UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Vascular Solutions, Inc.,

Plaintiff,

v.

Boston Scientific Corporation,

Defendant.

Civil File No. 0:13-cv-01172 (JRT-SER)

DECLARATION OF HOWARD ROOT IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I, Howard Root, hereby declare and state as follows:

1. I am the Chief Executive Officer of Plaintiff Vascular Solutions, Inc. ("VSI"). I make this Declaration in connection with VSI's motion for a preliminary injunction. I have personal knowledge of the matters set forth below and, if called as a witness, I could and would testify as follows.

Background

2. I was originally trained as a lawyer and worked in private practice from 1985-90. In 1990, I left private practice to serve as General Counsel to ATS Medical, Inc., a medical device company. I left ATS Medical and founded VSI in 1997, and I have acted as the Chief Executive Officer of VSI since its founding. Since 1997, I have been personally involved in the creation and development of VSI's products. I am a named inventor on 10 patents relating to a variety of VSI's products, including patents in the following areas: vascular access closure systems, coaxial guide extension catheters, guidewire tipped laser fibers, screw tipped penetrating catheters, and retraction belts.

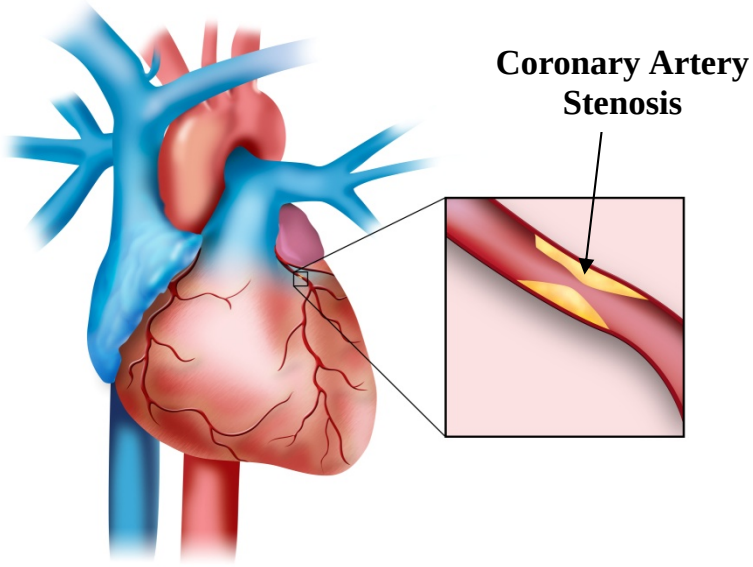
3. At different times during the company's history, I have directly managed the VSI sales force, product development and marketing departments, and during all times have been personally active in VSI's sales, product development, legal and marketing efforts.

4. VSI is a medical device company focused on bringing new clinically unique solutions for vascular diseases to physicians worldwide. VSI has developed and markets over 75 different medical device products through its 91employee U.S. sales force and international distribution network covering 49 countries. VSI had revenue of $98 million in 2012.

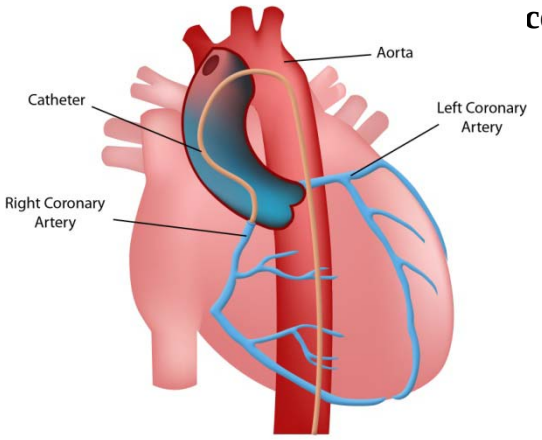
Background on the Technology of this Case

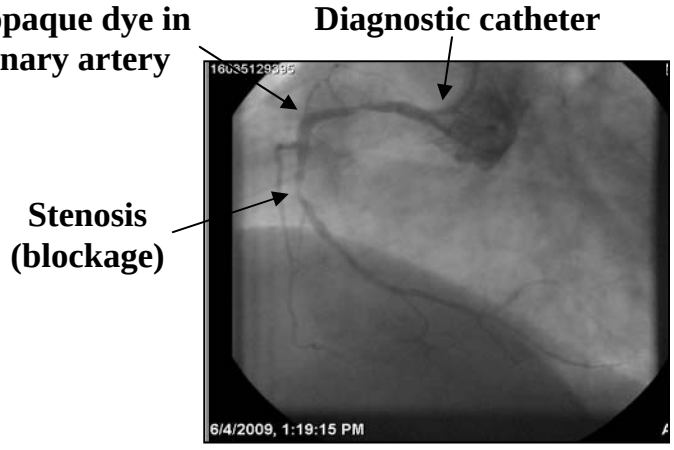
5. The technology involved in this case involves cardiac (heart) catheterization, and more specifically, a medical advance that enables cardiologists to navigate medical instruments such as stents through narrow and tortuous arteries in order to treat arterial disease in coronary vessels that often could not be reached with previous technologies.

6. In coronary artery disease, a coronary artery is narrowed or occluded, often by the buildup of plaque which can reduce or entirely obstruct blood flow through the artery. A narrowing in an artery is referred to as a lesion or a stenosis. If a stenosis becomes severe, the heart muscle will not receive sufficient blood flow to continue to function appropriately, which can result in an acute myocardial infarction, commonly known as a heart attack. A coronary artery stenosis is depicted in the drawing below:

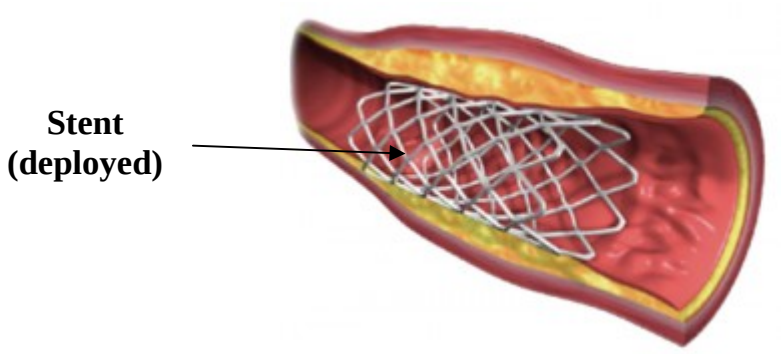


7. When a patient is suspected of having a significant stenosis in a coronary artery, the cardiologist often will perform a diagnostic coronary catheterization procedure to confirm the condition. A diagnostic catheterization consists of injecting contrast (radiopaque dye visible on an x-ray) through a diagnostic catheter (a long, thin tube) placed into the beginning of the coronary artery while viewing the artery under x-ray. The x-ray will show the presence of the radiopaque dye in the open portion of the coronary artery and the absence of dye in the area of the stenosis. A drawing of a diagnostic catheterization and an x-ray image from a diagnostic catheterization are shown below:



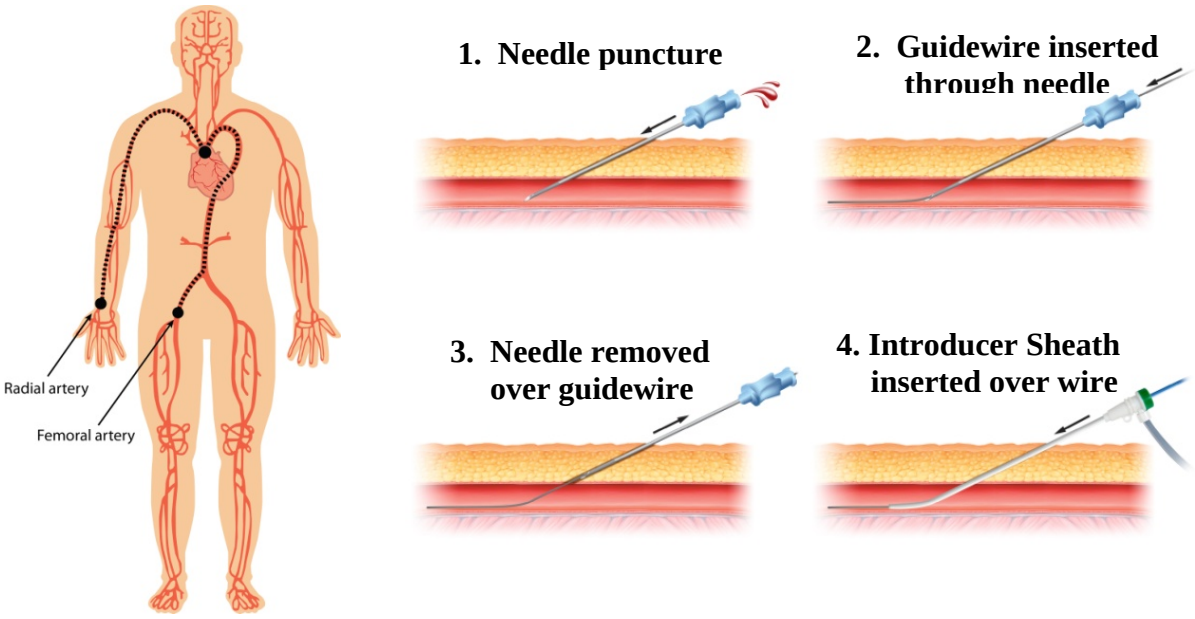


8. If the diagnostic catheterization confirms a clinically significant stenosis (such as identified in the x-ray above), the cardiologist will often perform what is called an interventional catheterization to treat (or intervene) by opening the stenosis. An interventional catheterization procedure consists of delivering medical instruments such as stents and balloons into the coronary artery and across the stenosis and then expanding the balloon and/or stent to push the stenosis to the arterial wall and re-open flow through the artery. Below is a drawing of a stent that has been opened to push a stenosis to the arterial wall and restore flow through the artery:



9. Cardiac catheterization procedures, whether diagnostic or interventional, are non-surgical, minimally invasive medical procedures. A cardiac catheterization starts with a needle puncture in the radial (wrist) or femoral (leg) artery of the patient in order to gain access to the arterial system. Through the hollow needle that punctured the artery a guidewire is inserted, after which the needle is removed and an introducer sheath (a short, thin tube with a valve on the end outside the body to prevent blood from leaking out) is inserted over the wire and into the artery. The introducer sheath is then used to provide continued access to the artery for the introduction of guidewires, catheters and stents during the procedure. This type of arterial access is commonly known as the

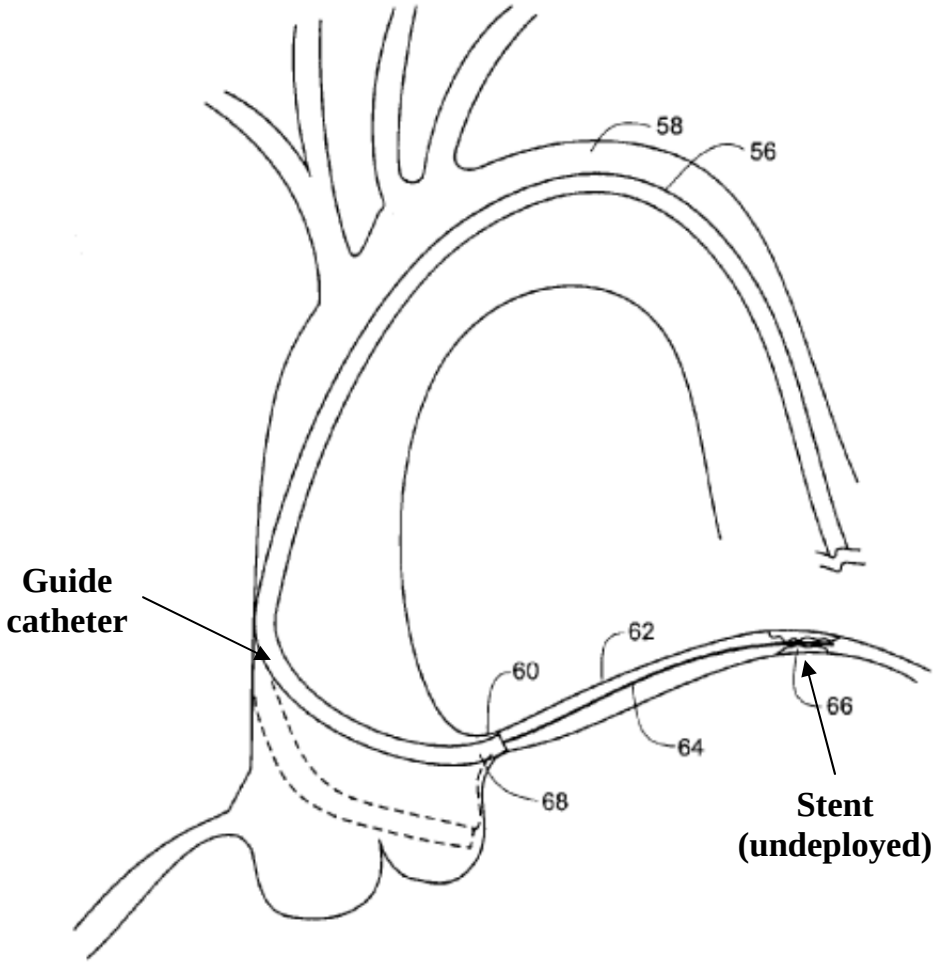
Seldinger technique, and is shown in the drawings below



10. Using the introducer sheath as the conduit, to perform a diagnostic catheterization procedure the cardiologist will advance a diagnostic catheter into and through the aorta until it is pointing at the opening (ostium) of the coronary artery to be diagnosed (the right or left coronary artery). Once in position, dye is injected through the diagnostic catheter and into the coronary artery to allow the size and shape (and any lesions) of the artery to be observed under x-ray (see the drawing and image in paragraph 7 above). Because only dye (which is in liquid form) is injected into the coronary artery during a diagnostic catheterization procedure, a diagnostic catheter can have a small inner diameter and the tip of the diagnostic catheter does not need to precisely match the shape of the ostium of the coronary artery.

11. In an interventional catheterization procedure, instead of using a diagnostic catheter the cardiologist will use what is commonly referred to as a "guide catheter" to deliver (or guide) medical devices (such as stents) into the coronary artery to the site of

the stenosis to perform the intervention. Because the purpose of an interventional catheterization is to deliver medical instruments such as stents deep into the coronary artery and across the stenosis, a guide catheter must have a large enough inner diameter to allow passage of the commonly-used stents as well as an appropriate shape and structure to prevent dislodgement during delivery of the devices. Below is a drawing of a guide catheter seated in the coronary artery ostium (shown at 60) with an unexpanded stent in place across a stenosis (shown at 66) from Figure 7 of VSI's U.S. Patent No. 8,048,032 ('032 patent):

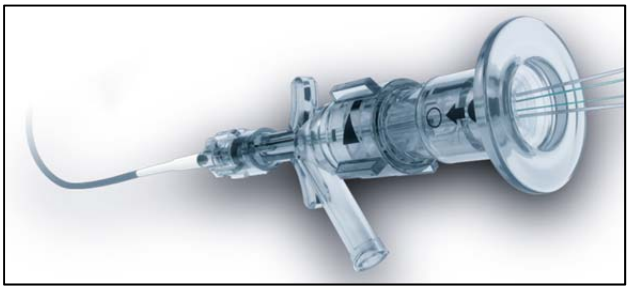


12. The guide catheter is a critical component of an interventional coronary catheterization procedure, as it is a required tool to provide the pathway for medical devices to be delivered from a distal arterial access point to a lesion for treatment. Many companies manufacture and sell guide catheters, including Boston Scientific. A standard guide catheter has a length of 100cm and has a diameter measured on the French scale (abbreviated "F"), where 1F is 1/3mm. The most common size of guide catheter is 6F (i.e., it has an outside diameter of 2mm (0.079in)), while other common sizes are 7F and 8F. Below is a drawing of a guide catheter:

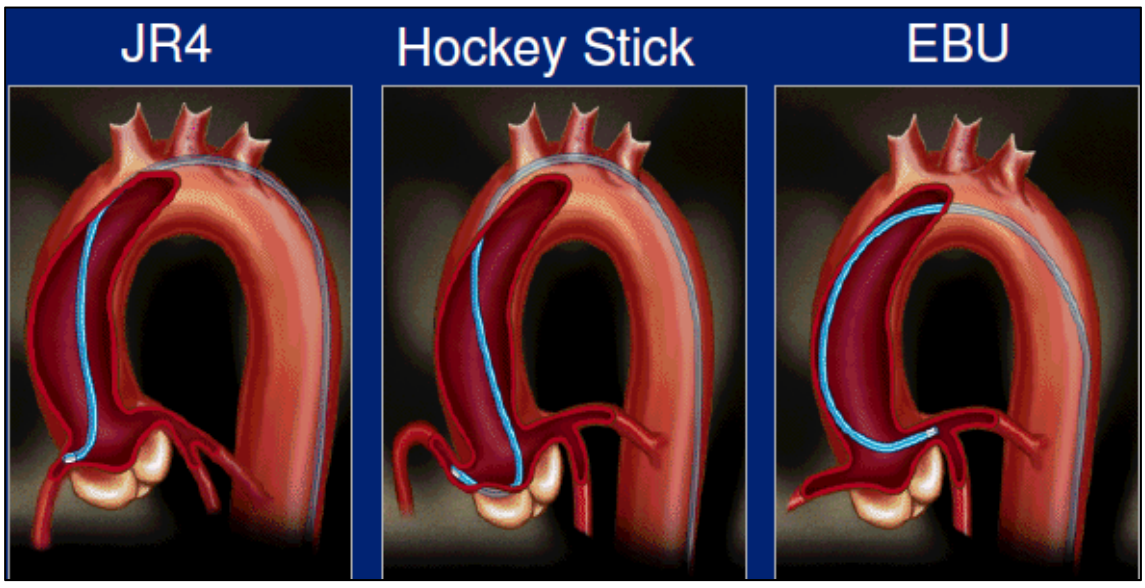
Guide catheter

13. During use, the proximal end (i.e., the end outside the body) of a guide catheter must be sealed to prevent blood loss during the catheterization procedure. To provide this seal (while still allowing the guide catheter to be opened for delivery of medical devices), a hemostasis valve (such as the one depicted below) is attached to the proximal end of the guide catheter.

Hemostasis valve



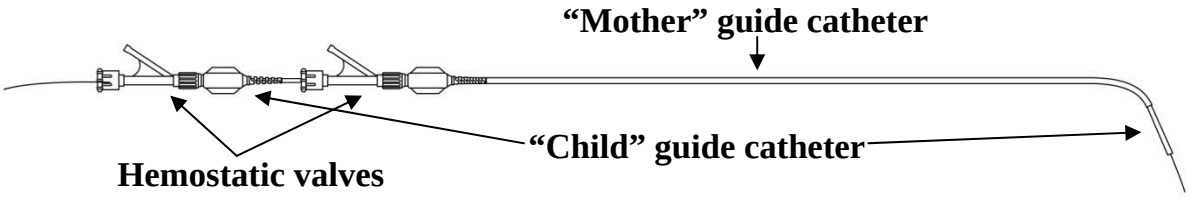
14. A guide catheter must be sufficiently rigid to allow it to maintain its distal curve (the distal end being the far end, deepest inside the body) while medical devices such as stents (which are relatively inflexible) are directed from the aorta through a 90° bend and into the ostium of the coronary artery to be treated. The guide catheter also must provide sufficient "backup" support to prevent the guide catheter from moving backwards and becoming dislodged from the ostium as the medical devices are pushed through a tight stenosis. Without this combination of guide catheter rigidity and backup support, medical devices such as stents may not be able to traverse the artery and cross the stenosis, causing the intervention to fail. Because the shape and location of coronary ostia vary widely among patients, guide catheters are manufactured with a wide variety of curve shapes to provide orientation and back-up support in these variations. Below are three common distal curve styles of guide catheters for right (JR4 and Hockey Stick) and left (EBU) coronary artery catheterizations:

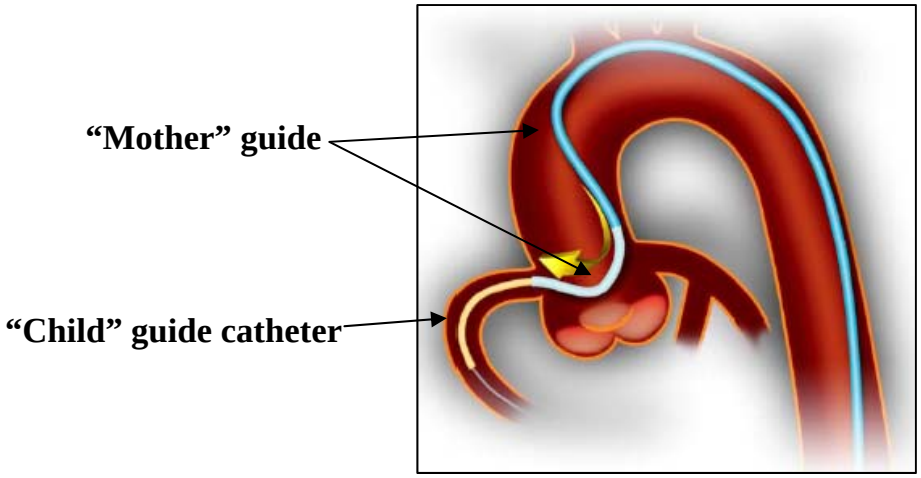


15. However, because of the curve and rigidity of a guide catheter, it generally cannot be safely "deep seated" (i.e., extended past the ostium) into the coronary artery, and instead must rest in the ostium. Therefore, while deep-seating of the guide would be helpful to significantly increase the resistance to backup and dislodgement during the stent delivery, it is generally not performed. The resulting limitation on backup support can result in dislodgement of the guide catheter and failure to deliver the treatment in challenging cases where the anatomy is tortuous and the lesion is severe, which are precisely the cases where treatment is often most needed.

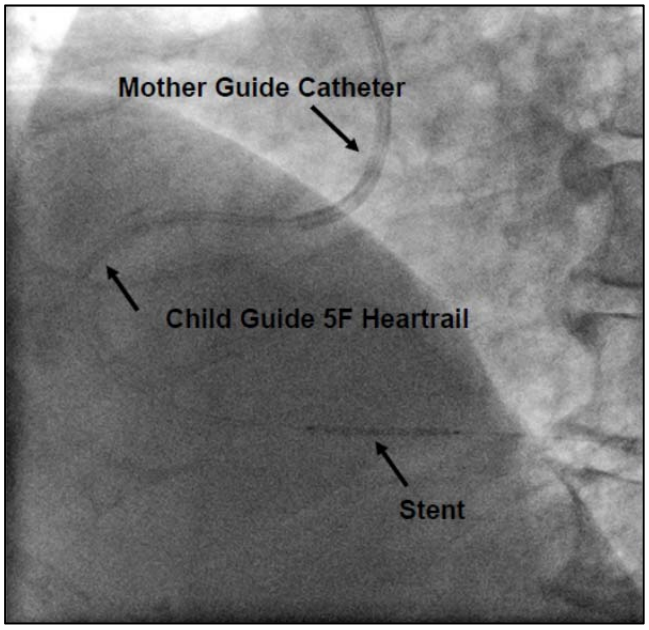
16. There have been prior attempts to solve this desire to safely deep seat a guide catheter, as discussed in VSI's '032 patent, at col. 1, ln. 41, to col. 2, ln. 44. One prior approach is referred to as a "mother and child" guide catheter. It involves inserting, for example, a 5F, 120cm "child" guide catheter that has a relatively flexible and straight distal tip through a standard 6F, 100cm "mother" guide catheter that is already in place at the ostium of the coronary artery. The distal end of the child catheter, being flexible and straight, can therefore safely extend through the ostium, into the bend in the artery and provide excellent backup support. Drawings of a mother and child guide catheter system and its use in a coronary artery are below:

Mother and child OTW system





17. The Heartrail guide catheter manufactured by Terumo Corporation is an example of this “mother and child” guide catheter system, comprised of a 120cm long 5F child guide catheter extension paired with a 100cm long 6F mother guide catheter. The radiographic image below depicts the Terumo Heartrail mother and child system in use under x-ray visualization, with a stent extended through both the mother and child:



18. The mother and child system promoted by Terumo, however, has several drawbacks. One drawback is that the system requires two hemostatic valves: one to seal

the mother catheter, and a second to seal the child catheter. This tends to make the system cumbersome to use. Another drawback is the length of the system – the mother and child combination results in a 120cm long guide catheter, which limits the sites that can be treated since balloons, stents and wires are designed to be used with 100cm guide catheters. Third, to insert or remove the child catheter, all of the previously inserted medical devices, such as guidewires, must be removed. This is particularly problematic in situations where the cardiologist did not originally plan to use a child catheter, but instead the need arose in the middle of the procedure, but then requires removing all guidewires that have already been appropriately placed and starting the intervention over from the first step. As a result, before the GuideLiner, the mother and child system was rarely used.

19. The mother and child guide system utilized by Terumo is an example of an over-the-wire, or OTW, catheter. An OTW catheter has at least one uninterrupted lumen that runs the entire length of the catheter which is used for delivery of the catheter over a guidewire (i.e., the entire length of the OTW catheter is delivered "over the wire") and into the artery. Because an OTW catheter is generally between 100cm and 150cm in length, it usually requires a long (between 260 and 300cm) guidewire for deployment, which necessitates two operators to control both ends of the catheter at the same time as it is being deployed. Shown below is a schematic drawing of a standard OTW catheter with a guidewire extending through it:

Over-the-wire (OTW) catheter

20. An alternative type of catheter used in coronary catheterization procedures is referred to as monorail, rapid exchange, single operator, or sliding rail. All of these names refer to the same type of catheter construction with a relatively short (generally 20cm – 40cm) lumen used to deliver the catheter over a guidewire, attached to a longer and stiffer push rod that is used to push and retract the catheter but runs independent of and next to the guidewire. With the monorail construction, a single operator is able to deliver the catheter and control both ends during delivery. It also allows the use of shorter guidewires (between 150cm and 190cm in length). This rail technique is explained in an article by Bonzel et al., Z. Kardiol. 1987; 76 Suppl. 6:119-22. A true and correct copy of the Bonzel et al. article is attached as **Exhibit 1**. Shown below is a schematic drawing showing a standard "rail" or rapid exchange catheter with a guidewire placed through it:

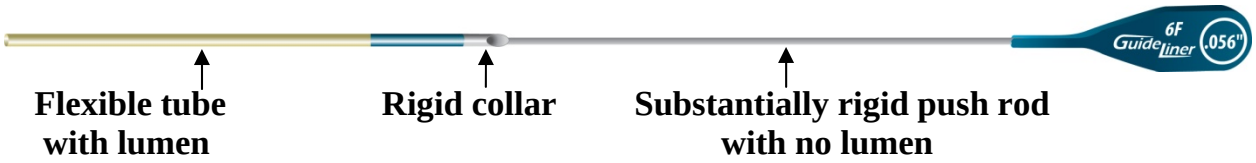
Rail (rapid exchange) catheter

VSI's Development of the GuideLiner® Catheter and the Patents-in-Suit

21. Starting in 2004, I, along with other VSI employees Gregg Sutton, Jeffrey Welch, and Jason Garrity, conceived of and began to work on a new idea for a guide extension catheter that would provide "mother and child" guide extension, but without the disadvantages of the OTW construction. After years of research and testing, we developed our idea into VSI's GuideLiner catheter, which was first sold in 2009. The GuideLiner catheter provides the advantages of "mother and child" guide extension with

the ease of monorail or rapid exchange delivery. The original GuideLiner catheter is depicted below.

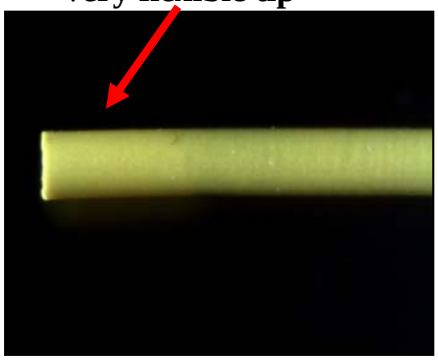
VSI's GuideLiner catheter



Flexible tube with lumen | **Rigid collar** | **Substantially rigid push rod with no lumen**

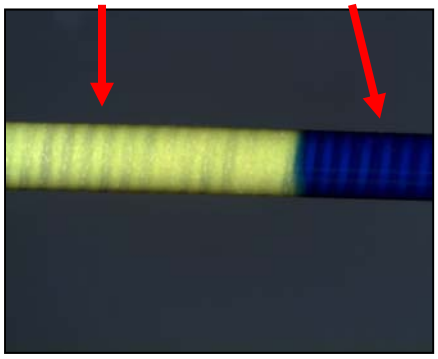
22. The distal end (yellow and blue portion) of the GuideLiner catheter is a relatively flexible tube with a lumen. This flexible portion has three zones: a very flexible yellow tip, a less flexible yellow coil reinforced portion, and a further less flexible blue portion made from a stiffer polymer as shown below:

GuideLiner very flexible tip



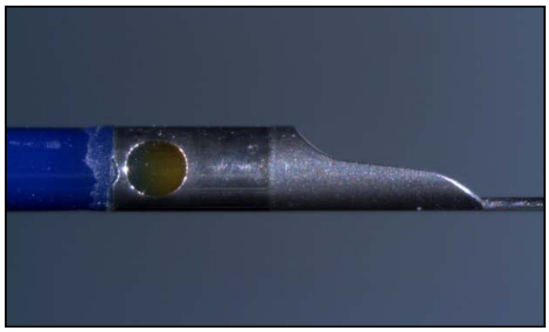
Coil reinforced portion

More flexible **Less flexible**

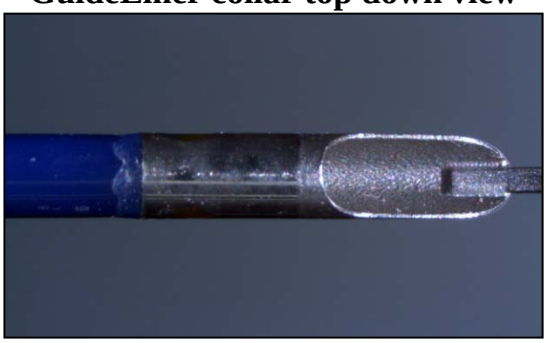


23. The flexible tube portion of the GuideLiner is joined to a relatively inflexible metal collar where the lumen ends with a sloped opening:

GuideLiner collar side view

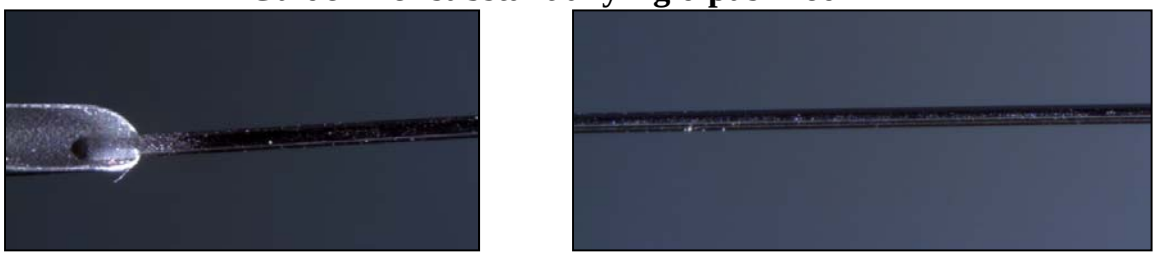


GuideLiner collar top down view



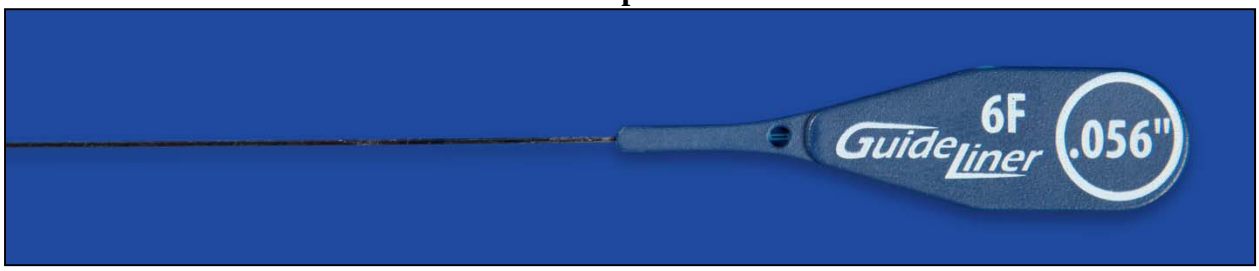
24. The collar is then connected to a substantially rigid push rod that extends for the remainder of the length of the GuideLiner catheter:

GuideLiner substantially rigid push rod



25. The proximal end of the push rod is embedded into a tab used to identify the GuideLiner catheter and prevent it from being inadvertently pushed through the hemostatic valve:

GuideLiner proximal tab

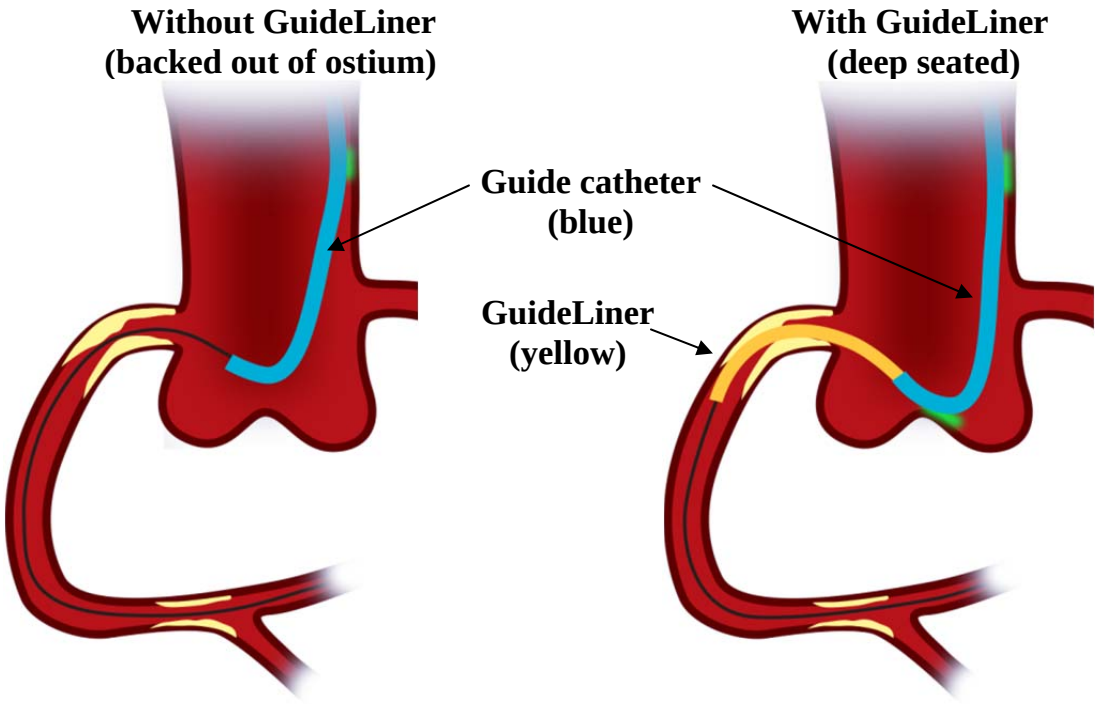


26. In use, the "child" GuideLiner catheter is inserted into the "mother" guide catheter by threading the lumen of the GuideLiner catheter's tubular portion over the in-place guidewire. The GuideLiner catheter's flexible tip is pushed through the guide catheter by the attached push rod and out the distal end of the "mother" guide catheter for deep seating into the coronary artery. After the GuideLiner catheter has been fully inserted into the guide catheter, when a cardiologist inserts a device such as a stent into the guide catheter, the device will travel down the guide catheter, next to the push rod, until it encounters the collar, where it will pass through the sloped opening in the collar

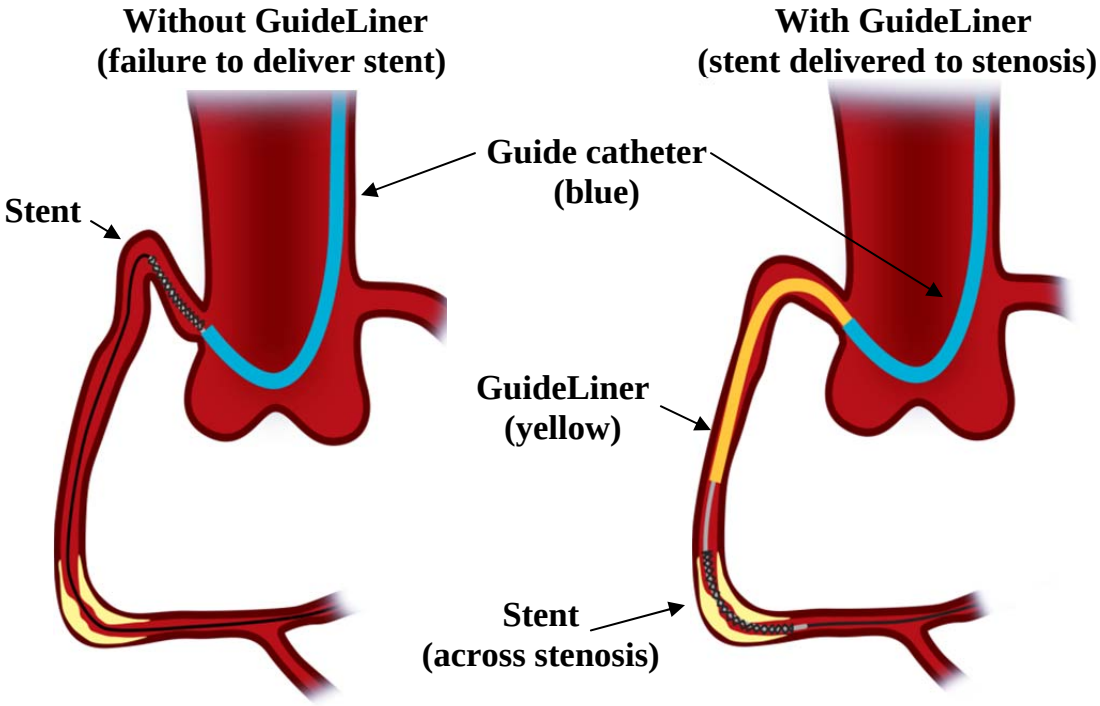
and into the flexible tip portion and continue until it exits the distal end of the GuideLiner catheter's flexible tip portion, into the artery to be treated.

27. By extending past the distal tip of the guide catheter and into the artery to be treated, the GuideLiner catheter provides superior back-up support through effective deep seating. And because the GuideLiner catheter's tip is flexible, the catheter can be deep seated without the risks associated with deep seating standard, much more rigid guide catheters.

28. The use of the GuideLiner catheter is illustrated in the two figures below. In the figure on the left, without the GuideLiner in place, the guide catheter has backed out of the coronary ostium, possibly from the force exerted on advancing the guidewire. In the figure on the right, the GuideLiner catheter extension has been deep seated, thus providing added support for the advancement of guidewires and stents into the artery.



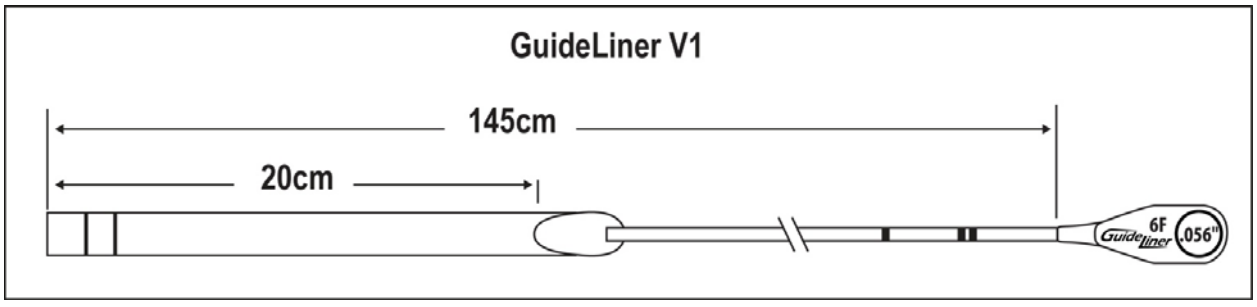
29. In another example of the use of the GuideLiner, in the illustration below on the left, without the use of a GuideLiner catheter the rigid stent cannot navigate the sharp downward turn of the vessel to reach the lesion, and therefore the procedure cannot be completed. In the figure on the right, with the use of the GuideLiner the angulated vessel's sharp angle is turned into a gentle curve, which allows the stent to make the turn and be delivered to the lesion.

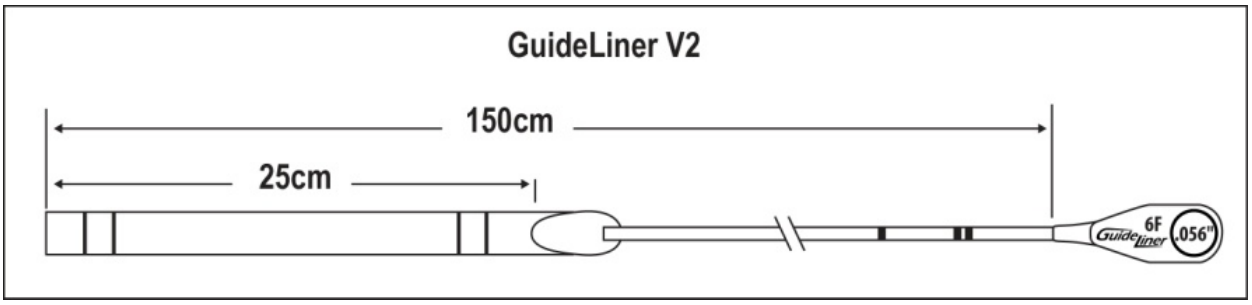


30. The monorail construction of the GuideLiner catheter provides multiple advantages to the user over the OTW construction used in prior "mother and child" systems. Because only the push rod extends through the hemostatic valve when using the GuideLiner catheter, a second hemostatic valve is not needed. In addition, since only one hemostatic valve is used, there is no need to use longer devices to reach the lesion or any limitation on the length of devices used. Furthermore, the monorail construction allows

the existing guidewires to remain in place while delivering the GuideLiner catheter into the artery, which is particularly beneficial in unplanned uses.

31. A second version of the GuideLiner catheter named the V2 was developed and sold beginning in 2012. The changes in the V2 version did not change the deployment, use or general construction of the GuideLiner catheter. The only changes made in the V2 version from the original GuideLiner (now called V1) were (a) the length of the guide extension segment was increased from 20cm to 25cm, (b) a second radiopaque marker band was added to the collar section of the catheter, and (c) the metal of the collar section was replaced with a polymer material. The first figure below is a schematic of the original ("V1") GuideLiner catheter, and the second figure is a schematic of the second version ("V2") of the GuideLiner catheter.





32. On May 3, 2006, my coinventors and I filed a patent application on our invention in the U.S. Patent Office. Our application led to three U.S. patents, each of which is assigned to VSI: the '032 patent, which issued November 1, 2011; U.S. Patent No. 8,142,413 ('413 patent), which issued March 27, 2012; and U.S. Patent No. 8,292,850 ('850 patent), which issued October 23, 2012. Each of these patents is entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures."

33. A true and correct copy of VSI's '032 patent is attached as **Exhibit 2**.

34. A true and correct copy of VSI's '413 patent is attached as **Exhibit 3**.

35. A true and correct copy of VSI's '850 patent is attached as **Exhibit 4**.

36. Both the GuideLiner V1 and the GuideLiner V2 are embodiments of the coaxial guide catheter described and claimed in the VSI patents. In general, the '032 patent claims the device, the '413 patent claims methods of using the device, and the '850 patent claims systems combining the GuideLiner device with a guide catheter. For example, claim 1 of the '032 patent claims a device for use with a standard guide catheter to provide guide extension, with the device having a "flexible tip portion" and a "substantially rigid portion" as described above in my description of the GuideLiner products.

Success of VSI's GuideLiner catheter

37. VSI obtained CE mark clearance from its European notified body and commenced international sales of the GuideLiner catheter in September 2009.

38. VSI obtained 510(k) regulatory clearance from the U.S. Food & Drug Administration and commenced U.S. sales of the GuideLiner catheter in November 2009.

39. The GuideLiner catheter has been a very successful product for VSI. Worldwide sales of the GuideLiner catheter since launch are provided in the table below.

Year	**Worldwide Sales**
2009 (4th quarter only)	$318,000
2010	$4,632,000
2011	$9,753,000
2012	$14,742,000
2013 (1st quarter only)	$4,781,000
Total (through March 31, 2013)	**$34,226,000**

40. From 2010 to current, the GuideLiner catheter has been VSI's fastest growing product, with sales growth of 48% in the first quarter of 2013 over the first quarter of 2012.

41. In 2012, the GuideLiner catheter was VSI's third highest-selling product in the United States, and second highest-selling product worldwide. I expect that GuideLiner catheters will be VSI's highest-selling product both in the United States and worldwide in 2013. GuideLiner catheter sales currently represent approximately 20% of VSI's total revenue.

42. Because of the completely unique nature of the GuideLiner catheter, it provides our sales force access to hospitals to sell other VSI products, and gives our sales force added credibility in that sales process. Many U.S. hospitals that have purchased the GuideLiner catheter had not purchased a VSI product in the year prior to their initial

purchase of a GuideLiner catheter. VSI would not have had access to these customers, and most of these customers subsequently purchased additional VSI products. I have prepared as **Exhibit 41** a chart setting out the total number of U.S. hospitals that have purchased a GuideLiner catheter since launch, the number of those customers who were new customers to VSI, in the sense that they had not purchased a VSI product in the year before their purchase of the GuideLiner catheter, and the average number of additional VSI products purchased by these new customers after purchasing the GuideLiner. VSI considers this level of detailed customer information to be confidential, and I respectfully ask that the Court allow us to file that exhibit under seal. I understand that counsel will be filing a separate motion seeking permission to file Exhibit 41 under seal.

43. Since 2010, twenty-two articles have been published in medical journals on the GuideLiner catheter and five medical symposia have been held on the GuideLiner catheter at medical meetings held in the United States and Europe. In addition, VSI has published twelve case reports on a range of beneficial clinical uses of the GuideLiner catheter. Attached as **Exhibit 5** is a true and correct copy of a bibliography listing GuideLiner catheter publications, symposia, and case reports. Attached as **Exhibits 6-13** are true and correct copies of articles on the GuideLiner catheter. Attached as **Exhibit 14** are clinical case reports on GuideLiner published by VSI.

44. The GuideLiner catheter has been recognized by physicians as a unique and substantial advance in cardiac catheterization. For example:

a. From the article *Device of the Month: Catheter addresses challenging coronary interventions* (Ex. 6):

- "The GuideLiner catheter, released in November 2009 and now available for sale in the United States and Europe, is being called a 'game-changer' for the treatment of complex endovascular lesions."

- "[Use of GuideLiner] greatly facilitates stent delivery, leading to a successful outcome after failure of conventional techniques. This allows complex disease to be treated more confidently, more easily and more safely." (quoting Douglas G. Fraser, MD, BM, BChir)

- "I've been able to treat arteries previously deemed 'untreatable' and have reported on this. It is not hyperbole to refer to the GuideLiner as a game-changing device." (quoting Kanwar P. Singh, MD, FACC)

- "According to Singh, currently in the United States, there is no competitor device to the GuideLiner."

b. From the article *The GuideLiner™ "child" catheter* (Ex. 7):

- "In this case, stent delivery was impossible despite the use of a highly supportive guiding catheter. By using the GuideLiner™, the stent was deployed easily and successfully because of the extra-back up support and deep intubation without any displacement of the guide catheter or any vessel trauma. The GuideLiner™ provides a new alternative for performing complex interventions."

c. From the article *Usefulness and safety of the GuideLiner catheter to enhance intubation and support of guide catheters: insights from the Twente GuideLiner registry* (Ex. 8):

- "[GuideLiner] use resulted in increased back-up and guide catheter alignment for stent delivery in unfavourable tortuous anatomies and complex, heavily calcified, and often distally located lesions, which otherwise may have been considered unsuitable for PCI [percutaneous coronary intervention]. Procedural success rate was high and there were no major complications."

- GuideLiner "is a novel rapid exchange guide catheter extension system."

- "During the first months, the GL was used as a bailout device in challenging cases, when the 'old familiar tricks' (e.g., deep-seating manoeuvres or use of buddy wires) had failed."

d. From the article *GuideLiner Catheter Facilitated PCI – A Novel Device with Multiple Applications* (Ex. 9):

- "The GuideLiner catheter (*Vascular Solutions, Inc.*) is a novel device that is FDA approved and CE marked for assistance with device delivery during coronary interventional procedures."

- "The GuideLiner catheter has greatly simplified coronary intervention and broadened the lesion subsets that can be safely treated with 6 Fr guiding catheters and via the radial approach."

e. From the article *Use of the GuideLiner Catheter for the Treatment of a Bifurcational Total Occlusion of the Native Left Anterior Descending Artery through a Tortuous Composite Venous Graft* (Ex. 11):

- "Our case illustrates the efficacy of the GuideLiner catheter in providing the support needed for crossing a CTO and for stent delivery in challenging cases. We used it up front due to previous failure in advancing a guidewire and a support catheter through the SVG."

- "We report the first case of GuideLiner use in complex native coronary artery intervention through a venous graft. The atraumatic deep-seating allowed by this device provided the extra support needed to cross a CTO beyond tortuous segments and to advance devices through sharp angulations. In addition, its monorail design allowed its easy advancement through the hemostatic valve and easy handling of balloons and stents."

f. From the article *The GuideLiner "Child" Catheter for Percutaneous Coronary Intervention – Early Clinical Experience* (Ex. 12):

- "All cases involved intervention of the RCA, for which extra backup support is often required. In some cases, stent delivery was impossible despite the use of a highly supportive guiding catheter, buddy wires and a buddy balloon. The GuideLiner catheter provided the additional backup support required for stent delivery. Deep target-vessel intubation was possible without displacement of the guiding catheter/wire or vessel trauma."

g. From the article *Distal Stent Delivery With Guideliner Catheter: First in Man Experience* (Ex. 13):

- "The GuideLiner catheter was used for stent delivery following prior failure using conventional techniques or upfront use due to anticipated failure . . . . Balloon and stent delivery was successfully achieved in all cases and the device was simple both to deploy and remove and was not associated with a procedural complication in any case."

