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Attorney Docket No. 2005.86USREI3

REISSUE APPLICATION TRANSMITTAL

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

Commissioner:

Transmitted herewith for filing under 37 CFR. § 1.171 is the reissue patent application of U.S. Patent No.
INVENTOR(S): Howard Root, Gregg Sutton, Jeffrey M. Welch, Jason M. Garrity
FOR: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
Enclosed are:

[X] Specification and Abstract - 5 pages (from issued patent)
[X] Drawings - 13 sheets (Figs. 1-22), copies of drawings from issued patent
[ ] Reissue Application Declaration and Power of Attorney
[X] Consent of Assignee
[ ] Statement Under 37 CFR. 3.73(b)
[X] Preliminary Amendment
[ ] Information Disclosure Statement
[X] Copy of U.S. Patent No. 8,292,850
[X] Other - Copy of Certificate of Correction

The filing fee has been calculated as shown below:						
Application as Filed - Part 1						
	(1) Claims in Patent	(2) Claims Filed in Reissue Application	(3) Number Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee				$140	OR	$280
Reissue Search Fee				$300	OR	$600
Reissue Examination Fee				$1080	OR	$2160
Total Claims	24	44	= 24	x 40 = $960	OR	x 80 = $
Independent Claims	2	4	= 1	x210 = $210	OR	x 420 = $
Presence of Multiple Dependent Claim				+ 390	OR	+ 780
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 200 = $0	OR	x 400 = $
			TOTAL	$2,690.00	OR	$0
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets						

Application as Amended - Part 2						
	(1) Claims Remaining After Amendment	(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	OR	Large Entity Rate
Total Claims	44	minus 44	= 0	x 40 = $0	OR	x 80 = $
Independent Claims	4	minus 4	= 0	X210 = $0	OR	x 420 = $
Presence of Multiple Dependent Claim				+ 390	OR	+ 780
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 200 = $0	OR	x 400 = $
			TOTAL	**$0**	OR	$
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets						

*If (D) is less than (C), enter "0" in column 3. For reissues filed on or after Dec. 8, 2004, enter (D) minus 3 or "0" if (D) is less than 3.
**If the "Highest Number of Total Claims Previously Paid For" is less than 20, enter "20" in this space.
***After any cancellation of claims.
****If (A) is greater than 20, enter (B) - (A); if (A) is 20 or less, enter (B) - 20. For reissues filed on or after Dec. 8, 2004 enter (B) - 20.
*****For amendments filed on or after Dec. 8, 2004, enter the "Highest Number of Independent Claims Previously Paid For."
For amendments filed prior to Dec. 8, 2004, enter the higher of the Number Previously Paid or Number of Independent Claims in Patent.

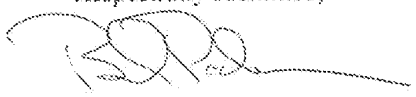
At least one error upon which reissue is based in described below. This is a broadening reissue and a claim that the application seeks to broaden is identified.

The issued independent claims of the patent claim less than patentee had a right to claim. Accordingly, patentee seeks to broaden the claims by reissue. Patented independent claim 1 is directed to a system including a guide catheter and a device for use with the guide catheter. Neither independent claim 1 nor independent claim 12 recites means plus function limitations for the device or a method of manufacture of the device.

[X] Applicants are entitled to small entity status in accordance with 37 CFR 1.27.

[ ] A check in the amount of $_____ to cover the filing fee is enclosed. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 CFR §§ 1.16 and 1.17 that may be required during the entire pendency of this application to Deposit Account No. 16-0631.

Respectfully submitted,



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

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root et al.	Confirmation No.: Unknown
Application No.: Unknown	Examiner: Unknown
Filed: Herewith	Group Art Unit: Unknown

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

PRELIMINARY AMENDMENT

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

Commissioner:

INTRODUCTORY COMMENTS

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

The present amendment comprises the following sections:

A. Amendments to the Claims

C. Amendments to the Drawings

D. 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. (Original) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

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

a device adapted for use with the guide catheter, including:

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

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

rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. (Original) The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

4. (Original) The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

5. (Original) The system of claim 1, wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

6. (Original) The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

7. (Original) The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

8. (Original) The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

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

10. (Original) The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

11. (Original) The system of claim 1, further comprising a kit that includes the guide catheter and the device in a common sterile package.

12. (Original) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the 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 continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

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

a flexible tip portion defining a tubular structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion 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, connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide

catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

13. (Original) The system of claim 12, 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.

14. (Original) The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

15. (Original) The system of claim 12, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents 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.

16. (Original) The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

17. (Original) The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.

18. (Original) The system of claim 12, 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.

19. (Original) The system of claim 12, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

20. (Original) The system of claim 12, 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.

21. (Original) The system of claim 20, 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.

22. (Original) The system of claim 20, 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.

23. (Original) The system of claim 12, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

24. (Original) The system of claim 12, further comprising a kit that includes the guide catheter and the device in a common sterile package.

25. (New) A system comprising:

means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and

means for receiving the interventional device from the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,

the means for guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when a distal end of the tip portion is extended distally of a distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of a proximal end of the substantially rigid portion extends proximally of a proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,

the tip portion, the reinforced portion, the side opening, and the substantially rigid portion configured to be passed, at least in part, through a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and

the side opening including a portion having an arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape and positioned adjacent to, or incorporated with, the distal end portion of the substantially rigid portion or a proximal end portion of the reinforced portion.

26. (New) The system of claim 25, wherein the side opening includes at least one inclined slope.

27. (New) The system of claim 26, wherein the side opening includes at least two different inclined slopes.

28. (New) The system of claim 25, wherein the portion of the side opening having the arcuate cross-sectional shape includes 25% to 40% of a full circumference.

29. (New) The system of claim 25, wherein the portion of the side opening having the arcuate cross-sectional shape includes a less than 180° portion.

30. (New) The system of claim 25, wherein the side opening includes a portion having a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and the portion having the full circumference cross-sectional shape.

31. (New) The system of claim 25, wherein the reinforced portion includes one or more braided elements embedded in a polymer.

32. (New) The system of claim 25, wherein an inner diameter of a lumen of the means for guiding the interventional device deeper into the branch vessel is not more than one French smaller than an inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel.

33. (New) The system of claim 25, where the means for guiding the interventional device deeper into the branch vessel includes a concave track along a portion of its length.

34. (New) A method of forming a device adapted for use with a guide catheter having a lumen, the method comprising:

providing a substantially rigid portion;

providing a reinforced portion including one or more metallic elements covered with a polymer and a lumen;

providing a tip portion including a low durometer polymer or elastomeric material and a lumen continuous with the lumen of the reinforced portion;

coupling a distal end of the substantially rigid portion to a proximal end of the reinforced portion; and

coupling a distal end of the reinforced portion to a proximal end of the tip portion,

wherein providing the substantially rigid portion, the reinforced portion, and the tip portion includes forming a device length such that when a distal end of the tip portion is extended distally of a distal end of the guide catheter, a portion of a proximal end of the substantially rigid portion extends proximally of a proximal end of the guide catheter, and

wherein providing one or both of the substantially rigid portion and the reinforced portion includes providing a side opening extending for a distance along a longitudinal axis of the device and accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive an interventional device.

35. (New) The method of claim 34, wherein providing the substantially rigid portion includes forming or obtaining a hypo tube or metal rail structure.

36. (New) The method of claim 34, wherein providing the side opening includes forming or obtaining an inclined sidewall with a first slope.

37. (New) The method of claim 36, wherein providing the side opening includes forming or obtaining an inclined sidewall with a second slope different from the first slope.

38. (New) The method of claim 34, wherein providing the side opening includes forming or obtaining, in a proximal to distal direction, a first segment having an arcuate cross-sectional shape, a second segment having a hemicylindrical cross-sectional shape, and a third segment having a full circumference cross-sectional shape.

39. (New) The method of claim 34, wherein providing the reinforced portion includes covering one or more braided metallic elements with the polymer.

40. (New) The method of claim 34, wherein providing the reinforced portion including the lumen includes forming or obtaining a reinforced portion including a lumen having an inner diameter that is not more than one French smaller than an inner diameter of the lumen of the guide catheter.

41. (New) The method of claim 34, wherein providing the substantially rigid portion, the reinforced portion, and the tip portion includes, starting at a distal end of the tip portion and moving proximally toward a proximal end of the substantially rigid portion, forming or obtaining at least a first structure having a first flexural modulus, a second structure having a second flexural modulus greater than the first flexural modulus, and a third structure having a third flexural modulus greater than the second flexural modulus.

42. (New) The method of claim 41, wherein forming or obtaining the first structure having the first flexural modulus includes forming a structure having a flexural modulus of about 13,000

PSI plus or minus 5,000 PSI, wherein forming or obtaining the second structure having the second flexural modulus includes forming a structure having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, and wherein forming or obtaining the third structure having the third flexural modulus includes forming a structure having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI.

43. (New) The method of claim 34, wherein providing one or both of the reinforced portion and the tip portion includes lining a lumen thereof with polytetrafluoroethylene.

44. (New) The method of claim 34, wherein providing the tip portion includes covering a marker with the low durometer polymer or elastomeric material.

REMARKS

Claims 1-24 are pending. By this Amendment, no claims are cancelled, no claims are amended and new claims 25-44 are added.

Entry of this Preliminary Amendment for the above-identified reissue application is respectfully requested.

Claims 25-44 are added. No claims are cancelled. Accordingly, upon entry of this Preliminary Amendments, claims 1-44 will be pending.

The amendments and additions to the claims are made to correct one or more defects causing U.S. Patent No. 8,292,850 to be partly inoperative or invalid.

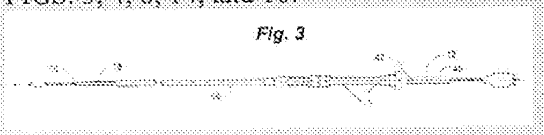
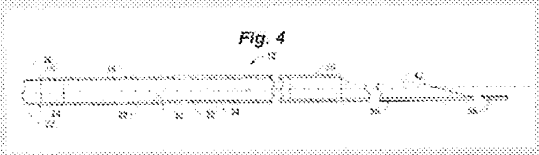
Examination and reconsideration of this application are respectfully requested.

Formal Request for Telephonic Interview

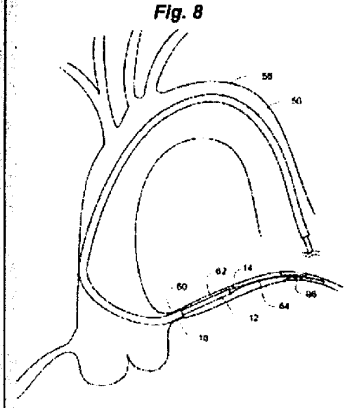
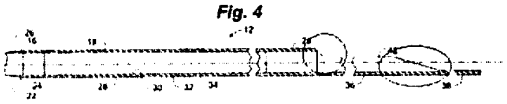
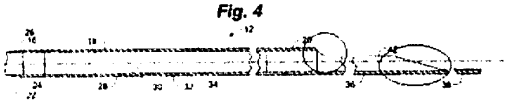
If the present claim amendments and additions do not result in allowance of this reissue application, the undersigned formally requests that, before issuance of any Office Action, a telephonic interview be held between the Examiner and the undersigned, at the Examiner's convenience. The Examiner is kindly requested to phone the undersigned at 612.349.5774 to arrange a time for such telephonic interview.

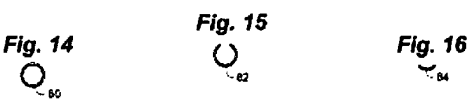
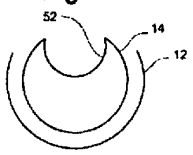
Support for Claim Amendments and Additions

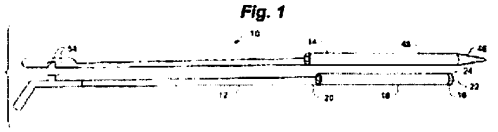
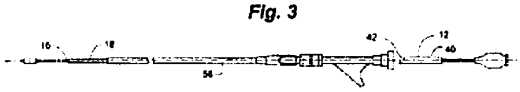
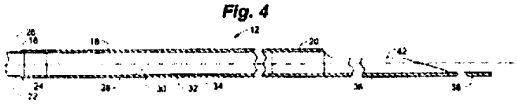
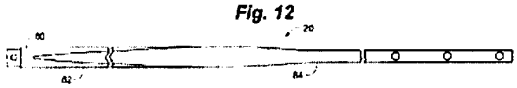
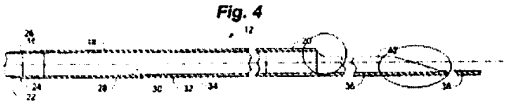
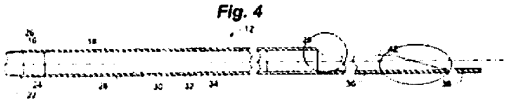
As required by 37 C.F.R. § 1.173 and MPEP § 1453, support for new claims 25-44 can be found in the originally-filed patent application, as presented in the following table:

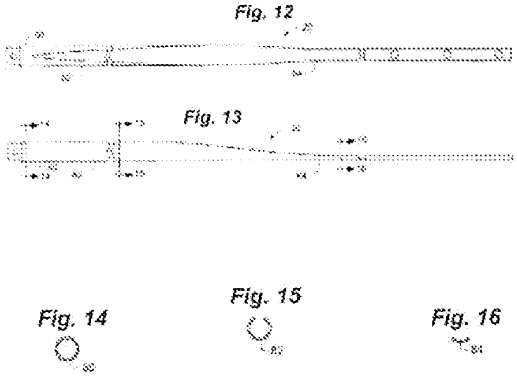
Claim No.	Claim Amendment(s) and/or Addition(s)[1]	Example(s) of Support in U.S. Application Serial No. 13/359,059, filed on Jan. 26, 2012
25	A system comprising: means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and means for receiving the interventional device from the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel, the means for guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when a distal end of the tip portion is extended distally of a distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of a proximal end of the substantially rigid portion extends proximally of a proximal end of the means for guiding the interventional device to the location near the	Page 5, lines 5-7 Page 6, lines 1-4 and 15-22 Page 7, line 14 – page 8, line 2 Page 9, lines 12-14 Page 11, lines 13-16 Page 12, lines 12-18 Page 15, lines 1-18 Page 19, lines 2-22 Original claims 3, 4, 9, and 14 FIGS. 3, 4, 8, 14, and 16:  

[1] In the table, bracketed language indicates deletions and underlined language indicates additions.

	ostium of the branch vessel, the tip portion, the reinforced portion, the side opening, and the substantially rigid portion configured to be passed, at least in part, through a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and the side opening including a portion having an arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape and positioned adjacent to, or incorporated with, the distal end portion of the substantially rigid portion or a proximal end portion of the reinforced portion	Fig. 8  Fig. 14 Fig. 15 Fig. 16
26	The system of claim 36, wherein the side opening includes at least one inclined slope	FIG. 4: 
27	The system of claim 37, wherein the side opening includes at least two different inclined slopes	FIG. 4: 
28	The system of claim 36, wherein the portion of the side opening having the arcuate cross-sectional shape includes 25% to 40% of a full circumference	Page 13, lines 1 and 2
29	The system of claim 36, wherein the portion of the side opening having the arcuate cross-sectional shape includes a less than 180° portion	Page 16, lines 16, 18, and 19
30	The system of claim 36, wherein the side opening includes a portion having a hemicylindrical cross-sectional shape between the portion having the arcuate	Page 12, lines 14-16 and 19-21 Original claim 9

	cross-sectional shape and the portion having the full circumference cross-sectional shape	FIG.15: Fig. 14 Fig. 15 Fig. 16 
31	The system of claim 36, wherein the reinforced portion includes one or more braided elements embedded in a polymer	Page 6, lines 10-14 Page 12, lines 5-7 Page 18, lines 11 and 12
32	The system of claim 36, wherein an inner diameter of a lumen of the means for guiding the interventional device deeper into the branch vessel is not more than one French smaller than an inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel	Page 5, lines 8-18 Original claims 8 and 18
33	The system of claim 36, where the means for guiding the interventional device deeper into the branch vessel includes a concave track along a portion of its length	Page 13, lines 10 and 11 FIG. 6: Fig. 6 
34	A method of forming a device adapted for use with a guide catheter having a lumen, the method comprising: providing a substantially rigid portion; providing a reinforced portion including one or more metallic elements covered with a polymer and a lumen; providing a tip portion including a low durometer polymer or elastomeric material and a lumen continuous with the lumen of the reinforced portion; coupling a distal end of the	Page 6, lines 1-14 Page 12, lines 2-8, 12, and 13 Page 17, lines 15-17 Page 18, lines 11-19 Original claims 3, 4, and 14 FIGS. 1, 3, 4, and 12:

	substantially rigid portion to a proximal end of the reinforced portion; and coupling a distal end of the reinforced portion to a proximal end of the tip portion, wherein providing the substantially rigid portion, the reinforced portion, and the tip portion includes forming a device length such that when a distal end of the tip portion is extended distally of a distal end of the guide catheter, a portion of a proximal end of the substantially rigid portion extends proximally of a proximal end of the guide catheter, and wherein providing one or both of the substantially rigid portion and the reinforced portion includes providing a side opening extending for a distance along a longitudinal axis of the device and accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive an interventional device	   
35	The method of claim 45, wherein providing the substantially rigid portion includes forming or obtaining a hypo tube or metal rail structure	Page 6, lines 15 and 16 Page 12, lines 13 and 14
36	The method of claim 45, wherein providing the side opening includes forming or obtaining an inclined sidewall with a first slope	FIG. 4: 
37	The method of claim 47, wherein providing the side opening includes forming or obtaining an inclined sidewall with a second slope different from the first slope	FIG. 4: 

38	The method of claim 45, wherein providing the side opening includes forming or obtaining, in a proximal to distal direction, a first segment having an arcuate cross-sectional shape, a second segment having a hemicylindrical cross-sectional shape, and a third segment having a full circumference cross-sectional shape	Page 6, lines 16-22 Page 12, lines 14-21 Original claims 9 and 19 FIGS.12-16: 
39	The method of claim 45, wherein providing the reinforced portion includes covering one or more braided metallic elements with the polymer	Page 6, lines 10-12 Page 12, lines 5-8
40	The method of claim 45, wherein providing the reinforced portion including the lumen includes forming or obtaining a reinforced portion including a lumen having an inner diameter that is not more than one French smaller than an inner diameter of the lumen of the guide catheter	Page 5, lines 8-18 Original claims 8 and 18
41	The method of claim 45, wherein providing the substantially rigid portion, the reinforced portion, and the tip portion includes, starting at a distal end of the tip portion and moving proximally toward a proximal end of the substantially rigid portion, forming or obtaining at least a first structure having a first flexural modulus, a second structure having a second flexural modulus greater than the first flexural modulus, and a third structure	Page 13, line 15 – page 14, line 8

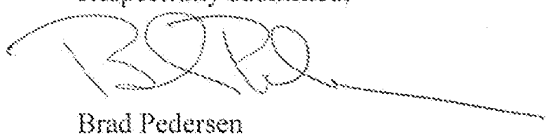
	having a third flexural modulus greater than the second flexural modulus	
42	The method of claim 52, wherein forming or obtaining the first structure having the first flexural modulus includes forming a structure having a flexural modulus of about 13,000 PSI plus or minus 5,000 PSI, wherein forming or obtaining the second structure having the second flexural modulus includes forming a structure having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, and wherein forming or obtaining the third structure having the third flexural modulus includes forming a structure having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI	Page 13, line 15 – page 14, line 8
43	The method of claim 45, wherein providing one or both of the reinforced portion and the tip portion includes lining a lumen thereof with polytetrafluoroethylene	Page 6, lines 5-14 Page 12, lines 2, 3, 7, and 8 Page 19, line 1
44	The method of claim 45, wherein providing the tip portion includes covering a marker with the low durometer polymer or elastomeric material	Page 5, lines 20-22 Page 6, lines 5-9 Page 11, line 18 Page 12, lines 1-4 Page 18, lines 14 and 15

Conclusion

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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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Howard Root et al.	Examiner:	Unkonwn
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	Herewith	Docket:	2005.86USREI3
Title:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		

OFFER TO SURRENDER ORIGINAL PATENT

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

In accordance with the requirement of 37 C.F.R. § 1.178, Assignee hereby offers to surrender the original patent, U.S. Patent No. 8,292,850, which issued on Oct. 23, 2012 to Howard Root et al. and is titled "COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES." If the original patent is lost or inaccessible, an affidavit to such effect will be supplied before allowance of the above-identified reissue application.

Respectfully submitted,

Date: Nov. 1, 2013

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Please charge any fee due to Deposit Account No. 16-0631.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Howard Root et al.	Examiner: Unkonwn	
Serial No.:	Unknown	Group Art Unit: Unknown	
Filed:	Herewith	Docket: 2005.86USRI3	
Customer No.:	24113	Confirmation No.: Unknown	
Reissue of U.S. Patent No. 8,292,850		Issue Date: Oct. 23, 2012	
Title:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		

CONSENT BY ASSIGNEE OF ENTIRE OWNERSHIP INTEREST TO FILE REISSUE APPLICATION OF U.S. PATENT NO. 8,292,850 PURSUANT TO 37 C.F.R. § 1.172

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

I, Howard Root, declare that:

1. I am Chief Executive Officer of Vascular Solutions, Inc.

2. I state that Vascular Solutions, Inc. is the assignee of the entire right, title and interest in and to U.S. Patent No. 8,292,850, which issued on Oct. 23, 2012 and is titled "COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES."

3. I state that Vascular Solutions, Inc. received assignment of all right, title and interest according to the title transfer from the inventors, Gregg Sutton, Jeffrey Welch, Jason Garrity and me, which is recorded at reel and frame numbers 027973/0984 and 027729/0760 of the Patent Assignment, Abstract of Title recordation department of the U.S. Patent and Trademark Office.

4. As Chief Executive Officer of Vascular Solutions, Inc., I have caused the company to request herewith a broadening reissue of U.S. Patent No. 8,292,850.

5. Pursuant to 37 C.F.R. § 1.172 and as the assignee of all right, title and interest in and to U.S. Patent No. 8,292,850, I state on behalf of Vascular Solutions, Inc. that the company consents to the filing of this reissue application of U.S. patent No. 8,292,850 and to the enlargement of the claimed subject matter as presented by the preliminary amendment filed herewith.

6. I 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. The 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 this application or any patent issuing thereon.

7. Further Declarant sayeth not.

Date Oct. 25, 2013

By _____
Howard Root
Chief Executive Officer
Vascular Solutions, Inc.

US008292850B2

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

(10) **Patent No.: US 8,292,850 B2**
(45) **Date of Patent: Oct. 23, 2012**

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

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

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

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

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

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

(65) **Prior Publication Data**

US 2012/0165756 A1 Jun. 28, 2012

Related U.S. Application Data

(62) Division of application No. 12/824,734, filed on Jun. 28, 2010, now Pat. No. 8,142,413, which is a division of application No. 11/416,629, filed on May 3, 2006, now Pat. No. 8,048,032.

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

(52) **U.S. Cl.** **604/164.01**; 604/525

(58) **Field of Classification Search** 604/103.04, 604/103.09, 160–162, 164.01, 164.02, 164.09–164.11, 604/525

See application file for complete search history.

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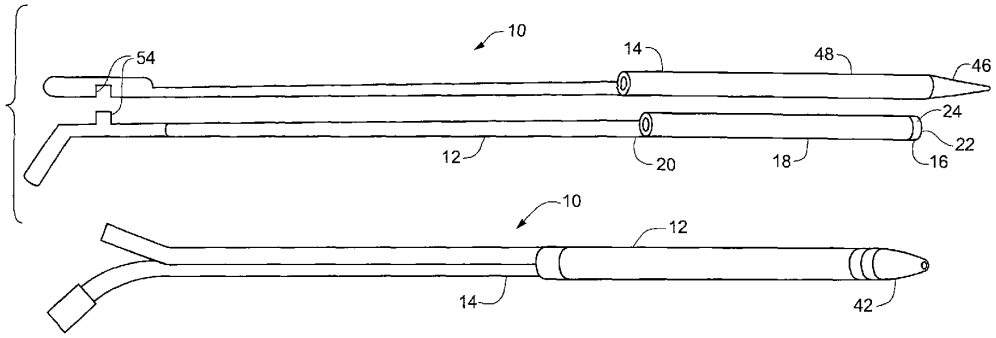
Primary Examiner — Kevin C Sirmons
Assistant Examiner — Bradley Osinski
(74) *Attorney, Agent, or Firm* — Patterson Thuente Christensen Pedersen, P.A.

(57) **ABSTRACT**

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

24 Claims, 13 Drawing Sheets



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U.S. Appl. No. 11/416,629, filed Jun. 28, 2010; Howard Root et al.
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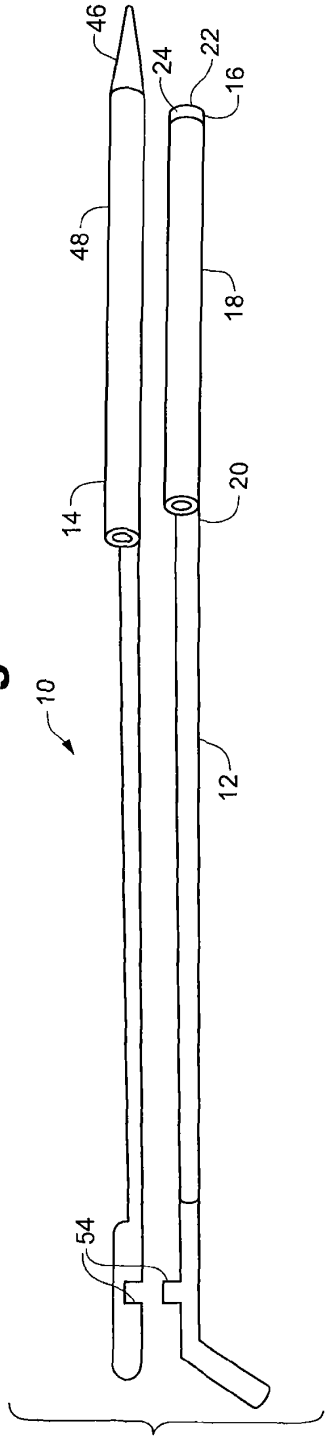


Fig. 1

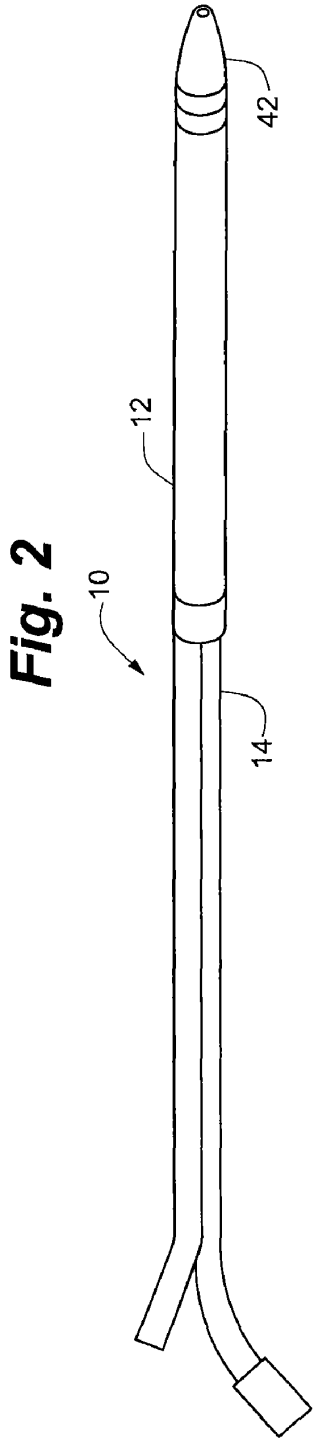


Fig. 2

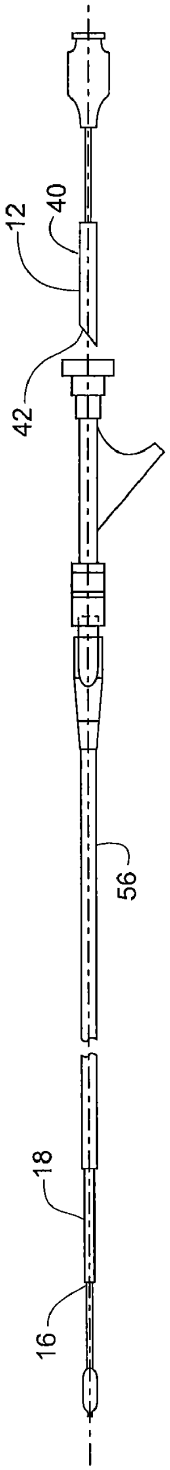


Fig. 3

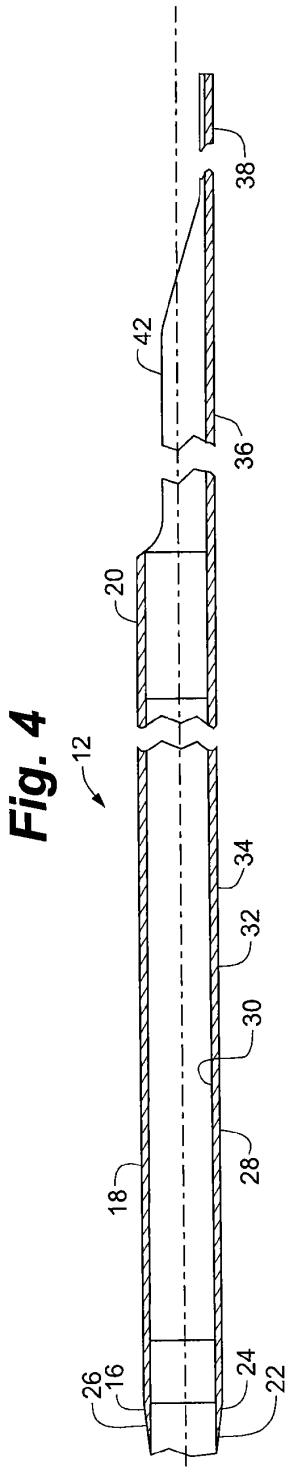


Fig. 4

Fig. 5

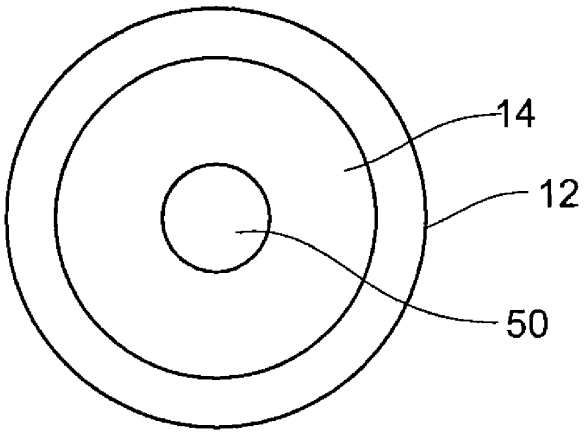
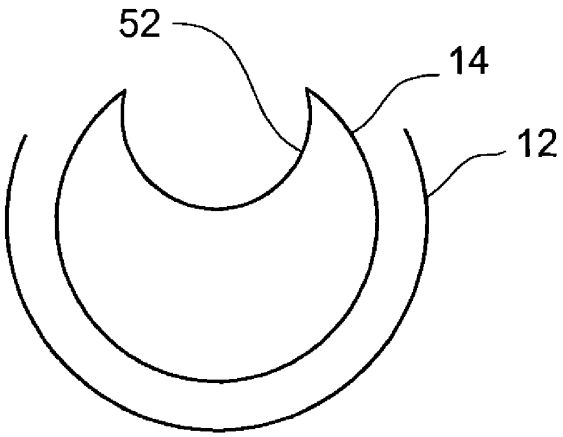


Fig. 6



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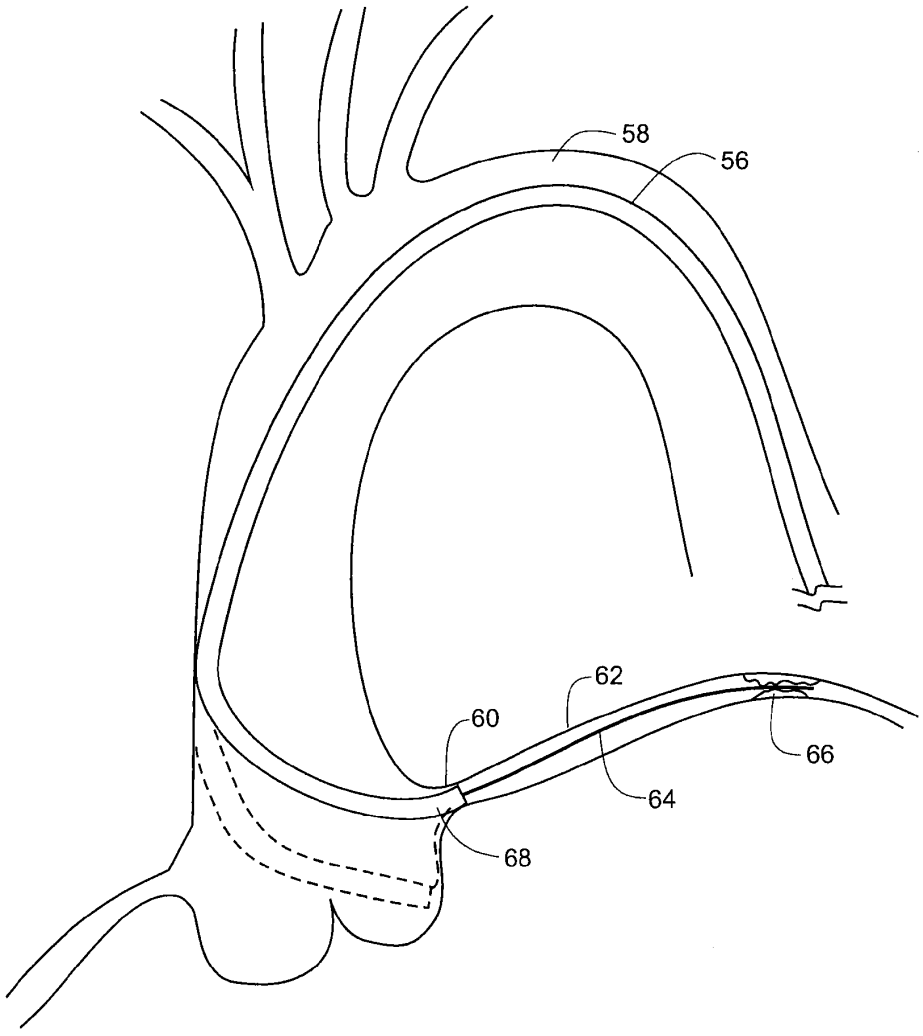


Fig. 8

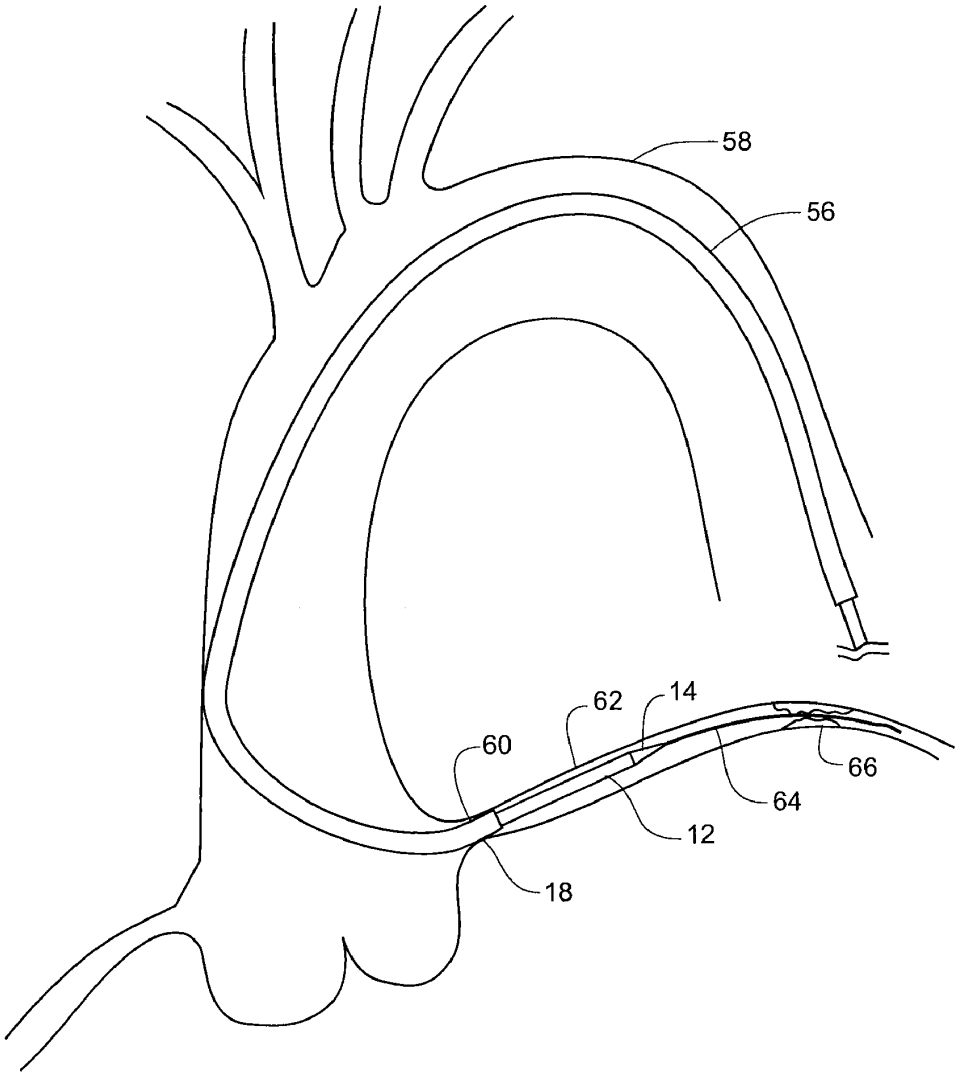
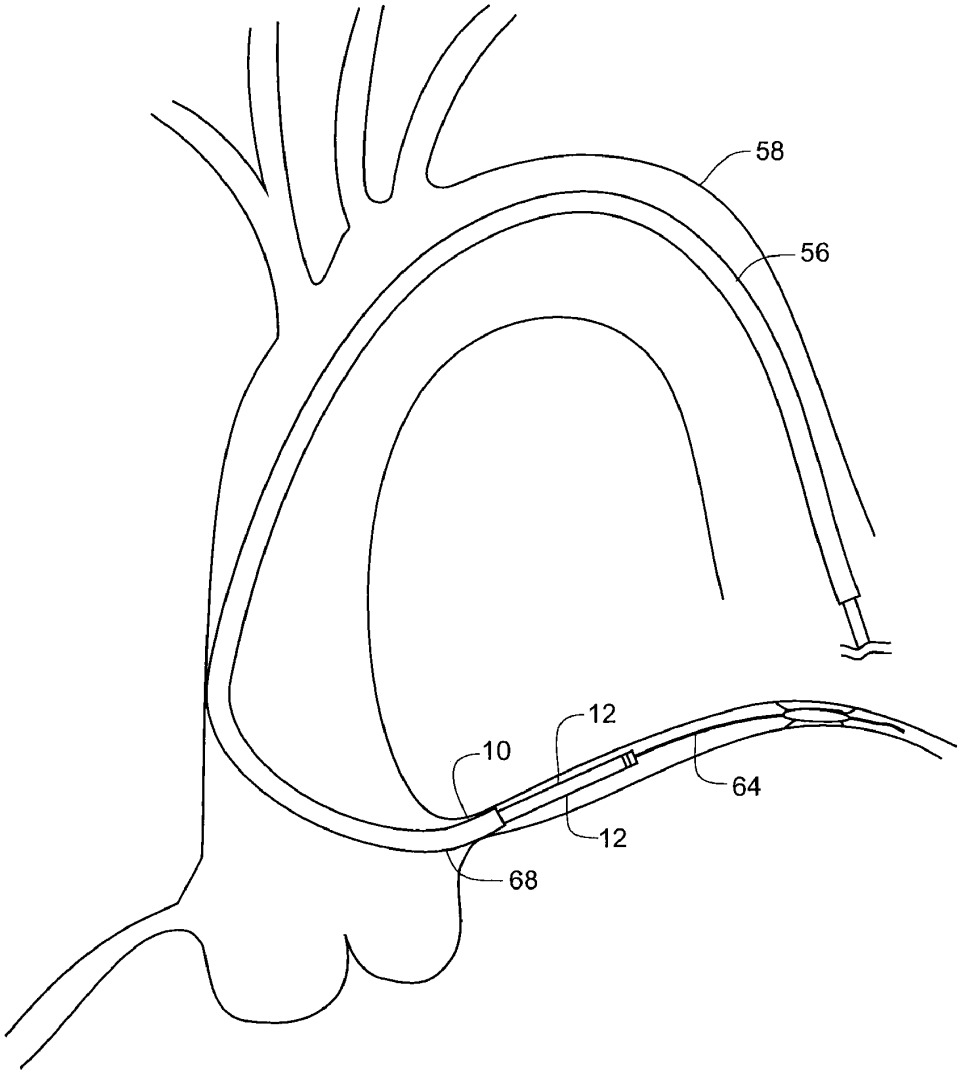


Fig. 9



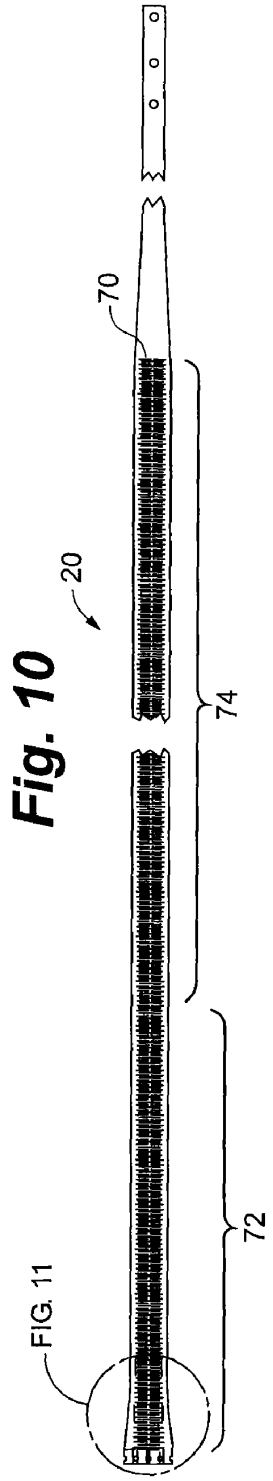


Fig. 10

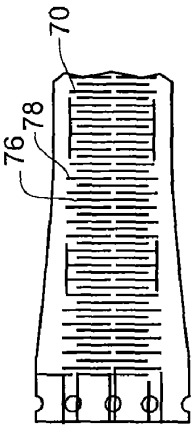


Fig. 11

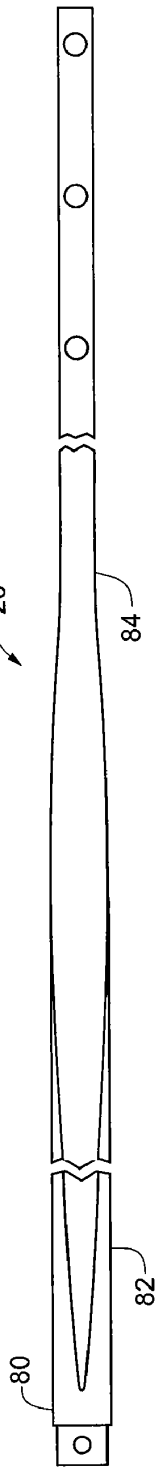


Fig. 12

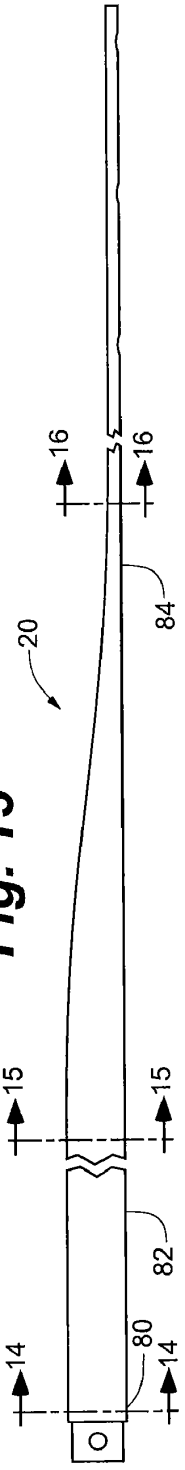


Fig. 13

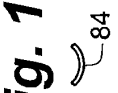


Fig. 16

Fig. 15

Fig. 14

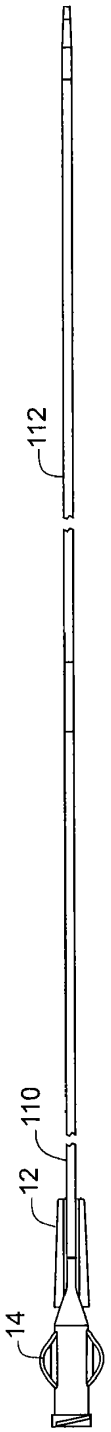


Fig. 17

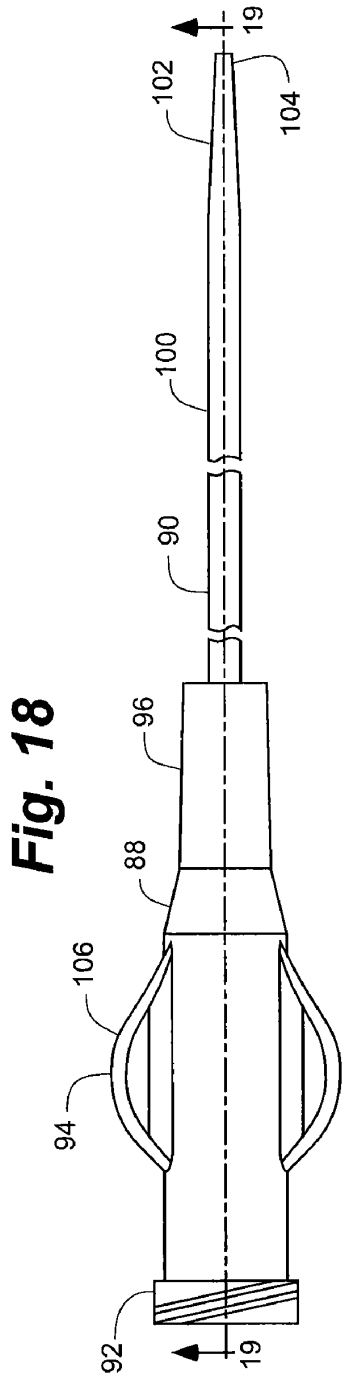
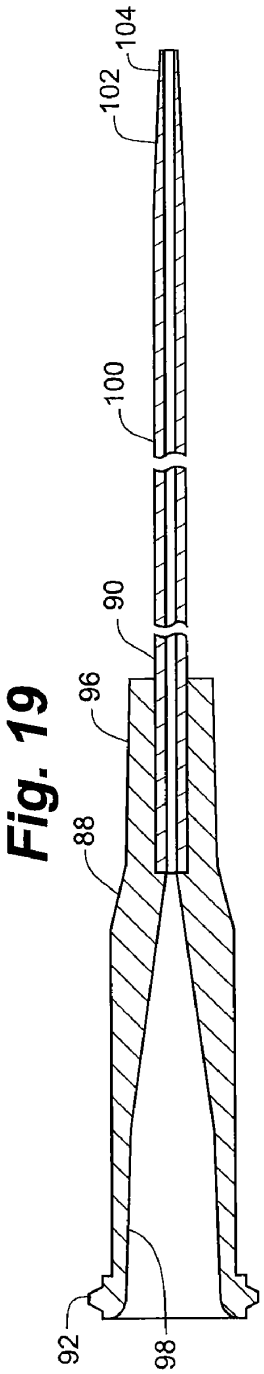


Fig. 18



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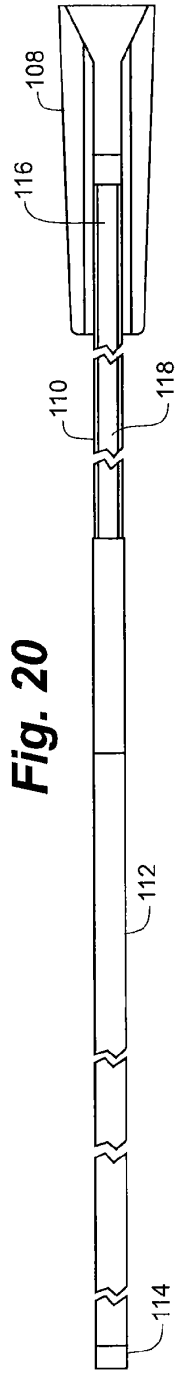


Fig. 20

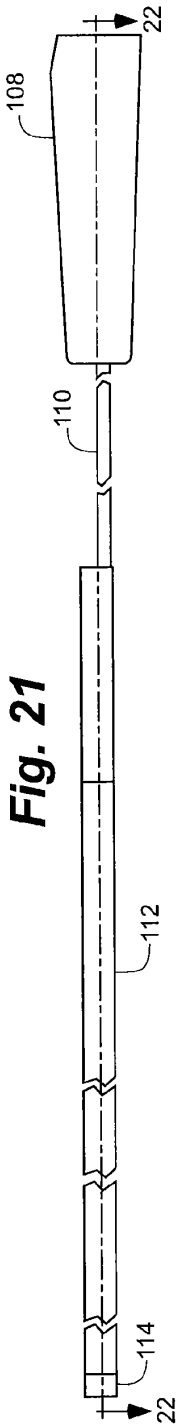


Fig. 21

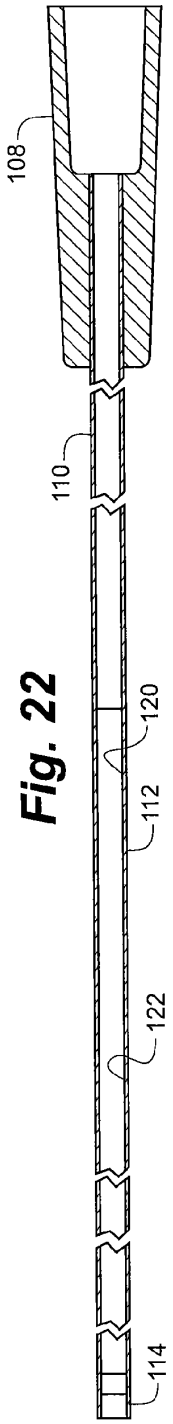


Fig. 22

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

RELATED APPLICATIONS

This application is a divisional of application Ser. No. 12/824,734, filed Jun. 28, 2010 now U.S. Pat. No. 8,142,413 entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures", which is divisional of application Ser. No. 11/416,629, filed May 3, 2006 now U.S. Pat. No. 8,048,032 entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures".

FIELD OF THE INVENTION

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

BACKGROUND OF THE INVENTION

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

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

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

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

Second are guiding catheters that include a retractable appendage. The appendage in these catheters can be extended to engage the opposing wall of the aortic arch to provide backup support or the appendage may be placed under tension to stiffen a bend in the catheter to provide backup support. Examples of this approach may be found in U.S. Pat. No. 4,813,930 issued to Elliot; U.S. Pat. No. 5,098,412 issued to Shiu; and U.S. Pat. No. 6,860,876 issued to Chen. These guiding catheters tend to be somewhat mechanically complex and have not been widely adopted by practitioners.

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

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

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

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

SUMMARY OF THE INVENTION

The present invention is a coaxial guide catheter that is deliverable through standard guide catheters by utilizing a guidewire rail segment to permit delivery without blocking 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 act 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 DRAWINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Referring to FIG. **16**, another embodiment of coaxial guide catheter assembly **10** includes coaxial guide catheter **12** and

tapered inner catheter **14**. Tapered inner catheter **14** is keyed to coaxial guide catheter **12** at hub **86**.

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

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

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

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

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

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

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

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

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

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

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

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

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

One advantage of the present invention over prior art approaches is that the present invention does not interfere with 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.

The invention claimed is:

1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

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

a device adapted for use with the guide catheter, including:

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

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

the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. The system of claim **2**, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

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

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

6. The system of claim **5**, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

7. The system of claim **2**, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

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

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

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

11. The system of claim **1**, further comprising a kit that includes the guide catheter and the device in a common sterile package.

12. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the 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 continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

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

structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion 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, connected to, and more rigid along a longitudinal axis rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

13. The system of claim **12**, 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.

14. The system of claim **12**, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

15. The system of claim **12**, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents 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.

16. The system of claim **12**, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

17. The system of claim **12**, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.

18. The system of claim **12**, 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.

19. The system of claim **12**, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

20. The system of claim **12**, 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.

21. The system of claim **20**, 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.

22. The system of claim **20**, 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.

23. The system of claim **12**, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

24. The system of claim **12**, further comprising a kit that includes the guide catheter and the device in a common sterile package.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,292,850 B2
APPLICATION NO. : 13/359059
DATED : October 23, 2012
INVENTOR(S) : Howard Root et al.

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

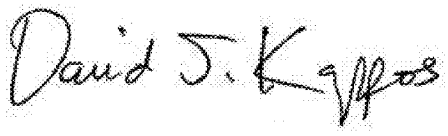
In Column 10, claim 1, line 46, prior to "structure", insert
-- a flexible tip portion defining a tubular --

In Column 10, claim 1, line 57, delete "rain a" and insert -- than the flexible tip portion and defining a rail" --

In Column 11, claim 12, line 64, prior to "structure", insert
-- a flexible tip portion defining a tubular --

In Column 12, claim 12, lines 11-12, prior to "structure", insert
-- than the flexible tip portion and defining a --

Signed and Sealed this
Twenty-second Day of January, 2013



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

Electronic Acknowledgement Receipt	
EFS ID:	17296438
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Ann Pommier
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86USREI3
Receipt Date:	01-NOV-2013
Filing Date:	
Time Stamp:	17:30:14
Application Type:	Reissue (Utility)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Reissue Application	2005_86USREI3_TRANS.pdf	362078 ab7e61076ca9fde8563710364555ce930f008b1b	no	2

Warnings:
Information:

2		2005_86USREI3_PREAMD.pdf	1779913 1b5755205755536d7aa1751565eabff676c3a9ff	yes	22
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Preliminary Amendment		1	2	
	Claims		3	14	
	Applicant Arguments/Remarks Made in an Amendment		15	22	
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	2005_86USREI3_OFFER.pdf	230735 756c56823324eb4c0fe794b14d58ef8f5679ad24	no	1
Warnings:					
Information:					
4	Consent of Assignee accompanying the declaration	2005_86USREI3_CONSENT.pdf	86921 366f0983abf8d12d8f85ee30b83705e40d5d2be0	no	2
Warnings:					
Information:					
5	Miscellaneous Incoming Letter	2005_86USREI3_PATENT.pdf	197948 b50dc38c7ee23b4c00494b0ed8893b38c69e55db	no	23
Warnings:					
Information:					
		Total Files Size (in bytes):	2657595		

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

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

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. 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 14/070,161	Filing Date 11/01/2013	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	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 $310 ($155 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	

APPLICATION AS AMENDED – PART II

AMENDMENT	11/01/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 44	Minus	** 44	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

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

LIE
/CORALIA BETANCOURT/

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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UNITED STATES DEPARTMENT OF COMMERCE
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/070,161	11/01/2013	3767	0.00	2005.86USREI3	44	4

CONFIRMATION NO. 8790

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

FILING RECEIPT

Date Mailed: 11/19/2013

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

Inventor(s)

Howard Root, Residence Not Provided;

Applicant(s)

Howard Root, Residence Not Provided;

Assignment For Published Patent Application

VASCULAR SOLCUTIONS INC.

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

Domestic Applications for which benefit is claimed - None.
A proper domestic benefit claim must be provided in an Application Data Sheet in order to constitute a claim for domestic benefit. See 37 CFR 1.76 and 1.78.

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 11/18/2013

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/070,161**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

Title

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

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

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

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

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

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/070,161

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	280
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	600
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	2160
TOTAL CLAIMS (37 CFR 1.16(i))	44 minus 20 =	* 24			OR	x 80 =	1920
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1				x 420 =	420
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	5380

APPLICATION AS AMENDED - PART II

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
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))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
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))									
	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 found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/070,161	11/01/2013	Howard Root	2005.86USREI3

CONFIRMATION NO. 8790

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

FORMALITIES LETTER

OC000000065066273

Date Mailed: 11/19/2013

NOTICE TO FILE MISSING PARTS OF REISSUE APPLICATION

Filing Date Granted

An application number and filing date have been accorded to this reissue 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 $**280** to complete the basic filing fee for an undiscounted entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27) or make a certification of entitlement to micro entity status and pay the micro entity filing fee (37 CFR 1.29).*
- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  APPLICATION DATA SHEET (ADS) AND OATH OR DECLARATION IS MISSING.
  The inventor's oath or declaration is informal for the reasons stated in the present notice.
- Assignee's statement under 37 CFR 3.73(c) establishing ownership of the patent is missing. 37 CFR 1.172 requires that all assignees consenting to the reissue application establish their ownership interest in the patent by filing in the reissue application a statement in accordance with 37 CFR 3.73(c).

  An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 (and 37 CFR 1.175) executed by or with respect to each inventor is required. For a reissue application, the inventor's oath or declaration must be submitted prior to examination and cannot be postponed. See 37 CFR 1.175(e). An assignee of the entire interest can execute the oath or declaration if: (1) the application does not seek to enlarge the scope of the claims of the original patent; or (2) the application for the original patent was filed under 37 CFR 1.46 by the assignee of the entire interest. A substitute statement under 37 CFR 1.64 in lieu of an oath or declaration may be submitted in the circumstances provided for in 35 U.S.C. 115(d) and 37 CFR 1.64.

The applicant needs to satisfy supplemental fees problems indicated below.

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

- Additional claim fees of $ **2340** as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- A surcharge (for late submission of the basic filing fee, search fee, examination fee or inventor's oath or declaration) as set forth in 37 CFR 1.16(f) of $ **140** for an undiscounted entity, must be submitted.

SUMMARY OF FEES DUE:

Total fee(s) required within **TWO MONTHS** from the date of this Notice is $ **5520** for an undiscounted entity

- $ **280** Statutory basic filing fee.
- $ **140** Surcharge.
- The application search fee has not been paid. Applicant must submit $ **600** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit $ **2160** to complete the examination fee for an undiscounted entity.
- Total additional claim fee(s) for this application is $ **2340**
  - $ **420** for **1** independent claims over the original patent.
  - $ **1920** for **24** total claims over the higher of 20, or the amount in the original patent.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

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

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/meday/

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

REISSUE PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI3

Howard Root et al. Confirmation No.: 8790

Application No.: 14/070,161 Group Art Unit: 3767

Filed: November 1, 2013 Examiner: Unassigned

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Reissue of U.S. Patent No.: 8,292,850

Issued: October 23, 2012

RESPONSE TO NOTICE TO FILE MISSING PARTS OF REISSUE APPLICATION

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

Commissioner:

In response to the Notice to File Missing Parts of Application - Filing Date Granted mailed November 19, 2013, submitted herewith are an executed Reissue Application Declaration by The Assignee, Reissue Application Declaration by the Inventors, Power of Attorney, Application Data Sheet, and Statement Under 37 C.F.R. 3.73(b).

