UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

VASCULAR SOLUTIONS, INC., Plaintiff,	)	
v.	)	Civil File No. 0:13-cv-01172-JRT-SER
BOSTON SCIENTIFIC CORP., Defendant.	)	

DECLARATION OF ANTHONY C. VRBA

I, Anthony Vrba, declare and state as follows:

1. I have reviewed the Motion for Preliminary Injunction filed by Vascular Solutions, Inc. ("VSI") against Defendant Boston Scientific Corp. ("BSC"). BSC has asked me to determine whether the elements of certain claims of U.S. Patent No. 8,048,032 B2 (the " '032 patent"), U.S. Patent No. 8,142,413 B2 (the " '413 patent"), and U.S. Patent No. 8,292,850 B2 (the " '850 patent") (collectively, the "VSI patents") were (1) disclosed in U.S. Patent No. 5,527,292 (the "Adams '292 patent"), (2) known, as of 2004, to those of ordinary skill in art of designing of catheters for use in interventional cardiology and the treatment of vascular disease, and (3) disclosed in other patents relating to the design of catheters for use in interventional cardiology and the treatment of vascular disease that issued prior to 2004. I have also been asked to opine on the meaning of the term "lumen," as it is generally used and understood in the art, and how it would be construed with respect to the asserted claims of the VSI patents.

2. I have reviewed the VSI patents and believe that the field to which they relate is the design of catheters for use in interventional cardiology and the treatment of vascular disease. I

believe that I am a person of at least ordinary skill in that art based on the following: (1) my education as a degreed mechanical engineer; (2) my experience in the relevant technology having worked within the space of vascular medical devices for the past 22 years; (3) my extensive experience in vascular medical device design and development, including the design and development of catheters; (4) my research, development, and laboratory experiences with various types of guide catheters and other vascular medical devices at various stages of pre-clinical prototype evaluation and clinical observation; (5) my involvement in the invention and development of commercial guide catheter products; (6) my review of the medical and patent literature; and (7) my review of documents pertaining to this litigation.

I am currently the General Manager and Senior Vice President of Product Development for Devicix, a medical device product development design firm. I am familiar with the history of guide catheters and related technologies in the vascular medical device field. I have managed the design and development of numerous vascular medical devices during the course of my career, including interventional access devices such as guide sheaths, guide catheters, guidewires, and interventional therapeutic devices such as balloon catheters and stents. I currently have 46 patents and 50 pending patent applications on a range of interventional devices including guidewires, balloons, stents and stent delivery systems.

3. BSC is compensating me for the time I am expending in connection with this case at the rate of $ 250 per hour and reimbursing me for any expenses I incur in connection with the case. I have no interest in the outcome of the case.

4. In connection with the preparation of this declaration, I have reviewed the VSI patents, the Adams ‘292 patent, and portions of certain other patents referenced in Exhibit 1 to this declaration. I have also reviewed the declaration of VSI’s CEO Howard Root filed in support of VSI’s motion for a preliminary injunction. During the course of my review and

analysis I have also relied on my own education and experience in the field of designing catheters for use in interventional cardiology and the treatment of vascular disease.

5. I believe that all of the elements of claims 1-8, 11-17, and 19 of the '032 patent, claims 1, 2, 4, 5, and 7-13 of the '413 patent, and claims 1-8, 12-18, and 20 of the '850 patent (the "asserted claims") were (1) disclosed in the Adams '292 patent, (2) known, as of 2004, to those of ordinary skill in art of designing catheters for use in interventional cardiology and the treatment of vascular disease, and/or (3) disclosed in other patents relating to the design of catheters for use in interventional cardiology and the treatment of vascular disease that issued prior to 2004. Indeed, the Adams '292 patent, by itself, discloses all of the elements of many of the asserted claims. Further, any elements of the asserted claims not expressly disclosed by the Adams '292 patent comprise only minor, obvious variations on the Adams '292 technology. That such variations would have been obvious in 2004 to one of skill in the art is apparent from my own knowledge and experience in the field and underscored by the wealth of art reading on such limitations that was published as of 2004. The bases for my conclusions—including citations to specific portions of specific patents—are set forth in detail in the chart attached to this declaration at Exhibit A.

6. Within the field of catheter design, the term "lumen" generally refers to the space or cavity within a tubular structure. Accordingly, I believe the "push rod" of Guidezilla has a lumen. Guidezilla's push rod is constructed from a stainless steel hypotube, which is essentially a tube with a lumen through its center. I have used the term "lumen" and have heard it used in the context of catheter design throughout my career. Based on my understanding of how those of skill in the art use the term "lumen," a hypotube has a lumen even if it is flattened or blocked

at one or both ends. Thus, Guidezilla's push rod, which is part of the "substantially rigid portion," has a lumen.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 7 day of July, 2013, in [illegible] County, Minnesota

Anthony Vitra

EXHIBIT A

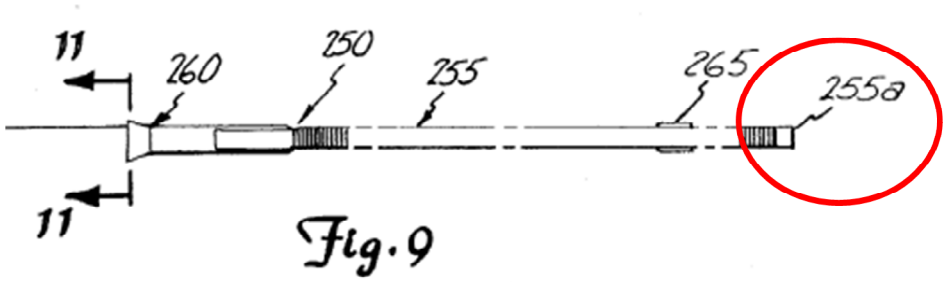
EXHIBIT A

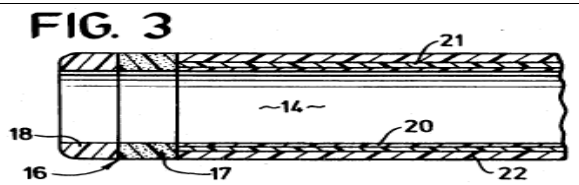
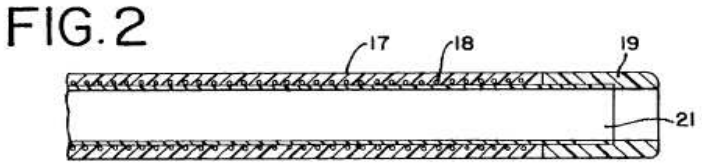
INVALIDITY CHART

U.S. PATENT NO. 8,048,032 B2 ('032 PATENT)

Claim Element No.	Claim Element	Discussion of Prior Art
1.1.1	1. A device for use with a standard guide catheter,	U.S. Patent No. 5,527,292 (the "Adams '292 patent") (attached hereto as Exhibit B) discloses a device for use with a standard guide catheter: "For use in combination with a guide catheter …, an intravascular device …" (col. 23, ll. 33-35) "An intravascular device … for insertion into a coronary vessel beyond a distal end of a guide catheter." (abstract)
1.1.2	the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,	The Adams '292 patent discloses a standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery: "The guide catheter 12 is an elongated, flexible, tubular member defining a first guide catheter lumen 27 therethrough." (col. 5, ll. 30-32) "a guide catheter having a proximal end, a distal end, and a central lumen," (col. 23, ll. 33-34) "The guide catheter manifold 16 is mounted at the proximal end of the guide catheter 12…. [T]he guide catheter manifold 16 comprises a Y-shaped structure having a primary channel leg 17…. A hemostasis valve (not shown) on channel leg 17 provides hemostatic control for the guide catheter system…." (col. 5, ll. 16-29; *see* col. 11, ll. 20-30) "the guide catheter is … advanced through a patient's arterial system to

		the coronary ostium of the artery requiring treatment." (col. 4, ll.56-58) Standard guide catheters having continuous lumens extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery were known to those of ordinary skill in the art by the mid-2000s.
1.1.3	the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,	The Adams '292 patent discloses that the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery: "Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or some other angioplasty device is disposed and guided to a stenosis or obstruction." (col. 11, ll. 17-20) "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." (col. 16, ll. 39-44)
1.2.1	the device comprising: a flexible tip portion defining a tubular structure having a circular cross-section and	The Adams '292 patent discloses a device comprising: a flexible tip portion defining a tubular structure having a circular cross-section: "An intravascular device having an elongated flexible tube" (abstract) "The intravascular device includes a relatively flexible tube…. The flexible tube has an inner diameter" (col. 2, ll. 44-50) "a relatively flexible tube having ... an internal lumen" (col. 23, ll. 36-37)

		"The guide catheter extension 14A … has a longitudinal guide catheter extension lumen, a rounded distal tip 36A and may be reinforced by a coil 40A." (col. 7, ll. 4-7)  Fig. 9 A person of ordinary skill in the art would have known of a tubular structure that includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion Patents issued prior to 2004 disclosed a tubular structure that includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion. For example: "An intravascular catheter such as a guiding catheter … having a nontraumatic distal tip comprising a proximal elastomeric tubular element and a distal elastomeric tubular element formed of a softer material…." U.S. Patent No. 5,234,416 ("Macaulay") (attached hereto as Exhibit C) (abstract)

		 Macaulay (Fig. 3). "At the distal end of the segmented catheter 10 is an atraumatic tip 19 that possesses softness or even elastic properties as will be generally appreciated by those skilled in the art." U.S. Patent No. 5,658,263 ("Dang") (attached hereto as Exhibit D) (col. 6, ll. 9-12)  Dang (Fig. 2). "[G]uiding catheter bodies are typically formed with…relatively short and soft distal tips…." U.S. Patent No. 6,592,472 B1 ("Noone") (attached hereto as Exhibit E) (col. 2, ll. 22-24)
1.2.2	a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	The Adams '292 patent discloses a tubular structure having a length that is shorter than the predefined length of the continuous lumen of the guide catheter: *See* Fig. 1 (the second guide catheter lumen 33 of the elongated flexible tube 32 of the guide catheter extension 14 (red) is shorter than the guide catheter lumen 27 of the guide catheter 12 (green))

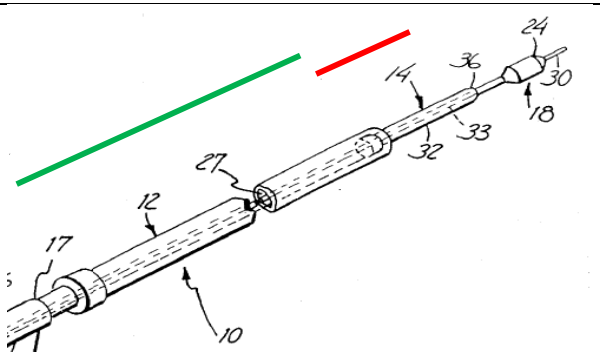
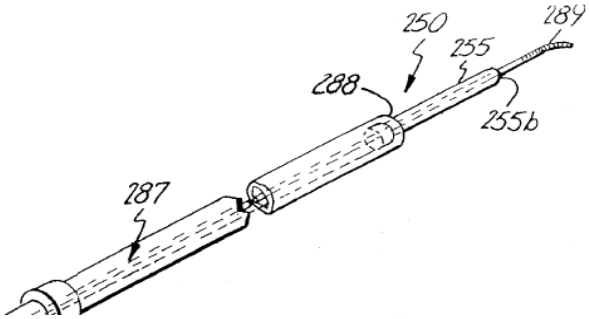
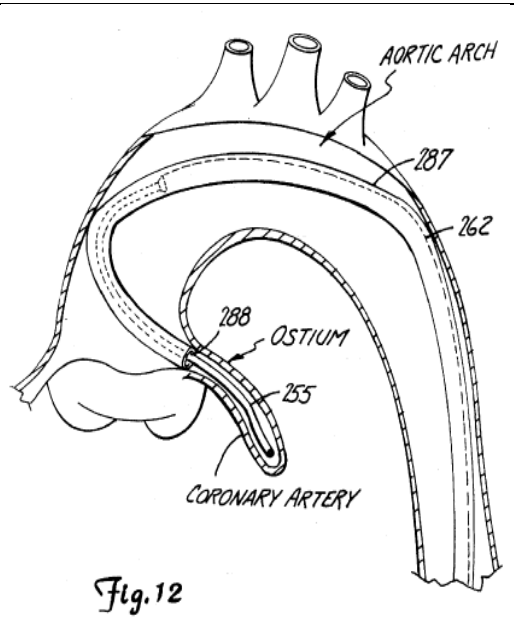
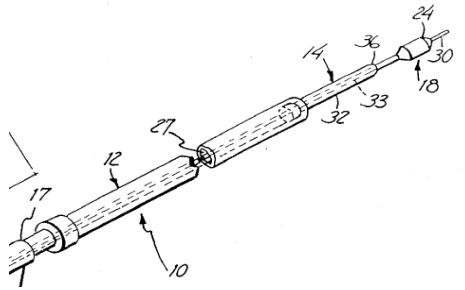
		 *See* Figs. 12, 13 (flexible tube 255 is shorter than guide catheter 287) 

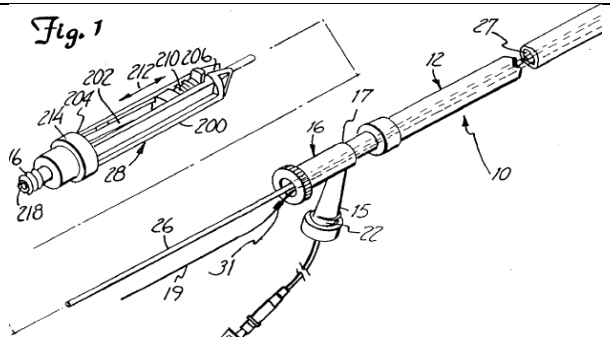
EXHIBIT A

		 Fig. 12 The Adams '292 patent discloses that [t]he length of the flexible tube 32 is preferably approximately 6 to 10 inches" (col. 5, ll. 61-63). One of ordinary skill in the art would have known that a standard guide catheter is 100cm or approximately 40 inches long.
1.2.3	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	The Adams '292 patent discloses a tubular structure having cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen 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 …" (col. 5, ll. 64-67) "a relatively flexible tube having … an outer diameter … wherein the outer diameter is sized for insertion through the central lumen of the

		guide catheter …" (col. 23, ll. 37-40)
1.2.4	defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	The Adams '292 patent discloses a tubular structure defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable: "the flexible tube being concentrically aligned with the guide catheter" (col. 22, ll. 42-43) "The inner diameter of the flexible tube is larger than the outer diameter of a typical angioplasty balloon catheter or other coronary treatment device." (col. 2, ll. 62-64) "For use in combination with a guide catheter for insertion and advancement of a coronary treatment device ..., an anchoring device comprising … a relatively flexible tube …" (col. 22, ll. 35-40) "The flexible tube 255 of the intravascular device 250 is designed for coaxial placement relative to the guide catheter …" (col. 15, ll. 65-66) "During use, the guide catheter extension tube 70 is coaxially disposed within the guide catheter 52." (col. 11, ll. 58-60)
1.3.1	a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and	The Adams '292 patent discloses 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: "shaft 19 or push rod is attached to a proximal end of the elongated flexible tube 32" (col. 6, ll. 1-2) "One embodiment is shown in FIG. 2 and the shaft 19 or push rod is defined by an elongated wire." (col. 6, ll. 1-2)

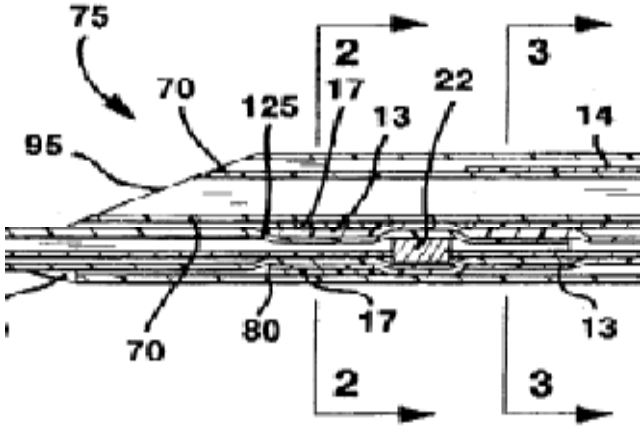
		"The shaft 19A or push rod in this embodiment comprises a tubular shaft member 172.... The tubular shaft member 172 is preferably formed from a stainless steel hypotube….The tubular shaft member 172 has a flattened distal end which assumes an elongated cross-section…. The flattened distal end provides sufficient surface area to secure the tubular shaft member 172 to the proximal end of the elongated flexible tube 32A…." (col. 7, ll. 13-26) "The push rod 262 is preferably formed of a nitinol wire.…. The nitinol construction helps reduce wire kinking as the push rod 262 is manipulated." (col. 15, ll. 8-12)
1.3.2	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	The Adams '292 patent discloses a substantially rigid portion having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion: "The elongated wire 34 is of small diameter, preferably 0.010 to 0.016 of an inch in diameter." (col. 6, ll. 15-17) "The tubular shaft member 172 is preferably formed from a stainless steel hypotube with an outside diameter of 0.016 inch." (col. 7, ll. 18-21) The Adams '292 patent discloses that "the outer diameter of the elongated tube would be approximately 0.065 inch…." (col. 8, ll. 24-25) One of ordinary skill in the art would have known that the inner diameter of standard guide catheters (and, thus, the maximum outer diameter of the guide catheter extension) is 5F to 8F or 0.058 inch to 0.088 inch.
1.3.3	having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the	The Adams '292 patent discloses a substantially rigid portion 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:

	longitudinal axis that is longer than the continuous lumen of the guide catheter,	"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 to 51.5 inches." (col. 15, ll. 49-53) One of ordinary skill in the art would have known that a standard guide catheter is 100 cm or approximately 40 inches long.
1.4	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.	The Adams '292 patent discloses that when a distal portion of the flexible tip portion is extended distally of the distal end of the guide catheter, 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: "The elongated flexible tube 32 of the guide catheter extension 14 is designed to extend beyond a distal end of the guide catheter 12…." (col. 6, ll. 8-10)  "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." (col. 6, ll. 1-4)