- "Advantages of the Guideliner include not needing to remove and reconnect the Y connector, less risk of air embolism, easier control of the mother catheter, easier advancement and removal, and ability to advance a stent further distal beyond the catheter tip."

- "The Guideliner is an easy to use guide catheter extension that greatly facilitates backup support and stent delivery, significantly extending the scope of coronary intervention possible within a 6F mother guide catheter."

45. Cardiologists have provided comments about the use of the GuideLiner catheter that VSI has included in GuideLiner marketing materials, among them these:

- Douglas Fraser, M.D., of Manchester Heart Centre in Manchester, United Kingdom, stated: "The GuideLiner is as easy to insert as a standard rapid exchange balloon catheter and has quickly become a routine part of my angioplasty practice."

- Matthew Price, M.D., FACC, FSCAI, of Scripps Clinic in La Jolla, California, stated: "The GuideLiner has become an indispensable part of my tool kit for complex PCI. Simply put, it's a game changer."

- Mehdi Shishehbor, DO, MPH, of Cleveland Clinic in Cleveland, Ohio, stated: "All interventional cardiologists should be familiar with the GuideLiner – it can really save you one day!"

- Ashish Pershad, M.D., FACC, FSCAI, of Heart and Vascular Center of Arizona, in Phoenix, Arizona, stated: "The GuideLiner allows me to successfully complete previously unimaginable interventions."

Attached as **Exhibit 15** are true and correct copies of the forms verifying the physicians' consent to use their statements.

Boston Scientific and its Infringing Guidezilla Catheter

46. Boston Scientific is a large medical device company, which based on public filings had reported worldwide revenue of $7.2 billion in 2012. Attached as **Exhibit 16** is a true and correct copy of an excerpt from Boston Scientific's website, printed on May 27, 2013. Attached as **Exhibit 17** is a true and correct excerpt from Boston Scientific's 2012 Annual Report.

47. According to its website and Annual Report, Boston Scientific develops and markets medical devices through seven divisions: cardiac rhythm management, electrophysiology, endoscopy, interventional cardiology, neuromodulation, peripheral interventions, and urology and women's health. *See* Ex. 16 at 1-7; Ex. 17 at 3. The interventional cardiology business accounted for 30% of Boston Scientific's sales in 2012. *See* Ex. 17 at 2.

48. Boston Scientific is the largest medical device company in the U.S. market for interventional cardiology devices, with a 40% share of the market according to 2010 market research estimates. Attached as **Exhibit 18** is a true and correct copy of a market research report. Through its interventional cardiology division, Boston Scientific sells a variety of medical devices in eleven product sub-categories into this market, including drug-eluting stents, balloon catheters, guide wires, and guide catheters. In its Annual Report, Boston Scientific attributes the success of its interventional cardiology business largely to its coronary stent product offerings. *See* Ex. 17 at 7. Boston Scientific promotes more than forty separate interventional cardiology products on its website. *See*

Ex. 16 at 8-18. Even within the specific category of "guide catheters," Boston Scientific promotes four different products. *See* Ex. 16 at 13.

49. Since VSI launched its GuideLiner catheter in 2009, interventional cardiologists have used VSI's GuideLiner catheter to deliver Boston Scientific's drug-eluting stents into coronary arteries. I expect, based on my experience in this industry, that Boston Scientific's sales and marketing employees are aware of the use of GuideLiner in delivering Boston Scientific's stents.

50. According to public records, on February 14, 2012 Boston Scientific filed a trademark application on "Guidezilla" for use as a medical guide catheter with the U.S. Patent & Trademark Office. Attached as **Exhibit 19** is a true and correct copy of Boston Scientific's trademark application, printed from the records of the U.S. Patent & Trademark Office.

51. On October 2, 2012, I met the president of Boston Scientific's Interventional Cardiology Division, Kevin Ballinger, at an event sponsored by the trade organization LifeScience Alley, in St. Louis Park, Minnesota. I had previously heard rumors that Boston Scientific may be developing a new guide extension catheter, so at the event I asked Mr. Ballinger if Boston Scientific was developing a new guide catheter called Godzilla or Guidezilla. In response, Mr. Ballinger stated that Boston Scientific had not developed a new guide catheter in over a decade.

52. On October 16, 2012, I sent a letter to Mr. Ballinger informing him of the patents-in-suit. Attached as **Exhibit 20** is a true and correct copy of the letter (without copies of the patents, which were enclosed). Mr. Ballinger did not respond.

53. I regularly track the Food & Drug Administration ("FDA") filings for new medical devices. During March 2013, I discovered that Boston Scientific had prepared a 510(k) application with the FDA for the Guidezilla catheter on December 6, 2012 and filed it on February 19, 2013. Attached as **Exhibit 21** is a true and correct copy of the application and clearance letter from the FDA website.

54. Boston Scientific's 510(k) filing identifies the GuideLiner catheter as the only predicate device for the Guidezilla catheter. The Guidezilla catheter's "Intended Use / Indications for Use" included in the 510(k) application is the same as the current Intended Use that VSI created and provides with its GuideLiner catheter.

55. As part of its filing with the FDA, Boston Scientific stated the following: "The GUIDEZILLA™ Guide Extension Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as the GuideLiner V2 (K112082)." Ex. 21 at 1.

56. Boston Scientific received 510(k) clearance from the FDA for the Guidezilla catheter on March 19, 2013. *See* Ex. 21.

57. Sam Rasmussen was employed as a Senior Product Manager at VSI from June 2006 through November 2006, a time period during which VSI was actively developing its GuideLiner catheter and during which time Rasmussen's office was close to members of the GuideLiner product development team. Rasmussen voluntarily left VSI's employ in November 2006 and is currently employed as a Senior Product Manager at Boston Scientific. Based on information received through VSI's sales force, I believe

that Rasmussen is responsible for providing marketing leadership for the launch of the Guidezilla catheter at Boston Scientific.

58. On March 21, 2013, Rasmussen contacted VSI's sales representative for the Minnesota territory, Matt Nigon, wanting to discuss the GuideLiner catheter. Rasmussen asked Nigon about the market size and pricing for the GuideLiner catheter.

59. On April 12, 2013, I learned from Susan Griffith, a VSI account manager, that Boston Scientific had provided a Guidezilla catheter for clinical use at Barnes Jewish Hospital in St. Louis, Missouri, where it was used on a patient. At that time, I still had not seen an actual Guidezilla catheter. I subsequently learned through various account managers and physicians that additional Guidezilla catheters have been provided by Boston Scientific since April 12, 2013, for clinical use in California, Illinois, New York, and numerous other states across the United States.

60. On April 25, 2013, I sent another letter to Mr. Ballinger, asking to see any analysis performed by Boston Scientific with respect to the patents-in-suit, to purchase a sample of the Guidezilla for evaluation, and to discuss the issue. Attached as **Exhibit 22** is a true and correct copy of the letter. On May 3, 2013, I received a written reply stating only that Mr. Ballinger had forwarded my letter to his legal department for review. Attached as **Exhibit 23** is a true and correct copy of the reply. No further response was received from Ballinger or Boston Scientific until after VSI served its Complaint.

61. On May 6, 2013, I obtained my first sample of the Guidezilla catheter from an outside source. I obtained a second sample on May 8, 2013, along with the Guidezilla Directions for Use and packaging. I personally examined Boston Scientific's Guidezilla

catheter. Photographs of the catheter were taken at my direction.

62. Attached as **Exhibit 24** is a true and correct photograph of the front and back of the box in which Boston Scientific sells its Guidezilla catheter, as well as a photograph of the inner pouch containing the catheter. Boston Scientific's packaging indicates that its Guidezilla catheter is "Made in U.S.A."

63. Boston Scientific includes with the Guidezilla catheter shipped to a customer in the United States its Directions for Use. Attached as **Exhibit 25** is a true and correct copy of the Directions for Use for the Guidezilla catheter that I received.

64. Boston Scientific describes its Guidezilla catheter in its Directions for Use as "a single lumen rapid exchange catheter" with "a stainless steel proximal shaft with a 25 cm single lumen distal guide segment . . . ." Ex. 25 at 2. This description is the same as VSI's description of its GuideLiner catheter in its Instructions for Use ("IFU") as "a single lumen rapid exchange catheter" with "a stainless steel shaft with a 25cm single lumen . . . ." A true and correct copy of the GuideLiner V2 IFU is attached as **Exhibit 26**.

65. VSI obtained copyright registrations for both its GuideLiner V1 and GuideLiner V2 IFUs. Attached as **Exhibit 27** are true and correct copies of U.S. Copyright Registration Nos. TX-7-679-165 and TX-7-679-167.

66. Boston Scientific's Directions for Use for its Guidezilla catheter is a copy of the VSI IFU for its GuideLiner catheter, including the "Deployment Procedure" / "Delivery Procedure" section as shown below (language copied from GuideLiner catheter Instructions into Guidezilla Directions is shown in bold):

GuideLiner	Guidezilla
Deploy **the Guide**Liner catheter **according to the following steps:**	Deliver **the Guide**zilla device **according to the following steps:**
1. Secure the previously inserted guidewire and backload the distal tip of the Guide Liner catheter **onto the guidewire and advance until the** catheter **is just proximal to the hemostasis valve.**	**1. Secure the previously inserted guidewire and backload the distal tip of the Guide**zilla device **onto the guidewire and advance until the** device **is just proximal to the hemostasis valve.**
2. Open the hemostasis valve and advance the Guide Liner catheter **through the hemostasis valve and into the guide catheter.**	**2. Open the hemostasis valve and advance the Guide**zilla device **through the hemostasis valve and into the guide catheter.**
3. Under fluoroscopy, advance the Guide Liner catheter **up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel.**	**3. Under fluoroscopy, advance the Guide**zilla device **up to a maximum of 15 cm beyond the distal tip of the guide catheter and into the desired location within the vessel.**
Warning: Never advance the Guide Liner catheter **into a vessel with an effective diameter less than 2.5mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the Guide**Liner **catheter, withdraw the Guide**Liner **catheter until the pressure returns to normal.**	**Warning: Never advance the Guide**zilla device **into a vessel with an effective diameter less than 2.5 mm. Vessel injury, ischemia, and/or occlusion may result. If pressure in a vessel dampens after inserting the Guide**zilla **catheter, withdraw the Guide**zilla **catheter until the pressure returns to normal.**
Warning: Due to the size and non-tapered tip of the Guide Liner, **extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.**	**Warning: Due to the size and non-tapered tip of the Guide**zilla device, **extreme care must be taken to avoid vessel occlusion and damage to the wall of the vessels through which this catheter passes.***
4. Using fluoroscopy, confirm the desired position of the Guide Liner catheter **in the vessel.**	**4. Using fluoroscopy, confirm the desired position of the Guide**zilla device **in the vessel.**
5. If performing an interventional procedure, backload the interventional device over the in place **guidewire and advance the device through the guide catheter and Guide**Liner catheter **into the**	**5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guide**zilla device **into the**

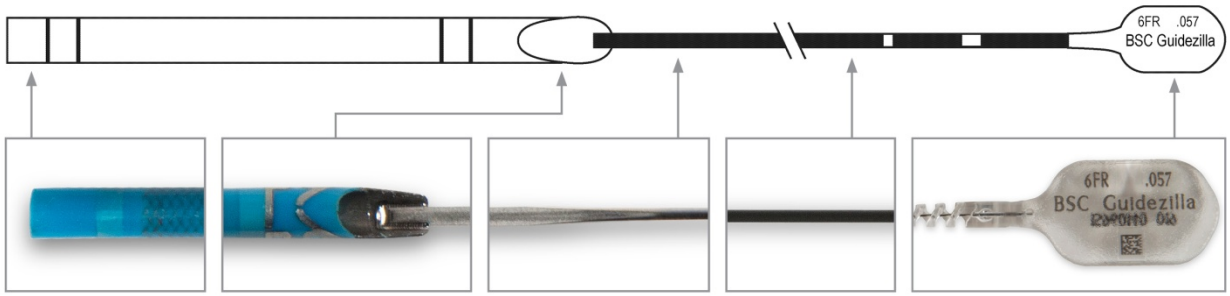
desired vascular space.	**desired vascular space.** Note: Use caution when advancing the interventional device into the distal guide segment.
6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guide Liner catheter **to prevent back-bleeding.**	**6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guide**zilla device **to prevent back-bleeding.**
7. Perform the catheterization procedure. After completing the procedure, remove the Guide Liner catheter **prior to removing the guide catheter from the vessel.**	**7. Perform the catheterization procedure. After completing the procedure, remove the Guide**zilla device **prior to removing the guide catheter from the vessel.**

* The order of the two warnings is reversed in the Guidezilla document. *Compare* Ex. 25 at 3 (Guidezilla), *with* Ex. 26 at 2 (GuideLiner).

67. In connection with its clinical evaluation process, which Boston Scientific refers to as its "Guidezilla Limited Market Evaluation," I understand that Boston Scientific provides physicians with a "New Product Evaluation Form." Attached as **Exhibit 28** is a true and correct copy of a New Product Evaluation Form that was completed after the use of a Guidezilla device at Memorial Medical Center in Springfield, Illinois which I received on April 23, 2013 from Tony Palma, a VSI associate account manager. The form asks physicians to disclose, among other information, the type of GuideLiner catheter they use in their practices, the percentages of cases in which they use the GuideLiner catheter, and the current cost of a GuideLiner catheter for their facility. The form also asks physicians to complete a "GUIDEZILLA Catheter vs. GuideLiner Catheter Evaluation."

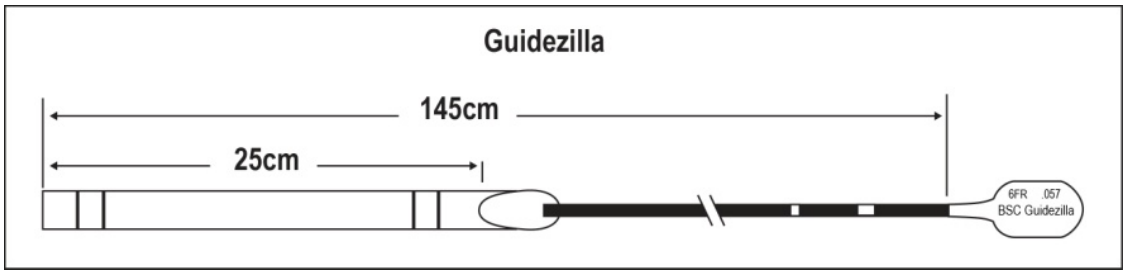
68. The drawing and section photographs below are true and correct representations and photographs of Boston Scientific's Guidezilla catheter, prepared and taken at my direction.

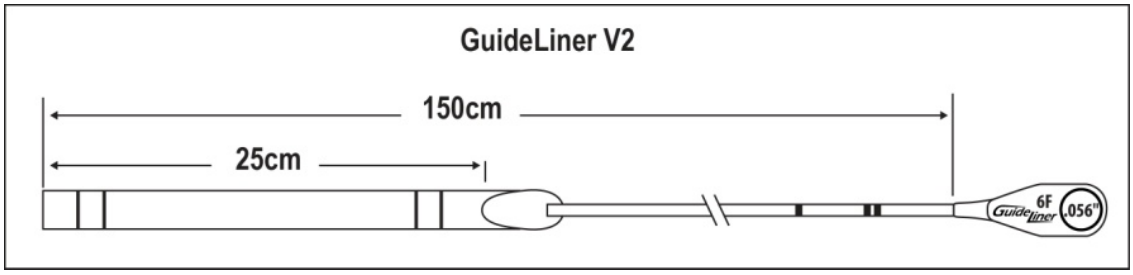
Boston Scientific's Guidezilla catheter

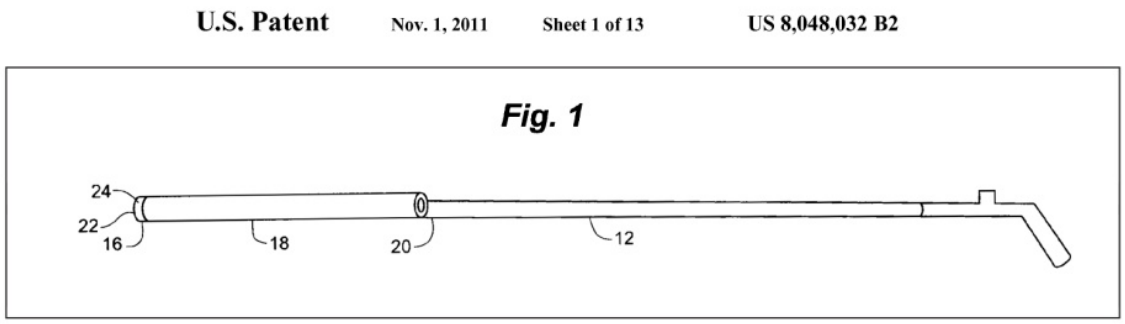


69. Boston Scientific's Guidezilla catheter is a copy of VSI's GuideLiner catheter. Guidezilla's design and dimensions are materially the same as those of the GuideLiner catheter and those described and claimed in the patents-in-suit. Attached as **Exhibit 29** is a true and correct copy of drawings comparing the dimensions of the Guidezilla catheter, the GuideLiner V1 catheter, and the Guideliner V2 catheter, and comparing aspects of the Guidezilla catheter to figures in the '032 patent. Attached as **Exhibit 30** is a true and correct series of photographs comparing aspects of the Guidezilla catheter to the GuideLiner V1 and V2 catheters.

70. The drawings below show a comparison of the Guidezilla catheter to the GuideLiner V2 catheter and to an excerpt of Figure 1 of the patents-in-suit (the orientation of the patent drawing has been flipped for comparison purposes):



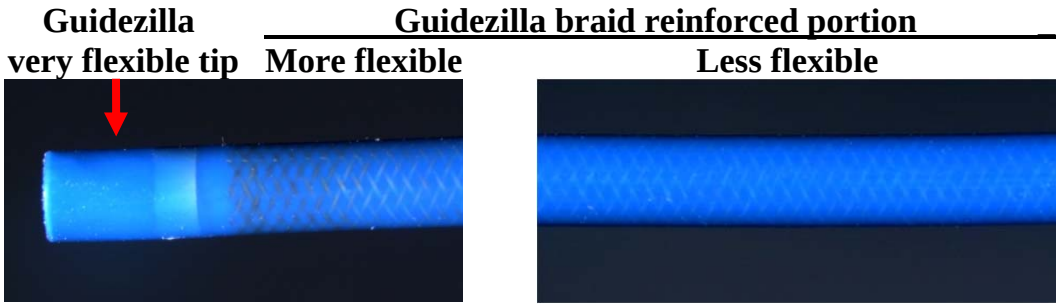




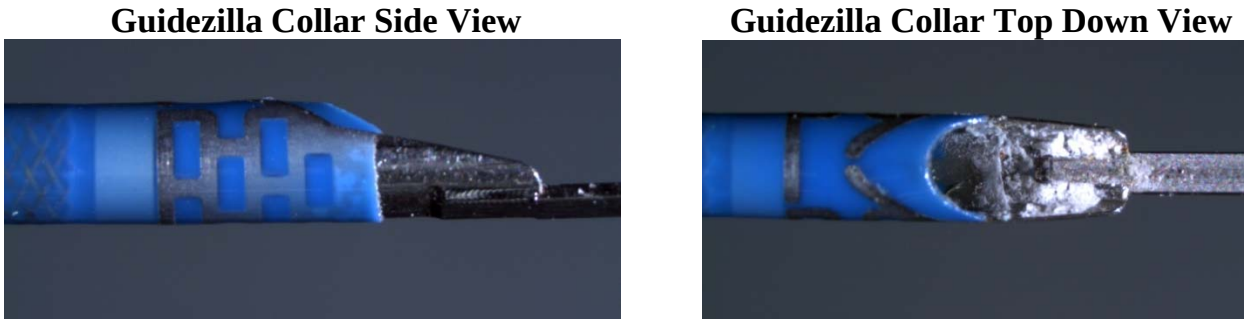
See Ex. 29.

71. The same as GuideLiner, the distal end of the Guidezilla is a relatively flexible tube with a lumen. The Guidezilla's flexible tube portion has the same three zones as GuideLiner: a very flexible blue tip, a less flexible blue portion, reinforced with

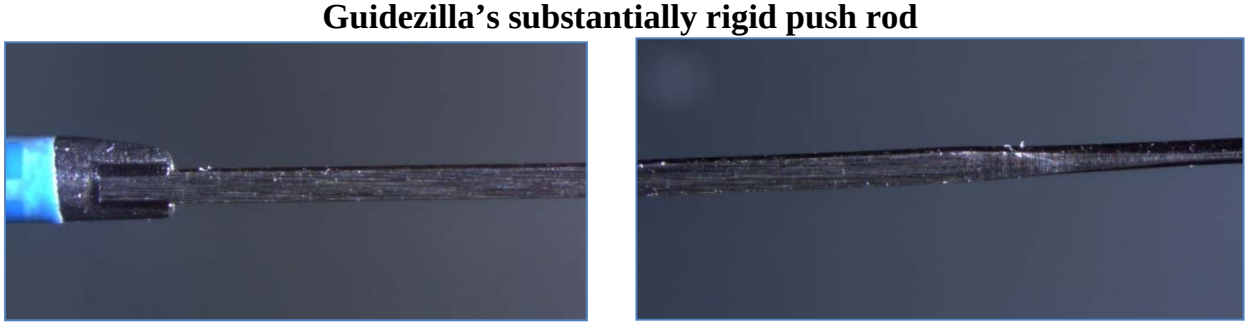
a braid, and further less flexible slightly darker blue portion made from a stiffer polymer as shown below:



72. The same as GuideLiner V1, the flexible tube portion of Guidezilla is joined to a relatively inflexible metal collar where the lumen ends with a sloped opening:

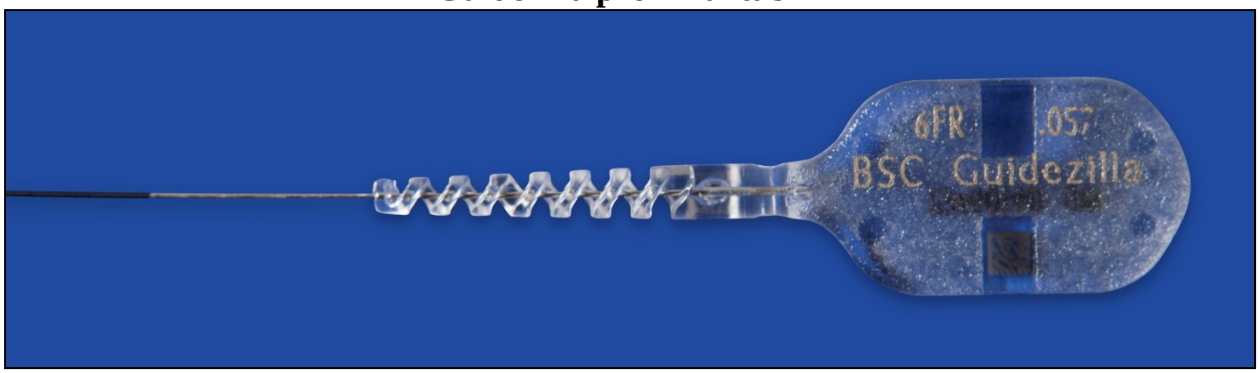


73. The same as GuideLiner V1, the metal collar of Guidezilla is then connected to a substantially rigid push rod that extends for the remainder of the length of the Guidezilla catheter:



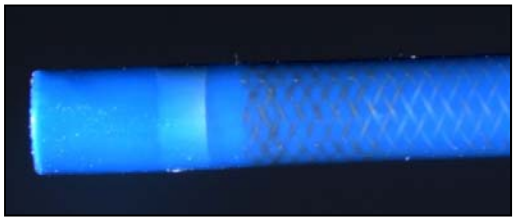
74. The same as GuideLiner, the proximal end of the push rod of Guidezilla is embedded into a tab which is used to identify the catheter and prevent it from being inadvertently pushed through the hemostatic valve:

Guidezilla proximal tab

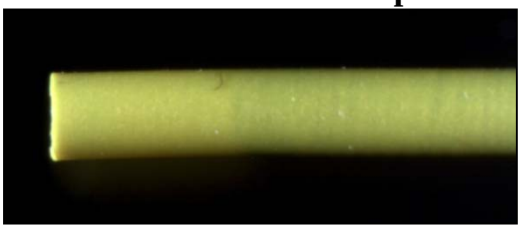


75. The construction of the flexible tip portion of the Guidezilla catheter provides the same guide extension functionality as the GuideLiner and as described and claimed in VSI's patents-in-suit. *See* Ex. 30. Because Guidezilla's flexible tip portion has a lumen, it allows medical devices such as stents to pass through the Guidezilla for placement in a coronary artery, the same as with GuideLiner.

Guidezilla flexible tip

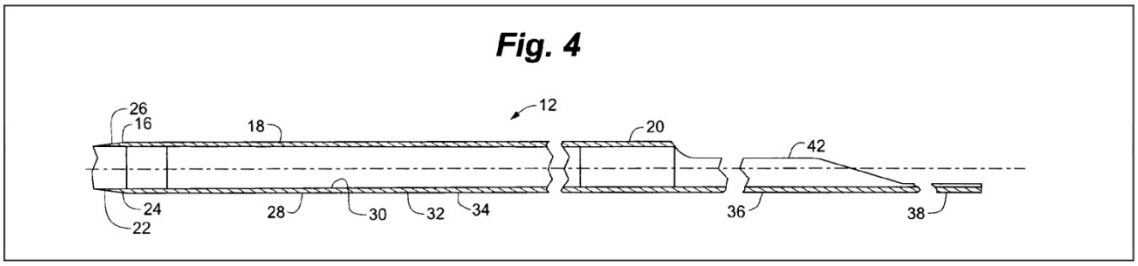


GuideLiner flexible tip

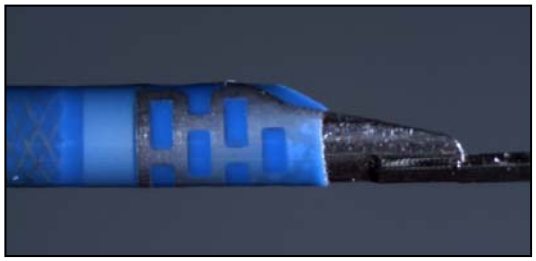


76. The construction of the collar portion of the Guidezilla catheter provides the same rapid exchange, or "rail," technology as VSI's GuideLiner catheter and as described and claimed in VSI's patents-in-suit. *See* Exs. 29, 30. The drawing and photographs

below show a comparison of the rapid exchange transition of the Guidezilla and VSI's GuideLiner catheters and Figure 1 of VSI's patents-in-suit:



Guidezilla collar



GuideLiner V1 collar

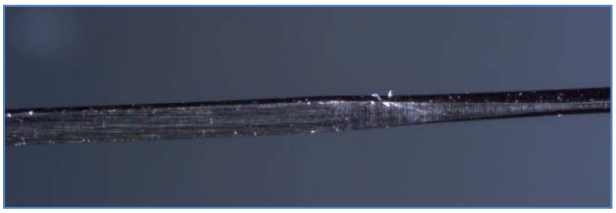
77. The construction of the push rod section of the Guidezilla catheter provides the same substantially rigid delivery without a lumen as VSI's GuideLiner catheter and as described and claimed in VSI's patents-in-suit. *See* Ex. 30. The Guidezilla push rod is made from a stainless steel hypotube, with the proximal end embedded in a plastic tab and has no opening.

Guidezilla substantially rigid portion

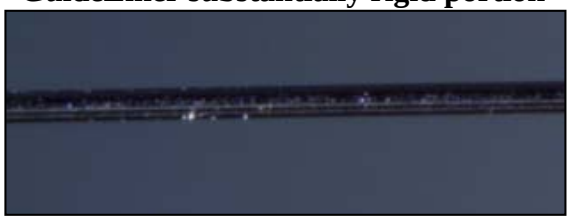
GuideLiner substantially rigid portion

78. The distal 2cm of the Guidezilla push rod section has been crushed flat and welded shut to the collar and has no opening. As a result, no medical device (or even a liquid or gas) can be delivered into or passed through Guidezilla's push rod.

Guidezilla "crushed" substantially rigid portion

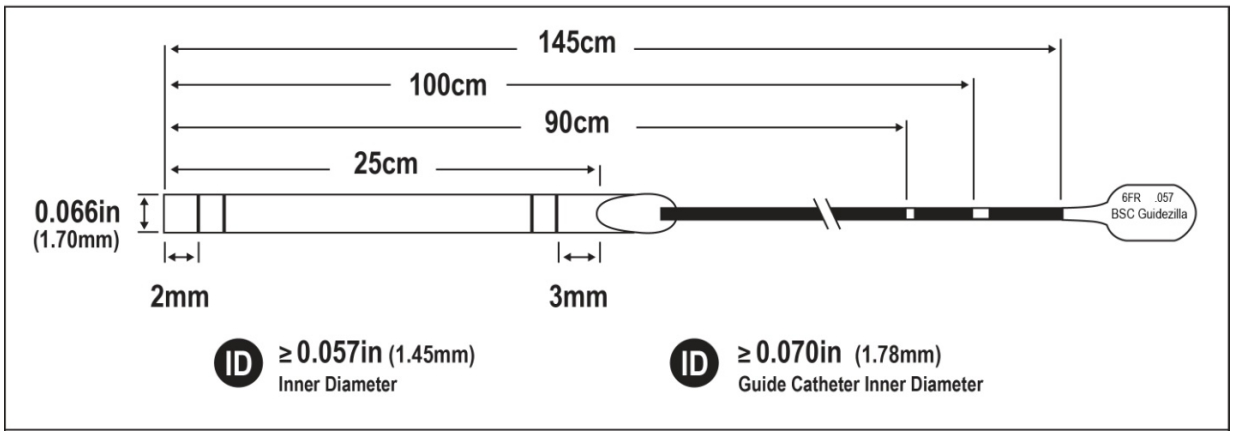


GuideLiner substantially rigid portion

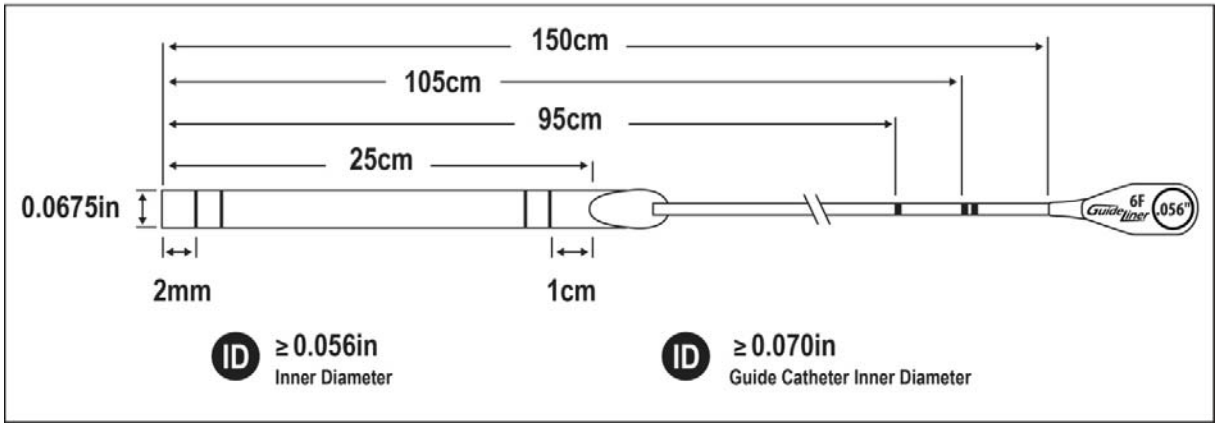


79. The construction and dimensions of the Guidezilla are an almost exact copy of the construction and dimensions of the GuideLiner as shown in the schematic below (*see* Ex. 29):

Guidezilla



GuideLiner V2



Boston Scientific's Guidezilla Catheter Infringes The VSI Patents

80. I have examined the Boston Scientific Guidezilla catheter and compared it to the claims of VSI's patents. As explained below and in the attached claim charts, the Guidezilla catheter infringes VSI's '032, '413, and '850 patents.

81. The Boston Scientific Guidezilla catheter meets every limitation of at least claims 1-8, 11-17, and 19 of the ‘032 patent. A claim chart showing my detailed comparison of the Guidezilla product to the limitations of the asserted claims of the ‘032 patent is attached as **Exhibit 31**.

82. By way of example, I have analyzed below claim 1 of the ‘032 patent as compared to Boston Scientific’s Guidezilla catheter.

83. The preamble of the ‘032 patent, claim 1 describes a device for use with a standard guide catheter, as set forth below:

Preamble	Guidezilla
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 Guidezilla Directions for Use (Ex. 25) indicate that the Guidezilla catheter is intended to be used in connection with a 6F standard guide catheter, which has a predefined length (100 cm) and a continuous lumen extending from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, sized such that interventional cardiology devices such as balloons or stents are insertable into and through the lumen to the branch artery.

84. Claim 1 of the ‘032 patent also requires that the device have a “flexible tip” portion, as described below:

Flexible tip	Guidezilla
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined 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,	The Guidezilla catheter has a flexible tip portion that defines a tubular structure with a circular cross-section. The Guidezilla catheter is described in the Directions for Use as a “single lumen rapid exchange catheter” through which interventional devices are insertable. (Ex. 25). The flexible tip portion is about 25 cm long and thus shorter than the 100 cm length of the continuous lumen of a standard guide catheter. The tubular structure has a cross-sectional outer diameter that allows it to be insertable in a standard guide catheter (“approximately 1 French smaller than the guide catheter”), and a cross-sectional inner diameter through which interventional cardiology devices are insertable.

85. Claim 1 of the ‘032 patent also requires a “substantially rigid portion” as described below:

Substantially rigid portion	Guidezilla
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	The Guidezilla catheter has “a stainless steel proximal shaft” (Ex. 25) which is substantially rigid, proximal of and operably connected to, and more rigid than, the flexible tip portion. The shaft portion defines a rail structure, without a lumen (as discussed in detail below), and has a maximal cross-sectional

flexible tip portion and having a length that, when combined with the length of the flexible distal 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,	dimension at a proximal portion that is smaller than the cross-sectional outer diameter of 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 (145 cm) that is longer than the length of the continuous lumen of the guide catheter (100 cm).

86. Claim 1 of the ‘032 patent also requires that the device be capable of being used for guide extension, as set forth below:

Guide extension	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 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 (including the proximal tab) extends through the hemostatic valve. The Guidezilla 510(k) states that the Guidezilla “acts as an extension to a traditional catheter.” (Ex. 21) The Guidezilla Directions for Use instruct that the Guidezilla catheter be advanced up to a maximum of 15 cm “beyond the distal tip of the guide catheter” and advanced “through the hemostasis valve and into the guide catheter.” (Ex. 25)

87. Similarly, I have performed an analysis of the other asserted claims of the ‘032 patent, and the Guidezilla catheter meets those claim limitations. *See* Ex. 31.

88. On June 3, 2013, counsel for Boston Scientific sent a letter to VSI's counsel, claiming that the Guidezilla catheter did not meet the requirement that the substantially rigid portion define a rail structure "without a lumen." According to Boston Scientific's counsel, the substantially rigid portion of the Guidezilla is formed from a hypotube that "has a continuous lumen running its entire length." This is the first substantive response of any kind that VSI has received from Boston Scientific. Attached as **Exhibit 32** is a true and correct copy of counsel's June 3, 2013 letter.

89. I have studied the substantially rigid portion (the push rod) of the Guidezilla device and Boston Scientific's instructional materials describing the same. The Guidezilla's pushrod is made of a stainless steel hypotube. A hypotube is an extremely thin hollow tube. The term "hypo" means "under", and a hypotube is generally thought of as a thin hollow tube that can be used to make a hypodermic needle that is placed under the skin.

90. With the Guidezilla hypotube, Boston Scientific has crushed flat its most distal two centimeters where it is welded to the collar. At the other end of the hypotube, Boston Scientific has embedded and sealed the hypotube into Guidezilla's plastic proximal tab**.** As a result, there is no opening to the space inside the hypotube to deliver any device through it or even into it. Furthermore, there is no space remaining inside the

hypotube for the final two centimeters where it has been crushed and welded to the collar. The following photographs of the Guidezilla hypotube were taken at my direction.

Guidezilla hypotube push rod sections

Welded to collar	Crushed flat (2cm)	Round	Sealed in plastic tab
			

91. VSI's patents, all of which have a common specification, teach that the patented device's substantially rigid portion, or pushrod, can be formed from a hypotube. The patent contains this teaching in three different places. The patent states, "Rigid portion 20 may be formed from a hypotube or a section of stainless steel or Nitinol tubing." Ex. 2, col. 6, lns. 35-37; *see also id.* at col. 3, lns. 47-48 and col. 7, lns. 24-25.

92. As I understand the term "lumen" as used in the patents and in the field of interventional cardiology, it refers to the interior of a tubular structure, open at both ends to allow the passage of medical devices (for example, stents or balloons) and contrast medium. In the context of medical devices used in interventional cardiology, an inner cavity or void is not a lumen.

93. Definitions and usages from medical literature concerning medical devices are consistent with the discussion above. In the medical device context, "lumen" is defined as "the bore of a hollow needle, catheter, etc.," or "a hollow space, as in the bore of a hollow needle or in a bodily duct or tract." All of these medical devices allow some material, whether solid, liquid or gas, to pass through the lumen. Attached as **Exhibit 33** are true and correct copies of these definitions.

94. Attached as **Exhibit 34** are true and correct copies of literature from the field of interventional cardiology, marked up to show the use of the term "lumen." These uses of the term "lumen" are consistent with my understanding of the term.

95. Boston Scientific also uses the term "lumen" with its other products in this same way. Attached as **Exhibit 35** is a true and correct copy of excerpts from Boston Scientific's website.

96. The claims of the VSI patents themselves state that a lumen allows interventional cardiology devices to pass through the lumen to reach the artery. Claim 1 of the '032 patent (Ex. 2) recites:

- "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"; and
- "a flexible tip portion defining a tubular structure . . . defining a coaxial lumen [with the guide catheter] having a cross-sectional inner diameter through which interventional cardiology devices are insertable."

97. In addition, all other independent claims of the VSI patents contain this same type of language. Claim 1 of the '413 patent, for example, recites, "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." Ex. 3.

98. The specification of the three VSI patents uses the term "lumen" to refer to a passage through which interventional cardiology devices are able to pass, so that the device can reach the arterial site. This usage starts with the Abstract. The '032 patent's Abstract states,

> The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

The remainder of the specification also uses "lumen" in this manner. For example, the '032 patent states:

- "a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis," Ex. 2, col. 1, lns. 32-36;
- "Both the straight portion and the tapered portion are pierced by a lumen through which a guidewire may be passed." Ex. 2, col. 4, lns. 2-4;
- "the lumen that passes through the straight portion and the tapered portion," Ex. 2, col. 4, lns. 5-7;
- "tapered portion 46 and straight portion 48 are pierced by lumen 50," Ex. 2, col. 6, lns. 60-61; and
- "An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter 12 which remains inside guide catheter 56." Ex. 2, col. 9, lns. 59-63.

99. The phrase "defining a rail structure without a lumen" was added to the claims at the end of prosecution of the '032 patent. I attach as **Exhibits 36-38** file history excerpts showing the addition of that language to the claims of all three patents.

100. The use of the term "lumen" in the VSI patents distinguishes VSI's invention from prior OTW guide catheter extensions. With OTW guide catheter extensions (such as Terumo's Heartrail), medical devices (such as stents) are passed through the child catheter's lumen, which runs the entire length of the catheter. VSI's invention, however, provides that medical devices are only passed through the lumen of

the distal flexible tip portion, and not through the proximal push rod. Therefore, with VSI's invention the substantially rigid push rod is "defining a rail structure without a lumen" because it does not provide for the delivery of medical devices through the push rod. Instead, the substantially rigid portion, or the push rod, is used only to push the flexible tip over a guidewire and through the guide catheter. When VSI's invention is used, interventional and other devices are able to pass through the guide catheter next to, but not through, the substantially rigid portion.

101. As part of any medical device sold in the U.S., the manufacturer must write, approve and supply with every device shipped a document known either as the Instructions for Use, or sometimes referred to as Directions for Use. In the "Device Description" section of the Directions for Use for Guidezilla, Boston Scientific described the Guidezilla catheter as "a single lumen rapid exchange catheter" "with a 25cm single lumen distal guide segment" through which interventional devices are insertable. (Ex. 25). By stating in an FDA-required and corporate-approved document that there is only a single lumen in the Guidezilla catheter and that the single lumen is the distal flexible 25cm section, Boston Scientific's regulatory, marketing and business managers recognized that the Guidezilla push rod does not have a lumen, because nothing can be inserted into or through it.

102. Even with the cavity that exists in its hypotube, the Guidezilla's substantially rigid portion is substantially the same as the substantially rigid portion claimed in the VSI patent claims. The existence of Guidezilla's cavity sealed at both ends makes no practical or functional difference to the patent's "substantially rigid

portion . . . defining a rail structure without a lumen" since it performs substantially the same function, in substantially the same way, to obtain the same result, as the claim element of a substantially rigid portion. The Guidezilla's substantially rigid portion, like the claim element of the substantially rigid portion, is insertable through the hemostatic valve, is used to push the Guidezilla's flexible tip portion over the guidewire and through the guide catheter, allows for rapid exchange, and is a "rail" system in contrast to the "over the wire" system described in detail above.

103. Because nothing can pass through the cavity in the Guidezilla's substantially rigid portion, it does not in any way function as a "lumen," and indeed serves no functional purpose. The Guidezilla catheter's substantially rigid portion thus provides the exact same functional result, in the exact same way, to achieve the same result as the "substantially rigid portion. . . defining a rail structure without a lumen" set forth in the claims.

The Guidezilla's Infringement of the '413 and '850 Patents

104. Boston Scientific's Guidezilla catheter, when used as intended and as directed by Boston Scientific in its Directions for Use and elsewhere, also meets every limitation of at least claims 1, 2, 4, 5, and 7-13 of the '413 patent. A claim chart showing my detailed comparison of the Guidezilla catheter and Boston Scientific's directions for using the Guidezilla catheter to the limitations of the asserted claims of the '413 patent is attached as **Exhibit 39**. The Guidezilla catheter is specially made for uses covered by the asserted claims of the '413 patent, it is not a staple article of commerce, and it is not suitable for any substantial noninfringing use.

105. Boston Scientific's Guidezilla catheter, when used with a standard guide catheter as directed by Boston Scientific, meets every limitation of at least claims 1-8, 12-18, and 20 of the '850 patent. A claim chart showing my detailed comparison of the Guidezilla catheter to the limitations of the asserted claims of the '850 patent is attached as **Exhibit 40**. The Guidezilla catheter is specially made for use as part of a system covered by the asserted claims of the '850 patent, it is not a staple article of commerce, and it is not suitable for any substantial noninfringing use.

106. I know that Boston Scientific is aware of the VSI patents, because I sent a letter to Mr. Ballinger in October 2012 bringing VSI's patents-in-suit to Boston Scientific's attention. As explained in Exhibits 39 and 40, following the Boston Scientific Directions for Use necessarily results in infringement of the '413 and '850 patents. The Guidezilla catheter has no uses other than to practice the VSI patents. As discussed in Exhibit 39, the Guidezilla catheter is designed and intended, and as instructed by Boston Scientific, for use with the method claimed in VSI's '413 patent. As further discussed in Exhibit 40, the Guidezilla catheter is designed and intended, and as instructed by Boston Scientific, for use with a guide catheter, thereby necessarily resulting in a system that infringes VSI's '850 patent.

VSI Will Continue to Suffer Irreparable Harm Until Boston Scientific's Sales of the Guidezilla Catheter Are Enjoined

107. Before Boston Scientific introduced its infringing Guidezilla product, VSI's patented GuideLiner catheter was a one of a kind product, the only guide extension catheter using rail technology. According to physicians using the product, the

GuideLiner had "no competitor device." Thus, in 2009, VSI created a new market in which it had no competitors.

108. I understand that Boston Scientific has only recently begun marketing its Guidezilla catheter, and is providing the product to certain physicians for clinical use and evaluation across the country and in Europe.

109. Boston Scientific has the resources to cause substantial and irreparable harm to VSI between now and the time of trial. Boston Scientific has substantially greater resources than VSI to devote to sales efforts and it has many more products and relationships that it can leverage to displace sales of GuideLiner with sales of Guidezilla. Because Boston Scientific copied VSI's product, rather than investing in the R&D necessary to develop its own, and because VSI already invested substantially in the education of physicians worldwide regarding its innovative product, Boston Scientific will be able to quickly reap the benefit of VSI's substantial investment.

110. The GuideLiner catheter is VSI's fastest-growing product, and represents approximately 20% of VSI's annual sales revenue. VSI's ability to continue to increase GuideLiner catheter sales and maintain its exclusive market position is extremely important to VSI. If Boston Scientific is allowed to sell its infringing Guidezilla product in competition with VSI over the next 12-18 months, VSI will suffer severe and irreversible harm that cannot be compensated by a money judgment. I explain below the various harms that are likely to result if Boston Scientific's infringement is not stopped.

111. Irreparable distraction of VSI's sales force. VSI's sales force will be forced to devote substantial time and attention to deal with Boston Scientific's competition. Our

salespeople will necessarily have to try to retain their existing GuideLiner customers against the competition (when none previously existed), rather than seeking new customers or selling additional VSI products. Even after the Guidezilla catheter is off the market, the sales force will have to spend time gaining back the lost accounts. It is not possible to quantify how many additional VSI products could have sold if Boston Scientific had not been allowed to continue infringing because the VSI sales force has to spend time dealing with Boston Scientific's copycat product.

112. Irreparable price erosion. Boston Scientific's market dominating size and large portfolio of other products will allow it to undercut VSI's price for the GuideLiner catheter. Boston Scientific can easily charge a lower price for its Guidezilla catheter, since it is a copy of VSI's device and Boston Scientific did not have to invest in developing its own product. Boston Scientific has many other products which it can bundle with the Guidezilla catheter, thereby lowering the Guidezilla pricing for the customer but making up the shortfall on other products Boston Scientific sells. Because of its size, Boston Scientific also can withstand reduced pricing on a small revenue product (for it) like Guidezilla to take market share from the much smaller VSI where GuideLiner sales matter to a much higher degree. Boston Scientific's infringement will completely alter the pricing structure of the market for VSI's GuideLiner catheter, in ways that cannot be measured and compensated for by a money judgment 12-18 months from now.

113. Boston Scientific is already undercutting VSI on price, even during its early marketing of the Guidezilla product. I learned from a VSI account manager, James

Capizzuto, that on May 7, 2013, he visited Columbia Presbyterian Hospital in New York, which until that time was one of VSI's largest GuideLiner accounts. Capizzuto told me that he witnessed the Cardiac Catheterization Laboratory manager with a Boston Scientific representative comparing Guidezilla brochures and GuideLiner brochures on a computer, and then comparing product pricing in the inventory system. Capizzuto subsequently confirmed that Boston Scientific had undercut VSI's price by $29 per unit, and that Columbia Presbyterian loaded Boston Scientific's Guidezilla 6F catheter into its inventory system for purchase.

114. If Boston Scientific is allowed to continue to infringe, VSI will almost certainly be forced to lower its GuideLiner catheter prices, in order to try to maintain market share. Once VSI lowers its pricing on its GuideLiner catheters, VSI will not be able to easily raise its prices again if an injunction is issued 12-18 months from now. VSI's customers are under substantial pressure to cut costs, and many of them will resist future price increases once a price has been lowered. It is not possible to quantify or predict how long this effect will last, or how much harm it will cause VSI.

115. Loss of associated sales of other VSI products. The GuideLiner catheter is VSI's most visible product, giving VSI greater credibility and opening the door into virtually every cardiac catheterization lab in the United States. As explained above in Paragraph 42 and Exhibit 41 (filed under seal), VSI has gained many new customers because of the GuideLiner catheter, and has been able to sell those new customers many other VSI products, generating substantial sales revenue.

116. The infringing competition from the Guidezilla catheter will hamper VSI's efforts to gain and maintain customer relationships. If customers are buying the Guidezilla catheter, VSI will lose not only the sales of the GuideLiner catheter, but also the sales of other VSI products we could have sold, if our salespeople had been able to form and maintain relationships with those customers. In my judgment, it is not possible to quantify 12-18 months from now how many new customers we could have gained or customers for other VSI products we would have kept but for Boston Scientific's infringement, nor is it possible to quantify the loss of sales revenue. At a minimum, such losses will be extremely difficult to quantify to a reasonable degree of certainty, which I understand to be the legal standard we would have to meet.

117. Lack of revenue to fund R&D. VSI's practice is to allocate 10-12% of revenue for research and development. This R&D spending is critical to the company's long-term health, as without investment in R&D, VSI will not have new and improved products to sell. No medical device company can survive, let alone prosper, without new and improved products, as our competitors are constantly attempting to innovate as well.

118. Currently, the GuideLiner catheter revenues are 20% of VSI's sales, and growing very quickly. If those sales fail to grow as projected because of Boston Scientific's infringement, VSI will have to reduce its planned investment in research and development. That reduction would necessarily reduce VSI's hiring of new employees, and if the reduction is severe enough, could require lay-offs.

119. The reduction in R&D investment will harm VSI in ways that cannot be calculated, because it is not possible to quantify how current investment in R&D results

in long-term sales revenue from new and improved products. At a minimum, it is not possible to quantify such harm to a reasonable degree of certainty required for a damages award.

120. Sales force attrition. VSI employs 91 sales employees, largely comprised of account managers, in the United States. Our sales force is the lifeblood of our business, as a good sales force is critical to VSI's ability to sell its products.

121. Our account managers are responsible for selling VSI's products directly to physicians – principally to interventional cardiologists who use the majority of our products. VSI's account managers, over time, develop relationships with their physician customers, as well as with the nurses, lab technicians, and purchasing managers, who are often involved in the buying decision.

122. VSI's sales force has to have a thorough understanding of VSI's products, as well as the needs of VSI's current customers, in order to successfully sell VSI's products. Account managers are often present during a medical procedure using a VSI product to explain the functionality of the particular medical device they are selling and servicing. The majority of VSI's sales representatives have some clinical experience or qualifications.

