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Table with 5 columns: APPLICATION NO., ISSUE DATE, PATENT NO., ATTORNEY DOCKET NO., CONFIRMATION NO.
Row 1: 12/824,734, 03/27/2012, 8142413, 2005.86US02, 1416

24113 7590 03/07/2012
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 0 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, Maple Grove, MN;
Jeffrey M. Welch, Maple Grove, MN;
Jason M. Garrity, Minneapolis, MN;

Receipt date: 11/19/2010

12824734 - GAU: 3767

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>			
				Application Number	12/824,734		
				Filing Date	June 28, 2010		
				First Named Inventor	Howard Root et al.		
				Art Unit	3734		
Examiner Name	Not Yet Assigned						
Attorney Docket Number	2005.86US02						
Sheet	1	of	3				
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		
		Number-Kind Code <sup>2</sup> (if known)					
		US-4,813,930		03-21-1989	Elliott		
		US-4,832,028		05-23-1989	Patel		
		US-4,932,413		06-12-1990	Shockey et al.		
		US-5,098,412		03-24-1992	Shiu		
		US-5,122,125		<del>04</del> -16-1992	Deuss		
		US-5,472,425		12-05-1995	Teirstein		
		US-5,658,263		08-19-1997	Dang et al.		
		US-5,776,141		07-07-1998	Klein et al.		
		US-6,159,195		12-12-2000	Ha et al.		
		US-6,338,725		01-15-2002	Hermann et al.		
		US-6,475,195		11-05-2002	Voda		
		US-6,595,952		07-22-2003	Forsberg		
		US-6,610,068		08-26-2003	Yang		
		US-6,638,268		10-28-2003	Niazi		
		US-2003/0195546		10-16-2003	Solar et al.		
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)					
EXAMINER SIGNATURE	/Bradley Osinski/ (07/28/2011)			DATE CONSIDERED			
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.                  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.</small>							

Change(s) applied to document, /M.A.H./ 2/22/2012

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

VSI\_00000455

A01787

**PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
 Commissioner for Patents  
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 or Fax (571)-273-2885**

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

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

24113 7590 01/17/2012  
**PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.**  
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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

**Certificate of Mailing or Transmission**

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

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

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

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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

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

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "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.</p>	<p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,</p> <p>(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.</p>
--	--

1 Patterson Thuente  
 2 Christensen Pedersen PA  
 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)

**Vascular Solutions, Inc. 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

<p>4a. The following fee(s) are submitted:</p> <p><input checked="" type="checkbox"/> Issue Fee</p> <p><input checked="" type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input checked="" type="checkbox"/> Payment by credit card.</p> <p><input checked="" type="checkbox"/> The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number <u>160631</u> (enclose an extra copy of this form).</p>
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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 2-20-2012

Typed or printed name Paul C. Onderick Registration No. 45354

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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

<b>Application Number:</b>	12824734			
<b>Filing Date:</b>	28-Jun-2010			
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES			
<b>First Named Inventor/Applicant Name:</b>	Howard Root			
<b>Filer:</b>	Paul C. Onderick/Allison Goette			
<b>Attorney Docket Number:</b>	2005.86U502			
Filed as Small Entity				
<b>Utility under 35 USC 111(a) Filing Fees</b>				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Basic Filing:</b>				
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				
<b>Post-Allowance-and-Post-Issuance:</b>				
Utility Appl issue fee	2501	1	870	870
Publ. Fee- early, voluntary, or normal	1504	1	300	300

VSI\_00000457



Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Extension-of-Time:</b>				
<b>Miscellaneous:</b>				
<b>Total in USD (\$)</b>				<b>1170</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	12113641
<b>Application Number:</b>	12824734
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1416
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Allison Goette
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	20-FEB-2012
<b>Filing Date:</b>	28-JUN-2010
<b>Time Stamp:</b>	16:20:12
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1170
RAM confirmation Number	11663
Deposit Account	160631
Authorized User	ONDERICK,PAUL C
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <ul style="list-style-type: none"> <li>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</li> <li>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</li> </ul>	

VSI\_00000459

A01791

<b>File Listing:</b>					
<b>Document Number</b>	<b>Document Description</b>	<b>File Name</b>	<b>File Size(Bytes)/ Message Digest</b>	<b>Multi Part /.zip</b>	<b>Pages (if appl.)</b>
1	Issue Fee Payment (PTO-85B)	2005_86US02_IssueFee.pdf	86799 c371bfcd193d7f52bcbaf5f2e5f351e57e1a892	no	1
<b>Warnings:</b>					
<b>Information:</b>					
2	Fee Worksheet (SB06)	fee-info.pdf	31809 e6a5cb03c9c0b383b87407c4e4aaba438fc84e0	no	2
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			118608		
<p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p>					



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NOTICE OF ALLOWANCE AND FEE(S) DUE

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

EXAMINER
OSINSKI, BRADLEY JAMES

ART UNIT PAPER NUMBER
3767

DATE MAILED: 01/17/2012

Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Table with 7 columns: APPLN. TYPE, SMALL ENTITY, ISSUE FEE DUE, PUBLICATION FEE DUE, PREV. PAID ISSUE FEE, TOTAL FEE(S) DUE, DATE DUE

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**

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24113                      7590                      01/17/2012  
**PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.**  
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(Depositor's name)
(Signature)
(Date)

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

TITLE OF INVENTION: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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

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

<p>1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).</p> <p><input type="checkbox"/> Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.</p> <p><input type="checkbox"/> "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. <b>Use of a Customer Number is required.</b></p>	<p>2. For printing on the patent front page, list</p> <p>(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, _____ 1</p> <p>(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. _____ 2</p> <p>_____ 3</p>
---	---

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

<p>4a. The following fee(s) are submitted:</p> <p><input type="checkbox"/> Issue Fee</p> <p><input type="checkbox"/> Publication Fee (No small entity discount permitted)</p> <p><input type="checkbox"/> Advance Order - # of Copies _____</p>	<p>4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)</p> <p><input type="checkbox"/> A check is enclosed.</p> <p><input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.</p> <p><input type="checkbox"/> 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).</p>
---	--

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. \_\_\_\_\_

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Row 2: 24113, 7590, 01/17/2012, PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A., 4800 IDS CENTER, 80 SOUTH 8TH STREET, MINNEAPOLIS, MN 55402-2100
Row 3: EXAMINER OSINSKI, BRADLEY JAMES
Row 4: ART UNIT 3767, PAPER NUMBER

DATE MAILED: 01/17/2012

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

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

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

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

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

## 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.

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

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

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

1.  This communication is responsive to 11/1/2011.
2.  An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_\_; the restriction requirement and election have been incorporated into this action.
3.  The allowed claim(s) is/are 1-5,7 and 21-28.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

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

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

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

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|---|

/Bhisma Mehta/  
Primary Examiner, Art Unit 3767

/Bradley J Osinski/  
Examiner, Art Unit 3767



### **EXAMINER'S AMENDMENT**

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

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

The application has been amended as follows:

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

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

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

"6" has been deleted, and

--1-- has been inserted.

### **REASONS FOR ALLOWANCE**

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

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

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

### ***Conclusion***

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

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

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

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Art Unit: 3767

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

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

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<b>Index of Claims</b> 	<b>Application/Control No.</b> 12824734	<b>Applicant(s)/Patent Under Reexamination</b> ROOT ET AL.
	<b>Examiner</b> BRADLEY OSINSKI	<b>Art Unit</b> 3767

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

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## EAST Search History

## EAST Search History (Prior Art)

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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
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		\$ 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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S37	1	("5411514").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2009/11/17 15:06

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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
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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 (I nterference)**

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L6	0	(604/525).CCLS.	UPAD	OR	OFF	2011/12/27 13:25
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S60	0	(604/525).CCLS.	UPAD	OR	OFF	2011/07/27 15:34

12/ 27/ 2011 1:34:18 PM


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<b>Issue Classification</b> 	<b>Application/Control No.</b> 12824734	<b>Applicant(s)/Patent Under Reexamination</b> ROOT ET AL.
	<b>Examiner</b> BRADLEY OSINSKI	<b>Art Unit</b> 3767

ORIGINAL				INTERNATIONAL CLASSIFICATION											
CLASS		SUBCLASS		CLAIMED				NON-CLAIMED							
604		510		A	6	1	M	31 / 00 (2006.0)							
<b>CROSS REFERENCE(S)</b>				A	6	1	M	25 / 00 (2006.0)							
				A	6	1	M	5 / 178 (2006.0)							
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604	164.1	525													

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/BRADLEY OSINSKI/ Examiner.Art Unit 3767	12/27/2011	<b>Total Claims Allowed:</b>	
(Assistant Examiner)	(Date)	14	
/BHISMA MEHTA/ Primary Examiner.Art Unit 3767	01/11/2012	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	8

<b>Search Notes</b>  	<b>Application/Control No.</b> 12824734	<b>Applicant(s)/Patent Under Reexamination</b> ROOT ET AL.
	<b>Examiner</b> BRADLEY OSINSKI	<b>Art Unit</b> 3767

SEARCHED			
Class	Subclass	Date	Examiner
604	103.04,103.09,16-162,164.01,164.01-164.11,525	7/28/2011	bjc
604	164.1,525,164.01,164.09-164.11, 510	12/27/2011	bjc

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search, mostly from parent app 11/416,629	7/28/2011	bjc
Final Search	12/27/2011	bjc

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
604	164.1,510,525	12/27/2011	bjc

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86US02

Howard Root et al.

Confirmation No.: 1416

Application No.: 12/824,734

Examiner: Bradley James Osinski

Filed: June 28, 2010

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

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AMENDMENT

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

Sir:

INTRODUCTORY COMMENTS

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

The present amendment comprises the following sections:

- A. Amendments to the Claims
- B. Remarks

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

VSI\_00000489

A01821



AMENDMENTS TO THE CLAIMS

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

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

inserting the standard guide catheter into ~~[[the]]~~ a first ~~blood vessel~~ artery over a guidewire, the standard guide catheter having ~~a first lumen and~~ a distal end;

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

inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, ~~over a the guidewire and~~ into the ~~[[first]]~~ continuous lumen of the standard guide catheter, ~~the coaxial guide catheter having a second lumen and~~

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

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

advancing [[the]] a distal [[tip]] portion of ~~the coaxial guide catheter~~ the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery blood vessel such that the flexible distal [[tip]] portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve;

and at least a portion of the reinforced portion extend out of the distal end of the guide catheter and into the second blood vessel; and

inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion through the lumen of the coaxial guide catheter and into contact with or past a lesion in the second artery blood vessel.

2. (Currently Amended) The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal ~~[[tip]]~~ portion of the coaxial guide catheter remains seated in the second ~~blood vessel~~ artery in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.

3. (Currently Amended) The method as claimed in claim 1, further comprising:  
keying ~~[[the]]~~ a tapered inner catheter to the coaxial guide catheter at a proximal portion thereof;  
~~inserting a guidewire having a tip into a first blood vessel; and~~  
~~inserting the tip of the guidewire into a second blood vessel that branches off of the first blood vessel.~~

4. (Original) The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining ~~[[the]]~~ an opening along a side thereof.

5. (Currently Amended) The method as claimed in claim 1, further comprising selecting the standard guide catheter to further comprise a Y-adapter and the method further comprising injecting a fluid through the Y-adapter into the ~~second lumen~~ standard guide catheter.

6. (Cancelled)

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

8-20. (Canceled).

Please add new claims 21-28 as follows:

21 (New) The method as claimed in claim 1, further comprising extending a distal portion of the tubular structure beyond the distal end of the standard guide catheter while a proximal portion remains within the lumen of the standard guide catheter, such that the coaxial guide catheter assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the standard catheter from the branch artery.

22 (New) The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.

23. (New) The method of claim 22, further comprising  
extending the interventional cardiology device through the proximal side opening;  
advancing the interventional cardiology device through structure defining a full  
circumference portion; and  
advancing the interventional cardiology device through structure defining a partially  
cylindrical portion.
24. (New) The method of claim 22, further comprising extending the interventional  
cardiology device through a flexible cylindrical distal tip portion and a flexible cylindrical  
reinforced portion of the tubular structure proximal to the flexible distal tip portion.
25. (New) The method of claim 24 further comprising extending the interventional  
cardiology device through the flexible cylindrical reinforced portion that is reinforced with  
metallic elements in a braided or coiled pattern.
26. (New) The method of claim 21, further comprising extending the interventional  
cardiology device past a radiopaque marker proximate a distal tip of the coaxial guide catheter.
27. (New) The method of claim 1, further comprising selecting the cross-sectional inner  
diameter of the coaxial lumen of the tubular structure to be not more than one French smaller  
than the cross-sectional inner diameter of the guide catheter.

28. (New) The method of claim 1, further comprising extending the interventional cardiology device through the substantially rigid portion from proximal to distal through a cross-sectional shape having an arcuate portion, a hemicylindrical portion and a full circumference portion,

REMARKS

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

35 U.S.C. § 112

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

35 U.S.C. § 103

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

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



inserting the standard guide catheter into a first artery over a guidewire, the standard guide catheter having a distal end;

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

inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and

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

advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and

inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery.

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

inserting the interventional cardiology device into and through the continuous lumen of the standard guide catheter alongside of the substantially rigid portion and advancing the interventional cardiology device through and beyond a lumen of the flexible tip portion into contact with or past a lesion in the second artery

now recited in amended claim 1.

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


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

Application No. 12/824,734

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

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

Respectfully submitted,

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

Paul C. Onderick  
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## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	11312151
<b>Application Number:</b>	12824734
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1416
<b>Title of Invention:</b>	Coaxial Guide Catheter for Interventional Cardiology Procedures
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Allison Goette
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	01-NOV-2011
<b>Filing Date:</b>	28-JUN-2010
<b>Time Stamp:</b>	16:07:29
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86US02_Amendment.pdf	335076 3f6d18fee27e99613e2daf527d891e854e681d37	yes	12

VSI\_00000501

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A01833

<b>Multipart Description/PDF files in .zip description</b>			
<b>Document Description</b>		<b>Start</b>	<b>End</b>
Amendment/Req. Reconsideration-After Non-Final Reject		1	1
Claims		2	8
Applicant Arguments/Remarks Made in an Amendment		9	12

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**Information:**

**Total Files Size (in bytes):**

335076

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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.**

VSI\_00000502

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

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875					Application or Docket Number <b>12/824,734</b>		Filing Date <b>06/28/2010</b>		<input type="checkbox"/> To be Mailed			
<b>APPLICATION AS FILED – PART I</b>					SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY					
(Column 1)		(Column 2)										
FOR		NUMBER FILED	NUMBER EXTRA			RATE (\$)	FEE (\$)					
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A	N/A			N/A						
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>		N/A	N/A			N/A						
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A	N/A			N/A						
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>		minus 20 =	*			X \$ =		OR				
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =	*			X \$ =		OR				
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		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).										
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>												
					TOTAL		TOTAL					
* If the difference in column 1 is less than zero, enter "0" in column 2.												
<b>APPLICATION AS AMENDED – PART II</b>					SMALL ENTITY OR		OTHER THAN SMALL ENTITY					
(Column 1)		(Column 2)		(Column 3)								
AMENDMENT	<b>11/01/2011</b>	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)				
	Total <small>(37 CFR 1.16(i))</small>	* 14	Minus	** 20	= 0		X \$30 =	0	OR			
	Independent <small>(37 CFR 1.16(h))</small>	* 1	Minus	*** 3	= 0		X \$125 =	0	OR			
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
							TOTAL ADD'L FEE	<b>0</b>	OR		TOTAL ADD'L FEE	
(Column 1)		(Column 2)		(Column 3)								
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE (\$)	ADDITIONAL FEE (\$)				
	Total <small>(37 CFR 1.16(i))</small>	*	Minus	**	=		X \$ =		OR			
	Independent <small>(37 CFR 1.16(h))</small>	*	Minus	***	=		X \$ =		OR			
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>											
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>											
							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:  
/CHERYL CLARK/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
 If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86US02

Howard Root et al.