		 17 is the primary channel leg of the catheter manifold, where the hemostatic valve (not shown) is located. (col. 5, ll. 17-29.) 26 is a balloon catheter shaft. (col. 8, l. 40) 19 is the shaft or push rod, which exits the manifold at the same point as the balloon catheter shaft. "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." (col. 17, ll. 3-7)
2.1	2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,	The Adams '292 patent discloses a tubular structure that 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: "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." (col. 16, ll. 60-64) "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…." (col. 9, ll. 17-22)

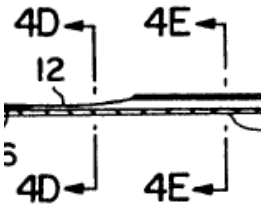
		"The length of the tube is sized so that the proximal end … of the tube 255 is enclosed within the guide catheter while the distal end of the flexible tube 255 reaches the treatment site." (col. 15, ll. 57-60) "In use, the flexible tube has its proximal end within a guide catheter and has its distal end extending to a treatment site within a coronary artery." (abstract)
2.2	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.	The Adams '292 patent discloses 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: "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 defines an anchoring device for securing the guide catheter 12 for operation." (col. 9, ll. 12-17) "[A]s 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." (col. 16, ll. 49-58)
3	3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the	A person of ordinary skill in the art would have known and been motivated to shape the proximal side opening of the tubular structure disclosed in the Adams '292 patent to extend for a distance along the longitudinal axis such that it would thereby be accessible from a longitudinal side defined transverse to the longitudinal axis to receive an interventional cardiology device into the coaxial

	longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.	lumen with the proximal portion of the tube remaining within the lumen of the guide catheter: The type of proximal side opening described in claim 3 was well known in the art prior to 2004 as a common means of shaping points of entry into a lumen through which devices are received for the facilitation of insertion and strengthening known points of weakness through gradual transitioning at portions joining one material to another or one degree of flexibility to another. Accordingly, utilizing such a design at the proximal end of the flexible tube disclosed by Adams '292 would have been obvious to a person of ordinary skill in the art as a means of creating a smooth transition for devices to travel from the substantially rigid portion into the coaxial lumen of the flexible tube. By 2004, sloped or angled openings to lumens were well known to persons of ordinary skill in the art of rapid exchange catheters, as well as the art of interventional catheters generally. Examples of patents prior to 2004 disclosing this feature within the relevant field of technology include: U.S. Patent No. 5,690,613 ("Verbeek") (attached hereto as Exhibit F) discloses cutting an angled proximal side opening commonly known as a "skive" in the inner lumen tube of a rapid exchange catheter for the receipt of a guidewire. *See, e.g.*, Fig. 1B (depicting "longitudinal cross-section of the transition section"):



"Skive 95 the proximal end of the inner lumen tubing 70 at an angle of approximately 10 degrees for a length of 2 mm." Verbeek (col. 6, ll. 9-11).

All prior art catheters with such side openings have "full circumference portions" and "partially cylindrical portions," as depicted in U.S. Patent No. 5,328,472 ("Steinke") (issued in July 1994), for a "Catheter with Flexible Side Port Entry," (attached hereto as Exhibit G), where "12" is defined as the "side port entry":



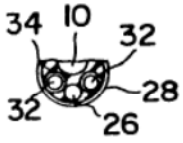
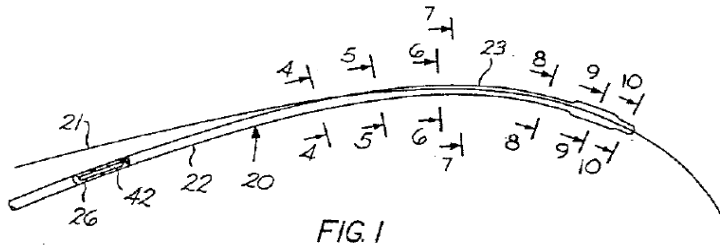
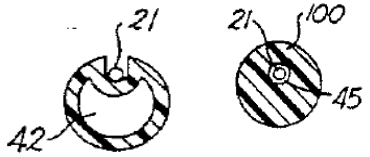
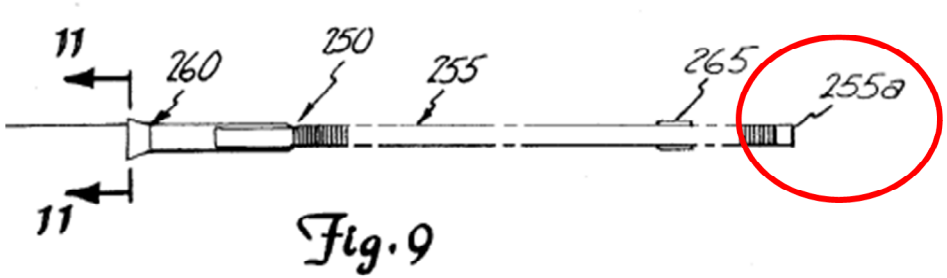


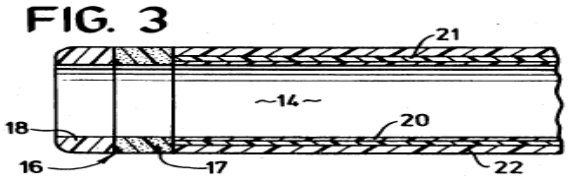
FIG.4D

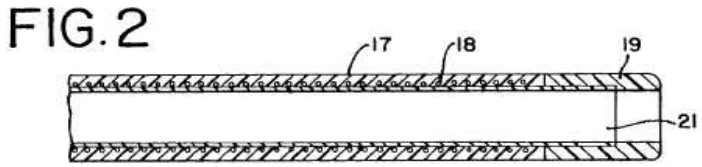
FIG.4E

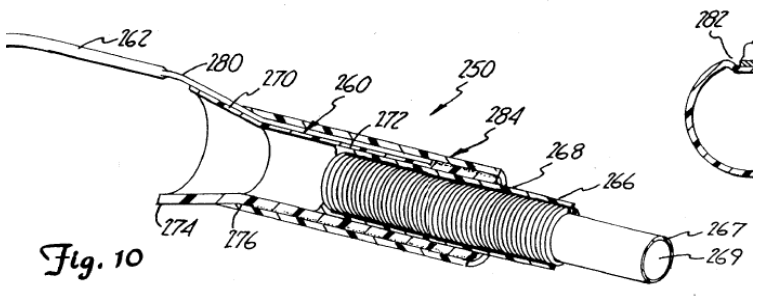
		Steinke discloses a catheter shaft defining a lumen with a proximal side port whereby "said lumen [is] adapted to receive a guidewire in a sliding fit." Steinke (col. 4, ll. 1-2) "Generally, the method ... includes the steps of providing a side port entry in the transition region" Steinke (col. 3, ll. 33-34) "Preferably the side port entry is located about 20 centimeters from the distal tip 14 of the catheter. A guidewire 16 can be slidingly received within the inner lumen." Steinke (col. 6, ll. 7-10) U.S. Patent No. 5,102,403 ("Alt") (attached hereto as Exhibit H) discloses "a substantially cylindrical catheter body with an outer wall … with the outer wall gradually changing in shape along the catheter body length toward the distal end from an entrance groove …" Alt (col. 6, ll. 62-66) Alt (Fig. 1):  FIG. 1 "Novel features of this catheter include the transition of the catheter tubing … to accommodate a second guide wire lumen …" Alt (col. 2, l. 65-col. 3, l. 2) "Thus guide wire 21 enters the catheter body axially …" Alt (col. 6, l. 4)

		Persons of skill in the art would have been motivated to combine their knowledge and the disclosures cited above with the disclosures of the Adams '292 patent because they all address the delivery of devices for interventional cardiology and treatment of vascular disease.
4	4. The device of claim 3 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.	A person of ordinary skill in the art would have known of a proximal side opening that includes a structure defining a full circumference portion and a partially cylindrical portion: Patents issued prior to 2004 disclosed proximal side openings with structures defining full circumference portions and partially cylindrical portions: "guide catheter 21 enters the catheter body axially … through a groove, a crescent shaped semi-enveloping configuration, FIGS. 5 and 6, and then completely surrounded as in FIGS. 7 through 10." Alt (col. 6, ll. 4-8) "a crescent shaped catheter body configuration partly surrounding the wire and … a closed cylinder wall surrounding a second guide lumen for encompassing the guide wire." Alt (col. 6, l. 67-col. 7, l. 4) Alt (Figs. 5, 10):  FIG. 5 FIG. 10 Persons of skill in the art would have been motivated to combine their knowledge and the disclosures cited above with the disclosures of the Adams

		patent because the all address delivery of devices for interventional cardiology and treatment of vascular disease
5	5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.	The Adams '292 patent discloses that the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip: "a radiopaque marker 43 may be placed just proximal to the rounded distal tip 36 of the guide catheter extension tube 32…." (col. 6, ll. 48-50) "an annular radiopaque marker 265 … is provided at the distal end of the flexible tube 255…." (col. 14, ll. 8-10)
6	6. The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.	The Adams '292 patent discloses that the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion: "the relatively flexible tube of the intravascular device includes a coil spring extending along and defining at least a portion of the flexible tube." (col. 20, ll. 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 coil 40A." (col. 7, ll. 4-7)  Fig. 9

		A person of ordinary skill in the art would have known of a tubular structure that includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion Patents issued prior to 2004 disclosed a tubular structure that includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion: "An intravascular catheter such as a guiding catheter … having a nontraumatic distal tip comprising a proximal elastomeric tubular element and a distal elastomeric tubular element formed of a softer material…. The catheter shaft includes an inner tubular member of braided polymeric fibrous strands … having an outer jacket or coating of thermoplastic polyurethane secured to the braided tubular member." Macaulay (abstract) Macaulay (Fig. 3):  "The guiding catheter of this invention is generally comprised of … at least three catheter segments which are progressively more flexible in the distal direction, and an atra[u]matic tip at the distal end." Dang (col. 3, ll. 10-13) "The segments of polymer preferably are molded about a braid of stainless steel or the like. Such braid is commonly used by those skilled in the art to enhance rigidity." Dang (col. 3, ll. 61-64)

		"At the distal end of the segmented catheter 10 is an atraumatic tip 19 that possesses softness or even elastic properties as will be generally appreciated by those skilled in the art." Dang (col. 6, ll. 9-12) Dang (Fig. 2):  "[G]uiding catheter bodies are typically formed with relatively long and stiff proximal sections or shafts and relatively short and soft distal tips…." Noone (col. 2, ll. 22-24) "Typically, the proximal section or shaft is formed of an inner tube, metal or polymeric filaments braided overlying the inner tube, and an outer tube over the braid, thereby providing a reinforced catheter shaft as disclosed in the above-referenced '910, '416, and '149 patents." Noone (col. 2, ll. 22-24)
7	7. The device of claim 6 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	The Adams '292 patent discloses that the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern: "Preferably, the elongated flexible tube 32 is formed of a coiled spring 40 made of stainless steel or platinum alloy…. An outer coating of plastic is then added around the coil spring…." (col. 5, ll. 48-52) "As shown more clearly in FIG 10, the flexible tube 255 is formed of a coil spring 266 of … stainless steel and inner and outer polymer layers 267 and 268…." (col. 14, ll. 14-16)

		 Fig. 10
8	8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The Adams '292 patent discloses 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 inner diameter of the tubular structure must be smaller than the inner diameter of the guide catheter (*See* discussion of claim 1.2.3) The inner diameter of the tubular structure must accommodate interventional cardiology devices (*See* discussion of claim 1.2.4) Guide catheter differences between inner diameter and outer diameter are roughly between 8 to 11 thousandths of an inch, which is less than one french size. Therefore, one of ordinary skill in the art would know that a guide extension of similar or modified construction should be no more than one french size smaller than the guide catheter.
11.1.1	11. A device for use with a standard guide catheter,	The Adams '292 patent discloses a device for use with a standard guide catheter: *See* discussion of claim 1.1.1 ("1. A device for use with a standard guide catheter")

11.1.2	the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,	The Adams '292 patent discloses the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery: *See* discussion of claim element 1.1.2 ("the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,")
11.1.3	the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,	The Adams '292 patent discloses the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery: *See* discussion of claim element 1.1.3 ("the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,")
11.2	the device comprising: an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,	The Adams '292 patent discloses an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter: *See* discussion of claim 1.3.3 ("[the substantially rigid portion] 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")
11.3.1	the elongate structure including: a flexible tip portion defining a tubular structure	The Adams '292 patent discloses the elongate structure including: a flexible tip portion defining a tubular structure: *See* discussion of claim element 1.2.1 ("the device comprising: a flexible tip portion defining a tubular structure having a circular cross-section

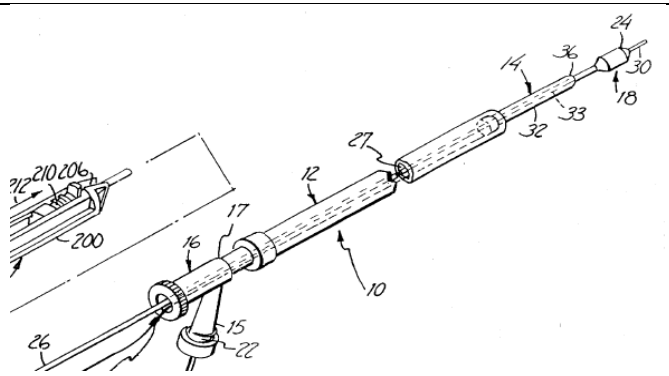
		and")
11.3.2	having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter	The Adams '292 patent discloses the tubular structure having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter *See* discussion of claim element 1.2.3 ("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")
11.3.3	and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	The Adams '292 patent discloses the tubular structure having a length that is shorter than the predefined length of the continuous lumen of the guide catheter: *See* discussion of claim element 1.2.2 ("a length that is shorter than the predefined length of the continuous lumen of the guide catheter")
11.3.4	the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter	The Adams '292 patent discloses the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter: *See* discussion of claim element 1.2.3 ("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")
11.3.5	and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;	The Adams '292 patent discloses the flexible tip portion defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable: *See* discussion of claim element 1.2.4 ("defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and")

11.4	a reinforced portion proximal to the flexible tip portion; and	The Adams '292 patent discloses, persons of ordinary skill in the art knew of, and other patents issued prior to 2004 disclosed a reinforced portion proximal to the flexible tip portion: *See* discussion of claim 6 ("6. The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.")
11.5.1	a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and	The Adams '292 patent discloses a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen: *See* discussion of claim element 1.3.1 ("a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and")
11.5.2	having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,	The Adams '292 patent discloses a substantially rigid portion having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion: *See* discussion of claim element 1.3.2 ("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")
11.6	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	The Adams '292 patent discloses 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:

	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.	*See* discussion of claim element 1.4 ("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.")
12.1	12. The device of claim 11 wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter,	The Adams '292 patent discloses that 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: *See* discussion of claim element 1.2.3 ("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 claim element 2.1 ("2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,")
12.2	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.	The Adams '292 patent discloses that 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: *See* discussion of claim element 2.2 ("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.")
13	13. The device of claim 11 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance	The Adams '292 patent discloses 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 that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the

	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.	device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion: *See* discussion of claim 3 ("3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.").
14.1	14. The device of claim 11 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen	The Adams '292 patent discloses that after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen: "During use, the guide catheter extension tube 70 is coaxially disposed within the guide catheter 52." (col. 11, ll. 58-60) "The flexible tube 255 of the intravascular device 250 is designed for coaxial placement relative to the guide catheter …" (col. 15, ll. 65-66) "the flexible tube being concentrically aligned with the guide catheter" (col. 22, ll. 42-43)
14.2	through which an interventional cardiology device may be inserted	The Adams '292 patent discloses that an interventional cardiology device may be inserted through the overall effective length of the coaxial lumen: "Guide catheter 52 is an elongated, flexible tubular member defining a first guide catheter lumen 53 through which an angioplasty balloon catheter 60 or some other angioplasty device is disposed and guided to a stenosis or obstruction." (col. 11, ll. 17-20) "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." (col. 16, ll. 41-44) "the flexible tube being concentrically aligned with the guide catheter" (col. 22, ll. 42-43) "The inner diameter of the flexible tube is larger than the outer diameter of a typical angioplasty balloon catheter or other coronary treatment device." (col. 2, ll. 62-64) "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 at the coronary ostium for guiding a coronary treatment device into the arteries beyond…" (col. 9, ll. 19-24)
14.3	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.	The Adams '292 patent discloses that interventional cardiology devices 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: "A hemostasis valve (not shown) on channel leg 17 provides hemostatic control for the guide catheter system 10 of the present invention." (col. 5, ll. 27-29)