123. VSI substantially invests in sales force training and retention. VSI conducts multiple training sessions each year for its sales employees, and holds a World Sales Meeting once a year. During these training sessions, account managers are instructed on how VSI's products are used in the medical field, how they compare to competitors' products, and techniques for selling VSI's products to physicians and hospitals.

124. A substantial part of the account managers' compensation is based on sales commissions and bonuses for hitting sales and growth targets. If GuideLiner sales decline due to Boston Scientific's infringing product sales, commissions and bonus payments to VSI's account managers will decline.

125. In my experience, lower compensation for sales employees causes significant attrition. For example, in 2001-2003, when VSI's sales of its first product, the Duett, did not grow as expected, we had more than 100% turnover in our sales force over a two year period of time. Based on that experience and my knowledge of the industry, I believe that even a short period of infringement by Boston Scientific will result in VSI losing some, and possibly a substantial number, of its sales employees.

126. One harmful and hard-to-quantify effect of losing sales employees is the loss of the relationships those employees have formed with their customers. Customer relationships are personal, and can last for many years. VSI account managers are not only sales personnel, but also provide their customers with training, information, and support. In most cases, those customers purchase multiple products from their VSI Account Manager. Thus, the loss of a relationship opens the door – not just for Boston Scientific to sell its infringing Guidezilla products, but for other companies selling products competing with other VSI products. It would be extremely difficult to identify, or quantify the value of, those lost customer relationships at the time of trial.

127. In addition, VSI must replace its lost sales employees. It takes up to four years to fully train a new sales employee on all of VSI's more than seventy-five products before he or she is completely proficient. In addition to VSI's added training costs, an

untrained Account Manager, just beginning to form relationships with customers, is unlikely to be as successful selling the GuideLiner product and VSI's other products. Boston Scientific's infringing Guidezilla device will cause long-lasting or permanent damage to VSI's sales structure and sales force, which has taken years for VSI to build.

128. VSI's reputation will change from innovator to competitor. Before Boston Scientific's Guidezilla product came into the market, VSI had the only catheter that combined the benefits of guide extension with rail technology. This unique product gave a tremendous boost to VSI's reputation as an innovative company. Boston Scientific's entry will change the market from a single player with an exclusive, patented product to one with a copycat product being sold by a major competitor. VSI will lose its market exclusivity, changing the market's perception of VSI and affecting VSI's credibility as an innovator in a way that cannot be reversed 12-18 months from now when Boston Scientific's product sales are enjoined.

129. Negative effects on VSI's stock price. VSI is a public company, and its stock price depends in significant part on our ability to continue VSI's track record of increasing sales and profitability. VSI has increased sales by more than 10% in each of the last nine years, and I expect that growth to continue in 2013. Without growth in GuideLiner sales, however, a 10% annual growth rate would be unlikely, and VSI's stock price will either decline or not increase as much as it would otherwise as a result of Boston Scientific's infringement.

130. As a public company, VSI's stock price is an important factor in our ability to grow, by attracting talented new employees, rewarding current employees with stock-

based compensation, and using our stock to make potential future acquisitions to build VSI's business. Those harms from a declining or even not increasing stock price cannot be adequately measured or compensated through a damages award for lost sales or a reasonable royalty years from now.

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

Executed on June 10, 2013, in Hennepin County, Minnesota.

s/ Howard Root
Howard Root

Exhibit 1

Z. Kardiol. 76, Supplement 6 (1987)

T. Bonzel, P.W. Serruys (Eds.)

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The sliding rail system (monorail): description of a new technique for intravascular instrumentation and its application to coronary angioplasty

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Summary: The sliding rail technique is a new technique for intravascular instrumentation, especially coronary stenosis dilatation. The so-called monorail balloon catheter is the first device which can be used according to this technique. The monorail catheter has a single lumen shaft and only a short central tube within the distal balloon part. With the guidewire inserted into the tube, the balloon can be advanced or retracted on the guidewire as on a sliding rail. The most relevant improvements for coronary dilatation are steerability, contrast flow and rapid and easy exchangeability of balloon catheters and other intracoronary devices. These characteristics are felt to result in a more simple and time- and fluoroscopy-saving dilatation procedure. A special transfusion catheter may also improve procedural safety. The first clinical results in 69 patients with a success rate of 96%, an emergency bypass rate of two patients (one infarction) and a stenosis improvement of 58% confirm the theoretically conceived advantages.

Key words: sliding rail technique; monorail balloon catheter; coronary stenosis dilatation; contrast agent flow; exchangeability of catheters.

Introduction

Two essential reasons can be cited for the success and spread of the clinical application of coronary stenosis balloon dilatation: firstly, the growth of personal experience and the accumulation of information from controlled studies, and secondly, the technological progress of radiological systems (1) and balloon catheter systems (2). Up to now the most important improvements of Grüntzig's original balloon catheter have been the steerable systems introduced by Simpson (3), catheters with improved trackability, introduced by Hartzler, and the long wire technique promoted by Kaltenbach (4). Nevertheless, some properties of dilatation systems still need to be improved, such as steerability, contrast flow and the rapid and safe exchangeability of intracoronary devices. To realise these demands, we have introduced the sliding rail technique for intravascular instrumentation and have applied the technique with the monorail catheter for coronary dilatation. The name "monorail" was coined by Meier and has been generally accepted.

Materials

The monorail catheter (Schneider-Shiley, Zurick) consists of a single lumen shaft with a distal balloon. A short central tube within the distal balloon with openings at the end and proximal to the balloon serves to take up the guidewire (Fig. 1). Thus the guidewire runs only over a short distance within the distal catheter and runs outside and parallel to the catheter shaft over the rest of the distance. The single lumen catheter shaft with a low profile of 3 F serves for balloon inflation and deflation and to advance and retract the balloon over the guidewire, as on a sliding rail. The guidewire itself is of normal length with a diameter of 0.3 or 0.35 mm (Fig. 2).

The procedure itself is modified as follows: first, the guidewire is advanced through a special

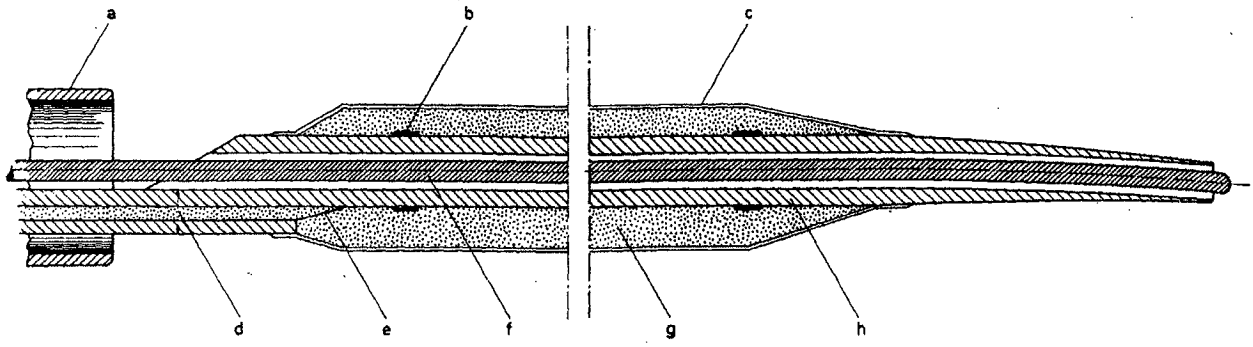

Fig. 1. Schematic representation of the monorail catheter based on the sliding rail principle. The catheter tip (balloon part) at the distal end of the guiding catheter and the guidewire are shown. (a) Guiding catheter, (b) gold markers, (c) balloon member, (d) single lumen catheter shaft, (e) indeflation tube, (f) guidewire, (g) contrast fluid, (h) central tube to take up the guidewire.

y-connector (with a variable coaxial opening) into the guiding catheter and across the stenosis. Thus friction is reduced to a minimum within the wide tube of the guiding catheter, resulting in unhindered steerability. Next the balloon is pushed onto the guidewire and with the guidewire fixed at the outside is advanced through the y-connector until crossing the stenosis. Correspondingly, the balloon may be retracted, readvanced or exchanged in favor of other devices or different balloon sizes. Due to the low shaft profile, the remaining space within the guiding catheter of 2 mm^2 cross sectional area permits a nearly normal contrast flow even with highly concentrated contrast medium of 370 mg/ml iodine. In comparison, this remaining space is 1.5 mm^2 with 3.6 F and 1.1 mm^2 with 4.3 F balloon catheter shafts (Fig. 3). Distal pressure measurement is not provided in standard monorail dilatation catheters.

A second device is a monorail transfusion catheter with a 4 F outer diameter and an especially wide lumen for autotransfusion of blood into the postocclusional coronary segment. This end open catheter has a soft distal tip and two side holes proximal to this tip as blood and guidewire exits. Flow rates between 40 and 60 ml/min or more of arterial blood may be transfused with a hand-operated syringe over a three-way stop cock at pres-

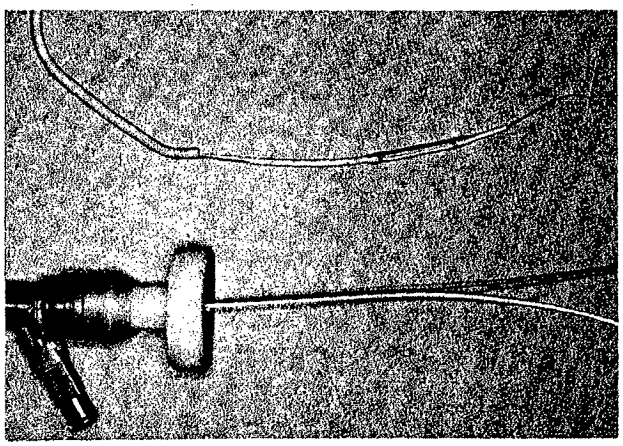

Fig. 2. Sliding rail dilatation system consisting of guiding catheter with y-connector (left) and monorail balloon catheter advanced along the guidewire and leaving the guiding catheter.

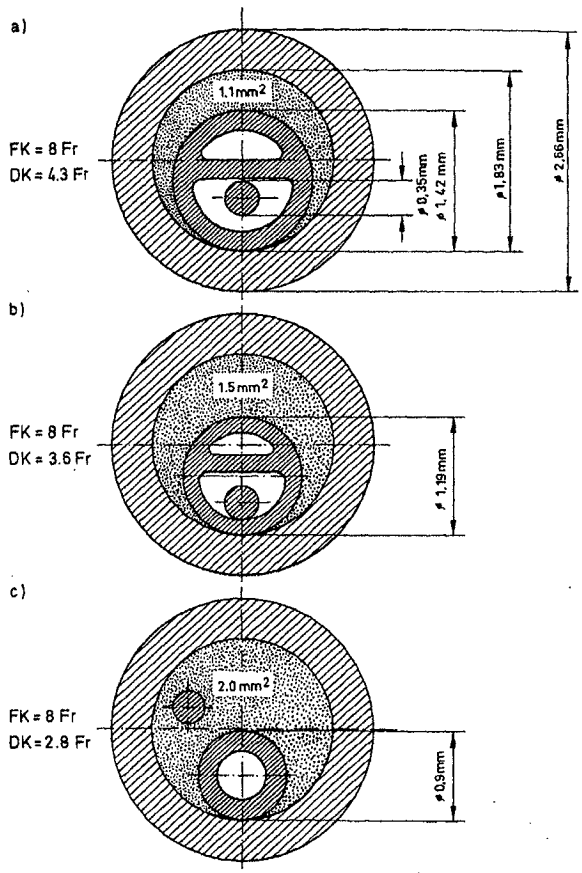

Fig. 3. Cross section of an 8 F guiding catheter (FK, hatched) with dilatation catheters inside (DK, dense hatching). Outer diameter of the FK 2.66 mm, inner diameter 1.83 mm. (a) 4.3 F, (b) 3.6 F dilatation catheter, each with two two luminae (white) to accommodate the guidewire (hatched circle) and for inflation/deflation of the balloon. (c) Monorail dilatation catheter according to the sliding rail principle: shaft with single lumen, guidewire beside it; large free cross-sectional area available for contrast medium (dotted, 2 mm^2).

sures of 2–5 bar. The transfusion catheter is a bail- out device to control ischemia during transfer for emergency surgery in the case of acute coronary occlusion.

Clinical results

The sliding rail principle was studied with the application of monorail balloon catheters in 69 consecutive patients (49 males and 16 females) aged 32 to 72 years with single vessel disease (>50%, mean 78% diameter reduction). Angioplasty was felt to be indicated with positive ECG or thallium exercise tests or with typical stable or unstable angina pectoris. Dilatation success was defined as diameter increase ⩾20% normal vessel diameter. Stenosis distribution was LAD 50, left circumflex 9, right coronary artery 4, others 6 stenoses. Monorail catheters were always used initially. Overall dilatation success rate was 96%. In five cases, special low profile catheters (Hartzler, Advanced Catheter Systems, Grüntzig Pass Key, Schneider Shiley) had to be used for first stenosis passage because of primary failure of the monorail balloon. Stenosis passage with the monorail guidewire itselfwas possible in 99% of cases. A stenosis reduction to ⩽30% was always attempted, necessitating the exchange of smaller in favour of larger balloons in 20 cases. The average final diameter improvement in successful dilatation was +58%. Mean guidewire and mean balloon passage times between y-connector and stenosis crossing were 98 s and 97 s, respectively. Mean balloon exchange time in 20 cases was 136 s, including withdrawl of the first balloon from the distal guiding catheter, switch of indeflator from first to second balloon, mounting of second balloon onto the guidewire and repassage of the coronary stenosis. Contrast flow through the guiding catheter was not impaired at any time, yielding optimal stenosis morphology images before, during and after the procedure.

In two cases, emergency bypass surgery had to be performed because of irreversible acute stenosis occlusion. In the second of these cases, a transfusion catheter (not available in the first case) was exchanged and arterial blood taken from the contralateral femoral artery was transfused by hand into the distal coronary segment. The procedure successfully reverted ischemia until surgery. Myocardial infarction, as documented by postsurgical ECG and LV-angiogram, could be avoided. Details of transfusion procedures will be published separately.

Discussion

It was claimed that the properties steerability, contrast agent flow and exchangeability are among the most important features of coronary balloon catheters (5). In theory, the sliding rail principle as described above provides these properties. The steerability of the monorail balloon catheter is principally that of the guidewire and is therefore related to the properties of the guidewire itself. It is not reduced by friction within the long shaft of standard steerable systems or by mechanical construction-related limitations of one-piece ("not over the wire") balloon catheters. Rapid exchange or extraction, tip reshaping and reinsertion of guidewires can be easily performed. In addition, contrast can be freely injected to deliniate the coronary passway. Clinical experience in our series showed a high stenosis crossing rate of nearly 100% and an average stenosis crossing time of 90 s.

Also, with the balloon catheter in place, contrast flow is not impaired because of the large remaining space within a standard 8 F guiding catheter. Optimal contrast filling of the coronary stenosis with detailed morphology outlining was always obtained in our patients.

On the other hand, transstenotic pressure gradients cannot be measured with standard monorail catheters. Pressure gradients are preferentially used by some investigators to assess dilatation results. However, the disadvantages of pressure gradients for this purpose are: (1) they can only be measured with the balloon across the stenosis and not in the observation period after dilatation, (2) the reliability of pressure tracings is limited and (3) most of all, pressure gradients depend on the relation between vessel size and deflated balloon profile. The latter would result in normal pressure gradients in large vessels even with residual stenoses of 50% (6) and in high residual pressure gradients in small or distal vessels. On the other hand, angiographic stenosis morphology provides primary and repeated information on stenosis diameter and also on the cause of eventual acute restenoses, e.g., dissection, thrombosis, etc. Thus, optimal visualization by undisturbed contrast flow in most cases will result in a broader and more meaningful information. This is especially relevant when the result of dilatation is not satisfactory and further therapeutic steps have to be considered. High resolution multidirectional imaging systems are prerequisites for this information (1).

Balloon exchange could be performed without technical difficulties in all cases within the very short time of little more than 2 min. The reason for exchange in favor of a larger balloon was usually an angiographically insufficient result, e.g., a residual stenosis of more than 30% or 40%. In some cases, when balloon passage of the stenoses was not possible, a smaller balloon was used for a first stenosis widening and was then reexchanged in favor of the first and larger bal-

loon. In addition, a transfusion catheter could be successfully used in one case. Transfusion or perfusion catheters are primarily designed as bail-out devices for temporary use in acute emergency situations. It is expected that the time to bypass surgery in this situation may be expanded with transfusion. Manually controlled extracorporeal autotransfusion – as the procedure may be called with the use of the monorail transfusion catheter – may be superior to perfusion techniques using the physiological pressure gradient across the stenosis. These techniques rely on stable aortic pressures and provide no information on distal coronary flow. In general, up to now the clinical reliability of bail-out systems has not been established and further investigation is needed.

The advantages of the sliding rail system in steerability, contrast flow and exchangeability of balloon catheters have in our experience resulted in a simplification of the standard dilatation procedure, an improvement in the assessment of dilatation results and an increase of safety in critical situations. This may be of special relevance in complicated stenoses of large vessels and in multivessel disease. The reduction of investigation and fluoroscopy time may also be the result of a more simple procedure. Intended future developments include different devices for intracoronary diagnostic and therapeutic interventions, such as low profile transstenotic pressure catheters, Doppler catheters and hot balloons for wall welding. The sliding rail technique principally enables the sequential use of such devices over a stable transstenotic guidewire.

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Exhibit 2

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,048,032 B2**
(45) **Date of Patent: Nov. 1, 2011**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

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(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

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(21) Appl. No.: **11/416,629**

(22) Filed: **May 3, 2006**

(65) **Prior Publication Data**

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A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.1**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.09–164.11, 604/525, 164.02
See application file for complete search history.

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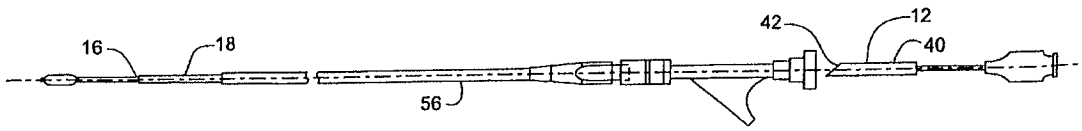
Primary Examiner — Jackie Ho
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente IP

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

22 Claims, 13 Drawing Sheets



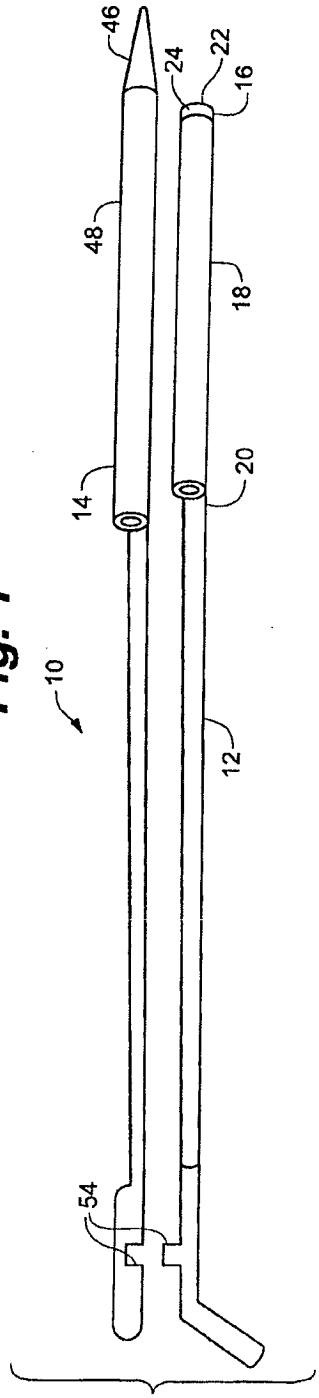


Fig. 1

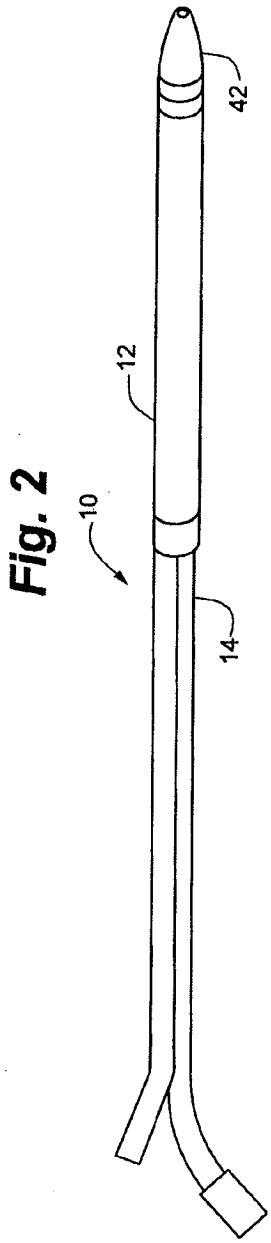


Fig. 2

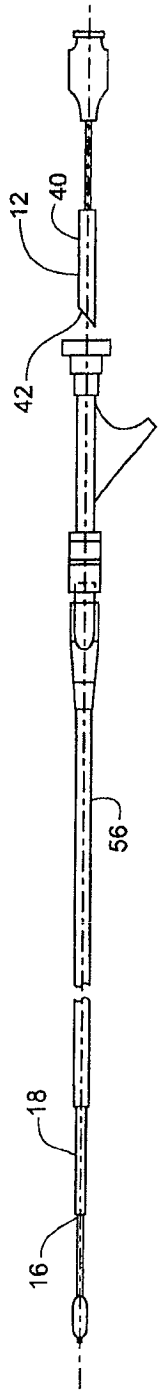


Fig. 3

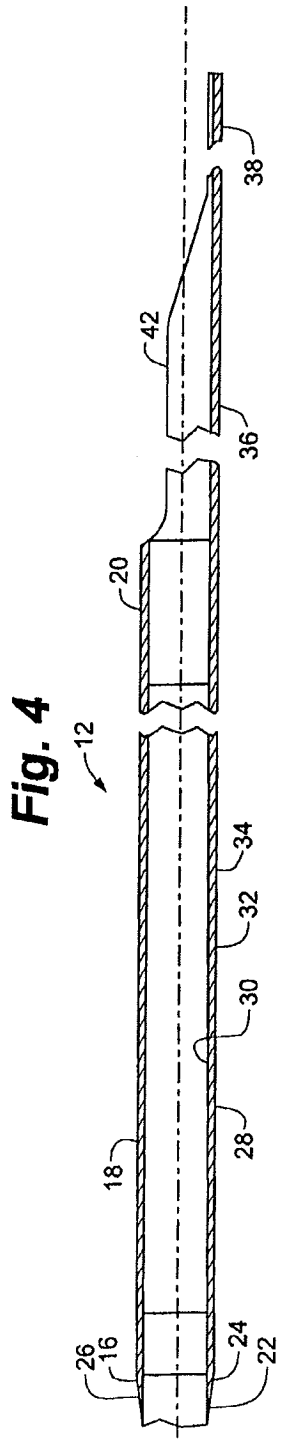
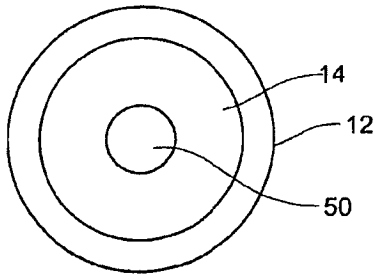


Fig. 4

Fig. 5



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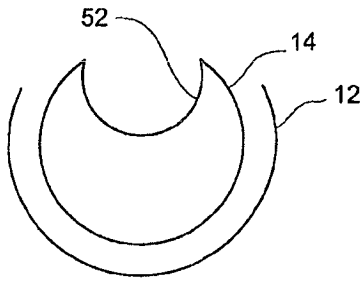

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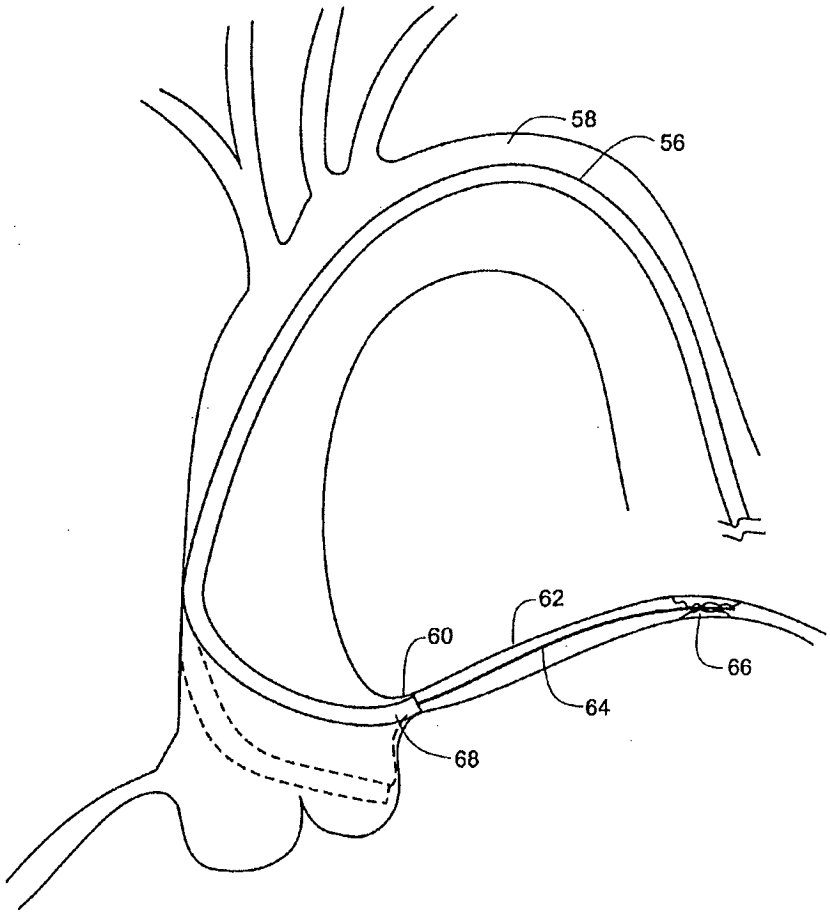

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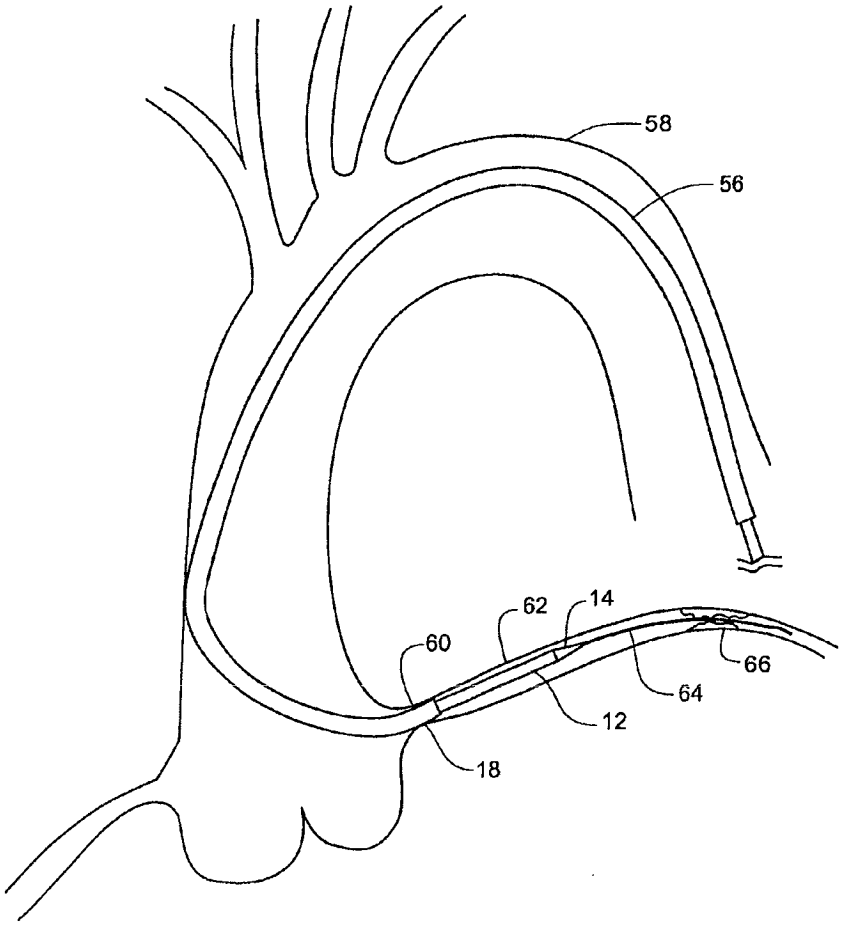

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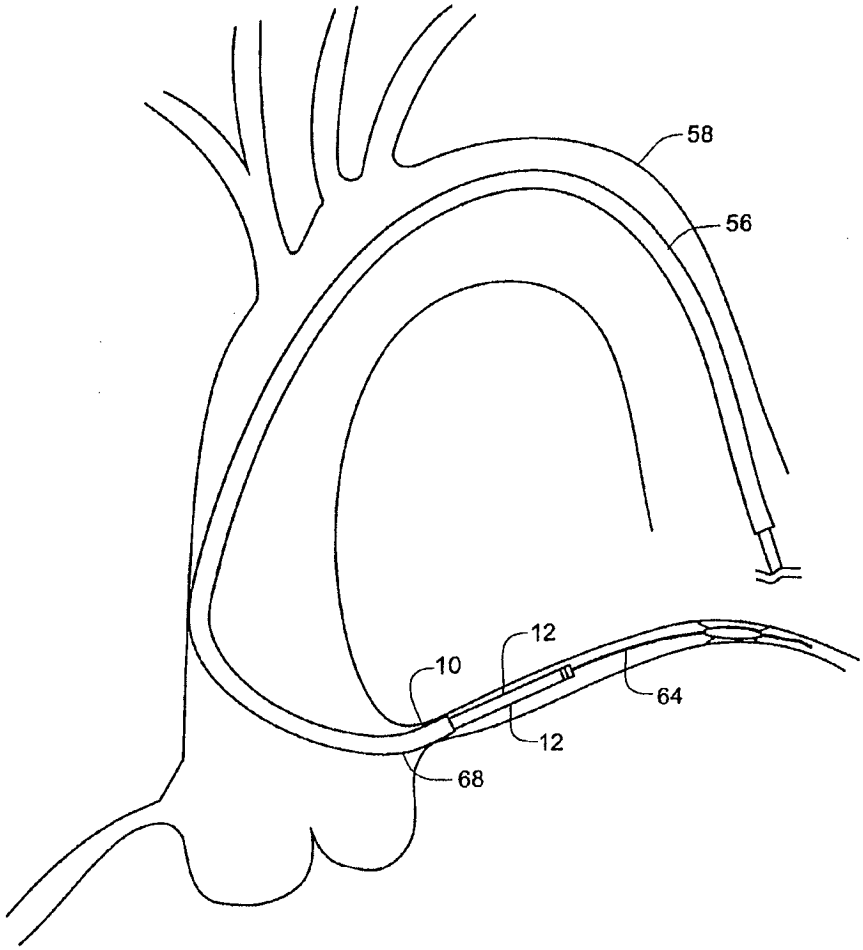

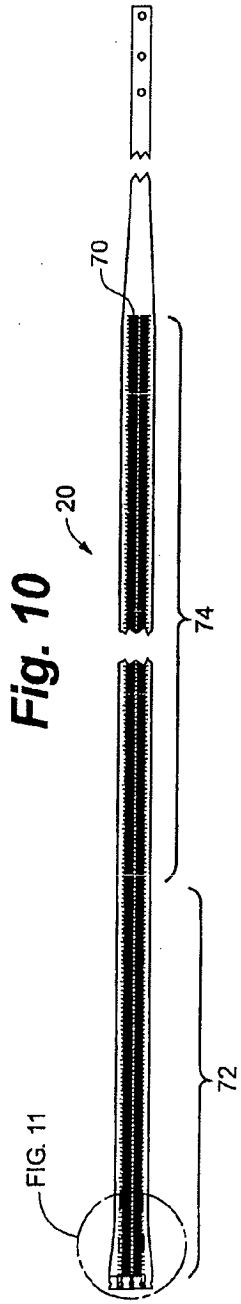

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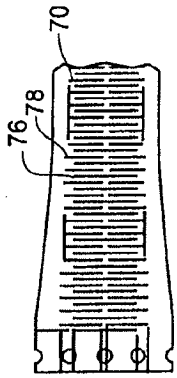

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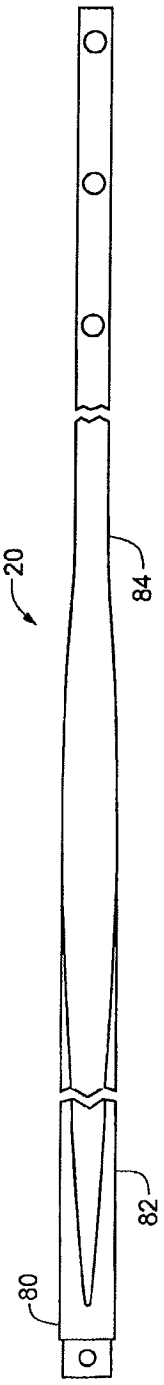


Fig. 12

Fig. 13

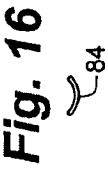


Fig. 16

Fig. 15

Fig. 14

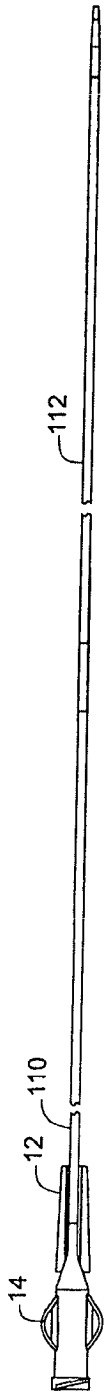


Fig. 17

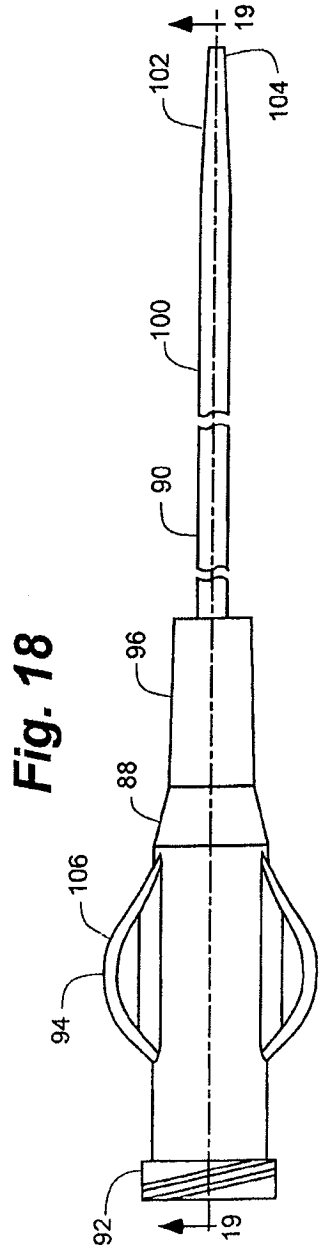


Fig. 18

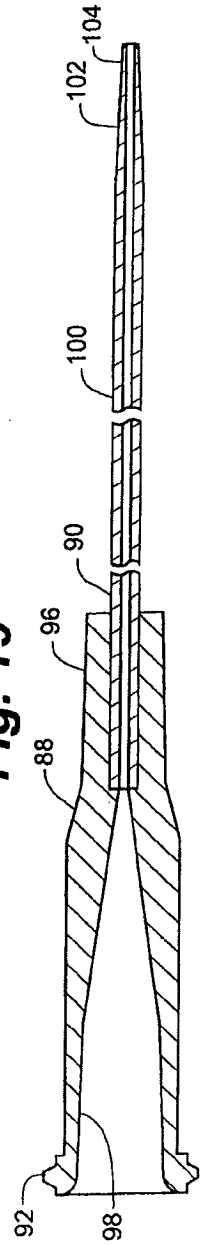


Fig. 19

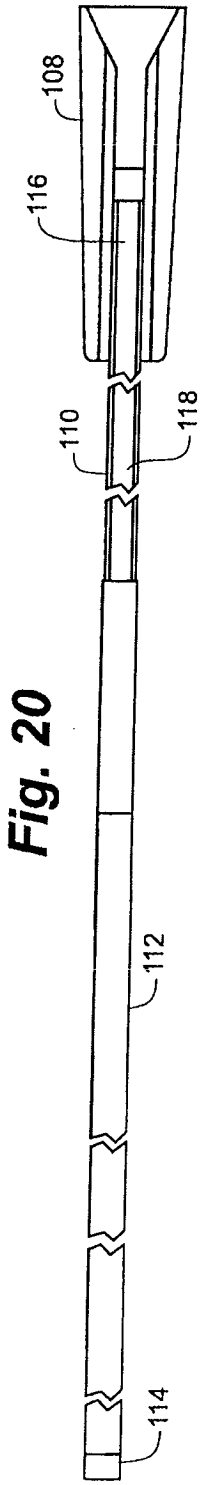


Fig. 20

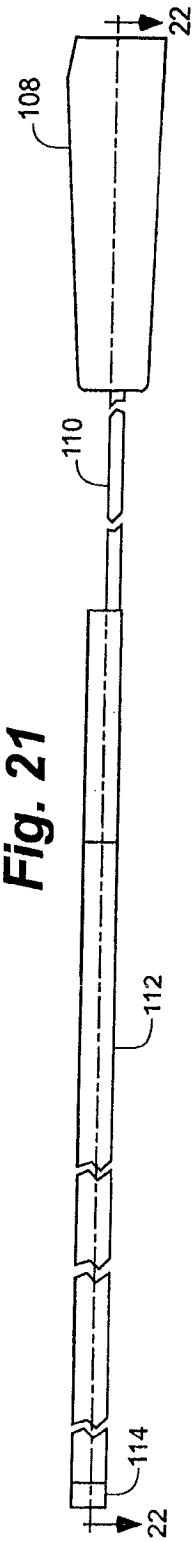


Fig. 21

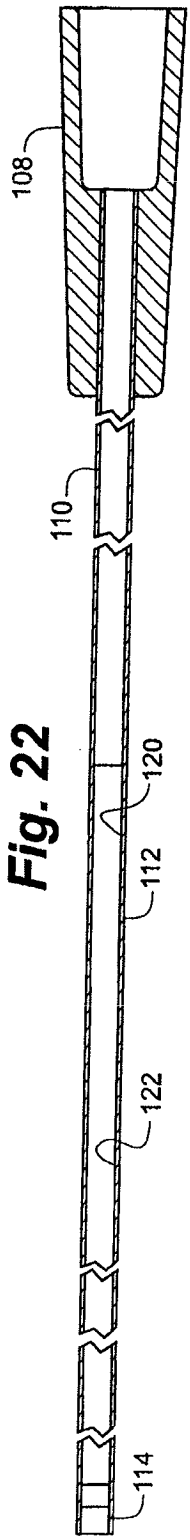


Fig. 22

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

FIELD OF THE INVENTION

The present invention relates generally to catheters used in interventional cardiology procedures. More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.

BACKGROUND OF THE INVENTION

Interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters. In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions. These lesions may totally obstruct the lumen of the artery or may dramatically narrow the lumen of the artery. Narrowing is referred to as stenosis. In order to diagnose and treat obstructive coronary artery disease it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery.

In treating a stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery. This is sometimes accomplished with the aid of a guidewire. A guide catheter is typically seated into the opening or ostium of the artery to be treated and a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis. Crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated. This can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.

Prior attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as "backup support") fall generally into four categories.

First are guiding catheters that, through a combination of shape and stiffness, are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed. Examples of this approach can be found in U.S. Pat. No. 6,475,195 issued to Voda and U.S. Pat. No. 5,658,263 issued to Dang et al. These guiding catheters all share the common limitation that a guide catheter stiff enough to provide adequate backup support is often too stiff to be safely inserted into the aorta without the possibility of causing damage to the aortic wall. In addition, attempts to deep seat the guide catheter have been made but the rigid nature of the guide catheter creates the risk that the guide catheter may damage the coronary artery wall or that the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

Second are guiding catheters that include a retractable appendage. The appendage in these catheters can be extended to engage the opposing wall of the aortic arch to provide backup support or the appendage may be placed under tension to stiffen a bend in the catheter to provide backup support. Examples of this approach may be found in U.S. Pat. Nos. 4,813,930 issued to Elliot; U.S. Pat. No. 5,098,412 issued to Shiu; and U.S. Pat. No. 6,860,876 issued to Chen.

These guiding catheters tend to be somewhat mechanically complex and have not been widely adopted by practitioners.

Third are guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium of the coronary artery to provide a force acting in opposition to the backward forces created when trying to maneuver a therapeutic device past a lesion or blockage in the coronary artery. These devices can include a balloon secured to a guidewire or a catheter or another device for expanding to grip the walls of the coronary artery from within. Examples of this approach may be found in U.S. Pat. Nos. 4,832,028 issued to Patel; U.S. Pat. No. 6,595,952 issued to Forsberg; and U.S. Published Application No. 2005/0182437 by Bonnette et al. Again, these devices tend to be mechanically complex and can completely occlude the coronary ostium thus stopping perfusion of the coronary artery.

A fourth technique includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents. This technique has been described in an article by Takahashi entitled "New Method to Increase a Backup Support of Six French Guiding Coronary Catheter," published in Catheterization and Cardiovascular Interventions, 63:452-456 (2004). This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

Thus, the interventional cardiology art would benefit from the availability of a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery.

SUMMARY OF THE INVENTION

The present invention is a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. The coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery. This feature also allows removal of the tapered inner catheter after the coaxial guide catheter is in place. The tapered inner catheter provides a gradual transition from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French.

The coaxial guide catheter preferably can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the

existing Y adapter. In addition, the coaxial guide catheter preferably has an inner diameter that is appropriate for delivering standard coronary treatment devices after it is placed in the coronary artery.

In one embodiment, the coaxial guide catheter is made in at least three sizes corresponding to the internal capacity of 8 French, 7 French, and 6 French guide catheters that are commonly used in interventional cardiology procedures. An 8 French catheter has an internal diameter greater than or equal to 0.088 inches. A 7 French catheter has an internal diameter greater than or equal to 0.078 inches. A 6 French guide catheter has an internal diameter greater than or equal to 0.070 inches. Thus, for three exemplary sizes the effective internal diameter of the coaxial guide catheter may be as follows. For a 7 French in 8 French coaxial guide catheter the internal diameter should be greater than or equal to 0.078 inches. For a 6 French in 7 French coaxial guide catheter the internal diameter should be greater than or equal to 0.070 inches. For a 5 French in 6 French coaxial guide catheter the internal diameter should be greater than or equal to 0.056 inches.

Interventional cardiology procedures are typically carried out under fluoroscopy or another x-ray or imaging technique. Therefore, one embodiment of the coaxial guide catheter of the present invention includes a radiopaque marker at its distal tip to facilitate positioning and manipulation of the coaxial guide catheter.

The present invention generally includes the coaxial guide catheter and a tapered inner catheter. The coaxial guide catheter includes a tip portion, a reinforced portion, and a substantially rigid portion. The coaxial guide catheter will generally have an overall length of preferably approximately 125 cm, though this should not be considered limiting.

In one embodiment, the tip portion may include a soft tip and a marker band. The soft tip is tapered and may be formed from a low durometer polymer or elastomer material such as polyether block amide polymer, (PEBA, Pebax®) the marker band may be formed from a platinum iridium alloy sandwiched between the Pebax® that extends from the bump tip and a PTFE liner.

In one embodiment, the reinforced portion may be reinforced, preferably with metallic fibers in a braided or coiled pattern. The braided or coiled portion is lined by a PTFE liner and may be covered on its exterior with Pebax®. The braided or coiled portion may extend approximately 20 to 110 cm in length. In one exemplary embodiment, the braided portion extends approximately 32 to 36 cm.

Preferably, the rigid portion may be advantageously formed from a stainless steel or Nitinol tube. The rigid portion may be joined to the braid or coil portion by welding. The rigid portion may include a cutout portion and a full circumference portion. For example, the cutout portion may include a section where about 45% of the circumference of the cylindrical tubular structure has been removed. The cutout portion may also include a section where 75-90% of the circumference of the tubular structure has been removed. In one exemplary embodiment, the portion having approximately 45% removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm. The full circumference portion of the rigid portion is typically located at the most proximal end of the coaxial guide catheter.

The rigid portion may include a plurality of radially oriented slits or other cuts in its distal portion to increase and control the flexibility of the rigid portion

In an exemplary embodiment, the tapered inner catheter generally includes a tapered inner catheter tip and a cutout portion. The tapered inner catheter tip includes a tapered portion and a straight portion. The tapered portion is typically at the most distal end of the tapered inner catheter. Both the straight portion and the tapered portion are pierced by a lumen through which a guidewire may be passed.

The cutout portion supports a track passing along the concave side thereof that continues from the lumen that passes through the straight portion and the tapered portion. The tapered inner catheter may also have a clip or snap attachment at its proximal end to releasably join the tapered inner catheter to the coaxial guide catheter.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. The tapered inner catheter is positioned so that the tapered inner catheter tip extends beyond the tip portion of the coaxial guide catheter. The coaxial guide catheter-tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta. The coaxial guide catheter-tapered inner catheter combination may be threaded over a preplaced 0.014 inch guidewire. The tapered inner catheter-coaxial guide catheter combination is advanced up the aorta until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed. During this entire process at least part of the coaxial guide catheter-tapered inner catheter combination is located inside of the guide catheter.

Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion such as a stenosis or a chronic arterial occlusion.

A guide catheter inserted into the ostium of a branch artery where it branches off from a larger artery is subject to force vectors that tend to dislodge the distal end of the guide catheter from the ostium of the branch artery when a physician attempts to direct a guidewire or other interventional cardiology device past an occlusive or stenotic lesion in the branch artery. This discussion will refer to a guide wire but it is to be understood that similar principles apply to other interventional cardiology devices including balloon catheters and stent catheters.

One of the forces that acts on the guide catheter is an axial force substantially along the axis of the branch artery and the portion of the guide catheter that is seated in the ostium. This force vector is a reactive force created by the pushing back of the guide wire against the guide catheter as the physician tries to force the guidewire through or past the lesion. It tends to push the distal end of the catheter out of the ostium in a direction parallel to the axis of the branch artery and the axis of the distal end of the guide catheter.

Another of the force vectors that acts on the guide catheter is a shearing force that tends to dislodge the distal end of the guide catheter from the ostium of the branch artery in a direction perpendicular to the axis of the branch artery and the axis of the distal end of the guide catheter. This force vector arises from curvature of the guide catheter near its distal end and the guide wire pushing on the curved portion of the guide catheter as the physician applies force to the guidewire. The coaxial guide catheter of the present invention assists in

resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.

The system is deliverable using standard techniques utilizing currently available equipment. The present invention also allows atraumatic placement within the coronary artery. Further, the invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters. Finally, the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic depiction of the coaxial guide catheter and a tapered inner catheter in accordance with the present invention;

FIG. **2** is schematic depiction of the coaxial guide catheter and tapered inner catheter assembled in accordance with the present invention;

FIG. **3** is a plan view of a guide catheter, the coaxial guide catheter, and a treatment catheter in accordance with the present invention;

FIG. **4** is a sectional view of the coaxial guide catheter in accordance with the present invention;

FIG. **5** is a cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

FIG. **6** is another cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

FIG. **7** is a schematic view of a guide catheter and a guidewire located in an aortic arch and a coronary artery and the guide catheter and guidewire in a second position depicted in phantom;

FIG. **8** is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter in accordance with the present invention and a tapered inner catheter located in the aortic arch and coronary artery;

FIG. **9** is a schematic view of a guide catheter, a guidewire and a coaxial guide catheter in accordance with the present invention located in the aortic arch and coronary artery;

FIG. **10** is a flat pattern for making relief cuts in a curved rigid portion of the coaxial guide catheter in accordance with the present invention;

FIG. **11** is a detailed view taken from FIG. **10**;

FIG. **12** is a plan view of the rigid portion in accordance with the present invention;

FIG. **13** is an elevational view of the rigid portion;

FIG. **14** is a sectional view of the rigid portion taken along section line **14-14** of FIG. **13**; and

FIG. **15** is a sectional view of the rigid portion taken along section line **15-15** of FIG. **13**.

FIG. **16** is a sectional view of the rigid portion taken along section line **16-16** of FIG. **13**.

FIG. **17** is a plan view of a coaxial guide catheter having a longer rail segment and a tapered inner catheter in accordance with the present invention.

FIG. **18** is a plan view of the tapered inner catheter as depicted in the FIG. **17**.

FIG. **19** is a cross-sectional view of the tapered inner catheter taken along section lines **19-19** of FIG. **18**.

FIG. **20** is a plan view of a coaxial guide catheter in accordance with the present invention.

FIG. **21** is an elevational view of a coaxial guide catheter in accordance with the present invention.

FIG. **22** is a cross-sectional view taken along section line **22-22** of FIG. **21**.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. **1** and **2**, coaxial guide catheter assembly **10** of the present invention generally includes coaxial guide catheter **12** and tapered inner catheter **14**.

Coaxial guide catheter **12** generally includes tip portion **16**, reinforced portion **18**, and rigid portion **20**. The overall length of the coaxial guide catheter typically can be approximately 125 cm. This length should not be considered limiting.

Tip portion **16** generally includes bump tip **22** and marker band **24**. Bump tip **22** includes taper **26**. Bump tip **24** is relatively flexible and may be formed, for example, from 4033 Pebax®. Bump tip **22** may be yellow or another high visibility color for ease of handling.

Marker band **24** is formed of a radiopaque material such as platinum/iridium alloy usually at a 90/10 ratio. Marker band **24** may be sandwiched between an outer Pebax® material **28** and a PTFE liner **30**. Outer Pebax® material **28** in this location may be formed of 5533 Pebax, for example.

