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EAST Search History (Interference)

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PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11416629	Filing Date	2006-05-03	Docket Number (if applicable)	2005.86US01	Art Unit	3767
First Named Inventor	Root et al.			Examiner Name	Bradley James Osinski		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

☐ Other _____

☒ Enclosed

☒ Amendment/Reply

☒ Information Disclosure Statement (IDS)

☐ Affidavit(s)/ Declaration(s)

☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 160631

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Signature of Registered U.S. Patent Practitioner			
Signature	/Brad Pedersen/	Date (YYYY-MM-DD)	2010-06-28
Name	Brad Pedersen	Registration Number	32432

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 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.

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

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

PRELIMINARY AMENDMENT

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

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of June 3, 2010, and as part of the Request for Continuing Examination submitted herewith, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

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

AMENDMENTS TO THE CLAIMS

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

1-57. (Canceled).

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

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

a substantially rigid portion proximal of and operably connected to the flexible tip portion and defining a non-tubular structure having a maximal cross-sectional dimension at a proximal portion that is non-circular and smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, is longer than the length of the continuous lumen of the guide catheter,

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

59. (New) The device of claim 58 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

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

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

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

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

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

65. (New) The device of claim 58 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

66. (New) The device of claim 58 wherein the substantially rigid portion includes from distal to proximal direction, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

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

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

a flexible tip portion defining a non-expandable tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the length of the continuous lumen of the guide catheter, the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-

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

a reinforced portion proximal to the flexible tip portion; and

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

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

68. (New) The device of claim 67 wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter, the device assists in resisting axial and shear forces exerted by an interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.

69. (New) The device of claim 67 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening along a side thereof adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

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

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

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

73. (New) The device of claim 67 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

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

75. (New) The device of claim 67 wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

76. (New) The device of claim 75 in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

77. (New) The device of claim 75 in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.

REMARKS

Claims 58-77 are pending. By this Amendment, claims 28-57 are cancelled and new claims 58-77 are added. No new matter has been added. Support for the claim can be found throughout the specification, including, for example, paragraphs [0012], [0013], [0017], [0074] as published and claims 8-16 as originally filed.

Claim Rejections – 35 U.S.C. § 112

The applicants do not acquiesce in any of these Section 112 rejections of claims 28-57 and expressly reserve the right to present claims of a similar scope in subsequent prosecution. Claims 28-57 have been cancelled in favor of new claims 58-82 solely to advance prosecution by the presentation of claims of a different claim scope. New independent apparatus claims 58 and 67 recite structural features of the device which are fully supported by the specification as originally filed.

Claim Rejections – 35 U.S.C. § 103

Prior claims 28-57 stood rejected in view of various combinations of Niazi in view of Solar and/or Klein. The applicants do not acquiesce in any of these prior art rejections of claims 28-57 and expressly reserve the right to present arguments with respect to the prior art for claims of a similar scope in subsequent prosecution.

With respect to new independent apparatus claim 58 and 67, it is respectfully submitted that Niazi teaches away from the claimed inventions by teaching the use of two hemostatic valves (56 and 57), one for each of the continuous lumens of the catheters (51 and 52,

respectively). It is also respectfully submitted that Solar teaches away from the claimed inventions as well as Solar teaches a tubular tracking member (7) at a distal end that is meant for tracking the device along a guidewire. Solar teaches away from a tubular structure at a distal end that defines a coaxial lumen sufficiently large enough to receive an interventional cardiology device as the balloon (10, 22) is always shown outside to the tubular tracking member. Moreover, the advancement member (5) of Solar is always shown as outside the hub (16, 29, 50). Consequently, it is respectfully submitted that Solar teaches away from the limitations present in newly submitted independent claim 58 and 67.

Even if there were a reasoned rationale for combining the cited references, none of which have been provided, the purported combination of the cited references does not result in the claimed inventions and would defeat the purpose of each of the cited references which use multiple hubs/valves (Niazi) or which track the interventional cardiology device outside of the tubular tracking member (Solar). Accordingly, it is respectfully submitted that the newly presented independent claims 58 and 67 are patentable over the cited art.

The applicants' specifically refute the unsupported assertion in the previous Office Action at page 5 that "One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Niazi and Solar because a non-circular cross-section would have the ability to perform the same function as the rod taught by Solar with only the expected result of minimizing the profile of the rod inside the device. Therefore, it would have been an obvious matter of design choice to modify Niazi and Solar to obtain the invention as specified in claim 28." First, the assertion is clearly improper use of hindsight as the purported rationale presented in this argument improperly starts off by evaluating the expectation

of the Applicant's invention, not the prior art. Second, a person skilled in the art would recognize the need for sufficient column strength of the push rod over the entire length of the push rod as a practical limit to the diameter of the rod. Making the push rod smaller as suggested in this argument would cause the rod to buckle as it was used to push the tracking collar within the guide catheter.

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

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

Respectfully submitted,

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Registration No. 32432

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

INFORMATION DISCLOSURE STATEMENT

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

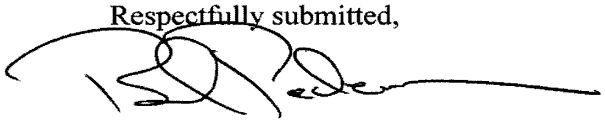
Sir:

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.

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 and in connection with the filing of a Request for Continued Examination under 37 CFR § 1.114. No certification or fee is required. 37 CFR § 1.97(b)(4).

Respectfully submitted,



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

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

U.S. PATENT DOCUMENTS

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

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

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

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

Utility under 35 USC 111(a) Filing Fees

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

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

Electronic Acknowledgement Receipt	
EFS ID:	7905760
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Michelle Arcand
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86US01
Receipt Date:	28-JUN-2010
Filing Date:	03-MAY-2006
Time Stamp:	15:29:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$405
RAM confirmation Number	2034
Deposit Account	160631
Authorized User	PEDERSEN,BRADLEY D.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	2005_86US01_RCE.pdf	768760 098355c4bbcde45308a74e3878a84f3c251faa4f	no	3
Warnings:					
Information:					
2		2005_86US01_PREAMEND.pdf	331957 c38627bed469d58ea01c3572488a2c8dd37e0c40	yes	11

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	8
Applicant Arguments/Remarks Made in an Amendment	9	11

Warnings:					
Information:					
3		2005_86US01_IDS1449.pdf	103662 7bf368ac50f4741b4654de803d40d123df5dad0b	yes	3

Multipart Description/PDF files in .zip description

Document Description	Start	End
Transmittal Letter	1	2
Information Disclosure Statement (IDS) Filed (SB/08)	3	3

Warnings:					
Information:					
4	Fee Worksheet (PTO-875)	fee-info.pdf	30200 4c0ddd673f59586690be0788da701c6178cd0e52	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1234579		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/416,629	05/03/2006	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 06/28/2010

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

AMENDMENT

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

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

Legal Instrument Examiner:
/NICOLLE I. SCRIVNER/

UNITED STATES PATENT AND TRADEMARK OFFICE

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

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

24113 7590 06/03/2010

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EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
06/03/2010	PAPER

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

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

PTOL-90A (Rev. 04/07)

VSI_00000232

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *19 February 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) *28-57* 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) *28-57* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Claim Rejections - 35 USC § 112

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

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

1. Claims 28-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims the proximal portion of the tubular structure of the coaxial guide catheter is unsuitable for extending beyond the distal en of the guide catheter. The Examiner could find no explanation of this in the specification, mapping of this limitation to the specification is requested.

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.

2. Claims 28-32 and 40 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 28-32, 56 and 57 include means (or step) plus function limitations that invoke 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The exact metes-and-bounds of the claim may not be determined.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

b. The terms "unsuitable" in claims 28, 42, 56 and 57 and “suitable" in 57 are relative terms which render the claims indefinite. The term "unsuitable"/”unsuitable” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The terms are thus interpreted as intended use.

Claim Rejections - 35 USC § 103

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

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

3. Claims 8, 12-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Solar (2003/0195546) and Klein et al (5,776,141).

c. Regarding claims 28 and 42, Niazi discloses a coaxial guide catheter 52 comprising a tubular structure (see figures 3 and 6) that has a circular cross-section and is sized to be insertable though the lumen of the guide catheter 51and defines a coaxial lumen though which cardiology devices are insertable. The distal portion of the coaxial guide catheter 52 includes a means for defining a distal portion via a taper (figure 3) that is flexible and is suitable for extending beyond the distal end of the guide catheter and a means for defining a proximal portion that is unsuitable for extending beyond the distal end of the catheter via abutment of the collars on the proximal end of the device with as seen in figure 3.

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

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

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

d. Regarding claims 29 and 43, Niazi discloses a means for defining a proximal portion further comprising means for defining a proximal opening along

and accessible form a longitudinal side to receive a cardiology device via the coil 55. The first proximal turn of the coil defines such a proximal opening.

e. Regarding claims 30 and 44, a partial turn of the coil defines a partial cylindrical portion and a full turn of the coil defines a full circumference portion.

f. Regarding claims 31 and 45, figure 3 shows the catheter with a flexible cylindrical distal tip and figure 6 shows a coil 55. Figure 3 shows the taper and figure 6 does not. Figure 6 appears to be slightly truncated as it also does not show the proximal end. Regardless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the embodiment in figure 6 with a soft distal tip (Col.3 lines 31-37) in order to allow the tip to better navigate tortuous anatomy.

g. Regarding claims 32 and 46, see claim 31, the tip is generally cylindrical and a soft polymer such as silicone (Col.5 lines 14-16).

h. Regarding claims 33 and 47, Niazi discloses the device as being made of silastic (a polymer) and broken into four different portions (see figure 2). Niazi and Solar further disclose decreasing the rigidity (directly related to flexural modulus) as one moves distally down the device. Alternatively, rigidity increases as one moves proximally.

i. Regarding claims 34, 35, 48 and 49, While Niazi substantially discloses the apparatus as claimed, it does not disclose the flexural modulus' or length of each section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific

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

j. Regarding claims 36 and 50, Niazi disclose the proximal portion is the most rigid. Claim 28 discusses replacing the entire portion proximal the coil with the push rod, but a plastic portion of the catheter can easily be left on to both assist with rigidity and prevent the coil from tearing through the silicone if too much stress is applied.

k. Regarding claims 38 and 52, Niazi discloses a reinforcing coil. However, Niazi does not disclose the coil made of metal specifically. It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose metal as the reinforcing coil material since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197. 125 USPQ 416 (CCPA 1960).*

l. Regarding claims 39 and 53 while Niazi substantially discloses the apparatus as claimed, it does not disclose a radiopaque marker proximate the distal tip. However, Solar discloses a radiopaque marker 17 to allow the system's position to be monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a radiopaque marker as taught by Solar to allow the system's position to be monitored.

m. Regarding claims 40, 41, 54 and 55, the guide catheter is insertable over a guidewire 81 with the coaxial guide catheter comprising a means for interfacing with the guidewire via either obturator 53 or its own lumen. A lumen is a concave track adapted to receive a guidewire.

n. Regarding claims 56 and 57, see claims 28-30 above.

4. Claims 37 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) and Solar (2003/0195546) as applied to claims 36 and 50 above, and further in view of Adams (2004/0127927)

o. Regarding claims 37 and 51, While Niazi substantially discloses the apparatus as claimed, it does not disclose the rigid portion defining a plurality of relief cuts controlling the rigidity of a portion of the rigid portion. However, Solar discloses a decreasing rigidity along the device as one travels distally. Adams discloses relief cuts as a method of forming a non-rigid bendable section in an otherwise straight member (Paragraph 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the

device of Niazi and Solar with relief cuts as taught by Adams to customize the rigidity of the device (as is taught as desirable by Solar.

Response to Arguments

5. Applicant's arguments filed 2/19/2010 have been fully considered but they are not persuasive.

p. Applicant argues that the entirely new, rewritten claims overcome the art. However, the Examiner agreed that structure on the proximal end of the tubular structure that prevents it form extending beyond the distal end of the guide catheter would overcome the art. Applicant has used the term "unsuitable" to reflect this. The Examiner does not find the term “unsuitable” to give the catheter any inherent structure that overcomes the art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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

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

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

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11416629	ROOT ET AL.
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☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009	05/21/2010					
	37				✓					
	38				✓					
	39				✓					
	40				✓					
	41				✓					
	42				✓					
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	44				✓					
	45				✓					
	46				✓					
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	49				✓					
	50				✓					
	51				✓					
	52				✓					
	53				✓					
	54				✓					
	55				✓					
	56				✓					
	57				✓					

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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 November 19, 2009, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

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

AMENDMENTS TO THE CLAIMS

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

1-27. (Canceled).

Please add new claims 28- as follows:

28. (New) A coaxial guide catheter for use within a guide catheter having a lumen through which interventional cardiology devices are insertable and a distal end that is preplaceable in a branch artery, the coaxial guide catheter comprising:

a tubular structure having a circular cross-section and sized to be insertable through the lumen of the guide catheter and defining a coaxial lumen through which interventional cardiology devices are insertable, the tubular structure positioned along a distal portion of the coaxial guide catheter and including means for defining a distal portion that is flexible and is suitable for extending beyond the distal end of the guide catheter and means for defining a proximal portion that is unsuitable for extending beyond the distal end of the guide catheter; and

an elongated structure operably coupled to the tubular structure and having a non-circular cross-section and sized so that a proximal end is extendable proximal of the guide catheter when the tubular structure is positioned with the means for defining the distal portion extending beyond the distal end of the guide catheter and further into the branch artery while the means for defining the proximal portion remains within the lumen of the 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 guide catheter from the branch artery.

29. (New) The coaxial guide catheter of claim 28 wherein the means for defining the proximal portion further comprises means for defining a proximal opening along and accessible from a longitudinal side to receive an interventional cardiology into the coaxial lumen while the means for defining the proximal portion remains within the lumen of the guide catheter.

30. (New) The coaxial guide catheter of claim 29 wherein the means for defining the proximal opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

31. (New) The coaxial guide catheter of claim 28 wherein the means for defining the distal portion includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

32. (New) The coaxial guide catheter of claim 28 wherein the means for defining the distal portion comprises generally cylindrical structure having a polymer exterior.

33. (New) The coaxial guide catheter of claim 32 wherein the polymer exterior has at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

34. (New) The coaxial guide catheter of claim 33 in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

35. (New) The coaxial guide catheter of claim 33 in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.

36. (New) The coaxial guide catheter of claim 28 wherein the means for defining the proximal portion comprises a substantially rigid portion proximal to a reinforced portion, the substantially rigid portion including a partially cylindrical portion defining an opening along a side thereof.

37. (New) The coaxial guide catheter of claim 36 wherein the means for defining the proximal portion further comprises a plurality of relief cuts defined in the substantially rigid portion, the relief cuts controlling a rigidity of at least a portion of the substantially rigid portion.

38. (New) The coaxial guide catheter of claim 28 wherein the means for defining the proximal portion comprises an exterior formed of a braid material or coil formed of metal.

39. (New) The coaxial guide catheter of claim 28 wherein the means for defining the proximal portion further comprises a radiopaque marker proximate the distal tip.

40. (New) The coaxial guide catheter of claim 28 wherein the guide catheter is inserted over a guidewire and the coaxial guide catheter further comprises means for interfacing with the guidewire while the coaxial guide catheter is inserted through the lumen of the guide catheter.

41. (New) The coaxial guide catheter of claim 40 wherein the means for interfacing with the guidewire includes a concave track adapted to receive the guidewire.