		
15	15. The device of claim 11, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.	The Adams '292 patent discloses a radiopaque marker proximate the distal portion of the flexible tip portion: *See* discussion of claim 5 ("5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.").
16	16. The device of claim 11, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	The Adams '292 patent discloses that the reinforced portion is reinforced with metallic elements in a braided or coiled pattern: *See* discussion of claim 7 ("7. The device of claim 6 wherein the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.").
17	17. The device of claim 11 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	The Adams '292 patent discloses that 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* discussion of claim 8 ("8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter

		of the guide catheter. ")
19	19. The device of claim 11 wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.	That 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 is obvious in light of the Adams '292 patent combined with the knowledge of a person of ordinary skill in the art and/or the prior art. Examples of such prior art include: U.S. Patent No. 5,911,715, entitled "Guide Catheter Having Selected Flexular Modulus Segments" ("Berg") (attached hereto as Exhibit I) teaches "[t]he discrete segments of outer tubular member are of selected flexibility or durometer to selectively vary the flexural modulus of the catheter tube or guide catheter distal region…." (Col. 2, ll. 47-55) Berg acknowledges "the current standard of each section of a catheter becoming more flexible as you move proximal to distal along a catheter shaft" (col. 2, ll. 57-61) "The guiding catheter of this invention is generally comprised of … at least three catheter segments which are progressively more flexible in the distal direction…." Dang (col. 3, ll. 10-13) "The segments of polymer preferably are molded about a braid of stainless steel or the like. Such braid is commonly used by those skilled in the art to enhance rigidity." Dang (col. 3, ll. 61-64) "This invention tailors flexibility by utilizing segments of different polymers which vary in hardness." Dang (col. 3, ll. 44-45) "Distal of the hub 11 is a segmented guiding catheter tube. Typically, it is comprised of at least three segments of progressively softer materials

		in the distal direction." Dang (col. 4, ll. 47-49) "Catheters constructed in accordance with the principles of the present invention comprise a catheter body … formed of a proximal section and at least one distal section that have differing flexibilities…." Noone (col. 4, ll. 35-39) "One or more intermediate catheter sections are optionally formed between the proximal and distal catheter section." Noone (col. 4, ll. 29-31) "the major proximal section of the catheter body … is the least flexible…. The distal catheter section possesses the greatest flexibility…. " Noone (col. 6, ll. 28-33)

U.S. PATENT NO. 8,292,850 ('850 PATENT)

Claim Element No.	Claim Element	Discussion of Prior Art
1.1.1	1. A system for use with interventional cardiology devices adapted to be insertable into a branch artery,	The Adams '292 patent discloses a system for use with interventional cardiology devices adapted to be insertable into a branch artery: "For use in combination with a guide catheter for insertion and advancement of a coronary treatment device ..., an anchoring device comprising … a relatively flexible tube …" (col. 22, ll. 35-40)
1.1.2	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	*See* discussion of claim element 1.1.2 of the '032 patent ("the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,")

	adapted to be placed in the branch artery,	
1.1.3	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;	*See* discussion of claim element 1.1.3 of the '032 patent ("the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,")
1.2.1	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	*See* discussion of claim element 1.2.1 of the '032 patent ("the device comprising: a flexible tip portion defining a tubular structure having a circular cross-section and")
1.2.2	a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	*See* discussion of claim element 1.2.2 of the '032 patent ("a length that is shorter than the predefined length of the continuous lumen of the guide catheter,")
1.2.3	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	*See* discussion of claim element 1.2.3 of the '032 patent ("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")
1.2.4	and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and	*See* discussion of claim element 1.2.4 of the '032 patent ("defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable; and")
1.3.1	a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than the	*See* discussion of claim element 1.3.1 of the '032 patent ("a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and")

	flexible tip portion and defining a rail structure without a lumen	
1.3.2	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	*See* discussion of claim element 1.3.2 of the '032 patent ("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")
1.3.3	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,	*See* discussion of claim element 1.3.3 of the '032 patent ("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,")
1.4	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.	*See* discussion of claim element 1.4 of the '032 patent ("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.").
2.1	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,	*See* discussion of claim element 2.1 of the '032 patent ("2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,")
2.2	such that the device assists in	*See* discussion of claim element 2.2 of the '032 patent ("such that the device

	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.	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	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.	*See* discussion of claim 3 of the ‘032 patent (“3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.”).
4	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.	*See* discussion of claim 4 of the ‘032 patent (“4. The device of claim 3 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.”).
5	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.	*See* discussion of claim 6 of the ‘032 patent (“6. The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.”).
6	6. The system of claim 5, wherein	*See* discussion of claim 7 of the ‘032 patent (“7. The device of claim 6 wherein

	the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.	the flexible cylindrical reinforced portion is reinforced with metallic elements in a braided or coiled pattern.”).
7	7. The system of claim 2, wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.	*See* discussion of claim 5 of the ‘032 patent (“5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.”).
8	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.	*See* discussion of claim 8 of the ‘032 patent (“8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.”).
12.1.1	12. A system for use with interventional cardiology devices adapted to be insertable into a branch artery,	*See* discussion of claim element 11.1.1 of the ‘032 patent (“11. A device for use with a standard guide catheter,”)
12.1.2	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,	*See* discussion of claim element 11.1.2 of the ‘032 patent (“the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,”)
12.1.3	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	*See* discussion of claim element 11.1.3 of the ‘032 patent (“the continuous lumen of the guide catheter having a circular cross-section and a cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,”)

	continuous lumen of the guide catheter;	
12.2	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,	*See* discussion of claim element 11.2 of the '032 patent ("the device comprising: an elongate structure having an overall length that is longer than the predefined length of the continuous lumen of the guide catheter,")
12.3.1	the elongate structure including: a flexible tip portion defining a tubular structure	*See* discussion of claim element 11.3.1 of the '032 patent ("the elongate structure including: a flexible tip portion defining a tubular structure")
12.3.2	and having a circular cross-section that is smaller than the circular crosssection of the continuous lumen of the guide catheter	*See* discussion of claim element 11.3.2 of the '032 patent ("having a circular cross-section that is smaller than the circular cross-section of the continuous lumen of the guide catheter")
12.3.3	and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,	*See* discussion of claim element 11.3.3 of the '032 patent ("and a length that is shorter than the predefined length of the continuous lumen of the guide catheter,")
12.3.4	the flexible tip portion having a cross-sectional outer diameter sized to be insertable through the crosssectional inner diameter of the continuous lumen of the guide catheter	*See* discussion of claim element 11.3.4 of the '032 patent ("the flexible tip portion being sized having a cross-sectional outer diameter sized to be insertable through the cross-sectional inner diameter of the continuous lumen of the guide catheter")
12.3.5	and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;	*See* discussion of claim element 11.3.5 of the '032 patent ("and defining a coaxial lumen having a cross-sectional inner diameter through which interventional cardiology devices are insertable;")
12.4	a reinforced portion proximal to the flexible tip portion; and	*See* discussion of claim element 11.4 of the '032 patent ("a reinforced portion proximal to the flexible tip portion; and")

12.5.1	a substantially rigid portion proximal of, connected to, and more rigid along a longitudinal axis rail than the flexible tip portion and defining a structure without a lumen	*See* discussion of claim element 11.5.1 of the '032 patent ("a substantially rigid portion proximal of and connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and")
12.5.2	having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,	*See* discussion of claim element 11.5.2 of the '032 patent ("having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion,")
12.6	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.	*See* discussion of claim element 11.6 of the '032 patent ("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.").
13.1	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,	*See* discussion of claim element 12.1 of the '032 patent ("12. The device of claim 11 wherein, when the distal portion of the flexible tip portion is insertable through the continuous lumen of the guide catheter and beyond the distal end of the guide catheter,").

13.2	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.	*See* discussion of claim element 12.2 of the '032 patent ("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	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.	*See* discussion of claim 13 of the '032 patent ("13. The device of claim 11 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and into the coaxial lumen while the device is inserted into the continuous lumen, the opening extending substantially along at least a portion of a length of the substantially rigid portion.").
15.1	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	*See* discussion of claim element 14.1 of the '032 patent ("14. The device of claim 11 wherein, after the device is inserted into the continuous lumen of the guide catheter, the device extends an overall effective length of a coaxial lumen").
15.2	through which an interventional cardiology device may be inserted	*See* discussion of claim element 14.2 of the '032 patent ("through which an interventional cardiology device may be inserted").

15.3	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.	*See* discussion of claim element 14.3 of the '032 patent ("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	16. The system of claim 12, the device further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.	*See* discussion of claim 15 of the '032 patent ("15. The device of claim 11, further comprising a radiopaque marker proximate the distal portion of the flexible tip portion.").
17	17. The system of claim 12, wherein the reinforced portion of the device is reinforced with metallic elements in a braided or coiled pattern.	*See* discussion of claim 16 of the '032 patent ("16. The device of claim 11, wherein the reinforced portion is reinforced with metallic elements in a braided or coiled pattern.").
18	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.	*See* discussion of claim element 17 of the '032 patent ("17. The device of claim 11 wherein the cross-sectional inner diameter of the coaxial lumen of the flexible distal portion is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.").
20	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	*See* discussion of claim element 19 of the '032 patent ("19. The device of claim 11 wherein the elongate structure includes, starting at the distal portion of the flexible distal portion, at least a first portion having a first flexural modulus, a second portion having a second flexural modulus greater than the first flexural modulus, and a third portion having a third flexural modulus greater than the second flexural modulus.").

	portion having a third flexural modulus greater than the second flexural modulus.	

U.S. PATENT NO. 8,292,413 ('413 PATENT)

Claim Element No.	Claim Element	Discussion of Prior Art
1.1.1	1. A method of providing backup support for an interventional cardiology device for use in the coronary vasculature,	The Adams '292 patent discloses a method of providing backup support for an interventional cardiology device for use in the coronary vasculature: "For use in combination with a guide catheter for insertion and advancement of a coronary treatment device ..., an anchoring device comprising … a relatively flexible tube …" (col. 22, ll. 35-40)
1.1.2	the interventional cardiology device being adapted to be passed through a standard guide catheter, the standard guide catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery,	*See* discussion of claim element 1.2.2 of the '032 patent ("a length that is shorter than the predefined length of the continuous lumen of the guide catheter,")
1.1.3	the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen,	*See* discussion of claim element 1.1.3 of the '032 patent ("the continuous lumen of the guide catheter having a circular cross-sectional inner diameter sized such that interventional cardiology devices are insertable into and through the lumen to the branch artery,")
1.2.1	the method comprising: inserting the standard guide catheter into a	*See* discussion of claim element 1.2.1 of the '032 patent ("the device comprising: a flexible tip portion defining a tubular structure having a circular cross-section

	first artery over a guidewire, the standard guide catheter having a distal end; positioning the distal end of the standard guide catheter in a branch artery that branches off from the first artery; inserting a flexible tip portion of a coaxial guide catheter defining a tubular structure having a circular cross-section	and")
1.2.2	and a length that is shorter than the predefined length of the continuous lumen of the standard guide catheter, into the continuous lumen of the standard guide catheter, and,	*See* discussion of claim element 1.2.2 of the '032 patent ("a length that is shorter than the predefined length of the continuous lumen of the guide catheter,")
1.3.1	further inserting a substantially rigid portion that is proximal of, operably connected to, and more rigid along a longitudinal axis than the flexible tip portion, into the continuous lumen of the standard guide catheter, the substantially rigid portion defining a rail structure without a lumen	*See* discussion of claim element 1.3.1 of the '032 patent ("a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a rail structure without a lumen and")
1.3.2	and having a maximal cross-sectional dimension at a proximal portion that is smaller than the cross-sectional outer diameter of the flexible tip portion and	*See* discussion of claim element 1.3.2 of the '032 patent ("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")
1.3.3	having a length that, when combined with the length of the flexible distal tip portion, defines a	*See* discussion of claim element 1.3.3 of the '032 patent ("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

	total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter;	lumen of the guide catheter,")
1.4	advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery such that the distal portion extends into the second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve; and	*See* discussion of claim element 1.4 of the '032 patent ("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.").
2.1	2. The method as claimed in claim 1, further comprising applying a force to a proximal portion of the coaxial guide catheter such that the distal portion of the coaxial guide catheter remains seated in the second artery	*See* discussion of claim element 2.1 of the '032 patent ("2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,")
2.2	in response to an opposing backward force exerted by the interventional cardiology device as the interventional cardiology device is advanced.	*See* discussion of claim element 2.2 of the '032 patent ("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.").
4	4. The method as claimed in claim 1, further comprising selecting the substantially rigid portion of the coaxial guide catheter such that it comprises a cylindrical portion	*See* discussion of claim 13 of the '032 patent ("13. The device of claim 11 wherein the substantially rigid portion further includes a partially cylindrical portion defining an opening extending for a distance along a side thereof defined transverse to a longitudinal axis that is adapted to receive an interventional cardiology device passed through continuous lumen of the guide catheter and

	and a partially cylindrical portion defining an opening along a side thereof.	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.”).
5	5. The method as claimed in claim 1, further comprising selecting the standard guide catheter to further comprise a Y-adapter and the method further comprising injecting a fluid through the Y-adapter into the standard guide catheter.	The Adams ‘292 patent discloses selecting the standard guide catheter to further comprise a Y-adapter and injecting a fluid through the Y-adapter into the standard guide catheter: “The 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. The guide catheter port 22 provides an inlet injection port into the guide catheter 12. Dye is injected into port 22, (from a fluid source--such as a syringe) and travels through the guide catheter system 10 to reach the stenosis. Alternatively, port 22 may be used to introduce drugs (i.e., thrombolytic drugs) through the guide gatheter12 ….” (col. 5, ll. 16-26) “The guide catheter manifold 54 is mounted at a proximal end of the guide catheter 52, and preferably comprised 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.” (col. 11, ll. 20-28)
7.1	7. The method as claimed in claim 1, further comprising extending a distal portion of the tubular structure beyond the distal end of the standard guide catheter while a proximal portion remains within the lumen of the standard guide catheter,	*See* discussion of claim element 2.1 of the ‘032 patent (“2. The device of claim 1 wherein the tubular structure includes a distal portion adapted to be extended beyond the distal end of the guide catheter while a proximal portion remains within the lumen of the guide catheter,”)
7.2	such that the coaxial guide catheter	*See* discussion of claim element 2.2 of the ‘032 patent (“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 standard catheter from the branch artery.	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.”).
8	8. The method of claim 7, further comprising extending the interventional cardiology device past a radiopaque marker proximate a distal tip of the coaxial guide catheter.	*See* discussion of claim 5 of the ‘032 patent (“5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.”).
9	9. The method as claimed in claim 1, further comprising extending the interventional cardiology device through a proximal side opening defined by the proximal portion of the tubular structure and extending for a distance along the longitudinal axis of the proximal portion of the tubular structure while the proximal portion remains within the lumen of the guide catheter.	*See* discussion of claim 3 of the ‘032 patent (“3. The device of claim 2 wherein the proximal portion of the tubular structure further comprises structure defining a proximal side opening extending for a distance along the longitudinal axis, and accessible from a longitudinal side defined transverse to the longitudinal axis, to receive an interventional cardiology device into the coaxial lumen while the proximal portion remains within the lumen of the guide catheter.”).
10	10. The method of claim 9, further comprising extending the interventional cardiology device through the proximal side opening; advancing the	*See* discussion of claim 4 of the ‘032 patent (“4. The device of claim 3 wherein the proximal side opening includes structure defining a full circumference portion and structure defining a partially cylindrical portion.”).

	interventional cardiology device through structure defining a full circumference portion; and advancing the interventional cardiology device through structure defining a partially cylindrical portion.	
11	11. The method of claim 9, further comprising extending the interventional cardiology device through a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion of the tubular structure proximal to the flexible distal tip portion.	*See* discussion of claim 6 of the '032 patent ("6. The device of claim 1 wherein the tubular structure includes a flexible cylindrical distal tip portion and a flexible cylindrical reinforced portion proximal to the flexible distal tip portion.").
12	The method of claim 11 further comprising extending the interventional cardiology device through the flexible cylindrical reinforced portion that is reinforced with metallic elements in a braided or coiled pattern.	*See* discussion of claim 5 of the '032 patent ("5. The device of claim 2 wherein the flexible cylindrical distal tip portion further comprises a radiopaque marker proximate a distal tip.").
13	13. The method of claim 1, further comprising selecting the cross-sectional inner diameter of the coaxial lumen of the tubular structure to be not more than one French smaller than the cross-sectional inner diameter of the guide catheter.	*See* discussion of claim 8 of the '032 patent ("8. The device of claim 1 wherein the cross-sectional inner diameter of the coaxial lumen of the tubular structure is not more than one French smaller than the cross-sectional inner diameter of the guide catheter.").

EXHIBIT B

US005527292A

United States Patent [19]

Adams et al.

[11] **Patent Number: 5,527,292**

[45] **Date of Patent: Jun. 18, 1996**

[54] **INTRAVASCULAR DEVICE FOR CORONARY HEART TREATMENT**

[75] Inventors: **Daniel O. Adams**, Orono; **Scott P. Thome**, Waite Park, both of Minn.

[73] Assignee: **SciMed Life Systems, Inc.**, Maple Grove, Minn.

[21] Appl. No.: **303,590**

[22] Filed: **Sep. 9, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 874,079, Apr. 24, 1992, abandoned, which is a continuation-in-part of Ser. No. 605,398, Oct. 29, 1990, abandoned.

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/171**; 604/264; 604/280; 604/96; 604/164; 128/772

[58] **Field of Search** 604/162, 163, 604/160, 158, 159, 161, 166, 282, 283, 93, 96, 100, 164, 171, 264, 280, 281, 284; 128/657, 658, 772; 606/108, 119, 121

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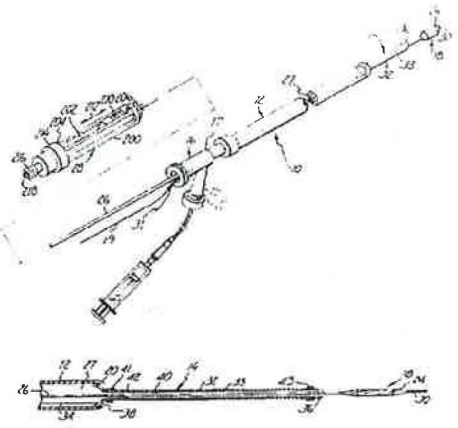
Primary Examiner—Corrine M. Maglione
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Kinney & Lange

[57] **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. 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. In certain applications, the intravascular device is used as a drug (or other fluid) delivery device or as an aspiration device. In other applications, the intravascular device is used as a guiding means for placement of an angioplasty device, such as a guide wire or a balloon catheter. Additionally, an attachment tube may be provided which is designed to couple with a proximal end of the flexible tube to provide a continuous conduit for aspiration or fluid delivery to a treatment site in a coronary artery.

