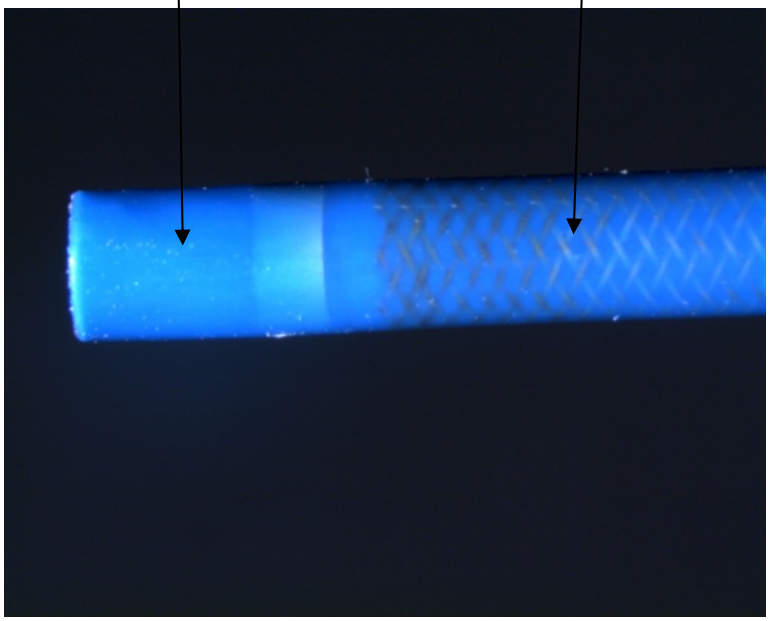
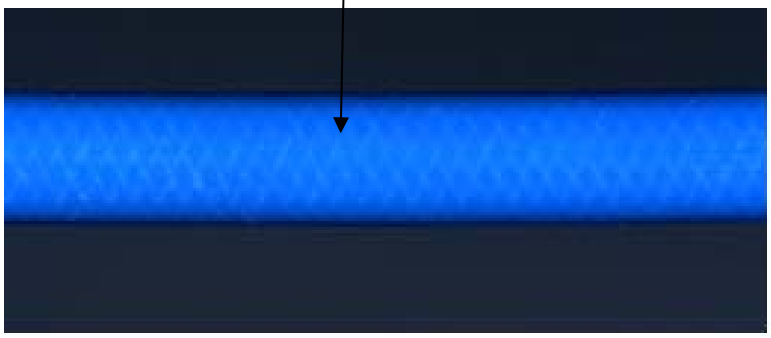
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,048,032, Claims 1-8, 11-17, and 19	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
modulus greater than the second flexural modulus.	First Flexural Modulus Second Flexural Modulus  Third Flexural Modulus 

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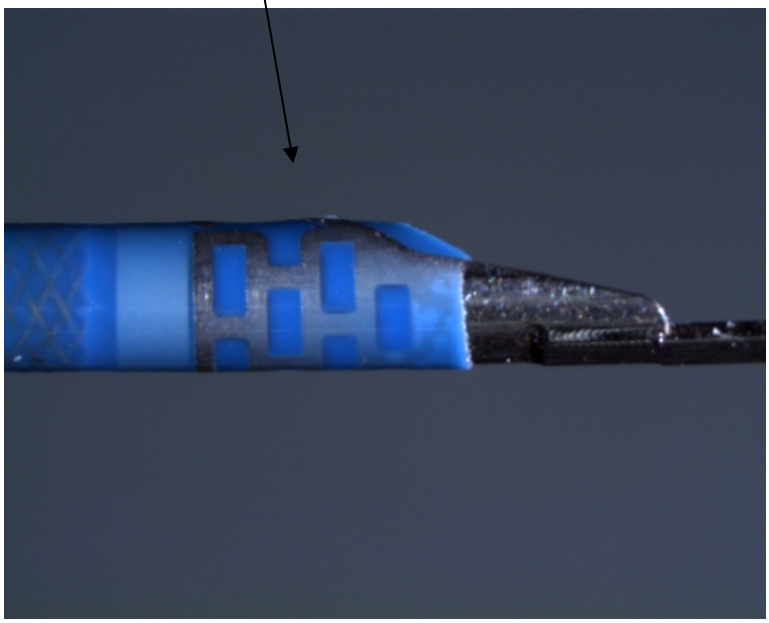
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	Fourth Flexural Modulus 

Exhibit 32

ARNOLD & PORTER LLP

Edward Han
Ed.Han@APORTER.COM
+1 202.942.5756
+1 202.942.5999 Fax
555 Twelfth Street, NW
Washington, DC 20004-1206

June 3, 2013

VIA E-MAIL & FIRST CLASS MAIL

J. Thomas Vitt, Esq.
DORSEY & WHITNEY, LLP
Suite 1500, 50 South Sixth Street
Minneapolis, MN 55402-1498

Re: *Vascular Solutions, Inc. v. Boston Scientific Corp.*

Dear Tom:

This will confirm our telephone conversations last week, in which you granted us a 30-day extension of the deadline for our answer or other response to the Amended Complaint, which will now be due on July 11, 2013. We are in the process of retaining local counsel and will have them contact you about documenting the extension.

With regard to your anticipated motion for preliminary injunction, you indicated that our opposition would be due 21 days after the motion was filed and that you would not seek more expedited briefing. If, after we have had a chance to review your motion, we believe we need more time, we will confer with you then.

You responded to our proposal for a meeting in June with our clients. In light of your client's determination to proceed with the preliminary injunction motion regardless, however, we do not believe that such a meeting would be productive at this time.

Substantively, although we have only recently begun our analysis of the complaint, we have already identified one issue that precludes not only Vascular Solutions' preliminary injunction motion but also its patent infringement claims in their entirety. Specifically, every independent claim of each of the asserted patents requires a substantially rigid portion "without a lumen." It is clear from the prosecution history that this limitation was added expressly to overcome examiner objections that would otherwise have prevented the patents from issuing. As is apparent from an inspection of Boston Scientific's accused device or the associated literature or labeling, if there is a

"substantially rigid portion" of that device for purposes of the claims, it could only be the portion of the device composed of a hypotube, which has a continuous lumen running its entire length. Accordingly, Vascular Solutions' patent infringement claims are unsustainable. Should you persist in asserting these claims, we reserve the right to seek appropriate sanctions at the conclusion of the case.

For at least this reason, the contemplated motion for preliminary injunction lacks merit and Boston Scientific will not delay the launch of the accused product. Unless you would like to discuss this further, you may assume that any obligation you may have to meet and confer regarding the preliminary injunction motion has been satisfied.

Sincerely,

Edward Han (dks)

Edward Han

cc: Matthew M. Wolf, Esq.
John Nilsson, Esq.

Exhibit 33

lumen

The definition of a lumen is the measure of brightness from a light source.

(noun)

An example of a lumen is the 13 lumens of a candle and the 1,200 lumens of a 100 watt light bulb.

See lumen in *Webster's New World College Dictionary*

noun pl. lumens or lumina

1. the basic unit used to measure the flow of light in the SI system, equal to the amount of light emitted through a solid angle of one steradian by a light source with the intensity of one candela (0.0015 watt): abbrev. *lm*
2. the bore of a hollow needle, catheter, etc.
3. ANAT. the passage within a tubular organ

Origin: ModL < L, light

See lumen in *American Heritage Dictionary 4*

noun pl. lu·mens or lu·mi·na **(-mə-nə)**

1. *Anatomy* The inner open space or cavity of a tubular organ, as of a blood vessel or an intestine.
2. *Abbr.* lm *Physics* The unit of luminous flux in the International System, equal to the amount of light given out through a solid angle by a source of

one candela intensity radiating equally in all directions. See Table at measurement.

3. *Botany* The cavity bounded by a plant cell wall.

Origin:

Origin: Latin *lūmen, an opening, light;* see *leuk-* in Indo-European roots

.

Related Forms:

- lu'men·al, lu'min·al *adjective*

Learn more about lumen

lumen *computer definition*
lumen *medical definition*
lumen *science*
lumen in a sentence

lu·men

pronunciation: lu mən

part of speech: noun

inflections: lumens, lumina

definition 1: a unit of measure of the flow of light, equal to the flow from a light source of one-candle strength, measured on a unit surface at a unit distance. (abbr.: lm)

definition 2: a hollow space, as in the bore of a hollow needle or in a bodily duct or tract.

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Exhibit 34

TEXTBOOK OF INTERVENTIONAL CARDIOLOGY

FIFTH EDITION

Eric J. Topol, MD

Director, Scripps Translational Science Institute
Chief Academic Officer, Scripps Health
Professor of Translational Genomics, The Scripps Research Institute
Senior Consultant, Division of Cardiovascular Diseases
Scripps Clinic
La Jolla, California

SAUNDERS
ELSEVIER

a patient who has clinical indications for the procedure. A balloon-tipped catheter is advanced to an area of coronary artery stenosis, the balloon is inflated, and the balloon is then deflated and the catheter removed. The patient must be pretreated with aspirin, and the procedure is performed in serial, logical steps to minimize risks and anticipate complications, demanding focused attention by the operator and the whole team.

It was necessary to gain a significant amount of knowledge about the balloon catheters, size of the original syringes, and pressures to ensure that the dilating force applied to the vessel was the correct amount.[13] In the beginning, the balloon catheters were large, not steerable, and inflexible, limited to accessing the coronaries, but these barriers were overcome in the mid-1980s with a diversification of the balloon angioplasty catheters.

Three types of guidewire interactions were developed. The earlier work was done with an on-the-wire (fixed wire) system,[32,33] which was limited by an inability to exchange balloons and by difficulty navigating the coronary artery. The over-the-wire system developed by Simpson and colleagues[6] in 1982 consisted of a guidewire passed through the balloon catheter lumen and independently guided down through the lesion. This system had good steerability, with the advantage that the balloon could be removed, but it was limited by needing an extension wire. Later, the monorail system[34] consisted of a short segment of catheter that slides over the guidewire, allowing introduction of the balloon after the lesion has been crossed without the need of an extension wire.

Another relevant aspect of PTCA is balloon compliance. The earlier balloons used by Gruentzig were made of PVC and were compliant. Subsequent balloons were compliant or noncompliant.

Longer balloons were developed to intervene in diffuse disease, serial lesions, lesions on a bend, or "tacking-up" dissections. The balloon to be delivered needs several favorable characteristics, including an appropriate profile, trackability, pushability, and lubricity. With experience, problems with the balloons, such as rupture, poor inflation or deflation, breakage, entrapment, or entanglement, became evident.

Because of expanded use of PTCA in higher-risk patients, such as those with multivessel disease, low ejection fraction, hypotension, or cardiogenic shock, the use of the intra-aortic balloon pump emerged as an important adjunctive device.[35]

Guiding Catheters

The guide catheter used for PTCA significantly differs from the diagnostic catheter. To perform PTCA, the guiding catheter should be larger and have lubrication, allowing smooth passage of the balloon catheter. The guide catheter also provides the platform to deliver a balloon in tortuous and often calcified coronary arteries.

Former guiding catheters were large (9.4 Fr) because the balloons were larger than their modern counterparts. Initially, the balloon catheters were made of polytetrafluoroethylene (Teflon, DuPont Co., Wilmington, DE) and were characterized by increased stiffness.[36] Significant improvements in the performance of guiding catheters have been possible with the use of stainless steel braiding that was implanted in the material of the shaft, improving torque control, and very thin Teflon liners were added to the internal lumen of the guiding catheter, enhancing lubricity.

Radiopaque soft catheter tips have reduced injury to the coronary ostium, allowing more manipulation of the guide catheter. Guide catheters provide outstanding backup for balloon transit.

Guide catheter selection is important. When faced with complex lesions and heavily calcified and tortuous vessels, the support that a guide catheter is able to provide can make the difference between a success and failure. If only balloon angioplasty is performed, the need for guide support is less compared with that required for stent implantation.

CLINICAL TRIALS OF PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY IN CORONARY ARTERY DISEASE

Overall, the objectives of coronary revascularization are the treatment of symptoms (e.g., angina), improvement in long-term survival, and prevention of nonfatal events (e.g., acute coronary syndromes, heart failure, arrhythmias). Although the risks of serious complications are small, careful patient selection must be undertaken before proceeding with PTCA. For instance, in the multicenter NHLBI Registry of PTCA experience from 1985 to 1986 of intervention in patients with single-vessel disease, the incidences of procedure-related death, nonfatal MI, and coronary artery bypass grafting (CABG) were 0.2%, 3.5%, and 2.9% respectively.[9]

Initially, clinical and angiographic criteria for candidates for PTCA were very restrictive. Patients had to have significant angina and considerable evidence of myocardial ischemia, and be suitable candidates for coronary artery bypass surgery, with preserved left ventricular function; single-vessel disease; and discrete, noncalcified, proximal stenosis. With these criteria in the Coronary Artery Surgery Study (CASS), only 3.7% of patients were eligible for PTCA.[37]

The original indication for PTCA was for chronic stable angina due to single-vessel disease with preserved ventricular function,[38] producing high success rates (>90%) for the treatment of simple lesions.[9] This indication evolved, and the use of PTCA expanded to many patients with coronary artery disease; initially, it was applied empirically, but later randomized trials confirmed its efficacy in stable coronary artery disease.[39] The ultimate success of PTCA is determined by patient characteristics, lesion characteristics, technique and devices, and the physicians' experience, underscoring the idea that PTCA is in some ways an art to be mastered.

intervention without distal protection. In most of the patients studied (60%-80%),[67-69] the devices successfully removed debris in the form of fresh thrombus, chronic thrombus, atheromatous fragments, and cholesterol clefts. Despite promising initial data, the use of these devices is not currently recommended, and additional investigation is needed before their use would become routine or mandatory.

Future Trials

Future trials should focus on demonstrating the impact of renal artery intervention on survival, major cardiovascular events, hypertension, and renal function. The role of EPDs and the benefit of drug eluting stents should be clarified. Several ongoing trials should provide new insights into these matters.

The Cardiovascular Outcomes of Renal Artery Lesions (CORAL) trial[70] is a randomized clinical trial comparing medical therapy alone versus stenting with medical therapy on a composite cardiovascular and renal end point: cardiovascular or renal death, myocardial infarction, hospitalization for congestive heart failure, stroke, doubling of serum creatinine, and need for renal replacement therapy. Effectiveness of revascularization in important subgroups of patients, improvement in quality of life, cost-effectiveness, and correlation between stenosis severity and longitudinal renal function will also be analyzed. The study will include 1080 patients with significant RAS (at least 60% stenosis with 20 mm Hg systolic pressure gradient or at least 80% stenosis with no gradient necessary) and hypertension (systolic hypertension of at least 155 mm Hg with at least two antihypertensive medications).

The Nephropathy Ischemic Therapy (NITER) trial[71] is an ongoing prospective, multi-center, randomized trial that is comparing medical therapy alone (antihypertensive, lipid-lowering, antiplatelet medications) with medical therapy plus renal artery stent placement. The study includes patients with RAS (70% or greater stenosis), hypertension, and stable renal failure (glomerular filtration rate [GFR] =30 mL/min). The combined primary end point includes death, dialysis initiation, or reduction of 20% or more in the GFR.

ASTRAL[72] is another multicenter, prospective, randomized, controlled trial that will include about 1000 patients with atherosclerotic RAS treated with percutaneous revascularization (balloon angioplasty and/or stent placement) or best medical therapy. The follow-up will be between 1 and 5 years, and the primary comparison end point is the rate of progression of renal failure. Secondary analyses will include blood pressure changes and cardiovascular events. Prespecified subgroup analyses will try to clarify the influence of important baseline characteristics on renal function outcome (e.g., baseline renal function, severity of RAS, ultrasound renal length).

PECTS

A low-osmolar or iso-osmolar, non-ionic contrast agent is sufficient for good visualization of the renal arteries. When DSA radiographic techniques are used, the contrast can be diluted (heparinized saline) to two-thirds strength and still produce a diagnostic-quality angiogram. Carbon dioxide or gadolinium may be used as a contrast agent to minimize iodinated contrast use in patients with compromised renal function (creatinine clearance<20 mL/min). However, the images produced with these agents are not of equal quality to those produced with the use of iodinated contrast material.

Another alternative is to use a 1:1 combination of gadolinium and an iodinated contrast agent. Carbon dioxide is a reasonable option for performing initial aortography to identify the number and location of renal arteries. Both of these alternatives, however, result in a compromise in image quality.

Access Site

The femoral approach is used in most cases (>90%), and some centers prefer to use contralateral access to the renal artery to be treated. Occasionally, upper extremity access (e.g., brachial approach) may be used in case of caudal takeoff of the renal artery, severe bilateral aortoiliac disease, or infrarenal abdominal aortic aneurysm.

Diagnostic Procedure

Usually a 4-, 5-, or 6-Fr sheath is used. Many authors prefer to use longer sheaths (23 cm) with radiopaque tips. For the aortogram, a 5-Fr Omniflush, straight flush, tennis racquet, or a pigtail catheter may by used. The catheter should be configured in the infrarenal abdominal aorta to minimize the likelihood of renal atheroembolism. The pigtail catheter and straight flush catheter sometimes result in more cephalic contrast injection, which could opacify the superior mesenteric artery and potentially obscure visualization of the renal arteries. The Omniflush catheter was designed to avoid this problem. The top of the flush catheter should be placed at the level of the superior margin of the first lumbar vertebra (L1) for optimal imaging. An alternative anatomic landmark is the superior apex of the left kidney, assuming that the right kidney is lower. DSA radiographic techniques should be used. The aortogram gives an idea about the configuration and the presence of pathology in the aorta. It identifies the number and location of renal arteries on either side and allows the operator to make an appropriate catheter selection for selective renal artery engagement. If a previous aortogram or renal angiogram is available for review, this first step should be skipped in the interest of reducing contrast volume and therefore minimizing the risk of contrast nephropathy. Previously deployed

stents can also be used as reference to proceed directly to selective engagement of the renal arteries.

To selectively engage the renal arteries, a 4- to 5-Fr diagnostic catheter at least 80 cm long is usually used. The shape of the catheter selected depends on the anatomy of the aorta and geometry of the takeoff of the renal arteries. Catheter shapes available for renal use include the Judkins right catheters (e.g., JR4), internal mammary catheter, renal standard curve catheter, renal double curve catheter, Cobra catheter, and SOS Omni II catheter (for difficult angulation). Great care should be exercised in manipulating a catheter in the region of the renal artery ostium to minimize the likelihood of atheroemboli or dissection complications. Occasionally, a 0.014-inch steerable medium- to high-support guide wire is used to traverse the extraparenchymal length of the renal artery before performing selective angiography. This tends to hold the catheter in place and prevents the diagnostic catheter from backing out during injections. It also allows for convenient subsequent intervention. Once the selective diagnostic catheter is in the renal ostium, a gently ramped but brisk hand injection of a small volume of contrast material can be administered, and imaging should be continued until the nephrogram is seen in its entirety.

In terms of angiographic views, the preference varies among different institutions and physicians. Shallow ipsilateral oblique projections (10-20 degrees), straight posteroanterior (PA) projections, and shallow contralateral oblique projections have been used. However, an adequate perpendicular view to the plane of the renal artery and aorta is preferable to assess the severity of the lesion or lesions. A cross-sectional image obtained by CTA or MRA can sometimes provide a good estimate of the necessary angle.

Interventional Procedure

Several guiding catheter shapes may be used (e.g., hockey stick, internal mammary artery, JR4, renal standard curves, multipurpose, SOS Omni II), usually in a 6- or 7-Fr, 65-cm size. In the telescoping technique, the diagnostic catheter is introduced through the guiding catheter, which enables subsequent atraumatic engagement with the guiding catheter over the diagnostic catheter for proceeding with intervention. Alternatively, the "direct engagement technique" may be used. In this technique, the catheter is primarily advanced into the ostium, which may result in trauma and embolization. A variation of this technique is the "no touch" technique, in which the tip of the guide catheter is placed near the ostium of the renal artery using a 0.035-inch guide wire, avoiding direct contact between the tip of the catheter and the ostium of the renal artery. Once the guide catheter is in the vicinity of the renal artery ostium, a 0.014-inch guidewire is used to engage the artery. The guide catheter can be gently advanced using the 0.014-inch guidewire as a monorail.

Presently, there is a trend toward the use of 0.014-inch guide wires, balloons, and stents in percutaneous renal revascularization. This trend opens the wide range of coronary wires, balloons, and stents to the renal intervention arena, in addition to equipment specifically designed for renal artery intervention using the 0.014-inch platform. Alternatively, 0.035-inch or 0.018-inch guide wire platforms may be used with the appropriate balloon and stent system. Hydrophilic guide wires should be used only when difficulty crossing the renal ostium is encountered due to the risk of dissection or perforation. Once the hydrophilic wire has been used to accomplish access, it should be exchanged for a different wire with a nonhydrophilic tip.

Monorail (rapid exchange, RX) balloons are preferred when using a 0.014-inch system. Alternatively, over-the-wire (OTW) balloons with a short shaft may be used. Generally, balloons 3.5 mm to 4 mm in diameter and 8 to 15 mm in length are used for predilatation of a renal stenosis. Some centers use as reference 1 mm less than the apparent normal vessel diameter to choose the predilatation balloon diameter. Smaller-diameter balloons may be required for initial angioplasty for a high-grade stenosis, large volume plaque, or subtotal occlusion. Longer length balloons may create an unnatural force on the renal artery and ultimately cause spasm or even dissection. OTW balloons may be useful for exchanging wires, especially if the initial wire used was one with a hydrophilic tip (although these wires are generally to be avoided). Postdilation balloon size selection varies depending on the size of the artery and stent. However, it is a good idea to have balloons between 4 and 8 mm in diameter available (bearing in mind that many 8-mm balloons do not fit through a 6-Fr guiding catheter). Systematic postdilation is recommended after deployment of ostial stents in order to flare the proximal end of the stent at the ostium into the aorta.

Balloon-expandable stents are used and are generally available in lengths of 12 to 20 mm and in diameters of 5 and 7 mm. Self-expanding stents have been used in to treat midsegment lesions but are not recommended for ostial or proximal renal artery lesions. Although stents with an open-cell design have more flexibility, those with a closed-cell design are preferred because they provide, in general, the most radial strength at the renal ostium. In most cases, it is essential to ensure complete coverage of the renal ostium, and sometimes the proximal stent will have to extend back into the aorta by 1 to 2 mm in a segment (arc) to achieve full circumferential coverage of the renal ostium.

EPDs may be used, but they are not currently mandatory nor recommended. If the operator decides to use such a device in a patient considered to be at high risk for embolization, essential technical aspects must be kept in mind. An adequate landing zone for the EPD must be present downstream of the target lesion. The EPD must be of adequate diameter to appose the entire circumference of the renal artery (coronary distal protection devices may not be large enough to

ensure complete vessel apposition). Early branching of the main renal trunk is highly unfavorable for the use of an EPD. It is useful to have a monorail version of the EPD available for use in the renal artery. On rare occasions, a "buddy" 0.014-inch wire is used if there is difficulty navigating through the lesion or the length of the artery. In the presence of a critical lesion, predilation may be necessary to safely advance the EPD.

In terms of the use of procedural anticoagulation and antiplatelet medication after the procedure, there is a paucity of scientific evidence. Many centers start antiplatelet aggregation monotherapy before the intervention. During the procedure, intravenous heparin is used as anticoagulation therapy and is titrated to maintain the activated clotting time (ACT) between 250 and 300 seconds. The use of glycoprotein IIb/IIIa inhibitors is not recommended, but they have been used in cases of acute thrombosis.[73] Bivalirudin was used in a prospective, single-arm study that showed it to be a safe alternative in terms of procedural anticoagulation.[74] Dual antiplatelet therapy (aspirin and clopidogrel) is currently used in many centers. The rationale for use of most of these therapeutic agents is extrapolated from coronary trials.

Complications and Follow-up

The equipment used to perform percutaneous renal artery revascularization has changed dramatically in the last decade, and the procedure has become safer and more reliably successful. However, deterioration in renal function is still the most important complication of the procedure and can be multifactorial (e.g., contrast toxicity, embolization, incorrect patient selection). Every effort should be made to avoid using an excessive volume of contrast material, and great care should be exercised in the manipulation of catheters and devices to reduce the risk of contrast nephropathy and embolic debris resulting in renal parenchymal damage. Both of these goals can be achieved by avoiding bilateral renal artery interventions in the same procedure. Other complications are less frequent but should also been kept in mind, because they can result in mortality and contribute to renal function deterioration.

Atheroembolism or thromboembolism to the distal renal artery branches: If embolization is documented during the procedure; treatment depends on the distal extent of the embolization. A more proximal, branch vessel embolus can be aspirated with commercially available aspiration catheters. A more distal or parenchymal-level embolus is more difficult to treat or manage. Infusion of a glycoprotein IIb/IIIa inhibitor may be used on a theoretical basis, but no direct clinical data exist to support its use in this setting.

Occlusion or thrombosis of renal artery: Either occurrence is another potential indication for the use of glycoprotein IIb/IIIa inhibitors and thrombectomy devices.

Renal artery dissection: If this occurs in the ostium or proximal artery segment, it should be treated by placing a stent. If a dissection occurs in a more distal (extraparenchymal) artery segment, then balloon angioplasty is the best option, because stent implantation compromises any possibility of a successful bailout surgery (though surgery usually is not an option if a distal bypass target is no longer present). If dissection occurs in a more distal (intraparenchymal) artery segment, only undersized balloon angioplasty is possible, because more aggressive angioplasty or stent implantation risks injury to the surrounding renal parenchyma.

Renal artery/aortic perforation: Extra caution and care is mandatory when stenting a renal artery adjacent to an aneurysm in the renal artery or aorta. Oversized stents or aggressive post-stent dilation should be avoided. Patient-reported flank pain during balloon inflation is usually a sign of reaching the maximum safe luminal diameter of the target artery, and further inflation is not recommended. The flank pain is the result of stretching the pain receptors located in the adventitia of the target artery segment. If a renal artery perforation does occur, a prolonged balloon inflation and/or reversal of procedural anticoagulation can safely treat a small perforation. In the setting of a larger perforation, a covered stent or a perfusion flow-balloon may be useful, and anticoagulation should be reversed. Surgery is a potential option for treatment of a larger perforation or a perforation that is not responsive to endovascular treatment. To maximize the benefit of the surgical option, early communication with a skilled surgeon is necessary.