The filing fee has been calculated as shown below:						
Application as Filed - Part 1						
	(1) Claims in Patent	(2) Claims Filed in Reissue Application	(3) Number Extra	Small Entity Rate	OR	Large Entity Rate
Basic Filing Fee				$140	OR	$280
Reissue Search Fee				$300	OR	$600
Reissue Examination Fee				$1,080	OR	$2,160
Total Claims	(A)24	(B)44	= 24	x 40 = $960	OR	x 80 = $
Independent Claims	(C)2	(D)4	= 1	x 210 = $210	OR	x 420 = $
Presence of Multiple Dependent Claim				+ 390	OR	+ 780

Surcharge - Late filing fee or oath or declaration	+ 70	OR	+ 140
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:	x 200 = $	OR	x 400 = $
TOTAL	**$2760.00**	OR	$
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets			

Application as Amended - Part 2						
	(1) Claims Remaining After Amendment	(2) Highest Number Previously Paid For	(3) Extra Claims Present	Small Entity Rate	OR	Large Entity Rate
Total Claims		minus	=	x 40 = $	OR	x 80 = $
Independent Claims		minus	=	x 210 = $	OR	x 420 = $
Presence of Multiple Dependent Claim				+ 390	OR	+ 780
Reissue Application Size Fee - each additional 50 sheets that exceeds 100 sheets:				x 200 = $	OR	x 400 = $
			TOTAL	$	OR	$
If the difference is less than zero, enter "0". Total # of sheets = (Spec and Abst pgs)+Dwg Sheets						

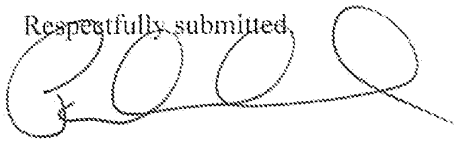
*If (D) is less than (C), enter "0" in column 3. For reissues filed on or after Dec. 8, 2004, enter (D) minus 3 or "0" if (D) is less than 3.
**If the "Highest Number of Total Claims Previously Paid For" is less than 20, enter "20" in this space.
***After any cancellation of claims.
****If (A) is greater than 20, enter (B) - (A); if (A) is 20 or less, enter (B) - 20. For reissues filed on or after Dec. 8, 2004 enter (B) - 20.
*****For amendments filed on or after Dec. 8, 2004, enter the "Highest Number of Independent Claims Previously Paid For."
For amendments filed prior to Dec. 8, 2004, enter the higher of the Number Previously Paid or Number of Independent Claims in Patent.

Applicants are entitled to small entity status in accordance with 37 CFR 1.27. Electronic payment is submitted by credit card 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. 45354

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

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

Doc Code: REIS.DECL
Document Description: Reissue Declaration Filed In Accordance With MPEP 1414

PTO/AIA/06 (06-12)
Approved for use through 08/31/2013. OMB 0651-0033
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.

REISSUE APPLICATION DECLARATION BY THE ASSIGNEE	Docket Number (optional) 2005.86USREI3

I hereby declare that:

The residence and mailing address of the inventor or joint inventors are stated below.

I am authorized to act on behalf of the following assignee: Vascular Solutions, Inc.

The entire title to the patent identified below is vested in said assignee.

Inventor Howard Root

Residence: City	State	Country
Tonka Bay	MN	US

Mailing Address
25 Fairhope Avenue

City	State	Zip	Country
Tonka Bay	MN	55331	US

☑ Additional Inventors are named on separately numbered sheets attached hereto.

Patent Number 8,292,850 B2	Date of Patent Issued October 23, 2012

I believe said inventor(s) to be the original inventor or original joint inventors of the subject matter which is described and claimed in said patent, for which a reissue patent is sought on the invention titled:

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

the specification of which

☐ is attached hereto.

☑ was filed on November 1, 2013 as reissue application number 14/070161.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below.
(Check all boxes that apply.)

☐ by reason of a defective specification or drawing.

☑ by reason of the patentee claiming more or less than he had the right to claim in the patent.

☐ by reason of other errors.

PTO/AIA/06 (06-12)
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REISSUE APPLICATION DECLARATION BY THE ASSIGNEE	Docket Number (Optional) 2005.86USR

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, a claim that the application seeks to broaden must be identified and the box below must be checked:

SEE ATTACHED

[Attach additional sheets, if needed.]

☑ **The application for the original patent was filed under 37 CFR 1.46 by the assignee of the entire interest.**

I hereby appoint:

☑ Practitioners associated with Customer Number: 24113

OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Correspondence Address: Direct all communications about the application to:

☑ The address associated with Customer Number: 24113

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature	Date (Optional) 12/9/13
Full name of person signing (given name, family name)	RICHARD ROOT, VICE PRESIDENT
Address of Assignee	6464 Sycamore Court North, Minneapolis, MN 55369

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI3

Howard Root et al. Confirmation No.: 8790

Application No.: 14/070,161 Examiner: Unassigned

Filed: November 1, 2013 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

ATTACHMENT TO REISSUE APPLICATION DECLARATION BY ASSIGNEE

ERROR STATEMENT

The issued independent claims of the patent claim less than patentee had a right to claim. Accordingly, patentee seeks to broaden the claims by reissue. Patented independent claim 1 is directed to a system including a guide catheter and a device for use with the guide catheter. Neither independent claim 1 nor independent claim 12 recites means plus function limitations for the device or a method of manufacture of the device.

Privacy Act Statement

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Doc Code: REIS.DECL
Document Description: Reissue Declaration Filed In Accordance With MPEP 1414

PTO/AIA/05 (06-12)
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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.

REISSUE APPLICATION DECLARATION BY THE INVENTOR	Docket Number (Optional) 2005.86USREI3

I hereby declare that:
Each inventor's residence and mailing address are stated below next to their name.
I believe I am the original inventor or an original joint inventor of the subject matter which is described and claimed in patent number 8,292,850 B2, granted October 23, 2012 and for which a reissue patent is sought on the invention titled COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES,

the specification of which

☐ is attached hereto.

☑ was filed on November 1, 2013 as reissue application number 14/070161.

The above-identified application was made or authorized to be made by me.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

I believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below. (Check all boxes that apply.)

☐ by reason of a defective specification or drawing.

☑ by reason of the patentee claiming more or less than he had the right to claim in the patent.

☐ by reason of other errors.

At least one error upon which reissue is based is described below. If the reissue is a broadening reissue, a claim that the application seeks to broaden must be identified:

This is a broadening reissue and a claim that the application seeks to broaden is identified.

The issued independent claims of the patent claim less than patentee had a right to claim. Accordingly, patentee seeks to broaden the claims by reissue. Patented independent claim 1 is directed to a system including a guide catheter and a device for use with the guide catheter. Neither independent claim 1 nor independent claim 12 recites means plus function limitations for the device or a method of manufacture of the device.

PTO/AIA/05 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(REISSUE APPLICATION DECLARATION BY THE INVENTOR, page 2)

Docket Number (Optional): 2005-86USREI3

Note: To appoint a power of attorney, use form PTO/AIA/81.

Correspondence Address: Direct all communications about the application to:

☑ The address associated with Customer Number: 24113

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Legal name of sole or first inventor (*E.g.*, Given Name (first and middle (if any) and Family Name or Surname)

Howard Root

Inventor's Signature		Date (Optional) 12/9/13	
Residence: City Tonka Bay	State MN	Country US	
Mailing Address 25 Fairhope Avenue			
City Tonka Bay	State MN	Zip 55331	Country US

|■| Additional joint inventors are named on the 1 supplemental sheet(s) PTO/AIA/10 attached hereto.

PTO/AIA/10 (06-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

SUPPLEMENTAL SHEET FOR DECLARATION | **ADDITIONAL INVENTOR(S)**
Supplemental Sheet (for PTO/AIA/08,09)
Page ____ of ____

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Gregg Sutton

Inventor's Signature | Date (Optional) 1/9/14

Residence: City: Plymouth | State: MN | Country: US

Mailing Address: 18400 31st Avenue North

City: Plymouth | State: MN | Zip: 55447 | Country: US

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Jeffrey M. Welch

Inventor's Signature | Date (Optional) 1/9/14

Residence: City: Maple Grove | State: MN | Country: US

Mailing Address: 8723 Cornstock Lane North

City: Maple Grove | State: MN | Zip: 55311 | Country: US

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Jason M. Garrity

Inventor's Signature | Date (Optional)

Residence: City: St. Louis Park | State: MN | Country: US

Mailing Address: 3056 Jersey Avenue

City: St. Louis Park | State: MN | Zip: 55426 | Country: US

PTO/AIA/10 (08-12)
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SUPPLEMENTAL SHEET FOR DECLARATION | **ADDITIONAL INVENTOR(S)** Supplemental Sheet (for PTO/AIA/08,09) Page ____ of ____

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Gregg Sutton

Inventor's Signature | Date (Optional)

Residence: City: Maple Grove | State: MN | Country: US

Mailing Address: 16917 73rd Place North

City: Maple Grove | State: MN | Zip: 55311 | Country: US

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Jeffrey M. Welch

Inventor's Signature | Date (Optional)

Residence: City: Maple Grove | State: MN | Country: US

Mailing Address: 8723 Cornstock Lane North

City: Maple Grove | State: MN | Zip: 55311 | Country: US

Legal Name of Additional Joint Inventor, if any:

(*E.g.*, Given Name (first and middle (if any)) and Family Name or Surname)

Jason M. Garrity

Inventor's Signature | Date (Optional)

Residence: City: ~~St. Louis Park~~ Lima | State: ~~MN~~ NY | Country: US

Mailing Address: ~~3056 Jersey Avenue~~ 2838 Livonia Center Rd

City: ~~St. Louis Park~~ Lima | State: ~~MN~~ NY | Zip: ~~55426~~ 14485 | Country: US

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	7	Attorney Docket Number	2005.86USREI3

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-8,292,850 B2	10-23-2012	Root et al.
		US-8,142,413 B2	03-27-2012	Root et al.
		US-8,048,032 B2	11-01-2011	Root et al.
		US-7,762,984 B2	07-27-2010	Kumoyama et al.
		US-7,717,899 B2	05-18-2010	Bowe et al.
		US-7,697,996 B2	04-13-2010	Manning et al.
		US-7,544,201 B2	06-09-2009	Pepper
		US-7,294,124 B2	11-13-2007	Eidenschink
		US-6,860,876	03-01-2005	Chen
		US-6,755,812	06-29-2004	Peterson et al.
		US-6,706,018	03-16-2004	Westlund et al.
		US-6,689,144	02-10-2004	Gerberding
		US-6,638,268 B2	10-28-2003	Niazi
		US-6,635,029 B1	10-21-2003	Venturelli
		US-6,610,068	08-26-2003	Yang

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]
		EP 0365993	05-02-1990	Terumo Kabushiki Kaisha	
		EP 0313558 (Published as US 5,002,531, also cited)	01-14-1988	BONZEL, Tassilo	
		EP 0380873	08-08-1990	C.R. Bard, Inc.	
		WO84/03633	09-27-1984	FOGARTY, Thomas J.	

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	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	2	of	7	Attorney Docket Number	2005.86USREI3

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-6,595,952	07-22-2003	Forsberg
		US-6,591,472 B1	07-15-2003	Noone et al.
		US-6,575,958 B1	06-10-2003	Happ et al.
		US-6,548,010 B1	04-15-2003	Stivland et al.
		US-6,503,353 B1	01-07-2003	Peterson et al.
		US-6,503,223 B1	01-07-2003	Sekido et al.
		US-6,488,655 B1	12-03-2002	Wantink et al.
		US-6,475,195	11-05-2002	Voda
		US-6,409,863 B1	06-25-2002	Williams et al.
		US-6,338,725	01-15-2002	Hermann et al.
		US-6,193,686 B1	02-27-2001	Estrada et al.
		US-6,159,195	12-12-3000	Ha et al.
		US-5,980,486	11-09-1999	Enger
		US-5,911,715	06-15-1999	Berg et al.
		US-5,792,124	08-11-1998	Horrigan et al.

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	

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[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.

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Substitute for form 1449/PTO				Complete if Known	
				Application Number	14/070,161
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	November 1, 2013
(Use as many sheets as necessary)				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	3	of	7	Attorney Docket Number	2005.86USREI3

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-5,690,613	11-25-1997	Verbeek
		US-5,658,263	08-19-1997	Dang et al.
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		US-5,527,292	06-18-1996	Adams et al.
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		US-5,257,974	11-02-1993	Cox
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		US-5,122,125	06-16-1992	Deuss

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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]

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[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.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	4	of	7	Attorney Docket Number	2005.86USREI3

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-5,102,403	04-07-1992	Alt
		US-5,098,412	03-24-1992	Shiu
		US-5,002,531	03-26-1991	Bonzel
		US-4,994,745	02-19-1991	Mizuta
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		US-4,932,413	06-12-1990	Shockey et al.
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		US-2007/0260219	11-08-2007	Root et al.
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FOREIGN PATENT DOCUMENTS

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				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	5	of	7	Attorney Docket Number	2005.86USREI3

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-2004/0127927	07-01-2004	Adams
		US-2003/0195546	10-16-2003	Solar et al.
		US-		
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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]

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				Art Unit	3767
				Examiner Name	Unassigned
Sheet	6	of	7	Attorney Docket Number	2005.86USREI3

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]
		Saeko TAKAHASHI, et al., "New Method to Increase a Backup Support Of A 6 French Guiding Coronary Catheter", *Catheterization and Cardiovascular Interventions*, 63:452-456 (2004), 5 Pages; Published online in *Wiley InterScience* (www.interscience.wiley.com),	
		Complaint, Jury Trial Demanded, Dated May 15, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 18 Pgs.	
		Amended Complaint, Jury Trial Demanded, Dated May 28, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 20 Pgs.	
		Plaintiff's Memorandum in Support of Motion for Preliminary Injunction, dated June 10, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 40 Pgs.	
		Declaration of Howard Root in Support of Plaintiff's Motion for Preliminary Injunction, Dated June 10, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 55 Pgs.	
		Declaration of Anthony C. Vrba, Dated July 8, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 4 Pgs.	
		Declaration of Tony J. Demartini, M.D., Dated July 8, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 3 Pgs.	
		Placeholder for Declaration of Sam Rasmusen, Dated July 8, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 1 Pg.	
		Boston Scientific Corporation's Answer to Amended Complaint and Counterclaims, Dated July 11, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 22 Pgs.	

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				Examiner Name	Unassigned
Sheet	7	of	7	Attorney Docket Number	2005.86USREI3

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		Plaintiff's Reply Memorandum in Suport of Motion for Preliminary Injunction ***REDACTED***, Filed July 24, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 27 Pgs.	
		Second Declaration of Howard Root in Support of Plaintiff's Motion for Preliminary Injunction, Dated July 24, 2013, Filed in District Court Case 0:13-cv-01172 (JRT-SER), Vascular Solutions, Inc., v. Boston Scientific Corporation, 22 Pgs.	

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Electronic Patent Application Fee Transmittal

Application Number:	14070161
Filing Date:	01-Nov-2013
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Paul C. Onderick/Mary Granger
Attorney Docket Number:	2005.86USREI3

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility Reissue Basic	2014	1	140	140
Design and utility Reissue Basic	2114	1	300	300
Design and utility Reissue Basic	2314	1	1080	1080
Pages:				
Claims:				
Reissue claims in Excess of 20 for Small	2205	24	40	960
Independent Claims Reissue-Small	2204	1	210	210
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Late Filing Fee for Oath or Declaration	2051	1	70	70
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2760**

Electronic Acknowledgement Receipt	
EFS ID:	17976443
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	21-JAN-2014
Filing Date:	01-NOV-2013
Time Stamp:	17:10:01
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2760
RAM confirmation Number	3591
Deposit Account	160631
Authorized User	ONDERICK, PAUL C
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	MissParts_Transmittal.pdf	228503 58a5e071f2edf422c5318abec134afcf58a67dc3	no	3
Warnings:					
Information:					
2	Oath or Declaration filed	AssigneeDeclaration.pdf	284517 635be65c3ba30f08c6234456cfd568f682e8f693	no	4
Warnings:					
Information:					
3	Oath or Declaration filed	InventorDeclaration.pdf	570672 4636a54349761fd011ef6c43e5f2710c91f6cee2	no	4
Warnings:					
Information:					
4	Power of Attorney	POA.pdf	504575 c41b23434504f262b3de96c1cb7dd0c54e80a38f	no	2
Warnings:					
Information:					
5	Assignee showing of ownership per 37 CFR 3.73.	CertUnder3_73c.pdf	62229 95cbeba9d01fa678d0845d001362c786f8c91b99	no	2
Warnings:					
Information:					
6	Application Data Sheet	ADS.pdf	1561702 66a21654ea5b69d1f01a0d0345916b975048671e	no	8
Warnings:					
Information:					
7	Foreign Reference	FR1_EP0365993A1.pdf	3273767 a8e27341a31945833c0fb7c7c23a8a7c723b1587	no	48
Warnings:					
Information:					
8	Foreign Reference	FR2_EP0313558.pdf	1762759 7923649a6bbf652af608a0ba622aabccade3cebe	no	25
Warnings:					

Information:					
9	Foreign Reference	FR3_EP0380873A2.pdf	734676 f6bc2fc68cf589e36c1e503e344463a713c64cc7	no	11
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Information:					
10	Foreign Reference	FR4_WO8403633A1.pdf	679124 39962068b121ba9bd07e9ea43d40050118302 62c	no	15
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11	Non Patent Literature	NPL1_Takahashi_EtAl_Article.pdf	597781 a4ed320a5a1051c69c5c7f632a91807085b0a932	no	5
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Information:					
12	Non Patent Literature	NPL2_Complaint.pdf	1001863 5b8d45c0ce2e5643984af2b4e5b49821e3b2f54b	no	18
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Information:					
13	Non Patent Literature	NPL3_Amended_Complaint.pdf	1100820 347cca84f079b7ab1493e2625713d50b7a1b3189	no	20
Warnings:					
Information:					
14	Foreign Reference	NPL4_PlntfMotnForPrelimInjunction.pdf	3075532 b0ab5abaf68831c802e651c48311e1706960de21	no	40
Warnings:					
Information:					
15	Foreign Reference	NPL5_Dec_Root_Sprt_Of_Motion.pdf	5828718 780805e696e575c7cb99f4ba033d75d9f65361b9	no	55
Warnings:					
Information:					
16	Non Patent Literature	NPL6_Dec_Vrba.pdf	173668 e69fcec35775fd2a86fbc659f05540890a9fe4cc	no	4
Warnings:					
Information:					
17	Non Patent Literature	NPL7_Dec_Demartini.pdf	103531 aec5e436857151d7665de641c10bc9e4320439e4	no	3
Warnings:					

Information:					
18	Non Patent Literature	NPL8_Placeholder_Rasmusen_Dec.pdf	47259 c0d07fbd26237797ec2c70152e4b8252c4d25004	no	1
Warnings:					
Information:					
19	Non Patent Literature	NPL9_BSC_Answr_Countrclms.pdf	1009983 a05c13e00347a892a54ecfb127b278f14dd037ea	no	22
Warnings:					
Information:					
20	Non Patent Literature	NPL10_RedactedReplyMemo.pdf	2723580 5f570ceb138dc5e038a3547392eb269a918e3bcf	no	27
Warnings:					
Information:					
21	Non Patent Literature	NPL11_2nd_Dec_Root.pdf	1659782 3f538a896da1fbabf479b3d7d3858af22e404c26	no	22
Warnings:					
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22		IDS.pdf	743485 10d611515ac818b9351466c8afdf59f826b00e3b	yes	9

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Transmittal Letter	1	2
Information Disclosure Statement (IDS) Form (SB08)	3	9

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23	Fee Worksheet (SB06)	fee-info.pdf	40495 45093144200a7b9fbaf1ea558071e661820edd19	no	2
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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.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
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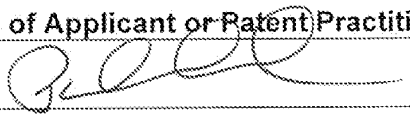
NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	14/070,161
Filing Date	11/01/2013
First Named Inventor	Howard Root
Title	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
Art Unit	3767
Examiner Name	Unassigned
Attorney Docket Number	2005.86USREI3

SIGNATURE of Applicant or Patent Practitioner

Signature		Date (Optional)	1-14-14
Name	Paul C. Onderick	Registration Number	45354
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 24113

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☑ The address associated with Customer Number: 24113

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address:

Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55402-2100

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	October 25, 2013
Name	Howard Root	Telephone	763-656-4200
Title	Chief Executive Officer		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root et al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: Unassigned
Filed: November 1, 2013	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

CERTIFICATE UNDER 37 CFR § 3.73(c)

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

Commissioner:

Vascular Solutions, Inc., a corporation, states that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel 027973, Frame 0984, or for which a copy thereof is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From _____ to _____

The document was recorded in the Patent and Trademark Office at Reel _____, Frame _____ or for which a copy thereof is attached.

2. From _____to _____

The document was recorded in the Patent and Trademark Office at Reel _____,

Frame _____or for which a copy thereof is attached.

3. From _____ to _____

The document was recorded in the Patent and Trademark Office at Reel _____,

Frame _____ or for which a copy thereof is attached.

[ ] Additional documents in the chain of title are listed on a supplemental sheet.

[ ] Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the assignee.

Date: 12/9/13

Signature

Howard Root

Name Printed or Typed

Chief Executive Officer

Title

PTO/AIA/14 (12-13)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Howard		Root	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Tonka Bay	State/Province	MN	Country of Residence i	US

Mailing Address of Inventor:

Address 1	25 Fairhope Avenue		
Address 2			
City	Tonka Bay	State/Province	MN
Postal Code	55331	Country i	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gregg		Sutton	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Plymouth	State/Province	MN	Country of Residence i	US

Mailing Address of Inventor:

Address 1	18400 31st Avenue North		
Address 2			
City	Plymouth	State/Province	MN
Postal Code	55447	Country i	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jeffrey	M.	Welch	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

PTO/AIA/14 (12-13)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

City	Maple Grove	State/Province	MN	Country of Residence i	US

Mailing Address of Inventor:

Address 1	8723 Cornstock Lane North		
Address 2			
City	Maple Grove	State/Province	MN
Postal Code	55311	Country i	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jason	M.	Garrity	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Lima	State/Province	NY	Country of Residence i	US

Mailing Address of Inventor:

Address 1	2838 Livonia Center Road		
Address 2			
City	Lima	State/Province	NY
Postal Code	14485	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	24113		
Email Address	onderick@ptslaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES		
Attorney Docket Number	2005.86USREI3	Small Entity Status Claimed	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	13	Suggested Figure for Publication (if any)	

Filing By Reference :

EFS Web 2.2.10

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

Only compete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country [i]

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	24113		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the application number blank.

Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
14070161	reissued of	13359059	2012-01-26	8292850	2012-10-23
Prior Application Status	Patented			Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13359059	Division of	12824734	2010-06-28	8142413	2012-03-27

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

Prior Application Status	Patented				Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
12824734	Division of	11416629	2006-05-03	8048032	2011-11-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(d). When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX) [i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(h)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country [i]	Filing Date (YYYY-MM-DD)	Access Code [i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Authorization to Permit Access:

☐ Authorization to Permit Access to the Instant Application by the Participating Offices

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing this Authorization.

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

(•) Assignee	( ) Legal Representative under 35 U.S.C. 117	( ) Joint Inventor
( ) Person to whom the inventor is obligated to assign.	( ) Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor :

If the Applicant is an Organization check here. [X]

Organization Name	Vascular Solutions, Inc.		
Mailing Address Information:			
Address 1	6464 Sycamore Court North		
Address 2			
City	Minneapolis	**State/Province**	MN
Country [i]	US	Postal Code	55369
Phone Number		Fax Number	

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
	Application Number	
Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

Email Address	

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not subsitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication . An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications

Signature	/Paul C. Onderick/			Date (YYYY-MM-DD)	2014-01-21
First Name	Paul C.	Last Name	Onderick	Registration Number	45354

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	2005.86USREI3
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Title of Invention	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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.

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 365 993 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **89119330.2**

(51) Int. Cl.5: **A61M 29/02 , A61M 25/10**

(22) Date of filing: **18.10.89**

(30) Priority: **20.10.88 JP 264888/88**
22.05.89 JP 827/89
02.08.89 JP 995/89

(43) Date of publication of application:
02.05.90 Bulletin '90/18

(84) Designated Contracting States:
BE DE ES FR GB IT NL SE

(71) Applicant: **Terumo Kabushiki Kaisha**
No. 44-1, Hatagaya 2-chome Shibuya-ku
Tokyo 151(JP)

(72) Inventor: **Sugiyama, Yoshiaki c/o Terumo K.K.**
2656-1, Ohbuchi
Fuji-shi Shizuoka-ken(JP)
Inventor: **Sagae, Kyuta c/o Terumo K.K.**
2656-1, Ohbuchi
Fuji-shi Shizuoka-ken(JP)

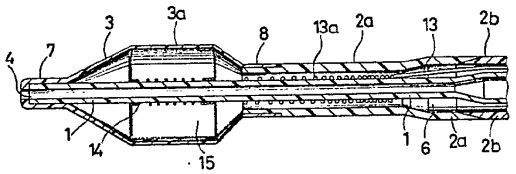
(74) Representative: **Casalonga, Axel et al**
BUREAU D.A. CASALONGA - JOSSE
Morassistrasse 8
D-8000 München 5(DE)

(54) Catheter equipped with expansible member and method of manufacturing the same.

(57) A catheter equipped with an expansible member (3) according to the present invention comprises a first lumen (4) whose tip is open, a second lumen whose tip is closed, a foldable expansible member (3) communicating with the second lumen (6), and a rigidity imparting member (13) consisting of a linear member extending in the axial direction disposed in the second lumen. Therefore, an extreme flection or bend of the catheter is prevented without decrease of the flexibility of the catheter, especially the elastic deformability in the lateral direction with respect to the axial direction of the catheter. Thus, the force applied to the base end portion of the catheter for advancing the tip end portion thereof is surely transmitted to the tip end portion. Further, a catheter equipped with an expansible member according to the present invention comprises a first lumen whose tip is open, a second lumen whose tip is closed, and a foldable expansible member communicating with the second lumen, the outer diameter of the tip end portion of the catheter including a portion to which the expansible member is attached is smaller than that of the base end portion of the catheter. Therefore, the tip end portion of the catheter can be inserted into a severer stricture portion or in a more peripheral blood vessel. Further, a catheter equipped with an expansible member according to the present invention comprises a first lumen whose tip is open, a second lumen whose tip is closed, and a foldable expansible member communicating with the second lumen, the tip of the expansible member forming the tip of the catheter. Therefore, the expansible member is prevented from peeling off and the tip end of the catheter is prevented from being an injury to the inner wall of a blood vessel when the catheter advances in the blood vessel.

EP 0 365 993 A1

FIG. 13



CATHETER EQUIPPED WITH EXPANSIBLE MEMBER AND METHOD OF MANUFACTURING THE SAME

BACKGROUND OF THE INVENTION

This invention relates to a catheter equipped with an expansible member for use in curing a stricture portion inside a blood vessel by expanding the stricture portion to improve the blood flow on the peripheral side of the stricture portion, and to a method of manufacturing the same.

Heretofore, as a catheter equipped with an expansible member for expanding a stricture portion inside a blood vessel, so-called Gruentich type disclosed, for example, in U.S. Patent Specification No.4,195,637, or so-called Simpson-Robert type disclosed, for example, in U.S. Patent Specification No.4,323,071 has been used. However, adaptible cases of vasodilatation using such a catheter were hitherto limited to those of locallized stricture near coronary artery from an anatomical viewpoint, which were lesions of about 15 to 20 mm length, monobranched lesions, non-calcified lesions, etc. Catheters of the above-mentioned types have been improved in order to extend the range of the adaptible cases. For this purpose, a catheter so-called low-profile shape which has the same structure as those of standard structures of the above-mentioned types but only the tip portion of which is narrowed, was developed. The catheter of this low-profile shape is adaptible to strictures in more peripheral blood vessel or severer strictures (subcomplete clogging).

In addition, the applicant of this application has proposed a catheter comprising an inner tube, an outer tube disposed coaxially with the inner tube, an expansible member attached to the inner and outer tubes, and a rigidity imparting member consisting of braided metal wire and disposed on the inner or outer tube as disclosed in the International Publication No.WO 88/06465.

In a catheter called Gruentich type as described above, an expansible member is attached to the tip portion of a catheter tube having two lumens. One of the lumens is open at the tip thereof to form a passage for a guide wire and for tip pressure measurement. The other of the lumens is in communication with the expansible member at the base end portion of the expansible member to form a passage for fluid such as vasographic contrast liquid injected under pressure for expanding the expansible member. The catheter of this type is made of flexible synthetic resin.

A catheter called Simpson-Robert type has a coaxial double-wall structure comprising an inner tube having a first lumen whose tip is open, and an outer tube which forms a second lumen between it and the inner tube and to the tip of which an expansible member is attached. An ultrafine metal pipe is disposed in the second lumen for removing bubbles therefrom. The catheter of this type is also made of flexible synthetic resin like the above-mentioned Gruentich type catheter.

As described above, a catheter to be inserted into a blood vessel is generally made of flexible synthetic resin for facilitating the insertion and avoiding an injury to the wall of the blood vessel. However, such a catheter has a possibility of being flexed in a blood vessel upon insertion because of its flexibility. Further, there is a case that a delicate movement of the tip of the catheter is required for making it reach the aimed portion in the blood vessel. For this purpose, the catheter must be moved or rotated at its base end portion in a delicate manner and the force or torque for the movement or rotation must be transmitted from the base end portion to the tip portion of the catheter. In a conventional catheter, however, the transmission of the force or torque is bad because the force or torque is apt to be absorbed owing to the flexibility of the catheter. Therefore, the conventional catheter is disadvantageous in its delicate operability.

The catheter disclosed in the above-mentioned International Publication No.WO 88/06465 solves those problems of the conventional Gruentich or Simpson-Robert type catheter by disposing the rigidity imparting member. In this catheter, the flection or collapse of the catheter is suppressed and the transmission of the force or torque is improved. However, the flexibility of this catheter is decreased by the rigidity imparted by the rigidity imparting member. The decrease of the flexibility lowers the followability of the catheter to curved portion of blood vessel and the operability of the insertion. Further, even this catheter including the rigidity imparting member of braided metal wire has a possibility of meandering in a blood vessel. In that case, the force applied to the base end portion of the catheter for pushing the catheter into the blood vessel is absorbed at the meandering portion. As the result, the operation of the catheter, particularly for advancing the tip portion of the catheter to a stricture portion inside a blood vessel becomes difficult.

Further, the above-mentioned catheter has a substantially equal outer diameter from the base end portion to the tip portion. In general, the physical properties of the catheter of this type are selected in order to meet the requirements for operating the catheter at its base end or intermediate portion. For this reason, in the above-men-

tioned catheter, the outer diameter at the tip portion is as large as that at the base end portion. As a result, there was a case that the tip portion of the catheter could not be inserted into a severer stricture portion of a blood vessel.

The tip portion of the catheter disclosed in the above-mentioned International Publication No.WO 88/06465 is beveled by grinding or with a solvent in order to avoid an injury to the inner surface of a blood vessel upon insertion into a curved portion of the blood vessel. In general, it is preferable that the expansible member of the catheter is disopsed as near to the tip of the catheter as possible. For this purpose, it is preferable that the mounting portion between the expansible member and the inner tube is as short as possible. Contrarily, a length to some extent of the mounting portion is required for reliable adhesion between the expansible member and the inner tube. However, beveling the tip portion of the catheter as described above decreases the length for the mounting portion and results in deteriorating the adhesion between the expansible member and the inner tube. As a result, there is a possibility that the necessary expansion of a blood vessel is not attained because of leak of fluid for expansion such as vasographic contrast liquid out of the expansible member at a peeling portion of the expansible member off the inner tube upon operating the catheter. Further, in the above-mentioned catheter, the tip portion of the expansible member at which the expansible member is attached to the inner tube is exposed outside of the catheter. Therefore, the catheter has a possibility that the tip portion of the expansible member partially peels off the inner tube upon insertion into a blood vessel and is an injury to the inner surface of the blood vessel.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a catheter equipped with an expansible member in which the flexibility of the catheter, particularly the elastic deformability in the lateral direction with respect to the axial direction of the catheter is not decreased, an extreme flection or bend of the catheter is prevented, the force applied to the base end portion of the catheter for advancing the tip portion thereof to a stricture portion inside a blood vessel is surely transmitted to the tip portion, and the operability of the catheter is good.

It is another object of the present invention to provide a catheter equipped with an expansible member which has physical properties required for the base end portion of the catheter and the tip portion of which is so slender as to be easily inserted into a severer stricture portion or in a more peripheral blood vessel.

It is still another object of the present invention to provide a method of manufacturing a catheter equipped with an expansible member including a step of making a tube having different outer diameters.

It is still another object of the present invention to provide a catheter equipped with an expansible member and a method of manufacturing the same in which the expansible member is disposed sufficiently near to the tip of the catheter, a length enough for the mounting portion between the expansible member and the inner tube is insured, and there is no possibility of being an injury to the inner wall of a blood vessel upon insertion of the catheter.

According to an aspect of the present invention, a catheter equipped with an expansible member comprises an inner tube having a base end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; a second opening formed in said base end portion of said outer tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen.

According to another aspect of the present invention, a catheter equipped with an expansible member comprises a catheter main body having a tip end portion and a base end portion and comprising an inner tube having a tip end portion, a base end portion and a first lumen whose tip is open, an outer tube capable of inserting said inner tube therein, having a tip end portion, a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube, and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said

inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; and a second opening formed in said base end portion of said outer tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter main body including a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter main body.

According to another aspect of the present invention, a catheter equipped with an expansible member comprises a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; a second opening formed in said base end portion of said catheter tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens.

According to another aspect of the present invention, a catheter equipped with an expansible member comprises a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; and a second opening formed in said base end portion of said catheter tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter tube including at least a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter tube.

According to another aspect of the present invention, a method of manufacturing a catheter equipped with an expansible member comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube.

According to another aspect of the present invention, a catheter equipped with an expansible member comprises an inner tube having a tip end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member, said tip end portion of said expansible member attached to said inner tube protruding beyond said inner tube toward the tip of said catheter to form a tip end portion of said catheter.

According to another aspect of the present invention, a method of manufacturing a catheter equipped with an expansible member comprises a

step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length shorter than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of said catheter by using said tip end portion of said expansible member with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features, and advantages of the present invention will be better understood from the following description taken in conjunction with the accompanying drawings, in which:

Fig.1 is an enlarged cross sectional view of the tip end portion of an embodiment of a catheter equipped with an expansible member according to the present invention;

Fig.2 is a view of the base end portion of the catheter of Fig.1;

Fig.3 is a cross sectional view of the intermediate portion of the catheter of Fig.1;

Fig.4 is a cross sectional view taken along line I-I of Fig.1;

Fig.5 is a cross sectional view taken along line II-II of Fig.1;

Fig.6 is a cross sectional view of one example of the base end portion of the catheter of the present invention;

Fig.7 is a side elevational view of one example of a rigidity imparting member used in the catheter of the present invention;

Fig.8 is an enlarged cross sectional view taken along line X-X of Fig.7;

Fig.9 is an enlarged cross sectional view taken along line XI-XI of Fig.7;

Figs.10, 11 and 12 are side elevational views of other examples of rigidity imparting members used in catheters of the present invention;

Fig.13 is a cross sectional view of another embodiment of a catheter equipped with an expansible member according to the present invention;

Fig.14 is an enlarged cross sectional view of the tip end portion of another embodiment of a catheter equipped with an expansible member according to the present invention;

Fig.15 is a cross sectional view taken along line III-III of Fig.14;

Fig.16 is a cross sectional view taken along line IV-IV of Fig.14;

Fig.17 is a cross sectional view of the base end portion of the catheter of Fig.14;

Figs.18 through 21 are views for illustrating a step of forming the rear outer tube of the catheter of Fig.3;

Figs.22 through 25 are views for illustrating a step of forming the front outer tube of the catheter of Fig.3;

Figs.26 through 30 are views for illustrating a step of connecting the rear outer tube to the front outer tube of the catheter of Fig.3;

Figs.31 through 34 are views for illustrating a step of forming the expansible member of the catheter of Fig.1;

Fig.35 is a view for illustrating a step of attaching the expansible member to the outer tube of the catheter of Fig.1;

Fig.36 is a view for illustrating a step of attaching the expansible member to the inner tube of the catheter of Fig.1;

Figs.37 through 43 are views for illustrating another process for manufacturing a catheter equipped with an expansible member according to the present invention; and

Figs.44 through 48 are views for illustrating the operation of the catheter of Fig.1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention will be described as to preferred embodiments shown in the attached drawings.

A catheter equipped with an expansible member according to the embodiments comprises an inner tube 1 having a base end portion and a first lumen 4 whose tip is open, an outer tube 2 capable of inserting the inner tube 1 therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of the inner tube 1, and forming a second lumen 6 between it and the outer surface of the inner tube

1, a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the inner tube 1, the base end portion 8 of the expansible member 3 being attached to the outer tube 2, the expansible member 3 communicating with the second lumen 6 at a portion near the base end portion 8 of the expansible member 3, a first opening 9 formed in the base end portion of the inner tube 1 to communicate with the first lumen 4, a second opening 11 formed in the base end portion of the outer tube 2 to communicate with the second lumen 6, and a rigidity imparting member 13 consisting of a linear member extending in the axial direction disposed in the second lumen 6.

Further, a catheter equipped with an expansible member according to the embodiments comprises a catheter main body having a tip end portion and a base end portion and comprising an inner tube 1 having a tip end portion, a base end portion and a first lumen 4 whose tip is open, an outer tube 2 capable of inserting the inner tube 1 therein, having a tip end portion, a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of the inner tube 1, and forming a second lumen 6 between it and the outer surface of the inner tube 1, and a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the inner tube 1, the base end portion 8 of the expansible member 3 being attached to the outer tube 2, the expansible member 3 communicating with the second lumen 6 at a portion near the base end portion 8 of the expansible member 3, a first opening 9 formed in the base end portion of the inner tube 1 to communicate with the first lumen 4, and a second opening 11 formed in the base end portion of the outer tube 2 to communicate with the second lumen 6, the outer diameter of the tip end portion of the catheter main body including a portion to which the expansible member 3 is attached is smaller than that of the base end portion of the catheter main body.

Hereinafter, detailed description will be made with the drawings.

A catheter equipped with an expansible member according to one embodiment of the present invention comprises a catheter main body including an inner tube 1, an outer tube 2 and an expansible member 3, and a branched hub 20.

The inner tube 1 has a first lumen 4 whose tip is open. The first lumen 4 is a lumen for inserting a guide wire therein and in communication with a first opening 9 which forms a guide wire port disposed in the branched hub 20. It is preferable that the outer diameter of the tip end portion of the inner tube 1 is smaller than that of the base end portion thereof. In this embodiment, as shown in Fig.3, the inner tube 1 consists of a front inner tube 1a and a rear inner tube 1b. The outer tube 2 described later also consists of a front outer tube 2a and a rear outer tube 2b. The outer diameters of the front inner and outer tubes 1a and 2a are smaller than those of the rear inner and outer tubes 1b and 2b, respectively. Therefore, the catheter of this embodiment can be inserted into more peripheral blood vessel than conventional one. It is preferable that the tip end portion of the catheter having the small outer diameter is as long as the distance from the inlet of a carronary artery to an aimed lesion part, particularly, a little longer than the distance from the inlet of the carronary artery to the aimed lesion part. Specifically, the length of the tip end portion is preferably about 50 to 700 mm, more preferably 80 to 400 mm, more preferably 100 to 300 mm. In addition, it is preferable that each of the inner and outer tubes is provided with a tapering portion at the connecting portion between the tip end portion 1a or 2a and the base end portion 1b or 2b to make the change of its inner and outer diameters smooth.

The front inner tube 1a of the inner tube 1 has preferably the outer diameter of 0.30 to 2.00 mm, more preferably 0.40 to 1.80 mm, and the inner diameter of 0.20 to 1.80 mm, more preferably 0.25 to 1.60 mm. The rear inner tube 1b has preferably the outer diameter of 0.40 to 2.50 mm, more preferably 0.55 to 2.40 mm, and the inner diameter of 0.25 to 2.35 mm, more preferably 0.30 to 1.80 mm.

As the inner tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear inner tubes 1a and 1b. Also in that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes.

The material for forming the inner tube 1 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetete copolymer, polyvinyl chloride, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

The outer tube 2 into which the inner tube 1 is inserted has a tip slightly recessed by a predetermined distance from the tip of the inner tube 1. As shown in Fig.4 which is a cross section taken along line I-I in Fig.1, a second lumen 6 is formed by the

inner surface of the outer tube 2 and the outer surface of the inner tube 1. Thus, the second lumen 6 has a sufficient volume. The tip portion of the second lumen 6 is in communication with the rear end portion of the inside of the expansible member 3 described later. The rear end portion of the second lumen 6 is in communication with a second opening 11 provided to the branched hub 20 to form an injection port for injecting fluid for expanding the expansible member (for example, vasographic contrast liquid). As shown in Fig. 3, the outer tube 2 consists of a front outer tube 2a and a rear outer tube 2b. The outer diameter of the front outer tube 2a is smaller than that of the rear outer tube 2b so as to facilitate insertion of the tip end portion of the catheter into more peripheral blood vessel. The front outer tube 2a of the outer tube 2 has preferably the outer diameter of 0. 50 to 4.00 mm, more preferably 0.60 to 3.70 mm, and the inner diameter of 0.40 to 3. 50 mm, more preferably 0.50 to 2.70 mm. The rear outer tube 2b has preferably the outer diameter of 0.75 to 4.30 mm, more preferably 1.00 to 4.00 mm, and the inner diameter of 0.70 to 3.80 mm, more preferably 0.80 to 3.00 mm. Also as the outer tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear outer tubes 2a and 2b. In that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes.

The material for forming the outer tube 2 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetete copolymer, polyvinyl chloride, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

As shown in Figs.1 and 3 through 6, a rigidity imparting member 13 is provided in the second lumen 6 formed by the inner surface of the outer tube 2 and the outer surface of the inner tube 1. The rigidity imparting member 13 extends from the base end portion to the tip end portion of the catheter. The rigidity imparting member 13 is for preventing an extreme flection and meandering of the catheter main body in a blood vessel without considerable decrease of the flexibility of the catheter and for facilitating insertion of the tip end portion of the catheter into a stricture portion inside a blood vessel.

As shown in Figs.1 and 3, the rigidity imparting member 13 consists of a linear member. The linear member preferably consists of metal wire, for example, made of elastic metal such as stainless steel, super elastic alloy, etc. desirably of the wire diameter of 0.05 to 1.50 mm, more desirably of 0.10 to 1.00 mm. Particulaly, it is preferably made of high tensile spring stainless steel, Cu or NI-Ti alloy. The tip and base end portions of the rigidity imparting member 13 may not be fixed. However, it is preferable that the tip end portion of the rigidity member 13 is fixed because the tip end portion of the rigidity imparting member 13 is prevented from being an injury to the expansible member 3 and the force applied to the base end portion of the catheter for advancing the tip end portion of the catheter is surely transmitted to the tip end portion of the catheter. In the embodiment shown in Fig.1, the tip end portion of the rigidity imparting member 13 is slenderer than the other portion thereof by, for example, grinding. The slenderer portion of the rigidity imparting member 13 is located between the tip end portion 7 of the expansible member 3 and the inner tube 1, and fixed to the tip end portion of the inner tube 1 together with the expansible member 3. The slenderer portion of the rigidity imparting member 13 prevents a step-like change of the outer surface of the expansible member 3 in its mounting portion. The average diameter of the slenderer portion is preferably about 1/5 to 1/10 of the diameter of its neighboring portion. It is preferable that the rigidity of the major body portion of the rigidity imparting member 13 is higher than that of the tip end portion thereof. This purpose can be attained by, for example, using a rigidity imparting member in which the cross section of its major body portion is larger than that of its tip end portion. Otherwise, to obtain a rigidity imparting member in which its tip end portion is relatively flexible and its major body portion has a high rigidity, a rigidity imparting member may be used in which a metal wire for the rigidity imparting member has been annealed with a temperature gradient that the temperature for the tip end portion is high and the temperature for the major body portion is low after cold working.

As the rigidity imparting member 13, a strand wire consisting of several fine metal wires braided may be used as shown in Fig.12. In that case, for making the tip end portion 13a of the rigidity imparting member 13 flexible and the major body portion 13b have a high rigidity, it is preferable that the diameter of the tip end portion 13a is smaller than that of the major body portion 13b. For this purpose, metal wires to be braided the diameter of the tip end portion of each of which is smaller than that of the major body portion may be used, or the number of metal wires braided may be decreased toward the tip end portion.

It is preferable that the portion except the tip and base end portions of the rigidity imparting member 13 is not fixed. By not fixing the intermediate portion of the rigidity imparting member 13, when the tip end portion of the catheter is bent, the rigidity imparting member 13 does not hamper the flexibility of the tip end portion of the catheter because the rigidity imparting member 13 can slip within the second lumen.

Such a rigidity imparting member 13 prevents the catheter main body from meandering in a blood vessel. Therefore, because the force applied to the base end portion of the catheter main body is not absorbed at the meandering portion, the force can be surely transmitted to the tip end portion of the catheter. As a result, the operability of the catheter, particularly the operation of advancing the tip end portion of the catheter to which the expansible member is attached, to a stricture portion inside a blood vessel becomes easy. In addition, insertion of the tip end portion of the catheter into a severer stricture portion (sub-complete clogging) becomes possible.

The rigidity imparting member 13 is not limited to that of the embodiment shown in Fig.1. For example, a rigidity imparting member 13 shown in Fig.7 is also usable adequately. In the rigidity imparting member 13 shown in Fig.7, the tip end portion is slenderer than the other portion of the rigidity imparting member 13 like that shown in Fig.1. In this example, however, the slenderer portion 13a is an oblate slenderer portion 13a having an elliptic cross section as shown in Fig.8 which is a cross sectional view taken along line X-X of Fig.7. By forming the tip end portion of the rigidity imparting member 13 into the oblate slenderer portion 13a, mounting it between the inner tube 1 and the tip end portion of the expansible member 3 becomes easy. The major body portion 13b of the rigidity imparting member 13 has a substantially circular cross section as shown in Fig.9 which is a cross sectional view taken along line XI-XI of Fig.7. Further, the rigidity imparting member 13 may be a coil spring type the whole of which consists of a fine metal wire as shown in Fig.10. In addition, as shown in Fig.11, a rigidity imparting member 13 may be used only the tip end portion of which consists of a fine metal wire into a coil spring and the major body portion of which consists of a linear metal wire.

The tip end portion of the rigidity imparting member 13 may not be fixed between the inner tube 1 and the tip end portion of the expansible member 3 as described above. For example, as shown in Fig.13, the tip end portion 13a of the rigidity imparting member 13 may be fixed by winding it around the outer surface of the inner tube 1. In that case, it is preferable that the tip end portion 13a of the rigidity imparting member 13 is fixed by winding it around a portion near the portion of the inner tube 1 corresponding to the portion of the outer tube 2 the diameter of which is decreased, and the tip end portion 13a of the rigidity imparting member 13 is wound to the portion of the inner tube 1 corresponding to the base end portion of the expansible member 3. By winding the tip end portion 13a of the rigidity imparting member 13 around the outer surface of the portion of the inner tube 1 the outer diameter of which is decreased, an flection of the slenderer portion of the inner tube 1 is prevented so that an flection of the slenderer portion of the outer tube 2 is prevented. In order to make the tip side portion of the slenderer portion of the inner tube 1 flexible, as shown in Fig.13, it is preferable to wind the tip end portion 13a of the rigidity imparting member 13 around the outer surface of the inner tube 1 such that it becomes close gradually from the tip end side to the base end side of the inner tube 1.

The expansible member 3 is foldable and it is folded on the outer circumference of the inner tube 1 in its non-expanded state. The expansible member 3 has a substantially cylindrical portion 3a having an approximatelly uniform diameter at least a part of which is substantially cylindrical for enabling to expand a stricture portion in a blood vessel. The substantially cylindrical portion 3a described above may not be completely cylindrical but may be polygonal. The base end portion 8 of the expansible member 3 is secured in a liquid-tight manner to the tip end portion of the outer tube 2 by adhesion, fusion or the like. The tip end portion 7 of the expansible member 3 is also secured in a liquid-tight manner .to the tip end portion of the inner tube 1. As shown in Fig.5 which is a cross sectional view taken along line II-II of Fig.1, the expansible member 3 forms an expanded space 15 between the inner surface of the expansible member 3 and the outer surface of the inner tube 1. The expanded space 15 is in communication over the entire circumference at its rear end portion with the second lumen 6. Thus, the rear end of the expansible member 3 is in communication with the second lumen 6 having a relatively large volume. Therefore, it is easy to inject expansion fluid through the second lumen 6 into the expansible member 3. The material for forming the expansible member 3 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetete copolymer, polyvinyl chloride, cross-linked ethylene-vinyl acetete copolymer, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the

above-mentioned cross-linked ethylene-vinyl acetete copolymer is more preferable. It is preferable that the forward and backward portions of the cylindrical portion 3a of the expansible member 3 are tapered. As the size of the expansible member 3, the cylindrical portion upon expanded has the outer diameter of 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm and the length of 3.00 to 80.00 mm, preferably 10.00 to 75.00 mm. The entire length of the expansible member 3 is 5.00 to 120.00 mm, preferably 15.00 to 100.00 mm.

It is preferable that a marker 14 is provided on the outer surface of the inner tube 1. As shown in Fig.1, the marker 14 is disposed from a portion near the portion on the rear side of the mounting portion between the expansible member 3 and the inner tube 1 to a portion near the portion on the tip end side of the mounting portion between the expansible member 3 and the outer tube 2. That is, the marker 14 has a length as long as that of the cylindrical portion 3a of the expansible member 3. The marker 14 is made of X-ray impermeable material (for example, gold, platinum, tungsten or alloy of them, or silver-palladium alloy). The marker 14 preferably consists of a coil spring. In that case, it is more preferable that the coil spring is wound closely in ranges of 1 to 4 mm, more preferably 2 to 3 mm from both ends of marker 14. This is for enabling to confirm easily the position of the expansible member 3 under X-ray perspection. Further, by forming the marker 14 into a spring shape, it functions as a reinforcement for preventing the inner tube within the expansible member from flexing or collapsing at its bend portion. Particularly, when the marker 14 consists of a spring coil wound around the inner tube 1 closely, the resistance against an external force becomes higher. Further, when the cross section of the coiled wire is circular, rectangular or elliptic, the resistance against an external force becomes much higher.

As shown in Fig.2, the branched hub 20 comprises an inner tube hub 22 secured to the inner tube 1 and having a first opening 9 which is in communication with the first lumen 4 to form a guide wire port, and an outer tube hub 23 secured to the outer tube 2 and having a second opening 11 which is in communication with the second lumen 6 to form an injection port. The inner and outer tube hubs 22 and 23 are connected to each other. For the material for forming the branched hub, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer. A cross section of an embodiment of the branched hub 20 is shown in Fig.6. In this embodiment, a flection-preventing tube 50 is disposed on one end portion of the outer tube 2. The flection-preventing tube 50 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 can be easily attached by the manner that the shrinkable tube 50 is put on one end portion of the outer tube 2 and then shrinked by heating, for example, with blowing hot air. The outer tube 2 to which the flection-preventing tube 50 has been attached is fixed to the outer tube hub 23 with a lock member 52, which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For fixing the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube 2 may be bonded to the outer tube hub 23 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

A flection-preventing tube 60 is disposed on one end portion of the inner tube 1. The tube 60 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 can be easily attached by the manner that the shrinkable tube 60 is put on one end portion of the inner tube 1 and then shrinked by heating, for example, with blowing hot air. The base end portion of the rigidity imparting member 13 is secured to the outer surface of the inner tube 1 with the flection-preventing tube 60. The base end portion of the rigidity imparting member 13 may not be secured. The inner tube 1 to which the flection-preventing tube 60 has been attached is fixed to the inner tube hub 22 with a lock member 62, which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For fixing the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube 1 may be bonded to the inner tube hub 22 with an adhesive applied to the outer surface of the flection-preventing tube 60. For the material for forming the inner tube hub 22, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate

and methacrylate-butylene-styrene copolymer. As shown in Fig.6, the inner and outer tube hubs 22 and 23 are connected to each other by the manner that the inner tube hub 22 is inserted from its tip end in the rear end portion of the outer tube hub 23 attached to the base end portion of the outer tube 2. In this case, an adhesive may be previously applied to the connecting portion between the inner and outer tube hubs 22 and 23 to make a reliable adhesion between them. Instead of the branched hub 20, for example, tubes each of which comprises a port member having an opening on its rear end may be connected in liquid-tight manner to the first and second lumens, respectively.

Next, an embodiment of a catheter equipped with an expansible member shown in Figs.14 through 17 will be described.

A catheter equipped with an expansible member according to this embodiment comprises a catheter tube 10 having a tip end portion, a base end portion, a first lumen 4 the tip of which is open, a second lumen 6 open at a position recessed by a predetermined distance from the tip of the first lumen 4; a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the tip end portion of the catheter tube 10, the base end portion 8 of the expansible member 3 being attached to a portion near an opening portion 12 formed near the tip of the catheter tube 10, the expansible member 3 communicating with the second lumen 6; a first opening formed in the base end portion of the catheter tube 10 to communicate with the first lumen 4; a second opening 11 formed in the base end portion of the catheter tube 10 to communicate with the second lumen 6; and a rigidity imparting member 13 consisting of a linear member extending in the axial direction disposed in at least one of the first and second lumens.

Further, a catheter equipped with an expansible member according to this embodiment comprises a catheter tube 10 having a tip end portion, a base end portion, a first lumen 4 at least the tip of which is open, a second lumen 6 open at a position recessed by a predetermined distance from the tip of the first lumen 4; a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the tip end portion of the catheter tube 10, the base end portion of the expansible member 3 being attached to a portion near an opening portion 12 formed near the tip of the catheter tube 10, the expansible member 3 communicating with the second lumen 6; a first opening 9 formed in the base end portion of the catheter tube 10 to communicate with the first lumen 4; and a second opening 11 formed in the base end portion of the catheter tube 10 to communicate with the second lumen 6, the outer diameter of the tip end portion of the catheter tube 10 including at least a portion to which the expansible member 3 is attached is smaller than that of the base end portion of the catheter tube 10.

A catheter equipped with an expansible member according to this embodiment comprises a catheter main body including a catheter tube 10 and an expansible member 3, and a branched hub 20.

The catheter tube 10 has a first lumen 4 whose tip is open and a second lumen 6 which is in communication with the inside of the expansible member 3 through an opening portion 12 at a position somewhat recessed from the tip to the base end side. As shown in Fig.16 which is a cross sectional view taken along line IV-IV of Fig.14, the first and second lumens 4 and 6 are formed within the catheter tube 10. The first lumen 4 is a lumen for inserting a guide wire therein and in communication with a first opening 9 which forms a guide wire port disposed in the branched hub 20. The tip portion of the second lumen 6 is in communication with the rear end portion of the inside of the expansible member 3. As shown in Fig.17, the rear end portion of the second lumen 6 is in communication with a second opening 11 provided to the branched hub 20 to form an injection port for injecting fluid for expanding the expansible member (for example, vasographic contrast liquid). It is preferable that the outer diameter of the tip end portion of the catheter tube 10 is smaller than that of the base end portion thereof. It is more preferable that a tapering portion is formed between the tip and base end portions of the catheter tube 10 to make the change of its inner and outer diameters smooth. The tip end portion of the catheter tube 10 has preferably the outer diameter of 0.5 to 4.0 mm, more preferably 0.6 to 3.7 mm. The inner diameter of the first lumen is preferably 0.2 to 2.25 mm, more preferably 0.25 to 1.6 mm. The inner diameter of the second lumen is preferably 0.1 to 1.45 mm, more preferably 0.3 to 1.3 mm. The base end portion of the catheter tube 10 has preferably the outer diameter of 0.75 to 4.3 mm, more preferably 1.0 to 4.0 mm. The inner diameter of the first lumen is preferably 0.1 to 2.35 mm, more preferably 0.3 to 1.8 mm. The inner diameter of the second lumen is preferably 0.1 to 1.7 mm, more preferably 0.3 to 1.6 mm. The catheter tube 10 is formed by, for example, extrusion molding. The material for forming the catheter tube 10 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetete copolymer, polyvinyl chloride and polyurethane; or polyamide

elastomer, silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

As shown in Figs.14 through 17, a rigidity imparting member 13 is provided in the second lumen 6. The rigidity imparting member 13 is for preventing an extreme flection or meandering of the catheter main body in a blood vessel without considerable decrease of the flexibility of the catheter and for facilitating insertion of the tip end portion of the catheter into a stricture portion inside a blood vessel. Although the rigidity imparting member 13 is preferably disposed in the second lumen 6, it may be disposed in the first lumen 4. In any case, the rigidity imparting member 13 described before can be suitably used.

The tip end portion 7 of the expansible member 3 is secured to the catheter tube 10 on the front side of the opening 12 while the base end portion 8 thereof is secured to the catheter tube 10 on the base end side of the opening 12. The opening 12 extends in the axial direction of the catheter tube 10 by a predetermined length. Also in this embodiment, the expansible member 3 described before can be suitably used. As shown in Fig.15 which is a cross sectional view taken along line III-III of Fig.14, the expansible member 3 forms an expanded space 15 between the inner surface of the expansible member 3 and the outer surface of the inner tube 1. The tip end portion of the second lumen 6 of the catheter tube 10 is filled with a filler 16 to be closed. The tip end portion of the rigidity imparting member 13 is located in the filler 16 and fixed. Both the tip and base end portions of the rigidity imparting member 13 may not be fixed. However, it is preferable to fix the tip end portion of the rigidity imparting member 13 because the tip end portion of the rigidity imparting member 13 is prevented from being an injury to the expansible member 3 and the trasmission of the force, which is applied to the base end portion of the catheter for advancing the catheter, to the tip end portion is improved.

The branched hub 20 as shown in Fig.17 is attached to the rear end portion of the catheter tube 10. The rear end portion of the rigidity imparting member 13 disposed in the second lumen 6 of the branched hub 20 is fixed with a filler 17. The rear end portion of the rigidity imparting member 13 may not be fixed. For the material for forming the branched hub, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

Next, a method of manufacturing a catheter equipped with an expansible member of the present invention will be described with reference to the drawings.

A method of manufacturing a catheter equipped with an expansible member according to this embodiment comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube.

Each step will be described with the catheter shown in Fig.1.

