UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

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

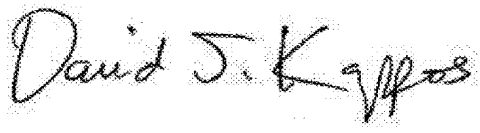
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

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

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



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

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OFFICE OF PETITIONS

In re Patent No. 8,048,032	:	DECISION ON
Root, et al.	:	PATENT TERM ADJUSTMENT
Issue Date: November 1, 2011	:	AND NOTICE OF INTENT
Application No. 11/416,629	:	TO ISSUE
Filed: May 3, 2006	:	CERTIFICATE OF
Attorney Docket No. 2005.86US01	:	CORRECTION

This is a decision on the "PETITION UNDER 37 C.F.R. 1.705(d)", filed November 10, 2011. Patentees request that the patent term adjustment indicated on the patent be corrected from four hundred thirty-seven (437) days to four hundred forty-four (444) days.

The petition is **GRANTED**.

The patent term adjustment indicated on the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of **four hundred forty-four (444)** days.

On November 1, 2011, the above-identified application matured into U.S. Patent No. 8,048,032. Patentees timely filed the instant application for patent term adjustment under 37 CFR 1.705(d) on November 10, 2011. Patentees assert that they should not have been assessed applicant delay of seventy-six (76) days for the submission of an IDS on August 18, 2011 and replacement drawings on September 22, 2011, after the Notice of Allowance was mailed on August 3, 2011 and a supplemental Notice of

Allowability was mailed on September 14, 2011. Rather, Patentees assert that they should have only been assessed applicant delay of twenty-eight (28) and forty-one (41) days for these two submissions under 37 CFR 1.704(c)(10).

37 CFR 1.704(c)(10) states that applicant delay shall be assessed "beginning on the date the...paper was filed and ending on the mailing date of the Office action or notice in response to the... paper". Here, Applicant filed an IDS on August 18, 2011, and the Office mailed a response (a Notice of Allowability) on September 14, 2011. Accordingly, Applicants should have been accorded 28 days of delay for this filing. In addition, Applicants filed replacement drawings on September 22, 2011. The Office did not mail a response until the patent issued on November 1, 2011. As such, 41 days of Applicant delay should have been assessed for this submission. The total assessment of 76 days for these two filings is incorrect. Rather, the total delay should have been 69 (28+41) days.

In view thereof, the correct determination of PTA at the time of issuance is four hundred forty-four (444) days (416 days of "A" delay and 129 days of "B" delay, reduced by 101 (32+28+41) days of applicant delay.

Receipt of the $200.00 fee set forth in 37 CFR §1.18(e) is acknowledged.

The application is being forwarded to the Certificates of Correction Branch for issuance of a certificate of correction in order to rectify the error regarding the patent term information. See 35 U.S.C. § 254 and 37 C.F.R. § 1.322. The certificate of correction will indicate that the term of the above-identified patent is extended or adjusted by **four hundred forty-four (444)** days subject to any disclaimers.

Telephone inquiries specific to this matter should be directed to the undersigned at (571)272-3207.

Cliff Congo
Petitions Attorney
Office of Petitions

Enc: draft certificate of correction

UNITED STATES PATENT AND TRADEMARK OFFICE

DRAFT CERTIFICATE OF CORRECTION

PATENT : 8,048,032 B2

DATED : **November 1, 2011**

INVENTOR(S) : Root et al.

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

On the cover page,

[*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by 437 days.

Delete the phrase "by 437 days" and insert – by 444 days--

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US01
Howard Root et al.	Confirmation No.: 5061
Application No.: 11/416,629	Examiner: Bradley James Osinski
Filed: May 3, 2006	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

PETITION UNDER 37 C.F.R. § 1.705(d)

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

Sir:

1. Applicant hereby petitions under 37 CFR § 1.705(d) that the patent term adjustment for U.S. Patent No. 8,048,032 be changed from 437 days to 444 days, in accordance with the requirements of justice.

STATEMENT OF FACTS

2. U.S. Patent No. 8,048,032 ("the '032 Patent") issued to inventors Howard Root et al., on November 1, 2011. The patent term adjustment, as determined by the USPTO under 35 USC § 154(b), and listed on the face of the '032 patent is 437 days. This patent is not subject to a terminal disclaimer. A copy of the '032 patent is attached as Attachment A.

3. The USPTO's determination of 437 days of patent term adjustment is in error in that the USPTO failed to properly account for the Supplemental Information Disclosure Statement submitted by Applicant on August 18, 2011 and submission of replacement drawings after the Notice of Allowance issued August 3, 2011, pursuant to 37 CFR 1.704(c)(10). See Attachment B comprising a hardcopy of the USPTO PTA calculation from the PAIR system.

4. Applicant submitted a Supplemental Information Disclosure Statement on August 18, 2011 after the Notice of Allowance of August 3, 2011.

5. The PTO issued a Supplemental Notice of Allowability on September 14, 2011, responding to the August 18, 2011 Supplemental Information Disclosure Statement in which the Examiner indicated that all references disclosed in the Supplemental Information Disclosure Statement were considered.

6. Applicant submitted replacement drawings September 22, 2011.

7. The replacement drawings were deemed considered as of the issue date of the patent November 1, 2011.

8. Under 37 CFR 1.704(c)(10), the period of adjustment is reduced where an applicant submits an amendment under 37 CFR 1.132 or other paper after a notice of allowance has been given or mailed, (i) for the period beginning on the date the amendment or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment or such other paper; or (ii) 4 months, whichever is less.

9. As Applicants' August 18, 2011 Supplemental Information Disclosure Statement was filed after the Notice of Allowance, Applicant should have been debited 28 days since the Amendment was considered in the September 14, 2011 Supplemental Notice of Allowability.

10. As Applicants' replacement drawings were deemed considered November 1, 2011 (the date the patent issued) Applicants should have been debited 41 days. As determined by the USPTO, there are believed to be no additional circumstances during prosecution of this application that constitute a failure to engage in reasonable efforts to conclude processing or examination as set forth in § 1.704. See Attachment B.

11. The USPTO's PTA calculation in PAIR indicates that the Applicant was debited 76 days for submission of the Supplemental Information Disclosure of August 18, 2011 and the submission of replacement drawings, rather than the 69 (28+41) days of debit believed appropriate by the Applicant. Accordingly, Applicant believes that this resulted in 7 days of excessive reduction to Applicant's PTA award.

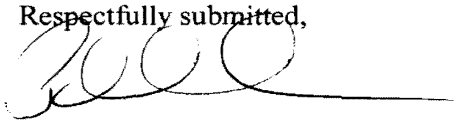
12. Therefore, the correct patent term adjustment is 444 days once the days of excessive reduction are properly taken into account.

13. The Applicants' credit of only 437 days of patent term adjustment for the '032 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and in excess of statutory jurisdiction, authority or limitation.

14. Accordingly, Applicants' and the undersigned respectfully submit that justice requires that the patent term adjustment credited to U.S. Patent No. 8,048,032 be changed from 437 days to 444 days.

Electronic payment is submitted by credit card to cover the fee. Please credit or debit Deposit Account No. 16-0631 as needed to ensure consideration of the disclosed information.

Respectfully submitted,



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ATTACHMENT A

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

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

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

(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 437 days.

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

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

(65) **Prior Publication Data**

US 2007/0260219 A1 Nov. 8, 2007

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

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

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

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Takahashi, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).
Office Action for U.S. Appl. No. 12/824,734; filed Jun. 28, 2010, Inventors Roots et al.; Office Action dated Aug. 1, 2011.

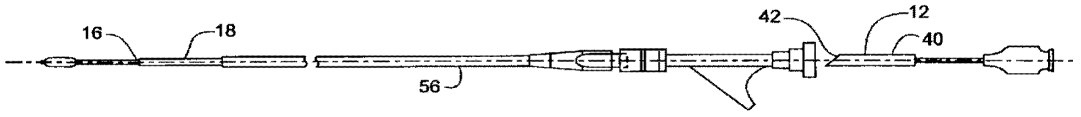
* cited by examiner

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

(57) **ABSTRACT**

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

22 Claims, 13 Drawing Sheets



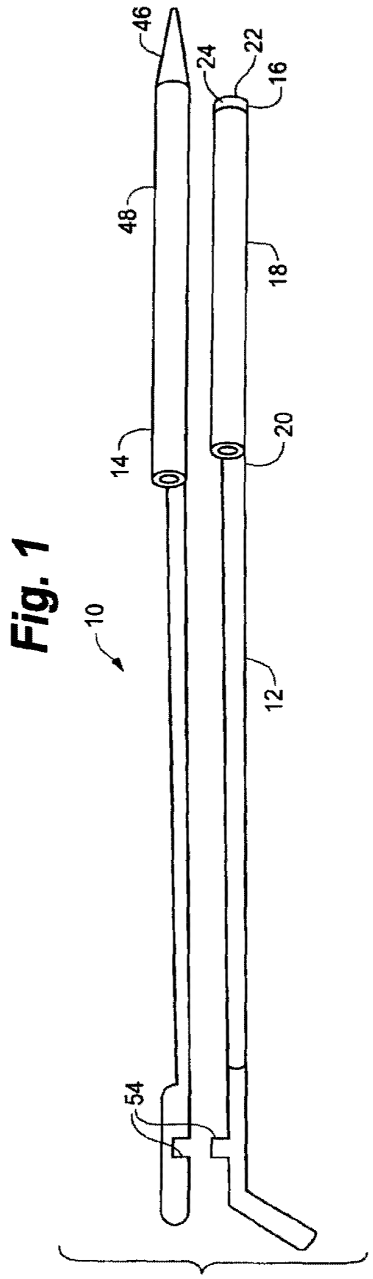


Fig. 1

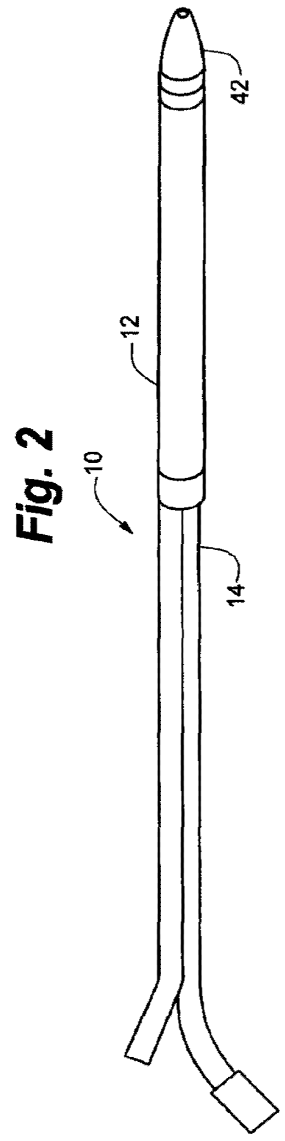
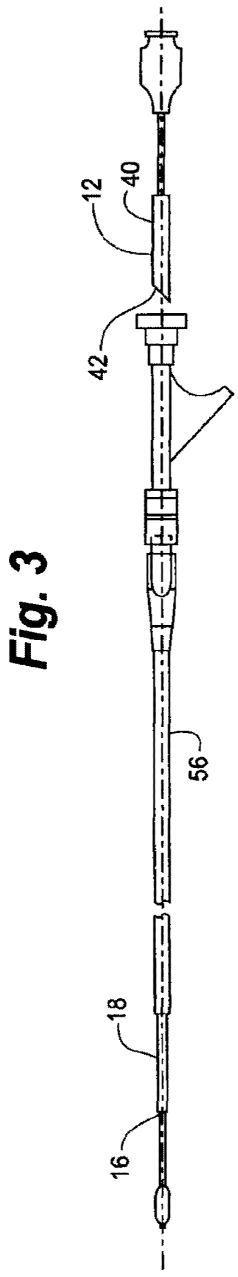


Fig. 2



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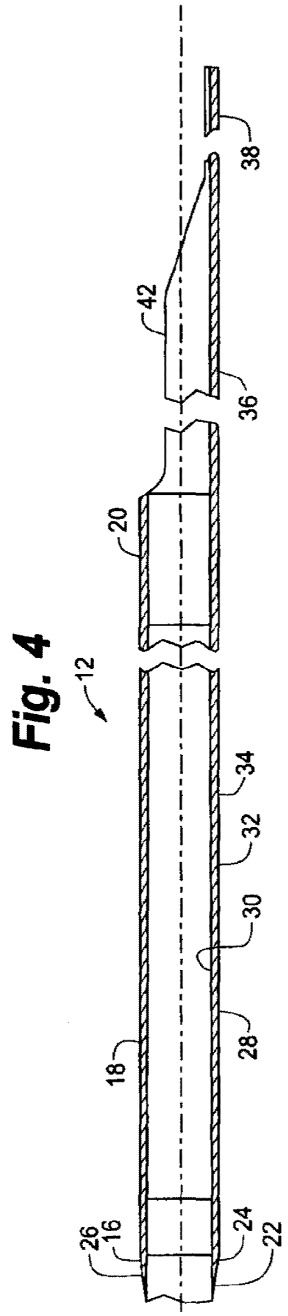


Fig. 4

Fig. 5

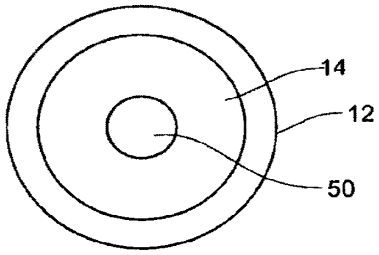


Fig. 6

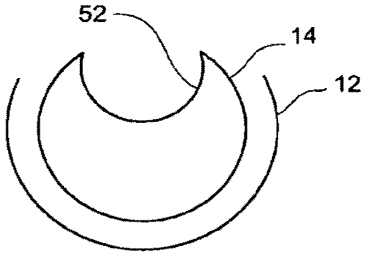
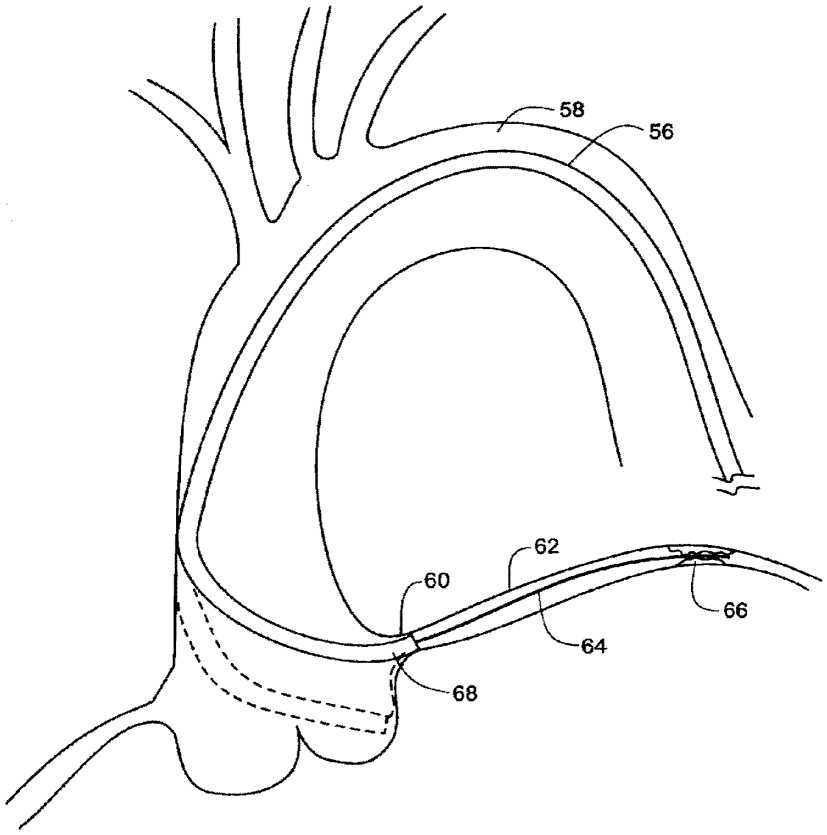