Parenchymal perforations/perinephric hematoma/retroperitoneal hematoma: Extra caution and care are mandatory when using hydrophilic coated or stiff guide wires. The distal tip of the guide wire should not be allowed to migrate out to the level of the renal cortex. Guide wire migration out to the level of the renal cortex increases the risk of distal artery perforation. Hemorrhage at this level can be intraparenchymal or extraparenchymal. Hemorrhage at either level results in local tissue injury and hydraulic tissue dissection, creating more sources of hemorrhage. If a distal artery perforation is noticed during the procedure, anticoagulation should be reversed and consideration made for temporary proximal flow occlusion with a balloon to control the hemorrhage. If proximal flow occlusion and reversal of procedural anticoagulation is unsuccessful in controlling the hemorrhage, prompt microparticle or microcoil embolization at the site of hemorrhage may be performed. If efforts at controlling hemorrhage are unsuccessful, the patient will require emergency surgery to control the hemorrhage and decompress the accumulated blood and clot. The risk of nephrectomy in such a circumstance is high.

Stent embolization: Dislodgement of the stent from the deployment balloon platform occurs less frequently with premounted or manufacturer-mounted stents compared with hand-crimping of a loose stent

The Evolution of Cardiac Catheterization and Interventional Cardiology

Edited by

Michel E. Bertrand
Lille Heart Institute
Lille, France

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St Albans AL1 5NW, UK

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The Evolution of Cardiac Catheterization and Interventional Cardiology
Michel E. Bertrand

Chapter 14

The monorail technique

Tassilo Bonzel

Introduction

By virtue of the impetus engendered by his courage and pioneering spirit, Andreas Gruentzig not only developed a new method of medical treatment, but he also inspired and motivated numerous curious young researchers and physicians. They worked with and began to improve the simple instruments that Gruentzig had to make do with, which, in retrospect, appear so rudimentary. So did I. Mulling over the problem and pencilling in ideas on a sketch block ultimately resulted in the first prototype model that was tested on my kitchen table. How impatient were my wife, Helen, and I when the first prototypes were locked away over Christmas and New Year 1984/85 in the closed custom office in Freiburg and we had no access to them. It is also remarkable that the really seminal ideas came from the physicians using these instruments and not from the engineers who afterwards developed the technology. The physicians knew what was needed and what had to be improved. The development work was mostly carried out by young companies with just as much pioneering spirit, in this case at the Schneider Company in Zurich. The development of the monorail technique is exemplary for successful implementation of an idea born out of practical experience until it became the accepted standard.

In the interest of clarity, I should like to draw attention to an exceptional feature. Relatively "simple" modifications to existing balloon catheters for the construction of a monorail catheter led to crucial changes in their application and handling. This in turn prompted a large number of new diagnostic and therapeutic catheter applications.

The technical situation at the onset of coronary intervention

Gruentzig's objective was to dilate arterial stenoses. The essential idea was to use an inelastic inflatable cylindrical balloon that could be deflated again (1, 2). The intention was to compress the material that had given rise to the stenosis in the wall of the artery. For this purpose, the balloon was fixed to the tip of a long dual-lumen catheter: it could be filled with fluid under high pressure and dilated. The result of the dilatation was determined on the basis of the pressure gradient across the stenosis that was measured via the second lumen filled with saline. At that time, x-ray technology was still poorly developed and the imaging of the coronary stenosis was often unsatisfactory. Initially, Gruentzig used catheters with such balloons in predominantly straight peripheral arteries, e.g. in the legs. He also aspired to use these catheters in life-threatening coronary stenoses. Although he revolutionized the treatment of coronary heart disease (3), it soon became apparent that, despite individual improvements, the catheters tested on peripheral vessels were not well suited for the coronary arteries since these arteries are far away from the site of puncture, have a tortuous course, and branch off.

The first catheters that were made specifically with coronary arteries in mind were the balloon catheters developed by Simpson with an independently movable wire running the entire length of the catheter (4). The curved tip of this wire was J-shaped and was fitted with a soft flexible spiral. Such a "coronary catheter system" could be manoeuvred into the main branches and side branches of the coronary system by rotating and advancing the wire and pushing the balloon behind it. The important stipulation of cardiologists with regard to steerability was thus fulfilled, while it remained possible to measure the gradient.

Gruentzig's successful principle of an inelastic cylindrical balloon for dilating the stenosis required balloons of a diameter exactly corresponding to the width of the stenosed vessel. However, at that time, the balloon materials were not very far advanced, so that a balloon that had to withstand 12 and more atmospheres pressure was difficult to fold up to a very small cross-section when empty. First of all, a balloon of small diameter was used for predilatation in very narrow stenoses and later

exchanged for a larger balloon. The stenosis that had in the meantime been traumatized by the predilatation had to be located once again and passed for a second time, entailing a high risk. In order to avoid this, Kaltenbach lengthened the steerable guide wire to 3 m; he left it in the coronary artery during the exchange of the balloon catheter in such a way that the tip reliably remained beyond the stenosis (5). This method was a major advance, but required lengthy fluoroscopy times during the exchange of the balloon catheters, the presence of at least one assistant, and a great deal of skill in keeping the tip of the wire in place a few millimetres distal to the stenosis, while the balloon catheter was pushed and pulled along the 3 m long wire.

This met the requirement of a second principle that is important for the coronary arteries, the exchange capability of balloon catheters.

The monorail concept

Early in 1980, a new biplane fluoroscopy device for cardiac catheterization, the first Biangioscope C from Siemens, was foresightedly put into service for the upcoming dilatations by Professor Just, the head of the cardiology division at the University of Freiburg. We could thus at last identify the terrain of coronary angiography under fluoroscopy and start coronary dilatation. The ramus interventricularis anterior (RIVA) stenosis of the first patient was dilated at the beginning of May 1980 with a Gruentzig catheter.

After introduction of the steerable coronary catheter, we also discovered the advantages of the long wire technique in Freiburg and made every effort to meet the demands posed by the long wires. As important as the exchange of balloon catheters may have been at that time, this cumbersome long wire technique was all we could conceive at the time. We had to find something better.

I listened to the first international presentation of coronary dilatations by Andreas Gruentzig at the meeting of the American Heart Association in Miami in November 1977 with great fascination, but also with scepticism. Gruentzig presented four successful dilatations with his first coronary balloon catheter system. The procedure was looked on as a curiosity, and the Gruentzig lecture was regarded as an insider's tip for cardiologists familiar with catheter techniques.

I had made the journey to Miami from Syracuse, where I had learned to perform cardiac catheter investigation under Professor Gensini, a pioneer and expert in diagnostic coronary angiography. In Gensini's department, among other people I met were Sones and Favaloro. Meanwhile, Sigwart was conducting the first dilatations under the direction of Professor Gleichmann at my home hospital in Germany, at the Gollwitz-Meier Institute in Bad Oeynhausen, from where I had started my journey to America. From 1977 to 1980, coronary dilatations passed through an experimental phase in Germany (where it was controlled by Gruentzig) and a few other centres elsewhere in the world. In 1980, the level of experience appeared to be sufficiently high for the method to be released for use in further centres where the necessary instruments were available. At that time, there was a danger that the still very imperfect coronary dilatation would be so discredited by complications caused by ill-considered application that it would be stopped by the influential critics who publicly rejected this method. For the cardiologists working manually with the catheter, coronary dilatation and all the concomitant phenomena of this pioneer period exerted a strong fascination and fuelled their desire to promote improvements with ideas of their own.

We must recall that the development of the major components important for the success of coronary dilatation, i.e. the guide wire, the balloon catheter, and guide catheter, were not very far advanced. The profile diameters of the components were large, and injections of contrast medium were correspondingly difficult. The stability, torqueability, and kink resistance were unsatisfactory. Smoothening of the surfaces with lubricant substances was unknown. All individual steps were therefore more laborious and time-consuming and entailed greater risks. In practice, steerability and exchangeability were possible, but were often so imperfect that an operation could not be carried successfully to completion, for example because the wires slipped owing to the high frictional forces and a partially dilated stenosis could not be passed again when dissection started.

These shortcomings of materials and a lack of experience entailed major risks to the patients. These risks could not be substantially reduced even by forming good teams well versed in the exchange of balloon catheters (in Freiburg, with Wollschläger and Wink). It was against this background that I was looking intensively in 1983 for possible means of exchanging balloon catheters easily and safely.

I used to think about this problem night and day. The best ideas come to me at night when half asleep, when out walking, or at concerts. Intense reflection led to the

following question: why does one need a guide wire with a length of about 3 m to exchange a balloon? The answer was because the operator could no longer hold the end of a normal wire about 170 cm long when the shaft of the balloon catheter was retracted out of the body. This simple experience accorded with the principle of the coaxial procedure, which was firmly established at that time as standard in any kind of catheter investigation. Even today, this remains the conventional approach in most investigations. Nevertheless, a better solution was not to exchange or to lengthen the wire, but to alter the catheter shaft in such a way that the wire could still be held in the hand even when the catheter was being retracted. For this purpose, one would have to open up the tube of the catheter shaft, so that the shaft would no longer coaxially envelop the wire, but run in parallel to the exposed wire.

The conventional coaxial principle was therefore abandoned. Starting from the proximal, one could open the shaft as far as to reach the balloon: the balloon catheter then has only a short distal coaxial segment which runs on the guide wire. In the extreme case, this segment may be as short as the balloon (**Figure 14.1**). I have termed such a balloon system a "sliding rail" system (6,7). Later, the term "monorail" was coined by Bernhard Meier, who was in Geneva at that time (**Figure 14.2**).

The alteration in the construction of the catheter brings about major changes in the procedure. The guide wire and the balloon catheter are introduced separately. There are appreciable advantages in first advancing the standard-length guide wire and threading it across the stenosis; it can be moved with little friction within the large-diameter guiding catheter. It also leaves enough space for injections of contrast medium (**Figure 14.3**) and before passing the stenosis it can be easily retracted, exchanged, and given a new curve, so that it is quick and easy to handle. When the tip of the wire has passed the stenosis, the monorail catheter is loaded onto the proximal end of the wire, on which it slides through

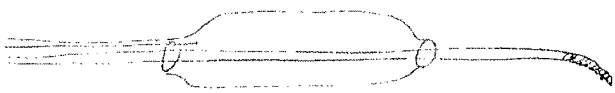

Figure 14.1 First freehand sketch of the sliding rail balloon coronary dilatation catheter (later "monorail"), drawn in 1983. The purpose of this drawing was to explain the functioning of the invention, i.e. sliding of the balloon on the (normal length) guide wire pushed by the shaft.

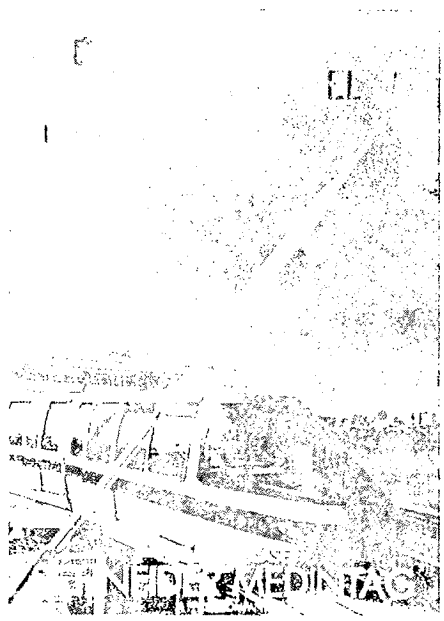

Figure 14.2 Early promotional poster depicting a monorail balloon catheter system with typical side opening for the guide wire exit and the "Monorail Train" in Vancouver. The term "monorail" was the idea of Bernhard Meier.

the body of the patient into the coronary artery and into the stenosis.

In a similar way, the balloon catheter can be retrieved again and exchanged for a new one. The guide wire can be held in the hand at any time during the advancement, retraction, and exchange of the balloon catheters. The tip of the guiding catheter can also be kept securely in place distal from the stenosis. The only function of the shaft of the balloon catheter now is to advance and to retract as well as to fill and empty the balloon over a hollow space. The cross-section of the shaft is thus reduced, i.e. the shaft becomes thinner. More space is left in the guide catheter, so that injection of contrast medium is facilitated and imaging of the stenosis can be improved; miniaturization of the systems can also progress. Standard guide catheters had been reduced in size from 9 French to 5 or 6 French in the meantime, which corresponds to a reduction in cross-section by about 70% or 55%

After I realized that it was not necessary to lengthen the wire but rather to open the shaft of the catheter in order to enable a firm hold on the standard-length wire, everything fell into place. The practical significance of the idea came to me immediately: I was excited from that first moment onwards.

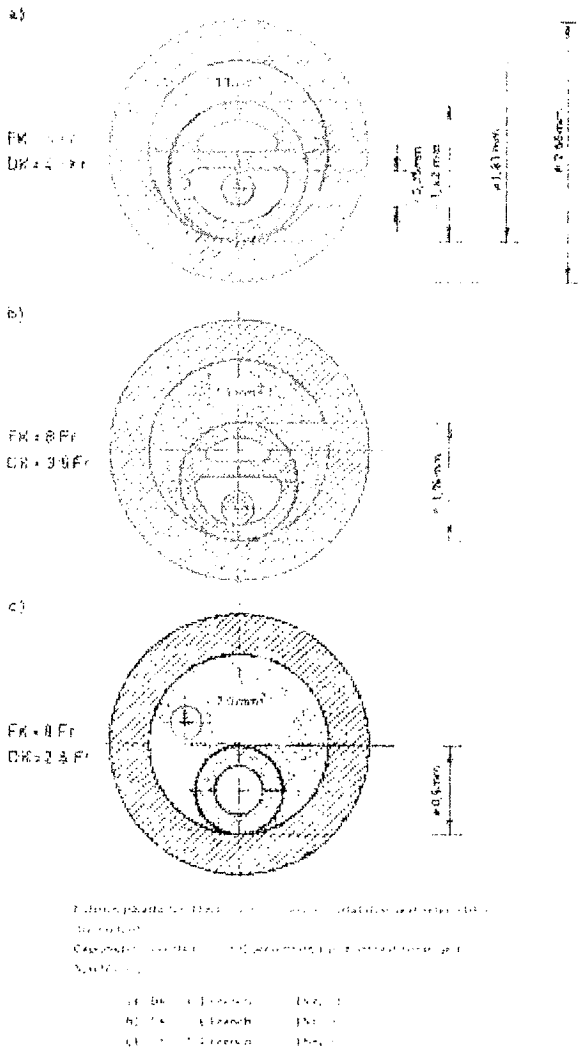

Figure 14.3 Influence of the shaft thickness of a coronary balloon catheter on the size of the remaining guide catheter lumen in over-the-wire catheters (A, B) and monorail catheter (C). Original figure with the catheter dimensions that were usual in about 1984. The space for flow of contrast medium is very much greater in the guide catheter enclosing the monorail catheter (C). FK = guide catheter. DK = balloon dilatation catheter.

Application for a patent

I had, at that time, been involved in coronary dilatation for six years. Supported by the head of the cardiology division, Professor Just, I had performed dilatations for three years in conjunction with Professor Wink and Professor Wollschläger. I had received thorough and sound training in diagnostic cardiac catheter investigations at three large centres in Germany and the USA. However, I had had no experience in the practical implementation of innovative technical ideas and patent application. The "Patentstelle" (Patent Office) of the Fraunhofer Society in Munich had been suggested as a potential source of information and assistance. The Patentstelle quickly declared their readiness to promote the patenting process and recommended Dr Rackette in Freiburg, a physicist and patent attorney, to take care of the legal side. With Dr Rackette's help, the patent was filed at the German Patent Office in Munich at the end of 1984, so that the invention could be offered to a company specializing in cardiac catheter technology.

Realization of the invention

I informed two companies about this invention to improve coronary dilatation. A member of the field staff of one company tried in vain to make an appointment for me to present the new invention at its European head office. This company wanted to know the details in advance, which I was not prepared to communicate. Knowing Heliane Canepa, and with the help of Mr Höhmann and Mr Widensohler of AD Krauth, Hamburg, distributors of Schneider products, I had the opportunity to present my new invention to the Schneider Company in Zurich in 1984, only 14 days after registering the German patent. The first Gruentzig catheters were made by hand by Schneider. Schneider has played a major role in supporting and promoting all catheter developments in Europe, and the Company has prospered.

Heliane Canepa, the executive director of Schneider, developed an exceptional style of personal communication with eminent interventional cardiologists in Germany and Europe and later in the USA. Particularly fascinating in these years was the flexible approach to a profusion of new ideas and techniques, which could be put into practice within a short time when they were found to be good. The important creative engineers at that time were Eugen Hoffmann and Werner Niederhauser, Eugen being responsible mostly for balloons and Werner for guide wires. At a convivial conclusion to one of the PTCA courses by Gruentzig and King in Atlanta in April 1982, I became friends with Ms Canepa. This began with a deal: at an informal get-together under the sunny skies of Atlanta, Andreas and Spencer wore fun T-shirts of the lab staff with the question: "Whoever

are Andreas Gruentzig and Spencer King?" printed on them. I was really desperate to have one. Heliane replied, "If you promise to take your next idea to Zurich ...". She came back with the T-shirt after two hours and I came back with the monorail after two years.

At the end of 1984, after the presentation of the invention in Zurich, Heliane Canepa and Eugen Hoffmann were cautiously optimistic. I received the first prototypes six weeks later. Together with Helmut Wollschläger, I was able to treat the first patient in Freiburg in spring 1985 and the small series of patients usual at that time in the summer and autumn of that year. In spring 1986, the monorail catheter and the results obtained in patients were presented at the PTCA course organized by Bernhard Meier in Geneva. Interest was enormous, yet doubts were cast on its practicability. In the next few years, experience with monorail catheters was communicated in several publications (8–11).

Construction and practical application

Three distinctive constructional features of the monorail catheter were intensively discussed for a long period. Firstly, initial scepticism centred on pushability and stability in the transition from a thick double-lumen shaft to a thin single-lumen shaft. In my view, this was merely a matter of engineering technology by making use of appropriate combinations of materials. Hartzler was very successful with his single-lumen slim balloon catheter for a long time without anyone doubting its pushability. In present-day monorail catheters, pushability (which is still greater in thicker over-the-wire catheters) is no longer a problem because of the improved materials available.

Secondly, the optimal length of the remaining catheter lumen which slides along the guide wire was discussed. At times, maximum lengths of about 30 cm to 40 cm were offered, but finally the length was settled at 15 cm to 25 cm, a length at which the balloon slides well on the wire and is easy to exchange.

Thirdly, dispensing with measurements of pressure in the coronary artery distal to the stenosis gave rise to much scientific discussion. It is possible to inject fluids via a guide wire lumen running the entire length of the dilatation catheter, but also to transfer pressure to a manometer. The catheter tip is distal to the stenosis. The transstenotic pressure gradient can therefore be measured, so that the result of dilatation can be appraised haemodynamically. If a pressure gradient is no longer measurable, the dilatation has been successful. With the slow flow of contrast medium and the initially poor resolution of fluoroscopy, this pressure measurement was important. However, as a result of the thinner monorail catheter shaft, imaging the stenosis was no longer a problem in consequence of the better flow of contrast medium through the guiding catheters into the coronary artery. Imaging reflected the results of dilatation more precisely than pressure gradient measurements on their own. x-ray systems were substantially improved at the beginning of the 1980s, so that small anatomical structures or wires of about 1/10 mm in size could also be readily discerned and the details of coronary angiography and dilatation in the x-ray image could be immediately appraised (12). The further development of x-ray technology was also an important prerequisite for the introduction and widespread acceptance of coronary dilatation.

The consequences of these changes for the coronary dilatation procedure – improved steerability of the bare guide wire, improved flow of contrast medium with better imaging and thus better appraisal of the result, and of course the quicker and safer investigation owing to the rapid exchange of catheters – were not always immediately apparent to many experienced cardiologists. I recall a long discussion in Atlanta with Richard Myler during one of the PTCA demonstrations about the advantages of distal pressure measurements or angiography alone to analyse the results of dilatation. This critical discussion was followed with great interest by the audience.

Other applications of the monorail technique

In view of the simple and easy handling of the monorail technique, this method was soon used for other kinds of catheter also. Once a guide wire has reached a distant target vessel, very diverse instruments can be introduced via this sliding rail. These include various therapeutic catheters, but also numerous diagnostic catheters which provide anatomical or functional information on healthy and diseased coronary arteries (**Table 14.1**). As an example, multifunctional probing catheters may be employed for distal injection of medication, to measure pressure, or to exchange wires, particularly in the coronary arteries, and can thus also be used for physiological investigations (13). Perfusion systems have been used to actively inject oxygenated blood into a coronary segment distal to an acutely occluded coronary artery (14). The principle of

Table 14.1 Monorail-type coronary catheters for a variety of applications as developed by Schneider Medintag AG, Zurich after 1985.

Monorail coronary catheter	Year	Application
Balloon	1985	Stenosis dilatation
Pressure monitoring	1987	Transstenotic fluid pressure gradient (3 French)
Perfusion	1987	Active transstenotic haemoperfusion (4 French)
Balloon distal pressure	1987	Dilatation and transstenotic fluid pressure
Doppler	1988	Transstenotic fluid pressure and Doppler distal flow velocity measurement (20 MHz)
Magnarail balloon	1988	Monorail balloon for magnum wire (recanalization)
Magnarail probing	1989	Total occlusion recanalization support
Speedflow	1992	Monorail perfusion catheter (modified original CPC Mainz perfusion catheter)
Multifunctional probing	1994	Guide wire exchange, distal fluid pressure measurement, distal drug or dye injection, probing/recanalization
Bypass Speedy	1995	Bypass dilatation, special length (160 cm) and large balloon (up to 6 mm)
Chubby	1995	High pressure stent post-dilatation
Medina multifunctional	1995	Adjustable balloon length (Inventor: Dr Medina)
Centring balloon	1996	Brachytherapy catheter
Monorail Magic Wallstent	1997	Self-expandable stent system

passive autotransfusion with an additional inner lumen has been applied to monorail balloon catheters (15). In the "magnarail" system, monorail and magnum techniques are combined (16, 17). All the above techniques have been used in medical praxis. One of my ideas never realized, however, is a double-walled monorail balloon catheter for extended autoperfusion or temporary stenting (**Figure 14.4**). The monorail technique with normal-length guide wires also favours the use of different diagnostic and therapeutic guide wires with special features (**Table 14.2**).

The monorail technique has proved to be less favourable for devices with rotating axes, including the rotablator catheter and the Simpson atherectomy catheter. Recently, the diagnostic instruments most frequently used with the monorail technique have been the ultrasound catheter for producing two-dimensional and three-dimensional images of the lumen and vascular walls (IVUS) and embolic protection systems from different companies (**Table 14.2**). In addition, the monorail technique is frequently applied in extracranial and intracranial vessels of the neck, where it is particularly advantageous.

After introduction of the monorail technique, further variants were suggested from various quarters in order to simplify the exchange of catheters with guide wires of normal length or with the long wire technique. I should like to mention some interesting modifications which mostly involved the wire and not the balloon catheter. By mounting a wire extension, it is, for example, possible to switch from a monorail to a long wire technique

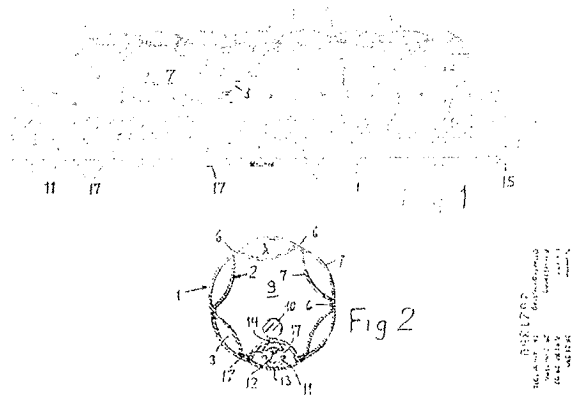

Figure 14.4 1986 draft of an autoperfusion monorail-type balloon catheter for temporary stenting of predilated coronary segments, e.g. in cases of occluding dissection. Longitudinal and cross-section. Note the double wall (3), deflated via the catheter shaft (11). The large central space (9) with indwelling guide wire (10) allows uninterrupted blood flow over an extended time period. Example of a system which was never realized due to technical difficulties and the arrival of metal stents.

Table 14.2 Selection of diagnostic sensor and imaging devices favouring the application of the monorail technique. The major advantage is the ease of sequential exchange of special devices, balloons, and stents over a variety of normal-length guide wires for advanced diagnostic and therapeutic purposes.

Catheters:
Angioscopy
Intravascular ultrasound
Thermography

Guide wires:
Pressure wires for transstenotic pressure gradients and fractional flow reserve
Flow velocity wires for coronary flow and flow reserve
Embolic protection systems

(18, 19). An intriguing and also functionally effective suggestion was based on the use of a magnet. A segment of the guide wire was magnetized. When replacing the catheter, the wire was held with the magnet placed outside the balloon catheter shaft containing the wire. The purpose of another invention was to attain mechanical replacement of the catheter using the long wire technique. For this purpose, the construction of a machine with a complicated cogwheel system was suggested (19). Only the wire extensions have become established, probably not least because the remaining techniques were either too complicated or too expensive, or both. Albeit, these inventions underscore the importance of quick catheter exchange.

Over the years, the early development of catheter technique before the beginning of coronary intervention was investigated assiduously from various angles (especially in terms of patent law) (20). None of the numerous examples cited fulfilled the criteria defining "precursor techniques" for coronary (or similar) interventions. However, I should like to give one example as a result of these investigations. Björn Nordenström was a pioneer of the catheter technique with a prodigious number of good ideas. He was the first to abandon the conventional coaxial technique, as early as 1962 (21). He simplified the introduction of diagnostic catheters through the skin by exiting a guide wire via a lateral opening of the catheter, so that the wire and the catheter ran in parallel over a short distance. The "non-coaxial" introduction was doubtless a good idea, but this technique was not developed further and was eventually forgotten.

Monorail stenting

At the beginning of the 1990s, the deflated profile of coronary balloon catheters became so low, owing to the use of improved materials, that even very narrow stenoses could be passed and dilated with a balloon of the target size aimed for. This initially reduced the need to exchange balloons. However, the use of stents has also increased very rapidly since 1990. As was proved by IVUS studies, the precision of stent dilatation up to an ideal diameter was of great importance for the rate of thrombosis and the rate of restenosis. At least two catheters had to be changed in ultrasonographically monitored stent implantation: first of all, predilatation was carried out with one balloon, the stent was then inserted with a second balloon, and finally the position of the stent was checked with an IVUS catheter. If necessary, a high-pressure balloon was used to attain extra dilatation of the stent. In any event, rapid exchange of the catheters was an important prerequisite for the development of stenting (22). This also applied to self-expanding stents, which can also be implanted using the monorail technique despite their coaxial design.