First, the step of forming an inner tube 1 having a lumen 4 extending from the tip end to the base end of the inner tube 1 can be taken place by a method of cutting a tube member made of thermoplastic resin for the inner tube 1 by extrusion molding into a predetermined length or by an injection molding method.

The step of forming an outer tube 2 comprises a step of forming a front outer tube 2a having a lumen extending from the tip end to the base end of the tube 2a; a step of forming a rear outer tube 2b having the outer diameter larger than that of the front outer tube 2a and a lumen extending from the tip end to the base end of the tube 2b; a step of tapering one end of the rear outer tube 2b; a step of enlarging the diameter of one end portion of the front outer tube 2a; and a step of connecting the tapering end of the rear outer tube 2b to the enlarged end of the front outer tube 2a.

Each of the front and rear outer tubes 2a and 2b can be formed by a method of cutting a tube member made of thermoplastic resin for the outer tube 2 by extrusion molding into a predetermined length or by an injection molding method. In the step of tapering the tip end portion of the rear outer

tube 2b, as shown in Fig.18, a tapering core 90 is inserted in the rear outer tube 2b. The tapering core 90 is used for preventing a formation of a step or the like between the front and rear outer tubes 2a and 2b upon fitting the tapering portion 92 of the rear outer tube 2b to a cone-shaped enlarged portion 94 of the front outer tube 2a as described later, and making the diameter change smooth. The tapering core 90 may be made of glass or metal. As shown in Fig.18, the tapering core 90 is inserted till one end of the rear outer tube 2b reachs a position near a tapering portion of the tapering core 90.

For tapering the tip end portion of the rear outer tube 2b, a tapering mold 91 as shown in Fig.19 is used. The tapering mold 91 may be made of glass or metal. It is preferable that the tapering mold 91 has a tapering inner surface corresponding to the tapering portion of the tapering core 90 for making the diameter change of the rear outer tube 2b smooth.

As shown in Fig.20, the tapering mold 91 is made to press the tip end portion of the rear outer tube 2b and heated by a heater such as a heat gun and a hot air torch (not shown) to taper the tip end portion of the rear outer tube 2b. Fig.21 shows the tip end portion of the rear outer tube 2b after removing the tapering mold 91, wherein the tip end portion of the rear outer tube 2b has a tapering portion 92.

Next, the step of enlarging the rear end portion of the front outer tube 2a into a cone shape will be described.

In this step, as shown in Fig.22, a slender portion 93a of an enlarging pin 93 is inserted in one end of the front outer tube 2a. As shown in Fig.22, the enlarging pin 93 comprising the slender portion 93a, a tapering portion and a thick portion 93b. The diameter of the slender portion 93a is as large as or a little smaller than the inner diameter of the front outer tube 2a. The diameter of the thick portion 93b is as large as or a little larger than the outer diameter of the rear outer tube 2b. The enlarging pin 93 is inserted from the slender portion 93a in one end of the front outer tube 2a gradually, and, as shown in Fig.23, the one end portion of the front outer tube 2a and the tapering portion of the enlarging pin 93 is heated by a heater such as a heat gun and a hot air torch (not shown) to enlarge the diameter of the one end portion of the front outer tube 2a. Particularly, in the case of the front outer tube 2a having a large thickness, it is preferable that the enlarging pin 93 is pushed in with heating otherwise the front outer tube 2a may be split along the axial direction.

The above operation is continued till the thick portion 93b of the enlarging pin 93 is inserted in the one end portion of the front outer tube 2a. The length of the one end portion of the front outer tube 2a overlapped by the thick portion 93b of the enlarging pin 93 is preferably as long as or a little smaller than the length of the tapering portion 92 formed in the rear outer tube 2b. This makes possible to prevent a formation of a step on the connecting portion between the cone-shaped enlarging portion 94 of the front outer tube 2a and the tapering portion 92 of the rear outer tube 2b, and make it smooth, as described later. As shown in Fig.25, the front outer tube 2a having the enlarged end portion is obtained by removing the enlarging pin 93.

Next, the step of connecting the tapering portion 92 of the rear outer tube 2b to the enlarged portion 94 of the front outer tube 2a will be described. Fig.26 illustrates this step.

First, the tapering portion 92 of the rear outer tube 2b shown in Fig.21 is inserted together with the tapering core 90 in the enlarged portion 94 of the front outer tube 2a. The outer diameter of the portion of the tapering core 90 inserted in the front outer tube 2a, that is, the outer diameter of the portion of the front side of the tapering portion of the tapering core 90 is as large as or a little smaller than the inner diameter of the front outer tube 2a. This is for obtaining a smooth finish from the front outer tube 2a to the connecting portion, further to the rear outer tube 2b. The leading portion of the tapering portion 92 of the rear outer tube 2b is preferably inserted into the leading portion of the cone-shaped enlarged portion 94 of the front outer tube 2a. It is preferable that the tip end portion of the leading portion of the cone-shaped enlarged portion 94 of the front outer tube 2a is as large as or a little smaller than the length of the tapering portion 92 of the rear outer tube 2b because a smooth finish of the outer tube is obtained and a formation of a step is prevented.

Next, a method for connecting the tapering portion 92 of the rear outer tube 2b to the enlarged portion 94 of the front outer tube 2a will be described.

As an embodiment of this step, a method using a mold for connecting as shown in Fig. 27 will be described.

A first connecting mold 95 has a pipe-shape profile. The first connecting mold 95 has an opening at one end wider than an opening at the other end as shown in Fig.27. The inner diameter of the first connecting mold 95 gradually decreases in a cone shape from the one end to an intermediate portion of the first connecting mold 95. An equal inner diameter portion 96 is formed from the intermediate portion to the other end of the first connecting mold 95. The cone-shaped portion of the first connecting mold 95 is for making possible to press gradually the cone-shaped enlarged portion

94 of the front outer tube 2a onto the tapering portion 92 of the rear outer tube 2b. The connecting portion of the front and rear outer tube 2a and 2b, which projects from the outer surface of the rear outer tube 2b because the thickness of the connecting portion becomes larger than the thickness of the rear outer tube 2b, can be easily inserted into the equal inner diameter portion 96 of the first connecting mold 95 because of the cone-shaped tapering portion of the first connecting mold 95. The first connecting mold 95 is for bonding the front and rear outer tube 2a and 2b at the connecting portion with heating. The first connecting mold 95 is preferably made of material capable of being heated from the external, for example, made of glass or metal. The inner diameter of the equal inner diameter portion 96 of the first connecting mold 95 is as large as or a little larger than the outer diameter of the rear outer tube 2b. This is for pressing the projecting portion of the connecting portion of the front and rear outer tube 2a and 2b. As shown in Fig.28, the equal inner diameter portion 96 of the first connecting mold 95 is put on the connecting portion of the front and rear outer tube 2a and 2b so that the cone-shaped enlarged portion 94 of the front outer tube 2a is welded to the tapering portion 92 of the rear outer tube 2b by being heated by a heater. Because the outer tube 2 is formed by inserting the tip end portion of the rear outer tube 2b in the rear end portion of the front outer tube 2a and bonding the former to the latter as described above, the connecting portion between the front and rear outer tubes 2a and 2b is hard to come off upon insertion of the catheter.

In the step described above, if a step is formed on the connecting portion of the front and rear outer tubes 2a and 2b, it is preferable to remove the step. For this purpose, a second connecting mold 97 as shown in Fig.29 is preferably used for surface treatment of the connecting portion in the similar manner to that of the first connecting mold 95.

The second connecting mold 97 has a similar shape to that of the first connecting mold 95 but the inner diameter of the second connecting mold 97 is a little smaller than that of the equal inner diameter portion 96 of the first connecting mold 95. This is for pressing strongly the connecting portion of the front and rear outer tubes 2a and 2b to bond them strongly to each other by welding with heat. The outer tube 2 consisting of a tube having different outer diameters as shown in Fig.30 is obtained by removing the connecting mold and the tapering core 90.

In the embodiment shown in Fig.1, the inner tube 1 also consists of a tube having different outer diameters. This inner tube 1 is preferably formed by the similar manner to that for the outer tube 2 described above. The order of the steps of forming the inner and outer tubes is optional. They may be taken place at a time.

Next, the step of forming a contractible or foldable expansible member having a tip end portion and a base end portion will be described.

The expansible member 3 preferably has a certain extent of flexibilty. For this purpose, the expansible member 3 is preferably made of thermoplastic resin, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetete copolymer and cross-linked ethylene-vinyl acetete copolymer; polyvinyl chloride and polyurethane. Particularly, it is preferable that the expansible member 3 is made of cross-linked ethylene-vinyl acetete copolymer. The expansible member 3 can be formed, for example, by the manner shown in Figs. 31 through 34.

First, as shown in Fig.31, a thermoplastic tube 130 for forming the expansible member 3 is formed. A tube holder 140 is attached to one end portion 132 of the tube 130. The lumen of the tube 130 is closed at a portion shown by arrows A near the tube holder 140. The closure is made by, for example, welding with heat, sealing with high frequency, or using a forceps. The tube 130 closed at the portion shown by arrows A is stretched by applying a load to the tube holder 140 to remove slacks from the tube 30. Fig.31 shows the tube 130 from which slacks have been removed. As shown in Fig.32, a portion of the tube 130 which is to form the expansible member 3 is heated to a temperature near the melting point of the material of the tube 130 by a heater (not shown). While keeping the tube 130 heated, as shown in Fig.33, a mold 142 which has an internal shape corresponding to a shape of the expanded expansible member 3 is put on the tube 130 and the heated portion of the tube 130 is pressed onto the inner surface of the mold 142 by introducing gas under pressure from the direction shown by an arrow C. The tube 130 is kept pressurized till the tube 130 comes back to the room temperature. The mold 142 is removed after the portion of the tube 130 which is to form the expansible member 3 is constricted by making the inside of the tube 130 at a negative pressure. The tube 130 is cut at the tip and rear end portions 134 and 136 to obtain the expansible member 3 as shown in Fig.34.

When at least the tip and base end portions of the expansible member 3 are shrinkable, the expansible member 3 can be easily attached to the inner and outer tubes 1 and 2 by shrinking. For making the tip and base end portions of the expansible member 3 shrinkable, the expansible member 3 may be made of cross-linked thermoplastic resin. Otherwise, in the step of forming the expansible

member 3 described above, the portion of the tube 130 which is to form the expansible member 3 may be heated to such a temperature that strains will remain after cooling. By this manner, the whole of the expansible member 3 can be made shrinkable. Further, for making the tip and base end portions of the expansible member 3 shrinkable, after the expansible member is formed such that the inner diameters of the tip and base end portions of the expansible member are a little smaller than outer diameters of the inner and outer tubes 1 and 2, respectively, the botn end portions of the expansible member may be enlarged (by drawing). The order of the steps of forming the expansible member and the inner and outer tubes described before is optional.

Next, a step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 will be described. It is preferable to form the opening 11 by attaching the outer tube hub 23 having an opening to the base end portion of the outer tube 2. This case will be described with reference to Fig.6.

First, the flection-preventing tube 50 is attached to one end portion of the outer tube 2. The flection-preventing tube 50 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 is attached by the manner that the shrinkable tube 50 is put on the one end portion of the outer tube 2 and then shrinked by heating, for example, with blowing hot air. The outer tube hub 23 is attached to the outer tube 2 to which the flection-preventing tube 50 has been attached. This attachment of the outer tube hub 23 is taken place by using a lock member 52 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For attaching the outer tube hub 23 to the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube hub 23 may be bonded to the outer tube 2 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

The step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 may be taken place at any time after forming the outer tube 2. This step is preferably taken place after the step of attaching the base end portion of the expansible member 3 to the tip end portion of the outer tube 2 described later. The order of this step and the step of forming the inner tube 1 is optional.

Next, a step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 will be described. It is preferable to form the opening 9 by attaching the inner tube hub 22 having an opening to the base end portion of the inner tube 1. This case will be described with reference to Fig.6.

First, the flection-preventing tube 60 is attached to one end portion of the inner tube 1. The flection-preventing tube 60 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 is attached by the manner that the shrinkable tube 60 is put on the one end portion of the inner tube 1 and then shrinked by heating, for example, with blowing hot air. In the embodiment shown in Fig.6, the rigidity imparting member 13 is disposed between the inner and outer tubes 1 and 2. One end portion of the rigidity imparting member 13 is fixed between the flection-preventing tube 60 and the inner tube 1. As shown in Fig.6, the one end portion of the rigidity imparting member 13 can be fixed at the same time that the tube 60 is attached to the inner tube 1 by taking place the heat treatment described above after the one end portion of the rigidity imparting member 13 is located between the tube 60 and the inner tube 1.

The inner tube hub 22 is attached to the inner tube 1 to which the flection-preventing tube 60 has been attached. This attachment of the inner tube hub 22 is taken place by using a lock member 62 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For attaching the inner tube hub 22 to the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube hub 22 may be bonded to the inner tube 1 with an adhesive applied to the outer surface of the flection-preventing tube 60. For the material for forming the inner tube hub, the same material as that of the outer tube hub can be suitably used. The step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 may be taken place at

any time after forming the inner tube 1. The order of this step and the steps of forming the outer tube 2, forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2, and forming the expansible member 3 is optional.

Next, the step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 will be described. As shown in Fig.35, for attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, a core mold 70 the outer diameter of which is as large as or a little smaller than the inner diameter of the outer tube 2 is inserted in the outer tube 2 from the tip or base end of the outer tube 2. Then, the expansible member 3 is put on the outer tube 2 from the tip end side of the core mold 70 such that the tip end of the base end portion 8 of the expansible member 3 corresponds to the tip end of the outer tube 2. A glass mold 72 for connecting is put on the base end portion 8 of the expansible member 3. The glass mold 72 is heated by a heater (not shown) to bond the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2. In the case of using the expansible member 3 the base end portion 8 of which is shrinkable, it is easy to fix the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 because the base end portion 8 of the expansible member 3 shrinks by being heated through the glass mold 72 described above. After fixing the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, the glass mold 72 is left till it comes back to the room temperature. After this, the glass mold 72 is moved back from the connecting portion of the expansible member 3 and the outer tube 2, and the core mold 70 is removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core mold 70 may be made of metal. In that case, an electrode for generating a high frequency may be put on the base end portion 8 of the expansible member 3 to weld the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 by high frequency induction heating. The base end portion 8 of the expansible member 3 may be welded to the tip end portion of the outer tube 2 with supersonic wave. The step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 may be taken place at any time after forming the outer tube 2 and the expansible member 3. The order of this step and the steps of forming the inner tube 1 and forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 is optional. In the case of using a split mold, which is capable of being split along its axial direction, as the glass or metal mold as described above, further, in the case of welding with high frequency or supersonic wave, the order of this step and the step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 is optional. However, this step is preferably taken place after forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 because of decreasing the possibility of damaging the expansible member upon manufacturing.

Next, a step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 and having the opening will be described.

As shown in Fig.6, the inner tube 1 is inserted from its tip end in the outer tube hub 23 attached to the base end portion of the outer tube 2. The insertion of the inner tube 1 is performed from the rear end side of the outer tube hub 23. At this time, it is preferable that the inner tube 1 is inserted with a core member which is inserted in the inner tube 1 to prevent a flection of the inner tube 1, and the tip end portion of the inner tube hub 22 is inserted into the rear end portion of the outer tube hub 23 and joined to the latter. It is also preferable that the inner and outer tube hubs 22 and 23 are surely bonded to each other with an adhesive applied to the connecting portion thereof. The step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 may be taken place at any time after the steps of forming the inner tube 1, disposing the inner tube hub 22 to the base end portion of the inner tube 1, forming the outer tube 2, and disposing the outer tube hub 23 to the base end portion of the outer tube 2. This step is preferably taken place after forming the expansible member 3 and attaching the expansible member 3 to the outer tube 2.

Next, the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 will be described.

Here, a case that the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 is taken place after attaching the expansible member 3 to the outer tube 2 and connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 will be described.

As shown in Fig.36, a core mold 80 the outer diameter of which is as large as or a little smaller than the inner diameter of the inner tube 1 is inserted in the inner tube 1 from the tip or base end of the inner tube 1. Because the expansible member 3 is attached to the outer tube 2, the inner tube 1 is inserted in the outer tube 2 and the inner and outer tube hubs 22 and 23 are connected to each other, the inner tube 1 protrudes beyond the tip of the outer tube 2 and the tip of the expansible member 3. Accordingly, the portion of the tip end portion of the inner tube 1 protruding beyond the tip of the expansible member 3 is cut off to fit in the tip of the expansible member 3. Then, a glass mold 82 for connecting is put from the tip end side of the core mold 80 on the tip end portion 7 of the expansible member 3. The glass mold 82 is heated by a heater (not shown) to bond the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1. In the case of using the expansible member 3 the tip end portion 7 of which is shrinkable, it is easy to fix the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 because the tip end portion 7 of the expansible member 3 shrinks by being heated through the glass mold 82 described above. After fixing the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1, the glass mold 82 is left till it comes back to the room temperature. After this, the glass mold 82 is moved back from the connecting portion of the expansible member 3 and the inner tube 1, and the core mold 80 is removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core mold 80 may be made of metal. In that case, an electrode for generating a high frequency may be put on the tip end portion 7 of the expansible member 3 to weld the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 by high frequency induction heating. The tip end portion 7 of the expansible member 3 may be welded to the tip end portion of the inner tube 1 with supersonic wave. The step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 is preferably taken place as the final step after attaching the expansible member 3 to the outer tube 2 and connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2. In the case of using a split mold, which is capable of being split along its axial direction, as the glass or metal mold as described above, further, in the case of welding with high frequency or supersonic wave, this step may be taken place at any time after forming the inner tube 1 and the expansible member 3. The order of this step and the steps of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1, forming the outer tube 2, and forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 is optional.

Further, after attaching the tip end portion of the expansible member to the tip end portion of the inner tube as described above, the tip end portion of the inner tube is preferably processed so that the outer diameter of the tip end portion of the inner tube decreases in a tapering shape toward the tip end of the inner tube or the inner tube has a rounded tip end. Such a processing can be easily performed by the manner that the tip end portion of the inner tube is inserted in a mold (for example, a glass or metal mold) having an internal shape corresponding to the aimed tip end shape of the inner tube and the mold is heated to deform the tip end portion of the inner tube in accordance with the internal shape of the mold. The tip end portion of the inner tube may be processed by using a metal mold as the above-mentioned mold and applying a high frequency or supersonic wave to the mold.

Next, a catheter equipped with an expansible member according to another embodiment of the present inention will be described with reference to the drawings.

A catheter equipped with an expansible member of this embodiment comprises an inner tube 1 having a first lumen 4 whose tip is open; an outer tube 2 capable of inserting the inner tube 1 therein, having the tip thereof at a position recessed by a predetermined distance from the tip of the inner tube 1, and forming a second lumen 6 between it and the outer surface of the inner tube 1; and a foldable expansible member 3 having a tip end portion 7 and a base end portion 8, the tip end portion 7 of the expansible member 3 being attached to the inner tube 1, the base end portion 8 of the expansible member 3 being attached to the outer tube 2, the expansible member 3 communicating with the second lumen 6 at a portion near the base end portion 8 of the expansible member 3, the tip end portion 7 of the expansible member 3 attached to the inner tube 1 protruding beyond the inner tube 1 toward the tip of the catheter to form a tip end portion of the catheter.

Hereinafter, detailed description will be made with Figs.1 through 6.

A catheter equipped with an expansible member of this embodiment comprises a catheter main body including an inner tube 1, an outer tube 2 and an expansible member 3, and a branched hub 20.

The inner tube 1 has a first lumen 4 whose tip is open. The first lumen 4 is a lumen for inserting a

guide wire therein and in communication with a first opening 9 which forms a guide wire port disposed in the branched hub 20. It is preferable that the outer diameter of the tip end portion of the inner tube 1 is smaller than that of the base end portion thereof. In this embodiment, as shown in Fig.3, the inner tube 1 consists of a front inner tube 1a and a rear inner tube 1b. The outer tube 2 described later also consists of a front outer tube 2a and a rear outer tube 2b. The outer diameters of the front inner and outer tubes 1a and 2a are smaller than those of the rear inner and outer tubes 1b and 2b, respectively. Therefore, the catheter of this embodiment can be inserted into more peripheral blood vessel than conventional one. It is preferable that the tip end portion of the catheter having the small outer diameter is as long as the distance from the inlet of a carronary artery to an aimed lesion part, particularly, a little longer than the distance from the inlet of the carronary artery to the aimed lesion part. Specifically, the length of the tip end portion is preferably about 50 to 700 mm, more preferably 80 to 400 mm, more preferably 100 to 300 mm.

It is preferable that each of the inner and outer tubes is provided with a tapering portion at the connecting portion between the tip end portion 1a or 2a and the base end portion 1b or 2b to make the change of its inner and outer diameters smooth. The front inner tube 1a of the inner tube 1 has preferably the outer diameter of 0.30 to 2.00 mm, more preferably 0.40 to 1.80 mm, and the inner diameter of 0.20 to 1.80 mm, more preferably 0.25 to 1.60 mm. The rear inner tube 1b has preferably the outer diameter of 0.40 to 2.50 mm, more preferably 0.55 to 2.40 mm, and the inner diameter of 0.25 to 2.35 mm, more preferably 0.30 to 1.80 mm. As the inner tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear inner tubes 1a and 1b. Also in that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes.

The material for forming the inner tube 1 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetete copolymer, polyvinyl chloride, polyamide elastomer and polyurethane; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

The outer tube 2 into which the inner tube 1 is inserted has a tip slightly recessed by a predetermined distance from the tip of the inner tube 1. As shown in Fig.4 which is a cross section taken along line I-I in Fig.1, a second lumen 6 is formed by the inner surface of the outer tube 2 and the outer surface of the inner tube 1. Thus, the second lumen 6 has a sufficient volume. The tip portion of the second lumen 6 is in communication with the rear end portion of the inside of the expansible member 3 described later. The rear end portion of the second lumen 6 is in communication with a second opening 11 provided to the branched hub 20 to form an injection port for injecting fluid for expanding the expansible member (for example, vasographic contrast liquid). As shown in Fig.3, the outer tube 2 consists of a front outer tube 2a and a rear outer tube 2b. The outer diameter of the front outer tube 2a is smaller than that of the rear outer tube 2b so as to facilitate insertion of the tip end portion of the catheter into more peripheral blood vessel. The front outer tube 2a of the outer tube 2 has preferably the outer diameter of 0. 50 to 4.00 mm, more preferably 0.60 to 3.70 mm, and the inner diameter of 0.40 to 3. 50 mm, more preferably 0.50 to 2.70 mm. The rear outer tube 2b has preferably the outer diameter of 0.75 to 4.30 mm, more preferably 1.00 to 4.00 mm, and the inner diameter of 0.70 to 3.80 mm, more preferably 0.80 to 3.00 mm. Also as the outer tube, a tube may be used which is made into one body by extrusion molding such that the outer diameter of the tip end portion of the tube is smaller than that of the base end portion thereof, instead of the tube 1 consisting of the front and rear outer tubes 2a and 2b. In that case, for making the change of the outer diameter of the tube smooth, it is preferable that a tapering portion is formed by the extrusion molding at the portion at which the outer diameter changes. The material for forming the outer tube 2 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer and ethylene-vinyl acetete copolymer, polyvinyl chloride, polyurethane and polyamide elastomer; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned polyolefin is more preferable.

It is preferable to provide a rigidity imparting member 13. As shown in Figs.1 and 3 through 6, the rigidity imparting member 13 is preferably disposed in the second lumen 6 formed by the inner surface of the outer tube 2 and the outer surface of the inner tube 1. The rigidity imparting member 13 preferably extends from the base end portion to the tip end portion of the catheter. The rigidity imparting member 13 is for preventing an extreme flection or bend of the catheter main body in a blood

vessel without considerable decrease of the flexibility of the catheter and for facilitating insertion of the tip end portion of the catheter into a stricture portion inside a blood vessel. The rigidity imparting member 13 preferably consists of a linear member. The linear member preferably consists of metal wire such as stainless steel, elastic metal, super elastic alloy, etc. desirably of the wire diameter of 0.05 to 1.50 mm, more desirably of 0.10 to 1.00 mm. Particulaly, it is preferably made of high tensile spring stainless steel, Cu or NI-Ti alloy. The tip and base end portions of the rigidity imparting member 13 may not be fixed. However, it is preferable that the tip end portion of the rigidity member 13 is fixed because the tip end portion of the rigidity imparting member 13 is prevented from being an injury to the expansible member 3 and the force applied to the base end portion of the catheter for advancing the tip end portion of the catheter is surely transmitted to the tip end portion of the catheter. In the embodiment shown in Fig.1, the tip end portion of the rigidity imparting member 13 is slenderer than the other portion thereof by, for example, grinding. The slenderer portion of the rigidity imparting member 13 is located between the tip end portion 7 of the expansible member 3 and the inner tube 1, and fixed to the tip end portion of the inner tube 1 together with the expansible member 3. The slenderer portion of the rigidity imparting member 13 prevents a step-like change of the outer surface of the expansible member 3 in its mounting portion. The average diameter of the slenderer portion is preferably about 1/5 to 1/10 of the diameter of its neighboring portion. It is preferable that the rigidity of the major body portion of the rigidity imparting member 13 is higher than that of the tip end portion thereof. This purpose can be attained by, for example, using a rigidity imparting member in which the cross section of its major body portion is larger than that of its tip end portion. It is preferable that the portion except the tip and base end portions of the rigidity imparting member 13 is not fixed. By not fixing the intermediate portion of the rigidity imparting member 13, when the tip end portion of the catheter is bent, the rigidity imparting member 13 does not hamper the flexibility of the tip end portion of the catheter because the rigidity imparting member 13 can slip within the second lumen.

The expansible member 3 is foldable and it is folded on the outer circumference of the inner tube 1 in its non-expanded state. The expansible member 3 has a substantially cylindrical portion 3a having an approximatelly uniform diameter at least a part of which is substantially cylindrical for enabling to expand a stricture portion in a blood vessel. The substantially cylindrical portion 3a described above may not be completely cylindrical but may be polygonal. The base end portion 8 of the expansible member 3 is secured in a liquid-tight manner to the tip end portion of the outer tube 2 by adhesion, fusion or the like. The tip end portion 7 of the expansible member 3 is also secured in a liquid-tight manner to the tip end portion of the inner tube 1. As shown in Fig.1, the tip end portion 7 of the expansible member 3 protrudes beyond the tip of the inner tube 1 toward the tip end of the catheter. A rounded portion 7a is formed on the protruding tip end of the tip end portion 7. The rounded portion 7a forms a tip end portion of the catheter. More specifically, the tip end of the tip end portion 7 of the expansible member 3 covers the outer surface of the tip end portion of the inner tube 1 and the tip end surface of the inner tube 1, and the portion of the tip end portion 7 of the expansible member 3 covering the tip end surface of the inner tube 1 is rounded. By this design, it becomes possible to prevent the expansible member 3 from coming off because the length for bonding the inner tube 1 to the tip end portion 7 of the expansible member 3 can be small while the area for bonding them to each other is large. Further, because the connecting end between the tip end portion 7 of the expansible member 3 and the inner tube 1 is not exposed in the outer surface of the catheter, it becomes possible to prevent the expansible member 3 from peeling off from the connecting end between them upon insertion of the catheter. Therefore, this design of the tip end portion of the catheter can prevent the tip end of the catheter from being an injury to the inner wall of a blood vessel when the catheter advances in the blood vessel. The rounded portion 7a can be easily formed by the manner that a mold having a round inner surface is put on the tip end of the tip end portion 7 of the expansible member 3 secured in a liquid-tight manner to the inner tube 1 as described later. The mold is put on after inserting a core member in the inner tube 1, and then heated. Although it is preferable that the tip end of the tip end portion 7 of the expansible member 3 is rounded as described above, the tip end portion 7 of the expansible member 3 may have a tapering shape such that the outer diameter of the tip end portion 7 decreases toward the tip end instead of providing the rounded portion 7a. Further, the tip end portion 7 of the expansible member 3 may have an end surface at the tip end. As shown in Fig.5 which is a cross sectional view taken along line II-II of Fig.1, the expansible member 3 forms an expanded space 15 between the inner surface of the expansible member 3 and the outer surface of the inner tube 1. The expanded space 15 is in communication over the entire circumference at its rear end portion with the second lumen 6. Thus, the rear end of the expansible

member 3 is in communication with the second lumen 6 having a relatively large volume. Therefore, it is easy to inject expansion fluid through the second lumen 6 into the expansible member 3. The material for forming the expansible member 3 preferably has a certain extent of flexibility. There are usable thermoplastic resins, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetete copolymer and cross-linked ethylene-vinyl acetete copolymer, polyvinyl chloride, polyurethane and polyamide elastomer; or silicone rubber, latex rubber, etc. The above-mentioned thermoplastic resin is preferable and the above-mentioned cross-linked ethylene-vinyl acetete copolymer is more preferable. It is preferable that the forward and backward portions of the cylindrical portion 3a of the expansible member 3 are tapered. As the size of the expansible member 3, the cylindrical portion upon expanded has the outer diameter of 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm and the length of 3.00 to 80.00 mm, preferably 10.00 to 75.00 mm. The entire length of the expansible member 3 is 5.00 to 120.00 mm, preferably 15.00 to 100.00 mm.

It is preferable that a marker 14 is provided on the outer surface of the inner tube 1. As shown in Fig.1, the marker 14 is disposed from a portion near the portion on the rear side of the mounting portion between the expansible member 3 and the inner tube 1 to a portion near the portion on the tip end side of the mounting portion between the expansible member 3 and the outer tube 2. That is, the marker 14 has a length as long as that of the cylindrical portion 3a of the expansible member 3. The marker 14 is made of X-ray impermeable material (for example, gold, platinum, tungsten or alloy of them, or silver-palladium alloy). The marker 14 preferably consists of a coil spring. In that case, it is more preferable that the coil spring is wound closely in ranges of 1 to 4 mm, more preferably 2 to 3 mm from both ends of marker 14. This is for enabling to confirm easily the position of the expansible member 3 under X-ray perspection. Further, by forming the marker 14 into a spring shape, it functions as a reinforcement for preventing the inner tube within the expansible member from flexing or collapsing at its bend portion.

Particularly, when the marker 14 consists of a spring coil wound around the inner tube 1 closely, the resistance against an external force becomes higher. Further, when the cross section of the coiled wire is circular, rectangular or elliptic, the resistance against an external force becomes much higher.

As shown in Fig.2, the branched hub 20 comprises an inner tube hub 22 secured to the inner tube 1 and having a first opening 9 which is in communication with the first lumen 4 to form a guide wire port, and an outer tube hub 23 secured to the outer tube 2 and having a second opening 11 which is in communication with the second lumen 6 to form an injection port. The inner and outer tube hubs 22 and 23 are connected to each other. For the material for forming the branched hub, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer. A cross section of an embodiment of the branched hub 20 is shown in Fig.6. In this embodiment, a flection-preventing tube 50 is disposed on one end portion of the outer tube 2. The flection-preventing tube 50 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 can be easily attached by the manner that the shrinkable tube 50 is put on one end portion of the outer tube 2 and then shrinked by heating, for example, with blowing hot air. The outer tube 2 to which the flection-preventing tube 50 has been attached is fixed to the outer tube hub 23 with a lock member 52, which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For fixing the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube 2 may be bonded to the outer tube hub 23 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

A flection-preventing tube 60 is disposed on one end portion of the inner tube 1. The tube 60 is made of shrinkable material such that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 can be easily attached by the manner that the shrinkable tube 60 is put on one end portion of the inner tube 1 and then shrinked by heating, for example, with blowing hot air. The base end portion of the rigidity imparting member 13 is secured to the outer surface of the inner tube 1 with the flection-preventing tube 60. The base end portion of the rigidity imparting member 13 may not be secured. The inner tube 1 to which the flection-preventing tube 60 has been attached is fixed to the inner tube hub 22 with a lock member 62, which has an enlarged rear end

portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For fixing the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube 1 may be bonded to the inner tube hub 22 with an adhesive applied to the outer surface of the flection-preventing tube 60. For the material for forming the inner tube hub 22, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer. As shown in Fig.6, the inner and outer tube hubs 22 and 23 are connected to each other by the manner that the inner tube hub 22 is inserted from its tip end in the rear end portion of the outer tube hub 23 attached to the base end portion of the outer tube 2. In this case, it is preferable that an adhesive is previously applied to the connecting portion between the inner and outer tube hubs 22 and 23 to make a reliable adhesion between them.

Instead of the branched hub 20, for example, tubes each having a port member forming an opening on its rear end may be connected in a liquid-tight manner to the first and second lumens, respectively.

Next, a method of manufacturing a catheter equipped with an expansible member of the present invention will be described with reference to an embodiment shown in the drawings.

A method of manufacturing a catheter equipped with an expansible member according to this embodiment comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length shorter than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of said catheter by using said tip end portion of said expansible member with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof.

Each step will be described with the catheter shown in Fig.1.

First, the step of forming an inner tube 1 having a lumen 4 extending from the tip end to the base end of the inner tube 1 can be taken place by a method of cutting a tube member made of thermoplastic resin for the inner tube 1 by extrusion molding into a predetermined length or by an injection molding method.

The step of forming an outer tube 2 comprises a step of forming a front outer tube 2a having a lumen extending from the tip end to the base end of the tube 2a; a step of forming a rear outer tube 2b having the outer diameter larger than that of the front outer tube 2a and a lumen extending from the tip end to the base end of the tube 2b; a step of tapering one end of the rear outer tube 2b; a step of enlarging the diameter of one end portion of the front outer tube 2a; and a step of connecting the tapering end of the rear outer tube 2b to the enlarged end of the front outer tube 2a.

Next, the step of forming a contractible or foldable expansible member having a tip end portion and a base end portion will be described.

The expansible member 3 preferably has a certain extent of flexibilty. For this purpose, the expansible member 3 is preferably made of thermoplastic resin, for example, polyolefin such as polyethylene, polypropylene, ethylene-propylene copolymer, ethylene-vinyl acetete copolymer and cross-linked ethylene-vinyl acetete copolymer; polyvinyl chloride and polyurethane. Particularly, it is preferable that the expansible member 3 is made of cross-linked ethylene-vinyl acetete copolymer. For example, a thermoplastic tube for forming the expansible member 3 is formed. A tube holder is attached to the distal end portion of the tube. The lumen of the tube is closed at a portion near the tube holder. The closed tube is stretched by applying a load to the tube holder to remove slacks from the tube. A portion of the tube which is to form the expansible member 3 is heated to a temperature near the melting point of the material of the tube. While keeping the tube heated, a mold which has a cavity corresponding to a shape of the expanded expansible member 3 is put on the tube and the heated portion of the tube is pressed onto the inner surface of the mold by introducing gas in the tube under pressure. The tube is kept pressurized till the tube comes back to the room temperature. The mold is removed after the portion of the tube which is to form the expansible member 3 is constricted by making the inside

of the tube at a negative pressure. The tube is cut at the tip and rear end portions to obtain the expansible member 3.

When at least the tip and base end portions of the expansible member 3 are shrinkable, the expansible member 3 can be easily attached to the inner and outer tubes 1 and 2 by shrinking. For making the tip and base end portions of the expansible member 3 shrinkable, the expansible member 3 may be made of cross-linked thermoplastic resin. Otherwise, in the step of forming the expansible member 3 described above, the portion of the tube 130 which is to form the expansible member 3 may be heated to such a temperature that strains will remain after cooling. By this manner, the whole of the expansible member 3 can be made shrinkable. Further, for making the tip and base end portions of the expansible member 3 shrinkable, after the expansible member is formed such that the inner diameters of the tip and base end portions of the expansible member are a little smaller than outer diameters of the inner and outer tubes 1 and 2, respectively, the botn end portions of the expansible member may be enlarged (by drawing). The order of the steps of forming the expansible member and the inner and outer tubes described before is optional.

Next, a step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 will be described. It is preferable to form the opening 11 by attaching the outer tube hub 23 having an opening to the base end portion of the outer tube 2. This case will be described with reference to Fig.6.

First, the flection-preventing tube 50 is attached to one end portion of the outer tube 2. The flection-preventing tube 50 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the outer tube 2. The flection-preventing tube 50 is attached by the manner that the shrinkable tube 50 is put on the one end portion of the outer tube 2 and then shrinked by heating, for example, with blowing hot air. The outer tube hub 23 is attached to the outer tube 2 to which the flection-preventing tube 50 has been attached. Fixing of the outer tube hub 23 is taken place by using a lock member 52 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 52 is as large as the inner diameter of the outer tube 2. For fixing the outer tube hub 23 to the outer tube 2, after the lock member 52 is inserted in the rear end portion of the outer tube 2, the outer tube 2 is inserted from its tip end in the outer tube hub 23 till the enlarged rear end portion of the lock member 52 passes on a projection 54 formed on the inner surface of the outer tube hub 23. The outer tube hub 23 may be bonded to the outer tube 2 with an adhesive applied to the outer surface of the flection-preventing tube 50. For the material for forming the outer tube hub 23, there can be suitably used thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate and methacrylate-butylene-styrene copolymer.

The step of forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2 may be taken place at any time after forming the outer tube 2. This step is preferably taken place after the step of attaching the base end portion of the expansible member 3 to the tip end portion of the outer tube 2 described later. The order of this step and the step of forming the inner tube 1 is optional.

Next, a step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 will be described. It is preferable to form the opening 9 by attaching the inner tube hub 22 having an opening to the base end portion of the inner tube 1. This case will be described with reference to Fig.6.

First, the flection-preventing tube 60 is attached to one end portion of the inner tube 1. The flection-preventing tube 60 consists of such a shrinkable tube that the inner diameter thereof after shrinkage is a little smaller than the outer diameter of the inner tube 1. The flection-preventing tube 60 is attached by the manner that the shrinkable tube 60 is put on the one end portion of the inner tube 1 and then shrinked by heating, for example, with blowing hot air. In the embodiment shown in Fig.6, the rigidity imparting member 13 is disposed between the inner and outer tubes 1 and 2. One end portion of the rigidity imparting member 13 is fixed between the flection-preventing tube 60 and the inner tube 1. As shown in Fig.6, the one end portion of the rigidity imparting member 13 can be fixed at the same time that the tube 60 is attached to the inner tube 1 by taking place the heat treatment described above after the one end portion of the rigidity imparting member 13 is located between the tube 60 and the inner tube 1.

The inner tube hub 22 is attached to the inner tube 1 to which the flection-preventing tube 60 has been attached. This attachment of the inner tube hub 22 is taken place by using a lock member 62 which has an enlarged rear end portion. The outer diameter of the portion except the rear end portion of the lock member 62 is as large as the inner diameter of the inner tube 1. For attaching the inner tube hub 22 to the inner tube 1, after the lock member 62 is inserted in the rear end portion of the inner tube 1, the inner tube 1 is inserted from its tip end in the inner tube hub 22 till the enlarged

rear end portion of the lock member 62 passes on a projection 64 formed on the inner surface of the inner tube hub 22. The inner tube hub 22 may be bonded to the inner tube 1 with an adhesive applied to the outer surface of the flection-preventing tube 60. For the material for forming the inner tube hub, the same material as that of the outer tube hub can be suitably used.

The step of forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 may be taken place at any time after forming the inner tube 1. The order of this step and the steps of forming the outer tube 2, forming the opening 11 which is in communication with the lumen 6 of the outer tube 2, in the base end portion of the outer tube 2, and forming the expansible member 3 is optional.

Next, the step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 will be described.

For attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, a core mold the outer diameter of which is as large as or a little smaller than the inner diameter of the outer tube 2 is inserted in the outer tube 2 from the tip or base end of the outer tube 2. Then, the expansible member 3 is put on the outer tube 2 from the tip end side of the core mold such that the tip end of the base end portion 8 of the expansible member 3 corresponds to the tip end of the outer tube 2. A glass mold for connecting is put on the base end portion 8 of the expansible member 3. The glass mold is heated by a heater to bond the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2. In the case of using the expansible member 3 the base end portion 8 of which is shrinkable, it is easy to fix the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 because the base end portion 8 of the expansible member 3 shrinks by being heated through the glass mold described above. After fixing the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2, the glass mold is left till it comes back to the room temperature. After this, the glass mold is moved back from the connecting portion of the expansible member 3 and the outer tube 2, and the core mold is removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core mold may be made of metal. In that case, an electrode for generating a high frequency may be put on the base end portion 8 of the expansible member 3 to weld the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 by high frequency induction heating. The base end portion 8 of the expansible member 3 may be welded to the tip end portion of the outer tube 2 with supersonic wave. The step of attaching the base end portion 8 of the expansible member 3 to the tip end portion of the outer tube 2 may be taken place at any time after forming the outer tube 1 and the expansible member 3. The order of this step and the steps of forming the inner tube 1 and forming the opening 9 which is in communication with the lumen 4 of the inner tube 1, in the base end portion of the inner tube 1 is optional.

Next, a step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 and having the opening will be described.

As shown in Fig.6, the inner tube 1 is inserted from its tip end in the outer tube hub 23 attached to the base end portion of the outer tube 2. The insertion of the inner tube 1 is performed from the rear end side of the outer tube hub 23. At this time, it is preferable that the inner tube 1 is inserted with a core member which is inserted in the inner tube 1 to prevent a flection of the inner tube 1, and the tip end portion of the inner tube hub 22 is inserted into the rear end portion of the outer tube hub 23 and joined to the latter. The inner and outer tube hubs 22 and 23 can be surely bonded to each other with an adhesive applied to the connecting portion thereof. The step of connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 and having the opening to the outer tube hub 23 attached to the base end portion of the outer tube 2 may be taken place at any time after the steps of forming the inner tube 1, disposing the inner tube hub 22 to the base end portion of the inner tube 1, forming the outer tube 2, and disposing the outer tube hub 23 to the base end portion of the outer tube 2. This step is preferably taken place after forming the expansible member 3 and attaching the expansible member 3 to the outer tube 2.

Next, the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 and the step of treating the attached tip end portion 7 of the expansible member 3 with heat will be described.

Here, a case that the step of attaching the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 is taken place after attaching the expansible member 3 to the outer tube 2 and connecting the inner tube hub 22 attached to the base end portion of the inner tube 1 to the outer tube hub 23 attached to the base end portion of the outer tube 2 will be described.

As shown in Fig.37, a core member 80 the outer diameter of which is as large as or a little

smaller than the inner diameter of the inner tube 1 is inserted in the inner tube 1 from the tip or base end of the inner tube 1 such that the tip end of the core member 80 protrudes beyond the tip end of the inner tube 1 by 10 to 15 mm. The inner tube 1 in which the core member 80 has been inserted is inserted from its tip end in the outer tube 2 to the base end portion of which the outer tube hub 23 has been attached and to the tip end portion of which the expansible member 3 has been attached. Then, the inner tube hub 22 attached to the base end portion of the inner tube 1 is connected to the outer tube hub 23. Fig.38 shows the tip end portion of the catheter in this state, wherein the inner tube 1 protrudes beyond the tip end of the outer tube 2 and the tip end of the inner tube 1 is within a tip-side extending portion of the expansible member 3. Then, as shown in Fig.39, a glass mold 82 for connecting is put from the tip end side of the core member 80 on the tip end portion 7 of the expansible member 3. The glass mold 82 is heated by a heater (not shown) to bond the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1. in the preferable case of using the expansible member 3 the tip end portion 7 of which is shrinkable, it is easy to fix the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 because the tip end portion 7 of the expansible member 3 shrinks of itself by being heated through the glass mold 82 described above. After fixing the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 as described above, the glass mold 82 is left till it comes back to the room temperature. Then, the glass mold 82 is moved back from the connecting portion of the expansible member 3 and the inner tube 1, and removed. Although the glass mold is used in this embodiment, a metal mold for connecting may be used instead of the glass mold, for example. Also the core member 80 may be made of metal. In that case, an electrode for generating a high frequency may be put on the tip end portion 7 of the expansible member 3 to weld the tip end portion 7 of the expansible member 3 to the tip end portion of the inner tube 1 by high frequency induction heating. The tip end portion 7 of the expansible member 3 may be welded to the tip end portion of the inner tube 1 with supersonic wave.

Then, the tip end portion of the expansible member is cut at a portion ahead of the tip end of the inner tube 1 by a predetermined distance. Specifically, as shown in Fig.40, the tip end portion (the tip-side extending portion 77) of the expansible member 3 is cut at a portion shown by arrows A ahead of the tip end of the inner tube 1 by about 1 mm. The tip end portion of the expansible member can be finely cut with a cutter such as a razor along the circumferential direction of the core member 80.

Next, the tip end portion of the expansible member which has been cut so as to protrude beyond the tip end of the inner tube 1 by a predetermined length, is treated with heat. Specifically, as shown in Fig.41, the tip end portion of the expansible member is inserted in a heating mold 96 till the tip end of the tip end portion touches the inner wall of the heating mold 96. The heating mold 96 has a cylindrical cavity 97 the inner diameter of which is as large as the outer diameter of the connecting portion of the tip end portion 7 of the expansible member 3 and the inner tube 1. A hole 98 capable of inserting the core member 80 therein is formed in the bottom center of the cavity 97. The bottom inner wall of the cylindrical cavity 97 is shaped such that an aimed shape of the tip end portion of the expansible member (for example, a rounded shape) can be obtained by heat treatment. By heating the heating mold 96 and pushing lightly the tip end portion of the expansible member therein, the protruding portion 77 of the expansible member becomes in a molten state. The portion of the expansible member in the molten state is deformed in accordance with the bottom shape of the cavity 97 and fills the space between the tip end of the inner tube 1 and the protruding portion 77 of the expansible member. As the result, as shown in Fig.42, the outer surface of the tip end portion of the inner tube 1 and the tip end surface thereof are covered with the portion of the expansible member and the tip end portion of the catheter having the rounded portion 7a is formed. Then, the heating mold 96 in which the tip end portion of the expansible member is inserted is cooled. The heating mold 96 can be cooled by the manner that the heating mold 96 in a hot state is put in a cooling vessel 99 containing a cooling medium such as cool water, as shown in Fig.42. The heating mold 96 is left therein till it is cooled sufficiently. After the heating mold 96 is cooled sufficiently, it is taken out from the cooling vessel 99 and removed from the tip end portion of the expansible member. After this, the core member 80 is drawn out from the inner tube 1 to obtain the catheter equipped with the expansible member having the rounded portion 7a in the tip end portion as shown in Fig.43.

Next, the operation of a catheter equipped with an expansible member according to the present invention will be described with reference to Figs.44 through 48 using the catheter equipped with the expansible member of the embodiment shown in Figs.1 through 6.

Before administering a dilatating cure of a stricture portion which has occurred in a blood vessel, air in the catheter equipped with the expansible member is preferably removed as completely as

possible. For this purpose, suction and injection means such as a syringe is attached to the second opening 11 of the catheter according to the present invention and liquid (X-ray contrast liquid, etc.) is charged in the syringe. By repeating suction and injection operations by syringe, the air in the second lumen and the expansible member is removed and replaced by the liquid.

Upon inserting the catheter equipped with the expansible member into a blood vessel, at first, the blood vessel is insured by means of Seldinger method or the like, a guide wire for guide catheter (not shown) is then retained in the blood vessel, the guide catheter 30 is inserted into the blood vessel along it, as shown in Fig.45, the guide catheter 30 is retained in the inlet 32 of the carronary artery including an aimed lesion part, and the guide wire for guide catheter is then withdrawn. As shown in Fig.44, the catheter 40 equipped with the expansible member according to the present invention into which a guide wire 34 for catheter equipped with expansible member is inserted, is inserted through a Y-shaped connector 50 disposed at the rear end of the guide catheter 30. Insertion into the blood vessel is performed in a state that the guide wire 34 for catheter equipped with expansible member is protruded beyond the tip of the catheter 40 equipped with the expansible member by several centimeters. The catheter 40 equipped with the expansible member advances in the guide catheter 30 and enters the blood vessel 35 including the aimed lesion part as shown in Fig.46. The guide wire 34 for catheter equipped with expansible member is then advanced to the aimed lesion part, passed through the stricture portion 36 and retained. The catheter 40 equipped with the expansible member advances in the blood vessel 35 along the guide wire 34 for catheter equipped with expansible member. When the catheter 40 equipped with the expansible member reachs the stricture portion 36, the expansible member 3 is positioned in the stricture portion 36 under X-ray perspection by using the X-ray impermeable marker 14 disposed on the inner tube 1 as a reference mark as shown in Fig.47. Subsequently, vasographic contrast liquid is injected at a pressure from several atmospheres to ten and several atmospheres by means of an injector 54 equipped with a pressure gauge connected to the second opening forming the injection port of the catheter 40 equipped with the expansible member to compress and expand the stricture portion 36 as shown in Fig.48. The contrast liquid is injected through a contrast liquid injection port 52 of the Y-shaped connector 50 of the guide catheter 30 to confirm the state of blood stream on the peripheral side by the X-ray perspection. When an improvement of the blood flow on the peripheral side is recognized, the catheter 40 equipped with the expansible member and the guide wire 34 for catheter equipped with expansible member are withdrawn and then the guide catheter is withdrawn and blood is stopped under pressure to complete the operation.

As described above, a catheter equipped with an expansible member according to the present invention comprises an inner tube having a base end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; a second opening formed in said base end portion of said outer tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen. Therefore, particularly because the rigidity imparting member is disposed in the second lumen, an extreme flection and meandering of the catheter is prevented without decrease of the flexibility of the catheter, especially the elastic deformability in the lateral direction with respect to the axial direction of the catheter. Therefore, the force applied to the base end portion of the catheter is not absorbed at the meandering portion. Thus, the force applied to the base end portion of the catheter for advancing the tip end portion thereof to a stricture portion inside a blood vessel is surely transmitted to the tip end portion so the operability of the catheter is good. In addition, because the second lumen which is in communication with the portion near the base end portion of the expansible member and into which expansion fluid for the expansible member is injected is formed between the inner and outer tubes and has a relatively large volume, even in the case that the expansion fluid has a high flow resistance such as vasographic contrast liquid, it can be easily injected.

Further, a catheter equipped with an expansible member according to the present invention comprises a catheter main body having a tip end portion and a base end portion and comprising an inner tube having a base end portion and a first lumen whose tip is open, an outer tube capable of

inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube, and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; and a second opening formed in said base end portion of said outer tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter main body including a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter main body. Therefore, the catheter has physical properties required for the base end portion of the catheter so that the tip portion of the catheter can be easily inserted into a severer stricture portion or in a more peripheral blood vessel.

Further, a catheter equipped with an expansible member according to the present invention comprises a catheter tube having a tip end portion, a base end portion, a first lumen at least the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; a second opening formed in said base end portion of said catheter tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens. Therefore, like the catheter described before, because the rigidity imparting member is disposed in the second lumen, an extreme flection and meandering of the catheter is prevented without decrease of the flexibility of the catheter, especially the elastic deformability in the lateral direction with respect to the axial direction of the catheter. Therefore, the force applied to the base end portion of the catheter is not absorbed at the meandering portion. Thus, the force applied to the base end portion of the catheter for advancing the tip end portion thereof to a stricture portion inside a blood vessel is surely transmitted to the tip end portion so the operability of the catheter is good.

Further, a catheter equipped with an expansible member according to the present invention comprises a catheter tube having a tip end portion, a base end portion, a first lumen at least the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; and a second opening formed in said base end portion of said catheter tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter tube including at least a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter tube. Therefore, the catheter has physical properties required for the base end portion of the catheter so that the tip portion of the catheter can be easily inserted into a severer stricture portion or in a more peripheral blood vessel.

Further, a method of manufacturing a catheter equipped with an expansible member according to the present invention comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear

outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube. Therefore, even in the case that the outer tube is a tube having different outer diameters which is hard to make by extrusion molding, it can be easily manufactured. In addition, because the front and rear outer tubes are connected without any joint, there is little possibility of disconnection of the tubes so the catheter can be used safely.

Further, a catheter equipped with an expansible member according to the present invention comprises an inner tube having a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member, said tip end portion of said expansible member attached to said inner tube protruding beyond said inner tube toward the tip of said catheter to form a tip end portion of said catheter. Therøfore, it becomes possible to prevent the expansible member from coming off because the length for bonding the inner tube to the tip end portion of the expansible member can be small while the area for bonding them to each other is large. Further, because the connecting end between the tip end portion of the expansible member and the inner tube is not exposed in the outer surface of the catheter, it becomes possible to prevent the expansible member from peeling off from the connecting end between them upon insertion of the catheter. Thus, there is no possibilty that the tip end of the catheter is an injury to the inner wall of a blood vessel when the catheter advances in the blood vessel.

Further, a method of manufacturing a catheter equipped with an expansible member according to the present invention comprises a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of said catheter by using said tip end portion of said expansible member with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof. Therefore, because the tip end portion of the expansible member and the tip end portion of the catheter are integrated, the catheter equipped with the expansible member described above can be surely and easily manufactured without any additional member.

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof, it is to be understood that the invention is not limited to the specific embodiments thereof except as defined in the appended claims.

Claims

1. A catheter equipped with an expansible member comprising an inner tube having a base end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; a second opening formed in said base end portion of said outer tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen.

2. A catheter equipped with an expansible member set forth in claim 1, wherein the rigidity of

the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

3. A catheter equipped with an expansible member set forth in claim 1, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

4. A catheter equipped with an expansible member comprising a catheter main body having a tip end portion and a base end portion and comprising an inner tube having a tip end portion, a base end portion and a first lumen whose tip is open, an outer tube capable of inserting said inner tube therein, having a tip end portion, a base end portion and the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube, and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member; a first opening formed in said base end portion of said inner tube to communicate with said first lumen; and a second opening formed in said base end portion of said outer tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter main body including a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter main body.

5. A catheter equipped with an expansible member set forth in claim 4, wherein said catheter further comprises a rigidity imparting member consisting of a linear member extending in the axial direction disposed in said second lumen.

6. A catheter equipped with an expansible member set forth in claim 4, wherein the outer diameter of said tip end portion of said inner tube is smaller than that of said base end portion of said inner tube.

7. A catheter equipped with an expansible member set forth in claim 4, wherein the outer diameter of said tip end portion of said outer tube is smaller than that of said base end portion of said outer tube.

8. A catheter equipped with an expansible member set forth in claim 5, wherein the rigidity of the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

9. A catheter equipped with an expansible member set forth in claim 5, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

10. A catheter equipped with an expansible member set forth in claim 4, wherein the length of said tip end portion of said catheter main body the outer diameter of which is small is a length near the distance from the inlet of a carronary artery to an aimed lesion part.

11. A catheter equipped with an expansible member comprising a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; a second opening formed in said base end portion of said catheter tube to communicate with said second lumen; and a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens.

12. A catheter equipped with an expansible member set forth in claim 11, wherein the rigidity of the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

13. A catheter equipped with an expansible member set forth in claim 11, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

14. A catheter equipped with an expansible member comprising a catheter tube having a tip end portion, a base end portion, a first lumen the tip of which is open, a second lumen open at a position recessed by a predetermined distance from said tip of said first lumen; a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said tip end portion of said catheter tube, said base end portion of said expansible member being attached to a portion near an opening portion formed near the tip of said catheter tube, said expansible member communicating with said second lumen; a first opening formed in said base end portion of said catheter tube to communicate with said first lumen; and a second opening formed in said base end portion of

said catheter tube to communicate with said second lumen, the outer diameter of said tip end portion of said catheter tube including at least a portion to which said expansible member is attached is smaller than that of said base end portion of said catheter tube.

15. A catheter equipped with an expansible member set forth in claim 14, wherein said catheter further comprises a rigidity imparting member consisting of a linear member extending in the axial direction disposed in at least one of said first and second lumens.

16. A catheter equipped with an expansible member set forth in claim 15, wherein the rigidity of the base end side of said rigidity imparting member is higher than that of the tip end side of said rigidity imparting member.

17. A catheter equipped with an expansible member set forth in claim 15, wherein the cross section of the base end side of said rigidity imparting member is larger than that of the tip end side of said rigidity imparting member.

18. A catheter equipped with an expansible member set forth in claim 15, wherein the length of said tip end portion of said catheter tube the outer diameter of which is small is a length near the distance from the inlet of a carronary artery to an aimed lesion part.

19. A method of manufacturing a catheter equipped with an expansible member comprising a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length smaller than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube, said step of forming said outer tube comprising a step of forming a front outer tube having a lumen extending from the tip end to the base end thereof, a step of forming a rear outer tube having an outer diameter larger than that of said front outer tube and a lumen extending the tip end to the base end of said rear outer tube, a step of tapering one end of said rear outer tube, a step of enlarging the diameter at one end of said front outer tube, and a step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube.

20. A method of manufacturing a catheter equipped with an expansible member set forth in claim 19, wherein said step of connecting the tapered end of said rear outer tube to the enlarged end of said front outer tube comprises a step of fitting said tapered end of said rear outer tube in said enlarged end of said front outer tube and a step of bonding them to each other.

21. A catheter equipped with an expansible member comprising an inner tube having a tip end portion and a first lumen whose tip is open; an outer tube capable of inserting said inner tube therein, having the tip thereof at a position recessed by a predetermined distance from the tip of said inner tube, and forming a second lumen between it and the outer surface of said inner tube; and a foldable expansible member having a tip end portion and a base end portion, said tip end portion of said expansible member being attached to said inner tube, said base end portion of said expansible member being attached to said outer tube, said expansible member communicating with said second lumen at a portion near said base end portion of said expansible member, said tip end portion of said expansible member attached to said inner tube protruding beyond said inner tube toward the tip of said catheter to form a tip end portion of said catheter.

22. A catheter equipped with an expansible member set forth in claim 21, wherein said tip end portion of said expansible member covers the outer surface of said tip end portion of said inner tube and the tip end surface of said inner tube.

23. A catheter equipped with an expansible member set forth in claim 21, wherein the tip of said expansible member is rounded.

24. A method of manufacturing a catheter equipped with an expansible member comprising a step of forming an inner tube having a tip end portion and a lumen extending from the tip end to the base end of said inner tube; a step of forming an outer tube having a tip end portion, a lumen extending from the tip end to the base end of said outer tube, an inner diameter larger than the outer diameter of said inner tube, and a length shorter than that of said inner tube by a predetermined length; a step of forming a contractible or foldable expansible member having a tip end portion and a base end portion; a step of inserting said inner tube in said outer tube; a step of attaching said base end portion of said expansible member to said tip end portion of said outer tube; and a step of attaching said tip end portion of said expansible member to said tip end portion of said inner tube; a step of cutting one end of said expansible member so that said end of said expansible member protrudes beyond said inner tube by a predetermined length; and a step of forming a tip end portion of

said catheter by using said tip end portion of said expansible member with heat treatment of the protruding portion of said expansible member beyond said inner tube by said predetermined length and coating the outer surface of said tip end portion of said inner tube and the tip end surface thereof.

