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Attorney Docket No. 2005.86USRE15

REISSUE APPLICATION TRANSMITTAL

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

Commissioner:

Transmitted herewith for filing under 37 CFR. § 1.171 is the continuation reissue patent application of U.S.

Patent No. 8,292,850 B2

INVENTOR(S): Howard C. Root, Gregg Sutton, Jeffrey M. Welch and Jason M. Garrity

FOR: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Enclosed are:

- Specification and Abstract - 7 pages (from issued patent)
- Drawings - 13 sheets (Figs. 1-22), copies of drawings from issued patent
- Reissue Application Declaration and Power of Attorney
- Consent of Assignee
- Statement Under 37 CFR. 3.73(b)
- Preliminary Amendment
- Information Disclosure Statement
- Copy of U.S. Patent No. 8,292,850 B2
- Other Application Data Sheet

Application as Filed - Part 1						
	(1) Claims in Patent	(2) Claims Filed in Reissue Application	(3) Number Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee				\$190	OR	\$380
Reissue Search Fee				\$310	OR	\$620
Reissue Examination Fee				\$375	OR	\$750
Total Claims	(A)	(B)	= ****	x 30 = \$	OR	x 60 = \$
Independent Claims	(C)	(D)	= *	x 125 =	OR	x 250 = \$
Presence of Multiple Dependent Claim				+ 225	OR	+ 450
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 155 = \$	OR	x 310 = \$
			<b>TOTAL</b>	\$	OR	\$
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets						

Application as Amended - Part 2						
	(1) Claims Remaining After Amendment	(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	OR	Large Entity Rate
Total Claims	***	minus **	=	x 30 = \$	OR	x 60 = \$
Independent Claims	***	minus *****	=	x 125 =	OR	x 250 = \$
Presence of Multiple Dependent Claim				+ 225	OR	+ 450
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 155 = \$	OR	x 310 = \$
			<b>TOTAL</b>	\$	OR	\$

If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs) + Dwg Sheets

\*If (D) is less than (C), enter "0" in column 3. For reissues filed on or after Dec. 8, 2004, enter (D) minus 3 or "0" if (D) is less than 3.

\*\*If the "Highest Number of Total Claims Previously Paid For" is less than 20, enter "20" in this space.

\*\*\*After any cancellation of claims.

\*\*\*\*If (A) is greater than 20, enter (B) - (A); if (A) is 20 or less, enter (B) - 20. For reissues filed on or after Dec. 8, 2004 enter (B) - 20.

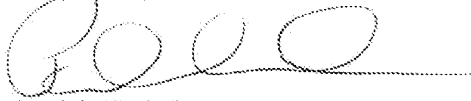
\*\*\*\*\*For amendments filed on or after Dec. 8, 2004, enter the "Highest Number of Independent Claims Previously Paid For."

For amendments filed prior to Dec. 8, 2004, enter the higher of the Number Previously Paid or Number of Independent Claims in Patent.

Applicants are entitled to small entity status in accordance with 37 CFR 1.27.

Electronic payment is submitted by credit card to cover the filing fee. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 CFR §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

Respectfully submitted,



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



US008292850B2

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

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

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

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

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

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

(65) **Prior Publication Data**  
US 2012/0165756 A1 Jun. 28, 2012

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

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

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

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

See application file for complete search history.

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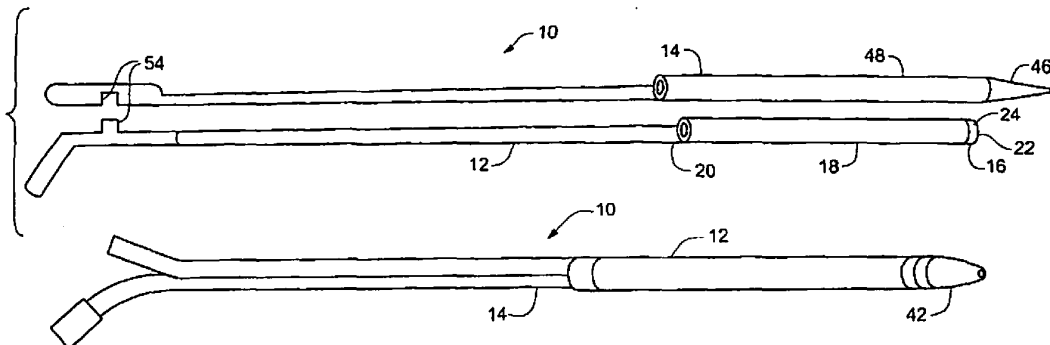
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(57) **ABSTRACT**

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

**24 Claims, 13 Drawing Sheets**



# US 8,292,850 B2

Page 2

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1

**COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES**

**RELATED APPLICATIONS**

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

**FIELD OF THE INVENTION**

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

**BACKGROUND OF THE INVENTION**

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

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

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

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

2

the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

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

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

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

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

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

**SUMMARY OF THE INVENTION**

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

3

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

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

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

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

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

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

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

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

4

removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm.

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

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

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

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

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

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

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

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

5

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

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

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

#### BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6

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

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

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

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

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

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

#### DETAILED DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

Hemicylindrical portion 36 tapers into arcuate portion 38. Arcuate portion 38 extends from 25% to 40% of the circumference of the tube. Arcuate portion 38 may extend linearly, for example, for about 15 cm.

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

7

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

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

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

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

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

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

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

Referring the FIG. 8 coaxial guide catheter 12 is depicted as used with guide catheter 56, guidewire 64, and tapered inner catheter 14. Here, coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guide catheter 56 has been placed in the ostium 60 of coronary artery 62, as depicted in FIG. 7. Coaxial guide catheter 12, with tapered inner catheter 14, provides an inner support

8

member for proper translation over guidewire 64. Tapered inner catheter tip 42 provides a distal tapered transition from guidewire 64 to coaxial guide catheter 12. Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Beginning at the distal end of coaxial guide catheter 12, tip portion 114 may be formed substantially of, for example, 2533 Pebax®. This may be followed by a section of 3533 Pebax®, then by a section of 5533 Pebax®, then by a further section of 7233 Pebax®. These Pebax® portions may all incorporate, for example, about 20% barium sulfate (BaSO<sub>4</sub>).

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

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

In operation, a guide catheter 56 is inserted into a major blood vessel in the body such as aortic arch 58 over guidewire 64 and the distal end 68 of guide catheter 56 is brought into proximity of ostium 60 of a smaller branch blood vessel, such as coronary artery 62, that it is desired to enter. Coaxial guide catheter 12, with tapered inner catheter 14, is inserted through guide catheter 56 and over guidewire 64. Guide catheter 56, guidewire 64, coaxial guide catheter 12, and tapered inner catheter 14 are manipulated to insert tapered inner catheter tip 42 into the ostium 60 of the blood vessel that branches off from the major blood vessel. The bump tip 22 of coaxial guide

catheter 12 is inserted with tapered inner catheter tip 42 well into ostium 60 of coronary artery 62 or other blood vessel until bump tip 22 of coaxial guide catheter 12 achieves a deep seated position. Tapered inner catheter 14 is then withdrawn from the lumen of coaxial guide catheter 12. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter 12 which remains inside guide catheter 56.

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

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

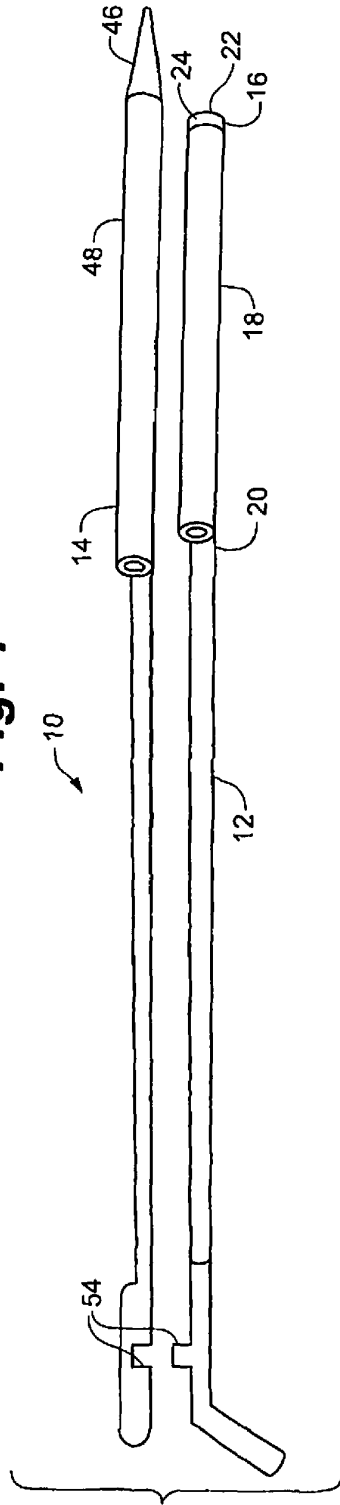
The present invention may be embodied in other specific forms without departing from the spirit of the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than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

The invention claimed is:

1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

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

**Fig. 1**



**Fig. 2**

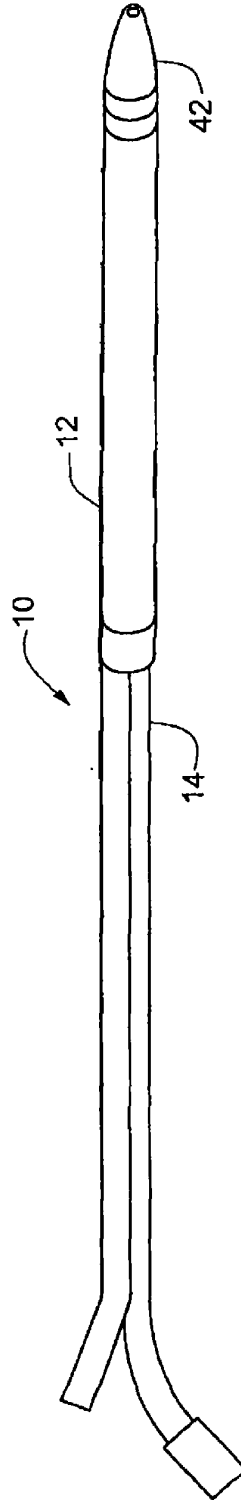


Fig. 3

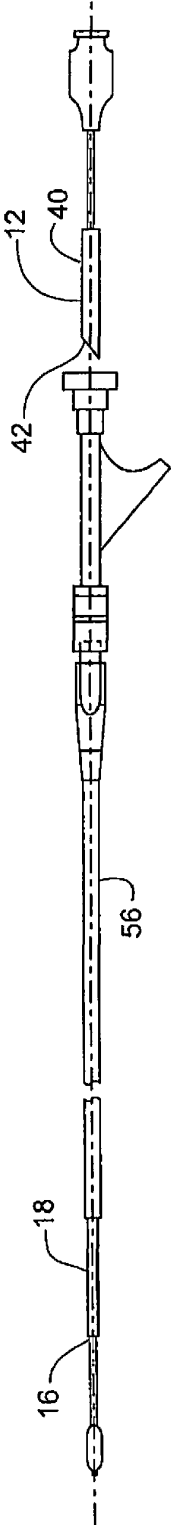
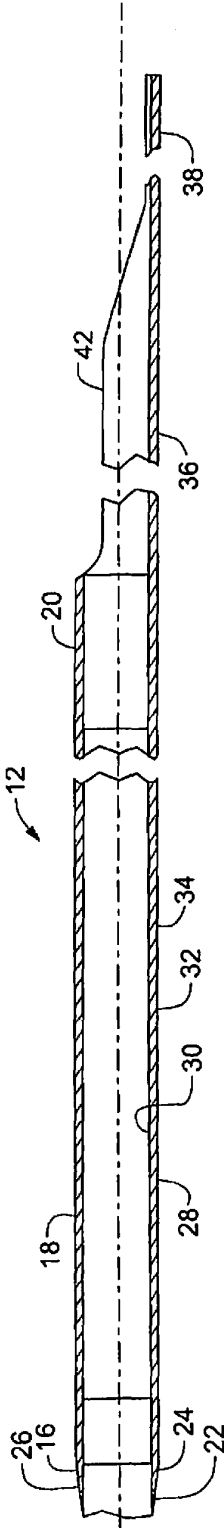
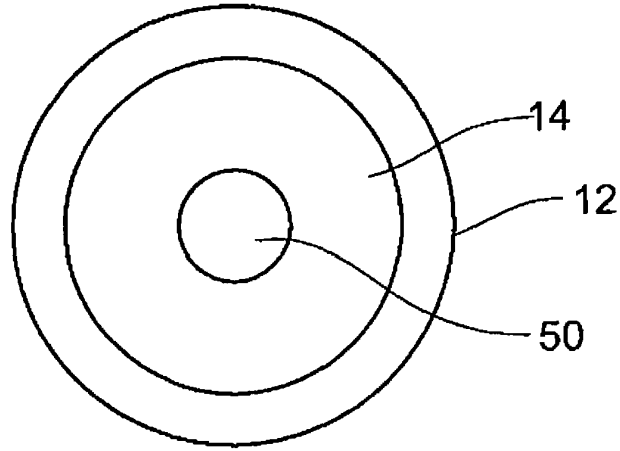




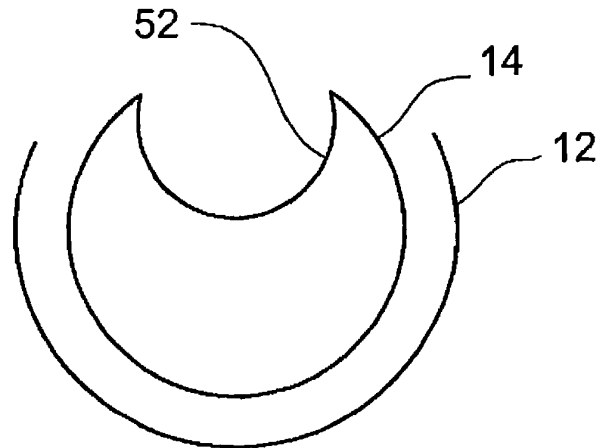
Fig. 4



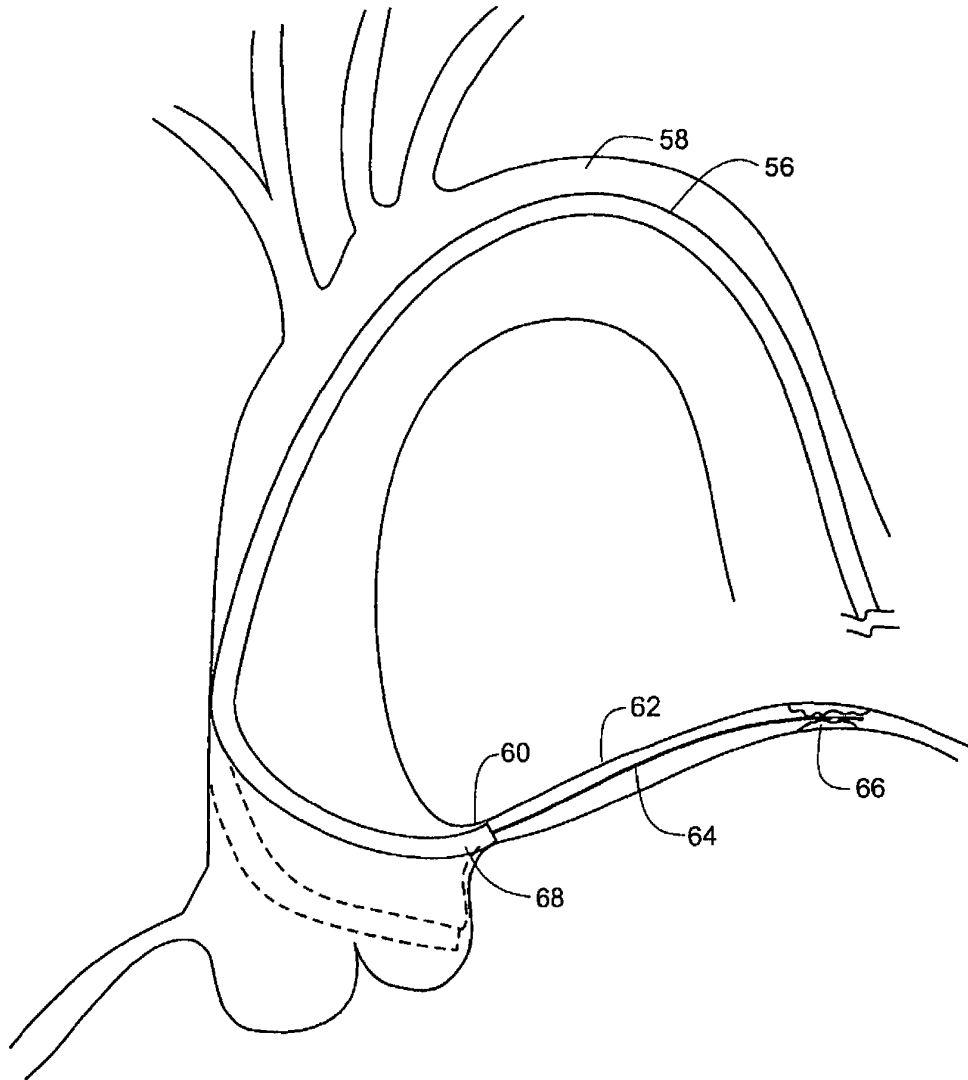
**Fig. 5**



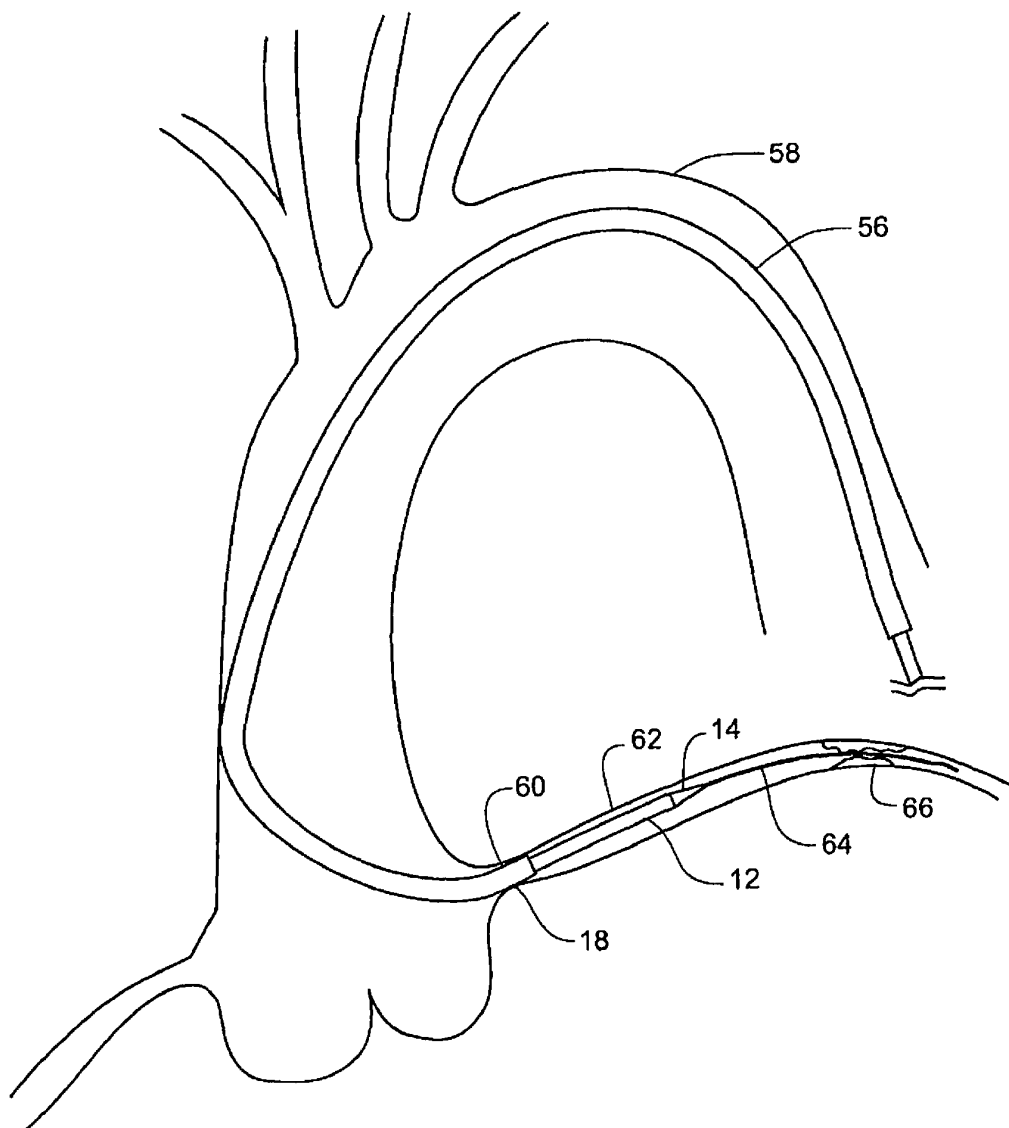
**Fig. 6**



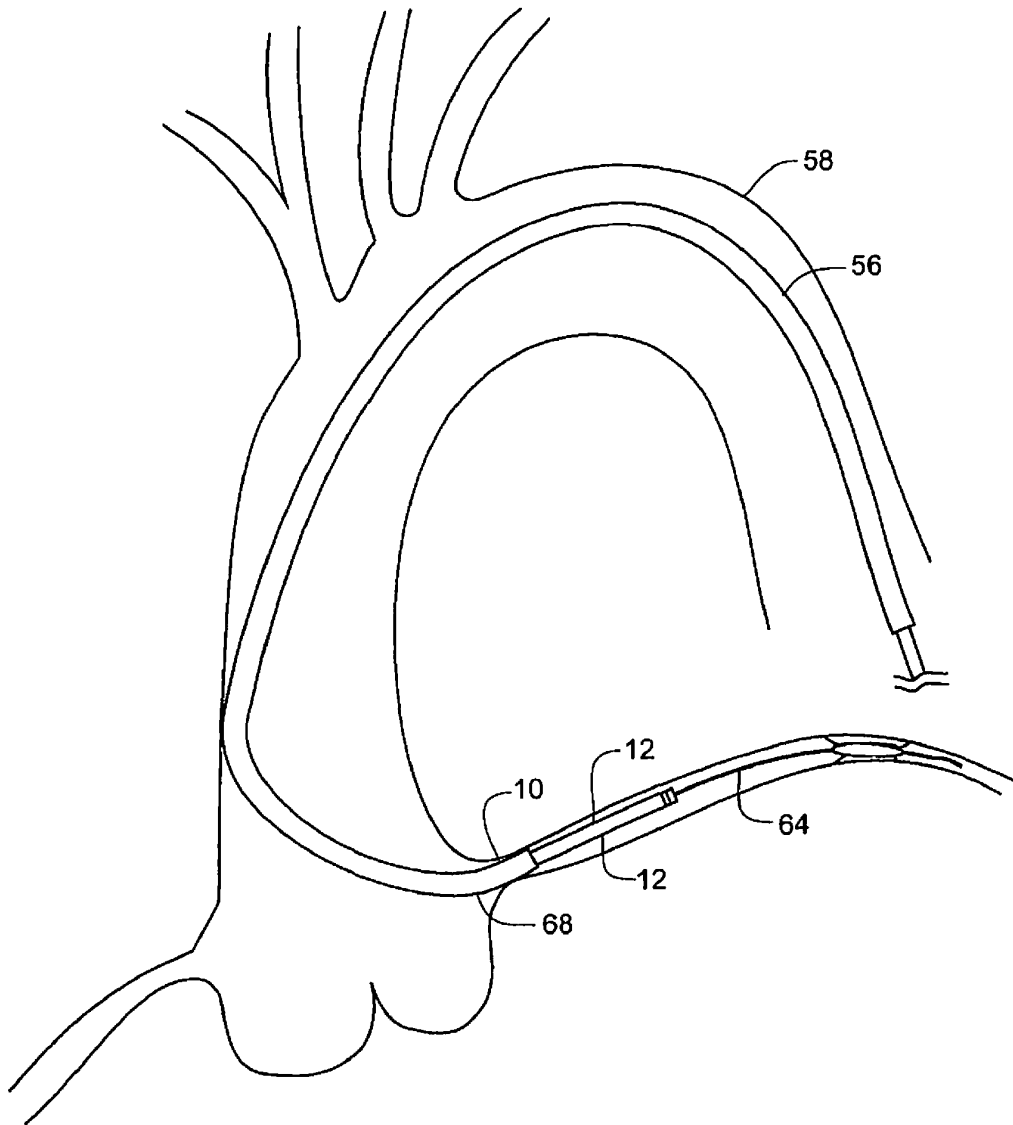
**Fig. 7**

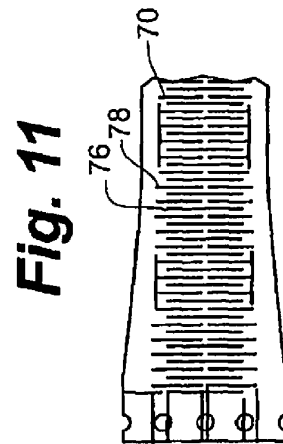
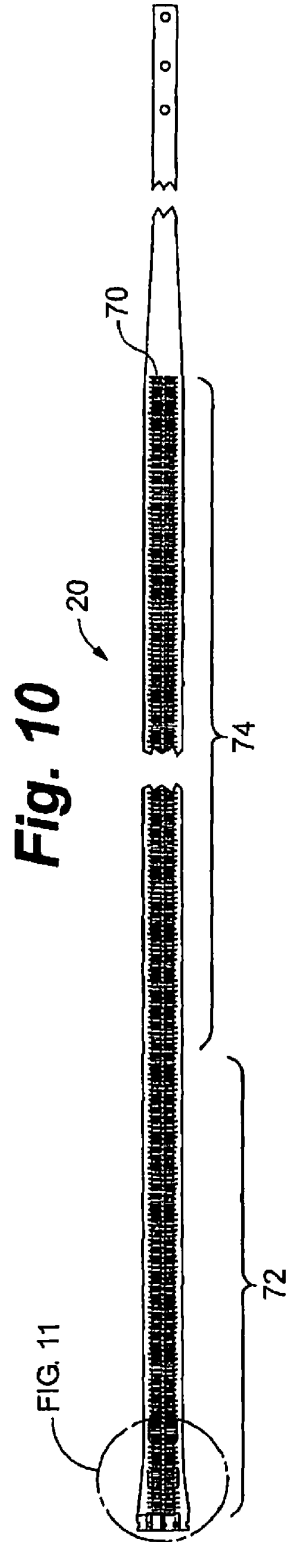


**Fig. 8**



**Fig. 9**





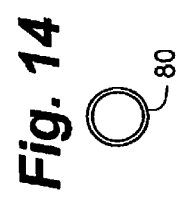
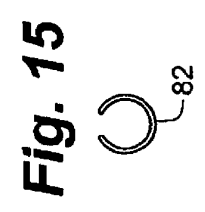
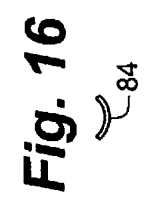
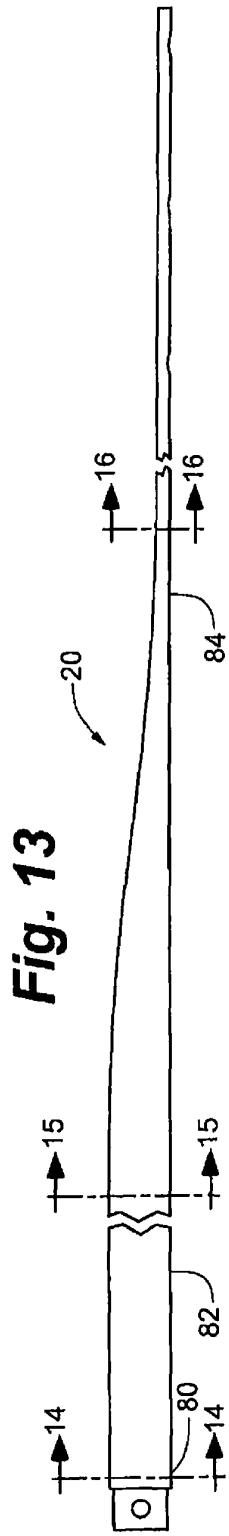
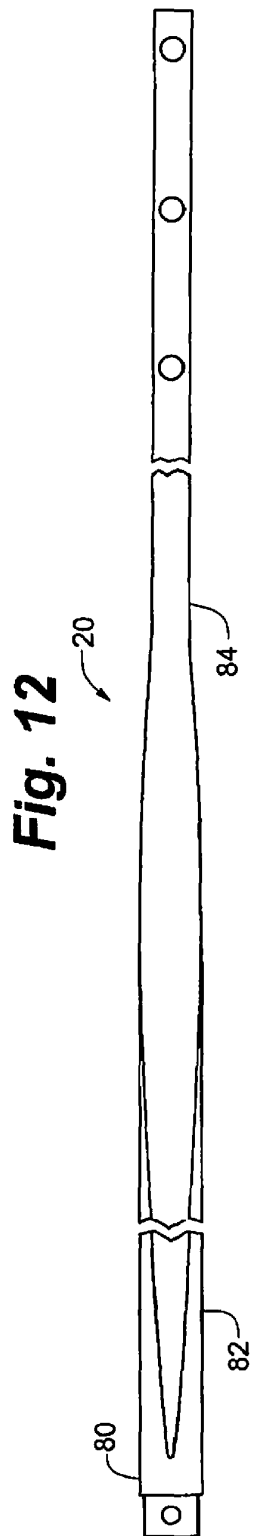
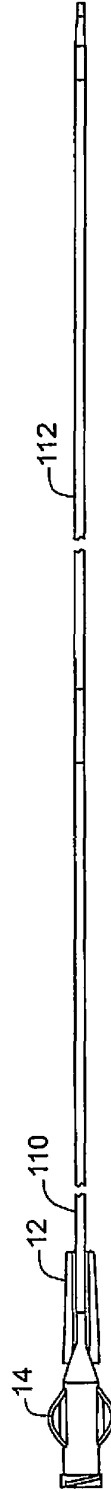
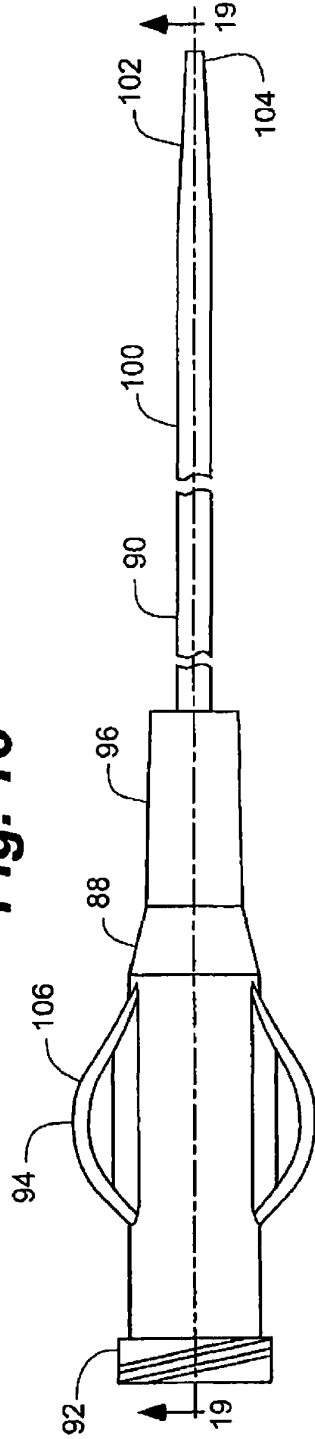


Fig. 17

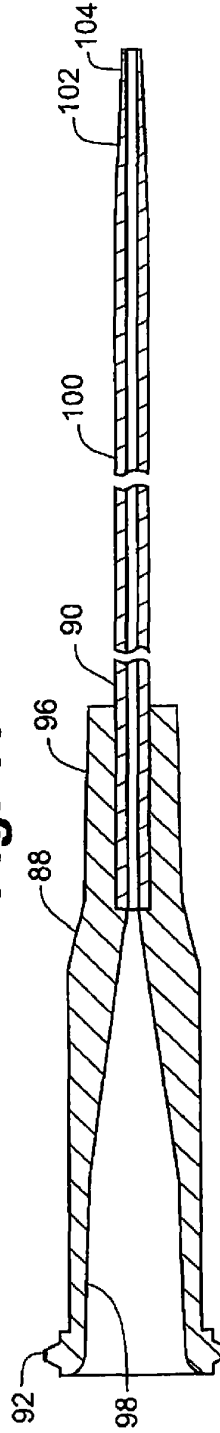


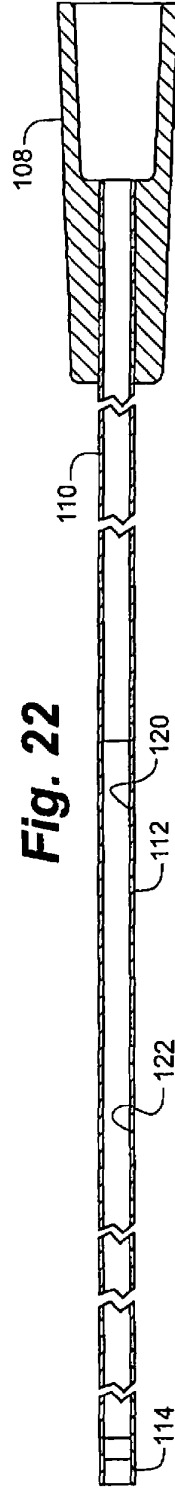
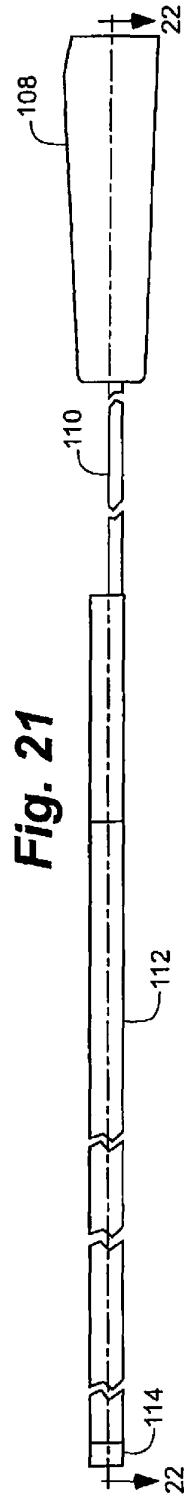
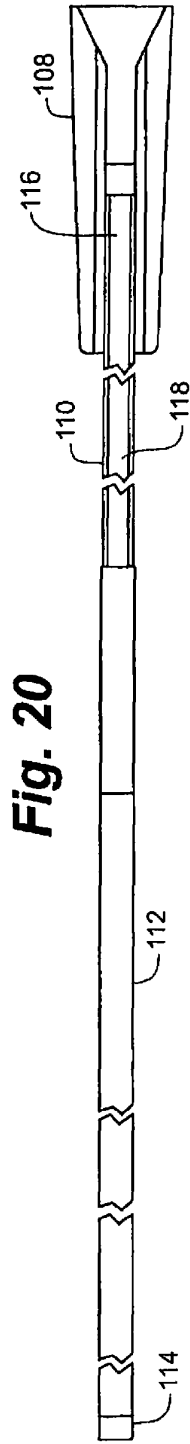


**Fig. 18**



**Fig. 19**





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US008292850B2

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

(10) **Patent No.:** **US 8,292,850 B2**

(45) **Date of Patent:** **Oct. 23, 2012**

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

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

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

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

(65) **Prior Publication Data**  
US 2012/0165756 A1 Jun. 28, 2012

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

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

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

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

See application file for complete search history.

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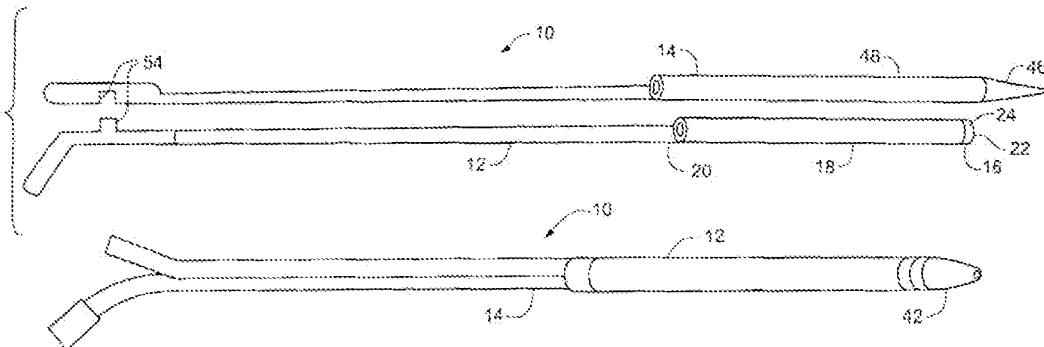
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*Primary Examiner* -- Kevin C. Sirmous  
*Assistant Examiner* -- Bradley Osinski  
(74) *Attorney, Agent, or Firm* -- Patterson Thunette Christensen Pedersen, P.A.

(57) **ABSTRACT**

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

**24 Claims, 13 Drawing Sheets**



**US 8,292,850 B2**

Page 2

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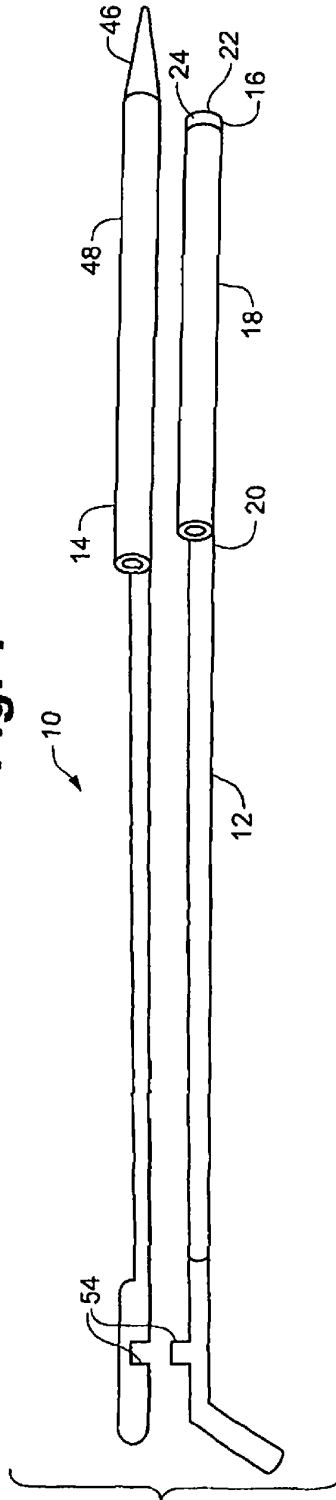
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**Fig. 1**



**Fig. 2**

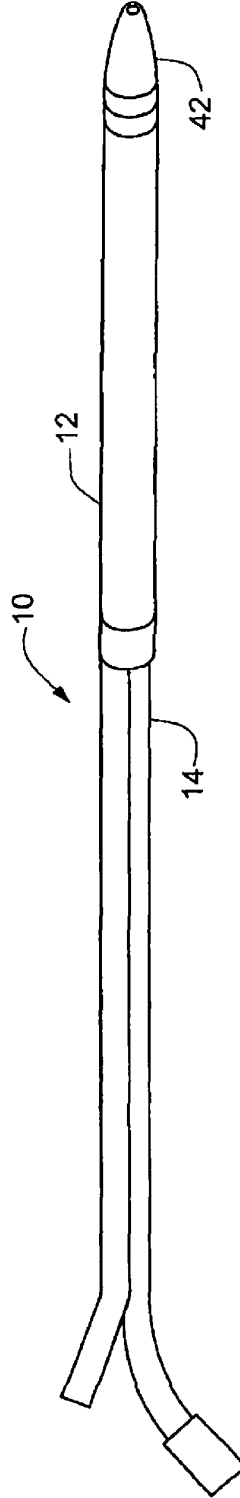


Fig. 3

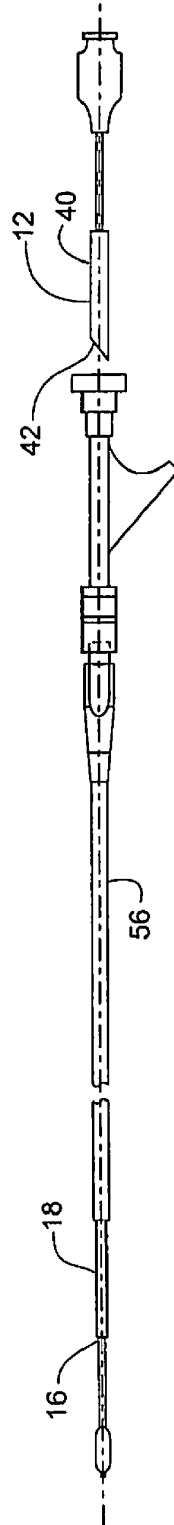
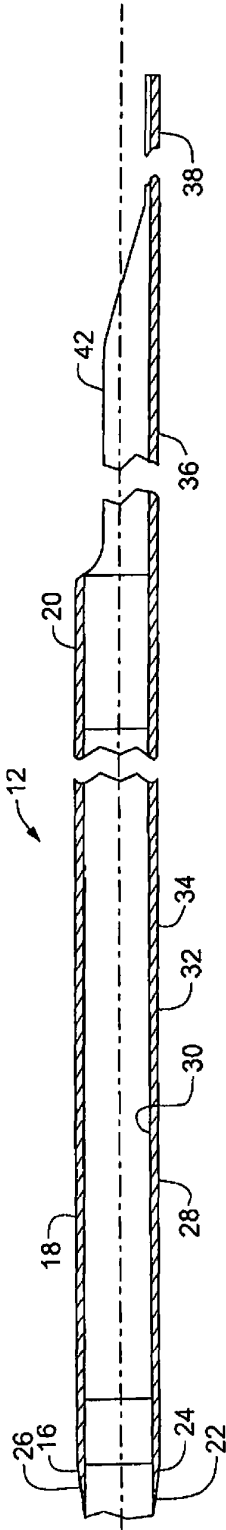
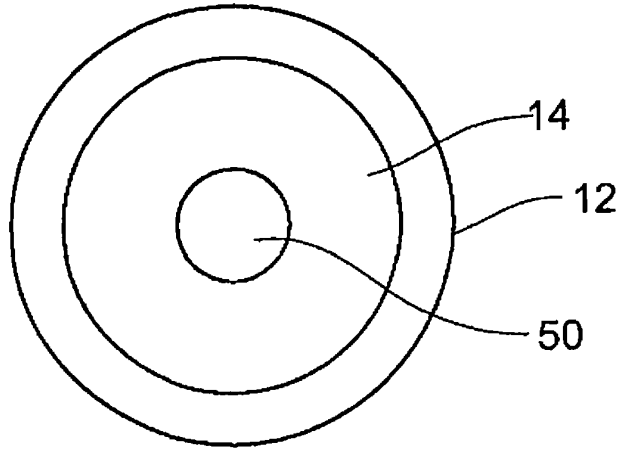


Fig. 4

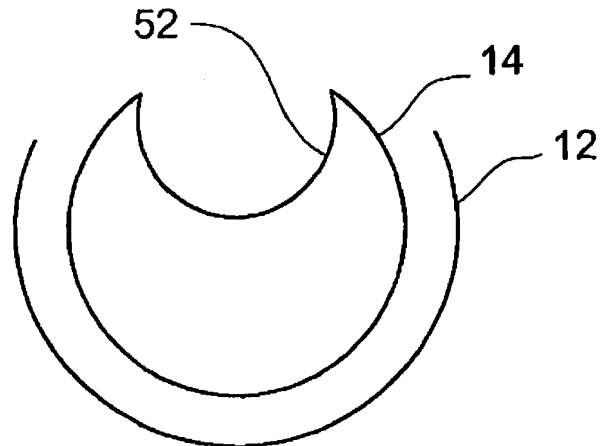




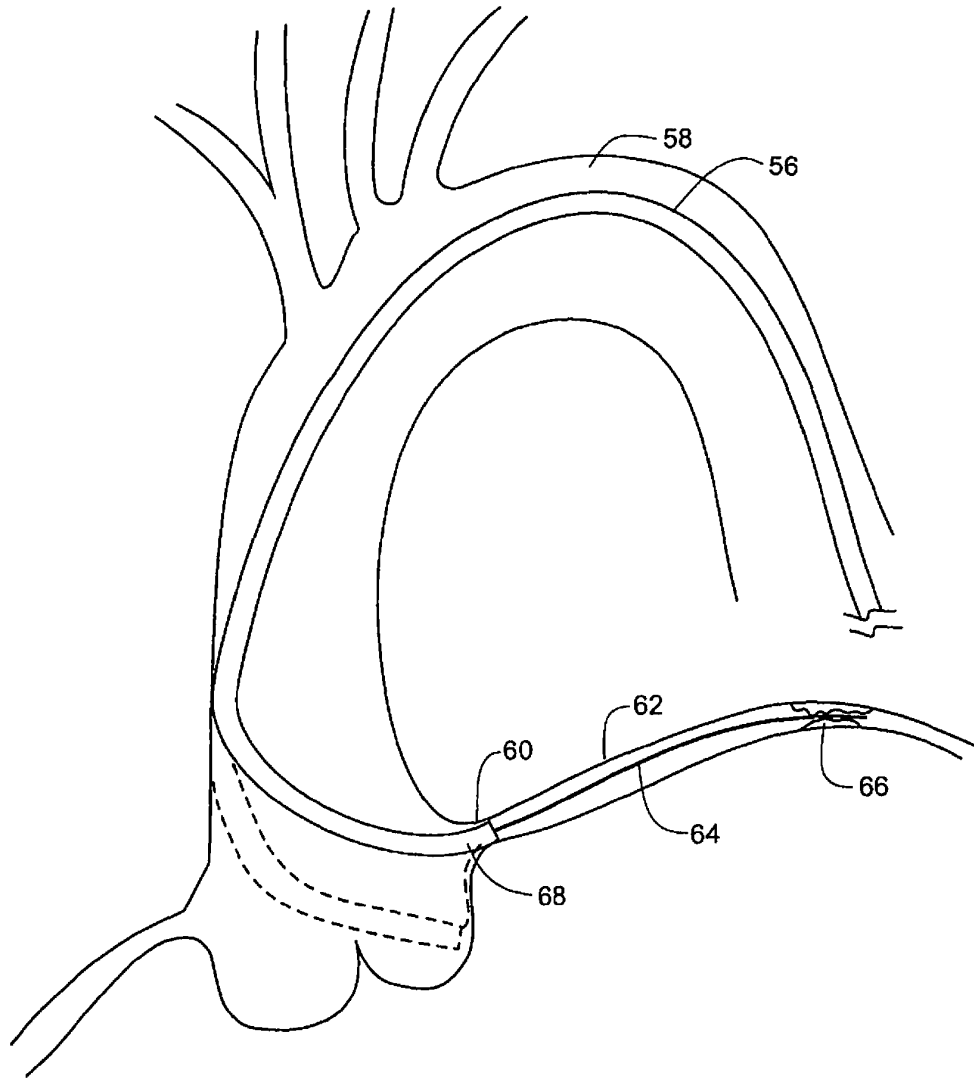
**Fig. 5**



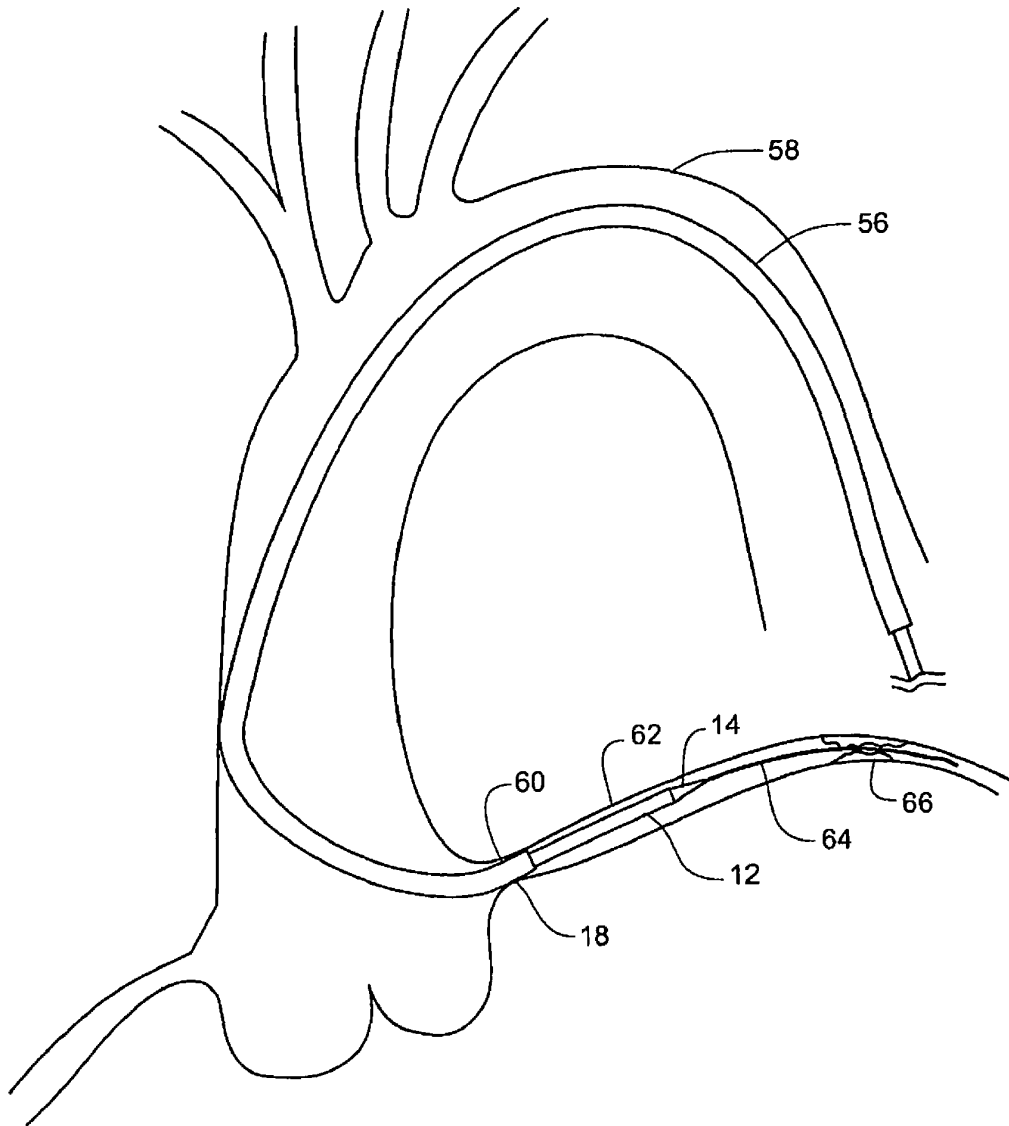
**Fig. 6**



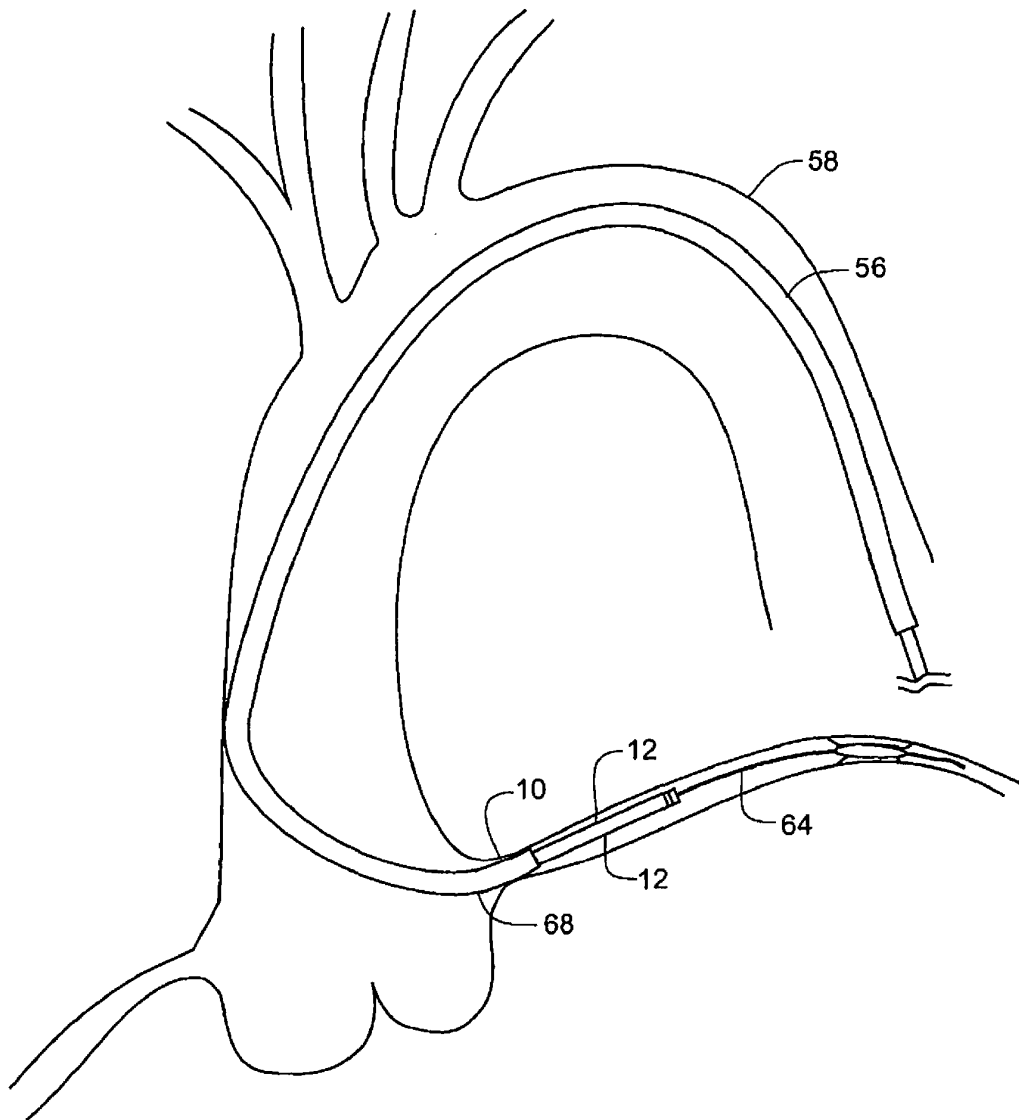
**Fig. 7**

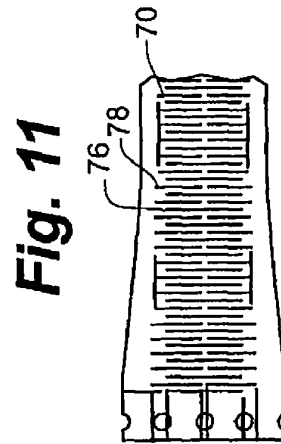
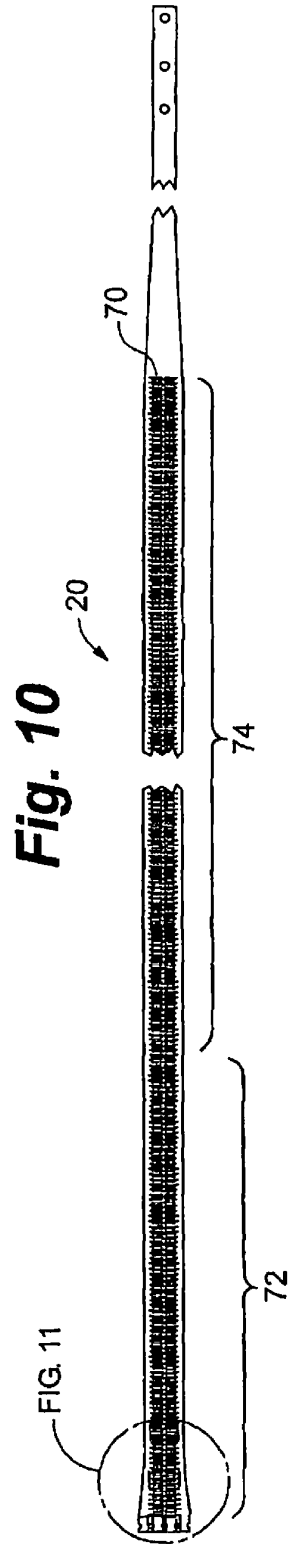


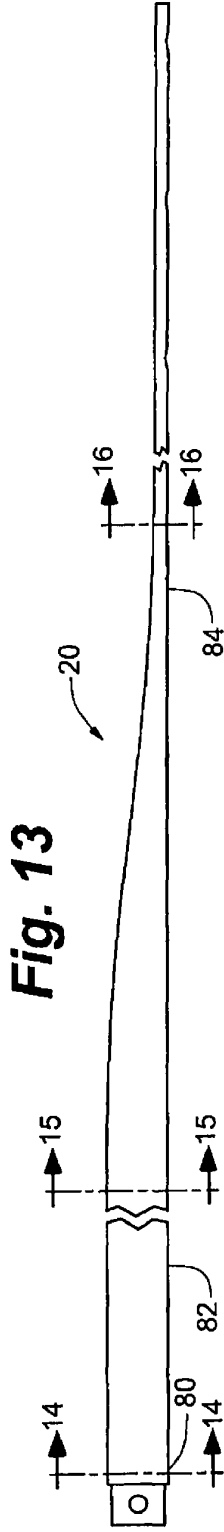
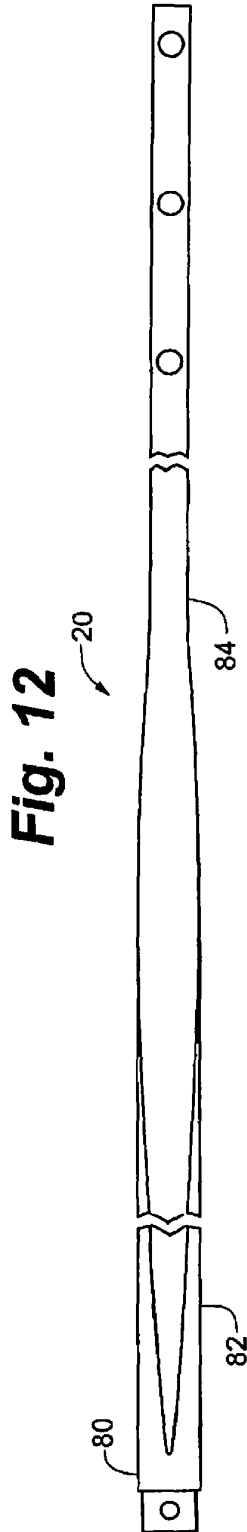
**Fig. 8**



**Fig. 9**







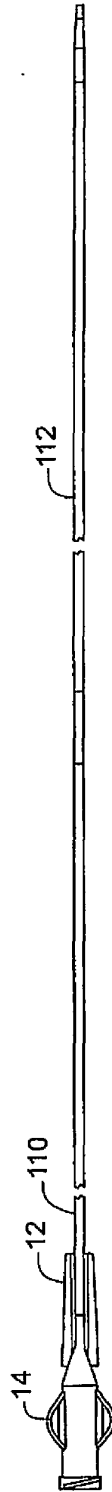
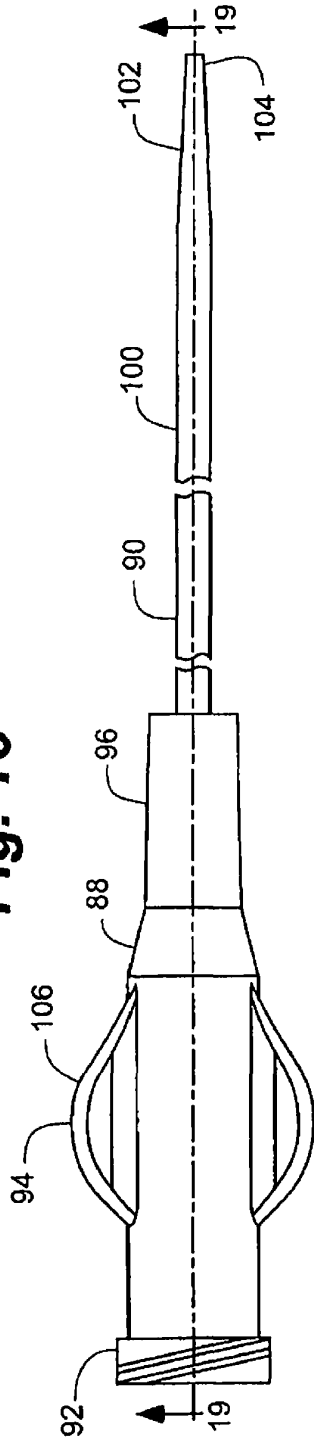
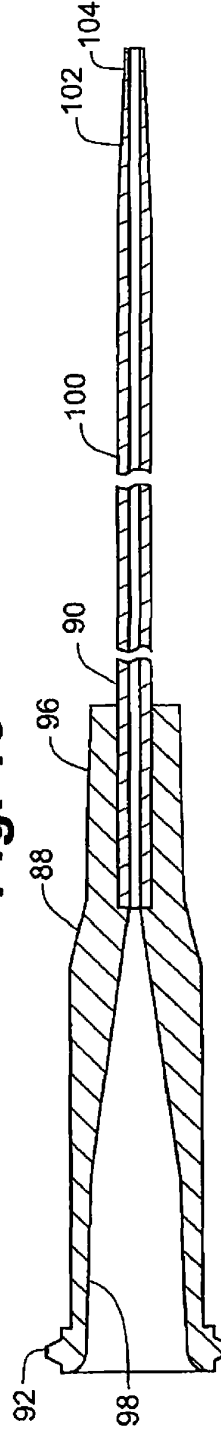


Fig. 17

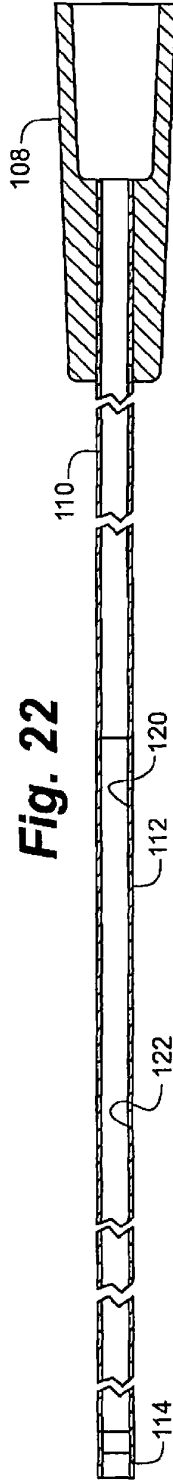
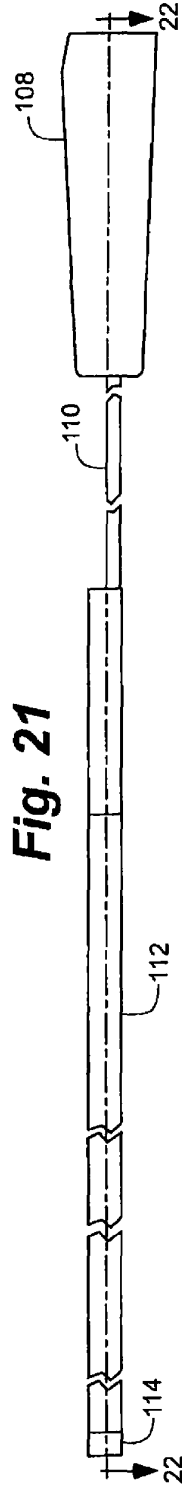
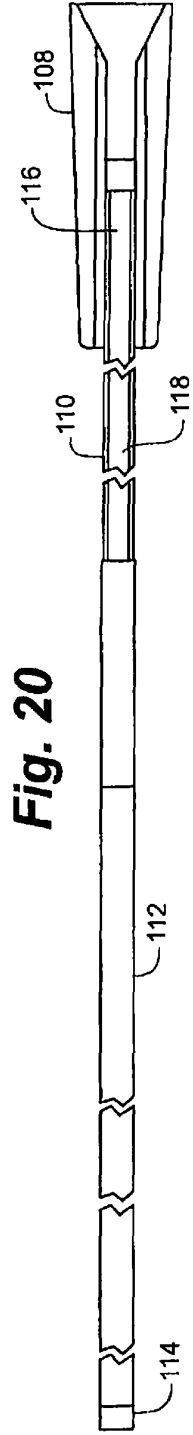
**Fig. 18**



**Fig. 19**







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## COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

### RELATED APPLICATIONS

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

### FIELD OF THE INVENTION

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

### BACKGROUND OF THE INVENTION

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

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

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

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

2

the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

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

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

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

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

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

### SUMMARY OF THE INVENTION

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

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

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

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

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

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

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

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

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

removed may extend for approximately 75 cm and the portion having 75-90% of the structure removed extends for about 15 cm.

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

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

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

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

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

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

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

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

5

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

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

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

#### BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6

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

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

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

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

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

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

#### DETAILED DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

Hemicylindrical portion 36 tapers into arcuate portion 38. Arcuate portion 38 extends from 25% to 40% of the circumference of the tube. Arcuate portion 38 may extend linearly, for example, for about 15 cm.

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

7

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

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

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

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

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

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

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

Referring the FIG. 8 coaxial guide catheter 12 is depicted as used with guide catheter 56, guidewire 64, and tapered inner catheter 14. Here, coaxial guide catheter 12 with tapered inner catheter 14 is passed through guide catheter 56 and over guidewire 64 into coronary artery 62 after the guide catheter 56 has been placed in the ostium 60 of coronary artery 62, as depicted in FIG. 7. Coaxial guide catheter 12, with tapered inner catheter 14, provides an inner support

8

member for proper translation over guidewire 64. Tapered inner catheter tip 42 provides a distal tapered transition from guidewire 64 to coaxial guide catheter 12. Once coaxial guide catheter 12 is in place, tapered inner catheter 14 is removed from the inside of coaxial guide catheter 12.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Beginning at the distal end of coaxial guide catheter 12, tip portion 114 may be formed substantially of, for example, 2533 Pebax®. This may be followed by a section of 3533 Pebax®, then by a section of 5533 Pebax®, then by a further section of 7233 Pebax®. These Pebax® portions may all incorporate, for example, about 20% barium sulfate (BaSO<sub>4</sub>).

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

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

In operation, a guide catheter 56 is inserted into a major blood vessel in the body such as aortic arch 58 over guidewire 64 and the distal end 68 of guide catheter 56 is brought into proximity of ostium 60 of a smaller branch blood vessel, such as coronary artery 62, that it is desired to enter. Coaxial guide catheter 12, with tapered inner catheter 14, is inserted through guide catheter 56 and over guidewire 64. Guide catheter 56, guidewire 64, coaxial guide catheter 12, and tapered inner catheter 14 are manipulated to insert tapered inner catheter tip 42 into the ostium 60 of the blood vessel that branches off from the major blood vessel. The bump tip 22 of coaxial guide

catheter 12 is inserted with tapered inner catheter tip 42 well into ostium 60 of coronary artery 62 or other blood vessel until bump tip 22 of coaxial guide catheter 12 achieves a deep seated position. Tapered inner catheter 14 is then withdrawn from the lumen of coaxial guide catheter 12. An interventional cardiology treatment device such as a catheter bearing a stent or a balloon (not shown) is then inserted through the lumen of coaxial guide catheter 12 which remains inside guide catheter 56.

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

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

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

The invention claimed is:

1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

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

## 11

the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

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

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

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

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

8. The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

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

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

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

12. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including: an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter, the elongate structure including:

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

## 12

lumen of the guide catheter, the flexible tip portion having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;

a reinforced portion proximal to the flexible tip portion; and

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

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

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

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

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

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

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

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

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

13

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

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

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

14

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

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

\* \* \* \* \*



UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

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

Page 1 of 1

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

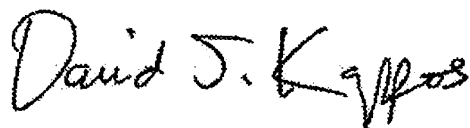
In Column 10, claim 1, line 46, prior to "structure", insert  
-- a flexible tip portion defining a tubular --

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

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

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

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



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

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

<b>Application Data Sheet 37 CFR 1.76</b>	Attorney Docket Number	2005.86USRE15
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.		

### Secrecy Order 37 CFR 5.2

<input type="checkbox"/>	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
--------------------------	---

### Inventor Information:

<b>Inventor 1</b> <span style="float: right; border: 1px solid black; padding: 2px;">Remove</span>				
<b>Legal Name</b>				
<b>Prefix</b>	<b>Given Name</b>	<b>Middle Name</b>	<b>Family Name</b>	<b>Suffix</b>
	Howard	C.	Root	
<b>Residence Information (Select One)</b> <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
<b>City</b>	Tonka Bay	<b>State/Province</b>	MN	<b>Country of Residence i</b>   US

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<b>Address 1</b>	25 Fairhope Avenue			
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<b>City</b>	Tonka Bay	<b>State/Province</b>	MN	
<b>Postal Code</b>	55331	<b>Country i</b>	US	

<b>Inventor 2</b> <span style="float: right; border: 1px solid black; padding: 2px;">Remove</span>				
<b>Legal Name</b>				
<b>Prefix</b>	<b>Given Name</b>	<b>Middle Name</b>	<b>Family Name</b>	<b>Suffix</b>
	Gregg		Sutton	
<b>Residence Information (Select One)</b> <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
<b>City</b>	Plymouth	<b>State/Province</b>	MN	<b>Country of Residence i</b>   US

<b>Mailing Address of Inventor:</b>				
<b>Address 1</b>	18400 31st Avenue North			
<b>Address 2</b>				
<b>City</b>	Plymouth	<b>State/Province</b>	MN	
<b>Postal Code</b>	55447	<b>Country i</b>	US	

<b>Inventor 3</b> <span style="float: right; border: 1px solid black; padding: 2px;">Remove</span>				
<b>Legal Name</b>				
<b>Prefix</b>	<b>Given Name</b>	<b>Middle Name</b>	<b>Family Name</b>	<b>Suffix</b>
	Jeffrey	M.	Welch	
<b>Residence Information (Select One)</b> <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				

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<b>Application Data Sheet 37 CFR 1.76</b>	Attorney Docket Number	2005.86USREI5
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

City	Maple Grove	State/Province	MN	Country of Residence i	US
------	-------------	----------------	----	------------------------	----

**Mailing Address of Inventor:**

Address 1	8723 Cornstock Lane North				
Address 2					
City	Maple Grove	State/Province	MN	Country i	US
Postal Code	55311	Country i	US		

Inventor 4

Remove

**Legal Name**

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jason	M.	Garrity	

**Residence Information (Select One)**  US Residency  Non US Residency  Active US Military Service

City	Lima	State/Province	NY	Country of Residence i	US
------	------	----------------	----	------------------------	----

**Mailing Address of Inventor:**

Address 1	2838 Livonia Center Road				
Address 2					
City	Lima	State/Province	NY	Country i	US
Postal Code	14485	Country i	US		

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.