42. (New) A coaxial guide catheter for use within a guide catheter having a lumen through which interventional cardiology devices are insertable and a distal end that is preplaceable in a branch artery, the coaxial guide catheter comprising:

a tubular structure having a circular cross-section and sized to be insertable through the lumen of the guide catheter and defining a coaxial lumen through which interventional cardiology devices are insertable, the tubular structure positioned along a distal portion of the coaxial guide catheter and including a flexible distal portion suitable to be extended beyond the distal end of the guide catheter and a relatively rigid proximal portion unsuitable to be extended beyond the distal end of the guide catheter; and

an elongated structure operably coupled to the proximal portion of the tubular structure and having a non-circular cross-section and sized so that a proximal end is extendable proximal of the guide catheter when the tubular structure is positioned with the

distal portion of the tubular structure extended beyond the distal end of the guide catheter while the proximal portion remains within the lumen of the 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 guide catheter from the branch artery.

43. (New) The coaxial guide catheter of claim 42 wherein the proximal portion further comprises structure defining a proximal opening along and accessible from a longitudinal side to receive an interventional cardiology into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

44. (New) The coaxial guide catheter of claim 43 wherein the proximal opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

45. (New) The coaxial guide catheter of claim 42 wherein the distal portion includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

46. (New) The coaxial guide catheter of claim 42 wherein the distal portion comprises generally cylindrical structure having a polymer exterior.

47. (New) The coaxial guide catheter of claim 46 wherein the polymer exterior has at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.

48. (New) The coaxial guide catheter of claim 47 in which the first flexural modulus is about 13,000 PSI plus or minus 5000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third portion flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

49. (New) The coaxial guide catheter of claim 47 in which the first portion is about 0.1 cm in length, the second portion is about three cm in length, and the third portion is about five cm in length.

50. (New) The coaxial guide catheter of claim 41 wherein the proximal portion comprises a substantially rigid portion proximal to a reinforced portion, the substantially rigid portion including a partially cylindrical portion defining an opening along a side thereof.

51. (New) The coaxial guide catheter of claim 50 wherein the proximal portion further comprises a plurality of relief cuts defined in the substantially rigid portion, the relief cuts controlling a rigidity of at least a portion of the substantially rigid portion.

52. (New) The coaxial guide catheter of claim 42 wherein the proximal portion comprises an exterior formed of a braid material or coil formed of metal.

53. (New) The coaxial guide catheter of claim 42 wherein the proximal portion further comprises a radiopaque marker proximate the distal tip.

54. (New) The coaxial guide catheter of claim 42 wherein the guide catheter is inserted over a guidewire and the coaxial guide catheter further comprises structure that interfaces with the guidewire while the coaxial guide catheter is inserted through the lumen of the guide catheter.

55. (New) The coaxial guide catheter of claim 54 wherein the structure that interfaces with the guidewire includes a concave track adapted to receive the guidewire.

56. (New) A backup support system for use with a guide catheter having a lumen through which interventional cardiology devices are insertable and a distal end that is preplaceable in a branch artery, the system comprising:

a coaxial guide cathether sized to be extended through the lumen of the guide catheter, the coaxial guide catheter including:

a tubular structure along a distal portion of a length of the coaxial guide catheter that defines a coaxial lumen having a continuous cylindrical wall structure through which interventional cardiology devices are insertable, the tubular structure including:

a flexible cylindrical distal tip portion defining a distal opening including means suitable for facilitating contact of the distal tip portion with an inner wall of the branch artery;

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

an intermediate portion proximal to the flexible reinforced portion, the intermediate portion including a full circumference portion and a partially cylindrical portion including means for defining a proximal opening along and accessible from a longitudinal side to receive an interventional cardiology into the coaxial lumen while the proximal opening is within the lumen of the guide catheter and means unsuitable for facilitating contact of the intermediate portion with the inner wall of the branch artery; and

an elongated structure operably coupled to the intermediate portion of the tubular structure and having a non-circular cross-section and sized so that a proximal end is extendable proximal of the guide catheter when the tubular structure is positioned with the at least the flexible distal tip portion extending beyond the distal end of the guide catheter and further into the branch artery while the intermediate portion remains within the lumen of the guide catheter,

such that when the tubular structure of the coaxial guide catheter is extended through the lumen and beyond the distal end of the guide catheter that has been preplaced in a branch artery, at least the flexible distal tip portion of the coaxial guide catheter

extends beyond the distal end of the guide catheter and further into the branch artery while the proximal opening of the tubular structure of the coaxial guide catheter remains within the lumen of the guide catheter and the coaxial guide catheter assists in resisting axial and shear forces exerted by the interventional cardiology device passed through the coaxial lumen and beyond the flexible distal tip portion that would otherwise tend to dislodge the guide catheter from the branch artery.

57. (New) A backup support system for use with a guide catheter having a lumen through which interventional cardiology devices are insertable and a distal end that is preplaceable in a branch artery, the system comprising:

a coaxial guide cathether sized to be extended through the lumen of the guide catheter, including:

a tubular structure having a circular cross-section that defines a coaxial lumen through which interventional cardiology devices are insertable, the tubular structure positioned along a distal portion of the coaxial guide catheter and including:

a flexible distal portion defining a distal opening and having means suitable for facilitating contact of the distal portion with an inner wall of the branch artery; and

a proximal portion defining a proximal opening and having means unsuitable for facilitating contact of the proximal portion with the inner wall of the branch artery, the proximal opening is adapted to receive an

interventional cardiology into the coaxial lumen while the proximal opening is within the lumen of the guide catheter; and

an elongated structure extending proximal of the tubular structure having a non-circular cross-section and sized to have a proximal end that extends proximally of the guide catheter when the tubular structure is positioned with the flexible distal portion extending beyond the distal end of the guide catheter that has been preplaced in a branch artery and further into the branch artery while the proximal opening of the tubular structure remains within the lumen of the guide catheter,

such that the coaxial guide catheter assists in resisting axial and shear forces exerted by the interventional cardiology device passed through the coaxial lumen and beyond the flexible distal portion that would otherwise tend to dislodge the guide catheter from the branch artery.

REMARKS

Claims 1-7, 17-20, 22-24, 26 and 27 are pending. By this Amendment, claims 1-27 are cancelled without prejudice, and new claims 28-57 are added. No new matter has been added and support for the amendments and newly added claims can be found throughout the specification.

Interview Summary

Applicant thanks Examiner Osinski and Examiner Bumgarner for their time and courtesy during the in person interview on January 19, 2010. During the interview, claims 8 and 17 were discussed as well as the prior art of record of Klein, Niazi and Solar. Based on the interview, Applicant believes that the claims as amended in herein should be patentable over the prior art currently of record in the application.

With respect to the limitations that may recite functional aspects of the claimed inventions, it is respectfully submitted that "functional language does not, in and of itself, rend an [apparatus] claim improper." *Ex parte Rodriguez,* (BPAI 2009), Appeal 2008-000693, pg. 33 (citing, *In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971). With the newly presented claims, Applicant respectfully submits that the functional limitations are properly presented either in terms of Section 112, paragraph 6 means plus function format, or in a manner in which there is a clear-cut indication of the scope of the subject matter embraced by the claim. *Id.*

Claim Rejections – 35 U.S.C. § 103

The Office Action rejected claims 8, 12-15 and 25 under 35 U.S.C. § 103(a) as being patentable over Niazi (U.S. Patent 6,638,268) in view of Solar (U.S. Publication 2003/0195546) and Klein et al. (U.S. Patent 5,776,141). While Applicant does not concur with the rejections, in

order to advance prosecution Applicant has presented the new claims along the lines discussed in the interview. Support for the amendments can be found throughout the application and drawings as originally filed for example at paragraphs 0022, 0087 and 0088 as published, as well as in the structural elements as indicated, for example, in the newly added dependent claims. The functional elements associated with the newly added means plus function limitations are associated with the structure of the lumen of the guide catheter and how that structure is used in operation.

Embodiments of the claimed invention are used in combination with a guide catheter to provide additional backup support to prevent dislodging of the guide catheter from the ostium of a branch coronary artery when other interventional cardiology devices are inserted through the guide catheter and the coaxial guide catheter of the present invention. The coaxial guide catheter of the claimed invention is advanced through the guide catheter after the guide catheter is in place with its distal end located in a branch coronary artery. In use, the coaxial guide catheter of the claimed invention is inserted through the preplaced guide catheter and advanced so that it partially extends outward from the distal end of the guide catheter into the branch coronary artery. The proximal end of the lumen portion of the claimed invention remains inside the guide catheter and provides a proximal opening for which the interventional cardiology device is passed on its way through the guide catheter, the coaxial guide catheter and outwardly into the branch coronary artery.

None of the Niazi, Solar or Klein references disclose or suggest the limitations recited in the newly presented claims. Accordingly, the independent claims as amended should be

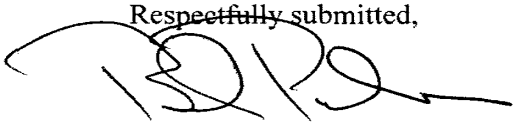
patentable over the cited prior art of Niazi, Solar and Klein. Applicant respectfully requests that the Examiner withdraw the rejection.

Amendments made herein are made without prejudice, disclaimer or waiver of subject matter and to advance prosecution. Applicants reserve the right to prosecute the same or similar claims in related or continuing applications.

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

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

Respectfully submitted,



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Electronic Patent Application Fee Transmittal

Application Number:	11416629
Filing Date:	03-May-2006
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Filer:	Bradley Pedersen/Michelle Arcand
Attorney Docket Number:	2005.86US01

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	2202	3	26	78
Independent claims in excess of 3	2201	1	110	110
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**188**

Electronic Acknowledgement Receipt	
EFS ID:	7051006
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Michelle Arcand
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86US01
Receipt Date:	19-FEB-2010
Filing Date:	03-MAY-2006
Time Stamp:	17:29:21
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$188
RAM confirmation Number	4223
Deposit Account	160631
Authorized User	PEDERSEN,BRADLEY D.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86US01_AMEND.pdf	446626 f03d83c32ad52b8f9217d80a0f3d99d2954b989e	yes	15

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	2
Claims	3	12
Applicant Arguments/Remarks Made in an Amendment	13	15

Warnings:

Information:

2	Fee Worksheet (PTO-875)	fee-info.pdf	31632 b4708d91c0ab890b1dd762dfca47f7c3cfa50c8a	no	2

Warnings:

Information:

Total Files Size (in bytes):	478258

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/416,629	Filing Date 05/03/2006	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 02/19/2010

	(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 30	Minus	** 27	= 3	X $26 =	78	OR	X $ =	
Independent (37 CFR 1.16(h))	* 4	Minus	***3	= 1	X $110 =	110	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	188	OR	TOTAL ADD'L FEE	

AMENDMENT

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

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

Legal Instrument Examiner:
/PAMELA YOUNG/

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.

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

All participants (applicant, applicant's representative, PTO personnel):

(1) *BRADLEY J. OSINSKI*. (3)*BRAD PETERSON*.

(2) *MELBA BUMGARNER*. (4)_____.

Date of Interview: *19 January 2010*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *Device was presented both in physical form and powerpoint form. The shape and flexibility were particularly pointed out.*.

Claim(s) discussed: *8 and 17*.

Identification of prior art discussed: *Art of record Klein, Niazi and Solar*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Bradley J Osinski/ Examiner, Art Unit 3767	/Melba Bumgarner/ Primary Examiner, AU 3767

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Discussion was held after the device was demonstrated and revolved around trying to include use in the proper form in the device claim to overcome the art of record. Of particular interest was the intended use to prevent the proximal end of the sheath from projecting beyond the distal end of the catheter as it does in the current art. Applicant's representative suggested adding 'means for' to the claims to reflect this. Agreement was reached that such an amendment would overcome the art of record, although further searching would be necessary..

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

24113 7590 11/19/2009

PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.
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EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
11/19/2009	PAPER

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

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

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *10 September 2009*.

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) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-7,17-20,22-24,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-16,21 and 25* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-10-2009 has been entered.

Claim Rejections - 35 USC § 103

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

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

1. Claims 8, 12-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Solar (2003/0195546) and Klein et al (5,776,141).

a. Regarding claim 8, Niazi discloses a device capable of being passed through a guide catheter and being used with interventional cardiology devices that are insertable into a branch artery. Niazi also discloses an elongate structure 52 defining a second lumen along its length and being sized to pass through the first lumen of the guide catheter 51, the elongate structure has a flexible tip (Col.5 line 14) a flexible reinforced portion proximal to the flexible tip portion

(Col.6 lines 46-54) and an intermediate portion (non-reinforced) proximal the flexible reinforced portion. The elongate structure 52, when extended through the lumen of the guide catheter 50 and beyond the distal end of the guide catheter, is capable of assisting in resisting the shear forces exerted by any device passed through the second lumen and beyond the flexible tip that would dislodge the guide catheter from the branch artery. Niazi also discloses only two openings in tube 52 that has a distal opening in the tip capable of receiving an interventional cardiology device and a proximal opening on the proximal end via which to pass the device. A continuous cylindrical wall structure is also present between the distal and proximal openings.

While Niazi substantially discloses the apparatus as claimed, it does not disclose the intermediate portion with both a fully cylindrical portion and a partially cylindrical portion.

Solar discloses an elongate device comprising a pushing member 5 and tracking member 7 that is rigid and becomes more flexible as it moves distally (Paragraph 25). Klein also discloses a pushing member 22 with a tracking member/sheath 60" that covers a delivery catheter 12 (disclosed for both fluid delivery and stent delivery). The sheath of Klein has a slant at the proximal end that gives it both fully cylindrical and partial cylindrical portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a rigid pushing structure (including the flexibility gradient) and tracking member (including the

cylindrical shape) as taught by Solar and Klein as it would provide the expected result of decreasing the amount of material required proximally, allow the guide catheter 50 to be guided to the desired location and also allow the tracking member to be used for fluid delivery.

b. Regarding claim 12, Niazi discloses the inner guide catheter 52 as being 8 French in diameter (Col.6 lines 33-34)

c. Regarding claim 13, Niazi discloses the device as being made of silastic (a polymer) and broken into four different portions (see figure 2). Niazi and Solar further disclose decreasing the rigidity (directly related to flexural modulus) as one moves distally down the device. Alternatively, rigidity increases as one moves proximally.

d. Regarding claims 14 and 15, While Niazi substantially discloses the apparatus as claimed, it does not disclose the flexural modulus' or length of each section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific flexural modulus' and lengths to each section of Niazi because Applicant has not disclosed that the lengths and modulus' provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the device of Niazi as both are customized for reaching a particular point in the body, customizing a device for a particular portion of the body was and is notoriously well known with in the art. Niazi itself is customized by adding bends

and support so that the proper location may be reached. Therefore, it would have been an obvious matter of design choice to modify Niazi as to obtain the invention as specified in claims 14 and 15.

e. Regarding claim 25, see claim 8 above, especially regarding the flexibility gradient along the length of the device. The proximal region is the most rigid/least flexible according to Niazi.

2. Claims 9-11, 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268), Klein et al (5,776,141) and Solar (2003/0195546) as applied to claim 8 above, and further in view of Adams (2004/0127927) and Hermann (6,338,725).

f. Regarding claim 9, Niazi discloses the reinforced portion is a braid/coil (figure 6) of a helical wire coil 55 (Col.6 line 51). While Niazi substantially discloses the apparatus as claimed, it does not disclose a radiopaque marker proximate the distal tip. However, Solar discloses a radiopaque marker 17 to allow the system's position to be monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a radiopaque marker as taught by Solar to allow the system's position to be monitored. While Niazi substantially discloses the apparatus as claimed, it does not disclose the rigid portion defining a plurality of relief cuts controlling the rigidity of a portion of the rigid portion. However, Solar discloses a decreasing rigidity along the device as one travels distally. Adams discloses relief cuts as a method of forming a non-rigid bendable section in an

otherwise straight member (Paragraph 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi and Solar with relief cuts as taught by Adams to customize the rigidity of the device (as is taught as desirable by Solar). Niazi also does not teach what the coil is made of. However, Hermann discloses a metal coil imbedded in a flexible sheath to avoid kinking and collapse during use. (Col.6, lines 4-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi by using a coil wire made of metal as taught by Hermann to avoid kinking and collapse during use.

g. Regarding claim 10, Niazi discloses a tapered inner catheter 53 proportioned to pass through catheter 52 and to extend outwardly from the flexible distal tip. The tapered inner catheter is removable prior to insertion of a cardiology device. While Niazi substantially discloses the apparatus as claimed, it does not disclose the tapered inner catheter having a lumen through which a guidewire may be passed. However, Solar discloses using a guidewire 9 to allow the system to advance easily to a desired location within a patient's body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a guidewire lumen as taught by Solar to allow the device to advance easily to a desired location within a patient's body.

h. Regarding claim 11, see claim 10 above, when the tapered inner catheter has a guidewire track introduced as taught by Solar, the tapered tip first portion will define a lumen and the cylindrical second portion will define a second lumen that is inherently concave (circular).

i. Regarding claim 16, the guide catheter and tapered inner catheter are keyed at their distal ends as they both have circular cross-sections that are frictionally engaged to prevent fluid from between the tow catheter when engaged.

j. Regarding claim 21, see end of claim 11 above.