Reinforced portion **18** includes braid or coil reinforcement **32**. Braid or coil reinforcement **32** may be formed of metal, plastic, graphite, or composite structures known to the art. Reinforced portion **18** may be lined on the interior by PTFE liner **30** and covered on the exterior by Pebax® material **28**. Tip portion **16** and reinforced portion **18** together form a substantially cylindrical structure. Braid or coil reinforcement **32** may extend approximately 20 to 30 cm. In one exemplary embodiment, braid or coiled portion has a length of approximately 32 to 36 cm.

Rigid portion **20** may be secured to braid or coil reinforcement by, for example, welding or bonding. Rigid portion **20** may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well. Rigid portion **20** includes first full circumference portion **34**, hemicylindrical portion **36**, arcuate portion **38**, and second full circumference portion **40**.

First full circumference portion **34** is joined to braid or coil reinforcement **32**. First full circumference portion **34** extends for a relatively short distance, for example, 0.25 cm.

Hemicylindrical portion **36** desirably includes 40% to 70% of the circumference of the tube. Hemicylindrical portion **36** may extend, for example, approximately 20 to 75 cm in length.

Hemicylindrical portion **36** tapers into arcuate portion **38**.

Arcuate portion **38** extends from 25% to 40% of the circumference of the tube. Arcuate portion **38** may extend linearly, for example, for about 15 cm.

Arcuate portion **38** connects to second full circumference portion **40**. Second full circumference portion **40** may extend for a short distance, for example, approximately 3 cm.

Tapered inner catheter **14** generally includes tapered inner catheter tip **42** and cutout portion **44**. Tapered inner catheter tip **42** tapers gradually from the diameter of a guide wire to the diameter of tip portion **16**.

Tapered inner catheter tip **42** includes tapered portion **46** at a distal end thereof, and straight portion **48**. Both tapered portion **46** and straight portion **48** are pierced by lumen **50**.

Cutout portion **44** defines a concave track **52** along its length. Concave track **52** is continuous with lumen **50**.

Tapered inner catheter **14** may also include clip **54** at a proximal end thereof to releasably join tapered inner catheter **14** to coaxial guide catheter **12**. Thus, tapered inner catheter **14** is keyed to coaxial guide catheter **12**.

Coaxial guide catheter **12** may include, starting at its distal end, a first portion having a flexural modulus of about 13,000 PSI plus or minus 5000 PSI, a second portion having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, a third portion having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI and a fourth portion having a flexural modulus of about 107,000 PSI plus or minus 20,000 PSI. Coaxial guide catheter **12** may be formed, for example, of 4033 Pebax® at bump tip **22** for the first 0.1 cm. This portion may followed by a section about three cm long of 5533 Pebax® that covers marker band **24** and the distal portion of braid or coil reinforcement **32**. Next may come an approximately five cm portion of 6333 Pebax® which encloses part of braid or coil reinforcement **32** followed by an approximately twenty seven cm portion of 7233 Pebax® covering the most proximal portion of braid or coil reinforcement **32**. Braid or coil reinforcement **32** is bonded to rigid portion **20** which may be formed from stainless steel or a similar biocompatible material. Rigid portion **20** may extend for approximately ninety cm and include first full circumference portion **34** (approximately 0.25 cm), hemicylindrical portion **36** (approximately seventy five cm), arcuate portion (approximately fifteen cm) and second full circumference portion (approximately three cm.) Rigid portion **20** may be formed from a stainless steel or Nitinol hypo tube.

FIG. **7** depicts a typical guide catheter **56** passing through aortic arch **58** into ostium **60** of coronary artery **62**. FIG. **7** also depicts guidewire **64** passing through the guide catheter **56** and into coronary artery **62**. Located in coronary artery **62** is stenotic lesion **66**. In a typical procedure, guidewire **64** is placed through the aortic arch **58** and into the ostium **60** of the coronary artery. **62**. The guide catheter **56** is passed over guidewire **64** until distal end **68** of guide catheter **56** is seated in ostium **60** of coronary artery **62**. Force is then applied to the guidewire **64** to push guidewire **64** past stenotic lesion **66** or an occlusive lesion (not shown). Once the guidewire **64** is pushed past stenotic lesion **66** or occlusive lesion (not shown), a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion **66** or occlusive lesion (not shown). The lesion can then be treated.

As can be seen in phantom, in FIG. **7**, the application of force to guidewire **64** can cause guide catheter **56** to dislodge from ostium **60** of coronary artery **62**. This can occur in the case of a tough stenotic lesion **66** or occlusive lesion (not shown) when it is difficult to pass the guidewire **64** beyond the stenotic lesion **66** or occlusive lesion (not shown).

Referring the FIG. **8** coaxial guide catheter **12** is depicted as used with guide catheter **56**, guidewire **64**, and tapered inner catheter **14**. Here, coaxial guide catheter **12** with tapered inner catheter **14** is passed through guide catheter **56** and over guidewire **64** into coronary artery **62** after the guide catheter **56** has been placed in the ostium **60** of coronary artery **62**, as depicted in FIG. **7**. Coaxial guide catheter **12**, with tapered inner catheter **14**, provide an inner support member for proper translation over guidewire **64**. Tapered inner catheter tip **42** provides a distal tapered transition from guidewire **64** to coaxial guide catheter **12**. Once coaxial guide catheter **12** is in place, tapered inner catheter **14** is removed from the inside of coaxial guide catheter **12**.

Coaxial guide catheter **12** is now ready to accept a treatment catheter such as a stent or balloon catheter. Referring to FIG. **9**, the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion. In addition, the improved back up support assists in the positioning of a treating catheter that may include a stent or balloon.

Referring to FIGS. **10** and **11**, in some embodiments of coaxial guide catheter **12**, rigid portion **20** may be perforated by relief cuts **70**. Relief cuts **70** may be classed into first group **72** and second group **74**.

First group **72** may be located near to the juncture between rigid portion **20** and reinforced portion **18**. First group **72** of relief cuts **70** are relatively closely spaced. For example, first group **72** of relief cuts **70** may be spaced approximately 0.010 inches apart. First group **72** of relief cuts **70** extends for a relatively short distance, for example, approximately 2 inches.

Second group **74** of relief cuts **70** may extend for a relatively long distance, for example, approximately 30-35 inches. Second group **74** of relief cuts **70** are spaced farther apart than first group **72**. For example, relief cuts **70** of second group **74** may be spaced approximately 0.020 inches between cuts. Referring particularly to FIG. **11**, relief cuts **70** may include single cuts **76** and double cuts **78**. Single cuts **76** may include an individual linear cut, as can be seen in FIG. **11**. Double cuts **78** may include two linear cuts along a single line but separated by a short section of uncut structure. Typically, single cuts **76** and double cuts **78** are alternated along the length of rigid portion **20**. Generally, the overall length of single cut **76** may be less than the overall length of two double cuts **78**.

In an embodiment depicted in FIGS. **12-15**, rigid portion includes full circumference portion **80**, greater than 180° portion **82**, and less than 180° portion **84**. Greater than 180° portion **82** may, for example, include structure forming approximately 300° of the circumference of the cylinder. Less than 180° portion may include, for example, structure forming approximately 90° of the circumference of a cylinder. Greater than 180° portion **82** may extend approximately 22-25 inches. Greater than 180° portion **82** holds tapered inner catheter **14** within rigid portion **20**.

When tapered inner catheter is inserted into coaxial guide catheter **12** greater than 180° portion **82** grips tapered inner catheter **14** which is exposed through the opening in greater than 180° portion **82**. Thus, the overall structure of tapered inner catheter **14** along with greater than 180° portion **82** is substantially cylindrical. Accordingly, when inserted through a guide catheter **56** having a Touhey-Borst style adapter, the Touhey-Borst style adapter can still seal around rigid portion **20** and enclosed inner tapered catheter **14**.

Referring to FIG. **16**, another embodiment of coaxial guide catheter assembly **10** includes coaxial guide catheter **12** and tapered inner catheter **14**. Tapered inner catheter **14** is keyed to coaxial guide catheter **12** at hub **86**.

Referring to FIGS. **17** and **18**, tapered inner catheter **14** generally includes connector hub **88** and catheter tube **90**.

Connector hub **88** generally includes connector portion **92**, grip portion **94** and joining portion **96**. Connector hub **88** defines funnel portion **98** therein.

Catheter tube **90** generally includes straight portion **100**, tapered portion **102** and marker band tip **104**. Catheter tube **90** is joined to connector hub **88** at joining portion **96**. Tapered inner catheter **14** may be formed in whole or in part from low-density polyethylene plastic, for example. Other suitable materials known to the catheter arts may be used as well.

Grip portion **94** desirably includes gripping ears **106**. Gripping ears **106** may extend outwardly from grip portion **94** substantially radially and be shaped for convenient gripping by a physician.

Referring to FIGS. **19** through **21**, in this embodiment, coaxial guide catheter **12** includes interrupted hub **108**, hemi-tube portion **110**, braided portion **112** and tip portion **114**.

Interrupted hub **108** defines an opening **116**, along a side thereof. Interrupted hub **108** may be substantially C-shaped or U-shaped in cross section. Opening **116** is sized so that tapered inner catheter **14** may be passed readily therethrough in a direction perpendicular to the long axes of both interrupted hub **108** and tapered inner catheter **14**. Hemi-tube portion **110** is immediately distal to interrupted hub **108**. Hemi-tube portion **110** may be formed, for example, from a metal hypo tube forming approximately 50% of the circumference of a cylinder. Hemi-tube portion **110** is aligned so that opening **116** of interrupted hub **108** is coextensive with opening **118** of hemi-tube portion **110**. Hemi-tube portion **110** is joined to braided portion **112**, for example, by adhesive, bonding or welding. The location where hemi-tube portion **110** and braided portion **112** join defines the entire circumference of a cylinder.

Braided portion **112** may be reinforced by a coil or braid, **120**. Coil or braid **120** may be formed of metal or another suitable reinforcing material.

Tip portion **114** is generally not reinforced and is substantially soft. Tip portion **114** is similarly structured to tapered inner catheter tip **42**. Tip portion **114** may include a radiopaque marker band **24**.

Beginning at the distal end of coaxial guide catheter **12**, tip portion **114** may be formed substantially of, for example, 2533 Pebax® This may be followed by a section of 3533 Pebax®, then by a section of 5533 Pebax®, then by a further section of 7233 Pebax®. These Pebax® portions may all incorporate, for example, about 20% barium sulfate ($BaSO_4$).

In one embodiment, tip portion **114** and braided portion **112** may have an overall length together of approximately one hundred nine centimeters. Hemi-tube portion **110** and interrupted hub **108** may together have an overall length of approximately eighteen centimeters.

In this embodiment, coaxial guide catheter **12** may be lined with a PTFE liner **122**.

In operation, a guide catheter **56** is inserted into a major blood vessel in the body such as aortic arch **58** over guidewire **64** and the distal end **68** of guide catheter **56** is brought into proximity of ostium **60** of a smaller branch blood vessel, such as coronary artery **62**, that it is desired to enter. Coaxial guide catheter **12**, with tapered inner catheter **14**, is inserted through guide catheter **56** and over guidewire **64**. Guide catheter **56**, guidewire **64**, coaxial guide catheter **12**, and tapered inner catheter **14** are manipulated to insert tapered inner catheter tip **42** into the ostium **60** of the blood vessel that branches off from the major blood vessel. The bump tip **22** of coaxial guide catheter **12** is inserted with tapered inner catheter tip **42** well into ostium **60** of coronary artery **62** or other blood vessel until bump tip **22** of coaxial guide catheter **12** achieves a deep seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

When the interventional cardiology device reaches a stenosis or blockage in coronary artery **62** or another branch blood vessel, force may be applied to the interventional cardiology device catheter while reinforced portion **18** and rigid portion **20** of coaxial guide catheter **12** provide back up support. The back force that would tend to dislodge bump tip **22** from a deep seated position in the ostium in the branch blood vessel is transferred through reinforced portion **18** to rigid portion **20** of coaxial guide catheter **12**. A physician may apply a force to the proximal end of the coaxial guide catheter **12** to resist dislodging of bump tip **22** from the ostium of the branch artery.

One advantage of the present invention over prior art approaches is that the present invention does not interfere the injection of fluids via the Y-adapter of guide catheter **56** as does the use of a smaller catheter within a larger catheter.

The present invention may be embodied in other specific forms without departing from the spirit of the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

What is claimed is:

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 inter-

ventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

4. The device of claim 3 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

6. The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

7. The device of claim 6 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

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.

9. The device of claim 1 wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

10. The device of claim 1 wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

11. 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-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion being sized 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;

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of and 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,

such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen 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.

12. The device of claim 11 wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

13. The device of claim 11 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

14. The device of claim 11 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.

15. The device of claim 11, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

16. The device of claim 11, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

17. The device of claim 11 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

18. The device of claim 11 wherein the substantially rigid portion includes, starting at a from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

19. The device of claim 11 wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

20. The device of claim 19 in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

21. The device of claim 19 in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.

22. The device of claim 11 wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,048,032 B2
APPLICATION NO. : 11/416629
DATED : November 1, 2011
INVENTOR(S) : Root et al.

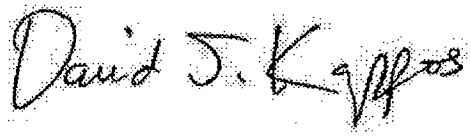
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 444 days.

Signed and Sealed this
Thirty-first Day of January, 2012



David J. Kappos
Director of the United States Patent and Trademark Office

Exhibit 3

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,142,413 B2**
(45) **Date of Patent: Mar. 27, 2012**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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A61M 5/178 (2006.01)

(52) **U.S. Cl.** **604/510**; 604/164.1; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 16–162, 164.01–164.11, 525, 604/510

See application file for complete search history.

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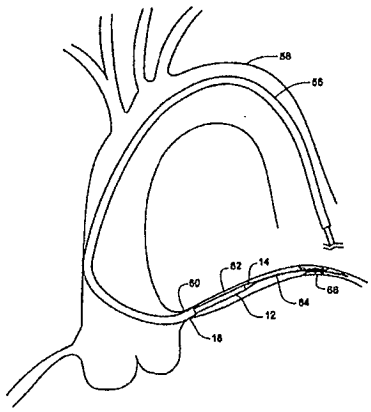
(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

14 Claims, 13 Drawing Sheets



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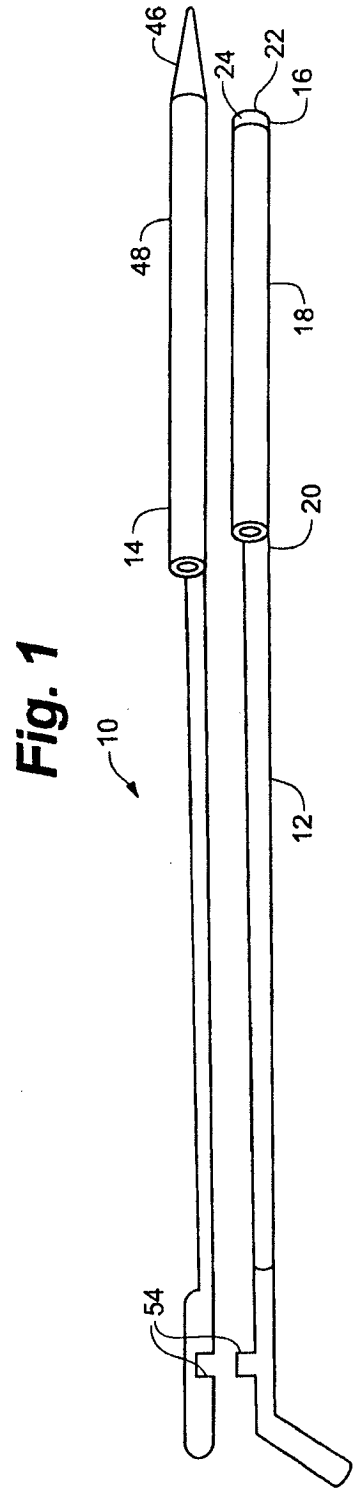


Fig. 1

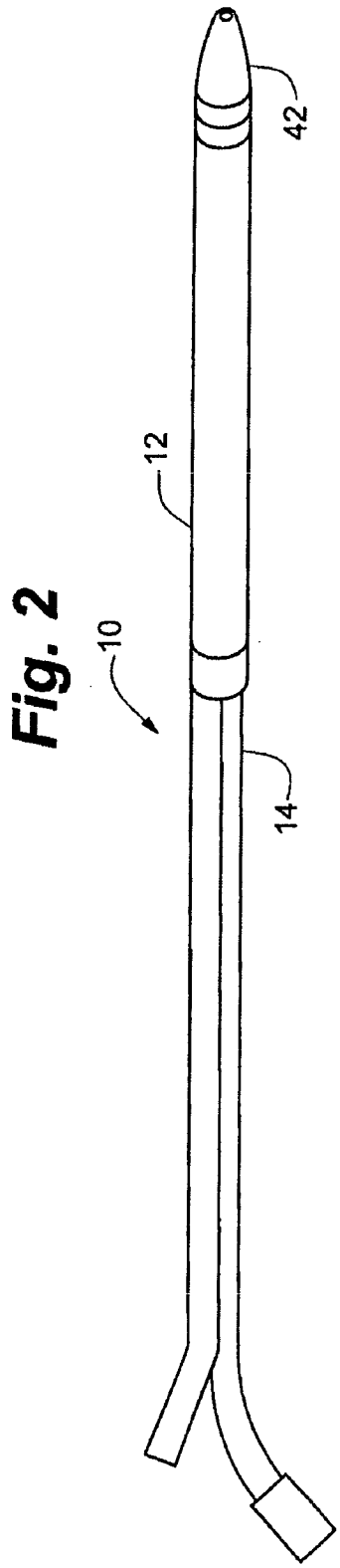
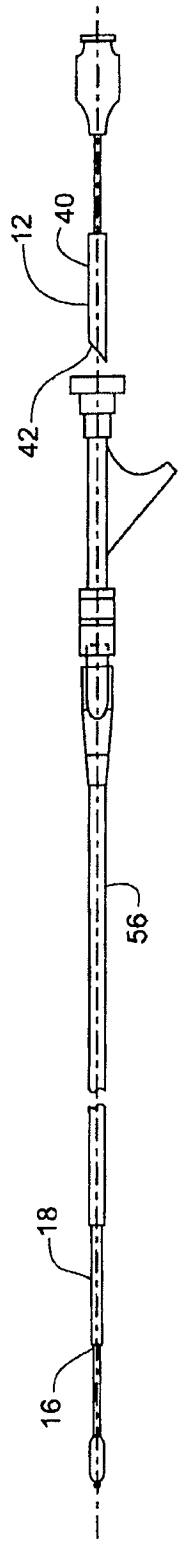


Fig. 2



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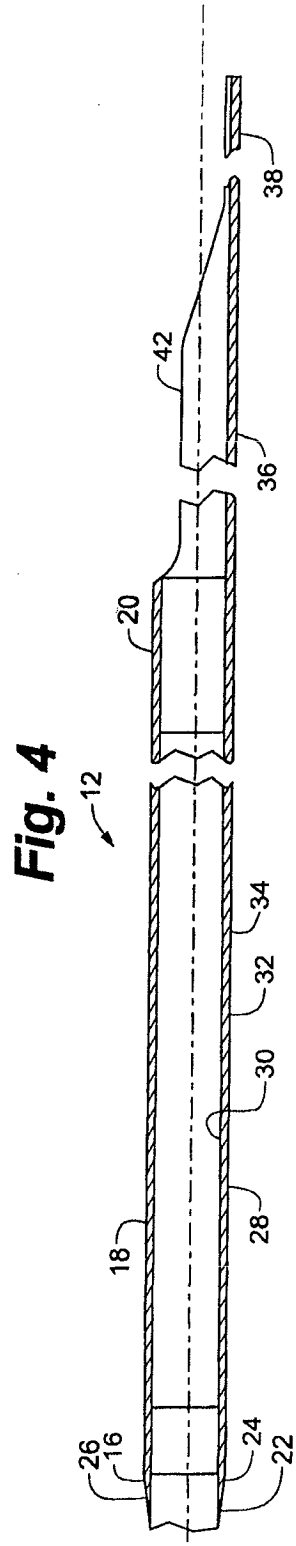
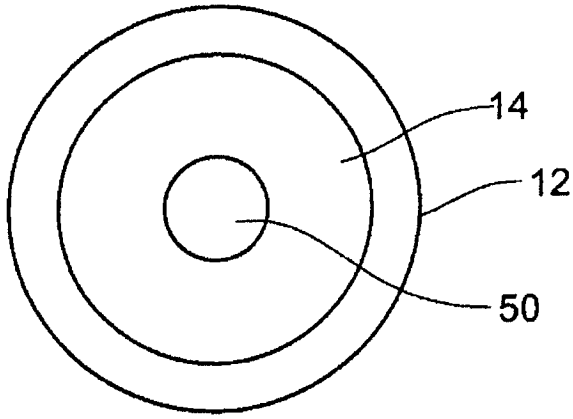


Fig. 4

Fig. 5



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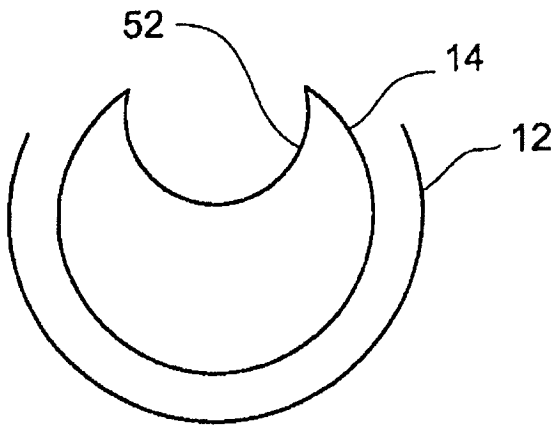

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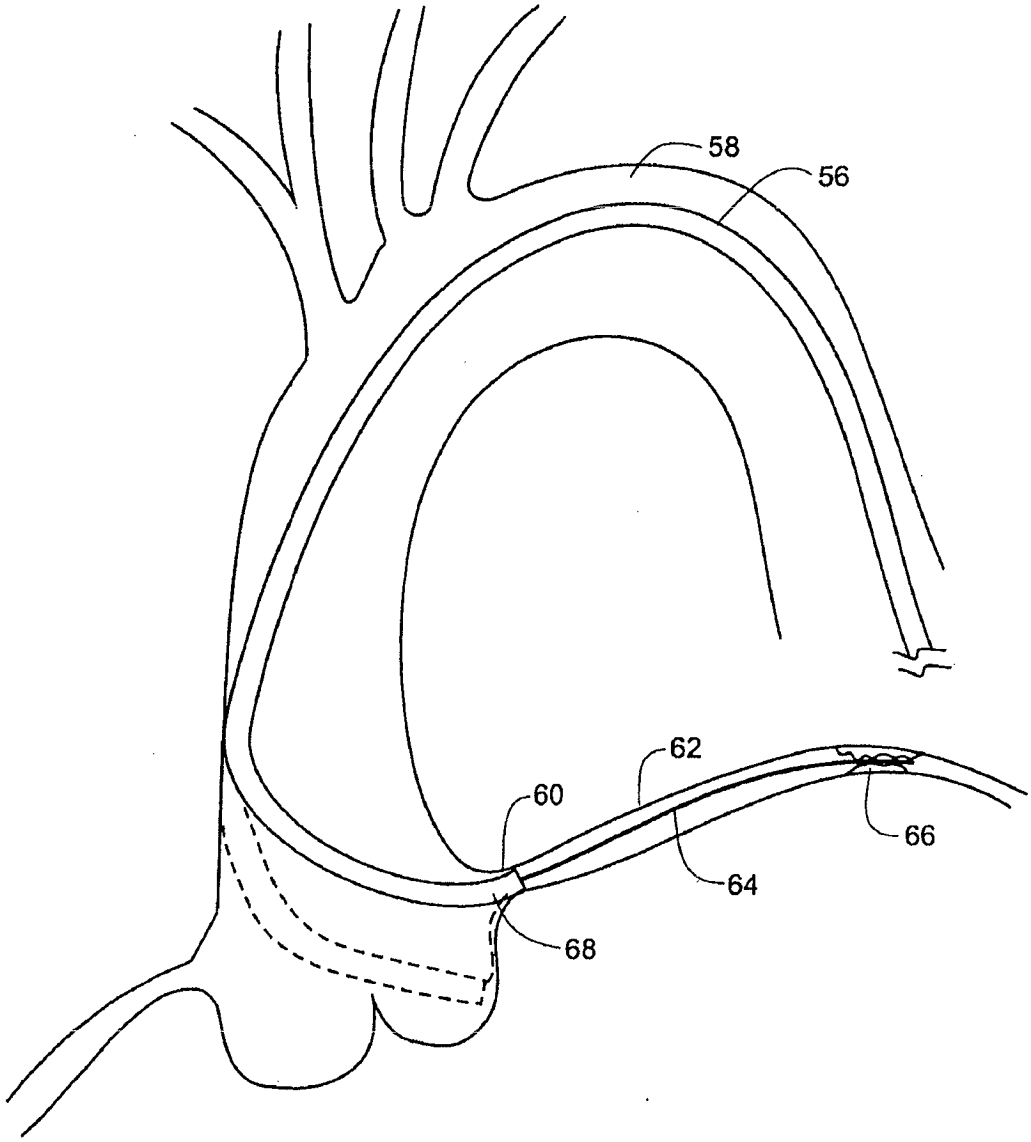

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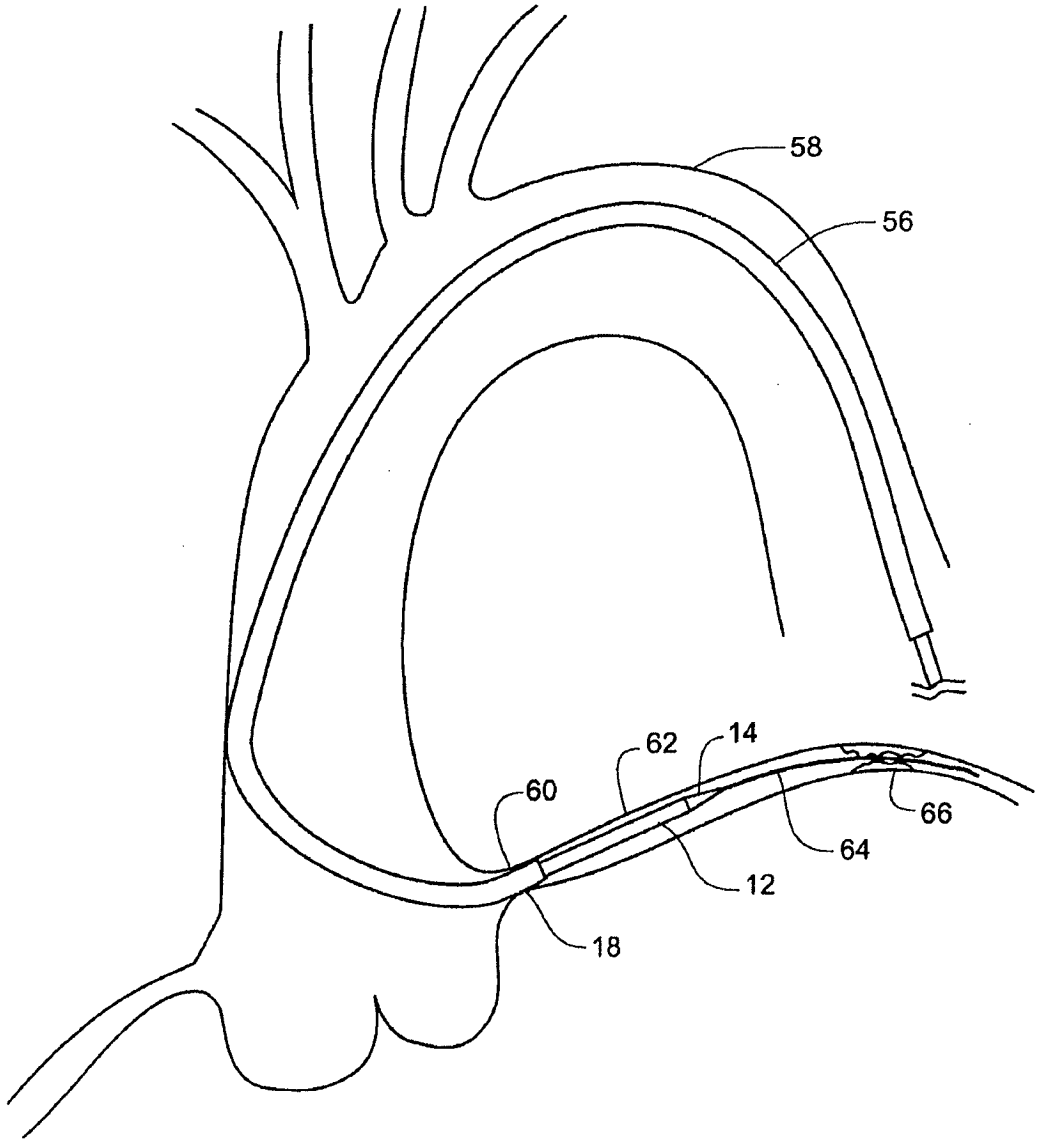

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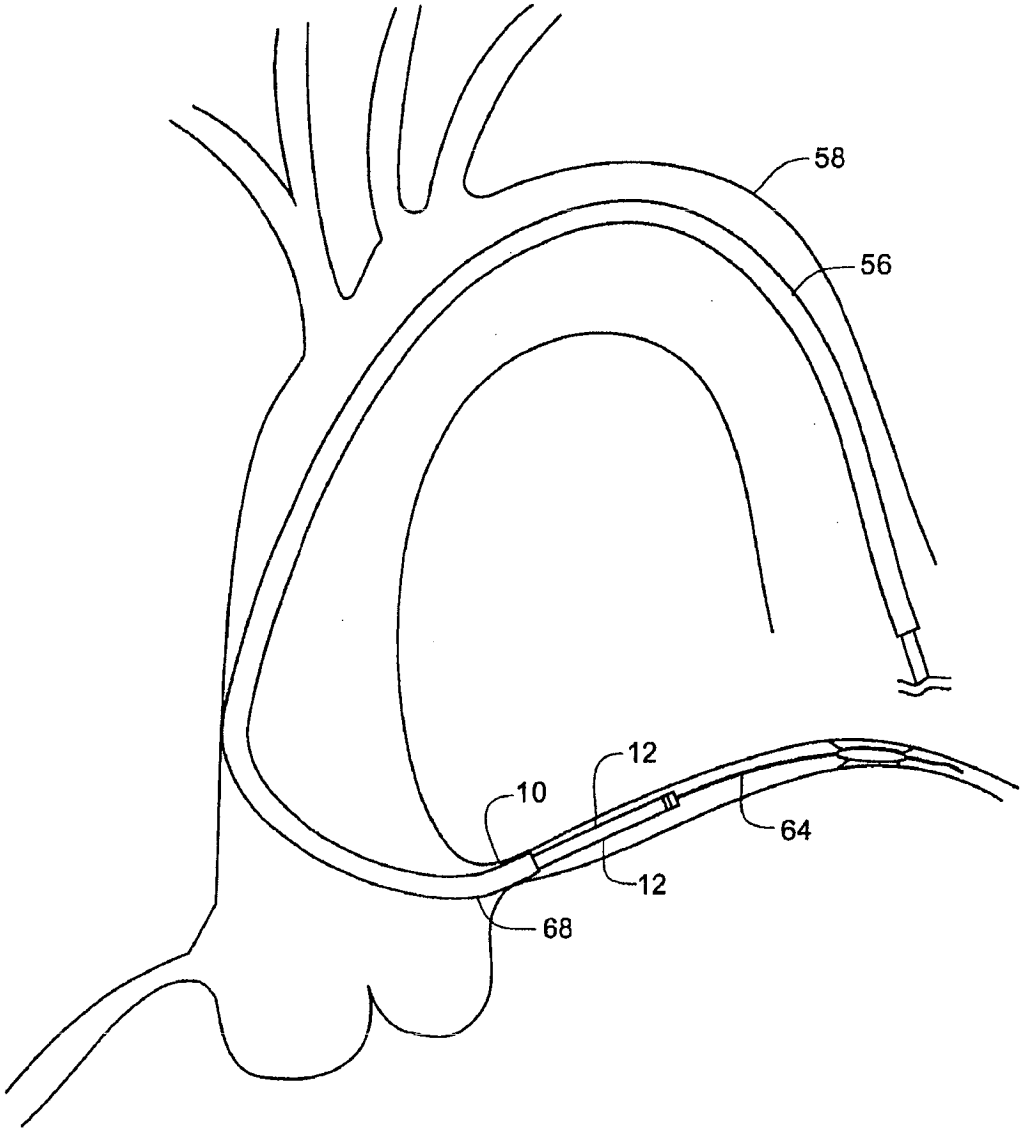


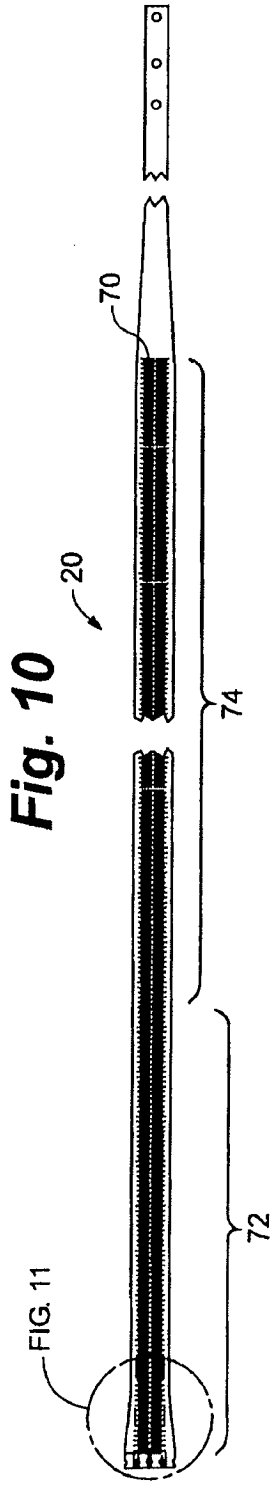
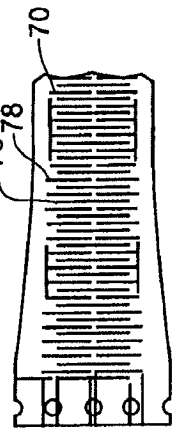


Fig. 10



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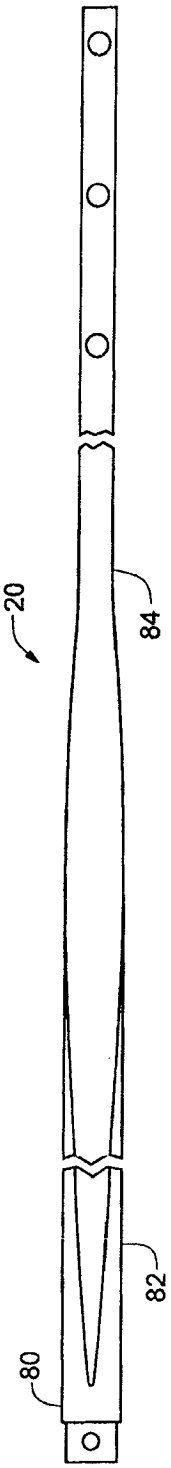


Fig. 12

Fig. 13

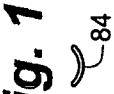


Fig. 16

Fig. 15

Fig. 14

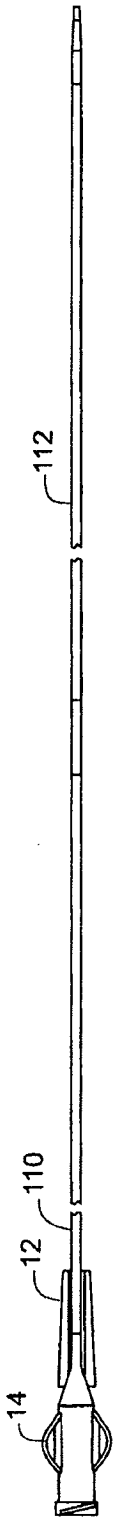
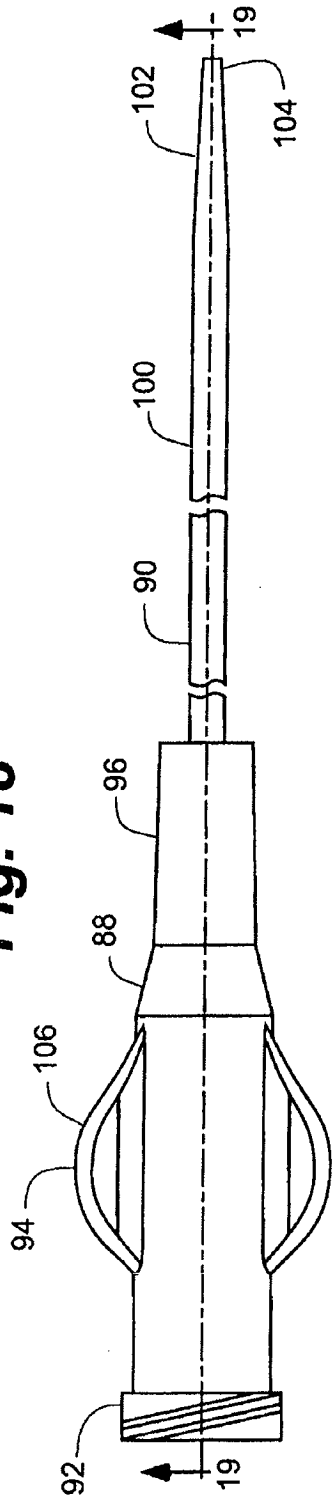


Fig. 17



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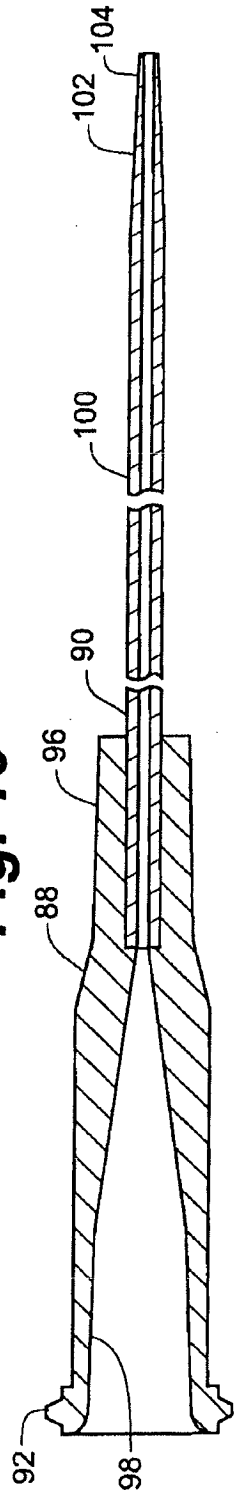

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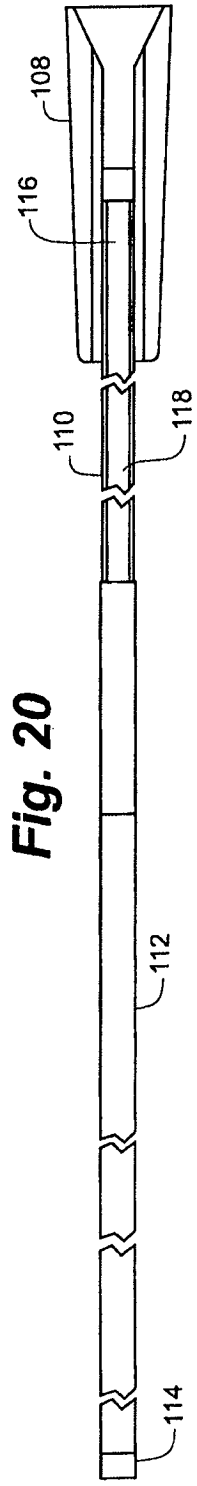

Fig. 20

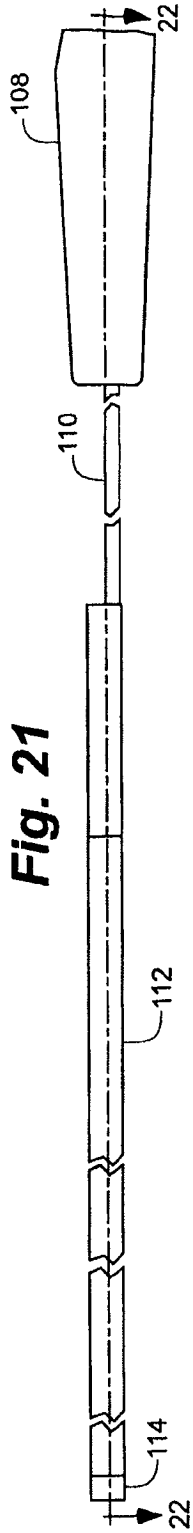

Fig. 21

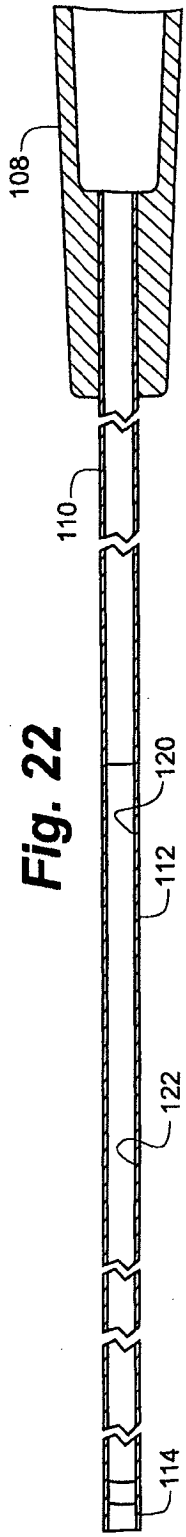

Fig. 22

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

RELATED APPLICATION

This application is a division of application Ser. No. 11/416,629 filed May 3, 2006, now U.S. Pat. No. 8,048,032 which is hereby fully incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to catheters used in interventional cardiology procedures. More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.

BACKGROUND OF THE INVENTION

Interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters. In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions. These lesions may totally obstruct the lumen of the artery or may dramatically narrow the lumen of the artery. Narrowing is referred to as stenosis. In order to diagnose and treat obstructive coronary artery disease it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery.

In treating a stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery. This is sometimes accomplished with the aid of a guidewire. A guide catheter is typically seated into the opening or ostium of the artery to be treated and a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis. Crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated. This can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.

Prior attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as "backup support") fall generally into four categories.

First are guiding catheters that, through a combination of shape and stiffness, are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed. Examples of this approach can be found in U.S. Pat. No. 6,475,195 issued to Voda and U.S. Pat. No. 5,658,263 issued to Dang et al. These guiding catheters all share the common limitation that a guide catheter stiff enough to provide adequate backup support is often too stiff to be safely inserted into the aorta without the possibility of causing damage to the aortic wall. In addition, attempts to deep seat the guide catheter have been made but the rigid nature of the guide catheter creates the risk that the guide catheter may damage the coronary artery wall or that the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

Second are guiding catheters that include a retractable appendage. The appendage in these catheters can be extended to engage the opposing wall of the aortic arch to provide backup support or the appendage may be placed under tension to stiffen a bend in the catheter to provide backup support. Examples of this approach may be found in U.S. Pat. Nos. 4,813,930 issued to Elliot; 5,098,412 issued to Shiu; and 6,860,876 issued to Chen. These guiding catheters tend to be somewhat mechanically complex and have not been widely adopted by practitioners.

Third are guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium of the coronary artery to provide a force acting in opposition to the backward forces created when trying to maneuver a therapeutic device past a lesion or blockage in the coronary artery. These devices can include a balloon secured to a guidewire or a catheter or another device for expanding to grip the walls of the coronary artery from within. Examples of this approach may be found in U.S. Pat. Nos. 4,832,028 issued to Patel; 6,595,952 issued to Forsberg; and U.S. Published Application No. 2005/0182437 by Bonnette et al. Again, these devices tend to be mechanically complex and can completely occlude the coronary ostium thus stopping perfusion of the coronary artery.

A fourth technique includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents. This technique has been described in an article by Takahashi entitled "New Method to Increase a Backup Support of Six French Guiding Coronary Catheter," published in Catheterization and Cardiovascular Interventions, 63:452-456 (2004). This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

Thus, the interventional cardiology art would benefit from the availability of a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery.

SUMMARY OF THE INVENTION

The present invention is a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. The coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard 0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery. This feature also allows removal of the tapered inner catheter after the coaxial guide catheter is in place. The tapered inner catheter provides a gradual transition

from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French.

The coaxial guide catheter preferably can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter. In addition, the coaxial guide catheter preferably has an inner diameter that is appropriate for delivering standard coronary treatment devices after it is placed in the coronary artery.

In one embodiment, the coaxial guide catheter is made in at least three sizes corresponding to the internal capacity of 8 French, 7 French, and 6 French guide catheters that are commonly used in interventional cardiology procedures. An 8 French catheter has an internal diameter greater than or equal to 0.088 inches. A 7 French catheter has an internal diameter greater than or equal to 0.078 inches. A 6 French guide catheter has an internal diameter greater than or equal to 0.070 inches. Thus, for three exemplary sizes the effective internal diameter of the coaxial guide catheter may be as follows. For a 7 French in 8 French coaxial guide catheter the internal diameter should be greater than or equal to 0.078 inches. For a 6 French in 7 French coaxial guide catheter the internal diameter should be greater than or equal to 0.070 inches. For a 5 French in 6 French coaxial guide catheter the internal diameter should be greater than or equal to 0.056 inches.

Interventional cardiology procedures are typically carried out under fluoroscopy or another x-ray or imaging technique. Therefore, one embodiment of the coaxial guide catheter of the present invention includes a radiopaque marker at its distal tip to facilitate positioning and manipulation of the coaxial guide catheter.

The present invention generally includes the coaxial guide catheter and a tapered inner catheter. The coaxial guide catheter includes a tip portion, a reinforced portion, and a substantially rigid portion. The coaxial guide catheter will generally have an overall length of preferably approximately 125 cm, though this should not be considered limiting.

In one embodiment, the tip portion may include a soft tip and a marker band. The soft tip is tapered and may be formed from a low durometer polymer or elastomer material such as polyether block amide polymer, (PEBA, Pebax®) the marker band may be formed from a platinum iridium alloy sandwiched between the Pebax® that extends from the bump tip and a PTFE liner.

In one embodiment, the reinforced portion may be reinforced, preferably with metallic fibers in a braided or coiled pattern. The braided or coiled portion is lined by a PTFE liner and may be covered on its exterior with Pebax®. The braided or coiled portion may extend approximately 20 to 110 cm in length. In one exemplary embodiment, the braided portion extends approximately 32 to 36 cm.

Preferably, the rigid portion may be advantageously formed from a stainless steel or Nitinol tube. The rigid portion may be joined to the braid or coil portion by welding. The rigid portion may include a cutout portion and a full circumference portion. For example, the cutout portion may include a section where about 45% of the circumference of the cylindrical tubular structure has been removed. The cutout portion may also include a section where 75-90% of the circumference of the tubular structure has been removed. In one exemplary embodiment, the portion having approximately 45% removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm. The full circumference portion of the rigid portion is typically located at the most proximal end of the coaxial guide catheter.

The rigid portion may include a plurality of radially oriented slits or other cuts in its distal portion to increase and control the flexibility of the rigid portion

In an exemplary embodiment, the tapered inner catheter generally includes a tapered inner catheter tip and a cutout portion. The tapered inner catheter tip includes a tapered portion and a straight portion. The tapered portion is typically at the most distal end of the tapered inner catheter. Both the straight portion and the tapered portion are pierced by a lumen through which a guidewire may be passed.

The cutout portion supports a track passing along the concave side thereof that continues from the lumen that passes through the straight portion and the tapered portion. The tapered inner catheter may also have a clip or snap attachment at its proximal end to releasably join the tapered inner catheter to the coaxial guide catheter.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. The tapered inner catheter is positioned so that the tapered inner catheter tip extends beyond the tip portion of the coaxial guide catheter. The coaxial guide catheter-tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta. The coaxial guide catheter-tapered inner catheter combination may be threaded over a preplaced 0.014 inch guidewire. The tapered inner catheter-coaxial guide catheter combination is advanced up the aorta until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed. During this entire process at least part of the coaxial guide catheter-tapered inner catheter combination is located inside of the guide catheter.

Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion such as a stenosis or a chronic arterial occlusion.

A guide catheter inserted into the ostium of a branch artery where it branches off from a larger artery is subject to force vectors that tend to dislodge the distal end of the guide catheter from the ostium of the branch artery when a physician attempts to direct a guidewire or other interventional cardiology device past an occlusive or stenotic lesion in the branch artery. This discussion will refer to a guide wire but it is to be understood that similar principles apply to other interventional cardiology devices including balloon catheters and stent catheters.

One of the forces that acts on the guide catheter is an axial force substantially along the axis of the branch artery and the portion of the guide catheter that is seated in the ostium. This force vector is a reactive force created by the pushing back of the guide wire against the guide catheter as the physician tries to force the guidewire through or past the lesion. It tends to push the distal end of the catheter out of the ostium in a direction parallel to the axis of the branch artery and the axis of the distal end of the guide catheter.

Another of the force vectors that acts on the guide catheter is a shearing force that tends to dislodge the distal end of the guide catheter from the ostium of the branch artery in a direction perpendicular to the axis of the branch artery and the

axis of the distal end of the guide catheter. This force vector arises from curvature of the guide catheter near its distal end and the guide wire pushing on the curved portion of the guide catheter as the physician applies force to the guidewire. The coaxial guide catheter of the present invention assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.