Add

**Correspondence Information:**Enter either **Customer Number** or complete the **Correspondence Information** section below. For further information see 37 CFR 1.33(a). An Address is being provided for the correspondence information of this application.

Customer Number	24113		
Email Address	onderick@ptslaw.com	Add Email	Remove Email

**Application Information:**

Title of the Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		
Attorney Docket Number	2005.86USREI5	Small Entity Status Claimed	<input checked="" type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	13	Suggested Figure for Publication (if any)	

**Filing By Reference :**

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<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86USREI5
		Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

### Publication Information:

Request Early Publication (Fee required at time of Request 37 CFR 1.219)

**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

### Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer number will be used for the Representative Information during processing.

Please Select One:	<input checked="" type="radio"/> Customer Number	<input type="radio"/> US Patent Practitioner	<input type="radio"/> Limited Recognition (37 CFR 11.9)
Customer Number	24113		

### Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the application number blank.

Prior Application Status	Pending	<input type="button" value="Remove"/>			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)		
	reissue of	14070161	2013-11-01		
Prior Application Status	Patented	<input type="button" value="Remove"/>			
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14070161	reissued of	13359059	2012-01-26	8292850	2012-10-23
Prior Application Status	Patented	<input type="button" value="Remove"/>			

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<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86USRE15		
		Application Number			
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES				
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13359059	Division of	12824734	2010-06-28	8142413	2012-03-27
Prior Application Status	Patented		<input type="button" value="Remove"/>		
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12824734	Division of	11416629	2006-05-03	8048032	2011-11-01
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the <b>Add</b> button.					<input type="button" value="Add"/>

**Foreign Priority Information:**

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) <sup>1</sup>the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country <sup>i</sup>	Filing Date (YYYY-MM-DD)	Access Code <sup>j</sup> (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications**

This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

**Authorization to Permit Access:**

Authorization to Permit Access to the Instant Application by the Participating Offices

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

<b>Application Data Sheet 37 CFR 1.76</b>	Attorney Docket Number	2005.86USRE15
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

## Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

**Applicant 1**

**Remove**

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

**Clear**

Assignee

Legal Representative under 35 U.S.C. 117

Joint Inventor

Person to whom the inventor is obligated to assign.

Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here.

Organization Name VASCULAR SOLUTIONS, INC.

### Mailing Address Information:

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Address 2

City Minneapolis

State/Province MN

Country <sup>i</sup> US

Postal Code 55369

Phone Number

Fax Number

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

<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86USREI5
		Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button.			<input type="button" value="Add"/>

### Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.				
<b>Assignee 1</b>				
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.				
				<input type="button" value="Remove"/>
If the Assignee or Non-Applicant Assignee is an Organization check here.				<input type="checkbox"/>
Prefix	Given Name	Middle Name	Family Name	Suffix
<b>Mailing Address Information For Assignee including Non-Applicant Assignee:</b>				
Address 1				
Address 2				
City		State/Province		
Country i	Postal Code			
Phone Number		Fax Number		
Email Address				
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>

### Signature:

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications				
Signature	/Paul C. Onderick/		Date (YYYY-MM-DD)	2014-03-03
First Name	Paul C.	Last Name	Onderick	Registration Number
Additional Signature may be generated within this form by selecting the Add button.				<input type="button" value="Add"/>

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

<b>Application Data Sheet 37 CFR 1.76</b>	Attorney Docket Number	2005.86USREI5
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USREI5

Howard C. Root et al.

Confirmation No.: Pending

Application No.: Pending

Examiner: Unassigned

Filed: Concurrently Herewith

Group Art Unit: Unassigned

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

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PRELIMINARY AMENDMENT

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

Commissioner:

INTRODUCTORY COMMENTS

Prior to examination, please amend the above-identified application as follows:

The present amendment comprises the following sections:

- A. Amendments to the Specification
- B. Amendments to the Claims
- C. Remarks

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

AMENDMENTS TO THE SPECIFICATION

In the Specification

Please substitute the following amended paragraph(s) and/or section(s) (deleted matter is shown by strikethrough and added matter is shown by underlining):

Page 1, section regarding “Related U.S. Applications”:

Related Applications

This Application is a continuation reissue of Application No. 14/070,161 which is an application for reissue of U.S. Patent 8,292,850 which issued from Application No. 13/359,059, filed January 26, 2012 entitled “Coaxial Guide Catheter for Interventional Cardiology Procedures” which is a divisional of Application No. 12/824,734, filed June 28, 2010 entitled “Coaxial Guide Catheter for Interventional Cardiology Procedures”, which is divisional of Application No. 11/416,629, filed May 3, 2006 now U.S. Patent 8,048,032 entitled “Coaxial Guide Catheter for Interventional Cardiology Procedures” now U.S. Patent 8,142,413; Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue application are Application No. 14/070,161, this application and continuation reissue Application Nos. \_\_\_\_\_ and \_\_\_\_\_ filed the same day as this application.

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 brackets; and 2. added matter is shown by underlining.

1. (Cancelled) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

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

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

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

the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. (Cancelled) The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

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

Attorney Docket No. 2005.86USRE15  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

5. (Cancelled) The system of claim 1, wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.
6. (Cancelled) The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.
7. (Cancelled) The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.
8. (Cancelled) The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.
9. (Cancelled) The system of claim 1, wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.
10. (Cancelled) The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

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

12. (Cancelled) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

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

an elongate structure having an overall length that is longer than the predefined

length of the continuous lumen of the guide catheter, the elongate structure including:

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;

a reinforced portion proximal to the flexible tip portion; and



a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis 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, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

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

lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

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

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

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

18. (Cancelled) 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.

Attorney Docket No. 2005.86USRE15  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

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

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

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

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

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

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

Please add new claims 25-54 as follows:

25. (New) A guide extension catheter for use with a guide catheter, comprising:  
a rail segment;  
a tubular structure defining a lumen and positioned distal to the rail segment; and  
a segment defining a partially cylindrical opening positioned between a distal end of the  
rail segment and a proximal end of the tubular structure, the segment defining the  
partially cylindrical opening having an angled proximal end, formed from a  
structure having a greater flexural modulus than a flexural modulus of the tubular  
structure, and configured to receive one or more interventional cardiology devices  
therethrough when positioned within the guide catheter,  
a cross-section of the guide extension catheter at the proximal end of the tubular structure  
including a single lumen.
26. (New) The guide extension catheter of claim 25, wherein the angled proximal end of the  
partially cylindrical opening originates adjacent the distal end of the rail segment and extends  
distally toward the tubular structure.

Attorney Docket No. 2005.86USRE15  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

27. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional.

28. (New) The guide extension catheter of claim 27, wherein the portion having the arcuate cross-sectional shape extends for a length of 15 cm.

29. (New) The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of the cross-sectional circumference of the segment defining the partially cylindrical opening.

30. (New) The guide extension catheter of claim 25, wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.

31. (New) The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from its proximal end to its distal end.

32. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape.

33. (New) The guide extension catheter of claim 32, wherein the portion having the hemicylindrical cross-sectional shape extends for a length of 20 cm to 75 cm.
34. (New) The guide extension catheter of claim 32, wherein the hemicylindrical cross-sectional shape radially extends 40% to 70% of the cross-sectional circumference of a tube.
35. (New) The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.
36. (New) The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.
37. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.
38. (New) The guide extension catheter of claim 25, wherein the rail segment is formed from a hypotube.
39. (New) The guide extension catheter of claim 25, wherein the rail segment is formed from

a section of stainless steel.

40. (New) The guide extension catheter of claim 25, wherein the rail segment is formed from a section of Nitinol tubing.

41. (New) The guide extension catheter of claim 25, wherein the rail segment is eccentrically positioned relative to a cross-section of the tubular structure.

42. (New) The guide extension catheter of claim 25, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure within and partially through the guide catheter, while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the rail segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.

43. (New) The guide extension catheter of claim 25, wherein the rail segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the rail segment.

44. (New) The guide extension catheter of claim 25, further comprising a tip portion positioned distal to a distal end of the tubular structure.

45. (New) The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of its length and surrounded by one or more polymer materials.

46. (New) The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is 20 to 30 cm.

47. (New) The guide extension catheter of claim 25, wherein the rail segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.

48. (New) The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter.

49. (New) The guide extension catheter of claim 25, wherein a material forming the partially cylindrical opening is more rigid than a material or material combination forming the tubular structure.

50. (New) A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:

a rail segment;



a tubular structure defining a lumen and positioned distal to the rail segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and

a segment defining a partially cylindrical opening positioned between a distal end of the rail segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter,

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

51. (New) The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure.

52. (New) The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape.

53. (New) The guide extension catheter of claim 50, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure of the guide extension catheter partially through the guide catheter and into a coronary artery, while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.

54. (New) The guide extension catheter of claim 50, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

REMARKS

Claims 1-24 are pending. By this Amendment, claims 1-24 are cancelled, no claims are amended and new claims 25-54 are added.

This application is a reissue application and is to be given priority in examination. MPEP 708.

Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue applications are reissue Application 14/070,161, this continuation reissue application and continuation reissue applications \_\_\_\_\_ and \_\_\_\_\_ expected to file the same day as this application.

“The parent and continuation reissue applications should be examined together if possible.” MPEP 1451(II)

This application is a continuation reissue application 14/070,161 filed November 1, 2013. New Claims in this Preliminary Amendment are numbered consecutively with the claims of the parent issued patent U.S. 8,292,850. However, Applicants note that this creates a claim numbering conflict with the parent reissue application 14/070,161 as well as with two other continuation reissue applications expected to be filed on the same day as this continuation reissue application which will have claims sharing the same numbering at least initially. Since the Patent Office Rules do not address how to resolve such a conflict and it is difficult to predict which of the related reissue applications will issue first, Applicants expect that this claim numbering conflict will be resolved by renumbering of the claims as appropriate if and when each of the related reissue applications receives an indication of allowable subject matter thus

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

assuring that the reissue patents arising from these applications do not have a claim numbering conflict.

This Preliminary Amendment indicates that claims 1-24 of the parent patent US 8,292,850 are to be cancelled. This is to comply with rules and practice related to continuation reissue applications. Claims 1-24 remain pending in reissue application 14/070,161 and cancellation of claims 1-24 herein is done without prejudice, disclaimer, waiver or surrender of the claims or of the claimed subject matter. No surrender of the claims or the claimed subject matter is intended or achieved by cancellation of claims 1-24 herein.

The filed broadening reissue claims are directed to an additional invention, embodiment or species not originally claimed that represent an overlooked aspect of the invention in the issued patent.

The amendments and additions to the claims are made to correct one or more defects causing U.S. Patent No. 8,292,850 to be partly inoperative or invalid.

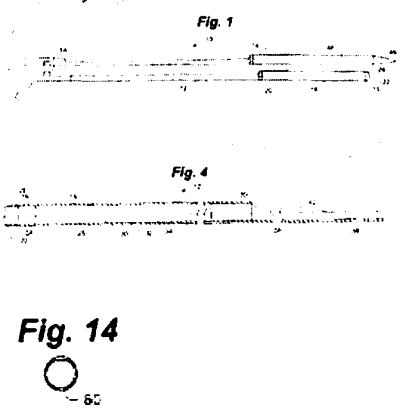
**Examination and reconsideration of this application are respectfully requested.**

**Formal Request for Telephonic Interview**

If the present claim amendments and additions do not result in allowance of this reissue application, the undersigned formally requests that, before issuance of any Office Action, a telephonic interview be held between the Examiner and the undersigned, at the Examiner's

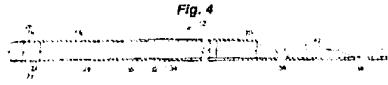
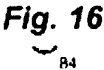
Attorney Docket No. 2005.86USREI5  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

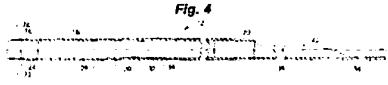

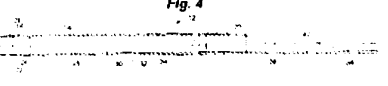
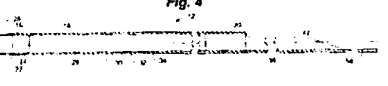
convenience. The Examiner is kindly requested to phone the undersigned at 612.349.5766 to arrange a time for such telephonic interview.

Claim No.	Claim Amendment(s) and/or Addition(s) <sup>1</sup>	Example(s) of Support in U.S. Application Serial No. 13/359,059, filed on Jan. 26, 2012
25	<p>A guide extension catheter for use with a guide catheter, comprising:</p> <ul style="list-style-type: none"> <li>a rail segment;</li> <li>a tubular structure defining a lumen and positioned distal to the rail segment; and</li> <li>a segment defining a partially cylindrical opening positioned between a distal end of the rail segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the</li> </ul>	<p>Page 6, lines 1-4</p> <p>Page 7, line 14 – page 8, line 2</p> <p>Page 9, lines 12-14</p> <p>Page 12, lines 12-16</p> <p>Page 13, line 15 – page 14, line 8</p> <p>Page 19, lines 12-14</p> <p>Original claims 1, 3, 12 and 20-22</p> <p>FIGS. 1, 4 and 14:</p> 

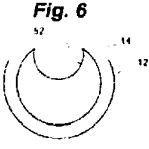
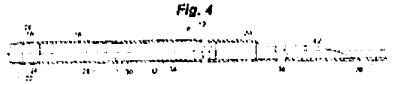
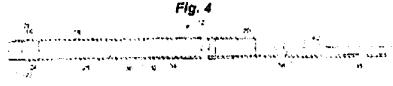
<sup>1</sup> In the table, bracketed language indicates deletions and underlined language indicates additions.

Attorney Docket No. 2005.86USREI5  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

	guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure including a single lumen.	
26	<u>The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent the distal end of the rail segment and extends distally toward the tubular structure.</u>	Original claim 9  FIG. 4: 
27	<u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional.</u>	Page 6, lines 16 and 17  Page 12, lines 14-16  Original claim 9  FIG. 16: 
28	<u>The guide extension catheter of claim 27, wherein the portion having the arcuate cross-sectional shape extends for a length of about 15 cm.</u>	Page 6, lines 17-22  Page 13, lines 1 and 2
29	<u>The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends about 25% to about 40% of the cross-sectional circumference of a tube.</u>	Page 13, lines 1 and 2
30	<u>The guide extension catheter of claim 25, wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.</u>	Page 5, lines 8-18  Original claims 8 and 18

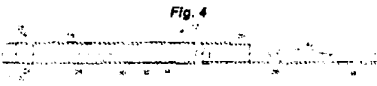
31	<u>The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from its proximal end to its distal end.</u>	Original claim 1  FIG. 4:  
32	<u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape.</u>	Page 6, lines 16 and 17  Page 12, lines 12-16, 19 and 20  Original claim 9  FIG. 15:  
33	<u>The guide extension catheter of claim 32, wherein the portion having the hemicylindrical cross-sectional shape extends for a length of about 20 cm to about 75 cm.</u>	Page 6, lines 17-22  Page 12, lines 19 and 20
34	<u>The guide extension catheter of claim 32, wherein the hemicylindrical cross-sectional shape radially extends about 40% to about 70% of the cross-sectional circumference of a tube.</u>	Page 12, lines 19 and 20
35	<u>The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.</u>	FIG. 4:  
36	<u>The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.</u>	FIG. 4:  

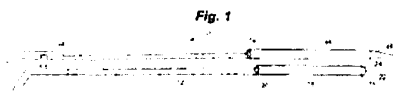
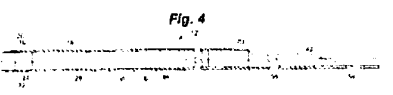

Attorney Docket No. 2005.86USREIS  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

37	<u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.</u>	Page 13, lines 10 and 11  FIG. 6:  
38	<u>The guide extension catheter of claim 25, wherein the rail segment is formed from a hypotube.</u>	Page 12, lines 13 and 14
39	<u>The guide extension catheter of claim 25, wherein the rail segment is formed from a section of stainless steel.</u>	Page 6, lines 15 and 16  Page 12, lines 13 and 14
40	<u>The guide extension catheter of claim 25, wherein the rail segment is formed from a section of Nitinol tubing.</u>	Page 6, lines 15 and 16  Page 12, lines 13 and 14
41	<u>The guide extension catheter of claim 25, wherein the rail segment is eccentrically positioned relative to a cross-section of the tubular structure.</u>	Page 12, lines 12 and 13  FIG. 4:  
42	<u>The guide extension catheter of claim 25, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure within and partially through the guide catheter, while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the rail segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.</u>	Page 5, lines 5-7  Page 8, lines 3-5  Page 15, lines 1-10  FIG. 4:  

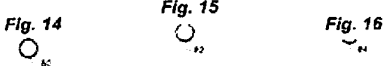

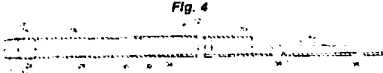


Attorney Docket No. 2005.86USRE15  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

43	<u>The guide extension catheter of claim 25, wherein the rail segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the rail segment.</u>	FIG. 4:  Original claims 1 and 12
44	<u>The guide extension catheter of claim 25, further comprising a tip portion positioned distal to a distal end of the tubular structure.</u>	Page 6, lines 1-9 Page 11, lines 15-20 Original claims 5 and 12
45	<u>The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of its length and surrounded by one or more polymer materials.</u>	Page 6, lines 10-14 Page 12, lines 5-11 Page 19, line 1 Original claims 5, 6 and 17
46	<u>The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is about 20 to 30 cm.</u>	Page 6, lines 10-14 Page 12, lines 9-11
47	<u>The guide extension catheter of claim 25, wherein the rail segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.</u>	Page 6, lines 16 and 17 Page 12, lines 12-18 Original claim 14
48	<u>The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter.</u>	Page 6, lines 1-4 and 10-14 Original claims 3 and 4
49	<u>The guide extension catheter of claim 25, wherein a material forming the partially cylindrical opening is more rigid than a material or material combination forming the tubular</u>	Page 6, lines 15 and 17 Page 14, lines 3-8 Page 13, line 15 – page 14, line 8

	<p><u>structure.</u></p>	
<p>50</p>	<p>A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:</p> <ul style="list-style-type: none"> <li>a rail segment;</li> <li>a tubular structure defining a lumen and positioned distal to the rail segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and</li> <li>a segment defining a partially cylindrical opening positioned between a distal end of the rail segment and a proximal end of the tubular structure, the segment defining partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter,</li> </ul> <p>a cross-section of the guide extension catheter at the proximal end of the tubular structure including a single</p>	<p>Page 5, lines 8-18</p> <p>Page 6, lines 1-4</p> <p>Page 7, line 14 – page 8, line 2</p> <p>Page 9, lines 12-14</p> <p>Page 12, lines 12-16</p> <p>Page 19, lines 12-14</p> <p>Original claims 1, 3, 8, 12 and 18</p> <p>FIGS. 1, 4 and 14:</p> <div style="text-align: center;">  <p>Fig. 1</p>  <p>Fig. 4</p>  <p>Fig. 14</p> </div>

Attorney Docket No. 2005.86USRE15  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

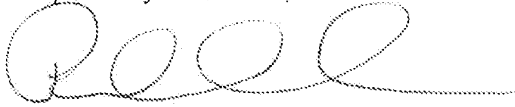
	lumen.	
51	<u>The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure.</u>	Page 6, lines 16 and 17 Page 13, line 15 – page 14, line 8 Original claims 20-22
52	<u>The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape.</u>	Page 12, lines 14-16 and 21 Page 16, lines 15-21 Original claims 9 and 19 FIGS. 14, 15, and 16: 
53	<u>The guide extension catheter of claim 50, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure of the guide extension catheter partially through the guide catheter and into a coronary artery, while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.</u>	Page 4, lines 16-18 Page 5, lines 5-7 Page 8, lines 3-5 Page 15, lines 1-10 FIG. 4: 
54	<u>The guide extension catheter of claim 50, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.</u>	FIG. 4: 

Attorney Docket No. 2005.86USRE15  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

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,

A handwritten signature in black ink, appearing to read "P. Onderick", with a long horizontal flourish extending to the right.

Paul C. Onderick  
Registration No. 45354

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## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	18353856
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Mary Granger
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	03-MAR-2014
<b>Filing Date:</b>	
<b>Time Stamp:</b>	17:10:11
<b>Application Type:</b>	Reissue (Utility)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Reissue Application	Reissue_Trans_App.pdf	2821298 <small>87815f62a9b9b1e9002e60e468a43dbb60353a4f</small>	no	45

### Warnings:

### Information:

2	Application Data Sheet	ADS.pdf	1561948	no	8
			d81037f0398a6dbb6c86f5c305313f509a37d8ba		
<b>Warnings:</b>					
<b>Information:</b>					
3		Preliminary_Amendment.pdf	1296691	yes	27
			8bf89c0e3ae090c4a1237fd7eccce823699189d0a		
<b>Multipart Description/PDF files in .zip description</b>					
		<b>Document Description</b>	<b>Start</b>	<b>End</b>	
		Preliminary Amendment	1	2	
		Claims	3	17	
		Applicant Arguments/Remarks Made in an Amendment	18	27	
<b>Warnings:</b>					
<b>Information:</b>					
			<b>Total Files Size (in bytes):</b>	5679937	
<p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p>					



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Table with 7 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY.DOCKET.NO, TOT CLAIMS, IND CLAIMS. Row 1: 14/195,413, 03/03/2014, 3767, 0.00, 2005.86USREI5, 30, 2

CONFIRMATION NO. 6135

24113
PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

FILING RECEIPT



Date Mailed: 03/06/2014

Receipt is acknowledged of this reissue patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Inventor(s)

Howard C. Root, Tonka Bay, MN;
Gregg Sutton, Plymouth, MN;
Jeffrey M. Welch, Maple Grove, MN;
Jason M. Garrity, Lima, NY;

Applicant(s)

Vascular Solutions, Inc., Minneapolis, MN

Power of Attorney: The patent practitioners associated with Customer Number 24113

Domestic Priority data as claimed by applicant

This application is a CON of 14/070,161 11/01/2013 \*
which is a REI of 13/359,059 01/26/2012 PAT 8292850
which is a DIV of 12/824,734 06/28/2010 PAT 8142413
which is a DIV of 11/416,629 05/03/2006 PAT 8048032
(\*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**Title**

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

**Preliminary Class**

604

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No**

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).



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**Title 37, Code of Federal Regulations, 5.11 & 5.15**

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**PATENT APPLICATION FEE DETERMINATION RECORD**

Substitute for Form PTO-875

Application or Docket Number

14/195,413

**APPLICATION AS FILED - PART I**

(Column 1)		(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	280
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	2160
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 = *	10			OR	x 80 =	800
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 = *					x 420 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
			TOTAL			TOTAL	3840

\* If the difference in column 1 is less than zero, enter "0" in column 2.

**APPLICATION AS AMENDED - PART II**

(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
Total (37 CFR 1.16(i))	*	Minus **	=	x	=	OR	x	=
Independent (37 CFR 1.16(h))	*	Minus ***	=	x	=	OR	x	=
Application Size Fee (37 CFR 1.16(s))						OR		
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
				TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
Total (37 CFR 1.16(i))	*	Minus **	=	x	=	OR	x	=
Independent (37 CFR 1.16(h))	*	Minus ***	=	x	=	OR	x	=
Application Size Fee (37 CFR 1.16(s))						OR		
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						OR		
				TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".  
 The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



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Table with 4 columns: APPLICATION NUMBER, FILING OR 371(C) DATE, FIRST NAMED APPLICANT, ATTY. DOCKET NO./TITLE

14/195,413

03/03/2014

Howard C. Root

2005.86USRE15

CONFIRMATION NO. 6135

FORMALITIES LETTER

24113
PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100



Date Mailed: 03/06/2014

NOTICE TO FILE MISSING PARTS OF REISSUE APPLICATION

Filing Date Granted

An application number and filing date have been accorded to this reissue application. The item(s) indicated below, however, are missing. Applicant is given TWO MONTHS from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
The application search fee must be submitted.
The application examination fee must be submitted.
The inventor's oath or declaration has not been submitted.
Consent of assignee is missing. 37 CFR 1.172 requires that a reissue oath/declaration be accompanied by the written consent of all assignees.
Assignee's statement under 37 CFR 3.73(c) establishing ownership of the patent is missing. 37 CFR 1.172 requires that all assignees consenting to the reissue application establish their ownership interest in the patent by filing in the reissue application a statement in accordance with 37 CFR 3.73(c).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 (and 37 CFR 1.175) executed by or with respect to each inventor is required. For a reissue application, the inventor's oath or declaration must be submitted prior to examination and cannot be postponed. See 37 CFR 1.175(e). An assignee of the entire interest can execute the oath or declaration if: (1) the application does not seek to enlarge the scope of the claims of the original patent; or (2) the application for the original patent was filed under 37 CFR 1.46 by the assignee of the entire interest. A substitute statement under 37 CFR 1.64 in lieu of an oath or declaration may be submitted in the circumstances provided for in 35 U.S.C. 115(d) and 37 CFR 1.64.

- Additional claim fees of \$ 800 as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
The surcharge is due for any one of:
late submission of the basic filing fee, search fee, or examination fee,
late submission of inventor's oath or declaration,
filing an application that does not contain at least one claim on filing, or
submission of an application filed by reference to a previously filed application.

**SUMMARY OF FEES DUE:**

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- \$ **280** basic filing fee.
- \$ **140** surcharge.
- \$ **600** search fee.
- \$ **2160** examination fee.
- \$ **800** for **10** total claims over the higher of 20, or the amount in the original patent.
- \$ **( 0.00)** previous unapplied payment amount.
- \$ **3980** TOTAL FEE BALANCE DUE.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

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

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".  
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

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/dalyon/

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Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USRE15

Howard C. Root et al.

Confirmation No.: 6135

Application No.: 14/195,413

Examiner: Unassigned

Filed: March 3, 2014

Group Art Unit: Unassigned

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

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PRELIMINARY AMENDMENT

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

Commissioner:

INTRODUCTORY COMMENTS

Prior to examination, please amend the above-identified application as follows:

The present amendment comprises the following sections:

- A. Amendments to the Specification
- B. Amendments to the Claims
- C. Remarks

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

AMENDMENTS TO THE SPECIFICATION

In the Specification

Please substitute the following amended paragraph(s) and/or section(s) (deleted matter is shown by strikethrough and added matter is shown by underlining):

Page 1, section regarding “Related U.S. Applications”:

Related Applications

This Application is a continuation reissue of Application No. 14/070,161 which is an application for reissue of U.S. Patent 8,292,850 which issued from Application No. 13/359,059, filed January 26, 2012, entitled “Coaxial Guide Catheter for Interventional Cardiology Procedures” which is a divisional of Application No. 12/824,734, filed June 28, 2010 entitled “Coaxial Guide Catheter for Interventional Cardiology Procedures”, which is divisional of Application No. 11/416,629, filed May 3, 2006 now U.S. Patent 8,048,032 entitled “Coaxial Guide Catheter for Interventional Cardiology Procedures” now U.S. Patent 8,142,413; Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue application are Application No. 14/070,161, this application and continuation reissue Application Nos. 14/195,385 and 14/195,435 filed March 3, 2014, the same day as this application.

Attorney Docket No. 2005.86USREIS  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

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 brackets; and 2. added matter is shown by underlining.

1. (Cancelled) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

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

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

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



the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. (Cancelled) The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

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

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

5. (Cancelled) The system of claim 1, wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.
6. (Cancelled) The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.
7. (Cancelled) The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.
8. (Cancelled) The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.
9. (Cancelled) The system of claim 1, wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.
10. (Cancelled) The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

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

12. (Cancelled) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

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

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

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;

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis 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, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

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

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

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

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

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

18. (Cancelled) 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.

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

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

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

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

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

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

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

Please add new claims 25-54 as follows:

25. (New) A guide extension catheter for use with a guide catheter, comprising:  
a rail segment;  
a tubular structure defining a lumen and positioned distal to the rail segment; and  
a segment defining a partially cylindrical opening positioned between a distal end of the  
rail segment and a proximal end of the tubular structure, the segment defining the  
partially cylindrical opening having an angled proximal end, formed from a  
structure having a greater flexural modulus than a flexural modulus of the tubular  
structure, and configured to receive one or more interventional cardiology devices  
therethrough when positioned within the guide catheter,  
a cross-section of the guide extension catheter at the proximal end of the tubular structure  
including a single lumen.
26. (New) The guide extension catheter of claim 25, wherein the angled proximal end of the  
partially cylindrical opening originates adjacent the distal end of the rail segment and extends  
distally toward the tubular structure.

Attorney Docket No. 2005.86USREIS  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

27. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional.
28. (New) The guide extension catheter of claim 27, wherein the portion having the arcuate cross-sectional shape extends for a length of 15 cm.
29. (New) The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of the cross-sectional circumference of the segment defining the partially cylindrical opening.
30. (New) The guide extension catheter of claim 25, wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.
31. (New) The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from its proximal end to its distal end.
32. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape.



Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

33. (New) The guide extension catheter of claim 32, wherein the portion having the hemicylindrical cross-sectional shape extends for a length of 20 cm to 75 cm.
34. (New) The guide extension catheter of claim 32, wherein the hemicylindrical cross-sectional shape radially extends 40% to 70% of the cross-sectional circumference of a tube.
35. (New) The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.
36. (New) The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.
37. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.
38. (New) The guide extension catheter of claim 25, wherein the rail segment is formed from a hypotube.
39. (New) The guide extension catheter of claim 25, wherein the rail segment is formed from

a section of stainless steel.

40. (New) The guide extension catheter of claim 25, wherein the rail segment is formed from a section of Nitinol tubing.

41. (New) The guide extension catheter of claim 25, wherein the rail segment is eccentrically positioned relative to a cross-section of the tubular structure.

42. (New) The guide extension catheter of claim 25, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure within and partially through the guide catheter, while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the rail segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.

43. (New) The guide extension catheter of claim 25, wherein the rail segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the rail segment.

44. (New) The guide extension catheter of claim 25, further comprising a tip portion positioned distal to a distal end of the tubular structure.

45. (New) The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of its length and surrounded by one or more polymer materials.

46. (New) The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is 20 to 30 cm.

47. (New) The guide extension catheter of claim 25, wherein the rail segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.

48. (New) The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter.

49. (New) The guide extension catheter of claim 25, wherein a material forming the partially cylindrical opening is more rigid than a material or material combination forming the tubular structure.

50. (New) A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:

a rail segment;

a tubular structure defining a lumen and positioned distal to the rail segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and

a segment defining a partially cylindrical opening positioned between a distal end of the rail segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter,

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

51. (New) The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure.

52. (New) The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape.

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

53. (New) The guide extension catheter of claim 50, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure of the guide extension catheter partially through the guide catheter and into a coronary artery, while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.

54. (New) The guide extension catheter of claim 50, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

REMARKS

Claims 1-24 are pending. By this Amendment, claims 1-24 are cancelled, no claims are amended and new claims 25-54 are added.

This application is a reissue application and is to be given priority in examination. MPEP 708.

Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue applications are reissue Application 14/070,161, this continuation reissue application and continuation reissue applications 14/195,385 and 14/195,435 expected to file the same day as this application.

“The parent and continuation reissue applications should be examined together if possible.” MPEP 1451(II)

This application is a continuation reissue application 14/070,161 filed November 1, 2013. New Claims in this Preliminary Amendment are numbered consecutively with the claims of the parent issued patent U.S. 8,292,850. However, Applicants note that this creates a claim numbering conflict with the parent reissue application 14/070,161 as well as with two other continuation reissue applications expected to be filed on the same day as this continuation reissue application which will have claims sharing the same numbering at least initially. Since the Patent Office Rules do not address how to resolve such a conflict and it is difficult to predict which of the related reissue applications will issue first, Applicants expect that this claim numbering conflict will be resolved by renumbering of the claims as appropriate if and when each of the related reissue applications receives an indication of allowable subject matter thus

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

assuring that the reissue patents arising from these applications do not have a claim numbering conflict.

This Preliminary Amendment indicates that claims 1-24 of the parent patent US 8,292,850 are to be cancelled. This is to comply with rules and practice related to continuation reissue applications. Claims 1-24 remain pending in reissue application 14/070,161 and cancellation of claims 1-24 herein is done without prejudice, disclaimer, waiver or surrender of the claims or of the claimed subject matter. No surrender of the claims or the claimed subject matter is intended or achieved by cancellation of claims 1-24 herein.

The filed broadening reissue claims are directed to an additional invention, embodiment or species not originally claimed that represent an overlooked aspect of the invention in the issued patent.

The amendments and additions to the claims are made to correct one or more defects causing U.S. Patent No. 8,292,850 to be partly inoperative or invalid.

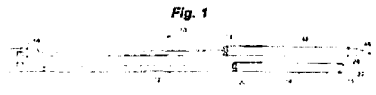
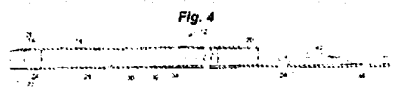

**Examination and reconsideration of this application are respectfully requested.**

*Formal Request for Telephonic Interview*

If the present claim amendments and additions do not result in allowance of this reissue application, the undersigned formally requests that, before issuance of any Office Action, a telephonic interview be held between the Examiner and the undersigned, at the Examiner's

Attorney Docket No. 2005.86USREI5  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

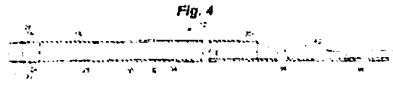
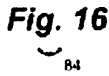
convenience. The Examiner is kindly requested to phone the undersigned at 612.349.5766 to arrange a time for such telephonic interview.

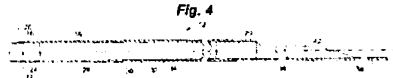

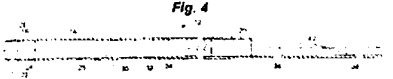
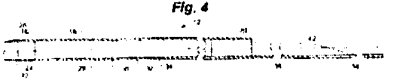
Claim No.	Claim Amendment(s) and/or Addition(s) <sup>1</sup>	Example(s) of Support in U.S. Application Serial No. 13/359,059, filed on Jan. 26, 2012
25	<p>A guide extension catheter for use with a guide catheter, comprising:</p> <ul style="list-style-type: none"> <li>a rail segment;</li> <li>a tubular structure defining a lumen and positioned distal to the rail segment; and</li> <li>a segment defining a partially cylindrical opening positioned between a distal end of the rail segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the</li> </ul>	<p>Page 6, lines 1-4</p> <p>Page 7, line 14 – page 8, line 2</p> <p>Page 9, lines 12-14</p> <p>Page 12, lines 12-16</p> <p>Page 13, line 15 – page 14, line 8</p> <p>Page 19, lines 12-14</p> <p>Original claims 1, 3, 12 and 20-22</p> <p>FIGS. 1, 4 and 14:</p>   

<sup>1</sup> In the table, bracketed language indicates deletions and underlined language indicates additions.

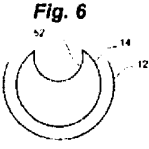
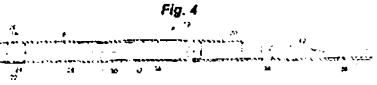
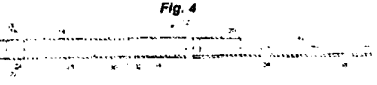


Attorney Docket No. 2005.86USREI5  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

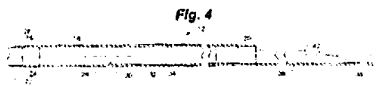
	guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure including a single lumen.	
26	<u>The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent the distal end of the rail segment and extends distally toward the tubular structure.</u>	Original claim 9  FIG. 4:  
27	<u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional.</u>	Page 6, lines 16 and 17  Page 12, lines 14-16  Original claim 9  FIG. 16:  
28	<u>The guide extension catheter of claim 27, wherein the portion having the arcuate cross-sectional shape extends for a length of about 15 cm.</u>	Page 6, lines 17-22  Page 13, lines 1 and 2
29	<u>The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends about 25% to about 40% of the cross-sectional circumference of a tube.</u>	Page 13, lines 1 and 2
30	<u>The guide extension catheter of claim 25, wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.</u>	Page 5, lines 8-18  Original claims 8 and 18

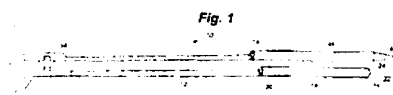
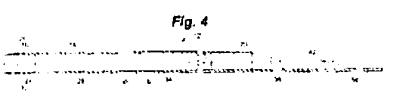

31	<u>The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from its proximal end to its distal end.</u>	Original claim 1  FIG. 4:  
32	<u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape.</u>	Page 6, lines 16 and 17  Page 12, lines 12-16, 19 and 20  Original claim 9  FIG. 15:  
33	<u>The guide extension catheter of claim 32, wherein the portion having the hemicylindrical cross-sectional shape extends for a length of about 20 cm to about 75 cm.</u>	Page 6, lines 17-22  Page 12, lines 19 and 20
34	<u>The guide extension catheter of claim 32, wherein the hemicylindrical cross-sectional shape radially extends about 40% to about 70% of the cross-sectional circumference of a tube.</u>	Page 12, lines 19 and 20
35	<u>The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.</u>	FIG. 4:  
36	<u>The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.</u>	FIG. 4:  

Attorney Docket No. 2005.86USREIS  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

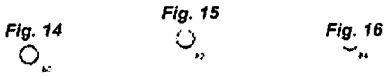
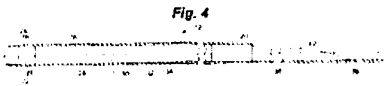
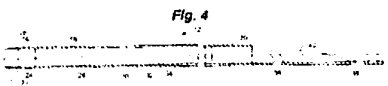
37	<u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.</u>	Page 13, lines 10 and 11 FIG. 6: 
38	<u>The guide extension catheter of claim 25, wherein the rail segment is formed from a hypotube.</u>	Page 12, lines 13 and 14
39	<u>The guide extension catheter of claim 25, wherein the rail segment is formed from a section of stainless steel.</u>	Page 6, lines 15 and 16 Page 12, lines 13 and 14
40	<u>The guide extension catheter of claim 25, wherein the rail segment is formed from a section of Nitinol tubing.</u>	Page 6, lines 15 and 16 Page 12, lines 13 and 14
41	<u>The guide extension catheter of claim 25, wherein the rail segment is eccentrically positioned relative to a cross-section of the tubular structure.</u>	Page 12, lines 12 and 13 FIG. 4: 
42	<u>The guide extension catheter of claim 25, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure within and partially through the guide catheter, while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the rail segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.</u>	Page 5, lines 5-7 Page 8, lines 3-5 Page 15, lines 1-10 FIG. 4: 

Attorney Docket No. 2005.86USREI5  
 REISSUE APPLICATION  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

43	<u>The guide extension catheter of claim 25, wherein the rail segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the rail segment.</u>	FIG. 4:  Original claims 1 and 12
44	<u>The guide extension catheter of claim 25, further comprising a tip portion positioned distal to a distal end of the tubular structure.</u>	Page 6, lines 1-9 Page 11, lines 15-20 Original claims 5 and 12
45	<u>The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of its length and surrounded by one or more polymer materials.</u>	Page 6, lines 10-14 Page 12, lines 5-11 Page 19, line 1 Original claims 5, 6 and 17
46	<u>The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is about 20 to 30 cm.</u>	Page 6, lines 10-14 Page 12, lines 9-11
47	<u>The guide extension catheter of claim 25, wherein the rail segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.</u>	Page 6, lines 16 and 17 Page 12, lines 12-18 Original claim 14
48	<u>The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter.</u>	Page 6, lines 1-4 and 10-14 Original claims 3 and 4
49	<u>The guide extension catheter of claim 25, wherein a material forming the partially cylindrical opening is more rigid than a material or material combination forming the tubular</u>	Page 6, lines 15 and 17 Page 14, lines 3-8 Page 13, line 15 – page 14, line 8

	<p><u>structure.</u></p>	
<p><b>50</b></p>	<p>A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:</p> <ul style="list-style-type: none"> <li>a rail segment;</li> <li>a tubular structure defining a lumen and positioned distal to the rail segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and</li> <li>a segment defining a partially cylindrical opening positioned between a distal end of the rail segment and a proximal end of the tubular structure, the segment defining partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter,</li> </ul> <p>a cross-section of the guide extension catheter at the proximal end of the tubular structure including a single</p>	<p>Page 5, lines 8-18</p> <p>Page 6, lines 1-4</p> <p>Page 7, line 14 – page 8, line 2</p> <p>Page 9, lines 12-14</p> <p>Page 12, lines 12-16</p> <p>Page 19, lines 12-14</p> <p>Original claims 1, 3, 8, 12 and 18</p> <p>FIGS. 1, 4 and 14:</p> <div style="text-align: center;">  <p>Fig. 1</p>  <p>Fig. 4</p>  <p>Fig. 14</p> </div>

Attorney Docket No. 2005.86USREI5  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

	lumen.	
51	<u>The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure.</u>	Page 6, lines 16 and 17 Page 13, line 15 – page 14, line 8 Original claims 20-22
52	<u>The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape.</u>	Page 12, lines 14-16 and 21 Page 16, lines 15-21 Original claims 9 and 19 FIGS. 14, 15, and 16: 
53	<u>The guide extension catheter of claim 50, wherein a cross-section of the rail segment is sufficiently sized and configured to advance the tubular structure of the guide extension catheter partially through the guide catheter and into a coronary artery, while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.</u>	Page 4, lines 16-18 Page 5, lines 5-7 Page 8, lines 3-5 Page 15, lines 1-10 FIG. 4: 
54	<u>The guide extension catheter of claim 50, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.</u>	FIG. 4: 

Attorney Docket No. 2005.86USRE15  
REISSUE APPLICATION  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

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,

A handwritten signature in black ink, appearing to read "POO", written over a horizontal dotted line.

Paul C. Onderick  
Registration No. 45354

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

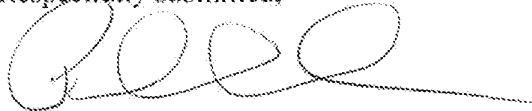




Application No.: 14/195,413

This Information Disclosure Statement is being filed without a certification or fee because this Information Disclosure Statement is being filed within three months of the U.S. filing date. No certification or fee is required. 37 CFR § 1.97(b)(1)(2).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. Onderick", with a long horizontal line extending to the right.

Paul C. Onderick  
Registration No. 45354

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Telephone: 612.349.5766

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

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	14/195,413
				Filing Date	March 3, 2014
				First Named Inventor	Howard C. Root Et Al.
				Art Unit	Unassigned
Examiner Name	Unassigned				
Sheet	1	of	7	Attorney Docket Number	2005.86USRE15

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> (if known)		
		US-8,292,850 B2	10-23-2012	Root et al.
		US-8,142,413 B2	03-27-2012	Root et al.
		US-8,048,032 B2	11-01-2011	Root et al.
		US-7,762,984 B2	07-27-2010	Kumoyama et al.
		US-7,717,899 B2	05-18-2010	Bowe et al.
		US-7,697,996 B2	04-13-2010	Manning et al.
		US-7,544,201 B2	06-09-2009	Pepper
		US-7,294,124 B2	11-13-2007	Eidenschink
		US-6,860,876	03-01-2005	Chen
		US-6,755,812	06-29-2004	Peterson et al.
		US-6,706,018	03-16-2004	Westlund et al.
		US-6,689,144	02-10-2004	Gerberding
		US-6,638,268 B2	10-28-2003	Niazi
		US-6,635,029 B1	10-21-2003	Venturelli
		US-6,610,068	08-26-2003	Yang

**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			
		EP 0365993	05-02-1990	Terumo Kabushiki Kaisha	
		EP 0313558 (Published as US 5,002,531, also cited)	01-14-1988	BONZEL, Tassilo	
		EP 0380873	08-08-1990	C.R. Bard, Inc.	
		WO84/03633	09-27-1984	FOGARTY, Thomas J.	

EXAMINER SIGNATURE	DATE CONSIDERED
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.  
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				Filing Date	March 3, 2014
				First Named Inventor	Howard C. Root Et Al.
				Art Unit	Unassigned
Examiner Name	Unassigned				
Sheet	2	of	7	Attorney Docket Number	2005.86USRE15

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> (if known)		
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			

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Sheet	4	of	7	Attorney Docket Number	2005.86USRE15	

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			

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				Art Unit	Unassigned
Examiner Name	Unassigned				
Sheet	5	of	7	Attorney Docket Number	2005.86USRE15

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Examiner Name	Unassigned		Attorney Docket Number	2005.86USRE15		
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**NON PATENT LITERATURE DOCUMENTS**

EXAMINER INITIAL*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Saeko TAKAHASHI, et al., "New Method to Increase a Backup Support Of A 6 French Guiding Coronary Catheter", <i>Catheterization and Cardiovascular Interventions</i> , 63:452-456 (2004), 5 Pages; Published online in <i>Wiley InterScience</i> ( <a href="http://www.interscience.wiley.com">www.interscience.wiley.com</a> ),	
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**EUROPEAN PATENT APPLICATION**

(21) Application number: **89119330.2**      (51) Int. Cl.<sup>5</sup>: **A61M 29/02 , A61M 25/10**  
 (22) Date of filing: **18.10.89**

(30) Priority: **20.10.88 JP 264888/88**  
                   **22.05.89 JP 827/89**  
                   **02.08.89 JP 995/89**

(43) Date of publication of application:  
**02.05.90 Bulletin '90/18**

(84) Designated Contracting States:  
**BE DE ES FR GB IT NL SE**

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**Fuji-shi Shizuoka-ken(JP)**

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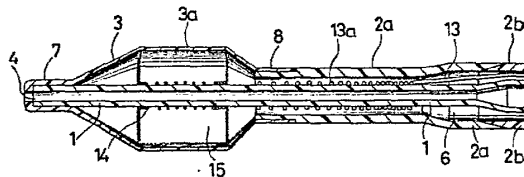
**(54) Catheter equipped with expansible member and method of manufacturing the same.**

(57) A catheter equipped with an expansible member (3) according to the present invention comprises a first lumen (4) whose tip is open, a second lumen whose tip is closed, a foldable expansible member (3) communicating with the second lumen (6), and a rigidity imparting member (13) consisting of a linear member extending in the axial direction disposed in the second lumen. Therefore, an extreme flexion or bend of the catheter is prevented without decrease of the flexibility of the catheter, especially the elastic deformability in the lateral direction with respect to the axial direction of the catheter. Thus, the force applied to the base end portion of the catheter for advancing the tip end portion thereof is surely transmitted to the tip end portion. Further, a catheter equipped with an expansible member according to the present invention comprises a first lumen whose tip is open, a second lumen whose tip is closed, and a foldable expansible member communicating with the second lumen, the outer diameter of the tip end portion of the catheter including a portion to which the expansible member is attached is smaller than that of the base end portion of the catheter. Therefore, the tip end portion of the catheter can be inserted into a severer stricture portion or in a more

peripheral blood vessel. Further, a catheter equipped with an expansible member according to the present invention comprises a first lumen whose tip is open, a second lumen whose tip is closed, and a foldable expansible member communicating with the second lumen, the tip of the expansible member forming the tip of the catheter. Therefore, the expansible member is prevented from peeling off and the tip end of the catheter is prevented from being an injury to the inner wall of a blood vessel when the catheter advances in the blood vessel.

**EP 0 365 993 A1**

**FIG. 13**



## CATHETER EQUIPPED WITH EXPANSIBLE MEMBER AND METHOD OF MANUFACTURING THE SAME

### BACKGROUND OF THE INVENTION

This invention relates to a catheter equipped with an expansible member for use in curing a stricture portion inside a blood vessel by expanding the stricture portion to improve the blood flow on the peripheral side of the stricture portion, and to a method of manufacturing the same.

Heretofore, as a catheter equipped with an expansible member for expanding a stricture portion inside a blood vessel, so-called Gruentich type disclosed, for example, in U.S. Patent Specification No.4,195,637, or so-called Simpson-Robert type disclosed, for example, in U.S. Patent Specification No.4,323,071 has been used. However, adaptable cases of vasodilatation using such a catheter were hitherto limited to those of localized stricture near coronary artery from an anatomical viewpoint, which were lesions of about 15 to 20 mm length, monobranched lesions, non-calcified lesions, etc. Catheters of the above-mentioned types have been improved in order to extend the range of the adaptable cases. For this purpose, a catheter so-called low-profile shape which has the same structure as those of standard structures of the above-mentioned types but only the tip portion of which is narrowed, was developed. The catheter of this low-profile shape is adaptable to strictures in more peripheral blood vessel or severer strictures (sub-complete clogging).

In addition, the applicant of this application has proposed a catheter comprising an inner tube, an outer tube disposed coaxially with the inner tube, an expansible member attached to the inner and outer tubes, and a rigidity imparting member consisting of braided metal wire and disposed on the inner or outer tube as disclosed in the International Publication No.WO 88/06465.

In a catheter called Gruentich type as described above, an expansible member is attached to the tip portion of a catheter tube having two lumens. One of the lumens is open at the tip thereof to form a passage for a guide wire and for tip pressure measurement. The other of the lumens is in communication with the expansible member at the base end portion of the expansible member to form a passage for fluid such as vasographic contrast liquid injected under pressure for expanding the expansible member. The catheter of this type is made of flexible synthetic resin.

A catheter called Simpson-Robert type has a coaxial double-wall structure comprising an inner tube having a first lumen whose tip is open, and an outer tube which forms a second lumen between it

and the inner tube and to the tip of which an expansible member is attached. An ultrafine metal pipe is disposed in the second lumen for removing bubbles therefrom. The catheter of this type is also made of flexible synthetic resin like the above-mentioned Gruentich type catheter.

As described above, a catheter to be inserted into a blood vessel is generally made of flexible synthetic resin for facilitating the insertion and avoiding an injury to the wall of the blood vessel. However, such a catheter has a possibility of being flexed in a blood vessel upon insertion because of its flexibility. Further, there is a case that a delicate movement of the tip of the catheter is required for making it reach the aimed portion in the blood vessel. For this purpose, the catheter must be moved or rotated at its base end portion in a delicate manner and the force or torque for the movement or rotation must be transmitted from the base end portion to the tip portion of the catheter. In a conventional catheter, however, the transmission of the force or torque is bad because the force or torque is apt to be absorbed owing to the flexibility of the catheter. Therefore, the conventional catheter is disadvantageous in its delicate operability.

The catheter disclosed in the above-mentioned International Publication No.WO 88/06465 solves those problems of the conventional Gruentich or Simpson-Robert type catheter by disposing the rigidity imparting member. In this catheter, the flexion or collapse of the catheter is suppressed and the transmission of the force or torque is improved. However, the flexibility of this catheter is decreased by the rigidity imparted by the rigidity imparting member. The decrease of the flexibility lowers the followability of the catheter to curved portion of blood vessel and the operability of the insertion. Further, even this catheter including the rigidity imparting member of braided metal wire has a possibility of meandering in a blood vessel. In that case, the force applied to the base end portion of the catheter for pushing the catheter into the blood vessel is absorbed at the meandering portion. As the result, the operation of the catheter, particularly for advancing the tip portion of the catheter to a stricture portion inside a blood vessel becomes difficult.

Further, the above-mentioned catheter has a substantially equal outer diameter from the base end portion to the tip portion. In general, the physical properties of the catheter of this type are selected in order to meet the requirements for operating the catheter at its base end or intermediate portion. For this reason, in the above-men-

tioned catheter, the outer diameter at the tip portion is as large as that at the base end portion. As a result, there was a case that the tip portion of the catheter could not be inserted into a severer stricture portion of a blood vessel.

The tip portion of the catheter disclosed in the above-mentioned International Publication No. WO 88/06465 is beveled by grinding or with a solvent in order to avoid an injury to the inner surface of a blood vessel upon insertion into a curved portion of the blood vessel. In general, it is preferable that the expansible member of the catheter is disposed as near to the tip of the catheter as possible. For this purpose, it is preferable that the mounting portion between the expansible member and the inner tube is as short as possible. Contrarily, a length to some extent of the mounting portion is required for reliable adhesion between the expansible member and the inner tube. However, beveling the tip portion of the catheter as described above decreases the length for the mounting portion and results in deteriorating the adhesion between the expansible member and the inner tube. As a result, there is a possibility that the necessary expansion of a blood vessel is not attained because of leak of fluid for expansion such as vasographic contrast liquid out of the expansible member at a peeling portion of the expansible member off the inner tube upon operating the catheter. Further, in the above-mentioned catheter, the tip portion of the expansible member at which the expansible member is attached to the inner tube is exposed outside of the catheter. Therefore, the catheter has a possibility that the tip portion of the expansible member partially peels off the inner tube upon insertion into a blood vessel and is an injury to the inner surface of the blood vessel.

#### SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a catheter equipped with an expansible member in which the flexibility of the catheter, particularly the elastic deformability in the lateral direction with respect to the axial direction of the catheter is not decreased, an extreme flexion or bend of the catheter is prevented, the force applied to the base end portion of the catheter for advancing the tip portion thereof to a stricture portion inside a blood vessel is surely transmitted to the tip portion, and the operability of the catheter is good.

It is another object of the present invention to provide a catheter equipped with an expansible member which has physical properties required for the base end portion of the catheter and the tip

portion of which is so slender as to be easily inserted into a severer stricture portion or in a more peripheral blood vessel.

It is still another object of the present invention to provide a method of manufacturing a catheter equipped with an expansible member including a step of making a tube having different outer diameters.

It is still another object of the present invention to provide a catheter equipped with an expansible member and a method of manufacturing the same in which the expansible member is disposed sufficiently near to the tip of the catheter, a length enough for the mounting portion between the expansible member and the inner tube is insured, and there is no possibility of being an injury to the inner wall of a blood vessel upon insertion of the catheter.

According to an aspect of the present invention, a catheter equipped with an expansible member comprises an inner tube having a base end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; a second opening formed in said base end portion of said outer tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen.

According to another aspect of the present invention, a catheter equipped with an expansible member comprises a catheter main body having a tip end portion and a base end portion and comprising an inner tube having a tip end portion, a base end portion and a first lumen whose tip is open, an outer tube capable of inserting said inner tube therein, having a tip end portion, a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube, and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said

inner tube, said base end portion of said expandable member being attached to said outer tube, said expandable member communicating with said second lumen at a portion near said base end portion of said expandable member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; and a second opening formed in said base end portion of said outer tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter main body including a portion to which said expandable member is attached is smaller than that of said base end portion of said catheter main body.

According to another aspect of the present invention, a catheter equipped with an expandable member comprises a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expandable member having a tip end portion and a base end portion, said tip end portion of said expandable member being attached to said tip end portion of said catheter tube, said base end portion of said expandable member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expandable member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; a second opening formed in said base end portion of said catheter tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens.

According to another aspect of the present invention, a catheter equipped with an expandable member comprises a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expandable member having a tip end portion and a base end portion, said tip end portion of said expandable member being attached to said tip end portion of said catheter tube, said base end portion of said expandable member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expandable member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; and a second opening formed in said base end portion of said catheter tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter tube including at least a

portion to which said expandable member is attached is smaller than that of said base end portion of said catheter tube.

According to another aspect of the present invention, a method of manufacturing a catheter equipped with an expandable member comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expandable member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expandable member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expandable member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube.

According to another aspect of the present invention, a catheter equipped with an expandable member comprises an inner tube having a tip end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; and a foldable expandable member having a tip end portion and a base end portion, said tip end portion of said expandable member being attached to said inner tube, said base end portion of said expandable member being attached to said outer tube, said expandable member communicating with said second lumen at a portion near said base end portion of said expandable member, said tip end portion of said expandable member attached to said inner tube protruding beyond said inner tube toward the tip of said catheter to form a tip end portion of said catheter.

According to another aspect of the present invention, a method of manufacturing a catheter equipped with an expandable member comprises a

step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length shorter than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of said catheter by using said tip end portion of said expansible member with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features, and advantages of the present invention will be better understood from the following description taken in conjunction with the accompanying drawings, in which:

Fig.1 is an enlarged cross sectional view of the tip end portion of an embodiment of a catheter equipped with an expansible member according to the present invention;

Fig.2 is a view of the base end portion of the catheter of Fig.1;

Fig.3 is a cross sectional view of the intermediate portion of the catheter of Fig.1;

Fig.4 is a cross sectional view taken along line I-I of Fig.1;

Fig.5 is a cross sectional view taken along line II-II of Fig.1;

Fig.6 is a cross sectional view of one example of the base end portion of the catheter of the present invention;

Fig.7 is a side elevational view of one example of a rigidity imparting member used in the catheter of the present invention;

Fig.8 is an enlarged cross sectional view taken along line X-X of Fig.7;

Fig.9 is an enlarged cross sectional view taken along line XI-XI of Fig.7;

Figs.10, 11 and 12 are side elevational views of other examples of rigidity imparting members used in catheters of the present invention;

Fig.13 is a cross sectional view of another embodiment of a catheter equipped with an expansible member according to the present invention;

Fig.14 is an enlarged cross sectional view of the tip end portion of another embodiment of a catheter equipped with an expansible member according to the present invention;

Fig.15 is a cross sectional view taken along line III-III of Fig.14;

Fig.16 is a cross sectional view taken along line IV-IV of Fig.14;

Fig.17 is a cross sectional view of the base end portion of the catheter of Fig.14;

Figs.18 through 21 are views for illustrating a step of forming the rear outer tube of the catheter of Fig.3;

Figs.22 through 25 are views for illustrating a step of forming the front outer tube of the catheter of Fig.3;

Figs.26 through 30 are views for illustrating a step of connecting the rear outer tube to the front outer tube of the catheter of Fig.3;

Figs.31 through 34 are views for illustrating a step of forming the expansible member of the catheter of Fig.1;

Fig.35 is a view for illustrating a step of attaching the expansible member to the outer tube of the catheter of Fig.1;

Fig.36 is a view for illustrating a step of attaching the expansible member to the inner tube of the catheter of Fig.1;

Figs.37 through 43 are views for illustrating another process for manufacturing a catheter equipped with an expansible member according to the present invention; and

Figs.44 through 48 are views for illustrating the operation of the catheter of Fig.1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention will be described as to preferred embodiments shown in the attached drawings.

A catheter equipped with an expansible member according to the embodiments comprises an inner tube 1 having a base end portion and a first lumen 4 whose tip is open, an outer tube 2 capable of inserting the inner tube 1 therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of the inner tube 1, and forming a second lumen 6 between it and the outer surface of the inner tube

1, a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the inner tube 1, the base end portion 8 of the expansible member 3 being attached to the outer tube 2, the expansible member 3 communicating with the second lumen 6 at a portion near the base end portion 8 of the expansible member 3, a first opening 9 formed in the base end portion of the inner tube 1 to communicate with the first lumen 4, a second opening 11 formed in the base end portion of the outer tube 2 to communicate with the second lumen 6, and a rigidity imparting member 13 consisting of a linear member extending in the axial direction disposed in the second lumen 6.

Further, a catheter equipped with an expansible member according to the embodiments comprises a catheter main body having a tip end portion and a base end portion and comprising an inner tube 1 having a tip end portion, a base end portion and a first lumen 4 whose tip is open, an outer tube 2 capable of inserting the inner tube 1 therein, having a tip end portion, a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of the inner tube 1, and forming a second lumen 6 between it and the outer surface of the inner tube 1, and a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the inner tube 1, the base end portion 8 of the expansible member 3 being attached to the outer tube 2, the expansible member 3 communicating with the second lumen 6 at a portion near the base end portion 8 of the expansible member 3, a first opening 9 formed in the base end portion of the inner tube 1 to communicate with the first lumen 4, and a second opening 11 formed in the base end portion of the outer tube 2 to communicate with the second lumen 6, the outer diameter of the tip end portion of the catheter main body including a portion to which the expansible member 3 is attached is smaller than that of the base end portion of the catheter main body.

Hereinafter, detailed description will be made with the drawings.

A catheter equipped with an expansible member according to one embodiment of the present invention comprises a catheter main body including an inner tube 1, an outer tube 2 and an expansible member 3, and a branched hub 20.

The inner tube 1 has a first lumen 4 whose tip is open. The first lumen 4 is a lumen for inserting a guide wire therein and in communication with a first opening 9 which forms a guide wire port disposed in the branched hub 20. It is preferable that the outer diameter of the tip end portion of the inner

tube 1 is smaller than that of the base end portion thereof. In this embodiment, as shown in Fig.3, the inner tube 1 consists of a front inner tube 1a and a rear inner tube 1b. The outer tube 2 described later also consists of a front outer tube 2a and a rear outer tube 2b. The outer diameters of the front inner and outer tubes 1a and 2a are smaller than those of the rear inner and outer tubes 1b and 2b, respectively. Therefore, the catheter of this embodiment can be inserted into more peripheral blood vessel than conventional one. It is preferable that the tip end portion of the catheter having the small outer diameter is as long as the distance from the inlet of a coronary artery to an aimed lesion part, particularly, a little longer than the distance from the inlet of the coronary artery to the aimed lesion part. Specifically, the length of the tip end portion is preferably about 50 to 700 mm, more preferably 80 to 400 mm, more preferably 100 to 300 mm. In addition, it is preferable that each of the inner and outer tubes is provided with a tapering portion at the connecting portion between the tip end portion 1a or 2a and the base end portion 1b or 2b to make the change of its inner and outer diameters smooth.

The front inner tube 1a of the inner tube 1 has preferably the outer diameter of 0.30 to 2.00 mm, more preferably 0.40 to 1.80 mm, and the inner diameter of 0.20 to 1.80 mm, more preferably 0.25 to 1.60 mm. The rear inner tube 1b has preferably the outer diameter of 0.40 to 2.50 mm, more preferably 0.55 to 2.40 mm, and the inner diameter of 0.25 to 2.35 mm, more preferably 0.30 to 1.80 mm.

As the inner tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear inner tubes 1a and 1b. Also in that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes.

The material for forming the inner tube 1 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetate copolymer, polyvinyl chloride, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

The outer tube 2 into which the inner tube 1 is inserted has a tip slightly recessed by a predetermined distance from the tip of the inner tube 1. As shown in Fig.4 which is a cross section taken along line I-I in Fig.1, a second lumen 6 is formed by the

inner surface of the outer tube 2 and the outer surface of the inner tube 1. Thus, the second lumen 6 has a sufficient volume. The tip portion of the second lumen 6 is in communication with the rear end portion of the inside of the expansible member 3 described later. The rear end portion of the second lumen 6 is in communication with a second opening 11 provided to the branched hub 20 to form an injection port for injecting fluid for expanding the expansible member (for example, vasographic contrast liquid). As shown in Fig. 3, the outer tube 2 consists of a front outer tube 2a and a rear outer tube 2b. The outer diameter of the front outer tube 2a is smaller than that of the rear outer tube 2b so as to facilitate insertion of the tip end portion of the catheter into more peripheral blood vessel. The front outer tube 2a of the outer tube 2 has preferably the outer diameter of 0.50 to 4.00 mm, more preferably 0.60 to 3.70 mm, and the inner diameter of 0.40 to 3.50 mm, more preferably 0.50 to 2.70 mm. The rear outer tube 2b has preferably the outer diameter of 0.75 to 4.30 mm, more preferably 1.00 to 4.00 mm, and the inner diameter of 0.70 to 3.80 mm, more preferably 0.80 to 3.00 mm. Also as the outer tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear outer tubes 2a and 2b. In that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes.

The material for forming the outer tube 2 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetate copolymer, polyvinyl chloride, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

As shown in Figs.1 and 3 through 6, a rigidity imparting member 13 is provided in the second lumen 6 formed by the inner surface of the outer tube 2 and the outer surface of the inner tube 1. The rigidity imparting member 13 extends from the base end portion to the tip end portion of the catheter. The rigidity imparting member 13 is for preventing an extreme flexion and meandering of the catheter main body in a blood vessel without considerable decrease of the flexibility of the catheter and for facilitating insertion of the tip end portion of the catheter into a stricture portion inside a blood vessel.

As shown in Figs.1 and 3, the rigidity imparting

member 13 consists of a linear member. The linear member preferably consists of metal wire, for example, made of elastic metal such as stainless steel, super elastic alloy, etc. desirably of the wire diameter of 0.05 to 1.50 mm, more desirably of 0.10 to 1.00 mm. Particularly, it is preferably made of high tensile spring stainless steel, Cu or Ni-Ti alloy. The tip and base end portions of the rigidity imparting member 13 may not be fixed. However, it is preferable that the tip end portion of the rigidity imparting member 13 is fixed because the tip end portion of the rigidity imparting member 13 is prevented from being an injury to the expansible member 3 and the force applied to the base end portion of the catheter for advancing the tip end portion of the catheter is surely transmitted to the tip end portion of the catheter. In the embodiment shown in Fig.1, the tip end portion of the rigidity imparting member 13 is slendrer than the other portion thereof by, for example, grinding. The slendrer portion of the rigidity imparting member 13 is located between the tip end portion 7 of the expansible member 3 and the inner tube 1, and fixed to the tip end portion of the inner tube 1 together with the expansible member 3. The slendrer portion of the rigidity imparting member 13 prevents a step-like change of the outer surface of the expansible member 3 in its mounting portion. The average diameter of the slendrer portion is preferably about 1/5 to 1/10 of the diameter of its neighboring portion. It is preferable that the rigidity of the major body portion of the rigidity imparting member 13 is higher than that of the tip end portion thereof. This purpose can be attained by, for example, using a rigidity imparting member in which the cross section of its major body portion is larger than that of its tip end portion. Otherwise, to obtain a rigidity imparting member in which its tip end portion is relatively flexible and its major body portion has a high rigidity, a rigidity imparting member may be used in which a metal wire for the rigidity imparting member has been annealed with a temperature gradient that the temperature for the tip end portion is high and the temperature for the major body portion is low after cold working.

As the rigidity imparting member 13, a strand wire consisting of several fine metal wires braided may be used as shown in Fig.12. In that case, for making the tip end portion 13a of the rigidity imparting member 13 flexible and the major body portion 13b have a high rigidity, it is preferable that the diameter of the tip end portion 13a is smaller than that of the major body portion 13b. For this purpose, metal wires to be braided the diameter of the tip end portion of each of which is smaller than that of the major body portion may be used, or the number of metal wires braided may be decreased toward the tip end portion.

It is preferable that the portion except the tip and base end portions of the rigidity imparting member 13 is not fixed. By not fixing the intermediate portion of the rigidity imparting member 13, when the tip end portion of the catheter is bent, the rigidity imparting member 13 does not hamper the flexibility of the tip end portion of the catheter because the rigidity imparting member 13 can slip within the second lumen.

Such a rigidity imparting member 13 prevents the catheter main body from meandering in a blood vessel. Therefore, because the force applied to the base end portion of the catheter main body is not absorbed at the meandering portion, the force can be surely transmitted to the tip end portion of the catheter. As a result, the operability of the catheter, particularly the operation of advancing the tip end portion of the catheter to which the expansible member is attached, to a stricture portion inside a blood vessel becomes easy. In addition, insertion of the tip end portion of the catheter into a severer stricture portion (sub-complete clogging) becomes possible.

The rigidity imparting member 13 is not limited to that of the embodiment shown in Fig.1. For example, a rigidity imparting member 13 shown in Fig.7 is also usable adequately. In the rigidity imparting member 13 shown in Fig.7, the tip end portion is slenderer than the other portion of the rigidity imparting member 13 like that shown in Fig.1. In this example, however, the slenderer portion 13a is an oblate slenderer portion 13a having an elliptic cross section as shown in Fig.8 which is a cross sectional view taken along line X-X of Fig.7. By forming the tip end portion of the rigidity imparting member 13 into the oblate slenderer portion 13a, mounting it between the inner tube 1 and the tip end portion of the expansible member 3 becomes easy. The major body portion 13b of the rigidity imparting member 13 has a substantially circular cross section as shown in Fig.9 which is a cross sectional view taken along line XI-XI of Fig.7. Further, the rigidity imparting member 13 may be a coil spring type the whole of which consists of a fine metal wire as shown in Fig.10. In addition, as shown in Fig.11, a rigidity imparting member 13 may be used only the tip end portion of which consists of a fine metal wire into a coil spring and the major body portion of which consists of a linear metal wire.

The tip end portion of the rigidity imparting member 13 may not be fixed between the inner tube 1 and the tip end portion of the expansible member 3 as described above. For example, as shown in Fig.13, the tip end portion 13a of the rigidity imparting member 13 may be fixed by winding it around the outer surface of the inner tube 1. In that case, it is preferable that the tip end

portion 13a of the rigidity imparting member 13 is fixed by winding it around a portion near the portion of the inner tube 1 corresponding to the portion of the outer tube 2 the diameter of which is decreased, and the tip end portion 13a of the rigidity imparting member 13 is wound to the portion of the inner tube 1 corresponding to the base end portion of the expansible member 3. By winding the tip end portion 13a of the rigidity imparting member 13 around the outer surface of the portion of the inner tube 1 the outer diameter of which is decreased, an flexion of the slenderer portion of the inner tube 1 is prevented so that an flexion of the slenderer portion of the outer tube 2 is prevented. In order to make the tip side portion of the slenderer portion of the inner tube 1 flexible, as shown in Fig.13, it is preferable to wind the tip end portion 13a of the rigidity imparting member 13 around the outer surface of the inner tube 1 such that it becomes close gradually from the tip end side to the base end side of the inner tube 1.

The expansible member 3 is foldable and it is folded on the outer circumference of the inner tube 1 in its non-expanded state. The expansible member 3 has a substantially cylindrical portion 3a having an approximately uniform diameter at least a part of which is substantially cylindrical for enabling to expand a stricture portion in a blood vessel. The substantially cylindrical portion 3a described above may not be completely cylindrical but may be polygonal. The base end portion 8 of the expansible member 3 is secured in a liquid-tight manner to the tip end portion of the outer tube 2 by adhesion, fusion or the like. The tip end portion 7 of the expansible member 3 is also secured in a liquid-tight manner to the tip end portion of the inner tube 1. As shown in Fig.5 which is a cross sectional view taken along line II-II of Fig.1, the expansible member 3 forms an expanded space 15 between the inner surface of the expansible member 3 and the outer surface of the inner tube 1. The expanded space 15 is in communication over the entire circumference at its rear end portion with the second lumen 6. Thus, the rear end of the expansible member 3 is in communication with the second lumen 6 having a relatively large volume. Therefore, it is easy to inject expansion fluid through the second lumen 6 into the expansible member 3. The material for forming the expansible member 3 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetate copolymer, polyvinyl chloride, cross-linked ethylene-vinyl acetate copolymer, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the



above-mentioned cross-linked ethylene-vinyl acetate copolymer is more preferable. It is preferable that the forward and backward portions of the cylindrical portion 3a of the expansible member 3 are tapered. As the size of the expansible member 3, the cylindrical portion upon expanded has the outer diameter of 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm and the length of 3.00 to 80.00 mm, preferably 10.00 to 75.00 mm. The entire length of the expansible member 3 is 5.00 to 120.00 mm, preferably 15.00 to 100.00 mm.