Contribution of the monorail technique to the development of interventional catheter treatment, especially coronary treatment

Gruentzig's basic concept for dilatation of coronary stenoses with a cylindrical balloon was changed just as little by the invention of the monorail balloon catheter as it was by the introduction of the manoeuvrable catheter by Simpson or the long wire technique according to Kaltenbach. The merits of the monorail concept consist in the manifold improvements of the process of coronary intervention. But, of these improvements, the monorail catheter in particular brings an impressive simplification of the various steps in coronary dilatation. Furthermore, the monorail technique enables the use of various supplementary diagnostic or therapeutic instruments in coronary (or other vessel) dilatation, thus enabling the highest possible quality of diagnosis and treatment. For the catheter laboratory, simplification offers economic advantages by saving time and reducing staff requirements, and for the patient it means shorter investigation times and an increase in safety and accuracy. The monorail technique has thus become established as a basic technique for all procedures of coronary dilatation that has stood the test of time.

I would like to pay a debt of gratitude to my wife, Helen, who supported my work on the invention in many ways.

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Grossman's Cardiac Catheterization, Angiography, and Intervention

SEVENTH EDITION

EDITOR

DONALD S. BAIM, MD

Professor of Medicine, Harvard Medical School
Director, Center for Integration of Medicine and Innovative Technology
Brigham and Women's Hospital
Boston, Massachusetts

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22

Percutaneous Balloon Angioplasty and General Coronary Intervention

Donald S. Baim

Dotter and Judkins (1) first proposed the concept of transluminal angioplasty—enlargement of the lumen of a stenotic vessel by a catheter technique in 1964. They advanced a spring-coil guidewire across an atherosclerotic arterial stenosis and left this wire in place to serve as a rail over which a series of progressively larger rigid dilators were advanced to enlarge the vessel lumen. This Dotter technique proved effective in peripheral arteries, but the need to insert large caliber rigid dilators through the arterial puncture (and the high shear forces applied by the dilators as they crossed the atherosclerotic lesion) ultimately restricted clinical application. In 1974, Gruentzig (2) replaced the series of rigid dilators with an inflatable nonelastomeric balloon mounted on a comparatively smaller catheter shaft. As such, the tip of the balloon catheter could be introduced percutaneously, advanced across a vascular stenosis in its smaller (collapsed) state, and then inflated with sufficient force to enlarge the stenotic lumen. Although others had speculated about the possibility, Gruentzig was the first to refine balloon angioplasty into a usable clinical tool, through a series of experiments in animals, cadavers, peripheral arteries, and the coronary arteries of patients undergoing bypass surgery. This culminated in the first percutaneous transluminal coronary angioplasty (PTCA) of a stenotic coronary artery in a conscious human (September 16, 1977; 3).

PTCA remained the only catheter-based revascularization technique in widespread use until the mid-1990s, when a series of other modalities including atherectomy and stenting (see Chapters 23 and 24) were introduced. To recognize the inclusion of these additional modalities, the technique is now more commonly referred to as percutaneous coronary intervention (PCI) and now stands as the dominant form of coronary revascularization. Its widespread adoption has transformed the field of *invasive* cardiology (i.e., diagnostic cardiac catheterization as discussed in the initial chapters of this text), into the new field of *interventional* cardiology (use of cardiac catheters to deliver therapy). This chapter will review the basic equipment, techniques, and results of coronary angioplasty, as well as the utility of PTCA and PCI in specific clinical and anatomic situations, as a historical and conceptual foundation for the entire field of catheter-based percutaneous coronary intervention.

HISTORY

After Gruentzig's pioneering cases in 1977, most cardiologists viewed the new technique of balloon angioplasty with a great deal of skepticism. But a small group of cardiologists around the world recognized the great potential it might hold (4). In 1979, they met to form a registry of all coronary angioplasty cases worldwide under the sponsorship of the National Heart, Lung, and Blood Institute (NHLBI). That registry grew to 3,000 cases by 1981, although no more than 1,000 angioplasties were performed in any given year during that period. From these humble beginnings, progressive improvements in equipment and technique have produced dramatic growth in percutaneous

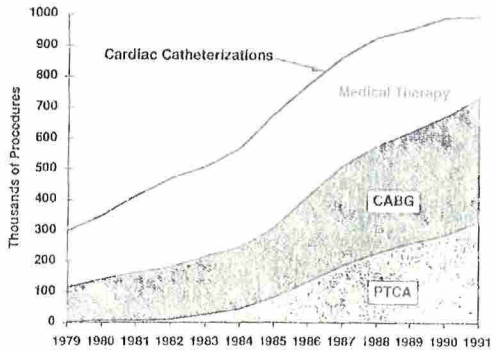

Figure 22.1 Early growth in the number of coronary angioplasty procedures (PTCA) is shown by the bottom *(stippled)* band, increasing from less than 1,000 per year in 1979–1981 to more than 300,000 per year by 1991. This was then similar to the annual number of bypass operations (CABG, *cross-hatched band*) and the number of patients remaining on medical therapy after roughly 1,000,000 diagnostic catheterizations. By 2004, the number of annual catheterizations in the United States had grown to approximately 2 million, with roughly 50% (1 million) of the patients who underwent diagnostic cardiac catheterization being referred for percutaneous coronary intervention and roughly 20% (400,000) being referred for bypass surgery. (From American College of Cardiology; also American Heart Association. *2004 Heart and Stroke Statistical Update*. Dallas, TX; American Heart Association, 2003.)

transluminal coronary angioplasty (PTCA) and transformed it into the dominant form of coronary revascularization (Fig. 22.1). By 1990, the annual number of coronary angioplasty procedures in the United States rose to 300,000, equaling the annual number of bypass surgeries. By 2000, catheter-based coronary revascularization was performed in more than 800,000 patients with ischemic syndromes owing to anatomically suitable coronary artery lesions, compared with some 350,000 who underwent bypass surgery. Currently, some 1,000,000 PCI procedures are performed annually in the United States (5), with a similar number of coronary interventions performed outside of the United States, making it one of the most common procedures worldwide.

Over the past decade, however, the central role of balloon dilation has become much less prominent as a standalone treatment. It now serves mostly as an *adjunctive* means of preparing for (i.e., predilating) or perfecting (i.e., postdilating) a coronary lesion during a stent placement or atherectomy procedure. Despite progressive broadening in its clinical and anatomic indications, the use of these newer interventional devices and adjunctive antithrombotic pharmacology (see Chapter 3) have improved the success rate of PCI to 98%, the procedural mortality to roughly 1%, the emergency bypass rate to <0.5%, and a 1-year recurrence rate to <10%.

EQUIPMENT

A coronary angioplasty system consists of three basic components (Fig. 22.2): (a) a guiding catheter, which provides stable access to the coronary ostium, a route for contrast administration, and a conduit for the advancement of the dilatation equipment; (b) a leading guidewire that can be passed through the guiding catheter, across the target lesion, and well into the distal coronary vasculature to provide a rail over which a series of therapeutic devices can be advanced; and (c) a nonelastomeric balloon dilatation catheter filled with liquid contrast medium. Technologic advances generate improvements in specific equipment each year, so any detailed description of current products would be outdated too soon to be of value here, but some general principles remain.

Guiding Catheters

Guiding catheters remain a crucial component in PTCA. The original guiding catheters were thick-walled 10 and 11F tubes that had small lumens, minimal torque control, and sharp edges. In contrast, current guiding catheter designs more closely emulate the performance of diagnostic coronary angiographic catheters. To allow passage of therapeutic instruments, however, guiding catheters must have a lumen diameter at least twice that of a typical diagnostic

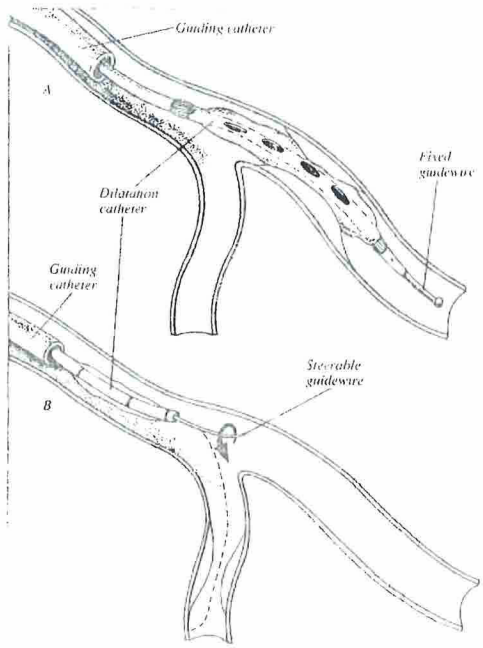

Figure 22.2 Components of the coronary angioplasty system. The original Gruentzig fixed guidewire balloon **(A)** compared with the steerable guide wire system **(B)**. Although both are advanced through a guiding catheter positioned in the coronary ostium, neither the wire shape nor its orientation could be changed once the original Gruentzig catheter was introduced, whereas the steerable design allows the guidewire to be advanced, withdrawn and reshaped, and steered independently of the balloon catheter to select the desired vessel. Once in place in the distal vessel beyond the target lesion, the guidewire serves as a rail over which the angioplasty balloon or other device can be advanced. (From Willerson JT, ed. *Treatment of Heart Diseases*. New York: Gower Medical, 1992.)

catheter (e.g., 0.076-inch [2 mm] versus 0.038-inch [1 mm]). To achieve this lumen in a catheter whose outer diameter is as small as 6F (2 mm, or 0.080 inch), the catheter walls must be very thin (<0.12 mm, or 0.005-inch). Yet the catheter must still incorporate a Teflon liner to reduce friction, metal or plastic braid to transmit torque and provide sufficient stiffness to offer backup support during device advancement, and a smooth outer coating to resist thrombus formation. The complexity of this design goal requires use of special materials whose properties are typically varied along the length of the catheter to optimize the balance between support and flexibility at each point. Most guiding catheters now also include a very soft material in the most distal 2 mm of the catheter to reduce the chance of vessel trauma during engagement of the nontapered tip.

Guiding catheters are now available in virtually all of the conventional Judkins and Amplatz curves, as well as a wide range of custom shapes (extra backup (XB), hockey stick, multipurpose, Voda, etc.) designed to ease engagement or provide better support during balloon advancement. As thin-wall technology has improved and balloon shaft diameters have decreased, the predominant size of guiding catheters has fallen progressively: 9F guiding catheters predominated in the early 1980s, with 8F (2.7-mm) catheters taking over in the late 1990s, and 6F guiding catheters in common use today. Although larger guiding catheters are sometimes still needed for bigger devices or treatment of bifurcation lesions, most procedures can be completed through a 6F guiding catheter introduced through the same sheath used to perform diagnostic coronary angiography. Some 5F guiding catheters are even available for use for radial artery access (see Chapter 4).

To function adequately, the guiding catheter must be able to selectively engage the ostium. This requires the selection of an appropriate catheter shape and the ability to manipulate the catheter under fluoroscopic guidance (see Chapter 11). Engagement of the desired vessel, however, should not interfere with arterial inflow. This is routinely possible in the left coronary artery, but damping of the guiding catheter pressure when the right coronary artery ostium is engaged was once a common and vexing problem. This has been overcome by the smaller diameter (i.e., 6F) guiding catheters and by the introduction of guiding catheters equipped with side holes that allow ongoing perfusion despite wedged engagement. Because the guiding catheter is also used to deliver small boluses of contrast medium into the involved vessel (as needed to visualize vascular side branches and the target lesion for angioplasty), however, contrast flow out of such side holes may increase the total contrast load used during a procedure.

A second important function of the guiding catheter is to provide adequate support for advancement of interventional devices across the target stenosis. This support derives from the intrinsic stiffness of the guiding catheter material, a catheter shape that buttresses it against the opposite aortic wall, and/or deep engagement of the guiding catheter into the coronary ostium (Fig. 22.3). While deep engagement of the guiding catheter is sometimes needed, it is also well-recognized as a potential cause of complications (i.e., ostial dissection). This complication has become far less frequent with incorporation of an atraumatic bumper on the tip of most guiding catheters and the performance of deep engagement only by coaxial advancement over the balloon catheter. After a deeply engaged guiding catheter

Figure 22.3 Use of deep guiding catheter engagement to facilitate coronary intervention. **Left.** Complex lesion in the right coronary artery including aneurysm *(dark arrow)* and diffuse distal disease *(open curved arrow)*. **Center.** Left Amplatz guiding catheter (AL-1) is deeply engaged to provide optimal support for stent placement. **Right.** After stent placement, the vessel is widely patent, but replacement of the Amplatz catheter with a conventional right Judkins catheter (JR4) shows how effective the Amplatz has been in straightening out a severe upward bend (shepherd's hook) in the proximal right coronary artery. Although progressive improvement in device profile and trackability has made such deep engagement less necessary, the technique is still of great value in selected cases. Deep seating of the guiding catheter needs to be done with great care and coaxial advancement of the guiding catheter over a balloon catheter to avoid injuring the proximal coronary artery.

has been used to push a dilatation balloon or other device across the lesion, the operator cannot forget to then withdraw the guiding catheter back to a more neutral position (just outside the vessel ostium) to avoid its migration into an even deeper position as the device is withdrawn. In this sense, the ability to use the guiding catheter actively constitutes one of the important skills required for effective management of the overall angioplasty equipment system.

Guidewires

The original dilatation catheter designed by Gruentzig had a short segment of guidewire (spring coil) attached to its tip to lead the balloon in the vessel lumen and help avoid subintimal passage as the catheter was passed across the stenosis (see Fig. 22.2). Because the shape or orientation of this leading wire could not be modified once the catheter had been introduced, it provided the operator no control over whether the catheter followed the desired path or was diverted into one or more side branches proximal to the lesion. In the early 1980s, Simpson designed a movable guidewire system in which a 0.018-inch Teflon-coated wire extended and moved freely through a central lumen within a coaxial dilatation catheter (6). If this guidewire selected the desired vessel, it was advanced until it crossed the target lesion. If the guidewire instead selected a more proximal side branch, the balloon catheter was advanced to a point just before the side branch as the wire was withdrawn and reshaped in an effort to choose the desired path beyond. By a series of such iterative advancements of wire and dilatation catheter, many lesions could be crossed with the guidewire and then with the dilatation catheter. In 1983, this concept advanced further with the introduction of the first steerable guidewires, whose rotational orientation could be controlled precisely using a "torquer" (pin vise) attached to the proximal end of the wire.

In contrast to crude early guidewires, modern guidewires are designed to combine tip softness, trackability around curves, radiographic visibility, and precise torque control, which together allow the guidewire to be steered past vascular side branches and through tortuous or stenotic segments. With these refinements, crossing a subtotal lesion with the guidewire has become a task that takes seconds rather than minutes to hours, opening up all portions of the epicardial coronary circulation to a variety of interventional devices. The basic guidewire consists of a solid core (stainless steel or superelastic nitinol) that is ground to a progressive taper in its distal portion. This taper helps retain torque control when the wire is steered around the series of bends located in the guiding catheter and proximal coronary anatomy and allows the stiffer proximal portions of the wire to follow the soft tip into side branches. This core is generally covered by a spring coil, which is usually Teflon-coated stainless steel on the body of the wire, and more radiopaque platinum on the distal 3 to 25 cm. A family of hydrophilic plastic-covered guidewires (i.e., Choice PT, Boston Scientific, Natick, MA) are also available to aid in crossing vessels with extreme tortuosity or total occlusion, but the spring-coil design is still dominant.

There is substantial choice of tip stiffness, driven by the way the tapered core wire is attached to the outer coil at the wire tip. In soft wires, the tapered core is welded to the coil via a flattened intermediary shaping ribbon that allows the operator to kink or bend the tip of the wire into a shape that is appropriate for navigating the vessel features it must pass while maintaining the required level of atraumatic softness. Experienced interventional operators use their thumbnail or the shaft of the guidewire introducer to shape the guidewire tip to meet the challenges of anatomic navigation—larger diameter bends are used for selecting left anterior descending (LAD) versus circumflex artery, whereas smaller kinks or bends are used for selecting branches (e.g., diagonal versus LAD).

When greater *probing force* is required (e.g., for probing a chronic total occlusion), stiffer tip designs are available. These core-to-tip guidewires are often graded by the force that the straight guidewire tip can apply to a strain gauge from a distance of 1 cm—wires are available with force increments from 3 gm, 4.5 gm, 6 gm, and ultrastiff 9 gm. Use of these stiff-tip guidewires requires a high degree of skill and feel to avoid unintentional vessel injury (dissection or perforation), and in general operators are well advised to start with soft conventional guidewires and work up to the specialty stiff wires progressively and only as needed.

Independent of the tip stiffness, advancing certain devices around bends may take more *shaft support* from the guidewire. This is provided by extra-support wires, which have a thicker and stiffer inner core. Alternatively, some operators prefer to place a second guidewire across the lesion in parallel (a "buddy" wire) to straighten vessel bends and facilitate device passage. The wire has a series of corrugations near its distal end (the Wiggle Wire Guidant, Santa Clara, CA) that can also be used to help deflect the leading edge of a device away from a calcified plaque or the leading edge of a previously placed stent when advancement over a conventional wire is difficult. With this variety of choices in 0.014-inch guidewires, it is currently rare to use larger-diameter guidewires in coronary work, although wires of 0.016 and 0.018 were previously used for this purpose (requiring, of course, the use of matching devices with larger internal lumen diameters). Smaller-diameter guidewires offer little advantage except with certain devices such as the 0.009-inch Rotablator wire (see Chapter 23), but some specialty total occlusion guidewires have a reduced diameter tip (reduced from 0.014 inch to 0.009–0.012 inch) to help them negotiate small residual lumens.

Standard coronary guidewires are 175 cm long, i.e., some 40 cm longer than the average balloon catheter. This allows the wire to be advanced across the lesion while the balloon catheter remains in the guiding catheter, but does

not generally offer sufficient length for exchange of one device for another. Most guidewires are therefore also available in a double- (i.e., 300-cm) exchange length, or are extendable to that length by attachment of a proximal additional segment. Such wires can be passed independently through the guiding catheter and across the target lesion, to remain in place as a series of devices (balloons, rotational atherectomy burrs, stents) is employed, without the risk of subintimal passage of the second guidewire as it crosses the partially dilated segment (7). A similar strategy can be followed with shorter (175-cm) guidewires, provided that rapid-exchange or monorail balloon catheters and stent delivery systems are used (see below). Although the movable guidewire concept (implemented in the current spectrum of highly sophisticated steerable guidewires) has simplified, shortened, and improved the success rate of coronary angioplasty, it is still important to heed the advice of Dotter and Judkins (1) that *"the guidewire is passed across the atheromatous block more by the application of judgment than of force."*

Dilatation Catheters

The dilatation catheters for coronary angioplasty have undergone radical evolution since 1977. As described above, the original Gruentzig catheters were designed with a short segment of guidewire permanently affixed to the catheter tip to decrease the risk of subintimal passage during advancement down the coronary tree. The shaft of this catheter had two lumens—one for inflation and deflation of the balloon and one for distal pressure measurement and/or contrast injection. This reflected the initial reliance on monitoring trans-stenotic (i.e., aortic root to distal coronary) pressure gradient as a way of assessing lesion severity, since it was very difficult to perform adequate contrast injections through small-lumen guiding catheters around the large (4.3F, 1.3-mm) shafts of early balloon catheters. In contrast, virtually all dilatation catheters now have an independently movable and/or steerable guidewire extending the entire length of the dilatation catheter, as described by Simpson and coworkers (see Fig. 22.2). The central lumen of such dilatation catheters must have a sufficient caliber to allow free movement of the guidewire, but is no longer generally used for either pressure measurement or contrast injection around the wire. The concept of using trans-stenotic pressure gradients to evaluate the significance and completeness of correction of coronary stenoses, however, has undergone renewed interest with the advent of solid state pressure measurement guidewires (see "Fractional Flow Reserve," Chapter 18). Occasionally, however, the distal balloon lumen is still used (after removal of the guidewire) for distal contrast or drug injection (i.e., for the treatment of no-reflow, see Chapter 3).

An important feature of the dilatation catheter is the diameter of the smallest opening through which the deflated balloon can be passed (its *profile*). The original Gruentzig catheters had a 0.060-inch (1.5-mm) profile, but current over-the-wire dilatation catheters have profiles as small as 0.025 inch (0.6 mm). To preserve the best balloon profile, a "negative" or "aspiration" preparation should be performed in which a contrast-filled 20-mL syringe is attached to the balloon inflation hub, the plunger is pulled back to apply a vacuum, and gently released to allow the balloon to draw in a small volume of dilute (1:2 dilution with saline) contrast. A "positive" prep, in which the balloon is first aspirated and then actively inflated with contrast material, should generally be avoided to avoid compromising the best possible crossing profile. The magnitude of this issue is seen when one attempts to reuse a previously inflated balloon to cross a second lesion and finds that the secondary (or rewrap) profile is far less satisfactory than the primary (prior to inflation) profile.

The field of angioplasty balloon catheters is now bifurcated into *over-the wire* (OTW) catheters in which the guidewire runs concentrically within the balloon shaft throughout its entire length and *monorail* (rapid-exchange, or Rx) catheters in which the wire is contained within the balloon shaft over only its distal 25 cm and then runs outside the balloon shaft more proximally. Such catheters can be exchanged quickly by a single operator over a standard length (175-cm) guidewire and generally have smaller shaft profiles to allow better contrast injection or simultaneous placement of two balloons for the treatment of bifurcation lesions. Specially designed *fixed-wire* devices, which consist of a balloon mounted directly on a steerable wire core, were developed and used widely in the late 1980s to provide deflated profiles as small as 0.020 inch (0.5 mm), but their use has become less common as refinements in balloon technology have allowed competitive performance from over-the-wire systems. Fixed-wire devices may still be of unique value in special situations (e.g., dilating side branches through the struts of a stent placed in the parent vessel).

Although profile is important, the ability of the balloon to bend so as to advance easily through tortuous vascular segments *(trackability)* and the presence of sufficient shaft stiffness *(pushability)* to force it through the stenosis are also important. Delivery of the balloon is also aided by the incorporation of a friction-resistant coating (silicone or a hydrophilic coating such as polyethylene oxide) to improve surface lubricity. Other specialized balloon catheters include perfusion balloon catheters, which have a series of side holes in the shaft proximal and distal to the balloon segment or a spiral channel within the balloon to allow ongoing antegrade blood flow and thereby mitigate myocardial ischemia during prolonged balloon inflations (Fig. 22.4). In an era where stents provide definitive control of elastic recoil and dissection, however, the use of perfusion balloons has become rare except for controlling hemorrhage from a coronary perforation without producing severe distal myocardial ischemia (see Chapter 3).

Figure 22.4 Use of a perfusion balloon catheter. **Top.** The inflated perfusion balloon *(arrow)* is shown in the left anterior descending artery and can be recognized by the presence of the non-contrast-filled *(white)* perfusion lumen running through the center of the balloon. **Bottom.** Injection through the guiding catheter *(left curved arrow)* shows direct opacification of the circumflex *(straight arrow)* as well as contrast flow into the distal left anterior descending. This flow enters through proximal side holes, passes through the perfusion lumen within the balloon, and flows out into the distal vessel *(right curved arrow)*. The 40- to 60-mL/minute flow to the distal vessel through the perfusion lumen helps mitigate myocardial ischemia during prolonged balloon inflations, but use of the high-profile devices has become less common with the advent of broad stent use.

Some special balloons exploit the concept of *focused force angioplasty*, in which a second guidewire or microblades on the balloon surface (cutting balloon, Boston Scientific, Natick, MA; Flx mini-rail Guidant, Santa Clara, CA) concentrate the delivery of dilating force from the balloon to the lesion to lower stenosis resolution pressure and reduce balloon slippage forward or backward during inflation (so-called watermelon seeding effect). These technologies have not, however, improved the long-term patency compared with conventional PTCA (8,9), and the cutting balloon carries a small but real risk of perforation when oversized.

Other than these factors, the most important characteristic of the dilatation catheter is its ability to inflate to a precisely defined diameter despite application of pressures that average 10 to 16 atm. This was not possible with early balloons manufactured from polyvinyl chloride (PVC), whose compliance led to balloon oversizing and rupture at pressures as low as 6 atm. More suitable performance can be readily achieved today using balloons manufactured from high-density polyethylene, polyethylene terephthalate (PET), or nylon, despite balloon wall thickness as low as 0.0003 to 0.0005 inch (3 to 5 ten-thousandths of an inch). Based on material and wall thickness, each balloon has an individual compliance characteristic reflecting the pressure at which the balloon reaches its specified (nominal) diameter and how much that diameter increases as the balloon is inflated to even higher pressures. More compliant balloon materials tend to reach their rated (nominal) diameter at 6 atm and then grow by ≤20% above their nominal size (i.e., a 3.0-mm balloon growing to 3.5 mm) at 10 atm. Semicompliant balloon materials such as high-density polyethylene or nylon grow by <10% over this pressure range, whereas truly noncompliant balloon materials such as PET can retain their defined diameter up to 20 atm to allow dilatation of calcific stenoses or full expansion of coronary stents (Fig. 22.5).

Balloon compliance characteristics must be kept in mind especially when inflating a compliant or semicompliant balloon to pressures above nominal (usually roughly 8–10 atm) to avoid overdistending the adjacent normal vessel. Because the noncompliant balloon materials preclude growth in normal segments upstream and downstream of a rigid lesion, they may be desirable whenever high pressures are needed and may also help to treat resistant lesions by concentrating dilating force on the stenosis itself (rather than in balloon growth and dilatation of the adjacent vessel).

