the guide catheter, which means that the inner lumen of the device is restricted in size as well. This would be prohibitive for many operations where it is desired to use an interventional device that would not pass through such a small lumen. Even apart from its size, the perpendicular opening of the device would be disadvantageous compared to the GuideLiner in that devices being inserted through the catheter would be more likely to

catch than on the GuideLiner's angled side opening. The GuideLiner's angled opening facilitates entry of interventional cardiology devices into the GuideLiner's tubular portion, thus addressing the problem of stent interaction, or stent catch.

177. The other embodiment in Adams, shown in Figures 9 and 10, has a perpendicular opening that is conical in shape. Although the conical opening would be preferable to the balloon design for reducing device-entry issues, the existence of the funnel (which is of considerable size relative to the lumen of the device) is like the balloon in that it necessarily implies the inner lumen of the device is smaller than the available space within the guide catheter, restricting the range of interventional devices that can be used. Finally, Adams suggests that both the balloon and cone embodiments may have difficulties with pushability, which would be undesirable. *See* Adams at 14:60-62 ("The tube 255 is so flexible that the tube must be inserted with the assistance of another coronary treatment device to provide sufficient pushability.").

178. **Crittenden.** Critten describes two embodiments: a balloon dilation catheter and a device that has a short length lumen attached to a push rod, similar to Adams. The balloon dilation catheter is not a substitute for the GuideLiner at all because it is an interventional device, and other interventional devices cannot pass through it. Crittenden's other embodiment suffers from similar disadvantages as Adams's short-lumen embodiments. Like those embodiments, Crittenden's device has a significantly smaller-diameter lumen than the guide catheter through which it passes, meaning that the range of compatible devices is significantly reduced. The smaller diameter of the lumen is evidenced by the cone located at its proximal end, which is intended to assist with device entry.

179. **Kontos.** Kontos describes several embodiments, but like Adams they fall into two categories: short-lumen devices attached to push rods and long-lumen devices without push rods. Kontos's short tube embodiments have a flare at their proximal end, which, like Crittenden and Adams, means that the lumen of the device is necessarily not as large as it could be within the confines of the guide catheter. Kontos's short-lumen embodiments are also intended to be placed across a lesion, unlike the GuideLiner, which further suggests that the diameter of the device is too small to be used effectively as a guide extension catheter. The long-lumen embodiment described in Figure 10 of Kontos is very similar to the long-lumen embodiment described in Adams, with a slit along the length of the device to eliminate the need for an exchange length guidewire. That design would suffer from the same disadvantages of the Adams device, namely difficulty of use, necessity of a second hemostatic valve, and restriction of fluid flow.

180. **Market availability.** As far as I am aware, none of the devices just described have been marketed significantly, if at all, in the United States. The lack of market success when compared with the great success of the GuideLiner and other covered devices bolsters my view that these devices would not be acceptable alternatives if marketed.

VII. CONCLUSION

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on 2 Jan, 2019, in St. Paul, Minnesota.

Peter Keith

PETER T. KEITH
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SUMMARY:

I am a seasoned innovator in medical device development with over 25 years of experience in a diverse range of medical specialties including cardiology, vascular surgery, otolaryngology, and orthopedics. I have founded several early stage companies, and consulted with numerous others. I have a passion for advancing technology in high impact areas of medicine for the benefit of patients and healthcare professionals, and I enjoy partnering with other innovators who share this passion.

EXPERIENCE:

Technical Consulting—Peter T Keith Consulting, LLC

1997 – present Consulting for early stage medical device technology companies in areas of product design, intellectual property development.

Selected Clients: **Caisson Interventional (LivaNova), Amphora Medical, Altura, Velocimed (St. Jude), CVRX, Mycor, Coaxia, eV3 (Medtronic/Covidien), ProtoStar, TERAMed (J&J)**.

Entrepreneurial Ventures

2006 – 2014 **Entellus Medical (ENTL),** Plymouth, MN. Development and commercialization of devices for treatment of Chronic Sinusitis. IPO in January 2015.

Co-founder, Director, Vice President R&D, Chief Technical Officer. Executive management responsibility for overall product development of FinESS™ and XprESS™ sinusitis treatment technologies, leadership of product development group, employee hiring, intellectual property, process development, and BoD responsibilities, long term technical advising.

2012 – 2015 **CoreMetrics,** Minneapolis, MN. Development of cardiology products. *Co-founder*. Responsible for device innovation, product development, and intellectual property.

2009 – 2013 **Tarsus Medical**, Sunnyvale, CA. Venture backed developer of extremities orthopedics. *Co-founder, Technical Advisor*. Technology Sold

2005 – 2006 **Incubex**, St. Cloud, MN. Development cardiovascular products. *Co-founder and CTO*. Responsible for device innovation, product development, and intellectual property. Technology sold.

2003 – 2011 **Aetherworks**, White Bear Lake, MN. Development of devices for cardiovascular diseases and smoking cessation. *Co-founder*. Responsible for device innovation, product development. Technology sold.

2000 – 2005 **Spinalabs**, White Bear Lake, MN. Development of devices for spinal disorders. *Co-founder*. Responsible for device innovation, product development. Technology sold.

Patent Litigation Expert Witness

2003	Grayzel v. BSC (01-CV-3844 (KSH))—Case involving rigid members in a dilation balloon. Expert for Defendants. Case settled prior to trial.
2005 – 2007	BSC v. Cordis (C 02-0790 SI) – Case involving angioplasty catheter extrusion technology. Expert for Plaintiffs, testified at trial.
2008	SciCo Tec GMBH v. BSC (9:07-cv-76 (RHC)) – Case involving "rapid exchange" angioplasty catheter designs. Expert for Defendants. Case settled prior to trial.

R&D Engineering

1985 – 1996	**Boston Scientific/SCIMED,** Minneapolis, MN. Development and commercialization of Interventional Cardiology products. Several positions starting from Engineering Intern to Director of R&D. Key accomplishments included design, development and project team leadership on ACE® and Express® market leading angioplasty catheters; IP development and management; product strategy; and growing and leading a large R&D organization.

PATENTS:

Named inventor on over 100 issued U.S. patents plus additional corresponding foreign patents. Numerous additional U.S. and foreign patents are still pending.

EDUCATION:

Bachelor of Science in Mechanical Engineering
University of Minnesota, Minneapolis, MN
June 1987, with High Distinction, GPA 3.9

REFERENCES:

Available upon request.

APPENDIX B – MATERIALS CONSIDERED

VSI Patents

U.S. Patent No. 8,048,032
U.S. Patent No. 8,142,413
U.S. Patent No. RE45,380
U.S. Patent No. RE45,760
U.S. Patent No. RE45,776
U.S. Patent No. RE46,116

Litigation Materials

Joint Claim Construction Statement	D.I. 36
Order on Claim Construction	D.I. 102
Deposition Transcript of G. Panarello and QXMédical	Aug. 1, 2018
Deposition Transcript of F. Di Caprio and QXMédical	Aug. 2-3, 2018
Declaration of Howard Root in Support of VSI's Markman Brief	D.I. 59
VSI's Infringement Disclosure and Claim Chart	Sept. 1, 2017
VSI's Infringement Contentions for '032 and '413 Patents	D.I. 42-8
VSI's First Amended Infringement Contentions	Nov. 11, 2018
QXMédical's Non-Infringement Chart	Oct. 30, 2017
QXMédical's Non-Infringement Chart – '032 Patent	Feb. 5, 2018
QXMédical's Non-Infringement Chart – '413 Patent	Feb. 5, 2018
QXMédical's Amended Prior Art Statement	Feb. 5, 2018
VSI's Amended Responsive Prior Art Statement	Feb. 19, 2018
VSI's First Supplemental Responses and Objections to QXM's Interrogatory Nos. 4, 5, and 11	July 12, 2018
VSI's Responses and Objections to QXM's Second Set of Interrogatories (Nos. 12-22)	
VSI's Responses and Objections to QXM's First Set of Requests for Admission (Nos. 1-56)	July 12, 2018

QXMédical Documents

Assembly drawing, Boosting Catheter sub-assembly, non-coated	QXM 78838-41
Assembly drawing, Boosting Catheter	QXM 6058-61
Boosting Catheter Instructions for Use, Rev. 02	QXM 119395-404
Boosting Catheter Instructions for Use, Rev. 03	QXM 85-94
Slide presentation, GuideX Boosting Catheter	QXM 93667-85
Design and Development Plan	QXM8239-44
Design Review Meeting Agenda and Minutes – Nov. 6, 2013	QXM 86455-58
Design Review Meeting Minutes – Nov. 6, 2013	QXM 8358-63
Design Review Meeting Agenda and Minutes – March 12, 2014	QXM 80495-501
Design Review Meeting Minutes and Agenda – Feb. 25, 2016	QXM 8513-18
Design Review Meeting Minutes and Agenda – Nov. 3, 2016	QXM 8627-66
Invention Disclosure	QXM 67-72

Proximal Entry Photos	QXM 73
Bill of Materials, Boosting Catheter	QXM 670
Notebook pages	QXM 1605-48
Notebook pages	QXM 1649-74
Notebook pages	QXM 1675-1701
FDA submission	QXM 6308-42
FDA response	QXM 106773-76
FDA supplement	QXM 7366-403
FDA approval	QXM 7359-60

QXMédical Patents and Patent Applications

Provisional Application No. 61/793,982	QXM 8164-8209
U.S. Patent No. 9,144,662	QXM 8140-63
Provisional Application No. 62/060,780	Di Caprio Depo. Ex. 39
Provisional Application No. 62/108,302	Di Caprio Depo. Ex. 40
Provisional Application No. 62/235,751	Di Caprio Depo. Ex. 41
U.S. Patent App. Pub. No. 2017/0095646	Di Caprio Depo. Ex. 42

Prior Art

U.S. Patent No. 5,527,292 to Adams	Di Caprio Depo. Ex. 72
U.S. Patent No. 5,385,562 to Adams	Di Caprio Depo. Ex. 73
U.S. Patent No. 5,290,247 to Crittenden	QXM 5610
U.S. Patent No. 5,439,445 to Kontos	QXM 5666

Other Documents

Assembly drawings, GuideLiner v3	VSIQXM 43758-827
GuideLiner Overview, Perfect Pitch & FAQs	VSIQXM 44793-813
Brochure – Cordis Vista Brite Tip	Di Caprio Depo. Ex. 48
Brochure – Merit Medical ConcierGE	Di Caprio Depo. Ex. 49
Medtronic Coronary Products Catalog – Winter 2012	Di Caprio Depo. Ex. 50
Matsumoto et al., *GuideLiner Catheter Use for Percutaneous Intervention Involving Anomalous Origin of a Single Coronary Trunk Arising from the Ascending Aorta*, Case Reports in Cardiology, Volume 2016	
Sugimoto et al., *Guide Catheter Extension Device Is Effective in Renal Angioplasty for Severely Calcified Lesions*, American Journal of Case Reports, Volume 2017	

APPENDIX C – DESCRIPTION OF LABORATORY TESTING

I. INTRODUCTION

1. As I explain in the body of my report, my assignment in this case included analyzing and offering my expert opinion on whether the asserted claims cover QXMédical's Boosting Catheter, Vascular Solutions' GuideLiner and TrapLiner catheters, and Boston Scientific's Guidezilla catheters. As part of my analysis, I performed a variety of laboratory tests on samples of those products. This appendix explains my methods and the results of my testing. The results are tabulated for easy reference in Appendix D. The results of certain tests are laid out in more detail in Appendices E-H.

2. In general terms, my testing included manual and visual inspections, microscope inspections, dimensional measurements, and various bending and crushing tests. Some of these tests were non-destructive, such as dimensional measurements, tactile flexibility observation, crush tests, and some distal shaft two point bend tests. However, most of the two point bending tests were destructive in that portions of the catheters were cut out for placement in the test fixture. I did not perform destructive testing on devices for which I had a limited number of samples, such as the GuideLiner V1 and V2, which are no longer made.

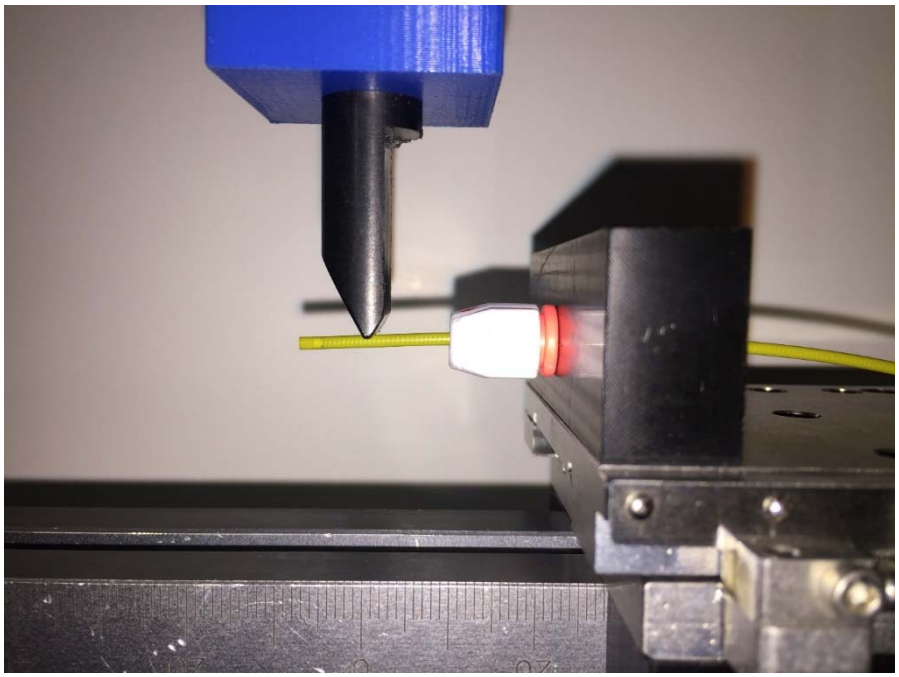
3. The samples I tested came from three different sources. Several of the Boosting Catheter samples were given to me by VSI's lawyers, who had obtained them from the lawyers for QXMédical. These samples were open when I received them, and it is my understanding that they had been opened before VSI's lawyers received them. I received other samples of the Boosting Catheter, sealed and unopened, from VSI, who obtained them from St. Cloud Hospital, a customer of QXMédical. The GuideLiner, TrapLiner, and Guidezilla samples were all provided by VSI or its lawyers. I understand that some of those devices were previously marked as exhibits at depositions in this case.

II. FLEXIBILITY TEST—"TWO POINT" BENDING TEST

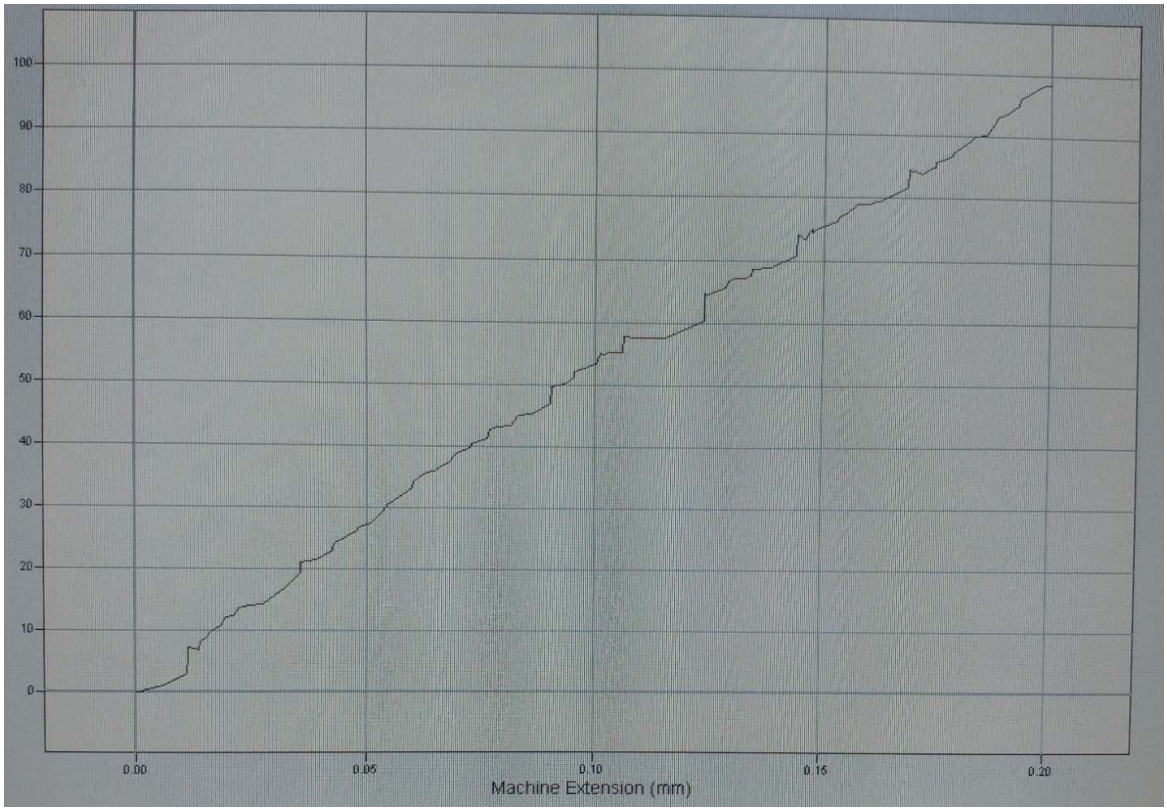
4. To test the various catheter sections for flexibility characteristics, I performed what is referred to as a "two point" bending test. Basically, different portions of the catheters are bent, and the forces required to bend those portions are measured. These portions of various catheter sections were tested in a fixture which securely anchors one spot of the sample, and then bends the catheter section by applying a lateral bending force at a nearby spot. I performed this catheter testing at VSI with the assistance of VSI engineers, using their "Universal testing machine," sometimes referred to as an "Instron" machine (see photo below).

5. A sample is anchored by clamping it in a suitable clamp secured to the testing machine in a horizontal fashion. The anchor prevents the sample from being rotated within the clamp. A movable vertical contact anvil is then brought into side contact with the sample at a prescribed distance from the clamp. The distance between the anchor and the movable contact

anvil is the cantilever distance. A calibrated load cell is attached to the contact anvil such that the contact forces against the sample can be measured. The contact anvil is then moved downward by the machine, in a perpendicular direction to the orientation of the sample, thus bending the sample in a lateral direction (see photo below).



6. As the contact is moved further, the sample is bent further. The contact is moved laterally at a smooth steady rate, from the position of initial contact to a final position wherein the sample is visibly bent. The forces are recorded continuously. The machine therefore traces out a "force-deflection" curve or line, which can then be analyzed as a measure of bending stiffness (see photo below).



7. The curve can be interpreted in many ways to ascertain the flexibility of stiffness of a certain part of a structure such as a part of a catheter. For example, the slope of the curve is representative of the stiffness. Also, at any point on the deflection, the corresponding force can be used to characterize the stiffness; for example, at the maximum deflection of the test, the force could be noted. As long as one is consistent, any of these measures can be used to compare the stiffness characteristic of one part of a catheter to another part of a catheter, or to another catheter.

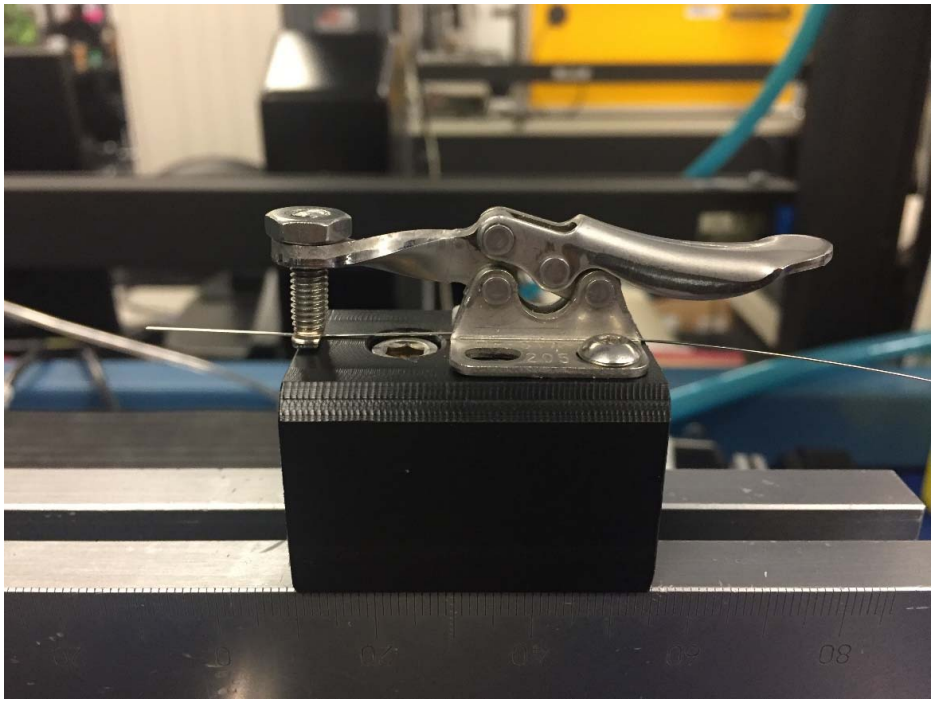
8. The "two point" flexibility test is a relatively standard way of characterizing the flexibility of an elongate structure, beam, or portion of a structure such as a catheter. In the case of catheter devices, it is a useful way to characterize flexibility or stiffness of different parts, zones, regions, or sections of a catheter. For example, a two point bending test can be used to

compare the stiffness or flexibility characteristics of the proximal shaft section of a catheter to the distal shaft section of a catheter. Or it can be used to compare the proximal shaft sections of two different catheters to each other. There are other tests that could be utilized as well, such as a "three point" test. Generally, the different ways of testing bending stiffness or flexibility will yield similar relative results, and any single test will suffice. I performed this bending test on two different portions of the distal tubular shaft, a portion of the proximal shaft, and the part of the catheters containing the side opening. So for each catheter tested, there were four portions tested.

9. When performing a two point bending test, there are some considerations for some of the setup variables. The cantilever length should be a length short enough to minimize the effects of gravity and to generate high enough forces to be reliably measured by the load cell. But it should not be so short as to make the clamp and the contact anvil interfere with each other. A cantilever length of anywhere from about 5 to 30 mm would suffice to give suitable relative bending stiffness measurements. Another setup variable in this test is the total deflection of the contact anvil. A preferred deflection will create a visible bend, but not bend so far as to create permanent damage such as kinking or other permanent deformation. This makes the results more relevant in the realm of the bends and curves that the device will take in advancing and navigating a path into a coronary vessel. The preferred deflection will also depend on the selected cantilever length—a shorter cantilever length will necessitate a shorter deflection to achieve the visible bend in the sample. And lastly the speed for the contact anvil is best set to yield a test curve in a reasonable amount of time, say a few seconds per test run. For many materials, the anvil speed will not affect the results much at all, but for polymers it can have some small effects. In the case of polymers, it is most important to set a speed and be consistent with that speed for all of the samples tested on different sections of the catheter, as well as on

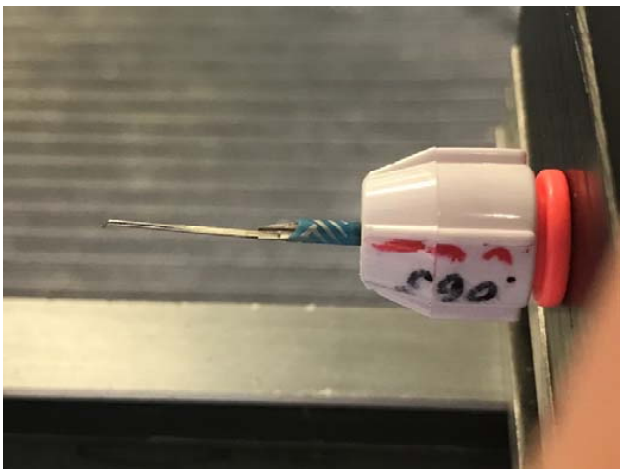
other catheters for comparison.

10. Clamp/anchor—In a two point test, the anchoring of the sample is an important consideration. An ideal anchor will prevent the sample from being able to rotate upwards or downwards at the securement point during the deflecting. The clamp will also prevent any motion in or out. And lastly, the clamp should not deform the sample appreciably, as this can have some impact the results. For metallic samples such as the proximal shaft portions of the catheters, the clamping is very unlikely to cause any meaningful deformation, as metal such as stainless steel is very hard and resistant to clamping deformation, so a simple clamp with a flat surface and square face is appropriate. For the two point tests on the proximal shaft portions, a squeezing clamp with a square face and bottom surface is appropriate (see below).



11. Polymeric tubular structures are more deformable, so a tube shaped clamp similar in diameter to the tube is preferred. To clamp the tubular portions of the test sample, I requested from VSI engineers a “pin vise” type clamp with a closed opening just slightly smaller than the

OD of the sample (see below). The samples were clamped by tightening the pin vise until contact with the sample was made, without over-tightening.



12. To aid in determining this test protocol and fixturing (and the crush test described below), some preliminary testing was performed on a 6F Boosting Catheter from the group of catheters provided by QXMédical, labeled as sample QXM2. Data from this preliminary testing is provided in the Data Summary, Appendix D.

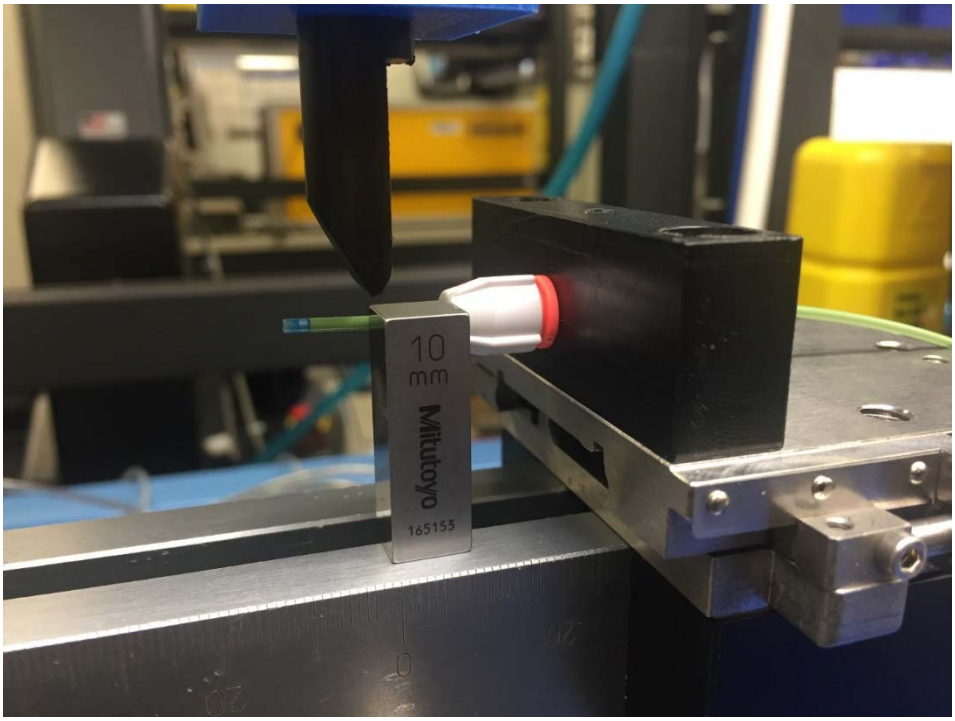
13. The protocol for the two point bend testing is now described. I chose a cantilever length of 1 cm (10 mm) as this is the approximate length of the side opening section of the QXM Boosting Catheter. If I use this same cantilever length for all sections tested in this way—the proximal shaft section, the distal shaft section, and the side opening section, I can compare all of these results to each other, and minimize the number of samples to be tested. For this cantilever length, I chose a total downward deflection of the anvil of 2 mm. I set the deflection speed at 0.2 mm per second.

14. For each of the catheters, 4 sections from each catheter were tested: a distal portion of the distal tube, a proximal portion of the distal tube, the side opening section, and the proximal shaft section. I ran the test on each section 3 times. This amount of testing assured

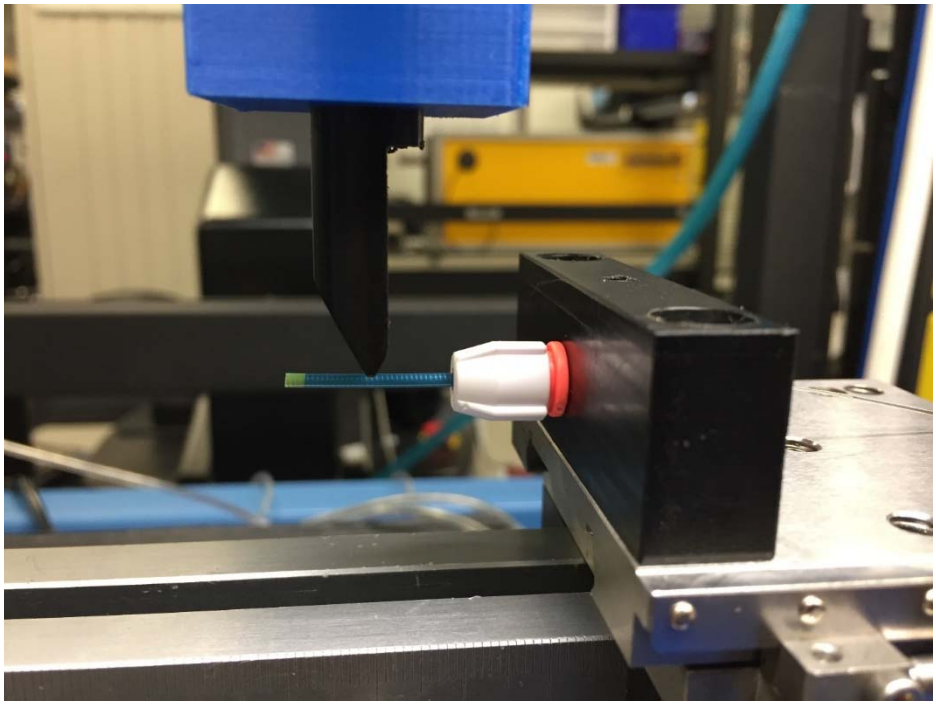
consistency of the test results, and also provided some insight into any variations from device to device. The raw data from this testing, as well as the load-deflection curves can be found in Appendices E and F. The Universal tester determines the maximum load encountered during the test run, and this maximum load information is captured in the raw data.

15. Each of the catheters was labelled prior to testing, and the devices were carefully handled before, during and after the testing was done. As the two point flexibility test entails cutting certain portions of the catheters out in order to do the test, these tested catheters are now in cut pieces.

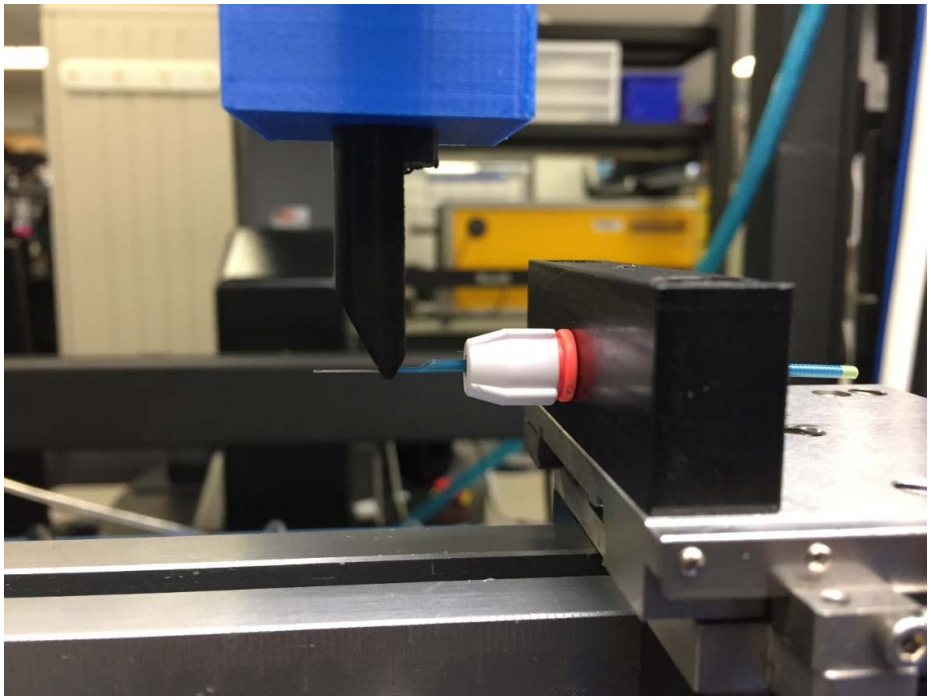
16. As mentioned above, 4 different sections of each of the catheters were tested in the two point flexibility testing. The distal tubular portion was fixtured and tested as represented in the photo below (test runs labeled as "Flex 1"). The cantilever length was 1 cm, and an additional 1 cm extended beyond the contact point of the anvil. Thus, the flexibility was tested for the catheter in the 1 cm zone, 1 cm proximal of the catheter tip. To start the test, the anvil was carefully brought into light contact with the sample (~0.1 Newtons force), the force re-set to zero, and then the test was run. By bringing the anvil into light contact first, the force-deflection curve will intersect the "0-0" point, rather than having a "lag" distance before generating any force, which can occur if the anvil is not in initial contact.

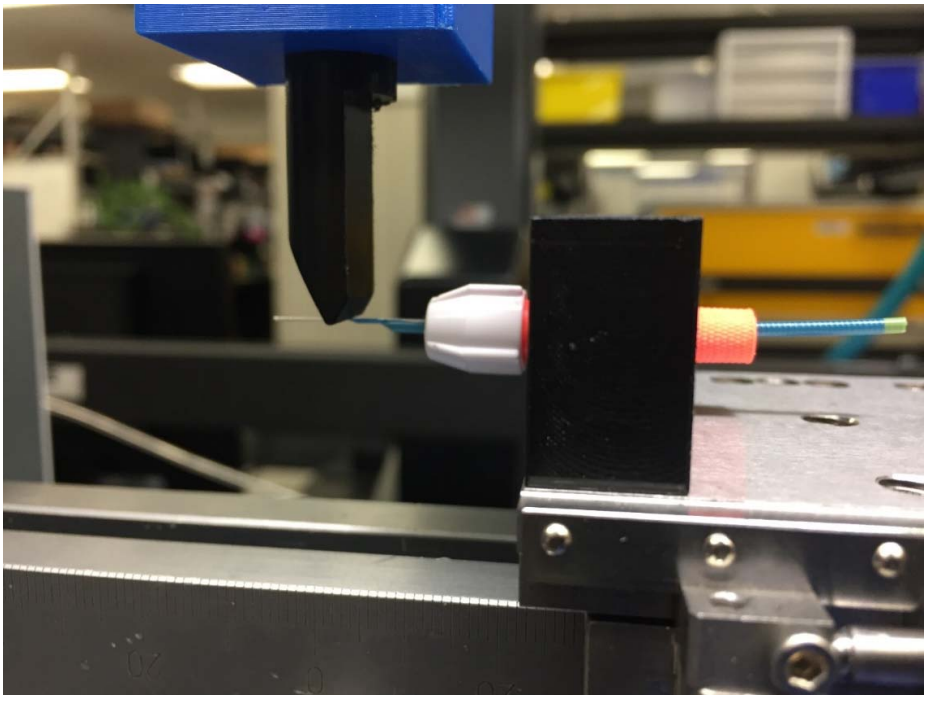


17. Similarly, a more proximal portion of the distal tubular shaft was tested in this flexibility tester (runs labeled as "Flex 2"). On all of the various catheters, the distal shaft incorporates a more rigid proximal region, visibly demarcated (e.g. by a different colored polymer). To test the flexibility of this zone, the samples were cut just distal to this transition. A cantilever length of 1 cm was established in the fixture, with an additional 1 cm projecting further distally, as represented by the photo below.



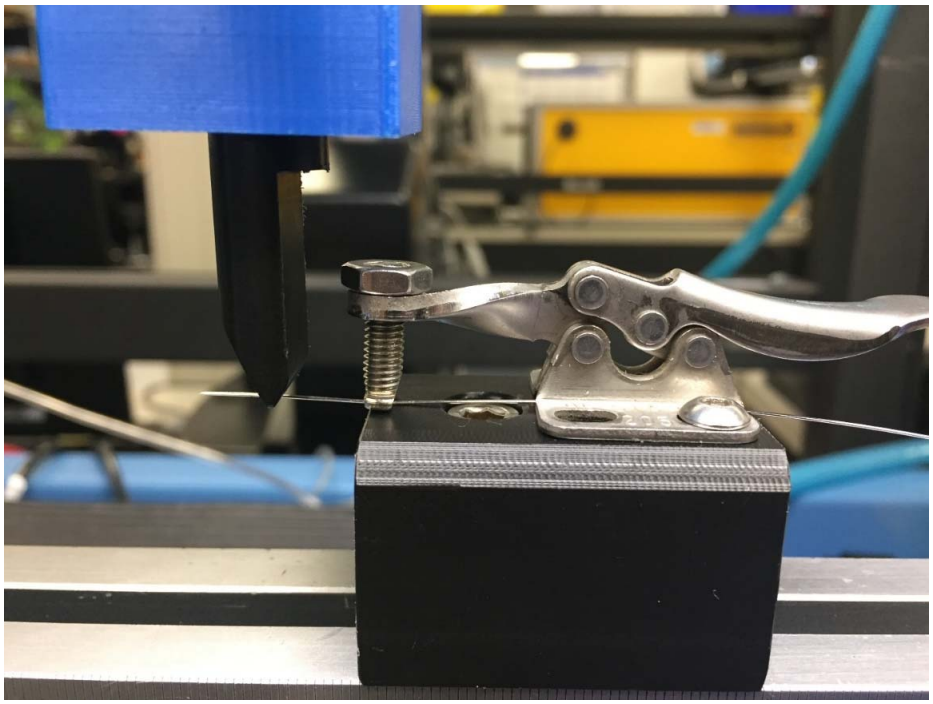
18. The side opening section of catheters was tested by clamping at its distal end, and cantilevering 1 cm proximal of that, at the proximal terminus of the polymeric tubing (for the QXMédical catheters), as seen in the first photo below (runs labeled as "Flex 3 up"). The opening is in the middle of this section. To account for potential differences in the flexibility characteristics due to the asymmetry of the opening, the sections were tested with the opening oriented up as well as down, as seen in the second photo below (runs labeled as "Flex 3 down").





19. The proximal shaft section was tested by placing a portion of the proximal shaft into the clamping fixture as depicted in the photo below (runs labeled as "Flex 4"). A cantilever

length of 1 cm plus an additional 1 cm were projected out of the clamp.



20. The same testing was performed for the other tested catheters.

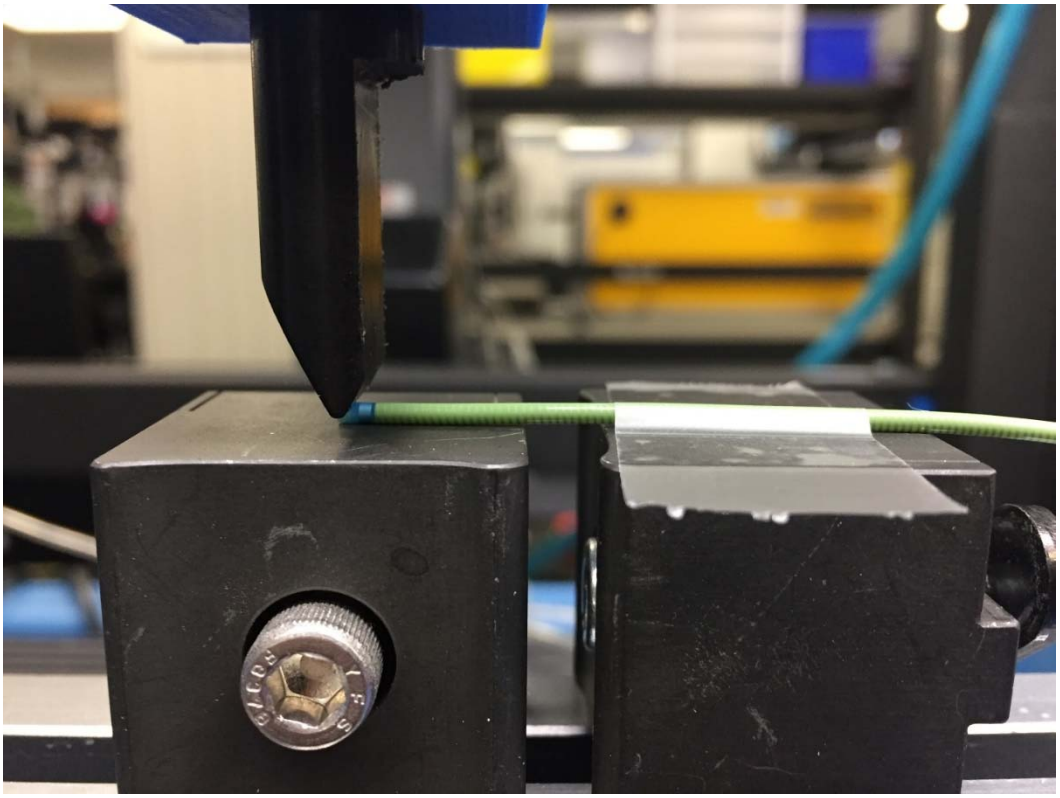
III. CRUSH TEST

21. Some of the claims of the patents discuss the relative flexibility of the distal tip portion to the flexibility of a more proximal reinforced portion. While one might consider performing a two point bending test to make that comparison, similar to the tests described above, the tip portion of the Boosting Catheter is quite short, just a few millimeters. That is too short of a cantilever length to perform this type of test. Another type of test that can compare flexibility characteristics is a so-called "crush" test. A crush test has the benefit of needing only a very short sample length to produce meaningful results, which meant that it was a better fir for testing the unreinforced tip portion of the Boosting Catheter. A crush test is also more appropriate given the functionality of the tip portion. It is desirable for catheters that are advanced into the vasculature to have so-called "soft tips" to minimize the traumaticity of the

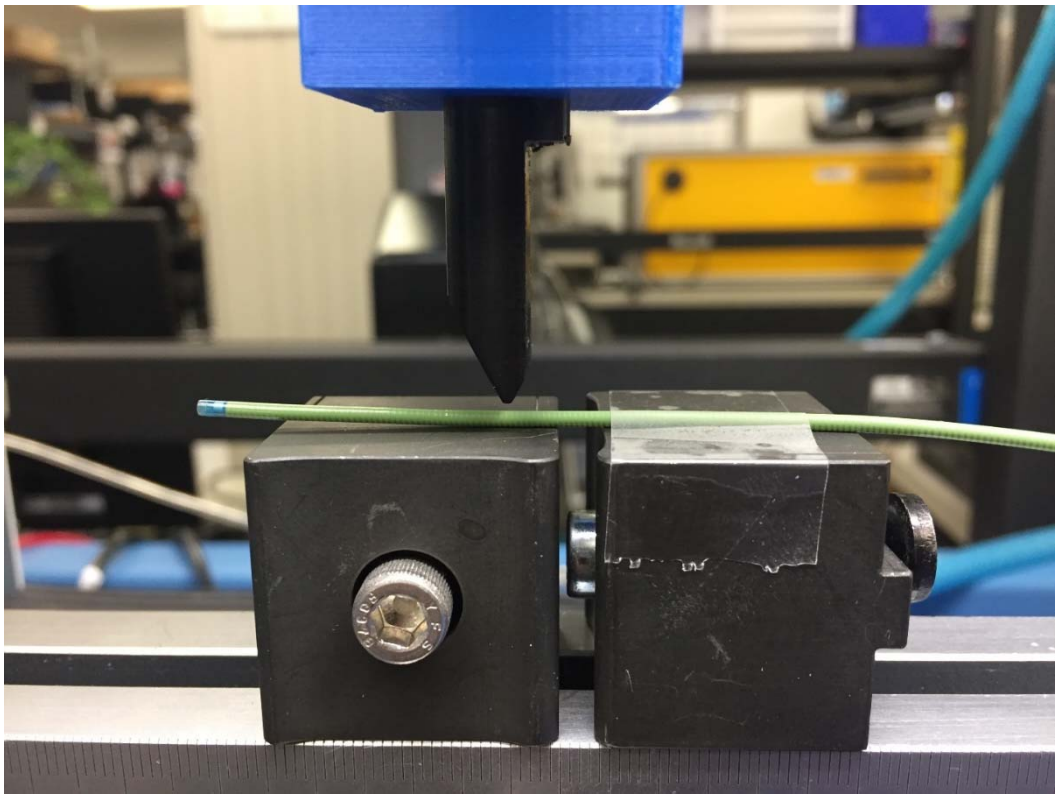
tips as they interact with the delicate vascular tissue. A test which can measure the relative "squeezability" of the tips in comparison to the adjacent portions of the distal shaft is an appropriate characterization. Portions of the catheter that are more easily squeezed or deflected inwards will show lower forces in a crush test than portions of the catheter that are stiffer or reinforced.

22. To perform the crush test, the Universal Test Machine was used, with some different fixturing and different settings compared to the two point flexibility testing described above. The same anvil was used, as this is able to apply a relatively concentrated load in one spot. A flat support surface is on the bottom of the sample. The amount of deflection for this test is smaller than that for the lateral bending test in the two point flexibility test, 0.2 mm (about 0.005 inch). The deflection rate was set to 0.01 mm/sec. The raw data and the load-deflection curves of all the runs of the test are included in Appendices G-H.

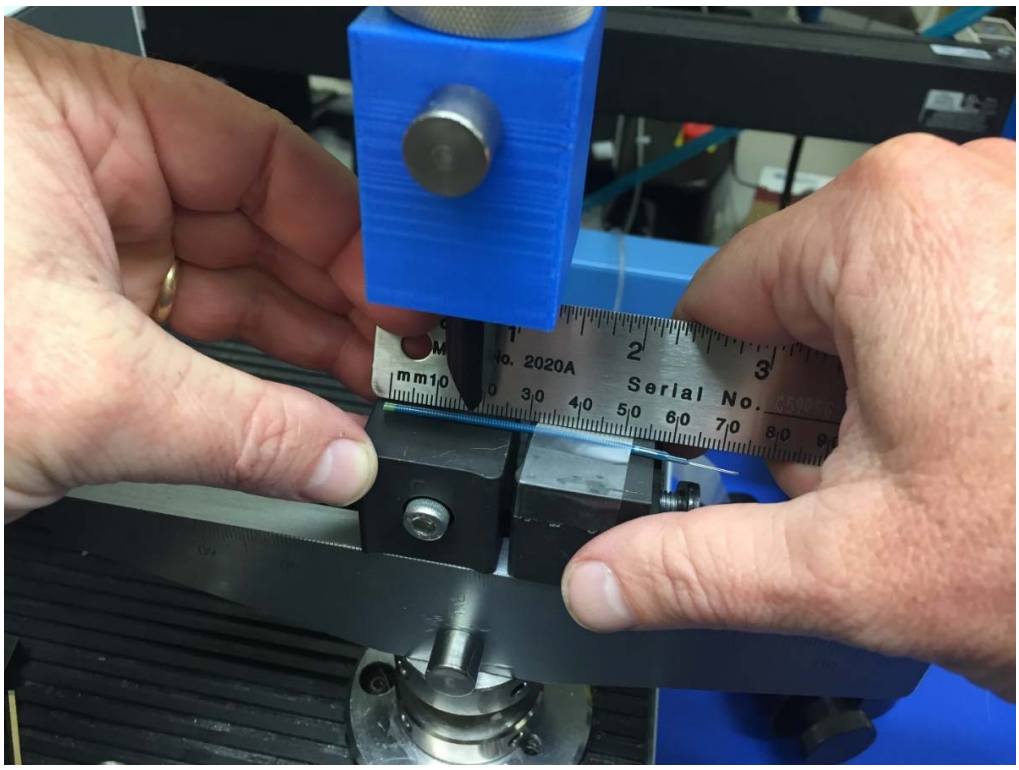
23. The non-reinforced tip portion (absent the reinforcing coil) of the catheters was placed into the test fixture, as represented by the photo below (runs labeled as "Crush 1"). The anvil was carefully brought into light contact with the sample (~0.1 Newtons force), and then the test was run. Note that in a couple instances, due to the samples not being straight, it was sometimes difficult to come into the same degree of light contact. In these cases, there was a noticeable "lag" between starting the anvil movement and generating any force. In some of these instances, the tests were re-run to yield three runs that were close to intersecting the "0-0" point. However, even in runs with "lag", the data are still usable; one simply needs to consider the ramping portion of the curve as the virtual "0-0" point. This is noted in the results. Even with some lag, the maximum force values are still usable, as long as they are similar to the other runs without lag.



24. The sample was then fixtured with the reinforced distal tubular shaft portion under the anvil (approximately 3 cm from the tip) to determine the relative resistance to inward crushing forces (see photo below) (runs labeled as “Crush 2”).



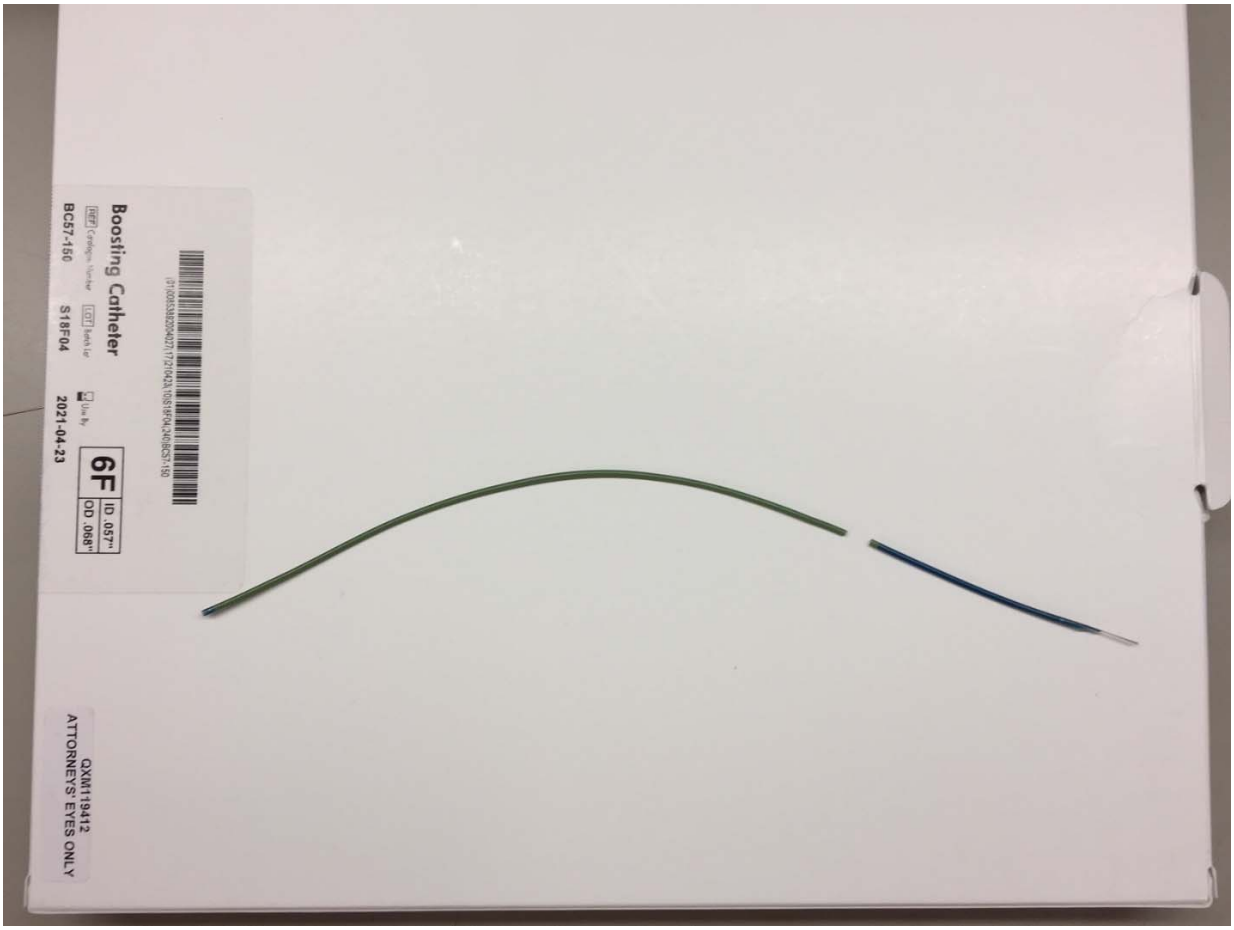
25. A portion of the more proximal tubular shaft was also tested in this crush test. The sample was fixtured approximately 2 cm proximal of the transition, as seen in the photo below (runs labeled as “Crush 3”).



26. The other catheters were tested in the same manner.

IV. DIAMETER MEASUREMENTS

27. The inner diameter (ID) and outer diameter (OD was measured on some of the samples. For ID measurements, calibrated pin gauges (increment 0.0005 inch) were carefully inserted at each end of the distal tubular shaft, as seen in first and second photo below. The pin gauges used are "plus" pins, which means that the calibrated pin diameters have a small diameter tolerance that is "one sided" to equal or slightly larger than the nominal diameter. The measured inner diameter was equal to the largest pin that could be inserted several mm without significant force. I tested the 6F Boosting Catheter samples that had already been cut into segments for the testing above (see photo below).



28. I was therefore able to make 4 different inner diameter measurements representing the tip ID, the distal tubular shaft ID, the proximal tubular shaft ID and the proximal opening ID (beyond any flared portion), as can be seen in the images below. In addition to the "plus" pin gauge sets, I also had a set of "minus" pin gauges, which have the small tolerance less than the nominal pin size. Any inner diameter measurements where I encountered excessive friction, I then used the "minus" version of that same pin for comparison. If the "minus" pin fit, then I used that size pin as the diameter measurement.


QX3 0.057 pin

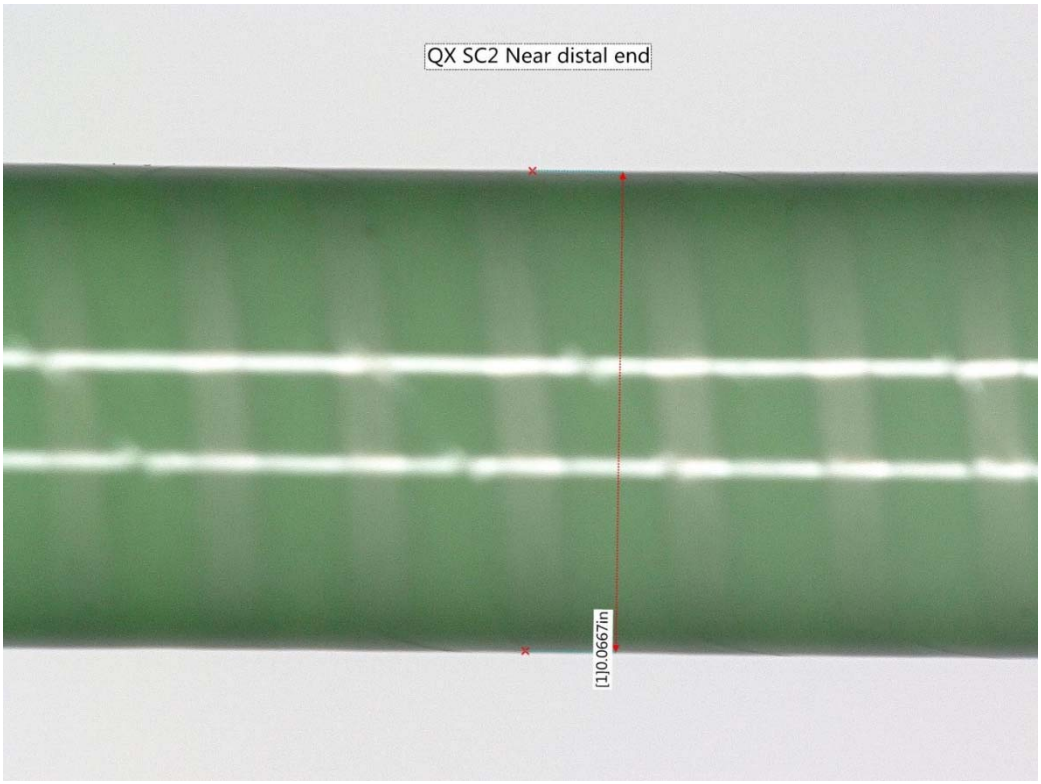

QX3 0.057 pin


QX3 0.057 pin

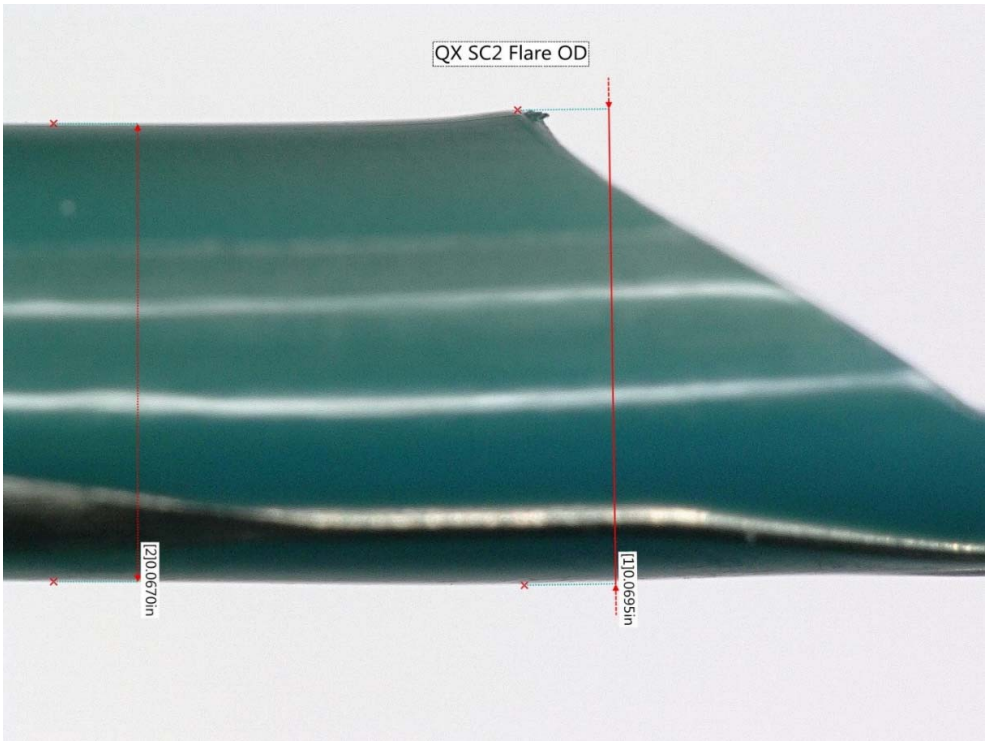

QX3 0.057 pin

29. If the side opening was noted to be “flared”, the ID just at the opening was also measured, as noted in the photo below.

30. The OD (outer diameter) measurements were made using a tool scope, as noted in the first photo below. To account for possible out of roundness, the measured samples were also rotated 90 degrees.



31. If the side opening was flared, the OD at the maximum size was measured, as seen in the photo below.



32. The diameter measurements are included in the "Summary of Testing Results," Appendix D.

V. PHYSICAL EXAMINATION AND VISUAL OBSERVATIONS (PE/VO)

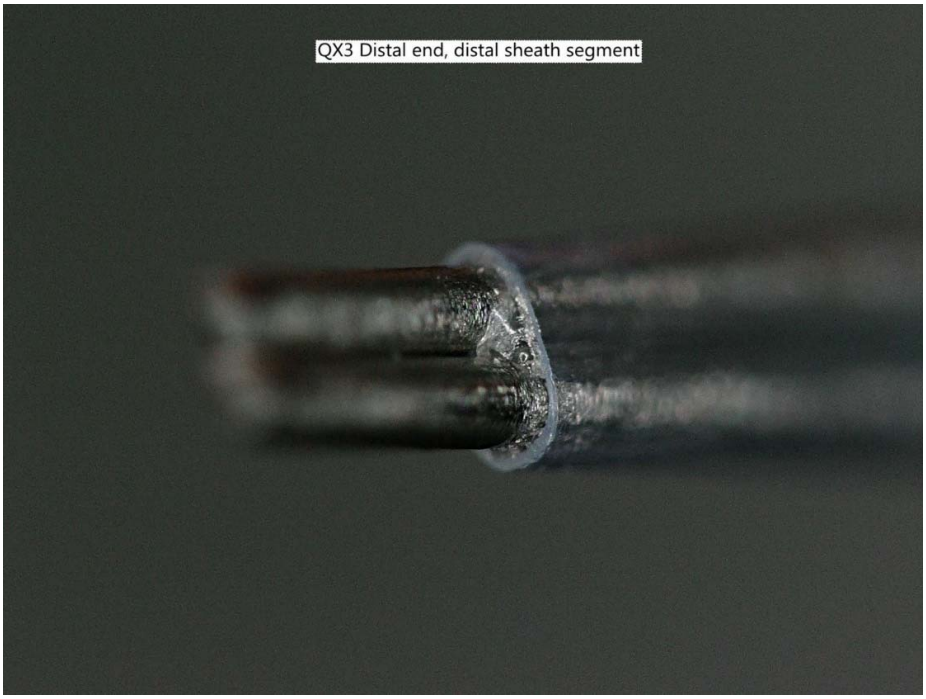
33. Catheter models that had limited availability to me for testing were only examined in non-destructive ways. Also, some models are similar to other models that were extensively tested, and therefore conclusions could be made without extensive testing.

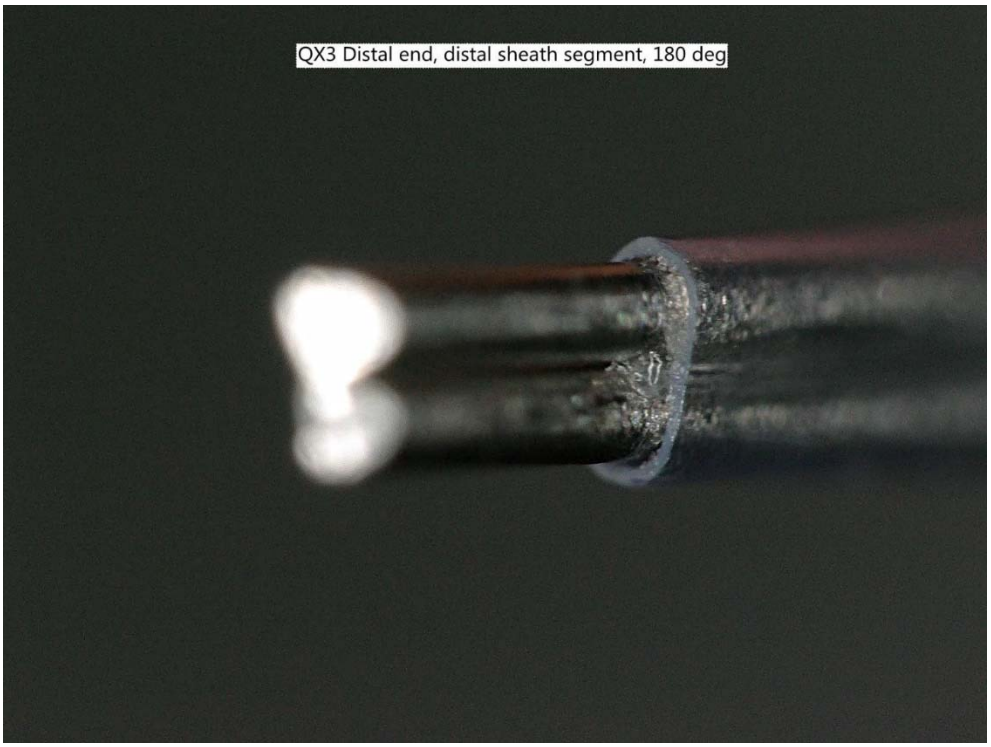
34. On the catheter samples that I could not actually do the two point flexibility testing on the Universal Tester (so as not to destroy them), I was still able to discern the relative bending flexibility of various portions of the catheters by bending the catheter and tactilely feeling with my fingers the relative amount of force required to bend the catheters. If there are significant differences in the flexibilities, this can be qualitatively felt. I was able to qualitatively compare the proximal shaft stiffness with the stiffnesses of the different ends of the distal tubular

shaft. These observations are noted in the data summary in the "Summary of Testing Results," Appendix D. I was also able to do a two point flexibility test of the distal portion of the distal tubular shaft of these samples in a non-destructive manner, to confirm that these catheters' distal shafts are relatively similar to the other devices that were fully tested in two point bending.

35. Similarly, the tip deformability or crushability can be qualitatively assessed by focal squeezing of the tip portions and comparing that to the more proximal portions of the distal tubular shaft. These observations are noted in the data summary in the "Summary of Testing Results," Appendix D.

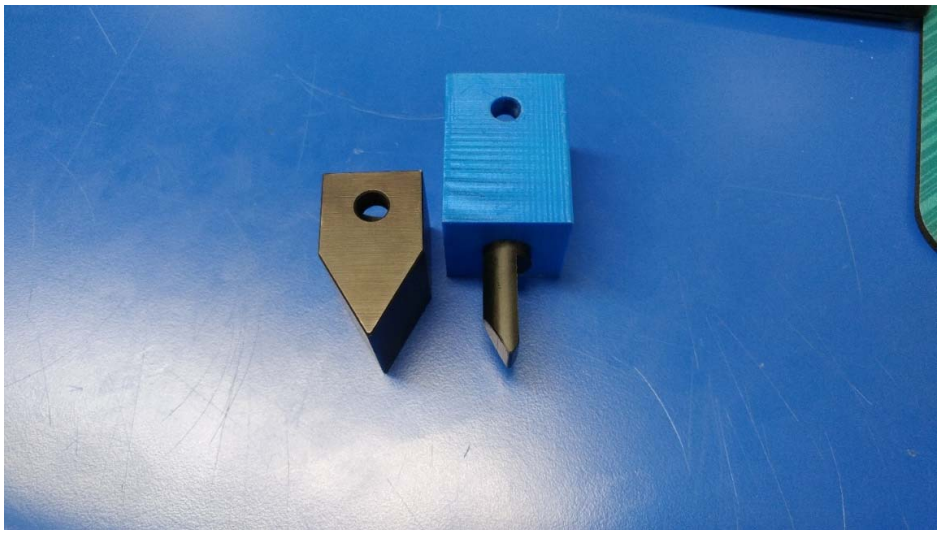
36. I also made observations of the QXMédical Boosting catheters under the microscope. One observation made pertained to the short sheath segment near the distal end of the proximal shaft. As noted in the data summary, the gaps at the distal end appeared to be filled with some substance, as noted in the photos below of QXM (6F) Sample 3.



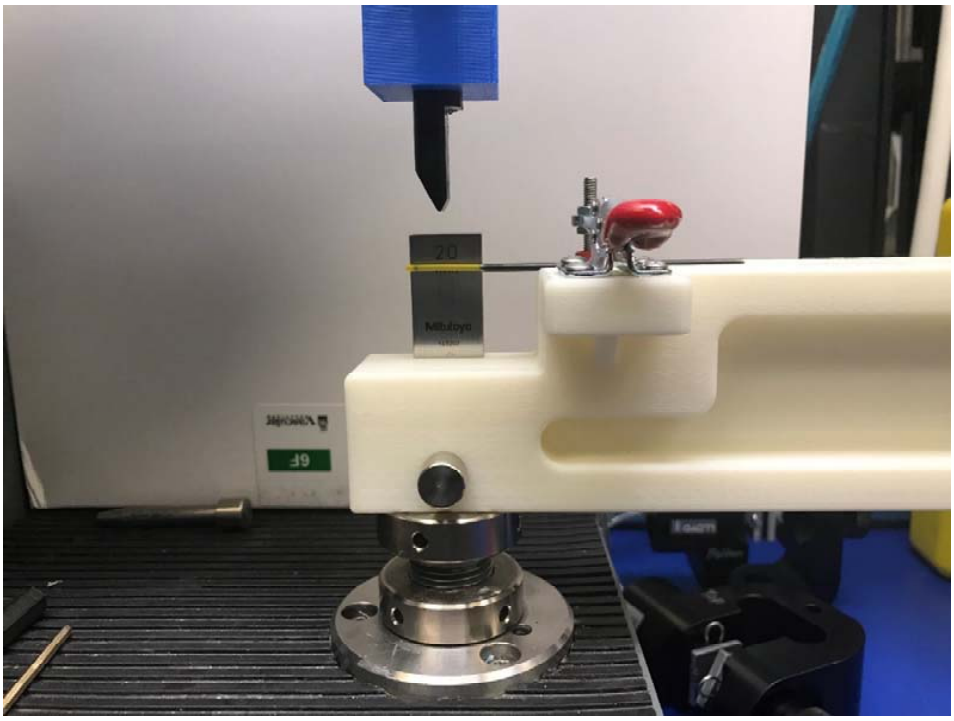


VI. ADDITIONAL NOTES ON PRELIMINARY TESTING

37. As noted above, to help establish some of the testing protocols and fixturing, I had performed some preliminary testing on a QXMédical 6F sample. Some of the fixturing was modified as a result of this testing. One modification involved the anvil. A new anvil was fabricated with a portion ground away to allow for closer placement of the anvil to the anchoring/clamping structure. This is seen in the photo below, with the newer anvil on the right.



38. As described above, the anchoring/clamping device was made to allow for secure anchoring of a tubular structure. In the preliminary testing, a close fitting hypotube was used for this purpose, as depicted in the photo below.



39. In the preliminary two point bend testing of the metallic proximal shaft portions,

the samples were held in place with tape and finger pressure, as seen in the photo below.

VII. TEST RESULTS

40. The raw data and associated charts of each run of the two point bend test and crush test are included in Appendices F and H. A more detailed spreadsheet of the raw data and some data analysis is included in Appendices E and G.

41. A summarized tabulation of the data from all of the testing is included in "Data Summary", Appendix D. The summarized table also has some test notes pertinent to some of the test results as observed during the testing.

VIII. OBSERVATIONS

42. **Two point bend testing**. The QXMédical Boosting Catheters tested demonstrated that the proximal shaft was significantly more rigid than the distal tubular shaft. This is observed, for example by comparing the maximum load values from "Flex 4" vs "Flex 1 for each of the QXMédical 6F Boosting Catheter samples tested. The QXMédical 8F Boosting Catheter tested

in the manner also showed that the proximal shaft was significantly more rigid than the distal tubular shaft. The other catheters tested in this manner (VSI GuideLiner V3 6F and 8F, VSI TrapLiner 6F, and the BSC GuideZilla Version 2 6F) also showed that the proximal shaft was significantly more rigid than the distal tubular shaft (see Appendices D and E).

43. The QXMédical Boosting Catheters tested also demonstrates that the side opening section of the catheter is more rigid than the distal tubular shaft portion. This can be seen by comparing the maximum load values from either "Flex 3 up" or "Flex 3 down" with the values from "Flex 1". This is true for each of the QXMédical 6F Boosting Catheter samples tested, as well as the QXMédical 8F Boosting Catheter. The other catheters tested in this manner (VSI GuideLiner V3 6F and 8F, VSI TrapLiner 6F, and the BSC GuideZilla Version 2 6F) also showed that the side opening section was more rigid than the distal tubular shaft (See Appendices D and E).

44. **Crush Testing**. The QXMédical Boosting Catheters tested demonstrate that they have a tip that is more flexible than another portion of the tubular distal shaft. This can be seen, for example, by comparing the maximum load values from the "Crush 1" with the "Crush 2" and "Crush 3" values for any of the tested samples, both for the 6F and the 8F tested samples. This is also the case for the other catheters tested in this manner (VSI GuideLiner V3 6F and 8F, VSI TrapLiner 6F, and the BSC GuideZilla Version 2 6F) (see Appendices D and G).

45. **Diameter Measurements**. The measured inner and outer diameters of the catheters measured are included in Appendix D. As mentioned above, it was observed that the QXMédical Boosting catheters measured were observed to have a flared proximal entry in the side entry section. This flared ID on the 6F devices was approximately 0.001 inch larger than the ID a few mm further distal.

46. **Other QXMédical Boosting Catheter models.** I tested 6F and 8F Boosting Catheter samples. I did not test the smaller 6F model (compatible with smaller than standard 6F guide catheters) or the 7F Boosting Catheter. The construction differences of these devices are such that they would also show the differences in flexibility and crush resistance noted for the 6F and 8F devices noted above. For example, it is represented that the proximal shaft of the 7F and 8F Boosting catheters is identical. The distal shaft of the 7F is smaller than that of the 8F device, and therefore the distal shaft of the 7F catheter is even more flexible than that of the 8F device, by virtue of a smaller dimension. So if the proximal shafts are the same, clearly the 7F device would demonstrate a distal tubular shaft more flexible than the proximal shaft. The same analysis holds true for the smaller 6F model when compared to the 6F compatible Boosting Catheter. Regarding the crushability, both the smaller 6F version and the 7F version have an unsupported (i.e. no reinforcing metallic coil) tip adjacent to a supported tubular shaft, and therefore would have similar crush resistance comparisons as the 6F and 8F models tested.

	QXM (6F) Samp 2 protocol set-up 10/12	**QXM (6F) Samp 3** 10/19 and 10/22	**QXM (8F) Samp 1** 10/19 and 10/22	**QXM (SCH) (6F) Samp 2** 10/19 and 10/22	**QXM (SCH) (6F) Samp 3** 10/19 and 10/22	**GL V1 (6F) Samp 1** 10/19 and 10/22	**GL V2 (6F) Samp 1** 10/19 and 10/22	**GL V3 (6F) Samp 2** 10/19 and 10/22	**GL V3 (8F) Samp 1** 10/19 and 10/22	**GZ V1 (6F) Samp 1** 10/19 and 10/22	**GZ V2 (6F) Samp 1** 10/19 and 10/22	**TL (6F) Samp 1** 10/19 and 10/22
Two point bend - maximum load in gf (grams force) using stated test parameters, average of 3 runs (2cm sample length; ~0.01N preload (re-zeroed); 2mm deflection at 0.2mm/sec; 1cm spacing b/t deflection point and support)												
Substantially rigid portion **(Flex 4)**	53.33*	67.21	89.35	69.33	62.19	PE/VO	PE/VO	74.18	91.37	PE/VO	128.18 (see note 5)	177.29
Side opening structure (facing up) **(Flex 3 up)**	40.55*	42.99	73.94	61.96	48.36	PE/VO	PE/VO	71.75	143.88	PE/VO	108.96	90.30
Side opening structure (facing down) **(Flex 3 down)**	39.06*	37.24	67.40	46.96	49.32	PE/VO	PE/VO	58.14	122.51	PE/VO	107.37	66.65
Side opening metallic material **(paddles flex)**	6.92* 11.54 retest w/ newer fixture (see note 14)	NT	NT	NT	NT	NT	NT	NT	NT	NT	NT	NT
Shaft Tubing (proximal) **(Flex 2)**	19.38*	26.75	58.43	25.80	29.10	PE/VO	PE/VO	32.42	55.30	PE/VO	42.92	25.39
Shaft Tubing (distal) **(Flex 1)**	12.5*	14.35	35.06	16.41	15.15	16.97	16.18	17.84	21.07	18.92	16.49	16.59
Crush - maximum load in gf (grams force) using stated test parameters, average of 3 runs (0.2mm deflection at 0.01mm/sec)												
Shaft Tubing (proximal) **(Crush 3)**	NT	163.44	123.57	132.81	123.71	220.54 (see note 6)	186.16	200.45	163.88	141.83	151.68	176.06

	QXM (6F) Samp 2 protocol set-up 10/12	**QXM (6F) Samp 3** 10/19 and 10/22	**QXM (8F) Samp 1** 10/19 and 10/22	**QXM (SCH) (6F) Samp 2** 10/19 and 10/22	**QXM (SCH) (6F) Samp 3** 10/19 and 10/22	**GL V1 (6F) Samp 1** 10/19 and 10/22	**GL V2 (6F) Samp 1** 10/19 and 10/22	**GL V3 (6F) Samp 2** 10/19 and 10/22	**GL V3 (8F) Samp 1** 10/19 and 10/22	**GZ V1 (6F) Samp 1** 10/19 and 10/22	**GZ V2 (6F) Samp 1** 10/19 and 10/22	**TL (6F) Samp 1** 10/19 and 10/22
Shaft Tubing (distal) **(Crush 2)**	98.66*	122.27	98.17	134.49	111.00	113.58 (see note 6)	121.81	135.84	99.74 (see note 4)	82.59	101.34	138.74
Tip **(Crush 1)**	37.62*	43.12 (see note 15)	39.52	38.07	53.21	12.50	14.41	22.14	9.72	11.31	11.34	18.30
Microscope observations												
Substantially rigid portion proximal wrap – adhesive both sides of wires at proximal end, distal end	No, No	No, No	No, No	No, No	No, No	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Substantially rigid portion distal wrap – adhesive both sides of wires at proximal end, distal end	No, Yes	No, Yes	No, Yes	No, Yes	No, Yes	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Dimensions - in inches (ID measurements based on "gentle placement" of mandrel pins)												
Side opening ID	NT	0.0575 (at entry) 0.057 (see note 16)	NT	0.0575 (at entry) 0.057 (see note 16)	0.0575 (at entry) 0.057 (see note 16)	NT (damaged – rely on product docs.)	NT (damaged – rely on product docs.)	0.056 (see note 7)	NT	NT (damaged – rely on product docs.)	NT (see box dim.)	0.056

	QXM (6F) Samp 2 protocol set-up 10/12	**QXM (6F) Samp 3** 10/19 and 10/22	**QXM (8F) Samp 1** 10/19 and 10/22	**QXM (SCH) (6F) Samp 2** 10/19 and 10/22	**QXM (SCH) (6F) Samp 3** 10/19 and 10/22	**GL V1 (6F) Samp 1** 10/19 and 10/22	**GL V2 (6F) Samp 1** 10/19 and 10/22	**GL V3 (6F) Samp 2** 10/19 and 10/22	**GL V3 (8F) Samp 1** 10/19 and 10/22	**GZ V1 (6F) Samp 1** 10/19 and 10/22	**GZ V2 (6F) Samp 1** 10/19 and 10/22	**TL (6F) Samp 1** 10/19 and 10/22
Side opening OD	NT	0.0684 (flare) 0.0651 (non-flare)	NT	0.0695 (flare) 0.0670 (non-flare)	0.0698 (flare) 0.0670 (non-flare)	NT (damaged – rely on product docs.)	NT (damaged – rely on product docs.)	0.0684	NT	NT (damaged – rely on product docs.)	NT (see box dim.)	NT
Tip ID	NT	0.057 (pin 1cm in)	NT	0.057 (pin 1cm in)	0.057 (pin 1cm in)	NT (damaged – rely on product docs.)	NT (damaged – rely on product docs.)	0.0565	NT	NT (damaged – rely on product docs.)	NT (see box dim.)	0.056
Distal Shaft ID	NT	0.057	NT	0.057	0.057	NT	NT	NT	NT	NT	NT	NT
Proximal Shaft ID	NT	0.057	NT	0.057	0.057	NT	NT	NT	NT	NT	NT	NT
Tip OD	NT	0.0672 0.0665 (90 degree turn)	NT	0.0667 0.0663 (90 degree turn)	0.0671 0.0674 (90 degree turn)	NT (damaged – rely on product docs.)	NT (damaged – rely on product docs.)	0.0673 0.0677 (90 degree turn)	NT	NT (damaged – rely on product docs.)	NT (see box dim.)	NT

***** = test fixtures used on 10/12 differed somewhat from those used on 10/19 and 10/22
NT = not tested
PE/VO = physical examination and visual observation by Pete Keith (see note 8)
N/A = not applicable

Notes:

1. No permanent deformation was noticed on any product sample following the tests
2. General order of tests:
    a. 2-point bend
        i. Tubing (distal)
        ii. Tubing (proximal)
        iii. Side opening structure (facing up)
        iv. Side opening structure (facing down)
        v. Substantially rigid portion
        vi. Side opening metallic material (only performed on QXM2 sample)
    b. Crush
        i. Tubing (proximal) - 2cm back from color transition
        ii. Tubing (distal) - 3cm from tip
        iii. Tip
3. For tests performed on 10/19/2018 and 10/22/2018, three data points were gathered for each test
4. For tubing (distal) crush test of GL4 sample, “yellow crush 1” should be “yellow crush 3”. This is also noted on the Crush test data and analysis spreadsheet, Appendix E
5. For 2-point bend test of the substantially rigid portion of the GZ2 sample, a tailored fixture was needed since it’s a hypotube; tests 1-3 used pin vise with observed ID rounding, tests 4-6 used pin vise without rounding (ground flat). Average of last 3 runs used.
6. GL1 sample has variable coil spacing observed visually
7. Dimensions were also measured for a second GL version 3 (6F) sample; results were as follows:
    a. Side opening ID = 0.0555
    b. Side opening OD = 0.0678
    c. Tip ID = 0.056
    d. Tip OD = 0.0681
8. Physical examination and visual observation findings:
    a. GL versions 1 and 2:
        i. Have a similar substantially rigid portion as GL version 3, which was measured
        ii. Have a very soft tip

iii. Version 1 has a hypotube side opening portion which is much more rigid than the tube; version 2 has a side opening portion that is made of a high durometer polymer embedded with a portion of the substantially rigid portion, and is more rigid than the tube

b. GZ version 1:
   i. Has stiff hypotube substantially rigid portion
   ii. Has a very soft tip
   iii. Has a side opening portion (full metal collar) even more rigid than GZ version 2

9. QXM samples provided (all previously opened prior to being received by VSI/Pete Keith):
   a. QXM1 = 5.5F (not tested; previously opened)
   b. QXM2 = 6F (tested as part of protocol set-up; previously opened)
   c. QXM3 = 6F (tested; previously opened)
   d. QXM4 = 6F (not tested; previously opened)
   e. QXM5 = 6F (not tested; previously opened)
   f. QXM6 = 6F (not tested; previously opened)
   g. QXM7 = 7F (not tested; previously opened)
   h. QXM8 = 8F (tested; previously opened)
10. St. Cloud Hospital samples provided:
   a. SCH1 = 6F (not tested since previously opened)
   b. SCH2 = 6F (tested; opened by Pete Keith)
   c. SCH3 = 6F (tested; opened by Pete Keith)
   d. SCH4 = 6F (not tested; remains unopened)
   e. SCH5 = 6F (not tested; remains unopened)
11. Vascular Solutions/Teleflex samples provided:
   a. GL version 1 (GL1) = 6F (tested; previously opened) – Root deposition exhibit no. 18
   b. GL version 2 (GL2) = 6F (tested; previously opened)
   c. GL version 3 (GL3) = 6F (tested; opened by Pete Keith)
   d. GL version 3 (GL4) = 8F (tested; opened by Pete Keith)
   e. TrapLiner (TL1) = 6F (tested; opened by Pete Keith)
12. Boston Scientific samples provided:
   a. GZ version 1 (GZ1) = 6F (tested; previously opened)

b. GZ version 2 (GZ2) = 6F (tested; previously opened)

13. Photographs taken at 20X and 100X zoom
14. The “paddles” from QXM (6F) Sample 2 were tested as described in my report, during the initial setup testing. With improved securing fixtures, they were re-tested.
15. When the crush test was initially run on this sample, the anvil was noted to be very close to the marker band, and some distance from the distal end. The test was re-run with the anvil positioned about 0.5mm further distally, and this position was used for subsequent tests on other devices.
16. The ID of the proximal opening several mm further distal from the flared entry was measured here. On all three QXM Boosting Catheters tested, this ID measurement was a little tight with the “plus” pin gauges, but was confirmed with the “minus” pin gauges.

Sample ID (shorthand)	Detailed Sample description	Detailed Test description	Run	Load at Maximum Load (grams force) rounded	Notes	Average of 3 runs (grams force)
GL3 2, Tip Def. 1	GL V3 (6F) Samp 2	Flexibility test of distal portion of distal tubular shaft ("Flex 1")	1	16.56		
GL3 2, Tip Def. 2			2	18.81		17.84
GL3 2, Tip Def. 3			3	18.16		
GL3 2, Prox. Tubing Def. 1		Flexibility test of proximal portion of distal tubular shaft ("Flex 2")	1	32.55		
GL3 2, Prox. Tubing Def. 2			2	32.71		32.42
GL3 2, Prox. Tubing Def. 3			3	32.01		
GL3 2, Opening up Def. 1		Flexibility test of side opening section, opening "up" ("Flex 3 up")	1	69.67		
GL3 2, Opening up Def. 2			2	73.55		71.75
GL3 2, Opening up Def. 3			3	72.02		
GL3 2, Opening down Def. 1		Flexibility test of side opening section, opening "down" ("Flex 3 down")	1	58.42		
GL3 2, Opening down Def. 2			2	58.25		58.14
GL3 2, Opening down Def. 3			3	57.74		
GL3 2, Prox. Shaft Def. 1		Flexibility test of proximal shaft ("Flex 4")	1	73.88		
GL3 2, Prox. Shaft Def. 2			2	74.47		74.18
GL3 2, Prox. Shaft Def. 3			3	74.19		
QX3, Dist. Tip Def. 1	QXM (6F) Samp 3	Flexibility test of distal portion of distal tubular shaft ("Flex 1")	1	13.96		
QX3, Dist. Tip Def. 2			2	14.43		14.35
QX3, Dist. Tip Def. 3			3	14.68		
QX3, Prox. Tubing Def. 1		Flexibility test of proximal portion of distal tubular shaft ("Flex 2")	1	25.35		
QX3, Prox. Tubing Def. 2			2	26.95		26.75
QX3, Prox. Tubing Def. 3			3	27.95		
QX3, Opening up Def. 1		Flexibility test of side opening section, opening "up" ("Flex 3 up")	1	43.02		
QX3, Opening up Def. 2			2	42.62		42.99
QX3, Opening up Def. 3			3	43.33		
QX3, Opening Down Def. 1		Flexibility test of side opening section, opening "down" ("Flex 3 down")	1	36.86		
QX3, Opening Down Def. 2			2	36.34		37.24
QX3, Opening Down Def. 3			3	38.52		
QX3, Prox.Shaft. Def. 1		Flexibility test of proximal shaft ("Flex 4")	1	65.44		
QX3, Prox.Shaft. Def. 2			2	67.79		67.21
QX3, Prox.Shaft. Def. 3			3	68.40		
GL1 1, Tip Def. 1	GL V1 (6F) Samp 1	Flexibility test of distal portion of distal tubular shaft ("Flex 1")	1	16.36		
GL1 1, Tip Def. 2			2	17.52		16.97

GL1 1, Tip Def. 3			3	17.03	
GL2 1, Tip Def. 1	GL V2 (6F) Samp 1	Flexibility test of distal portion of	1	15.47	
GL2 1, Tip Def. 2		distal tubular shaft ("Flex 1")	2	16.49	16.18
GL2 1, Tip Def. 3			3	16.57	
GZ1 1, Tip Def. 1	GZ V1 (6F) Samp 1	Flexibility test of distal portion of	1	18.55	
GZ1 1, Tip Def. 2		distal tubular shaft ("Flex 1")	2	19.05	18.92
GZ1 1, Tip Def. 3			3	19.17	
QXSC 2, Dist. Tip Def. 1	QXM (SCH) (6F) Samp 2	Flexibility test of distal portion of	1	16.20	
QXSC 2, Dist. Tip Def. 2		distal tubular shaft ("Flex 1")	2	16.40	16.41
QXSC 2, Dist. Tip Def. 3			3	16.64	
QXSC 2, Prox. Tube Def. 1		Flexibility test of proximal portion of	1	25.09	
QXSC 2, Prox. Tube Def. 2		distal tubular shaft ("Flex 2")	2	25.67	25.80
QXSC 2, Prox. Tube Def. 3			3	26.64	
QXSC 2, Opening up Def. 1		Flexibility test of side opening	1	60.82	
QXSC 2, Opening up Def. 2		section, opening "up" ("Flex 3 up")	2	62.07	61.96
QXSC 2, Opening up Def. 3			3	63.01	
QXSC 2, Open Down Def. 1		Flexibility test of side opening	1	47.26	
QXSC 2, Open Down Def. 2		section, opening "down" ("Flex 3	2	46.29	46.96
QXSC 2, Open Down Def. 3		down")	3	47.32	
QXSC 2, Prox. Shaft Def. 1		Flexibility test of proximal shaft	1	68.72	
QXSC 2, Prox. Shaft Def. 2		("Flex 4")	2	69.48	69.33
QXSC 2, Prox. Shaft Def. 3			3	69.81	
QX 2, Bunny Ears Def. 1	QXM (6F) Samp 2	Flexibility test of "bunny ear" section	1	11.44	
QX 2, Bunny Ears Def. 2		of proximal shaft ("bunny ears flex")	2	11.63	11.54
QX 2, Bunny Ears Def. 3			3	11.54	
QXSC 3, Dist. Tip Def. 1	QXM (SCH) (6F) Samp 3	Flexibility test of distal portion of	1	14.77	
QXSC 3, Dist. Tip Def. 2		distal tubular shaft ("Flex 1")	2	15.04	15.15
QXSC 3, Dist. Tip Def. 3			3	15.63	
QXSC 3, Prox. Tube Def. 1		Flexibility test of proximal portion of	1	27.56	
QXSC 3, Prox. Tube Def. 2		distal tubular shaft ("Flex 2")	2	29.31	29.10
QXSC 3, Prox. Tube Def. 3			3	30.45	
QXSC 3, Opening up Def. 1		Flexibility test of side opening	1	47.70	
QXSC 3, Opening up Def. 2		section, opening "up" ("Flex 3 up")	2	49.04	48.36
QXSC 3, Opening up Def. 3			3	48.34	

QXSC 3, Open Down Def. 1		Flexibility test of side opening	1	49.03		
QXSC 3, Open Down Def. 2		section, opening "down" ("Flex 3	2	49.32		49.32
QXSC 3, Open Down Def. 3		down")	3	49.62		
QXSC 3, Prox. Shaft Def. 1		Flexibility test of proximal shaft	1	61.65		
QXSC 3, Prox. Shaft Def. 2		("Flex 4")	2	62.38		62.19
QXSC 3, Prox. Shaft Def. 3			3	62.55		
QX8F, Tip Def. 1	QXM (8F) Samp 1	Flexibility test of distal portion of	1	32.66		
QX8F, Tip Def. 2		distal tubular shaft ("Flex 1")	2	36.12		35.06
QX8F, Tip Def. 3			3	36.39		
QX8F, Prox. Tube Def. 2		Flexibility test of proximal portion of	2	56.09	run 1 not in good contact, rerun	
QX8F, Prox. Tube Def. 3		distal tubular shaft ("Flex 2")	3	58.90		58.43
QX8F, Prox. Tube Def. 4			4	60.30		
QX8F, Opening up Def. 1		Flexibility test of side opening	1	73.39		
QX8F, Opening up Def. 2		section, opening "up" ("Flex 3 up")	2	74.43		73.94
QX8F, Opening up Def. 3			3	74.00		
QX8F, Opening Down Def. 1		Flexibility test of side opening	1	65.49		
QX8F, Opening Down Def. 2		section, opening "down" ("Flex 3	2	68.36		67.40
QX8F, Opening Down Def. 3		down")	3	68.36		
QX8F, Prox. Shaft Def. 1		Flexibility test of proximal shaft	1	88.32		
QX8F, Prox. Shaft Def. 2		("Flex 4")	2	90.09		89.35
QX8F, Prox. Shaft Def. 3			3	89.63		
GL38F 1, Tip Def. 1	GL V3 (8F) Samp 1	Flexibility test of distal portion of	1	20.10		
GL38F 1, Tip Def. 2		distal tubular shaft ("Flex 1")	2	20.63		21.07
GL38F 1, Tip Def. 3			3	22.48		
GL38F 1, Prox. Tube Def. 1		Flexibility test of proximal portion of	1	53.47		
GL38F 1, Prox. Tube Def. 2		distal tubular shaft ("Flex 2")	2	55.98		55.30
GL38F 1, Prox. Tube Def. 3			3	56.44		
GL38F 1, Opening up Def. 1		Flexibility test of side opening	1	139.80		
GL38F 1, Opening up Def. 2		section, opening "up" ("Flex 3 up")	2	144.69		143.88
GL38F 1, Opening up Def. 3			3	147.16		
GL38F 1, Open Down Def. 1		Flexibility test of side opening	1	120.97		
GL38F 1, Open Down Def. 2		section, opening "down" ("Flex 3	2	123.94		122.51
GL38F 1, Open Down Def. 3		down")	3	122.61		
GL38F 1, Prox. Shaft Def. 1		Flexibility test of proximal shaft	1	90.80		

GL38F 1, Prox. Shaft Def. 2		("Flex 4")	2	91.62		91.37
GL38F 1, Prox. Shaft Def. 3			3	91.69		
GZ2 1, Tip Def. 1	GZ V2 (6F) Samp 1	Flexibility test of distal portion of	1	15.09		
GZ2 1, Tip Def. 2		distal tubular shaft ("Flex 1")	2	17.23		16.49
GZ2 1, Tip Def. 3			3	17.16		
GZ2 1, Prox. Tube Def. 1		Flexibility test of proximal portion of	1	42.17		
GZ2 1, Prox. Tube Def. 2		distal tubular shaft ("Flex 2")	2	43.12		42.92
GZ2 1, Prox. Tube Def. 3			3	43.48		
GZ2 1, Opening Def. 1		Flexibility test of side opening	1	106.09	run 2 not in good contact, rerun	
GZ2 1, Opening Def. 3		section, opening "up" ("Flex 3 up")	3	110.12		108.96
GZ2 1, Opening Def. 4			4	110.67		
GZ2 1, Open Down Def. 1		Flexibility test of side opening	1	103.53		
GZ2 1, Open Down Def. 2		section, opening "down" ("Flex 3	2	107.89		107.37
GZ2 1, Open Down Def. 3		down")	3	110.68		
GZ2 1, Prox. Shaft Def. 1		Flexibility test of proximal shaft	1	114.60	New pin vise fixture created for metal	
GZ2 1, Prox. Shaft Def. 2		("Flex 4")	2	116.15	shaft, noted after run 3 that ID of pin	116.47
GZ2 1, Prox. Shaft Def. 3			3	118.67	clamp rounded. Ground flat, then reran	
GZ2 1, Prox. Shaft Def. 4			4	126.88	test for runs 4, 5, 6	
GZ2 1, Prox. Shaft Def. 5			5	127.46		128.18
GZ2 1, Prox. Shaft Def. 6			6	130.21		
TL1, Dist. Tip Def. 1	TL (6F) Samp 1	Flexibility test of distal portion of	1	15.81		
TL1, Dist. Tip Def. 2		distal tubular shaft ("Flex 1")	2	16.91		16.59
TL1, Dist. Tip Def. 3			3	17.05		
TL1, Prox. Tube Def. 1		Flexibility test of proximal portion of	1	24.79		
TL1, Prox. Tube Def. 2		distal tubular shaft ("Flex 2")	2	25.36		25.39
TL1, Prox. Tube Def. 3			3	26.03		
TL1, Opening up Def. 1		Flexibility test of side opening	1	88.78		
TL1, Opening up Def. 2		section, opening "up" ("Flex 3 up")	2	91.43		90.30
TL1, Opening up Def. 3			3	90.67		
TL1, Open Down Def. 1		Flexibility test of side opening	1	66.98		
TL1, Open Down Def. 2		section, opening "down" ("Flex 3	2	65.13		66.65
TL1, Open Down Def. 3		down")	3	67.83		
TL1, Prox. Shaft Def. 1		Flexibility test of proximal shaft	1	173.62		
TL1, Prox. Shaft Def. 2		("Flex 4")	2	179.36		177.29

TL1, Prox. Shaft Def. 3	3	178.90

Two Point Bend Testing

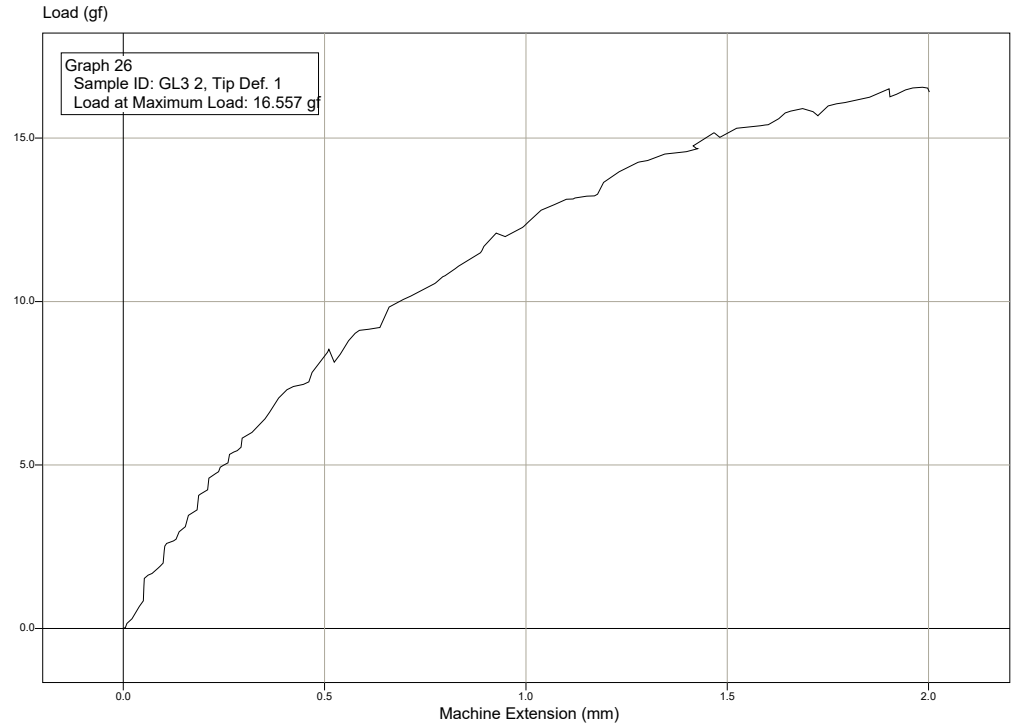
This report contains all the data from the two point bend testing performed in order to evaluate various different guide extension catheters

Sample ID	Speed	Limit	Load at Maximum Load
GL3 2, Tip Def. 1	0.200 mm/s	2.0000 mm	16.557 gf
GL3 2, Tip Def. 2	0.200 mm/s	2.0000 mm	18.812 gf
GL3 2, Tip Def. 3	0.200 mm/s	2.0000 mm	18.156 gf
GL3 2, Prox. Tubing Def. 1	0.200 mm/s	2.0000 mm	32.545 gf
GL3 2, Prox. Tubing Def. 2	0.200 mm/s	2.0000 mm	32.707 gf
GL3 2, Prox. Tubing Def. 3	0.200 mm/s	2.0000 mm	32.010 gf
GL3 2, Opening up Def. 1	0.200 mm/s	2.0000 mm	69.671 gf
GL3 2, Opening up Def. 2	0.200 mm/s	2.0000 mm	73.547 gf
GL3 2, Opening up Def. 3	0.200 mm/s	2.0000 mm	72.018 gf
GL3 2, Opening down Def. 1	0.200 mm/s	2.0000 mm	58.421 gf
GL3 2, Opening down Def. 2	0.200 mm/s	2.0000 mm	58.253 gf
GL3 2, Opening down Def. 3	0.200 mm/s	2.0000 mm	57.744 gf
GL3 2, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	73.883 gf
GL3 2, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	74.472 gf
GL3 2, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	74.194 gf
QX3, Dist. Tip Def. 1	0.200 mm/s	2.0000 mm	13.956 gf
QX3, Dist. Tip Def. 2	0.200 mm/s	2.0000 mm	14.427 gf
QX3, Dist. Tip Def. 3	0.200 mm/s	2.0000 mm	14.679 gf
QX3, Prox. Tubing Def. 1	0.200 mm/s	2.0000 mm	25.354 gf
QX3, Prox. Tubing Def. 2	0.200 mm/s	2.0000 mm	26.945 gf
QX3, Prox. Tubing Def. 3	0.200 mm/s	2.0000 mm	27.954 gf
QX3, Opening up Def. 1	0.200 mm/s	2.0000 mm	43.015 gf
QX3, Opening up Def. 2	0.200 mm/s	2.0000 mm	42.616 gf
QX3, Opening up Def. 3	0.200 mm/s	2.0000 mm	43.331 gf
QX3, Opening Down Def. 1	0.200 mm/s	2.0000 mm	36.860 gf
QX3, Opening Down Def. 2	0.200 mm/s	2.0000 mm	36.340 gf
QX3, Opening Down Def. 3	0.200 mm/s	2.0000 mm	38.519 gf
QX3, Prox.Shaft. Def. 1	0.200 mm/s	2.0000 mm	65.439 gf
QX3, Prox.Shaft. Def. 2	0.200 mm/s	2.0000 mm	67.790 gf
QX3, Prox.Shaft. Def. 3	0.200 mm/s	2.0000 mm	68.400 gf
GL1 1, Tip Def. 1	0.200 mm/s	2.0000 mm	16.361 gf
GL1 1, Tip Def. 2	0.200 mm/s	2.0000 mm	17.517 gf
GL1 1, Tip Def. 3	0.200 mm/s	2.0000 mm	17.033 gf
GL2 1, Tip Def. 1	0.200 mm/s	2.0000 mm	15.471 gf
GL2 1, Tip Def. 2	0.200 mm/s	2.0000 mm	16.485 gf
GL2 1, Tip Def. 3	0.200 mm/s	2.0000 mm	16.572 gf
GZ1 1, Tip Def. 1	0.200 mm/s	2.0000 mm	18.547 gf
GZ1 1, Tip Def. 2	0.200 mm/s	2.0000 mm	19.051 gf
GZ1 1, Tip Def. 3	0.200 mm/s	2.0000 mm	19.171 gf
QXSC 2, Dist. Tip Def. 1	0.200 mm/s	2.0000 mm	16.195 gf
QXSC 2, Dist. Tip Def. 2	0.200 mm/s	2.0000 mm	16.398 gf
QXSC 2, Dist. Tip Def. 3	0.200 mm/s	2.0000 mm	16.638 gf
QXSC 2, Prox. Tube Def. 1	0.200 mm/s	2.0000 mm	25.087 gf
QXSC 2, Prox. Tube Def. 2	0.200 mm/s	2.0000 mm	25.669 gf
QXSC 2, Prox. Tube Def. 3	0.200 mm/s	2.0000 mm	26.637 gf

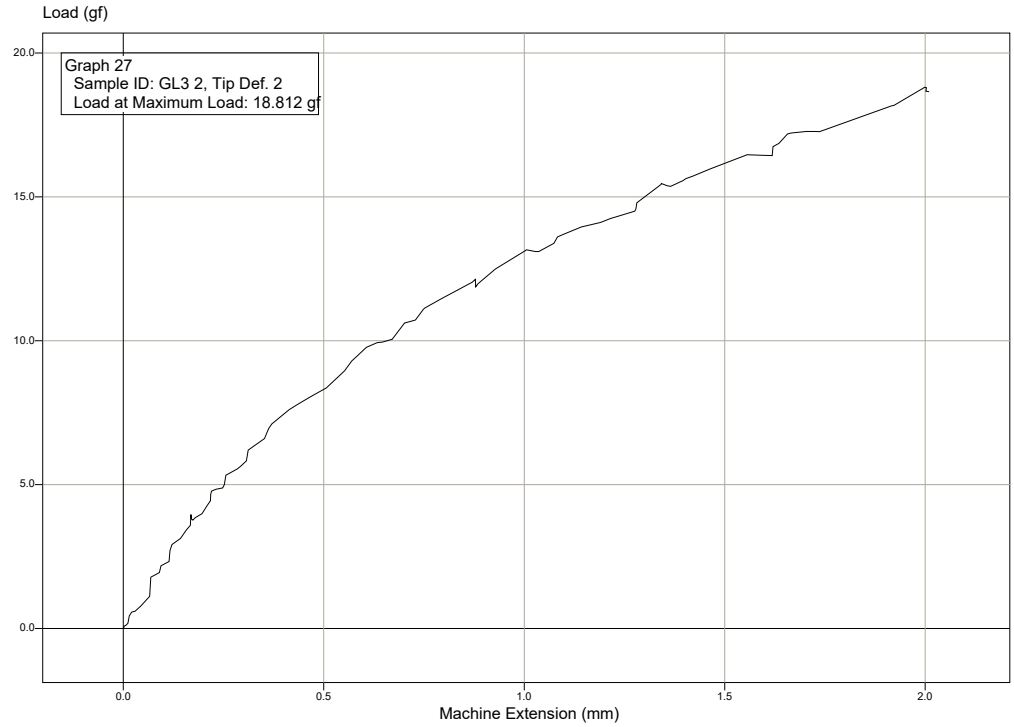
QXSC 2, Opening up Def. 1	0.200 mm/s	2.0000 mm	60.817 gf
QXSC 2, Opening up Def. 2	0.200 mm/s	2.0000 mm	62.065 gf
QXSC 2, Opening up Def. 3	0.200 mm/s	2.0000 mm	63.009 gf
QXSC 2, Open Down Def. 1	0.200 mm/s	2.0000 mm	47.257 gf
QXSC 2, Open Down Def. 2	0.200 mm/s	2.0000 mm	46.290 gf
QXSC 2, Open Down Def. 3	0.200 mm/s	2.0000 mm	47.324 gf
QXSC 2, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	68.716 gf
QXSC 2, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	69.476 gf
QXSC 2, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	69.807 gf
QX 2, Bunny Ears Def. 1	0.200 mm/s	2.0000 mm	11.441 gf
QX 2, Bunny Ears Def. 2	0.200 mm/s	2.0000 mm	11.627 gf
QX 2, Bunny Ears Def. 3	0.200 mm/s	2.0000 mm	11.541 gf
QXSC 3, Dist. Tip Def. 1	0.200 mm/s	2.0000 mm	14.767 gf
QXSC 3, Dist. Tip Def. 2	0.200 mm/s	2.0000 mm	15.043 gf
QXSC 3, Dist. Tip Def. 3	0.200 mm/s	2.0000 mm	15.632 gf
QXSC 3, Prox. Tube Def. 1	0.200 mm/s	2.0000 mm	27.555 gf
QXSC 3, Prox. Tube Def. 2	0.200 mm/s	2.0000 mm	29.308 gf
QXSC 3, Prox. Tube Def. 3	0.200 mm/s	2.0000 mm	30.447 gf
QXSC 3, Opening up Def. 1	0.200 mm/s	2.0000 mm	47.702 gf
QXSC 3, Opening up Def. 2	0.200 mm/s	2.0000 mm	49.039 gf
QXSC 3, Opening up Def. 3	0.200 mm/s	2.0000 mm	48.343 gf
QXSC 3, Open Down Def. 1	0.200 mm/s	2.0000 mm	49.030 gf
QXSC 3, Open Down Def. 2	0.200 mm/s	2.0000 mm	49.315 gf
QXSC 3, Open Down Def. 3	0.200 mm/s	2.0000 mm	49.618 gf
QXSC 3, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	61.648 gf
QXSC 3, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	62.380 gf
QXSC 3, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	62.545 gf
QX8F, Tip Def. 1	0.200 mm/s	2.0000 mm	32.657 gf
QX8F, Tip Def. 2	0.200 mm/s	2.0000 mm	36.124 gf
QX8F, Tip Def. 3	0.200 mm/s	2.0000 mm	36.392 gf
QX8F, Prox. Tube Def. 2	0.200 mm/s	2.0000 mm	56.090 gf
QX8F, Prox. Tube Def. 3	0.200 mm/s	2.0000 mm	58.904 gf
QX8F, Prox. Tube Def. 4	0.200 mm/s	2.0000 mm	60.297 gf
QX8F, Opening up Def. 1	0.200 mm/s	2.0000 mm	73.389 gf
QX8F, Opening up Def. 2	0.200 mm/s	2.0000 mm	74.430 gf
QX8F, Opening up Def. 3	0.200 mm/s	2.0000 mm	73.999 gf
QX8F, Opening Down Def. 1	0.200 mm/s	2.0000 mm	65.488 gf
QX8F, Opening Down Def. 2	0.200 mm/s	2.0000 mm	68.361 gf
QX8F, Opening Down Def. 3	0.200 mm/s	2.0000 mm	68.359 gf
QX8F, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	88.319 gf
QX8F, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	90.094 gf
QX8F, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	89.632 gf
GL38F 1, Tip Def. 1	0.200 mm/s	2.0000 mm	20.104 gf
GL38F 1, Tip Def. 2	0.200 mm/s	2.0000 mm	20.625 gf
GL38F 1, Tip Def. 3	0.200 mm/s	2.0000 mm	22.476 gf
GL38F 1, Prox. Tube Def. 1	0.200 mm/s	2.0000 mm	53.465 gf
GL38F 1, Prox. Tube Def. 2	0.200 mm/s	2.0000 mm	55.983 gf
GL38F 1, Prox. Tube Def. 3	0.200 mm/s	2.0000 mm	56.442 gf
GL38F 1, Opening up Def. 1	0.200 mm/s	2.0000 mm	139.797 gf
GL38F 1, Opening up Def. 2	0.200 mm/s	2.0000 mm	144.688 gf
GL38F 1, Opening up Def. 3	0.200 mm/s	2.0000 mm	147.162 gf
GL38F 1, Open Down Def. 1	0.200 mm/s	2.0000 mm	120.971 gf
GL38F 1, Open Down Def. 2	0.200 mm/s	2.0000 mm	123.938 gf
GL38F 1, Open Down Def. 3	0.200 mm/s	2.0000 mm	122.607 gf
GL38F 1, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	90.798 gf
GL38F 1, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	91.615 gf

GL38F 1, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	91.691 gf
GZ2 1, Tip Def. 1	0.200 mm/s	2.0000 mm	15.090 gf
GZ2 1, Tip Def. 2	0.200 mm/s	2.0000 mm	17.229 gf
GZ2 1, Tip Def. 3	0.200 mm/s	2.0000 mm	17.164 gf
GZ2 1, Prox. Tube Def. 1	0.200 mm/s	2.0000 mm	42.168 gf
GZ2 1, Prox. Tube Def. 2	0.200 mm/s	2.0000 mm	43.120 gf
GZ2 1, Prox. Tube Def. 3	0.200 mm/s	2.0000 mm	43.476 gf
GZ2 1, Opening Def. 1	0.200 mm/s	2.0000 mm	106.090 gf
GZ2 1, Opening Def. 3	0.200 mm/s	2.0000 mm	110.120 gf
GZ2 1, Opening Def. 4	0.200 mm/s	2.0000 mm	110.672 gf
GZ2 1, Open Down Def. 1	0.200 mm/s	2.0000 mm	103.534 gf
GZ2 1, Open Down Def. 2	0.200 mm/s	2.0000 mm	107.891 gf
GZ2 1, Open Down Def. 3	0.200 mm/s	2.0000 mm	110.681 gf
GZ2 1, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	114.600 gf
GZ2 1, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	116.148 gf
GZ2 1, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	118.671 gf
GZ2 1, Prox. Shaft Def. 4	0.200 mm/s	2.0000 mm	126.884 gf
GZ2 1, Prox. Shaft Def. 5	0.200 mm/s	2.0000 mm	127.459 gf
GZ2 1, Prox. Shaft Def. 6	0.200 mm/s	2.0000 mm	130.208 gf
TL1, Dist. Tip Def. 1	0.200 mm/s	2.0000 mm	15.811 gf
TL1, Dist. Tip Def. 2	0.200 mm/s	2.0000 mm	16.905 gf
TL1, Dist. Tip Def. 3	0.200 mm/s	2.0000 mm	17.046 gf
TL1, Prox. Tube Def. 1	0.200 mm/s	2.0000 mm	24.792 gf
TL1, Prox. Tube Def. 2	0.200 mm/s	2.0000 mm	25.356 gf
TL1, Prox. Tube Def. 3	0.200 mm/s	2.0000 mm	26.028 gf
TL1, Opening up Def. 1	0.200 mm/s	2.0000 mm	88.781 gf
TL1, Opening up Def. 2	0.200 mm/s	2.0000 mm	91.430 gf
TL1, Opening up Def. 3	0.200 mm/s	2.0000 mm	90.674 gf
TL1, Open Down Def. 1	0.200 mm/s	2.0000 mm	66.978 gf
TL1, Open Down Def. 2	0.200 mm/s	2.0000 mm	65.134 gf
TL1, Open Down Def. 3	0.200 mm/s	2.0000 mm	67.833 gf
TL1, Prox. Shaft Def. 1	0.200 mm/s	2.0000 mm	173.618 gf
TL1, Prox. Shaft Def. 2	0.200 mm/s	2.0000 mm	179.358 gf
TL1, Prox. Shaft Def. 3	0.200 mm/s	2.0000 mm	178.897 gf

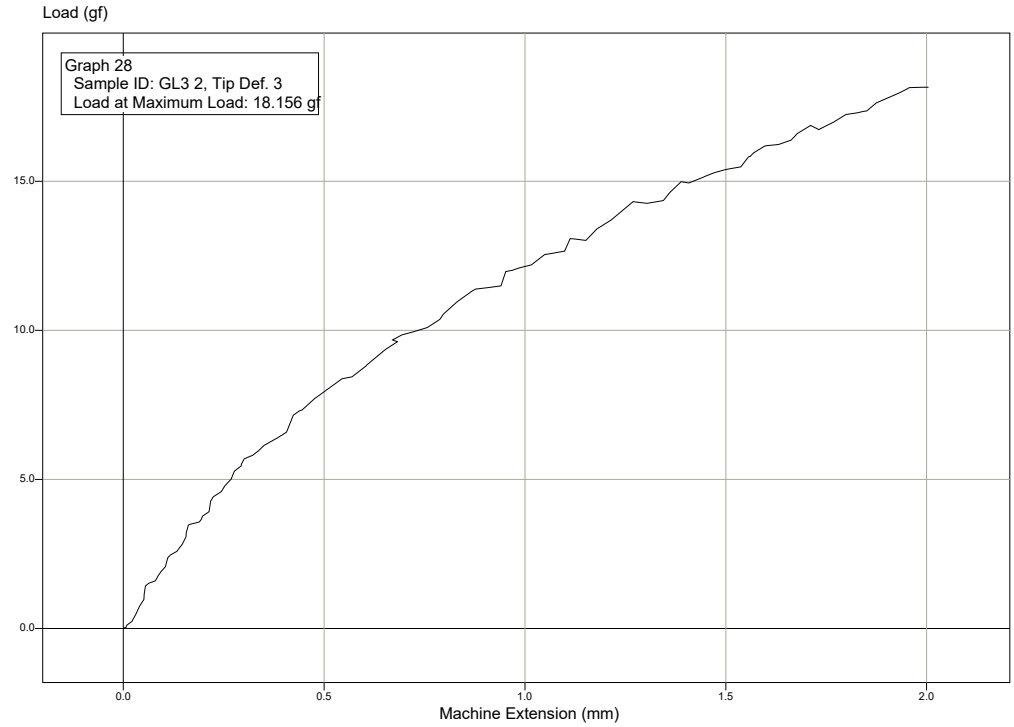
Graph 26


Load (gf)
Graph 26
Sample ID: GL3 2, Tip Def. 1
Load at Maximum Load: 16.557 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

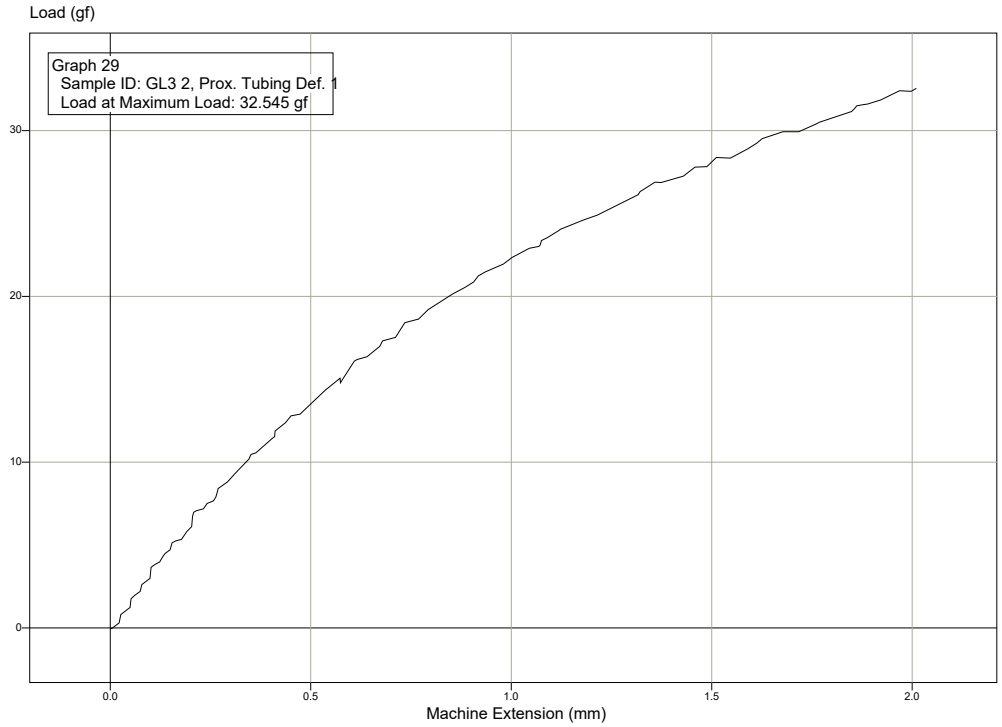
Graph 27



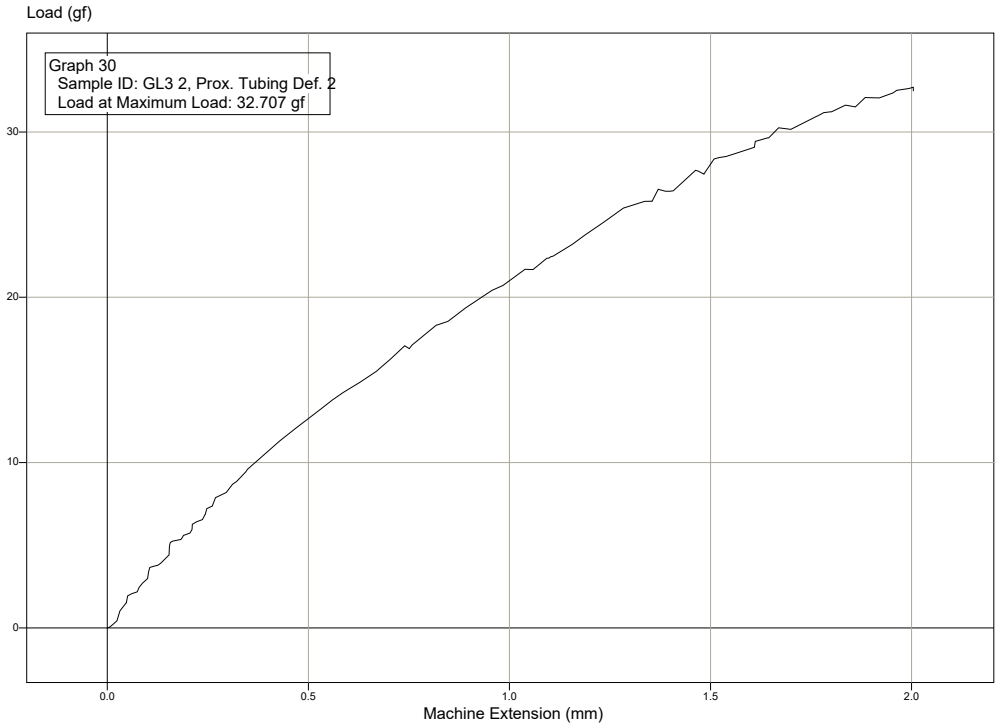
Graph 28


Load (gf)
Graph 28
Sample ID: GL3 2, Tip Def. 3
Load at Maximum Load: 18.156 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

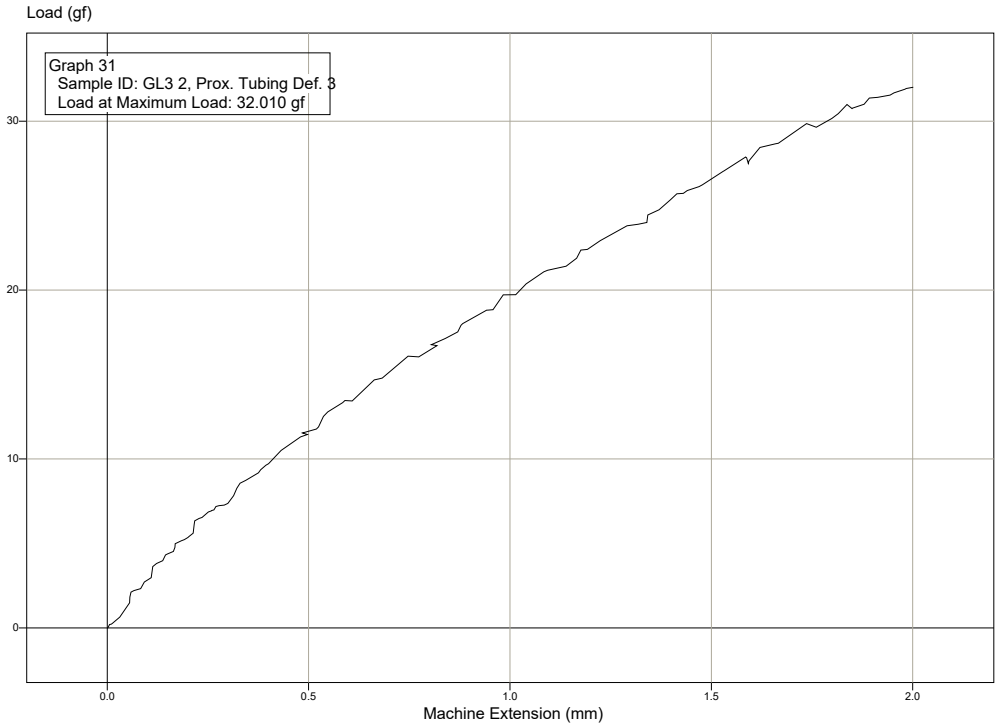
Graph 29


Load (gf)
Graph 29
Sample ID: GL3 2, Prox. Tubing Def. 1
Load at Maximum Load: 32.545 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

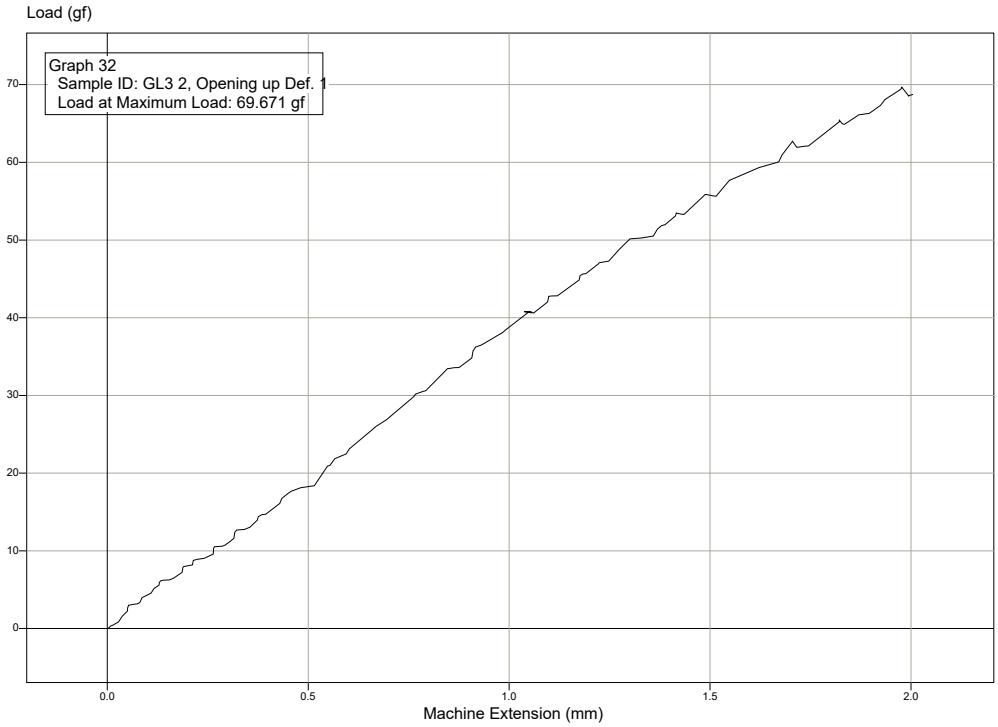
Graph 30


Load (gf)
Graph 30
Sample ID: GL3 2, Prox. Tubing Def. 2
Load at Maximum Load: 32.707 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

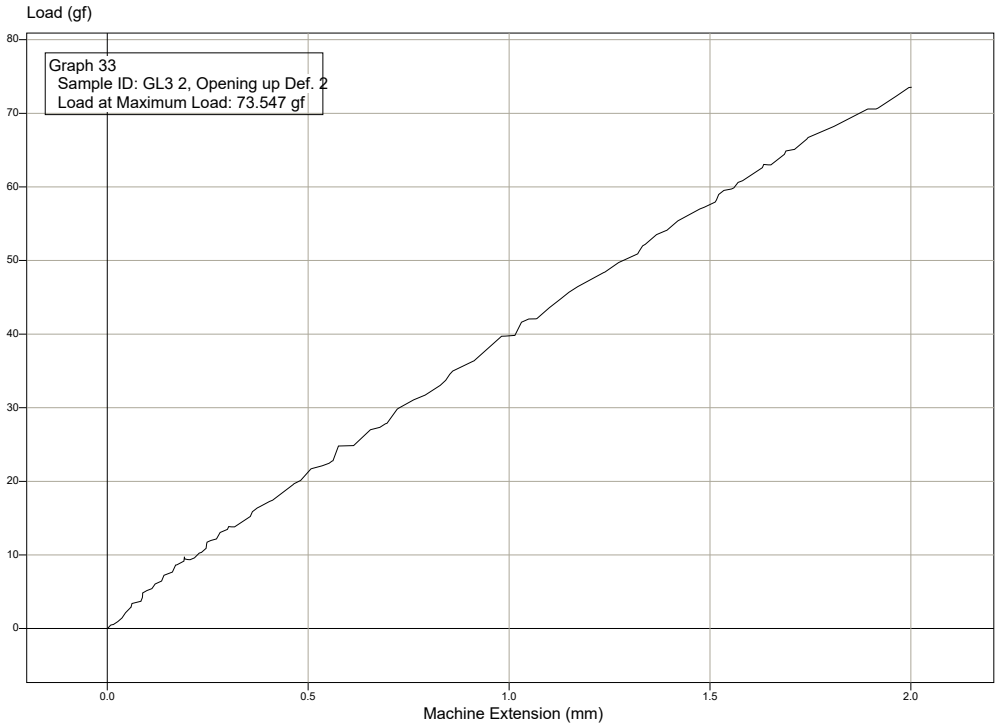
Graph 31


Load (gf)
Graph 31
Sample ID: GL3 2, Prox. Tubing Def. 3
Load at Maximum Load: 32.010 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

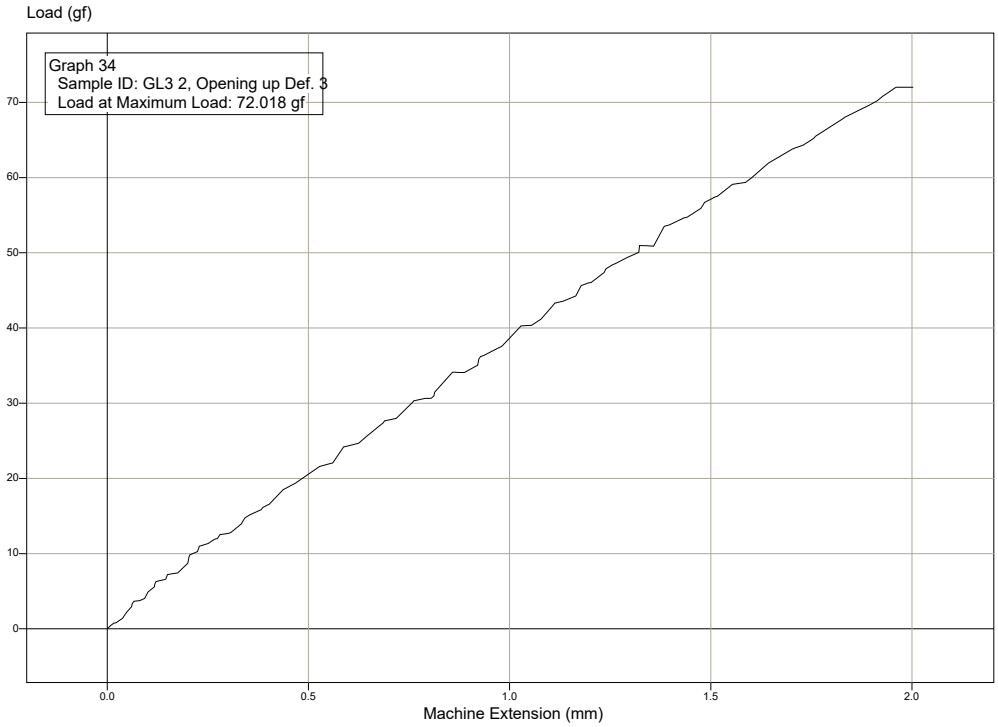
Graph 32



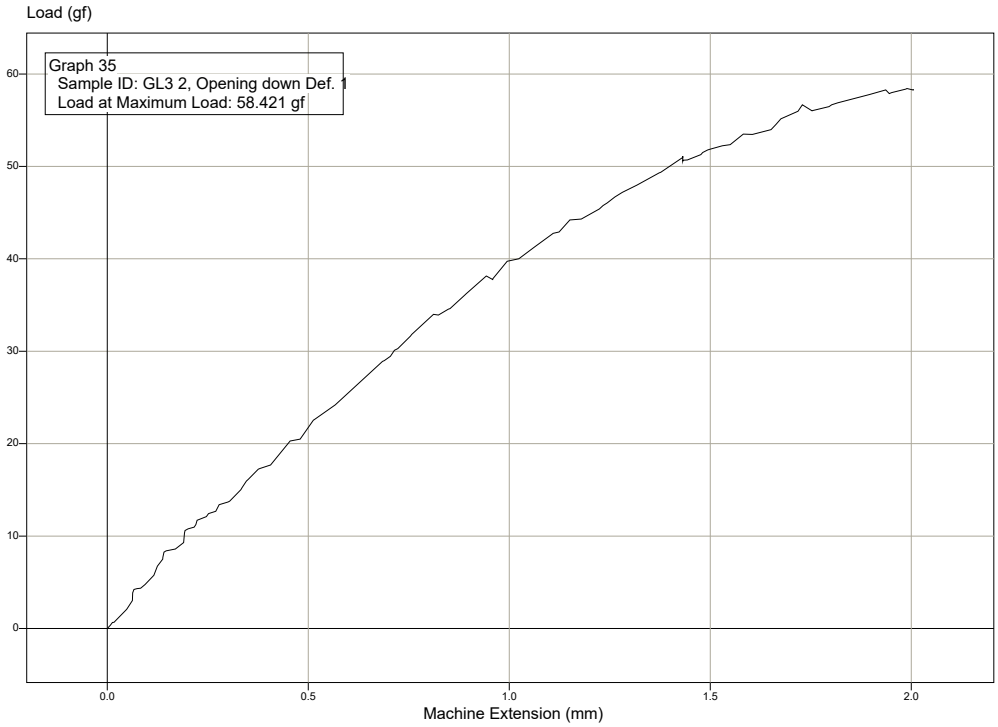
Graph 33


Load (gf)
Graph 33
Sample ID: GL3 2, Opening up Def. 2
Load at Maximum Load: 73.547 gf
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

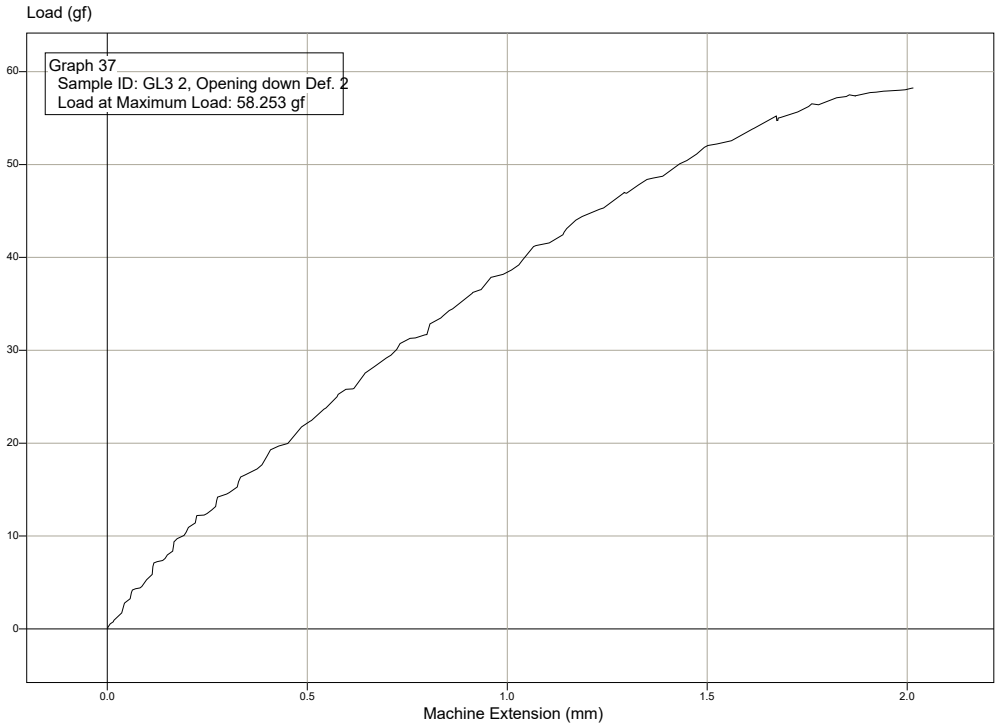
Graph 34


Load (gf)
Graph 34
Sample ID: GL3 2, Opening up Def. 3
Load at Maximum Load: 72.018 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