The system is deliverable using standard techniques utilizing currently available equipment. The present invention also allows atraumatic placement within the coronary artery. Further, the invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters. Finally, the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic depiction of the coaxial guide catheter and a tapered inner catheter in accordance with the present invention;

FIG. **2** is schematic depiction of the coaxial guide catheter and tapered inner catheter assembled in accordance with the present invention;

FIG. **3** is a plan view of a guide catheter, the coaxial guide catheter, and a treatment catheter in accordance with the present invention;

FIG. **4** is a sectional view of the coaxial guide catheter in accordance with the present invention;

FIG. **5** is a cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

FIG. **6** is another cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

FIG. **7** is a schematic view of a guide catheter and a guidewire located in an aortic arch and a coronary artery and the guide catheter and guidewire in a second position depicted in phantom;

FIG. **8** is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter in accordance with the present invention and a tapered inner catheter located in the aortic arch and coronary artery;

FIG. **9** is a schematic view of a guide catheter, a guidewire and a coaxial guide catheter in accordance with the present invention located in the aortic arch and coronary artery;

FIG. **10** is a flat pattern for making relief cuts in a curved rigid portion of the coaxial guide catheter in accordance with the present invention;

FIG. **11** is a detailed view taken from FIG. **10**;

FIG. **12** is a plan view of the rigid portion in accordance with the present invention;

FIG. **13** is an elevational view of the rigid portion;

FIG. **14** is a sectional view of the rigid portion taken along section line **14-14** of FIG. **13**; and

FIG. **15** is a sectional view of the rigid portion taken along section line **15-15** of FIG. **13**.

FIG. **16** is a sectional view of the rigid portion taken along section line **16-16** of FIG. **13**.

FIG. **17** is a plan view of a coaxial guide catheter having a longer rail segment and a tapered inner catheter in accordance with the present invention.

FIG. **18** is a plan view of the tapered inner catheter as depicted in the FIG. **17**.

FIG. **19** is a cross-sectional view of the tapered inner catheter taken along section lines **19-19** of FIG. **18**.

FIG. **20** is a plan view of a coaxial guide catheter in accordance with the present invention.

FIG. **21** is an elevational view of a coaxial guide catheter in accordance with the present invention.

FIG. **22** is a cross-sectional view taken along section line **22-22** of FIG. **21**.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. **1** and **2**, coaxial guide catheter assembly **10** of the present invention generally includes coaxial guide catheter **12** and tapered inner catheter **14**.

Coaxial guide catheter **12** generally includes tip portion **16**, reinforced portion **18**, and rigid portion **20**. The overall length of the coaxial guide catheter typically can be approximately 125 cm. This length should not be considered limiting.

Tip portion **16** generally includes bump tip **22** and marker band **24**. Bump tip **22** includes taper **26**. Bump tip **24** is relatively flexible and may be formed, for example, from 4033 Pebax®. Bump tip **22** may be yellow or another high visibility color for ease of handling.

Marker band **24** is formed of a radiopaque material such as platinum/iridium alloy usually at a 90/10 ratio. Marker band **24** may be sandwiched between an outer Pebax® material **28** and a PTFE liner **30**. Outer Pebax® material **28** in this location may be formed of 5533 Pebax, for example.

Reinforced portion **18** includes braid or coil reinforcement **32**. Braid or coil reinforcement **32** may be formed of metal, plastic, graphite, or composite structures known to the art. Reinforced portion **18** may be lined on the interior by PTFE liner **30** and covered on the exterior by Pebax® material **28**. Tip portion **16** and reinforced portion **18** together form a substantially cylindrical structure. Braid or coil reinforcement **32** may extend approximately 20 to 30 cm. In one exemplary embodiment, braid or coiled portion has a length of approximately 32 to 36 cm.

Rigid portion **20** may be secured to braid or coil reinforcement by, for example, welding or bonding. Rigid portion **20** may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well. Rigid portion **20** includes first full circumference portion **34**, hemicylindrical portion **36**, arcuate portion **38**, and second full circumference portion **40**.

First full circumference portion **34** is joined to braid or coil reinforcement **32**. First full circumference portion **34** extends for a relatively short distance, for example, 0.25 cm.

Hemicylindrical portion **36** desirably includes 40% to 70% of the circumference of the tube. Hemicylindrical portion **36** may extend, for example, approximately 20 to 75 cm in length.

Hemicylindrical portion **36** tapers into arcuate portion **38**.

Arcuate portion **38** extends from 25% to 40% of the circumference of the tube. Arcuate portion **38** may extend linearly, for example, for about 15 cm.

Arcuate portion **38** connects to second full circumference portion **40**. Second full circumference portion **40** may extend for a short distance, for example, approximately 3 cm.

Tapered inner catheter **14** generally includes tapered inner catheter tip **42** and cutout portion **44**. Tapered inner catheter tip **42** tapers gradually from the diameter of a guide wire to the diameter of tip portion **16**.

Tapered inner catheter tip **42** includes tapered portion **46** at a distal end thereof, and straight portion **48**. Both tapered portion **46** and straight portion **48** are pierced by lumen **50**.

Cutout portion **44** defines a concave track **52** along its length. Concave track **52** is continuous with lumen **50**.

Tapered inner catheter **14** may also include clip **54** at a proximal end thereof to releasably join tapered inner catheter **14** to coaxial guide catheter **12**. Thus, tapered inner catheter **14** is keyed to coaxial guide catheter **12**.

Coaxial guide catheter **12** may include, starting at its distal end, a first portion having a flexural modulus of about 13,000 PSI plus or minus 5000 PSI, a second portion having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, a third portion having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI and a fourth portion having a flexural modulus of about 107,000 PSI plus or minus 20,000 PSI. Coaxial guide catheter **12** may be formed, for example, of 4033 Pebax® at bump tip **22** for the first 0.1 cm. This portion may followed by a section about three cm long of 5533 Pebax® that covers marker band **24** and the distal portion of braid or coil reinforcement **32**. Next may come an approximately five cm portion of 6333 Pebax® which encloses part of braid or coil reinforcement **32** followed by an approximately twenty seven cm portion of 7233 Pebax® covering the most proximal portion of braid or coil reinforcement **32**. Braid or coil reinforcement **32** is bonded to rigid portion **20** which may be formed from stainless steel or a similar biocompatible material. Rigid portion **20** may extend for approximately ninety cm and include first full circumference portion **34** (approximately 0.25 cm), hemicylindrical portion **36** (approximately seventy five cm), arcuate portion (approximately fifteen cm) and second full circumference portion (approximately three cm.) Rigid portion **20** may be formed from a stainless steel or Nitinol hypo tube.

FIG. **7** depicts a typical guide catheter **56** passing through aortic arch **58** into ostium **60** of coronary artery **62**. FIG. **7** also depicts guidewire **64** passing through the guide catheter **56** and into coronary artery **62**. Located in coronary artery **62** is stenotic lesion **66**. In a typical procedure, guidewire **64** is placed through the aortic arch **58** and into the ostium **60** of the coronary artery. **62**. The guide catheter **56** is passed over guidewire **64** until distal end **68** of guide catheter **56** is seated in ostium **60** of coronary artery **62**. Force is then applied to the guidewire **64** to push guidewire **64** past stenotic lesion **66** or an occlusive lesion (not shown). Once the guidewire **64** is pushed past stenotic lesion **66** or occlusive lesion (not shown), a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion **66** or occlusive lesion (not shown). The lesion can then be treated.

As can be seen in phantom, in FIG. **7**, the application of force to guidewire **64** can cause guide catheter **56** to dislodge from ostium **60** of coronary artery **62**. This can occur in the case of a tough stenotic lesion **66** or occlusive lesion (not shown) when it is difficult to pass the guidewire **64** beyond the stenotic lesion **66** or occlusive lesion (not shown).

Referring the FIG. **8** coaxial guide catheter **12** is depicted as used with guide catheter **56**, guidewire **64**, and tapered inner catheter **14**. Here, coaxial guide catheter **12** with tapered inner catheter **14** is passed through guide catheter **56** and over guidewire **64** into coronary artery **62** after the guide catheter **56** has been placed in the ostium **60** of coronary artery **62**, as depicted in FIG. **7**. Coaxial guide catheter **12**, with tapered inner catheter **14**, provide an inner support member for proper translation over guidewire **64**. Tapered inner catheter tip **42** provides a distal tapered transition from guidewire **64** to coaxial guide catheter **12**. Once coaxial guide catheter **12** is in place, tapered inner catheter **14** is removed from the inside of coaxial guide catheter **12**.

Coaxial guide catheter **12** is now ready to accept a treatment catheter such as a stent or balloon catheter. Referring to FIG. **9**, the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion. In addition, the improved back up support assists in the positioning of a treating catheter that may include a stent or balloon.

Referring to FIGS. **10** and **11**, in some embodiments of coaxial guide catheter **12**, rigid portion **20** may be perforated by relief cuts **70**. Relief cuts **70** may be classed into first group **72** and second group **74**.

First group **72** may be located near to the juncture between rigid portion **20** and reinforced portion **18**. First group **72** of relief cuts **70** are relatively closely spaced. For example, first group **72** of relief cuts **70** may be spaced approximately 0.010 inches apart. First group **72** of relief cuts **70** extends for a relatively short distance, for example, approximately 2 inches.

Second group **74** of relief cuts **70** may extend for a relatively long distance, for example, approximately 30-35 inches. Second group **74** of relief cuts **70** are spaced farther apart than first group **72**. For example, relief cuts **70** of second group **74** may be spaced approximately 0.020 inches between cuts. Referring particularly to FIG. **11**, relief cuts **70** may include single cuts **76** and double cuts **78**. Single cuts **76** may include an individual linear cut, as can be seen in FIG. **11**. Double cuts **78** may include two linear cuts along a single line but separated by a short section of uncut structure. Typically, single cuts **76** and double cuts **78** are alternated along the length of rigid portion **20**. Generally, the overall length of single cut **76** may be less than the overall length of two double cuts **78**.

In an embodiment depicted in FIGS. **12-15**, rigid portion includes full circumference portion **80**, greater than 180° portion **82**, and less than 180° portion **84**. Greater than 180° portion **82** may, for example, include structure forming approximately 300° of the circumference of the cylinder. Less than 180° portion may include, for example, structure forming approximately 90° of the circumference of a cylinder. Greater than 180° portion **82** may extend approximately 22-25 inches. Greater than 180° portion **82** holds tapered inner catheter **14** within rigid portion **20**.

When tapered inner catheter is inserted into coaxial guide catheter **12** greater than 180° portion **82** grips tapered inner catheter **14** which is exposed through the opening in greater than 180° portion **82**. Thus, the overall structure of tapered inner catheter **14** along with greater than 180° portion **82** is substantially cylindrical. Accordingly, when inserted through a guide catheter **56** having a Touhey-Borst style adapter, the Touhey-Borst style adapter can still seal around rigid portion **20** and enclosed inner tapered catheter **14**.

Referring to FIG. **16**, another embodiment of coaxial guide catheter assembly **10** includes coaxial guide catheter **12** and tapered inner catheter **14**. Tapered inner catheter **14** is keyed to coaxial guide catheter **12** at hub **86**.

Referring to FIGS. **17** and **18**, tapered inner catheter **14** generally includes connector hub **88** and catheter tube **90**.

Connector hub **88** generally includes connector portion **92**, grip portion **94** and joining portion **96**. Connector hub **88** defines funnel portion **98** therein.

Catheter tube **90** generally includes straight portion **100**, tapered portion **102** and marker band tip **104**. Catheter tube **90** is joined to connector hub **88** at joining portion **96**. Tapered inner catheter **14** may be formed in whole or in part from low-density polyethylene plastic, for example. Other suitable materials known to the catheter arts may be used as well.

Grip portion **94** desirably includes gripping ears **106**. Gripping ears **106** may extend outwardly from grip portion **94** substantially radially and be shaped for convenient gripping by a physician.

Referring to FIGS. **19** through **21**, in this embodiment, coaxial guide catheter **12** includes interrupted hub **108**, hemi-tube portion **110**, braided portion **112** and tip portion **114**.

Interrupted hub **108** defines an opening **116**, along a side thereof. Interrupted hub **108** may be substantially C-shaped or U-shaped in cross section. Opening **116** is sized so that tapered inner catheter **14** may be passed readily therethrough in a direction perpendicular to the long axes of both interrupted hub **108** and tapered inner catheter **14**. Hemi-tube portion **110** is immediately distal to interrupted hub **108**. Hemi-tube portion **110** may be formed, for example, from a metal hypo tube forming approximately 50% of the circumference of a cylinder. Hemi-tube portion **110** is aligned so that opening **116** of interrupted hub **108** is coextensive with opening **118** of hemi-tube portion **110**. Hemi-tube portion **110** is joined to braided portion **112**, for example, by adhesive, bonding or welding. The location where hemi-tube portion **110** and braided portion **112** join defines the entire circumference of a cylinder.

Braided portion **112** may be reinforced by a coil or braid, **120**. Coil or braid **120** may be formed of metal or another suitable reinforcing material.

Tip portion **114** is generally not reinforced and is substantially soft. Tip portion **114** is similarly structured to tapered inner catheter tip **42**. Tip portion **114** may include a radiopaque marker band **24**.

Beginning at the distal end of coaxial guide catheter **12**, tip portion **114** may be formed.substantially of, for example, 2533 Pebax® This may be followed by a section of 3533 Pebax®, then by a section of 5533 Pebax®, then by a further section of 7233 Pebax®. These Pebax® portions may all incorporate, for example, about 20% barium sulfate ($BaSO_4$).

In one embodiment, tip portion **114** and braided portion **112** may have an overall length together of approximately one hundred nine centimeters. Hemi-tube portion **110** and interrupted hub **108** may together have an overall length of approximately eighteen centimeters.

In this embodiment, coaxial guide catheter **12** may be lined with a PTFE liner **122**.

In operation, a guide catheter **56** is inserted into a major blood vessel in the body such as aortic arch **58** over guidewire **64** and the distal end **68** of guide catheter **56** is brought into proximity of ostium **60** of a smaller branch blood vessel, such as coronary artery **62**, that it is desired to enter. Coaxial guide catheter **12**, with tapered inner catheter **14**, is inserted through guide catheter **56** and over guidewire **64**. Guide catheter **56**, guidewire **64**, coaxial guide catheter **12**, and tapered inner catheter **14** are manipulated to insert tapered inner catheter tip **42** into the ostium **60** of the blood vessel that branches off from the major blood vessel. The bump tip **22** of coaxial guide catheter **12** is inserted with tapered inner catheter tip **42** well into ostium **60** of coronary artery **62** or other blood vessel until bump tip **22** of coaxial guide catheter **12** achieves a deep seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

When the interventional cardiology device reaches a stenosis or blockage in coronary artery **62** or another branch blood vessel, force may be applied to the interventional cardiology device catheter while reinforced portion **18** and rigid portion **20** of coaxial guide catheter **12** provide back up support. The back force that would tend to dislodge bump tip **22** from a deep seated position in the ostium in the branch blood vessel is transferred through reinforced portion **18** to rigid portion **20** of coaxial guide catheter **12**. A physician may apply a force to the proximal end of the coaxial guide catheter **12** to resist dislodging of bump tip **22** from the ostium of the branch artery.

One advantage of the present invention over prior art approaches is that the present invention does not interfere the injection of fluids via the Y-adapter of guide catheter **56** as does the use of a smaller catheter within a larger catheter.

The present invention may be embodied in other specific forms without departing from the spirit of the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

What is claimed is:

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.

2. The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal portion of the coaxial guide catheter remains seated in the second artery in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.

3. The method as claimed in claim 1, further comprising:

keying a tapered inner catheter to the coaxial guide catheter at a proximal portion thereof.

4. The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof.

5. The method as claimed in claim 1, further comprising selecting the standard guide catheter to further comprise a Y-adapter and the method further comprising injecting a fluid through the Y-adapter into the standard guide catheter.

6. The method as claimed in claim 1, further comprising placing a tapered inner catheter inside the lumen of the flexible tip portion of the coaxial guide catheter, the tapered inner catheter including a tapered distal portion, advancing the tapered distal portion to extend beyond the distal tip of the coaxial guide catheter; and

removing the tapered inner catheter from the coaxial guide catheter.

7. The method as claimed in claim 1, further comprising extending a distal portion of the tubular structure beyond the distal end of the standard guide catheter while a proximal portion remains within the lumen of the standard guide catheter, such that the coaxial guide catheter 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 standard catheter from the branch artery.

8. The method of claim 7, further comprising extending the interventional cardiology device past a radiopaque marker proximate a distal tip of the coaxial guide catheter.

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.

10. The method of claim 9, further comprising

extending the interventional cardiology device through the proximal side opening;

advancing the interventional cardiology device through structure defining a full circumference portion; and

advancing the interventional cardiology device through structure defining a partially cylindrical portion.

11. The method of claim 9, further comprising extending the interventional cardiology device through a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion of the tubular structure proximal to the flexible distal tip portion.

12. The method of claim 11 further comprising extending the interventional cardiology device through the flexible cylindrical reinforced portion that is reinforced with metallic elements in a braided or coiled pattern.

13. The method of claim 1, further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

14. The method of claim 1, further comprising extending the interventional cardiology device through the substantially rigid portion from proximal to distal through a cross-sectional shape having an arcuate portion, a hemicylindrical portion and a full circumference portion.

* * * * *

Exhibit 4

(12) **United States Patent**
Root et al.

(10) **Patent No.: US 8,292,850 B2**
(45) **Date of Patent: Oct. 23, 2012**

(54) **COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

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(73) Assignee: **Vascular Solutions, Inc.**, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/359,059**

(22) Filed: **Jan. 26, 2012**

(65) **Prior Publication Data**

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Related U.S. Application Data

(62) Division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

(51) **Int. Cl.**
A61M 5/178 (2006.01)
A61M 25/00 (2006.01)

(52) **U.S. Cl.** **604/164.01**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.02, 164.09–164.11, 604/525

See application file for complete search history.

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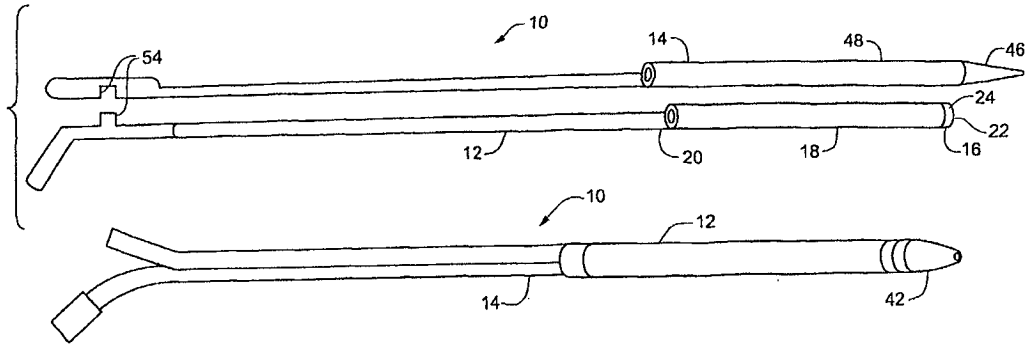
Primary Examiner — Kevin C Sirmons
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente Christensen Pedersen, P.A.

(57) **ABSTRACT**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the guide catheter and beyond the distal end of the guide catheter and inserted into the branch artery. The device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through the second lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

24 Claims, 13 Drawing Sheets



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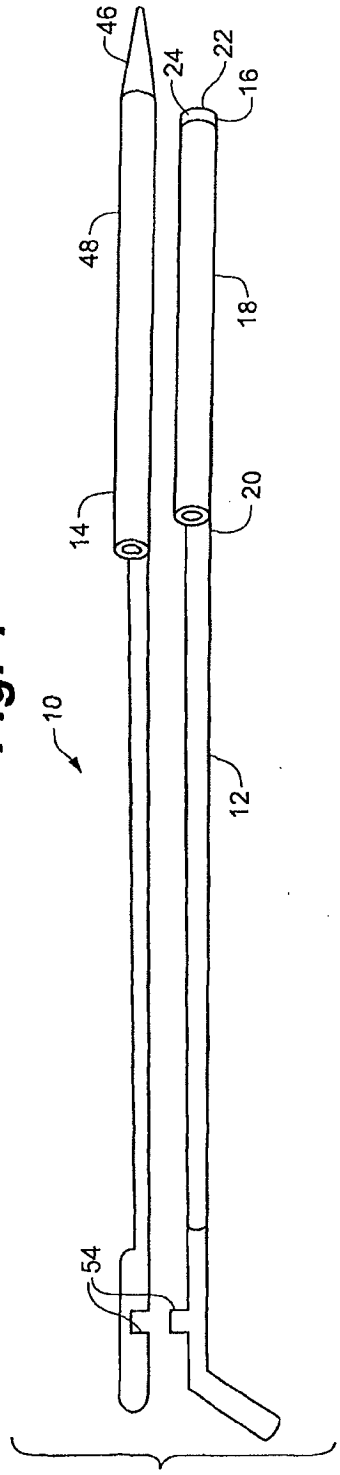


Fig. 1

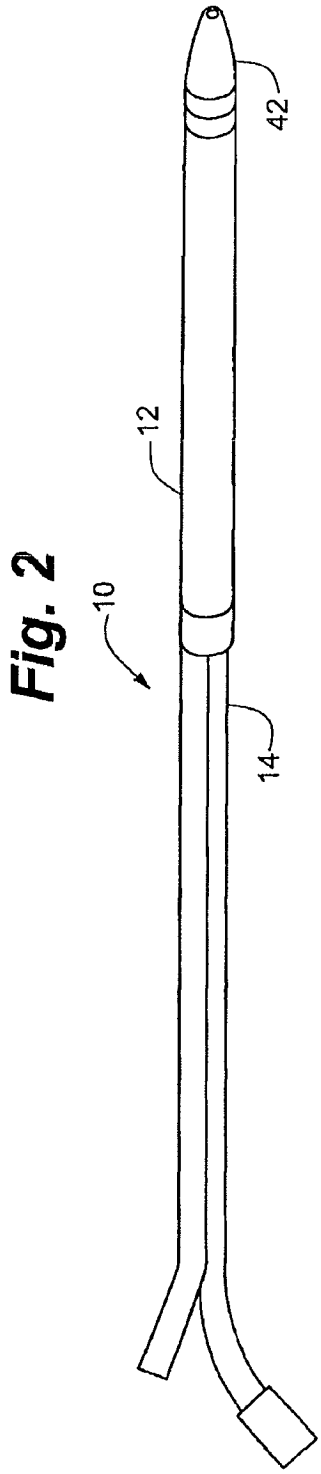


Fig. 2

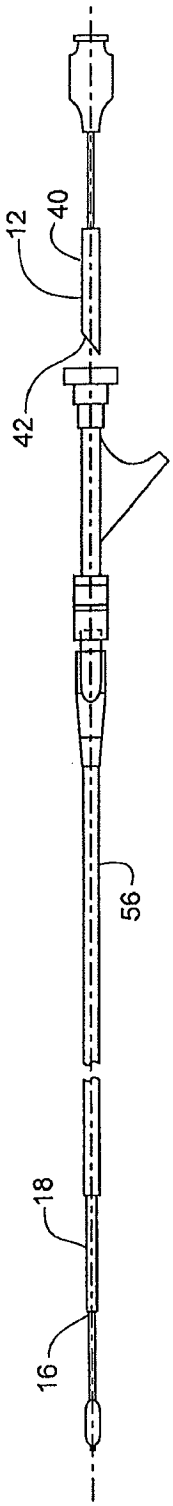


Fig. 3

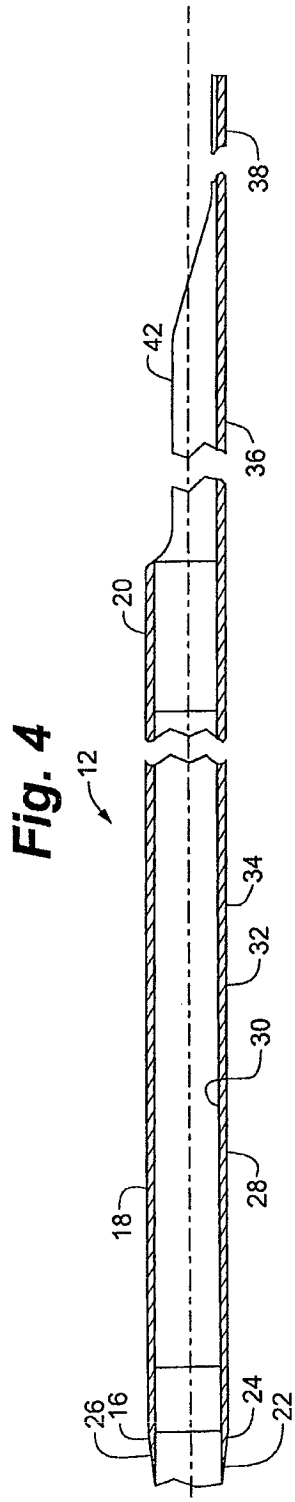


Fig. 4

Fig. 5

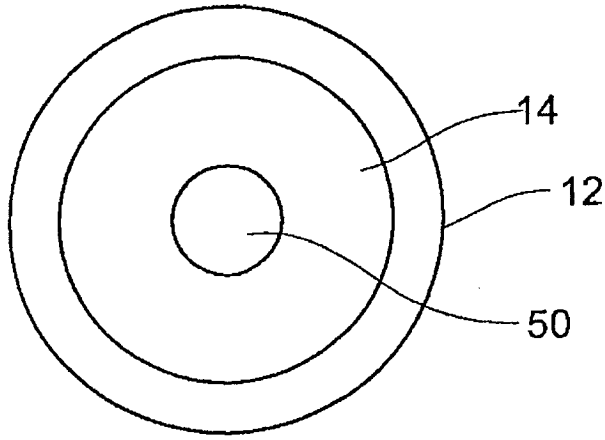


Fig. 6

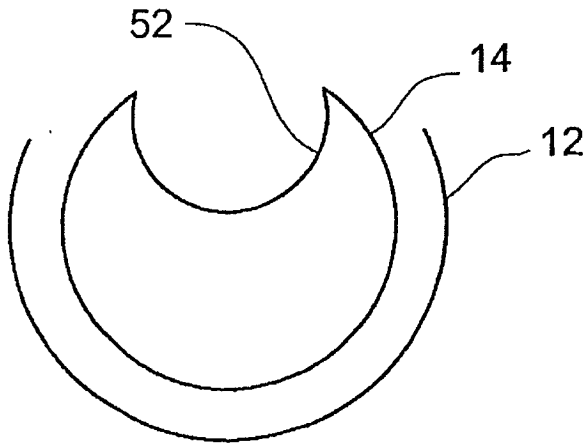


Fig. 7

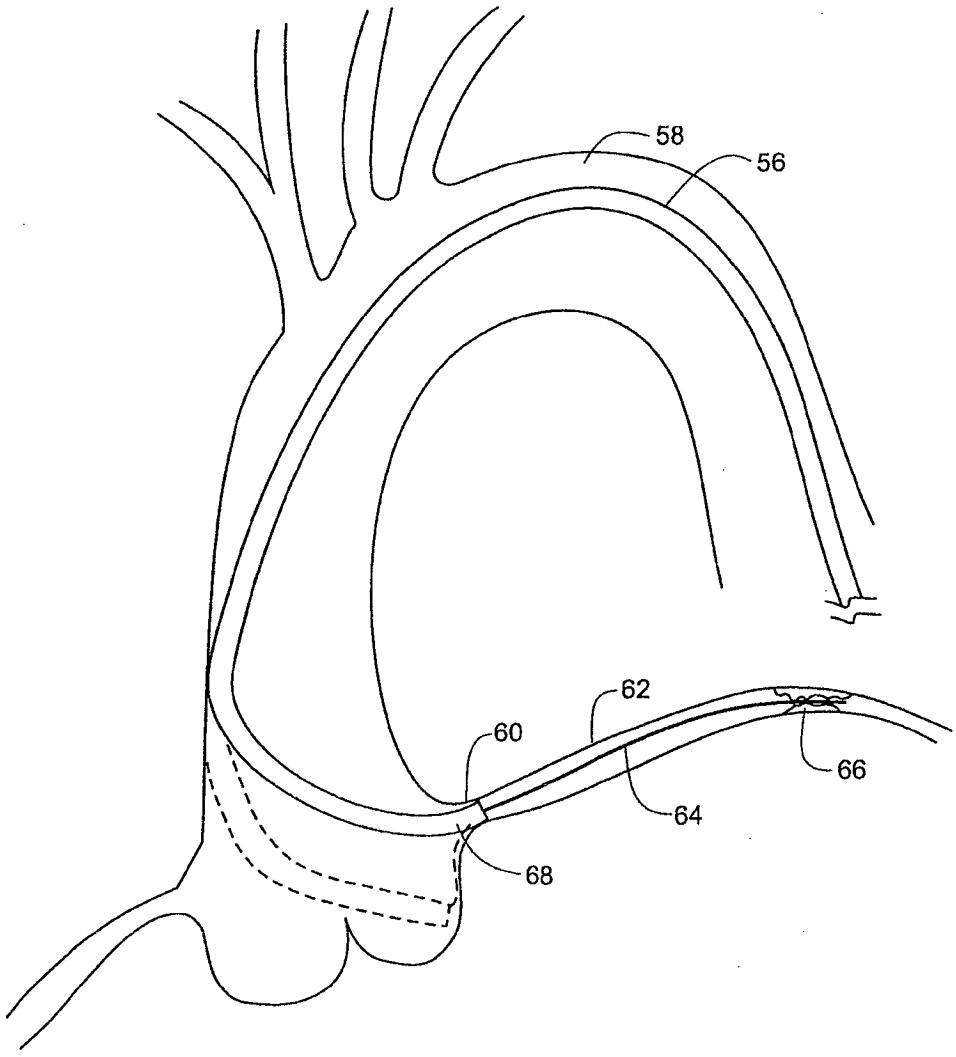


Fig. 8

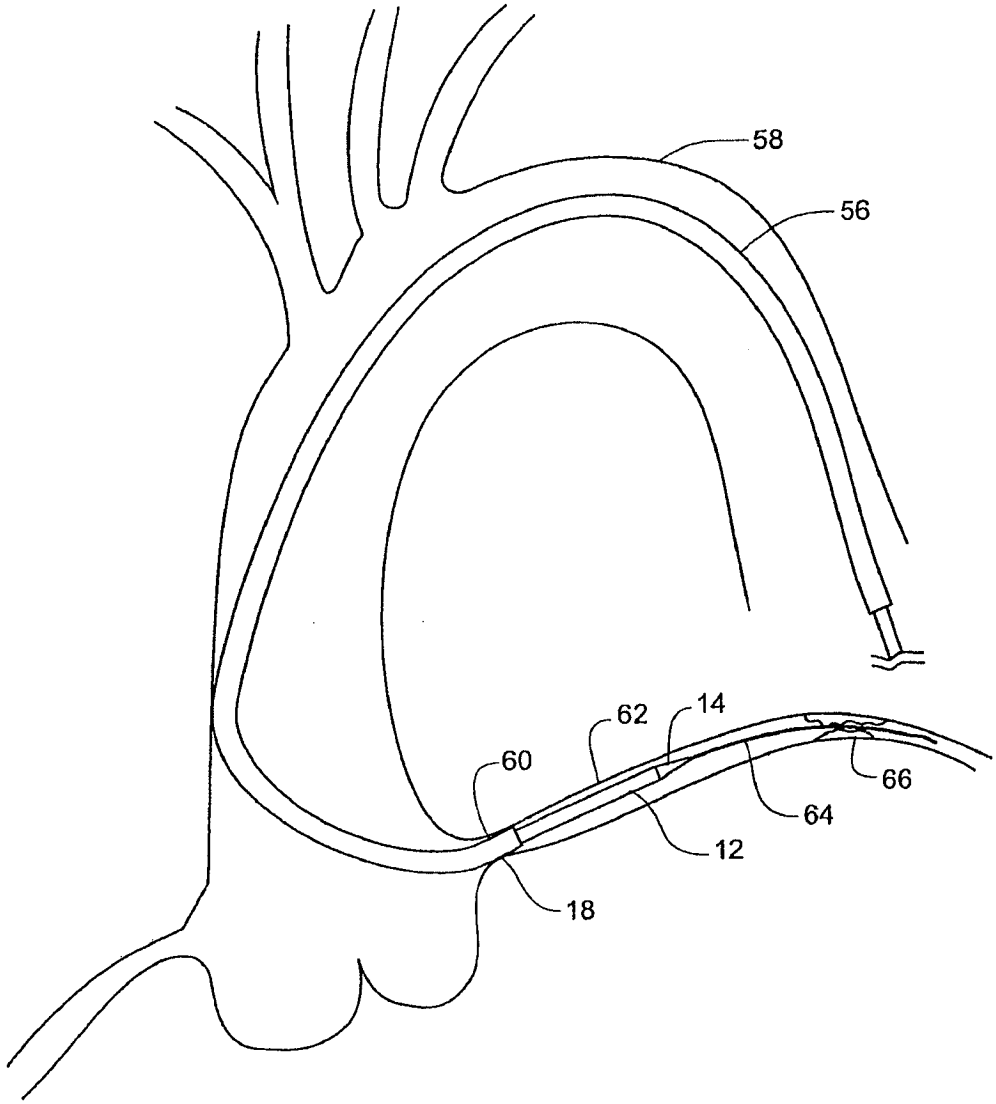
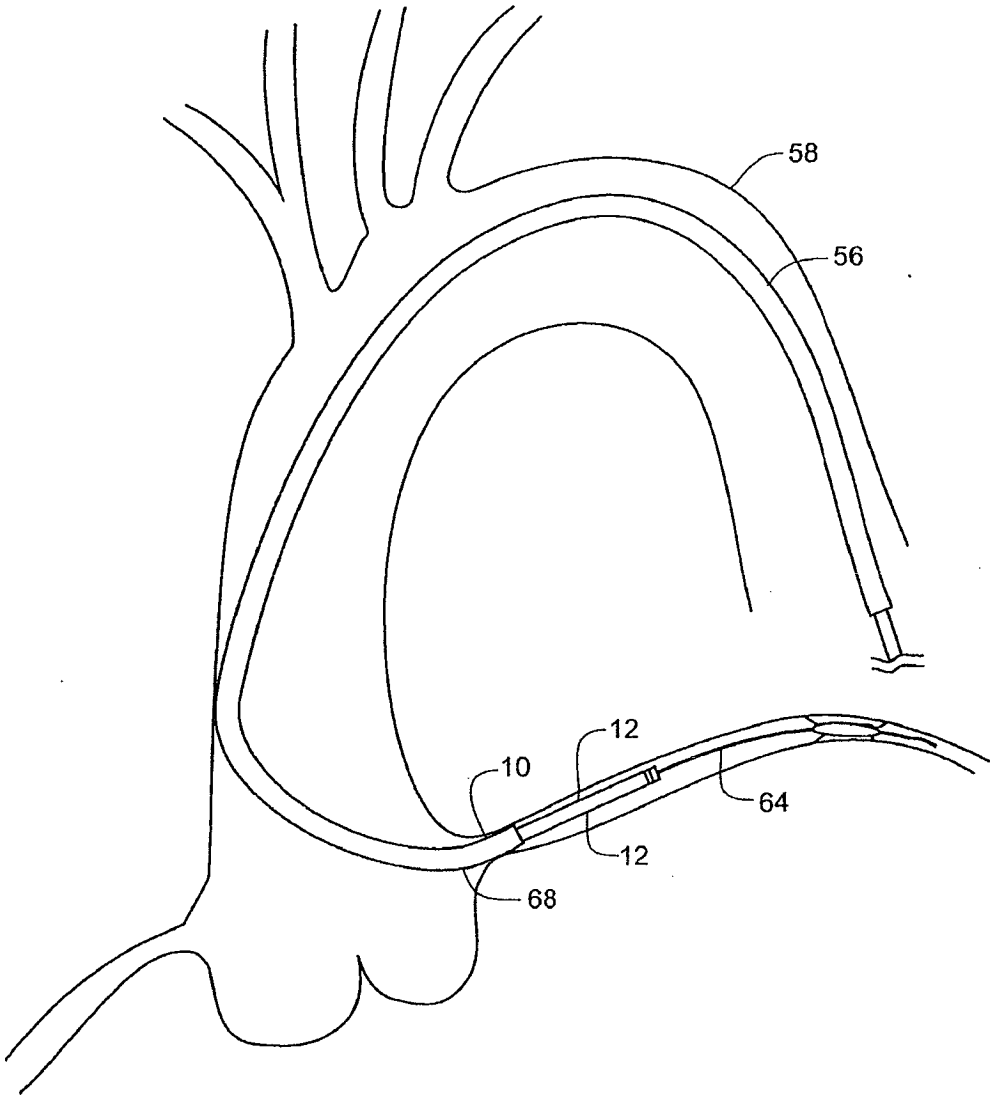


Fig. 9



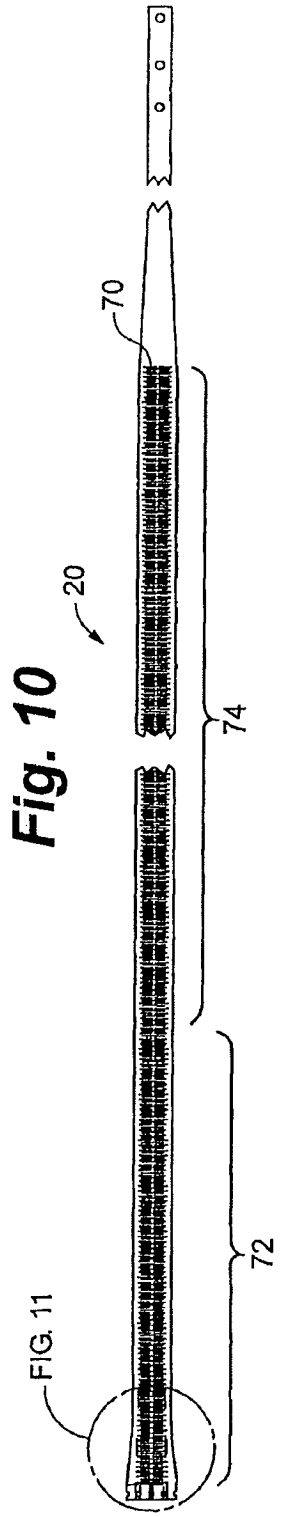


Fig. 10

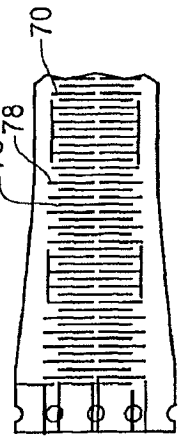


Fig. 11

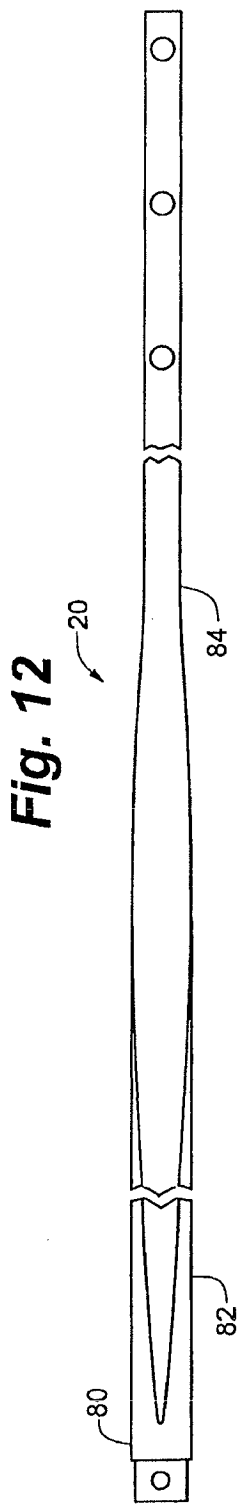


Fig. 12

Fig. 13

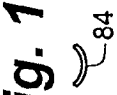


Fig. 16

Fig. 15

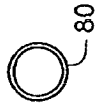


Fig. 14

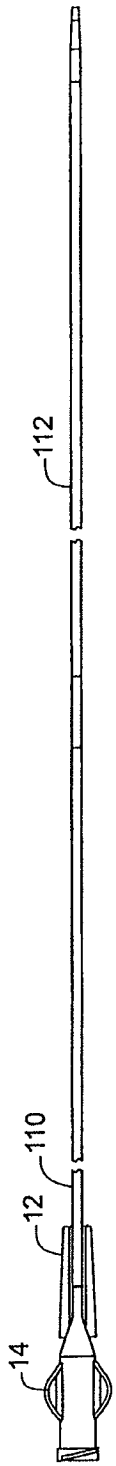


Fig. 17

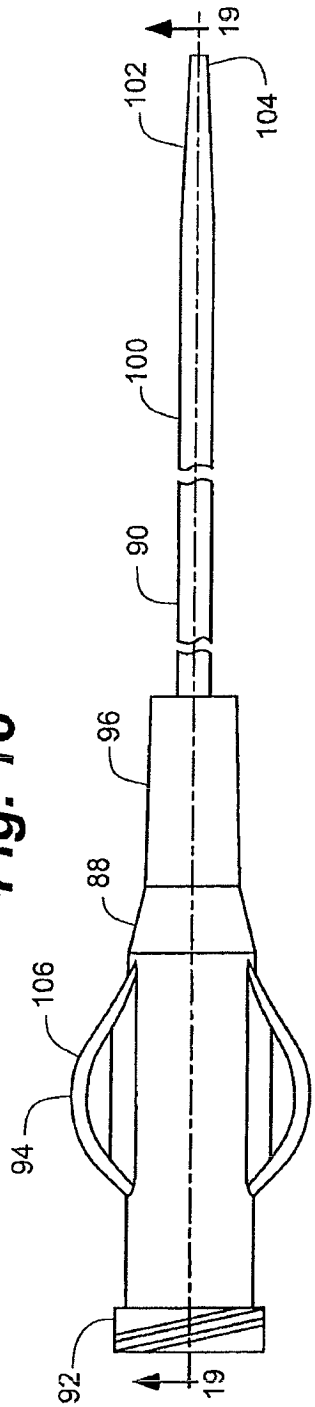


Fig. 18

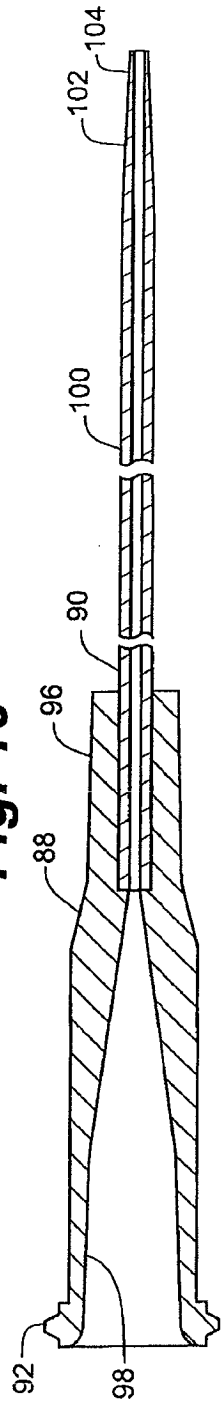


Fig. 19

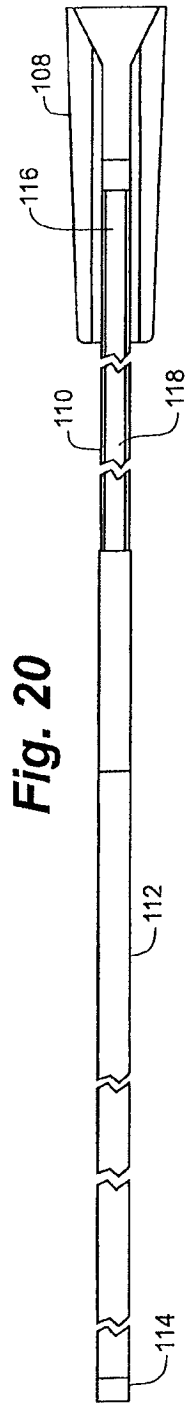


Fig. 20

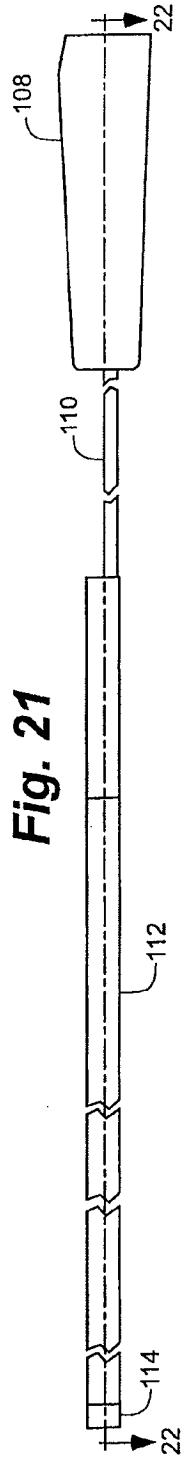


Fig. 21

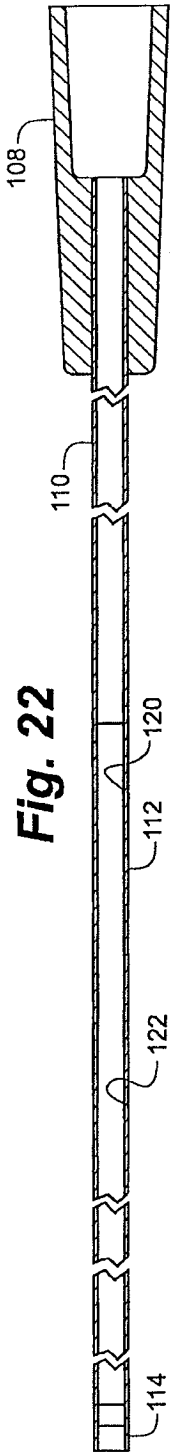


Fig. 22

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

RELATED APPLICATIONS

This application is a divisional of application Ser. No. 12/824,734, filed Jun. 28, 2010 now U.S. Pat. No. 8,142,413 entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures", which is divisional of application Ser. No. 11/416,629, filed May 3, 2006 now U.S. Pat. No. 8,048,032 entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures".

FIELD OF THE INVENTION

The present invention relates generally to catheters used in interventional cardiology procedures. More particularly the present invention relates to methods and apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.

BACKGROUND OF THE INVENTION

Interventional cardiology procedures often include inserting guidewires or other instruments through catheters into coronary arteries that branch off from the aorta. For the purposes of this application, the term "interventional cardiology devices" is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters. In coronary artery disease the coronary arteries may be narrowed or occluded by atherosclerotic plaques or other lesions. These lesions may totally obstruct the lumen of the artery or may dramatically narrow the lumen of the artery. Narrowing is referred to as stenosis. In order to diagnose and treat obstructive coronary artery disease it is commonly necessary to pass a guidewire or other instruments through and beyond the occlusion or stenosis of the coronary artery.

In treating a stenosis, a guide catheter is inserted through the aorta and into the ostium of the coronary artery. This is sometimes accomplished with the aid of a guidewire. A guide catheter is typically seated into the opening or ostium of the artery to be treated and a guidewire or other instrument is passed through the lumen of the guide catheter and inserted into the artery beyond the occlusion or stenosis. Crossing tough lesions can create enough backward force to dislodge the guide catheter from the ostium of the artery being treated. This can make it difficult or impossible for the interventional cardiologist to treat certain forms of coronary artery disease.

Prior attempts to provide support to the guiding catheter to prevent backward dislodgement from the coronary ostium (referred to as "backup support") fall generally into four categories.

First are guiding catheters that, through a combination of shape and stiffness, are configured to draw backup support from engaging the wall of the aortic arch opposing the ostium of the coronary artery that is being accessed. Examples of this approach can be found in U.S. Pat. No. 6,475,195 issued to Voda and U.S. Pat. No. 5,658,263 issued to Dang et al. These guiding catheters all share the common limitation that a guide catheter stiff enough to provide adequate backup support is often too stiff to be safely inserted into the aorta without the possibility of causing damage to the aortic wall. In addition, attempts to deep seat the guide catheter have been made but the rigid nature of the guide catheter creates the risk that the guide catheter may damage the coronary artery wall or that the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

Second are guiding catheters that include a retractable appendage. The appendage in these catheters can be extended to engage the opposing wall of the aortic arch to provide backup support or the appendage may be placed under tension to stiffen a bend in the catheter to provide backup support. Examples of this approach may be found in U.S. Pat. No. 4,813,930 issued to Elliot; U.S. Pat. No. 5,098,412 issued to Shiu; and U.S. Pat. No. 6,860,876 issued to Chen. These guiding catheters tend to be somewhat mechanically complex and have not been widely adopted by practitioners.

Third are guide catheters that have a portion that seeks to expand laterally to grip the interior wall of the ostium of the coronary artery to provide a force acting in opposition to the backward forces created when trying to maneuver a therapeutic device past a lesion or blockage in the coronary artery. These devices can include a balloon secured to a guidewire or a catheter or another device for expanding to grip the walls of the coronary artery from within. Examples of this approach may be found in U.S. Pat. No. 4,832,028 issued to Patel; U.S. Pat. No. 6,595,952 issued to Forsberg; and U.S. Published Application No. 2005/0182437 by Bonnette et al. Again, these devices tend to be mechanically complex and can completely occlude the coronary ostium thus stopping perfusion of the coronary artery.

A fourth technique includes the placement of a smaller guide catheter within a larger guide catheter in order to provide added support for the crossing of lesions or for the distal delivery of balloons and stents. This technique has been described in an article by Takahashi entitled "New Method to Increase a Backup Support of Six French Guiding Coronary Catheter," published in Catheterization and Cardiovascular Interventions, 63:452-456 (2004). This technique is used in order to provide a method of deep seating the guide catheter within the ostium of the coronary artery. Deep seating refers to inserting the catheter more deeply into the ostium of the coronary artery than typically has been done before. Unfortunately, deep seating by this technique with a commonly available guide catheter creates the risk that the relatively stiff, fixed curve, guide catheter will damage the coronary artery. This damage may lead to dissection of the coronary artery when the catheter is advanced past the ostium.

Several other problems arise when using a standard guide catheter in this catheter-in-a-catheter fashion. First, the inner catheters must be substantially longer than the one hundred centimeter guide catheter. Second, a new hemostasis valve must be placed on the inner guide catheter which prevents the larger guide catheter from being used for contrast injections or pressure measurements. Third, the smaller guide catheter still must be inserted into the coronary vessel with great care since the smaller guide catheter has no tapered transition or dilator at its tip and does not run over a standard 0.014 inch guidewire.

Thus, the interventional cardiology art would benefit from the availability of a system that would be deliverable through standard guide catheters for providing backup support by providing the ability to effectively create deep seating in the ostium of the coronary artery.