FIG. 1

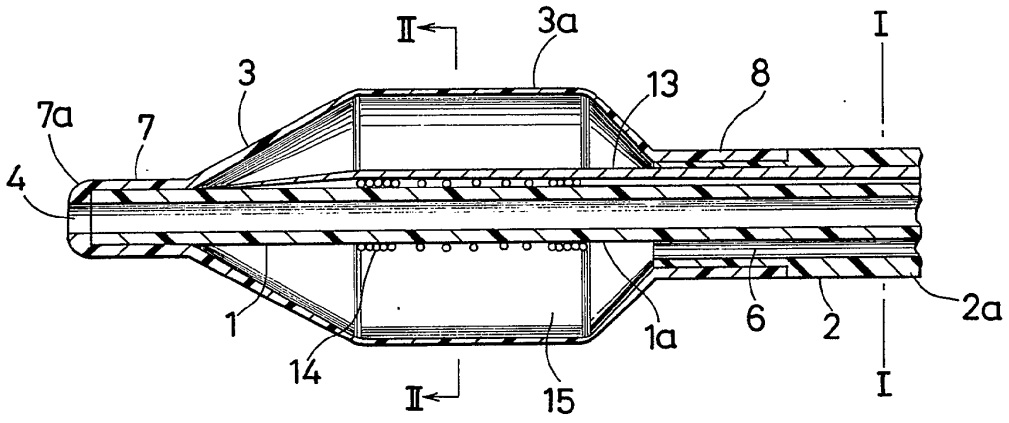


FIG. 2

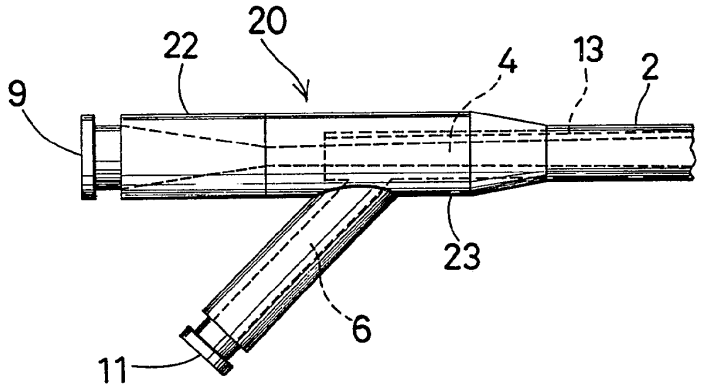


FIG. 3

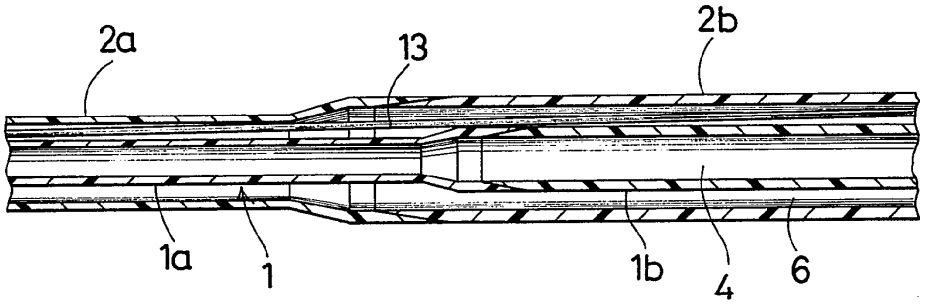


FIG. 4

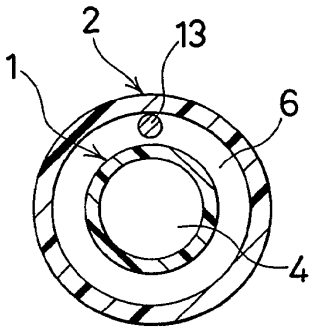


FIG. 5

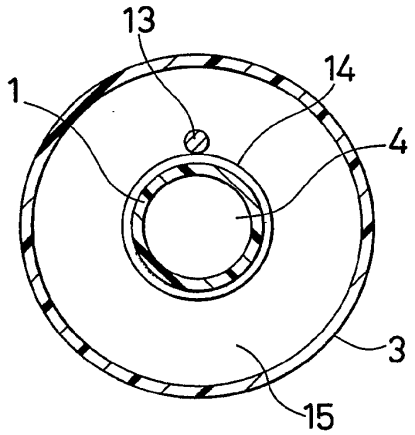


FIG. 10

FIG. 11

FIG. 12

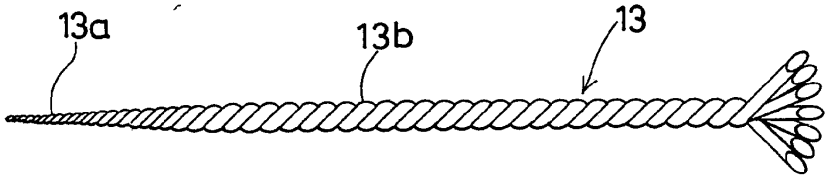


FIG. 13

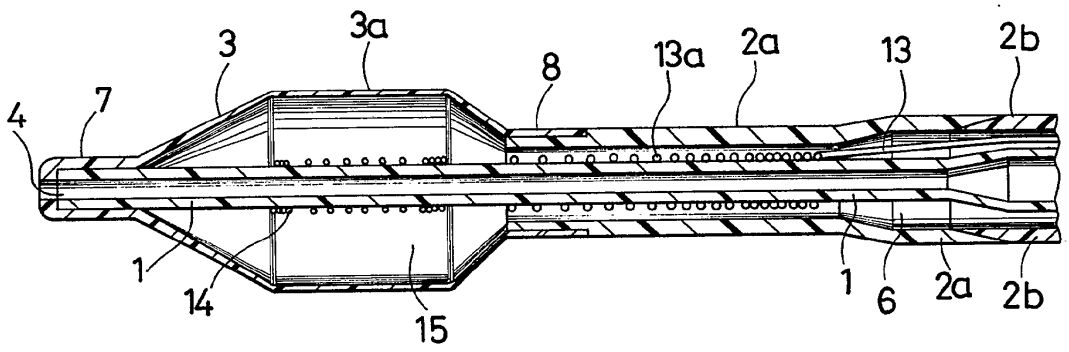


FIG. 6

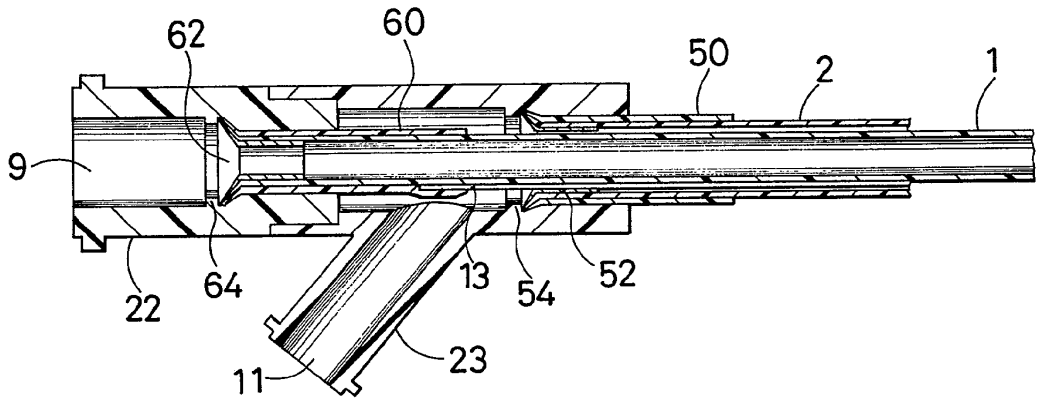


FIG. 7

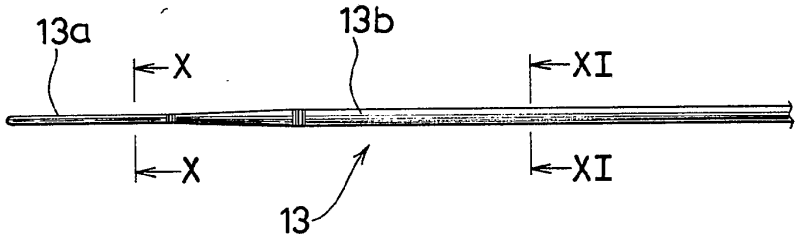


FIG. 8

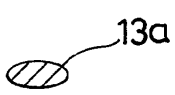


FIG. 9

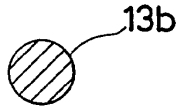


FIG. 14

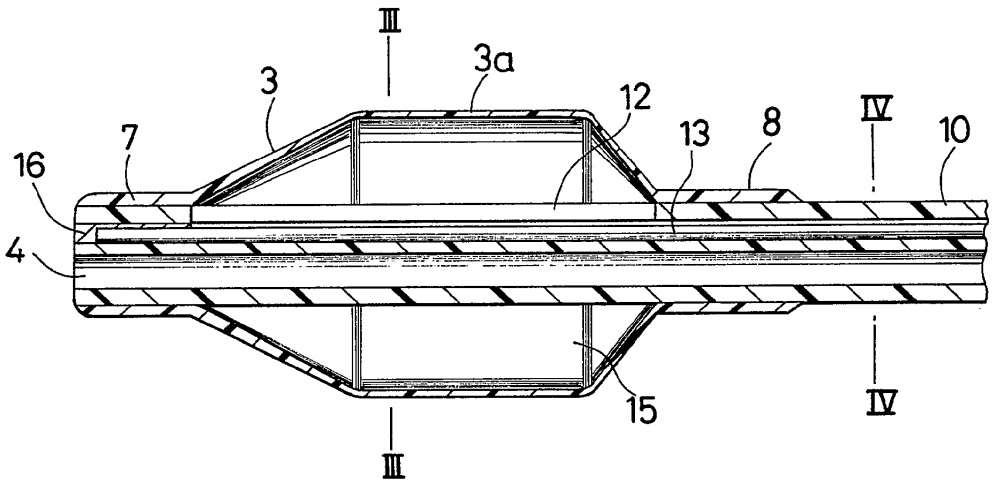


FIG. 15

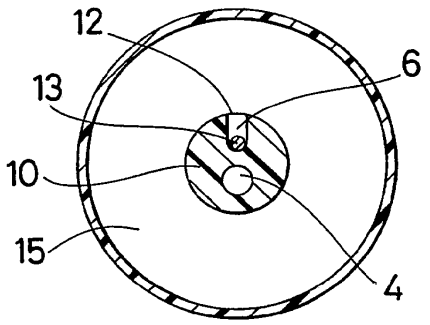


FIG. 16

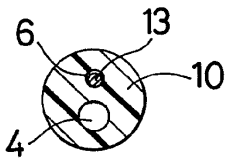


FIG. 17

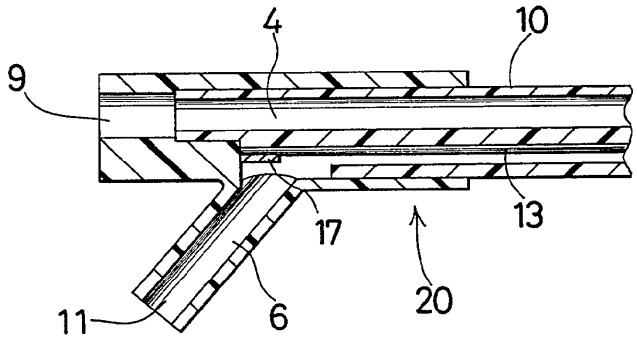


FIG. 18

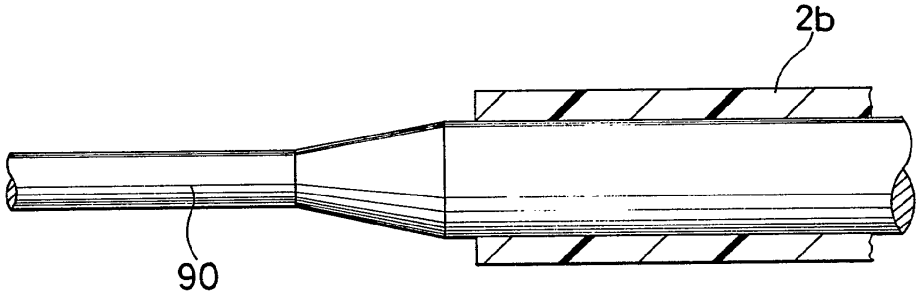


FIG. 19

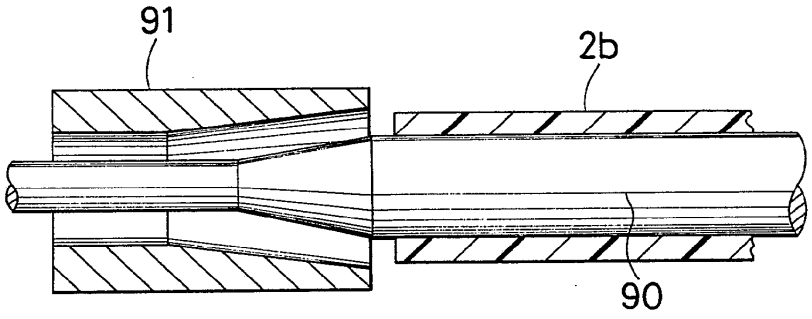


FIG. 20

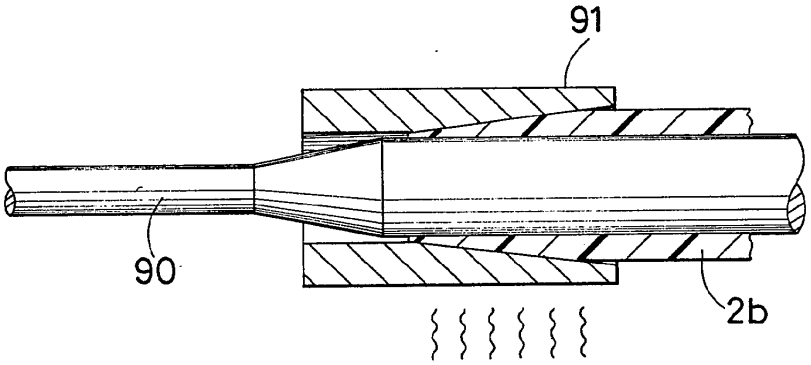


FIG. 21

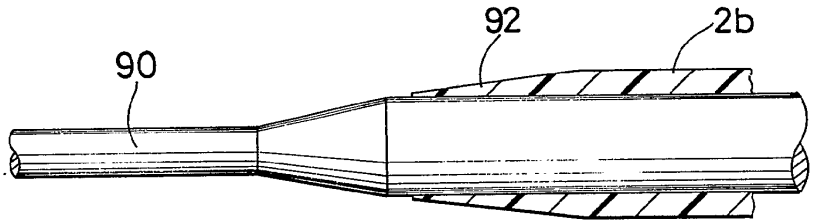


FIG. 22

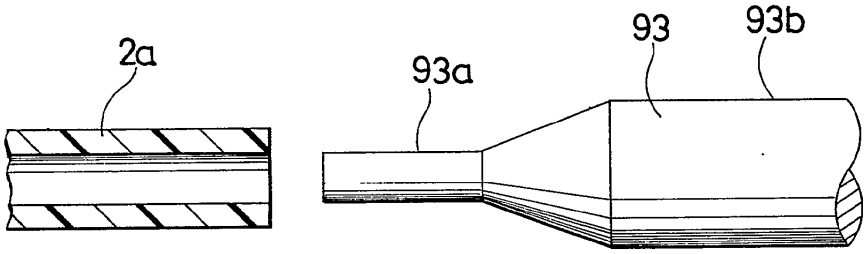


FIG. 23

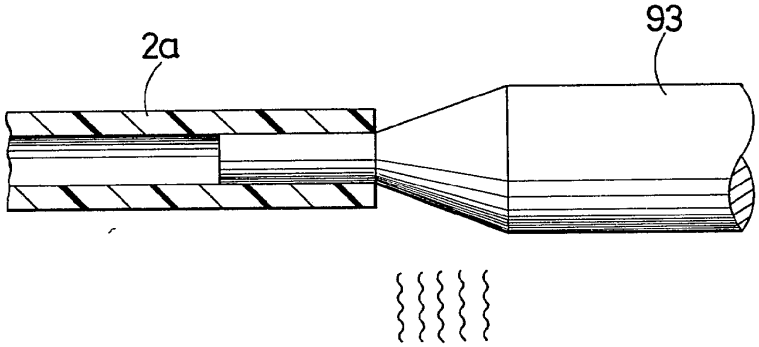


FIG. 24

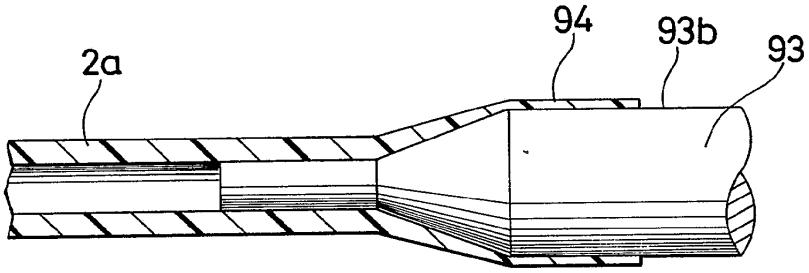


FIG. 25

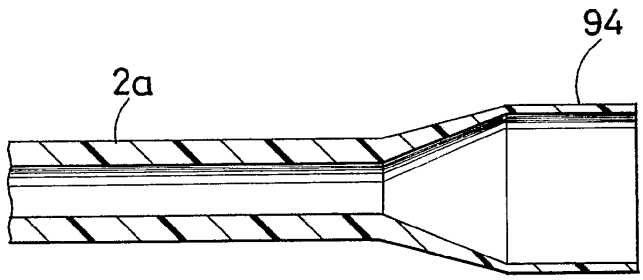


FIG. 26

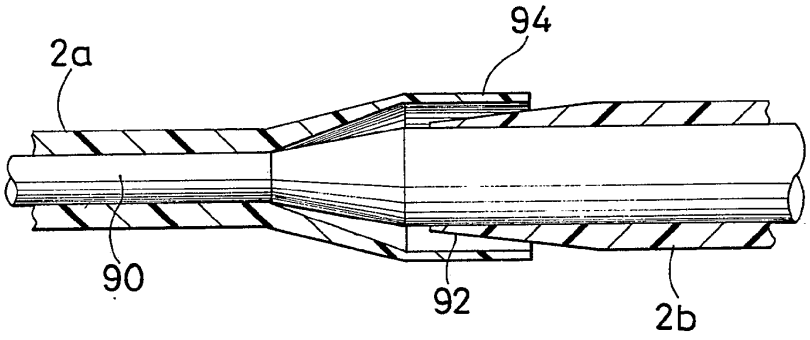


FIG. 27

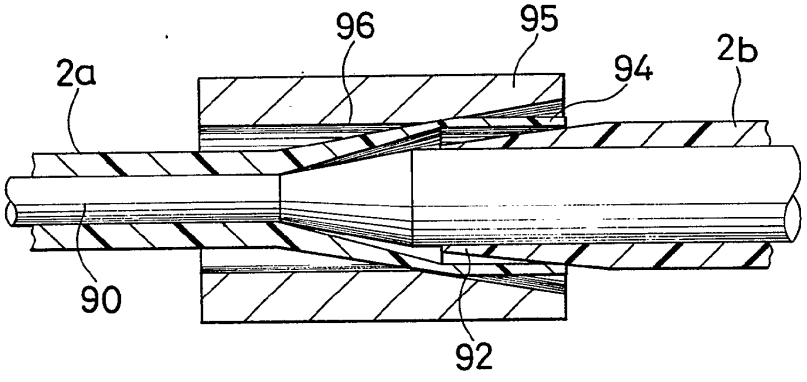


FIG. 28

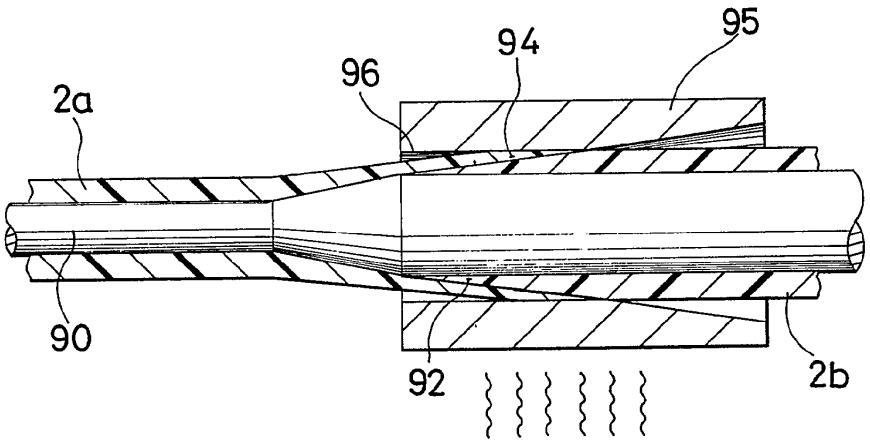


FIG. 29

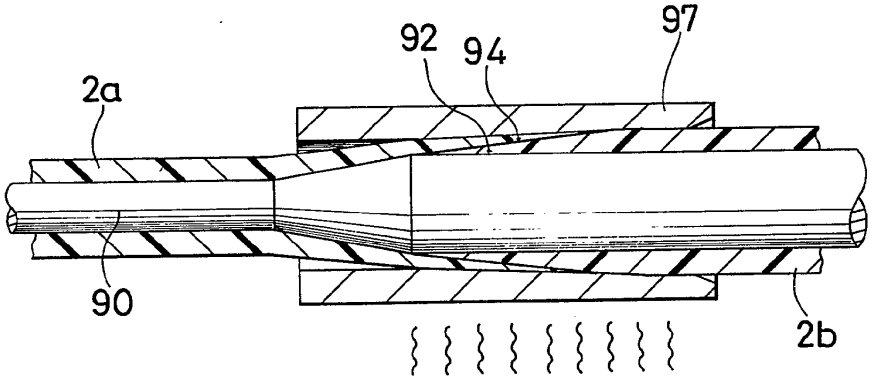


FIG. 30

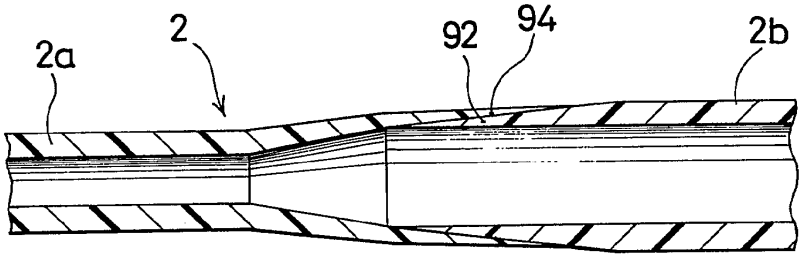


FIG. 31

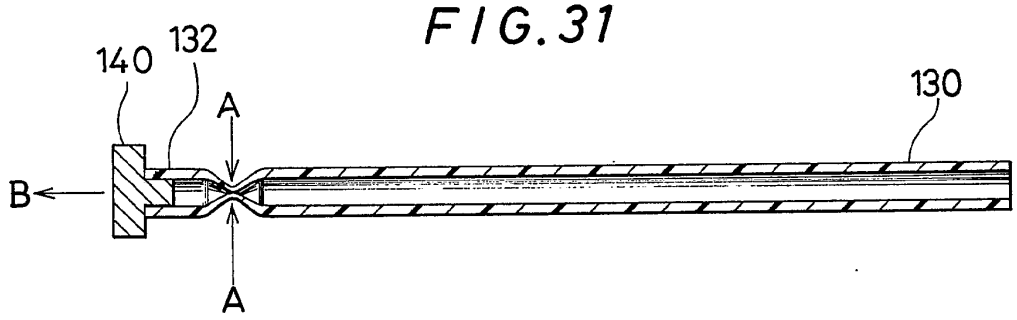


FIG. 32

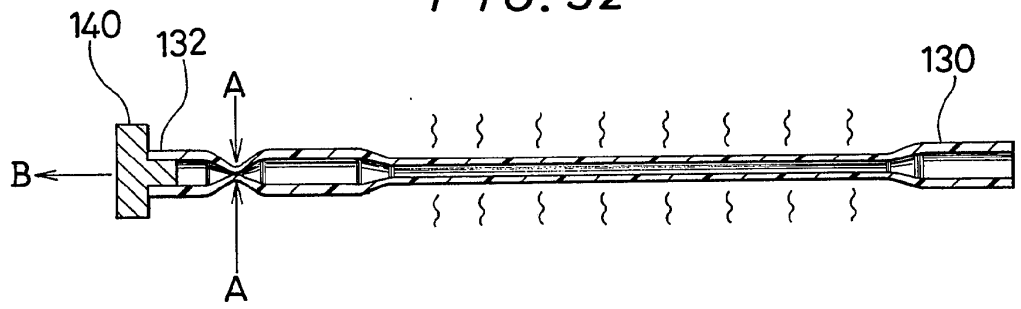


FIG. 33

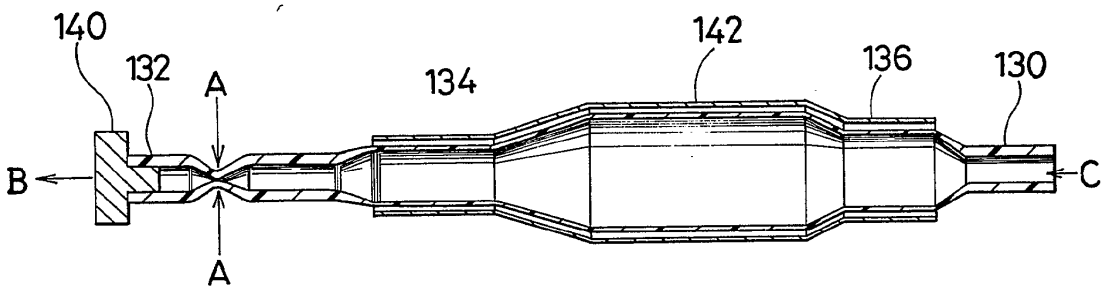


FIG. 34

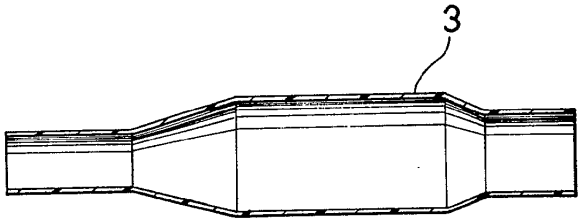


FIG. 35

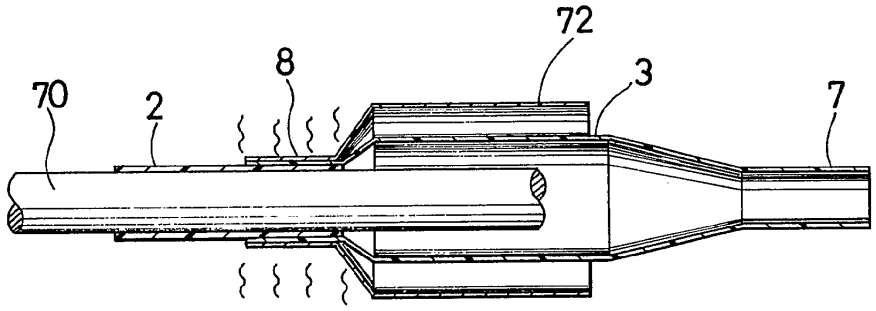


FIG. 36

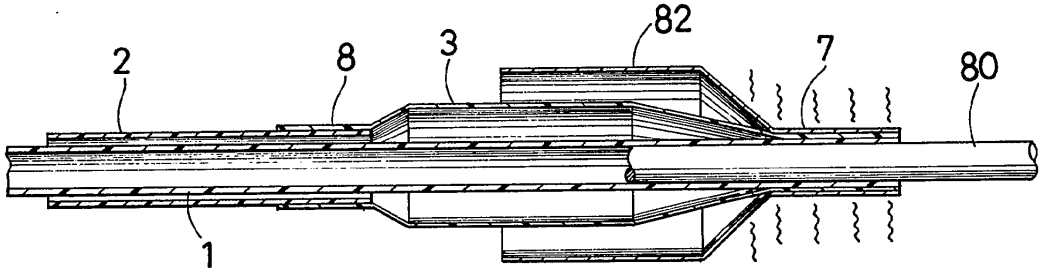


FIG. 37

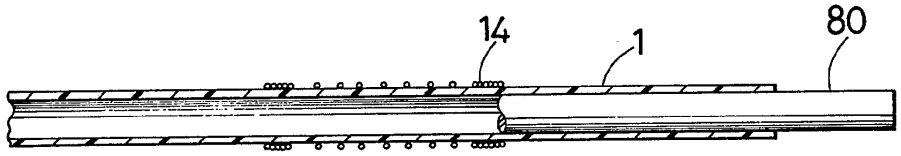


FIG. 38

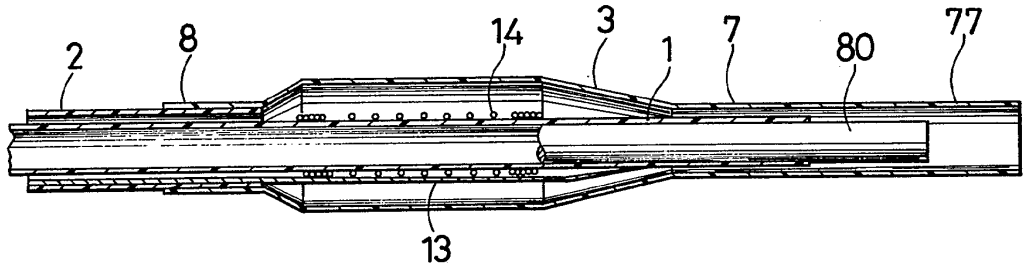


FIG. 39

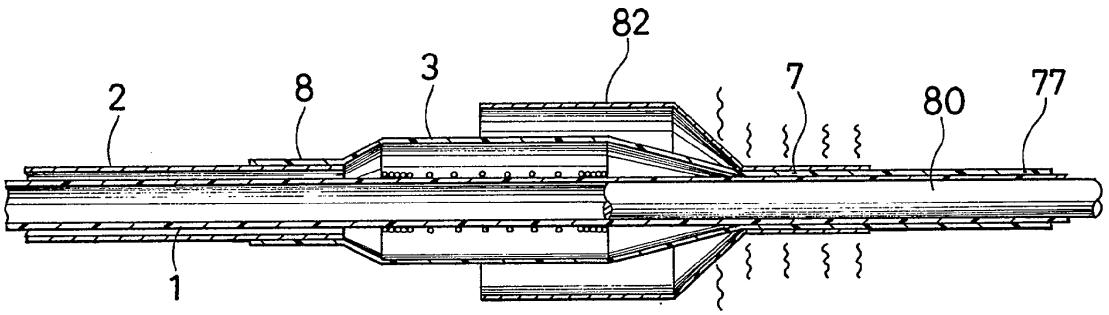


FIG. 40

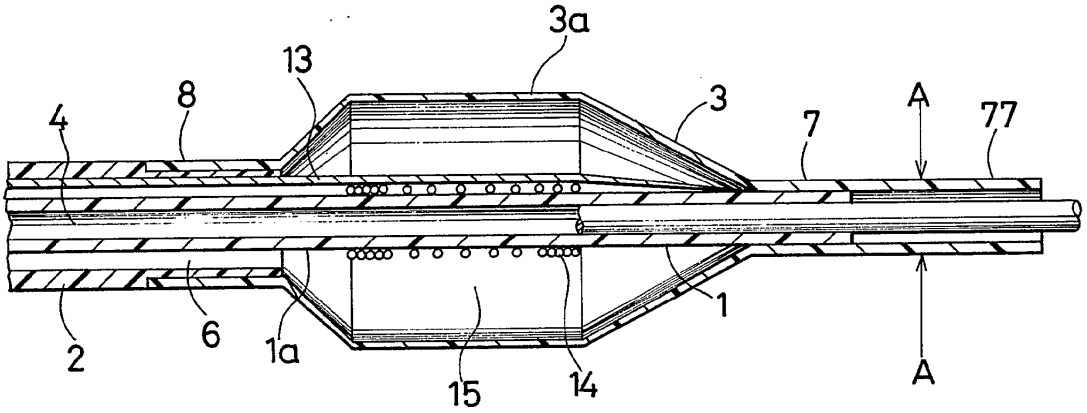


FIG. 41

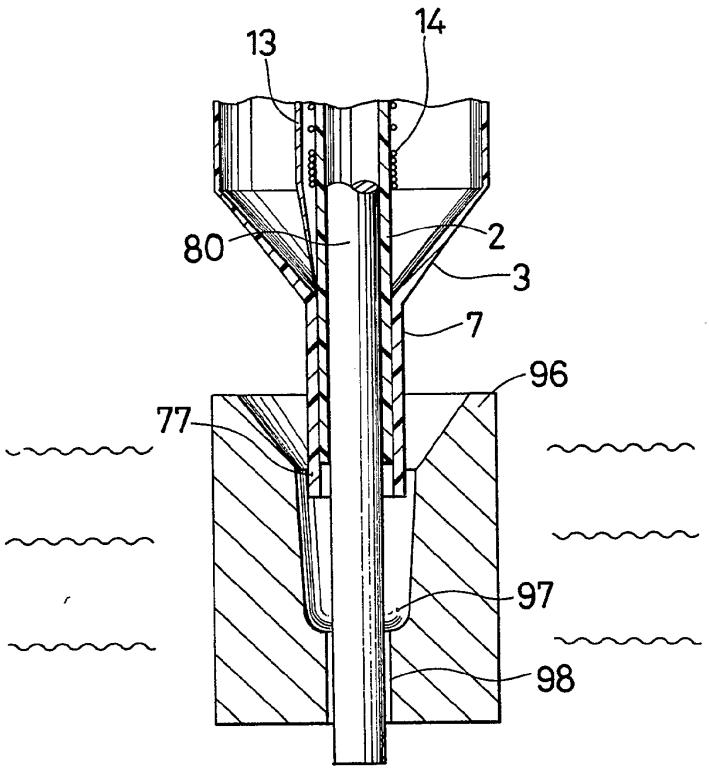


FIG. 42

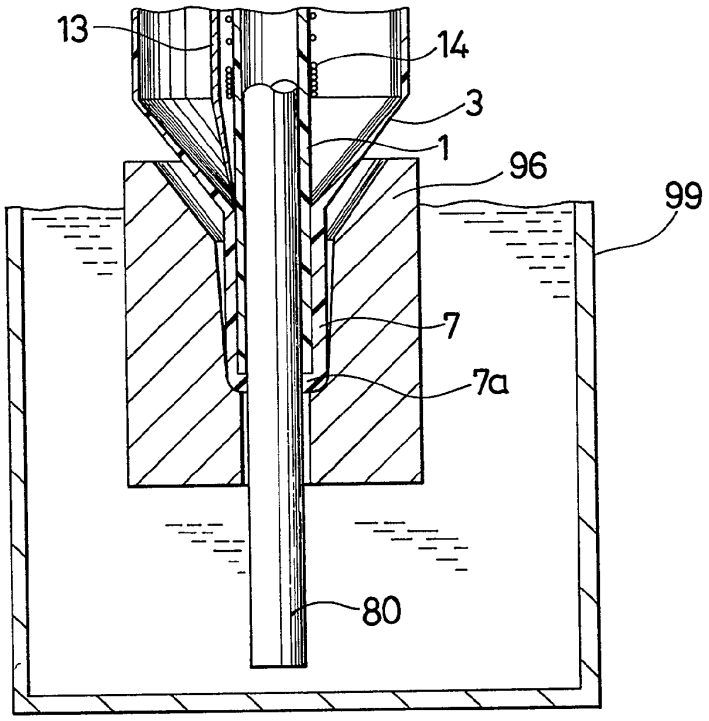


FIG. 43

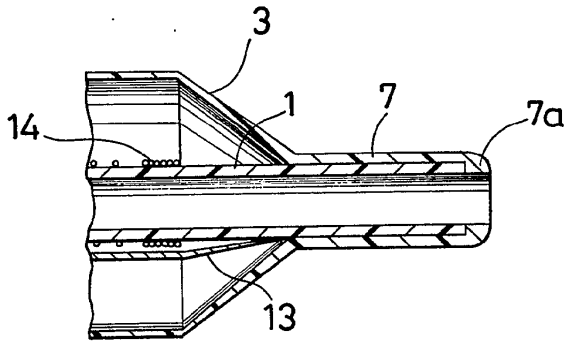


FIG. 44

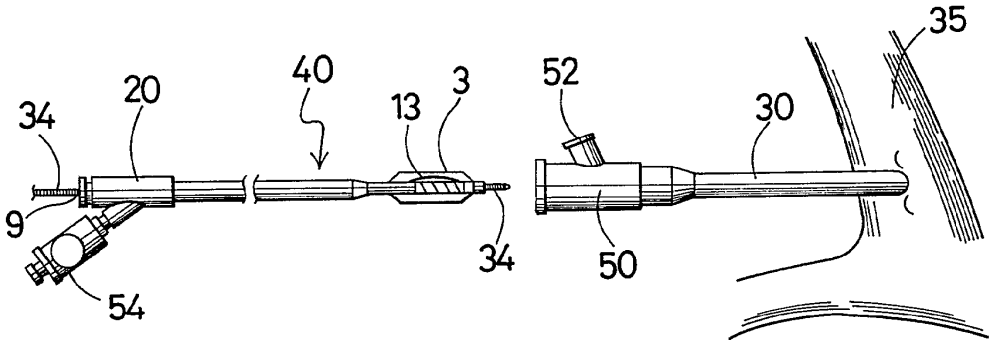


FIG. 45

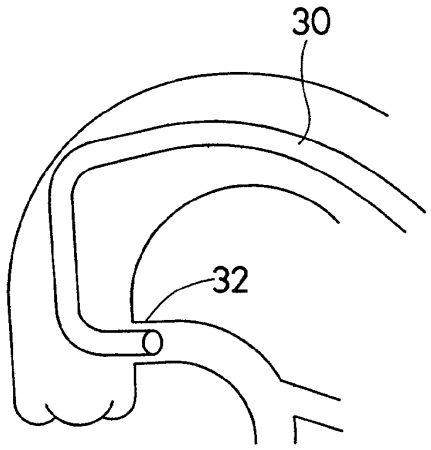


FIG. 46

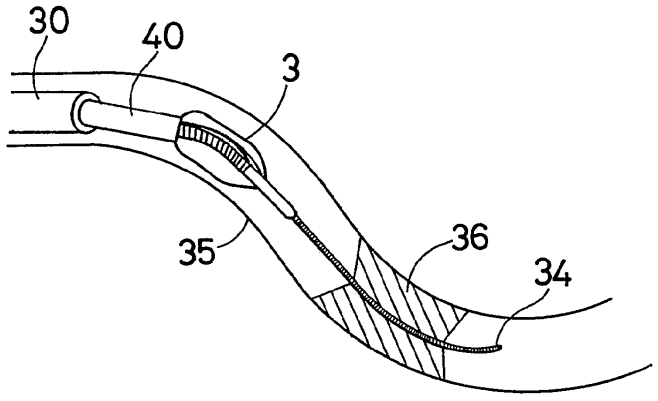


FIG. 47

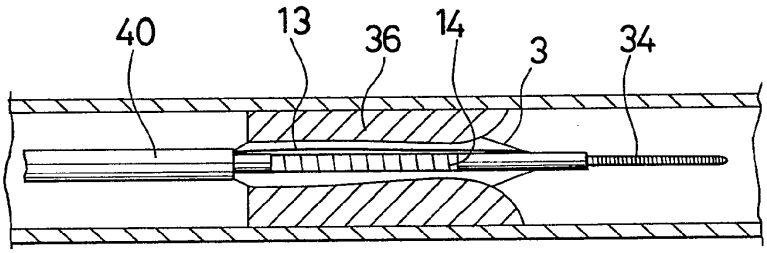
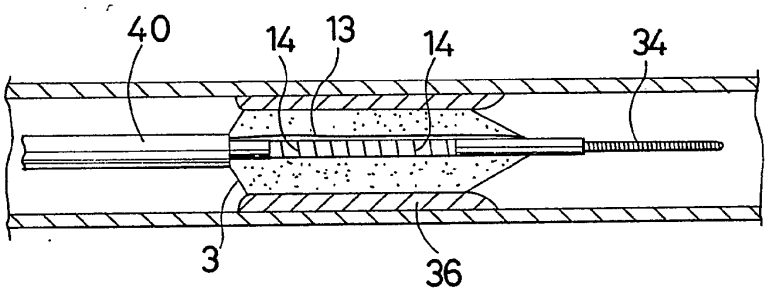


FIG. 48



European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 11 9330

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	EP-A-0 266 957 (C.R. BARD, INC.) * Figures 3,6; column 5, lines 18-39 *	1,4-6, 10-11, 14-16, 18,21-22	A 61 M 29/02 A 61 M 25/10
Y		2-3,7-9 ,12-13, 17,23	
X	US-A-4 597 755 (SAMSON et al.) * Figure 2 *	1,4-6, 10-11, 14-16, 18,21-22	
X,D	WO-A-8 806 465 (TERUMO KABUSHKI KAMSHA) * Abstract; claims 1,17-28 *	1,4-5, 10,11, 19-20, 24	
Y	US-A-4 639 252 * Abstract; figures 1,4; column 6, line 48 - column 7, line 24 *	2-3,7-9 ,12-13, 17,23	TECHNICAL FIELDS SEARCHED (Int. Cl.5) A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	26-01-1990	MIR Y GUILLEN V.

CATEGORY OF CITED DOCUMENTS

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D : document cited in the application
L : document cited for other reasons

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EPO FORM 1503 03.82 (P0401)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Veröffentlichungsnummer:
(11) Publication number:
(11) Numéro de publication:

0 313 558

Internationale Anmeldung veröffentlicht durch die Weltorganisation für geistiges Eigentum unter der Nummer:

WO 88/00071 (art.158 des EPÜ).

International application published by the World Intellectual Property Organisation under number:

WO 88/00071 (art.158 of the EPC).

Demande internationale publiée par l'Organisation Mondiale de la Propriété Intellectuelle sous le numéro:

WO 88/00071 (art.158 de la CBE).

Espacenet

Bibliographic data: WO8800071 (A1) — 1988-01-14

DILATATION CATHETER WITH EXPANDING BALLOON

No documents available for this priority number.

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Applicant(s): BONZEL TASSILO [DE] ± (BONZEL, TASSILO)

Classification: - international:***A61M25/00; A61M29/02;*** (IPC1-7): A61M29/02
- cooperative: **A61M25/0032**; **A61M25/104**; A61M2025/0063; A61M2025/1086

Application number: WO1987DE00264 19870606

Priority number (s): DE19863621350 19860626

Also published as: DE3621350 (A1) DE3621350 (C2) US5002531 (A) JPH01501042 (A) JPH0317507 (B2) more

Abstract of WO8800071 (A1)

A dilatation catheter is provided with an expanding balloon which can be made to advance into a narrowed coronary artery along a guide wire (10) placed by a guide catheter. An inflation tube (11) is provided for expanding the balloon, which consists of a hose-like outer envelope (1) to which is connected, at the axially oriented edges (4, 5), an inner envelope (2) also having a hose-like shape. Between the inner envelope (2) and the outer envelope (1) is an inner annular space (3) which surrounds an open central lumen (9) extending axially through the balloon and ensures during dilatation a constant flow of blood into the coronary artery.

DESCRIPTION DE3621350

The invention relates to a dilatation catheter having an inflatable balloon, which is connected along a extending through a guide catheter guide wire into a constricted coronary artery advanceable and an inflation tube through which the expansion of the balloon, a medium into the balloon interior is pressed.

Such a dilatation catheter is disclosed in DE-OS 34 42 736 and is used in particular for expanding constrictions in coronary arteries.

For this purpose, a guiding catheter is demonstrated with a wide inner lumen of the groin or elbow of a patient from the large body arteries until the disposal of the coronary arteries in the aortic arch, a radiological imaging of the coronary vessel and the concentration under fluoroscopy with intermittent administration of contrast medium is performed through the guiding catheter.

To guide the dilatation catheter to be used a fine guide wire with a soft tip will be demonstrated in the coronary artery beyond the narrowing through the guiding catheter.

A control of the guide wire is made possible by a rotation at variable pre-curved peak.

The dilatation catheter is advanced into the next step from the outside over the guide wire which serves as a guide rail, and through the guide catheter until the balloon of the dilatation catheter is located in the constriction.

The expansion then takes place through a single or repeated filling of the balloon with a pressure of about 500 to 1200 kPa. Clinical experience has shown that prolonged dilation to stabilize the enlarged vascular constriction are more beneficial than shorter dilation.

During dilation is interrupted during use of the known dilatation catheters of Blutst in the vessel, wherein the time of the interruption of blood flow to the heart muscle should not exceed 30 to 120 seconds.

If, under the pressure of the balloon the narrowing is expanded in the coronary artery, the layered structure of the vessel wall may be damaged, resulting complications can arise.

These consist in a closure of the vessel after the enlargement by replacing u incident to the inner wall layers and in rare cases in a Wandzerreissung to bleeding.

If, after the Dilatat and removal of the balloon to any of the above complications with vascular closure so this has in some cases, immediate surgery and an increased risk for the patient.

Dilatations of large coronary arteries are therefore performed in acute surgical readiness, whereby the organizational effort and the cost of an operation using a dilatation increase significantly.

Another disadvantage of the known dilatation catheter is that blood flow is interrupted in the vessel during the expansion process, resulting in low perfusion of the downstream tissues.

Starting from this prior art, the invention has the object to provide a dilatation catheter which permits, during dilatation and in the case of a complication to ensure an adequate continuous flow of blood for a sufficient time to allow an extension of the Dilatationszeit.

This object is achieved by the fact that the balloon has a tubular balloon outer shell and connected thereto at least at the points in the axial direction edges tubular balloon inner hull, between which one is connected, formed with an inflation tube in cross-section substantially annular balloon interior, in a axial direction on both sides open central lumen surrounds.

Characterized in that the balloon interior forms an annular arrangement with a central erectile tissue lumen, the blood flow in the vessel during the dilatation of the use of the dilatation catheter according to the invention is not interrupted, so that the Dilatationszeit can be extended considerably.

In this way, it is possible to achieve better stabilization of the wall and in the case of a complication to prolong the period up to surgery or even to dispense according to a stabilization of the vessel wall to a surgical procedure.

In an expedient embodiment of the invention, the balloon outer sheath and the balloon inner shell are connected at a plurality of points in the manner of stitching with each other to form a plurality of cushion-shaped spongy, liquid tubular which is provided with a central lumen after the injection of a gas or E or imparting a sufficiently high strength and dilation force tubular dilatation catheter.

Expedient embodiments and further developments of the invention are characterized in the dependent claims.

An embodiment of the invention with reference to an embodiment shown in the drawing will be described.

In the drawings:

1 shows a dilatation catheter according to the invention in longitudinal section and

Figure 2 shows a dilatation catheter according to the invention in cross section.

That shown in Figure 1 in longitudinal section and in cross section in Figure 2 has a double-walled balloon dilatation catheter outer casing 1 which is made of an elastic or non-elastic material as required, and forms an outer tube of the double-walled substantially dilatation catheter.

Approximately concentrically to the balloon outer shell 1 a balloon inner shell 2 is provided, which consists of an elastic or non-elastic material as required.

The balloon inner sleeve 2 is also tubular essentially, wherein between the balloon outer shell 1 and the balloon inner casing 2, a balloon interior 3 is formed, which can for example be designed as an annular gap between the balloon outer shell 1 and the balloon inner sleeve 2.

The balloon outer shell 1 and inner shell 2, the balloon are bonded with each other at their axial edges 4, 5, or welded, so that the balloon interior space 3 is closed in the axial direction.

The thus larger the balloon skin 1 diameter. and the balloon inner shell 2 of smaller diameter formed tubular or hose-shaped balloon can be fixed in its structure, for example by a plurality of axially and / or radially extending bonds or welds between the balloon outer shell 1 and the balloon inner shell 2 and be stabilized.

In the embodiment illustrated in Figures 1 and 2, the balloon formed by the outer shell 1 and inner shell 2, the balloon tubular balloon in the manner of a quilting is structured by a plurality of point connections 6.

To the point 6 connections between the balloon outer shell 1 and inner shell 2, the balloon may be bonded to each other or these are welded together.

In this way, corpus cavernosum in the form of cushion-shaped partitions 7 of the balloon inner space 3, wherein the individual pillow-shaped partitions 7 are in each case via connecting-free portions 8 with each other, so that a liquid or gas between the cushion-shaped partitions 7 of the balloon interior space 3 is used to expand the double-walled dilatation can communicate, that can penetrate into all pincushion subdivisions 7 of the balloon interior 3 of the non-bonded areas 8.

The outwardly facing side of the annular balloon dilatation catheter and of the inward-facing side of the balloon are therefore in the expanded state in their surface structure similar to a quilt trained.

Due to the internal pressure in the balloon interior space 3, which is equal to the steady state in each pillow-shaped partitions 7, the balloon is formed with its balloon outer shell 1 and inner shell 2 of its balloon-like structure or a tubular structure of a double-walled pipe.

This results in a mechanical strength and a special self-stability, although the balloon inner casing 2, a central lumen 9 leaves open which extends in the axial direction through the dilatation catheter and permits blood flow through the expanded vessel in the expanded state of the dilatation catheter.

As seen in Figures 1 and 2, extends through the central lumen 9, a guide wire 10 which serves as a guide rail or guide rail and along the advancing of the balloon dilatation catheter through a conventional tubular guide catheter through to the location of the desired intervention in cardiac Crane Tender Herie can be.

Here, the interior of balloon 3 is preferably not filled with a filling medium during advancement so that the radial dimension of the balloon of the dilatation catheter and of the central lumen 9 to reach the surgical site is smaller than in Figures 1 and 2 is shown.

As seen in Figures 1 and 2, an inflation tube 11 projects eccentrically into the balloon of the dilatation catheter.

The inflation tube 11 is reinforced, and transmits within the guide catheter, not shown in the drawing in the axial direction required for advancing and retracting the balloon forces.

For stiffening and increasing the buckling strength may be in the interior of the inflation tube 11, a stabilizing wire 12 may be provided, which is illustrated in Figures 1 and 2.

The inflation tube 11 preferably extends in axial direction from one end 5 to the opposite end 4 of the inner shell 1 and the balloon, the balloon skin 2 and from there over the required length for the connection for the filling medium.

Adjacent to the inflation tube 11 on both sides of a plurality of aligned point connections 6 are provided at an axial distance by which the position of the inflation tube is fixed to 11 in the visible in Figure 2, in the annular space between the balloon outer shell 1 and the balloon inner shell 2.

In addition, the inflation tube 11 along the contact lines 13, 14 may be glued or welded to the outer shell 1 balloon and the balloon inner sleeve 2.

On the left side in Figure 1 of the inflation tube 11 in a manner not shown in detail in Figure 1 connected in the circumferential direction along the outer surface of the dilation catheter to the balloon 3 to seal the interior from the outside.

On the right in Figure 1 side of the inflation tube 11 is closed at its forward end 15.

Along the forward end 15 is a connecting bead 16 is provided, are connected to each other for sealing the balloon space inside the balloon 3 through the outer shell 1 and the inner balloon envelope 2.

In Figures 1 and 2 it can be seen that the inflation tube 11 is connected via a plurality of openings 17 to the balloon interior space 3, so that the press-fit into the inflation tube 11 filling medium can pass into the cushion-shaped divisions 7 in order in this way the expand the collapsed tubular balloon in a deflated condition and to have become stiff.

When the balloon inner shell 2 made of elastic material and said balloon outer casing 1 made of a non-elastic material, as this causes the outside diameter of the balloon of the dilatation catheter of the pressure of the reference liquid is substantially independent.

In this way, the balloon outer casing 1 acts as a holding membrane.

The elastic balloon inner casing 2 may be very small (small surface area), causing the non-filled condition in the deflation of the balloon due to elastic restoring forces of a significant reduction in diameter.

In this way, a particularly easy passage of the dilatation catheter results in the advance or retract through the guide catheter and / or the respective vessel.

If instead the balloon inner shell 2, only the outer shell of the balloon 1 is made of an elastic material, the balloon size can be changed in dependence on the filling pressure of the filling medium, wherein the cross-sectional area of the central lumen 9 remains substantially constant at a filled balloon.

If both the balloon outer shell 1 and inner shell 2, the balloon made of an elastic material causes an increase of the filling pressure of the filling medium mainly an extension of the outer membrane, that is, the balloon outer shell 1

When filling medium 3 rapidly absorbable gases such as CO2 and N2O can be used instead of liquids due to the very small volume of the balloon interior.

While the bursting of the balloon dilatation catheter of the air quantities of such

, 1/10 mm <3> damage, small amounts of N2O or CO2 of less than 1/10 mm <3> are rapidly absorbed and unlikely to cause damage.

This makes it possible to keep the lumen of the inflation tube 11 is extremely small.

If desired, allowing the above-discussed structure of the dilatation catheter to exert only a low pressure effect on the surrounding tissue.

It follows that the use of the dilatation catheter with a double-walled annular balloon is especially useful when higher pressures are not required.

This is not the case with calcified vascular narrowing and stenosis, which has already been widened by means of a conventional balloon catheter, in particular, when the use of a central lumen having no conventional balloon catheter complications have occurred.

In such a case, it is possible to quickly replace the above described dilatation catheter against the previously used single-walled balloon catheter in order to avoid complications, or to achieve stabilization occurred complications permanently or until surgery.

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INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)

(51) Internationale Patentklassifikation 4 : A61M 29/02	A1	**(11) Internationale Veröffentlichungsnummer:** WO 88/ 00071 **(43) Internationales Veröffentlichungsdatum:** 14. Januar 1988 (14.01.88)

(21) Internationales Aktenzeichen: PCT/DE87/00264

(22) Internationales Anmeldedatum: 6. Juni 1987 (06.06.87)

(31) Prioritätsaktenzeichen: P 36 21 350.0

(32) Prioritätsdatum: 26. Juni 1986 (26.06.86)

(33) Prioritätsland: DE

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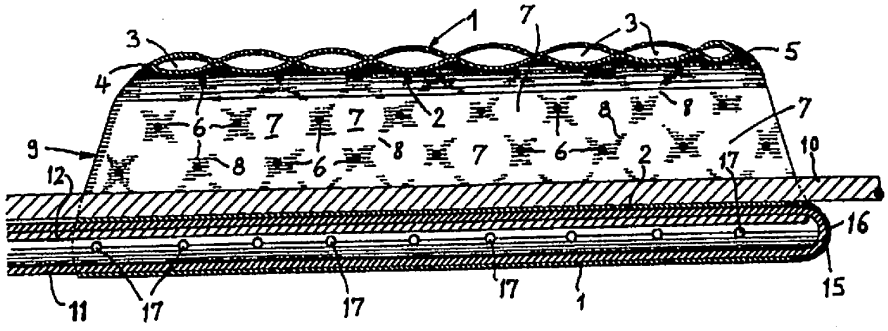
(81) Bestimmungsstaaten: AT (europäisches Patent), AU, BE (europäisches Patent), BG, BR, CH (europäisches Patent), DE (europäisches Patent), DK, FR (europäisches Patent), GB (europäisches Patent), HU, IT (europäisches Patent), JP, LU (europäisches Patent), NL (europäisches Patent), NO, SE (europäisches Patent), SU, US.

Veröffentlicht
Mit internationalem Recherchenbericht.

(54) Title: DILATATION CATHETER WITH EXPANDING BALLOON

(54) Bezeichnung: DILATIONSKATHETER MIT EINEM AUFWEITBAREN BALLON



(57) Abstract

A dilatation catheter is provided with an expanding balloon which can be made to advance into a narrowed coronary artery along a guide wire (10) placed by a guide catheter. An inflation tube (11) is provided for expanding the balloon, which consists of a hose-like outer envelope (1) to which is connected, at the axially oriented edges (4, 5), an inner envelope (2) also having a hose-like shape. Between the inner envelope (2) and the outer envelope (1) is an inner annular space (3) which surrounds an open central lumen (9) extending axially through the balloon and ensures during dilatation a constant flow of blood into the coronary artery.

(57) Zusammenfassung

Ein Dilatationskatheter verfügt über einen aufweitbaren Ballon, der entlang einem durch einen Führungskatheter verlegten Führungsdraht (10) in eine verengte Herzkranzarterie vorschiebbar ist. Zum Aufweiten des Ballons ist ein Inflationstubus (11) vorgesehen. Der Ballon besteht aus einer schlauchförmigen Ballonaußenhülle (1) und einer mit dieser an den in axialer Richtung weisenden Rändern (4, 5) verbundenen schlauchförmigen Balloninnenhülle (2). Zwischen der Balloninnenhülle (2) und der Ballonaußenhülle (1) befindet sich ein ringförmiger Balloninnenraum (3), der ein sich in axialer Richtung durch den Ballon erstreckendes offenes Zentrallumen (9) umgibt, durch das während der Dilatation ein Blut-

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Dilatationskatheter mit einem aufweitbaren Ballon

Die Erfindung betrifft einen Dilatationskatheter mit einem aufweitbaren Ballon, der entlang einem sich durch einen Führungskatheter erstreckenden Führungsdraht in eine verengte Herzkranzarterie vorschiebbar und mit einem Inflationstubus verbunden ist, durch den zum Aufweiten des Ballons ein Medium in den Balloninnenraum eindrückbar ist.

Ein derartiger Dilatationskatheter ist aus der DE-OS 34 42 736 bekannt und dient insbesondere zum Aufweiten von Verengungen in Herzkranzgefäßen. Dazu wird ein Führungskatheter mit weitem Innenlumen von der Leiste oder Ellenbeuge eines Patienten aus durch die großen Körperarterien bis vor den Abgang der Herzkranzgefäße im Aortenbogen vorgeführt, wobei eine radiologische Darstellung des Herzkranzgefäßes und der Einengung unter Durchleuchtung bei intermittierender Kontrastmittelgabe durch den Führungskatheter erfolgt. Zur Führung des einzusetzenden Dilatationskatheters wird durch den Führungskatheter ein feiner Führungsdraht mit einer weichen Spitze in die Herzkranzarterie bis über die Einengung vorgeführt. Ein Steuerung des Führungsdrahtes ist dabei durch eine Drehung bei variabel vorgebogener Spitze möglich.

Der Dilatationskatheter wird in einem nächsten Arbeitsschritt von außen über den Führungsdraht, der als Leitschiene dient, und durch den Führungskatheter vorgeführt, bis der Ballon des Dilatationskatheters in der Einengung liegt. Die Aufweitung erfolgt dann durch ein- oder mehrmaliges Auffüllen des Ballons mit einem Überdruck von etwa 500 bis 1200 kPa. Klinische Erfahrungen haben gezeigt, daß längere Dilatationszeiten zur

Stabilisierung der erweiterten Gefäßeinengung günstiger sind als kürzere Dilatationszeiten. Während der Dilatation wird jedoch beim Einsatz der bekannten Dilatationskatheter der Blutstrom im Gefäß unterbrochen, wobei die Zeit der Unterbrechung des Blutstromes im Herzmuskel 30 bis 120 Sekunden nicht überschreiten sollte.