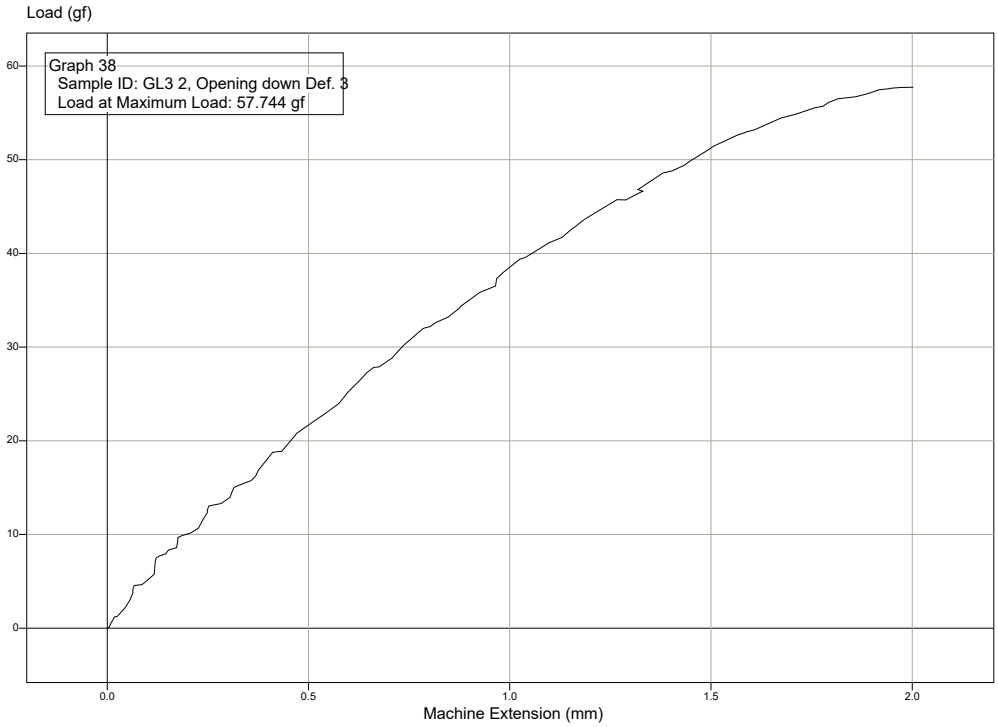
Graph 35


Load (gf)
Graph 35
Sample ID: GL3 2, Opening down Def. 1
Load at Maximum Load: 58.421 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

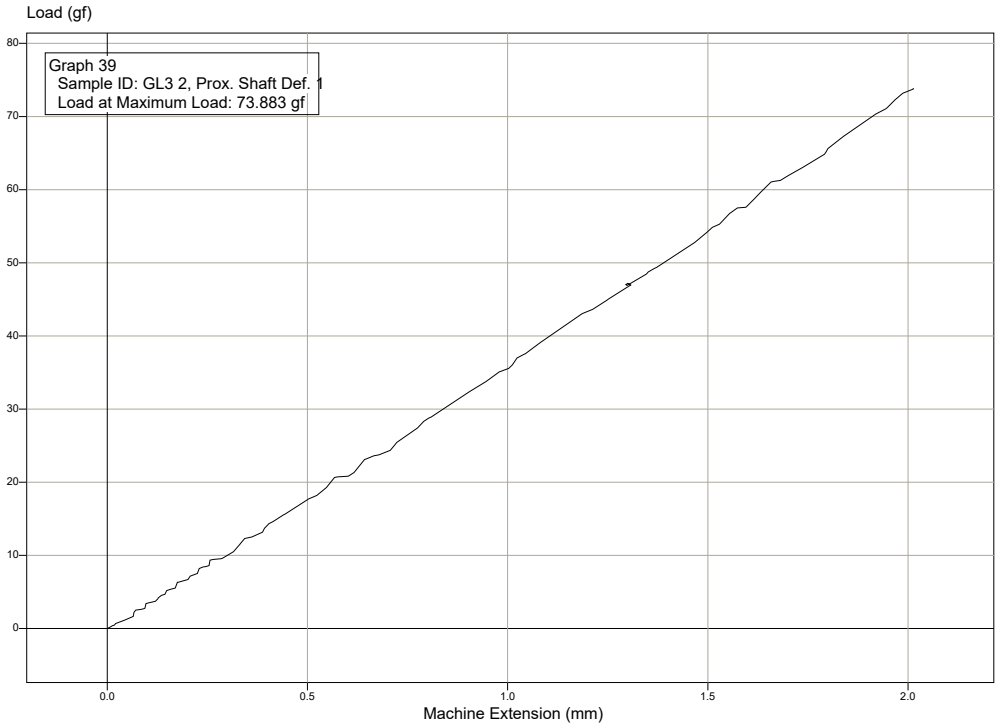
Graph 37


Load (gf)
Graph 37
Sample ID: GL3 2, Opening down Def. 2
Load at Maximum Load: 58.253 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

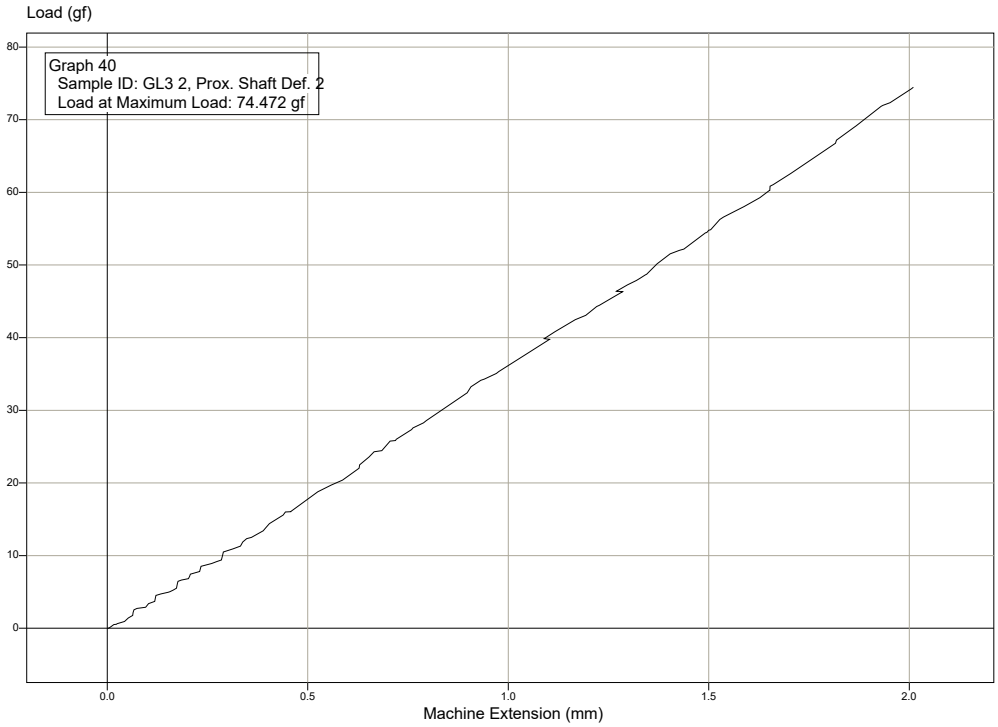
Graph 38


Load (gf)
Graph 38
Sample ID: GL3 2, Opening down Def. 3
Load at Maximum Load: 57.744 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

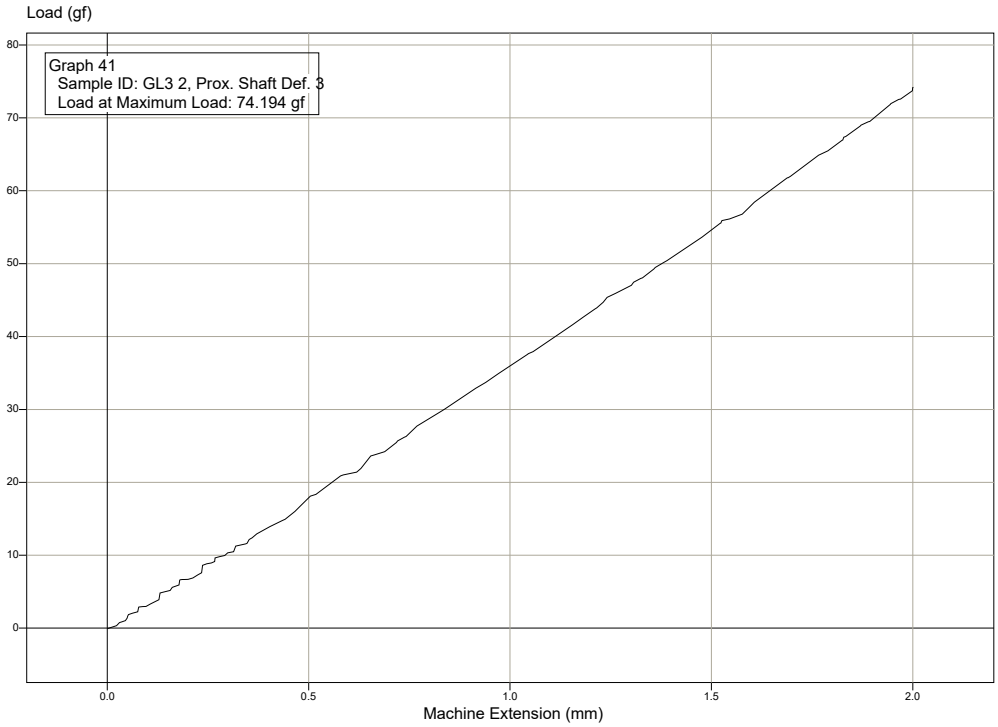
Graph 39


Load (gf)
Graph 39
Sample ID: GL3 2, Prox. Shaft Def. 1
Load at Maximum Load: 73.883 gf
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

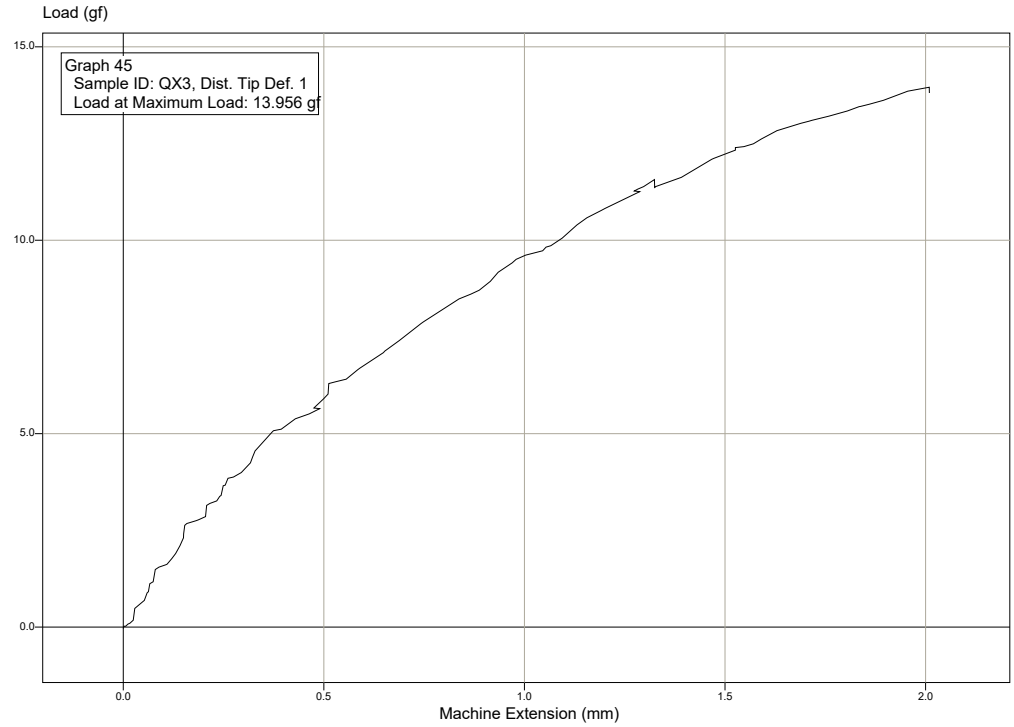
Graph 40



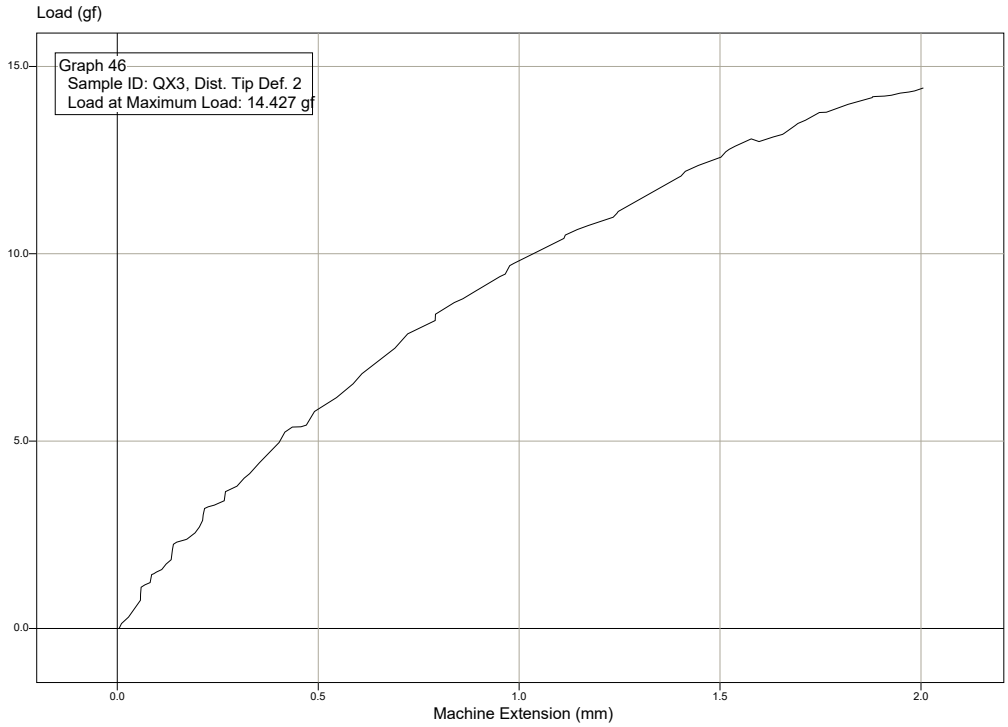
Graph 41


Load (gf)
Graph 41
Sample ID: GL3 2, Prox. Shaft Def. 3
Load at Maximum Load: 74.194 gf
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

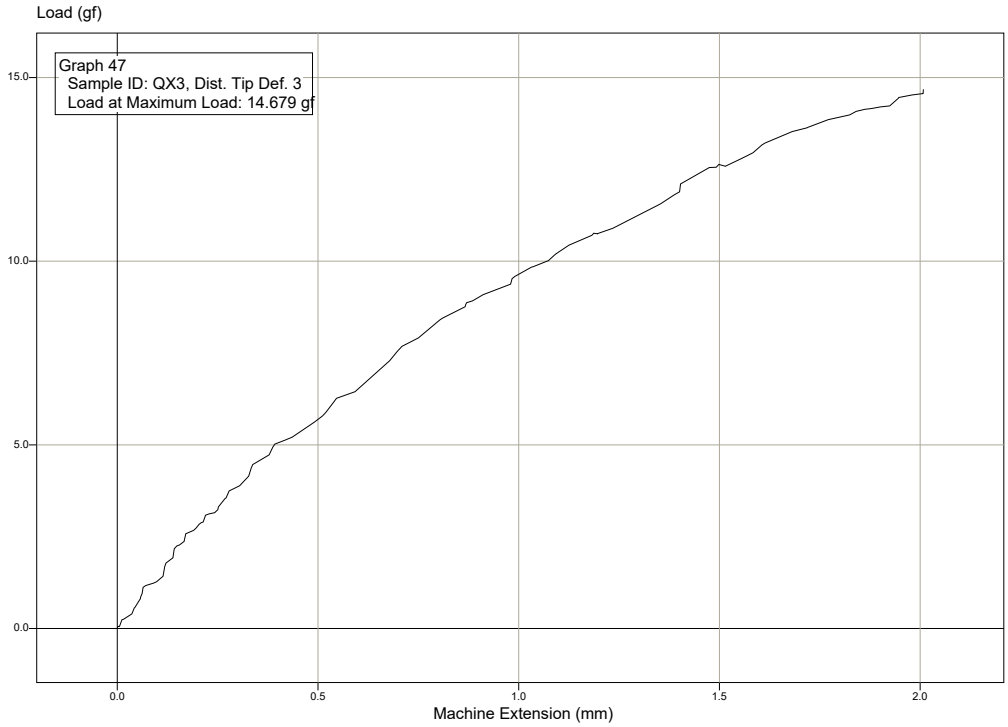
Graph 45


Load (gf)
15.0
10.0
5.0
0.0
Graph 45
Sample ID: QX3, Dist. Tip Def. 1
Load at Maximum Load: 13.956 gf
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

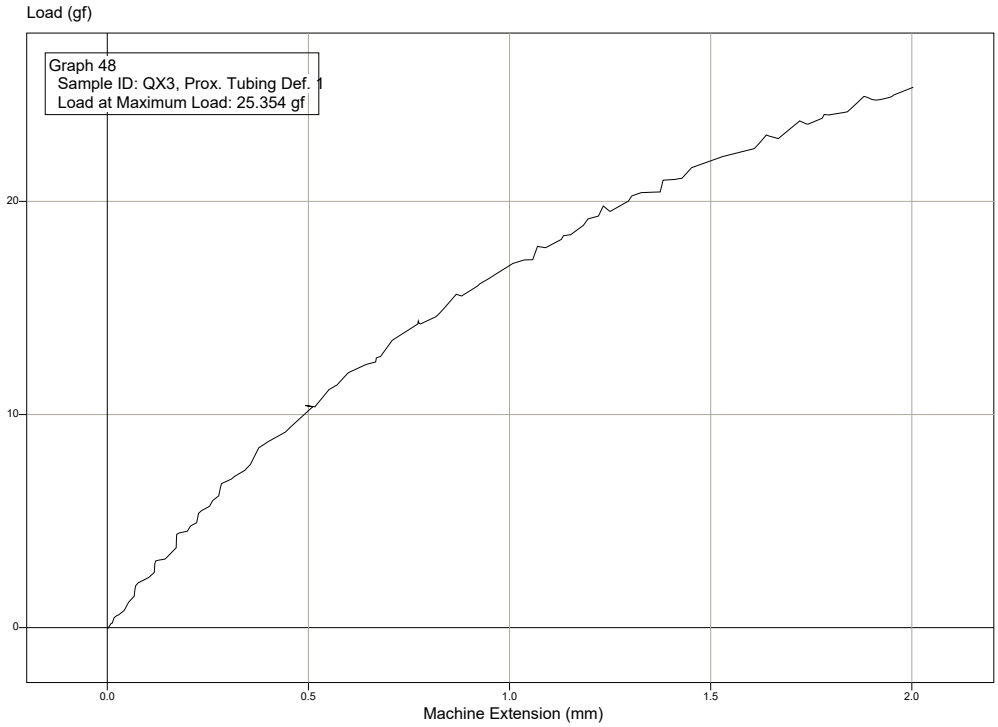
Graph 46


Load (gf)
Graph 46
Sample ID: QX3, Dist. Tip Def. 2
Load at Maximum Load: 14.427 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

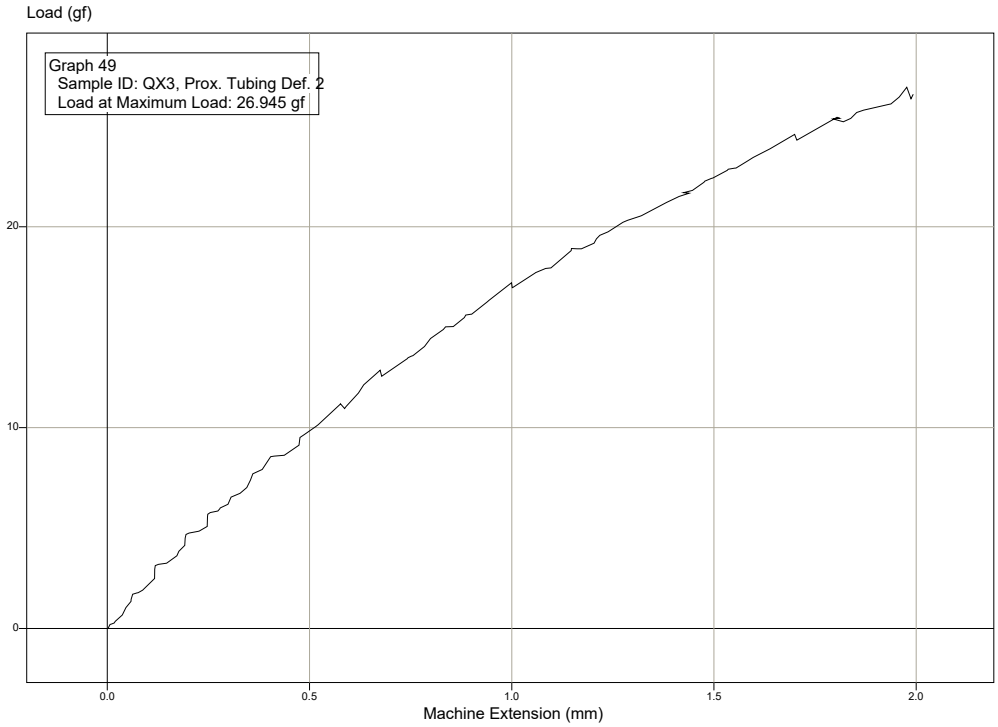
Graph 47


Load (gf)
Graph 47
Sample ID: QX3, Dist. Tip Def. 3
Load at Maximum Load: 14.679 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

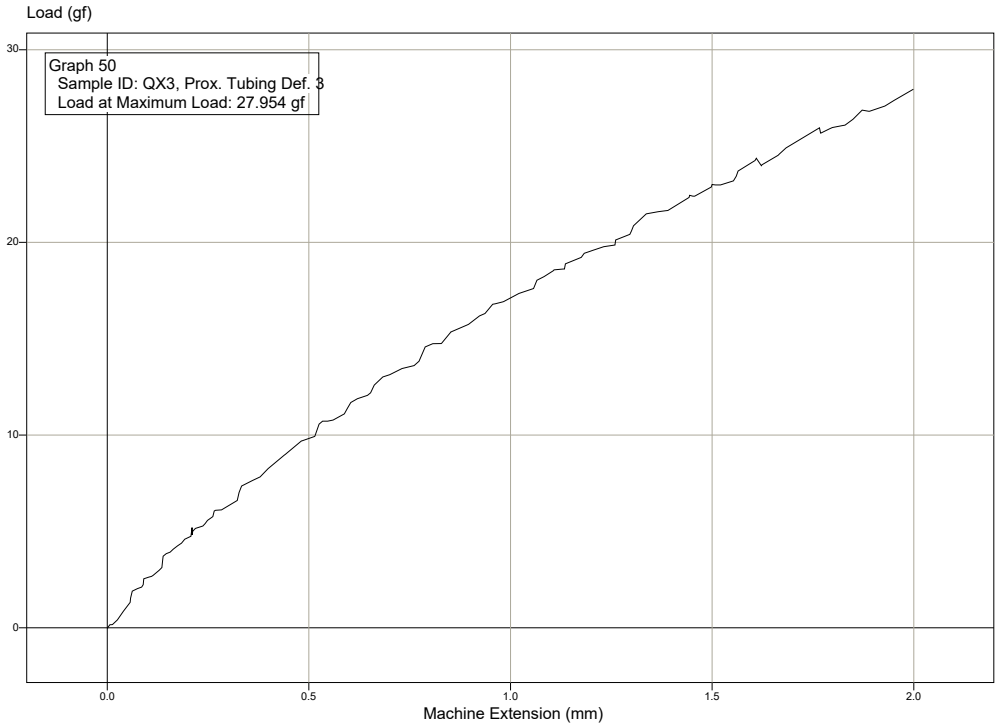
Graph 48



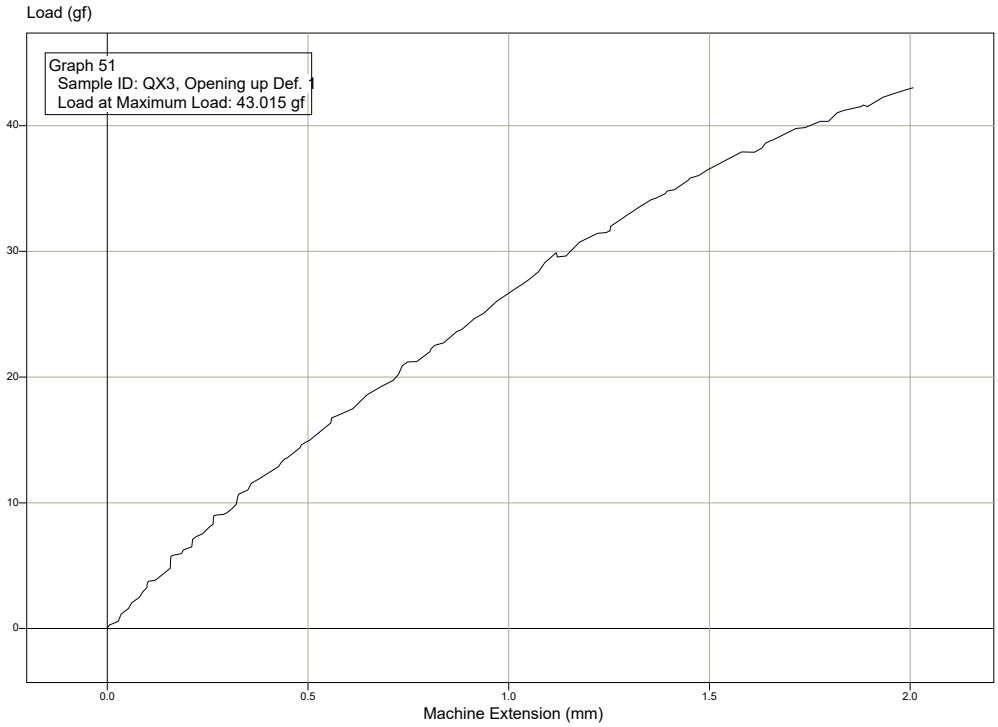
Graph 49



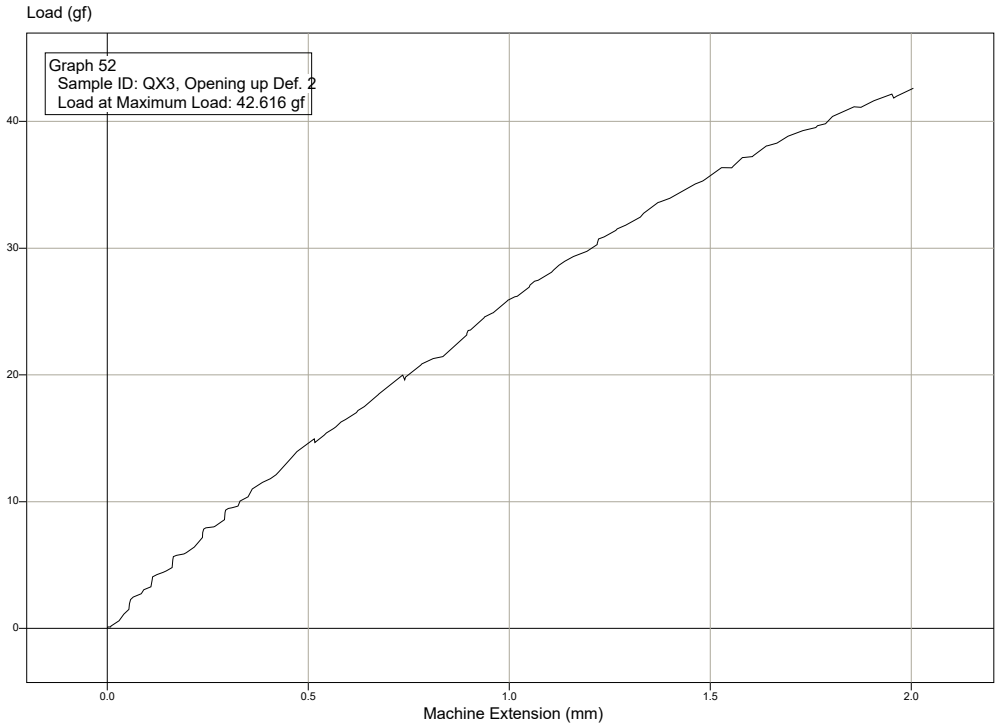
Graph 50



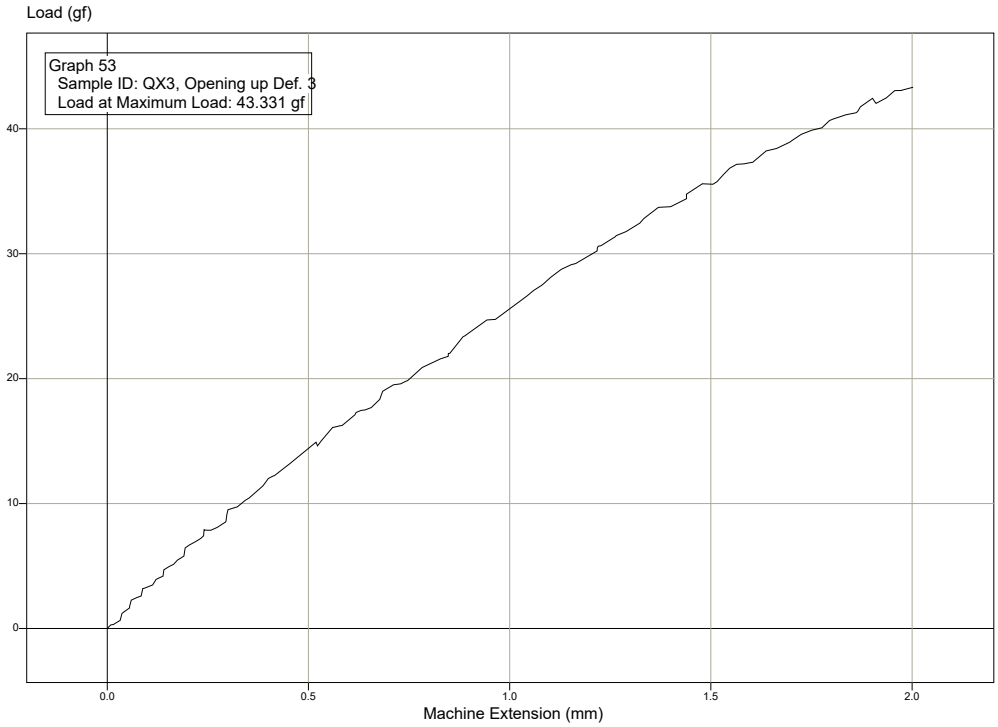
Graph 51


Load (gf)
Graph 51
Sample ID: QX3, Opening up Def. 1
Load at Maximum Load: 43.015 gf
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

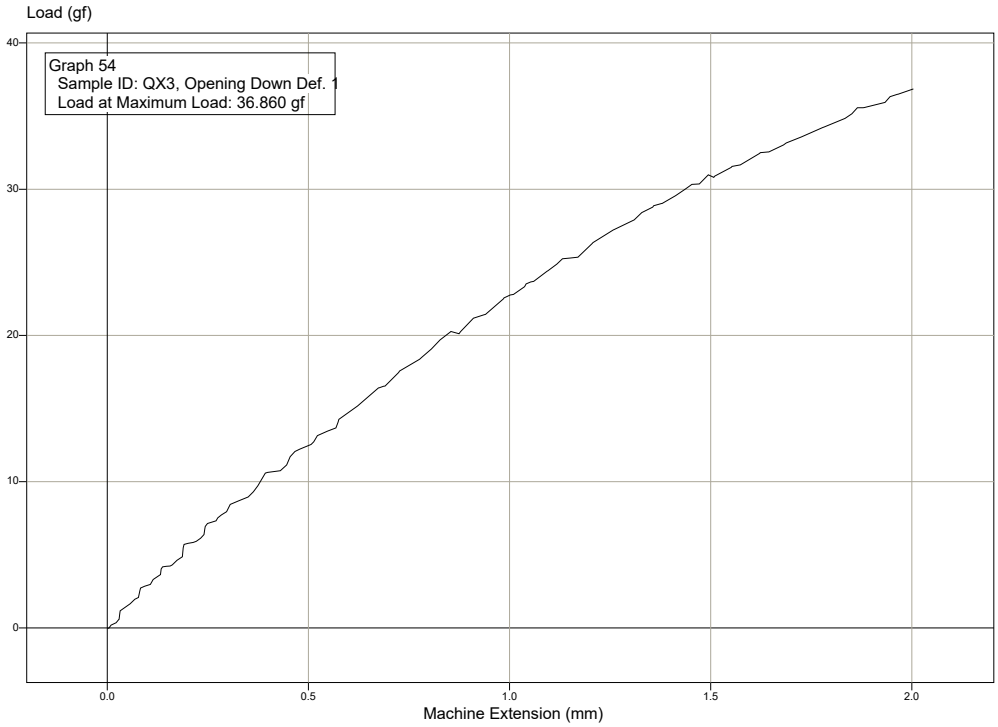
Graph 52


Load (gf)
Graph 52
Sample ID: QX3, Opening up Def. 2
Load at Maximum Load: 42.616 gf
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

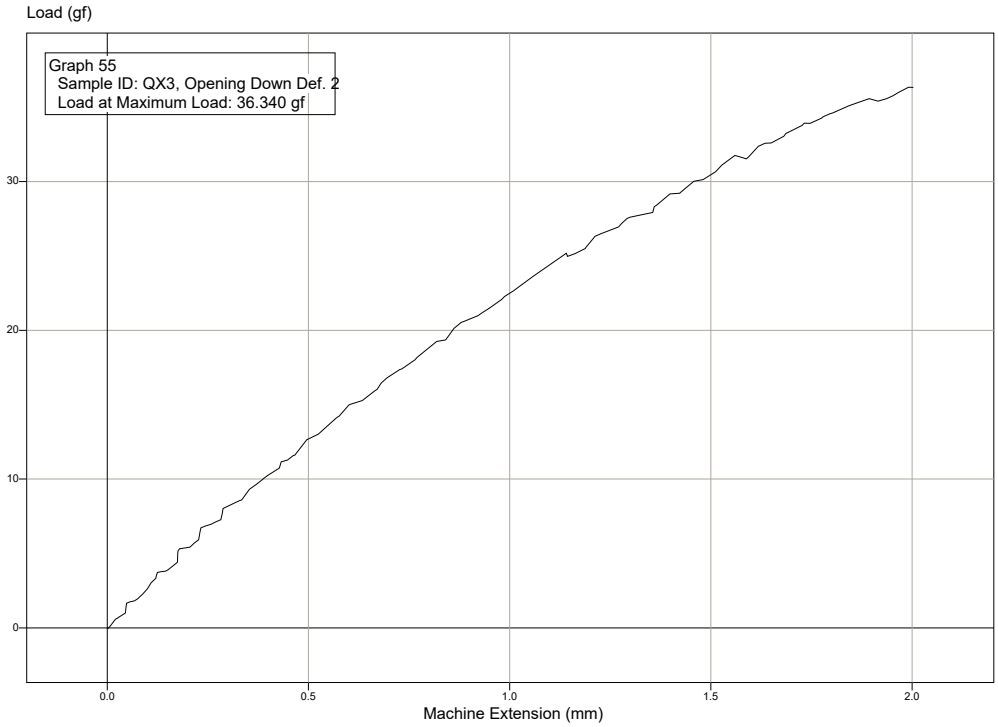
Graph 53


Load (gf)
Graph 53
Sample ID: QX3, Opening up Def. 3
Load at Maximum Load: 43.331 gf
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

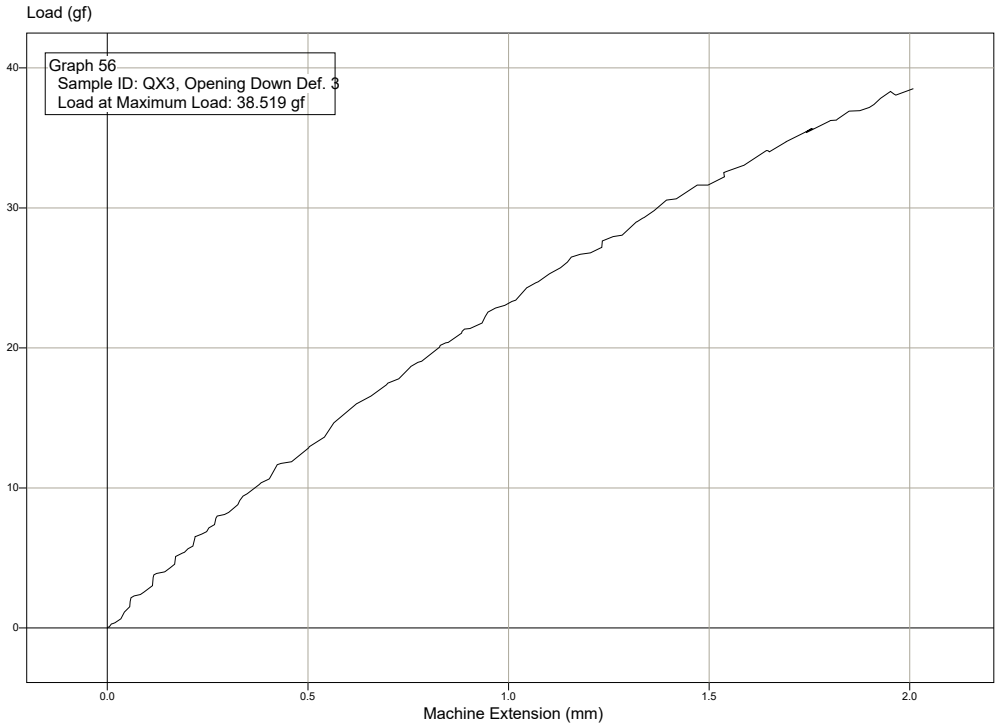
Graph 54



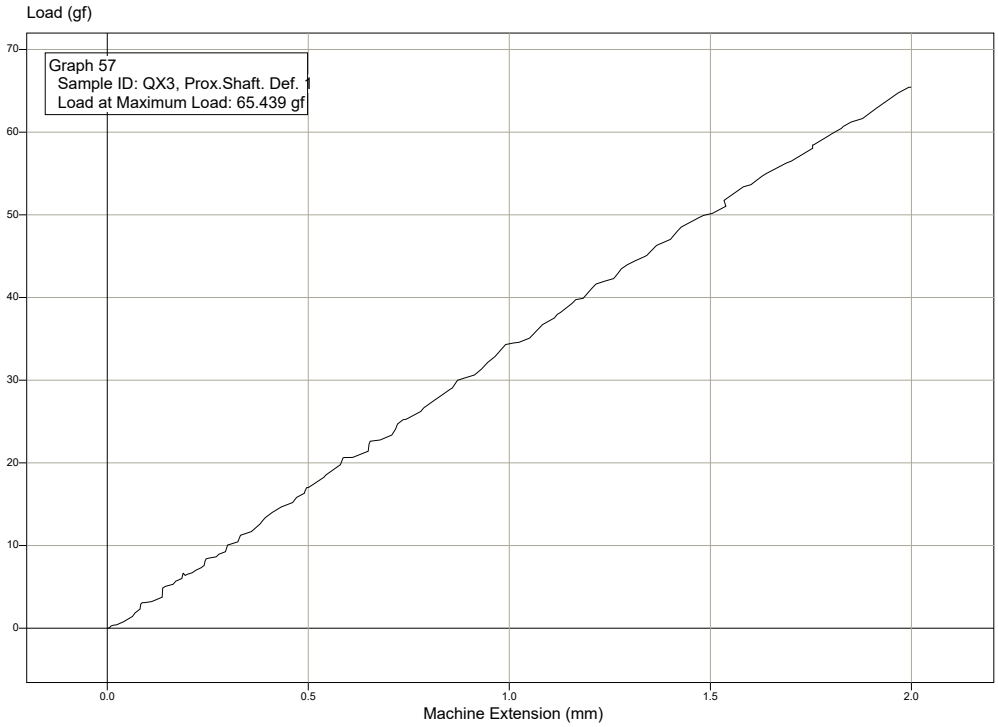
Graph 55



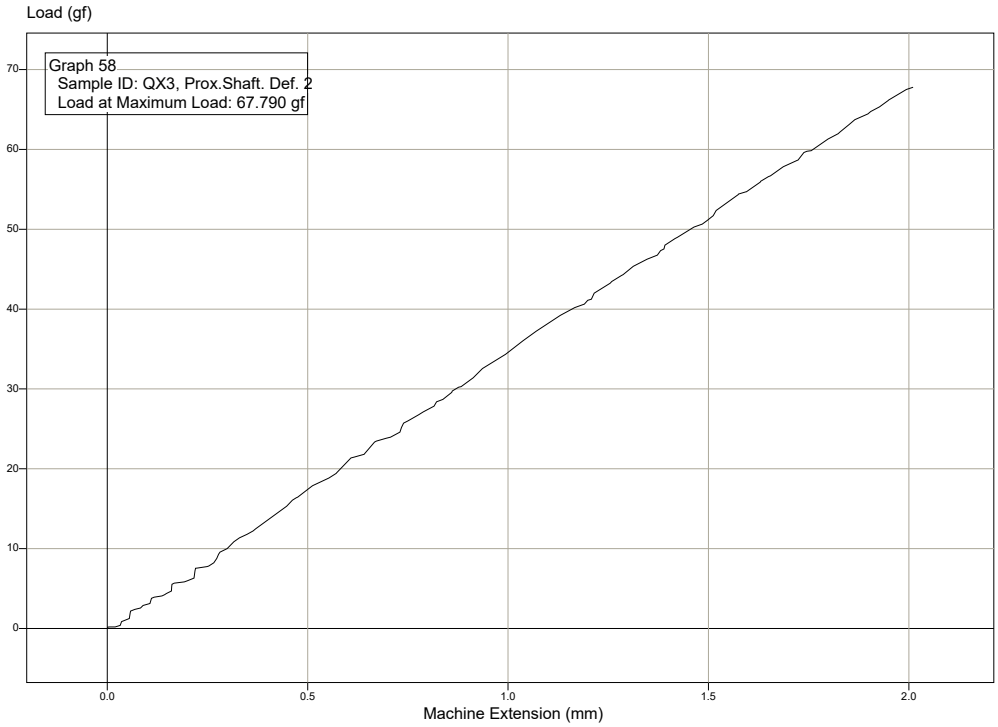
Graph 56



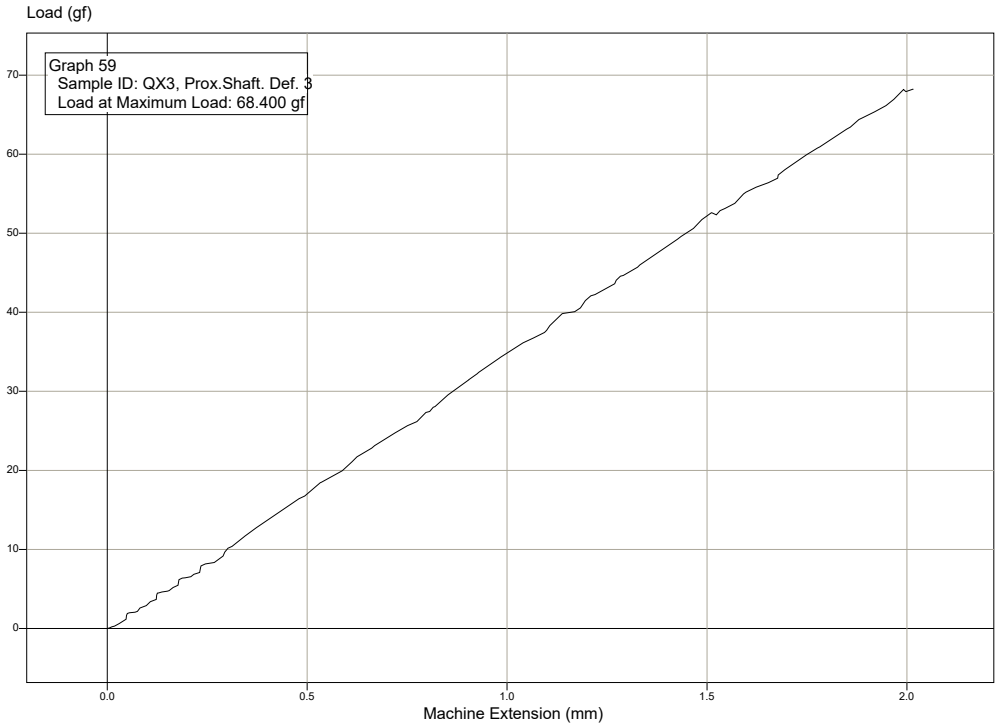
Graph 57


Load (gf)
Graph 57
Sample ID: QX3, Prox.Shaft. Def. 1
Load at Maximum Load: 65.439 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

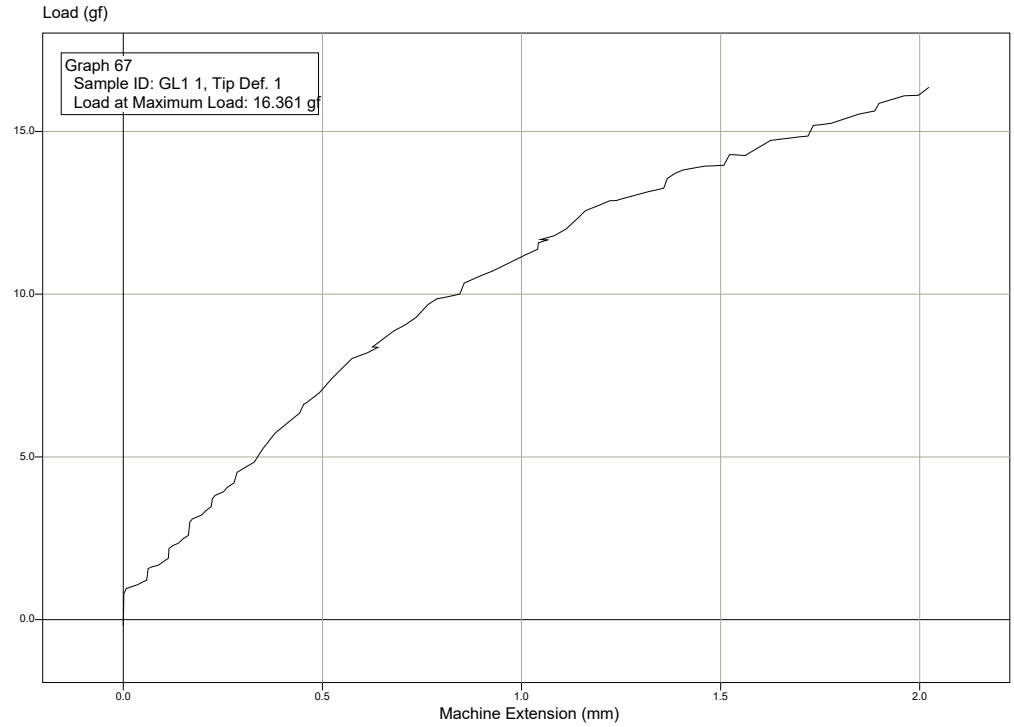
Graph 58


Load (gf)
Graph 58
Sample ID: QX3, Prox.Shaft. Def. 2
Load at Maximum Load: 67.790 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

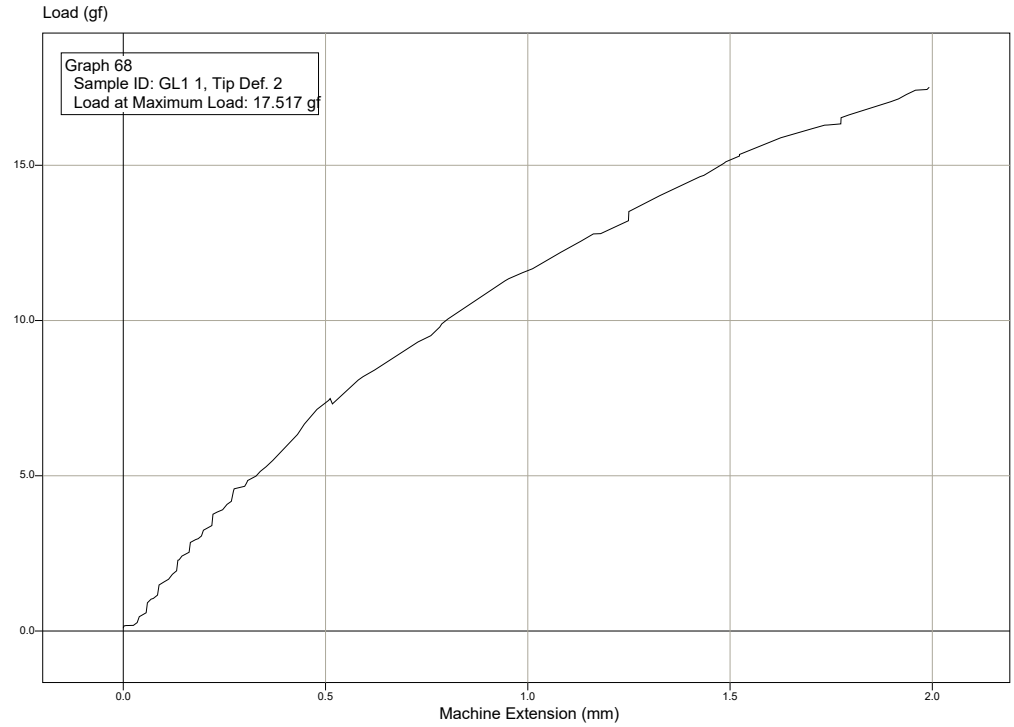
Graph 59


Load (gf)
Graph 59
Sample ID: QX3, Prox.Shaft. Def. 3
Load at Maximum Load: 68.400 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

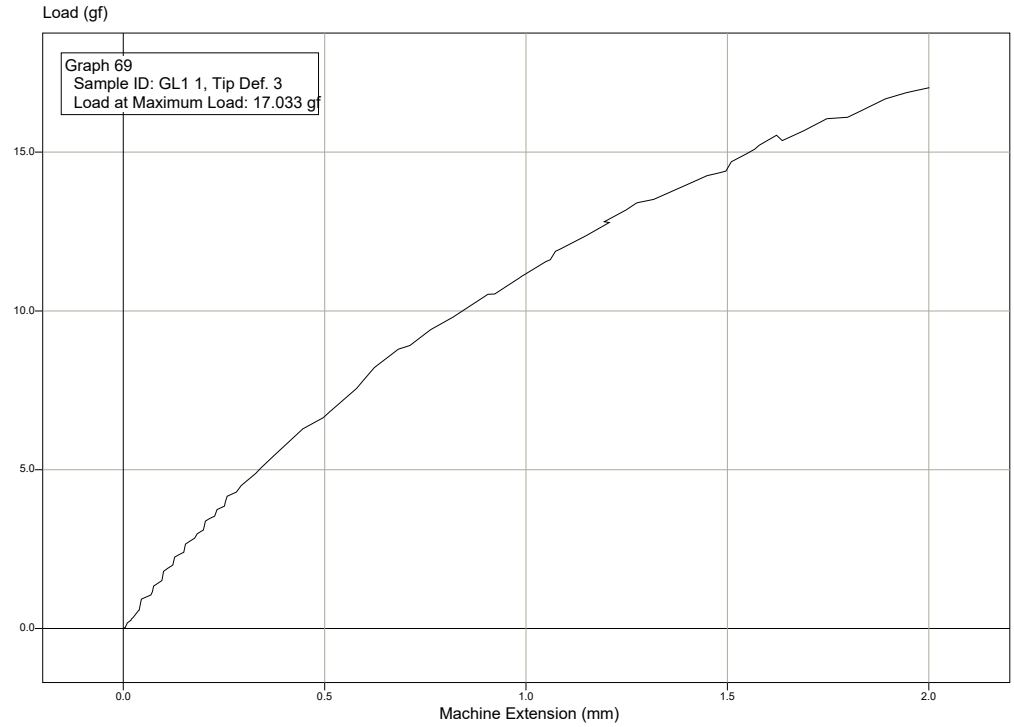
Graph 67



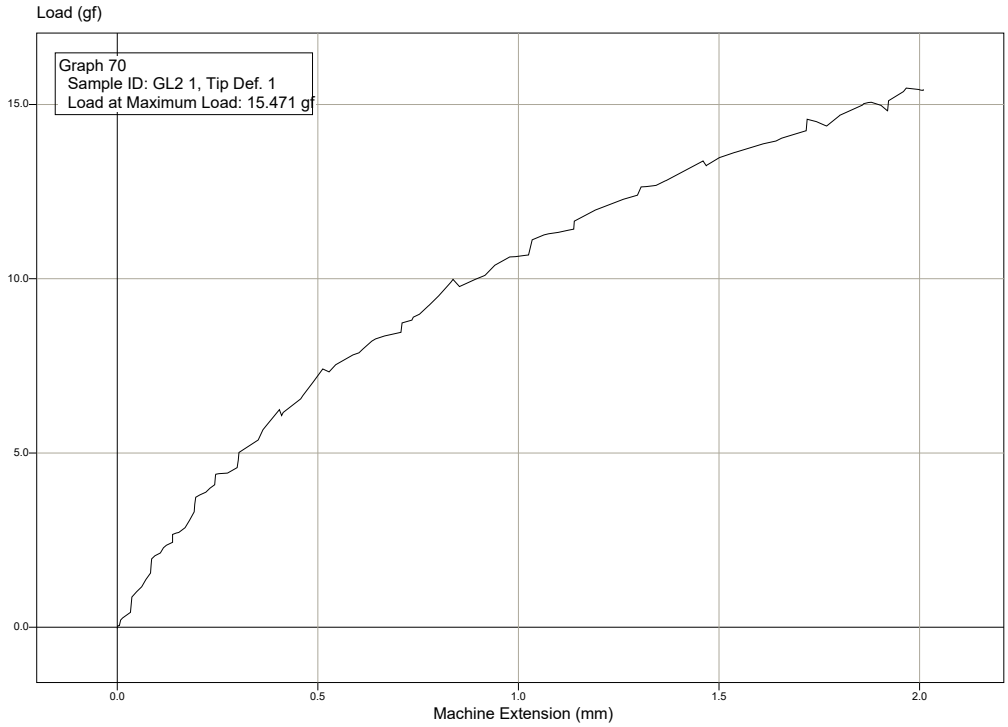
Graph 68



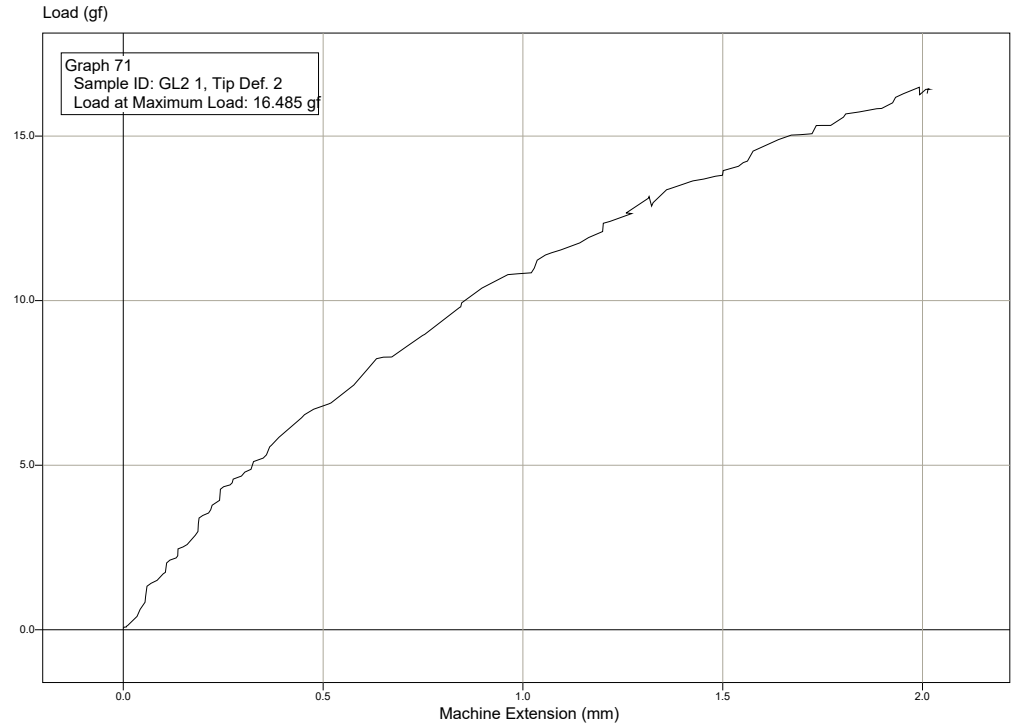
Graph 69


Load (gf)
Graph 69
Sample ID: GL1 1, Tip Def. 3
Load at Maximum Load: 17.033 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

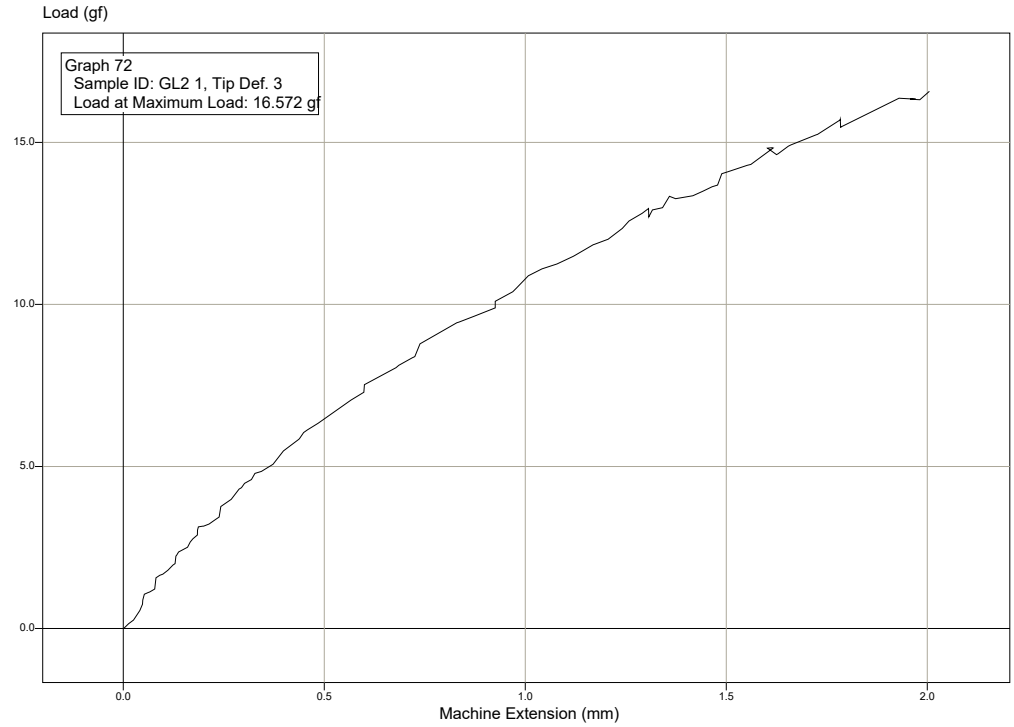
Graph 70


Load (gf)
Graph 70
Sample ID: GL2 1, Tip Def. 1
Load at Maximum Load: 15.471 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

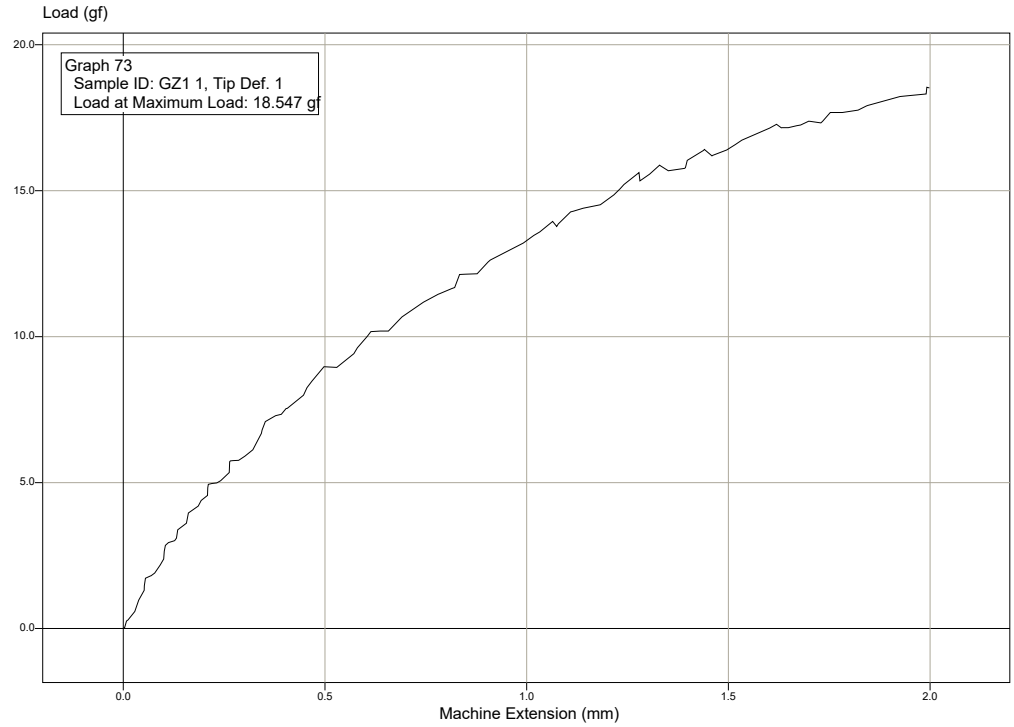
Graph 71


Load (gf)
Graph 71
Sample ID: GL2 1, Tip Def. 2
Load at Maximum Load: 16.485 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

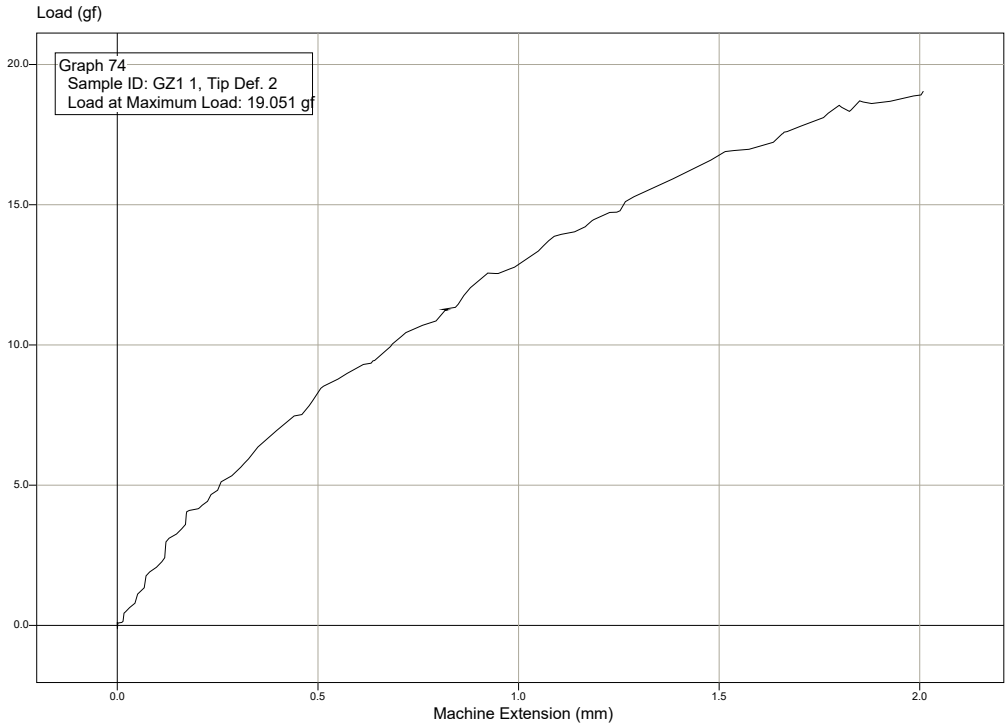
Graph 72


Load (gf)
Graph 72
Sample ID: GL2 1, Tip Def. 3
Load at Maximum Load: 16.572 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

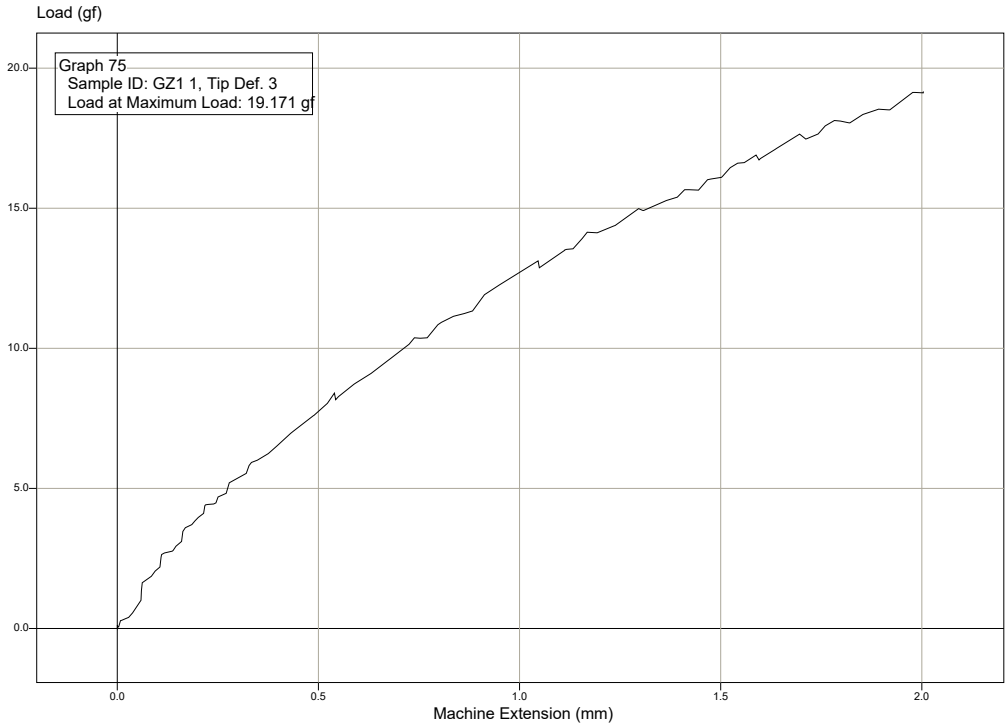
Graph 73



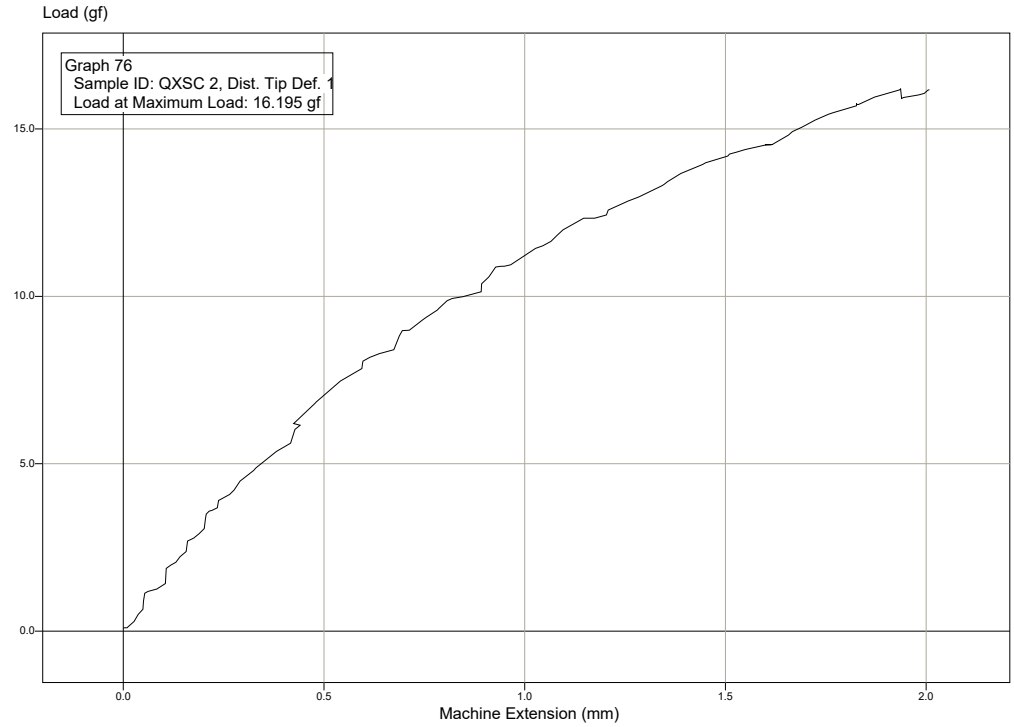
Graph 74



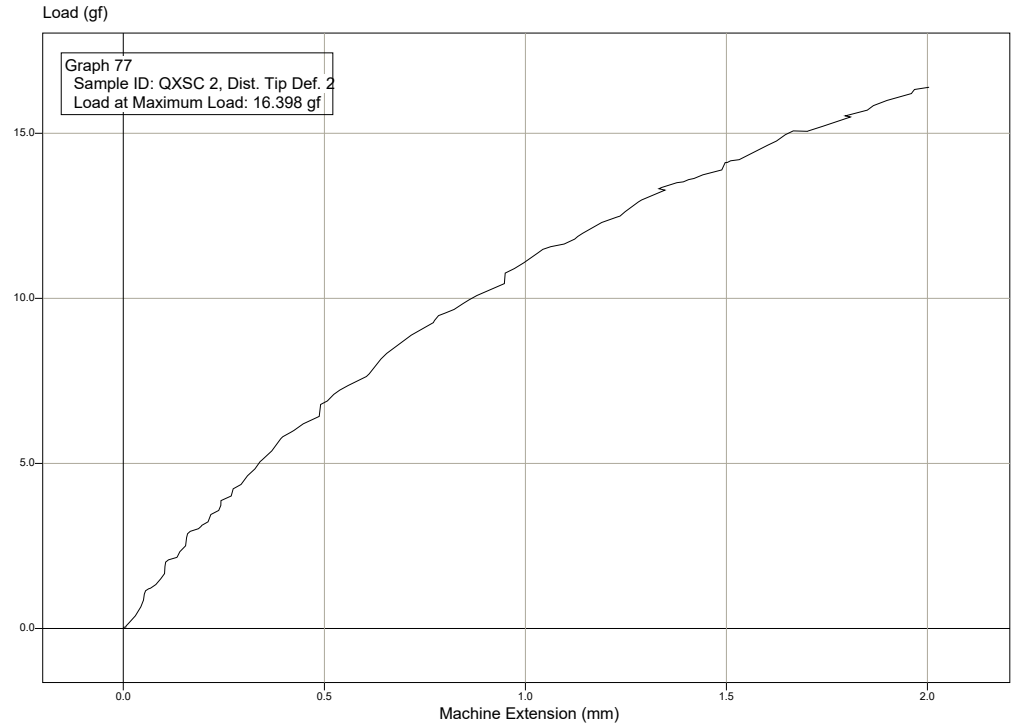
Graph 75



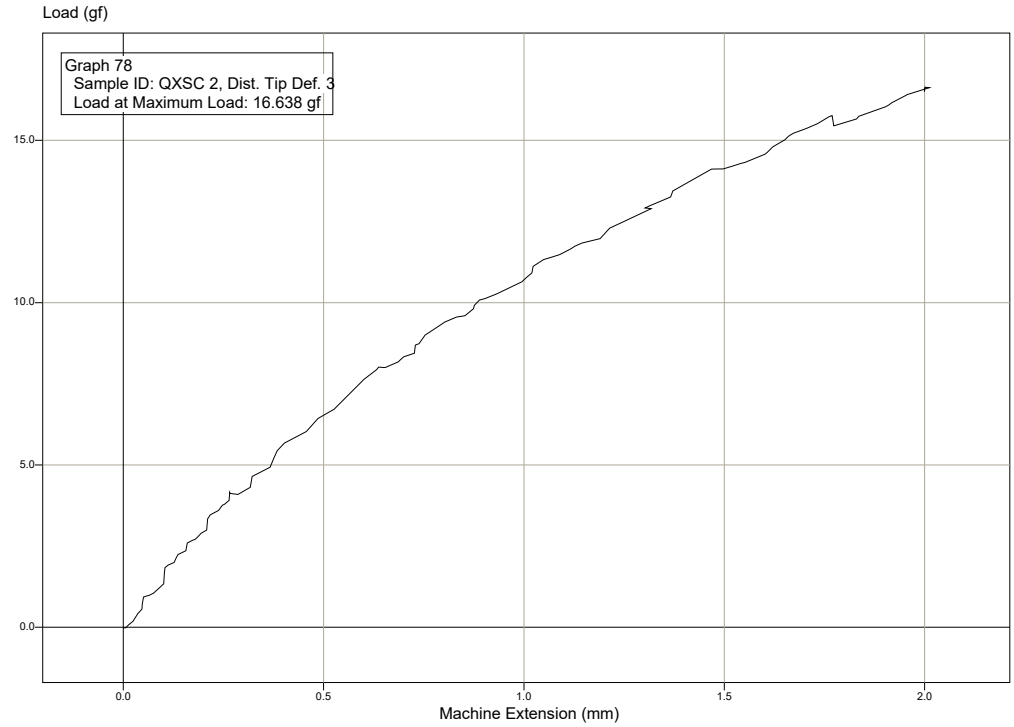
Graph 76



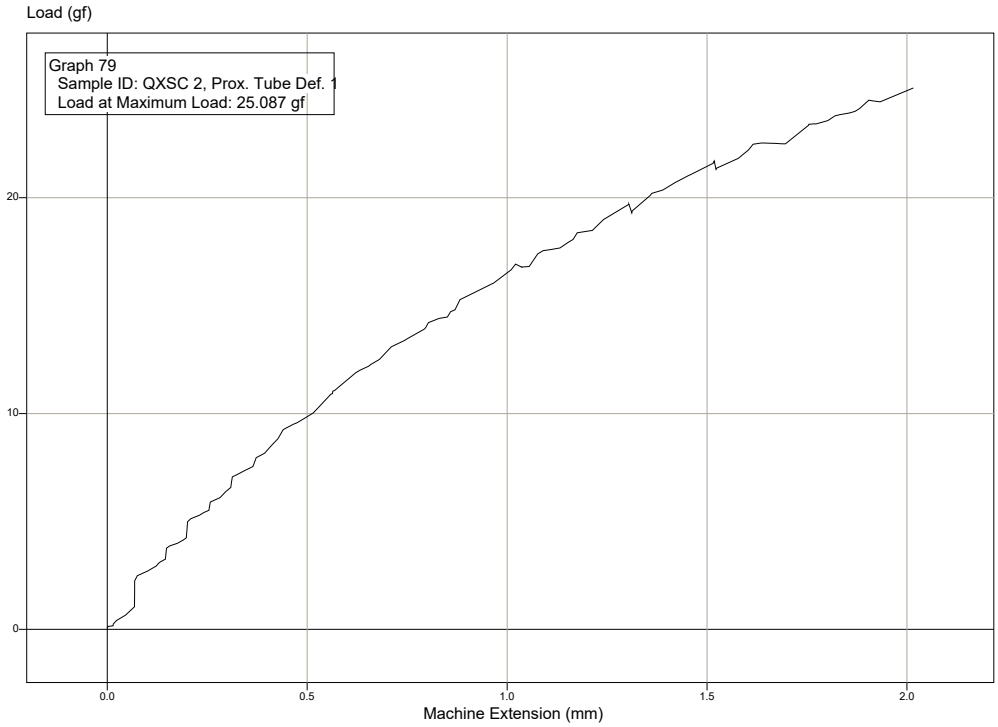
Graph 77


Load (gf)
Graph 77
Sample ID: QXSC 2, Dist. Tip Def. 2
Load at Maximum Load: 16.398 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

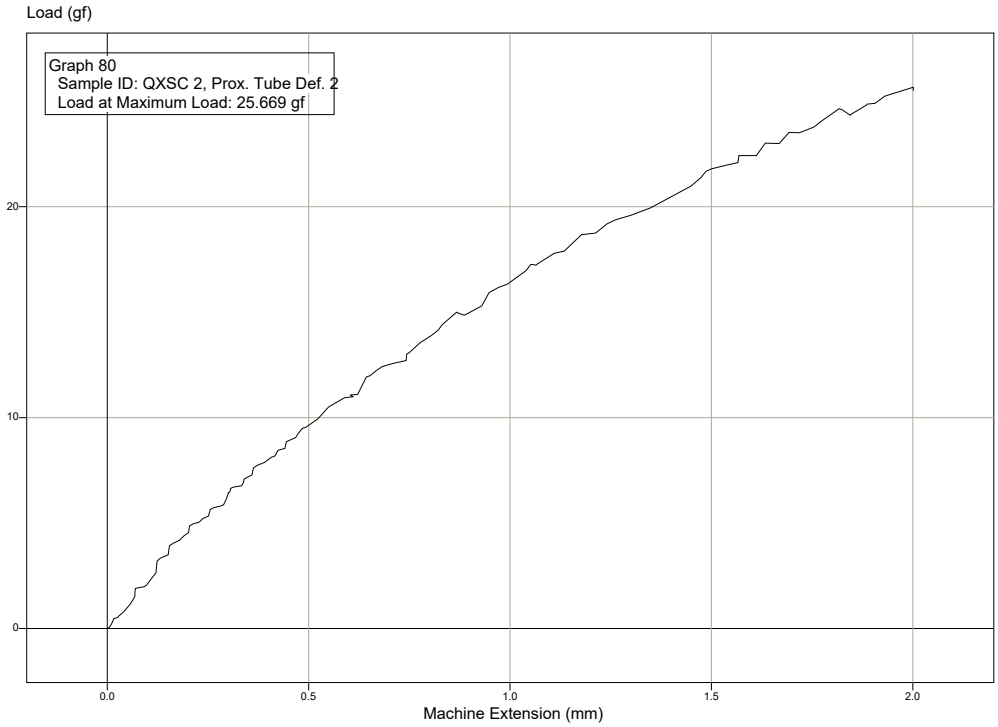
Graph 78



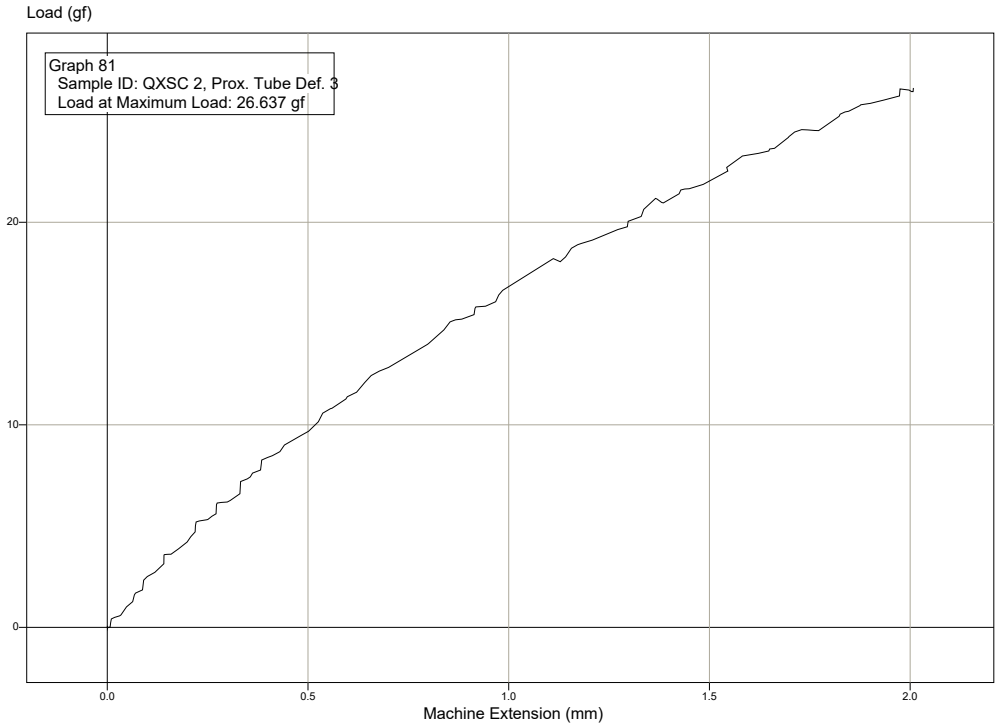
Graph 79


Load (gf)
Graph 79
Sample ID: QXSC 2, Prox. Tube Def. 1
Load at Maximum Load: 25.087 gf
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

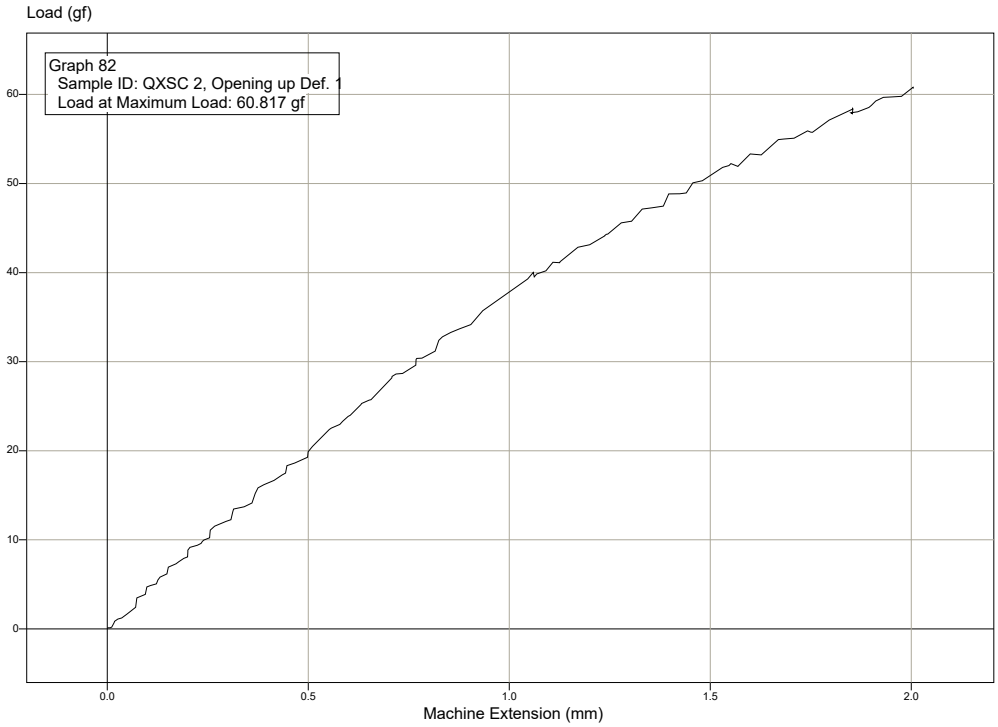
Graph 80



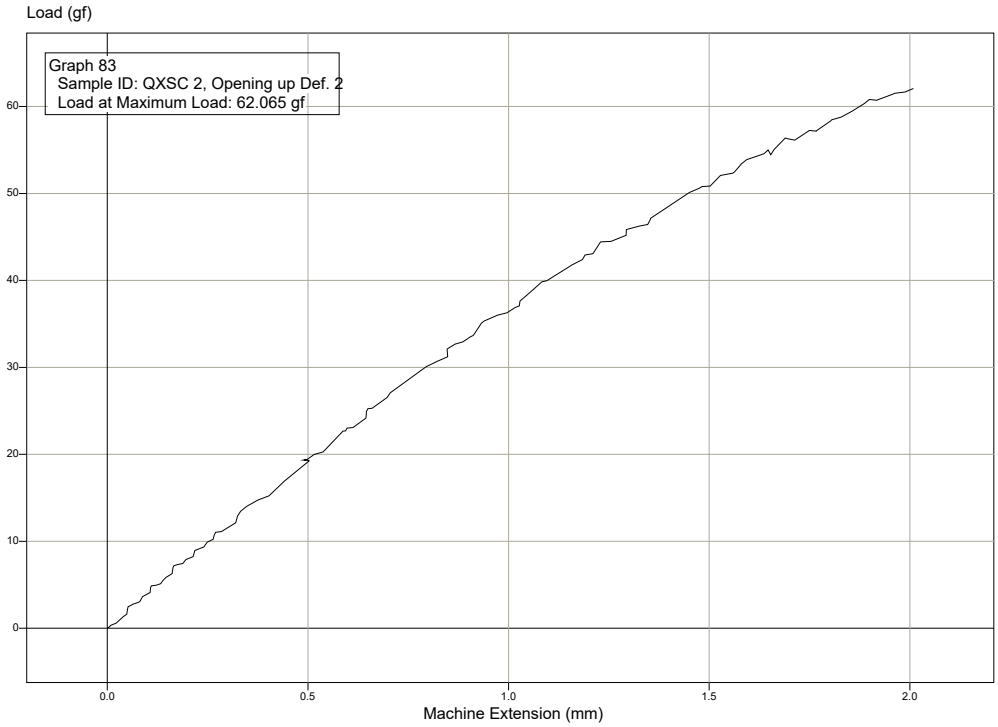
Graph 81



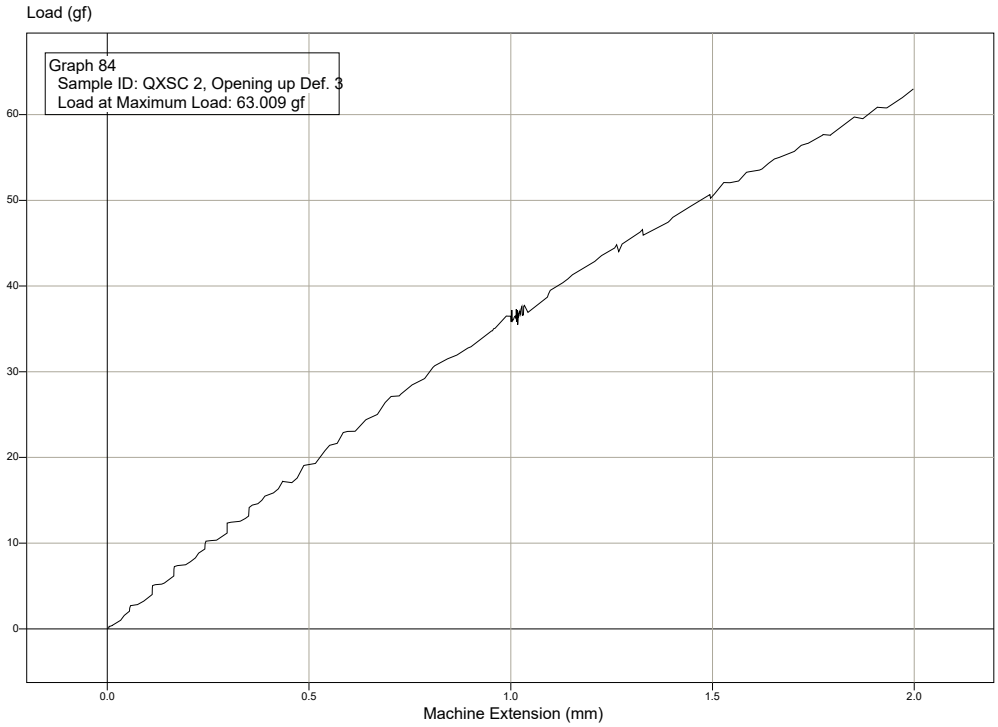
Graph 82


Load (gf)
Graph 82
Sample ID: QXSC 2, Opening up Def. 1
Load at Maximum Load: 60.817 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

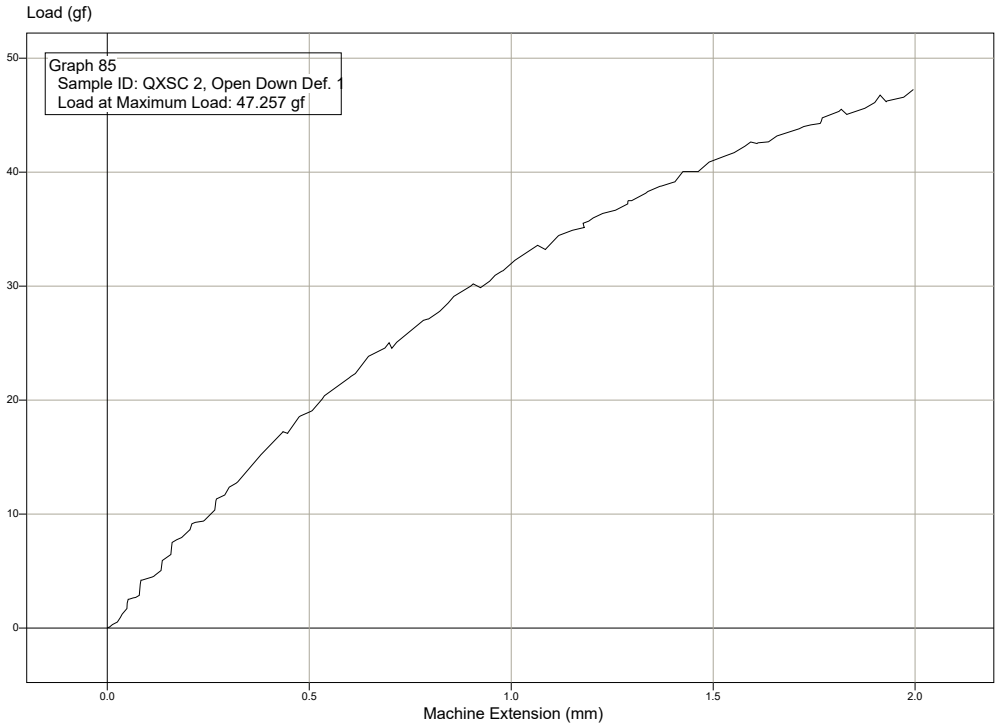
Graph 83


Load (gf)
Graph 83
Sample ID: QXSC 2, Opening up Def. 2
Load at Maximum Load: 62.065 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

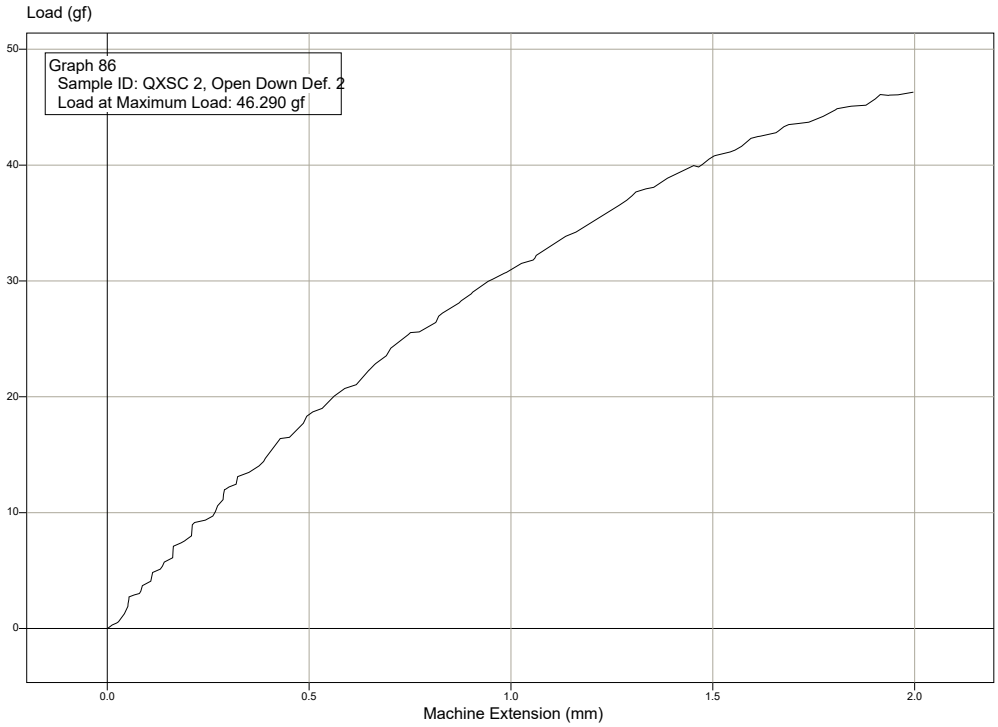
Graph 84


Load (gf)
Graph 84
Sample ID: QXSC 2, Opening up Def. 3
Load at Maximum Load: 63.009 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

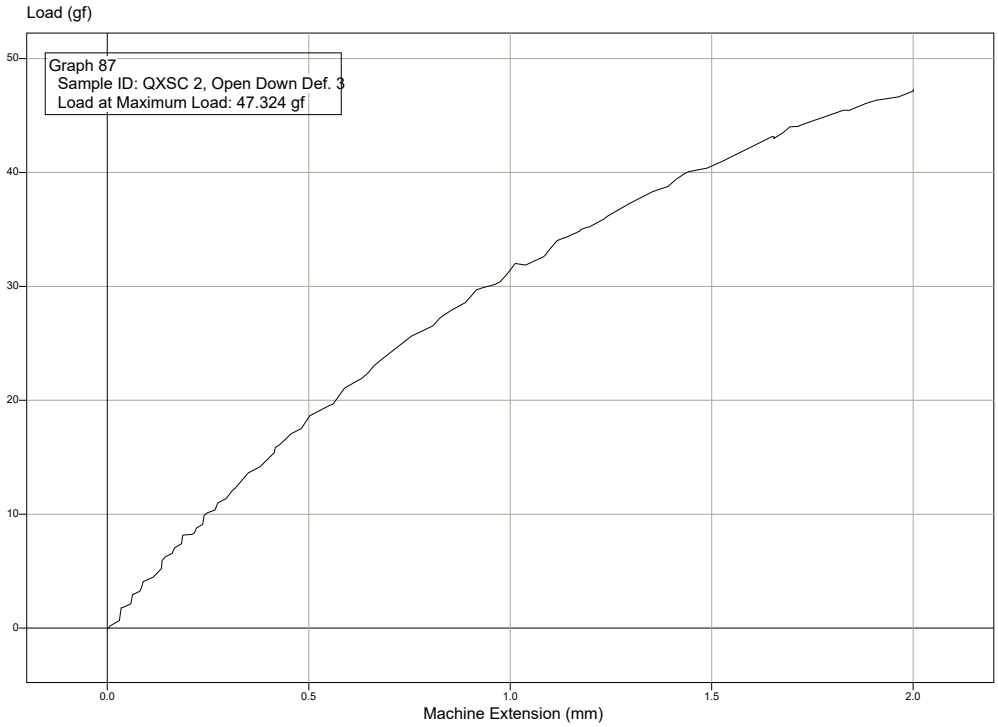
Graph 85


Load (gf)
Graph 85
Sample ID: QXSC 2, Open Down Def. 1
Load at Maximum Load: 47.257 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

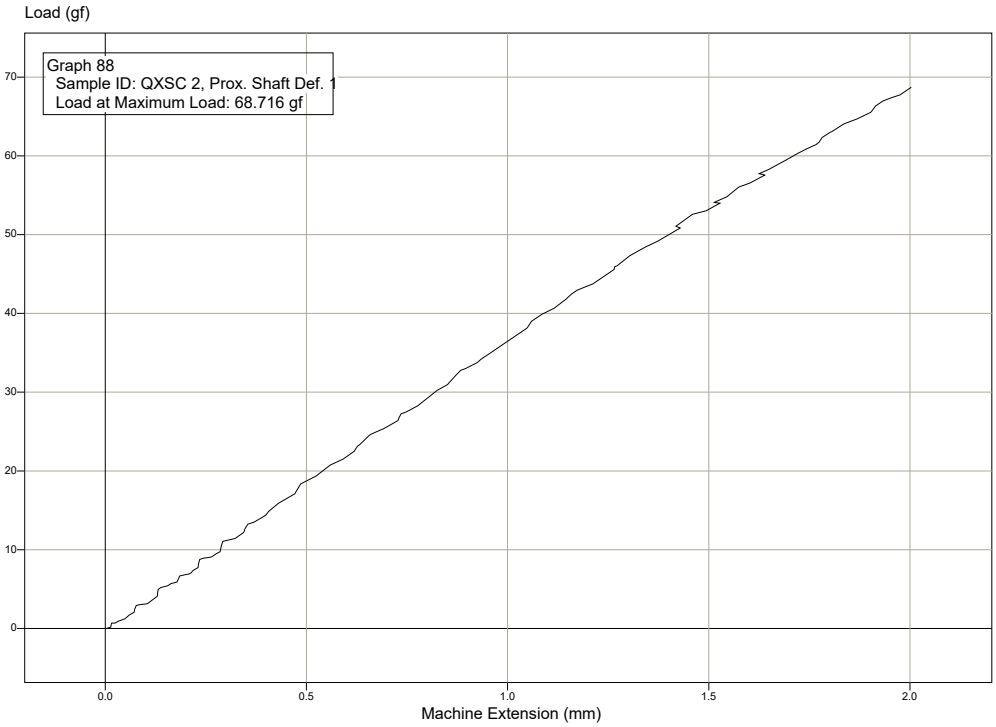
Graph 86


Load (gf)
Graph 86
Sample ID: QXSC 2, Open Down Def. 2
Load at Maximum Load: 46.290 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

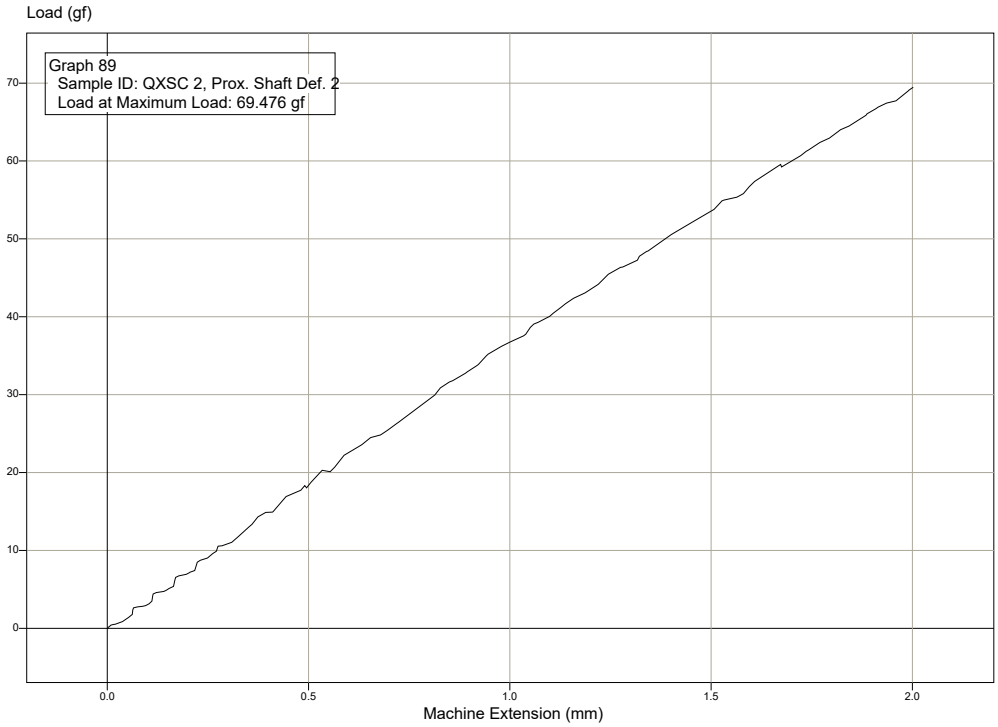
Graph 87


Load (gf)
Graph 87
Sample ID: QXSC 2, Open Down Def. 3
Load at Maximum Load: 47.324 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

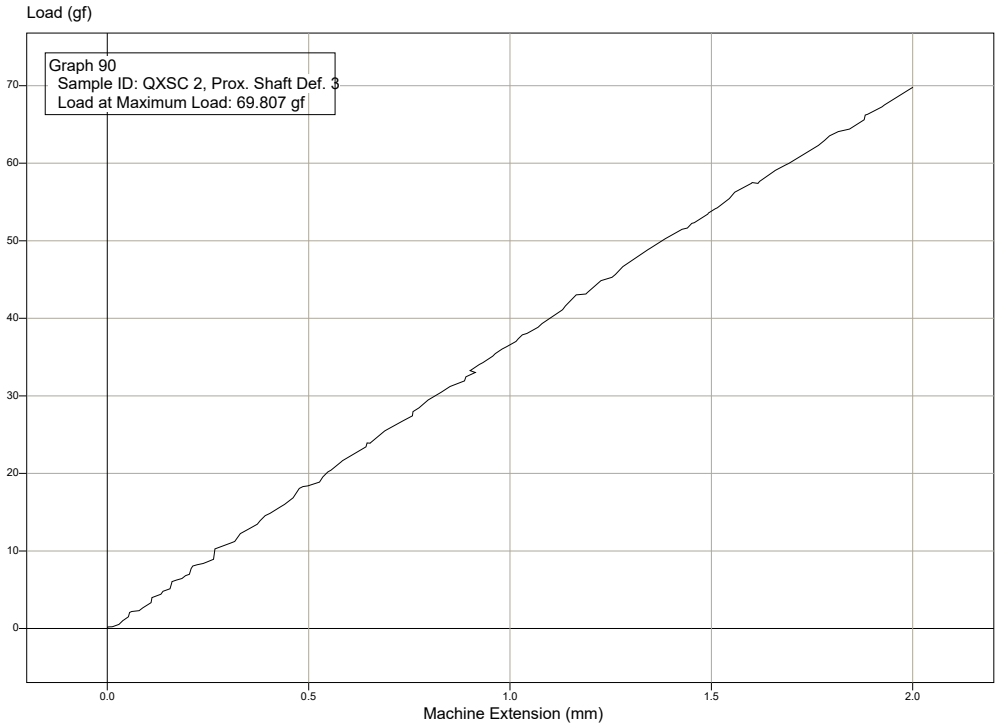
Graph 88


Load (gf)
Graph 88
Sample ID: QXSC 2, Prox. Shaft Def. 1
Load at Maximum Load: 68.716 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

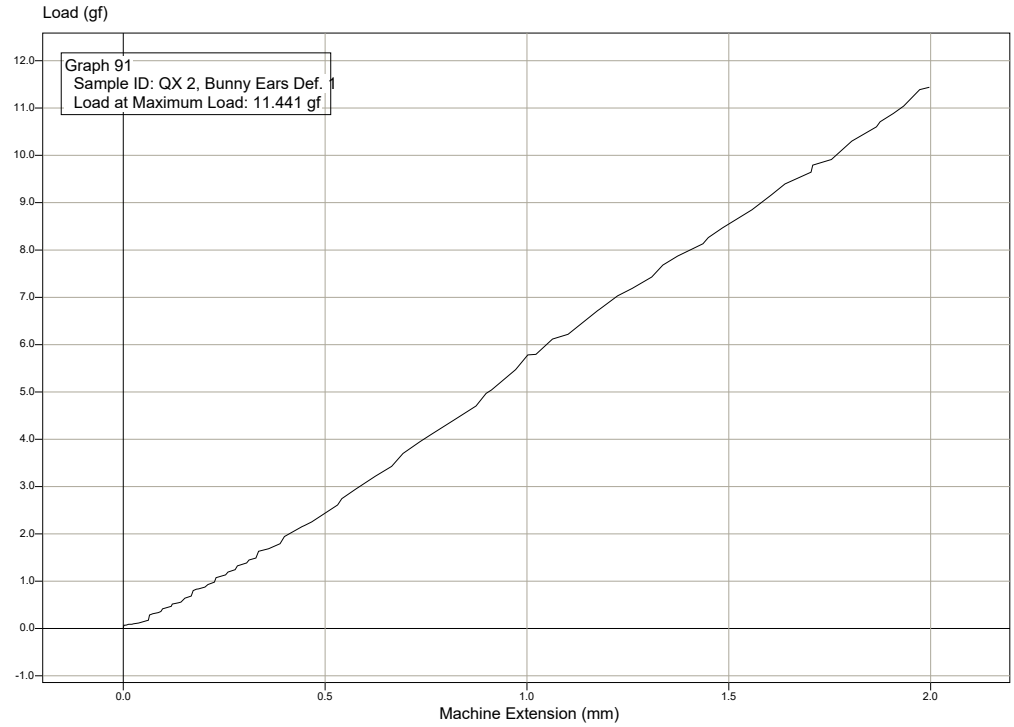
Graph 89


Load (gf)
Graph 89
Sample ID: QXSC 2, Prox. Shaft Def. 2
Load at Maximum Load: 69.476 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

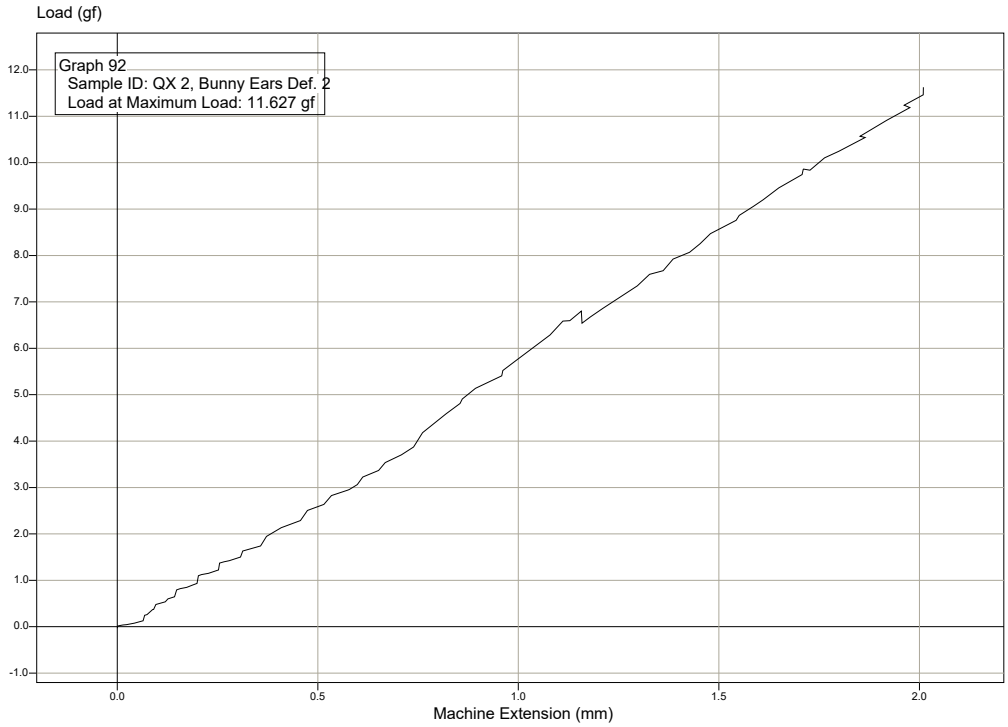
Graph 90


Load (gf)
Graph 90
Sample ID: QXSC 2, Prox. Shaft Def. 3
Load at Maximum Load: 69.807 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

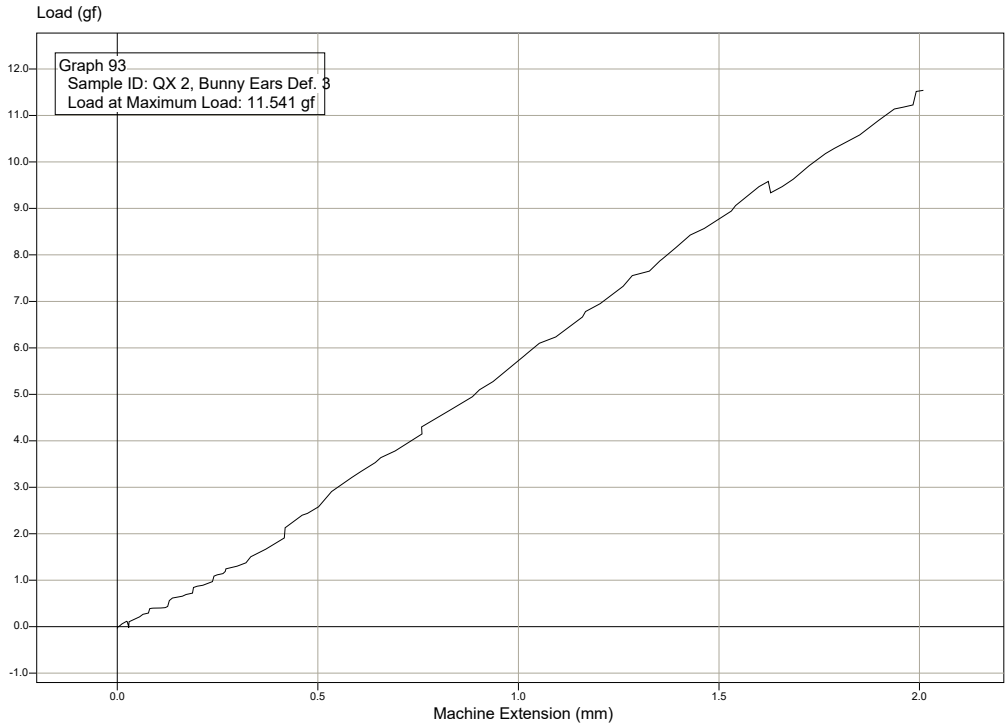
Graph 91


Load (gf)
Graph 91
Sample ID: QX 2, Bunny Ears Def. 1
Load at Maximum Load: 11.441 gf
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

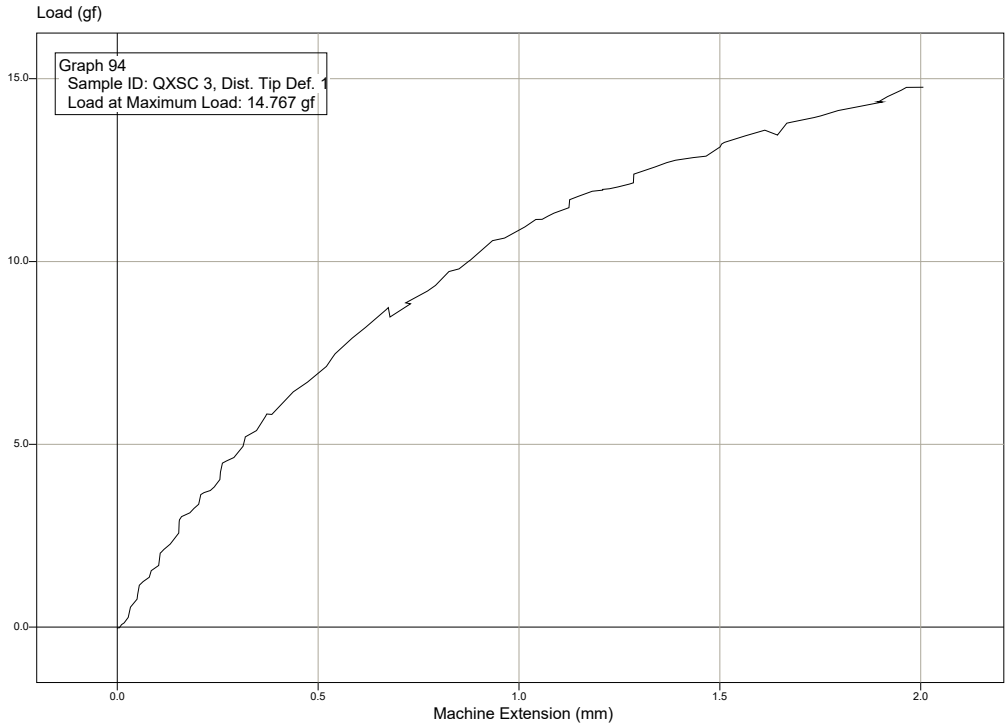
Graph 92


Load (gf)
Graph 92
Sample ID: QX 2, Bunny Ears Def. 2
Load at Maximum Load: 11.627 gf
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

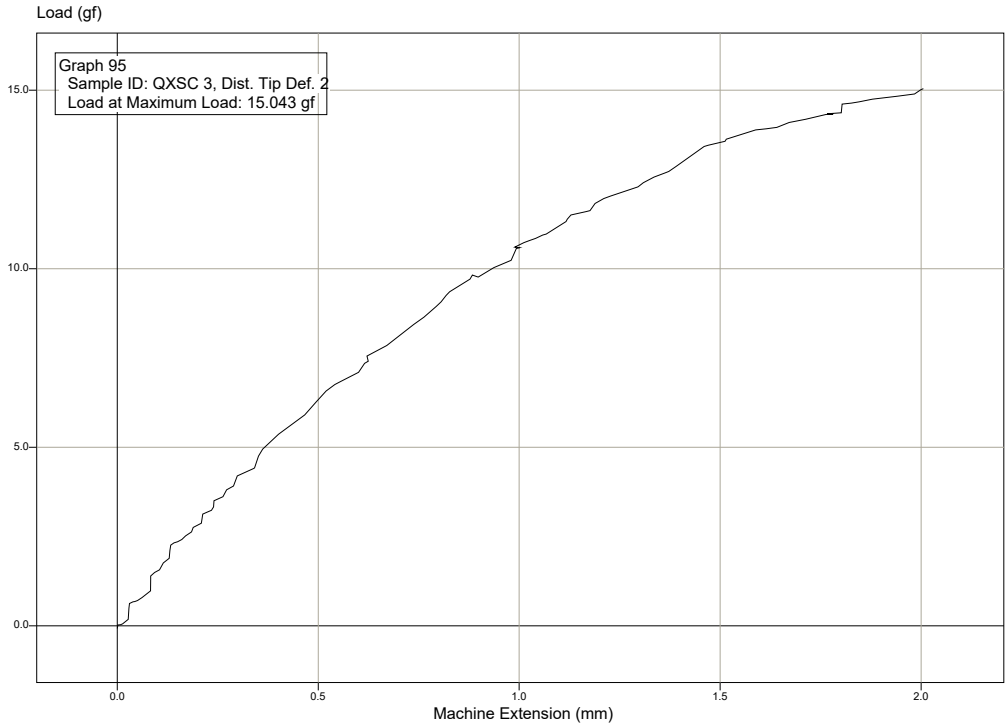
Graph 93



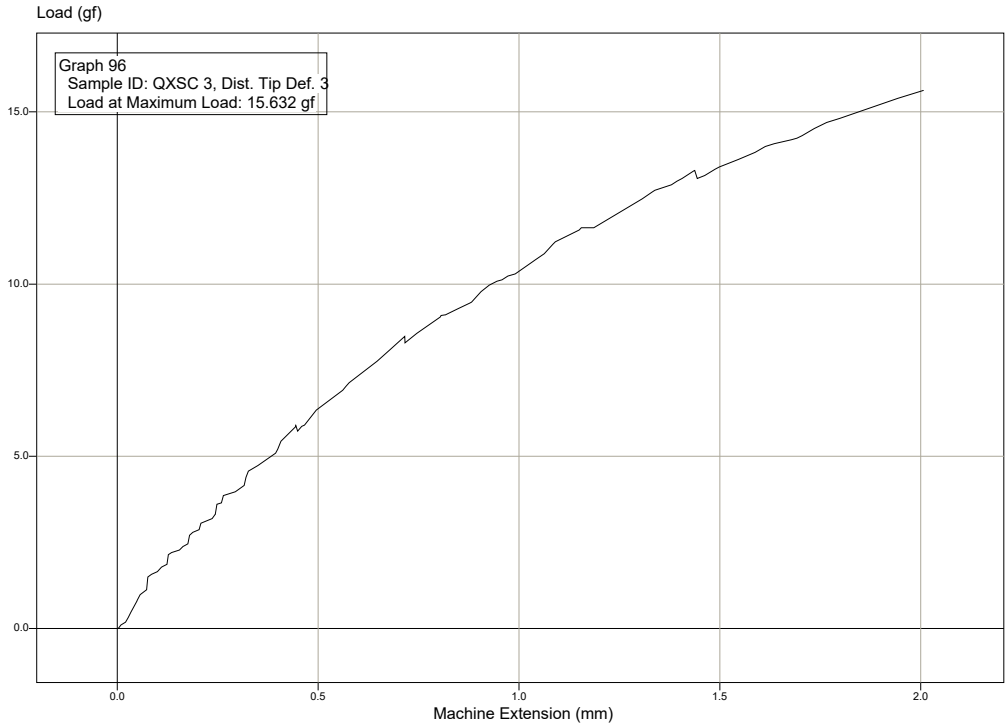
Graph 94



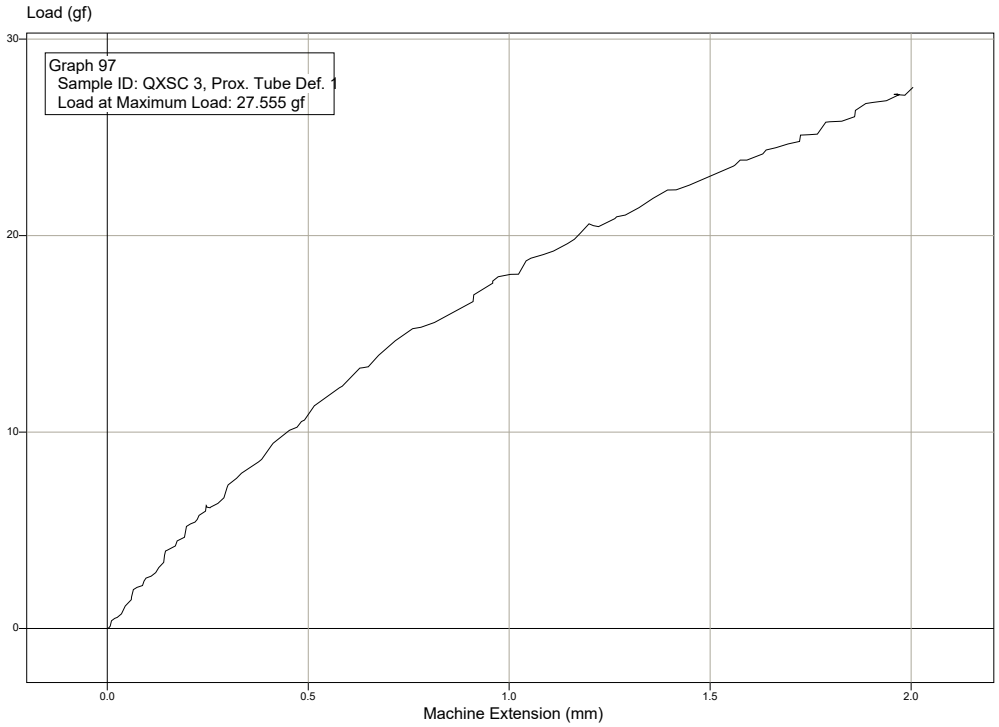
Graph 95


Load (gf)
Graph 95
Sample ID: QXSC 3, Dist. Tip Def. 2
Load at Maximum Load: 15.043 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

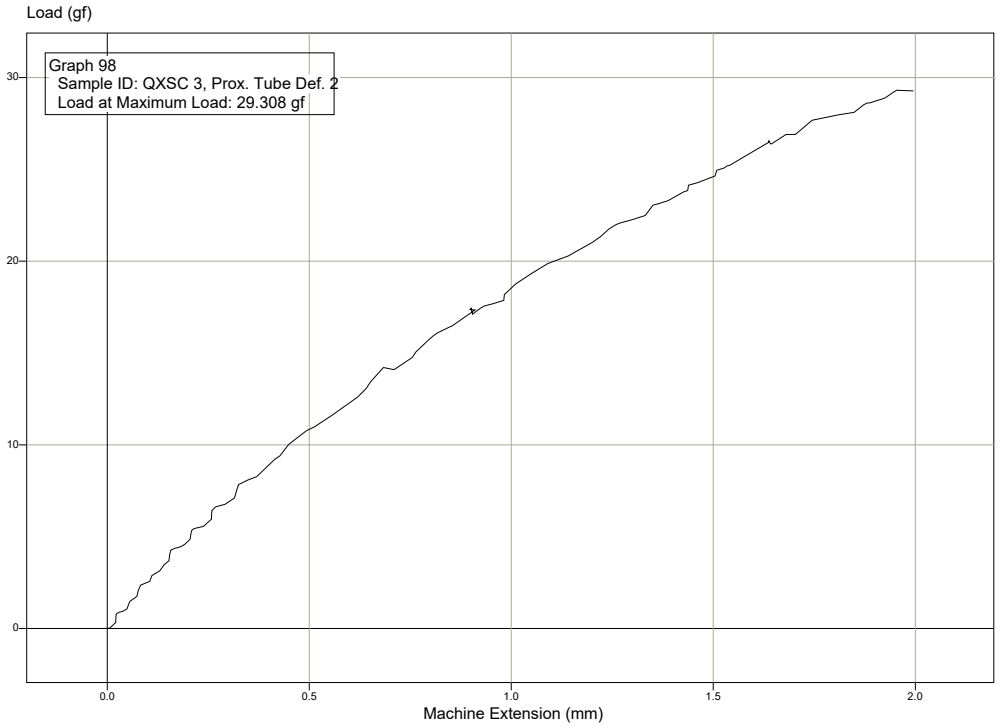
Graph 96


Load (gf)
Graph 96
Sample ID: QXSC 3, Dist. Tip Def. 3
Load at Maximum Load: 15.632 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

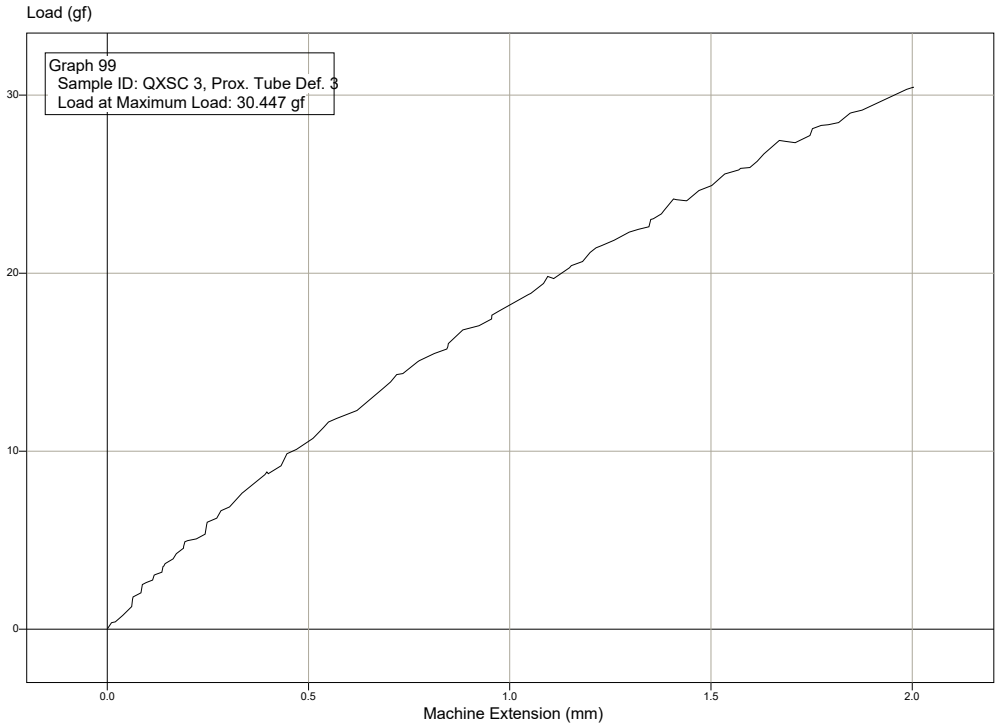
Graph 97


Load (gf)
Graph 97
Sample ID: QXSC 3, Prox. Tube Def. 1
Load at Maximum Load: 27.555 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

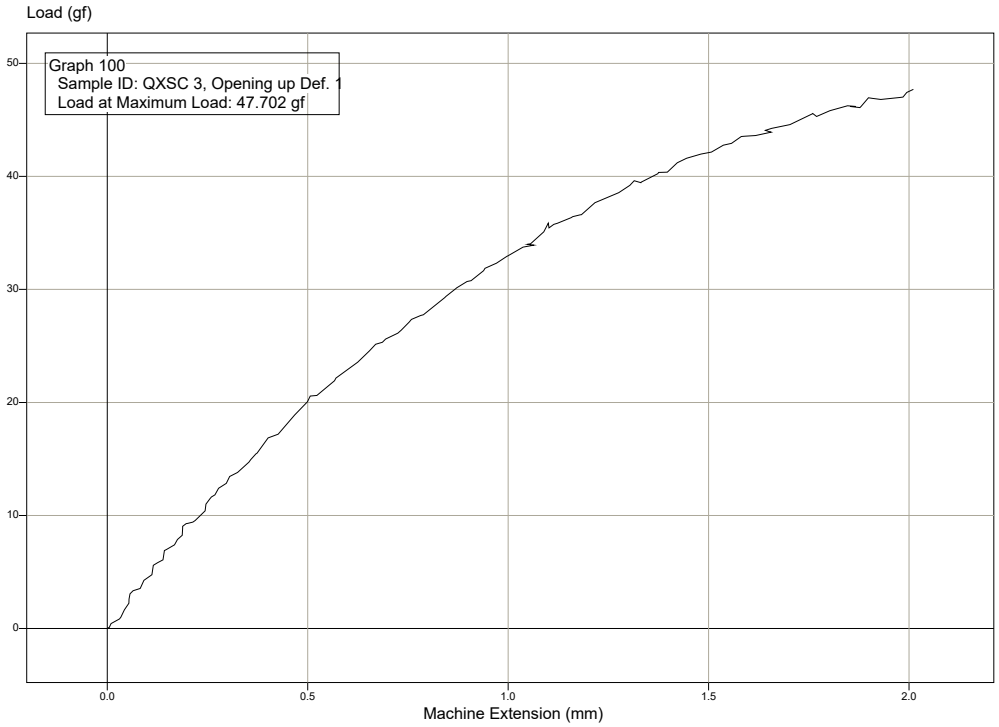
Graph 98


Load (gf)
Graph 98
Sample ID: QXSC 3, Prox. Tube Def. 2
Load at Maximum Load: 29.308 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

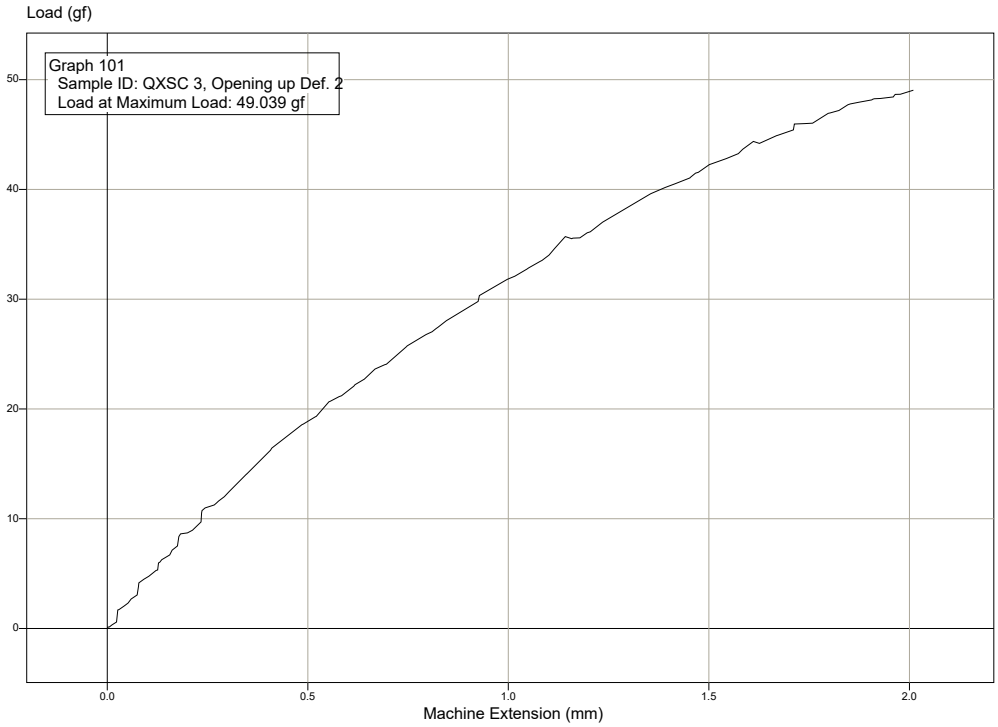
Graph 99


Load (gf)
Graph 99
Sample ID: QXSC 3, Prox. Tube Def. 3
Load at Maximum Load: 30.447 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

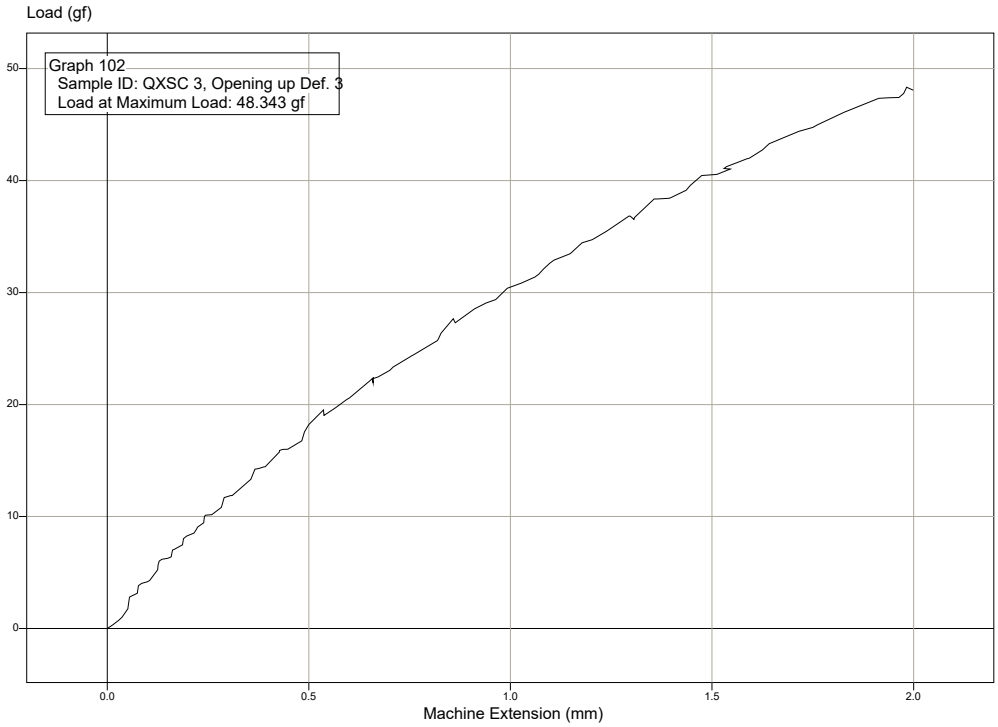
Graph 100


Load (gf)
Graph 100
Sample ID: QXSC 3, Opening up Def. 1
Load at Maximum Load: 47.702 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

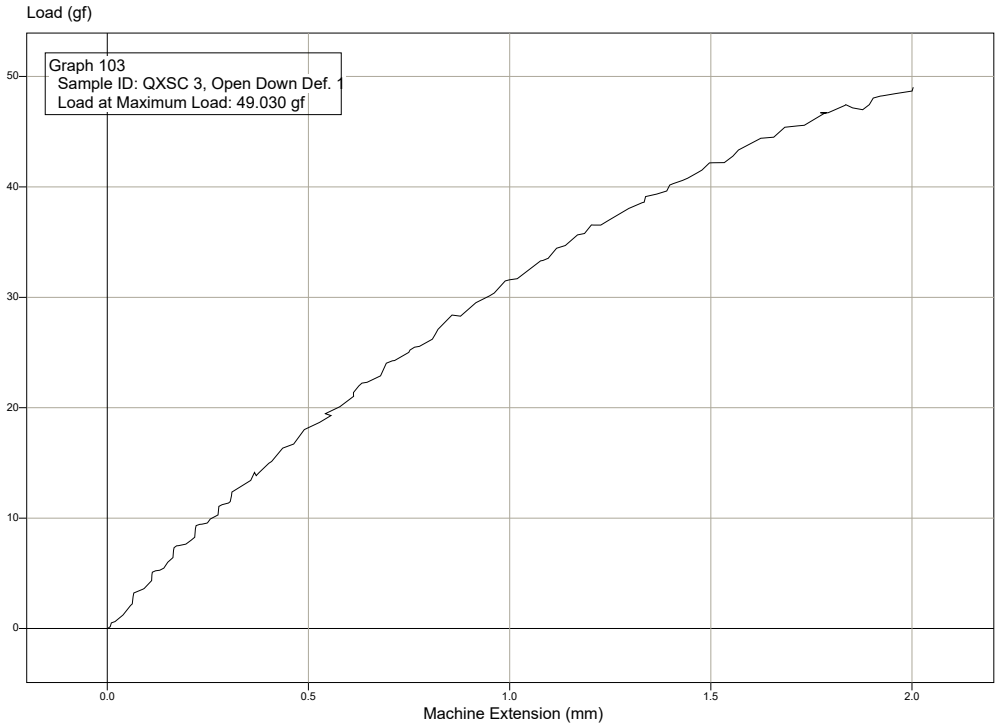
Graph 101


Load (gf)
Graph 101
Sample ID: QXSC 3, Opening up Def. 2
Load at Maximum Load: 49.039 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