Response to Arguments

3. Applicant's arguments filed 12/5/2008 have been fully considered but they are not persuasive.

k. Applicant further argues that Niazi does not disclose a flexible distal tip and a flexible reinforced portion proximal to the flexible distal tip in the same embodiment. Niazi discloses both embodiments within the same reference. Niazi also offers a reason to provide the coil (for reinforcement). Thus the rejection is not based upon hindsight.

l. Applicant argues that no evidence is disclosed that Niazi is capable of assisting in resisting shear forces exerted by any device passed through the second lumen and beyond the flexible tip that would dislodge the guide catheter from the branch artery. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and

the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. (see MPEP form paragraph 7.37.09) In the instant case the reinforcing coil structure is seen as the structure that gives the device such a capability. The Examiner reiterates his argument that the reinforcing coil of Niazi gives the device the ability to resist axial and shear forces.

m. Applicant argues that Solar does not disclose or suggest a polymer coating having specific qualities relating to flexibility. The Examiner believes Niazi already discloses a flexibility gradient via the inclusion of the reinforcing member in an embodiment. Solar is cited for further support and how it takes customizing the flexibility one step further. One of ordinary skill in the art would recognize the difference between metals and plastics and would know of the plethora of methods via which to customize flexibility.

n. Applicant argues spiral relief cut of Adams of Fucci would not create the invention as claimed and would destroy the function of the present invention because there would be nothing in the present invention to hold the spiral cut tube together. However, the spiral cut does not cut all the way through the body, only removes some of the wall to decrease the rigidity. Adams does not say this specifically, but if one were to read Adams and look at Fucci which Adams specifically mentions in the same sentence, the cuts are shown and described as such.

o. Applicant argues that the advancement member is not a polymer exterior and having the flexural modulus gradient. However, Niazi clearly discloses the catheter as made of a polymer (the entire wall is a polymer, except for the reinforcing coil, including the exterior). Solar discloses that a flexural modulus gradient is contemplated and why it is desirable.

p. Applicant argues that the assigning of specific flexural modulus and length to each section is not a matter of design choice. The Examiner is convinced that the two devices are designed for different parts of the body, but is still not convinced that assigning particular values different segments is not a matter of design choice. Customizing a device for a particular portion of the body was and is notoriously well known with in the art. Niazi itself is customized by adding bends and support so that the proper location may be reached. Modifying it so that it may be used with a different part of the body is a matter of obvious design choice and would be well within the art of one of ordinary skill in the art.

Conclusion

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

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

Notice of References Cited	Application/Control No. 11/416,629	Applicant(s)/Patent Under Reexamination ROOT ET AL.	
	Examiner BRADLEY J. 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-5,776,141	07-1998	Klein et al.	623/1.11
	B	US-			
	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.

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

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

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

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009	11/17/2009						
	1	N	N	N						
	2	N	N	N						
	3	N	N	N						
	4	N	N	N						
	5	N	N	N						
	6	N	N	N						
	7	N	N	N						
	8	✓	✓	✓						
	9	✓	✓	✓						
	10	✓	✓	✓						
	11	✓	✓	✓						
	12	✓	✓	✓						
	13	✓	✓	✓						
	14	✓	✓	✓						
	15	✓	✓	✓						
	16	✓	✓	✓						
	17	N	N	N						
	18	N	N	N						
	19	N	N	N						
	20	N	N	N						
	21	✓	✓	✓						
	22	N	N	N						
	23	N	N	N						
	24	N	N	N						
	25		✓	✓						
	26		N	N						
	27		N	N						

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	111416629	ROOT ET AL.
	Examiner	Art Unit
	BRADLEY J OSINSKI	3767

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

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Terms	11/6/2008	bjo

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Howard Root et al. Confirmation No.: 5061

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

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PRIOCEDURES

REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

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

Sir:

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

1. Submission required under 37 CFR § 1.114

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

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

VSI_00000282

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

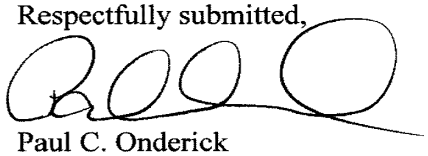
	Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra (Equals)	Small Entity Rate	Fee	OR	Large Entity Rate	Fee
Total	27	- 27	= 0	x 26	$		x 52	$
Indep.	3	-3	= 0	x 110	$		x 220	$
RCE fee				+ 405	$405		+ 810	$
Mult. Dep.			=	+ 195	$		+ 390	$
				TOTAL	$405	OR	TOTAL	$

[ ] First Presentation of Multiple Dependent Claim [MDC]

* If the entry in Column 1 is less than the entry in Column 2, write "0" in Column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Column 1 of a prior Amendment or the number of claims originally filed.

3. [X] Electronic payment is submitted by credit card (The RCE fee under 37 CFR § 1.17(e) is required by 37 CFR § 1.114 when the RCE is filed). The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 CFR §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

Respectfully submitted,



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

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Howard Root et al. Confirmation No.: 5061

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

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

PRELIMINARY AMENDMENT

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

Sir:

INTRODUCTORY COMMENTS

In response to the Office Action of June 10, 2009, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

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

AMENDMENTS TO THE CLAIMS

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

1. (Withdrawn-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 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 along at least part of a length thereof; and

a flexible cylindrical distal tip portion;

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

an intermediate portion proximal to the reinforced portion, the intermediate portion including a full circumference portion and a partially cylindrical portion and defining only a distal opening to receive the interventional cardiology device and a proximal opening through which the interventional cardiology device is passable and a continuous cylindrical wall structure between the distal opening and the proximal opening, the distal opening being directed distally and the proximal opening being an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the proximal opening extending substantially along at least a portion of a length of the intermediate portion and being dimensioned and oriented to receive the interventional cardiology device into and through the second lumen; 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) The method as claimed in claim 26, 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Currently Amended) 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 along at least part of a length thereof and being sized to pass through the first lumen of the guide catheter, the elongate structure including:

a flexible cylindrical distal tip portion;

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

an intermediate portion proximal to the flexible reinforced portion,

the intermediate portion including a full circumference portion and a partially cylindrical portion and defining only a distal opening to receive the interventional cardiology device and a proximal opening through which the interventional cardiology device is passable and a continuous cylindrical wall structure between the distal opening and the proximal opening, the distal opening being directed distally and the proximal opening being an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the proximal opening extending substantially along at least a portion of a length of the intermediate portion and being dimensioned and oriented to receive the interventional cardiology device into and through the second lumen ; and

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]] the 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. (Previously Presented) The device as claimed in claim 25, 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Withdrawn-Previously Presented) A kit for performing interventional cardiology procedures that include insertion of a treatment catheter into a blood vessel, for use with a guide catheter having a first lumen, the kit comprising:

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 flexible reinforced portion proximal to the flexible distal tip portion;

an intermediate portion proximal to the reinforced portion, the intermediate portion including a partially cylindrical portion defining an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the opening extending substantially along at least a portion of a length of the intermediate portion; and

18. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

21. (Previously Presented) The device as claimed in claim 8, wherein the reinforced portion comprises a braid or coil formed of metal.

22. (Withdrawn-Previously Presented) The device as claimed in claim 8, wherein the intermediate portion comprises a full circumference portion, a greater than one hundred eighty degree portion and a less than one hundred eighty degree portion.

23. (Withdrawn- Previously Presented) The device as claimed in claim 8, wherein the opening is bounded by a beveled border.

24. (Withdrawn-Previously Presented) The kit as claimed in claim 17, further comprising:

instructions to insert the guide catheter into the first blood vessel, the guide catheter having 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 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 flexible 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.

25. (Previously Presented) The device as claimed in claim 8, wherein the intermediate portion further comprises:

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including the partially cylindrical portion defining an opening along the side thereof.

26. (Previously Presented) The method as claimed in claim 1, wherein the intermediate portion of the guide
catheter further comprises:

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including the partially cylindrical portion defining an opening along the side thereof.

27. (Previously Presented) The kit as claimed in claim 17, wherein the intermediate portion of the guide catheter further comprises:

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including the partially cylindrical portion defining an opening along the side thereof.

REMARKS

Claims 1-27 are pending. By this Amendment, no claims are cancelled, claims 1, 4, and 8 are amended and no new claims are added.

Claim Rejections – 35 U.S.C. § 103

The Office Action rejected claims 8, 12-15 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Niazi (U.S. Patent 6,638,268) in view of Solar (U.S. Publication 2003/0195546). By this Amendment, Applicant has amended claim 8 as well as withdrawn claim 1 to recite the limitations:

> the intermediate portion including a full circumference portion and a partially cylindrical portion and defining only a distal opening to receive the interventional cardiology device and a proximal opening through which the interventional cardiology device is passable and a continuous cylindrical wall structure between the distal opening and the proximal opening, the distal opening being directed distally and the proximal opening being an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the proximal opening extending substantially along at least a portion of a length of the intermediate portion and being dimensioned and oriented to receive the interventional cardiology device into and through the second lumen

These limitations along with the other limitations recited in claim 8 are not disclosed or suggested by Niazi or Solar either individually or in combination. Specifically, claim 8 now recites "that the intermediate portion includes a full circumference portion and a partially cylindrical portion that defines only a distal opening and a proximal opening with a continuous cylindrical wall structure in between. These limitations are not disclosed or suggested by Niazi or Solar. In particular, these limitations preclude the side holes 21 as disclosed by Solar as the Office Action has previously argued. Accordingly, independent claim 8 is now patentable over Niazi and Solar. Claims 9-16 and 25 depend directly or indirectly from claim 8 and are patentable for at least the same reasons as claim 8. Applicant respectfully requests that the Examiner withdraw the rejections.

Withdrawn claim 1, as amended, recites all of the above limitations of claim 8 and should be patentable for the same reasons as claim 8. Claims 2-7, 21-23 and 25 depend from claim 1 and should be patentable for at least the same reasons as claim 1.

Response to Arguments

Under the responses to arguments paragraph K, the Office Action indicates that the placement of the holes is a matter of intended use. Applicant respectfully traverses this assertion and requests that the Examiner cite a reference to support this assertion. Placement of holes is not at issue presently, but placement of holes is clearly a structural limitation and does not constitute a statement of intended use.

With regard to paragraph L, the Office Action asserts "additionally the first embodiment does not preclude using the helical wire and specifically states that the coil is used on the bend 56 to prevent the collapsing of the device". While a prior art disclosure may not preclude something, for a prior art disclosure to contribute to establishing a prima facie case of anticipation or obviousness the prior art disclosure must disclose or reasonably suggest a claim limitation. For the prior art to merely "not preclude" the limitation is not sufficient. As such, Applicant respectfully traverses the assertion.

With regard to paragraph M, the Office Action indicates a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention of the prior art. First, applicant does not agree that the addressed limitation is a statement of intended use. Second, Applicant respectfully requests that the Examiner provide a citation to law in support of this assertion. The paragraph continues that if the prior art structure is capable of performing the intended use then it meets the claim. Applicant's position is that no evidence has been presented to support the conclusion that prior art structure assists in resisting axial and shear forces as recited in the claims. As such, a *prima facie* case of obviousness has not been established and the claims should be allowable.

Paragraph N, the Office Action states "Applicant argues that the advancement member fiber solar is not applicable for its teachings." Respectfully, Applicant has not made this argument. Applicant has taken the position that a reference that discloses variable flexibility of the advancement member, which is a metal wire, does not disclose or suggest the claimed

limitations of a polymer coating having specific qualities related to flexibility as recited in the claims. Accordingly, this limitation has not been demonstrated to exist in the prior art and a *prima facie* case of obviousness has not been established.

With regards to paragraph O, the Office Action indicates that "however the spiral cut does not cut all the way through the body and only removes some of the wall to decrease rigidity." Applicant respectfully requests that the Examiner provide a citation to the precise disclosure of Adams where such a partial thickness cut is described. Applicant is unable to identify such a disclosure in Adams.

With regard to paragraph P, the Office Action indicates that the Niazi clearly discloses the catheter is made of polymer and that Solar discloses that a flexure modulus gradient is contemplated as desirable. This may be true, however, the combination of Niazi and Solar still do not disclose or suggest a polymer coating that has a flexure modulus gradient as recited in the pending claims along with the other limitations of the pending claims. Applicants respectfully take the position that a prima facie case of obviousness has not been established.

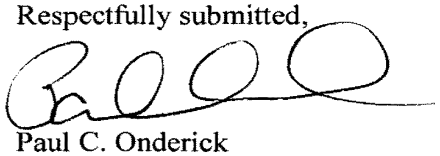
With regard to paragraph Q, the Office Action indicates "it was stated that both devices are used to reach the same part of the body (coronary arteries)". It is correct that the Office Action states this, however, this is not a correct understanding of the prior art. The Niazi reference specifically describes that the device is used for "cannulation of the coronary sinus." The coronary sinus is part of the venous drainage of the heart and is not the same as the coronary arteries which supply blood flow to the tissue of the heart. The problems encountered in inserting medical devices in the coronary arteries are much different than those addressed in Niazi regarding the placement of pacing leads in the coronary sinus. The coronary arteries are

thicker walled, have more muscular structure and are prone to having atheromatous plaques in them. These issues are discussed in the present application. The veins of the coronary sinus are thinner, subject to much lower blood pressure and not prone to developing atheromatous plaques therein. Because of these structural differences between the arterial and venous vasculature the Niazi reference does not address the same problems as the present invention. Accordingly, this does not support the rejection. The specific parameters selected are not obvious because they are not disclosed or suggested by the cited prior art and, absent hindsight analysis based on the Applicant's disclosure, no reason has been provided as to why one of ordinary skill would use these parameters. Claims reciting these parameters should be patentable for at least this additional reason.

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

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

Respectfully submitted,



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

Utility under 35 USC 111(a) Filing Fees

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

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

Electronic Acknowledgement Receipt	
EFS ID:	6044954
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick
Filer Authorized By:	
Attorney Docket Number:	2005.86US01
Receipt Date:	10-SEP-2009
Filing Date:	03-MAY-2006
Time Stamp:	14:19:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$405
RAM confirmation Number	523
Deposit Account	160631
Authorized User	ONDERICK,PAUL C
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees) Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees) Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request for Continued Examination (RCE)	2005_86US01_RCETransmittal.pdf	67273 8803bab8fdda95c686c339f4862dee1f571f7ab0	no	2
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2		2005_86US01_PRELAMENDMENT.pdf	508122 a03a430f5be0bc7851f5fc623aa8aeb91394e9b1	yes	16

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Claims	2	11
Applicant Arguments/Remarks Made in an Amendment	12	16

Warnings:					
Information:					
3	Fee Worksheet (PTO-875)	fee-info.pdf	30303 edd6c6f64b56f2f84fab42d042099969210ac62d	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	605698		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/416,629	Filing Date 05/03/2006	☐ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
	09/10/2009	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 27	Minus	** 37	= 0	X $26 =	0	OR	X $ =	
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $110 =	0	OR	X $ =	
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

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

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

Legal Instrument Examiner:
/TONI HAKIM/

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.