It is preferable that a marker 14 is provided on the outer surface of the inner tube 1. As shown in Fig.1, the marker 14 is disposed from a portion near the portion on the rear side of the mounting portion between the expansible member 3 and the inner tube 1 to a portion near the portion on the tip end side of the mounting portion between the expansible member 3 and the outer tube 2. That is, the marker 14 has a length as long as that of the cylindrical portion 3a of the expansible member 3. The marker 14 is made of X-ray impermeable material (for example, gold, platinum, tungsten or alloy of them, or silver-palladium alloy). The marker 14 preferably consists of a coil spring. In that case, it is more preferable that the coil spring is wound closely in ranges of 1 to 4 mm, more preferably 2 to 3 mm from both ends of marker 14. This is for enabling to confirm easily the position of the expansible member 3 under X-ray perspection. Further, by forming the marker 14 into a spring shape, it functions as a reinforcement for preventing the inner tube within the expansible member from flexing or collapsing at its bend portion. Particularly, when the marker 14 consists of a spring coil wound around the inner tube 1 closely, the resistance against an external force becomes higher. Further, when the cross section of the coiled wire is circular, rectangular or elliptic, the resistance against an external force becomes much higher.

As shown in Fig.2, the branched hub 20 comprises an inner tube hub 22 secured to the inner tube 1 and having a first opening 9 which is in communication with the first lumen 4 to form a guide wire port, and an outer tube hub 23 secured to the outer tube 2 and having a second opening 11 which is in communication with the second lumen 6 to form an injection port. The inner and outer tube hubs 22 and 23 are connected to each other. For the material for forming the branched hub, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer. A cross section of an embodiment of the branched hub 20 is shown in Fig.6. In this embodiment, a flection-preventing tube 50 is disposed on one end portion of the outer tube 2. The flection-preventing tube 50 is made of shrinkable

material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 can be easily attached by the manner that the shrinkable tube 50 is put on one end portion of the outer tube 2 and then shrunked by heating, for example, with blowing hot air. The outer tube 2 to which the flection-preventing tube 50 has been attached is fixed to the outer tube hub 23 with a lock member 52, which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For fixing the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube 2 may be bonded to the outer tube hub 23 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

A flection-preventing tube 60 is disposed on one end portion of the inner tube 1. The tube 60 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 can be easily attached by the manner that the shrinkable tube 60 is put on one end portion of the inner tube 1 and then shrunked by heating, for example, with blowing hot air. The base end portion of the rigidity imparting member 13 is secured to the outer surface of the inner tube 1 with the flection-preventing tube 60. The base end portion of the rigidity imparting member 13 may not be secured. The inner tube 1 to which the flection-preventing tube 60 has been attached is fixed to the inner tube hub 22 with a lock member 62, which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For fixing the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube 1 may be bonded to the inner tube hub 22 with an adhesive applied to the outer surface of the flection-preventing tube 60. For the material for forming the inner tube hub 22, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate

and methacrylate-butylene-styrene copolymer. As shown in Fig.6, the inner and outer tube hubs 22 and 23 are connected to each other by the manner that the inner tube hub 22 is inserted from its tip end in the rear end portion of the outer tube hub 23 attached to the base end portion of the outer tube 2. In this case, an adhesive may be previously applied to the connecting portion between the inner and outer tube hubs 22 and 23 to make a reliable adhesion between them. Instead of the branched hub 20, for example, tubes each of which comprises a port member having an opening on its rear end may be connected in liquid-tight manner to the first and second lumens, respectively.

Next, an embodiment of a catheter equipped with an expansible member shown in Figs.14 through 17 will be described.

A catheter equipped with an expansible member according to this embodiment comprises a catheter tube 10 having a tip end portion, a base end portion, a first lumen 4 the tip of which is open, a second lumen 6 open at a position recessed by a predetermined distance from the tip of the first lumen 4; a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the tip end portion of the catheter tube 10, the base end portion 8 of the expansible member 3 being attached to a portion near an opening portion 12 formed near the tip of the catheter tube 10, the expansible member 3 communicating with the second lumen 6; a first opening formed in the base end portion of the catheter tube 10 to communicate with the first lumen 4; a second opening 11 formed in the base end portion of the catheter tube 10 to communicate with the second lumen 6; and a rigidity imparting member 13 consisting of a linear member extending in the axial direction disposed in at least one of the first and second lumens.

Further, a catheter equipped with an expansible member according to this embodiment comprises a catheter tube 10 having a tip end portion, a base end portion, a first lumen 4 at least the tip of which is open, a second lumen 6 open at a position recessed by a predetermined distance from the tip of the first lumen 4; a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the tip end portion of the catheter tube 10, the base end portion of the expansible member 3 being attached to a portion near an opening portion 12 formed near the tip of the catheter tube 10, the expansible member 3 communicating with the second lumen 6; a first opening 9 formed in the base end portion of the catheter tube 10 to communicate with the first lumen 4; and a second opening 11 formed in the base end

portion of the catheter tube 10 to communicate with the second lumen 6, the outer diameter of the tip end portion of the catheter tube 10 including at least a portion to which the expansible member 3 is attached is smaller than that of the base end portion of the catheter tube 10.

A catheter equipped with an expansible member according to this embodiment comprises a catheter main body including a catheter tube 10 and an expansible member 3, and a branched hub 20.

The catheter tube 10 has a first lumen 4 whose tip is open and a second lumen 6 which is in communication with the inside of the expansible member 3 through an opening portion 12 at a position somewhat recessed from the tip to the base end side. As shown in Fig.16 which is a cross sectional view taken along line IV-IV of Fig.14, the first and second lumens 4 and 6 are formed within the catheter tube 10. The first lumen 4 is a lumen for inserting a guide wire therein and in communication with a first opening 9 which forms a guide wire port disposed in the branched hub 20. The tip portion of the second lumen 6 is in communication with the rear end portion of the inside of the expansible member 3. As shown in Fig.17, the rear end portion of the second lumen 6 is in communication with a second opening 11 provided to the branched hub 20 to form an injection port for injecting fluid for expanding the expansible member (for example, vasographic contrast liquid). It is preferable that the outer diameter of the tip end portion of the catheter tube 10 is smaller than that of the base end portion thereof. It is more preferable that a tapering portion is formed between the tip and base end portions of the catheter tube 10 to make the change of its inner and outer diameters smooth. The tip end portion of the catheter tube 10 has preferably the outer diameter of 0.5 to 4.0 mm, more preferably 0.6 to 3.7 mm. The inner diameter of the first lumen is preferably 0.2 to 2.25 mm, more preferably 0.25 to 1.6 mm. The inner diameter of the second lumen is preferably 0.1 to 1.45 mm, more preferably 0.3 to 1.3 mm. The base end portion of the catheter tube 10 has preferably the outer diameter of 0.75 to 4.3 mm, more preferably 1.0 to 4.0 mm. The inner diameter of the first lumen is preferably 0.1 to 2.35 mm, more preferably 0.3 to 1.8 mm. The inner diameter of the second lumen is preferably 0.1 to 1.7 mm, more preferably 0.3 to 1.6 mm. The catheter tube 10 is formed by, for example, extrusion molding. The material for forming the catheter tube 10 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetate copolymer, polyvinyl chloride and polyurethane; or polyamide

elastomer, silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

As shown in Figs.14 through 17, a rigidity imparting member 13 is provided in the second lumen 6. The rigidity imparting member 13 is for preventing an extreme flexion or meandering of the catheter main body in a blood vessel without considerable decrease of the flexibility of the catheter and for facilitating insertion of the tip end portion of the catheter into a stricture portion inside a blood vessel. Although the rigidity imparting member 13 is preferably disposed in the second lumen 6, it may be disposed in the first lumen 4. In any case, the rigidity imparting member 13 described before can be suitably used.

The tip end portion 7 of the expansible member 3 is secured to the catheter tube 10 on the front side of the opening 12 while the base end portion 8 thereof is secured to the catheter tube 10 on the base end side of the opening 12. The opening 12 extends in the axial direction of the catheter tube 10 by a predetermined length. Also in this embodiment, the expansible member 3 described before can be suitably used. As shown in Fig.15 which is a cross sectional view taken along line III-III of Fig.14, the expansible member 3 forms an expanded space 15 between the inner surface of the expansible member 3 and the outer surface of the inner tube 1. The tip end portion of the second lumen 6 of the catheter tube 10 is filled with a filler 16 to be closed. The tip end portion of the rigidity imparting member 13 is located in the filler 16 and fixed. Both the tip and base end portions of the rigidity imparting member 13 may not be fixed. However, it is preferable to fix the tip end portion of the rigidity imparting member 13 because the tip end portion of the rigidity imparting member 13 is prevented from being an injury to the expansible member 3 and the transmission of the force, which is applied to the base end portion of the catheter for advancing the catheter, to the tip end portion is improved.

The branched hub 20 as shown in Fig.17 is attached to the rear end portion of the catheter tube 10. The rear end portion of the rigidity imparting member 13 disposed in the second lumen 6 of the branched hub 20 is fixed with a filler 17. The rear end portion of the rigidity imparting member 13 may not be fixed. For the material for forming the branched hub, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

Next, a method of manufacturing a catheter equipped with an expansible member of the present invention will be described with reference

to the drawings.

A method of manufacturing a catheter equipped with an expansible member according to this embodiment comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube.

Each step will be described with the catheter shown in Fig.1.

First, the step of forming an inner tube 1 having a lumen 4 extending from the tip end to the base end of the inner tube 1 can be taken place by a method of cutting a tube member made of thermoplastic resin for the inner tube 1 by extrusion molding into a predetermined length or by an injection molding method.

The step of forming an outer tube 2 comprises a step of forming a front outer tube 2a having a lumen extending from the tip end to the base end of the tube 2a; a step of forming a rear outer tube 2b having the outer diameter larger than that of the front outer tube 2a and a lumen extending from the tip end to the base end of the tube 2b; a step of tapering one end of the rear outer tube 2b; a step of enlarging the diameter of one end portion of the front outer tube 2a; and a step of connecting the tapering end of the rear outer tube 2b to the enlarged end of the front outer tube 2a.

Each of the front and rear outer tubes 2a and 2b can be formed by a method of cutting a tube member made of thermoplastic resin for the outer tube 2 by extrusion molding into a predetermined length or by an injection molding method. In the step of tapering the tip end portion of the rear outer

tube 2b, as shown in Fig.18, a tapering core 90 is inserted in the rear outer tube 2b. The tapering core 90 is used for preventing a formation of a step or the like between the front and rear outer tubes 2a and 2b upon fitting the tapering portion 92 of the rear outer tube 2b to a cone-shaped enlarged portion 94 of the front outer tube 2a as described later, and making the diameter change smooth. The tapering core 90 may be made of glass or metal. As shown in Fig.18, the tapering core 90 is inserted till one end of the rear outer tube 2b reaches a position near a tapering portion of the tapering core 90.

For tapering the tip end portion of the rear outer tube 2b, a tapering mold 91 as shown in Fig.19 is used. The tapering mold 91 may be made of glass or metal. It is preferable that the tapering mold 91 has a tapering inner surface corresponding to the tapering portion of the tapering core 90 for making the diameter change of the rear outer tube 2b smooth.

As shown in Fig.20, the tapering mold 91 is made to press the tip end portion of the rear outer tube 2b and heated by a heater such as a heat gun and a hot air torch (not shown) to taper the tip end portion of the rear outer tube 2b. Fig.21 shows the tip end portion of the rear outer tube 2b after removing the tapering mold 91, wherein the tip end portion of the rear outer tube 2b has a tapering portion 92.

Next, the step of enlarging the rear end portion of the front outer tube 2a into a cone shape will be described.

In this step, as shown in Fig.22, a slender portion 93a of an enlarging pin 93 is inserted in one end of the front outer tube 2a. As shown in Fig.22, the enlarging pin 93 comprising the slender portion 93a, a tapering portion and a thick portion 93b. The diameter of the slender portion 93a is as large as or a little smaller than the inner diameter of the front outer tube 2a. The diameter of the thick portion 93b is as large as or a little larger than the outer diameter of the rear outer tube 2b. The enlarging pin 93 is inserted from the slender portion 93a in one end of the front outer tube 2a gradually, and, as shown in Fig.23, the one end portion of the front outer tube 2a and the tapering portion of the enlarging pin 93 is heated by a heater such as a heat gun and a hot air torch (not shown) to enlarge the diameter of the one end portion of the front outer tube 2a. Particularly, in the case of the front outer tube 2a having a large thickness, it is preferable that the enlarging pin 93 is pushed in with heating otherwise the front outer tube 2a may be split along the axial direction.

The above operation is continued till the thick portion 93b of the enlarging pin 93 is inserted in the one end portion of the front outer tube 2a. The

length of the one end portion of the front outer tube 2a overlapped by the thick portion 93b of the enlarging pin 93 is preferably as long as or a little smaller than the length of the tapering portion 92 formed in the rear outer tube 2b. This makes possible to prevent a formation of a step on the connecting portion between the cone-shaped enlarging portion 94 of the front outer tube 2a and the tapering portion 92 of the rear outer tube 2b, and make it smooth, as described later. As shown in Fig.25, the front outer tube 2a having the enlarged end portion is obtained by removing the enlarging pin 93.

Next, the step of connecting the tapering portion 92 of the rear outer tube 2b to the enlarged portion 94 of the front outer tube 2a will be described. Fig.26 illustrates this step.

First, the tapering portion 92 of the rear outer tube 2b shown in Fig.21 is inserted together with the tapering core 90 in the enlarged portion 94 of the front outer tube 2a. The outer diameter of the portion of the tapering core 90 inserted in the front outer tube 2a, that is, the outer diameter of the portion of the front side of the tapering portion of the tapering core 90 is as large as or a little smaller than the inner diameter of the front outer tube 2a. This is for obtaining a smooth finish from the front outer tube 2a to the connecting portion, further to the rear outer tube 2b. The leading portion of the tapering portion 92 of the rear outer tube 2b is preferably inserted into the leading portion of the cone-shaped enlarged portion 94 of the front outer tube 2a. It is preferable that the tip end portion of the leading portion of the cone-shaped enlarged portion 94 of the front outer tube 2a is as large as or a little smaller than the length of the tapering portion 92 of the rear outer tube 2b because a smooth finish of the outer tube is obtained and a formation of a step is prevented.

Next, a method for connecting the tapering portion 92 of the rear outer tube 2b to the enlarged portion 94 of the front outer tube 2a will be described.

As an embodiment of this step, a method using a mold for connecting as shown in Fig. 27 will be described.

A first connecting mold 95 has a pipe-shape profile. The first connecting mold 95 has an opening at one end wider than an opening at the other end as shown in Fig.27. The inner diameter of the first connecting mold 95 gradually decreases in a cone shape from the one end to an intermediate portion of the first connecting mold 95. An equal inner diameter portion 96 is formed from the intermediate portion to the other end of the first connecting mold 95. The cone-shaped portion of the first connecting mold 95 is for making possible to press gradually the cone-shaped enlarged portion

94 of the front outer tube 2a onto the tapering portion 92 of the rear outer tube 2b. The connecting portion of the front and rear outer tube 2a and 2b, which projects from the outer surface of the rear outer tube 2b because the thickness of the connecting portion becomes larger than the thickness of the rear outer tube 2b, can be easily inserted into the equal inner diameter portion 96 of the first connecting mold 95 because of the cone-shaped tapering portion of the first connecting mold 95. The first connecting mold 95 is for bonding the front and rear outer tube 2a and 2b at the connecting portion with heating. The first connecting mold 95 is preferably made of material capable of being heated from the external, for example, made of glass or metal. The inner diameter of the equal inner diameter portion 96 of the first connecting mold 95 is as large as or a little larger than the outer diameter of the rear outer tube 2b. This is for pressing the projecting portion of the connecting portion of the front and rear outer tube 2a and 2b. As shown in Fig.28, the equal inner diameter portion 96 of the first connecting mold 95 is put on the connecting portion of the front and rear outer tube 2a and 2b so that the cone-shaped enlarged portion 94 of the front outer tube 2a is welded to the tapering portion 92 of the rear outer tube 2b by being heated by a heater. Because the outer tube 2 is formed by inserting the tip end portion of the rear outer tube 2b in the rear end portion of the front outer tube 2a and bonding the former to the latter as described above, the connecting portion between the front and rear outer tubes 2a and 2b is hard to come off upon insertion of the catheter.

In the step described above, if a step is formed on the connecting portion of the front and rear outer tubes 2a and 2b, it is preferable to remove the step. For this purpose, a second connecting mold 97 as shown in Fig.29 is preferably used for surface treatment of the connecting portion in the similar manner to that of the first connecting mold 95.

The second connecting mold 97 has a similar shape to that of the first connecting mold 95 but the inner diameter of the second connecting mold 97 is a little smaller than that of the equal inner diameter portion 96 of the first connecting mold 95. This is for pressing strongly the connecting portion of the front and rear outer tubes 2a and 2b to bond them strongly to each other by welding with heat. The outer tube 2 consisting of a tube having different outer diameters as shown in Fig.30 is obtained by removing the connecting mold and the tapering core 90.

In the embodiment shown in Fig.1, the inner tube 1 also consists of a tube having different outer diameters. This inner tube 1 is preferably formed by the similar manner to that for the outer tube 2

described above. The order of the steps of forming the inner and outer tubes is optional. They may be taken place at a time.

Next, the step of forming a contractible or foldable expansible member having a tip end portion and a base end portion will be described.

The expansible member 3 preferably has a certain extent of flexibility. For this purpose, the expansible member 3 is preferably made of thermoplastic resin, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetate copolymer and cross-linked ethylene-vinyl acetate copolymer; polyvinyl chloride and polyurethane. Particularly, it is preferable that the expansible member 3 is made of cross-linked ethylene-vinyl acetate copolymer. The expansible member 3 can be formed, for example, by the manner shown in Figs. 31 through 34.

First, as shown in Fig.31, a thermoplastic tube 130 for forming the expansible member 3 is formed. A tube holder 140 is attached to one end portion 132 of the tube 130. The lumen of the tube 130 is closed at a portion shown by arrows A near the tube holder 140. The closure is made by, for example, welding with heat, sealing with high frequency, or using a forceps. The tube 130 closed at the portion shown by arrows A is stretched by applying a load to the tube holder 140 to remove slacks from the tube 30. Fig.31 shows the tube 130 from which slacks have been removed. As shown in Fig.32, a portion of the tube 130 which is to form the expansible member 3 is heated to a temperature near the melting point of the material of the tube 130 by a heater (not shown). While keeping the tube 130 heated, as shown in Fig.33, a mold 142 which has an internal shape corresponding to a shape of the expanded expansible member 3 is put on the tube 130 and the heated portion of the tube 130 is pressed onto the inner surface of the mold 142 by introducing gas under pressure from the direction shown by an arrow C. The tube 130 is kept pressurized till the tube 130 comes back to the room temperature. The mold 142 is removed after the portion of the tube 130 which is to form the expansible member 3 is constricted by making the inside of the tube 130 at a negative pressure. The tube 130 is cut at the tip and rear end portions 134 and 136 to obtain the expansible member 3 as shown in Fig.34.

When at least the tip and base end portions of the expansible member 3 are shrinkable, the expansible member 3 can be easily attached to the inner and outer tubes 1 and 2 by shrinking. For making the tip and base end portions of the expansible member 3 shrinkable, the expansible member 3 may be made of cross-linked thermoplastic resin. Otherwise, in the step of forming the expansible

member 3 described above, the portion of the tube 130 which is to form the expansible member 3 may be heated to such a temperature that strains will remain after cooling. By this manner, the whole of the expansible member 3 can be made shrinkable. Further, for making the tip and base end portions of the expansible member 3 shrinkable, after the expansible member is formed such that the inner diameters of the tip and base end portions of the expansible member are a little smaller than outer diameters of the inner and outer tubes 1 and 2, respectively, the both end portions of the expansible member may be enlarged (by drawing). The order of the steps of forming the expansible member and the inner and outer tubes described before is optional.

Next, a step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 will be described. It is preferable to form the opening 11 by attaching the outer tube hub 23 having an opening to the base end portion of the outer tube 2. This case will be described with reference to Fig.6.

First, the flection-preventing tube 50 is attached to one end portion of the outer tube 2. The flection-preventing tube 50 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 is attached by the manner that the shrinkable tube 50 is put on the one end portion of the outer tube 2 and then shrunked by heating, for example, with blowing hot air. The outer tube hub 23 is attached to the outer tube 2 to which the flection-preventing tube 50 has been attached. This attachment of the outer tube hub 23 is taken place by using a lock member 52 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For attaching the outer tube hub 23 to the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube hub 23 may be bonded to the outer tube 2 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

The step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 may

be taken place at any time after forming the outer tube 2. This step is preferably taken place after the step of attaching the base end portion of the expansible member 3 to the tip end portion of the outer tube 2 described later. The order of this step and the step of forming the inner tube 1 is optional.

Next, a step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 will be described. It is preferable to form the opening 9 by attaching the inner tube hub 22 having an opening to the base end portion of the inner tube 1. This case will be described with reference to Fig.6.

First, the flection-preventing tube 60 is attached to one end portion of the inner tube 1. The flection-preventing tube 60 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 is attached by the manner that the shrinkable tube 60 is put on the one end portion of the inner tube 1 and then shrunked by heating, for example, with blowing hot air. In the embodiment shown in Fig.6, the rigidity imparting member 13 is disposed between the inner and outer tubes 1 and 2. One end portion of the rigidity imparting member 13 is fixed between the flection-preventing tube 60 and the inner tube 1. As shown in Fig.6, the one end portion of the rigidity imparting member 13 can be fixed at the same time that the tube 60 is attached to the inner tube 1 by taking place the heat treatment described above after the one end portion of the rigidity imparting member 13 is located between the tube 60 and the inner tube 1.

The inner tube hub 22 is attached to the inner tube 1 to which the flection-preventing tube 60 has been attached. This attachment of the inner tube hub 22 is taken place by using a lock member 62 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For attaching the inner tube hub 22 to the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube hub 22 may be bonded to the inner tube 1 with an adhesive applied to the outer surface of the flection-preventing tube 60. For the material for forming the inner tube hub, the same material as that of the outer tube hub can be suitably used. The step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 may be taken place at

any time after forming the inner tube 1. The order of this step and the steps of forming the outer tube 2, forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2, and forming the expansible member 3 is optional.

Next, the step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 will be described. As shown in Fig.35, for attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, a core mold 70 the outer diameter of which is as large as or a little smaller than the inner diameter of the outer tube 2 is inserted in the outer tube 2 from the tip or base end of the outer tube 2. Then, the expansible member 3 is put on the outer tube 2 from the tip end side of the core mold 70 such that the tip end of the base end portion 8 of the expansible member 3 corresponds to the tip end of the outer tube 2. A glass mold 72 for connecting is put on the base end portion 8 of the expansible member 3. The glass mold 72 is heated by a heater (not shown) to bond the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2. In the case of using the expansible member 3 the base end portion 8 of which is shrinkable, it is easy to fix the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 because the base end portion 8 of the expansible member 3 shrinks by being heated through the glass mold 72 described above. After fixing the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, the glass mold 72 is left till it comes back to the room temperature. After this, the glass mold 72 is moved back from the connecting portion of the expansible member 3 and the outer tube 2, and the core mold 70 is removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core mold 70 may be made of metal. In that case, an electrode for generating a high frequency may be put on the base end portion 8 of the expansible member 3 to weld the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 by high frequency induction heating. The base end portion 8 of the expansible member 3 may be welded to the tip end portion of the outer tube 2 with supersonic wave. The step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 may be taken place at any time after forming the outer tube 2 and the expansible member 3. The order of this step and the steps of forming the inner tube 1 and forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner

tube 1 is optional. In the case of using a split mold, which is capable of being split along its axial direction, as the glass or metal mold as described above, further, in the case of welding with high frequency or supersonic wave, the order of this step and the step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2, is optional. However, this step is preferably taken place after forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 because of decreasing the possibility of damaging the expansible member upon manufacturing.

Next, a step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 and having the opening will be described.

As shown in Fig.6, the inner tube 1 is inserted from its tip end in the outer tube hub 23 attached to the base end portion of the outer tube 2. The insertion of the inner tube 1 is performed from the rear end side of the outer tube hub 23. At this time, it is preferable that the inner tube 1 is inserted with a core member which is inserted in the inner tube 1 to prevent a flection of the inner tube 1, and the tip end portion of the inner tube hub 22 is inserted into the rear end portion of the outer tube hub 23 and joined to the latter. It is also preferable that the inner and outer tube hubs 22 and 23 are surely bonded to each other with an adhesive applied to the connecting portion thereof. The step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 may be taken place at any time after the steps of forming the inner tube 1, disposing the inner tube hub 22 to the base end portion of the inner tube 1, forming the outer tube 2, and disposing the outer tube hub 23 to the base end portion of the outer tube 2. This step is preferably taken place after forming the expansible member 3 and attaching the expansible member 3 to the outer tube 2.

Next, the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 will be described.

Here, a case that the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 is taken place after attaching the expansible member 3 to the outer tube 2 and connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 will be described.

As shown in Fig.36, a core mold 80 the outer diameter of which is as large as or a little smaller than the inner diameter of the inner tube 1 is inserted in the inner tube 1 from the tip or base end of the inner tube 1. Because the expansible member 3 is attached to the outer tube 2, the inner tube 1 is inserted in the outer tube 2 and the inner and outer tube hubs 22 and 23 are connected to each other, the inner tube 1 protrudes beyond the tip of the outer tube 2 and the tip of the expansible member 3. Accordingly, the portion of the tip end portion of the inner tube 1 protruding beyond the tip of the expansible member 3 is cut off to fit in the tip of the expansible member 3. Then, a glass mold 82 for connecting is put from the tip end side of the core mold 80 on the tip end portion 7 of the expansible member 3. The glass mold 82 is heated by a heater (not shown) to bond the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1. In the case of using the expansible member 3 the tip end portion 7 of which is shrinkable, it is easy to fix the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 because the tip end portion 7 of the expansible member 3 shrinks by being heated through the glass mold 82 described above. After fixing the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1, the glass mold 82 is left till it comes back to the room temperature. After this, the glass mold 82 is moved back from the connecting portion of the expansible member 3 and the inner tube 1, and the core mold 80 is removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core mold 80 may be made of metal. In that case, an electrode for generating a high frequency may be put on the tip end portion 7 of the expansible member 3 to weld the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 by high frequency induction heating. The tip end portion 7 of the expansible member 3 may be welded to the tip end portion of the inner tube 1 with supersonic wave. The step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 is preferably taken place as the final step after attaching the expansible member 3 to the outer tube 2 and connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2. In the case of using a split mold, which is capable of being split along its axial direction, as the glass or metal mold as described above, further, in the case of welding with high frequency or supersonic wave, this step may be taken place at any time after forming the inner

tube 1 and the expansible member 3. The order of this step and the steps of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1, forming the outer tube 2, and forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 is optional.

Further, after attaching the tip end portion of the expansible member to the tip end portion of the inner tube as described above, the tip end portion of the inner tube is preferably processed so that the outer diameter of the tip end portion of the inner tube decreases in a tapering shape toward the tip end of the inner tube or the inner tube has a rounded tip end. Such a processing can be easily performed by the manner that the tip end portion of the inner tube is inserted in a mold (for example, a glass or metal mold) having an internal shape corresponding to the aimed tip end shape of the inner tube and the mold is heated to deform the tip end portion of the inner tube in accordance with the internal shape of the mold. The tip end portion of the inner tube may be processed by using a metal mold as the above-mentioned mold and applying a high frequency or supersonic wave to the mold.

Next, a catheter equipped with an expansible member according to another embodiment of the present invention will be described with reference to the drawings.

A catheter equipped with an expansible member of this embodiment comprises an inner tube 1 having a first lumen 4 whose tip is open; an outer tube 2 capable of inserting the inner tube 1 therein, having the tip thereof at a position recessed by a predetermined distance from the tip of the inner tube 1, and forming a second lumen 6 between it and the outer surface of the inner tube 1; and a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the inner tube 1, the base end portion 8 of the expansible member 3 being attached to the outer tube 2, the expansible member 3 communicating with the second lumen 6 at a portion near the base end portion 8 of the expansible member 3, the tip end portion 7 of the expansible member 3 attached to the inner tube 1 protruding beyond the inner tube 1 toward the tip of the catheter to form a tip end portion of the catheter.

Hereinafter, detailed description will be made with Figs.1 through 6.

A catheter equipped with an expansible member of this embodiment comprises a catheter main body including an inner tube 1, an outer tube 2 and an expansible member 3, and a branched hub 20.

The inner tube 1 has a first lumen 4 whose tip is open. The first lumen 4 is a lumen for inserting a



guide wire therein and in communication with a first opening 9 which forms a guide wire port disposed in the branched hub 20. It is preferable that the outer diameter of the tip end portion of the inner tube 1 is smaller than that of the base end portion thereof. In this embodiment, as shown in Fig.3, the inner tube 1 consists of a front inner tube 1a and a rear inner tube 1b. The outer tube 2 described later also consists of a front outer tube 2a and a rear outer tube 2b. The outer diameters of the front inner and outer tubes 1a and 2a are smaller than those of the rear inner and outer tubes 1b and 2b, respectively. Therefore, the catheter of this embodiment can be inserted into more peripheral blood vessel than conventional one. It is preferable that the tip end portion of the catheter having the small outer diameter is as long as the distance from the inlet of a coronary artery to an aimed lesion part, particularly, a little longer than the distance from the inlet of the coronary artery to the aimed lesion part. Specifically, the length of the tip end portion is preferably about 50 to 700 mm, more preferably 80 to 400 mm, more preferably 100 to 300 mm.

It is preferable that each of the inner and outer tubes is provided with a tapering portion at the connecting portion between the tip end portion 1a or 2a and the base end portion 1b or 2b to make the change of its inner and outer diameters smooth. The front inner tube 1a of the inner tube 1 has preferably the outer diameter of 0.30 to 2.00 mm, more preferably 0.40 to 1.80 mm, and the inner diameter of 0.20 to 1.80 mm, more preferably 0.25 to 1.60 mm. The rear inner tube 1b has preferably the outer diameter of 0.40 to 2.50 mm, more preferably 0.55 to 2.40 mm, and the inner diameter of 0.25 to 2.35 mm, more preferably 0.30 to 1.80 mm. As the inner tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear inner tubes 1a and 1b. Also in that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes.

The material for forming the inner tube 1 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetate copolymer, polyvinyl chloride, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

The outer tube 2 into which the inner tube 1 is

inserted has a tip slightly recessed by a predetermined distance from the tip of the inner tube 1. As shown in Fig.4 which is a cross section taken along line I-I in Fig.1, a second lumen 6 is formed by the inner surface of the outer tube 2 and the outer surface of the inner tube 1. Thus, the second lumen 6 has a sufficient volume. The tip portion of the second lumen 6 is in communication with the rear end portion of the inside of the expandible member 3 described later. The rear end portion of the second lumen 6 is in communication with a second opening 11 provided to the branched hub 20 to form an injection port for injecting fluid for expanding the expandible member (for example, vasographic contrast liquid). As shown in Fig.3, the outer tube 2 consists of a front outer tube 2a and a rear outer tube 2b. The outer diameter of the front outer tube 2a is smaller than that of the rear outer tube 2b so as to facilitate insertion of the tip end portion of the catheter into more peripheral blood vessel. The front outer tube 2a of the outer tube 2 has preferably the outer diameter of 0.50 to 4.00 mm, more preferably 0.60 to 3.70 mm, and the inner diameter of 0.40 to 3.50 mm, more preferably 0.50 to 2.70 mm. The rear outer tube 2b has preferably the outer diameter of 0.75 to 4.30 mm, more preferably 1.00 to 4.00 mm, and the inner diameter of 0.70 to 3.80 mm, more preferably 0.80 to 3.00 mm. Also as the outer tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 2 consisting of the front and rear outer tubes 2a and 2b. In that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes. The material for forming the outer tube 2 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetate copolymer, polyvinyl chloride, polyurethane and polyamide elastomer; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

It is preferable to provide a rigidity imparting member 13. As shown in Figs.1 and 3 through 6, the rigidity imparting member 13 is preferably disposed in the second lumen 6 formed by the inner surface of the outer tube 2 and the outer surface of the inner tube 1. The rigidity imparting member 13 preferably extends from the base end portion to the tip end portion of the catheter. The rigidity imparting member 13 is for preventing an extreme flexion or bend of the catheter main body in a blood

vessel without considerable decrease of the flexibility of the catheter and for facilitating insertion of the tip end portion of the catheter into a stricture portion inside a blood vessel. The rigidity imparting member 13 preferably consists of a linear member. The linear member preferably consists of metal wire such as stainless steel, elastic metal, super elastic alloy, etc. desirably of the wire diameter of 0.05 to 1.50 mm, more desirably of 0.10 to 1.00 mm. Particularly, it is preferably made of high tensile spring stainless steel, Cu or Ni-Ti alloy. The tip and base end portions of the rigidity imparting member 13 may not be fixed. However, it is preferable that the tip end portion of the rigidity member 13 is fixed because the tip end portion of the rigidity imparting member 13 is prevented from being an injury to the expansible member 3 and the force applied to the base end portion of the catheter for advancing the tip end portion of the catheter is surely transmitted to the tip end portion of the catheter. In the embodiment shown in Fig.1, the tip end portion of the rigidity imparting member 13 is slenderer than the other portion thereof by, for example, grinding. The slenderer portion of the rigidity imparting member 13 is located between the tip end portion 7 of the expansible member 3 and the inner tube 1, and fixed to the tip end portion of the inner tube 1 together with the expansible member 3. The slenderer portion of the rigidity imparting member 13 prevents a step-like change of the outer surface of the expansible member 3 in its mounting portion. The average diameter of the slenderer portion is preferably about 1/5 to 1/10 of the diameter of its neighboring portion. It is preferable that the rigidity of the major body portion of the rigidity imparting member 13 is higher than that of the tip end portion thereof. This purpose can be attained by, for example, using a rigidity imparting member in which the cross section of its major body portion is larger than that of its tip end portion. It is preferable that the portion except the tip and base end portions of the rigidity imparting member 13 is not fixed. By not fixing the intermediate portion of the rigidity imparting member 13, when the tip end portion of the catheter is bent, the rigidity imparting member 13 does not hamper the flexibility of the tip end portion of the catheter because the rigidity imparting member 13 can slip within the second lumen.

The expansible member 3 is foldable and it is folded on the outer circumference of the inner tube 1 in its non-expanded state. The expansible member 3 has a substantially cylindrical portion 3a having an approximately uniform diameter at least a part of which is substantially cylindrical for enabling to expand a stricture portion in a blood vessel. The substantially cylindrical portion 3a described above may not be completely cylindrical

but may be polygonal. The base end portion 8 of the expansible member 3 is secured in a liquid-tight manner to the tip end portion of the outer tube 2 by adhesion, fusion or the like. The tip end portion 7 of the expansible member 3 is also secured in a liquid-tight manner to the tip end portion of the inner tube 1. As shown in Fig.1, the tip end portion 7 of the expansible member 3 protrudes beyond the tip of the inner tube 1 toward the tip end of the catheter. A rounded portion 7a is formed on the protruding tip end of the tip end portion 7. The rounded portion 7a forms a tip end portion of the catheter. More specifically, the tip end of the tip end portion 7 of the expansible member 3 covers the outer surface of the tip end portion of the inner tube 1 and the tip end surface of the inner tube 1, and the portion of the tip end portion 7 of the expansible member 3 covering the tip end surface of the inner tube 1 is rounded. By this design, it becomes possible to prevent the expansible member 3 from coming off because the length for bonding the inner tube 1 to the tip end portion 7 of the expansible member 3 can be small while the area for bonding them to each other is large. Further, because the connecting end between the tip end portion 7 of the expansible member 3 and the inner tube 1 is not exposed in the outer surface of the catheter, it becomes possible to prevent the expansible member 3 from peeling off from the connecting end between them upon insertion of the catheter. Therefore, this design of the tip end portion of the catheter can prevent the tip end of the catheter from being an injury to the inner wall of a blood vessel when the catheter advances in the blood vessel. The rounded portion 7a can be easily formed by the manner that a mold having a round inner surface is put on the tip end of the tip end portion 7 of the expansible member 3 secured in a liquid-tight manner to the inner tube 1 as described later. The mold is put on after inserting a core member in the inner tube 1, and then heated. Although it is preferable that the tip end of the tip end portion 7 of the expansible member 3 is rounded as described above, the tip end portion 7 of the expansible member 3 may have a tapering shape such that the outer diameter of the tip end portion 7 decreases toward the tip end instead of providing the rounded portion 7a. Further, the tip end portion 7 of the expansible member 3 may have an end surface at the tip end. As shown in Fig.5 which is a cross sectional view taken along line II-II of Fig.1, the expansible member 3 forms an expanded space 15 between the inner surface of the expansible member 3 and the outer surface of the inner tube 1. The expanded space 15 is in communication over the entire circumference at its rear end portion with the second lumen 6. Thus, the rear end of the expansible

member 3 is in communication with the second lumen 6 having a relatively large volume. Therefore, it is easy to inject expansion fluid through the second lumen 6 into the expansible member 3. The material for forming the expansible member 3 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetate copolymer and cross-linked ethylene-vinyl acetate copolymer, polyvinyl chloride, polyurethane and polyamide elastomer; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned cross-linked ethylene-vinyl acetate copolymer is more preferable. It is preferable that the forward and backward portions of the cylindrical portion 3a of the expansible member 3 are tapered. As the size of the expansible member 3, the cylindrical portion upon expanded has the outer diameter of 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm and the length of 3.00 to 80.00 mm, preferably 10.00 to 75.00 mm. The entire length of the expansible member 3 is 5.00 to 120.00 mm, preferably 15.00 to 100.00 mm.

It is preferable that a marker 14 is provided on the outer surface of the inner tube 1. As shown in Fig.1, the marker 14 is disposed from a portion near the portion on the rear side of the mounting portion between the expansible member 3 and the inner tube 1 to a portion near the portion on the tip end side of the mounting portion between the expansible member 3 and the outer tube 2. That is, the marker 14 has a length as long as that of the cylindrical portion 3a of the expansible member 3. The marker 14 is made of X-ray impermeable material (for example, gold, platinum, tungsten or alloy of them, or silver-palladium alloy). The marker 14 preferably consists of a coil spring. In that case, it is more preferable that the coil spring is wound closely in ranges of 1 to 4 mm, more preferably 2 to 3 mm from both ends of marker 14. This is for enabling to confirm easily the position of the expansible member 3 under X-ray perspection. Further, by forming the marker 14 into a spring shape, it functions as a reinforcement for preventing the inner tube within the expansible member from flexing or collapsing at its bend portion.

Particularly, when the marker 14 consists of a spring coil wound around the inner tube 1 closely, the resistance against an external force becomes higher. Further, when the cross section of the coiled wire is circular, rectangular or elliptic, the resistance against an external force becomes much higher.

As shown in Fig.2, the branched hub 20 comprises an inner tube hub 22 secured to the inner tube 1 and having a first opening 9 which is in

communication with the first lumen 4 to form a guide wire port, and an outer tube hub 23 secured to the outer tube 2 and having a second opening 11 which is in communication with the second lumen 6 to form an injection port. The inner and outer tube hubs 22 and 23 are connected to each other. For the material for forming the branched hub, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer. A cross section of an embodiment of the branched hub 20 is shown in Fig.6. In this embodiment, a flecion-preventing tube 50 is disposed on one end portion of the outer tube 2. The flecion-preventing tube 50 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flecion-preventing tube 50 can be easily attached by the manner that the shrinkable tube 50 is put on one end portion of the outer tube 2 and then shrunked by heating, for example, with blowing hot air. The outer tube 2 to which the flecion-preventing tube 50 has been attached is fixed to the outer tube hub 23 with a lock member 52, which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For fixing the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube 2 may be bonded to the outer tube hub 23 with an adhesive applied to the outer surface of the flecion-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

A flecion-preventing tube 60 is disposed on one end portion of the inner tube 1. The tube 60 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flecion-preventing tube 60 can be easily attached by the manner that the shrinkable tube 60 is put on one end portion of the inner tube 1 and then shrunked by heating, for example, with blowing hot air. The base end portion of the rigidity imparting member 13 is secured to the outer surface of the inner tube 1 with the flecion-preventing tube 60. The base end portion of the rigidity imparting member 13 may not be secured. The inner tube 1 to which the flecion-preventing tube 60 has been attached is fixed to the inner tube hub 22 with a lock member 62, which has an enlarged rear end

portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For fixing the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube 1 may be bonded to the inner tube hub 22 with an adhesive applied to the outer surface of the flexion-preventing tube 60. For the material for forming the inner tube hub 22, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer. As shown in Fig.6, the inner and outer tube hubs 22 and 23 are connected to each other by the manner that the inner tube hub 22 is inserted from its tip end in the rear end portion of the outer tube hub 23 attached to the base end portion of the outer tube 2. In this case, it is preferable that an adhesive is previously applied to the connecting portion between the inner and outer tube hubs 22 and 23 to make a reliable adhesion between them.

Instead of the branched hub 20, for example, tubes each having a port member forming an opening on its rear end may be connected in a liquid-tight manner to the first and second lumens, respectively.

Next, a method of manufacturing a catheter equipped with an expansible member of the present invention will be described with reference to an embodiment shown in the drawings.

A method of manufacturing a catheter equipped with an expansible member according to this embodiment comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length shorter than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of said catheter by using said tip end portion of said expansible member

with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof.

Each step will be described with the catheter shown in Fig.1.

First, the step of forming an inner tube 1 having a lumen 4 extending from the tip end to the base end of the inner tube 1 can be taken place by a method of cutting a tube member made of thermoplastic resin for the inner tube 1 by extrusion molding into a predetermined length or by an injection molding method.

The step of forming an outer tube 2 comprises a step of forming a front outer tube 2a having a lumen extending from the tip end to the base end of the tube 2a; a step of forming a rear outer tube 2b having the outer diameter larger than that of the front outer tube 2a and a lumen extending from the tip end to the base end of the tube 2b; a step of tapering one end of the rear outer tube 2b; a step of enlarging the diameter of one end portion of the front outer tube 2a; and a step of connecting the tapering end of the rear outer tube 2b to the enlarged end of the front outer tube 2a.

Next, the step of forming a contractible or foldable expansible member having a tip end portion and a base end portion will be described.

The expansible member 3 preferably has a certain extent of flexibility. For this purpose, the expansible member 3 is preferably made of thermoplastic resin, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetate copolymer and cross-linked ethylene-vinyl acetate copolymer; polyvinyl chloride and polyurethane. Particularly, it is preferable that the expansible member 3 is made of cross-linked ethylene-vinyl acetate copolymer. For example, a thermoplastic tube for forming the expansible member 3 is formed. A tube holder is attached to the distal end portion of the tube. The lumen of the tube is closed at a portion near the tube holder. The closed tube is stretched by applying a load to the tube holder to remove stacks from the tube. A portion of the tube which is to form the expansible member 3 is heated to a temperature near the melting point of the material of the tube. While keeping the tube heated, a mold which has a cavity corresponding to a shape of the expanded expansible member 3 is put on the tube and the heated portion of the tube is pressed onto the inner surface of the mold by introducing gas in the tube under pressure. The tube is kept pressurized till the tube comes back to the room temperature. The mold is removed after the portion of the tube which is to form the expansible member 3 is constricted by making the inside

of the tube at a negative pressure. The tube is cut at the tip and rear end portions to obtain the expansible member 3.

When at least the tip and base end portions of the expansible member 3 are shrinkable, the expansible member 3 can be easily attached to the inner and outer tubes 1 and 2 by shrinking. For making the tip and base end portions of the expansible member 3 shrinkable, the expansible member 3 may be made of cross-linked thermoplastic resin. Otherwise, in the step of forming the expansible member 3 described above, the portion of the tube 130 which is to form the expansible member 3 may be heated to such a temperature that strains will remain after cooling. By this manner, the whole of the expansible member 3 can be made shrinkable. Further, for making the tip and base end portions of the expansible member 3 shrinkable, after the expansible member is formed such that the inner diameters of the tip and base end portions of the expansible member are a little smaller than outer diameters of the inner and outer tubes 1 and 2, respectively, the both end portions of the expansible member may be enlarged (by drawing). The order of the steps of forming the expansible member and the inner and outer tubes described before is optional.

Next, a step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 will be described. It is preferable to form the opening 11 by attaching the outer tube hub 23 having an opening to the base end portion of the outer tube 2. This case will be described with reference to Fig.6.

First, the flection-preventing tube 50 is attached to one end portion of the outer tube 2. The flection-preventing tube 50 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 is attached by the manner that the shrinkable tube 50 is put on the one end portion of the outer tube 2 and then shrunked by heating, for example, with blowing hot air. The outer tube hub 23 is attached to the outer tube 2 to which the flection-preventing tube 50 has been attached. Fixing of the outer tube hub 23 is taken place by using a lock member 52 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For fixing the outer tube hub 23 to the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the

outer tube hub 23. The outer tube hub 23 may be bonded to the outer tube 2 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

The step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 may be taken place at any time after forming the outer tube 2. This step is preferably taken place after the step of attaching the base end portion of the expansible member 3 to the tip end portion of the outer tube 2 described later. The order of this step and the step of forming the inner tube 1 is optional.

Next, a step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 will be described. It is preferable to form the opening 9 by attaching the inner tube hub 22 having an opening to the base end portion of the inner tube 1. This case will be described with reference to Fig.6.

First, the flection-preventing tube 60 is attached to one end portion of the inner tube 1. The flection-preventing tube 60 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 is attached by the manner that the shrinkable tube 60 is put on the one end portion of the inner tube 1 and then shrunked by heating, for example, with blowing hot air. In the embodiment shown in Fig.6, the rigidity imparting member 13 is disposed between the inner and outer tubes 1 and 2. One end portion of the rigidity imparting member 13 is fixed between the flection-preventing tube 60 and the inner tube 1. As shown in Fig.6, the one end portion of the rigidity imparting member 13 can be fixed at the same time that the tube 60 is attached to the inner tube 1 by taking place the heat treatment described above after the one end portion of the rigidity imparting member 13 is located between the tube 60 and the inner tube 1.

The inner tube hub 22 is attached to the inner tube 1 to which the flection-preventing tube 60 has been attached. This attachment of the inner tube hub 22 is taken place by using a lock member 62 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For attaching the inner tube hub 22 to the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged

rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube hub 22 may be bonded to the inner tube 1 with an adhesive applied to the outer surface of the flexion-preventing tube 60. For the material for forming the inner tube hub, the same material as that of the outer tube hub can be suitably used.

The step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1, may be taken place at any time after forming the inner tube 1. The order of this step and the steps of forming the outer tube 2, forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2, and forming the expansible member 3 is optional.

Next, the step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 will be described.

For attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, a core mold the outer diameter of which is as large as or a little smaller than the inner diameter of the outer tube 2 is inserted in the outer tube 2 from the tip or base end of the outer tube 2. Then, the expansible member 3 is put on the outer tube 2 from the tip end side of the core mold such that the tip end of the base end portion 8 of the expansible member 3 corresponds to the tip end of the outer tube 2. A glass mold for connecting is put on the base end portion 8 of the expansible member 3. The glass mold is heated by a heater to bond the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2. In the case of using the expansible member 3 the base end portion 8 of which is shrinkable, it is easy to fix the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 because the base end portion 8 of the expansible member 3 shrinks by being heated through the glass mold described above. After fixing the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, the glass mold is left till it comes back to the room temperature. After this, the glass mold is moved back from the connecting portion of the expansible member 3 and the outer tube 2, and the core mold is removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core mold may be made of metal. In that case, an electrode for generating a high frequency may be put on the base end portion 8 of the expansible member 3 to weld the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 by high frequency induction heating.

The base end portion 8 of the expansible member 3 may be welded to the tip end portion of the outer tube 2 with supersonic wave. The step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 may be taken place at any time after forming the outer tube 1 and the expansible member 3. The order of this step and the steps of forming the inner tube 1 and forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 is optional.

Next, a step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 and having the opening will be described.

As shown in Fig.6, the inner tube 1 is inserted from its tip end in the outer tube hub 23 attached to the base end portion of the outer tube 2. The insertion of the inner tube 1 is performed from the rear end side of the outer tube hub 23. At this time, it is preferable that the inner tube 1 is inserted with a core member which is inserted in the inner tube 1 to prevent a flexion of the inner tube 1, and the tip end portion of the inner tube hub 22 is inserted into the rear end portion of the outer tube hub 23 and joined to the latter. The inner and outer tube hubs 22 and 23 can be surely bonded to each other with an adhesive applied to the connecting portion thereof. The step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 may be taken place at any time after the steps of forming the inner tube 1, disposing the inner tube hub 22 to the base end portion of the inner tube 1, forming the outer tube 2, and disposing the outer tube hub 23 to the base end portion of the outer tube 2. This step is preferably taken place after forming the expansible member 3 and attaching the expansible member 3 to the outer tube 2.

Next, the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 and the step of treating the attached tip end portion 7 of the expansible member 3 with heat will be described.

Here, a case that the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 is taken place after attaching the expansible member 3 to the outer tube 2 and connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 to the outer tube hub 23 attached to the base end portion of the outer tube 2 will be described.

As shown in Fig.37, a core member 80 the outer diameter of which is as large as or a little

smaller than the inner diameter of the inner tube 1 is inserted in the inner tube 1 from the tip or base end of the inner tube 1 such that the tip end of the core member 80 protrudes beyond the tip end of the inner tube 1 by 10 to 15 mm. The inner tube 1 in which the core member 80 has been inserted is inserted from its tip end in the outer tube 2 to the base end portion of which the outer tube hub 23 has been attached and to the tip end portion of which the expansible member 3 has been attached. Then, the inner tube hub 22 attached to the base end portion of the inner tube 1 is connected to the outer tube hub 23. Fig.38 shows the tip end portion of the catheter in this state, wherein the inner tube 1 protrudes beyond the tip end of the outer tube 2 and the tip end of the inner tube 1 is within a tip-side extending portion of the expansible member 3. Then, as shown in Fig.39, a glass mold 82 for connecting is put from the tip end side of the core member 80 on the tip end portion 7 of the expansible member 3. The glass mold 82 is heated by a heater (not shown) to bond the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1. in the preferable case of using the expansible member 3 the tip end portion 7 of which is shrinkable, it is easy to fix the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 because the tip end portion 7 of the expansible member 3 shrinks of itself by being heated through the glass mold 82 described above. After fixing the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 as described above, the glass mold 82 is left till it comes back to the room temperature. Then, the glass mold 82 is moved back from the connecting portion of the expansible member 3 and the inner tube 1, and removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core member 80 may be made of metal. In that case, an electrode for generating a high frequency may be put on the tip end portion 7 of the expansible member 3 to weld the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 by high frequency induction heating. The tip end portion 7 of the expansible member 3 may be welded to the tip end portion of the inner tube 1 with supersonic wave.

Then, the tip end portion of the expansible member is cut at a portion ahead of the tip end of the inner tube 1 by a predetermined distance. Specifically, as shown in Fig.40, the tip end portion (the tip-side extending portion 77) of the expansible member 3 is cut at a portion shown by arrows A ahead of the tip end of the inner tube 1 by about 1 mm. The tip end portion of the expansible member can be finely cut with a cutter such as a razor

along the circumferential direction of the core member 80.

Next, the tip end portion of the expansible member which has been cut so as to protrude beyond the tip end of the inner tube 1 by a predetermined length, is treated with heat. Specifically, as shown in Fig.41, the tip end portion of the expansible member is inserted in a heating mold 96 till the tip end of the tip end portion touches the inner wall of the heating mold 96. The heating mold 96 has a cylindrical cavity 97 the inner diameter of which is as large as the outer diameter of the connecting portion of the tip end portion 7 of the expansible member 3 and the inner tube 1. A hole 98 capable of inserting the core member 80 therein is formed in the bottom center of the cavity 97. The bottom inner wall of the cylindrical cavity 97 is shaped such that an aimed shape of the tip end portion of the expansible member (for example, a rounded shape) can be obtained by heat treatment. By heating the heating mold 96 and pushing lightly the tip end portion of the expansible member therein, the protruding portion 77 of the expansible member becomes in a molten state. The portion of the expansible member in the molten state is deformed in accordance with the bottom shape of the cavity 97 and fills the space between the tip end of the inner tube 1 and the protruding portion 77 of the expansible member. As the result, as shown in Fig.42, the outer surface of the tip end portion of the inner tube 1 and the tip end surface thereof are covered with the portion of the expansible member and the tip end portion of the catheter having the rounded portion 7a is formed. Then, the heating mold 96 in which the tip end portion of the expansible member is inserted is cooled. The heating mold 96 can be cooled by the manner that the heating mold 96 in a hot state is put in a cooling vessel 99 containing a cooling medium such as cool water, as shown in Fig.42. The heating mold 96 is left therein till it is cooled sufficiently. After the heating mold 96 is cooled sufficiently, it is taken out from the cooling vessel 99 and removed from the tip end portion of the expansible member. After this, the core member 80 is drawn out from the inner tube 1 to obtain the catheter equipped with the expansible member having the rounded portion 7a in the tip end portion as shown in Fig.43.

Next, the operation of a catheter equipped with an expansible member according to the present invention will be described with reference to Figs.44 through 48 using the catheter equipped with the expansible member of the embodiment shown in Figs.1 through 6.

Before administering a dilatating cure of a stricture portion which has occurred in a blood vessel, air in the catheter equipped with the expansible member is preferably removed as completely as

possible. For this purpose, suction and injection means such as a syringe is attached to the second opening 11 of the catheter according to the present invention and liquid (X-ray contrast liquid, etc. ) is charged in the syringe. By repeating suction and injection operations by syringe, the air in the second lumen and the expansible member is removed and replaced by the liquid.

Upon inserting the catheter equipped with the expansible member into a blood vessel, at first, the blood vessel is insured by means of Seldinger method or the like, a guide wire for guide catheter (not shown) is then retained in the blood vessel, the guide catheter 30 is inserted into the blood vessel along it, as shown in Fig.45, the guide catheter 30 is retained in the inlet 32 of the coronary artery including an aimed lesion part, and the guide wire for guide catheter is then withdrawn. As shown in Fig.44, the catheter 40 equipped with the expansible member according to the present invention into which a guide wire 34 for catheter equipped with expansible member is inserted, is inserted through a Y-shaped connector 50 disposed at the rear end of the guide catheter 30. Insertion into the blood vessel is performed in a state that the guide wire 34 for catheter equipped with expansible member is protruded beyond the tip of the catheter 40 equipped with the expansible member by several centimeters. The catheter 40 equipped with the expansible member advances in the guide catheter 30 and enters the blood vessel 35 including the aimed lesion part as shown in Fig.46. The guide wire 34 for catheter equipped with expansible member is then advanced to the aimed lesion part, passed through the stricture portion 36 and retained. The catheter 40 equipped with the expansible member advances in the blood vessel 35 along the guide wire 34 for catheter equipped with expansible member. When the catheter 40 equipped with the expansible member reaches the stricture portion 36, the expansible member 3 is positioned in the stricture portion 36 under X-ray perspection by using the X-ray impermeable marker 14 disposed on the inner tube 1 as a reference mark as shown in Fig.47. Subsequently, vasographic contrast liquid is injected at a pressure from several atmospheres to ten and several atmospheres by means of an injector 54 equipped with a pressure gauge connected to the second opening forming the injection port of the catheter 40 equipped with the expansible member to compress and expand the stricture portion 36 as shown in Fig.48. The contrast liquid is injected through a contrast liquid injection port 52 of the Y-shaped connector 50 of the guide catheter 30 to confirm the state of blood stream on the peripheral side by the X-ray perspection. When an improvement of the blood flow on the peripheral side is

recognized, the catheter 40 equipped with the expansible member and the guide wire 34 for catheter equipped with expansible member are withdrawn and then the guide catheter is withdrawn and blood is stopped under pressure to complete the operation.

As described above, a catheter equipped with an expansible member according to the present invention comprises an inner tube having a base end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; a second opening formed in said base end portion of said outer tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen. Therefore, particularly because the rigidity imparting member is disposed in the second lumen, an extreme flection and meandering of the catheter is prevented without decrease of the flexibility of the catheter, especially the elastic deformability in the lateral direction with respect to the axial direction of the catheter. Therefore, the force applied to the base end portion of the catheter is not absorbed at the meandering portion. Thus, the force applied to the base end portion of the catheter for advancing the tip end portion thereof to a stricture portion inside a blood vessel is surely transmitted to the tip end portion so the operability of the catheter is good. In addition, because the second lumen which is in communication with the portion near the base end portion of the expansible member and into which expansion fluid for the expansible member is injected is formed between the inner and outer tubes and has a relatively large volume, even in the case that the expansion fluid has a high flow resistance such as vasographic contrast liquid, it can be easily injected.

Further, a catheter equipped with an expansible member according to the present invention comprises a catheter main body having a tip end portion and a base end portion and comprising an inner tube having a base end portion and a first lumen whose tip is open, an outer tube capable of



inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube, and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; and a second opening formed in said base end portion of said outer tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter main body including a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter main body. Therefore, the catheter has physical properties required for the base end portion of the catheter so that the tip portion of the catheter can be easily inserted into a severer stricture portion or in a more peripheral blood vessel.

Further, a catheter equipped with an expansible member according to the present invention comprises a catheter tube having a tip end portion, a base end portion, a first lumen at least the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; a second opening formed in said base end portion of said catheter tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens. Therefore, like the catheter described before, because the rigidity imparting member is disposed in the second lumen, an extreme flexion and meandering of the catheter is prevented without decrease of the flexibility of the catheter, especially the elastic deformability in the lateral direction with respect to the axial direction of the catheter. Therefore, the force applied to the base end portion of the catheter is not absorbed at the meandering portion. Thus, the force applied to

the base end portion of the catheter for advancing the tip end portion thereof to a stricture portion inside a blood vessel is surely transmitted to the tip end portion so the operability of the catheter is good.

Further, a catheter equipped with an expansible member according to the present invention comprises a catheter tube having a tip end portion, a base end portion, a first lumen at least the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; and a second opening formed in said base end portion of said catheter tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter tube including at least a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter tube. Therefore, the catheter has physical properties required for the base end portion of the catheter so that the tip portion of the catheter can be easily inserted into a severer stricture portion or in a more peripheral blood vessel.

Further, a method of manufacturing a catheter equipped with an expansible member according to the present invention comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear

outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube. Therefore, even in the case that the outer tube is a tube having different outer diameters which is hard to make by extrusion molding, it can be easily manufactured. In addition, because the front and rear outer tubes are connected without any joint, there is little possibility of disconnection of the tubes so the catheter can be used safely.

Further, a catheter equipped with an expansible member according to the present invention comprises an inner tube having a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member, said tip end portion of said expansible member attached to said inner tube protruding beyond said inner tube toward the tip of said catheter to form a tip end portion of said catheter. Therefore, it becomes possible to prevent the expansible member from coming off because the length for bonding the inner tube to the tip end portion of the expansible member can be small while the area for bonding them to each other is large. Further, because the connecting end between the tip end portion of the expansible member and the inner tube is not exposed in the outer surface of the catheter, it becomes possible to prevent the expansible member from peeling off from the connecting end between them upon insertion of the catheter. Thus, there is no possibility that the tip end of the catheter is an injury to the inner wall of a blood vessel when the catheter advances in the blood vessel.

Further, a method of manufacturing a catheter equipped with an expansible member according to the present invention comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member hav-

ing a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of said catheter by using said tip end portion of said expansible member with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof. Therefore, because the tip end portion of the expansible member and the tip end portion of the catheter are integrated, the catheter equipped with the expansible member described above can be surely and easily manufactured without any additional member.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof, it is to be understood that the invention is not limited to the specific embodiments thereof except as defined in the appended claims.

### Claims

1. A catheter equipped with an expansible member comprising an inner tube having a base end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; a second opening formed in said base end portion of said outer tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen.

2. A catheter equipped with an expansible member set forth in claim 1, wherein the rigidity of

the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

3. A catheter equipped with an expansible member set forth in claim 1, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

4. A catheter equipped with an expansible member comprising a catheter main body having a tip end portion and a base end portion and comprising an inner tube having a tip end portion, a base end portion and a first lumen whose tip is open, an outer tube capable of inserting said inner tube therein, having a tip end portion, a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube, and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; and a second opening formed in said base end portion of said outer tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter main body including a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter main body.

5. A catheter equipped with an expansible member set forth in claim 4, wherein said catheter further comprises a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen.

6. A catheter equipped with an expansible member set forth in claim 4, wherein the outer diameter of said tip end portion of said inner tube is smaller than that of said base end portion of said inner tube.

7. A catheter equipped with an expansible member set forth in claim 4, wherein the outer diameter of said tip end portion of said outer tube is smaller than that of said base end portion of said outer tube.

8. A catheter equipped with an expansible member set forth in claim 5, wherein the rigidity of the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

9. A catheter equipped with an expansible member set forth in claim 5, wherein the cross

section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

10. A catheter equipped with an expansible member set forth in claim 4, wherein the length of said tip end portion of said catheter main body the outer diameter of which is small is a length near the distance from the inlet of a coronary artery to an aimed lesion part.

11. A catheter equipped with an expansible member comprising a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; a second opening formed in said base end portion of said catheter tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens.

12. A catheter equipped with an expansible member set forth in claim 11, wherein the rigidity of the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

13. A catheter equipped with an expansible member set forth in claim 11, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

14. A catheter equipped with an expansible member comprising a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; and a second opening formed in said base end portion of

said catheter tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter tube including at least a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter tube.

15. A catheter equipped with an expansible member set forth in claim 14, wherein said catheter further comprises a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens.

16. A catheter equipped with an expansible member set forth in claim 15, wherein the rigidity of the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

17. A catheter equipped with an expansible member set forth in claim 15, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

18. A catheter equipped with an expansible member set forth in claim 15, wherein the length of said tip end portion of said catheter tube the outer diameter of which is small is a length near the distance from the inlet of a coronary artery to an aimed lesion part.

19. A method of manufacturing a catheter equipped with an expansible member comprising a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending from the tip end to the base end of said rear outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube.

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20. A method of manufacturing a catheter equipped with an expansible member set forth in claim 19, wherein said step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube comprises a step of fitting said tapered end of said rear outer tube in said enlarged end of said front outer tube and a step of bonding them to each other.

21. A catheter equipped with an expansible member comprising an inner tube having a tip end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member, said tip end portion of said expansible member attached to said inner tube protruding beyond said inner tube toward the tip of said catheter to form a tip end portion of said catheter.

22. A catheter equipped with an expansible member set forth in claim 21, wherein said tip end portion of said expansible member covers the outer surface of said tip end portion of said inner tube and the tip end surface of said inner tube.

23. A catheter equipped with an expansible member set forth in claim 21, wherein the tip of said expansible member is rounded.

24. A method of manufacturing a catheter equipped with an expansible member comprising a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length shorter than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of

said catheter by using said tip end portion of said  
expansible member with heat treatment of the pro-  
truding portion of said expansible member beyond  
said inner tube by said predetermined length and  
coating the outer surface of said tip end portion of  
said inner tube and the tip end surface thereof.