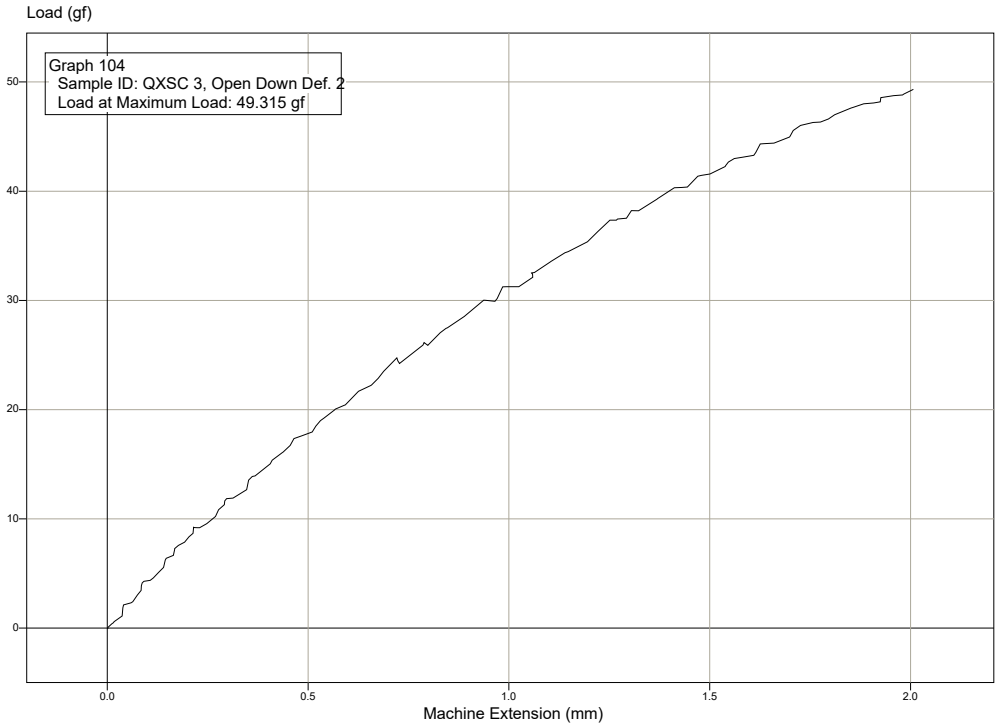
Graph 102


Load (gf)
Graph 102
Sample ID: QXSC 3, Opening up Def. 3
Load at Maximum Load: 48.343 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

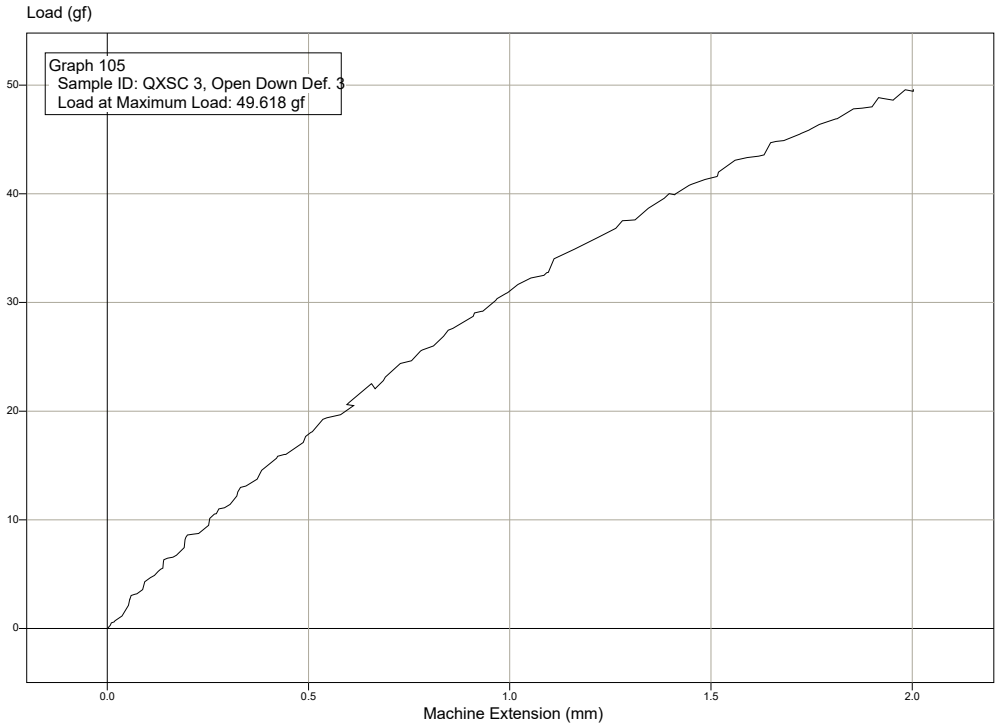
Graph 103


Load (gf)
Graph 103
Sample ID: QXSC 3, Open Down Def. 1
Load at Maximum Load: 49.030 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

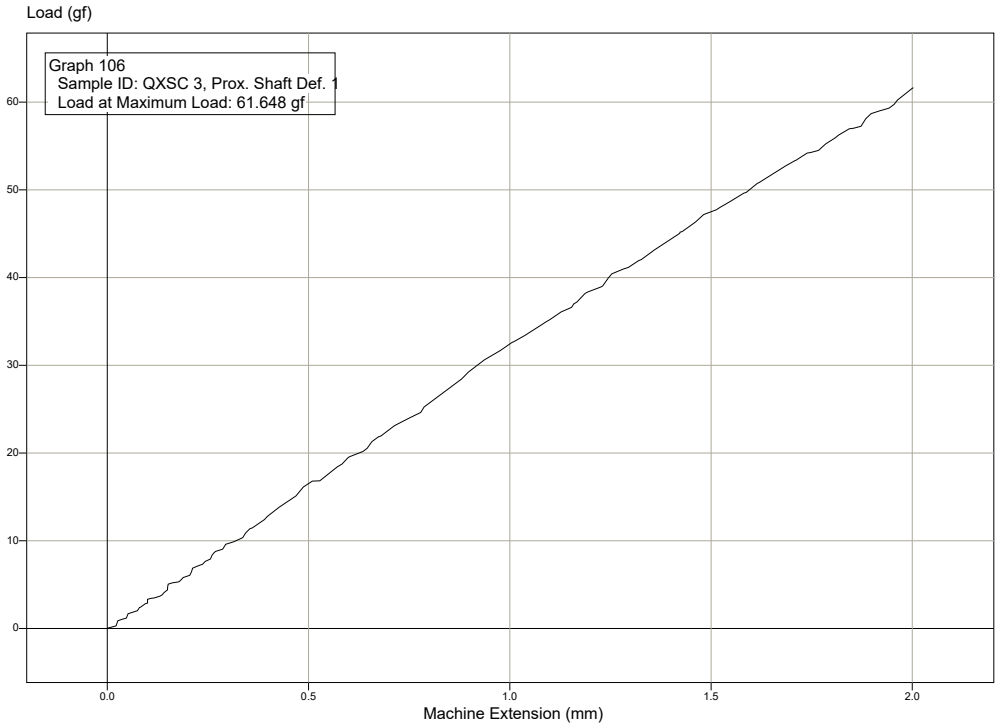
Graph 104


Load (gf)
Graph 104
Sample ID: QXSC 3, Open Down Def. 2
Load at Maximum Load: 49.315 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

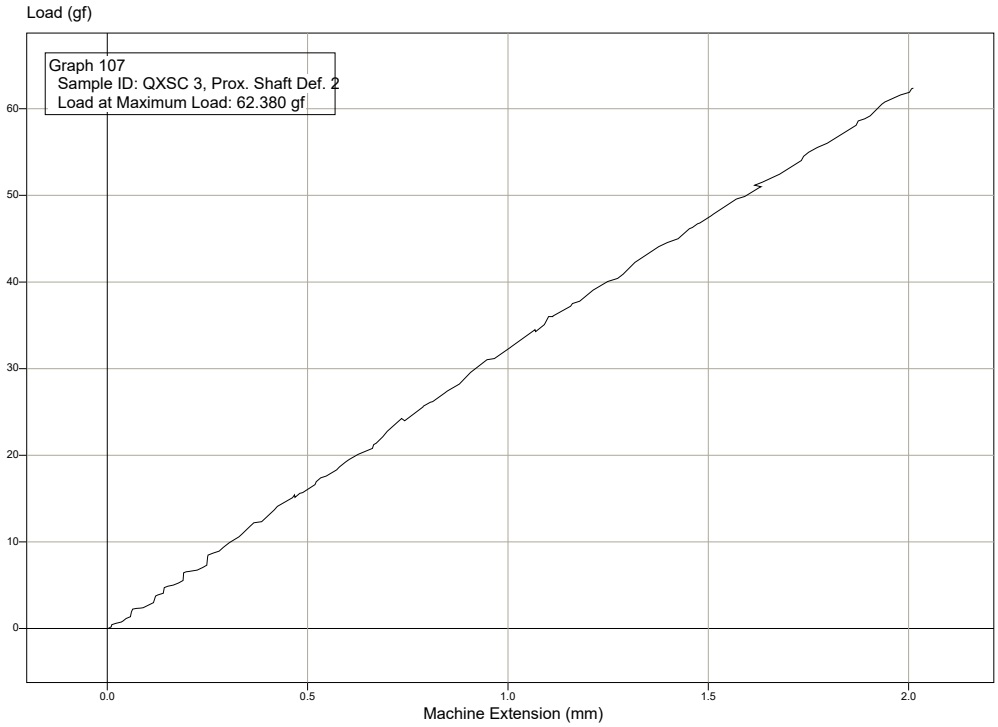
Graph 105


Load (gf)
Graph 105
Sample ID: QXSC 3, Open Down Def. 3
Load at Maximum Load: 49.618 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

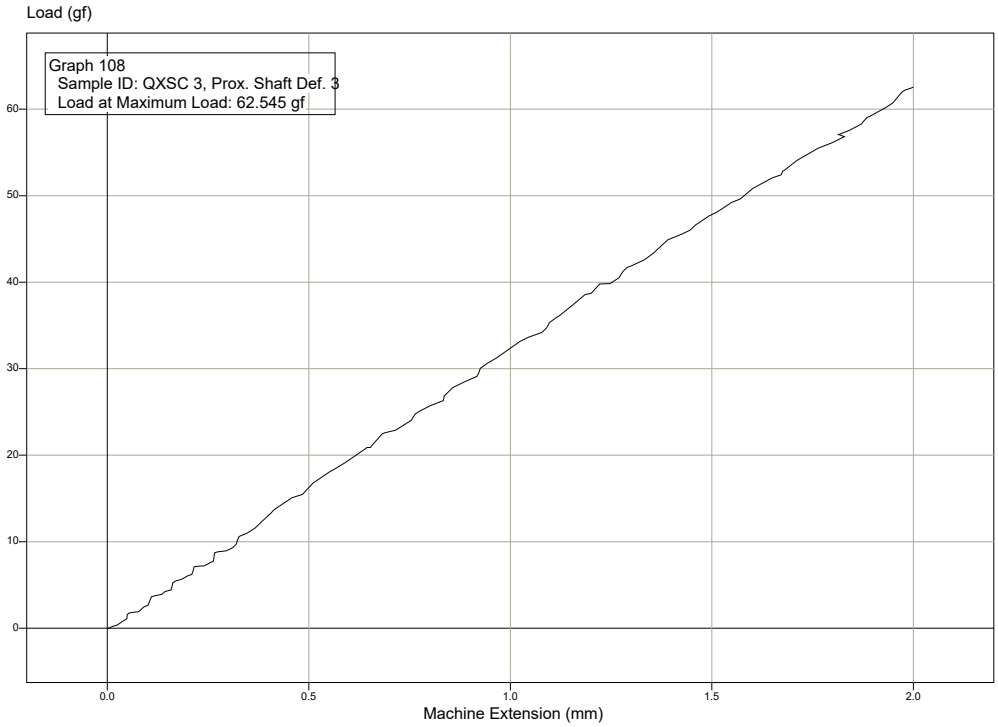
Graph 106


Load (gf)
Graph 106
Sample ID: QXSC 3, Prox. Shaft Def. 1
Load at Maximum Load: 61.648 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

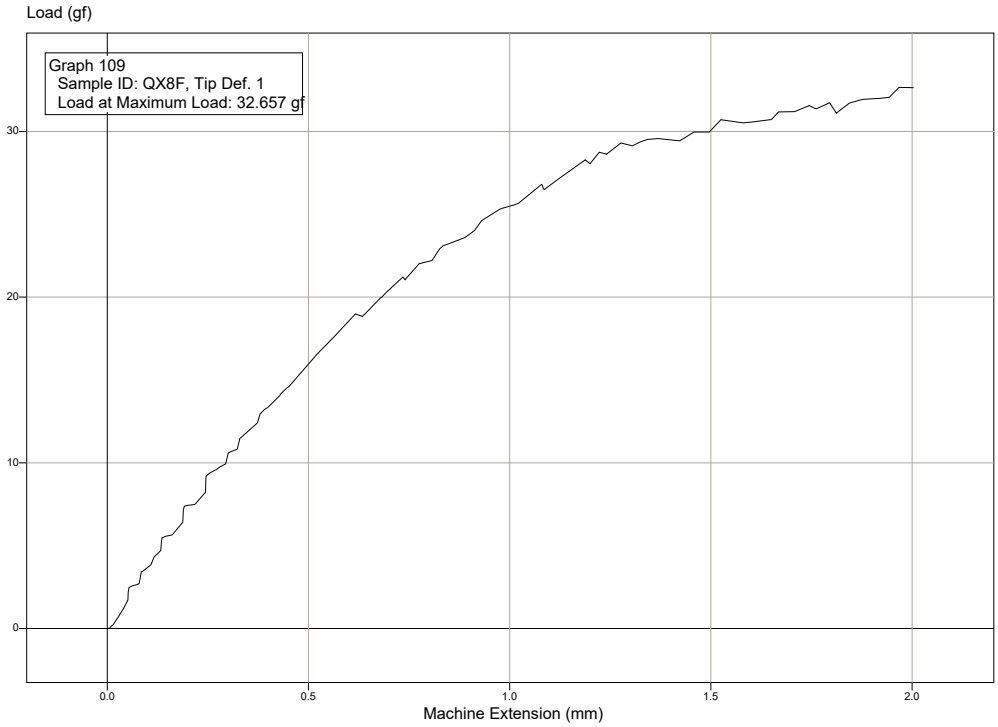
Graph 107


Load (gf)
Graph 107
Sample ID: QXSC 3, Prox. Shaft Def. 2
Load at Maximum Load: 62.380 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

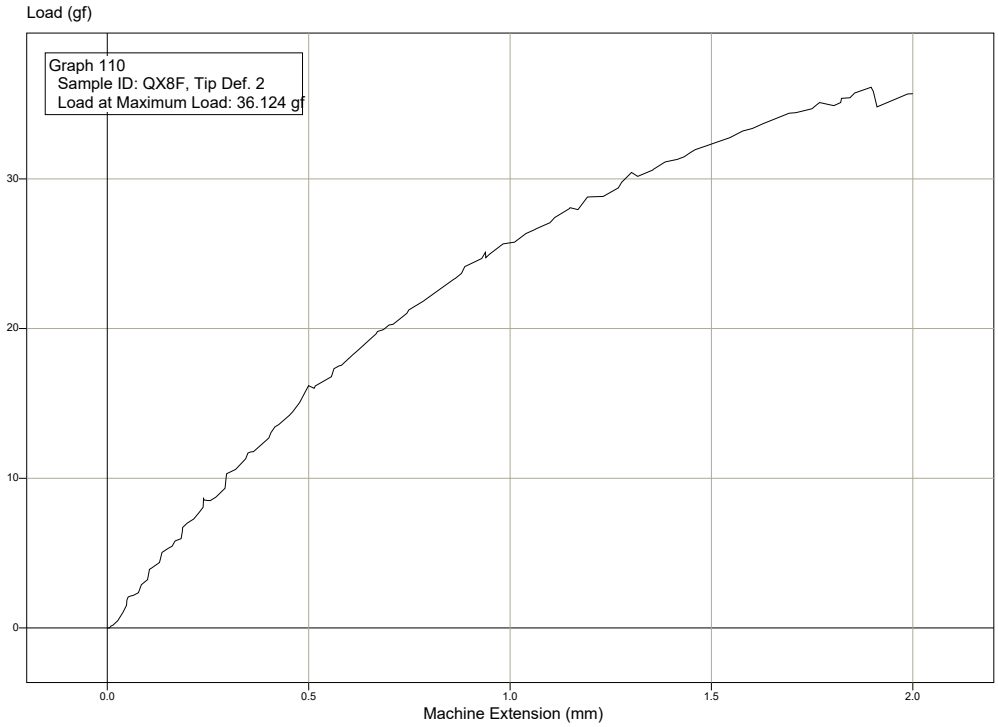
Graph 108


Load (gf)
Graph 108
Sample ID: QXSC 3, Prox. Shaft Def. 3
Load at Maximum Load: 62.545 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

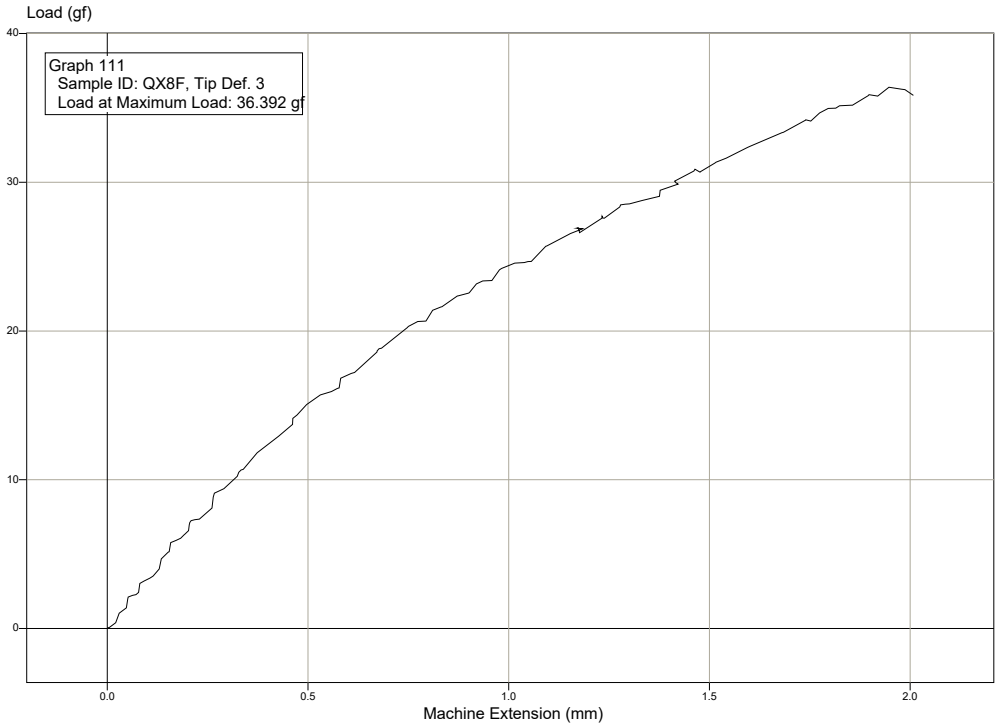
Graph 109


Load (gf)
Graph 109
Sample ID: QX8F, Tip Def. 1
Load at Maximum Load: 32.657 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

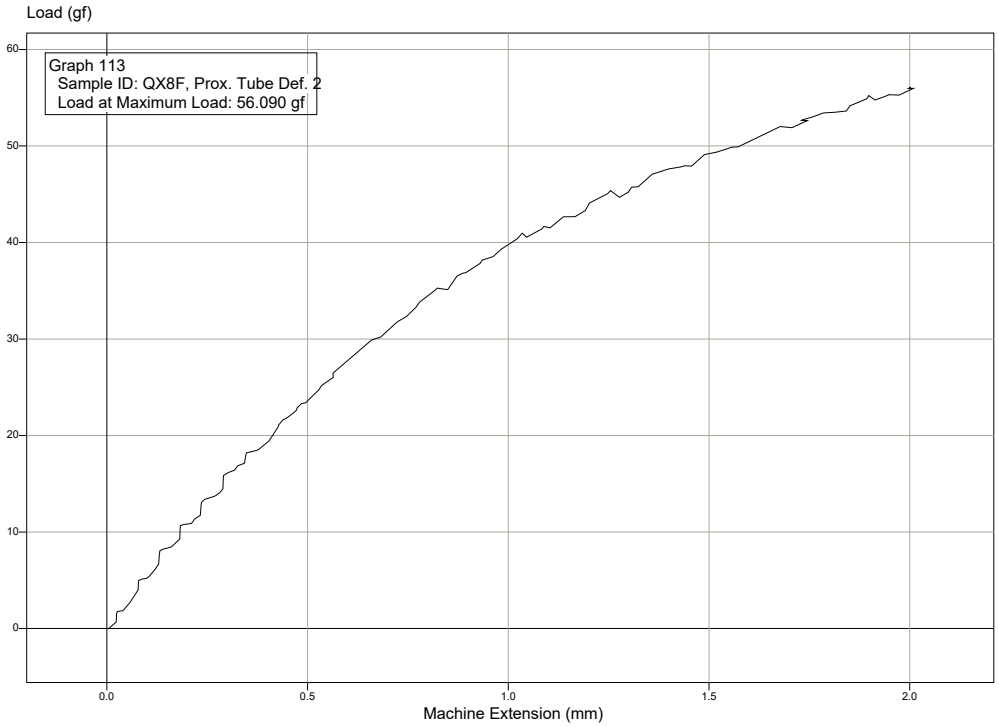
Graph 110


Load (gf)
Graph 110
Sample ID: QX8F, Tip Def. 2
Load at Maximum Load: 36.124 gf
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

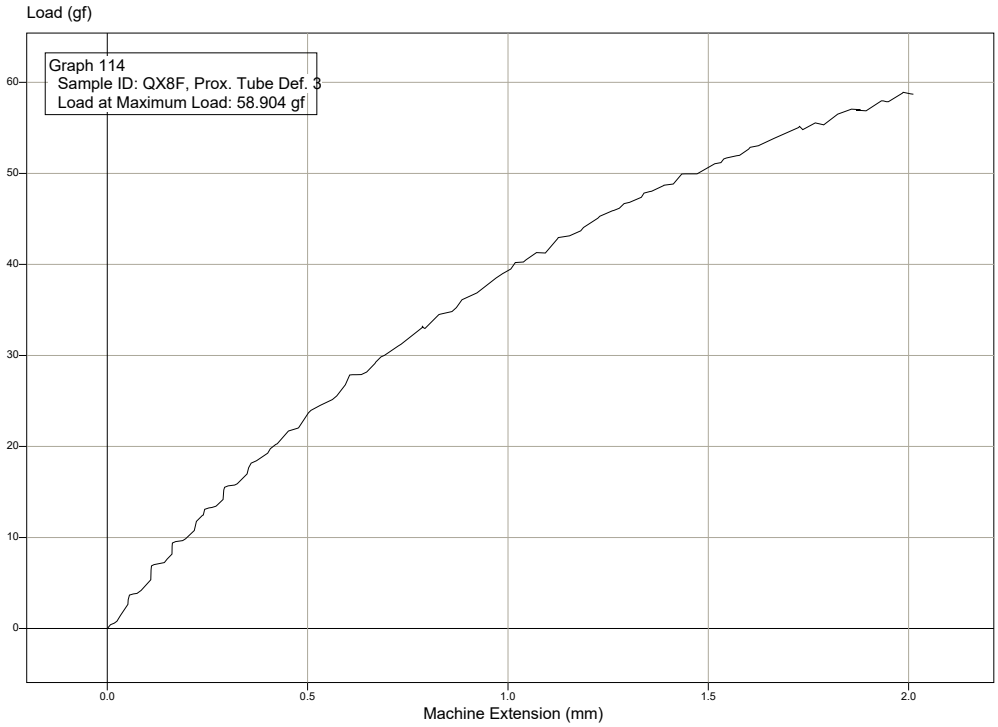
Graph 111



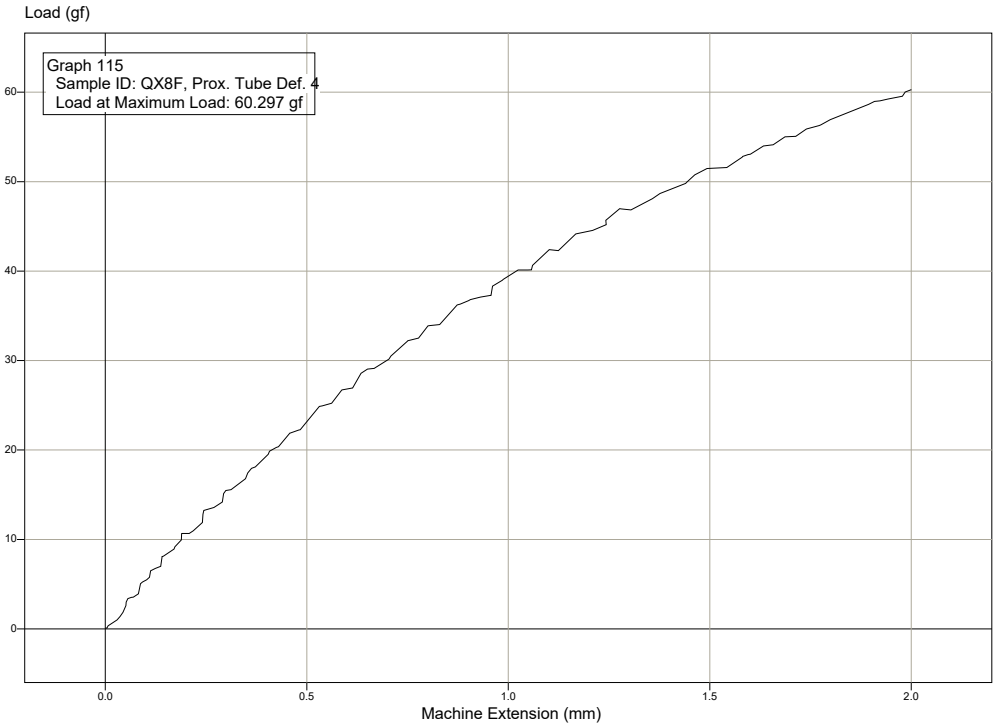
Graph 113


Load (gf)
Graph 113
Sample ID: QX8F, Prox. Tube Def. 2
Load at Maximum Load: 56.090 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

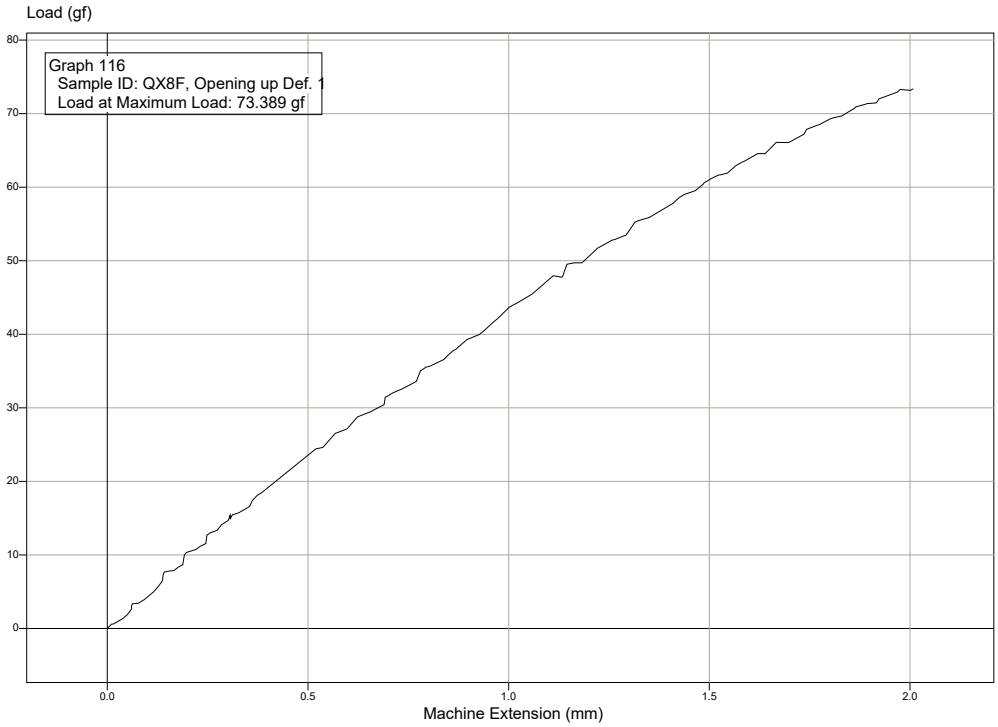
Graph 114


Load (gf)
Graph 114
Sample ID: QX8F, Prox. Tube Def. 3
Load at Maximum Load: 58.904 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

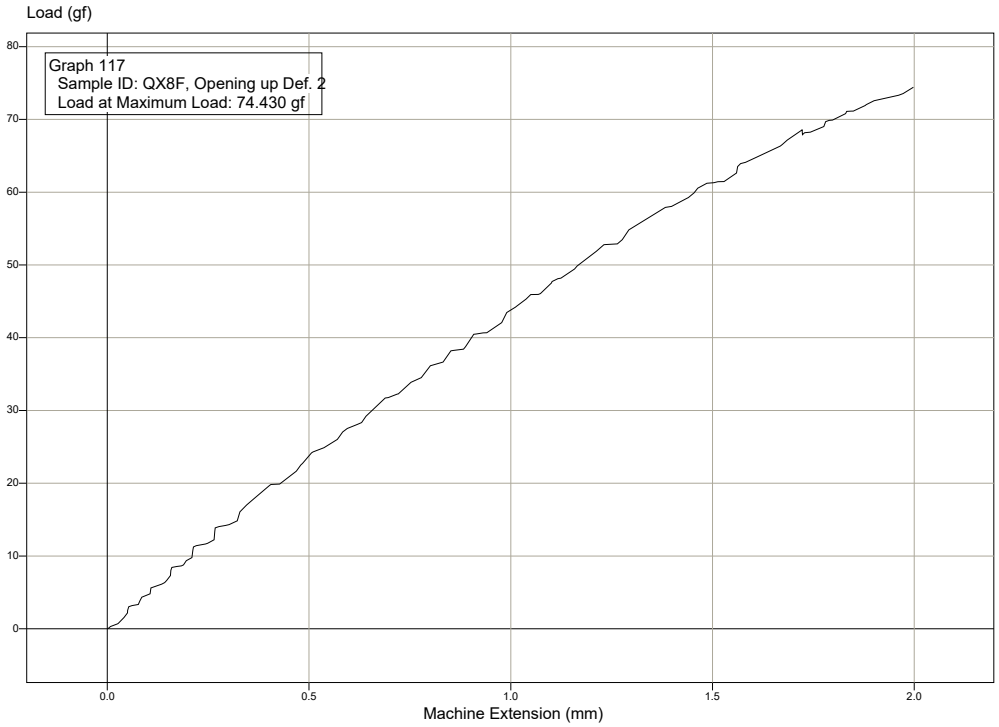
Graph 115


Load (gf)
Graph 115
Sample ID: QX8F, Prox. Tube Def. 4
Load at Maximum Load: 60.297 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

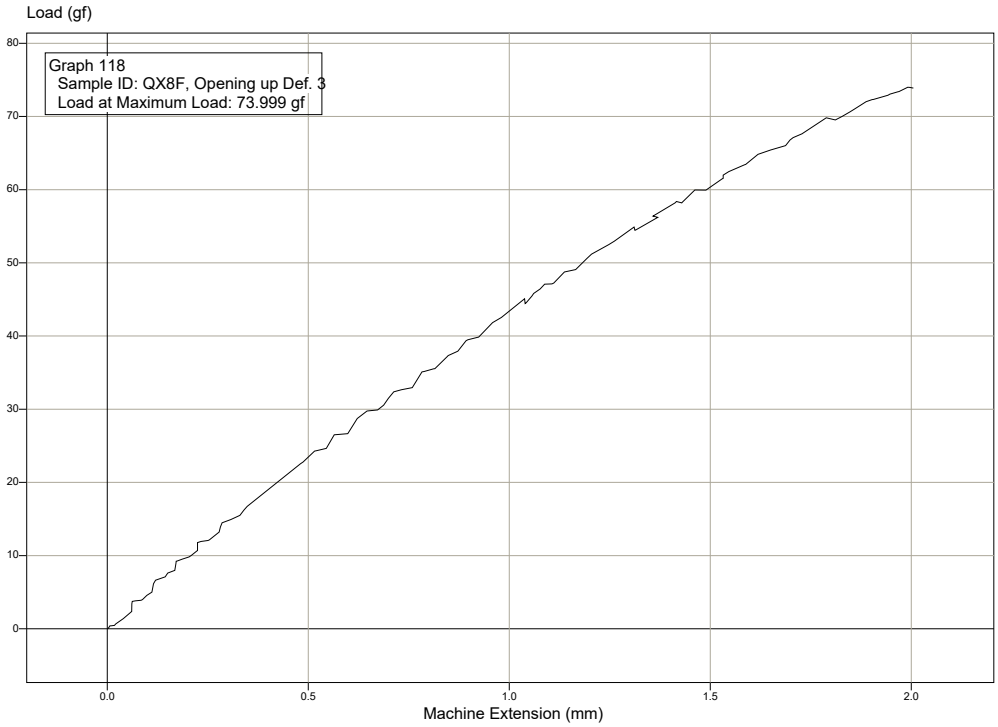
Graph 116


Load (gf)
Graph 116
Sample ID: QX8F, Opening up Def. 1
Load at Maximum Load: 73.389 gf
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

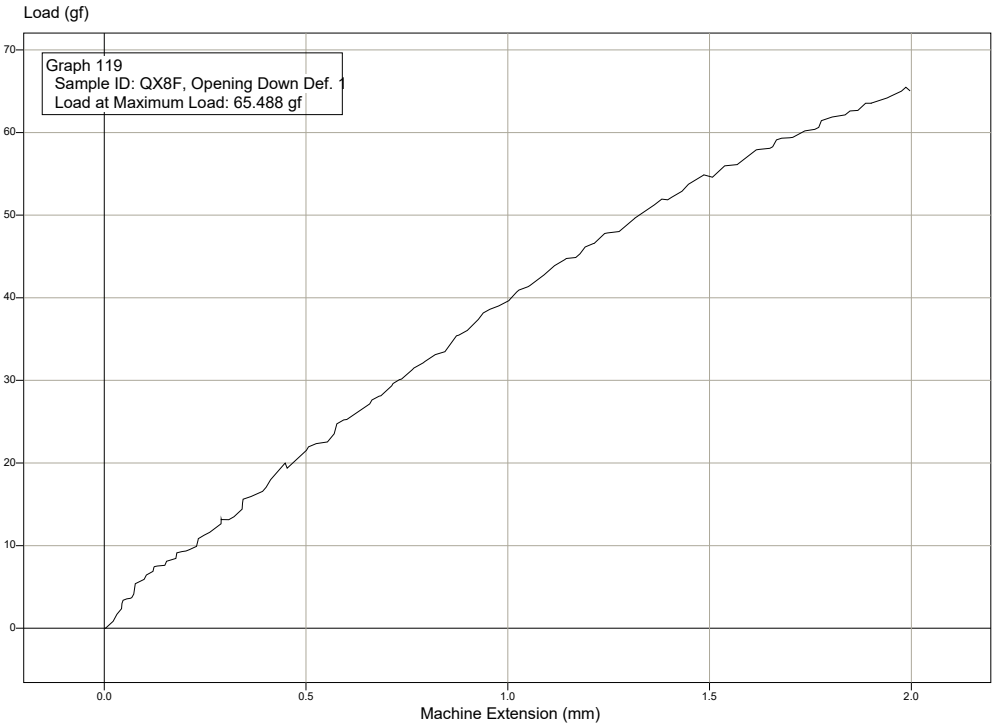
Graph 117


Load (gf)
Graph 117
Sample ID: QX8F, Opening up Def. 2
Load at Maximum Load: 74.430 gf
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

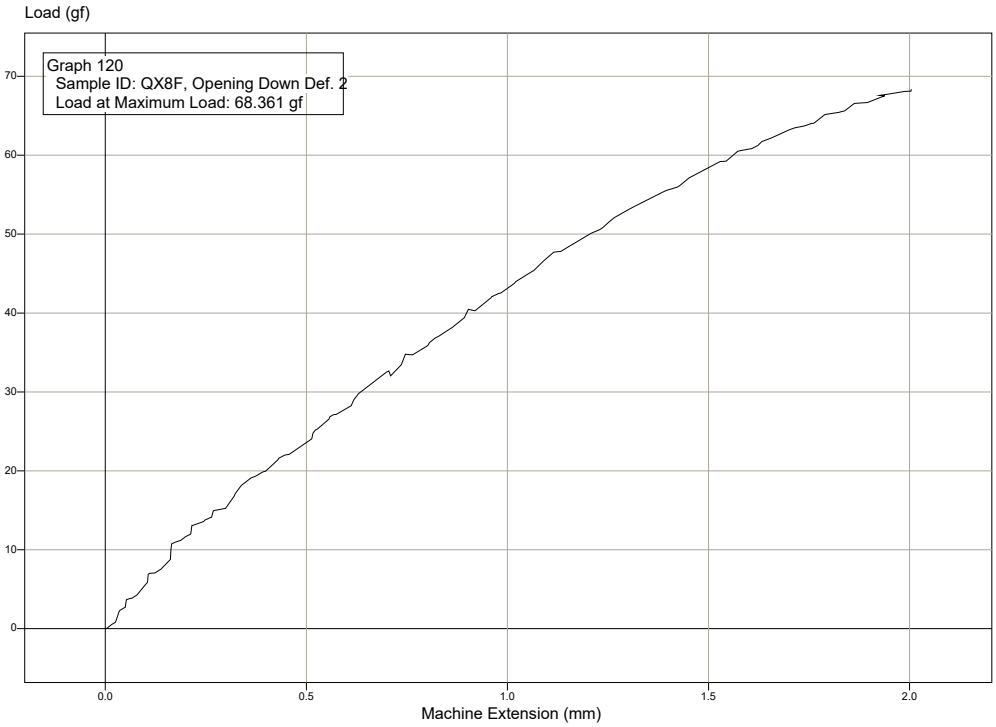
Graph 118


Load (gf)
Graph 118
Sample ID: QX8F, Opening up Def. 3
Load at Maximum Load: 73.999 gf
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

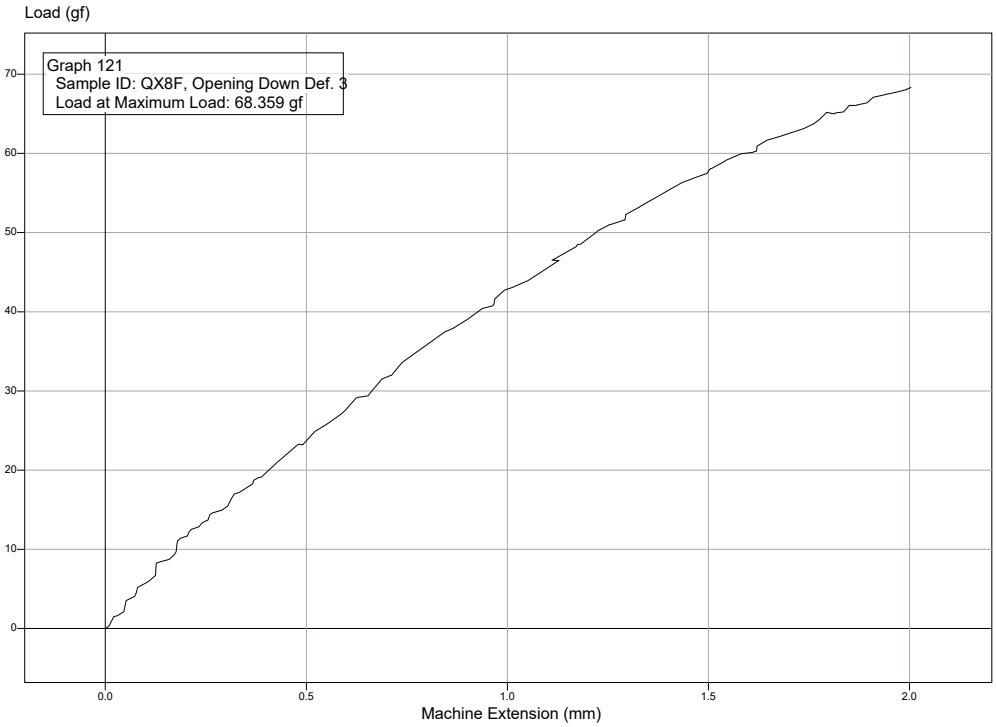
Graph 119


Load (gf)
Graph 119
Sample ID: QX8F, Opening Down Def. 1
Load at Maximum Load: 65.488 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

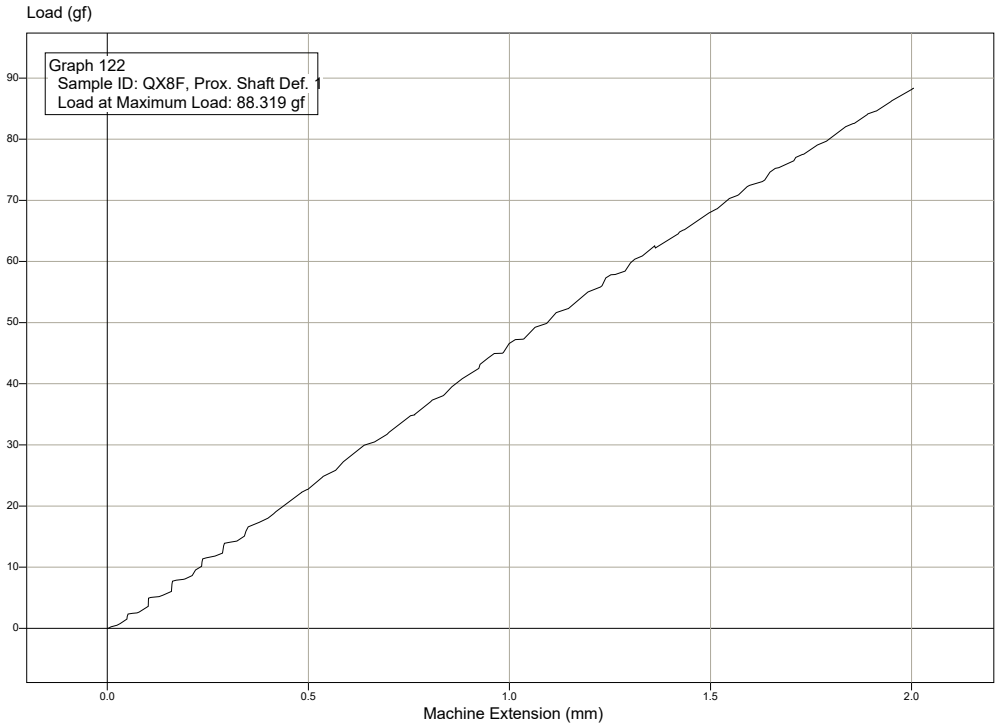
Graph 120


Load (gf)
Graph 120
Sample ID: QX8F, Opening Down Def. 2
Load at Maximum Load: 68.361 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

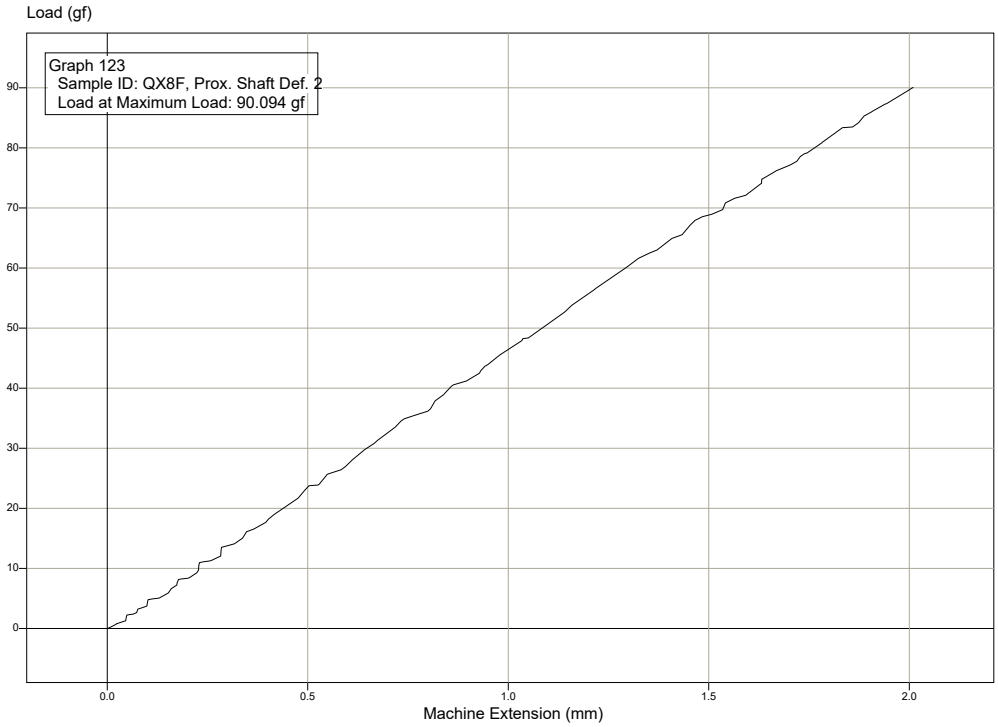
Graph 121


Load (gf)
Graph 121
Sample ID: QX8F, Opening Down Def. 3
Load at Maximum Load: 68.359 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

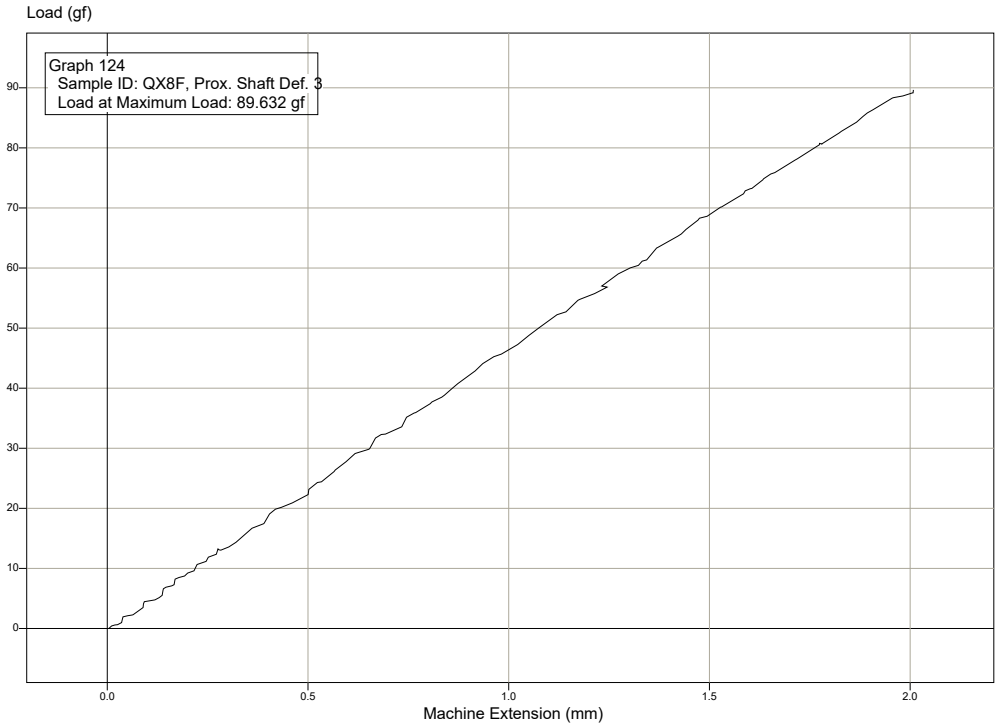
Graph 122


Load (gf)
Graph 122
Sample ID: QX8F, Prox. Shaft Def. 1
Load at Maximum Load: 88.319 gf
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

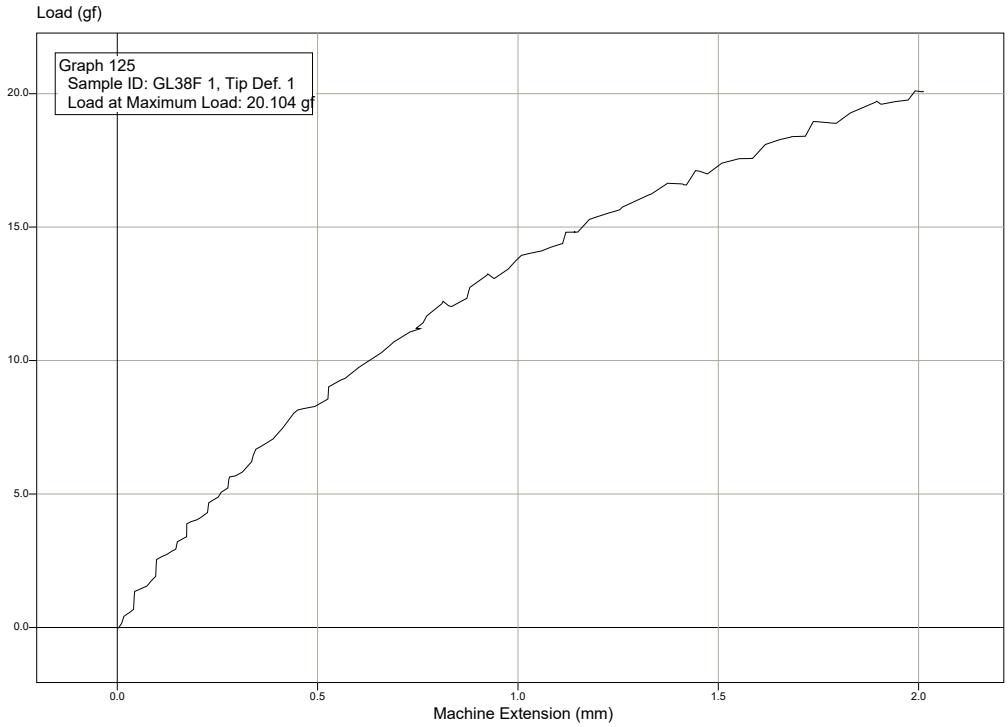
Graph 123


Load (gf)
Graph 123
Sample ID: QX8F, Prox. Shaft Def. 2
Load at Maximum Load: 90.094 gf
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

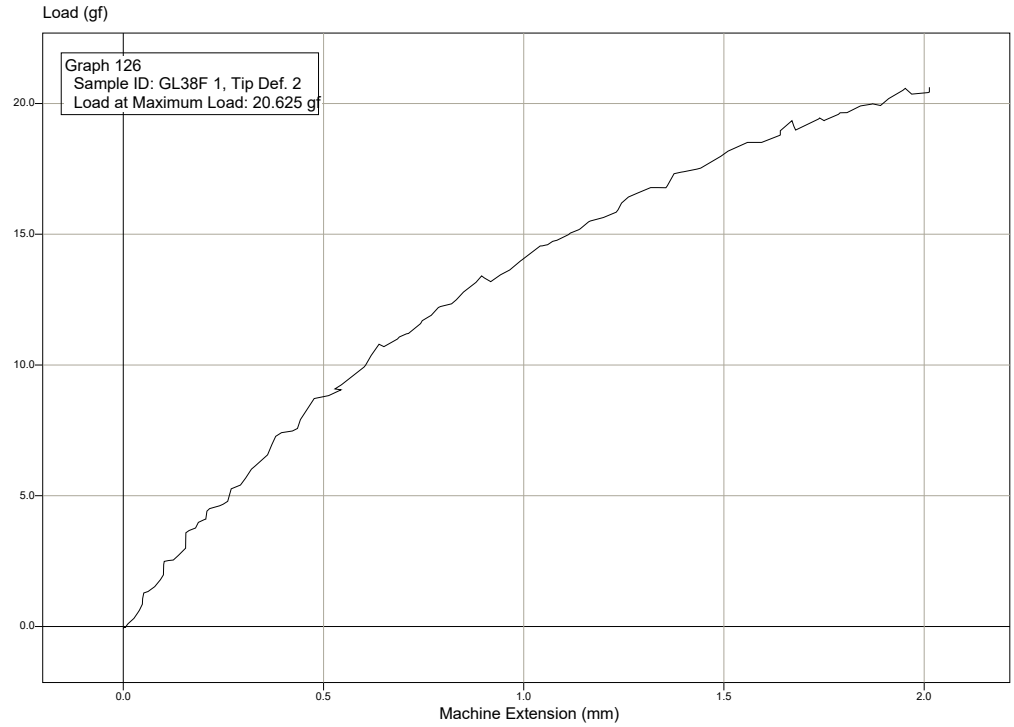
Graph 124


Load (gf)
Graph 124
Sample ID: QX8F, Prox. Shaft Def. 3
Load at Maximum Load: 89.632 gf
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

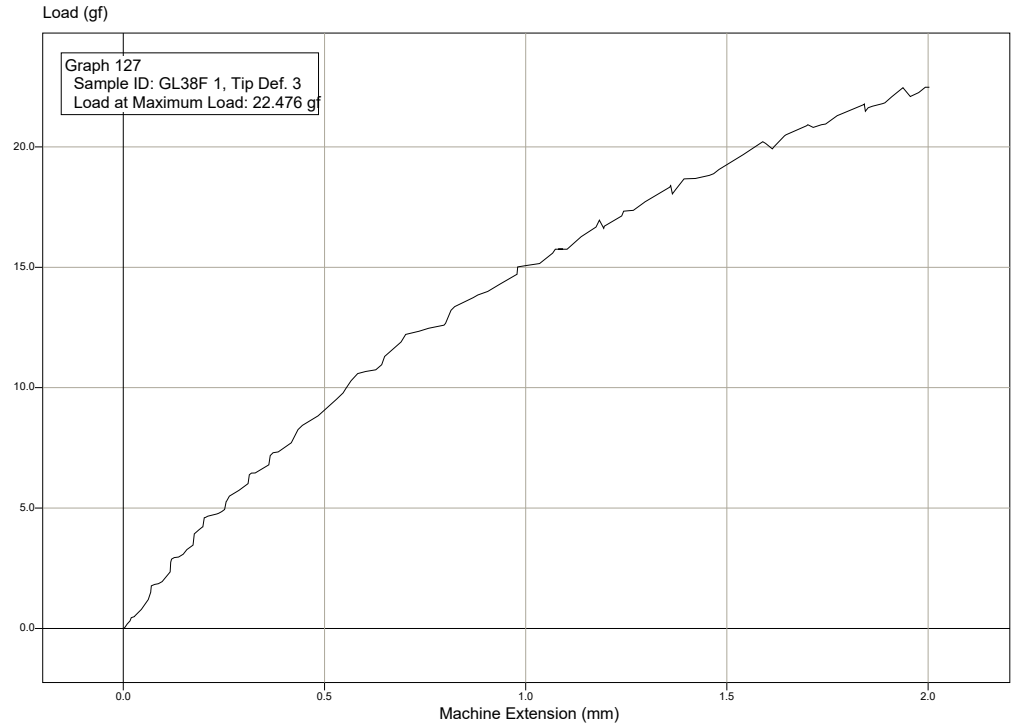
Graph 125


Load (gf)
Graph 125
Sample ID: GL38F 1, Tip Def. 1
Load at Maximum Load: 20.104 gf
20.0
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

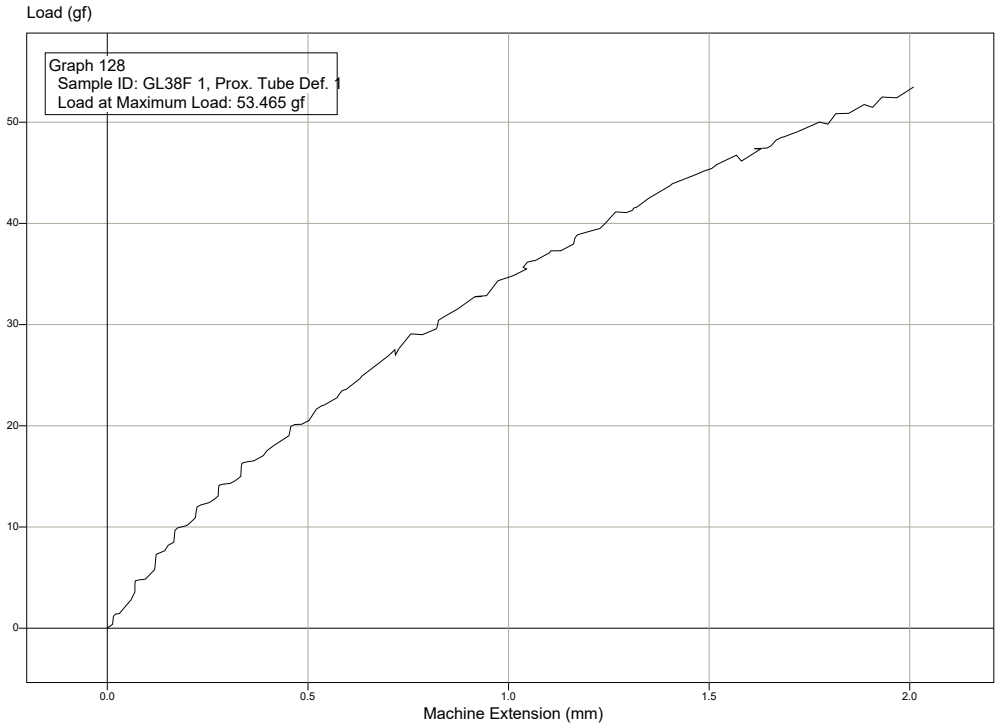
Graph 126



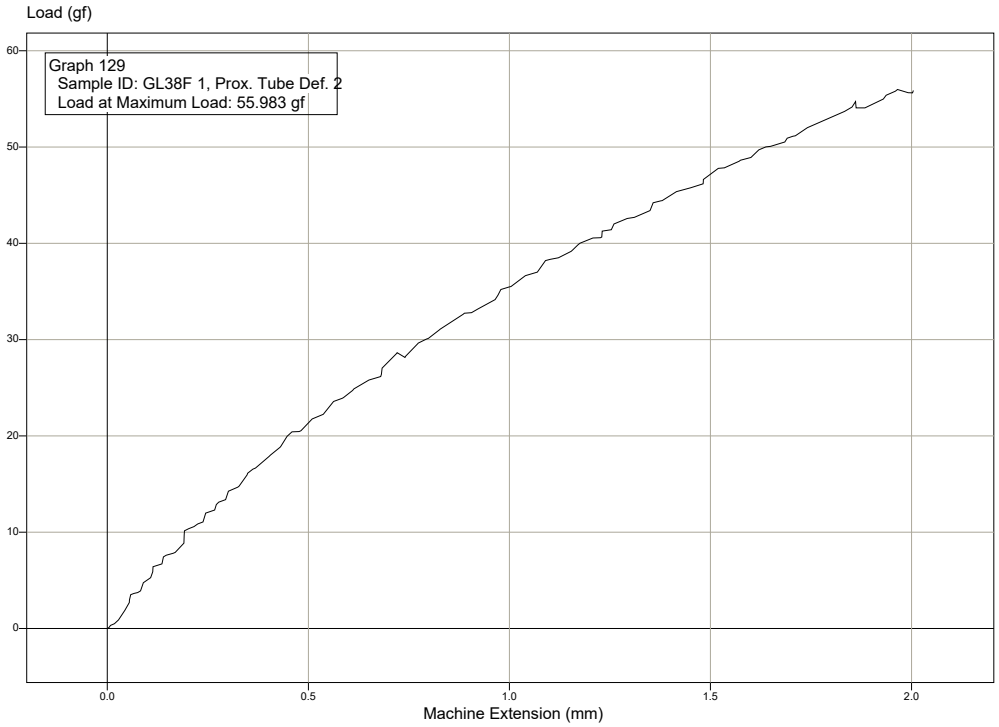
Graph 127


Load (gf)
Graph 127
Sample ID: GL38F 1, Tip Def. 3
Load at Maximum Load: 22.476 gf
20.0
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

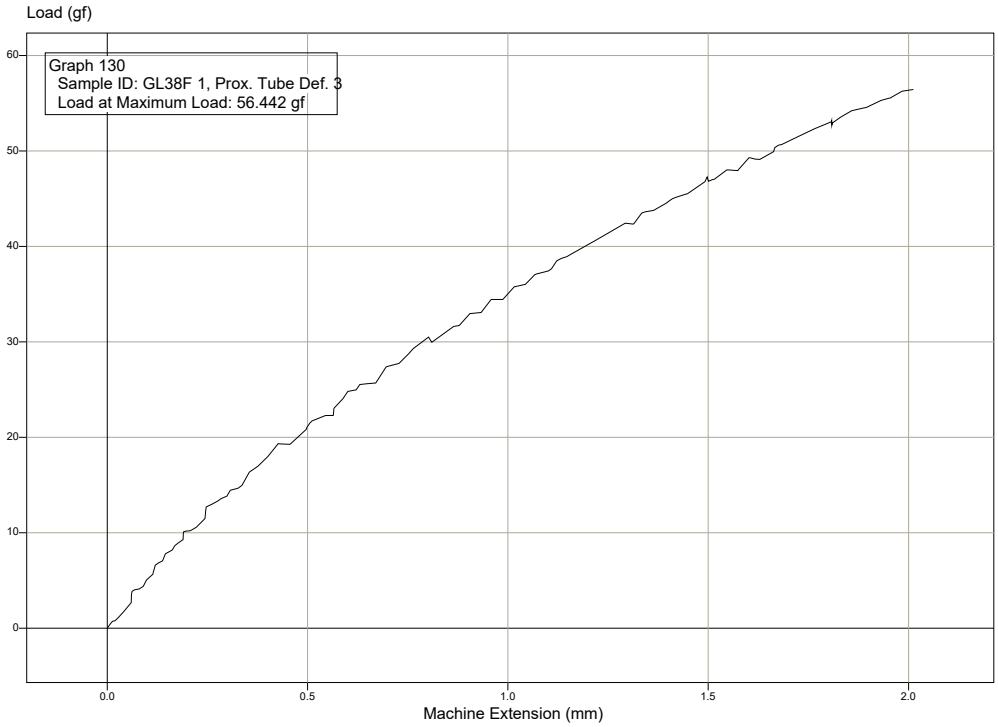
Graph 128


Load (gf)
Graph 128
Sample ID: GL38F 1, Prox. Tube Def. 1
Load at Maximum Load: 53.465 gf
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

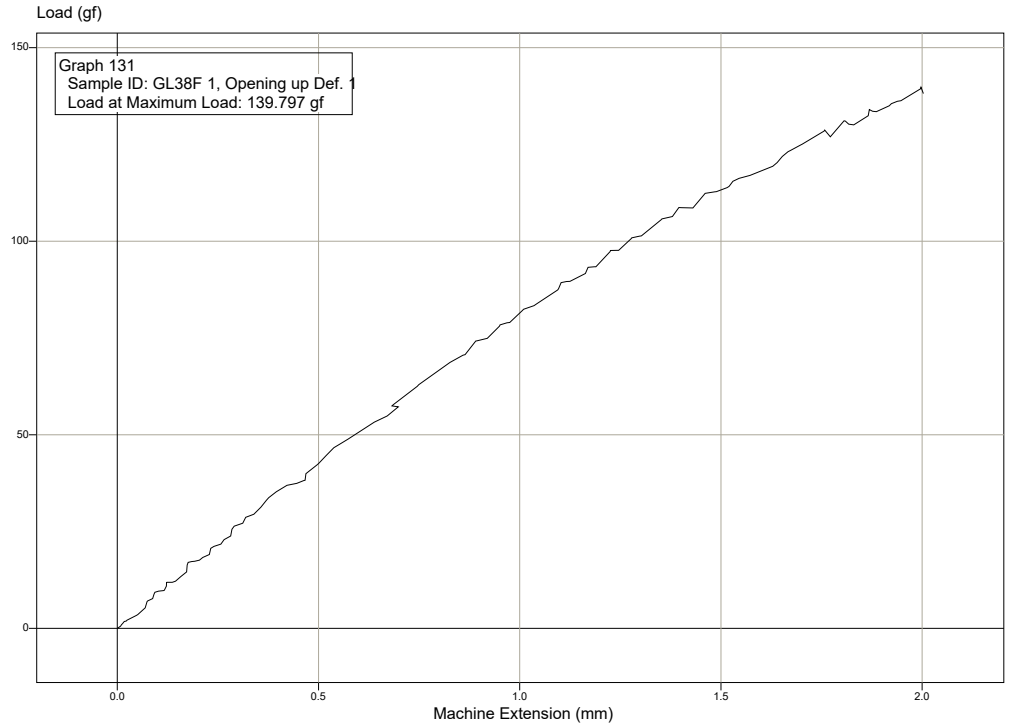
Graph 129


Load (gf)
Graph 129
Sample ID: GL38F 1, Prox. Tube Def. 2
Load at Maximum Load: 55.983 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

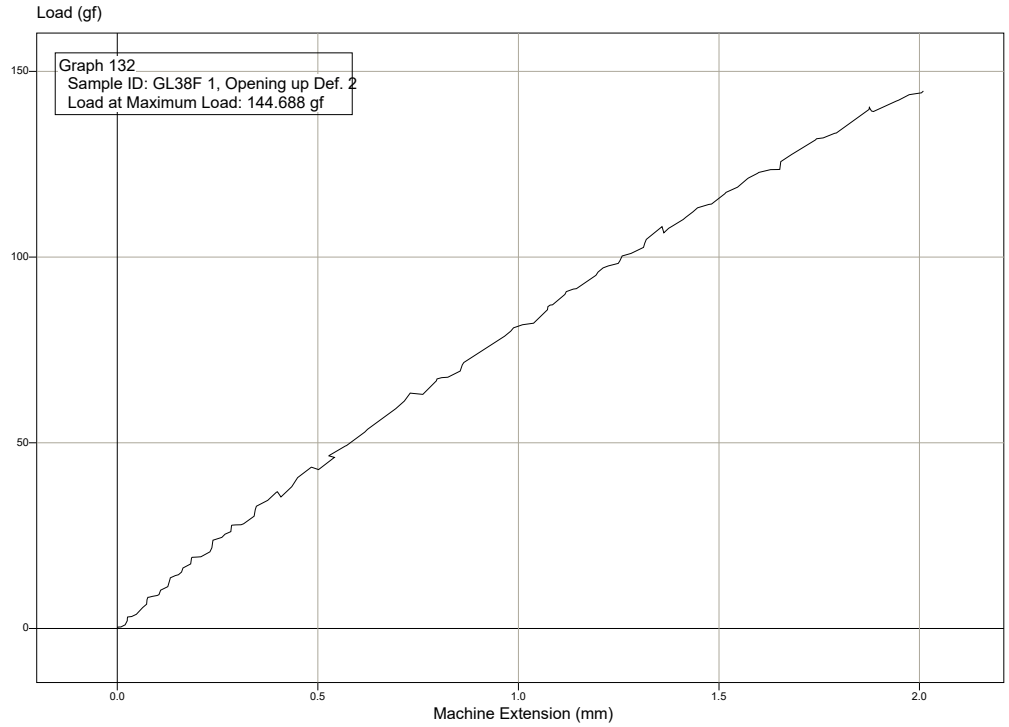
Graph 130


Load (gf)
Graph 130
Sample ID: GL38F 1, Prox. Tube Def. 3
Load at Maximum Load: 56.442 gf
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

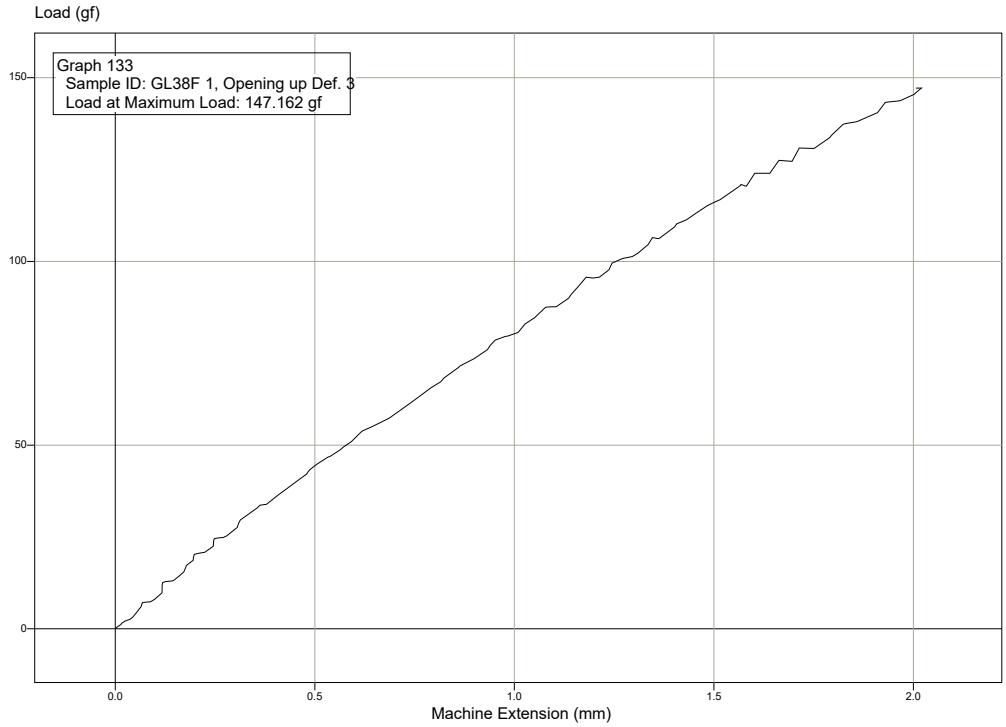
Graph 131


Load (gf)
150
100
50
0
Graph 131
Sample ID: GL38F 1, Opening up Def. 1
Load at Maximum Load: 139.797 gf
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

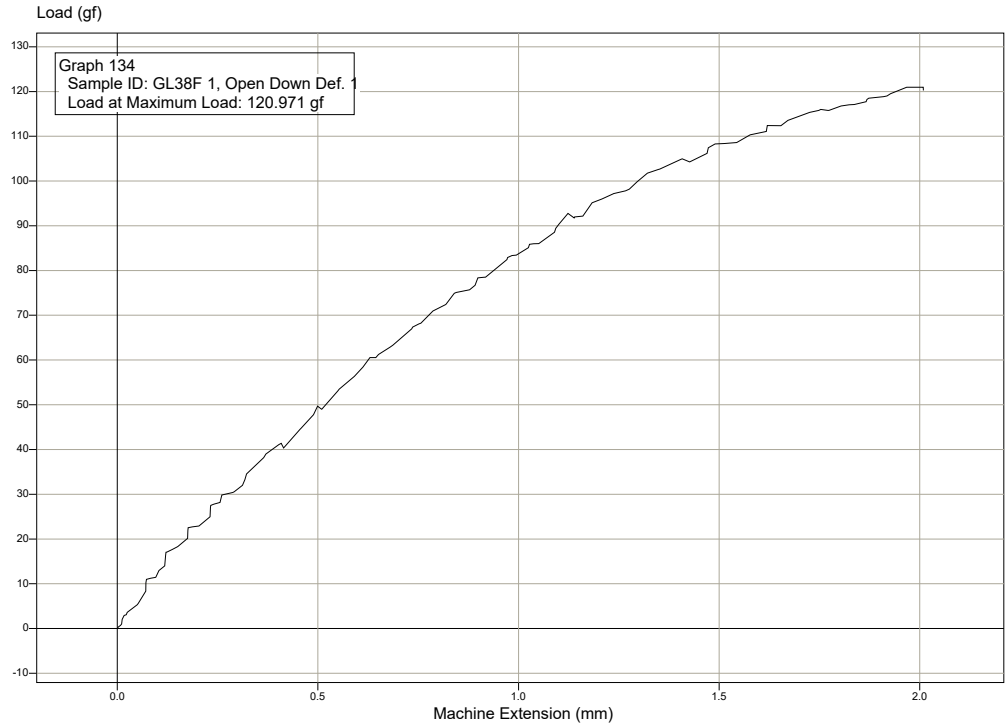
Graph 132


Load (gf)
Graph 132
Sample ID: GL38F 1, Opening up Def. 2
Load at Maximum Load: 144.688 gf
150
100
50
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

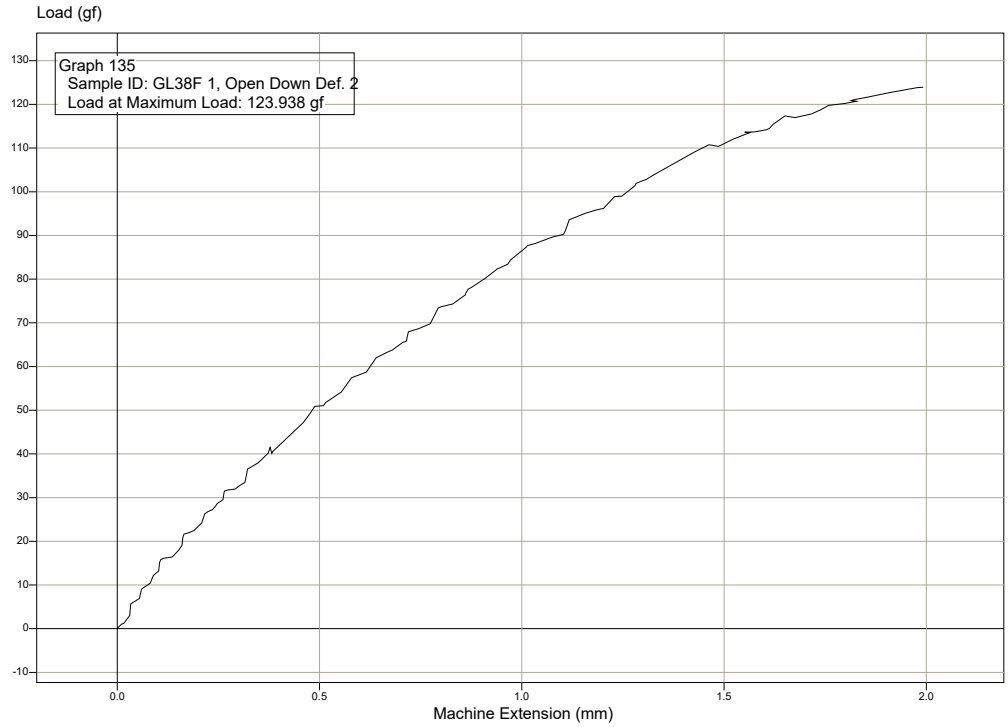
Graph 133


Load (gf)
Graph 133
Sample ID: GL38F 1, Opening up Def. 3
Load at Maximum Load: 147.162 gf
150
100
50
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

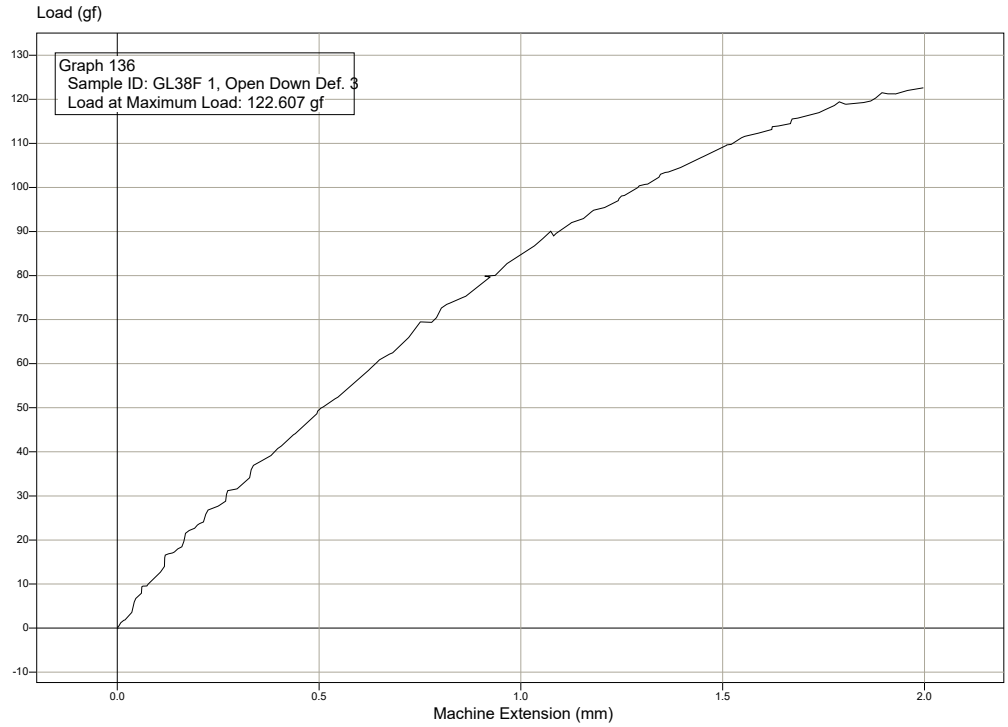
Graph 134


Load (gf)
Graph 134
Sample ID: GL38F 1, Open Down Def. 1
Load at Maximum Load: 120.971 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

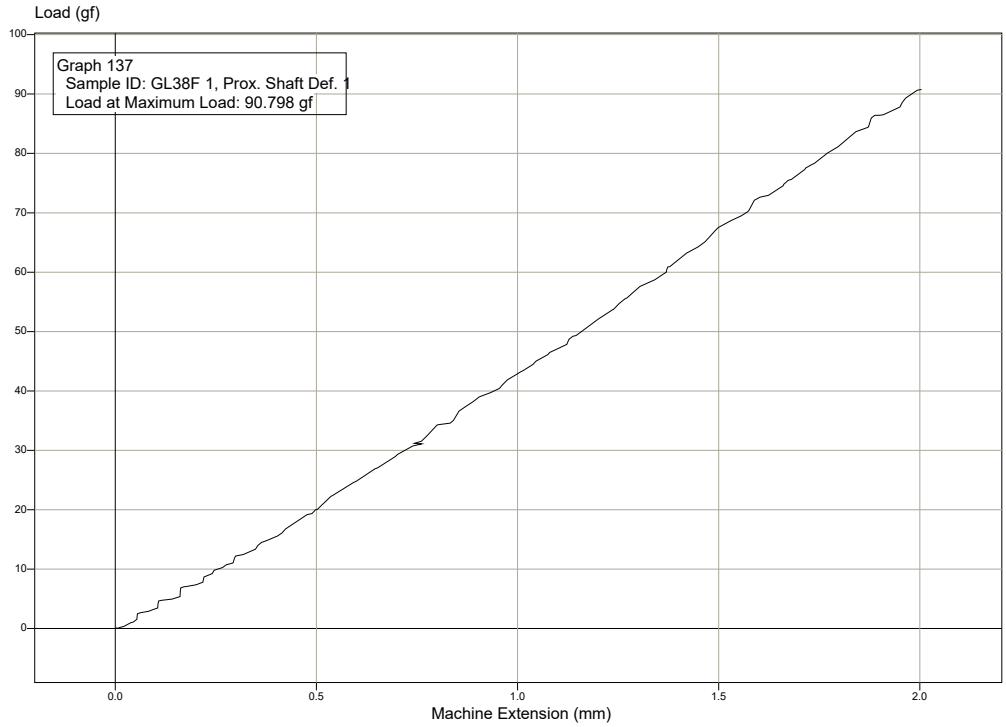
Graph 135


Load (gf)
Graph 135
Sample ID: GL38F 1, Open Down Def. 2
Load at Maximum Load: 123.938 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

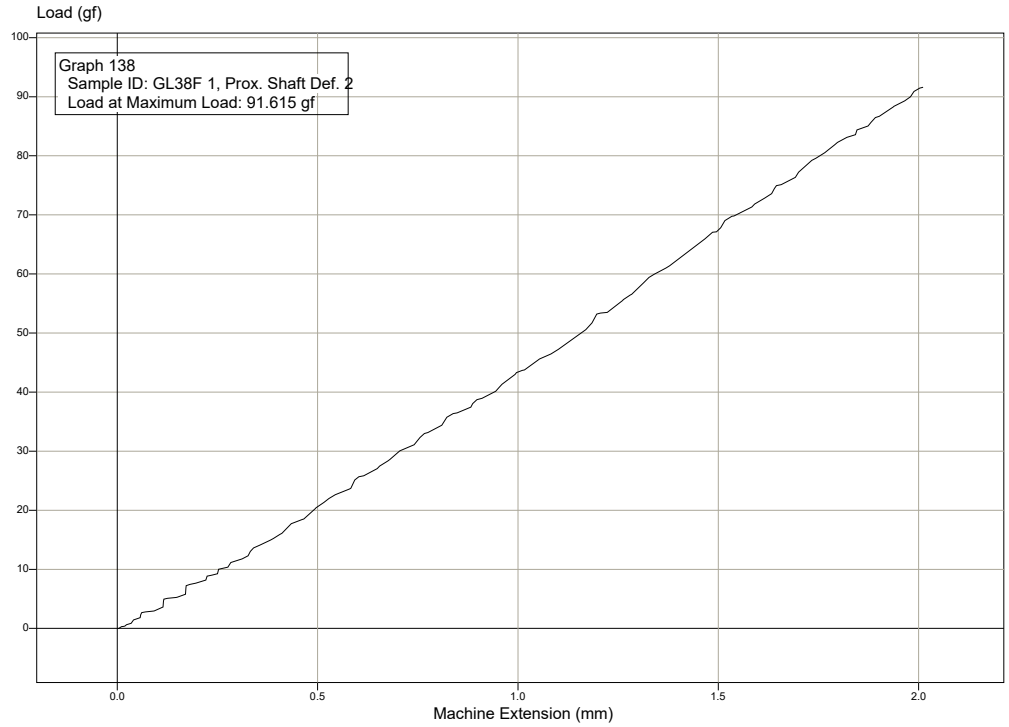
Graph 136


Load (gf)
Graph 136
Sample ID: GL38F 1, Open Down Def. 3
Load at Maximum Load: 122.607 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

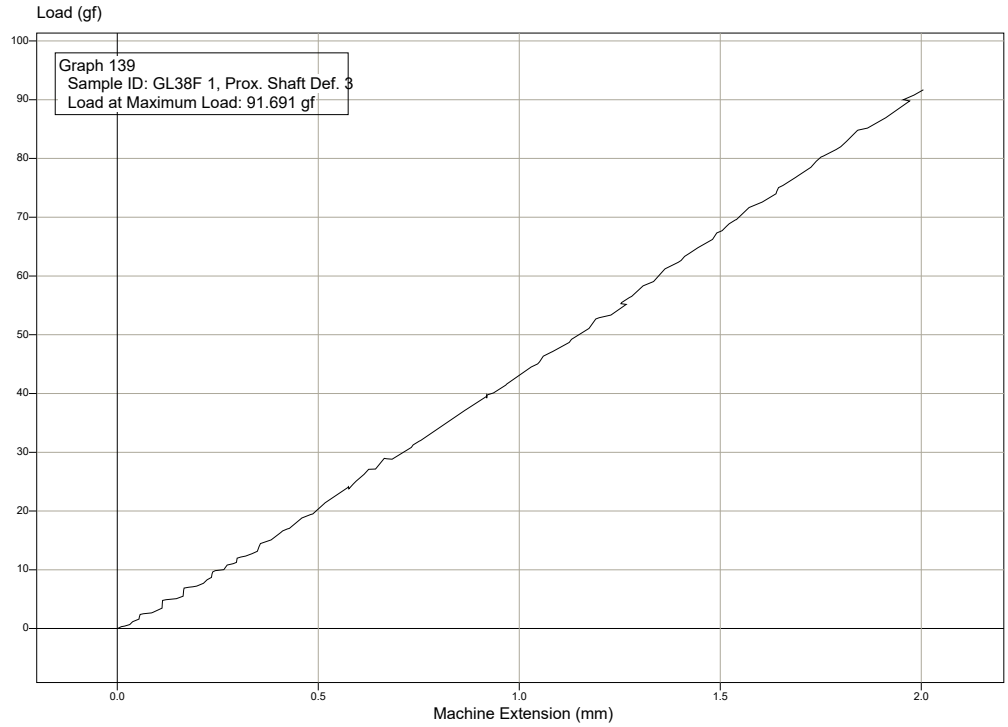
Graph 137


Load (gf)
Graph 137
Sample ID: GL38F 1, Prox. Shaft Def. 1
Load at Maximum Load: 90.798 gf
100
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

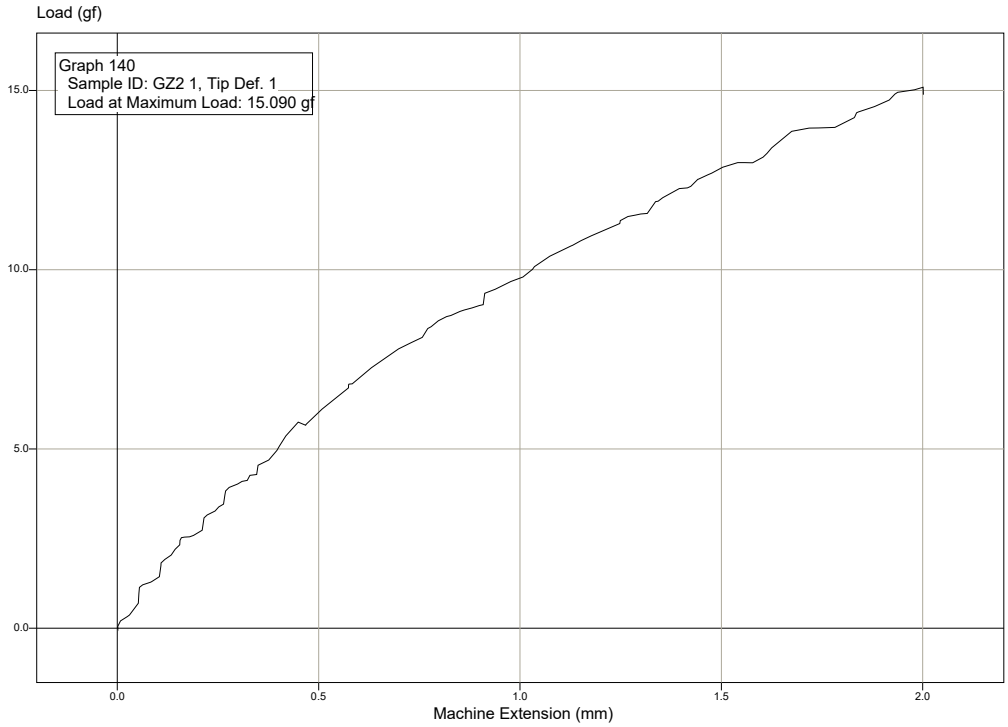
Graph 138


Load (gf)
Graph 138
Sample ID: GL38F 1, Prox. Shaft Def. 2
Load at Maximum Load: 91.615 gf
100
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

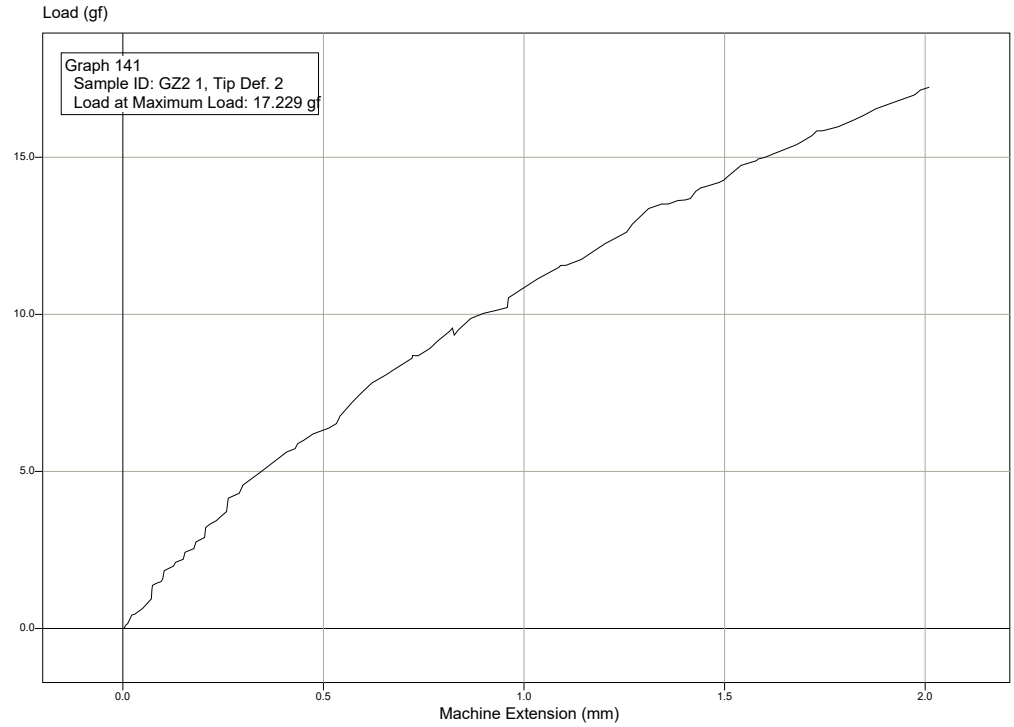
Graph 139


Load (gf)
Graph 139
Sample ID: GL38F 1, Prox. Shaft Def. 3
Load at Maximum Load: 91.691 gf
100
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

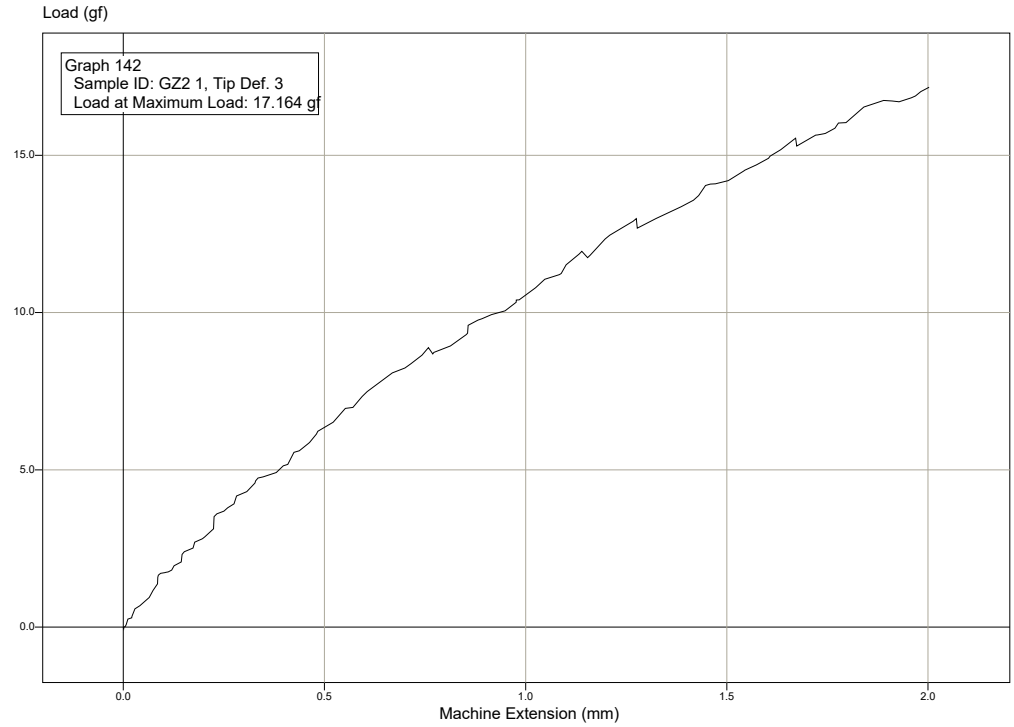
Graph 140


Load (gf)
Graph 140
Sample ID: GZ2 1, Tip Def. 1
Load at Maximum Load: 15.090 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

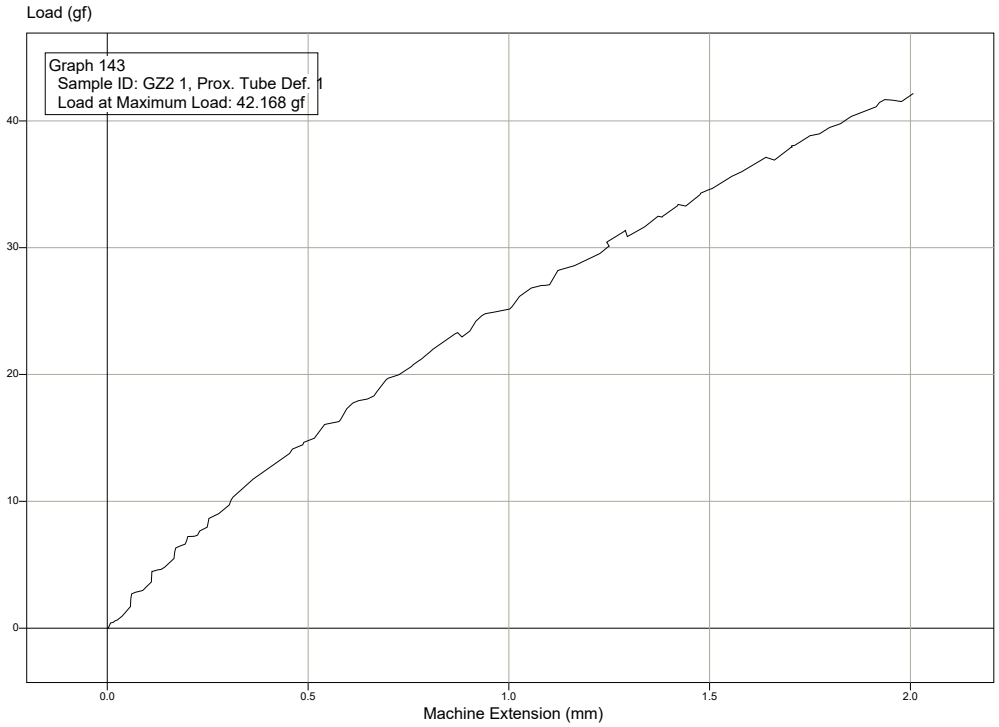
Graph 141


Load (gf)
Graph 141
Sample ID: GZ2 1, Tip Def. 2
Load at Maximum Load: 17.229 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

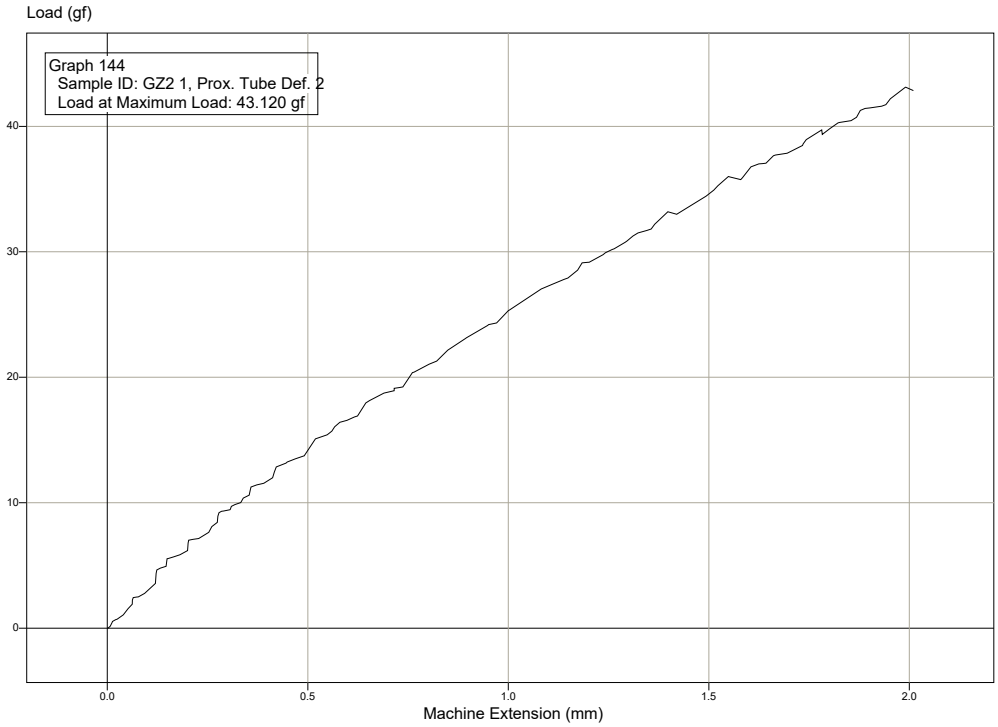
Graph 142



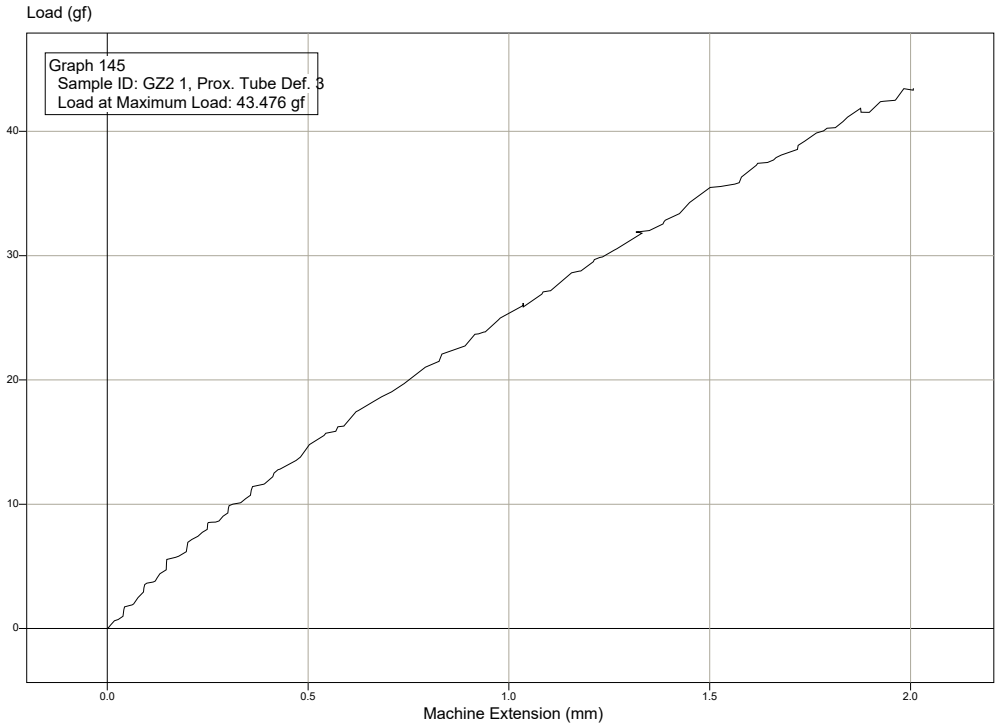
Graph 143


Load (gf)
Graph 143
Sample ID: GZ2 1, Prox. Tube Def. 1
Load at Maximum Load: 42.168 gf
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

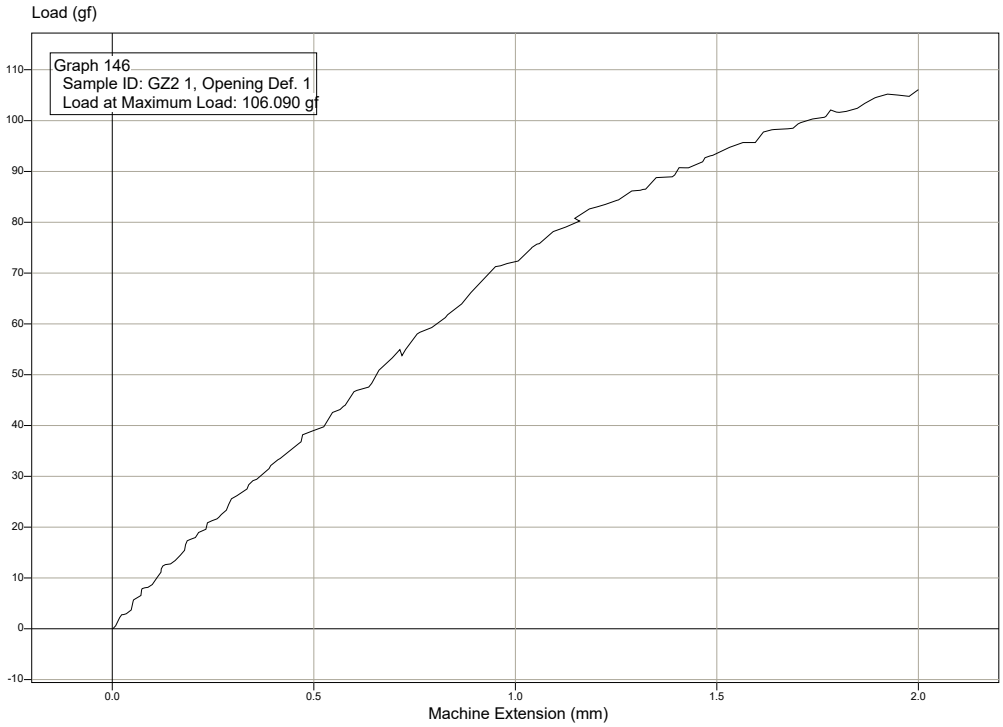
Graph 144


Load (gf)
Graph 144
Sample ID: GZ2 1, Prox. Tube Def. 2
Load at Maximum Load: 43.120 gf
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

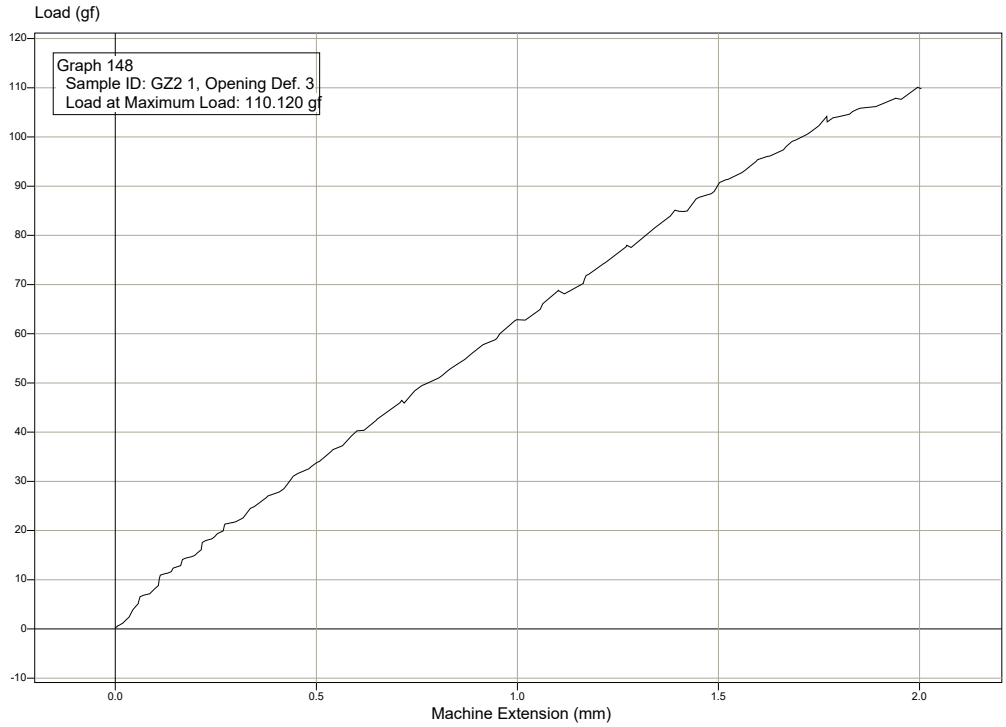
Graph 145


Load (gf)
Graph 145
Sample ID: GZ2 1, Prox. Tube Def. 3
Load at Maximum Load: 43.476 gf
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

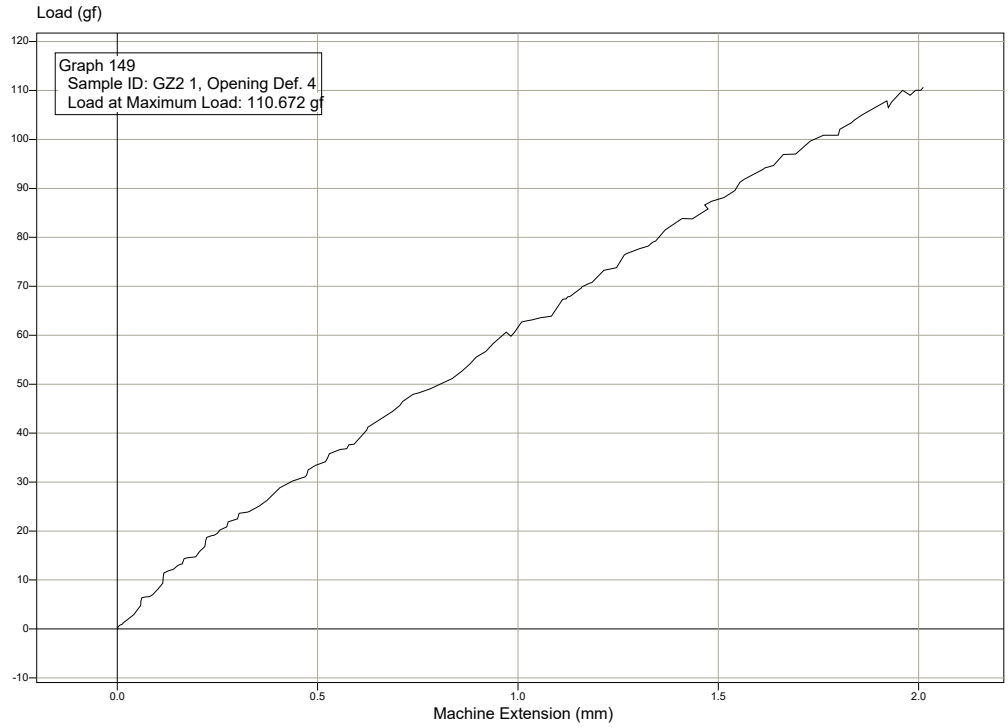
Graph 146


Load (gf)
Graph 146
Sample ID: GZ2 1, Opening Def. 1
Load at Maximum Load: 106.090 gf
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

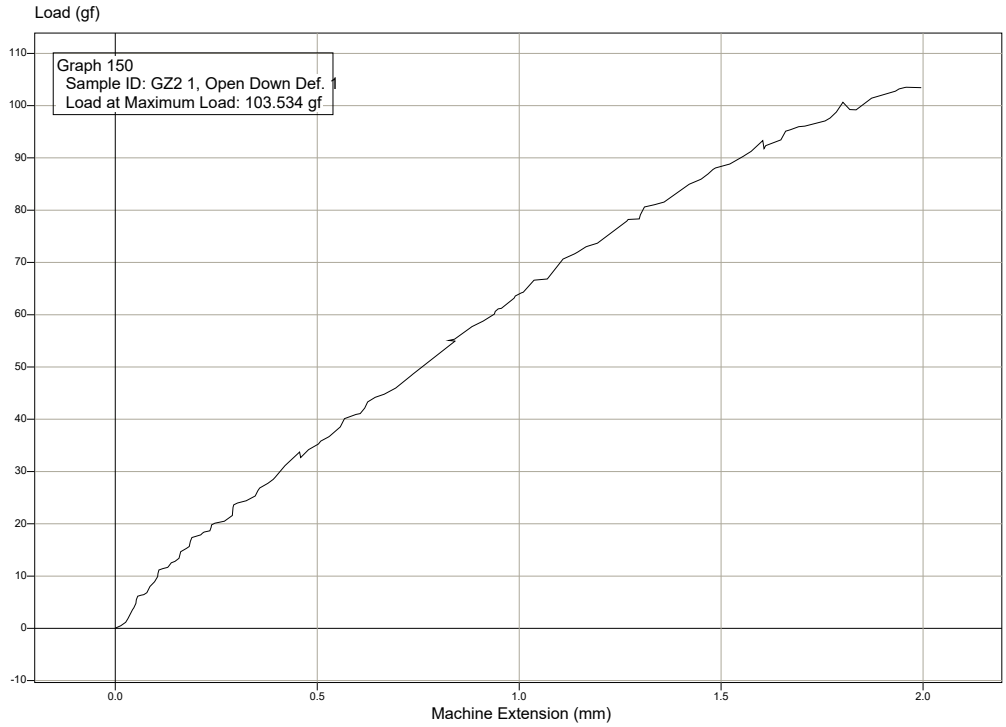
Graph 148


Load (gf)
Graph 148
Sample ID: GZ2 1, Opening Def. 3
Load at Maximum Load: 110.120 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

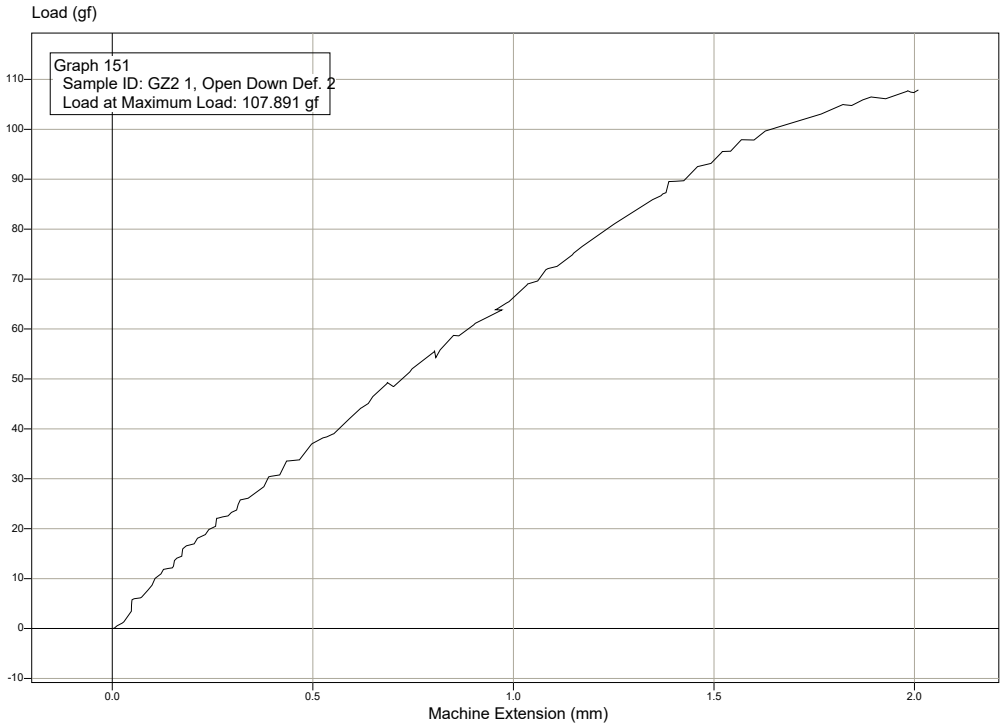
Graph 149


Load (gf)
Graph 149
Sample ID: GZ2 1, Opening Def. 4
Load at Maximum Load: 110.672 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

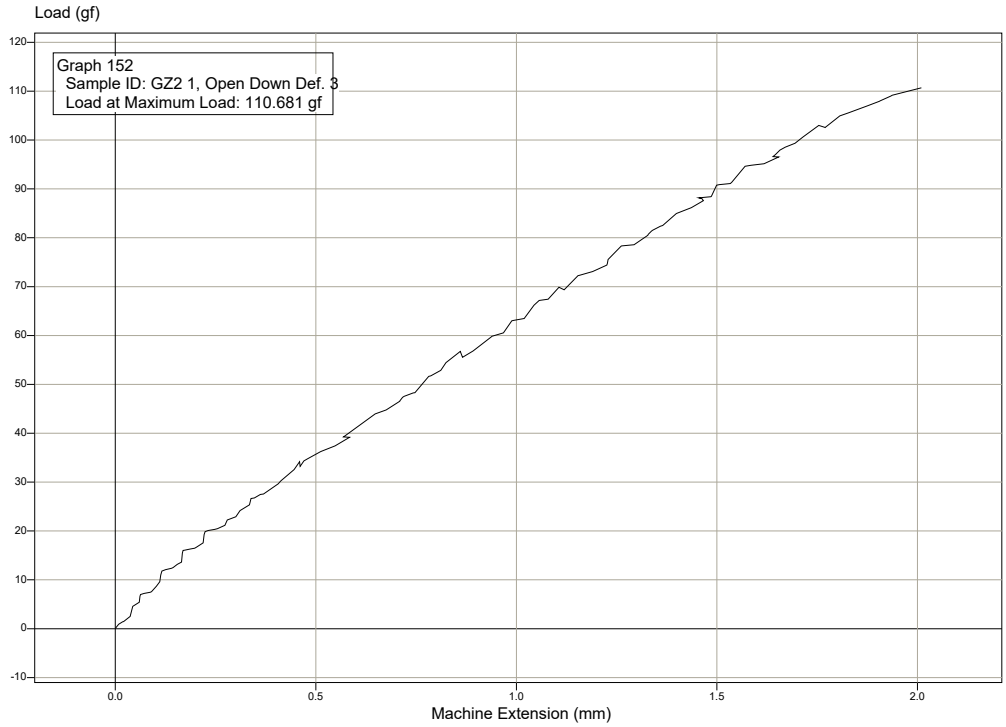
Graph 150



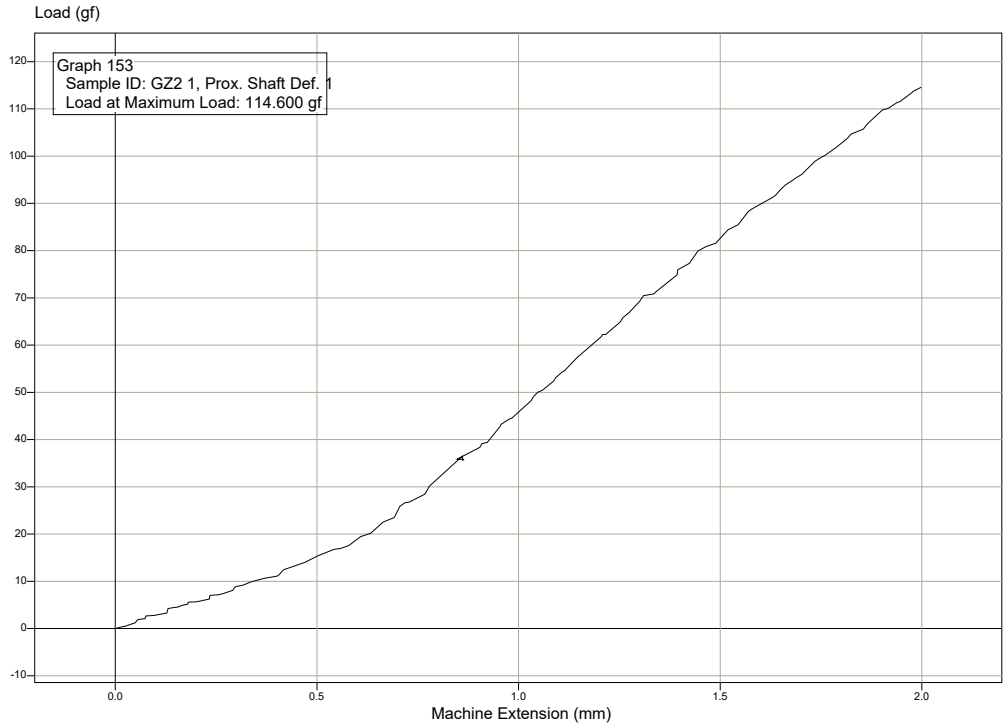
Graph 151



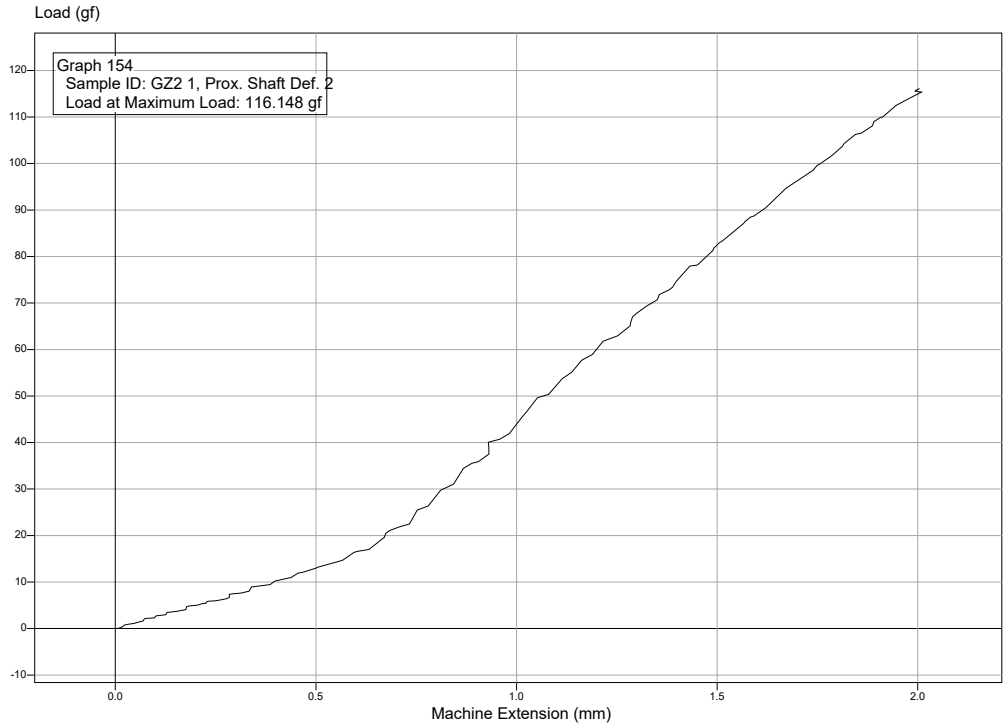
Graph 152


Load (gf)
Graph 152
Sample ID: GZ2 1, Open Down Def. 3
Load at Maximum Load: 110.681 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

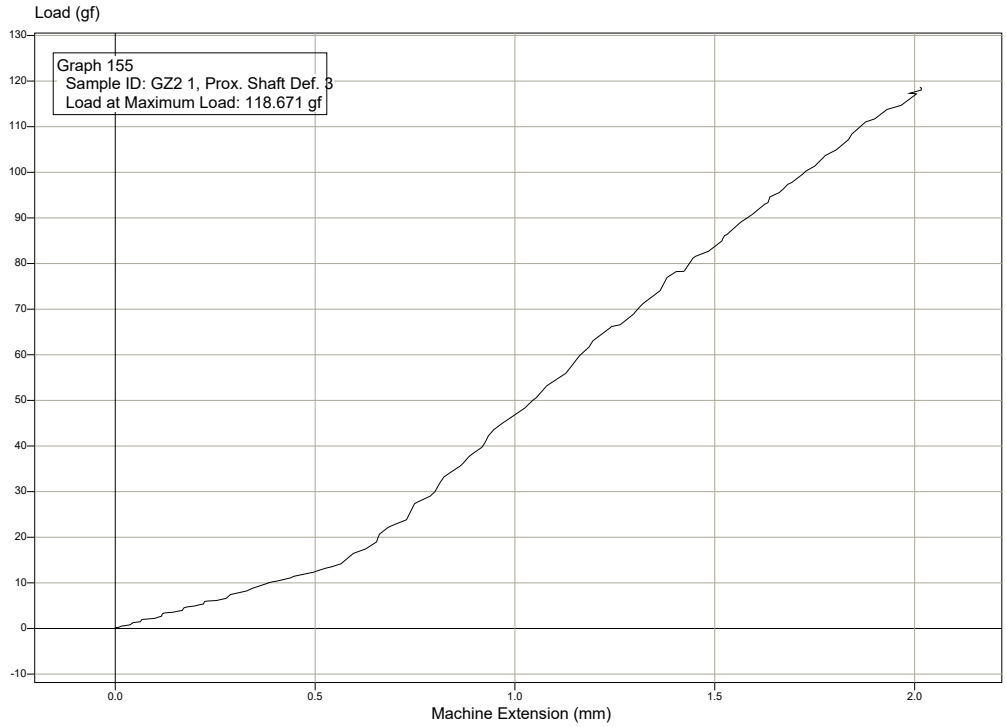
Graph 153



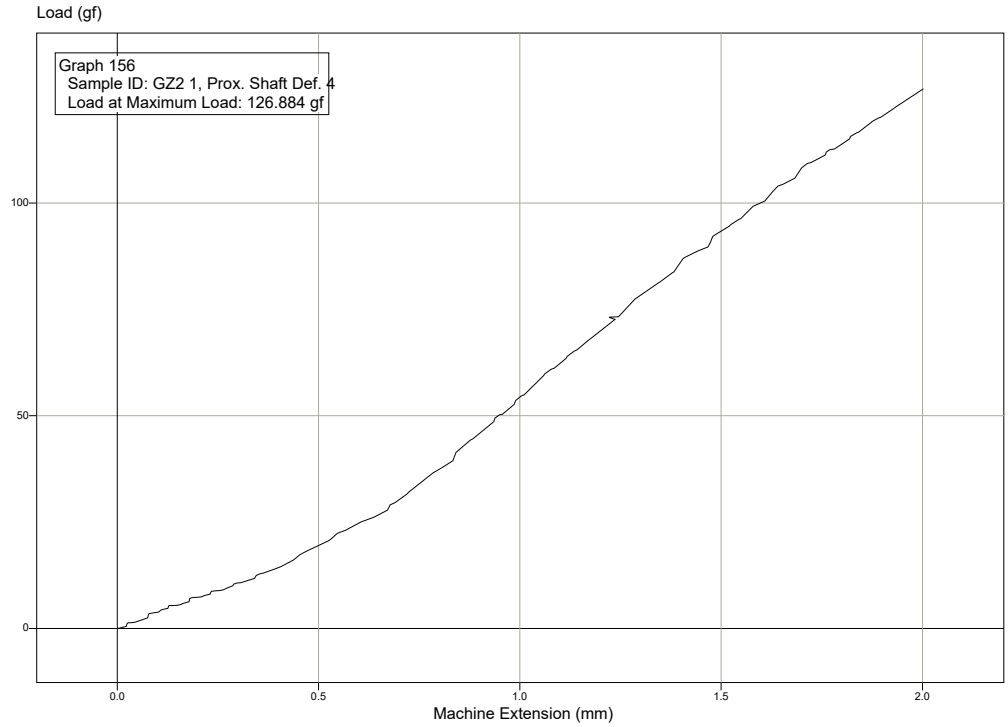
Graph 154


Load (gf)
Graph 154
Sample ID: GZ2 1, Prox. Shaft Def. 2
Load at Maximum Load: 116.148 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

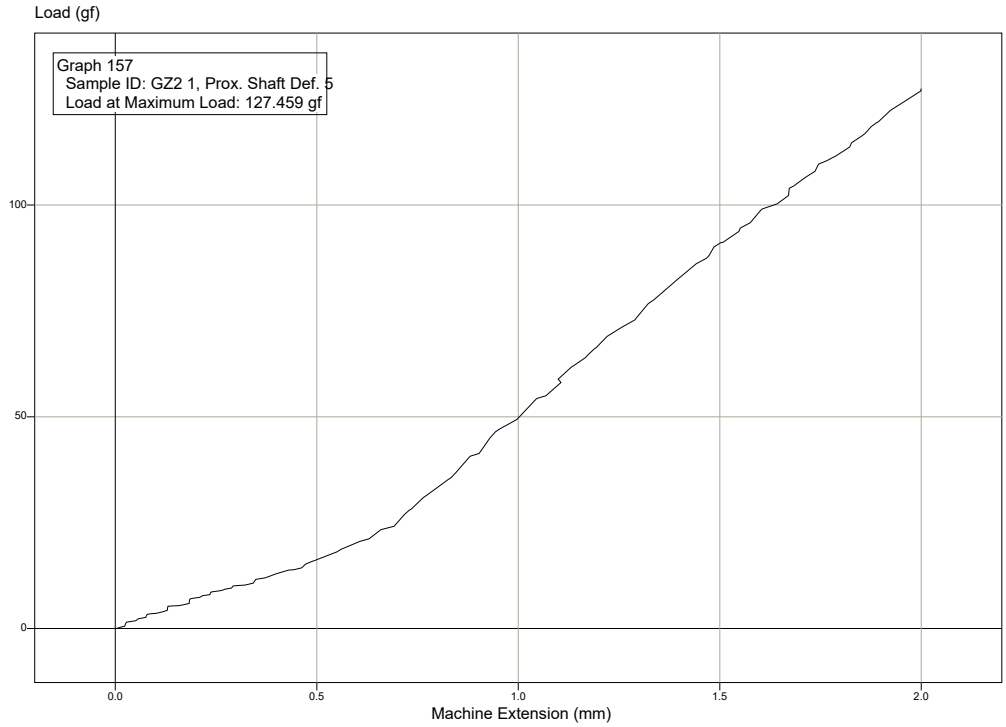
Graph 155



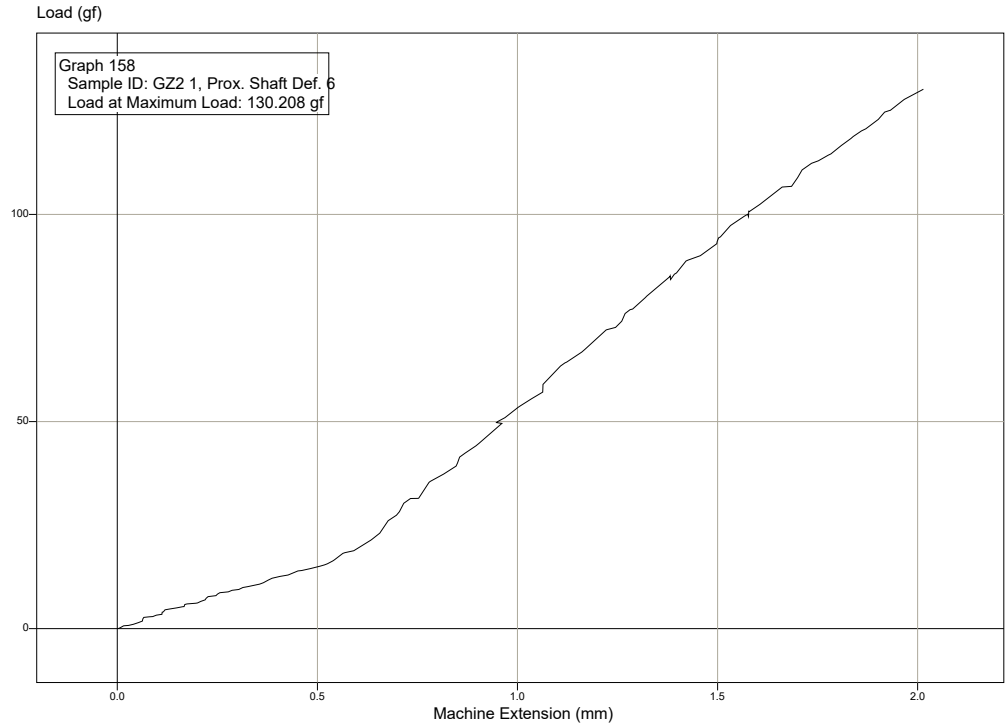
Graph 156



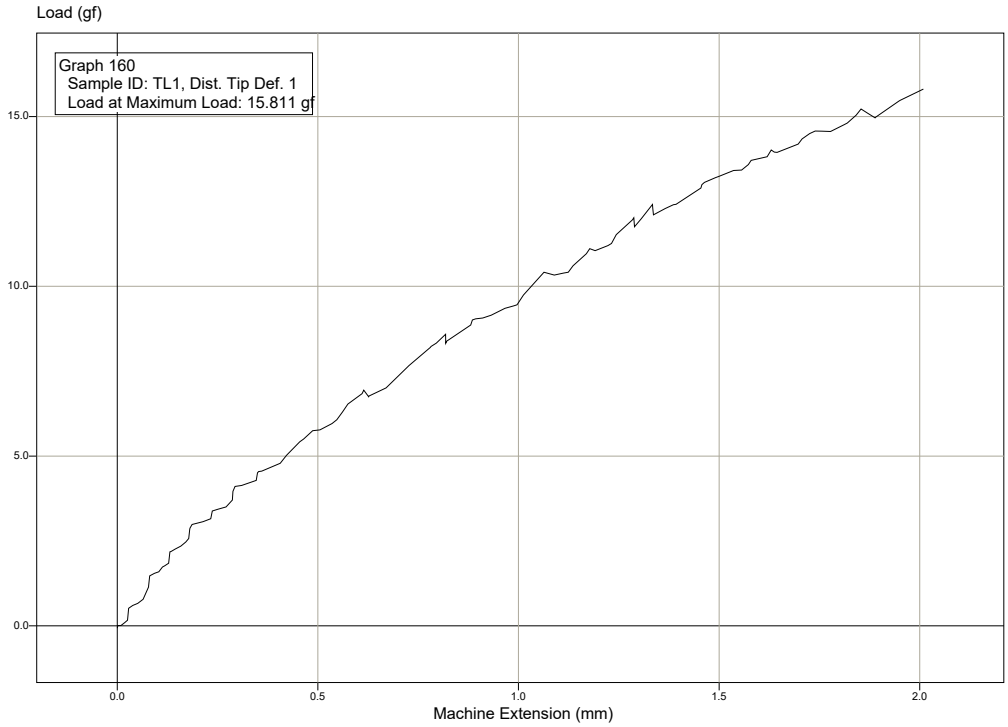
Graph 157



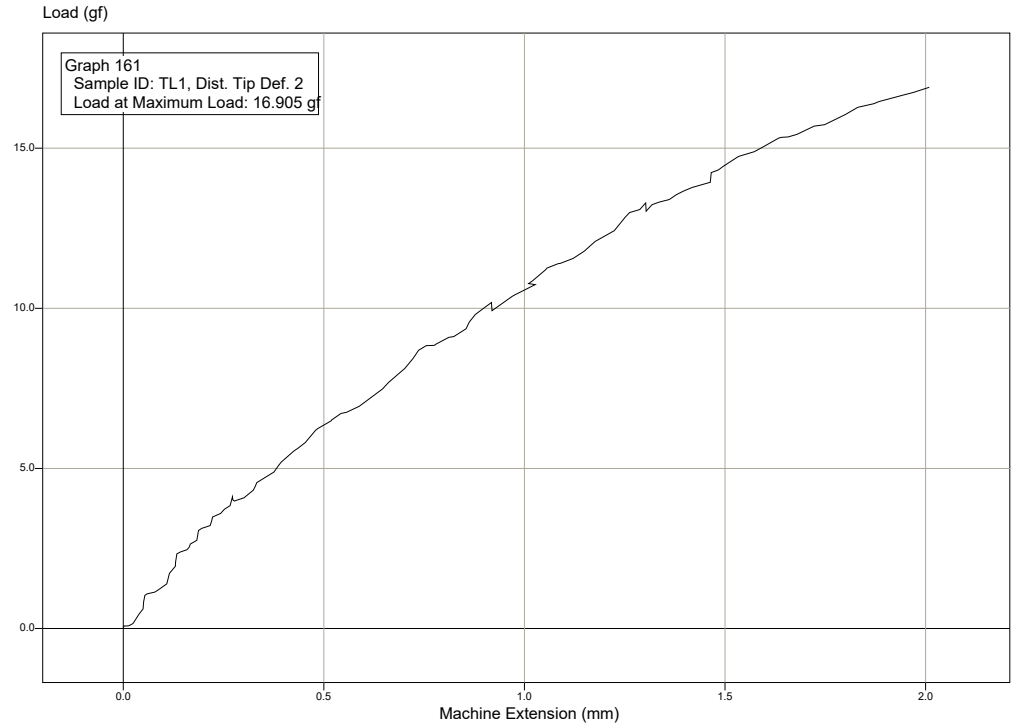
Graph 158


Load (gf)
Graph 158
Sample ID: GZ2 1, Prox. Shaft Def. 6
Load at Maximum Load: 130.208 gf
100
50
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