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

24113 7590 06/10/2009

PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.
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MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

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

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

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *05 December 2008*.

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) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1-7,17-20,22-24,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-16,21 and 25* is/are rejected.

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

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

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Claim Rejections - 35 USC § 103

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

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

1. Claims 8, 12-15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Solar (2003/0195546).

a. Regarding claim 8, Niazi discloses a device capable of being passed through a guide catheter and being used with interventional cardiology devices that are insertable into a branch artery. Niazi also discloses an elongate structure 52 defining a second lumen along its length and being sized to pass through the first lumen of the guide catheter 51, the elongate structure has a flexible tip (Col.5 line 14) a flexible reinforced portion proximal to the flexible tip portion (Col.6 lines 46-54) and an intermediate portion (non-reinforced) proximal the flexible reinforced portion. The elongate structure 52, when extended through the lumen of the guide catheter 50 and beyond the distal end of the guide catheter, it is capable of assisting in resisting the shear forces exerted by any device passed through the second lumen and beyond the flexible tip that would dislodge the guide catheter from the branch artery.

While Niazi substantially discloses the apparatus as claimed, it does not disclose the elongate structure with a cylindrical portion defining an opening

along a longitudinal side thereof, the opening extending at least a portion of the length of the intermediate portion.

Solar discloses an elongate device comprising a pushing member 5 and tracking member 7 that is rigid and becomes more flexible as it moves distally (Paragraph 25). The device of Solar has a partially cylindrical portion 7 with an opening in the circular sides that extends substantially along a length of the rigid portion. Solar also discloses that in an alternate embodiment (figure 4) that the tracking member may be single or multi lumen, with the multi-lumen tracking member may have side holes 21 that provide communication from lumen 20 to the exterior of the tracking member 19. It would be a matter of design choice of a finite number of possibilities on where to place the holes in order to use them for fluid delivery. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a rigid pushing structure (including the flexibility gradient) and tracking member (including the cylindrical shape and holes in the side wall) as taught by Solar et al as it would provide the expected result of decreasing the amount of material required proximally, allow the guide catheter 50 to be guided to the desired location and also allow the tracking member to be used for fluid delivery.

b. Regarding claim 12, Niazi discloses the inner guide catheter 52 as being 8 French in diameter (Col.6 lines 33-34)

c. Regarding claim 13, Niazi discloses the device as being made of silastic (a polymer) and broken into four different portions (see figure 2). Niazi and Solar

further disclose decreasing the rigidity (directly related to flexural modulus) as one moves distally down the device. Alternatively, rigidity increases as one moves proximally.

d. Regarding claims 14 and 15, While Niazi substantially discloses the apparatus as claimed, it does not disclose the flexural modulus' or length of each section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific flexural modulus' and lengths to each section of Niazi because Applicant has not disclosed that the lengths and modulus' provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the device of Niazi as both are designed for use in reaching coronary arteries specifically. Therefore, it would have been an obvious matter of design choice to modify Niazi as to obtain the invention as specified in claims 14 and 15.

e. Regarding claim 25, see claim 8 above, especially regarding the flexibility gradient along the length of the device. The proximal region is the most rigid/least flexible according to Niazi.

2. Claims 9-11, 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) and Solar (2003/0195546) as applied to claim 8 above, and further in view of Adams (2004/0127927) and Hermann(6,338,725).

f. Regarding claim 9, Niazi discloses the reinforced portion is a braid/coil (figure 6) of a helical wire coil 55 (Col.6 line 51). While Niazi substantially

discloses the apparatus as claimed, it does not disclose a radiopaque marker proximate the distal tip. However, Solar discloses a radiopaque marker 17 to allow the system's position to be monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a radiopaque marker as taught by Solar to allow the system's position to be monitored. While Niazi substantially discloses the apparatus as claimed, it does not disclose the rigid portion defining a plurality of relief cuts controlling the rigidity of a portion of the rigid portion. However, Solar discloses a decreasing rigidity along the device as one travels distally. Adams discloses relief cuts as a method of forming a non-rigid bendable section in an otherwise straight member (Paragraph 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi and Solar with relief cuts as taught by Adams to customize the rigidity of the device (as is taught as desirable by Solar). Niazi also does not teach what the coil is made of. However, Hermann discloses a metal coil imbedded in a flexible sheath to avoid kinking and collapse during use. (Col.6, lines 4-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi by using a coil wire made of metal as taught by Hermann to avoid kinking and collapse during use.

g. Regarding claim 10, Niazi discloses a tapered inner catheter 53 proportioned to pass through catheter 52 and to extend outwardly from the

flexible distal tip. The tapered inner catheter is removable prior to insertion of a cardiology device. While Niazi substantially discloses the apparatus as claimed, it does not disclose the tapered inner catheter having a lumen through which a guidewire may be passed. However, Solar discloses using a guidewire 9 to allow the system to advance easily to a desired location within a patient's body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a guidewire lumen as taught by Solar to allow the device to advance easily to a desired location within a patient's body.

h. Regarding claim 11, see claim 10 above, when the tapered inner catheter has a guidewire track introduced as taught by Solar, the tapered tip first portion will define a lumen and the cylindrical second portion will define a second lumen that is inherently concave (circular).

i. Regarding claim 16, the guide catheter and tapered inner catheter are keyed at their distal ends as they both have circular cross-sections that are frictionally engaged to prevent fluid from between the tow catheter when engaged.

j. Regarding claim 21, see end of claim 11 above.

Response to Arguments

3. Applicant's arguments filed 12/5/2008 have been fully considered but they are not persuasive.

k. Applicant argues the new amendment regarding the opening being along a portion of the length of the intermediate portion with the longitudinal side being parallel to the long axis of the second lumen overcomes the current art. However, as addressed above, Solar discloses side holes in the tracking member (paragraph 51). The side holes are in the longitudinal sides of the cylinder and perpendicular to the longitudinal axis. The holes are disclosed for use in fluid delivery. The placement of the holes is therefore a matter of intended use.

l. Applicant further argues that Niazi does not disclose a flexible distal tip and a flexible reinforced portion proximal to the flexible distal tip in the same embodiment. However, in the alternative embodiment only (Col.6 lines 46-54), the device is disclosed as still having a flexible distal tip (Col.6 line 54) with a reinforcing portion proximal the distal-most-end/tip and an intermediate section proximal the reinforcing portion. Additionally the first embodiment does not preclude using the helical wire coil and specifically states that the coil is used on the bend 56 to prevent the collapsing of the device. The less stiff (without reinforcing wire) tip of the first embodiment is still capable of being used with the reinforced tubing section of the alternative embodiment and would allow the device to better navigate tortuous pathways.

m. Applicant argues that no evidence is disclosed that Niazi is capable of assisting in resisting shear forces exerted by any device passed through the second lumen and beyond the flexible tip that would dislodge the guide catheter from the branch artery. However, a recitation of the intended use of the claimed

invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case the reinforcing coil structure is seen as the structure that gives the device such a capability.

n. Applicant argues that the advancement member 5 of Solar is not applicable for its teachings. However, as advancement member 5 and tracking member 7 of Solar are bound together, the advancement member 5 is seen as an extension of tracking member 5 because it is how the tracking member 7 is pushed in the body. Thus the teaching of tracking member 5 are relevant for incorporation into the tracking member.

o. Applicant argues spiral relief cut of Adams and Fucci would not create the invention as claimed and would destroy the function of the present invention because there would be nothing in the present invention to hold the spiral cut tube together. However, the spiral cut does not cut all the way through the body, only removes some of the wall to decrease the rigidity.

p. Applicant argues that the advancement member is not a polymer exterior and having the flexural modulus gradient. However, Niazi clearly discloses the catheter as made of a polymer (the entire wall is a polymer, except for the reinforcing coil, including the exterior). Solar discloses that a flexural modulus gradient is contemplated and why it is desirable.

q. Applicant argues that the assigning of specific flexural modulus and length to each section is not a matter of design choice. While the Examiner is well aware of the BPAI position, the rejection does explain why the above combination would be a matter of design choice. More specifically, it was stated that both devices are used to reach the same part of the body (coronary arteries). Determining and assigning the appropriate flexural modulus for each section would thus be a matter of design choice and routine experimentation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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

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

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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

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

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Terms	11/6/2008	bjo

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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

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

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

CLAIM		DATE								
Final	Original	12/02/2008	06/05/2009							
	1	N	N							
	2	N	N							
	3	N	N							
	4	N	N							
	5	N	N							
	6	N	N							
	7	N	N							
	8	✓	✓							
	9	✓	✓							
	10	✓	✓							
	11	✓	✓							
	12	✓	✓							
	13	✓	✓							
	14	✓	✓							
	15	✓	✓							
	16	✓	✓							
	17	N	N							
	18	N	N							
	19	N	N							
	20	N	N							
	21	✓	✓							
	22	N	N							
	23	N	N							
	24	N	N							
	25		✓							
	26		N							
	27		N							

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Howard Root et al. Confirmation No.: 5061

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

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

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 December 5, 2008, amendment to the above-identified patent application is requested.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

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

AMENDMENTS TO THE CLAIMS

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

1. (Withdrawn-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 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 along at least part of a length thereof; and

a flexible distal tip portion;

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

~~a substantially rigid~~ an intermediate portion proximal to the reinforced portion, the ~~substantially rigid portion~~ intermediate portion including a partially cylindrical portion defining an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the opening extending substantially along at least a portion of a length of the ~~rigid~~ intermediate portion; 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn-Currently Amended) The method as claimed in claim [[1]] 26, 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Currently Amended) 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 along at least part of a length thereof and being sized to pass through the first lumen of the guide catheter, the elongate structure including:

a flexible distal tip portion;

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

~~a substantially rigid~~ an intermediate portion proximal to the flexible reinforced portion, the ~~substantially~~

~~rigid portion~~ intermediate portion including a partially cylindrical portion defining an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the opening extending substantially along at least a portion of a length of the ~~rigid~~ intermediate portion; and

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. (Currently Amended) The device as claimed in claim [[8]] 25, 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Withdrawn-Currently Amended) A kit for performing interventional cardiology procedures that include insertion of a treatment catheter into a blood vessel, for use with a guide catheter having a first lumen, the kit comprising:

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 flexible reinforced portion proximal to the flexible distal tip portion;

~~a substantially rigid~~ an intermediate portion proximal to the reinforced portion, the ~~substantially~~

~~rigid portion~~ intermediate portion including a partially cylindrical portion defining an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the opening extending substantially along at least a portion of a length of the ~~rigid~~ intermediate portion; and

18. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

21. (Previously Presented) The device as claimed in claim 8, wherein the reinforced portion comprises a braid or coil formed of metal.

22. (Withdrawn-Currently Amended) The device as claimed in claim 8, wherein the ~~substantially rigid~~ intermediate portion comprises a full circumference portion, a greater than one hundred eighty degree portion and a less than one hundred eighty degree portion.

23. (Withdrawn- Previously Presented) The device as claimed in claim 8, wherein the opening is bounded by a beveled border.

24. (Withdrawn- Currently Amended) The kit as claimed in claim 17, further comprising:

instructions to insert the guide catheter into the first blood vessel, the guide catheter having 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 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 flexible 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.

25. (New) The device as claimed in claim 8, wherein the intermediate portion further comprises:

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including the partially cylindrical portion defining an opening along the side thereof.

26. (New) The method as claimed in claim 1, wherein the intermediate portion of the guide catheter further comprises:

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including the partially cylindrical portion defining an opening along the side thereof.

27. (New) The kit as claimed in claim 17, wherein the intermediate portion of the guide catheter further comprises:

a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including the partially cylindrical portion defining an opening along the side thereof.

REMARKS

Claims 1-24 are pending. Claims 1-7, 17-20 and claims 22-24 are withdrawn from consideration. By this Amendment, no claims are canceled, claims 1, 8, 9 and 17 are amended and new claims 25-27 are added

Election/Restriction

Initially, Applicants note that the disposition of claims in the Office Action Summary is incomplete. The disposition of claims indicates that claims 8-16 and 21 are pending in the application but makes no comment on the status of claims 1-7, 17-20 and 22-24 which also remain pending. As indicated above, claims 1-24 remain pending in the application, while Applicants have requested that claims 1-7, 17-20 and 22-24 be withdrawn from consideration. Applicants respectfully request that the Examiner correct the record to reflect the disposition of the claims in the case as it currently stands. In particular, Applicant respectfully requests that the Examiner indicate that claims 1-7, 17-20 and 22-24 are withdrawn from consideration and have not been canceled from the application.

Claim Rejections – 35 U.S.C. § 103

The Office Action rejected claims 9 and 12-15 under 35 U.S.C. § 103(a) as being unpatentable over Niazi (U.S. 6,638,268) in view of Solar (U.S. Publication 2003/0195546). Initially, while the Office Action states that claims 9 and 12-15 are so rejected, the Office Action then continues on to address the limitations of claim 8. Applicant therefore assumes that a typographical error was made and the Examiner intended to refer to claims 8 and 12-15. Applicants respectfully traverse the rejection.

Claim 8 and new claim 25

Amended claim 8 recites the limitations "the intermediate portion including a partially cylindrical portion defining an opening along and accessible from a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the opening extending substantially along at least a portion of a length of the intermediate portion."

The Office Action admits that Niazi does not disclose an elongate structure with a cylindrical portion defining an opening along a side thereof." However, the Office Action asserts that Solar discloses such a structure. Applicants respectfully traverse the assertion and the rejection.

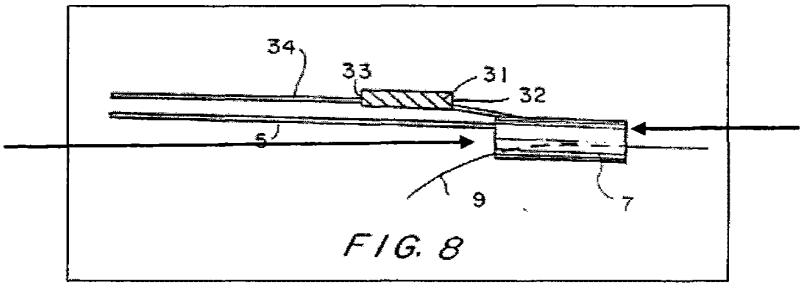
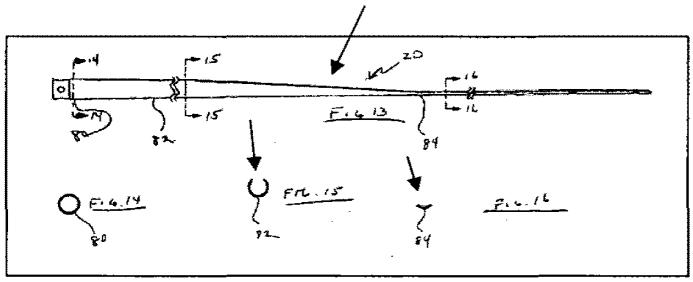


FIG. 8

As can be seen in representative Fig. 8 of Solar, reproduced above, Solar discloses no "opening along a side" of a portion as recited in claim 8 and described, depicted and claimed in the application. Note that the side is defined as being generally parallel to the long axis of the second lumen. Arrows have been added to indicate openings only on the ends of the device disclosed by Solar. These ends are not generally parallel to a long axis of the second lumen as recited in claim 8. Amended Claim 8 further recites "the opening extending substantially along at least a portion of a length of the intermediate portion." Solar does not disclose or suggest this

limitation either. Rather, Solar discloses that "[t]racking member 7 has an open proximal end 11 and an open distal end 7." Paragraph 0026. However, Solar does not disclose or suggest "the intermediate portion including a partially cylindrical portion defining an opening along a longitudinal side thereof, the longitudinal side being generally parallel to a long axis of the second lumen, the opening extending substantially along at least a portion of a length of the intermediate portion" as recited in claim 8.