Wenn unter dem Druck des Ballons die Einengung in der Herzkranzarterie aufgeweitet wird, wird der schichtweise Aufbau der Gefäßwand möglicherweise beschädigt, woraus sich Komplikationen ergeben können. Diese bestehen in einem Verschluß des Gefäßes nach der Erweiterung durch Ablösung und Vorfall der inneren Wandschichten sowie in seltenen Fällen in einer Wandzerreißung mit einer Blutung. Kommt es nach der Dilatation und Entfernung des Ballons zu einer der oben genannten Komplikationen mit Gefäßverschluß so hat dies in einzelnen Fällen einen sofortigen operativen Eingriff und ein erhöhtes Risiko für den Patienten zur Folge. Dilatationen von größeren Koronargefäßen werden daher in akuter Operationsbereitschaft durchgeführt, wodurch sich der organisatorische Aufwand und die Kosten einer Operation unter Einsatz eines Dilatationskatheters wesentlich erhöhen.

Ein weiterer Nachteil der bekannten Dilatationskatheter besteht darin, daß während des Aufweitungsvorgangs der Blutfluß im Gefäß unterbrochen wird, was zur Minderperfusion des nachgeschalteten Gewebes führt.

Ausgehend von diesem Stand der Technik liegt der Erfindung die Aufgabe zugrunde, einen Dilatationskatheter zu schaffen, der es gestattet, während der Dilatation sowie im Falle einer Komplikation einen ausreichenden kontinuierlichen Blutfluß für einen ausreichenden

Zeitraum zu gewährleisten, um eine Verlängerung der Dilatationszeit zu gestatten.

Diese Aufgabe wird erfindungsgemäß dadurch gelöst, daß der Ballon eine schlauchförmige Ballonaußenhülle und eine mit dieser wenigstens an den in axialer Richtung weisenden Rändern verbundene schlauchförmige Ballooninnenhülle aufweist, zwischen denen ein mit einem Inflationstubus verbundener, im Querschnitt im wesentlichen ringförmiger Balloninnenraum ausgebildet ist, der ein in axialer Richtung beidseitig offenes Zentrallumen umgibt.

Dadurch, daß der Balloninnenraum eine Anordnung ringförmiger Schwellkörper mit einem Zentrallumen bildet, wird beim Einsatz des erfindungsgemäßen Dilatationskatheters der Blutstrom im Gefäß während der Dilatation nicht unterbrochen, so daß die Dilatationszeit erheblich verlängert werden kann. Auf diese Weise ist es möglich, eine bessere Stabilisierung der Wand zu erreichen und im Falle einer Komplikation den Zeitraum bis zum operativen Eingriff zu verlängern oder sogar nach einer Stabilisierung der Gefäßwand auf einen operativen Eingriff zu verzichten.

Bei einem zweckmäßigen Ausführungsbeispiel der Erfindung sind die Ballonaußenhülle und die Balloninnenhülle an einer Vielzahl von Punkten in der Art einer Steppung miteinander verbunden, um eine Vielzahl von kissenförmigen Schwellkörpern zu bilden, die nach dem Einspritzen eines Gases oder einer Flüssigkeit dem mit einem Zentrallumen versehenen röhrenartigen oder schlauchartigen Dilatationskatheter eine ausreichend hohe Steifigkeit und Dilatationskraft verleihen.

Zweckmäßige Ausgestaltungen und Weiterbildungen der Erfindung sind in den Unteransprüchen gekennzeichnet.

Nachfolgend wird ein Ausführungsbeispiel der Erfindung anhand eines in der Zeichnung dargestellten Ausführungsbeispiels näher beschrieben. Es zeigen:

Fig. 1 einen Dilatationskatheter gemäß der Erfindung im Längsschnitt und

Fig. 2 einen Dilatationskatheter gemäß der Erfindung im Querschnitt.

Der in Fig. 1 im Längsschnitt und in Fig. 2 im Querschnitt dargestellte doppelwandige Dilatationskatheter verfügt über eine Ballonaußenhülle 1, die je nach Bedarf aus einem elastischen oder nicht elastischen Material hergestellt ist und im wesentlichen einen äußeren Schlauch für den doppelwandigen Dilatationskatheter bildet. In etwa konzentrisch zur Ballonaußenhülle 1 ist eine Balloninnenhülle 2 vorgesehen, die je nach Bedarf aus einem elastischen oder nicht elastischen Material besteht. Die Balloninnenhülle 2 ist ebenfalls im wesentlichen schlauchförmig, wobei zwischen der Ballonaußenhülle 1 und der Balloninnenhülle 2 ein Balloninnenraum 3 gebildet ist, der beispielsweise als Ringspalt zwischen der Ballonaußenhülle 1 und der Balloninnenhülle 2 ausgebildet sein kann. Die Ballonaußenhülle 1 und die Balloninnenhülle 2 sind an ihren axialen Rändern 4, 5 miteinander verklebt oder verschweißt, so daß der Balloninnenraum 3 in axialer Richtung abgeschlossen ist.

Der auf diese Weise durch die Ballonaußenhülle 1 größeren Durchmessers und die Balloninnenhülle 2 kleineren Durchmessers gebildete rohrförmige oder schlauchförmige Ballon kann in seiner Struktur beispielsweise durch mehrere sich in axialer und/oder radialer Richtung erstreckende Verklebungen oder Verschweißungen zwischen der Ballonaußenhülle 1 und der Balloninnenhülle 2 fixiert und stabilisiert werden.

Bei dem in den Figuren 1 und 2 dargestellten Ausführungsbeispiel ist der durch die Ballonaußenhülle 1 und die Balloninnenhülle 2 gebildete rohrförmige Ballon in der Art einer Steppung durch eine Vielzahl von Punktverbindungen 6 strukturiert. An den Punktverbindungen 6 zwischen der Ballonaußenhülle 1 und der Balloninnenhülle 2 können diese miteinander verklebt oder miteinander verschweißt sein. Auf diese Weise entstehen Schwellkörper in Gestalt kissenförmiger Unterteilungen 7 des Balloninnenraums 3, wobei die einzelnen kissenförmigen Unterteilungen 7 jeweils über verbindungsfreie Bereiche 8 miteinander in Verbindung stehen, so daß eine zum Aufweiten des doppelwandigen Dilatationskatheters verwendete Flüssigkeit oder Gas zwischen den kissenförmigen Unterteilungen 7 des Balloninnenraums 3 kommunizieren kann, d.h. über die verbindungsfreien Bereiche 8 in alle kissenförmige Unterteilungen 7 des Balloninnenraums 3 vordringen kann. Die nach außen weisende Seite des ringförmigen Ballons des Dilatationskatheters und die nach innen weisende Seite des Ballons sind daher im aufgeweiteten Zustand in ihrer Oberflächenstruktur ähnlich einer Steppdecke ausgebildet. Aufgrund des Innendruckes im Balloninnenraum 3, der in allen kissenförmigen Unterteilungen 7 im stationären Zustand gleich ist, bildet der Ballon mit seiner Ballonaußenhülle 1 und seiner Balloninnenhülle 2 eine

rohrartige Struktur oder die Struktur eines doppelwandigen Rohrs. Hierdurch ergibt sich eine mechanische Festigkeit und eine besondere Eigenstabilität, obwohl die Balloninnenhülle 2 ein Zentrallumen 9 offenläßt, das sich in axialer Richtung durch den Dilatationskatheter erstreckt und im aufgeweiteten Zustand des Dilatationskatheters einen Blutdurchfluß durch das aufgeweitete Gefäß gestattet.

Wie man in den Fig. 1 und 2 erkennt, erstreckt sich durch das Zentrallumen 9 ein Führungsdraht 10, der als Gleitschiene oder Leitschiene dient und entlang dem der Ballon des Dilatationskatheters durch einen üblichen schlauchartigen Führungskatheter hindurch bis zum Ort des gewünschten Eingriffs in der Herzkranzartherie vorgeschoben werden kann. Dabei ist der Balloninnenraum 3 vorzugsweise während des Vorschiebens noch nicht mit einem Füllmedium gefüllt, so daß die radiale Abmessung des Ballons des Dilatationskatheters und des Zentrallumens 9 bis zum Erreichen des Operationsortes kleiner sind als in den Figuren 1 und 2 dargestellt ist.

Wie man in den Figuren 1 und 2 erkennt, ragt ein Inflationstubus 11 exzentrisch in den Ballon des Dilatationskatheters hinein. Der Inflationstubus 11 ist versteift und überträgt innerhalb des in der Zeichnung nicht dargestellten Führungskatheters in axialer Richtung die zum Vorschieben und Zurückziehen des Ballons erforderlichen Kräfte. Zur Versteifung und zur Erhöhung der Knickfestigkeit kann im Innern des Inflationstubus 11 ein Stabilisierungsdraht 12 vorgesehen sein, der in den Fig. 1 und 2 dargestellt ist.

Der Inflationstubus 11 erstreckt sich vorzugsweise in axialer Richtung ausgehend von einem Ende 5 bis zum gegenüberliegenden Ende 4 der Balloninnenhülle 1 sowie der Ballonaußenhülle 2 und von dort über die erforderliche Länge zum Anschluß für das Füllmedium. Auf beiden Seiten neben dem Inflationstubus 11 sind im axialen Abstand mehrere miteinander fluchtende Punktverbindungen 6 vorgesehen, durch die die Lage des Inflationstubus 11 in der in Fig. 2 erkennbaren Weise im ringförmigen Zwischenraum zwischen der Ballonaußenhülle 1 und der Balloninnenhülle 2 fixiert ist. Außerdem kann der Inflationstubus 11 entlang den Berührungslinien 13, 14 mit der Ballonaußenhülle 1 und der Balloninnenhülle 2 verklebt oder verschweißt sein.

Auf der in Fig. 1 linken Seite ist der Inflationstubus 11 in einer in Fig. 1 nicht näher dargestellten Weise in Umfangsrichtung entlang seiner Außenfläche mit dem Dilatationskatheter verbunden, um den Balloninnenraum 3 nach außen hin abzudichten. Auf der in Fig. 1 rechten Seite ist der Inflationstubus 11 an seinem vorderen Ende 15 verschlossen. Entlang dem vorderen Ende 15 ist eine Verbindungswulst 16 vorgesehen, durch die Ballonaußenhülle 1 und die Balloninnehülle 2 zur Abdichtung des Balloninnenraums 3 miteinander verbunden sind.

In den Fig. 1 und 2 erkennt man, daß der Inflationstubus 11 über eine Vielzahl von Öffnungen 17 mit dem Balloninnenraum 3 in Verbindung steht, so daß ein in den Inflationstubus 11 eingepreßtes Füllmedium in die kissenförmigen Unterteilungen 7 gelangen kann, um auf diese Weise den im entleerten Zustand zusammengefalteten rohrförmigen Ballon aufzuweiten und steif werden zu lassen.

Wenn die Balloninnenhülle 2 aus elastischem Material besteht und die Ballonaußenhülle 1 aus einem nicht elastischen Material, so bewirkt dies, daß der Außendurchmesser des Ballons des Dilatationskatheters vom Druck des Füllmediums im wesentlichen unabhängig ist. Auf diese Weise wirkt die Ballonaußenhülle 1 als Haltemembran. Die elastische Balloninnenhülle 2 könnte im nicht gefüllten Zustand sehr klein sein (kleine Oberfläche) und bei der Entleerung des Ballons durch elastische Rückstellkräfte eine wesentliche Durchmesserverkleinerung bewirken. Auf diese Weise ergibt sich eine besonders leichte Passage des Dilatationskatheters beim Vorschieben oder Zurückziehen durch den Führungskatheter und/oder das jeweilige Gefäß.

Wenn statt der Balloninnenhülle 2 nur die Ballonaußenhülle 1 aus einem elastischen Material hergestellt ist, kann die Ballonweite in Abhängigkeit vom Fülldruck des Füllmediums verändert werden, wobei die Querschnittsfläche des Zentrallumens 9 bei gefülltem Ballon im wesentlichen konstant bleibt.

Wenn sowohl die Ballonaußenhülle 1 als auch die Balloninnenhülle 2 aus elastischem Material hergestellt sind, bewirkt eine Zunahme des Fülldrucks des Füllmediums überwiegend eine Dehnung der äußeren Membran, d.h. der Ballonaußenhülle 1.

Als Füllmedium können infolge des besonders kleinen Volumens des Balloninnenraums 3 schnell resorbierbare Gase wie CO_2 und N_2O statt Flüssigkeiten benutzt werden. Während beim Platzen des Ballons des Dilatationskatheters Luftmengen von z.B. 1/10 mm^3 zu Schäden führen, werden kleine Mengen N_2O oder CO_2 von weniger

als 1/10 mm^3 schnell resorbiert und führen kaum zu Schäden. Dies ermöglicht es, das Lumen im Inflationstubus 11 extrem klein zu halten. Falls dies erwünscht ist, gestattet es der oben erörterte Aufbau des Dilatationskatheters, eine nur geringe Druckwirkung auf das umgebende Gewebe auszuüben. Hieraus ergibt sich, daß der Einsatz des Dilatationskatheters mit einem doppelwandigem ringförmigen Ballon besonders dann sinnvoll ist, wenn höhere Drücke nicht erforderlich sind. Dies ist der Fall bei nicht verkalkten Gefäßeinengungen und bei Stenosen, die mit Hilfe eines konventionellen Ballonkatheters bereits aufgeweitet worden sind, und zwar insbesondere dann, wenn beim Einsatz eines kein Zentrallumen aufweisenden üblichen Ballonkatheters Komplikationen aufgetreten sind. In einem solchen Fall ist es möglich, den oben beschriebenen Dilatationskatheter schnell gegen den vorher benutzten einwandigen Ballonkatheter auszuwechseln, um Komplikationen zu vermeiden oder bei eingetretenen Komplikationen eine Stabilisierung dauerhaft oder bis zum operativen Eingriff zu erreichen.

PATENTANSPRÜCHE

1. Dilatationskatheter mit einem aufweitbaren Ballon, der entlang einem sich durch einen Führungskatheter erstreckenden Führungsdraht in eine verengte Herzkranzarterie vorschiebbar und mit einem Inflationstubus verbunden ist, durch den zum Aufweiten des Ballons ein Medium in den Balloninnenraum eindrückbar ist, dadurch gekennzeichnet, daß der Ballon eine schlauchförmige Ballonaußenhülle (1) und eine mit dieser wenigstens an den in axialer Richtung weisenden Rändern (4, 5) verbundene schlauchförmige Balloninnenhülle (2) aufweist, zwischen denen ein mit einem Inflationstubus (11) verbundener, im Querschnitt im wesentlichen ringförmiger Balloninnenraum (3) ausgebildet ist, der ein in axialer Richtung beidseitig offenes Zentrallumen (9) umgibt.

2. Dilatationskatheter nach Anspruch 1, dadurch gekennzeichnet, daß sich der Führungsdraht (10) durch das Zentrallumen (9) im Ballon erstreckt.

3. Dilatationskatheter nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß der Inflationstubus (11) durch eine sich in Längsrichtung erstreckende Stabilisierung (12) versteift ist.

4. Dilatationskatheter nach Anspruch 3, dadurch gekennzeichnet, daß die Stabilisierung durch einen Stabilisierungsdraht (12) realisiert ist.

5. Dilatationskatheter nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß der Inflationstubus (11) den Balloninnenraum (3) in axialer Richtung durchquert und über mehrere in den Balloninnenraum (3) mündende Öffnungen (17) verfügt.

6. Dilatationskatheter nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß der Inflationstubus (11) an der Eintrittsstelle in den Balloninnenraum (3) nach außen abgedichtet ist.

7. Dilatationskatheter nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Balloninnenhülle (2) und die Ballonaußenhülle (1) entlang mehreren sich in axialer Richtung erstreckenden unterbrochenen Linien miteinander verbunden sind.

8. Dilatationskatheter nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Balloninnenhülle (2) und die Ballonaußenhülle (1) an einer Vielzahl von Punkten (6) in der Art einer Steppung miteinander verbunden sind.

9. Dilatationskatheter nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß die Ballonaußenhülle (1) und die Balloninnenhülle (2) aus nichtelastischem Material bestehen.

10. Dilatationskatheter nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß die Ballonaußenhülle (1) und die Balloninnenhülle (2) aus elastischem Material bestehen.

11. Dilatationskatheter nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß die Ballonaußenhülle (1) aus einem elastischem und die Balloninnenhülle (2) aus einem nichtelastischem Material besteht.

12. Dilatationskatheter nach Anspruch 7 oder 8, dadurch gekennzeichnet, daß die Ballonaußenhülle (1) aus einem nichtelastischen und die Balloninnenhülle (2) aus einem elastischen Material besteht.

13. Dilatationskatheter nach einem der vorstehenden Ansprüche, dadurch gekennzeichnet, daß die in axialer Richtung weisenden Ränder (4, 5) schräg gegenüber der Längsachse des Inflationstubus (11) verlaufen, wobei die axiale Länge der Ballonhülle an der freien, dem Inflationstubus (11) gegenüberliegenden Wand kleiner ist als an der mit dem Inflationstubus (11) verbundenen Wand.

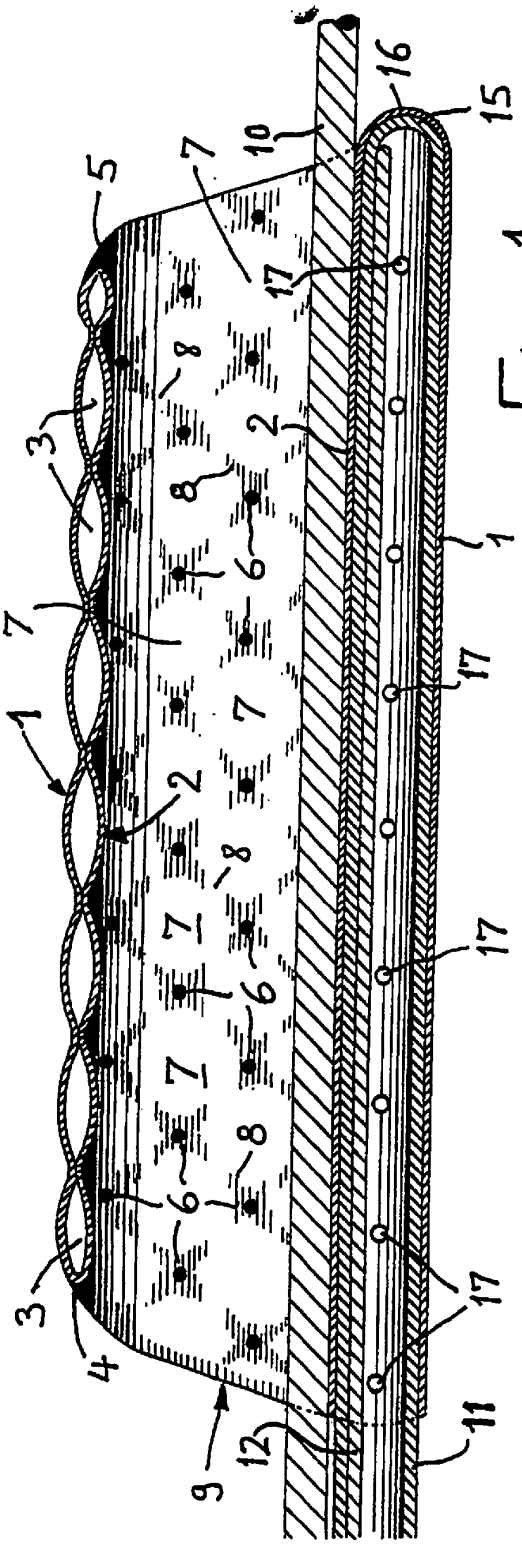

Fig. 1

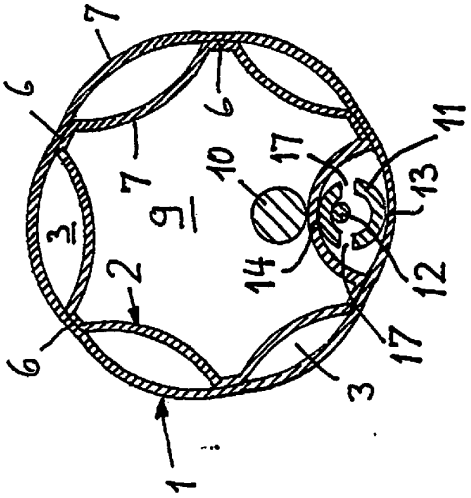

Fig. 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/DE 87/00264

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.[4] A 61 M 29/02

II. FIELDS SEARCHED

Classification System	Minimum Documentation Searched [7] Classification Symbols
Int.Cl.[4]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with Indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US, A, 4141364 (SCHULTZE) 27 February 1979 see column 4, line 44 - column 5, line 14; figures 6-9	1-8,10
Y	DE, A, 3442736 (BONZEL) 05 June 1986 see description; figures cited in the application	1-8,10
A	US, A, 4403612 (FOGARTY) 13 September 1983 see column 2, lines 32-35	9,11
A	GB, A, 2077111 (BROWN) 16 December 1981 see abstract; figures	5,6

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
09 August 1987 (09.08.87)	12 October 1987 (12.10.87)
International Searching Authority	**Signature of Authorized Officer**
European Patent Office	

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/DE 87/00264 (SA 17424)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 23/09/87

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A- 4141364	27/02/79	None		
DE-A- 3442736	05/06/86	WO-A-	8603129	05/06/86
		EP-A-	0203945	10/12/86
US-A- 4403612	13/09/83	US-A-	4338942	13/07/82
GB-A- 2077111	16/12/81	FR-A,B	2483773	11/12/81

For more details about this annex :
see Official Journal of the European Patent Office, No. 12/82

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen PCT/DE 87/00264

I. KLASSIFIKATION DES ANMELDUNGSGEGENSTANDS (bei mehreren Klassifikationssymbolen sind alle anzugeben)[6]

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

Int. Cl.4 A 61 M 29/02

II. RECHERCHIERTE SACHGEBIETE

Recherchierter Mindestprüfstoff[7]

Klassifikationssystem	Klassifikationssymbole
Int. Cl.4	A 61 M

Recherchierte nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Sachgebiete fallen[8]

III. EINSCHLÄGIGE VERÖFFENTLICHUNGEN[9]

Art*	Kennzeichnung der Veröffentlichung[11], soweit erforderlich unter Angabe der maßgeblichen Teile[12]	Betr. Anspruch Nr.[13]
Y	US, A, 4141364 (SCHULTZE) 27. Februar 1979 siehe Spalte 4, Zeile 44 - Spalte 5, Zeile 14; Figuren 6-9 --	1-8,10
Y	DE, A, 3442736 (BONZEL) 5. Juni 1986 siehe Beschreibung; Figuren in der Anmeldung erwähnt --	1-8,10
A	US, A, 4403612 (FOGARTY) 13. September 1983 siehe Spalte 2, Zeilen 32-35 --	9,11
A	GB, A, 2077111 (BROWN) 16. Dezember 1981 siehe Zusammenfassung; Figuren	5,6

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* Besondere Kategorien von angegebenen Veröffentlichungen[10]:

"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist

"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist

"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)

"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht

"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist

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"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden

"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist

"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

IV. BESCHEINIGUNG

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
9. August 1987	12 OCT 1987
Internationale Recherchenbehörde: Europäisches Patentamt	Unterschrift des bevollmächtigten Bediensteten: M. VAN MOL

Formblatt PCT/ISA/210 (Blatt 2) (Januar 1985)

ANHANG ZUM INTERNATIONALEN RECHERCHENBERICHT ÜBER DIE

INTERNATIONALE PATENTANMELDUNG NR. PCT/DE 87/00264 (SA 17424)

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben. Die Angaben über die Familienmitglieder entsprechen dem Stand der Datei des Europäischen Patentamts am 23/09/87

Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
US-A- 4141364	27/02/79	Keine		
DE-A- 3442736	05/06/86	WO-A-	8603129	05/06/86
		EP-A-	0203945	10/12/86
US-A- 4403612	13/09/83	US-A-	4338942	13/07/82
GB-A- 2077111	16/12/81	FR-A,B	2483773	11/12/81

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 380 873 A2**

(12) **EUROPEAN PATENT APPLICATION**

(21) Application number: **89312612.8**

(51) Int. Cl.5: **A61M 29/02**

(22) Date of filing: **04.12.89**

(30) Priority: **30.01.89 US 303803**

(43) Date of publication of application:
08.08.90 Bulletin 90/32

(84) Designated Contracting States:
BE DE ES FR GB IT NL

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(54) **Rapidly exchangeable coronary catheter.**

(57) A rapidly exchangeable catheter for use in the coronary arteries includes an elongate relatively stiff proximal segment that defines an inflation lumen, an intermediate, shorter segment formed from a more flexible plastic material and having two lumens, and a third, single lumen distal segment. A balloon or other instrumentality adapted to operate in a coronary artery is mounted to the distal region of the catheter. The intermediate and distal segments include a guidewire lumen by which the catheter may be advanced along a guidewire. The proximal segment may include an inflation lumen when the operating instrumentality at the distal end of the catheter is a balloon. The intermediate and distal segments of the catheter are of a length of between about 35 to 45 cm such that when the catheter is advanced into the most remote distal portions of the coronary anatomy, the flexible plastic intermediate and distal segments will extend over the aortic arch of the patient thereby containing the guidewire over the aortic arch and maintaining the juncture of the relatively stiff proximal segment and the more flexible intermediate segment proximally of the aortic arch. The relatively stiff proximal section thus extends generally along a straight line from the femoral artery into the descending aorta but not so far as into the aortic arch. Buckling of the catheter is avoided so that the catheter is more easily manipulated.

EP 0 380 873 A2

RAPIDLY EXCHANGEABLE CORONARY CATHETER

FIELD OF THE INVENTION

This invention relates to balloon dilatation catheters and particularly to such catheters as are used in percutaneous transluminal coronary angioplasty.

BACKGROUND OF THE INVENTION

Dilatation catheters, and particularly, those used for percutaneous transluminal coronary angioplasty (PTCA), typically include an elongate flexible shaft of the order of 150 cm long having a dilatation balloon mounted to the distal end of the shaft and an inflation lumen extending longitudinally within the shaft from its proximal end to the interior of the balloon so that the balloon may be inflated and deflated. Typically, such PTCA catheters also are provided with a full length guidewire lumen that is open at the distal tip of the shaft at a distal outlet opening. The proximal end of the guidewire lumen is open at the proximal end of the catheter. The guidewire lumen receives a guidewire which, when the guidewire and catheter are placed within a patient's artery, can be manipulated to guide the wire and catheter to the desired branch of the patient's arteries.

Typically, the balloon dilatation catheter and guidewire are guided to the entrance to the coronary arteries by a previously placed guide catheter. The guide catheter commonly is percutaneously inserted into the patient's femoral artery and is advanced along the aorta toward the heart. The guide catheter typically is provided with a preshaped distal tip adapted to remain at the coronary ostium leading to the coronary artery. Once placed, the guide catheter provides direct, quick access to the entrance to the coronary arteries.

It is common during a PTCA procedure for the physician to exchange the balloon catheter for another catheter, for example, if it is desired to change balloon sizes. This may occur, for example, if the physician initially performed a partial dilatation with a small diameter balloon and then wished to further dilate the patient's artery by using a catheter having a larger balloon. Such a catheter exchange may be accomplished in several ways. In one technique, the conventional guidewire which may be approximately 175 cm long is removed from the in situ balloon catheter and is replaced with a longer exchange wire, typically about 300 cm long. The length of the exchange wire that extends out of the patient is greater than the length of the balloon catheter thus providing a means by which the guidewire may be grasped at all times to prevent inadvertent withdrawal of the guidewire as the catheter is withdrawn. Once the catheter is withdrawn over the exchange wire, the next catheter can be threaded over the exchange wire and inserted into the patient, the exchange wire providing a direct path to guide the catheter to the portion of the artery to be dilated. If desired, the exchange wire then may be removed and replaced with a shorter conventional wire, although some physicians may prefer to permit the exchange wire to remain in place for the remainder of the procedure.

Another technique omits the necessity for an exchange wire by providing a guidewire extension that is attached to the proximal end of the guidewire thereby effectively extending the length of the guidewire that protrudes out of a patient sufficiently to permit the catheter to be withdrawn and a new catheter to be threaded back into the patient without losing guidewire position.

Still another technique for performing a catheter exchange is that described in "New Instruments for Catheterization and Angiocardiography" by Bjorn Nordenstrom, Radiology, Vol. 85, 1965, pp. 256-259, which describes a catheter having a relatively short guidewire lumen at the distal end of the catheter, the guidewire lumen having a proximal terminal opening located distally of the proximal end of the catheter shaft. In this arrangement, the guidewire passes through the catheter shaft only for a segment of the length of the shaft. The catheter can be moved along the guidewire in the fashion of a "monorail". Because the guidewire lumen is relatively short and is considerably shorter than the overall length of the catheter, the catheter can be withdrawn from the patient over the original guidewire without dragging the guidewire out of the artery together with the catheter because the length of guidewire protruding from the patient is longer than the length of the guidewire lumen of the catheter. Thus, a portion of the guidewire is exposed at all times and may be grasped by the physician. Such a monorail system has recently been incorporated into PTCA catheters as illustrated, for example, in U.S. Patent Nos. 4,762,129 (Bonzel) and 4,748,982 (Horzewski).

Although the use of the monorail system facilitates catheter exchanges, the PTCA catheters in which the monorail system have been incorporated have presented some difficulties. One of the problems presented is that because the guidewire only extends through a relatively small portion of the overall length of the catheter, the remaining portion

of the catheter shaft is unsupported by the guidewire. When the balloon catheter and guidewire are advanced through the guide catheter by pushing the catheter shaft, the unsupported portion of the catheter shaft tends to buckle within the guide catheter. Buckling of the catheter shaft within the guide catheter increases the number and area of points of contact between the catheter shaft and the inner surface of the guide catheter lumen, thus increasing friction and causing the balloon catheter to bind up in the guide catheter and impairing the ability of the catheter to be pushed along the guidewire. The tendency to become bound up in the guide catheter increases with the extent to which the catheter is advanced through the guide catheter and prevents the catheter from being advanced into distal coronary vasculature. The tendency for the dilatation catheter shaft to buckle is particularly acute in the region of the aortic arch.

It is among the general objects of the invention to provide an improved PTCA catheter having a rapid exchange feature which avoids the foregoing and other difficulties.

SUMMARY OF THE INVENTION

The catheter of the present invention is formed from a composite shaft that includes an elongate proximal segment formed from a relatively stiff metal tube and defining an inflation lumen, an intermediate, shorter segment formed from a more flexible, plastic material and having two lumens, and a third single lumen distal segment. The intermediate segment includes an inflation lumen that is a continuation of the inflation lumen of the proximal segment and a second, parallel guidewire lumen. The third, distal tubular segment is formed from flexible plastic material and has a single lumen which is a continuation of the guidewire lumen in the intermediate segment and opens at a distal outlet tip. The dilatation balloon is mounted on the distal end of the catheter with its proximal end mounted to the intermediate segment and its distal end mounted to the distal segment. The guidewire lumen has a proximal opening proximally of the balloon and communicates with the lumen of the distal segment and distal outlet opening distally of the balloon.

The intermediate and distal segments are of a combined length, between about 35 cm to 45 cm, such that with the catheter advanced into the most remote distal portions of the coronary anatomy, the flexible plastic intermediate segment will extend over the aortic arch of the patient. The juncture of the relatively stiff proximal segment and the more flexible intermediate segment thus remains proximally of the aortic arch so that the relatively stiff elongate proximal section extends generally along a straight line from the femoral artery into the descending aorta, but not so far as into the aortic arch. The moderately flexible proximal segment is sufficiently stiff and is self-supporting so that it will not buckle in the guide catheter as the catheter is pushed in a distal direction. Additionally, the intermediate and distal segments of the catheter are fully supported by the guidewire that extends through the guidewire lumen and thereby provides substantial support for the intermediate and distal segments of the catheter. The catheter construction does not tend to bind up within the guide catheter and thereby facilitates advancement of the distal balloon end of the catheter into more distal regions of a patient's coronary anatomy. Moreover, because the cross-section of the metal tubular proximal segment is relatively small, it presents reduced obstruction through the guide catheter to a flow of radiopaque contrast liquid and, thereby, makes it easier for the physician to inject contrast liquid into the patient's coronary arteries in order to visualize them fluoroscopically.

It is among the general objects of the invention to provide an improved rapidly exchangeable balloon dilatation catheter.

Another object of the invention is to provide a rapidly exchangeable balloon dilatation catheter which is provided with axial support along the full length of the catheter.

Another object of the invention is to provide a rapidly exchangeable catheter having a relatively flexible distal portion that receives a guidewire and is of sufficient length that it can extend from the distal coronary anatomy over the aortic arch and into the descending aorta.

A further object of the invention is to provide a rapidly exchangeable catheter having an elongate moderately flexible self supporting proximal section and at least one distal section that is more flexible and has a guidewire lumen extending therethrough whereby the guidewire may support said distal segments.

A further object of the invention is to provide a rapidly exchangeable catheter which has a reduced tendency to buckle within the guide catheter.

Another object of the invention is to provide a rapidly exchangeable catheter which provides reduced friction in the guide catheter.

A further object of the invention is to provide a rapidly exchangeable catheter which better enables the physician to advance the distal end of the catheter into the distal coronary anatomy of a patient.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a fragmented illustration of the catheter:

FIG. 2 is an enlarged illustration of the catheter;

FIG. 3 is a diagrammatic illustration of a patient showing the manner in which a balloon catheter is advanced from the femoral artery through the aorta to the patient's heart;

FIG. 4 is an illustration of the aorta leading from the heart and coronary arteries with a guide catheter in place and the catheter of the present invention extending through the guide catheter;

FIG. 5 is a cross-sectional illustration of the two lumen segment of the intermediate segment of the catheter as seen along the line 5-5 of FIG. 2;

FIG. 6 is an enlarged illustration of the proximal end of the balloon and its point of attachment to the intermediate segment;

FIG. 7 is a sectional longitudinal illustration of the catheter in the region where the proximal metal tubular segment is joined to the intermediate more flexible plastic segment; and

FIG. 8 is an enlarged longitudinal sectional illustration of the distal end of the catheter showing the balloon and the manner of its attachment to the intermediate and distal segments.

DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENT

FIG. 3 illustrates, diagrammatically, a conventional over-the-wire balloon dilatation catheter 10 and a guidewire 12 inserted into the patient's vasculature through a guide catheter 14. The guide catheter 14 is initially placed, percutaneously, into the patient's femoral artery 16 and is advanced along the descending aorta 18 over the aortic arch 20 and into the ascending aorta 22 that leads from the heart 24. As will be appreciated by those skilled in the art, the distal end of the guide catheter is specially shaped so that the distal tip 23 of the guide catheter will easily lodge in the entrance to the right 25 or left 27 coronary artery (see FIG. 4).

When it is desired to exchange the balloon catheter 10 for another, it is important that the guidewire 12 be maintained within the patient's artery so that it may guide the next succeeding catheter quickly and efficiently to the intended site in the patient's vascular system. Typically, the clearances between the guidewire 12 and the inner lumen of the catheter 10, coupled with the bends which the catheter 10 and guidewire 12 must follow along the patient's artery are such that withdrawal of the catheter 10 tends to drag the guidewire 12 out with the catheter 10. In order to maintain the guidewire 12 in place while the catheter 10 is withdrawn, it is necessary to hold the guidewire 12 by its proximal end while withdrawing the catheter 10 over the guidewire 12.

Among the techniques for facilitating a catheter exchange is the use of a monorail-type of catheter in which the guidewire lumen in the catheter extends only over a relatively short length of the catheter at the distal end of the catheter. Because the guidewire lumen is shorter than the portion of the guidewire that protrudes out of the patient, some part of the guidewire is always exposed and may be grasped to maintain guidewire position. With the monorail system, it is unnecessary to use exchange wires or other devices to increase the effective length of the guidewire in order to perform a catheter exchange.

FIG. 2 is a fragmented illustration of a catheter in accordance with the invention. The catheter 26 includes an elongate proximal segment 28 which is formed from metallic hypodermic tubing, preferably stainless steel. The proximal segment may be of the order of 100 to 110 cm long. The tubing 28 may be of the order of 0.022" outer diameter with a wall thickness of about 0.003". The catheter 26 also includes an intermediate segment 30 attached at its proximal end to the distal end of the metal tube 28 and being shorter in length than the metal tube 28. The catheter also includes a distal segment 32 (FIGS. 2 and 8) attached to the distal end of the intermediate segment 30. A dilatation balloon 34 is mounted on the distal segment 32 as will be described. The metallic tubular proximal segment 28 defines a lumen 36 (FIG. 7) that extends fully through its length. A luer fitting 38 is attached to the proximal end of the tubing 28 to connect the lumen 36 with an inflation/deflation device, such as a syringe (not shown). The lumen 36 communicates with a lumen 40 in the intermediate segment 30. The lumen 40 terminates at a port 42 disposed within the balloon 34. Thus, the balloon 34 may be inflated and deflated through the inflation/deflation lumens 36, 40 in the metal tube 28 and intermediate segment 30, respectively.

As will be described, the metal tubular segment 28 provides for a high degree of column strength and enables the catheter to be pushed from its proximal end without buckling. The metal tube 28 may be coated with a thin film of lubricious material, such as Teflon, polytetrafluoroethylene.

The flexible plastic intermediate segment 30 may be an extruded tube of suitable plastic such as high density polyethylene. The intermediate segment 30 may be of the order of .045 inches outer diameter. The length of the intermediate segment 30 is between about 30 to 40 cm for reasons discussed below. The intermediate segment 30 has two lumens including the inflation lumen 40 which may be somewhat D-shaped as illustrated in FIG. 5. The other lumen 44 may be circular as shown in FIG. 5 and is adapted to receive the guidewire 12. The guidewire lumen 44 may be of the order of .020 inches diameter. The guidewire lumen terminates in a proximal opening 46 so that the guidewire is exposed proximally of the intermediate segment 30. Thus, the guidewire may extend within the guide catheter 14 in parallel to and outside of the proximal segment 28.

The distal segment 32 of the catheter is formed from a separate length of single lumen tubing which may be extruded from a relatively flexible plastic material such as low density polyethylene. The distal segment 32 is circular in cross-section and has a circular lumen 48 FIG. 6 which is an extension of the guidewire lumen 44 in the intermediate segment 30. The distal tip of the distal segment 32 is open at a distal outlet orifice 33 FIG. 8. The distal segment 32 may be attached by fusing its proximal end to the distal end of the intermediate segment 30 while maintaining continuation of the guidewire lumen 44, 48 and the opening 42 of the inflation lumen 40 by inserting mandrels in those lumens during the fusion process. A highly radiopaque marker band preferably is mounted on the distal segment 32 and is encapsulated in an overlying thin polyethylene sleeve 37, the sleeve 37 extending proximally over the joint 39 between the intermediate segment 30 and distal segment 32. The sleeve 37 also is heat fused to the shaft. The distal segment 32 may have a wall thickness of the order of .0035 inches thereby making it more flexible than the more massive intermediate segment 30. A radiopaque marker band 35 formed from an appropriate radiopaque material, such as gold or platinum, may be mounted on the distal segment 32.

The balloon 34 is mounted on the distal region of the catheter. The balloon 34 may be formed from a suitably flexible strong and relatively inelastic material such as polyethylene terephthalate. The balloon may be formed in a procedure described in U.S. Patent No. 4,490,421 to Levy. The balloon may be of the order of 20 mm long and may have a balloon diameter when inflated of from about 1.5 mm to 4.0 mm. The wall thickness may be of the order of 0.0005" to 0.001". The balloon includes an elongate cylindrical portion having integral tapering conical sections 49, 51 at each of its proximal and distal ends. Each of the conical sections merges into a small diameter cylindrical neck, the neck 52 at the proximal end of the balloon being larger in diameter than the neck 54 at the distal end. The proximal neck 52 is mounted on the distal region of the intermediate segment 30 and the distal neck 54 is mounted on the distal portion of the distal segment 32. The neck portions 52, 54 are securely bonded to the intermediate and distal segments 30, 32, respectively, by an appropriate adhesive such as an epoxy.

The manner in which the catheter of the present invention is used will be appreciated from FIGS. 3 and 4. In a typical procedure, the femoral artery 16 is accessed percutaneously by a hollow needle. After inserting the needle into the femoral artery, a relatively large diameter guidewire (about 0.038" diameter) is advanced through the needle and into the femoral artery. The needle is removed and an introducer sheath and dilator are placed inside the artery. The dilator is then removed. The guide catheter is inserted over the guidewire and is advanced along with the guidewire to the ascending aorta when the .038" guidewire is removed. The distal end of the guide catheter 14 is shaped specially to be easily inserted into the entrance of one of the two coronary ostia to access either the right or left main coronary arteries. FIG. 4 illustrates a guide catheter 14 seated in the left coronary ostium. Once the guide catheter is in place, the 0.038" guidewire may be removed. The guide catheter 14 then is ready to receive the dilatation catheter and its small diameter (e.g., .010"-.018" diameter) guidewire.

In placing the small diameter steerable guidewire 12 and the conventional over the wire balloon dilatation catheter 10, it is conventional practice to first assemble the guidewire 12 with the balloon catheter 10 and then pass them both in unison through the guide catheter. Alternately, with the present invention, the guidewire 12 may be inserted through the guide catheter by itself. The guidewire is advanced to the coronary ostium and then may be further advanced into the coronary arteries. The guidewire may be of the type described in U.S. Patent 4,545,390 to Leary and may be steerable so that it can be manipulated and guided to the desired branch of the coronary arteries to be treated. The progress of the guidewire through the patient's coronary arteries may be monitored fluoroscopically by the physician. The physician also may inject radiopaque contrast liquid through the guide catheter to visualize the coronary anatomy on the fluoroscope. Once the guidewire 12 has been advanced through the stenosis to be treated, the balloon catheter 26 of the present invention is advanced over the guidewire 12 and within the guide catheter 14. The

catheter 26 will track smoothly and easily along the guidewire with no significant tendency to buckle. This results from the relatively stiff, pushable nature of the elongate metal tubular proximal segment 28 of the catheter. Additionally, the intermediate and distal segments 30, 32 are supported by the guidewire 12 which provides significant resistance to buckling of the intermediate and distal segments 30, 32. It will be appreciated, therefore, that when the catheter 26 is advanced over the guidewire, the catheter will have significant axial, column support fully along its length. In this regard, it is important to note that the proximal end of the guidewire lumen 44 in the intermediate segment 30 overlaps longitudinally, the distal end of the metal tubular proximal segment 28 that is embedded in the proximal end of the intermediate segment 30. Thus, when the catheter is advanced over the guidewire 12, there is column support fully along the length of the catheter, from its proximal to its distal end. As a result, there is considerably reduced tendency for any portion of the catheter to buckle longitudinally. Consequently, the friction between the balloon dilatation catheter 26 and the guide catheter 14 is substantially reduced thereby enabling the distal end of the catheter to be advanced into distal, remote and tortuous regions of the patient's coronary anatomy.

In order to better grasp the proximal end of the catheter to push it through the guide catheter, a gripping device 56 may be mounted on the proximal segment 28. The gripping device 56 includes a nut 58 which is threaded into a tubular collet 60. The collet 60 and nut 58 are screwed together over the proximal segment 28 to cause the collet 60 to securely grip the proximal segment 28. The position of the gripping device 56 may be adjusted by loosening the nut and repositioning the device.

It should be noted that the length of the intermediate and distal segments 30, 32 are selected so that when the balloon is placed in a very distal region of the coronary anatomy, the juncture of the proximal end of the intermediate segment with the proximal tubular segment 28 is disposed in the descending aorta 18 and does not extend into the aortic arch 20. Thus, the combined length of the intermediate and distal segments 30, 32 should be between 35 to 45 cm long, with a length of 40 cm being preferred for most patients' anatomies. It will be appreciated from the foregoing construction that the flexible intermediate and distal portions 30, 32 will pass easily through the curve of the aortic arch 20 without tendency to buckle because they are fully supported by the guidewire 12. The relatively stiff elongate metal proximal segment 28 does not pass through the aortic arch 20 and maintains its relatively straight configuration so that its pushable characteristics are not compromised. There is minimal tendency of the catheter to dislodge the distal tip of the guide catheter from its position in the coronary ostium.

Should it be desired to exchange the balloon catheter 26 for another catheter, there is no need to use an extended length guidewire. Typically, about 50 cm of the guidewire 12 will protrude exterioraly of the patient. When the catheter 26 is withdrawn, a segment of the guidewire 12 will be exposed at all times, thereby enabling the guidewire 12 to be grasped to maintain its position in the patient. Thus, the catheter 26 may be withdrawn without dragging the guidewire 12 out of position. After the first catheter has been removed, another catheter may be threaded onto the guidewire and advanced through the guide catheter and into the coronary anatomy, guided by the guidewire 12. The catheter constructed in accordance with the invention will be advanced easily, without tendency to buckle or develop high friction within the guide catheter and with no significant tendency to dislodge the guide catheter from its position at the coronary ostium.

From the foregoing, it will be appreciated that the invention provides an improved rapidly exchangeable catheter construction and catheterization method.

It should be understood, however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications and embodiments may be apparent to those skilled in the art without departing from its spirit.

For example, although the invention has been illustrated in connection with a balloon dilatation catheter, it may also be incorporated in other types of catheters, such as laser catheters, hot tip catheters, infusion catheters, artherectomy catheters and the like.

Claims

1. A balloon dilatation catheter for percutaneous transluminal coronary angioplasty comprising:
an elongate proximal segment formed from a relatively stiff tubular shaft having an inflation lumen extending therethrough;
an intermediate catheter segment attached to the distal end of the proximal segment, the intermediate segment being formed from a more flexible elongate plastic member having two lumens formed therethrough including a first lumen in communication with the inflation lumen of the proximal segment to define a continuation of the inflation lumen, the inflation lumen in the intermediate segment terminating in an outlet port, the intermediate segment having a second, guidewire lumen extend-

ing parallel to the first lumen and being adapted to receive a guidewire, the guidewire lumen having a proximal opening in the region of the juncture of the intermediate and proximal segments;
a distal segment attached to the distal end of the intermediate segment and defining an elongate lumen in communication with and defining a continuation of the distal end of the guidewire lumen of the intermediate segment, and terminating, at its distal tip, in a distal outlet;
a dilatation balloon mounted on the distal and intermediate segment, the interior of the balloon being in communication with the outlet port of the inflation lumen;
whereby when a guidewire is received in the guidewire lumen the catheter will have continuous column support fully along its length from the proximal end of the tubular shaft to the distal outlet of the distal segment.

2. A balloon dilatation catheter as defined in claim 1 wherein the proximal end of the balloon is mounted to the distal end of the intermediate segment and the distal end of the balloon is mounted to the distal end of the distal segment.

3. A balloon dilatation catheter as defined in claim 2 wherein the distal segment is of smaller diameter and is more flexible than the intermediate segment.

4. A balloon dilatation catheter as defined in and of claims 1-3 wherein the distal and intermediate segments extend over a length of between 35 to 45 cm and wherein the overall length of the catheter is between about 145 to 155 cm.

5. A balloon dilatation catheter as defined in claim 4 wherein the length of the distal and intermediate segments is about 40 cm.

6. A balloon dilatation catheter as defined in any of claims 1-3 or 5 further comprising, in combination, a guidewire extending through the guidewire lumen.

7. A balloon dilatation catheter as defined in claim 4 further comprising, in combination, a guidewire extending through the guidewire lumen.

8. A catheter for accessing the coronary arteries in a human comprising:
an elongate proximal segment comprising a relatively stiff tube;
a relatively flexible elongate plastic member mounted to the distal end of the proximal segment, the plastic member being more flexible than the proximal segment and having a guidewire lumen formed therethrough, the guidewire lumen having a proximal opening in the region of the juncture of the plastic member and the proximal segment and having a distal opening at its distal end whereby when a guidewire is contained within the lumen, the catheter will have continuous longitudinal support from its proximal end to its distal tip; and
means carried by the distal end of the plastic member for performing a procedure in a coronary artery.

9. A catheter as defined in claim 8 wherein the means for performing a procedure in an artery comprises a dilatation balloon and where the proximal segment and the plastic member have an inflation lumen communicating the interior of the balloon with the proximal end of the catheter.

10. A catheter as defined in either of claims 7 or 8 wherein the plastic segment is between 35 to 45 cm long.

11. A catheter as defined in claim 9 wherein the plastic segment is about 40 cm long.

12. A catheter as defined in any of claims 8, 9 and 11 further comprising, in combination, a guidewire extending through the guidewire lumen.

13. A catheter as defined in claim 10 further comprising, in combination, a guidewire in the guidewire lumen.

14. A catheter as defined in either of claims 4 or 9 wherein the guidewire is about 175 cm long.

15. A catheter as defined in any of claims 1-3 and 8-11 wherein the proximal segment is formed from metal.

16. A catheter as defined in claim 4 wherein the proximal segment is formed from metal.

17. A catheter as defined in claim 6 wherein the proximal segment is formed from metal.

18. A catheter as defined in claim 12 wherein the proximal segment is formed from metal.

19. A catheter as defined in claim 10 wherein the proximal segment is formed from metal.

20. A catheter as defined in claim 14 wherein the proximal segment is formed from metal.

21. A method for performing a procedure in a coronary artery comprising:
percutaneously placing the small diameter steerable guidewire in the patient's arteries and advancing the guidewire into a selected coronary artery;
percutaneously inserting a catheter as defined in either of claims 4, 8 or 10 into the patient's arterial system over the guidewire;
advancing the catheter through the patient's arterial system over the guidewire to place the distal end of the catheter in the coronary artery, with the juncture of the plastic portion and proximal portion of the catheters being disposed proximally of the aortic arch;
whereby the relatively stiff proximal segment of the catheter will remain substantially straight within the descending aorta and the catheter will be supported by the guidewire fully through the aortic arch and into the patient's coronary arteries.

22. A method as defined in claim 21 further comprising:
performing a catheter exchange including the steps of withdrawing the catheter while holding the

guidewire from its proximal end thereby to maintain the position of the guidewire;
advancing another catheter constructed as defined in claims 4, 8 or 10 over the guidewire and advancing the catheter along the guidewire to the intended site in the patient's coronary arteries.

23. A method as defined in claim 21 wherein the proximal segment of the catheter is formed from metal.

24. A method as defined in claim 22 wherein the proximal segment of the catheter is formed from metal.

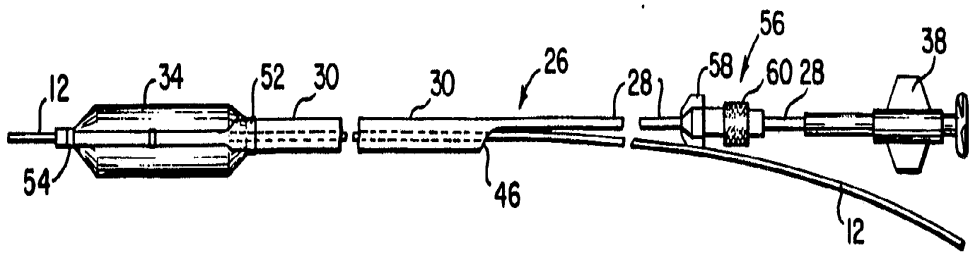

Fig. 1

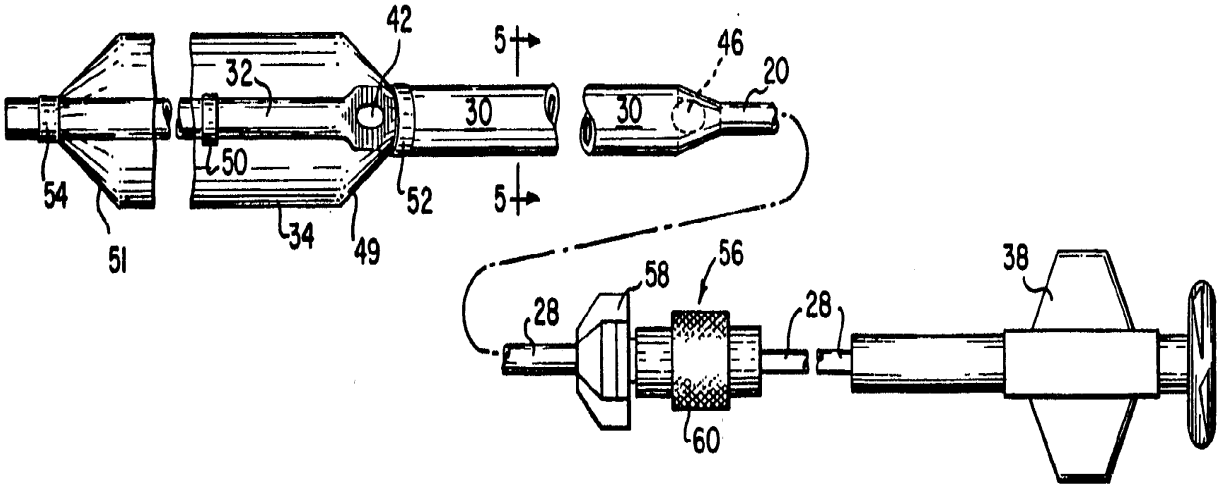

Fig. 2

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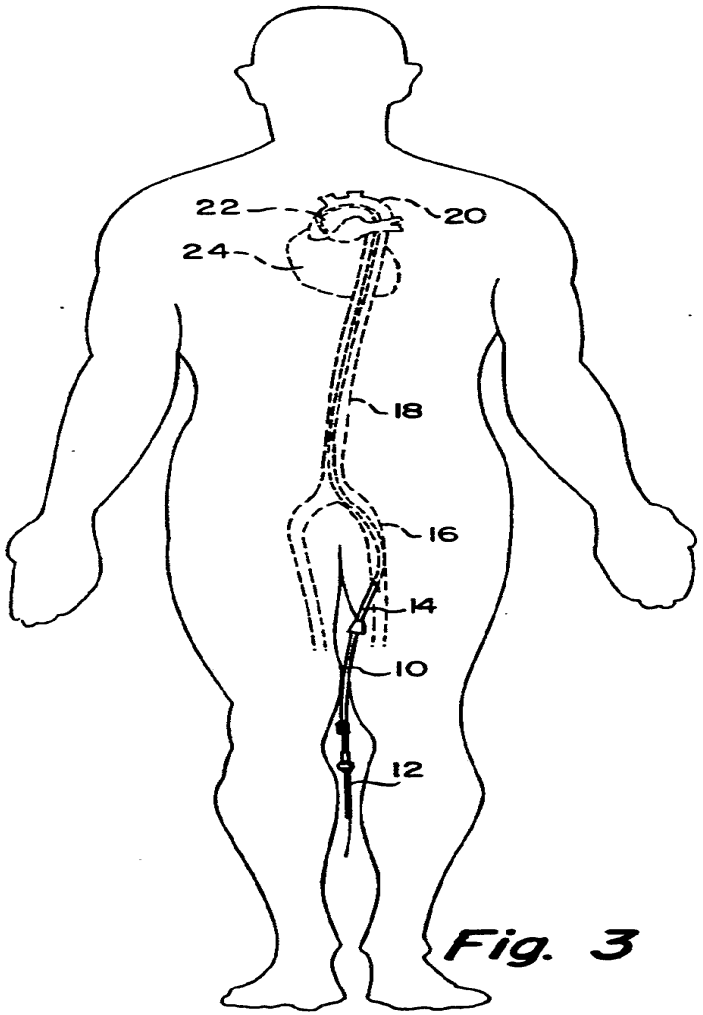

Fig. 3

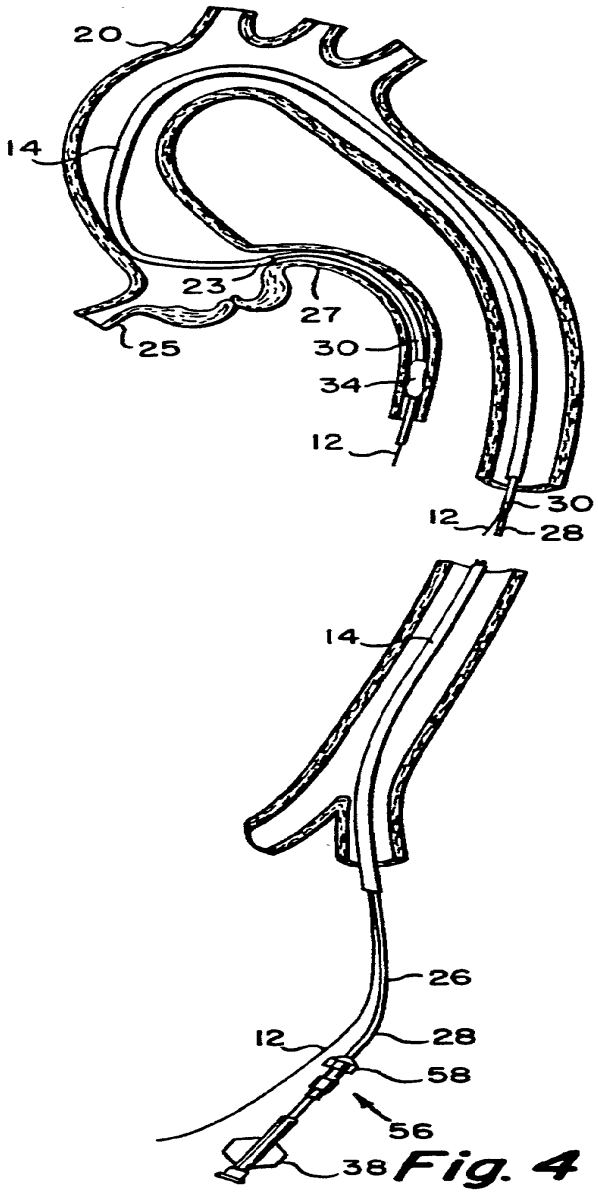

Fig. 4

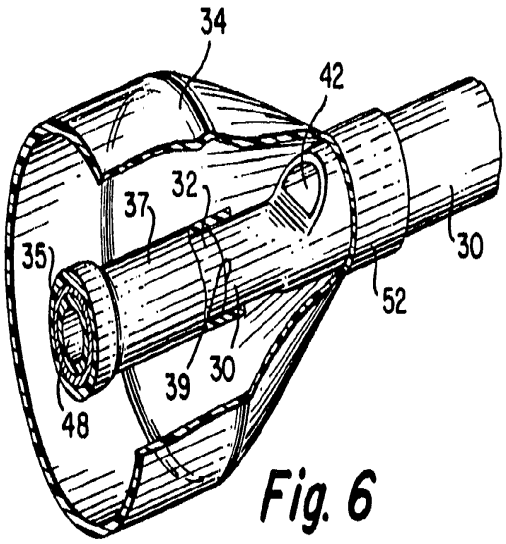

Fig. 6

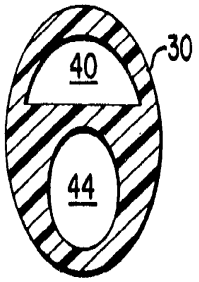

Fig. 5

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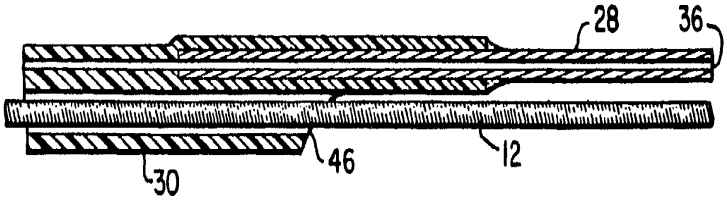

Fig. 7

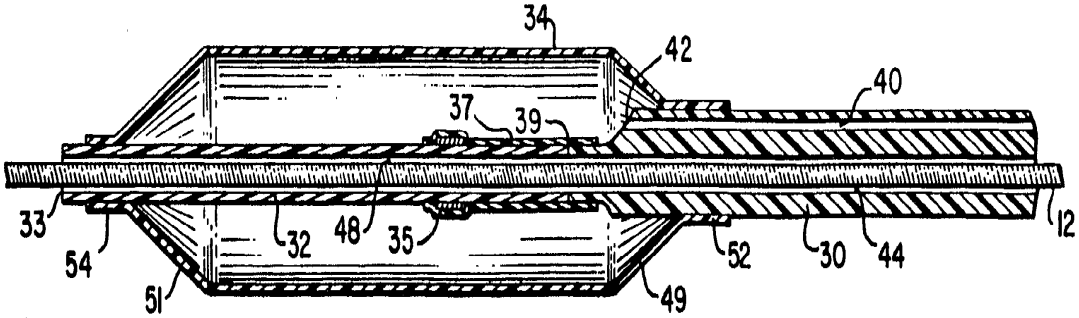

Fig. 8

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(51) International Patent Classification 3 : A61M 29/02 — A1

(11) International Publication Number: WO 84/ 03633

(43) International Publication Date: 27 September 1984 (27.09.84)

(21) International Application Number: PCT/US84/00455

(22) International Filing Date: 23 March 1984 (23.03.84)

(31) Priority Application Number: 478,708

(32) Priority Date: 25 March 1983 (25.03.83)

(33) Priority Country: US

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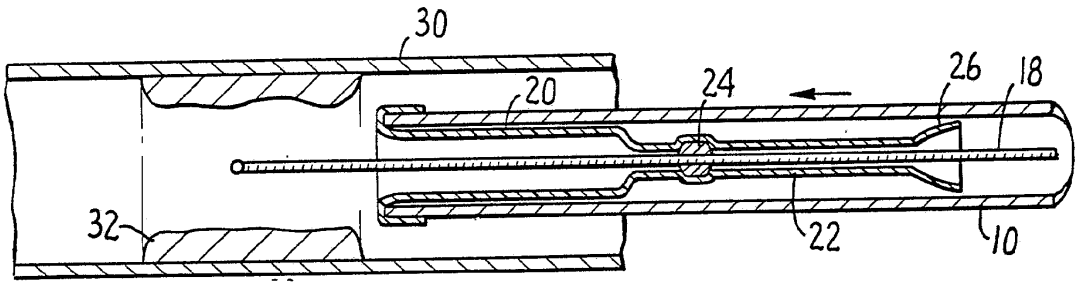
(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: INVERTED BALLOON CATHETER HAVING SEALED THROUGH LUMEN



(57) Abstract

A balloon catheter (20) of the linear eversion type is provided with a sealed through lumen (22-24) which will pass guide wires (18) and other objects without disturbing the sealed nature of the balloon system.