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FIG. 3

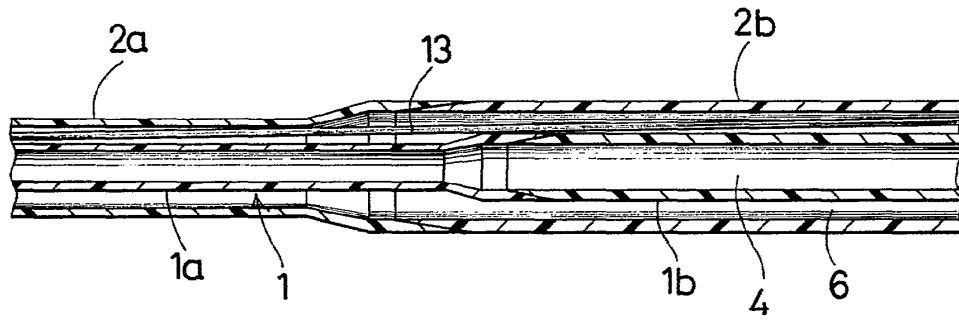


FIG. 4

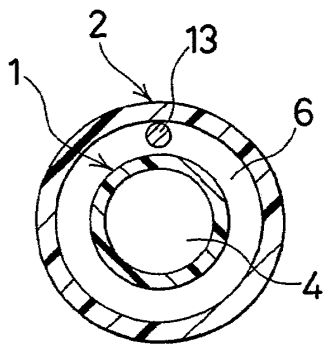


FIG. 5

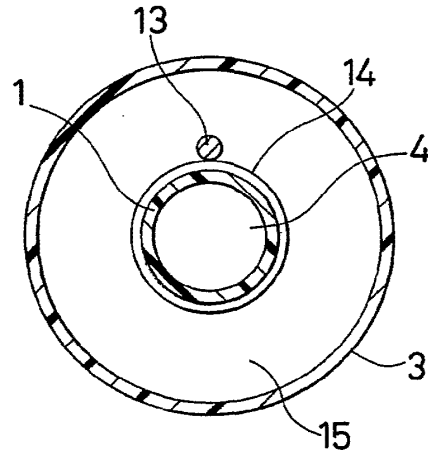


FIG. 10



FIG. 11



FIG. 12

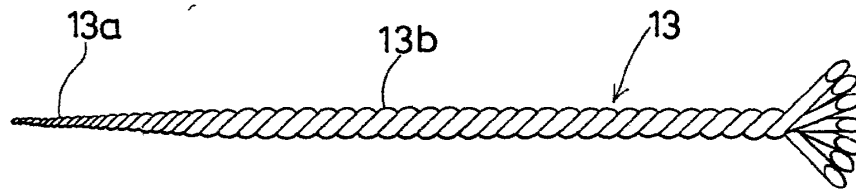


FIG. 13

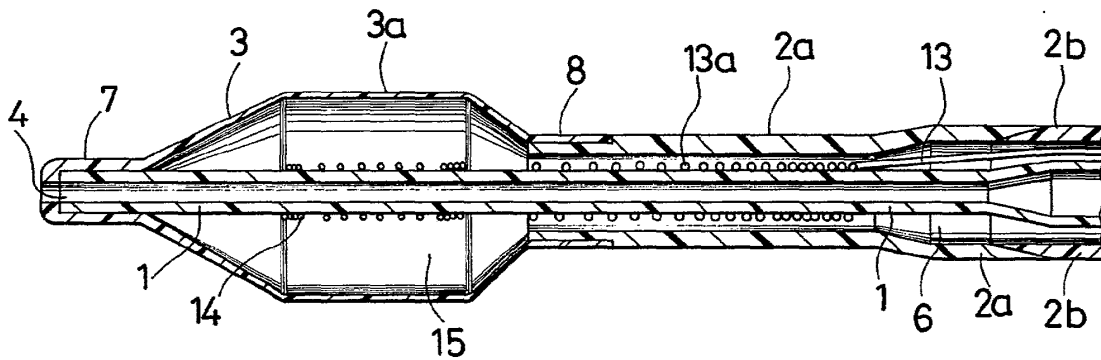




FIG. 6

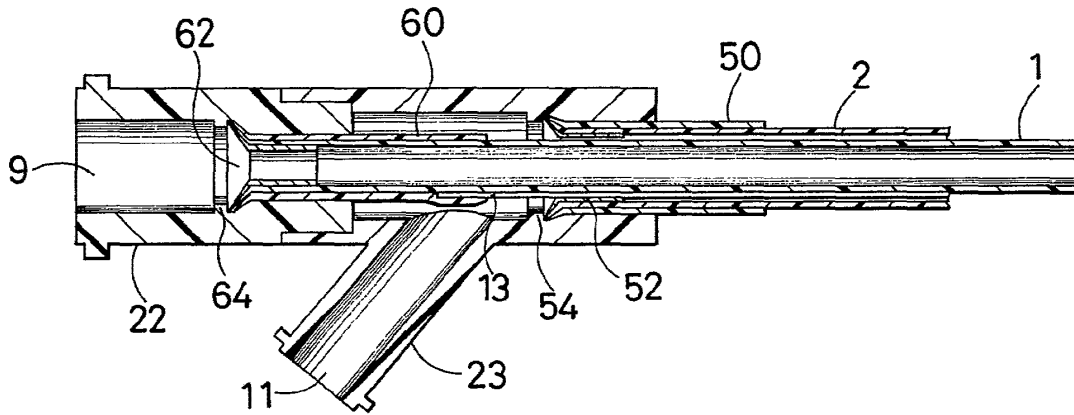


FIG. 7

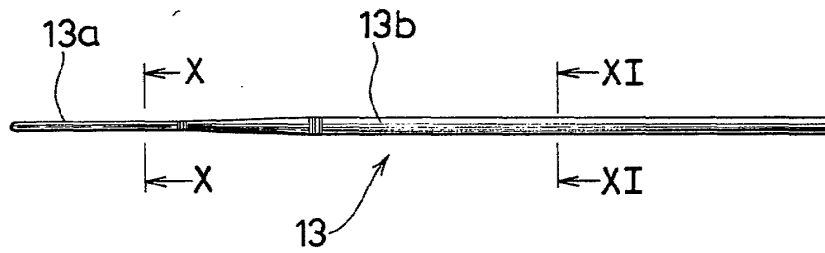


FIG. 8

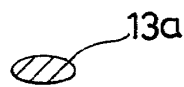


FIG. 9

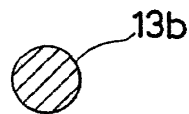


FIG. 14

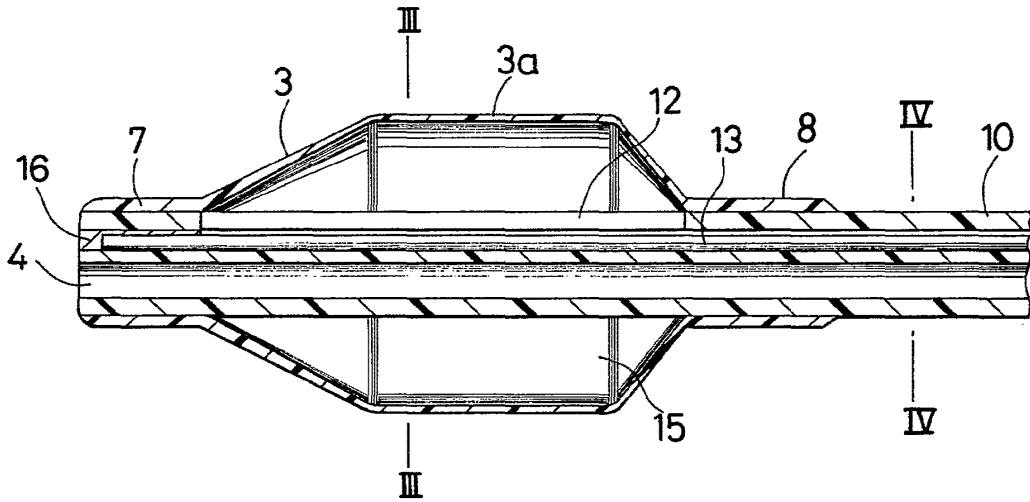


FIG. 15

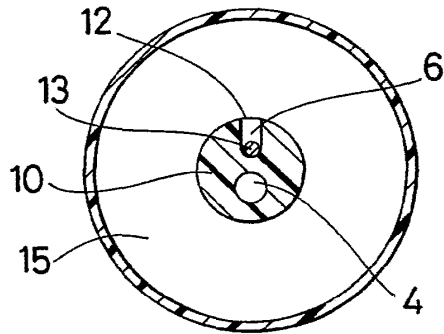


FIG. 16

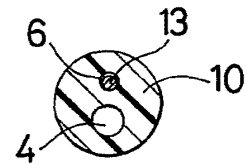


FIG. 17

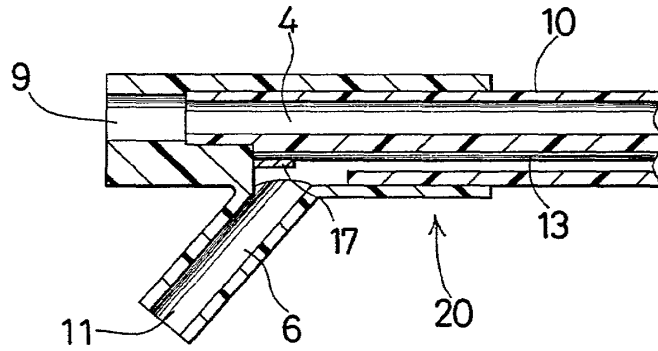


FIG. 18

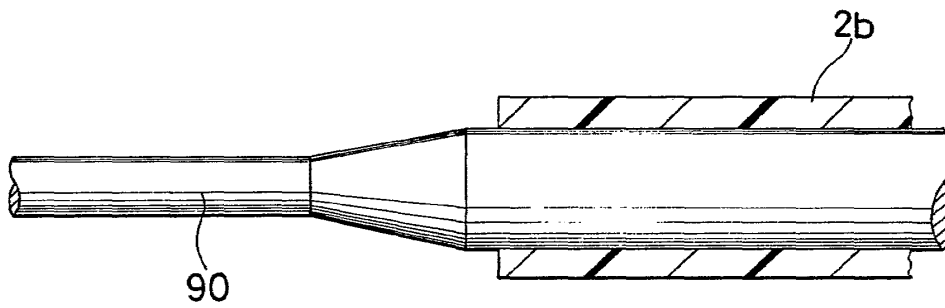


FIG. 19

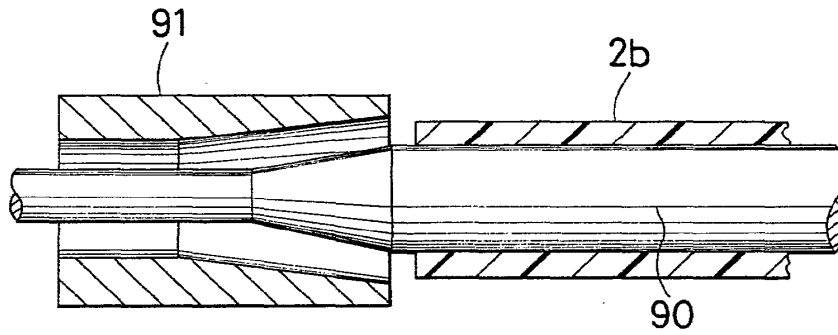


FIG. 20

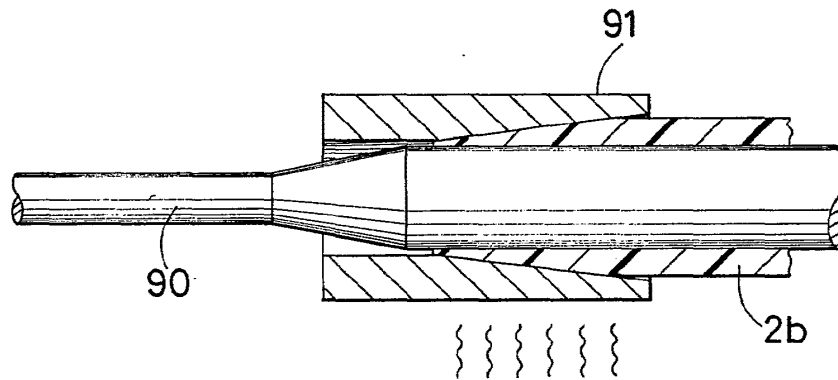


FIG. 21

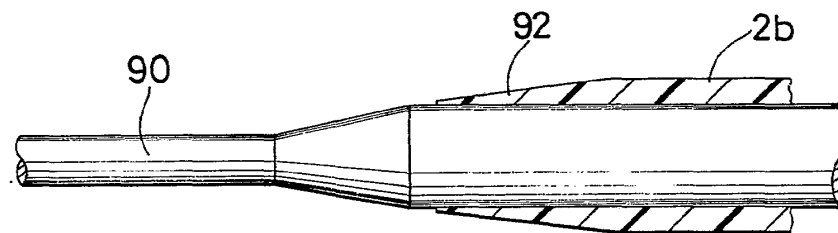


FIG. 22

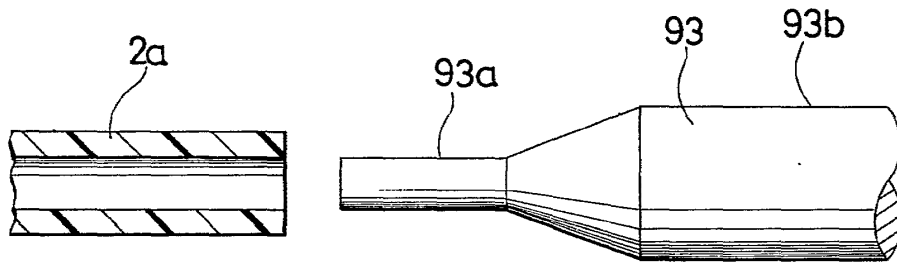


FIG. 23

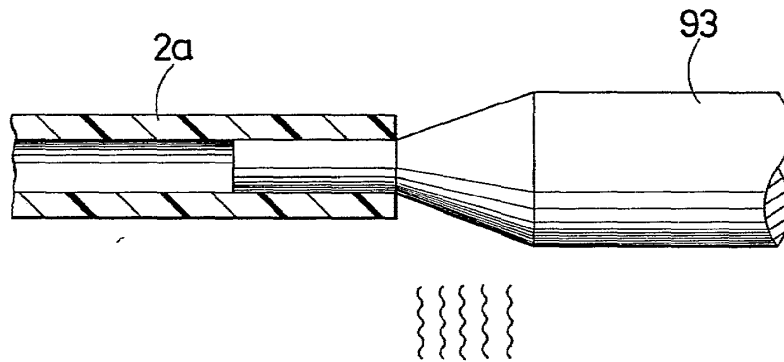


FIG. 24

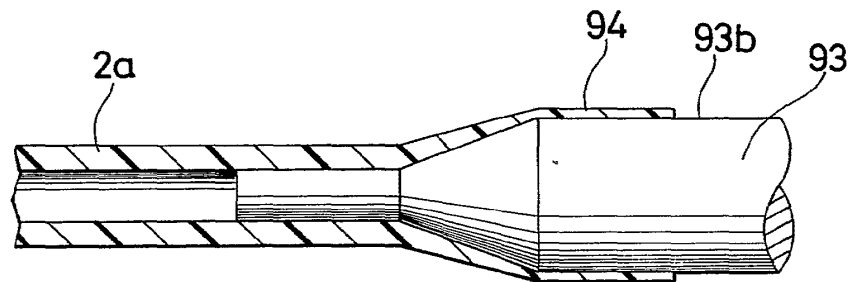


FIG. 25

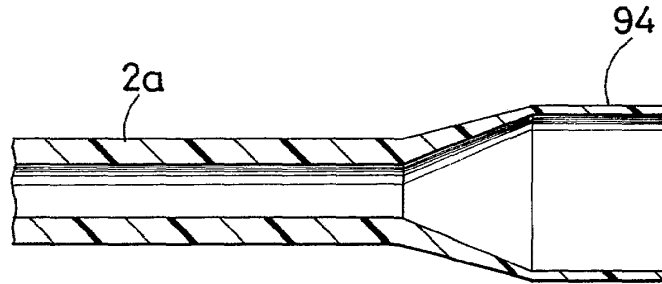


FIG. 26

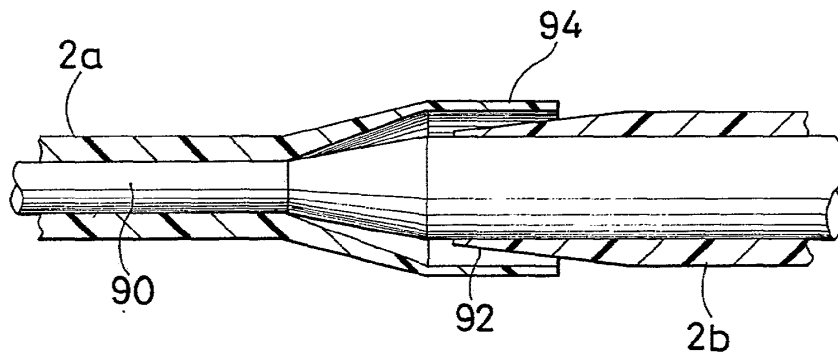


FIG. 27

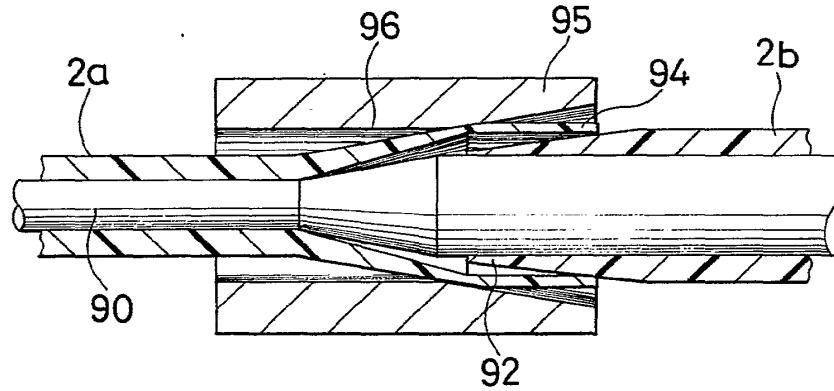


FIG. 28

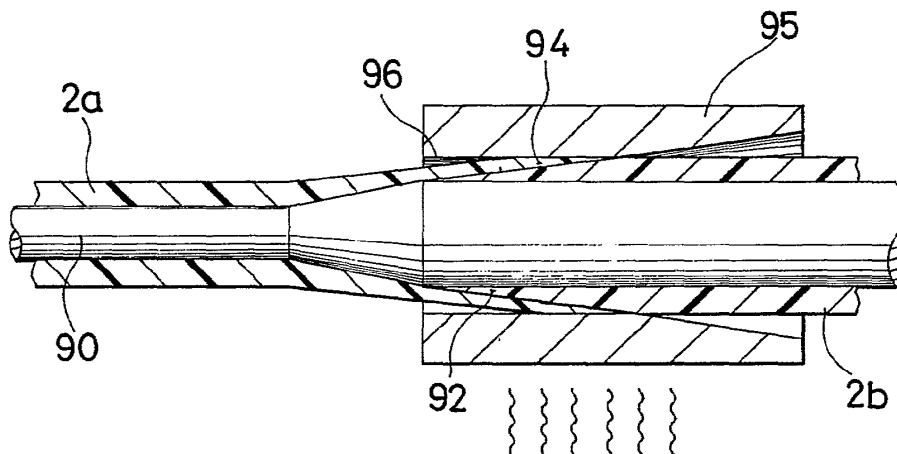


FIG. 29

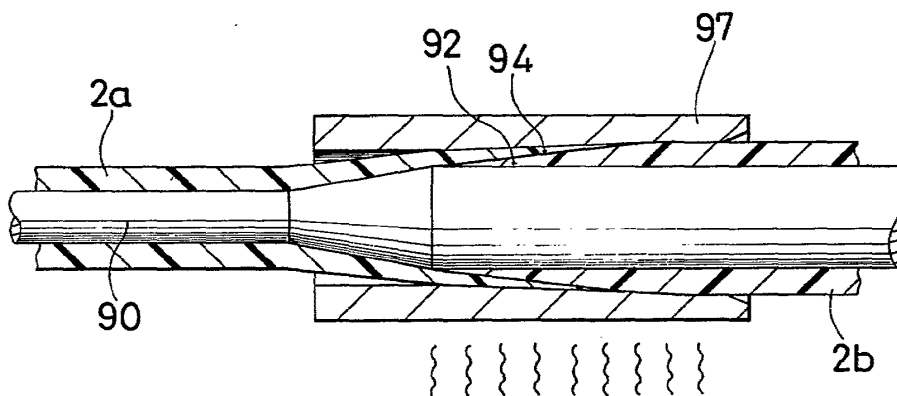


FIG. 30

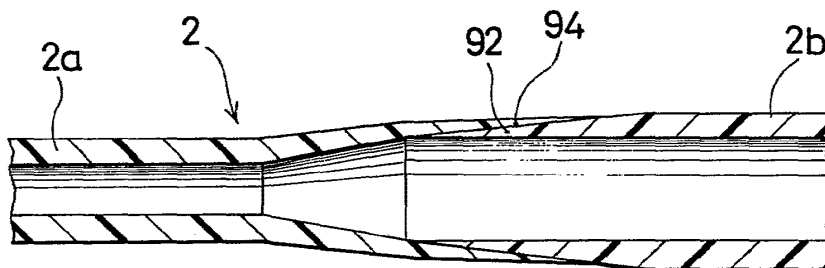


FIG. 31

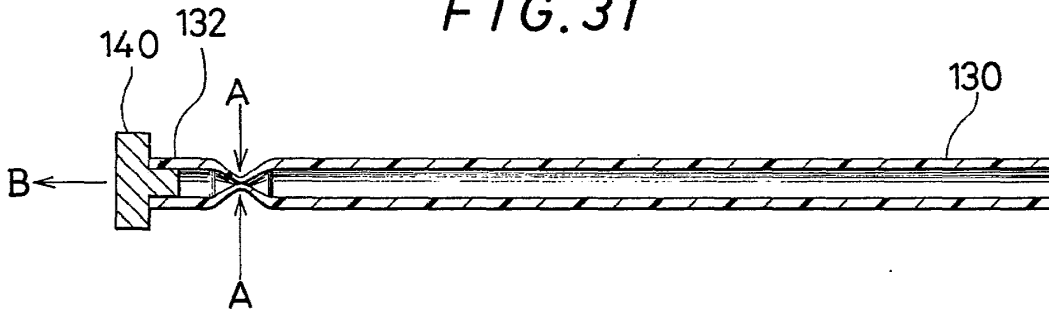


FIG. 32

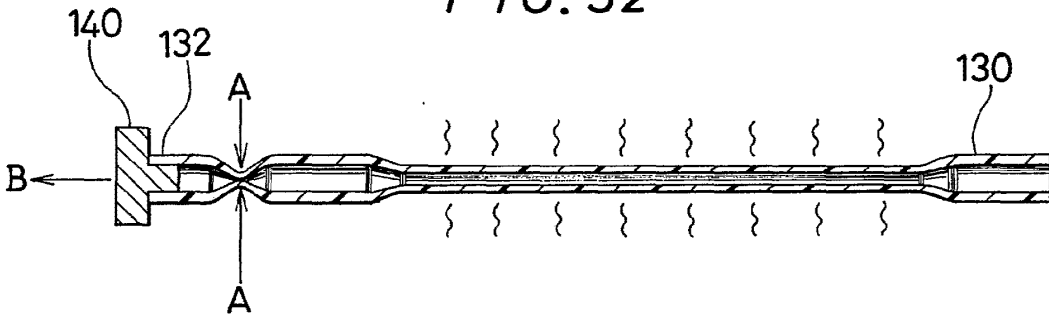


FIG. 33

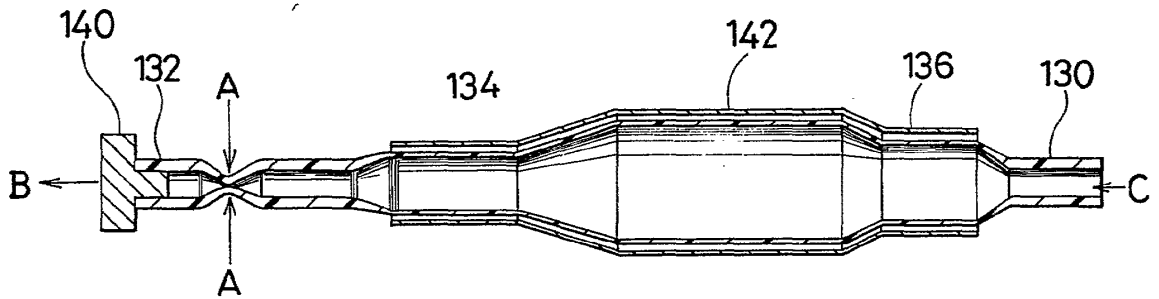


FIG. 34

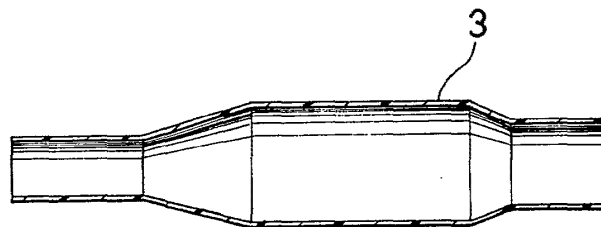




FIG. 35

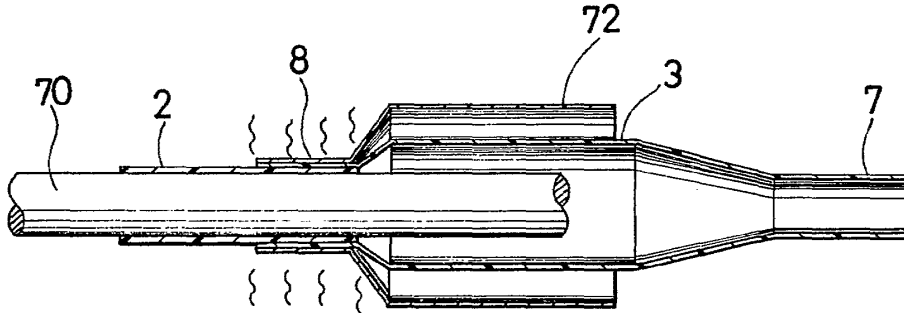


FIG. 36

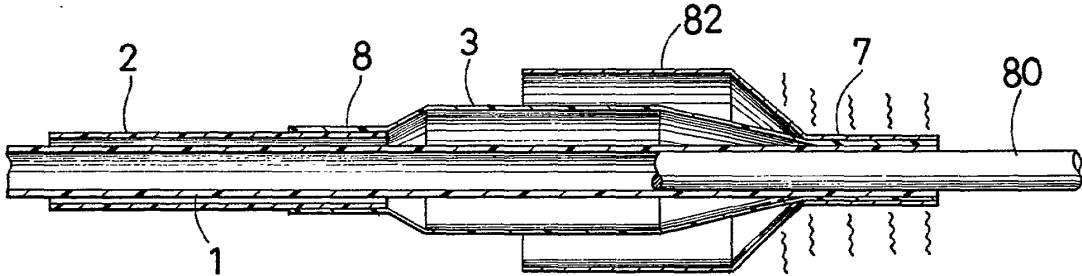


FIG. 37

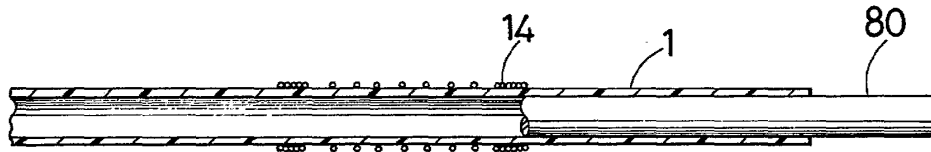


FIG. 38

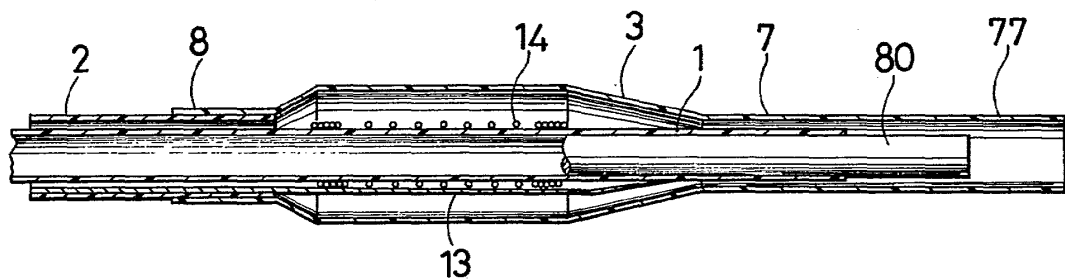


FIG. 39

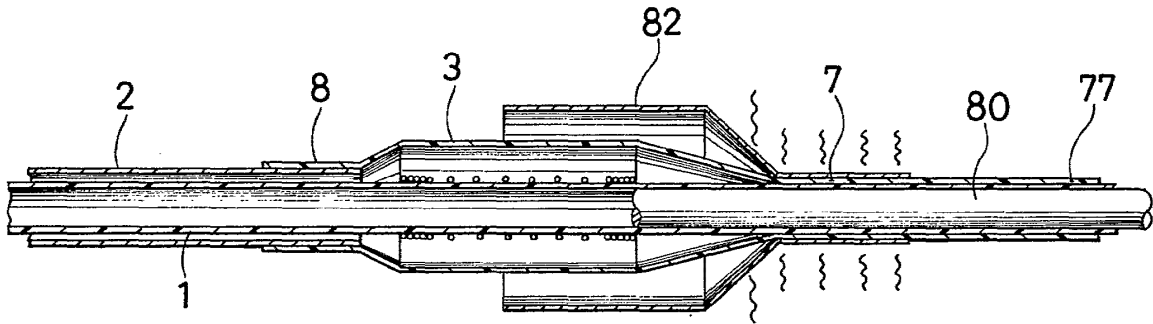


FIG. 40

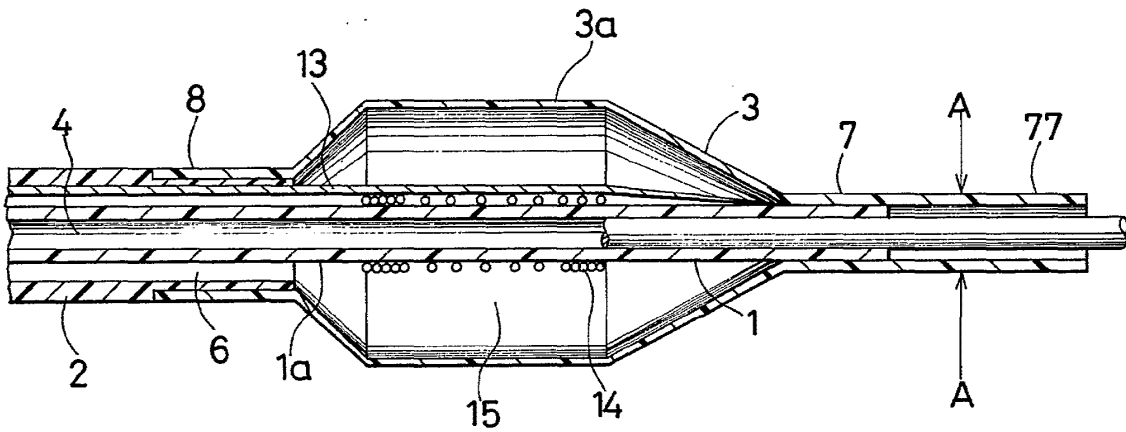


FIG. 41

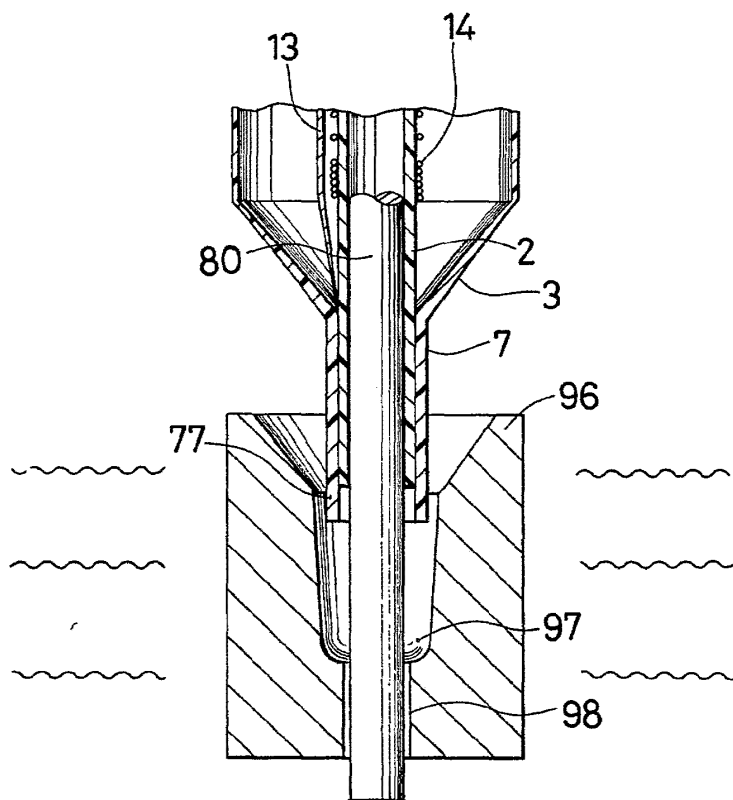


FIG. 42

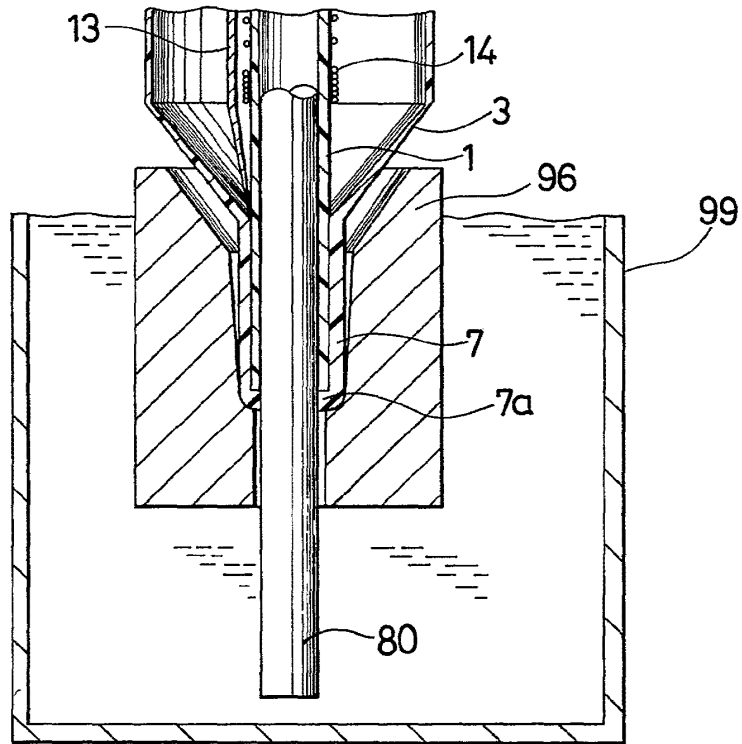


FIG. 43

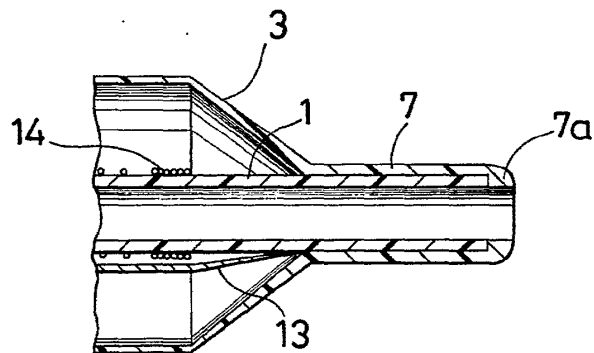


FIG. 44

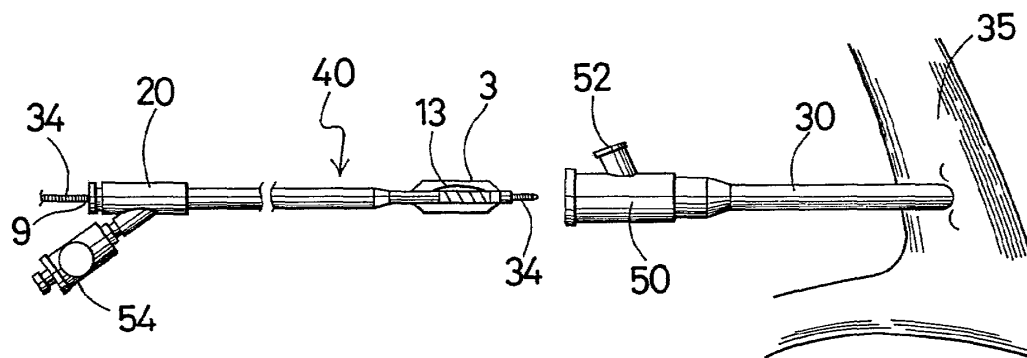


FIG. 45

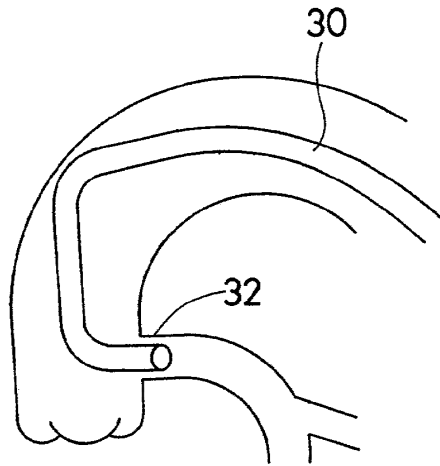


FIG. 46

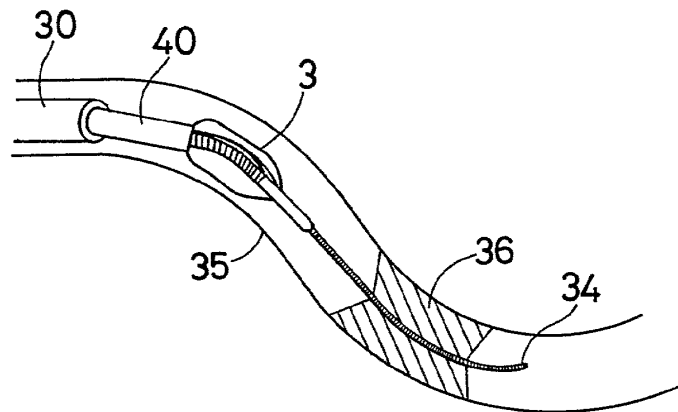


FIG. 47

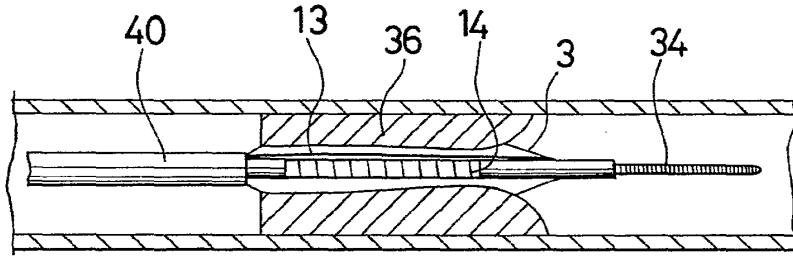
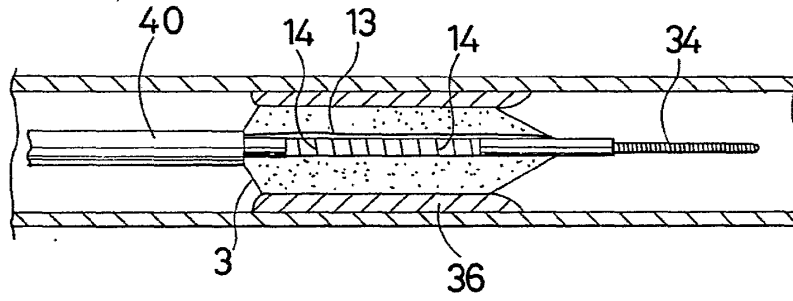


FIG. 48





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 266 957 (C.R. BARD, INC.) * Figures 3,6; column 5, lines 18-39 *	1,4-6, 10-11, 14-16, 18,21- 22	A 61 M 29/02 A 61 M 25/10
Y		2-3,7-9 ,12-13, 17,23	
X	--- US-A-4 597 755 (SAMSON et al.) * Figure 2 *	1,4-6, 10-11, 14-16, 18,21- 22	
X,D	--- WO-A-8 806 465 (TERUMO KABUSHKI KAMSHA) * Abstract; claims 1,17-28 *	1,4-5, 10,11, 19-20, 24	
Y	--- US-A-4 639 252 * Abstract; figures 1,4; column 6, line 48 - column 7, line 24 *	2-3,7-9 ,12-13, 17,23	TECHNICAL FIELDS SEARCHED (Int. Cl.5)  A 61 M
The present search report has been drawn up for all claims			
Place of search <b>THE HAGUE</b>		Date of completion of the search <b>26-01-1990</b>	Examiner <b>MIR Y GUILLEN V.</b>
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... & : member of the same patent family, corresponding document	

EPO FORM 1503 03.82 (P/0401)





**Espacenet**

**Bibliographic data: EP0313558 (A1) — 1989-05-03**

**DILATATION CATHETER WITH EXPANDING BALLOON.**

No documents available for this priority number.

**Inventor(s):** BONZEL TASSILO ± (BONZEL, TASSILO)

**Applicant(s):** BONZEL TASSILO ± (BONZEL, TASSILO)

**Classification:** - international: **A61M25/00; A61M29/02**; (IPC1-7): A61M29/02  
 - cooperative: **A61M25/0032; A61M25/104; A61M2025/0063;**  
A61M2025/1086

**Application number:** EP19870903683 19870606

**Priority number(s):** DE19863621350 19860626

**Also published as:** EP0313558 (B1) DE3621350 (A1) DE3621350 (C2) US5002531 (A)  
JPH01501042 (A) more

**Abstract not available for EP0313558 (A1)**

Last updated: 11.12.2013 Worldwide Database 5.8.15.10: 92p



Europäisches Patentamt  
European Patent Office  
Office européen des brevets

④ Veröffentlichungsnummer:

④ Publication number:

④ Numéro de publication:

0 3 1 3 5 5 8

Internationale Anmeldung veröffentlicht durch die  
Weltorganisation für geistiges Eigentum unter der Nummer:

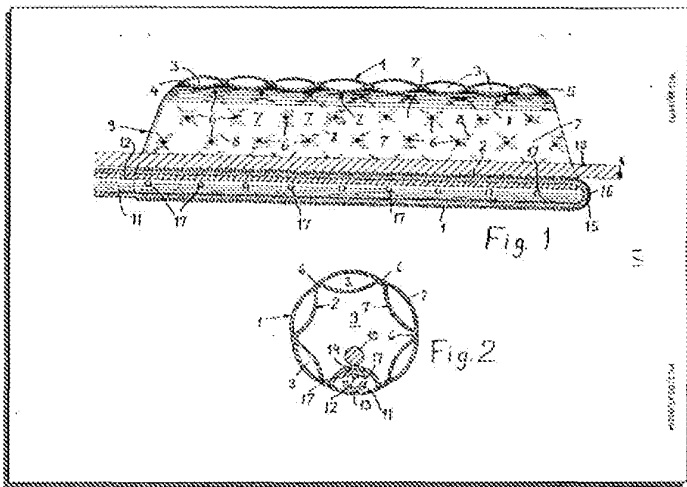
**WO 88/00071** (art.158 des EPÜ).

International application published by the World  
Intellectual Property Organisation under number:

**WO 88/00071** (art.158 of the EPC).

Demande internationale publiée par l'Organisation  
Mondiale de la Propriété Intellectuelle sous le numéro:

**WO 88/00071** (art.158 de la CBE).



Drawing pages of EP0313558 A1



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### DESCRIPTION DE3621350

The invention relates to a dilatation catheter having an inflatable balloon, which is connected along a extending through a guide catheter guide wire into a constricted coronary artery advanceable and an inflation tube through which the expansion of the balloon, a medium into the balloon interior is pressed.

Such a dilatation catheter is disclosed in DE-OS 34 42 736 and is used in particular for expanding constrictions in coronary arteries.

For this purpose, a guiding catheter is demonstrated with a wide inner lumen of the groin or elbow of a patient from the large body arteries until the disposal of the coronary arteries in the aortic arch, a radiological imaging of the coronary vessel and the concentration under fluoroscopy with intermittent administration of contrast medium is performed through the guiding catheter.

To guide the dilatation catheter to be used a fine guide wire with a soft tip will be demonstrated in the coronary artery beyond the narrowing through the guiding catheter.

A control of the guide wire is made possible by a rotation at variable pre-curved peak.

The dilatation catheter is advanced into the next step from the outside over the guide wire which serves as a guide rail, and through the guide catheter until the balloon of the dilatation catheter is located in the constriction.

The expansion then takes place through a single or repeated filling of the balloon with a pressure of about 500 to 1200 kPa. Clinical experience has shown that prolonged dilation to stabilize the enlarged vascular constriction are more beneficial than shorter dilation.

During dilation is interrupted during use of the known dilatation catheters of Blutst in the vessel, wherein the time of the interruption of blood flow to the heart muscle should not exceed 30 to 120 seconds.

If, under the pressure of the balloon the narrowing is expanded in the coronary artery, the layered structure of the vessel wall may be damaged, resulting complications can arise.

These consist in a closure of the vessel after the enlargement by replacing u incident to the inner wall layers and in rare cases in a Wandzerreissung to bleeding.

If, after the Dilatat and removal of the balloon to any of the above complications with vascular closure so this has in some cases, immediate surgery and an increased risk for the patient.

Dilatations of large coronary arteries are therefore performed in acute surgical readiness, whereby the organizational effort and the cost of an operation using a dilatation increase significantly.

Another disadvantage of the known dilatation catheter is that blood flow is interrupted in the vessel during the expansion process, resulting in low perfusion of the downstream tissues.

Starting from this prior art, the invention has the object to provide a dilatation catheter which permits, during dilatation and in the case of a complication to ensure an adequate continuous flow of blood for a sufficient time to allow an extension of the Dilatationszeit.

This object is achieved by the fact that the balloon has a tubular balloon outer shell and connected thereto at least at the points in the axial direction edges tubular balloon inner hull, between which one is connected, formed with an inflation tube in cross-section substantially annular balloon interior, in a axial direction on both sides open central lumen surrounds.

In that the balloon interior forms an annular arrangement with a central erectile tissue lumen, the blood flow in the vessel during the dilatation of the use of the dilatation catheter according to the invention is not interrupted, so that the Dilatationszeit can be extended considerably.

In this way, it is possible to achieve better stabilization of the wall and in the case of a complication to prolong the period up to surgery or even to dispense according to a stabilization of the vessel wall to a surgical procedure.

In an expedient embodiment of the invention, the balloon outer sheath and the balloon inner shell are connected at a plurality of points in the manner of stitching with each other to form a plurality of cushion-shaped spongy, liquid tubular which is provided with a central lumen after the injection of a gas or E or imparting a sufficiently high strength and dilation force tubular dilatation catheter.

Expedient embodiments and further developments of the invention are characterized in the dependent claims.

An embodiment of the invention with reference to an embodiment shown in the drawing will be described.

In the drawings:

1 shows a dilatation catheter according to the invention in longitudinal section and

Figure 2 shows a dilatation catheter according to the invention in cross section.

That shown in Figure 1 in longitudinal section and in cross section in Figure 2 has a double-walled balloon dilatation catheter outer casing 1 which is made of an elastic or non-elastic material as required, and forms an outer tube of the double-walled substantially dilatation catheter.

Approximately concentrically to the balloon outer shell 1 a balloon inner shell 2 is provided, which consists of an elastic or non-elastic material as required.

The balloon inner sleeve 2 is also tubular essentially, wherein between the balloon outer shell 1 and the balloon inner casing 2, a balloon interior 3 is formed, which can for example be designed as an annular gap between the balloon outer shell 1 and the balloon inner sleeve 2.

The balloon outer shell 1 and inner shell 2, the balloon are bonded to each other at their axial edges 4, 5, or welded, so that the balloon interior space 3 is closed in axial direction.

The thus larger the balloon skin 1 diameter, and the balloon inner shell 2 of smaller diameter formed tubular or hose-shaped balloon can be fixed in its structure, for example by a plurality of axially and / or radially extending bonds or welds between the balloon outer shell 1 and the balloon inner shell 2 and be stabilized.

In the embodiment illustrated in Figures 1 and 2, the balloon formed by the outer shell 1 and inner shell 2, the balloon tubular balloon in the manner of a quilting is structured by a plurality of point connections 6.

To the point 6 connections between the balloon outer shell 1 and inner shell 2, the balloon may be bonded to each other or these are welded together.

In this way, corpus cavernosum in the form of cushion-shaped partitions 7 of the balloon inner space 3, wherein the individual pillow-shaped partitions 7 are in each case via connecting-free portions 8 with each other, so that a liquid or gas between the cushion-shaped partitions 7 of the balloon interior space 3 is used to expand the double-walled dilatation can communicate, that can penetrate into all pincushion subdivisions 7 of the balloon interior 3 of the non-bonded areas 8.

The outwardly facing side of the annular balloon dilatation catheter and of the inward-facing side of the balloon are therefore in the expanded state in their surface structure similar to a quilt trained.

Due to the internal pressure in the balloon interior space 3, which is equal to the steady state in each pillow-shaped partitions 7, the balloon is formed with its balloon outer shell 1 and inner shell 2 of its balloon-like structure or a tubular structure of a double-walled pipe.

This results in a mechanical strength and a special self-stability, although the balloon inner casing 2, a central lumen 9 leaves open which extends in the axial direction through the dilatation catheter and permits blood flow through the expanded vessel in the expanded state of the dilatation catheter.

As seen in Figures 1 and 2, extends through the central lumen 9, a guide wire 10 which serves as a guide rail or guide rail and along the advancing of the balloon dilatation catheter through a conventional tubular guide catheter through to the location of the desired intervention in cardiac Crane Tender Herie can be.

Here, the interior of balloon 3 is preferably not filled with a filling medium during advancement so that the radial dimension of the balloon of the dilatation catheter and of the central lumen 9 to reach the surgical site is smaller than in Figures 1 and 2 is shown.

As seen in Figures 1 and 2, an inflation tube 11 projects eccentrically into the balloon of the dilatation catheter.

The inflation tube 11 is reinforced, and transmits within the guide catheter, not shown in the drawing in the axial direction required for advancing and retracting the balloon forces.

For stiffening and increasing the buckling strength may be in the interior of the inflation tube 11, a stabilizing wire 12 may be provided, which is illustrated in Figures 1 and 2.

The inflation tube 11 preferably extends in axial direction from one end 5 to the opposite end 4 of the inner shell 1 and the balloon, the balloon skin 2 and from there over the required length for the connection for the filling medium.

Adjacent to the inflation tube 11 on both sides of a plurality of aligned point connections 6 are provided at an axial distance by which the position of the inflation tube is fixed to 11 in the visible in Figure 2, in the annular space between the balloon outer shell 1 and the balloon inner shell 2.

In addition, the inflation tube 11 along the contact lines 13, 14 may be glued or welded to the outer shell 1 balloon and the balloon inner sleeve 2.

On the left side in Figure 1 of the inflation tube 11 in a manner not shown in detail in Figure 1 connected in the circumferential direction along the outer surface of the dilation catheter to the balloon 3 to seal the interior from the outside.

On the right in Figure 1 side of the inflation tube 11 is closed at its forward end 15.

Along the forward end 15 is a connecting bead 16 is provided, are connected to each other for sealing the balloon space inside the balloon 3 through the outer shell 1 and the inner balloon envelope 2.

In Figures 1 and 2 it can be seen that the inflation tube 11 is connected via a plurality of openings 17 to the balloon interior space 3, so that the press-fit into the inflation tube 11 filling medium can pass into the cushion-shaped divisions 7 in order in this way the expand folded tubular balloon in a deflated condition and to have become stiff.

When the balloon inner shell 2 made of elastic material and said balloon outer casing 1 made of a non-elastic material, as this causes the outside diameter of the balloon of the dilatation catheter of the pressure of the reference liquid is substantially independent.

In this way, the balloon outer casing 1 acts as a holding membrane.

The elastic balloon inner casing 2 may be very small (small surface area), causing the non-filled condition in the deflation of the balloon due to elastic restoring forces of a significant reduction in diameter.

In this way, a particularly easy passage of the dilatation catheter results in the advance or retract through the guide catheter and / or the respective vessel.

If instead the balloon inner shell 2, only the outer shell of the balloon 1 is made of an elastic material, the balloon size can be changed in dependence on the filling pressure of the filling medium, wherein the cross-sectional area of the central lumen 9 remains substantially constant at a filled balloon.

If both the balloon outer shell 1 and inner shell 2, the balloon made of an elastic material causes an increase of the filling pressure of the filling medium mainly an extension of the outer membrane, that is, the balloon outer shell 1

When filling medium 3 rapidly absorbable gases such as CO<sub>2</sub> and N<sub>2</sub>O can be used instead of liquids due to the very small volume of the balloon interior.

While the bursting of the balloon dilatation catheter of the air quantities of such

, 1/10 mm <3> damage. small amounts of N<sub>2</sub>O or CO<sub>2</sub> of less than 1/10 mm <3> are rapidly absorbed and unlikely to cause damage.

This makes it possible to keep the lumen of the inflation tube 11 is extremely small.

If desired, allowing the above-discussed structure of the dilatation catheter to exert only a low pressure effect on the surrounding tissue.

It follows that the use of the dilatation catheter with a double-walled annular balloon is especially useful when higher pressures are not required.

This is not the case with calcified vascular narrowing and stenosis, which has already been widened by means of a conventional balloon catheter, in particular, when the use of a central lumen having no conventional balloon catheter complications have occurred.

In such a case, it is possible to quickly replace the above described dilatation catheter against the previously used single-walled balloon catheter in order to avoid complications, or to achieve stabilization occurred complications permanently or until surgery.



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### CLAIMS DE3621350

1 A dilatation catheter having a inflatable balloon, which is connected along a extending through a guide catheter guide wire into a constricted coronary artery advanceable and an inflation tube through which the expansion of the balloon, a medium is pressed into the balloon interior, characterized in that the balloon, a tubular balloon outer shell (1) and connected to this at least at the points in the axial direction edges (4, 5) tubular balloon inner shell (2), between which a with an inflation tube (11) is connected, is formed in cross-section is substantially ring-shaped balloon interior (3) surrounding an open on both sides in the axial direction of the central lumen (9).

2

A dilatation catheter according to claim 1, characterized in that the guidewire (10) extends through the central lumen (9) in the balloon.

3 A dilatation catheter according to claim 1 or 2, characterized in that the inflation tube (11) is stiffened by a longitudinally extending stabilizing (12).

4 A dilatation catheter according to claim 3, characterized in that the stabilization is realized by a stabilizing wire (12).

5 The dilatation catheter of any one of claims 1 to 4, characterized in that the inflation tube (11) passes through the balloon interior space (3) in the axial direction and opens out via a plurality of the balloon interior (3) openings (17) has.

6

The dilatation catheter of any one of claims 1 to 5, characterized in that the inflation tube (11) is sealed at the entry point into the balloon interior (3) to the outside.

7 A dilatation catheter according to one of claims 1 to 6, characterized in that the balloon inner shell (2) and the balloon outer envelope (1) along a plurality of axially-extending dashed lines are connected.

8 A dilatation catheter according to one of claims 1 to 6, characterized in that the inner balloon envelope (2) and the outer balloon envelope (1) are connected at a plurality of points (6) in the manner of a quilting together.

9 A dilatation catheter according to claim 7 or 8, characterized in that the balloon outer shell (1) and the inner balloon envelope (2) made of inelastic material.

10

A dilatation catheter according to claim 7 or 8, characterized in that the balloon outer shell (1) and the inner balloon envelope (2) made of elastic material.

11 A dilatation catheter according to claim 7 or 8, characterized in that the balloon outer envelope (1) made of an elastic balloon and the inner sheath (2) consists of a non-elastic material.



12 A dilatation catheter according to claim 7 or 8, characterized in that the balloon outer envelope (1) made of a non-elastic balloon and the inner sheath (2) consists of an elastic material.

13 A dilatation catheter according to any one of the preceding claims, characterized in that the points in the axial direction of the edges (4, 5) obliquely with respect to the longitudinal axis of the inflation tube (11), wherein the axial length of the balloon envelope at the free, the inflation tube (11) opposite wall is smaller than in the associated with the inflation tube (11) wall.

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**EUROPEAN PATENT APPLICATION**

21 Application number: **89312612.8**

51 Int. Cl.<sup>5</sup>: **A61M 29/02**

22 Date of filing: **04.12.89**

30 Priority: **30.01.89 US 303803**

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43 Date of publication of application:  
**08.08.90 Bulletin 90/32**

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84 Designated Contracting States:  
**BE DE ES FR GB IT NL**

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54 **Rapidly exchangeable coronary catheter.**

57 A rapidly exchangeable catheter for use in the coronary arteries includes an elongate relatively stiff proximal segment that defines an inflation lumen, an intermediate, shorter segment formed from a more flexible plastic material and having two lumens, and a third, single lumen distal segment. A balloon or other instrumentality adapted to operate in a coronary artery is mounted to the distal region of the catheter. The intermediate and distal segments include a guidewire lumen by which the catheter may be advanced along a guidewire. The proximal segment may include an inflation lumen when the operating instrumentality at the distal end of the catheter is a balloon. The intermediate and distal segments of the catheter are of a length of between about 35 to 45 cm such that when the catheter is advanced into the most remote distal portions of the coronary anatomy, the flexible plastic intermediate and distal segments will extend over the aortic arch of the patient thereby containing the guidewire over the aortic arch and maintaining the juncture of the relatively stiff proximal segment and the more flexible intermediate segment proximally of the aortic arch. The relatively stiff proximal section thus extends generally along a straight line from the femoral artery into the descending aorta but not so far as into the aortic arch. Buckling of the catheter is avoided so that the catheter is more easily manipulated.

**EP 0 380 873 A2**

## RAPIDLY EXCHANGEABLE CORONARY CATHETER

### FIELD OF THE INVENTION

This invention relates to balloon dilatation catheters and particularly to such catheters as are used in percutaneous transluminal coronary angioplasty.

### BACKGROUND OF THE INVENTION

Dilatation catheters, and particularly, those used for percutaneous transluminal coronary angioplasty (PTCA), typically include an elongate flexible shaft of the order of 150 cm long having a dilatation balloon mounted to the distal end of the shaft and an inflation lumen extending longitudinally within the shaft from its proximal end to the interior of the balloon so that the balloon may be inflated and deflated. Typically, such PTCA catheters also are provided with a full length guidewire lumen that is open at the distal tip of the shaft at a distal outlet opening. The proximal end of the guidewire lumen is open at the proximal end of the catheter. The guidewire lumen receives a guidewire which, when the guidewire and catheter are placed within a patient's artery, can be manipulated to guide the wire and catheter to the desired branch of the patient's arteries.

Typically, the balloon dilatation catheter and guidewire are guided to the entrance to the coronary arteries by a previously placed guide catheter. The guide catheter commonly is percutaneously inserted into the patient's femoral artery and is advanced along the aorta toward the heart. The guide catheter typically is provided with a preshaped distal tip adapted to remain at the coronary ostium leading to the coronary artery. Once placed, the guide catheter provides direct, quick access to the entrance to the coronary arteries.

It is common during a PTCA procedure for the physician to exchange the balloon catheter for another catheter, for example, if it is desired to change balloon sizes. This may occur, for example, if the physician initially performed a partial dilatation with a small diameter balloon and then wished to further dilate the patient's artery by using a catheter having a larger balloon. Such a catheter exchange may be accomplished in several ways. In one technique, the conventional guidewire which may be approximately 175 cm long is removed from the in situ balloon catheter and is replaced with a longer exchange wire, typically about 300 cm long. The length of the exchange wire that extends out of the patient is greater than the length

of the balloon catheter thus providing a means by which the guidewire may be grasped at all times to prevent inadvertent withdrawal of the guidewire as the catheter is withdrawn. Once the catheter is withdrawn over the exchange wire, the next catheter can be threaded over the exchange wire and inserted into the patient, the exchange wire providing a direct path to guide the catheter to the portion of the artery to be dilated. If desired, the exchange wire then may be removed and replaced with a shorter conventional wire, although some physicians may prefer to permit the exchange wire to remain in place for the remainder of the procedure.

Another technique omits the necessity for an exchange wire by providing a guidewire extension that is attached to the proximal end of the guidewire thereby effectively extending the length of the guidewire that protrudes out of a patient sufficiently to permit the catheter to be withdrawn and a new catheter to be threaded back into the patient without losing guidewire position.

Still another technique for performing a catheter exchange is that described in "New Instruments for Catheterization and Angiocardiology" by Bjorn Nordenstrom, Radiology, Vol. 85, 1965, pp. 256-259, which describes a catheter having a relatively short guidewire lumen at the distal end of the catheter, the guidewire lumen having a proximal terminal opening located distally of the proximal end of the catheter shaft. In this arrangement, the guidewire passes through the catheter shaft only for a segment of the length of the shaft. The catheter can be moved along the guidewire in the fashion of a "monorail". Because the guidewire lumen is relatively short and is considerably shorter than the overall length of the catheter, the catheter can be withdrawn from the patient over the original guidewire without dragging the guidewire out of the artery together with the catheter because the length of guidewire protruding from the patient is longer than the length of the guidewire lumen of the catheter. Thus, a portion of the guidewire is exposed at all times and may be grasped by the physician. Such a monorail system has recently been incorporated into PTCA catheters as illustrated, for example, in U.S. Patent Nos. 4,762,129 (Bonzel) and 4,748,982 (Horzewski).

Although the use of the monorail system facilitates catheter exchanges, the PTCA catheters in which the monorail system have been incorporated have presented some difficulties. One of the problems presented is that because the guidewire only extends through a relatively small portion of the overall length of the catheter, the remaining portion

of the catheter shaft is unsupported by the guidewire. When the balloon catheter and guidewire are advanced through the guide catheter by pushing the catheter shaft, the unsupported portion of the catheter shaft tends to buckle within the guide catheter. Buckling of the catheter shaft within the guide catheter increases the number and area of points of contact between the catheter shaft and the inner surface of the guide catheter lumen, thus increasing friction and causing the balloon catheter to bind up in the guide catheter and impairing the ability of the catheter to be pushed along the guidewire. The tendency to become bound up in the guide catheter increases with the extent to which the catheter is advanced through the guide catheter and prevents the catheter from being advanced into distal coronary vasculature. The tendency for the dilatation catheter shaft to buckle is particularly acute in the region of the aortic arch.

It is among the general objects of the invention to provide an improved PTCA catheter having a rapid exchange feature which avoids the foregoing and other difficulties.

#### SUMMARY OF THE INVENTION

The catheter of the present invention is formed from a composite shaft that includes an elongate proximal segment formed from a relatively stiff metal tube and defining an inflation lumen, an intermediate, shorter segment formed from a more flexible, plastic material and having two lumens, and a third single lumen distal segment. The intermediate segment includes an inflation lumen that is a continuation of the inflation lumen of the proximal segment and a second, parallel guidewire lumen. The third, distal tubular segment is formed from flexible plastic material and has a single lumen which is a continuation of the guidewire lumen in the intermediate segment and opens at a distal outlet tip. The dilatation balloon is mounted on the distal end of the catheter with its proximal end mounted to the intermediate segment and its distal end mounted to the distal segment. The guidewire lumen has a proximal opening proximally of the balloon and communicates with the lumen of the distal segment and distal outlet opening distally of the balloon.

The intermediate and distal segments are of a combined length, between about 35 cm to 45 cm, such that with the catheter advanced into the most remote distal portions of the coronary anatomy, the flexible plastic intermediate segment will extend over the aortic arch of the patient. The juncture of the relatively stiff proximal segment and the more

flexible intermediate segment thus remains proximally of the aortic arch so that the relatively stiff elongate proximal section extends generally along a straight line from the femoral artery into the descending aorta, but not so far as into the aortic arch. The moderately flexible proximal segment is sufficiently stiff and is self-supporting so that it will not buckle in the guide catheter as the catheter is pushed in a distal direction. Additionally, the intermediate and distal segments of the catheter are fully supported by the guidewire that extends through the guidewire lumen and thereby provides substantial support for the intermediate and distal segments of the catheter. The catheter construction does not tend to bind up within the guide catheter and thereby facilitates advancement of the distal balloon end of the catheter into more distal regions of a patient's coronary anatomy. Moreover, because the cross-section of the metal tubular proximal segment is relatively small, it presents reduced obstruction through the guide catheter to a flow of radiopaque contrast liquid and, thereby, makes it easier for the physician to inject contrast liquid into the patient's coronary arteries in order to visualize them fluoroscopically.

It is among the general objects of the invention to provide an improved rapidly exchangeable balloon dilatation catheter.

Another object of the invention is to provide a rapidly exchangeable balloon dilatation catheter which is provided with axial support along the full length of the catheter.

Another object of the invention is to provide a rapidly exchangeable catheter having a relatively flexible distal portion that receives a guidewire and is of sufficient length that it can extend from the distal coronary anatomy over the aortic arch and into the descending aorta.

A further object of the invention is to provide a rapidly exchangeable catheter having an elongate moderately flexible self supporting proximal section and at least one distal section that is more flexible and has a guidewire lumen extending therethrough whereby the guidewire may support said distal segments.

A further object of the invention is to provide a rapidly exchangeable catheter which has a reduced tendency to buckle within the guide catheter.

Another object of the invention is to provide a rapidly exchangeable catheter which provides reduced friction in the guide catheter.

A further object of the invention is to provide a rapidly exchangeable catheter which better enables the physician to advance the distal end of the catheter into the distal coronary anatomy of a patient.

### DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a fragmented illustration of the catheter;

FIG. 2 is an enlarged illustration of the catheter;

FIG. 3 is a diagrammatic illustration of a patient showing the manner in which a balloon catheter is advanced from the femoral artery through the aorta to the patient's heart;

FIG. 4 is an illustration of the aorta leading from the heart and coronary arteries with a guide catheter in place and the catheter of the present invention extending through the guide catheter;

FIG. 5 is a cross-sectional illustration of the two lumen segment of the intermediate segment of the catheter as seen along the line 5-5 of FIG. 2;

FIG. 6 is an enlarged illustration of the proximal end of the balloon and its point of attachment to the intermediate segment;

FIG. 7 is a sectional longitudinal illustration of the catheter in the region where the proximal metal tubular segment is joined to the intermediate more flexible plastic segment; and

FIG. 8 is an enlarged longitudinal sectional illustration of the distal end of the catheter showing the balloon and the manner of its attachment to the intermediate and distal segments.

### DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

FIG. 3 illustrates, diagrammatically, a conventional over-the-wire balloon dilatation catheter 10 and a guidewire 12 inserted into the patient's vasculature through a guide catheter 14. The guide catheter 14 is initially placed, percutaneously, into the patient's femoral artery 16 and is advanced along the descending aorta 18 over the aortic arch 20 and into the ascending aorta 22 that leads from the heart 24. As will be appreciated by those skilled in the art, the distal end of the guide catheter is specially shaped so that the distal tip 23 of the guide catheter will easily lodge in the entrance to the right 25 or left 27 coronary artery (see FIG. 4).

When it is desired to exchange the balloon catheter 10 for another, it is important that the guidewire 12 be maintained within the patient's artery so that it may guide the next succeeding

catheter quickly and efficiently to the intended site in the patient's vascular system. Typically, the clearances between the guidewire 12 and the inner lumen of the catheter 10, coupled with the bends which the catheter 10 and guidewire 12 must follow along the patient's artery are such that withdrawal of the catheter 10 tends to drag the guidewire 12 out with the catheter 10. In order to maintain the guidewire 12 in place while the catheter 10 is withdrawn, it is necessary to hold the guidewire 12 by its proximal end while withdrawing the catheter 10 over the guidewire 12.

Among the techniques for facilitating a catheter exchange is the use of a monorail-type of catheter in which the guidewire lumen in the catheter extends only over a relatively short length of the catheter at the distal end of the catheter. Because the guidewire lumen is shorter than the portion of the guidewire that protrudes out of the patient, some part of the guidewire is always exposed and may be grasped to maintain guidewire position. With the monorail system, it is unnecessary to use exchange wires or other devices to increase the effective length of the guidewire in order to perform a catheter exchange.

FIG. 2 is a fragmented illustration of a catheter in accordance with the invention. The catheter 26 includes an elongate proximal segment 28 which is formed from metallic hypodermic tubing, preferably stainless steel. The proximal segment may be of the order of 100 to 110 cm long. The tubing 28 may be of the order of 0.022" outer diameter with a wall thickness of about 0.003". The catheter 26 also includes an intermediate segment 30 attached at its proximal end to the distal end of the metal tube 28 and being shorter in length than the metal tube 28. The catheter also includes a distal segment 32 (FIGS. 2 and 8) attached to the distal end of the intermediate segment 30. A dilatation balloon 34 is mounted on the distal segment 32 as will be described. The metallic tubular proximal segment 28 defines a lumen 36 (FIG. 7) that extends fully through its length. A luer fitting 38 is attached to the proximal end of the tubing 28 to connect the lumen 36 with an inflation/deflation device, such as a syringe (not shown). The lumen 36 communicates with a lumen 40 in the intermediate segment 30. The lumen 40 terminates at a port 42 disposed within the balloon 34. Thus, the balloon 34 may be inflated and deflated through the inflation/deflation lumens 36, 40 in the metal tube 28 and intermediate segment 30, respectively.

As will be described, the metal tubular segment 28 provides for a high degree of column strength and enables the catheter to be pushed from its proximal end without buckling. The metal tube 28 may be coated with a thin film of lubricious material, such as Teflon, polytetrafluoroethylene.

The flexible plastic intermediate segment 30 may be an extruded tube of suitable plastic such as high density polyethylene. The intermediate segment 30 may be of the order of .045 inches outer diameter. The length of the intermediate segment 30 is between about 30 to 40 cm for reasons discussed below. The intermediate segment 30 has two lumens including the inflation lumen 40 which may be somewhat D-shaped as illustrated in FIG. 5. The other lumen 44 may be circular as shown in FIG. 5 and is adapted to receive the guidewire 12. The guidewire lumen 44 may be of the order of .020 inches diameter. The guidewire lumen terminates in a proximal opening 46 so that the guidewire is exposed proximally of the intermediate segment 30. Thus, the guidewire may extend within the guide catheter 14 in parallel to and outside of the proximal segment 28.

The distal segment 32 of the catheter is formed from a separate length of single lumen tubing which may be extruded from a relatively flexible plastic material such as low density polyethylene. The distal segment 32 is circular in cross-section and has a circular lumen 48 FIG. 6 which is an extension of the guidewire lumen 44 in the intermediate segment 30. The distal tip of the distal segment 32 is open at a distal outlet orifice 33 FIG. 8. The distal segment 32 may be attached by fusing its proximal end to the distal end of the intermediate segment 30 while maintaining continuation of the guidewire lumen 44, 48 and the opening 42 of the inflation lumen 40 by inserting mandrels in those lumens during the fusion process. A highly radiopaque marker band preferably is mounted on the distal segment 32 and is encapsulated in an overlying thin polyethylene sleeve 37, the sleeve 37 extending proximally over the joint 39 between the intermediate segment 30 and distal segment 32. The sleeve 37 also is heat fused to the shaft. The distal segment 32 may have a wall thickness of the order of .0035 inches thereby making it more flexible than the more massive intermediate segment 30. A radiopaque marker band 35 formed from an appropriate radiopaque material, such as gold or platinum, may be mounted on the distal segment 32.

The balloon 34 is mounted on the distal region of the catheter. The balloon 34 may be formed from a suitably flexible strong and relatively inelastic material such as polyethylene terephthalate. The balloon may be formed in a procedure described in U.S. Patent No. 4,490,421 to Levy. The balloon may be of the order of 20 mm long and may have a balloon diameter when inflated of from about 1.5 mm to 4.0 mm. The wall thickness may be of the order of 0.0005" to 0.001". The balloon includes an elongate cylindrical portion having integral tapering conical sections 49, 51 at each of its proximal and

distal ends. Each of the conical sections merges into a small diameter cylindrical neck, the neck 52 at the proximal end of the balloon being larger in diameter than the neck 54 at the distal end. The proximal neck 52 is mounted on the distal region of the intermediate segment 30 and the distal neck 54 is mounted on the distal portion of the distal segment 32. The neck portions 52, 54 are securely bonded to the intermediate and distal segments 30, 32, respectively, by an appropriate adhesive such as an epoxy.

The manner in which the catheter of the present invention is used will be appreciated from FIGS. 3 and 4. In a typical procedure, the femoral artery 16 is accessed percutaneously by a hollow needle. After inserting the needle into the femoral artery, a relatively large diameter guidewire (about 0.038" diameter) is advanced through the needle and into the femoral artery. The needle is removed and an introducer sheath and dilator are placed inside the artery. The dilator is then removed. The guide catheter is inserted over the guidewire and is advanced along with the guidewire to the ascending aorta when the .038" guidewire is removed. The distal end of the guide catheter 14 is shaped specially to be easily inserted into the entrance of one of the two coronary ostia to access either the right or left main coronary arteries. FIG. 4 illustrates a guide catheter 14 seated in the left coronary ostium. Once the guide catheter is in place, the 0.038" guidewire may be removed. The guide catheter 14 then is ready to receive the dilatation catheter and its small diameter (e.g., .010"-.018" diameter) guidewire.

In placing the small diameter steerable guidewire 12 and the conventional over the wire balloon dilatation catheter 10, it is conventional practice to first assemble the guidewire 12 with the balloon catheter 10 and then pass them both in unison through the guide catheter. Alternately, with the present invention, the guidewire 12 may be inserted through the guide catheter by itself. The guidewire is advanced to the coronary ostium and then may be further advanced into the coronary arteries. The guidewire may be of the type described in U.S. Patent 4,545,390 to Leary and may be steerable so that it can be manipulated and guided to the desired branch of the coronary arteries to be treated. The progress of the guidewire through the patient's coronary arteries may be monitored fluoroscopically by the physician. The physician also may inject radiopaque contrast liquid through the guide catheter to visualize the coronary anatomy on the fluoroscope. Once the guidewire 12 has been advanced through the stenosis to be treated, the balloon catheter 26 of the present invention is advanced over the guidewire 12 and within the guide catheter 14. The

catheter 26 will track smoothly and easily along the guidewire with no significant tendency to buckle. This results from the relatively stiff, pushable nature of the elongate metal tubular proximal segment 28 of the catheter. Additionally, the intermediate and distal segments 30, 32 are supported by the guidewire 12 which provides significant resistance to buckling of the intermediate and distal segments 30, 32. It will be appreciated, therefore, that when the catheter 26 is advanced over the guidewire, the catheter will have significant axial, column support fully along its length. In this regard, it is important to note that the proximal end of the guidewire lumen 44 in the intermediate segment 30 overlaps longitudinally, the distal end of the metal tubular proximal segment 28 that is embedded in the proximal end of the intermediate segment 30. Thus, when the catheter is advanced over the guidewire 12, there is column support fully along the length of the catheter, from its proximal to its distal end. As a result, there is considerably reduced tendency for any portion of the catheter to buckle longitudinally. Consequently, the friction between the balloon dilatation catheter 26 and the guide catheter 14 is substantially reduced thereby enabling the distal end of the catheter to be advanced into distal, remote and tortuous regions of the patient's coronary anatomy.

In order to better grasp the proximal end of the catheter to push it through the guide catheter, a gripping device 56 may be mounted on the proximal segment 28. The gripping device 56 includes a nut 58 which is threaded into a tubular collet 60. The collet 60 and nut 58 are screwed together over the proximal segment 28 to cause the collet 60 to securely grip the proximal segment 28. The position of the gripping device 56 may be adjusted by loosening the nut and repositioning the device.

It should be noted that the length of the intermediate and distal segments 30, 32 are selected so that when the balloon is placed in a very distal region of the coronary anatomy, the juncture of the proximal end of the intermediate segment with the proximal tubular segment 28 is disposed in the descending aorta 18 and does not extend into the aortic arch 20. Thus, the combined length of the intermediate and distal segments 30, 32 should be between 35 to 45 cm long, with a length of 40 cm being preferred for most patients' anatomies. It will be appreciated from the foregoing construction that the flexible intermediate and distal portions 30, 32 will pass easily through the curve of the aortic arch 20 without tendency to buckle because they are fully supported by the guidewire 12. The relatively stiff elongate metal proximal segment 28 does not pass through the aortic arch 20 and maintains its relatively straight configuration so that its pushable characteristics are not compromised. There is mini-

mal tendency of the catheter to dislodge the distal tip of the guide catheter from its position in the coronary ostium.

Should it be desired to exchange the balloon catheter 26 for another catheter, there is no need to use an extended length guidewire. Typically, about 50 cm of the guidewire 12 will protrude exteriorly of the patient. When the catheter 26 is withdrawn, a segment of the guidewire 12 will be exposed at all times, thereby enabling the guidewire 12 to be grasped to maintain its position in the patient. Thus, the catheter 26 may be withdrawn without dragging the guidewire 12 out of position. After the first catheter has been removed, another catheter may be threaded onto the guidewire and advanced through the guide catheter and into the coronary anatomy, guided by the guidewire 12. The catheter constructed in accordance with the invention will be advanced easily, without tendency to buckle or develop high friction within the guide catheter and with no significant tendency to dislodge the guide catheter from its position at the coronary ostium.