Regardless of which balloon type is used, it is important to stay within the prescribed range of inflation pressure is also important to prevent balloon rupture. This pressure range is specified in terms of the *rated burst pressure* (i.e., an inflation pressure at which the probability of balloon rupture is <0.1%). Taking any balloon catheter above its rated burst pressure (usually 16 to 20 atm) increases the risk of balloon rupture, with the potential for air embolization (if the balloon was incompletely purged), vessel rupture, local dissection, or difficulty in removing the balloon from an incompletely dilated lesion (10). This risk grows the further above rated burst pressure that the balloon is inflated, until it reaches 50% risk of rupture when the average burst pressure is reached. Instead of relying solely on high balloon inflation pressures, there are many other alternatives for dealing with the resistant lesion. It is usually better to use focused force angioplasty, rotational atherectomy, or

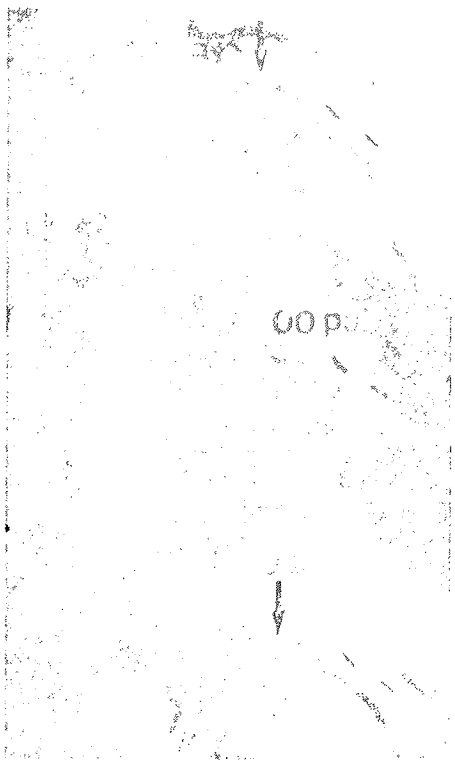

Figure 22.5 Successful dilatation of a rigid calcific lesion. This rigid lesion **(top)** in the midleft anterior descending coronary artery of a postbypass patient (note surgical clips) resisted dilatation at 300 lb/in^2 (20 atm), but yielded to an inflation pressure of 330 lb/in^2 (22 atm; **middle two views**) with an excellent angiographic result **(bottom).** Such pressures are obtainable only with special high-pressure balloon construction because standard angioplasty balloons have rated rupture pressures of only 14 to 16 atm. In current practice, such lesions would more likely be treated by rotational atherectomy (see Chapter 23).

laser atherectomy, Chap. 24, rather than to inflate any balloon catheter to pressures more than 2 to 3 atm above its rated burst pressure. A rare exception to this rule is stent postdilatation in a calcified or fibrotic lesion that has not been adequately predilated or pretreated with rotational atherectomy before stent placement, and where there is no alternative for achieving full stent expansion.

Various manufacturers currently provide dilatation catheters that meet these design specifications with inflated diameters of 1.5, 2.0, 2.5, 3.0, 3.5, and 4.0 mm to match the size of the coronary artery in which the stenosis is located. Larger balloons (i.e., 4.5, 5.0, and 6.0 mm) are occasionally needed for treatment of large right coronary arteries or saphenous vein grafts. Quarter-sized balloons (e.g., 2.25, 2.75, and 3.25 mm) are also available, but that degree of precision probably exceeds the operator's ability to gauge vessel size, and stocking quarter-sizes tends unfavorably to increase the size of a laboratory's balloon inventory. The usual length of the inflatable balloon segment is either 15 or 20 mm, but balloons are also available in shorter (10 mm for dilating or postdilating focal lesions) or longer (30 or 40 mm for dilation of a diffusely diseased segment) inflated segment lengths (11). Although most lesions can be dilated effectively with balloon catheters from any of the several manufacturers, subtle differences in performance characteristics can make the difference between success and failure; therefore, each interventional laboratory still needs to stock a variety of balloon types. Although balloon prices were once nearly $700, competition has brought current prices down to $200 to $250, giving little incentive for resterilization and reuse, with the risk of infection, prolonged procedure time, and device failures with resterilized products (12,13).

PROCEDURE

A coronary angioplasty procedure bears a superficial resemblance to diagnostic cardiac catheterization in that catheters are introduced percutaneously under local anesthesia. However, since angioplasty involves superselective cannulation of diseased coronary arteries with guidewires and balloon catheters, temporary occlusion of antegrade coronary arterial flow, as well as manipulation of the offending atherosclerotic lesion by balloon inflation, the procedure is significantly more complicated and entails roughly 10 times the risk (i.e., 1% versus 0.1%) compared with a purely diagnostic catheterization (14). The risks of coronary angioplasty vary greatly with the baseline clinical condition of the patient, the characteristics of the lesion to be treated, and the techniques that are used (see "Complications" below and Chapter 3). When obtaining informed consent, the individual estimated risks should be discussed in detail with the patient and family prior to the procedure. To mitigate the very real risks of major complications, angioplasty should be attempted only by experienced personnel and generally only in a setting where full cardiac surgical and anesthetic support is available (15,16). One exception is the performance of emergency coronary angioplasty for the treatment of acute ST-elevation myocardial infarction (STEMI), where the need for rapid revascularization has led to the allowance of such procedures in approved catheterization laboratories staffed by experienced interventional operators, even when on-site cardiac surgery is not available (16,17). The practice of elective angioplasty without on site surgery, however, remains outside the PCI Guidelines at this time (16a).

Patients were once admitted the night before elective angioplasty, but current cost driven protocols call for admission on the morning of the procedure. Details of the patient evaluation, informed consent, and preprocedure laboratory work will thus generally have been completed in a separate outpatient visit or be compressed into a very brief encounter immediately prior to the procedure. This is particularly true for patients who come to catheter-based intervention at the conclusion of what began as a diagnostic catheterization that progressed to coronary

intervention (so-called ad hoc angioplasty or cath with PCI stand-by; 18). If angioplasty is not available at the diagnostic catheterization facility, if the combined procedure is likely to exceed safe contrast loading limits, or if high anticipated procedural risk makes surgical consultation or additional discussions with the patient and family desirable before proceeding with a nonemergent intervention, the procedure may still be concluded after only the diagnostic portion with the PCI as a separate procedure. Similar considerations apply to the decision to stage a complex multivessel procedure into two or more sessions (i.e., patient tolerance, clinical stability, total contrast load, stability of the initial treatment results), but current techniques generally make staging (between diagnostic and interventional procedures, or between treatment of some lesions and others) an uncommon clinical necessity, the reason for which should be documented in the patient chart.

Oral intake should be restricted after midnight on the evening prior to the procedure, and the patient should be pretreated with *aspirin* 325 mg/day to diminish platelet deposition on the disrupted endothelium (19). In the aspirin-allergic patient, a graded aspirin desensitization protocol (20) may be used before PCI or immediately after PCI in which other antiplatelet therapy has been provided (see below). An *oral platelet ADP-receptor antagonist* (such as clopidogrel) may be administered prior to the procedure (21), often supplemented by intravenous platelet glycoprotein IIb/IIIa receptor blockers (22), to reduce the incidence of periprocedural myocardial infarction or repeat emergency revascularization for vessel closure or stent-thrombosis. Since aspirin reduces late cardiac mortality in patients with coronary disease, it is generally continued indefinitely after the procedure. Similar data now exist for longer-term clopidogrel treatment (23).

Angioplasty is generally done from the femoral approach, although brachial and radial approaches can be used based on considerations about vascular access, as well as operator and patient preference. Most catheter-based interventions can be performed safely without right heart catheterization, but a right heart catheter may provide potentially valuable measurements of both baseline filling pressures and intraprocedural hemodynamic deterioration in patients with abnormal baseline left ventricular function or treatment of major vascular territories. The venous sheath also allows rapid initiation of ventricular pacing, although placement of a prophylactic pacemaker is seldom needed except in cases where rotational atherectomy or rheolytic thrombectomy of vessels supplying the right or dominant circumflex coronary artery is planned (see Chapter 23).

After placement of the arterial sheath, intravenous antithrombin therapy is initiated (see Chapter 3). The most common agent is still *unfractionated heparin* (70 units/kg, or 7,000 to 10,000 units), which may be reduced to 50U/kg when administration of a platelet glycoprotein IIb/IIIa receptor blocker is planned. Alternatives include *low-molecular weight heparin* (e.g., enoxaparin) in patients who have been on such agents preprocedure (24), or one of the *direct thrombin antagonists* (e.g., bivalirudin [Angiomax, the Medicines Company, Parsippany, NJ]; 25, 25a). If unfractionated heparin is used, it should be noted that there is wide patient-to-patient variability in heparin binding and activity, so that an ACT (activated clotting time) should be measured and additional heparin should be administered as needed to prolong the ACT to 275 to 300 seconds (reduced to 250 seconds if a platelet glycoprotein IIb/IIIa receptor blocker is to be given) *before any angioplasty devices are introduced*. Additional doses or an infusion of the antithrombotic agent may be required to maintain the ACT at this level throughout the case—ACTs <250 seconds are associated with a marked increase in the incidence of occlusive complications unless an adjunctive IIb/IIIa receptor blocker is used, whereas ACTs >300 to 350 seconds tend to increase the risk of bleeding (26). ACTs may also be used to monitor the effect of direct thrombin inhibitors such as bivalirudin, which have found increasing use during PCI based on more predictable dose-response characteristics than heparin, greater efficacy against clot-bound thrombin, reduced platelet activation, less bleeding, and lack of cross reactivity in patients with the heparin-induced thrombocytopenia or thrombosis syndrome (HITTS, Chapter 3). Since low-molecular weight heparin has relatively more activity against factor Xa than against thrombin, it causes less prolongation of the ACT so that specialized anti-Xa assays are required to monitor low-molecular weight heparin effects.

Baseline angiograms are then obtained of one or both coronary arteries using either a standard diagnostic catheter or the angioplasty guiding catheter. Baseline angiography serves to (a) evaluate any potential changes in angiographic appearance (interval development of total occlusion, thrombus formation) since the prior diagnostic catheterization, (b) permit the selection of the angiographic views that allow optimal visualization of the stenoses, and (c) aid in planning of the detailed interventional strategy. Coronary injections should be repeated after the administration of 200 mg of intracoronary nitroglycerin to demonstrate that spasm is not a significant component of the target stenosis and to minimize the occurrence of coronary spasm during the subsequent angioplasty--we have seen cases where the intended target of a catheter-based intervention resolved with intracoronary nitroglycerin, and an unnecessary intervention was avoided! The best working views that show the target lesions and adjacent side branches most clearly and with the least foreshortening are recorded and transferred to the road-map monitor for reference during the procedure. The approximate reference diameter and length of each target lesion is estimated by comparing it to the 6F (2 mm) diagnostic catheter or selected guiding catheter. Decisions are then made regarding the sequence of lesions to be approached (integrating lesion severity, myocardial territory involved,

and noninvasive test data) and the specific interventional approach that will be used. For example, a bifurcation lesion that may require kissing balloon inflations and a simultaneous kissing stents implantation (see Chapter 24) may suggest use of a guiding catheter larger than 6F.

The appropriate guiding catheter is connected to the pressure manifold (see Chapter 11) by way of an extension tube and a rotating hemostatic valve (Tuohy Borst valve) and positioned in the appropriate coronary ostium. The hemostatic valve contains an adjustable O-ring that allows introduction and free movement of the angioplasty balloon while maintaining a sufficient seal around the balloon shaft to permit pressure measurement and contrast injection. The angioplasty guidewire is then introduced into the guiding catheter, either loaded into the initial angioplasty balloon or inserted through a needlelike guidewire introducer (*bare-wire* technique), and steered across the target lesion. The guidewire is advanced across the lesion with the aid of puffs of contrast material through the guiding catheter as the vessel is imaged fluoroscopically in a projection that shows the desired path free of foreshortening or overlapping side branches. Once the position of the wire tip in the distal vasculature has been confirmed by contrast angiography, the desired angioplasty balloon or other device is selected.

Experience has shown that the best and safest standalone angioplasty results were obtained using a balloon whose diameter closely approximates that of the presumably nondiseased reference segment adjacent to the site being treated (balloon/artery ratio 0.9:1.1; 27,28). Slightly larger balloons (approximately 1.1 to 1.2 times the size of the reference lumen) were sometimes used if intravascular ultrasound (see Chapter 19) showed that the outer vessel diameter in the reference segment (external elastic membrane [EEM]) diameter was significantly larger than the reference lumen. On the other hand, slightly smaller initial balloons were used when it was difficult to estimate the correct reference size of a diffusely diseased or rapidly tapering vessel, or when great difficulty was anticipated in crossing the lesion. In the era where stenting (especially drug-eluting stenting) has become the definitive treatment, however, it is routine to predilate the target lesion with a balloon that is slightly undersized relative to the reference vessel and roughly the same length as the target lesion (see Chapter 24). Modern low-profile stents can often be delivered without predilation of the target lesion (so-called *direct stenting*), but predilation makes delivery and accurate placement of the stent within the lesion easier, facilitates the selection of the correct stent diameter and length (by comparison with the diameter and length of the inflated predilating balloon), and ensures that lesion compliance is sufficient to allow full expansion of the stent without pretreatment by rotational atherectomy (see Chapter 23).

The selected balloon is prepared by flushing the central (guidewire) lumen with heparinized saline and filling the balloon inflation lumen with a dilute (1:2) radiographic contrast material. When balloon burst pressures were lower and rupture was more frequent, contrast filling was accomplished by a "positive prep" in which the balloon was aspirated, inflated with contrast, and then aspirated again to remove any air. With more robust balloon materials, however, it is now more common to perform only a "negative prep" in which a contrast-filled syringe is used to pull air from the balloon lumen and then let the balloon aspirate a small amount of contrast material when vacuum on the syringe is released. This method of preparing the balloon catheter avoids inflation before it is across the target lesion and thus helps maintain the lowest possible deflated profile for crossing a severe stenosis. Some operators prefer to prepare the balloon before introduction and attach a three-way stopcock to its inflation hub to maintain a vacuum, whereas others prefer to prep the balloon in the body just before crossing the lesion. The balloon catheter is then loaded onto the free end of the guidewire, advanced through the loosened O-ring, down the proximal vessel, and across the lesion.

Once the dilatation catheter has been positioned within the target stenosis, the balloon is inflated progressively using a screw-powered handheld inflation device equipped with a pressure dial. At low pressure (i.e., 2 to 4 atm), the balloon typically exhibits an hourglass appearance owing to central restriction by the coronary stenosis being treated. In soft lesions, this restriction (or "waist") may expand gradually as the inflation pressure is increased, allowing the balloon to assume its full cylindrical shape. In more rigid lesions, the restriction may remain prominent until the balloon expands abruptly at a *stenosis resolution pressure* that may be anywhere between 4 and 20 atm (29). Some operators prefer to increase pressure rapidly until all balloon deformity resolves, but this increases the risk of dissection when a fibrotic or calcified plaque yields suddenly or when the ends of a somewhat compliant balloon grow to excessive diameter on either side of the resistant lesion. If a calcified plaque resists expansion at 10 to 14 atm, one may thus prefer to consider use of the Rotablator (see Chapter 23) rather than pushing to the very high balloon inflation pressures (≥20 atm, Fig. 22.5) that may be required for full dilation.

At the other extreme, elastic (usually eccentric) stenoses may allow full balloon expansion at low pressures but then tend to recoil promptly once the balloon is deflated. This type of lesion was once treated by repeated inflations, cautious use of oversized balloons, or directional atherectomy, but stent implantation is now the routine treatment. Focused force dilation (with a cutting balloon or external guidewire balloon may also be helpful in dilating the fibrotic or elastic lesion effectively (see below). There is little objective evidence that slower speed of inflation or prolonged (1 minute or more) inflations offer more benefit than the 30-second inflations (30). Exploration of even longer (15-minute) inflations using a perfusion balloon

showed slightly better acute results with no difference in long-term patency (31).

Whatever inflation strategy is selected, the response of each lesion to balloon dilation must then be assessed individually so that the dilation protocol can be tailored to achieve the best possible result. The most common way to assess lesion response to balloon dilation is repeat angiography performed through the guiding catheter. By leaving the exchange-length guidewire in place during such angiography or using a rapid-exchange balloon catheter, the balloon can be removed from the guiding catheter without losing access to the distal vessel or the ability to perform additional intervention (repeat balloon inflation, stent placement, etc.). Complete normalization of the vessel lumen would be the ideal end result of coronary angioplasty, but a typical result of even a successful angioplasty is a 30% residual diameter stenosis (i.e., a 1.9-mm lumen in a 3-mm vessel) with some degree of intimal disruption (reflected as localized haziness, filling defect, or dissection). Although this once created a dilemma about whether to persist with additional balloon inflations (weighed against the risk of creating a vessel dissection), the need to obtain a perfect result with balloon angioplasty is now moot in the stent era—*any lesion that can be stented is stented.* In the current view, the best position for stand-alone balloon angioplasty is thus in lesions that are poorly suited to stenting owing to vessel size below 2 mm or branch ostial disease where bifurcation stenting is not contemplated.

Given the importance of achieving the best acute angiographic result, and the uncertainty inherent in angiographic assessment of the irregular lumen postangioplasty, a number of other techniques have been used to grade the quality of an angioplasty result. Initially, PTCA operators relied heavily on the trans-stenotic gradient as an index of dilatation adequacy, seeking a postdilation pressure difference of <15 mm Hg between the aortic pressure (measured through the guiding catheter) and the distal coronary artery pressure (measured through the tip of the dilatation catheter). In practice, such measurements were complicated by the presence of the dilatation catheter within the stenosis and the small size of the dilatation catheter lumen, which led to abandonment of the gradient measurement by 1988 (32). There has been some recent reawakened interest based on the availability of using newer solid state *pressure-measuring* guidewires that can be used to assess the trans-stenotic gradient at baseline flow and during maximal hyperemia (33; see Chapter 18). The goal is to achieve a fractional flow reserve (FFR)—defined as the ratio of distal coronary pressure to aortic pressure during adenosine-induced hyperemia—>0.95 in a successful PCI. The same type of physiologic assessment can be done using Doppler *flow measuring* guidewires to assess diastolic/systolic flow ratios or coronary flow reserve (CFR) as an index of baseline lesion significance and a confirmation of adequate dilation. Alternatively, *intravascular ultrasound* (IVUS; see Chap. 19) can more accurately measure lumen diameter and cross-sectional area after dilation, and can detect vessel dissection or hematoma more accurately. Although IVUS has provided important mechanistic insights into balloon angioplasty, it is not used in more than 5 to 10% of routine clinical cases because of the added procedural time and expense. In most laboratories, the postdilation angiogram thus remains the gold standard of whether or not an adequate result has been obtained.

Once adequate dilatation is deemed to have been achieved, it is common to withdraw the balloon catheter completely from the guiding catheter, leaving the guidewire across the dilated segment for several minutes to allow observation of the treated vessel for signs of angiographic deterioration. With more predictable interventions such as stenting, however, a single set of postprocedure angiograms in orthogonal views with the guidewire removed is usually sufficient to document a suitable result in the treated lesion and the absence of dissections, branch occlusions, or guidewire perforations in the adjacent portions of the vessel. At that point, other significant lesions may be dilated similarly, or the procedure may be concluded and the patient transferred to the recovery area.

POSTPROCEDURE MANAGEMENT

Postprocedure management after PCI has been progressively streamlined (14). It was once common to leave the arterial sheath in place overnight with continued heparin infusion, while perfusing the sheath lumen and monitoring for distal limb ischemia. This practice allowed prompt vascular reaccess should delayed abrupt closure occur (34). With the advent of stenting and IIb/IIIa receptor blocker, such delayed abrupt closures occur so infrequently that the practice shifted to removal of the sheaths later the same day as soon as the heparin effect wore off (ACT <160 seconds), with no postprocedure heparin infusion (35,36). In fact, now with the wide adoption of femoral puncture site closure devices, it is common to remove the arterial sheath in the cath lab at the end of the interventional procedure, despite a fully anticoagulated state (see Chapter 4).

After sheath removal, the patient typically remains at bed rest for 18 to 24 hours and then ambulates before discharge. The time to ambulation is reduced significantly, however, if a femoral closure device has been used. If a IIb/IIIa receptor blocker was used intraprocedurally, it is commonly infused for approximately 18 hours postprocedure. Aspirin (325 mg/day) is continued indefinitely, and patients who have received a stent are given clopidogrel (Plavix) as a 300–600 mg loading dose at the end of the procedure and 75 mg per day for 2 to 4 weeks (bare-metal stent) or 3 to 6 months (drug-eluting stent or brachytherapy). Beginning clopidogrel 3 to 6 hours before the intervention obviates the need for a postprocedure loading dose and may attenuate the additional benefit provided by a IIb/IIIa receptor blocker. Longer-term clopidogrel may also reduce

INVASIVE CARDIOLOGY

A MANUAL FOR CATH LAB PERSONNEL

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SANDY WATSON, RN, BN, NFESC
Swiss Cardiovascular Centre
University Hospital
Bern, Switzerland

KENNETH A. GORSKI, RN, RCIS, RCSA, FSICP
Cardiovascular Laboratories
Cleveland Clinic Heart and Vascular Institute
Cleveland, Ohio

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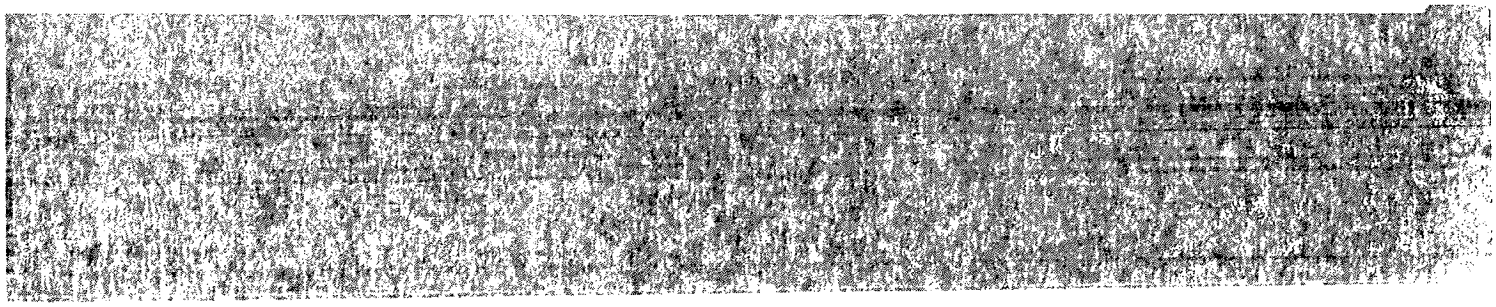

World Headquarters
Jones & Bartlett Learning
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978-443-5000
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Jones & Bartlett Learning Canada
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with an o ring allows manipulation of the guide wire and PCI device, while the side arm enables injections of contrast media through the guiding catheter.
- Guide wire, generally 0.014 inches diameter for crossing the lesion
- Steering device (torque tool) for guide wire manipulation.
- Intracoronary nitroglycerin Adenosine, Nitroprusside, and Verapamil should be available.
- Sterile cups
- Sterile syringes for intracoronary medication, ACTs, and lab tests

Additional sterile towels, clips, gauze, and stopcocks may be necessary. Intracoronary nitroglycerin should be ready for immediate administration. Wet gauze saturated in saline should be available to use for wiping and anchoring the wires and balloons as they are used and seated. The balloon/stent inflation device should be filled with the diluted contrast and purged of air.

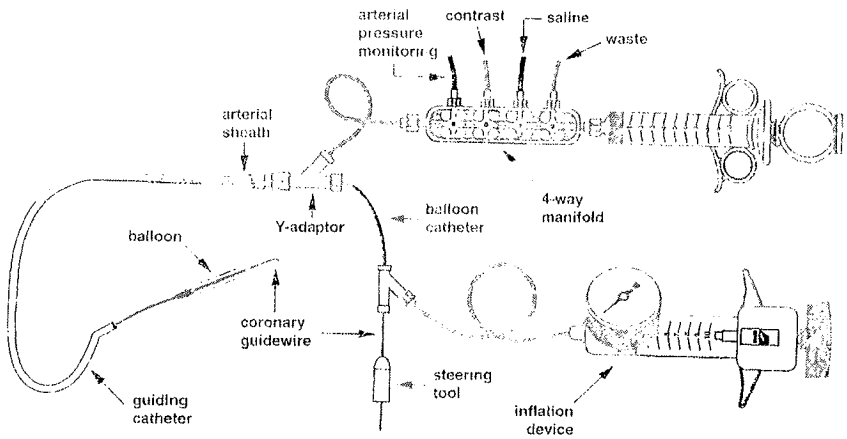
The sterile field should be organized and uncluttered as possible to provide a clean work area for balloon and stent preparation.

The success of coronary interventions can be greatly affected by the choices made of the interventional equipment used. Having a solid understanding of how different materials work with and against each other in a myriad of situations is how the experienced interventionalist teams define their excellence. Although success is not guaranteed, the array of modern equipment offers every chance to obtain the best outcome possible.

Guiding Catheters

The guiding catheter may be the most important decision for a timely and successful intervention. The guiding catheter will provide the optimal support for the insertion of a guide wire and balloon catheter or device to the target lesion. The operator's assessment of aortic arch/root morphology and coronary artery ostial position during diagnostic imaging will assist in choosing the correct catheter. An important consideration is the relationship between the catheter French (F) size, curve, and potential damping of coronary blood flow.

Figure 15-1. Basic PTCA equipment and setup.



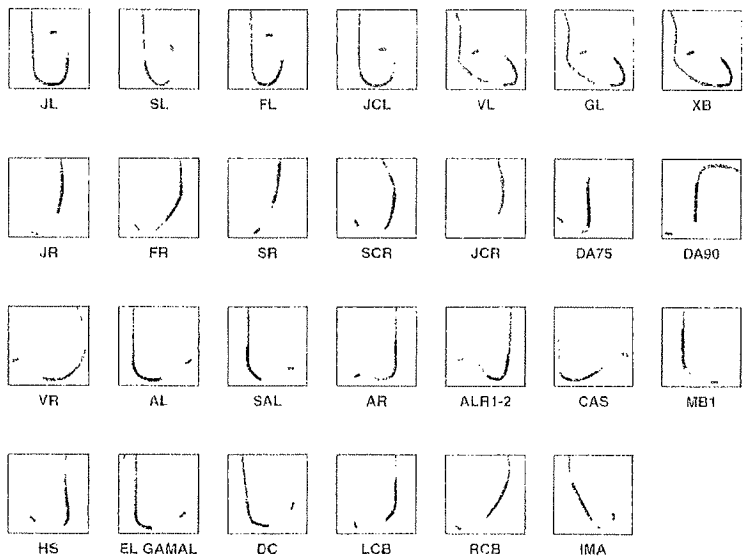
The majority of PCI cases currently performed use 6F equipment, thanks to the smaller, more flexible tools now available. Smaller, 5F guide catheters are also available in limited curves. 5F guides are rarely used today, with the exception of radial access interventions. The difficulty of maneuvering 5F PCI equipment to the lesion can be challenging, and the amount of back-up support required from the guiding system should be assessed carefully. Where maximum support is needed, physicians may choose a larger 7F- or 8F-sized system to keep the catheter comfortably seated. Larger lumen-guiding catheters have a tendency to be stiffer, which may aid in improving backup for inserting interventional equipment to the target area.