Confirmation No.: 1416

Application No.: 12/824,734

Examiner: Bradley James Osinski

Filed: June 28, 2010

Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

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SUBMISSION OF REPLACEMENT DRAWINGS

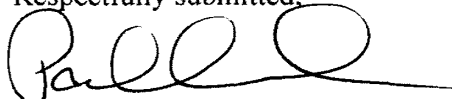
Mail Stop Issue Fee  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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,



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Patterson Thuyente Christensen Pedersen, P.A.  
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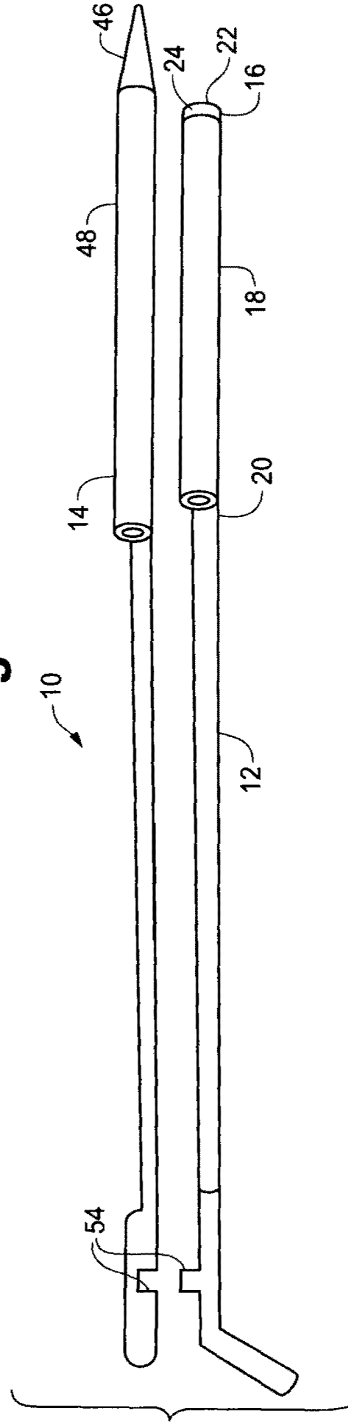
*Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.*

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A01836

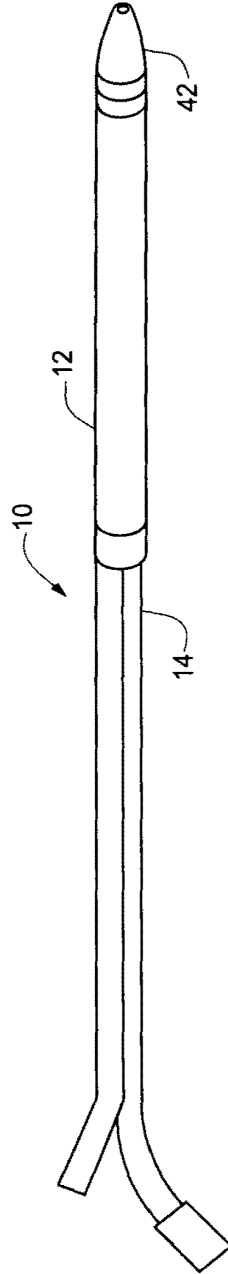
Page 51 of 191

**Fig. 1**

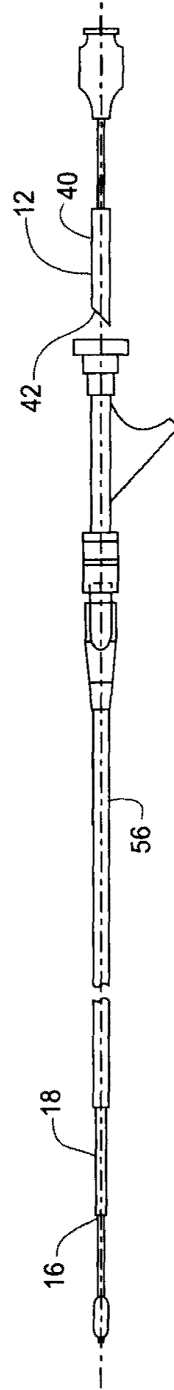




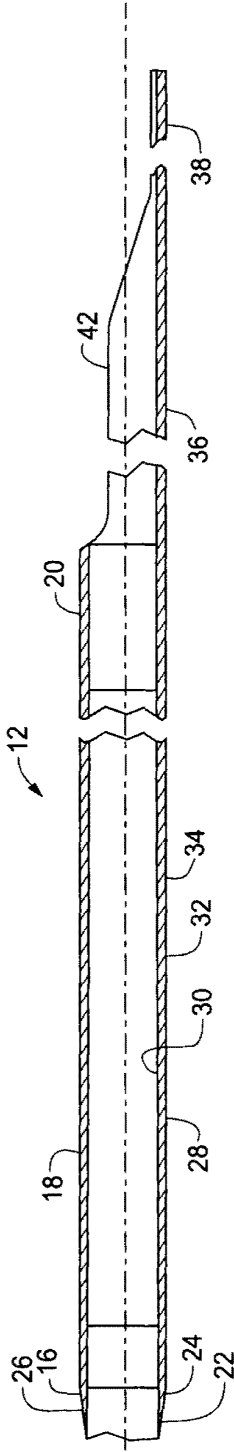
**Fig. 2**



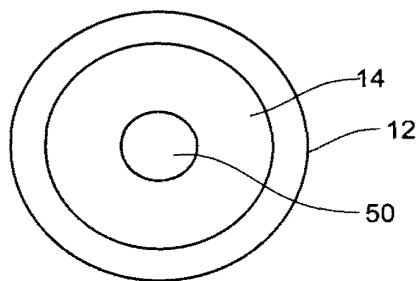
**Fig. 3**



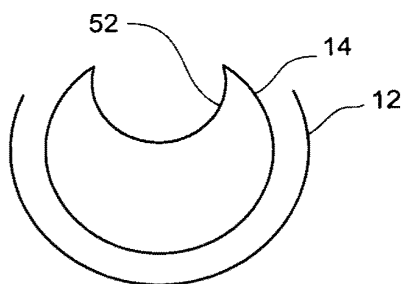
**Fig. 4**



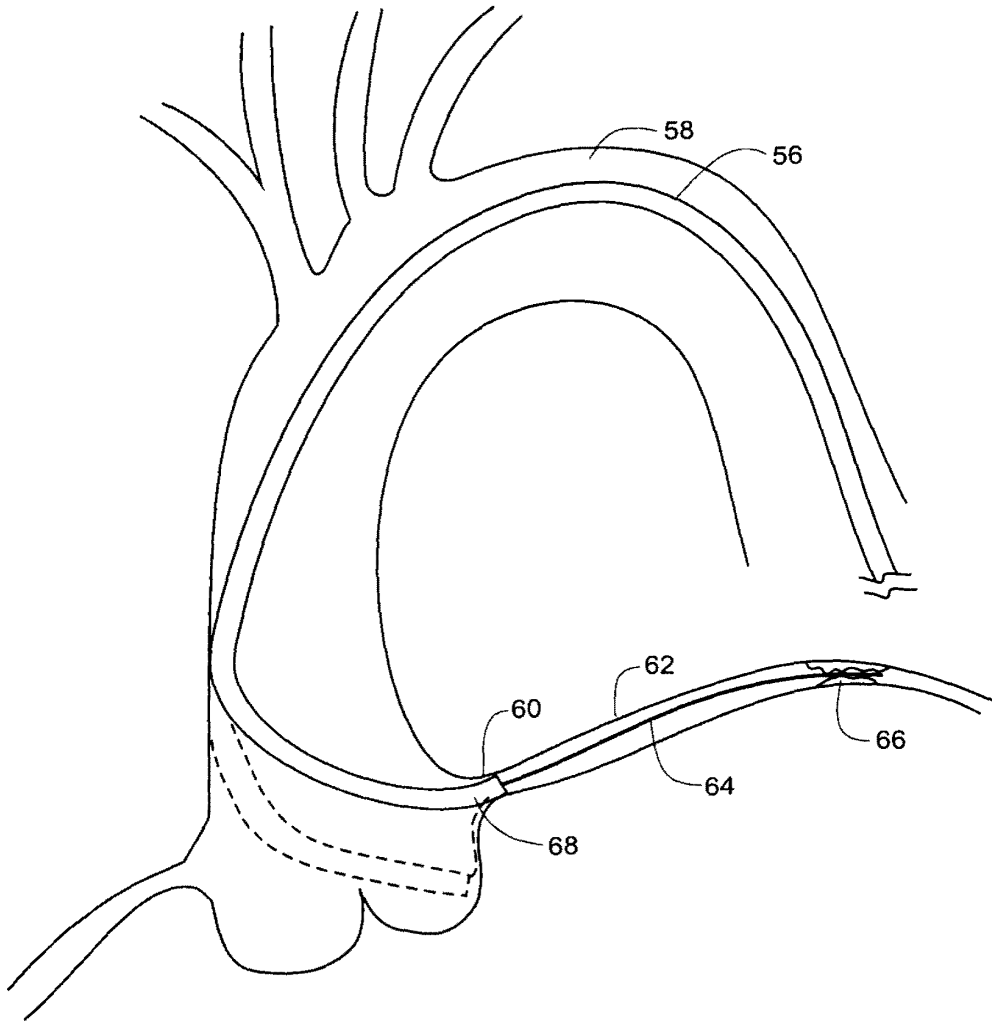
**Fig. 5**



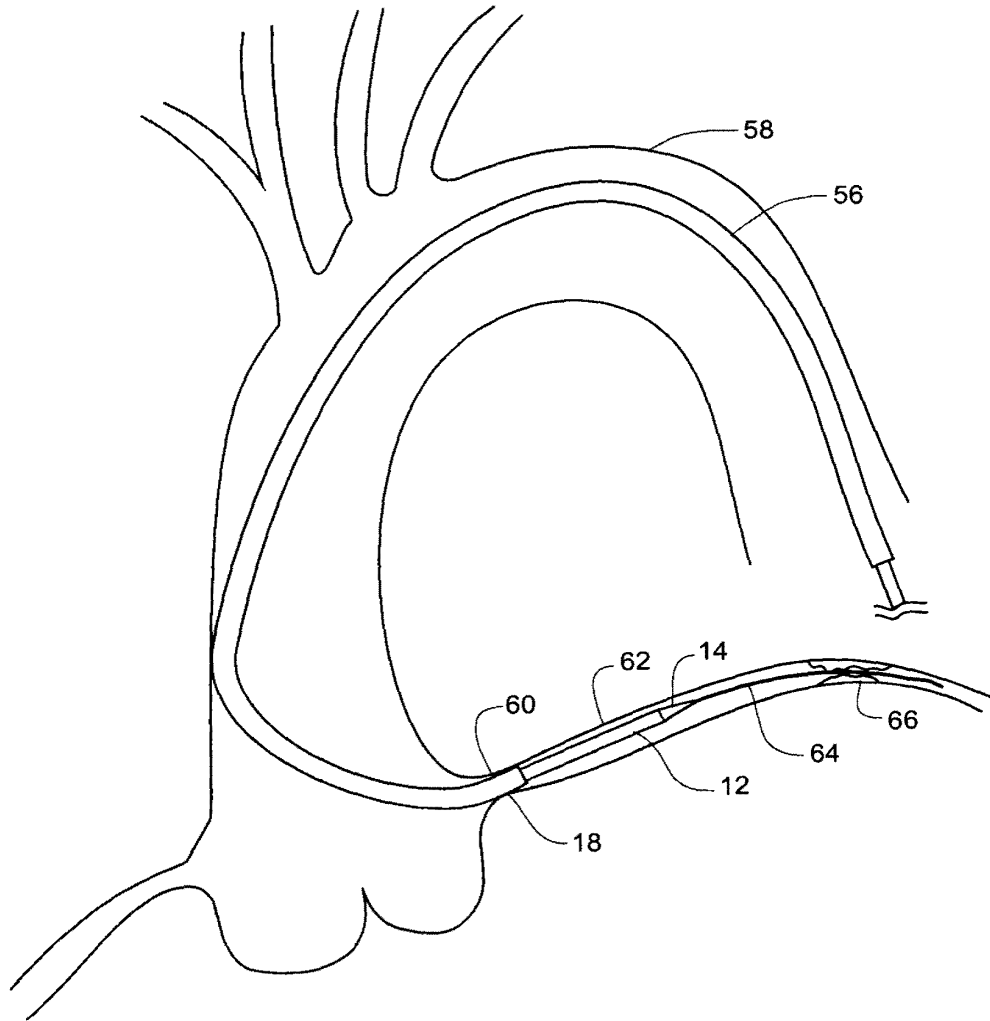
**Fig. 6**



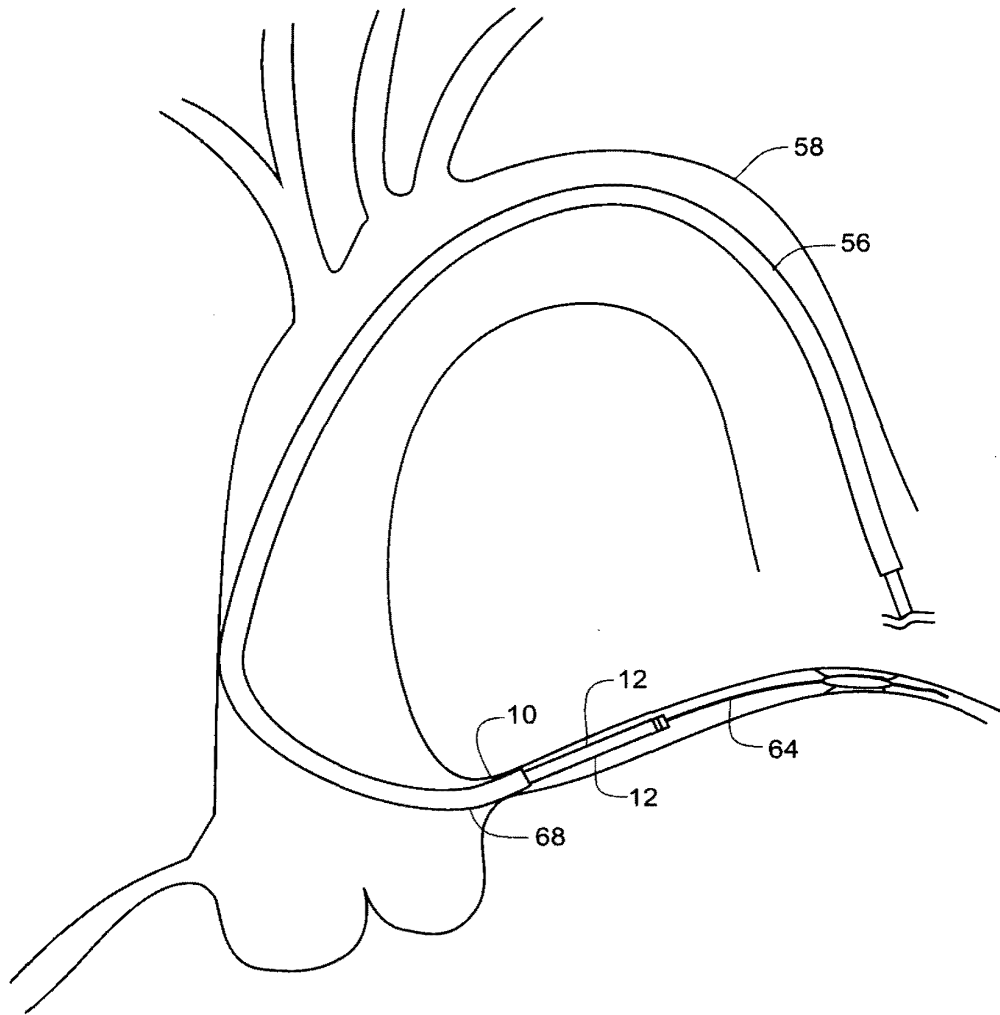
**Fig. 7**

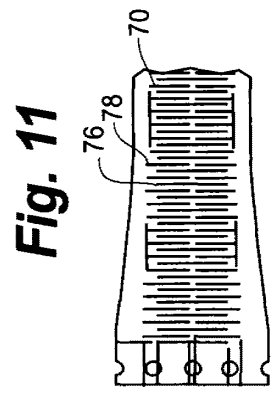
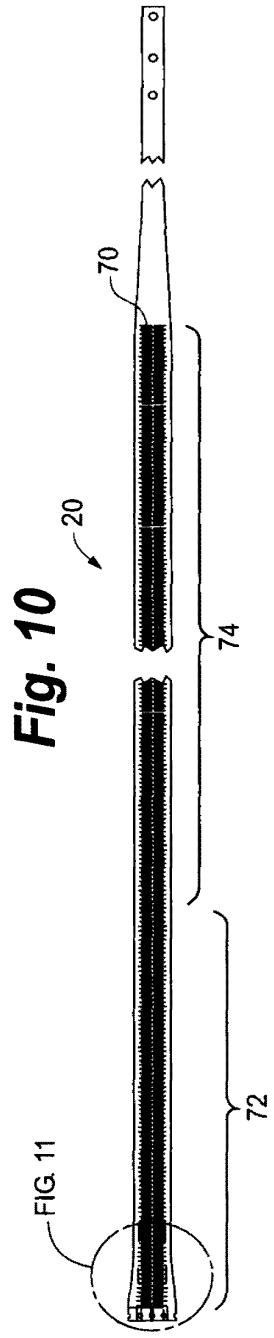