From the foregoing, it will be appreciated that the invention provides an improved rapidly exchangeable catheter construction and catheterization method.

It should be understood, however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications and embodiments may be apparent to those skilled in the art without departing from its spirit.

For example, although the invention has been illustrated in connection with a balloon dilatation catheter, it may also be incorporated in other types of catheters, such as laser catheters, hot tip catheters, infusion catheters, artherectomy catheters and the like.

## Claims

1. A balloon dilatation catheter for percutaneous transluminal coronary angioplasty comprising:
  - an elongate proximal segment formed from a relatively stiff tubular shaft having an inflation lumen extending therethrough;
  - an intermediate catheter segment attached to the distal end of the proximal segment, the intermediate segment being formed from a more flexible elongate plastic member having two lumens formed therethrough including a first lumen in communication with the inflation lumen of the proximal segment to define a continuation of the inflation lumen, the inflation lumen in the intermediate segment terminating in an outlet port, the intermediate segment having a second, guidewire lumen extend-

ing parallel to the first lumen and being adapted to receive a guidewire, the guidewire lumen having a proximal opening in the region of the juncture of the intermediate and proximal segments;

a distal segment attached to the distal end of the intermediate segment and defining an elongate lumen in communication with and defining a continuation of the distal end of the guidewire lumen of the intermediate segment, and terminating, at its distal tip, in a distal outlet;

a dilatation balloon mounted on the distal and intermediate segment, the interior of the balloon being in communication with the outlet port of the inflation lumen;

whereby when a guidewire is received in the guidewire lumen the catheter will have continuous column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

2. A balloon dilatation catheter as defined in claim 1 wherein the proximal end of the balloon is mounted to the distal end of the intermediate segment and the distal end of the balloon is mounted to the distal end of the distal segment.

3. A balloon dilatation catheter as defined in claim 2 wherein the distal segment is of smaller diameter and is more flexible than the intermediate segment.

4. A balloon dilatation catheter as defined in and of claims 1-3 wherein the distal and intermediate segments extend over a length of between 35 to 45 cm and wherein the overall length of the catheter is between about 145 to 155 cm.

5. A balloon dilatation catheter as defined in claim 4 wherein the length of the distal and intermediate segments is about 40 cm.

6. A balloon dilatation catheter as defined in any of claims 1-3 or 5 further comprising, in combination, a guidewire extending through the guidewire lumen.

7. A balloon dilatation catheter as defined in claim 4 further comprising, in combination, a guidewire extending through the guidewire lumen.

8. A catheter for accessing the coronary arteries in a human comprising:

an elongate proximal segment comprising a relatively stiff tube;

a relatively flexible elongate plastic member mounted to the distal end of the proximal segment, the plastic member being more flexible than the proximal segment and having a guidewire lumen formed therethrough, the guidewire lumen having a proximal opening in the region of the juncture of the plastic member and the proximal segment and having a distal opening at its distal end whereby when a guidewire is contained within the lumen, the catheter will have continuous longitudinal support from its proximal end to its distal tip; and

means carried by the distal end of the plastic member for performing a procedure in a coronary artery.

9. A catheter as defined in claim 8 wherein the means for performing a procedure in an artery comprises a dilatation balloon and where the proximal segment and the plastic member have an inflation lumen communicating the interior of the balloon with the proximal end of the catheter.

10. A catheter as defined in either of claims 7 or 8 wherein the plastic segment is between 35 to 45 cm long.

11. A catheter as defined in claim 9 wherein the plastic segment is about 40 cm long.

12. A catheter as defined in any of claims 8, 9 and 11 further comprising, in combination, a guidewire extending through the guidewire lumen.

13. A catheter as defined in claim 10 further comprising, in combination, a guidewire in the guidewire lumen.

14. A catheter as defined in either of claims 4 or 9 wherein the guidewire is about 175 cm long.

15. A catheter as defined in any of claims 1-3 and 8-11 wherein the proximal segment is formed from metal.

16. A catheter as defined in claim 4 wherein the proximal segment is formed from metal.

17. A catheter as defined in claim 6 wherein the proximal segment is formed from metal.

18. A catheter as defined in claim 12 wherein the proximal segment is formed from metal.

19. A catheter as defined in claim 10 wherein the proximal segment is formed from metal.

20. A catheter as defined in claim 14 wherein the proximal segment is formed from metal.

21. A method for performing a procedure in a coronary artery comprising:

percutaneously placing the small diameter steerable guidewire in the patient's arteries and advancing the guidewire into a selected coronary artery; percutaneously inserting a catheter as defined in either of claims 4, 8 or 10 into the patient's arterial system over the guidewire;

advancing the catheter through the patient's arterial system over the guidewire to place the distal end of the catheter in the coronary artery, with the juncture of the plastic portion and proximal portion of the catheters being disposed proximally of the aortic arch;

whereby the relatively stiff proximal segment of the catheter will remain substantially straight within the descending aorta and the catheter will be supported by the guidewire fully through the aortic arch and into the patient's coronary arteries.

22. A method as defined in claim 21 further comprising:

performing a catheter exchange including the steps of withdrawing the catheter while holding the



guidewire from its proximal end thereby to maintain the position of the guidewire; advancing another catheter constructed as defined in claims 4, 8 or 10 over the guidewire and advancing the catheter along the guidewire to the intended site in the patient's coronary arteries.

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23. A method as defined in claim 21 wherein the proximal segment of the catheter is formed from metal.

24. A method as defined in claim 22 wherein the proximal segment of the catheter is formed from metal.

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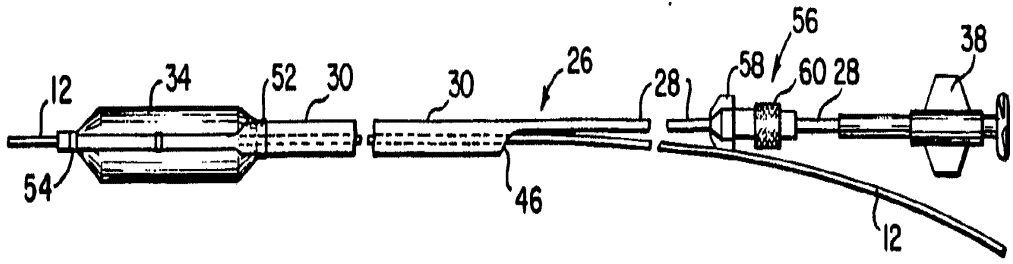
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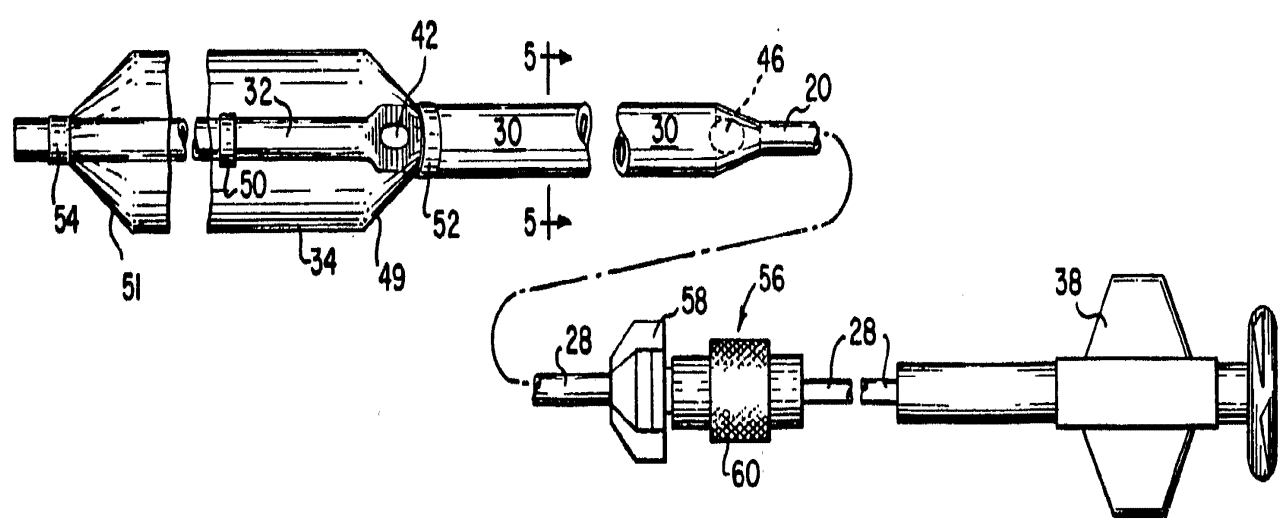
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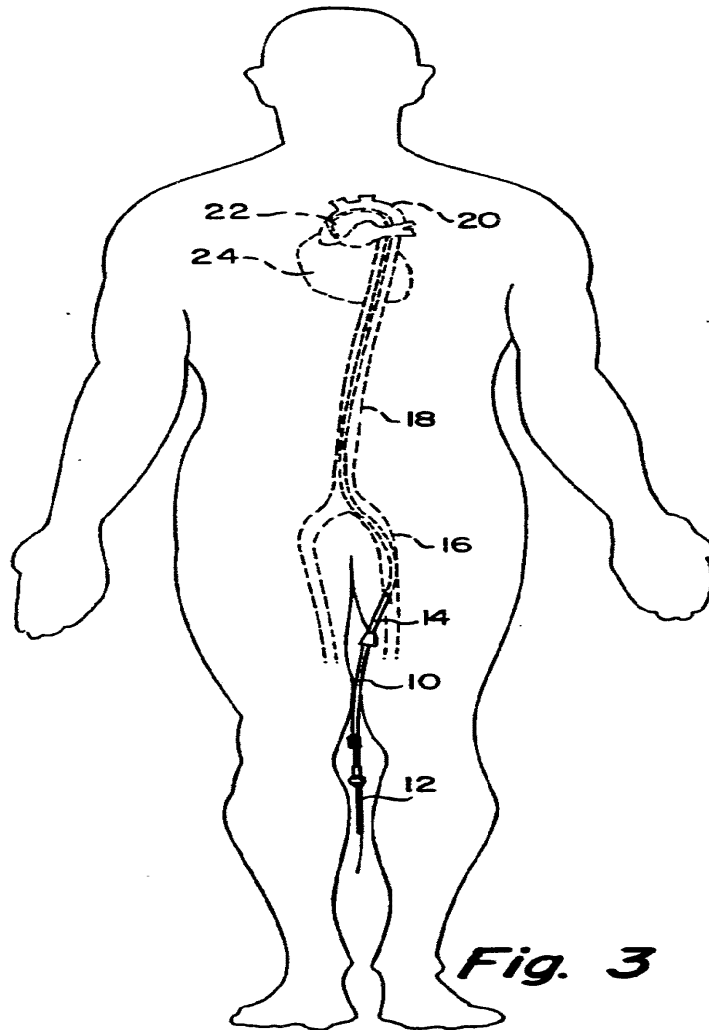


*Fig. 1*

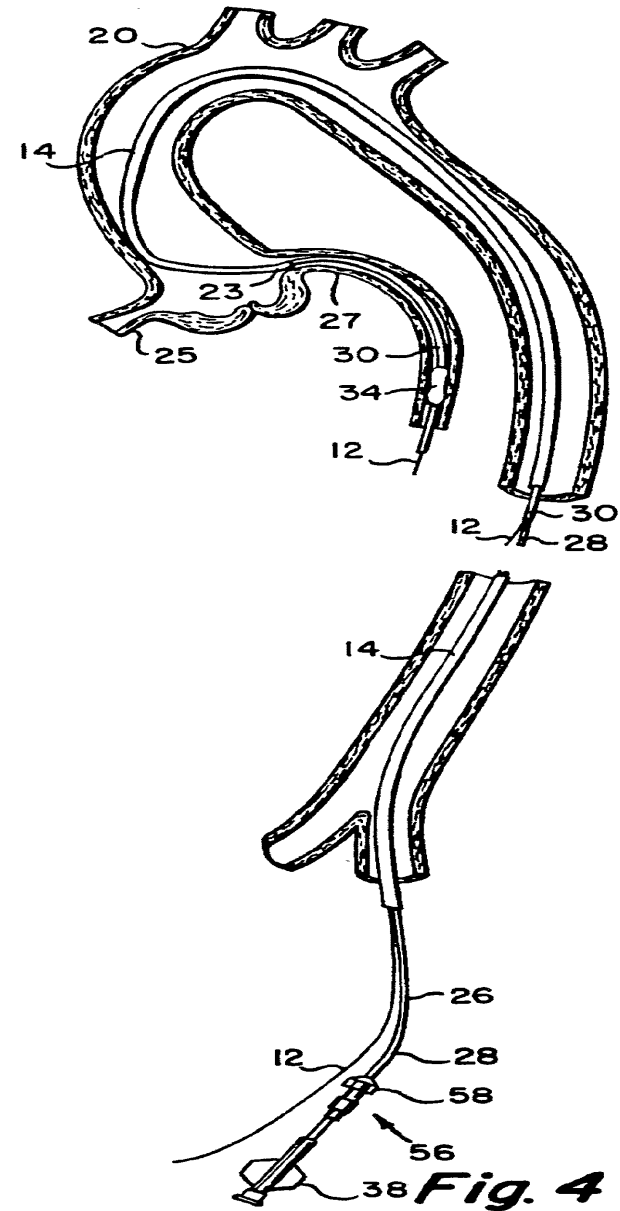


*Fig. 2*

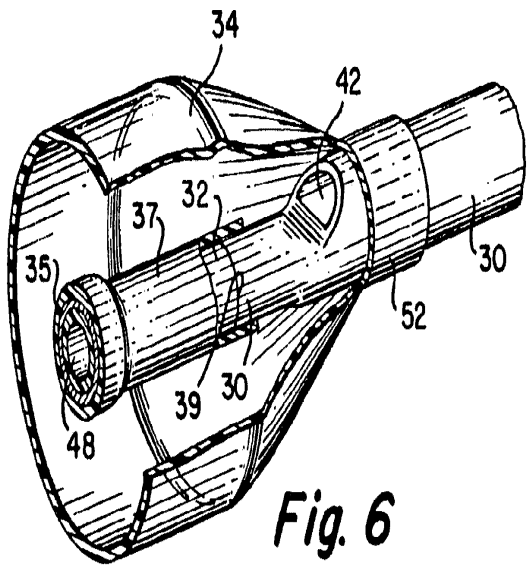
EP 0 380 873 A2



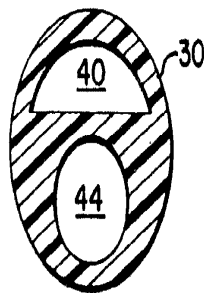
**Fig. 3**



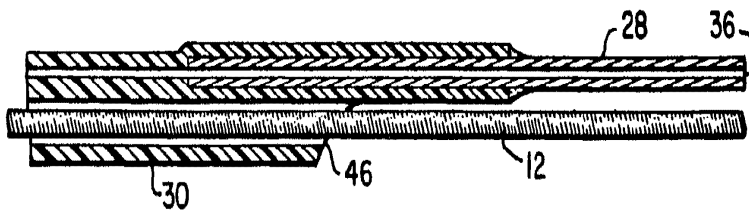
**Fig. 4**



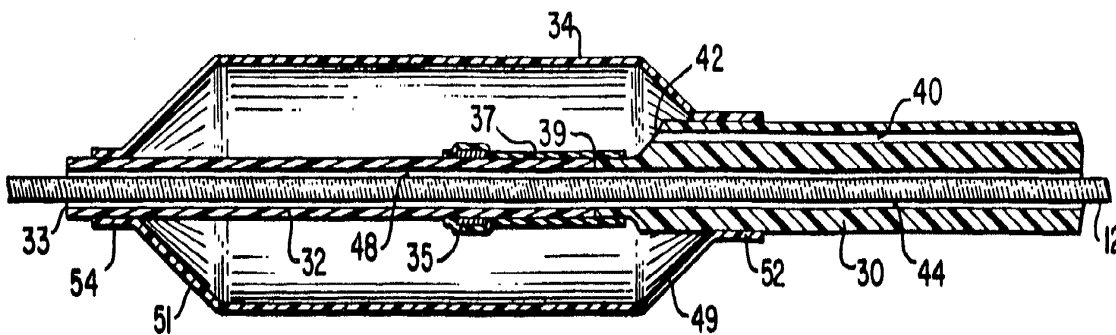
**Fig. 6**



**Fig. 5**



**Fig. 7**



**Fig. 8**

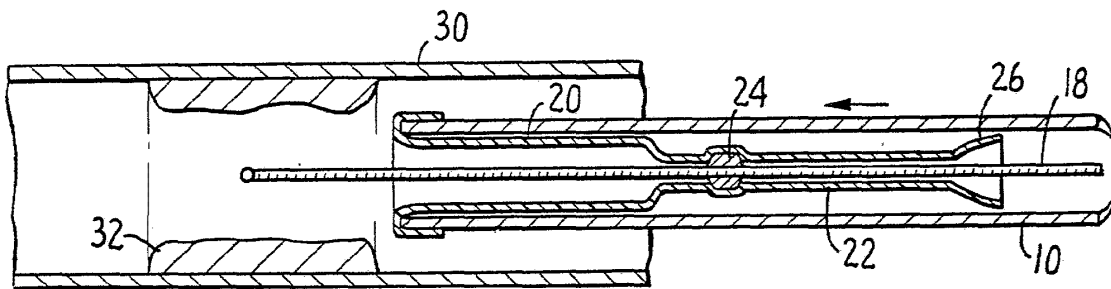
EP 0 380 873 A2



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification<sup>3</sup> : <b>A61M 29/02</b></p>	<p>A1</p>	<p>(11) International Publication Number: <b>WO 84/ 03633</b>                   (43) International Publication Date: 27 September 1984 (27.09.84)</p>
<p>(21) International Application Number: PCT/US84/00455                  (22) International Filing Date: 23 March 1984 (23.03.84)                  (31) Priority Application Number: 478,708                  (32) Priority Date: 25 March 1983 (25.03.83)                  (33) Priority Country: US                   (71)(72) Applicant and Inventor: FOGARTY, Thomas, J. [US/US]; 770 Welch Road, Palo Alto, CA 94304 (US).                  (72) Inventors: FINN, James, C., III ; Hulme 8H, Escondido Village, Stanford, CA 94305 (US). KINNEY, Thomas, B. ; 541 El Medio Avenue, Mountain View, CA 94040 (US).                  (74) Agent: UILKEMA, John, K.; Limbach, Limbach &amp; Sutton, 2001 Ferry Building, San Francisco, CA 94111 (US).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), SE (European patent).   <b>Published</b>  <i>With international search report.</i></p>

(54) Title: INVERTED BALLOON CATHETER HAVING SEALED THROUGH LUMEN



(57) Abstract

A balloon catheter (20) of the linear eversion type is provided with a sealed through lumen (22-24) which will pass guide wires (18) and other objects without disturbing the sealed nature of the balloon system.

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-1-

INVERTED BALLOON CATHETER  
HAVING SEALED THROUGH LUMENBACKGROUND OF THE INVENTION1. Field of the Invention

5           The field of the invention is dilatation catheters  
having evertable-invertible balloons for dilating strictures  
or stenoses of tubular elements and passageways of the body.  
More specifically, the field of the invention is the provision  
in such catheters of a central through lumen provided with  
10 means enabling the passage through the balloon of a guide  
wire or other element while providing a sealed balloon system  
at all times.

2. Description of the Prior Art

15           In the dilatation catheter art, it is old to provide  
such catheters with evertable-invertible balloon elements.  
Attention is directed to U.S. patent No. 4,254,774 in this  
regard. Such balloon catheters, however, have not, insofar as  
we are aware, been provided with sealed through lumens enabling  
the passage through the balloons of guide wires and other  
20 instruments.

SUMMARY OF THE INVENTION

25           The essential object of the invention is to provide  
a balloon catheter of the evertable-invertible type with a  
means for passing an object, such as a guide wire or a cannula,  
through the balloon while maintaining a sealed balloon system.

          This is accomplished, in a preferred way, by providing  
the free end of the balloon with a small axial elastomeric plug



-2-

and providing the plug with a normally closed passageway such as one formed by pushing a needle through the plug and by then withdrawing the needle. When the balloon is subjected to inflation pressure the plug acts as an imperforate part of the balloon whether or not a guide wire or the like is extending  
5 through the plug.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a view in perspective of a preferred embodiment of the catheter of the invention.

10 Fig. 2 is an enlarged view in diametral cross-section of said catheter.

Fig. 3 is a similar view showing the catheter strung on a guide wire and positioned adjacent a stenosis to be treated.

15 Fig. 4 is a similar view showing the balloon everted and within the stenosis.

Fig. 5 is a similar view showing the balloon inflated to dilate the stenosis.

Fig. 6 is a similar view showing an open ended tube extending along the lumen of the catheter.

20 Fig. 7 is a view of tube and plug elements prior to their securement together, the tube being shown in diametral section.

Fig. 8 is a view of the balloon and plug assemblage prior to the attachment of the assemblage to the catheter.

25 Fig. 9 shows the assemblage of Fig. 8 in attached relation to the catheter and in inverted position therein.

Fig. 10 is a detail view in diametral cross-section of a sealing means which may be employed at the proximal end of the catheter to maintain the balloon pressurized while a  
30 guide wire extends through the catheter.

Fig. 11 is a view showing a form of purging system which may be employed with the catheter.

Fig. 12 shows another form of purging system which may be employed with the catheter.





-3-

Fig. 13 illustrates a means for inverting the balloon.

Fig. 14 shows a modified form of balloon inversion means.

Fig. 15 shows how the catheter may be moved from one stenosis to another without inverting the balloon.

Fig. 16 is a view in diametral section of another embodiment of the catheter.

Fig. 17 is an enlarged detail view illustrating how the lumen sealing means of this embodiment operates.

Fig. 18 is a view in perspective of the distal end of still a further embodiment of the subject catheter.

Fig. 19 shows the distal end of the catheter of Fig. 18 with the balloon being in inverted position.

Fig. 20 is a view illustrating the sealing action which occurs when the catheter of Fig. 19 is subjected to balloon-inflating pressures.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The catheter of Figs. 1-15 comprises a flexible tubular body 10, fluid feed fitting 12, hub 14, screw plug 16, guide wire 18, balloon 20, balloon tubular extension 22, plug 24 and funnel-like end 26 formed on extension 22. The end of the balloon is folded over the distal end of tube 10 and sealingly secured thereto.

Figs. 7-9 illustrate the preferred way of making the balloon and balloon extension assemblage. The plug 24 (Fig. 7) of elastomeric material, such as silicone adhesive/sealer, is pierced axially with a needle which is then withdrawn, thereby forming a normally closed or sealed passageway 28 through the seal. The plug is then placed within a tube 11 of polyethylene or other suitable material for an expansible non-elastic balloon. By heat treatment the tube is caused to shrink in the region surrounding and adjacent to the plug so as to form the shape of the assemblage shown in Fig. 8. The plug is gripped and embraced by the containing tube, or extension 22. The assemblage



-4-

is then secured to the tube 10, as shown in Fig. 9.

30 is an artery or other body tube having a stenosis or stricture 32. The sequence of usage of the catheter to accomplish dilatation of the stenosis 32 is shown in Figs. 3-5. The catheter is threaded along guide wire 18 which traverses the plug passageway 28 and the entire catheter. When the distal end of the catheter is positioned adjacent stenosis 32, the guide wire is preferably withdrawn from the balloon and balloon extension assemblage 20, 22. The wire may remain in the proximal end of the catheter to serve as part of a sealing means (Fig. 10) comprising wire 18, compressible O-ring 34 and screw plug 16 to compress ring 34 into sealing and gripping relation with wire 18.

Inflation fluid is then injected through fitting 12 to cause eversion of the balloon into stenosis 32, as shown in Fig. 4. After balloon eversion, the balloon is further inflated to expand radially and dilate the stenosis, as shown in Fig. 5. During all this inflation activity, the plug passageway 28 remains in its normally closed position. The balloon and balloon extension are thereby provided with a sealed through lumen.

Regardless of the condition of the balloon, whether it is inverted, everted or radially inflated, thin, tubular elements, such as 36 in Fig. 6, may be passed through the plug. The tube 36 may be then used to monitor pressure conditions at the distal tip of the catheter; it may be used for the delivery of diagnostic or therapeutic substances to the distal end of the catheter; it may be used for the sampling of body fluids, such as blood; and it may be used for the passage of instruments or tools through the catheter, such as temperature monitors or fiber optic cords.

Fig. 15 illustrates how the catheter may be moved from one stenosis to another without bothering to first invert the balloon. For this purpose the extension 22 is preferably provided with a step 37. A stylet 38 having a round or flat tip 40 is inserted into the extension to abut the step. The catheter tube



-5-

or body 10 and stylet 38 are then jointly moved to position the everted balloon within the next adjacent stenosis 32.

Figs. 11 and 12 illustrate two purging systems for the catheter. In Fig. 11 the catheter is provided with a purge lumen through which purge liquid is passed to the interior of the catheter through fitting 12. When the catheter has been filled with the purge liquid, issuance of liquid through a bleeder valve, not shown, indicates that all of the air has been purged from the catheter. In Fig. 11 the purge liquid is introduced into the catheter through a needle-like fitting 44 which extends through plug passageway 28. Coupling of the proximal end of the catheter to a vacuum source causes the catheter to be filled with purge fluid.

Figs. 13 and 14 illustrate a retraction means to re-invert the balloon. Extension 22 may have tube 46 frictionally fitted within the end thereof. When the tube 46 is pulled to the right, the balloon becomes re-inverted. As shown in Fig. 14, the tube or rod 46 may have a threaded end 48. The corresponding threads in extension 22 may be pre-formed or formed by self-threading.

A further embodiment of the catheter is shown in Figs. 16-17. Between the plug 24 and balloon 20, extension 22 encloses a length 24 of elastomeric tubing 50. One end of this tubing is bonded to the extension 22 in the region 52. The other end of tubing 50 may be integral with the end of the balloon 20. Extension 22 is bonded to the balloon in the region 54. Extension 22 is provided with aperture 56 in overlying relation to tube 50. When inflation liquid is introduced into the catheter, the liquid enters chamber 58 between extension 22 and the tube 50 to compress the latter and close the passage along tube 50, as illustrated in Fig. 17. Further application of inflation liquid causes eversion of the balloon, and still further application of inflation liquid produces radial expansion of the balloon. The longitudinal passage through tube 50 remains closed under the effect of inflation liquid pressure during all of these operations.



-6-

A further embodiment of the catheter is shown in Figs. 18-20. Here the balloon 20, preferably made of polyethylene, is provided with an open end 21 of reduced diameter. A collapsible elastomeric balloon 23 is sleeved over end 21 and bonded thereto. The balloon 23 is provided with a self-closing hole or slit 25. When inflation liquid pressure is applied to the balloons 20 and 23, the balloon 23 collapses to form a seal and close off the interior of the catheter from the exterior thereof.

In the embodiment of Figs. 16 and 17, the guide wire 18 may be passed through the sealed through lumen in either direction, while in the embodiment of Figs. 18-20 such passage must be made from the distal end of the catheter in order to avoid collapsing of the balloon 23.

It is to be pointed out that the elastomeric plug 24 of the embodiments of Figs. 1-17 can be fixed in place in various ways. The preferred way, as disclosed, is to shrink the containing tube partially around the ends of the plug, thereby mechanically bracing the plug in position. The plug can be adhesively secured to the containing tube, either with or without the mechanical bracing relationship between tube and plug.

All of the above-described embodiments allow placement of the catheter body over a guide wire which has previously been manipulated into the desired lumen or space. This provides important advantages over previous linear extrusion catheters which are incapable of being used directly over a guide wire and must be positioned with a guiding catheter, if that is possible, or without any guide or aid at all. The expertise which physicians have in placing guide wires, particularly in the cardiovascular and urological systems, makes this wire-compatibility feature of particular importance.

The catheter embodiments of Figs. 1-17 allow replacement of the guide wire after balloon extrusion, or eversion, if desired, simply by pushing the guide wire back through the seal and past the limit of balloon eversion and then by withdrawing



-7-

the catheter over the guide wire (i.e., guide wires or other thin objects may be passed in either direction through the seal). The physician can thereby easily maintain guide wire access to a difficultly reached lumen or space if further

5 procedures or measurements are required in that space or another space which is reached through it. The present catheter provides these advantages while maintaining the advantages of the linear extrusion catheter.



-8-

## WHAT IS CLAIMED IS:

1. A dilatation catheter comprising a catheter body, a balloon attached to the distal end of said body and inverted within said body, means including a tubular extension  
5 attached to said balloon defining a through lumen, closure means for said lumen operable to maintain said balloon in sealed condition for eversion and subsequent radial expansion, said closure means being penetrable by a guide wire, thin cannula, or other thin element without loss of the sealed  
10 condition of said balloon.

2. The catheter of Claim 1, said extension having a funnel-like element at its distal end to guide said wire, thin cannula, or other thin element into said lumen.

3. The catheter of Claim 1, said closure means  
15 comprising an elastomeric plug secured transversely to said extension in blocking relation to said lumen, said plug having a normally closed, puncture-like axial passageway therein adapted to yieldingly accommodate said wire, thin cannula, or other thin element without loss of the sealed  
20 condition of said balloon.

4. The catheter of Claim 3, said extension having a funnel-like element at its distal end to guide said wire, thin cannula, or other thin element into said lumen.

5. The catheter of Claim 3, said plug fitting  
25 within a radially enlarged portion of said extension and being secured in place between radially diminished portions of said extension.



-9-

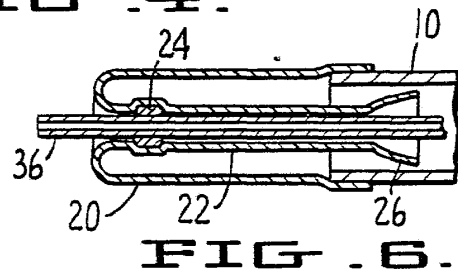
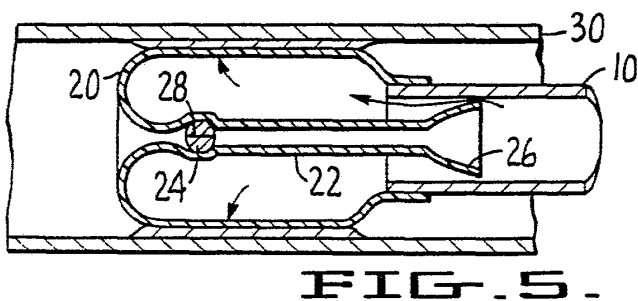
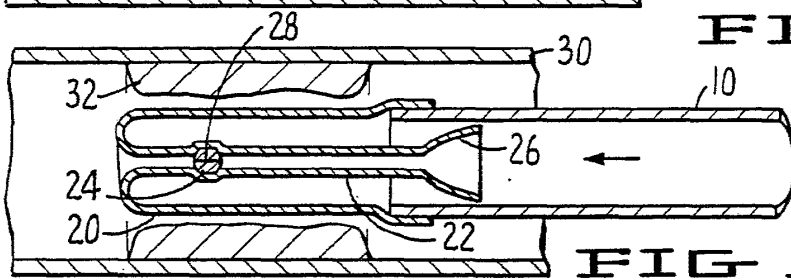
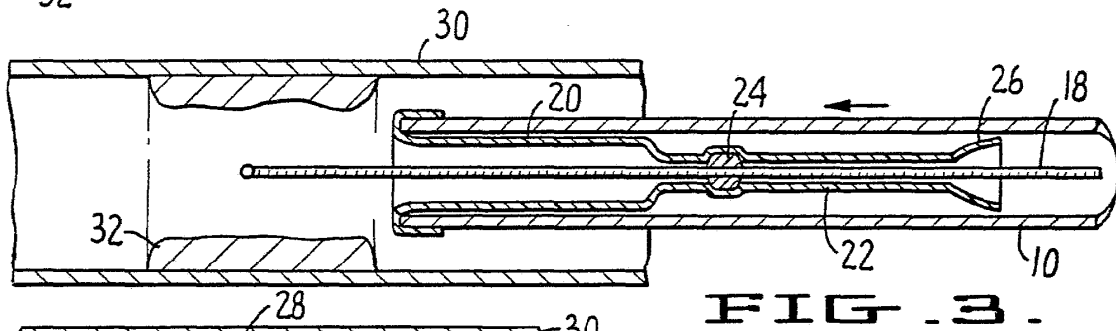
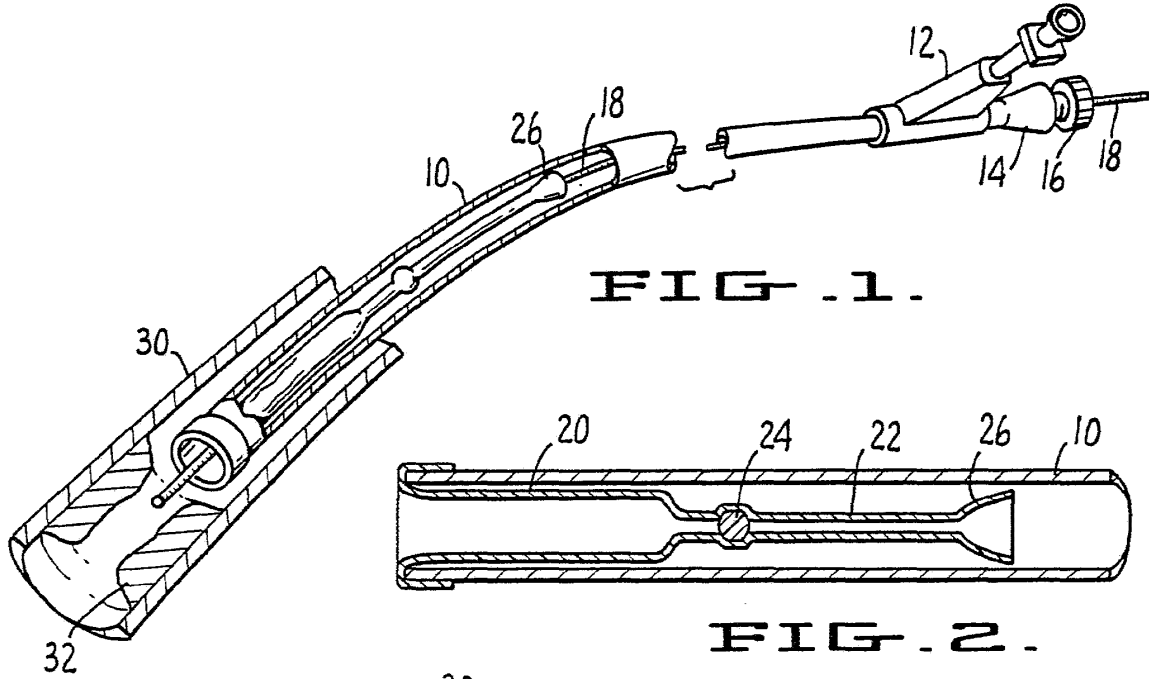
6. The catheter of Claim 3, said closure means further comprising an elastomeric sleeve within said extension, said sleeve having one end fixedly attached to said balloon and the other end fixedly attached to said plug, said extension  
5 having an aperture which provides communication for the application of balloon-eversion fluid pressure to an annular chamber between said extension and said sleeve to thereby collapse said sleeve upon itself and seal said lumen against fluid flow.

7. The catheter of Claim 6, said extension having  
10 a funnel-like element at its distal end to guide said wire, thin cannula, or other thin element into said lumen.

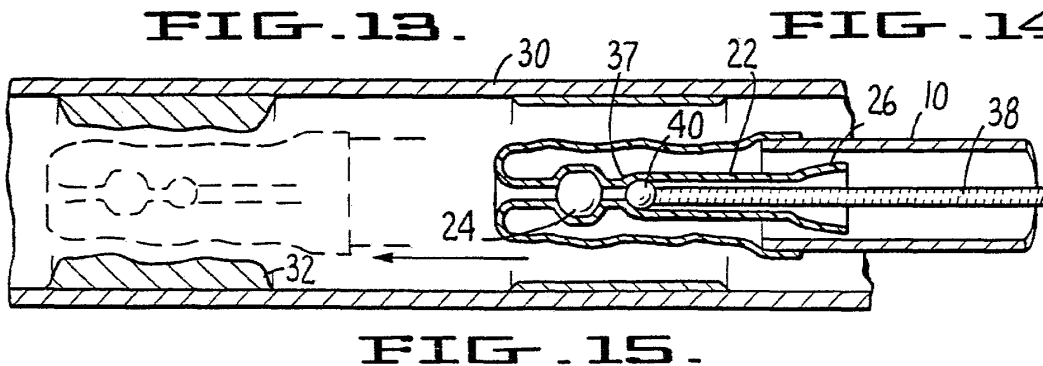
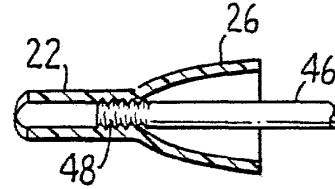
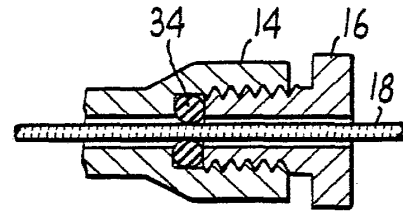
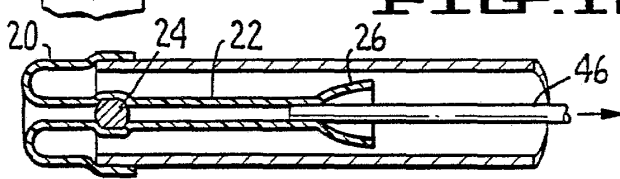
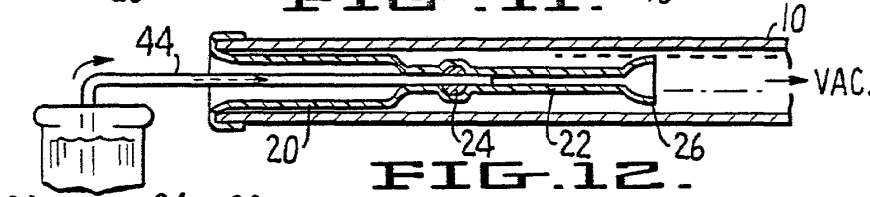
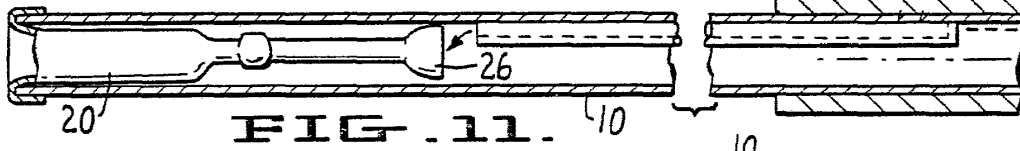
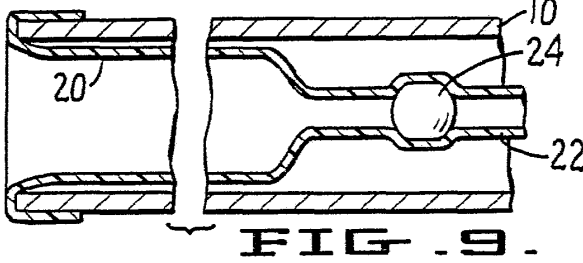
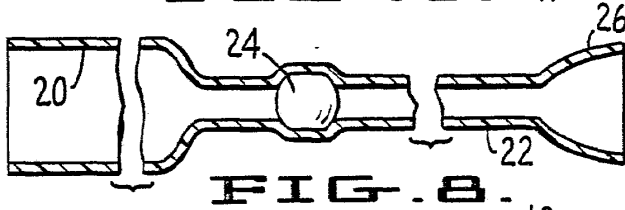
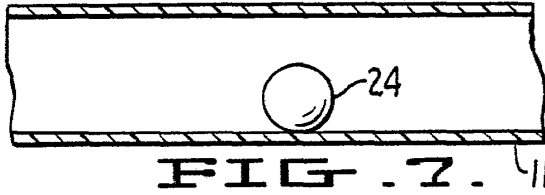
8. The catheter of Claim 1, said tubular extension having its proximal end secured to said balloon and having its distal end closed except for a puncture-like normally closed  
15 passageway extending therethrough, said tubular extension being collapsible upon itself upon the application thereto of balloon-eversion fluid pressure to seal said lumen against fluid flow.

9. A method of providing a dilatation catheter of  
20 the evertible-invertible balloon type with a sealed through lumen to enable said catheter to be moved along a guide wire while maintaining a sealed balloon system, said method comprising the steps of initially forming said balloon with an axial opening at its distal end, sealing said opening with an  
25 elastomeric plug which has been formed with a normally closed axial passageway through said plug to accommodate a guide wire while said balloon system remains sealed.









SUBSTITUTE SHEET



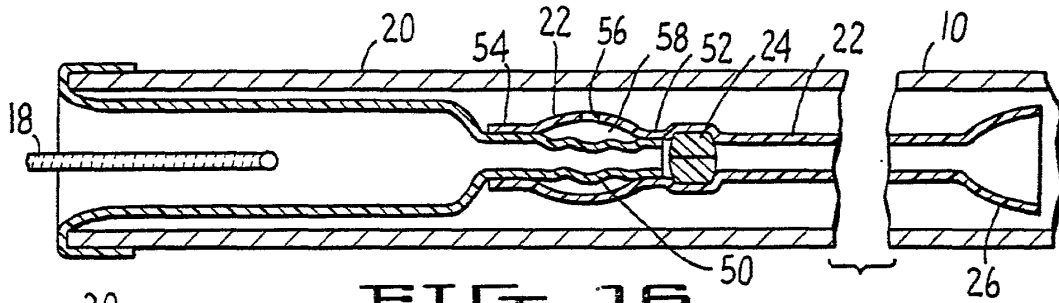


FIG. 16.

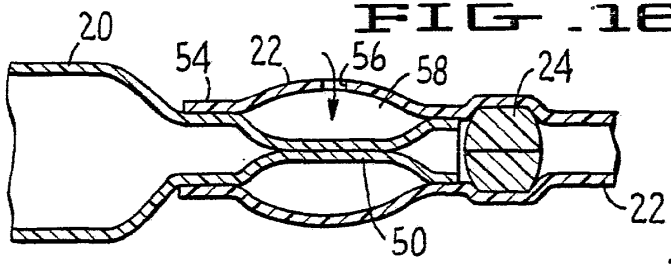


FIG. 17.

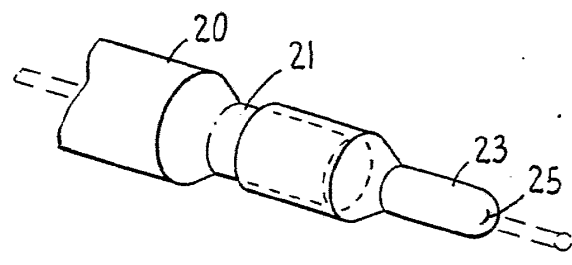


FIG. 18.

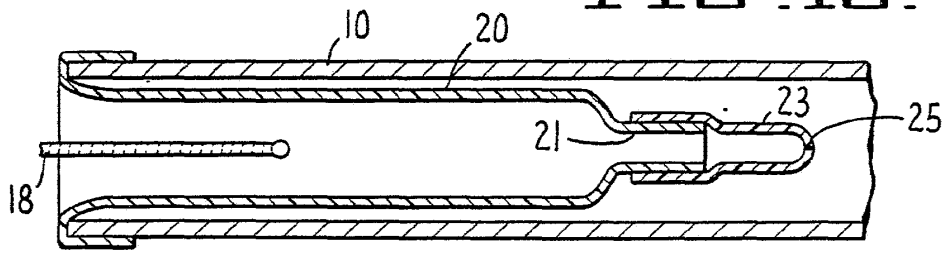


FIG. 19.

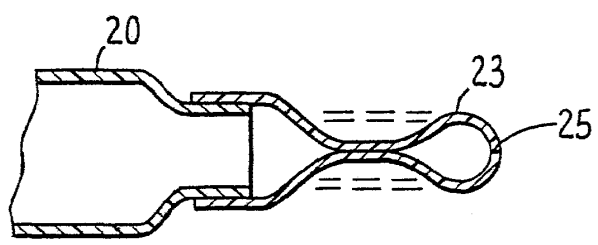
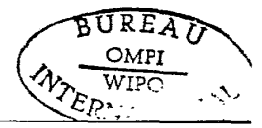



FIG. 20.

SUBSTITUTE SHEET



## INTERNATIONAL SEARCH REPORT

International Application No **PCT/US84/00455**

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>3</sup>			
According to International Patent Classification (IPC) or to both National Classification and IPC			
Int Cl <b>A61M 29/02</b>			
US Cl <b>128/344</b>			
<b>II. FIELDS SEARCHED</b>			
Minimum Documentation Searched <sup>4</sup>			
Classification System	Classification Symbols		
US	128/328, 341, 344, 348.1 604/96, 102, 167		
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>5</sup>			
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>14</sup>			
Category *	Citation of Document, <sup>16</sup> with indication, where appropriate, of the relevant passages <sup>17</sup>		Relevant to Claim No. <sup>18</sup>
A, P	US, A, 4,403,612	13 September 1983 FOGARTY	
X, Y	US, A, 4,324,262	13 April 1982 HALL	1-4, 9
Y	US, A, 3,409,016	05 November 1968 FOLEY	2, 4
Y	US, A, 3,253,594	31 May 1966 MATTHEWS et al	5, 8-9
<p>* Special categories of cited documents: <sup>15</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>			
<b>IV. CERTIFICATION</b>			
Date of the Actual Completion of the International Search <sup>2</sup>		Date of Mailing of this International Search Report <sup>2</sup>	
05 June 1984		<b>19 JUN 1984</b>	
International Searching Authority <sup>1</sup>		Signature of Authorized Officer <sup>29</sup>	
ISA/US		 <b>C. FRED ROSENBAUM</b>	

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## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	18392754
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Mary Granger
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	06-MAR-2014
<b>Filing Date:</b>	03-MAR-2014
<b>Time Stamp:</b>	16:09:06
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		03062014_Preliminary_Amendment.pdf	1307699 <small>f2f0e4c2356f1c17f6686b186ae890ce028d260b</small>	yes	27

Multipart Description/PDF files in .zip description					
Document Description		Start	End		
Preliminary Amendment		1	1		
Specification		2	2		
Claims		3	17		
Applicant Arguments/Remarks Made in an Amendment		18	27		
<b>Warnings:</b>					
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7	Non Patent Literature	NPL1_Takahashi_EtAl_Article.pdf	597782 fc3781703a516eb60c0bd4d2d633bbb238a8414	no	5
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<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			25113117		
<p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p>					

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.

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number 14/195,413	Filing Date 03/03/2014	<input type="checkbox"/> To be Mailed
---	--	---------------------------	---------------------------------------

ENTITY:  LARGE  SMALL  MICRO

**APPLICATION AS FILED – PART I**

FOR	NUMBER FILED (Column 1)	NUMBER EXTRA (Column 2)	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (j), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 = *		X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

**APPLICATION AS AMENDED – PART II**

	(Column 1)	(Column 2)	(Column 3)	(Column 4)	RATE (\$)	ADDITIONAL FEE (\$)
<b>AMENDMENT</b>	03/06/2014	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0	x \$40 = 0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	x \$210 = 0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	<b>0</b>

	(Column 1)	(Column 2)	(Column 3)	(Column 4)	RATE (\$)	ADDITIONAL FEE (\$)
<b>AMENDMENT</b>		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
					TOTAL ADD'L FEE	

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE  
/RUTH GRADEN/

This collection of information is required by 37 CFR 1.16. 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.





reissue applications is presently shortened by any terminal disclaimer," in the event that said prior patents and reissue applications later:

expire for failure to pay a maintenance fee;

are held unenforceable;

are found invalid by a court of competent jurisdiction;

are statutorily disclaimed in whole or terminally disclaimed under 37 CFR § 1.321;

have all claims canceled by a reexamination certificate;

are reissued; or

are in any manner terminated prior to the expiration of their full statutory term as presently shortened by any terminal disclaimer.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Electronic payment is submitted by credit card in payment of the fee required under 37 CFR § 1.321(b) and § 1.20(d). The Commissioner is hereby authorized to grant any extension of time necessary for consideration of this paper, and/or to charge any fee or credit any overpayment to Deposit Account No. 16-0631.

The undersigned is an attorney or agent of record.

Respectfully submitted,



Paul C. Onderick  
Registration No. 45354

Customer No. 24113  
Patterson Thuente 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.*

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	14195413			
<b>Filing Date:</b>	03-Mar-2014			
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES			
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root			
<b>Filer:</b>	Paul C. Onderick/Mary Granger			
<b>Attorney Docket Number:</b>	2005.86USREI5			
Filed as Small Entity				
<b>Utility under 35 USC 111(a) Filing Fees</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Miscellaneous:</b>				
Statutory or Terminal Disclaimer	1814	1	160	160
<b>Total in USD (\$)</b>				<b>160</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	18573215
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Mary Granger
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	25-MAR-2014
<b>Filing Date:</b>	03-MAR-2014
<b>Time Stamp:</b>	12:07:57
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$160
RAM confirmation Number	10471
Deposit Account	160631
Authorized User	ONDERICK, PAUL C

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:  
 Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)  
 Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	2005_86USREI5_Terminal_Disclaimer.pdf	274029 e71d24d52a6fbc40fa5b50d1a8ab5f4821b3874b	no	2

**Warnings:**

**Information:**

2	Fee Worksheet (SB06)	fee-info.pdf	30349 223f6e8b4b39a1151147dec1f37695f2931ae1c2	no	2
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**Warnings:**

**Information:**

**Total Files Size (in bytes):** 304378

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**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

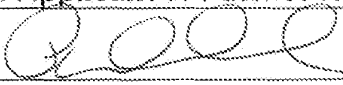
**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**

## TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	14/195,413
Filing Date	March 3, 2014
First Named Inventor	Howard C. Root
Title	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
Art Unit	
Examiner Name	
Attorney Docket Number	2005.86USREI5

### SIGNATURE of Applicant or Patent Practitioner

Signature		Date (Optional)	3-28-2014
Name	Paul C. Onderick	Registration Number	45354
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

**NOTE:** This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

\*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 1.11 and 1.14. This collection is estimated to take 3 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

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## POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

<b>Application Number</b>	<b>Filing Date</b>
14/195,413	March 3, 2014

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

- I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 24113
- OR
- I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

**Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:**

- The address associated with the above-mentioned Customer Number
- OR
- The address associated with Customer Number:
- OR


Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

- Inventor or Joint Inventor (title not required below)
- Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)
- Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)
- Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

### SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature	Date (Optional)	
	March 3, 2014	
Name	Howard C. Root	
Title	CEO, Vascular Solutions, Inc.	

**NOTE:** Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

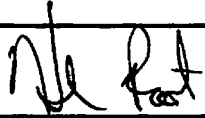
Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 1.11 and 1.14. This collection is estimated to take 3 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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<b>REISSUE APPLICATION: CONSENT OF ASSIGNEE; STATEMENT OF NON-ASSIGNMENT</b>		Docket Number (Optional)  2005.86USRE15
This is part of the application for a reissue patent based on the original patent identified below.		
Name of Patentee(s) Howard C. Root et al.		
Patent Number 8,292,850 B2	Date Patent Issued October 23, 2012	
Title of Invention COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		
<p>1. <input checked="" type="checkbox"/> Filed herein is a statement under 37 CFR 3.73(c). (Form PTO/AIA/96)</p> <p>2. <input type="checkbox"/> Ownership of the patent is in the inventor(s), and no assignment of the patent is in effect.</p> <p>One of boxes 1 or 2 above must be checked. If multiple assignees, complete this form for each assignee. If box 2 is checked, skip the next entry and go directly to "Name of Assignee."</p> <p>The written consent of all assignees and inventors owning an undivided interest in the original patent is included in this application for reissue.</p>		
The assignee(s) owning an undivided interest in said original patent is/are <u>VASCULAR SOLUTIONS, INC.</u> , and the assignee(s) consents to the accompanying application for reissue.		
Name of assignee/inventor (if not assigned)		
Signature 	Date March 27, 2014	
Typed or printed name and title of person signing for assignee (if assigned)  Howard C. Root, CEO, Vascular Solutions, Inc.		

This collection of information is required by 37 CFR 1.172. 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 6 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_,  
Frame \_\_\_\_\_ or for which a copy thereof is attached.

3. From \_\_\_\_\_ to \_\_\_\_\_

The document was recorded in the Patent and Trademark Office at Reel \_\_\_\_\_,  
Frame \_\_\_\_\_ or for which a copy thereof is attached.

Additional documents in the chain of title are listed on a supplemental sheet.

Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to sign this statement on  
behalf of the assignee.

Date: March 27, 2014

  
\_\_\_\_\_  
Signature

Howard Root  
\_\_\_\_\_  
Name Printed or Typed

Cheif Executive Officer  
\_\_\_\_\_  
Title

## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	14195413			
<b>Filing Date:</b>	03-Mar-2014			
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES			
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root			
<b>Filer:</b>	Paul C. Onderick/Mary Granger			
<b>Attorney Docket Number:</b>	2005.86USREI5			
Filed as Small Entity				
<b>Utility under 35 USC 111(a) Filing Fees</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
Utility Reissue Basic	2014	1	140	140
Design and utility Reissue Basic	2114	1	300	300
Design and utility Reissue Basic	2314	1	1080	1080
<b>Pages:</b>				
<b>Claims:</b>				
Reissue claims in Excess of 20 for Small	2205	10	40	400
<b>Miscellaneous-Filing:</b>				
Late Filing Fee for Oath or Declaration	2051	1	70	70

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				
<b>Miscellaneous:</b>				
<b>Total in USD (\$)</b>				<b>1990</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	18617029
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Mary Granger
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	28-MAR-2014
<b>Filing Date:</b>	03-MAR-2014
<b>Time Stamp:</b>	17:02:01
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1990
RAM confirmation Number	3676
Deposit Account	160631
Authorized User	ONDERICK, PAUL C

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		MissingParts.pdf	1698080 <small>3779fb75eaf7785dfaa290ec6a91826cd9a914e0</small>	yes	16
<b>Multipart Description/PDF files in .zip description</b>					
	<b>Document Description</b>		<b>Start</b>		<b>End</b>
	Applicant Response to Pre-Exam Formalities Notice		1		3
	Reissue dec filed in accordance with MPEP 1414		4		8
	Reissue dec filed in accordance with MPEP 1414		9		11
	Power of Attorney		12		13
	Consent of Assignee accompanying the declaration		14		14
	Assignee showing of ownership per 37 CFR 3.73.		15		16
<b>Warnings:</b>					
<b>Information:</b>					
2	Fee Worksheet (SB06)	fee-info.pdf	38566 <small>38af171b202522a5d70b7ddd76c6b26af9dde87a</small>	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			1736646		

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**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



REISSUE PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI5  
 Howard C. Root et al. Confirmation No.: 6135  
 Application No.: 14/195,413 Group Art Unit: 3767  
 Filed: March 3, 2014 Examiner: Unassigned  
 For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL  
 CARDIOLOGY PROCEDURES  
 Reissue of U.S. Patent No.: 8,292,850  
 Issued: October 23, 2012

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RESPONSE TO NOTICE TO FILE MISSING PARTS  
 OF REISSUE APPLICATION

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

Commissioner:

In response to the Notice to File Missing Parts of Application - Filing Date Granted mailed March 6, 2014, submitted herewith are an executed Reissue Application Declaration by the Inventor(s), Reissue Application Declaration of Assignee, Power of Attorney, Consent of Assignee and Statement Under 37 C.F.R. 3.73(c).

The filing fee has been calculated as shown below:						
Application as Filed - Part 1						
	(1) Claims in Patent	(2) Claims Filed in Reissue Application	(3) Number Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee				\$140	OR	\$280
Reissue Search Fee				\$300	OR	600
Reissue Examination Fee				\$1080	OR	\$2,160
Total Claims	(A)	(B)	= ****	x 40 = \$	OR	x 80 = \$
Independent Claims	(C)	(D)	= *	x 210 =	OR	x 420 = \$
Presence of Multiple Dependent Claim				+ 390	OR	+ 780
Surcharge - Late filing fee or oath or declaration				+ 70	OR	+ 140

Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:	x 200 = \$	OR	x 400 = \$
<b>TOTAL</b>	<b>\$1,590.00</b>	OR	<b>\$</b>
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets			

Application as Amended - Part 2						
	(1) Claims Remaining After Amendment	(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	OR	Large Entity Rate
Total Claims	30	minus 20	= 10	x 40 = \$400.00	OR	x 80 = \$
Independent Claims	2	minus 3	= 0	x 210 = 0	OR	x 420 = \$
Presence of Multiple Dependent Claim				+ 390	OR	+ 780
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 200 = \$	OR	x 400 = \$
<b>TOTAL</b>				<b>\$1,990.00</b>	OR	<b>\$</b>
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets						

\*If (D) is less than (C), enter "0" in column 3. For reissues filed on or after Dec. 8, 2004, enter (D) minus 3 or "0" if (D) is less than 3.

\*\*If the "Highest Number of Total Claims Previously Paid For" is less than 20, enter "20" in this space.

\*\*\*After any cancellation of claims.

\*\*\*\*If (A) is greater than 20, enter (B) - (A); if (A) is 20 or less, enter (B) - 20. For reissues filed on or after Dec. 8, 2004 enter (B) - 20.

\*\*\*\*\*For amendments filed on or after Dec. 8, 2004, enter the "Highest Number of Independent Claims Previously Paid For."

For amendments filed prior to Dec. 8, 2004, enter the higher of the Number Previously Paid or Number of Independent Claims in Patent.

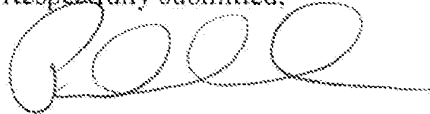
Applicants are entitled to small entity status in accordance with 37 CFR 1.27. Electronic payment is submitted by credit card for the surcharge and filing fee. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

Entry of these documents should complete all of the filing formalities and fully satisfy all requirements of the Notice to File Missing Parts. Accordingly, examination and allowance of this application in due course are respectfully solicited.

Application No. 14/195,413

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 16-0631.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. Onderick", written over a horizontal line.

Paul C. Onderick  
Registration No. 45354

Customer No. 24113  
Patterson Thuente 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.*

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.

<b>REISSUE APPLICATION DECLARATION BY THE INVENTOR</b>	Docket Number (Optional) <b>2005.86USREI5</b>
--	--

I hereby declare that:

Each inventor's residence and mailing address are stated below next to their name.

I believe I am the original inventor or an original joint inventor of the subject matter which is described and claimed

in patent number 8,292,850 B2, granted October 23, 2012 and for which a reissue patent is sought on the invention titled COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES,

the specification of which

is attached hereto.

was filed on March 3, 2014 as reissue application number 14/195,413.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

by reason of a defective specification or drawing.

by reason of the patentee claiming more or less than he had the right to claim in the patent.

by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, a claim that the application seeks to broaden must be identified:


The issued independent claims of the patent claim less than patentee had a right to claim. Accordingly, patentee seeks to broaden the claims by reissue. In particular, patentee seeks to broaden independent claims 1 and 12 of the issued patent. Patented independent claim 1 is directed to a system including a guide catheter and a device for use with the guide catheter. Neither independent claim 1 nor independent claim 12 of the issued patent recites a guide extension catheter including a rail segment, a tubular segment and a segment defining a partially cylindrical opening having an angled proximal end formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure as recited in reissue claim 25. Further, neither independent claim 1 nor independent claim 12 of the issued patent recites a guide extension catheter including a rail segment and a tubular structure defining a lumen and positioned distal to the rail segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter as recited in reissue claim 50.

[Page 1 of 2]

This collection of information is required by 37 CFR 1.175. 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 1.11 and 1.14. This collection is estimated to take 30 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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.

(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)		Docket Number (Optional) <b>2005.86USRE15</b>	
Note: To appoint a power of attorney, use form PTO/AIA/81.			
Correspondence Address: Direct all communications about the application to:			
<input checked="" type="checkbox"/> The address associated with Customer Number:		24113	
OR			
<input type="checkbox"/> Firm or Individual Name			
Address			
City	State	Zip	
Country			
Telephone	Email		
<p><b>WARNING:</b></p> <p>Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.</p>			
Legal name of sole or first inventor (E.g., Given Name (first and middle (if any) and Family Name or Surname)			
Howard C. Root			
Inventor's Signature		Date (Optional)	
		March 3, 2014	
Residence: City	State	Country	
Tonka Bay	MN	US	
Mailing Address			
25 Fairhope Avenue			
City	State	Zip	Country
Tonka Bay	MN	55331	US
<p><input type="checkbox"/> Additional joint inventors are named on the _____ supplemental sheet(s) PTO/AIA/10 attached hereto.</p>			

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

**SUPPLEMENTAL SHEET FOR DECLARATION****ADDITIONAL INVENTOR(S)**

Supplemental Sheet (for PTO/AIA/08,09)

Page \_\_\_\_\_ of \_\_\_\_\_

**Legal Name of Additional Joint Inventor, if any:**

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Gregg Sutton

Inventor's  
Signature

Date (Optional)

Residence: City

Plymouth

State

MN

Country

US

18400 31st Avenue North

Mailing Address

City

Plymouth

State

MN

Zip

55447

Country

US

**Legal Name of Additional Joint Inventor, if any:**

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Jeffrey M. Welch

Inventor's  
Signature

Date (Optional)

Residence: City

Maple Grove

State

MN

Country

US

8723 Cornstock Lane North

Mailing Address

City

Maple Grove

State

MN

Zip

55311

Country

US

**Legal Name of Additional Joint Inventor, if any:**

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Jason M. Garrity

Inventor's  
Signature

Date (Optional)

Residence: City

Lima

State

NY

Country

US

2838 Livonia Center Road

Mailing Address

City

Lima

State

NY

Zip

14485

Country

US

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 21 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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

**SUPPLEMENTAL SHEET FOR DECLARATION****ADDITIONAL INVENTOR(S)**

Supplemental Sheet (for PTO/AIA/08,09)

Page \_\_\_\_\_ of \_\_\_\_\_

**Legal Name of Additional Joint Inventor, if any:**

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Gregg Sutton

Inventor's  
Signature

Date (Optional)

Residence: City  
PlymouthState  
MNCountry  
US

18400 31st Avenue North

Mailing Address

City  
PlymouthState  
MNZip  
55447Country  
US**Legal Name of Additional Joint Inventor, if any:**

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Jeffrey M. Welch

Inventor's  
Signature

Date (Optional)

Residence: City  
Maple GroveState  
MNCountry  
US

8723 Cornstock Lane North

Mailing Address

City  
Maple GroveState  
MNZip  
55311Country  
US**Legal Name of Additional Joint Inventor, if any:**

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Jason M. Garrity

Inventor's  
Signature

Date (Optional)

Residence: City  
LimaState  
NYCountry  
US

2838 Livonia Center Road

Mailing Address

City  
LimaState  
NYZip  
14485Country  
US

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 21 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.



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.

<b>REISSUE APPLICATION DECLARATION BY THE ASSIGNEE</b>		Docket Number (optional) <b>2005.86USREI5</b>	
I hereby declare that:			
The residence and mailing address of the inventor or joint inventors are stated below.			
I am authorized to act on behalf of the following assignee: <u>Vascular Solutions, Inc.</u>			
The entire title to the patent identified below is vested in said assignee.			
Inventor <b>Howard C. Root</b>			
Residence: City <b>Tonka Bay</b>		State <b>MN</b>	Country <b>US</b>
Mailing Address <b>25 Fairhope Avenue</b>			
City <b>Tonka Bay</b>	State <b>MN</b>	Zip <b>55331</b>	Country <b>US</b>
<input checked="" type="checkbox"/> Additional Inventors are named on separately numbered sheets attached hereto.			
Patent Number <b>8,292,850 B2</b>		Date of Patent Issued <b>October 23, 2012</b>	
I believe said inventor(s) to be the original inventor or original joint inventors of the subject matter which is described and claimed in said patent, for which a reissue patent is sought on the invention titled:			
<b>COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES</b>			
the specification of which			
<input type="checkbox"/> is attached hereto.			
<input checked="" type="checkbox"/> was filed on <u>March 3, 2014</u> as reissue application number <u>14/195,413</u> .			
The above-identified application was made or authorized to be made by me.			
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.			
I believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)			
<input type="checkbox"/> by reason of a defective specification or drawing.			
<input checked="" type="checkbox"/> by reason of the patentee claiming more or less than he had the right to claim in the patent.			
<input type="checkbox"/> by reason of other errors.			

[Page 1 of 2]

This collection of information is required by 37 CFR 1.175. 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 1.11 and 1.14. This collection is estimated to take 30 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**REISSUE APPLICATION DECLARATION BY THE ASSIGNEE** Docket Number (Optional) 2005.86USR

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, a claim that the application seeks to broaden must be identified and the box below must be checked:

SEE ATTACHED

[Attach additional sheets, if needed.]

The application for the original patent was filed under 37 CFR 1.46 by the assignee of the entire interest.

I hereby appoint:

Practitioners associated with Customer Number: 24113

OR

Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Correspondence Address: Direct all communications about the application to:

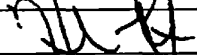
The address associated with Customer Number: 24113

OR

<input type="checkbox"/> Firm or Individual Name				
Address				
City		State		Zip
Country				
Telephone		Email		

**WARNING:**

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature  Date (Optional) March 3, 2014

Full name of person signing (given name, family name) **Howard C. Root, CEO of Assignee**

Address of Assignee **6464 Sycamore Court North, Minneapolis, MN 55369**

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USREI5

Howard Root et al.

Confirmation No.: 6135

Application No.: 14/195,413

Examiner: Unassigned

Filed: March 3, 2014

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

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ATTACHMENT TO REISSUE APPLICATION DECLARATION BY ASSIGNEE

ERROR STATEMENT

The issued independent claims of the patent claim less than patentee had a right to claim. Accordingly, patentee seeks to broaden the claims by reissue. In particular, patentee seeks to broaden independent claims 1 and 12 of the issued patent. Patented independent claim 1 is directed to a system including a guide catheter and a device for use with the guide catheter. Neither independent claim 1 nor independent claim 12 of the issued patent recites a guide extension catheter including a rail segment, a tubular segment and a segment defining a partially cylindrical opening having an angled proximal end formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure as recited in reissue claim 25. Further, neither independent claim 1 nor independent claim 12 of the issued patent recites a guide extension catheter including a rail segment and a tubular structure defining a lumen and positioned distal to the rail segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter as recited in reissue claim 50.

**PATENT APPLICATION FEE DETERMINATION RECORD**

Substitute for Form PTO-875

Application or Docket Number

14/195,413

**APPLICATION AS FILED - PART I**

(Column 1) (Column 2)

FOR	NUMBER FILED	NUMBER EXTRA
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 = *	10
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 = *	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).	
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))		

**SMALL ENTITY**

RATE(\$)	FEE(\$)
N/A	140
N/A	300
N/A	1080
x 40 =	400
x 210 =	0.00
	0.00
	0.00
<b>TOTAL</b>	<b>1920</b>

OR

**OTHER THAN SMALL ENTITY**

RATE(\$)	FEE(\$)
N/A	
N/A	
N/A	
<b>TOTAL</b>	

\* If the difference in column 1 is less than zero, enter "0" in column 2.

**APPLICATION AS AMENDED - PART II**

(Column 1) (Column 2) (Column 3)

AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	Application Size Fee (37 CFR 1.16(s))				
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					

**SMALL ENTITY**

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
<b>TOTAL ADD'L FEE</b>	

OR

**OTHER THAN SMALL ENTITY**

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
<b>TOTAL ADD'L FEE</b>	

(Column 1) (Column 2) (Column 3)

AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total (37 CFR 1.16(i))	*	Minus	**	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=
	Application Size Fee (37 CFR 1.16(s))				
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					

**SMALL ENTITY**

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
<b>TOTAL ADD'L FEE</b>	

OR

**OTHER THAN SMALL ENTITY**

RATE(\$)	ADDITIONAL FEE(\$)
x =	
x =	
<b>TOTAL ADD'L FEE</b>	

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".  
 The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.



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

Table with 7 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY.DOCKET.NO, TOT CLAIMS, IND CLAIMS. Row 1: 14/195,413, 03/03/2014, 3767, 1990, 2005.86USREI5, 30, 2

CONFIRMATION NO. 6135

UPDATED FILING RECEIPT

24113
PATTERSON THUENTE PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
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Date Mailed: 04/02/2014

Receipt is acknowledged of this reissue patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections

Inventor(s)

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Applicant(s)

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Power of Attorney: The patent practitioners associated with Customer Number 24113

Domestic Priority data as claimed by applicant

This application is a CON of 14/070,161 11/01/2013 \*
which is a REI of 13/359,059 01/26/2012 PAT 8292850
which is a DIV of 12/824,734 06/28/2010 PAT 8142413
which is a DIV of 11/416,629 05/03/2006 PAT 8048032
(\*)Data provided by applicant is not consistent with PTO records.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the Patent Prosecution Highway program at the USPTO. Please see http://www.uspto.gov for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 04/01/2014

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US 14/195,413

Projected Publication Date: None, application is not eligible for pre-grant publication

**Non-Publication Request:** No

**Early Publication Request:** No

**\*\* SMALL ENTITY \*\***

**Title**

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

**Preliminary Class**

604

**Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications:** No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
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14/195,413

03/03/2014

Howard C. Root

2005.86USRE15

**CONFIRMATION NO. 6135**

**POA ACCEPTANCE LETTER**

24113  
PATTERSON THUENTE PEDERSEN, P.A.  
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Date Mailed: 04/02/2014

**NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY**

This is in response to the Power of Attorney filed 03/28/2014.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/dalyon/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USREIS

Howard C. Root et al.

Confirmation No.: 6135

Application No.: 14/195,413

Examiner: Unassigned

Filed: March 3, 2014

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

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THIRD PRELIMINARY AMENDMENT

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

Commissioner:

INTRODUCTORY COMMENTS

Prior to examination, please amend the above-identified application as follows:

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.*



REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

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 brackets; and 2. added matter is shown by underlining.