Fig. 7



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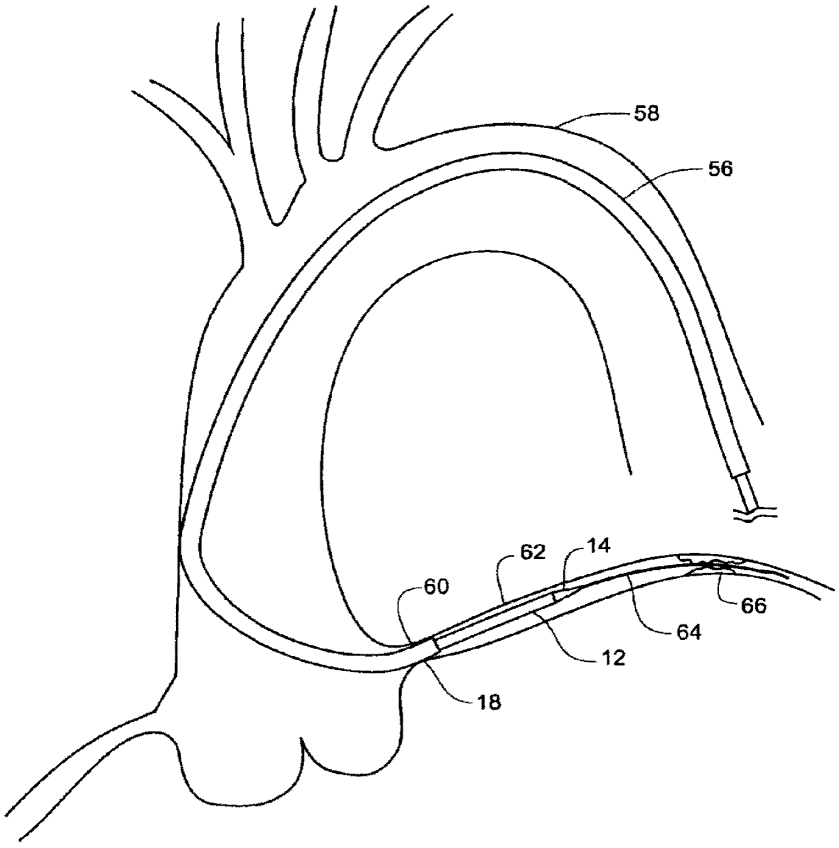
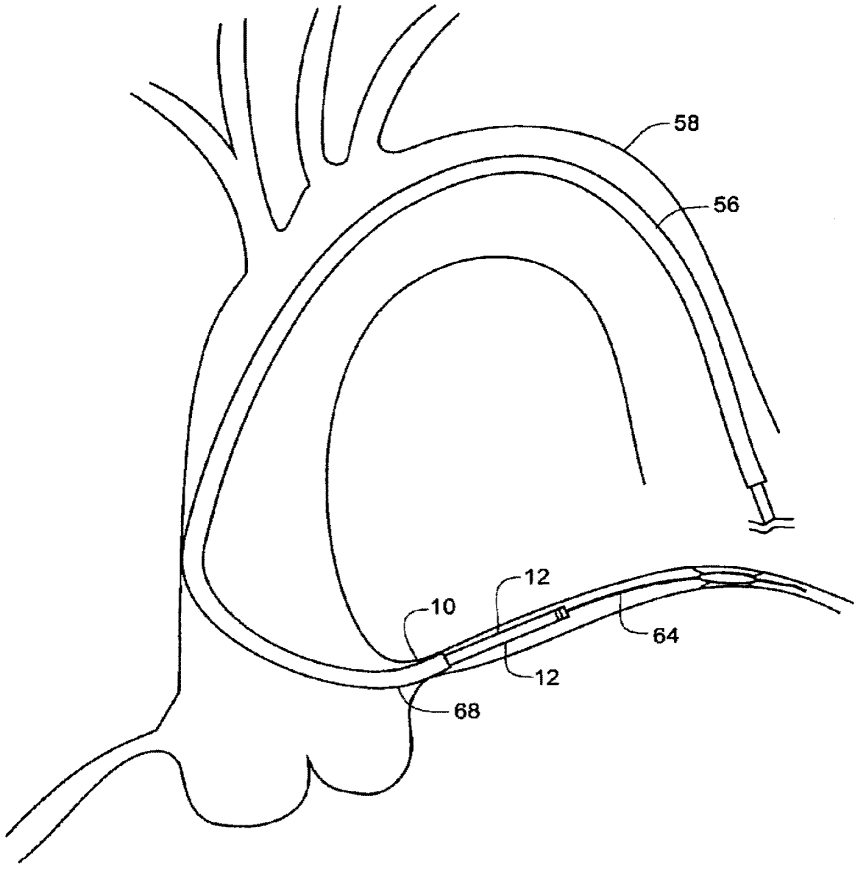
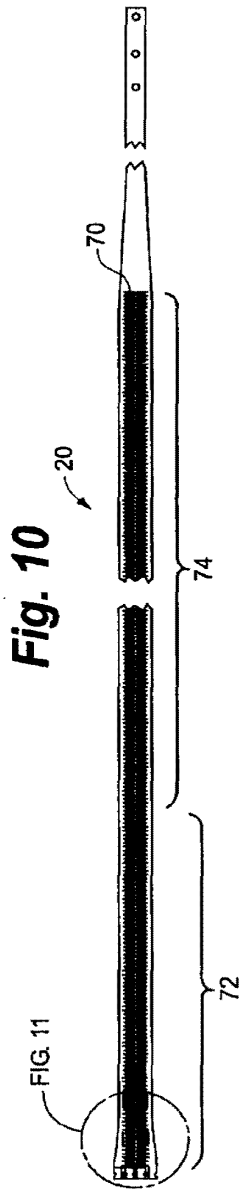


Fig. 9





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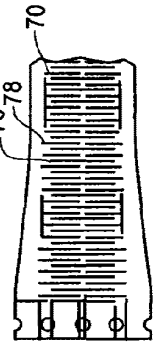

Fig. 11

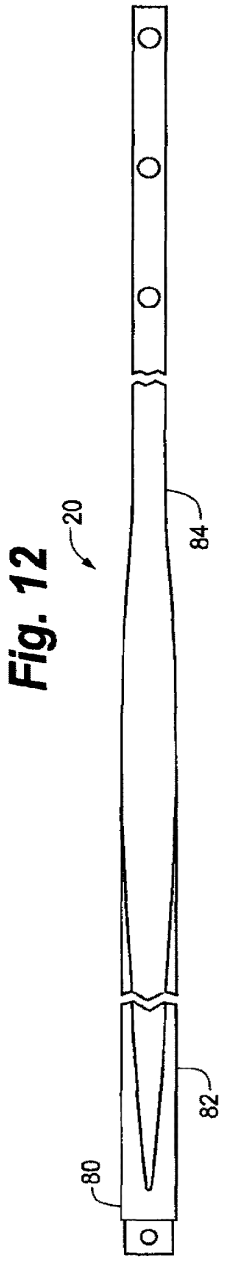

Fig. 12

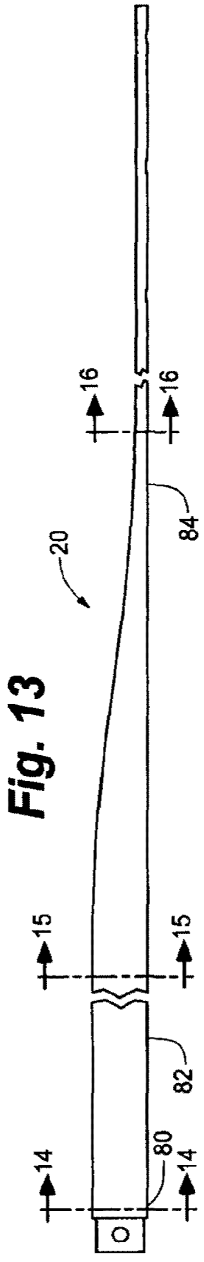

Fig. 13

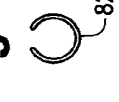

Fig. 15

Fig. 16

Fig. 14

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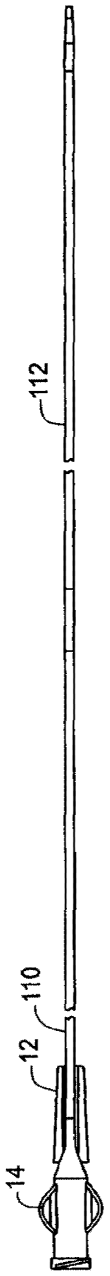

Fig. 17

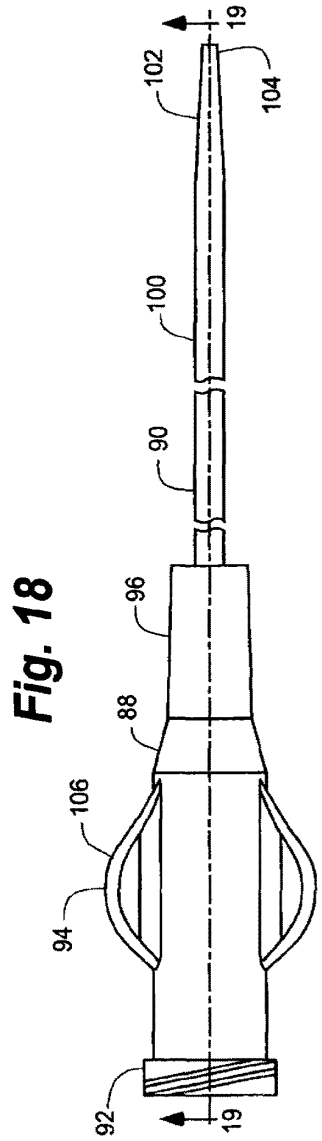

Fig. 18

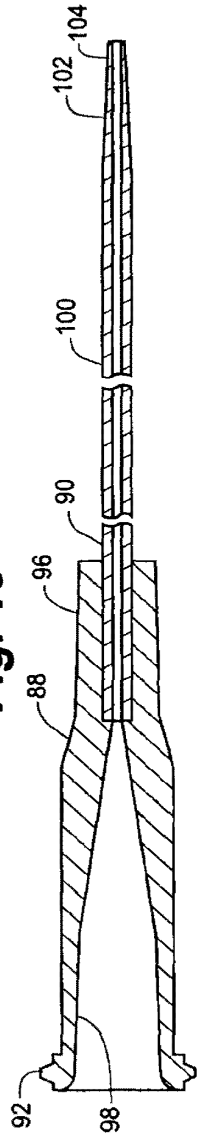

Fig. 19

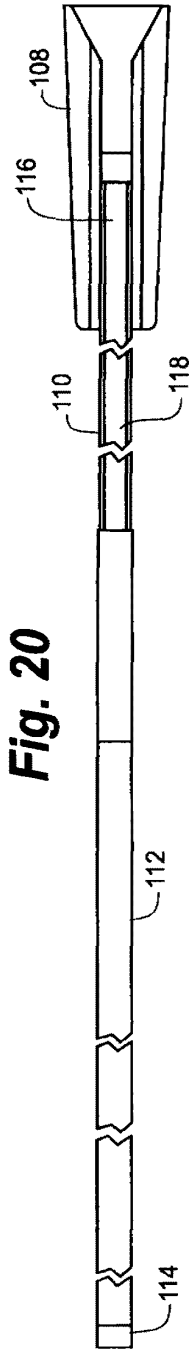

Fig. 20

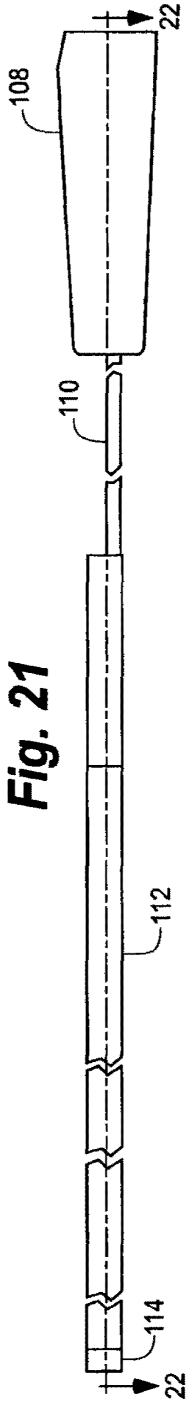

Fig. 21

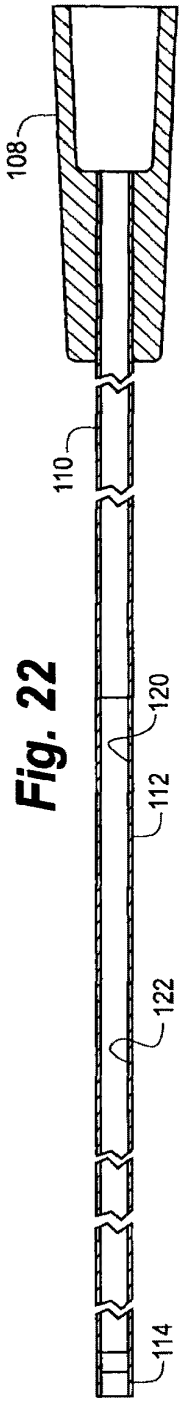

Fig. 22

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

SUMMARY OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DETAILED DESCRIPTION OF THE INVENTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

What is claimed is:

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

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

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

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

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

3. The device of claim **2** wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an inter-

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

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

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

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

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

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

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

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

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

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

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

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,

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

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

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

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

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

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

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

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

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

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

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

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

* * * * *

11/416,629	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	2005.86US01	10-20-2011::15:54:43

Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 11/416,629

Filing or 371(c) Date:	05-03-2006	Overlapping Days Between {A and B} or {A and C}:	0
Issue Date of Patent:	-	Non-Overlapping USPTO Delays:	545
A Delays:	416	PTO Manual Adjustments:	0
B Delays:	129	Applicant Delays:	108
C Delays:	0	Total PTA Adjustments:	437

Patent Term Adjustment History **Explanation Of Calculations**

Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
92.5	09-09-2009	PTA 36 Months	129		0.5
92	11-01-2011	Patent Issue Date Used in PTA Calculation			0
91	09-23-2011	Export to Final Data Capture			0
90	09-22-2011	Dispatch to FDC			0
89	09-21-2011	Application Is Considered Ready for Issue			0
88	09-20-2011	Issue Fee Payment Verified			0
87	09-20-2011	Issue Fee Payment Received			0
86	09-14-2011	Mailing Corrected Notice of Allowability			0
85	09-09-2011	Finished Initial Data Capture			0
84	09-12-2011	Office Action Review			0
83	09-12-2011	Corrected Notice of Allowability			0
82	08-18-2011	Information Disclosure Statement considered			0
81	08-19-2011	Reference capture on IDS			0
80	08-18-2011	Information Disclosure Statement (IDS) Filed		76	0
79	08-18-2011	Information Disclosure Statement (IDS) Filed			0
78	08-10-2011	Export to Initial Data Capture			0
77	08-03-2011	Mail Notice of Allowance	42		62
76	08-01-2011	Office Action Review			0