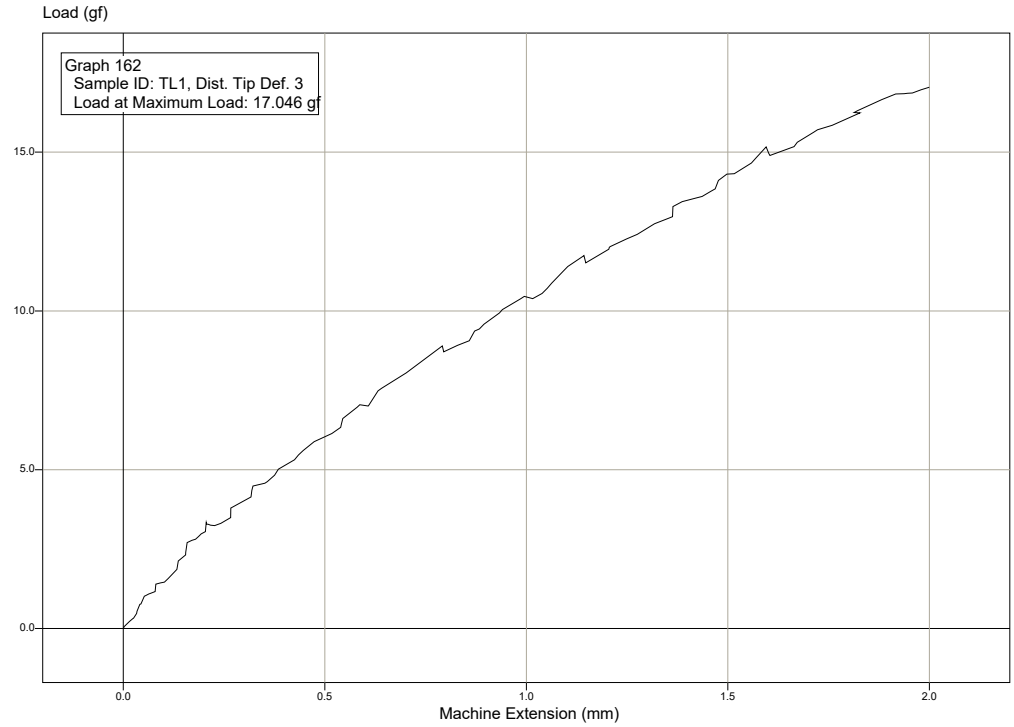
Graph 160



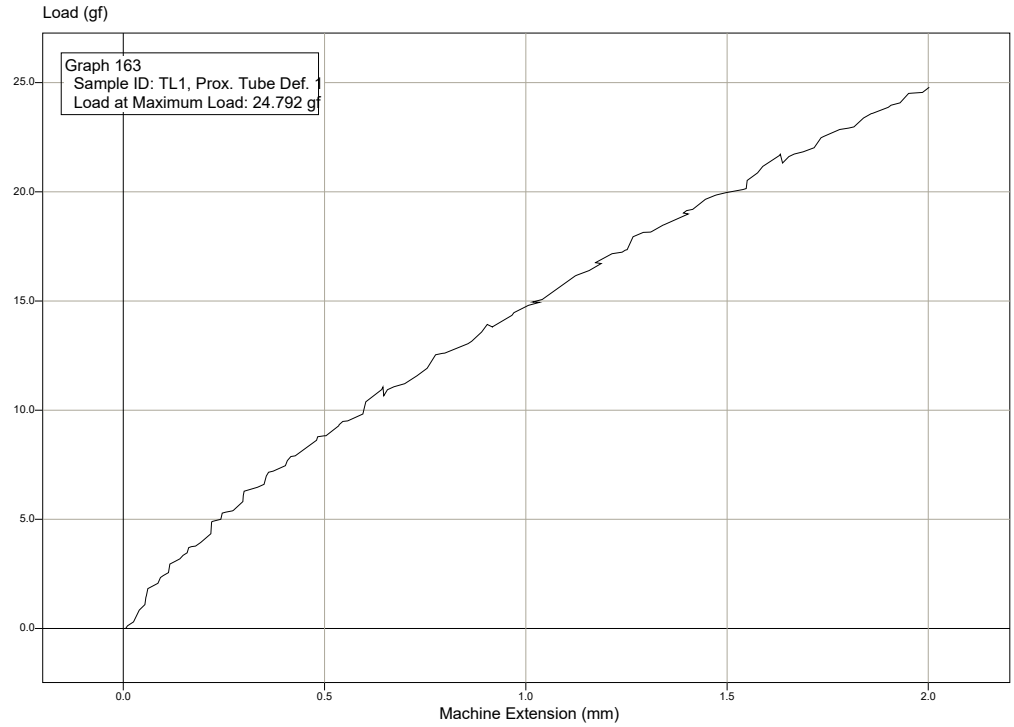
Graph 161


Load (gf)
Graph 161
Sample ID: TL1, Dist. Tip Def. 2
Load at Maximum Load: 16.905 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

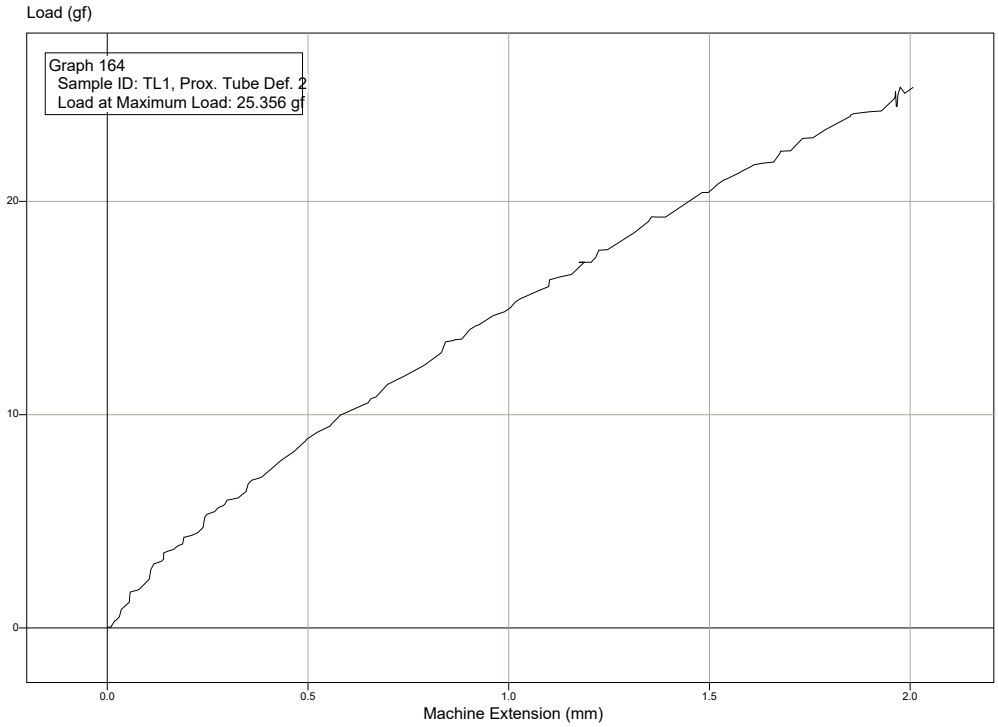
Graph 162


Load (gf)
Graph 162
Sample ID: TL1, Dist. Tip Def. 3
Load at Maximum Load: 17.046 gf
15.0
10.0
5.0
0.0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

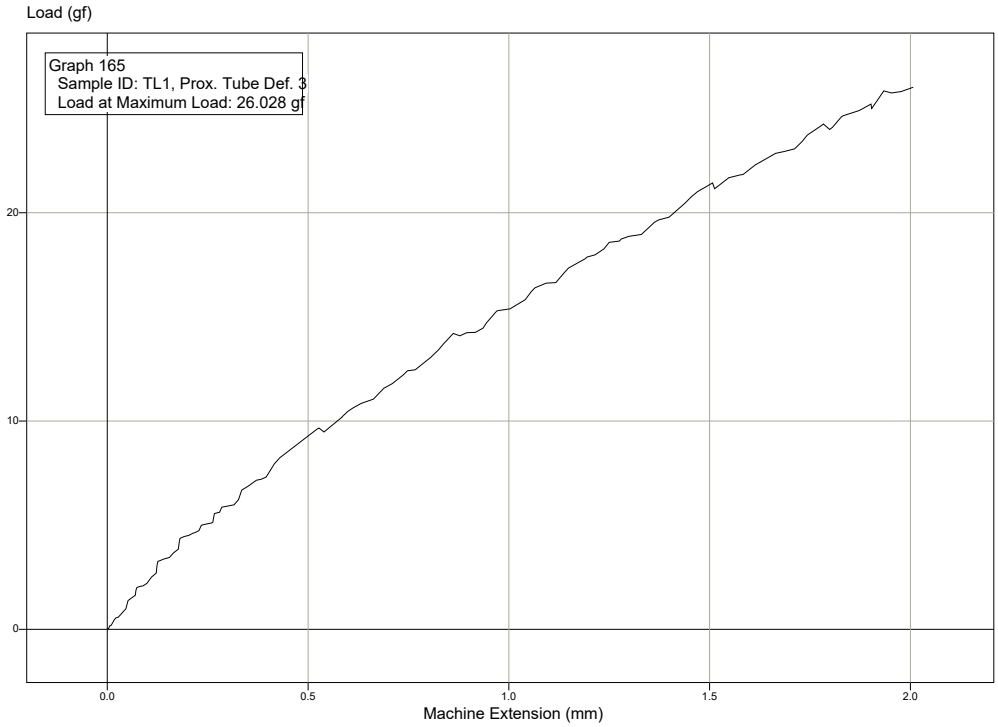
Graph 163



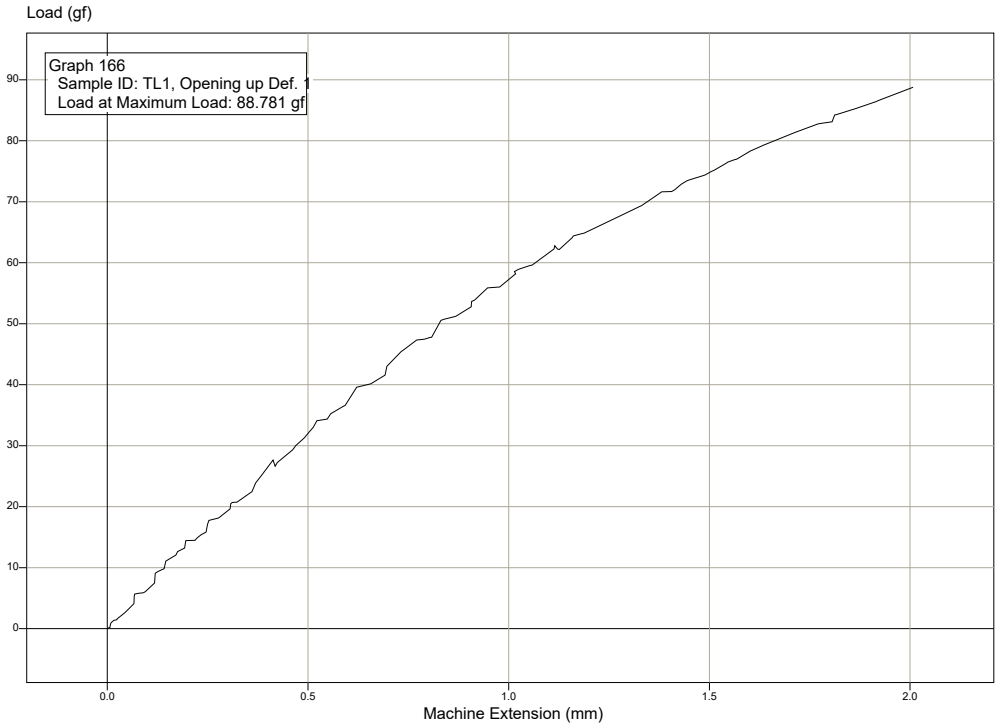
Graph 164



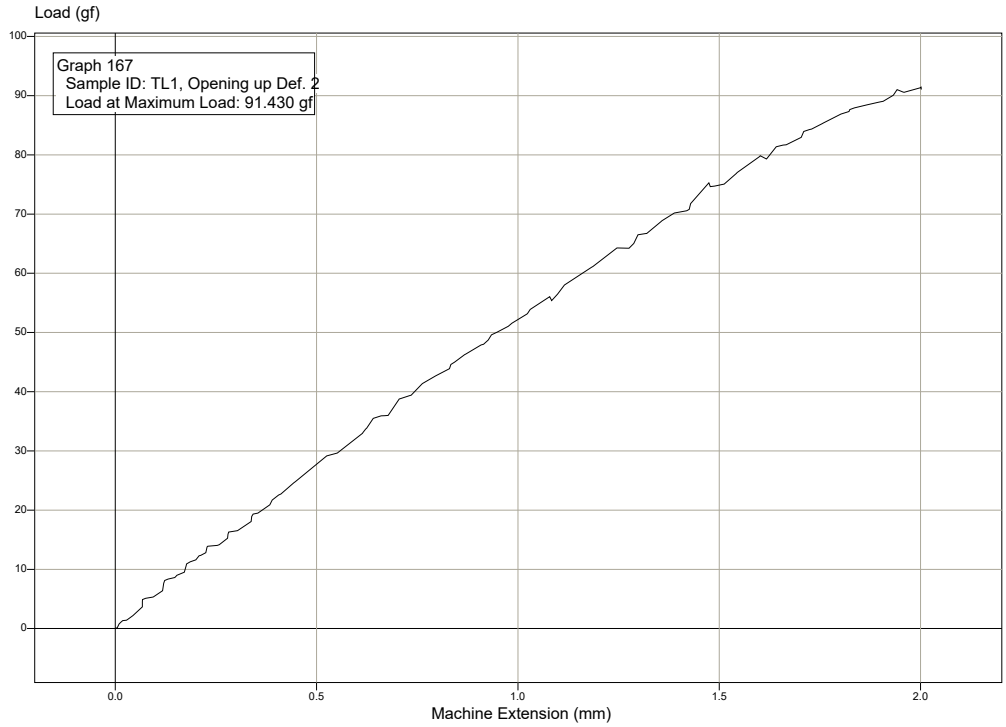
Graph 165



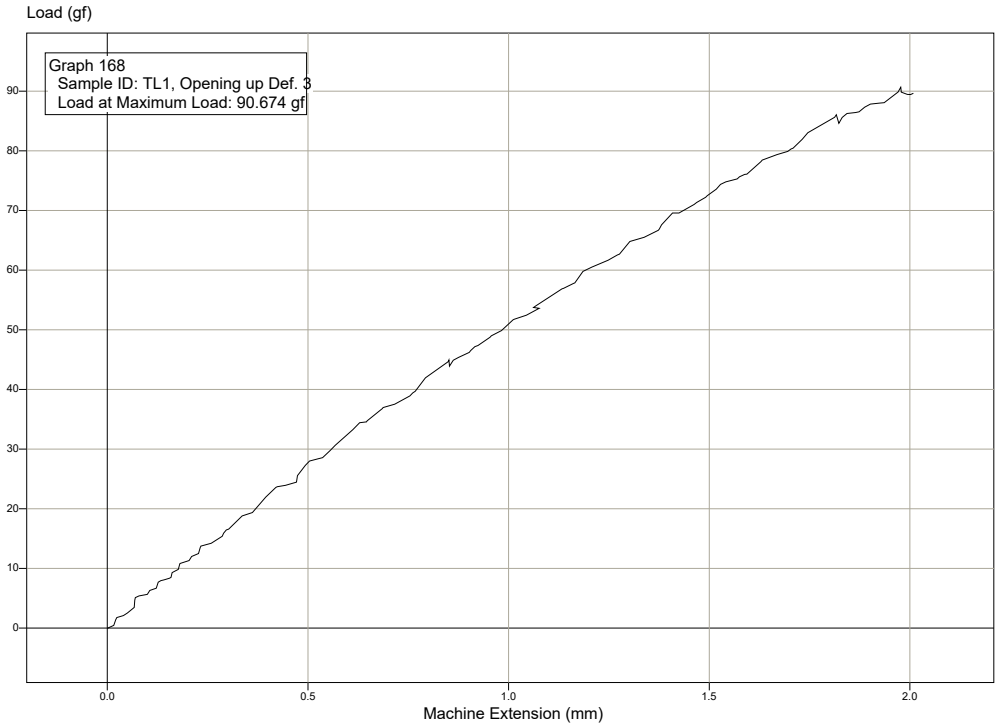
Graph 166



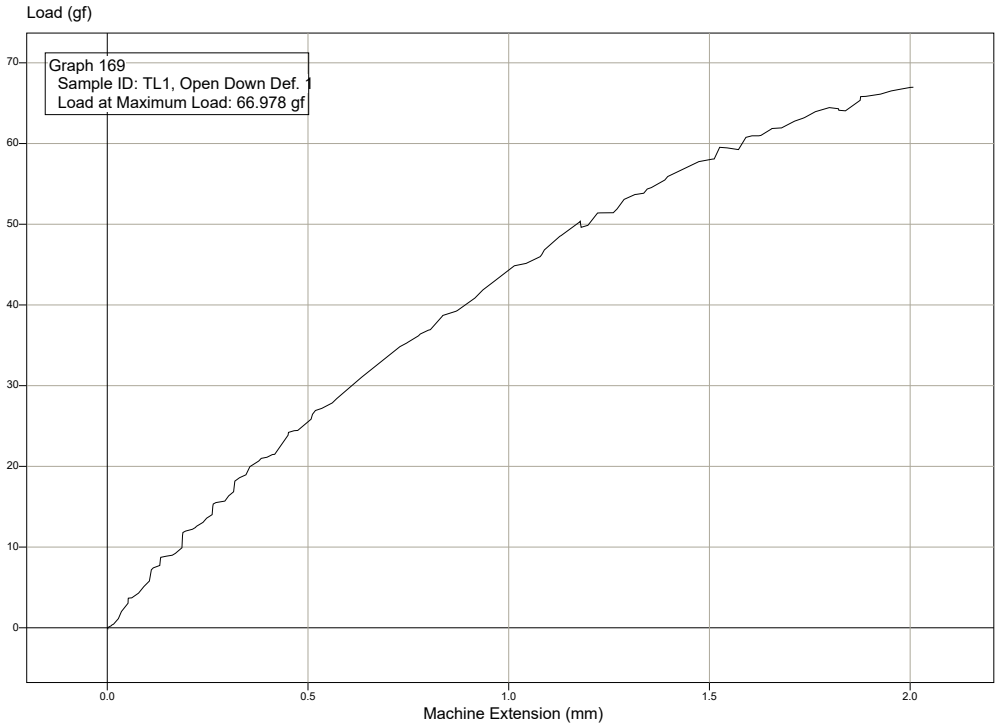
Graph 167


Load (gf)
Graph 167
Sample ID: TL1, Opening up Def. 2
Load at Maximum Load: 91.430 gf
100
90
80
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

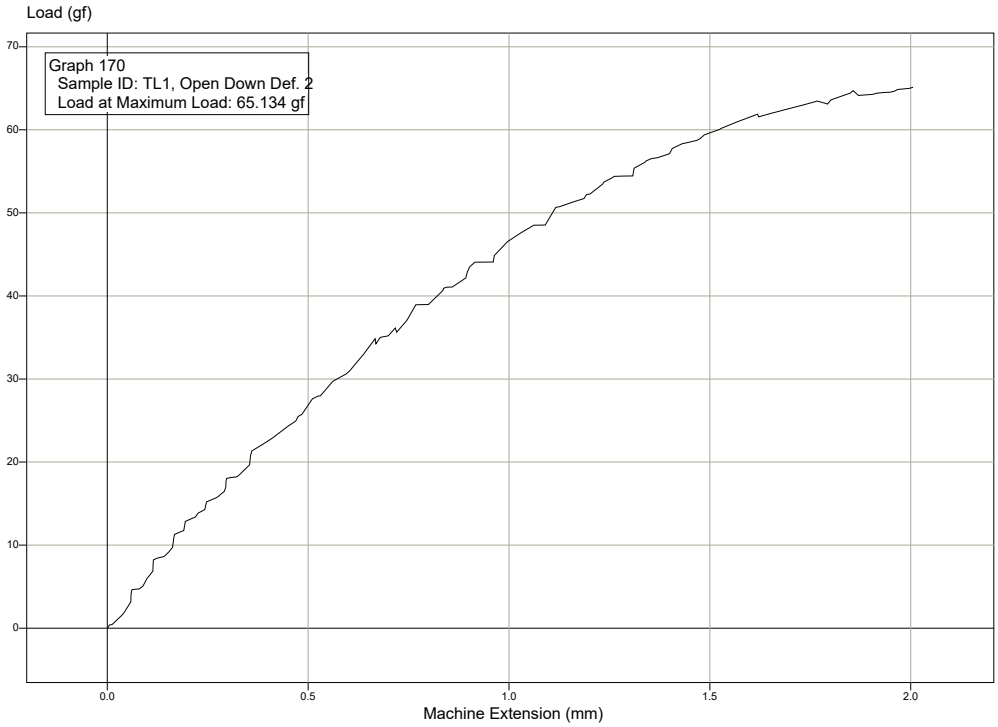
Graph 168



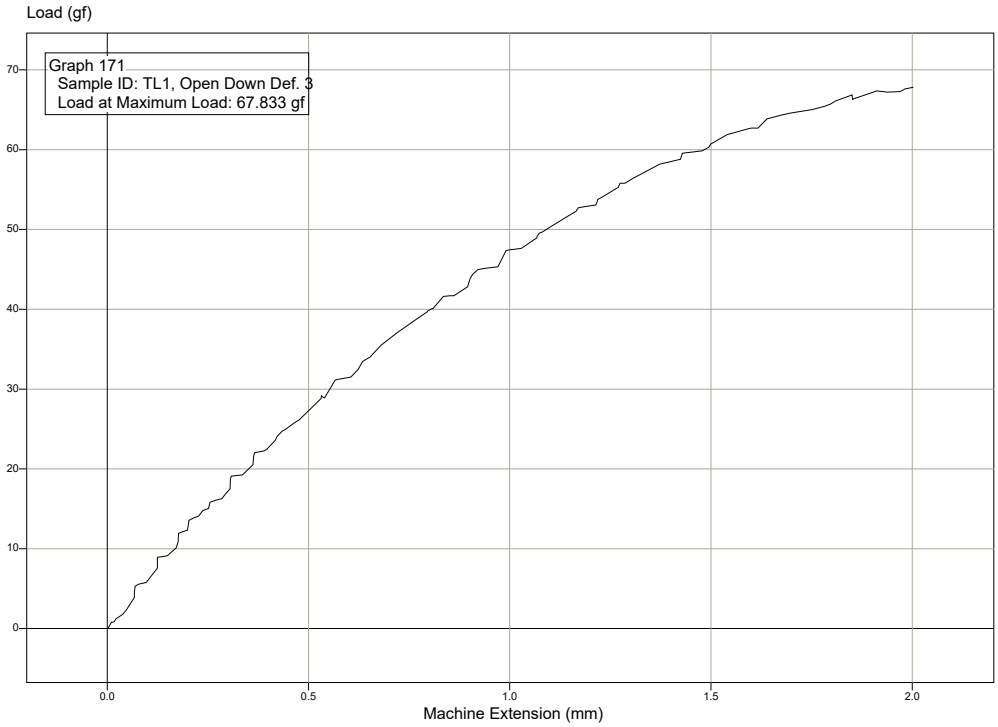
Graph 169


Load (gf)
Graph 169
Sample ID: TL1, Open Down Def. 1
Load at Maximum Load: 66.978 gf
70
60
50
40
30
20
10
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

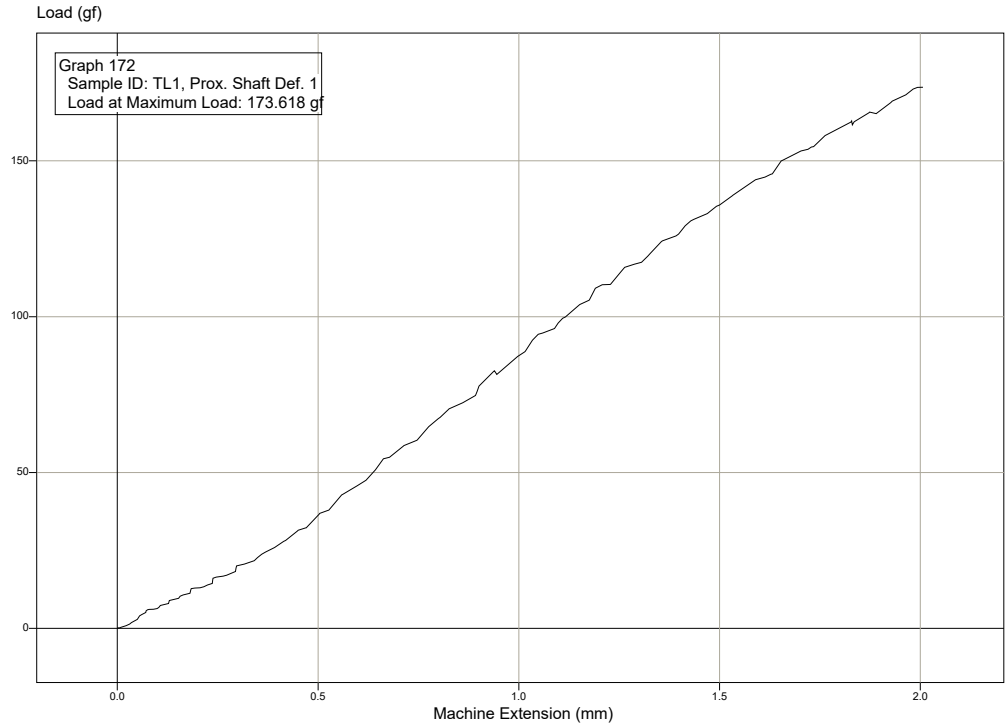
Graph 170



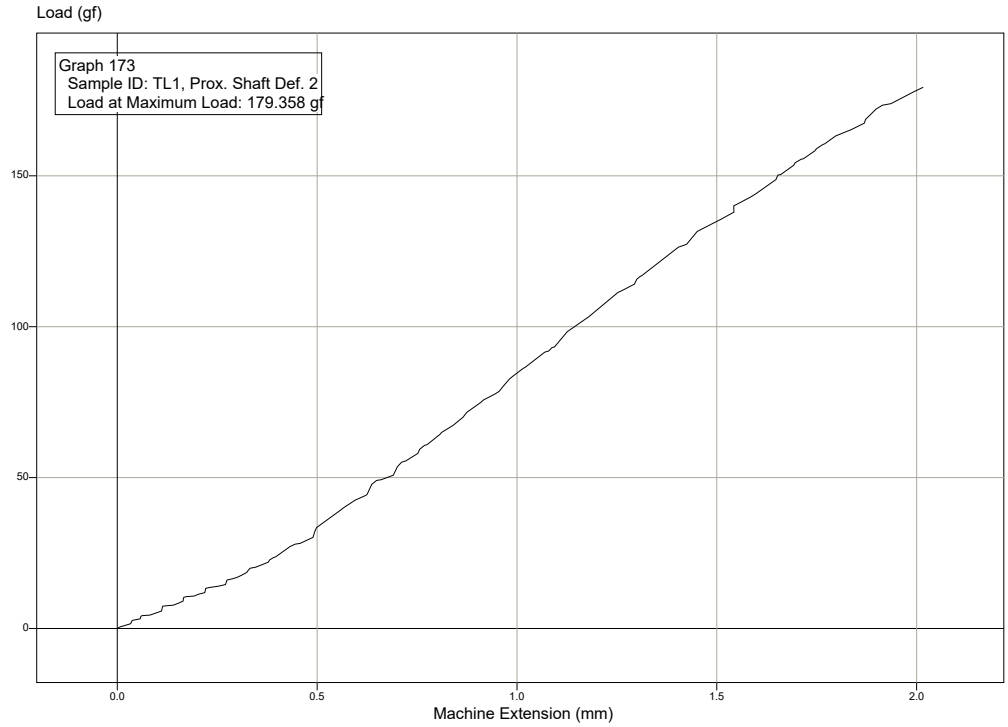
Graph 171



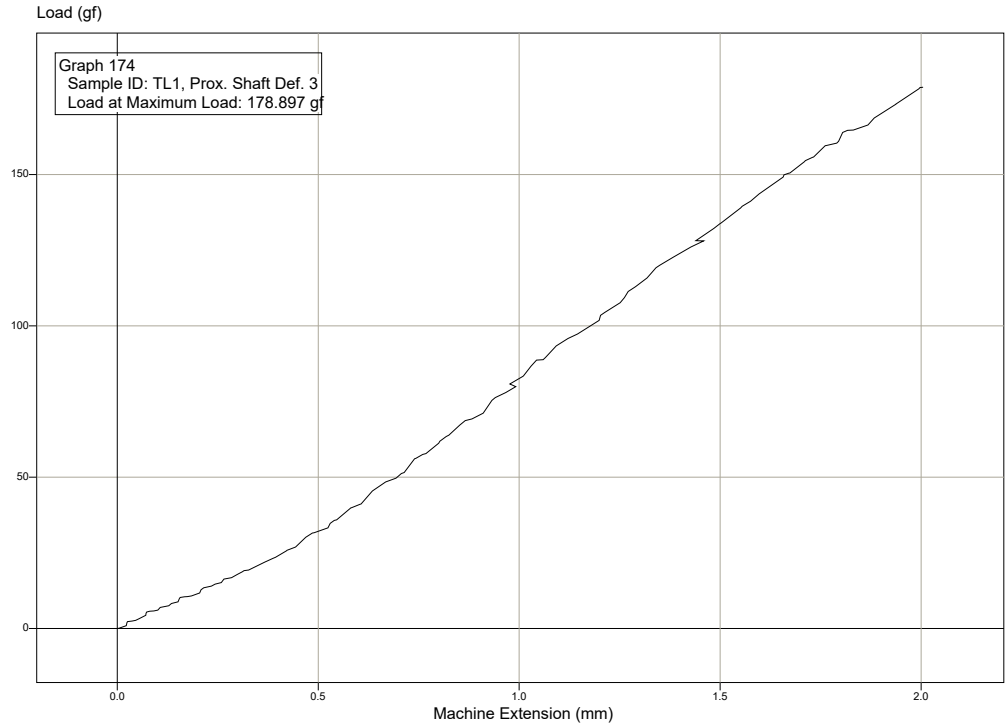
Graph 172


Load (gf)
Graph 172
Sample ID: TL1, Prox. Shaft Def. 1
Load at Maximum Load: 173.618 gf
150
100
50
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

Graph 173


Load (gf)
Graph 173
Sample ID: TL1, Prox. Shaft Def. 2
Load at Maximum Load: 179.358 gf
150
100
50
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

Graph 174


Load (gf)
Graph 174
Sample ID: TL1, Prox. Shaft Def. 3
Load at Maximum Load: 178.897 gf
150
100
50
0
0.0
0.5
1.0
1.5
2.0
Machine Extension (mm)

Sample ID (shorthand)	Detailed Sample description	Detailed Test description	Run	Load at Maximum Load (grams force) rounded	Notes	Average of 3 runs (grams force)
GL3 2 - Dist. Tip Crush 1	GL V3 (6F) Samp 2	Distal tip (unsupported) crush	1	21.23		
GL3 2 - Dist. Tip Crush 2		test ("Crush 1")	2	22.27		22.14
GL3 2 - Dist. Tip Crush 3			3	22.91		
GL3 2 - Yellow Crush 2		Distal portion of reinforced distal	2	136.93	run 1 not in good contact, rerun	
GL3 2 - Yellow Crush 3		shaft crush test ("Crush 2")	3	135.22		135.84
GL3 2 - Yellow Crush 4			4	135.37		
GL3 2 - Blue Crush 1		Proximal portion of reinforced	1	195.29		
GL3 2 - Blue Crush 2		distal shaft crush test ("Crush	2	203.89		200.45
GL3 2 - Blue Crush 3		3")	3	202.18		
GX3 - Dits. Tip Crush 2*	QXM (6F) Samp 3	Distal tip (unsupported) crush	2	49.95	run 1 not in good contact, rerun	
GX3 - Dits. Tip Crush 3*		test ("Crush 1")	3	51.76	*should be QX3	51.24
GX3 - Dits. Tip Crush 4*			4	52.02		
GX3 - Really Dist. Tip Crush 1*		Distal tip (unsupported) crush	1	42.19	Previous 3 runs re-done, as fixture	
GX3 - Really Dist. Tip Crush 2*		test ("Crush 1")	2	44.21	noted to be too close to marker band	43.12
GX3 - Really Dist. Tip Crush 3*			3	42.95	*should be QX3	
GX3 - Green Crush 1*		Distal portion of reinforced distal	1	115.66	*should be QX3	
GX3 - Green Crush 2*		shaft crush test ("Crush 2")	2	125.68		122.27
GX3 - Green Crush 3*			3	125.47		
GX3 - Blue Crush 1*		Proximal portion of reinforced	1	160.43	*should be QX3	
GX3 - Blue Crush 2*		distal shaft crush test ("Crush	2	166.82		163.44
GX3 - Blue Crush 3*		3")	3	163.09		
GLV1 1 - Tip Crush 1	GL V1 (6F) Samp 1	Distal tip (unsupported) crush	1	12.35		
GLV1 1 - Tip Crush 2		test ("Crush 1")	2	11.95		12.50
GLV1 1 - Tip Crush 3			3	13.21		
GLV1 1 - Yellow Crush 1		Distal portion of reinforced distal	1	116.93		
GLV1 1 - Yellow Crush 2		shaft crush test ("Crush 2")	2	113.67		113.58
GLV1 1 - Yellow Crush 3			3	110.12		
GLV1 1 - Blue Crush 1		Proximal portion of reinforced	1	210.98		
GLV1 1 - Blue Crush 2		distal shaft crush test ("Crush	2	226.12		220.54
GLV1 1 - Blue Crush 3		3")	3	224.52		
GLV2 1 - Dist. Tip Crush 1	GL V2 (6F) Samp 1	Distal tip (unsupported) crush	1	14.43		
GLV2 1 - Dist. Tip Crush 2		test ("Crush 1")	2	14.92		14.41

GLV2 1 - Dist. Tip Crush 3			3	13.88		
GLV2 1 - Yellow Crush 1		Distal portion of reinforced distal	1	117.59		
GLV2 1 - Yellow Crush 2		shaft crush test ("Crush 2")	2	125.54		121.81
GLV2 1 - Yellow Crush 3			3	122.31		
GLV2 1 - Blue Crush 2		Proximal portion of reinforced	1	186.18		
GLV2 1 - Blue Crush 3		distal shaft crush test ("Crush	2	184.75		186.16
GLV2 1 - Blue Crush 4		3")	3	187.56		
GZ1 1 - Tip Crush 1	GZ V1 (6F) Samp 1	Distal tip (unsupported) crush	1	9.72		
GZ1 1 - Tip Crush 2		test ("Crush 1")	2	11.63		11.31
GZ1 1 - Tip Crush 3			3	12.57		
GZ1 1 - Dist. Tube Crush 1		Distal portion of reinforced distal	1	79.08		
GZ1 1 - Dist. Tube Crush 2		shaft crush test ("Crush 2")	2	82.91		82.59
GZ1 1 - Dist. Tube Crush 3			3	85.78		
GZ1 1 - Prox. Tube Crush 1		Proximal portion of reinforced	1	139.28	low due to poor initial contact	
GZ1 1 - Prox. Tube Crush 2		distal shaft crush test ("Crush	2	149.44		141.83
GZ1 1 - Prox. Tube Crush 3		3")	3	136.78	low due to poor initial contact	
QXSC 2 - Tip Crush 1	QXM (SCH) (6F) Samp 2	Distal tip (unsupported) crush	1	35.96		
QXSC 2 - Tip Crush 2		test ("Crush 1")	2	39.34		38.07
QXSC 2 - Tip Crush 3			3	38.90		
QXSC 2 - Green Crush 1		Distal portion of reinforced distal	1	132.41		
QXSC 2 - Green Crush 2		shaft crush test ("Crush 2")	2	132.95		134.49
QXSC 2 - Green Crush 3			3	138.10		
QXSC 2 - Blue Crush 1		Proximal portion of reinforced	1	137.64		
QXSC 2 - Blue Crush 2		distal shaft crush test ("Crush	2	128.50		132.81
QXSC 2 - Blue Crush 3		3")	3	132.29		
QXSC 3 - Tip Crush 1	QXM (SCH) (6F) Samp 3	Distal tip (unsupported) crush	1	53.58		
QXSC 3 - Tip Crush 2		test ("Crush 1")	2	52.44		53.21
QXSC 3 - Tip Crush 3			3	53.60		
QXSC 3 - Green Crush 1		Distal portion of reinforced distal	1	109.12		
QXSC 3 - Green Crush 2		shaft crush test ("Crush 2")	2	112.42		111.00
QXSC 3 - Green Crush 3			3	111.45		
QXSC 3 - Blue Crush 1		Proximal portion of reinforced	1	118.72		
QXSC 3 - Blue Crush 2		distal shaft crush test ("Crush	2	129.26		123.71
QXSC 3 - Blue Crush 3		3")	3	123.16		

QX8F - Tip Crush 1	QXM (8F) Samp 1	Distal tip (unsupported) crush	1	38.62		
QX8F - Tip Crush 2		test ("Crush 1")	2	40.14		39.52
QX8F - Tip Crush 3			3	39.78		
QX8F - Green Crush 1		Distal portion of reinforced distal	1	95.73		
QX8F - Green Crush 2		shaft crush test ("Crush 2")	2	98.77		98.17
QX8F - Green Crush 3			3	100.01		
QX8F - Blue Crush 1		Proximal portion of reinforced	1	117.76	low due to poor initial contact	
QX8F - Blue Crush 2		distal shaft crush test ("Crush	2	124.18	low due to poor initial contact	123.57
QX8F - Blue Crush 3		3")	3	128.76		
GL38F - Tip Crush 1	GL V3 (8F) Samp 1	Distal tip (unsupported) crush	1	9.26		
GL38F - Tip Crush 2		test ("Crush 1")	2	9.94		9.72
GL38F - Tip Crush 3			3	9.97		
GL38F - Yellow Crush 1		Distal portion of reinforced distal	1	90.96	low due to poor initial contact	
GL38F - Yellow Crush 2		shaft crush test ("Crush 2")	2	106.50		99.74
GL38F - Yellow Crush 1**			3	101.76	**should be labeled run 3	
GL38F - Blue Crush 1		Proximal portion of reinforced	1	167.37		
GL38F - Blue Crush 2		distal shaft crush test ("Crush	2	158.12		163.88
GL38F - Blue Crush 3		3")	3	166.14		
GZ2 1 - Tip Crush 1	GZ V2 (6F) Samp 1	Distal tip (unsupported) crush	1	10.47		
GZ2 1 - Tip Crush 2		test ("Crush 1")	2	10.95		11.34
GZ2 1 - Tip Crush 3			3	12.61		
GZ2 1 - Dist. Tube Crush 1		Distal portion of reinforced distal	1	93.34		
GZ2 1 - Dist. Tube Crush 2		shaft crush test ("Crush 2")	2	105.61		101.34
GZ2 1 - Dist. Tube Crush 3			3	105.06		
GZ2 1 - Prox. Tube Crush 1		Proximal portion of reinforced	1	145.63		
GZ2 1 - Prox. Tube Crush 2		distal shaft crush test ("Crush	2	154.25		151.68
GZ2 1 - Prox. Tube Crush 3		3")	3	155.16		
TL1 - Dist. Tip Crush 1	TL (6F) Samp 1	Distal tip (unsupported) crush	1	17.46		
TL1 - Dist. Tip Crush 2		test ("Crush 1")	2	18.34		18.30
TL1 - Dist. Tip Crush 3			3	19.11		
TL1 - Yellow Crush 1		Distal portion of reinforced distal	1	134.66		
TL1 - Yellow Crush 2		shaft crush test ("Crush 2")	2	139.07		138.74
TL1 - Yellow Crush 3			3	142.48		
TL1 - Blue Crush 1		Proximal portion of reinforced	1	174.11		

TL1 - Blue Crush 2	distal shaft crush test ("Crush	2	177.19	176.06
TL1 - Blue Crush 3	3")	3	176.88	

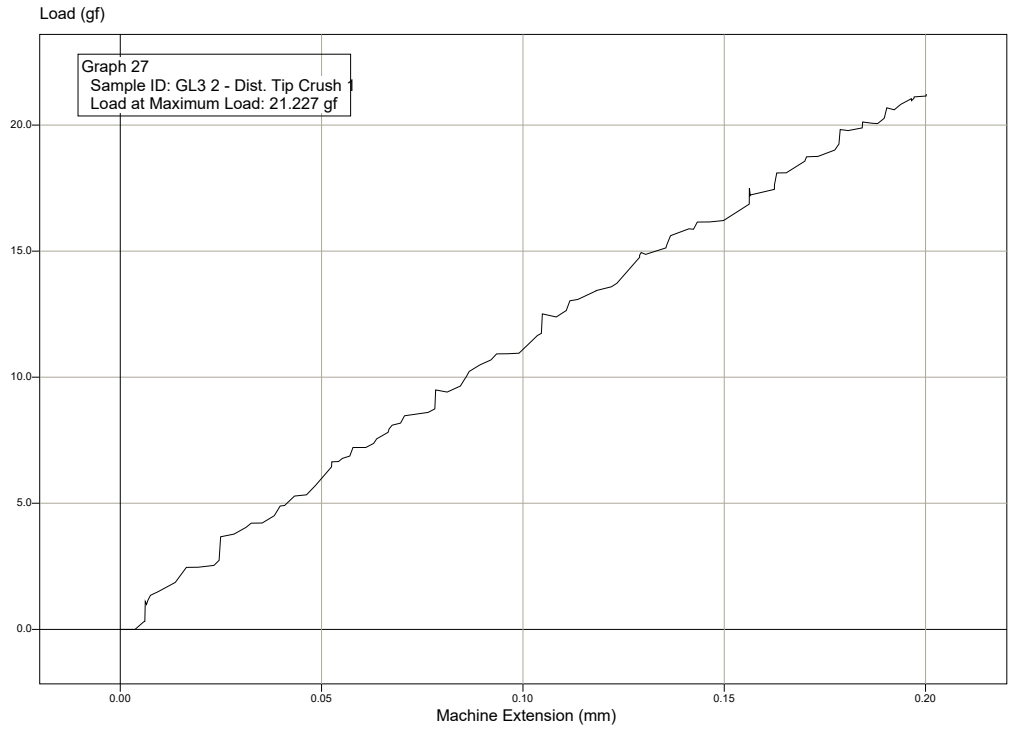
Crush Testing

This report contains the data from the various crush tests performed in order to evaluate guide extension catheters

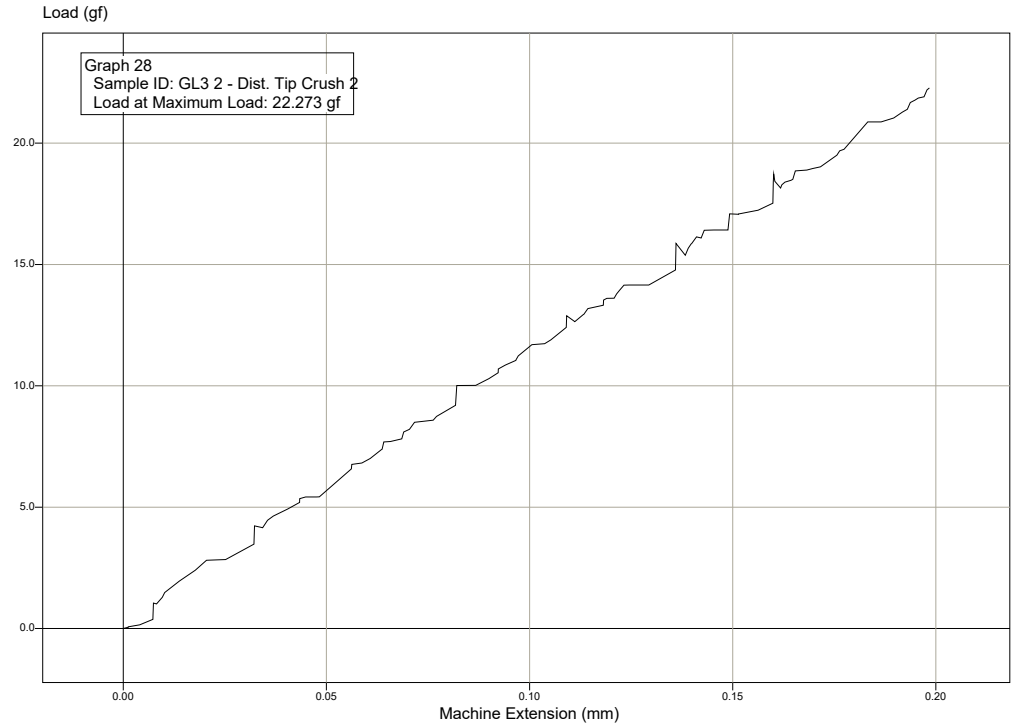
Sample ID	Speed	Limit	Load at Maximum Load
GL3 2 - Dist. Tip Crush 1	0.0100 mm/s	0.20000 mm	21.227 gf
GL3 2 - Dist. Tip Crush 2	0.0100 mm/s	0.20000 mm	22.273 gf
GL3 2 - Dist. Tip Crush 3	0.0100 mm/s	0.20000 mm	22.905 gf
GL3 2 - Yellow Crush 2	0.0100 mm/s	0.20000 mm	136.927 gf
GL3 2 - Yellow Crush 3	0.0100 mm/s	0.20000 mm	135.215 gf
GL3 2 - Yellow Crush 4	0.0100 mm/s	0.20000 mm	135.374 gf
GL3 2 - Blue Crush 1	0.0100 mm/s	0.20000 mm	195.292 gf
GL3 2 - Blue Crush 2	0.0100 mm/s	0.20000 mm	203.887 gf
GL3 2 - Blue Crush 3	0.0100 mm/s	0.20000 mm	202.175 gf
GX3 - Dits. Tip Crush 2	0.0100 mm/s	0.20000 mm	49.947 gf
GX3 - Dits. Tip Crush 3	0.0100 mm/s	0.20000 mm	51.762 gf
GX3 - Dits. Tip Crush 4	0.0100 mm/s	0.20000 mm	52.023 gf
GX3 - Really Dist. Tip Crush 1	0.0100 mm/s	0.20000 mm	42.194 gf
GX3 - Really Dist. Tip Crush 2	0.0100 mm/s	0.20000 mm	44.210 gf
GX3 - Really Dist. Tip Crush 3	0.0100 mm/s	0.20000 mm	42.948 gf
GX3 - Green Crush 1	0.0100 mm/s	0.20000 mm	115.655 gf
GX3 - Green Crush 2	0.0100 mm/s	0.20000 mm	125.677 gf
GX3 - Green Crush 3	0.0100 mm/s	0.20000 mm	125.466 gf
GX3 - Blue Crush 1	0.0100 mm/s	0.20000 mm	160.425 gf
GX3 - Blue Crush 2	0.0100 mm/s	0.20000 mm	166.820 gf
GX3 - Blue Crush 3	0.0100 mm/s	0.20000 mm	163.087 gf
GLV1 1 - Tip Crush 1	0.0100 mm/s	0.20000 mm	12.353 gf
GLV1 1 - Tip Crush 2	0.0100 mm/s	0.20000 mm	11.945 gf
GLV1 1 - Tip Crush 3	0.0100 mm/s	0.20000 mm	13.214 gf
GLV1 1 - Yellow Crush 1	0.0100 mm/s	0.20000 mm	116.930 gf
GLV1 1 - Yellow Crush 2	0.0100 mm/s	0.20000 mm	113.673 gf
GLV1 1 - Yellow Crush 3	0.0100 mm/s	0.20000 mm	110.124 gf
GLV1 1 - Blue Crush 1	0.0100 mm/s	0.20000 mm	210.984 gf
GLV1 1 - Blue Crush 2	0.0100 mm/s	0.20000 mm	226.121 gf
GLV1 1 - Blue Crush 3	0.0100 mm/s	0.20000 mm	224.519 gf
GLV2 1 - Dist. Tip Crush 1	0.0100 mm/s	0.20000 mm	14.432 gf
GLV2 1 - Dist. Tip Crush 2	0.0100 mm/s	0.20000 mm	14.915 gf
GLV2 1 - Dist. Tip Crush 3	0.0100 mm/s	0.20000 mm	13.882 gf
GLV2 1 - Yellow Crush 1	0.0100 mm/s	0.20000 mm	117.591 gf
GLV2 1 - Yellow Crush 2	0.0100 mm/s	0.20000 mm	125.544 gf
GLV2 1 - Yellow Crush 3	0.0100 mm/s	0.20000 mm	122.305 gf
GLV2 1 - Blue Crush 2	0.0100 mm/s	0.20000 mm	186.181 gf
GLV2 1 - Blue Crush 3	0.0100 mm/s	0.20000 mm	184.746 gf
GLV2 1 - Blue Crush 4	0.0100 mm/s	0.20000 mm	187.557 gf
GZ1 1 - Tip Crush 1	0.0100 mm/s	0.20000 mm	9.722 gf
GZ1 1 - Tip Crush 2	0.0100 mm/s	0.20000 mm	11.627 gf
GZ1 1 - Tip Crush 3	0.0100 mm/s	0.20000 mm	12.566 gf
GZ1 1 - Dist. Tube Crush 1	0.0100 mm/s	0.20000 mm	79.083 gf
GZ1 1 - Dist. Tube Crush 2	0.0100 mm/s	0.20000 mm	82.911 gf
GZ1 1 - Dist. Tube Crush 3	0.0100 mm/s	0.20000 mm	85.784 gf
GZ1 1 - Prox. Tube Crush 1	0.0100 mm/s	0.20000 mm	139.277 gf

GZ1 1 - Prox. Tube Crush 2	0.0100 mm/s	0.20000 mm	149.438 gf
GZ1 1 - Prox. Tube Crush 3	0.0100 mm/s	0.20000 mm	136.780 gf
QXSC 2 - Tip Crush 1	0.0100 mm/s	0.20000 mm	35.964 gf
QXSC 2 - Tip Crush 2	0.0100 mm/s	0.20000 mm	39.335 gf
QXSC 2 - Tip Crush 3	0.0100 mm/s	0.20000 mm	38.902 gf
QXSC 2 - Green Crush 1	0.0100 mm/s	0.20000 mm	132.406 gf
QXSC 2 - Green Crush 2	0.0100 mm/s	0.20000 mm	132.951 gf
QXSC 2 - Green Crush 3	0.0100 mm/s	0.20000 mm	138.104 gf
QXSC 2 - Blue Crush 1	0.0100 mm/s	0.20000 mm	137.644 gf
QXSC 2 - Blue Crush 2	0.0100 mm/s	0.20000 mm	128.501 gf
QXSC 2 - Blue Crush 3	0.0100 mm/s	0.20000 mm	132.290 gf
QXSC 3 - Tip Crush 1	0.0100 mm/s	0.20000 mm	53.579 gf
QXSC 3 - Tip Crush 2	0.0100 mm/s	0.20000 mm	52.439 gf
QXSC 3 - Tip Crush 3	0.0100 mm/s	0.20000 mm	53.604 gf
QXSC 3 - Green Crush 1	0.0100 mm/s	0.20000 mm	109.124 gf
QXSC 3 - Green Crush 2	0.0100 mm/s	0.20000 mm	112.418 gf
QXSC 3 - Green Crush 3	0.0100 mm/s	0.20000 mm	111.447 gf
QXSC 3 - Blue Crush 1	0.0100 mm/s	0.20000 mm	118.715 gf
QXSC 3 - Blue Crush 2	0.0100 mm/s	0.20000 mm	129.259 gf
QXSC 3 - Blue Crush 3	0.0100 mm/s	0.20000 mm	123.160 gf
QX8F - Tip Crush 1	0.0100 mm/s	0.20000 mm	38.619 gf
QX8F - Tip Crush 2	0.0100 mm/s	0.20000 mm	40.144 gf
QX8F - Tip Crush 3	0.0100 mm/s	0.20000 mm	39.784 gf
QX8F - Green Crush 1	0.0100 mm/s	0.20000 mm	95.725 gf
QX8F - Green Crush 2	0.0100 mm/s	0.20000 mm	98.765 gf
QX8F - Green Crush 3	0.0100 mm/s	0.20000 mm	100.014 gf
QX8F - Blue Crush 1	0.0100 mm/s	0.20000 mm	117.764 gf
QX8F - Blue Crush 2	0.0100 mm/s	0.20000 mm	124.180 gf
QX8F - Blue Crush 3	0.0100 mm/s	0.20000 mm	128.757 gf
GL38F - Tip Crush 1	0.0100 mm/s	0.20000 mm	9.258 gf
GL38F - Tip Crush 2	0.0100 mm/s	0.20000 mm	9.935 gf
GL38F - Tip Crush 3	0.0100 mm/s	0.20000 mm	9.969 gf
GL38F - Yellow Crush 1	0.0100 mm/s	0.20000 mm	90.962 gf
GL38F - Yellow Crush 2	0.0100 mm/s	0.20000 mm	106.504 gf
GL38F - Yellow Crush 1	0.0100 mm/s	0.20000 mm	101.759 gf
GL38F - Blue Crush 1	0.0100 mm/s	0.20000 mm	167.371 gf
GL38F - Blue Crush 2	0.0100 mm/s	0.20000 mm	158.119 gf
GL38F - Blue Crush 3	0.0100 mm/s	0.20000 mm	166.141 gf
GZ2 1 - Tip Crush 1	0.0100 mm/s	0.20000 mm	10.470 gf
GZ2 1 - Tip Crush 2	0.0100 mm/s	0.20000 mm	10.950 gf
GZ2 1 - Tip Crush 3	0.0100 mm/s	0.20000 mm	12.606 gf
GZ2 1 - Dist. Tube Crush 1	0.0100 mm/s	0.20000 mm	93.340 gf
GZ2 1 - Dist. Tube Crush 2	0.0100 mm/s	0.20000 mm	105.610 gf
GZ2 1 - Dist. Tube Crush 3	0.0100 mm/s	0.20000 mm	105.062 gf
GZ2 1 - Prox. Tube Crush 1	0.0100 mm/s	0.20000 mm	145.627 gf
GZ2 1 - Prox. Tube Crush 2	0.0100 mm/s	0.20000 mm	154.249 gf
GZ2 1 - Prox. Tube Crush 3	0.0100 mm/s	0.20000 mm	155.160 gf
TL1 - Dist. Tip Crush 1	0.0100 mm/s	0.20000 mm	17.460 gf
TL1 - Dist. Tip Crush 2	0.0100 mm/s	0.20000 mm	18.341 gf
TL1 - Dist. Tip Crush 3	0.0100 mm/s	0.20000 mm	19.107 gf
TL1 - Yellow Crush 1	0.0100 mm/s	0.20000 mm	134.664 gf
TL1 - Yellow Crush 2	0.0100 mm/s	0.20000 mm	139.071 gf
TL1 - Yellow Crush 3	0.0100 mm/s	0.20000 mm	142.477 gf
TL1 - Blue Crush 1	0.0100 mm/s	0.20000 mm	174.113 gf
TL1 - Blue Crush 2	0.0100 mm/s	0.20000 mm	177.185 gf
TL1 - Blue Crush 3	0.0100 mm/s	0.20000 mm	176.879 gf

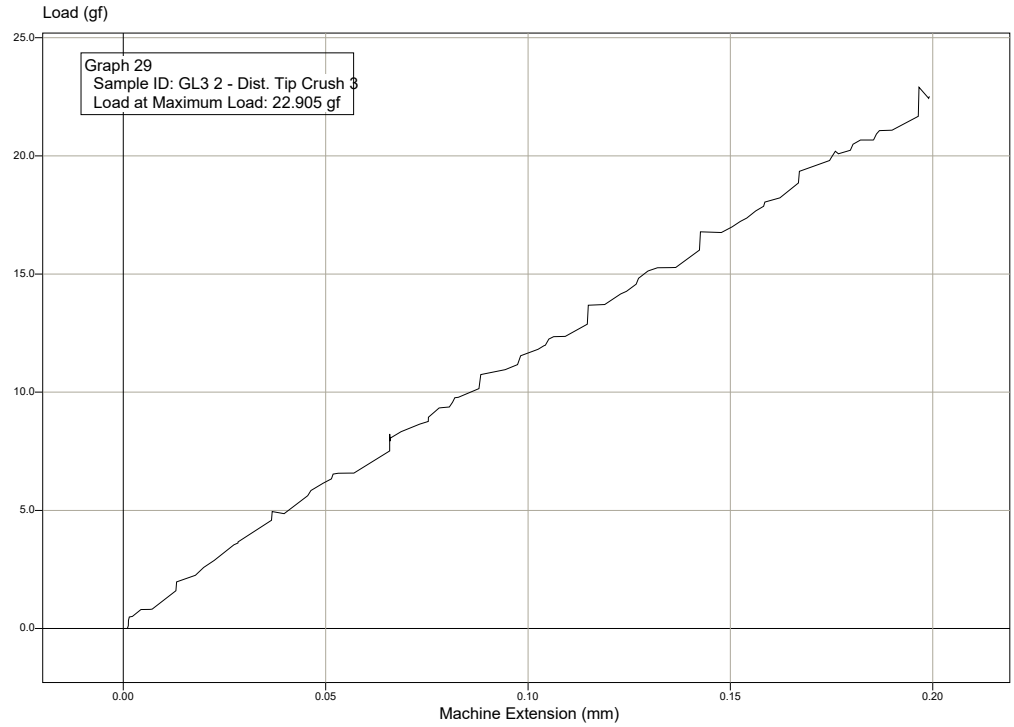
Graph 27



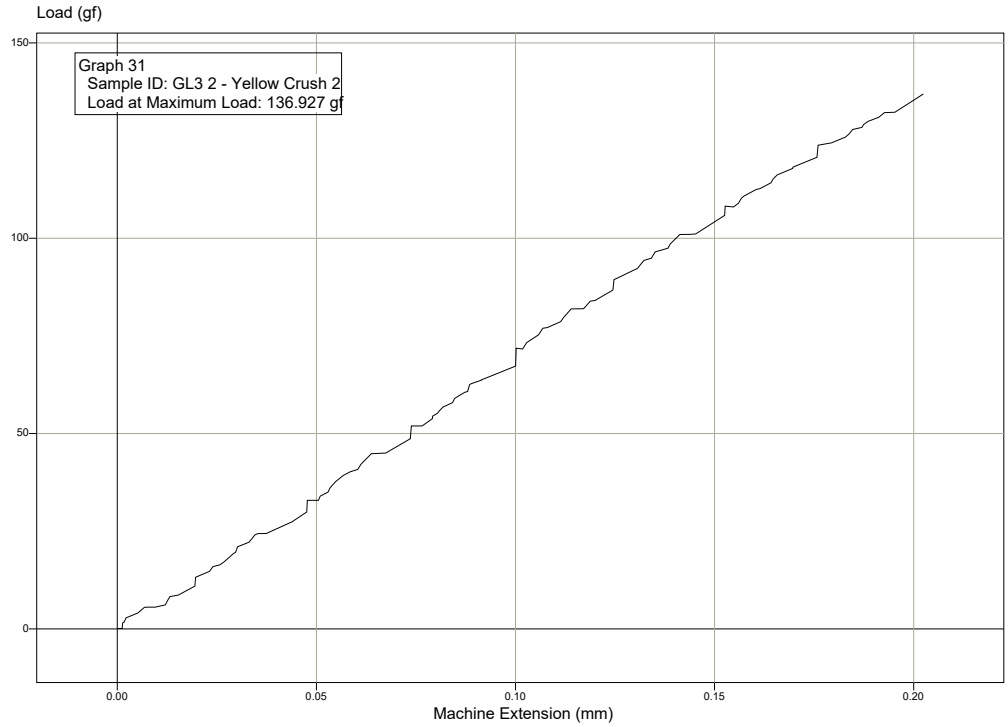
Graph 28



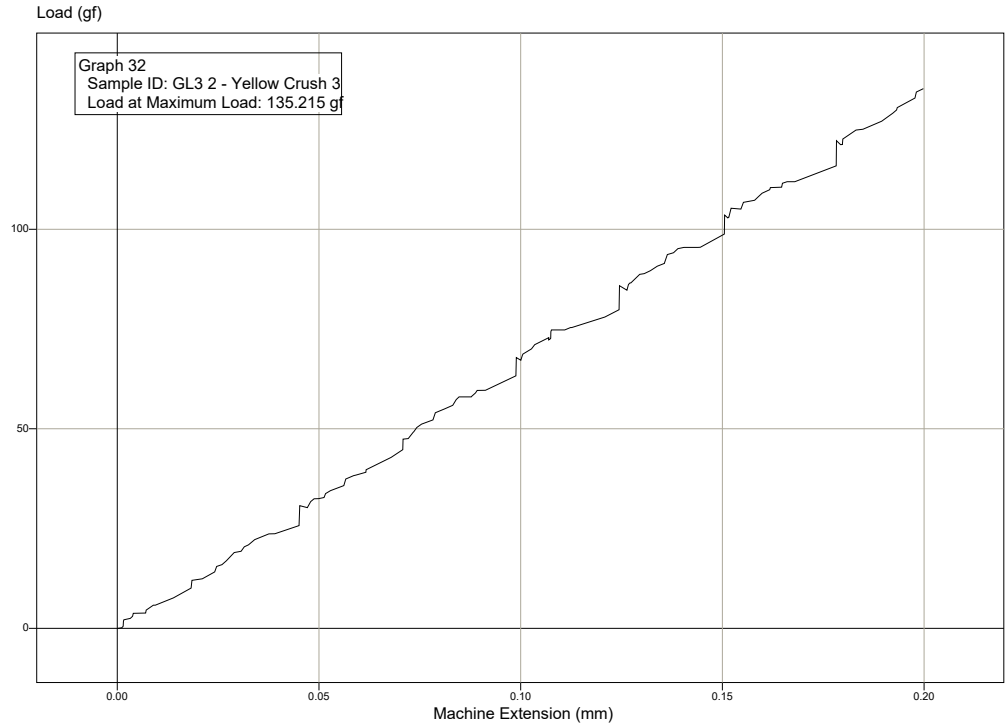
Graph 29


Load (gf)
Graph 29
Sample ID: GL3 2 - Dist. Tip Crush 3
Load at Maximum Load: 22.905 gf
25.0
20.0
15.0
10.0
5.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

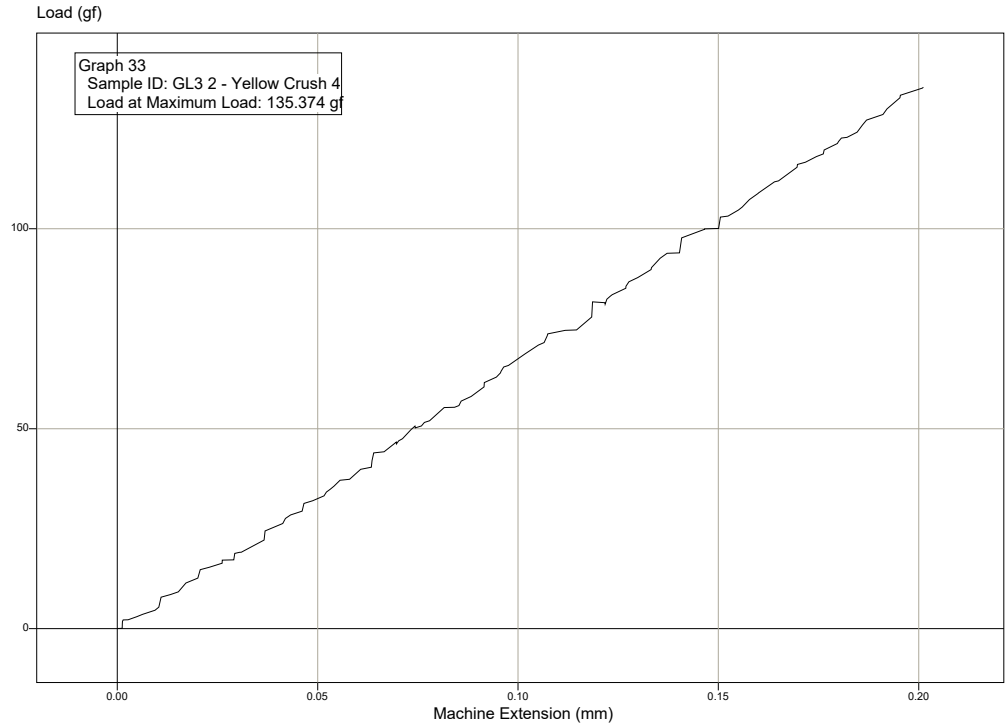
Graph 31


Load (gf)
150
100
50
0
Graph 31
Sample ID: GL3 2 - Yellow Crush 2
Load at Maximum Load: 136.927 gf
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

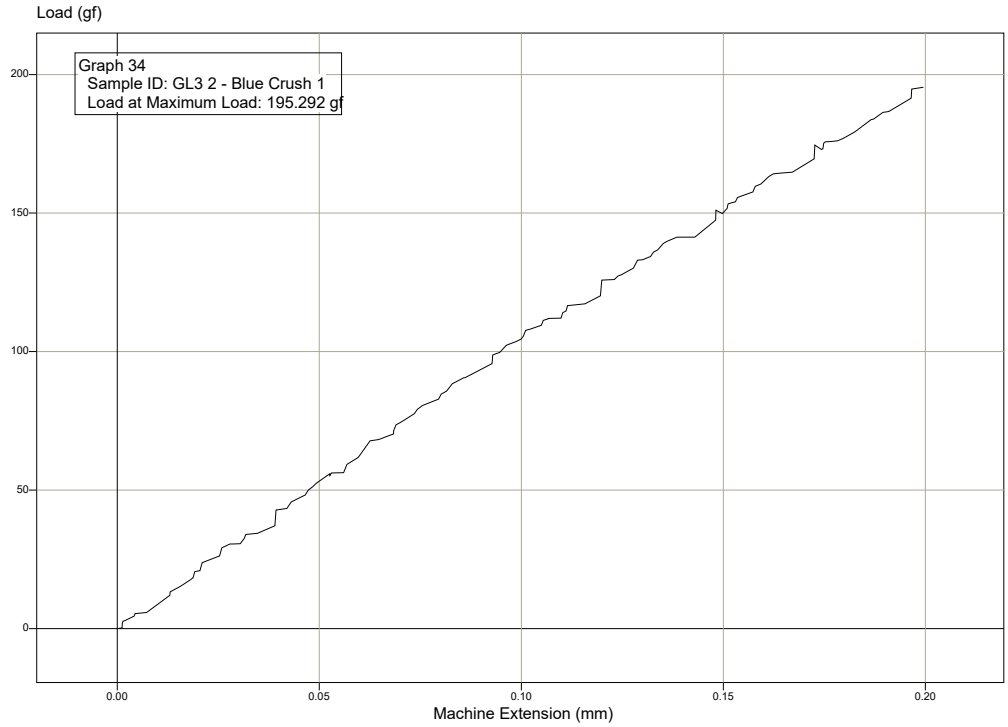
Graph 32



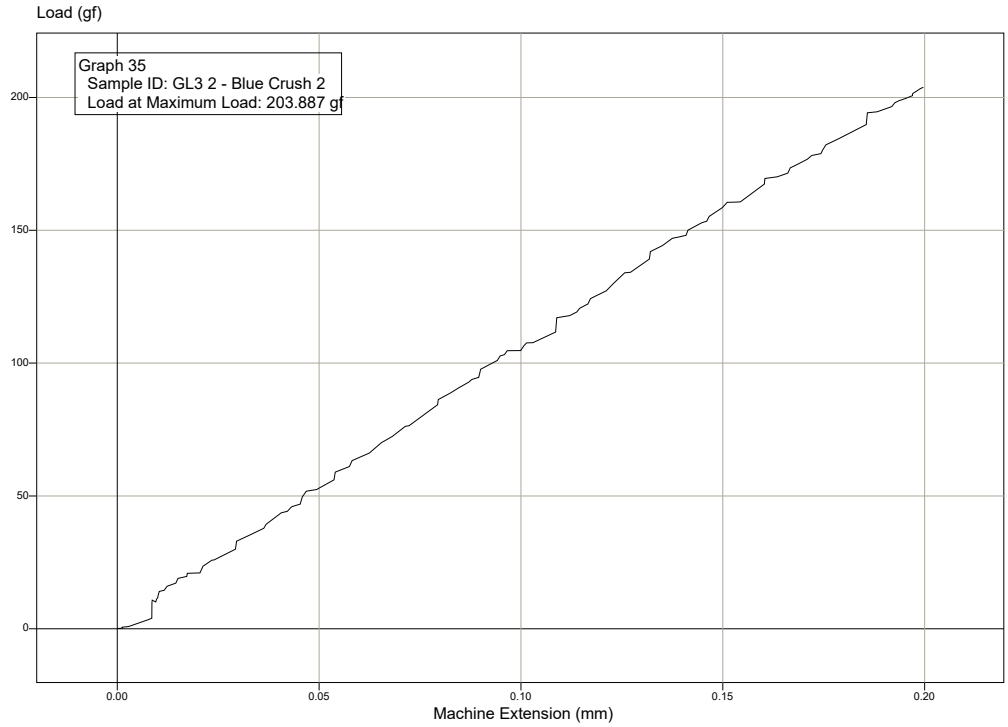
Graph 33



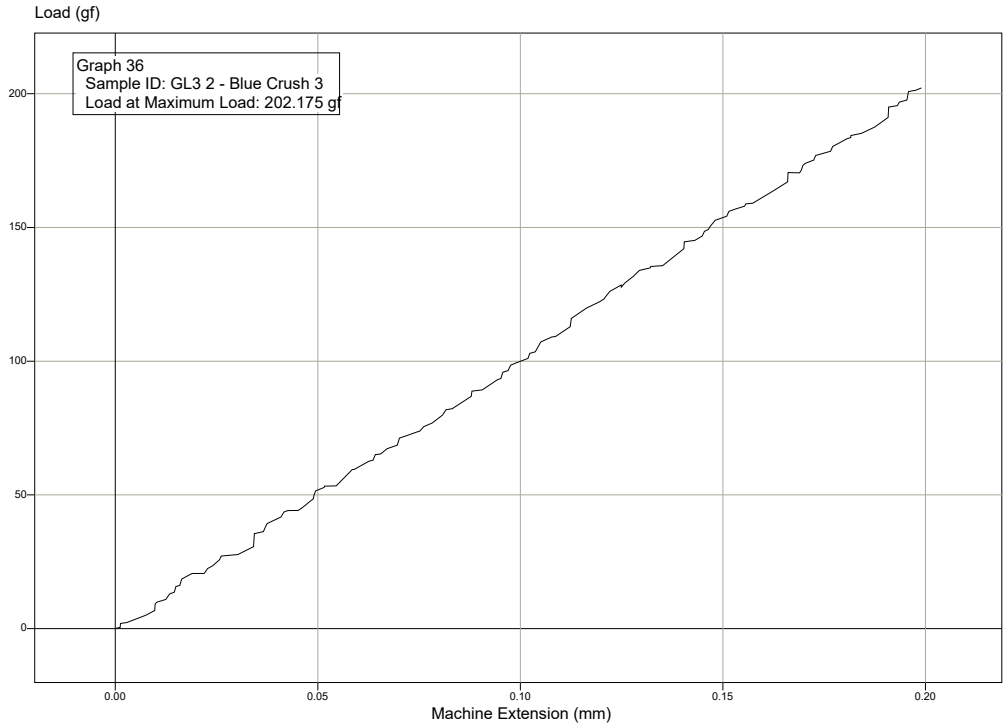
Graph 34


Load (gf)
Graph 34
Sample ID: GL3 2 - Blue Crush 1
Load at Maximum Load: 195.292 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

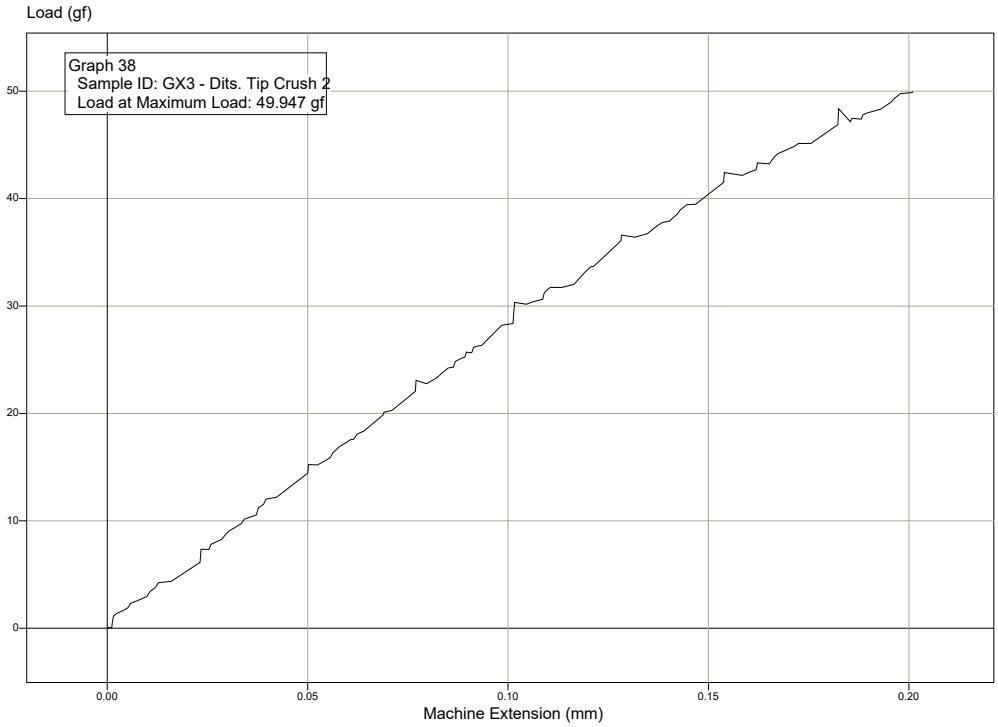
Graph 35


Load (gf)
Graph 35
Sample ID: GL3 2 - Blue Crush 2
Load at Maximum Load: 203.887 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

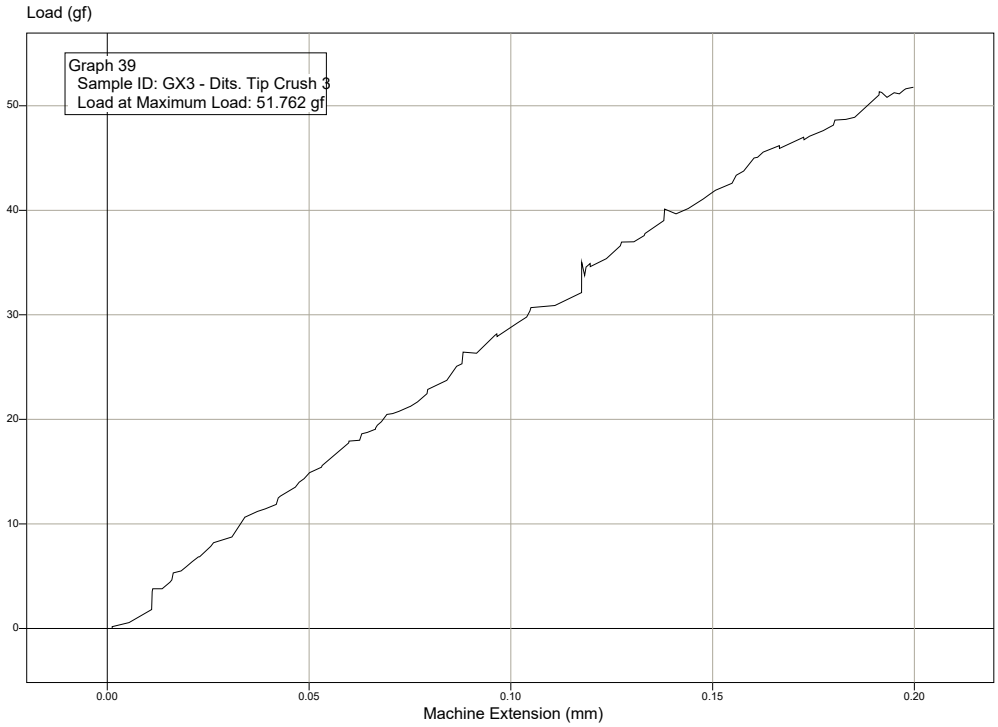
Graph 36


Load (gf)
Graph 36
Sample ID: GL3 2 - Blue Crush 3
Load at Maximum Load: 202.175 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

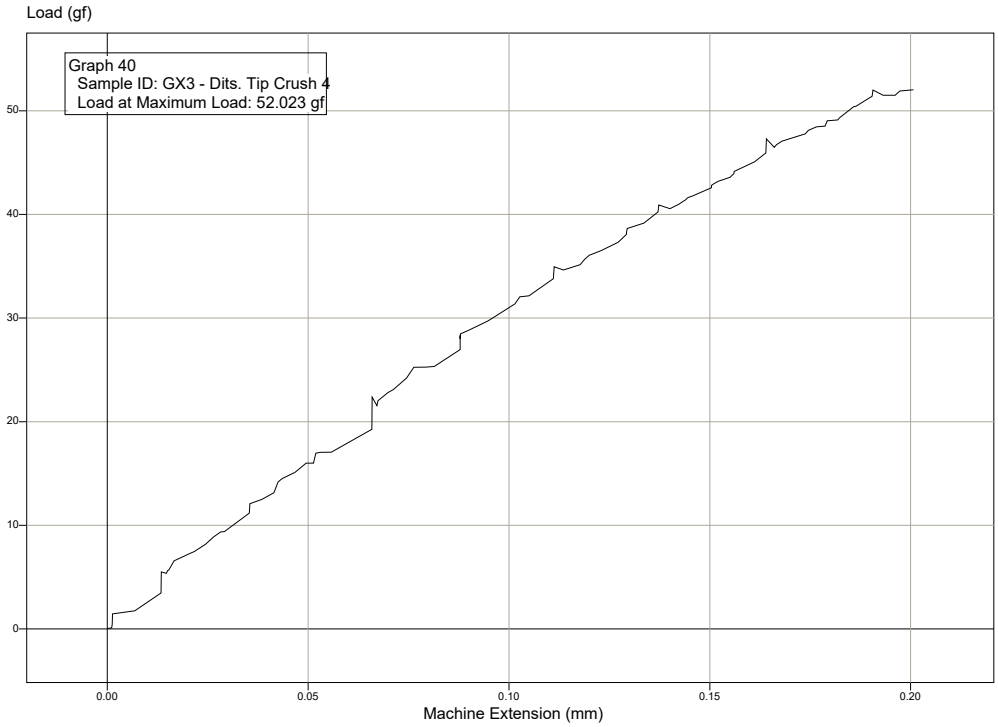
Graph 38


Load (gf)
Graph 38
Sample ID: GX3 - Dits. Tip Crush 2
Load at Maximum Load: 49.947 gf
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

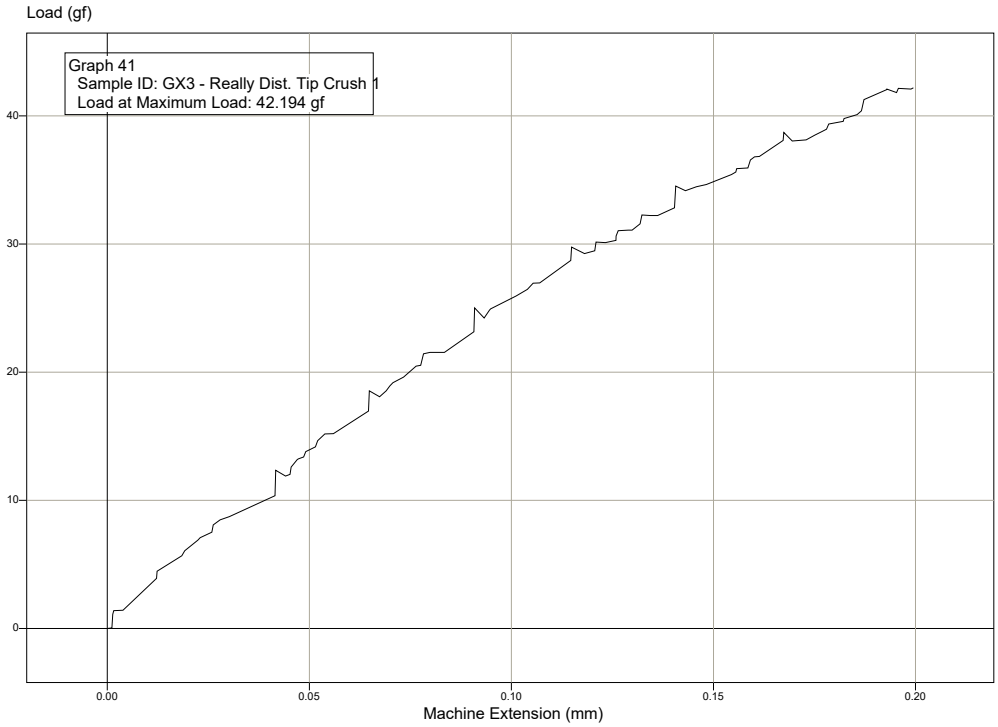
Graph 39


Load (gf)
Graph 39
Sample ID: GX3 - Dits. Tip Crush 3
Load at Maximum Load: 51.762 gf
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

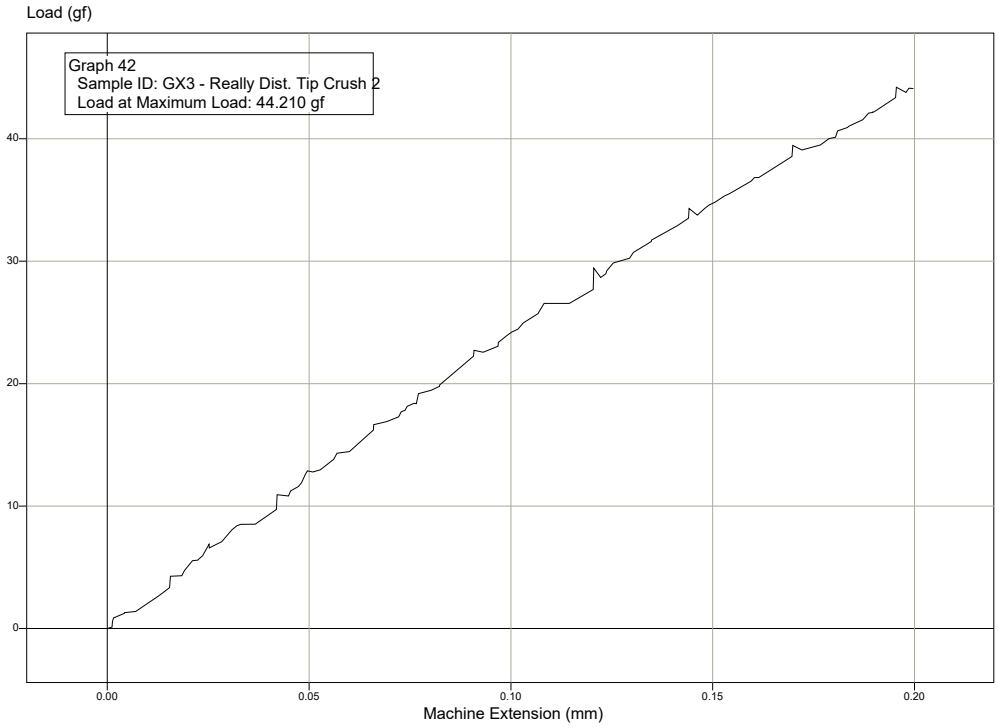
Graph 40


Load (gf)
Graph 40
Sample ID: GX3 - Dits. Tip Crush 4
Load at Maximum Load: 52.023 gf
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

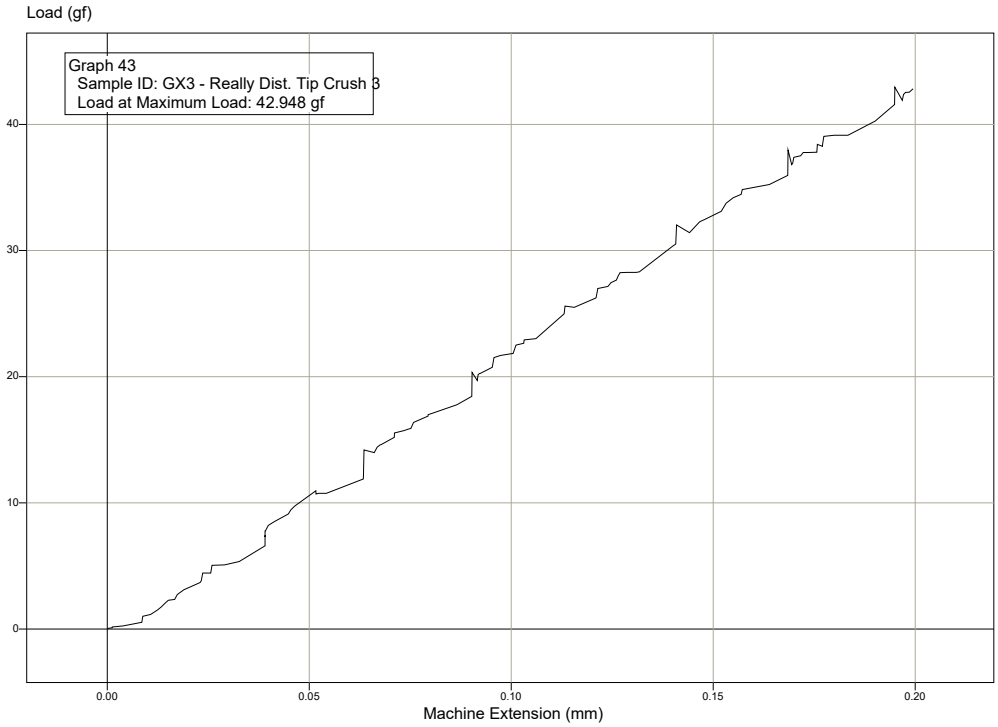
Graph 41


Load (gf)
Graph 41
Sample ID: GX3 - Really Dist. Tip Crush 1
Load at Maximum Load: 42.194 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

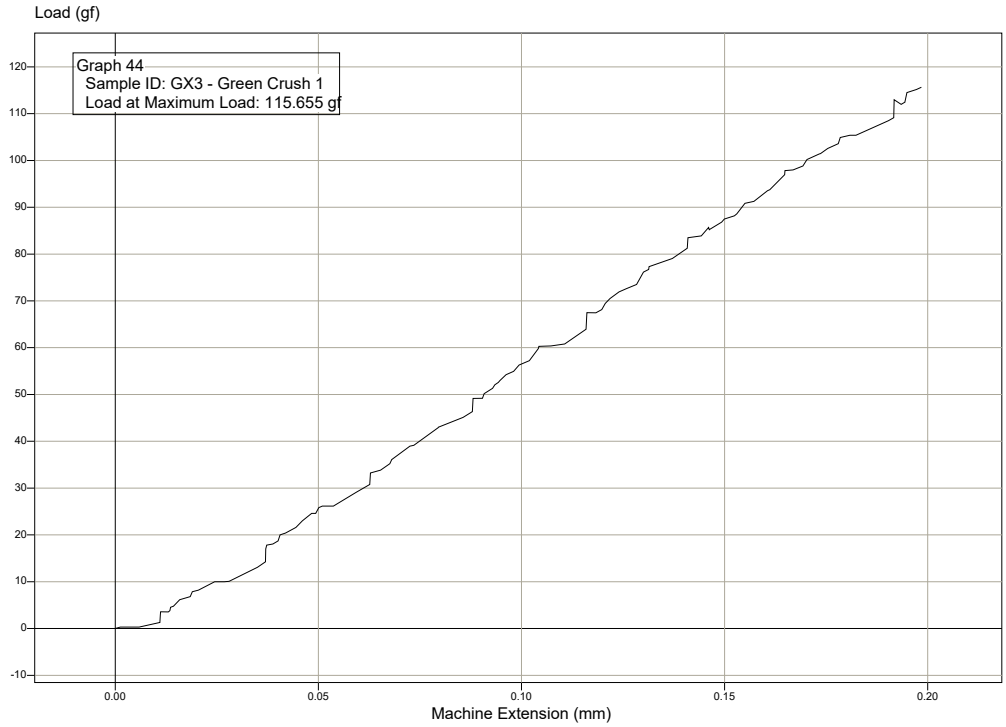
Graph 42


Load (gf)
Graph 42
Sample ID: GX3 - Really Dist. Tip Crush 2
Load at Maximum Load: 44.210 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

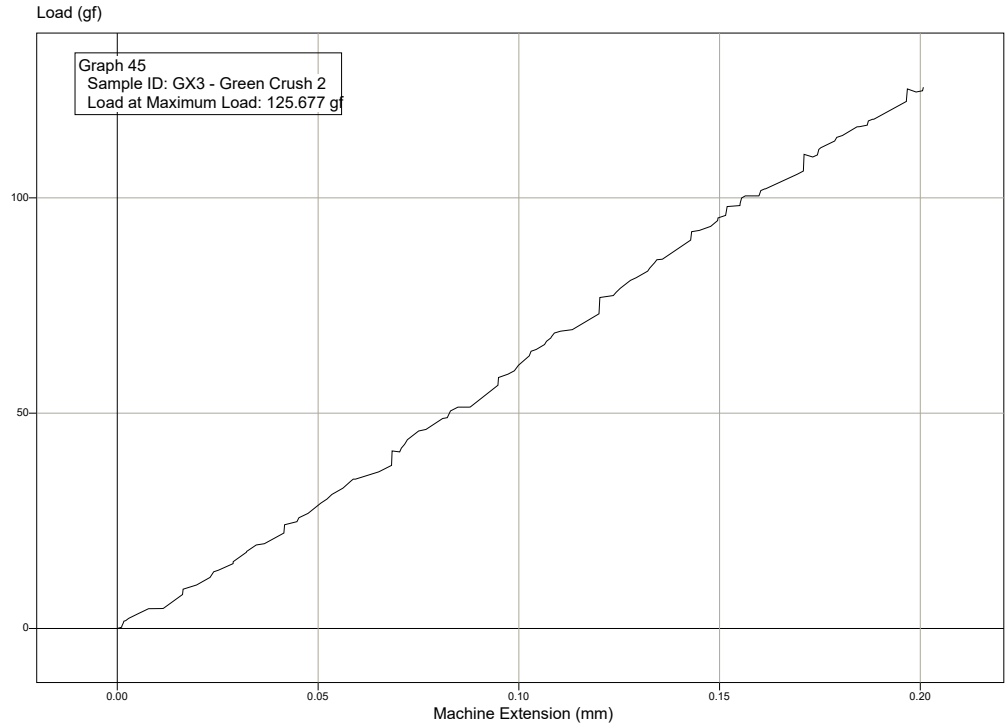
Graph 43


Load (gf)
Graph 43
Sample ID: GX3 - Really Dist. Tip Crush 3
Load at Maximum Load: 42.948 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

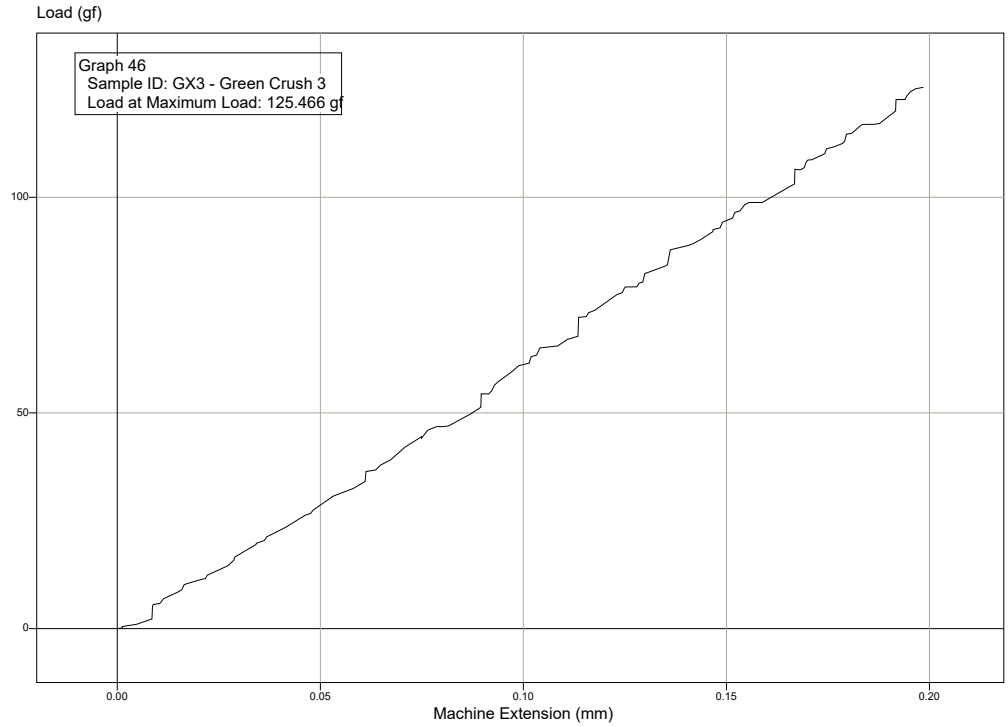
Graph 44


Load (gf)
Graph 44
Sample ID: GX3 - Green Crush 1
Load at Maximum Load: 115.655 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

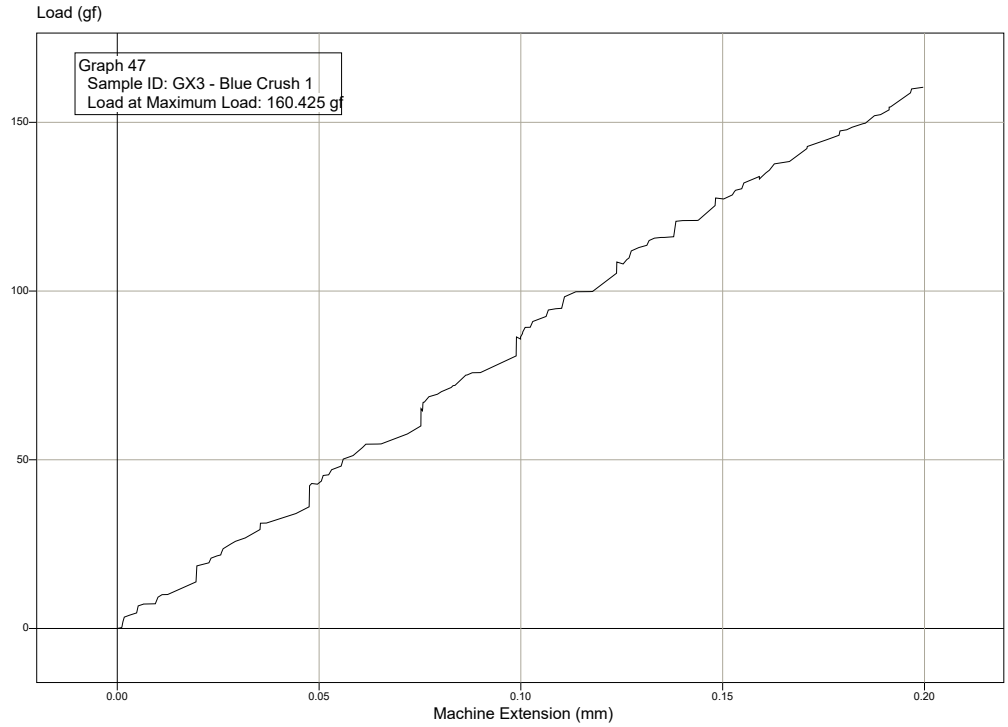
Graph 45


Load (gf)
Graph 45
Sample ID: GX3 - Green Crush 2
Load at Maximum Load: 125.677 gf
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

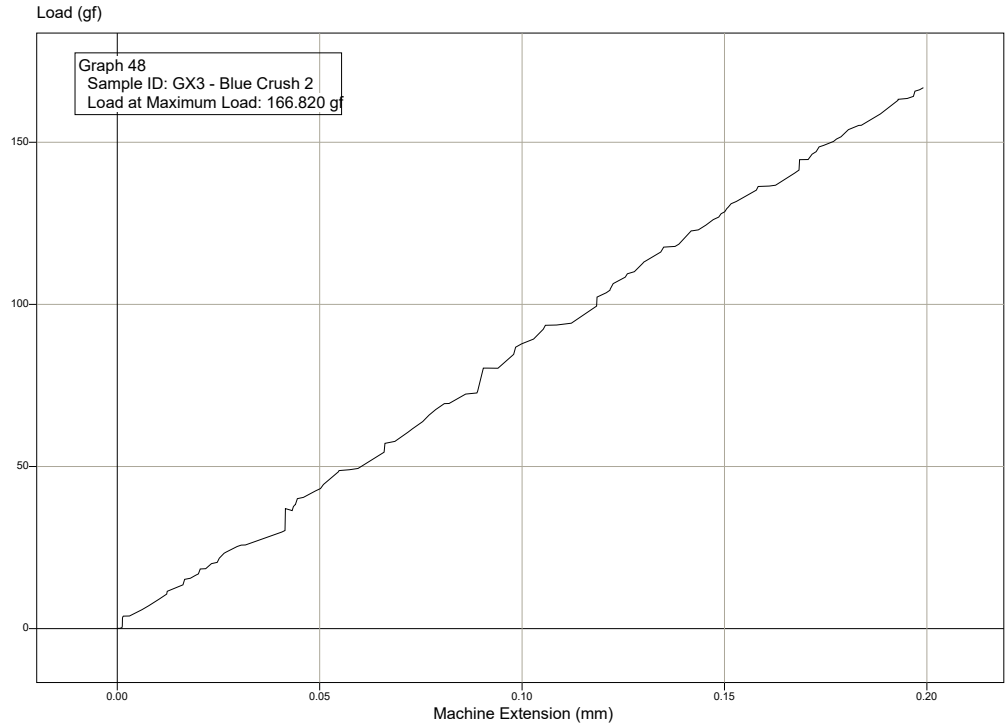
Graph 46


Load (gf)
Graph 46
Sample ID: GX3 - Green Crush 3
Load at Maximum Load: 125.466 gf
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

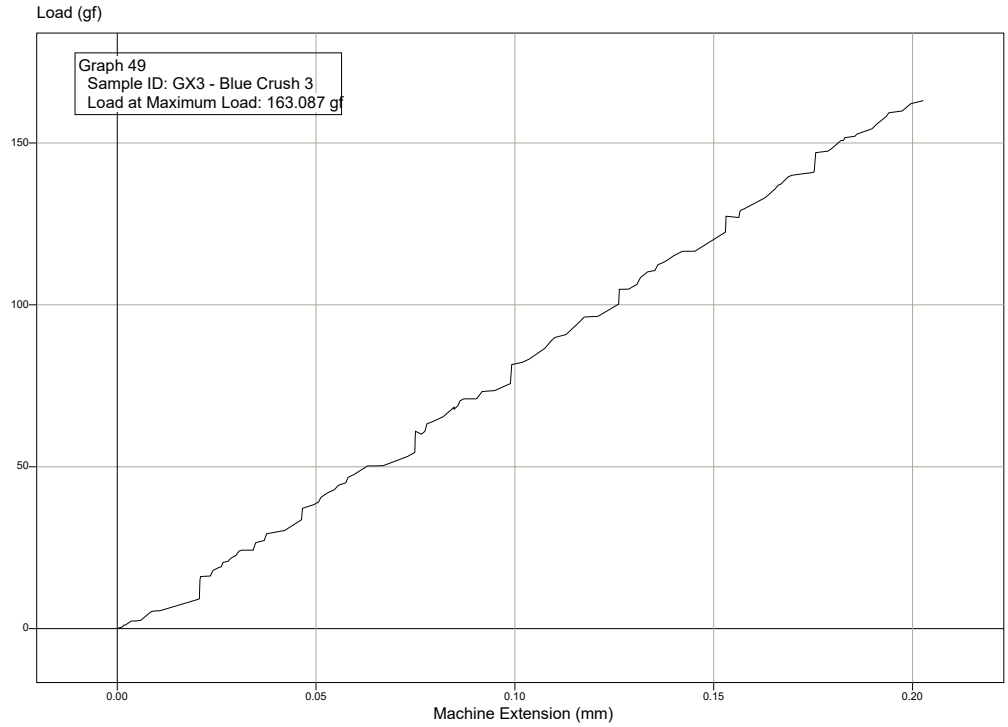
Graph 47


Load (gf)
Graph 47
Sample ID: GX3 - Blue Crush 1
Load at Maximum Load: 160.425 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

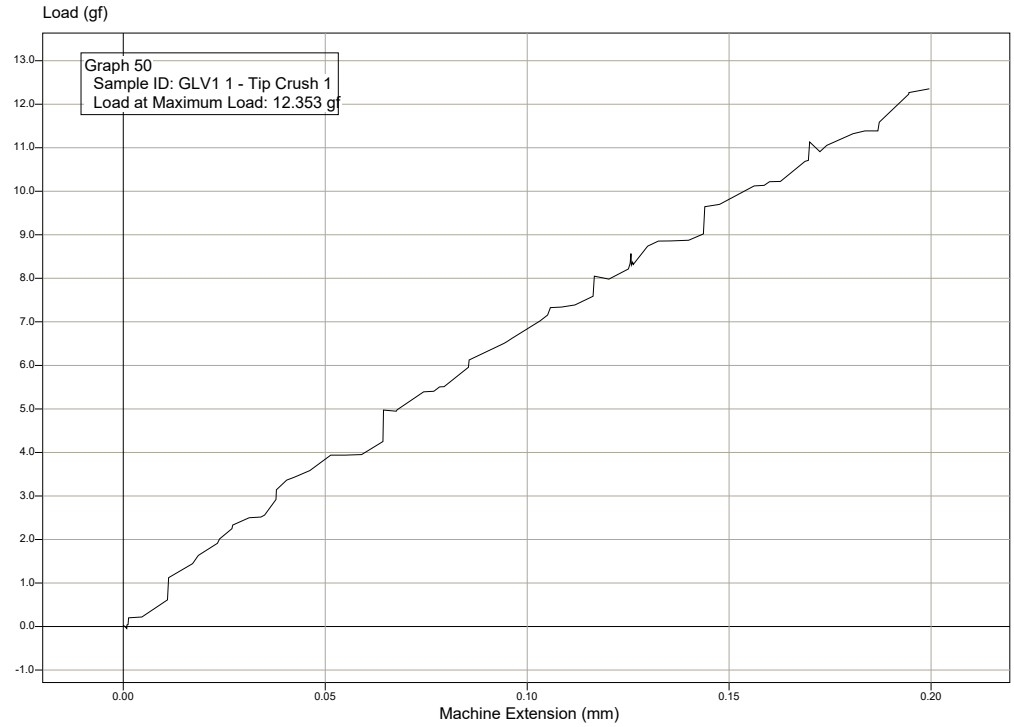
Graph 48


Load (gf)
Graph 48
Sample ID: GX3 - Blue Crush 2
Load at Maximum Load: 166.820 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

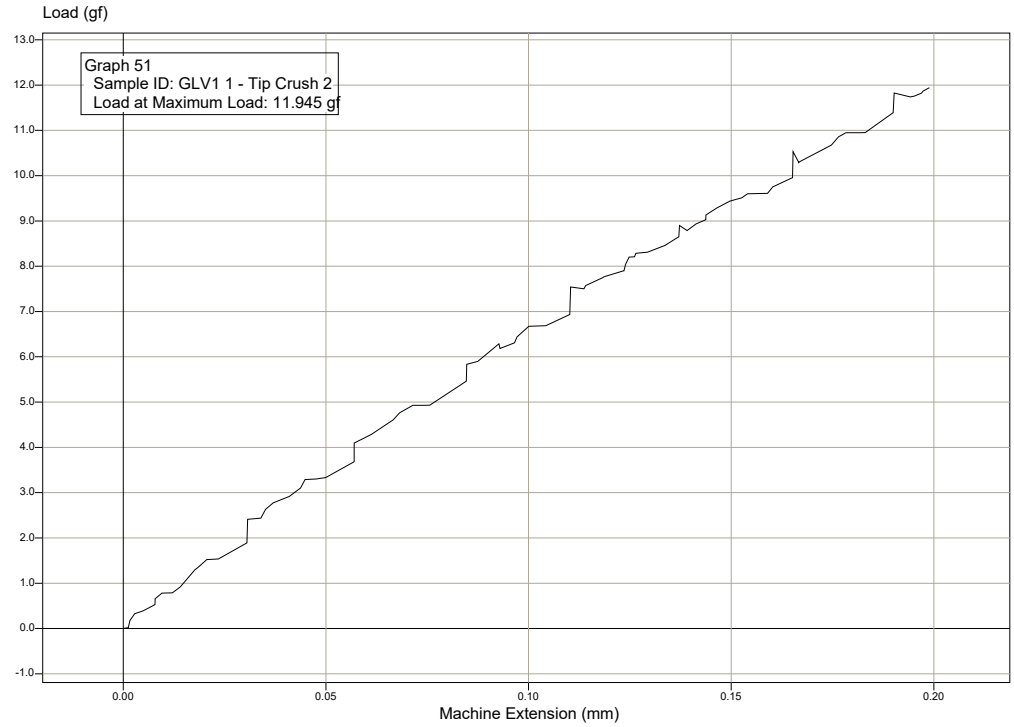
Graph 49


Load (gf)
Graph 49
Sample ID: GX3 - Blue Crush 3
Load at Maximum Load: 163.087 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

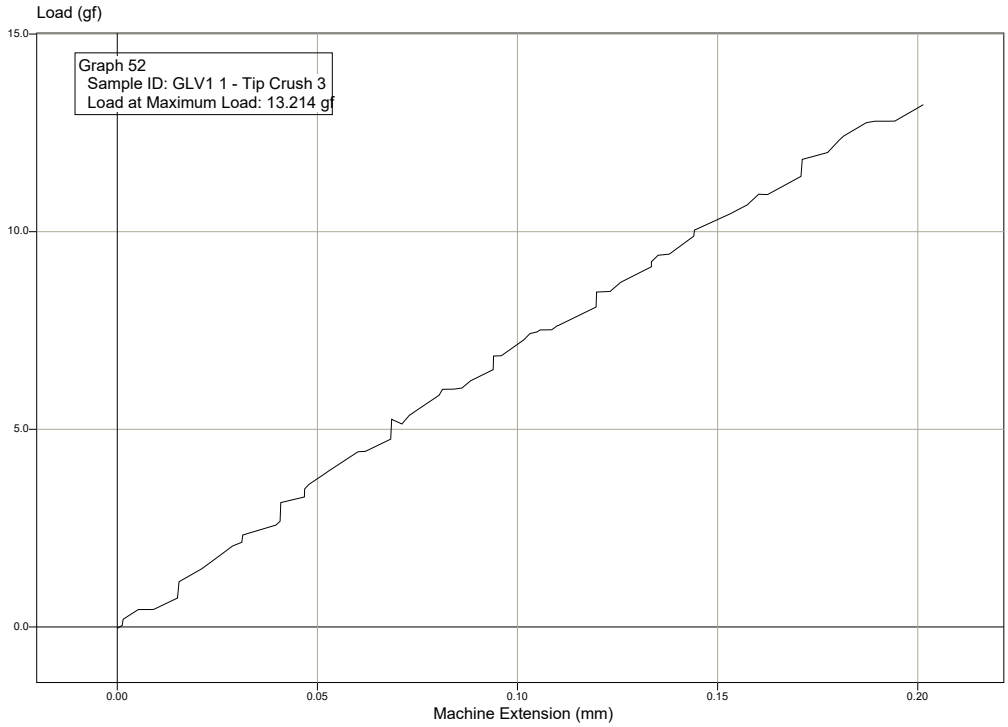
Graph 50


Load (gf)
Graph 50
Sample ID: GLV1 1 - Tip Crush 1
Load at Maximum Load: 12.353 gf
13.0
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

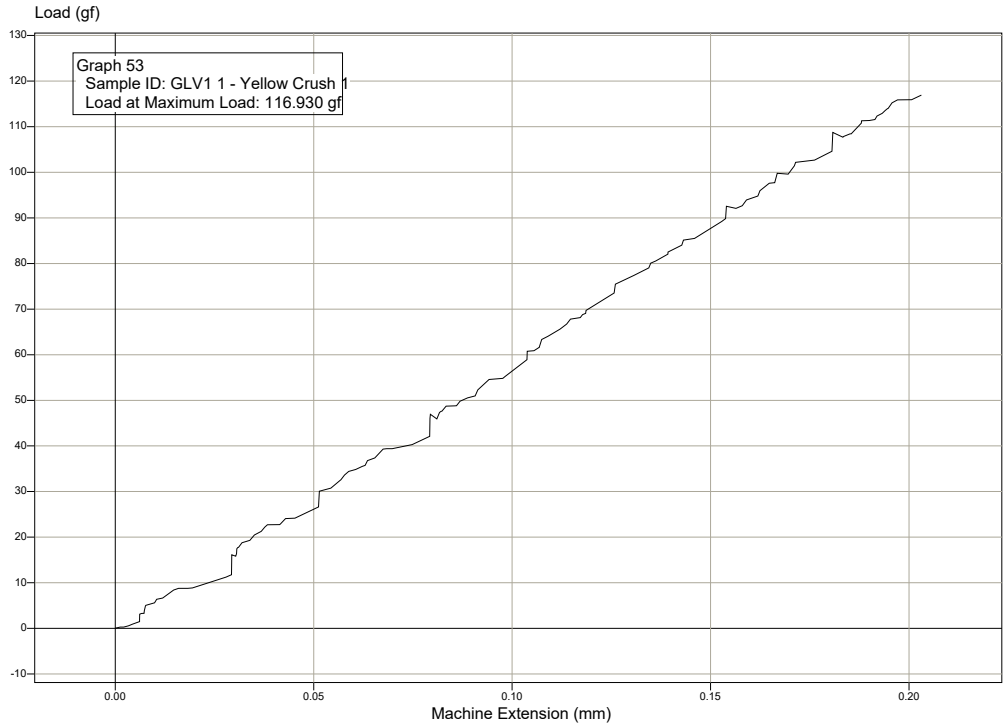
Graph 51


Load (gf)
Graph 51
Sample ID: GLV1 1 - Tip Crush 2
Load at Maximum Load: 11.945 gf
13.0
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

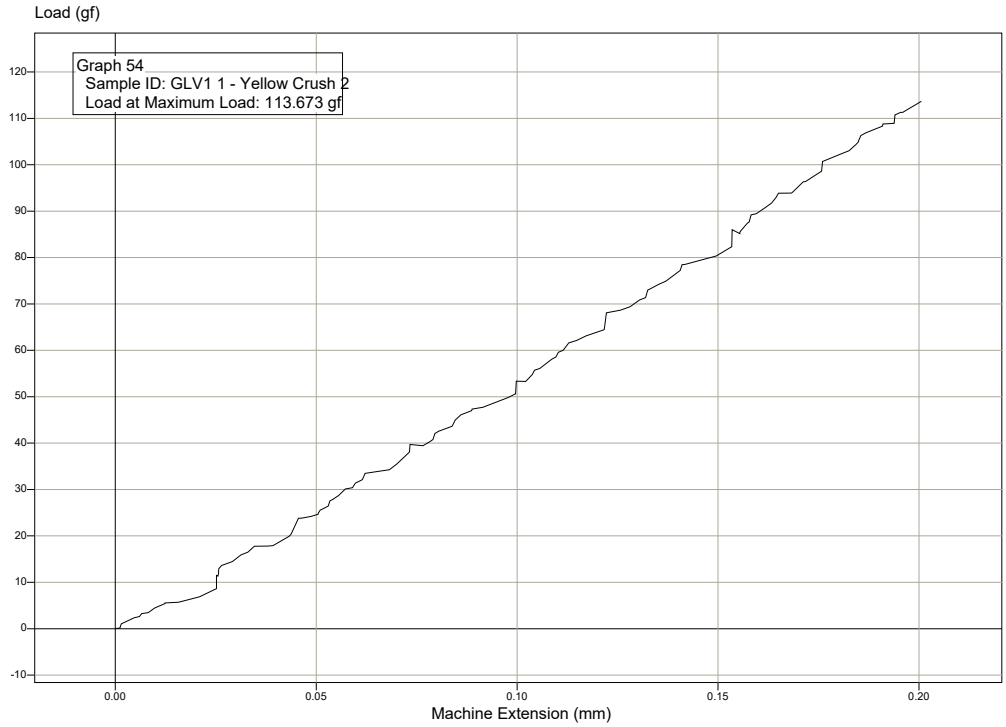
Graph 52


Load (gf)
15.0
10.0
5.0
0.0
Graph 52
Sample ID: GLV1 1 - Tip Crush 3
Load at Maximum Load: 13.214 gf
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

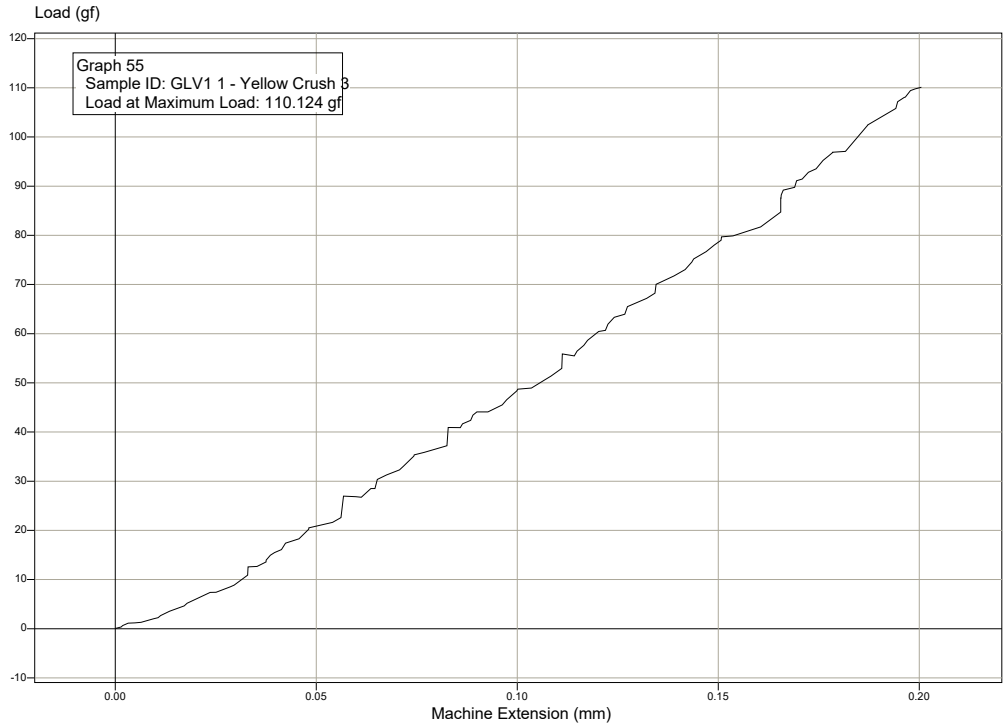
Graph 53


Load (gf)
Graph 53
Sample ID: GLV1 1 - Yellow Crush 1
Load at Maximum Load: 116.930 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

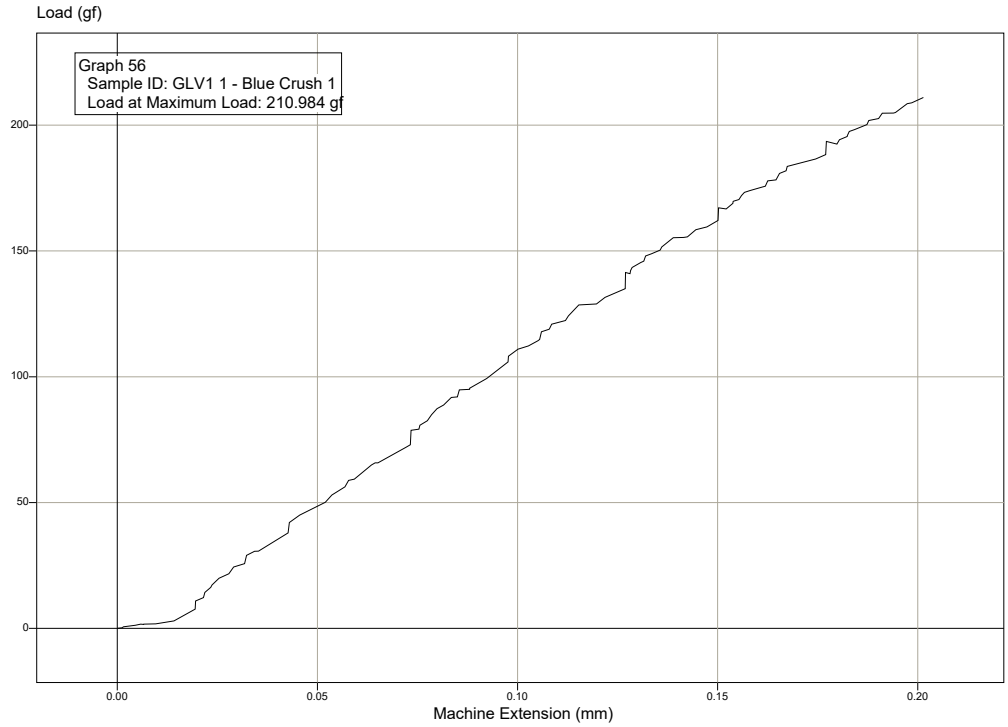
Graph 54


Load (gf)
Graph 54
Sample ID: GLV1 1 - Yellow Crush 2
Load at Maximum Load: 113.673 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

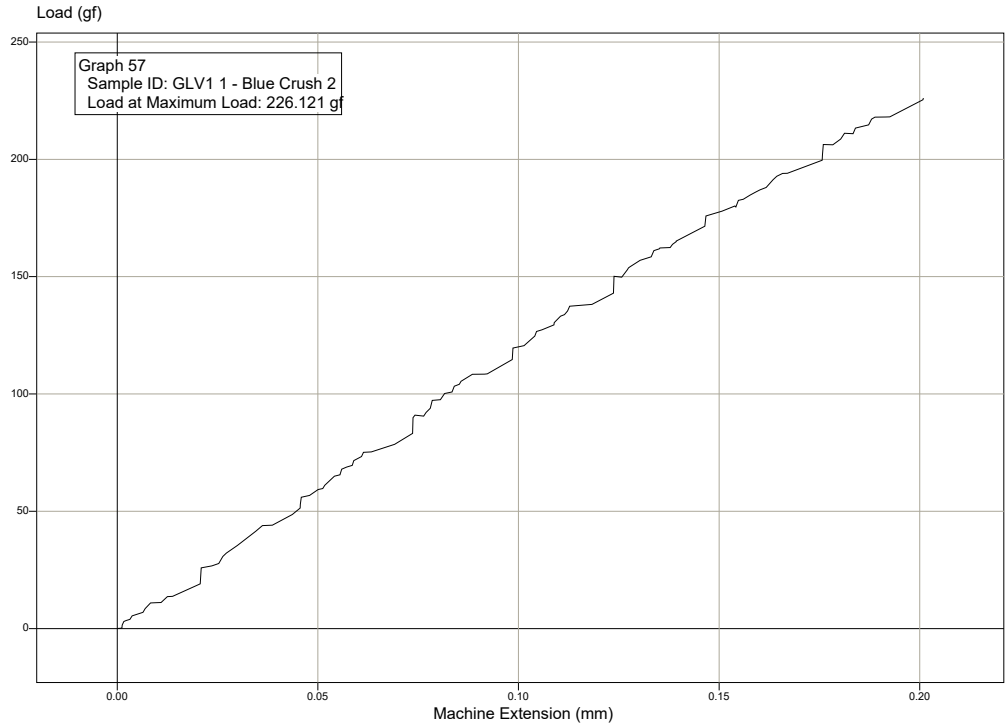
Graph 55


Load (gf)
Graph 55
Sample ID: GLV1 1 - Yellow Crush 3
Load at Maximum Load: 110.124 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

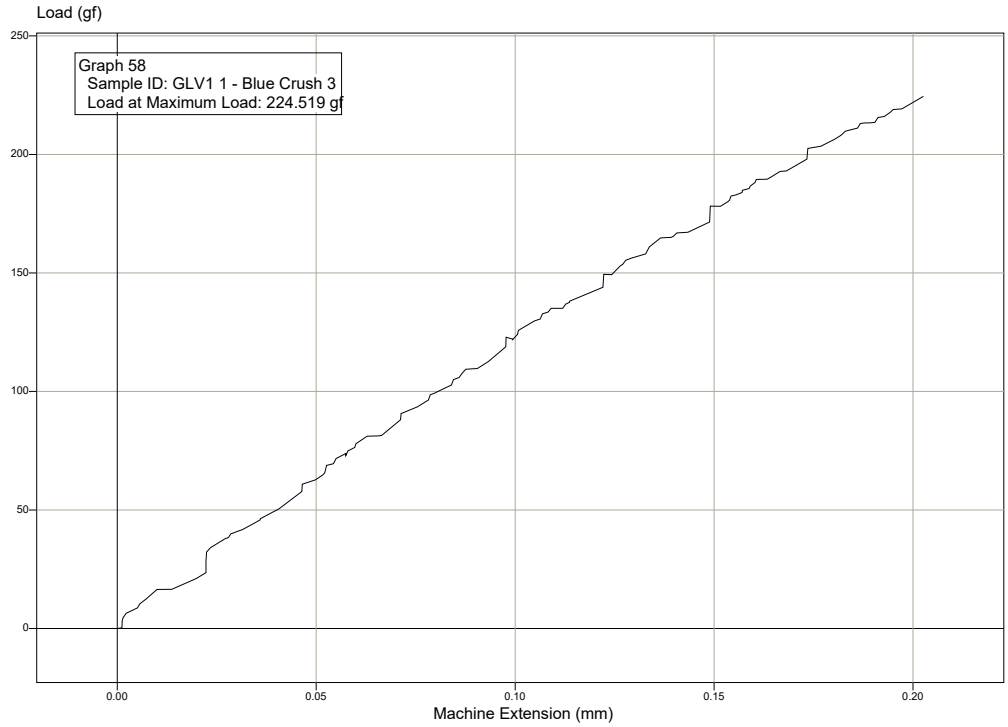
Graph 56


Load (gf)
Graph 56
Sample ID: GLV1 1 - Blue Crush 1
Load at Maximum Load: 210.984 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

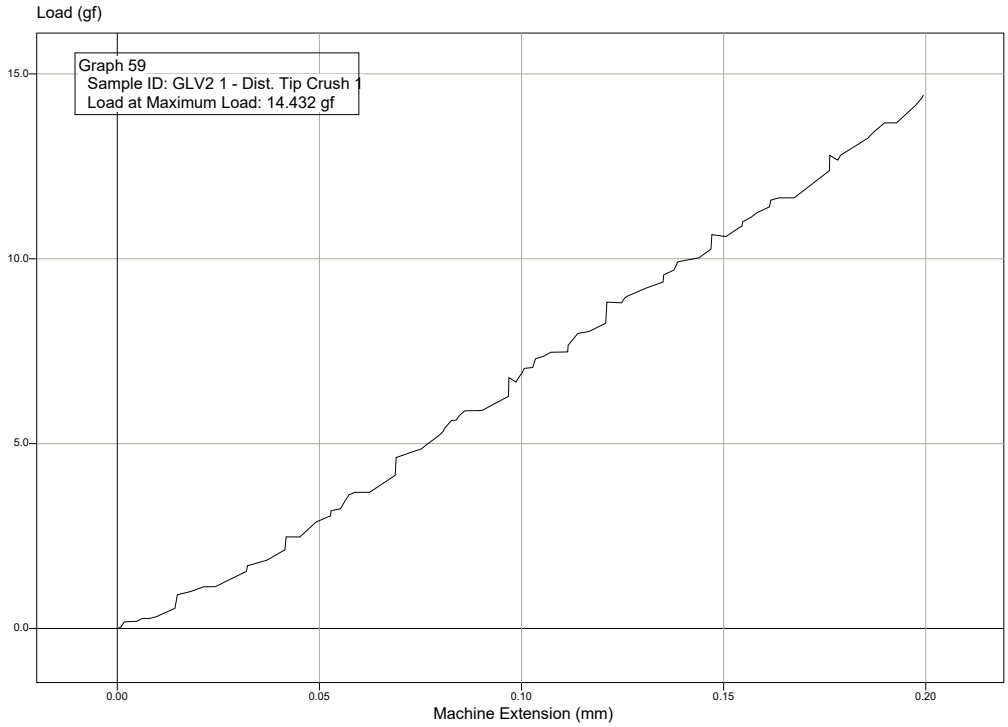
Graph 57


Load (gf)
Graph 57
Sample ID: GLV1 1 - Blue Crush 2
Load at Maximum Load: 226.121 gf
250
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

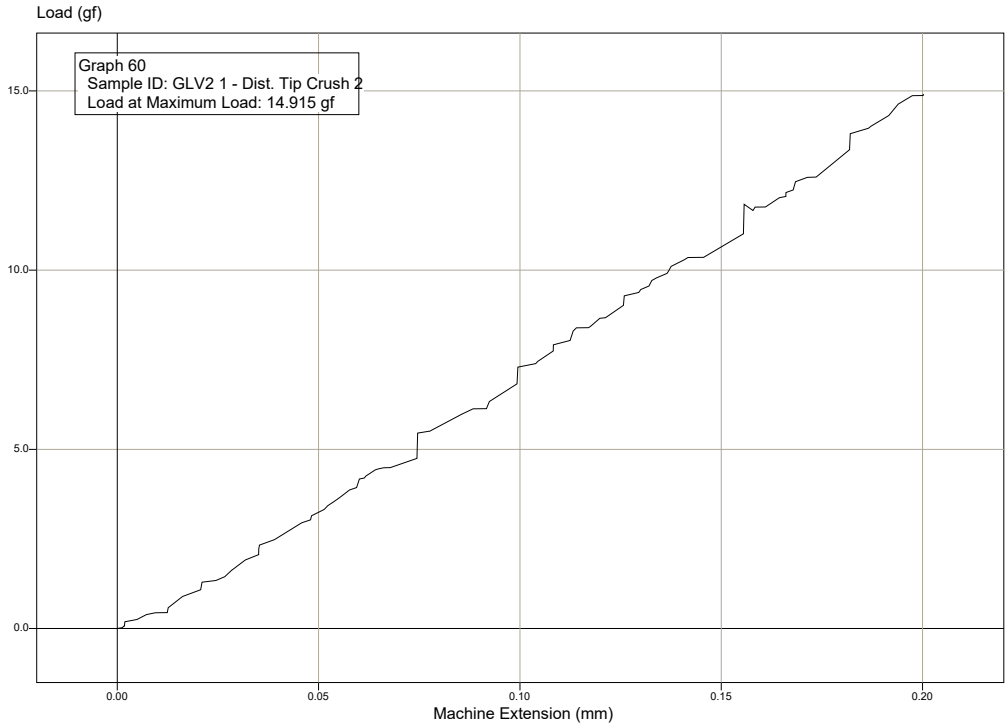
Graph 58


Load (gf)
250
200
150
100
50
0
Graph 58
Sample ID: GLV1 1 - Blue Crush 3
Load at Maximum Load: 224.519 gf
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

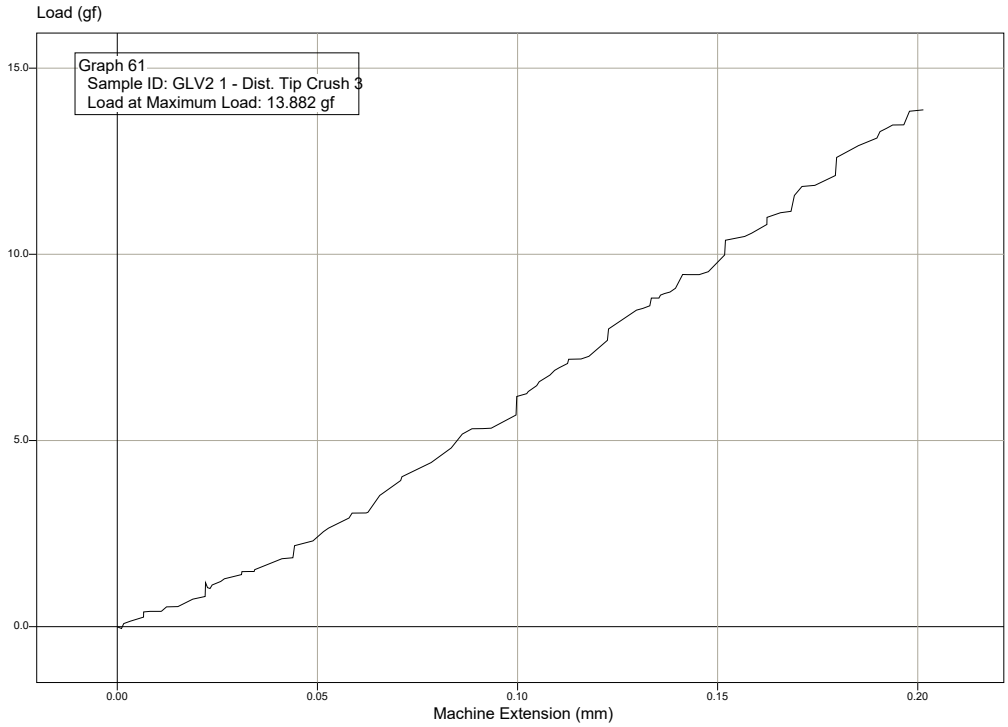
Graph 59



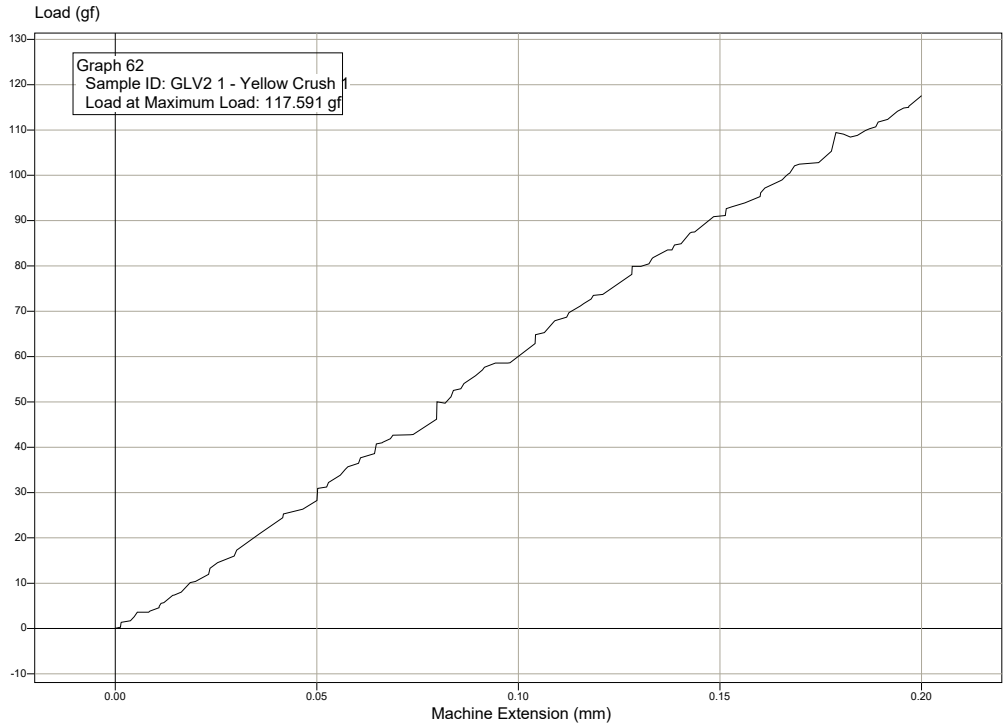
Graph 60



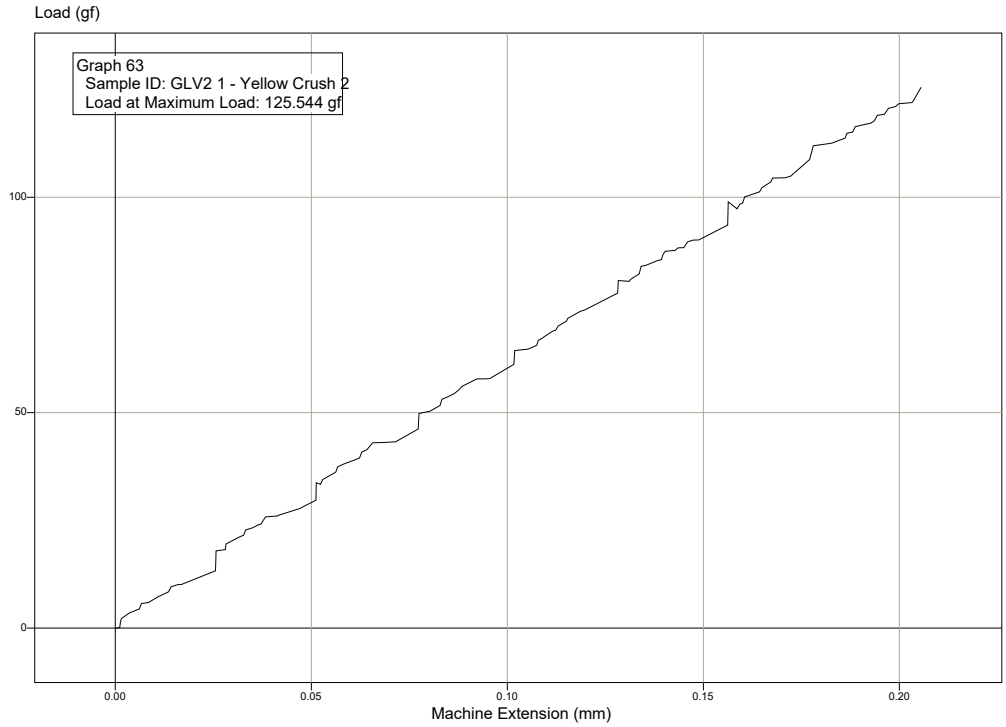
Graph 61


Load (gf)
Graph 61
Sample ID: GLV2 1 - Dist. Tip Crush 3
Load at Maximum Load: 13.882 gf
15.0
10.0
5.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

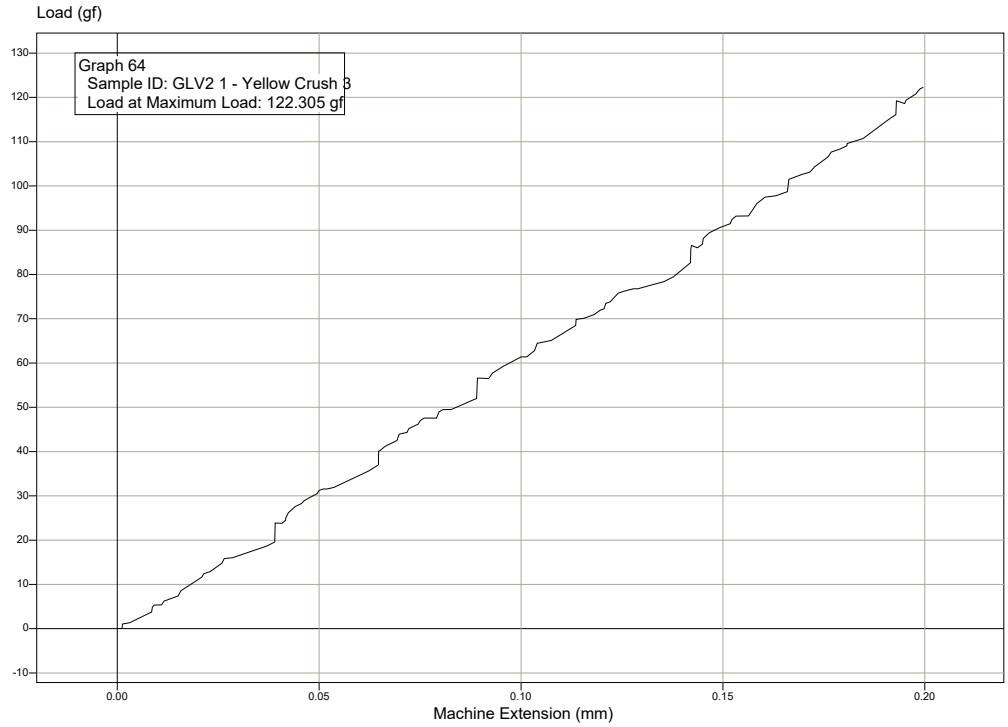
Graph 62


Load (gf)
Graph 62
Sample ID: GLV2 1 - Yellow Crush 1
Load at Maximum Load: 117.591 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