An example structure can be seen, for example, in Figs. 13, 15 and 16 of the present application. In particular, Figs. 15 and 16 depict an example opening and partially cylindrical portion identified by the arrows added. Thus, at least this limitation of claim 8 is not disclosed or suggested by the cited prior art and the Office Action does not make out a prima facie case of obviousness for at least this reason.

Claim 8 previously recited the limitations:

"an elongate structure defining a second lumen along at least part of a length thereof and being sized to pass through the first lumen of the guide catheter, the elongate structure including:

a flexible distal tip portion;

a flexible reinforced portion proximal to the flexible distal tip portion."

These limitations are now partially contained in new claim 25.

The Office Action indicates that "Niazi also discloses an elongate structure 52 defining a second lumen along its length and being sized to pass through the first lumen of the guide catheter 51." The Office Action goes on to state that "the elongate structure has flexible tip" citing Col. 5, line 14. Niazi recites:

> "Inner guiding catheter 52 made of a soft, pliable material such as silicone, and in this example is 2.6 mm in outer diameter and 2.3 mm in inner diameter. *It has no longitudinal braiding, which makes it extremely flexible* and able to conform to various shapes. Inner catheter 52 is designed to advance over a guide wire into a side branch of the coronary sinus, in conjunction with the obturator 53. Its flexibility allows it to negotiate tortuous vessels and side branches that originate from the coronary sinus at an acute angle." Column 5, Lines 15-22.

Thus, Niazi clearly indicates that the flexible tip referred to at Col. 5, line 14 is the tip of inner guide catheter 52 which is a separate structure from guide catheter 51 which is not indicated to have a flexible tip portion.

The Office Action goes on to state that a flexible reinforced portion proximal to the flexible tip portion is described at Col. 6, lines 46-54. Applicant respectfully traverses the assertion, Col. 6, lines 46-54 of Niazi describes an alternate version of the inner catheter 52 which is depicted in Figure 6, and reference to Figure 6 clearly shows that the reinforced portion is not proximal to the flexible portion that is described at Column 5, Lines 15-22 but that in the described alternate embodiment the reinforced portion extends all the way to the distal end of the depicted inner guide catheter 52. The alternate embodiment has no distal portion that is "soft and pliable" as is the embodiment disclosed at Column 5, Lines 14-27, which is described as

having "no longitudinal braiding." Instead, the alternate embodiment is reinforced all the way to its distal end.

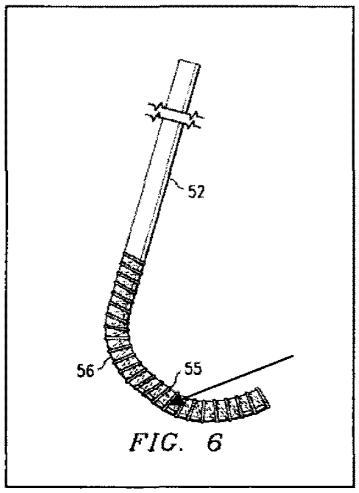


FIG. 6

Thus, the flexible tip is part of one version of the inner guide catheter while the depicted reinforced portion is the tip of another embodiment of the inner guide catheter. In particular, Niazi does not disclose or suggest "a flexible distal tip portion" and "a flexible reinforced portion *proximal to the flexible distal tip portion*" as recited in independent claim 8. Thus, aside from potential hindsight reasoning based on the Applicants' disclosure, the Niazi reference does not disclose or suggest the limitations recited in the claims of the present application and no reason is presented as to why one would arrange the flexible distal tip portion and the and the flexible reinforced portion relative to each other as recited in the presently pending claims. For these further reasons, the present invention as claimed is not rendered obvious over Niazi in view of Solar. Applicants respectfully request that the Examiner withdraw the rejection.

The Office Action goes on to indicate "the elongate structure 52 when extended through the lumen guide catheter 50, and beyond the distal end of the guide catheter, it is capable (sic) of assisting in resisting shear forces exerted by any device passed through the second lumen and beyond the flexible tip that would dislodge the guide catheter from the branch artery." The Office Action cites no evidence in Niazi to support this conclusory assertion and Applicant finds no indication of this limitation being disclosed or suggested in the Niazi reference. Absent supporting evidence, Applicant respectfully takes the position that the office action does not make out a *prima facie* case of obviousness for at least this additional reason because the Office Action does not show that this limitation is disclosed or suggested in the cited prior art. Applicants respectfully request that the Examiner withdraw the rejection.

With regard to claim 8 and limitations that are now, in part, presented in dependent claim 25, the Office Action cites to paragraph 25 of Solar as supporting the assertion that the tracking member 7 of Solar is rigid and becomes more flexible as it moves distally. Paragraph 25 of Solar states:

> "Preferably, *advancement member 5* (also depicted in Fig. 8 of Solar above) is rigid at its proximal end and becomes increasingly more flexible as it extends distally. This may be accomplished by a number of ways known in the art, including, but not limited to, tapering, selective heat treatment and/or forming advancement member 5 from a composite of materials with various properties."

According to Solar, it is only "*advancement member 5*" that is described as being "rigid at its proximal end" and "increasingly more flexible as it extends distally." Thus, Solar does not disclose or suggest the claimed limitations "a flexible distal tip portion; a flexible reinforced

portion proximal to the flexible distal tip portion; and a substantially rigid portion proximal to the reinforced portion" as recited in claim 8 in combination with new claim 25. Therefore, the Office Action does not make out a *prima facie* case of obviousness for at least this additional reason.

The Office Action further asserts that the device of Solar has "partially cylindrical portion 7 with an opening in the circular sides that extends substantially discloses the apparatus as claimed, it does not disclose along a length of a rigid portion." Applicant respectfully notes, that as demonstrated above, Solar does not disclose or suggest a *partially cylindrical* portion as recited in claim 8 and defined in the specification of the present application nor does it disclose any openings in the side of a partially cylindrical portion as recited in claim 8. The indicated portion of Niazi is a full cylinder. An example partially cylindrical portion is depicted for example in Figs. 15 and 16 of the present application which are reproduced above.

Thus, the cited prior art Office Action does not anticipate or render obvious amended claim 8 because the prior art cited does not disclose or suggest all of the elements recited in claim 8. Applicants respectfully request that the Examiner withdraw the rejection.

Claims 9-16, 21 and new claim 25 depend directly or indirectly from claim 8 and should be patentable for at least the same reasons as claim 8. Applicants respectfully request that the Examiner withdraw the rejections.

Claim 9

Claim 9 recites the limitations "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." With regard to claim 9, the Office Action cites to Adams (US

2004/0127927) which in turn cites to Fucci (US 5,601,586 and 5,411,514) as disclosing relief cuts. However, the single "spiral relief cut" of Adams and Fucci would not create the invention as claimed and would destroy the function of the present invention because there would be nothing in the present invention as claimed in claim 9 to hold a spiral cut tube together and facilitate the passage of another device through the lumen of the spiral cut tube as compared to the multiple staggered relief cuts claimed and depicted for example in Figs. 10 and 11. Applicants respectfully request that the Examiner withdraw the rejection.

Claim 13

With regard to claim 13, the Office Action indicates "Niazi and Solar further disclose decreasing the rigidity (directly related to flexural modulus) as one moves distally down the device. Applicant respectfully traverses this assertion. While the statement regarding Niazi and Solar may be true, Claim 13 recites "further comprising, starting at a distal end, *a polymer exterior*" and then goes on to define *the polymer exterior* as "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." The Office Action provides no citation to the references as to where this disclosure is allegedly found and Applicants cannot identify any such disclosure in either the Niazi or the Solar reference other than the comments related to the *advancement member* discussed above. The advancement member is not a *polymer exterior* as recited in claim 13. As such, neither the Niazi reference nor the Solar reference discloses or suggests a device with a *polymer exterior* meeting the recited limitations related to flexural modulus. Thus, Applicant respectfully takes

the position that the Office Action has not made out a *prima facie* case of obviousness with regard to claim 13 for this additional reason. Applicants respectfully request that the Examiner withdraw the rejection.

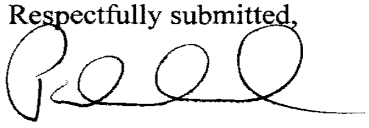
With regard to claims 14 and 15, the Office Action asserts "it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific flexural modulus and length to each section of Niazi, because Applicant has not disclose if the lengths and modulus provide an advantage, is used for a particular purpose or solves a stated problem." Applicant respectfully traverses the assertion. The Board of Patent Appeals and Interferences has an addressed the issue of rejections based on "obvious matter of design choice" in *ex parte Roger Massey*. Appeal No. 2003-1660, slip op. at 6. The Board stated with regard to rejections under § 103 of the patent statute "It is not enough to merely allege that something is 'well known,' is an 'obvious matter of design choice,' or 'lacks criticality.'" The Board then cited *In re Lee,* which indicates "The factual inquiry whether to combine the references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with." 277 F.3d 1338, 1343, 61 USPQ 2d 1430, 1433 (Fed. Cir. 2002). The patent office must not only assure that the requisite findings to support a conclusion of obviousness are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion. *In re Lee* at 1434. Thus the Office Action does not make out a *prima facie* case of obviousness with relation to claims 14 and 15 for at least this additional reason. Applicants respectfully request that the Examiner withdraw the rejection.

Applicant has also amended withdrawn independent claims 1 and 17 to recite the limitation of claim 8. Thus, claims 1-8 and 17-24, 26 and 27 should be allowable as well. Applicants, respectfully request that these claims be rejoined in the application upon a finding of allowable subject matter in claim 8.

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

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

Respectfully submitted,



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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Howard Root et al. Confirmation No.: 5061

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

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

PETITION FOR EXTENSION OF PERIOD FOR RESPONSE
UNDER 37 CFR § 1.136(a)

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

Sir:

Pursuant to 37 CFR § 1.136(a), an extension of time of one (1) month (from March 5, 2009 to April 5, 2009) within which to respond to the Office Action dated December 5, 2008 is requested. Electronic payment is submitted by credit card to cover the extension fee. Applicants are entitled to small entity status in accordance with 37 CFR 1.27. The Commissioner is authorized to charge to Deposit Account No. 16-0631 any underpayments, overpayments or additionally required fees.

Respectfully submitted,

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

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

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	2251	1	65	65

VSI_00000341

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**65**

Electronic Acknowledgement Receipt	
EFS ID:	5099460
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick
Filer Authorized By:	
Attorney Docket Number:	2005.86US01
Receipt Date:	06-APR-2009
Filing Date:	03-MAY-2006
Time Stamp:	14:15:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$65
RAM confirmation Number	508
Deposit Account	160631
Authorized User	ONDERICK,PAUL C
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

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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		2005_86US01_Amendment.pdf	663965 c42cc6508061002c2d519db570c56ba5ff8934ad	yes	21

Multipart Description/PDF files in .zip description

Document Description	Start	End
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	11
Applicant Arguments/Remarks Made in an Amendment	12	21

Warnings:

Information:

2	Extension of Time	2005_86US01_EOT.pdf	35988 d9903335823e2ed6b4eb48d8b30ded2b19dcb6d8	no	1

Warnings:

Information:

3	Fee Worksheet (PTO-06)	fee-info.pdf	30302 48f859b2ea5cdbb09e3265ed7533fda8e8f7a981	no	2

Warnings:

Information:

Total Files Size (in bytes):	730255

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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.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☒ To be Mailed
11/416,629	05/03/2006	

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT **10/01/2008**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 24	Minus	** 20	= 4	X $25 =	100	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	100	OR	TOTAL ADD'L FEE	

AMENDMENT **04/06/2009**

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 27	Minus	** 24	= 3	X $26 =	78	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	*** 3	= 0	X $110 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	78	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".
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/416,629	05/03/2006	Howard Root	2005.86US01	5061

24113 7590 12/05/2008

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

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

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

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

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

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

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) *8-16 and 21* 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) *8-16 and 21* 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 *7-24-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 8-16 in the reply filed on 10-1-2008 is acknowledged. The traversal is on the ground(s) that there is no significant burden to search these claims as well. This is not found persuasive because they would be classified differently, require different fields of search (including different classes or subclasses and search queries) and prior art applicable to one would not likely be applicable to another of the inventions. Applicant was correct in citing that once allowable subject matter is found, the withdrawn claims may be reintroduced as long as they incorporate all of the allowable subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

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

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

1. Claims 9 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) in view of Solar (2003/0195546).

a. Regarding claim 8, Niazi discloses a device capable of being passed through a guide catheter and being used with interventional cardiology devices that are insertable into a branch artery. Niazi also discloses an elongate structure 52 defining a second lumen along its length and being sized to pass through the

first lumen of the guide catheter 51, the elongate structure has a flexible tip (Col.5 line 14) a flexible reinforced portion proximal to the flexible tip portion (Col.6 lines 46-54). The elongate structure 52, when extended through the lumen of the guide catheter 50 and beyond the distal end of the guide catheter, it is capable of assisting in resisting the shear forces exerted by any device passed through the second lumen and beyond the flexible tip that would dislodge the guide catheter from the branch artery. While Niazi substantially discloses the apparatus as claimed, it does not disclose the elongate structure with a substantially rigid portion proximal to the reinforced portion, including a cylindrical portion defining an opening along a side thereof, the opening extending at least a portion of the length of the rigid portion. However, Solar discloses an elongate device comprising a pushing member 5 and tracking member 7 that is rigid and becomes more flexible as it moves distally (Paragraph 25). The device of Solar has a partially cylindrical portion 7 with an opening in the circular sides that extends substantially discloses the apparatus as claimed, it does not disclose along a length of the rigid portion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the elongate structure of Niazi with a rigid pushing structure and tracking member as taught by Solar et al as it would provide the expected result of decreasing the amount of material required proximally and allow the guide catheter 50 to be guided to the desired location.

b. Regarding claim 12, Niazi discloses the inner guide catheter 52 as being 8 Frinch in diameter (Col.6 lines 33-34)

c. Regarding claim 13, Niazi discloses the device as being made of silastic (a polymer) and broken into four different portions (see figure 2). Niazi and Solar further disclose decreasing the rigidity (directly related to flexural modulus) as one moves distally down the device. Alternatively, rigidity increases as one moves proximally.

d. Regarding claims 14 and 15, While Niazi substantially discloses the apparatus as claimed, it does not disclose the flexural modulus' or length of each section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to assign specific flexural modulus' and lengths to each section of Niazi because Applicant has not disclosed that the lengths and modulus' provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the device of Niazi as both are designed for use in reaching coronary arteries specifically. Therefore, it would have been an obvious matter of design choice to modify Niazi as to obtain the invention as specified in claims 14 and 15.

2. Claims 9-11, 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niazi (6,638,268) and Solar (2003/0195546) as applied to claim 8 above, and further in view of Adams (2004/0127927) and Hermann(6,338,725).

e. Regarding claim 9, Niazi discloses the reinforced portion is a braid/coil (figure 6) of a helical wire coil 55 (Col.6 line 51). While Niazi substantially discloses the apparatus as claimed, it does not disclose a radiopaque marker proximate the distal tip. However, Solar discloses a radiopaque marker 17 to allow the system's position to be monitored. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a radiopaque marker as taught by Solar to allow the system's position to be monitored. While Niazi substantially discloses the apparatus as claimed, it does not disclose the rigid portion defining a plurality of relief cuts controlling the rigidity of a portion of the rigid portion. However, Solar discloses a decreasing rigidity along the device as one travels distally. Adams discloses relief cuts as a method of forming a non-rigid bendable section in an otherwise straight member (Paragraph 5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi and Solar with relief cuts as taught by Adams to customize the rigidity of the device (as is taught as desirable by Solar). Niazi also does not teach what the coil is made of. However, Hermann discloses a metal coil imbedded in a flexible sheath to avoid kinking and collapse during use. (Col.6, lines 4-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi by using a coil wire made of metal as taught by Hermann to avoid kinking and collapse during use.

f. Regarding claim 10, Niazi discloses a tapered inner catheter 53 proportioned to pass through catheter 52 and to extend outwardly from the flexible distal tip. The tapered inner catheter is removable prior to insertion of a cardiology device. While Niazi substantially discloses the apparatus as claimed, it does not disclose the tapered inner catheter having a lumen through which a guidewire may be passed. However, Solar discloses using a guidewire 9 to allow the system to advance easily to a desired location within a patient's body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Niazi with a guidewire lumen as taught by Solar to allow the device to advance easily to a desired location within a patient's body.

g. Regarding claim 11, see claim 10 above, when the tapered inner catheter has a guidewire track introduced as taught by Solar, the tapered tip first portion will define a lumen and the cylindrical second portion will define a second lumen that is inherently concave (circular).

h. Regarding claim 16, the guide catheter and tapered inner catheater are keyed at their distal ends as they both have circular cross-sections that are frictionally engaged to prevent fluid from between the tow catheter when engaged.

i. Regarding claim 21, See end of claim 11 above.