**Fig. 8**



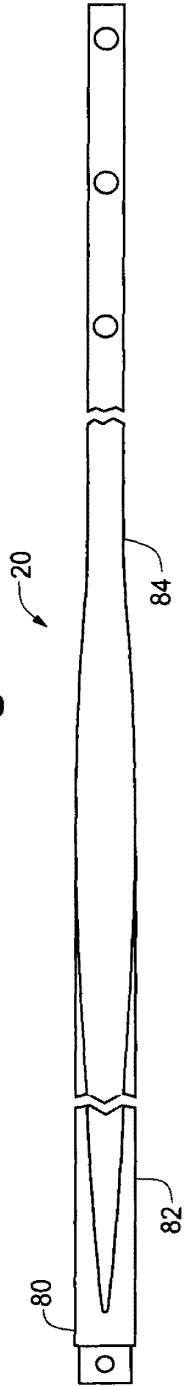
**Fig. 9**



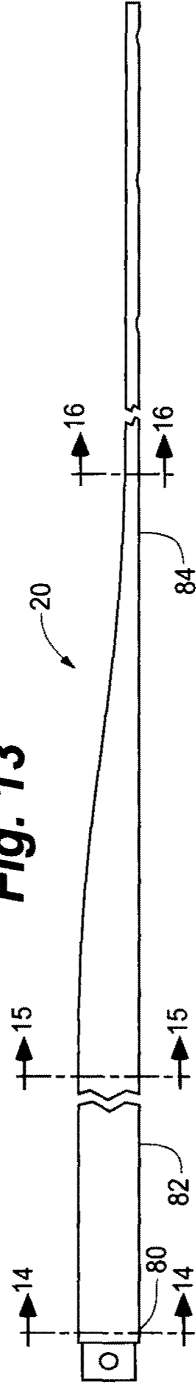




**Fig. 12**



**Fig. 13**



**Fig. 15**



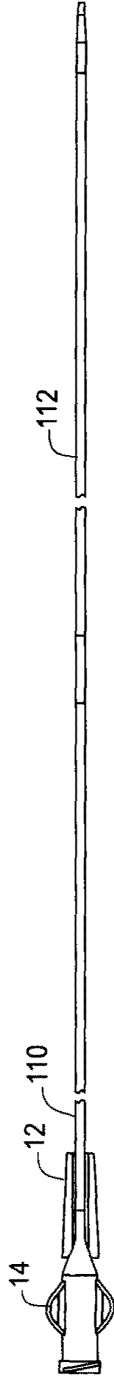
**Fig. 16**



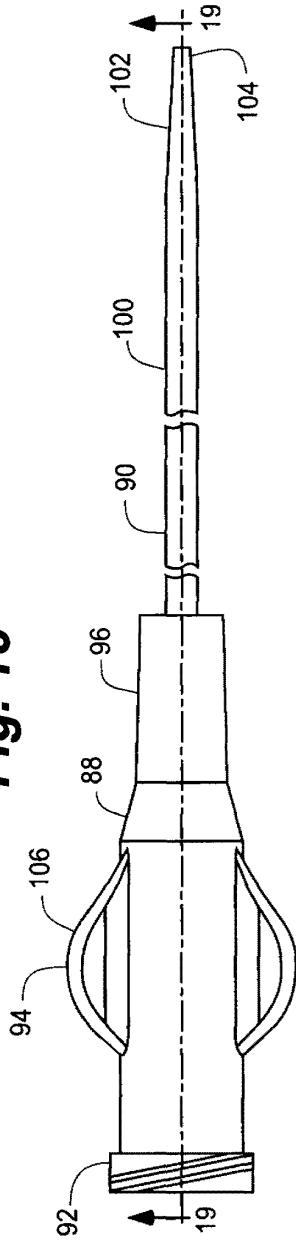
**Fig. 14**



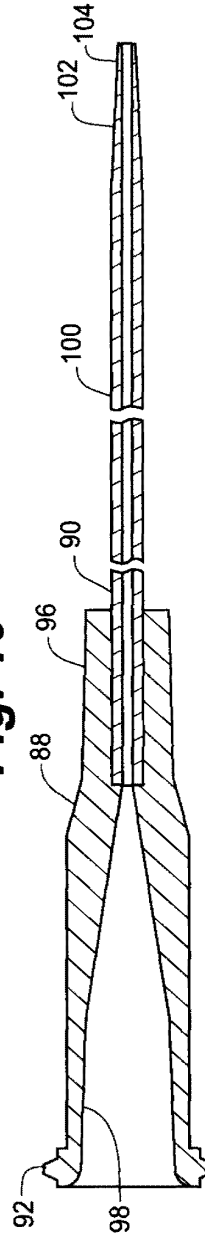
**Fig. 17**



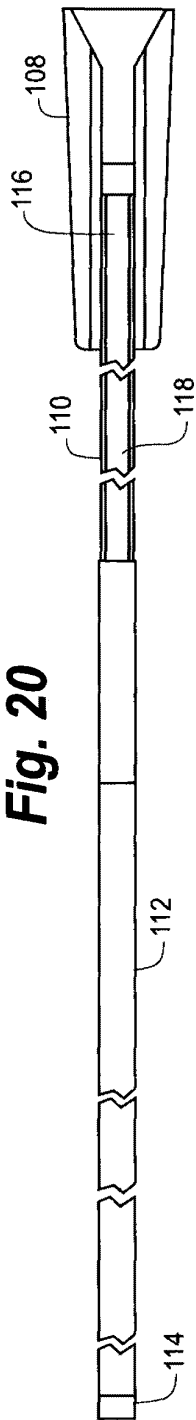
**Fig. 18**



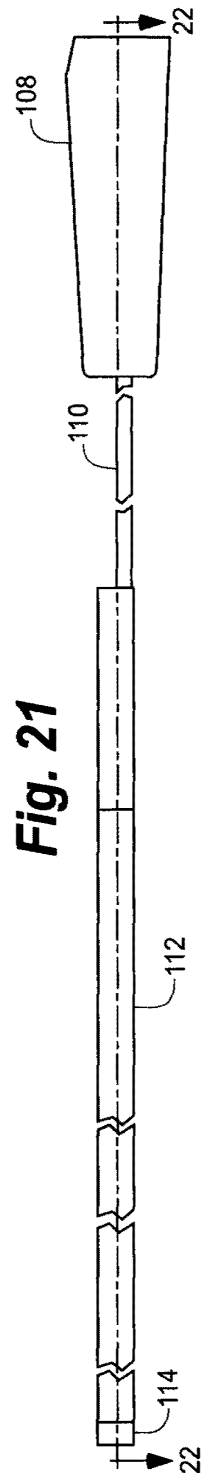
**Fig. 19**



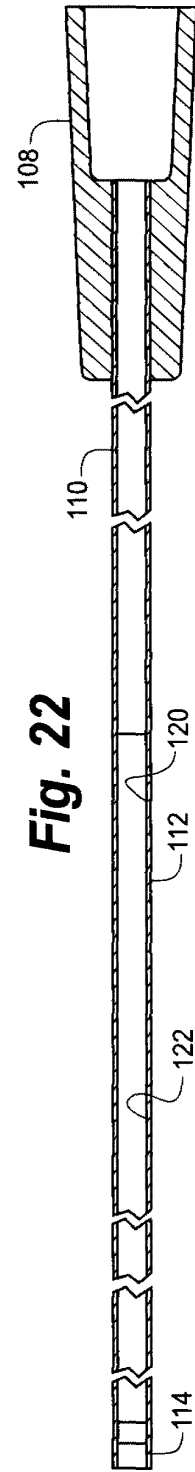
**Fig. 20**



**Fig. 21**



**Fig. 22**



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	11066400
<b>Application Number:</b>	12824734
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1416
<b>Title of Invention:</b>	Coaxial Guide Catheter for Interventional Cardiology Procedures
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick/Allison Goette
<b>Filer Authorized By:</b>	Paul C. Onderick
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	28-SEP-2011
<b>Filing Date:</b>	28-JUN-2010
<b>Time Stamp:</b>	12:57:21
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Drawings-only black and white line drawings	2005_86US02_ReplacementDrawings.pdf	147893 <small>b8a5231e36ebc3dfa904a78195c4fdc0241cd270</small>	no	14

**Warnings:**

**Information:**

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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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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 12/824,734 filed 06/28/2010 by Howard Root, attorney 2005.86US02, confirmation 1416. Also includes examiner OSINSKI, BRADLEY JAMES, art unit 3767, and mail date 08/01/2011.

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.

<b>Office Action Summary</b>	<b>Application No.</b> 12/824,734	<b>Applicant(s)</b> ROOT ET AL.	
	<b>Examiner</b> BRADLEY OSINSKI	<b>Art Unit</b> 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) 1-7 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) 1-7 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 11/19/2010.
- 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 second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 2, 4, 5 and 7 recite the limitation "the guidewire" in claim 1.

There is insufficient antecedent basis for this limitation in the claim. (Claims 3 and 6 both claim a guidewire and thus fix this antecedent basis)

b. Claim 3 recites the limitation "the tapered inner catheter" in claim 3. There is insufficient antecedent basis for this limitation.

c. Claim 5 recites the limitation "the second lumen" in claim 5. There is insufficient antecedent basis for this limitation.

***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 negated by the manner in which the invention was made.

2. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Osborne et al (2005/0004523).

d. Regarding claim 1, Niazi discloses for insertion into the coronary vasculature (coronary sinus specifically - title), the method comprising inserting a guide catheter 51 with a lumen and distal end (figure 3) into a first blood vessel (figure 7, top blood vessel), positioning the distal end of catheter 51 in a second blood vessel that branches off from the first blood vessel (figure 7), inserting a coaxial guide catheter 52 over a guidewire (Col.5 lines 18-20) and into the first lumen of the guide catheter. The catheter 52 has a lumen for obturator 53, a flexible distal portion (Col.5 lines 20-24), a reinforced portion 56 proximal to the distal tip portion (all figures besides 6 show the end of 52 has a taper to fit more easily into a branch, comparing figures 4-6, it is apparent the tip of 52 would not extend beyond the end of 51 as is required for the invention, as such figure 6 is considered a cut out which does not show the distal end of the catheter). An opening is present along the proximal end of the device via an opening in fluid communication with side port 59).The distal tip of the coaxial guide catheter is advanced into the second blood vessel such that the flexible tip extends out of the distal end of the guide catheter and into the second blood vessel (figure 7). Finally, an interventional cardiology device in the form of a pacing lead 83 is passed through the guide catheter into contact with or past a lesion (in this case damaged tissue that does not properly propagate pacing signals) in the second blood vessel.

While Niazi substantially discloses the apparatus as claimed, it does not disclose a rigid portion proximal to the reinforced portion and at least a portion of

the reinforced portion extending out of the distal end of the guide catheter and into the second blood vessel.

However, Osborne discloses a reinforcing portion 52 and a stiffening cannula 50 within inner cannula 20 to avoid kinking (Paragraph 36) and provide stiffening (Paragraph 35). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a reinforcing portion and stiffening portion as taught by Osborne to the device of Niazi to provide kind resistance and stiffening.

e. Regarding claim 2, while Niazi does not disclose applying a force to the coaxial guide catheter, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such a force so that the device does not become unseated before the procedure has been finished.

f. Regarding claims 3 and 6, an inner catheter 53 is tapered (figure 3) and keyed to the to the coaxial guide catheter 52 as it is sized to fit within the lumen of catheter 52. Figure 7 shows guidewire 81 inserted into first and second blood vessels.

g. Regarding claim 4, see claim 1 above. A side port exists in the side of catheter 52 for contrast media (Col.5 lines 25-28). The part of the catheter along the same longitudinal length as the side port is partially cylindrical and the surrounding areas are fully cylindrical.

h. Regarding claim 5, a Y-adaptor 58 allows for injection of saline and contrast medium into a second lumen that meets up with the first lumen (Col.5 lines 12 and 13 and figure 3).

i. Regarding claim 7, a tapered inner catheter 53 is inserted into the lumen of catheter 52, the catheter 53 has a distal tapered portion and extends beyond the guide catheter. Niazi further discloses removing catheter 53 and guide wire 81 (so that guide wire 82 and lead 83 may be placed – Col.5 lines 46-64).

***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

<b>Notice of References Cited</b>	Application/Control No. 12/824,734	Applicant(s)/Patent Under Reexamination ROOT ET AL.	
	Examiner BRADLEY OSINSKI	Art Unit 3767	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A US-6,638,268	10-2003	Niazi, Imran K.	604/528
*	B US-2005/0004523	01-2005	Osborne et al.	604/164.01
	C US-			
	D US-			
	E US-			
	F US-			
	G US-			
	H US-			
	I US-			
	J US-			
	K US-			
	L US-			
	M US-			


**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N				
	O				
	P				
	Q				
	R				
	S				
	T				

**NON-PATENT DOCUMENTS**

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	
V	
W	
X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.


<b>Search Notes</b>  	<b>Application/Control No.</b> 12824734	<b>Applicant(s)/Patent Under Reexamination</b> ROOT ET AL.
	<b>Examiner</b> BRADLEY OSINSKI	<b>Art Unit</b> 3767

<b>SEARCHED</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>
604	103.04,103.09,16-162,164.01,164.01-164.11,525	7/28/2011	bj0

<b>SEARCH NOTES</b>		
<b>Search Notes</b>	<b>Date</b>	<b>Examiner</b>
EAST Search, mostly from parent app 11/416,629	7/28/2011	bj0

<b>INTERFERENCE SEARCH</b>			
<b>Class</b>	<b>Subclass</b>	<b>Date</b>	<b>Examiner</b>

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<b>Index of Claims</b> 	<b>Application/Control No.</b> 12824734	<b>Applicant(s)/Patent Under Reexamination</b> ROOT ET AL.
	<b>Examiner</b> BRADLEY OSINSKI	<b>Art Unit</b> 3767

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

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA			<input type="checkbox"/> T.D.			<input type="checkbox"/> R.1.47		
CLAIM		DATE									
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BIB DATA SHEET

CONFIRMATION NO. 1416

<b>SERIAL NUMBER</b> 12/824,734	<b>FILING or 371(c) DATE</b> 06/28/2010 <b>RULE</b>	<b>CLASS</b> 604	<b>GROUP ART UNIT</b> 3767	<b>ATTORNEY DOCKET NO.</b> 2005.86US02		
<b>APPLICANTS</b> Howard Root, Excelsior, MN; Gregg Sutton, Maple Grove, MN; Jeffrey M. Welch, Maple Grove, MN; Jason M. Garrity, Minneapolis, MN; <b>** CONTINUING DATA *****</b> This application is a DIV of 11/416,629 05/03/2006 <b>** FOREIGN APPLICATIONS *****</b> <b>** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** ** SMALL ENTITY **</b> 07/07/2010						
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Met after Allowance	<b>STATE OR COUNTRY</b> MN	<b>SHEETS DRAWINGS</b> 13	<b>TOTAL CLAIMS</b> 7	<b>INDEPENDENT CLAIMS</b> 1
Verified and Acknowledged	/BRADLEY JAMES OSINSKI/ Examiner's Signature	Initials				
<b>ADDRESS</b> PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100 UNITED STATES						
<b>TITLE</b> Coaxial Guide Catheter for Interventional Cardiology Procedures						
<b>FILING FEE RECEIVED</b> 462	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit			

## EAST Search History

## EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
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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
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S19	33	("4323071"   "4456011"   "4995872"   "5053007"   "5053008"   "5108419"   "5147317"   "5151105"   "5190529"   "5242399"   "5330446"   "5531715"   "5549551"   "5702410"   "5702417"   "5769816"   "5814064"   "5843027"   "5846260"   "5849248"   "5891159"   "5897567"   "5916193"   "5980503"   "6048331"   "6068621"   "6090097"   "6093173"   "6129713"   "6231544"   "6251119"   "6290710"   "6391044").PN. OR ("6689152").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 12:58
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

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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.				
S29	7	S28 and (metal with (coil braid))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/02 17:34
S30	2	"5601586".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2009/06/05 12:33
S31	3	("2003/0195546").URPN.	USPAT	OR	ON	2009/11/09 16:32
S32	208	("20010001890"   "20010049548"   "20020019664"   "20020019665"   "20020022874"   "20020038140"   "20020038141"   "20020052640"   "20020072755"   "20020111675"   "20020116045"   "20020120320"   "20020138966"   "20020165598"   "20030023298"   "20030055483"   "20030055484"   "20030130716"   "20030144671"   "20030181923"   "20030192164"   "20030195546"   "20040172119"   "20040199239"   "20040260379"   "20050149161"   "20050154442"   "20050273149"   "3792603"   "4448195"   "4461163"   "4484585"   "4578982"   "4601701"   "4769005"   "4776337"   "4913141"   "4994071"	US-PGPUB; USPAT; USOCR	OR	ON	2009/11/09 16:33

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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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Receipt date: 11/19/2010

12824734 - GAU: 3767

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>		
				Application Number	12/824,734	
				Filing Date	June 28, 2010	
				First Named Inventor	Howard Root et al.	
				Art Unit	3734	
Examiner Name	Not Yet Assigned					
Attorney Docket Number	2005.86US02					
Sheet	1	of	3			
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	
		Number-Kind Code <sup>2</sup> (if known)				
		US-4,813,930		03-21-1989	Elliott	
		US-4,832,028		05-23-1989	Patel	
		US-4,932,413		06-12-1990	Shockey et al.	
		US-5,098,412		03-24-1992	Shiu	
		US-5,122,125		01-16-1992	Deuss	
		US-5,472,425		12-05-1995	Teirstein	
		US-5,658,263		08-19-1997	Dang et al.	
		US-5,776,141		07-07-1998	Klein et al.	
		US-6,159,195		12-12-2000	Ha et al.	
		US-6,338,725		01-15-2002	Hermann et al.	
		US-6,475,195		11-05-2002	Voda	
		US-6,595,952		07-22-2003	Forsberg	
		US-6,610,068		08-26-2003	Yang	
		US-6,638,268		10-28-2003	Niazi	
		US-2003/0195546		10-16-2003	Solar et al.	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
EXAMINER SIGNATURE	/Bradley Osinski/ (07/28/2011)			DATE CONSIDERED		
<small>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.  <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.                  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.</small>						

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /BJO/

VSI\_00000543

A01875

Receipt date: 11/19/2010

12824734 - GAU: 3767

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>		
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				Filing Date	June 28, 2010	
				First Named Inventor	Howard Root et al.	
				Art Unit	3734	
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Sheet	2	of	3	Attorney Docket Number	2005.86US02	
<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	
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		US-6,689,144		02-10-2004	Gerberding	
		US-6,706,018		03-16-2004	Westlund et al.	
		US-6,755,812		06-29-2004	Peterson et al.	
		US-2004/0127927		07-01-2004	Kenneth Adams	
		US-6,860,876		03-01-2005	Chen	
		US-2005/0182437		08-18-2005	Bonnette et al.	
		US-2007/0260219		11-08-2007	Root et al.	
		US-7,697,996		04-13-2010	Manning et al.	
		US-7,717,899		05-18-2010	Bowe et al.	
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<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
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EXAMINER SIGNATURE	/Bradley Osinski/ (07/28/2011)			DATE CONSIDERED		
<p>*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.</p> <p><sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.</p> <p>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.</p>						

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A01876

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
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				Filing Date	June 28, 2010
				First Named Inventor	Howard Root et al.
				Art Unit	3734
				Examiner Name	<i>Not Yet Assigned</i>
Sheet	3	of	3	Attorney Docket Number	2005.86US02
<b>NON PATENT LITERATURE DOCUMENTS</b>					
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
		Saeko Takahashi et al.; New Method to Increase A Backup Support Of A 6 French Guiding Coronary Catheter; Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages; Published online in Wiley InterScience (www.interscience.wiley.com).			
		Image File Wrapper of Appln. No. 11/416,629; filed June 28, 2010; Howard Root et al.			
EXAMINER SIGNATURE	/Bradley Osinski/ (07/28/2011)			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. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. 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. <b>DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.</b>					
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Table with 4 columns: APPLICATION NUMBER (12/824,734), FILING OR 371(C) DATE (06/28/2010), FIRST NAMED APPLICANT (Howard Root), ATTY. DOCKET NO./TITLE (2005.86US02)

CONFIRMATION NO. 1416

PUBLICATION NOTICE

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



Title:Coaxial Guide Catheter for Interventional Cardiology Procedures

Publication No.US-2010-0324567-A1

Publication Date:12/23/2010

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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

PATENT APPLICATION  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US02
Howard Root et al.	Confirmation No.: 1416
Application No.: 12/824,734	Examiner: <i>Not Yet Assigned</i>
Filed: June 28, 2010	Group Art Unit: 3734
For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

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INFORMATION DISCLOSURE STATEMENT

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

Sir:

Pursuant to 37 CFR § 1.56, 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.