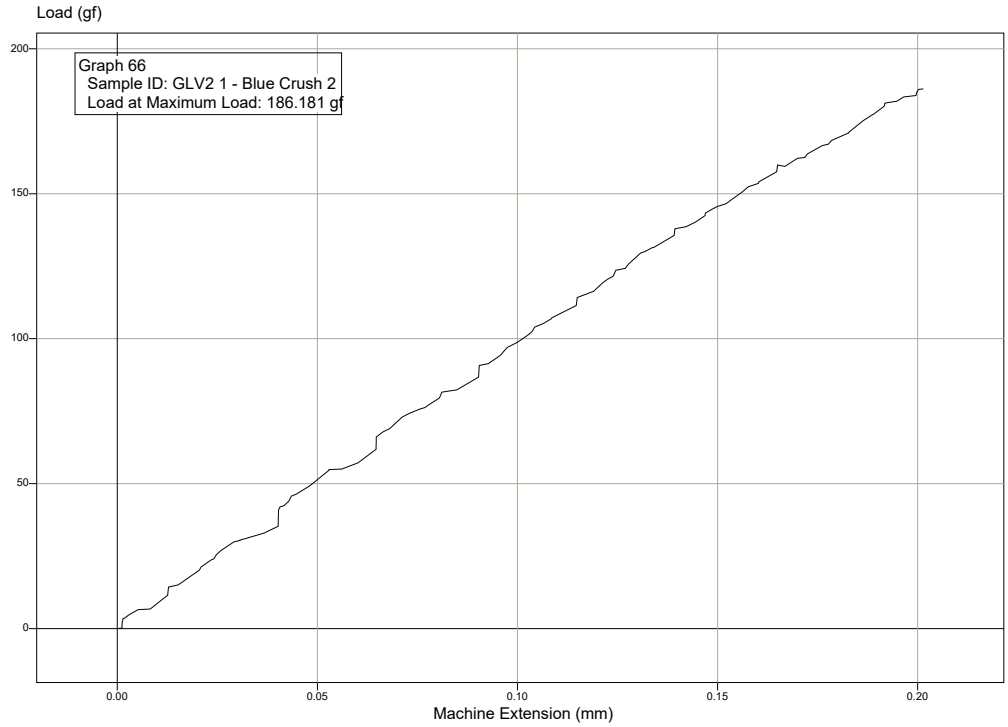
Graph 63


Load (gf)
Graph 63
Sample ID: GLV2 1 - Yellow Crush 2
Load at Maximum Load: 125.544 gf
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

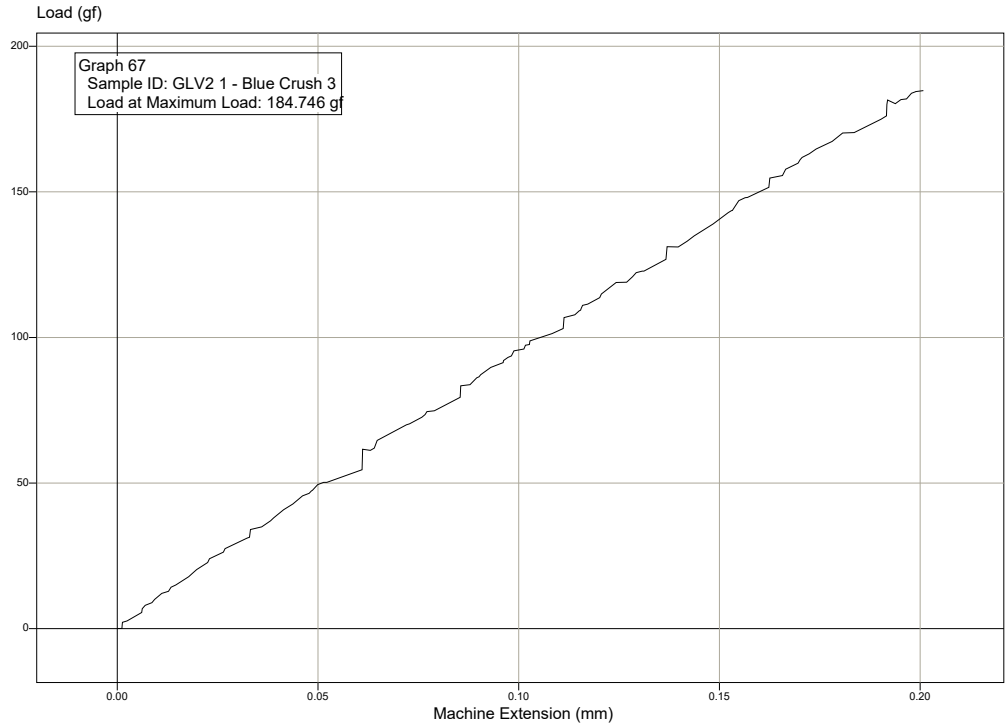
Graph 64


Load (gf)
Graph 64
Sample ID: GLV2 1 - Yellow Crush 3
Load at Maximum Load: 122.305 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

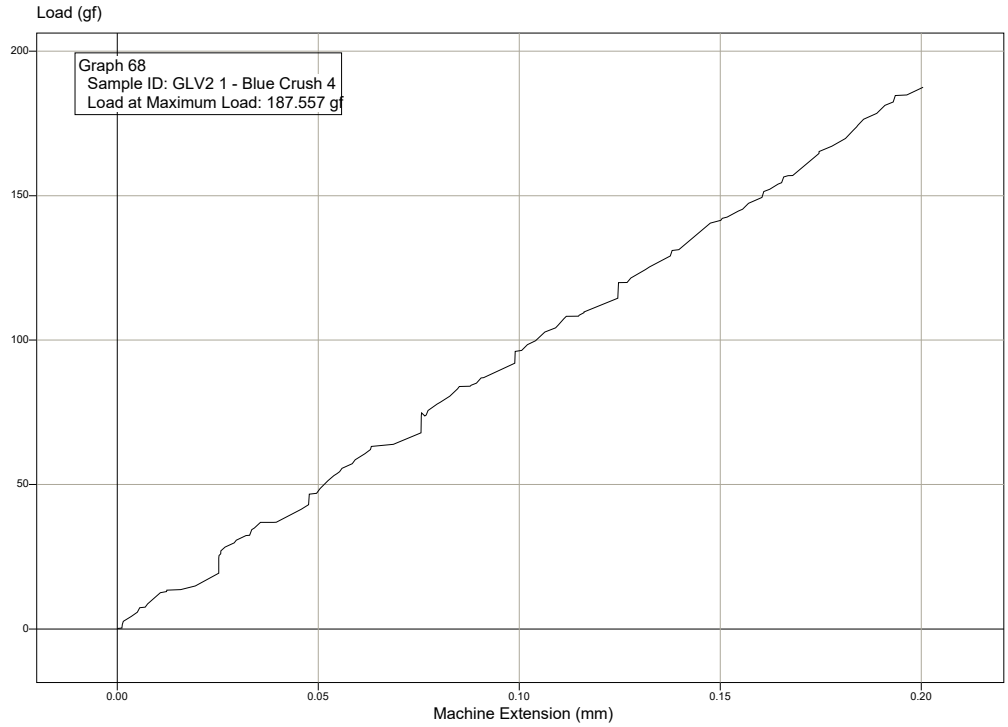
Graph 66


Load (gf)
Graph 66
Sample ID: GLV2 1 - Blue Crush 2
Load at Maximum Load: 186.181 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

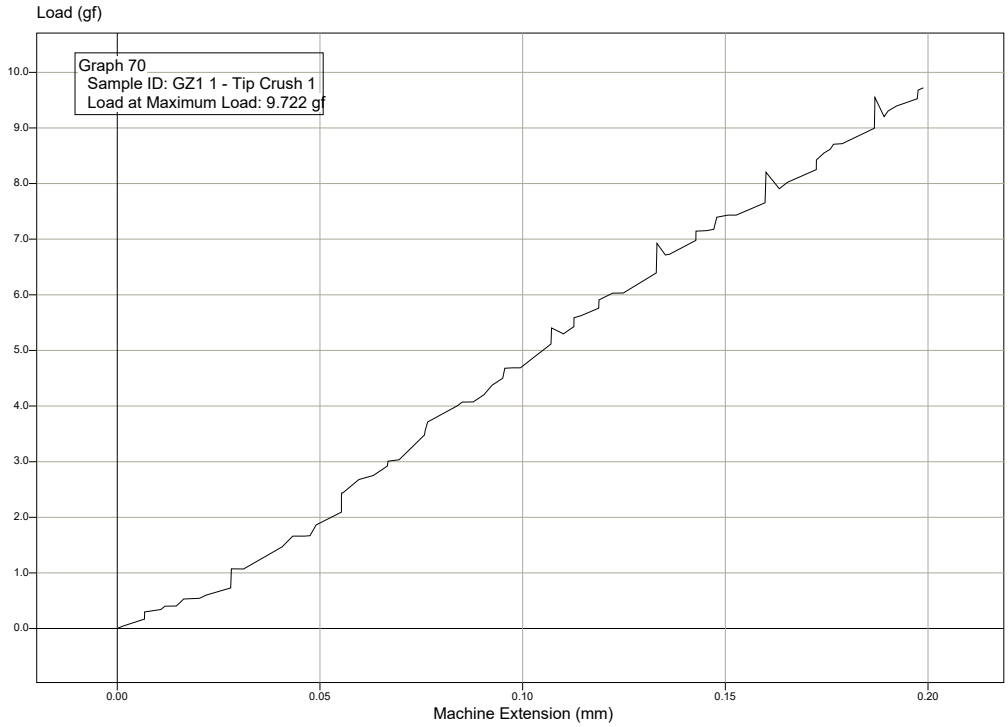
Graph 67


Load (gf)
Graph 67
Sample ID: GLV2 1 - Blue Crush 3
Load at Maximum Load: 184.746 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

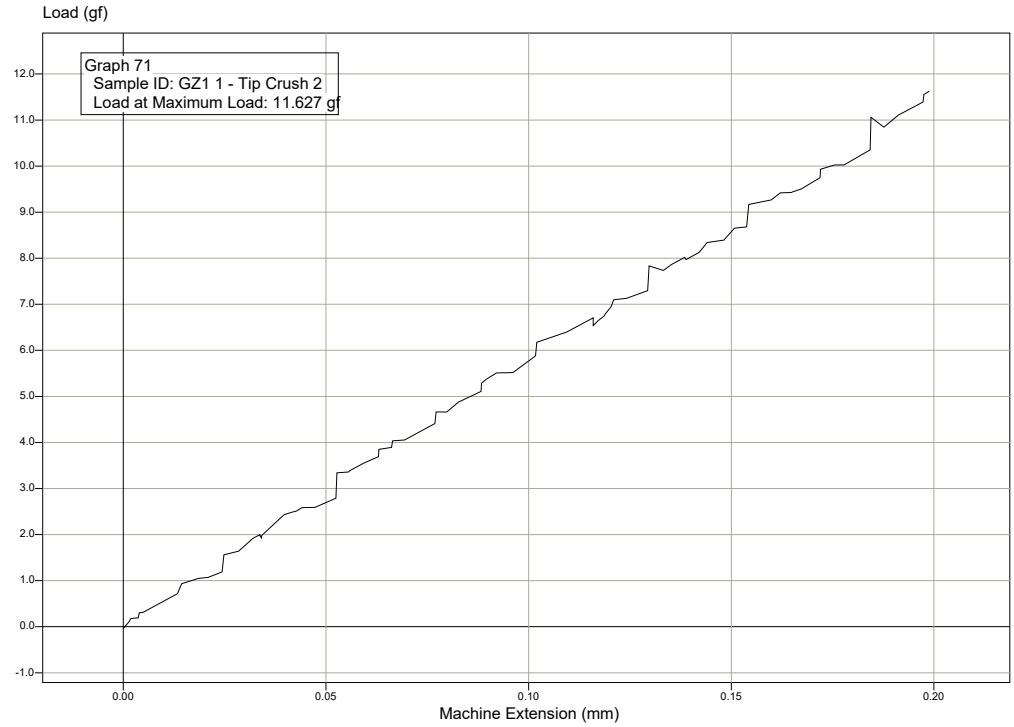
Graph 68


Load (gf)
Graph 68
Sample ID: GLV2 1 - Blue Crush 4
Load at Maximum Load: 187.557 gf
200
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

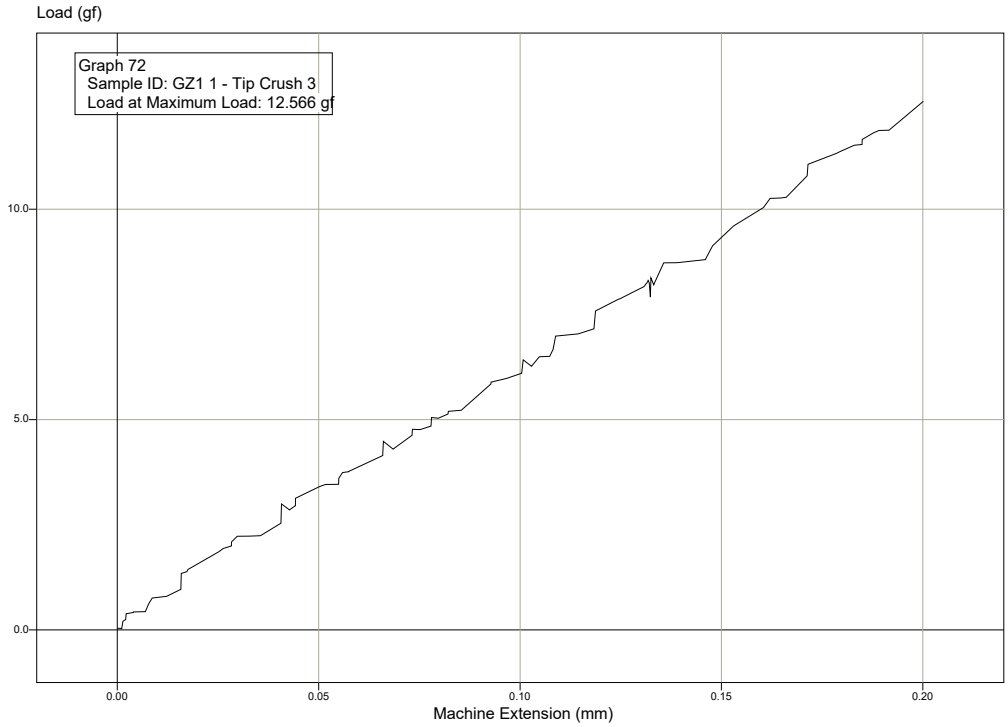
Graph 70


Load (gf)
Graph 70
Sample ID: GZ1 1 - Tip Crush 1
Load at Maximum Load: 9.722 gf
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

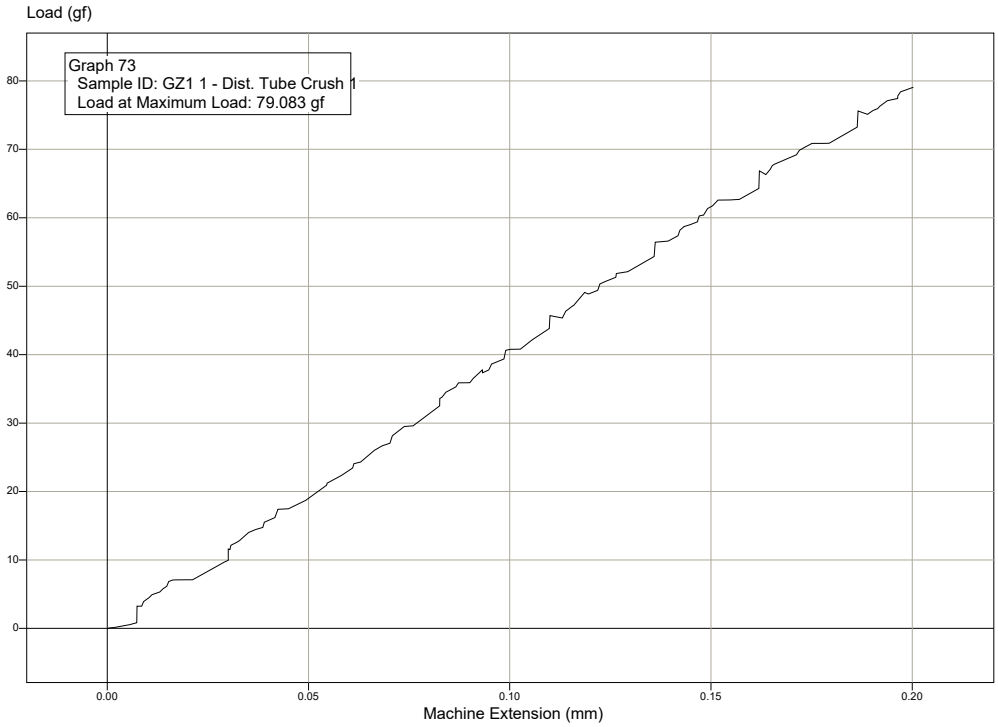
Graph 71


Load (gf)
Graph 71
Sample ID: GZ1 1 - Tip Crush 2
Load at Maximum Load: 11.627 gf
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

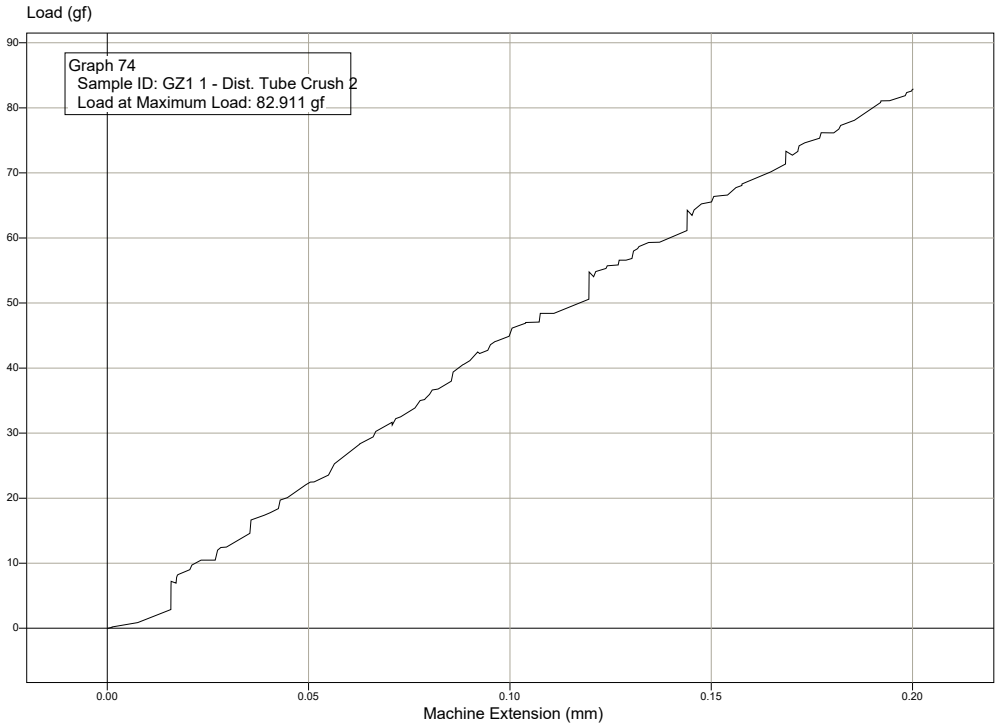
Graph 72


Load (gf)
Graph 72
Sample ID: GZ1 1 - Tip Crush 3
Load at Maximum Load: 12.566 gf
10.0
5.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

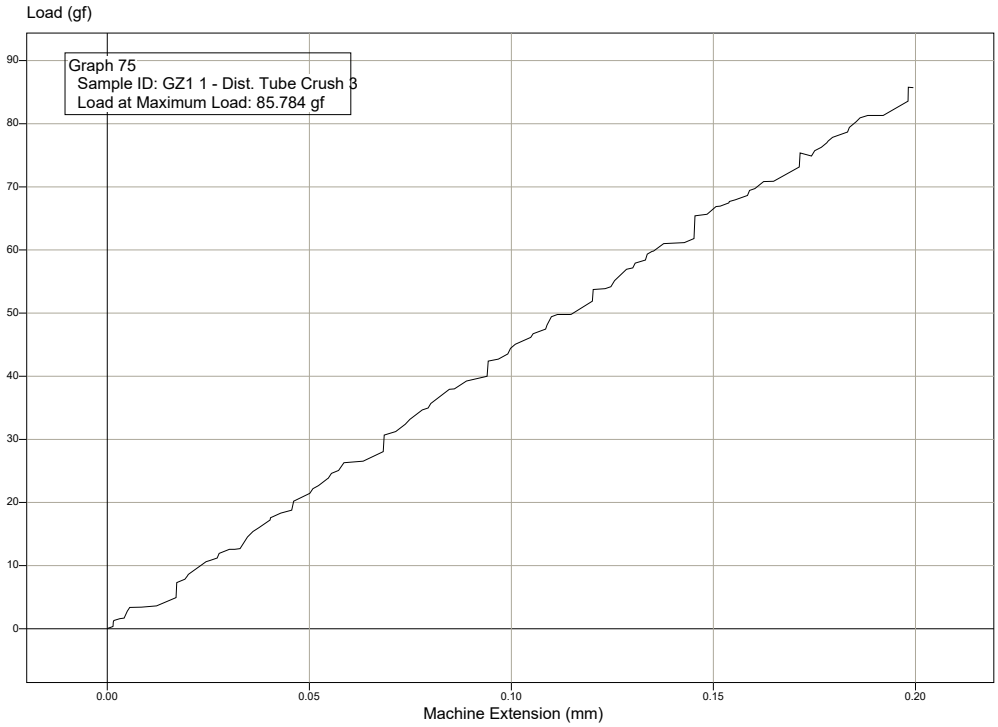
Graph 73



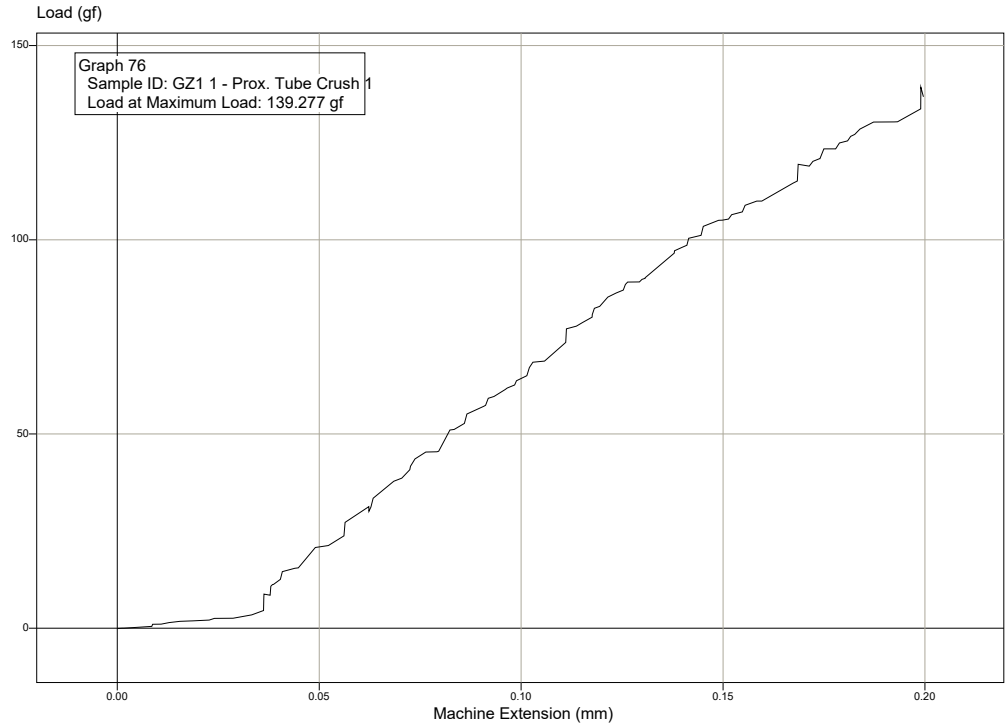
Graph 74



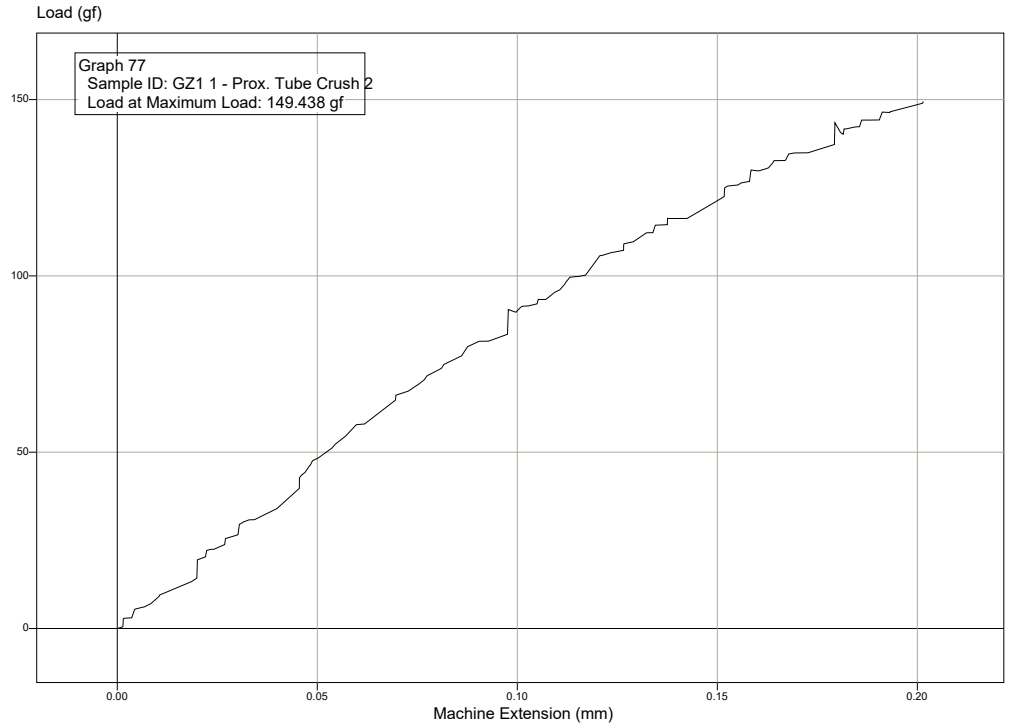
Graph 75



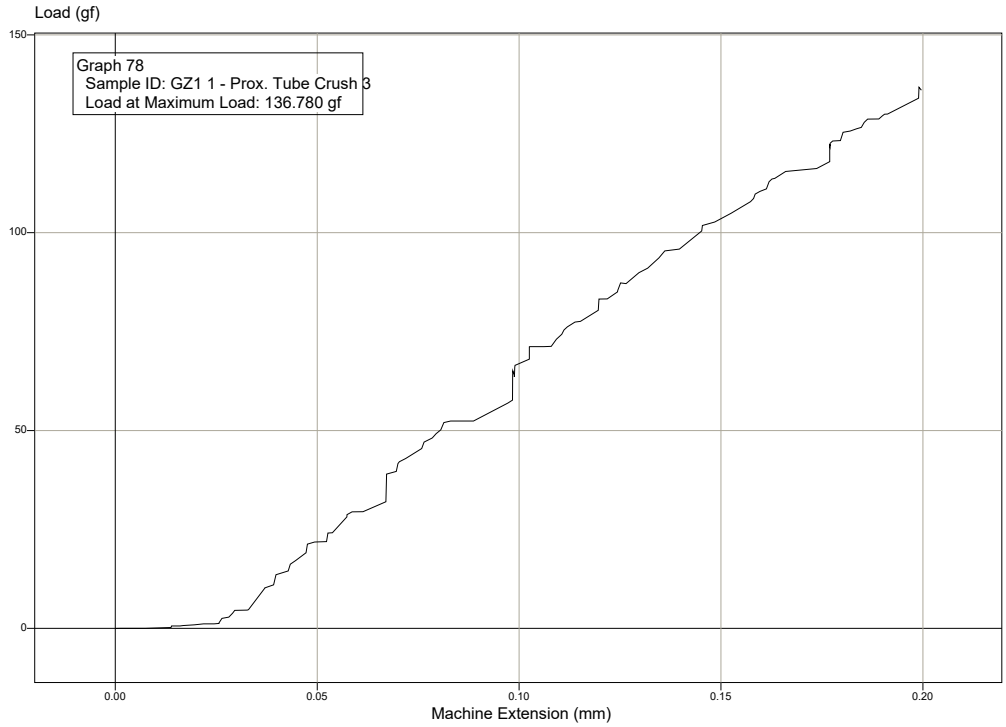
Graph 76



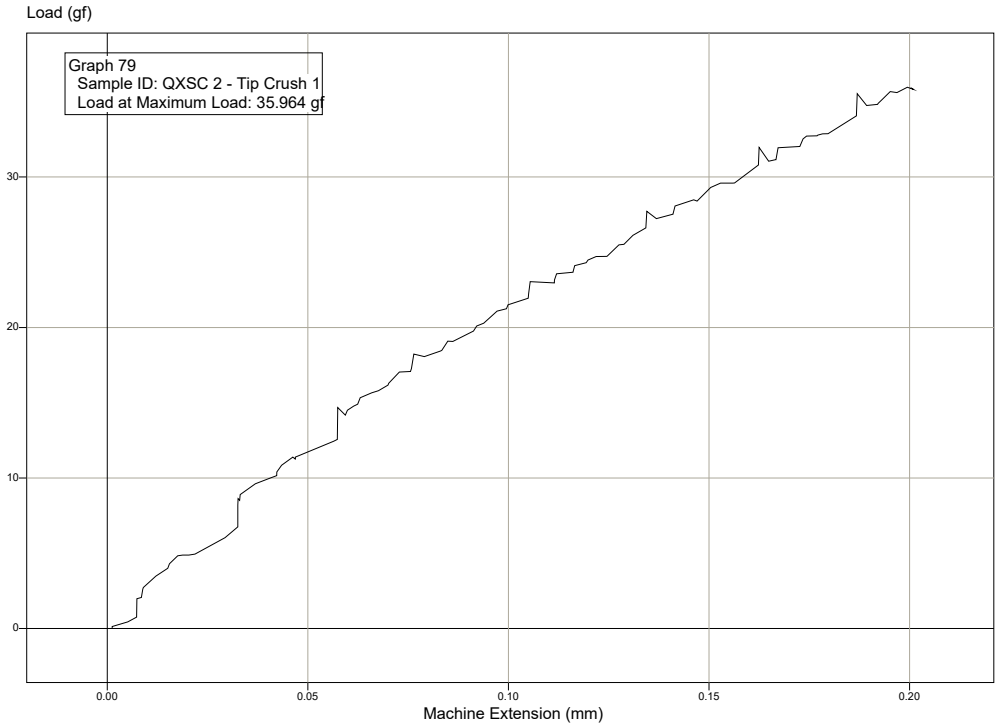
Graph 77


Load (gf)
Graph 77
Sample ID: GZ1 1 - Prox. Tube Crush 2
Load at Maximum Load: 149.438 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

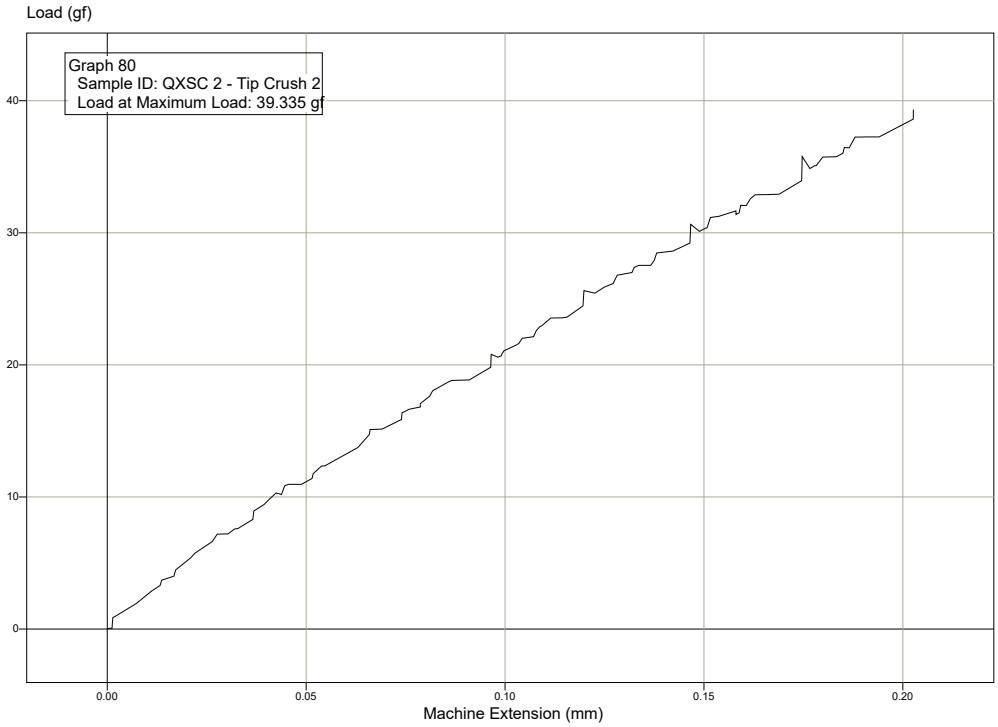
Graph 78



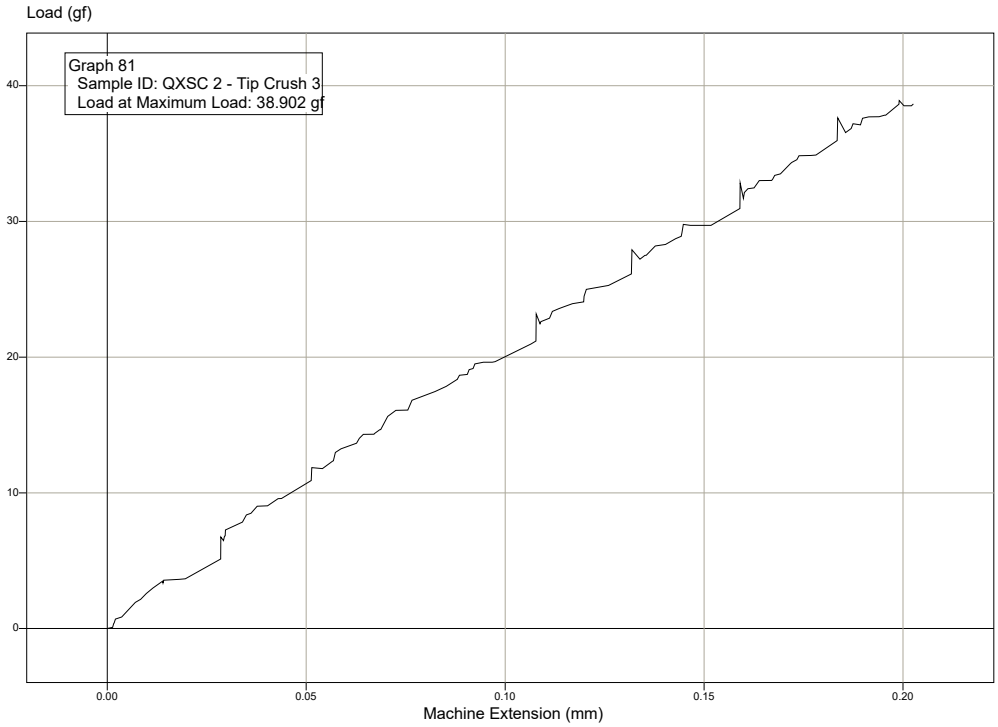
Graph 79



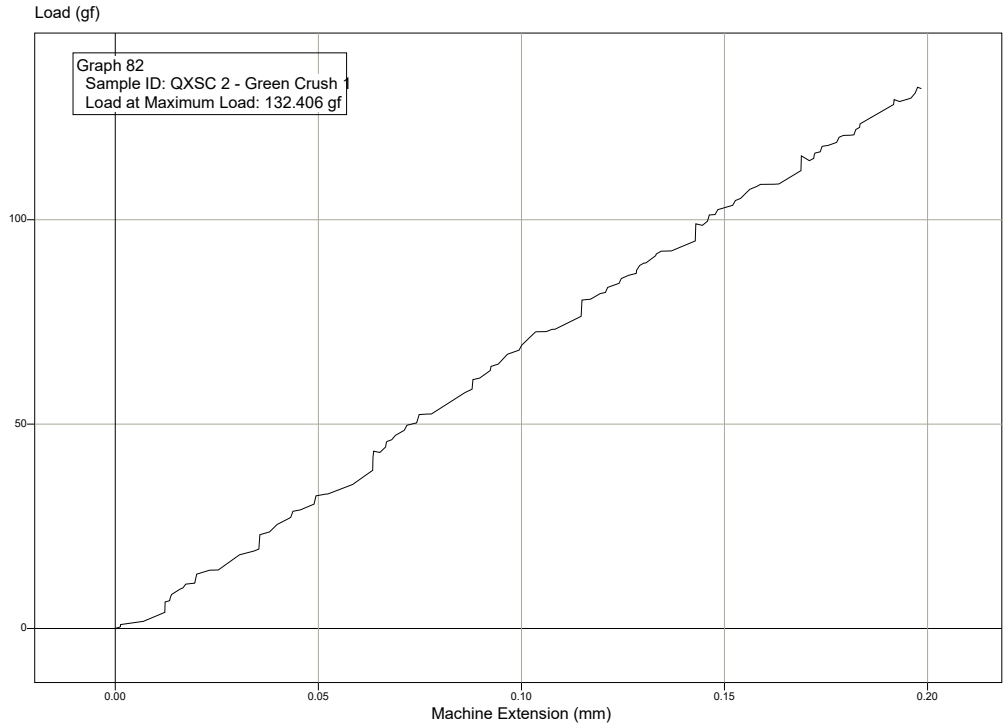
Graph 80


Load (gf)
Graph 80
Sample ID: QXSC 2 - Tip Crush 2
Load at Maximum Load: 39.335 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

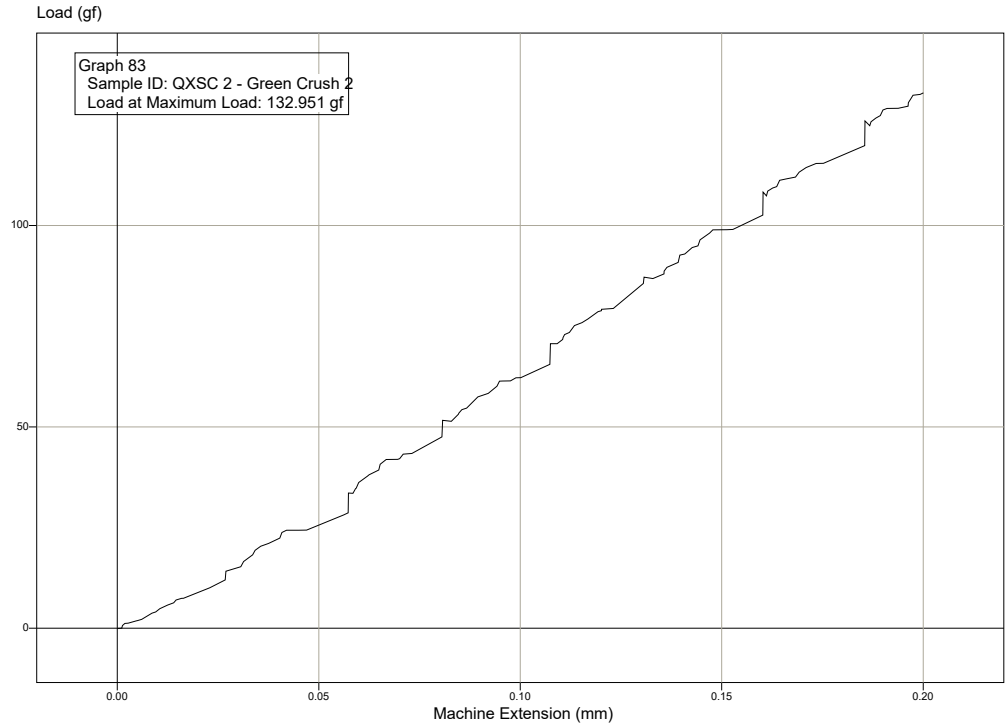
Graph 81


Load (gf)
Graph 81
Sample ID: QXSC 2 - Tip Crush 3
Load at Maximum Load: 38.902 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

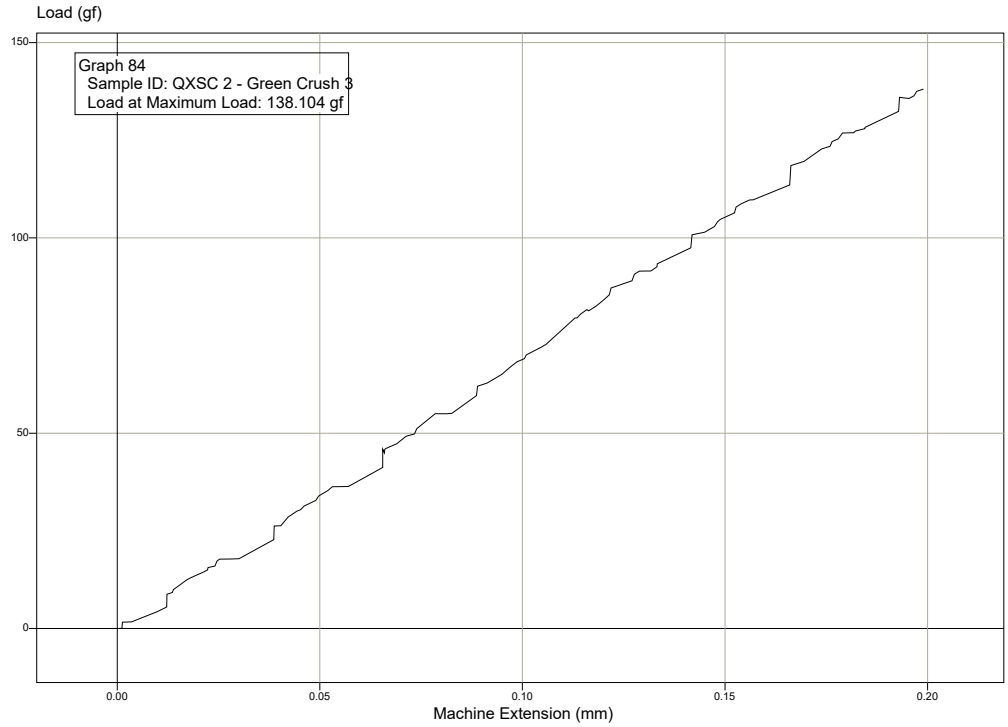
Graph 82


Load (gf)
Graph 82
Sample ID: QXSC 2 - Green Crush 1
Load at Maximum Load: 132.406 gf
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

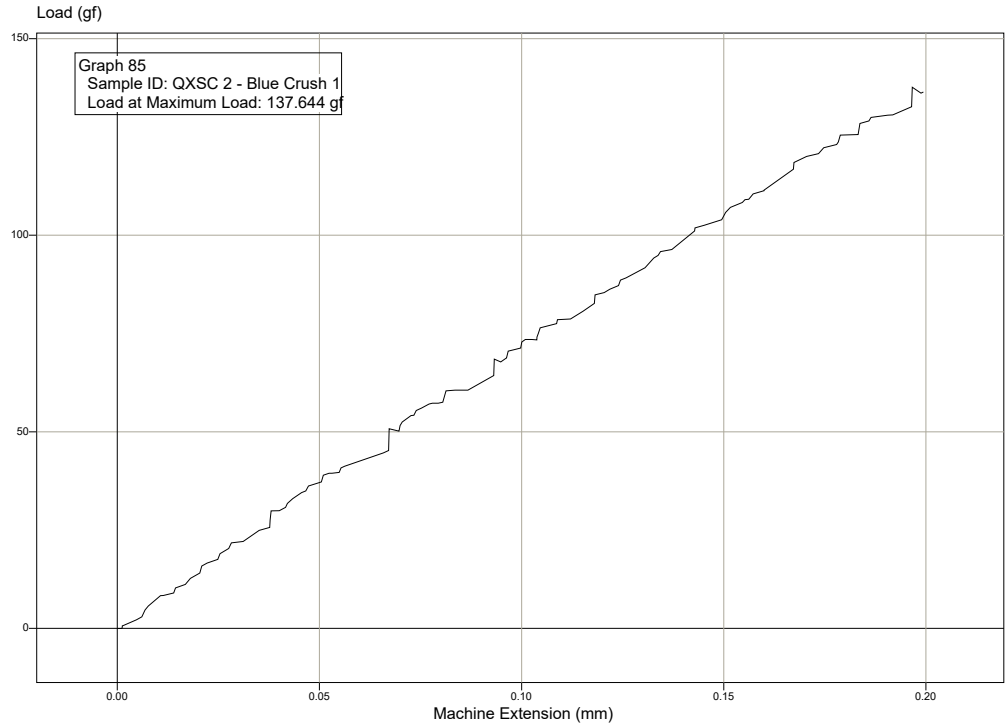
Graph 83



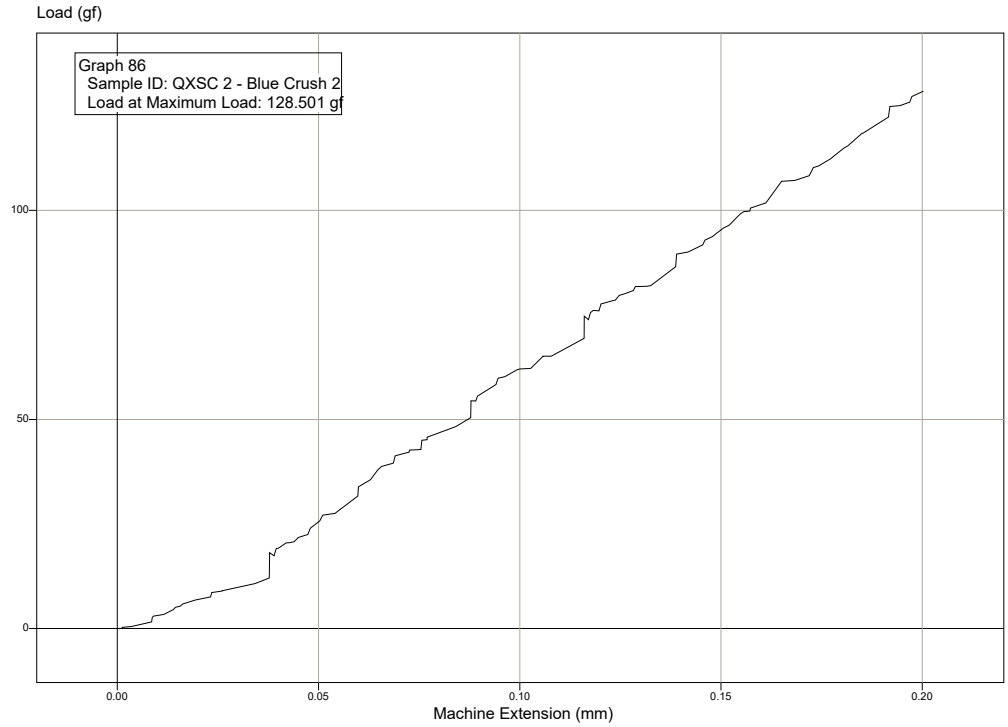
Graph 84



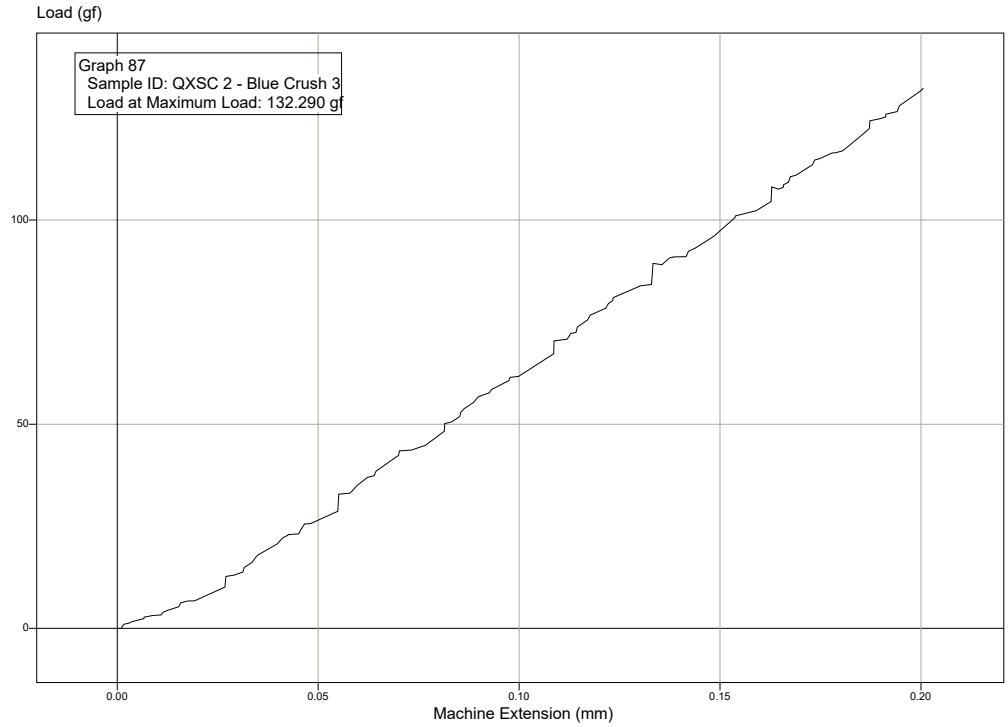
Graph 85


Load (gf)
150
100
50
0
Graph 85
Sample ID: QXSC 2 - Blue Crush 1
Load at Maximum Load: 137.644 gf
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

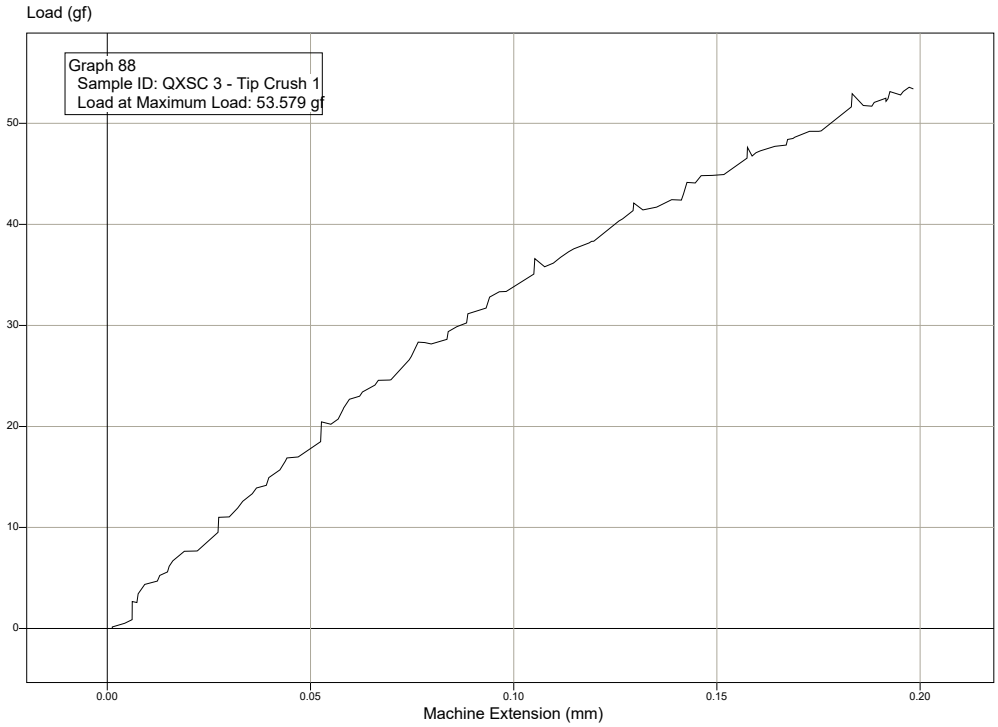
Graph 86



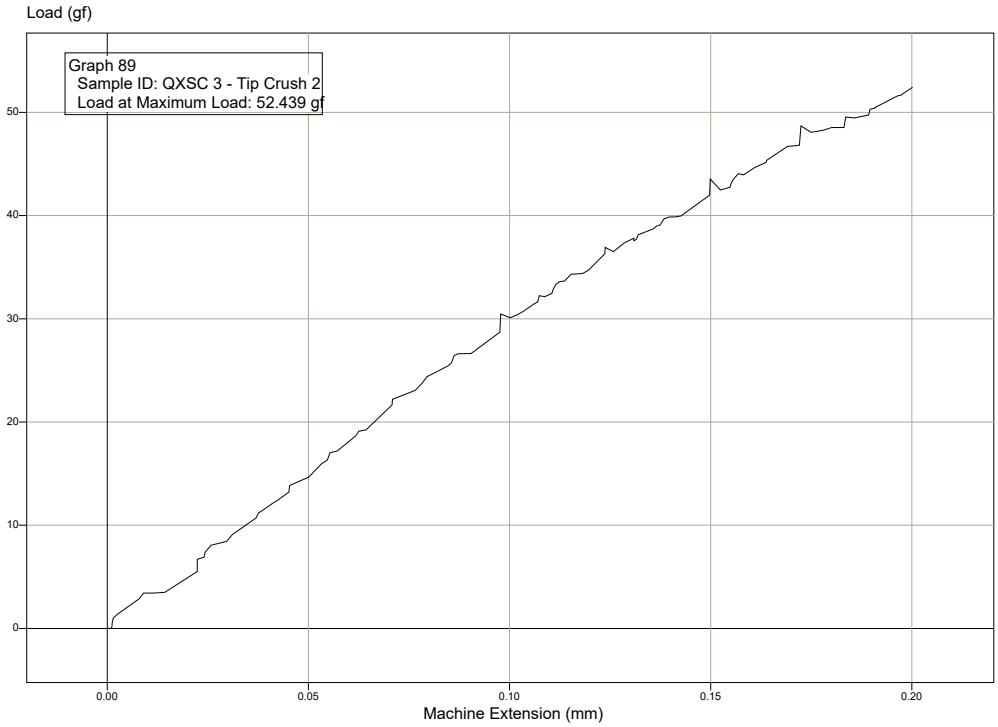
Graph 87


Load (gf)
Graph 87
Sample ID: QXSC 2 - Blue Crush 3
Load at Maximum Load: 132.290 gf
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

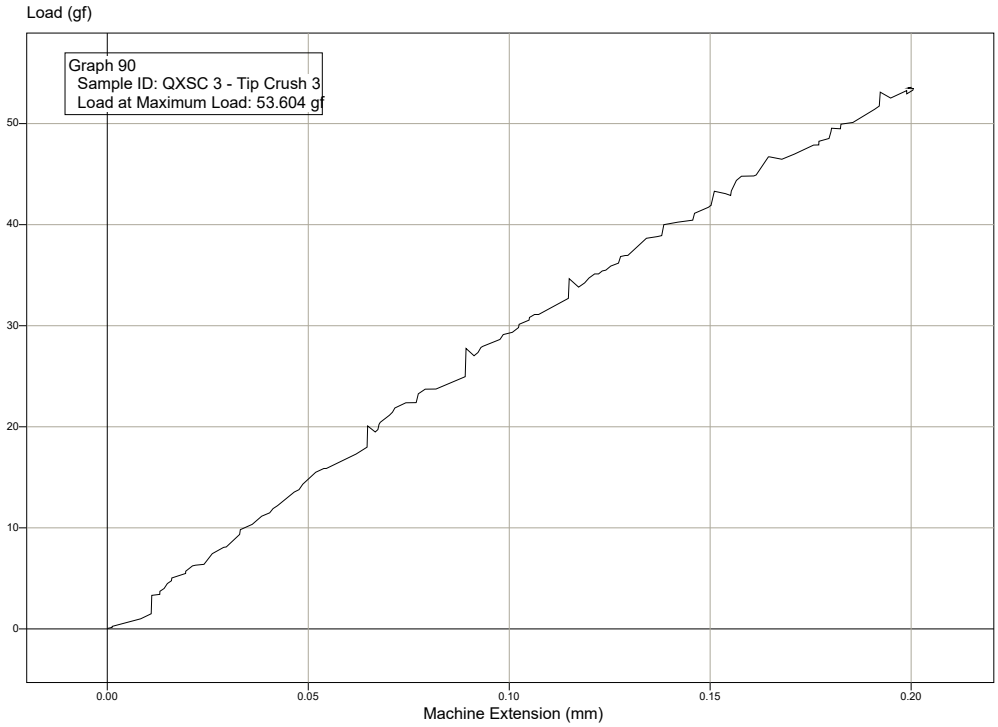
Graph 88


Load (gf)
Graph 88
Sample ID: QXSC 3 - Tip Crush 1
Load at Maximum Load: 53.579 gf
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

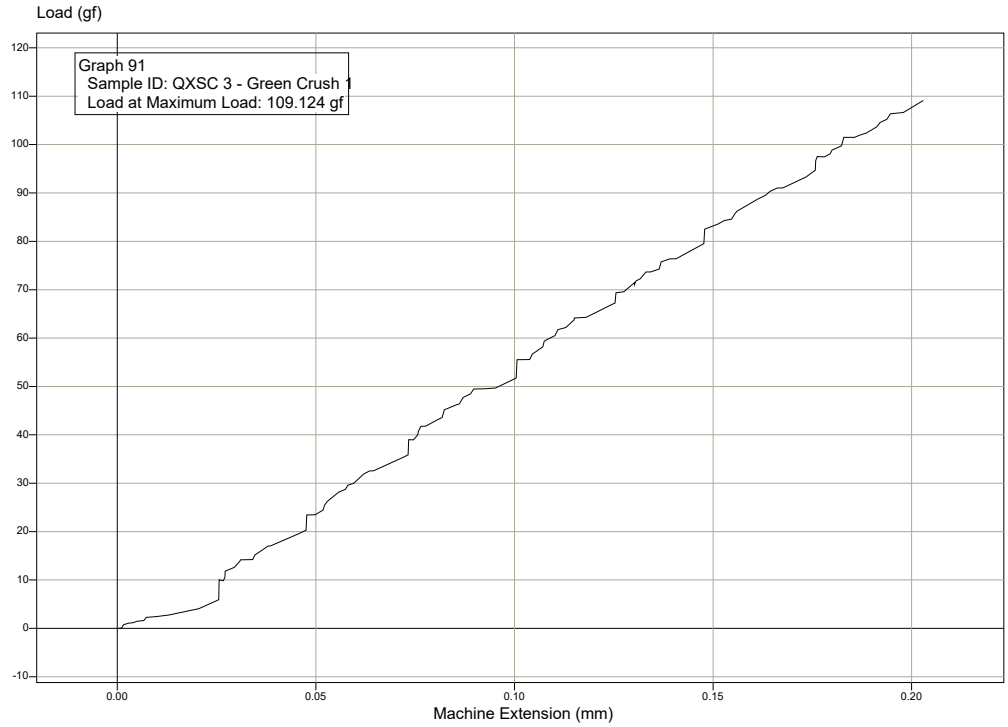
Graph 89


Load (gf)
Graph 89
Sample ID: QXSC 3 - Tip Crush 2
Load at Maximum Load: 52.439 gf
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

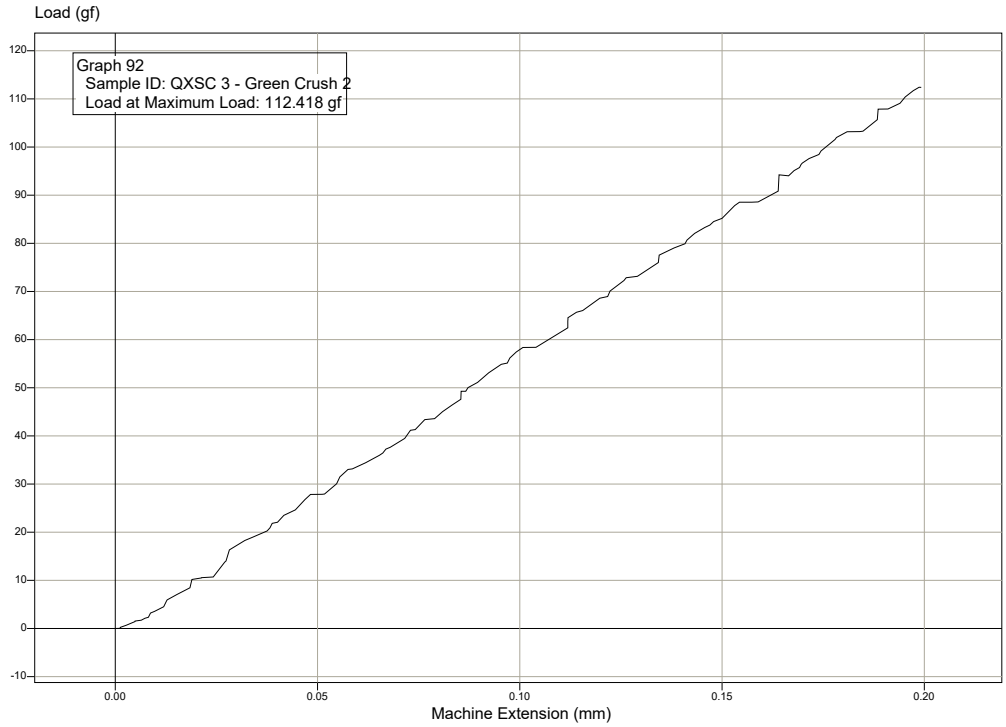
Graph 90


Load (gf)
Graph 90
Sample ID: QXSC 3 - Tip Crush 3
Load at Maximum Load: 53.604 gf
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

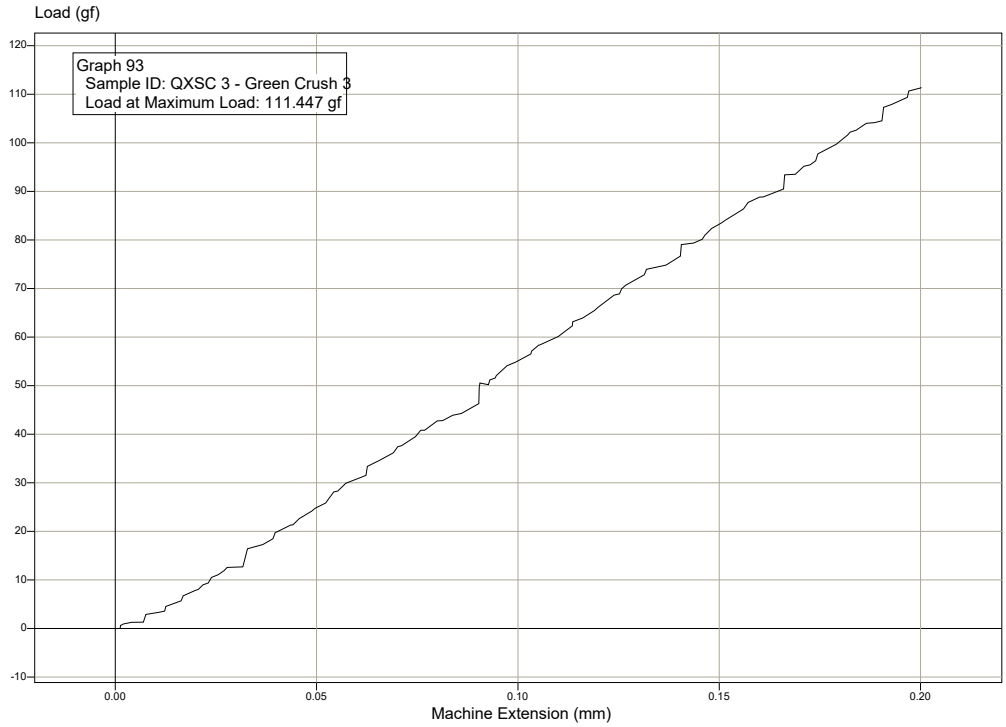
Graph 91


Load (gf)
Graph 91
Sample ID: QXSC 3 - Green Crush 1
Load at Maximum Load: 109.124 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

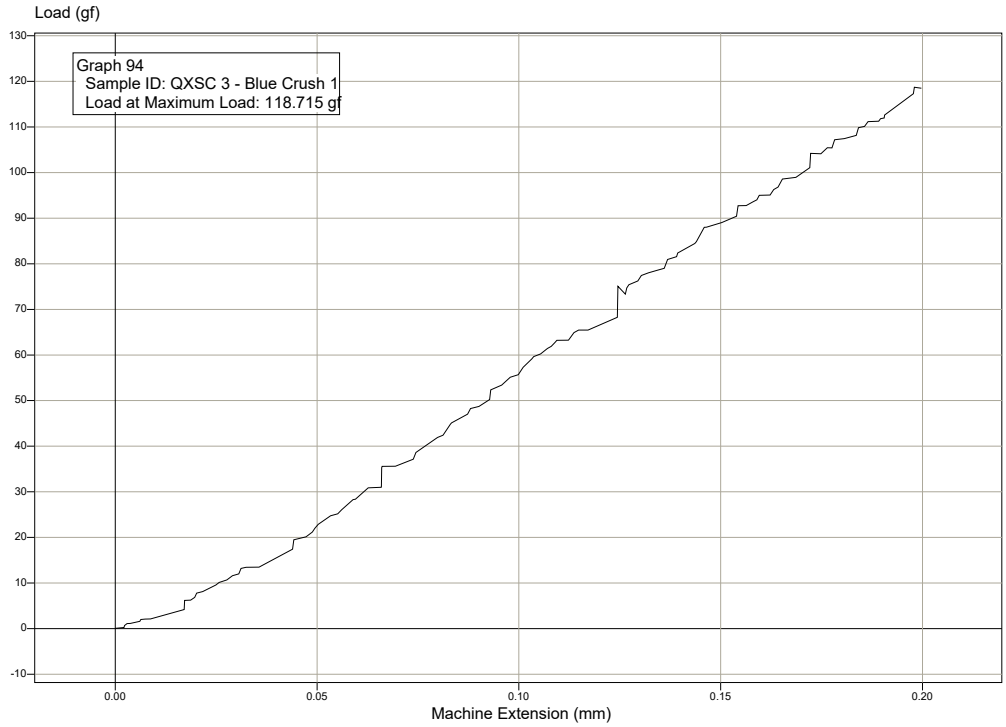
Graph 92


Load (gf)
Graph 92
Sample ID: QXSC 3 - Green Crush 2
Load at Maximum Load: 112.418 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

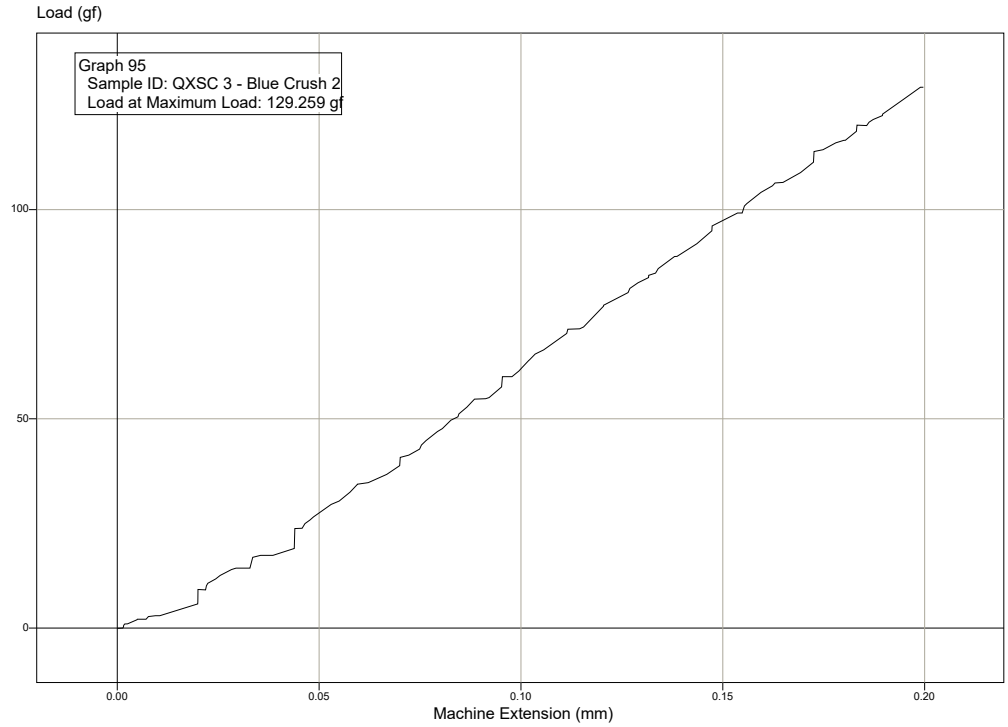
Graph 93


Load (gf)
Graph 93
Sample ID: QXSC 3 - Green Crush 3
Load at Maximum Load: 111.447 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

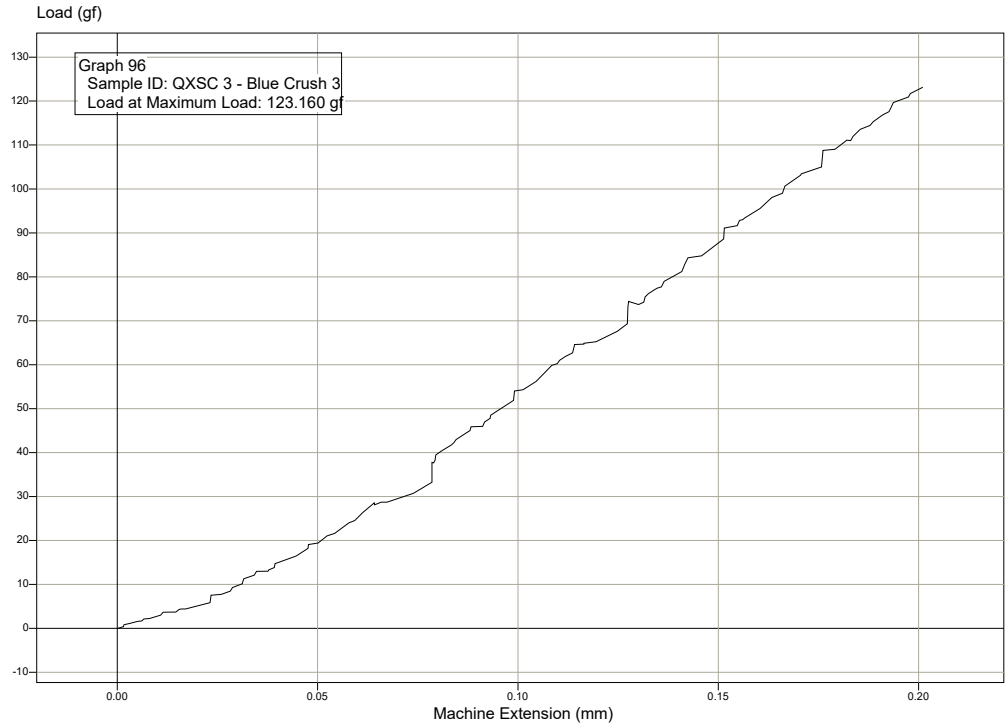
Graph 94


Load (gf)
Graph 94
Sample ID: QXSC 3 - Blue Crush 1
Load at Maximum Load: 118.715 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

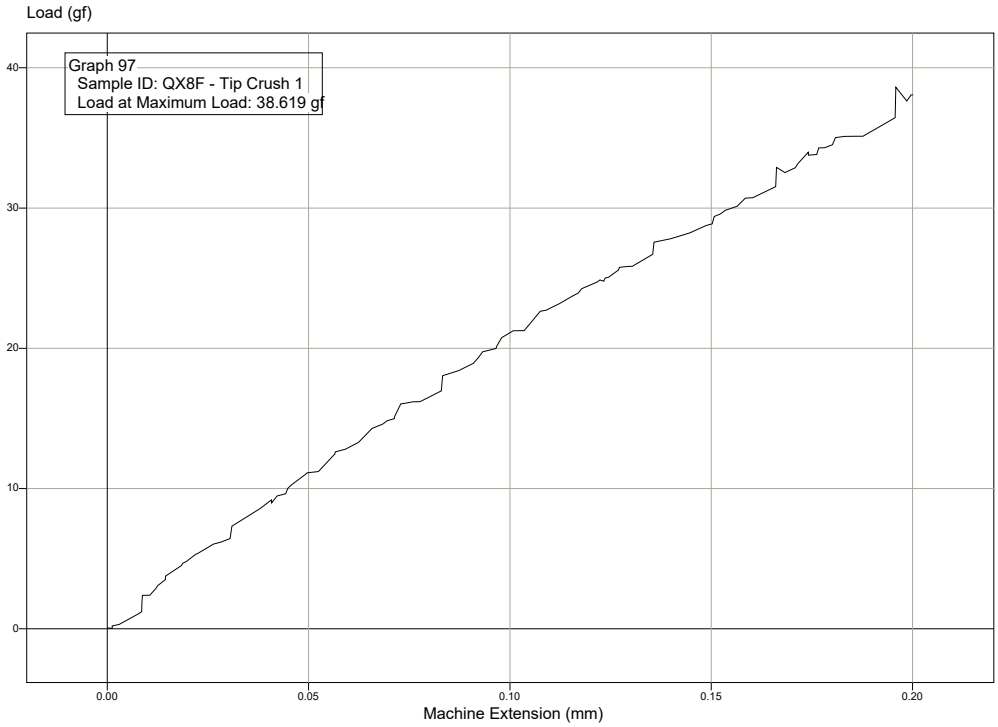
Graph 95



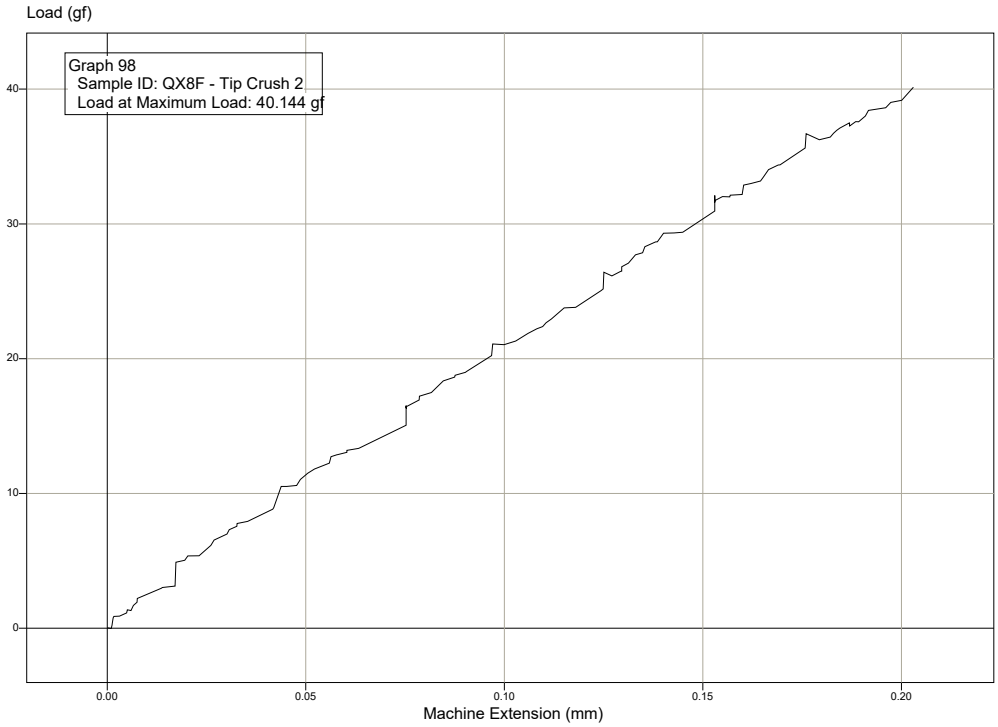
Graph 96


Load (gf)
Graph 96
Sample ID: QXSC 3 - Blue Crush 3
Load at Maximum Load: 123.160 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

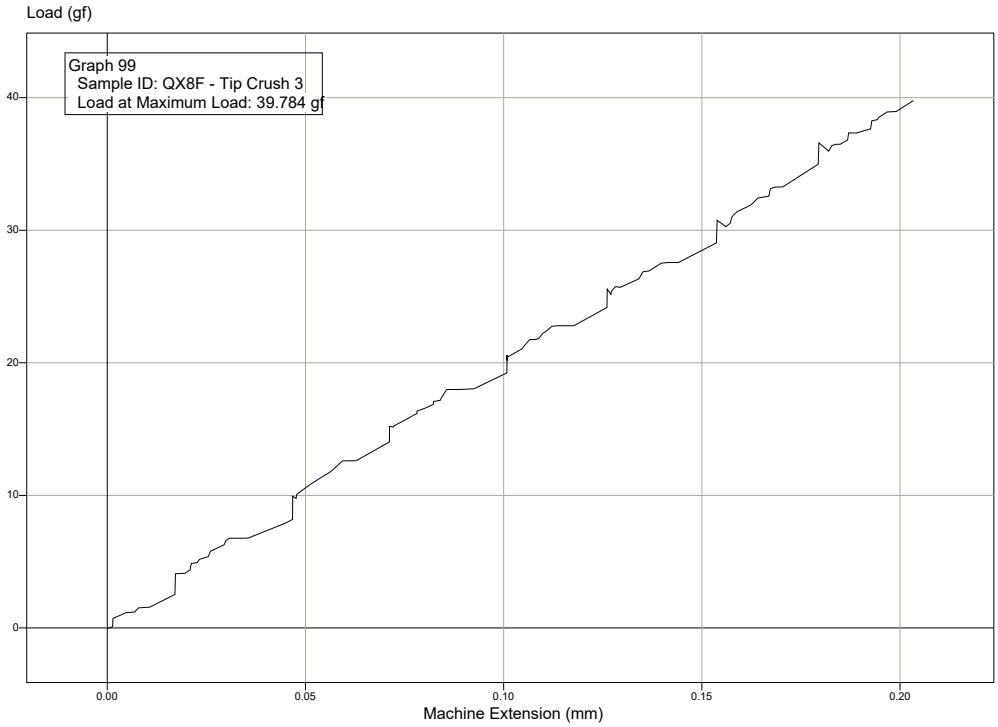
Graph 97


Load (gf)
Graph 97
Sample ID: QX8F - Tip Crush 1
Load at Maximum Load: 38.619 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

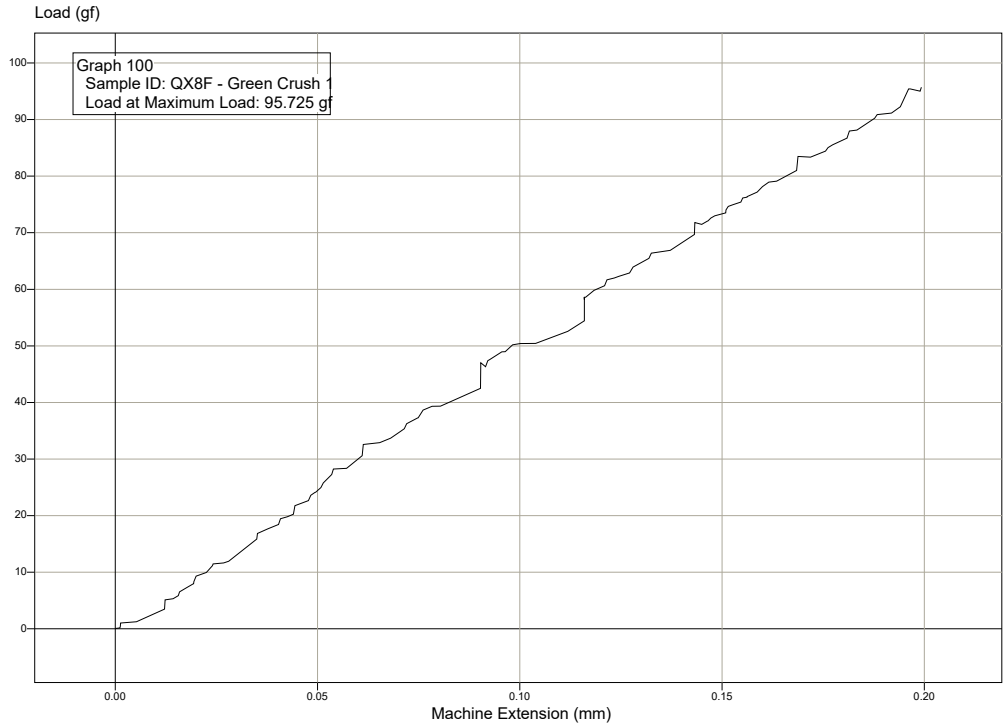
Graph 98


Load (gf)
Graph 98
Sample ID: QX8F - Tip Crush 2
Load at Maximum Load: 40.144 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

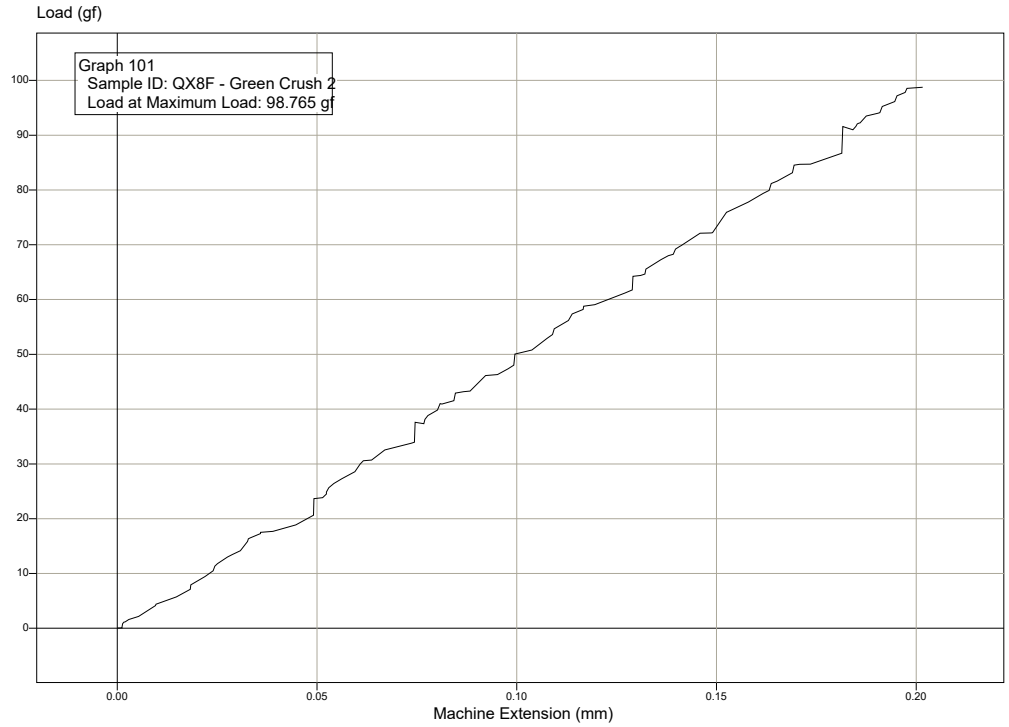
Graph 99


Load (gf)
Graph 99
Sample ID: QX8F - Tip Crush 3
Load at Maximum Load: 39.784 gf
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

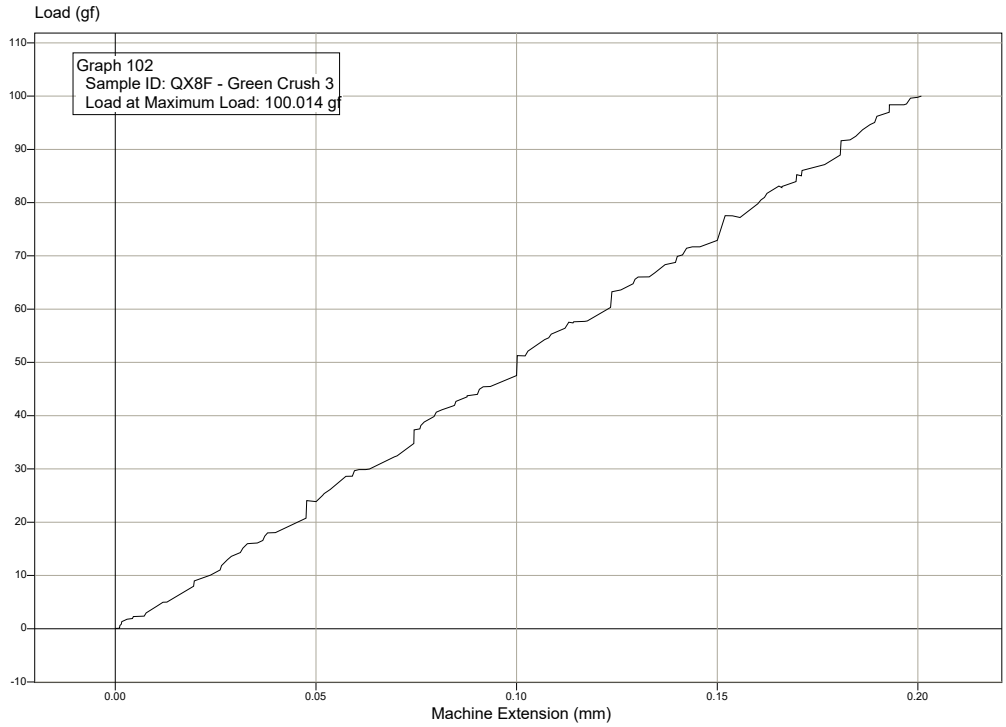
Graph 100


Load (gf)
Graph 100
Sample ID: QX8F - Green Crush 1
Load at Maximum Load: 95.725 gf
100
90
80
70
60
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

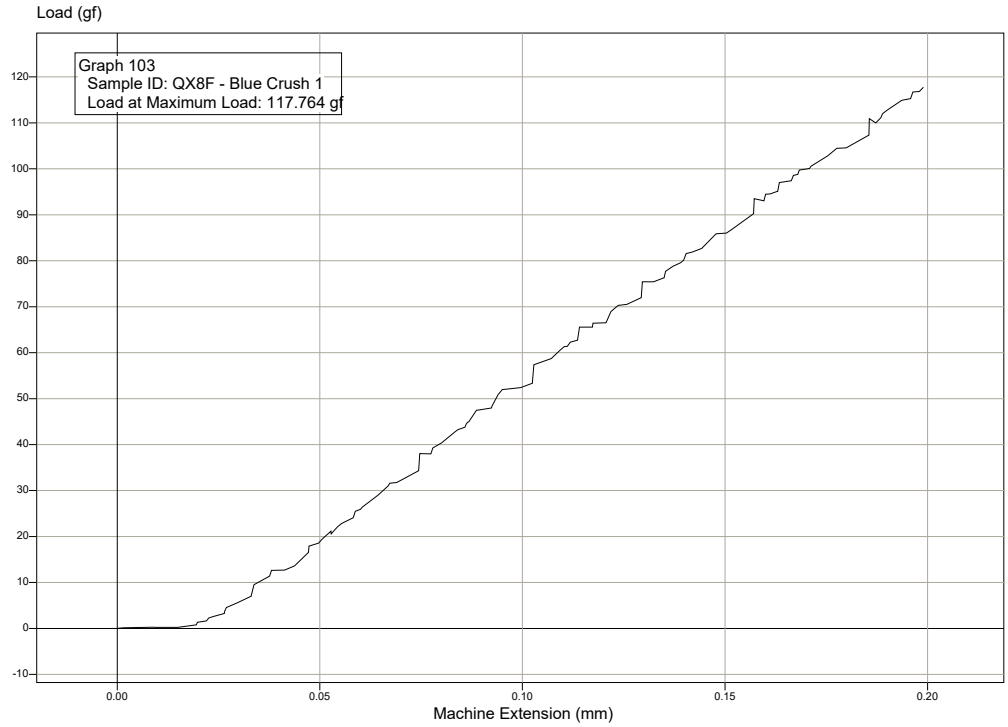
Graph 101


Load (gf)
Graph 101
Sample ID: QX8F - Green Crush 2
Load at Maximum Load: 98.765 gf
100
90
80
70
60
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

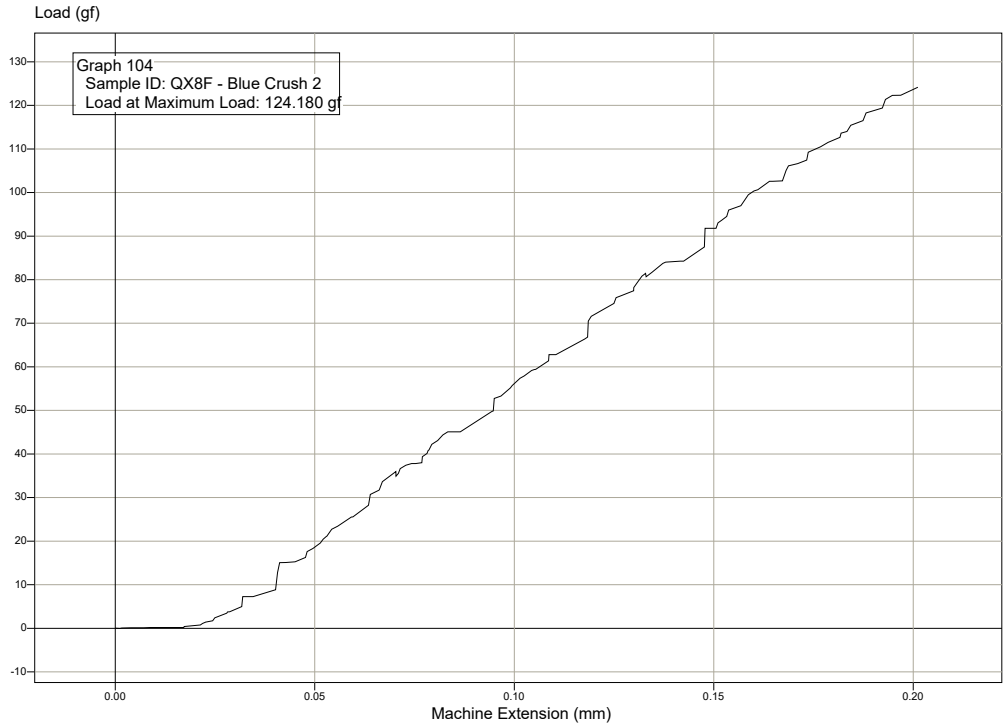
Graph 102


Load (gf)
Graph 102
Sample ID: QX8F - Green Crush 3
Load at Maximum Load: 100.014 gf
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

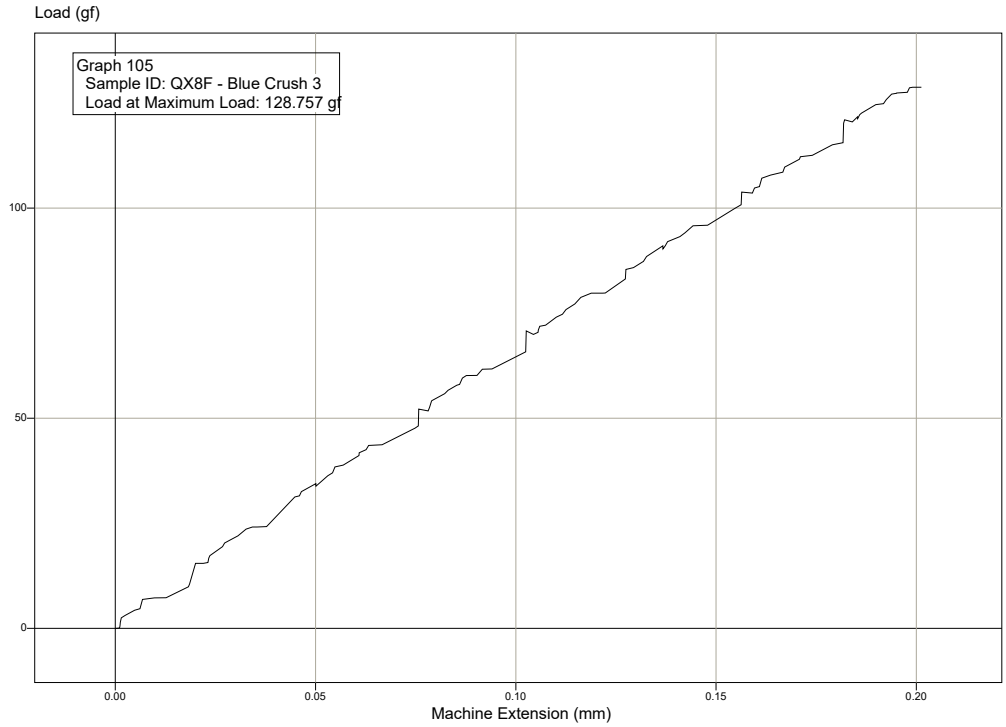
Graph 103


Load (gf)
Graph 103
Sample ID: QX8F - Blue Crush 1
Load at Maximum Load: 117.764 gf
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

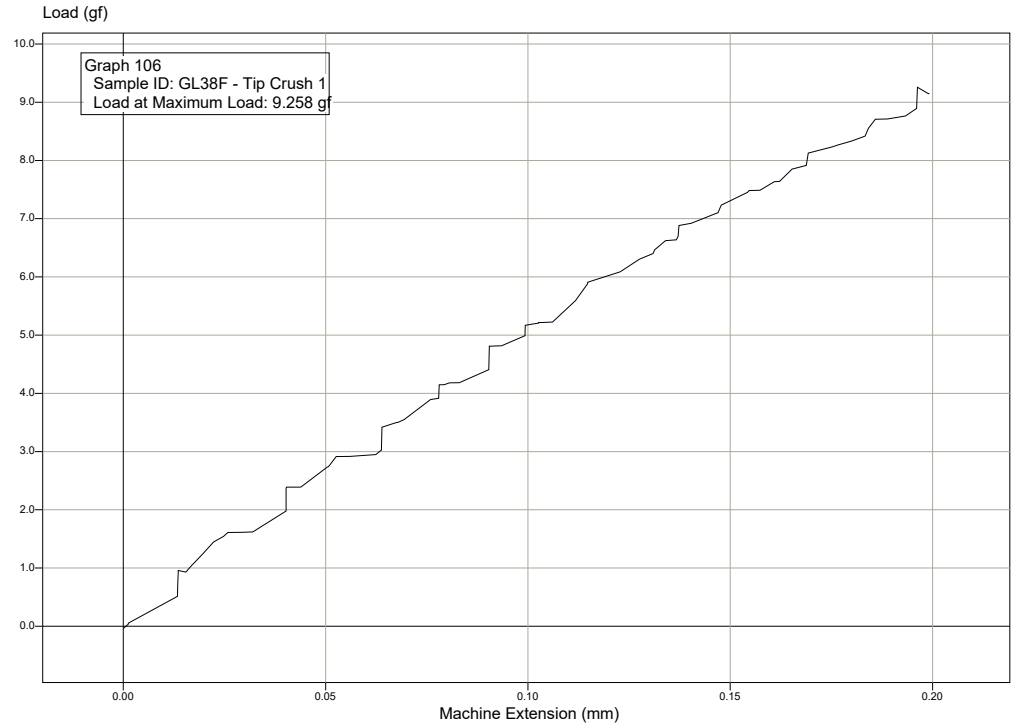
Graph 104


Load (gf)
Graph 104
Sample ID: QX8F - Blue Crush 2
Load at Maximum Load: 124.180 gf
130
120
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

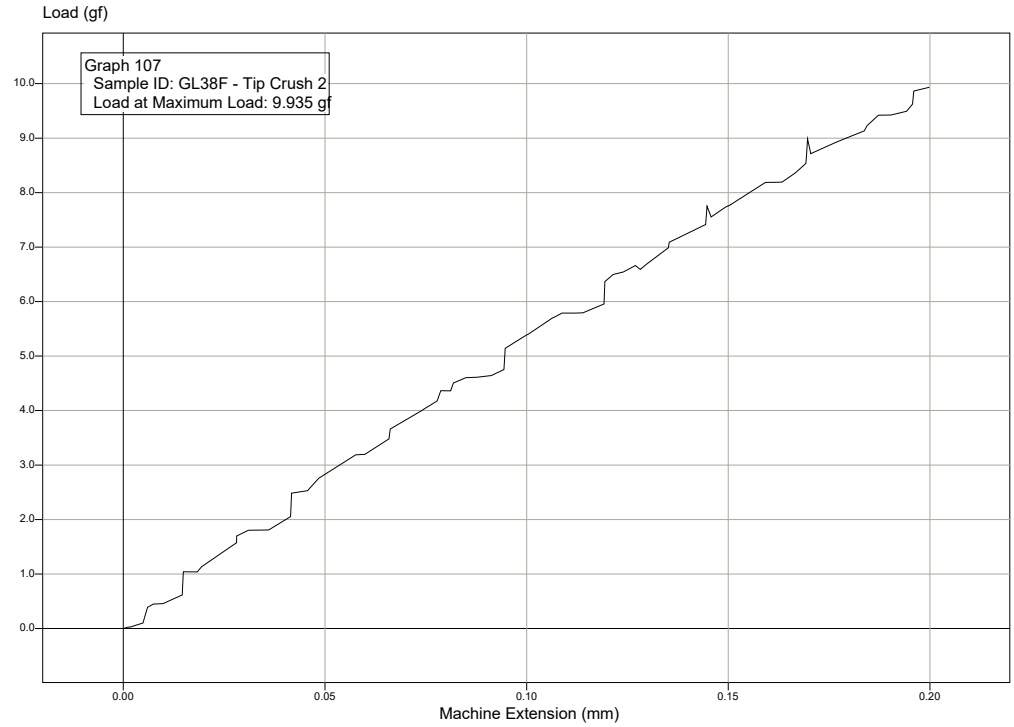
Graph 105


Load (gf)
Graph 105
Sample ID: QX8F - Blue Crush 3
Load at Maximum Load: 128.757 gf
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

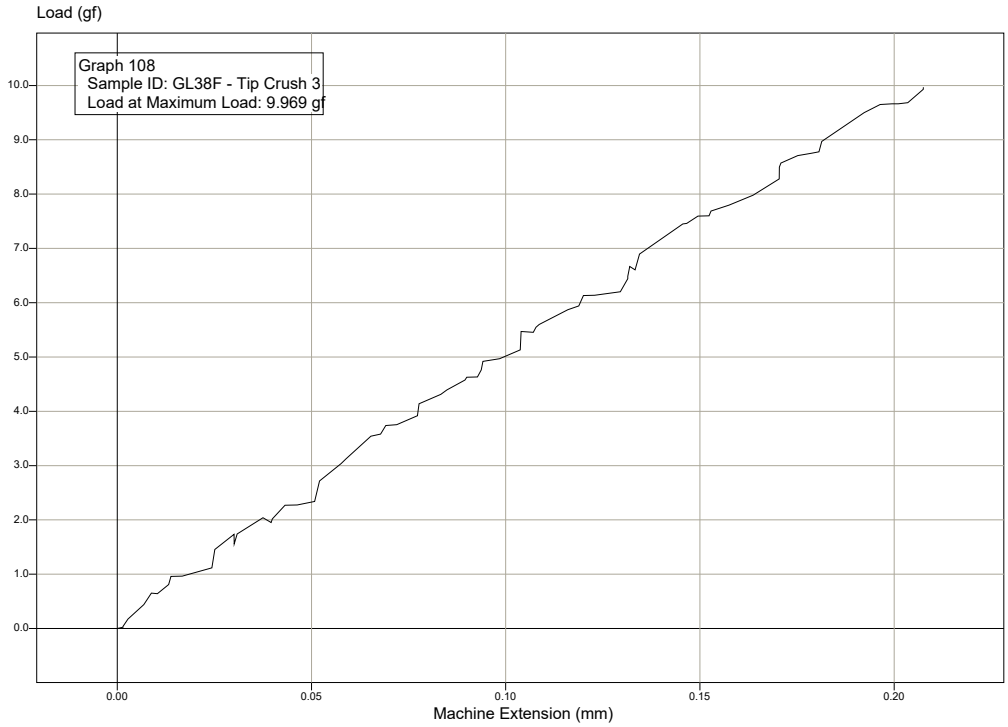
Graph 106



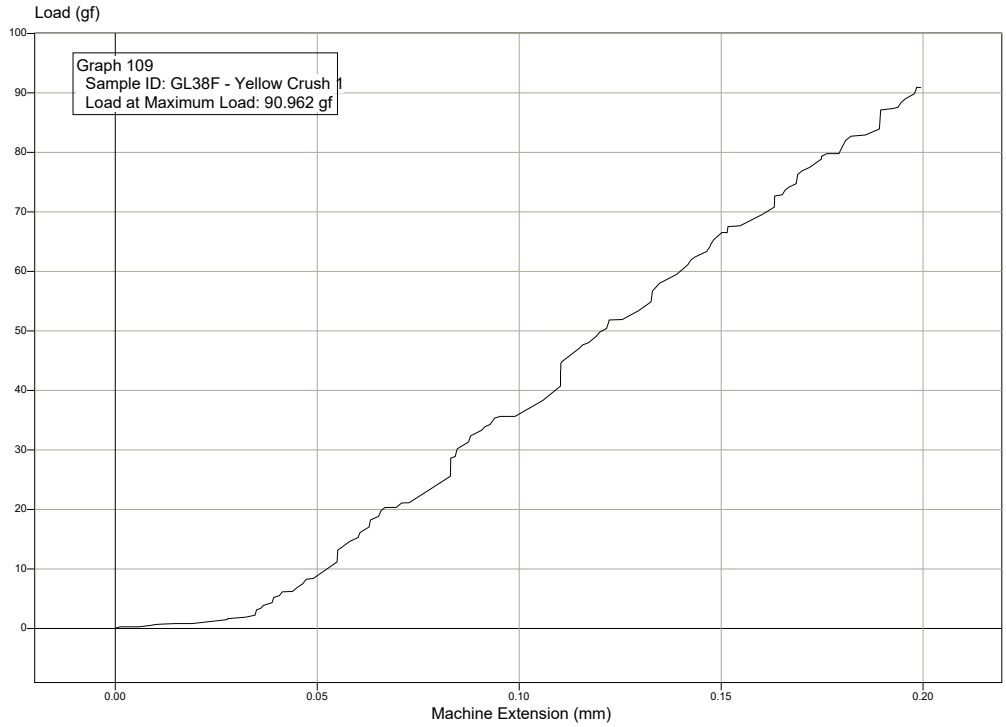
Graph 107


Load (gf)
Graph 107
Sample ID: GL38F - Tip Crush 2
Load at Maximum Load: 9.935 gf
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

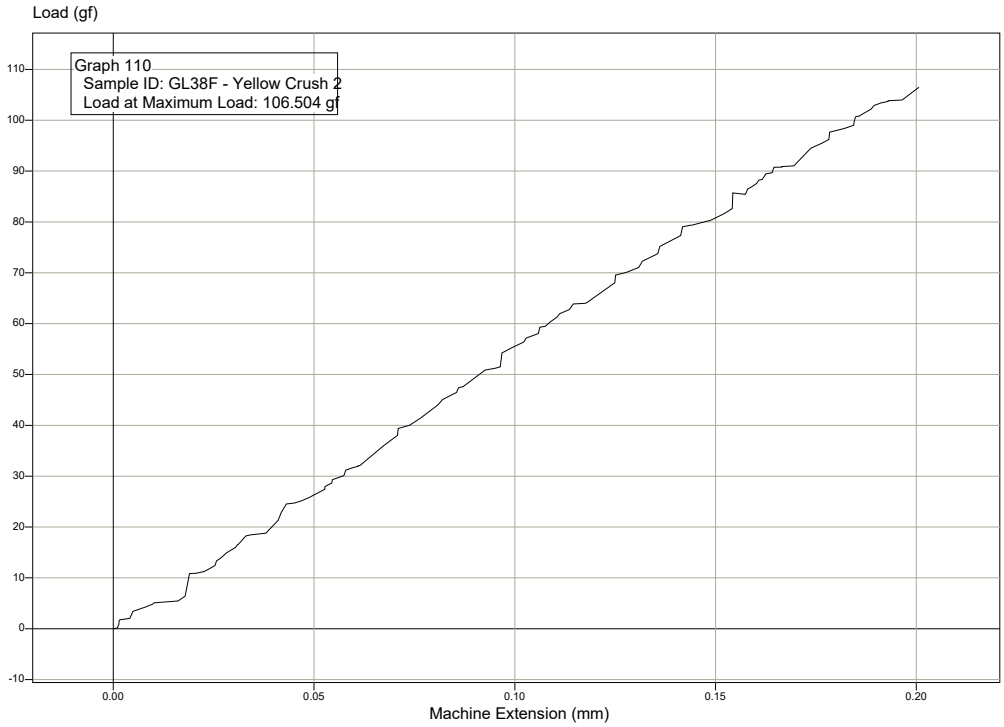
Graph 108


Load (gf)
Graph 108
Sample ID: GL38F - Tip Crush 3
Load at Maximum Load: 9.969 gf
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

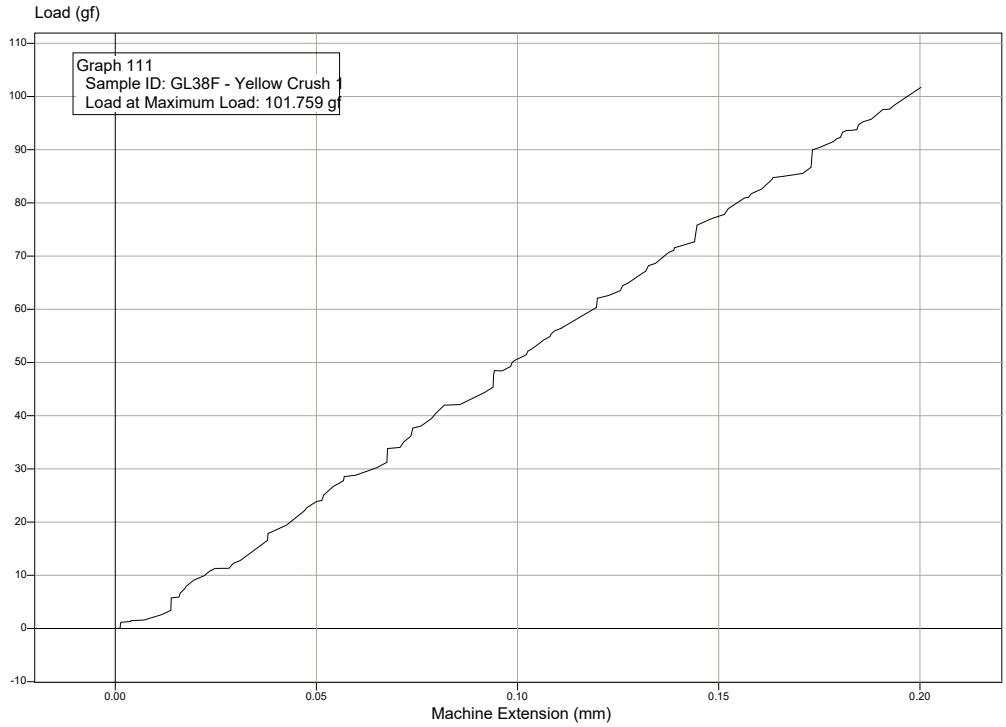
Graph 109


Load (gf)
Graph 109
Sample ID: GL38F - Yellow Crush 1
Load at Maximum Load: 90.962 gf
100
90
80
70
60
50
40
30
20
10
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

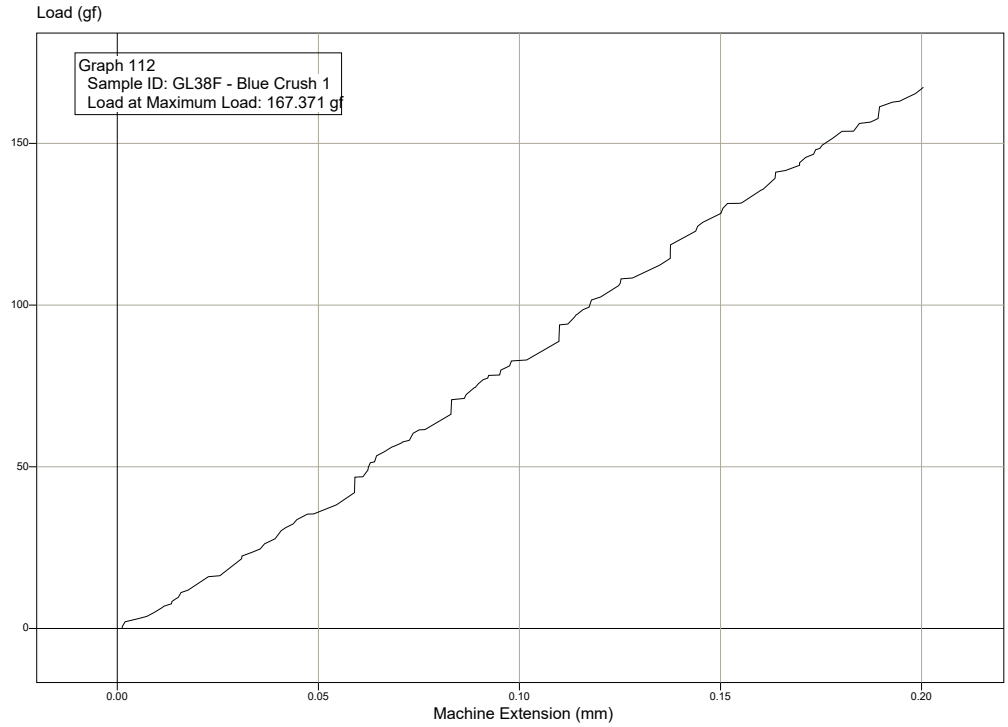
Graph 110


Load (gf)
Graph 110
Sample ID: GL38F - Yellow Crush 2
Load at Maximum Load: 106.504 gf
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

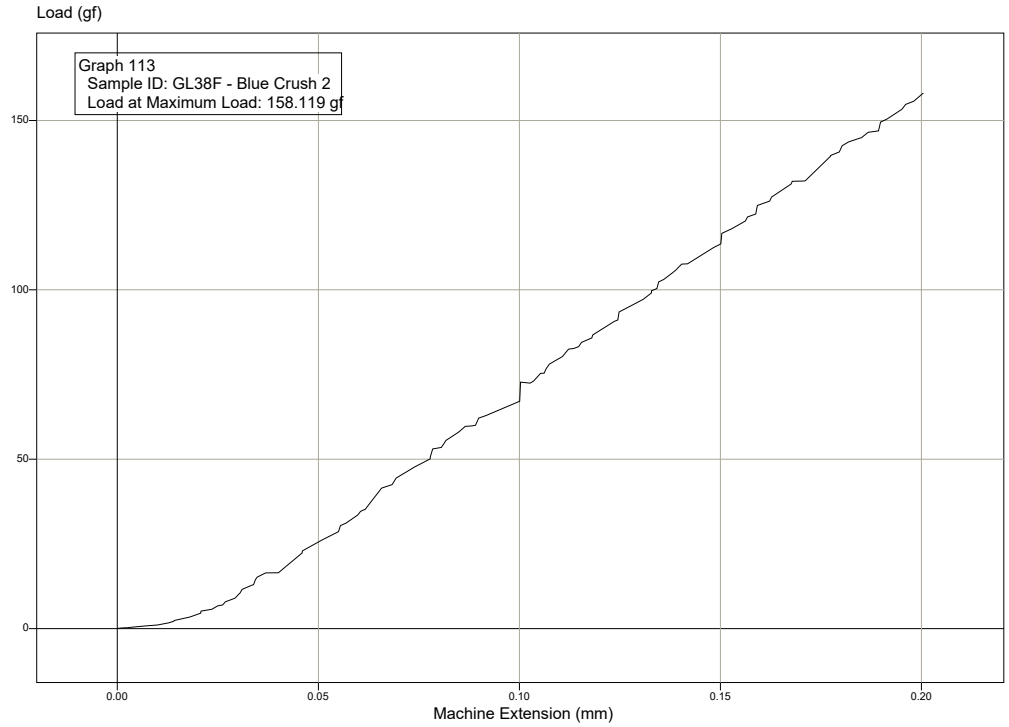
Graph 111


Load (gf)
Graph 111
Sample ID: GL38F - Yellow Crush 1
Load at Maximum Load: 101.759 gf
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

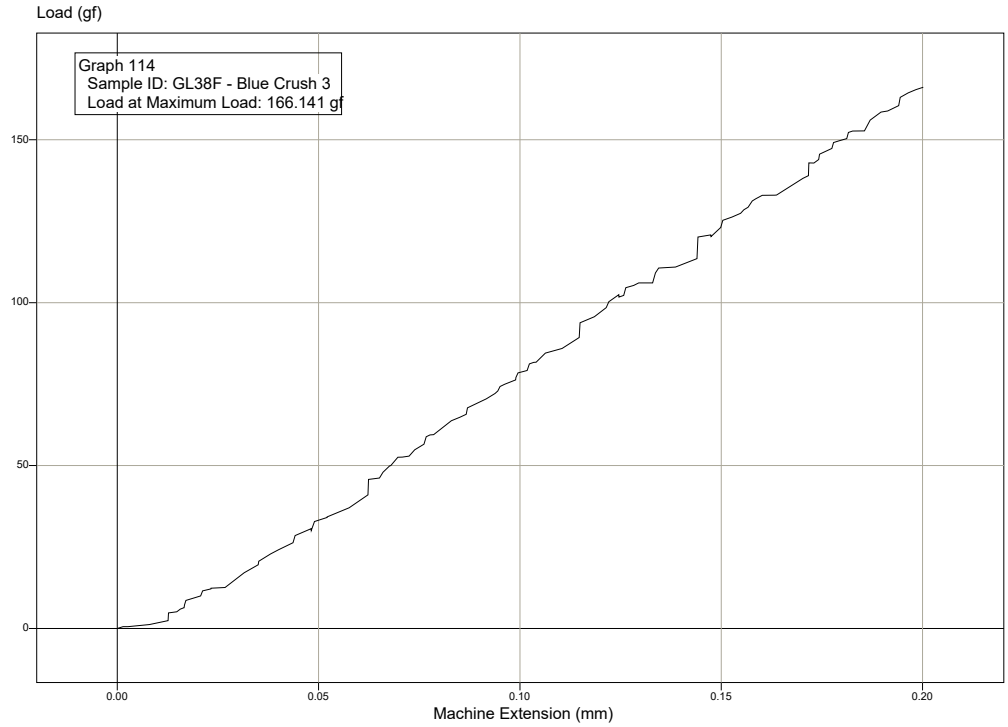
Graph 112


Load (gf)
Graph 112
Sample ID: GL38F - Blue Crush 1
Load at Maximum Load: 167.371 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

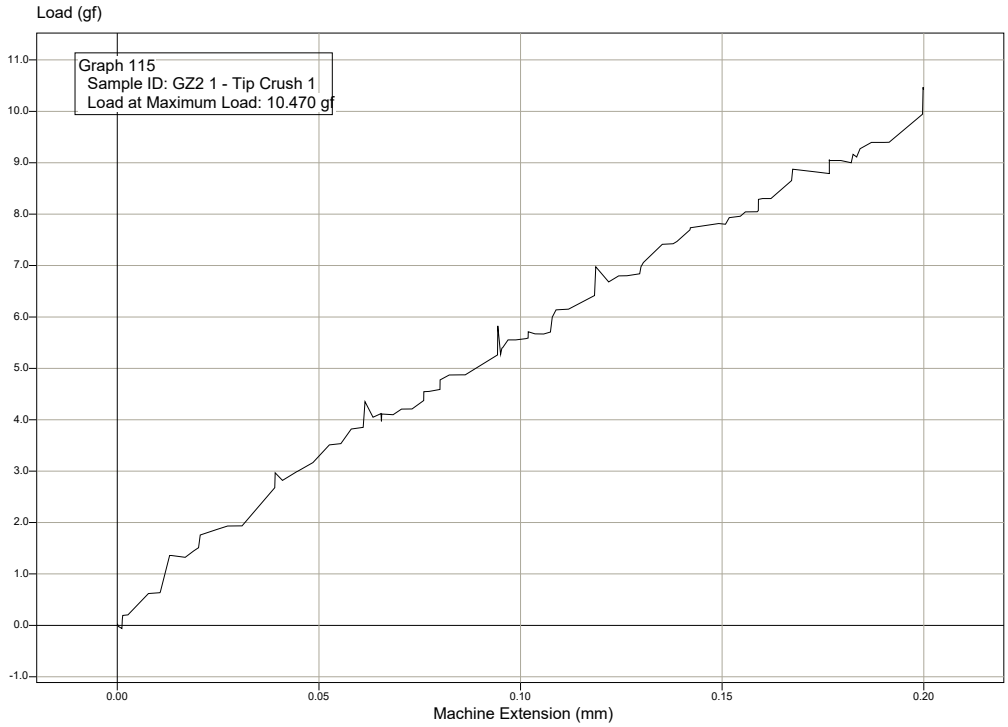
Graph 113



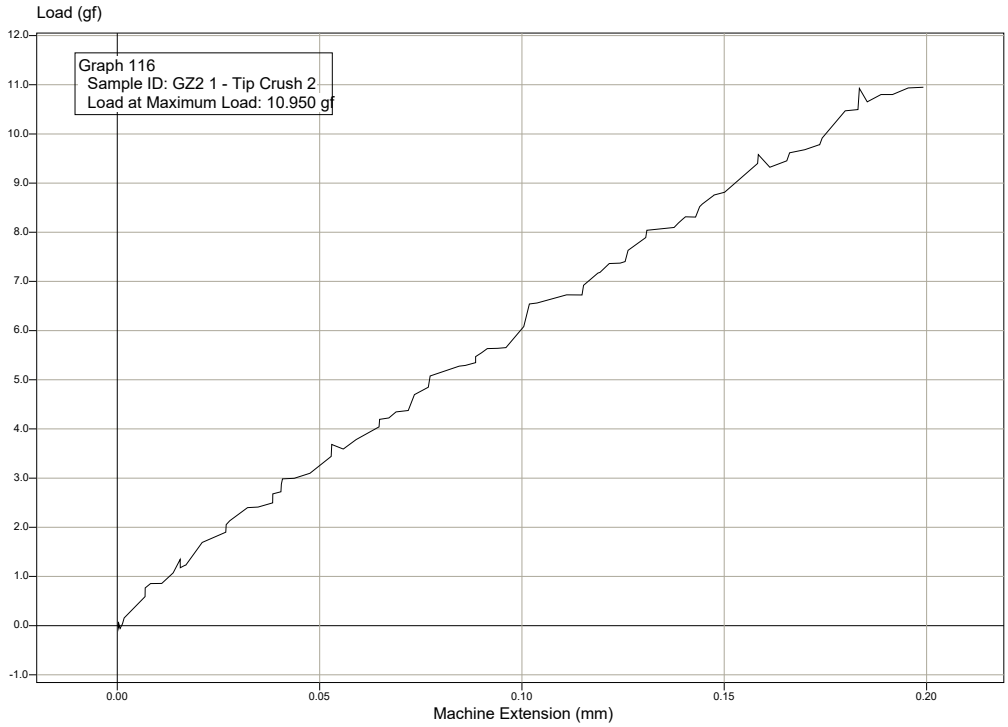
Graph 114


Load (gf)
Graph 114
Sample ID: GL38F - Blue Crush 3
Load at Maximum Load: 166.141 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

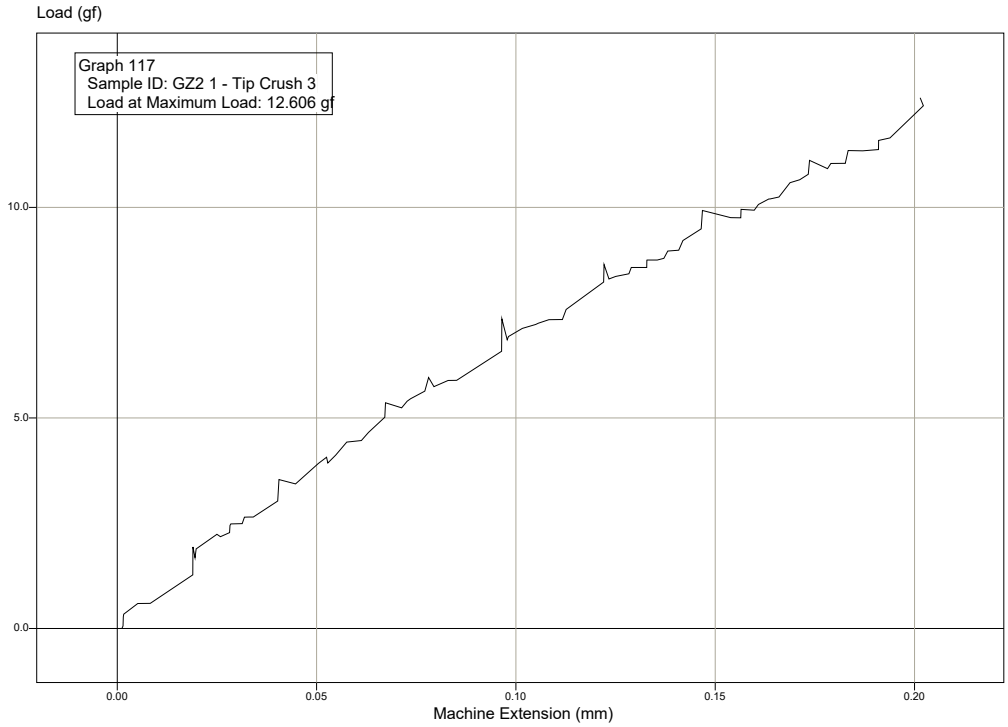
Graph 115


Load (gf)
Graph 115
Sample ID: GZ2 1 - Tip Crush 1
Load at Maximum Load: 10.470 gf
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

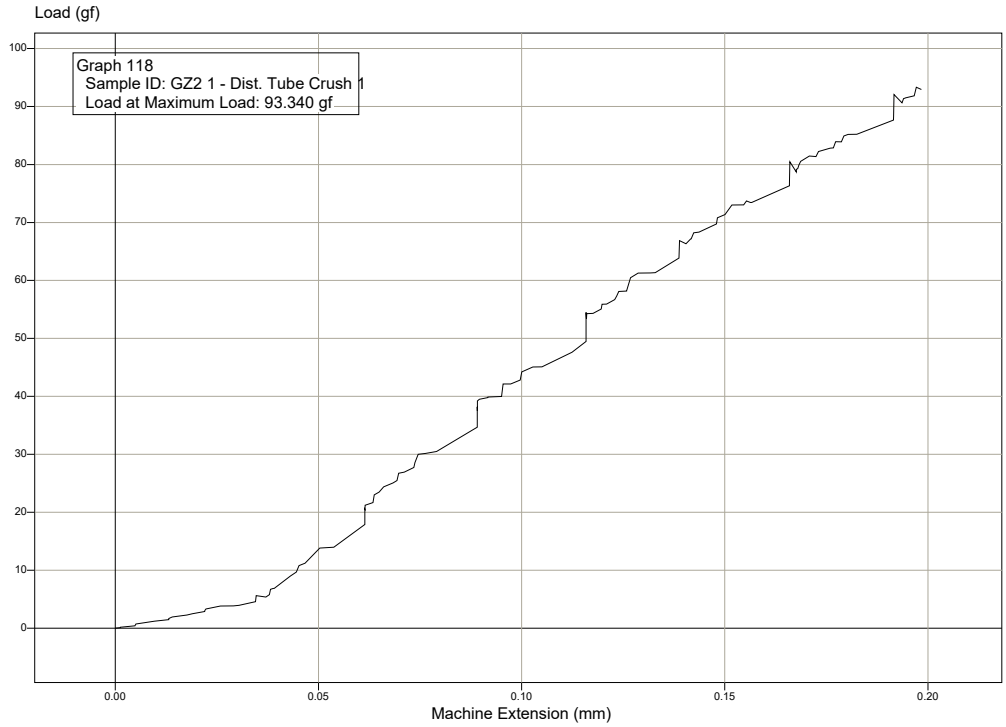
Graph 116


Load (gf)
Graph 116
Sample ID: GZ2 1 - Tip Crush 2
Load at Maximum Load: 10.950 gf
12.0
11.0
10.0
9.0
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
-1.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

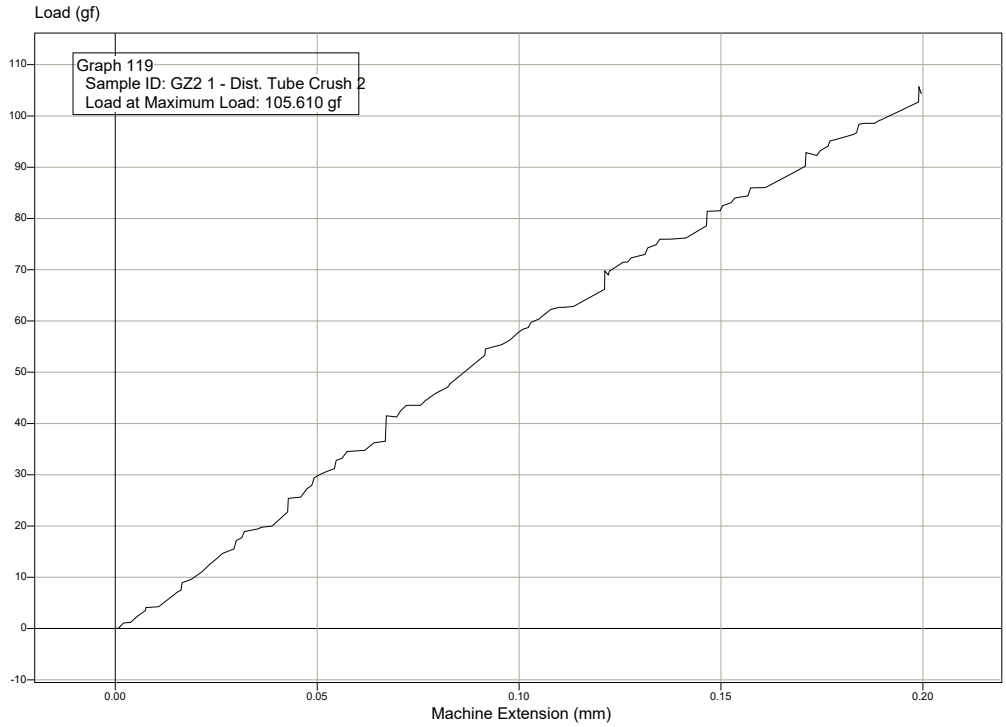
Graph 117


Load (gf)
Graph 117
Sample ID: GZ2 1 - Tip Crush 3
Load at Maximum Load: 12.606 gf
10.0
5.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

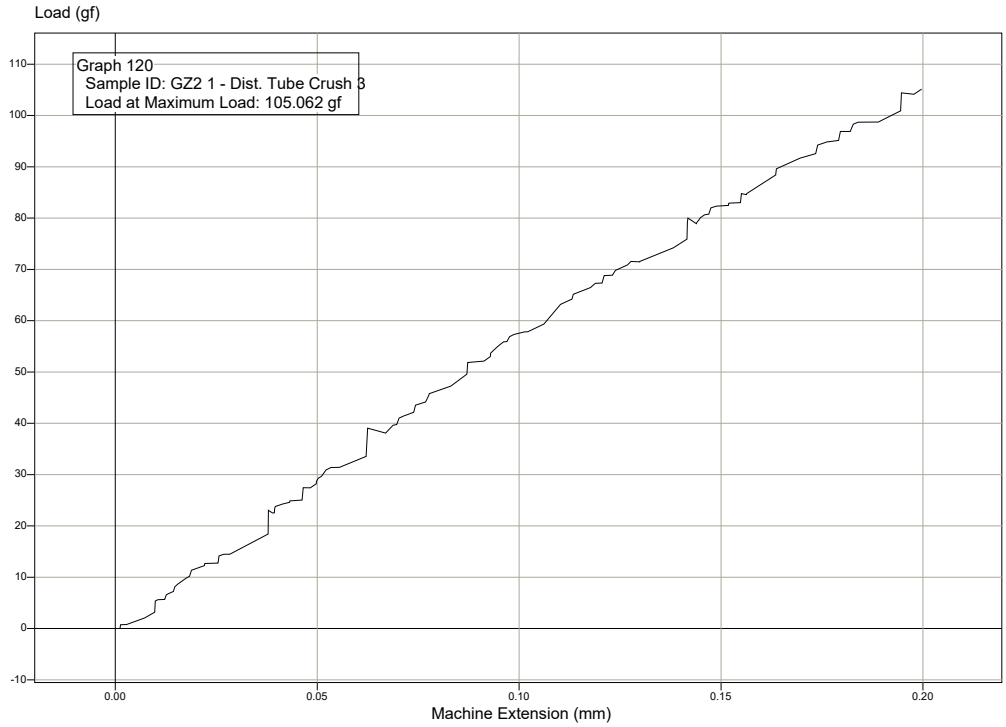
Graph 118



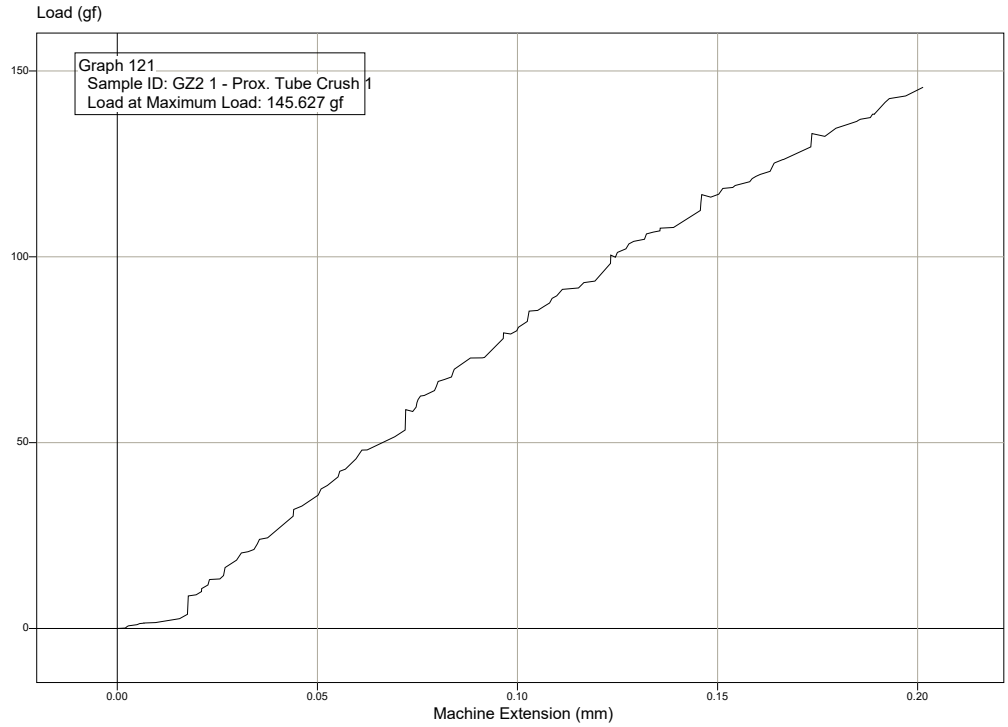
Graph 119


Load (gf)
Graph 119
Sample ID: GZ2 1 - Dist. Tube Crush 2
Load at Maximum Load: 105.610 gf
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

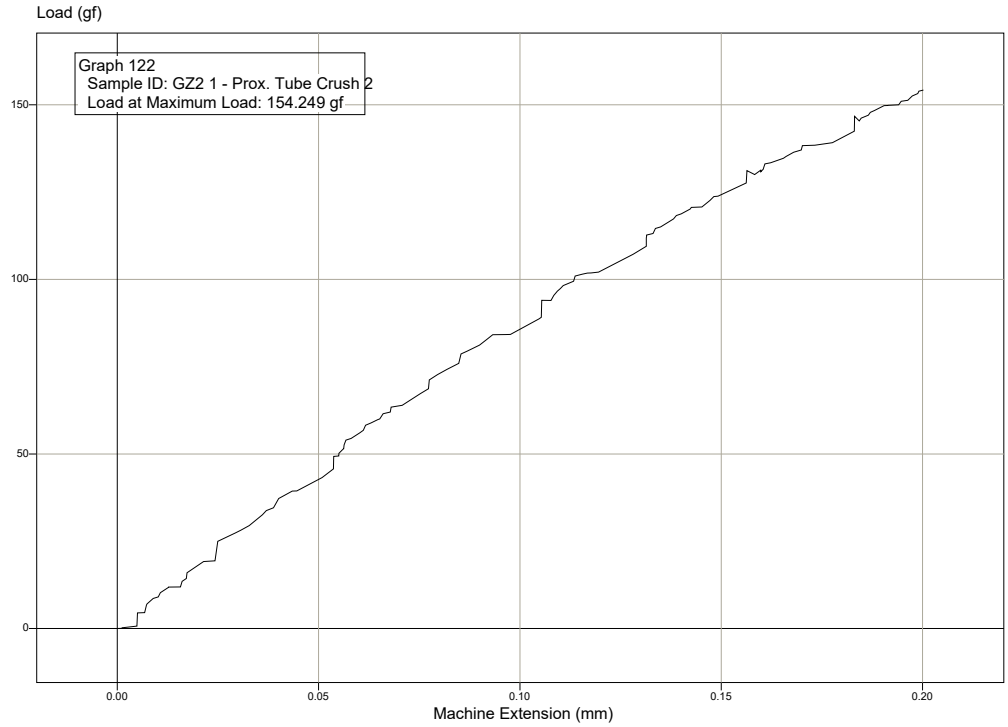
Graph 120


Load (gf)
Graph 120
Sample ID: GZ2 1 - Dist. Tube Crush 3
Load at Maximum Load: 105.062 gf
110
100
90
80
70
60
50
40
30
20
10
0
-10
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