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72	08-01-2011	Notice of Allowance Data Verification Completed	0
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67	07-29-2011	Allowed Case Returned to the Examiner for Clerical Processing	0
66	07-29-2011	Document Verification	0
65	07-28-2011	Reasons for Allowance	0
64	07-28-2011	Examiner's Amendment Communication	0
63	07-28-2011	Allowability Notice	0
62	02-22-2011	Request for Continued Examination (RCE)	0
61	02-23-2011	Disposal for a RCE / CPA / R129	0
60	02-23-2011	Date Forwarded to Examiner	0
59	02-22-2011	Amendment Submitted/Entered with Filing of CPA/RCE	0
58	02-22-2011	Workflow - Request for RCE - Begin	0
57	12-21-2010	Mail Final Rejection (PTOL - 326)	0
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55	10-18-2010	Date Forwarded to Examiner	0
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48	06-30-2010	Date Forwarded to Examiner		0
47	06-28-2010	Amendment Submitted/Entered with Filing of CPA/RCE		0
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38	11-19-2009	Mail Non-Final Rejection		0
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28	04-20-2009	Date Forwarded to Examiner		0
27	04-06-2009	Response after Non-Final Action	32	25
26	04-06-	Request for Extension of Time - Granted		0

	2009			
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19	11-03-2008	Date Forwarded to Examiner		0
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17	10-01-2008	Request for Extension of Time - Granted		0
16	07-11-2008	Mail Restriction Requirement	374	0.5
15	07-07-2008	Restriction/Election Requirement		0
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13	01-16-2008	Case Docketed to Examiner in GAU		0
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11	08-23-2006	IFW TSS Processing by Tech Center Complete		0
10	07-24-2006	Reference capture on IDS		0
9.7	07-24-2006	Information Disclosure Statement (IDS) Filed		0
9	07-24-2006	Information Disclosure Statement (IDS) Filed		0
8	07-12-2006	Application Dispatched from OIPE		0
7	07-12-2006	Application Is Now Complete		0
6	06-21-2006	Payment of additional filing fee/Preexam		0
5	06-21-2006	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic		0
4	05-24-2006	Notice Mailed--Application Incomplete--Filing Date Assigned		0
3	05-12-2006	Cleared by OIPE CSR		0
2	05-06-2006	IFW Scan & PACR Auto Security Review		0
1	05-03-2006	Initial Exam Team nn		0
0.5	05-03-2006	Filing date		0

Electronic Patent Application Fee Transmittal	
Application Number:	11416629
Filing Date:	03-May-2006
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Paul C. Onderick/Allison Goette
Attorney Docket Number:	2005.86US01
Filed as Small Entity	

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Application for patent term adjustment	1455	1	200	200
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

VSI_00000033

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt	
EFS ID:	11383110
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Allison Goette
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86US01
Receipt Date:	10-NOV-2011
Filing Date:	03-MAY-2006
Time Stamp:	17:00:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$200
RAM confirmation Number	4178
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 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

VSI_00000035

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Patent Term Adjustment Petition	2005_86US01_Petition.pdf	1022823 854a41491c243352003aaa6bc0371c645705b47a	no	28
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30422 73af1213415ee84f00418d5dfce58d230796be91	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1053245		

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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.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/416,629	11/01/2011	8048032	2005.86US01	5061

24113 7590 10/12/2011

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

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 437 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Howard Root, Excelsior, MN;
Gregg Sutton, Mapple Grove, MN;
Jeffrey M. Welch, Maple Grove, MN;
Jason M. Garrity, Minneapolis, MN;

IR103 (Rev. 10/09)

VSI_00000037

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/416,629
Filing Date	May 3, 2006
First Named Inventor	Howard Root et al.
Art Unit	3763
Examiner Name	Not Assigned
Attorney Docket Number	2005.86US01

Sheet 1 of 1

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,475,195	~~11-05-2005~~	Voda 11/2002
Change(s) applied to document, /A.J.P./ 9/9/2011		US-6,860,876	03-01-2005	Chen
		US-6,689,144	02-10-2004	Gerberding
		US-6,595,952	07-22-2003	Forsberg
		US-6,610,068	08-26-2003	Yang
		US-6,159,195	12-12-2000	Ha et al.
		US-5,658,263	08-19-1997	Dang et al.
		US-5,472,425	12-05-1995	Teirstein
		US-5,098,412	03-24-1992	Shiu
		US-5,122,125	~~01-16-1992~~	Deuss 06/1992
Change(s) applied to document, /A.J.P./ 9/7/2011		US-4,932,413	06-12-1990	Shockey et al.
		US-4,832,028	05-23-1989	Patel
		US-4,813,930	03-21-1989	Elliott
		2005/0182437	08-18-2005	Bonnette et al.
		US-		
		US-		
		US-		
		US-		
		US-		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (11/06/2008)	DATE CONSIDERED	

*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.
[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.O./

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86US01

Howard Root et al. Confirmation No.: 5061

Application No.: 11/416,629 Examiner: Bradley James Osinksi

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

SUBMISSION OF REPLACEMENT DRAWINGS

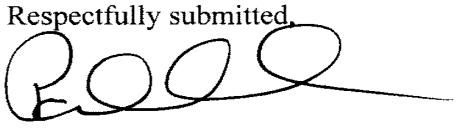
Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Original drawings were submitted for filing with the above-identified patent application.

Enclosed for filing are 13 sheets (Fig. 1 to Fig. 22) of replacement drawings.

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

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

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

Fig. 1

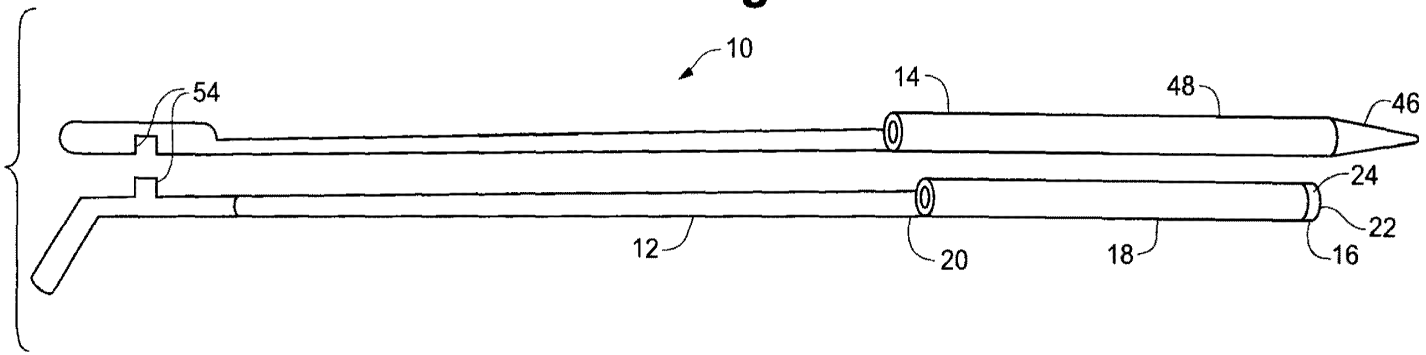


Fig. 2

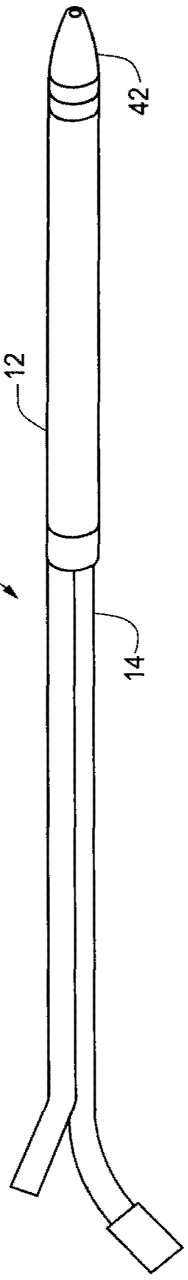
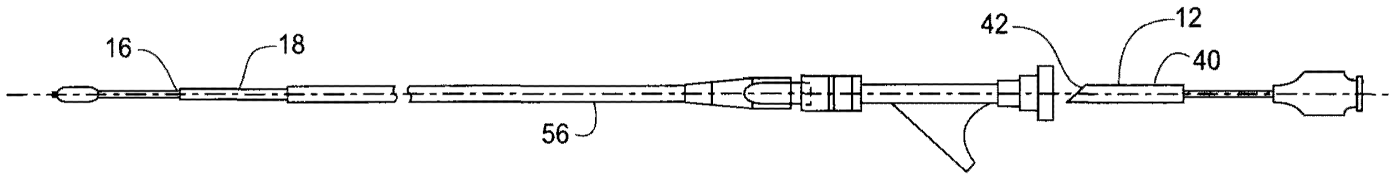


Fig. 3



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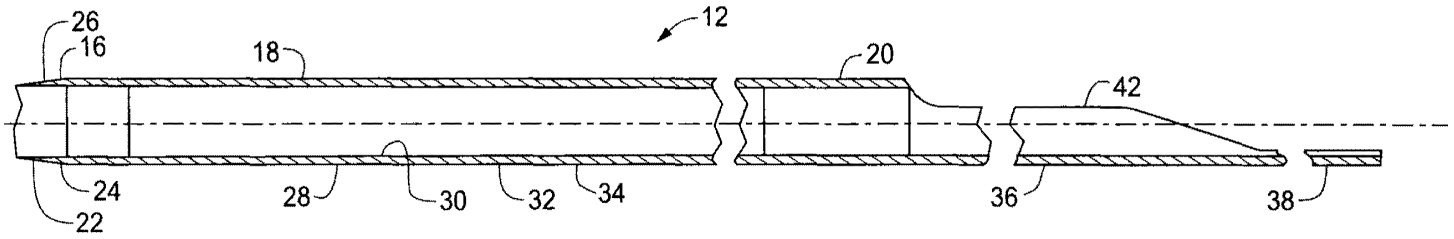

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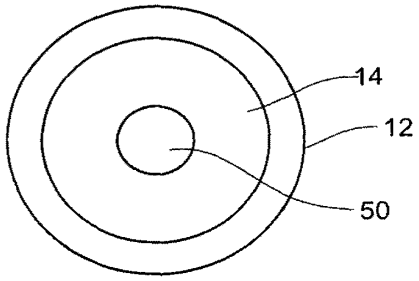

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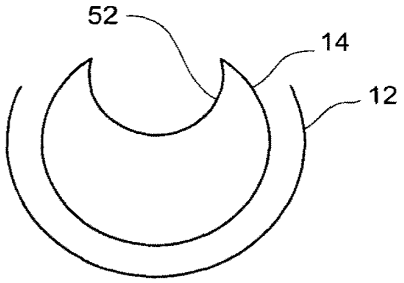

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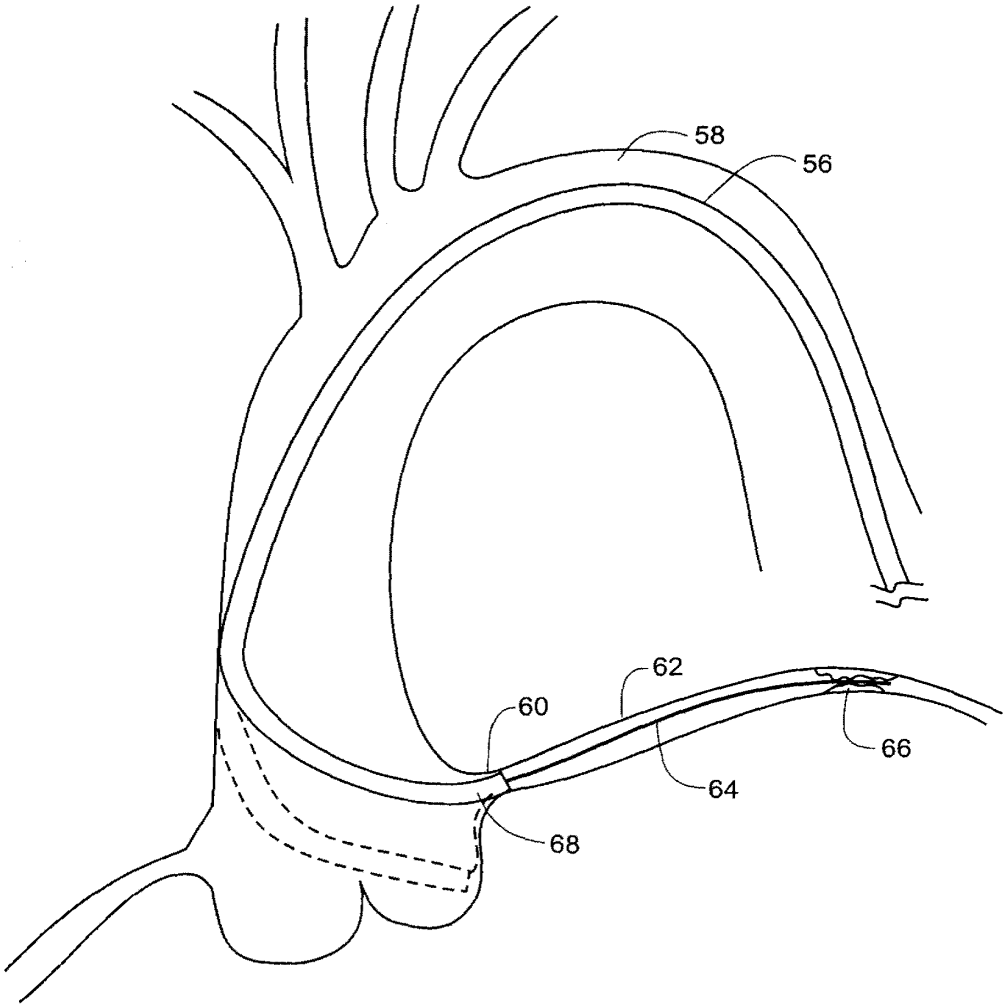

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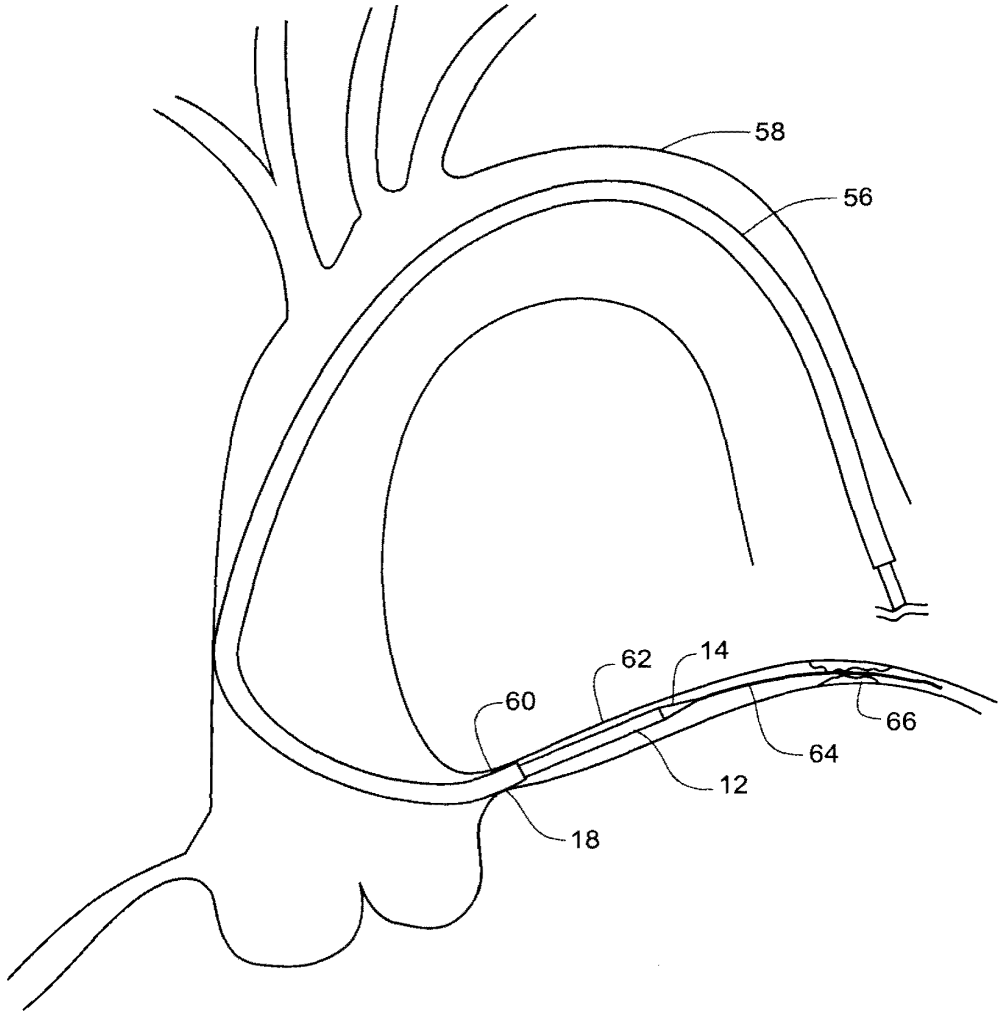