41 Claims, 10 Drawing Sheets



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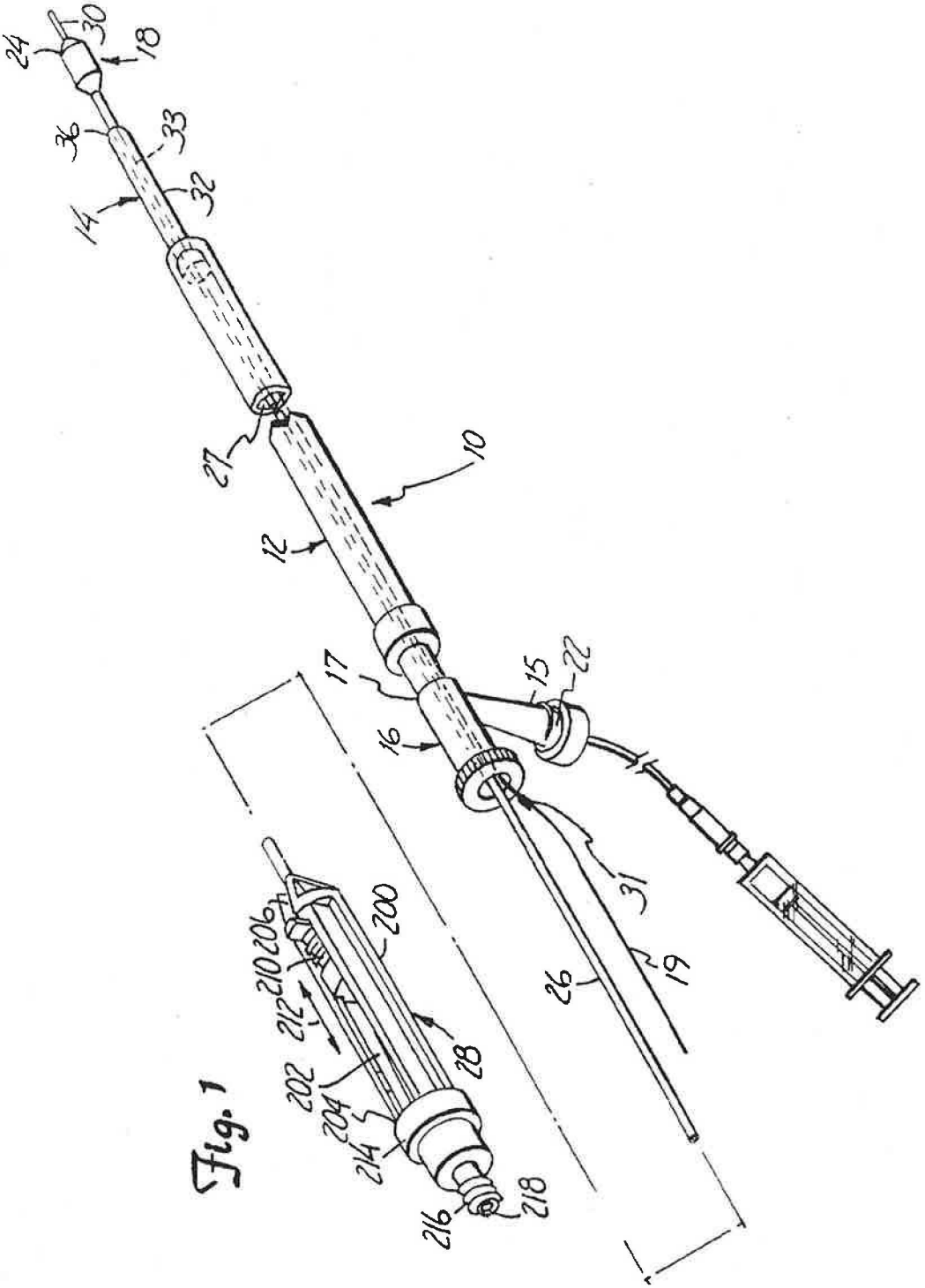
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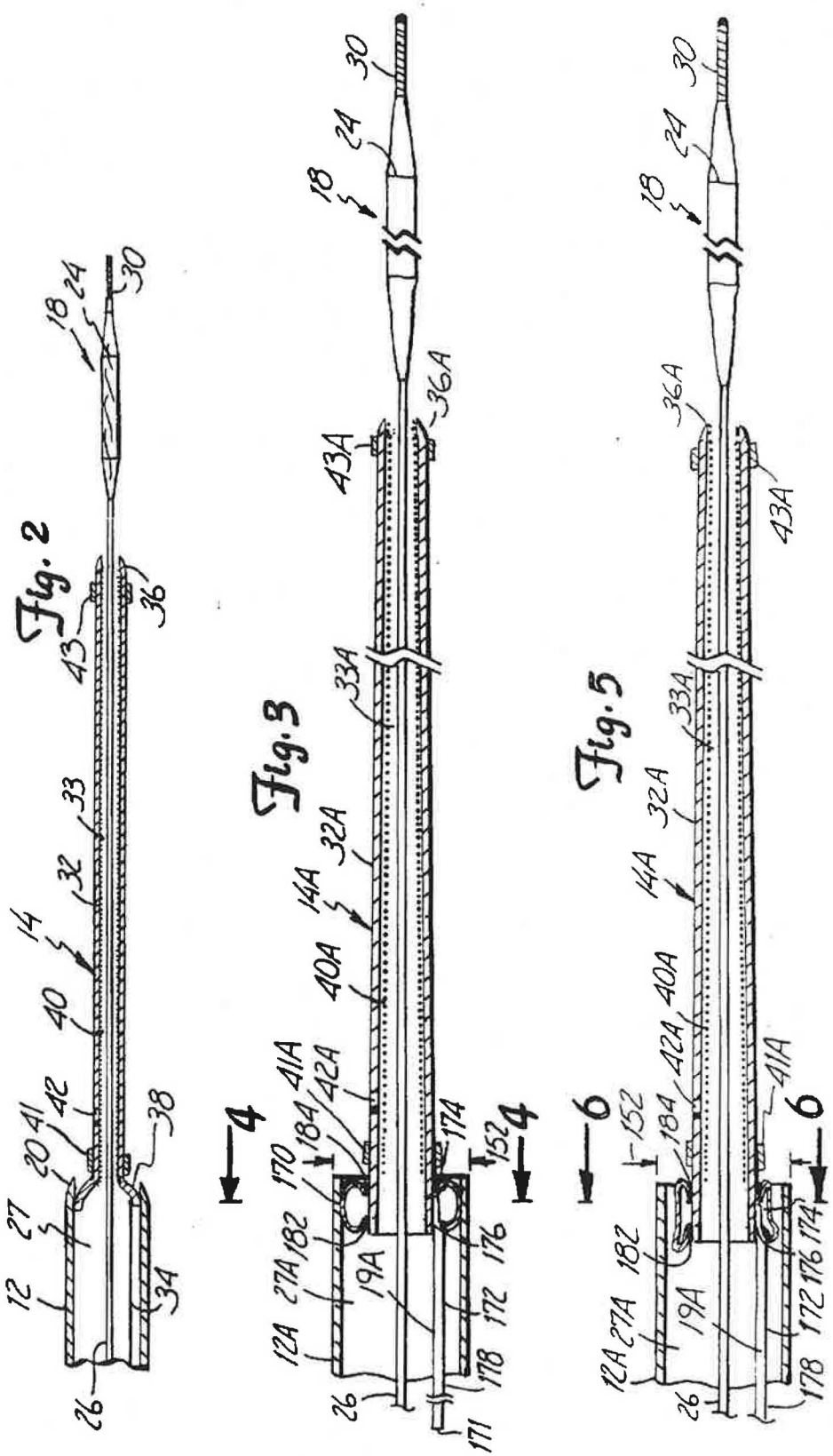
Fig. 1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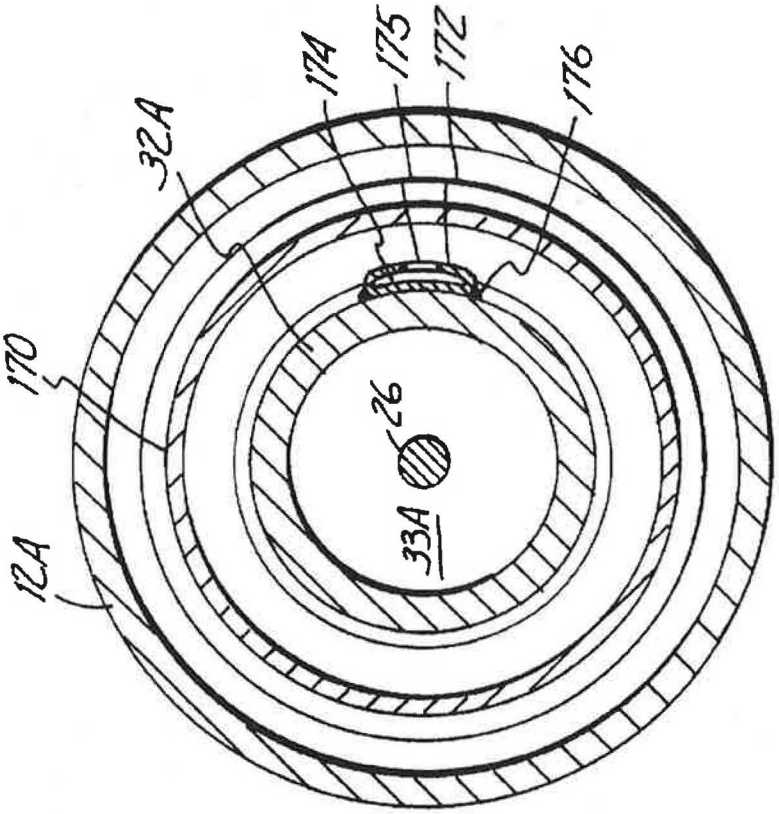
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Fig. 6

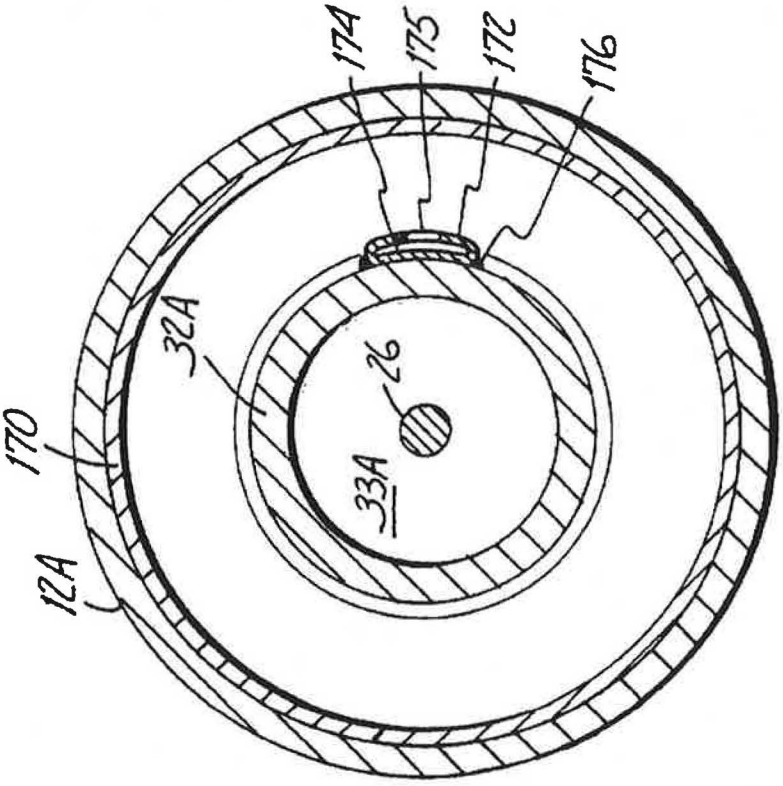
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Fig. 4

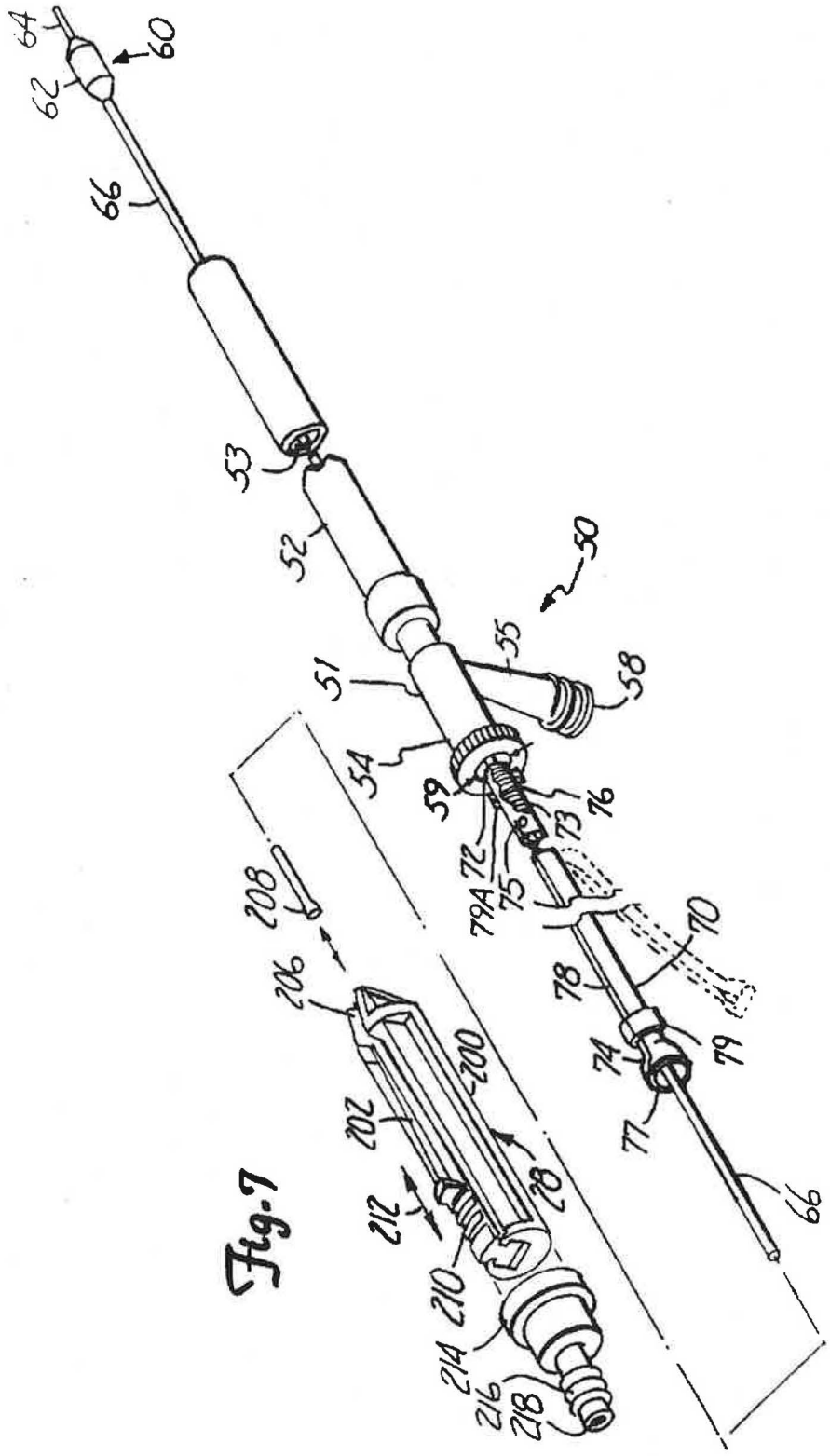
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Fig. 7