In some cases, where stiff backup plus a larger lumen is needed, some operators may choose a guiding catheter with factory-made side holes to allow distal coronary artery perfusion. Side-hole catheters give a false sense of security, however, the catheter tip may still be occluding flow into the vessel, while guide catheter side holes sit outside of the coronary ostium and reflect the aortic pressure on the hemodynamic monitors. The use of side-hole catheters may also increase the CM dose (spilling out of the side holes) and can reduce the ability to fill large lumen arteries/grafts in higher perfusion states.

Interventional guiding catheters offer variable construction designs to give the operator choices between flexibility and seating within the coronary ostium. Some manufacturers offer guiding catheters with both stiff and soft secondary curves to aid in manipulation. Almost all interventional guiding catheters have a soft, pliable tip to decrease the risk of damage or dissection of the coronary ostium.

Guide catheters come in traditional curves (Judkins, Amplatz, multipurpose; see Figure 15-2). Proprietary extra-support guide catheter curves (XB, Voda, GL) have a long terminal primary curve and a stiff secondary curve to seat the catheter firmly in the aortic root, much like an

Figure 15-2. Common guiding catheter configurations.



amplatz catheter but with more maneuverability. These shapes greatly improve the ability to firmly seat smaller French-size catheters in the coronary ostium and support delivery of the guide wire and PCI device.

Guide Wires

Guide wire choice will be the second critical element because of the relationship between guiding catheter and the trackability of the guide wire and device. The purpose of guide wire placement is to provide safe and stable access to the lesion for the balloon, stent, or other interventional device.

Guide wire lengths can vary according to application, but are primarily one of two lengths: approximately 145 cm and 300 cm (exchange length), depending on the manufacturer. The shorter guide wires are designed for rapid exchange/monorail systems and are controlled by the operator for most of the procedure. Exchange length guide wires are good for complex interventions where frequent device exchange is anticipated.

Interventional guide wires generally have a soft, atraumatic tip that may be shaped by the operator (see Figure 15-3). Shaping is performed to enhance the ability of the wire to pass through and around the curves of the target coronary artery. The transition point of a guide wire refers to how it is constructed between the microthin tip and the 0.014-inch main body. The transition of the guide wire determines many of its properties and best applications. Most operators have a "workhorse" guide wire they turn to first, giving an edge in predictability of how it reacts as it is advanced. Most guide wire manufacturers will offer wall charts or pocket guides classifying their products and recommended applications; some include competitive products in their listings.

Traditionally, guide wires are primarily classified as floppy, intermediate, or standard (see Figure 15-4). Stiffer standard and intermediate wires have more pushability, whereas more flexible or floppy wires tend to track more easily through a tortuous artery.

There are literally hundreds of guide wires available, made of different materials and coated with a choice of agents. Each one has a unique property of use and technical applications. Many guide wires have coatings such as Teflon to aid in smooth tracking of the balloon over the wire. Hydrophilic-coated guide wires are an invaluable tool for crossing thrombosed coronary arteries because of their lubricious nature, but the hydrophilic agent also increases the chance of dissection and perforation with the guide wire tip.

Some guide wires are constructed of Nitinol rather than the more common stainless steel. Nitinol retains a "memory" of its original shape and can be helpful for use in certain conditions requiring a balance of pushability and tracking.

Figure 15-3. Guide wire construction.

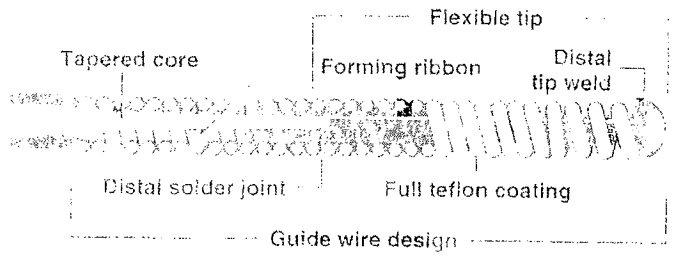
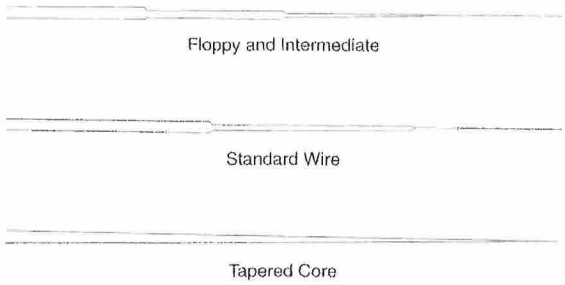


Figure 15-4. Guide wire core construction.



Nitinol guide wires should be wiped frequently with heparinized solution gauze while exposed to air to promote smooth device movement.

Specialty guide wires are available with markers that aid in measuring target lesion length, taking away the guesswork in measuring around tortuous lesions.

A second guide wire is often used to protect side branch vessels when intervening on main artery. Many operators will choose this option so that in the event of acute closure of the side branch, there will still be access through the area, hopefully to enable PCI if necessary.

A second guide wire is also used when employing the "kissing balloon" technique, whereby, two guide wires and two balloons are advanced simultaneously down a main vessel and side branch (such as an LAD and a diagonal). The balloons are then positioned one against the other, and simultaneously inflated at low pressures to perform a bifurcation, or "kissing balloon" angiosplasty. One complication that can occur with this procedure is that the two guide wires can become wrapped or entwined together during positioning. When advancing the first balloon, if there is significant resistance to further advancement past the bifurcation without an obvious cause, pull back the remaining guide wire and readvance. This will usually remedy the situation and enable the other balloon to push forward.

Advancing any coronary guide wire should be done with extreme caution. Intimal staining with contrast dye indicates possible dissection and should be assessed before proceeding further.

Angioplasty Balloons

Balloon choices are made based on experience and preference by the physician. The primary differences between balloons that affect their performance are: material design, tracking ability, and length.

There are three main types of balloon catheter systems (see Figure 15-5):

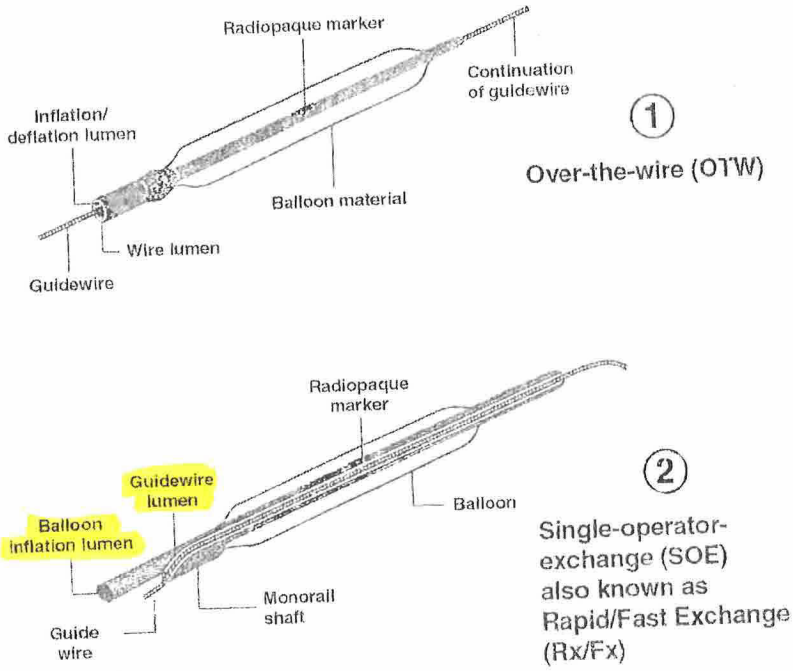
Over the Wire

Over-the-wire balloons have a central guide wire lumen that runs from the proximal hub to the distal tip. These balloons can be loaded onto the guide wire from either the front or back after the lesion has been crossed. With guide wire support within the entire catheter body, these balloons may offer more flexibility and trackability than rapid-exchange balloons.

Single-Operator Exchange

Single-operator exchange, more often referred to as rapid-exchange (RX) or monorail balloons, are

Figure 15-5. Balloon catheter designs.



designed to be more easily handled by one person. These balloons load only from the front end with the guide wire exiting approximately 30 cm from the tip. This enables the operator to control both the wire and balloon while crossing into and away from the coronary artery. This design also allows for balloon-catheter exchange without the use of a 300 cm wire, guide wire extension, or exchange assist device (such as the Boston Scientific Trapper or Magnet). The catheter body of single operator balloons tends to be stiffer for more pushability.

Fixed-Wire Balloons

The original balloon designed by Andreas Gruentzig was a fixed wire. The over-the-wire design of John Simpson quickly improved on Gruentzig's concept. Because of limitations in technology, fixed-wire designs resurfaced as a way to treat smaller distal vessels, side branch lesions, and some bypass graft lesions.

Advances in balloon design and materials have overcome earlier limitations. Today, the need for fixed-wire balloon catheters is not as common, and they are no longer available in the United States.

Perfusion Balloons

Perfusion balloons were designed to enable blood "flow" into the distal coronary artery when the balloon is inflated. It is necessary pull the guide wire back between the proximal and distal balloon ports. Commonly called the "bailout" balloon for spontaneous closure, perfusion balloons were an important development in early PTCA before stenting.

Like fixed-wire balloons, the onset of direct stenting and use of newer antiplatelet agents have eliminated the need for perfusion balloons. These devices now are simply an interesting note in the annals of coronary intervention.

Balloon Compliance

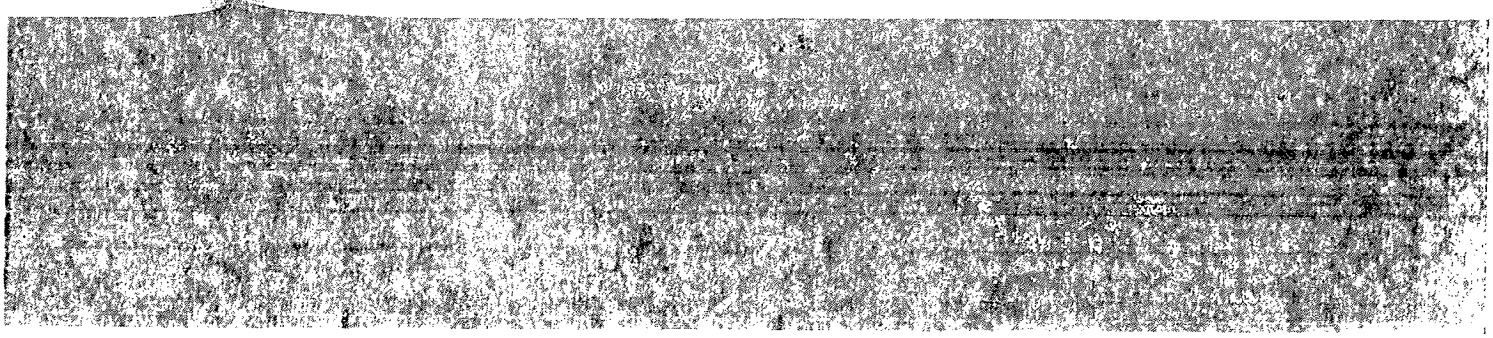
Balloons are constructed of a variety of material to fit different applications. Most of the early-generation balloons were made of polymers like the outer wrap of a cigarette pack. Balloons were stiffer and had higher profiles, making distal and complex lesions difficult to reach because of limited flexibility. Later designs brought on the development of new polymer hybrids to meet specific anatomic and technical challenges.

Compliant Balloons

These polymers are more responsive to balloon inflation pressures, having a tendency to increase in diameter with each ATM applied. Balloons with materials are classified as compliant, because of their nature to predictably increase in diameter with increased pressures. Compliant balloons are flexible and trackable over guide wires through high-degree, tortuous coronary lesions. Compliant balloons also have a tendency to shape to the artery as they are inflated. Unfortunately, compliant balloons have the tendency to "dog-bone" over highly stenotic and/or calcific lesions, increasing the risk of intimal disruption and dissection with higher inflation pressures.

Noncompliant Balloons

The polyethyleneterphthalate (PET) balloons are suited to long inflation balloon angioplasty and coronary stenting. Good stent apposition requires firm deployment of higher pressures at the lesion site, and the noncompliant balloons serve well. Once inflated to their maximum designed diameter, PET balloons do not tend to comply with increased diameter under rising pressure. This noncompliance holds across the length of the balloon, minimizing the dog-bone effect. The nature of noncompliance makes these balloons ideal for unstable and calcified lesions where overinflation increases the risk of intimal



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Professor of Medicine
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The J. Gerard Mudd Cardiac Catheterization Laboratory
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- Vascular injury (e.g., pseudoaneurysm of femoral artery)
- Restenosis (see Chapter 7).

Note: Restenosis at the site of PCI occurs in approximately 10–30% of patients and may lead to recurrence of anginal symptoms. Typically, restenosis occurs most frequently within the initial 6 months after PCI. This biologic effect is *not* considered a complication but rather a clinical part of angioplasty.

PCI EQUIPMENT

The most commonly used PCI equipment consists of four basic elements: a guiding catheter, a coronary guidewire, a balloon catheter, and a stent (Fig. 1-2, Table 1-2).

The Guiding Catheter

A special large lumen catheter is used to guide the coronary balloon catheter and other interventional devices to the vessel with the lesion to be dilated.

Functions of the Guiding Catheter

A guiding catheter serves three major functions during angioplasty: (1) balloon catheter delivery and guidance; (2) backup support for balloon advancement; and (3) pressure monitoring. Construction of a guiding catheter is shown in Figure 1-3.

Table 1-2

Approximate Costs of Coronary Angioplasty Equipment

Equipment	Cost ($)
Balloon dilatation catheter	500
Guiding catheter	100
Guidewire	100
Exchange guidewire (300 cm)	100
Indeflator	50
Y connector	15
Sheath introducer	10
Torque tool	10
Nonballoon devices	
Stent (noncoated)	1200
Stent (drug-eluting)	2800
Directional atherectomy catheter	1200
Rotoblator	1200

Balloon Catheter Delivery and Guidance. To deliver the balloon catheter to the coronary ostium, the guiding catheter should be seated with the tip parallel to the artery (coaxial). Coaxial alignment permits safer transmission of force needed to advance the balloon across a stenosis. This act may require guide catheter repositioning or deep seating into the artery.

Adequate contrast injection through the guide catheter is critical to position the balloon and depends on the size of the guide catheter lumen with the angioplasty device in place. A guiding catheter must be large enough to permit adequate contrast administration with the PCI catheter in place to opacify the target vessel and visualize the lesion. Large, nonballoon PCI devices (rotoblator, directional coronary atherectomy, Angio-Jet Aspiration catheter, or some stents) in small guide catheters may not allow adequate vessel visualization during angiography. This problem has been overcome with larger lumen, small guide catheters, and power injectors in some labs.

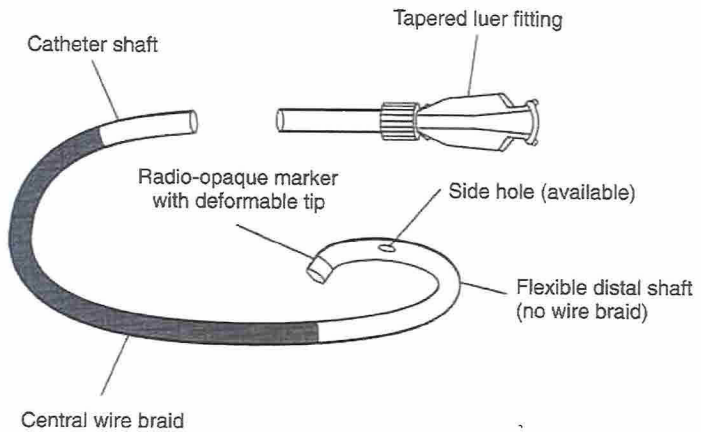

Fig. 1-3 Construction of a guiding catheter. The features noted differentiate it from diagnostic catheters. (From Avedissian MG, *et al.* Percutaneous transluminal coronary angioplasty: a review of current balloon dilation systems. *Cathet Cardiovasc Diagn* 1989;18:263.)

Operators should select a guide catheter with a lumen diameter large enough to allow adequate contrast flow around the PCI device to obtain a clear angiographic image of the lesion. As balloon and PCI catheters have become smaller, the size of internal diameter of the guiding catheter has become less important for achieving adequate visualization. A large guide catheter lumen, however, is critical to facilitate easy passage of atherectomy devices, and double balloon/stent systems for complex or bifurcation lesions.

Backup Support for Balloon Catheter and Stent Advancement. Support or "backup" for stent advancement is achieved after seating (cannulation) the guide catheter in the coronary ostium. The guiding catheter provides a platform from which one can push the stent over the guidewire through the artery and across the stenosis.

Inadequate backup support will result in failure to cross a lesion and an unsuccessful procedure. Backup support requires a combination of correct coaxial (in-line with the artery ostium) alignment, as well as the ability to provide carefully controlled advancement (deep seating) of the guiding catheter into the coronary ostium.

The improved quality and size of currently used stents have reduced the need for robust backup support in most situations. For more complex and technically difficult lesions, the choice of an appropriate guiding catheter for adequate support and lesion visualization remains essential (see Chapter 3). Although commercially formed catheters are generally adequate, a guiding catheter will rarely need to be reshaped in the catheterization laboratory using a heat gun for successful coronary cannulation and backup support.

When there is insufficient backup in crossing a very tight stenosis, the guiding catheter may be disengaged from the coronary ostium and backed out into the aortic root. When pressure is applied to the stent catheter during attempt to cross the lesion, repositioning the guide catheter in a stepwise fashion as the stent is advanced may overcome this loss of support. However, aggressive intubation of the coronary ostium may damage the vessel, stopping the procedure prematurely, and may require additional stenting for an ostial dissection.

Deep seating of the guide catheter is achieved by manipulating the guide catheter over the balloon catheter shaft, past the aortocoronary ostium and farther into the vessel, to obtain increased backup support for crossing difficult lesions. This maneuver typically is used as a last resort because of the increased chance of guide catheter-induced dissection of the left main or proximal vessel.

Pressure Monitoring. The guiding catheter measures aortic pressure during the case. Pressure wave damping may occur during coronary artery engagement if there is plaque in the coronary ostium. In addition, pressure measured proximal to the stenotic area can be compared to distal transstenotic pressure measured with a pressure sensor guidewire for assessment of lesion severity before and after PCI. Some catheters have side holes near the tip to permit perfusion into the artery when the catheter is deeply seated and obstructing flow.

Guide Catheter Construction

Catheter Characteristics. Compared to the diagnostic catheters, the guiding catheters have thinner walls, larger lumens, and stiffer shafts. A large catheter lumen is achieved at the expense of catheter wall thickness and thus may result in decreased catheter wall strength, less torque control, or catheter kinking. The guiding catheters are generally stiffer to provide backup support during the PCI catheter advancement into the coronary artery and, therefore, respond differently to manipulation than diagnostic catheters. The guiding catheter tip is not tapered. Pressure-wave damping upon engaging the coronary ostium is seen more often than with similar-size diagnostic angiographic catheters. Some guide catheters have relatively shorter and more flexible tips to decrease catheter-induced trauma.

Side Holes. Guiding catheters with small side holes permit blood to enter the coronary artery when the ostium is blocked by the guide catheter. Side holes are used when the guide catheter either partially or totally occludes blood flow into the coronary artery. The guide catheter coronary occlusion is noted by the change in the arterial pressure waveform to one of "damping." Catheter side holes eliminate or reduce ischemia

when the guiding catheter is seated in a small artery. However, side holes may lead to inadequate artery visualization from loss of contrast media exiting the catheter before entering the artery. Although side holes may provide reliable aortic pressure, coronary flow can still be compromised during the angioplasty procedure. The guide catheter and side holes act as a "second stenosis" at the coronary ostium.

Small-Shaft-Diameter Catheters. The most frequently used size of guiding catheter is currently 6 French. The use of smaller-diameter guide catheters, conceptually, will result in fewer vascular complications and allow earlier ambulation of patients. However, this advantage is offset by the compromised quality of coronary angiograms with smaller catheter lumen sizes. Small-size (≤5F) guide catheters do not allow for the use of some stents. 7 or 8F guide catheters are used for complex procedures involving larger PCI devices or bifurcation lesions.

Balloon Dilatation Catheter Systems

Types of Balloon Catheter. There are three types of PCI balloon catheter (Fig. 1-4): over-the-wire, monorail, and fixed-wire balloon catheters. The over-the-wire and monorail balloons, but not fixed-wire balloons, are also used to deliver stents that are mounted by the manufacturer on a specific balloon. The advantages and limitations are summarized in Table 1-3.

Over-the-Wire Angioplasty Balloon Catheters. A standard over-the-wire angioplasty balloon catheter has a central lumen throughout the length of the catheter for the guidewire and another separate lumen for balloon inflation. These balloons are approximately 145–155 cm long and may be designed to be used with guidewires of various dimensions (1.010–0.018 inches). In these systems, the guidewire and the balloon catheter move independently. The major advantage is the ability to maintain distal artery access with the guidewire beyond the lesion while exchanging one over-the-wire balloon catheter for another. To exchange balloons, the balloon is tracked over the wire to a distal position. The wire may then be removed from the balloon. The wire may then be reshaped and reintroduced through the central lumen or exchanged for a longer guidewire (300 cm) to maintain distal position while

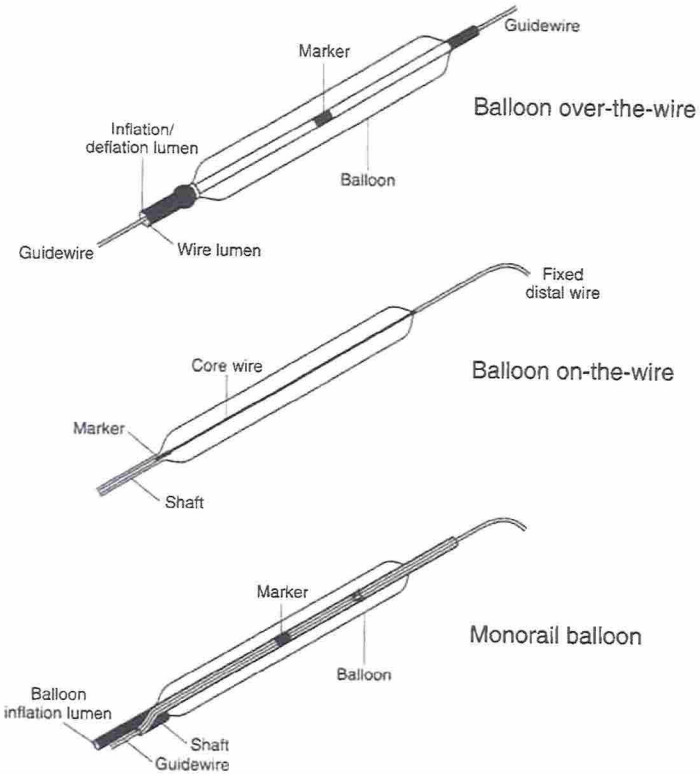

Fig. 1-4 Three common types of coronary balloon angioplasty catheter design. (Modified from Freed M, Grines C, eds. *Manual of interventional cardiology*. Birmingham, MI: Physicians' Press, 1992: 29.)

the balloon catheter is completely withdrawn over the guidewire and another balloon catheter is introduced over the same long guidewire for additional dilatations. An alternative method of balloon catheter exchange is to "trap" or secure a regular guidewire (145 cm) in the guide while the balloon catheter is exchanged (see exchange methods later). Over-the-wire catheters can accept multiple guidewires, which allows for exchanging additional devices that may require stronger, stiffer guidewires.

Over-the-wire angioplasty balloon catheters have several limitations. These catheters are, in general, slightly larger than

Table 1-3

Advantages and Limitations of Angioplasty Balloon Types

Advantages	Limitations
Over the wire	
Distal wire position	Two experienced personnel required
Distal port available for pressure measurement or contrast media injection	± Larger profile
Accepts multiple guidewires	
Rapid exchange	
Distal wire position	Exchanging balloons at hemostatic valve may be technically demanding
Enhanced visualization	
Low-profile balloons	
Single-operator system	
Fixed wire	
Enhanced visualization	Lack of through lumen
Single-operator system	Inability to recross lesion without removing system
Use with small guiding catheters	
Low-profile balloons	

Modified from Kern MJ, ed. *The cardiac catheterization handbook,* 2nd ed. St Louis, MO: Mosby, 1995.

the rapid-exchange (monorail) and fixed-wire catheters. Additional personnel may be required to help with long guidewire exchanges.

Rapid-Exchange (Monorail) PCI Balloon Catheters. "Rapid-exchange" monorail catheters were developed to improve the exchanging of angioplasty balloon catheters by single operators. Rapid-exchange catheters have only a short (~30–40 cm) length of the catheter shaft containing two lumens. One lumen runs the entire length of the catheter and is used for balloon inflation. The other lumen, which extends through only a portion of the catheter shaft, houses the guidewire. Because only a limited portion of the balloon requires dual lumens, rapid-exchange catheters are smaller in diameter than over-the-wire balloon catheters. Figure 1-5

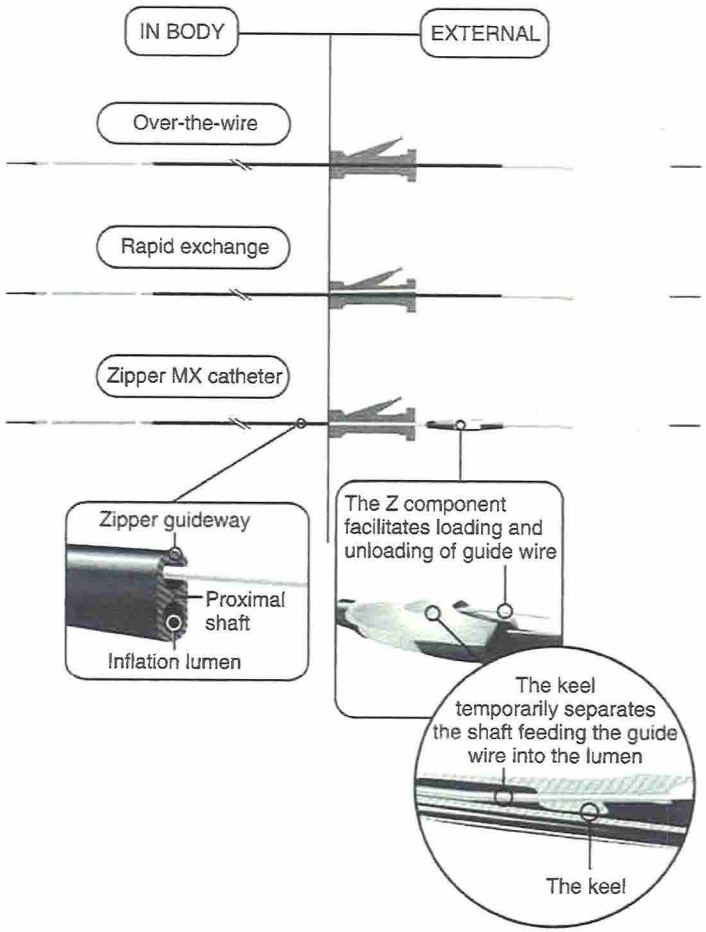

Fig. 1-5 Zipper balloon (Medtronic, Minneapolis, MN) allows variable length monorail to be converted to over-the-wire method at any time.

shows a novel type of "convertible" monorail using a zipper-type technique. Figures 1-6 and 1-7 show OTW and monorail balloon catheters.