SUMMARY OF THE INVENTION

The present invention is a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking use of the guide catheter. The coaxial guide catheter preferably includes a tapered inner catheter that runs over a standard

0.014 inch coronary guidewire to allow atraumatic placement within the coronary artery. This feature also allows removal of the tapered inner catheter after the coaxial guide catheter is in place. The tapered inner catheter provides a gradual transition from the standard 0.014 inch diameter guidewire to the diameter of the coaxial guide catheter which is typically five to eight French.

The coaxial guide catheter preferably can be delivered through commonly existing hemostatic valves used with guide catheters while still allowing injections through the existing Y adapter. In addition, the coaxial guide catheter preferably has an inner diameter that is appropriate for delivering standard coronary treatment devices after it is placed in the coronary artery.

In one embodiment, the coaxial guide catheter is made in at least three sizes corresponding to the internal capacity of 8 French, 7 French, and 6 French guide catheters that are commonly used in interventional cardiology procedures. An 8 French catheter has an internal diameter greater than or equal to 0.088 inches. A 7 French catheter has an internal diameter greater than or equal to 0.078 inches. A 6 French guide catheter has an internal diameter greater than or equal to 0.070 inches. Thus, for three exemplary sizes the effective internal diameter of the coaxial guide catheter may be as follows. For a 7 French in 8 French coaxial guide catheter, the internal diameter should be greater than or equal to 0.078 inches. For a 6 French in 7 French coaxial guide catheter the internal diameter should be greater than or equal to 0.070 inches. For a 5 French in 6 French coaxial guide catheter the internal diameter should be greater than or equal to 0.056 inches.

Interventional cardiology procedures are typically carried out under fluoroscopy or another x-ray or imaging technique. Therefore, one embodiment of the coaxial guide catheter of the present invention includes a radiopaque marker at its distal tip to facilitate positioning and manipulation of the coaxial guide catheter.

The present invention generally includes the coaxial guide catheter and a tapered inner catheter. The coaxial guide catheter includes a tip portion, a reinforced portion, and a substantially rigid portion. The coaxial guide catheter will generally have an overall length of preferably approximately 125 cm, though this should not be considered limiting.

In one embodiment, the tip portion may include a soft tip and a marker band. The soft tip is tapered and may be formed from a low durometer polymer or elastomer material such as polyether block amide polymer, (PEBA, Pebax®) the marker band may be formed from a platinum iridium alloy sandwiched between the Pebax® that extends from the bump tip and a PTFE liner.

In one embodiment, the reinforced portion may be reinforced, preferably with metallic fibers in a braided or coiled pattern. The braided or coiled portion is lined by a PTFE liner and may be covered on its exterior with Pebax®. The braided or coiled portion may extend approximately 20 to 110 cm in length. In one exemplary embodiment, the braided portion extends approximately 32 to 36 cm.

Preferably, the rigid portion may be advantageously formed from a stainless steel or Nitinol tube. The rigid portion may be joined to the braid or coil portion by welding. The rigid portion may include a cutout portion and a full circumference portion. For example, the cutout portion may include a section where about 45% of the circumference of the cylindrical tubular structure has been removed. The cutout portion may also include a section where 75-90% of the circumference of the tubular structure has been removed. In one exemplary embodiment, the portion having approximately 45% removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm.

The full circumference portion of the rigid portion is typically located at the most proximal end of the coaxial guide catheter.

The rigid portion may include a plurality of radially oriented slits or other cuts in its distal portion to increase and control the flexibility of the rigid portion

In an exemplary embodiment, the tapered inner catheter generally includes a tapered inner catheter tip and a cutout portion. The tapered inner catheter tip includes a tapered portion and a straight portion. The tapered portion is typically at the most distal end of the tapered inner catheter. Both the straight portion and the tapered portion are pierced by a lumen through which a guidewire may be passed.

The cutout portion supports a track passing along the concave side thereof that continues from the lumen that passes through the straight portion and the tapered portion. The tapered inner catheter may also have a clip or snap attachment at its proximal end to releasably join the tapered inner catheter to the coaxial guide catheter.

In operation, the tapered inner catheter is inserted inside and through the coaxial guide catheter. The tapered inner catheter is positioned so that the tapered inner catheter tip extends beyond the tip portion of the coaxial guide catheter. The coaxial guide catheter-tapered inner catheter combination may then be inserted into a blood vessel that communicates with the aorta. The coaxial guide catheter-tapered inner catheter combination may be threaded over a preplaced 0.014 inch guidewire. The tapered inner catheter-coaxial guide catheter combination is advanced up the aorta until the tapered inner catheter is passed into the ostium of a coronary artery over the guidewire. Once the coaxial guide catheter-tapered inner catheter combination has been inserted sufficiently into the ostium of the coronary artery to achieve deep seating the tapered inner catheter may be removed. During this entire process at least part of the coaxial guide catheter-tapered inner catheter combination is located inside of the guide catheter.

Once the tapered inner catheter is removed a cardiac treatment device, such as a guidewire, balloon or stent, may be passed through the coaxial guide catheter within the guide catheter and into the coronary artery. As described below, the presence of the coaxial guide catheter provides additional backup support to make it less likely that the coaxial guide catheter guide catheter combination will be dislodged from the ostium of the coronary artery while directing the coronary therapeutic device past a tough lesion such as a stenosis or a chronic arterial occlusion.

A guide catheter inserted into the ostium of a branch artery where it branches off from a larger artery is subject to force vectors that tend to dislodge the distal end of the guide catheter from the ostium of the branch artery when a physician attempts to direct a guidewire or other interventional cardiology device past an occlusive or stenotic lesion in the branch artery. This discussion will refer to a guide wire but it is to be understood that similar principles apply to other interventional cardiology devices including balloon catheters and stent catheters.

One of the forces that act on the guide catheter is an axial force substantially along the axis of the branch artery and the portion of the guide catheter that is seated in the ostium. This force vector is a reactive force created by the pushing back of the guide wire against the guide catheter as the physician tries to force the guidewire through or past the lesion. It tends to push the distal end of the catheter out of the ostium in a

direction parallel to the axis of the branch artery and the axis of the distal end of the guide catheter.

Another of the force vectors that acts on the guide catheter is a shearing force that tends to dislodge the distal end of the guide catheter from the ostium of the branch artery in a direction perpendicular to the axis of the branch artery and the axis of the distal end of the guide catheter. This force vector arises from curvature of the guide catheter near its distal end and the guide wire pushing on the curved portion of the guide catheter as the physician applies force to the guidewire. The coaxial guide catheter of the present invention assists in resisting both the axial forces and the shearing forces that tend to dislodge a guide catheter from the ostium of a branch artery.

The system is deliverable using standard techniques utilizing currently available equipment. The present invention also allows atraumatic placement within the coronary artery. Further, the invention is deliverable through an existing hemostatic valve arrangement on a guide catheter without preventing injections through existing Y adapters. Finally, the invention has an inner diameter acceptable for delivering standard coronary devices after it is placed in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic depiction of the coaxial guide catheter and a tapered inner catheter in accordance with the present invention;

FIG. **2** is schematic depiction of the coaxial guide catheter and tapered inner catheter assembled in accordance with the present invention;

FIG. **3** is a plan view of a guide catheter, the coaxial guide catheter, and a treatment catheter in accordance with the present invention;

FIG. **4** is a sectional view of the coaxial guide catheter in accordance with the present invention;

FIG. **5** is a cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

FIG. **6** is another cross sectional view of the coaxial guide catheter and tapered inner catheter in accordance with the present invention;

FIG. **7** is a schematic view of a guide catheter and a guidewire located in an aortic arch and a coronary artery and the guide catheter and guidewire in a second position depicted in phantom;

FIG. **8** is a schematic view of a guide catheter, a guidewire, a coaxial guide catheter in accordance with the present invention and a tapered inner catheter located in the aortic arch and coronary artery;

FIG. **9** is a schematic view of a guide catheter, a guidewire and a coaxial guide catheter in accordance with the present invention located in the aortic arch and coronary artery;

FIG. **10** is a flat pattern for making relief cuts in a curved rigid portion of the coaxial guide catheter in accordance with the present invention;

FIG. **11** is a detailed view taken from FIG. **10**;

FIG. **12** is a plan view of the rigid portion in accordance with the present invention;

FIG. **13** is an elevational view of the rigid portion;

FIG. **14** is a sectional view of the rigid portion taken along section line **14-14** of FIG. **13**; and

FIG. **15** is a sectional view of the rigid portion taken along section line **15-15** of FIG. **13**.

FIG. **16** is a sectional view of the rigid portion taken along section line **16-16** of FIG. **13**.

FIG. **17** is a plan view of a coaxial guide catheter having a longer rail segment and a tapered inner catheter in accordance with the present invention.

FIG. **18** is a plan view of the tapered inner catheter as depicted in the FIG. **17**.

FIG. **19** is a cross-sectional view of the tapered inner catheter taken along section lines **19-19** of FIG. **18**.

FIG. **20** is a plan view of a coaxial guide catheter in accordance with the present invention.

FIG. **21** is an elevational view of a coaxial guide catheter in accordance with the present invention.

FIG. **22** is a cross-sectional view taken along section line **22-22** of FIG. **21**.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIGS. **1** and **2**, coaxial guide catheter assembly **10** of the present invention generally includes coaxial guide catheter **12** and tapered inner catheter **14**.

Coaxial guide catheter **12** generally includes tip portion **16**, reinforced portion **18**, and rigid portion **20**. The overall length of the coaxial guide catheter typically can be approximately 125 cm. This length should not be considered limiting.

Tip portion **16** generally includes bump tip **22** and marker band **24**. Bump tip **22** includes taper **26**. Bump tip **24** is relatively flexible and may be formed, for example, from 4033 Pebax®. Bump tip **22** may be yellow or another high visibility color for ease of handling.

Marker band **24** is formed of a radiopaque material such as platinum/iridium alloy usually at a 90/10 ratio. Marker band **24** may be sandwiched between an outer Pebax® material **28** and a PTFE liner **30**. Outer Pebax® material **28** in this location may be formed of 5533 Pebax, for example.

Reinforced portion **18** includes braid or coil reinforcement **32**. Braid or coil reinforcement **32** may be formed of metal, plastic, graphite, or composite structures known to the art. Reinforced portion **18** may be lined on the interior by PTFE liner **30** and covered on the exterior by Pebax® material **28**. Tip portion **16** and reinforced portion **18** together form a substantially cylindrical structure. Braid or coil reinforcement **32** may extend approximately 20 to 30 cm. In one exemplary embodiment, braid or coiled portion has a length of approximately 32 to 36 cm.

Rigid portion **20** may be secured to braid or coil reinforcement by, for example, welding or bonding. Rigid portion **20** may be formed from a hypotube or a section of stainless steel or Nitinol tubing. Other substantially rigid materials may be used as well. Rigid portion **20** includes first full circumference portion **34**, hemicylindrical portion **36**, arcuate portion **38**, and second full circumference portion **40**.

First full circumference portion **34** is joined to braid or coil reinforcement **32**. First full circumference portion **34** extends for a relatively short distance, for example, 0.25 cm.

Hemicylindrical portion **36** desirably includes 40% to 70% of the circumference of the tube. Hemicylindrical portion **36** may extend, for example, approximately 20 to 75 cm in length.

Hemicylindrical portion **36** tapers into arcuate portion **38**.

Arcuate portion **38** extends from 25% to 40% of the circumference of the tube. Arcuate portion **38** may extend linearly, for example, for about 15 cm.

Arcuate portion **38** connects to second full circumference portion **40**. Second full circumference portion **40** may extend for a short distance, for example, approximately 3 cm.

Tapered inner catheter **14** generally includes tapered inner catheter tip **42** and cutout portion **44**. Tapered inner catheter tip **42** tapers gradually from the diameter of a guide wire to the diameter of tip portion **16**.

Tapered inner catheter tip **42** includes tapered portion **46** at a distal end thereof, and straight portion **48**. Both tapered portion **46** and straight portion **48** are pierced by lumen **50**.

Cutout portion **44** defines a concave track **52** along its length. Concave track **52** is continuous with lumen **50**.

Tapered inner catheter **14** may also include clip **54** at a proximal end thereof to releasably join tapered inner catheter **14** to coaxial guide catheter **12**. Thus, tapered inner catheter **14** is keyed to coaxial guide catheter **12**.

Coaxial guide catheter **12** may include, starting at its distal end, a first portion having a flexural modulus of about 13,000 PSI plus or minus 5000 PSI, a second portion having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, a third portion having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI and a fourth portion having a flexural modulus of about 107,000 PSI plus or minus 20,000 PSI. Coaxial guide catheter **12** may be formed, for example, of 4033 Pebax® at bump tip **22** for the first 0.1 cm. This portion may followed by a section about three cm long of 5533 Pebax® that covers marker band **24** and the distal portion of braid or coil reinforcement **32**. Next may come an approximately five cm portion of 6333 Pebax® which encloses part of braid or coil reinforcement **32** followed by an approximately twenty seven cm portion of 7233 Pebax® covering the most proximal portion of braid or coil reinforcement **32**. Braid or coil reinforcement **32** is bonded to rigid portion **20** which may be formed from stainless steel or a similar biocompatible material. Rigid portion **20** may extend for approximately ninety cm and include first full circumference portion **34** (approximately 0.25 cm), hemicylindrical portion **36** (approximately seventy five cm), arcuate portion (approximately fifteen cm) and second full circumference portion (approximately three cm.) Rigid portion **20** may be formed from a stainless steel or Nitinol hypo tube.

FIG. **7** depicts a typical guide catheter **56** passing through aortic arch **58** into ostium **60** of coronary artery **62**. FIG. **7** also depicts guidewire **64** passing through the guide catheter **56** and into coronary artery **62**. Located in coronary artery **62** is stenotic lesion **66**. In a typical procedure, guidewire **64** is placed through the aortic arch **58** and into the ostium **60** of the coronary artery. **62**. The guide catheter **56** is passed over guidewire **64** until distal end **68** of guide catheter **56** is seated in ostium **60** of coronary artery **62**. Force is then applied to the guidewire **64** to push guidewire **64** past stenotic lesion **66** or an occlusive lesion (not shown). Once the guidewire **64** is pushed past stenotic lesion **66** or occlusive lesion (not shown), a treating catheter including a stent or balloon can be passed along the guidewire to stenotic lesion **66** or occlusive lesion (not shown). The lesion can then be treated.

As can be seen in phantom, in FIG. **7**, the application of force to guidewire **64** can cause guide catheter **56** to dislodge from ostium **60** of coronary artery **62**. This can occur in the case of a tough stenotic lesion **66** or occlusive lesion (not shown) when it is difficult to pass the guidewire **64** beyond the stenotic lesion **66** or occlusive lesion (not shown).

Referring the FIG. **8** coaxial guide catheter **12** is depicted as used with guide catheter **56**, guidewire **64**, and tapered inner catheter **14**. Here, coaxial guide catheter **12** with tapered inner catheter **14** is passed through guide catheter **56** and over guidewire **64** into coronary artery **62** after the guide catheter **56** has been placed in the ostium **60** of coronary artery **62**, as depicted in FIG. **7**. Coaxial guide catheter **12**, with tapered inner catheter **14**, provides an inner support member for proper translation over guidewire **64**. Tapered inner catheter tip **42** provides a distal tapered transition from guidewire **64** to coaxial guide catheter **12**. Once coaxial guide catheter **12** is in place, tapered inner catheter **14** is removed from the inside of coaxial guide catheter **12**.

Coaxial guide catheter **12** is now ready to accept a treatment catheter such as a stent or balloon catheter. Referring to FIG. **9**, the combination of guide catheter **56** with coaxial guide catheter **12** inserted into ostium **60** of coronary artery **62** provides improved distal anchoring of guide catheter **56** and coaxial guide catheter **12**. The presence of coaxial guide catheter **12** within guide catheter **56** also provides stiffer back up support than guide catheter **56** alone. The combination of improved distal anchoring and stiffening of the guide catheter **56**/coaxial guide catheter **12** combination provides additional back up support to resist dislodging of guide catheter **56** from ostium **60** when force is applied to guidewire **64** to pass through stenotic lesion **66** or another lesion. In addition, the improved back up support assists in the positioning of a treating catheter that may include a stent or balloon.

Referring to FIGS. **10** and **11**, in some embodiments of coaxial guide catheter **12**, rigid portion **20** may be perforated by relief cuts **70**. Relief cuts **70** may be classed into first group **72** and second group **74**.

First group **72** may be located near to the juncture between rigid portion **20** and reinforced portion **18**. First group **72** of relief cuts **70**, are relatively closely spaced. For example, first group **72** of relief cuts **70** may be spaced approximately 0.010 inches apart. First group **72** of relief cuts **70** extends for a relatively short distance, for example, approximately 2 inches.

Second group **74** of relief cuts **70** may extend for a relatively long distance, for example, approximately 30-35 inches. Second group **74** of relief cuts **70** are spaced farther apart than first group **72**. For example, relief cuts **70** of second group **74** may be spaced approximately 0.020 inches between cuts. Referring particularly to FIG. **11**, relief cuts **70** may include single cuts **76** and double cuts **78**. Single cuts **76** may include an individual linear cut, as can be seen in FIG. **11**. Double cuts **78** may include two linear cuts along a single line but separated by a short section of uncut structure. Typically, single cuts **76** and double cuts **78** are alternated along the length of rigid portion **20**. Generally, the overall length of single cut **76** may be less than the overall length of two double cuts **78**.

In an embodiment depicted in FIGS. **12-15**, rigid portion includes full circumference portion **80**, greater than 180° portion **82**, and less than 180° portion **84**. Greater than 180° portion **82** may, for example, include structure forming approximately 300° of the circumference of the cylinder. Less than 180° portion may include, for example, structure forming approximately 90° of the circumference of a cylinder. Greater than 180° portion **82** may extend approximately 22-25 inches. Greater than 180° portion **82** holds tapered inner catheter **14** within rigid portion **20**.

When tapered inner catheter is inserted into coaxial guide catheter **12** greater than 180°, portion **82** grips tapered inner catheter **14** which is exposed through the opening in greater than 180° portion **82**. Thus, the overall structure of tapered inner catheter **14** along with greater than 180° portion **82** is substantially cylindrical. Accordingly, when inserted through a guide catheter **56** having a Touhey-Borst style adapter, the Touhey-Borst style adapter can still seal around rigid portion **20** and enclosed inner tapered catheter **14**.

Referring to FIG. **16**, another embodiment of coaxial guide catheter assembly **10** includes coaxial guide catheter **12** and

tapered inner catheter **14**. Tapered inner catheter **14** is keyed to coaxial guide catheter **12** at hub **86**.

Referring to FIGS. **17** and **18**, tapered inner catheter **14** generally includes connector hub **88** and catheter tube **90**.

Connector hub **88** generally includes connector portion **92**, grip portion **94** and joining portion **96**. Connector hub **88** defines funnel portion **98** therein.

Catheter tube **90** generally includes straight portion **100**, tapered portion **102** and marker band tip **104**. Catheter tube **90** is joined to connector hub **88** at joining portion **96**. Tapered inner catheter **14** may be formed in whole or in part from low-density polyethylene plastic, for example. Other suitable materials known to the catheter arts may be used as well.

Grip portion **94** desirably includes gripping ears **106**. Gripping ears **106** may extend outwardly from grip portion **94** substantially radially and be shaped for convenient gripping by a physician.

Referring to FIGS. **19** through **21**, in this embodiment, coaxial guide catheter **12** includes interrupted hub **108**, hemi-tube portion **110**, braided portion **112** and tip portion **114**.

Interrupted hub **108** defines an opening **116**, along a side thereof. Interrupted hub **108** may be substantially C-shaped or U-shaped in cross section. Opening **116** is sized so that tapered inner catheter **14** may be passed readily therethrough in a direction perpendicular to the long axes of both interrupted hub **108** and tapered inner catheter **14**. Hemi-tube portion **110** is immediately distal to interrupted hub **108**. Hemi-tube portion **110** may be formed, for example, from a metal hypo tube forming approximately 50% of the circumference of a cylinder. Hemi-tube portion **110** is aligned so that opening **116** of interrupted hub **108** is coextensive with opening **118** of hemi-tube portion **110**. Hemi-tube portion **110** is joined to braided portion **112**, for example, by adhesive, bonding or welding. The location where hemi-tube portion **110** and braided portion **112** join defines the entire circumference of a cylinder.

Braided portion **112** may be reinforced by a coil or braid, **120**. Coil or braid **120** may be formed of metal or another suitable reinforcing material.

Tip portion **114** is generally not reinforced and is substantially soft. Tip portion **114** is similarly structured to tapered inner catheter tip **42**. Tip portion **114** may include a radiopaque marker band **24**.

Beginning at the distal end of coaxial guide catheter **12**, tip portion **114** may be formed substantially of, for example, 2533 Pebax® This may be followed by a section of 3533 Pebax®, then by a section of 5533 Pebax®, then by a further section of 7233 Pebax®. These Pebax® portions may all incorporate, for example, about 20% barium sulfate ($BaSO_4$).

In one embodiment, tip portion **114** and braided portion **112** may have an overall length together of approximately one hundred nine centimeters. Hemi-tube portion **110** and interrupted hub **108** may together have an overall length of approximately eighteen centimeters.

In this embodiment, coaxial guide catheter **12** may be lined with a PTFE liner **122**.

In operation, a guide catheter **56** is inserted into a major blood vessel in the body such as aortic arch **58** over guidewire **64** and the distal end **68** of guide catheter **56** is brought into proximity of ostium **60** of a smaller branch blood vessel, such as coronary artery **62**, that it is desired to enter. Coaxial guide catheter **12**, with tapered inner catheter **14**, is inserted through guide catheter **56** and over guidewire **64**. Guide catheter **56**, guidewire **64**, coaxial guide catheter **12**, and tapered inner catheter **14** are manipulated to insert tapered inner catheter tip **42** into the ostium **60** of the blood vessel that branches off from the major blood vessel. The bump tip **22** of coaxial guide catheter **12** is inserted with tapered inner catheter tip **42** well into ostium **60** of coronary artery **62** or other blood vessel until bump tip **22** of coaxial guide catheter **12** achieves a deep seated position. Tapered inner catheter **14** is then withdrawn from the lumen of coaxial guide catheter **12**. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter **12** which remains inside guide catheter **56**.

When the interventional cardiology device reaches a stenosis or blockage in coronary artery **62** or another branch blood vessel, force may be applied to the interventional cardiology device catheter while reinforced portion **18** and rigid portion **20** of coaxial guide catheter **12** provide back up support. The back force that would tend to dislodge bump tip **22** from a deep seated position in the ostium in the branch blood vessel is transferred through reinforced portion **18** to rigid portion **20** of coaxial guide catheter **12**. A physician may apply a force to the proximal end of the coaxial guide catheter **12** to resist dislodging of bump tip **22** from the ostium of the branch artery.

One advantage of the present invention over prior art approaches is that the present invention does not interfere with the injection of fluids via the Y-adapter of guide catheter **56** as does the use of a smaller catheter within a larger catheter.

The present invention may be embodied in other specific forms without departing from the spirit of the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

The invention claimed is:

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:

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 rain a 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.

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.

4. The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

5. The system of claim 1, wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

6. The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

7. The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

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.

9. The system of claim 1, wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

10. The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

11. The system of claim 1, further comprising a kit that includes the guide catheter and the device in a common sterile package.

12. 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-section and a 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:

an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion 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;

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis 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, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen 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.

13. The system of claim 12, wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

14. The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

15. The system of claim 12, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.

16. The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

17. The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.

18. The system of claim 12, wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

19. The system of claim 12, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

20. The system of claim 12, wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater

than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

21. The system of claim **20**, in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

22. The system of claim **20**, in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.

23. The system of claim **12**, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

24. The system of claim **12**, further comprising a kit that includes the guide catheter and the device in a common sterile package.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,292,850 B2
APPLICATION NO. : 13/359059
DATED : October 23, 2012
INVENTOR(S) : Howard Root et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 10, claim 1, line 46, prior to "structure", insert
-- a flexible tip portion defining a tubular --

In Column 10, claim 1, line 57, delete "rain a" and insert -- than the flexible tip portion and defining a rail" --

In Column 11, claim 12, line 64, prior to "structure", insert
-- a flexible tip portion defining a tubular --

In Column 12, claim 12, lines 11-12, prior to "structure", insert
-- than the flexible tip portion and defining a --

Signed and Sealed this
Twenty-second Day of January, 2013

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

Exhibit 5

GuideLiner® Catheter Bibliography

January 2013

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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.

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

Exhibit 6

DEVICE OF THE MONTH

Catheter addresses challenging coronary interventions

Features of the GuideLiner enable direct delivery to a target lesion.

The GuideLiner catheter, released in November 2009 and now available for sale in the United States and Europe, is being called a "game-changer" for the treatment of complex endovascular lesions.

According to a press release, the catheter, manufactured by Vascular Solutions, has a unique coaxial "mother and child" guide extension with rapid exchange convenience that allows deep seating, guide backup support and selective deep intubation in difficult coronary interventions. It has a soft and flexible straight tip that permits crossing tortuous anatomy to enable direct equipment delivery to a target lesion.

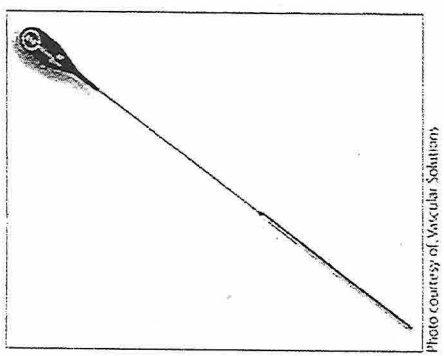

Photo courtesy of Vascular Solutions

The GuideLiner can be effective in tortuous and heavily calcified vessels.

Also stated in the release, the catheter is intended for use in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to enable placement and exchange of guidewires and other interventional devices. It is compatible with standard guide catheters and available in three sizes that correspond to 6, 7 and 8 French guides.

As the first person to use this catheter for coronary angioplasty and a member of a group that was the first to publish data on the catheter's use in a series of patients, **Douglas G. Fraser, MD, BM, BChir,** with the Manchester Heart Centre, United Kingdom, witnessed the benefits of the device in patients with extensive coronary disease, particularly in the setting of tortuosity and calcification. In these patients, "stent delivery is frequently a challenge, sometimes consuming a considerable amount of time and equipment as successive predilation is performed, buddy and support wires are selected, shorter and lower profile stents are tried, and more and more contrast and X-ray dose is used," Fraser said in an interview. "Ultimately, failure to deliver a stent occurs in up to 5% of cases, and when it occurs is associated with an adverse outcome in up to 20% of these cases.

"By deeply intubating the coronary artery, the GuideLiner greatly increases backup support and may itself transverse proximal points of obstruction where a rigid stent is unable to cross," he said. "The very flexible and soft tip minimizes vessel trauma during deep intubation. This greatly facilitates stent delivery, leading to a successful outcome after failure of conventional techniques. This allows complex disease to be treated more confidently, more easily and more safely."

Kanwar P. Singh, MD, FACC, director, vascular medicine and intervention, The Pat and Jim Calhoun Cardiology Center, University of Connecticut Health Center, said he was also enthusiastic about using the device in clinical practice.

"The GuideLiner catheter has added substantially to the repertoire of treating complex endovascular lesions," Singh told CARDIOLOGY TODAY. "While my experience has primarily been in treating advanced CAD, I have also applied it to mesenteric and renal arterial disease. I've been able to treat arteries previously deemed 'untreatable' and have reported on this. It is not hyperbole to refer to the GuideLiner as a game-changing device."

According to Singh, currently in the United States, there is no competitor device to the GuideLiner. "While there are alternatives in Europe and Japan, if an operator wants to be able to atraumatically deeply intubate a coronary artery for treating complex, calcified, previously stented or anomalous anatomy, there is no match to the GuideLiner," he said, adding that in his lab, "The GuideLiner has become our 'first pull' device to deal with inadequate support that at times plagues the radial approach." – *by Brian Ellis* ■

Disclosures: Dr. Fraser is a paid consultant for Vascular Solutions. Dr. Singh reports no relevant financial disclosures.

Exhibit 7

Intervention

The GuideLiner™ "child" catheter

Usha Rao[1], MBBS, MRCP; Diana Gorog[1,2], MRCP, MD, PhD; Jacek Syzgula[1], MD, PhD; Sanjay Kumar, BSc, MBBS, MRCP; Carley Stone[3]; Neville Kukreja[1], MA, MBBS, MRCP

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Carley Stone is an employee of Pyramed Ltd. The other authors have no conflict of interest to declare.

Introduction

Despite the advancement in percutaneous interventional procedures including newer stents and better delivery systems, the failure to deliver a stent to the target lesion, especially in arteries with complex anatomy, remains a common problem. Various techniques have been used to solve or rather help with this dilemma including straightening the artery with a second "buddy" wire[1] or "buddy" balloon, larger and more supportive guiding catheters, or deep intubation with the guiding catheter for back up support. The Heartrail II (Terumo, Tokyo, Japan) "five in six catheter system" also called "mother and child", involving the insertion of a flexible tipped extra length (120 cm) 5 Fr catheter for deeper intubation with extra back-up support, has been described in the literature, and is an accepted technique for improving support and delivering stents in difficult cases[2-5]. More recently, a new "child" support catheter has been introduced: the GuideLiner™ (Vascular Solutions, Minneapolis, MN, USA). The device received CE marking in September 2009.

Device and technical details

The GuideLiner™ catheter is a coaxial guide extension with the convenience of rapid exchange. In difficult and challenging interventions guide catheters have a tendency to back out of the artery whereas the GuideLiner™ allows guide extension into the vessel for deep seating. This simplified mother and child technique is useful in challenging interventions and for rapid exchange.

It is composed of a flexible 20 cm straight guide extension for deep seating, connected to a stainless steel push tube with a "collar" which can be deployed through the existing Y-adapter for rapid exchange delivery (Figure 1). Unlike the Heartrail catheter, the GuideLiner™ does not increase the overall guiding catheter length or require a second haemostatic valve, and due to its monorail design is simpler to use than the Heartrail. The GuideLiner™ can be delivered through standard guide catheters, resulting in an inner diameter that is approximately one French size smaller than the guide. The GuideLiner™ is currently available in three sizes: 5-in-6 (0.056" internal diameter), 6-in-7 (0.062" internal diameter) and 7-in-8 (0.071" internal diameter).

The extension is 20 cm long, but a maximum extension of only 10 cm is recommended and has a silicon coating for lubricity. The extension section is a component built tube composed of an inner polytetrafluoroethylene (PTFE: Teflon) liner, a middle stainless steel coil (which provides maximum flexibility while retaining radial strength) and an outer polyether block amide (Pebax) polymer extrusion (same material as a guide catheter, and does not soften at body temperature). There is a radio-opaque marker located 0.105" (2.66 mm) from the tip (Figure 1). The guide extension is connected to the push tube with a "collar": guidewires, balloons and stents enter the collar within the guide catheter (Figures 1 and 2). The delivery through the guide is designed to be tight in order to prevent slippage within the guide catheter. There are white positioning markers on the push tube at 95 cm (single) and 105 cm (double) to assist in placement through the guide (Figure 1).

Indications for use

1. Deep seating for added back-up guide support in challenging coronary cases to facilitate device delivery.
2. Coaxial alignment when irregular coronary ostium take-off prevents guide placement.

Use of the GuideLiner™ catheter is contraindicated in vessels with less than a 2.5 mm diameter.

Tips and tricks for optimal performance

1. The GuideLiner™ should be inserted into the guide catheter over a 0.014" primary guidewire to a maximum of 10 cm beyond the guide tip under fluoroscopy and in no case more than 20 cm to prevent the metal collar from exiting the guiding catheter.

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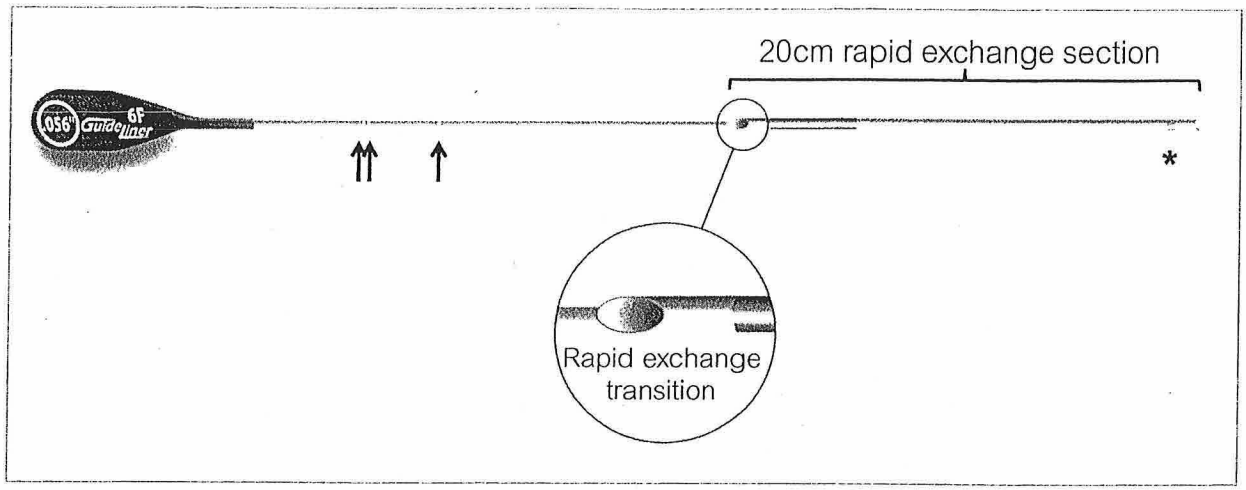

*Figure 1. The GuideLiner™ catheter. This consists of a flexible 20 cm straight guide extension connected to a stainless steel push tube. * radiopaque marker 2.66 mm from tip. Arrows: white positioning markers at 94 cm (single arrow) and 105 cm (double arrows).*

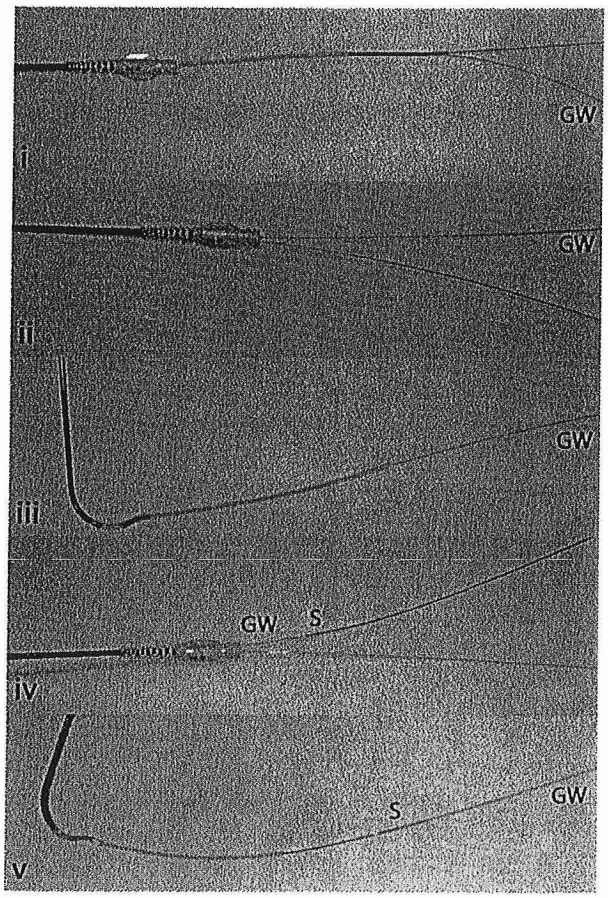

Figure 2. Insertion of the GuideLiner™. The monorail GuideLiner catheter is inserted into a guiding catheter over a guidewire (GW) (i). Once advanced into the guiding catheter, the GuideLiner push tube can be advanced whilst holding the GW in place (ii). The GuideLiner can be advanced up to 10 cm beyond the guiding catheter tip (iii). Balloons or stents (S) can be advanced along the guidewire (iv), through the GuideLiner to the target lesion (v).

2. On initial insertion of the GuideLiner™, the flat push-rod should be oriented in a lateral position within the guiding catheter and should be advanced within the guiding catheter without rotation to avoid wrapping the guidewire around it.
3. Deep seating of the GuideLiner™ in the coronary artery can be facilitated by using an un-inflated balloon catheter over the primary wire into distal vessel – if necessary this can then be inflated at the target lesion to act as an anchor, followed by gentle advancement of the GuideLiner™.
4. Stents should be advanced over the primary guidewire through the GuideLiner™ as secondary wires may wrap around the GuideLiner™ push tube, obstructing stent insertion.
5. In case of resistance while inserting a guidewire or stent through the GuideLiner™, the location of the wire or stent in relationship to the metal collar of the GuideLiner™ should be checked and the stent inspected for signs of damage prior to re-advancement. To correct any resistance that occurs at (or proximal to) the collar:
   a. Ensure the combination of the wire and stent is compatible with the internal diameter of the GuideLiner™.
   b. If a secondary wire is in use, check for wire wrapping of the secondary wire around the GuideLiner™. If so, consider either pulling back the secondary wire or re-advancing it, or if the primary wire (placed before GuideLiner™ insertion) is still in place consider advancing the stent over the primary wire.
   c. If a stent continues to encounter resistance at the metal collar, pull the stent and guidewire back together 3-5 cm and try re-advancing the stent and guidewire together through the metal collar. If resistance is again encountered, check the stent for signs of damage and either choose a lower profile stent or change the guidewire.

Clinical experience

A 74 year-old patient with previous coronary artery bypass grafting in 2003 was admitted with a non–ST elevation myocardial infarction (NSTEMI) and inferolateral ST segment changes. His angiogram showed a moderate lesion in the proximal left anterior descending artery

(LAD) and a tight stenosis in the circumflex ostium. The graft to the LAD was occluded but there was a patent jump graft to an obtuse marginal and posterior descending artery. The right coronary artery (RCA) was tortuous and calcified with tight stenoses in the proximal and mid vessel (Figures 3a and 3b). Percutaneous intervention to the native RCA was performed transfemorally using a 6 Fr sheath inserted in the right femoral artery. Initially a Hockey stick guiding catheter was used which was changed to an Amplatz Left (AL) 1 guide for better engagement. The RCA was then wired using a BMW wire (Abbott Vascular, Redwood City, CA, USA) and pre-dilated with a 2.5 x 15 Maverick balloon (Boston Scientific, Natick, MA, USA) (Figures 3c and 3d). However, due to a combination of calcification and tortuosity, a stent could not be delivered. After further dilation with a 3.0 x 15 mm Maverick balloon, it was still impossible to advance a stent. Therefore, a GuideLiner™ catheter was deployed through the AL1 guide and advanced into the mid RCA to aid stent delivery (Figure 3e). This enabled the easy deployment of four overlapping drug-eluting stents from the mid-vessel to the ostium (3.5 x 15 mm, 3.5 x 18 mm, 3.5 x 23 mm and 3.5 x 8 mm; all Promus; Boston Scientific, Natick, MA, USA). The overlaps were post-dilated with a 3.5 x 8 mm non-compliant balloon (Quantum Maverick; Boston Scientific, Natick, MA, USA) whilst the ostium of RCA was post-dilated and flared with a 4 x 8 mm non-compliant balloon (Quantum Maverick; Boston Scientific, Natick, MA, USA). A good angiographic result was achieved (Figure 3f). The patient was discharged the following day with no complications.

Discussion

In this case, stent delivery was impossible despite the use of a highly supportive guiding catheter. By using the GuideLiner™, the stent was deployed easily and successfully because of the extra-back up support and deep intubation without any displacement of the guide catheter or the wire or any vessel trauma.

The GuideLiner™ provides a new alternative for performing complex interventions. Benefits include:

1. Deep seating with a straight, highly flexible guide extension.
   - Unlike deep intubation of a guiding catheter, there is no primary curve to potentially damage and dissect the vessel.
   - Coil backbone provides superior flexibility while retaining radial strength.
2. The device only reduces the lumen by approximately one French size, so almost all devices will still fit through a 6 Fr GuideLiner™ (internal diameter 0.056").
3. Rapid exchange aids deployment through the existing haemostatic valve without extending the guiding catheter length, and so does not limit the usable length of balloons and wires.

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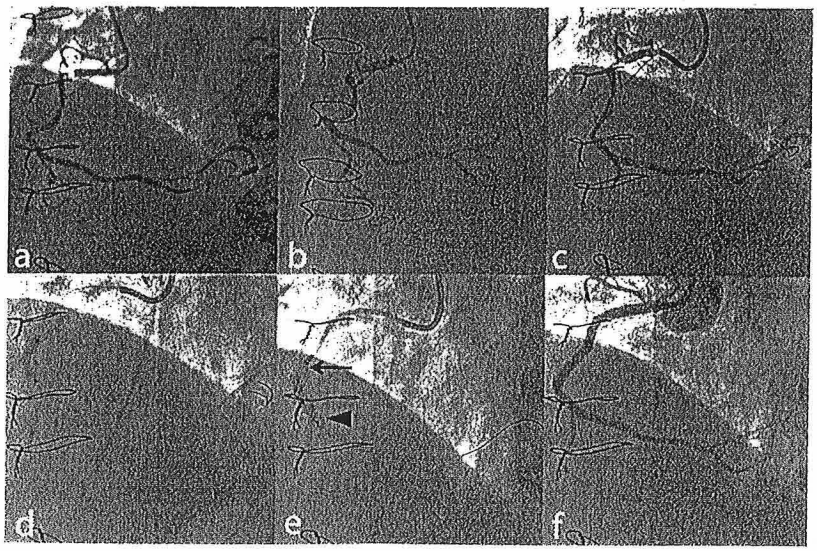

Figure 3. Clinical use of the GuideLiner™. (a) and (b) Diagnostic angiogram of the right coronary artery. (c) Using an Amplatz Left 1 guide, the lesions were crossed with a BMW wire. (d) The lesions were pre-dilated but a stent could not be advanced. (e) The GuideLiner™ (arrow) was advanced up to the lesion to allow deployment of the stent (arrowhead). (f) Final angiographic result.

Exhibit 8

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Usefulness and safety of the GuideLiner catheter to enhance intubation and support of guide catheters: insights from the Twente GuideLiner registry

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KEYWORDS

- angiography
- bypass graft
- complex lesions
- coronary artery disease
- drug-eluting stents

Abstract

Aims: Optimal ostial seating and adequate back-up of guide catheters are required for challenging percutaneous coronary interventions (PCI). The GuideLiner™ (GL) (Vascular Solutions Inc., Minneapolis, MN, USA) is a guide catheter extension system that provides active back-up support by deep coronary intubation. We aimed to assess feasibility and safety of GL-use in routine clinical practice.

Methods and results: We prospectively recorded patient and procedural details, technical success, and in-hospital outcome of 65 consecutive patients undergoing "5-in-6" Fr GL-facilitated PCI of 70 target vessels. The GL was mainly used for PCI of complex coronary lesions: 97% (68/70) had American Heart Association/American College of Cardiology (AHA/ACC) lesion types B2/C; 53% (37/70) were distally located; and 23% (17/70) were heavily calcified. Indications were to increase back-up of the guide and facilitate stent delivery (59%; 41/70), achievement of coaxial alignment of the guide catheter (29%; 20/70), and selective contrast injections (13%; 9/70). Device success rate was 93% (65/70). There were no major complications and two minor complications managed without clinical sequelae: one air embolism and one stent dislodgement.

Conclusions: GL-use resulted in increased back-up and guide catheter alignment for stent delivery in unfavourable tortuous coronary anatomies and complex, heavily calcified, and often distally located lesions, which otherwise may have been considered unsuitable for PCI. Procedural success rate was high and there were no major complications.

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Abbreviations

ACS	acute coronary syndrome
CK	creatine kinase
CTO	chronic total occlusion
DES	drug-eluting stents
GEA	gastroepiploic artery
GL	GuideLiner
LAD	left anterior descending coronary artery
LCX	left circumflex coronary artery
LM	left main
NSTEMI	non-ST-elevation myocardial infarction
PCI	percutaneous coronary intervention
STEMI	ST-elevation myocardial infarction
RCA	right coronary artery
UAP	unstable angina pectoris

Introduction

Despite the advancements made in percutaneous coronary interventions, the interventional cardiologist nowadays has to deal with an increasing complexity of procedures. A good back-up of the guide catheter is essential to advance guidewires and balloons, and to deliver stents. Support of the guide can be increased by use of extra back-up guides and larger guide dimensions. In addition, the stability of the guide can be improved by advancing a buddy wire, and use of stiffer guidewires or anchoring balloons[1,2]. Another way to increase back-up support is deep intubation of the guide[3,4]. There is, however, a considerable risk of dissecting the vessel. Introduction of guide catheter extension systems, in which a long guide catheter with a flexible tip is advanced through the mother guide, has further refined this concept[5-7]. Besides the improvement in back-up support, the use of guide catheter extensions provides selective visualisation of the target vessel, improves the stability of the guide and allows coaxial alignment of the guide.

There are three systems available: the Heartrail® II catheter (Terumo Corp., Tokyo, Japan), the Proxis™ device (St Jude Medical, St Paul, MN, USA) and the GuideLiner™ catheter (Vascular Solutions Inc., Minneapolis, MN, USA). The Heartrail® II catheter and Proxis™ device are 120 cm catheters that are introduced into the mother guide by removing the Y-connector[6-9]. The GuideLiner (GL) catheter **(Figure 1)** is a novel rapid exchange guide catheter extension system that provides active guide support by its 20 cm-long flexible tubular end, which can be deeply advanced into target vessels[10-18]. Its handling is particularly easy, as it is does not require disconnection of the haemostatic valve at the proximal end of the guide catheter and is compatible with standard 180 cm-long guidewires. Its soft distal tip promises a low risk of dissecting vessels compared to the deep-seating of regular guide catheters.

So far, only a limited number of reports and case series have been published on the GL guide catheter extension[10-18]. Mamas et al reported a case series of 13 complex coronary interventions, performed via the radial artery with the "5-in-6" Fr GL system[10]. Although their success rate was high, the main limitation encountered was stent damage upon advancement of the stent across the metallic collar of the GL (two out of 32 stents)[10]. Recently, Luna et al published their experience with the GL catheter in a series of 21 patients[15]. In their study, a transfemoral approach and 7 Fr guide catheters were used in the majority of the cases with a procedural success rate of 90%. Pressure dampening was seen in 57% of their patients, contributing to three out of four unsuccessful cases. There was one major complication in the series reported by Luna et al, which was a flow-limiting dissection in the proximal left anterior descending coronary artery (LAD) but they noted no case of stent damage[15]. The purpose of the present Twente GuideLiner registry was to assess feasibility and safety of use of the "5-in-6" Fr GL guide catheter extension system during routine, clinical PCI procedures as performed at Thoraxcentrum Twente, a high-volume PCI centre located in Enschede, The Netherlands.

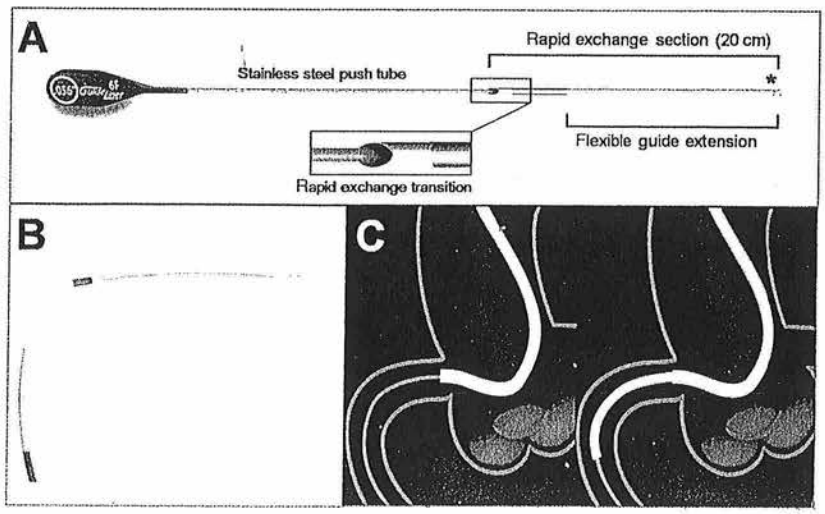

Figure 1. *Schematic presentation of the GuideLiner catheter.*

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Methods

STUDY POPULATION

Between November 2010 and July 2011, we prospectively collected data from a consecutive series of 65 patients, in whom the GL was applied to facilitate routine PCI. The patients had a background of stable or unstable angina pectoris, or presented with an acute myocardial infarction.

INTERVENTIONAL PROCEDURES

A team of five interventional cardiologists performed the PCI procedures; each of them had performed PCI for more than five years (250-500 PCI procedures per operator annually; total PCI experience of 4,000 or more per operator). PCI procedures were performed according to standard clinical protocols via the femoral or radial routes, using 6 Fr guide catheters as a standard. All patients received a bolus of unfractionated heparin (5,000 IE or 70-100 IE/kg). Prior to PCI, all patients received adequate loading doses of acetylsalicylic acid (300 mg) and clopidogrel (300-600 mg), if not pretreated. During the procedure, an intracoronary bolus of nitrates was administered. The choice of interventional approaches, devices, and techniques was left at the operators' discretion, considering current clinical protocols and guidelines. Following PCI, clopidogrel was prescribed for one year (75 mg once daily [o.d.] in addition to life-long treatment with acetylsalicylic acid [at least 100 mg o.d.]).

THE GUIDELINER CATHETER AND ITS USE

The GL (Vascular Solutions, Minneapolis, MN, USA) consists of a flexible, 20 cm, straight, flexible, soft-tipped extension tube that is connected via a metal collar to a thin 115 cm-long stainless steel shaft (**Figure 1A** and **Figure 1B**). The extension tube has a silicon coating for lubricity. The procedure starts by positioning the mother guide and advancing the guidewire across the target lesion. Then the GL is advanced over the guidewire through the haemostatic valve of the Y-adapter (handling comparable to regular balloons) to intubate the target coronary artery or bypass graft (**Figure 1C**). The GL reduces the inner diameter of the mother guide by approximately 1 Fr, but it does not lengthen the guide outside the patient. When the GL is in place, balloons and stents can be delivered over the same initial guidewire. The GL is available in sizes of 6 Fr, 7 Fr, and 8 Fr. In this study, only 6 Fr GL were used (also called the "5-in-6" Fr system), which has an internal diameter of 0.056" (1.422 mm). Notably, the use in vessels <2.5 mm is discouraged by the manufacturer. Bifurcation lesions in our study were treated as follows: two wires were advanced through the guide. Then, the GL was advanced over both wires simultaneously. Provisional stenting was the strategy of choice. In cases where a kissing balloon technique was demanded, a wire exchange was performed followed by balloon dilation of the side branch through the stent struts. Before the final kissing balloon inflation could be performed, the GL had to be removed.