1. (Cancelled) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

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

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

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

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. (Cancelled) The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

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

5. (Cancelled) 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.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

6. (Cancelled) The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.
7. (Cancelled) The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.
8. (Cancelled) The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.
9. (Cancelled) The system of claim 1, wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.
10. (Cancelled) The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.
11. (Cancelled) The system of claim 1, further comprising a kit that includes the guide catheter and the device in a common sterile package.
12. (Cancelled) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and

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

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

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;

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis 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, 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

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

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

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



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

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

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

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

20. (Cancelled) 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.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

21. (Cancelled) The system of claim 20, in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.
22. (Cancelled) The system of claim 20, in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.
23. (Cancelled) The system of claim 12, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.
24. (Cancelled) The system of claim 12, further comprising a kit that includes the guide catheter and the device in a common sterile package.

Please add new claims 25-59 as follows:

25. (New) A guide extension catheter for use with a guide catheter, comprising:  
a substantially rigid segment;  
a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and  
a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a structure having a

greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional cardiology devices therethrough when positioned within the guide catheter.

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

26. (New) The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent a distal end of the substantially rigid segment and extends distally toward the tubular structure.

27. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape.

28. (New) The guide extension catheter of claim 27, wherein the portion having the arcuate cross-sectional shape extends for a length of 15 cm.

29. (New) The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of a cross-sectional circumference of a tube.

30. (New) The guide extension catheter of claim 25, wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.

31. (New) The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from a proximal end to a distal end of the tubular structure.

32. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape.

33. (New) The guide extension catheter of claim 32, wherein the portion having the hemicylindrical cross-sectional shape extends for a length of 20 cm to 75 cm.

34. (New) The guide extension catheter of claim 32, wherein the hemicylindrical cross-sectional shape radially extends 40% to 70% of a cross-sectional circumference of a tube.

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

36. (New) The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

37. (New) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.

38. (New) The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a hypotube.

39. (New) The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a section of stainless steel.

40. (New) The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a section of Nitinol tubing.

41. (New) The guide extension catheter of claim 25, wherein the substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure.

42. (New) The guide extension catheter of claim 25, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure to be advanced within and partially through the guide catheter while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the substantially rigid segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.

43. (New) The guide extension catheter of claim 25, wherein the substantially rigid segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the substantially rigid segment.

44. (New) The guide extension catheter of claim 25, further comprising a tip portion positioned distal to the distal end of the tubular structure.

45. (New) The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of a length of the tubular structure and surrounded by one or more polymer materials.

46. (New) The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is 20 to 30 cm.

47. (New) The guide extension catheter of claim 25, wherein the substantially rigid segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.

48. (New) The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter.

49. (New) The guide extension catheter of claim 25, wherein a material forming the partially cylindrical opening is more rigid than a material or material combination forming the tubular structure.

50. (New) A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:

a substantially rigid segment;

a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter;

and

a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen.

51. (New) The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

52. (New) The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape.

53. (New) The guide extension catheter of claim 50, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be advanced partially through the guide catheter and into a coronary artery while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.

54. (New) The guide extension catheter of claim 50, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.

55. (New) The guide extension catheter of claim 25, wherein a distal portion of the tubular structure is configured to anchor within an ostium of a coronary vessel and resist axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion.

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



REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

57. (New) The guide extension catheter of any one of claims 25, 28, 30, 31, 33, 35, 38, 47, 49-51 or 54-56, wherein the segment defining the partially cylindrical opening includes one or more cuts.

58. (New) The guide extension catheter of claim 57, wherein at least one cut includes two circumferential cuts along a single line and separated by a section of uncut structure.

59. (New) The system of claim 57, wherein a first cut is spaced approximately 0.010 inches apart from a second cut.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

REMARKS

Claims 1-24 are pending. By this Amendment, claims 1-24 are cancelled, no claims are amended and new claims 25-54 are added.

This application is a reissue application and is to be given priority in examination. MPEP 708.

Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue applications are reissue Application 14/070,161, this continuation reissue application and continuation reissue applications 14/195,385 and 14/195,435 filed March 3, 2014.

“The parent and continuation reissue applications should be examined together if possible.” MPEP 1451(II)

This application is a continuation reissue application of 14/070,161 filed November 1, 2013. New Claims in this Preliminary Amendment are numbered consecutively with the claims of the parent issued patent U.S. 8,292,850. However, Applicants note that this creates a claim numbering conflict with the parent reissue application 14/070,161 as well as with two other continuation reissue applications filed March 3, 2014, the same day as this continuation reissue application which will have claims sharing the same numbering at least initially. Since the Patent Office Rules do not address how to resolve such a conflict and it is difficult to predict which of the related reissue applications will issue first, Applicants expect that this claim numbering conflict will be resolved by renumbering of the claims as appropriate if and when each of the related reissue applications receives an indication of allowable subject matter thus

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

assuring that the reissue patents arising from these applications do not have a claim numbering conflict.

This Preliminary Amendment indicates that claims 1-24 of the parent patent US 8,292,850 are to be cancelled. This is to comply with rules and practice related to continuation reissue applications. Claims 1-24 remain pending in reissue application 14/070,161 and cancellation of claims 1-24 herein is done without prejudice, disclaimer, waiver or surrender of the claims or of the claimed subject matter. No surrender of the claims or the claimed subject matter is intended or achieved by cancellation of claims 1-24 herein.

The filed broadening reissue claims are directed to an additional invention, embodiment or species not originally claimed that represent an overlooked aspect of the invention in the issued patent.

The amendments and additions to the claims are made to correct one or more defects causing U.S. Patent No. 8,292,850 to be partly inoperative or invalid.

**Examination and reconsideration of this application are respectfully requested.**

**Formal Request for Telephonic Interview**

The undersigned formally requests that, before issuance of any Office Action, a telephonic interview be held between the Examiner and the undersigned, at the Examiner's convenience. The Examiner is kindly requested to phone the undersigned at 612.349.5740 to arrange a time for such telephonic interview.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

Explanation of Amendments to the New Claims

Claims 25, 26, 29, 30, 38, 39, 40, 41, 42, 43, 44, 47, 50 and 53 are amended as follows as compared to the similarly numbered claims filed in the first and second Preliminary Amendments in this application.

25. (Currently Amended) A guide extension catheter for use with a guide catheter, comprising:

a[[ rail]] substantially rigid segment;

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

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

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

26. (Currently Amended) The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent the distal end of the[[ rail]] substantially rigid segment and extends distally toward the tubular structure.

27. (Currently Amended) The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape.

29. (Currently Amended) The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of ~~[[the]]~~ a cross-sectional circumference of ~~the segment defining the partially cylindrical opening~~ a tube.

30. (Currently Amended) The guide extension catheter of claim 25, wherein ~~[[ a]]~~ the cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than ~~[[ a]]~~ the cross-sectional inner diameter of a lumen of the guide catheter.

31. (Currently Amended) The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from ~~[[its]]~~ a proximal end to ~~[[its]]~~ a distal end of the tubular structure.

38. (Currently Amended) The guide extension catheter of claim 25, wherein the ~~[[ rail]]~~ substantially rigid segment is formed from a hypotube.

39. (Currently Amended) The guide extension catheter of claim 25, wherein the ~~[[ rail]]~~ substantially rigid segment is formed from a section of stainless steel.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

40. (Currently Amended) The guide extension catheter of claim 25, wherein the[[ rail]] substantially rigid segment is formed from a section of Nitinol tubing.

41. (Currently Amended) The guide extension catheter of claim 25, wherein the[[ rail]] substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure.

42. (Currently Amended) The guide extension catheter of claim 25, wherein a cross-section of the[[ rail]] substantially rigid segment is sufficiently sized and configured to ~~advance~~ permit the tubular structure to be advanced within and partially through the guide catheter[.,] while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the[[ rail]] substantially rigid segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.

43. (Currently Amended) The guide extension catheter of claim 25, wherein the[[ rail]] substantially rigid segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the[[ rail]] substantially rigid segment.

44. (Currently Amended) The guide extension catheter of claim 25, further comprising a tip portion positioned distal to[[ a]] the distal end of the tubular structure.

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

45. (Currently Amended) The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of ~~[[its]]~~ a length of the tubular structure and surrounded by one or more polymer materials.

47. (Currently Amended) The guide extension catheter of claim 25, wherein the ~~[[ rail]]~~ substantially rigid segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.

50. (Currently Amended) A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:

a ~~[[ rail]]~~ substantially rigid segment;

a tubular structure defining a lumen and positioned distal to the ~~[[ rail]]~~ substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and

a segment defining a partially cylindrical opening positioned between a distal end of the ~~[[ rail]]~~ substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter,

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

a cross-section of the guide extension catheter at the proximal end of the tubular structure ~~including~~ defining a single lumen.

53. (Currently Amended) The guide extension catheter of claim 50, wherein a cross-section of the [[ rail]] substantially rigid segment is sufficiently sized and configured to ~~advance~~ permit the tubular structure of the guide extension catheter to be advanced partially through the guide catheter and into a coronary artery[[,]] while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.

New Claims Added in this Preliminary Amendment

New claims 55-59 are added as compared to the first and second Preliminary Amendments in this application.

55. (New) The guide extension catheter of claim 25, wherein a distal portion of the tubular structure is configured to anchor within an ostium of a coronary vessel and resist axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion.

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



REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

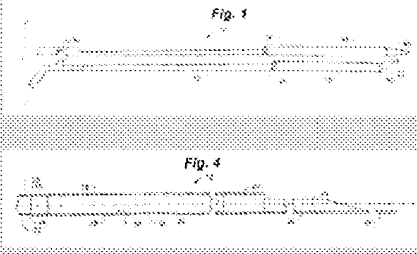

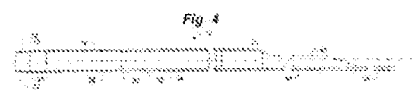
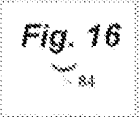
57. (New) The guide extension catheter of any one of claims 25, 28, 30, 31, 33, 35, 38, 47, 49-51 or 54-56, wherein the segment defining the partially cylindrical opening includes one or more cuts.

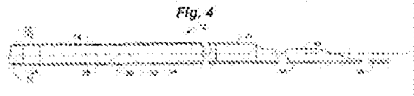

58. (New) The guide extension catheter of claim 57, wherein at least one cut includes two circumferential cuts along a single line and separated by a section of uncut structure.

59. (New) The system of claim 57, wherein a first cut is spaced approximately 0.010 inches apart from a second cut.

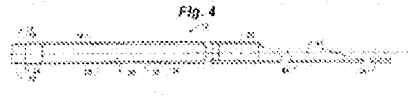
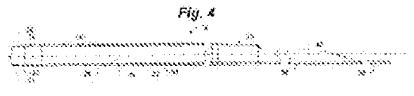
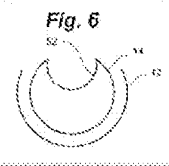
Claim No.	Claim Amendment(s) and/or Addition(s) <sup>1</sup>	Example(s) of Support in U.S. Application Serial No. 13/359,059, filed on Jan. 26, 2012
25	<u>A guide extension catheter for use with a guide catheter, comprising:</u> <u>a substantially rigid segment;</u> <u>a tubular structure defining a lumen and positioned distal to the substantially rigid segment; and</u> <u>a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having an angled proximal end, formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure, and configured to receive one or more interventional</u>	Page 6, lines 1-4  Page 7, line 14 – page 8, line 2  Page 9, lines 12-14  Page 12, lines 12-16  Page 13, line 15 – page 14, line 8  Page 19, lines 12-14  Original claims 1, 3, 12 and 20-22  FIGS. 1, 4 and 14;

<sup>1</sup> In the table, bracketed language indicates deletions and underlined language indicates additions.

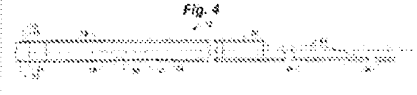
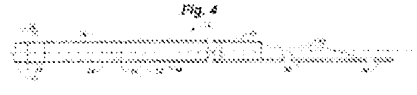
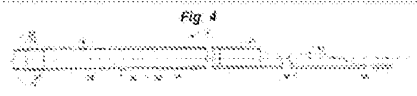
	<p><u>cardiology devices therethrough when positioned within the guide catheter, wherein a the cross-section of the guide extension catheter at the proximal end of the tubular structure defines a single lumen.</u></p>	 <p><b>Fig. 14</b></p> 
<p>26</p>	<p><u>The guide extension catheter of claim 25, wherein the angled proximal end of the partially cylindrical opening originates adjacent a distal end of the substantially rigid segment and extends distally toward the tubular structure.</u></p>	<p>Page 6, lines 2 and 3                  Original claim 9                  FIG. 4:</p> 
<p>27</p>	<p><u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape.</u></p>	<p>Page 6, lines 16 and 17                  Page 12, lines 14-16                  Original claim 9                  FIG. 16:</p> 
<p>28</p>	<p><u>The guide extension catheter of claim 27, wherein the portion having the arcuate cross-sectional shape extends for a length of 15 cm.</u></p>	<p>Page 6, lines 17-22                  Page 13, lines 1 and 2</p>
<p>29</p>	<p><u>The guide extension catheter of claim 27, wherein the arcuate cross-sectional shape radially extends 25% to 40% of a cross-sectional circumference of a tube.</u></p>	<p>Page 13, lines 1 and 2</p>

30	<p><u>The guide extension catheter of claim 25, wherein a cross-sectional inner diameter of the lumen of the tubular structure is not more than one French size smaller than a cross-sectional inner diameter of a lumen of the guide catheter.</u></p>	<p>Page 5, lines 8-18</p> <p>Original claims 8 and 18</p>
31	<p><u>The guide extension catheter of claim 30, wherein the cross-sectional inner diameter of the lumen of the tubular structure is uniform in size from a proximal end to a distal end of the tubular structure.</u></p>	<p>Original claim 1</p> <p>FIG. 4:</p> 
32	<p><u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening includes a portion having a hemicylindrical cross-sectional shape.</u></p>	<p>Page 6, lines 16 and 17</p> <p>Page 12, lines 12-16, 19 and 20</p> <p>Original claim 9</p> <p>FIG. 15:</p> 
33	<p><u>The guide extension catheter of claim 32, wherein the portion having the hemicylindrical cross-sectional shape extends for a length of 20 cm to 75 cm.</u></p>	<p>Page 6, lines 17-22</p> <p>Page 12, lines 19 and 20</p>
34	<p><u>The guide extension catheter of claim 32, wherein the hemicylindrical cross-sectional shape radially extends 40% to 70% of a cross-sectional circumference of a tube.</u></p>	<p>Page 12, lines 19 and 20</p>

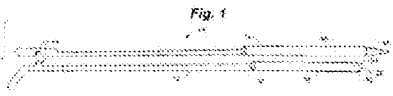
REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

35	<p><u>The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least one inclined region that tapers into a non-inclined region.</u></p>	<p>FIG. 4:</p> 
36	<p><u>The guide extension catheter of claim 25, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.</u></p>	<p>FIG. 4:</p> 
37	<p><u>The guide extension catheter of claim 25, wherein the segment defining the partially cylindrical opening defines a concave track that is continuous with the lumen of the tubular structure.</u></p>	<p>Page 13, lines 10 and 11</p> <p>FIG. 6:</p> 
38	<p><u>The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a hypotube.</u></p>	<p>Page 6, lines 2 and 3</p> <p>Page 12, lines 13 and 14</p>
39	<p><u>The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a section of stainless steel.</u></p>	<p>Page 6, lines 2 and 3</p> <p>Page 6, lines 15 and 16</p> <p>Page 12, lines 13 and 14</p>
40	<p><u>The guide extension catheter of claim 25, wherein the substantially rigid segment is formed from a section of Nitinol tubing.</u></p>	<p>Page 6, lines 2 and 3</p> <p>Page 6, lines 15 and 16</p> <p>Page 12, lines 13 and 14</p>
41	<p><u>The guide extension catheter of claim 25, wherein the substantially rigid segment is eccentrically positioned relative to a cross-section of the tubular structure.</u></p>	<p>Page 6, lines 2 and 3</p> <p>Page 12, lines 12 and 13</p> <p>FIG. 4:</p>

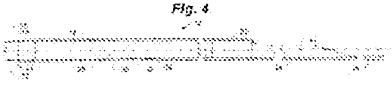




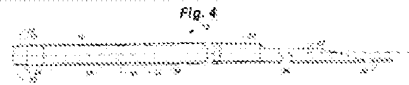
REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

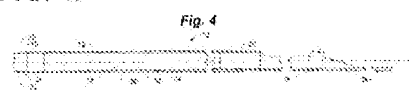
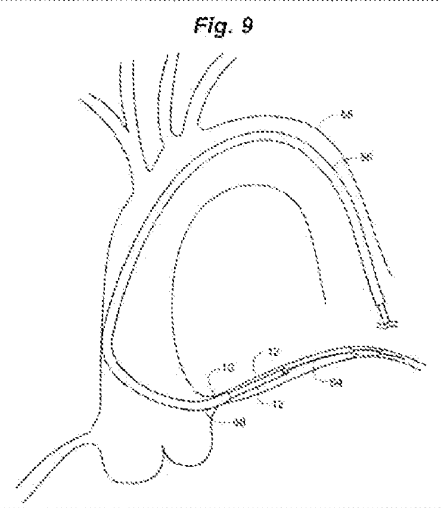
		
42	<p><u>The guide extension catheter of claim 25, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure to be advanced within and partially through the guide catheter while permitting at least partial delivery of the one or more received interventional cardiology devices alongside the substantially rigid segment, through the angled proximal end of the partially cylindrical opening, and through the lumen of the tubular structure.</u></p>	<p>Page 5, lines 5-7</p> <p>Page 6, lines 2 and 3</p> <p>Page 8, lines 3-5</p> <p>Page 15, lines 1-10</p> <p>FIG. 4:</p> 
43	<p><u>The guide extension catheter of claim 25, wherein the substantially rigid segment has an outer size and the lumen of the tubular structure has an inner size, the inner size of the lumen being greater than the outer size of the substantially rigid segment.</u></p>	<p>Page 6, lines 2 and 3</p> <p>FIG. 4:</p>  <p>Original claims 1 and 12</p>
44	<p><u>The guide extension catheter of claim 25, further comprising a tip portion positioned distal to the distal end of the tubular structure.</u></p>	<p>Page 6, lines 1-9</p> <p>Page 11, lines 15-20</p> <p>Original claims 5 and 12</p>
45	<p><u>The guide extension catheter of claim 25, wherein the tubular structure includes a reinforcing braid or coil extending along a portion of a length of the tubular structure and surrounded by one or more polymer materials.</u></p>	<p>Page 6, lines 10-14</p> <p>Page 12, lines 5-11</p> <p>Page 19, line 1</p> <p>Original claims 5, 6 and 17</p>
46	<p><u>The guide extension catheter of claim 45, wherein a length of the reinforcing braid or coil is 20 to 30 cm.</u></p>	<p>Page 6, lines 10-14</p> <p>Page 12, lines 9-11</p>

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

47	<p><u>The guide extension catheter of claim 25, wherein the substantially rigid segment and the partially cylindrical opening comprise a rigid portion of the guide extension catheter.</u></p>	<p>Page 6, lines 2 and 3</p> <p>Page 6, lines 16 and 17</p> <p>Page 12, lines 12-18</p> <p>Original claim 14</p>
48	<p><u>The guide extension catheter of claim 25, wherein the partially cylindrical opening and the tubular structure comprise a reinforced portion of the guide extension catheter.</u></p>	<p>Page 6, lines 1-4 and 10-14</p> <p>Original claims 3 and 4</p>
49	<p><u>The guide extension catheter of claim 25, wherein a material forming the partially cylindrical opening is more rigid than a material or material combination forming the tubular structure.</u></p>	<p>Page 6, lines 15 and 17</p> <p>Page 14, lines 3-8</p> <p>Page 13, line 15 – page 14, line 8</p>
50	<p><u>A guide extension catheter for use with a guide catheter having a lumen with a cross-sectional inner diameter, comprising:</u></p> <p style="padding-left: 40px;"><u>a substantially rigid segment;</u></p> <p style="padding-left: 40px;"><u>a tubular structure defining a lumen and positioned distal to the substantially rigid segment, the lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter; and</u></p> <p style="padding-left: 40px;"><u>a segment defining a partially cylindrical opening positioned between a distal end of the substantially rigid segment and a proximal end of the tubular structure, the segment defining the partially cylindrical opening having</u></p>	<p>Page 5, lines 8-18</p> <p>Page 6, lines 1-4</p> <p>Page 7, line 14 – page 8, line 2</p> <p>Page 9, lines 12-14</p> <p>Page 12, lines 12-16</p> <p>Page 19, lines 12-14</p> <p>Original claims 1, 3, 8, 12 and 18</p> <p>FIGS. 1, 4 and 14:</p> 

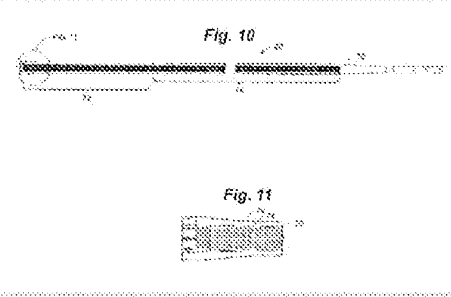
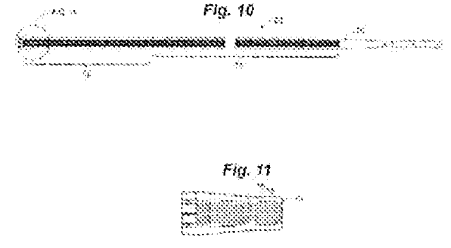


	<p><u>an angled proximal end and configured to receive one or more interventional cardiology devices when positioned within the lumen of the guide catheter, a cross-section of the guide extension catheter at the proximal end of the tubular structure defining a single lumen.</u></p>	 <p><b>Fig. 14</b></p> 
<p>51</p>	<p><u>The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening is formed from a structure having a greater flexural modulus than a flexural modulus of the tubular structure.</u></p>	<p>Page 6, lines 16 and 17</p> <p>Page 13, line 15 – page 14, line 8</p> <p>Original claims 20-22</p>
<p>52</p>	<p><u>The guide extension catheter of claim 50, wherein the segment defining the partially cylindrical opening includes a portion having an arcuate cross-sectional shape, a portion having a hemicylindrical cross-sectional shape, and a portion having a full circumference cross-sectional shape.</u></p>	<p>Page 12, lines 14-16 and 21</p> <p>Page 16, lines 15-21</p> <p>Original claims 9 and 19</p> <p>FIGS. 14, 15, and 16:</p>   
<p>53</p>	<p><u>The guide extension catheter of claim 50, wherein a cross-section of the substantially rigid segment is sufficiently sized and configured to permit the tubular structure of the guide extension catheter to be advanced partially through the guide catheter and into a coronary artery while preserving space of the cross-sectional inner diameter of the lumen of the guide catheter.</u></p>	<p>Page 4, lines 16-18</p> <p>Page 5, lines 5-7</p> <p>Page 6, lines 2 and 3</p> <p>Page 8, lines 3-5</p> <p>Page 15, lines 1-10</p> <p>FIG. 4:</p> 

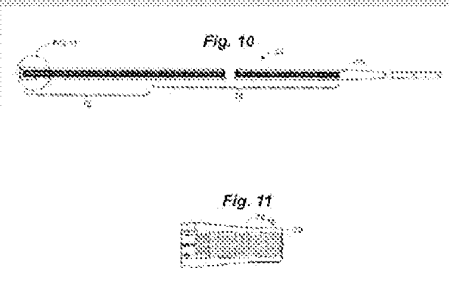
54	<p><u>The guide extension catheter of claim 50, wherein the segment defining the angled proximal end of the partially cylindrical opening includes at least two inclined regions.</u></p>	<p>FIG. 4:</p> 
55	<p><u>The guide extension catheter of claim 25, wherein a distal portion of the tubular structure is configured to anchor within an ostium of a coronary vessel and resist axial and shear forces exerted by the received one or more interventional cardiology devices that would otherwise tend to dislodge the distal portion.</u></p>	<p>Page 9, lines 6-8</p> <p>Page 15, lines 10-17</p> <p>Original claim 2</p> <p>FIG. 9</p> 
56	<p><u>The guide extension catheter of claim 30, wherein the lumen of the tubular structure is configured to receive a stent and a balloon catheter.</u></p>	<p>Page 8, lines 3-5</p> <p>Page 14, lines 16-18</p>



REISSUE APPLICATION NO. 14/195,413  
 TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

		<p>Page 15, lines 9, 10, 17 and 18</p> <p>Page 19, lines 12-14</p>
<p>57</p>	<p><u>The guide extension catheter of any one of claims 25, 28, 30, 31, 33, 35, 38, 47, 49-51 or 54-56, wherein the segment defining the partially cylindrical opening includes one or more cuts.</u></p>	<p>Page 7, lines 3 and 4</p> <p>Page 10, lines 15-17</p> <p>Page 15, line 19 – page 16, line 14</p> <p>FIGS. 10 and 11</p> 
<p>58</p>	<p><u>The guide extension catheter of claim 57, wherein at least one cut includes two circumferential cuts along a single line and separated by a section of uncut structure.</u></p>	<p>Page 7, lines 3 and 4</p> <p>Page 10, lines 15-17</p> <p>Page 15, line 19 – page 16, line 14</p> <p>FIGS. 10 and 11</p> 

REISSUE APPLICATION NO. 14/195,413  
TO BE GIVEN PRIORITY IN EXAMINATION (MPEP 708)

59	<u>The system of claim 57, wherein a first cut is spaced approximately 0.010 inches apart from a second cut.</u>	Page 7, lines 3 and 4 Page 10, lines 15-17 Page 15, line 19 -- page 16, line 14 FIGS. 10 and 11 
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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,



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## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>	14195413			
<b>Filing Date:</b>	03-Mar-2014			
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES			
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root			
<b>Filer:</b>	Bradley Pedersen/Mary Granger			
<b>Attorney Docket Number:</b>	2005.86USREI5			
Filed as Small Entity				
<b>Utility under 35 USC 111(a) Filing Fees</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
Claims in excess of 20	2202	35	40	1400
Multiple Dependent Claims	2203	1	390	390
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Extension-of-Time:</b>				
<b>Miscellaneous:</b>				
<b>Total in USD (\$)</b>				<b>1790</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	19279502
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Bradley Pedersen/Mary Granger
<b>Filer Authorized By:</b>	Bradley Pedersen
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	11-JUN-2014
<b>Filing Date:</b>	03-MAR-2014
<b>Time Stamp:</b>	18:44:05
<b>Application Type:</b>	Utility under 35 USC 111(a)

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Payment was successfully received in RAM	\$1790
RAM confirmation Number	5225
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86USREI5_PreAmd.pdf	4195871 <small>80244e15a45a866b6d3e1d47f2260183d72cda0b</small>	yes	33

**Multipart Description/PDF files in .zip description**

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	16
Applicant Arguments/Remarks Made in an Amendment	17	33

**Warnings:**

**Information:**

2	Fee Worksheet (SB06)	fee-info.pdf	32181 <small>cd6583f82d419a6280ad77e3a40f36acc6806614</small>	no	2
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**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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.

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875	Application or Docket Number 14/195,413	Filing Date 03/03/2014	<input type="checkbox"/> To be Mailed
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ENTITY:  LARGE  SMALL  MICRO

**APPLICATION AS FILED – PART I**

FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (j), or (m))	N/A	N/A	N/A	
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		X \$ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X \$ =	
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	

**APPLICATION AS AMENDED – PART II**

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
	<b>06/11/2014</b>	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(i))	* 74	Minus ** 30	= 44	x \$40 =	1760
	Independent (37 CFR 1.16(h))	* 2	Minus ***3	= 0	x \$210 =	0
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input checked="" type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
						<b>390</b>
						<b>TOTAL ADD'L FEE</b>
						<b>2150</b>

AMENDMENT	(Column 1)	(Column 2)	(Column 3)	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)
		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR			
	Total (37 CFR 1.16(i))	*	Minus **	=	X \$ =	
	Independent (37 CFR 1.16(h))	*	Minus ***	=	X \$ =	
	<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))					
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					
						TOTAL ADD'L FEE

\* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.  
 \*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".  
 \*\*\* If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

LIE  
/TERRY MALLOY/

This collection of information is required by 37 CFR 1.16. 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
 If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	14/195,413
				Filing Date	March 3, 2014
				First Named Inventor	Howard C. Root et al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	2005.86USRE15

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL <sup>*</sup>	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> <i>(if known)</i>		
		US-7,232,452 B2	06-19-2007	Adams et al.
		US-		
		US-		
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**FOREIGN PATENT DOCUMENTS**

EXAMINER INITIAL <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> <i>(if known)</i>			

EXAMINER SIGNATURE	DATE CONSIDERED
--------------------	-----------------

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  
<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.  
 This collection of information is required by 37 CFR 1.97 and 1.98. 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 2 hours 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, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	19285221
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Mary Granger
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	12-JUN-2014
<b>Filing Date:</b>	03-MAR-2014
<b>Time Stamp:</b>	13:12:52
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86USREI5_SppIDS.pdf	366380 <small>854eb72e430846ed7e5abd6b8bd31ed6a8e9af3f</small>	yes	4

<b>Multipart Description/PDF files in .zip description</b>		
<b>Document Description</b>	<b>Start</b>	<b>End</b>
Transmittal Letter	1	3
Information Disclosure Statement (IDS) Form (SB08)	4	4
<b>Warnings:</b>		
<b>Information:</b>		
<b>Total Files Size (in bytes):</b>		366380
<p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p>		

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USREI5

Howard C. Root et al.

Confirmation No.: 6135

Application No.: 14/195,413

Examiner: Unassigned

Filed: March 3, 2014

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

---

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

Pursuant to 37 CFR § 1.56, and in addition to information disclosed in any previously filed prior Information Disclosure Statements, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of the above-referenced application, and be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information may not be prior art, and/or prove that this information may not be enabling for any aspect of the information provided herewith.

This Information Disclosure Statement is being filed without a certification or fee because this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR § 1.97(b)(3).

The Examiner's attention is directed to the applications or patents, if any, to which priority is claimed, as well as to any continuing applications which claim priority to the above-referenced application, and to applications, if any, that may be related by virtue of similar claimed subject matter as the above-referenced application (collectively, the "Related Case(s)"). The Related Case(s), or documents associated with the Related Case(s), are identified on the attached form PTO-1449 by serial number, publication number and/or patent number, along with a copy of the current prosecution history, downloaded from PAIR where available. The current prosecution history for the Related Case(s) is submitted as an NPL document for the convenience of the Examiner.

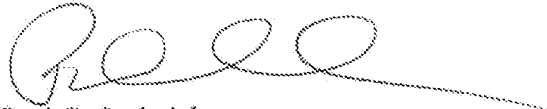
The prosecution history for any and all of these Related Case(s) may include information material to patentability of the above-referenced application including Office Actions, Responses, Office Communications or Notices of Allowance, all of which are readily accessible to the Examiner via PAIR/PALM. To promote consistency and full disclosure during the prosecution of the above-referenced application together with the prosecution of any of the Related Case(s) and to assist the Examiner in complying with the obligations of MPEP 2001.06(b), the Examiner is respectfully requested to review the prosecution history of each of the Related Case(s). **This request for review should be considered ongoing throughout the prosecution of the above-referenced application with an updated review via PAIR/PALM of the prosecution histories of any Related Case(s) being made prior to issuance of any**

Application No. 14/195,413

Notice of Allowance for the above-referenced application. The identification of any of the Related Case(s) for purposes of this Information Disclosure Statement should not be construed as a waiver of secrecy, if applicable, as to such applications now or upon issuance of the above-referenced application as a patent. For purposes of the Related Case(s), it should be noted that all of the Related Case(s) are published or otherwise publicly available on PAIR.

Please note that copies of the references that were cited by or submitted to the Office in applications which are relied upon for an earlier filing date under 35 U.S.C. § 120 may be found in the appropriate records via PAIR/PALM. 37 CFR § 1.98(d).


Respectfully submitted,



Paul C. Onderick  
Registration No. 45354

Customer No. 24113  
Patterson Thuente 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.*

<b>Application Number</b> 	<b>Application/Control No.</b> 14/195,413	<b>Applicant(s)/Patent under Reexamination</b> ROOT ET AL.	
<b>Document Code - DISQ</b>		<b>Internal Document – DO NOT MAIL</b>	

<b>TERMINAL DISCLAIMER</b>	<input checked="" type="checkbox"/> <b>APPROVED</b>	<input type="checkbox"/> <b>DISAPPROVED</b>
Date Filed : 3/25/14	<b>This patent is subject to a Terminal Disclaimer</b>	

**Approved/Disapproved by:**

JEAN PROCTOR



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	19663424
<b>Application Number:</b>	14195413
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	6135
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard C. Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Mary Granger
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86USREI5
<b>Receipt Date:</b>	23-JUL-2014
<b>Filing Date:</b>	03-MAR-2014
<b>Time Stamp:</b>	16:36:22
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		SupplDS.pdf	396839 <small>57b40c57b28ea980af8397b7318d4b7f3ba edce6</small>	yes	4



Multipart Description/PDF files in .zip description					
Document Description			Start	End	
Transmittal Letter			1	3	
Information Disclosure Statement (IDS) Form (SB08)			4	4	
<b>Warnings:</b>					
<b>Information:</b>					
2	Non Patent Literature	NPL1_Defndnt_BSCs_PriorArtStmt.pdf	1018777 0e032058e49bb40c849c1699c2470b0be82eb5b6	no	97
<b>Warnings:</b>					
<b>Information:</b>					
3	Non Patent Literature	NPL2_BSCs_1st_AmendedPriorArtStmt.pdf	927970 6cd9ccc6e0c1fd2d5f80772310f630e5e60261f4	no	102
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<b>Information:</b>					
4	Non Patent Literature	NPL3_VSIs_Resp_to_BSCs_PriorArtStmt.pdf	805092 1b6fff0ee35d9e4484a225b2d24e4a4f6d77e73a	no	16
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<b>Information:</b>					
5	Non Patent Literature	NPL4_VSIs_Resp_to_1st_AmendedPriorArtStmt.pdf	954667 1a720908920fc07a5f311ab6e43d16519a13b44b	no	18
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			4103345		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

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**New International Application Filed with the USPTO as a Receiving Office**

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USREI5

Howard C. Root et al.

Confirmation No.: 6135

Application No.: 14/195,413

Examiner: Unassigned

Filed: March 3, 2014

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

---

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

Pursuant to 37 CFR § 1.56, and in addition to information disclosed in any previously filed prior Information Disclosure Statements, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of the above-referenced application, and be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information may not be prior art, and/or prove that this information may not be enabling for any aspect of the information provided herewith.

This Information Disclosure Statement is being filed without a certification or fee because this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR § 1.97(b)(3).

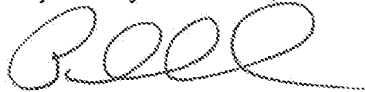
The Examiner's attention is directed to the applications or patents, if any, to which priority is claimed, as well as to any continuing applications which claim priority to the above-referenced application, and to applications, if any, that may be related by virtue of similar claimed subject matter as the above-referenced application (collectively, the "Related Case(s)"). The Related Case(s), or documents associated with the Related Case(s), are identified on the attached form PTO-1449 by serial number, publication number and/or patent number, along with a copy of the current prosecution history, downloaded from PAIR where available. The current prosecution history for the Related Case(s) is submitted as an NPL document for the convenience of the Examiner.

The prosecution history for any and all of these Related Case(s) may include information material to patentability of the above-referenced application including Office Actions, Responses, Office Communications or Notices of Allowance, all of which are readily accessible to the Examiner via PAIR/PALM. To promote consistency and full disclosure during the prosecution of the above-referenced application together with the prosecution of any of the Related Case(s) and to assist the Examiner in complying with the obligations of MPEP 2001.06(b), the Examiner is respectfully requested to review the prosecution history of each of the Related Case(s). **This request for review should be considered ongoing throughout the prosecution of the above-referenced application with an updated review via PAIR/PALM**

of the prosecution histories of any Related Case(s) being made prior to issuance of any Notice of Allowance for the above-referenced application. The identification of any of the Related Case(s) for purposes of this Information Disclosure Statement should not be construed as a waiver of secrecy, if applicable, as to such applications now or upon issuance of the above-referenced application as a patent. For purposes of the Related Case(s), it should be noted that all of the Related Case(s) are published or otherwise publicly available on PAIR.

Please note that copies of the references that were cited by or submitted to the Office in applications which are relied upon for an earlier filing date under 35 U.S.C. § 120 may be found in the appropriate records via PAIR/PALM. 37 CFR § 1.98(d).

Respectfully submitted,



Paul C. Onderick  
Registration No. 45354

Customer No. 24113  
Patterson Thuente 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.*

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86USRE15

Howard Root Et Al.

Confirmation No.: 6135

Application No.: 14/195,413

Examiner: Unassigned

Filed: March 3, 2014

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

---

NOTIFICATION OF CONCURRENT PROCEEDINGS

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

Sir:

In accordance with 37 C.F.R. §1.56, 37 C.F.R. § 1.178(b) and MPEP §2001.06, the attention of the Office is hereby directed to pending *Inter Partes* Review Case Number IPR2014-00762 (U.S. Patent No. 8,292,850) and *Inter Partes* Review Case Number IPR2014-00763 (U.S. Patent No. 8,292,850) which relate to the patent upon which this reissue application is based.

The attention of the Office is also hereby directed to pending; *Inter Partes* Review Case Number IPR2014-00759 (U.S. Patent No. 8,142,413); *Inter Partes* Review Case Number IPR2014-00760 (U.S. Patent No. 8,048,032); and *Inter Partes* Review Case Number IPR2014-00761 (U.S. Patent No. 8,048,032). These relate to family members of the patent upon which this reissue application is based. The Examiner is respectfully requested to consider these *Inter*

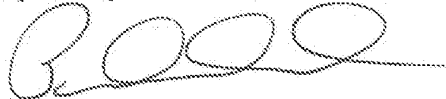
Application No. 14/195,413

*Partes* Review's, their file wrappers and prosecution records, information, and the art cited therein during examination. No fee is believed due with this submission.

All of these *Inter Partes* Review Cases are subject to an Order Authorizing Joint Motions to Terminate dated August 6, 2014.

Copies of the Petitions for *Inter Partes* Review Under 37 C.F.R. § 42.100 as filed in each of the above-identified cases are attached hereto for the Examiner's convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. Onderick', with a horizontal line extending to the right.

Paul C. Onderick  
Registration No. 45354

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

*Please charge any fee due with this submission to Deposit Account No. 16-0631*

# ATTACHMENT A



UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

BOSTON SCIENTIFIC CORPORATION and  
BOSTON SCIENTIFIC SCIMED, INC.  
Petitioner

v.

VASCULAR SOLUTIONS, INC.  
Patent Owner

---

Case IPR: Unassigned  
Patent 8,292,850

---

Attorney Docket No. 0025216-00057

---

**PETITION FOR INTER PARTES REVIEW  
UNDER 37 C.F.R. § 42.100**

# ATTACHMENT A

**TABLE OF CONTENTS**

	<u>Page</u>
I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)).....	1
A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) .....	1
B. Related Matters (37 C.F.R. § 42.8(b)(2)).....	1
C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a)) .....	2
D. Service Information (37 C.F.R. § 42.8(b)(4)) .....	2
II. PAYMENT OF FEES (37 C.F.R. § 42.103) .....	2
III. SUMMARY OF RELEVANT TECHNOLOGY AND ‘850 PATENT .....	3
A. Overview Of Interventional Cardiology Procedures .....	3
B. Description Of The Alleged Invention Of The ‘850 Patent.....	4
C. Effective Filing Date of the Contested Patent.....	7
D. Summary of the Prosecution History of the ‘850 Patent .....	7
IV. REQUIREMENTS FOR INTER PARTES REVIEW .....	8
A. Grounds for Standing Under 37 C.F.R. § 42.104(a).....	9
B. Identification of Challenge and Relief Requested .....	9
C. Claims for Which <i>Inter Partes</i> Review Is Requested .....	9
D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2) .....	9
V. Non-Redundancy of Proposed Alternative Grounds.....	10
VI. Level of Skill In the Art.....	12
A. Construction Of The Challenged Claims .....	13
1. “rail structure without a lumen”.....	14
2. “interventional cardiology device(s)”.....	15
3. “to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter” / “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” .....	16
4. “adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device assed through and	

	beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery”.....	18
B.	The Prior Art References.....	19
	1. Adams ‘292.....	19
	2. Klein.....	20
	3. Adams ‘452.....	20
	4. Steinke.....	21
	5. Takahashi.....	22
C.	How The Construed Claim(s) Are Unpatentable.....	22
D.	Supporting Evidence Under 37 C.F.R. § 42.104(b)(5).....	22
VII.	DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b) (4).....	23
A.	Claims 1, 2, 8, 12, And 18 Are Anticipated Under 35 U.S.C. §102(b) By Adams’292.....	23
	1. Claim 1.....	23
	2. Claim 2.....	25
	3. Claim 12.....	25
	4. Claims 8 and 18.....	25
VIII.	Obviousness of Challenged Claims.....	38
A.	Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Klein.....	38
B.	Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of Adams ‘452.....	44
C.	Claims 1-4, 8, 12, 14 and 18 Are Obvious Under 35 U.S.C. § 103 Over Adams ‘292 In View Of Steinke.....	50
D.	Claims 1, 2, 8, 12 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of The Knowledge of One Of Skill In The Art.....	56
E.	Claims 1, 2, 8, 12 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Takahashi.....	57
IX.	CONCLUSION.....	59

**Exhibit List for Inter Partes Review of U.S. Patent No. 8,292,850**

Exhibit Description	Exhibit No.
U.S. Patent No. 8,292,850 B2 to Root, et al.	1001
File History for U.S. Patent No. 8,292,850	1002
Declaration of Ronald Jay Solar, Ph.D., with attached Appendix 1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,048,032 to Root, et al.	1004
U.S. Patent No. 8,142,413 to Root, et al.	1005
File History for U.S. Patent No. 8,048,032	1006
File History for U.S. Patent No. 8,142,413	1007
Copy of a Second Petition (excluding exhibits) for <i>Inter Partes</i> Review Filed Concurrently by Petitioner on the '850 Patent	1008B
U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1009
Translation of Japanese Patent Application No. 2003-070808	1010
U.S. Patent No. 5,527,292 to Adams et al.	1011
U.S. Publication No. 2007/0260219 A1 to Root et al.	1012
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1013
U.S. Patent No. 6,638,268 to Niazi	1014
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1015
U.S. Publication No. 2004/0127927 to Adams	1016
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1017
U.S. Patent No. 5,776,141 to Klein et al.	1018
U.S. Patent No. 7,232,452 to Adams et al.	1019
U.S. Patent No. 5,328,472 to Steinke et al.	1020
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," <i>Catherization and Cardiovascular Interventions</i> 63:452-456 (2004)	1021
U.S. Patent No. 5,690,613 to Verbeek	1022
U.S. Patent No. 5,156,594 to Keith	1023
U.S. Patent No. 5,102,403 to Alt	1024
Kucklick, Theodore R., <i>The Medical Device R&amp;D Handbook</i> (2006)	1025
Amended Complaint filed by Vascular Solutions, Inc. in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (May 28, 2013)	1026
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn).	1027

Exhibit Description	Exhibit No.
(June 10, 2013)	
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (June 10, 2013)	1028
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (July 28, 2013)	1029
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (December 19, 2013)	1030
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed December 27, 2013	1031
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed January 3, 2014	1032
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir). filed January 7, 2014	1033
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir). filed January 29, 2014	1034
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir). filed February 3, 2014	1035
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir).	1036
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1037
Joint Claim Construction Statement filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (February 21, 2014)	1038
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1039
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1040
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1041
U.S. Patent No. 5,267,958 to Buchbinder et al.	1042

*Inter partes* review is respectfully requested for claims 1-4, 8, 12, 14, 18 of U.S. Patent No. 8,292,850 (“the ‘850 Patent”) (Exh. 1001).

**I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))**

The following mandatory notices are provided as part of this Petition.

**A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))**

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively “Petitioner”) are the real parties-in-interest.

**B. Related Matters (37 C.F.R. § 42.8(b)(2))**

The ‘850 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 1:13-cv-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of the ‘850 Patent on other grounds in another petition to be filed concurrently herewith. Further, Petitioner is filing two separate petitions on non-redundant grounds seeking *inter partes* review of U.S. Patent No. 8,048,032 (the “‘032 patent”) and one petition seeking review of U.S. Patent No. 8,142,413 (the “‘413 patent”) to be filed concurrently herewith. In all, five petitions will be filed. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and are directed generally to the same subject matter. Specifically, the ‘850 patent is a division of application No. 12/824,734, which issued as the ‘413 patent, and the ‘413 patent is a division of

application No. 11/416,629, which issued as the '032 patent. The claims challenged therein are method ('413 patent (Exh. 1005)) and apparatus ('032 patent (Exh. 1004)) versions of the system claims of the '850 patent challenged herein.

**C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))**

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

Lead Counsel	Back-Up Counsel
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**D. Service Information (37 C.F.R. § 42.8(b)(4))**

Petitioner consents to service by email to lead and backup counsel at xBSC\_VSI\_IPRService@aporter.com.

**II. PAYMENT OF FEES (37 C.F.R. § 42.103)**

The undersigned authorizes the Office to charge Deposit Account No. 50-2387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for



any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

### **III. SUMMARY OF RELEVANT TECHNOLOGY AND '850 PATENT**

#### **A. Overview Of Interventional Cardiology Procedures**

The claims of the '850 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (*See* Exh. 1001, 1:7-36). During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*See* Declaration of Ronald Jay Solar, Ph.D. (“Solar Declaration”) (Exh. 1003 ¶ 8)). The physician introduces the treatment device into the patient’s vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id.*) Often, to create a passage for such treatment devices, physicians insert a “guide catheter” earlier in the procedure. (*Id.*) In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id.*) The '850 patent is directed to an apparatus that is deliverable through a standard guide catheter for extension

beyond the ostium to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (*See, e.g.*, Exh. 1001, 2:45-49).

**B. Description Of The Alleged Invention Of The ‘850 Patent**

The ‘850 Patent (Exh. 1001) contains 24 system claims, including two independent claims (claims 1 and 12). The specification of the ‘850 patent states that it relates “generally to catheters used in interventional cardiology procedures” and “[m]ore particularly ... apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta.” (Exh. 1001, 1:18-22).

The challenged claims of the ‘850 patent are not straightforward. Unlike typical system claims, the ‘850 patent claims are replete with functional language and ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Claim 1 of the ‘850 patent is representative of the independent claims:

1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; a device adapted for use with the guide catheter, including: a flexible tip portion defining a tubular structure and having a circular cross-section and a

length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the 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.

(Exh. 1001, 10:35-11:4).

Dependent claim 2 of the '850 patent depends from independent claim 1 and requires that "the tubular structure includes a distal portion *adapted to be extended beyond* the distal end of the guide catheter ... *such that* the device assists in resisting axial and shear forces exerted by the interventional cardiology device

passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.” (*Id.*, 11:5-2).

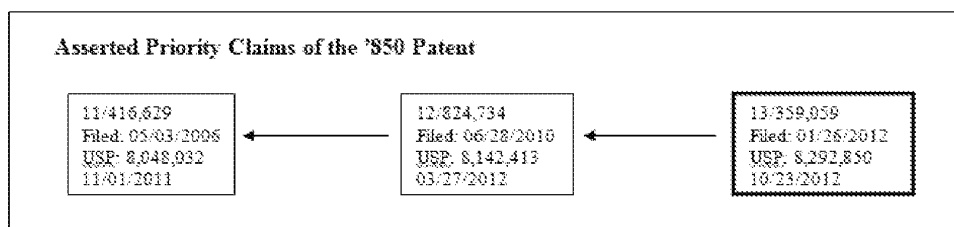
Dependent claim 3 (depending from independent claim 1 and dependent claim 2), is directed to a “proximal side opening” in a proximal portion of the tubular structure, where such opening “extend[s] for a distance along the longitudinal axis” and is “transverse [*i.e.*, at an angle] to the longitudinal axis.” Dependent claim 14 (depending from independent claim 12) contains substantially similar limitation, except that the “partially cylindrical portion defining an opening extending for a distance along a side thereof” in the substantially rigid (as opposed to tubular) portion. (*Id.*, 11:13-20).

Dependent claim 4 depends from claim 3 and requires a “structure defining a full circumference portion and structure defining a partially cylindrical portion,” (*id.*, 11:21-23) as would result from a tube being skived at an angle for part of its length. These ‘side opening claims’ are directed to that which was well known in the art when the ‘850 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle.

Dependent claim 8 (depending from independent claim 1) and 18 (depending from independent claim 12) require that “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.”

**C. Effective Filing Date of the Contested Patent**

As depicted below, the ‘850 patent asserts priority back to May 3, 2006 through a chain of two applications: (1) U.S. Patent Application No. 11/416,629 (filed May 3, 2006 and issued as U.S. Patent No. 8,048,032 (the “’032 patent”), and (2) U.S. Patent Application No. 12/824,734 (filed June 28, 2010 and issued as U.S. Patent No. 8,142,413 (the “’413 patent”)).<sup>1</sup>



**D. Summary of the Prosecution History of the ‘850 Patent**

<sup>1</sup> Petitioner’s depiction of the asserted priority claims of the ‘850 patent is for illustrative purposes only. Petitioner notes that it is contesting the asserted priority date of the ‘850 patent in a concurrently filed parallel Petition, “Petition B,” challenging the claims of the ‘850 patent on different grounds. (See Exh. 1008). Since the prior art relied upon for purposes of this Petition has an effective prior art date well before Patent Owner’s asserted priority date of May 3, 2006, Petitioner applies this as the presumed effective date of the ‘850 patent exclusively for purposes of its analysis herein.

The '850 Patent was filed as U.S. App. Serial No. 13/359,059 on January 26, 2012 (Exh. 1002, paper 1). The prosecution of the '032 patent, to which the '850 claims priority, spanned five years and three months. During that time, the Examiner issued numerous rejections of claims which are nearly identical to the system claims of the '850 patent challenged herein. Ultimately, however, following at least six rejections and eight amendments, the Examiner conditioned patentability of the claims on the addition of a "rail structure without a lumen" limitation within the substantially rigid portion.

The claims of the '850 patent issued following an amendment by the same Examiner of independent claims 1 and 12 moving the location of the "rail structure without a lumen" limitation from the tubular structure of the flexible tip portion (where the Patent Owner had sought to include it), to the substantially rigid portion, where it had been included in the '032 patent. The Examiner's stated reasons for allowance were that, "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." A Notice of Allowance was mailed August 22, 2012, and the '850 Patent issued on October 23, 2012. (Exh. 1002 at 16).

#### **IV. REQUIREMENTS FOR INTER PARTES REVIEW**

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '850 Patent is satisfied.

**A. Grounds for Standing Under 37 C.F.R. § 42.104(a)**

Petitioner certifies that the '850 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

**B. Identification of Challenge and Relief Requested**

Pursuant to 37 C.F.R. § 42.104(b), the precise relief requested by Petitioner is that claims 1-4, 8, 12, 14, and 18 of the '850 Patent be found unpatentable.

**C. Claims for Which *Inter Partes* Review Is Requested**

Pursuant to 37 C.F.R. § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1-4, 8, 12, 14, and 18 of the '850 Patent.

**D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)**

This Petition, supported by the grounds set forth below and the Solar Declaration, demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C. § 314(a). Dr. Solar, an expert with 37 years of academic and industry experience in the field of interventional cardiology devices, has reviewed the claim charts submitted in the '850 Petition and is in agreement with the grounds of invalidity and the evidentiary

support set forth therein. (See Exh. 1003 ¶ 82). *Inter partes* review is requested in view of the following references and specific grounds for rejection.

No.	Grounds
1	Claims 1-2, and 12 are anticipated by US 5,527,292 (“Adams ‘292”)
2	Claims 1-4, 12 and 14 are obvious over Adams ‘292 in view of US 5,776,141 (“Klein”)
3	Claims 1-4, 12 and 14 are obvious over Adams ‘292 in view of US 7,232,452 (“Adams ‘452”)
4	Claims 1-4, 12 and 14 are obvious over Adams ‘292 in view of US 5,328,472 (“Steinke”)
5	Claims 1-2, 8, 12 and 18 are obvious over Adams ‘292 in view of Knowledge of One of Skill in the Art
6	Claims 1-2, 8, 12 and 18 are obvious over Adams ‘292 in view of “New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter,” 2004, Takahashi Online Article (“Takahashi”)

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

**V. Non-Redundancy of Proposed Alternative Grounds**

Petitioner urges the Board to adopt each ground of unpatentability raised with respect to claims 1-4, 8, 12, 14 and 18 of the ‘850 patent for at least the following reasons. The proposed grounds for institution presented in the present Petition (“Petition A”) are not redundant over each other, or over the grounds of rejection presented in the concurrently filed parallel Petition for *inter partes* review of the challenged claims of the ‘850 patent, (“Petition B” (Exh. 1008)), because several differences exist between the applied prior art and their respective grounds for unpatentability. For example, the primary prior art reference (Mihara) in



parallel Petition B differs from the primary prior art reference raised herein (Adams '292). Mihara anticipates a different set of dependent claims (claims 3, 4, and 14) through its disclosure of a skived proximal side opening in Figures 1-3. Adams '292 anticipates the claimed difference in diameter between the inner diameter of the device and the inner diameter of the standard guide catheter of "not more than one French" (claims 8 and 18). As a result, during the course of this proceeding, if instituted, Patent Owner could amend the claims to be limited to just one of these claimed embodiments that is not covered by anticipation in view of Adams '292 (Petition A) or Mihara (Petition B) alone. Accordingly, all grounds based on both Adams '292 and Mihara are needed to cover all of the embodiments encompassed by claims 1, 2, and 12, and, as such, are not redundant. Indeed, because of the Patent Owner's unreasonably functional and broad claims, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structures of the systems in the cited references, and so that Petitioner may address any arguments by the Patent Owner regarding the ability of structures in the prior art to perform the various functions recited in each of the challenged claims.

Petitioner's asserted ground of unpatentability in Petition B based on Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the '032 patent), is not redundant of the other grounds of

unpatentability raised herein because it renders obvious all challenged claims only if the '850 patent is denied the benefit of its claimed May 3, 2006 priority date.

For similar reasons, the grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 3, 4, and 14 are not redundant given that the far reaching functional language of such claims necessitate Petitioner's alternative proposed grounds of unpatentability on the basis of both anticipation in view of Mihara and obviousness over Mihara in view of the knowledge of one of skill in the art.

If the PTAB disagrees and determines that the grounds raised herein are redundant of those raised in Petition A, and will institute only on the grounds of one Petition, Petitioner respectfully requests institution on the basis of Petition A. Moreover, if the PTAB determines that there is redundancy with respect to the grounds raised herein regarding anticipation in view of Mihara and obviousness of claims 3, 4, and 14 over Mihara in combination with the knowledge of one of skill in the art, Petitioner suggests institution on the grounds of Mihara in view of the knowledge of one of skill in the art.

#### **VI. Level of Skill In the Art**

A person of ordinary skill in the art ("POSA") at the time of the alleged invention of the '850 patent would have been someone with at least the equivalent of a medical degree from an accredited institution (usually denoted in this country

as a M.D. degree) or someone with the equivalent of a masters degree from an accredited institution (usually denoted in this country as an M.S. degree) in biomedical engineering. The person must have at least three years of experience working as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer. Extensive experience and technical training might substitute for educational requirements, while advanced degrees might substitute for experience. (Exh. 1003 ¶¶ 28-31).

**A. Construction Of The Challenged Claims**

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” Because the standards of claim interpretation used by the Courts in patent litigation differ from those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation (“BRI”) in light of the

patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.<sup>2</sup>

**1. “rail structure without a lumen”**

Because the ‘850 patent does not disclose any structure for the “rail structure without a lumen” limitation of independent claims 1 and 11, it is invalid under 35 U.S.C. §112, ¶ 2. The word “rail” appears in the specification of the ‘850 patent only twice. *First*, the Summary of the Invention refers to a “guidewire rail segment,” defined as “permit[ing] delivery without blocking the use of the guide catheter.” (Exh. 1001, 2:65). *Second*, Fig. 17 is described as “a plan view of a coaxial guide catheter having a longer rail segment,” without any guidance as to which portion(s) of Figure 17 constitute the “rail segment.” Neither of these references discloses any meaning for “rail” in the claim term “rail structure without a lumen.” (Exh. 1003 ¶ 64). Moreover, nothing in the specification suggests that the rail structure consists of the “tapered inner catheter,” “full circumference portion,” “cutout portion,” “reinforced portion,” “hemicylindrical portion,” “second full circumference portion,” “arcuate portion,” “braid or coil reinforcement,” “most proximal portion of braid or coil reinforcement,” “relief cut,” “hemi-tube portion,”

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<sup>2</sup> Petitioner reserves the right to challenge the validity of the ‘032 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

“single cuts,” “double cuts,” “connector hub,” “funnel portion,” “grip portion,” to name a few, nor would be so read by a POSA. (*Id.*)

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent apparatus claims 1 and 12 under 35 U.S.C. §§ 102 and 103, and claims 2, 3, 4, 8, 14, and 18 depending therefrom, Petitioner submits that, a POSA would understand “rail structure” to refer to a pushing or advancement structure. “Monorail” or rapid exchange catheters are characterized by a relatively short guide wire lumen; this cannot be the “rail structure” for purposes of the claim, however, because the claimed structure must be “without a lumen.” (Exh. 1003 ¶¶ 64-66). A POSA would therefore understand the “rail structure” to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id.*) Accordingly, the term “rail structure without a lumen” can be construed for purposes of this Petition to mean a “pushing or advancement structure without a lumen.”

## **2. “interventional cardiology device(s)”**

Interventional cardiology devices are thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to

treat a blockage or narrowing in the arteries due to atherosclerotic plaques or other lesions. (Exh. 1003 ¶ 67). The specification of the '850 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001, 1:28-31) ("For the purposes of this application, the term 'interventional cardiology devices is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters").

3. **"to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "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"**

Dependent claim 3 recites that the structure of the proximal side opening to which the claim is directed is "to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." Dependent claim 14 similarly recites an opening "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..." This language merely indicates the intended use of the claimed proximal opening (to receive an interventional cardiology device), and the device itself (for use within a guide catheter) as well as the order in which such intended uses may occur (receiving the device "into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter"). Accordingly,

such language should not be read as positive limitations on apparatus claims 3 or 14 of the '850 patent. To the extent that there is doubt, the BRI of the claims suggests that only the structural limitation(s) of claims 3 and 14 (namely, a skewed proximal opening) be accorded patentable weight. The Federal Circuit has made clear that the validity of an apparatus claim depends *solely* “on the claimed structure [and] not on the use or purpose of that structure.” *Catalina Mktg. Int’l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

Because the '850 patent claims are system claims, the requisite invalidity analysis turns on a direct comparison of the claimed *structures* to prior art *structures*. See *In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) *Carolina Mktg. Int’l*, 289 F.3d at 810 (“To hold otherwise would effectively impose a method limitation on an apparatus claim without justification”). The functional statements in claims 3 and 14 are not structural because the entire structure of the proximal side opening is described elsewhere in the claim; deletion of the functional phrases from claims 3 and 14 would not affect the structure of the claimed proximal opening. At most, the language requires a proximal opening large enough to allow passage of an interventional cardiology device.

Petitioner has, nevertheless, included sufficient evidence such that, even if the Board were to construe these functional statements of intended use as

positive limitations of claims 3 and 14, the grounds for unpatentability set forth below still render the challenged claims invalid in view of the cited art.

4. **“adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery”**

Dependent claim 2 recites: “the system of claim 1 wherein the tubular structure includes a distal portion *adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.*” (Exh. 1001, claim 2). These are statements of intended use, not structural language. The relevant structural limitations—a tubular structure having distal and proximal portions—is included elsewhere in the claim. As discussed above, to patentably distinguish the claimed invention from the prior art, a recitation of intended use must result in a structural difference between the claimed invention and the prior art. *See, e.g.*, Practitioner’s Manual of Patent Examining Proc. § 707 (paragraph 7.37.09). As long as a prior art structure would be *capable of* performing the intended use, then it meets the claim. *Id.* In any event, even if



this functional language in dependent claim 2 were accorded patentable weight, the prior art expressly discloses this function, as set forth below.

**B. The Prior Art References**

As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under §102(b), some of which also constitute prior art under §102(a), as set forth below.<sup>3</sup>

**1. Adams '292**

U.S. Patent No. 5,527,292 to Adams, *et al.* ("Adams '292") (Exh. 1011) matured from an application filed on September 9, 1994, prior to the earliest filing date the benefit of which is claimed by the '850 patent and is therefore available as prior art to the '850 patent under 35 U.S.C. § 102(b). Adams '292 describes a guide catheter extension: "The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter" (Exh. 1002 4:35-38; Exh. 1003 ¶¶ 69-70), and discloses, *inter alia*:

An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide

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<sup>3</sup> All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

catheter and has its distal end extending to a treatment site in a coronary artery. The device also including a push rod attached to a proximal end of the flexible tube to facilitate placement of the flexible tube within the coronary artery requiring treatment.

(*Id.* at Abstract). A benefit of the device disclosed in Adams '292 is the ability to extend the flexible tube beyond the distal tip of the guide catheter so that it is sufficiently deep-seated beyond the ostium to anchor the position of the guide catheter during treatment:

A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond....

(Exh. 1011, 9:12-24; *see* Exh. 1003 ¶¶ 32, 69-70).

## **2. Klein**

U.S. Patent No. 5,776,141 to Klein ("Klein") matured from an application filed on August 26, 1996, prior to the earliest filing date the benefit of which is claimed by the '850 patent and, thus, qualifies as prior art under §102(b). Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter and a proximal shaft attached to the proximal end of the tubular catheter body. (Exh. 1003 ¶ 35).

## **3. Adams '452**

U.S. Patent No. 7,232,452 to Adams (“Adams ‘452”) matured from an application filed on July 12, 2002, prior to the earliest filing date the benefit of which is claimed by the ‘850 patent, and thus qualifies as prior art under § 102(b). The Adams ‘452 patent discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” (Exh. 1011, 8:47-50; Exh. 1003 ¶ 36). Adams ‘452 further discloses “A proximal wire or other control means....” (Exh. 1011, 8:27-30). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1003 ¶ 36). The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (Exh. 1011, Figs 2A-C).

#### **4. Steinke**

U.S. Patent No. 5,328,472 to Steinke (“Steinke”) (Ex. 1020) matured from an application filed on July 27, 1992, prior to the earliest filing date the benefit of which is claimed by the ‘850 patent and, thus, qualifies as prior art under § 102(b). Steinke discloses “a catheter which allows rapid exchange” where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that

extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh.1020, 3:1-2; Exh. 1003 ¶ 37).

## **5. Takahashi**

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions Exh. 1021, 452-456 (“Takahashi”) is an article that was published in 2004 and, thus, qualifies as prior art under § 102(b). Takahashi describes method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶ 38). The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is one French or less. (*Id.*).

### **C. How The Construed Claim(s) Are Unpatentable**

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1-4, 8, 12, 14, and 18 of the ‘850 Patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section V below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration (Exh. 1003).

### **D. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)**

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including

identification of specific portions of the evidence that support the challenge, are provided below and in the corresponding claim charts.

**VII. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b) (4)**

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to achieve predictable results, all of which were well known to persons of ordinary skill in the art in the field of interventional cardiology procedures at the time to which the '850 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

**A. Claims 1, 2, 8, 12, And 18 Are Anticipated Under 35 U.S.C. §102(b) By Adams'292**

As shown below, each element recited in claims 1, 2, 8, 12, And 18 is anticipated by Adams '292, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '850 patent. (An unrelated patent by a different inventor with the last name "Adams" was disclosed). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

**1. Claim 1**

Claim 1 of the '850 patent discloses a "system comprising: a guide catheter ..."; Adams '292 similarly teaches "The invention is directed to the

structure and use of a distal extension (intravascular device) for a guide catheter.” (Exh. 1011, 4:36-37). Claim 1 of the 850 patent recites “a flexible tip portion defining a tubular structure having a circular cross-section” (Exh. 1001, ; Adams discloses that “The intravascular device includes a relatively flexible tube 45...” (Exh. 1011, 2:44-51). Claim 1 of the ‘850 patent further recites “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 ...”; Adams discloses that “The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the 65 guide catheter 12 so that it may be slidably disposed therethrough and to permit insertion of the tube 32 ...” (Exh. 1011, 5:64-67). Claim 1 of the ‘850 patent further recites “a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion ...” (Exh. 1001, claim 1); Adams discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a “flattened distal end which assumes an elongated cross-section” that provides “sufficient surface area” through which it is secured “to the proximal end of the elongated flexible tube.” (Exh. 1011, 7:13-26). Finally, claim 1 of the ‘850 patent recites “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 continuous lumen of the guide catheter ...”

(Exh. 1001, claim 1); Adams ‘292 similarly discloses that “The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches” (Exh. 1011, 15:49-53), which is longer than a standard guide catheter—approximately 40 inches. (Exh. 1003 ¶ 98). Thus, the Adams ‘292 discloses every element of claim 1 of the ‘850 patent.

## **2. Claim 2**

Both the ‘850 patent and Adams ‘292 are directed to the deep seating of a guide extension within a branch artery in order to secure the position of the guide catheter and facilitate the delivery of intravascular devices. (*Compare* Exh. 1001, claim 2 *with* Ex. 1011, 16:49-58; *see* Exh. 1003 ¶¶ 102-07).

## **3. Claim 12**

As discussed above, claim 12 of the ‘850 patent includes the same limitations as claim 1, with the exception of one additional element, a “reinforced portion” proximal to the substantially rigid portion. Accordingly, Petitioner references and includes its analysis of all elements of claim 1 set forth above and in the chart below. Adams ‘292 also disclosed the “reinforced portion” of claim 12, as shown in the claim chart below. (Exh. 1003 ¶¶ 100-01).