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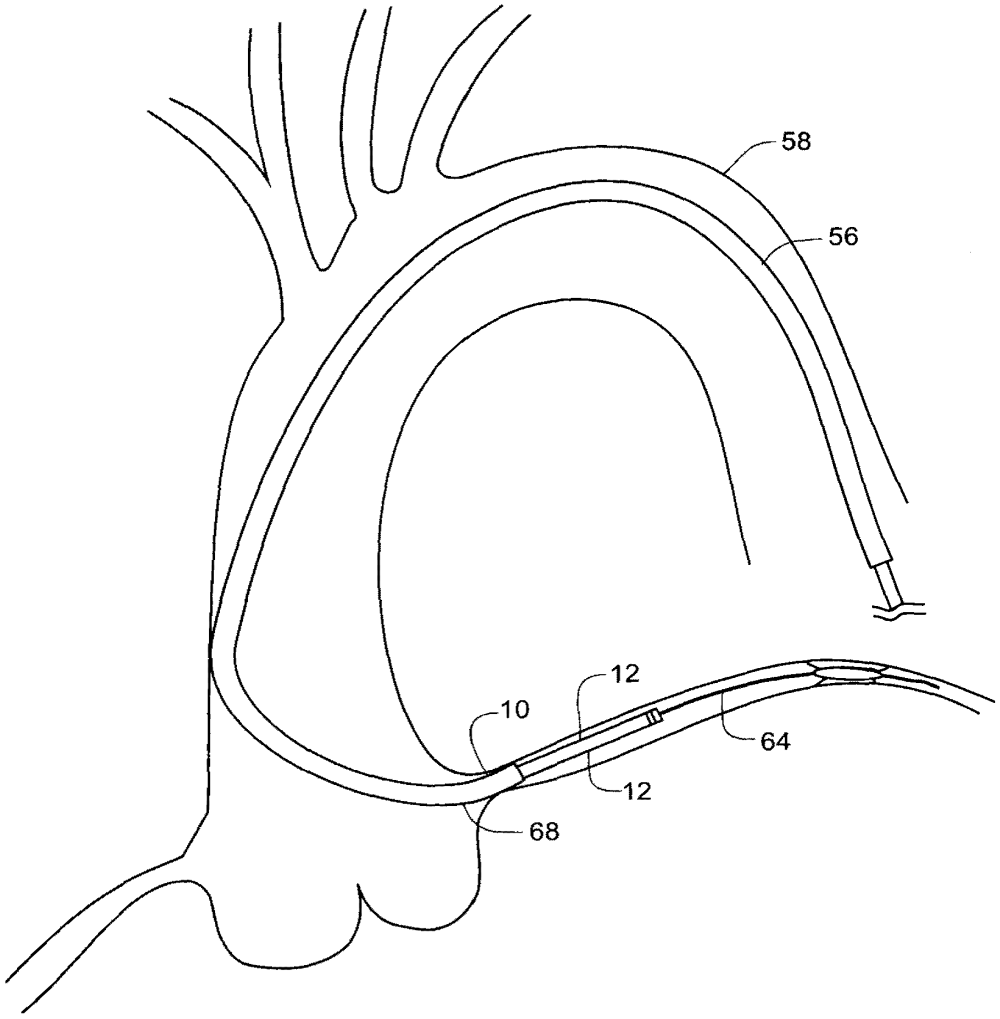
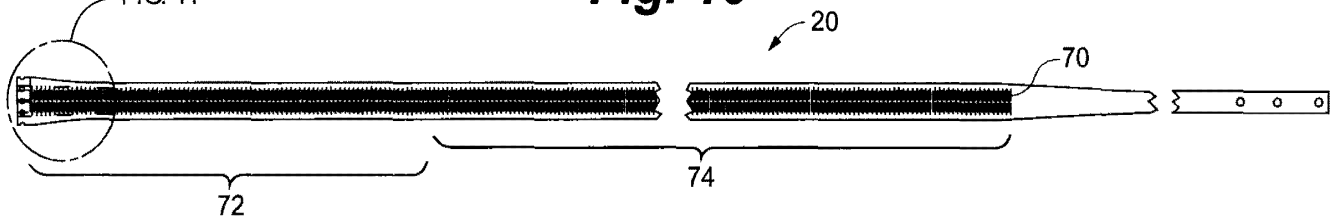


FIG. 11

Fig. 10



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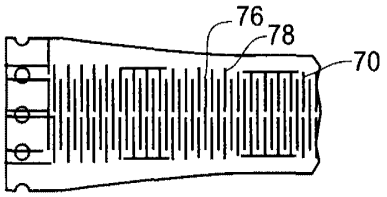

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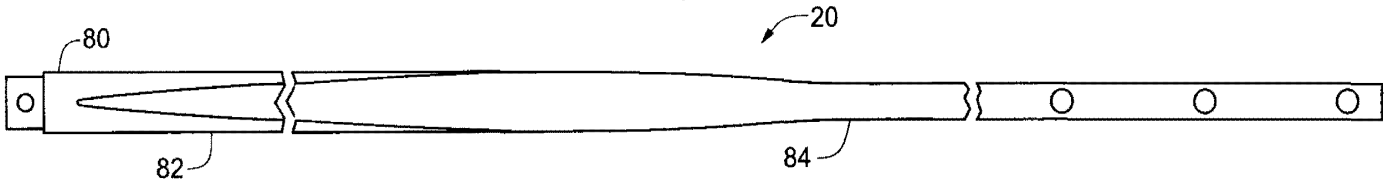

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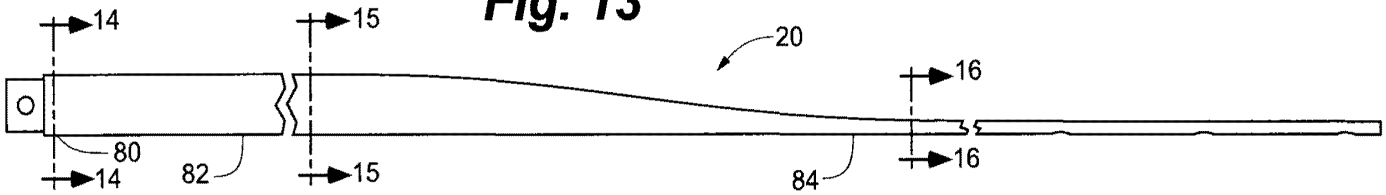


Fig. 14

Fig. 15

Fig. 16

APPLICATION NO. 11/416,629
REPLY TO NOTICE OF ALLOWANCE
REPLACEMENT SHEET

Fig. 17

Fig. 18

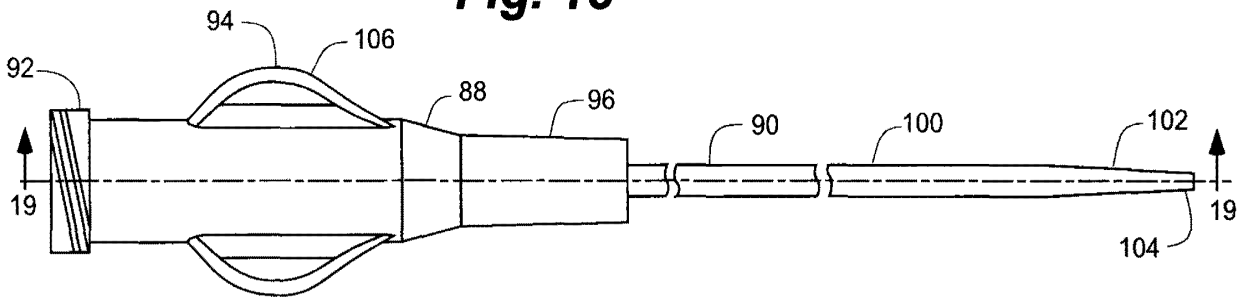


Fig. 19

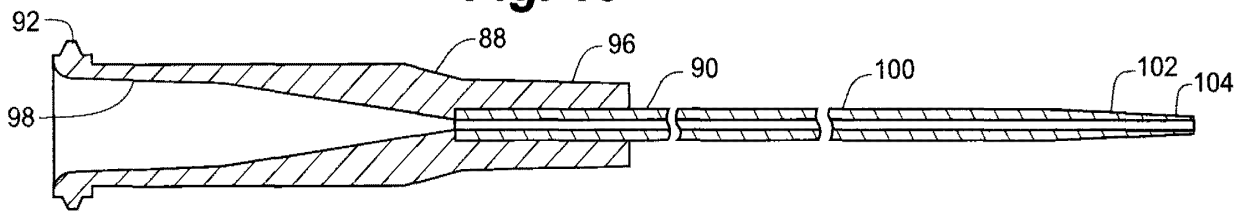


Fig. 20

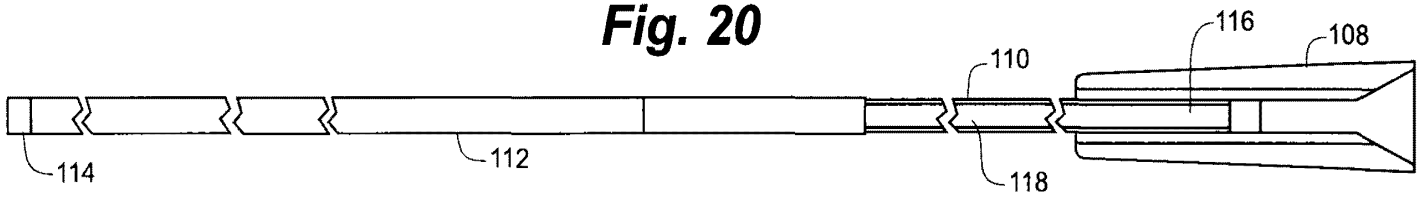


Fig. 21

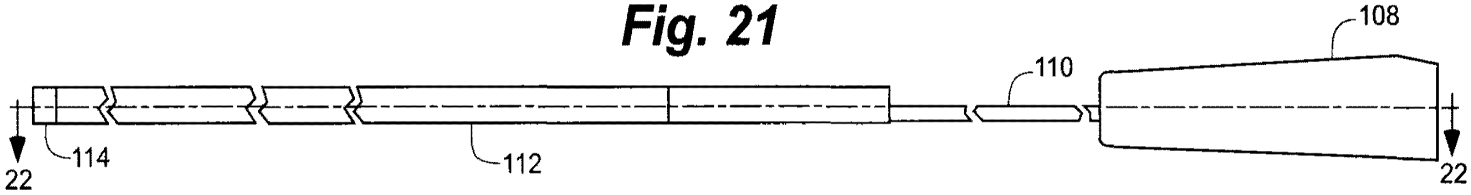
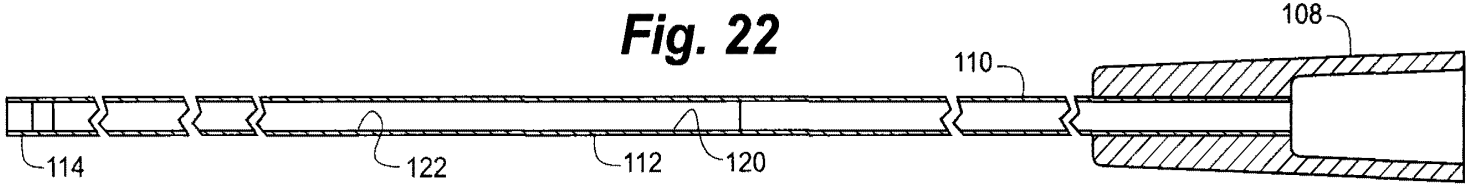


Fig. 22



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EFS ID:	11019316
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Allison Goette
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86US01
Receipt Date:	22-SEP-2011
Filing Date:	03-MAY-2006
Time Stamp:	16:48:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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Warnings:					
Information:					

VSI_00000053

Total Files Size (in bytes):	158058

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
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.

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

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

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

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

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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

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

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

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

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

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

(A) NAME OF ASSIGNEE: Vascular Solutions, Inc.
(B) RESIDENCE: (CITY and STATE OR COUNTRY): Minneapolis, Minnesota

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

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

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
☐ A check is enclosed.
☒ Payment by credit card.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 24113 (enclose an extra copy of this form).

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

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

Authorized Signature _____ Date 9/20/11

Typed or printed name Brad Pedersen Registration No. 32432

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

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

Electronic Patent Application Fee Transmittal

Application Number:	11416629
Filing Date:	03-May-2006
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Bradley Pedersen/Michelle Arcand
Attorney Docket Number:	2005.86US01

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	755	755
Publ. Fee- early, voluntary, or normal	1504	1	300	300

VSI_00000056

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1055**

Electronic Acknowledgement Receipt	
EFS ID:	10991325
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Michelle Arcand
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86US01
Receipt Date:	20-SEP-2011
Filing Date:	03-MAY-2006
Time Stamp:	15:51:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1055
RAM confirmation Number	2947
Deposit Account	160631
Authorized User	PEDERSEN,BRADLEY D.
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 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

VSI_00000058

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	Issue Fee Payment (PTO-85B)	2005_86US01_ISSUEFEETRANS.pdf	86749 84486abda1753bbd346e7d16626e5f303bd8f9c3	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32080 e473731d70c86abcc0408b6d03364a1e84ba95df	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	118829		

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
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New International Application Filed with the USPTO as a Receiving Office
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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

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

24113 7590 09/14/2011

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

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	**PAPER NUMBER**
3767	
MAIL DATE	**DELIVERY MODE**
09/14/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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

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

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

1. ☒ This communication is responsive to *8/18/2011*.

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

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

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

   * Certified copies not received: _____.

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

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

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

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

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

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 8/18/2011
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Bradley J Osinski/
Examiner, Art Unit 3767

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY J OSINSKI	3767

SEARCHED			
Class	Subclass	Date	Examiner
604	103.04, 103.09, 160-162, 164.01, 164.09-164.11, 525	11/6/2008	bjo
604	164.01,164.02,525	7/27/2011	bjo

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Terms	11/6/2008	bjo
IDS	7/28/2010	bjo
Updated Search	12/14/2010	bjo
Final Search	7/27/2011	bjo
IDS that allowance was withdrawn for. References are not seen as reading upon claims	8/26/2011	bjo

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
604	164.1,525	7/27/2011	bjo

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known	
Application Number	11/416,629
Filing Date	May 3, 2006
First Named Inventor	Roots et al.
Art Unit	3767
Examiner Name	Bradley James Osinski
Attorney Docket Number	2005.86US01

Sheet	1	of	2

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,638,268 B2	10-28-2003	Niazi
		US-2005/0004523 A1	01-06-2005	Osborne et al.
		US-		
		US-		
		US-		
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		US-		
		US-		
		US-		
		US-		

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*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.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

VSI_00000063

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	2005.86US01
				Filing Date	May 3, 2006
				First Named Inventor	Root et al.
				Art Unit	3767
				Examiner Name	Bradley James Osinski
Sheet	2	of	2	Attorney Docket Number	2005.86US01

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	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[2]
		Office Action for U.S. Patent Application Serial No. 12/824,734; filed June 28, 2010, Inventors Roots et al.; Office Action dated August 1, 2011.	