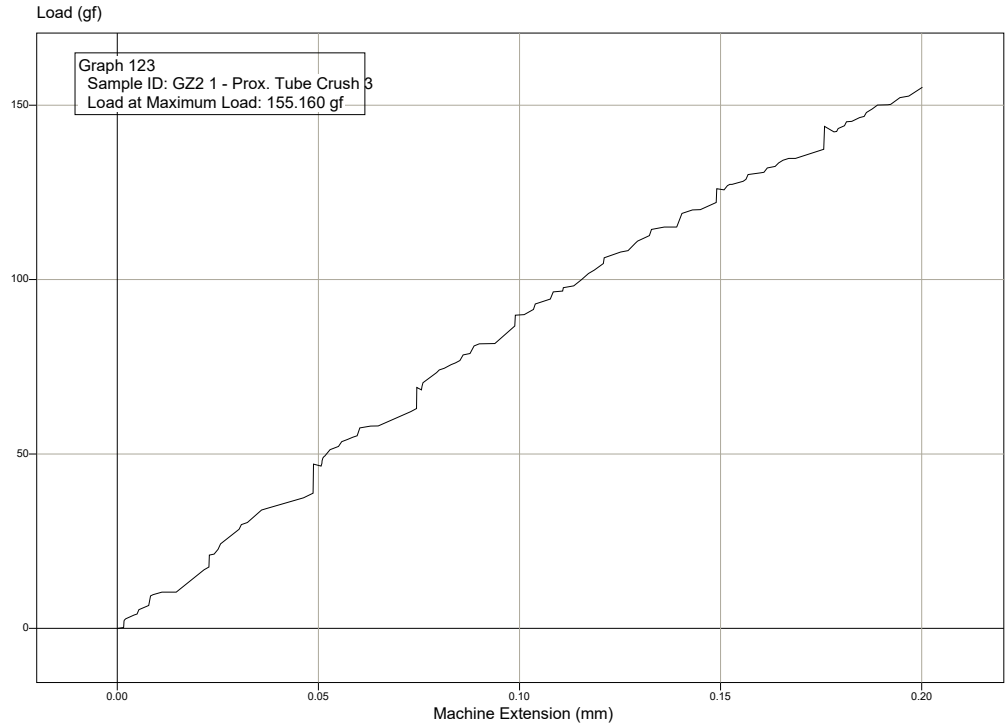
Graph 121


Load (gf)
Graph 121
Sample ID: GZ2 1 - Prox. Tube Crush 1
Load at Maximum Load: 145.627 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

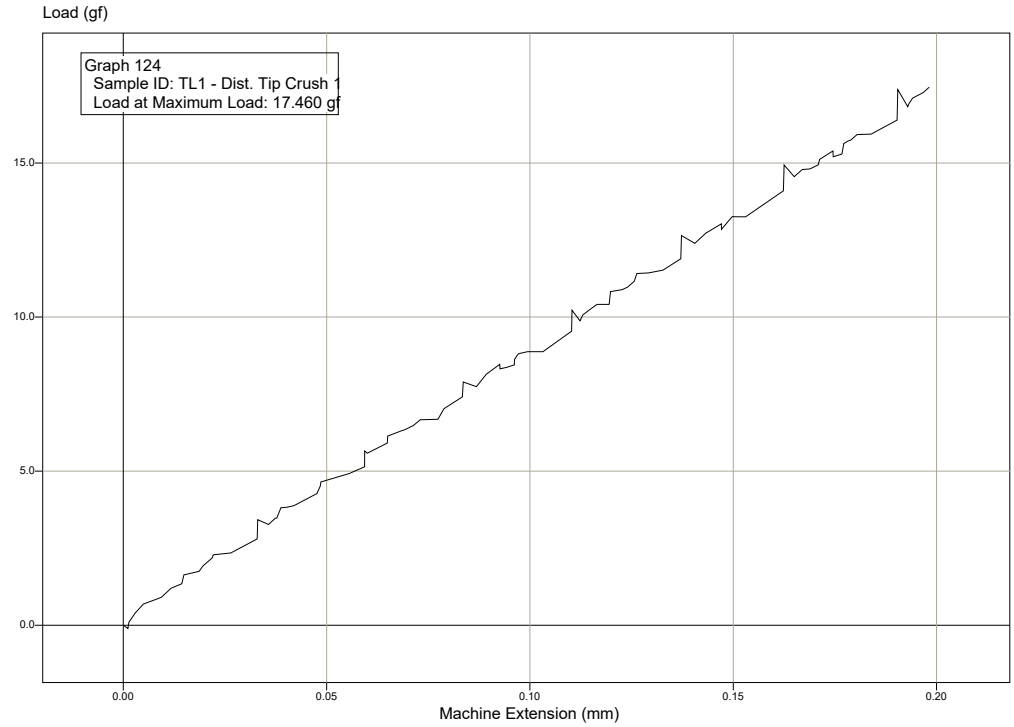
Graph 122


Load (gf)
Graph 122
Sample ID: GZ2 1 - Prox. Tube Crush 2
Load at Maximum Load: 154.249 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

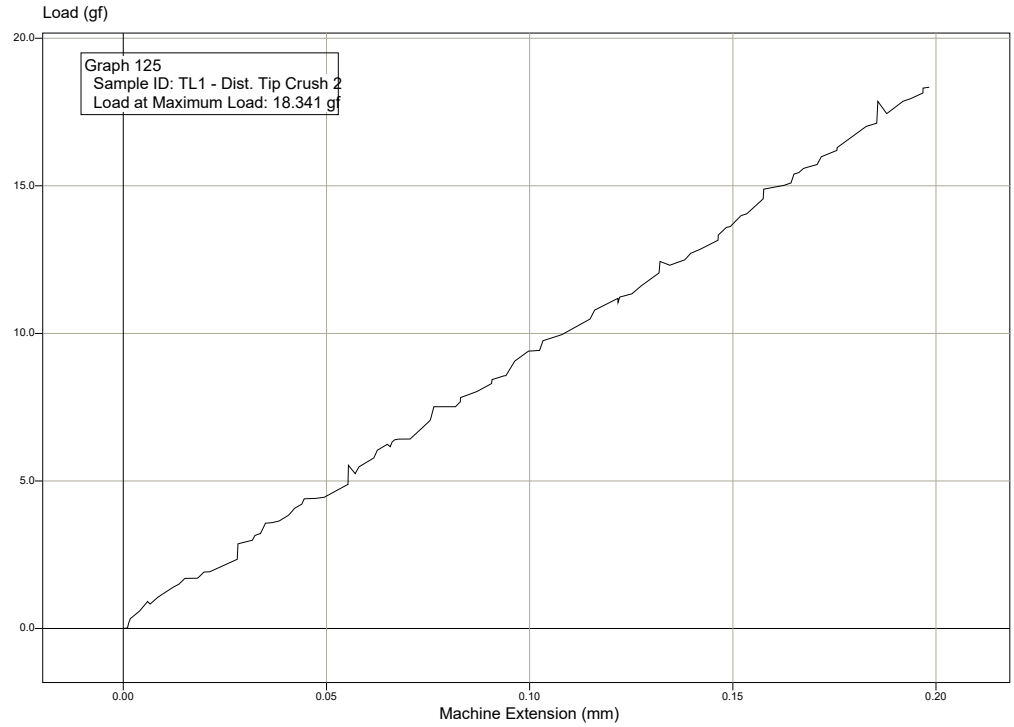
Graph 123


Load (gf)
Graph 123
Sample ID: GZ2 1 - Prox. Tube Crush 3
Load at Maximum Load: 155.160 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

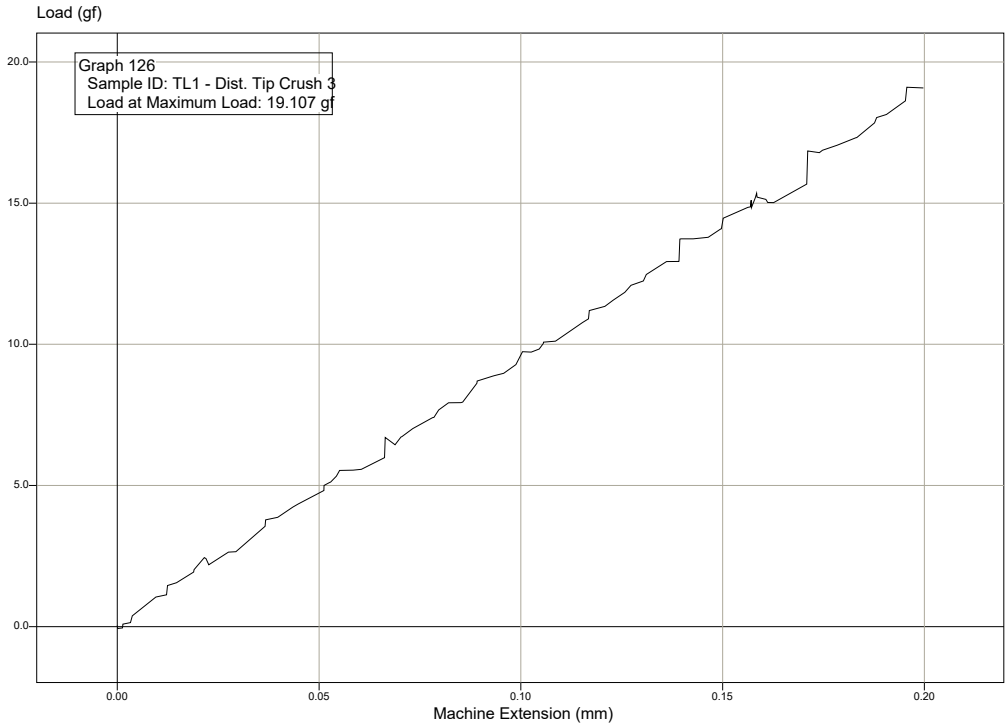
Graph 124


Load (gf)
Graph 124
Sample ID: TL1 - Dist. Tip Crush 1
Load at Maximum Load: 17.460 gf
15.0
10.0
5.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

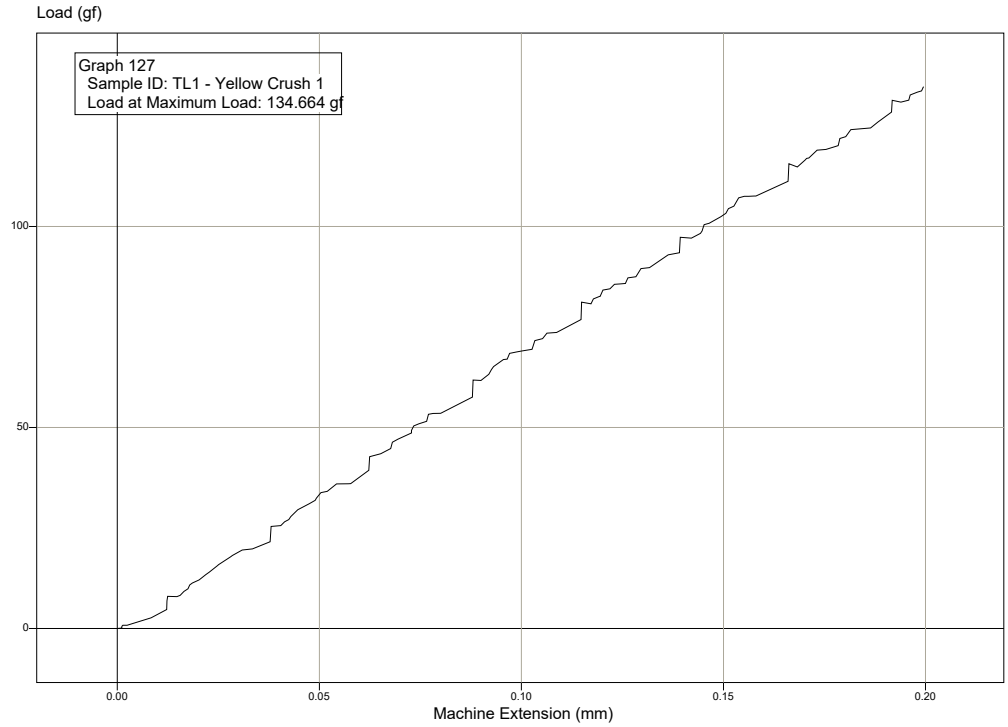
Graph 125


Load (gf)
Graph 125
Sample ID: TL1 - Dist. Tip Crush 2
Load at Maximum Load: 18.341 gf
20.0
15.0
10.0
5.0
0.0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

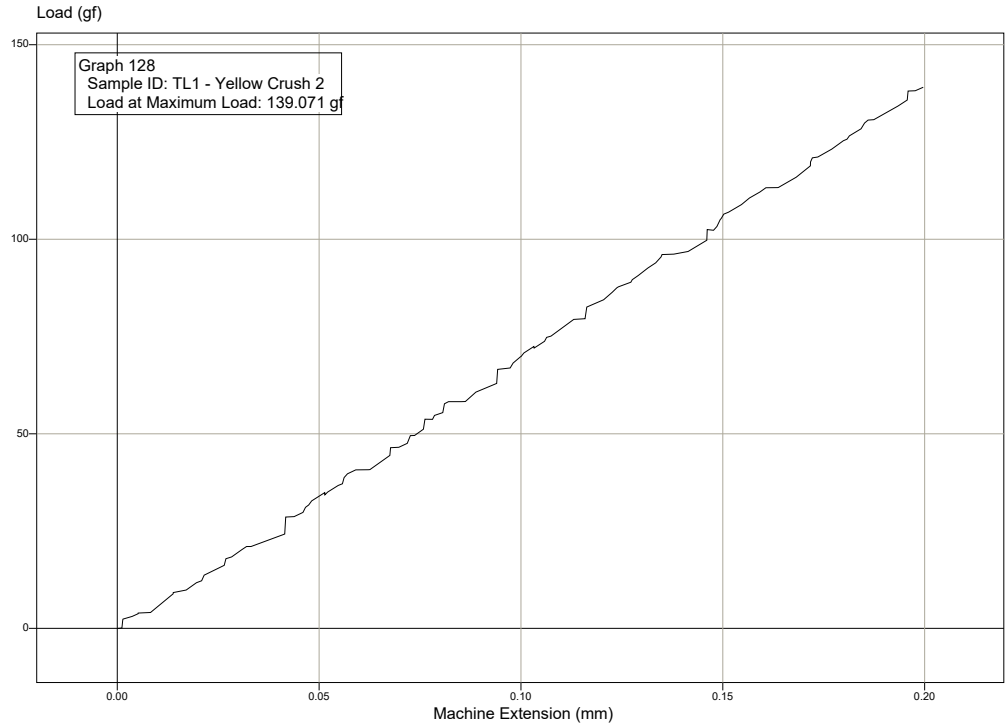
Graph 126



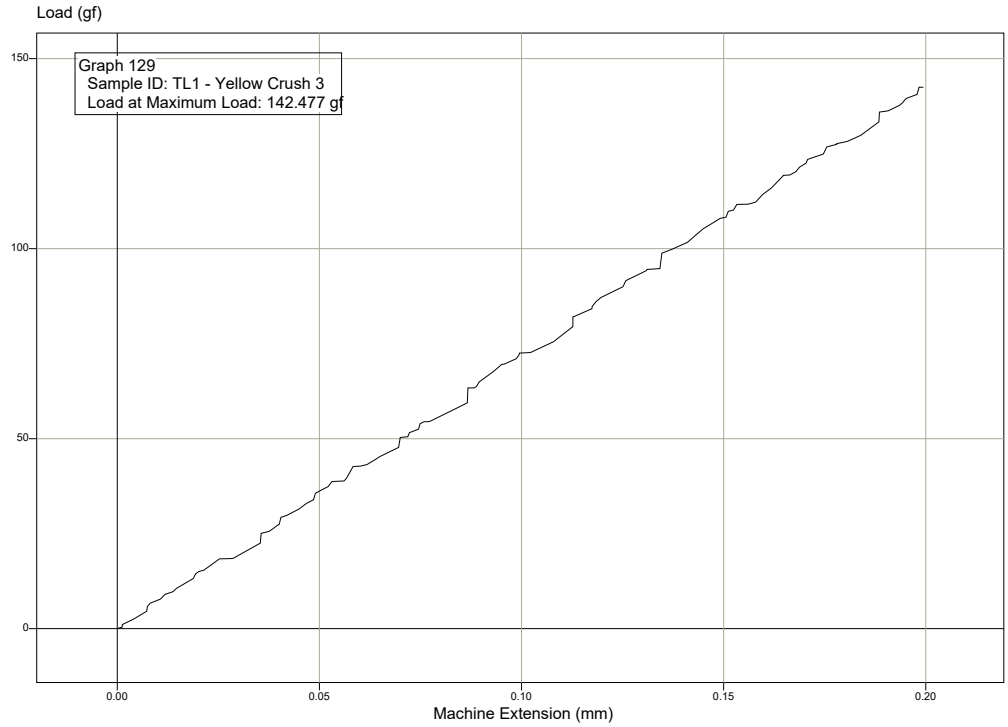
Graph 127



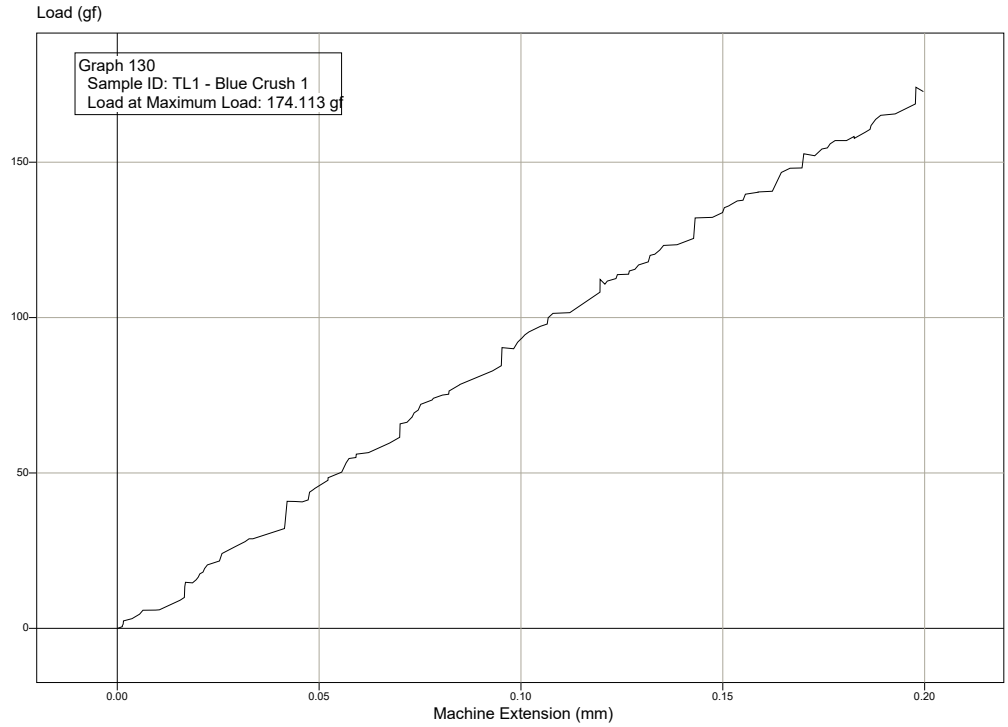
Graph 128



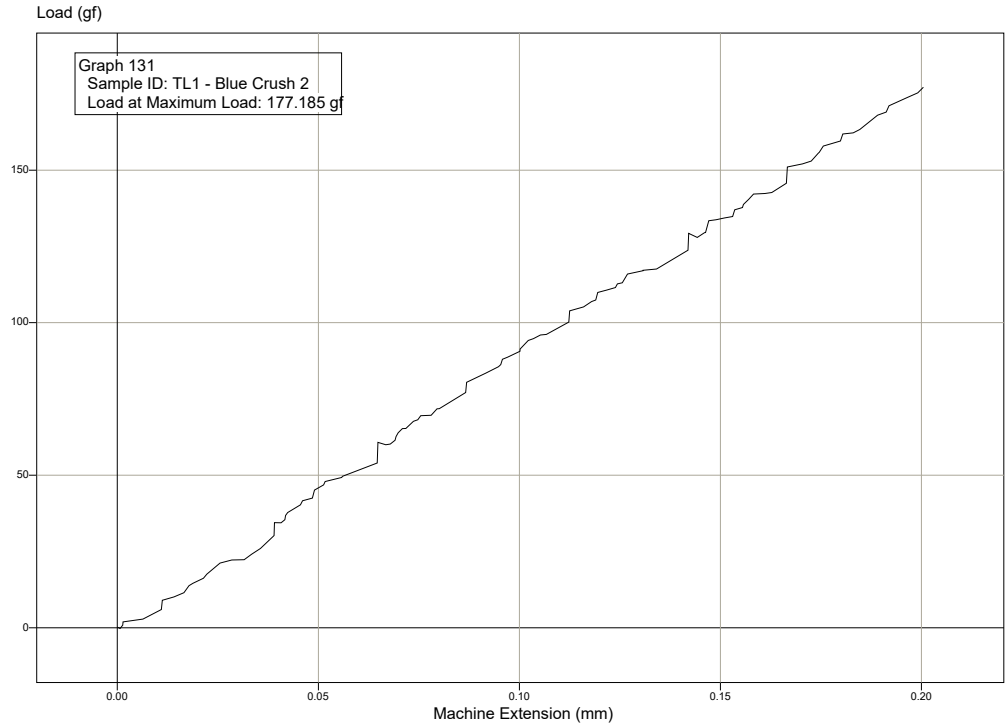
Graph 129


Load (gf)
Graph 129
Sample ID: TL1 - Yellow Crush 3
Load at Maximum Load: 142.477 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

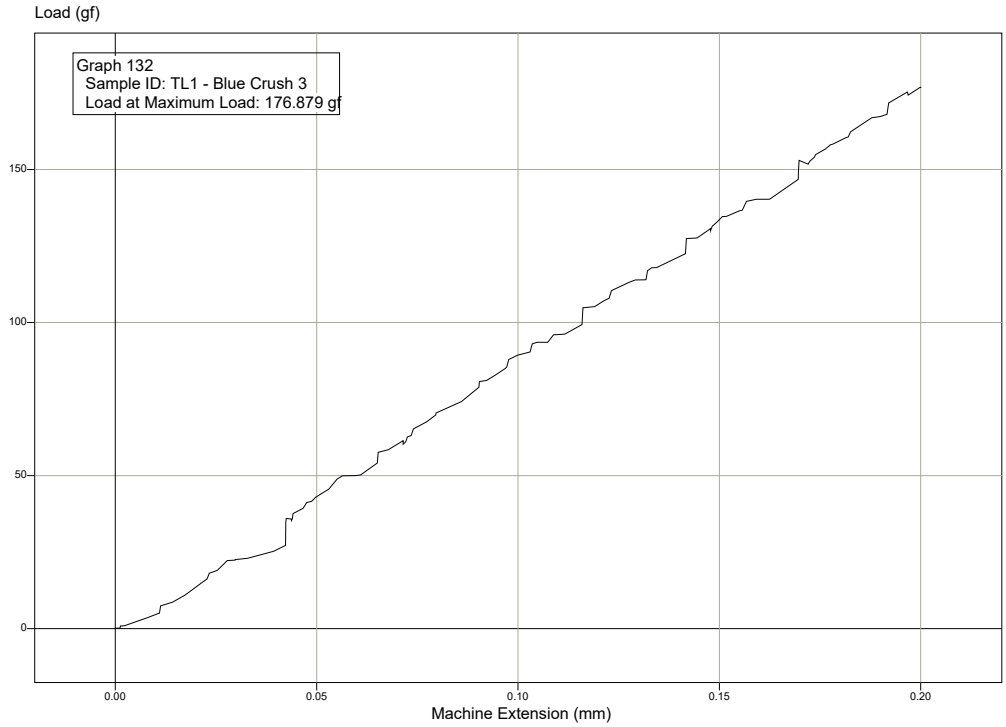
Graph 130

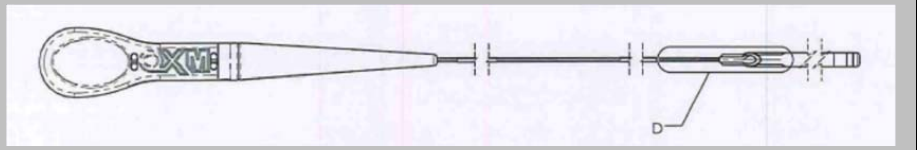

Load (gf)
Graph 130
Sample ID: TL1 - Blue Crush 1
Load at Maximum Load: 174.113 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

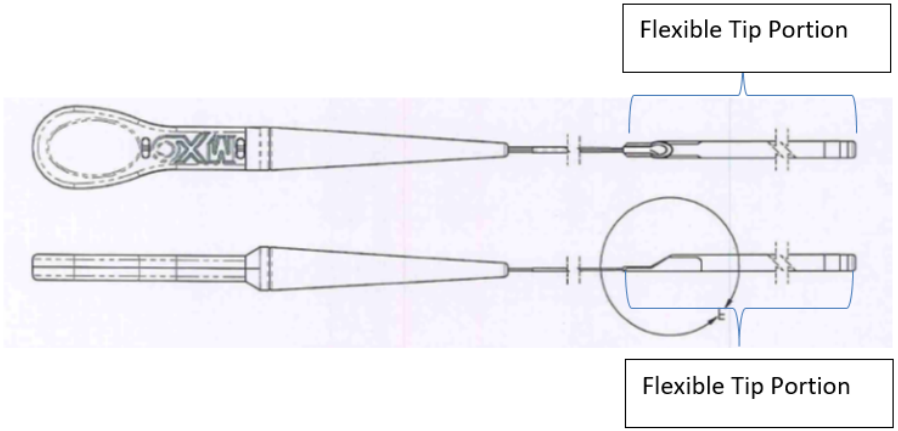
Graph 131

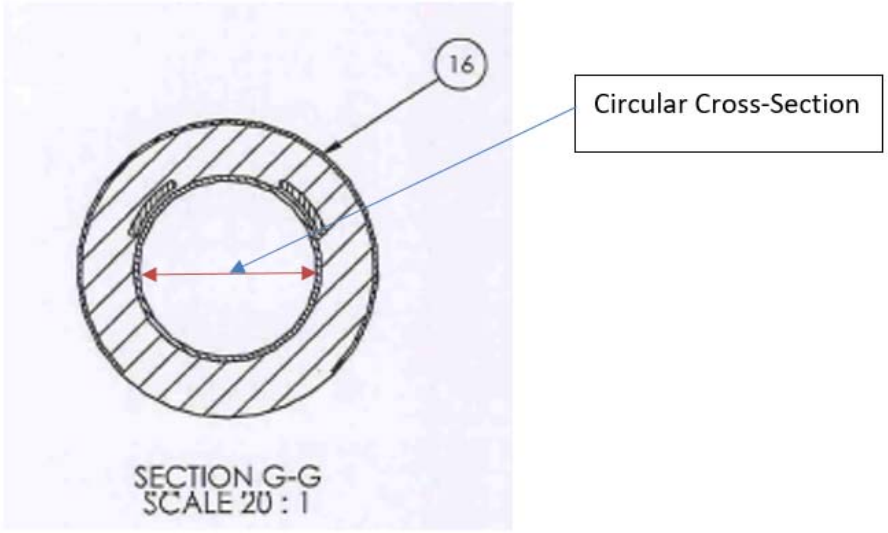

Load (gf)
Graph 131
Sample ID: TL1 - Blue Crush 2
Load at Maximum Load: 177.185 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

Graph 132

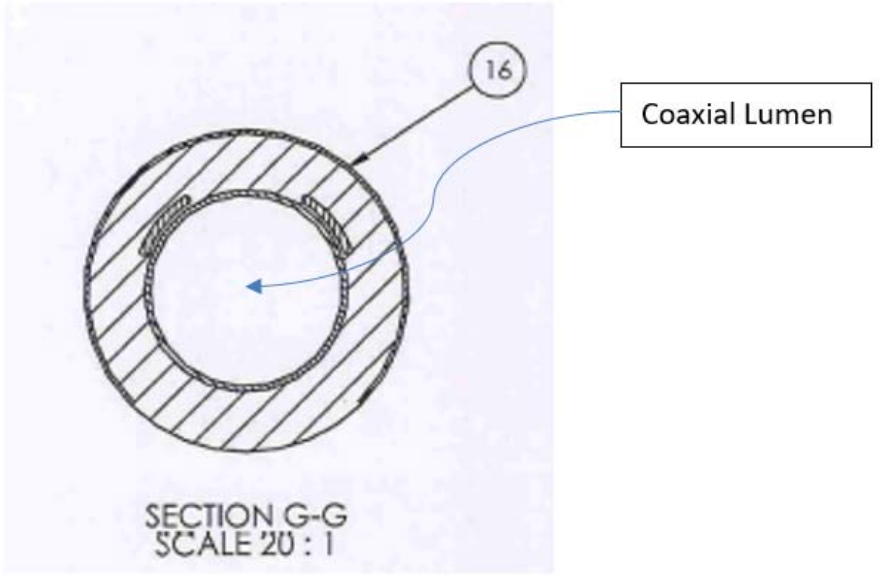

Load (gf)
Graph 132
Sample ID: TL1 - Blue Crush 3
Load at Maximum Load: 176.879 gf
150
100
50
0
0.00
0.05
0.10
0.15
0.20
Machine Extension (mm)

U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**QXMédical's Boosting Catheter**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	**The combination of a Boosting Catheter with a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery.**
[a] a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	**A typical guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, such as coronary arteries, where the continuous lumen of the guide catheter has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.**
[b] a device adapted for use with the guide catheter, including:	**The Boosting Catheter is a device adapted for use with a guide catheter.**  Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

	"The QXMedical Boosting Catheter is an over-the-wire support/guiding catheter with an atraumatic tip. The catheter is used in combination with guiding catheters or sheaths in interventional procedures to assist with delivery of other interventional devices (including guidewires) and procedural fluids to the coronary and peripheral vasculature. The catheter is offered in four (4) sizes compatible with 6Fr (small & large lumen), 7Fr and 8Fr guiding catheters." Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7397; *id.* at Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87. "The Boosting Catheter is delivered over a guidewire and through a guiding catheter or sheath resulting in a passageway with an inner diameter that is smaller than that of the guiding catheter or sheath." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87.
[c] a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	**Based on my inspection of the Boosting Catheter, it is my opinion that the Boosting Catheter has a flexible tip portion, as marked in the drawings below:** 

	Defendants' Depo. Ex. 52 at QXM 6061 (assembly drawing). **The Boosting Catheter's flexible tip portion defines a tubular structure, with a circular cross-section, as confirmed by my examination of the product, and as indicated in QXMédical's documents.**  Defendants' Depo. Ex. 52 at QXM 6061 (assembly drawing). **The Boosting Catheter's flexible tip portion has a length that is shorter than the predefined length of the continuous lumen of the guide catheter.** "The Boosting Catheter has a 'single operator' configuration in that the guidewire lumen (defined by the distal guiding catheter segment) runs only a portion of the entire catheter length and allows a physician the opportunity to simultaneously

	handle both the catheter and guidewire." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6323. **Specifically, a typical guide catheter is 100cm, and the Boosting Catheter's flexible tip portion is 25cm:** "The catheter is 150cm long comprised of a 125cm long manipulation shaft connected to a 25cm distal tube segment." Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7397; *id.* at Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87. **The Boosting Catheter's tubular structure has a cross-sectional outer diameter that is sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter.** "The QXMedical Boosting Catheter is an over-the-wire support/guiding catheter with an atraumatic tip. The catheter is used in combination with guiding catheters …. The catheter is offered in four (4) sizes compatible with 6Fr (small & large lumen), 7Fr and 8Fr guiding catheters…." Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7397; *id.* at Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87. "The Boosting Catheter is delivered over a guidewire and through a guiding catheter or sheath resulting in a passageway with an inner diameter that is smaller than that of the guiding catheter or sheath." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87. **The Boosting Catheter's flexible tip portion defines a coaxial lumen:**

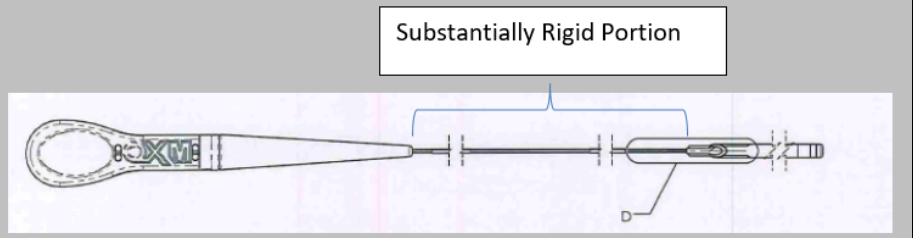


Defendants' Depo. Ex. 52 at QXM 6061 (assembly drawing).

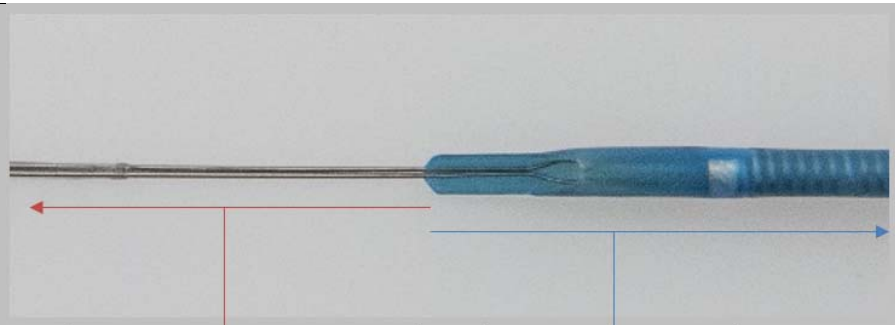
"The catheter provides improved coaxial alignment to assist with device delivery and exchange making it ideal for both radial and femoral access procedures." Defendant Vascular Solutions, Inc.'s Infringement Disclosure and Claim Chart, Ex. C (QXMédical's website), at 2.

The flexible tip portion's lumen has a cross-sectional inner diameter through which interventional cardiology devices are insertable:

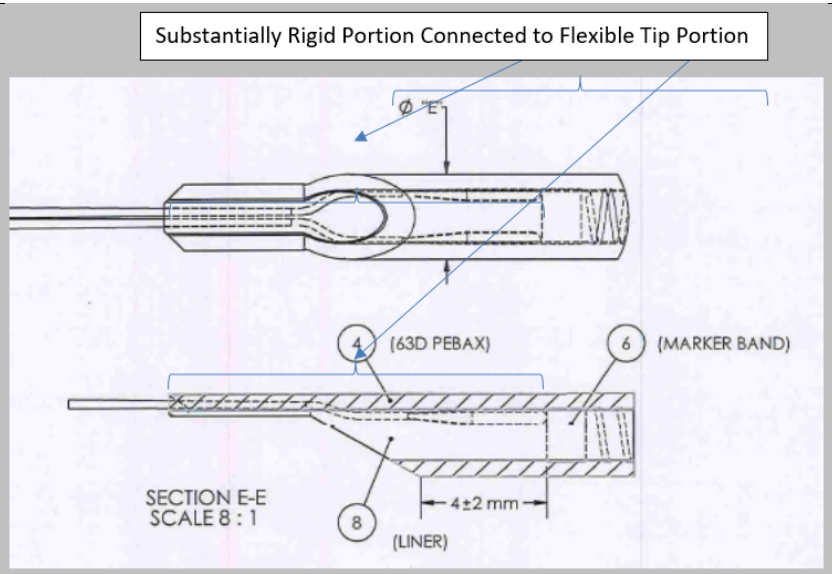
"The device is intended/indicated for use with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support interventional devices, including guidewires, traverse discrete portions of the

	vasculature, allow for interventional device exchanges and provide a conduit for the infusion of saline solution, diagnostic contrast agents and therapeutic agents." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6308; *see id.* at QXM 6314; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7398. "The Boosting Catheter provides complementary support in challenging cases allowing diagnostic and therapeutic devices (such as balloon catheters and stents) to track to distal and torturous treatment sites." Defendant Vascular Solutions, Inc.'s Infringement Disclosure and Claim Chart, Ex. C (QXMédical's website), at 2.
[d] a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with	**I understand that the Court has construed "substantially rigid" to mean "rigid enough to allow the device to be advanced within the guide catheter." Order at 15.** **The Boosting Catheter has a substantially rigid portion that is proximal of and operably connected to the flexible tip portion, as indicated below:**  Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing). **Based on my physical examination of the Boosting Catheter, it is my opinion that the Boosting Catheter's substantially rigid portion is rigid enough to allow the Boosting Catheter to be advanced through the guide catheter.**

interventional cardiology devices that are insertable into the guide catheter;	**Further, QXMédical's documents refer to the Boosting Catheter's substantially rigid portion as a "twin-rail" or "manipulation shaft," used to advance the Boosting Catheter through the guide catheter:** "Patented 'twin-rail' compliant shaft designed to maximize pushability." Defendants' Depo. Ex. 66 (Medinol presentation) at QXM 94239. "The Boosting Catheter is constructed with a proximal manipulation shaft connected to a distal tube or guiding catheter segment. The manipulation shaft is used to advance the distal tube segment over a guidewire and through a guiding catheter (or sheath) to a desired location in the coronary or peripheral vasculature." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6316. "The 2 proximal shafts acting in tandem are torsionally compliant and yet have sufficient column strength to be able to push the distal tube as required through the guiding catheter and vasculature." Defendants' Depo. Ex. 16 (Invention Disclosure) at QXM 69. **The Boosting Catheter's substantially rigid portion is operably connected to the Boosting Catheter's flexible tip portion. The photo below shows the connection of the substantially rigid portion with the flexible tip portion:**



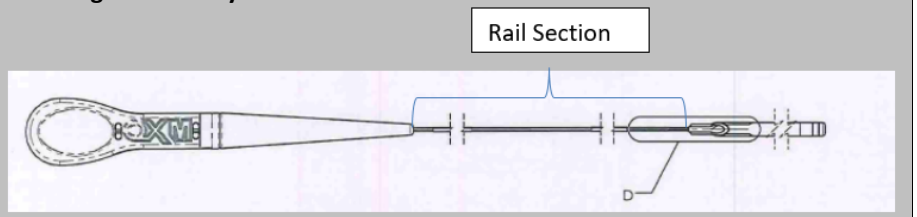
"The QXMedical Boosting Catheter is an over-the-wire catheter consisting of a distal guiding catheter (or tube) segment attached to a proximal manipulation shaft." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6308, 6316.



Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

"The Boosting Catheter is constructed with a proximal manipulation shaft connected to a distal tube or guiding catheter segment." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6316; *id.* at 6308.

"The Boosting Catheter is constructed with a proximal manipulation shaft connected to a distal tube or guiding catheter segment. The manipulation shaft is used to advance the distal tube segment over a guidewire and through a guiding catheter (or sheath) to a desired location in the coronary or peripheral vasculature." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6316.

	The Boosting Catheter's substantially rigid portion is more rigid along a longitudinal axis than the flexible tip portion. In the two point bend testing of the Boosting Catheter, every catheter sample tested had a higher maximum force value for the proximal shaft portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values—Expert Report, Appendix D at 1. **I understand that the Court has construed "rail structure" to mean "structure … that facilitates monorail or sliding rail delivery," and that the Court stated that this "definition … is sufficiently broad to capture the push rod." Order at 20.** **It is my opinion that the Boosting Catheter's substantially rigid portion as shown below meets the claimed "rail structure" limitation because it facilitates monorail or sliding rail delivery.**  Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing). "The Boosting Catheter has a 'single operator' configuration in that the guidewire lumen (defined by the distal guiding catheter segment) runs only a portion of the entire catheter length and allows a physician the opportunity to simultaneously handle both the catheter and guidewire." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6323.

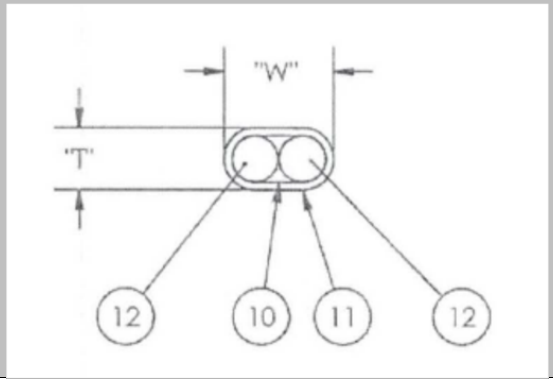
	The Boosting Catheter's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25. **I understand that QXMédical contends that the rail structure of the Boosting Catheter's substantially rigid portion does not meet the "without a lumen" limitation because, in some places and for some Boosting Catheters, there is a non-functional minute void between the side-by-side stainless steel rods and the wrap surrounding them. It is my opinion that that void is not a lumen because it is not the cavity of a tube, and, therefore, that the Boosting Catheter's substantially rigid portion literally meets the "without a lumen" limitation. It further is my opinion that the cavity of the tube formed by the wrap is filled (except for the minute void) by the stainless steel rods and the adhesive that joins them, and that the remaining space is neither a tube nor the cavity of a tube.** **It further is my opinion that the rail structure of the Boosting Catheter's substantially rigid portion also meets the "without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void between the side-by-side stainless steel rods and the surrounding wrap is insubstantially different from having no void at all. Nothing can pass through the void between the stainless steel rods and the wrap of the Boosting Catheter; it serves no meaningful purpose or function. The Boosting Catheter's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside).**

QXMédical's deposition testimony confirms that nothing can pass through the void that it claims is a lumen:

> Q. At the end of the day when the final shaft is embedded into the strain relief and the handle, is there any access from the outside to that space that is inside the shaft?
> A. No.
>
> Q. If you wanted to put something through there, you couldn't?
> A. Obviously not.

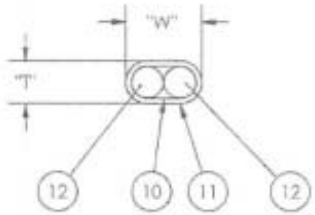
August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 252-53.

Further, the small void in the Boosting Catheter's rail structure does not increase the outside dimensions of the substantially rigid portion and does not at all change the space that the substantially rigid portion takes up within the guide catheter, as can be seen in the following depiction of the cross-section of the Boosting Catheter's rail structure; specifically, dimension "T" is not affected by what QXMédical is referring to as a "lumen":



	Defendants' Depo. Ex. 52 at QXM 6059 (assembly drawing). Indeed, by my calculation the void is only about 6% of the cross-sectional area of the shaft inside of the wrap. **It is my opinion that the void does not have any function in the Boosting Catheter. I have reviewed QXMédical's FDA submissions, Defendants' Depo. Ex. 44 (FDA submission); Defendants' Depo. Ex. 46 (second FDA submission), and while those documents repeatedly refer to the Boosting Catheter's flexible tip portion as having a lumen, they make no reference to a lumen in the Boosting Catheter's rail structure.** **The Boosting Catheter's substantially rigid portion has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion. QXMédical's assembly drawings confirm that the maximum dimension of the largest Boosting Catheter's substantially rigid portion is .028 +/- .002:**

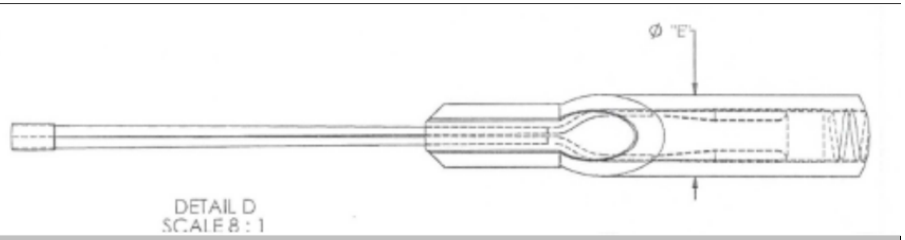
	W	T
9005-001	.026 ± .002	.015 ± .002
9005-002	.026 ± .002	.015 ± .002
9005-003	.028 ± .002	.016 ± .002
9005-004	.028 ± .002	.016 ± .002



SECTION C-C
SCALE 20 : 1

Defendants' Depo. Ex. 52 at QXM 6059 (assembly drawing).

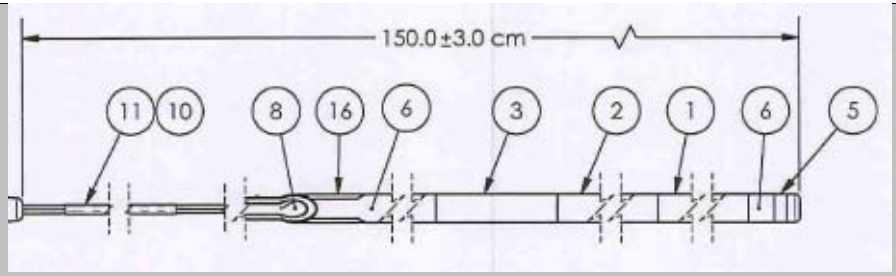
QXMédical's assembly drawings further confirm that the smallest dimension of the smallest Boosting Catheter's flexible tip portion is .066, and therefore each model demonstrates this difference in maximal dimension between the proximal shaft portion and flexible tip portion:



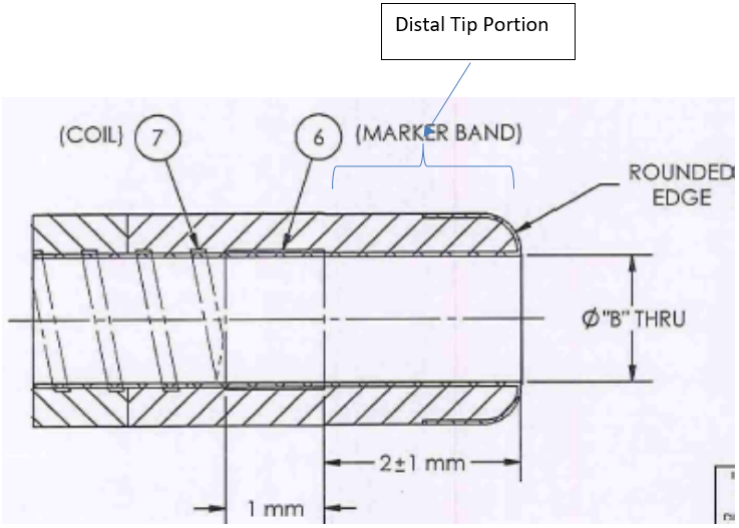
P/N	OD "E" IN 63D ZONE MAXIMUM
9005 - 001	.066"
9005 - 002	.070"
9005 - 003	.078"
9005 - 004	.088"

Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

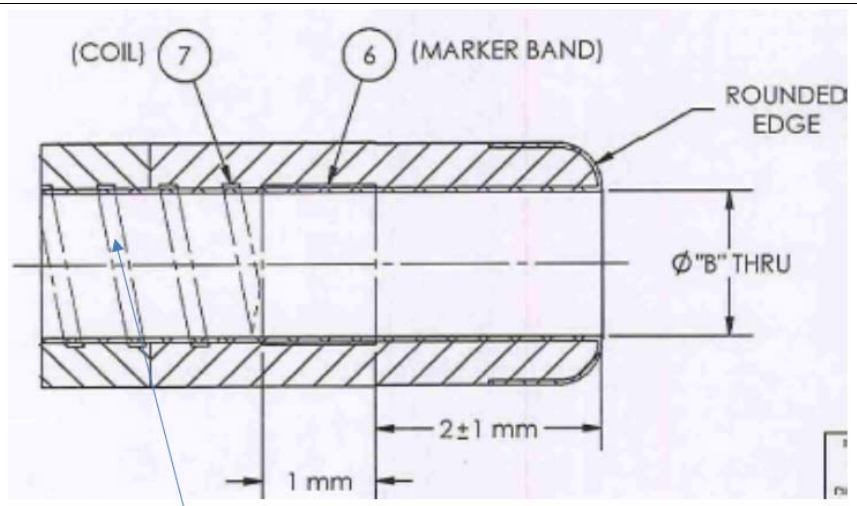
The Boosting Catheter's substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. Specifically, the Boosting Catheter's substantially rigid portion and flexible tip portion together are 150cm, which is longer than a standard 100cm guide catheter:

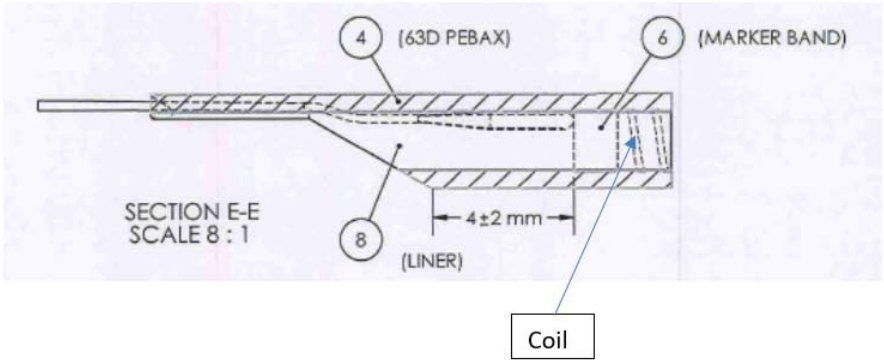
	 Defendants' Depo. Ex. 52 at QXM 6058 (assembly drawing). "The catheter is 150cm long comprised of a 125cm long manipulation shaft connected to a 25cm distal tube segment." Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7397; *id.* at Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87. **If the entire distal shaft portion were advanced distal to the distal end of the guide catheter lumen, leaving just the side opening within the guide catheter lumen, the 125 cm long manipulation shaft would still extend proximally of the guide catheter 25 cm, a distance more than adequate to extend through the hemostatic valve as well.**
[e] wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	**The Boosting Catheter's tubular structure includes a flexible cylindrical distal tip portion, i.e., the distal tip of the tubular structure:**

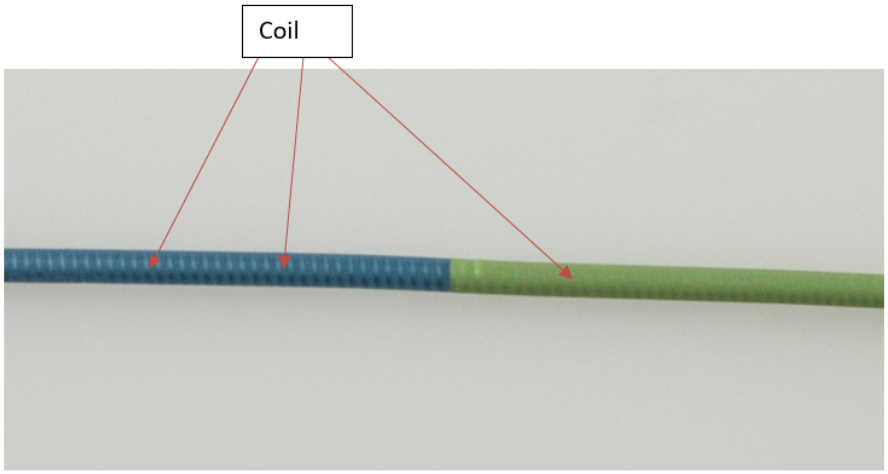

Distal Tip Portion


Distal Tip Portion
(COIL) 7
6 (MARKER BAND)
ROUNDED EDGE
Ø"B" THRU
2±1 mm
1 mm

	Defendants' Depo. Ex. 52 at QXM 6059-60 (assembly drawing). Based on my physical inspection of the Boosting Catheter, and as confirmed by QXMédical's documents**,** the Boosting Catheter's distal-most portion does not have a reinforcing coil or braid: "The distal tip of the tube segment is constructed by rolling over the PTFE on the distal end onto the outer PeBax (PEBA) and re-flowing the tip." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6328. **The Boosting Catheter has a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion. I understand that the parties have agreed that "reinforced portion" means "portion made stronger by additional material or support." Joint Claim Construction Statement at 2. Specifically, the Boosting Catheter's flexible tip portion has a reinforced portion, which is a portion reinforced by a metal coil:**


(COIL) 7
6 (MARKER BAND)
ROUNDED EDGE
Ø"B" THRU
2±1 mm
1 mm
Coil

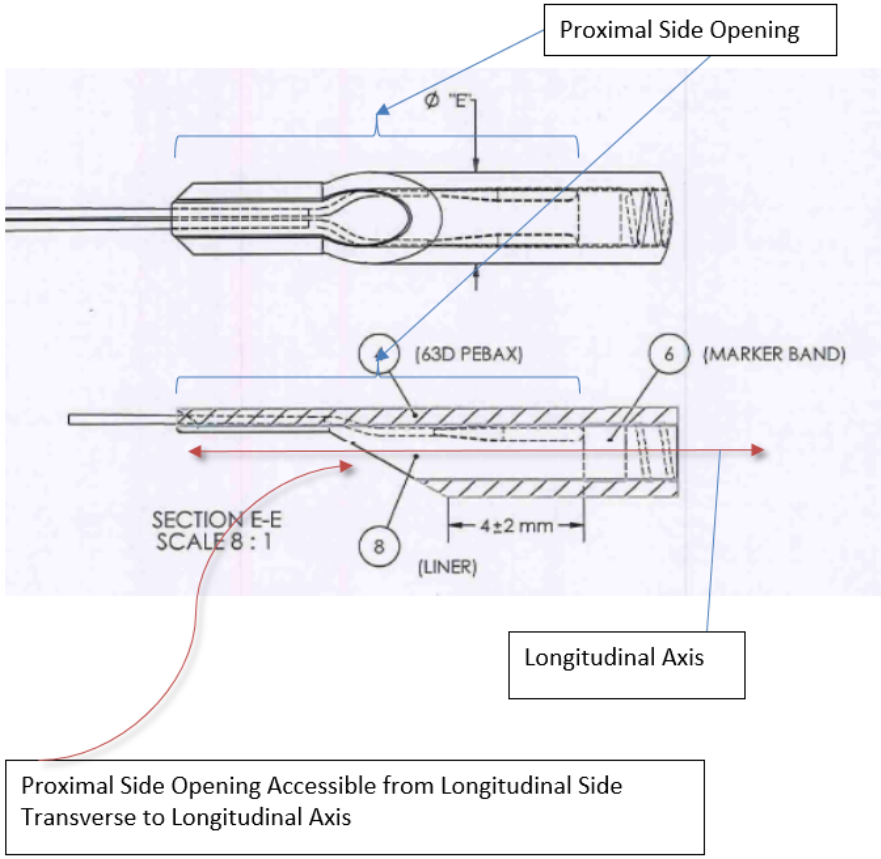

4 (63D PEBAX)
6 (MARKER BAND)
SECTION E-E
SCALE 8 : 1
8
4±2 mm
(LINER)
Coil

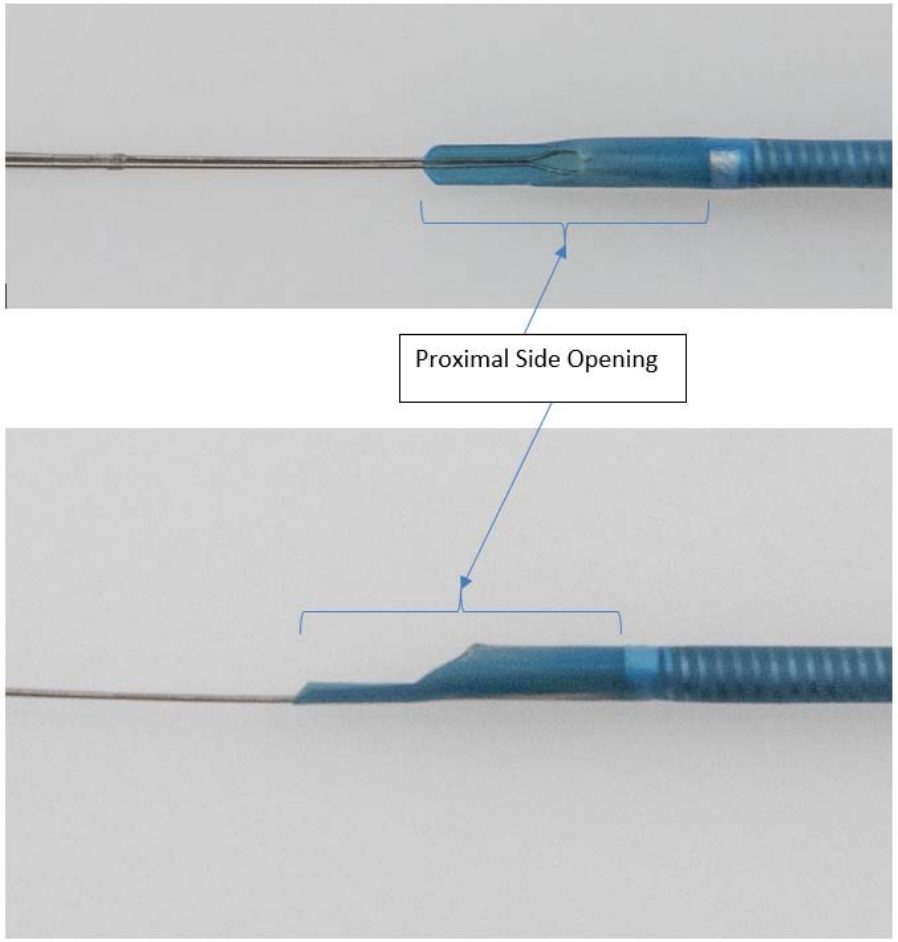
	Defendants' Depo. Ex. 52 at QXM 6059-60 (assembly drawing). **QXMédical's documents confirm that the coil reinforces the flexible tip portion:** "Enhanced trackability resulting from: Unique multi-stiffness coil reinforced distal tube…." Defendants' Depo. Ex. 58 (sales training materials) at QXM 1140. **The coil in the reinforced portion of the Boosting Catheter's flexible tip portion is visible as the vertical lines in the distal tip portion:**  **Test results confirm that the portion of the flexible tip portion with the coil is stronger than the portion that does not have the metal reinforcing coil, and that the Boosting Catheter's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. The portion with the coil is reinforced**

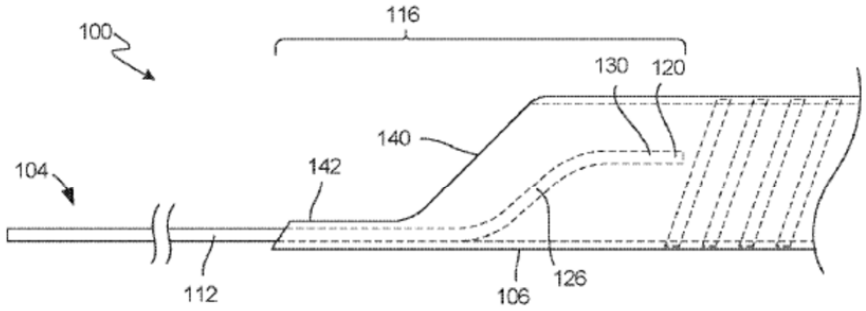
	because it is made stronger by the addition of the coil. Non-reinforced tubular structures have a tendency to kink when bent in a tight curve (analogous to kinking a garden hose). The kink is actually a localized inwardly deformed flattened portion of the tube. A reinforcement such as a coil embedded in the wall helps to prevent kinking by resisting the localized inward deformation leading to kinking. Such reinforcement also prevents any inward deformation caused by externally applied localized forces ("crushing" forces), and as such stiffens the structure in an inward fashion. The tips of catheters are often made softer, i.e. more easily deformable from localized external deforming forces to make them less traumatic to sensitive tissues such as coronary blood vessels. Measurement of the resistance to localized external deforming forces illustrates this. The results of the "crush" testing clearly show that the Boosting Catheter's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. See Appendix D at 1-2, comparing "Crush 1" values to "Crush 2" and "Crush 3" values for the QXM catheter samples.
2. [NOT ASSERTED] The system of claim 1, wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	**The tubular structure of QXMédical's Boosting Catheter includes a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery:** "Robust back-up support assists in delivery of interventional devices to distal vessel locations." Defendants' Depo. Ex. 57 (GuideX presentation) at QXM 93672; *id.* at Defendants' Depo. Ex. 59 (Medtronic presentation) at QXM 94727. "[I]ntended for use in conjunction with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support interventional devices, including guidewires, traverse discrete portions of the vasculature, allow for interventional device exchanges and provide a conduit for

	infusion of saline solution, diagnostic contrast agents and therapeutic agents." Defendants' Depo. Ex. 57 (GuideX presentation) at QXM 93681. "The QXMedical Boosting Catheter takes guide extension support to the next level. Whether the challenge is deep-seating for coaxial support, distal device delivery in tortuous anatomy or improved access during transradial or complex cases." Defendants' Depo. Ex. 58 (sales training materials) at QXM 1138. "The catheter is introduced into a guiding catheter (through the hemostasis valve) and the distal portion of the tubular section is pushed beyond the distal tip of the guiding catheter into the vasculature. This placement of the catheter (within the guiding catheter and vasculature) provides support for the advancement of other interventional devices which are subsequently passed through both the guiding catheter and guide extension catheter." Defendants' Depo. Ex. 14 (Design and Development Plan) at QXM 8239.
3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	**I understand that the Court has ruled that the phrases "side opening," "proximal side opening," "a segment defining a side opening," and "a segment defining a partially cylindrical opening" do not need to be construed and will be given their plain and ordinary meaning. Order at 26.** **The proximal portion of the Boosting Catheter's tubular structure has structure defining a proximal side opening that extends for a distance along the longitudinal axis and is accessible from a longitudinal side defined transverse to the longitudinal axis. The QXMédical Boosting Catheter has a proximal side opening, i.e., an angled side opening on the proximal end of its distal tube that extends from where the stainless steel rods are embedded in the Boosting Catheter's polymer segment to where the segment defining the partially cylindrical opening transitions into the tubular structure, which includes where materials specific to the segment defining the partially cylindrical opening, including laminated material(s) and the embedded stainless steel rods,**

	terminate, near the marker band and the beginning of the coil-reinforced portion, as generally depicted below:



	Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing). 

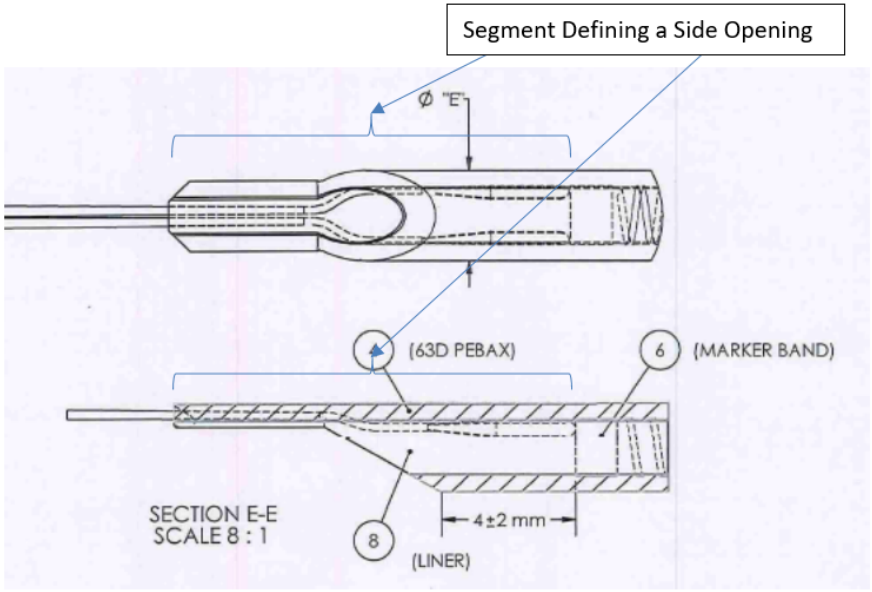
	The proximal side opening receives interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. QXMédical states that it uses this proximal side opening to facilitate entry of interventional cardiology devices into the Boosting Catheter's flexible tip portion: "The proximal entry is skived (trimmed) to facilitate entry of interventional devices." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6328. "[A]s best shown in FIG. 7B, the distal tube 102 has a tapered proximal opening 140 and a proximal extension 142 that is configured to receive the manipulation shaft 104 as shown…. [T]he tapered proximal opening 140 provides easier access and insertion for any device being positioned through the lumen 122 of the distal tube 102, while the proximal extension 142 provides enhanced strength to the connection between the manipulation shaft 104 and the distal tube 102." Defendants' Depo. Ex. 42 (U.S. Patent Publication No. 2017/0095646), ¶ 151 (emphasis added).  *FIG. 7B*

	Defendants' Depo. Ex. 42 (U.S. Patent Publication No. 2017/0095646), Fig. 7B. **In use, the Boosting Catheter's 25 cm long flexible tip portion is extended not more than 15 cm out of the distal tip of the guide catheter. Accordingly, the proximal end of the flexible tip portion remains in the guide catheter.** "Never advance the Boosting Catheter more than 15cm beyond the tip of the guiding catheter or sheath as the catheter may become lodged in the guiding catheter or sheath making it difficult to remove." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 89.
8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	**It is my opinion that the six French Boosting Catheter meets this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches or less, and under the doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.071 inches.** **I have measured the inner diameter of the distal tip of the six French Boosting Catheter at .057 inches. The proximal opening of the Boosting Catheter's lumen is partially flared, and measures at least .0575 inches. *See* Appendix D at 3.** **Mathematically, those of ordinary skill in the art define one French as .0131 inches. The .057-inch inner diameter of the six French Boosting Catheter is therefore within one French size of the standard .070 guide catheter. As such, combining the six French Boosting Catheter with a standard .070 guide catheter would literally infringe these system claims.** **It is my opinion that the six French Boosting Catheter meets this limitation under the doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.071 inches. The .057-inch inner diameter of QXMédical's six French Boosting Catheter is 0.014 inches smaller than a 0.071-inch guide catheter. Put**

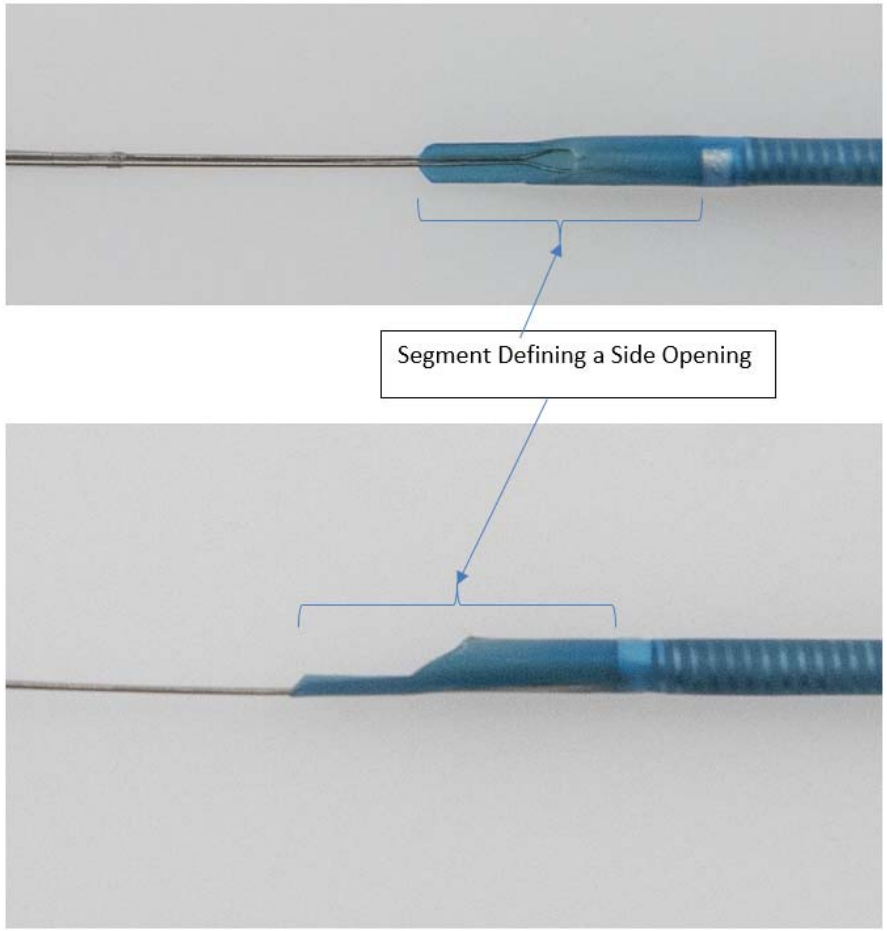
	differently, the six French Boosting Catheter is only nine ten-thousandths of an inch (.0009 inch) more than one French size smaller than the inner diameter of a standard .071-inch six French guide catheter. It is my opinion that any difference between using a .057 inner diameter Boosting Catheter with a .070 versus .071 inner diameter guide catheter would be insubstantial. I note that, when QXMédical changed its IFUs to state that the six French compatible guiding catheter is .071, it did not submit this labeling change to the FDA, indicating that it did not consider that change to be significant to the safety or efficacy of the product. Whether QXMédical's six French Boosting Catheter is used with a standard .070-inch guide catheter or a .071-inch guide catheter, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Boosting Catheter without catching on the proximal end opening of the Boosting Catheter's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French Boosting Catheter with a 0.071-inch guide catheter meets this limitation under the doctrine of equivalents.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**QXMédical's Boosting Catheter**
25. A system, comprising:	**The combination of a Boosting Catheter with a guide catheter forms a system.**
[a] a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	**A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, where the guide catheter has a lumen that extends from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.**
[b] a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through	**The Boosting Catheter is a guide extension catheter that is configured to be partially advanceable through the guide catheter and into the coronary artery.** See '380 patent, claim element 1[b], page 1 above. **The Boosting Catheter has a length such that a distal end of the Boosting Catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the Boosting Catheter is extendable through the hemostatic valve at the proximal end of the guide catheter. Specifically, the Boosting Catheter's length is 150cm, which is longer than a standard 100cm guide catheter.**

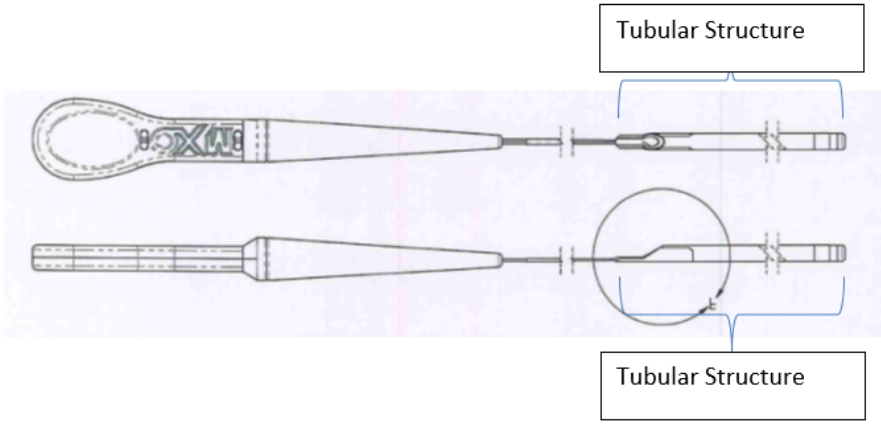
the hemostatic valve at the proximal end of the guide catheter,	See '380 patent, claim element 1[d], page 6 above.
[c] the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	**The Boosting Catheter is a guide extension catheter that includes a substantially rigid segment.** See '380 patent, claim element 1[d], page 6 above. **The Boosting Catheter has a segment defining a side opening that extends for a distance along the longitudinal axis of the segment and is accessible from a longitudinal side defined transverse to the longitudinal axis, i.e., the segment extends from where the stainless steel rods are embedded in the Boosting Catheter's polymer segment to where the segment defining the side opening transitions into the tubular structure, which includes where materials specific to the segment defining the side opening, including laminated material(s) and the embedded stainless steel rods, terminate, near the marker band and the beginning of the coil-reinforced portion, as generally depicted below:**



Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).



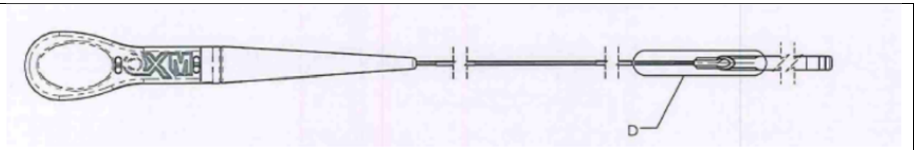
The Boosting Catheter includes a tubular structure, indicated below, that defines a lumen coaxial with the lumen of the guide catheter, where the lumen of the

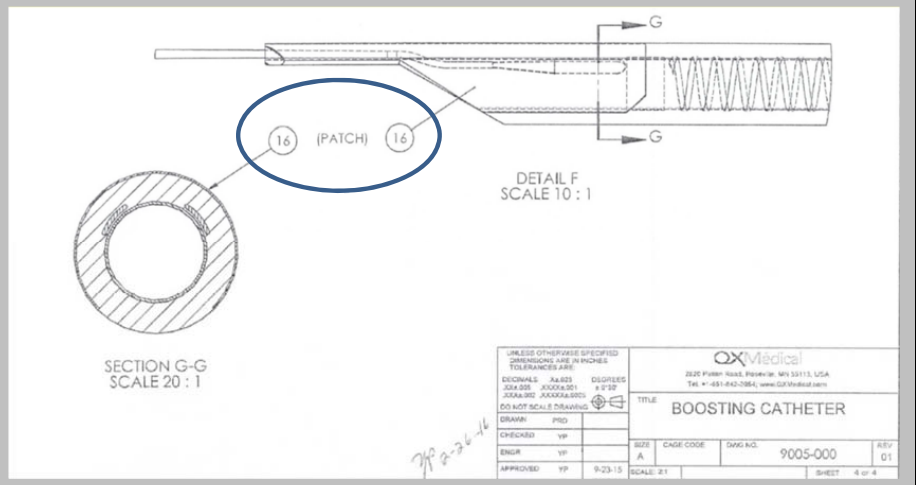
	tubular structure has a length that is shorter than the length of the lumen of the guide catheter.  Defendants' Depo. Ex. 52 at QXM 6061 (assembly drawing). **I note from my product observations that the cross-sectional diameter of the Boosting Catheter's tubular structure appears uniform along its length, apart from the flare at the proximal side opening, as confirmed by the inner diameter measurements discussed above in my report, and further that QXMédical's assembly drawings do not suggest that the Boosting Catheter's flexible tip portion's inner diameter is not uniform.** **The Boosting Catheter's tubular structure is in fluid communication with the lumen of the guide catheter.** "The device is intended/indicated for use with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support

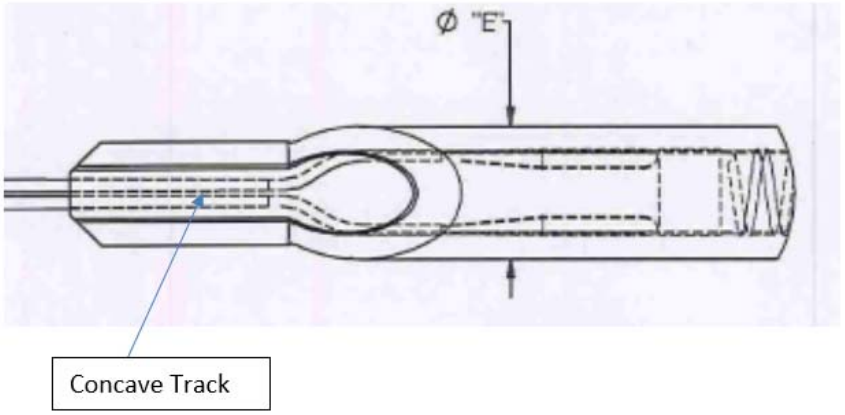
	interventional devices, including guidewires, traverse discrete portions of the vasculature, allow for interventional device exchanges and provide a conduit for the infusion of saline solution, diagnostic contrast agents and therapeutic agents." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6308; *see id.* at QXM 6314; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7398. "FLUID INFUSION "To use the Boosting Catheter for fluid infusion, maintain the catheter position and withdraw any interventional device other than a guidewire. A guidewire may be left in place during fluid infusion. Ensure the Y-adaptor hemostasis valve is securely tightened around the proximal shaft of the Boosting Catheter (and possibly the guidewire) to avoid any fluid loss. Attach a hand-held syringe (filled with desired fluid) to the Y connector on the hemostasis valve. If required, a stopcock may be desired for additional fluid control. Inject the desired fluid." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 92. **The six French Boosting Catheter's tubular structure has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of a typical guide catheter. This limitation is met literally for guide catheters having an inner diameter of 0.070 inches or less and by doctrine of equivalents for guide catheters having an inner diameter of 0.071 inches.** See '380 patent, claim 8, page 26 above. **The Boosting Catheter's side opening and the lumen of the tubular structure are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter.**

	"The Boosting Catheter provides complementary support in challenging cases allowing diagnostic and therapeutic devices (such as balloon catheters and stents) to track to distal and torturous treatment sites." Defendant Vascular Solutions, Inc.'s Infringement Disclosure and Claim Chart, Ex. C (QXMédical's website), at 2. "The device is intended/indicated for use with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support interventional devices, including guidewires, traverse discrete portions of the vasculature, allow for interventional device exchanges and provide a conduit for the infusion of saline solution, diagnostic contrast agents and therapeutic agents." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6308; *see id.* at QXM 6314; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7398. Q. Advances it so that the distal tube wewere looking at extends out past the end of the guide catheter into the coronary artery, right? A. Yes. Q. Once it's in place, your instructions for use say don't extend it more than 15 centimeters into the coronary artery, is that right? A. Yes. Q. You have got 15 centimeters of the distal tube we looked at.At the most in the coronary artery you have got ten centimeters inside the guide catheter, right? A. Yes. Q. So your junction area we looked at is going to be inside the guide catheter?

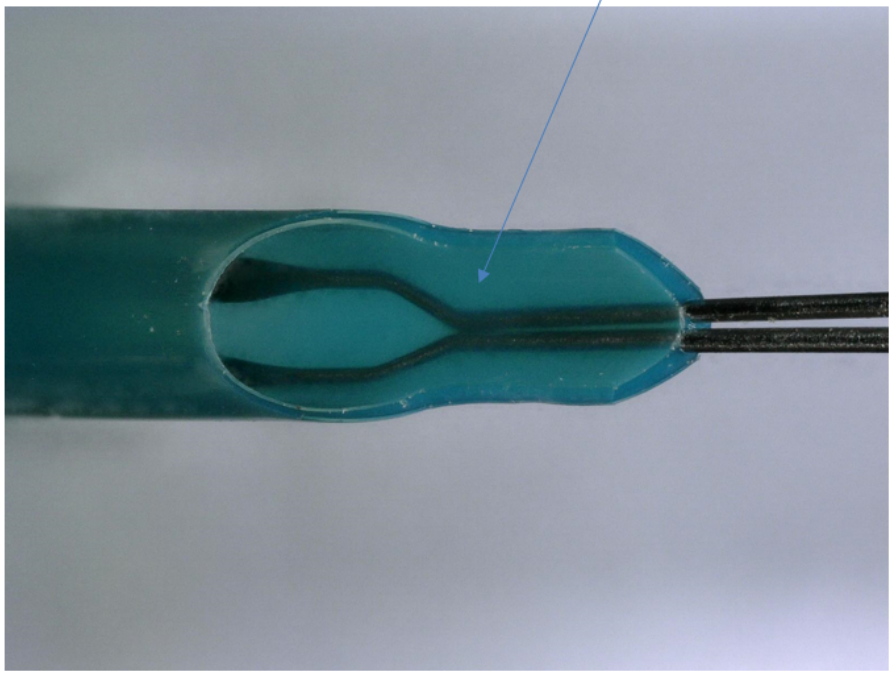
	A. Typically, yes. Q. You wouldn't put the junction past, right? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295. Q. Once the guide extension catheter is then in place, you understand that the physician – the typical thing to do would be to place a stent, use it for a stent? A. Yes. Q. You understand the physician then advances that stent over the guide wire so that it goes down the guide catheter and then into your distal tube at the junction? A. Yes. Q. Then the physician advances that stent further through the distal tube and then out the end of the distal tube of your Boosting catheter, right? A. Yes. Q. At that point … the physician will deploy the stent? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295-96. **The Boosting Catheter's substantially rigid segment, segment defining a side opening, and tubular structure are arranged in a proximal to distal direction:**

	 Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).
[d] wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	**I understand that the Court has construed "wherein a material forming the segment defining the side opening is more rigid than the tubular structure" to mean "wherein the matter forming the segment defining the side opening is more rigid than the tubular structure." Order at 31.** **The matter forming the segment defining the side opening of the Boosting Catheter is more rigid than the Boosting Catheter's tubular structure.** **The two point bend testing of the Boosting Catheter shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.** **It appears that the side opening being more rigid than the tubular structure is by design. For example, I note that, along the sides of the side opening, a discrete "patch" of PTFE is added to the structure, providing further rigidity and resistance to deformation to this segment. This material has a flexural modulus of 72,000 psi (see Appendix M), which is greater than the flexural modulus of the PEBAX 6333 used in the polymer just distal to the side opening segment (flexural modulus of 41,300 psi) (see Appendix N), and greater than the even "softer" and more flexible PEBAX forumulations used further distally in the tubular shaft portion. QXMédical's assembly drawings show the patch, marked with reference number 16 below:**

	 Defendants' Depo. Ex. 52 at QXM 6061 (assembly drawing).
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	**The segment defining the side opening of the Boosting Catheter defines a concave track:**

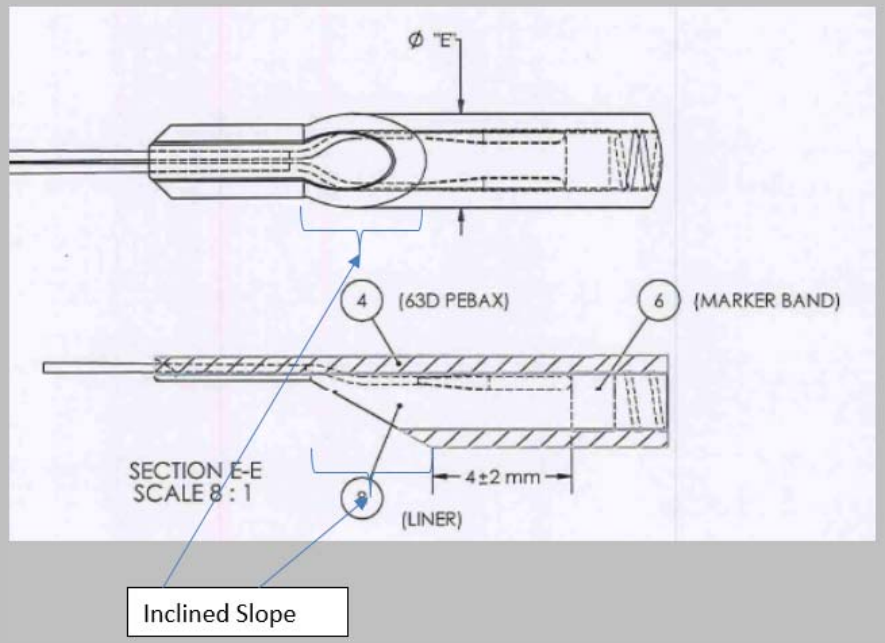


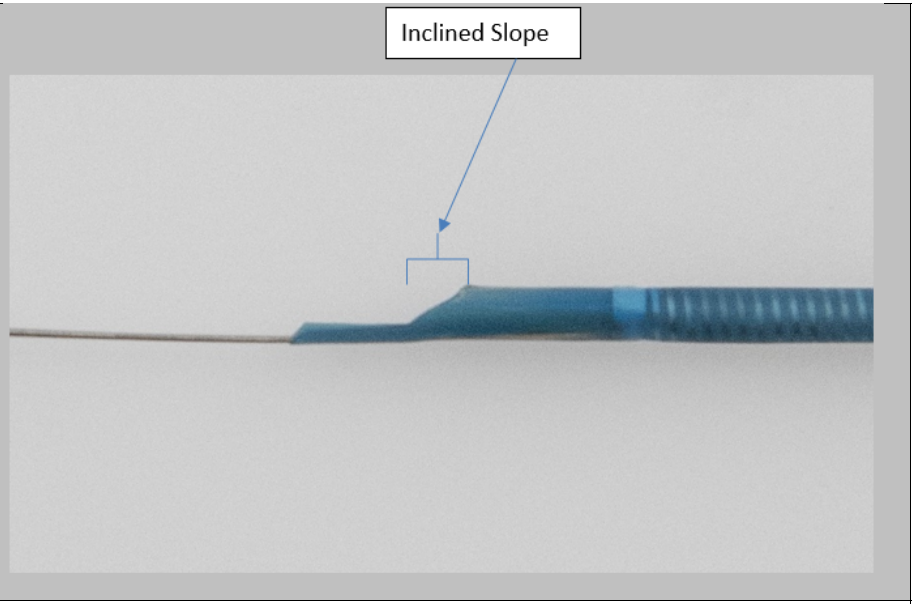
Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

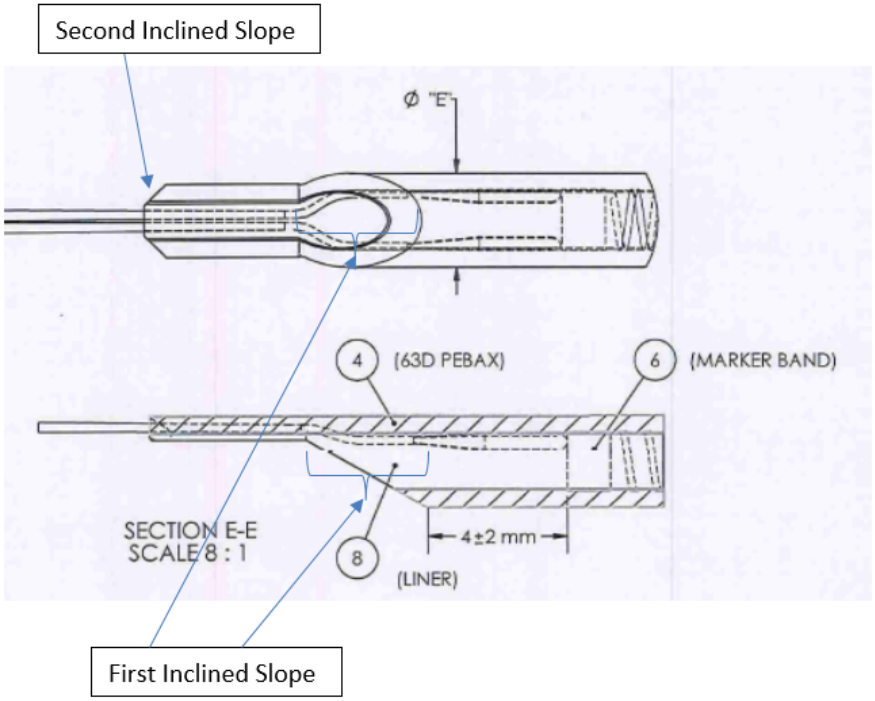


The concave track is configured to guide one or more stents or balloon catheters along a length of the concave track.

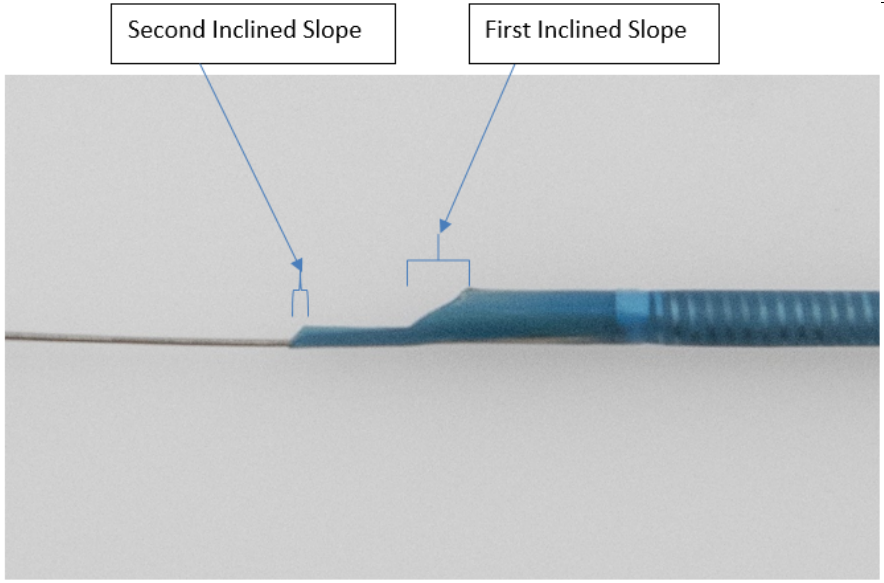
See '760 patent, claim element 25[c].

31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	**The Boosting Catheter's segment defining a side opening includes at least one inclined slope:**  Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

	
32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.	**The Boosting Catheter's segment defining a side opening has two inclined slopes:**



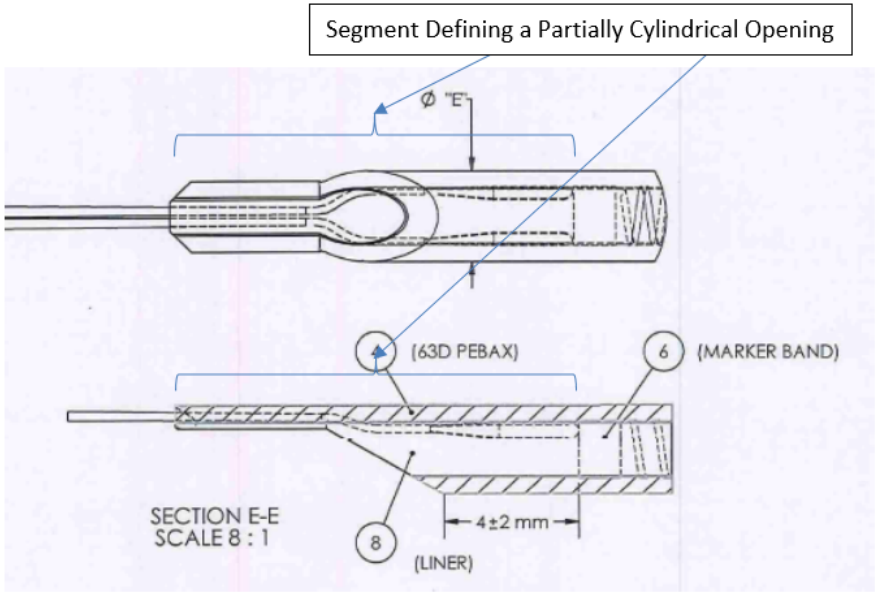
Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

	
48. A system, comprising:	**The combination of the Boosting Catheter with a guide catheter forms a system.**
[a] a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	See '380 patent, claim element 1[a], page 1 above.
[b] a guide extension catheter configured to be partially advanceable through the guide	See '380 patent, claim element 1[b], page 1 above, and claim element 1[d], page 6 above.

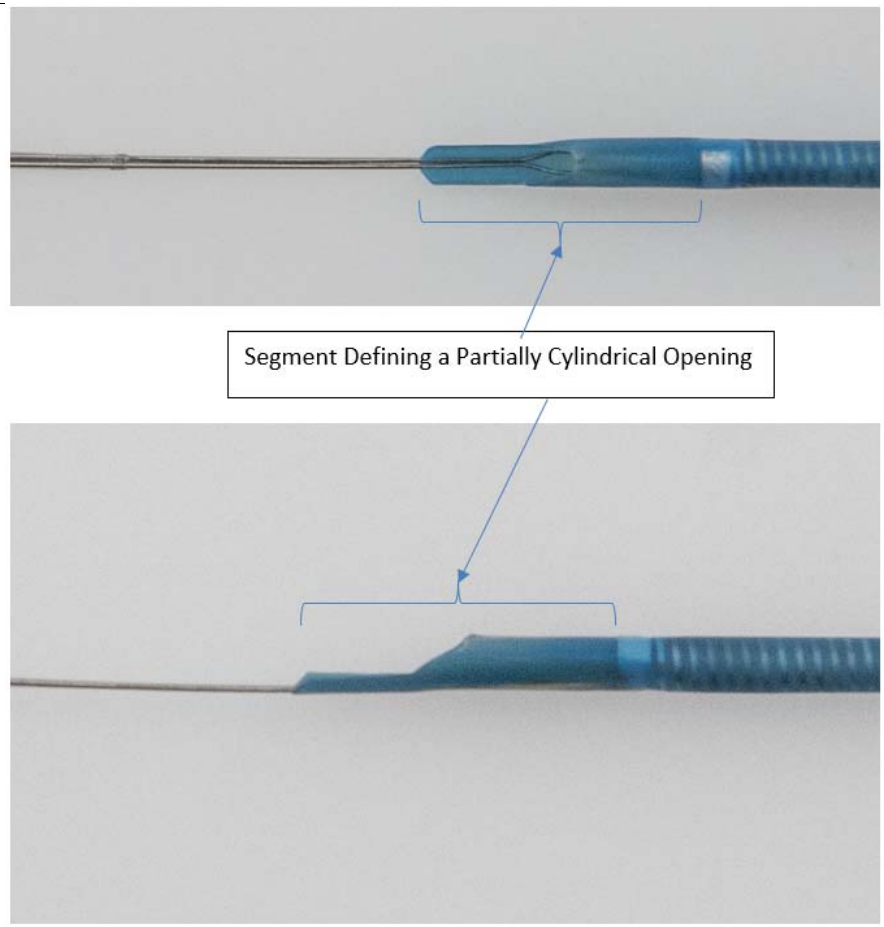
catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	
[c] the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal	See '760 patent, claim element 25[c], page 29 above.

end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	
[d] wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.	**Element [b] above indicates that "the distal end portion" is the portion that extends beyond the distal end of the guide catheter in use ("the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter"). For the Boosting Catheter, this is the distal-most portion of the device, up to 15 cm.** "Never advance the Boosting Catheter more than 15cm beyond the tip of the guiding catheter or sheath as the catheter may become lodged in the guiding catheter or sheath making it difficult to remove." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 89. **Test results confirm that the segment defining the side opening of the Boosting Catheter comprises a portion of the Boosting Catheter that is more rigid than a distal end portion of the tubular structure. Specifically, two point bend testing of the Boosting Catheters shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.**

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**QXMédical's Boosting Catheter**
25. A guide extension catheter for use with a guide catheter, comprising:	**The Boosting Catheter is a guide extension catheter for use with a guide catheter, as described below.** See '380 patent, claim element 1[b], page 1 above.
[a] a substantially rigid segment;	See '380 patent, claim element 1[d], page 6 above.
[b] a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	See '760 patent, claim element 25[c], page 29 above.
[c] a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	**The Boosting Catheter has a segment that defines a partially cylindrical opening that is positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, where the segment defining the partially cylindrical opening has an angled proximal end. Specifically, the Boosting Catheter's segment that defines a partially cylindrical opening extends from where the stainless steel rods are embedded in the Boosting Catheter's polymer segment to where the segment defining the partially cylindrical opening transitions into the tubular structure, which includes where materials specific to the segment defining the partially cylindrical opening, including laminated material(s) and the embedded stainless steel rods, terminate, near the marker band and the beginning of the coil-reinforced portion, as generally depicted below:**

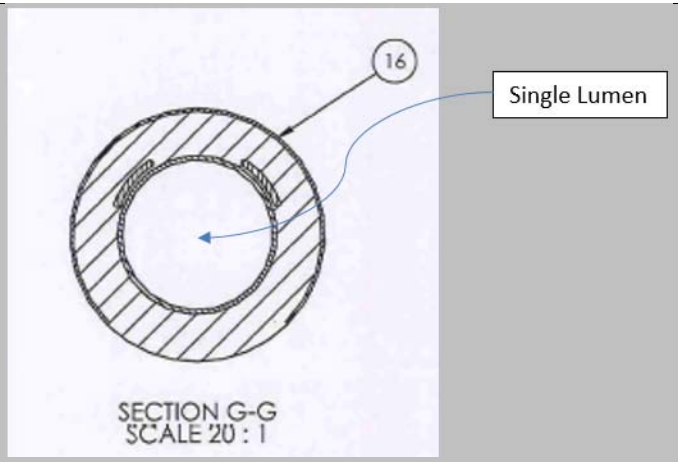


Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

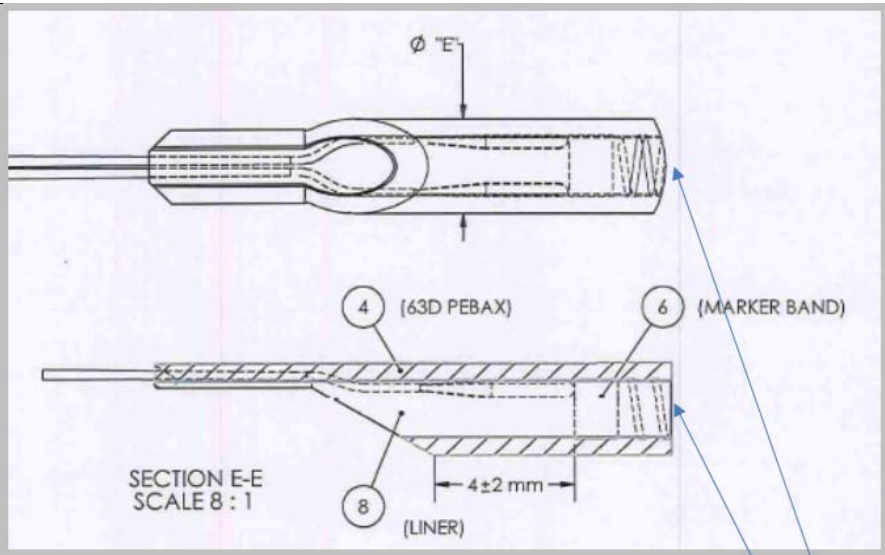


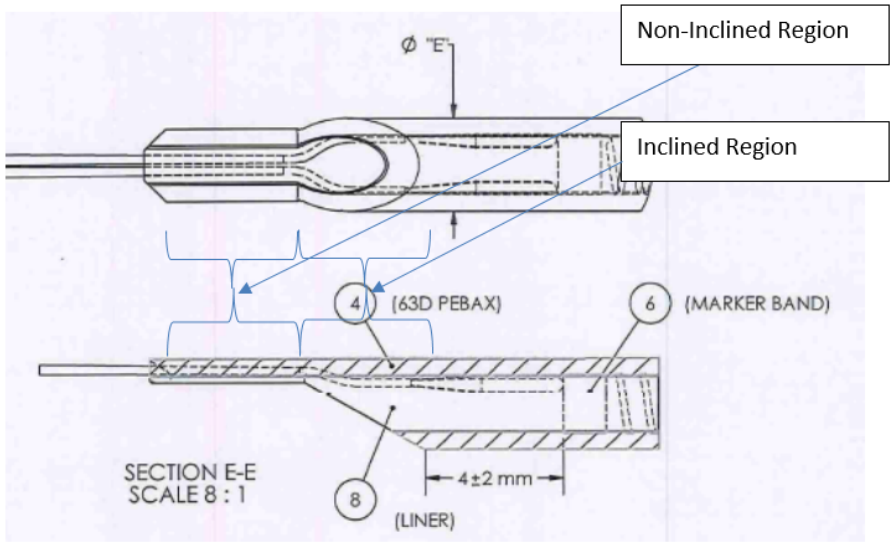
The Boosting Catheter is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

	See '760 patent, claim element 25[c], page 29 above. **I understand that the Court has construed "formed from a material more rigid than a material or material combination forming the tubular structure" to mean "formed from matter that is more rigid than the matter forming the tubular structure." Order at 32.** **The Boosting Catheter's segment defining a partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure. The two point bend testing of the Boosting Catheters shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.**
[d] wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.	**A cross-section of the Boosting Catheter at the proximal end of the tubular structure defines a single lumen:**



Defendants' Depo. Ex. 52 at QXM 6061 (assembly drawing).

	 Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing). "The catheter provides improved coaxial alignment to assist with device delivery and exchange making it ideal for both radial and femoral access procedures." Defendant Vascular Solutions, Inc.'s Infringement Disclosure and Claim Chart, Ex. C (QXMédical's website), at 2.
30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-	**The six French Boosting Catheter is a guide catheter for use with a .070-inch or .071-inch guide catheter. The cross-sectional inner diameter of the lumen of the tubular structure of the six French Boosting Catheter is not more than one French size smaller than the cross-sectional inner diameter of such a guide catheter,**

sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.	**literally for a 0.070-inch guide catheter and by doctrine of equivalents for a 0.071-inch guide catheter.** See '380 patent, claim 8, page 26 above.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	See '760 patent, claim element 25[c], page 29 above.
36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.	**The Boosting Catheter's segment defining an angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.**  Defendants' Depo. Ex. 52 at QXM 6060 (assembly drawing).

52. A guide extension catheter for use with a guide catheter, comprising:	**The Boosting Catheter is a guide extension catheter for use with a guide catheter, as described below.** See '380 patent, claim element 1[b], page 1 above.
a substantially rigid segment;	See '380 patent, claim element 1[d], page 6 above.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	See '760 patent, claim element 25[c], page 29 above.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	**The Boosting Catheter has a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, where the segment defining the partially cylindrical opening has an angled proximal end.** See '776 patent, claim element 25[c], page 46 above. **The Boosting Catheter's partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.** See '776 patent, claim element 25[c], page 46 above. **I understand that the parties have agreed that "flexural modulus," as used in claim 52 of the '776 patent, means "a numeric, dimension-independent material property that captures the tendency of a material to bend." Joint Claim Construction Statement at 2. I further understand that the Court has construed "formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure" to mean "formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure." Order at 32.** **In view of the Court's claim construction, it is my opinion that the Boosting Catheter's partially cylindrical opening is formed from matter having a greater**

	flexural modulus than a flexural modulus of the tubular structure, as evidenced by the test results in Appendix D at 1. The two point bend testing of the Boosting Catheters shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	See '776 patent, claim element 25[d], page 49 above.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	See '760 patent, claim element 32, page 41 above.
53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	**The Boosting Catheter is a guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, as described below.** See '380 patent, claim element 1[b], page 1 above.
a substantially rigid segment;	See '380 patent, claim element 1[d], page 6 above.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and	**The Boosting Catheter's tubular structure defines a lumen and is positioned distal to the substantially rigid segment.** See '760 patent, claim element 25[c], page 29 above. **The six French Boosting Catheter is a guide catheter for use with a .070-inch or .071-inch guide catheter. The cross-sectional inner diameter of the lumen of the tubular structure of the six French Boosting Catheter is not more than one French size smaller than the cross-sectional inner diameter of such a guide catheter,**

	literally for a 0.070-inch guide catheter and by doctrine of equivalents for a 0.071-inch guide catheter. See '380 patent, claim 8, page 26 above.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	**The Boosting Catheter's segment defining a partially cylindrical opening is positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, and has an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter.** See '776 patent, claim element 25[c], page 46 above. **A cross-section of the Boosting Catheter at the proximal end of the tubular structure defines a single lumen.** See '776 patent, claim element 25[d], page 49 above.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	See '760 patent, claim 32, page 41 above.

U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**QXMédical's Boosting Catheter**
25. A method, comprising:	**The method of claim 25 is performed by cardiologists using the Boosting Catheter with a guide catheter and balloon catheter or stent for a coronary vascular procedure.**
[a] advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	**A guide catheter has a lumen.** **A cardiologist using the Boosting Catheter for a coronary vascular procedure will advance a distal end of the guide catheter through a main blood vessel to an ostium of a coronary artery.** Q. [W]hen the physician does the coronary catheterization, he uses a guide catheter.The end of that guide catheter is in place at the ostium in a coronary artery? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 294.
[b] advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter	**A cardiologist using the Boosting Catheter for a coronary vascular procedure will advance a distal end of the Boosting Catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of the Boosting Catheter's tubular structure while a segment defining a side opening of the Boosting Catheter remains within the guide catheter.**

beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	"Use standard techniques to place guiding catheter and guidewire. Ensure a Y-adaptor with hemostasis valve is connected to guiding catheter. Thread the Boosting Catheter over the guidewire and carefully advance through the hemostasis valve. Under fluoroscopy, manipulate the catheter and the guidewire to achieve the desired position. The Boosting Catheter may be advanced up to 15cm beyond the tip of the guiding catheter. Note: Do NOT torque the catheter. Perform the catheterization procedure." Defendants' Depo. Ex. 58 (sales training materials) at QXM 1143-44. Q. Advances it so that the distal tube wewere looking at extends out past the end of the guide catheter into the coronary artery, right? A. Yes. Q. Once it's in place, your instructions for use say don't extend it more than 15 centimeters into the coronary artery, is that right? A. Yes. Q. You have got 15 centimeters of the distal tube we looked at.At the most in the coronary artery you have got ten centimeters inside the guide catheter, right? A. Yes. Q. So your junction area we looked at is going to be inside the guide catheter? A. Typically, yes. Q. You wouldn't put the junction past, right?

	A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295. Q. Once you are in place, your distal tube -- Boosting catheter distal tube is sticking out the end of the guide catheter? A. Yes. Q. The tube of the guide catheter is in fluid communication, in other words, fluids can get from the guide catheter into your distal tube? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 302. **The Boosting Catheter has a segment defining a side opening, where the side opening extends for a distance along a longitudinal axis of the guide extension catheter and is accessible from a longitudinal side defined transverse to the longitudinal axis.** See '760 patent, claim element 25[c], page 29 above. **In use, a cardiologist "advance[es] a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter." A typical six French guide catheter can have an inner diameter of 0.070 or 0.071 inches. The six French Boosting Catheter's tubular structure has a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of such a guide catheter, literally for a 0.070-inch guide catheter and by doctrine of equivalents for a 0.071-inch guide catheter.** See '380 patent, claim 8, page 26 above.

[c] maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and	**Element [b] above indicates that "the distal end portion" is the portion that extends beyond the distal end of the guide catheter in use ("advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter"). In use, a cardiologist maintains the distal end portion of the Boosting Catheter's tubular structure in position beyond the distal end of the guide catheter:** Q. Advances it so that the distal tube wewere looking at extends out past the end of the guide catheter into the coronary artery, right? A. Yes. Q. Once it's in place, your instructions for use say don't extend it more than 15 centimeters into the coronary artery, is that right? A. Yes. Q. You have got 15 centimeters of the distal tube we looked at.At the most in the coronary artery you have got ten centimeters inside the guide catheter, right? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295.

[d] while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	**In use, while the distal end of the Boosting Catheter is positioned beyond the distal end of the guide catheter, a balloon catheter or stent is advanced at least partially through the guide catheter and the guide extension catheter and into the coronary artery, which includes advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment (see '380 patent, claim element 1[d], page 6 above) of the guide extension catheter, through the side opening, and through the tubular structure:** Q. Advances it so that the distal tube wewere looking at extends out past the end of the guide catheter into the coronary artery, right? A. Yes. Q. Once it's in place, your instructions for use say don't extend it more than 15 centimeters into the coronary artery, is that right? A. Yes. Q. You have got 15 centimeters of the distal tube we looked at.At the most in the coronary artery you have got ten centimeters inside the guide catheter, right? A. Yes. Q. So your junction area we looked at is going to be inside the guide catheter? A. Typically, yes. Q. You wouldn't put the junction past, right?

	A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295. Q. Once the guide extension catheter is then in place, you understand that the physician – the typical thing to do would be to place a stent, use it for a stent? A. Yes. Q. You understand the physician then advances that stent over the guide wire so that it goes down the guide catheter and then into your distal tube at the junction? A. Yes. Q. Then the physician advances that stent further through the distal tube and then out the end of the distal tube of your Boosting catheter, right? A. Yes. Q. At that point … the physician will deploy the stent? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295-96. See '760 patent, claim elements 25[b], page 28 above, 25[c], page 29 above.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes	See '760 patent, claim element 25[c], page 29 above.

establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	
52. A method, comprising: [NOT ASSERTED]	**The method of claim 52 is performed by a cardiologists using the Boosting Catheter with a guide catheter and balloon catheter or stent for a coronary vascular procedure.**
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	See '116 patent, claim element 25[a], page 56 above.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;	See '116 patent, claim element 25[b], page 56 above, and '760 patent, claim element 48[d], page 45 above.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and	See '116 patent, claim element 25[c], page 59 above.
while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at	See '116 patent, claim element 25[d], page 60 above.

least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	**A cardiologist using the Boosting Catheter advances the distal end of the Boosting Catheter through the guide catheter, positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter:** Q. Advances it so that the distal tube wewere looking at extends out past the end of the guide catheter into the coronary artery, right? A. Yes. Q. Once it's in place, your instructions for use say don't extend it more than 15 centimeters into the coronary artery, is that right? A. Yes. Q. You have got 15 centimeters of the distal tube we looked at.At the most in the coronary artery you have got ten centimeters inside the guide catheter, right? A. Yes. Q. So your junction area we looked at is going to be inside the guide catheter?

	A. Typically, yes. Q. You wouldn't put the junction past, right? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295.

U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**QXMédical's Boosting Catheter**
1. [NOT ASSERTED] A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	**The Boosting Catheter is a device for use with a standard guide catheter that has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, where the continuous lumen of the guide catheter has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, as described below.** See '380 patent, claim elements 1[a] and 1[b], page 1 above.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter	See '380 patent, claim element 1[c], page 2 above.

through which interventional cardiology devices are insertable; and	
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,	See '380 patent, claim element 1[d], page 6 above.
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	See '380 patent, claim element 1[d], page 6 above.
2. [NOT ASSERTED] The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the	See '380 patent, claim 2, page 21 above.

device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	
3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	See '380 patent, claim 3, page 22 above.
8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	**The six French Boosting Catheter is a device for use with a 0.070-inch or 0.071-inch guide catheter. The cross-sectional inner diameter of the coaxial lumen of the tubular structure of the six French Boosting Catheter is not more than one French smaller than the cross-sectional inner diameter of such a guide catheter, literally for a 0.070-inch guide catheter and by doctrine of equivalents for a 0.071-inch guide catheter.** See '380 patent, claim 8, page 26 above. **Six French guide catheters having inner diameters of 0.070 and of 0.071 inches are standard guide catheters. Based on my analysis of market data, about 52.5% of six French guide catheters sold from 2016 to 2018 had an inner diameter of 0.070 inches and about 44% had an inner diameter of 0.071 inches. See Appendix S, produced in native form as VSIQXM_E00056325.** *See* Defendants' Depo. Exs. 48-50.

U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	QXMédical's Boosting Catheter
1. [NOT ASSERTED] A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	**A cardiologist using the Boosting Catheter with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1.** **In use, the cardiologist passes an interventional cardiology device through a standard guide catheter, where the standard guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and where the continuous lumen of the guide catheter has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen.** See '380 patent, claim element 1[a], page 1 above.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	**In use, the cardiologist typically inserts a standard guide catheter that has a distal end into an artery over a guidewire.**

positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	**In use, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery:** Q. [W]hen the physician does the coronary catheterization, he uses a guide catheter. The end of that guide catheter is in place at the ostium in a coronary artery? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 294. See '116 patent, claim 25, page 56 above.
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	**The Boosting Catheter has a flexible tip portion of a coaxial guide catheter that defines a tubular structure with a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter.** See '380 patent, claim element 1[c], page 2 above. **In use, the Boosting Catheter's flexible tip portion is inserted into the continuous lumen of the standard guide catheter.** "10.5 Using fluoroscopic imaging, carefully advance the catheter to the desired location in the vasculature. If resistance is encountered at any time during the insertion procedure, do not force passage or torque the device. The radiopaque marker on the distal end of the catheter will provide visual fluoroscopic guidance. "The Boosting Catheter may be advanced up to 15cm beyond the tip of the guiding catheter or sheath." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 92.
further inserting a substantially rigid portion that is proximal of, operably connected to,	**The Boosting Catheter includes a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible**

and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	**tip portion, where the substantially rigid portion defines a rail structure without a lumen and has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter.** See '380 patent, claim element 1[d], page 6 above. **In use, the Boosting Catheter's substantially rigid portion is inserted into the continuous lumen of the standard guide catheter to push the flexible tip portion, which is shorter than the guide catheter, past the guide catheter's distal end, into the vessel requiring treatment.** "The device is intended/indicated for use with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support interventional devices, including guidewires, traverse discrete portions of the vasculature, allow for interventional device exchanges and provide a conduit for the infusion of saline solution, diagnostic contrast agents and therapeutic agents." Defendants' Depo. Ex. 44 (FDA submission) at QXM 6308; see id. at QXM 6314; Defendants' Depo. Ex. 46 (second FDA submission) at QXM 7398. "The QXMedical Boosting Catheter is an over-the-wire support/guiding catheter with an atraumatic tip. The catheter is used in combination with guiding catheters or sheaths in interventional procedures to assist with delivery of other interventional devices (including guidewires) and procedural fluids to the coronary and peripheral vasculature. The catheter is offered in four (4) sizes compatible with 6Fr (small & large lumen), 7Fr and 8Fr guiding catheters…. The catheter is used in conjunction with … guidewires up to 0.014" diameter while accessing the coronary vasculature. The catheter is 150cm long comprised of a 125cm long manipulation shaft connected to a 25cm distal tube segment." Defendants' Depo.

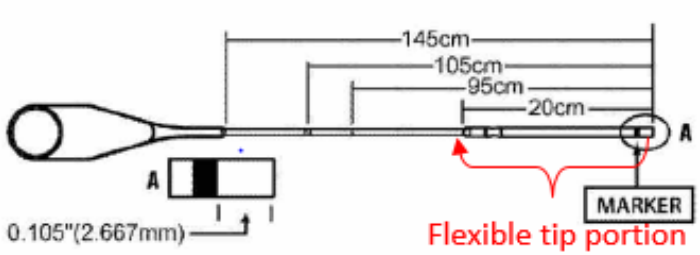
	Ex. 46 (second FDA submission) at QXM 7397; see also Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 87. "10.5 Using fluoroscopic imaging, carefully advance the catheter to the desired location in the vasculature. If resistance is encountered at any time during the insertion procedure, do not force passage or torque the device. The radiopaque marker on the distal end of the catheter will provide visual fluoroscopic guidance. "The Boosting Catheter may be advanced up to 15cm beyond the tip of the guiding catheter or sheath." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 92.
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	**In use, a distal portion of the Boosting Catheter's flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve.** "Use standard techniques to place guiding catheter and guidewire. Ensure a Y-adaptor with hemostasis valve is connected to guiding catheter. Thread the Boosting Catheter over the guidewire and carefully advance through the hemostasis valve. Under fluoroscopy, manipulate the catheter and the guidewire to achieve the desired position. The Boosting Catheter may be advanced up to 15cm beyond the tip of the guiding catheter. Note: Do NOT torque the catheter. Perform the catheterization procedure." Defendants' Depo. Ex. 58 (sales training materials) at QXM 1143-44. "10.5 Using fluoroscopic imaging, carefully advance the catheter to the desired location in the vasculature. If resistance is encountered at any time during the insertion procedure, do not force passage or torque the device. The radiopaque marker on the distal end of the catheter will provide visual fluoroscopic guidance.

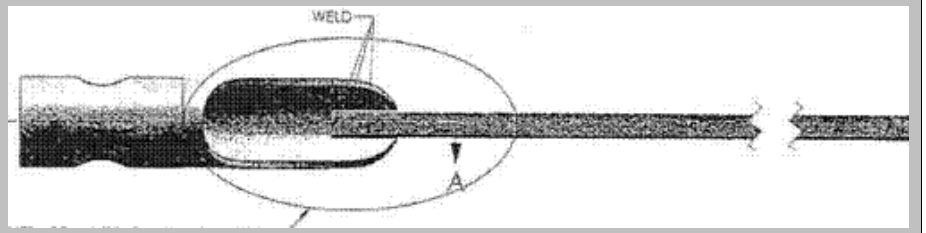
	"The Boosting Catheter may be advanced up to 15cm beyond the tip of the guiding catheter or sheath." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 92.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	**In use of the Boosting Catheter, an interventional cardiology device is inserted into and through the continuous lumen of the standard guide catheter alongside the substantially rigid portion, and advanced through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery:** "The Boosting Catheter may be advanced up to 15cm beyond the tip of the guiding catheter or sheath. "10.6 Using fluoroscopic imaging manipulate the guidewire and catheter in order to achieve the desired position. Do not torque the catheter. Also, do not advance or withdraw the catheter without the guidewire in place and extending beyond the distal end of the catheter. "10.7 Perform the catheterization procedure. Follow the individual manufacturer's instructions for any interventional devices used during the procedure. Consult Table A regarding passageway requirements. "10.8 When removing the catheter, use fluoroscopic imaging and make sure to maintain guidewire position. Remove the catheter prior to removing the guiding catheter or sheath. "DEVICE EXCHANGE "When exchanging interventional devices, including guidewires, maintain the Boosting Catheter position and carefully withdraw the interventional device under fluoroscopic imaging. Without moving the catheter, insert new interventional device through the hemostasis valve, guiding catheter (or sheath) and Boosting Catheter under fluoroscopic imaging. Do not advance the Boosting catheter without the guidewire in place and extending beyond the distal end of the catheter…." Defendants' Depo. Ex. 56 (IFUs Rev. 03) at QXM 92.

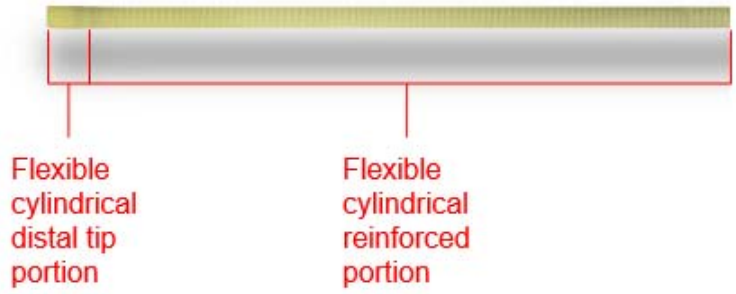
	Q. Once the guide extension catheter is then in place, you understand that the physician – the typical thing to do would be to place a stent, use it for a stent? A. Yes. Q. You understand the physician then advances that stent over the guide wire so that it goes down the guide catheter and then into your distal tube at the junction? A. Yes. Q. Then the physician advances that stent further through the distal tube and then out the end of the distal tube of your Boosting catheter, right? A. Yes. Q. At that point … the physician will deploy the stent? A. Yes. August 3, 2018, Rule 30(b)(6) Deposition of QXMédical (Di Caprio) at 295-96.
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure	See '413 patent, claim 1, immediately above, and '380 patent, claim 3, page 22 above.

while the proximal portion remains within the lumen of the guide catheter.	

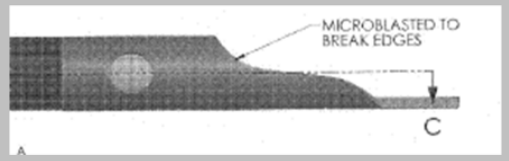
U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 1**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	The combination of a Guideliner Version 1 and a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	A typical guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.
a device adapted for use with the guide catheter, including:	The Guideliner Version 1 is a device adapted for use with a guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.

a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The GuideLiner Version 1 has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:  GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner Version 1 has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. "When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." *Id.*

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;	The GuideLiner Version 1 includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  VSIQXM_E00043457. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is more rigid along a longitudinal axis than the flexible tip portion. The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends

	proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. A typical guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. … 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	As shown below, the tubular structure of the GuideLiner Version 1 structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion.  The flexible cylindrical distal tip portion (unreinforced bumper tip) is more flexible than the flexible cylindrical reinforced portion (coil-reinforced portion of the lumen). The results of the "crush" testing clearly show that

<table>
<tr><td></td><td>the GuideLiner v1's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. See Appendix D at 1-2, comparing "Crush 1" values to "Crush 2" and "Crush 3" values.</td></tr>
<tr><td>3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.</td><td>As shown below, the proximal portion of the tubular structure of the GuideLiner Version 1 further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

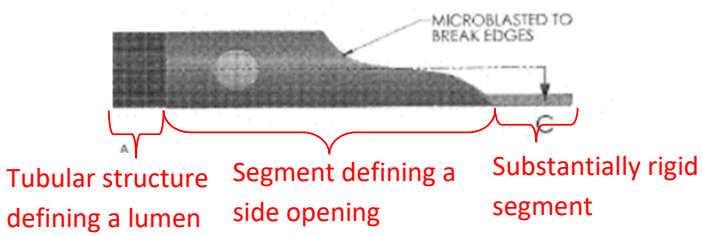
 

VSIQXM_E00043457.</td></tr>
<tr><td>8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.</td><td>The cross-sectional inner diameter of the GuideLiner Version 1's coaxial lumen is approximately one French smaller than the cross-sectional inner diameter of the guide catheter with which it is intended for use. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.

SPECIFICATIONS
<table>
<tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner Min. I.D.</th><th>GuideLiner Tip O.D.</th></tr>
<tr><td>5571
6F
(5-in-6)</td><td>≥ 6F (≥ 0.070" / 1.78mm I.D.)</td><td>0.056" / 1.42mm</td><td>0.067" / 1.70mm</td></tr>
<tr><td>5572
7F
(6-in-7)</td><td>≥ 7F (≥ 0.078"/ 1.98mm I.D.)</td><td>0.062" / 1.57mm</td><td>0.074" / 1.88mm</td></tr>
<tr><td>5573
8F
(7-in-8)</td><td>≥ 8F (≥ 0.088" / 2.24mm I.D.)</td><td>0.071" / 1.80mm</td><td>0.084" / 2.13mm</td></tr>
</table></td></tr>
</table>

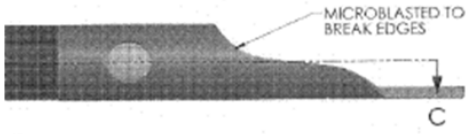
	GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.

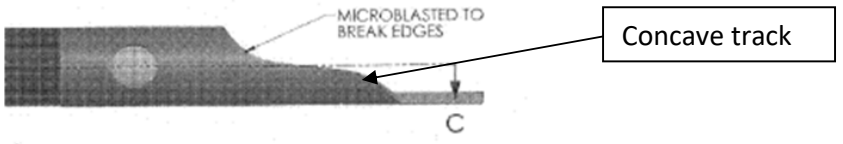
U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 1**
25. A system, comprising:	The combination of the Guideliner Version 1 and a guide catheter forms a system. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the	The GuideLiner Version 1 is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner Version 1 is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter.

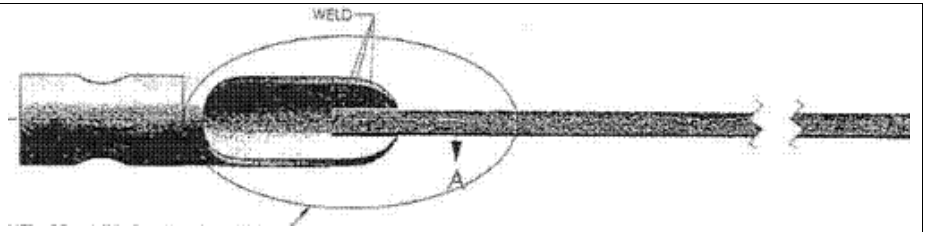
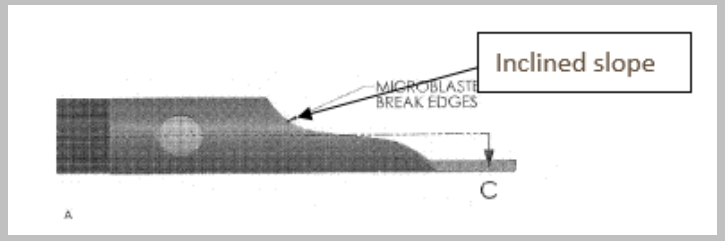
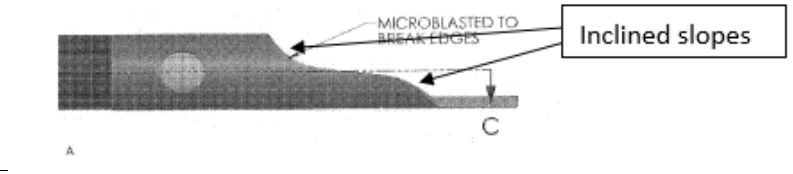
guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	"The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. … 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure	The GuideLiner Version 1 includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  VSIQXM_E00043457. The GuideLiner Version 1 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter.

are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The lumen of the tubular structure of the 6 French device has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. **SPECIFICATIONS** GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

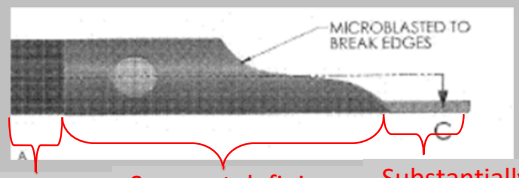
Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5571 6F (5-in-6)	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F (6-in-7)	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.074" / 1.88mm
5573 8F (7-in-8)	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.084" / 2.13mm

	The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. The side opening of the GuideLiner Version 1 extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  VSIQXM_E00043457.

	The side opening and lumen of the tubular structure of the GuideLiner Version 1 are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the GuideLiner Version 1 extends beyond the distal end of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	Based on my physical examination of the GuideLiner v1, it is my opinion that the matter forming the segment defining the side opening is more rigid than the tubular structure.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown below, the segment defining the side opening of the GuideLiner Version 1 defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.  VSIQXM_E00043457.

	 VSIQXM_E00043457.
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown below, the segment defining the side opening of the GuideLiner Version 1 includes at least one inclined slope.  VSIQXM_E00043457.
32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.	As shown below, the segment defining the side opening of the GuideLiner Version 1 includes at least two inclined slopes. 

	VSIQXM_E00043457.
48. A system, comprising:	The combination of the GuideLiner Version 1 with a guide catheter forms a system. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	The GuideLiner Version 1 is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner Version 1 is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the

	guide catheter. … 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The GuideLiner Version 1 includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  VSIQXM_E00043457. The GuideLiner Version 1 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter. The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. A typical guide catheter has a length of 100cm. The lumen of the tubular structure of the 6 French version has a uniform cross-sectional inner diameter that is not more than one French size smaller

than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.

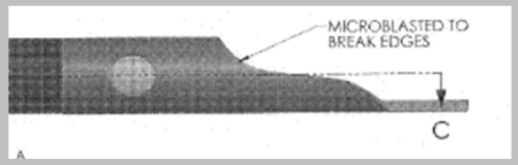
"The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5571 6F (5-in-6)	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F (6-in-7)	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.074" / 1.88mm
5573 8F (7-in-8)	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.084" / 2.13mm

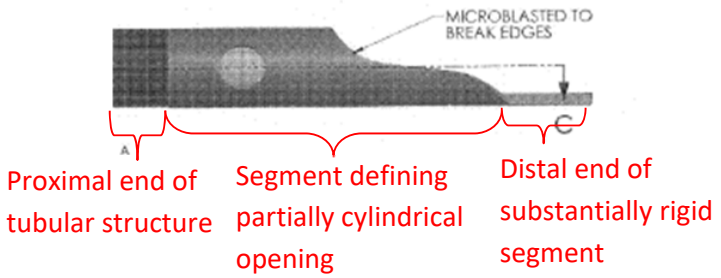
GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

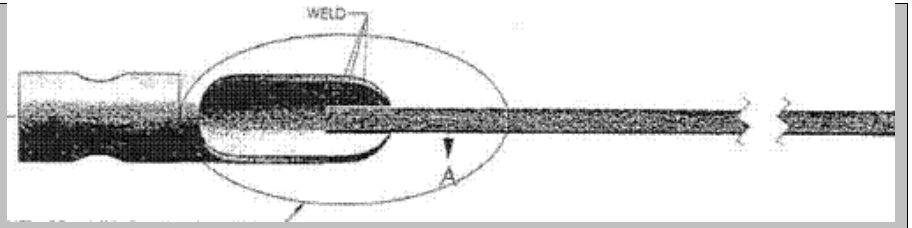
The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just

	barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. The side opening of the GuideLiner Version 1 extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  VSIQXM_E00043457. The side opening and lumen of the tubular structure of the GuideLiner Version 1 are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and

	the distal end of the GuideLiner Version 1 extends beyond the distal end of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.	Based on my physical examination of the GuideLiner v1, it is my opinion that the segment defining the side opening of the GuideLiner Version 1 is more rigid than a distal end portion of the tubular structure.

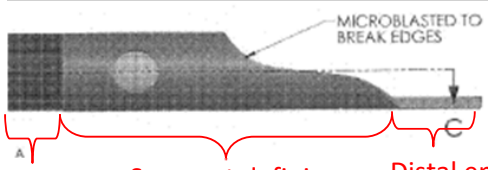
U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 1**
25. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner Version 1 is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The GuideLiner Version 1 includes a substantially rigid segment, namely a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner Version 1 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices	The GuideLiner Version 1 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

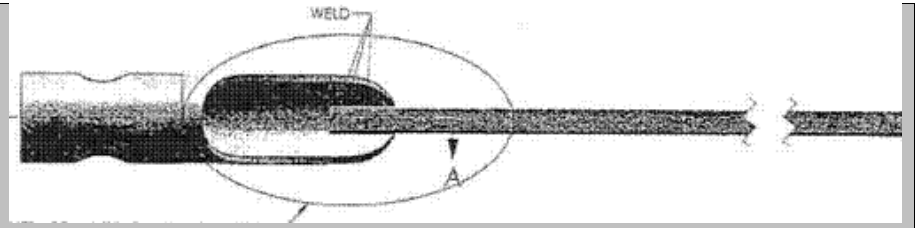
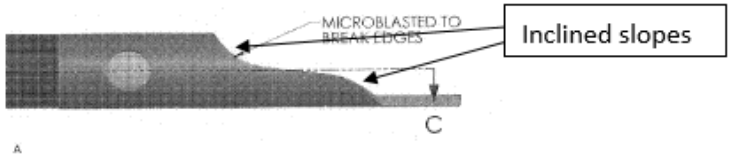
therethrough when positioned within the guide catheter,	 VSIQXM_E00043457. Based on my physical examination of the GuideLiner v1, it is my opinon that the segment defining the partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.	The cross-section of the GuideLiner Version 1 at the proximal end of the tubular structure defines a single lumen, as shown below:

	 VSIQXM_E00043457.
30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.	The lumen of the tubular structure of the 6 French version has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. **SPECIFICATIONS** Model / Compatible Guide Catheter / GuideLiner Min. I.D. / GuideLiner Tip O.D. 5571 6F (5-in-6) / ≥ 6F (≥ 0.070" / 1.78mm I.D.) / 0.056" / 1.42mm / 0.067" / 1.70mm 5572 7F (6-in-7) / ≥ 7F (≥ 0.078"/ 1.98mm I.D.) / 0.062" / 1.57mm / 0.074" / 1.88mm 5573 8F (7-in-8) / ≥ 8F (≥ 0.088" / 2.24mm I.D.) / 0.071" / 1.80mm / 0.084" / 2.13mm GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the

	Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	The lumen of the tubular structure of the GuideLiner Version 1 is configured to receive a stent and a balloon catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices."

	GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. "When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." *Id.*
52. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner Version 1 is a guide extension catheter for use with a guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a substantially rigid segment;	The GuideLiner Version 1 includes a substantially rigid segment, namely a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner Version 1 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a	The GuideLiner Version 1 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	 Proximal end of tubular structure Segment defining partially cylindrical opening Distal end of substantially rigid segment VSIQXM_E00043457. Based on my physical examination of the GuideLiner v1, it is my opinion that the segment defining the partially cylindrical opening is formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	The cross-section of the GuideLiner Version 1 at the proximal end of the tubular structure defines a single lumen, as shown below:

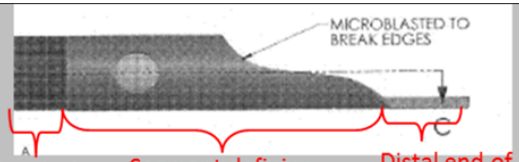
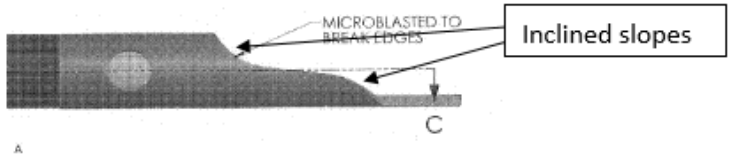
	 VSIQXM_E00043457.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The GuideLiner Version 1's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:  VSIQXM_E00043457.
53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	The GuideLiner Version 1 is a guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
a substantially rigid segment;	The GuideLiner Version 1 includes a substantially rigid segment, namely a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter.

<table>
<tr><td></td><td>“The 145cm device has a stainless steel shaft ....” GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.</td></tr>
<tr><td>a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and</td><td>The GuideLiner Version 1 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment and the 6 French version has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.