## **4. Claims 8 and 18**

Dependent claims 8 (depending from claim 1) and 18 (depending from claim 12) require that “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 Adams ‘292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1011, 5: 64-67; Exh 1003 ¶ 121-24 ) In disclosing a range overlapping or touching the claimed range, the Adams ‘292 thereby anticipates the claimed range with sufficient specificity. *See, e.g., ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

The ‘850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams ‘292 (Exh. 1011)
<p><b>1.</b> A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are</p>	<p><b>[1]</b> To the extent that the preamble is a limitation, Adams discloses a system for use with interventional cardiology devices adapted to be insertable for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract (“An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery”); 4:36-37 (“The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter.”)</p> <p><b>[2]</b> The guide catheter used with the Adams device has a continuous central lumen and a proximal end with a mounted manifold having a primary channel that contains a hemostatic valve. 5:16-29 (“The</p>

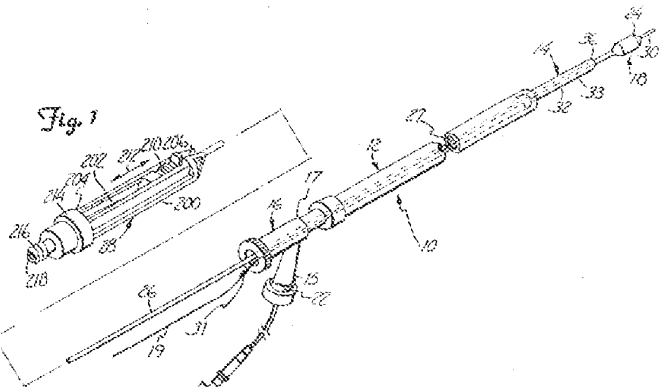


The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
<p>insertable into and through the continuous lumen of the guide catheter; a device adapted for use with the guide catheter, including:</p>	<p>guide catheter manifold 16 is mounted at the proximal end of the guide catheter 12. Preferably, the guide catheter manifold 16 comprises a Y-shaped structure having a primary channel leg 17 and an extension leg 15 with a guide catheter port 22 on the extension leg 15.... A hemostasis valve (not shown) on channel leg 17 provides hemostatic control for the guide catheter system 10 of the present invention”); 11:20-30 (“Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or other angioplasty device is disposed and guided to a stenosis or obstruction. The guide catheter manifold 54 is mounted at a proximal end of the guide catheter 52, and preferably comprises a Y-shaped structure having a primary channel leg 51 and an extension leg 55 with a guide catheter port 58. The guide catheter port 58 provides an inlet injection port for dye to travel through the guide catheter system 50 to the arterial system or alternatively for the introduction of drugs into the patient to a treatment site. A hemostatic valve (not shown) on the primary channel leg 51 provides hemostatic control for the guide catheter.”)</p> <p>[3] The lumen of the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. 6:29-31 (“In the embodiment shown in FIG. 2, the elongated tube 32 has a radially flared proximal end 38. The flared proximal end 38 of the elongated flexible tube 32 is configured to coincide with the inner diameter of the guide catheter 12 so that a catheter advanced, or other angioplasty device such as a guide wire, into and through the first guide catheter lumen 27 is piloted into the flared tip 38 and second guide catheter lumen 33”); 8:40-45</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	<p>(“The diameter of the first guide catheter lumen 27 in the guide catheter 12 and the second guide catheter lumen 33 in the guide catheter extension 32 are larger than the outer diameters of the hollow balloon catheter shaft 26 and balloon 24 (deflated) which are advanced therethrough”); 16:39-44 (“a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary, artery requiring treatment”).</p>
<p>a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,</p>	<p>[1] Adams discloses a flexible tip portion defining a tubular structure in the form of a “relatively flexible tube.” 2:44-51 (“The intravascular device includes a relatively flexible tube 45...”).</p> <p>[2] having an inner and outer diameter. 2:44-50 (“The flexible tube has an inner diameter sized for insertion over an angioplasty device”); 23:36-37 (“a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen ...”).</p> <p>[3] Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). Fig. 12 also shows that flexible tube 255 is shorter than guide catheter 287.</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
<p>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 defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and</p>	<p>[1] Adams discloses that the outer diameter of the flexible tube is smaller than and sized for insertion through the guide catheter lumen. 5:64-67 (“The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the 65 guide catheter 12 so that it may be slidably disposed therethrough and to permit insertion of the tube 32 ...”); 23:37-40.</p> <p>[2] The flexible tube is placed coaxially relative to the guide catheter. 8:57-61 (“the angioplasty balloon catheter 18 and guide catheter extension 14 are coaxially positioned within the guide catheter 12 ...”); 11:58-60 (“During use, the guide catheter extension tube 70 is coaxially disposed within the guide catheter 52”); 15:65-66 (“The flexible tube 255 of the intravascular device 250 is 65 designed for coaxial placement relative to the guide catheter ...”).</p> <p>[3] When used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen for the insertion and advancement of coronary treatment devices. 22:35-43 (“For use in combination with a guide catheter for insertion and advancement of a coronary treatment device through a coronary vessel having an ostium to a treatment site, the guide catheter having a central lumen, a distal end and a distal opening, an</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	anchoring device comprising: a relatively flexible tube sized for insertion through the central lumen of the guide catheter into the coronary vessel, the flexible tube being concentrically aligned with the guide catheter ..."); 16:38-44 ("the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment").
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	Adams discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." 7:13-26; <i>see</i> Abstract; 2:47-48; 6:1-2; 6:13-15; 15:8-12; 22:51-52; 23- 44-45.
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	Adams discloses that the diameter of the wire or stainless steel hypotube of the substantially rigid push rod is smaller (0.016 inch) than that of the flexible tube (0.065 inch). 6:15-17 ("the shaft 19 or push rod is defined by an elongated wire 34. The elongated wire 34 is of small diameter, preferably 0.010 to 0.016 of an inch in diameter"); 6:56-62 ("The rather thin dimension of the wire 34 eliminates or substantially reduces surface friction introduced by the longitudinal movement of an element within the guide catheter 12"); 7:18-21 ("The tubular shaft member 172 is preferably formed from stainless steel hypotube with an inside diameter of 0.010 inch and an outside diameter of 0.016 inch"); 8:24-25 ("For example, the outer diameter of the elongated tube 32A at its proximal end would be approximately 0.065 inch and the outer diameter at its distal end would be approximately 0.053 inch (with a 0.045

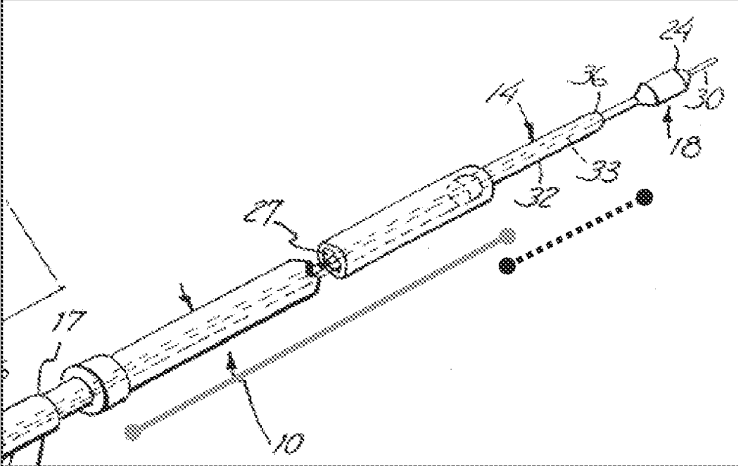
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
<p>and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the continuous lumen of the guide 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.</p>	<p>inch distal tubular opening ...”).</p> <p>[1] Adams discloses that the combined length of the flexible tube and the push rod (50.5 to 51.5 inches) is longer than the guide catheter lumen (about 40 inches). 15:49-53 (“The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length. The push rod is: approximately 40.0 to 45.0 inches in length. The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches”).</p> <p>[2] When the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon catheter shaft:</p>  <p>“As seen in FIG. 1, shaft 19 or push rod ... extends proximally ... outside the guide catheter 12 so that it is accessible to the user.... The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12....” 6:1-10. 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. 5:17-29. 26 is a</p>

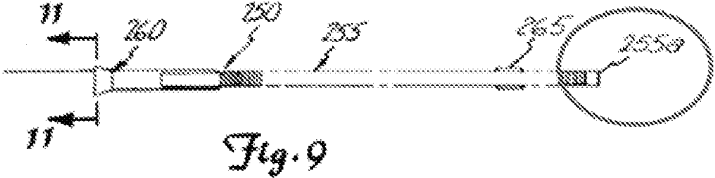
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. 17:3-7 (“The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient”).
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,	The Adams '292 patent discloses that the proximal end of the flexible tube remains within a guide catheter while a distal portion of the flexible tube extends beyond the distal end of the guide catheter: “In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site within a coronary artery.” (Abstract); 9:17-22 (“A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends ... beyond the distal end of the guide catheter 12....”); 15:57-60 (“The length of the tube is sized so that the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube 255 reaches the treatment site”); 16:60-64 (“A distal portion of the flexible tube 255 is advanced past the distal opening 288 of the guide catheter 287 ... while a proximal portion thereof and the push rod 262 remain within the guide catheter 287”).
such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond to the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	4:63-67 (“the distal extension may be advanced into and through the coronary arteries to the lesion or obstruction to facilitate original placement of angioplasty devices by serving to anchor the guide catheter at the coronary ostium of the vessel requiring treatment...”); 9:12-24 (“The extension of the elongated flexible tube 32 into the smaller dimension arteries also serves to maintain the position of the guide catheter 12 at the coronary ostium during operation.... [T]he flexible tube 32

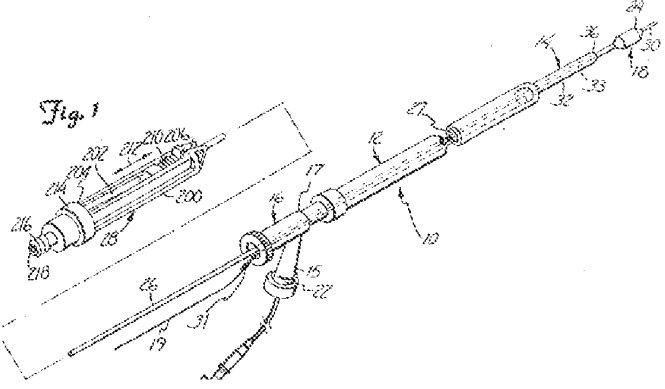
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	<p>defines an anchoring device for securing the guide catheter 12 for operation.... [A] significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond....”; 16:49-58 (“as a coronary device is advanced, the position of the distal opening 288 of the guide catheter 287 may shift out of alignment with the coronary ostium making placement of the coronary treatment device into the coronary artery requiring treatment more difficult. As previously explained, the present invention discloses an anchoring device for securing the guide catheter 287 relative to the coronary ostium of a patient to facilitate original insertion and subsequent insertion of a coronary treatment device”); 22:53-56 (“the flexible tube anchors the distal opening of the guide catheter relative to the ostium of the coronary vessel to secure the guide catheter and facilitate insertion of the coronary treatment device therethrough”).</p>
<p>8. The system of claim 1</p>	<p>Adams '292 discloses the system of claim 1 (see above).</p>
<p>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</p>	<p>Adams '292 discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter:</p> <p>“The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the guide catheter 12 so that it may be slidably disposed therethrough....” (5:64-67).</p>
<p>12. A system for use with interventional cardiology</p>	<p>[1] To the extent that the preamble is a limitation, Adams discloses a system for use with interventional</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
<p>devices adapted to be insertable into a branch artery, the system comprising:</p> <p>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</p>	<p>cardiology devices for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract and 4:36-37.</p> <p>[2] The guide catheter used with the Adams device has a continuous central lumen and a proximal end with a mounted manifold having a primary channel that contains a hemostatic valve. 5:16-29 and 11:20-30.</p> <p>[3] The lumen of the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. 8:40-45 and 16:39-44.</p>
<p>a device adapted for use with the guide catheter; including:</p> <p>an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,</p>	<p>Adams discloses that the combined length of the flexible tube and the push rod (50.5 to 51.5 inches) is longer than the guide catheter lumen (about 40 inches). 15:49-53.</p>
<p>the elongate structure including:</p> <p>a flexible tip portion defining a tubular structure and having a circular cross-section that is smaller than the</p>	<p>[1] Adams discloses a flexible tip portion defining a tubular structure in the form of a "relatively flexible tube"</p> <p>[2] having an inner and outer diameter. 2:44-50 and 23:36-37.</p>



The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
<p>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,</p>	<p>[3] Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). This is also depicted in Fig. 12 which shows flexible tube 255 is shorter than guide catheter 287.</p> 
<p>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;</p>	<p>[1] Adams discloses that the outer diameter of the flexible tube is smaller than and sized for insertion through the guide catheter lumen. 5:64-67 and 23:37-40.</p> <p>[2] The flexible tube is placed coaxially relative to the guide catheter. 2:62-64; 11:58-60 and 15:65-66.</p> <p>[3] When used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen for the insertion and advancement of coronary treatment devices. 22:35-43.</p>
<p>a reinforced portion proximal to the flexible tip portion; and</p>	<p>“the relatively flexible tube of the intravascular device includes a coil spring extending along and defining at least a portion of the flexible tube.” 20:3-6. “The guide catheter extension 14A ... has a longitudinal guide catheter extension lumen, a rounded distal tip 36A and may be reinforced by a</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	<p>coil 40A." 7:4-7.</p>  <p style="text-align: center;"><i>Fig. 9</i></p>
<p>a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis rail than the flexible tip portion defining a structure without a lumen</p>	<p>Adams discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." 7:13-26; see also Abstract; 2:47-48; 6:1-2; 6:13-15; 15:8-12; 22:51-52; and 23- 44-45.</p>
<p>having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,</p>	<p>Adams discloses that the diameter of the wire or stainless steel hypotube of the substantially rigid push rod is smaller (0.016 inch) than that of the flexible tube (0.065 inch). 6:15-17; 6:56-62; 7:18-21 and 8:24-25.</p>
<p>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</p>	<p>Adams discloses that when the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon catheter shaft:</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
<p>hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.</p>	 <p>“As seen in FIG. 1, shaft 19 or push rod ... extends proximally ... outside the guide catheter 12 so that it is accessible to the user.... The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12....” 6:1-10. 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. 5:17-29. 26 is a balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. “The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient.” 17:3-7.</p>
<p>18. The system of claim 12,</p>	<p>Adams '292 discloses the system of claim 12 (<i>See A-1, above</i>).</p>
<p>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.</p>	<p><i>See Adams '292 disclosures set forth in claim 8 (above).</i></p>

### **VIII. Obviousness of Challenged Claims**

The below challenged claims of the '850 patent are rendered obvious under §103(a) in view of the prior art references set forth below,<sup>4</sup> either in view of the knowledge of one of ordinary skill in the art, or in the combinations expressly described herein. Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418-20, 82 U.S.P.Q.2d 1385 (2007); *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

#### **A. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Klein**

Klein (Exh. 1018) was cited during prosecution of the '032 Patent but was not considered in combination with Adams '292 (Exh. 1011), nor was it considered during prosecution of the '850 Patent. As shown below, each element recited in claims 1-4, 8, 12, 14 And 18 is obvious over Adams '292 in view of Klein. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above.

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<sup>4</sup> All references cited herein are patents and printed publications constituting prior art under §102(b).

As set forth in section VII above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107, 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292 and Klein. (*See* Exh. 1003 ¶¶ 108-111).

Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter. As set forth in the chart below, this disclosure satisfies the structural limitations of claim 3, requiring that “the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,” the requirement of claim 4 that “the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion,” and the limitation of claim 14 that “the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis.”

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.*, Exh. 1011,

15:57-16:13) (“the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...”). *See* (Exh. 1011, 16:11-14).

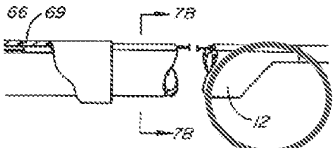
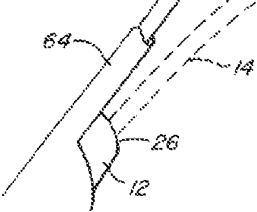
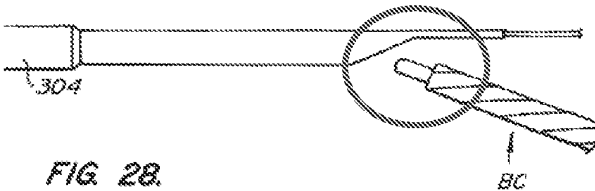
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86, 108-111), a POSA would have found it obvious to modify the proximal opening of the Adams ‘292 device in view of Klein to meet the limitations of the challenged claims. Adams ‘292 and Klein are both analogous to the ‘850 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the ‘850 patent. (Exh. 1003 ¶¶ 71-74). As such, one of skill in the art would have been aware of these references and would have referred to Adams ‘850 and Klein in addressing the problem addressed by the ‘850 patent.

Adams ‘292 highlights the advantages of varied designs for the proximal opening to the catheter’s device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the device disclosed by Adams ‘292 with the teaching in Klein of the delivery of larger interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening of cardiovascular treatment catheter. This is particularly true given that

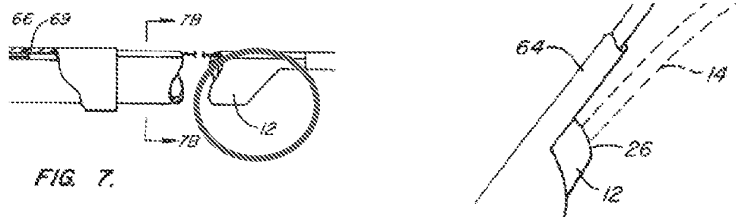
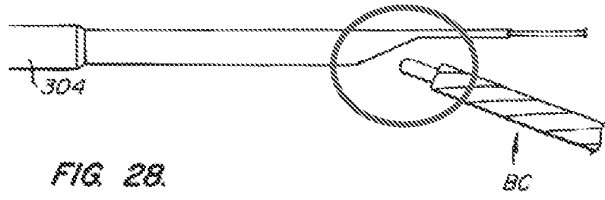
Klein and Adams '292 device both disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. (Exh. 1003 ¶¶ 84-86, 108-111).

Accordingly, Klein shows that using skived proximal openings for the delivery of interventional cardiology devices such as balloon catheters was well known by the time of the '850 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (See Exh. 1003 ¶¶ 108-11).

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	Adams '292 in view of Klein
3. The system of claim 2,	Adams '292 discloses the system of claim 2 ( <i>See</i> A-1, above).
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	“Tubular catheter body 16 includes an internal lumen 24 which extends from a proximal port 26 to a distal port 28 to receive the balloon catheter 14. In particular, the lumen 24 will be sized sufficiently large to receive the balloon 30 of the balloon catheter 14.” 9:17-23. The length of “the tubular body 12” is “sufficient to extend from a treatment site within the coronary arteries back into a guiding catheter.... In this way, the entry port 26 will remain within the guiding catheter at all times.” 10:16-22. Annotated Fig. 7 (below) depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	Adams '292 in view of Klein
to the longitudinal axis,	  <p>FIG. 7.</p> <p>(Fig. 6). 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.</p>  <p>FIG. 28.</p> <p>In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (See also Figs. 1, 8, 9, 9A, 10-15, 20-27).</p>
to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	<p>Adams '292 discloses “the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ....” 15:57-16:13.</p>
4.. The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical	<p>(See, e.g., Klein, Figs. 7, 28)., see also above.</p>



Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	Adams '292 in view of Klein
portion.	
14. The system of claim 12,	Adams '292 discloses the system of claim 12 ( <i>See A-1, above</i> ).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	<p>"Tubular catheter body 16 includes an internal lumen 24 which extends from a proximal port 26 to a distal port 28 to receive the balloon catheter 14. In particular, the lumen 24 will be sized sufficiently large to receive the balloon 30 of the balloon catheter 14." 9:17-23. The length of "the tubular body 12" is "sufficient to extend from a treatment site within the coronary arteries back into a guiding catheter.... In this way, the entry port 26 will remain within the guiding catheter at all times." 10:16-22. Annotated Fig. 7 (below) depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:</p>  <p>(Fig. 6). 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.</p>  <p>In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (<i>See also Figs. 1, 8, 9, 9A, 10-15, 20-27</i>).</p>
that is adapted to receive an interventional cardiology device	Adams '292 is "directed to the structure and use of a distal extension ... for a guide catheter" (Adams '292, 4:36-37 (Exh. 100_)), wherein "[g]uide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	Adams '292 in view of Klein
passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	through which an angioplasty balloon catheter 60 or some other angioplasty device is disposed and guided to a stenosis or obstruction.” ( <i>Id.</i> , 11:17-20); and “the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ....” 15:57-16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	( <i>See, e.g., Klein, Figs. 7, 28</i> ),, <i>see also above.</i>

**B. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Adams '452**

As shown below, each element recited in claims 1-4, 8, 12, 14 And 18 is obvious over Adams '292 in view of Adams '452, which was not cited or considered either alone or in combination with Adams '292 during prosecution of the '850 Patent. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above. As set forth in section VII above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107 and 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary

skill in the art from the disclosures of analogous art, particularly Adams '292 and Adams '452. *See* (Exh. 1003 ¶¶ 84-86, 112-15).

The Adams '452 patent discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” (Exh. 1011, 8:47-50). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (*See* Exh. 1003 ¶ 36). The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*Id*).

This disclosure satisfies the structural limitations of claim 3 requiring that “the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,” the requirement of claim 4 that “the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion,” and the limitation of claim 14 that “the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis.” (*See* Exh. 1003 ¶¶ 112-15).

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.*, Exh. 1003 ¶¶ 112-115; Exh. 1011, 15:57-16:13 (“the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...”).

As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86 and 112-15), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims. Adams '292 and Adams '452 are both analogous to the '850 patent as they are directed to the same type of device, are in the same field of endeavor and are reasonably pertinent to the problem faced by the inventor of the '850 patent. (*See* Exh. 1003 ¶¶ 71, 75-76). As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Adams '452 in addressing the problem addressed by the '850 patent. (*See id.* ¶¶ 84-86, 112-115).

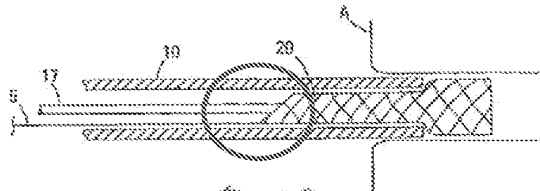
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the disclosure of Adams '292 with the teaching in Adams '452 of the advantages of a skived proximal

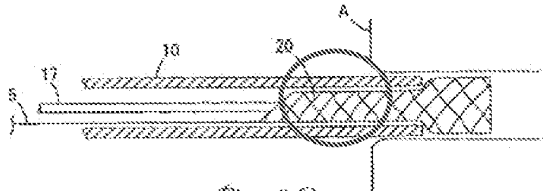
opening to the device lumen of a cardiovascular treatment device for facilitating a smoother withdrawal of the device from the guide catheter. (See Exh. 1003 ¶¶ 84-86, 112-115). This is particularly true given that the devices of Adams ‘452 and Adams ‘292 are both directed to the receipt of interventional cardiology devices through a proximal opening of the device while a proximal portion of the device is within the standard guide catheter. (*Id.* ¶¶ 32, 36, 71 and 75-76). Moreover, Adams ‘292 and Adams ‘452 were both issued to the same named inventor, Daniel O. Adams; the fact that the inventor of the Adams ‘292 device in 1992 included a skived proximal side opening when designing a similar device (Adams ‘292 is cited as prior art on the face of the Adams ‘452 patent) ten years later is further evidence that, by 2006, a POSA would routinely include a skived or angular side opening in such rapid exchange devices.

In sum, Adams ‘452 shows that using skived proximal lumen openings for the delivery of devices while the proximal opening is within the lumen of a guide catheter was well known by the time of the ‘850 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams ‘292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (See Exh. 1003 ¶¶ 112-15).

Claim Chart A-4: CL. 3-4, 14	
The ‘850 Patent	Adams ‘292 (1011) in view of Adams‘452 (1019)

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	Adams '292 (1011) in view of Adams'452 (1019)
3. The system of claim 2,	Adams '292 discloses the system of claim 2 (See A-1, above).
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	<p>Adams '452 discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” 8:47-50. “A proximal wire ... extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter.” 8:47-50. The guide seal has a “portion which remains in the lumen of the guide catheter when the guide seal is deployed.” 8:55-56. The guide seal may be formed of braided wires with a polymer covering or membrane attached. 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:</p> <div style="text-align: center;"> <p style="text-align: center;"><i>Fig. 2C</i></p> </div> <p>The proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.</p>
to receive the interventional cardiology devices into the coaxial lumen while the proximal	Adams '292 discloses “the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	Adams '292 (1011) in view of Adams'452 (1019)
portion remains within the lumen of the guide catheter.	to direct an angioplasty device into lumen 269 of extension 250 ....” 15:57- 16:13.
4.. The system of claim 3,	As shown above, Adams '292 in combination with Adams '452 discloses the system of claim 3.
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	As shown above, the Adams '452 patent discloses a proximal opening of a lumen in a catheter skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion.
14. The system of claim 12,	Adams '292 discloses the system of claim 12 ( <i>See A-1, above</i> ).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	<p>Adams '452 discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” 8:47-50. “A proximal wire ... extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter.” 8:47-50. The guide seal has a “portion which remains in the lumen of the guide catheter when the guide seal is deployed.” 8:55-56. The guide seal may be formed of braided wires with a polymer covering or membrane attached. 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:</p>  <p>The proximal portion of the guide seal 20 remains</p>

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	Adams '292 (1011) in view of Adams'452 (1019)
	within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
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,	Adams '292 discloses "the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57- 16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	As shown above, Adams '452, Fig. 2C; 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis:   <p style="text-align: center;"><i>Fig. 2C</i></p>

**C. Claims 1-4, 8, 12, 14 and 18 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Steinke**

As shown below, each element recited in claims 1-4, 8, 12, 14 and 18 is obvious over Adams '292 in view of Steinke, which was not cited or considered either alone or in combination with Adams '292 during prosecution of the '850 Patent. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set



forth above. As set forth above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107 and 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292 and Steinke. *See* (Exh. 1003 ¶¶ 108-111).

Steinke discloses “a catheter which allows rapid exchange” (Exh. 1020, 3:1-2) where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. A POSA would understand that the skived proximal “entry port” of Steinke functions as both an entryway and exit for an interventional cardiology device as a guidewire is passed or “received” therethrough upon delivering and removing the Steinke balloon catheter during treatment. (Ex. 1003 ¶¶ 35 and 72). This disclosure satisfies the structural limitations of claim 3 requiring that “the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,” the requirement of claim 4 that “the proximal side opening includes structure defining a full circumference portion and

structure defining a partially cylindrical portion,” and the limitation of claim 14 that “the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis.”

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams ‘292 expressly discloses such functions. (*See, e.g.*; Exh. 1011, 15:57-16:13 (“the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...”)).

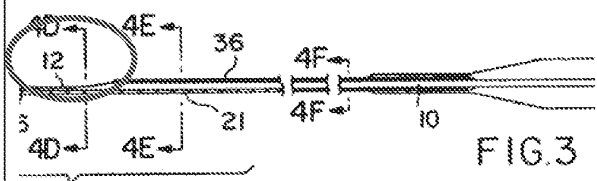
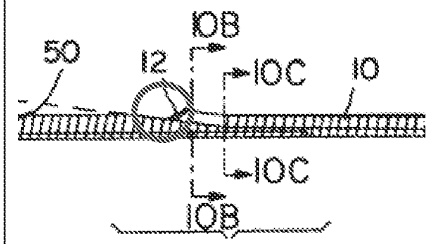
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86 and 116-119), a POSA would have found it obvious to modify the proximal opening of the Adams ‘292 device in view of Steinke to meet the limitations of the challenged claims. Adams ‘292 and Steinke are both in the same field of endeavor as the ‘850 patent and are pertinent to the problem faced by the inventor of the ‘850 patent. (*Id.*, 77-78). As such, one of skill in the art would have been aware of these references and would have referred to Adams ‘292 and Steinke in addressing the problem addressed by the ‘850 patent. (*Id.*, 116-119).

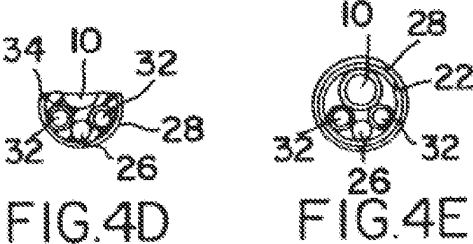
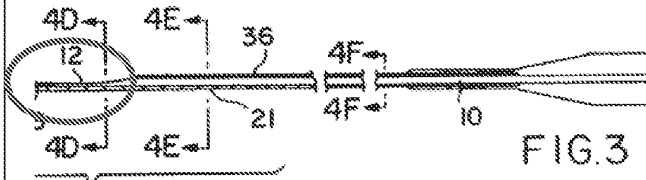
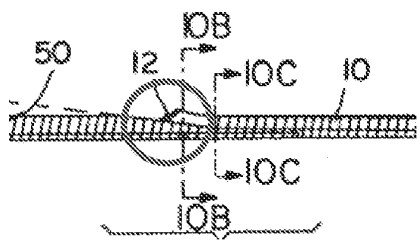
Adams ‘292 highlights the advantages of varied designs for the proximal opening to the catheter’s device delivery lumen. (*Compare* Exh. 1011, 6:24-34

(flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the Adams ‘292 disclosure with the teaching in Steinke of the advantages of a skived proximal opening to the device lumen of a cardiovascular treatment catheter for “varying flexibility along the length of the catheter, without abrupt changes in stiffness or an undesirably stiff transition region.” (Exh. 1020, 3:1-7). This is particularly true given that both Steinke and Adams ‘292 disclose rapid exchange devices, for use within a standard guide catheter, and are directed to extension beyond the distal end of the guide catheter to the treatment site. (Exh. 1003 ¶¶ 32-34, 37 and 84-86).

In sum, Steinke shows that using skived proximal openings with rapid exchange catheters was well known by the time of the ‘850 patent, and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams ‘292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*Id.* ¶ 116-19).

Claim Chart A-5: Cl. 3-4, 14 Adams ‘292 (1011) in view of US 5,328,472 (“Steinke”)	
The ‘850 Patent	Steinke (Exh. 1020)
3. The system of claim 2,	Adams discloses the system of claim 2 ( <i>See</i> A-1, above).
wherein the proximal portion of the tubular structure further comprises structure	Steinke discloses “a catheter which allows rapid exchange,” 3:1-2, where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	Steinke (Exh. 1020)
defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	<p>and which is accessible from a side transverse to the longitudinal axis as depicted in Fig. 3:</p>  <p>FIG. 3</p> <p>FIG. 9</p>  <p>12 is "the guidewire entry 12 (also referred to as the distal entry or side port entry)." 6:51-54.</p> <p>Steinke further discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit..." 9:66-10:1.</p>
to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	<p>Adams '292 discloses "the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57-16:13.</p>
4.. The system of claim 3,	(See claim 3 above).
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical	Steinke discloses skived side port entry depicted in Figs. 4D, 4E defines a full circumference portion and a partially cylindrical portion:

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	Steinke (Exh. 1020)
portion.	 <p>FIG. 4D      FIG. 4E</p>
14. The system of claim 12,	Adams discloses the system of claim 12 ( <i>See</i> A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	<p>Steinke discloses “a catheter which allows rapid exchange,” 3:1-2, where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:</p>  <p>FIG. 3</p> <p>12 is “the guidewire entry 12 (also referred to as the distal entry or side port entry).” 6:51-54.</p>  <p>FIG. 9</p> <p>Steinke further discloses “a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit...” 9:66-10:1.</p>
that is adapted to receive an interventional cardiology device passed through continuous lumen of the	Adams '292 discloses “the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ....”

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	Steinke (Exh. 1020)
guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	15:57-16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	Steinke discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit...." 9:66-10:1.

**D. Claims 1, 2, 8, 12 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of The Knowledge of One Of Skill In The Art**

Dependent claims 8 (depending from claim 1) and 18 (depending from claim 12) require that "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 Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1011, 5:64-67). A POSA reading this disclosure of the Adams '292 patent at the time of the claimed invention would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner

diameter of the outer guide catheter and, therefore, would have been motivated to practice the invention within the claimed range of not more than one French. (Exh. 1003 ¶¶ 125-26).

In this case, the disclosed range for the difference in diameters between the outer guide catheter and the inner guide catheter of the device was already known in the field by the time of the '850 patent and, therefore, a POSA would have been motivated to conform to such teachings in practicing the Adams '292 invention with the predictable and expected results of allowing for the insertion of larger devices and avoiding the possibility of the guidewire becoming disposed in the space between the inner and outer guide catheters. (*Id.*)

**E. Claims 1, 2, 8, 12 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Takahashi**

As shown below, each element recited in dependent claims 8 and 18 is obvious over Adams '292 in view of Takahashi, which was cited during prosecution of the '032 Patent but was not discussed in any Office Action of either the '032 Patent or the '850 Patent, or considered in combination with Adams '292. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above. As set forth in section above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107, 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would

have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292 and the Takahashi article. *See* (Exh. 1003 ¶¶ 127-29).

Claims 8 and 18 require that “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.”

Takahashi satisfies the limitations of claims 8 and 18 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter such that the cross-sectional inner diameter of the 5 French catheter is not more than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner diameter of the outer guide catheter, and would recognize that this teaching of Takahashi’s 5-in-6 system could be applied to any guide extension device for insertion through a standard guide catheter, such as the Adams '292, and would have been motivated to do so. (Ex. 1003 ¶ 122, 127-29).

Claim Chart A-6: Cl. 8, 18	
<b>The '850 Patent</b>	<b>Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1021)</b>
8. The system of claim 1,	Adams '292 discloses the system of claim 1 ( <i>See</i> A-1, above).
wherein the cross-sectional inner diameter of the	“The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a



Claim Chart A-6: Cl. 8, 18	
The '850 Patent	Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1021)
coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A)." (Exh. 1021 at 452). "The inner lumen of the 5 Fr Heartrail catheter is 0.059' in diameter.... The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter...." ( <i>Id.</i> ). "In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter...." ( <i>Id.</i> ). "Only inserting the 5 Fr guiding catheter into the 6Fr catheter increased backup support...." ( <i>Id.</i> ). "A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter." ( <i>Id.</i> at 454).
18. The system of claim 12	Adams discloses the system of claim 12 ( <i>See</i> A-1, above).
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.	<i>See</i> Takahashi disclosures set forth in claim 8 (above).

## IX. CONCLUSION

Based on the foregoing, it is clear that claims 1, 2, 8, 12, and 18 of the '850 Patent define subject matter that is anticipated in view of Adams '292 and that the claims 1-4, 8, 12, 14, and 18 of the '850 Patent define subject matter that is obvious in view of the knowledge of a POSA combined with Adams '292 and the

teachings of the additional references cited above. Adams '292 and the prior art combinations cited above were never considered by the Examiner; if they had been, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '850 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 16, 2014, to the USPTO correspondence address of record listed below:

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# ATTACHMENT B

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BOSTON SCIENTIFIC CORPORATION and  
BOSTON SCIENTIFIC SCIMED, INC.  
Petitioner

v.

VASCULAR SOLUTIONS, INC.  
Patent Owner

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Case IPR: Unassigned  
Patent 8,292,850

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Attorney Docket No. 0025216-00057

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**PETITION FOR INTER PARTES REVIEW  
UNDER 37 C.F.R. § 42.100**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)).....	1
A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) .....	1
B. Related Matters (37 C.F.R. § 42.8(b)(2)).....	1
C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a)) .....	2
D. Service Information (37 C.F.R. § 42.8(b)(4)) .....	2
II. PAYMENT OF FEES (37 C.F.R. § 42.103) .....	2
III. SUMMARY OF RELEVANT TECHNOLOGY AND ‘850 PATENT .....	3
A. Overview Of Interventional Cardiology Procedures .....	3
B. Description Of The Alleged Invention Of The ‘850 Patent.....	4
C. Summary of the Prosecution History of the ‘850 Patent .....	7
IV. REQUIREMENTS FOR INTER PARTES REVIEW .....	8
A. Grounds for Standing Under 37 C.F.R. § 42.104(a).....	8
B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested .....	8
C. Claims for Which <i>Inter Partes</i> Review Is Requested .....	8
D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2) .....	8
V. Non-Redundancy of Proposed Alternative Grounds.....	9
A. Construction Of The Challenged Claims .....	12
1. “rail structure without a lumen”.....	13
2. “interventional cardiology device(s)”.....	14
3. “to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter” / “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” .....	15
4. “adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery”.....	17
1. No Disclosure of “Rail Structure without a Lumen”.....	20

C.	The Prior Art References.....	21
1.	Mihara .....	21
2.	Takahashi .....	22
D.	How The Construed Claim(s) Are Unpatentable .....	23
E.	Supporting Evidence Under 37 C.F.R. § 42.104(b)(5) .....	23
VII.	DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4).....	23
A.	Claims 1, 2, 3, 4, 12, and 14 Are Anticipated Under 35 U.S.C. §102(b) By Mihara .....	24
1.	Claim 1 .....	24
2.	Claim 2 .....	31
VIII.	Obviousness of Challenged Claims.....	31
A.	Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. § 103 Over Adams In View Of Mihara.....	32
1.	Claim 12.....	35
B.	Claims 1-4, 8, 12, 14 And 17 Are Obvious Under 35 U.S.C. § 103 Over Pub. No. U.S. 2007/0260219 .....	52
C.	Claims 1-4, 12, and 14 Are Obvious Under 35 U.S.C. § 103 Over Mihara In View of the Knowledge of a Person of Ordinary Skill in the Art.....	53
D.	Claims 1-4, 8, 12, 14 and 18 Are Obvious Under 35 U.S.C. § 103(a) Over Mihara In View Of Takahashi .....	53
IX.	CONCLUSION.....	56

**Exhibit List for Inter Partes Review of U.S. Patent No. 8,292,850**

Exhibit Description	Exhibit No.
U.S. Patent No. 8,292,850 B2 to Root, et al.	1001
File History for U.S. Patent No. 8,292,850	1002
Declaration of Ronald Jay Solar, Ph.D., with attached Appendix 1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,048,032 to Root, et al.	1004
U.S. Patent No. 8,142,413 to Root, et al.	1005
File History for U.S. Patent No. 8,048,032	1006
File History for U.S. Patent No. 8,142,413	1007
Copy of a Second Petition (excluding exhibits) for <i>Inter Partes</i> Review Filed Concurrently by Petitioner on the '850 Patent	1008
U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1009
Translation of Japanese Patent Application No. 2003-070808	1010
U.S. Patent No. 5,527,292 to Adams et al.	1011
U.S. Publication No. 2007/0260219 A1 to Root et al.	1012
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1013
U.S. Patent No. 6,638,268 to Niazi	1014
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1015
U.S. Publication No. 2004/0127927 to Adams	1016
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1017
U.S. Patent No. 5,776,141 to Klein et al.	1018
U.S. Patent No. 7,232,452 to Adams et al.	1019
U.S. Patent No. 5,328,472 to Steinke et al.	1020
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," <i>Catherization and Cardiovascular Interventions</i> 63:452-456 (2004)	1021
U.S. Patent No. 5,690,613 to Verbeek	1022
U.S. Patent No. 5,156,594 to Keith	1023
U.S. Patent No. 5,102,403 to Alt	1024
Kucklick, Theodore R., <i>The Medical Device R&amp;D Handbook</i> (2006)	1025
Amended Complaint filed by Vascular Solutions, Inc. in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (May 28, 2013)	1026
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn).	1027



Exhibit Description	Exhibit No.
(June 10, 2013)	
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (June 10, 2013)	1028
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (July 28, 2013)	1029
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (December 19, 2013)	1030
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed December 27, 2013	1031
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed January 3, 2014	1032
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir). filed January 7, 2014	1033
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir). filed January 29, 2014	1034
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir). filed February 3, 2014	1035
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir).	1036
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1037
Joint Claim Construction Statement filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn). (February 21, 2014)	1038
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1039
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1040
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1041
U.S. Patent No. 5,267,958 to Buchbinder et al.	1042

*Inter partes* review is respectfully requested for claims 1-4, 8, 11, 13, 17 of U.S. Patent No. 8,292,850 (“the ‘850 Patent”) (Exh. 1001).

**I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))**

The following mandatory notices are provided as part of this Petition.

**A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))**

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively “Petitioner”) are the real parties-in-interest.

**B. Related Matters (37 C.F.R. § 42.8(b)(2))**

The ‘850 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 1:13-cv-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of the ‘850 Patent on other grounds in another petition to be filed concurrently herewith. Further, Petitioner is filing two separate petitions on non-redundant grounds seeking *inter partes* review of U.S. Patent No. 8,048,032 (the “‘032 patent”) and one petition seeking review of U.S. Patent No. 8,142,413 (the “‘413 patent”) to be filed concurrently herewith. In all, five petitions will be filed. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and are directed generally to the same subject matter. Specifically, the ‘850 patent is a division of application No.

12/824,734, which issued as the '413 patent, and the '413 patent is a division of application No. 11/416,629, which issued as the '032 patent. The claims challenged therein are method ('413 patent) and apparatus ('032 patent) versions of the system claims of the '850 patent challenged herein.

**C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))**

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

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**D. Service Information (37 C.F.R. § 42.8(b)(4))**

Petitioner consents to service by email to lead and backup counsel at xBSC\_VSI\_IPRService@aporter.com.

**II. PAYMENT OF FEES (37 C.F.R. § 42.103)**

The undersigned authorizes the Office to charge Deposit Account No. 502387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment

for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

### **III. SUMMARY OF RELEVANT TECHNOLOGY AND ‘850 PATENT**

#### **A. Overview Of Interventional Cardiology Procedures**

The claims of the ‘850 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (See Exh. 1001, 1:7-36). During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.*; see Declaration of Ronald Jay Solar, Ph.D. (“Solar Declaration”) (Exh. 1003) ¶ 9). The physician introduces the treatment device into the patient’s vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id.*) Often, to create a passage for such treatment devices, physicians insert a “guide catheter” earlier in the procedure. *Id.* In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id.*) The ‘850 patent is directed to an apparatus that is deliverable through a standard guide catheter for extension

beyond the ostium to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (*See, e.g.*, Exh. 1001, 2:55-69).

**B. Description Of The Alleged Invention Of The ‘850 Patent**

The ‘850 Patent (Exh. 1001) contains 24 system claims, including two independent claims (claims 1 and 12). The specification of the ‘850 patent states that it relates “generally to catheters used in interventional cardiology procedures,” and “[m]ore particularly, ... apparatus for increasing backup support for catheters inserted into the coronary arteries of the aorta.” (Exh. 1001, 1:18-22).

The challenged claims of the ‘850 patent are not straightforward. Unlike typical system claims, the ‘850 patent claims are replete with functional language and ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Claim 1 is representative of the independent claims in the ‘850 patent:

1. A system *for use with* interventional cardiology devices *adapted to be insertable into* a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end *adapted to be placed in* the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter *sized such that* interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and a device *adapted for use with* the guide catheter, including: a flexible tip portion defining a tubular structure and having a circular cross-section

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

Dependent claim 2 of the '850 patent depends from independent claim 1 and requires that "the tubular structure includes a distal portion *adapted to be extended beyond* the distal end of the guide catheter ... *such that* the device assists in resisting axial and shear forces exerted by the interventional cardiology device

passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.”

Dependent claim 3 (depending from independent claim 1 and dependent claim 2), is directed to a “proximal side opening” in a proximal portion of the tubular structure, where such opening “extend[s] for a distance along the longitudinal axis” and is “transverse [*i.e.*, at an angle] to the longitudinal axis.” Dependent claim 14 (depending from independent claim 12) contains substantially similar limitation, except that the “partially cylindrical portion defining an opening extending for a distance along a side thereof” in the substantially rigid (as opposed to tubular) portion.

Dependent claim 4 depends from claim 3 and requires a “structure defining a full circumference portion and structure defining a partially cylindrical portion,” as would result from a tube being skived at an angle for part of its length. These “side opening claims” are directed to that which was well known in the art when the ‘850 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle.

Dependent claim 8 (depending from independent claim 1) and 18 (depending from independent claim 12) require that “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.”

### **C. Summary of the Prosecution History of the '850 Patent**

The '850 Patent was filed as U.S. App. Serial No. 13/359,059 on January 26, 2012 (*see* Exh. 1002, paper 1). The prosecution of the '032 patent, to which the '850 claims priority, spanned five years and three months. During that time, the Examiner issued numerous rejections of claims which are nearly identical to the system claims of the '850 patent challenged herein. Ultimately, however, following at least six rejections and eight amendments, the Examiner conditioned patentability of the claims on the addition of a "rail structure without a lumen" limitation within the substantially rigid portion.

The claims of the '850 patent issued following an amendment by the same Examiner of independent claims 1 and 12 moving the location of the "rail structure without a lumen" limitation from the tubular structure of the flexible tip portion (where the Patent Owner had sought to include it) to the substantially rigid portion, where it had been included in the '032 patent. The Examiner's stated reasons for allowance were that, "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." A Notice of Allowance was mailed August 22, 2012, and the '850 Patent issued on October 23, 2012. (Exh. 1002 at 16).



#### **IV. REQUIREMENTS FOR INTER PARTES REVIEW**

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '850 Patent is satisfied.

##### **A. Grounds for Standing Under 37 C.F.R. § 42.104(a)**

Petitioner certifies that the '850 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

##### **B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested**

The precise relief requested by Petitioner is that claims 1-4, 8, 12, 14, and 18 of the '850 Patent be found unpatentable.

##### **C. Claims for Which *Inter Partes* Review Is Requested**

Pursuant to 37 C.F.R. § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1-4, 8, 12, 14, and 18 of the '850 Patent.

##### **D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)**

This Petition, supported by the grounds set forth below and the Solar Declaration (Ex. 1003), demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C. § 314(a). *Inter partes* review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103.

No.	Grounds
1	Claims 1-4, 8, 12, 14, and 18 are obvious over Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the '032 patent)
2	Claims 1-4, 12, and 13 are anticipated by U.S. Pub. No. 2004/0236215 to Mihara, <i>et. al.</i>
3	Claims 1-4, 12, 13 are obvious over Mihara in view of the Knowledge of One of Skill in the Art
4	Claims 1-4, 8, 12, 18 are obvious over Mihara in view of "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," 2004, Takahashi Online Article ("Takahashi")

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

**V. Non-Redundancy of Proposed Alternative Grounds**

Petitioner urges the Board to adopt each ground of unpatentability raised with respect to claims 1-4, 8, 12, 14 and 18 of the '850 patent for at least the following reasons. The proposed grounds for institution presented in the present Petition ("Petition B") are not redundant over each other, or over the grounds of rejection presented in the concurrently filed parallel Petition for *inter partes* review of the challenged claims of the '850 patent ("Petition A" (Exh. 1008)) because several differences exist between the applied prior art and their respective grounds for unpatentability. For example, the primary prior art reference in parallel Petition A (Adams '292) differs from the primary prior art reference raised herein (Mihara). Mihara anticipates a different set of dependent claims (claims 3, 4, and 14) through its disclosure of a skived proximal side opening in Figures 1-3. Adams '292

anticipates the claimed difference in diameter between the inner diameter of the device and the inner diameter of the standard guide catheter of “not more than one French” (claims 8 and 18). As a result, during the course of this proceeding, if instituted, Patent Owner could amend the claims to limit them to just one of the claimed embodiments that is anticipated by Adams ‘292 (Petition A) or Mihara (Petition B) alone. Accordingly, all grounds based on both Adams ‘292 and Mihara are needed to encompass all of the embodiments of claims 1, 2, and 12, and, as such, are not redundant. Indeed, because of the Patent Owner’s unreasonably functional and broad claims, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structures of the systems in the cited references, and so that Petitioner may address any arguments by the Patent Owner regarding the ability of structures in the prior art to perform the various functions recited in each of the challenged claims.

Petitioner’s asserted ground of unpatentability in the present Petition based on Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the ‘032 patent), is not redundant of the other grounds of unpatentability raised herein or in Petition A because it renders obvious all challenged claims only if the ‘850 patent is denied the benefit of its claimed May 3, 2006 priority date.

Similarly, the grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 3, 4, and 14 are not redundant given that the far reaching functional language of such claims necessitate Petitioner's alternative proposed grounds of unpatentability on the basis of both anticipation in view of Mihara and obviousness over Mihara in view of the knowledge of one of skill in the art.

If the PTAB disagrees and determines that the grounds raised herein are redundant of those raised in Petition A, and will institute only on the grounds of one Petition, Petitioner respectfully requests institution on the basis of Petition A. Moreover, if the PTAB determines that there is redundancy with respect to the grounds raised herein regarding anticipation in view of Mihara and obviousness of claims 3, 4, and 14 over Mihara in combination with the knowledge of one of skill in the art, Petitioner suggests institution on the grounds of Mihara in view of the knowledge of one of skill in the art.

#### **VI. Level of Skill In the Art**

A person of ordinary skill in the art ("POSA") at the time of the alleged invention of the '850 patent would have been someone with at least the equivalent of a medical degree from an accredited institution (usually denoted in this country as a M.D. degree) or someone with the equivalent of a masters degree from an accredited institution (usually denoted in this country as an M.S. degree) in

biomedical engineering. The person must have at least three years of experience working as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer. Extensive experience and technical training might substitute for educational requirements, while advanced degrees might substitute for experience. (Exh. 1003 ¶ 29).

**A. Construction Of The Challenged Claims**

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” Because the standards of claim interpretation used by the Courts in patent litigation differ from those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation (“BRI”) in light of the

patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.<sup>1</sup>

**1. “rail structure without a lumen”**

Because the ‘850 patent does not disclose any structure for the “rail structure without a lumen” limitation of independent claims 1 and 12, it is invalid under 35 U.S.C. §112, ¶ 2. The word “rail” appears in the specification of the ‘850 patent only twice. *First*, the Summary of the Invention refers to a “guidewire rail segment,” defined as “permit[ing] delivery without blocking the use of the guide catheter.” (Exh. 1001, 2:65-69). *Second*, Fig. 17 is described as “a plan view of a coaxial guide catheter having a longer rail segment,” without any guidance as to which portion(s) of Figure 17 constitute the “rail segment.” Neither of these references discloses any meaning for “rail” in the claim term “rail structure without a lumen.” (1003 ¶ 52). Moreover, nothing in the specification suggests that the rail structure consists of the “tapered inner catheter,” “full circumference portion,” “cutout portion,” “reinforced portion,” “hemicylindrical portion,” “second full circumference portion,” “arcuate portion,” “braid or coil reinforcement,” “most proximal portion of braid or coil reinforcement,” “relief cut,” “hemi-tube portion,”

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<sup>1</sup> Petitioner reserves the right to challenge the validity of the ‘032 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

“single cuts,” “double cuts,” “connector hub,” “funnel portion,” “grip portion,” to name a few, nor would be so read by a POSA. (*Id.*)

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent claims 1 and 12 under 35 U.S.C. §§ 102 and 103, and claims 3, 4, 8, 14 and 18 depending therefrom, Petitioner submits that, a POSA would understand “rail structure” to refer to a pushing or advancement structure. “Monorail” or rapid exchange catheters are characterized by a relatively guide wire lumen; this cannot be the “rail structure” for purposes of the claim, however, because the claimed structure must be “without a lumen.” (Exh. 1003 ¶ 53). A POSA would therefore understand the “rail structure” to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id.* ¶ 54). Accordingly, the term “rail structure without a lumen” can be construed for purposes of this Petition to mean a “pushing or advancement structure without a lumen.” (*Id.*)

## **2. “interventional cardiology device(s)”**

Interventional cardiology devices are thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to

treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. The specification of the '850 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001, 1:28-31 ("For the purposes of this application, the term 'interventional cardiology devices is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters")). (Exh. 1003, ¶ 55).

3. **"to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "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"**

Dependent claim 3 recites that the structure of the proximal side opening to which the claim is directed is "to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." (Exh. 1001, 11:-17-20 Dependent claim 14 similarly recites an opening "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...." (Exh. 1001, claim 3 (emphasis added). ) This language merely indicates the intended use of the claimed proximal opening (to receive an interventional cardiology device), and the device itself (for use within a guide catheter) as well as the order in which such intended uses may occur



(receiving the device “into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter”). (*Id.*, 11:18-20) Accordingly, such language should not be read as positive limitations on apparatus claims 3 or 14 of the ‘850 patent. To the extent that there is any doubt, the BRI of the claims suggests that only the structural limitation(s) of claims 3 and 14 (namely, a skived proximal opening) should be accorded patentable weight. The Federal Circuit has made clear that the validity of a system claim depends *solely* on the claimed structure and not on the use or purpose of that structure. *Catalina Mktg Int’l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

Because the ‘850 patent claims are system claims, the requisite invalidity analysis turns on a direct comparison of the claimed *structures* with the prior art *structures*. See *Catalina Mktg. Int’l*, 289 F.3d at 810 (“To hold otherwise would effectively impose a method limitation on an apparatus claim without justification”); *In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). The functional statements in claims 3 and 14 are not structural because the entire structure of the proximal side opening is described elsewhere in the claim; deletion of the functional phrases from claims 3 and 14 would not affect the structure of the claimed proximal opening. At most, the language requires a proximal opening large enough to allow passage of an interventional cardiology device.

Petitioner has, nevertheless, included sufficient evidence such that, even if the Board were to construe these functional statements of intended use as positive limitations of claims 3 and 14, the grounds for unpatentability set forth below still render the challenged claims invalid in view of the cited art.

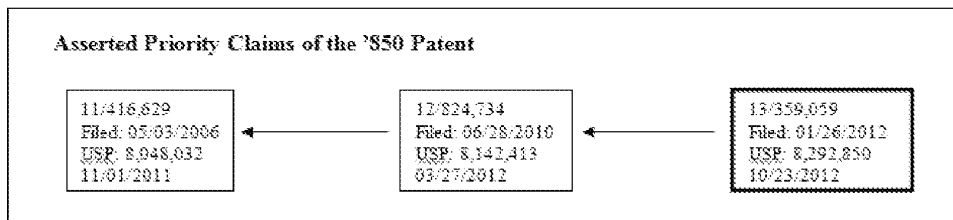
4. **“adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery”**

Dependent claim 2 recites: “the system of claim 1 wherein the tubular structure includes a distal portion *adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.*” (Exh. 1001, claim 2). These are statements of intended use, not structural language. The relevant structural limitations—a tubular structure having distal and proximal portions—is included elsewhere in the claim. As discussed above, to patentably distinguish the claimed invention from the prior art, a recitation of intended use must result in a structural difference between the claimed invention and the prior art. *See, e.g.,* Practitioner’s Manual of Patent Examining

Proc. § 707 (paragraph 7.37.09). As long as a prior art structure would be *capable of* performing the intended use, then it meets the claim. *Id.* In any event, even if this functional language in dependent claim 2 were accorded patentable weight, the prior art expressly discloses this function, as set forth below.

**B. The '850 Patent Is Not Entitled To Claim Priority to the Filing Date of Either U.S. Application 11/416,629 or U.S. Application 12/874, 734**

As depicted below, the '850 patent asserts priority back to May 3, 2006 through a chain of two divisional applications: (1) U.S. Patent Application No. 11/416,629 (filed May 3, 2006 and issued as U.S. Patent No. 8,048,032 (the "'032 patent")), and (2) U.S. Patent Application No. 12/824,734 (filed June 28, 2010 and issued as U.S. Patent No. 8,142,413 (the "'413 patent")):



The challenged claims of the '850 patent are not entitled to the filing dates of either U.S. Application 11/416,629 (the '032 patent application) or U.S. Application 12/874,734 (the '413 patent application) since their disclosures lack written description of the "rail structure without a lumen" in independent claims 1 and 12, from which all other challenged claims depend, and of "the tubular structure further compris[ing] [a] structure defining a proximal side opening

extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis” of claim 3 from which claim 4 depends. Accordingly, none of the challenged claims are entitled to the priority dates of either U.S. Application 11/416,629 or U.S. Application 12/874,734. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1303, 1306 (Fed. Cir. 2008) (affirming district court determination that claims “were not entitled to the prior date of the Original Application because the written description of the Original Application did not support the later issued claims”).

Indeed, as the Manual of Patent Examining Procedure Section 201.1 states: “[t]he later filed application must be an application for an invention which is also disclosed in the prior application ... and the disclosure in the prior application ... must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. *See Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).” MPEP § 201.1.

As written description may not be challenged in this proceeding, Petitioner submits that, if even one of the limitations of the challenged claims is not supported by the applications to which the ‘850 patent claims priority, then its effective priority date is no earlier than January 26, 2012. *See, e.g., Medtronic, Inc. v. Nuvasive, Inc.*, Case IPR2014-00087, Paper 10, 10 (April 8, 2014) (citing

*Polaris Wireless, Inc. v. TruePosition, Inc.*, Case IPR2013-00323, Paper 9, 29 (PTAB 2013)).

**1. No Disclosure of “Rail Structure without a Lumen”**

As discussed in above, the term “rail structure without a lumen” can be construed to mean pushing or advancement structure without a lumen. The word “rail” appears in the specification of U.S. Application 11/416,629 and U.S. Application 12/874,734 only twice. *First*, the Summary of the Invention refers to a “guidewire rail segment,” defined as “permit[ing] delivery without blocking the use of the guide catheter.” (Exh. 1001, 2:65). *Second*, Fig. 17 is described as “a plan view of a coaxial guide catheter having a longer rail segment,” without any guidance as to which portion(s) of Figure 17 constitute the “rail segment.” (*Id.*, 6:1-3). Neither of these citations discloses any meaning for “rail” in the claim term “rail structure without a lumen.” (Exh. 1003, ¶ 52)..

Because a POSA would understand the word ‘rail’ at best in the context of the term ‘monorail,’ which is used in the art to denote a shortened distal tube defining a guidewire lumen in a rapid exchange catheter (the term ‘monorail’ connotes the appearance of the short distal tube as it ‘rides’ over the guidewire during delivery as being similar to that of a monorail train riding along a track), U.S. Application 11/416,629 and U.S. Application 12/874,734 lack written description support for the term “rail structure without a lumen.” (Ext. 1003 ¶ 53).

As such, the '850 Patent is entitled to a priority date no earlier than January 26, 2012.

### **C. The Prior Art References**

As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under at least §102(b).<sup>2</sup>

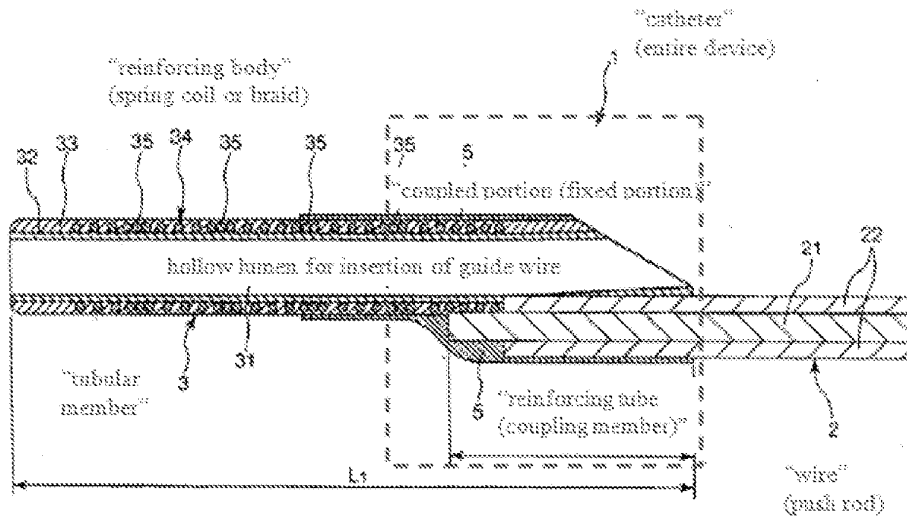
#### **1. Mihara**

U.S. Pub. No. 2004/0236215 (“Mihara”) (Exh. 1009) is an application published on November 25, 2004, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under § 102(b). The Mihara publication discloses a “catheter for penetrating a stenotic lesion occurred in a lumen in a human body, including: a linear wire; and a tubular body placed on a distal end side of the wire and allowing a guide wire to be inserted through its hollow portion.” (Exh. 1009, Abstract; Exh. 1003 ¶¶ 33-34). An annotated version of Fig. 2 (below) provides a cross-sectional view of the Mihara catheter (the left side of Fig. 2 depicts a “distal end” of the device, and the right side depicts a “proximal end”) (Exh. 1009, Fig. 2, [0028], [0031]):

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<sup>2</sup> All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

FIG. 2



As shown in Fig. 2, “the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31.” (Exh. 1009, [0033]).

## 2. Takahashi

Takahashi, *New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter*, *Catheterization and Cardiovascular Interventions* 63:452-456 (“Takahashi,” Exh, 1021) is an article published in 2004 and, thus, qualifies as prior art under § 102(b). Takahashi describes a method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶ 35). The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is one French or less. (*Id.*)

**D. How The Construed Claim(s) Are Unpatentable**

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1-4, 8, 12, 14, and 18 of the '850 Patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration.

**E. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)**

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below in Section VII and VIII and the corresponding claim charts set forth therein. Dr. Solar, an expert with 37 years of academic and industry experience in the field has reviewed the claim charts and evidentiary support submitted in this Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein.

**VII. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4)**

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to



achieve predictable results, all of which were well known to persons of ordinary skill in the art in the field of interventional cardiology procedures at the time to which the '850 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

**A. Claims 1, 2, 3, 4, 12, and 14 Are Anticipated Under 35 U.S.C. §102(b) By Mihara**

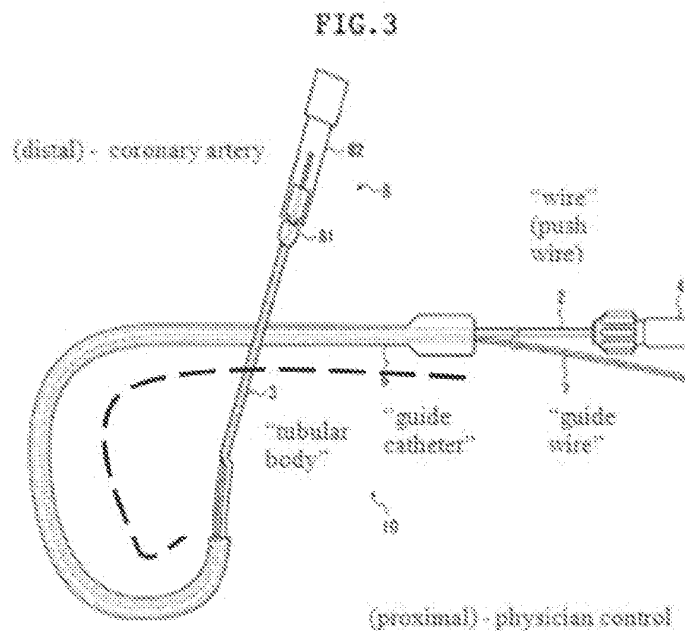
As shown below, each element recited in claims 1, 2, 3, 4, 12 and 14 is anticipated by Mihara, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '850 patent. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See, e.g., In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

**1. Claim 1**

Claim 1 of the '850 patent discloses:

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

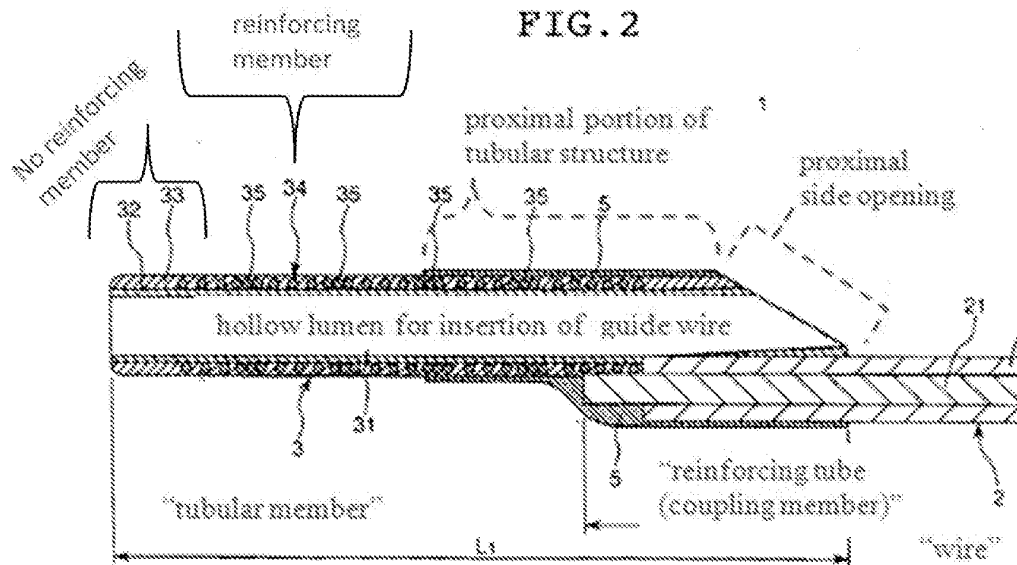
The preamble of a patent may not be limiting. *See, e.g., STX LLC v. Brine, Inc.*, 211 F.3d 588, 591 (Fed. Cir. 2000); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). Nevertheless, all limitations recited in the preamble are disclosed by Mihara. Specifically, Mihara discloses a system for use with a standard guide catheter. (Exh. 1009, [0092]) (“First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery”). In annotated Figure 3 below, the guide catheter 6 (dashed line) used with the Mihara catheter has a continuous central lumen and a proximal end which a POSA would understand is directed to insertion through a hemostatic valve. (*Id.*, Fig. 3; Exh. 1003 ¶ 68).



Mihara also discloses that the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. (Exh. 1009, [0005]) (“a long hollow tube called a guide catheter is inserted into a blood vessel, and placed at an entrance of a coronary artery. After that, the guide wire is pulled out, and another guide wire and a balloon catheter are inserted in a lumen of the guide catheter”); *see id.* Fig. 3; [0092]-[0093]).

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

Mihara discloses a flexible tip portion defining a tubular structure in the form of a “tubular body,” having an inner and outer diameter. Specifically, annotated Fig. 2 of Mihara (below) discloses a catheter wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being “preferably formed of a fluorine resin such as polytetrafluoroethylene (PTFE).” (Exh. 1009, [0051]). The outer layer 33 is also described as being preferably “composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof.” (*Id.*, [0052]).



The tubular structure defined by the flexible tip is disclosed as having a circular cross section: “Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm.” (Exh. 1009, [0056]).

The tubular structure 3 is also shorter (10-40 cm) than the predefined length of the continuous lumen of the guide catheter 6 (100 cm). (Exh. 1009, [0057]) (“Although the length of the tubular body 3...is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm.”).

*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 defining a coaxial lumen*

*having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and*

Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm). (Exh. 1009, [0081]-[0092]). As shown in annotated Fig. 3 in the claim chart below, Mihara further discloses that the flexible tube (“tubular body 3”) is placed coaxially relative to the guide catheter 6.

Mihara also discloses that, when used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen through which the interventional cardiology device of guide wire 7 is insertable. (Exh. 1009, [0033] (“As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end portion of the wire 2”); *id.*, [0049]) (“The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31”).

*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*

Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: (Exh. 1009, [0036] (“As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed”); *id.*, [0037] (“The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2”)).

As detailed above, the broadest reasonable construction of “rail structure without a lumen” is “a pushing or advancement structure without a lumen.” As such, the rigid push wire of Mihara meets the limitations of this claim element in that it constitutes a structure without a lumen that is substantially rigid relative to the flexible tube to which it is proximal and operably connected.

*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*

Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip. (Exh. 1009, [0048] (“The outer diameter of the wire 2 in the proximal portion is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm”); *id.*, [0055] (“the outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm”)).

*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 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.*

Mihara discloses that the combined length of the tubular member and the substantially rigid portion of the device is “preferably in the range of 1110-1500 mm” (110-150 cm), which is longer than the length of a standard guide catheter lumen (100 cm). (Exh. 1009, [0092]-[0034]; *see id.* [0073]-[0075]).

Figure 3 further depicts how Mihara discloses to a POSA that, when the tubular member 3 is extended beyond the distal end of the guide catheter 6, the

push wire 2 extends proximally outside the guide catheter at the same point as the guidewire 7 (where, in practice, the hemostatic valve is located). (Exh. 1003 ¶ 77).

## **2. Claim 2**

Both the '850 patent and Mihara are directed to a catheters that provide strong backup support or “pushability” for deep intubation beyond the ostium, providing a counter-force to the force/resistance created by the advancement of a guidewire into a tight or substantially occluded target vessel. (Exh. 1003 ¶¶ 32-33). These are purely functional characteristics as claim 2 recites no additional structural features from those included in the limitations of claim 1. As noted above, claim scope is not limited by nonstructural language and statements of intended use for a claimed system.

Even if the functional language in dependent claim 2 regarding the intended use of the system is found to limit the scope of claim 2, Mihara expressly discloses the function claimed therein as detailed in the claim charts below. Specifically, Mihara discloses that “the catheter of the present invention has an excellent push-in property. Therefore a push-in force applied from a proximal end side is transmitted to a distal end portion exactly, and as a result, the catheter can penetrate a stenotic lesion occurred in a lumen in the human body easily and rapidly.” (Exh. 1009, [0024]).

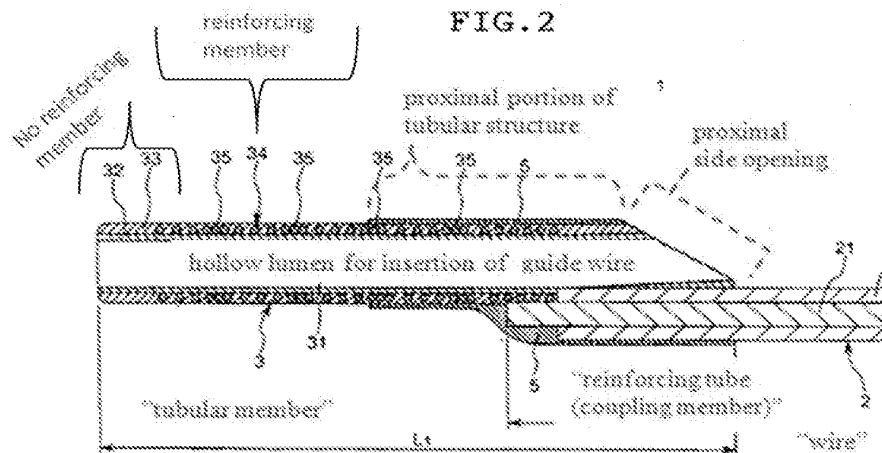
## **VIII. Obviousness of Challenged Claims**



The below challenged claims of the '850 patent are rendered obvious under §103(a) in view of the prior art references set forth below, either in view of the knowledge of one of ordinary skill in the art, or in the combinations expressly described herein. Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418-20, 82 U.S.P.Q.2d 1385 (2007); *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

**A. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. § 103 Over Adams In View Of Mihara**

Dependent claims 3, 4, and 14 are all directed to a skived proximal side opening to a lumen through which interventional cardiology devices are received. Mihara was neither cited nor considered during the prosecution of the '032 Patent. Figure 2 of Mihara depicts how the proximal opening of the tubular body 3 to the guide wire lumen 31 of the catheter 1 is skived or cut at an angle where the tubular body 3 overlaps with and is connected to the wire push rod 2.



Specifically:

- “the wire 2 is provided with appropriate rigidity (flexural rigidity and torsional rigidity), which enhances a push-in property and transmittance of a torque.” (Exh. 1009, [0043]).
- “The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion). Therefore high coupling strength can be obtained, and the enlargement of the distal end portion of the catheter 1 can be prevented.” (Exh. 1009, [0061]).
- “Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer

circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5.... [t]he overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process.” (Exh. 1009, [0062]).

The proximal opening in the tubular body 3—and in the reinforcing tube 5 surrounding the overlapped portion of the wire 2 and tubular body 3—thereby defines a side opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis such that “[t]he hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31.” (Exh. 1009, [0049]).

This disclosure satisfies the structural limitations of dependent claim 3 (which depends from claims 1 and 2) requiring that “the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,” the requirement of dependent claim 4 (depending from claims 1, 2, and 3) that “the proximal side opening includes structure defining a full circumference portion and structure

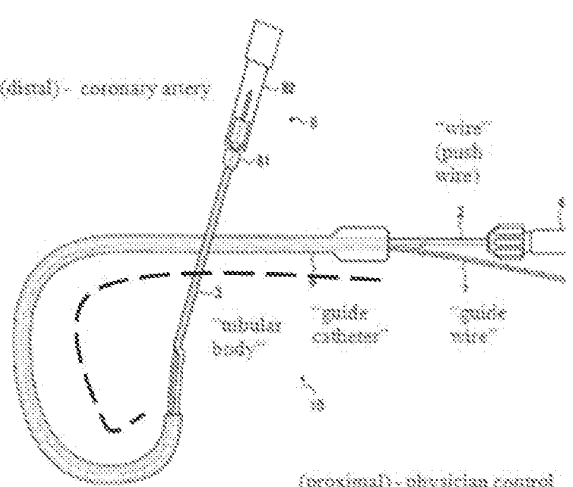
defining a partially cylindrical portion,” and the limitation of claim 14 (depending from claim 12) that “the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis.”

**1. Claim 12**

*a reinforced portion proximal to the flexible tip portion;*

As discussed above, claim 12 of the ‘850 patent includes the same limitations as claim 1, with the exception of one additional element, a “reinforced portion” proximal to the substantially rigid portion. Accordingly, Petitioner references and includes its analysis of all elements of claim 1 set forth above and in the chart below. Mihara also disclosed the “reinforced portion” of claim 12, as shown in the claim chart below.