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This Information Disclosure Statement is being filed without a certification or fee because this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 CFR § 1.97(b)(3).

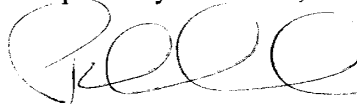
The Examiner's attention is directed to the applications or patents, if any, to which priority is claimed, as well as to any continuing applications which claim priority to the above-referenced application, and to applications, if any, that may be related by virtue of similar claimed subject matter as the above-referenced application (collectively, the "Related Case(s)"). The Related Case(s), or documents associated with the Related Case(s), are identified on the attached form PTO-1449 by serial number, publication number and/or patent number, along with a copy of the current prosecution history, downloaded from PAIR where available. The current prosecution history for the Related Case(s) is submitted as an NPL document for the convenience of the Examiner.

The prosecution history for any and all of these Related Case(s) may include information material to patentability of the above-referenced application including Office Actions, Responses, Office Communications or Notices of Allowance, all of which are readily accessible to the Examiner via PAIR/PALM. To promote consistency and full disclosure during the prosecution of the above-referenced application together with the prosecution of any of the Related Case(s) and to assist the Examiner in complying with the obligations of MPEP 2001.06(b), the Examiner is respectfully requested to review the prosecution history of each of the Related Case(s). **This request for review should be considered ongoing throughout the prosecution of the above-referenced application with an updated review via PAIR/PALM of the prosecution histories of any Related Case(s) being made prior to issuance of any**

**Notice of Allowance for the above-referenced application.** The identification of any of the Related Case(s) for purposes of this Information Disclosure Statement should not be construed as a waiver of secrecy, if applicable, as to such applications now or upon issuance of the above-referenced application as a patent. For purposes of the Related Case(s), it should be noted that all of the Related Case(s) are published or otherwise publicly available on PAIR.

Please note that copies of the references that were cited by or submitted to the Office in applications which are relied upon for an earlier filing date under 35 U.S.C. § 120 may be found in the appropriate records via PAIR/PALM. 37 CFR § 1.98(d).

Respectfully submitted,



Paul C. Onderick  
Registration No. 45354

Customer No. 24113  
Patterson Thuent 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.*

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>		
				Application Number	12/824,734	
				Filing Date	June 28, 2010	
				First Named Inventor	Howard Root et al.	
				Art Unit	3734	
				Examiner Name	Not Yet Assigned	
Sheet	1	of	3	Attorney Docket Number	2005.86US02	

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> (if known)		
		US-4,813,930	03-21-1989	Elliott
		US-4,832,028	05-23-1989	Patel
		US-4,932,413	06-12-1990	Shockey et al.
		US-5,098,412	03-24-1992	Shiu
		US-5,122,125	01-16-1992	Deuss
		US-5,472,425	12-05-1995	Teirstein
		US-5,658,263	08-19-1997	Dang et al.
		US-5,776,141	07-07-1998	Klein et al.
		US-6,159,195	12-12-2000	Ha et al.
		US-6,338,725	01-15-2002	Hermann et al.
		US-6,475,195	11-05-2002	Voda
		US-6,595,952	07-22-2003	Forsberg
		US-6,610,068	08-26-2003	Yang
		US-6,638,268	10-28-2003	Niazi
		US-2003/0195546	10-16-2003	Solar et al.

**FOREIGN PATENT DOCUMENTS**

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

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

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				Application Number	12/824,734	
				Filing Date	June 28, 2010	
				First Named Inventor	Howard Root et al.	
				Art Unit	3734	
				Examiner Name	<i>Not Yet Assigned</i>	
Sheet	2	of	3	Attorney Docket Number	2005.86US02	

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> (if known)		
		US-6,689,144	02-10-2004	Gerberding
		US-6,706,018	03-16-2004	Westlund et al.
		US-6,755,812	06-29-2004	Peterson et al.
		US-2004/0127927	07-01-2004	Kenneth Adams
		US-6,860,876	03-01-2005	Chen
		US-2005/0182437	08-18-2005	Bonnette et al.
		US-2007/0260219	11-08-2007	Root et al.
		US-7,697,996	04-13-2010	Manning et al.
		US-7,717,899	05-18-2010	Bowe et al.
		US-		
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**FOREIGN PATENT DOCUMENTS**

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

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

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				Art Unit	3734	
				Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	2005.86US02	
<b>NON PATENT LITERATURE DOCUMENTS</b>						
EXAMINER INITIAL*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>	
		Saeko Takahashi et al.; New Method to Increase A Backup Support Of A 6 French Guiding Coronary Catheter; Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages; Published online in Wiley InterScience (www.interscience.wiley.com).				
		Image File Wrapper of Appln. No. 11/416,629; filed June 28, 2010; Howard Root et al.				
EXAMINER SIGNATURE		DATE CONSIDERED				
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.</p> <p>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. <b>SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.</b></p> <p style="text-align: center;"><i>If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.</i></p>						

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## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	8877825
<b>Application Number:</b>	12824734
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1416
<b>Title of Invention:</b>	Coaxial Guide Catheter for Interventional Cardiology Procedures
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Paul C. Onderick
<b>Filer Authorized By:</b>	
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	19-NOV-2010
<b>Filing Date:</b>	28-JUN-2010
<b>Time Stamp:</b>	16:18:17
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Filed (SB/08)	2005_86US02_IDS.pdf	257386 <small>f50dd00b83940fe21987e08fd61022b82d7 a6a62</small>	no	6

**Warnings:**

**Information:**

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This is not an USPTO supplied IDS fillable form

2	NPL Documents	2005_86US02_IFW_11416629_P PART1.pdf	4772206	no	139
			aef83bb89a40b8474b65b1da2770099e99c 04390		

**Warnings:**

**Information:**

3	NPL Documents	2005_86US02_IFW_11416629_P PART2.pdf	5136386	no	155
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**Warnings:**

**Information:**

4	NPL Documents	2005_86US02_NPL1.pdf	421541	no	5
			24f8b5349b948c329483ebeeec960aad4d 3059d		

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>			10587519		
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**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.**



UNITED STATES PATENT AND TRADEMARK OFFICE

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

Table with 6 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY DOCKET NO, TOT CLAIMS, IND CLAIMS. Row 1: 12/824,734, 06/28/2010, 3734, 462, 2005.86US02, 7, 1

CONFIRMATION NO. 1416

UPDATED FILING RECEIPT

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



Date Mailed: 09/16/2010

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

Applicant(s)

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

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

Domestic Priority data as claimed by applicant

This application is a DIV of 11/416,629 05/03/2006

Foreign Applications

If Required, Foreign Filing License Granted: 07/07/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US 12/824,734

Projected Publication Date: 12/23/2010

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

**Title**

Coaxial Guide Catheter for Interventional Cardiology Procedures

**Preliminary Class**

623

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

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

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

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

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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**Page 103 of 191**

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86US02

Root et al.

Confirmation No.: 1416

Application No.: 12/824,734

Examiner: *unassigned*

Filed: June 28, 2010

Group Art Unit: 3734

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

---

RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS

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

Sir:

In response to the Notice to File Corrected Application Papers mailed July 8, 2010,  
submitted herewith is thirteen (13) replacement drawings.

Respectfully submitted,



Brad Pedersen  
Registration No. 32432

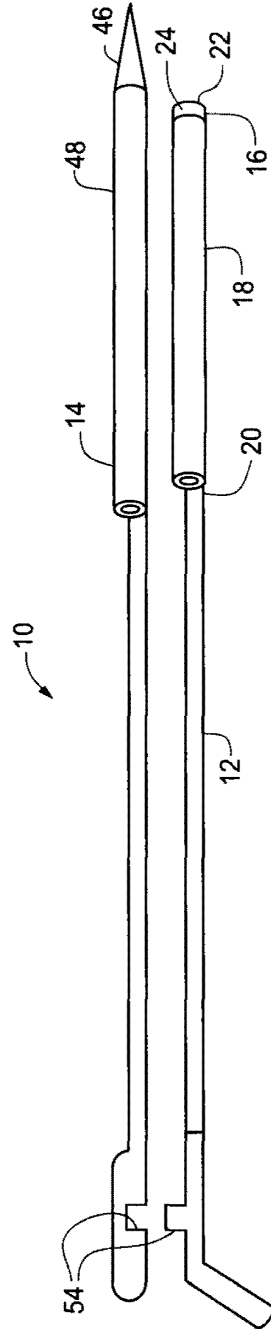
Customer No. 24113  
Patterson Thuente Christensen Pedersen, P.A.  
4800 IDS Center  
80 South 8th Street  
Minneapolis, Minnesota 55402-2100  
Telephone: 612.349.5774

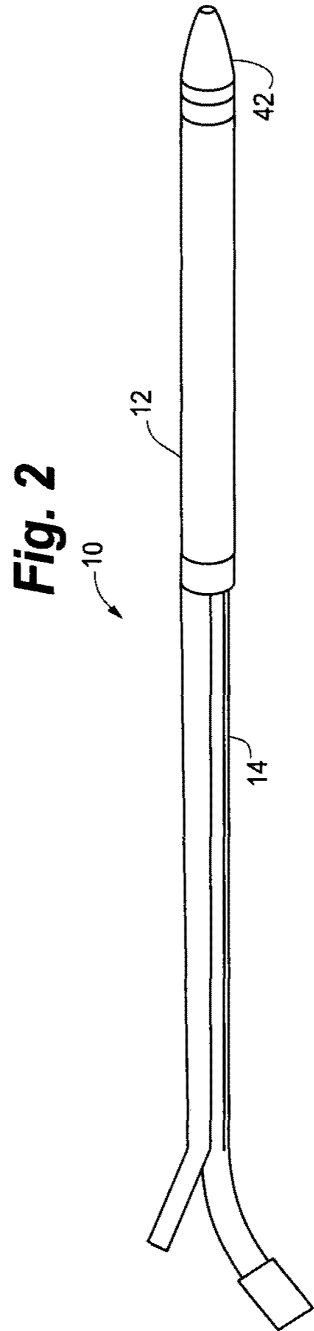
*Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 16-0631.*

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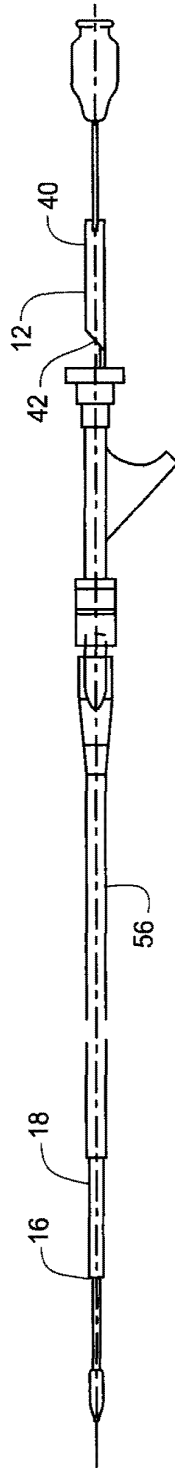
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**Fig. 1**