EXAMINER SIGNATURE	/Bradley Osinski/ (08/26/2011)	DATE CONSIDERED	

*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. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 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 120 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

VSI_00000064

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY OSINSKI	3767

ORIGINAL		INTERNATIONAL CLASSIFICATION														
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED									
604	164.1	A	6	1	M	5 / 178 (2006.01.01)										
CROSS REFERENCE(S)		A	6	1	M	25 / 00 (2006.01.01)										
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)															
604	525															

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	58	17	73												
2	59	18	74												
3	60	19	75												
4	61	20	76												
5	64	21	77												
6	62	22	79												
7	63														
8	65														
9	66														
10	78														
11	67														
12	68														
13	69														
14	70														
15	71														
16	72														

/BRADLEY OSINSKI/ Examiner.Art Unit 3767	7/27/2011	Total Claims Allowed:	
(Assistant Examiner)	(Date)	22	
/JACKIE HO/ Supervisory Patent Examiner.Art Unit 3763	08/29/2011	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	58	3

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010	07/27/2011			
	1	N	N	N	-	-	-			
	2	N	N	N	-	-	-			
	3	N	N	N	-	-	-			
	4	N	N	N	-	-	-			
	5	N	N	N	-	-	-			
	6	N	N	N	-	-	-			
	7	N	N	N	-	-	-			
	8	✓	✓	✓	-	-	-			
	9	✓	✓	✓	-	-	-			
	10	✓	✓	✓	-	-	-			
	11	✓	✓	✓	-	-	-			
	12	✓	✓	✓	-	-	-			
	13	✓	✓	✓	-	-	-			
	14	✓	✓	✓	-	-	-			
	15	✓	✓	✓	-	-	-			
	16	✓	✓	✓	-	-	-			
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	23	N	N	N	-	-	-			
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	25		✓	✓	-	-	-			
	26		N	N	-	-	-			
	27		N	N	-	-	-			
	28				✓	-	-			
	29				✓	-	-			
	30				✓	-	-			
	31				✓	-	-			
	32				✓	-	-			
	33				✓	-	-			
	34				✓	-	-			
	35				✓	-	-			
	36				✓	-	-			

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010	07/27/2011			
	37				✓	-	-			
	38				✓	-	-			
	39				✓	-	-			
	40				✓	-	-			
	41				✓	-	-			
	42				✓	-	-			
	43				✓	-	-			
	44				✓	-	-			
	45				✓	-	-			
	46				✓	-	-			
	47				✓	-	-			
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	51				✓	-	-			
	52				✓	-	-			
	53				✓	-	-			
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5	64					✓	=			
8	65					✓	=			
9	66					✓	=			
11	67					✓	=			
12	68					✓	=			
13	69					✓	=			
14	70					✓	=			
15	71					✓	=			
16	72					✓	=			

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010	07/27/2011			
17	73					✓	=			
18	74					✓	=			
19	75					✓	=			
20	76					✓	=			
21	77					✓	=			
10	78						=			
22	79						=			

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	2	(("6638268") or ("20050004523")).PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/08/26 10:02
S1	171	(604/510).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2008/11/06 16:26
S2	28	("20050182437" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "6159195" | "6475195" | "6595952" | "6610068" | "6689144" | "6860678").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/06 16:27
S3	70	("3430631" | "3902492" | "4117836" | "4195637" | "4299226" | "4323071" | "4423725" | "4445892" | "4453545" | "4581017" | "4601706" | "4610662" | "4655746" | "4689041"). PN. OR ("4832028"). URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 16:30
S4	51	("3811448" | "4195637" | "4323071" | "4493711" | "4573470" | "4619263" | "4641649" | "4643186" | "4748982" | "4762129" | "4790315" | "4798193" | "4824435" | "5003990" | "5040548" | "5045061" | "5061273" | "5090957" | "5090958" | "5324257" | "5324259" | "5395332" | "5413557" | "5415634" | "5505702" | "5540659" | "5569199" | "5571087" | "5575771" | "5578009" | "5605543" | "5667493" | "5667521" | "5690642" | "5706827" | "5718680" | "5728067" | "5730698" | "5752932" | "5863285" | "5879305" | "5882334" | "6071285" | "6394995" | "6447501" | "6500147" | "RE31800").PN. OR ("6740104").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:04

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S6	285	604/103.04	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S7	213	604/103.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S8	540	604/160	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S9	594	604/161	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S10	605	604/162	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S11	1217	604/164.01	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S12	235	604/164.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S13	196	604/164.1	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S14	311	604/164.11	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S15	484	604/525	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:23
S16	12	("4100393" | "4377165" | "4401433" | "4449973" | "4702735" | "4762516" | "4790817" | "4950252" | "4957488" | "4957489" | "D247975").PN. OR ("5971957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 08:54
S17	32	("4166469" | "4243050" | "4345606").PN. OR ("5667514").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 09:15
S18	36	("3352306" | "3565074" | "4230123" | "4581019" | "4629450" | "4772264" | "4911691" | "4978334" | "4994027" | "4995866").PN. OR ("5242410").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 10:45

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S20	31	("20020103474" | "4790831" | "4886506" | "5290229" | "5336182" | "5505698" | "5584803" | "5643231" | "5690611" | "5782741" | "5785706" | "5807249" | "5824031" | "5846229" | "5879295" | "5916214" | "6001085" | "6002955" | "6006137" | "6022341" | "6080151" | "6090084" | "6093173" | "6122552" | "6179809" | "6228052" | "6273881"). PN. OR ("6638268"). URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 13:04
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S22	9	("5667514" | "5868754" | "5947995" | "6001118"). PN. OR ("6254610"). URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/10 13:46
S23	2	"relief cuts" SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46

S24	2	"relief cut" SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S25	1370	cut SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S26	345	cut with rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S27	95	"relief cuts" SAME rigid$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:51
S28	49	(US-20080058759-$ or US-20070093783-$ or US-20030233068-$ or US-20030195546-$ or US-20020133118-$ or US-20070112302-$ or US-20060135973-$ or US-20060129101-$ or US-20050004523-$ or US-20040138562-$ or US-20060135962-$ or US-20080172036-$ or US-20010034514-$ or US-20050159767-$ or US-20040225308-$).did. or (US-5484412-$ or US-5059178-$ or US-4581017-$ or US-7141050-$ or US-6746464-$ or US-6740104-$ or US-6447501-$ or US-4994027-$ or US-6780199-$ or US-6692482-$ or US-6976991-$ or US-7306618-$ or US-5971957-$ or US-5667514-$ or US-6254610-$ or US-5242410-$ or US-5169387-$ or US-5688253-$ or US-5158543-$ or US-6692462-$ or US-6689152-$ or US-6093173-$ or US-6641564-$ or US-6638268-	US-PGPUB; USPAT	OR	ON	2008/12/02 17:34

		$ or US-6338725-$ or US-7056294-$).did. or (US-6702782-$ or US-6645194-$ or US-7169105-$ or US-6481436-$ or US-6179809-$ or US-6165163-$ or US-6099518-$ or US-6053903-$).did.				
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S35	734	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/10 10:13
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S37	1	("5411514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/17 15:06

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S43	742	(604/524-525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/12/14 09:21

S44	4	("20060247661" | "5534007").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 09:46
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S46	6514	S45 and (catheter tube medica$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:51
S49	5948	S45 and (catheter tube)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:52
S50	2092	S45 same (catheter tube)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:52
S51	156	S50 and catheter	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 12:40
S52	13	("5667514" | "5868754" | "5947995" | "6001118"). PN. OR ("6254610"). URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2011/07/26 15:45
S53	910	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S54	94	(604/164.02).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S55	112	(604/164.1).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S56	337	(604/525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34

S57	238	(howard and root).in. (gregg and sutton).in. (jeffrey and welch).in. (jason and garrity).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/07/27 15:35
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EAST Search History (Interference)

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S60	0	(604/525).CCLS.	UPAD	OR	OFF	2011/07/27 15:34

8/26/2011 10:02:58 AM
C:\Documents and Settings\bosinski\My Documents\EAST\Workspaces\11416629.wsp

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/416,629
				Filing Date	May 3, 2006
				First Named Inventor	Roots et al.
				Art Unit	3767
				Examiner Name	Bradley James Osinski
Sheet	1	of	2	Attorney Docket Number	2005.86US01

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-6,638,268 B2	10-28-2003	Niazi
		US-2005/0004523 A1	01-06-2005	Osborne et al.
		US-		
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE		DATE CONSIDERED	

*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.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]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.**

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	2005.86US01
				Filing Date	May 3, 2006
				First Named Inventor	Root et al.
				Art Unit	3767
				Examiner Name	Bradley James Osinski
Sheet	2	of	2	Attorney Docket Number	2005.86US01

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	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[2]
		Office Action for U.S. Patent Application Serial No. 12/824,734; filed June 28, 2010, Inventors Roots et al.; Office Action dated August 1, 2011.	

EXAMINER SIGNATURE		DATE CONSIDERED	

*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. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 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 120 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Electronic Patent Application Fee Transmittal	
Application Number:	11416629
Filing Date:	03-May-2006
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Bradley Pedersen/Michelle Arcand
Attorney Docket Number:	2005.86US01
Filed as Small Entity	

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

VSI_00000083

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
		Total in USD ($)		**180**

Electronic Acknowledgement Receipt	
EFS ID:	10768955
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Michelle Arcand
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86US01
Receipt Date:	18-AUG-2011
Filing Date:	03-MAY-2006
Time Stamp:	17:38:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$180
RAM confirmation Number	4075
Deposit Account	160631
Authorized User	PEDERSEN,BRADLEY D.
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 1.16 (National application filing, search, and examination fees) 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		2005_86US01_SIDS1449.pdf	164454 b4529a17951fdf40a1dac92ae72843d035b25a7d	yes	4
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	4	
Warnings:					
Information:					
2	Non Patent Literature	2005_86US01_OFFICEACTION.pdf	428927 e65e258d6e9f187bc0060f61b15bc259a33188bf	no	11
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30538 bf3f2cbff78fa35f53cfcd797eef1db2c5329450	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	623919		

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
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.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US01
Root et al.	Confirmation No.: 5061
Application No.: 11/416,629	Examiner: Bradley James Osinski
Filed: May 3, 2006	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

Sir:

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.

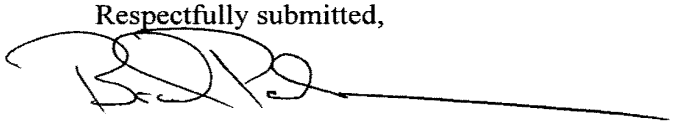
The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information 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 more than three months after the U.S. filing date and after the mailing date of a Final Action or Notice of Allowance, or an action

that otherwise closes prosecution in the application but before payment of the Issue Fee, but with a certification pursuant to the 37 CFR § 1.97(d)(1) and with a fee as provided for under 37 CFR § 1.97(d)(2). It is hereby requested that the Information Disclosure Statement be considered in accordance with the payment in the amount of $180 for the petition fee under 37 CFR § 1.17(p) that is submitted herewith. Electronic payment is submitted by credit card to cover the fee. Please credit or debit Deposit Account No. 16-0631 as needed to ensure consideration of the disclosed information.

I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement. This thirty-day period is not extendable. 37 CFR § 1.704(d). A copy of the communication from the patent office is enclosed for the Examiner's convenience.

Respectfully submitted,



Brad D. Pedersen
Registration No. 32432

Customer No. 24113
Patterson Thuente Christensen Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5774

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

24113 7590 08/03/2011

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

EXAMINER
OSINSKI, BRADLEY JAMES

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/03/2011

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

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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

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

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

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

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

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

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

If the SMALL ENTITY is shown as NO:

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

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

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

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

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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

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

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

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

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

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

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

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

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

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

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

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

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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

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

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

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

24113 7590 08/03/2011

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

EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 08/03/2011

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

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

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

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

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

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.

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

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

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

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

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

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

   * Certified copies not received: _____.

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

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

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

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

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

Attachment(s)

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

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

EXAMINER'S AMENDMENT

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

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

The application has been amended as follows:

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

''structure" has been deleted and

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

REASON FOR ALLOWANCE

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

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

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

Conclusion

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

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

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

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

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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S46	6514	S45 and (catheter tube medica$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:51
S49	5948	S45 and (catheter tube)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:52
S50	2092	S45 same (catheter tube)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 11:52
S51	156	S50 and catheter	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/12/14 12:40
S52	13	("5667514" | "5868754" | "5947995" | "6001118"). PN. OR ("6254610"). URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2011/07/26 15:45
S53	910	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S54	94	(604/164.02).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S55	112	(604/164.1).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34
S56	337	(604/525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2011/07/27 15:34

S57	238	(howard and root).in. (gregg and sutton).in. (jeffrey and welch).in. (jason and garrity).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/07/27 15:35
S58	49	("20030195546" | "20030195546" | "20040127927" | "20050182437" | "20070260219" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "5776141" | "6159195" | "6338725" | "6475195" | "6595952" | "6610068" | "6638268" | "6638268" | "6689144" | "6706018" | "6755812" | "6860678" | "7697996" | "7717899").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2011/07/27 15:36

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S59	0	(604/164.1).CCLS.	UPAD	OR	OFF	2011/07/27 15:34
S60	0	(604/525).CCLS.	UPAD	OR	OFF	2011/07/27 15:34

7/27/2011 11:32:13 PM
C:\Documents and Settings\bosinski\My Documents\EAST\Workspaces\11416629.wsp

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY J OSINSKI	3767

SEARCHED			
Class	Subclass	Date	Examiner
604	103.04, 103.09, 160-162, 164.01, 164.09-164.11, 525	11/6/2008	bjo
604	164.01,164.02,525	7/27/2011	bjo

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Terms	11/6/2008	bjo
IDS	7/28/2010	bjo
Updated Search	12/14/2010	bjo
Final Search	7/27/2011	bjo

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
604	164.1,525	7/27/2011	bjo

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010	07/27/2011			
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	3	N	N	N	-	-	-			
	4	N	N	N	-	-	-			
	5	N	N	N	-	-	-			
	6	N	N	N	-	-	-			
	7	N	N	N	-	-	-			
	8	✓	✓	✓	-	-	-			
	9	✓	✓	✓	-	-	-			
	10	✓	✓	✓	-	-	-			
	11	✓	✓	✓	-	-	-			
	12	✓	✓	✓	-	-	-			
	13	✓	✓	✓	-	-	-			
	14	✓	✓	✓	-	-	-			
	15	✓	✓	✓	-	-	-			
	16	✓	✓	✓	-	-	-			
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	26		N	N	-	-	-			
	27		N	N	-	-	-			
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	32				✓	-	-			
	33				✓	-	-			
	34				✓	-	-			
	35				✓	-	-			
	36				✓	-	-			

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
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8	65					✓	=			
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11	67					✓	=			
12	68					✓	=			
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14	70					✓	=			
15	71					✓	=			
16	72					✓	=			

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
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21	77					✓	=			
10	78						=			
22	79						=			

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY OSINSKI	3767

ORIGINAL		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
604	164.1	A	6	1	M	5 / 178 (2006.01.01)					
CROSS REFERENCE(S)		A	6	1	M	25 / 00 (2006.01.01)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)										
604	525										

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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2	59	18	74												
3	60	19	75												
4	61	20	76												
5	64	21	77												
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8	65														
9	66														
10	78														
11	67														
12	68														
13	69														
14	70														
15	71														
16	72														

/BRADLEY OSINSKI/ Examiner.Art Unit 3767	7/27/2011	Total Claims Allowed:	
(Assistant Examiner)	(Date)	22	
/KEVIN C SIRMONS/ Supervisory Patent Examiner.Art Unit 3767	07/28/2011	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	58	3

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86US01

Howard Root et al. Confirmation No.: 5061

Application No.: 11/416,629 Examiner: James Bradley Osinski

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

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

Sir:

This is a Request for Continued Examination (RCE) under 37 CFR § 1.114 of the above-identified application.