Rapid-exchange balloon catheters address certain inherent limitations of over-the-wire catheters. First, over-the-wire balloon exchanges require a long (or extension) guidewire, an unnecessary maneuver for the rapid-exchange type. Second, a single operator can use rapid-exchange balloon catheters

Fig. 1-6 Quantum Maverick OTW. Over-the-wire "Quantum" Maverick Balloon. (Courtesy of SciMed-Boston Scientific, Boston, MA.)

without the aid of other assistants to maintain distal guidewire position.

Limitations of monorail catheters include the need for more expertise in manipulation of the guidewire, balloon catheter, and guiding catheter. Excessive blood loss at the rotating hemostatic valve during removal of the balloon catheter (back-out) maneuver may occur but valved "Y" connectors have reduced this problem. More caution when moving the balloon is needed. If the monorail balloon is advanced beyond the wire, the wire may come out of its short lumen, necessitating reassembly of the balloon and guidewire, especially when monorail catheters with relatively short "rails" are used.

If the balloon catheter requires force to advance beyond a lesion, a loop of guidewire may sometimes form outside the guide catheter in the aorta. This loop is nearly invisible but should be considered if the operator advances the catheter without seeing motion at the balloon tip.

Fixed-Wire Angioplasty Balloon Catheters. The fixed-wire catheter has the balloon mounted on a central hollow wire with a distal flexible steering tip. The proximal end of the catheter consists of a single port connected to a thin metal tube (hypotube). A core wire extends from the hypotube to the end of the distal steerable tip. This assembly is coated with a thin plastic shaft that enhances flexibility. Fixed-wire balloons have only one enclosed lumen for balloon inflation.

The on-the-wire balloon catheter is a fixed wire system, where the guidewire cannot be advanced independently of the balloon and the balloon cannot be exchanged without

Fig. 1-7 Maverick 2 Monorail. Monorail balloon catheter. (Courtesy of SciMed-Boston Scientific, Boston, MA.)

removing the entire system. Since the wire is attached to the distal end of the balloon, there is no central balloon lumen, resulting in a lower total profile than an over-the-wire or monorail system. Its principal advantages relate to its low profile, enabling passage through very tight stenoses, and good contrast visualization of the lesion being dilated around the balloon catheter.

The small shaft size provides excellent coronary visualization. Because the balloon is mounted on the distal guidewire, the device was designed to be used by a single operator. Fixed-wire balloon catheters are particularly useful for distal lesions, subtotal stenoses, and lesions located in tortuous vasculature.

The limitations of fixed-wire catheters include lack of the inherent safety advantage of over-the-wire and rapid-exchange systems because there is no movable wire available to exchange for a stent if a dissection occurs. To exchange this catheter the catheter must be removed completely. The lesion is then recrossed with a new guidewire and balloon catheter. A dissected lesion may not permit recrossing with a guidewire or advancement of another balloon catheter. Further attempts at recrossing may even close the vessel. In such cases, an angioplasty guidewire can be introduced alongside the fixed-wire balloon catheter before removing the catheter to assist in placing another balloon.

Characteristics of Balloon Catheters. The plastic material of the balloon determines its compliance and tensile strength. The main differentiation among balloons is related to compliant or noncompliant materials. Inflation of a compliant balloon above nominal pressure (i.e., a set pressure for a known balloon size) will lead to further expansion of the balloon approximately 10–20% over the rated diameter. Noncompliant balloons, on the other hand, remain very close to their rated diameter even when inflated several atmospheres above nominal pressure. The advantages and disadvantages of balloon materials remain controversial. A compliant balloon may be more cost-effective and result in fewer balloons being used in a given case. However, a compliant balloon may result in oversizing, particularly on second and third inflations, resulting in dissections. The complication rate of such mechanisms has not been tested in randomized clinical trials.

Exhibit 35

Boston Scientific Interventional Cardiology

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Mach 1® Guide Catheter

Overview

A large lumen and optimal shaft performance offers precise handling, device delivery options and clinical versatility

Unique Polymer

- Enhances back-up support and curve retention

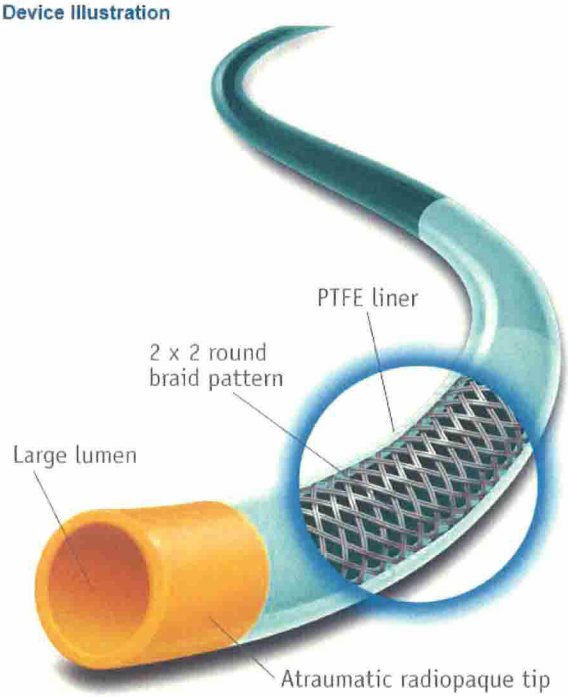
Large Lumen Design

- Offers the device compatibility needed for a multitude of treatment options and treatment scenarios
- Enables catheter downsizing
- Provides improved dye flow for better visualization

Design and Performance Dynamics

- Softer shaft guide catheter designed for active users accustomed to deep seating
- Available in 6F (0.070"), 7F (0.081") and 8F (0.091") sizes

Device Illustration



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Reimbursement
The C-code used for this product is C1887: Catheter, guiding (may include infusion/perfusion capability). C-codes are used for hospital outpatient device reporting for Medicare and some private payers

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Imaging System
Plaque Modification

RunWay® Guide Catheter

Overview

High-performance design for exceptional support, strength and control in case after case

Primary and Secondary Curve Firmness

- Provides outstanding back-up support
- Enhances pushability through tortuous anatomy
- Innovative polymer specially designed to enhance curve retention

Large Lumen Design

- Offers the device compatibility needed for a multitude of treatment options and treatment scenarios
- Provides improved dye flow for better visualization

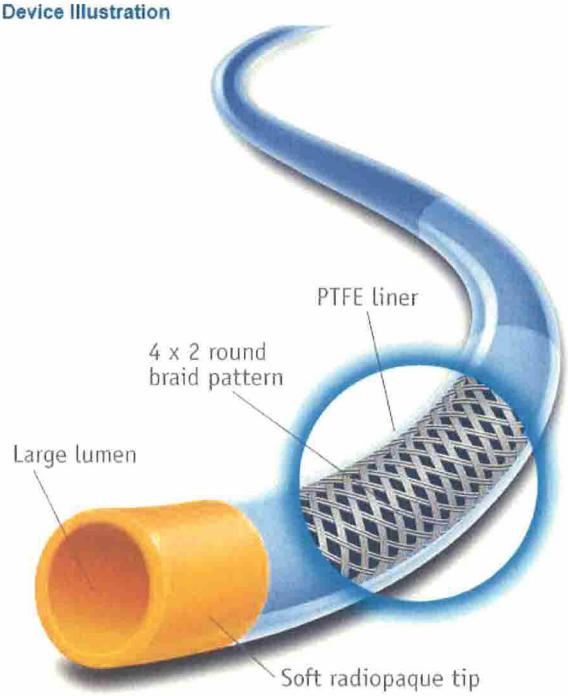
Improved Curve Retention and Tip Softness*

- Maintains primary curve shape 40% better than the Launcher Guide Catheter
- 40% softer tip than the Launcher Guide Catheter for improved placement confidence

Design and Performance Dynamics

- Firm catheter shaft for users preferring a passive guide catheter
- Available in 6F lumen size (0.070")

Device Illustration



* Bench test data on file. N=22 for Launcher; N=15 for RunWay. Bench test results may not necessarily be indicative of clinical performance.

Curve Retention: Testing measures the ability of the catheter to effectively retain its curve shape while placed in water at body temperature (37° C). Smaller changes in the curve angles may increase the catheter's ability to direct the therapy device to the intended target site. Tip Softness: Testing measures the force absorbed by the catheter's tip when compressed or deflected at 0.02". Lower force indicates a softer tip.

ADDITIONAL PRODUCT INFORMATION

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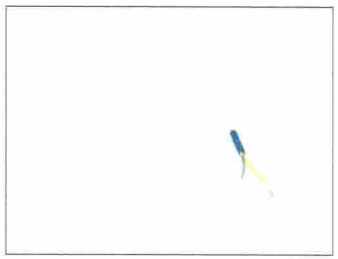
Dual Lumen Ureteral Catheters

Overview

Dual lumen catheter designed for over-the-wire placement, providing two separate working channels for second wire placement or injection.



Design Features

- Independent .038" guidewire lumen and .050 diameter injection lumen
- Large injection lumen aids in the delivery of irrigation fluids to the ureter and drainage of fluids from the urinary tract
- Access, advancement or exchange of ancillary devices including guidwires

Placement

- Tapered Tip design to facilitate access to the urinary tract
- Excellent radiopacity for improved visualization

Sizes

- 10Fr diameter with length of 50cm
- Guidewire Lumen .038" (Green)
- Injection Lumen .050" (Yellow)

Latex Information

This product contains no detectable latex.

Ordering Information

Order Number	O.D. Size	Working Length(cm)	Recommended Guidewire(in)	Injection Lumen(in)	Quantity
M0064051000	10F	54	.038	.050	Each

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Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

PeriVac™ Pericardiocentesis Kits

Return to product overview

Prescriptive Information
Refer to the operator's manual for complete instructions for use.

Indications
The PeriVac Pericardiocentesis Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.

Contraindications
There are no known contraindications for pericardial aspiration, although recurrent effusion or unresolved tamponade may warrant surgical intervention.

Warnings
Coagulation therapy may be required for patients that have been anti-coagulated to in order to prevent excessive bleeding. The risk of bleeding (which can occur due to needle laceration of the heart, or from other causes) should therefore be weighed carefully vs. the risks and benefits of anticoagulation and any treatment given to reverse the anticoagulation before proceeding with the pericardiocentesis.

Care must be taken to ensure that there is no electrical potential difference and that the cardiac monitor meets relevant safety standards.

- Ensure that the external portion of the guidewire is stabilized prior to catheter introduction
- If resistance is encountered during advancement or withdrawal of the catheter, STOP DO NOT CONTINUE without first determining the cause of the resistance and taking remedial action
- If it is necessary to reintroduce the guidewire, use extreme caution to assure that the guidewire exits through the end hole. Damage to the catheter may occur if the guidewire exits through a side hole
- Movement of the patient with the straight catheter in place is not recommended due to risk of cardiac perforation.
- Do not reintroduce effluent to patient
- If no drainage is seen accumulating over several hours, the lumen of this catheter may be obstructed by cellular debris. Gentle flushing of the catheter with sterile saline may be requested by the physician.

Potential Adverse Events
Complications: The following complications have been associated with pericardial drainage procedures:

Arrhythmias, Pericarditis, Endocarditis, Hemothorax or pneumothorax, Perforation of the ventricle, atrium, or coronary vessels, Sepsis/Infection, Tamponade, Death

Strict adherence to the foregoing instructions will help reduce the incidence of complications.

Precautions
Before use, inspect contents of the kit for physical damage including electrical insulation on the cables and other damage on the shaft of the catheter. Replace damaged components.

- Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific representative.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Careful attention to aseptic technique should be employed.
- This kit should be used only by persons thoroughly trained in the techniques of pericardiocentesis.
- Take proper care to ensure that all patient-contact electrical equipment is properly isolated and grounded.
- Do not wipe catheter with organic solvents (e.g. alcohols, ethers, esters, phenols etc.).
- CT scan, fluoroscopic, or echocardiographic examinations are recommended to evaluate needle and catheter placement.
- Pericardiocentesis should ideally be carried out in the Special Procedures Laboratory or Cardiac Catheterization Laboratory, utilizing equipment capable of cardiac monitoring. When performed at bedside, electrocardiographic monitoring should be employed continuously.
- After use, dispose of product and packaging in accordance with hospital administrative and/or local government policy.

ADDITIONAL PRODUCT INFORMATION

Prescriptive Information
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PeriVac Kit Product Brochure
Product specifications and order information for the PeriVac Kit.
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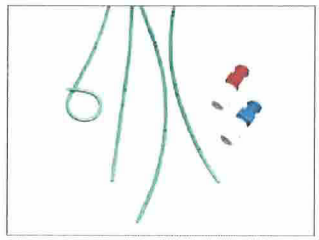
C-Flex® Ureteral Catheters

Overview

Single lumen tapered catheter with flexible tip and firm catheter shaft designed to provide excellent column strength for atraumatic Ureteral access and smooth advancement.



Design Features

- Combination of Firm C-Flex catheter shaft and Soft C-Flex catheter tip
- Soft C-Flex Single lumen with injection hub for injection of contrast or establishment of post-procedure drainage collection

Placement

- Tapered Tip design to facilitate access to the urinary tract
- Graduated placement markers
- Excellent radiopacity for improved visualization

Multiple Sizes

- Offered in various Open Tip and Pigtail configuration
- 4F – 8F diameter with length of 70cm

Latex Information

This product contains no detectable latex.

Ordering Information

Order Number	Description	Catheter O.D. Size	Working Length(cm)	Quantity
M0064001500	Open End Set	4.8F	70	Each
M0064001510	Open End Set	6F	70	Each
M0064001520	Open End Set	7F	70	Each
M0064001530	Open End Set	8F	70	Each
M0064001610	Firm Stamey Open Tip Set	4F	70	Each
M0064001620	Firm Stamey Open Tip Set	4.8F	70	Each
M0064001630	Firm Stamey Open Tip Set	6F	70	Each
M0064001640	Firm Stamey Open Tip Set	7F	70	Each
M0064001700	Pigtail Catheters	4.8F	70	Each
M0064001710	Pigtail Catheters	6F	70	Each
M0064001720	Pigtail Catheters	7F	70	Each
M0064001730	Pigtail Catheters	8F	70	Each
M0064001400	Flexible Tip Open End Set	6F	70	Each
M0064001410	Flexible Tip Open End Set	7F	70	Each

C-Flex is a registered trademark of Cook Urological.

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- PCNL Kits
- Renal Sheaths
- Retrieval Devices
- Stents
- Ureteral Catheters

Procedure
- PCNL
- Ureteroscopy

Flexima® Ureteral Catheters

Overview

Single lumen catheter designed with a variety of tip configurations and sizes to facilitate ureteral access

Design Features

- Biocompatible catheter material available in a variety of tip configurations and sizes
- Single lumen with injection hub provided for access and collection

Placement

- Various tip designs to facilitate access to the urinary tract
- Can be placed retrograde
- Excellent radiopacity for improved visualization

Multiple Sizes

- Offered in various Open Tip configuration
- 4F – 8F diameter with length of 70cm

Latex Information

This product contains no detectable latex

Ordering Information

Order Number	Description	Catheter O.D. Size	Working Length(cm)	Tip O.D. Size	Quantity
M0064002001	Open End	4F	70	-	Box 20
M0064002011	Open End	5F	70	-	Box 20
M0064002021	Open End	6F	70	-	Box 20
M0064002031	Open End	7F	70	-	Box 20
M0064002041	Open End	8F	70	-	Box 20
M0064002111	Cone Tip	5F	70	8F	Box 20
M0064002121	Cone Tip	6F	70	10F	Box 20
M0064002131	Cone Tip	7F	70	12F	Box 20
M0064002141	Cone Tip	8F	70	14F	Box 20
M0064002201	Whistle Tip	4F	70	-	Box 20
M0064002211	Whistle Tip	5F	70	-	Box 20
M0064002221	Whistle Tip	6F	70	-	Box 20
M0064002301	Olive Tip	4F	70	-	Box 20
M0064002311	Olive Tip	5F	70	-	Box 20
M0064002361	Spiral Tip	5F	70	-	Box 20
M0064002371	Spiral Tip	6F	70	-	Box 20
M0064002411	Wedge Tip	5F	70	14F	Box 20
M0064002510	Angled Tip Set w/ GW .035 PTFE Bentson Tip	5F	70	-	Each
M0064002520	Angled Tip Set w/ GW .035 PTFE Bentson Tip	6F	70	-	Each

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Renal Sheaths
Retrieval Devices
Stents
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Procedure
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Ureteroscopy

Imager™ II Catheters

Overview

Torqueable Catheters

Single lumen torqueable catheter designed to facilitate difficult access in PCNL and Ureteroscopic procedures

Design Features

- Single lumen, torqueable Imager catheter are available in five tip configurations and 3 working lengths
- Biocompatible polymer reinforced with a stainless steel braided wire
- Luer lock hub attached at the proximal end

Multiple Sizes

- Offered in 5 Open Tip configuration
- 5F diameter with 3 working lengths

Placement

- Facilitates access to the urinary tract with various tip designs
- Can be placed either retrograde or antegrade
- Excellent radiopacity for improved visualization

Latex Information

This product contains no detectable latex

Ordering Information

Order Number	Description	O.D. Size	Working Length(cm)	Quantity
M0064003001	C1	5F	65	Box 5
M0064003011	C2	5F	65	Box 5
M0064003021	Straight	5F	65	Box 5
M0064003031	Bern	5F	65	Box 5
M0064003041	JB1	5F	65	Box 5
M0064004021	Straight	5F	100	Box 5
M0064004031	Bern	5F	100	Box 5
M0064004041	JB1	5F	100	Box 5
M0064005031	Bern	5F	40	Box 5

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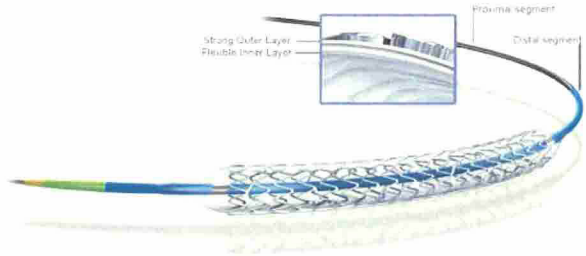
- Drug / Clinical Data

PROMUS Element™ Plus Everolimus-Eluting Platinum Chromium Stent System—Exceptional Deliverability

The PROMUS Element Plus Stent System exhibits exceptional deliverability when compared to leading cobalt alloy stents. The Bi-Segment™ Inner Lumen catheter and dual-layer balloon work synergistically with the Platinum Chromium stent platform to create this highly deliverable system with exceptional pushability and trackability.

Highly Deliverable Stent System

The unique dual-layer balloon fuses a strong outer layer with a more flexible inner layer for better trackability. The Bi-Segment Inner Lumen catheter provides the appropriate level of pushability and flexibility to create enhanced deliverability.



PROMUS Element Plus Stent System

- Up to 15% more pushability than cobalt alloy stents*
- Up to 31% more trackability than cobalt alloy stents*
- Up to 28% more flexible than cobalt alloy stents*

PROMUS Element Plus Stent System Specifications

» Learn more about the PROMUS Element™ Plus Stent System »

* Data on File. Testing completed by Boston Scientific. (2.5 mm x 28 mm Stent Products, N=6 for Profile, N=3 for Flexibility and Push. PROMUS Element™ Plus Stent System, Endeavor™ Stent System, Xience V® Stent System, Xience Prime™ Stent System). Bench test results may not necessarily be indicative of clinical performance.

Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

View PROMUS Element™ Plus Stent System Prescriptive Information »

IC-61502-AB AUG2012

Product Finder:
Axxcess™ Ureteral Catheters
Go

Featured Products
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Category
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Accessories
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Dilatation Devices
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PCNL Drainage Devices
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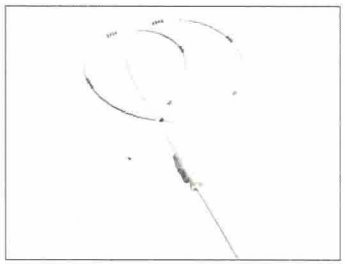
PCNL Kits
Renal Sheaths
Retrieval Devices
Stents
Ureteral Catheters

Procedure
PCNL
Ureteroscopy

Axxcess™ Ureteral Catheters

Overview

Single lumen ureteral catheter designed with tapered tip to provide atraumatic access for delivery of contrast or a guidewire



Design Features

- Soft Percuflex® Material
- Single lumen with injection hub for injection of contrast or establishment of post-procedure drainage collection

Placement

- Tapered Tip design to facilitate access to the urinary tract
- Graduated placement markers
- Excellent radiopacity for improved visualization

Sizes

- 6F diameter with length of 70cm

Latex Information

This product contains no detectable latex.

Ordering Information

Order Number	Description	Catheter O.D. Size(Fr)	Working Length(cm)	Tip O.D. Size(Fr)	Quantity
M0064001161	Open End	6F	70	-	Box 10

ADDITIONAL INFORMATION

Prescriptive Information
View prescriptive information

Customer Service
To order product by phone, dial 888-272-1001.

eOrder
You can now order product online.
• Click here to login

Contact Us
Request a Boston Scientific Field Sales Representative visit.
• Email Boston Scientific

Reimbursement
View Reimbursement Information here

Supporting Materials
Procedural Accessories Brochure

Exhibit 36

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

24113 7590 08/22/2012

PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	**PAPER NUMBER**
3767	

DATE MAILED: 08/22/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/359,059	01/26/2012	Howard Root	2005.86US03	6559

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	11/23/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7590 08/22/2012
PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/359,059	01/26/2012	Howard Root	2005.86US03	6559

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	11/23/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
OSINSKI, BRADLEY JAMES	3767	604-527000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/359,059	01/26/2012	Howard Root	2005.86US03	6559

24113 7590 08/22/2012

PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
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80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/22/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No. 13/359,059	Applicant(s) ROOT ET AL.	
	Examiner BRADLEY OSINSKI	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *1/26/2012*.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-24*.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4/9/2012
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Bradley J Osinski/ Examiner, Art Unit 3767	/KEVIN C. SIRMONS/ Supervisory Patent Examiner, Art Unit 3767

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul Onderick on 8/6/2012.

The application has been amended as follows:

In both claims 1 and 12:

after "a flexible tip portion defining a tubular",

"rail structure without a lumen" has been changed to --structure--, and

after "than, the flexible tip portion and defining a",

"structure" has been changed to --rail structure without a lumen--.

In the specification, page 1, in the Related Applications section:

After "filed June 28, 2010", --now U.S. Patent 8,142,413 -- has been inserted.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: just as in the parent applications, the examiner did not find any teaching or suggestion for the claimed arrangement. Specifically, adding a guide catheter to the claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767

Exhibit 37

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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24113 7590 01/17/2012

PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
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MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 01/17/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/824,734	06/28/2010	Howard Root	2005.86US02	1416

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	04/17/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

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HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7590 01/17/2012
PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/824,734	06/28/2010	Howard Root	2005.86US02	1416

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$300	$0	$1170	04/17/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
OSINSKI, BRADLEY JAMES	3767	604-510000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/824,734	06/28/2010	Howard Root	2005.86US02	1416

24113 7590 01/17/2012

PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 01/17/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No. 12/824,734	Applicant(s) ROOT ET AL.	
	Examiner BRADLEY OSINSKI	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *11/1/2011*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *1-5,7 and 21-28*.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Bhisma Mehta/ Primary Examiner, Art Unit 3767	/Bradley J Osinski/ Examiner, Art Unit 3767

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul Onderick on 1/11/2012.

The application has been amended as follows:

In the specification, in the paragraph titled "Related Applications" added in the single page amendment dated 6/28/2010, after "filed May 3, 2006,",

--now U.S. Patent No. 8,048,032, -- has been inserted.

In claim 7, after "as claimed in claim",

"6" has been deleted, and

--1-- has been inserted.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: This method application is a divisional of apparatus application 11/416,629, now patent application 8.048,032. The reasons for allowance are similar as the patented apparatus overlaps with the apparatus used by the method. There is no teaching or suggestion of using the

claimed multi-catheter system which includes a rail structure attached to a tubular tip to access an artery of the coronary vasculature.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Bhisma Mehta/
Primary Examiner, Art Unit 3767

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86US02

Howard Root et al. Confirmation No.: 1416

Application No.: 12/824,734 Examiner: Bradley James Osinski

Filed: June 28, 2010 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

AMENDMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of August 1, 2011, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remain(s) under examination in the application is presented below. The claims are presented in ascending order and each includes one status identifier. Those claims not cancelled or withdrawn but amended by the current amendment utilize the following notations for amendment: 1. deleted matter is shown by strikethrough for six or more characters and double brackets for five or fewer characters; and 2. added matter is shown by underlining.

1. (Currently Amended) 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 [[the]] a first ~~blood vessel~~ artery over a guidewire, the standard guide catheter having ~~a first lumen and~~ a distal end;

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

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, ~~over a the guidewire and~~ into the [[first]] continuous lumen of the standard guide catheter, ~~the coaxial guide catheter having a second lumen~~ and

~~a flexible distal tip portion,~~

~~a reinforced portion proximal to the distal tip portion, and~~

~~a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion having an opening along a side thereof~~,

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 [[the]] a distal [[tip]] portion of ~~the coaxial guide catheter~~ the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery ~~blood vessel~~ such that the ~~flexible~~ distal [[tip]] 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 at least a portion of the reinforced portion extend out of the distal end of the guide catheter and into the second blood vessel;~~ 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 ~~through the lumen of the coaxial guide catheter and~~ into contact with or past a lesion in the second artery ~~blood vessel~~.

2. (Currently Amended) 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 [[tip]] portion of the coaxial guide catheter remains seated in the second ~~blood vessel~~ artery in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.