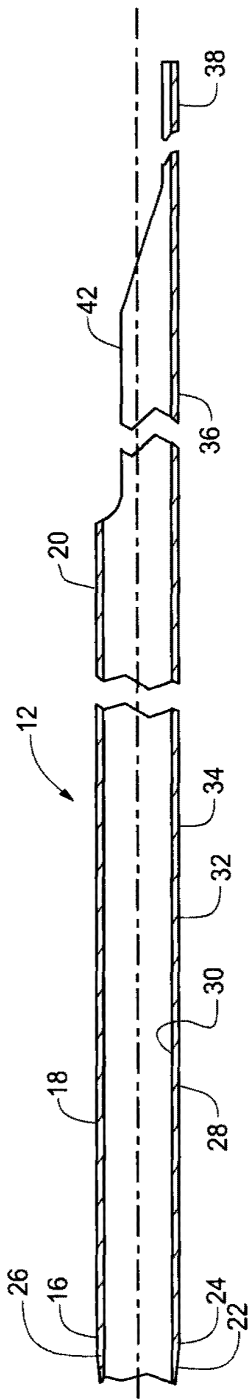


**Fig. 3**

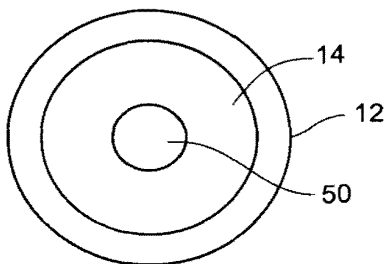




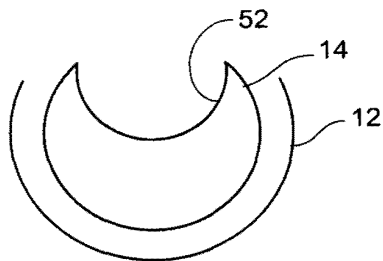
**Fig. 4**



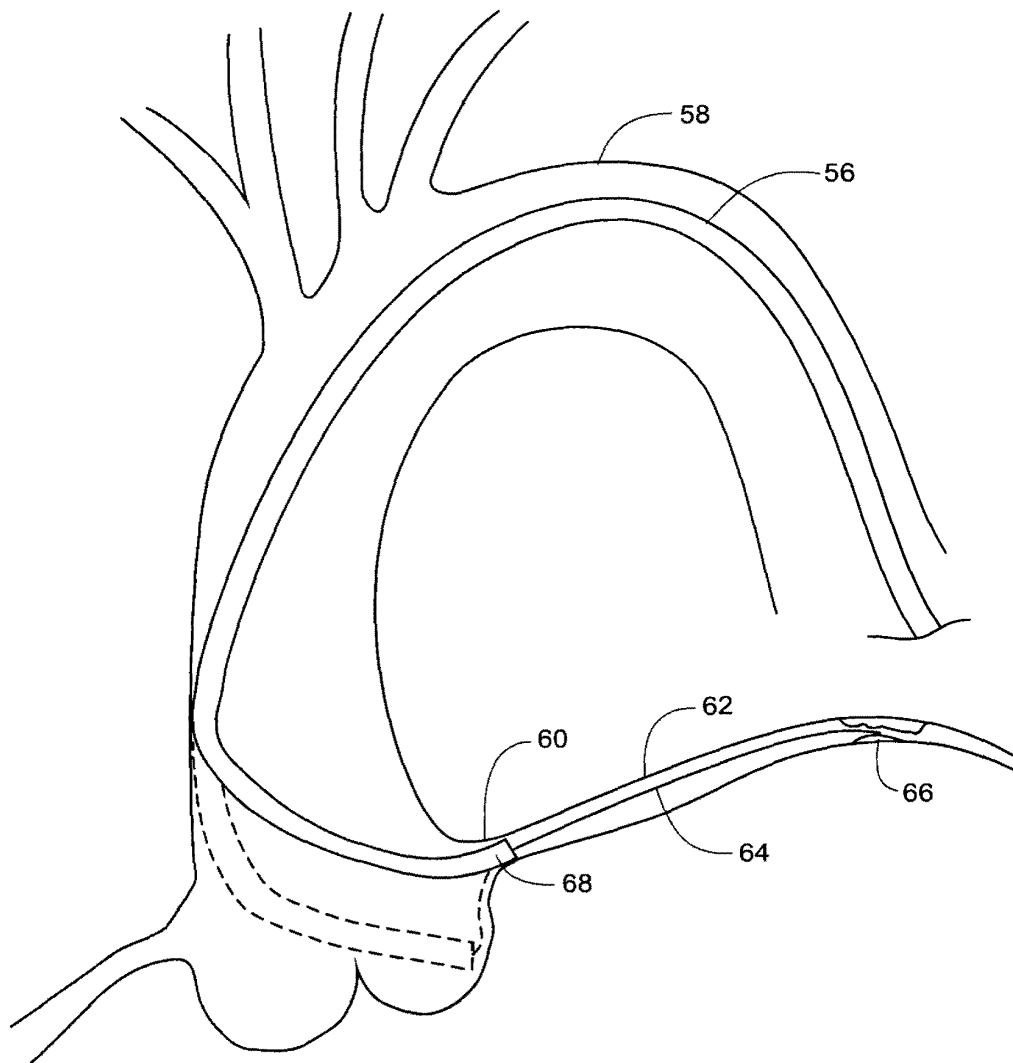
**Fig. 5**



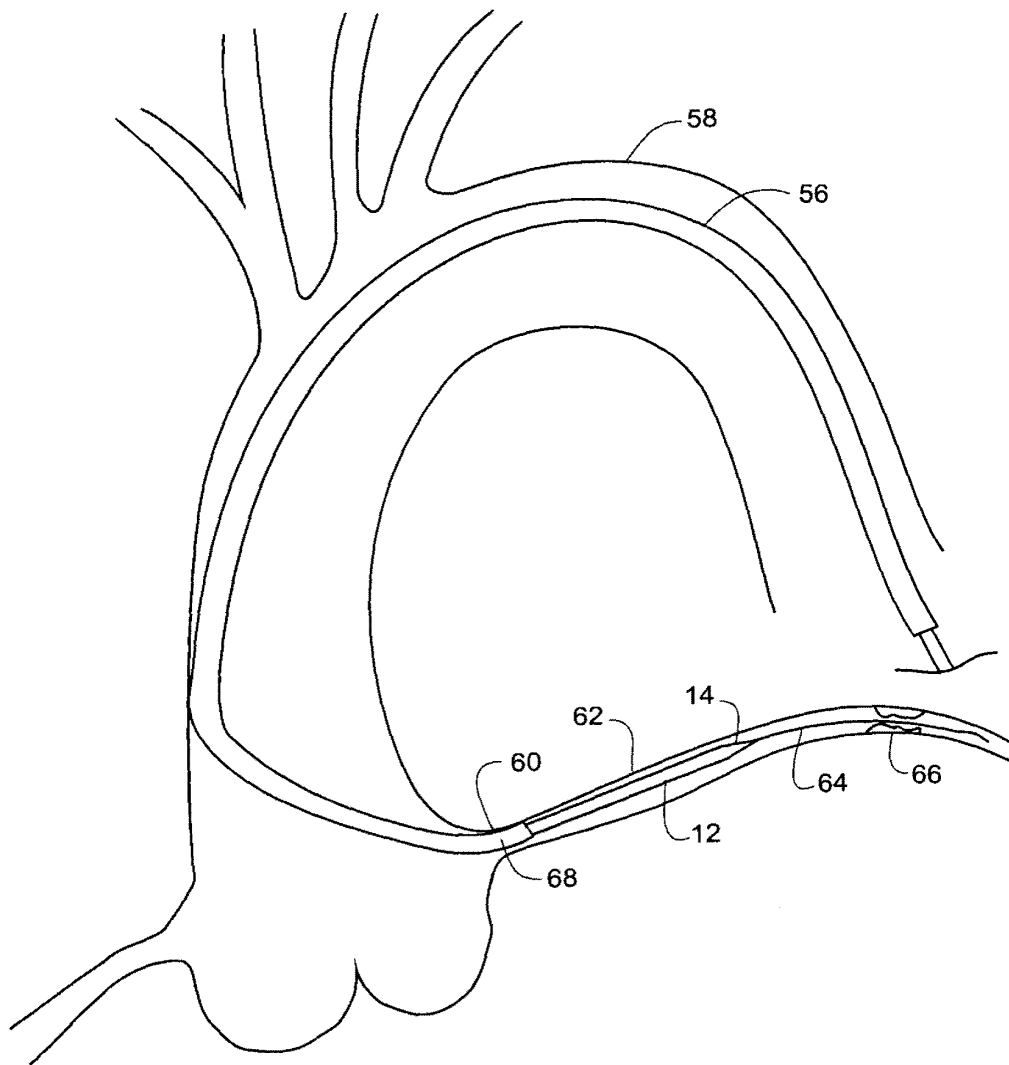
**Fig. 6**



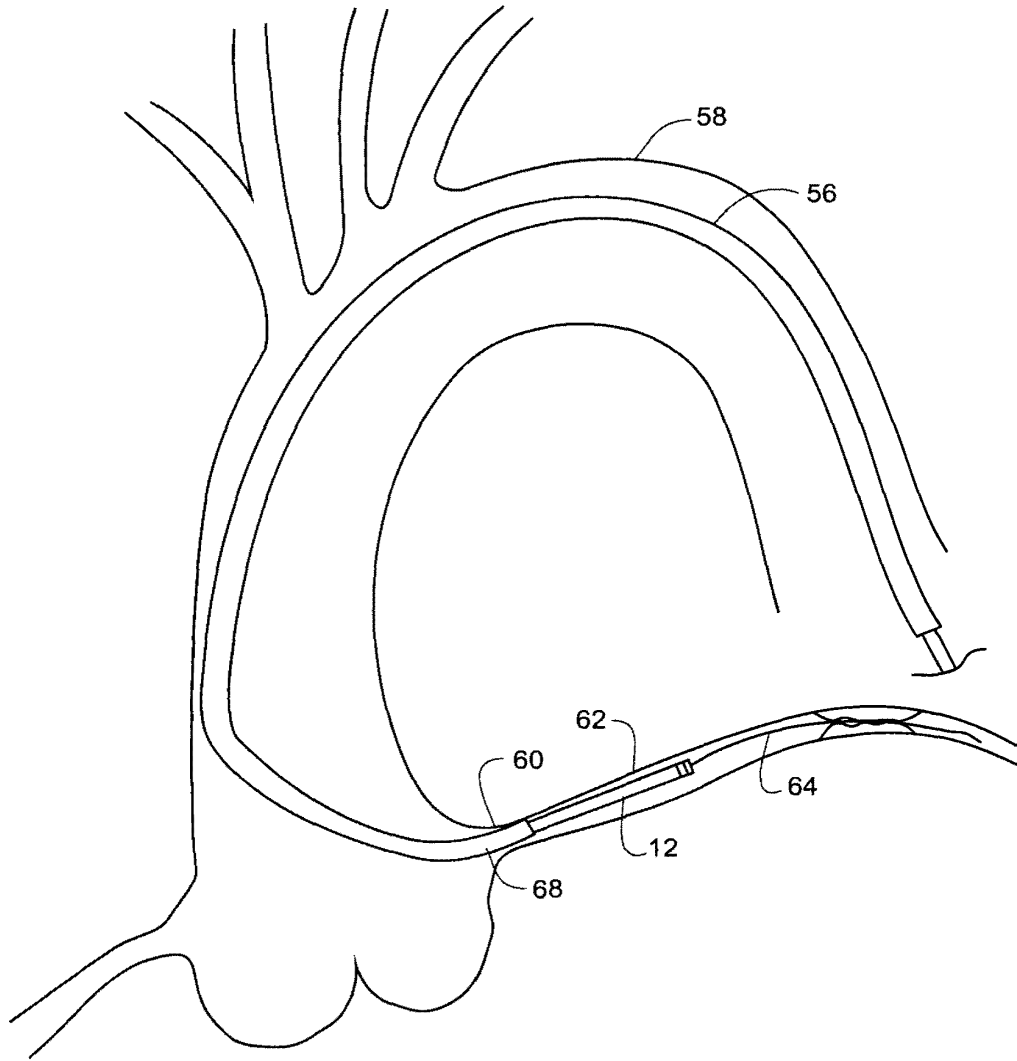
**Fig. 7**

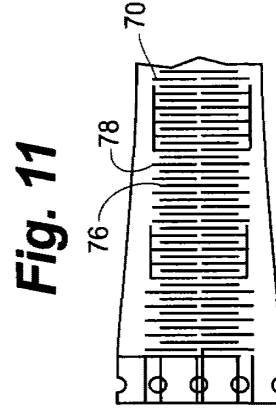
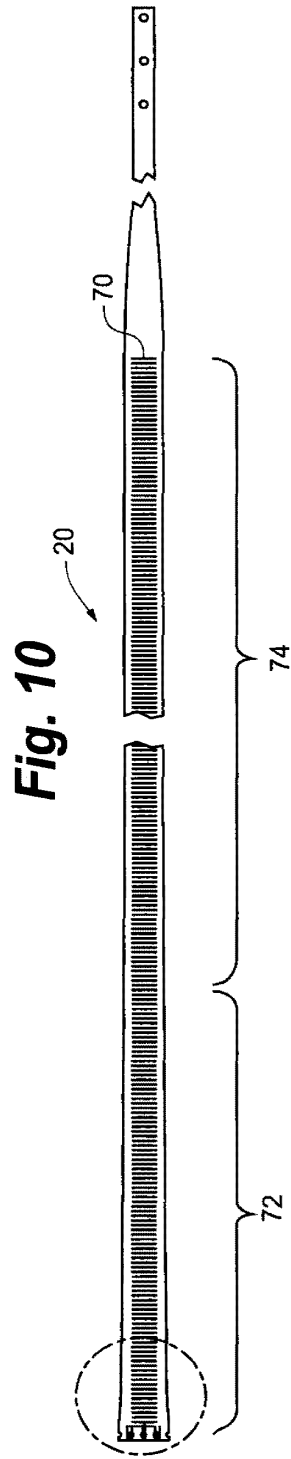


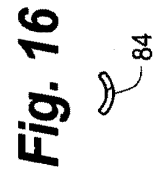
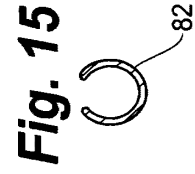
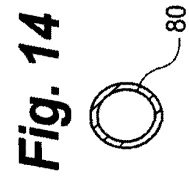
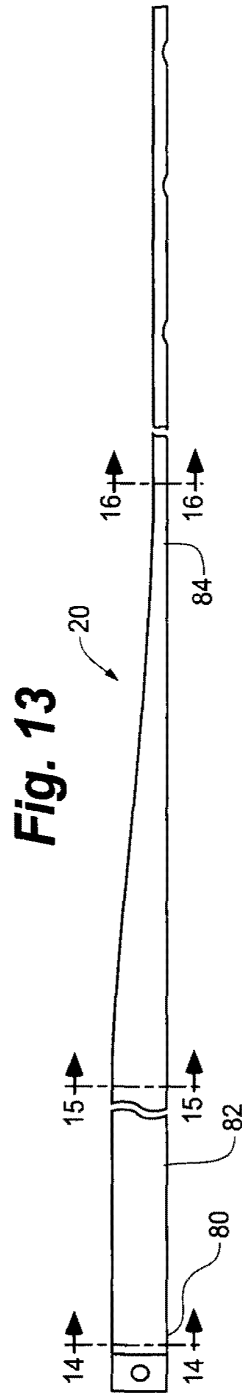
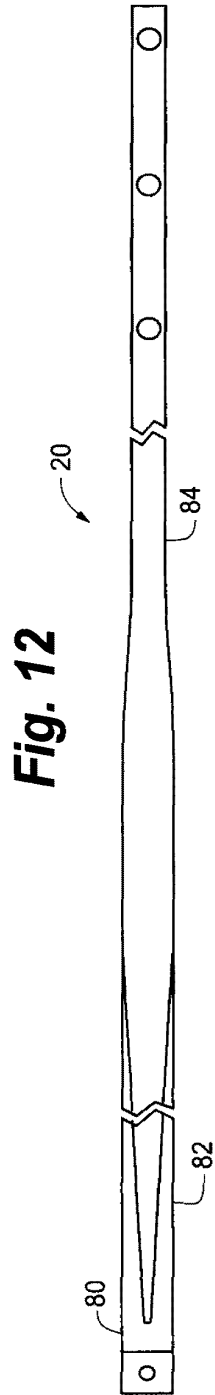
**Fig. 8**



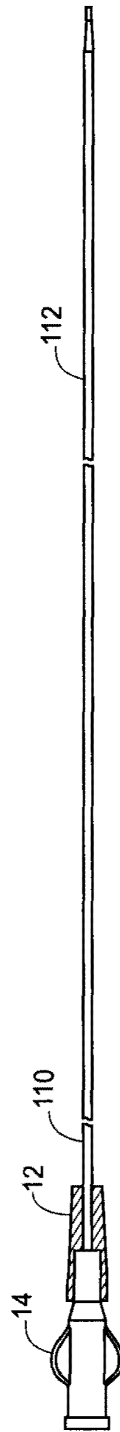
**Fig. 9**





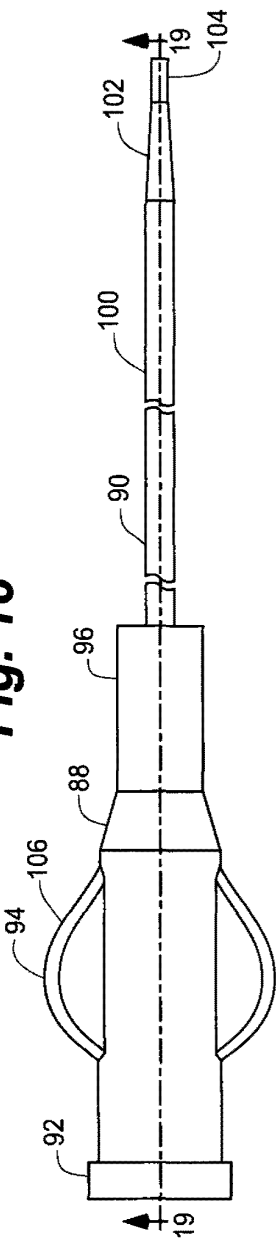


**Fig. 17**

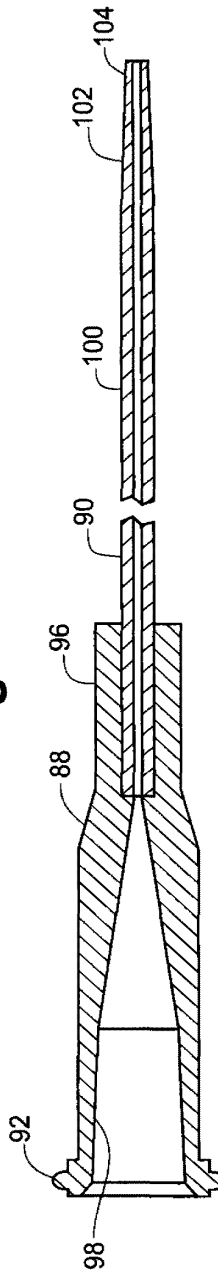




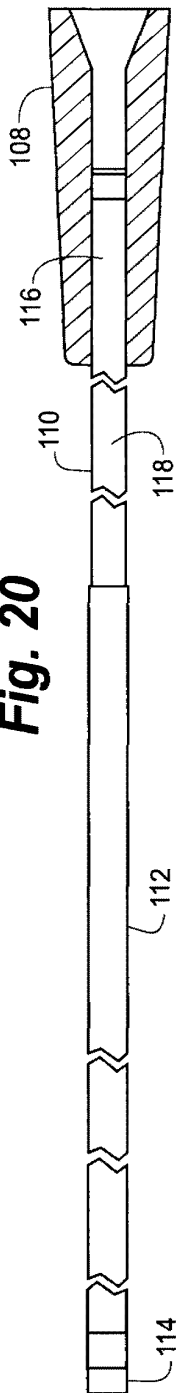
**Fig. 18**



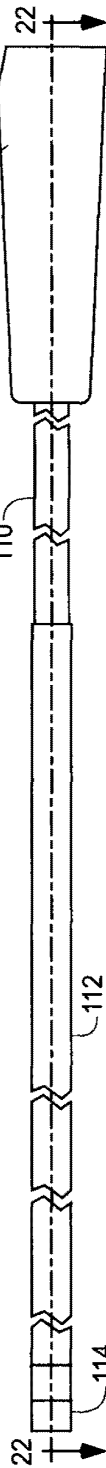
**Fig. 19**



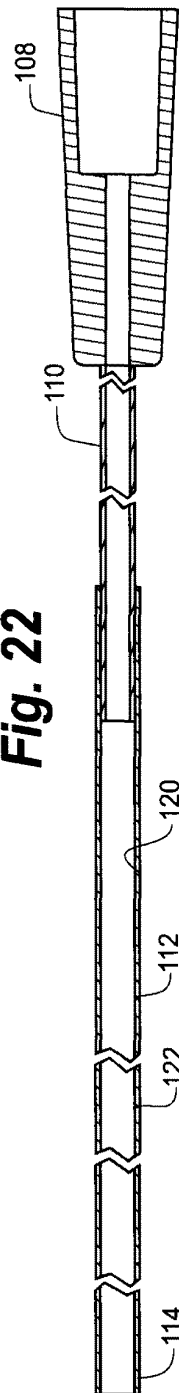
**Fig. 20**



**Fig. 21**



**Fig. 22**



## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	8371464
<b>Application Number:</b>	12824734
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1416
<b>Title of Invention:</b>	Coaxial Guide Catheter for Interventional Cardiology Procedures
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Bradley Pedersen/Michelle Arcand
<b>Filer Authorized By:</b>	Bradley Pedersen
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	08-SEP-2010
<b>Filing Date:</b>	28-JUN-2010
<b>Time Stamp:</b>	11:09:05
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86US02_RESTOCORRECT PAPERS.pdf	161031 <small>361571a53452a72e3da5af566a13958f6179745e</small>	yes	14

VSI\_00000572

Multipart Description/PDF files in .zip description		
Document Description	Start	End
Applicant Response to Pre-Exam Formalities Notice	1	1
Drawings-only black and white line drawings	2	14
<b>Warnings:</b>		
<b>Information:</b>		
<b>Total Files Size (in bytes):</b>		161031
<p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  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.</p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>		



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Table with 6 columns: APPLICATION NUMBER, FILING or 371(c) DATE, GRP ART UNIT, FIL FEE REC'D, ATTY DOCKET NO, TOT CLAIMS, IND CLAIMS. Row 1: 12/824,734, 06/28/2010, 3734, 462, 2005.86US02, 7, 1

CONFIRMATION NO. 1416

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

FILING RECEIPT



Date Mailed: 07/08/2010

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

Applicant(s)

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

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

Domestic Priority data as claimed by applicant

This application is a DIV of 11/416,629 05/03/2006

Foreign Applications

If Required, Foreign Filing License Granted: 07/07/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US 12/824,734

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

\*\* SMALL ENTITY \*\*

**Title**

Coaxial Guide Catheter for Interventional Cardiology Procedures

**Preliminary Class**

623

**PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES**

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

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

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

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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page 2 of 3

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**Page 122 of 191**

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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Table with 4 columns: APPLICATION NUMBER (12/824,734), FILING OR 371(C) DATE (06/28/2010), FIRST NAMED APPLICANT (Howard Root), ATTY. DOCKET NO./TITLE (2005.86US02)

CONFIRMATION NO. 1416

FORMALITIES LETTER



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

Date Mailed: 07/08/2010

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
• The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) 1.
• The drawings submitted to the Office are not electronically reproducible because portions of figures 17-21 are missing and/or blurry.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.



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/tketsela/

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

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Attorney Docket No.: 2005.86US02

Root et al.

Application No.: *of even date*

Filed: *of even date*

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY  
PROCEDURES

---

PRELIMINARY AMENDMENT

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

Sir:

INTRODUCTORY COMMENTS

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

The present amendment comprises the following sections:

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

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

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A01911

AMENDMENTS TO THE SPECIFICATION

In the Specification

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

Page 1, prior to line 6, please insert the following:

**Related Application**

This application is a division of Application No. 11/416,629 filed May 3, 2006, which is hereby fully incorporated herein by reference.

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. (Original) A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a guide catheter, the method comprising:

inserting the guide catheter into the first blood vessel, the guide catheter having a first lumen and a distal end;

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

inserting a coaxial guide catheter over the guidewire and into the first lumen of the guide catheter, the coaxial guide catheter having a second lumen and

a flexible distal tip portion,

a reinforced portion proximal to the distal tip portion, and

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

advancing the distal tip portion of the coaxial guide catheter into the second blood vessel such that the flexible distal tip portion and at least a portion of the reinforced portion extend out of the distal end of the guide catheter and into the second blood vessel; and

inserting the interventional cardiology device through the lumen of the coaxial guide catheter and into contact with or past a lesion in the second blood vessel.