Conclusion

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

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

Notice of References Cited	Application/Control No. 11/416,629	Applicant(s)/Patent Under Reexamination ROOT ET AL.	
	Examiner BRADLEY J. 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-2003/0195546	10-2003	Solar et al.	606/192
*	C	US-6,338,725	01-2002	Hermann et al.	604/95.04
*	D	US-2004/0127927	07-2004	Adams, Kenneth	606/170
	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.

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

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

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

CLAIM		DATE								
Final	Original	12/02/2008								
	1	N								
	2	N								
	3	N								
	4	N								
	5	N								
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	7	N								
	8	✓								
	9	✓								
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	16	✓								
	17	N								
	18	N								
	19	N								
	20	N								
	21	✓								
	22	N								
	23	N								
	24	N								

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

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

SEARCH NOTES		
Search Notes	Date	Examiner
EAST Search Terms	11/6/2008	bjo

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	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-$ 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-	US-PGPUB; USPAT	OR	ON	2008/12/02 17:34

		6053903-$).did.				
L3	7	2 and (metal with (coil braid))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/12/02 17:34
S1	171	(604/510).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2008/11/06 16:26
S2	28	("20050182437" | "4813930" | "4832028" | "4932413" | "5098412" | "5122125" | "5472425" | "5658263" | "6159195" | "6475195" | "6595952" | "6610068" | "6689144" | "6860678").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/06 16:27
S3	70	("3430631" | "3902492" | "4117836" | "4195637" | "4299226" | "4323071" | "4423725" | "4445892" | "4453545" | "4581017" | "4601706" | "4610662" | "4655746" | "4689041").PN. OR ("4832028").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 16:30
S4	51	("3811448" | "4195637" | "4323071" | "4493711" | "4573470" | "4619263" | "4641649" | "4643186" | "4748982" | "4762129" | "4790315" | "4798193" | "4824435" | "5003990" |	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:04

		"5040548" | "5045061" | "5061273" | "5090957" | "5090958" | "5324257" | "5324259" | "5395332" | "5413557" | "5415634" | "5505702" | "5540659" | "5569199" | "5571087" | "5575771" | "5578009" | "5605543" | "5667493" | "5667521" | "5690642" | "5706827" | "5718680" | "5728067" | "5730698" | "5752932" | "5863285" | "5879305" | "5882334" | "6071285" | "6394995" | "6447501" | "6500147" | "RE31800").PN. OR ("6740104").URPN.				
S5	13	("5053007" | "5129887" | "5224939" | "5389090" | "5401258" | "5445625").PN. OR ("5492530").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:10
S6	285	604/103.04	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S7	213	604/103.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:18
S8	540	604/160	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S9	594	604/161	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:20
S10	605	604/162	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21

S11	1217	604/164.01	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S12	235	604/164.09	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S13	196	604/164.1	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S14	311	604/164.11	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:21
S15	484	604/525	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/06 17:23
S16	12	("4100393" | "4377165" | "4401433" | "4449973" | "4702735" | "4762516" | "4790817" | "4950252" | "4957488" | "4957489" | "D247975").PN. OR ("5971957").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 08:54
S17	32	("4166469" | "4243050" | "4345606").PN. OR ("5667514").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 09:15
S18	36	("3352306" | "3565074" | "4230123" | "4581019" | "4629450" | "4772264" | "4911691" | "4978334" | "4994027" | "4995866").PN. OR ("5242410").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 10:45
S19	33	("4323071" | "4456011" | "4995872" | "5053007" | "5053008" | "5108419" | "5147317" | "5151105" | "5190529" | "5242399" | "5330446" | "5531715" | "5549551" | "5702410" |	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 12:58

		"5702417" | "5769816" | "5814064" | "5843027" | "5846260" | "5849248" | "5891159" | "5897567" | "5916193" | "5980503" | "6048331" | "6068621" | "6090097" | "6093173" | "6129713" | "6231544" | "6251119" | "6290710" | "6391044").PN. OR ("6689152").URPN.				
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

S21	13	("2541402" | "4909248" | "5067496" | "5222487" | "5279610" | "5323771" | "5546937" | "5791338" | "5919183" | "5937860").PN. OR ("6481436").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/07 16:11
S22	9	("5667514" | "5868754" | "5947995" | "6001118").PN. OR ("6254610").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2008/11/10 13:46
S23	2	"relief cuts" SAME rigid $4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S24	2	"relief cut" SAME rigid $4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S25	1370	cut SAME rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S26	345	cut with rigid$4 and "604"/$.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:46
S27	95	"relief cuts" SAME rigid $4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2008/11/10 14:51

12/ 2/ 2008 5:47:01 PM
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BIB DATA SHEET

CONFIRMATION NO. 5061

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/416,629	05/03/2006	604	3767	2005.86US01

APPLICANTS

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

**** CONTINUING DATA ***************************

**** FOREIGN APPLICATIONS ***************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **
05/23/2006

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /BRADLEY JAMES OSINSKI/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		MN	13	20	3

ADDRESS

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

TITLE

Coaxial guide catheter for interventional cardiology procedures

FILING FEE RECEIVED		
565	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

VSI_00000365

A01697

Substitute for form 1449/PTO

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

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

Sheet 1 of 1

U.S. PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

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

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

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

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/416,629
				Filing Date	May 3, 2006
				First Named Inventor	Howard Root et al.
				Art Unit	3763
				Examiner Name	Not Assigned
Sheet	1	of	1	Attorney Docket Number	2005.86US01

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		TAKAHASHI, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).	

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

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

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

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

VSI_00000367

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

RESPONSE TO RESTRICTION REQUIREMENT

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

Dear Sir:

In response to the Office Action dated July 11, 2008, Applicants', through their attorney, elects Groups II consisting of claims 8-16 and new claim 21 with traverse. Applicants' request that claims 1-7, 17-20 and new claims 22-24 be withdrawn.

The present amendment comprises the following sections:

A. Amendments to the Claims

B. Remarks

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

AMENDMENTS TO THE CLAIMS

A detailed listing of all claims that are, or were, in the present application, irrespective of whether the claim(s) remains under examination in the application are presented below. The claims are presented in ascending order and each includes one status identifier.

1. (Withdrawn-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 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 along at least part of a length thereof; and

a flexible distal tip portion,

a flexible 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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. (Currently Amended) 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 along at least part of a length thereof and being sized to pass through the first lumen of the guide catheter, the elongate structure including:

a flexible distal tip portion;

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

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; and

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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Withdrawn-Currently Amended) A kit for performing interventional cardiology procedures that include insertion of a treatment catheter into a blood vessel, for use with a guide catheter having a first lumen, 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 flexible 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~~ at least a portion of a length of the rigid portion.

18. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

21. (New) The device as claimed in claim 8, wherein the reinforced portion comprises a braid or coil formed of metal.

22. (Withdrawn-New) The device as claimed in claim 8, wherein the substantially rigid portion comprises a full circumference portion, a greater than one hundred eighty degree portion and a less than one hundred eighty degree portion.

23. (Withdrawn-New) The device as claimed in claim 8, wherein the opening is bounded by a beveled border.

24. (Withdrawn-New) The kit as claimed in claim 17, further comprising:

instructions to insert the guide catheter into the first blood vessel, the guide catheter having 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 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.

REMARKS

Claims 1-20 are pending. In response to the restriction requirement, Applicant requests that claims 1-7 and 17-20 be withdrawn. Claims 1, 8 and 17 are amended, no claims are cancelled and new claims 21-24 are added

In response to the Office Action dated July 11, 2008, Applicants, through their attorney, elects Groups II consisting of claims 8-16 and new claim 21 with traverse. Applicants' request that claims 1-7, 17-20 and new claims 22-24 be withdrawn.

Applicants traverse to the extent that claims 17-24 include all the limitations of the elected claims and should be allowable if the elected claims are allowed. There should be no significant burden on the Examiner to search these claims as well.

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

Respectfully submitted,

Paul C. Onderick
Registration No. 45,354

Customer No. 24113
Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5766

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Howard Root et al. Confirmation No.: 5061

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

Filed: May 3, 2006 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

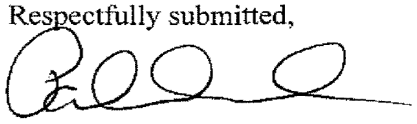
PETITION FOR EXTENSION OF PERIOD FOR RESPONSE
UNDER 37 CFR § 1.136(a)

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

Sir:

Pursuant to 37 CFR § 1.136(a), an extension of time of two (2) months (from August 11, 2008 to October 11, 2008) within which to respond to the Office Action dated July 11, 2008 is requested. Electronic payment is submitted by credit card to cover the extension fee. Applicants are entitled to small entity status in accordance with 37 CFR 1.27. The Commissioner is authorized to charge to Deposit Account No. 16-0631 any underpayments, overpayments or additionally required fees.

Respectfully submitted,



Paul C. Onderick
Registration No. 45,354

Customer No. 24113
Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5766

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

Electronic Patent Application Fee Transmittal

Application Number:	11416629
Filing Date:	03-May-2006
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Filer:	Paul C. Onderick/Allison Goette
Attorney Docket Number:	2005.86US01

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with $0 paid	2252	1	230	230

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**230**

Electronic Acknowledgement Receipt	
EFS ID:	4043334
Application Number:	11416629
International Application Number:	
Confirmation Number:	5061
Title of Invention:	Coaxial guide catheter for interventional cardiology procedures
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick
Filer Authorized By:	
Attorney Docket Number:	2005.86US01
Receipt Date:	01-OCT-2008
Filing Date:	03-MAY-2006
Time Stamp:	16:22:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$230
RAM confirmation Number	1844
Deposit Account	160631
Authorized User	ONDERICK,PAUL C
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86US01_RR.pdf	230713 b88f673ee0781e49bd548f54cefe593b99455e8c	yes	11

Multipart Description/PDF files in .zip description

Document Description	Start	End
Response to Election / Restriction Filed	1	1
Claims	2	10
Applicant Arguments/Remarks Made in an Amendment	11	11

Warnings:

Information:

2	Extension of Time	2005_86US01_EOT.pdf	29153 936c87b4827643ecbe8d1270de17b40de3d1a1f0	no	1

Warnings:

Information:

3	Fee Worksheet (PTO-06)	fee-info.pdf	30331 ca18345246346c121e24f1579fb4980a6c200b09	no	2

Warnings:

Information:

Total Files Size (in bytes):	290197

VSI_00000383

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.

Document code: WFEE

United States Patent and Trademark Office
Sales Receipt for Accounting Date: 04/20/2009

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

24113 7590 07/11/2008

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MINNEAPOLIS, MN 55402-2100

EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
07/11/2008	PAPER

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

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

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

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 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 *03 May 2006*.

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) *1-20* 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) _____ is/are rejected.

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

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

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

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

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

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

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

Priority under 35 U.S.C. § 119

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

a)☐ All b)☐ Some * c)☐ None of:

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

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

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

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

Attachment(s)

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

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method of providing support for a cardiology device, classified in class 604, subclass 510.

II. Claims 8-16, drawn to a device for use with a cardiology device, classified in class 604, subclass 524.

III. Claims 17-20, drawn to a kit with two guide catheters, classified in class 206, subclass 364.

The inventions are distinct, each from the other because of the following reasons:

Inventions (II and III) and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the devices of groups II and III may be used in a materially different process, such as inserting a device into plumbing.

Inventions III and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and

(2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require a guide catheter. The subcombination has separate utility such as a guidewire, it does not need to be used with a second catheter.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Paul Onderick on 6/2/2008 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

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

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

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/416,629	05/03/2006	Howard Root	2005.86US01

CONFIRMATION NO. 5061

24113
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN55402-2100

Title: Coaxial guide catheter for interventional cardiology procedures

Publication No. US-2007-0260219-A1
Publication Date: 11/08/2007

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.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Pre-Grant Publication Division, 703-605-4283

VSI_00000394

PATTERSON | THUENTE
SKAAR | CHRISTENSEN | IP

Patent, Trademark, Copyright, Internet & Related Causes | Patterson, Thuente, Skaar & Christensen, P.A.

4800 IDS Center
80 South 8th Street
Minneapolis, MN
55402-2100

t: 612.349.5740
t: 800.331.4537
f: 612.349.9266
www.ptslaw.com

FACSIMILE COVER SHEET

TOTAL NUMBER OF PAGES BEING SENT (INCLUDING COVER SHEET): 10

[ ] Original documents to follow by mail [X] No originals will be sent

DATE: July 24, 2006

TO: Examiner Not Assigned
Group Art Unit 3763

FAX #: 571-273-8300

PHONE #:

Application No.: 11/416,629
Applicant: Howard Root et al.
Due Date: N/A

OUR REF.: 2005.86US01

FROM: Paul C. Onderick
PHONE #: 612-349-5766

Attached please find the following for filing in the above-identified application:

(1) Information Disclosure Statement; and
(2) Substitute for form 1449/PTO.

Respectfully submitted,

Paul C. Onderick
Registration No. 45,354

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 571-273-8300 on the date shown below.

7-24-2006
Date

Paul C. Onderick

FACSIMILE SENT BY JMS

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86US01
Howard Root et al.	Confirmation No.: 5061
Application No.: 11/416,629	Examiner: Not Assigned
Filed: May 3, 2006	Group Art Unit: 3763

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

INFORMATION DISCLOSURE STATEMENT

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

Sir:

Pursuant to 37 C.F.R. § 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 this application, and that the references 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 that the reference is material to patentability.

This Information Disclosure Statement is being filed within three months of the U.S. filing date. No certification or fee is required.

This information is being filed before the mailing date of a first Office Action on the merits. No certification or fee is required.

This application was filed after June 30, 2003; therefore, copies of cited U.S. patents and U.S. published applications are not included.

Respectfully submitted,

Paul C. Onderick
Registration No. 45,354

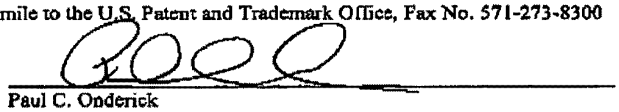
Customer No. 24113
Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5766

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

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 571-273-8300 on the date shown below.

7-24-2006
Date of Deposit



Paul C. Onderick

Substitute for form 1449/PTO

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

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

Sheet 1 of 1

U.S. PATENT DOCUMENTS

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

FOREIGN PATENT DOCUMENTS

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

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	11/416,629
				Filing Date	May 3, 2006
				First Named Inventor	Howard Root et al.
				Art Unit	3763
				Examiner Name	Not Assigned
Sheet	1	of	1	Attorney Docket Number	2005.86US01

NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIAL*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		TAKAHASHI, New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions 63:452-456 (2004), 5 pages, published online in Wiley InterScience (www.interscience.wiley.com).	

EXAMINER SIGNATURE		DATE CONSIDERED	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.**

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

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Root, et al. Confirmation No.: 5061

Application No.: 11/416,629 Examiner: Unknown

Filed: May 3, 2006 Group Art Unit: 3763

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

RESPONSE TO NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

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

Sir:

In response to the Notice to File Missing Parts of Application - Filing Date Granted (copy attached) mailed May 24, 2006, submitted herewith is an executed Combined Declaration and Power of Attorney.