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KP	Democratic People's Republic of Korea	**US**	United States of America

INVERTED BALLOON CATHETER HAVING SEALED THROUGH LUMEN

BACKGROUND OF THE INVENTION

1. Field of the Invention

The field of the invention is dilatation catheters having evertable-invertible balloons for dilating strictures or stenoses of tubular elements and passageways of the body. More specifically, the field of the invention is the provision in such catheters of a central through lumen provided with means enabling the passage through the balloon of a guide wire or other element while providing a sealed balloon system at all times.

2. Description of the Prior Art

In the dilatation catheter art, it is old to provide such catheters with evertable-invertible balloon elements. Attention is directed to U.S. patent No. 4,254,774 in this regard. Such balloon catheters, however, have not, insofar as we are aware, been provided with sealed through lumens enabling the passage through the balloons of guide wires and other instruments.

SUMMARY OF THE INVENTION

The essential object of the invention is to provide a balloon catheter of the evertable-invertible type with a means for passing an object, such as a guide wire or a cannula, through the balloon while maintaining a sealed balloon system.

This is accomplished, in a preferred way, by providing the free end of the balloon with a small axial elastomeric plug

and providing the plug with a normally closed passageway such as one formed by pushing a needle through the plug and by then withdrawing the needle. When the balloon is subjected to inflation pressure the plug acts as an imperforate part of the balloon whether or not a guide wire or the like is extending through the plug.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a view in perspective of a preferred embodiment of the catheter of the invention.

Fig. 2 is an enlarged view in diametral cross-section of said catheter.

Fig. 3 is a similar view showing the catheter strung on a guide wire and positioned adjacent a stenosis to be treated.

Fig. 4 is a similar view showing the balloon everted and within the stenosis.

Fig. 5 is a similar view showing the balloon inflated to dilate the stenosis.

Fig. 6 is a similar view showing an open ended tube extending along the lumen of the catheter.

Fig. 7 is a view of tube and plug elements prior to their securement together, the tube being shown in diametral section.

Fig. 8 is a view of the balloon and plug assemblage prior to the attachment of the assemblage to the catheter.

Fig. 9 shows the assemblage of Fig. 8 in attached relation to the catheter and in inverted position therein.

Fig. 10 is a detail view in diametral cross-section of a sealing means which may be employed at the proximal end of the catheter to maintain the balloon pressurized while a guide wire extends through the catheter.

Fig. 11 is a view showing a form of purging system which may be employed with the catheter.

Fig. 12 shows another form of purging system which may be employed with the catheter.

Fig. 13 illustrates a means for inverting the balloon.

Fig. 14 shows a modified form of balloon inversion means.

Fig. 15 shows how the catheter may be moved from one stenosis to another without inverting the balloon.

Fig. 16 is a view in diametral section of another embodiment of the catheter.

Fig. 17 is an enlarged detail view illustrating how the lumen sealing means of this embodiment operates.

Fig. 18 is a view in perspective of the distal end of still a further embodiment of the subject catheter.

Fig. 19 shows the distal end of the catheter of Fig. 18 with the balloon being in inverted position.

Fig. 20 is a view illustrating the sealing action which occurs when the catheter of Fig. 19 is subjected to balloon-inflating pressures.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The catheter of Figs. 1-15 comprises a flexible tubular body 10, fluid feed fitting 12, hub 14, screw plug 16, guide wire 18, balloon 20, balloon tubular extension 22, plug 24 and funnel-like end 26 formed on extension 22. The end of the balloon is folded over the distal end of tube 10 and sealingly secured thereto.

Figs. 7-9 illustrate the preferred way of making the balloon and balloon extension assemblage. The plug 24 (Fig. 7) of elastomeric material, such as silicone adhesive/sealer, is pierced axially with a needle which is then withdrawn, thereby forming a normally closed or sealed passageway 28 through the seal. The plug is then placed within a tube 11 of polyethylene or other suitable material for an expansible non-elastic balloon. By heat treatment the tube is caused to shrink in the region surrounding and adjacent to the plug so as to form the shape of the assemblage shown in Fig. 8. The plug is gripped and embraced by the containing tube, or extension 22. The assemblage

is then secured to the tube 10, as shown in Fig. 9.

30 is an artery or other body tube having a stenosis or stricture 32. The sequence of usage of the catheter to accomplish dilatation of the stenosis 32 is shown in Figs. 3-5. The catheter is threaded along guide wire 18 which traverses the plug passageway 28 and the entire catheter. When the distal end of the catheter is positioned adjacent stenosis 32, the guide wire is preferably withdrawn from the balloon and balloon extension assemblage 20, 22. The wire may remain in the proximal end of the catheter to serve as part of a sealing means (Fig. 10) comprising wire 18, compressible O-ring 34 and screw plug 16 to compress ring 34 into sealing and gripping relation with wire 18.

Inflation fluid is then injected through fitting 12 to cause eversion of the balloon into stenosis 32, as shown in Fig. 4. After balloon eversion, the balloon is further inflated to expand radially and dilate the stenosis, as shown in Fig. 5. During all this inflation activity, the plug passageway 28 remains in its normally closed position. The balloon and balloon extension are thereby provided with a sealed through lumen.

Regardless of the condition of the balloon, whether it is inverted, everted or radially inflated, thin, tubular elements, such as 36 in Fig. 6, may be passed through the plug. The tube 36 may be then used to monitor pressure conditions at the distal tip of the catheter; it may be used for the delivery of diagnostic or therapeutic substances to the distal end of the catheter; it may be used for the sampling of body fluids, such as blood; and it may be used for the passage of instruments or tools through the catheter, such as temperature monitors or fiber optic cords.

Fig. 15 illustrates how the catheter may be moved from one stenosis to another without bothering to first invert the balloon. For this purpose the extension 22 is preferably provided with a step 37. A stylet 38 having a round or flat tip 40 is inserted into the extension to abut the step. The catheter tube

or body 10 and stylet 38 are then jointly moved to position the everted balloon within the next adjacent stenosis 32.

Figs. 11 and 12 illustrate two purging systems for the catheter. In Fig. 11 the catheter is provided with a purge lumen through which purge liquid is passed to the interior of the catheter through fitting 12. When the catheter has been filled with the purge liquid, issuance of liquid through a bleeder valve, not shown, indicates that all of the air has been purged from the catheter. In Fig. 11 the purge liquid is introduced into the catheter through a needle-like fitting 44 which extends through plug passageway 28. Coupling of the proximal end of the catheter to a vacuum source causes the catheter to be filled with purge fluid.

Figs. 13 and 14 illustrate a retraction means to re-invert the balloon. Extension 22 may have tube 46 frictionally fitted within the end thereof. When the tube 46 is pulled to the right, the balloon becomes re-inverted. As shown in Fig. 14, the tube or rod 46 may have a threaded end 48. The corresponding threads in extension 22 may be pre-formed or formed by self-threading.

A further embodiment of the catheter is shown in Figs. 16-17. Between the plug 24 and balloon 20, extension 22 encloses a length 24 of elastomeric tubing 50. One end of this tubing is bonded to the extension 22 in the region 52. The other end of tubing 50 may be integral with the end of the balloon 20. Extension 22 is bonded to the balloon in the region 54. Extension 22 is provided with aperture 56 in overlying relation to tube 50. When inflation liquid is introduced into the catheter, the liquid enters chamber 58 between extension 22 and the tube 50 to compress the latter and close the passage along tube 50, as illustrated in Fig. 17. Further application of inflation liquid causes eversion of the balloon, and still further application of inflation liquid produces radial expansion of the balloon. The longitudinal passage through tube 50 remains closed under the effect of inflation liquid pressure during all of these operations.

A further embodiment of the catheter is shown in Figs. 18-20. Here the balloon 20, preferably made of polyethylene, is provided with an open end 21 of reduced diameter. A collapsible elastomeric balloon 23 is sleeved over end 21 and bonded thereto. The balloon 23 is provided with a self-closing hole or slit 25. When inflation liquid pressure is applied to the balloons 20 and 23, the balloon 23 collapses to form a seal and close off the interior of the catheter from the exterior thereof.

In the embodiment of Figs. 16 and 17, the guide wire 18 may be passed through the sealed through lumen in either direction, while in the embodiment of Figs. 18-20 such passage must be made from the distal end of the catheter in order to avoid collapsing of the balloon 23.

It is to be pointed out that the elastomeric plug 24 of the embodiments of Figs. 1-17 can be fixed in place in various ways. The preferred way, as disclosed, is to shrink the containing tube partially around the ends of the plug, thereby mechanically bracing the plug in position. The plug can be adhesively secured to the containing tube, either with or without the mechanical bracing relationship between tube and plug.

All of the above-described embodiments allow placement of the catheter body over a guide wire which has previously been manipulated into the desired lumen or space. This provides important advantages over previous linear extrusion catheters which are incapable of being used directly over a guide wire and must be positioned with a guiding catheter, if that is possible, or without any guide or aid at all. The expertise which physicians have in placing guide wires, particularly in the cardiovascular and urological systems, makes this wire-compatibility feature of particular importance.

The catheter embodiments of Figs. 1-17 allow replacement of the guide wire after balloon extrusion, or eversion, if desired, simply by pushing the guide wire back through the seal and past the limit of balloon eversion and then by withdrawing

the catheter over the guide wire (i.e., guide wires or other thin objects may be passed in either direction through the seal). The physician can thereby easily maintain guide wire access to a difficultly reached lumen or space if further procedures or measurements are required in that space or another space which is reached through it. The present catheter provides these advantages while maintaining the advantages of the linear extrusion catheter.

WHAT IS CLAIMED IS:

1. A dilatation catheter comprising a catheter body, a balloon attached to the distal end of said body and inverted within said body, means including a tubular extension attached to said balloon defining a through lumen, closure means for said lumen operable to maintain said balloon in sealed condition for eversion and subsequent radial expansion, said closure means being penetrable by a guide wire, thin cannula, or other thin element without loss of the sealed condition of said balloon.

2. The catheter of Claim 1, said extension having a funnel-like element at its distal end to guide said wire, thin cannula, or other thin element into said lumen.

3. The catheter of Claim 1, said closure means comprising an elastomeric plug secured transversely to said extension in blocking relation to said lumen, said plug having a normally closed, puncture-like axial passageway therein adapted to yieldingly accommodate said wire, thin cannula, or other thin element without loss of the sealed condition of said balloon.

4. The catheter of Claim 3, said extension having a funnel-like element at its distal end to guide said wire, thin cannula, or other thin element into said lumen.

5. The catheter of Claim 3, said plug fitting within a radially enlarged portion of said extension and being secured in place between radially diminished portions of said extension.

6. The catheter of Claim 3, said closure means further comprising an elastomeric sleeve within said extension, said sleeve having one end fixedly attached to said balloon and the other end fixedly attached to said plug, said extension having an aperture which provides communication for the application of balloon-eversion fluid pressure to an annular chamber between said extension and said sleeve to thereby collapse said sleeve upon itself and seal said lumen against fluid flow.

7. The catheter of Claim 6, said extension having a funnel-like element at its distal end to guide said wire, thin cannula, or other thin element into said lumen.

8. The catheter of Claim 1, said tubular extension having its proximal end secured to said balloon and having its distal end closed except for a puncture-like normally closed passageway extending therethrough, said tubular extension being collapsible upon itself upon the application thereto of balloon-eversion fluid pressure to seal said lumen against fluid flow.

9. A method of providing a dilatation catheter of the evertible-invertable balloon type with a sealed through lumen to enable said catheter to be moved along a guide wire while maintaining a sealed balloon system, said method comprising the steps of initially forming said balloon with an axial opening at its distal end, sealing said opening with an elastomeric plug which has been formed with a normally closed axial passageway through said plug to accommodate a guide wire while said balloon system remains sealed.

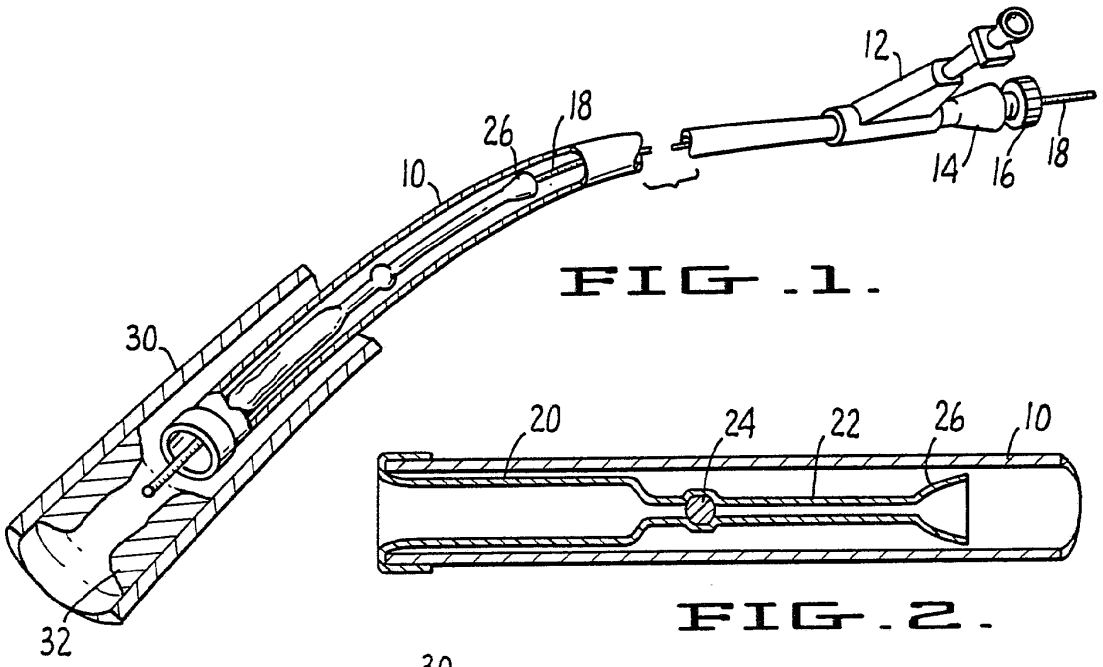


FIG. 1.

FIG. 2.

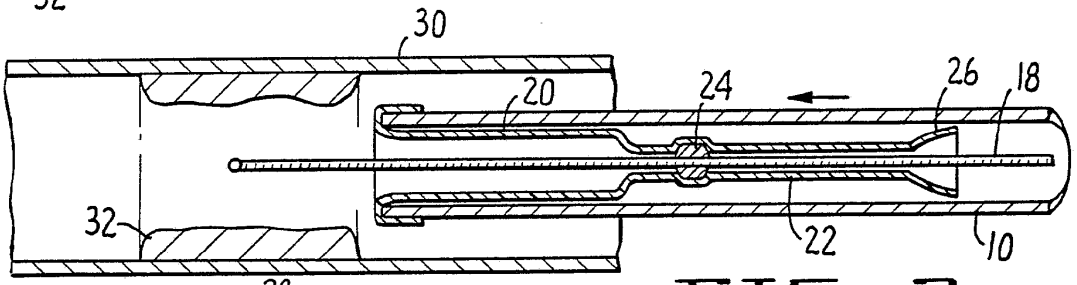


FIG. 3.

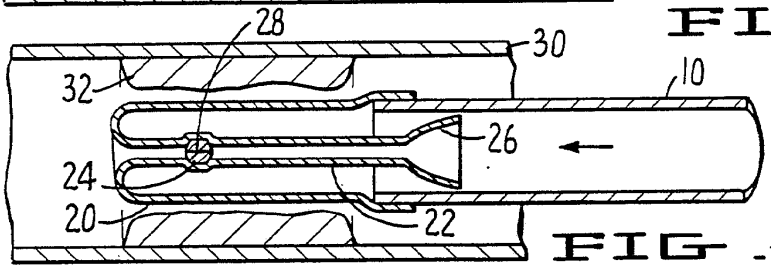


FIG. 4.

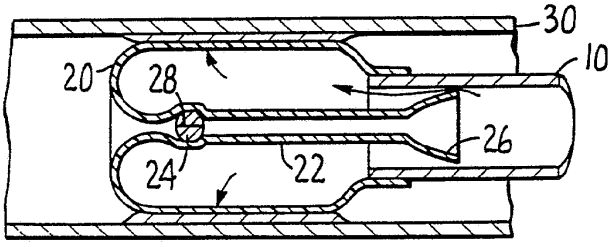


FIG. 5.

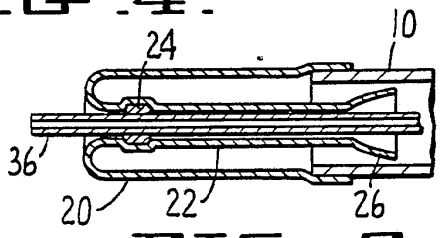


FIG. 6.

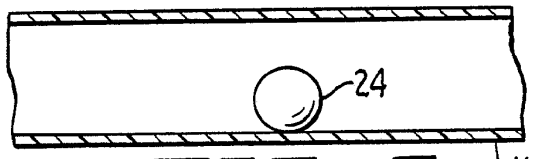


FIG. 7.

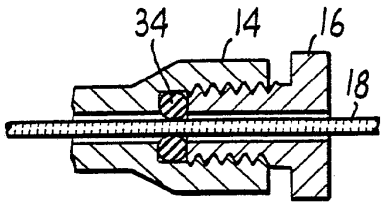


FIG. 10.

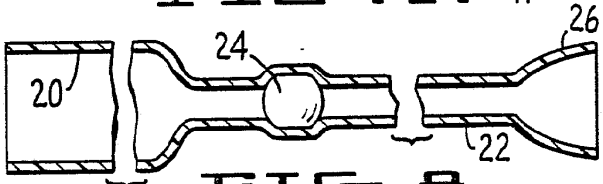


FIG. 8.

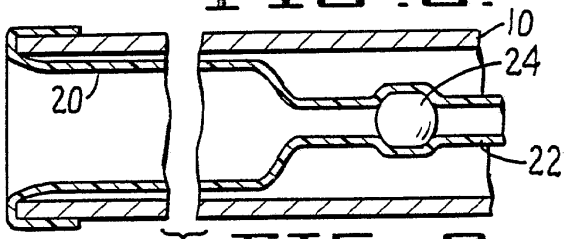


FIG. 9.

FIG. 11.

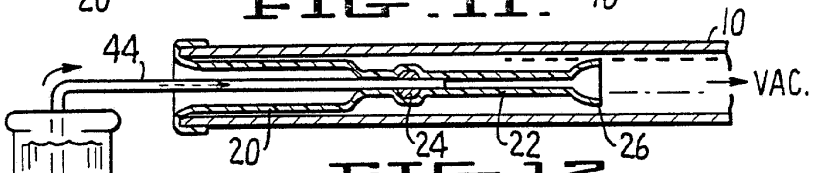


FIG. 12.

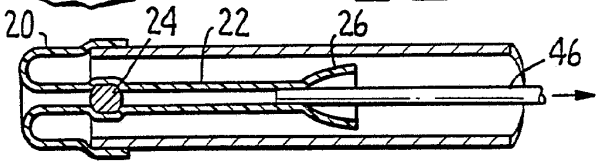


FIG. 13.

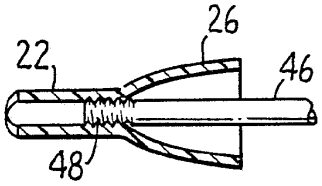


FIG. 14

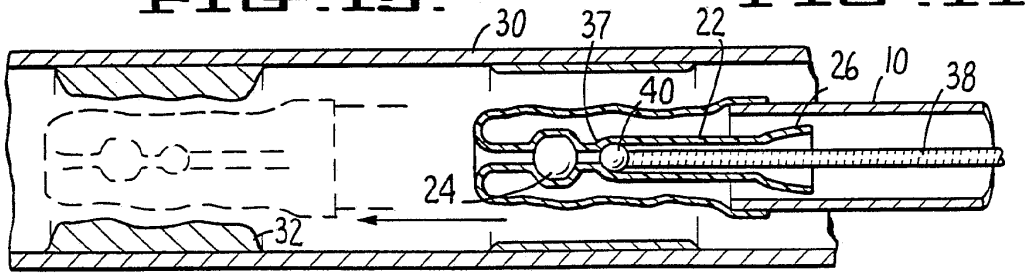


FIG. 15.

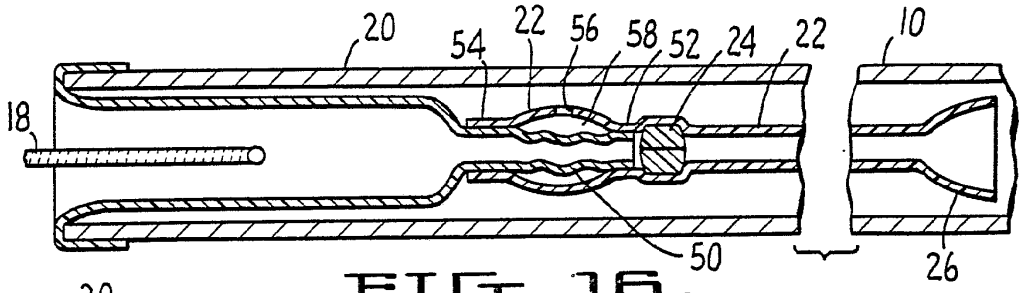


FIG. 16.

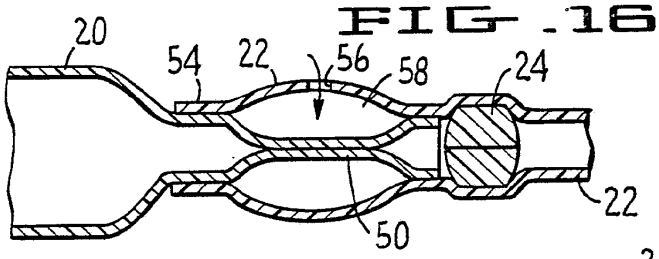


FIG. 17.

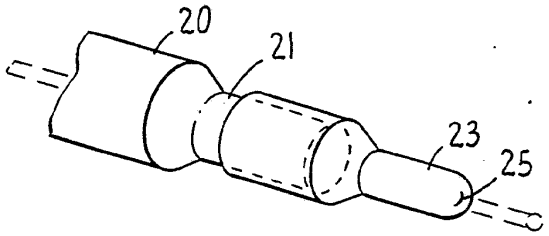


FIG. 18.

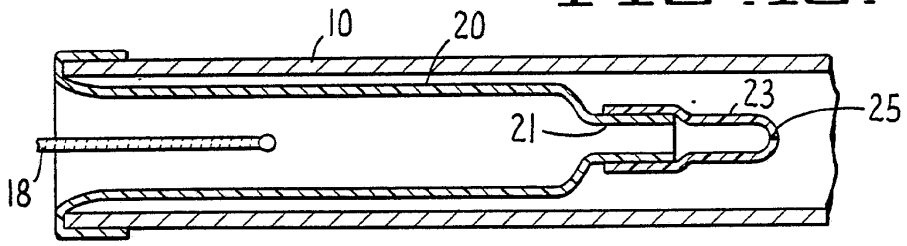


FIG. 19.

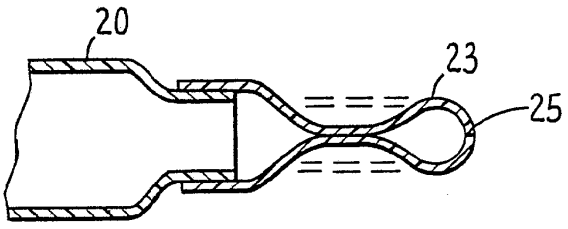


FIG. 20.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00455

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl [3] A61M 29/02
US Cl 128/344

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/328, 341, 344, 348.1 604/96, 102, 167

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
A, P	US, A, 4,403,612	13 September 1983 FOGARTY	
X, Y	US, A, 4,324,262	13 April 1982 HALL	1-4, 9
Y	US, A, 3,409,016	05 November 1968 FOLEY	2, 4
Y	US, A, 3,253,594	31 May 1966 MATTHEWS et al	5, 8-9

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
05 June 1984	19 JUN 1984
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	C. FRED ROSENBAUM

Form PCT/ISA/210 (second sheet) (October 1981)

BAD ORIGINAL

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root et al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: Unassigned
Filed: November 1, 2013	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

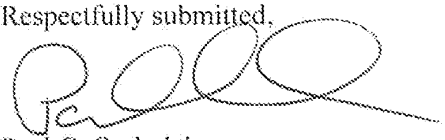
Commissioner:

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 within three months of the U.S. filing date. No certification or fee is required. 37 CFR § 1.97(b)(1)(2).

Respectfully submitted,



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Telephone: 612.349.5766

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

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 14/070,161

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	140		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	300		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	1080		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	44 minus 20 =	* 24	x 40 =	960	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	x 210 =	210			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	2690		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(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))	*	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	

AMENDMENT B

	(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 found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/070,161	11/01/2013	3767	2760	2005.86USREI3	44	4

CONFIRMATION NO. 8790

UPDATED FILING RECEIPT

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

OC000000067095550

Date Mailed: 03/12/2014

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

Inventor(s)

Howard Root, Tonka Bay, MN;
Gregg Sutton, Plymouth, MN;
Jeffrey M. Welch, Maple Grove, MN;
Jason M. Garrity, Lima, NY;

Applicant(s)

VASCULAR SOLUTIONS, INC., Minneapolis, MN

Assignment For Published Patent Application

VASCULAR SOLCUTIONS INC., Minneapolis, MN

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

Domestic Priority data as claimed by applicant

This application is a REI of 13/359,059 01/26/2012 PAT 8292850
which is a DIV of 12/824,734 06/28/2010 PAT 8142413
which is a DIV of 11/416,629 05/03/2006 PAT 8048032

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

If Required, Foreign Filing License Granted: 11/18/2013
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/070,161**
Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **
Title

COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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

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Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI3

Howard Root Et Al. Confirmation No.: 8790

Application No.: 14/070,161 Examiner: Unassigned

Filed: November 1, 2013 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

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

Commissioner:

The applicant, Vascular Solutions, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior U.S. Patent Nos. 8,043,032, 8,142,413, 8,292,850, and Reissue Application Nos. 14/195,413, 14/195,435 and 14/195,385** as the term of said **prior patents and reissue applications** is presently shortened by any disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patents and reissue applications** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon grantee, its successors or assigns.

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reissue applications is presently shortened by any terminal disclaimer," in the event that said **prior patents and reissue applications** later:

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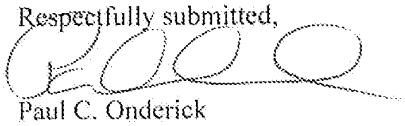
The undersigned is an attorney or agent of record.

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:	14070161
Filing Date:	01-Nov-2013
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Paul C. Onderick/Mary Granger
Attorney Docket Number:	2005.86USREI3
Filed as Large 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($)
Miscellaneous:				
Statutory or Terminal Disclaimer	1814	1	160	160
		Total in USD ($)		**160**

Electronic Acknowledgement Receipt	
EFS ID:	18572797
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	25-MAR-2014
Filing Date:	01-NOV-2013
Time Stamp:	11:43:08
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$160
RAM confirmation Number	10183
Deposit Account	160631
Authorized User	ONDERICK, PAUL C
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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	Terminal Disclaimer Filed	2005_86USREI3_Terminal_Disclaimer.pdf	290966 72ae4ac52a1fcfa14bd36b5fc9079d41fee57e9c	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30313 21d401e61ea667f47dbef1546c75c87b841ca628	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	321279		

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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	14/070,161	ROOT ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 03/25/14	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Angie Walker

U.S. Patent and Trademark Office

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI3

Howard Root et al. Confirmation No.: 8790

Application No.: 14/070,161 Examiner: Osinski, B.

Filed: November 1, 2013 Group Art Unit: 3763

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

SECOND PRELIMINARY AMENDMENT

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

Commissioner:

INTRODUCTORY COMMENTS

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

The present amendment comprises the following sections:

A. Amendments to the Specification

B. Amendments to the Claims

C. Remarks

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

AMENDMENTS TO THE SPECIFICATION

In the Specification

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

Page 1, section regarding "Related U.S. Applications":

This Application is an application for reissue of U.S. Patent 8,292,850 which issued from Application No. 13/359,059, filed January 26, 2012 entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures" which is a divisional of Application No. 12/824,734, filed June 28, 2010 now U.S. Patent 8,142,413; entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures", which is divisional of Application No. 11/416,629, filed May 3, 2006 now U.S. Patent 8,048,032 entitled "Coaxial Guide Catheter for Interventional Cardiology Procedures" Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue applications are this Application and continuation reissue Application Nos. 14/195,385, 14/195,413 and 14/195,435 filed March 3, 2014.

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 brackets; and 2. added matter is shown by underlining.

1. (Original) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

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

a device adapted for use with the guide catheter, including:

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

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

rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

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

3. (Original) The system of claim 2, wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.

4. (Original) The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.

5. (Original) The system of claim 1, wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.

6. (Original) The system of claim 5, wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.

7. (Original) The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.

8. (Original) The system of claim 1, wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.

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

10. (Original) The system of claim 1, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

11. (Original) The system of claim 1, further comprising a kit that includes the guide catheter and the device in a common sterile package.

12. (Original) A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising:

a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the 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 continuous lumen of the guide catheter; and

a device adapted for use with the guide catheter, including:

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

a flexible tip portion defining a tubular structure and having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the flexible tip portion 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, connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion, such that when at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter with at least proximal portion of the reinforced portion remaining within the continuous lumen of the guide

catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.

13. (Original) The system of claim 12, 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.

14. (Original) The system of claim 12, wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.

15. (Original) The system of claim 12, wherein, after the device is inserted into the continuous lumen of the guide catheter, the device presents 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.

16. (Original) The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.

17. (Original) The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.

18. (Original) The system of claim 12, 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.

19. (Original) The system of claim 12, wherein the substantially rigid portion includes, from distal to proximal, a cross-sectional shape having a full circumference portion, a hemicylindrical portion and an arcuate portion.

20. (Original) The system of claim 12, 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.

21. (Original) The system of claim 20, 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.

22. (Original) The system of claim 20, 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.

23. (Original) The system of claim 12, wherein the predefined length of the guide catheter is about 100 cm and the total length of the device is about 125 cm.

24. (Original) The system of claim 12, further comprising a kit that includes the guide catheter and the device in a common sterile package.

25. (New) A system comprising:

means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and

means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,

the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having

a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,

wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and

the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion.

26. (New) The system of claim 25, wherein the side opening includes at least one inclined slope.

27. (New) The system of claim 26, wherein the side opening includes at least two different inclined slopes.

28. (New) The system of claim 25, wherein a portion of the side opening includes an arcuate cross-sectional shape extending less than 180° of a full circumference.

29. (New) The system of claim 28, wherein the portion of the side opening having the arcuate cross-sectional shape extends 25% to 40% of a full circumference.

30. (New) The system of claim 28, wherein the side opening includes a portion having a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape.

31. (New) The system of claim 25, wherein the reinforced portion includes one or more braided elements embedded in a polymer.

32. (New) The system of claim 25, wherein a uniform inner diameter of a lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is not more than one French smaller than a second inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel.

33. (New) The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes a concave track along a portion of a length thereof.

34. (New) A method of forming a device adapted for use with a guide catheter having a lumen, the method comprising:

assembling together a device that includes:

a substantially rigid portion that includes a side opening extending for a distance along a longitudinal axis of the device and accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive an interventional device; a reinforced portion including one or more metallic elements, covered with a polymer, and a lumen; and

a tip portion including a low durometer polymer or elastomeric material and a lumen continuous with the lumen of the reinforced portion;

such that when the distal end of the tip portion is extended distally of a distal end of the guide catheter, a portion of the proximal end of the substantially rigid portion extends proximally of a proximal end of the guide catheter,

wherein the assembling together the device is performed by:

operably coupling the distal end of the substantially rigid portion and the proximal end of the reinforced portion; and

operably coupling the distal end of the reinforced portionand the proximal end of the tip portion.

35. (New) The method of claim 34, wherein the substantially rigid portion includes a hypo tube or metal rail structure.

36. (New) The method of claim 34, wherein the side opening includes an inclined sidewall with a first slope.

37. (New) The method of claim 36, wherein the side opening includes an inclined sidewall with a second slope different from the first slope.

38. (New) The method of claim 34, wherein the side opening includes, in a proximal to distal direction, a first segment having an arcuate cross-sectional shape and a second segment having a hemicylindrical cross-sectional shape.

39. (New) The method of claim 34, wherein the reinforced portion includes covering one or more braided metallic elements with the polymer.

40. (New) The method of claim 34, wherein the reinforced portion including the lumen includes a reinforced portion including a lumen having a uniform inner diameter that is not more than one French smaller than an inner diameter of the lumen of the guide catheter.

41. (New) The method of claim 34, wherein the substantially rigid portion, the reinforced portion, and the tip portion includes, starting at the distal end of the tip portion and moving proximally toward the proximal end of the substantially rigid portion, at least a first structure having a first flexural modulus, a second structure having a second flexural modulus greater than the first flexural modulus, and a third structure having a third flexural modulus greater than the second flexural modulus.

42. (New) The method of claim 41, wherein the first structure having the first flexural modulus includes a structure formed having a flexural modulus of about 13,000 PSI plus or minus 5,000 PSI, wherein the second structure having the second flexural modulus includes a structure formed having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, and wherein the third structure having the third flexural modulus includes a structure formed having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI.

43. (New) The method of claim 34, wherein one or both of the reinforced portion and the tip portion includes lining a lumen thereof with polytetrafluoroethylene.

44. (New) The method of claim 34, wherein the tip portion includes a marker covered with the low durometer polymer or elastomeric material.

45. (New) The system of claim 25, wherein the side opening is incorporated with the distal end of the substantially rigid portion.

46. (New) The system of claim 25, wherein the side opening is incorporated with the proximal end of the reinforced portion.

47. (New) The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes, starting at the distal end of the tip 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.

48. (New) The system of claim 47, wherein the first flexural modulus is about 13,000 PSI plus or minus 5,000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

49. (New) The system of claim 25, wherein a distal portion of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to anchor within the ostium of the branch vessel and resist axial and shear forces exerted by the received interventional device that would otherwise tend to dislodge the distal portion.

50. (New) The system of claim 32, wherein the lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to receive a stent and a balloon catheter.

51. (New) The system of any one of claims 25-29, 32, 45 or 47-50, wherein a structure forming the side opening includes one or more cuts.

52. (New) The system of claim 51, wherein at least one cut includes two radial cuts along a single line and separated by a section of uncut structure.

53. (New) The system of claim 51, wherein a first cut is spaced approximately 0.010 inches apart from a second cut.

54. (New) The method of any one of claims 34-38 or 40-42, wherein the side opening includes a structure having at least two aligned cuts separated by a section of uncut structure.

REMARKS

Claims 1-54 are pending. By this Amendment, no claims are cancelled, claims 25, 28, 29, 30, 32, 34, 38, 40 and 41 are amended and new claims 45-54 are added.

This application is a reissue application and is to be given priority in examination. MPEP 708.

Notice: more than one reissue application has been filed for the reissue of Patent 8,292,850; the reissue applications are this application and continuation reissue Application Nos. 14/195,385, 14/195,413 and 14/195,435 filed March 3, 2014.

"The parent and continuation reissue applications should be examined together if possible." MPEP 1451(II)

Entry of this Preliminary Amendment for the above-identified reissue application is respectfully requested.

The filed broadening reissue claims are directed to an additional invention, embodiment or species not originally claimed that represent an overlooked aspect of the invention in the issued patent.

The amendments and additions to the claims are made to correct one or more defects causing U.S. Patent No. 8,292,850 to be partly inoperative or invalid.

Examination and reconsideration of this application are respectfully requested.

Explanation of Amendments to the New Claims

Claims 25, 28, 29, 30, 32, 34, 38, 40 and 41 are amended as follows as compared to the similarly numbered claims filed in the first Preliminary Amendment in this application.

25. (Currently Amended) A system comprising:

means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and

means for receiving the interventional device from ~~the location near the ostium of the branch vessel~~ an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel,

the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when[[a]] the distal end of the tip portion is extended distally of[[a]] the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of[[a]] the proximal end of the substantially rigid portion extends proximally of[[a]] the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel,

wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, ~~through~~ into a lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel, and

the side opening ~~including a portion having an arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape and positioned adjacent to, or~~

~~incorporated with, the distal end portion of~~ and the substantially rigid portion ~~or a proximal end portion of the reinforced portion~~ are configured to be more rigid along a length thereof than the tip portion.

28. (Currently Amended) The system of claim 25, wherein[[the]] a portion of the side opening ~~having the~~ includes an arcuate cross-sectional shape ~~includes 25% to 40%~~ extending less than 180° of a full circumference.

29. (Currently amended) The system of claim[[25]] 28, wherein the portion of the side opening having the arcuate cross-sectional shape ~~includes a less than 180° portion~~ extends 25% to 40% of a full circumference.

30. (Currently Amended) The system of claim [[25]] 28, wherein the side opening includes a portion having a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and[[the]] a portion having[[the]] a full circumference cross-sectional shape.

32. (Currently Amended) The system of claim 25, wherein[[an]] a uniform inner diameter of a lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is not more than one French smaller than[[an]] the inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel.

33. (Currently Amended) wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes a concave track along a portion of [[its]] a length thereof.

34. (Currently Amended) A method of forming a device adapted for use with a guide catheter having a lumen, the method comprising:

providing assembling together a device that includes:

a substantially rigid portion that includes a side opening extending for a distance along a longitudinal axis of the device and accessible from a longitudinal side, defined transverse to the longitudinal axis , to receive an interventional device;

providing a reinforced portion including one or more metallic elements, covered with a polymer, and a lumen;

providing a tip portion including a low durometer polymer or elastomeric material and a lumen continuous with the lumen of the reinforced portion;

such that when the distal end of the tip portion is extended distally of a distal end of the guide catheter, a portion of the proximal end of the substantially rigid portion extends proximally of a proximal end of the guide catheter,

wherein the assembling together the device is performed by:

operably coupling[[a]] the distal end of the substantially rigid portion[[to a]] and the proximal end of the reinforced portion; and

operably coupling[[a]] the distal end of the reinforced portion[[to a]] and the proximal end of the tip portion~~,~~

~~wherein providing the substantially rigid portion, the reinforced portion, and the tip portion includes forming a device length such that when a distal end of the tip portion is extended distally of a distal end of the guide catheter, a portion of aproximal end of the substantially rigid portion extends proximally ofaproximal end of the guide catheter, and wherein providing one or both of the substantially rigid portion and the reinforced portion includes providing a side opening extending for a distance along a longitudinal axis of the device and accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive an interventional device~~.

35. (Currently Amended) The method of claim 34, wherein ~~providing~~ the substantially rigid portion includes ~~forming or obtaining~~ a hypo tube or metal rail structure.

36. (Currently Amended) The method of claim 34, wherein ~~providing~~ the side opening includes ~~forming or obtaining~~ an inclined sidewall with a first slope.

37. (Currently Amended) The method of claim 36, wherein ~~providing~~ the side opening includes ~~forming or obtaining~~ an inclined sidewall with a second slope different from the first slope.

38. (Currently Amended) The method of claim 34, wherein ~~providing~~ the side opening includes ~~forming or obtaining~~, in a proximal to distal direction, a first segment having an arcuate cross-sectional shape[[,]] and a second segment having a hemicylindrical cross-sectional shape~~, and a third segment having a full circumference cross-sectional shape~~.

39. (Currently Amended) The method of claim 34, wherein ~~providing~~ the reinforced portion includes covering one or more braided metallic elements with the polymer.

40. (Currently Amended) The method of claim 34, wherein ~~providing the reinforced portion including~~ the lumen ~~includes forming or obtaining a reinforced portion including a lumen having an~~ has a uniform inner diameter that is not more than one French smaller than an inner diameter of the lumen of the guide catheter.

41. (Currently Amended) The method of claim 34, wherein providing the substantially rigid portion, the reinforced portion, and the tip portion includes, starting at[[a]] the distal end of the tip portion and moving proximally toward[[a]] the proximal end of the substantially rigid portion, ~~forming or obtaining~~ at least a first structure having a first flexural modulus, a second structure having a second flexural modulus greater than the first flexural modulus, and a third structure having a third flexural modulus greater than the second flexural modulus.

42. (Previously Presented) The method of claim 41, wherein ~~forming or obtaining~~ the first structure having the first flexural modulus includes ~~forming~~ a structure formed having a flexural

modulus of about 13,000 PSI plus or minus 5,000 PSI, wherein ~~forming or obtaining~~ the second structure having the second flexural modulus includes ~~forming~~ a structure formed having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, and wherein ~~forming or obtaining~~ the third structure having the third flexural modulus includes ~~forming~~ a structure formed having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI.

43. (Previously Presented) The method of claim 34, wherein ~~providing~~ one or both of the reinforced portion and the tip portion includes lining a lumen thereof with polytetrafluoroethylene.

44. (Previously Presented) The method of claim 34, wherein ~~providing~~ the tip portion includes ~~covering~~ a marker covered with the low durometer polymer or elastomeric material.

New Claims Added in this Preliminary Amendment

New claims 45-54 are added as compared to the first Preliminary Amendment in this application.

45. (New) The system of claim 25, wherein the side opening is incorporated with the distal end of the substantially rigid portion.

46. (New) The system of claim 25, wherein the side opening is incorporated with the proximal end of the reinforced portion.

47. (New) The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes, starting at the distal end of the tip 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.

48. (New) The system of claim 47, wherein the first flexural modulus is about 13,000 PSI plus or minus 5,000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.

49. (New) The system of claim 25, wherein a distal portion of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to anchor within the ostium of the branch vessel and resist axial and shear forces exerted by the received interventional device that would otherwise tend to dislodge the distal portion.

50. (New) The system of claim 32, wherein the lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to receive a stent and a balloon catheter.

51. (New) The system of any one of claims 25-29, 32, 45 or 47-50, wherein a structure forming the side opening includes one or more cuts.

52. (New) The system of claim 51, wherein at least one cut includes two radial cuts along a single line and separated by a section of uncut structure.

53. (New) The system of claim 51, wherein a first cut is spaced approximately 0.010 inches apart from a second cut.

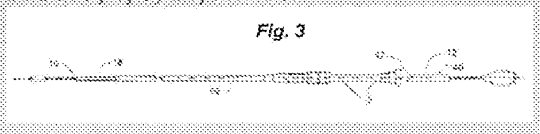
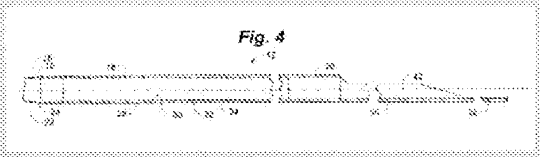
54. (New) The method of any one of claims 34-38 or 40-42, wherein the side opening includes a structure having at least two aligned cuts separated by a section of uncut structure.

Formal Request for Telephonic Interview

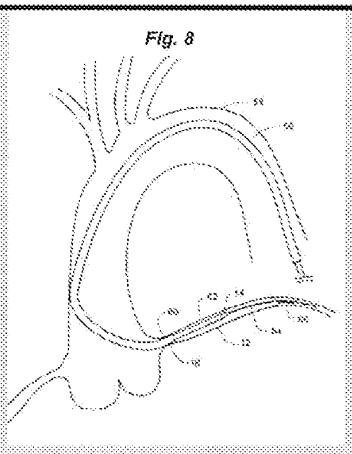
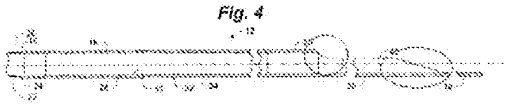
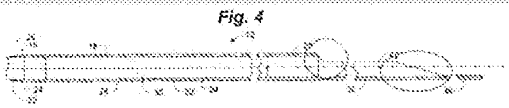
The undersigned formally requests that, before issuance of any Office Action, a telephonic interview be held between the Examiner and the undersigned, at the Examiner's convenience. The Examiner is kindly requested to phone the undersigned at 612.349.5740 to arrange a time for such telephonic interview.

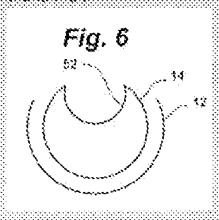
Support for Claim Amendments and Additions

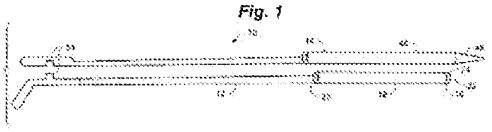
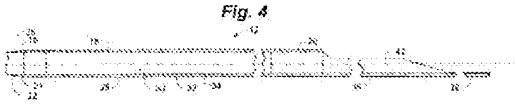
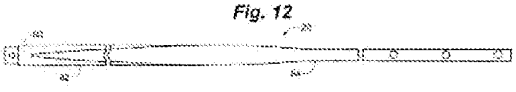
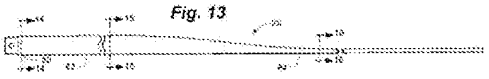
As required by 37 C.F.R. § 1.173 and MPEP § 1453, support for new claims 25-44 can be found in the originally-filed patent application, as presented in the following table:

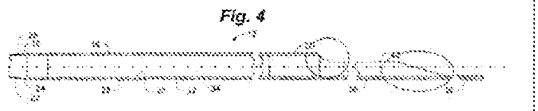
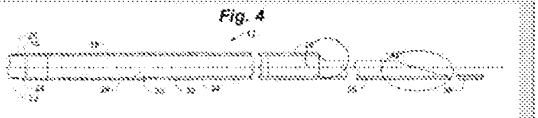
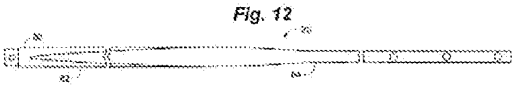
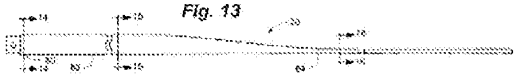
Claim No.	Claim Amendment(s) and/or Addition(s)[1]	Example(s) of Support in U.S. Application Serial No. 13/359,059, filed on Jan. 26, 2012
25	A system comprising: means for guiding an interventional device from a location outside of a subject, through a main vessel, to a location near an ostium of a branch vessel; and means for receiving the interventional device from an intermediate or distal portion of the means for guiding the interventional device to the location near the ostium of the branch vessel and guiding the interventional device deeper into the branch vessel, the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel including, in a distal to proximal direction, a tip portion, a reinforced portion, a side opening, and a substantially rigid portion, and having a length such that when the distal end of the tip portion is extended distally of the distal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, a portion of the proximal end of the substantially rigid portion extends proximally of the proximal end of the means for guiding the interventional device to the location near the ostium of the branch vessel, wherein the tip portion, the reinforced portion, the side opening, and the substantially rigid portion are configured to be passed, at least in part, into a lumen of the means for guiding	Page 4, lines 16-18 Page 5, lines 5-7 Page 6, lines 1-4 and 15-22 Page 7, line 14 – page 8, line 2 Page 9, lines 12-14 Page 11, lines 13-16 Page 12, lines 12-18 Page 15, lines 1-18 Page 19, lines 2-22 Original claims 1, 3, 4, 9, and 14 FIGS. 3, 4, 8, 14, and 16:  

[1] In the table, bracketed language indicates deletions and underlined language indicates additions.

	the interventional device to the location near the ostium of the branch vessel, and the side opening and the substantially rigid portion are configured to be more rigid along a length thereof than the tip portion.	 
26	The system of claim 25, wherein the side opening includes at least one inclined slope.	FIG. 4: 
27	The system of claim 26, wherein the side opening includes at least two different inclined slopes.	FIG. 4: 
28	The system of claim 25, wherein a portion of the side opening includes an arcuate cross-sectional shape extending less than 180° of a full circumference.	Page 13, lines 1 and 2 Page 16, lines 16, 18 and 19
29	The system of claim 28, wherein the portion of the side opening having the arcuate cross-sectional shape extends 25% to 40% of a full circumference.	Page 13, lines 1 and 2 Page 16, lines 16, 18, and 19

30	The system of claim 28, wherein the side opening includes a portion having a hemicylindrical cross-sectional shape between the portion having the arcuate cross-sectional shape and a portion having a full circumference cross-sectional shape.	Page 12, lines 14-16 and 19-21 Original claim 9 FIG.15: Fig. 14 Fig. 15 Fig. 16
31	The system of claim 25, wherein the reinforced portion includes one or more braided elements embedded in a polymer.	Page 6, lines 10-14 Page 12, lines 5-7 Page 18, lines 11 and 12
32	The system of claim 25, wherein a uniform inner diameter of a lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is not more than one French smaller than a second inner diameter of the lumen of the means for guiding the interventional device to the location near the ostium of the branch vessel.	FIG. 4 Page 5, lines 8-18 Original claims 8 and 18
33	The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes a concave track along a portion of a length thereof.	Page 13, lines 10 and 11 FIG. 6:  Fig. 6
34	A method of forming a device adapted for use with a guide catheter having a lumen, the method comprising: assembling together a device that includes: a substantially rigid portion that	Page 4, lines 16-18 Page 6, lines 1-14 Page 12, lines 2-8, 12, and 13

	includes a side opening extending for a distance along a longitudinal axis of the device and accessible from a longitudinal side, defined transverse to the longitudinal axis, to receive an interventional device; a reinforced portion including one or more metallic elements, covered with a polymer, and a lumen; and a tip portion including a low durometer polymer or elastomeric material and a lumen continuous with the lumen of the reinforced portion; such that when the distal end of the tip portion is extended distally of a distal end of the guide catheter, a portion of the proximal end of the substantially rigid portion extends proximally of a proximal end of the guide catheter, wherein the assembling together the device is performed by: operably coupling the distal end of the substantially rigid portion and the proximal end of the reinforced portion; and operably coupling the distal end of the reinforced portion[[to a]] and the proximal end of the tip portion.	Page 17, lines 15-17 Page 18, lines 11-19 Original claims 1, 3, 4, and 14 FIGS. 1, 3, 4, and 12-16: Fig. 1  Fig. 3  Fig. 4  Fig. 12  Fig. 13  Fig. 14  Fig. 15  Fig. 16
35	The method of claim 34, wherein the substantially rigid portion includes a hypo tube or metal rail structure.	Page 6, lines 15 and 16 Page 12, lines 13 and 14

36	The method of claim 34, wherein the side opening includes an inclined sidewall with a first slope.	FIG. 4:  Fig. 4
37	The method of claim 36, wherein the side opening includes an inclined sidewall with a second slope different from the first slope.	FIG. 4:  Fig. 4
38	The method of claim 34, wherein the side opening includes, in a proximal to distal direction, a first segment having an arcuate cross-sectional shape and a second segment having a hemicylindrical cross-sectional shape.	Page 6, lines 16-22 Page 12, lines 14-21 Original claims 9 and 19 FIGS.12-16:  Fig. 12  Fig. 13  Fig. 14 Fig. 15 Fig. 16
39	The method of claim 34, wherein the reinforced portion includes covering one or more braided metallic elements with the polymer.	Page 6, lines 10-12 Page 12, lines 5-8
40	The method of claim 34, wherein the reinforced portion including the lumen includes a reinforced portion including a lumen having a uniform inner diameter that is not more than one French smaller than an inner diameter of the lumen of the guide catheter.	FIG. 4 Page 5, lines 8-18 Original claims 8 and 18

41	The method of claim 34, wherein the substantially rigid portion, the reinforced portion, and the tip portion includes, starting at the distal end of the tip portion and moving proximally toward the proximal end of the substantially rigid portion, at least a first structure having a first flexural modulus, a second structure having a second flexural modulus greater than the first flexural modulus, and a third structure having a third flexural modulus greater than the second flexural modulus.	Page 13, line 15 – page 14, line 8
42	The method of claim 41, wherein the first structure having the first flexural modulus includes a structure formed having a flexural modulus of about 13,000 PSI plus or minus 5,000 PSI, wherein the second structure having the second flexural modulus includes a structure formed having a flexural modulus of about 29,000 PSI plus or minus 10,000 PSI, and wherein the third structure having the third flexural modulus includes a structure formed having a flexural modulus of about 49,000 PSI plus or minus 10,000 PSI.	Page 13, line 15 – page 14, line 8
43	The method of claim 34, wherein one or both of the reinforced portion and the tip portion includes lining a lumen thereof with polytetrafluoroethylene.	Page 6, lines 5-14 Page 12, lines 2, 3, 7, and 8 Page 19, line 1
44	The method of claim 34, wherein the tip portion includes a marker covered with the low durometer polymer or elastomeric material.	Page 5, lines 20-22 Page 6, lines 5-9 Page 11, line 18 Page 12, lines 1-4

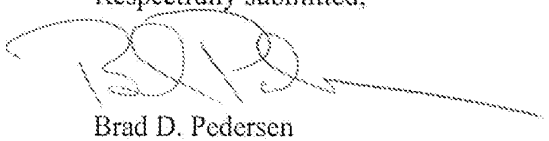
		Page 18, lines 14 and 15
45	The system of claim 25, wherein the side opening is incorporated with the distal end of the substantially rigid portion.	Page 4, lines 16-18 Original claims 1 and 14 FIGS. 12-16
46	The system of claim 25, wherein the side opening is incorporated with the proximal end of the reinforced portion.	Original claim 25
47	The system of claim 25, wherein the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel includes, starting at the distal end of the tip 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.	Page 13, lines 15-19 Original claims 20 and 21
48	The system of claim 47, wherein the first flexural modulus is about 13,000 PSI plus or minus 5,000 PSI, the second flexural modulus is about 29,000 PSI plus or minus 10,000 PSI, and the third flexural modulus is about 49,000 PSI plus or minus 10,000 PSI.	Page 13, lines 15-19 Original claims 20 and 21
49	The system of claim 25, wherein a distal portion of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to anchor within the ostium of the branch vessel and resist axial and shear forces exerted by the received	Page 9, lines 6-8 Page 15, lines 10-17 Original claim 2 FIG. 9

	interventional device that would otherwise tend to dislodge the distal portion.	
50	The system of claim 32, wherein the lumen of the means for receiving the interventional device and guiding the interventional device deeper into the branch vessel is configured to receive a stent and a balloon catheter.	Page 8, lines 3-5 Page 14, lines 16-18 Page 15, lines 9, 10, 17 and 18 Page 19, lines 12-14
51	The system of any one of claims 25-29, 32, 45 or 47-50, wherein a structure forming the side opening includes one or more cuts.	Page 7, lines 3 and 4 Page 10, lines 15-17 Page 15, line 19 – page 16, line 14 FIGS. 10 and 11
52	The system of claim 51, wherein at least one cut includes two radial cuts along a single line and separated by a section of uncut structure.	Page 7, lines 3 and 4 Page 10, lines 15-17 Page 15, line 19 – page 16, line 14 FIGS. 10 and 11
53	The system of claim 51, wherein a first cut is spaced approximately 0.010 inches apart from a second cut.	Page 7, lines 3 and 4 Page 10, lines 15-17 Page 15, line 19 – page 16, line 14 FIGS. 10 and 11
54	The method of any one of claims 34-38 or 40-42, wherein the side opening includes a structure having at least two aligned cuts separated by a section of uncut structure.	Page 7, lines 3 and 4 Page 10, lines 15-17 Page 15, line 19 – page 16, line 14 FIGS. 10 and 11

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,



Brad D. Pedersen
Registration No. 32432

Customer No. 24113
Patterson Thuente Pedersen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: 612.349.5740

Electronic Patent Application Fee Transmittal

Application Number:	14070161
Filing Date:	01-Nov-2013
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Filer:	Bradley Pedersen/Mary Granger
Attorney Docket Number:	2005.86USREI3

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	10	40	400
Multiple Dependent Claims	2203	1	390	390
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**790**

Electronic Acknowledgement Receipt	
EFS ID:	19279317
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Bradley Pedersen/Mary Granger
Filer Authorized By:	Bradley Pedersen
Attorney Docket Number:	2005.86USREI3
Receipt Date:	11-JUN-2014
Filing Date:	01-NOV-2013
Time Stamp:	18:29:25
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$790
RAM confirmation Number	5069
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 1.17 (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_86USREI3_PreAmd.pdf	3930536 49041d41dd47016713e74767df3097c6420fa9e5	yes	35

Multipart Description/PDF files in .zip description

Document Description	Start	End
Preliminary Amendment	1	1
Specification	2	2
Claims	3	17
Applicant Arguments/Remarks Made in an Amendment	18	35

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	32267 7bb63f5854aecb5bd7d6cd42033a5bc7488a5935	no	2

Warnings:

Information:

Total Files Size (in bytes):	3962803

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.