The ‘850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of</p>	<p>[1] To the extent that the preamble is a limitation, Mihara discloses a device for use with “guiding catheter 6” (<i>see</i> dashed blue line in annotated Fig. 3 below) having a continuous lumen extending for a predefined length from a proximal end to a distal end adapted to be placed in a branch artery:</p>

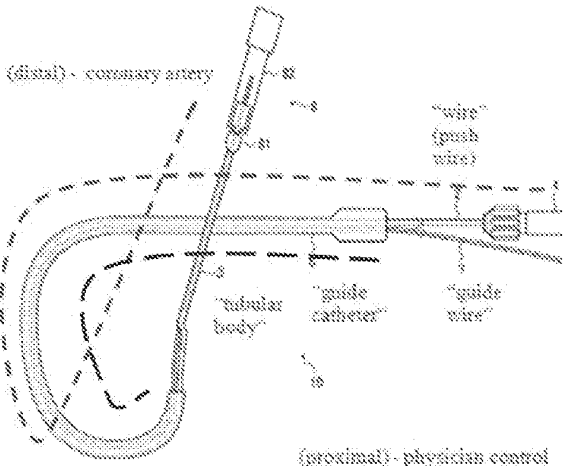
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and a device adapted for use with the guide catheter, including:</p>	<p style="text-align: center;">FIG. 3</p>  <p>“(discal)- coronary artery”</p> <p>“(proximal)- physician control”</p> <p>“wire (push wire)”</p> <p>“tubular body”</p> <p>“guide catheter”</p> <p>“guide wire”</p> <p>“First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery.” (Exh. 1009, [0092]).</p> <p>[2] As shown in annotated Fig. 3 above, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. “First the guiding catheter 6 ... having an inner diameter of 1.8 mm ... was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7... was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7.” (Exh. 1009, [0092]-[0093]).</p>
<p>a flexible tip portion defining a tubular structure</p>	<p>[1] Annotated Fig. 2 of Mihara (below) discloses a catheter wherein the distal-most tip portion of the</p>

<p><b>The '850 Patent</b></p>	<p><b>Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)</b></p>
<p>having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,</p>	<p>tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being “preferably formed of a fluorine resin such as polytetrafluoroethylene (PTFE).” (Exh. 1009, [0051]). The outer layer 33 is further described as being preferably “composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof.” (<i>Id.</i>, [0052]).</p> <div data-bbox="646 808 1356 1207" data-label="Diagram"> </div> <p>[2] The tubular structure defined by the flexible tip is disclosed as having a circular cross section: “Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm.” (Exh. 1009, [0056]).</p> <p>[3] “Although the length of the tubular body 3... is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm.” (Exh. 1009, [0057]).</p>
<p>the tubular structure having a cross-sectional outer</p>	<p>[1] Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for</p>

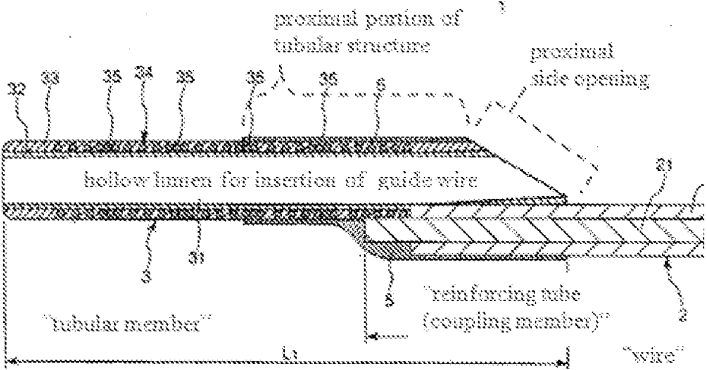
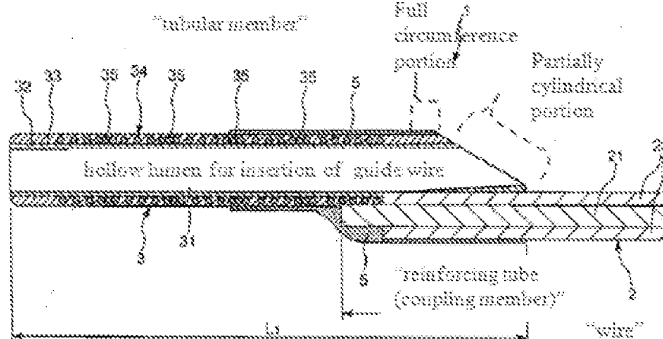
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and</p>	<p>insertion through the guide catheter lumen (1.8 mm): “Outer diameter of a portion between 0 and 90 mm from the proximal end side of the tubular body 3: 0.87 mm.” (Exh. 1009, [0081]). “First, the guiding catheter 6...having an inner diameter of 1.8 mm...” (Exh. 1009, [0092]).</p> <p>[2] As shown in annotated Fig. 3 below, Mihara discloses that the flexible tube (“tubular body 3”) is placed coaxially relative to the guide catheter 6:</p> <div data-bbox="641 808 1201 1323" data-label="Diagram"> </div> <p>[3] “As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end of the wire 2” (Exh. 1009, [0033]). “The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31.” (Exh. 1009,</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>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</p>	<p>[0049]). Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: "As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed." (Exh. 1009, [0036]). "The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2." (Exh. 1009, [0037])</p>
<p>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</p>	<p>Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip: "The outer diameter of the wire 2 in the proximal portion . . . is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm." (Exh. 1009, [0048]). "[T]he outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm." (Exh. 1009, [0055]).</p>
<p>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 continuous</p>	<p>As shown in annotated Fig. 3 below, Mihara discloses that the combined length of the wire 2 and tubular body 3 (dashed red line) is longer than the guide catheter lumen 6 (dashed blue line). (Exh. 1009, Fig. 3).</p>

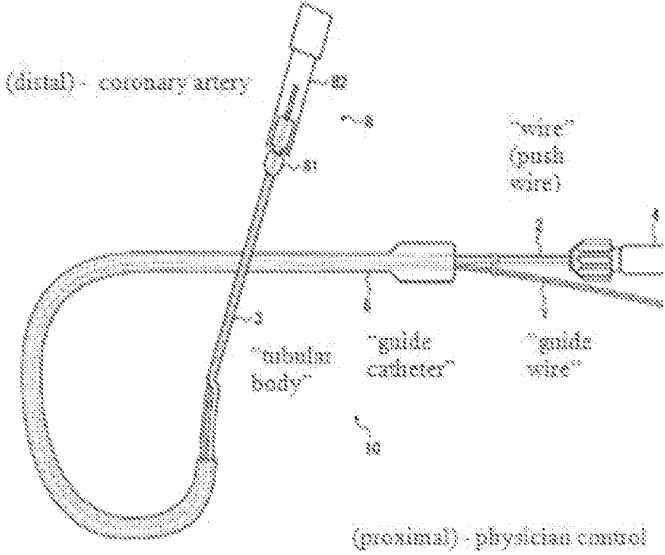


The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>lumen of the guide catheter, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.</p>	<p style="text-align: center;">FIG. 3</p>  <p><i>Compare</i> 1006, [0092]: (“the guiding catheter 6 (Heart Rail 6, produced by Terumo Corp.; having an inner diameter of 1.8 mm and a length of 100 cm)”), <i>with</i> [0034] (“The entire length of the catheter 1 is not particularly limited, but preferably in the range of 900 to 1700 mm, and more preferably in the range of 1100 to 11500 mm”); <i>see</i> [0073]-[0075] (“Length of the wire 2: 1060 mm[;] Length of L2: 10 mm[;] Length of L1: 250 mm”)</p>
<p>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,</p>	<p>Mihara discloses the device of claim 1 (<i>see above</i>)</p>

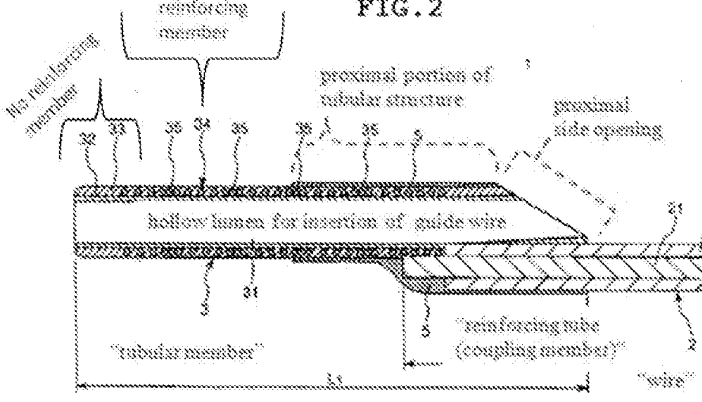
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.</p>	<p>“As shown in Table 1, it was confirmed that the catheter of the present invention (Example 1) has a high striking resistance and an excellent push-in property, compared with the catheter with the guide wire lumen formed over the entire length of the catheter (Comparative Example).” (Exh. 1009, [0100]). “An object of the present invention is to provide a catheter excellent in push-in property, capable of easily and rapidly penetrating a stenotic lesion....” (Exh. 1009, [0010]). “As described below, the catheter of the present invention has an excellent push-in property. Therefore, a push-in force applied from a proximal end side is transmitted to a distal end portion exactly, and as a result, the catheter can penetrate a stenotic lesion occurred in a lumen in the human body easily and rapidly.” (Exh. 1009, [0024]).</p>
<p>3. The device of claim 2</p>	<p>Mihara discloses the device of claim 2. (<i>see above</i>)</p>
<p>wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,</p>	<p>Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a proximal side opening extending for a distance along the longitudinal axis and accessible from a longitudinal side defined transverse to the longitudinal axis. (Exh. 1009, Fig. 1).</p>

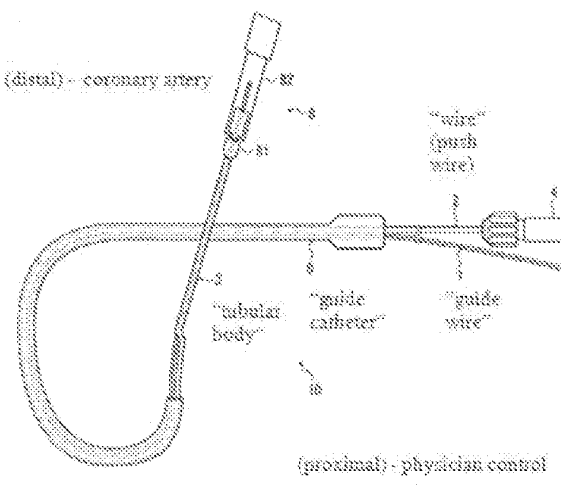
<p>The '850 Patent</p>	<p>Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)</p>
	<p style="text-align: center;">FIG. 2</p> 
<p>to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.</p>	<p>“The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31.” (Exh. 1009, [0049]).</p>
<p>4. The system of claim 3</p>	<p>Mihara discloses the device of claim 3. (<i>see above</i>)</p>
<p>wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.</p>	<p>Annotated Fig. 2 (below) of Mihara discloses a catheter wherein the proximal side opening to the hollow device lumen (31) of the tubular body (3) is skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion:</p> <p style="text-align: center;">FIG. 2</p> 
<p>12. A system for use with interventional cardiology</p>	<p>[1] To the extent that the preamble is a limitation, Mihara discloses a device for use with “guiding</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>devices adapted to be insertable into a branch artery, the system comprising:</p> <p>a guide catheter having a continuous lumen extending for a predefined length from a proximal end 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</p>	<p>catheter 6" (<i>see</i> dashed blue line in annotated Fig. 3 below) having a continuous lumen extending for a predefined length from a proximal end to a distal end adapted to be placed in a branch artery:</p> <div data-bbox="646 562 1214 1092" data-label="Diagram"> </div> <p>“First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery.” (Exh. 1009, [0092]).</p> <p>[2] As shown in annotated Fig. 3 above, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. “First the guiding catheter 6...having an inner diameter of 1.8 mm...was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7...was</p>

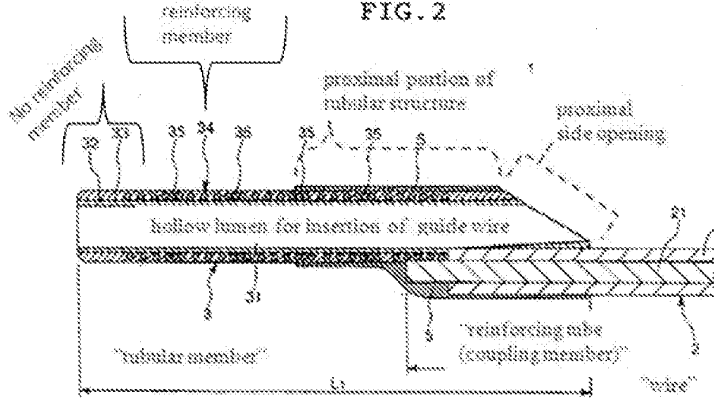
<p>The '850 Patent</p>	<p>Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)</p>
	<p>inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7.” (Exh. 1009, [0092]-[0093]).</p> <p>“First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery.” (Exh. 1009, [0092]).</p> <p>[2] As shown in annotated Fig. 3 below, the guide catheter 6 used with the Mihara device has a continuous central lumen</p> <p style="text-align: center;">FIG. 3</p>  <p>[4] As shown in annotated Fig. 3 below, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. “First the guiding catheter 6 ... having an inner</p>

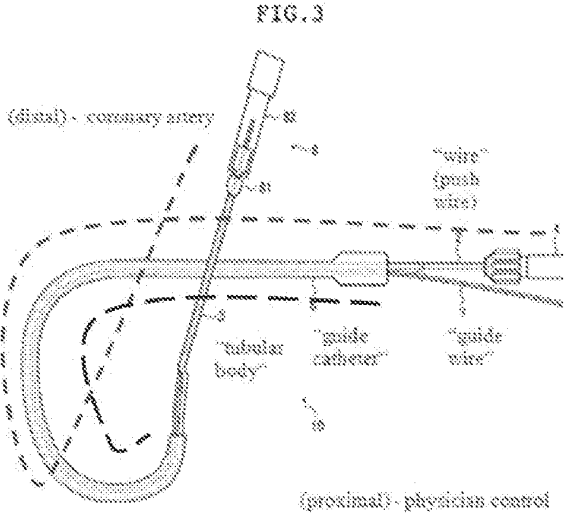
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	<p>diameter of 1.8 mm...was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7...was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7.” (Exh. 1009, [0092]-[0093]).</p>
<p>an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,</p>	<p>Mihara discloses that the combined length of the wire 2 and tubular body 3 is longer than the guide catheter lumen. (See Fig. 3 below). As shown in Fig. 3, catheter is longer than the continuous lumen of the guide catheter 6 as the wire 2 extends beyond the proximal end of the catheter and tubular body 3 extends beyond the distal end of the guide catheter 6.</p>
<p>the elongate structure including: a flexible tip portion defining a tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,</p>	<p>Annotated Fig. 2 of Mihara (below) discloses an elongate structure 1 including a flexible tip portion defining a tubular body 3 wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being “preferably formed of a fluorine resin such as polytetrafluoroethylene (PTFE).” (Exh. 1009, [0051]). The outer layer 33 is further described as being preferably “composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof.” (<i>Id.</i>, [0052]).</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	<p style="text-align: center;"><b>FIG. 2</b></p>  <p>[2] The tubular structure defined by the flexible tip is disclosed as having a circular cross section:  “Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm.” (Exh. 1009, [0056]).</p> <p>[3] “Although the length of the tubular body 3 ... is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm.” (Exh. 1009, [0057]).</p>
<p>the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;</p>	<p>[1] Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm):  “Outer diameter of a portion between 0 and 90 mm from the proximal end side of the tubular body 3: 0.87 mm.” (Exh. 1009, [0081]). “First, the guiding catheter 6 ... having an inner diameter of 1.8 mm....” (Exh. 1009, [0092]).</p> <p>[2] As shown in annotated Fig. 3 below, Mihara discloses that the flexible tube (“tubular body 3”) is placed coaxially relative to the guide catheter 6:</p>

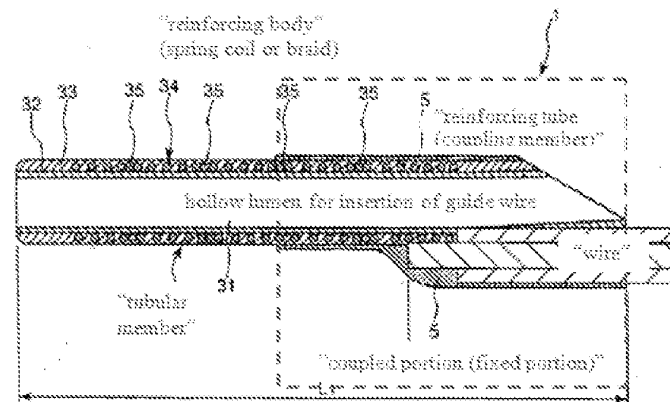
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	<p style="text-align: center;">FIG. 3</p>  <p>[3] “As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end of the wire 2” (Exh. 1009, [0033]). “The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31.” (Exh. 1009, [0049]).</p>
<p>a reinforced portion proximal to the flexible tip portion; and</p>	<p>As shown in annotated Fig. 1 below: “The tubular body 3 has an inner layer 32 positioned on an inner circumferential side, an outer layer 33 formed on an outer circumferential side of the inner layer 32, and a reinforcing body (reinforcing member) 34 placed between the inner layer 32 and the outer layer 33.” (Exh. 1009, [0050]). “In this embodiment, the reinforcing body 34 is a spiral coil composed of tungsten. The reinforcing body 34 is placed in such a manner that the reinforcing body 34 is buried in the</p>

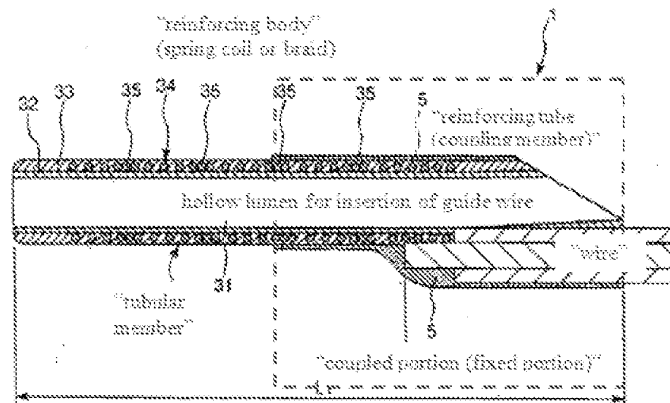


<p>The '850 Patent</p>	<p>Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)</p>
	<p>outer layer 33 (or the inner layer 32). The reinforcing body 34 is not limited to a spiral coil, and may be a braided body (net-shaped body), a bar-shaped body, or the like.” (<i>Id.</i>, 0053)]; Its material is not limited to tungsten. The reinforcing body 34 may be made of stainless steel or the like. “the reinforcing body 34 composed of a spiral coil at several portions.” (<i>Id.</i>, [0059]).</p> 
<p>a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen</p>	<p>Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: “As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed.” (Exh. 1009, [0036]). “The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter</p>

<p><b>The '850 Patent</b></p>	<p><b>Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)</b></p>
	<p>1 (tubular body 3) exactly by the wire 2.” (Exh. 1009, [0037]).</p>
<p>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,</p>	<p>Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip: “The outer diameter of the wire 2 in the proximal portion . . . is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm.” (Exh. 1009, [0048]). “[T]he outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm.” (Exh. 1009, [0055]).</p>
<p>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 rigid portion of the substantially rigid portion extends proximally through the hemostatic valve in common with a guide wire 7 that is insertable into the guide catheter.</p>	<p>As shown in annotated Fig. 3 below, Mihara discloses that when at least a distal portion of the tubular body 3 is extended distally of the distal end of the guide catheter 6 with at least proximal portion of the rigid push wire 2 remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally in common with a guide wire 7 that is insertable into the guide catheter. (Exh. 1009, Fig. 3).</p> 
<p><b>14.</b> The system of claim 11</p>	<p>Mihara discloses the system of claim 11 (<i>See</i> cl. 11</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
<p>wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis</p>	<p>above).</p> <p>“The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion). Therefore high coupling strength can be obtained, and the enlargement of the distal end portion of the catheter 1 can be prevented.” (Exh. 1009, [0061]).</p> <p>“Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5. . . . [t]he overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process.” (Exh. 1009, [0062]).</p> <p>Annotated Fig. 2 (below) depicts that the proximal side opening (that includes a partially cylindrical portion) to the hollow device lumen 31 of the reinforcing tube 5 surrounding the overlapped portion of the wire 2 and tubular body 3 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:</p>

<p>The '850 Patent</p>	<p>Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)</p>
	<p style="text-align: center;"><b>FIG. 2</b> "catheter" (entire device)</p>  <p>“the wire 2 is provided with appropriate rigidity (flexural rigidity and torsional rigidity), which enhances a push-in property and transmittance of a torque.” (Exh. 1009, [0043]).</p>
<p>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,</p>	<p>“The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31.” (Exh. 1009, [0049]).</p>
<p>the opening extending substantially along at least a portion of a length of the substantially rigid portion.</p>	<p>Annotated Fig. 2 (below) of Mihara discloses a proximal opening extending substantially along at least a portion of a length of the substantially rigid portion.</p>

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	<p style="text-align: center;"><b>FIG. 2</b> "catheter" (entire device)</p>  <p>The diagram shows a cross-section of a catheter. At the top, a dashed line indicates the "reinforcing body" (spring coil or braid). Below it is a "reinforcing tube (coupling member)". The central part is a "hollow lumen for insertion of guide wire". A "tubular member" is shown below the lumen. At the distal end, a "coupled portion (fixed portion)" is shown with a "wire" inserted. Reference numerals 22, 33, 35, 34, 36, 35, 5, 31, and 5 are used to identify various components.</p>

**B. Claims 1-4, 8, 12, 14 And 17 Are Obvious Under 35 U.S.C. § 103 Over Pub. No. U.S. 2007/0260219**

As discussed above, all challenged claims of the '850 patent are, at best, only entitled to an effective filing date of January 26 2012, which is the filing date of the '850 patent. The publication of U.S. Patent Application 11/416,629 (the application of the '032 patent), Pub. No. U.S. 2007/0260219 (Exh. 1012), was publicly available more than one year before the filing date of the '850 patent and thus constitutes prior art under §102(b). While the disclosure set forth in Pub. No. U.S. 2007/0260219 has insufficient written description to support a claim of priority for the reasons discussed above, it would have been obvious to replace a 'monorail' tube—which has a lumen with the stiffening element or advancement member of a "rail without a lumen" because stiff proximal low profile structures

for pushing the tubular structure of a rapid exchange catheter through to the treatment site were known to be necessary for the delivery of monorail rapid exchange devices. (Exh. 1003 ¶¶ 53-54).

**C. Claims 1-4, 12, and 14 Are Obvious Under 35 U.S.C. § 103 Over Mihara In View of the Knowledge of a Person of Ordinary Skill in the Art**

To the extent that the Board concludes that the order and intended use limitations of claims 1, 2, 3, 4, 12, and 14 are not expressly or inherently disclosed by Mihara, Petitioner asserts that those characteristics should be deemed obvious based on Mihara alone. All of the structural recitations of the claims are expressly disclosed by Mihara as discussed above, and therefore, Petitioner references the analysis and claim charts for those elements as part of its obviousness analysis here. *See Intellectual Ventures Mgmt., LLC v. Xilinx*, IPR2012-00020, 9 (Feb. 11, 2014) (“A reference need not teach every feature for it to render a claimed invention obvious...[A]n obviousness determination takes into account what a person of ordinary skill in the art would have known at the time of the invention and is not limited to what is contained within the four corners of a parent or printed publication.”); *see Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

**D. Claims 1-4, 8, 12, 14 and 18 Are Obvious Under 35 U.S.C. § 103(a) Over Mihara In View Of Takahashi**

As shown below, each element recited in claims 1-4, 8, 12, 14 and 18 is obvious over Mihara in view of Takahashi. Although Takahashi was cited during prosecution of the '032 Patent, it was not discussed in any Office Action or considered in combination with Mihara.

Mihara, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Mihara and Takahashi. (1003, ¶ 36).

Claims 8 and 18 require that “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.” Takahashi satisfies the limitations of claims 8 and 18 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter such that the cross-sectional inner diameter of the 5 French catheter is not more than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner diameter of the outer guide catheter, and would recognize that this teaching of Takahashi’s 5-in-6 system could be applied to any coaxial catheter directed to insertion through a standard guide catheter for purposes of providing backup support during interventional

cardiology procedures, such as Mihara, and would have been motivated to do so. (Ex. 1003 ¶¶ 92-94).

In 2004, the same year in which the Mihara publication was filed and published on behalf of assignee Terumo (and within which the Terumo Heartrail is expressly discussed as being used during testing of the Mihara support catheter), the Takahashi article disclosed use of Terumo’s Heartrail guide catheter in teaching the advantages of minimizing differences in diameter for purposes of achieving the functionality of both a support catheter (enhanced pushability and backup support) and a guide catheter (working channel between the site of vascular access and the target vessel).

A POSA reviewing the device disclosed by Mihara at the time of the claimed invention would, therefore, have been motivated by Takahashi to achieve the advantages of having minimal difference in diameter by practicing the invention of Mihara within the claimed range of not more than one French with the predictable and expected results of allowing for the insertion of larger devices through the creation of a larger working channel. (See Exh. 1003 ¶¶ 64-65 and 86-97.

<b>Claim Chart A-2: Cl. 8, 18</b>	
<b>The ‘850 Patent</b>	<b>Mihara (Exh. 1009) in view of Takahashi (Exh. 1021)</b>
<b>8. The system of claim 1,</b>	Mihara discloses the system of claim 1 (See A-1, above).



Claim Chart A-2: Cl. 8, 18	
The '850 Patent	Mihara (Exh. 1009) in view of Takahashi (Exh. 1021)
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.	<p>“The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).” (Exh. 1021 at 452).</p> <p>“The inner lumen of the 5 Fr Heartrail catheter is 0.059’ in diameter.... The inner lumen of the outer 6 Fr catheter needs to be more than 0.071’ in diameter to accommodate the 5 Fr Heartrail catheter....” (<i>Id.</i>) “In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter....” (<i>Id.</i> at 453) “Only inserting the 5 Fr guiding catheter into the 6 Fr catheter increased backup support....” (<i>Id.</i>) “A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter.” (<i>Id.</i> at 454).</p>
18. The system of claim 12	Mihara discloses the device of claim 11. ( <i>See above.</i> )
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.	<i>See Takahashi disclosures set forth in claim 8. (See above).</i>

## IX. CONCLUSION

Based on the foregoing, it is clear that claims 1-4, 12, and 14 of the '850 Patent define subject matter that is anticipated by Mihara and that claims 1-4, 8, 12, 14, and 18 of the '850 patent define subject matter that is obvious in view of

Mihara combined with the teachings of Takahashi. Mihara and the prior art combination cited above were never considered by the Examiner; if they had been, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '850 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 16, 2014, to the USPTO correspondence address of record listed below:

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# ATTACHMENT C

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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BOSTON SCIENTIFIC CORPORATION and  
BOSTON SCIENTIFIC SCIMED, INC.  
Petitioner

v.

VASCULAR SOLUTIONS, INC.  
Patent Owner

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Case IPR: Unassigned  
Patent 8,142,413 B2

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Attorney Docket No. 0025216-00057

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**PETITION FOR INTER PARTES REVIEW  
UNDER 37 C.F.R. § 42.100**

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1)).....	5
A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1)) .....	5
B. Related Matters (37 C.F.R. § 42.8(b)(2)).....	5
C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a)) .....	6
D. Service Information (37 C.F.R. § 42.8(b)(4)) .....	6
II. PAYMENT OF FEES (37 C.F.R. § 42.103) .....	6
III. SUMMARY OF RELEVANT TECHNOLOGY AND ‘413 PATENT .....	6
A. Overview Of Interventional Cardiology Procedures .....	7
B. Description Of The Alleged Invention Of The ‘413 Patent.....	8
C. Summary of the Prosecution History of the ‘413 Patent .....	10
IV. REQUIREMENTS FOR INTER PARTES REVIEW .....	12
A. Grounds for Standing Under 37 C.F.R. § 42.104(a).....	12
B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested .....	12
C. Claims for Which <i>Inter Partes</i> Review Is Requested.....	12
D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2) .....	12
E. Construction Of The Challenged Claims .....	13
1. “rail structure without a lumen”.....	14
2. “interventional cardiology device(s)” .....	16
F. The Prior Art References.....	16
1. Adams ‘292.....	17
2. Klein.....	18
3. Adams ‘452.....	18
4. Mihara .....	19
5. Steinke.....	19
6. Takahashi .....	20
G. How The Construed Claim(s) Are Unpatentable .....	20
H. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5) .....	21
V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4).....	21
A. Claims 1 And 13 Are Anticipated Under 35 U.S.C. §102(b) By Adams’292 .....	21
1. Claim 1 .....	22

2.	Claim 13 .....	24
B.	Statement Of Non-Redundancy: Skived Proximal Opening Disclosures in Klein, Adams ‘452, Mihara, And Steinke .....	31
C.	Claims 1, 4, 9, And 10 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of The Knowledge Of One Of Ordinary Skill In The Art .....	33
D.	Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of Klein .....	35
E.	Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of Adams ‘452 .....	40
F.	Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of Mihara .....	45
G.	Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of Steinke .....	50
H.	Claim13 Is Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of The Knowledge Of One Of Ordinary Skill In The Art .....	55
I.	Claims 1 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of Takahashi .....	57
VI.	CONCLUSION.....	59

**Exhibit List for Inter Partes Review of U.S. Patent No. 8,142,413**

Exhibit Description	Exhibit No.
U.S. Patent No. 8,142,413 to Root, et al.	1001
File History for U.S. Patent No. 8,142,413	1002
Declaration of Ronald Jay Solar, Ph.D., with attached Appendix 1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,048,032 to Root, et al.	1004
U.S. Patent No. 8,292,850 to Root, et al.	1005
File History for U.S. Patent No. 8,048,032	1006
File History for U.S. Patent No. 8,292,850	1007
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1008
U.S. Patent No. 6,638,268 to Niazi	1009
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1010
U.S. Publication No. 2004/0127927 to Adams	1011
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1012
U.S. Patent No. 5,527,292 to Adams et al.	1013
U.S. Patent No. 5,776,141 to Klein et al.	1014
U.S. Patent No. 7,232,452 to Adams et al.	1015
U.S. Patent No. 5,328,472 to Steinke et al.	1016
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," <i>Catherization and Cardiovascular Interventions</i> 63:452-456 (2004)	1017
U.S. Patent No. 5,690,613 to Verbeek	1018
U.S. Patent No. 5,156,594 to Keith	1019
U.S. Patent No. 5,102,403 to Alt	1020
Kucklick, Theodore R., <i>The Medical Device R&amp;D Handbook</i> (2006)	1021
Amended Complaint filed by Vascular Solutions, Inc. in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (May 28, 2013)	1022
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1023
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (June 10, 2013)	1024



Exhibit Description	Exhibit No.
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (July 28, 2013)	1025
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (December 19, 2013)	1026
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed December 27, 2013	1027
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir.) filed January 3, 2014	1028
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir.) filed January 7, 2014	1029
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir.) filed January 29, 2014	1030
Declaration of Anthony Vrba In Support of Boston Scientific Opposition to Motion for Preliminary Injunction filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (July 8, 2013)	1031
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir.) filed February 3, 2014	1032
Transcript of Oral Argument Proceedings held on April 8, 2014 (Fed. Cir.)	1033
Federal Circuit Order Vacating Preliminary Injunction (April 15, 2014)	1034
Joint Claim Construction Statement filed in <i>Vascular Solutions, Inc. v. Boston Scientific Corporation</i> , No. 13-cv-1172 (JRT-SER) (D. Minn.) (February 21, 2014)	1035
U.S. Patent No. 6,997,908 B2 to Carrillo, Jr., et al.	1036
Monorail Piccolino Publication, Introducing the Schneider MONORAIL-GEX™ Guidewire Exchange Catheter Brochure	1037
U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1038
U.S. Patent No. 5,267,958 to Buchbinder et al.	1039
U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1040

*Inter partes* review is respectfully requested for claims 1, 4, 9, 10, and 13 of U.S. Patent No. 8,142,413 B2 (“the ‘413 Patent”) (Exh. 1001).

**I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))**

The following mandatory notices are provided as part of this Petition.

**A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))**

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively “Petitioner”) are the real parties-in-interest.

**B. Related Matters (37 C.F.R. § 42.8(b)(2))**

The ‘413 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 12-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of U.S. Patent No. 8,048,032 B2 (the “‘032 patent”) and U.S. Patent No. 8,292,850 (the “‘850 patent”) in four petitions being filed concurrently herewith. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and directed generally to the same subject matter. The ‘850 patent is a divisional of application No. 12/824,734, which issued as the ‘413 patent, and the ‘413 patent is a divisional of application No. 11/416,629, which issued as the ‘032 patent. The claims challenged in the

concurrently filed petitions are apparatus ('032 patent) and system ('850 patent) versions of the method claims of the '413 patent challenged herein.

**C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))**

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

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**D. Service Information (37 C.F.R. § 42.8(b)(4))**

Petitioner consents to service by email to lead and backup counsel at xBSC\_VSI\_IPRService@aporter.com.

**II. PAYMENT OF FEES (37 C.F.R. § 42.103)**

The undersigned authorizes the Office to charge Deposit Account No. 50-2387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

**III. SUMMARY OF RELEVANT TECHNOLOGY AND '413 PATENT**

### **A. Overview Of Interventional Cardiology Procedures**

The claims of the '413 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (See Exh. 1001, 1:21-44). During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.*; see Declaration of Ronald Jay Solar, Ph.D. (“Solar Declaration”) ¶ 8 (Exh. 1003)). The physician introduces the treatment device into the patient’s vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id.*) Often, to create a passage for such treatment devices, physicians insert a “guide catheter” earlier in the procedure. (*Id.*) In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id.*) The '413 patent is directed to methods for delivering an apparatus through a standard guide

catheter, extending beyond the ostium, to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (See, e.g., Exh. 1001, 2:51-55).

## **B. Description Of The Alleged Invention Of The '413 Patent**

The '413 Patent contains 14 method claims, including one independent claim (claim 1). The specification of the '413 patent states that it relates “generally to catheters used in interventional cardiology procedures,” and “[m]ore particularly, ... methods ... for increasing backup support for catheters inserted into the coronary arteries of the aorta.” (Exh. 1001, 1:13-17).

The challenged claims of the '413 patent are not straightforward; they are replete ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Independent claim 1 of the '413 patent recites:

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen, the method comprising:

inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;  
positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;

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

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

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

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

Dependent claim 4 of the '413 patent depends from independent claim 1 and recites a method "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."

Dependent claim 9 of the '413 patent depends from independent claim 1 and recites a method "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."

Dependent claim 10 of the '413 patent (depending from claim 9) recites a method "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."

Dependent claim 13 of the '413 patent depends from independent claim 1 and recites a method "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."

**C. Summary of the Prosecution History of the '413 Patent**

The '413 Patent was filed as U.S. App. Serial No. 12/824,734 on June 28, 2010 (*see* Exh. 1002, paper 1) and claims priority to application No. 11/416,629, filed on May 3, 2006, which issued as the '032 patent.

Claims 1-7 were rejected as obvious over U.S. Patent 6,638,268 ("Niazi") in view of U.S. Patent Application Publication No. 2005/0004523 to Osborne, *et al.*, ("Osborne"). The Examiner found that Niazi disclosed all but "a rigid portion proximal to the reinforced portion and at least a portion of the reinforced portion extending out of the distal end of the guide catheter and into the second blood vessel." (Non Final Office Action (Aug. 1, 2011) at 3-4 (Exh. 1002, at 70-71). The element missing from Niazi was, however, disclosed by Osborne: "a reinforcing portion 52 and a stiffening cannula 50 within inner cannula 20 to avoid kinking (Paragraph 36) and provide stiffening (Paragraph 35). Therefore, it would have been obvious ... to include a reinforcing portion and stiffening portion as taught by Osborne to the device of Niazi to provide kind resistance and stiffening." (*Id.* at 4.)

Regarding claim 4, the Examiner asserted that "[a] side port exists in the side of catheter 52 for contrast media (5:25-28). The part of the catheter along the same longitudinal length as the side port is partially cylindrical and the surrounding areas are fully cylindrical." (*Id.* at 4).

In response, Applicant amended claims 1-3, 5, and 7 (corresponding to claims 1-6 of the '413 patent) and cancelled claim 6.



A Notice of Allowance was mailed January 17, 2012, and the '413 Patent issued on March 27, 2012.

#### **IV. REQUIREMENTS FOR INTER PARTES REVIEW**

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '032 Patent is satisfied.

##### **A. Grounds for Standing Under 37 C.F.R. § 42.104(a)**

Petitioner certifies that the '413 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

##### **B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested**

The precise relief requested by Petitioner is that claims 1, 4, 9, 10, and 13 of the '413 Patent be found unpatentable.

##### **C. Claims for Which *Inter Partes* Review Is Requested**

Pursuant to 37 C.F.R. § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1, 4, 9, 10, and 13 of the '413 Patent.

##### **D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)**

This Petition, supported by the grounds set forth below and the Solar Declaration (Ex. 1003), demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C.

§ 314(a). *Inter partes* review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103.

No.	Grounds
1	Claims 1 and 13 are anticipated by US 5,527,292 (“Adams ‘292”)
2	Claims 1, 4, 9, 10 and 13 are obvious over Adams ‘292 in view of knowledge of one of ordinary skill in the art
3	Claims 1, 4, 9, 10 and 13 are obvious over Adams ‘292 in view of US 5,776,141 (“Klein”)
4	Claims 1, 4, 9, 10 and 13 are obvious over Adams ‘292 in view of US 7,232,452 (“Adams ‘452”)
5	Claims 1, 4, 9, 10 and 13 are obvious over Adams ‘292 in view of US Pub. 2004/0236215 (“Mihara”)
6	Claims 1, 4, 9, 10 and 13 are obvious over Adams ‘292 in view of US 5,328,472 (“Steinke”)
7	Claim 13 is obvious over Adams ‘292 in view of knowledge of one ordinary skill in the art
8	Claim 13 is obvious over Adams ‘292 in view of “New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter,” 2004, Takahashi Online Article (“Takahashi”)

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

#### **E. Construction Of The Challenged Claims**

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the “broadest reasonable construction in light of the specification of the patent in which [they] appear[.]” *See In re Swanson*, 540 F.3d 1368, 1377-78 (Fed. Cir. 2008); *In re Trans Texas Holding Corp.*, 498 F.3d 1290, 1298 (Fed. Cir. 2007) (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)). Because the standards of claim interpretation used by the Courts in patent litigation differ from

those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation (“BRI”) in light of the patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.<sup>1</sup>

**1. “rail structure without a lumen”**

Because the ‘413 patent does not disclose any structure for the “rail structure without a lumen” limitation of independent claim 1, it is invalid under 35 U.S.C. § 112, ¶ 2. The word “rail” appears in the specification of the ‘413 patent only twice. *First*, the Summary of the Invention refers to a “guidewire rail segment,” defined as “permit[ing] delivery without blocking the use of the guide catheter.” (Exh. 1001, 2:62). *Second*, Fig. 17 is described as “a plan view of a coaxial guide catheter having a longer rail segment,” without any guidance as to which portion(s) of Figure 17 constitute the “rail segment.” Neither of these references discloses any

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<sup>1</sup> Petitioner reserves the right to challenge the validity of the ‘413 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

meaning for “rail” in the claim term “rail structure without a lumen.” (Exh. 1003, ¶ 67). Moreover, nothing in the specification suggests that the rail structure consists of the “tapered inner catheter,” “full circumference portion,” “cutout portion,” “reinforced portion,” “hemicylindrical portion,” “second full circumference portion,” “arcuate portion,” “braid or coil reinforcement,” “most proximal portion of braid or coil reinforcement,” “relief cut,” “hemi-tube portion,” “single cuts,” “double cuts,” “connector hub,” “funnel portion,” “grip portion,” to name a few, nor would be so read by a POSA. (*Id.*)

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent claim 1 under 35 U.S.C. §§ 102 and 103<sup>2</sup>, and claims 4, 9, 10, and 13 depending therefrom, Petitioner submits that, a POSA would understand “rail structure” to refer to a pushing or advancement structure. “Monorail” or rapid exchange catheters are characterized by a relatively guide wire lumen; this cannot be the “rail structure” for purposes of the claim, however, because the claimed structure must be “without a lumen.” (Exh. 1003 ¶ 68). A POSA would therefore

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<sup>2</sup> All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing dates of the patents at issue.

understand the “rail structure” to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id.* ¶ 69). Accordingly, the term “rail structure without a lumen” can be construed for purposes of this Petition to mean a “pushing or advancement structure without a lumen.” (*Id.*)

## **2. “interventional cardiology device(s)”**

The specification of the ‘413 patent expressly defines the term “interventional cardiology devices”: “For the purposes of this application, the term ‘interventional cardiology devices is to be understood to include but not be limited to guidewires, balloon catheters, stents and stent catheters.” (Exh. 1001, 1:23-26). A person of ordinary skill in the art would understand the term “interventional cardiology devices” to include other thin, flexible treatment devices used in treating a blockages (occlusions) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions, such as embolic protection devices, such as filters. (Exh. 1003 ¶ 70).

## **F. The Prior Art References**

As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under §102(b), some of which also constitute prior art under §102(a), as set forth below.<sup>3</sup>

**1. Adams '292**

U.S. Patent No. 5,527,292 to Adams, *et al.* ("Adams '292") (Exh. 1013) matured from an application filed on September 9, 1994, prior to the earliest filing date the benefit of which is claimed by the '032 patent and is therefore available as prior art to the '032 patent under 35 U.S.C. § 102(b). Adams '292 describes a guide catheter extension: "The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter" (Exh. 1013, 4:35-38; Exh. 1003 ¶ 72), and discloses, *inter alia*:

An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery. The device also including a push rod attached to a proximal end of the flexible tube to facilitate placement of the flexible tube within the coronary artery requiring treatment.

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<sup>3</sup> All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

(Exh. 1013 at Abstract). A benefit of the device disclosed in Adams '292 is the ability to extend the flexible tube beyond the distal tip of the guide catheter so that it is deep-seated beyond the ostium to anchor the guide catheter during treatment:

A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond....

(Exh. 1013, 9:12-24; *see* Exh. 1003 ¶¶ 31 and 72).

## **2. Klein**

U.S. Patent No. 5,776,141 to Klein (“Klein”) (Exh. 1005) matured from an application filed on August 26, 1996, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under §102(b). Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter and a proximal shaft attached to the proximal end of the tubular catheter body. (Exh. 1003 ¶¶ 33 and 75).

## **3. Adams '452**

U.S. Patent No. 7,232,452 to Adams (“Adams '452”) (Exh. 1015) matured from an application filed on July 12, 2002, prior to the earliest filing date the benefit of which is claimed by the '032 patent, and thus qualifies as prior art under § 102(b). The Adams '452 patent discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large

enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” (Exh. 1015, 8:47-50; Exh. 1003 ¶¶ 34 and 78). Adams ‘452 further discloses “A proximal wire or other control means...” (Exh. 1013, 8:27-30). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1003 ¶ 78). The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*Id.* ¶ 34).

#### **4. Mihara**

Patent Application Publication No. US 2004/0236215 A1 to Mihara, *et al.* (“Mihara”) (Ex. 1040) was filed on March 12, 2004, prior to the earliest filing date the benefit of which is claimed by the ‘413 patent and, thus, qualifies as prior art under § 102(b). Mihara discloses “a linear wire” and “a tubular body placed on a distal end side of the wire allowing a guide wire to be inserted through its hollow portion.” (Exh.1040, ¶¶ [0013], [0014]). The proximal opening to the hollow tube is skived or cut at an angle. (*Id.*, FIG. 2).

#### **5. Steinke**

U.S. Patent No. 5,328,472 to Steinke (“Steinke”) (Ex. 1016) matured from an application filed on July 27, 1992, prior to the earliest filing date the benefit of



which is claimed by the '032 patent and, thus, qualifies as prior art under § 102(b). Steinke discloses “a catheter which allows rapid exchange” where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1016, 3:1-2; Exh. 1003, ¶ 35)

## **6. Takahashi**

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions, 63:452-456 (“Takahashi”) (Exh. 1017) is an article published in 2004 and, thus, qualifies as prior art under § 102(b). In fact, Takahashi is admitted to be prior art on the face of the '413 patent. Takahashi describes method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶¶ 36 and 84). The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is less one French or less. (*Id.*)

## **G. How The Construed Claim(s) Are Unpatentable**

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1, 4, 9, 10, and 13 of the '413 patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section

V below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration.

**H. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)**

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below in Section V and the corresponding claim charts set forth therein. Dr. Solar, an expert with thirty-seven years of academic and industry experience in the field of interventional cardiology devices, has reviewed the claim charts submitted in the '413 Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein. (*See generally* Exh. 1003).

**V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4)**

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to achieve predictable results, all of which were well known to persons of ordinary skill in the art in the field of interventional cardiology procedures at the time to which the '413 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

**A. Claims 1 And 13 Are Anticipated Under 35 U.S.C. §102(b) By Adams'292**

As shown below, each element recited in claims 1 and 13 is anticipated by Adams '292, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '413 patent. (An unrelated application by a different inventor with the last name "Adams" was disclosed). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *E.g., In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

#### **1. Claim 1**

Claim 1 of the '413 patent discloses: "[a] method of providing backup support for an interventional cardiology device ... adapted to be passed through a standard guide catheter...." (Exh. 1001, 10:28-30); Adams '292 similarly, teaches: "For use in combination with a guide catheter for insertion and advancement of a coronary treatment device ... an anchoring device...." (Exh. 1013, 22:35-40). Claim 1 of the '413 patent discloses "inserting the standard guide catheter into a first artery over a guidewire; a POSA would understand that the guide catheter is advanced over a guidewire. (Exh. 1003 ¶ 97). Claim 1 of the '413 patent further discloses "inserting the flexible tip portion of a coaxial guide catheter defining a tubular structure having ... a length that is shorter than the ... length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter. (Exh. 1001, 10:45-49); Adams '292 similarly discloses "a

relatively flexible tube having ... an outer diameter ... sized for insertion through the central lumen of the guide catheter ...” (Exh. 1013, 23:37-40) and “[t]he length of the flexible tube 32 is preferably approximately 6 to 10 inches” (*id.*, 5:61-63), which a POSA would understand to be shorter than the length of a standard guide catheter—approximately 40 inches. (*See* Exh. 1003 ¶ 100). Claim 1 of the ‘413 patent also discloses: “a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion ... defining a rail structure without a lumen ...” (Exh. 1001, 10:50-55); Adams ‘292 similarly teaches that a “shaft 19 or push rod is attached to a proximal end of the elongated flexible tube 32” (Exh. 1013, 6:1-2) and that “[o]ne embodiment is shown in FIG. 2 and the shaft 19 or push rod is defined by an elongated wire.” (*Id.*) Claim 1 of the ‘413 patent discloses that the combined length of the substantially rigid portion and the distal tip portion is greater than the length of the guide catheter; Adams ‘292 similarly discloses that the combined length of the push rod and the flexible tube is preferably 50.5 inches to 51.5 inches, while a POSA would understand that a standard guide catheter is approximately 40 inches. (Exh. 1003 ¶ 103). Finally, claim 1 of the ‘413 patent requires “advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter” while “at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve” (Exh. 1001, 10:62-

67); likewise, Figure 1 of Adams ‘292 shows the flexible tube 32 extending beyond the distal tip of the guide catheter 12, while the push rod 19 extends proximally through the channel leg of the manifold 17 (where the hemostatic valve is located). Thus, Adams ‘292 discloses every element of claim 1 of the ‘413 patent.

**2. Claim 13**

Claim 13 (depending from claim 1) of the ‘413 patent requires “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.” The Adams ‘292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube; a POSA would understand that the largest tubes within that range would have an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1001, 5:64-67). In disclosing a range overlapping or touching the claimed range, the Adams ‘292 thereby anticipates the claimed range with sufficient specificity. *See, e.g., ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

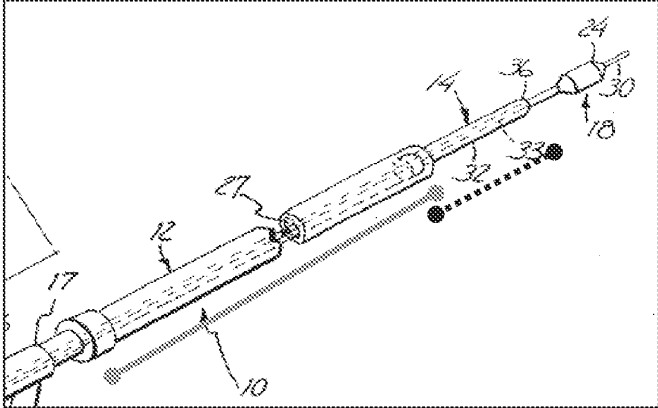
The ‘413 Patent	Claim Chart A-1: Claim 1 in view of Adams ‘292
1. A method of providing backup support for [1] an	“For use in combination with a guide catheter for insertion and advancement of a coronary treatment

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
<p>interventional cardiology device for use in the coronary vasculature, [2] the interventional cardiology device being adapted to be passed through a standard guide catheter, [3] 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, [4] 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:</p>	<p>device through a coronary vessel having an ostium to a treatment site, the guide catheter having a central lumen, a distal end and a distal opening, an anchoring device comprising: a relatively flexible tube sized for insertion through the central lumen of the guide catheter into the coronary vessel, the flexible tube being concentrically aligned with the guide catheter ..." (Exh. 1013, 22:35-43.)</p> <p>[1] "An intravascular device...." (<i>Id.</i>, Abstract.)</p> <p>"The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter." (<i>Id.</i>, 4:36-37.)</p> <p>[2] "... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for insertion through the central lumen of the guide catheter...." (<i>Id.</i>, 23:36-44.)</p> <p>[3] "The guide catheter 12 is an elongated, flexible, tubular member defining a first guide catheter lumen 27 therethrough." (<i>Id.</i>, 5:30-32.)</p> <p>"Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or other angioplasty device is disposed and guided to a stenosis or obstruction. The guide catheter manifold 54 is mounted at a proximal end of the guide catheter 52, and preferably comprises a Y-shaped structure having a primary channel leg 51 and an extension leg 55 with a guide catheter port 58.... A hemostatic valve (not shown) on the primary channel leg 51 provides hemostatic control for the guide catheter. (<i>Id.</i>, 11:20-30; <i>see id.</i>, 5:6-29.)</p>

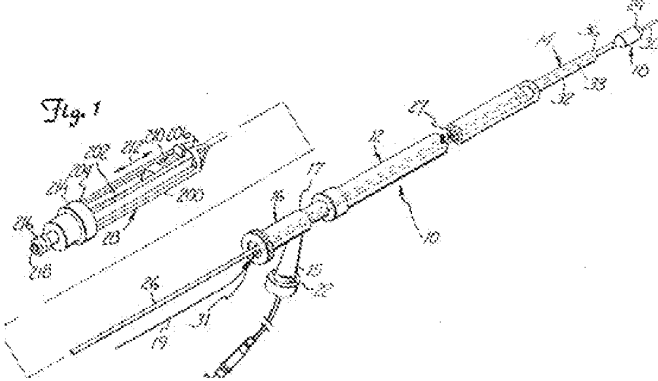
The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
	<p>“the guide catheter 287 is manipulated until <i>a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium</i> so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary, artery requiring treatment.” (<i>Id.</i>, 16:9-44 (emphasis added).)</p> <p>[4] “The diameter of the first guide catheter lumen 27 in the guide catheter 12 and the second guide catheter lumen 33 in the guide catheter extension 32 are larger than the outer diameters of the hollow balloon catheter shaft 26 and balloon 24 (deflated) which are advanced therethrough.” (<i>Id.</i>, 8:40-45.)</p> <p>“... a guide catheter 287 is inserted into the patient and advanced until <i>a distal end of the guide catheter 287</i> reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment.” (<i>Id.</i>, 16:9-44 (emphasis added).)</p>
<p>inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;</p>	<p>“the guide catheter is inserted at the femoral artery and advanced through a patient’s arterial system to the coronary ostium requiring treatment.” (Exh. 1013, 4:56-58; <i>id.</i>, 16:9-44 (“... a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient”).)</p> <p>“the angioplasty balloon catheter 18 may be</p>

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
	<p>advanced beyond <i>the distal end of the guide catheter</i> ... with the assistance of the guide catheter extension....” (<i>Id.</i>, 9:2-5 (emphasis added).)</p> <p>“A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond <i>the distal end of the guide catheter</i> 12....” (<i>Id.</i>, 12:19-25 (emphasis added).)</p> <p>“... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for insertion through the central lumen of the guide catheter so that the distal end of the tube may be positioned beyond <i>the distal end of the guide catheter</i> to extend the flexible tube to a treatment site....” (<i>Id.</i>, 23:36-44 (emphasis added).)</p>
<p>positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery;</p>	<p>“... a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment.” (<i>Id.</i>, 16:9-44.)</p>
<p>[1] inserting [2] a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and [3] a length that is shorter than the predefined length of the continuous lumen of</p>	<p>[1] “... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for <i>insertion through the central lumen of the guide catheter</i>....” (Exh. 1013, 23:36-44 (emphasis added).)</p> <p>“The outer diameter of the elongated flexible tube 32</p>



The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
<p>the standard guide catheter, [1] into the continuous lumen of the standard guide catheter, and,</p>	<p>is smaller than the first guide catheter lumen 27 defined by the guide catheter 12 so that it may be slidably disposed therethrough and to permit <i>insertion of the tube ...</i>" (<i>Id.</i>, 5:64-67 (emphasis added).)</p> <p>[2] "The guide catheter extension (distal extension) comprises an elongated flexible tube...." (Exh. 1013, 5:38-39.)</p> <p>"The intravascular device includes a relatively flexible tube...." (<i>Id.</i>, 2:50-51.)</p> <p>[3] Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). This is also depicted in Fig. 12 which shows flexible tube 255 is shorter than guide catheter 287.</p>  <p>"The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length." (<i>Id.</i>, 15:50-51.)</p>
<p>further [1] inserting a substantially rigid portion that is proximal of,</p>	<p>[1] "A push rod is attached to a proximal end of the tube for slidably positioning the tube...." (Exh. 1013, 2:48-50.)</p>

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
<p>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 [2] 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;</p>	<p>“the shaft 19 or push rod is defined by an elongated wire 34.” (<i>Id.</i>, 6:15-16.)</p> <p>“The extension length of the elongated flexible tube 32 is lengthened by <i>advancing the wire 34 distally into the guide catheter</i>.... (<i>Id.</i> 6:35-37.)</p> <p>“The use of the elongated wire 34 to adjust the extension length of the elongated flexible tube 32 provides several advantages.” (<i>Id.</i>, 6:56-58.)</p> <p>[2] “The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length. The push rod is approximately 40.0 to 45.0 inches in length. The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches.” (<i>Id.</i>, 15:50-54.)</p>
<p>[1] 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 [2] such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and</p>	<p>[1] “... a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for <i>insertion through the central lumen of the guide catheter so that the distal end of the tube may be positioned beyond the distal end of the guide catheter to extend the flexible tube to a treatment site</i>....” (Exh. 1013, 23:36-44 (emphasis added).)</p> <p>“The elongated flexible tube 32 of the guide catheter extension 14 is designed to <i>extend beyond a distal end of the guide catheter 12 into the coronary arteries</i>.” (<i>Id.</i>, 6:8-11 (emphasis added).)</p> <p>[2] When the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon</p>

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
	<p>catheter shaft:</p>  <p>“As seen in FIG. 1, shaft 19 or push rod ... extends proximally ... outside the guide catheter 12 so that it is accessible to the user.... The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12....” (<i>Id.</i>, 6:1-10.) 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. (<i>Id.</i>, 5:17-29.) 26 is a balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. (<i>Id.</i>, 17:3-7 (“The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient”).)</p>
<p>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</p>	<p>“The flexible tube has an inner diameter sized for <i>insertion over an angioplasty device.</i>” (Exh. 1013, 2:62-64 (emphasis added).)</p> <p>“the angioplasty balloon catheter 18 may be advanced beyond the distal end of the guide catheter 12 proximate to or across the stenosis or obstruction with the assistance of the guide catheter extension....” (<i>Id.</i>, 9:2-5.)</p>

The '413 Patent	Claim Chart A-1: Claim 1 in view of Adams '292
a lumen of the flexible tip portion into contact with or past a lesion in the second artery.	“A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for <i>guiding a coronary treatment device into the arteries beyond...</i> ” ( <i>Id.</i> , 12:19-25 (emphasis added).)
13. The method of claim 1,	Adams '292 discloses the method of claim 1 ( <i>See A-1, above</i> ).
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.	“The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the guide catheter...” (Exh. 1013, 5:64-67.)

**B. Statement Of Non-Redundancy: Skived Proximal Opening Disclosures in Klein, Adams '452, Mihara, And Steinke**

The grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 4, 9, and 10 are not redundant given the far reaching functional language of such claims. Although the alternative combinatory references of Adams '292 in view of either Klein, Adams '452, Mihara, or Steinke are encompassing of the functionality of each of the disclosed systems, (each of these references discloses systems for receiving an interventional cardiology device through a lumen having a skived proximal

opening), they are structurally different from each other in numerous other respects. Adams '452 explicitly discloses the insertion of devices through the skived proximal opening of its claimed device when a distal portion of the device is extended beyond the end of a guide catheter, and while the proximal portion is within the guide catheter lumen. Mihara discloses a support catheter directed to insertion beyond the ostium having a proximal skive with a rapid exchange design. Klein discloses the insertion of larger devices such as balloon catheters (in addition to guidewires), through its skived proximal opening, as was found by the Examiner during the prosecution of the '032 patent to which the '413 claims priority. Finally, Steinke discloses a proximal side "entry port" through which a guidewire is received, wherein the shape of the port clearly defines both full circumference and hemicylindrical portions.

If the PTAB determines that there is redundancy with respect to the grounds raised herein regarding obviousness of claims 4, 9, and 10 over Adams '292 in combination with either the knowledge of one of skill in the art, Klein, Adams '452, Mihara, or Steinke, Petitioner suggests institution on the grounds of Adams '292 in combination with either Mihara or Klein. Finally, to the extent that the Board finds redundant Petitioner's proposed grounds of unpatentability for the claimed range of "not more than one French" in claims 13 based on anticipation in view of substantial disclosure by Adams '292, obviousness over Adams '292 in

view of the knowledge of one of skill in the art, and Adams ‘292 in combination with the specific disclosure of the claimed range in the analogous art of Takahashi, Petitioner suggests institution by the Board on the basis of Adams ‘292 in combination with Takahashi.

**C. Claims 1, 4, 9, And 10 Are Obvious Under 35 U.S.C. §103 Over Adams ‘292 In View Of The Knowledge Of One Of Ordinary Skill In The Art**

Claims 1, 4, 9, and 10 are obvious over Adams ‘292 in view of the knowledge of one of ordinary skill in the art. As shown above, Claim 1 and is anticipated by Adams ‘292, which discloses every limitation of that claim. (Exh. 1003, ¶¶ 92-105). To the extent that any such limitations are not expressly disclosed in Adams ‘292, such limitations would have been known or obvious to a POSA or could be found by a POSA in one or more other references or analogous art. (*Id.*, 109-110).

Dependent claim 4 of the ‘413 patent depends from claim 1, every element of which, as shown above, is disclosed in Adams ‘292. Claim 4 further requires “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.” (Exh. 1001, claim 4). A POSA at the time of the ‘413 patent would know to use a skived or angled proximal lumen opening in rapid

exchange catheters. (Exh. 1003 ¶ 110). Such a skived or angled opening would define a partially cylindrical portion and a full circumference portion. (*Id.*)

Claim 9 of the '413 patent requires "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." Adams '292 discloses extending the interventional cardiology device through a proximal opening in the tubular structure while the proximal portion remains within the lumen of the guide catheter. (*See* Exh. 1013, 9:36-52). A POSA at the time of the '413 patent would know that the proximal opening could be skived or angled, thereby defining 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. (Exh. 1003 ¶ 110).

Claim 10 of the '413 patent further requires extending the interventional cardiology device through a full circumference portion and a partially cylindrical portion. Adams '292 discloses extending the interventional cardiology device through a proximal opening of the tubular structure. (Exh. 1003 ¶ 105). A POSA at the time of the '413 patent would know that the proximal opening could be skived

or angled, thereby defining a full circumference portion and a partially cylindrical portion. (Exh. 1003 ¶ 110).

**D. Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Klein**

Claims 1, 4, 9, 10, and 13 are obvious over Adams '292 in view of Klein, which was cited during prosecution of the '413 patent, but was not considered in combination with Adams '292. (Exh. 1003, ¶¶ 111-113). As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (*Id.*, ¶¶ 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Klein. (*Id.*, ¶¶ 111-113).

Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter. (*See, e.g.*, Exh. 1014, Fig. 28). This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires “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.” (Exh. 1003 ¶ 112).

Dependent claim 9 of the '413 patent requires “extending the interventional cardiology device through a proximal side opening” in the tubular structure while claim 10 (which depends from claim 9) requires “advancing” such device through the “full circumference” and the “partially cylindrical” portions of such opening.



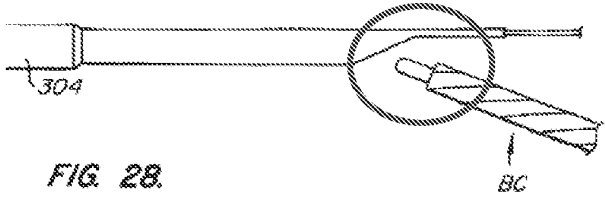
Adams '292 discloses the function of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003, ¶ 105). Klein discloses the claimed structure of a proximal side opening extending for a distance along a proximal portion of the tubular structure, defining a full circumference portion and a partially cylindrical portion. (*Id.* ¶ 112). Extending the interventional cardiology device through the proximal side opening would therefore entail advancing the device through structures defining a full circumference portion and a partially cylindrical portion.

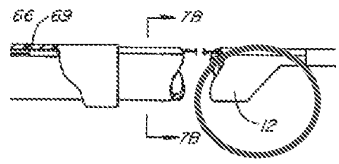
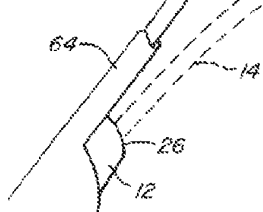
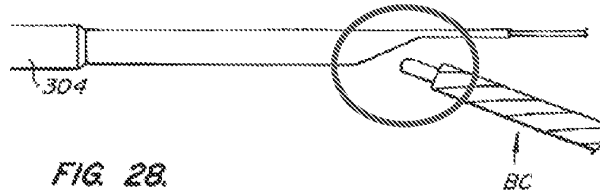
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 112-114), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Klein to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams '292 and Klein are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*Id.*, 71-77) Specifically, both Klein and Adams '292 disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. Accordingly, a POSA would have been motivated to combine the guide catheter extension disclosed by Adams '292 with the skived proximal

lumen opening of Klein. (*Id.*, 89-91). Indeed, Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1013, 6:24-34 (flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)).

Thus, Adams '292 and Klein show that using skived proximal openings for the delivery of interventional cardiology devices such as balloon catheters was well known by the time of the '413 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (Exh. 1003, 111-114).

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	Adams '292 in view of Klein
4. The method as claimed in claim 1	Adams '292 discloses the method of claim 1. ( <i>See</i> A-1, above).
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.	<p>Annotated Figure 7 of Klein (below) shows that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming a cylindrical portion and a partially cylindrical portion defining an opening along a side thereof:</p> <div style="text-align: center;"> </div> <p>(Fig. 6.) 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.</p>

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	Adams '292 in view of Klein
	 <p><b>FIG. 28.</b></p> <p>In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (See also Figs. 1, 8, 9, 9A, 10-15, 20-27.)</p>
9. The method as claimed in claim 1	Adams '292 discloses the method of claim 1. (See A-1, above).
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.	<p>Adams '292 discloses extending the interventional cardiology device through a proximal opening in the tubular structure while the proximal portion remains within the lumen of the guide catheter. (See Exh. 1013, 9:36-52 (“The guide catheter extension 14 (distal extension) which is the subject of this invention provides a means for establishing a path proximate to or across the obstruction or stenosis and directing a substitute angioplasty balloon catheter thereto. Before the original angioplasty balloon catheter 18 is withdrawn, the elongated flexible tube 32 is positioned proximate to or across the lesion.... Then, the original angioplasty balloon catheter 18 is withdrawn and the new angioplasty balloon catheter is substituted therefor. During the insertion thereof, the guide catheter 12 and the guide catheter extension 14 cooperate to direct the new angioplasty balloon catheter to the stenosis.”); <i>id.</i>, 15:57-16:13 (“the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ....”))</p> <p>Klein discloses a proximal side opening defined by the proximal portion of the tubular structure extending for a distance along the longitudinal axis of the proximal portion of the tubular structure which remains within the guide catheter. (Exh. 1014, 10:16-22 (“the entry port 26 will remain within the guiding catheter at all times”).) Annotated Fig. 7 (below)</p>

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	Adams '292 in view of Klein
	<p>depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis of the tubular structure:</p>   <p>(Fig. 6.) 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.</p>  <p>In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (See also Figs. 1, 8, 9, 9A, 10-15, 20-27.)</p>
10. The method of claim 9,	Adams '292 and Klein disclose the method of claim 9. (See discussion of claim 9, above).
further comprising extending the interventional cardiology device through the proximal side opening;	As shown above, Adams '292 and Klein disclose extending the interventional cardiology device through the proximal side opening. (See discussion of claim 9.)
advancing the interventional cardiology device through structure defining a full circumference portion; and	As shown above, Klein discloses a proximal side opening with structure defining a full circumference portion. (See discussion of claim 9.)

Claim Chart A-2: Cl. 4, 9, 10	
The '413 Patent	Adams '292 in view of Klein
advancing the interventional cardiology device through structure defining a partially cylindrical portion.	As shown above, Klein discloses a proximal side opening with structure defining a partially cylindrical portion. (See claim 9, above.)

**E. Claims 1, 4, 9, 10 And 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Adams '452**

Claims 1, 4, 9, 10, and 13 are obvious over Adams '292 in view of Adams '452, neither of which was cited or considered, either alone or in combination, during prosecution of the '413 patent or the '032 patent, from which it claims priority. As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (Exh. 1003, 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Adams '452. (*Id.*, 109-110).

The Adams '452 patent discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” (Exh. 1015, 8:47-50). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis. (See Exh. 1003 ¶¶ 34 and 116). The guide seal 20 receives an interventional

device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*See id.* ¶ 78). This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires “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.” (*See id.* ¶ 116).

Dependent claim 9 of the '413 patent requires “extending the interventional cardiology device through a proximal side opening” in the tubular structure while claim 10 (which depends from claim 9) requires “advancing” such device through the “full circumference” and the “partially cylindrical” portions of such opening. Adams '292 discloses the functions of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003, ¶ 105). Extending the interventional cardiology device through the proximal side opening would therefore entail advancing the device through structure defining a full circumference portion.

As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 116-118), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams '292 and Adams

'452 are both analogous to the '413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '413 patent. (*Id.*, ¶¶ 71-74 and 78-79). Specifically, both Adams '452 and Adams '292 disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. Accordingly, a POSA would have been motivated to combine the guide catheter extension disclosed by Adams '292 with the skived proximal lumen opening of Adams '452. Indeed, Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1013, 6:24-34 (flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)).

Notably, Adams '292 and Adams '452 were both issued to the same named inventor, Daniel O. Adams; the fact that the inventor of the Adams '292 device in 1992 included a skived proximal side opening when designing a similar device (Adams '292 is cited as prior art on the face of the Adams '452 patent) ten years later is further evidence that, by 2006, a POSA would routinely include a skived or angular side opening in such rapid exchange devices.

In sum, Adams '292 and Adams '452 show that using skived proximal lumen openings for the delivery of devices while the proximal opening is within the lumen of a guide catheter was well known by the time of the '413 patent and

employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (Exh. 1003, 89-91 and 115-118).

Claim Chart A-3: Claims 4, 9, 10	
The '413 Patent	Adams '292 in view of Adams'452
<p>4. The method as claimed in claim 1</p> <p>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.</p>	<p>Adams '292 discloses the method of claim 1 (<i>See A-1, above</i>).</p> <p>Adams '452 discloses a guide seal that “comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver ... an expandable filter or balloon.” (Exh. 1015, 8:47-50.) “A proximal wire ... extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter.” (<i>Id.</i>, 8:27-30.) The guide seal has a “portion which remains in the lumen of the guide catheter when the guide seal is deployed.” (Exh.1015, 8:55-56.) The guide seal may be formed of braided wires with a polymer covering or membrane attached. (Exh. 1015, 9:11-46.) The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:</p> <div style="text-align: center;"> <p style="text-align: center;"><i>Fig. 2C</i></p> </div> <p>The proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the</p>



Claim Chart A-3: Claims 4, 9, 10	
The '413 Patent	Adams '292 in view of Adams'452
	distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
9. The method as claimed in claim 1	As shown above, Adams '292 discloses the method of 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.	Adams '292 discloses "the proximal end ... of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site.... [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." (Exh. 1013, 15:57- 16:13.)  As shown above, the Adams '452 patent discloses a proximal opening of a lumen in a catheter skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion.
10. The method of claim 9,	Adams '292 and Adams '452 disclose the method of claim 9 ( <i>See claim 9, above</i> ).
further comprising extending the interventional cardiology device through the proximal side opening;	As shown above, Adams '292 and Adams '452 disclose extending the interventional cardiology device through the proximal side opening. ( <i>See claim 9, above.</i> )
advancing the interventional cardiology device through structure defining a full circumference portion; and	As shown above, Adams '452 discloses a proximal side opening with structure defining a full circumference portion. ( <i>See claim 9, above.</i> )
advancing the interventional cardiology device through structure defining a partially	As shown above, Adams '452 discloses a proximal side opening with structure defining a partially cylindrical portion. ( <i>See claim 9, above.</i> )

Claim Chart A-3: Claims 4, 9, 10	
The '413 Patent	Adams '292 in view of Adams'452
cylindrical portion.	

**F. Claims 1, 4, 9, 10 and 13 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Mihara**

Claims 1, 4, 9, 10, 13 of the '413 patent are obvious over Adams '292 in view of Mihara, neither of which was cited or considered, either alone or in combination, during prosecution of the '413 patent or the '032 patent, from which it claims priority. As shown above, Claims 1 and 13 are anticipated by Adams '292, which discloses every limitation of those claims. (Exh. 1003, ¶¶ 92-108). To the extent that any such limitations are not expressly disclosed in Adams '292, such limitations would have been obvious to a POSA from the disclosure of Adams '292 in view of Mihara. (*Id.* 109-110 and 119-121).

Mihara discloses a catheter “for penetrating a stenotic lesion” having a tubular catheter body with a skived proximal opening sized to receive a guidewire. (Exh. 1040, Figs. 1-3). This disclosure satisfies the limitations of claim 4 of the '413 patent, which requires “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.” (Exh. 1003 ¶ 120).

Dependent claim 9 of the '413 patent requires “extending the interventional cardiology device through a proximal side opening” in the tubular structure while claim 10 (which depends from claim 9) requires “advancing” such device through

the “full circumference” and the “partially cylindrical” portions of such opening. Adams ‘292 discloses the functions of extending or advancing an interventional cardiology device through the proximal opening of the tube. (Exh. 1003 ¶ 105). Mihara discloses the claimed structure of a proximal side opening extending for a distance along a proximal portion of the tubular structure, defining a full circumference portion and a partially cylindrical portion. (*Id.* ¶ 120). Extending the interventional cardiology device through the proximal side opening would therefore entail advancing the device through structures defining a full circumference portion and a partially cylindrical portion. (*Id.*)

As confirmed by the Solar Declaration (Exh. 1003, ¶¶ 120-21), a POSA would have found it obvious to modify the proximal opening of the Adams ‘292 device in view of Mihara to meet the limitations of the challenged claims, including the delivery of interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening. Adams ‘292 and Mihara are both analogous to the ‘413 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the ‘413 patent. (*Id.*, 71-74 and 80-81). Specifically, both Adams ‘452 and Mihara disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. (*Id.*, 78 and 80.)