The filing fee has been calculated as shown below:

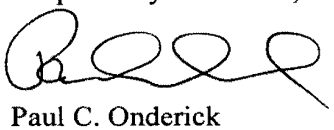
Application filed on or after December 8, 2004:					
	No. Filed	No. Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee			$150	OR	$300
Utility Search Fee			$250	OR	$500
Utility Examination Fee			$100	OR	$200
Total Claims	20 - 20	= 0	x 25 = $0	OR	x 50 = $
Independent Claims	3 - 3	= 0	x 100 = $0	OR	x 200 = $
Presence of Multiple Dependent Claim			+ 180	OR	+ 360
Surcharge - Late filing fee or oath or declaration			+ 65	OR	+ 130
Utility Application Size Fee - per each additional 50 sheets that exceeds 100 sheets:			0 x 125 = $0	OR	* x 250 = $
		TOTAL	**$565.00**	**TOTAL**	**$**
**If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets					

Applicants are entitled to small entity status in accordance with 37 CFR 1.27. A check in the amount of $565.00 is enclosed for the surcharge and filing fee. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

Entry of these documents should complete all of the filing formalities and fully satisfy all requirements of the Notice to File Missing Parts. Accordingly, examination and allowance of this application in due course are respectfully solicited.

The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 16-0631.

Respectfully submitted,



Paul C. Onderick
Registration No. 45,354

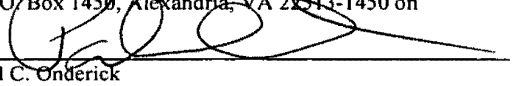
Customer No. 24113
Patterson, Thuente, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-5766

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

CERTIFICATE OF MAILING

I hereby certify that this document is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

6-16-2006
Date of Deposit



Paul C. Onderick

ITW $

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/416,629	05/03/2006	Howard Root	2005.86US01

CONFIRMATION NO. 5061
FORMALITIES LETTER

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

Date Mailed: 05/24/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing.
  Applicant must submit $ **150** *to complete the basic filing fee for a small entity.*
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

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

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

06/22/2006 MAHMED1 00000061 11416629
01 FC:2011 150.00 OP
02 FC:2111 250.00 OP
03 FC:2311 100.00 OP
04 FC:2051 65.00 OP

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$565** for a Small Entity.

- **$150** Statutory basic filing fee.
- **$65** Surcharge.

VSI_00000402

- The application search fee has not been paid. Applicant must submit **$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 2 - COPY TO BE RETURNED WITH RESPONSE

Attorney Docket No. 2005.86US01

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, Thuente, 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:

[x] 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)

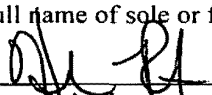
I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of 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)

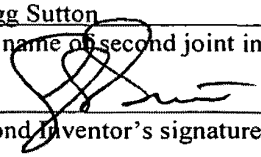

Inventor's signature

May 22, 2006
Date

Excelsior, Minnesota — US
Residence (City and either State or Foreign Country) — Citizenship

c/o Vascular Solutions, Inc.; 6464 Sycamore Court; Minneapolis, Minnesota 55369
Mailing Address

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


Second Inventor's signature

5/22/06
Date

Maple Grove, Minnesota — US
Residence (City and either State or Foreign Country) — Citizenship

16917 73rd Place North; Maple Grove, Minnesota 55311
Mailing Address

Jeffrey M. Welch
Full name of third joint inventor, if any (given name, family name)

Third Inventor's signature — Date: 5/18/06

Maple Grove, Minnesota — US
Residence (City and either State or Foreign Country) — Citizenship

8723 Comstock Lane North; Maple Grove, Minnesota 55311
Mailing Address

Jason M. Garrity
Full name of fourth joint inventor, if any (given name, family name)

Fourth Inventor's signature — Date: 5-18-06

Minneapolis, Minnesota — US
Residence (City and either State or Foreign Country) — Citizenship

3056 Jersey Avenue South; Minneapolis, Minnesota 55426
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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/416,629	05/03/2006	Howard Root	2005.86US01

CONFIRMATION NO. 5061

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

FORMALITIES LETTER

Date Mailed: 05/24/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

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

- The statutory basic filing fee is missing.
  Applicant must submit $ **150** *to complete the basic filing fee for a small entity.*
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

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

• To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$565** for a Small Entity

- **$150** Statutory basic filing fee.
- **$65** Surcharge.

- The application search fee has not been paid. Applicant must submit **$250** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **$100** to complete the examination fee for a small entity in compliance with 37 CFR 1.27

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
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Attorney Docket No. 2005.86US01

APPLICATION TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
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Sir:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) is the patent application of

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

FOR: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Enclosed are:

[X] Specification and Abstract - 29 pages.

[X] Drawings - 13 sheets (Figs. 1-22).

[ ] Combined Declaration and Power of Attorney.

[ ] Information Disclosure Statement.

[ ] CD-ROM or CD-R in duplicate, and Compact Disc Transmittal.

[ ] Request and Certification Under 35 U.S.C. 122(b)(2)(B)(i) (nonpublication).

[ ] _____.

The filing fee has been calculated as shown below:					
	No. Filed	No. Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee			$150	OR	$300
Utility Search Fee			$250	OR	$500
Utility Examination Fee			$100	OR	$200
Total Claims	20	= 0	x 25 = $	OR	x 50 = $
Independent Claims	3	= 0	x 100 = $	OR	x 200 = $
Presence of Multiple Dependent Claim			+ 180	OR	+ 360
Utility Application Size Fee - per each additional 50 sheets that exceeds 100 sheets:			x 125 = $	OR	x 250 = $
		TOTAL	**$500**	**TOTAL**	**$**
**If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets					

[X] Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.

[ ] A check in the amount of $ 0 to cover the filing fee is attached. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

[ ] This application claims the benefit of U.S. Provisional Application No. _____, filed _____.

Respectfully submitted,

Paul C. Onderick
Registration No. 45,354

CERTIFICATE OF EXPRESS MAIL

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

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Doris Whitcomb
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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 to75 cm in length.

Hemicylindrical portion 36 tapers into arcuate portion 38.

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

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

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

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

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

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

Coaxial guide catheter 12 may include, starting at its distal end, a first portion having a flexural modulus of about 13,000 PSI plus or minus 5000 PSI, a second portion having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, a third portion having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI and a fourth portion having a flexural modulus of about 107,000 PSI plus or minus 20,000 PSI. Coaxial guide catheter 12 may be formed, for example, of 4033 Pebax ® at bump tip 22 for the first 0.1 cm. This portion may followed by a section about three cm long of 5533 Pebax® that covers marker band 24 and the distal portion of braid or coil reinforcement 32. Next may come an approximately five cm portion of 6333 Pebax® which encloses part of braid or coil reinforcement 32 followed by an approximately twenty seven cm portion of 7233 Pebax® covering the most proximal portion of braid or coil reinforcement 32. Braid or coil reinforcement 32 is bonded to rigid portion 20 which may be formed from stainless steel or a similar biocompatible material. Rigid portion 20 may extend for approximately ninety cm and include first full circumference portion 34 (approximately .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 ($BaSO_4$).

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

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

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

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

force to the proximal end of the coaxial guide catheter 12 to resist dislodging of bump tip 22 from the ostium of the branch artery.

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

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

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.