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New International Application Filed with the USPTO as a Receiving Office
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Substitute for form 1449/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	2005.86USREI3

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-7,232,452 B2	06-19-2007	Adams et al.
		US-		
		US-		
		US-		
		US-		
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		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.**

Electronic Acknowledgement Receipt	
EFS ID:	19285319
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	12-JUN-2014
Filing Date:	01-NOV-2013
Time Stamp:	13:17:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		2005_86USREI3_SppIDS.pdf	366981 07fa538bb47bb71b4e26d5a53ae9ec0cac573ff8	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Transmittal Letter	1	3
	Information Disclosure Statement (IDS) Form (SB08)	4	4
Warnings:			
Information:			
	Total Files Size (in bytes):	366981	

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New International Application Filed with the USPTO as a Receiving Office
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REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2005.86USREI3

Howard Root Et Al. Confirmation No.: 8790

Application No.: 14/070,161 Examiner: Unassigned

Filed: November 1, 2013 Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

Pursuant to 37 CFR § 1.56, and in addition to information disclosed in any previously filed prior Information Disclosure Statements, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO-1449. It is respectfully requested that the information be expressly considered during the prosecution of the above-referenced application, and be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

The listing of a reference herein is not an admission that the reference is prior art or is material to patentability. 37 CFR § 1.97(h). Applicant reserves the right to establish the patentability of any claimed invention over any of the information provided herewith, and/or prove that this information may not be prior art, and/or prove that this information may not be enabling for any aspect of the information provided herewith.

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

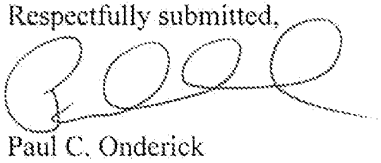
The Examiner's attention is directed to the applications or patents, if any, to which priority is claimed, as well as to any continuing applications which claim priority to the above-referenced application, and to applications, if any, that may be related by virtue of similar claimed subject matter as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

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

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

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

Respectfully submitted,



Paul C. Onderick
Registration No. 45354

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

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 14/070,161	Filing Date 11/01/2013	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	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 $310 ($155 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	

APPLICATION AS AMENDED – PART II

AMENDMENT	06/12/2014	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 54	Minus	** 44	= 10	X $40 =	400
	Independent (37 CFR 1.16(h))	* 5	Minus	***4	= 1	X $210 =	210
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	**610**

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

LIE
/STELLA LITTLE/

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT *(Use as many sheets as necessary)*				*Complete if Known*	
				Application Number	14/070,161
				Filing Date	November 1, 2013
				First Named Inventor	Howard Root Et Al.
				Art Unit	3767
				Examiner Name	Unassigned
Sheet	1	of	1	Attorney Docket Number	2005.86USREI3

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]
		Defendant, Boston Scientific Corporation's Prior Art Statement, Dated December 20, 2013, cited in Civil No. 0:13-cv-01172-JRT-SER.	
		Defendant, Boston Scientific Corporation's First Amended Prior Art Statement, Dated April 25, 2014, cited in Civil No. 0:13-cv-01172-JRT-SER	
		Plaintiff, Vascular Solutions, Inc.'s Response to Defendant Boston Scientific Corporation's Prior Art Statement, Dated January 23, 2014, Civil No. 0:13-cv-01172-JRT-SER.	
		Plaintiff, Vascular Solutions, Inc.'s Response to Defendant Boston Scientific Corporation's First Amended Prior Art Statement, Dated July 1, 2014, Civil No. 0:13-cv-01172-JRT-SER.	

EXAMINER SIGNATURE		DATE CONSIDERED	

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

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

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

Electronic Acknowledgement Receipt	
EFS ID:	19663171
Application Number:	14070161
International Application Number:	
Confirmation Number:	8790
Title of Invention:	COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES
First Named Inventor/Applicant Name:	Howard Root
Customer Number:	24113
Filer:	Paul C. Onderick/Mary Granger
Filer Authorized By:	Paul C. Onderick
Attorney Docket Number:	2005.86USREI3
Receipt Date:	23-JUL-2014
Filing Date:	01-NOV-2013
Time Stamp:	16:27:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		SuppIDS.pdf	387408 4e56f1007f347dbf741e71ae0dae9e61af4d3d9e	yes	4

	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Transmittal Letter		1	3	
	Information Disclosure Statement (IDS) Form (SB08)		4	4	
Warnings:					
Information:					
2	Non Patent Literature	NPL1_Defndnt_BSCs_PriorArtStmt.pdf	1018777 0e032058e49bb40c849c1699c2470b0be82eb5b6	no	97
Warnings:					
Information:					
3	Non Patent Literature	NPL2_BSCs_1st_AmendedPriorArtStmt.pdf	927970 6cd9ccc6e0c1fd2d5f80772310f630e5e60261f4	no	102
Warnings:					
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4	Non Patent Literature	NPL3_VSIs_Resp_to_BSCs_PriorArtStmt.pdf	805092 1b6fff0ee35d9e4484a225b2d24e4a4f6d77e73a	no	16
Warnings:					
Information:					
5	Non Patent Literature	NPL4_VSIs_Resp_to_1st_AmendedPriorArtStmt.pdf	954667 1a720908920fc07a5f311ab6e43d16519a13b44b	no	18
Warnings:					
Information:					
		Total Files Size (in bytes):	4093914		

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root Et Al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: Unassigned
Filed: November 1, 2013	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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

Commissioner:

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

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

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

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

Respectfully submitted,

Paul C. Onderick
Registration No. 45354

Customer No. 24113
Patterson Thuente Pedersen, P.A.
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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.

REISSUE PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2005.86USREI3
Howard Root Et Al.	Confirmation No.: 8790
Application No.: 14/070,161	Examiner: B. Osinski
Filed: November 1, 2013	Group Art Unit: 3767

For: COAXIAL GUIDE CATHETER FOR INTERVENTIONAL CARDIOLOGY PROCEDURES

NOTIFICATION OF CONCURRENT PROCEEDINGS

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

Sir:

In accordance with 37 C.F.R. §1.56, 37 C.F.R. § 1.178(b) and MPEP §2001.06, the attention of the Office is hereby directed to pending *Inter Partes* Review Case Number IPR2014-00762 (U.S. Patent No. 8,292,850) and *Inter Partes* Review Case Number IPR2014-00763 (U.S. Patent No. 8,292,850) which relate to the patent upon which this reissue application is based.

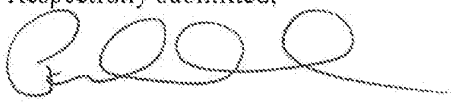
The attention of the Office is also hereby directed to pending; *Inter Partes* Review Case Number IPR2014-00759 (U.S. Patent No. 8,142,413); *Inter Partes* Review Case Number IPR2014-00760 (U.S. Patent No. 8,048,032); and *Inter Partes* Review Case Number IPR2014-00761 (U.S. Patent No. 8,048,032). These relate to family members of the patent upon which this reissue application is based. The Examiner is respectfully requested to consider these *Inter*

Partes Review's, their file wrappers and prosecution records, information, and the art cited therein during examination. No fee is believed due with this submission.

All of these *Inter Partes* Review Cases are subject to an Order Authorizing Joint Motions to Terminate dated August 6, 2014.

Copies of the Petitions for *Inter Partes* Review Under 37 C.F.R. § 42.100 as filed in each of the above-identified cases are attached hereto for the Examiner's convenience.

Respectfully submitted,



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Please charge any fee due with this submission to Deposit Account No. 16-0631

ATTACHMENT A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,292,850

Attorney Docket No. 0025216-00057

PETITION FOR INTER PARTES REVIEW
UNDER 37 C.F.R. § 42.100

ATTACHMENT A

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Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,292,850

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Declaration of Ronald Jay Solar, Ph.D., with attached Appendix1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
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U.S. Publication No. 2007/0260219 A1 to Root et al.	1012
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1013
U.S. Patent No. 6,638,268 to Niazi	1014
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Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn).	1027

Exhibit Description	Exhibit No.
(June 10, 2013)	
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn). (June 10, 2013)	1028
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Inter partes review is respectfully requested for claims 1-4, 8, 12, 14, 18 of U.S. Patent No. 8,292,850 ("the '850 Patent") (Exh. 1001).

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '850 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 1:13-cv-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of the '850 Patent on other grounds in another petition to be filed concurrently herewith. Further, Petitioner is filing two separate petitions on non-redundant grounds seeking *inter partes* review of U.S. Patent No. 8,048,032 (the "'032 patent") and one petition seeking review of U.S. Patent No. 8,142,413 (the "'413 patent") to be filed concurrently herewith. In all, five petitions will be filed. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and are directed generally to the same subject matter. Specifically, the '850 patent is a division of application No. 12/824,734, which issued as the '413 patent, and the '413 patent is a division of

application No. 11/416,629, which issued as the '032 patent. The claims challenged therein are method ('413 patent (Exh. 1005)) and apparatus ('032 patent (Exh. 1004)) versions of the system claims of the '850 patent challenged herein.

C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

Lead Counsel	Back-Up Counsel
David R. Marsh (Reg. No. 41,408) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5068 Facsimile: 202.942.5999 Email: david.marsh@aporter.com	Kristan L. Lansbery (Reg. No. 53,183) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5186 Facsimile: 202.942.5999 Email: kristan.lansbery@aporter.com

D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to service by email to lead and backup counsel at xBSC_VSI_IPRService@aporter.com.

II. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 50-2387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for

any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF RELEVANT TECHNOLOGY AND '850 PATENT

A. Overview Of Interventional Cardiology Procedures

The claims of the '850 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (*See* Exh. 1001, 1:7-36). During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*See* Declaration of Ronald Jay Solar, Ph.D. ("Solar Declaration") (Exh. 1003 ¶ 8)). The physician introduces the treatment device into the patient's vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id*). Often, to create a passage for such treatment devices, physicians insert a "guide catheter" earlier in the procedure. (*Id*). In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id*). The '850 patent is directed to an apparatus that is deliverable through a standard guide catheter for extension

beyond the ostium to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (*See, e.g.*, Exh. 1001, 2:45-49).

B. Description Of The Alleged Invention Of The '850 Patent

The '850 Patent (Exh. 1001) contains 24 system claims, including two independent claims (claims 1 and 12). The specification of the '850 patent states that it relates "generally to catheters used in interventional cardiology procedures" and "[m]ore particularly ... apparatus for increasing backup support for catheters inserted into the coronary arteries from the aorta." (Exh. 1001, 1:18-22).

The challenged claims of the '850 patent are not straightforward. Unlike typical system claims, the '850 patent claims are replete with functional language and ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Claim 1 of the '850 patent is representative of the independent claims:

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

length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the 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.

(Exh. 1001, 10:35-11:4).

Dependent claim 2 of the '850 patent depends from independent claim 1 and requires that "the tubular structure includes a distal portion *adapted to be extended beyond* the distal end 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." (*Id.*, 11:5-2).

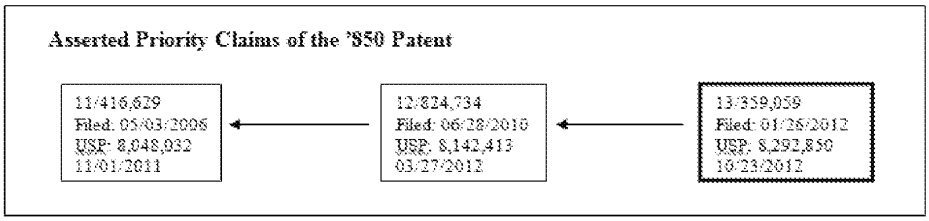
Dependent claim 3 (depending from independent claim 1 and dependent claim 2), is directed to a "proximal side opening" in a proximal portion of the tubular structure, where such opening "extend[s] for a distance along the longitudinal access" and is "transverse [*i.e.*, at an angle] to the longitudinal axis." Dependent claim 14 (depending from independent claim 12) contains substantially similar limitation, except that the "partially cylindrical portion defining an opening extending for a distance along a side thereof" in the substantially rigid (as opposed to tubular) portion. (*Id.*, 11:13-20).

Dependent claim 4 depends from claim 3 and requires a "structure defining a full circumference portion and structure defining a partially cylindrical portion," (*id.*, 11:21-23) as would result from a tube being skived at an angle for part of its length. These 'side opening claims' are directed to that which was well known in the art when the '850 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle.

Dependent claim 8 (depending from independent claim 1) and 18 (depending from independent claim 12) require that "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."

C. Effective Filing Date of the Contested Patent

As depicted below, the '850 patent asserts priority back to May 3, 2006 through a chain of two applications: (1) U.S. Patent Application No. 11/416,629 (filed May 3, 2006 and issued as U.S. Patent No. 8,048,032 (the "'032 patent"), and (2) U.S. Patent Application No. 12/824,734 (filed June 28, 2010 and issued as U.S. Patent No. 8,142,413 (the "'413 patent")).[1]



D. Summary of the Prosecution History of the '850 Patent

[1] Petitioner's depiction of the asserted priority claims of the '850 patent is for illustrative purposes only. Petitioner notes that it is contesting the asserted priority date of the '850 patent in a concurrently filed parallel Petition, "Petition B," challenging the claims of the '850 patent on different grounds. (*See* Exh. 1008). Since the prior art relied upon for purposes of this Petition has an effective prior art date well before Patent Owner's asserted priority date of May 3, 2006, Petitioner applies this as the presumed effective date of the '850 patent exclusively for purposes of its analysis herein.

The '850 Patent was filed as U.S. App. Serial No. 13/359,059 on January 26, 2012 (Exh. 1002, paper 1). The prosecution of the '032 patent, to which the '850 claims priority, spanned five years and three months. During that time, the Examiner issued numerous rejections of claims which are nearly identical to the system claims of the '850 patent challenged herein. Ultimately, however, following at least six rejections and eight amendments, the Examiner conditioned patentability of the claims on the addition of a "rail structure without a lumen" limitation within the substantially rigid portion.

The claims of the '850 patent issued following an amendment by the same Examiner of independent claims 1 and 12 moving the location of the "rail structure without a lumen" limitation from the tubular structure of the flexible tip portion (where the Patent Owner had sought to include it), to the substantially rigid portion, where it had been included in the '032 patent. The Examiner's stated reasons for allowance were that, "just as in the parent applications, the examiner did not find any teaching or suggestion for the claimed arrangement. Specifically, adding a guide catheter to the claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art." A Notice of Allowance was mailed August 22, 2012, and the '850 Patent issued on October 23, 2012. (Exh. 1002 at 16).

IV. REQUIREMENTS FOR INTER PARTES REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '850 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '850 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

B. Identification of Challenge and Relief Requested

Pursuant to 37 C.F.R. § 42.104(b), the precise relief requested by Petitioner is that claims 1-4, 8, 12, 14, and 18 of the '850 Patent be found unpatentable.

C. Claims for Which *Inter Partes* Review Is Requested

Pursuant to 37 C.F.R. § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1-4, 8, 12, 14, and 18 of the '850 Patent.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

This Petition, supported by the grounds set forth below and the Solar Declaration, demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C. § 314(a). Dr. Solar, an expert with 37 years of academic and industry experience in the field of interventional cardiology devices, has reviewed the claim charts submitted in the '850 Petition and is in agreement with the grounds of invalidity and the evidentiary

support set forth therein. (*See* Exh. 1003 ¶ 82). *Inter partes* review is requested in view of the following references and specific grounds for rejection.

No.	Grounds
1	Claims 1-2, and 12 are anticipated by US 5,527,292 ("Adams '292")
2	Claims 1-4, 12 and 14 are obvious over Adams '292 in view of US 5,776,141 ("Klein")
3	Claims 1-4, 12 and 14 are obvious over Adams '292 in view of US 7,232,452 ("Adams '452"")
4	Claims 1-4, 12 and 14 are obvious over Adams '292 in view of US 5,328,472 ("Steinke")
5	Claims 1-2, 8, 12 and 18 are obvious over Adams '292 in view of Knowledge of One of Skill in the Art
6	Claims 1-2, 8, 12 and 18 are obvious over Adams '292 in view of "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," 2004, Takahashi Online Article ("Takahashi")

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

V. Non-Redundancy of Proposed Alternative Grounds

Petitioner urges the Board to adopt each ground of unpatentability raised with respect to claims 1-4, 8, 12, 14 and 18 of the '850 patent for at least the following reasons. The proposed grounds for institution presented in the present Petition ("Petition A") are not redundant over each other, or over the grounds of rejection presented in the concurrently filed parallel Petition for *inter partes* review of the challenged claims of the '850 patent, ("Petition B" (Exh. 1008)), because several differences exist between the applied prior art and their respective grounds for unpatentability. For example, the primary prior art reference (Mihara) in

parallel Petition B differs from the primary prior art reference raised herein (Adams '292). Mihara anticipates a different set of dependent claims (claims 3, 4, and 14) through its disclosure of a skived proximal side opening in Figures 1-3. Adams '292 anticipates the claimed difference in diameter between the inner diameter of the device and the inner diameter of the standard guide catheter of "not more than one French" (claims 8 and 18). As a result, during the course of this proceeding, if instituted, Patent Owner could amend the claims to be limited to just one of these claimed embodiments that is not covered by anticipation in view of Adams '292 (Petition A) or Mihara (Petition B) alone. Accordingly, all grounds based on both Adams '292 and Mihara are needed to cover all of the embodiments encompassed by claims 1, 2, and 12, and, as such, are not redundant. Indeed, because of the Patent Owner's unreasonably functional and broad claims, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structures of the systems in the cited references, and so that Petitioner may address any arguments by the Patent Owner regarding the ability of structures in the prior art to perform the various functions recited in each of the challenged claims.

Petitioner's asserted ground of unpatentability in Petition B based on Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the'032 patent), is not redundant of the other grounds of

unpatentability raised herein because it renders obvious all challenged claims only if the '850 patent is denied the benefit of its claimed May 3, 2006 priority date.

For similar reasons, the grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 3, 4, and 14 are not redundant given that the far reaching functional language of such claims necessitate Petitioner's alternative proposed grounds of unpatentability on the basis of both anticipation in view of Mihara and obviousness over Mihara in view of the knowledge of one of skill in the art.

If the PTAB disagrees and determines that the grounds raised herein are redundant of those raised in Petition A, and will institute only on the grounds of one Petition, Petitioner respectfully requests institution on the basis of Petition A. Moreover, if the PTAB determines that there is redundancy with respect to the grounds raised herein regarding anticipation in view of Mihara and obviousness of claims 3, 4, and 14 over Mihara in combination with the knowledge of one of skill in the art, Petitioner suggests institution on the grounds of Mihara in view of the knowledge of one of skill in the art.

VI. Level of Skill In the Art

A person of ordinary skill in the art ("POSA") at the time of the alleged invention of the '850 patent would have been someone with at least the equivalent of a medical degree from an accredited institution (usually denoted in this country

as a M.D. degree) or someone with the equivalent of a masters degree from an accredited institution (usually denoted in this country as an M.S. degree) in biomedical engineering. The person must have at least three years of experience working as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer. Extensive experience and technical training might substitute for educational requirements, while advanced degrees might substitute for experience. (Exh. 1003 ¶¶ 28-31).

A. Construction Of The Challenged Claims

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." Because the standards of claim interpretation used by the Courts in patent litigation differ from those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation ("BRI") in light of the

patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.[2]

1. "rail structure without a lumen"

Because the '850 patent does not disclose any structure for the "rail structure without a lumen" limitation of independent claims 1 and 11, it is invalid under 35 U.S.C. §112, ¶ 2. The word "rail" appears in the specification of the '850 patent only twice. *First*, the Summary of the Invention refers to a "guidewire rail segment," defined as "permit[ing] delivery without blocking the use of the guide catheter." (Exh. 1001, 2:65). *Second*, Fig. 17 is described as "a plan view of a coaxial guide catheter having a longer rail segment," without any guidance as to which portion(s) of Figure 17 constitute the "rail segment." Neither of these references discloses any meaning for "rail" in the claim term "rail structure without a lumen." (Exh. 1003 ¶ 64). Moreover, nothing in the specification suggests that the rail structure consists of the "tapered inner catheter," "full circumference portion," "cutout potion," "reinforced portion," "hemicylindrical portion," "second full circumference portion," "arcuate portion," "braid or coil reinforcement," "most proximal portion of braid or coil reinforcement," "relief cut," "hemi-tube portion,"

[2] Petitioner reserves the right to challenge the validity of the '032 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

"single cuts," "double cuts," "connector hub," "funnel portion," "grip portion," to name a few, nor would be so read by a POSA. (*Id*).

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent apparatus claims 1 and 12 under 35 U.S.C. §§ 102 and 103, and claims 2, 3, 4, 8, 14, and 18 depending therefrom, Petitioner submits that, a POSA would understand "rail structure" to refer to a pushing or advancement structure. "Monorail" or rapid exchange catheters are characterized by a relatively short guide wire lumen; this cannot be the "rail structure" for purposes of the claim, however, because the claimed structure must be "without a lumen." (Exh. 1003 ¶¶ 64-66). A POSA would therefore understand the "rail structure" to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id*). Accordingly, the term "rail structure without a lumen" can be construed for purposes of this Petition to mean a "pushing or advancement structure without a lumen."

2. "interventional cardiology device(s)"

Interventional cardiology devices are thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to

treat a blockage or narrowing in the arteries due to atherosclerotic plaques or other lesions. (Exh. 1003 ¶ 67). The specification of the '850 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001, 1:28-31) ("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").

3. "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "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"

Dependent claim 3 recites that the structure of the proximal side opening to which the claim is directed is "to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." Dependent claim 14 similarly recites an opening "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…." This language merely indicates the intended use of the claimed proximal opening (to receive an interventional cardiology device), and the device itself (for use within a guide catheter) as well as the order in which such intended uses may occur (receiving the device "into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter"). Accordingly,

such language should not be read as positive limitations on apparatus claims 3 or 14 of the '850 patent. To the extent that there is doubt, the BRI of the claims suggests that only the structural limitation(s) of claims 3 and 14 (namely, a skived proximal opening) be accorded patentable weight. The Federal Circuit has made clear that the validity of an apparatus claim depends ***solely*** "on the claimed structure [and] not on the use or purpose of that structure." *Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

Because the '850 patent claims are system claims, the requisite invalidity analysis turns on a direct comparison of the claimed ***structures*** to prior art ***structures***. *See In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) *Carolina Mktg. Int'l*, 289 F.3d at 810 ("To hold otherwise would effectively impose a method limitation on an apparatus claim without justification"). The functional statements in claims 3 and 14 are not structural because the entire structure of the proximal side opening is described elsewhere in the claim; deletion of the functional phrases from claims 3 and 14 would not affect the structure of the claimed proximal opening. At most, the language requires a proximal opening large enough to allow passage of an interventional cardiology device.

Petitioner has, nevertheless, included sufficient evidence such that, even if the Board were to construe these functional statements of intended use as

positive limitations of claims 3 and 14, the grounds for unpatentability set forth below still render the challenged claims invalid in view of the cited art.

4. "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"

Dependent claim 2 recites: "the system of claim 1 wherein the tubular structure includes a distal portion ***adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery***." (Exh. 1001, claim 2). These are statements of intended use, not structural language. The relevant structural limitations—a tubular structure having distal and proximal portions—is included elsewhere in the claim. As discussed above, to patentably distinguish the claimed invention from the prior art, a recitation of intended use must result in a structural difference between the claimed invention and the prior art. *See, e.g.,* Practitioner's Manual of Patent Examining Proc. § 707 (paragraph 7.37.09). As long as a prior art structure would be ***capable of*** performing the intended use, then it meets the claim. *Id.* In any event, even if

this functional language in dependent claim 2 were accorded patentable weight, the prior art expressly discloses this function, as set forth below.

B. The Prior Art References

As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under §102(b), some of which also constitute prior art under §102(a), as set forth below.[3]

1. Adams '292

U.S. Patent No. 5,527,292 to Adams, *et al.* ("Adams '292") (Exh. 1011) matured from an application filed on September 9, 1994, prior to the earliest filing date the benefit of which is claimed by the '850 patent and is therefore available as prior art to the '850 patent under 35 U.S.C. § 102(b). Adams '292 describes a guide catheter extension: "The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter" (Exh. 1002 4:35-38; Exh. 1003 ¶¶ 69-70), and discloses, *inter alia*:

> An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide

[3] All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

> catheter and has its distal end extending to a treatment site in a coronary artery. The device also including a push rod attached to a proximal end of the flexible tube to facilitate placement of the flexible tube within the coronary artery requiring treatment.

(*Id.* at Abstract). A benefit of the device disclosed in Adams '292 is the ability to extend the flexible tube beyond the distal tip of the guide catheter so that it is sufficiently deep-seated beyond the ostium to anchor the position of the guide catheter during treatment:

> A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond….

(Exh. 1011, 9:12-24; *see* Exh. 1003 ¶¶ 32, 69-70).

2. Klein

U.S. Patent No. 5,776,141 to Klein ("Klein") matured from an application filed on August 26, 1996, prior to the earliest filing date the benefit of which is claimed by the '850 patent and, thus, qualifies as prior art under §102(b). Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter and a proximal shaft attached to the proximal end of the tubular catheter body. (Exh. 1003 ¶ 35).

3. Adams '452

U.S. Patent No. 7,232,452 to Adams ("Adams '452") matured from an application filed on July 12, 2002, prior to the earliest filing date the benefit of which is claimed by the '850 patent, and thus qualifies as prior art under § 102(b). The Adams '452 patent discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." (Exh. 1011, 8:47-50; Exh. 1003 ¶ 36). Adams '452 further discloses "A proximal wire or other control means…." (Exh. 1011, 8:27-30). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh. 1003 ¶ 36). The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (Exh. 1011, Figs 2A-C).

4. Steinke

U.S. Patent No. 5,328,472 to Steinke ("Steinke") (Ex. 1020) matured from an application filed on July 27, 1992, prior to the earliest filing date the benefit of which is claimed by the '850 patent and, thus, qualifies as prior art under § 102(b). Steinke discloses "a catheter which allows rapid exchange" where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that

extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (Exh.1020, 3:1-2; Exh. 1003 ¶ 37).

5. Takahashi

Takahashi, New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions Exh. 1021, 452-456 ("Takahashi") is an article that was published in 2004 and, thus, qualifies as prior art under § 102(b). Takahashi describes method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶ 38). The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is one French or less. (*Id*)..

C. How The Construed Claim(s) Are Unpatentable

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1-4, 8, 12, 14, and 18 of the '850 Patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section V below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration (Exh. 1003).

D. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including

identification of specific portions of the evidence that support the challenge, are provided below and in the corresponding claim charts.

VII. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b) (4)

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to achieve predictable results, all of which were well known to persons of ordinary skill in the art in the field of interventional cardiology procedures at the time to which the '850 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

A. Claims 1, 2, 8, 12, And 18 Are Anticipated Under 35 U.S.C. §102(b) By Adams'292

As shown below, each element recited in claims 1, 2, 8, 12, And 18 is anticipated by Adams '292, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '850 patent. (An unrelated patent by a different inventor with the last name "Adams" was disclosed). "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

1. Claim 1

Claim 1 of the '850 patent discloses a "system comprising: a guide catheter …"; Adams '292 similarly teaches "The invention is directed to the

structure and use of a distal extension (intravascular device) for a guide catheter." (Exh. 1011, 4:36-37). Claim 1 of the 850 patent recites "a flexible tip portion defining a tubular structure having a circular cross-section" (Exh. 1001, ; Adams discloses that "The intravascular device includes a relatively flexible tube 45...." (Exh. 1011, 2:44-51). Claim 1 of the '850 patent further recites "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 ..."; Adams discloses that "The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the 65 guide catheter 12 so that it may be slidably disposed therethrough and to permit insertion of the tube 32 ..." (Exh. 1011, 5:64-67). Claim 1 of the '850 patent further recites "a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion ..." (Exh. 1001, claim 1); Adams discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." (Exh. 1011, 7:13-26). Finally, claim 1 of the '850 patent recites "having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the continuous lumen of the guide catheter ..."

(Exh. 1001, claim 1); Adams '292 similarly discloses that "The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches" (Exh. 1011, 15:49-53), which is longer than a standard guide catheter—approximately 40 inches. (Exh. 1003 ¶ 98). Thus, the Adams '292 discloses every element of claim 1 of the '850 patent.

2. Claim 2

Both the '850 patent and Adams '292 are directed to the deep seating of a guide extension within a branch artery in order to secure the position of the guide catheter and facilitate the delivery of intravascular devices. (*Compare* Exh. 1001, claim 2 *with* Ex. 1011, 16:49-58; *see* Exh. 1003 ¶¶ 102-07).

3. Claim 12

As discussed above, claim 12 of the '850 patent includes the same limitations as claim 1, with the exception of one additional element, a "reinforced portion" proximal to the substantially rigid portion. Accordingly, Petitioner references and includes its analysis of all elements of claim 1 set forth above and in the chart below. Adams '292 also disclosed the "reinforced portion" of claim 12, as shown in the claim chart below. (Exh. 1003 ¶¶ 100-01).

4. Claims 8 and 18

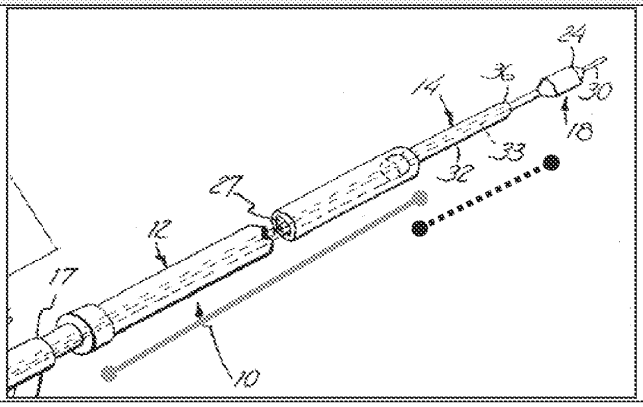
Dependent claims 8 (depending from claim 1) and 18 (depending from claim 12) require that "the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner

diameter of the guide catheter." The Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1011, 5: 64-67; Exh 1003 ¶ 121-24) In disclosing a range overlapping or touching the claimed range, the Adams '292 thereby anticipates the claimed range with sufficient specificity. *See, e.g., ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340, 1345 (Fed. Cir. 2012).

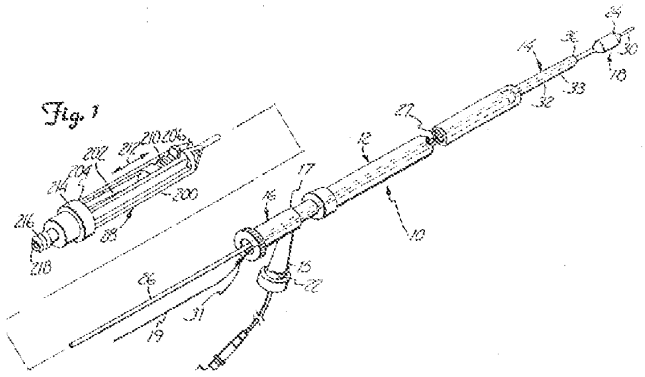
The '850 Patent	**Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are	**[1]** To the extent that the preamble is a limitation, Adams discloses a system for use with interventional cardiology devices adapted to be insertable for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract ("An intravascular device having an elongated flexible tube sized for insertion into a coronary vessel beyond a distal end of a guide catheter. In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site in a coronary artery"); 4:36-37 ("The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter.") **[2]** The guide catheter used with the Adams device has a continuous central lumen and a proximal end with a mounted manifold having a primary channel that contains a hemostasic valve. 5:16-29 ("The

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
insertable into and through the continuous lumen of the guide catheter; a device adapted for use with the guide catheter, including:	guide catheter manifold 16 is mounted at the proximal end of the guide catheter 12. Preferably, the guide catheter manifold 16 comprises a Y-shaped structure having a primary channel leg 17 and an extension leg 15 with a guide catheter port 22 on the extension leg 15…. A hemostasis valve (not shown) on channel leg 17 provides hemostatic control for the guide catheter system 10 of the present invention"); 11:20-30 ("Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or other angioplasty device is disposed and guided to a stenosis or obstruction. The guide catheter manifold 54 is mounted at a proximal end of the guide catheter 52, and preferably comprises a Y-shaped structure having a primary channel leg 51 and an extension leg 55 with a guide catheter port 58. The guide catheter port 58 provides an inlet injection port for dye to travel through the guide catheter system 50 to the arterial system or alternatively for the introduction of drugs into the patient to a treatment site. A hemostatic valve (not shown) on the primary channel leg 51 provides hemostatic control for the guide catheter.") **[3]** The lumen of the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. 6:29-31 ("In the embodiment shown in FIG. 2, the elongated tube 32 has a radially flared proximal end 38. The flared proximal end 38 of the elongated flexible tube 32 is configured to coincide with the inner diameter of the guide catheter 12 so that a catheter advanced, or other angioplasty device such as a guide wire, into and through the first guide catheter lumen 27 is piloted into the flared tip 38 and second guide catheter lumen 33"); 8:40-45

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	("The diameter of the first guide catheter lumen 27 in the guide catheter 12 and the second guide catheter lumen 33 in the guide catheter extension 32 are larger than the outer diameters of the hollow balloon catheter shaft 26 and balloon 24 (deflated) which are advanced therethrough"); 16:39-44 ("a guide catheter 287 is inserted into the patient and advanced until a distal end of the guide catheter 287 reaches the aortic arch of the patient. More particularly, the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary, artery requiring treatment").
a flexible tip portion defining a tubular structure having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	**[1]** Adams discloses a flexible tip portion defining a tubular structure in the form of a "relatively flexible tube." 2:44-51 ("The intravascular device includes a relatively flexible tube 45…"). **[2]** having an inner and outer diameter. 2:44-50 ("The flexible tube has an inner diameter sized for insertion over an angioplasty device"); 23:36-37 ("a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen …"). **[3]** Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). Fig. 12 also shows that flexible tube 255 is shorter than guide catheter 287.

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	
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 defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	**[1]** Adams discloses that the outer diameter of the flexible tube is smaller than and sized for insertion through the guide catheter lumen. 5:64-67 ("The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the 65 guide catheter 12 so that it may be slidably disposed therethrough and to permit insertion of the tube 32 …"); 23:37-40. **[2]** The flexible tube is placed coaxially relative to the guide catheter. 8:57-61 ("the angioplasty balloon catheter 18 and guide catheter extension 14 are coaxially positioned within the guide catheter 12 ..."); 11:58-60 ("During use, the guide catheter extension tube 70 is coaxially disposed within the guide catheter 52"); 15:65-66 ("The flexible tube 255 of the intravascular device 250 is 65 designed for coaxial placement relative to the guide catheter …"). **[3]** When used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen for the insertion and advancement of coronary treatment devices. 22:35-43 ("For use in combination with a guide catheter for insertion and advancement of a coronary treatment device through a coronary vessel having an ostium to a treatment site, the guide catheter having a central lumen, a distal end and a distal opening, an

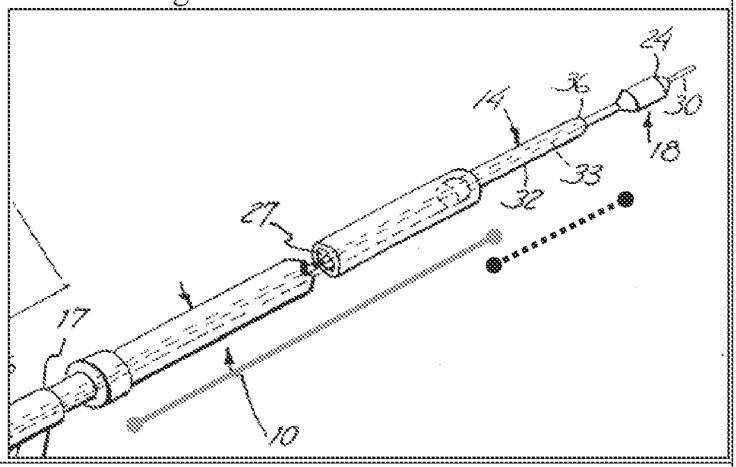
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	anchoring device comprising: a relatively flexible tube sized for insertion through the central lumen of the guide catheter into the coronary vessel, the flexible tube being concentrically aligned with the guide catheter …"); 16:38-44 ("the guide catheter 287 is manipulated until a distal opening 288 of the guide catheter 287 is aligned with the coronary ostium so that the guide catheter 287 will direct an original coronary treatment device, such as an angioplasty balloon catheter, or a subsequent coronary treatment device into the coronary artery requiring treatment").
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Adams discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." 7:13-26; *see* Abstract; 2:47-48; 6:1-2; 6:13-15; 15:8-12; 22:51-52; 23- 44-45.
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion	Adams discloses that the diameter of the wire or stainless steel hypotube of the substantially rigid push rod is smaller (0.016 inch) than that of the flexible tube (0.065 inch). 6:15-17 ("the shaft 19 or push rod is defined by an elongated wire 34. The elongated wire 34 is of small diameter, preferably 0.010 to 0.016 of an inch in diameter"); 6:56-62 ("The rather thin dimension of the wire 34 eliminates or substantially reduces surface friction introduced by the longitudinal movement of an element within the guide catheter 12"); 7:18-21 ("The tubular shaft member 172 is preferably formed from stainless steel hypotube with an inside diameter of 0.010 inch and an outside diameter of 0.016 inch"); 8:24-25 ("For example, the outer diameter of the elongated tube 32A at its proximal end would.be approximately 0.065 inch and the outer diameter at its distal end would be approximately 0.053 inch (with a 0.045

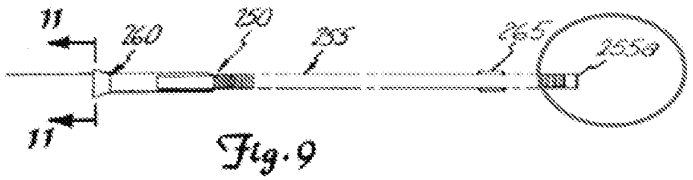
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	inch distal tubular opening …").
and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the 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.	**[1]** Adams discloses that the combined length of the flexible tube and the push rod (50.5 to 51.5 inches) is longer than the guide catheter lumen (about 40 inches). 15:49-53 ("The flexible tube 255 is approximately 6.0 to 12.0 inches in length, and preferably 9.5 to 10.0 inches in length. The push rod is:approximately 40.0 to 45.0 inches in length. The overall length of the extension 250 is preferably 50.5 inches to 51.5 inches"). **[2]** When the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon catheter shaft:  Fig. 1 "As seen in FIG. 1, shaft 19 or push rod … extends proximally … outside the guide catheter 12 so that it is accessible to the user…. The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12…." 6:1-10. 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. 5:17-29. 26 is a

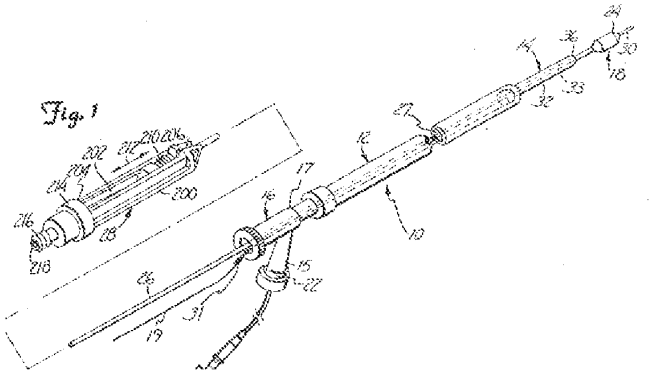
The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. 17:3-7 ("The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient").
2. The system of claim 1, wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,	The Adams '292 patent discloses that the proximal end of the flexible tube remains within a guide catheter while a distal portion of the flexible tube extends beyond the distal end of the guide catheter: "In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site within a coronary artery." (Abstract); 9:17-22 ("A proximal end of the flexible tube 32 is advanced so that a significant portion of the flexible tube 32 extends … beyond the distal end of the guide catheter 12…."); 15:57-60 ("The length of the tube is sized so that the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube 255 reaches the treatment site"); 16:60-64 ("A distal portion of the flexible tube 255 is advanced past the distal opening 288 of the guide catheter 287 … while a proximal portion thereof and the push rod 262 remain within the guide catheter 287").
such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond to the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.	4:63-67 ("the distal extension may be advanced into and through the coronary arteries to the lesion or obstruction to facilitate original placement of angioplasty devices by serving to anchor the guide catheter at the coronary ostium of the vessel requiring treatment…"); 9:12-24 ("The extension of the elongated flexible tube 32 into the smaller dimension arteries also serves to maintain the position of the guide catheter 12 at the coronary ostium during operation…. [T]he flexible tube 32

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	defines an anchoring device for securing the guide catheter 12 for operation…. [A] significant portion of the flexible tube 32 extends into the artery beyond the distal end of the guide catheter 12 to secure the guide catheter 12 at the coronary ostium for guiding a coronary treatment device into the arteries beyond…."); 16:49-58 ("as a coronary device is advanced, the position of the distal opening 288 of the guide catheter 287 may shift out of alignment with the coronary ostium making placement of the coronary treatment device into the coronary artery requiring treatment more difficult. As previously explained, the present invention discloses an anchoring device for securing the guide catheter 287 relative to the coronary ostium of a patient to facilitate original insertion and subsequent insertion of a coronary treatment device"); 22:53-56 ("the flexible tube anchors the distal opening of the guide catheter relative to the ostium of the coronary vessel to secure the guide catheter and facilitate insertion of the coronary treatment device therethrough").
8. The system of claim 1	Adams '292 discloses the system of claim 1 (see above).
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	Adams '292 discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter: "The outer diameter of the elongated flexible tube 32 is smaller than the first guide catheter lumen 27 defined by the guide catheter 12 so that it may be slidably disposed therethrough…." (5:64-67).
12. A system for use with interventional cardiology	**[1]** To the extent that the preamble is a limitation, Adams discloses a system for use with interventional

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the 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 continuous lumen of the guide catheter; and	cardiology devices for extension through a standard guide catheter, the distal end being adapted for placement in a branch artery. Abstract and 4:36-37. **[2]** The guide catheter used with the Adams device has a continuous central lumen and a proximal end with a mounted manifold having a primary channel that contains a hemostasic valve. 5:16-29 and 11:20-30. **[3]** The lumen of the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. 8:40-45 and 16:39-44.
a device adapted for use with the guide catheter; including: an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,	Adams discloses that the combined length of the flexible tube and the push rod (50.5 to 51.5 inches) is longer than the guide catheter lumen (about 40 inches). 15:49-53.
the elongate structure including: a flexible tip portion defining a tubular structure and having a circular cross-section that is smaller than the	**[1]** Adams discloses a flexible tip portion defining a tubular structure in the form of a "relatively flexible tube" **[2]** having an inner and outer diameter. 2:44-50 and 23:36-37.

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
circular cross-section of the continuous lumen of the guide catheter and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	**[3]** Annotated Fig. 1 (cropped) below shows how the length of the flexible tube 14 (dashed black line) is shorter than the length of the continuous lumen 27 of the guide catheter 12 (solid grey line). This is also depicted in Fig. 12 which shows flexible tube 255 is shorter than guide catheter 287. 
the flexible tip portion 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;	**[1]** Adams discloses that the outer diameter of the flexible tube is smaller than and sized for insertion through the guide catheter lumen. 5:64-67 and 23:37-40. **[2]** The flexible tube is placed coaxially relative to the guide catheter. 2:62-64; 11:58-60 and 15:65-66. **[3]** When used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen for the insertion and advancement of coronary treatment devices. 22:35-43.
a reinforced portion proximal to the flexible tip portion; and	"the relatively flexible tube of the intravascular device includes a coil spring extending along and defining at least a portion of the flexible tube." 20:3-6. "The guide catheter extension 14A … has a longitudinal guide catheter extension lumen, a rounded distal tip 36A and may be reinforced by a

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
	coil 40A." 7:4-7.  Fig. 9
a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis rail than the flexible tip portion defining a structure without a lumen	Adams discloses a substantially rigid push rod defined by a wire or stainless steel hypotube and having a "flattened distal end which assumes an elongated cross-section" that provides "sufficient surface area" through which it is secured "to the proximal end of the elongated flexible tube." 7:13-26; see also Abstract; 2:47-48; 6:1-2; 6:13-15; 15:8-12; 22:51-52; and 23- 44-45.
having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,	Adams discloses that the diameter of the wire or stainless steel hypotube of the substantially rigid push rod is smaller (0.016 inch) than that of the flexible tube (0.065 inch). 6:15-17; 6:56-62; 7:18-21 and 8:24-25.
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	Adams discloses that when the flexible tube is extended beyond the distal end of the guide catheter, the shaft or push rod extends proximally outside the guide catheter through the catheter manifold, where the hemostatic valve is located, at the same point as the balloon catheter shaft:

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 8, 12 and 18 in view of Adams '292 (Exh. 1011)
hemostatic valve in common with interventional cardiology devices that are insertable into the guide catheter.	 "As seen in FIG. 1, shaft 19 or push rod … extends proximally … outside the guide catheter 12 so that it is accessible to the user…. The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12…." 6:1-10. 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. 5:17-29. 26 is a balloon catheter shaft. 8:40. The shaft 19 or push rod extends from the manifold 17 at the same point as the balloon catheter shaft 26. "The total length of the extension 250 permits the flexible tube 255 to remain with the guide catheter 287 and to extend beyond a distal end of guide catheter 287 into and through a coronary artery while the control knob 264 remains outside the patient." 17:3-7.
18. The system of claim 12,	Adams '292 discloses the system of claim 12 (*See* A-1, above).
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.	*See* Adams '292 disclosures set forth in claim 8 (above).

VIII. Obviousness of Challenged Claims

The below challenged claims of the '850 patent are rendered obvious under §103(a) in view of the prior art references set forth below,[4] either in view of the knowledge of one of ordinary skill in the art, or in the combinations expressly described herein. Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex, Inc.,* 550 U.S. 398, 418-20, 82 U.S.P.Q.2d 1385 (2007)*; In re Jones,* 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992)*; In re Fine,* 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

A. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Klein

Klein (Exh. 1018) was cited during prosecution of the '032 Patent but was not considered in combination with Adams '292 (Exh. 1011), nor was it considered during prosecution of the '850 Patent. As shown below, each element recited in claims 1-4, 8, 12, 14 And 18 is obvious over Adams '292 in view of Klein. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above.

[4] All references cited herein are patents and printed publications constituting prior art under §102(b).

As set forth in section VII above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107, 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292 and Klein. (*See* Exh. 1003 ¶¶ 108-111).

Klein discloses a delivery catheter having a tubular catheter body with a skived proximal opening sized to receive a balloon catheter. As set forth in the chart below, this disclosure satisfies the structural limitations of claim 3, requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of claim 4 that "the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion," and the limitation of claim 14 that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis."

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.,* Exh. 1011,

15:57-16:13) ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ..."). *See* (Exh. 1011, 16:11-14).

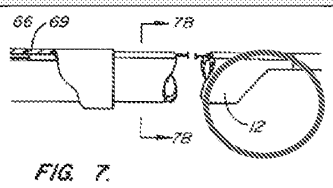
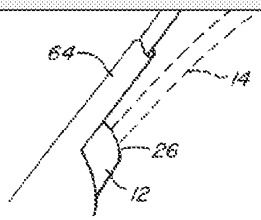
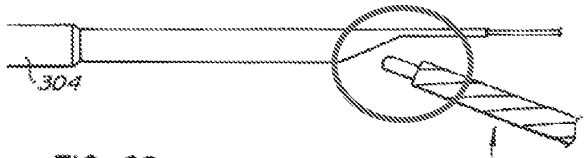
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86, 108-111), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Klein to meet the limitations of the challenged claims. Adams '292 and Klein are both analogous to the '850 patent as they are directed to the same type of device, are in the same field of endeavor, and are reasonably pertinent to the problem faced by the inventor of the '850 patent. (Exh. 1003 ¶¶ 71-74). As such, one of skill in the art would have been aware of these references and would have referred to Adams '850 and Klein in addressing the problem addressed by the '850 patent.

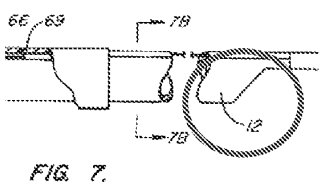
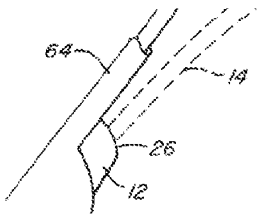
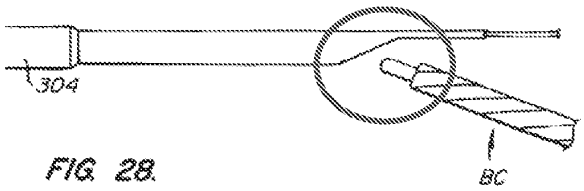
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the device disclosed by Adams '292 with the teaching in Klein of the delivery of larger interventional cardiology devices, such as balloon catheters and stents, through a skived proximal opening of cardiovascular treatment catheter. This is particularly true given that

Klein and Adams '292 device both disclose intravascular devices for use within a standard guide catheter directed to the delivery of interventional cardiology devices such as stents and balloon catheters. (Exh. 1003 ¶¶ 84-86, 108-111).

Accordingly, Klein shows that using skived proximal openings for the delivery of interventional cardiology devices such as balloon catheters was well known by the time of the '850 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*See* Exh. 1003 ¶¶ 108-11).

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	**Adams '292 in view of Klein**
3. The system of claim 2,	Adams '292 discloses the system of claim 2 (*See* A-1, above).
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse	"Tubular catheter body 16 includes an internal lumen 24 which extends from a proximal port 26 to a distal port 28 to receive the balloon catheter 14. In particular, the lumen 24 will be sized sufficiently large to receive the balloon 30 of the balloon catheter 14." 9:17-23. The length of "the tubular body 12" is "sufficient to extend from a treatment site within the coronary arteries back into a guiding catheter…. In this way, the entry port 26 will remain within the guiding catheter at all times." 10:16-22. Annotated Fig. 7 (below) depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	**Adams '292 in view of Klein**
to the longitudinal axis,	 FIG. 7.  (Fig. 6). 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.  FIG. 28. In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (*See also* Figs. 1, 8, 9, 9A, 10-15, 20-27).
to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57-16:13.
4.. The system of claim 3, wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical	(*See, e.g.*, Klein, Figs. 7, 28)., *see also above*.

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	**Adams '292 in view of Klein**
portion.	
14. The system of claim 12,	Adams '292 discloses the system of claim 12 (*See* A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	"Tubular catheter body 16 includes an internal lumen 24 which extends from a proximal port 26 to a distal port 28 to receive the balloon catheter 14. In particular, the lumen 24 will be sized sufficiently large to receive the balloon 30 of the balloon catheter 14." 9:17-23. The length of "the tubular body 12" is "sufficient to extend from a treatment site within the coronary arteries back into a guiding catheter…. In this way, the entry port 26 will remain within the guiding catheter at all times." 10:16-22. Annotated Fig. 7 (below) depicts that the proximal entry port of the tubular catheter body is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  FIG. 7.  (Fig. 6). 12 is the tubular catheter body, 26 is the proximal entry port, and 14 is the balloon catheter.  FIG. 28. In figure 28, the balloon catheter (BC) is shown entering the skived or angled proximal entry port of the tubular catheter body. (*See also* Figs. 1, 8, 9, 9A, 10-15, 20-27).
that is adapted to receive an interventional cardiology device	Adams '292 is "directed to the structure and use of a distal extension … for a guide catheter" (Adams '292, 4:36-37 (Exh. 100_)), wherein "[g]uide catheter 52 is an elongated, flexible tubular member defining a first guide cathter lumen 53

Claim Chart A-2: Cl. 3-4, 14	
The '850 Patent	**Adams '292 in view of Klein**
passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	through which an angioplasty balloon catheter 60 or some other angioplasty device is disposed and guided to a stenosis or obstruction." (*Id*., 11:17-20); and "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57-16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	(*See, e.g.*, Klein, Figs. 7, 28)., *see also above.*

B. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of Adams '452

As shown below, each element recited in claims 1-4, 8, 12, 14 And 18 is obvious over Adams '292 in view of Adams '452, which was not cited or considered either alone or in combination with Adams '292 during prosecution of the '850 Patent. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above. As set forth in section VII above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107 and 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary

skill in the art from the disclosures of analogous art, particularly Adams '292 and Adams '452. *See* (Exh. 1003 ¶¶ 84-86, 112-15).

The Adams '452 patent discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." (Exh. 1011, 8:47-50). The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. (*See* Exh. 1003 ¶ 36). The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10. (*Id*).

This disclosure satisfies the structural limitations of claim 3 requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of claim 4 that "the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion," and the limitation of claim 14 that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis." (*See* Exh. 1003 ¶¶ 112-15).

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.,* Exh. 1003 ¶¶ 112-115; Exh. 1011, 15:57-16:13 ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...")).

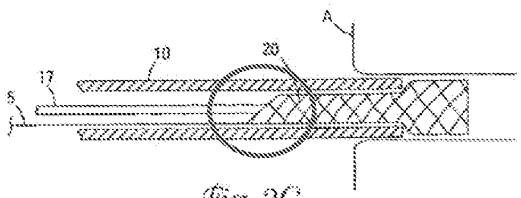
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86 and 112-15), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Adams '452 to meet the limitations of the challenged claims. Adams '292 and Adams '452 are both analogous to the '850 patent as they are directed to the same type of device, are in the same field of endeavor and are reasonably pertinent to the problem faced by the inventor of the '850 patent. (*See* Exh. 1003 ¶¶ 71, 75-76). As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Adams '452 in addressing the problem addressed by the '850 patent. (*See id.* ¶¶ 84-86, 112-115).

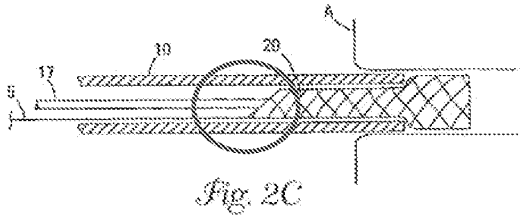
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34 (flared proximal end 38), *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the disclosure of Adams '292 with the teaching in Adams '452 of the advantages of a skived proximal

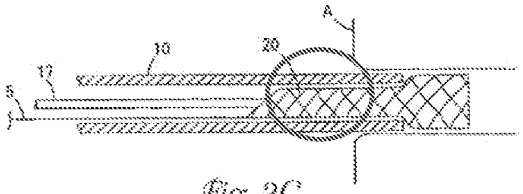
opening to the device lumen of a cardiovascular treatment device for facilitating a smoother withdrawal of the device from the guide catheter. (*See* Exh. 1003 ¶¶ 84-86, 112-115). This is particularly true given that the devices of Adams '452 and Adams '292 are both directed to the receipt of interventional cardiology devices through a proximal opening of the device while a proximal portion of the device is within the standard guide catheter. (*Id.* ¶¶ 32, 36, 71 and 75-76). Moreover, Adams '292 and Adams '452 were both issued to the same named inventor, Daniel O. Adams; the fact that the inventor of the Adams '292 device in 1992 included a skived proximal side opening when designing a similar device (Adams '292 is cited as prior art on the face of the Adams '452 patent) ten years later is further evidence that, by 2006, a POSA would routinely include a skived or angular side opening in such rapid exchange devices.

In sum, Adams '452 shows that using skived proximal lumen openings for the delivery of devices while the proximal opening is within the lumen of a guide catheter was well known by the time of the '850 patent and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*See* Exh. 1003 ¶¶ 112-15).

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**
3. The system of claim 2,	Adams '292 discloses the system of claim 2 (*See* A-1, above).
wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	Adams '452 discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." 8:47-50. "A proximal wire … extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter." 8:47-50. The guide seal has a "portion which remains in the lumen of the guide catheter when the guide seal is deployed." 8:55-56. The guide seal may be formed of braided wires with a polymer covering or membrane attached. 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  *Fig. 2C* The proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
to receive the interventional cardiology devices into the coaxial lumen while the proximal	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**
portion remains within the lumen of the guide catheter.	to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57- 16:13.
4.. The system of claim 3,	As shown above, Adams '292 in combination with Adams '452 discloses the system of claim 3.
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	As shown above, the Adams '452 patent discloses a proximal opening of a lumen in a catheter skived or cut at an angle, forming structure defining a full circumference portion and structure defining a partially cylindrical portion.
14. The system of claim 12,	Adams '292 discloses the system of claim 12 (*See* A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	Adams '452 discloses a guide seal that "comprises an elongate body defining an interior cavity which, when deployed in a vessel, is large enough to allow passage of a catheter used to deliver … an expandable filter or balloon." 8:47-50. "A proximal wire … extends axially and controls acuation of the guide seal by its position relative to the distal end of the guide catheter." 8:47-50. The guide seal has a "portion which remains in the lumen of the guide catheter when the guide seal is deployed." 8:55-56. The guide seal may be formed of braided wires with a polymer covering or membrane attached. 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  *Fig. 2C* The proximal portion of the guide seal 20 remains

Claim Chart A-4: Cl. 3-4, 14	
The '850 Patent	**Adams '292 (1011) in view of Adams'452 (1019)**
	within the lumen of the guide catheter 10 while the distal portion of the guide seal 20 extends beyond the distal end of the guide catheter 10. The guide seal 20 receives an interventional device (the delivery catheter 17) while the proximal portion of the guide seal 20 remains within the lumen of the guide catheter 10.
that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57- 16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	As shown above, Adams '452, Fig. 2C; 9:11-46. The proximal opening of the guide seal 20 is skived or cut at an angle, forming an opening that extends for a distance along the longitudinal axis:  *Fig. 2C*

C. Claims 1-4, 8, 12, 14 and 18 Are Obvious Under 35 U.S.C. § 103 Over Adams '292 In View Of Steinke

As shown below, each element recited in claims 1-4, 8, 12, 14 and 18 is obvious over Adams '292 in view of Steinke, which was not cited or considered either alone or in combination with Adams '292 during prosecution of the '850 Patent. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set

forth above. As set forth above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107 and 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292 and Steinke. *See* (Exh. 1003 ¶¶ 108-111).

Steinke discloses "a catheter which allows rapid exchange" (Exh. 1020, 3:1-2) where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis. A POSA would understand that the skived proximal "entry port" of Steinke functions as both an entryway and exit for an interventional cardiology device as a guidewire is passed or "received" therethrough upon delivering and removing the Steinke balloon catheter during treatment. (Ex. 1003 ¶¶ 35 and 72). This disclosure satisfies the structural limitations of claim 3 requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of claim 4 that "the proximal side opening includes structure defining a full circumference portion and

structure defining a partially cylindrical portion," and the limitation of claim 14 that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis."

Even if the functional language of claims 3 and 14 are accorded patentable weight, Adams '292 expressly discloses such functions. (*See, e.g.*; Exh. 1011, 15:57-16:13 ("the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...")).