2. (Original) The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal tip portion of the coaxial guide

catheter remains seated in the second blood vessel in response to an opposing backward force exerted by the interventional cardiology device.

3. (Original) The method as claimed in claim 1, further comprising:  
keying the tapered inner catheter to the coaxial guide catheter at a proximal portion thereof;  
inserting a guidewire having a tip into a first blood vessel; and  
inserting the tip of the guidewire into a second blood vessel that branches off of the first blood vessel.

4. (Original) The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining the opening along a side thereof.

5. (Original) The method as claimed in claim 1, further comprising selecting the guide catheter to further comprise a Y-adapter and the method further comprising injecting a fluid through the Y-adapter into the second lumen.

6. (Original) The method as claimed in claim 1, further comprising inserting a guidewire having a tip into a first blood vessel; and  
inserting the tip of the guidewire into a second blood vessel that branches off of the first blood vessel.

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

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

removing the guidewire from the coaxial guide catheter.

8-20. (Canceled).

REMARKS

Claims 1-20 are pending. By this Amendment 8-20 are canceled.

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

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

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'BRAD PEDERSEN', with a long horizontal line extending to the right.

Brad Pedersen  
Registration No. 32,432

Customer No. 24113  
Patterson Thuente Christensen Pedersen, P.A.  
4800 IDS Center  
80 South 8th Street  
Minneapolis, Minnesota 55402-2100  
Telephone: (612) 349-5774



## Electronic Patent Application Fee Transmittal

<b>Application Number:</b>				
<b>Filing Date:</b>				
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES			
<b>First Named Inventor/Applicant Name:</b>	Howard Root			
<b>Filer:</b>	Bradley Pedersen/Michelle Arcand			
<b>Attorney Docket Number:</b>	2005.86US02			
Filed as Small Entity				
<b>Utility under 35 USC 111(a) Filing Fees</b>				
<b>Description</b>	<b>Fee Code</b>	<b>Quantity</b>	<b>Amount</b>	<b>Sub-Total in USD(\$)</b>
<b>Basic Filing:</b>				
Utility filing Fee (Electronic filing)	4011	1	82	82
Utility Search Fee	2111	1	270	270
Utility Examination Fee	2311	1	110	110
<b>Pages:</b>				
<b>Claims:</b>				
<b>Miscellaneous-Filing:</b>				
<b>Petition:</b>				
<b>Patent-Appeals-and-Interference:</b>				

VSI\_00000586

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
<b>Post-Allowance-and-Post-Issuance:</b>				
<b>Extension-of-Time:</b>				
<b>Miscellaneous:</b>				
<b>Total in USD (\$)</b>				<b>462</b>

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	7906131
<b>Application Number:</b>	12824734
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	1416
<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Bradley Pedersen/Michelle Arcand
<b>Filer Authorized By:</b>	Bradley Pedersen
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	28-JUN-2010
<b>Filing Date:</b>	
<b>Time Stamp:</b>	15:45:09
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$462
RAM confirmation Number	2382
Deposit Account	160631
Authorized User	PEDERSEN,BRADLEY D.
<p>The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:</p> <ul style="list-style-type: none"> <li>Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)</li> <li>Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)</li> </ul>	

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A01920

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 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	Application Data Sheet	2005_86US02_ADS.pdf	1210496 a6461af14ecd344e9c260d851356050b55972b6	no	5

**Warnings:**

**Information:**

2		2005_86US02_DIVAPPLN.pdf	156507 7ee950494ed70776c3cadb0d31d636716f144c41	yes	29
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**Multipart Description/PDF files in .zip description**

Document Description	Start	End
Specification	1	21
Claims	22	28
Abstract	29	29

**Warnings:**

**Information:**

3	Drawings-only black and white line drawings	2005_86US02_DRAW.pdf	129505 7593ad043cf6f903f5c817f7344299c92ea5063	no	13
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**Warnings:**

**Information:**

4	Oath or Declaration filed	2005_86US02_DECLARATION.pdf	103024 e8567781df5e37265536710b63e9c681e4a05803	no	3
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**Warnings:**

**Information:**

5		2005_86US02_PREAMEND.pdf	136961 9a54c2443032dc761aeeef32d438bd59f50f0dd6	yes	7
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**Multipart Description/PDF files in .zip description**

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2

VSI\_0000589

	Claims		3	6
	Applicant Arguments/Remarks Made in an Amendment		7	7
<b>Warnings:</b>				
<b>Information:</b>				
6	Fee Worksheet (PTO-875)	fee-info.pdf	33314 435fa8426692bfd529e1efa1c48390f0a3029427	no 2
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<b>Information:</b>				
<b>Total Files Size (in bytes):</b>			1769807	
<p><b>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</b></p> <p><b><u>New Applications Under 35 U.S.C. 111</u></b>  <b>If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</b></p> <p><b><u>National Stage of an International Application under 35 U.S.C. 371</u></b>  <b>If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</b></p> <p><b><u>New International Application Filed with the USPTO as a Receiving Office</u></b>  <b>If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</b></p>				

## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	7906131
<b>Application Number:</b>	12824734
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<b>Title of Invention:</b>	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
<b>First Named Inventor/Applicant Name:</b>	Howard Root
<b>Customer Number:</b>	24113
<b>Filer:</b>	Bradley Pedersen/Michelle Arcand
<b>Filer Authorized By:</b>	Bradley Pedersen
<b>Attorney Docket Number:</b>	2005.86US02
<b>Receipt Date:</b>	28-JUN-2010
<b>Filing Date:</b>	
<b>Time Stamp:</b>	15:45:09
<b>Application Type:</b>	Utility under 35 USC 111(a)

### Payment information:

Submitted with Payment	yes
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Payment was successfully received in RAM	\$462
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Authorized User	PEDERSEN,BRADLEY D.
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**File Listing:**

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2005_86US02_ADS.pdf	1210496 a6461af14ecd344e9c260d851356050b55972b6	no	5

**Warnings:**

**Information:**

2		2005_86US02_DIVAPPLN.pdf	156507 7ee950494ed70776c3cadb0d31d636716f144c41	yes	29
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**Multipart Description/PDF files in .zip description**

Document Description	Start	End
Specification	1	21
Claims	22	28
Abstract	29	29

**Warnings:**

**Information:**

3	Drawings-only black and white line drawings	2005_86US02_DRAW.pdf	129505 7593ad043cf6f903f5c817f7344299c92ea5063	no	13
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**Warnings:**

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4	Oath or Declaration filed	2005_86US02_DECLARATION.pdf	103024 e8567781df5e37265536710b63e9c681e4a05803	no	3
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**Warnings:**

**Information:**

5		2005_86US02_PREAMEND.pdf	136961 9a54c2443032dc761aeeef32d438bd59f50f0dd6	yes	7
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**Multipart Description/PDF files in .zip description**

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2

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	Claims		3		6
	Applicant Arguments/Remarks Made in an Amendment		7		7
<b>Warnings:</b>					
<b>Information:</b>					
6	Fee Worksheet (PTO-875)	fee-info.pdf	33314	no	2
			435fa8426692bffd529e1efaf1c48390f0a3029427		
<b>Warnings:</b>					
<b>Information:</b>					
<b>Total Files Size (in bytes):</b>			1769807		
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<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86US02
		Application Number	
Title of Invention	Coaxial Guide Catheter for Interventional Cardiology Procedures		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

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**Applicant Information:**

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<b>Applicant Authority</b> <input checked="" type="radio"/> Inventor		<input type="radio"/> Legal Representative under 35 U.S.C. 117		<input type="radio"/> Party of Interest under 35 U.S.C. 118	
<b>Prefix</b>	<b>Given Name</b>	<b>Middle Name</b>	<b>Family Name</b>	<b>Suffix</b>	
	Howard		Root		
<b>Residence Information (Select One)</b> <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					
<b>City</b>	Excelsior	<b>State/Province</b>	MN	<b>Country of Residence i</b>	US
<b>Citizenship under 37 CFR 1.41(b) i</b>		US			
<b>Mailing Address of Applicant:</b>					
<b>Address 1</b>					
<b>Address 2</b>					
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<b>Applicant 2</b>					<input type="button" value="Remove"/>
<b>Applicant Authority</b> <input checked="" type="radio"/> Inventor		<input type="radio"/> Legal Representative under 35 U.S.C. 117		<input type="radio"/> Party of Interest under 35 U.S.C. 118	
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<b>Citizenship under 37 CFR 1.41(b) i</b>		US			
<b>Mailing Address of Applicant:</b>					
<b>Address 1</b>					
<b>Address 2</b>					
<b>City</b>		<b>State/Province</b>			
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<b>Applicant 3</b>					<input type="button" value="Remove"/>
<b>Applicant Authority</b> <input checked="" type="radio"/> Inventor		<input type="radio"/> Legal Representative under 35 U.S.C. 117		<input type="radio"/> Party of Interest under 35 U.S.C. 118	
<b>Prefix</b>	<b>Given Name</b>	<b>Middle Name</b>	<b>Family Name</b>	<b>Suffix</b>	
	Jeffrey	M.	Welch		
<b>Residence Information (Select One)</b> <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service					
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<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86US02	
		Application Number		
Title of Invention	Coaxial Guide Catheter for Interventional Cardiology Procedures			
Citizenship under 37 CFR 1.41(b) i	US			
<b>Mailing Address of Applicant:</b>				
Address 1				
Address 2				
City		State/Province		
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				<input type="button" value="Remove"/>
<b>Applicant 4</b>				
Applicant Authority	<input checked="" type="radio"/> Inventor	<input type="radio"/> Legal Representative under 35 U.S.C. 117	<input type="radio"/> Party of Interest under 35 U.S.C. 118	
Prefix	Given Name	Middle Name	Family Name	Suffix
	Jason	M.	Garrity	
<b>Residence Information (Select One)</b> <input checked="" type="radio"/> US Residency <input type="radio"/> Non US Residency <input type="radio"/> Active US Military Service				
City	Minneapolis	State/Province	MN	Country of Residence <sup>i</sup> US
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<input type="checkbox"/> An Address is being provided for the correspondence information of this application.			
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**Application Information:**

Title of the Invention	Coaxial Guide Catheter for Interventional Cardiology Procedures		
Attorney Docket Number	2005.86US02	Small Entity Status Claimed	<input checked="" type="checkbox"/>
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)		Suggested Figure for Publication (if any)	

<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86US02
		Application Number	
Title of Invention	Coaxial Guide Catheter for Interventional Cardiology Procedures		

**Publication Information:**

<input type="checkbox"/>	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
<input type="checkbox"/>	<b>Request Not to Publish.</b> I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application <b>has not and will not</b> be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Prior Application Status	Pending	<input type="button" value="Remove"/>	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Division of	11416629	2006-05-03
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the <b>Add</b> button.			<input type="button" value="Add"/>

**Foreign Priority Information:**

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Application Number	Country <sup>i</sup>	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
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<b>Application Data Sheet 37 CFR 1.76</b>		Attorney Docket Number	2005.86US02	
		Application Number		
Title of Invention	Coaxial Guide Catheter for Interventional Cardiology Procedures			
If the Assignee is an Organization check here. <input type="checkbox"/>				
Prefix	Given Name	Middle Name	Family Name	Suffix
<b>Mailing Address Information:</b>				
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**Signature:**

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<b>Signature</b>	/Brad Pedersen/		<b>Date (YYYY-MM-DD)</b>	2010-06-28	
<b>First Name</b>	Brad	<b>Last Name</b>	Pedersen	<b>Registration Number</b>	32432

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## **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. Patent No. 6,475,195 issued to Voda and U.S. Patent No. 5,658,263 issued to Dang et al. These guiding catheters all share the common limitation that a guide catheter stiff enough to provide adequate backup support is often too stiff to be safely inserted into the aorta without the possibility of causing damage to the aortic wall. In addition, attempts to deep seat the guide catheter have been made but the rigid nature of the guide catheter creates the risk that the guide 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. Patent Nos. 4,813, 930 issued

to Elliot; 5,098,412 issued to Shiu; and 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. Patent Nos. 4,832,028 issued to Patel; 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, .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 be followed by a section about three cm long of 5533 Pebax® that covers marker band 24 and the distal portion of braid or coil reinforcement 32. Next may come an approximately five cm portion of 6333 Pebax® which encloses part of braid or coil reinforcement 32 followed by an approximately twenty seven cm portion of 7233 Pebax® covering the most proximal portion of braid or coil reinforcement 32. Braid or coil reinforcement 32 is bonded to rigid portion 20 which may be formed from stainless steel or a similar biocompatible material. Rigid portion 20 may extend for approximately ninety cm and include first full circumference portion 34 (approximately .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 .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 .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<sub>4</sub>).

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

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

In operation, a guide catheter 56 is inserted into a major blood vessel in the body such as aortic arch 58 over guidewire 64 and the distal end 68 of guide catheter 56 is brought into proximity of ostium 60 of a smaller branch blood vessel, such as coronary artery 62, that it is



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

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

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

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

**Claims**

What is claimed is:

1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature, the interventional cardiology device being adapted to be passed through a guide catheter, the method comprising:

inserting the guide catheter into the first blood vessel, the guide catheter having a first lumen and a distal end;

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

inserting a coaxial guide catheter over the guidewire and into the first lumen of the guide catheter, the coaxial guide catheter having a second lumen and

a flexible distal tip portion,

a reinforced portion proximal to the distal tip portion, and

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

advancing the distal tip portion of the coaxial guide catheter into the second blood vessel such that the flexible distal tip portion and at least a portion of the reinforced portion extend out of the distal end of the guide catheter and into the second blood vessel; and

inserting the interventional cardiology device through the lumen of the coaxial guide catheter and into contact with or past a lesion in the second blood vessel.

2. The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal tip portion of the coaxial guide catheter remains seated in the second blood vessel in response to an opposing backward force exerted by the interventional cardiology device.

3. The method as claimed in claim 1, further comprising:  
keying the tapered inner catheter to the coaxial guide catheter at a proximal portion thereof;  
inserting a guidewire having a tip into a first blood vessel; and  
inserting the tip of the guidewire into a second blood vessel that branches off of the first blood vessel.

4. The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion and a partially cylindrical portion defining the opening along a side thereof.

5. The method as claimed in claim 1, further comprising selecting the guide catheter to further comprise a Y-adapter and the method further comprising injecting a fluid through the Y-adapter into the second lumen.

6. The method as claimed in claim 1, further comprising inserting a guidewire having a tip into a first blood vessel; and

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

7. The method as claimed in claim 6, further comprising placing a tapered inner catheter inside the second lumen of the coaxial guide catheter, the tapered inner catheter including a tapered distal portion, the tapered distal portion being positioned to extend beyond the distal tip of the coaxial guide catheter;

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

removing the guidewire from the coaxial guide catheter.

8. A device 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 first artery, the device comprising:

an elongate structure defining a second lumen and being sized to pass through the first lumen of the guide catheter, the elongate structure including

a flexible distal tip portion;

a reinforced portion proximal to the flexible distal tip portion; and

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including a partially cylindrical portion defining an opening along a side thereof, the opening extending substantially along at least a portion of a length of the rigid portion;

such that when the device 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.

9. The device as claimed in claim 8, further comprising:

a radiopaque marker proximate the distal tip;

wherein the reinforced portion comprises a braid or coil formed of metal; and

wherein the substantially rigid portion defines a plurality of relief cuts therein, the relief cuts controlling the rigidity of at least a portion of the substantially rigid portion.

10. The device as claimed in claim 8, further comprising a tapered inner catheter proportioned to pass through the second lumen and to extend outwardly from the flexible distal tip, the tapered inner catheter defining a third lumen through which the tapered inner catheter may be passed over a guidewire to facilitate insertion of the device, the tapered inner catheter being removable prior to insertion of the interventional cardiology device.

11. The device as claimed in claim 10, wherein the tapered inner catheter has a first portion and a second portion, the first portion defining a lumen therethrough and the second portion defining a concave track.

12. The device as claimed in claim 8, wherein portions of the device intended for passage into the guide catheter have a size selected from a group consisting of about eight French, about seven French and about six French.

13. The device as claimed in claim 8, further comprising, starting at a distal end, a polymer exterior having a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, a third portion having a third flexural modulus greater than the second flexural modulus and a fourth portion having a fourth flexural modulus greater than the third flexural modulus.

14. The device as claimed in claim 13, 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, the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI and the fourth flexural modulus is about 107,000 PSI plus or minus 20,000 PSI.

15. The device as claimed in claim 13, in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, the third portion is about five cm in length and the fourth portion is about twenty seven cm in length.

16. The device as claimed in claim 10, wherein the coaxial guide catheter and the tapered inner catheter are keyed at their respective distal ends to allow releasable connection of the coaxial guide catheter and the tapered inner catheter to each other.

17. A kit for performing interventional cardiology procedures that include insertion of a treatment catheter into a blood vessel, the kit comprising:

- a guide catheter having a first lumen;

- a coaxial guide catheter comprising an elongate structure defining a second lumen and being sized to pass through the first lumen of the guide catheter, the coaxial guide catheter including:

- a flexible distal tip portion;

- a reinforced portion proximal to the flexible distal tip portion; and

- a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including a short cylindrical portion and a partially cylindrical portion defining an opening along a side thereof, the opening extending substantially along a majority of a length of the rigid portion.



18. The kit as claimed in claim 17, further comprising a tapered inner catheter sized to fit within the second lumen having a tapered distal tip and defining a third lumen through which a guidewire may be passed.

19. The kit as claimed in claim 17, the coaxial guide catheter further comprising, starting at a distal end, a polymer exterior having a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, a third portion having a third flexural modulus greater than the second flexural modulus and a fourth portion having a fourth flexural modulus greater than the third flexural modulus.

20. The kit as claimed in 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, the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI and the fourth flexural modulus is about 107,000 PSI plus or minus 20,000 PSI.

**Abstract of the Disclosure**

A coaxial guide catheter to be passed through guide catheter having a first lumen, for use with interventional cardiology devices that are insertable into a branch artery that branches off from a main artery. The coaxial guide catheter is extended through the lumen of the 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.