1. Submission required under 37 CFR § 1.114

a. [ ] Previously submitted
- [ ] Please enter in the present application the unentered Amendment under 37 CFR § 1.116, with any attachments, filed on _____ in said prior application.
- [ ] Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- [ ] Other _____

b. [X] Enclosed
- [X] A Preliminary Amendment is enclosed. Claims added by this Amendment are properly numbered consecutively beginning with the number next following the highest numbered claim in the prior application.
- [ ] Affidavit(s)/Declaration(s)
- [ ] Information Disclosure Statement (IDS)
- [ ] Other _____

2. [X] The filing fee is calculated below:

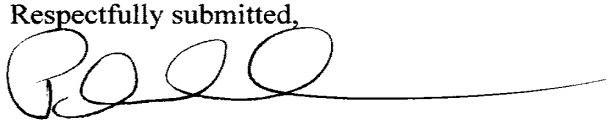
	Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra (Equals)	Small Entity Rate	Fee	OR	Large Entity Rate	Fee
Total	22	- 30	= 0	x 26	$0		x 52	$
Indep.	2	- 4	= 0	x 110	$0		x 220	$
RCE fee				+ 405	$405		+ 810	$
Mult. Dep.			=	+ 195	$0		+ 390	$
				TOTAL	$405	OR	TOTAL	$

[ ] First Presentation of Multiple Dependent Claim [MDC]

* 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, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Column 1 of a prior Amendment or the number of claims originally filed.

3. [X] Electronic payment is submitted by credit card (The RCE fee under 37 CFR § 1.17(e) is required by 37 CFR § 1.114 when the RCE is filed). 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,



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

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US01
Howard Root et al.	Confirmation No.: 5061
Application No.: 11/416,629	Examiner: James Bradley Osinski
Filed: May 3, 2006	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

PRELIMINARY AMENDMENT

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

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of December 21, 2010, and in connection with the Request for Continuing Examination (RCE) filed herewith, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

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

AMENDMENTS TO THE CLAIMS

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

1-57. (Canceled).

58. (Currently Amended) A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

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

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a ~~non-tubular~~ structure having a maximal cross-sectional dimension at a proximal portion that is ~~non-circular and~~ 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.

59. (Previously Presented) The device of claim 58 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.

60. (Currently Amended) The device of claim 59 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

61. (Currently Amended) The device of claim 60 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

62. (Previously Presented) The device of claim 58 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

63. (Previously Presented) The device of claim 62 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

64. (Previously Presented) The device of claim 59 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

65. (Previously Presented) The device of claim 58 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.

66. (Previously Presented) The device of claim 58 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.

67. (Currently Amended) A device for use with a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such

that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

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

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

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a ~~non-tubular~~ structure having a maximal cross-sectional dimension at a proximal portion that is ~~non-circular and~~ 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.

68. (Previously Presented) The device of claim 67 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.

69. (Currently Amended) The device of claim 67 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.

70. (Previously Presented) The device of claim 67 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.

71. (Previously Presented) The device of claim 67, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

72. (Currently Amended) The device of claim 67, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern [[l]].

73. (Previously Presented) The device of claim 67 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.

74. (Previously Presented) The device of claim 67 wherein the substantially rigid portion includes, starting at a from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

75. (Previously Presented) The device of claim 67 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.

76. (Previously Presented) The device of claim 75 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.

77. (Previously Presented) The device of claim 75 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.

78. (New) The device of claim 58 wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

79. (New) The device of claim 67 wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

REMARKS

Claims 58-77 are pending. By this Amendment, claims 58, 60, 61, 67, 69 and 72 are amended for clarification, and new claims 78 and 79 are added. Support for the clarifying amendments can be found throughout the specification as originally filed. Support for the new claims can be found at pg. 4, lines 4-5 and pg. 6, line 6.

Presentation of the claim amendments made herein is not an admission of any lack of either inherent or explicit written description support for the pending claim language, and Applicants maintain the right to present new arguments, amendments, and claims in subsequent prosecution.

No narrowing amendments are intended and no new matter has been added by the amendments.

Claim Rejections – 35 U.S.C. § 112

With respect to paragraph 1.a and 4.u of the Office Action, Applicants submit that the rejection of independent claims 58 and 67 for lack of written description is an improper attempt to limit Applicant's claim scope to only the specific embodiments depicted. The MPEP, including MPEP § 2111.01, as well as Federal Circuit case law, repeatedly emphasize that claim scope is not to be limited to the embodiments depicted in the specification and that limitations in the specification should not be read into the claims. *See, Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)

Satisfaction of the written description requires only that the specification convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. MPEP § 2163(I)(B) (citing *Vas-Cath, Inc. v. Marhurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)). The application as filed clearly describes and differentiates circular, cylindrical tubular shapes from those that are partially circumferential, non-circular or non-tubular, for example, and conveys the description of the claimed invention to one skilled in the art. The rejection of paragraph 1.a. of the Office Action and the arguments present in paragraph 4.u of the Office Action would seek to require Applicants to submit an essentially unlimited number of figures describing every conceivable shape other than circular in order for the applicant to be entitled to use the term non-circular. Plainly, this is not what is intended or required by the statute or the case law. Such a rejection is both legally improper and factually unfounded.

Without acquiescing in the Examiner's position with respect to the negative limitations in independent claims 58 and 67, and without surrendering any claim scope or right to assert similar claims in a future application, Applicant has amended these claims to remove these terms solely for the purpose of advancing prosecution, and the rejection under paragraph 1.a of the Office Action should be withdrawn.

With respect to the rejection of dependent claim 65 in paragraph 1.b. of the Office Action, support for the 1 French difference between the diameter of the claimed device and the diameter of a standard guidewire can be clearly found, for example, in the paragraph of the specification as originally filed at page 5, starting at line 8. While the word "gap" may not be used in this paragraph, without a doubt the concept of a 1 French difference between the two

diameters is described. Accordingly, the rejection in paragraph 1.b. of the Office Action should be withdrawn.

With respect to the rejection of claim 70 in paragraph 1.c. of the Office Action, it is noted that the arguments made in the previous response with respect to this rejection were not addressed in the Office Action. In addition to the support for a single hemostatic valve as previously identified in Figure 4, additional support can be at page 9 of the specification as originally filed, beginning at line 15 describing the ability to use embodiments of the invention with existing hemostatic valve arrangements. When read in context in view of the entire disclosure that describes the disadvantages of needing additional hemostatic valves (e.g., page 4, line 5), a person skilled in the art would plainly understand that the passage at page 9 is describing the use of the invention with a single hemostatic valve as is preferred in the existing hemostatic value arrangements. Accordingly, this rejection in paragraph 1.c. of the Office Action should be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 58-65, 67, 68, 70-73 and 75-77 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (U.S. Patent No. 6,638,268) in view of Solar (U.S. Publ. No. 2003/0195546A1). These rejections are respectfully traversed as a *prima facie* case of obviousness has not been established.

With respect to paragraphs 2.d, 2.l, and 4.v of the Office Action, independent claims 58 and 67 have been amended to clarify that it is the "predefined length" of the "standard guide catheter" which is being used as the basis for the limits on the claimed length of the "flexible tip portion." No narrowing of intended claim scope is made by these clarifying amendments.

Contrary to the arguments set forth in paragraph 4.v., the recitation of the "predefined length" in the preamble must be treated as a claim limitation. "Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." MPEP § 2111.02(I). Plainly, the reference to the "predefined length" is a limitation that limits the structure of the "flexible tip portion" of the claim invention. Accordingly, Niazi's tip portion 52 cannot satisfy this claim limitation.

With respect to paragraphs 2.d, 2.l, and 4.w of the Office Action, independent claims 58 and 67 have been amended to clarify that the intended scope of the claims was that the "flexible tip" is less rigid than the "rigid portion" by adding the clarifying language that the "rigid portion" is "more rigid along a longitudinal axis than, the flexible tip portion." No narrowing of intended claim scope is made by these clarifying amendments. In view of the clarifying amendment, the argument in paragraph 4.w based on the misconstruction of the intended scope of the claims has been overcome. Accordingly, as Niazi's distal portion is reinforced and rigid, Niazi cannot satisfy this claim limitation.

With respect to paragraphs 2.d, 2.l, and 4.x of the Office Action, the arguments for a reasoned rationale for combining Niazi with Solar based on the motivation of "using less material" made in paragraph 4.x are traversed. First, the argument of "using less material" is effectively an argument for a "less expensive product." However, the amount of material alone does not dictate the cost of a product such as the claimed invention. A person skilled in the art would recognize that changing the shape or eliminating material from that of an off-the-shelf tube actually would result in a more expensive product, not a less expensive product, due to the additional processing requirements, or the requirement for a specially constructed tube, or the

requirements for joining together two different members of different shapes. Second, the argument of "using less material" effectively ignores the reasoning recited in paragraph 4.w of the Office Action that the device must be "rigid enough to allow the device to be advanced through the guide catheter." The need for sufficient rigidity in the claimed invention in order to operate as designed works against any kind of blanket assertion that it would be obvious to reduce cost by reducing material.

With respect to paragraphs 2.f, 3.t, and 4.y of the Office Action, dependent claims 60 and 69 have been amended to clarify that the intended scope of the claims was that the "side opening" is not an end by adding the clarifying language to claim 60 of "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," and the clarifying language to claim 69 of "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." No narrowing of intended claim scope is made by these clarifying amendments. In view of the clarifying amendments, the argument in paragraph 4.y based on the misconstruction of the intended scope of the claims as reading on an end instead of a side has been overcome. With respect to paragraphs 2.e, 2.m and 2.n of the Office Action, independent claims 58 and 67 have been amended have been amended to clarify that the intended scope of the claims in that the rigid portion has "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".

With respect to paragraphs 2.g and 2.r of the Office Action, it is respectfully submitted that the argument that a hypothetical partial turn of a coil could satisfy the claimed limitation of a "partially cylindrical portion a specious argument as the coil 55 is surrounding the inner guide catheter 52 and does nothing to alter the fact that the inner guide catheter 52 is, admittedly, a circular, cylindrical construction and does not show a non-circular, partially cylindrical structure as required by dependent claim 61 or a hemicylindrical portion as required by dependent claim 74.

With respect to paragraph 2.s of the Office Action, it is respectfully submitted that the present application has shown the particular purpose and stated problem that the claimed structural arrangement overcomes, as recited, for example, in dependent claim 59. The argument advanced in paragraph 2.s of the Office Action is a classical example of the use of impermissible hindsight.

Claims 66, 69 and 74 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi in view of Solar and further in view of Klein et al (U.S. Patent No. 5,776,141). These rejections are respectfully traversed as a *prima facie* case of obviousness has not been established.

With respect to paragraphs 2.n, 3.t, and 4.z of the Office Action, as the argument in paragraph 4.z can best be understood, the sections of Klein or any of the other references may be labeled however the Examiner would like; however, the teaching of each of these references must be applied to the invention as claimed. Here the claimed inventions include numerous limitations with respect to the proximal and distal relation of sections of the device along a longitudinal axis of the device. Contrary to the assertion made in paragraph 2.n that "One may

assemble the device as they see fit, as there is no structure preventing such", there are numerous claim limitations defining the structural proximal and distal relation of the sections along the longitudinal axis. Applicants respectfully submit that however Klein, Solar or Niazi are labeled, none of them teach the claimed arrangement of sections along that longitudinal axis. All of the cited references teach an arrangement of sections along a longitudinal axis having different flexibilities than the claimed inventions. Accordingly, a *prima facie* case of obviousness has not been established for the claimed inventions.

The arguments made in the prior responses are hereby adopted and incorporated by reference.

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

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

Respectfully submitted,

Paul C. Onderick
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Electronic Patent Application Fee Transmittal	
Application Number:	11416629
Filing Date:	03-May-2006
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Filer:	Paul C. Onderick/Mary Peterson
Attorney Docket Number:	2005.86US01
Filed as Small Entity	

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	2801	1	405	405
		Total in USD ($)		**405**

Electronic Acknowledgement Receipt	
EFS ID:	9495321
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Peterson
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86US01
Receipt Date:	22-FEB-2011
Filing Date:	03-MAY-2006
Time Stamp:	16:55:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$405
RAM confirmation Number	4037
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 1.16 (National application filing, search, and examination fees) 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	Request for Continued Examination (RCE)	2005_86US01_RCE.pdf	66940 cf6f660df5f86fc833311a57af4d932389f3e8a2	no	2
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2		2005_86US01_amdt.pdf	527326 a86cf1dfabdf2e9842d4f4de8760a3abedec01a3	yes	16

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	9
Applicant Arguments/Remarks Made in an Amendment	10	16

Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30135 309dbaec3b933a8ec7732d03bc0d0d1107ab29b9	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	624401		

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
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.

Electronic Acknowledgement Receipt	
EFS ID:	9495321
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Peterson
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86US01
Receipt Date:	22-FEB-2011
Filing Date:	03-MAY-2006
Time Stamp:	16:55:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$405
RAM confirmation Number	4037
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 1.16 (National application filing, search, and examination fees) 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	Request for Continued Examination (RCE)	2005_86US01_RCE.pdf	66940 cf6f660df5f86fc833311a57af4d932389f3e8a2	no	2
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2		2005_86US01_amdt.pdf	527326 a86cf1dfabdf2e9842d4f4de8760a3abedec01a3	yes	16

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	9
Applicant Arguments/Remarks Made in an Amendment	10	16

Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30135 309dbaec3b933a8ec7732d03bc0d0d1107ab29b9	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	624401		

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
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.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/416,629	Filing Date 05/03/2006	☐ To be Mailed

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	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 = *		X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 = *		X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT	02/22/2011	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 22	Minus	** 30	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***4	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) 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))									
	☐ 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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/POLIN ANG/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

24113 7590 12/21/2010

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MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	**PAPER NUMBER**
3767	
MAIL DATE	**DELIVERY MODE**
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/416,629	ROOT ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 58-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. In independent claims 58 and 67, Applicant includes numerous negative limitations that are not in the original application including non-expandable, non-tubular and non-circular. These negative limitations, while precluding certain shapes, encompass shapes that were not in the application as originally filed.

b. Claim 65, Applicant includes another limitation limiting the gap between the tubular structure and guide catheter to be less than one french. However, this was not found during a word search of the specification.

c. Claim 70, Applicant includes another negative limitation regarding only a single hemostatic valve and some intended use that is also not immediately found in the specification. Mapping the claim to the specification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 58-65, 67, 68, 70-73 and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Solar (2003/0195546).

d. Regarding claim 58, Niazi discloses a coaxial guide catheter 52 comprising a tubular structure (see figures 3 and 6) that has a circular cross-section and is sized to be insertable though the lumen of the guide catheter 51 and defines a coaxial lumen though which cardiology devices are insertable. The distal flexible tip of the coaxial guide catheter 52 includes a taper (figure 3) that is flexible and is suitable for extending beyond the distal end of the guide catheter and is of a size that an interventional cardiology device is insertable. A rigid portion is proximal of and connected to the flexible tip portion. that when combined with the tip is longer than the lumen of the catheter (figure 3). The hemostatic valve 56 allows the rigid portion to extend proximally while the flexible tip is extended distally of the catheter with an interventional cardiology device (such as an obturator) within the catheter (such as figure 3).

While Niazi substantially discloses the apparatus as claimed, it does not disclose the rigid portion coupled to the tubular structure having a non-circular cross section.