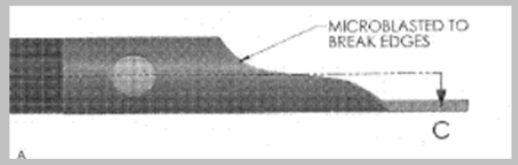
“The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter.” GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.

SPECIFICATIONS
<table><tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner Min. I.D.</th><th>GuideLiner Tip O.D.</th></tr><tr><td>5571
6F
(5-in-6)</td><td>≥ 6F (≥ 0.070" / 1.78mm I.D.)</td><td>0.056" / 1.42mm</td><td>0.067" / 1.70mm</td></tr><tr><td>5572
7F
(6-in-7)</td><td>≥ 7F (≥ 0.078"/ 1.98mm I.D.)</td><td>0.062" / 1.57mm</td><td>0.074" / 1.88mm</td></tr><tr><td>5573
8F
(7-in-8)</td><td>≥ 8F (≥ 0.088" / 2.24mm I.D.)</td><td>0.071" / 1.80mm</td><td>0.084" / 2.13mm</td></tr></table>
GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.</td></tr>
</table>

	The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	The GuideLiner Version 1 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

	 VSIQXM_E00043457. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The GuideLiner Version 1's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:  VSIQXM_E00043457.

U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 1**
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the GuideLiner Version 1 with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00044256.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner Version 1 includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than	The intended method of using a GuideLiner Version 1 includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide

one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	catheter. 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57. The segment defining a side opening of the GuideLiner Version 1, shown below, extends for a distance along a longitudinal axis of the guide extension catheter and is accessible from a longitudinal side defined transverse to the longitudinal axis.  VSIQXM_E00043457. The tubular structure of the 6 French GuideLiner Version 1 has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5571 6F (5-in-6)	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F (6-in-7)	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.074" / 1.88mm
5573 8F (7-in-8)	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.084" / 2.13mm

GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is

	insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a GuideLiner Version 1 includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.

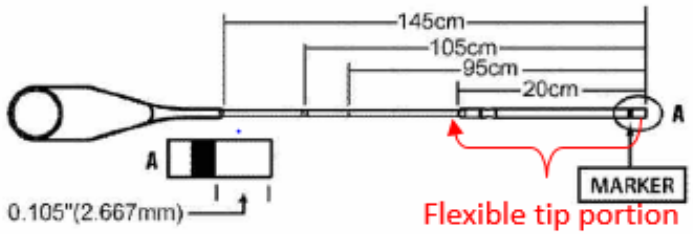
	"3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57. The GuideLiner Version 1 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	While the GuideLiner Version 1 is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the GuideLiner Version 1 and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 52 is performed by a cardiologist using the GuideLiner Version 1 with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00044256.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner Version 1 includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery.

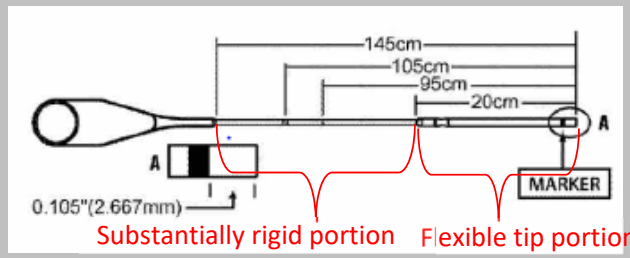
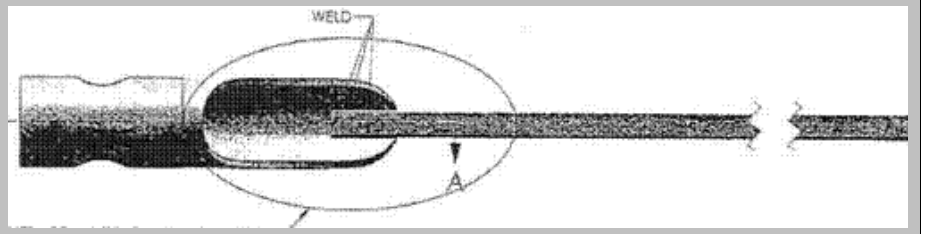
	"GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;	The intended method of using a GuideLiner Version 1 includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57. Based on my physical examination of the GuideLiner v2, it is my opinion that the segment defining the side opening of the GuideLiner Version 1 comprises a portion of the device that is more rigid than the distal end portion of the tubular structure.

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a GuideLiner Version 1 includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57. The GuideLiner Version 1 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v1, it is my opinion that the

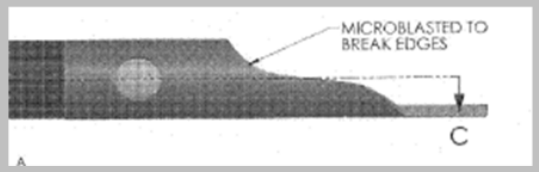
	stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	In the intended method of using a GuideLiner Version 1, advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.

U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 1**
1. [NOT ASSERTED] A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	The GuideLiner Version 1 is used in conjunction with a standard guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lument of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through	The GuideLiner Version 1 has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:

which interventional cardiology devices are insertable; and	 GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner Version 1 has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. "When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space." *Id.*
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and	The GuideLiner Version 1 includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the guide catheter.

having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	"The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.  VSIQXM_E00043457. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is more rigid along a longitudinal direction than the flexible tip portion.

	The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. A standard guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. … 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	The tubular structure of the GuideLiner Version 1 has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the

	interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57. The GuideLiner Version 1 assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	As shown below, the proximal portion of the tubular structure of the GuideLiner Version 1 further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.  VSIQXM_E00043457.
8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the GuideLiner Version 1's coaxial lumen is approximately one French smaller than the cross-sectional inner diameter of the guide catheter with which it is intended for use. "The GuideLiner catheters are delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5571 6F (5-in-6)	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F (6-in-7)	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.074" / 1.88mm
5573 8F (7-in-8)	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.084" / 2.13mm

GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. Six French GuideLiner v1 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043457. At least some GuideLiner v1 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow

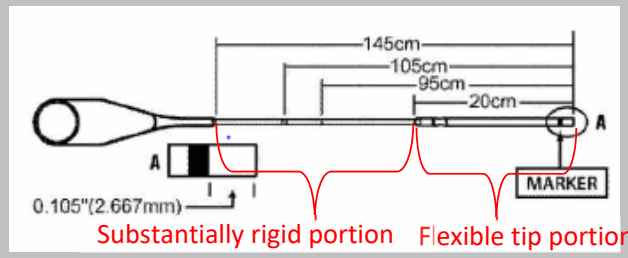
	interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v1 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.

U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 1**
1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be paseed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	A cardiologist using the GuideLiner Version 1 with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	To use the GuideLiner Version 1, a standard guide catheter is inserted into a first artery over a guidewire. "1. Secure the previously inserted guidewire …" GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the GuideLiner Version 1, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery.

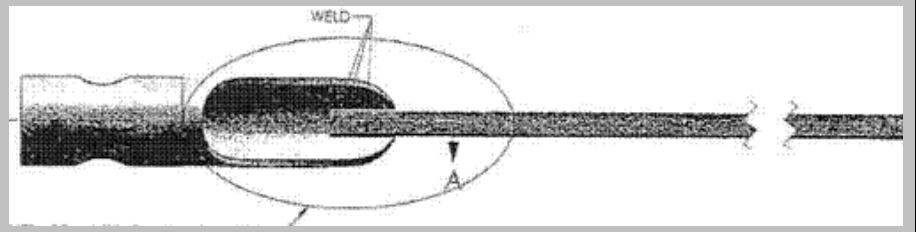
	"GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	The intended method of using the GuideLiner Version 1 includes inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. "The 145cm device has a stainless steel shaft ...." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256. A standard guide catheter has a length of 100cm. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	The intended method of using the GuideLiner Version 1 includes further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter The GuideLiner Version 1 has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. This is the stainless steel shaft of the device. Based on my physical examination of the GuideLiner v1, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v1 through the

guide catheter and that the stainless steel shaft is more rigid along a longitudinal axis than the tubular portion of the device.

The drawings below depict the stainless steel shaft, which is substantially rigid, proximal of, and operably connected to, and more rigid than the flexible tip portion, and defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.



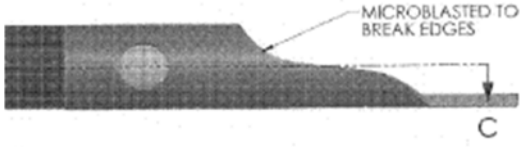
GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256.



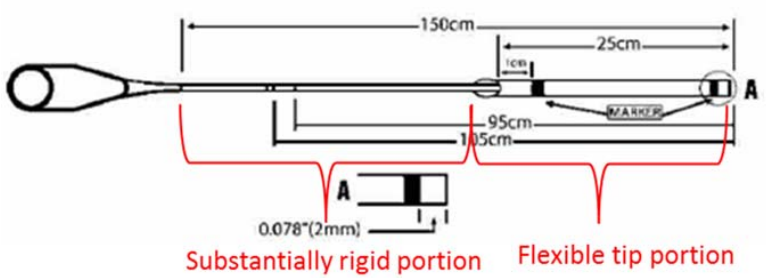
VSIQXM_E00043457.

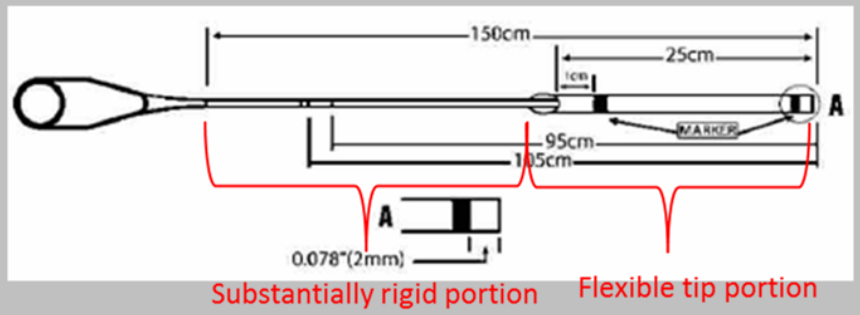
The substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 145 cm, longer than the standard 100cm length of the continuous lumen of the guide catheter.

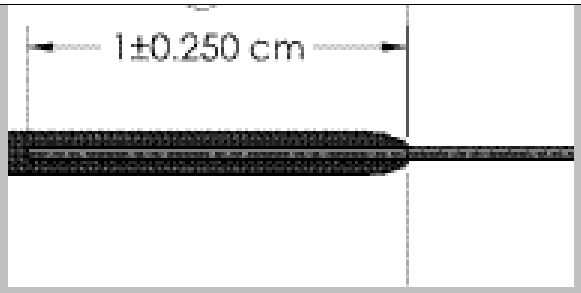
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	In the intended method of using the GuideLiner Version 1, a distal portion of the flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. … 3. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 10cm beyond the distal end of the guide catheter … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	In the intended method of using a GuideLiner Version 1, an interventional cardiology device is inserted into and through the continuous lumen of the standard guide catheter alongside the substantially rigid portion of the GuideLiner. The interventional cardiology device is advanced through and beyond the lumen of the flexible tip portion into contact with or past a lesion in the second artery. "5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular	In the intended method of using the GuideLiner Version 1, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along

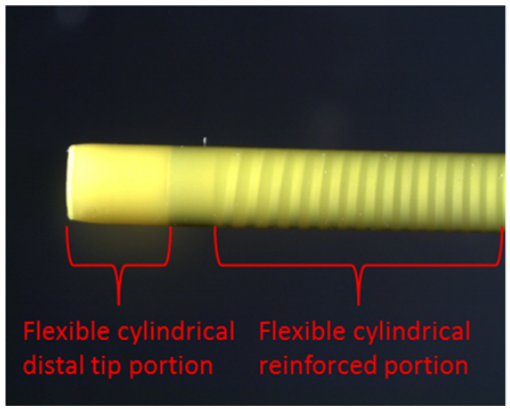
structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure is shown below:  VSIQXM_E00043457. In use, the proximal portion of the tubular structure remains within the lumen of the guide catheter. "5. When inserted for an interventional procedure, position the metal collar of the GuideLiner catheter in a straight section of the guide catheter. Backload the interventional device over the in place guidewire and advance through the metal collar of the GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 1 Instructions for Use, VSIQXM_E00044256-57.

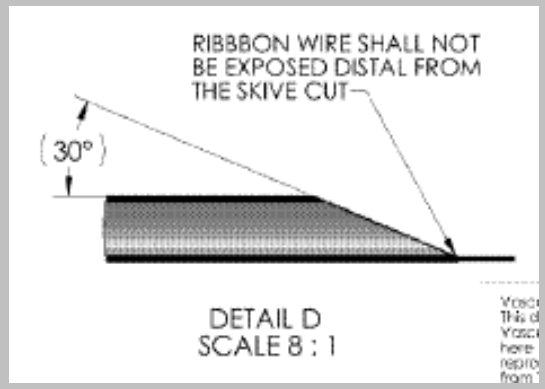
U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 2**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	The combination of the Guideliner Version 2 with a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	A typical guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.
a device adapted for use with the guide catheter, including:	The Guideliner Version 2 is a device adapted for use with a guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional

	devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The GuideLiner Version 2 has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:  GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner Version 2 has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. "When inserted for an interventional procedure, backload the interventional device over the in place

	guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." *Id.*
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;	The GuideLiner Version 2 includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

	 VSIQXM_E00043704. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is more rigid along a longitudinal axis than the flexible tip portion. The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 150cm device has a stainless steel shaft ...." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. A typical guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond

	the distal tip of the guide catheter and into the desired location within the vessel. … 5. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	As shown below, the tubular structure of the GuideLiner Version 2 structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion.  The flexible cylindrical distal tip portion (unreinforced bumper tip) is more flexible than the flexible cylindrical reinforced portion (coil-reinforced portion of the lumen). The results of the "crush" testing clearly show that the GuideLiner v2's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. See Appendix D at 1-2, comparing "Crush 1" values to "Crush 2" and "Crush 3" values.
3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a	As shown below, the proximal portion of the tubular structure of the GuideLiner Version 2 further comprises structure defining a

proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.  VSIQXM_E00043704.
8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the GuideLiner Version 2's coaxial lumen is approximately one French smaller than the cross-sectional inner diameter of the guide catheter with which it is intended for use. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

SPECIFICATIONS

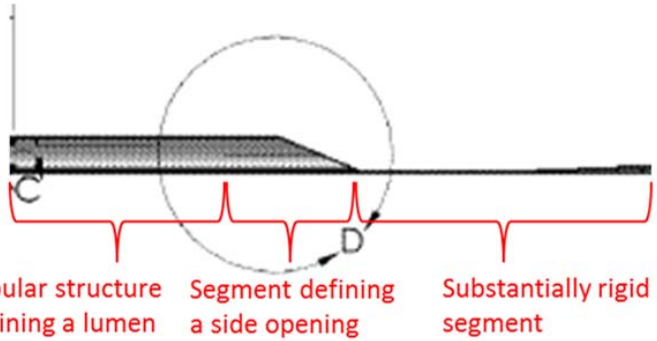
Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5570 5.5F	≥ 6F (≥ 0.067" / 1.70mm I.D.)	0.051" / 1.30mm	0.063" / 1.60mm
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.075" / 1.90mm
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.085" / 2.16mm

GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. Six French GuideLiner v2 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043704. At least some GuideLiner v2 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide

	catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 2**
25. A system, comprising:	The combination of the Guideliner Version 2 with a guide catheter forms a system. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension	The GuideLiner Version 2 is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner Version 2 is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter.

catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The GuideLiner Version 2 includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  VSIQXM_E00043704. The GuideLiner Version 2 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical

examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter.

The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. "The 150cm device has a stainless steel shaft ...." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. A typical guide catheter has a length of 100cm.

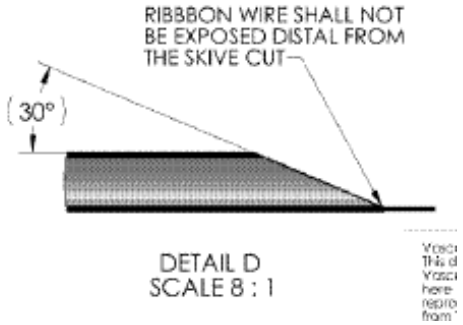
For the 6 French version, the lumen of the tubular structure has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.

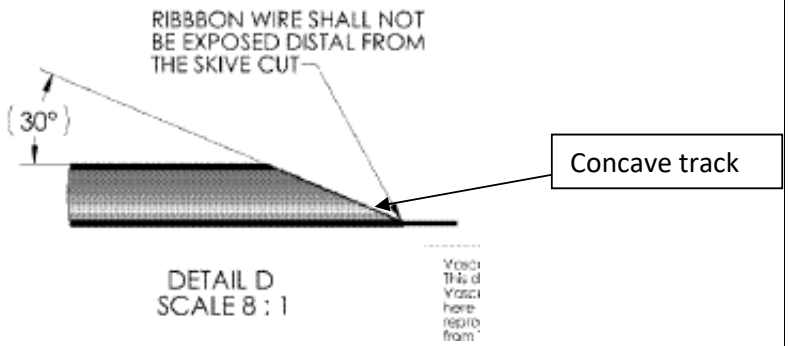
"The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

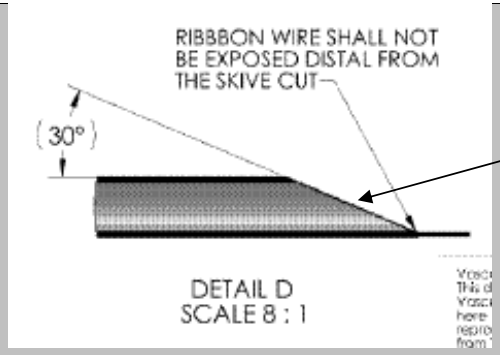
SPECIFICATIONS

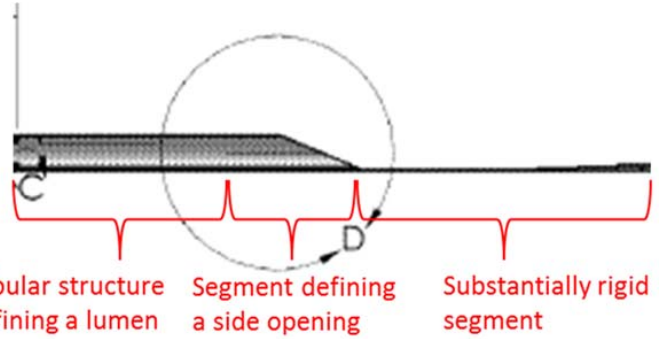
Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5570 5.5F	≥ 6F (≥ 0.067" / 1.70mm I.D.)	0.051" / 1.30mm	0.063" / 1.60mm
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.075" / 1.90mm
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.085" / 2.16mm

	GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. Six French GuideLiner v2 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043704. At least some GuideLiner v2 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v2 meets this limitation by doctrine of equivalents

	when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. The side opening of the GuideLiner Version 2 extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  VSIQXM_E00043704. The side opening and lumen of the tubular structure of the GuideLiner Version 2 are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the GuideLiner Version 2 extends beyond the distal end of the guide catheter. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal end of the guide catheter and into the desired location within the vessel. … 4. When

	inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	Based on my physical examination of the GuideLiner v2, it is my opinion that the matter forming the segment defining the side opening is more rigid than the tubular structure.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown below, the segment defining the side opening of the GuideLiner Version 2 defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.  VSIQXM_E00043704.
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown below, the segment defining the side opening of the GuideLiner Version 2 includes at least one inclined slope.

	 VSIQXM_E00043704.
48. A system, comprising:	The combination of the GuideLiner Version 2 with a guide catheter forms a system. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length	The GuideLiner Version 2 is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner Version 2 is such

such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel … 5. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned	The GuideLiner Version 2 includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below: 

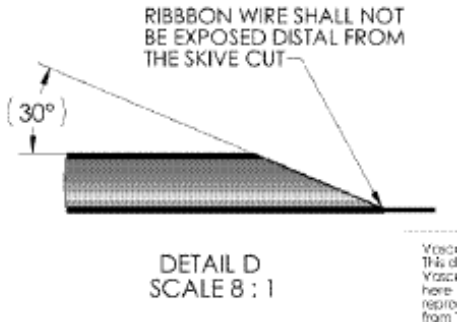
within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	VSIQXM_E00043704. The GuideLiner Version 2 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter. The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. "The 150cm device has a stainless steel shaft ...." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. A typical guide catheter has a length of 100cm. For the 6 French version, the lumen of the tubular structure has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5570 5.5F	≥ 6F (≥ 0.067" / 1.70mm I.D.)	0.051" / 1.30mm	0.063" / 1.60mm
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.075" / 1.90mm
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.085" / 2.16mm

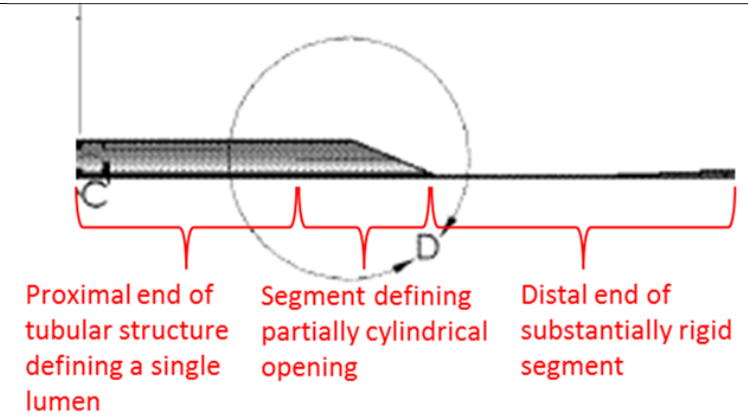
GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. Six French GuideLiner v2 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043704. At least some GuideLiner v2 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in

	substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. The side opening of the GuideLiner Version 2 extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  VSIQXM_E00043704.

	The side opening and lumen of the tubular structure of the GuideLiner Version 2 are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the GuideLiner Version 2 extends beyond the distal end of the guide catheter. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. … 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.	Based on my physical examination of the GuideLiner v2, it is my opinion that the segment defining the side opening of the GuideLiner Version 2 is more rigid than a distal end portion of the tubular structure.

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 2**
25. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner Version 2 is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The GuideLiner Version 2 includes a substantially rigid segment, namely a stainless steel shaft. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter. "The 150cm device has a stainless steel shaft ...." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner Version 2 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment. "The 150cm device has a stainless steel shaft ...." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices	The GuideLiner Version 2 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

therethrough when positioned within the guide catheter,	 VSIQXM_E00043704. Based on my physical examination of the GuideLiner v2, it is my opinion that the segment defining the partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. … 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.

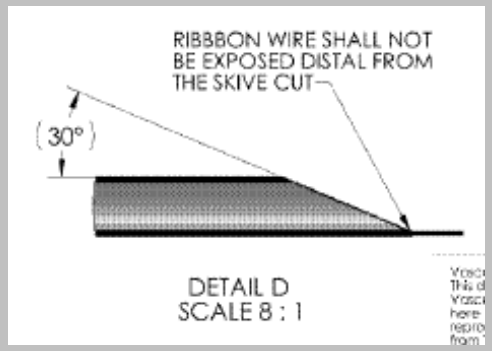
<table>
<tr><td>wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.</td><td>The cross-section of the GuideLiner Version 2 at the proximal end of the tubular structure defines a single lumen.</td></tr>
<tr><td>30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.</td><td>The six French version of the GuideLiner v2 meets this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use.

SPECIFICATIONS
<table><tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner Min. I.D.</th><th>GuideLiner Tip O.D.</th></tr><tr><td>5570
5.5F</td><td>≥ 6F (≥ 0.067" / 1.70mm I.D.)</td><td>0.051" / 1.30mm</td><td>0.063" / 1.60mm</td></tr><tr><td>5571
6F</td><td>≥ 6F (≥ 0.070" / 1.78mm I.D.)</td><td>0.056" / 1.42mm</td><td>0.067" / 1.70mm</td></tr><tr><td>5572
7F</td><td>≥ 7F (≥ 0.078"/ 1.98mm I.D.)</td><td>0.062" / 1.57mm</td><td>0.075" / 1.90mm</td></tr><tr><td>5573
8F</td><td>≥ 8F (≥ 0.088" / 2.24mm I.D.)</td><td>0.071" / 1.80mm</td><td>0.085" / 2.16mm</td></tr></table>
GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. Six French GuideLiner v2 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. See VSIQXM_E00043704. At least some GuideLiner v2 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either</td></tr>
</table>

	case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	The lumen of the tubular structure of the GuideLiner Version 2 is configured to receive a stent and a balloon catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. "When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." *Id.*
[redacted]	[redacted]

U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 2**
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the GuideLiner Version 2 with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner Version 2 includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined	The intended method of using a GuideLiner Version 2 includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 3. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the

transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	vessel. 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75. The segment defining a side opening of the GuideLiner Version 2, shown below, extends for a distance along a longitudinal axis of the guide extension catheter and is accessible from a longitudinal side defined transverse to the longitudinal axis.  VSIQXM_E00043704. For the 6 French version, the tubular structure of the GuideLiner Version 2 has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Min. I.D.	GuideLiner Tip O.D.
5570 5.5F	≥ 6F (≥ 0.067" / 1.70mm I.D.)	0.051" / 1.30mm	0.063" / 1.60mm
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm	0.067" / 1.70mm
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" / 1.57mm	0.075" / 1.90mm
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" / 1.80mm	0.085" / 2.16mm

GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. Six French GuideLiner v2 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043704. At least some GuideLiner v2 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of

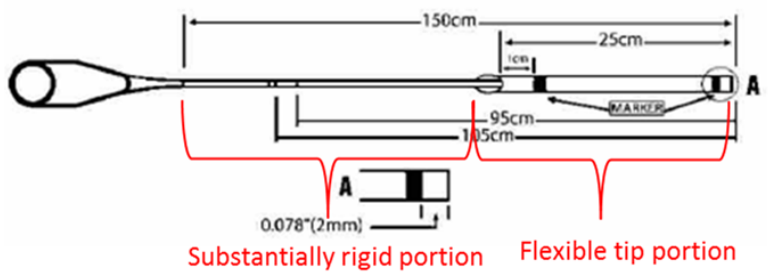
	space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a GuideLiner Version 2 includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 3. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75. The GuideLiner Version 2 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v2, it

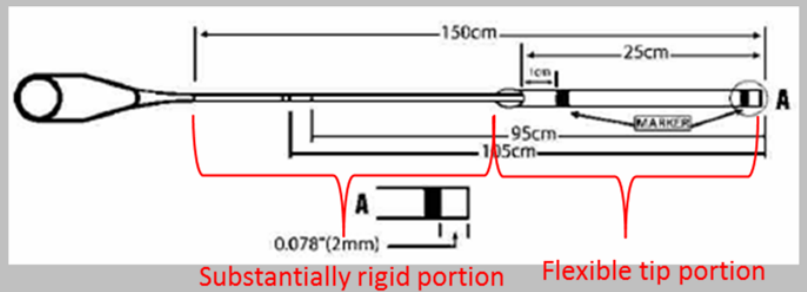
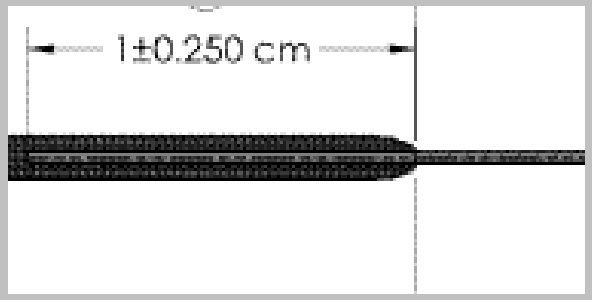
	is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	While the GuideLiner Version 2 is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the GuideLiner Version 2 and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 52 is performed by a cardiologist using the GuideLiner Version 2 with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00044274.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner Version 2 includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the	The intended method of using a GuideLiner Version 2 includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location

guide extension catheter that is more rigid than the distal end portion of the tubular structure;	within the vessel. … 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75. Based on my physical examination of the GuideLiner v2, it is my opinion that the segment defining the side opening of the GuideLiner Version 2 comprises a portion of the device that is more rigid than the distal end portion of the tubular structure.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a GuideLiner Version 2 includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 3. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.

	The GuideLiner Version 2 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	In the intended method of using a GuideLiner Version 2, advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 3. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.

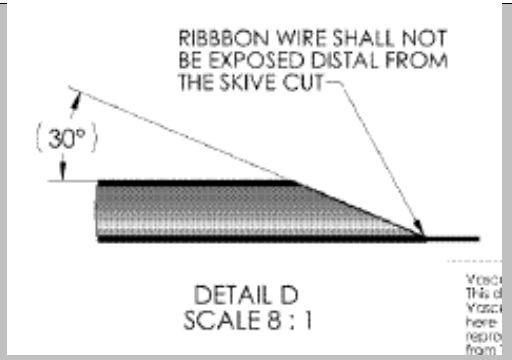
U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 2**
1. [NOT ASSERTED] A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	The GuideLiner Version 2 is used in conjunction with a standard guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lument of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-	The GuideLiner Version 2 has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:

sectional inner diameter through which interventional cardiology devices are insertable; and	 GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner Version 2 has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. "When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." *Id.*
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at	The GuideLiner Version 2 includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless

a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.  VSIQXM_E00043704.

	Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is more rigid along a longitudinal axis than the flexible tip portion. The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 150cm device has a stainless steel shaft ...." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. A standard guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear	The tubular structure of the GuideLiner Version 2 has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter.

forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	"2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 3. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75. The GuideLiner Version 2 assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	As shown below, the proximal portion of the tubular structure of the GuideLiner Version 2 further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

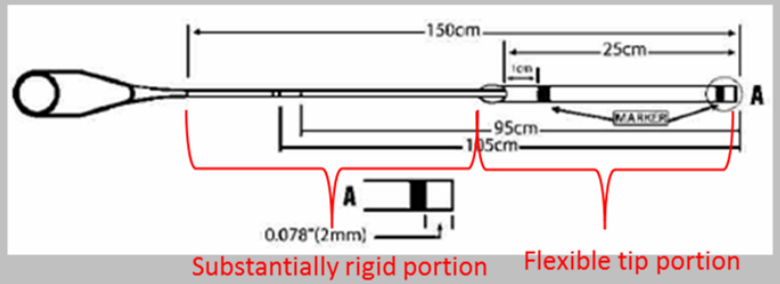
	 VSIQXM_E00043704.
8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the GuideLiner Version 2's coaxial lumen is approximately one French smaller than the cross-sectional inner diameter of the guide catheter with which it is intended for use. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. **SPECIFICATIONS** Model | Compatible Guide Catheter | GuideLiner Min. I.D. | GuideLiner Tip O.D. 5570 5.5F | ≥ 6F (≥ 0.067" / 1.70mm I.D.) | 0.051" / 1.30mm | 0.063" / 1.60mm 5571 6F | ≥ 6F (≥ 0.070" / 1.78mm I.D.) | 0.056" / 1.42mm | 0.067" / 1.70mm 5572 7F | ≥ 7F (≥ 0.076"/ 1.98mm I.D.) | 0.062" / 1.57mm | 0.075" / 1.90mm 5573 8F | ≥ 8F (≥ 0.088" / 2.24mm I.D.) | 0.071" / 1.80mm | 0.085" / 2.16mm

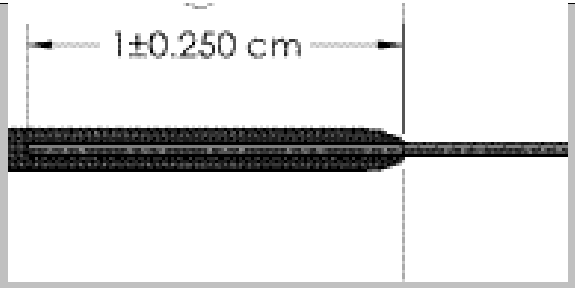
	GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. Six French GuideLiner v2 devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00043704. At least some GuideLiner v2 devices had an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner v2 meets this limitation by doctrine of equivalents when a 0.057-inch catheter combined with a 0.071-inch guide catheter or

	when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.

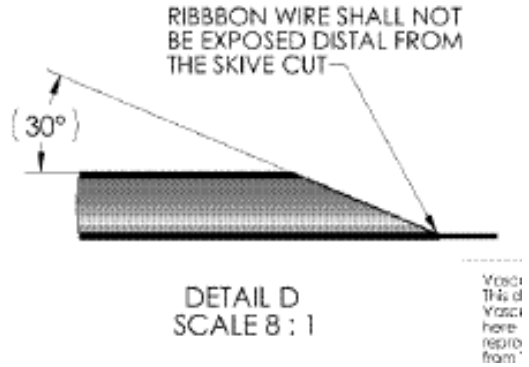
U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 2**
1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	A cardiologist using the GuideLiner Version 2 with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	To use the GuideLiner Version 2, a standard guide catheter is inserted into a first artery over a guidewire. "1. Backload the distal tip of the GuideLiner catheter onto the proximal end of the guidewire that is already in place in the distal vasculature." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the GuideLiner Version 2, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	The intended method of using the GuideLiner Version 2 includes inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. A standard guide catheter has a length of 100cm. "1. Backload the distal tip of the GuideLiner catheter onto the proximal end of the guidewire that is already in place in the distal vasculature. 2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a	The intended method of using the GuideLiner Version 2 includes further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a

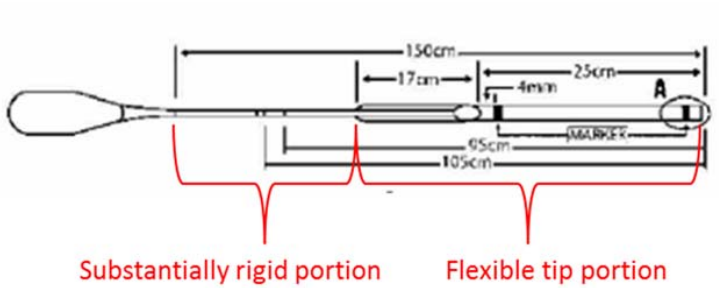
length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter The GuideLiner Version 2 has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. This is the stainless steel shaft of the device. Based on my physical examination of the GuideLiner v2, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v2 through the guide catheter and that the stainless steel shaft is more rigid along a longitudinal axis than the tubular portion of the device. The drawings below depict the stainless steel shaft, which is substantially rigid, proximal of, and operably connected to, and more rigid than the flexible tip portion, and defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274.

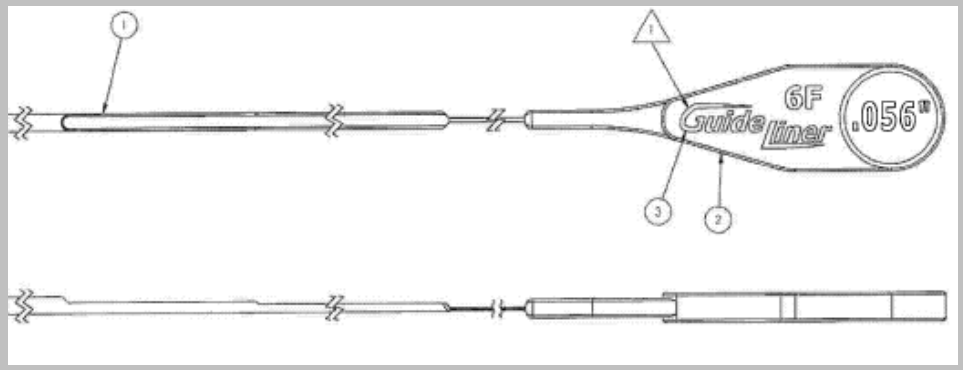
	 VSIQXM_E00043704. The substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 150 cm, longer than the standard 100cm length of the continuous lumen of the guide catheter.
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	In the intended method of using the GuideLiner Version 2, a distal portion of the flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "2. Under fluoroscopy, advance the GuideLiner catheter up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and	In the intended method of using a GuideLiner Version 2, an interventional cardiology device is inserted into and through the continuous lumen of the standard guide catheter alongside the

advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	substantially rigid portion of the GuideLiner. The interventional cardiology device is advanced through and beyond the lumen of the flexible tip portion into contact with or past a lesion in the second artery. "4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	In the intended method of using the GuideLiner Version 2, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure is shown below:

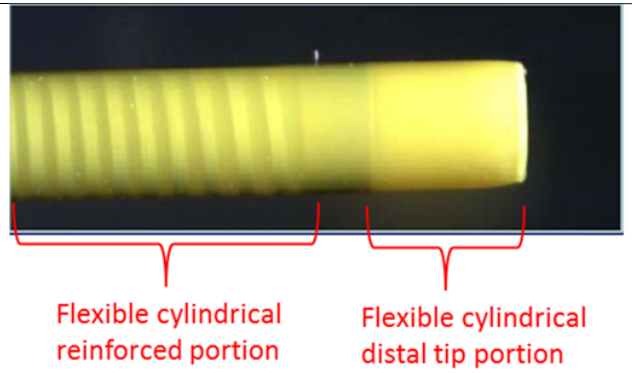
	 VSIQXM_E00043704. In use, the proximal portion of the tubular structure remains within the lumen of the guide catheter. "4. When inserted for an interventional procedure, backload the interventional device over the in place guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 6. Perform the catheterization procedure." GuideLiner Version 2 Instructions for Use, VSIQXM_E00044274-75.

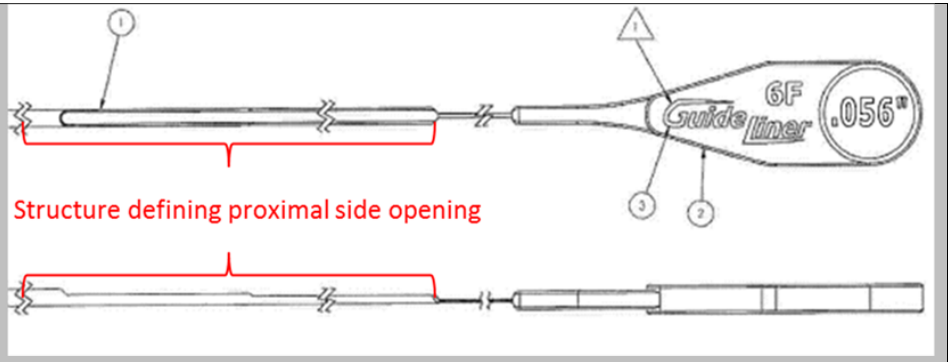
U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 3**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	The combination of a Guideliner Version 3 and a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	A typical guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.
a device adapted for use with the guide catheter, including:	The Guideliner Version 3 is a device adapted for use with a guide catheter.

	"GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The GuideLiner Version 3 has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner Version 3 has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. "If performing an interventional procedure, backload the interventional device over the existing

	guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." *Id.*
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;	The GuideLiner Version 3 includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  VSIQXM_E00043764. The stainless steel shaft is more rigid along a longitudinal axis than the flexible tip portion. In the two point bend testing of the GuideLiner v3, every catheter sample tested had a higher maximum force value for the proximal shaft portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values—Expert Report, Appendix D at 1.

	The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 150cm device has a 125cm stainless steel shaft section covered on the distal 17cm with a semi-circular polymer. The steel shaft is followed distally by a 25cm lumen section wiped with silicone." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. A typical guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	As shown below, the tubular structure of the GuideLiner Version 3 structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion.

	 The flexible cylindrical distal tip portion (unreinforced bumper tip) is more flexible than the flexible cylindrical reinforced portion (coil-reinforced portion of the lumen). The results of the "crush" testing clearly show that the GuideLiner v3's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. See Appendix D at 1-2, comparing "Crush 1" values to "Crush 2" and "Crush 3" values.
3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	As shown below, the proximal portion of the tubular structure of the GuideLiner Version 3 further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

<table>
<tr><td></td><td> 

VSIQXM_E00043764.</td></tr>
<tr><td>8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.</td><td>The five and six French models of the GuideLiner Version 3 meet this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use.

SPECIFICATIONS
<table><tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner Minimum I.D.</th><th>GuideLiner Tip O.D. (X)</th></tr><tr><td>5569
5F</td><td>≥ 5F
(≥ 0.056" / 1.42mm I.D.)</td><td>0.046"
(1.17mm)</td><td>0.053"
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(≥ 0.066" / 1.68mm I.D.)</td><td>0.051"
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(2.16mm)</td></tr></table></td></tr>
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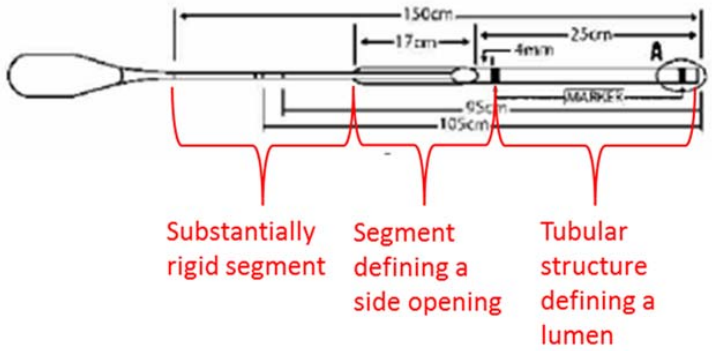
	GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The 5 French model of the GuideLiner v3 meets this limitation literally because the minimum inner diameter of the device, 0.046 inches, is not more than one French smaller than the inner diameter of a compatible 5 French guide catheter, 0.056 inches. The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 3**
25. A system, comprising:	The combination of the Guideliner Version 3 and a guide catheter forms a system. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such	The GuideLiner Version 3 is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner Version 3 is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is

that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	extendable through the hemostatic valve at the proximal end of the guide catheter. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or	The GuideLiner Version 3 includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.

<table>
<tr>
<td>more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;</td>
<td>The GuideLiner Version 3 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.

The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. “The 150cm device has a 125cm stainless steel shaft section covered on the distal 17cm with a semi-circular polymer. The steel shaft is followed distally by a 25cm lumen section wiped with silicone.” GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. A typical guide catheter has a length of 100cm.

The five and six French versions of the GuideLiner meet this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use.

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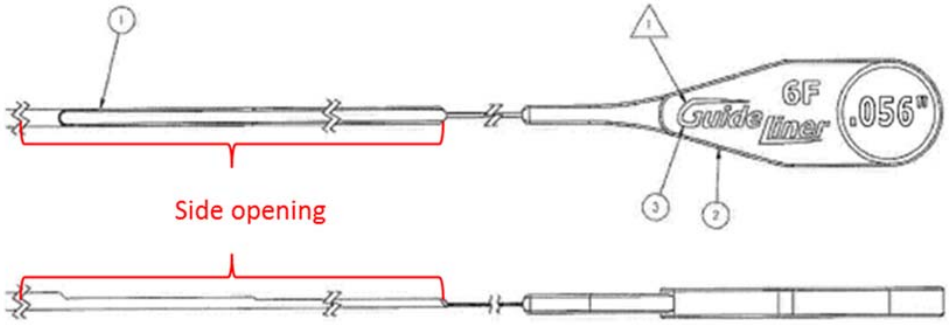
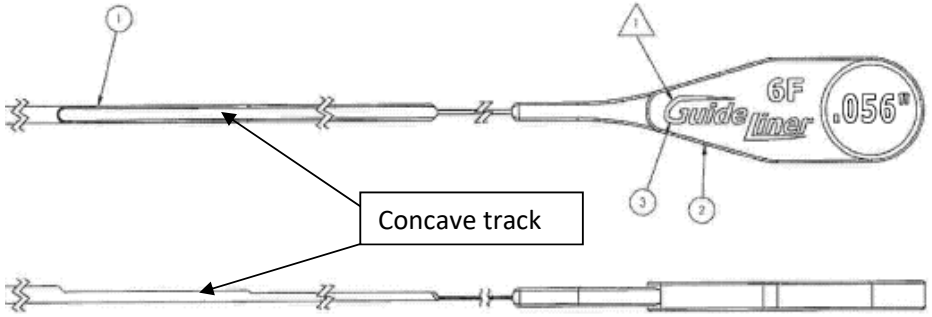
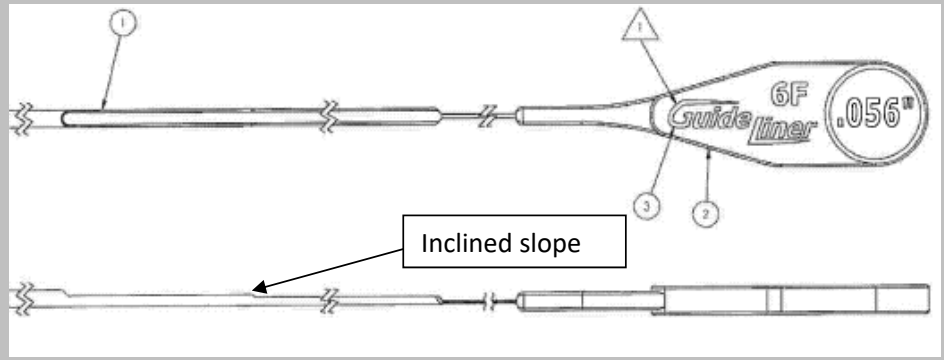
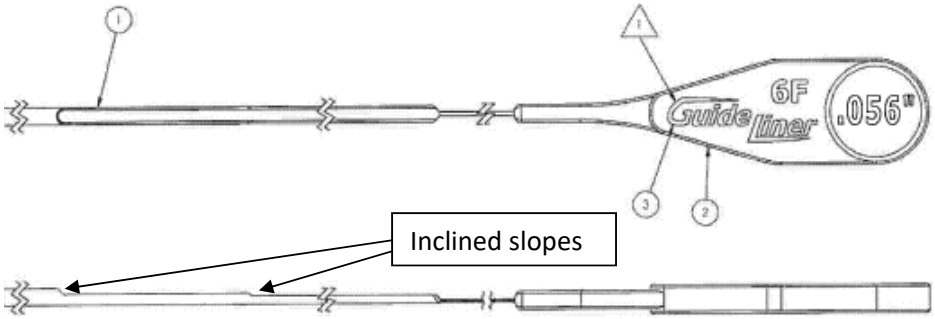
(2.16mm)</td></tr>
</table>
</td>
</tr>
</table>

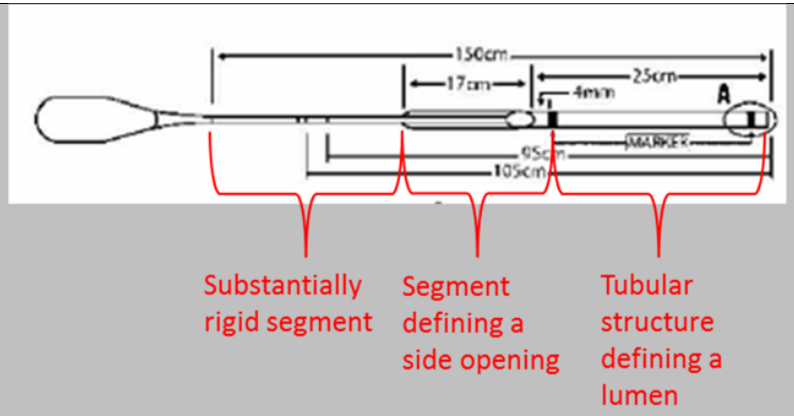
	GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The 5 French model of the GuideLiner v3 meets this limitation literally because the minimum inner diameter of the device, 0.046 inches, is not more than one French smaller than the inner diameter of a compatible 5 French guide catheter, 0.056 inches. The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents. The side opening of the GuideLiner Version 3 extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:

	 VSIQXM_E00043764. The side opening and lumen of the tubular structure of the GuideLiner Version 3 are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the GuideLiner Version 3 extends beyond the distal end of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	The matter forming the segment defining the side opening is more rigid than the tubular structure. Two point bend testing of the GuideLiner v3 shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all

	higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown below, the segment defining the side opening of the GuideLiner Version 3 defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.  VSIQXM_E00043764.
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown below, the segment defining the side opening of the GuideLiner Version 3 includes at least one inclined slope.  VSIQXM_E00043764.

32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.	As shown below, the segment defining the side opening of the GuideLiner Version 3 includes at least two inclined slopes.  VSIQXM_E00043764.
48. A system, comprising:	The combination of the GuideLiner Version 3 with a guide catheter forms a system. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.

end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	The GuideLiner Version 3 is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner Version 3 is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of	The GuideLiner Version 3 includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:

the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	 GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The GuideLiner Version 3 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter. The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. A typical guide catheter has a length of 100cm. The five and six French versions of the GuideLiner meet this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Minimum I.D.	GuideLiner Tip O.D. (X)
5569 5F	≥ 5F (≥ 0.056" / 1.42mm I.D.)	0.046" (1.17mm)	0.053" (1.35mm)
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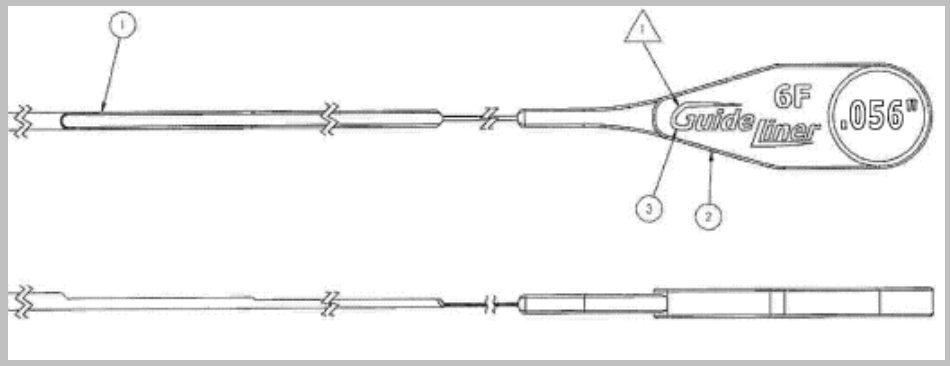
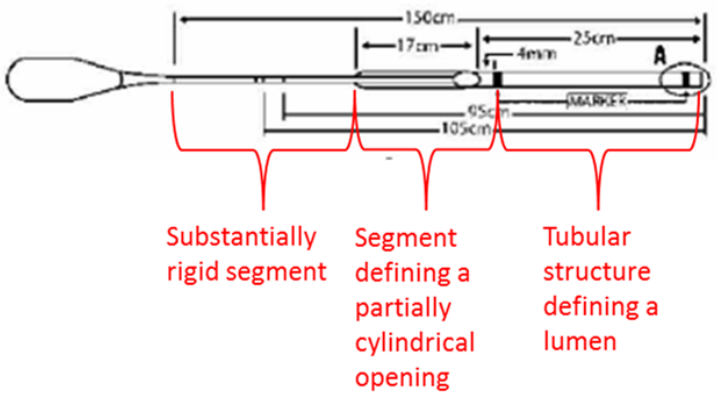
GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The 5 French model of the GuideLiner v3 meets this limitation literally because the minimum inner diameter of the device, 0.046 inches, is not more than one French smaller than the inner diameter of a compatible 5 French guide catheter, 0.056 inches.

The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is

	insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents. The side opening of the GuideLiner Version 3 extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  VSIQXM_E00043764. The side opening and lumen of the tubular structure of the GuideLiner Version 3 are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure

	are positioned within the lumen of the guide catheter and the distal end of the GuideLiner Version 3 extends beyond the distal end of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.	The segment defining the side opening of the GuideLiner Version 3 is more rigid than a distal end portion of the tubular structure. Two point bend testing of the GuideLiner v3 shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 3**
25. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner Version 3 is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The GuideLiner Version 3 includes a substantially rigid segment, namely a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner Version 3 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The GuideLiner Version 3 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:



GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.

The GuideLiner v3's segment defining the partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure. The two point bend testing of the GuideLiner v3 shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

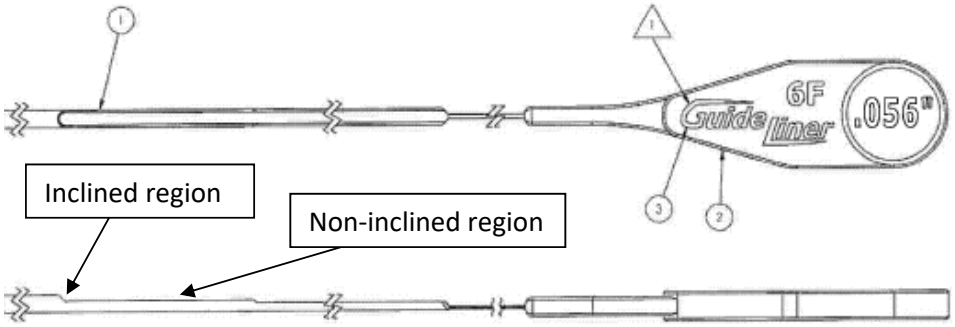
"3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and

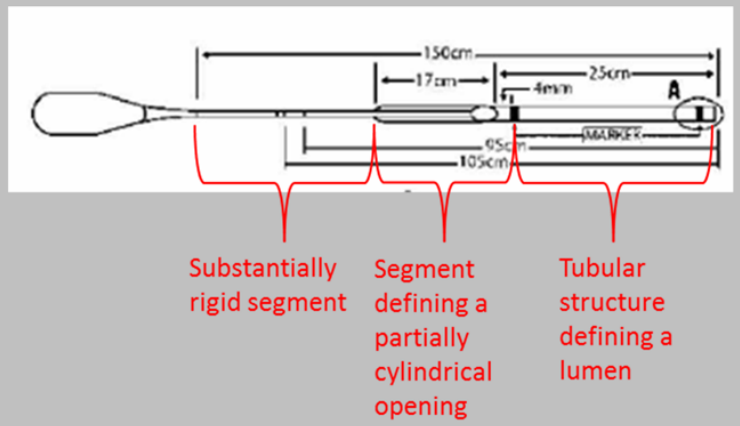
<table>
<tr><td></td><td>GuideLiner catheter into the desired vascular space.” GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.</td></tr>
<tr><td>wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.</td><td>The cross-section of the GuideLiner Version 3 at the proximal end of the tubular structure defines a single lumen.</td></tr>
<tr><td>30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.</td><td>The six French version of the GuideLiner v3 meets this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use.

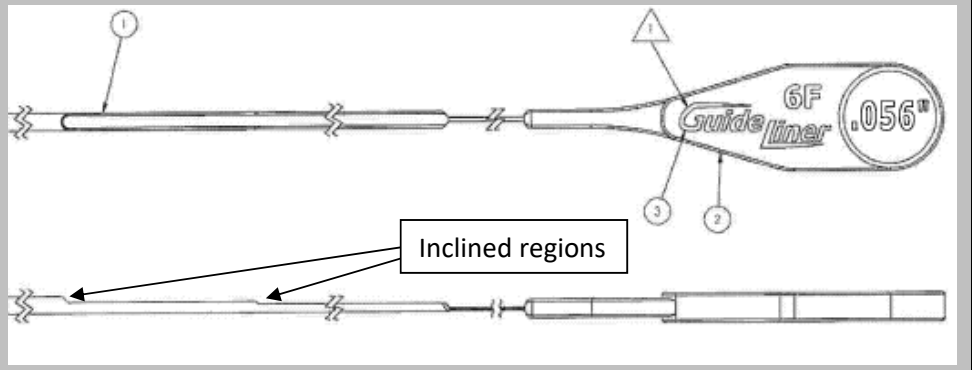
SPECIFICATIONS
<table><tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner Minimum I.D.</th><th>GuideLiner Tip O.D. (X)</th></tr><tr><td>5569
5F</td><td>≥ 5F
(≥ 0.056" / 1.42mm I.D.)</td><td>0.046"
(1.17mm)</td><td>0.053"
(1.35mm)</td></tr><tr><td>5570
5.5F</td><td>≥ 6F
(≥ 0.066" / 1.68mm I.D.)</td><td>0.051"
(1.30mm)</td><td>0.063"
(1.60mm)</td></tr><tr><td>5571
6F</td><td>≥ 6F
(≥ 0.070" / 1.78mm I.D.)</td><td>0.056"
(1.42mm)</td><td>0.067"
(1.70mm)</td></tr><tr><td>5572
7F</td><td>≥ 7F
(≥ 0.078"/ 1.98mm I.D.)</td><td>0.062"
(1.57mm)</td><td>0.075"
(1.90mm)</td></tr><tr><td>5573
8F</td><td>≥ 8F
(≥ 0.088" / 2.24mm I.D.)</td><td>0.071"
(1.80mm)</td><td>0.085"
(2.16mm)</td></tr></table>
GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.

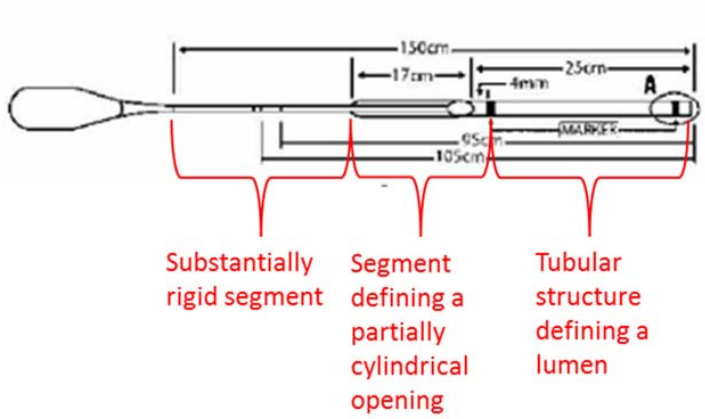
The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of</td></tr>
</table>

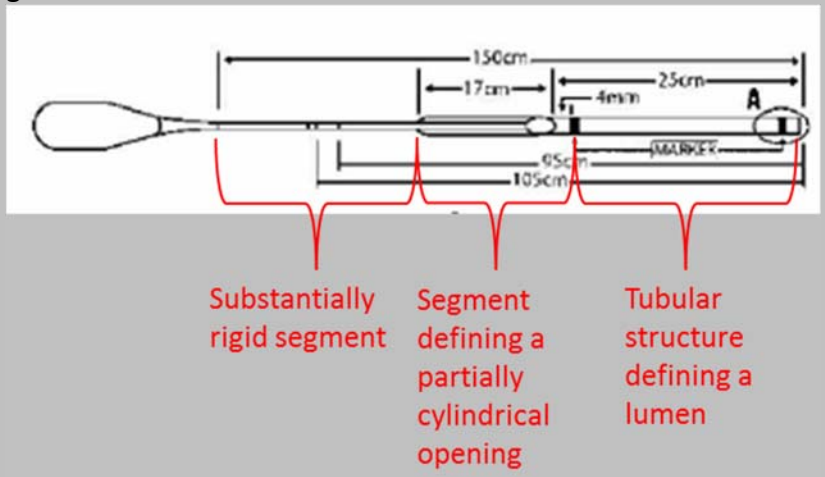
	0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	The lumen of the tubular structure of the GuideLiner Version 3 is configured to receive a stent and a balloon catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. "If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." *Id.*

36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.	As shown below, the segment defining the angled proximal end of the partially cylindrical opening of the GuideLiner Version 3 includes at least one inclined region that tapers into a non-inclined region.  VSIQXM_E00043764.
52. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner Version 3 is a guide extension catheter for use with a guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
a substantially rigid segment;	The GuideLiner Version 3 includes a substantially rigid segment, namely a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.

a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner Version 3 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The GuideLiner Version 3 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The GuideLiner v3's segment defining the partially cylindrical opening is formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure, as evidenced by the test results in Appendix D at 1. The two point bend testing of the GuideLiner v3 shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

	In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	The cross-section of the GuideLiner Version 3 at the proximal end of the tubular structure defines a single lumen.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The GuideLiner Version 3's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:  VSIQXM_E00043764.

53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	The GuideLiner Version 3 is a guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
a substantially rigid segment;	The GuideLiner Version 3 includes a substantially rigid segment, namely a stainless steel shaft.  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-	The GuideLiner Version 3 includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment and has a uniform cross-sectional inner diameter that, for the 6 French version, is not more than one

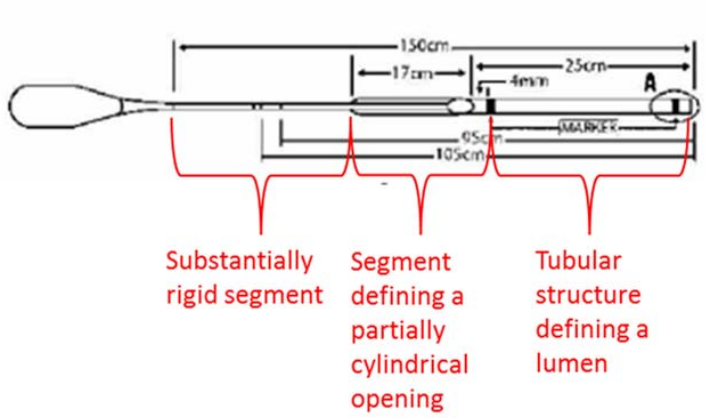
sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and	French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The five and six French versions of the GuideLiner meet this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use.

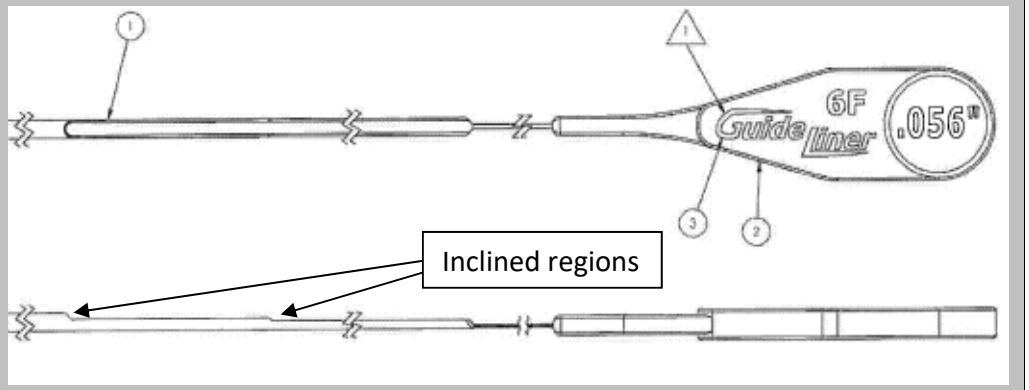
SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Minimum I.D.	GuideLiner Tip O.D. (X)
5569 5F	≥ 5F (≥ 0.056" / 1.42mm I.D.)	0.046" (1.17mm)	0.053" (1.35mm)
5570 5.5F	≥ 6F (≥ 0.066" / 1.68mm I.D.)	0.051" (1.30mm)	0.063" (1.60mm)
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" (1.42mm)	0.067" (1.70mm)
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" (1.57mm)	0.075" (1.90mm)
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" (1.80mm)	0.085" (2.16mm)

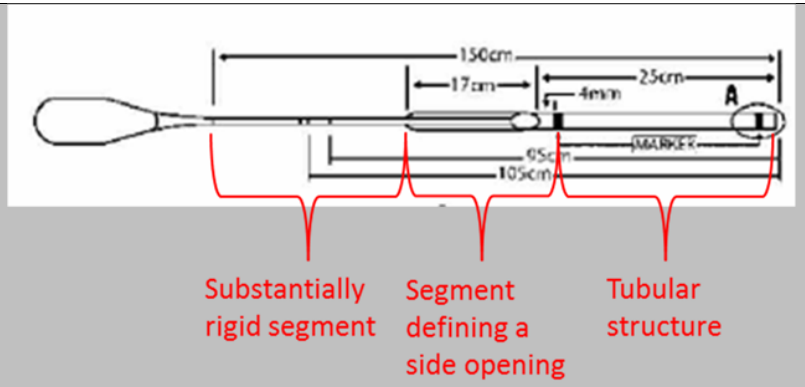
GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The 5 French model of the GuideLiner v3 meets this limitation literally because the minimum inner diameter of the device, 0.046 inches, is not more than one French smaller than the inner diameter of a compatible 5 French guide catheter, 0.056 inches.

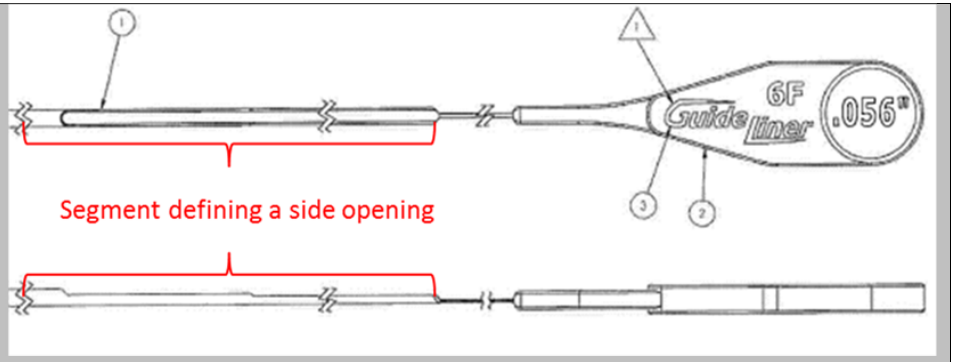
The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of

	the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	The GuideLiner Version 3 includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.

	In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The GuideLiner Version 3's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:  VSIQXM_E00043764.

U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 3**
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the GuideLiner Version 3 with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00044276.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner Version 3 includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a	The intended method of using a GuideLiner Version 3 includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter.

longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	 GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277. The segment defining a side opening of the GuideLiner Version 3, shown below, extends for a distance along a longitudinal axis of the guide extension catheter and is accessible from a longitudinal side defined transverse to the longitudinal axis.



VSIQXM_E00043764.

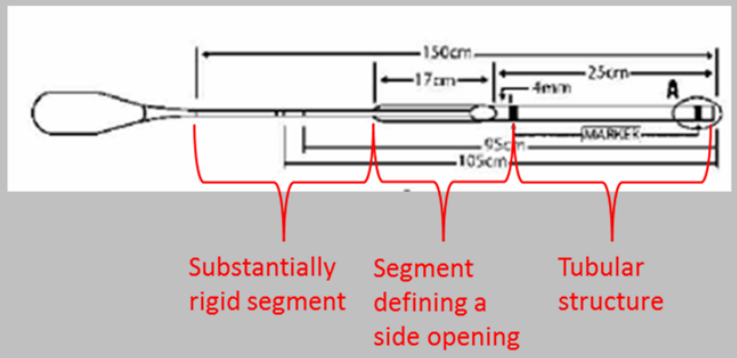
The five and six French versions of the GuideLiner meet this limitation when used with a compatible guide catheter as set forth in the Instructions for Use.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner Minimum I.D.	GuideLiner Tip O.D. (X)
5569 5F	≥ 5F (≥ 0.056" / 1.42mm I.D.)	0.046" (1.17mm)	0.053" (1.35mm)
5570 5.5F	≥ 6F (≥ 0.066" / 1.68mm I.D.)	0.051" (1.30mm)	0.063" (1.60mm)
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" (1.42mm)	0.067" (1.70mm)
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" (1.57mm)	0.075" (1.90mm)
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" (1.80mm)	0.085" (2.16mm)

	GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The 5 French model of the GuideLiner v3 meets this limitation literally because the minimum inner diameter of the device, 0.046 inches, is not more than one French smaller than the inner diameter of a compatible 5 French guide catheter, 0.056 inches. The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when used with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that using the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and	The intended method of using a GuideLiner Version 3 includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through

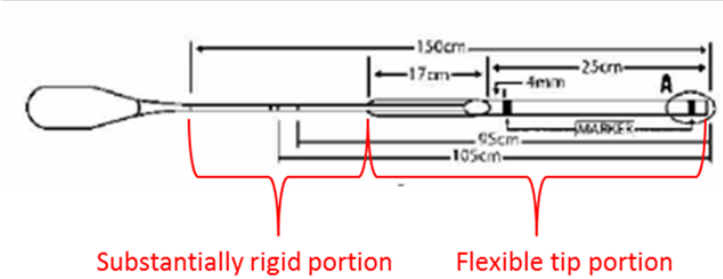
while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277. The GuideLiner Version 3 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	While the GuideLiner Version 3 is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the GuideLiner Version 3 and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 52 is performed by a cardiologist using the GuideLiner Version 3 with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00044276.

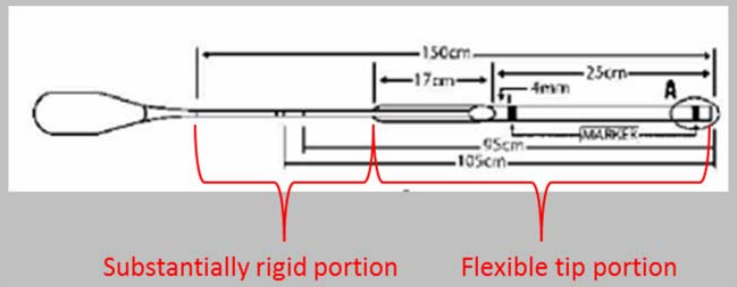
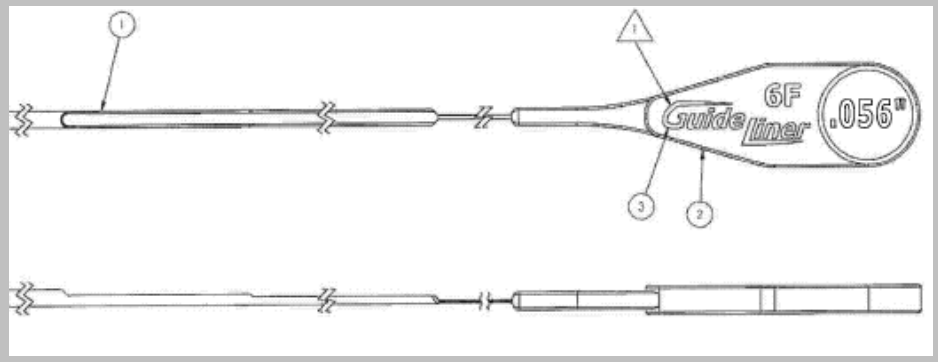
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner Version 3 includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;	The intended method of using a GuideLiner Version 3 includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter.  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional

	procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277. The segment defining the side opening of the GuideLiner Version 3 comprises a portion of the device that is more rigid than the distal end portion of the tubular structure. Two point bend testing of the GuideLiner v3 shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a GuideLiner Version 3 includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.

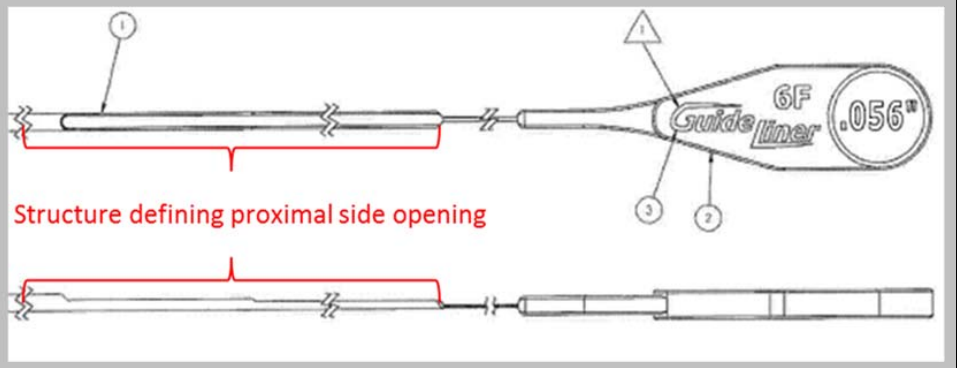
	The GuideLiner Version 3 includes a substantially rigid segment in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	In the intended method of using a GuideLiner Version 3, advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.

U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 3**
1. [NOT ASSERTED] A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	The GuideLiner Version 3 is a device for use with a standard guide catheter. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lument of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter	The GuideLiner Version 3 has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:

through which interventional cardiology devices are insertable; and	 GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner Version 3 has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner catheter is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. "If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space." *Id.*
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is	The GuideLiner Version 3 includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.

smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.  VSIQXM_E00043764. The stainless steel shaft is more rigid along a longitudinal direction than the flexible tip portion. In the two point bend testing of the Boosting Catheter, every catheter sample tested had a higher maximum force value for the proximal shaft

	portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values—Expert Report, Appendix D at 1. The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 150cm device has a 125cm stainless steel shaft section covered on the distal 17cm with a semi-circular polymer. The steel shaft is followed distally by a 25cm lumen section wiped with silicone." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. A standard guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the	The tubular structure of the GuideLiner Version 3 has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired

interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277. The GuideLiner Version 3 assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	As shown below, the proximal portion of the tubular structure of the GuideLiner Version 3 further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.  VSIQXM_E00043764.
8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one	The five and six French versions of the GuideLiner meet this limitation when used with a compatible guide catheter as set forth in the Instructions for Use.

French smaller than the cross-sectional inner diameter of the guide catheter.	**SPECIFICATIONS** | Model	Compatible Guide Catheter	GuideLiner Minimum I.D.	GuideLiner Tip O.D. (X)
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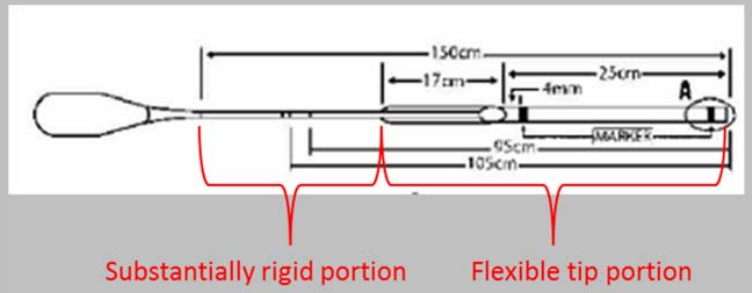
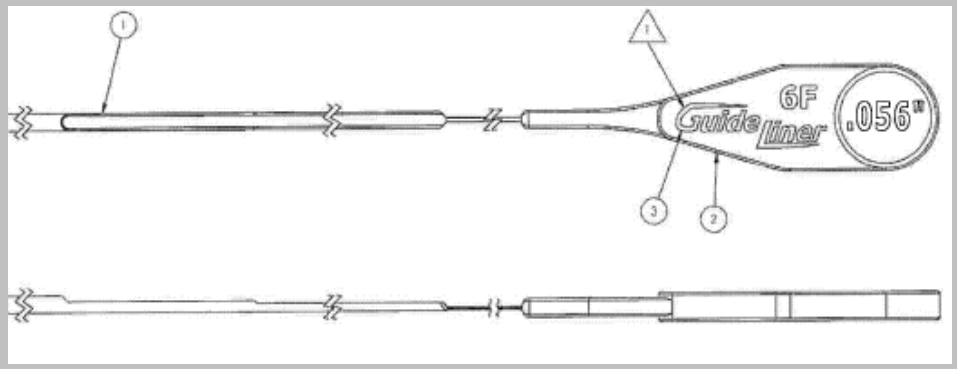
5569 5F	≥ 5F (≥ 0.056" / 1.42mm I.D.)	0.046" (1.17mm)	0.053" (1.35mm)
5570 5.5F	≥ 6F (≥ 0.066" / 1.68mm I.D.)	0.051" (1.30mm)	0.063" (1.60mm)
5571 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" (1.42mm)	0.067" (1.70mm)
5572 7F	≥ 7F (≥ 0.078"/ 1.98mm I.D.)	0.062" (1.57mm)	0.075" (1.90mm)
5573 8F	≥ 8F (≥ 0.088" / 2.24mm I.D.)	0.071" (1.80mm)	0.085" (2.16mm)	 GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. The 5 French model of the GuideLiner v3 meets this limitation literally because the minimum inner diameter of the device, 0.046 inches, is not more than one French smaller than the inner diameter of a compatible 5 French guide catheter, 0.056 inches. The 6 French model of the GuideLiner v3 meets this limitation by doctrine of equivalents when used with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the GuideLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. Therefore, the difference in diameter between the 6 French GuideLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is

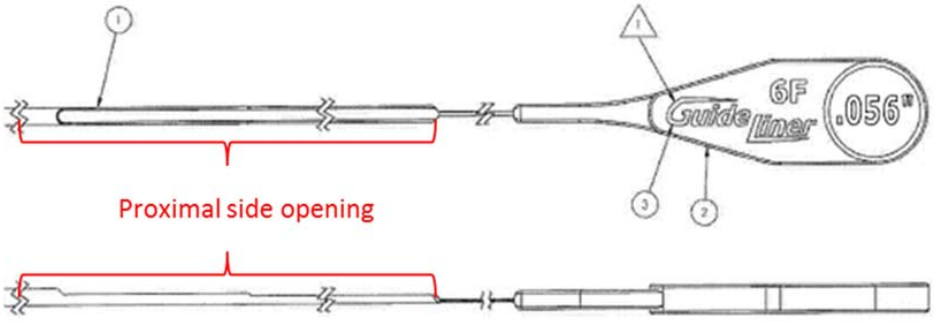
	insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that using the six French GuideLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.

U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner Version 3**
1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	A cardiologist using the GuideLiner Version 3 with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1. "GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	To use the GuideLiner Version 3, a standard guide catheter is inserted into a first artery over a guidewire. "1. Secure the previously inserted guidewire …" GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the GuideLiner Version 3, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery.

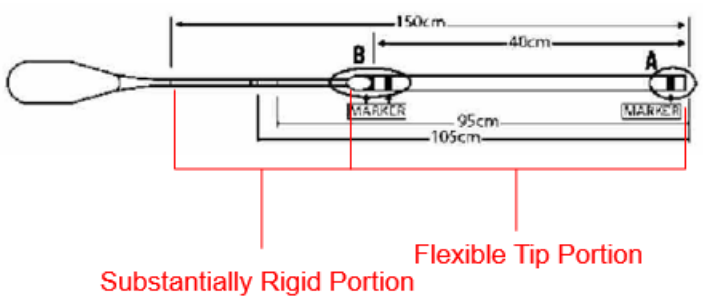
	"GuideLiner catheters are intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	The intended method of using the GuideLiner Version 3 includes inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. A standard guide catheter has a length of 100cm. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	The intended method of using the GuideLiner Version 3 includes further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter The GuideLiner Version 3 has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. The drawings below depict the stainless steel shaft, which is substantially rigid, proximal of, and operably connected to, and more rigid than the flexible tip portion, and defines a rail structure without a lumen that has a maximal cross-

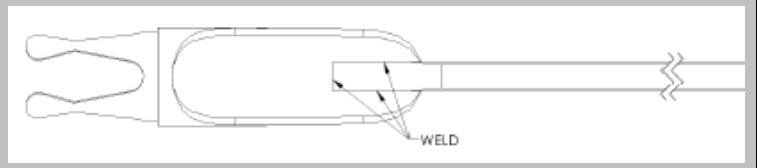
	sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion. Based on my physical examination of the GuideLiner v3, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner v3 through the guide catheter.  GuideLiner Version 3 Instructions for Use, VSIQXM_E00044276.  VSIQXM_E00043764. The stainless steel shaft is more rigid along a longitudinal direction than the flexible tip portion. In the two point bend testing of the Boosting Catheter, every catheter sample tested had a higher maximum force value for the proximal shaft

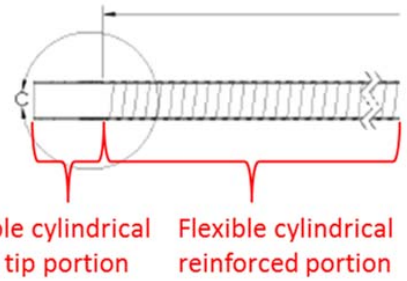
	portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values—Expert Report, Appendix D at 1. The substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 150 cm, longer than the standard 100cm length of the continuous lumen of the guide catheter.
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	In the intended method of using the GuideLiner Version 3, a distal portion of the flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "2. Open the hemostasis valve and advance the GuideLiner catheter through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner catheter to prevent back-bleeding." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	In the intended method of using a GuideLiner Version 3, an interventional cardiology device is inserted into and through the continuous lumen of the standard guide catheter alongside the substantially rigid portion of the GuideLiner. The interventional cardiology device is advanced through and beyond the lumen of the flexible tip portion into contact with or past a lesion in the second artery. "5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.

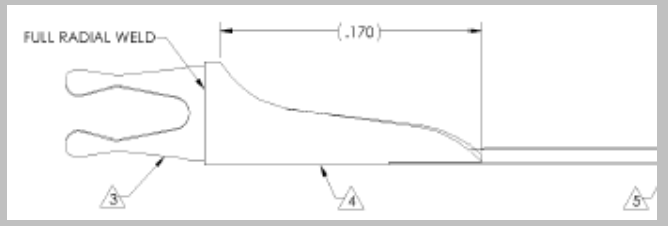
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	In the intended method of using the GuideLiner Version 3, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure is shown below:  VSIQXM_E00043764. In use, the proximal portion of the tubular structure remains within the lumen of the guide catheter. "5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and GuideLiner catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner Version 3 Instructions for Use, VSIQXM_E00044277.

U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner XL**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	The combination of a Guideliner XL and a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	A typical guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.
a device adapted for use with the guide catheter, including:	The Guideliner XL is a device adapted for use with a guide catheter. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of

	interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The GuideLiner XL has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:  GuideLiner XL Instructions for Use, VSIQXM_E00044308. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. The tubular structure of the GuideLiner XL has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308. "If performing an interventional

	procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." *Id.*
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;	The GuideLiner XL includes a substantially rigid portion in the form of a stainless steel shaft. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  VSIQXM_E00044073. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is more rigid along a longitudinal axis than the flexible tip portion. The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the

	hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. A typical guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner XL to prevent back-bleeding." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	As shown below, the tubular structure of the GuideLiner XL structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion.  VSIQXM_E00044076.

	The flexible cylindrical distal tip portion (unreinforced bumper tip) is more flexible than the flexible cylindrical reinforced portion (coil-reinforced portion of the lumen).
3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	As shown below, the proximal portion of the tubular structure of the GuideLiner XL further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.  VSIQXM_E00044073.
8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the GuideLiner XL's coaxial lumen is approximately one French smaller than the cross-sectional inner diameter of the guide catheter with which it is intended for use. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308.

SPECIFICATIONS

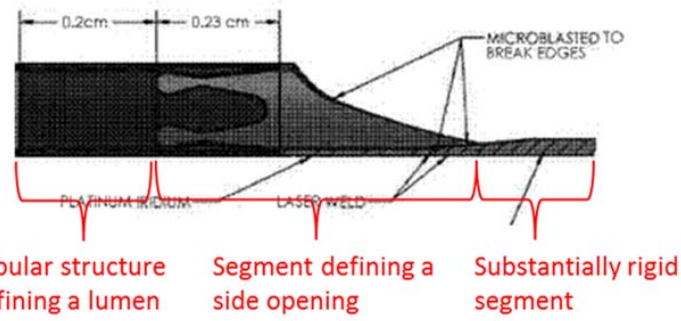
Model	Compatible Guide Catheter	GuideLiner XL Minimum I.D.
5576 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm

Id. GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the

	guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner XL**
25. A system, comprising:	The combination of the Guideliner XL and a guide catheter forms a system. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the	The GuideLiner XL is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner XL is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter.

hemostatic valve at the proximal end of the guide catheter,	When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner XL to prevent back-bleeding." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The GuideLiner XL includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  VSIQXM_E00044073. The GuideLiner XL includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the

GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter.

The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. A typical guide catheter has a length of 100cm.

The lumen of the tubular structure of the GuideLiner XL has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.

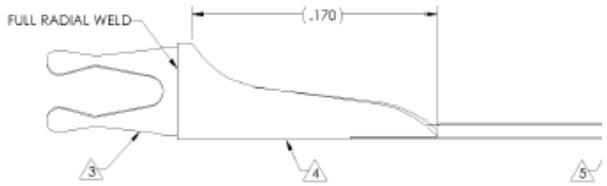
"The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308.

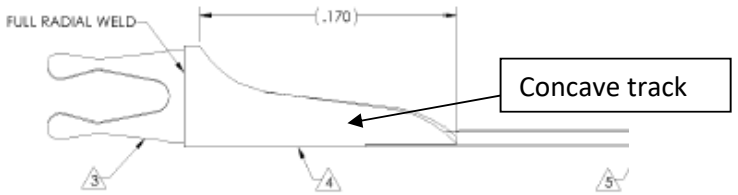
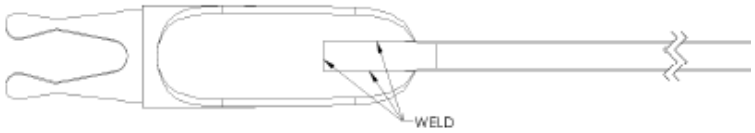
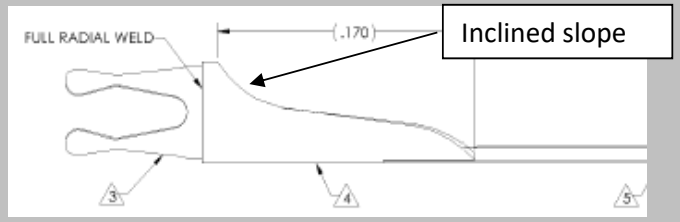
SPECIFICATIONS

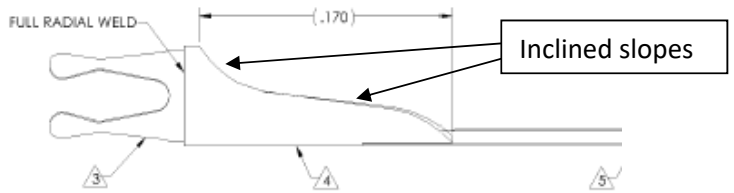
Model	Compatible Guide Catheter	GuideLiner XL Minimum I.D.
5576 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm

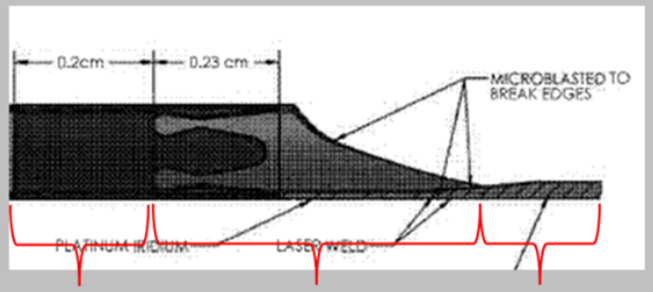
Id. GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a

	manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. The side opening of the GuideLiner XL extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:

	 VSIQXM_E00044073. The side opening and lumen of the tubular structure of the GuideLiner XL are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the GuideLiner XL extends beyond the distal end of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	Based on my physical examination of the device, it is my opinion that the matter forming the segment defining the side opening is more rigid than the tubular structure.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown below, the segment defining the side opening of the GuideLiner XL defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.

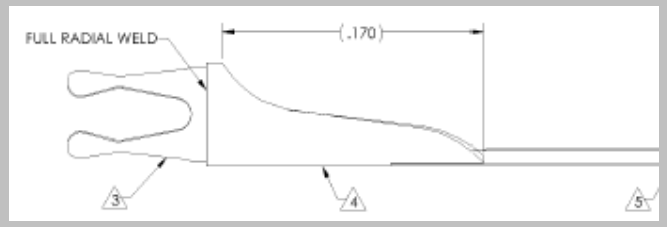
	 VSIQXM_E00044073.  VSIQXM_E00044073.
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown below, the segment defining the side opening of the GuideLiner XL includes at least one inclined slope.  VSIQXM_E00044073.
32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.	As shown below, the segment defining the side opening of the GuideLiner XL includes at least two inclined slopes.

	 VSIQXM_E00044073.
48. A system, comprising:	The combination of the GuideLiner XL with a guide catheter forms a system. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the	The GuideLiner XL is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the GuideLiner XL is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter.

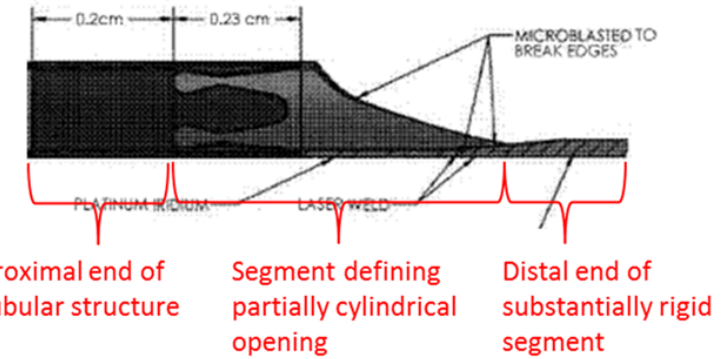
hemostatic valve at the proximal end of the guide catheter,	"The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner XL to prevent back-bleeding." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide	The GuideLiner XL includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  VSIQXM_E00044073.

catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The GuideLiner XL includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter. The lumen of the tubular structure has a length that is shorter than the length of the lumen defined by the guide catheter. A typical guide catheter has a length of 100cm. The lumen of the tubular structure of the GuideLiner XL has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308. **SPECIFICATIONS** **Model** | **Compatible Guide Catheter** | **GuideLiner XL Minimum I.D.** 5576 6F | ≥ 6F (≥ 0.070" / 1.78mm I.D.) | 0.056" / 1.42mm *Id.* GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a

	manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. The side opening of the GuideLiner XL extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:

	 VSIQXM_E00044073. The side opening and lumen of the tubular structure of the GuideLiner XL are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the GuideLiner XL extends beyond the distal end of the guide catheter. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.	Based on my physical examination of the device, it is my opinion that the segment defining the side opening of the GuideLiner XL is more rigid than a distal end portion of the tubular structure.

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner XL**
25. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner XL is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The GuideLiner XL includes a substantially rigid segment, namely a stainless steel shaft. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner XL includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The GuideLiner XL includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

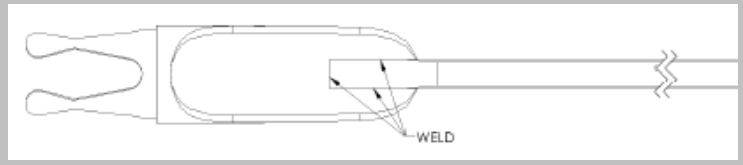


VSIQXM_E00044073.

Based on my physical examination of the device, it is my opinion that the segment defining the GuideLiner XL's partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure.

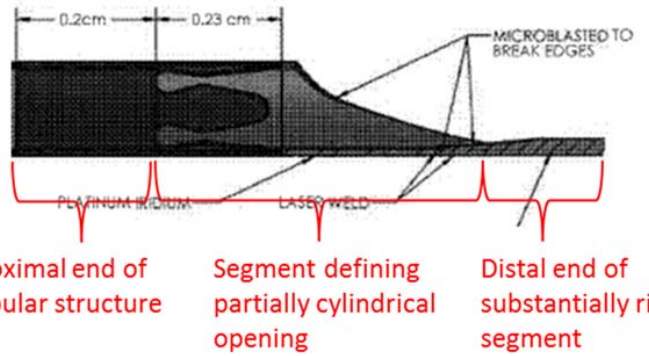
In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

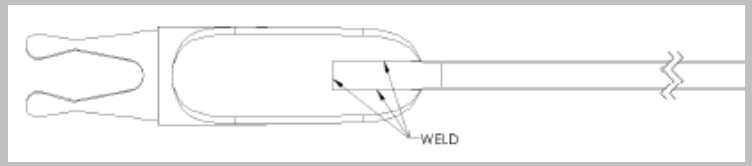
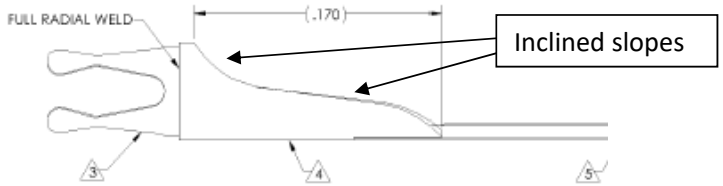
"3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309.

wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.	The cross-section of the GuideLiner XL at the proximal end of the tubular structure defines a single lumen, as shown below:  VSIQXM_E00044073.
30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.	The lumen of the tubular structure of the GuideLiner XL has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308. **SPECIFICATIONS** Model / Compatible Guide Catheter / GuideLiner XL Minimum I.D. 5576 6F / ≥ 6F (≥ 0.070" / 1.78mm I.D.) / 0.056" / 1.42mm *Id.* GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a

	manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	The lumen of the tubular structure of the GuideLiner XL is configured to receive a stent and a balloon catheter. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or

	peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308. "If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." *Id.*
52. A guide extension catheter for use with a guide catheter, comprising:	The GuideLiner XL is a guide extension catheter for use with a guide catheter. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
a substantially rigid segment;	The GuideLiner XL includes a substantially rigid segment, namely a stainless steel shaft. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The GuideLiner XL includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the	The GuideLiner XL includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the

segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:  VSIQXM_E00044073. Based on my physical examination of the device, it is my opinion that the segment defining the partially cylindrical opening is formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into

	the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	The cross-section of the GuideLiner XL at the proximal end of the tubular structure defines a single lumen, as shown below:  VSIQXM_E00044073.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The GuideLiner XL's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:  VSIQXM_E00044073.
53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	The GuideLiner XL is a guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.

<table>
<tr><td>a substantially rigid segment;</td><td>The GuideLiner XL includes a substantially rigid segment, namely a stainless steel shaft.

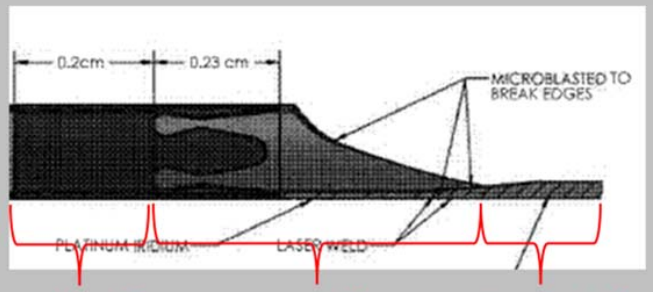
“The 150cm device has a 110cm stainless steel shaft ....” GuideLiner XL Instructions for Use, VSIQXM_E00044308.

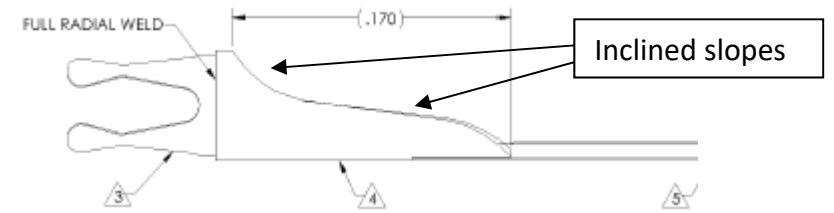
Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter.</td></tr>
<tr><td>a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and</td><td>The GuideLiner XL includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment and has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.

“The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter.” GuideLiner XL Instructions for Use, VSIQXM_E00044308.

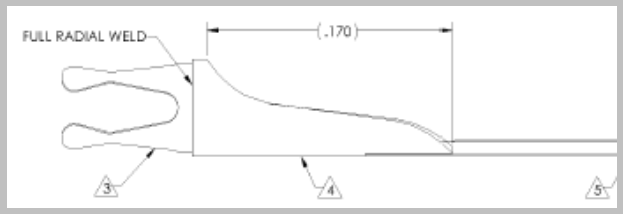
SPECIFICATIONS
<table><tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner XL Minimum I.D.</th></tr><tr><td>5576
6F</td><td>≥ 6F
(≥ 0.070” / 1.78mm I.D.)</td><td>0.056” / 1.42mm</td></tr></table>
Id. GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design</td></tr>
</table>

	specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter. The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having	The GuideLiner XL includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	 VSIQXM_E00044073. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The GuideLiner XL's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:

	 VSIQXM_E00044073.

U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner XL**
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the GuideLiner XL with a guide catheter and balloon catheter or stent as described in the Instructions for Use, VSIQXM_E00044308.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner XL includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than	The intended method of using a GuideLiner XL includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter. "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3.

one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309. The segment defining a side opening of the GuideLiner XL, shown below, extends for a distance along a longitudinal axis of the guide extension catheter and is accessible from a longitudinal side defined transverse to the longitudinal axis.  VSIQXM_E00044073. The tubular structure of the GuideLiner XL has a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308.

SPECIFICATIONS

Model	Compatible Guide Catheter	GuideLiner XL Minimum I.D.
5576 6F	≥ 6F (≥ 0.070" / 1.78mm I.D.)	0.056" / 1.42mm

Id. GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. *See* VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space

	inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a GuideLiner XL includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL

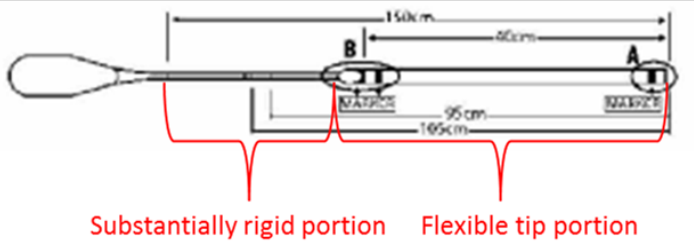
	catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner XL Instructions for Use, VSIQXM_E00044309. The GuideLiner XL includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	While the GuideLiner XL is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the GuideLiner XL and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 52 is performed by a cardiologist using the GuideLiner XL with a guide catheter and balloon or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00044308.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a GuideLiner XL includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the	The intended method of using a GuideLiner XL includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including

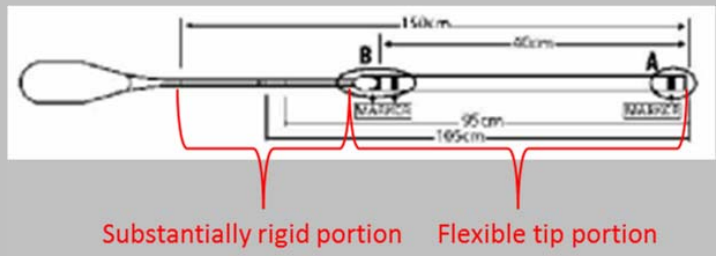
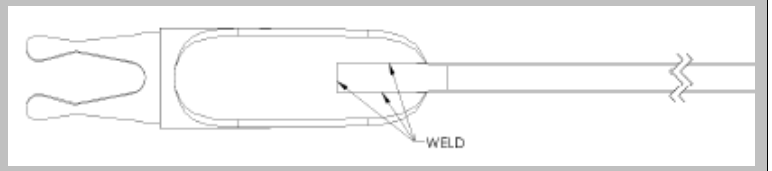
distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;	advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter. "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." GuideLiner XL Instructions for Use, VSIQXM_E00044309. Based on my physical examination of the device, it is my opinion that the segment defining the side opening of the GuideLiner XL comprises a portion of the device that is more rigid than the distal end portion of the tubular structure.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the	The intended method of using a GuideLiner XL includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension

guide extension catheter, through the side opening, and through the tubular structure.	catheter, through the side opening, and through the tubular structure. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner XL Instructions for Use, VSIQXM_E00044309. The GuideLiner XL includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	In the intended method of using a GuideLiner XL, advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter. "3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance

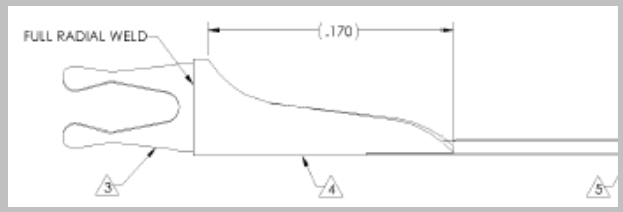
	the device through the guide catheter and GuideLiner XL catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner XL Instructions for Use, VSIQXM_E00044309.

U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner XL**
1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	The GuideLiner XL is is a device for use with a standard guide catheter. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lument of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner	The GuideLiner XL has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown below:

diameter through which interventional cardiology devices are insertable; and	 GuideLiner XL Instructions for Use, VSIQXM_E00044308. The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. The tubular structure of the GuideLiner XL has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308. "If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space." *Id.*

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	The GuideLiner XL includes a substantially rigid portion in the form of a stainless steel shaft. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter and more rigid along a longitudinal direction than the flexible tip portion. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. As shown below, the stainless steel shaft is proximal of and operably connected to the flexible tip portion and defines a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner XL Instructions for Use, VSIQXM_E00044308.  VSIQXM_E00044073.

	The stainless steel shaft has a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. A standard guide catheter has a length of 100cm. When the device is used as intended, the proximal portion of the stainless steel shaft extends proximally through the hemostatic valve: "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner XL to prevent back-bleeding." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional	The tubular structure of the GuideLiner XL has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter.

cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	"3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 4. Using fluoroscopy, confirm the desired position of the GuideLiner catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner XL Instructions for Use, VSIQXM_E00044309. The GuideLiner XL assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	As shown below, the proximal portion of the tubular structure of the GuideLiner XL further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.  VSIQXM_E00044073.

<table>
<tr>
<td>8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.</td>
<td>The cross-sectional inner diameter of the GuideLiner XL's coaxial lumen is approximately one French smaller than the cross-sectional inner diameter of the guide catheter with which it is intended for use. "The GuideLiner XL is delivered through a 6F guide catheter resulting in an inner diameter that is approximately 1 French smaller than the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044308.

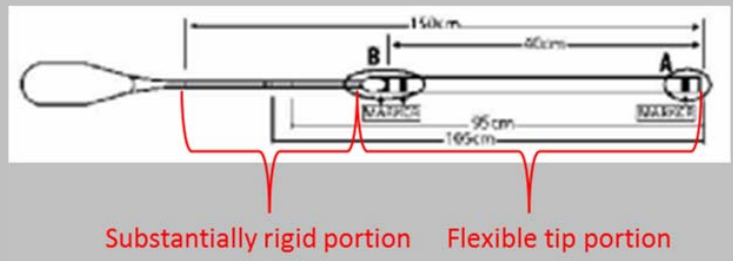
SPECIFICATIONS
<table><tr><th>Model</th><th>Compatible Guide Catheter</th><th>GuideLiner XL Minimum I.D.</th></tr><tr><td>5576
6F</td><td>≥ 6F
(≥ 0.070" / 1.78mm I.D.)</td><td>0.056" / 1.42mm</td></tr></table>
Id. GuideLiner XL devices having an inner diameter of 0.057 inches meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches. Although the minimum diameter stated in the Instructions for Use is .056 inches, the design specifications call for an inner diameter of .057 inches with a manufacturing tolerance of .001 inches in either direction. See VSIQXM_E00044001. At least some GuideLiner XL devices have an inner diameter of 0.057 inches, which is less than one French smaller than the inner diameter of a 0.070-inch catheter.

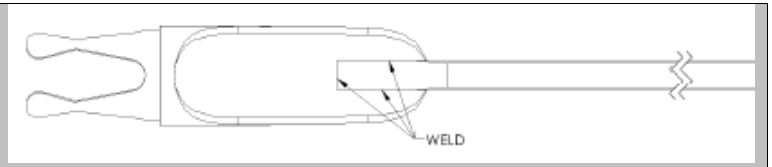
The GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter. In either case, the difference in diameter between the devices is 0.014 inches—</td>
</tr>
</table>

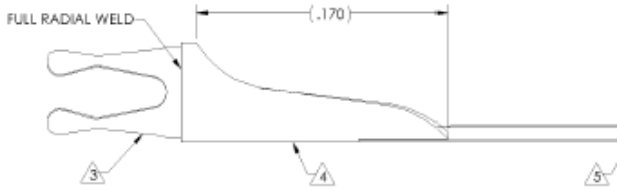
	just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the GuideLiner without catching on the proximal end opening of the GuideLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the GuideLiner XL meets this limitation by doctrine of equivalents when a 0.057-inch catheter is combined with a 0.071-inch guide catheter or when a 0.056-inch catheter is combined with a 0.070-inch guide catheter.

U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**GuideLiner XL**
1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be paseed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	A cardiologist using the GuideLiner XL with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	To use the GuideLiner XL, a standard guide catheter is inserted into a first artery over a guidewire. "1. Secure the previously inserted guidewire …" GuideLiner XL Instructions for Use, VSIQXM_E00044308.

positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the GuideLiner XL, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery. "GuideLiner XL catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." GuideLiner XL Instructions for Use, VSIQXM_E00044308.
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	The intended method of using the GuideLiner XL includes inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. "The 150cm device has a 110cm stainless steel shaft ...." GuideLiner XL Instructions for Use, VSIQXM_E00044308. A standard guide catheter has a length of 100cm. "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device	The intended method of using the GuideLiner XL includes further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of

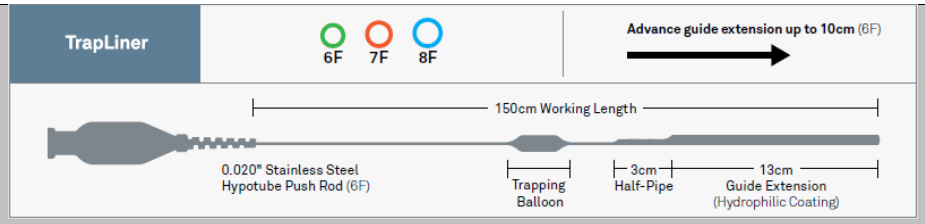
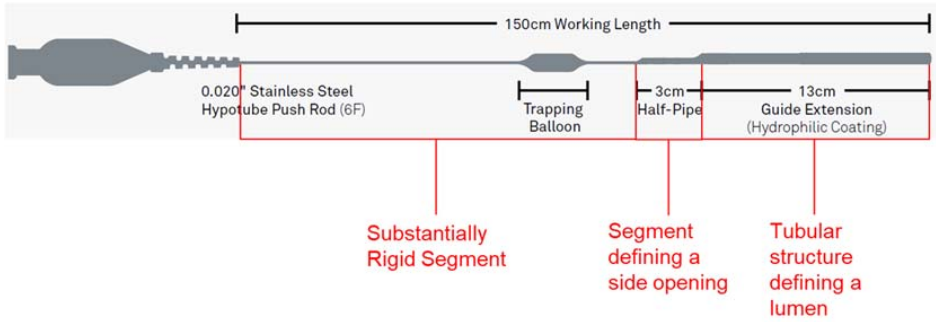
along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter. The GuideLiner XL has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. This is the stainless steel shaft of the device. Based on my physical examination of the GuideLiner XL, it is my opinion that the stainless steel shaft is rigid enough to advance the GuideLiner XL through the guide catheter and more rigid along a longitudinal direction than the flexible tip portion. The drawings below depict the stainless steel shaft, which is substantially rigid, proximal of, and operably connected to, and more rigid than the flexible tip portion, and defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  GuideLiner XL Instructions for Use, VSIQXM_E00044308.

	 VSIQXM_E00044073. The substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 150 cm, longer than the standard 100cm length of the continuous lumen of the guide catheter.
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	In the intended method of using the GuideLiner XL, a distal portion of the flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "2. Open the hemostasis valve and advance the GuideLiner XL through the hemostasis valve and into the guide catheter. 3. Under fluoroscopy, advance the GuideLiner XL beyond the distal tip of the guide catheter and into the desired location within the vessel. … 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the GuideLiner XL to prevent back-bleeding." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of	In the intended method of using a GuideLiner XL, an interventional cardiology device is inserted into and through the continuous lumen of the standard guide catheter alongside the substantially rigid portion of the GuideLiner. The

the flexible tip portion into contact with or past a lesion in the second artery.	interventional cardiology device is advanced through and beyond the lumen of the flexible tip portion into contact with or past a lesion in the second artery. "5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner XL Instructions for Use, VSIQXM_E00044309.
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	In the intended method of using the GuideLiner XL, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure is shown below:  VSIQXM_E00044073.

	In use, the proximal portion of the tubular structure remains within the lumen of the guide catheter. "5. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and GuideLiner XL catheter into the desired vascular space. … 7. Perform the catheterization procedure." GuideLiner XL Instructions for Use, VSIQXM_E00044309.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**TrapLiner**
25. A system, comprising:	The combination of a TrapLiner and a guide catheter forms a system. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and	The TrapLiner is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the TrapLiner is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter.

beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	 TrapLiner Product Brochure, VSIQXM_E00056367. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel hypotube extends proximally through the hemostatic valve.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the	The TrapLiner includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  TrapLiner Product Brochure, VSIQXM_E00056367. The TrapLiner includes a substantially rigid segment in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.

segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;

The lumen of the tubular structure has a length (13cm) that is shorter than the length of the lumen defined by the guide catheter. A typical guide catheter has a length of 100cm.

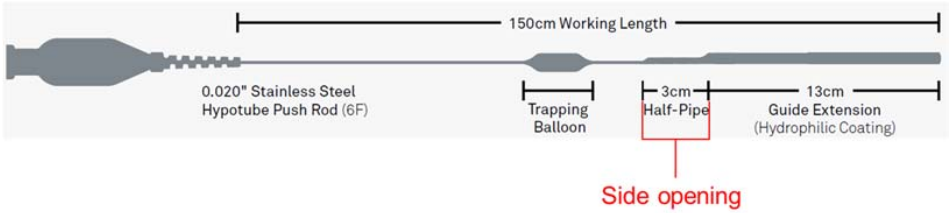
The 6 French model of the TrapLiner meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the Instructions for Use.

SPECIFICATIONS

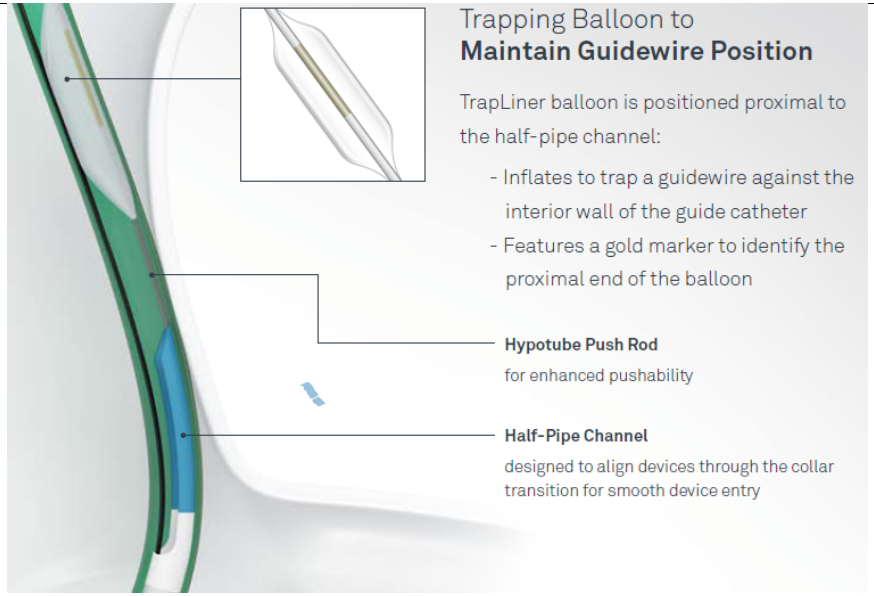
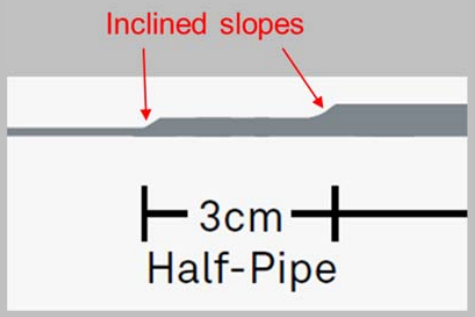
Model / Size	5566 / 6F	5567 / 7F	5568 / 8F
Minimum guide catheter size	6F (0.070" / 1.78mm I.D.)	7F (0.078" / 1.98mm I.D.)	8F (0.088" / 2.24mm I.D.)
Pushrod outer diameter	0.020" / 0.51mm	0.025" / 0.64mm	
Guide extension inner diameter	0.056" / 1.42mm	0.062" / 1.57mm	0.071" / 1.80mm

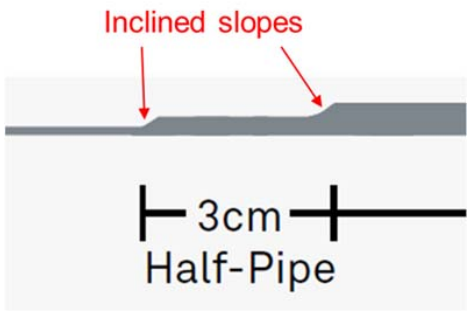
TrapLiner Instructions for Use, VSIQXM_E00056337.

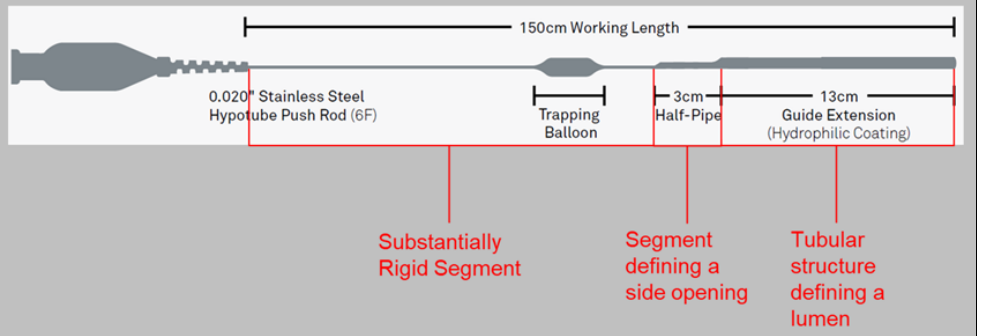
Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the TrapLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. VSIQXM_E00056369. Therefore, the difference in diameter between the 6 French TrapLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138,

	or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the TrapLiner without catching on the proximal end opening of the TrapLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French TrapLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents. The side opening of the TrapLiner extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  TrapLiner Product Brochure, VSIQXM_E00056367. The side opening and lumen of the tubular structure of the TrapLiner are configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the TrapLiner extends beyond the distal end of the guide catheter.

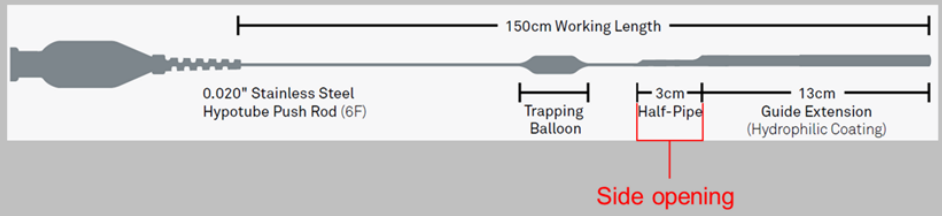
	"1. … Backload the distal tip of the TrapLiner catheter onto the proximal end of the guidewire and advance through the hemostatis valve and into the guide catheter. 2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056337-38.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	The matter forming the segment defining the side opening is more rigid than the tubular structure. Two point bend testing of the TrapLiner shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown below, the segment defining the side opening of the TrapLiner defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.

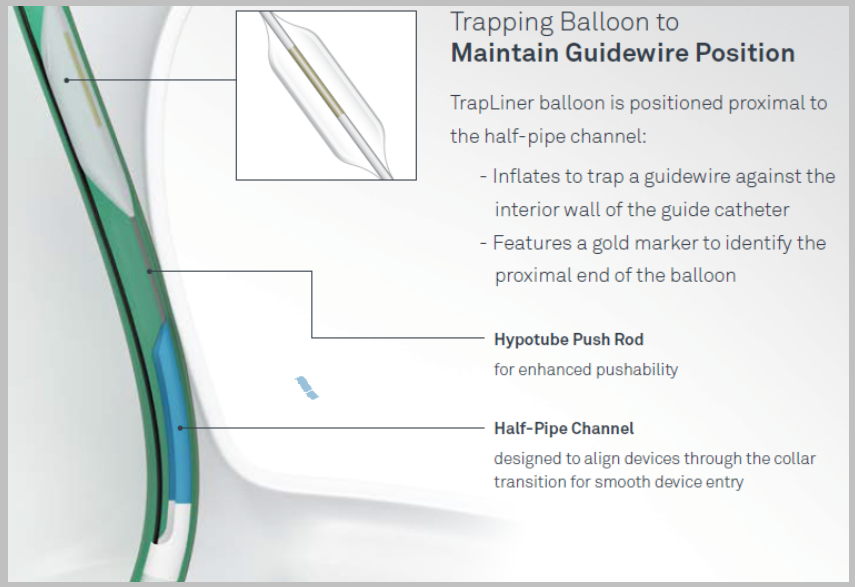
	 TrapLiner Product Brochure, VSIQXM_E00056367.
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown below, the segment defining the side opening of the TrapLiner includes at least one inclined slope.  TrapLiner Product Brochure, VSIQXM_E00056367.

32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.	As shown below, the segment defining the side opening of the TrapLiner includes at least two inclined slopes.  TrapLiner Product Brochure, VSIQXM_E00056367.
48. A system, comprising:	The combination of the TrapLiner with a guide catheter forms a system. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	A typical guide catheter is configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery and has a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery.

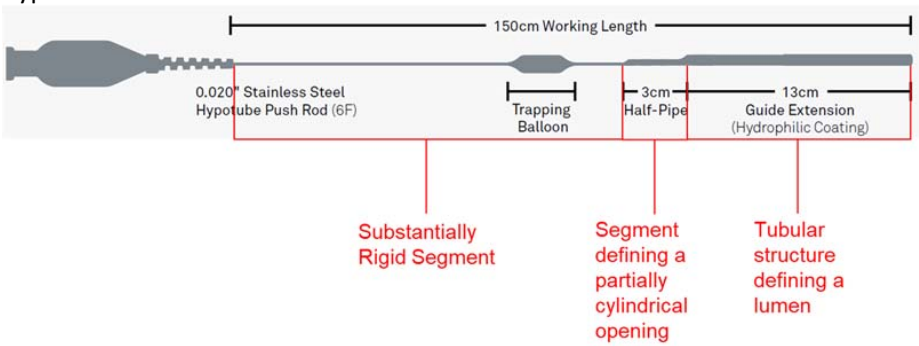
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	The TrapLiner is a guide extension catheter configured to be partially advanceable through a guide catheter and into the coronary artery. The length of the TrapLiner is such that the distal end is extendable through the lumen and beyond the end of the guide catheter and the proximal end is extendable through the hemostatic valve at the proximal end of the guide catheter. When the device is used as intended, the distal portion extends distally through the distal end of the guide catheter and the proximal portion of the stainless steel hypotube extends proximally through the hemostatic valve: "1. … Backload the distal tip of the TrapLiner catheter onto the proximal end of the guidewire and advance through the hemostasis valve and into the guide catheter. 2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel." TrapLiner Instructions for Use, VSIQXM_E00056337-38.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis,	The TrapLiner includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  TrapLiner Product Brochure, VSIQXM_E00056367.

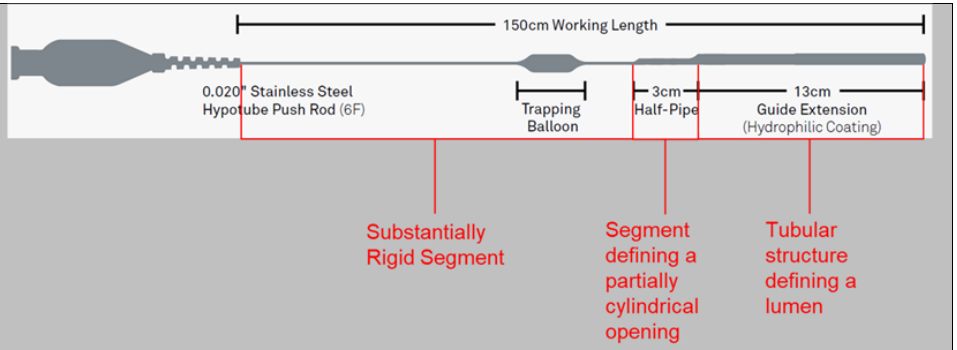
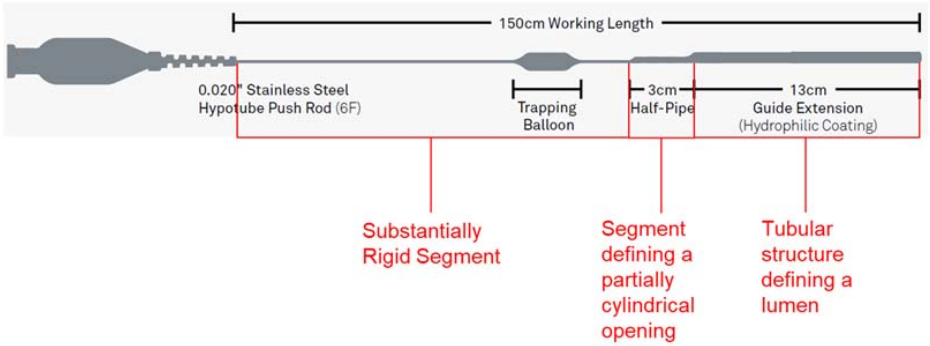
and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The TrapLiner includes a substantially rigid segment in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter. The lumen of the tubular structure has a length (13cm) that is shorter than the length of the lumen defined by the guide catheter. A typical guide catheter has a length of 100cm. The six French version of the TrapLiner meets this limitation when combined with a compatible guide catheter as set forth in the Instructions for Use. **SPECIFICATIONS** **Model / Size** | **5566 / 6F** | **5567 / 7F** | **5568 / 8F** Minimum guide catheter size | 6F (0.070" / 1.78mm I.D.) | 7F (0.078" / 1.98mm I.D.) | 8F (0.088" / 2.24mm I.D.) Pushrod outer diameter | 0.020" / 0.51mm | 0.025" / 0.64mm Guide extension inner diameter | 0.056" / 1.42mm | 0.062" / 1.57mm | 0.071" / 1.80mm TrapLiner Instructions for Use, VSIQXM_E00056337. The 6 French model of the TrapLiner meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches. Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the TrapLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the

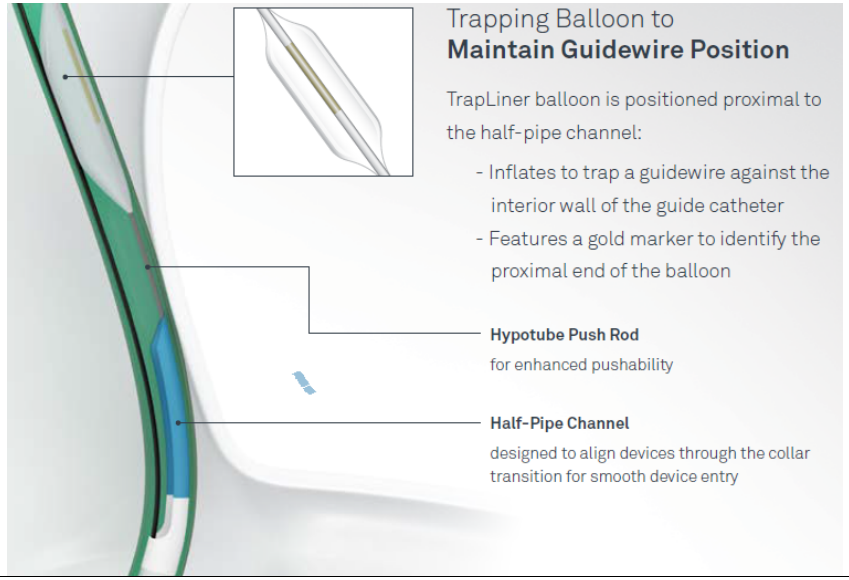
	outer diameter of those mandrels is 0.0564 ± 0.0002 inches. VSIQXM_E00056369. Therefore, the difference in diameter between the 6 French TrapLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the TrapLiner without catching on the proximal end opening of the TrapLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French TrapLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents. The side opening of the TrapLiner extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis, as shown below:  TrapLiner Product Brochure, VSIQXM_E00056367. The side opening and lumen of the tubular structure of the TrapLiner are configured to receive one or more stents or balloon catheters when the segment

	defining the side opening and a proximal end of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the TrapLiner extends beyond the distal end of the guide catheter. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338.  TrapLiner Product Brochure, VSIQXM_E00056367.
wherein the segment defining the side opening comprises a portion of the guide	The segment defining the side opening of the TrapLiner is more rigid than a distal end portion of the tubular structure. Two point bend testing of the TrapLiner shows that the side opening segment is more rigid than the tubular structure.

extension catheter that is more rigid than a distal end portion of the tubular structure.	The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**TrapLiner**
25. A guide extension catheter for use with a guide catheter, comprising:	The TrapLiner is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The TrapLiner includes a substantially rigid segment, namely a stainless steel hypotube.  TrapLiner Product Brochure, VSIQXM_E00056367. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The TrapLiner includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment.

	 TrapLiner Product Brochure, VSIQXM_E00056367.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The TrapLiner includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:  TrapLiner Product Brochure, VSIQXM_E00056367. The TrapLiner's segment defining the partially cylindrical opening is formed from matter more rigid than the matter forming the tubular structure. The two point bend testing of the TrapLiner shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load

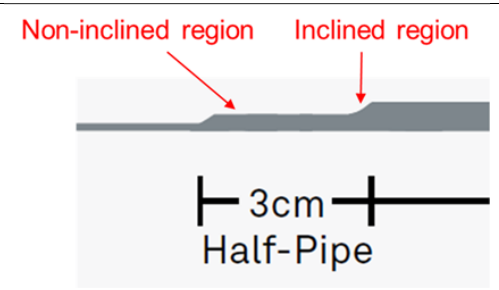
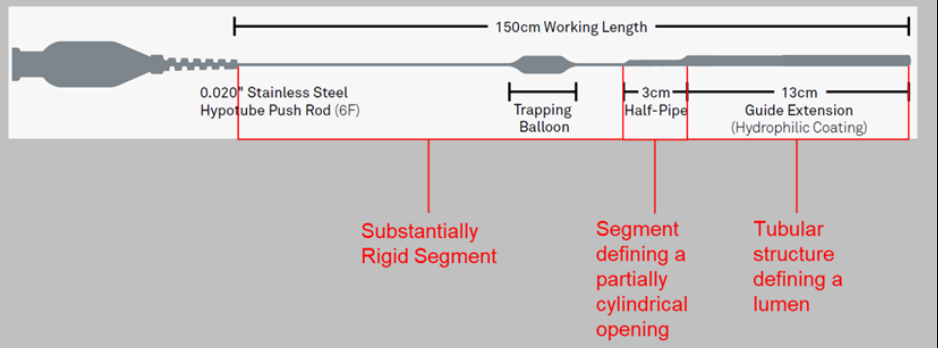
	values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338. 

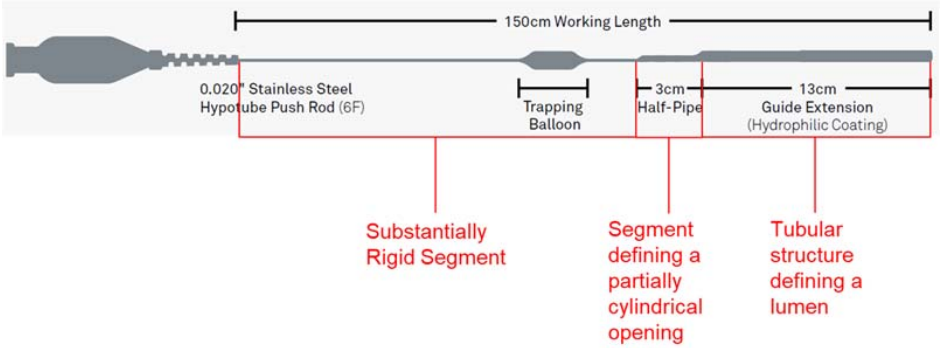
<table>
<tr><td></td><td>TrapLiner Product Brochure, VSIQXM_E00056367.</td></tr>
<tr><td>wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.</td><td>The cross-section of the TrapLiner at the proximal end of the tubular structure defines a single lumen.</td></tr>
<tr><td>30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.</td><td>The 6 French model of the TrapLiner meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the Instructions for Use.

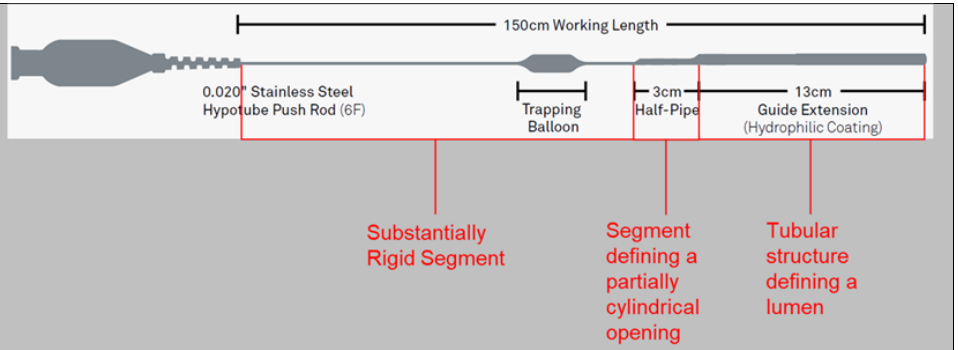
SPECIFICATIONS
<table><tr><th>Model / Size</th><th>5566 / 6F</th><th>5567 / 7F</th><th>5568 / 8F</th></tr><tr><td>Minimum guide catheter size</td><td>6F (0.070" / 1.78mm I.D.)</td><td>7F (0.078" / 1.98mm I.D.)</td><td>8F (0.088" / 2.24mm I.D.)</td></tr><tr><td>Pushrod outer diameter</td><td>0.020" / 0.51mm</td><td colspan="2">0.025" / 0.64mm</td></tr><tr><td>Guide extension inner diameter</td><td>0.056" / 1.42mm</td><td>0.062" / 1.57mm</td><td>0.071" / 1.80mm</td></tr></table>TrapLiner Instructions for Use, VSIQXM_E00056337.

Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the TrapLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. VSIQXM_E00056369. Therefore, the difference in diameter between the 6 French TrapLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is</td></tr>
</table>

	0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the TrapLiner without catching on the proximal end opening of the TrapLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French TrapLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	The lumen of the tubular structure of the TrapLiner is configured to receive a stent and a balloon catheter. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337. "If performing an interventional procedure, backload the interventional device over the existing guidewire and advance through the guide catheter and TrapLiner catheter into the desired vascular space." *Id.*
36. The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.	As shown below, the segment defining the angled proximal end of the partially cylindrical opening of the TrapLiner includes at least one inclined region that tapers into a non-inclined region.

	 TrapLiner Product Brochure, VSIQXM_E00056367.
52. A guide extension catheter for use with a guide catheter, comprising:	The TrapLiner is a guide extension catheter for use with a guide catheter. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337.
a substantially rigid segment;	The TrapLiner includes a substantially rigid segment, namely a stainless steel hypotube.  TrapLiner Product Brochure, VSIQXM_E00056367.

	Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The TrapLiner includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment.  TrapLiner Product Brochure, VSIQXM_E00056367.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The TrapLiner includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

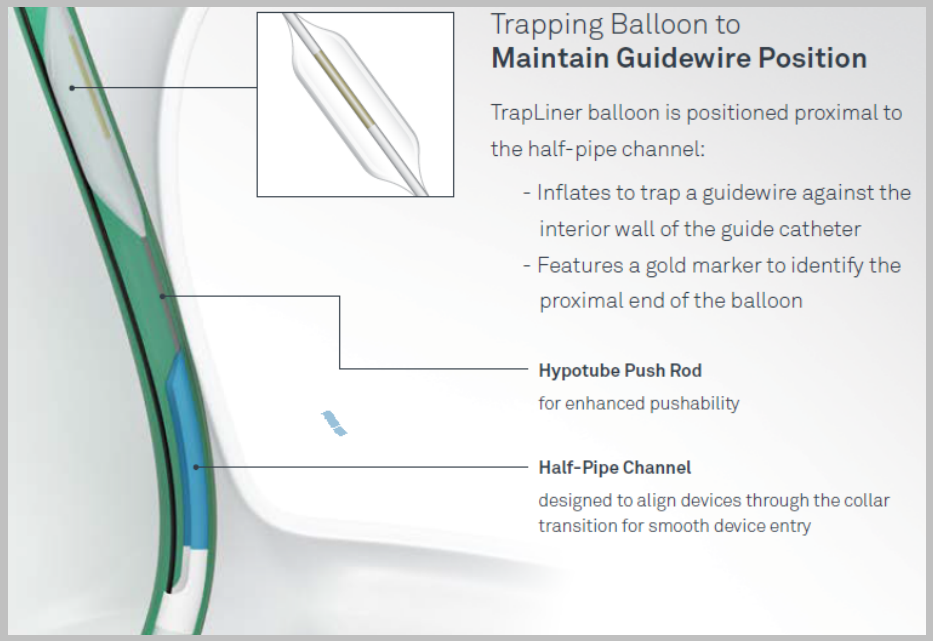


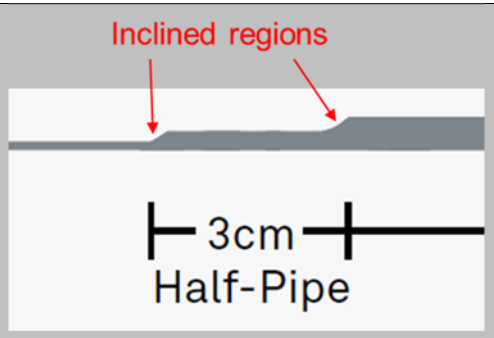
TrapLiner Product Brochure, VSIQXM_E00056367.