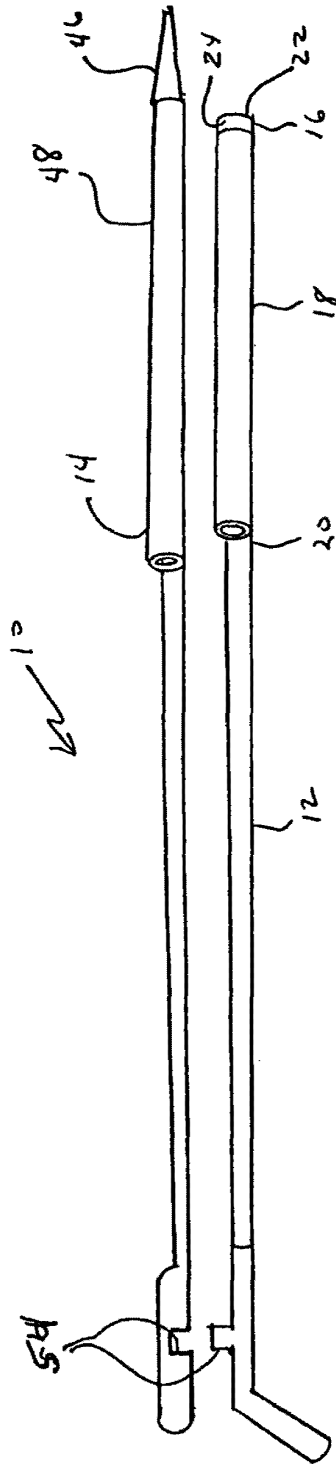


FIG. 1

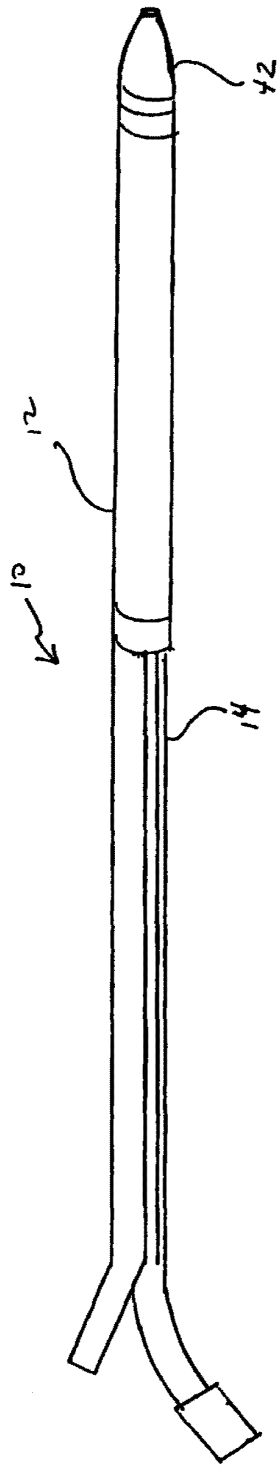


FIG 2

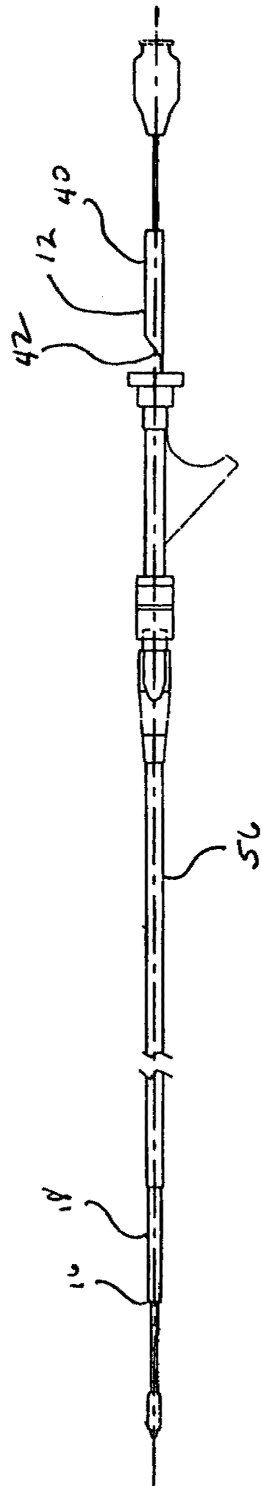
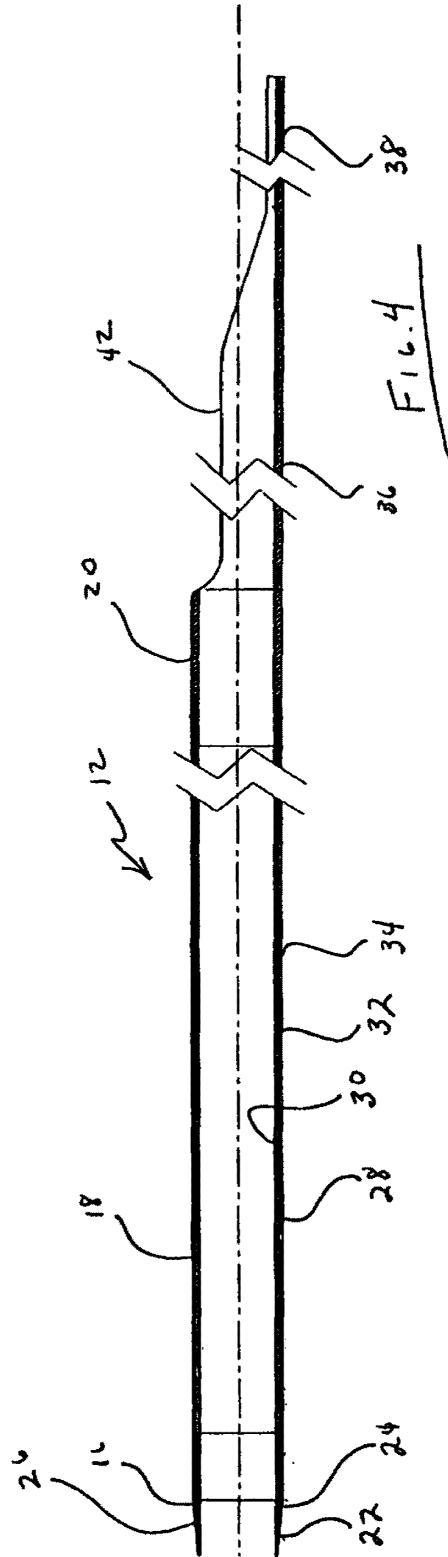


Fig. 3



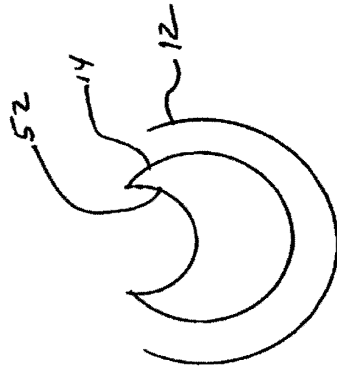


Fig. 6

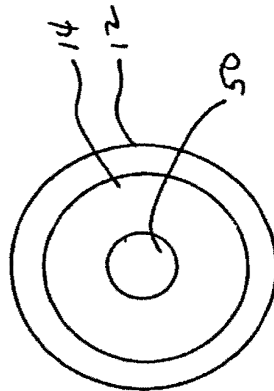
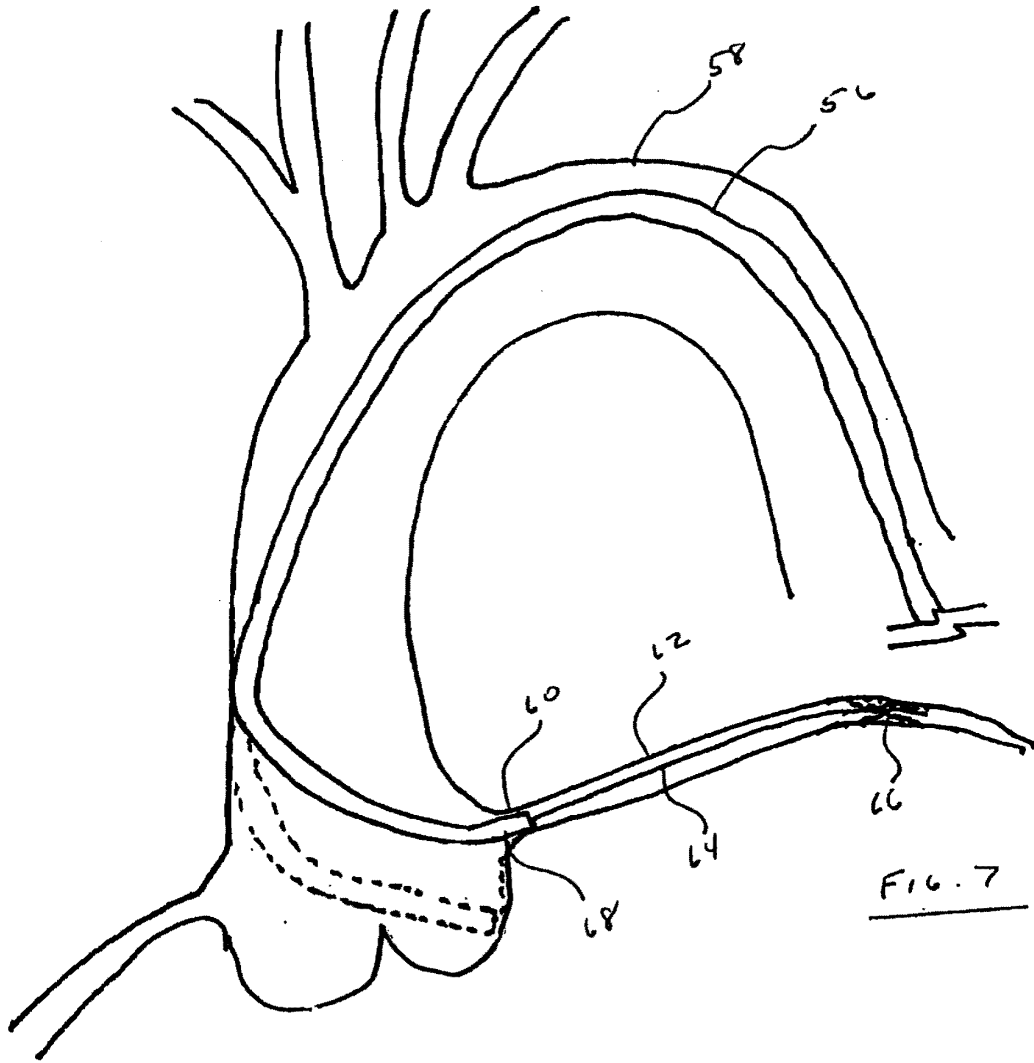