However, Solar discloses an elongate device comprising a pushing member 5 and tracking member 7 that is rigid and becomes more flexible as it moves distally (Paragraph 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the elongate structure of Niazi proximal the coil 55 with a rigid pushing structure (including the flexibility gradient) as taught by Solar as it would provide the expected result of decreasing the amount of material required proximally and allow the guide catheter 50 to be guided to the desired location.

Regarding the non-circular shape specifically, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the pushing member 5 to be non-circular because Applicant has not disclosed that such a limitation provides an unexpected advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Niazi and Solar because a non-circular cross-section would have the ability to perform the same function as the rod taught by Solar with only the expected result of minimizing the profile of the rod inside the device. Therefore, it would have been an obvious matter of design choice to modify Niazi and Solar to obtain the invention as specified in claim 28.

e. Regarding claim 59, as can be seen in figure 3 (figure 1 may also be used to assist in the visualization) the device is capable of/adapted to extend beyond 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 a device passing through the catheter that would otherwise dislodge the catheter (Col.6 lines 6-9).

f. Regarding claim 60, Niazi discloses a coil 55. The first proximal turn of the coil defines a proximal opening along and accessible from a longitudinal side that is capable of receiving an interventional cardiology device (such as the obturator) into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

g. Regarding claim 61, a partial turn of the coil defines a partial cylindrical portion and a full turn of the coil defines a full circumference portion.

h. Regarding claim 62, the tubular structure is comprised of a flexible cylindrical distal tip (figures 3 and 6) and a reinforced portion proximal the distal tip (Col.6 lines 49-51).

i. Regarding claim 63, Niazi discloses a reinforcing coil. However, Niazi does not disclose the coil made of metal specifically. It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose metal as the reinforcing coil material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197. 125 USPQ 416 (CCPA 1960).*

j. Regarding claim 64, while Niazi substantially discloses the apparatus as claimed, it does not disclose a radiopaque marker proximate the distal tip.

However, Solar discloses a radiopaque marker 17 to allow the system's position to be monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a radiopaque marker as taught by Solar to allow the system's position to be monitored.

k. Regarding claim 65, while Niazi discloses the catheter 52 is 8 French and the outer catheter is 9 French, making it one French smaller.

l. Regarding claim 67, see claim 58 above. Also see the reinforcing portion via coil 55.

m. Regarding claim 68, see claim 59 above.

n. Regarding claim 70, as can be seen in figure 3, the device extends an overall effective length of a coaxial lumen through which a cardiology device (such as the obturator) may be inserted while using only the hemostatic valve on the device since the device does not have to be used with the guide catheter of Niazi. Since the guide catheter itself is not claimed (other than in the preamble) any guide catheter may potentially be used with the device, including ones without a hemostatic valve. The assembly order is also intended use since these are apparatus claims. One may assemble the device as they see fit, as there is no structure preventing such.

o. Regarding claim 71, see claim 64 above.

p. Regarding claim 72, see claim 63 above (this claim also appears to have an extra letter 'l' at the end of it).

q. Regarding claim 73, see claim 65 above.

r. Regarding claim 74, see claim 66 above.

s. Regarding claims 75-77, While Niazi substantially discloses the apparatus as claimed, it does not disclose the flexural modulus' or length of each section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific flexural modulus' and lengths to each section of Niazi because Applicant has not disclosed that the lengths and modulus' provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the device of Niazi as both are customized for reaching a particular point in the body, customizing a device for a particular portion of the body was and is notoriously well known with in the art. Niazi itself is customized by adding bends and support so that the proper location may be reached. Therefore, it would have been an obvious matter of design choice to modify Niazi as to obtain the invention as specified in claims 34 and 35.

3. Claims 66, 69 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) and Solar (2003/0195546) as applied to claims 58 and 67 above and further in view of Klein et al (5,776,141).

t. Regarding claims 66, 69 and 74, while Niazi and Solar substantially disclose the apparatus as claimed, they do not disclose a hemicylindrical portion of an arcuate portion (it is unclear what shape the pusher of Solar is). However,

Klein discloses a circular pushing member 22 (circles being complete arcs) with a tracking member/sheath 60" that covers a delivery catheter 12 (disclosed for both fluid delivery and stent delivery). The sheath of Klein has a slant at the proximal end that gives it both fully cylindrical and partial cylindrical portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a rigid pushing structure (including the flexibility gradient) and tracking member (including the cylindrical shape) as taught by Klein (and Solar) as it would provide the expected result of decreasing the amount of material required proximally, allow the guide catheter 50 to be guided to the desired location and also allow the tracking member to be used for fluid delivery.

Response to Arguments

4. Applicant's arguments filed 10/8/2010 have been fully considered but they are not persuasive.

u. Applicant argues that support is present for the negative limitations rejected above. The Examiner is not convinced by Applicant's arguments as the amendments, if allowed, would entitle them to more coverage than is disclosed in their application. Additionally, the mete-and-bounds of such negative limitations are not clear. For example, regarding the non-circular limitation, page 13 states that the rigid member may have a fully circumferential section and a hemicylindrical section (in addition to other sections). The fully circumferential section is circular and the hemi-cylindrical section is partially circular. Thus at

least part of the rigid portion seems cylindrical, contrary to Applicant's claims. While the hemispherical portion is non-circular under one interpretation, it does not provide support for other interpretations of non-circular, such as rectangular, square, other polygonal shapes or ovular. The same is applicable to non-tubular and non-expandable, it is uncertain where the threshold is for each negative limitation is such that they may encompass structures not disclosed by Applicant and thus they constitute new matter.

v. Applicant argues Niazi does not disclose a flexible tip portion that has the claimed length. This is not persuasive for two reasons. The first is that Applicant has not positively claimed the guide catheter. It is only present in the preamble and the preamble makes it clear a device is being claimed (second word of claim) and that said device that does not include the guide catheter in the 'comprising' section. Thus any guide catheter may be imagined which has a length significantly longer than the tip portion. Secondly, the combination rejection above makes it clear that the entire length of Niazi's 52 is not being considered the tip *portion*.

w. Applicant argues that Niazi does not disclose the claimed invention as Niazi teaches the distal portion should be reinforced and more rigid. The Examiner is not convinced as the section of Niazi is reinforced only so that it does not collapse, figures 1-3 show that the reinforced section must be flexible, otherwise it would not be movable in the guide catheter. Col.6 lines 51-54 also specifically stat that the hoop reinforcements are only for preventing collapse and

do not prevent the device from bending in a flexible manner. Additionally, Applicant never claims the tip is less rigid than the proximal portion. The proximal portion is disclosed as being substantially rigid. This is interpretable as it is only rigid enough to allow the device to be advanced within the guide catheter.

x. Applicant argues that the motivation of "using less material" is not a reasoned rationale for combining two references. The Examiner is not convinced as cost-savings is as much a reason for inventing something as other reasons. Reducing the material needed by the device would certainly reduce production costs which is a driving factor for any business. Niazi discloses an internal tube 52 that exits from both ends of catheter 51. Since catheter 51 already provides a closed lumen, there is no need for internal tube 52 to do so as well, other than where it exits and enters the catheter 51.

y. Applicant agues that an end does not constitute a longitudinal side. The Examiner maintains that an end is a longitudinal opening and on one of the three sides of a cylinder.

z. Applicant argues against the Klein combination with reference to parts of pushing member 22 and catheter 12 belonging to each other. However, Klein shows a transition of a hemi-spherical portion between a fully circumferential catheter portion 12 and pushing member 22. The Applicant argues that such a transition must automatically belong to the catheter portion 12. However, the Examiner reserves the right to label each section of the device so long as it remains consistent with the labels meaning. The transition section may just as

easily be considered part of pushing member 22 (which meets the claim) as it may catheter 12.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	742	(604/524-525).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2010/12/14 09:21
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EAST Search History (Interference)

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
11416629	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY J OSINSKI	3767

SEARCHED			
Class	**Subclass**	**Date**	**Examiner**
604	103.04, 103.09, 160-162, 164.01, 164.09-164.11, 525	11/6/2008	bjo

SEARCH NOTES		
Search Notes	**Date**	**Examiner**
EAST Search Terms	11/6/2008	bjo
IDS	7/28/2010	bjo
Updated Search	12/14/2010	bjo

INTERFERENCE SEARCH			
Class	**Subclass**	**Date**	**Examiner**

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US01
Root et al.	Confirmation No.: 5061
Application No.: 11/416,629	Examiner: Bradley James Osinski
Filed: May 3, 2006	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

RESPONSE

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

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of July 30, 2010, entry of the following remarks to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Claims

B. Remarks

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

PRESENTATION OF THE CLAIMS

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

1-57. (Canceled).

58. (Previously Presented) A device for use with a guide catheter having a continuous lumen extending for a 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 cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

a flexible tip portion defining a non-expandable tubular structure having a circular cross-section and a length that is shorter than the 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 the flexible tip portion and defining a non-tubular structure having a maximal cross-sectional dimension at a proximal portion that is non-circular and 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, 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.

59. (Previously Presented) The device of claim 58 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.

60. (Previously Presented) The device of claim 59 wherein the proximal portion of the tubular structure further comprises structure defining a proximal opening along and accessible from a longitudinal side to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

61. (Previously Presented) The device of claim 60 wherein the proximal opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

62. (Previously Presented) The device of claim 58 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

63. (Previously Presented) The device of claim 62 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

64. (Previously Presented) The device of claim 59 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

65. (Previously Presented) The device of claim 58 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.

66. (Previously Presented) The device of claim 58 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.

67. (Previously Presented) A device for use with a guide catheter having a continuous lumen extending for a length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery, the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery, the device comprising:

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

a flexible tip portion defining a non-expandable 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 length of the continuous lumen of the guide catheter, the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable

through the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;

a reinforced portion proximal to the flexible tip portion; and

a substantially rigid portion proximal of and connected to the flexible tip portion and defining a non-tubular structure having a maximal cross-sectional dimension at a proximal portion that is non-circular and 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.

68. (Previously Presented) The device of claim 67 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.

69. (Previously Presented) The device of claim 67 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening along a side thereof 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.

70. (Previously Presented) The device of claim 67 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen through which an interventional cardiology device may be inserted while utilizing only a single hemostatic valve and without any telescoping structure preassembled prior to the device being inserted into the continuous lumen of the guide catheter.

71. (Previously Presented) The device of claim 67, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

72. (Previously Presented) The device of claim 67, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern l.

73. (Previously Presented) The device of claim 67 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.

74. (Previously Presented) The device of claim 67 wherein the substantially rigid portion includes, starting at a from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

75. (Previously Presented) The device of claim 67 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.

76. (Previously Presented) The device of claim 75 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.

77. (Previously Presented) The device of claim 75 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.

REMARKS

Claims 58-77 are pending. By this Amendment, no claims are amended, added or canceled.

Section 112

Claims 58-77 stand rejected under 35 U.S.C. 112, first paragraph for purportedly failing to comply with the written description requirement, particularly with respect to independent claims 58 and 67, and dependent claims 65 and 70. These rejections are respectfully traversed as a *prima facie* case has not been established.

"The current view of the courts is that there is nothing inherently ambiguous or uncertain about a negative limitation." MPEP 2173.05(i). Moreover, merely noting "a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)." MPEP 2173.05(i).

Specifically, with respect to the limitations "non-expandable, non-tubular and non-circular" in independent claims 58 and 67, written description support for all of these claim limitations can be found throughout the specification and drawings, for example, with respect to Figs. 1, 2, 5 and 6, and the nature of the claimed invention as including first full circumference, hemicylindrical and arcuate portions is discussed extensively beginning at page 13 of the specification as originally filed.

With respect to the limitations of dependent claim 65, it is respectfully submitted that the mere failure to find a word in the original specification based on a keyword search cannot be a

proper basis establishing a written description rejection. The written description requirement does not require *ipsis verbis* antecedent basis of specific claim terms in the original specification. In terms of the claimed differences in inner diameter as set forth in this dependent claim, various exemplary embodiments showing this relationship are described, for example, at page 5 of the specification as originally filed.

With respect to the limitations of dependent claim 70 regarding only a single hemostatic valve, the Fig. 4 clearly shows a single hemostatic valve and the background section expressly discusses the disadvantages of having to use a "new" (i.e., another or a second) hemostatic valve at page 4 of the specification as originally filed.

Accordingly, it is respectfully requested that these rejections should be withdrawn.

Section 103

Claims 58-65, 67, 68, 70-73 and 75-77 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (U.S. Patent No. 6,638,268) in view of Solar (U.S. Publ. No. 2003/0195546A1). These rejections are respectfully traversed as a *prima facie* case of obviousness has not been established.

It is respectfully submitted that, even if there were a reasoned rationale to combine Solar with Niazi, which there is not, the proposed combination still fails to show all of the claimed limitations of at least independent claims 58 and 67. Contrary to the assertion in the Office Action, Niazi does not teach a "flexible *tip* portion" that has "a length that is shorter than the length of the continuous lumen" of the guide catheter. As is clearly shown in Fig. 3 of Niazi the "inner guide or catheter 52" that is circular in cross-section extends both proximally of the

hemostatic valve 56 and distally of the end of "outer guiding catheter 51." Thus, the catheter 52 of Niazi is exactly opposite of the claimed "flexible *tip* portion" because Niazi teaches that catheter 52 is longer than, *not shorter than*, the length of the continuous lumen of the outer guide catheter 51.

The argument in the Office Action then proposes that, if the coil 55 of Niazi (instead of the entire inner guide catheter 52), is assumed to be the "flexible *tip* portion," that it would have been obvious to "replace the elongate structure of Niazi proximal the coil 55 with a rigid plastic structure." However, the alternate embodiment described by Niazi uses the coil 55 to "reinforce" the inner guide catheter 52 at the *distal end.* (See Col. 6, lines 46-54). Thus, Niazi is, again, teaching opposite of the claimed invention by teaching that it is the distal portion of inner guide catheter 52, and not the proximal portion, that should be reinforced and more rigid.

Despite the subsequent argument regarding reinforced coil portion 55 in Niazi, the Office Action admits that Niazi does not teach "a rigid portion coupled [proximal] to the tubular structure having a non-circular cross section." To supply this missing element, the Office Action proposes a combination of Solar with Niazi for the reason of "decreasing the amount of material needed" for the device. Not only is the proposed combination not motivated or suggested by either reference or by the stated reason of decreasing the material needed, the proposed combination still fails to teach all of the elements and limitations of the claimed invention.

First, the elongate device of Solar is admittedly a "tracking" arrangement where the tubular tracking member 7 is designed to track over a "standard guide wire 9." Because the operation of a tracking guide wire arrangement is fundamentally different than the operation of a guide catheter arrangement, the suggestion that a person skilled in the art would be motivated to

somehow smash together these two different approaches is simply not well founded. See, for example, the discussion in Solar of how using the guide wire apparatus without any kind of guide catheter avoids the need for the bulky catheter structures [0031]. It is respectfully submitted that advancing a generalized design objective of "using less material" cannot, by itself, even begin to meet the requirement for presenting a reasoned rationale for combining two references with such completely different approaches for vascular access. Such an argument is facially insufficient in view of the recently promulgated KSR guidelines for evaluating the obviousness of claimed inventions.

Second, the advancement member 5 of Solar is only discussed in terms of "a flexible wire or, alternatively, a spring hollow hypotubing." [0025]. Both of these configurations would not meet the claim limitation that the proximal rigid portion be "non-circular". Contrary to the unsupported assertion in the Office Action that the cross-section of the advancement member 5 could be a matter of design choice, there is simply nothing in Solar that the advancement member could be non-circular. The lack of any such teaching completely undermines the purported combination of these two references when Solar is being used for the admitted reason that Niazi lacks the very *non-circular* rigid portion that Solar is supposedly to be supplying.

