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Attorney Docket No. 2005.86US01

APPLICATION TRANSMITTAL

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

Sir:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) is the patent application of
INVENTOR(S): Howard Root, Gregg Sutton; Jeffrey M. Welch, and Jason M. Garrity
FOR: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Enclosed are:

- Specification and Abstract - 29 pages.
- Drawings - 13 sheets (Figs. 1-22).
- Combined Declaration and Power of Attorney.
- Information Disclosure Statement.
- CD-ROM or CD-R in duplicate, and Compact Disc Transmittal.
- Request and Certification Under 35 U.S.C. 122(b)(2)(B)(i) (nonpublication).
- _____

The filing fee has been calculated as shown below:					
	No. Filed	No. Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee			\$150	OR	\$300
Utility Search Fee			\$250	OR	\$500
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Total Claims	20	= 0	x 25 = \$	OR	x 50 = \$
Independent Claims	3	= 0	x 100 = \$	OR	x 200 = \$
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Utility Application Size Fee - per each additional 50 sheets that exceeds 100 sheets:			x 125 = \$	OR	x 250 = \$
		TOTAL	\$500	TOTAL	\$
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Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.

Attorney Docket No. 2005.86US01

- [] A check in the amount of \$0 to cover the filing fee is attached. 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.
- [] This application claims the benefit of U.S. Provisional Application No. _____, filed _____.

Respectfully submitted,



Paul C. Onderick
Registration No. 45,354

CERTIFICATE OF EXPRESS MAIL

"Express Mail" mailing label number EV824529593US. Date of Deposit: May 3, 2006. I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

DORIS WHITCOMB
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Doris Whitcomb
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Abstract of the Disclosure

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
5 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.

**COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY
PROCEDURES**

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Field of the Invention

10 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

15 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
20 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.

25 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
5 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.
10 Patent No. 6,475,195 issued to Voda and U.S. Patent 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
15 catheter may damage the coronary artery wall or that the guide catheter may occlude the coronary artery and interfere with blood flow to the heart muscle.

Second are guiding catheters that include a retractable appendage. The appendage in these catheters can be extended to engage the opposing wall of the aortic arch to provide backup support or the appendage may be placed under tension to stiffen a bend in the catheter to
20 provide backup support. Examples of this approach may be found in U.S. Patent Nos. 4,813, 930

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