Fig. 5





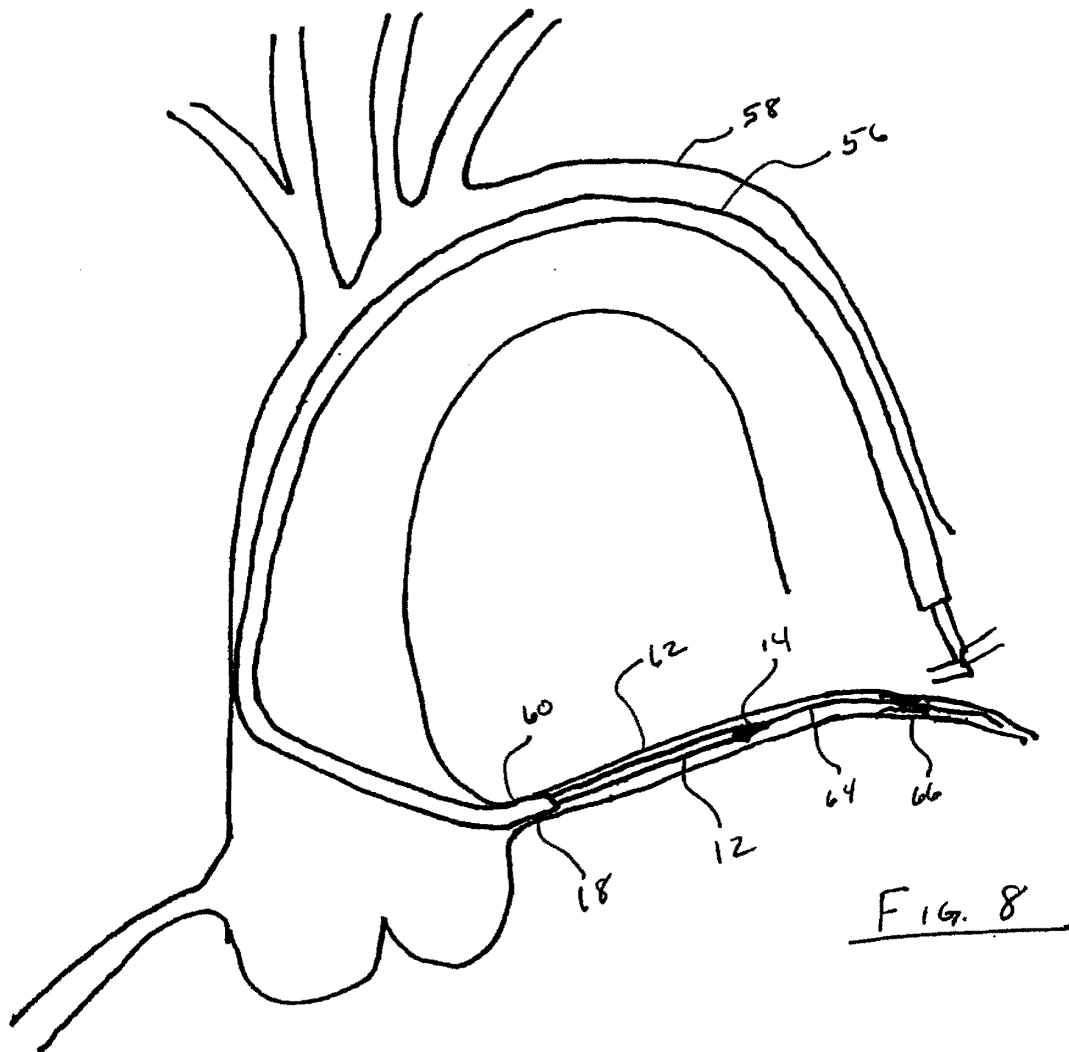


FIG. 8

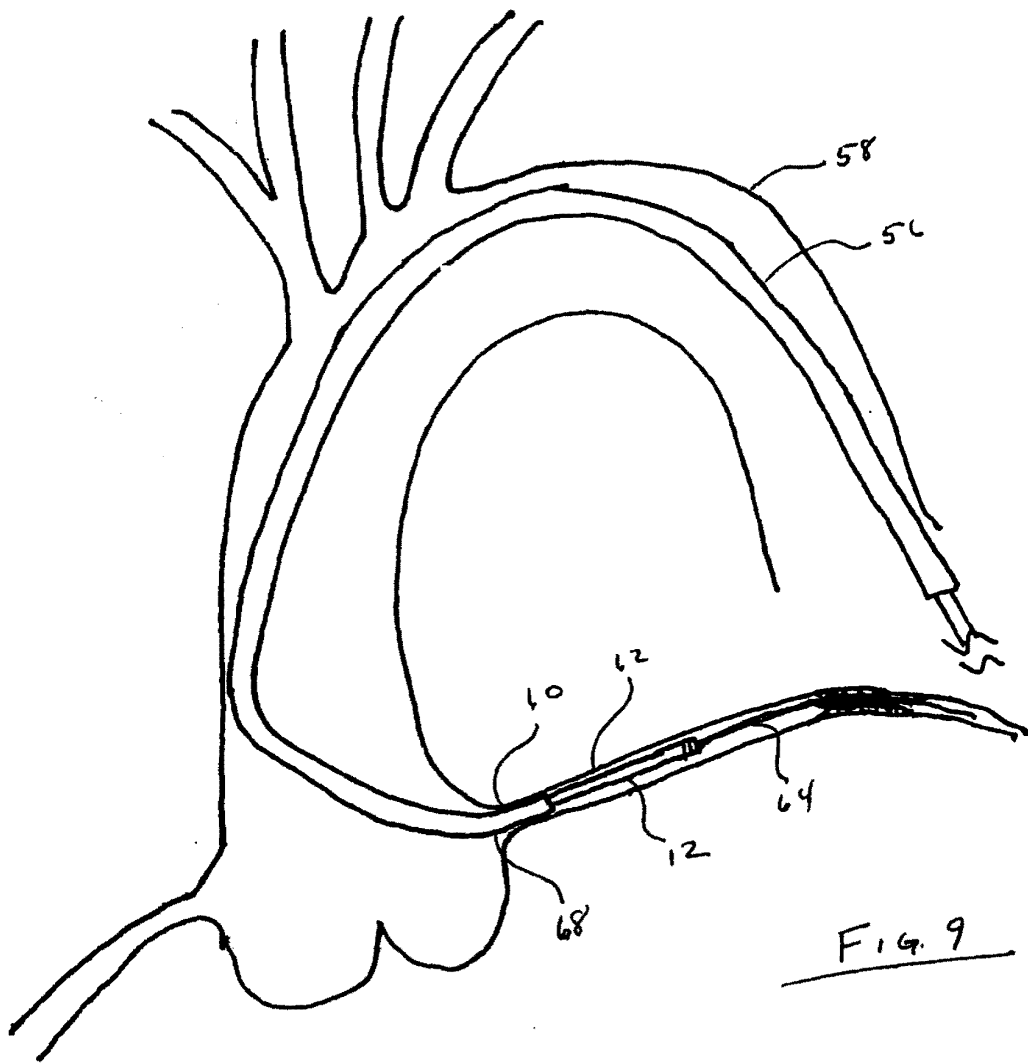
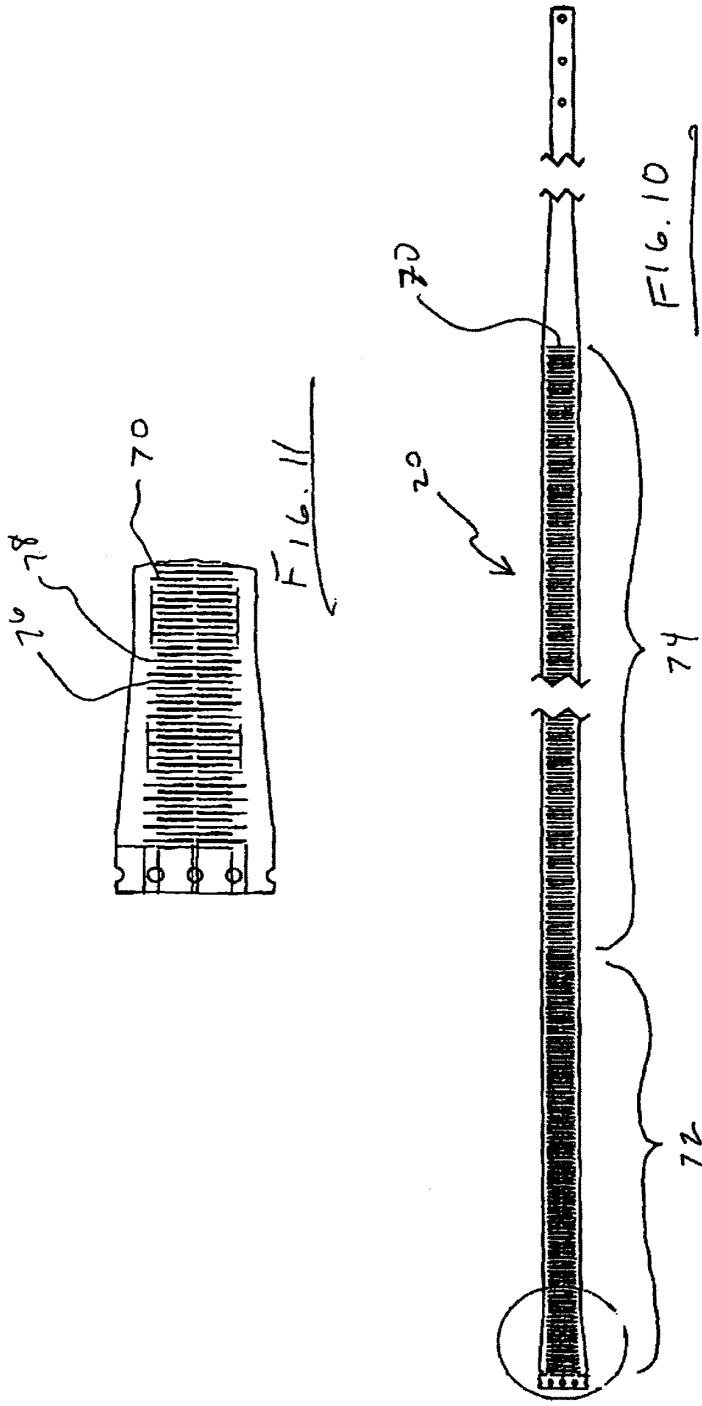
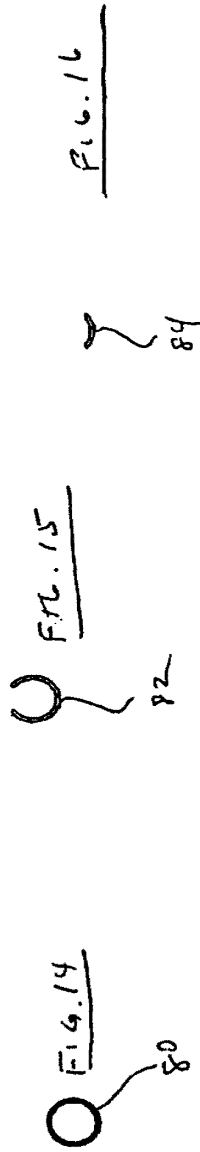
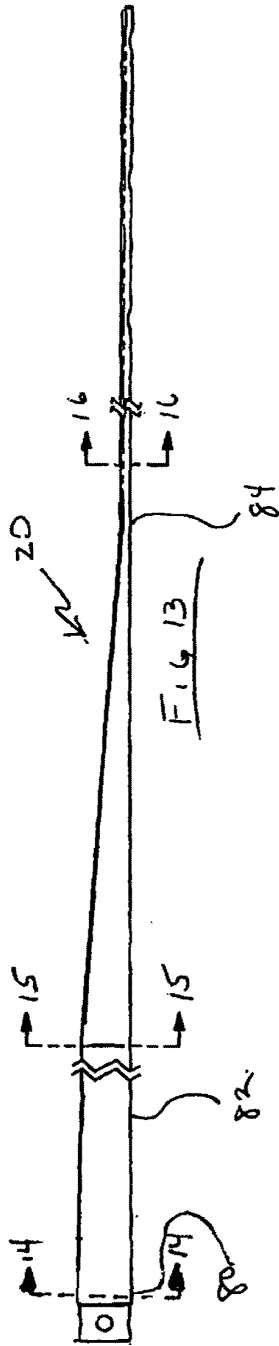
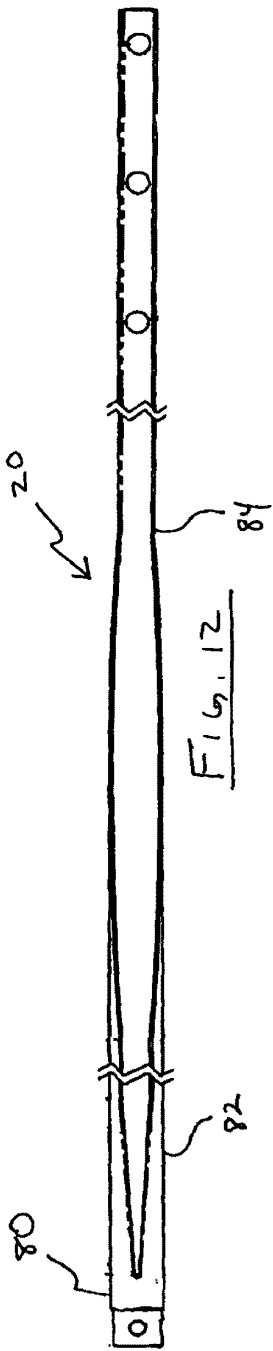


FIG. 9





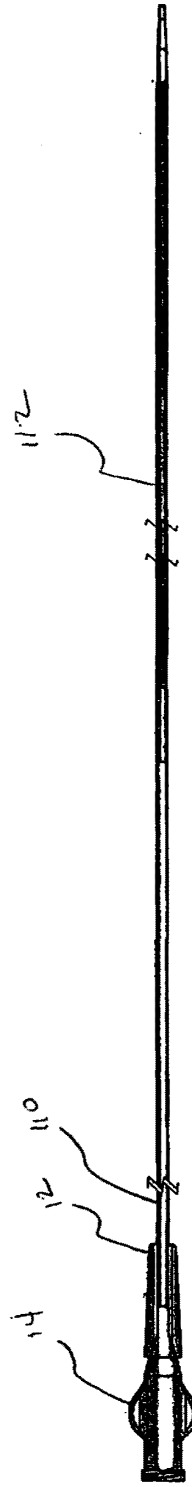


Fig. 17

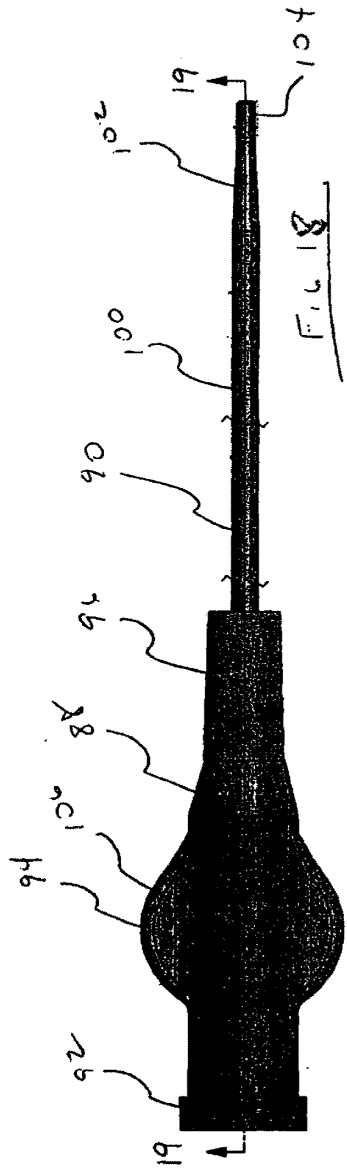


FIG. 18

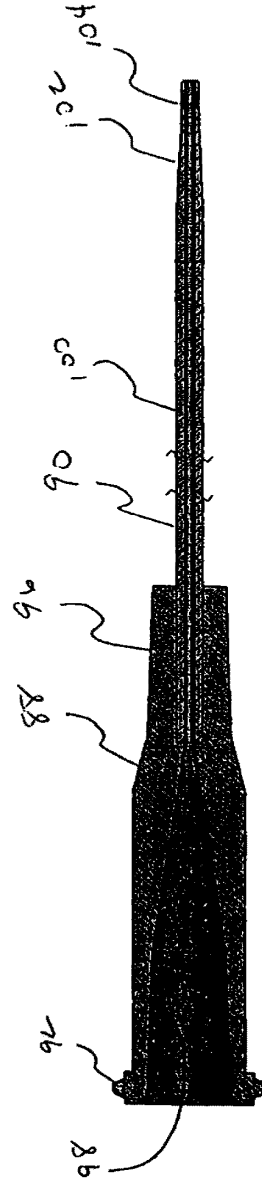
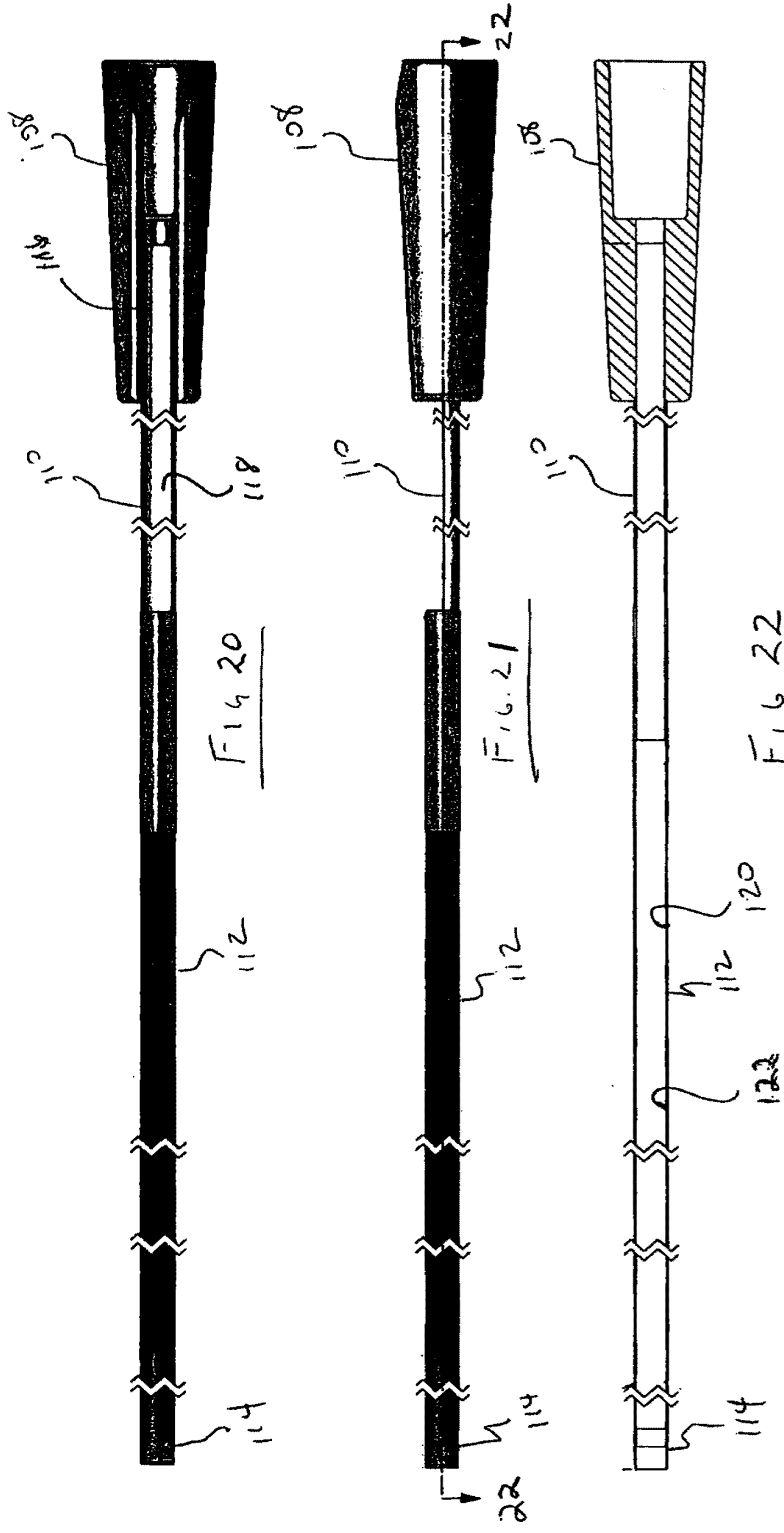


FIG. 19



**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby appoint the practitioners associated with **Customer Number 24113** to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Address all telephone calls to: Paul C. Onderick at telephone number (612) 349-5766.

Address all correspondence to: Customer Number 24113  
Paul C. Onderick  
Patterson, Thunte, Skaar & Christensen, P.A.  
4800 IDS Center, 80 South 8th Street  
Minneapolis, Minnesota 55402-2100

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES, the specification of which is attached hereto unless the following is checked:

The specification was filed on May 3, 2006 as United States Application Number or PCT International Application Number 11/416,629 and was amended on.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Claimed
(Number)	(Country)	(Day/Month/Year Filed)	(Yes/No)
(Number)	(Country)	(Day/Month/Year Filed)	(Yes/No)



I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

\_\_\_\_\_  
(Application Number) (Filing Date)

\_\_\_\_\_  
(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

\_\_\_\_\_  
(Application Number) (Filing Date) (Status - patented, pending, abandoned)

\_\_\_\_\_  
(Application Number) (Filing Date) (Status - patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Howard Root  
Full name of sole or first inventor (given name, family name)

  
Inventor's signature

May 22, 2006  
Date

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Mailing Address

Gregg Sutton  
Full name of second joint inventor, if any (given name, family name)

  
Second inventor's signature

5/22/06  
Date

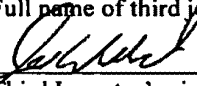
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Jeffrey M. Welch

Full name of third joint inventor, if any (given name, family name)

  
Third Inventor's signature

5/18/06  
Date

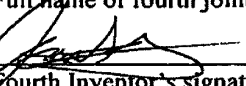
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Jason M. Garrity

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Fourth Inventor's signature

5-18-06  
Date

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Mailing Address

\_\_\_\_\_  
Full name of fifth joint inventor, if any (given name, family name)

\_\_\_\_\_  
Fifth Inventor's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Residence (City and either State or Foreign Country)

\_\_\_\_\_  
Citizenship

\_\_\_\_\_  
Mailing Address

[ ] Additional inventors are named on the attached sheets.

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

<b>PATENT APPLICATION FEE DETERMINATION RECORD</b> Substitute for Form PTO-875					Application or Docket Number <b>12/824,734</b>		Filing Date <b>06/28/2010</b>		<input type="checkbox"/> To be Mailed							
<b>APPLICATION AS FILED – PART I</b>							<b>OTHER THAN</b>									
(Column 1)			(Column 2)		SMALL ENTITY <input checked="" type="checkbox"/>		OR		SMALL ENTITY							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)		RATE (\$)		FEE (\$)				
<input type="checkbox"/> BASIC FEE <small>(37 CFR 1.16(a), (b), or (c))</small>		N/A		N/A		N/A				N/A						
<input type="checkbox"/> SEARCH FEE <small>(37 CFR 1.16(k), (l), or (m))</small>		N/A		N/A		N/A				N/A						
<input type="checkbox"/> EXAMINATION FEE <small>(37 CFR 1.16(o), (p), or (q))</small>		N/A		N/A		N/A				N/A						
TOTAL CLAIMS <small>(37 CFR 1.16(i))</small>		minus 20 =		*		X \$ =		OR		X \$ =						
INDEPENDENT CLAIMS <small>(37 CFR 1.16(h))</small>		minus 3 =		*		X \$ =				X \$ =						
<input type="checkbox"/> APPLICATION SIZE FEE <small>(37 CFR 1.16(s))</small>		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).														
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT <small>(37 CFR 1.16(j))</small>																
* If the difference in column 1 is less than zero, enter "0" in column 2.																
<b>APPLICATION AS AMENDED – PART II</b>							<b>OTHER THAN</b>									
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY		OR		SMALL ENTITY					
<b>AMENDMENT</b>	<b>06/28/2010</b>		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)		RATE (\$)		ADDITIONAL FEE (\$)	
	Total <small>(37 CFR 1.16(i))</small>		* 7		Minus ** 20		= 0		X \$26 =		0		OR		X \$ =	
	Independent <small>(37 CFR 1.16(h))</small>		* 1		Minus *** 3		= 0		X \$110 =		0		OR		X \$ =	
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>															
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>															
TOTAL ADD'L FEE		<b>0</b>						OR		TOTAL ADD'L FEE						
<b>AMENDMENT</b>	(Column 1)		(Column 2)		(Column 3)		RATE (\$)		ADDITIONAL FEE (\$)		RATE (\$)		ADDITIONAL FEE (\$)			
	Total <small>(37 CFR 1.16(i))</small>		*		Minus **		=		X \$ =		OR		X \$ =			
	Independent <small>(37 CFR 1.16(h))</small>		*		Minus ***		=		X \$ =		OR		X \$ =			
	<input type="checkbox"/> Application Size Fee <small>(37 CFR 1.16(s))</small>															
	<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM <small>(37 CFR 1.16(j))</small>															
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:  
/CRYSTAL QUEEN/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**  
 If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.