3. (Currently Amended) The method as claimed in claim 1, further comprising:

keying [[the]] a tapered inner catheter to the coaxial guide catheter at a proximal portion thereof~~;~~

~~inserting a guidewire having a tip into a first blood vessel; and~~

~~inserting the tip of the guidewire into a second blood vessel that branches off of the first blood vessel~~.

4. (Original) 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 [[the]] an opening along a side thereof.

5. (Currently Amended) 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 ~~second lumen~~ standard guide catheter.

6. (Cancelled)

7. (Currently Amended) The method as claimed in claim 6, further comprising placing a tapered inner catheter inside the ~~second~~ 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 ~~being positioned~~ to extend beyond the distal tip of the coaxial guide catheter; and

removing the tapered inner catheter from the coaxial guide catheter~~; and~~

~~removing the guidewire from the coaxial guide catheter~~.

8-20. (Canceled).

Please add new claims 21-28 as follows:

21 (New) 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.

22 (New) 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.

23 (New) The method of claim 22, 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.

24. (New) The method of claim 22, 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.

25. (New) The method of claim 24 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.

26. (New) The method of claim 21, further comprising extending the interventional cardiology device past a radiopaque marker proximate a distal tip of the coaxial guide catheter.

27. (New) 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.

28. (New) 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,

REMARKS

Claims 1-7 are pending, claims 8-20 having been previously cancelled. By this Amendment, claim 6 is cancelled, claims 1-3, 5 and 7 are amended and new claims 21-28 are added.

35 U.S.C. § 112

The Office Action rejected claims 1-5 and 7 under 35 U.S.C. § 112, second paragraph, as being indefinite. By this Amendment, Applicant has amended claims 1-5 and 7 to correct for a lack of antecedent basis identified by the Examiner. Applicant respectfully requests that the Examiner withdraw the rejections.

35 U.S.C. § 103

The Office Action rejected claims 1-7 under 35 U.S.C. § 103(a) as being unpatentable over Niazi (U.S. Patent 6,638,268) in view of Osborne et al. (U.S. Publication 2005/0004523). By this Amendment, Applicant has amended claim 1 to recite the limitations:

> 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.

These limitations are not disclosed or suggested by Niazi nor are they disclosed or suggested by Osborne. For example, neither Niazi nor Osborne discloses or suggests insertion into an artery, the coronary sinus being a vein. Nor does Niazi or Osborne disclose or suggest the other limitations related to the insertion of a flexible tip portion of the coaxial guide catheter, insertion of the substantially rigid portion of the coaxial guide catheter and the limitations:

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

now recited in amended claim 1.

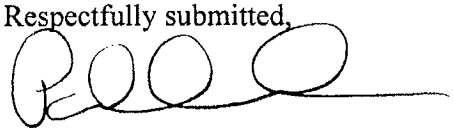
Claims 2, 3,5 and 7 are amended for consistency with amended claim 1.

Accordingly, independent claim 1 should be patentable for at least these reasons. Dependent claims 2-7 depend from claim 1 and should be patentable for at least the same reasons as claim 1. New dependent claims 21-28 also depend from claim 1 and should be patentable for at least the same reasons as claim 1. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejections.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Christensen Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5766

Exhibit 38

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US03
Howard Root et al.	Confirmation No.: 6559
Application No.: 13/359,059	Examiner: Bradley James Osinski
Filed: January 26, 2012	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

TELEPHONE INTERVIEW SUMMARY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

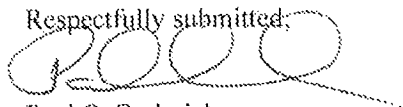
Sir:

Applicants thank the Examiner for the courtesy extended to their undersigned representative in a telephone interview on August 6, 2012.

During the telephone interview, correction of informalities of independent claims 1 and 12 was discussed. Agreement was reached and Applicants' undersigned representative authorized the making of an Examiner's Amendment as reflected in the Notice of Allowance mailed August 22, 2012.

Applicants thank the Examiner for his attention to the claims and for the subsequent Notice of Allowance.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Christensen Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5766

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

24113 7590 08/03/2011

PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/03/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/416,629	05/03/2006	Howard Root	2005.86US01	5061

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	11/03/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

24113 7590 08/03/2011
PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/416,629	05/03/2006	Howard Root	2005.86US01	5061

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	11/03/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
OSINSKI, BRADLEY JAMES	3767	604-164100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
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- ☐ A check is enclosed.
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- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/416,629	05/03/2006	Howard Root	2005.86US01	5061

24113 7590 08/03/2011

PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/03/2011

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 384 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 384 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No. 11/416,629	Applicant(s) ROOT ET AL.	
	Examiner BRADLEY OSINSKI	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *2/22/2011*.

2. ☒ The allowed claim(s) is/are *58-79*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Bradley J Osinski/ Examiner, Art Unit 3767	/KEVIN C. SIRMONS/ Supervisory Patent Examiner, Art Unit 3767

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brad Pederson in July of 2011.

The application has been amended as follows:

In both claims 58 and 67, after "the flexible tip portion and defining a",

"structure" has been deleted and

--rail structure without a lumen and-- has been inserted.

REASON FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: the examiner did not find any teaching or suggestion for the claimed arrangement. While many of the structures are known, the arrangement of a claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

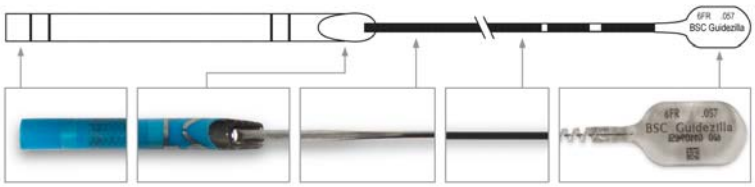
/Bradley J Osinski/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767

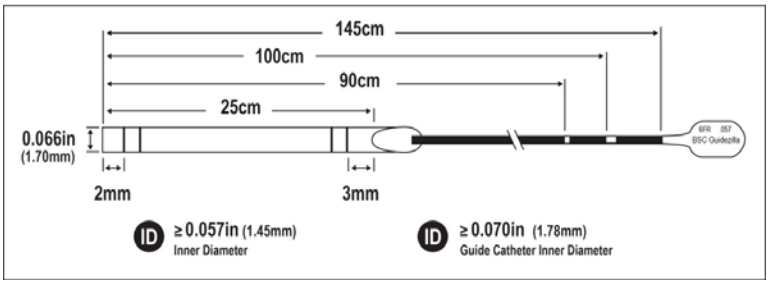
Exhibit 39

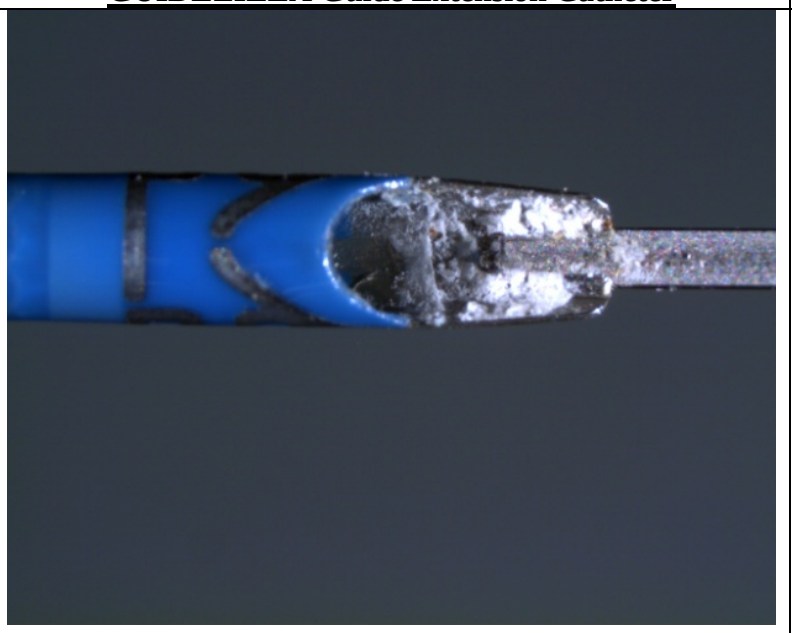
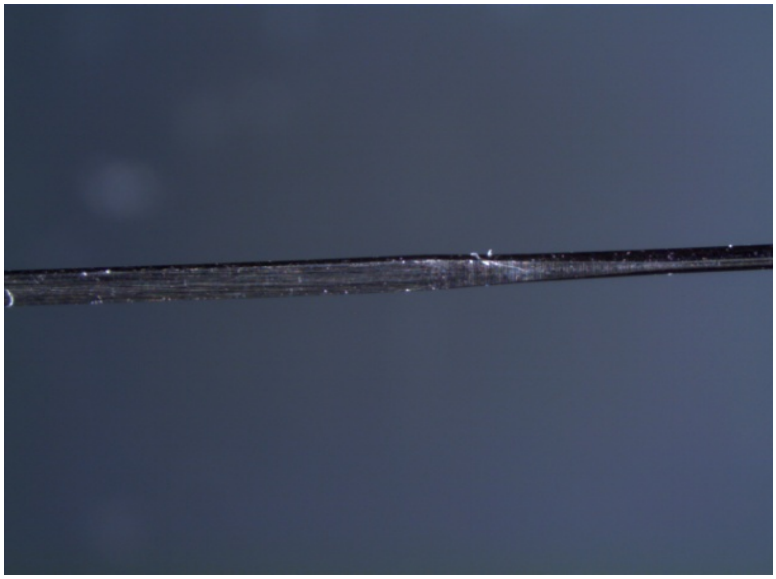
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'413 patent, claim 1. 1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be 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:	This is preamble language, which I understand may not necessarily limit the scope of the claim. Notwithstanding, Boston Scientific's Guidezilla is used to provide backup support for an interventional cardiology device for use in the coronary vasculature, where the interventional cardiology device is passed through a standard guide catheter that has a continuous lumen that extends from a proximal end at a hemostatic valve to a distal end that is placed in a branch artery. That Boston Scientific instructs users to use the Guidezilla in a manner that meets all steps of this claim 1 is clear from the Boston Scientific Directions for Use (Ex. 25). Excerpts from these Directions for Use are included below, but, for clarity, and because these Directions for Use show that Boston Scientific instructs users to use the Guidezilla in a manner that meets all steps of claim 1, the "Delivery Procedure" portion of the Directions for Use are reproduced here, as follows: "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter. "3. Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. . . . . "4. Using fluoroscopy, confirm the desired position of the Guidezilla device in the vessel. "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	"**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 Guidezilla device to prevent back-bleeding. "7. Perform the catheterization procedure. After completing the procedure, remove the Guidezilla device prior to removing the guide catheter from the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Other items required but not provided: Guide catheter with an inner diameter large enough to accommodate the Guidezilla™ device." Guidezilla Directions for Use at 3 (Ex. 25). "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary (Ex. 21); see also Guidezilla Directions for Use at 2 (Ex. 25). A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.
inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;	To use the Guidezilla, a standard guide catheter is inserted into a first artery over a guidewire. Boston Scientific's documents confirm that a guidewire is used with the catheter (see above) and Guidezilla. "Never advance the Guidezilla device into a vessel without a leading guidewire. . . ." Guidezilla Directions for Use at 2 (Ex. 25). "Other items required but not provided: . . . Guidewire with diameter ≤ 0.014 in (0.36 mm)." Guidezilla Directions for Use at 3 (Ex. 25).

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;	To use the Guidezilla, the distal end of the standard guide catheter is positioned in a branch artery that branches off from the first artery. "The Guidezilla guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Guidezilla Directions for Use at 2 (Ex. 25).
inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	Boston Scientific documents instruct the user to insert the flexible tip portion of the Guidezilla coaxial guide catheter into the continuous lumen of the standard guide catheter. "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: "1. Secure the previously inserted guidewire and backload the distal tip of the Guidezilla device onto the guidewire and advance until the device is just proximal to the hemostasis valve. . . ." Guidezilla Directions for Use at 3 (Ex. 25). Guidezilla has a flexible tip portion with a tubular structure and a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter. That Guidezilla has a flexible tip portion that defines a tubular structure with a circular cross-section, which is the blue, tubular structure in the following photographs and the tubular structure in the diagram below:

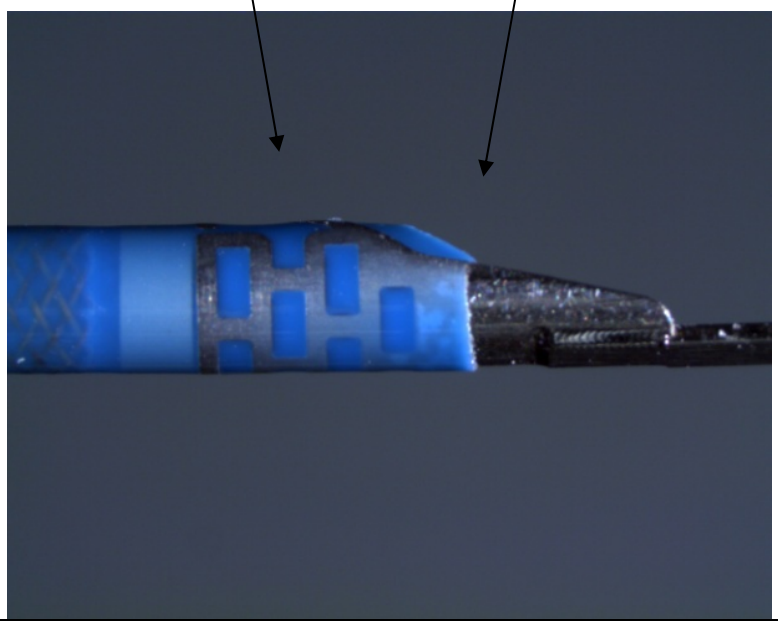
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	  Guidezilla has a tubular structure. It has "a single lumen distal guide segment." Guidezilla Directions for Use at 2. "GUIDEZILLA consists of . . . a distal guide catheter segment through which interventional devices may be delivered." Boston Scientific's 510(k) Summary (Ex. 21). The flexible tip portion's length is shorter than the length of the continuous lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a tubular structure that is 25cm in length:

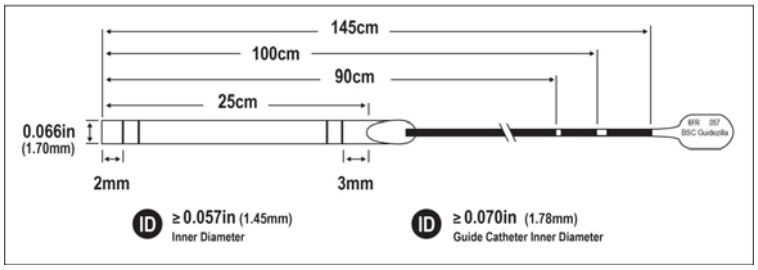
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the	Guidezilla  A standard 6F guide catheter length is 100cm. The tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable. "The Guidezilla guide extension catheter is "a single lumen rapid exchange catheter. . . " with "a stainless steel proximal shaft with a 25cm single lumen distal guide segment . . . ." Guidezilla Directions for Use at 2 (Ex. 25). Guidezilla has a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion. This is the "stainless steel proximal shaft" of the Guidezilla device. Guidezilla Directions for Use at 2 (Ex. 25). As the attached photographs depict, this "stainless steel proximal shaft" is substantially rigid, defines a rail structure without a lumen, and has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion. That the Guidezilla's substantially rigid portion does not have a lumen is discussed in more detail in my declaration, at ¶¶ 89-103.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
guide catheter;	  The rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is 145cm, longer than the standard 100cm length of the continuous lumen of the guide catheter. When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a

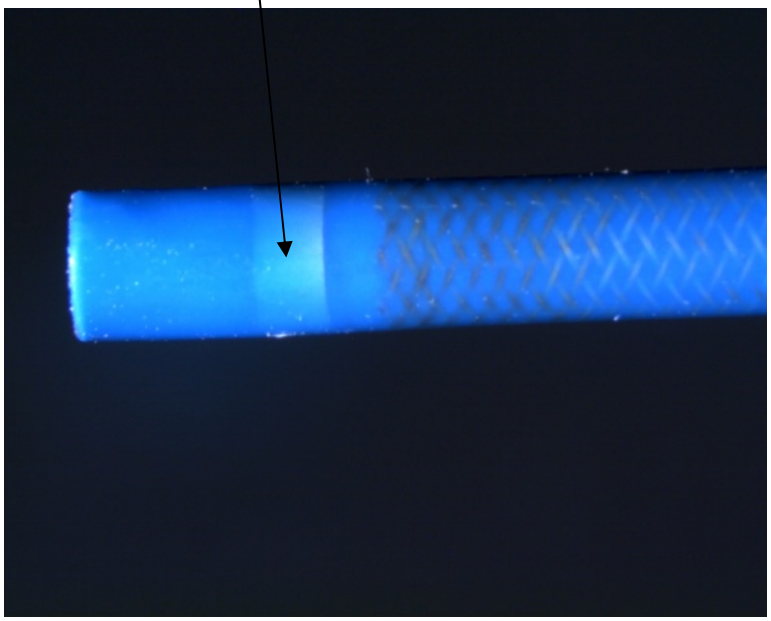
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21).
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	The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3 (Ex. 25). This substantially rigid portion of the Guidezilla device is inserted into the continuous lumen of the standard guide catheter, as noted above from the Directions for Use, which instruct the user to insert the Guidezilla device into the guide catheter "until the device is just proximal to the hemostasis valve." Guidezilla Directions for Use at 3 (Ex. 25). A distal portion of the Guidezilla's flexible tip portion is advanced distally beyond the distal end of the standard guide catheter and into the second artery, such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. "**Delivery Procedure**

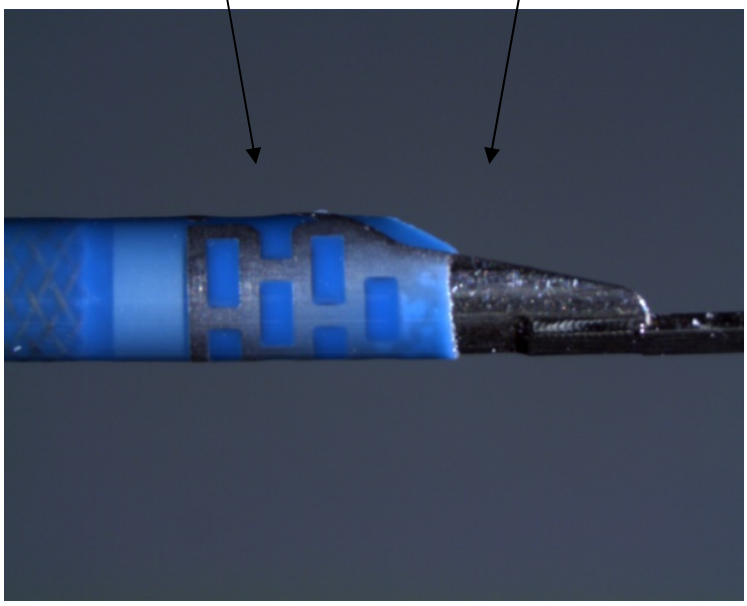
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
inserting the interventional cardiology device into and through the 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.	"Deliver the Guidezilla device according to the following steps: . . . . "2. Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter. "3. Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel. . . . . "6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guidezilla device to prevent back-bleeding." Guidezilla Directions for Use at 3 (Ex. 25). Boston Scientific's documents instruct the user to insert the interventional cardiology device into and through the continuous lumen of the standard guide catheter, alongside the substantially rigid portion, and to advance the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery. "**Delivery Procedure** "Deliver the Guidezilla device according to the following steps: . . . . "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3 (Ex. 25).
'413 patent, claim 2. 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	In use, the Guidezilla's distal portion remains seated in the second artery as a force is applied to a proximal portion of the Guidezilla in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced. Boston

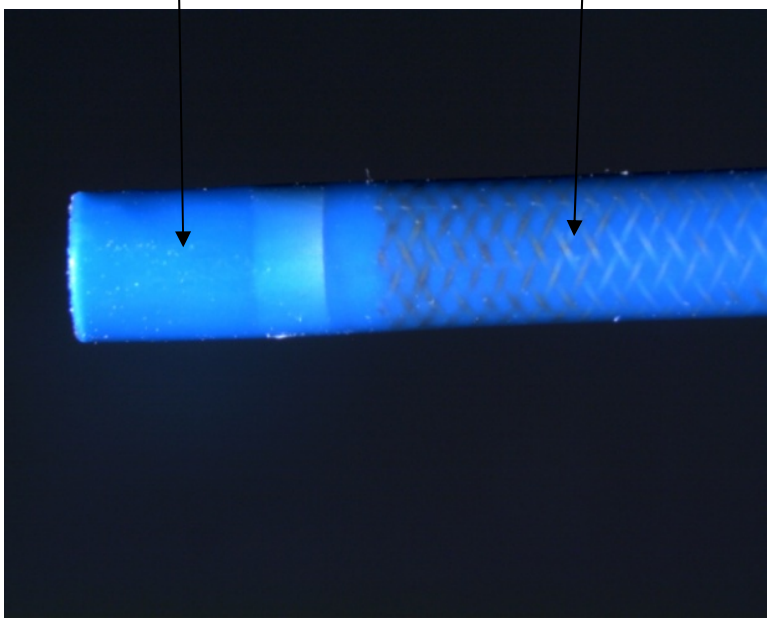
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
catheter remains seated in the second artery in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.	Scientific's documents indicate that this use is intended. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25).
'413 patent, claim 4. 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.	The substantially rigid portion of the Guidezilla is selected so that it comprises a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof, as can be seen in the photograph below of the Guidezilla device: Cylindrical Portion — Partially Cylindrical Portion 

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'413 patent, claim 5. 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.	In use, the Guidezilla uses a Y-adapter. "6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the Guidezilla device to prevent back-bleeding." Guidezilla Directions for Use at 3 (Ex. 25). The physician injects a fluid through the Y-adapter into the standard guide catheter. For example, a physician will inject a contrast dye through the Y-adaptor when using Guidezilla in order to visualize the vessel under fluoroscopy.
'413 patent, claim 7. 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.	Boston Scientific's documents instruct the user to extend 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. The following Boston Scientific drawing shows that the Guidezilla has a tubular structure that is 25cm in length: Guidezilla  That the tubular structure has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter can be seen in that the length of the tubular structure is 25cm, but not more than 15cm of the tubular structure is advanced past the distal tip of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). By having the distal portion of the Guidezilla's tubular structure extend beyond the distal end of the standard guide catheter while a proximal portion remains within the lumen of the standard guide catheter, the Guidezilla 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.
'413 patent, claim 8. 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.	Guidezilla has two radiopaque markers located in the tubular structure. "The guide catheter segment incorporates two radiopaque marker bands to aid in positioning the device during the procedure." Boston Scientific's 510(k) Summary (Ex. 21). One of Guidezilla's radiopaque marker is positioned in the device's flexible cylindrical distal tip portion proximate a distal tip. "The Guidezilla device has two platinum-iridium marker bands, which enable visibility while using standard fluoroscopic methods. The distal marker band is located 2 mm from the distal tip. The proximal marker band is located 3 mm distal to the opening of the guide segment." Guidezilla Directions for Use at 2 (Ex. 25). The distal marker can be seen in the following photograph of the Guidezilla device:

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	Radiopaque Marker  When the Guidezilla is used, the interventional cardiology device is extended past the radiopaque marker. See above, in the discussion of claim 7.
'413 patent, claim 9. 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.	See above, in the discussion of claim 4 and 7. When the Guidezilla is used, the interventional cardiology device is extended through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter. The Guidezilla Directions for Use state: "5. If performing an interventional procedure, backload the interventional device over the guidewire and advance the device through the guide catheter and Guidezilla device

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	into the desired vascular space. "**Note:** Use caution when advancing the interventional device into the distal guide segment." Guidezilla Directions for Use at 3 (Ex. 25).
'413 patent, claim 10. 10. The method of claim 9, further comprising	
extending the interventional cardiology device through the proximal side opening;	See above, in the discussion of claim 9. Guidezilla has structure defining a full circumference portion and structure defining a partially cylindrical portion: Full Circumference Portion Partially Cylindrical Portion 
advancing the interventional cardiology device through structure defining a full circumference portion; and	In use, the interventional cardiology device is extended through both the full circumference portion and the partially cylindrical portion.
advancing the interventional cardiology device through	

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
structure defining a partially cylindrical portion.	
'413 patent, claim 11. 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.	The Guidezilla device's tubular structure has a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion, as can be seen in the following photograph: Flexible Cylindrical Distal Tip Portion Flexible Cylindrical Reinforced Portion  When the Guidezilla device is used, the interventional cardiology device is extended through the flexible cylindrical distal tip portion and the flexible cylindrical reinforced portion of the tubular structure. See above, in the discussion of claim 9.
'413 patent, claim 12. 12. The method of claim 11 further comprising extending the interventional cardiology device through the flexible cylindrical	See above, in the discussion of claim 11. As can be seen in the following photograph, the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided pattern:

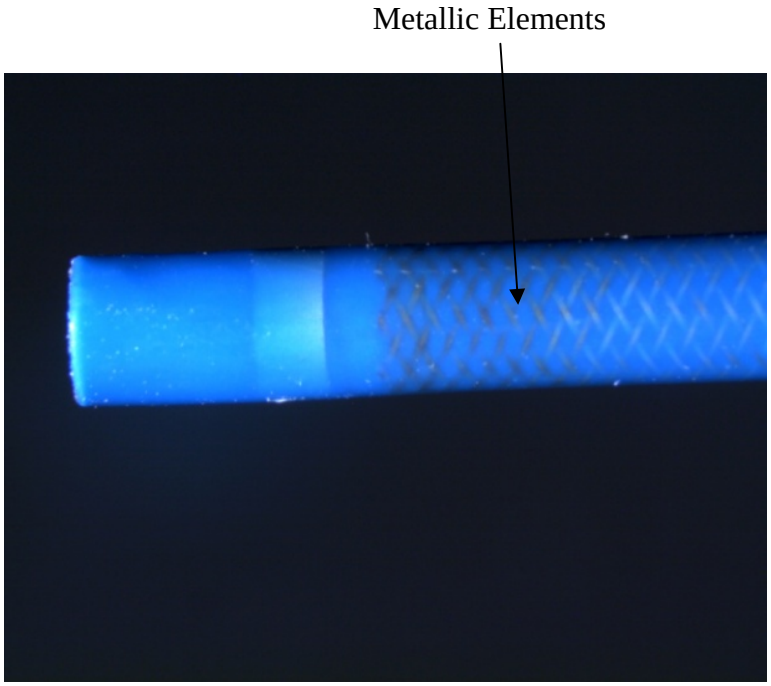
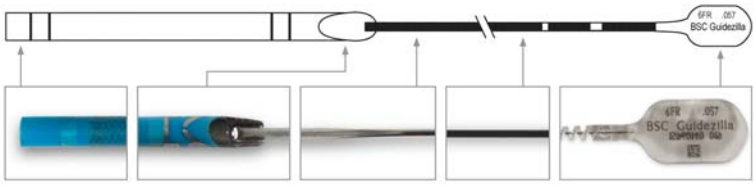
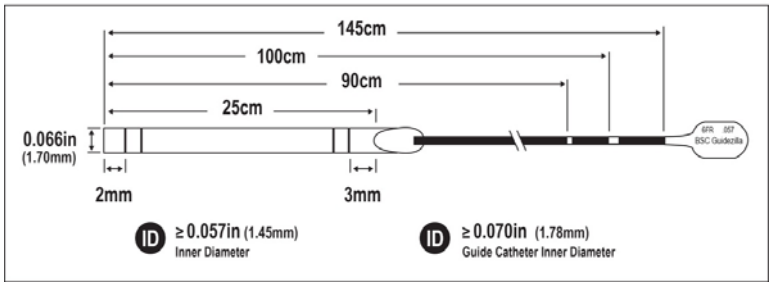
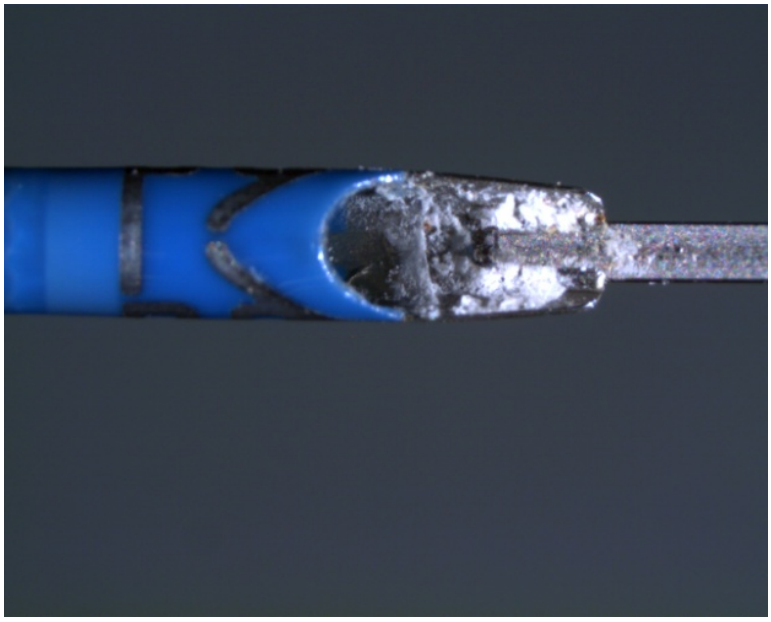
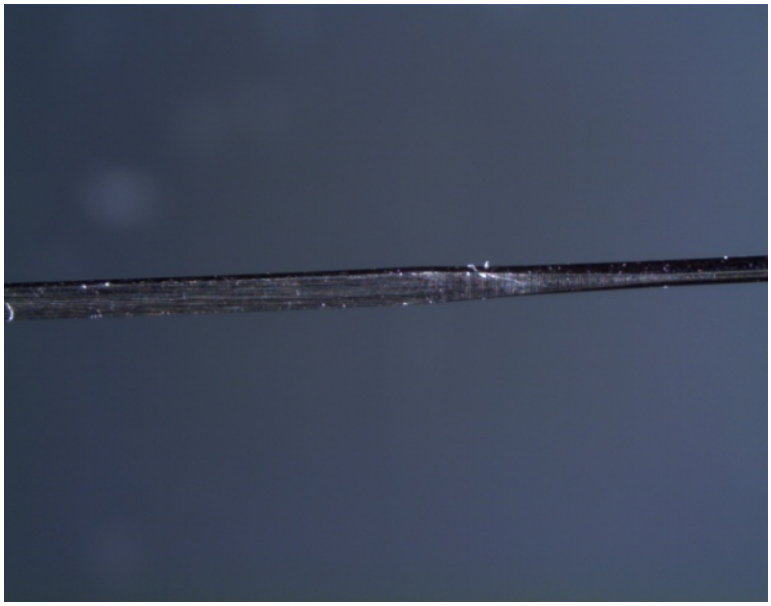
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,142,413, Claims 1, 2, 4, 5, and 7-13	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
reinforced portion that is reinforced with metallic elements in a braided or coiled pattern.	
'413 patent, claim 13. 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.	Boston Scientific's documents state that the use of the Guidezilla device results in a cross-sectional inner diameter of the coaxial lumen of the tubular structure that is one French size smaller than the cross-sectional inner diameter of the 6F guide catheter that it is used with. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2 (Ex. 25).

Exhibit 40

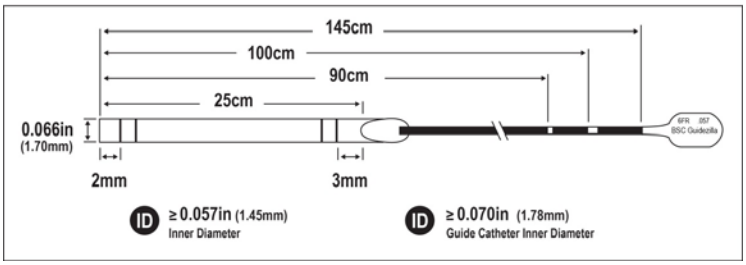
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'850 patent, claim 1. 1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:	This is preamble language, which I understand may not necessarily limit the scope of the claim. Notwithstanding, Boston Scientific Corp.'s Guidezilla is for use with interventional cardiology devices and is adapted to be insertable into a branch artery with a standard guide catheter.
a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and	The Guidezilla is used with a guide catheter that has continuous lumen that extends for a predefined length from its proximal end at a hemostatic valve to its distal end, which is adapted to be placed in the branch artery. The guide catheter has a continuous lumen with a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter. "Other items required but not provided: Guide catheter with an inner diameter large enough to accommodate the Guidezilla™ device." Guidezilla Directions for Use at 3 (Ex. 25). "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). "The GUIDEZILLA™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices." Boston Scientific's 510(k) Summary (Ex. 21); see also Guidezilla Directions for Use at 2 (Ex. 25). A standard guide catheter has a continuous lumen that extends for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, and that has a circular cross-sectional inner diameter that is sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery.

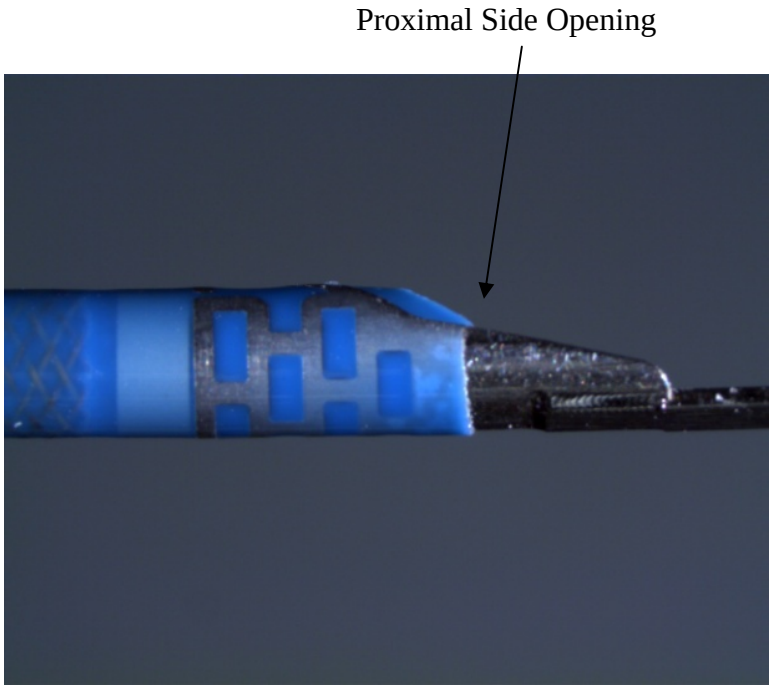
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
a device adapted for use with the guide catheter, including:	This is introductory language.
a flexible tip portion defining a tubular structure and having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The Guidezilla has a flexible tip portion that defines a tubular structure with a circular cross-section, which is the blue, tubular structure in the following photographs and the tubular structure in the diagram below:   Guidezilla has "a single lumen distal guide segment." Guidezilla Directions for Use at 2 (Ex. 25).

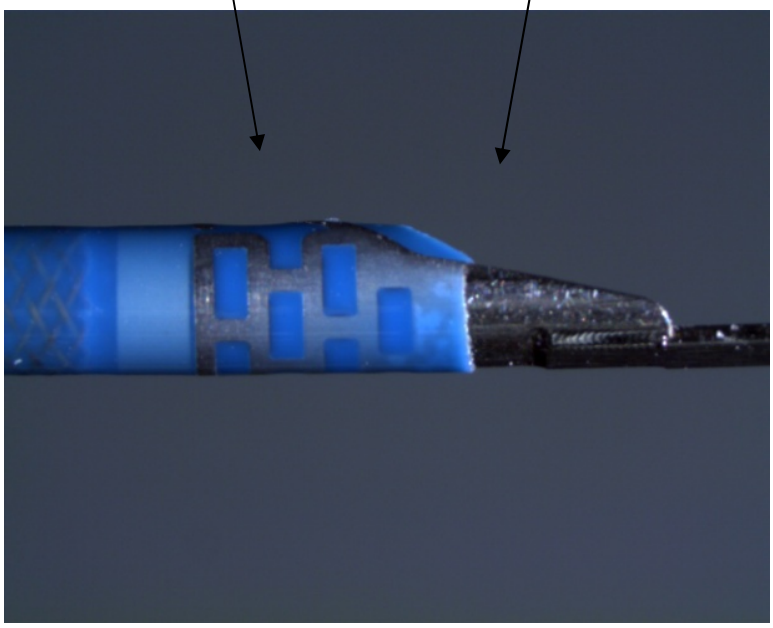
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	"GUIDEZILLA consists of . . . a distal guide catheter segment through which interventional devices may be delivered." Boston Scientific's 510(k) Summary (Ex. 21). The flexible tip portion's 25cm length is shorter than the 100cm length of the continuous lumen of a standard guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a tubular structure that is 25cm in length: Guidezilla  A standard 6F guide catheter length is 100cm long. The tubular structure has a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter, and it defines a coaxial lumen with a cross-sectional inner diameter through which interventional cardiology devices are insertable.
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of	"The Guidezilla guide extension catheter is a single lumen rapid exchange catheter. . . ." with "a stainless steel proximal shaft with a 25cm single lumen distal guide segment . . . ." Guidezilla Directions for Use at 2 (Ex. 25). As the attached photographs depict, this "stainless steel proximal shaft" is substantially rigid, proximal of and operably connected to, and more rigid than the flexible tip portion, and it is a rail structure without a lumen that has a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the

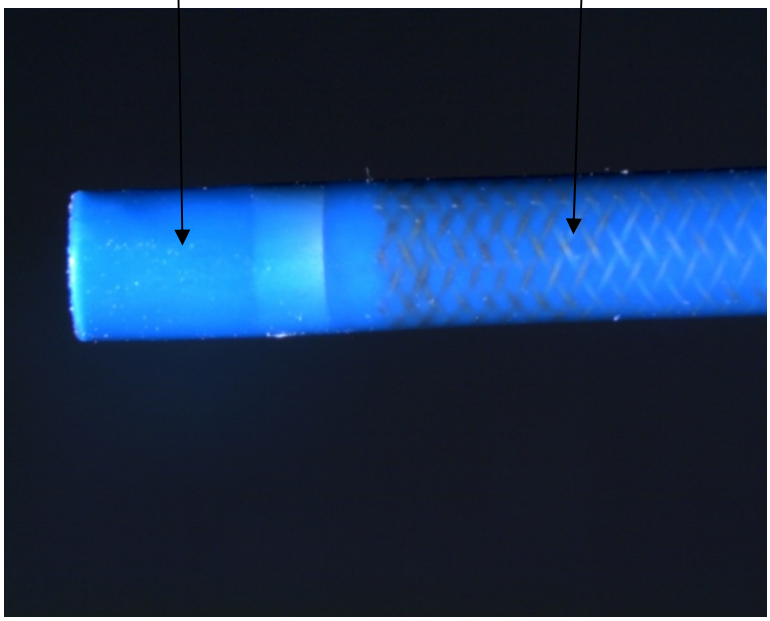
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, 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.	flexible tip portion. That the Guidezilla's substantially rigid portion does not have a lumen is discussed in more detail in my declaration, at ¶¶ 89-103.  

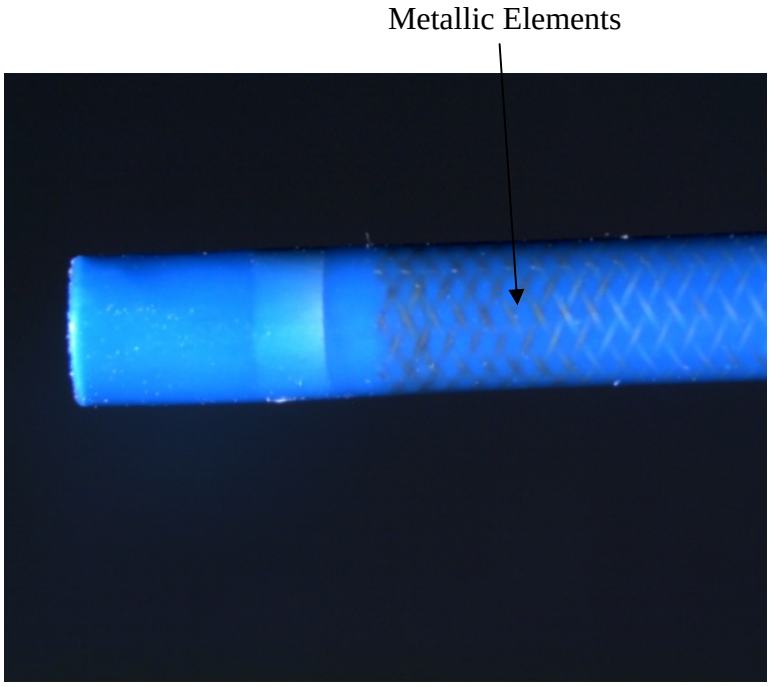
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	The rigid portion has a length that, when combined with the length of the flexible distal tip portion, defines a total length that is longer than the length of the continuous lumen of the guide catheter. When the distal end of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends through the hemostatic valve. "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). The distal end of the Guidezilla extends past the distal end of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2. At the same time, the proximal end of the Guidezilla extends from the proximal end of the guide catheter, through a hemostasis device. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use at 3 (Ex. 25).
'850 patent, claim 2. 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	The Guidezilla's the tubular structure has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter. The following Boston Scientific drawing shows that the Guidezilla has a tubular structure that is 25cm in length:

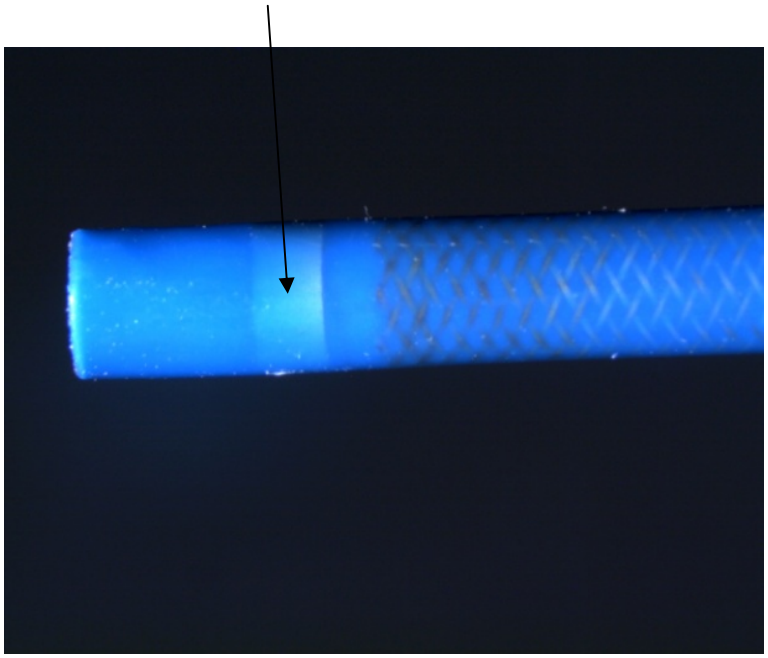
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	Guidezilla  That the tubular structure has a distal portion that is adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter can be seen in that the length of the tubular structure is 25cm, but not more than 15cm of the tubular structure is advanced past the distal tip of the guide catheter: "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25). "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). See also above, in the discussion regarding claim 1. The Guidezilla device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen, where those forces would otherwise tend to dislodge the guide catheter from the branch artery.
'850 patent, claim 3. 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	The proximal portion of the Guidezilla's tubular structure includes a proximal side opening that extends for a distance along the device's longitudinal axis and is accessible from a longitudinal side that is transverse to the longitudinal axis, so that the opening can receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter. This opening is shown in the following

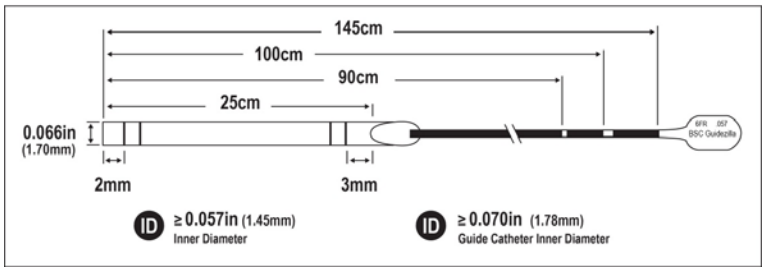
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	photograph of the Guidezilla device: 
'850 patent, claim 4. 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.	The Guidezilla device's proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion, as can be seen in the photograph below of the Guidezilla device:

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
'850 patent, claim 5. 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.	The Guidezilla device's tubular structure has a flexible cylindrical distal tip portion, and a flexible cylindrical reinforced portion that is proximal to the flexible distal tip portion, as can be seen in the following photograph: Flexible Cylindrical Distal Tip Portion Flexible Cylindrical Reinforced Portion 
'850 patent, claim 6. 6. The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	The Guidezilla device's flexible cylindrical reinforced portion is reinforced with metallic elements in a braided pattern, as can be seen in the following photograph:

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	
'850 patent, claim 7. 7. The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.	Guidezilla has two radiopaque markers located in the tubular structure. "The guide catheter segment incorporates two radiopaque marker bands to aid in positioning the device during the procedure." Boston Scientific's 510(k) Summary (Ex. 21). One of Guidezilla's radiopaque markers is positioned in the device's flexible cylindrical distal tip portion, proximate a distal tip. "The Guidezilla device has two platinum-iridium marker bands, which enable visibility while using standard fluoroscopic methods. The distal marker band is located 2 mm from the distal tip. The proximal marker band is located 3 mm distal to the opening of the guide segment." Guidezilla Directions for Use at 2 (Ex. 25). The distal marker can be seen in the following photograph of the Guidezilla device:

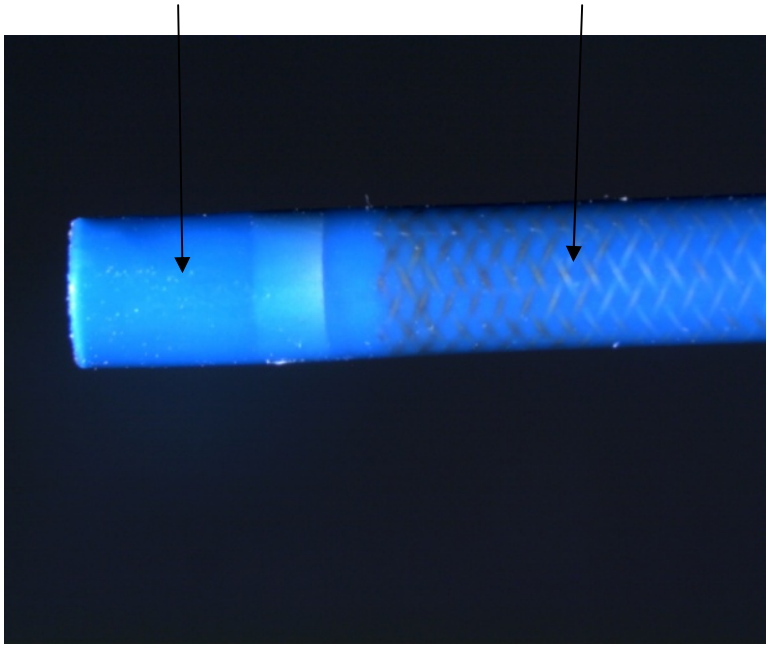
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	Radiopaque Marker 
'850 patent, claim 8. 8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The cross-sectional inner diameter of the Guidezilla's coaxial lumen of the tubular structure is one French size smaller than the cross-sectional inner diameter of the standard 6F guide catheter. "The Guidezilla device is delivered through a guide catheter resulting in an inner diameter that is approximately 1 French size smaller than the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). "GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). "Guide Extension Catheter (5-in-6)." Guidezilla Directions for Use at 2 (Ex. 25).
'850 patent, claim 12. 12. A system for use with	See above, in the discussion of claim 1.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
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	See above, in the discussion of claim 1.
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:	See above, in the discussion of claim 1. Guidezilla has an elongate structure with an overall length that is longer than the lumen of the guide catheter. Guidezilla is 145cm in length, as the following Boston Scientific drawing shows. A standard 6F guide catheter is 100cm long. **Guidezilla**  "The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter." Boston Scientific's 510(k) Summary (Ex. 21). In use, the proximal end of the Guidezilla extends through the hemostatis valve. "Open the hemostasis valve and advance the Guidezilla device through the hemostasis valve and into the guide catheter." Guidezilla Directions for Use

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	at 3 (Ex. 25). The distal end of the Guidezilla extends beyond the distal end of the guide catheter. "Never advance the Guidezilla device more than 15cm beyond the tip of the guide catheter." Guidezilla Directions for Use at 2 (Ex. 25). "Under fluoroscopy, advance the Guidezilla device up to a maximum of 15cm beyond the distal tip of the guide catheter and into the desired location within the vessel." Guidezilla Directions for Use at 3 (Ex. 25).
a flexible tip portion defining a tubular 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;	See above, in the discussion of claim 1.
a reinforced portion proximal to the flexible tip portion; and	See above, in the discussion of claim 5.
a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis rail than the flexible tip portion and defining a structure without a lumen having a maximal cross-sectional dimension at a	See above, in the discussion of claim 1.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
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.	
'850 patent, claim 13. 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.	See above, in the discussion of claim 2.
'850 patent, claim 14. 14. The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an	See above, in the discussion of claim 3.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
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.	
'850 patent, claim 15. 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.	See above, in the discussion of claims 1, 2, and 12.
'850 patent, claim 16. 16. The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.	See above, in the discussion of claim 7.
'850 patent, claim 17. 17. The system of claim 12, wherein the reinforced portion of	See above, in the discussion of claim 6.

PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
the device is reinforced with metallic elements in a braided or coiled pattern.	
'850 patent, claim 18. 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.	See above, in the discussion of claim 8.
'850 patent, claim 20. 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.	The Guidezilla device is an elongate structure that includes, starting at the distal portion of the flexible distal portion, at least four different portions, as shown in the photographs below, having increasing levels of stiffness. Claim 20 requires only three such portions, so any three of the four portions shown below establish infringement of this claim. First Flexural Modulus Second Flexural Modulus 

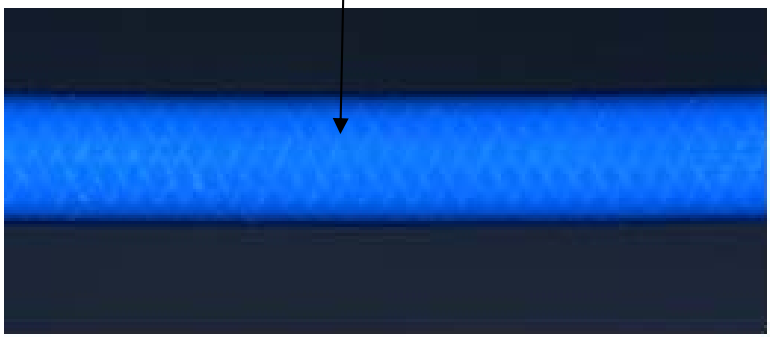
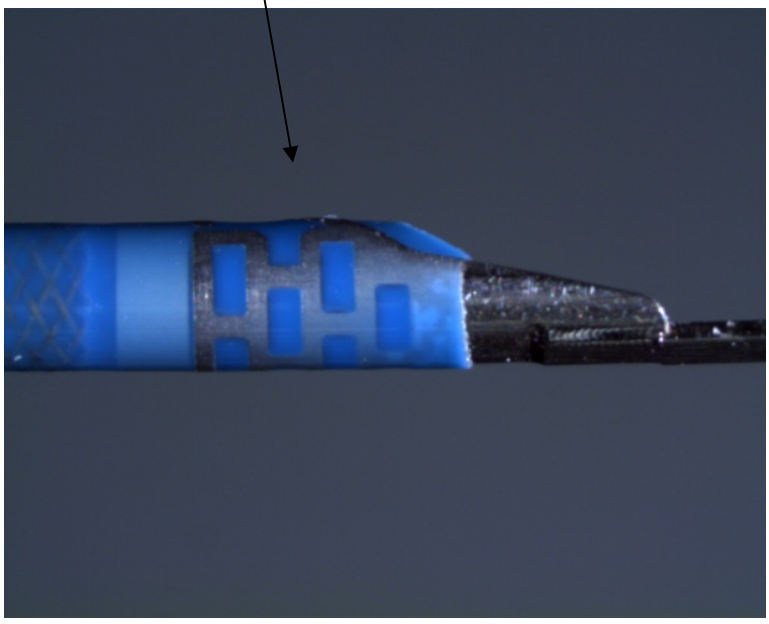
PLAINTIFF VASCULAR SOLUTIONS, INC.'S CLAIM CHART Comparison of Boston Scientific's GUIDEZILLA Guide Extension Catheter to U.S. Patent No. 8,292,850, Claims 1-8, 12-18, and 20	
Claim Language	**GUIDEZILLA Guide Extension Catheter**
	Third Flexural Modulus  Fourth Flexural Modulus 

Exhibit 41

*** To be filed after court grants leave to seal.**