STUDY PARAMETERS AND DATA ACQUISITION

To assess the usefulness (feasibility and safety) of the GL in clinical practice, we prospectively recorded various procedural data and clinical details on the in-hospital outcome of a consecutive series of 65 patients, who underwent PCI with the use of the GL. Patient demographics, indication for GL use, angiographic and procedural details including technical success, and all complications were recorded. Quantitative coronary angiography (QCA) was used to determine the intubation depth of the GL catheter. Procedural success was defined as the achievement of <20% diameter stenosis with TIMI 3 flow in the target vessel. Routine peri-interventional assessment of cardiac biomarkers was performed to screen for PCI-induced myocardial necrosis up to 24 hours after PCI or until the highest value of creatine kinase (CK) was measured. Peri-PCI myocardial infarction was defined as two times the upper reference limit of CK, confirmed by significant elevation of other specific biomarkers (MB-fraction of CK or troponin).

STATISTICAL ANALYSIS

Values are expressed as mean±SD. Comparison of continuous variables was performed with the Student's t-test. Categorical variables are presented as numbers or percentages and were tested with the chi-square test or Fisher's exact test. A p-value <0.05 was considered statistically significant. Statistical analysis was performed with SPSS version 15.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

PATIENT POPULATION AND LESION CHARACTERISTICS

The demographic characteristics of the study population are presented in **Table 1**. The majority of patients were male (74%), and the mean age was 67±13 years. Target lesions were relatively complex as is shown in **Table 2**. Most lesions (97%) had American Heart Association/American College of Cardiology (AHA/ACC) lesion types B2 or C, with more than half of them being located in distal vessel segments. A total of 90% of lesions was classified as being calcified: 67% mild to moderately and 23% heavily calcified. Mean lesion length was 38±26 mm, which is indicative of long lesions.

Table 1. Demographic characteristics of study population.

Age (years)	67±13
Male gender	74% (48/65)
Hypertension	57% (37/61)
Hypercholesterolaemia	54% (35/61)
Diabetes	25% (16/65)
Current smoking	22% (14/61)
Family history of CAD	28% (18/61)
Prior myocardial infarction	32% (21/65)
Prior PCI	26% (17/65)
Prior CABG	26% (17/65)
Indication for PCI	
ST-elevation MI	12% (8/65)
Non-ST-elevation MI	20% (13/65)
Unstable angina	6% (4/65)
Stable angina	62% (40/65)

CAD: coronary artery disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; MI: myocardial infarction

Table 2. Target vessels and lesion characteristics.

Target vessels	
Left anterior descending artery	17/70 (24%)
Left circumflex artery	20/70 (29%)
Right coronary artery	23/70 (33%)
Vein graft	10/70 (14%)
Target lesions	
Type B2/C lesion	68/70 (97%)
Distal location	37/70 (53%)
Severe calcification	16/70 (23%)
Chronic total occlusion	12/70 (17%)
Reference vessel diameter (mm)	3.0±0.5
Diameter stenosis (%)	89±13
Lesion length (mm)	38±26

Table 3. Procedural details, success, failures, and complications.

Procedural details	
Radial access	22/65 (34%)
Multivessel procedure	19/65 (29%)
Procedural time (min)	79±43
Volume of contrast (ml)	220±118
Total length of stents implanted (mm)	41±29
Number of stents implanted	1.8±1.2
Depth of GuideLiner intubation (mm)	33±21
Primary indication for GuideLiner use	
Improvement of back-up and facilitated stent delivery	41/70 (59%)
More selective contrast injection	9/70 (13%)
Improvement of alignment of the guide	20/70 (29%)
Success, failures, and complications	
Device success	65/70 (93%)
Procedural success	64/70 (91%)
Major complications	0/70
Minor complications	2/70 (3%)
Air embolism	1/70 (1%)
Stent dislodgement	1/70 (1%)

INDICATION FOR GL USE AND PROCEDURAL DETAILS

All procedures were carried out with the "5-in-6" Fr GL device. As shown in **Figure 3**, the primary indications for GL use were to increase back-up of the guide catheter, in general to facilitate stent delivery (59%), and to improve alignment of the guide catheter (29%) **(Table 3)**. In a few patients (13%), the GL was used for selective contrast injection, predominantly because of dominant left coronary artery (LCA) and/or renal impairment. There were differences between the application in right coronary artery

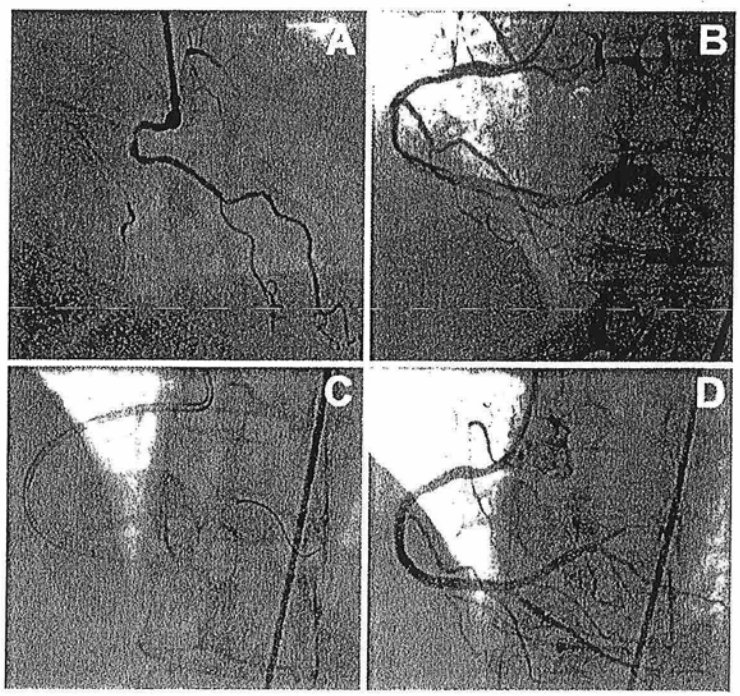

Figure 2. *Angiography of a chronically occluded RCA in a 55-year-old female patient (A). Wire crossing was achieved using a pilot 50 wire. After subsequent passage and dilation with low profile balloons, the flow is partially restored and a long dissection can be noted that extends into the postero-lateral branch (B). Passage of a stent was unsuccessful due to marked resistance in the distal segment of the vessel. With the help of an anchoring balloon, the GuideLiner catheter was deeply intubated over the guidewire (C). Then, several drug-eluting stents were successfully delivered and postdilated, with a good final angiographic result (D).*

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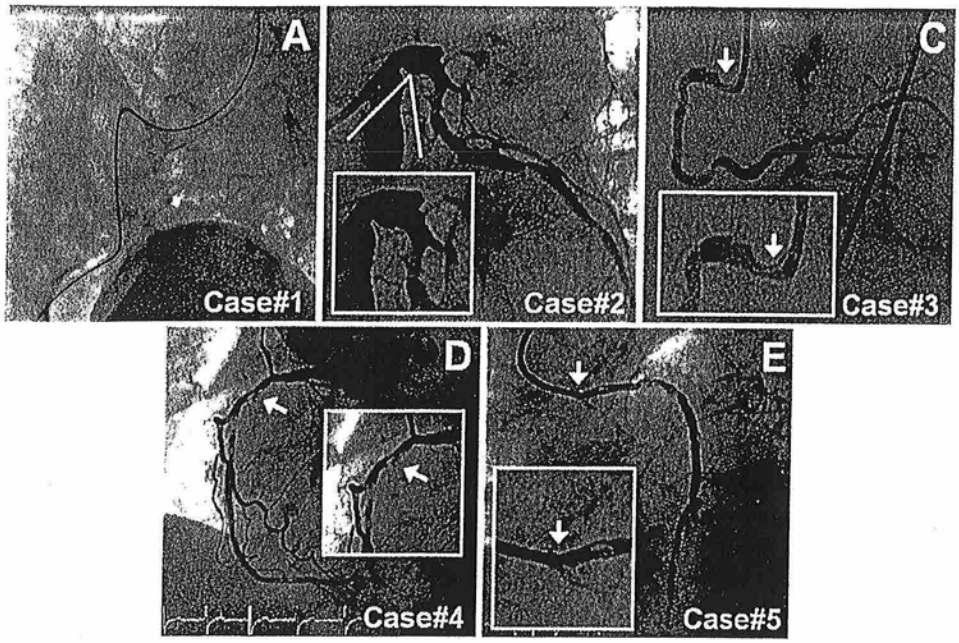

Figure 3. *Angiographic overview of the device failures: Case #1) The first case was a 79-year-old male patient with an acute inferior MI. The target lesion was located in a diffusely diseased, heavily calcified RCA. The GL could not be advanced through the guide catheter because of severe iliac tortuosity (A), but procedural success was accomplished by use of a 3DRC guide catheter, two guidewires, and a distal anchoring balloon. Case #2) The second case was a long and calcified proximal LCX lesion, located behind a sharp angle between the LM and LCX that prevented GL intubation (B). Case #3) The third case was a 56-year-old subject who underwent an elective PCI of a diffusely diseased RCA. The GL catheter could not be intubated in the vessel due to a proximal lesion (C). The procedure was finished successfully with an AL1 guide. Case #4) In the fourth patient, the target lesion was a heavily calcified long mid RCA lesion (D). The proximal RCA segment was diffusely diseased, which prevented deep GL intubation (a depth of only 5 mm) and resulted in insufficient support; however, this problem was solved by rotablation of the ostium. Case #5) The fifth case was a vital 87-year-old female with stable angina due to a severely calcified proximal lesion in an 18-year-old saphenous vein graft. An AL2 guide catheter was positioned in the ostium and a flexible guidewire with hydrophilic coating was advanced across the lesion. Use of the GL was attempted to increase back-up support but the GL could not be advanced into the ostium (E), and the PCI procedure was terminated as a second guidewire could not pass the ostium either. We discussed the patient with our thoracic surgeons, who then performed an elective repeat bypass surgery with an uneventful clinical course.*

(RCA) and LCA interventions. In the LCA, the GL catheter was used regularly to improve the alignment of the guide or enhance selective contrast injections, whereas its use in RCA interventions was mainly to increase catheter back-up (p=0.024). An example is shown in **Figure 2**.

A 6 Fr guide catheter was used in all subjects, while radial access was chosen in one third of cases. Multivessel procedures were performed in almost one third of the patients, and there were 17% of chronic total occlusions. Of all 126 stents implanted, 123 (98%) were third-generation drug-eluting stents (DES). In this registry, we noted a single stent that was damaged upon advancement across the metallic collar of the GL; damage to the (secondary) guidewire tip when passing the metallic collar of the GL occurred slightly more often (4/70; 6%).

DEVICE SUCCESS AND DEVICE FAILURE

The overall success rate of the GL was 93%. The average depth to which the GL was intubated in the proximal target vessels was 33±22 mm (range: 0 to 106 mm), however, these generally deep intubations did not cause any coronary dissections. The rate of procedural success of the transradial and transfemoral access routes was 95.5% and 88.4% (p=0.35), respectively, but the power of the study was insufficient to draw sound conclusions from this comparison. There were five device failures (5/70; 7%), which are illustrated in **Figure 3**.

COMPLICATIONS

We noted no major complications or coronary dissections. There were two minor complications, which are outlined below. In the first case, during PCI of a diffusely diseased RCA in a 53-year-old male, the GL was deeply advanced (61 mm intubation depth) to increase back-up support and to pass a balloon catheter across the heavily calcified distal RCA stenosis. During this manoeuvre, some air embolism was noted as a result of insufficient venting of the wedged GL, which caused a brief phase of stasis of coronary flow that was rapidly resolved. The second minor complication occurred during PCI of a long mid lesion in an RCA with "shepherd's crook" anatomy. After predilatation and stenting of the mid RCA, an attempt to advance a second stent through the first one was made, which turned out to be extremely difficult. To increase support, the GL was advanced over both guidewires and the second stent balloon

system (stent still undeployed), which led to dislodgement of the stent from the balloon. Eventually the dislodged stent was crushed behind a third stent and was postdilated with high balloon pressures, leading to a good final angiographic result with an uneventful clinical course until the eight-month follow-up.

Discussion

Good back-up of the guide catheter is crucial for both wiring and equipment delivery. The development of guide catheter extension systems has further expanded the therapeutic arsenal of the interventional cardiologist[5-12]. Intubation of the guide catheter extension system into the target vessel provides enhancement of equipment delivery in challenging coronary lesions, and facilitates engagement in case of difficult takeoff of the coronary ostium. Takahashi et al demonstrated that a guide catheter extension system provides a substantial improvement in back-up support[5]. The support was directly related to the depth of intubation. For example, insertion of a 5 Fr guide catheter 15 mm into a 6 Fr catheter doubled the back-up support. The guide catheter extension system may be used as a tool for deeper intubation of the guide, referred to as "rail-roading", as was described in detail by Farooq et al[18]. Its use in graft interventions is well recognised as aiding graft cannulation and enhancing the stability of the guide in the graft ostium. Further back-up may be achieved by advancing the extension catheter, thereby allowing the guide to back out and down until it rests on the aortic valve or contralateral aortic wall (Swan-neck manoeuvre)[18]. And finally, guide catheter extension systems can be used as an aspiration device[18].

The Twente GuideLiner registry reports on a consecutive series of GL applications in 65 patients, treating 70 target vessels with implantation of 126 stents (98% being third-generation DES). So far, this is the largest registry on the use of the GL in routine daily practice. Demographics and clinical characteristics of the study population are similar to previous all-comers stent studies and our general PCI population[19-25]. However, lesion characteristics differed a lot from the general patient population as the majority of target lesions were long and complex: all but two target lesions (97%) were classified as lesion type B2 or C with more than half of them being located distally, and the vast majority being at least moderately calcified.

During the first months, the GL was used as a bailout device in challenging cases, when the "old familiar tricks" (e.g., deep-seating manoeuvres or use of buddy wires) had failed. However, after becoming more familiar with the device, we switched to a more upfront use in difficult anatomical situations. In our present series, the main indication for GL use was to improve guide support to facilitate stent delivery (59%). An illustration is shown in **Figure 2**. However, in one third of the cases the GL was used to improve coaxial alignment of the guide catheter in anatomical situations with an abnormal takeoff of the target vessel (e.g., shepherd's crook-shaped proximal RCA) or a vertical takeoff of either RCA or left main stem. In particular, a vertical offspring of the left main stem, as may be seen in young lean patients or patients with pulmonary emphysema, bears an increased risk of dissecting the left main stem with a guide catheter. Gentle intubation of the GL substantially facilitated the intervention in such patients **(Figure 4)**. In a small number of patients, the GL was used to perform selective contrast injections for a better visualisation of the vessel of interest with smaller amounts of contrast; this indication for GL use may be considered in patients with large calibre vessels, such as a dominant left coronary artery, and an impaired renal function, or if an adequate visualisation cannot be achieved by other means[26].

The GL may also be useful to facilitate demanding diagnostic coronary angiographies, which has not been described so far and was beyond the scope of our registry of GL use in PCI patients. Nevertheless, we would not like to withhold the information that our group also used the GL in several demanding cases of diagnostic angiographic visualisation of bypass grafts. **Figure 5** shows an example of a gastroepiploic artery (GEA) graft, visualised both with and without use of a GL. It should be emphasised that in case of coronary angiography, the operator should refrain from the use of intracoronary wires and devices as much as possible. However, there are

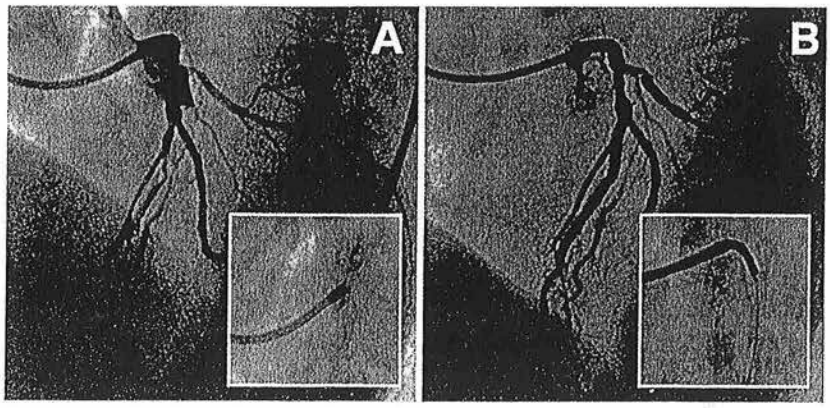

Figure 4. *Angiographic overview of a subject with a vertical offspring of the left main (A and B). The GuideLiner catheter was used for coaxial alignment of the guiding catheter, providing gentle intubation in the LM and good support to treat the LAD lesion.*

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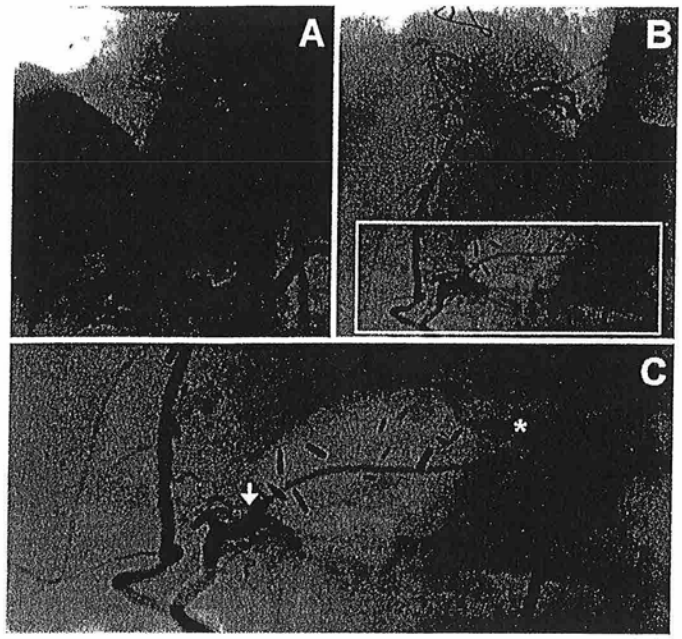

Figure 5. *Visualisation of a gastroepiploic artery (GEA) graft in a 66-year-old male patient. Panel A shows vague images of the GEA graft, obtained during routine angiography two years earlier. Panel B illustrates the difference in image quality, obtained recently with the use of the GuideLiner (GL) catheter. The arrow in Panel C is pointed at the tip of the GL catheter.*

circumstances in which a graft cannot be properly visualised. Instead of accepting a poor visualisation, the use of a guide catheter extension system can be considered in order to achieve conclusive angiographic imaging. It should be used by an interventional cardiologist with great care, and maximum effort should be taken to ensure that such manoeuvres do not give rise to a coronary dissection.

SUCCESS RATE, SHORTCOMINGS, AND POTENTIAL PROCEDURAL RISK

The success rate of the GL was 93% in our study, which is in agreement with previously reported smaller case series[10,15,17,18]. Stent damage at the site of the metallic collar of the GL occurred in one out of 126 stents implanted, which was a drug-eluting stent with a nominal diameter of 3.5 mm. Others have reported a higher rate of stent damage (6%) due to the collar of the GL catheter[10]. Therefore, we discourage the use of stents with a nominal diameter of 4 mm or more through a "5-in-6" Fr GL catheter. Murphy et al recently reported an uncommon case of balloon damage at the site of the metallic collar[16]. In addition, secondary (buddy) guidewires can be damaged upon advancement when the GL is in place, as reported in our present study. The "5-in-6" Fr GL catheter permits the passage of virtually all regular balloon catheters, contemporary optical coherence tomography (OCT) catheters, and coronary stents up to a nominal diameter of 3.5 mm. However, it does not allow the use of larger devices such as thrombectomy catheters, some intravascular ultrasound (IVUS) probes, and simultaneous kissing balloon inflations.

Although the GL turned out to be generally beneficial with a relatively low rate of device failure, we identified some scenarios, in which the usefulness of the GL may be questionable. Firstly, a difficult access due to iliac tortuosity may impede the advancement of the GL through the mother guide, as was seen in one of our patients. Secondly, the proximal part of the target vessel should be suitable for intubation of the GL catheter; therefore, ostial/very proximal lesions or sharp angles of coronary arteries may lead to device failure, as was noted in the majority of our cases with device failure.

In general, use of the GL turned out to be safe. No major complications were noted, but there were two minor complications with favourable outcomes and an otherwise uneventful clinical course. There was one case of air embolism due to insufficient venting. In the second case, a stent was dislodged from the balloon by the tip of the GL when advancing the GL over a stent balloon system. Both complications could have been avoided, if more care had been taken and the instructions of the manufacturer had been followed. Luna et al[15] reported a substantially higher number of cases with pressure dampening (57%) during engagement of the GL catheter; however, dissimilar to our study, they used a "6-in-7" Fr system in the majority of cases.

HOW TO USE THE GUIDELINER AND HOW TO AVOID COMPLICATIONS

Several considerations can be mentioned in order to choose or refrain from the use of a guide catheter extension. If more back-up of the guide catheter is required, the first step can be the use of buddy wires, extra stiff wires, or buddy balloons. However, if these measures fail, a GL catheter may be considered, which allows the mother guide and

wires to be left in place. The operator should, however, be convinced that the proximal part of the target vessel is suitable for intubation. If the lesion extends to the proximal segment or if there is sharp angulation, the use of a guide catheter extension system is generally not recommended. Alternatively, the proximal segment may be stented first, followed by gentle intubation of the GL catheter and treatment of the distal segment (so-called proximal-to-distal stenting). However, care should be taken to avoid deformation or longitudinal compression of a proximally implanted stent[27,28]. If there is a problem with coaxial alignment of the available guide catheters, the operator should estimate the risk of performing the procedure with a suboptimal position of the tip of the guide (in case of a simple proximal lesion one may continue). However, if substantial back-up is required, it appears wise to use a guide catheter extension. This decreases the risk of guide-induced dissections and improves the back-up of the mother guide. If the patient has an impaired renal function and the operator expects to use large amounts of contrast (e.g., in a dominant left coronary artery system), a guide catheter extension system may be considered as a valuable first choice. And finally, if the operator intends to treat a bifurcation lesion, it should be realised that a "5-in-6" Fr system does not allow the simultaneous use of two balloons. Therefore, a choice should be made to use a larger guide catheter extension system ("6-in 7" Fr system or Proxis™ device), remove the guide catheter extension system before the kissing procedure, or refrain from its use and adhere to usual practice.

A WORD OF CAUTION

Intubation of the GL bears the risk of causing a dissection in a proximal coronary artery and should be performed carefully. If resistance is encountered when advancing the device, the GL can be retrieved into the mother guide and then re-advanced over a balloon catheter (to improve alignment) into the target vessel[17]. After advancing the GL into the vessel, the operator should check the coronary pressure waves and verify the presence of adequate, preserved antegrade coronary flow. Since use of the GL reduces the size of the working lumen, there is an increased risk of air embolism, which can be diminished by slow advancement and withdrawal of the equipment; time should then be taken to carefully vent the system. A limitation of the GL device is the metallic collar located at the entrance of the extension tube. In case of resistance while advancing the stent, the location of the stent in relation to the metallic collar of the GL should be checked and the stent should be inspected for damage. If the collar is located at a bend in the catheter, the GL should be retrieved gently into a straight section of the mother guide in order to allow more coaxial alignment of the collar[17]. The use of more than one guidewire in combination with a relatively large size of the stent delivery system may sometimes render stent passage through the collar of the GL difficult and occasionally impossible. Factors such as operator awareness, experience, number and type of guidewires, size of the stent, vascular anatomy, the shape of the guide catheter, and indication for GL use may have an effect on the incidence of this problem, which differs between case series[17].

LIMITATIONS

The present registry of a consecutive series of PCI patients treated with the use of the "5-in-6" Fr GL provides some "real-life" insight into efficacy, limitations, and the potential risk of this device. Although our patient population is larger than that of all previously reported cases and patient series altogether[10-18] the population is still relatively small. In addition, due to well-known limitations inherent to registries, this single centre registry cannot provide the scientific level of insight that might be obtained from a randomised study. During the course of this registry, use of highly deliverable third-generation DES in most patients was our standard of care[29], which could have affected our results. We cannot exclude that in cases with upfront use of the GL, a standard guide catheter or other manoeuvres and tricks (e.g., deep intubations or buddy wires) could also have led to procedural success.

CONCLUSIONS

Use of the GuideLiner catheter resulted in an increased back-up support and guide catheter alignment for stent delivery in the presence of unfavourable tortuous coronary anatomies and in complex, heavily calcified, and often distally located lesions, which otherwise may have been considered unsuitable for PCI. The procedural success rate of the GL was high without major complications.

FUNDING

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Conflict of interest statement

C. von Birgelen is a consultant to and has received lecture fees or travel expenses from Abbott, Medtronic, and Boston Scientific and has received a speaker's honorarium from Merck Sharp & Dohme. All of the other authors have no conflict of interest to declare.

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Exhibit 9

GuideLiner Catheter Facilitated PCI – A Novel Device with Multiple Applications

Ashish Pershad, MD, Victor Sein, MD, Nathan Laufer, MD

ABSTRACT: Objective. The GuideLiner catheter (*Vascular Solutions, Inc.*) is a monorail guiding catheter extension that serves to facilitate stent delivery and is approved for providing extra support and coaxial guide engagement. The objective of this manuscript is to familiarize interventionalists with this new device, describe its versatile uses, and its limitations with case-based examples. **Background.** Failure of stent delivery is responsible for 5% of procedural failures in coronary interventions in the current era. Different techniques to enhance guiding catheter support and facilitate device delivery have been described. These include use of buddy wires, anchoring balloons at different locations for extra support for device delivery, and even rotational atherectomy in the most calcified lesions. **Methods.** The database of coronary interventions at Banner Good Samaritan Medical Center was queried for use of the GuideLiner catheter and stents. The angiograms of all those cases were reviewed and selections of cases highlighting different uses of the catheter were chosen for inclusion in this manuscript. **Results.** All potential uses of the GuideLiner catheter are described in this manuscript. Nuances about use and tips and tricks related to the device are also discussed in the case examples. **Conclusions.** The manuscript provides a complete summary of the different uses and limitations of the catheter and its contemporary role in modern day coronary intervention.

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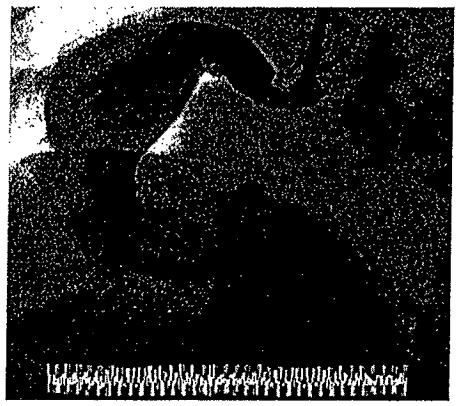

Figure 1. *LAO image of the RCA with aneurysm in the proximal RCA and occlusion of the RCA at the crux just prior to the bifurcation of the PDA and posterolateral branches.*

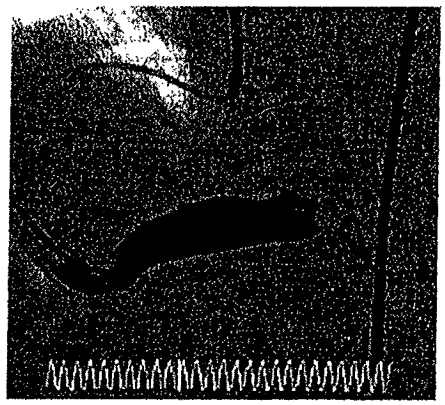

Figure 2. *AP cranial image of the RCA with GuideLiner catheter in the distal aspect of the RCA past the aneurysmal portion of the RCA.*

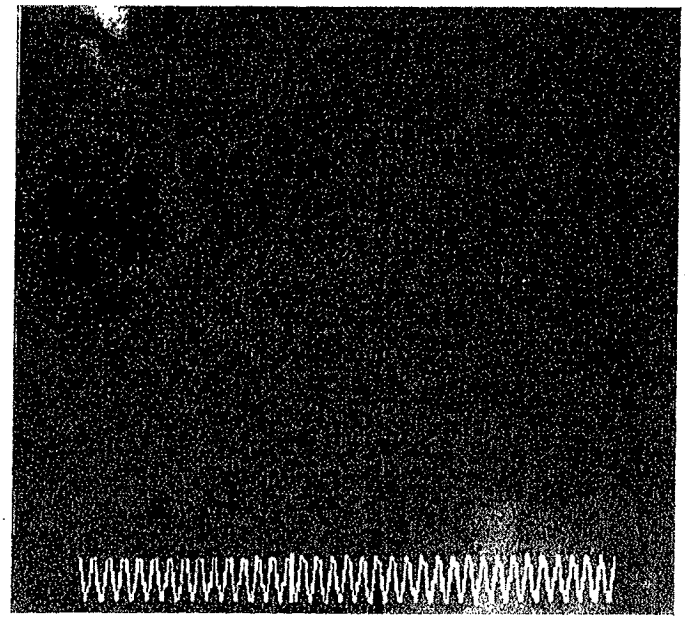

Figure 3. *AP cranial projection of the RCA after implantation of two 4 mm BMS at the crux.*

PCI has been simplified greatly over the last decade. Lower profile balloons and versatile guidewires have made coronary device delivery and interventions relatively simple as compared to a few decades ago. However in about 5% of cases, stent delivery is unsuccessful and is one of the main causes of procedural failure.[1] Drug-eluting stents have a higher profile as compared to bare metal stents and are more difficult to deliver, but they provide a remarkable benefit with respect to reduction in target lesion revascularization. Use of multiple shorter drug-eluting stents is not economical. Longer drug-eluting stents are not easy to deliver to the lesion site especially in tortuous and calcified

From Banner Good Samaritan Medical Center Interventional CV Program, Phoenix, Arizona.

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.

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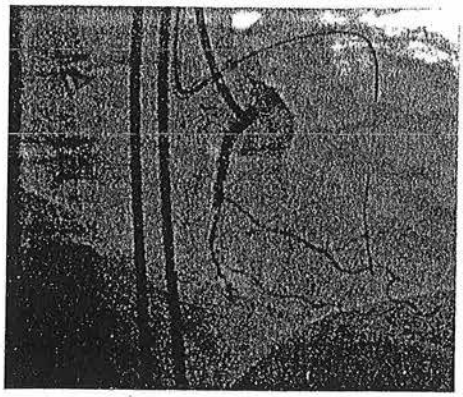

Figure 4. *RAO projection of the occluded RCA with faint opacification of the PDA from septal perforator collaterals.*

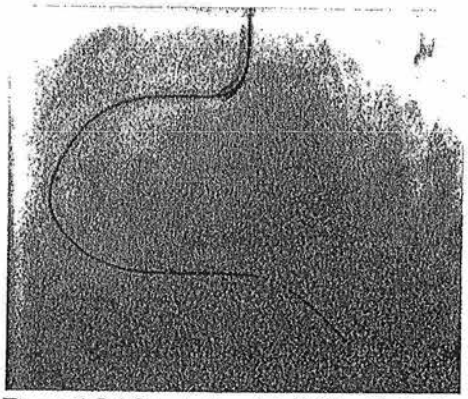

Figure 5. *LAO projection of the RCA with GuideLiner in the mid RCA and a Finecross catheter and Miracle Bros 0.014 wire in the distal RCA.*

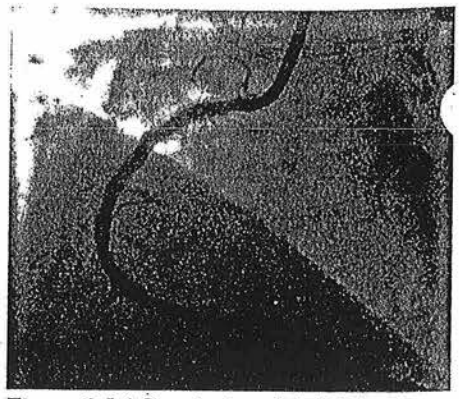

Figure 6. *LAO projection of the RCA successfully stented.*

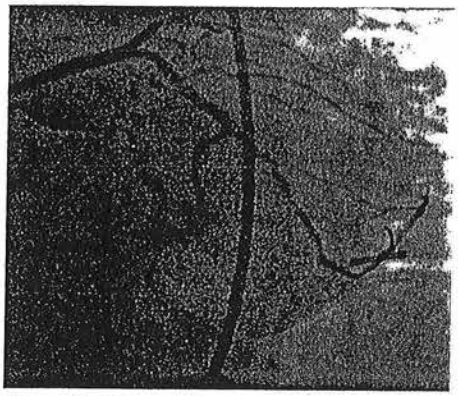

Figure 7. *AP caudal projection of the circumflex artery with a long stenosis of the OM system.*

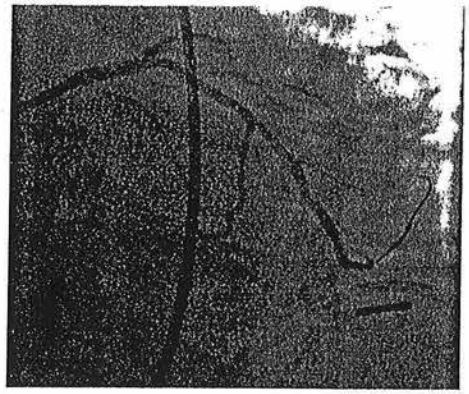

Figure 8. *AP caudal projection of the circumflex artery with GuideLiner in circumflex artery assisting stent delivery to the OM stenosis.*

Figure 9. *AP projection of the circumflex artery after DES implantation and treatment of stenosis.*

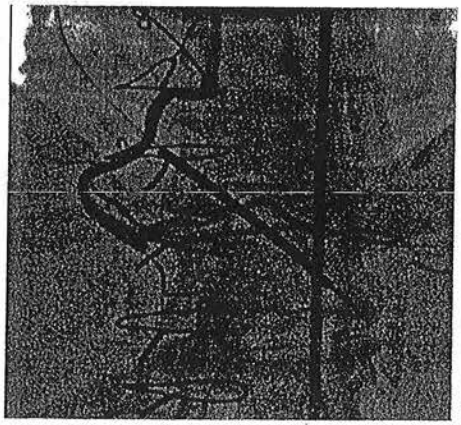

Figure 10. *AP projection of the RCA with Amplatz guiding catheter in the RCA and high grade*

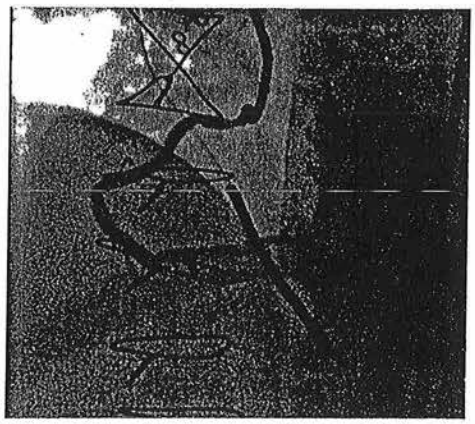

Figure 11. *AP projection of the RCA following PTCA of the PDA artery, demonstrating a non-flow limiting dissection in the PDA.*

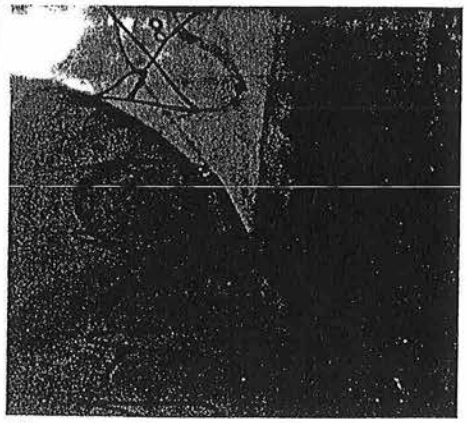

Figure 12. *AP projection of the RCA with the GuideLiner catheter half way down the RCA past the stents in the proximal RCA.*

coronary vessels. This poses new dilemmas to operators and presents a new challenge in coronary stenting. This may have added significance when more and more interventional procedures are being done using smaller guiding catheters via the radial approach.

The GuideLiner catheter (*Vascular Solutions, Inc.*) is a novel device that is FDA approved and CE marked for assistance with device delivery during coronary interventional procedures. It is an extension of the mother-and-child guide concept, but the advantage over the Heartrail mother-and-child guiding catheter is that the entire procedure can be completed using the same guide catheter with the convenience of a rapid exchange format.[2] In this article, all the different applications of the GuideLiner

Figure 13. *AP projection of the RCA after stent deployment in the PDA.*

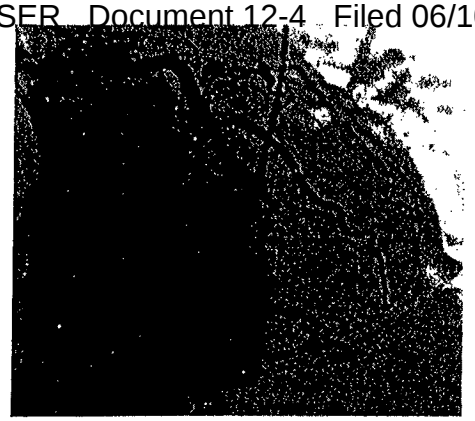

Figure 14. *AP caudal projection of the circumflex artery demonstrating a high-grade lesion in the posterolateral branch of the circumflex artery with extreme angulation.*

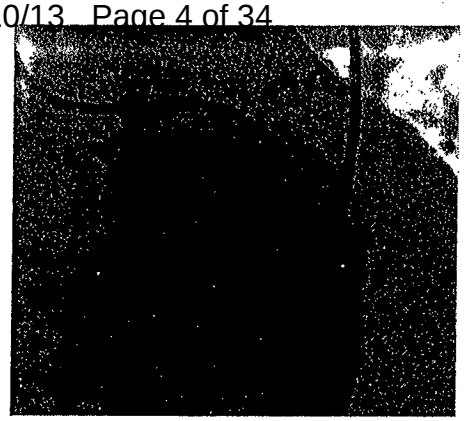

Figure 15. *AP projection of the circumflex demonstrating the GuideLiner deeply engaged in the circumflex and the stent on the angulated segment across the lesion.*

catheter will be presented with case examples. A brief discussion of the limitations as well as some tips related to its use will be highlighted.

Case 1. *A 63-year-old African American female presented with chest pain, bradycardia, and ECG evidence of a STEMI. The culprit vessel was the right coronary artery (RCA). The RCA was noted to have a complete occlusion at the bifurcation of the posterior descending artery (PDA) and posterolateral branches (Figure 1). The proximal RCA had a huge aneurysm measuring 1.0–1.2 cm with swirling of contrast in the aneurysmal segment and no visualization of the distal vessel even with injections of 20cc of contrast through an automated injection system (ACIST CVi). PCI of the RCA was planned urgently. A 7 Fr JR4 (Medtronic) guiding catheter was used to engage the RCA. A 2 mm over the wire Sprinter balloon (Medtronic) was advanced into the distal RCA over a Prowater Flex 0.014 coronary guidewire (Abbott Vascular). The wire was unable to cross the occlusion and attempts to visualize the distal vessel were futile because of the proximal aneurysm and the swirling of contrast in the proximal RCA. At this point it was decided to place a GuideLiner catheter beyond the aneurysm in the distal RCA to facilitate subselective injection into the distal RCA. This was effectively achieved over the same wire (Figure 2). Once it was possible to see the distal vessel better, a hydrophilic 0.014-inch guidewire was advanced into the posterolateral and then the PDA respectively; PCI of both vessels was performed successfully using 24 mm Vision (Abbott Vascular) bare metal stents (Figure 3).*

This case highlights another niche role of the GuideLiner catheter. In addition to providing support for facilitating stent delivery and enhanced backup for coronary interventions, this device allows safe subselective injections for better visualization of the distal vessel and decreasing contrast load. This particular application of the GuideLiner catheter has not been described in the literature thus far.

Case 2. *A 50-year-old male with known occlusion of his RCA and inferior wall ischemia was referred for angiography. Bilateral femoral access with 8 Fr sheaths was obtained and simultaneous injections of the RCA and left coronary were performed (Figure 4) with a JR4 guiding catheter in the RCA. The CTO was successfully crossed using the antegrade approach and the GuideLiner catheter was then used to deliver long DES successfully (Figure 5). The final angiogram demonstrated the RCA successfully recanalized and a diffuse negatively modeled distal vessel (Figure 6).*

Case 3. *A 65-year-old male presented with unstable angina. Diagnostic angiography demonstrated triple vessel coronary disease and normal ventricular function (Figure 7). After intervention on the RCA was performed, attention was turned to the circumflex artery (Figure 8). A 7 Fr EBU (Medtronic Vascular) guiding catheter was used for the intervention on the circumflex artery. A BMW (Abbott Vascular) guidewire was used to cross the lesion in the circumflex artery and angioplasty performed with a 3mm Voyager (Abbott Vascular) balloon. After predilatation, there was difficulty advancing the stents through the calcified proximal vessel (Figure 8). A GuideLiner catheter was then advanced into the circumflex artery and this facilitated delivery of long drug-eluting stents to treat the stenosis successfully without need for a different wire or a different guiding catheter (Figure 9).*

The GuideLiner catheter allowed a second vessel (circumflex) to be treated ad hoc by greatly simplifying a complex procedure and minimizing contrast load and radiation exposure to the patient. The patient was then brought back for treatment of the LAD chronic total occlusion. This enabled complete revascularization for this patient.

Case 4. *In this case, another potential advantage of the GuideLiner is highlighted. A 66-year-old male presented with stable angina and a history of prior CABG and inferior ischemia on noninvasive perfusion imaging. The culprit lesion was identified in the PDA. The proximal and mid RCA were previously stented, the ostium of the RCA was anterior, and the vessel was very tortuous proximally (Figures 10 and 11). A 7 Fr AL 0.75 guiding catheter engaged the RCA ostium coaxially. After a BMW wire was used to*

Figure 16. *AP projection of the circumflex demonstrating the lesion in the posterolateral branch adequately stented.*

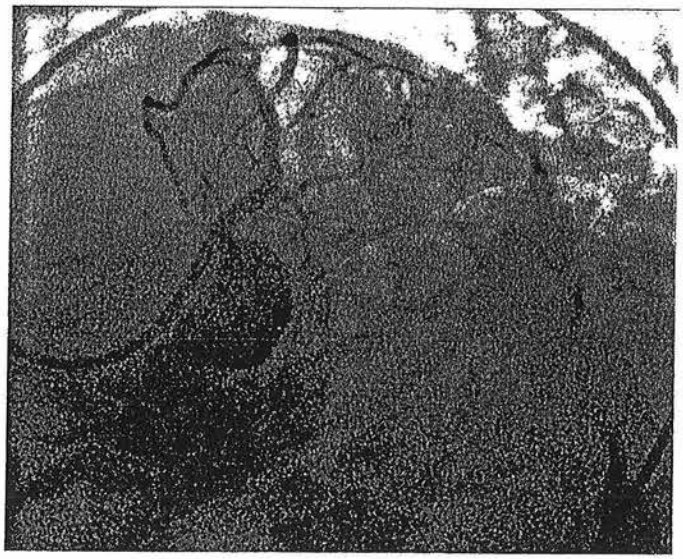

Figure 17. *LAO caudal projection of the circumflex demonstrating a chronic total occlusion with extreme angulation of the circumflex.*

cross the lesion, predilatation of the lesion was performed with a 2.75 mm balloon and then the GuideLiner catheter was advanced past the previously placed stents (Figure 12). This permitted placement of a 2.75 mm x 23 mm Promus (Boston Scientific) DES with relative ease (Figure 13). The GuideLiner allows delivery of stents distally past previously placed stents, which is an advantage in cases like this when there is a new de novo lesion beyond previously placed stents or even in difficult cases in stenting a distal dissection after placement of freshly placed stents. This challenges the well-established dictum of stenting from distally in the vessel to proximally in the vessel because the atraumatic soft tip of the GuideLiner catheter can easily be placed past freshly placed stents for extra support to deliver a stent distally in the vessel.

Case 5. *A distal lesion in a small posterolateral vessel was successfully treated after very deep engagement of the GuideLiner catheter (Figures 14–16). In the past, this lesion would either be treated medically or with balloon angioplasty, but with the availability of drug-eluting stents in smaller diameters (2.25 mm) and low late loss of 0.1 mm, these patients can be offered relief of their angina as was demonstrated in this case. Caution needs to be exercised with such maneuvers with the catheter.*

Case 6. *This case demonstrates the utility of the GuideLiner catheter in coaxial alignment for delivering stents even in very proximal coronary segments because of difficulties related to extreme proximal vessel tortuosity. An extremely angulated take off of the left circumflex artery off the left main coronary artery was dealt with by placing a GuideLiner catheter into the distal left main. Even though the GuideLiner did not actually enter the circumflex artery, it provided enough support for the delivery of a drug-eluting stent to treat the entire proximal stenosis successfully with one stent (Figures 17–19).*

Discussion. The GuideLiner catheter is a coaxial guiding catheter extension delivered through a standard guiding catheter on a monorail. It is comprised of a 20 cm yellow straight extension whose inner diameter is 1 Fr size smaller than the guiding catheter.[3] This extension is tri-layered. The inner most layer is PTFE; the second layer is a stainless steel coil, which imparts flexibility and strength; and the outer lining is that of pebax polymer with silicone coating. The silicone coating imparts lubricity. This is connected to a stainless steel push tube and a metal collar that can be deployed through the "Y" adapter. There is a radiopaque marker 2.6 mm from the tip of the extension and 2 white positioning markers at 95 cm and 105 cm on the push tube. This construction and design does not lengthen the guiding catheter. By not adding length to the guiding catheter it does not reduce working length of balloons and stents. This may confer an advantage when treating distal lesions. Also, this does not require a separate hemostatic valve. These are significant advantages over the Heartrail mother-and-child catheter.

After guide catheter and wire placement, the GuideLiner catheter can be advanced over the wire through the hemostatic valve as an extension to the guide catheter for extra back up and deep guide engagement. The rest of the interventional procedure is completed as usual through the same hemostatic valve and guide catheter without need for disconnection and reattachment. The interventional equipment tracks over the wire and through the GuideLiner collar with exit at the distal tip of the catheter at the desired vascular location. On completion of the case, the GuideLiner catheter can be removed in a similar fashion to removal of a monorail balloon. In the first case, the use of the GuideLiner catheter as a tool for distal vessel visualization and subselective injection of contrast is showcased. This has never been described previously in the literature. Without the GuideLiner catheter, due to the presence of a coronary aneurysm the distal vessel was unable to be opacified. This was

in spite of injecting 20 cc of contrast (10 cc/sec for 2 sec) via the ACIST CVi automatic injection system. Once advanced past the aneurysm, the GuideLiner allowed for subselective injection, providing complete distal vessel opacification utilizing <8 cc of contrast. This can be used to our advantage in coronary intervention on patients with compromised renal function minimizing contrast load and thereby potentially reducing the incidence of contrast associated nephropathy. This is especially important given the knowledge about adverse outcomes in patients with CIN following PCI.[4] In this particular case, an unusual problem was elegantly solved with the assistance of the GuideLiner catheter.

Chronic total occlusions represent a unique challenge with respect to the diffuse nature of the disease even proximal to the occluded segment of the vessel and the small negatively remodeled distal target vessel. The GuideLiner catheter lends itself to use in this lesion subset because of the ability for deep engagement of the guiding catheter atraumatically and providing the support necessary for delivery of long drug-eluting stents for definitive treatment. The safety of the GuideLiner when used for deep intubation relies on the absence of a primary curve for the extension. It provides a safer alternative to using aggressive guiding catheters like the Amplatz left curves for the RCA. This is amply demonstrated in the second case in which the RCA chronic total occlusion was successfully treated with deep atraumatic engagement of the RCA ostium and subsequent delivery of long relatively inflexible first generation drug-eluting stents. The device allows for robust support for secure delivery of equipment to distal segments of the coronary tree. During *in vitro* testing, when extended 15 cm into the vessel, the 6 Fr GuideLiner catheter provides greater back up support than even an 8 Fr guiding catheter.

In the third, fourth, and fifth cases, the reason for the development of this device, facilitating distal stent delivery, is demonstrated. Commonly used methods to overcome difficulty with stent delivery include straightening of the vessel with a buddy wire, use of an anchor balloon, and using large diameter guiding catheters with more supportive curves. The GuideLiner facilitates delivery of stents to distal segments of the coronary vessel (Figures 4 and 5) by allowing safe deep vessel intubation. This provides the necessary extra back-up support needed for stent delivery. In an era when radial artery intervention is making a comeback into the mainstream, this may have added significance because the vast majority of cases via the radial artery are performed with 6 Fr guiding catheters. Also because of the angle of entry from the radial approach into the aortic sinus, coaxial guide placement is difficult. The GuideLiner catheter may allow for maintaining coaxial guide orientation. In case 3, a long circumflex artery stenosis was treated with deep engagement of the GuideLiner catheter to deliver 2 long DES as opposed to several shorter length drug-eluting stents. This may have incremental value in an era of cost containment by treating long lesions with fewer drug-eluting stents, thus lowering the cost per case.

With this technique, use an inflated low profile balloon or a microcatheter on the wire while the catheter is advanced into the coronary artery. This reduces the dead space between the GuideLiner catheter and guidewire, providing a tapered, atraumatic leading edge. It also stiffens the rail over which the device can be advanced. This decreases the incidence of coronary dissections in the proximal vessel. An extension of this concept involves using the GuideLiner catheter even with aggressive guiding catheters, especially when there is a need for delivery of long stents to distal portions of the vessel. This is amply illustrated in cases 4 and 5 of this series. When delivering stents to distal parts of the vessel, caution needs to be exercised when the metal collar of the GuideLiner extends past the secondary curve of the guiding catheter. This is the basis for the recommended deep seating distance of 10 cm from the tip of the guide. If necessary, deeper engagement (>10 cm) can be performed without risk to the vessel or the patient.