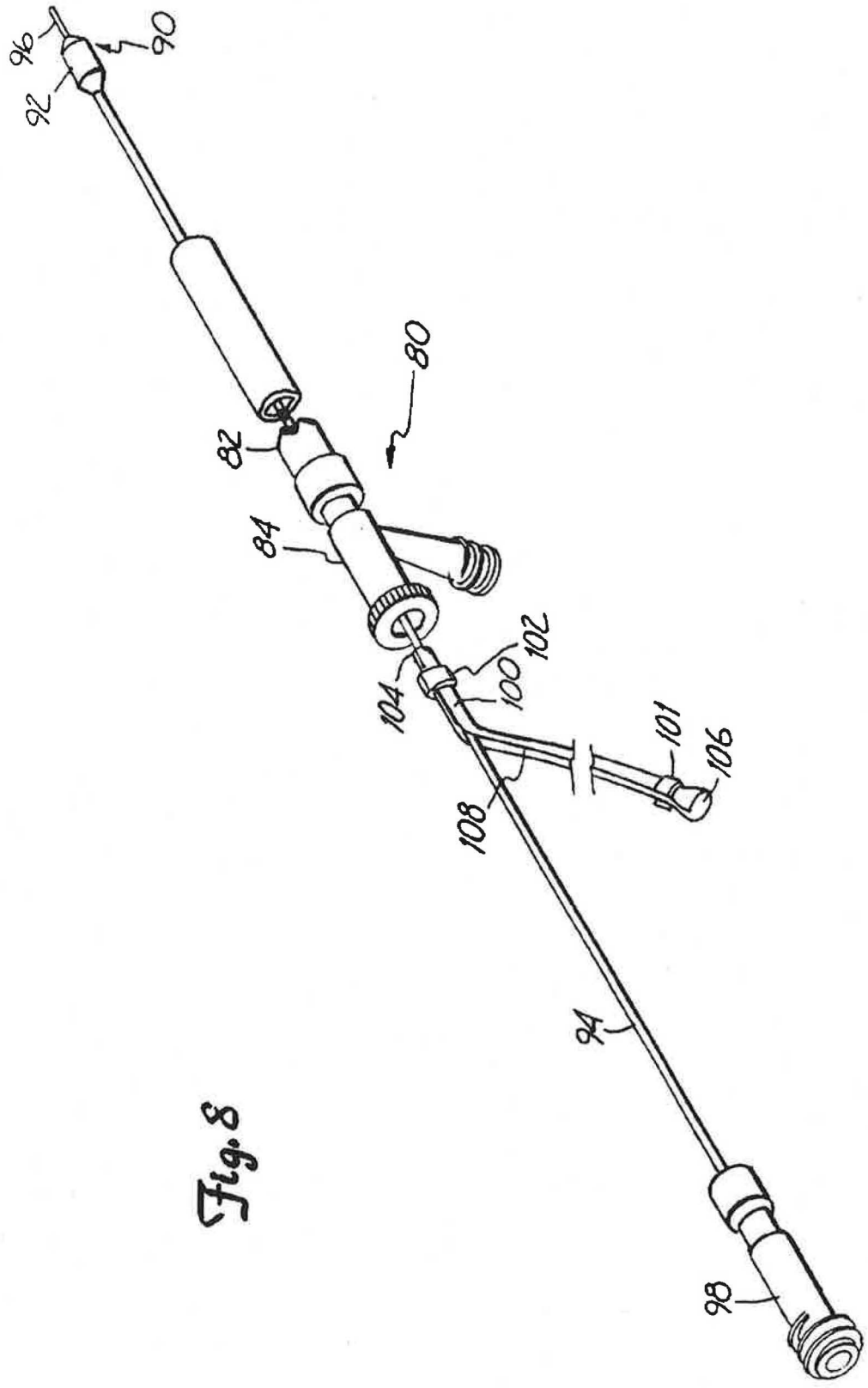

Fig. 8

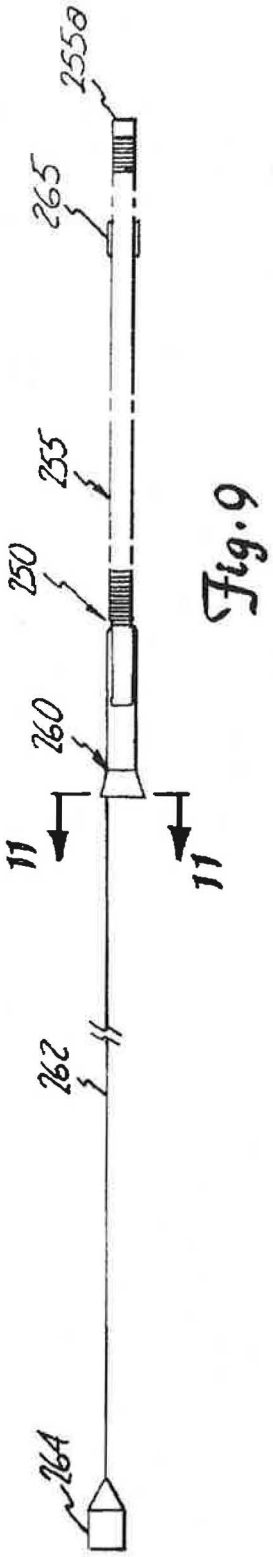

Fig. 9

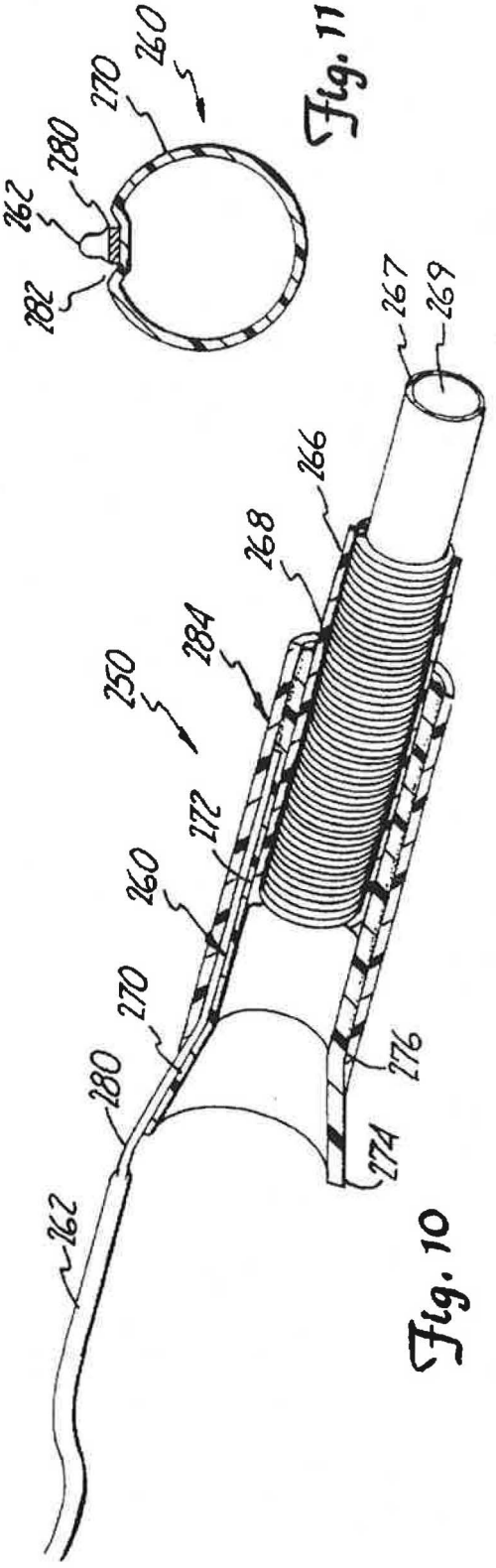

Fig. 10

Fig. 11

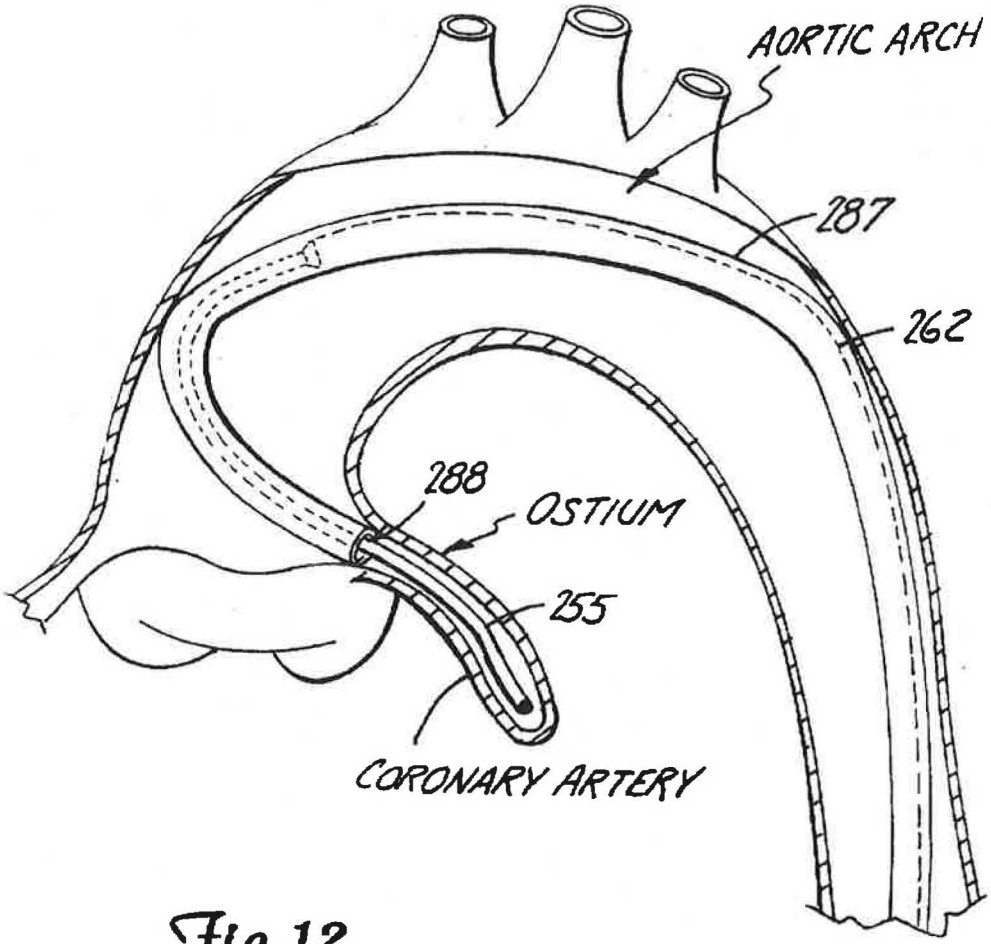

Fig. 12

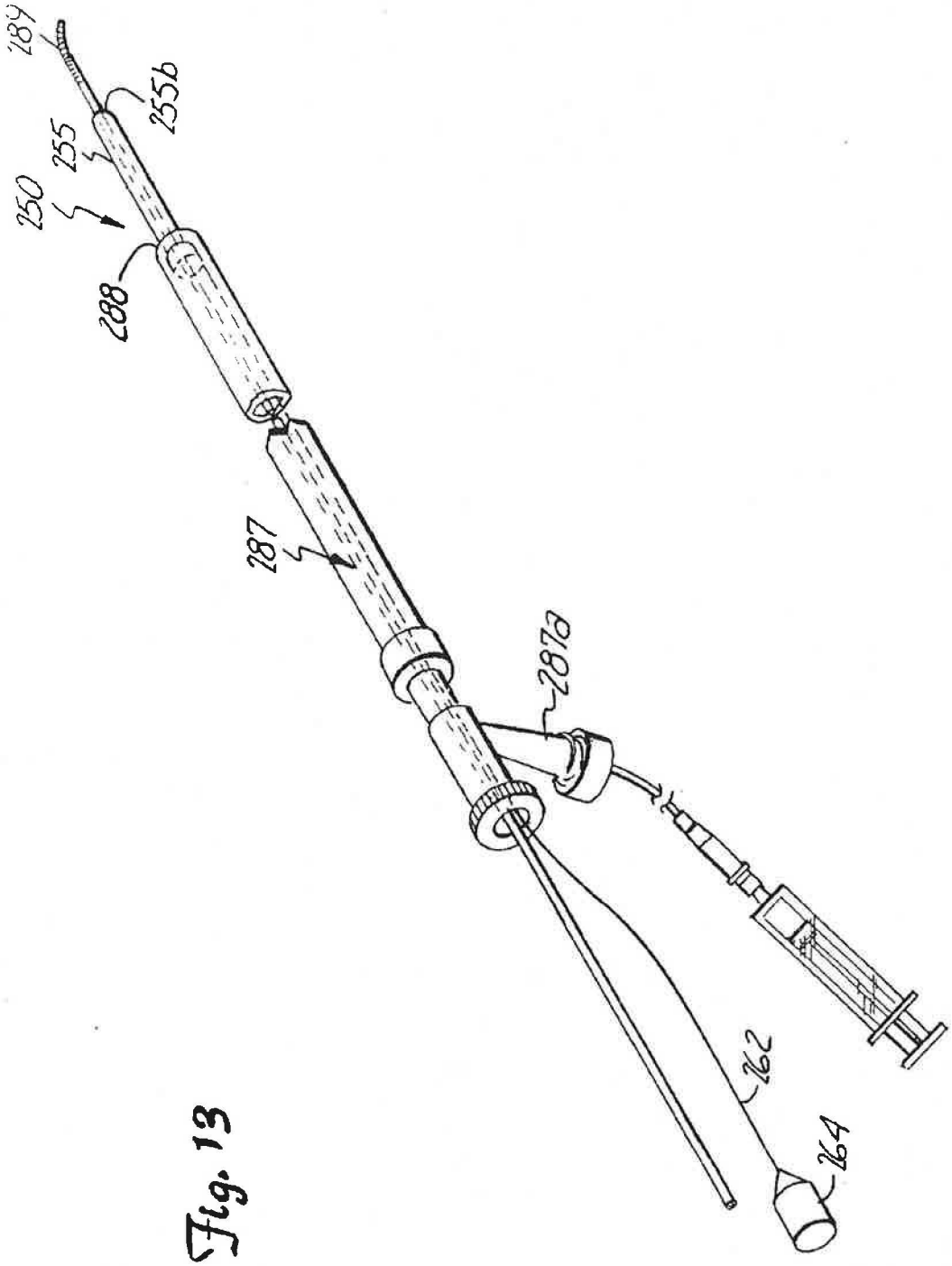

Fig. 13

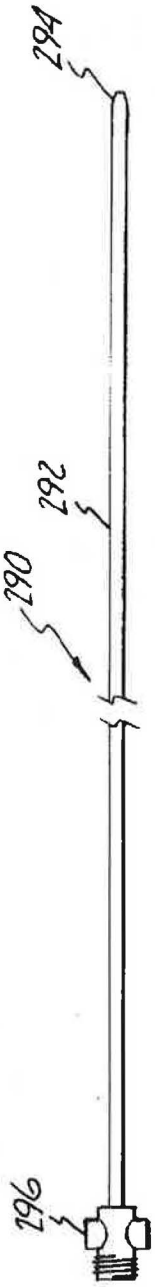

Fig. 14

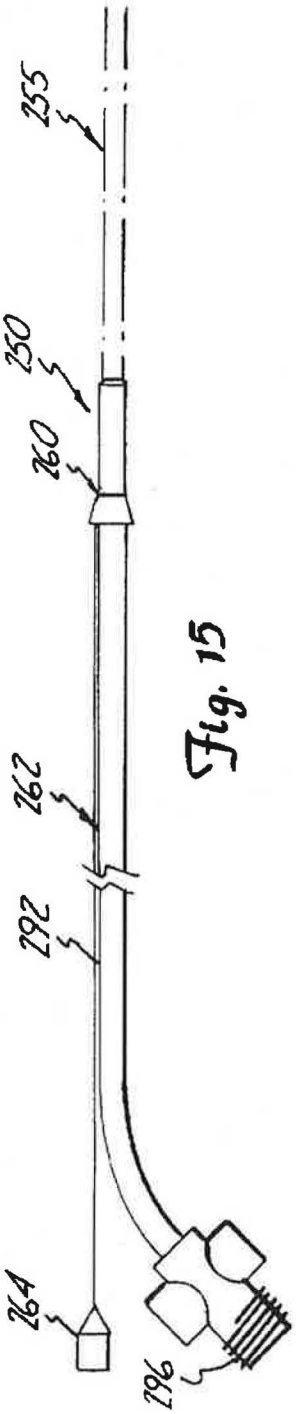

Fig. 15

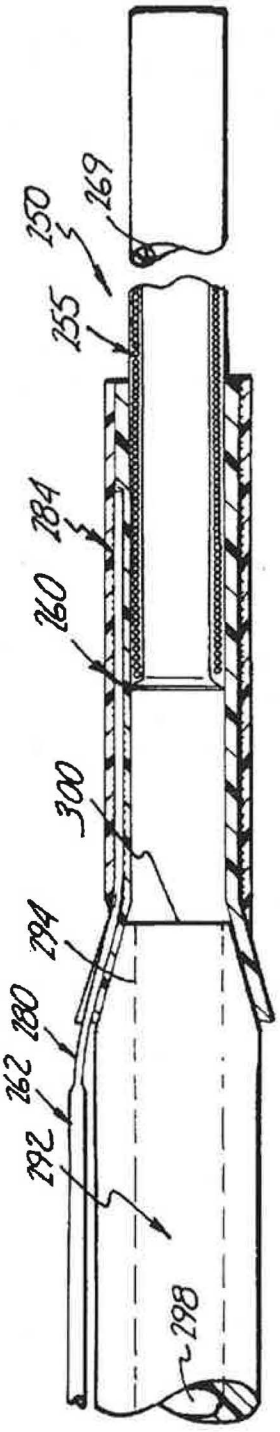

Fig. 16

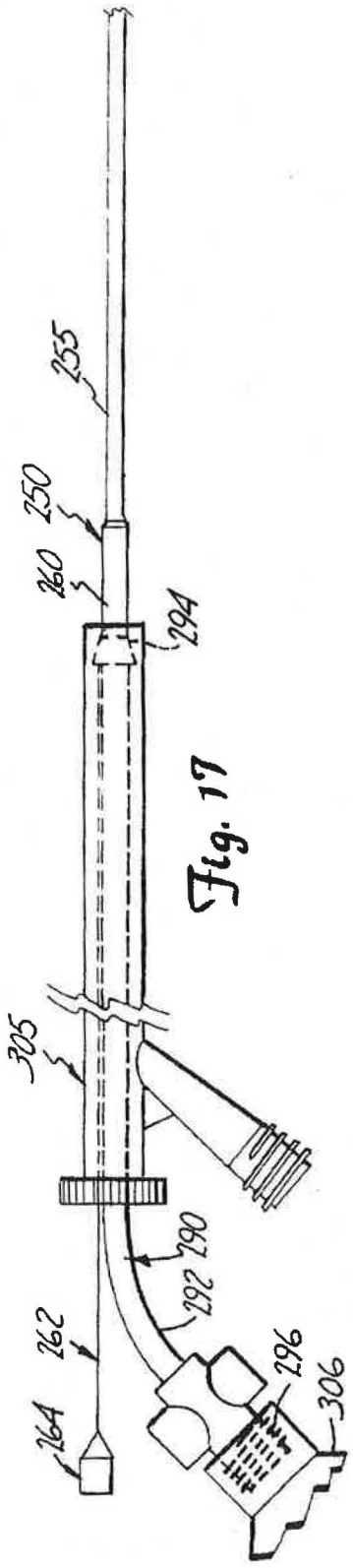

Fig. 17

INTRAVASCULAR DEVICE FOR CORONARY HEART TREATMENT

This is a file wrapper continuation of application Ser. No. 07/874,079, filed Apr. 24, 1992, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 07/605,398, filed Oct. 29, 1990, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to the field of treatment of heart disease. In particular, the present invention relates to an intravascular device, particularly suited for use for percutaneous transluminal treatment for heart disease.