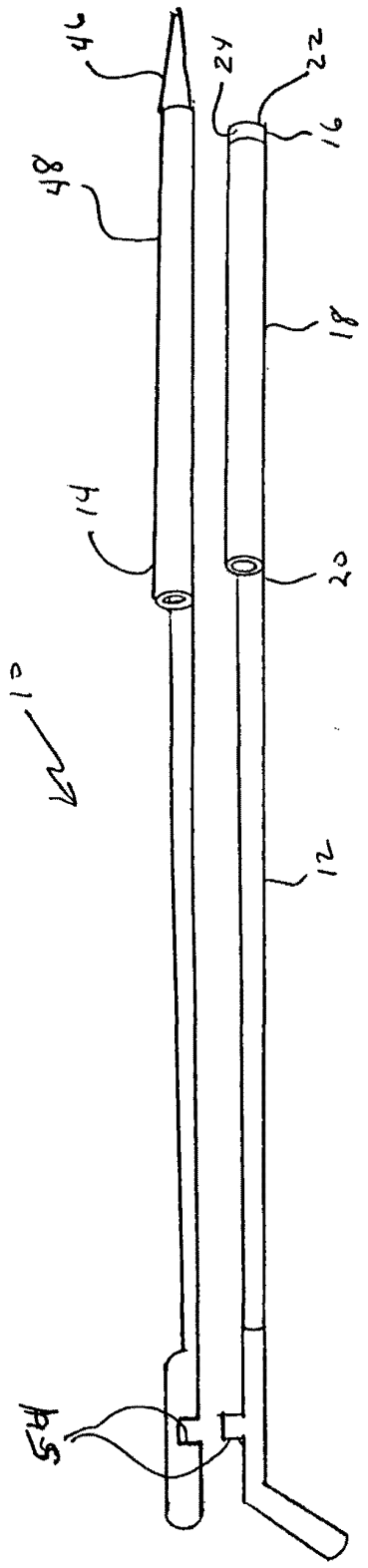

FIG. 1

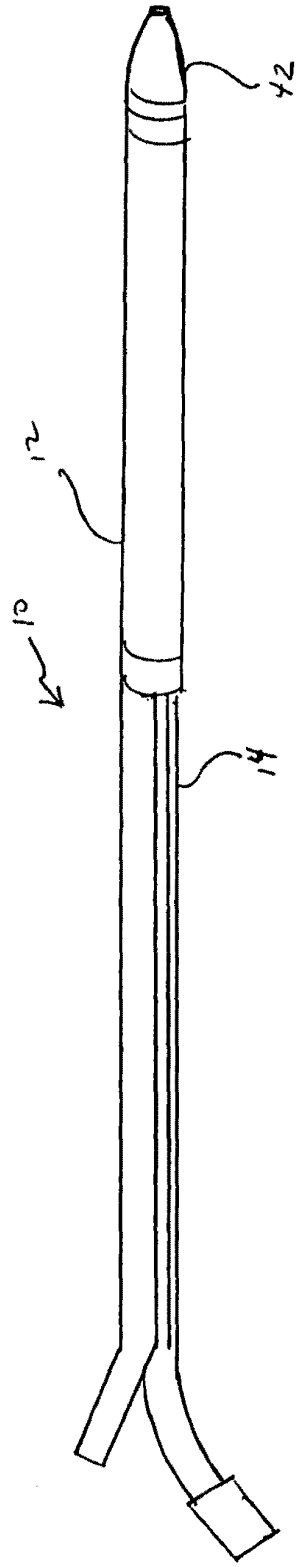

Fig. 2

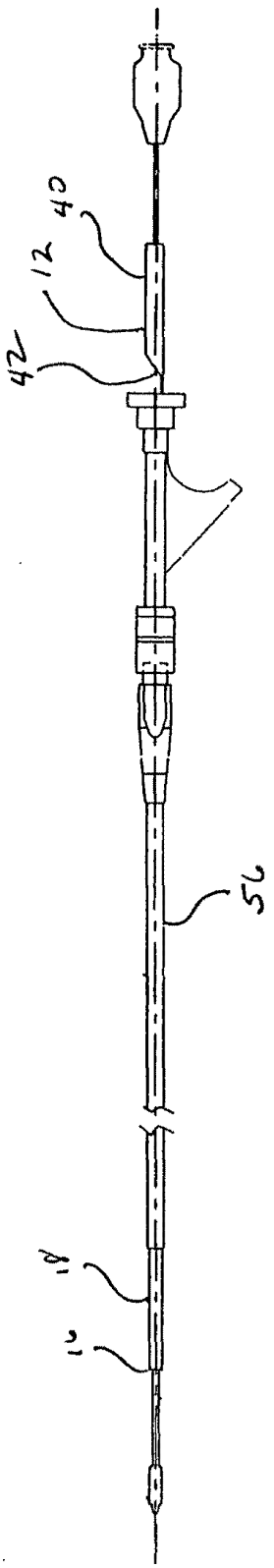

Fig. 3

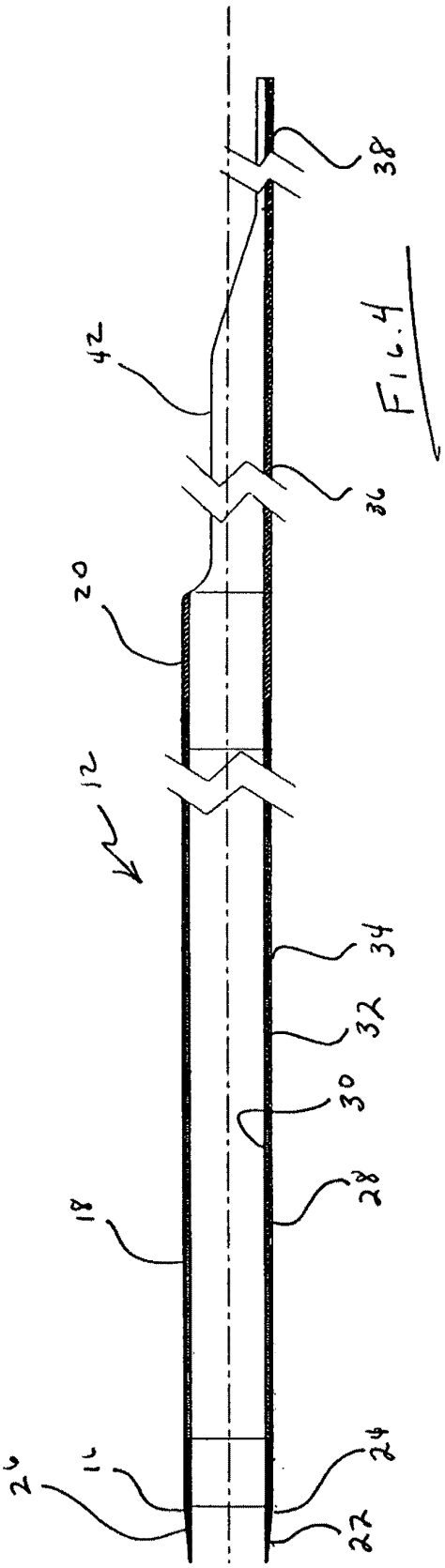

FIG. 4

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Fig. 4

Fig. 5

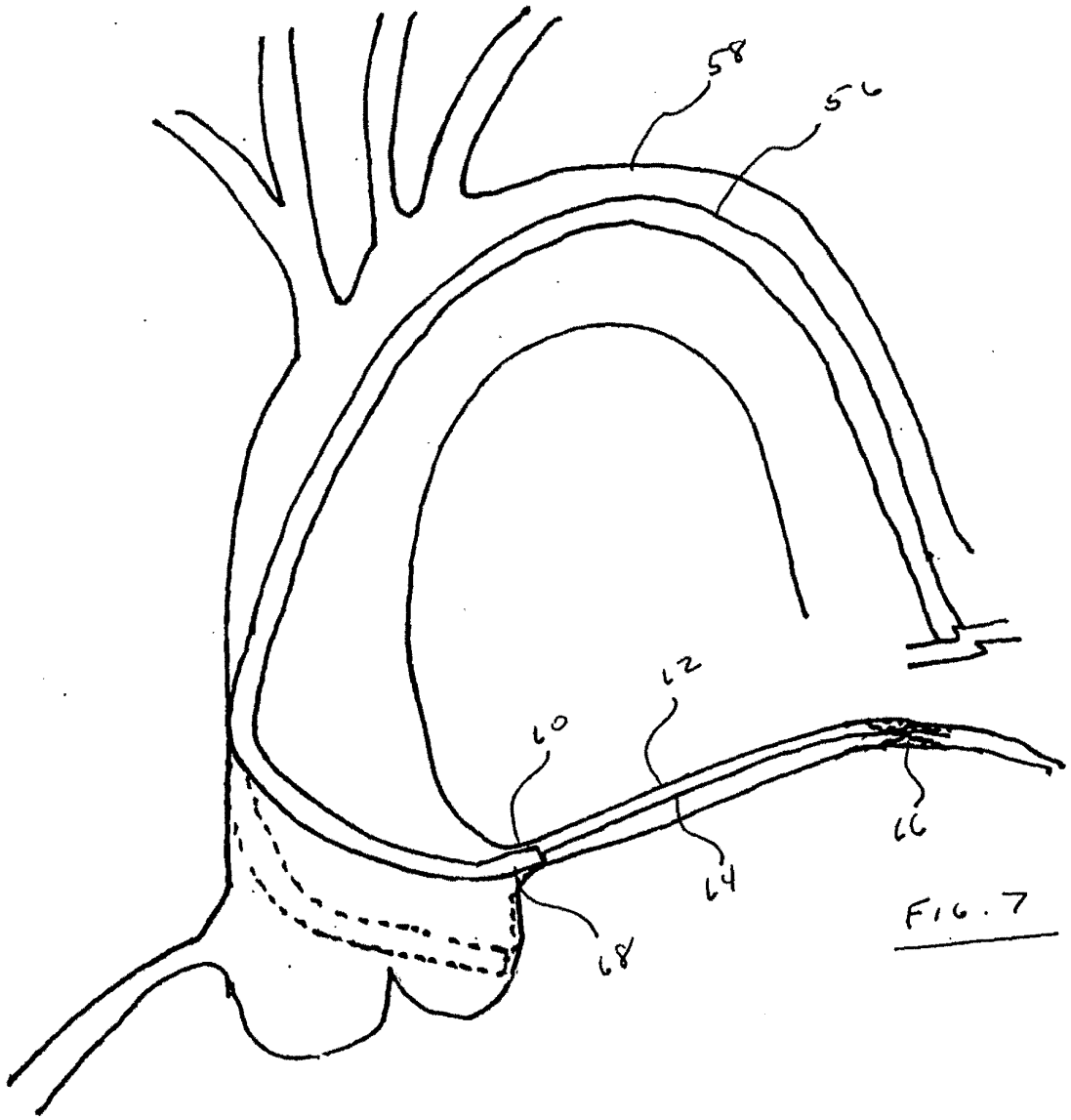

FIG. 7

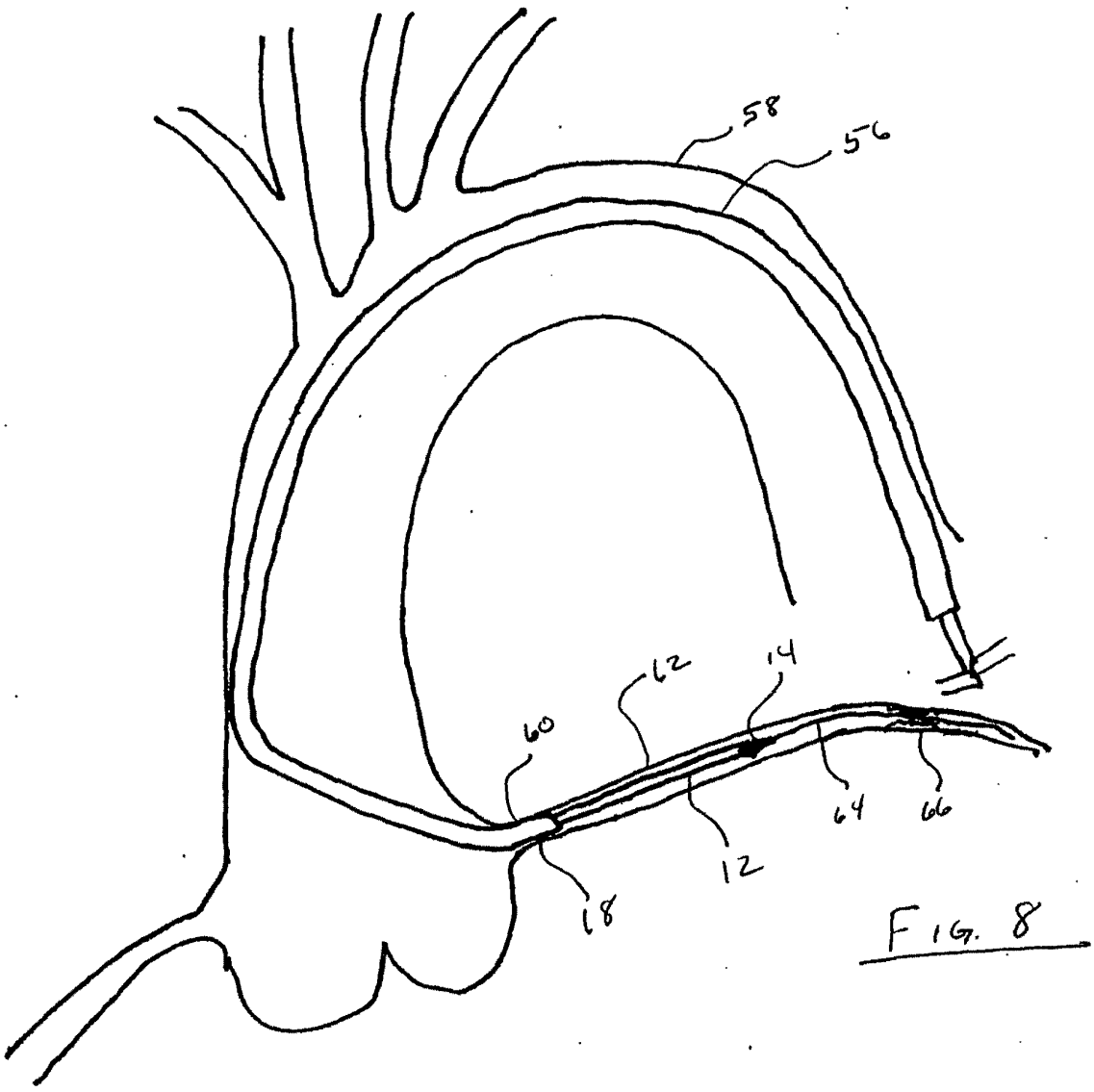

FIG. 8

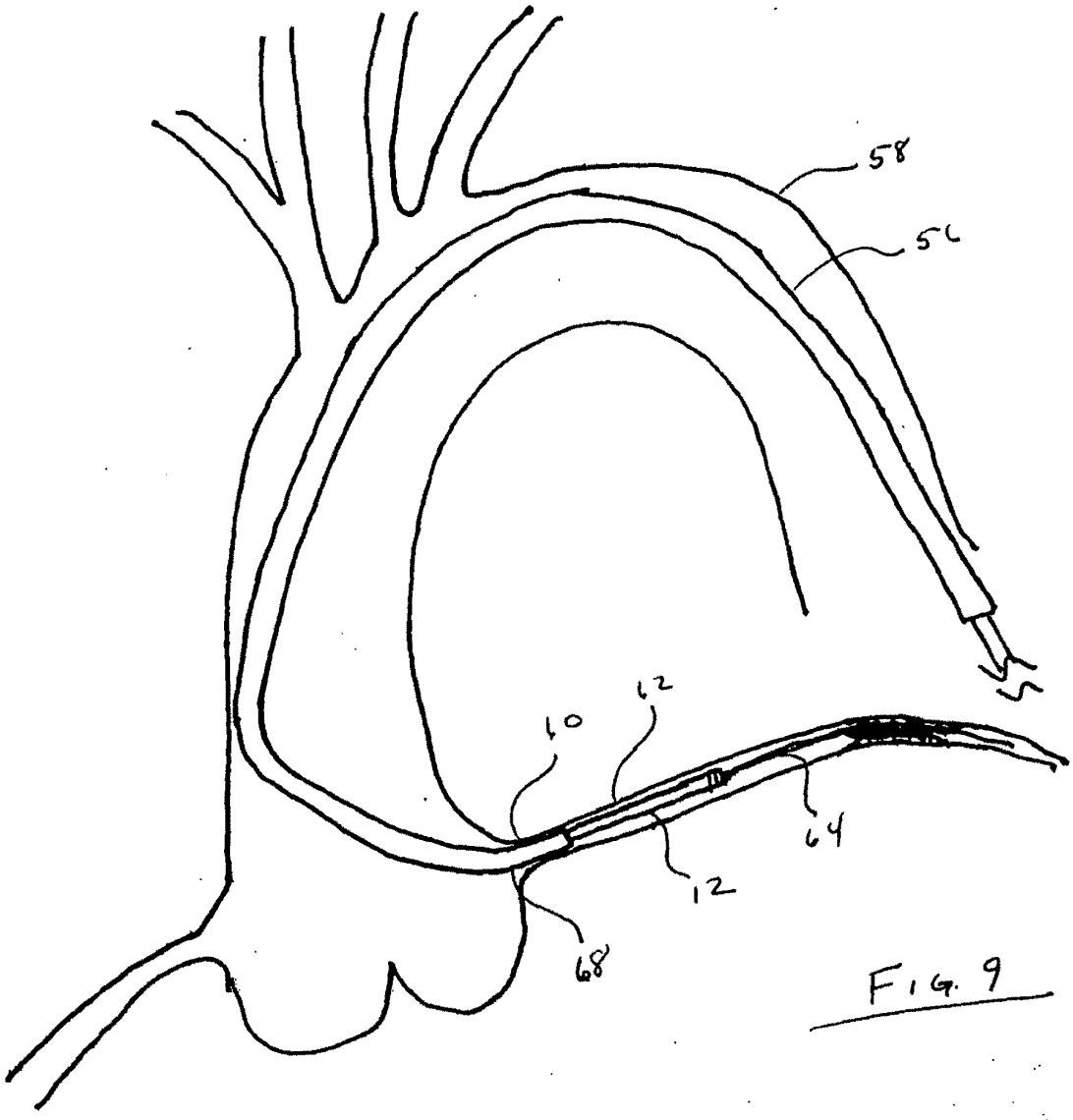

Fig. 9

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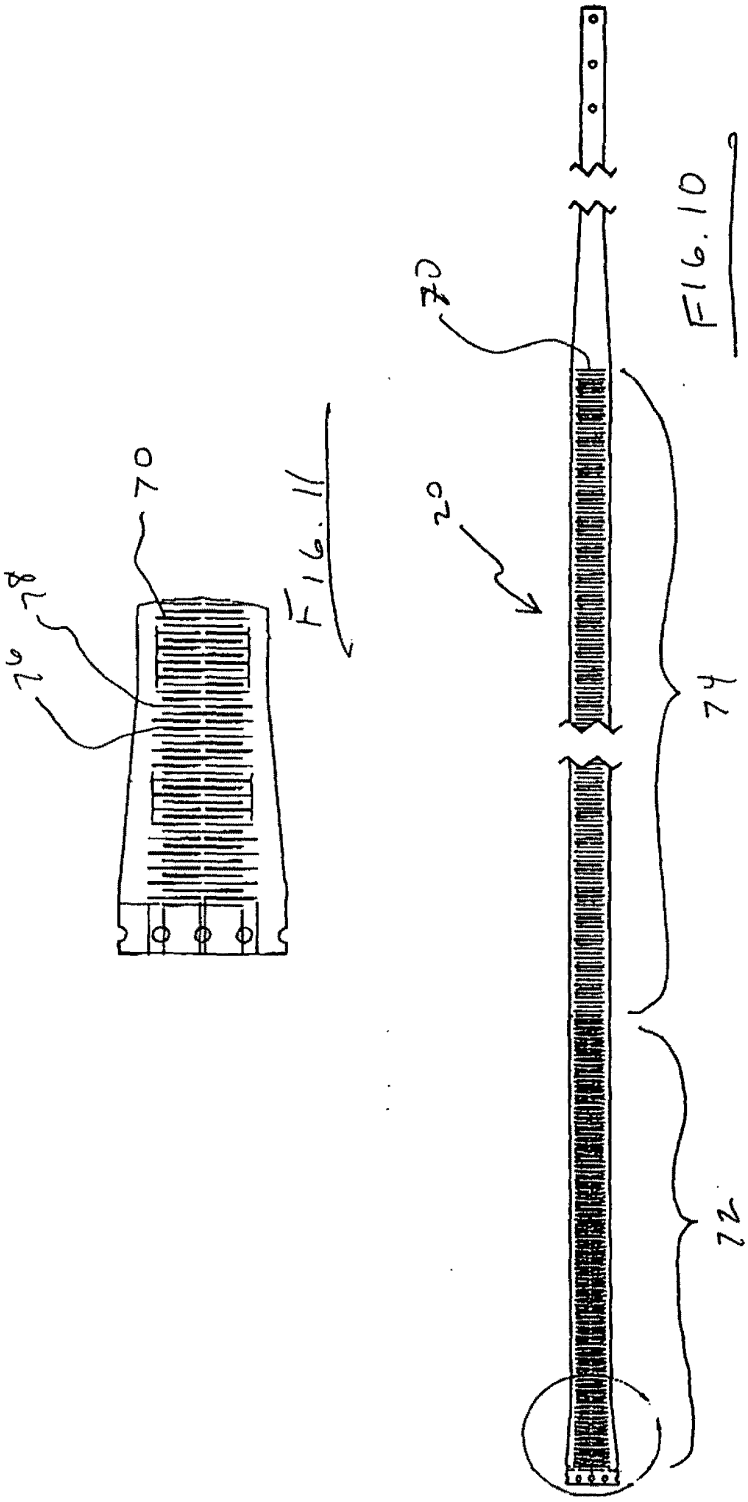

FIG. 10

FIG. 11

FIG. 12

FIG. 13

FIG. 16

FIG. 15

FIG. 14

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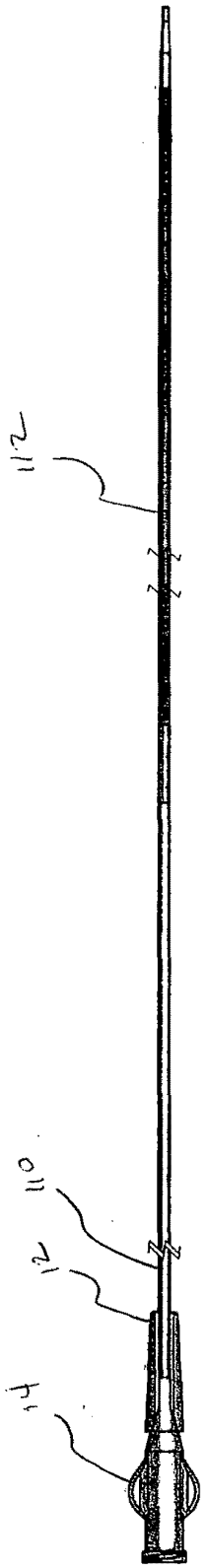

FIG. 17

FIG. 18

FIG. 19

FIG. 20

FIG. 21

FIG. 22

PTO/SB/06 (12-04)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/416,629

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	250		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	100		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	20	*	X 25=		OR	X 50=	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	*	X 100=			X 200=	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			N/A			N/A	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	500		TOTAL	

APPLICATION AS AMENDED – PART II

		(Column 1)		(Column 2)	(Column 3)	SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDI-TIONAL FEE ($)		RATE ($)	ADDI-TIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
						TOTAL ADD'T FEE		OR	TOTAL ADD'T FEE	

		(Column 1)		(Column 2)	(Column 3)			OR		
		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE ($)	ADDI-TIONAL FEE ($)		RATE ($)	ADDI-TIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	X =		OR	X =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X =		OR	X =	
	Application Size Fee (37 CFR 1.16(s))							OR		
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					N/A		OR	N/A	
						TOTAL ADD'T FEE		OR	TOTAL ADD'T 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.

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

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