Another situation where the GuideLiner finds utility in coronary intervention is in the setting of proximal vessel tortuosity illustrated in case 6. In this case, the extreme angulation of the origin of the circumflex artery from the left main artery

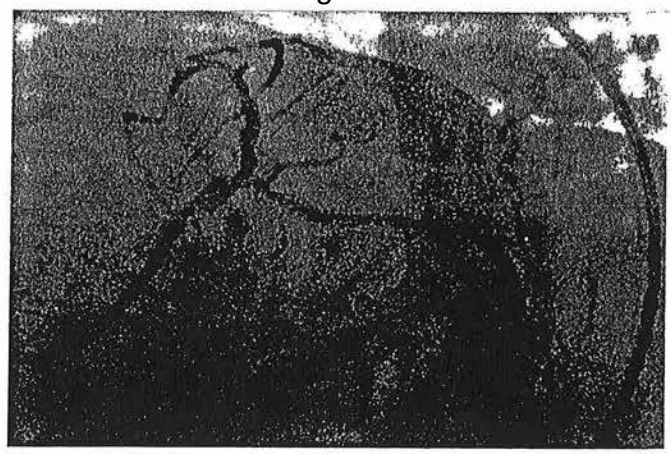

Figure 18. *LAO projection of the circumflex artery with the GuideLiner catheter maintaining coaxial engagement and a single long DES across the entire lesion.*

Figure 19. *LAO caudal projection of the circumflex, after successful stenting of the CTO.*

made it impossible to advance the stent past the proximal vessel even after straightening out the proximal vessel with stiff coronary guidewires and with deep engagement of the guiding catheter. The soft atraumatic tip of the GuideLiner catheter allowed delivery of stents relatively easily after negotiating the proximal bend of the vessel. This can greatly shorten the case and fluoroscopy times and minimize contrast load to the patient.

Limitations. Every time a catheter is used for deep intubation of a coronary vessel, regardless of how soft the tip is, there remains a risk of dissection of the ostium and/or the proximal aspect of the vessel. It is no different with the GuideLiner catheter with reported dissection rates of 0.5%–1%. One of the techniques described in this manuscript involves using a low-profile balloon to eliminate the dead space between the catheter tip and wire, which greatly reduces the risk of dissection. Particular caution needs to be exercised in the setting of an anomalous origin of a vessel and in the setting of a diffusely diseased proximal segment. The GuideLiner is less likely to dissect the coronary ostia than a guiding catheter because of the lack of a primary curve in the GuideLiner catheter and the inner coating of the GuideLiner tip provides atraumatic support. Another drawback of this device is the potential for stents especially larger profile stents to get caught on the metal collar of the device. This can damage the stent and may even cause it to shear off, if this is not readily recognized. The cause of this complication is wire wrap around the metal collar. If any resistance is encountered during advancement of the stent through the GuideLiner catheter, the stent should not be pushed but instead withdrawn and inspected for damage to its integrity.

Wire wrap is another important consideration while using this device. When two wires are used in a coronary intervention, the GuideLiner catheter should be advanced only over the primary wire as the secondary wires may wrap around the GuideLiner catheter and prevent advancement of devices. When inserting the GuideLiner into the guiding catheter, the flat push tube should be oriented laterally and be advanced without rotation to avoid wrapping of even the primary guidewire.

Conclusion. The GuideLiner catheter has greatly simplified coronary intervention and broadened the lesion subsets that can be safely treated with 6 Fr guiding catheters and via the radial approach. The catheter could be used upfront or if difficulty is encountered delivering stents or devices as a bailout option. Like all new devices there are certain precautions and limitations that operators need to be aware of prior to using this device.

Future iterations of the device may aim to provide modifications at the steel collar to minimize risk of damage to larger profile stents and find ways to avoid wire wrap.

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Exhibit 10

Catheterization and Cardiovascular Interventions 00:000–000 (2011)

Case Report

Novel Use of the GuideLiner Catheter to Minimize Contrast Use During PCI in a Patient With Chronic Kidney Disease

Anuradha Tunuguntla, MD, Benoit Daneault, MD, and Ajay J. Kirtane,* MD, SM

The GuideLiner catheter (Vascular Solutions, Minneapolis, MN) is a rapid-exchange "mother and child" guide extension that increases support in complex percutaneous coronary intervention (PCI). While this device was primarily designed to facilitate balloon and stent delivery, we describe the use of this device to reduce contrast volume through sub-selective visualization in a patient with chronic kidney disease (CKD) undergoing PCI of the left coronary system. © 2011 Wiley Periodicals, Inc.

Key words: acute coronary syndrome; chronic renal insufficiency; contrast media

INTRODUCTION

The GuideLiner catheter (Vascular Solutions, Minneapolis, MN) is a rapid-exchange "mother and child" guide extension that enables additional support during complex percutaneous coronary intervention (PCI). The catheter consists of a coaxial guiding catheter extension delivered through the standard guiding catheter on a monorail shaft. It is composed of a flexible yellow 20 cm straight extension with an internal diameter approximately one French size smaller than the guiding catheter (Fig. 1). The extension comprises of an inner polytetrafluoroethylene (PTFE: Teflon) lining, surrounded by a stainless-steel coil and an outer layer of Pebax polymer. The GuideLiner catheter is currently available in three sizes: 5-in-6 French (internal diameter 0.056″), 6-in-7 French (0.062″), and 7-in-8 French (0.071″).

The GuideLiner catheter permits deep and subselective intubation of the target vessel, thus providing backup support in addition to that provided by the standard guiding catheter. Because of the flexibility of the device, the deeply engaged extension is typically aligned coaxial to the target vessel, an attribute that can be useful if the takeoff of the coronary ostium prevents coaxial engagement of the guiding catheter. Additionally, because the device is based upon a monorail-based rapid-exchange platform, contrast dye injections through the guiding catheter enter the proximal portion of the GuideLiner and exit it distally (selectively in the target vessel). Because there is no loss of contrast into more proximal side branches, the volume of dye necessary for target vessel opacification is typically lower than if dye were injected through the guiding catheter alone. This is especially relevant for PCI of the left coronary system. We describe a case of a patient at high risk for contrast-induced nephropathy (CIN) in which the device was expressly used to reduce the amount of contrast necessary for PCI.

CASE REPORT

A frail 60-year-old female with history of hypertension, diabetes mellitus complicated by diabetic retinopathy and nephropathy, Stage IV chronic kidney disease (CKD) (baseline creatinine: 2.8; GFR 17 mL/min/1.73 m^2), and anemia presented to the hospital with a non-ST elevation myocardial infarction. The patient was prehydrated for 6 hr and treated with *n*-acetylcysteine prior to the procedure. Diagnostic cardiac

Columbia University Medical Center, New York Presbyterian Hospital and Cardiovascular Research Foundation, New York

Conflict of interest: Nothing to report.

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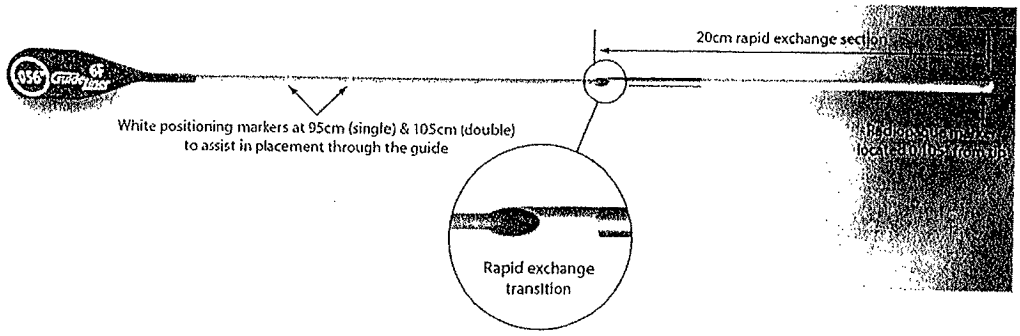

Fig. 1. Guideliner Catheter.

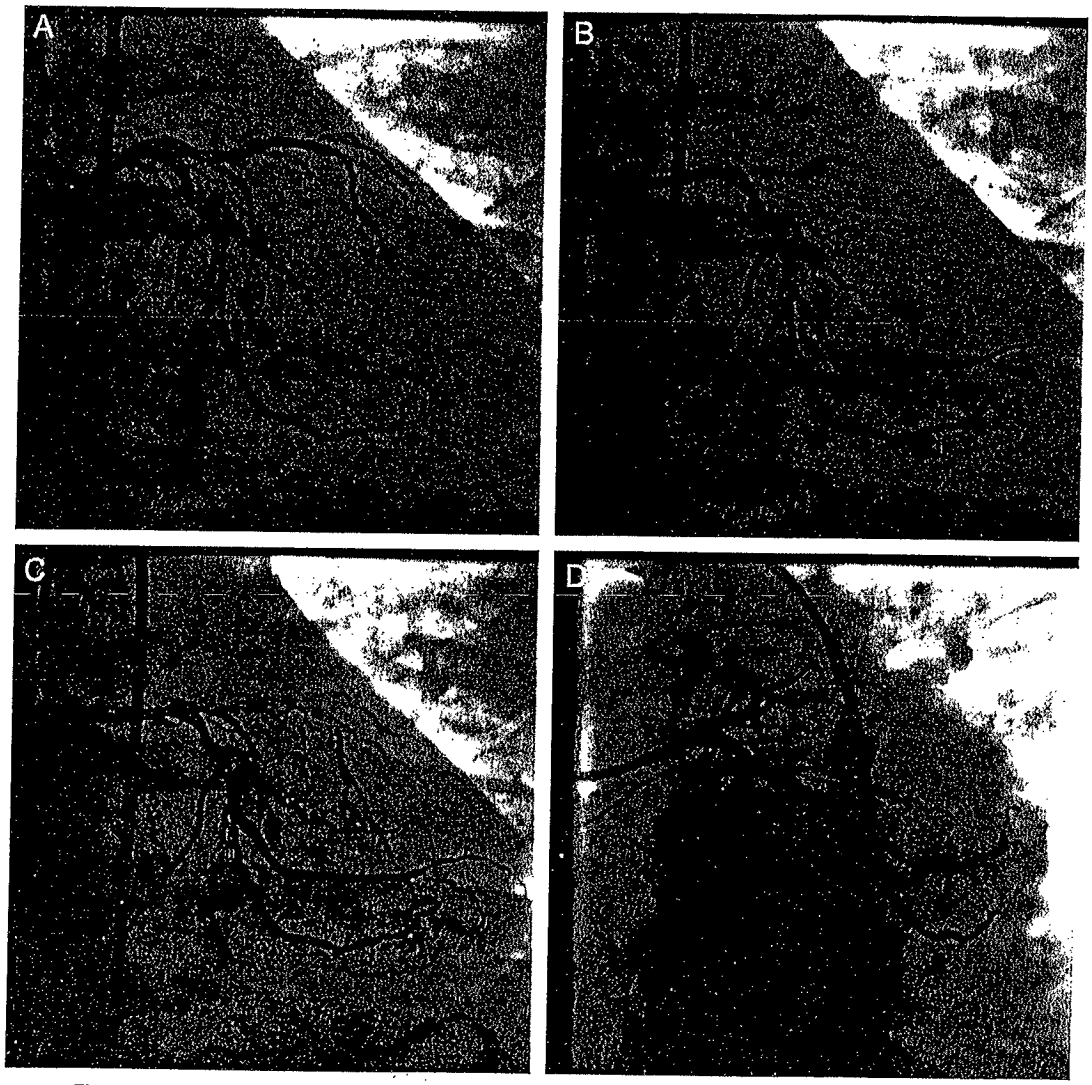

Fig. 2. Panel A: Coronary angiography of the left coronary system, revealing significant OM1 and OM2 lesions. Panel B: The GuideLiner is deep seated into the proximal circumflex. Panel C: The lesions in OM2 and OM3 after predilatation with 2.5 mm balloon. Panel D: Final angiography status post PCI of OM2 and OM3.

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catheterization with limited views revealed LCX disease with a likely culprit lesion in the obtuse marginal branch (Fig. 2, Panel A). Due to concerns about further contrast administration during PCI, a 7 French EBU 3.5 guiding catheter was used to intubate the left main, and after wire crossing, a 6-in-7 French Guideliner catheter was used to selectively intubate the proximal LCX over a balloon catheter. This permitted the use of <2 cc contrast injections for the remainder of the case with adequate visualization within the target vessel. The lesion in OM2 was predilated and then treated with a 2.5 × 12 mm^2 DES, and OM3 was treated with focal stand-alone balloon angioplasty with excellent results (Fig. 2, Panels B–D). The case was completed using 40 cc of contrast; there was no evidence of proximal LCX disruption. Follow-up assessment confirmed the absence of CIN and the patient has done well at 6 months of follow-up.

DISCUSSION

Although the GuideLiner catheter was originally designed to facilitate guide backup support through deep intubation in complex PCI, this case demonstrates that by facilitating sub-selective visualization of the coronary arteries (particularly in the left coronary system), this device also has a potential use in minimizing contrast delivery during PCI. In this case, adequate visualization of the artery of interest was possible with less dye administered per injection due to the subselective position of the guide extension catheter.

CIN is a serious clinical problem associated with increased morbidity and mortality, particularly among at-risk patients with CKD undergoing PCI. While several correlates of risk for CIN have been identified, the options for modifying the risk of CIN are limited, primarily comprising: prehydration regimens (with or without sodium bicarbonate), adjunctive agents such as *N*-acetylcysteine, the use of alternative contrast agents, and techniques to reduce the volume of contrast delivered during coronary procedures [1–3]. Several studies have documented independent correlations between volume of contrast and the risk of incident CIN, although a recent study demonstrated a low risk of CIN among patients receiving less than 100 cc of contrast [4–6]. Nonetheless, it is generally accepted that methods to decrease contrast during PCI (including the use of smaller guiding catheters, intravascular ultrasound-guided PCI, magnetically-assisted PCI) may have a role in the prevention of CIN [7,8].

Our case demonstrates a novel approach to reduce contrast delivery during PCI through the use of the GuideLiner catheter as a "mother–child" guide extension. This technique capitalizes on two specific attributes of this catheter: (1) the catheter's flexibility, which permits the catheter to remain coaxial with the target vessel even when sub-selectively engaged and (2) the rapid-exchange system, which allows dye injected into the guiding catheter to enter the proximal end of the catheter and exit subselectively within the vessel of interest, without loss of dye in more proximal side branches. While this technique proved useful in this particular case, subselective engagement of the artery of interest and injections through the GuideLiner should be performed carefully. Our practice is to deliver the GuideLiner catheter over a balloon catheter and wire in order to prevent vessel injury and mechanical dissections. Additionally, meticulous attention to continuously monitored pressure waveforms prior to contrast injections is critical to avoid hydraulic dissections. Finally, it is our practice to perform a final angiogram with the wire and device removed in order to visualize the proximal segment of the treated artery and ensure that there has been no proximal trauma.

In summary, the GuideLiner catheter can be deep-seated within an artery segment proximal to the target lesion, enabling the subselective injection of reduced amounts of contrast dye during PCI. Further prospective study is warranted to investigate the efficacy and safety of this technique for the prevention of CIN.

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Exhibit 11

Use of the GuideLiner Catheter for the Treatment of a Bifurcational Total Occlusion of the Native Left Anterior Descending Artery through a Tortuous Composite Venous Graft

Elias B. Hanna, MD, Tarun W. Dasari, MD, Thomas A. Hennebry, MD

ABSTRACT: Difficulty in stent delivery is frequently encountered in cases of tortuous or calcified coronary arteries. Chronic total occlusion interventions often require extra back-up that may not be adequately provided by guiding catheters, even the most supportive guiding catheters. We report the first successful stenting of a complex native coronary artery occlusion through an angulated bypass graft with the support of a GuideLiner catheter.

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Despite current improvements in delivery systems, failure to deliver stents still occurs in up to 5% of percutaneous coronary interventions (PCI),[1] particularly in tortuous or heavily calcified arteries. Newer generations of stents are characterized by high longitudinal flexibility and low profile, however, crossing a severely tortuous segment still represents a challenge. In addition, in complex coronary interventions, particularly chronic total occlusion (CTO) interventions, guiding catheter back-up is of paramount importance to allow advancing a wire or balloon across the CTO, hence the frequent need for large guides, guides with opposite aortic wall contact and deep-seating maneuvers to provide support.

We describe a case of a complex bifurcational native left anterior descending artery (LAD) CTO treated through a tortuous venous graft with the support of a new device, the GuideLiner *(Vascular Solutions, Inc., Minneapolis, Minnesota)*. To our knowledge, this is the first reported use of the GuideLiner for treatment of a complex native coronary artery stenosis through a graft.

Case Report. *A 70-year-old man presented with severe exertional angina that had been progressive for the previous 3 months. He had a history of 2 prior coronary artery bypass graft surgeries, the last one 22 years prior to presentation. A coronary angiogram performed at an outside facility revealed severe three-vessel native coronary artery disease with a totally occluded LAD past the first septal and diagonal branches, and a composite Y saphenous venous graft (SVG) that had a single origin and three limbs with three distal anastomoses (mid-LAD, obtuse marginal branch and distal right coronary artery) (Figure 1). The anastomosis of the venous graft with the LAD had a 75% stenosis, and the LAD had a total occlusion immediately past the anastomosis with a thrombolysis in myocardial infarction (TIMI) 2 distal flow. His left ventricular function was normal. Percutaneous therapy of the LAD occlusion was attempted at the outside facility,*

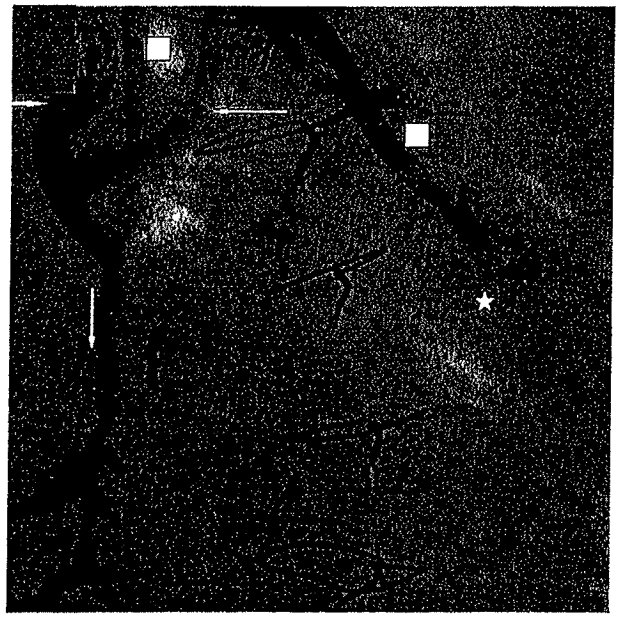

Figure 1. *Composite saphenous venous graft with a common origin (top left arrow), a first limb that goes to the distal right coronary artery (bottom down-oriented arrow), a second limb that loops up and down (rectangles) and is anastomosed to the left anterior descending artery (LAD) after two sharp angulations, and a third limb that connects to an obtuse marginal branch (right arrow). Note the stenosis at the anastomosis of the venous graft with the LAD and the total occlusion of the antegrade LAD beyond the anastomosis (star).*

Editor's Note: *"This case further highlights the difficulty we can face in some complex cases and its solution by providing extra back-up support using the GuideLiner catheter. Clearly, the GuideLiner should be reserved for challenging cases requiring extra back-up support."*

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The authors report no conflicts of interest regarding the content herein.

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Figure 2. *GuideLiner advanced 5 cm beyond the guide into the venous graft as an extension of the guide (horizontal arrow). It provides extra-support across the first venous graft angulation. FineCross catheter is advanced over the wire and provides the third line of support for wire pushability (vertical arrow), the three lines of support being the guide, the GuideLiner and the FineCross catheters.*

Figure 3. *Cutting balloon inflation across the venous graft-to-LAD anastomosis. GuideLiner provided enough support to advance the cutting balloon. LAD = left anterior descending artery.*

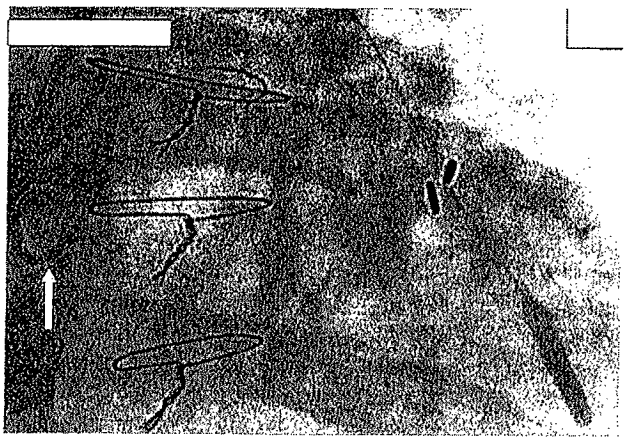

Figure 4. *Antegrade stenting of the totally occluded left anterior descending artery through the venous graft. Note how the GuideLiner is extra deeply intubated beyond the first graft angulation, thus providing the support needed for stent delivery (arrow).*

Figure 5. *Final angiographic result after culotte stenting of the venous-graft-to-retrograde left anterior descending artery (LAD) stenosis (top arrow) and venous graft-to-antegrade LAD occlusion (bottom arrow).*

but delivery of a guidewire and a support catheter through the SVG bends was not successful (a 6 Fr Judkins right 4 guide was used to engage the graft). The patient was placed on medical therapy then referred to us 3 months later for PCI. We accessed the right femoral artery, then engaged the SVG with a 7 Fr Judkins right 4 guide (after failure of our attempt to engage the SVG with an Amplatz left 1 guide). We advanced a GuideLiner catheter 5 cm beyond the SVG ostium up to the first SVG loop (Figure 2). We then unsuccessfully attempted to cross the CTO of the LAD using a PT Graphix wire (Boston Scientific Corp., Natick, Massachusetts) and the additional support of a FineCross catheter (Terumo, Japan) advanced distally in the SVG. Further attempts were performed using Whisper (Abbott Vascular, Abbott Park, Illinois), Confianza (Abbott Vascular) and PT 2 (Boston Scientific) wires, with no success (Figure 2). Subsequently, we decided to wire the retrograde segment of the LAD through the SVG and we treated the anastomotic lesion with a 3 x 6 mm cutting balloon, then with a 3.5 x 12 mm Promus® stent (Boston Scientific) extending from the SVG retrogradely into the mid LAD (Figure 3). Afterward, the flow significantly worsened in the distal LAD (TIMI 1 flow). At this point, we reattempted wiring the CTO using a PT 2 wire and were immediately successful, probably because of the modification of the CTO cap and angulation after adjacent stenting. The LAD was antegradely stented with a 2.75 x 20 mm Promus stent that extended into the SVG (the two stents overlapped in a culotte fashion) (Figure 4). Post-stent dilatation was performed with a high-pressure balloon. The final angiogram showed excellent flow in the LAD both antegradely and retrogradely (Figure 5).

Discussion. Guide support is critical in complex intervention and is improved by selection of larger guides (*e.g.,* 7 Fr), coaxial guides, guides with a large contact area on the opposite aortic wall and by the deep-seating maneuver. Several other techniques have been used to improve guide support in tortuous lesions and in CTO interventions.[2] These include guide stabilization by wire anchoring, wherein a stiffer wire is advanced in a proximal side-branch; guide stabilization by balloon anchoring, wherein a small

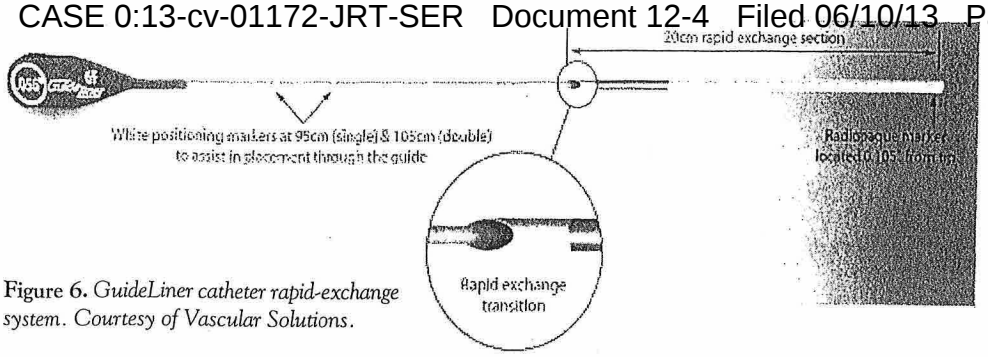

Figure 6. *GuideLiner catheter rapid-exchange system. Courtesy of Vascular Solutions.*

Table 1.

Size	Required Guide Inner Diameter	GuideLiner Inner Diameter	Rapid Exchange Length	Working Length
6 Fr (5-in-6)	6 Fr (≥ 0.070 inch)	0.056 inch	20 cm	135 cm
7 Fr (6-in-7)	7 Fr (≥ 0.078 inch)	0.062 inch	20 cm	135 cm
8 Fr (7-in-8)	8 Fr (≥ 0.088 inch)	0.071 inch	20 cm	135 cm

1.5 mm balloon is inserted in a small proximal branch or in the distal main vessel and inflated at low pressure, therefore preventing the guide from backing out. However, these techniques have caveats. Deep-seating may damage the coronary ostium and lead to ostial dissection or late ostial stenosis, while the anchoring techniques may lead to side-branch endothelial damage.

In addition, difficulty in advancing a stent may be encountered in tortuous and in calcified or diffusely diseased arteries. Several technical manipulations have been described to allow stent delivery:[3,4]

1. Optimization of guide support as described above;
2. Buddy-wire technique with a stiffer wire that allows guide stabilization but also straightens the arterial segment proximal to the lesion and allows less friction during stent delivery;
3. Treatment of a proximal calcified or rough plaque resistive to stent passage;
4. Changing the stent to a shorter stent or to a more flexible brand of stent.

These techniques may, however, fail. Our case illustrates the efficacy of the GuideLiner catheter in providing the support needed for crossing a CTO and for stent delivery in challenging cases. We used it up front due to previous failure in advancing a guidewire and a support catheter through the SVG. The GuideLiner is a flexible catheter that is 1 French size smaller than the guide catheter and that is delivered through the guide. It has a rapid-exchange design and is advanced over standard-length guidewires, with a monorail length of 20 cm and a working length of 135 cm (Figure 6). The GuideLiner extends beyond the guiding catheter and is seated deeply in the coronary artery, allowing support and coaxial alignment for advancement of guidewires, balloons and stents during coronary interventions. It also allows coaxial alignment when an unusual coronary ostium takeoff prevents appropriate guide engagement. While the extension is 20 cm long, a maximum extension of only 10 cm beyond the guide tip is recommended and has a silicone coating for lubricity. The GuideLiner is available in three sizes (Table 1): 6 Fr (5 Fr GuideLiner that goes inside a 6 Fr guide, therefore called "5-in-6" system), 7 Fr and 8 Fr. Most devices and coronary stents will fit through a 5-in-6 system. In light of its size, the GuideLiner is contraindicated in vessels that are < 2.5 mm in diameter.

The flexible and soft design of the GuideLiner allows atraumatic extra-deep intubation of the native coronary arteries and of arterial and venous bypass grafts, and is theoretically associated with a low risk of coronary injury in comparison to deep-seating of the guiding catheter. In fact, it has no primary curve to potentially damage and dissect the vessel. Moreover, it has a coil backbone that provides superior flexibility while retaining radial strength, and it can be seated much deeper than the guiding catheter. This allows advancement of a device through a tortuous or angulated or calcified proximal segment without getting exposed to friction with the vessel wall. One *in-vitro* experiment has shown that a 5 Fr catheter protruding by 5 mm into an arterial experimental system provided more backup than a 7 Fr guide catheter system.[5] Few reports have previously documented the efficacy and safety of the use of a "5-in-6" system in cases of tortuous or heavily calcified vessels or CTOs.[6-8] The initial 5-in-6 system consisted of an over-the-wire 5 Fr catheter *(Heartrail II, Terumo)*, but the current rapid-exchange design of GuideLiner is easier to use and allows delivery through the preexisting Y-adapter without limiting the effective length of devices used in the intervention.

Conclusion. We report the first case of GuideLiner use in complex native coronary artery intervention through a venous graft. The atraumatic deep-seating allowed by this device provided the extra support needed to cross a CTO beyond tortuous segments and to advance devices through sharp angulations. In addition, its monorail design allowed its easy advancement through the hemostatic valve and easy handling of balloons and stents.

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Exhibit 12

The GuideLiner "Child" Catheter for Percutaneous Coronary Intervention — Early Clinical Experience

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ABSTRACT: The failure to deliver a stent across the target lesion during percutaneous coronary intervention, especially in arteries with calcified tortuous anatomy, is often due to insufficient back-up support from the guiding catheter. Deep-vessel intubation with the guiding catheter may overcome this problem, but risks coronary dissection. The Heartrail II (Terumo, Japan) "five–in-six catheter system" (or "mother-and-child" catheter) comprises a flexible-tipped long 5 Fr catheter advanced through a standard 6 Fr guiding catheter to deeply intubate the target vessel, thus providing enough back-up support to enable stent delivery. Here we describe a newly developed "child" support catheter (The GuideLiner; Vascular Solutions, Inc., Minneapolis, Minnesota), report its successful use in a series of 4 difficult cases and discuss practical tips to optimize its performance.

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The failure to deliver a stent across the target lesion during percutaneous coronary intervention (PCI), especially in arteries with calcified tortuous anatomy, is often due to insufficient backup support from the guiding catheter. Commonly used methods to overcome this problem include vessel straightening with a second "buddy" wire[1,2] or "buddy" balloon,[3] the use of an anchor balloon[4] and the use of guiding catheters of larger caliber and more supportive shape. Deep-vessel intubation with the guiding catheter may also help, but risks coronary dissection. The Heartrail II (*Terumo, Japan*) "five-in-six catheter system" (or "mother-and-child" catheter) comprises a flexible-tipped, long (120 cm) 5 French (Fr) catheter advanced through a standard 6 Fr guiding catheter to deeply intubate the target vessel.[5-7] This system uses the target vessel itself to provide the extra backup support required for stent delivery. Furthermore, the absence of a primary curve and the flexibility of its tip permit the "child" catheter to remain coaxial with the target vessel, thereby minimizing the risk of catheter-induced coronary dissection. Here we describe a newly developed "child" support catheter[8] (*GuideLiner; Vascular Solutions, Inc., Minneapolis, Minnesota*), report its successful use in a series of 4 difficult cases and discuss practical tips to optimize its performance.

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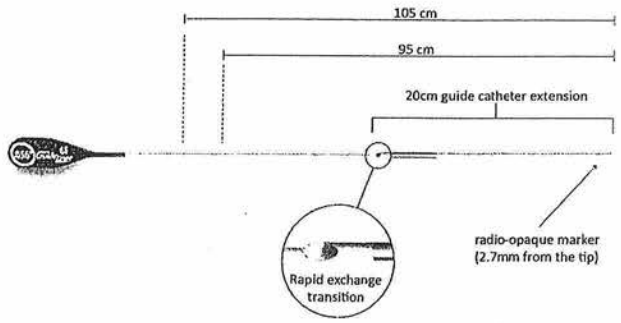

Figure 1. *The GuideLiner catheter. This consists of a flexible 20 cm straight guide extension connected to a stainless-steel push tube.*

Device and Technical Detail

The GuideLiner catheter is a coaxial guiding catheter extension delivered through a standard guiding catheter on a monorail. It comprises a flexible yellow 20 cm straight extension (internal diameter approximately one French size smaller than the guiding catheter) connected to a stainless-steel push tube, with a "collar" that can be deployed through the existing Y-adapter for rapid exchange delivery (Figure 1). It neither lengthens the guiding catheter nor requires a second hemostatic valve. The extension comprises an inner polytetrafluoroethylene (PTFE: Teflon) lining, surrounded by a stainless-steel coil (imparts flexibility and strength) and an outer layer of Pebax® polymer. Its silicon coating imparts lubricity.

Passage of the Guideliner through the guiding catheter is designed to be tight in order to prevent slippage. Delivery of the extension into the target vessel is aided by a radiopaque marker located 0.105" (2.66 mm) from the tip and white positioning markers on the push tube at 95 cm (single) and 105 cm (double) (Figure 2). The GuideLiner is currently available in three sizes: 5-in-6 Fr (internal diameter 0.056"), 6-in-7 Fr (0.062") and 7-in-8 Fr (0.071").

The GuideLiner catheter permits very deep intubation of the target vessel, thus providing backup support to facilitate stent delivery across heavily calcified lesions in tortuous vessels. The deeply-engaged extension is always aligned coaxial to the target vessel, and this is particularly useful if the takeoff of the coronary ostium prevents coaxial engagement of the guiding catheter. Furthermore, it enables the injection of radiocontrast

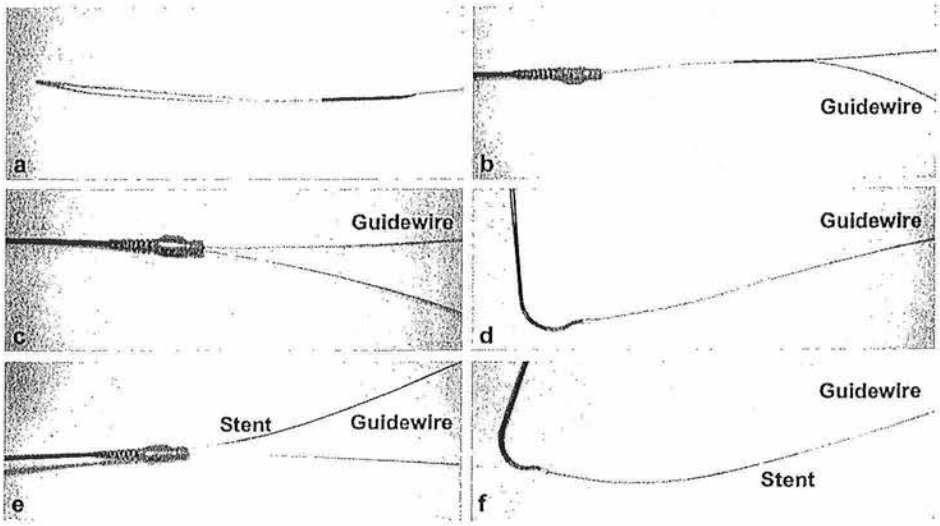

Figure 2. *Insertion of the GuideLiner.* (a) *The monorail GuideLiner catheter is inserted into a guiding catheter over a guidewire* (b). *Once advanced into the guiding catheter, the GuideLiner push tube can be advanced while holding the guidewire in place* (c). *The GuideLiner can be advanced up to 10 cm beyond the guiding catheter tip* (d). *Balloons or stents can be advanced along the guidewire* (e), *through the GuideLiner to the target lesion* (f).

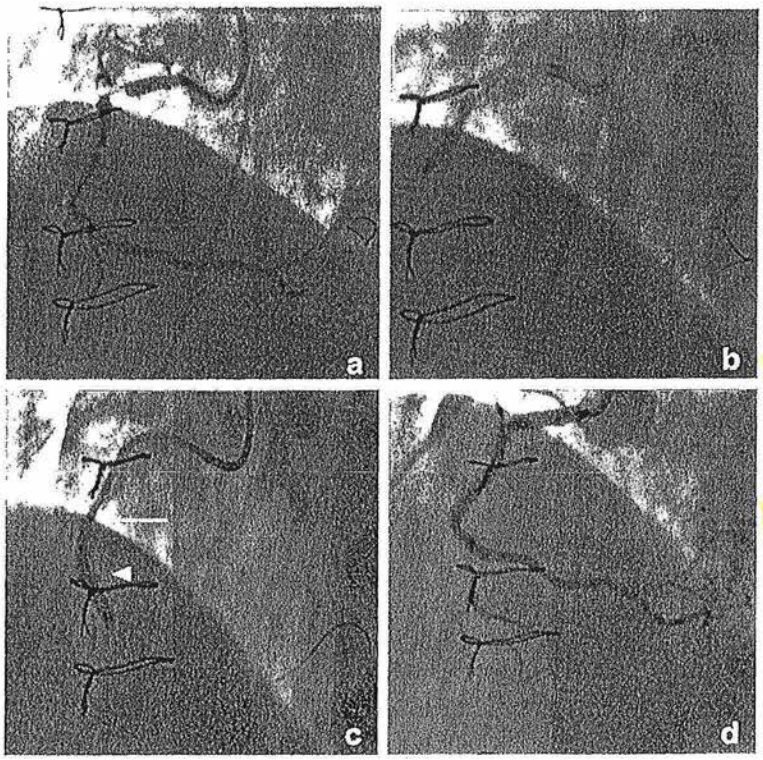

Figure 3. *Case 1: Percutaneous coronary intervention of a tortuous calcified right coronary artery (RCA).* (a) *Diagnostic angiogram of the RCA. Using an Amplatz Left 1 guiding catheter, the lesions were crossed with a BMW guidewire. Following balloon pre-dilatation* (b), *a stent could not be advanced.* (c) *The GuideLiner (arrow) was advanced up to the lesion to allow deployment of the stent (arrowhead).* (d) *Final angiographic result.*

close to the target lesion, improving its visualization. The manufacturer does not recommend its use in target vessels of < 2.5 mm diameter, in saphenous vein grafts, or in carotid artery intervention.

Case 1. Percutaneous intervention of a tortuous calcified mid RCA. *A 74-year-old patient who had previously undergone coronary artery bypass grafting was admitted with an inferolateral non-ST-elevation myocardial infarction (NSTEMI). His angiogram showed a moderate proximal stenosis of the left anterior descending artery (LAD) and a severe proximal stenosis of the small circumflex. The graft to the LAD was occluded, but there was a patent graft which back-filled the right posterior descending artery up to the crux. The right coronary artery (RCA) was tortuous and calcified, with severe stenoses of the proximal and mid vessel (Figure 3a), rendering the posterolateral territory a substrate for ischemia.*

Angioplasty to the native RCA was performed using a 6 Fr sheath inserted in the right femoral artery. An Amplatz Left (AL) 1 guiding catheter was used after failure to adequately engage the RCA with a Hockey Stick catheter. A Balance MiddleWeight (BMW) wire (Abbott Vascular, Santa Clara, California) was passed to the distal RCA. Despite predilatation of the mid-RCA lesion with both 2.5 x 15 mm and 3.0 x 15 mm Maverick balloons (Boston Scientific Corp., Natick, Massachusetts) (Figure 3B) and the use of a "buddy" balloon, a stent could not be delivered across the lesion due to a combination of vessel calcification and tortuosity. Therefore, a GuideLiner catheter was inserted into the 6 Fr guiding catheter, and the Guideliner tip was advanced up to the mid RCA to provide the support required for stent delivery (Figure 3c). This permitted the easy deployment of 4 overlapping drug-eluting stents from the mid vessel to the ostium of the RCA (3.5 x 15 mm, 3.5 x 18 mm, 3.5 x 23 mm and 3.5 x 8 mm Promus stents; Boston Scientific). After serial postdilatation of the entire stented segment with noncompliant balloons, a good final angiographic result was achieved (Figure 3d). The patient was discharged the following day without complications.

Case 2. Percutaneous intervention of severe in-stent restenosis of the RCA. *A 55-year old diabetic male had previously undergone coronary bypass surgery, and more recently angioplasty with multiple stents to the large native RCA (proximal and mid-thirds, and its posterolateral branch [PLA]). He re-presented with NSTEMI. Diagnostic angiography (Figure 4a) revealed the culprit to be restenosis*

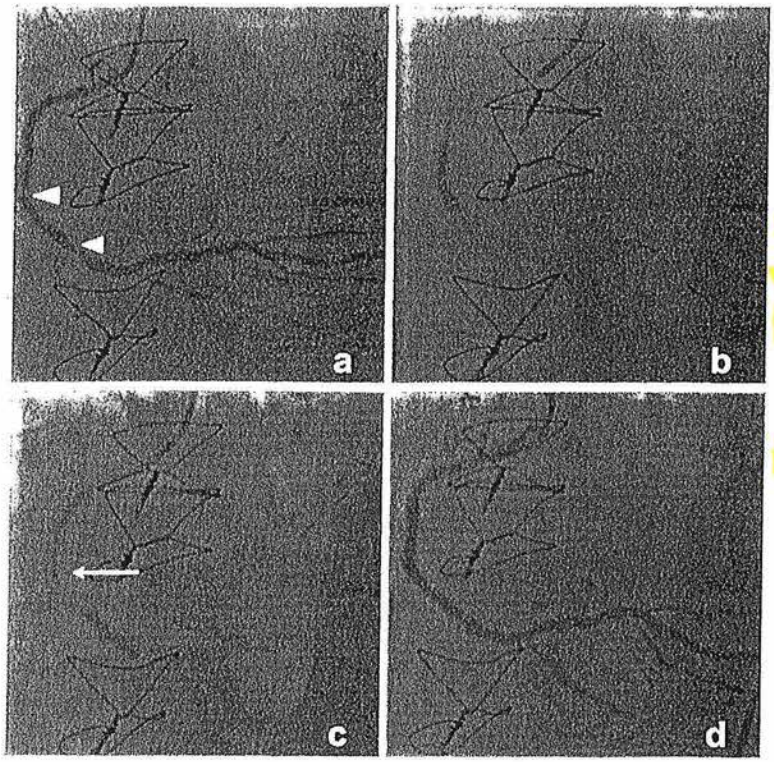

Figure 4. *Case 2: Percutaneous coronary intervention of a severe in-stent restenosis.* **(a)** *Diagnostic angiography revealed 2 severe focal segments (arrowheads) of in-stent restenosis in the right coronary artery (RCA).* **(b)** *Despite balloon predilatation, a stent could not be delivered across the mid-RCA stenosis.* **(c)** *Deep coronary intubation with the GuideLiner (arrow) permitted improved guiding catheter engagement and facilitated stent delivery.* **(d)** *Final angiographic result.*

of the RCA (severe at the mid-vessel and just proximal to the crux, subtending a very large posterolateral branch). Angioplasty to the native RCA was performed using a 6 Fr Hockey stick guiding catheter from the right femoral approach. A BMW wire was passed to the PLA. Despite serial predilatations of the mid and distal RCA with a 3.0 x 15 mm noncompliant balloon (Figure 4b), and despite employing a "buddy" wire, a stent could not be delivered across the distal lesion. This was in part due to the rigidity of the extensively stented vessel, and partly because the vessel could not be adequately intubated with the guiding catheter (leading to poor backup support). A 5 Fr GuideLiner catheter was passed down the RCA to the mid-vessel lesion (Figure 4c), enabling full intubation of the proximal RCA with the guiding catheter and permitting stent delivery to the distal restenosis (3.5 x 13 mm Cypher Select; Cordis Corp., Miami Lakes, Florida). The mid-RCA stenosis was treated with a 3.5 x 23 mm Promus stent (Boston Scientific). The final angiographic result was very good (Figure 4d).

Case 3. Percutaneous intervention of a chronic total occlusion of the RCA. *A 68-year-old male with stable angina underwent diagnostic angiography which revealed occlusion of the mid-RCA just distal to its right ventricular branch, and only minor branch disease in the left coronary artery. Angioplasty of the RCA was performed via the right femoral artery using a well-engaged 6 Fr AR1 guiding catheter. A Whisper MS (Abbott Vascular) wire was passed to the distal RCA, with the intraluminal wire position confirmed by retrograde filling from a contralateral injection of the left coronary artery. A 1.0 x 10 mm over-the-wire balloon was required to cross and predilate the lesion. Serial predilatations with a 2.0 x 12 mm Maverick (Boston Scientific) and a 2.5 x 12 mm Quantum Maverick balloon (Boston Scientific) were performed, but no stent could be passed beyond the tortuous proximal RCA. Therefore, a 5 Fr GuideLiner catheter was passed beyond the proximal RCA, employed to deliver a 3.0 x 28 mm Promus stent (Boston Scientific) across the mid RCA, and postdilated with a 3.5 x 12 mm Quantum Maverick balloon. The final angiographic result was very good.*

Case 4. Percutaneous intervention of a chronic total occlusion of the RCA. *A 77-year-old female developed recurrent angina 7 years after coronary artery bypass graft surgery. Diagnostic angiography revealed patent LAD and circumflex grafts and occlusion of the RCA vein graft. The native RCA was occluded in its mid course, with significant stenosis proximal to the occlusion (Figure 5a). The distal RCA was seen to backfill from a contralateral injection of the left internal mammary graft via distal LAD collaterals, which, owing to their epicardial location, were considered unsuitable for a retrograde approach to the RCA.*

Therefore, antegrade angioplasty of the RCA chronic total occlusion was undertaken via the right femoral artery using a 6 Fr FR4 guiding catheter. Firstly, the proximal RCA was treated with a 2.75 x 16 mm Promus Element stent (Boston Scientific) to facilitate the distal passage of equipment. The occlusion was successfully crossed (confirmed by contralateral injection) with a Pilot 50 wire (Abbott Vascular) and 1.0 mm over-the-wire (OTW) balloon support. However, it was not possible to pass any equipment across the occlusion (1.0 mm OTW balloon, 1.25 mm Maverick balloon, a Corsair catheter and a Tornus catheter all failed to cross), even with additional guide-catheter support from an "anchor" balloon placed in the right ventricular branch. Therefore, a 5 Fr GuideLiner "child" catheter was passed to the mid RCA (Figure 5b), after which a 0.9 mm laser catheter was employed, and this crossed the occlusion with ease. With the GuideLiner catheter in situ, serial predilatations of the occlusion were performed and 4 additional overlapping Promus Element stents were deployed (2.75 x 12, 3.0 x 12, 3.0 x 16 and 3.0 x 16 mm), with a good final angiographic result (Figure 5c).

Discussion

This is to our knowledge the first published case series of coronary intervention using the GuideLiner "child" catheter. All cases involved intervention of the RCA, for which extra backup support is often required. In some cases, stent delivery was impossible despite the use of a highly supportive guiding catheter, buddy wires and a buddy balloon. The GuideLiner

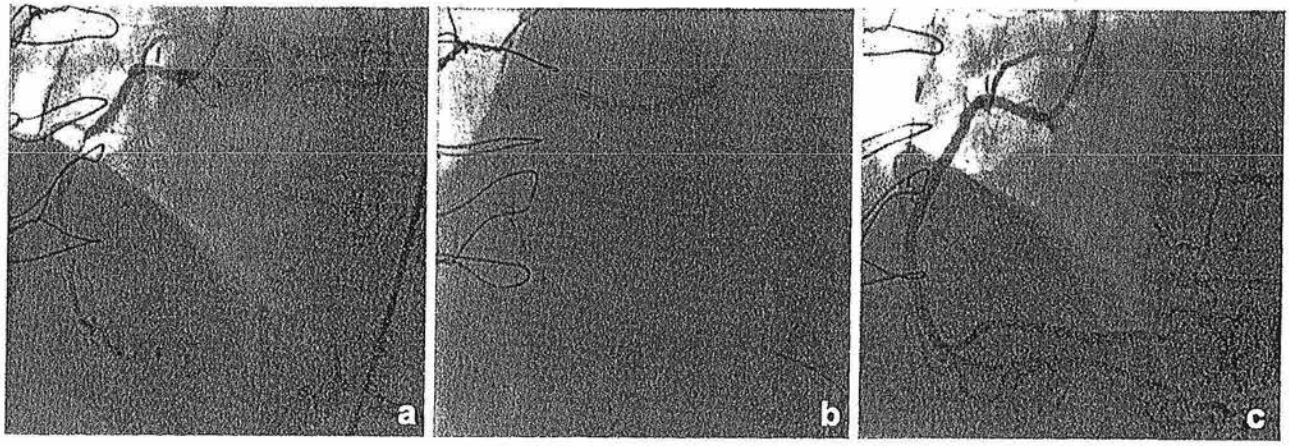

Figure 5. *Case 4: Percutaneous coronary intervention of a chronic total occlusion of the right coronary artery (RCA).* (a) *Diagnostic angiography reveals significant proximal stenosis leading into a chronic total occlusion of the mid-RCA.* (b) *The occlusion point is treated with a stent delivered through a deep-seated GuideLiner catheter.* (c) *Final angiographic result.*

catheter provided the additional backup support required for stent delivery. Deep target-vessel intubation was possible without displacement of the guiding catheter/wire or vessel trauma. Its safety relates to the flexibility of the guide extension and the absence of a primary curve, thereby minimizing the risk of catheter-induced target vessel dissection. Its coil backbone imparts both flexibility and strength to the catheter. Its use results in the loss of only 1 French size, so that almost all devices will still fit through a 6 Fr GuideLiner (internal diameter 0.056"). For a larger working lumen, the GuideLiner can easily be removed while the wires are left in place. Rapid exchange helps with deployment through the existing hemostatic valve without extending the guiding catheter length, and so does not limit the useable length of balloons and wires.

Tips for Optimal Performance

- The GuideLiner should be inserted through the guiding catheter over a 0.014" primary guidewire to a maximum of 10 cm beyond the guiding catheter tip under fluoroscopy. This limit is prescribed to avoid extending the collar over the secondary curve of the guiding catheter. Intubation by more than 20 cm will result in the whole extension exiting the guiding catheter.
- When inserting the GuideLiner into the guiding catheter, the flat push-tube should be oriented in a lateral position and should be further advanced without rotation to avoid wrapping of the guidewire.
- Deep-vessel engagement by the GuideLiner can be facilitated by passage of a balloon catheter over the primary wire into the distal vessel, followed by low-pressure balloon inflation. This acts as an anchor to support gentle advancement of the GuideLiner.
- Stents should be advanced through the GuideLiner over the primary guidewire, as secondary wires may wrap around the GuideLiner and obstruct stent insertion.
- In cases of resistance while inserting a guidewire or stent through the GuideLiner, the location of the wire or stent in relation to the metal collar of the GuideLiner should be checked and the stent inspected for signs of damage prior to readvancement. To correct any resistance that occurs at (or proximal to) the collar:
  - If a secondary wire is in use, check for wrapping of the secondary wire around the GuideLiner. If wire wrap is evident, consider pulling back the secondary wire and readvancing it. Alternatively, if the primary wire is still in place, consider advancing the stent over the primary wire.
  - If a stent continues to encounter resistance at the metal collar, pull the stent and guidewire back together 3–5 cm and try readvancing the stent and guidewire together through the metal collar. If resistance is again encountered, check the stent for signs of damage and either choose a lower-profile stent or change the guidewire.

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Exhibit 13