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Attorney Docket No. 2005.86USREI3

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 reissue patent application of U.S. Patent No. INVENTOR(S): Howard Root, Gregg Sutton, Jeffrey M. Welch, Jason M. Garrity
 FOR: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Enclosed are:

- Specification and Abstract - 5 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
- Other - Copy of Certificate of Correction

The filing fee has been calculated as shown below:						
Application as Filed - Part I						
	(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	\$2160
Total Claims	24	44	= 24	x 40 = \$960	OR	x 80 = \$
Independent Claims	2	4	= 1	x210 = \$210	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 = \$0	OR	x 400 = \$
			TOTAL	\$2,690.00	OR	\$0
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets						

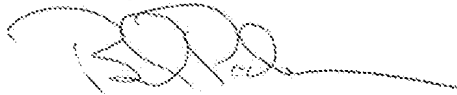
Application as Amended - Part 2						
	(1) Claims Remaining After Amendment	(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	OR	Large Entity Rate
Total Claims	44	minus 44	= 0	x 40 = \$0	OR	x 80 = \$
Independent Claims	4	minus 4	= 0	x 210 = \$0	OR	x 420 = \$
Presence of Multiple Dependent Claim				+ 390	OR	+ 780
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 200 = \$0	OR	x 400 = \$
			TOTAL	\$0	OR	\$

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 **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.

At least one error upon which reissue is based in described below. This is a broadening reissue and a claim that the application seeks to broaden is 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. 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 recites means plus function limitations for the device or a method of manufacture of the device.

- Applicants are entitled to small entity status in accordance with 37 CFR 1.27.
- A check in the amount of \$_____ to cover the filing fee is enclosed. 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,

 Brad D. Pedersen
 Registration No. 32432

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



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(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**

(75) Inventors: **Howard Root**, Excelsior, MN (US); **Gregg Sutton**, Maple Grove, MN (US); **Jeffrey M Welch**, Maple Grove, MN (US); **Jason M Garrity**, Minneapolis, MN (US)

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

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

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

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

(65) **Prior Publication Data**
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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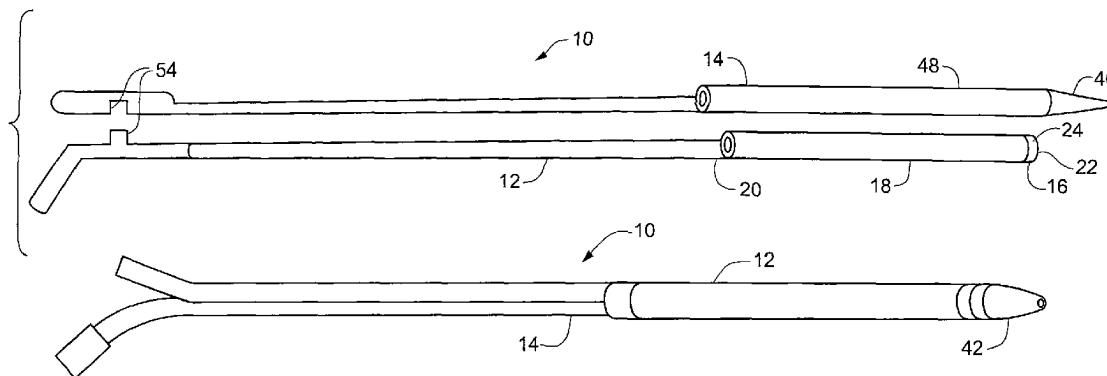
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(57) **ABSTRACT**

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



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U.S. Appl. No. 12/824,734, filed Jun. 28, 2010, Howard Root et al.

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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

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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

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