A normal artery is composed of essentially, three layers, the intima, the media and the adventitia. The intima is the innermost layer of the artery. It is composed of a thin layer of endothelial cells that provide a smooth surface between the blood and an interior wall of the artery. The media is an intermediate layer which is separated from the intima by an internal elastic membrane, which allows material to diffuse through the intima and into the medial tissue. The media is a muscle layer composed of a network of smooth muscle cells. The smooth muscle cells of the media contract and relax to regulate vessel tone which in turn affects blood pressure and local blood flow. The outermost layer or adventitia is composed of a connective tissue and scattered smooth muscle cell bundles.

Atherosclerosis is a disease which affects a normal artery restricting the function of the artery. Atherosclerosis involves the gradual build up over time of atherocelerotic plaque or atheroma. Atherocelerotic plaque buildup begins in the intimal layer of the artery and progresses with the deposit of fatty debris from the blood through the endothelium. As the formation progresses, the endothelium becomes irregular and the artery constricts because of the build up of the plaque. The build up is so significant that the plaque now diminishes the effectiveness or area of the artery.

Balloon dilatation angioplasty has become recognized as an efficient and effective method for treating atherocelerotic buildup in coronary arteries. A dilatation balloon catheter is inserted preferably into the femoral artery of the patient and it is advanced to the obstructed area of the coronary artery. The balloon is inflated to compress the plaque against the artery wall and also to stretch the artery to dissect the plaque and open the artery thereby permitting an acceptable artery blood flow.

Before an angioplasty procedure is performed, radiography is used to survey the extent of damage or disease present in the artery. Dilatation balloon catheters are rated for different functions depending on the extent to which the artery is occluded or obstructed by plaque and the stage to which the atherocelrotic deterioration has progressed.

However, often times, the nature and extent of the damage is not apparent from the pre-angioplasty analysis and it is necessary to substitute the original balloon catheter inserted for an alternate sized balloon catheter. This process is generally referred to as a catheter exchange. A catheter exchange becomes a very arduous procedure if it is necessary to retrace the second catheter through the tortious anatomy (i.e., through a coronary artery) of a patient to position the balloon at the occluded area.

There are generally two type of balloon catheters, over-the-wire catheters and non-over-the wire-type catheters. In an over-the-wire catheter, the wire is slidably disposed within the catheter so that the catheter may be withdrawn independently of the wire, and the wire can remain in place to guide a substitute catheter to the treatment site. In a non-over-the-wire catheter the entire catheter is withdrawn during a catheter exchange so the tortious path to the treatment site must be retraced.

The condition of the patient may also be affected by thrombolytic buildup which can also occlude the lumen of the artery. Thrombolytic buildup results from platelet found in red blood cells which is thought to promote coagulation. In a healthy artery, endothohelial cells produce substances that inhibit platelet. Thus, there is a propensity for thrombolytic buildup at the diseased site in an artery. Further stagnation of the blood flow and platelet during angioplasty increases the risk of thrombolytic buildup.

Thrombolytic drugs and agents are generally used to dissolve the blood clot caused by the "build up" of platelet matter and to reverse the build up of the platelet matter. Alternatively, aspiration is another technique for treating thrombus "build up". It is important that the thrombolytic drugs or other treatment be administered before blood flow through the artery is completely or significantly restricted. Furthermore, thrombolytic drugs are generally extremely expensive so it is desirable that the drug be administered effectively and efficiently without waste.

Accordingly, it is important to be able to selectively provide a means for efficiently introducing a thrombolytic agent into the diseased artery during a balloon dilatation procedure. Also, if necessary it is desirable to be able to easily substitute one size catheter for a different size catheter if the original catheter inserted can not properly dilate the lesion.

SUMMARY OF THE INVENTION

The present invention relates to a catheter system for treating coronary heart disease. In particular, the present invention relates to an intravascular device suited for use during angioplasty treatment. The device is sized for insertion through a coronary artery to reach an occluded area for treatment. Although use of the device is explained with reference for treating coronary arteries it should be understood that the device may also be used for treating other diseased vessel in a patient.

The intravascular device includes a relatively flexible tube having a proximal and a distal end. The tube is designed to extend from a distal end of a guide catheter through a coronary artery requiring treatment. A push rod is attached to a proximal end of the tube for slidably positioning the tube beyond a distal end of a guide catheter into and through the artery. The flexible tube has an inner diameter sized for insertion over an angioplasty device.

The tube of the intravascular device has sufficient flexibility to provide for trackability of the flexible tube through the tortuous coronary arteries. Thus, the relatively flexible tube may be advanced into an artery until the distal end thereof is positioned at a treatment site.

Since the tube is flexible, the tube is not very pushable. The flexible tube may be advanced over an angioplasty balloon catheter or other coronary treatment device to provide pushability for placement of the flexible tube through the artery. The inner diameter of the flexible tube is larger than the outer diameter of a typical angioplasty balloon catheter or other coronary treatment device.

It is contemplated, that the intravascular device may be used for the placement of an angioplasty balloon catheter or alternatively a guide wire into a coronary artery requiring

treatment. Furthermore, the intravascular device is particularly suited for use during a catheter exchange or a guide wire exchange.

Also the intravascular device may be used for drug treatment to relieve thrombolytic build-up in a coronary artery. Since the intravascular device is inserted into and through the coronary artery, it provides a conduit for drug delivery thereto. Thrombolytic drugs may be delivered to a treatment site in combination with a guide catheter and the intravascular device. Additionally, the drugs may be delivered in combination with a proximal drug delivery attachment. The proximal drug delivery attachment includes an elongated attachment tube designed for placement through a guide catheter. The drug delivery attachment also includes a coupling means for fluidly sealing the attachment tube relative to the proximal end of the intravascular device to define a continuous lumen therealong for drug delivery.

In addition, the intravascular device may be used for aspirating thrombus from a coronary vessel. Again, since the intravascular device is inserted into and through the coronary vessel requiring treatment, the intravascular device provides a conduit, in combination with a guide catheter, for pulling a net negative pressure for withdrawing thrombus from the vessel. Alternatively, net negative pressure may be applied in combination with a proximal attachment tube and the intravascular device for aspiration treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further described with reference to the accompanying drawings where like numbers refer to like parts in several views and wherein:

FIG. **1** is a broken-away perspective view of an embodiment of the guide catheter system of the present invention shown with a dilatation balloon in an inflated position.

FIG. **2** is a transverse view in partial cross section of one embodiment of the guide catheter extension tube (distal extension) of FIG. **1**.

FIG. **3** is a transverse view in partial cross section of another embodiment of the guide catheter extension tube (distal extension) of FIG. **1**, the extension tube including a restriction balloon, which is shown in an inflated condition.

FIG. **4** is a sectional view as taken on line **4—4** of FIG. **3** showing the restriction balloon in an inflated condition.

FIG. **5** is a transverse view in partial cross section of the guide catheter extension tube (distal extension) of FIG. **3** with the restriction balloon shown in a deflated condition.

FIG. **6** is a sectional view as taken on line **6—6** of FIG. **5** showing the restriction balloon in a deflated condition.

FIG. **7** is a broken-away perspective view of another embodiment of the guide catheter system of the present invention with a dilatation balloon shown in an inflated condition.

FIG. **8** is a broken-away perspective view of another embodiment of the guide catheter system of the present invention with a dilatation balloon shown in an inflated condition.

FIG. **9** is an elevational view of an alternate embodiment of a distal extension (intravascular device), similar to FIGS. **2–6**.

FIG. **10** is a perspective view, in partial cross-sectional, of the distal extension of FIG. **9**.

FIG. **11** is a cross-sectional view as taken along lines **11—11** of FIG. **9**.

FIG. **12** is an illustrative view of the distal extension of FIG. **9** and the guide catheter relative to the aortic arch, a coronary ostium and coronary artery for placement of angioplasty devices into an occluded vessel for treatment.

FIG. **13** is a broken-away perspective view of a guide catheter system including the distal extension of FIG. **9** for placement of a guide wire.

FIG. **14** is an elevational view of a proximal elongated attachment tube of the present invention.

FIG. **15** is an elevational view of the distal extension (intravascular device) shown coupled with the proximal elongated attachment tube of FIG. **14**.

FIG. **16** is a transverse view, in partial cross-section, of the distal extension coupled with the proximal elongated attachment tube of FIG. **14**.

FIG. **17** is an elevational view of a guide catheter system including the distal extension (intravascular device) of FIG. **9** and the proximal elongated attachment tube of FIG. **14**.

While the above identified drawing figures set forth several preferred embodiments, other embodiments of the present invention are also contemplated, as noted in the discussion. In all cases, this disclosure presents illustrated embodiments of the present invention by way of representation and not limitation. It should be understood that numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of this invention. It should be noted that the figures have not been drawn to scale as it has been necessary to enlarge certain portions for clarity.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention is directed to the structure and use of a distal extension (intravascular device) for a guide catheter. Quite often, after a dilatation balloon catheter is inserted into a patient, it is necessary to withdraw the balloon catheter to substitute an alternate sized balloon catheter. This is done during a catheter exchange. This invention allows relatively easy and accurate exchanges for "non-over-the-wire" catheters, guide wires and other coronary treatment devices and is disclosed in several alternative embodiments.

The distal extension (intravascular device) for the guide catheter disclosed may also be used for drug delivery to a treatment site. The distal extension disclosed has a small outer diameter sized for insertion through the arterial system of a patient beyond a distal end of the guide catheter into a coronary artery. The distal extension is formed of a relatively flexible tube to permit the extension to track through the tortuous coronary arteries to a treatment site. Since the extension reaches a treatment site, it may be used to provide a conduit for applying negative pressure for aspirating thrombus from a diseased coronary vessel.

Specifically, the guide catheter is inserted at the femoral artery and advanced through a patient's arterial system to the coronary ostium of the artery requiring treatment. The construction of the guide catheter (diameter and rigidity) does not permit the guide catheter to advance beyond the ostium into the artery requiring treatment. The distal extension however is designed for insertion through coronary arteries requiring treatment. Thus, 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 for

placement of an angioplasty device or other coronary treatment device into the vessel (e.g., guide wire placement and angioplasty balloon catheter placement) and to provide a less difficult means for performing guide wire exchanges and "non-over-the-wire" catheter exchanges and alternately to provide a means for delivering drugs or providing negative pressure to a treatment site.

It is understood that the embodiments of the present invention are illustrative, and should not be construed to limit the scope of the invention. In a first embodiment the distal extension (intravascular device) is shown in association with a guide catheter system **10** (FIG. **1**). The guide catheter system **10** includes a guide catheter **12**, a guide catheter extension **14** and a guide catheter manifold **16** (FIG. **1**).

The 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**. The guide catheter port **22** provides an inlet injection port into the guide catheter **12**. Dye is injected into port **22**, (from a fluid source—such as a syringe) and travels through the guide catheter system **10** to reach the stenosis. Alternatively, port **22** may be used to introduce drugs (i.e., thrombolytic drugs) through the guide catheter **12** or to apply negative pressure for aspiration. A hemostasis valve (not shown) on channel leg **17** provides hemostatic control for the guide catheter system **10** of the present invention.

The guide catheter **12** is an elongated, flexible, tubular member defining a first guide catheter lumen **27** therethrough. Guide catheter **12** is preferably formed of a polyurethane tube. The guide catheter **12** may be preformed in various shapes to facilitate its passage to the coronary ostium or region within the body where the stenosis is located.

The guide catheter extension (distal extension) **14** comprises an elongated flexible tube **32** defining a second guide catheter lumen **33** and a shaft **19** or a push rod. The elongated flexible tube **32** is preferably formed from a soft, flexible material such as polyolefin, polyethylene or polyurethane and has a rounded distal tip **36** to facilitate insertion and trackability through the coronary arteries. The tube **32** may be loaded with barium sulfate or other suitable material to provide radiopacity. The inner surface of the elongated flexible tube is coated with silicone to provide a slippery surface. Preferably, the elongated flexible tube **32** is formed of a coil spring **40** made from stainless steel or a platinum alloy to provide radiopacity under fluoroscopy (see FIG. **2**). An outer coating of plastic is then added around the coil spring **40** using a heat shrink or some similar manufacturing technique to define the tube **32**.

If desired, the elongated flexible tube **32** may include one or more holes **42** (FIG. **2**) in the sidewall thereof to facilitate the passage of dye from the elongated flexible tube **32** into the artery and to also allow blood from the artery to flow into and through lumen **33** and out the distal end to facilitate distal artery perfusion. However, holes **42** prohibit use of the tube **32** as a drug delivery device for transport of drugs into the coronary arteries to a treatment site. The length of the elongated flexible tube **32** is preferably approximately 6 to 10 inches.

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 and to permit insertion of the tube **32** into the coronary arteries. As seen in FIG. **1**, shaft **19** or push rod is attached to a proximal end of the elongated flexible tube **32** and extends proximally therefrom outside the guide catheter **12** so that it is accessible to the user. The shaft **19** allows the user to position the guide catheter extension **14** (distal extension) within the patient by either extending or retracting the length of the shaft **19** to advance the guide catheter extension **14** as necessary. The elongated flexible tube **32** of the guide catheter extension **14** is designed to extend beyond a distal end of the guide catheter **12** into the coronary arteries.

Alternate embodiments for a guide catheter extension (distal extension) having an elongated flexible tube and a shaft attached thereto are shown in FIGS. **2–6**. One embodiment is shown in FIG. **2**, and 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. As discussed, the length of the elongated wire **34** is designed to extend from the elongated flexible tube **32** outside the patient so that it is accessible to the doctor or other user. Accessibility of the elongated wire **34** permits the doctor to adjust the extension length of the flexible tube **32** relative to the guide catheter **12** to position the flexible tube **32** in the coronary arteries.

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**. The close fit of the flared proximal end **38** to the inner diameter of the first guide catheter lumen **27** also directs fluid (such as dye or drugs for treatment) injected into the guide catheter **12** through the second guide catheter lumen **33** of the guide catheter extension **32**. The extension length of the elongated flexible tube **32** is lengthened by advancing the wire **34** distally into the guide catheter **12** and into the patient. The length of the flexible tube **32** may be completely extended by advancing the elongated **34** wire until the flared proximal end **38** of the guide catheter extension **14** is just proximal to a distal tip **20** of the guide catheter **12**.

An optional radiopaque marker **41** of a platinum alloy may be placed on the proximal end of the extension tube **32** just distal to the flared proximal end **38** to give fluoroscopic imaging of the position of the flared proximal end **38** of the tube **32** relative to the distal tip **20** of the guide catheter **12**. Additionally, a radiopaque marker **43** may be placed just proximal to the rounded distal tip **36** of the guide catheter extension tube **32** to located the distal end thereof during operation. Another alternative is to place a visual mark **31** (FIG. **1**) on shaft **19** outside the body that indicates a maximum advancement position of the extension tube **32** to prevent passage of the flared proximal end **38** beyond the distal tip **20** of the guide catheter **12**.

The use of the elongated wire **34** to adjust the extension length of the elongated flexible tube **32** provides several advantages. 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**. Reduced frictional force allows greater ease in extending and retrieving the guide catheter extension **14**. Also, the thin diameter of the wire **34** does not significantly interfere with the flow of dye or other fluid through the guide catheter **12**.

Alternatively, there is shown in FIGS. **3–6** another embodiment of a guide catheter extension **14A** (distal exten-

sion) having an elongated flexible tube **32A** connected to a shaft **19A** or push rod. The guide catheter extension **14A** is operable with a guide catheter **12A** which has a longitudinal guide catheter lumen **27A**. The guide catheter extension **14A** in turn has a longitudinal guide catheter extension lumen **33A** therethrough, a rounded distal tip **36A** and may be reinforced by a coil **40A**. If desired, one or more holes **42A** are provided for dye introduction and distal blood perfusion. Also, radiopaque markers **41A** and **43A** are included at the proximal and distal ends of the tube **32A** respectively to provide fluoroscopic imaging of the position of the tube **32A** relative to the guide catheter **12A**.

The shaft **19A** or push rod in this embodiment comprises a tubular shaft member **172** which extends proximally from a proximal end of the elongated flexible tube **32A** outside the patient so that it is accessible to the user to continually adjust the extended length of the elongated flexible tube **32A** relative to the guide catheter **12A**. 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.

The tubular shaft member **172** has a flattened distal end which assumes an elongated cross-section as shown in FIGS. **4** and **6**. The flattened distal end provides sufficient surface area to secure the tubular shaft member **172** to the proximal end of the elongated flexible tube **32A**, preferably by an epoxy bond **176**. The tubular shaft member **172** includes a proximally placed inlet port **171** (FIG. **3**) which is mounted to a luer fitting (not shown), a distally placed outlet port **174** defined by the flattened cross-section and an inflation lumen **178** therethrough. One or more side holes **175** (FIGS. **4** and **6**) may be included to define additional distal outlet ports for the tubular shaft member **172**.

An expandable restriction balloon **170** is wrapped about the proximal end of the elongated flexible tube **32A**. The restriction balloon **170** extends around the proximal end of the elongated flexible tube **32A** as well as the flattened distal end of the tubular shaft member **172** attached to the elongated flexible tube **32A**. The restriction balloon **170** is bonded to the elongated flexible tube **32A** and the tubular shaft member **172** by a proximal annular bond **182** and a distal annular bond **184**. The restriction balloon **170** is preferably formed of a polyolefin. Its position about the flattened distal end of the tubular shaft member **172** and side holes **175** (if included) places the restriction balloon **170** in fluid communication with the inflation lumen **178** of the tubular shaft member **172**. The inlet port **171** of the tubular shaft member **172** is connected to an inflation device (not shown) which provides inflation medium to inflate the restriction balloon **170** connected thereto.

In operation, the restriction balloon **170** is inflated to press against an inner surface wall of the guide catheter **12A**. The friction caused by the restriction balloon's **170** interaction with the inner surface wall of the guide catheter **12A** serves to inhibit longitudinal movement of the elongated flexible tube **32A** through the guide catheter lumen **27A** of guide catheter **12A**. Accordingly, when the extension length of the elongated flexible tube **32A** is properly positioned, the restriction balloon **170** is inflated to prohibit the retraction or advancement of the elongated flexible tube **32A** through a distal opening **152** of the guide catheter **12A** to hold the elongated flexible tube **32A** in position during a catheter exchange procedure or while the extension is in use as a drug delivery device (FIGS. **3** and **4**).