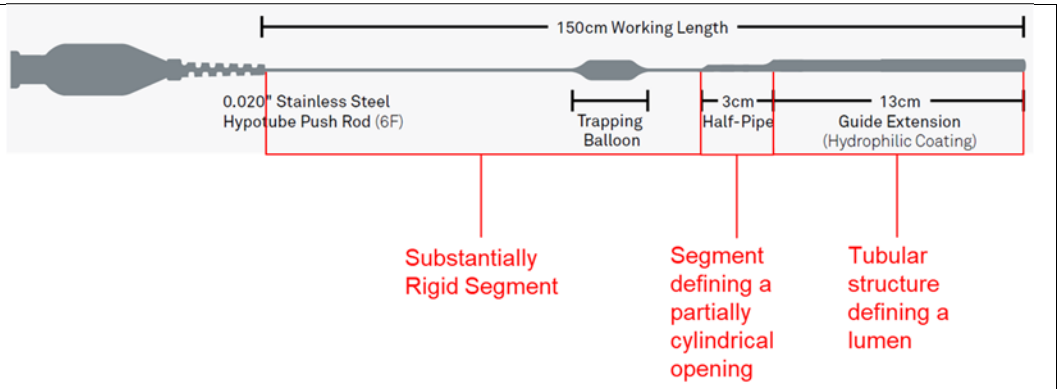
The TrapLiner's segment defining the partially cylindrical opening is formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure, as evidenced by the test results in Appendix D at 1. The two point bend testing of the TrapLiner shows that the segment defining a partially cylindrical opening is more rigid than the tubular structure. The maximum load values for the segment defining a partially cylindrical opening ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

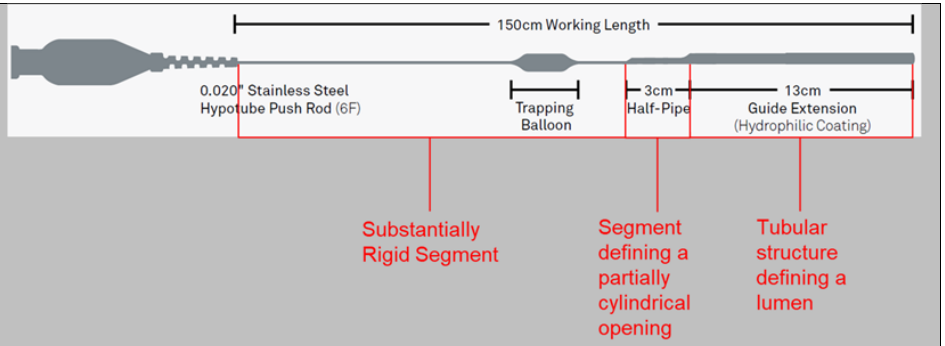
In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

"2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338.

	 TrapLiner Product Brochure, VSIQXM_E00056367.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	The cross-section of the TrapLiner at the proximal end of the tubular structure defines a single lumen.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The TrapLiner's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:

	 TrapLiner Product Brochure, VSIQXM_E00056367.
53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	The TrapLiner is a guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337.
a substantially rigid segment;	The TrapLiner includes a substantially rigid segment, namely a stainless steel hypotube.

	 TrapLiner Product Brochure, VSIQXM_E00056367. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and	The TrapLiner includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment and has a uniform cross-sectional inner diameter that, for the 6 French version, is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter with which it is intended for use.



TrapLiner Product Brochure, VSIQXM_E00056367.

The 6 French model of the TrapLiner meets this limitation by doctrine of equivalents when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the Instructions for Use.

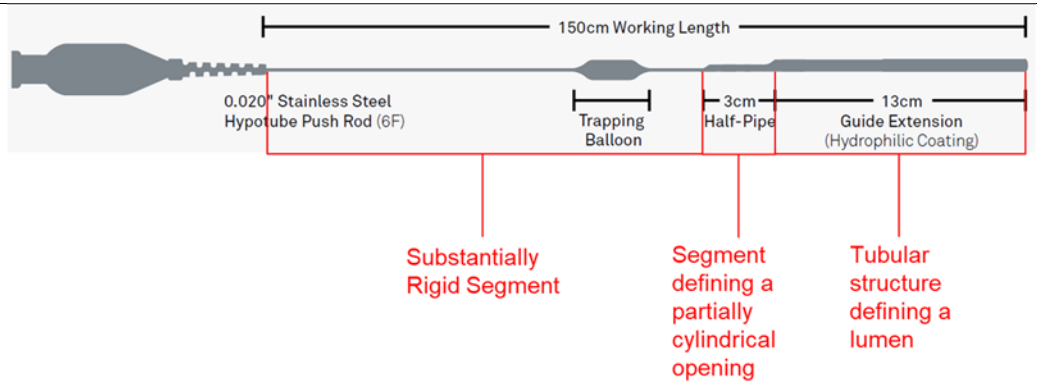
SPECIFICATIONS

Model / Size	5566 / 6F	5567 / 7F	5568 / 8F
Minimum guide catheter size	6F (0.070" / 1.78mm I.D.)	7F (0.078" / 1.98mm I.D.)	8F (0.088" / 2.24mm I.D.)
Pushrod outer diameter	0.020" / 0.51mm	0.025" / 0.64mm	
Guide extension inner diameter	0.056" / 1.42mm	0.062" / 1.57mm	0.071" / 1.80mm

TrapLiner Instructions for Use, VSIQXM_E00056337.

Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the TrapLiner v3 may be greater, and is

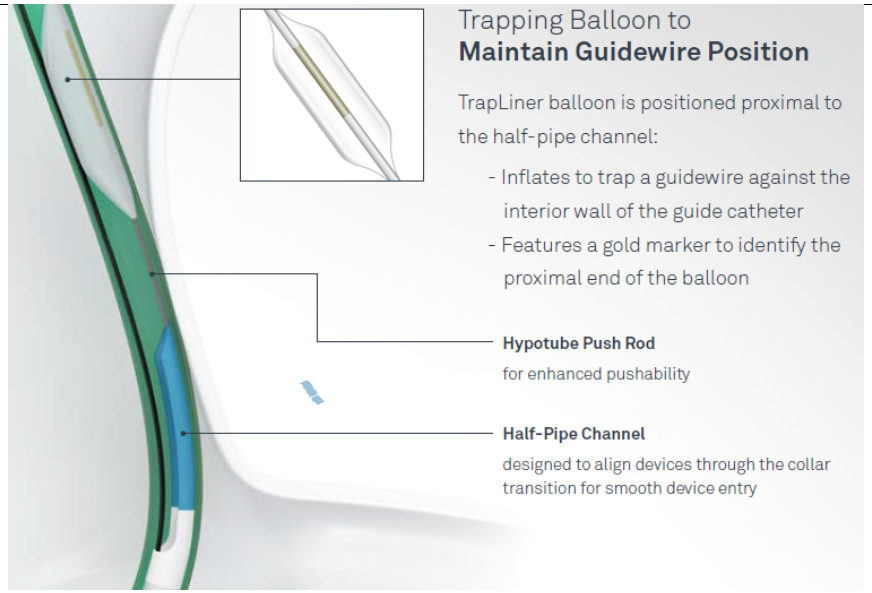
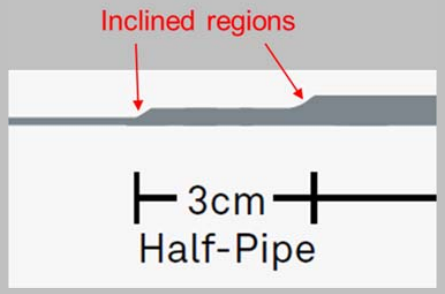
	typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. VSIQXM_E00056369. Therefore, the difference in diameter between the 6 French TrapLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the TrapLiner without catching on the proximal end opening of the TrapLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that combining the six French TrapLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	The TrapLiner includes a segment defining a partially cylindrical opening having an angled proximal end positioned between the distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:



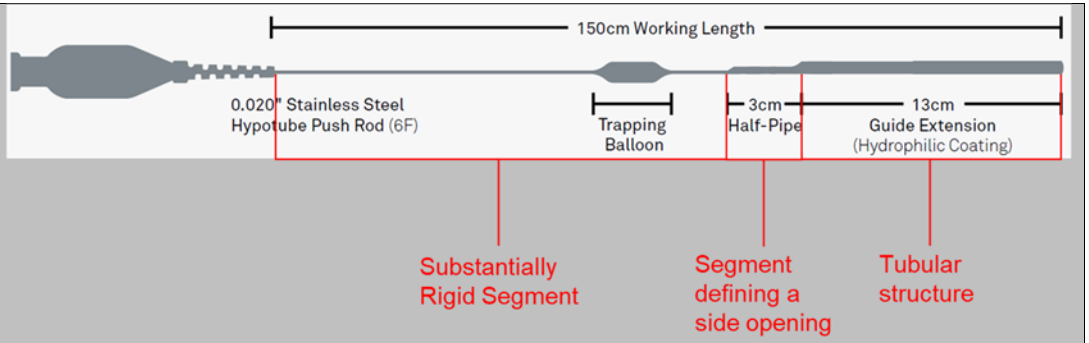
TrapLiner Product Brochure, VSIQXM_E00056367.

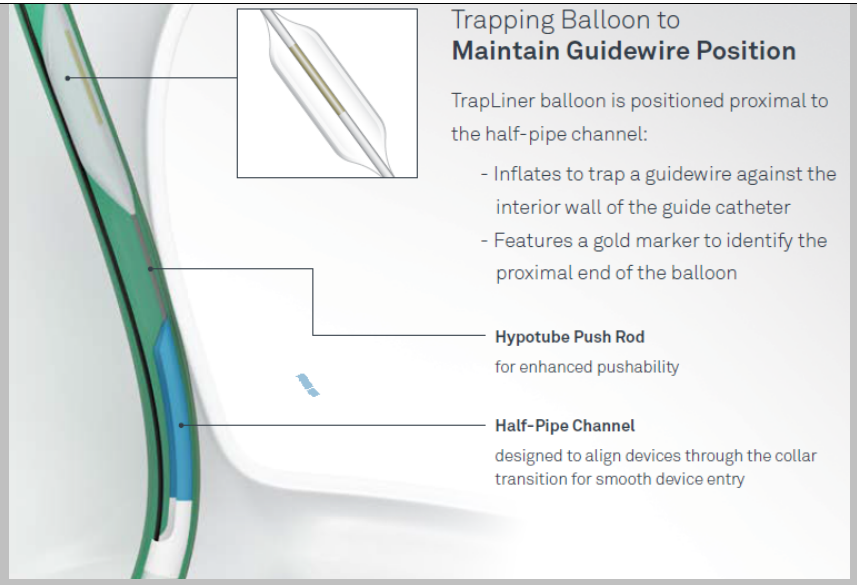
In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

"2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338.

	 TrapLiner Product Brochure, VSIQXM_E00056367.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	The TrapLiner's segment defining the proximal end of the partially cylindrical opening includes at least two inclined regions, as shown below:  TrapLiner Product Brochure, VSIQXM_E00056367.

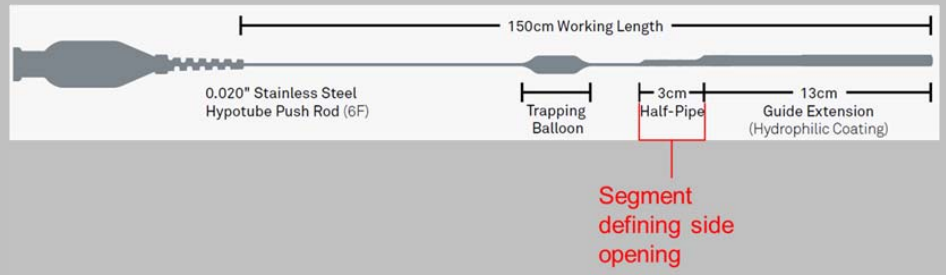
U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**TrapLiner**
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the TrapLiner with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00056337.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a TrapLiner includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide	The intended method of using a TrapLiner includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter.

extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	 TrapLiner Product Brochure, VSIQXM_E00056367. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338.



TrapLiner Product Brochure, VSIQXM_E00056367.

The segment defining a side opening of the TrapLiner, shown below, extends for a distance along a longitudinal axis of the guide extension catheter and is accessible from a longitudinal side defined transverse to the longitudinal axis.



TrapLiner Product Brochure, VSIQXM_E00056367.

The 6 French model of the TrapLiner meets this limitation by doctrine of equivalents when used with a guide catheter having an inner diameter of 0.070 inches as set forth in the Instructions for Use.

SPECIFICATIONS

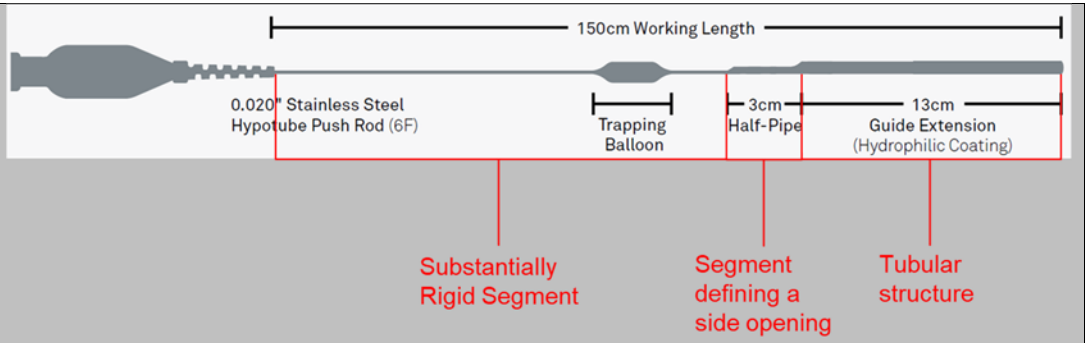
Model / Size	5566 / 6F	5567 / 7F	5568 / 8F
Minimum guide catheter size	6F (0.070" / 1.78mm I.D.)	7F (0.078" / 1.98mm I.D.)	8F (0.088" / 2.24mm I.D.)
Pushrod outer diameter	0.020" / 0.51mm	0.025" / 0.64mm	
Guide extension inner diameter	0.056" / 1.42mm	0.062" / 1.57mm	0.071" / 1.80mm

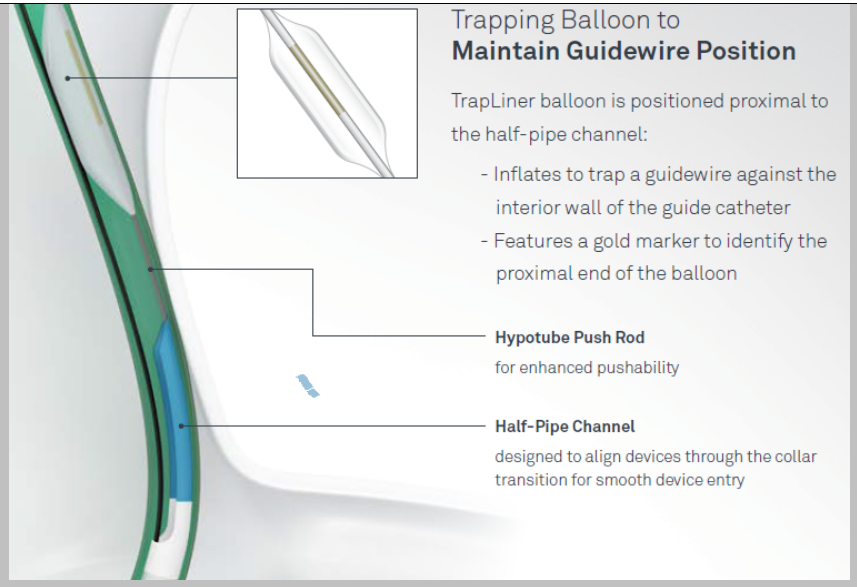
TrapLiner Instructions for Use, VSIQXM_E00056337.

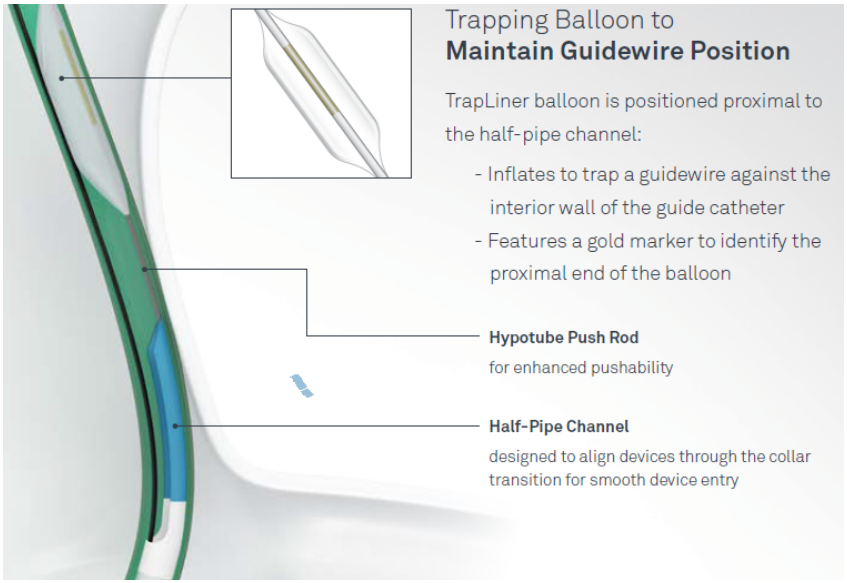
Although the stated minimum inner diameter of the device is 0.056 inches, the actual cross-sectional inner diameter of the TrapLiner v3 may be greater, and is typically determined by the outer diameter of the mandrel used to build the distal tubing of the device. According to specifications, the outer diameter of those mandrels is 0.0564 ± 0.0002 inches. VSIQXM_E00056369. Therefore, the difference in diameter between the 6 French TrapLiner v3 and a compatible guide catheter is between 0.0134 and 0.0138 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.0134, 0.0138, or 0.0131 inches, the device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the

	guide catheter to allow interventional cardiology devices to pass into the TrapLiner without catching on the proximal end opening of the TrapLiner's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that using the six French TrapLiner with a 0.070-inch guide catheter meets this limitation under the doctrine of equivalents.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	The intended method of using a TrapLiner includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338. The TrapLiner includes a substantially rigid segment in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.

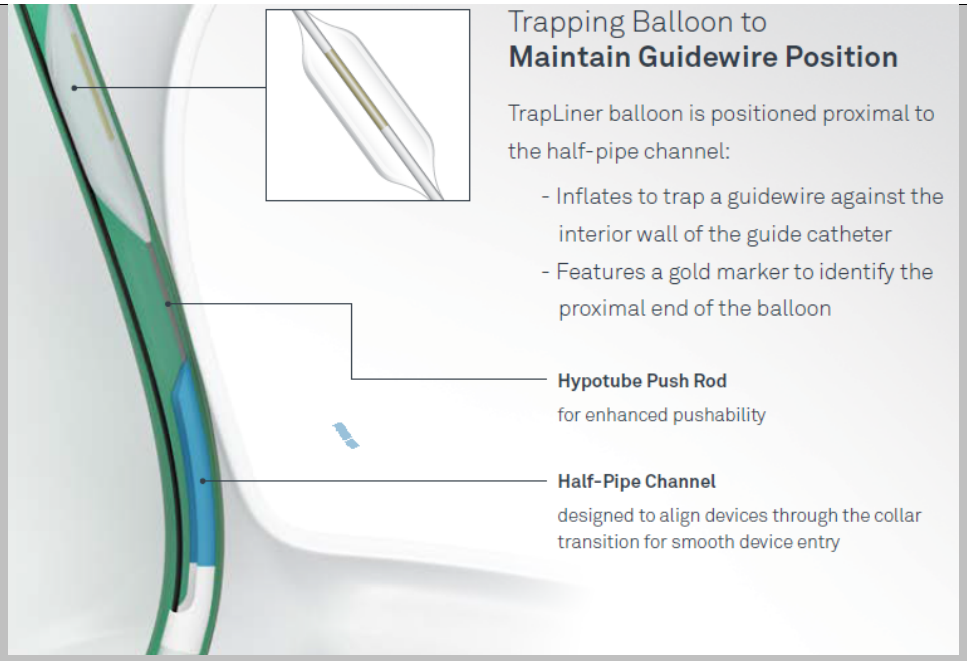
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	While the TrapLiner is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the TrapLiner and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 52 is performed by a cardiologist using the TrapLiner with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use, VSIQXM_E00056337.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	The intended method of using a TrapLiner includes advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery. "The TrapLiner catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, to facilitate placement of interventional devices, and to facilitate the exchange of an interventional device while maintaining the position of a guidewire within the vasculature." TrapLiner Instructions for Use, VSIQXM_E00056337.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension	The intended method of using a TrapLiner includes advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter.

catheter that is more rigid than the distal end portion of the tubular structure;	 TrapLiner Product Brochure, VSIQXM_E00056367. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056337-38.

	 TrapLiner Product Brochure, VSIQXM_E00056367. The segment defining the side opening of the TrapLiner comprises a portion of the device that is more rigid than the distal end portion of the tubular structure at least in part because of the stainless steel backbone reinforcing the segment defining the side opening. Two point bend testing of the TrapLiner shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and	The intended method of using a TrapLiner includes maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter and, while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the

while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338.  TrapLiner Product Brochure, VSIQXM_E00056367.

	The TrapLiner includes a substantially rigid segment in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	In the intended method of using a TrapLiner, advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter. "2. Under fluoroscopy, advance the TrapLiner catheter beyond the distal tip of the guide catheter and into the desired location within the vessel. 3. If performing an interventional procedure, backload the interventional device over the existing guidewire and advance the device through the guide catheter and TrapLiner catheter and into the desired vascular space." TrapLiner Instructions for Use, VSIQXM_E00056338.



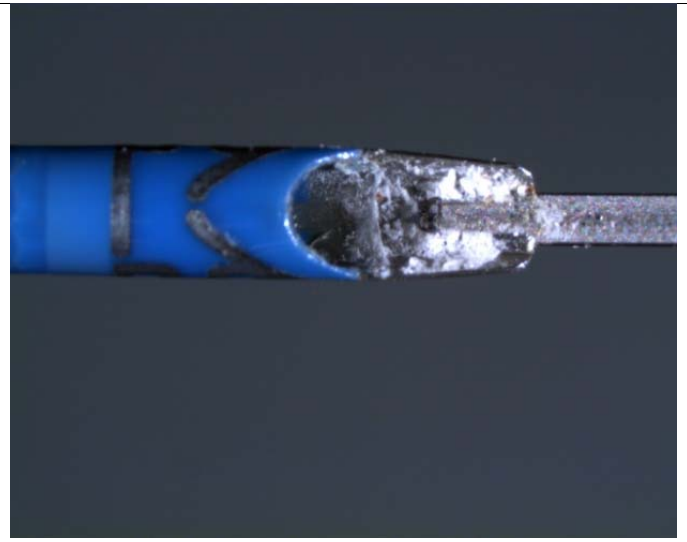
TrapLiner Product Brochure, VSIQXM_E00056367.

U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**Guidezilla**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	The combination of Boston Scientific's Guidezilla and a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	The Guidezilla is used in conjunction with a guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2. **"Delivery Procedure** "Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." A typical guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, where the continuous

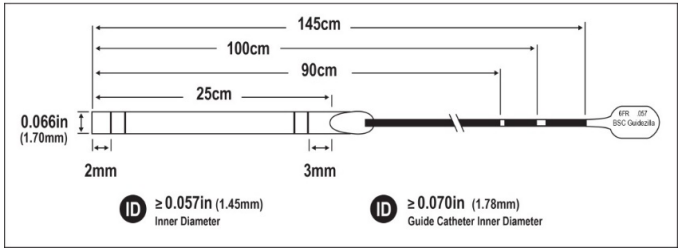
	lumen of the guide catheter has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.
a device adapted for use with the guide catheter, including:	The Guidezilla is adapted for use with a guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2.
a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The Guidezilla has a flexible tip portion that defines a tubular structure with a circular cross-section, which is the blue, tubular structure in the following photographs, and the tubular structure in the following drawing:

The Guidezilla has "a single lumen distal guide segment." Guidezilla Directions for Use at 2.

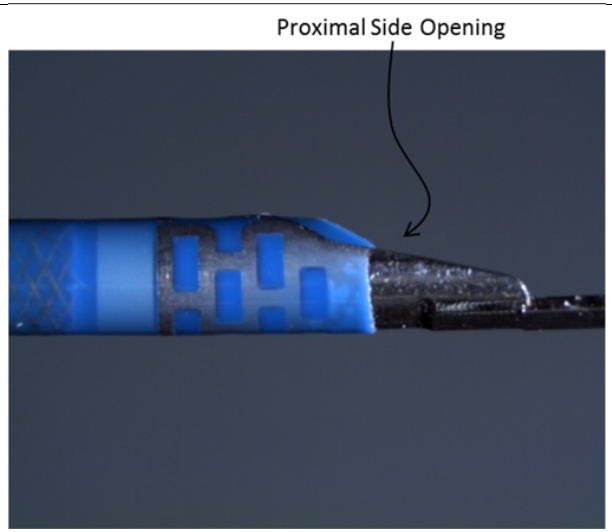
	"GUIDEZILLA consists of . . . a distal guide catheter segment through which interventional devices may be delivered." Boston Scientific's 510(k) Summary. The flexible tip is shorter than the 100cm length of the continuous lumen of a typical guide catheter. The tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable.
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;	The Guidezilla includes a substantially rigid portion in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter and is more rigid along a longitudinal axis that the flexible tip portion of the device. "The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2. The attached photographs depict the Guidezilla's "stainless steel proximal shaft," which is substantially rigid, proximal of and operably connected to, and more rigid than the flexible tip portion, and it defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.



	The Guidezilla's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25. Guidezilla's substantially rigid portion is a stainless steel hypotube that is sealed shut at both ends. Although there is a minute, inaccessible, non-functional void inside the hypotube, it is my opinion that hypotube meets the "rail structure without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void inside the hypotube is insubstantially different from having no void at all. Nothing can pass through the hypotube because it it closed at both ends; it serves no meaningful purpose or function. The Guidezilla's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside). The substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is longer than the length of the continuous lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A typical 6F guide catheter is 100cm long.

	Guidezilla  "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary. The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve. At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through

	the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3. "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3.
wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	The tubular structure of the Guidezilla includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the distal tip portion. The distal tip portion is more flexible than the reinforced portion. The results of the "crush" testing clearly show that the Guidezilla's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. See Appendix D at 1-2, comparing "Crush 1" values to "Crush 2" and "Crush 3" values.
3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	The proximal portion of the Guidezilla's tubular structure includes a proximal side opening that extends for a distance along the device's longitudinal axis and is accessible from a longitudinal side that is transverse to the longitudinal axis, so that the opening can receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. This opening is shown in the following photograph of the Guidezilla device:

	
8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a typical 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary. "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2.

Product Reference

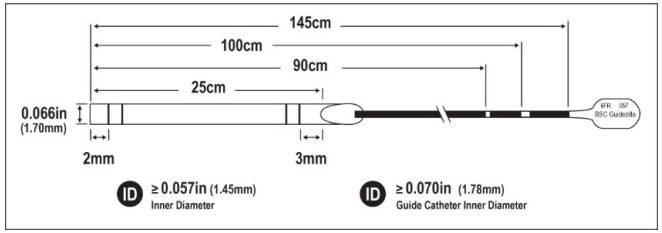
Reference	Compatible Guide Catheter	Guidezilla I.D. /O.D.
H7493924215050	≥ 6F / ≥ 0.070 in (1.78 mm) I.D.	0.057 in (1.45 mm) 0.066 in (1.68 mm)

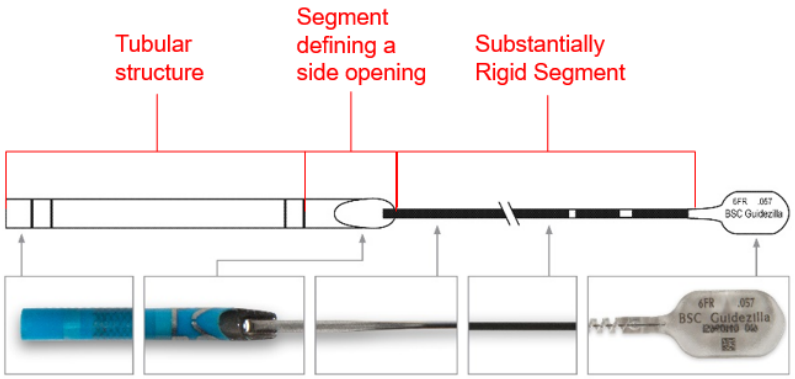
Guidezilla Product Brochure, page 2.

Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines.

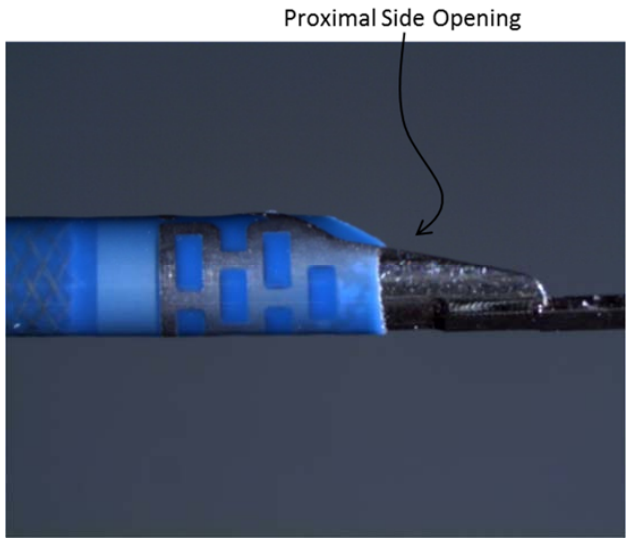
Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
25. A system, comprising:	The combination of the Guidezilla with a guide catheter forms a system.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	The Guidezilla is used in conjunction with a guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2. **"Delivery Procedure** "Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." A typical guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, e.g., adjacent the ostium of a coronary artery.

a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	The Guidezilla is a guide extension catheter configured to be partially advanceable through a guide catheter into the coronary artery. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary. Guidezilla has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A typical 6F guide catheter is 100cm long: **Guidezilla**  When the distal end of the Guidezilla is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the Guidezilla extends through a hemostatic valve. The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3.

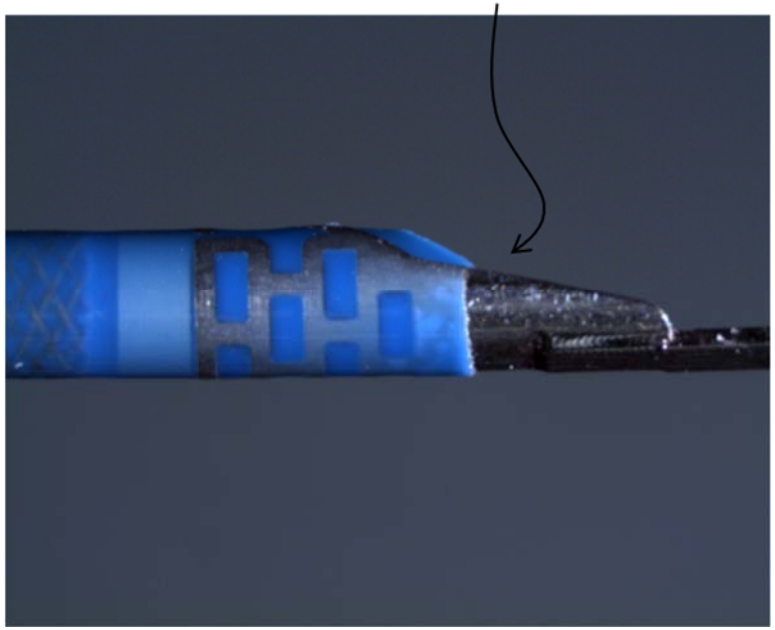
	"Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	The Guidezilla includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:  The Guidezilla includes a substantially rigid portion in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.

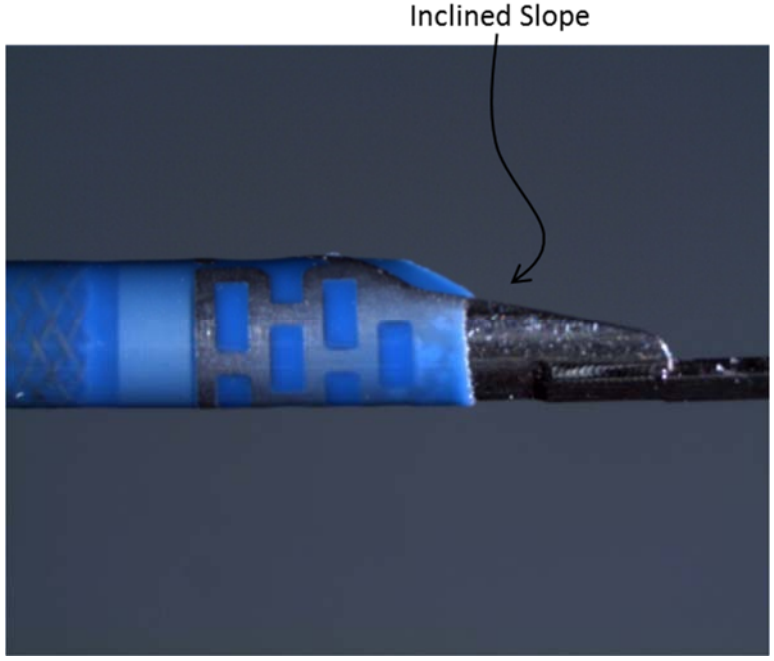
	The tubular structure has a uniform cross-sectional inner diameter through which interventional cardiology devices are insertable. The uniform cross-sectional inner diameter of the lumen of the tubular structure is one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. The side opening of the Guidezilla extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis. This opening is shown in the following photograph of the Guidezilla device:

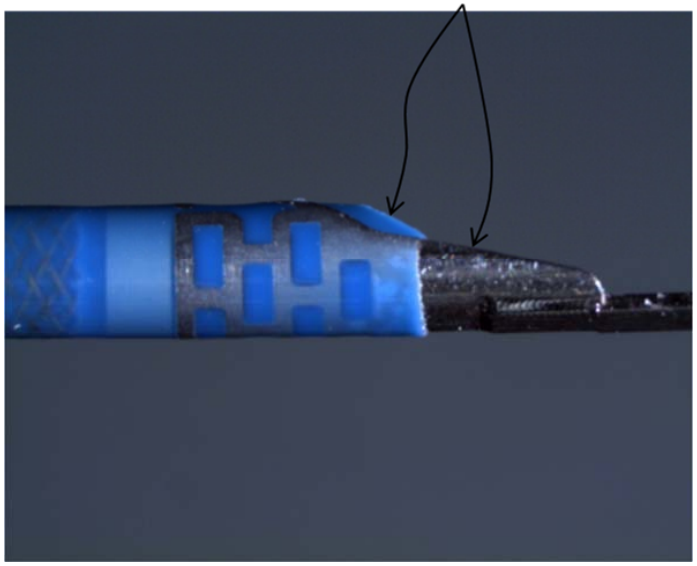
	 When the Guidezilla is used, an interventional cardiology device, e.g., a stent or balloon catheter, is extended through the side opening and the lumen of the tubular structure. The Guidezilla Directions for Use state: "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3. Because the guide catheter defines a lumen having a length of 100 cm, when the distal end of the Guidezilla extends beyond the distal end of

	the guide catheter, the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter. The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a typical 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary. "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2. **Product Reference** | Reference | Compatible Guide Catheter | Guidezilla I.D. /O.D. | | --- | --- | --- | | H7493924215050 | ≥ 6F / ≥ 0.070 in (1.78 mm) I.D. | 0.057 in (1.45 mm) 0.066 in (1.68 mm) | Guidezilla Product Brochure, page 2. Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely

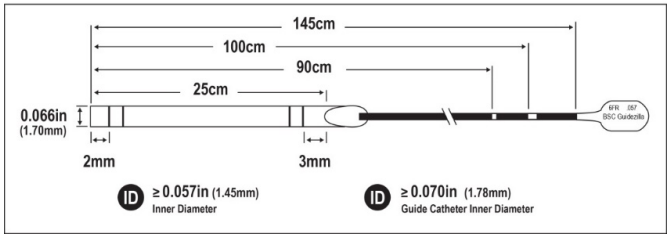
	more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	Based on my physical examination of the device, it is my opinion that the matter forming the segment of the side opening is more rigid than the tubular structure.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown in the photograph below, the segment defining the side opening of the Guidezilla defines a concave track configured to guide an interventional device, e.g., a stent or balloon catheter, along a length thereof:

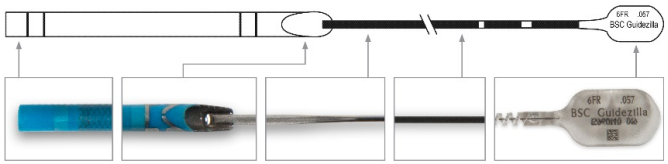
	
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown in the photograph below, the segment defining the side opening of the Guidezilla defines at least one inclined slope:

	
32. The system of claim 25, wherein the segment defining the side opening includes at least two inclined slopes.	As shown in the photograph below, the segment defining the side opening of the Guidezilla defines at least two inclined slopes:

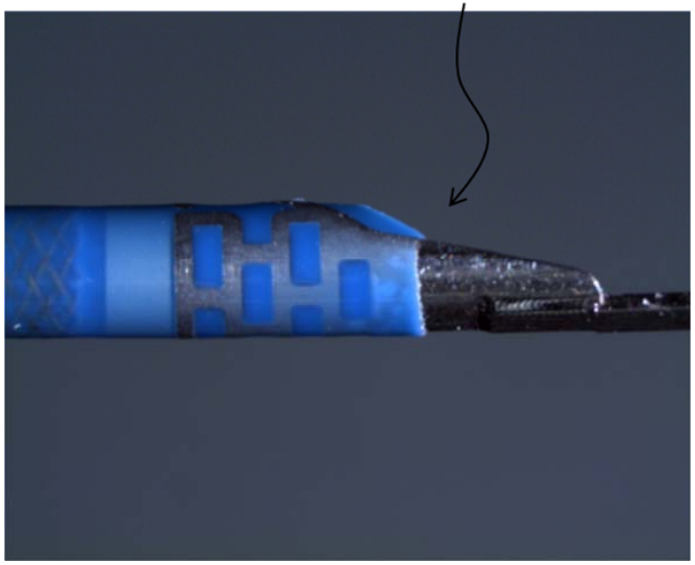
	
[redacted]	
48. A system, comprising:	The combination of the Guidezilla with a guide catheter forms a system.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	The Guidezilla is used in conjunction with a guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2. **"Delivery Procedure** "Deliver the Guidezilla device according to the following steps:

	"1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." A typical guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, e.g., adjacent the ostium of a coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	The Guidezilla is a guide extension catheter configured to be partially advanceable through a guide catheter into the coronary artery. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary. The tubular structure of the Guidezilla has a distal end that is adapted to be extended beyond the distal end of the guide catheter while a proximal end of the Guidezilla is extendable through the hemostatic valve at the proximal end of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A typical 6F guide catheter is 100cm long:

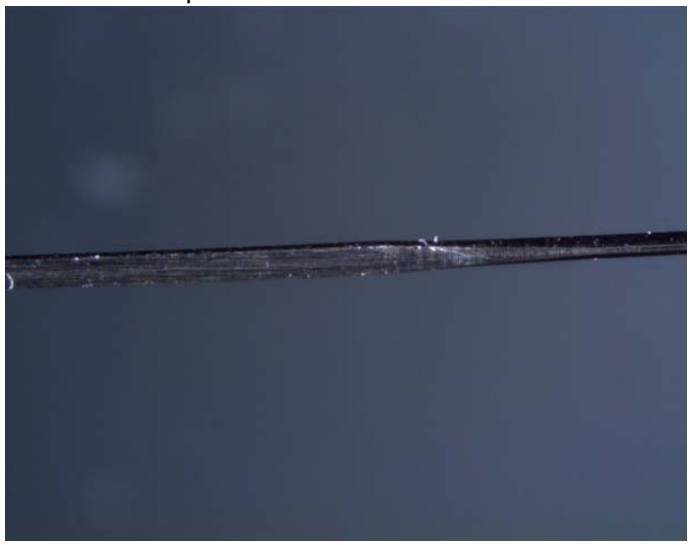
	Guidezilla  The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner	The Guidezilla includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown below:

diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	 The lumen of the tubular structure is shorter than the 100 cm length of the lumen defined by the guide catheter. The tubular structure has a uniform cross-sectional inner diameter through which interventional cardiology devices are insertable. The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a typical 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary. "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2. **Product Reference** | Reference | Compatible Guide Catheter | Guidezilla I.D. /O.D. | | --- | --- | --- | | H7493924215050 | ≥ 6F / ≥ 0.070 in (1.78 mm) I.D. | 0.057 in (1.45 mm) 0.066 in (1.68 mm) | Guidezilla Product Brochure, page 2. Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter

	having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. The side opening of the Guidezilla extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis. This opening is shown in the following photograph of the Guidezilla device:

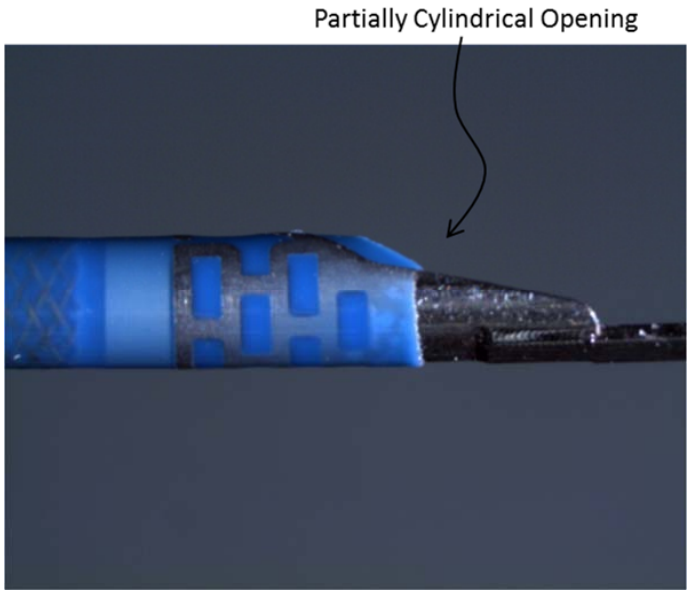
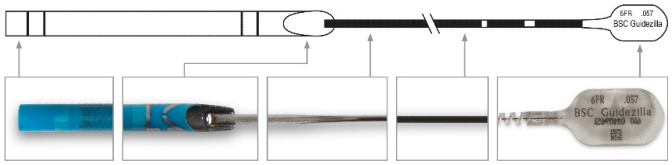
	 When the Guidezilla is used, an interventional cardiology device, e.g., a stent or balloon catheter, is extended through the side opening and the lumen of the tubular structure. The Guidezilla Directions for Use state: "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3.

	Because a guide catheter defines a lumen having a length of 100 cm, when the distal end of the Guidezilla extends beyond the distal end of the guide catheter, the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter.
wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than a distal end portion of the tubular structure.	Based on my physical examination of the device, it is my opinion that the segment defining the side opening comprises a portion of the device that is more rigid than a distal end of the tubular structure.

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
25. A guide extension catheter for use with a guide catheter, comprising:	Boston Scientific's Guidezilla is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ."Guidezilla Directions for Use at 2. The attached photographs show Guidezilla's substantially rigid "stainless steel proximal shaft." 

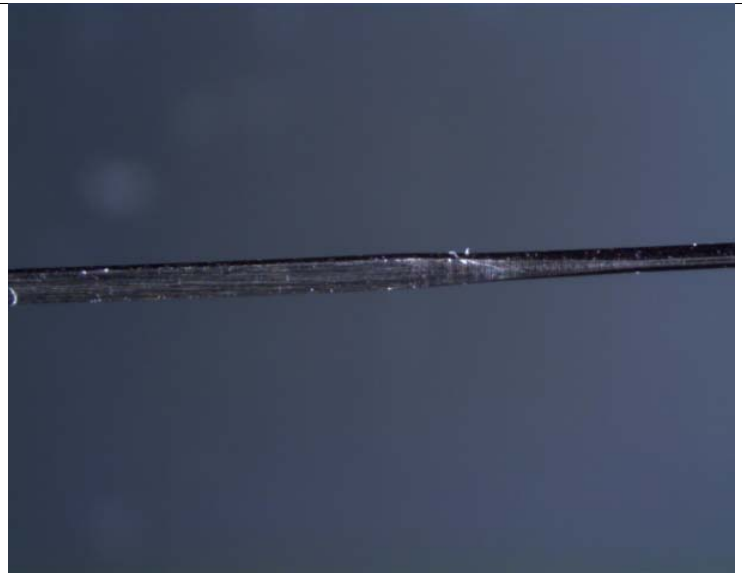
	Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The Guidezilla includes a tubular structure defining a lumen, which is blue, and is positioned distal to the substantially rigid segment, as shown below:

	 The Guidezilla has "a single lumen distal guide segment." Guidezilla Directions for Use at 2.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical	The Guidezilla defines a partially cylindrical opening having an angled proximal end positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

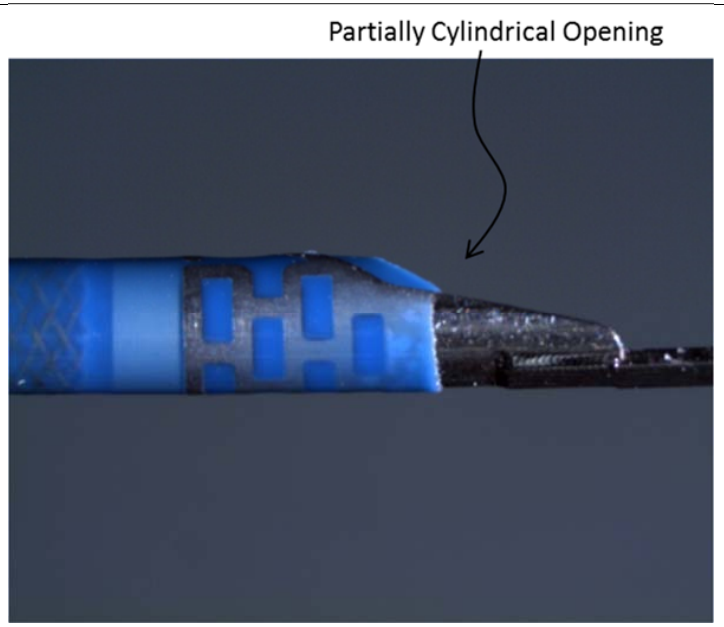
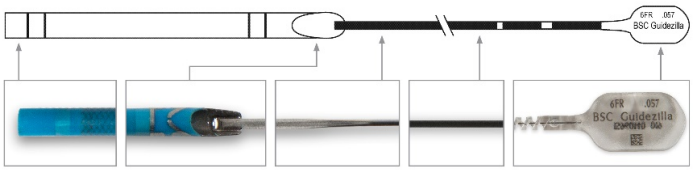
opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	  Based on my physical examination of the GuideLiner v2, it is my opinion that the the segment defining the partially cylindrical opening is formed from matter that is more rigid than the matter forming the tubular structure. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.	A cross-section of the proximal end of the tubular structure of the Guidezilla defines a single lumen. "The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2.
30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.	The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a typical 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary. "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2. **Product Reference** Reference | Compatible Guide Catheter | Guidezilla I.D. /O.D. H7493924215050 | ≥ 6F / ≥ 0.070 in (1.78 mm) I.D. | 0.057 in (1.45 mm) 0.066 in (1.68 mm) Guidezilla Product Brochure, page 2. Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines.

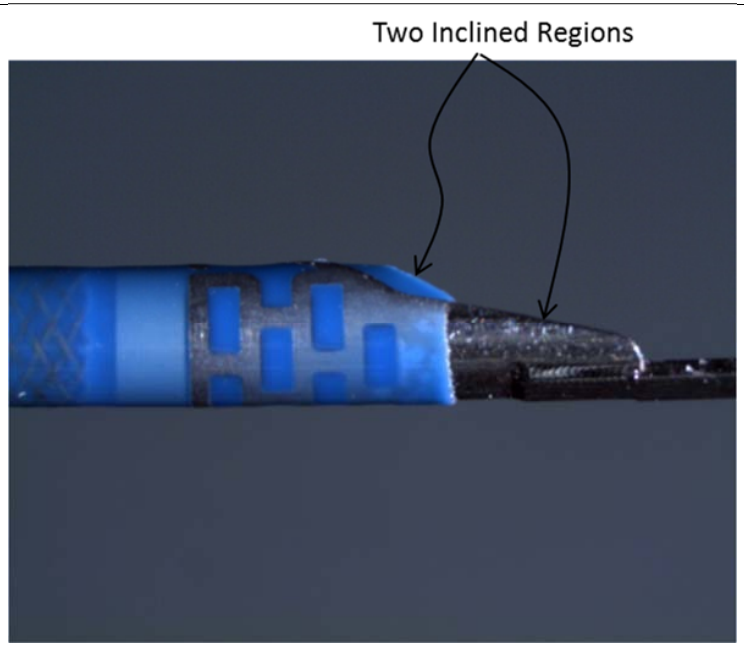
	Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	When the Guidezilla is used, an interventional cardiology device, e.g., a stent or balloon catheter, is extended through the lumen of the tubular structure.
52. A guide extension catheter for use with a guide catheter, comprising:	Boston Scientific's Guidezilla is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2. The attached photographs depict Guidezilla's substantially rigid "stainless steel proximal shaft."

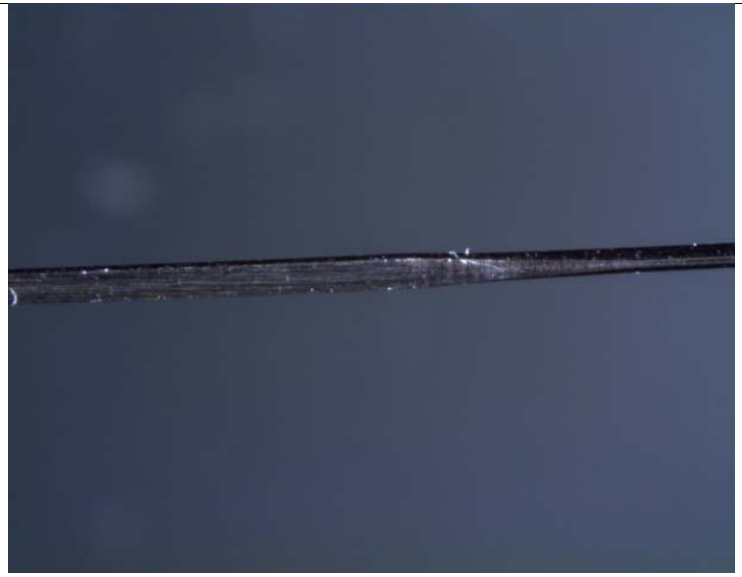
	 Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The Guidezilla includes a tubular structure defining a lumen, which is blue, and is positioned distal to the substantially rigid segment, as shown below:

	 The Guidezilla has "a single lumen distal guide segment." Guidezilla Directions for Use at 2.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical	The Guidezilla defines a partially cylindrical opening having an angled proximal end positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown below:

opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	  Based on product observation, the segment defining the partially cylindrical opening has a greater flexural modulus than the flexural modulus of the tubular structure.

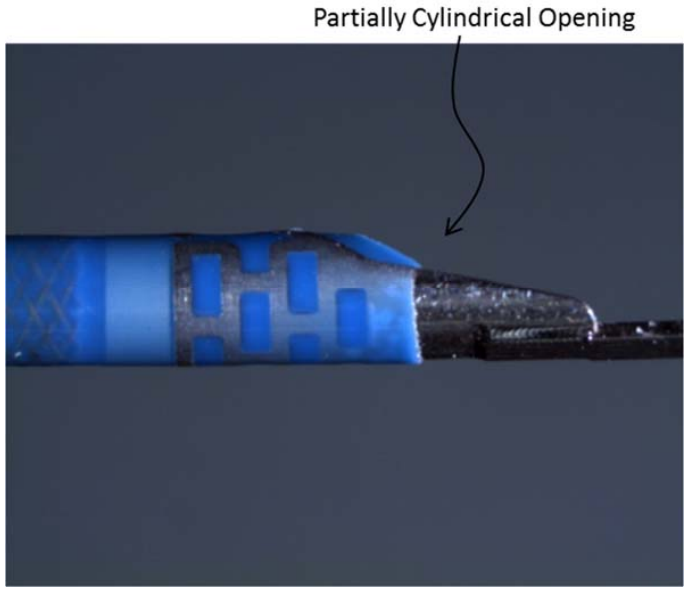
	In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	A cross-section of the proximal end of the tubular structure of the Guidezilla defines a single lumen. "The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	As shown in the photograph below, the segment defining the side opening of the Guidezilla defines at least two inclined regions:

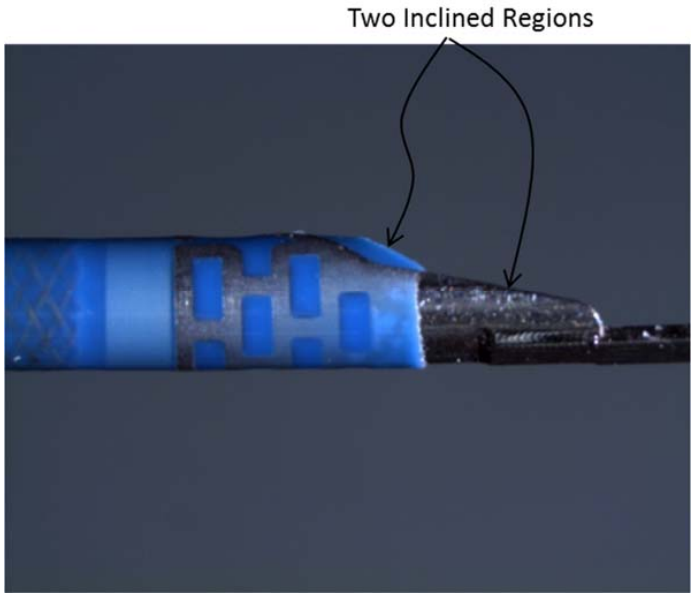
	
53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	Boston Scientific's Guidezilla is a guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter.
a substantially rigid segment;	"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2. The attached photographs depict Guidezilla's substantially rigid "stainless steel proximal shaft."

	 Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and	The Guidezilla includes a tubular structure defining a lumen, which is blue, and is positioned distal to the substantially rigid segment, as shown below:

The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a typical 6F guide catheter.

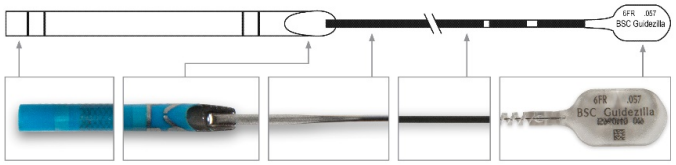
	"The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary. "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2. **Product Reference** | Reference | Compatible Guide Catheter | Guidezilla I.D. /O.D. | | --- | --- | --- | | H7493924215050 | ≥ 6F / ≥ 0.070 in (1.78 mm) I.D. | 0.057 in (1.45 mm) 0.066 in (1.68 mm) | Guidezilla Product Brochure, page 2. Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into

	the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	The Guidezilla defines a partially cylindrical opening having an angled proximal end positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown in the following annotated photographs:  A cross-section of the proximal end of the tubular structure of the Guidezilla defines a single lumen.

	"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2. In operation, the partially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	As shown in the photograph below, the segment defining the side opening of the Guidezilla defines at least two inclined slopes: 
U.S. Patent No. RE46,116	

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES Root et al.	
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the Guidezilla with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	To use the Guidezilla, a distal end of a typical guide catheter having a lumen is advanced through a main blood vessel to a branch artery, e.g., an ostium of a coronary artery. Boston Scientific's documents confirm that Guidezilla is used with a guide catheter. "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter	Boston Scientific documents instruct the user to insert the distal end of the Guidezilla through, and beyond the distal end of, the guide catheter, such that a distal end portion of a tubular structure of Guidezilla extends beyond the distal end of the guide catheter while a

beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	segment defining a side opening of Guidezilla remains within the catheter. The tubular structure and segment defining a side opening are shown in the photographs below, with the tubular portion colored blue: 

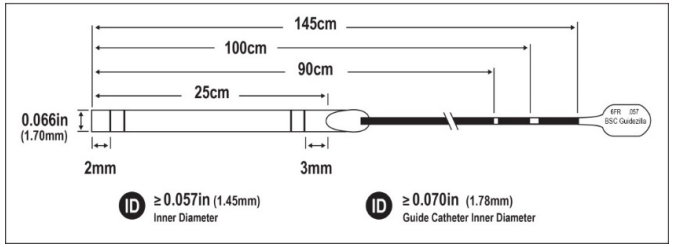


"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2.

The Guidezilla defines a total length that is longer than the length of the continuous lumen of the guide catheter, such that a distal end portion of its tubular structure extends beyond the distal end of the guide catheter when inserted therethrough.

The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A typical 6F guide catheter is 100cm long.

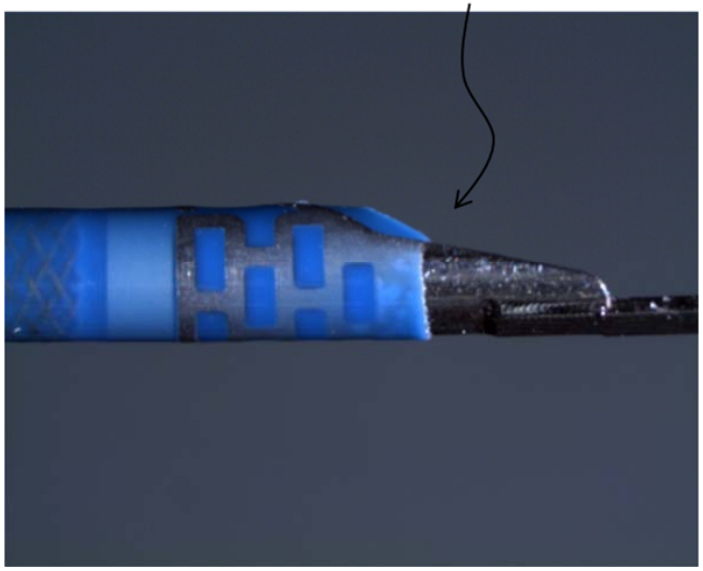
Guidezilla



"The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary.

The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into

	the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. Because the guide catheter defines a lumen having a length of 100 cm, when the distal end of the Guidezilla extends beyond the distal end of the guide catheter, the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter. The side opening of the Guidezilla extends for a distance along the longitudinal axis thereof and is accessible from a longitudinal side defined transverse to the longitudinal axis. This opening is shown in the following photograph of the Guidezilla device:

	 The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a typical 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary. "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2.

Product Reference

Reference	Compatible Guide Catheter	Guidezilla I.D. /O.D.
H7493924215050	≥ 6F / ≥ 0.070 in (1.78 mm) I.D.	0.057 in (1.45 mm) 0.066 in (1.68 mm)

Guidezilla Product Brochure, page 2.

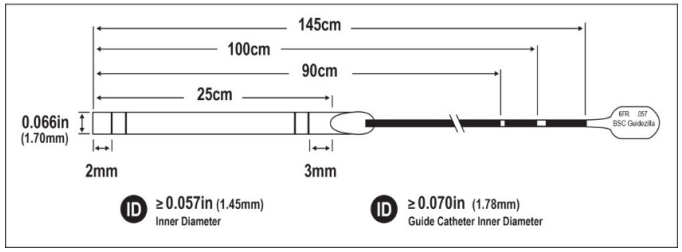
Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines.

Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.

maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	During use, the distal end portion of the Guidezilla tubular structure is maintained in position beyond the distal end of the guide catheter. While maintaining the distal end of the Guidezilla beyond the distal end of the guide catheter, an interventional device, such as a balloon catheter or stent, is advanced at least partially through the guide catheter and the Guidezilla and into the coronary artery, which involves advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along the substantially rigid segment of the Guidezilla, through the side opening, and through the tubular structure. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	When the distal end of the Guidezilla is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the Guidezilla and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 52 is performed by cardiologists using the Guidezilla with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	To use the Guidezilla, a distal end of a guide catheter having a lumen is advanced through a main blood vessel to a branch artery, e.g., an ostium of a coronary artery. Boston Scientific's documents confirm that Guidezilla is used with a guide catheter. "**Delivery Procedure**

	"Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;	Boston Scientific documents instruct the user to insert the distal end of Guidezilla through, and beyond the distal end of, the guide catheter, such that a distal end portion of a tubular structure of Guidezilla extends beyond the distal end of the guide catheter while a segment defining a side opening of Guidezilla remains within the catheter. The tubular structure and segment defining a side opening are shown in the photographs below, with the tubular portion colored blue:

"The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary.

	The Guidezilla defines a total length that is longer than the length of the continuous lumen of the guide catheter, such that a distal end portion of its tubular structure extends beyond the distal end of the guide catheter when inserted therein. The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A typical 6F guide catheter is 100cm long. **Guidezilla**  "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: . . . . "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter. "3. Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. . . . . "6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guidezilla device to prevent back-bleeding." Guidezilla Directions for Use at 3.

	The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. Because the guide catheter defines a lumen having a length of 100 cm, when the distal end of the Guidezilla extends beyond the distal end of the guide catheter, the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter. Based on my physical examination of the device, it is my opinion that the segment defining the side opening comprises a portion of the device that is more rigid than the distal end portion of the tubular structure.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and	During use, the distal end portion of the tubular structure is maintained in position beyond the distal end of the guide catheter.
while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid	Boston Scientific's documents instruct the user to insert the interventional cardiology device, e.g., a balloon catheter or stent, into and through the typical guide catheter and the Guidezilla and into the coronary artery. The balloon or stent is advanced through a hemostatic valve associated with a proximal end of the typical guide catheter, along the substantially rigid segment of the Guidezilla, through the side opening, and through the tubular structure. The Guidezilla Directions for Use state:

segment of the guide extension catheter, through the side opening, and through the tubular structure.	"5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.	In use, advancing the distal end of the Guidezilla through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.

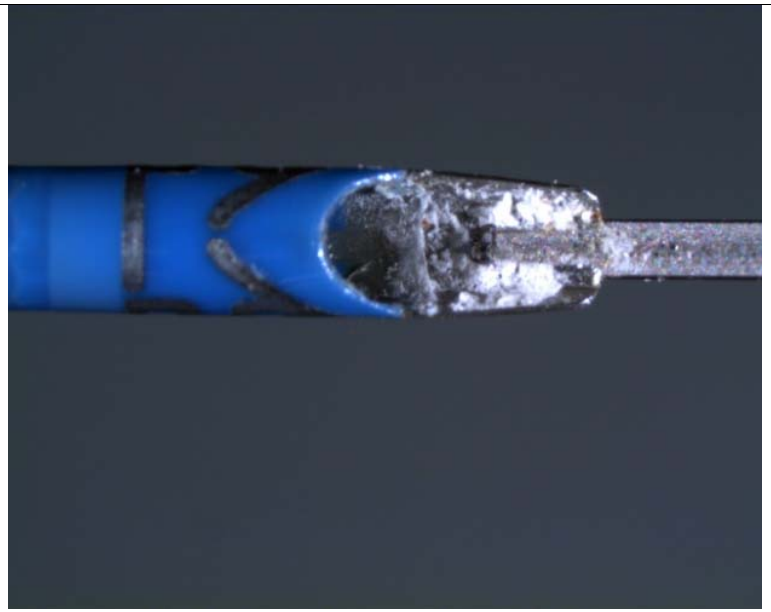
U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner	Boston Scientific's Guidezilla is a device for use with a standard guide catheter. "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of

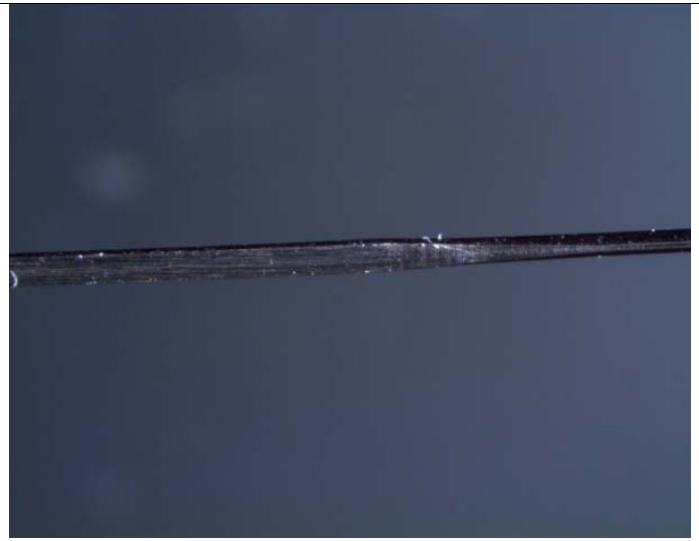
diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	interventional devices." Boston Scientific's 510(k) Summary; see also Guidezilla Directions for Use at 2. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The Guidezilla has a flexible tip portion that defines a tubular structure with a circular cross-section, which is the blue, tubular structure in the following photographs, and the tubular structure in the following drawing:

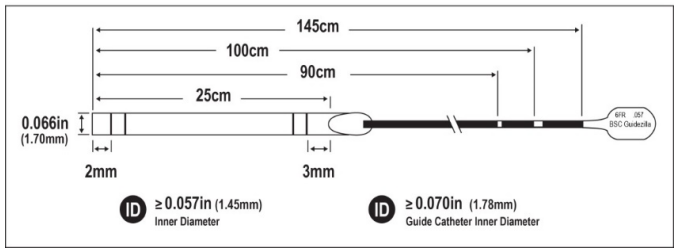
The Guidezilla has "a single lumen distal guide segment." Guidezilla Directions for Use at 2.

"GUIDEZILLA consists of . . . a distal guide catheter segment through which interventional devices may be delivered." Boston Scientific's 510(k) Summary.

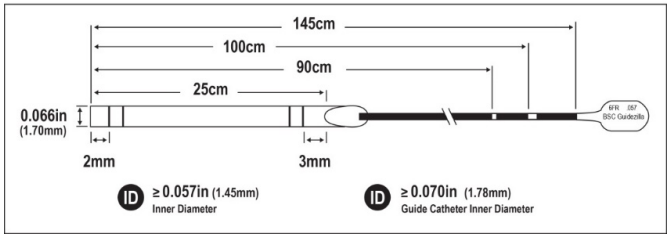
	The flexible tip portion's length is shorter than the 100cm length of the continuous lumen of a standard guide catheter. The tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable.
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,	"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." Guidezilla Directions for Use at 2. The attached photographs depict the Guidezilla's "stainless steel proximal shaft," which is substantially rigid, proximal of and operably connected to, and more rigid than the flexible tip portion, and it defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.

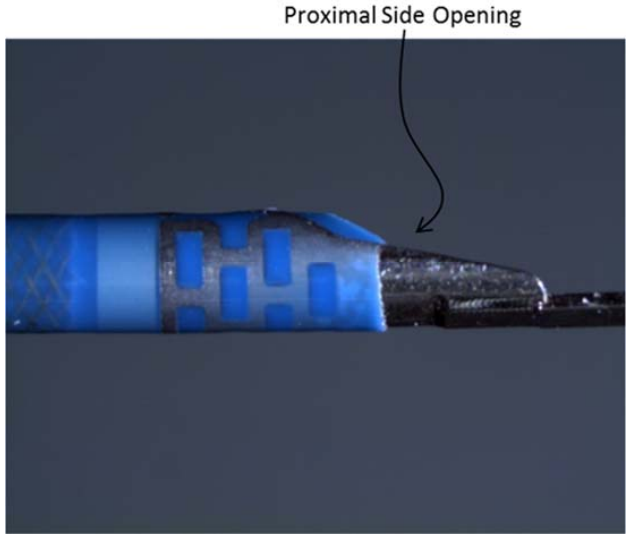
	

	 Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter and more rigid along a longitudinal direction than the flexible tip portion. The Guidezilla's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25. Guidezilla's substantially rigid portion is a stainless steel hypotube that is sealed shut at both ends. Although there is a minute, inaccessible, non-functional void inside the hypotube, it is my opinion that hypotube meets the "rail structure without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void inside the hypotube is insubstantially different from having no void at all. Nothing can pass

	through the hypotube because it it closed at both ends; it serves no meaningful purpose or function. The Guidezilla's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside). The rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is longer than the length of the continuous lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a length of 145cm. A standard 6F guide catheter is 100cm long. Guidezilla 
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common	When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve.

with interventional cardiology devices that are insertable into the guide catheter.	"The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary. The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3.
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	The tubular structure of the Guidezilla has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a tubular structure:

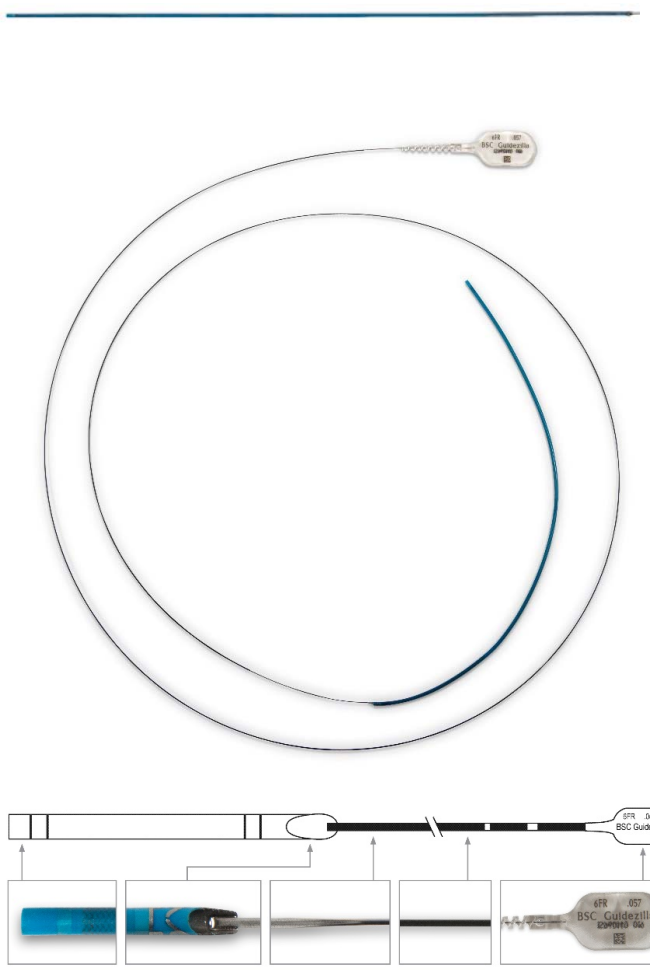
	Guidezilla  That the tubular structure has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter can be seen in that the tubular structure is advanced past the distal tip of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. See also above, in the discussion regarding claim 1. The Guidezilla device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible	The proximal portion of the Guidezilla's tubular structure includes a proximal side opening that extends for a distance along the device's longitudinal axis and is accessible from a longitudinal side that is transverse to the longitudinal axis, so that the opening can receive an

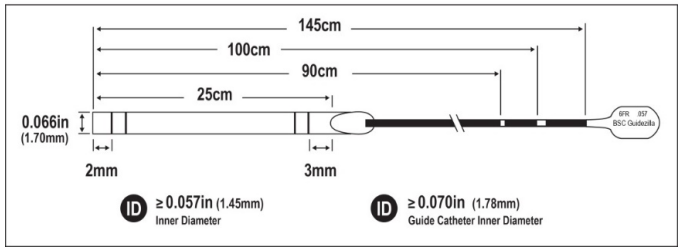
from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. This opening is shown in the following photograph of the Guidezilla device: 
8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of a standard 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2. "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary.

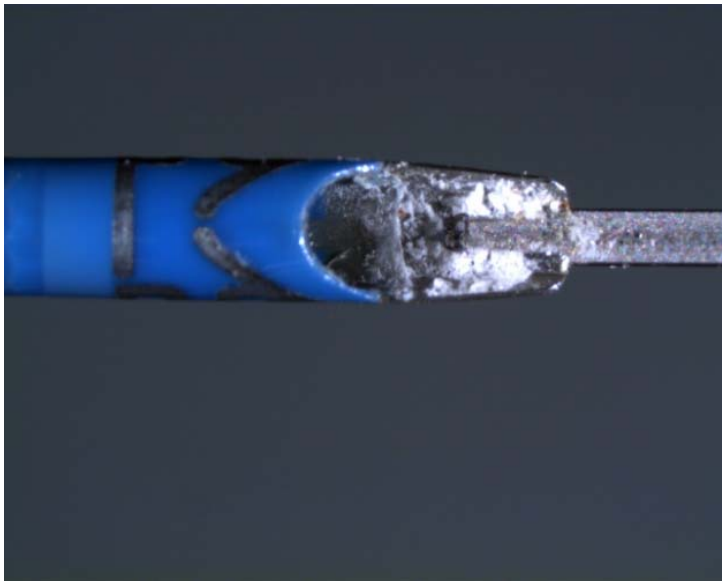
	"Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2. **Product Reference** Reference | Compatible Guide Catheter | Guidezilla I.D. /O.D. H7493924215050 | ≥ 6F / ≥ 0.070 in (1.78 mm) I.D. | 0.057 in (1.45 mm) 0.066 in (1.68 mm) Guidezilla Product Brochure, page 2. Guidezilla devices have an inner diameter of 0.057 inches and therefore meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. Guidezilla devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.

U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	A cardiologist using Boston Scientific's Guidezilla with a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	To use the Guidezilla, a standard guide catheter is inserted into a first artery over a guidewire. Boston Scientific's documents confirm that a guidewire is used with the catheter (see above) and Guidezilla. "Never advance the Guidezilla device into a vessel without a leading guidewire. . . ." Guidezilla Directions for Use at 2.

	"Other items required but not provided: . . . Guidewire with diameter ≤ 0.014 in (0.36 mm)." Guidezilla Directions for Use at 3.
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the Guidezilla, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery. "The Guidezilla guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Guidezilla Directions for Use at 2.
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	Boston Scientific documents instruct the user to insert the flexible tip portion of the Guidezilla coaxial guide catheter into the continuous lumen of the standard guide catheter. "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. . . ." Guidezilla Directions for Use at 3. Guidezilla has a flexible tip portion with a tubular structure and a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter. Guidezilla has a flexible tip portion that defines a tubular structure with a circular cross-section, which

	is the blue, tubular structure in the following photographs and the tubular structure in the diagram below: 

	Guidezilla has a tubular structure. It has "a single lumen distal guide segment." Guidezilla Directions for Use at 2. "GUIDEZILLA consists of . . . a distal guide catheter segment through which interventional devices may be delivered." Boston Scientific's 510(k) Summary. The flexible tip portion's length is shorter than the length of the continuous lumen of the guide catheter: **Guidezilla**  A standard 6F guide catheter length is 100cm. The tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The Guidezilla guide extension catheter is "a single lumen rapid exchange catheter. . . " Guidezilla Directions for Use at 2.
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis	Guidezilla has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis

than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	than the flexible tip portion. This is the "stainless steel proximal shaft" of the Guidezilla device. Guidezilla Directions for Use at 2. The attached photographs depict Guidezilla's "stainless steel proximal shaft," which is substantially rigid, proximal of and operably connected to, and more rigid than the flexible tip portion, and it defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion. 

	 The Guidezilla's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25. Guidezilla's substantially rigid portion is a stainless steel hypotube that is sealed shut at both ends. Although there is a minute, inaccessible, non-functional void inside the hypotube, it is my opinion that hypotube meets the "rail structure without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void inside the hypotube is insubstantially different from having no void at all. Nothing can pass through the hypotube because it it closed at both ends; it serves no meaningful purpose or function. The Guidezilla's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without

	blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside). Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter and more rigid than a longitudinal axis than the flexible tip portion. The rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 145cm, longer than the standard 100cm length of the continuous lumen of the guide catheter. When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary. The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3.

	"Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3. This substantially rigid portion of the Guidezilla device is inserted into the continuous lumen of the standard guide catheter, as noted above from the Directions for Use, which instruct the user to insert the Guidezilla device into the guide catheter "until the device is just proximal to the hemostasis valve." Guidezilla Directions for Use at 3.
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	A distal portion of the Guidezilla's flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: . . . . "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter.

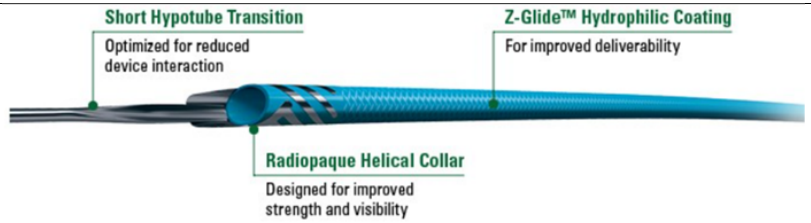
	"3. Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. . . . . "6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guidezilla device to prevent back-bleeding." Guidezilla Directions for Use at 3.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	Boston Scientific's documents instruct the user to insert the interventional cardiology device into and through the continuous lumen of the standard guide catheter, alongside the substantially rigid portion, and to advance the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery. "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: . . . . "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3.
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure	When the Guidezilla is used, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion

while the proximal portion remains within the lumen of the guide catheter.	of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The Guidezilla Directions for Use state: "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3.

U.S. Patent No. RE45,380 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	**Guidezilla II**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	The combination of Boston Scientific's Guidezilla II and a guide catheter forms a system for use with interventional cardiology devices adapted to be insertable into a branch artery.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	The Guidezilla II is used in conjunction with a guide catheter. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335. A typical guide catheter has a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, where the continuous lumen of the guide catheter has a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter.
a device adapted for use with the guide catheter, including:	The Guidezilla II is adapted for use with a guide catheter. "We designed Guidezilla II to self-align upon insertion into a guide catheter." Boston Scientific's "GUIDEZILLA II Guide Extension Catheter Development Video" at 2:03 (viewed

	July 2, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html)
a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The Guidezilla II has a flexible tip portion that defines a tubular structure with a circular cross-section, as shown in the following drawing:  "It has a soft, atraumatic tip to prevent vessel damage." Boston Scientific's "GUIDEZILLA II Guide Extension Catheter Development Video" at 1:00 (viewed July 2, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html) The flexible tip portion is shorter than the predefined length of the continuous lumen of the guide catheter into which it is inserted. "The Guidezilla II Guide Extension Catheter consists of … a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The flexible tip portion's length is shorter than the 100 cm length of the continuous lumen of a typical guide catheter. Based on my physical examination of the product, it is my opinion that the tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a

	coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable.
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter;	The Guidezilla II includes a substantially rigid portion in the form of a stainless steel hypotube. The stainless steel hypotube is rigid enough to advance the device within a guide catheter and is more rigid along a longitudinal axis that the flexible tip portion of the device. In the two point bend testing, the Guidezilla II had a higher maximum force value for the proximal shaft portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values. See Expert Report, Appendix D at 1. "The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube, which includes a handle used for device identification, and a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered. The proximal hypotube is connected to the distal guide catheter segment by a small collar." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The drawing below depicts the stainless steel hypotube, which is proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, and defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.

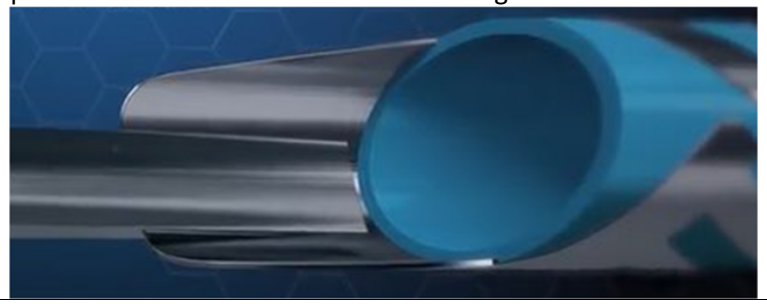


The Guidezilla II's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25.

Guidezilla II's substantially rigid portion is a stainless steel hypotube that is sealed shut at both ends. Although there is a minute, inaccessible, non-functional void inside the hypotube, it is my opinion that hypotube meets the "rail structure without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void inside the hypotube is insubstantially different from having no void at all. Nothing can pass through the hypotube because it it closed at both ends; it serves no meaningful purpose or function. The Guidezilla II's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside).

Boston Scientific's Guidezilla II webpage shows that the Guidezilla II has a length of 150cm. A typical 6F guide catheter is 100 cm long. Accordingly, the rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is longer than the length of the continuous lumen of the guide catheter.

The distal end of the Guidezilla II extends past the distal end of the guide catheter: "The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and

	extends an additional 15 cm out the distal end of the parent guide catheter." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Based on my physical examination of the product, it is my opinion that when the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve.
wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible cylindrical distal tip portion and wherein the flexible cylindrical distal tip portion is more flexible than the flexible cylindrical reinforced portion.	The tubular structure of the Guidezilla II includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the distal tip portion. Based on my physical examination of the device, it is my opinion that the distal tip portion is more flexible than the reinforced portion. The results of the "crush" testing clearly show that the Guidezilla II's flexible cylindrical distal tip portion is more flexible than its flexible cylindrical reinforced portion. See Appendix D at 1-2, comparing "Crush 1" values to "Crush 2" and "Crush 3" values.
3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	The proximal portion of the Guidezilla II's tubular structure includes a proximal side opening that extends for a distance along the device's longitudinal axis and is accessible from a longitudinal side that is transverse to the longitudinal axis, so that the opening can receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. 

<table>
<tr><td></td><td>  </td></tr>
<tr><td>8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.</td><td>For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II’s coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter.

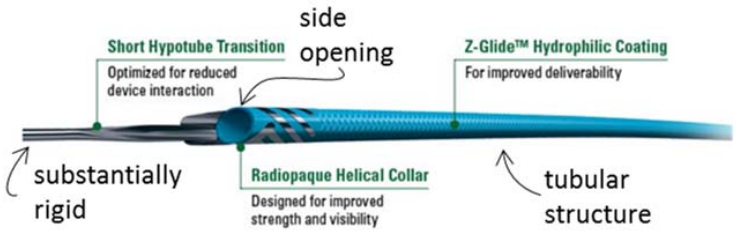
The Guidezilla II has an “expanded size matrix” that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific’s Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335.

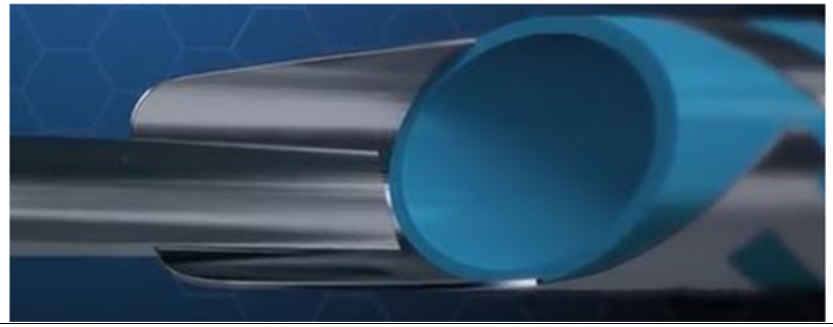
The inner diameter of the 6F devices is .057 inches.

<table>
<tr><th>Size</th><th>GTIN</th><th>Ref/Catalog Number</th><th>Compatible Guide Catheter</th><th>Inner Diameter</th></tr>
<tr><td>6F</td><td>08714729939450</td><td>H7493933515060</td><td>6F I.D. ≥0.070" (1.78mm)</td><td>0.057" (1.45 mm)</td></tr>
<tr><td>6F LONG (40 cm)</td><td>08714729939467</td><td>H74939335150610</td><td>6F I.D. ≥0.070" (1.78 mm)</td><td>0.057" (1.45 mm)</td></tr>
<tr><td>7F</td><td>08714729939474</td><td>H7493933515070</td><td>6F I.D. ≥0.078" (1.98 mm)</td><td>0.063" (1.60 mm)</td></tr>
<tr><td>8F</td><td>08714729939481</td><td>H7493933515080</td><td>6F I.D. ≥0.088" (2.24 mm)</td><td>0.072" (1.83 mm)</td></tr>
</table>
</td></tr>
</table>

	6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. 6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.

U.S. Patent No. RE45,760 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
25. A system, comprising:	The combination of the Guidezilla II with a guide catheter forms a system.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	The Guidezilla II is used in conjunction with a guide catheter. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335. A typical guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, e.g., adjacent the ostium of a coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter having a length such that a distal end of the guide extension catheter is extendable through the lumen and	The Guidezilla II is a guide extension catheter configured to be partially advanceable through a guide catheter into the coronary artery. The tubular structure of the Guidezilla II has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter. "The Boston Scientific Guidezilla™ and Guidezilla™ II LONG Guide Extension Catheters act as extensions to traditional guide catheters. The Guidezilla II Guide Extension Catheter

beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter, providing physicians with additional support to advance interventional devices into the vasculature." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The Boston Scientific Guidezilla II webpage shows that the Guidezilla II has a length of 150cm. A typical 6F guide catheter is 100 cm long. Accordingly, the Guidezilla II has a total length that is longer than the length of the continuous lumen of the guide catheter. When the distal end of the Guidezilla II is extended distally of the distal end of the guide catheter, at least a portion of the proximal end is extendable through the hemostatic valve.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side opening extending for a distance along a longitudinal axis of the	The Guidezilla II includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown in the following annotated drawing:  The Guidezilla II includes a substantially rigid portion in the form of a stainless steel hypotube. Based on my physical examination of the device, it is my opinion that the stainless steel hypotube is rigid enough to advance the device within a guide catheter.

segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	"The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube, which includes a handle used for device identification, and a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered. The proximal hypotube is connected to the distal guide catheter segment by a small collar." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The lumen of the tubular structure has a length that is shorter than the 100 cm length of the lumen defined by the guide catheter. Based on my physical examination of the product, it is my opinion that the tubular structure has a uniform cross-sectional inner diameter through which interventional cardiology devices are insertable. The side opening of the Guidezilla II extends for a distance along the longitdunal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis. This opening is shown in the following drawings of the device: 

	 When the Guidezilla is used, an interventional cardiology device, e.g., a stent or balloon catheter, is extended through the side opening and the lumen of the tubular structure. "GUIDEZILLA II Guide Extension Catheter creates a smooth pathway for balloon and/or stent delivery by providing greater flexibility and a smooth surface." Boston Scientific's Guidezilla II webpage - Product Details (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335. Because the guide catheter defines a lumen having a length of 100 cm, when the distal end of the Guidezilla II extends beyond the distal end of the guide catheter, the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter. For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter.

The Guidezilla II has an "expanded size matrix" that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific's Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335.

The inner diameter of the 6F devices is .057 inches.

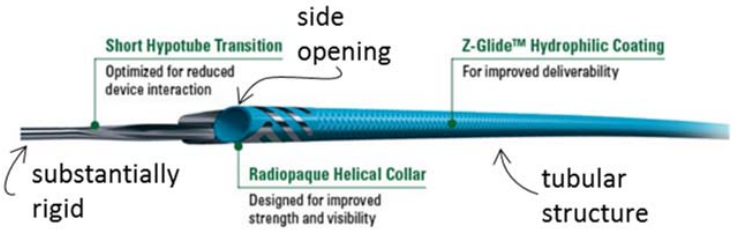
Size	GTIN	Ref/Catalog Number	Compatible Guide Catheter	Inner Diameter
6F	08714729939450	H7493933515060	6F I.D. ≥0.070" (1.78mm)	0.057" (1.45 mm)
6F LONG (40 cm)	08714729939467	H74939335150610	6F I.D. ≥0.070" (1.78 mm)	0.057" (1.45 mm)
7F	08714729939474	H7493933515070	6F I.D. ≥0.078" (1.98 mm)	0.063" (1.60 mm)
8F	08714729939481	H7493933515080	6F I.D. ≥0.088" (2.24 mm)	0.072" (1.83 mm)

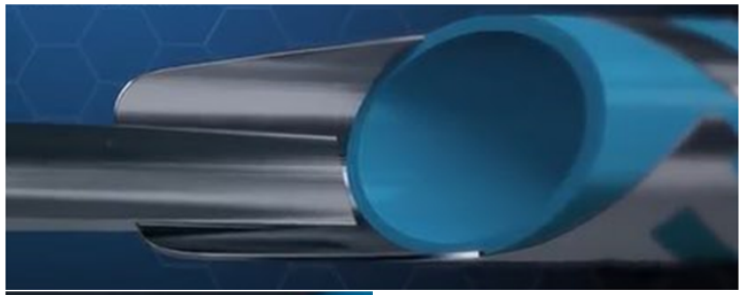
6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines.

6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my

	opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
wherein a material forming the segment defining the side opening is more rigid than the tubular structure.	The matter forming the segment of the side opening is more rigid than the tubular structure. Two point bend testing of the Guidezilla II shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
30. The system of claim 25, wherein the segment defining the side opening defines a concave track configured to guide the one or more stents or balloon catheters along a length of the concave track.	As shown in the drawing below, the segment defining the side opening of the Guidezilla II defines a concave track configured to guide an interventional device, e.g., a stent or balloon catheter, along a length thereof: 
31. The system of claim 25, wherein the segment defining the side opening includes at least one inclined slope.	As shown in the drawing below, the segment defining the side opening of the Guidezilla II defines at lease one inclined slope:

	
48. A system, comprising:	The combination of the Guidezilla II with a guide catheter forms a system.
a guide catheter configured to be advanceable through a main blood vessel to a position adjacent an ostium of a coronary artery, the guide catheter having a lumen extending from a hemostatic valve at a proximal end of the guide catheter to a distal end of the guide catheter that is adapted to be positioned adjacent the ostium of the coronary artery; and	The Guidezilla II is used in conjunction with a guide catheter. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335. A typical guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, e.g., adjacent the ostium of a coronary artery.
a guide extension catheter configured to be partially advanceable through the guide catheter and into the coronary artery, the guide extension catheter	The Guidezilla II is a guide extension catheter configured to be partially advanceable through a guide catheter into the coronary artery. The tubular structure of the Guidezilla II has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal end of the Guidezilla II is extendable through the hemostatic valve at the proximal end of the guide catheter.

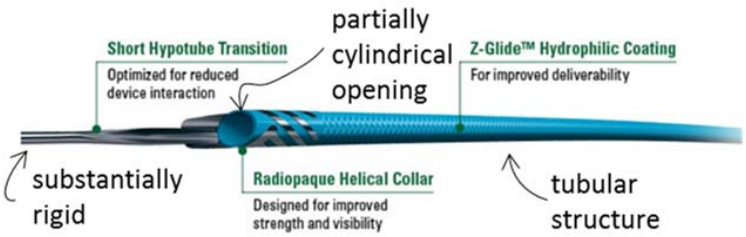
having a length such that a distal end of the guide extension catheter is extendable through the lumen and beyond the distal end of the guide catheter, and a proximal end of the guide extension catheter is extendable through the hemostatic valve at the proximal end of the guide catheter,	"The Boston Scientific Guidezilla™ and Guidezilla™ II LONG Guide Extension Catheters act as extensions to traditional guide catheters. The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter, providing physicians with additional support to advance interventional devices into the vasculature." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Boston Scientific's Guidezilla II webpage shows that the Guidezilla II has a length of 150cm. A typical 6F guide catheter is 100 cm long. Accordingly, the Guidezilla II has a total length that is longer than the length of the continuous lumen of the guide catheter. When the distal end of the Guidezilla II is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve.
the guide extension catheter including, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, the lumen of the tubular structure having a length that is shorter than the length of the lumen of the guide catheter and having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, the side	The Guidezilla II includes, in a proximal to distal direction, a substantially rigid segment, a segment defining a side opening, and a tubular structure defining a lumen coaxial and in fluid communication with the lumen of the guide catheter, as shown in the following annotated drawing:  "The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube, which includes a handle used for device identification, and a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered. The proximal

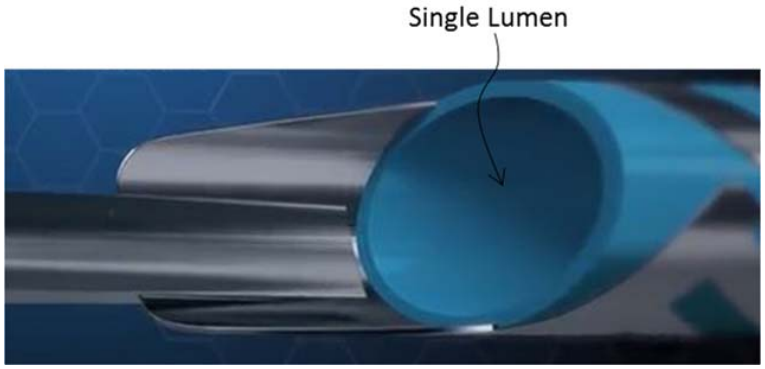
opening extending for a distance along a longitudinal axis of the segment defining the side opening and accessible from a longitudinal side defined transverse to the longitudinal axis, and the side opening and the lumen of the tubular structure configured to receive one or more stents or balloon catheters when the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter and the distal end of the guide extension catheter extends beyond the distal end of the guide catheter;	hypotube is connected to the distal guide catheter segment by a small collar." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The lumen of the tubular structure has a length which is shorter than the 100 cm length of the lumen defined by the guide catheter. Based on my physical examination of the product, it is my opinion that the tubular structure has a uniform cross-sectional inner diameter through which interventional cardiology devices are insertable. The side opening of the Guidezilla II extends for a distance along the longitudinal axis of the segment defining the side opening and is accessible from a longitudinal side defined transverse to the longitudinal axis. This opening is shown in the following drawings of the device:  

	When the Guidezilla is used, an interventional cardiology device, e.g., a stent or balloon catheter, is extended through the side opening and the lumen of the tubular structure. "GUIDEZILLA II Guide Extension Catheter creates a smooth pathway for balloon and/or stent delivery by providing greater flexibility and a smooth surface." Boston Scientific's Guidezilla II webpage - Product Details (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056326. Because the the guide catheter defines a lumen having a length of 100 cm, when the distal end of the Guidezilla II extends beyond the distal end of the guide catheter, the segment defining the side opening and a proximal end portion of the tubular structure are positioned within the lumen of the guide catheter. For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter. The Guidezilla II has an "expanded size matrix" that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific's Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335. The inner diameter of the 6F devices is .057 inches.

	<table><tr><th>Size</th><th>GTIN</th><th>Ref/Catalog Number</th><th>Compatible Guide Catheter</th><th>Inner Diameter</th></tr><tr><td>6F</td><td>08714729939450</td><td>H7493933515060</td><td>6F I.D. ≥0.070" (1.78mm)</td><td>0.057" (1.45 mm)</td></tr><tr><td>6F LONG (40 cm)</td><td>08714729939467</td><td>H74939335150610</td><td>6F I.D. ≥0.070" (1.78 mm)</td><td>0.057" (1.45 mm)</td></tr><tr><td>7F</td><td>08714729939474</td><td>H7493933515070</td><td>6F I.D. ≥0.078" (1.98 mm)</td><td>0.063" (1.60 mm)</td></tr><tr><td>8F</td><td>08714729939481</td><td>H7493933515080</td><td>6F I.D. ≥0.088" (2.24 mm)</td><td>0.072" (1.83 mm)</td></tr></table> 6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. 6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
wherein the segment defining the side opening comprises a portion of the guide extension catheter that is	The segment defining the side opening comprises a portion of the device that is more rigid than a distal end of the tubular structure. Two point bend testing of the Guidezilla II shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all

more rigid than a distal end portion of the tubular structure.	higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

U.S. Patent No. RE45,776 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
25. A guide extension catheter for use with a guide catheter, comprising:	Boston Scientific's Guidezilla II is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The Guidezilla II includes a substantially rigid segment. "The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The Guidezilla II includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment, as shown in the annotated drawing below: 

a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material more rigid than a material or material combination forming the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The Guidezilla II defines a partially cylindrical opening having an angled proximal end positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown in the drawing above. The segment defining the partially cylindrical openining is formed from matter more rigid than the matter forming the tubular structure. Two point bend testing of the Guidezilla II shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1. In operation, the particially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.	Based on my physical examination of the product, it is my opinion that the cross-section of Guidezilla II at the proximal end of the tubular structure defines a single lumen, for example as shown in the drawing below: 

30. [NOT ASSERTED] The guide extension catheter of claim 25, wherein the guide catheter includes a lumen having a cross-sectional inner diameter of six French, seven French or eight French and wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.

For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter.

The Guidezilla II has an "expanded size matrix" that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific's Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335.

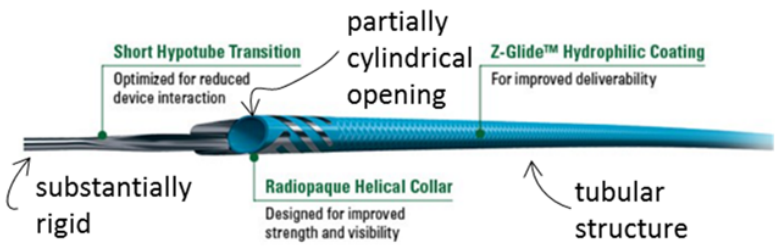
The inner diameter of the 6F devices is .057 inches.

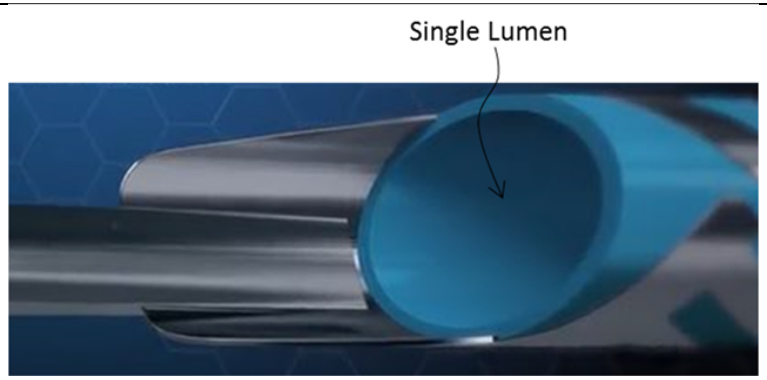
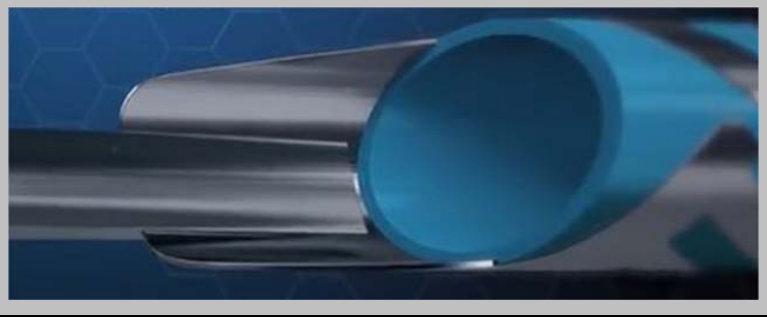
Size	GTIN	Ref/Catalog Number	Compatible Guide Catheter	Inner Diameter
6F	08714729939450	H7493933515060	6F I.D. ≥0.070" (1.78mm)	0.057" (1.45 mm)
6F LONG (40 cm)	08714729939467	H74939335150610	6F I.D. ≥0.070" (1.78 mm)	0.057" (1.45 mm)
7F	08714729939474	H7493933515070	6F I.D. ≥0.078" (1.98 mm)	0.063" (1.60 mm)
8F	08714729939481	H7493933515080	6F I.D. ≥0.088" (2.24 mm)	0.072" (1.83 mm)

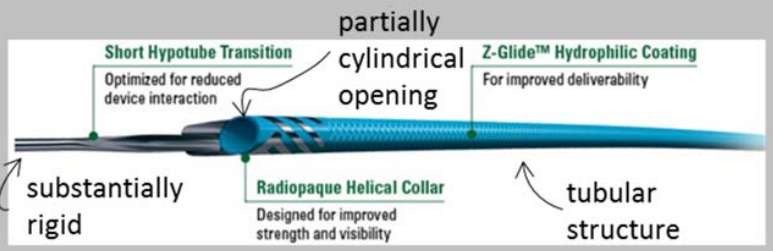
6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines.

6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside

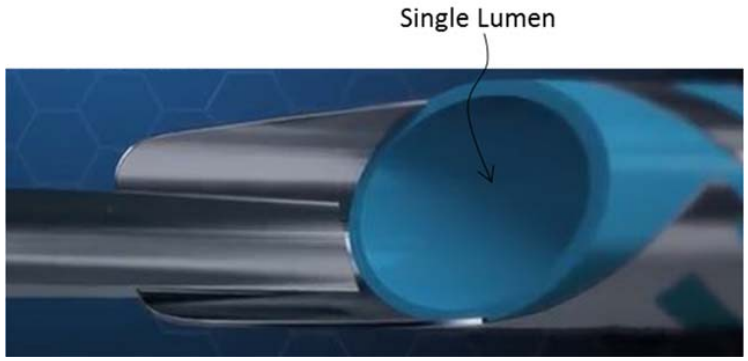
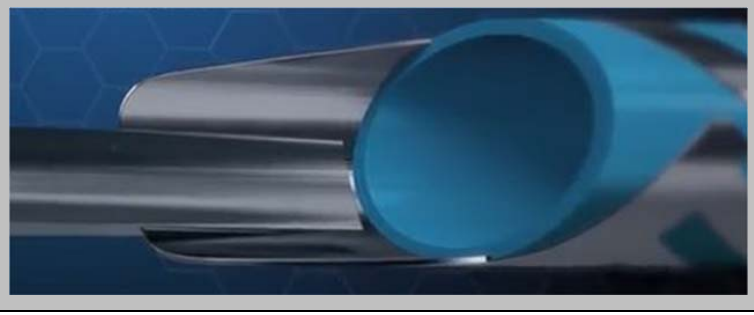
	the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
32. The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.	When the Guidezilla II is used, an interventional cardiology device, e.g., a stent or balloon catheter, is extended through the lumen of the tubular structure. "GUIDEZILLA II Guide Extension Catheter creates a smooth pathway for balloon and/or stent delivery by providing greater flexibility and a smooth surface." Boston Scientific's Guidezilla II webpage - Product Details (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html) , VSIQXM_E00056335.
52. A guide extension catheter for use with a guide catheter, comprising:	Boston Scientific's Guidezilla II is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The Guidezilla II includes a substantially rigid segment. "The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and	The Guidezilla II includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment, as shown in the annotated drawing below:

	
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a material having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter,	The Guidezilla II defines a partially cylindrical opening having an angled proximal end positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown in the drawing above. In operation, the particially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. The segment defining the partially cylindrical opening having an angled proximal end is formed from matter having a greater flexural modulus than a flexural modulus of the tubular structure. Two point bend testing of the Guidezilla II shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.
wherein a cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen;	Based on my physical examination of the product, it is my opinion that the cross-section of Guidezilla II at the proximal end of the tubular structure defines a single lumen, for example as shown in the drawing below:

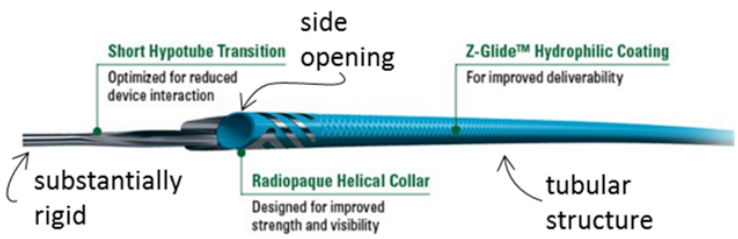
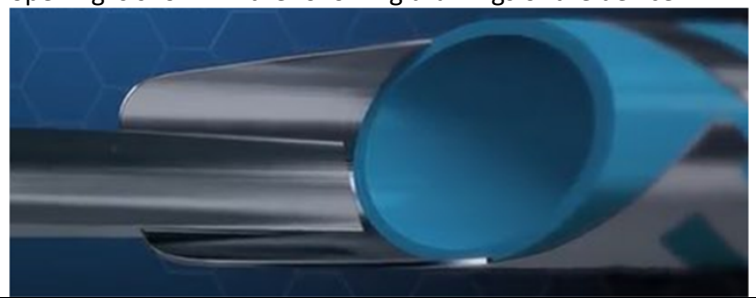
	
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	As shown in the photograph below, the segment defining the side opening of the Guidezilla II includes at least two inclined regions: 
53. A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:	Boston Scientific's Guidezilla II is a guide extension catheter for use with a guide catheter.
a substantially rigid segment;	The Guidezilla II includes a substantially rigid segment.

	"The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and	The Guidezilla II includes a tubular structure defining a lumen, which is positioned distal to the substantially rigid segment, as shown in the annotated drawing below:  For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter. The Guidezilla II has an "expanded size matrix" that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific's Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335. The inner diameter of the 6F devices is .057 inches.

	<table><tr><th>Size</th><th>GTIN</th><th>Ref/Catalog Number</th><th>Compatible Guide Catheter</th><th>Inner Diameter</th></tr><tr><td>6F</td><td>08714729939450</td><td>H7493933515060</td><td>6F I.D. ≥0.070" (1.78mm)</td><td>0.057" (1.45 mm)</td></tr><tr><td>6F LONG (40 cm)</td><td>08714729939467</td><td>H74939335150610</td><td>6F I.D. ≥0.070" (1.78 mm)</td><td>0.057" (1.45 mm)</td></tr><tr><td>7F</td><td>08714729939474</td><td>H7493933515070</td><td>6F I.D. ≥0.078" (1.98 mm)</td><td>0.063" (1.60 mm)</td></tr><tr><td>8F</td><td>08714729939481</td><td>H7493933515080</td><td>6F I.D. ≥0.088" (2.24 mm)</td><td>0.072" (1.83 mm)</td></tr></table> 6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. 6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular	The Guidezilla II defines a partially cylindrical opening having an angled proximal end positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, as shown in the drawing above.

structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen;	In operation, the particially cylindrical opening is configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter. Based on my physical examination of the product, it is my opinion that the cross-section of Guidezilla II at the proximal end of the tubular structure defines a single lumen, for example as shown in the drawing below: 
wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.	As shown in the photograph below, the segment defining the side opening of the Guidezilla II includes at least two inclined regions: 

U.S. Patent No. RE46,116 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
25. A method, comprising:	The method of claim 25 is performed by cardiologists using the Guidezilla II with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	To use the Guidezilla II, a distal end of a typical guide catheter having a lumen is advanced through a main blood vessel to a branch artery, e.g., an ostium of a coronary artery. Boston Scientific's marketing materials and FDA submissions confirm that the Guidezilla II is used with a guide catheter. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335.
advancing a distal end of a guide extension catheter through, and beyond the distal end of, the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension	Boston Scientific's public disclosures instruct the user to insert the distal end of the Guidezilla II through, and beyond the distal end of, the guide catheter, such that a distal end portion of a tubular structure of Guidezilla II extends beyond the distal end of the guide catheter while a segment defining a side opening of the Guidezilla II remains within the guide catheter. The tubular structure and segment defining a side opening are shown in the drawing below:

catheter remains within the guide catheter, the side opening extending for a distance along a longitudinal axis of the guide extension catheter and accessible from a longitudinal side defined transverse to the longitudinal axis, the tubular structure having a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter;	 "The Boston Scientific Guidezilla™ and Guidezilla™ II LONG Guide Extension Catheters act as extensions to traditional guide catheters. The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter, providing physicians with additional support to advance interventional devices into the vasculature." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The lumen of the tubular structure is shorter than the 100 cm length of the lumen defined by the guide catheter. Accordingly, when the distal end of the Guidezilla II extends beyond the distal end of the guide catheter, the segment defining the side opening remains within the guide catheter lumen. The side opening extends for a distance along a longitudinal axis of the Guidezilla II and is accessible from a longitudinal side defined transverse to the longitudinal axis. This opening is shown in the following drawings of the device: 

For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the typical 6F guide catheter.

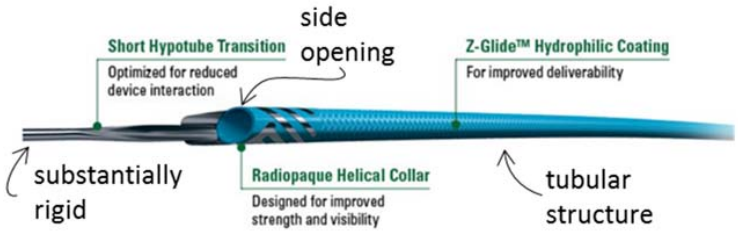
The Guidezilla II has an "expanded size matrix" that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific's Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335.

The inner diameter of the 6F devices is .057 inches.

Size	GTIN	Ref/Catalog Number	Compatible Guide Catheter	Inner Diameter
6F	08714729939450	H7493933515060	6F I.D. ≥0.070" (1.78mm)	0.057" (1.45 mm)
6F LONG (40 cm)	08714729939467	H74939335150610	6F I.D. ≥0.070" (1.78 mm)	0.057" (1.45 mm)
7F	08714729939474	H7493933515070	6F I.D. ≥0.078" (1.98 mm)	0.063" (1.60 mm)
8F	08714729939481	H7493933515080	6F I.D. ≥0.088" (2.24 mm)	0.072" (1.83 mm)

	6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines. 6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter	In use, the distal end portion of the tubular structure is maintained in position beyond the distal end of the guide catheter. While maintaining the distal end of the Guidezilla II beyond the distal end of the guide catheter, an interventional device, such as a balloon catheter or stent, is advanced at least partially through the guide catheter and the Guidezilla II and into the coronary artery, which involves advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along the substantially rigid segment of the Guidezilla II, through the side opening, and through the tubular structure. "GUIDEZILLA II Guide Extension Catheter creates a smooth pathway for balloon and/or stent delivery by providing greater flexibility and a smooth surface." Boston Scientific's Guidezilla II webpage - Product Details (accessed Dec. 14, 2018 at

and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
34. The method of claim 25, wherein advancing the distal end of the guide extension catheter through, and beyond the distal end of, the guide catheter includes establishing fluid communication between the tubular structure of the guide extension catheter and the lumen of the guide catheter.	When the distal end of the Guidezilla II is advanced through, and beyond the distal end of, the guide catheter, a fluid communication is established between the tubular structure of the Guidezilla II and the lumen of the guide catheter.
52. A method, comprising: [NOT ASSERTED]	The method of claim 25 is performed by cardiologists using the Guidezilla II with a guide catheter and balloon catheter or stent for a coronary vascular procedure as described in the Instructions for Use.
advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery;	To use the Guidezilla II, a distal end of a typical guide catheter having a lumen is advanced through a main blood vessel to a branch artery, e.g., an ostium of a coronary artery. Boston Scientific's marketing materials and FDA submissions confirm that the Guidezilla II is used with a guide catheter. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature,

	and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335.
advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter, wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;	Boston Scientific's public disclosures instruct the user to insert the distal end of the Guidezilla II through, and beyond the distal end of, the guide catheter, such that a distal end portion of a tubular structure of the Guidezilla II extends beyond the distal end of the guide catheter while a segment defining a side opening of the Guidezilla II remains within the guide catheter. The tubular structure and segment defining a side opening are shown in the drawing below:  "The Boston Scientific Guidezilla™ and Guidezilla™ II LONG Guide Extension Catheters act as extensions to traditional guide catheters. The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter, providing physicians with additional support to advance interventional devices into the vasculature." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The segment defining the side opening comprises a portion of the device that is more rigid than the the distal end portion of the tubular structure. Two point bend testing of the Guidezilla II shows that the side opening segment is more rigid than the tubular structure. The maximum load values for the side opening segment ("Flex 3 up" and "Flex 3 down") are all higher than the maximum load values for the distal tubular structure ("Flex 1"). Expert Report, Appendix D at 1.

	"It has a soft, atraumatic tip to prevent vessel damage." Boston Scientific's "GUIDEZILLA II Guide Extension Catheter Development Video" at 1:00 (viewed July 2, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html)
maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and	In use, the distal end portion of the tubular structure is maintained in position beyond the distal end of the guide catheter when in use.
while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure.	While maintaining the distal end of the Guidezilla II beyond the distal end of the guide catheter, an interventional device, such as a balloon catheter or stent, is advanced at least partially through the guide catheter and the Guidezilla II and into the coronary artery, which involves advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along the substantially rigid segment of the Guidezilla II, through the side opening, and through the tubular structure. "GUIDEZILLA II Guide Extension Catheter creates a smooth pathway for balloon and/or stent delivery by providing greater flexibility and a smooth surface." Boston Scientific's Guidezilla II webpage - Product Details (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter.
53. The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side	In use, advancing the distal end of the Guidezilla II through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter.

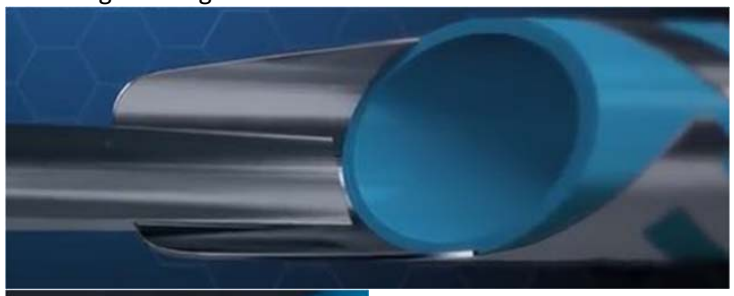
opening within the guide catheter for receiving the treatment catheter.	

U.S. Patent No. 8,048,032 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
1. A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:	Boston Scientific's Guidezilla II is a device for use with a standard guide catheter. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide	The Guidezilla II has a flexible tip portion defining a tubular structure having a circular cross-section, as shown in the following drawing:

catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	 "The Guidezilla II Guide Extension Catheter consists of … a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The flexible tip portion's length is shorter than the 100 cm length of the continuous lumen of a standard guide catheter. Based on my physical examination of the product, it is my opinion that the tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable.
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the	The Guidezilla II includes a substantially rigid portion comprised of a proximal stainless steel hypotube. The stainless steel shaft is rigid enough to advance the device within a guide catheter and more rigid along a longitudinal axis than the flexible tip portion. In the two point bend testing, the Guidezilla II had a higher maximum force value for the proximal shaft portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values. See Expert Report, Appendix D at 1. "The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube, which includes a handle used for device identification, and a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered. The proximal hypotube is connected to the distal guide catheter segment by a small collar." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335.

device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,	The drawing below depicts the Guidezilla II's stainless steel hypotube, which is proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, and defines a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  The Guidezilla II's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25. Guidezilla II's substantially rigid portion is a stainless steel hypotube that is sealed shut at both ends. Although there is a minute, inaccessible, non-functional void inside the hypotube, it is my opinion that hypotube meets the "rail structure without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void inside the hypotube is insubstantially different from having no void at all. Nothing can pass through the hypotube because it it closed at both ends; it serves no meaningful purpose or function. The Guidezilla II's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result (i.e., advancing the device while allowing interventional cardiology devices to pass alongside). The Boston Scientific Guidezilla II webpage shows that the Guidezilla II has a length of 150cm. A standard 6F guide catheter is 100 cm long. Accordingly, the substantially rigid

	portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is longer than the length of the continuous lumen of the guide catheter.
such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve. The distal end of the Guidezilla extends past the distal end of the guide catheter: "The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Based on my physical examination of the product, it is my opinion that the proximal end of the Guidezilla II extends from the proximal end of the guide catheter, through a hemostasis device.
2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	The tubular structure of the Guidezilla II has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter. That a proximal portion of the tubular structure remains within the lumen of the guide catheter while a distal portion is extended beyond the distal end of the guide catheter can be seen in that the length of the tubular structure is shorter than the 100 cm length of the lumen defined by the guide catheter. Accordingly, when the distal end of the Guidezilla II extends 15 cm beyond the distal end of the guide catheter, the segment defining the side opening remains within the guide catheter. The Guidezilla II assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
3. The device of claim 2 wherein the proximal portion of the tubular	The proximal portion of the tubular structure of the Guidezilla II includes a proximal side opening that extends for a distance along the device's longitudinal axis and is accessible

structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	from a longitudinal side that is transverse to the longitudinal axis, so that the opening can receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. This opening is shown in the following drawings of the device:  
8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	For the six French sizes of the Guidezilla II, the cross-sectional inner diameter of the Guidezilla II's coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the standard 6F guide catheter. The Guidezilla II has an "expanded size matrix" that includes sizes of 6F, 7F, 8F, and 6F long. Boston Scientific's Guidezilla II webpage – Design Changes (accessed Dec. 14, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html), VSIQXM_E00056335.

The inner diameter of the 6F devices is .057 inches.

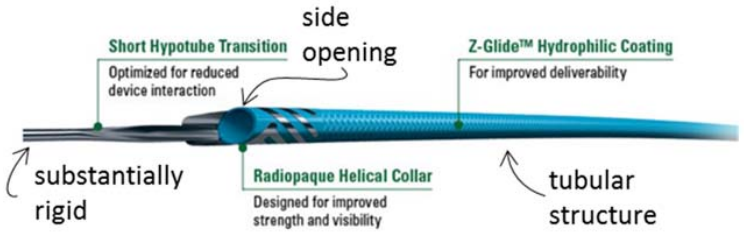
Size	GTIN	Ref/Catalog Number	Compatible Guide Catheter	Inner Diameter
6F	08714729939450	H7493933515060	6F I.D. ≥0.070" (1.78mm)	0.057" (1.45 mm)
6F LONG (40 cm)	08714729939467	H74939335150610	6F I.D. ≥0.070" (1.78 mm)	0.057" (1.45 mm)
7F	08714729939474	H7493933515070	6F I.D. ≥0.078" (1.98 mm)	0.063" (1.60 mm)
8F	08714729939481	H7493933515080	6F I.D. ≥0.088" (2.24 mm)	0.072" (1.83 mm)

6F Guidezilla II devices meet this limitation literally when combined with a guide catheter having an inner diameter of 0.070 inches as set forth in the product compatibility guidelines.

6F Guidezilla II devices also meet this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter. In that case, the difference in diameter between the devices is 0.014 inches—just barely more than one French. It is my opinion that any difference between this and the literal scope of the claim is insubstantial. Whether the difference in diameter is 0.014 or 0.0131 inches, the Guidezilla device is used in substantially the same way, i.e., by inserting the device into a guide catheter with a very small gap between the outer diameter of the device and the inner diameter of the guide catheter; to perform substantially the same function, i.e., maximizing use of space inside the guide catheter to allow interventional cardiology devices to pass into the Guidezilla without catching on the proximal end opening of the Guidezilla's flexible tip portion; to obtain substantially the same result, i.e., facilitating passage of interventional cardiology devices to the site in the patient's blood vessel that needs treatment. Accordingly, it is my opinion that the Guidezilla meets this limitation by doctrine of equivalents when combined with a 0.071-inch guide catheter.

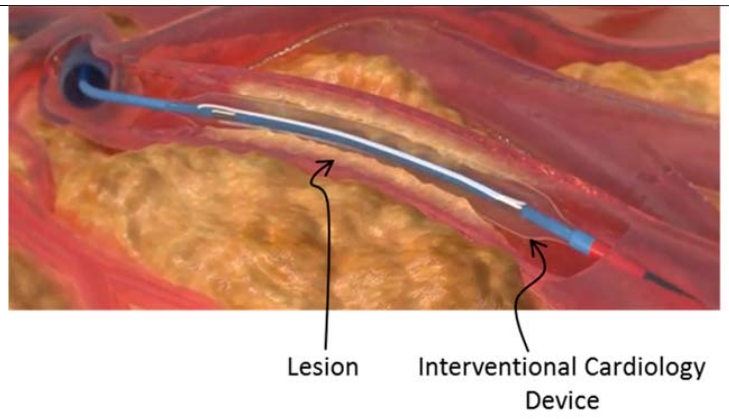
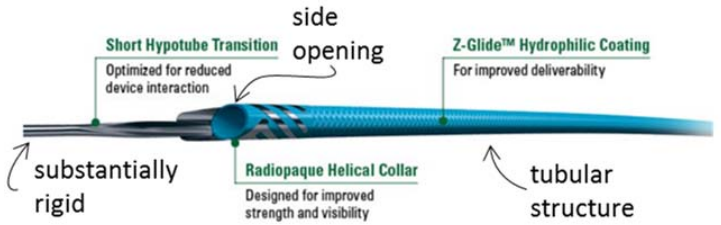
U.S. Patent No. 8,142,413 **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES** Root et al.	
1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:	A cardiologist using Boston Scientific's Guidezilla IIwith a guidewire, guide catheter, and interventional cardiology device (balloon catheter or stent) performs the method of claim 1. A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	In use, the cardiologist typically inserts a standard guide catheter that has a distal end into an artery over a guidewire.
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the Guidezilla II, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery. "The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Indications for Use, VSIQXM_E00056335.

inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	"We designed Guidezilla II to self-align upon insertion into a guide catheter." Boston Scientific's "GUIDEZILLA II Guide Extension Catheter Development Video" at 2:03 (viewed July 2, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html) "The Guidezilla II Guide Extension Catheter consists of … a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. The flexible tip portion's length is shorter than the 100 cm length of the continuous lumen of a standard guide catheter.
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	The Guidezilla II has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. This is the "proximal stainless steel hypotube" of the device. Based on my physical examination of the device, it is my opinion that the stainless steel shaft is rigid enough to advance the device within a guide catheter. Testing confirms that the shaft is more rigid along a longitudinal axis than the flexible tip portion. In the two point bend testing, the Guidezilla II had a higher maximum force value for the proximal shaft portion ("Flex 4" numbers) in comparison to the distal shaft maximum force values ("Flex 1") values. See Expert Report, Appendix D at 1. The drawing below depicts the "proximal stainless steel hypotube," which is substantially rigid, proximal of, and operably connected to, and more rigid than the flexible tip portion, and defines a rail structure without a lumen that has a

	maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion.  The Guidezilla II's substantially rigid portion defines a "rail structure without a lumen." I understand that the Court has construed "lumen" to mean "the cavity of a tube." Order at 25. Guidezilla II's substantially rigid portion is a stainless steel hypotube that is sealed shut at both ends. Although there is a minute, inaccessible, non-functional void inside the hypotube, it is my opinion that hypotube meets the "rail structure without a lumen" limitation by doctrine of equivalents. Having a tiny, non-functional void inside the hypotube is insubstantially different from having no void at all. Nothing can pass through the hypotube because it it closed at both ends; it serves no meaningful purpose or function. The Guidezilla II's rail structure performs substantially the same function as the claimed rail structure without a lumen (i.e., advancing the device through a guide catheter without blocking use of the guide catheter) in substantially the same way (i.e., by providing a rapid exchange rail with a minimal cross-sectional profile) to achieve substantially the same result

	(i.e., advancing the device while allowing interventional cardiology devices to pass alongside). The substantially rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 150 cm, longer than the standard 100cm length of the continuous lumen of the guide catheter.
advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	A distal portion of the Guidezilla II's flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "The Boston Scientific Guidezilla™ and Guidezilla™ II LONG Guide Extension Catheters act as extensions to traditional guide catheters. The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter, providing physicians with additional support to advance interventional devices into the vasculature." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve.
inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the	An interventional cardiology device is inserted into and through the continuous lumen of the standard guide catheter alongside the substantially rigid portion of the Guidezilla II.

interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	The interventional cardiology device is advanced through and beyond the lumen of the flexible tip portion into contact with or past a lesion in the second artery. "The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube, which includes a handle used for device identification, and a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered. The proximal hypotube is connected to the distal guide catheter segment by a small collar." Boston Scientific's 510(k) Device Description, VSIQXM_E00056335. Boston Scientific's marketing materials instruct the user to perform the aforementioned step, as shown below in the screenshot taken at the 0:50 mark of the "GUIDEZILLA II Guide Extension Catheter Development Video" (viewed July 2, 2018 at http://www.bostonscientific.com/en-US/products/catheters--guide/guidezilla-II-guide-extension-catheter.html).

	
9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	When the Guidezilla II is used, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure is shown below: 

WS Hampshire Inc.
Over 100 Years of Non-Metallic Material Fabrication

IAPD MEMBER

TEFLON

PolyTetraFluoroEthylene is a fluorocarbon-based polymer and is commonly abbreviated PTFE. The Teflon® brand of PTFE is manufactured only by DuPont. Several other manufacturers make their own brands of PTFE which can often be used as substitute materials. This fluoroplastic family offers high chemical resistance, low and high temperature capability, resistance to weathering, low friction, electrical and thermal insulation, and "slipperiness". (see also Teflon® PTFE and Teflon® FEP & PFA Specifications) PTFE's mechanical properties are low compared to other plastics, but its properties remain at a useful level over a wide temperature range of of -100°F to +400°F (-73°C to 204°C). Mechanical properties are often enhanced by adding fillers (see paragraph below). It has excellent thermal and electrical insulation properties and a low coefficient of friction. PTFE is very dense and cannot be melt processed -- it must be compressed and sintered to form useful shapes.

FILLED GRADES

PTFE's mechanical properties can be enhanced by adding fillers such as glass fibers, carbon, graphite, molybdenum disulphide, and bronze. Generally, filled PTFE's maintain their excellent chemical and high temperature characteristics, while fillers improve mechanical strength, stability, and wear resistance. The properties of 25% glass-filled and 25% carbon-filled PTFE grades are shown below for comparison purposes. There are literally dozens of different filled PTFE products and grades -- too many to be listed here. Please contact Boedeker Plastics for more information about other filled PTFE products for your application.

TYPICAL PROPERTIES of PTFE

ASTM or UL test	Property	PTFE (unfilled)	PTFE (25% glass filled)	PTFE (25% carbon filled)
	PHYSICAL			
	Density (lb/in³)	0.078	0.081	0.075
D792	(g/cm³)	2.16	2.25	2.08
D570	Water Absorption, 24 hrs (%)	< 0.01	0.02	0.05
	MECHANICAL			
D638	Tensile Strength (psi)	3,900	2,100	1,900
D638	Tensile Modulus (psi)	80,000	-	-
D638	Tensile Elongation at Break (%)	300	270	75
D790	Flexural Strength (psi)	No break	1,950	2,300
D790	Flexural Modulus (psi)	72,000	190,000	160,000
D695	Compressive Strength (psi)	3,500	1,000	1,700
D695	Compressive Modulus (psi)	70,000	110,000	87,000
D785	Hardness, Shore D	D50	D60	D62
D256	IZOD Notched Impact (ft-lb/in)	3.5	-	-
	THERMAL			
D696	Coefficient of Linear Thermal Expansion (x 10^{-5} in./in./°F)	7.5	6.4	6
D648	Heat Deflection Temp (°F / °C) at 264 psi	132 / 55	150 / 65	150 / 65
D3418	Melting Temp (°F / °C)	635 / 335	635 / 335	635 / 335
-	Max Operating Temp (°F / °C)	500 / 260	500 / 260	500 / 260
	Thermal Conductivity			
	(BTU-in/ft²-hr-°F)	1.7	3.1	4.5
C177	(x 10^{-4} cal/cm-sec-°C)	5.86	10.6	15.5
UL94	Flammability Rating	V-O	V-O	V-O
	ELECTRICAL			
D149	Dielectric Strength (V/mil) short time, 1/8" thick	285	-	-
D150	Dielectric Constant at 1 MHz	2.1	2.4	-
D150	Dissipation Factor at 1 MHz	< 0.0002	0.05	-
D257	Volume Resistivity (ohm-cm)at 50% RH	> 10^{18}	> 10^{15}	104

NOTE: The information contained herein are typical values intended for reference and comparison purposes only. They should NOT be used as a basis for design specifications or quality control. Contact us for manufacturers' complete material property datasheets.

All values at 73°F (23°C) unless otherwise noted. TEFLON ® is a registered trademark of DuPont

Arkema Pebax® 6333 SA 01 MED Polyether Block Amide (PEBA)

Categories: Polymer; Thermoplastic; Polyether Block Amide (PEBA)

Material Notes: Polyether block amide PEBAX® 6333 SA 01 MED is a thermoplastic elastomer made of flexible polyether and rigid polyamide. This grade offers the highest quality and it is specially designed to meet the stringent requirements of the medical applications such as minimally invasive devices. PEBAX® 6333 SA 01 MED also offers an excellent combination of properties such as: kink resistance, low friction coefficient and superior dynamic response. Upon request letters regarding USP Class IV testing can be provided.

Information provided by Arkema Group. Property data for dry samples, unless noted.

Vendors: **Click here to view all available suppliers for this material.**

Please click here if you are a supplier and would like information on how to add your listing to this material.

Physical Properties	Metric	English	Comments
Density	1.01 g/cc	0.0365 lb/in³	ISO 1183
Water Absorption	1.1 %	1.1 %	Sim. to ISO 62
Moisture Absorption	0.700 %	0.700 %	Sim. to ISO 62
Linear Mold Shrinkage, Flow	0.012 cm/cm	0.012 in/in	ISO 294-4 2577
Linear Mold Shrinkage, Transverse	0.014 cm/cm	0.014 in/in	ISO 294-4 2577

Mechanical Properties	Metric	English	Comments
Hardness, Shore D	58 @Time 15.0 sec	58 @Time 0.00417 hour	ISO 868
Tensile Strength, Yield	18.0 MPa	2610 psi	Conditioned; ISO 527-1/-2
	19.0 MPa	2760 psi	ISO 527-1/-2
Elongation at Break	>= 50 %	>= 50 %	Nominal, Conditioned; ISO 527-1/-2
	>= 50 %	>= 50 %	Nominal; ISO 527-1/-2
Elongation at Yield	22 %	22 %	ISO 527-1/-2
	22 %	22 %	Conditioned; ISO 527-1/-2
Tensile Modulus	0.285 GPa	41.3 ksi	Conditioned; ISO 527-1/-2
	0.307 GPa	44.5 ksi	ISO 527-1/-2
Flexural Modulus	0.285 GPa	41.3 ksi	Conditioned 15 days at 23°C - 50% RH; ISO 178
Charpy Impact Unnotched	NB @Temperature 23.0 °C	NB @Temperature 73.4 °F	Conditioned; ISO 179/1eU
	NB @Temperature -30.0 °C	NB @Temperature -22.0 °F	Conditioned; ISO 179/1eU
Charpy Impact, Notched	2.00 J/cm² @Temperature -30.0 °C	9.52 ft-lb/in² @Temperature -22.0 °F	Conditioned; ISO 179/1eA
	NB @Temperature 23.0 °C	NB @Temperature 73.4 °F	Conditioned; ISO 179/1eA

Thermal Properties	Metric	English	Comments
Melting Point	169 °C	336 °F	10°C/min; ISO 11357-1/-3
Vicat Softening Point	157 °C	315 °F	50°C/h 50N; ISO 306

Processing Properties	Metric	English	Comments
Melt Temperature	260 °C	500 °F	Injection Molding; ISO 294
Mold Temperature	30.0 °C	86.0 °F	Injection Molding; ISO 10724

Some of the values displayed above may have been converted from their original units and/or rounded in order to display the information in a consistent format. Users requiring more precise data for scientific or engineering calculations can click on the property value to see the original value as well as raw conversions to equivalent units. We advise that you only use the original value or one of its raw conversions in your calculations to minimize rounding error. We also ask that you refer to MatWeb's terms of use regarding this information. Click here to view all the property values for this datasheet as they were originally entered into MatWeb.

Users viewing this material also viewed the following:
Arkema Pebax® 7233 SA 01 MED Polyether Block Amide (PEBA)
Arkema Pebax® 5533 SA 01 MED Polyether Block Amide (PEBA)
Arkema Pebax® 7033 SA 01 MED Polyether Block Amide (PEBA)
Arkema Pebax® 4033 SA 01 MED Polyether Block Amide (PEBA)
Arkema Pebax® 6333 SP 01 Polyether Block Amide (PEBA)

PARKG740 / 142535

Year

2016

2017

2018

Quarter

Q1

Q2

Q3

Q4

Row Labels	Total Units	Total Dollars	Total ASP*	6F Guide Cath ID (inches)
Boston Scientific	**660,842**	**$30,916,891**	**$46.78**	
Convey	66,422	$3,292,313	$49.57	0.071
Mach 1	141,661	$7,292,045	$51.48	0.070
Runway	448,110	$20,125,433	$44.91	0.070
Wiseguide	4,649	$207,100	$44.55	0.066
Cardinal Health	**1,176,072**	**$64,934,368**	**$55.21**	
ADROIT	39,002	$1,661,577	$42.60	0.072
ENVOY	33,370	$11,299,170	$338.60	0.070
ENVOY XB	13,955	$5,087,602	$364.57	0.070
Vista Brite Tip	1,089,745	$46,886,019	$43.02	0.070
Medtronic	**1,505,354**	**$66,287,582**	**$44.03**	
Launcher	1,377,490	$60,448,983	$43.88	0.071
Sherpa NX Active	15,350	$745,650	$48.58	0.070
Sherpa NX Balanced	112,514	$5,092,949	$45.27	0.070
Merit Medical	**703**	**$29,704**	**$42.25**	
ConcierGE	703	$29,704	$42.25	0.070
Metronic	**79,943**	**$3,416,600**	**$42.74**	
Zuma	79,943	$3,416,600	$42.74	0.068
Terumo	**111,482**	**$10,086,303**	**$90.47**	
Chaperon	6,201	$2,157,234	$347.88	0.071
Heartrail	105,281	$7,929,069	$75.31	0.071
Grand Total	**3,534,396**	**$175,671,448**	**$49.70**	

Percent of 6F Coronary Guide Catheters having ID of 0.070 inches	**52.5**

Percent of 6F Coronary Guide Catheters having ID of 0.071 inches	**44.0**

number	fraction	percent
1855408	0.5249576	52.5
1555394	0.4400735	44.0