Finally, Solar, like Niazi, teaches away from a *distal "flexible tip* portion" and a *proximal "rigid* portion." The combined device in Solar of advancement member 5 and tubular tracking member 7 would result in a flexibility from proximal to distal end would be rigid-flexible-rigid as the tracking member 7 is necessarily more rigid than the flexible distal end of advancement member 5.

A person skilled in the art reading the teaching of Niazi as a whole would understand that Niazi is teaching a conventional, full-length catheter-within-catheter arrangement that uses two hemostatic valves (valve 57 for outer catheter 51 and valve 56 for inner guide catheter 52) and, in one embodiment, a reinforced and more rigid distal tip portion 55. There is nothing about Niazi or Solar that would suggest or motivate a person skilled in the art to alter the fundamental manner of operation of a catheter-within-catheter arrangement as has been suggested in the Office Action only with the improper benefit of the hindsight of the present invention. Even if there were some reasoned rationale to combine the very different approaches of a guide wire system with a guide catheter system, which has not been shown, it is respectfully submitted that both Niazi and Solar would be viewed by a person skilled in the art as teaching the desirability of a similar "flexibility" profile or either a guide catheter or a guide wire approach, namely having a more rigid, reinforced tubular portion at the distal end of the device.

With respect to dependent claim 60, it is respectfully submitted that the coil 55 of Niazi does not satisfy the limitation of "accessible from a longitudinal side." The coil 55 of Niazi is only accessible from an end, not a side.

With respect to dependent claim 61, it is respectfully submitted that the argument that a hypothetical partial turn of a coil could satisfy the claimed limitation of a "partially cylindrical portion a specious argument as the coil 55 is surrounding the inner guide catheter 52 and does nothing to alter the fact that the inner guide catheter 52 is, admittedly, a circular, cylindrical construction and does not show a non-circular, partially cylindrical structure.

With respect to dependent claim 62, it is respectfully submitted that, for the reasons discussed above about the distally positioned nature of reinforced coil 55, Niazi teaches the opposite of the limitations of this claim.

With respect to dependent claim 70, it is respectfully submitted that the claimed limitations of the "flexible tip portion" being shorter than a length of the continuous lumen as measured from a hemostasis valve as recited in the preamble positively claim and rebut the assertion in the Office Action that the device could or would be used in a guide catheter arrangement without a hemostasis valve.

Finally, regarding the broad assertion that the longitudinal flexibility of Niazi could have been modified in the manner as claimed, it is respectfully submitted for the reasons set forth that Niazi, and for that matter, Solar, both teach an arrangement of longitudinal flexibility that is different from, and opposite of, the claimed invention.

Claims 66, 69 and 74 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi in view of Solar and further in view of Klein et al. (U.S. Patent No. 5,776,141). This rejections are respectfully traversed as a *prima facie* case of obviousness has not been established.

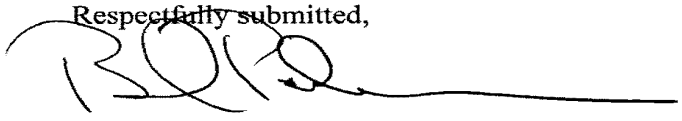
It is respectfully submitted that the citation of Klein supports, rather than defeats, the non-obviousness of the claimed inventions. As admitted in the Office Action, Klein shows a "*circular* pushing member 22." But the pushing member 22 would correspond to the rigid proximal, *non-circular* portion of the claimed invention, not the *tubular, flexible tip* portion of the claimed invention. Thus, regardless of whether the slanted end of the catheter 12 would or

would not satisfy the claimed limitations of these dependent claims, the slant taught by Klein is applied to wrong element of the claimed invention.

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 Acknowledgement Receipt	
EFS ID:	8588667
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Michelle Arcand
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86US01
Receipt Date:	08-OCT-2010
Filing Date:	03-MAY-2006
Time Stamp:	13:20:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86US01_AMEND.pdf	489296 c85e6f6c348e8b31511c75555c74f5242b27ad2b	yes	15

VSI_00000180

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	2
	Claims	3	8
	Applicant Arguments/Remarks Made in an Amendment	9	15
Warnings:			
Information:			
	Total Files Size (in bytes):	489296	

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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.

PTO/SB/06 (07-06)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/416,629	Filing Date 05/03/2006	☐ To be Mailed

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	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 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))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	10/08/2010	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 20	Minus	** 30	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 2	Minus	***4	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT		(Column 1)		(Column 2)	(Column 3)					
		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))									
	☐ 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 number found in the appropriate box in column 1.

Legal Instrument Examiner:
/ERIC V. BURNS/

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.**

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

24113 7590 07/30/2010

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

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

MAIL DATE	DELIVERY MODE
07/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/416,629	ROOT ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-28-2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/28/2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 58-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

   a. In independent claims 58 and 67, Applicant includes numerous negative limitations that are not in the original application including non-expandable, non-tubular and non-circular. These negative limitations, while precluding certain shapes, encompass shapes that were not in the application as originally filed.

b. Claim 65, Applicant includes another limitation limiting the gap between the tubular structure and guide catheter to be less than one french. However, this was not found during a word search of the specification.

c. Claim 70, Applicant includes another negative limitation regarding only a single hemostatic valve and some intended use that is also not immediately found in the specification. Mapping the claim to the specification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 58-65, 67, 68, 70-73 and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Solar (2003/0195546).

d. Regarding claim 58, Niazi discloses a coaxial guide catheter 52 comprising a tubular structure (see figures 3 and 6) that has a circular cross-section and is sized to be insertable though the lumen of the guide catheter 51 and defines a coaxial lumen though which cardiology devices are insertable. The distal flexible tip of the coaxial guide catheter 52 includes a taper (figure 3) that is flexible and is suitable for extending beyond the distal end of the guide catheter and is of a size that an interventional cardiology device is insertable. A rigid portion is proximal of and connected to the flexible tip portion. that when combined with the tip is longer than the lumen of the catheter (figure 3). The

hemostatic valve 56 allows the rigid portion to extend proximally while the flexible tip is extended distally of the catheter with an interventional cardiology device (such as an obturator) within the catheter (such as figure 3).

While Niazi substantially discloses the apparatus as claimed, it does not disclose the rigid portion coupled to the tubular structure having a non-circular cross section.

However, Solar discloses an elongate device comprising a pushing member 5 and tracking member 7 that is rigid and becomes more flexible as it moves distally (Paragraph 25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the elongate structure of Niazi proximal the coil 55 with a rigid pushing structure (including the flexibility gradient) as taught by Solar as it would provide the expected result of decreasing the amount of material required proximally and allow the guide catheter 50 to be guided to the desired location.

Regarding the non-circular shape specifically, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the pushing member 5 to be non-circular because Applicant has not disclosed that such a limitation provides an unexpected advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Niazi and Solar because a non-circular cross-section would have the ability to perform the same function as the

rod taught by Solar with only the expected result of minimizing the profile of the rod inside the device. Therefore, it would have been an obvious matter of design choice to modify Niazi and Solar to obtain the invention as specified in claim 28.

e. Regarding claim 59, as can be seen in figure 3 (figure 1 may also be used to assist in the visualization) the device is capable of/adapted to extend beyond 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 a device passing through the catheter that would otherwise dislodge the catheter (Col.6 lines 6-9).

f. Regarding claim 60, Niazi discloses a coil 55. The first proximal turn of the coil defines a proximal opening along and accessible from a longitudinal side that is capable of receiving an interventional cardiology device (such as the obturator) into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

g. Regarding claim 61, a partial turn of the coil defines a partial cylindrical portion and a full turn of the coil defines a full circumference portion.

h. Regarding claim 62, the tubular structure is comprised of a flexible cylindrical distal tip (figures 3 and 6) and a reinforced portion proximal the distal tip (Col.6 lines 49-51).

i. Regarding claim 63, Niazi discloses a reinforcing coil. However, Niazi does not disclose the coil made of metal specifically. It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose

metal as the reinforcing coil material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197. 125 USPQ 416 (CCPA 1960).*

j. Regarding claim 64, while Niazi substantially discloses the apparatus as claimed, it does not disclose a radiopaque marker proximate the distal tip. However, Solar discloses a radiopaque marker 17 to allow the system's position to be monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a radiopaque marker as taught by Solar to allow the system's position to be monitored.

k. Regarding claim 65, while Niazi discloses the catheter 52 is 8 French and the outer catheter is 9 French, making it one French smaller.

l. Regarding claim 67, see claim 58 above. Also see the reinforcing portion via coil 55.

m. Regarding claim 68, see claim 59 above.

n. Regarding claim 70, as can be seen in figure 3, the device extends an overall effective length of a coaxial lumen through which a cardiology device (such as the obturator) may be inserted while using only the hemostatic valve on the device since the device does not have to be used with the guide catheter of Niazi. Since the guide catheter itself is not claimed (other than in the preamble) any guide catheter may potentially be used with the device, including ones

without a hemostatic valve. The assembly order is also intended use since these are apparatus claims. One may assemble the device as they see fit, as there is no structure preventing such.

o. Regarding claim 71, see claim 64 above.

p. Regarding claim 72, see claim 63 above (this claim also appears to have an extra letter 'l' at the end of it).

q. Regarding claim 73, see claim 65 above.

r. Regarding claim 74, see claim 66 above.

s. Regarding claims 75-77, While Niazi substantially discloses the apparatus as claimed, it does not disclose the flexural modulus' or length of each section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific flexural modulus' and lengths to each section of Niazi because Applicant has not disclosed that the lengths and modulus' provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the device of Niazi as both are customized for reaching a particular point in the body, customizing a device for a particular portion of the body was and is notoriously well known with in the art. Niazi itself is customized by adding bends and support so that the proper location may be reached. Therefore, it would have been an obvious matter of design choice to modify Niazi as to obtain the invention as specified in claims 34 and 35.

3. Claims 66, 69 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) and Solar (2003/0195546) as applied to claims 58 and 67 above and further in view of Klein et al (5,776,141).

t. Regarding claims 66, 69 and 74, while Niazi and Solar substantially disclose the apparatus as claimed, they do not disclose a hemicylindrical portion of an arcuate portion (it is unclera what shape the pusher of Solar is). However, Klein discloses a circular pushing member 22 (circles being complete arcs) with a tracking member/sheath 60" that covers a delivery catheter 12 (disclosed for both fluid delivery and stent delivery). The sheath of Klein has a slant at the proximal end that gives it both fully cylindrical and partial cylindrical portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a rigid pushing structure (including the flexibility gradient) and tracking member (including the cylindrical shape) as taught by Klein (and Solar) as it would provide the expected result of decreasing the amount of material required proximally, allow the guide catheter 50 to be guided to the desired location and also allow the tracking member to be used for fluid delivery.

Response to Arguments

4. Applicant's arguments filed 6/28/2010 have been fully considered but they are not persuasive.

u. Applicant argues that Niazi teaches away from the invention by teaching two hemostatic valves. This limitation is only in dependent claim 70, not the

independent claims. Aside from the fact that support is not found for this limitation, Applicant is not claiming the guide catheter other than in the preamble. The interior catheter and obturator of Niazi are capable of being used with other guide catheters that do not include a hemostatic valve.

v. Applicant argues Solar teaches away from a lumen large enough to receive an interventional cardiology device. No inherent meaning is give to this cardiology device that precludes structures such as guide wires and obturators. While there are certainly devices too big too fit through the device of Solar, there are certainly devices small enough.

w. Applicant argues that the Examiner uses hindsight in the design choice paragraph regarding the shape of the rod and states that such a change would cause the rod to buckle. The Examiner states a reason not used by Applicant, namely minimizing the profile of the device, which is notoriously known within the medical arts for any invasive device and thus cannot be hindsight. There is also no evidence that surface of the area has to be decreased with non-circular push rods. The device could be changed to a common rectangler shape that make it flatter in one dimension, allowing for larger device to be used. There is also no evidence that the size cannot be made smaller resulting in a column strength that will be reduced to a value that is insufficient for its usage. Simple, routine experimentation would find a balance between size, profile and material.

Conclusion

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

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY J OSINSKI	3767

SEARCHED			
Class	Subclass	Date	Examiner
604	103.04, 103.09, 160-162, 164.01, 164.09-164.11, 525	11/6/2008	bjo

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Terms	11/6/2008	bjo
IDS	7/28/2010	bjo

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	**Art Unit**
	BRADLEY J OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010				
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	2	N	N	N	-	-				
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	35				✓	-				
	36				✓	-				

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
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	Examiner	**Art Unit**
	BRADLEY J OSINSKI	3767

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CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010				
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Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY J OSINSKI	3767

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010	07/28/2010				
	73					✓				
	74					✓				
	75					✓				
	76					✓				
	77					✓				

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use as many sheets as necessary)

Complete if Known	
Application Number	11/416,629
Filing Date	May 3, 2006
First Named Inventor	Root et al.
Art Unit	3767
Examiner Name	Bradley James Osinski
Attorney Docket Number	2005.86US01

Sheet	1	of	1

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-5,776,141	07-07-1998	Klein et al.
		US-6,638,268 B2	10-28-2003	Niazi
		US-6,706,018 B2	03-16-2004	Westlund et al.
		US-6,755,812 B2	06-29-2004	Peterson et al.
		US-7,697,996 B2	04-13-2010	Manning et al.
		US-7,717,899 B2	05-18-2010	Bowe et al.
		US-2003/0195546 A1	10-16-2003	Solar et al.
		US-2007/0260219 A1	11-08-2007	Root et al.
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]

EXAMINER SIGNATURE	/Bradley Osinski/ (07/28/2010)	DATE CONSIDERED	

*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.

[1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]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.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.O./

VSI_00000198

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	17	("20030195546" | "20070260219" | "5776141" | "6638268" | "6706018" | "6755812" | "7697996" | "7717899").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2010/07/28 19:31
S1	171	(604/510).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2008/11/06 16:26
S2	28	("20050182437" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "6159195" | "6475195" | "6595952" | "6610068" | "6689144" | "6860678").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/06 16:27
S3	70	("3430631" | "3902492" | "4117836" | "4195637" | "4299226" | "4323071" | "4423725" | "4445892" | "4453545" | "4581017" | "4601706" | "4610662" | "4655746" | "4689041").PN. OR ("4832028").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 16:30
S4	51	("3811448" | "4195637" | "4323071" | "4493711" | "4573470" | "4619263" | "4641649" | "4643186" | "4748982" | "4762129" | "4790315" | "4798193" | "4824435" | "5003990" | "5040548" | "5045061" | "5061273" | "5090957" | "5090958" | "5324257" | "5324259" | "5395332" | "5413557" | "5415634" | "5505702" | "5540659" | "5569199" | "5571087" | "5575771" | "5578009" | "5605543" | "5667493" | "5667521" | "5690642" | "5706827" | "5718680" | "5728067" | "5730698" | "5752932" | "5863285" | "5879305" | "5882334" |	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:04

		"6071285" | "6394995" | "6447501" | "6500147" | "RE31800").PN. OR ("6740104").URPN.				
S5	13	("5053007" | "5129887" | "5224939" | "5389090" | "5401258" | "5445625").PN. OR ("5492530").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:10
S6	285	604/103.04	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S7	213	604/103.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S8	540	604/160	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S9	594	604/161	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S10	605	604/162	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S11	1217	604/164.01	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S12	235	604/164.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S13	196	604/164.1	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S14	311	604/164.11	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S15	484	604/525	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:23
S16	12	("4100393" | "4377165" | "4401433" | "4449973" | "4702735" | "4762516" | "4790817" | "4950252" | "4957488" | "4957489" | "D247975").PN. OR ("5971957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 08:54
S17	32	("4166469" | "4243050" | "4345606").PN. OR ("5667514").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 09:15
S18	36	("3352306" | "3565074" | "4230123" | "4581019" | "4629450" | "4772264" | "4911691" | "4978334" | "4994027" | "4995866").PN. OR ("5242410").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 10:45