Alternatively, when the restriction balloon **170** is deflated (FIGS. **5** and **6**), it no longer restricts movement of the elongated flexible tube **32A** relative to the guide catheter **12A**. Thus, the elongated flexible tube **32A** may be slidably withdrawn through the guide catheter **12A** when its extension beyond the guide catheter **12A** is no longer needed. Thus, as described, the restriction balloon **170** provides sufficient friction to maintain a consistent extension length for the elongated flexible tube **32A**. The restriction balloon **170** is also adapted in a relaxed position to permit the continued adjustment of the elongated flexible tube **32A** within the guide catheter **12A**. The deflated balloon has a shape (FIGS. **5** and **6**) at the proximal end to facilitate guidance of a catheter **18** advanced through guide catheter lumen **27A** into the guide catheter extension lumen **33A** of the extension tube **14A** or to provide a fluid seal for drug delivery. Thus, the embodiment in FIGS. **3–6** provides an alternative arrangement to that shown in FIG. **2** for controlling the extension length of the elongated flexible tube **32A** relative to the guide catheter **12A**.

The elongated flexible tube **32A** of the embodiment shown in FIGS. **3–6** may be tapered to provide a small diameter section at its distal end to facilitate insertion through the smaller dimension coronary arteries, while maintaining a larger diameter proximal section to correspond to the distal opening **152** of the guide catheter **12A**. 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 inch distal tubular opening), the difference defining a gradual taper extending from the proximal end to the distal end of the tube **32A** (which is approximately 6 to 10 inches in length). Preferably, the tube **32A** has an interior coating of silicone, polyethylene or polytetraflouroethylene to provide a smooth, slick inner surface.

Referring now to FIGS. **1** and **2**, an angioplasty balloon catheter **18** is inserted into a patient's vascular system with the aid of the guide catheter **12** and guide catheter extension **14**. The angioplasty balloon catheter **18** includes a balloon **24**, a hollow balloon catheter shaft **26** and a balloon inflation assembly **28**, with the balloon **24** positioned at the distal end of the hollow balloon catheter shaft **26**. 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. A flexible spring tip **30** is mounted at the distal end of the balloon **24**, and generally assists the insertion of the balloon catheter **18** through the arterial system.

The balloon inflation assembly **28** (FIG. **1**) is mounted at a proximal end of the hollow balloon catheter shaft **26** and includes an inlet **218** thereon. Inflation medium (from an inflation device—not shown) is injected through the hollow balloon catheter shaft **26** to inflate the balloon **24** mounted at the end thereof.

In operation, the guide catheter **12** is inserted into a patient's arterial system and is advanced therethrough to locate the ostium of the arterial system containing the stenosis or obstruction. Thereafter, the angioplasty balloon catheter **18** and guide catheter extension **14** are coaxially positioned within the guide catheter **12** and are advanced therethrough for use. The angioplasty balloon catheter **18** is advanced so that it is positioned proximate to or across the stenosis or obstruction. Ordinarily, the outer diameter of the guide catheter **12** restricts its entry into the smaller coronary arteries and thus the angioplasty balloon catheter **18** must be advanced independently to access and cross the restriction point.

However, in the guide catheter system **10** of the present invention, the angioplasty balloon catheter **18** may be advanced beyond the distal end of the guide catheter **12** proximate to or across the stenosis or obstruction with the assistance of the guide catheter extension **14** by extending the elongated flexible tube **32**. The outer diameter of the elongated flexible tube **32** is small enough to permit its insertion into the smaller coronary arteries containing the obstruction and thus provides support or guidance for a non-over-the-wire catheter beyond the end of the guide catheter **12** and as far as the stenosis and beyond.

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. In particular, the flexible tube **32** defines an anchoring device for securing the guide catheter **12** for operation. The shaft **19** or push rod is used to advance the flexible tube **32** beyond a distal end of the guide catheter **12** and the coronary ostium into the coronary arteries. 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 as explained in further detail herein in relation to FIG. **12**.

Furthermore, as explained the guide catheter extension **14** is useful for performing a "non-over-the wire" catheter exchange. That is, once the balloon **24** is positioned across the stenosis, it often becomes apparent that a catheter exchange is necessary to substitute a larger balloon than the balloon originally inserted to apply sufficient pressure across the stenosis to reestablish an acceptable blood flow. During the catheter exchange, the angioplasty balloon catheter **18** is withdrawn from the patient so that a different diameter angioplasty balloon catheter can be substituted therefor.

The guide catheter extension **14** (distal extension) which is the subject of this invention provides a means for establishing a path proximate to or across the obstruction or stenosis and directing a substitute angioplasty balloon catheter thereto. Before the original angioplasty balloon catheter **18** is withdrawn, the elongated flexible tube **32** is positioned proximate to or across the lesion. This may be accomplished by advancing the shaft **19** (wire **34** in FIG. **2** and tubular shaft member **172** in FIGS. **3** and **5**) distally within the guide catheter **12** to position the elongated flexible tube **32** proximate to or across the lesion. Then, the original angioplasty balloon catheter **18** is withdrawn and the new angioplasty balloon catheter is substituted therefor. During the insertion thereof, the guide catheter **12** and the guide catheter extension **14** cooperate to direct the new angioplasty balloon catheter to the stenosis.

If it was not anticipated that a catheter exchange would be necessary and the guide catheter extension **14** was not pre-loaded in the guide catheter **12** when the original balloon catheter **18** was inserted, the guide catheter extension **14** may be inserted for use by first detaching the balloon inflation assembly **28** and mounting the flexible tube **32** of the guide catheter extension **14** over the catheter shaft **26**. The balloon inflation assembly **28** includes a coupler **200** (see FIGS. **1** and **7**) having a through slot **202** that extends from a proximal end **204** to a distal end **206** of the coupler **200**. The through slot **202** is configured to receive a tubular proximal portion **208** (FIG. **7**) of the catheter shaft **26** of the balloon catheter **18**.

The coupler **200** further includes a sliding member **210** having a generally planar engagement surface that is aligned parallel to a planar bottom wall of the through slot **202**. The sliding member **210** is movable longitudinally along the coupler (as represented by the directional arrow **212**) between a first state wherein the engagement surface of the sliding member **210** is spaced from the bottom wall of the through slot **202** such that the proximal portion **208** of the catheter shaft **26** can be readily inserted into the through slot **202** (FIG. **7**); and a second state wherein the proximal portion **208** is securely gripped between the engagement surface of the sliding member **210** and the bottom wall of the through slot **202** (FIG. **1**). As seen in FIG. **7**, the sliding member **210** is in the catheter shaft receiving first state when the sliding member **210** is positioned at the proximal end **204** of the coupler **200**. As seen in FIG. **1**, the sliding member **210** is in the catheter shaft gripped second state when the sliding member **210** is positioned near the distal end **206** of the coupler **200**.

The proximal end **204** of the coupler **200** includes a luer fitting **214** having a threaded portion **216** that is adapted to cooperate with a threaded distal end of an inflation device (not shown). The luer fitting includes a through opening **218** in aligned registry with the through slot **202** of the coupler **200**. An annular seal within the through opening **218** receives the proximal portion **208** of the catheter shaft **26** and forms a fluid tight seal between the balloon inflation assembly **28** and the balloon catheter **18** when the proximal portion **208** of the catheter shaft **26** is gripped within the coupler **200**. This arrangement permits inflation medium from the inflation device to enter the balloon catheter **18** through the proximal portion **208** and to travel up the catheter shaft **26** to inflate the balloon **24**. The balloon inflation assembly **28** as described may be readily attached to and detached from the balloon catheter **18** in the event a catheter exchange is necessary. The coupler **200** is further detailed in a co-pending application filed by the same assignee, SciMed Life Systems, Inc., on Oct. 24, 1990, and entitled "Catheter Exchange Apparatus with Removable Inflation Assembly." The disclosure of this co-pending application, Ser. No. 07/602,759, now abandoned is hereby incorporated by reference into the present application.

Thus, the sliding member **210** is slid towards the proximal end **204** of the coupler **200** (FIG. **7**) to release the inflation assembly **28** from the shaft **26**. Thereafter, the elongated flexible tube **32** of the guide catheter extension **14** is positioned about the catheter shaft **26** by aligning the distal end of the extension tube **32** over the proximal end of the catheter shaft **26** and coaxially advancing the extension tube **32** therealong. The elongated flexible tube **32** is introduced into the patient and is further advanced until the distal end thereof is positioned about the original angioplasty balloon catheter **18**, proximate to or across the stenosis. Once the flexible tube **32** is positioned proximate to or across the stenosis, the original balloon catheter **18** is then withdrawn and an alternate sized angioplasty catheter is inserted therefor. The guide catheter **12** and the flexible tube **32** of the guide catheter extension **14** cooperate to direct the new angioplasty balloon catheter to the previously established position of the stenosis.

With respect to the embodiment of the present invention illustrated in FIGS. **3–6**, a catheter exchange is accomplished in a generally similar manner. The angioplasty balloon catheter **18** is advanced distally through the guide catheter **12A** and perhaps the guide catheter extension **14A** to a desired position across a stenosis. Should a balloon catheter exchange be necessary, the shaft **172** is used to position the flexible tube **32A** across or proximal to the stenosis. Once the desired position of the flexible tube **32A**

is achieved, the restriction balloon **170** is inflated to hold the tube **32**A in place during the catheter exchange. The balloon catheter **18** is then withdrawn proximally through lumens **33**A and **27**A of the guide catheter extension **14**A and guide catheter **12**A respectively, and another angioplasty balloon catheter is advanced distally through those lumens to a desired position relative to the stenosis. Preferably, the guide catheter extension **14**A is flexible enough and small enough in diameter that its distal tip **36**A can be positioned adjacent to the stenosis so that a balloon catheter advanced therethrough is "guided" to its destination along nearly the entire path.

FIG. **7** illustrates another embodiment of a guide catheter system **50** of the present invention. The guide catheter system **50** includes a guide catheter **52**, a guide catheter extension tube **70** and a guide catheter manifold **54**.

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.

The guide catheter **52** assists the insertion of an angioplasty balloon catheter **60** to the stenosis or lesion. The angioplasty balloon catheter **60** includes a balloon **62**, a hollow catheter shaft **66**, a balloon inflation assembly **28**, and a flexible spring tip **64**. The spring tip **64** is disposed at the distal end of the catheter shaft **66** and generally assists the insertion of the angioplasty catheter **60** through the arterial system of a patient.

The balloon inflation assembly **28** is mounted at a proximal end of the hollow catheter shaft **66** and has an inlet port **218** thereon. Inflation medium (from an inflation device—not shown) is injected through the hollow balloon catheter shaft **66** to inflate the balloon **62** mounted at the end thereof.

The guide catheter extension tube **70** defines a second guide catheter lumen **77** and is made from a soft, relatively flexible material such as polyolefin, polyethylene or polyurethane. The guide catheter extension tube **70** has a reinforced flexible distal end portion **73**, a rounded distal tip **72** and a flared proximal end **74**. The reinforced distal end portion **73** of the guide catheter extension tube **70** is formed from a coated or sheathed wire coil **76** to provide flexibility and pushability therefor. One or more side holes **75** may be added in the distal end portion **73** for distal blood perfusion. The outside diameter of the guide catheter extension tube **70** is smaller than the inside diameter of the guide catheter **52** such that the guide catheter extension tube **70** may be inserted and slidably disposed therethrough. During use, the guide catheter extension tube **70** is coaxially disposed within the guide catheter **52**. The guide catheter extension tube **70** is longer than the guide catheter **52** so that a portion of the extension tube **70** extends beyond the distal end of the guide catheter **52** to bridge the gap between the distal end of the guide catheter **52** and the stenosis or obstruction.

The guide catheter extension tube **70** also includes a longitudinal slit **78** that extends from a proximal end of the reinforced distal end portion **73** to the flared proximal end **74**. The reinforced distal end portion **73** defines a rigid portion that may be mounted about the proximal end of the catheter shaft **66** and supported thereby prior to use of the extension tube **70**. This pre-use position of the reinforced distal end **73** and the extension tube **70** is depicted by the phantom line drawing in FIG. **7**. As shown, the slit **78** is formed to be normally resiliently closed but, it may be forcibly "peeled" opened to position the remaining length of the extension tube **70** (the portion extending from the flared proximal end **74** to the proximal end of the reinforced distal end portion **73**) about the catheter shaft **66** for insertion through the guide catheter **52**. The reinforced distal end portion **73** may be mounted over the catheter shaft **66** prior to insertion of the catheter **60** to assume the pre-use position depicted by the phantom line drawing in FIG. **7**. To position the reinforced distal end portion **73** about the catheter shaft **66** prior to insertion of the catheter **60**, the distal end portion **73** is installed over the distal end of the catheter shaft **66** and is advanced towards the proximal end thereof.

Alternatively, the reinforced distal end portion **73** may be mounted over the proximal end of the catheter shaft **66** as needed by detaching (as depicted in FIG. **7**) the balloon inflation assembly **28** from the proximal end of the catheter shaft **66**. The balloon inflation assembly **28** includes a coupler **200** as previously explained with reference to the balloon inflation assembly **28** (FIG. **1**). As described, (FIGS. **1** and **7**) the coupler **200** includes a through slot **202** configured to receive a tubular proximal portion **208** of the catheter shaft **66**. A sliding member **210** having a generally planar engagement surface is designed to grip the planar bottom wall of the through slot **202** when in an engaged position (in the engaged position the sliding member **210** is positioned near the distal end **206** of the coupler **200** as shown in FIG. **1**) to connect the catheter shaft **66** to the inflation assembly **28** for operation. The catheter shaft **66** is released from the inflation assembly **28** by moving the sliding member **210** longitudinally along the coupler towards the proximal end **204** (where the engagement surface of the sliding member **210** is spaced from the bottom wall of the through slot **202**). The balloon inflation assembly **28** as described can be readily attached and detached from the catheter shaft **66** in the event a catheter exchange is necessary to position the distal end portion **73** about the proximal portion **208** of the catheter shaft **66** for insertion into the patient.

A luer fitting **214** having a threaded portion **216** is mounted to the proximal end **204** of the coupler to provide an attachment for the inflation device (not shown). The luer fitting **214** includes a through opening **218** in aligned registry with the through slot **202** of the coupler **200**. An annular seal within the through opening **218** receives the proximal portion **208** of the catheter shaft **66** and forms a fluid tight seal between the balloon inflation assembly **28** and the balloon catheter **60** when the proximal portion **208** of the catheter shaft **66** is gripped within the coupler **200**. This arrangement permits inflation medium from the inflation device to enter the balloon catheter **60** through the proximal portion **208** and to travel up the catheter shaft **66** to inflate the balloon **62**.

To facilitate a catheter exchange, the reinforced distal end **73** of the guide catheter extension tube **70** is distally advanced into the guide catheter **52** from its position about the proximal portion of the catheter shaft **66**. The slit **78** is forced open to position the remaining length of the extension tube **70** about the catheter shaft **66** for insertion (depicted by the solid line structure, FIG. **7**). The guide catheter extension tube **70** is distally advanced until the distal tip **72** is

positioned proximate to the stenosis, or until the flared proximal end **74** thereof is just proximal to an opening **59** into the guide catheter **52**. The diameter of the flared proximal end **74** of the extension tube **70** is larger than the opening **59** into the guide catheter **52** to prevent the over insertion of the extension tube **70** into the guide catheter **52** so that a portion remains outside the patient for control. The length of the guide catheter extension tube **70** is long enough so that the distal tip **72** reaches the stenosis while a portion of the tube remains outside the patient for control. Further, the diameter of the extension tube **70** is larger than the balloon **62** (deflated) and the catheter shaft **66** so that the angioplasty balloon catheter **60** may be slid therethrough. Radiopaque markers **79** and **79A** may be included at the proximal end and the distal end of the guide catheter extension tube **70**, respectively, to assist with the insertion of the tube **70** through the patient's artery.

Once the guide catheter extension tube **70** is positioned proximate to or across the stenosis, the angioplasty balloon catheter is withdrawn and an alternate sized angioplasty balloon catheter is substituted therefor. As the new angioplasty balloon catheter is inserted, the guide catheter **52** and guide catheter extension tube **70** cooperate to direct the new angioplasty balloon catheter to the previously established position of the stenosis so that the stenosis may be further treated.

FIG. **8** illustrates another embodiment of a guide catheter system **80** of the present invention. As shown in FIG. **8**, the guide catheter system **80** has a guide catheter extension tube **100** designed for placement within a guide catheter **82**, which is mounted to a guide catheter manifold **84**. The guide catheter extension tube **100** includes a longitudinal slit **108** extending its entire length. The extension tube **100** has a rounded distal tip **104** and a flared proximal end **106**. The guide catheter extension tube **100** is used in association with an angioplasty catheter **90** having a hollow balloon catheter shaft **94**, a balloon inflation assembly **98**, a balloon **92** and a flexible spring tip **96**. The diameter of the balloon **92** (deflated) and the catheter shaft **94** are small enough so that the catheter **90** may be inserted into and slidably disposed through the extension tube **100**.

If a balloon catheter exchange is necessary, the guide catheter extension tube **100** is positioned about the catheter shaft **94**, and is inserted through the guide catheter **82**. As the extension tube **100** is inserted through the guide catheter **82**, the slit **108** is forced open beginning at the distal tip **104** and extending to the flared proximal end **106** to align the extension tube **100** about the catheter shaft **94** for insertion. The extension tube **100** is advanced within the guide catheter **82** until the distal tip **104** thereof is positioned proximate to the stenosis or until the flared proximal end **106** abuts the guide catheter manifold **84**. Radiopaque markers **101** and **102** may be included at the proximal end and the distal end of the guide catheter extension tube **100**, respectively to assist the insertion of the tube **100** through the patient's artery. The guide catheter extension tube **100** is longer than the guide catheter **82** to provide sufficient length for the extension tube **100** to extend beyond the distal end of the guide catheter **82** to the obstruction and to provide a portion that remains outside the patient for control (the flared proximal end **106** prevents over-insertion of the extension tube **100** into the guide catheter **82**). In this embodiment, the length of the longitudinal slit **108** extends the entire length of the extension tube **100**. Thus, the balloon manifold **98** does not need to be removed to position the extension tube **100** about the catheter shaft **94** for insertion into the guide catheter **82**.