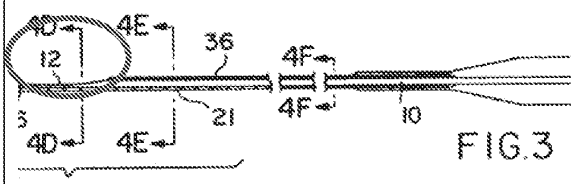
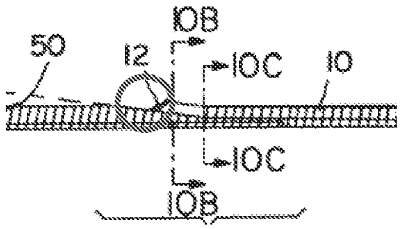
As confirmed by the Solar Declaration (Exh. 1003 ¶¶ 84-86 and 116-119), a POSA would have found it obvious to modify the proximal opening of the Adams '292 device in view of Steinke to meet the limitations of the challenged claims. Adams '292 and Steinke are both in the same field of endeavor as the '850 patent and are pertinent to the problem faced by the inventor of the '850 patent. (*Id.*, 77-78). As such, one of skill in the art would have been aware of these references and would have referred to Adams '292 and Steinke in addressing the problem addressed by the '850 patent. (*Id.*, 116-119).

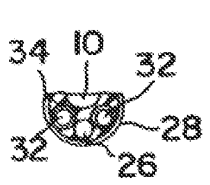
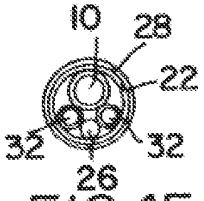
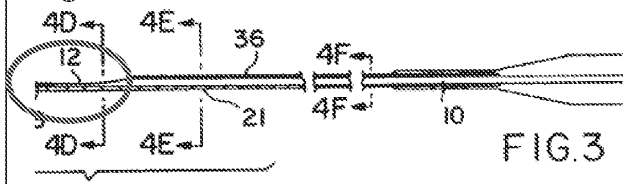
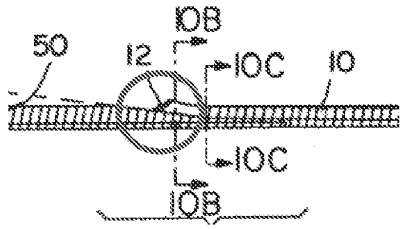
Adams '292 highlights the advantages of varied designs for the proximal opening to the catheter's device delivery lumen. (*Compare* Exh. 1011, 6:24-34

(flared proximal end 38) *with id.*, 11:65-12:12 (longitudinal slit 78)). Accordingly, a POSA would be motivated to combine the Adams '292 disclosure with the teaching in Steinke of the advantages of a skived proximal opening to the device lumen of a cardiovascular treatment catheter for "varying flexibility along the length of the catheter, without abrupt changes in stiffness or an undesirably stiff transition region." (Exh. 1020, 3:1-7). This is particularly true given that both Steinke and Adams '292 disclose rapid exchange devices, for use within a standard guide catheter, and are directed to extension beyond the distal end of the guide catheter to the treatment site. (Exh. 1003 ¶¶ 32-34, 37 and 84-86).

In sum, Steinke shows that using skived proximal openings with rapid exchange catheters was well known by the time of the '850 patent, and employing a skived (as opposed to perpendicular) design for the proximal opening of the Adams '292 device would have required no creativity, experimentation, or invention, but rather would have amounted to a simple substitution of a known element to obtain predictable results. (*Id.* ¶ 116-19).

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
3. The system of claim 2,	Adams discloses the system of claim 2 (*See* A-1, above).
wherein the proximal portion of the tubular structure further comprises structure	Steinke discloses "a catheter which allows rapid exchange," 3:1-2, where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis,	and which is accessible from a side transverse to the longitudinal axis as depicted in Fig. 3:  FIG.3 FIG.9  12 is "the guidewire entry 12 (also referred to as the distal entry or side port entry)." 6:51-54. Steinke further discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit…." 9:66-10:1.
to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...." 15:57-16:13.
4.. The system of claim 3,	(*See* claim 3 above).
wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical	Steinke discloses skived side port entry depicted in Figs. 4D, 4E defines a full circumference portion and a partially cylindrical portion:

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
portion.	 FIG.4D  FIG.4E
14. The system of claim 12,	Adams discloses the system of claim 12 (*See* A-1, above).
wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis	Steinke discloses "a catheter which allows rapid exchange," 3:1-2, where the proximal end of the inner lumen tubing is skived at an angle, forming an opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis:  FIG.3 FIG.9  12 is "the guidewire entry 12 (also referred to as the distal entry or side port entry)." 6:51-54. Steinke further discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit…." 9:66-10:1.
that is adapted to receive an interventional cardiology device passed through continuous lumen of the	Adams '292 discloses "the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube reaches the treatment site…. [T]he proximal funnel 260 serves to direct an angioplasty device into lumen 269 of extension 250 ...."

Claim Chart A-5: Cl. 3-4, 14 Adams '292 (1011) in view of US 5,328,472 ("Steinke")	
The '850 Patent	**Steinke (Exh. 1020)**
guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen,	15:57-16:13.
the opening extending substantially along at least a portion of a length of the substantially rigid portion.	Steinke discloses "a guidewire lumen extending from the spring coil shaft distal end to the side port, said guidewire lumen adapted to receive a guidewire in a sliding fit…." 9:66-10:1.

D. Claims 1, 2, 8, 12 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams '292 In View Of The Knowledge of One Of Skill In The Art

Dependent claims 8 (depending from claim 1) and 18 (depending from claim 12) require that "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." The Adams '292 patent discloses that the outer diameter of the flexible tube is smaller than the inner diameter of the guide catheter, defining a range of diameters for the flexible tube, the largest of which would include tubes with an inner diameter not more than one French smaller than the cross-sectional inner diameter of the guide catheter. (Exh. 1011, 5:64-67). A POSA reading this disclosure of the Adams '292 patent at the time of the claimed invention would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner

diameter of the outer guide catheter and, therefore, would have been motivated to practice the invention within the claimed range of not more than one French. (Exh. 1003 ¶¶ 125-26).

In this case, the disclosed range for the difference in diameters between the outer guide catheter and the inner guide catheter of the device was already known in the field by the time of the '850 patent and, therefore, a POSA would have been motivated to conform to such teachings in practicing the Adams '292 invention with the predictable and expected results of allowing for the insertion of larger devices and avoiding the possibility of the guidewire becoming disposed in the space between the inner and outer guide catheters. (*Id).*

E. Claims 1, 2. 8, 12 And 18 Are Obvious Under 35 U.S.C. §103 Over Adams In View Of Takahashi

As shown below, each element recited in dependent claims 8 and 18 is obvious over Adams '292 in view of Takahashi, which was cited during prosecution of the '032 Patent but was not discussed in any Office Action of either the '032 Patent or the '850 Patent, or considered in combination with Adams '292. Claims 1, 2, 8, 12, and 18 are anticipated by Adams '292 for the reasons set forth above. As set forth in section above, Adams '292 discloses all the limitations of the those claims. (Exh. 1003 ¶¶ 87-107, 120-124). To the extent any of the claim limitations are not explicitly disclosed in Adams '292, such limitations could be found by one of ordinary skill in one or more of the other references and would

have been in the possession of or obvious to one of ordinary skill in the art from the disclosures of analogous art, particularly Adams '292 and the Takahashi article. *See* (Exh. 1003 ¶¶ 127-29).

Claims 8 and 18 require that "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."

Takahashi satisfies the limitations of claims 8 and 18 in that it discloses a method of inserting a 5 French guiding catheter into a 6 French guiding catheter such that the cross-sectional inner diameter of the 5 French catheter is not more than one French smaller than the cross-sectional inner diameter of the 6 French catheter. A POSA would have understood the advantages of having minimal difference in diameter between the outer diameter of the inner guide catheter and the inner diameter of the outer guide catheter, and would recognize that this teaching of Takahashi's 5-in-6 system could be applied to any guide extension device for insertion through a standard guide catheter, such as the Adams '292, and would have been motivated to do so. (Ex. 1003 ¶ 122, 127-29).

Claim Chart A-6: Cl. 8, 18	
The '850 Patent	**Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1021)**
8. The system of claim 1,	Adams '292 discloses the system of claim 1 (*See* A-1, above).
wherein the cross-sectional inner diameter of the	"The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a

Claim Chart A-6: Cl. 8, 18	
The '850 Patent	**Adams '292 (Exh. 1011) in view of Takahashi (Exh. 1021)**
coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A)." (Exh. 1021 at 452). "The inner lumen of the 5 Fr Heartrail catheter is 0.059' in diameter…. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter…." (*Id*). "In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr. catheter…." (*Id*). "Only inserting the 5 Fr guiding catheter into the 6Fr catheter increased backup support…." (*Id*). "A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter." (*Id*. at 454).
18. The system of claim 12	Adams discloses the system of claim 12 (*See* A-1, above).
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.	*See* Takahashi disclosures set forth in claim 8 (above).

IX. CONCLUSION

Based on the foregoing, it is clear that claims 1, 2, 8, 12, and 18 of the '850 Patent define subject matter that is anticipated in view of Adams '292 and that the claims 1-4, 8, 12, 14, and 18 of the '850 Patent define subject matter that is obvious in view of the knowledge of a POSA combined with Adams '292 and the

teachings of the additional references cited above. Adams '292 and the prior art combinations cited above were never considered by the Examiner; if they had been, such claims would not have issued. In light of the evidence set forth herein, which establishes a reasonable likelihood that Petitioner will prevail on at least one claim of the '850 patent, Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Exhibits was served by depositing the same with Quick International Courier on May 16, 2014, to the USPTO correspondence address of record listed below:

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ATTACHMENT B

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BOSTON SCIENTIFIC CORPORATION and
BOSTON SCIENTIFIC SCIMED, INC.
Petitioner

v.

VASCULAR SOLUTIONS, INC.
Patent Owner

Case IPR: Unassigned
Patent 8,292,850

Attorney Docket No. 0025216-00057

PETITION FOR INTER PARTES REVIEW
UNDER 37 C.F.R. § 42.100

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Exhibit List for *Inter Partes* Review of U.S. Patent No. 8,292,850

Exhibit Description	Exhibit No.
U.S. Patent No. 8,292,850 B2 to Root, et al.	1001
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Declaration of Ronald Jay Solar, Ph.D., with attached Appendix1: Curriculum Vitae of Ronald Jay Solar, Ph.D. and attached Appendix 2: Prior Expert Testimony of Ronald Jay Solar, Ph.D	1003
U.S. Patent No. 8,048,032 to Root, et al.	1004
U.S. Patent No. 8,142,413 to Root, et al.	1005
File History for U.S. Patent No. 8,048,032	1006
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U.S. Publication No. 2004/0236215 A1 to Mihara et al.	1009
Translation of Japanese Patent Application No. 2003-070808	1010
U.S. Patent No. 5,527,292 to Adams et al.	1011
U.S. Publication No. 2007/0260219 A1 to Root et al.	1012
U.S. Publication No. 2003/0195546 A1 to Solar, et al.	1013
U.S. Patent No. 6,638,268 to Niazi	1014
U.S. Publication No. 2005/0004523 A1 to Osborne, et al.	1015
U.S. Publication No. 2004/0127927 to Adams	1016
U.S. Patent No. 6,338,725 B1 to Hermann et al.	1017
U.S. Patent No. 5,776,141 to Klein et al.	1018
U.S. Patent No. 7,232,452 to Adams et al.	1019
U.S. Patent No. 5,328,472 to Steinke et al.	1020
Takahashi et al., "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," *Catherization and Cardiovascular Interventions* 63:452-456 (2004)	1021
U.S. Patent No. 5,690,613 to Verbeek	1022
U.S. Patent No. 5,156,594 to Keith	1023
U.S. Patent No. 5,102,403 to Alt	1024
Kucklick, Theodore R., The Medical Device R&D Handbook (2006)	1025
Amended Complaint filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn). (May 28, 2013)	1026
Memorandum In Support of Motion for Preliminary Injunction filed by Vascular Solutions, Inc. in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn).	1027

Exhibit Description	Exhibit No.
(June 10, 2013)	
Declaration of Howard Root In Support of Vascular Solution, Inc.'s Motion for Preliminary Injunction with Non-Confidential Exhibits filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn). (June 10, 2013)	1028
Boston Scientific Corporation Opposition to Vascular Solutions, Inc.'s Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn). (July 28, 2013)	1029
Non-Confidential Memorandum Opinion and Order Granting In Part Plaintiff's Motion for Preliminary Injunction filed in *Vascular Solutions, Inc. v. Boston Scientific Corporation*, No. 13-cv-1172 (JRT-SER) (D. Minn). (December 19, 2013)	1030
Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed December 27, 2013	1031
Vascular Solutions, Inc.'s Opposition to Boston Scientific Corporation's Motion for An Interim Stay and Stay Pending Appeal, No. 2014-1185 (Fed. Cir). filed January 3, 2014	1032
Boston Scientific Corporation's Non-Confidential Opening Brief, No. 2014-1185 (Fed. Cir). filed January 7, 2014	1033
Vascular Solutions, Inc.'s Non-Confidential Responsive Brief, No. 2014-1185 (Fed. Cir). filed January 29, 2014	1034
Boston Scientific Corporation's Reply Brief, No. 2014-1185 (Fed. Cir). filed February 3, 2014	1035
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U.S. Publication No. 2002/0165598 A1 to Wahr et al.	1041
U.S. Patent No. 5,267,958 to Buchbinder et al.	1042

Inter partes review is respectfully requested for claims 1-4, 8, 11, 13, 17 of U.S. Patent No. 8,292,850 ("the '850 Patent") (Exh. 1001).

I. MANDATORY NOTICES (37 C.F.R. § 42.8(a)(1))

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

Boston Scientific Corporation and Boston Scientific Scimed, Inc. (collectively "Petitioner") are the real parties-in-interest.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

The '850 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Minnesota in a case titled *Vascular Solutions, Inc. v. Boston Scientific Corp.*, No. 1:13-cv-1172 (JRT/SER) (May 16, 2013). Petitioner is also seeking *inter partes* review of the '850 Patent on other grounds in another petition to be filed concurrently herewith. Further, Petitioner is filing two separate petitions on non-redundant grounds seeking *inter partes* review of U.S. Patent No. 8,048,032 (the "'032 patent") and one petition seeking review of U.S. Patent No. 8,142,413 (the "'413 patent") to be filed concurrently herewith. In all, five petitions will be filed. Petitioner requests that all of these petitions be assigned to the same Board for administrative efficiency, as all three patents are closely related and are directed generally to the same subject matter. Specifically, the '850 patent is a division of application No.

12/824,734, which issued as the '413 patent, and the '413 patent is a division of application No. 11/416,629, which issued as the '032 patent. The claims challenged therein are method ('413 patent) and apparatus ('032 patent) versions of the system claims of the '850 patent challenged herein.

C. Lead And Back-Up Counsel (37 C.F.R. §§ 42.8(b)(3), 42.10(a))

Petitioners designate undersigned David R. Marsh (Reg. No. 41,408) of Arnold & Porter LLP as lead counsel and Kristan L. Lansbery (Reg. No. 53,183), also of Arnold & Porter LLP, as back-up counsel.

Lead Counsel	Back-Up Counsel
David R. Marsh (Reg. No. 41,408) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5068 Facsimile: 202.942.5999 Email: david.marsh@aporter.com	Kristan L. Lansbery (Reg. No. 53,183) ARNOLD & PORTER LLP 555 Twelfth Street, NW Washington, DC 20004-1206 Telephone: 202.942.5186 Facsimile: 202.942.5999 Email: kristan.lansbery@aporter.com

D. Service Information (37 C.F.R. § 42.8(b)(4))

Petitioner consents to service by email to lead and backup counsel at xBSC_VSI_IPRService@aporter.com.

II. PAYMENT OF FEES (37 C.F.R. § 42.103)

The undersigned authorizes the Office to charge Deposit Account No. 502387 the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment

for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF RELEVANT TECHNOLOGY AND '850 PATENT

A. Overview Of Interventional Cardiology Procedures

The claims of the '850 patent are directed to the field of interventional cardiology procedures, such as the treatment of obstructive coronary artery disease. (*See* Exh. 1001, 1:7-36). During such procedures, physicians deploy thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. (*Id.; see* Declaration of Ronald Jay Solar, Ph.D. ("Solar Declaration") (Exh. 1003) ¶ 9). The physician introduces the treatment device into the patient's vascular system through the groin or wrist and advances it to the site of a blockage to perform a procedure—such as the inflation of a balloon or the placement of a stent—to relieve the blockage and restore blood flow. (*Id*). Often, to create a passage for such treatment devices, physicians insert a "guide catheter" earlier in the procedure. *Id.* In coronary interventions, this guide catheter typically runs from the groin or wrist to one of the coronary ostia (two openings in the aorta that open into the coronary arteries), but is too wide for advancement beyond the ostium. (*Id*). The '850 patent is directed to an apparatus that is deliverable through a standard guide catheter for extension

beyond the ostium to provide back up support—*i.e.*, to prevent the guide catheter from being dislodged during the procedure. (*See, e.g.*, Exh. 1001, 2:55-69).

B. Description Of The Alleged Invention Of The '850 Patent

The '850 Patent (Exh. 1001) contains 24 system claims, including two independent claims (claims 1 and 12). The specification of the '850 patent states that it relates "generally to catheters used in interventional cardiology procedures," and "[m]ore particularly, ... apparatus for increasing backup support for catheters inserted into the coronary arteries of the aorta." (Exh. 1001, 1:18-22).

The challenged claims of the '850 patent are not straightforward. Unlike typical system claims, the '850 patent claims are replete with functional language and ambiguous structural limitations that are unsupported by either the specification or knowledge in the art at the time of the claimed invention. Claim 1 is representative of the independent claims in the '850 patent:

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

and a length that is shorter than the predefined length of the continuous lumen of the guide catheter, the tubular structure having a cross-sectional outer diameter *sized to be insertable through* the cross-sectional inner diameter of the continuous lumen of the guide catheter and defining a coaxial lumen having a cross-sectional inner diameter *through which interventional cardiology devices are insertable*; and a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the flexible tip portion and defining a rail structure without a lumen having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter, *such that when* at least a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve in common with interventional cardiology devices that are *insertable into* the guide catheter.

Dependent claim 2 of the '850 patent depends from independent claim 1 and requires that "the tubular structure includes a distal portion *adapted to be extended beyond* the distal end 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."

Dependent claim 3 (depending from independent claim 1 and dependent claim 2), is directed to a "proximal side opening" in a proximal portion of the tubular structure, where such opening "extend[s] for a distance along the longitudinal access" and is "transverse [*i.e.*, at an angle] to the longitudinal axis." Dependent claim 14 (depending from independent claim 12) contains substantially similar limitation, except that the "partially cylindrical portion defining an opening extending for a distance along a side thereof" in the substantially rigid (as opposed to tubular) portion.

Dependent claim 4 depends from claim 3 and requires a "structure defining a full circumference portion and structure defining a partially cylindrical portion," as would result from a tube being skived at an angle for part of its length. These "side opening claims" are directed to that which was well known in the art when the '850 patent was filed: that the entryway to a lumen for the delivery of intravascular cardiology devices may be skived, or cut at an angle.

Dependent claim 8 (depending from independent claim 1) and 18 (depending from independent claim 12) require that "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."

C. Summary of the Prosecution History of the '850 Patent

The '850 Patent was filed as U.S. App. Serial No. 13/359,059 on January 26, 2012 (*see* Exh. 1002, paper 1). The prosecution of the '032 patent, to which the '850 claims priority, spanned five years and three months. During that time, the Examiner issued numerous rejections of claims which are nearly identical to the system claims of the '850 patent challenged herein. Ultimately, however, following at least six rejections and eight amendments, the Examiner conditioned patentability of the claims on the addition of a "rail structure without a lumen" limitation within the substantially rigid portion.

The claims of the '850 patent issued following an amendment by the same Examiner of independent claims 1 and 12 moving the location of the "rail structure without a lumen" limitation from the tubular structure of the flexible tip portion (where the Patent Owner had sought to include it) to the substantially rigid portion, where it had been included in the '032 patent. The Examiner's stated reasons for allowance were that, "just as in the parent applications, the examiner did not find any teaching or suggestion for the claimed arrangement. Specifically, adding a guide catheter to the claimed rail structure with the claimed flexible tip that is insertable through a hemostatic valve is not taught or suggested by the prior art." A Notice of Allowance was mailed August 22, 2012, and the '850 Patent issued on October 23, 2012. (Exh. 1002 at 16).

IV. REQUIREMENTS FOR INTER PARTES REVIEW

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '850 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner certifies that the '850 patent (Ex. 1001), is available for *inter partes* review and that Petitioner is not barred or estopped from requesting an *inter partes* review challenging the claims on the grounds identified in this petition.

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

The precise relief requested by Petitioner is that claims 1-4, 8, 12, 14, and 18 of the '850 Patent be found unpatentable.

C. Claims for Which *Inter Partes* Review Is Requested

Pursuant to 37 C.F.R. § 42.104(b)(1), Petitioner requests *inter partes* review of claims 1-4, 8, 12, 14, and 18 of the '850 Patent.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

This Petition, supported by the grounds set forth below and the Solar Declaration (Ex. 1003), demonstrates a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims and that each of the challenged claims is unpatentable for the reasons cited herein. *See* 35 U.S.C. § 314(a). *Inter partes* review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §§ 102 and 103.

No.	Grounds
1	Claims 1-4, 8, 12, 14, and 18 are obvious over Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the'032 patent)
2	Claims 1-4, 12, and 13 are anticipated by U.S. Pub. No. 2004/0236215 to Mihara, *et. al.*
3	Claims 1-4, 12, 13 are obvious over Mihara in view of the Knowledge of One of Skill in the Art
4	Claims 1-4, 8, 12, 18 are obvious over Mihara in view of "New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter," 2004, Takahashi Online Article ("Takahashi")

Petitioner reserves the right to present new arguments and prior art references if the Patent Owner moves to amend the challenged claims.

V. Non-Redundancy of Proposed Alternative Grounds

Petitioner urges the Board to adopt each ground of unpatentability raised with respect to claims 1-4, 8, 12, 14 and 18 of the '850 patent for at least the following reasons. The proposed grounds for institution presented in the present Petition ("Petition B") are not redundant over each other, or over the grounds of rejection presented in the concurrently filed parallel Petition for *inter partes* review of the challenged claims of the '850 patent ("Petition A" (Exh. 1008)) because several differences exist between the applied prior art and their respective grounds for unpatentability. For example, the primary prior art reference in parallel Petition A (Adams '292) differs from the primary prior art reference raised herein (Mihara). Mihara anticipates a different set of dependent claims (claims 3, 4, and 14) through its disclosure of a skived proximal side opening in Figures 1-3. Adams '292

anticipates the claimed difference in diameter between the inner diameter of the device and the inner diameter of the standard guide catheter of "not more than one French" (claims 8 and 18). As a result, during the course of this proceeding, if instituted, Patent Owner could amend the claims to limit them to just one of the claimed embodiments that is anticipated by Adams '292 (Petition A) or Mihara (Petition B) alone. Accordingly, all grounds based on both Adams '292 and Mihara are needed to encompass all of the embodiments of claims 1, 2, and 12, and, as such, are not redundant. Indeed, because of the Patent Owner's unreasonably functional and broad claims, it is imperative that each ground of unpatentability be adopted so that the Patent Owner will be forced to address the differences in the underlying structures of the systems in the cited references, and so that Petitioner may address any arguments by the Patent Owner regarding the ability of structures in the prior art to perform the various functions recited in each of the challenged claims.

Petitioner's asserted ground of unpatentability in the present Petition based on Pub. No. U.S. 2007/0260219 (publication of U.S. Patent Application 11,416,629, the application of the'032 patent), is not redundant of the other grounds of unpatentability raised herein or in Petition A because it renders obvious all challenged claims only if the '850 patent is denied the benefit of its claimed May 3, 2006 priority date.

Similarly, the grounds of unpatentability raised in the present Petition regarding the obviousness of the side-opening limitations of claims 3, 4, and 14 are not redundant given that the far reaching functional language of such claims necessitate Petitioner's alternative proposed grounds of unpatentability on the basis of both anticipation in view of Mihara and obviousness over Mihara in view of the knowledge of one of skill in the art.

If the PTAB disagrees and determines that the grounds raised herein are redundant of those raised in Petition A, and will institute only on the grounds of one Petition, Petitioner respectfully requests institution on the basis of Petition A. Moreover, if the PTAB determines that there is redundancy with respect to the grounds raised herein regarding anticipation in view of Mihara and obviousness of claims 3, 4, and 14 over Mihara in combination with the knowledge of one of skill in the art, Petitioner suggests institution on the grounds of Mihara in view of the knowledge of one of skill in the art.

VI. Level of Skill In the Art

A person of ordinary skill in the art ("POSA") at the time of the alleged invention of the '850 patent would have been someone with at least the equivalent of a medical degree from an accredited institution (usually denoted in this country as a M.D. degree) or someone with the equivalent of a masters degree from an accredited institution (usually denoted in this country as an M.S. degree) in

biomedical engineering. The person must have at least three years of experience working as an interventional cardiologist, interventional radiologist, cardiothoracic surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer. Extensive experience and technical training might substitute for educational requirements, while advanced degrees might substitute for experience. (Exh. 1003 ¶ 29).

A. Construction Of The Challenged Claims

Pursuant to 37 C.F.R. § 42.100(b), the claims subject to *inter partes* review shall receive the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." Because the standards of claim interpretation used by the Courts in patent litigation differ from those used by the Office in *inter partes* review proceedings, claim interpretations submitted herein to demonstrate a Reasonable Likelihood of Prevailing are not binding upon Petitioner in any litigation may not correspond to claim constructions under the legal standards that govern court proceedings. All claim terms not specifically addressed below have been accorded their broadest reasonable interpretation ("BRI") in light of the

patent specification, including their plain and ordinary meaning to the extent such a meaning could be determined by a skilled artisan.[1]

1. "rail structure without a lumen"

Because the '850 patent does not disclose any structure for the "rail structure without a lumen" limitation of independent claims 1 and 12, it is invalid under 35 U.S.C. §112, ¶ 2. The word "rail" appears in the specification of the '850 patent only twice. *First*, the Summary of the Invention refers to a "guidewire rail segment," defined as "permit[ing] delivery without blocking the use of the guide catheter." (Exh. 1001, 2:65-69). *Second*, Fig. 17 is described as "a plan view of a coaxial guide catheter having a longer rail segment," without any guidance as to which portion(s) of Figure 17 constitute the "rail segment." Neither of these references discloses any meaning for "rail" in the claim term "rail structure without a lumen." (1003 ¶ 52). Moreover, nothing in the specification suggests that the rail structure consists of the "tapered inner catheter," "full circumference portion," "cutout portion," "reinforced portion," "hemicylindrical portion," "second full circumference portion," "arcuate portion," "braid or coil reinforcement," "most proximal portion of braid or coil reinforcement," "relief cut," "hemi-tube portion,"

[1] Petitioner reserves the right to challenge the validity of the '032 patent claims based on a failure to comply with § 112 ¶¶ 1, 2, and 6, in any proceeding.

"single cuts," "double cuts," "connector hub," "funnel portion," "grip portion," to name a few, nor would be so read by a POSA. (*Id*).

However, 35 U.S.C. § 311(b) prevents Petitioner from challenging the validity of an original claim based on a failure to comply with 35 U.S.C. § 112 in this Petition. Accordingly, solely for the purpose of challenging the patentability of independent claims 1 and 12 under 35 U.S.C. §§ 102 and 103, and claims 3, 4, 8, 14 and 18 depending therefrom, Petitioner submits that, a POSA would understand "rail structure" to refer to a pushing or advancement structure. "Monorail" or rapid exchange catheters are characterized by a relatively guide wire lumen; this cannot be the "rail structure" for purposes of the claim, however, because the claimed structure must be "without a lumen." (Exh. 1003 ¶ 53). A POSA would therefore understand the "rail structure" to be the other feature of rapid exchange catheters, a stiffening element that makes the catheter sufficiently pushable to advance (even though it is not being advanced over a guide wire throughout its entire length). (*Id*. ¶ 54). Accordingly, the term "rail structure without a lumen" can be construed for purposes of this Petition to mean a "pushing or advancement structure without a lumen." (*Id*).

2. "interventional cardiology device(s)"

Interventional cardiology devices are thin, flexible treatment devices, such as guidewires, balloon catheters, filters, stents, stent catheters, or other devices to

treat a blockage (occlusion) or narrowing (stenosis) in the arteries due to atherosclerotic plaques or other lesions. The specification of the '850 patent expressly defines the term "interventional cardiology devices" consistently with this construction. (Exh. 1001, 1:28-31 ("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")). (Exh. 1003, ¶ 55).

3. "to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter" / "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"

Dependent claim 3 recites that the structure of the proximal side opening to which the claim is directed is "to receive the interventional cardiology devices into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter." (Exh. 1001, 11:-17-20 Dependent claim 14 similarly recites an opening "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…." (Exh. 1001, claim 3 (emphasis added).) This language merely indicates the intended use of the claimed proximal opening (to receive an interventional cardiology device), and the device itself (for use within a guide catheter) as well as the order in which such intended uses may occur

(receiving the device "into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter"). (*Id.*, 11:18-20) Accordingly, such language should not be read as positive limitations on apparatus claims 3 or 14 of the '850 patent. To the extent that there is any doubt, the BRI of the claims suggests that only the structural limitation(s) of claims 3 and 14 (namely, a skived proximal opening) should be accorded patentable weight. The Federal Circuit has made clear that the validity of a system claim depends ***solely*** on the claimed structure and not on the use or purpose of that structure. *Catalina Mktg Int'l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

Because the '850 patent claims are system claims, the requisite invalidity analysis turns on a direct comparison of the claimed ***structures*** with the prior art ***structures***. *See Catalina Mktg. Int'l, 289 F.3d at 810* ("To hold otherwise would effectively impose a method limitation on an apparatus claim without justification"); *In re Shreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). The functional statements in claims 3 and 14 are not structural because the entire structure of the proximal side opening is described elsewhere in the claim; deletion of the functional phrases from claims 3 and 14 would not affect the structure of the claimed proximal opening. At most, the language requires a proximal opening large enough to allow passage of an interventional cardiology device.

Petitioner has, nevertheless, included sufficient evidence such that, even if the Board were to construe these functional statements of intended use as positive limitations of claims 3 and 14, the grounds for unpatentability set forth below still render the challenged claims invalid in view of the cited art.

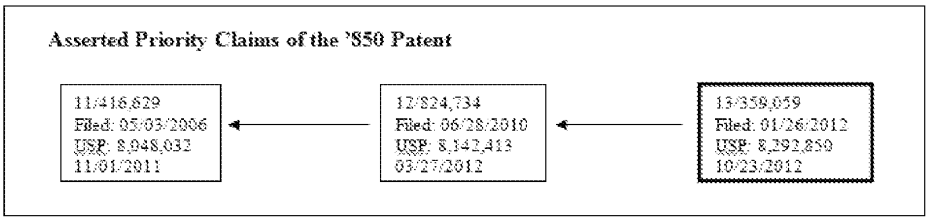
4. "adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen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

Dependent claim 2 recites: "the system of claim 1 wherein the tubular structure includes a distal portion ***adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter, such that the device assists in resisting axial and shear forces exerted by the interventional cardiology device passed through and beyond the coaxial lumen that would otherwise tend to dislodge the guide catheter from the branch artery.***" (Exh. 1001, claim 2). These are statements of intended use, not structural language. The relevant structural limitations—a tubular structure having distal and proximal portions—is included elsewhere in the claim. As discussed above, to patentably distinguish the claimed invention from the prior art, a recitation of intended use must result in a structural difference between the claimed invention and the prior art. *See, e.g.,* Practitioner's Manual of Patent Examining

Proc. § 707 (paragraph 7.37.09). As long as a prior art structure would be ***capable of*** performing the intended use, then it meets the claim. *Id*. In any event, even if this functional language in dependent claim 2 were accorded patentable weight, the prior art expressly discloses this function, as set forth below.

B. The '850 Patent Is Not Entitled To Claim Priority to the Filing Date of Either U.S. Application 11/416,629 or U.S. Application 12/874, 734

As depicted below, the '850 patent asserts priority back to May 3, 2006 through a chain of two divisional applications: (1) U.S. Patent Application No. 11/416,629 (filed May 3, 2006 and issued as U.S. Patent No. 8,048,032 (the "'032 patent"), and (2) U.S. Patent Application No. 12/824,734 (filed June 28, 2010 and issued as U.S. Patent No. 8,142,413 (the "'413 patent"):



The challenged claims of the '850 patent are not entitled to the filing dates of either U.S. Application 11/416,629 (the '032 patent application) or U.S. Application 12/874,734 (the '413 patent application) since their disclosures lack written description of the "rail structure without a lumen" in independent claims 1 and 12, from which all other challenged claims depend, and of "the tubular structure further compris[ing] [a] structure defining a proximal side opening

extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis" of claim 3 from which claim 4 depends. Accordingly, none of the challenged claims are entitled to the priority dates of either U.S. Application 11/416,629 or U.S. Application 12/874,734. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1303, 1306 (Fed. Cir. 2008) (affirming district court determination that claims "were not entitled to the prior date of the Original Application because the written description of the Original Application did not support the later issued claims").

Indeed, as the Manual of Patent Examining Procedure Section 201.1 states: "[t]he later filed application must be an application for an invention which is also disclosed in the prior application … and the disclosure in the prior application … must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. § 112. *See Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994)." MPEP § 201.1.

As written description may not be challenged in this proceeding, Petitioner submits that, if even one of the limitations of the challenged claims is not supported by the applications to which the '850 patent claims priority, then its effective priority date is no earlier than January 26, 2012. *See, e.g., Medtronic, Inc. v. Nuvasive, Inc.*, Case IPR2014-00087, Paper 10, 10 (April 8, 2014) (citing

Polaris Wireless, Inc. v. TruePosition, Inc., Case IPR2013-00323, Paper 9, 29 (PTAB 2013)).

1. No Disclosure of "Rail Structure without a Lumen"

As discussed in above, the term "rail structure without a lumen" can be construed to mean pushing or advancement structure without a lumen. The word "rail" appears in the specification of U.S. Application 11/416,629 and U.S. Application 12/874,734 only twice. *First*, the Summary of the Invention refers to a "guidewire rail segment," defined as "permit[ing] delivery without blocking the use of the guide catheter." (Exh. 1001, 2:65). *Second*, Fig. 17 is described as "a plan view of a coaxial guide catheter having a longer rail segment," without any guidance as to which portion(s) of Figure 17 constitute the "rail segment." (*Id.*, 6:1-3). Neither of these citations discloses any meaning for "rail" in the claim term "rail structure without a lumen." (Exh. 1003, ¶ 52)..

Because a POSA would understand the word 'rail' at best in the context of the term 'monorail,' which is used in the art to denote a shortened distal tube defining a guidewire lumen in a rapid exchange catheter (the term 'monorail' connotes the appearance of the short distal tube as it 'rides' over the guidewire during delivery as being similar to that of a monorail train riding along a track), U.S. Application 11/416,629 and U.S. Application 12/874,734 lack written description support for the term "rail structure without a lumen." (Ext. 1003 ¶ 53).

As such, the '850 Patent is entitled to a priority date no earlier than January 26, 2012.

C. The Prior Art References

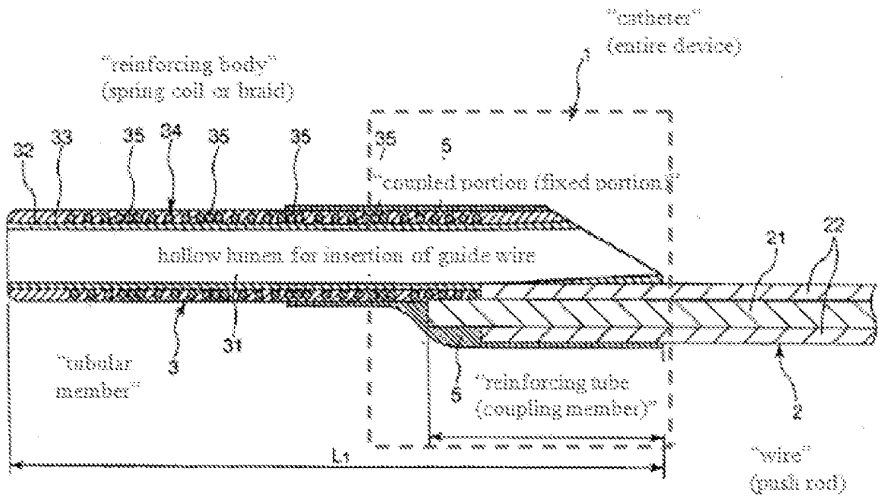
As set forth below, the references upon which Petitioner relies all constitute prior art to the '032 patent under at least §102(b).[2]

1. Mihara

U.S. Pub. No. 2004/0236215 ("Mihara") (Exh. 1009) is an application published on November 25, 2004, prior to the earliest filing date the benefit of which is claimed by the '032 patent and, thus, qualifies as prior art under § 102(b). The Mihara publication discloses a "catheter for penetrating a stenotic lesion occurred in a lumen in a human body, including: a linear wire; and a tubular body placed on a distal end side of the wire and allowing a guide wire to be inserted through its hollow portion." (Exh. 1009, Abstract; Exh. 1003 ¶¶ 33-34). An annotated version of Fig. 2 (below) provides a cross-sectional view of the Mihara catheter (the left side of Fig. 2 depicts a "distal end" of the device, and the right side depicts a "proximal end") (Exh. 1009, Fig. 2, [0028], [0031]):

[2] All references to 35 U.S.C. §§ 102 and 103 are to the pre-AIA version of the United States Code, in accordance with the filing date of the patent at issue.

FIG. 2



As shown in Fig. 2, "the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31." (Exh. 1009, [0033]).

2. Takahashi

Takahashi, *New Method to Increase Backup Support of a 6 French Guiding Coronary Catheter, Catheterization and Cardiovascular Interventions* 63:452-456 ("Takahashi," Exh, 1021) is an article published in 2004 and, thus, qualifies as prior art under § 102(b). Takahashi describes a method for deep-seating a guide catheter beyond the ostium for purposes of providing backup support during interventional cardiology procedures. (Exh. 1003 ¶ 35). The method involves the insertion of a 5 French guide catheter extension through a 6 French guide catheter, whereby the resulting difference in diameters is one French or less. (*Id*).

D. How The Construed Claim(s) Are Unpatentable

Pursuant to 37 C.F.R. § 42.104(b)(4), an explanation of how construed claims 1-4, 8, 12, 14, and 18 of the '850 Patent are unpatentable under the statutory grounds set forth below, including identification of where each element of the claim is found in the prior art patents or printed publications, is provided below, the corresponding descriptions and claim charts set forth therein, and the referenced portions of the Solar Declaration.

E. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below in Section VII and VIII and the corresponding claim charts set forth therein. Dr. Solar, an expert with 37 years of academic and industry experience in the field has reviewed the claim charts and evidentiary support submitted in this Petition and is in agreement with the grounds of invalidity and the evidentiary support set forth therein.

VII. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4)

The purported invention to which the challenged claims are directed is a combination of standard structural features, performing in expected ways, to

achieve predictable results, all of which were well known to persons of ordinary skill in the art in the field of interventional cardiology procedures at the time to which the '850 patent claims priority (hereafter "POSA"). The claimed limitations of the alleged invention are therefore unpatentable.

A. Claims 1, 2, 3, 4, 12, and 14 Are Anticipated Under 35 U.S.C. §102(b) By Mihara

As shown below, each element recited in claims 1, 2, 3, 4, 12 and 14 is anticipated by Mihara, which was not disclosed to, cited, or considered by the Examiner during prosecution of the '850 patent. "To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *See, e.g., In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

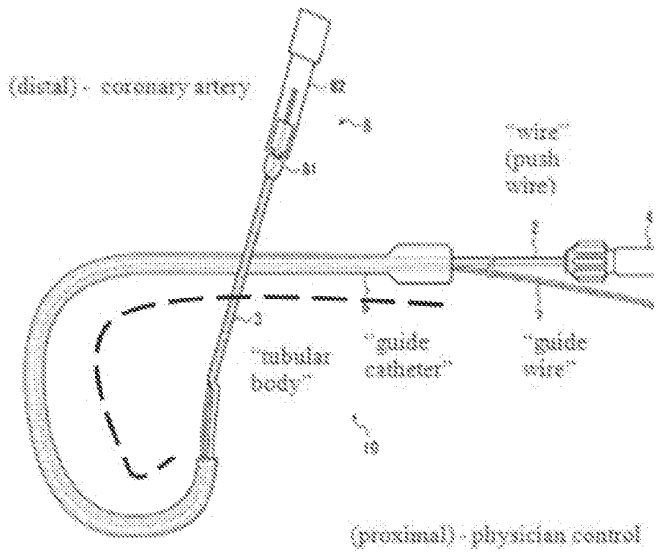
1. Claim 1

Claim 1 of the '850 patent discloses:

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

The preamble of a patent may not be limiting. *See, e.g.*, *STX LLC. v. Brine, Inc.*, 211 F.3d 588, 591 (Fed. Cir. 2000); *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). Nevertheless, all limitations recited in the preamble are disclosed by Mihara. Specifically, Mihara discloses a system for use with a standard guide catheter. (Exh. 1009, [0092]) ("First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery")). In annotated Figure 3 below, the guide catheter 6 (dashed line) used with the Mihara catheter has a continuous central lumen and a proximal end which a POSA would understand is directed to insertion through a hemostatic valve. (*Id.*, Fig. 3; Exh. 1003 ¶ 68).

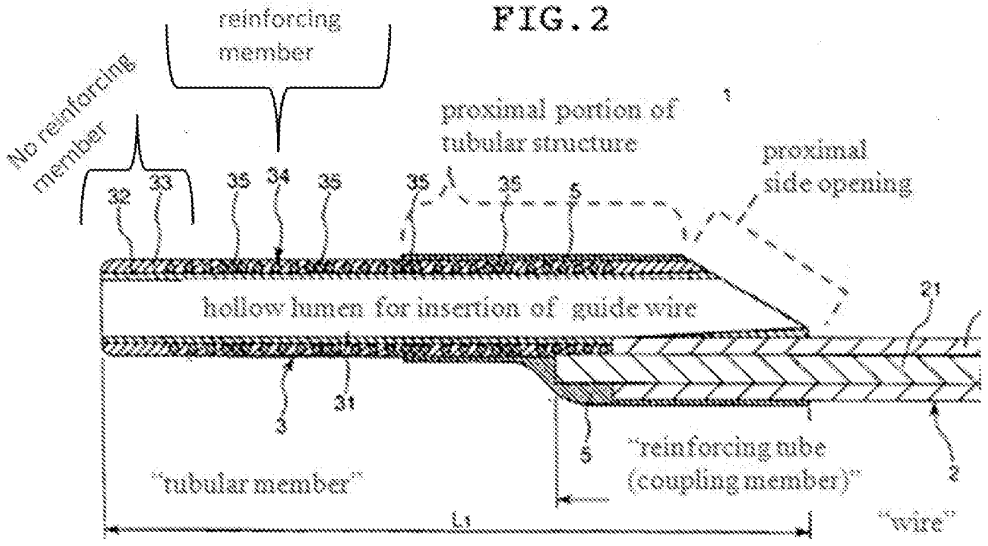
FIG. 3



Mihara also discloses that the guide catheter has a circular cross-section that is sized to allow for interventional cardiology devices to be passed therethrough and into a branch artery. (Exh. 1009, [0005]) ("a long hollow tube called a guide catheter is inserted into a blood vessel, and placed at an entrance of a coronary artery. After that, the guide wire is pulled out, and another guide wire and a balloon catheter are inserted in a lumen of the guide catheter"); *see id.* Fig. 3; [0092]-[0093]).

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

Mihara discloses a flexible tip portion defining a tubular structure in the form of a "tubular body," having an inner and outer diameter. Specifically, annotated Fig. 2 of Mihara (below) discloses a catheter wherein the distal-most tip portion of the tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being "preferably formed of a flourine resin such as polytetrafluoroethylene (PTFE)." (Exh. 1009, [0051]). The outer layer 33 is also described as being preferably "composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof." (*Id.*, [0052]).



The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm." (Exh. 1009, [0056]).

The tubular structure 3 is also shorter (10-40 cm) than the predefined length of the continuous lumen of the guide catheter 6 (100 cm). (Exh. 1009, [0057]) ("Although the length of the tubular body 3…is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm.").

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 defining a coaxial lumen

having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and

Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for insertion through the guide catheter lumen (1.8 mm). (Exh. 1009, [0081]-[0092]). As shown in annotated Fig. 3 in the claim chart below, Mihara further discloses that the flexible tube ("tubular body 3") is placed coaxially relative to the guide catheter 6.

Mihara also discloses that, when used in combination with the guide catheter, the concentrically aligned flexible tube defines a lumen through which the interventional cardiology device of guide wire 7 is insertable. (Exh. 1009, [0033] ("As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end portion of the wire 2"); *id.*, [0049]) ("The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31")).

a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen

Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: (Exh. 1009, [0036] ("As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed"); *id.*, [0037] ("The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2")).

As detailed above, the broadest reasonable construction of "rail structure without a lumen" is "a pushing or advancement structure without a lumen." As such, the rigid push wire of Mihara meets the limitations of this claim element in that it constitutes a structure without a lumen that is substantially rigid relative to the flexible tube to which it is proximal and operably connected.

and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion

Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip. (Exh. 1009, [0048] ("The outer diameter of the wire 2 in the proximal portion is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm"); *id.*, [0055] ("the outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm")).

> ***and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the 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.***

Mihara discloses that the combined length of the tubular member and the substantially rigid portion of the device is "preferably in the range of 1110-1500 mm" (110-150 cm), which is longer than the length of a standard guide catheter lumen (100 cm). (Exh. 1009, [0092]-[0034]; *see id.* [0073]-[0075]).

Figure 3 further depicts how Mihara discloses to a POSA that, when the tubular member 3 is extended beyond the distal end of the guide catheter 6, the

push wire 2 extends proximally outside the guide catheter at the same point as the guidewire 7 (where, in practice, the hemostatic valve is located). (Exh. 1003 ¶ 77).

2. Claim 2

Both the '850 patent and Mihara are directed to a catheters that provide strong backup support or "pushability" for deep intubation beyond the ostium, providing a counter-force to the force/resistance created by the advancement of a guidewire into a tight or substantially occluded target vessel. (Exh. 1003 ¶¶ 32-33). These are purely functional characteristics as claim 2 recites no additional structural features from those included in the limitations of claim 1. As noted above, claim scope is not limited by nonstructural language and statements of intended use for a claimed system.

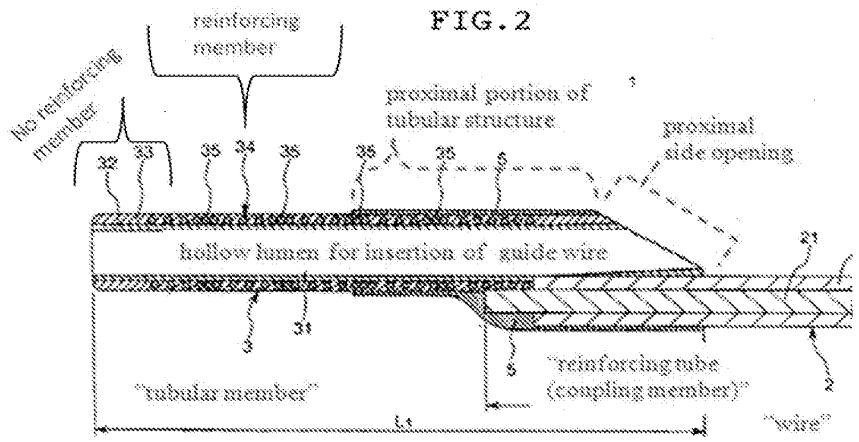
Even if the functional language in dependent claim 2 regarding the intended use of the system is found to limit the scope of claim 2, Mihara expressly discloses the function claimed therein as detailed in the claim charts below. Specifically, Mihara discloses that "the catheter of the present invention has an excellent push-in property. Therefore a push-in force applied from a proximal end side is transmitted to a distal end portion exactly, and as a result, the catheter can penetrate a stenotic lesion occurred in a lumen in the human body easily and rapidly." (Exh. 1009, [0024]).

VIII. Obviousness of Challenged Claims

The below challenged claims of the '850 patent are rendered obvious under §103(a) in view of the prior art references set forth below, either in view of the knowledge of one of ordinary skill in the art, or in the combinations expressly described herein. Obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 418-20, 82 U.S.P.Q.2d 1385 (2007); In re Jones, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).*

A. Claims 1-4, 8, 12, 14 And 18 Are Obvious Under 35 U.S.C. § 103 Over Adams In View Of Mihara

Dependent claims 3, 4, and 14 are all directed to a skived proximal side opening to a lumen through which interventional cardiology devices are received. Mihara was neither cited nor considered during the prosecution of the '032 Patent. Figure 2 of Mihara depicts how the proximal opening of the tubular body 3 to the guide wire lumen 31 of the catheter 1 is skived or cut at an angle where the tubular body 3 overlaps with and is connected to the wire push rod 2.



Specifically:

- "the wire 2 is provided with appropriate rigidity (flexural rigidity and torsional rigidity), which enhances a push-in property and transmittance of a torque." (Exh. 1009, [0043]).
- "The tubular body 3 and the wire 2 are coupled (fixed) under a condition that the distal end portion of the wire 2 and the proximal end portion of the tubular body 3 partially overlap with each other in a longitudinal direction. With this configuration, the wire 2 and the tubular body 3 overlap with each other in the coupled portion (fixed portion). Therefore high coupling strength can be obtained, and the enlargement of the distal end portion of the catheter 1 can be prevented." (Exh. 1009, [0061]).
- "Although a method for fixing the wire 2 and the tubular body 3 is not particularly limited, they are fixed by covering the outside (outer

circumference) of the overlapped portion between the wire 2 and the tubular body 3 with a reinforcing tube (coupling member) 5.... [t]he overlapped portion between the wire 2 and the tubular body 3 is covered with the reinforcing tube 5, and thereafter, they are fused, whereby the wire 2 and the tubular body 3 can be fixed more strongly in an easy process." (Exh. 1009, [0062]).

The proximal opening in the tubular body 3—and in the reinforcing tube 5 surrounding the overlapped portion of the wire 2 and tubular body 3—thereby defines a side opening that extends for a distance along the longitudinal axis and which is accessible from a side transverse to the longitudinal axis such that "[t]he hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009, [0049]).

This disclosure satisfies the structural limitations of dependent claim 3 (which depends from claims 1 and 2) requiring that "the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis," the requirement of dependent claim 4 (depending from claims 1, 2, and 3) that "the proximal side opening includes structure defining a full circumference portion and structure

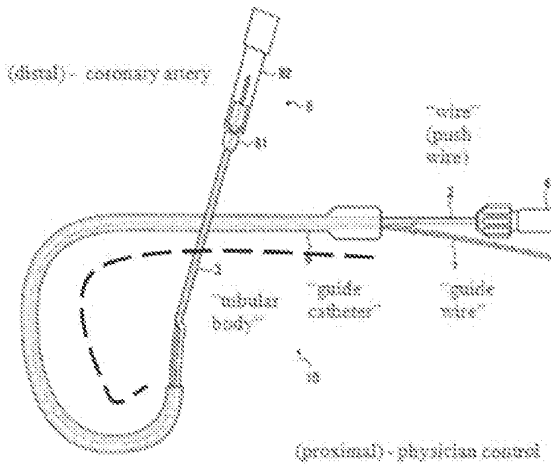
defining a partially cylindrical portion," and the limitation of claim 14 (depending from claim 12) that "the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis."

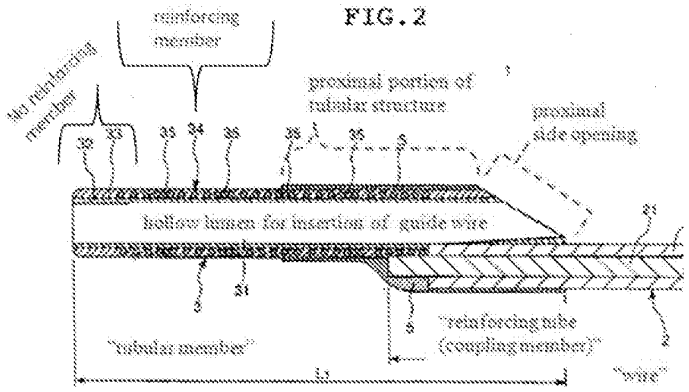
1. Claim 12

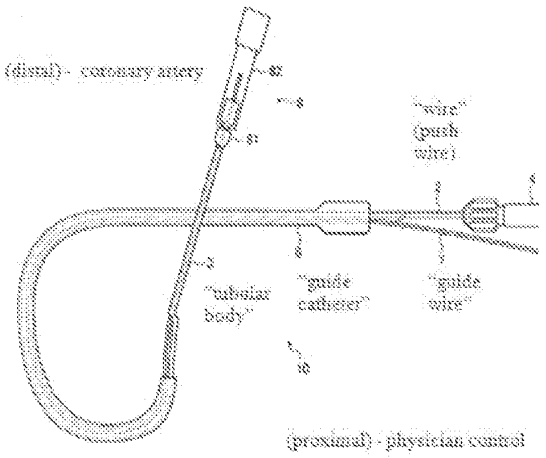
a reinforced portion proximal to the flexible tip portion;

As discussed above, claim 12 of the '850 patent includes the same limitations as claim 1, with the exception of one additional element, a "reinforced portion" proximal to the substantially rigid portion. Accordingly, Petitioner references and includes its analysis of all elements of claim 1 set forth above and in the chart below. Mihara also disclosed the "reinforced portion" of claim 12, as shown in the claim chart below.

The '850 Patent	**Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)**
1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery, the system comprising: a guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in the branch artery, the continuous lumen of	**[1]** To the extent that the preamble is a limitation, Mihara discloses a device for use with "guiding catheter 6" (*see* dashed blue line in annotated Fig. 3 below) having a continuous lumen extending for a predefined length from a proximal end to a distal end adapted to be placed in a branch artery:

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the continuous lumen of the guide catheter; and a device adapted for use with the guide catheter, including:	FIG. 3  "First, the guiding catheter 6 ... primed with distilled water was bent in a shape as shown in FIG. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery." (Exh. 1009, [0092]). **[2]** As shown in annotated Fig. 3 above, Mihara discloses that the lumen of the guide catheter 6 has a circular cross-section that is sized to allow for interventional cardiology devices (such as guide wire 7) to be passed therethrough and into a branch artery. "First the guiding catheter 6 … having an inner diameter of 1.8 mm … was bent in a shape as shown in Fig. 3 to produce a blood vessel model. The distal end of the guiding catheter 6 was placed at a position that was assumed to be engaged with an entrance of the coronary artery. Then, the guide wire 7…was inserted in the tubular body 3 of the above-described catheter 1. After that, the catheter 1 was inserted in the guiding catheter together with the guide wire 7." (Exh. 1009, [0092]-[0093]).
a flexible tip portion defining a tubular structure	**[1]** Annotated Fig. 2 of Mihara (below) discloses a catheter wherein the distal-most tip portion of the

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
having a circular cross-section and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	tubular structure does not include reinforcing members 34. Instead, the material of which the distal-most tip 32 is comprised is flexible, being "preferably formed of a flourine resin such as polytetrafluoroethylene (PTFE)." (Exh. 1009, [0051]). The outer layer 33 is further described as being preferably "composed of various kinds of thermoplastic elastomers such as a polyurethane elastomer, a polyester elastomer, and a polyamide elastomer, or a mixture thereof." (*Id.*, [0052]). FIG. 2  **[2]** The tubular structure defined by the flexible tip is disclosed as having a circular cross section: "Although the inner diameter of the tubular body 3, in other words, the diameter of the hollow portion 31, is not particularly limited, the inner diameter is preferably 0.4 to 0.8 mm, and more preferably 0.45 to 0.65 mm." (Exh. 1009, [0056]). **[3]** "Although the length of the tubular body 3…is not particularly limited, the length is preferably in the range of 100 to 400 mm, and more preferably 200-300 mm." (Exh. 1009, [0057]).
the tubular structure having a cross-sectional outer	**[1]** Mihara discloses that the outer diameter of the tubular body (0.8 mm) is smaller than and sized for

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	insertion through the guide catheter lumen (1.8 mm): "Outer diameter of a portion between 0 and 90 mm from the proximal end side of the tubular body 3: 0.87 mm." (Exh. 1009, [0081]). "First, the guiding catheter 6…having an inner diameter of 1.8 mm…." (Exh. 1009, [0092]). **[2]** As shown in annotated Fig. 3 below, Mihara discloses that the flexible tube ("tubular body 3") is placed coaxially relative to the guide catheter 6: FIG. 3  **[3]** "As shown in Figs. 1 and 2, the catheter 1 includes a linear wire 2, a tubular body 3 placed on a distal end side of the wire 2 and allowing a guide wire (not shown) to be inserted in (to penetrate) its hollow portion (lumen) 31, and an operation portion (holding portion) 4 placed on a proximal end of the wire 2" (Exh. 1009, [0033]). "The tubular body 3 is provided on the distal end side of the wire 2. The hollow portion 31 of the tubular body 3 is opened to the distal end and the proximal end of the tubular body 3, whereby a guide wire can be inserted (penetrate) in the hollow portion 31." (Exh. 1009,

The '850 Patent	Claim Chart A-1: Cls. 1, 2, 3, 4, 12, 14 in view of Mihara (Exh. 1009)
	[0049]).
a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen	Mihara discloses a substantially rigid portion 2 proximal of and operably connected to, and more rigid along a longitudinal axis than the tubular body comprising a flexible tip portion and defining a rail structure without a lumen: "As shown in FIG. 2, in the catheter 1, the hollow portion 31, functioning as a guide wire lumen through which a guide wire is inserted, is formed merely in a portion of the tubular body 3 positioned on a distal end side, and in a portion of the wire 2 positioned on a proximal end side with respect to the portion of the tubular body 3, no guide wire lumen is formed." (Exh. 1009, [0036]). "The portion of the wire 2 is solid, so that the wire 2 has relatively high flexural rigidity and torsional rigidity. Therefore, the push-in force applied by an operator from the proximal end side of the catheter 1 is transmitted to the distal end portion of the catheter 1 (tubular body 3) exactly by the wire 2." (Exh. 1009, [0037])
and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion	Mihara describes preferred embodiments where the diameter of the proximal end push wire 2 is smaller than the diameter of the tubular body 3 comprising the flexible tip: "The outer diameter of the wire 2 in the proximal portion . . . is preferably 0.5 to 1.5 mm, and more preferably 0.8 to 1.1 mm." (Exh. 1009, [0048]). "[T]he outer diameter of the tubular body 3 in a fixed portion with the wire 2 is preferably 0.8 to 1.5 mm and more preferably 1.0 to 1.3 mm." (Exh. 1009, [0055]).
and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the continuous	As shown in annotated Fig. 3 below, Mihara discloses that the combined length of the wire 2 and tubular body 3 (dashed red line) is longer than the guide catheter lumen 6 (dashed blue line). (Exh. 1009, Fig. 3).