FIGS. **9–11** illustrate another embodiment of a distal extension **250** similar to that disclosed in FIGS. **1–2**. The extension **250** includes a relatively flexible tube **255** having a proximal funnel **260**, a push rod **262** and a control knob **264**. The push rod **262** is attached to the flexible tube **255** adjacent the proximal funnel **260**. The control knob **264** is attached to a proximal end of the push rod **262**. Preferably, as shown in FIG. **9**, an annular radiopaque marker **265** of platinum alloy is provided at the distal end of the flexible tube **255** to trace the position of the extension **250** via fluoroscopic imaging. The flexible tube **255** preferably has an inner diameter dimension of about 0.046 inches and an outer diameter dimension of about 0.056 inches.

As shown more clearly in FIG. **10**, the flexible tube **255** is formed of a coil spring **266** of Type 304 stainless steel and inner and outer polymer layers **267** and **268**, respectively to define a lumen **269** therethrough (FIG. **10**). Preferably, the coil spring **266** is a flattened ribbon spring formed of a ribbon wire having a 0.002 inch by 0.005 inch cross-section. Each of the inner and outer layers **267** and **268** are polyurethane and are approximately 0.0015 inches thick.

The polyurethane coated coil spring **266** defining the flexible tube **255** is formed using a Teflon® coated cylindrical mandrel having a diameter of 0.046 inches. Teflon® is a registered trademark of E. I. Dupont Corporation of Delaware for polytetrafluorethylene. The mandrel is coated with polyurethane by a solvent dip coating process to form the inner polymer layer **267** of the flexible tube **255**. The mandrel is coated until the polyurethane coating on the mandrel is 0.0015 inches thick. The ribbon wire is wrapped around the coated mandrel to form the coil spring **266**. The number of wrapping turns per inch of the ribbon wire around the mandrel can vary. One example of a coil spring **266** has 100 turns/per inch of ribbon wire. The mandrel is dip coated again in polyurethane to form a 0.0015 inch thick outer polymer layer **268** enclosing the coil spring **266**.

A suitable polyurethane coating is sold under the tradename ESTANE by B. F. Goodrich Company of Akron Ohio. Prior to dip coating the outer layer **268**, the radiopaque marker **265** is attached to the ribbon spring so that the marker **265** is encapsulated by the outer polymer layer **268** to provide a relatively smooth outer surface for the flexible tube **255** for insertion. The dip coating process covers the longitudinal length of the ribbon spring as well as the ends so that the ribbon spring is totally encapsulated by a polymer coating. After the dip coating process is complete, the mandrel is removed.

An end tip **255***a* is formed by wicking cyanoacrylate adhesive between the inner and outer layers **267** and **268** and coil spring **266** to assure that the inner and outer layers **267** and **268** of the tip do not separate from the coil spring **266** as the extension **250** is advanced for use and treatment. A suitable adhesive is LOCTITE PRISM 405 cyanoacrylate, available from Loctite, Corp. (Newington, Conn.).

A hydrophilic polymer coating is added to the inner and outer polyurethane layers **267** and **268** to provide a slipperier surface. The coated coil spring **266** forming the tube **255** is extremely flexible to facilitate trackability through the tortuous coronary arteries. The tube **255** is so flexible that the tube must be inserted with the assistance of another coronary treatment device to provide sufficient pushability.

As shown in FIGS. **10** and **11**, the proximal funnel **260** includes a distally tapered frusto-conical portion **270** and an elongated tubular portion **272** having an internal diameter sized to fit over the proximal end of the flexible tube **255**. The taper of the frusto-conical portion defines a first proxi-

mal outer diameter **274** and a second smaller (distal) outer diameter **276**. The elongated tubular portion **272** of the funnel **260** surrounds the proximal end of the flexible tube **255**. Preferably, the proximal funnel **260** is formed of a polyolefin material. A suitable polyolefin is available from E. I. DuPont Nemours & Co. (Wilmington, Del.) under the tradename SURYLYN® (8527 POC) Ionomer.

The push rod **262** is preferably formed of a nitinol wire (a nickel-titanium intermetallic compound). The nitinol wire is Teflon® coated. The Teflon® coating provides a lubricous outer surface for the wire. The nitinol construction helps reduce wire kinking as the push rod **262** is manipulated. The control knob **264** is formed of a polycarbonate material and is attached to a proximal end of the push rod **262** to provide a means for manipulating the push rod **262** and the flexible tube **255** for placement of the extension **250**.

The push rod **262** is approximately 0.018 to 0.024 inches in diameter. A distal end of the wire is preferably flattened as shown in FIGS. **10** and **11** to define a rectangular cross-section **280** at the distal end thereof. The flattened rectangular cross-section **280** of the push rod **262** provides sufficient attachment surface area to attach the push rod **262** to the proximal funnel **260** and thus to the flexible tube **255** as shown in FIGS. **10** and **11**.

As shown in FIG. **11**, the frusto-conical portion **270** of the proximal funnel **260** includes a recessed wire channel **282**. The flattened distal end of the push rod **280** extends through the recessed wire channel **282** to align the push rod **262** essentially parallel to the flexible tube **255** and the elongated tubular portion **272** of the proximal funnel **260**.

An outer bond sleeve **284** (FIG. **10**) encloses the elongated tubular portion **272** of the proximal funnel **260** and the push rod **262**. The outer bond sleeve **284** is preferably formed of polyolefin material. The proximal funnel **260** and the push rod **262** are secured to the flexible tube **255** of the extension **250** by a suitable wicking adhesive (preferably urethane) between the outer bond sleeve **284** and the flexible tube **255**. A suitable urethane adhesive is available from H. B. Fuller & Company of Saint Paul, Minn. (Adhesive No. U.R. 3507).

The urethane adhesive surrounds the push rod **262** and the elongated tubular portion **272** of the proximal funnel **260** between the flexible tube **255** and the outer bond sleeve **284** to secure the proximal funnel **260** and the push rod **262** relative to the flexible tube **255**. The bonding arrangement with the outer bonding sleeve **284** provides a smooth outer transitional surface where the proximal funnel **260** and the push rod **262** are bonded to the flexible tube **255**.

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.

As explained, the extension **250** is advanced through a guide catheter until a distal end of the tube **255** reaches a treatment site. The length of the tube is sized so that the proximal end (i.e., proximal funnel **260**) of the tube **255** is enclosed within the guide catheter while the distal end of the flexible tube **255** reaches a treatment site. The proximal funnel **260** (frusto conical portion **270**) is never advanced beyond the distal end of the guide catheter so that a continuous lumen may be defined by the combination of the guide catheter and the flexible tube **255**.

The flexible tube **255** of the intravascular device **250** is designed for coaxial placement relative to the guide catheter and the flexible tube and in particular, the proximal funnel **260** is sized to fit through the guide catheter. The first outer diameter **274** of the frusto-conical portion **270** of the proximal funnel **260** coincides with the internal diameter of the guide catheter so that there is a close tolerance therebetween to facilitate the insertion of an angioplasty device through the guide catheter and then through the proximal end of the tube **255**. Additionally, the close tolerance provides a seal to facilitate the flow of liquids (such as dye and drugs) through the guide catheter and the tube **255** to a selected treatment site. However, the funnel **260** is sufficiently flexible to allow the extension **250** to be slidably advanced through the guide catheter without significant friction. Thus, the proximal funnel **260** serves to direct an angioplasty device into the lumen **269** of the extension **250**, or to provide a distal extension of the lumen of the guide catheter for fluid delivery.

Although, the tube **255** has good trackability, it does not have sufficient pushability to be independently advanced through a coronary artery of a patient. Accordingly, the flexible tube is advanced in cooperation with another coronary treatment device (such as shown in FIG. 1) for placement in the artery. Therefore, the inner diameter of the flexible tube **255** is large enough to be advanced over a treatment device. Examples of a treatment device which could be used to support the flexible tube to provide pushability for advancement include, but are not limited to, an angioplasty balloon catheter (as shown in FIG. 1) or a guide wire.

As previously explained, if a catheter exchange is necessary, the flexible tube **255** can be advanced along an angioplasty balloon catheter to the obstruction. Once the distal end of the flexible tube **255** is positioned adjacent to the obstruction or lesion, the original angioplasty catheter may be withdrawn and a substitute angioplasty catheter inserted therefor.

As shown in FIG. **12**, 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. It is important that the distal opening **288** of the guide catheter **287** be correctly aligned and that alignment be maintained so the coronary treatment device will be directed through the coronary ostium into the coronary artery requiring treatment. However, 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. The anchoring device is defined by the flexible tube **255** and push rod **262** (i.e., the distal extension **250**). A distal portion of the flexible tube **255** is advanced past the distal opening **288** of the guide catheter **287** and past the coronary ostium into the artery requiring treatment, while a proximal portion thereof and the push rod **262** remain within the guide catheter **287**. Since the flexible tube **255** extends along a portion of the guide catheter **287** and through the coronary ostium along an extent of the artery, the flexible tube **255** serves to aid in securing the distal

opening **288** of the guide catheter **287** relative to the coronary ostium.

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 the guide catheter **287** into and through a coronary artery while the control knob **264** remains outside the patient. The control knob **264** allows the user to control and adjust the position of the extension **250** through the arteries. The outer diameter of the flexible tube **255** is sized so that the flexible tube **255** may be advanced through the coronary arteries, without significant risk of occlusion to the vessel. Further, the flexibility of the tube **255** allows the tube **255** to track through the tortuous coronary arteries.

Alternatively, the extension **250** can be used as a guide wire placement device to assist in the insertion of a typical pre-formed guide wire as generally illustrated in FIG. **13**. In particular, the flexible tube **255** and a pre-formed guide wire **289** are cooperatively advanced through the coronary arteries for placement.

Guide wires are pre-formed in generally a J-shape or a straight tip where the practitioner is able to bend the tip to pre-form the wire prior to insertion. A pre-formed guide wire **289** may be advanced through a patient's vascular system within the guide catheter **287** and the flexible tube **255**. The pre-formed guide wire **289** is inserted in cooperation with the flexible tube **255** to straighten the guide wire **289** to permit the guide wire **289** and the flexible tube **255** to be advanced into the patient through a coronary artery. The extension **250** is advanced by manipulating the control knob **264** to move the flexible tube **255** through the arterial system of the patient. Thus, the flexible tube **255** straightens the tip of the pre-formed guide wire **289** to allow the guide wire **289** to advance through the patient.

If it is determined that an alternate shaped guide wire is necessary to reach the treatment site, the original guide wire **289** may be withdrawn. The original guide wire **289** is withdrawn through the flexible tube **255** and through the guide catheter **287**. An alternate shaped pre-formed guide wire is then inserted in cooperation with the guide catheter **287** and the flexible tube **255** to place the alternative guide wire into a coronary artery for treatment.

Another use for extension **250** is as a drug delivery device. In certain applications, it is useful to be able to provide rapid drug delivery to a treatment area to dissolve thrombolytic buildup caused, inter alia, because of the stagnation of blood flow during an angioplasty procedure. Thus, it is often necessary to provide intermediate drug delivery during an angioplasty procedure to dissolve platelet matter causing thrombolytic buildup. The flexible tube **255** is insertable into the arteries to define a tubular drug delivery extension (or drug deliver device) to provide a conduit for thrombolytic drugs and agents to reach an occluded area in a coronary artery to assure the thrombolytic drug reaches a treatment site.

As previously explained thrombolytic drugs and other liquids, such as contrast fluid or radiopaque dye may be introduced through a guide catheter (e.g., through port **287***a* of the guide catheter **287** by a syringe as shown in FIG. **13**) for delivery to an occluded coronary artery. The drug flows through the guide catheter **287** and is funneled through the proximal funnel **260** of the extension **250** and then through the flexible tube **255** (i.e., tubular drug deliver extension) to a treatment area. Preferably, drugs or other liquids are introduced through the guide catheter **287** and extension **250** by a 20 cc (cubic centimeters syringe).

The extension **250** may also be used for aspiration to withdraw thrombus from a coronary artery. Net negative pressure is pulled through the guide catheter **287** and the extension **250** via a syringe connected to through port **287***a* of the guide catheter **287** as shown in FIG. **13** to pull thrombus from the occluded vessel. Preferably a 50 cc (cubic centimeters) syringe is used.

Net negative pressure is applied to move the thrombus toward the extension **250**. The thrombus can be removed from the patient in a first manner by aspirating with sufficient force to pull the thrombus toward the extension to "plug" a distal end **255***b* thereof. Thereafter, the extension **250** is withdrawn from the vessel and the extension **250** is removed from the patient and the thrombus is scraped from the extension **250**. Alternatively, sufficient force may be applied to draw ("suck") the thrombus through the extension **250** and the guide catheter for disposal.

Alternatively, as shown in FIGS. **14–17**, a proximal elongated attachment tube **290** is designed to couple with the proximal funnel **260** of the distal extension **250** to define a proximal drug delivery attachment. Together, the elongated attachment tube **290** and the distal extension **250** define a continuous conduit for drug delivery. The proximal elongated attachment tube **290** may also define a proximal aspirator attachment to provide a conduit for aspiration in combination with the extension **250**. As shown in FIG. **14**, the proximal elongated attachment tube **290** includes an elongated flexible tube **292**, a distally tapered coupling cone **294** and a proximal luer fitting **296**. Preferably, the elongated tube **292** is formed from a polymer tube such as polyethylene.

As shown in FIGS. **15** and **16**, the elongated attachment tube **290** is designed to cooperate with the flexible tube **255** of the extension **250** to define a continuous path for drug delivery or aspiration. The coupling cone **294** has a hollow cross-section to define a continuous lumen **298** from the luer fitting **296** to a distal opening **300**. The distally tapered coupling cone **294** of the proximal elongated attachment tube **290** is sized for insertion into the distally tapered proximal funnel **260** of the extension **250**. Thus, as shown in FIGS. **15** and **16**, the distal coupling cone **294** of the proximal elongated attachment tube **290** and the proximal funnel **260** of the distal extension **250** mate so that the continuous lumen **298** of the elongated attachment tube **290** and the lumen **269** through tube **255** are in fluid communication to define a continuous path to a treatment site for drug delivery or for aspiration (i.e., for treatment of a stenosis or obstruction within a coronary artery).

The connection between the coupling cone **294** of the proximal elongated attachment tube **290** and the proximal funnel **260** of the extension **250** is adjusted by manipulating the push rod **262** relative to a proximal end of the elongated attachment tube **290**. That is, to provide a tighter relation between the extension **250** and the proximal elongated attachment tube **290**, the push rod **262** is moved by the user proximally while the attachment tube **290** is moved distally to force the coupling cone **294** and the proximal funnel **260** in tight relation to provide a tighter fluid connection therebetween.

As shown in FIG. **17**, the tube **292** of the proximal attachment tube **290** is sized for insertion through a guide catheter **305**. In use, the flexible tube **255** of the extension **250** is inserted into the coronary artery requiring treatment until a distal end reaches the occluded or treatment area. If drug treatment or aspiration is necessary, the proximal attachment tube **290** may be inserted and advanced through

the guide catheter **305** so that the coupling cone **294** mates with the proximal funnel **260** of the distal extension **250**.

Typically an angioplasty balloon catheter or other coronary treatment device was previously inserted into the patient for treatment or was inserted for placement of the extension **250**. Thus, prior to inserting the proximal attachment tube **290**, the angioplasty balloon catheter, or other coronary treatment device, is withdrawn and the proximal attachment tube **290** is inserted for drug treatment or aspiration.

Thrombolytic drugs are introduced through the tube **292** of the drug delivery attachment by a syringe **306** which attaches to the luer fitting **296** at the proximal end of tube **292**. Since the tube **292** has a smaller inner diameter than the guide catheter, a smaller quantity of drug is necessary to provide an effective dosage for treatment. Since a smaller dosage is required, treatment is less costly. Once in place as an extension of the guide catheter, the extension **250** can also serve to direct radiopaque solution to a selected artery.

Alternatively, if aspiration treatment is undertaken the syringe **306** is manipulated to apply a net negative pressure across the extension **250** and the tube **292** to withdraw thrombus from an occluded vessel. Preferably, a 50 cc (cubic centimeters) syringe is used.

After the drug or aspiration treatment is complete, if necessary, an angioplasty device may be reinserted for continued treatment through the proximal attachment tube **290** and the extension **250**. Alternatively, the proximal attachment tube **290** may be removed and an alternate angioplasty device may be inserted through the guide catheter and the flexible tube **255** of the extension **250**. In either event, extension **250** provides a guiding and "back-up" function to aid in the advancement of such devices therethrough.

Preferably, the tube **292** of the drug delivery attachment **290** has an outer diameter of 0.040 inches to 0.070 inches. The tube has an inner diameter of 0.030 inches to 0.06 inches. The length of the tube **292** is approximately 40.0 to 60.0 inches in length.

It should be noted that the figures have not been drawn to scale as it has been necessary to enlarge certain portions for clarity. Although the present invention has been described with reference to several embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. Also, it should be understood, that the invention is not limited to the uses specifically set forth in the preferred embodiment of the invention and the scope of the invention should not be limited thereby.

What is claimed is:

1. A guide catheter system comprising: a guide catheter;

a relatively flexible tube having an outer diameter sized for insertion into a coronary vessel and an inner diameter defining a lumen therethrough, the tube having a proximal end and a distal end, the extent therebetween defining an extension length of the flexible tube, the length of the tube being sized so that the proximal end of the tube is enclosed within the guide catheter and the distal end extends into the vessel to reach a treatment site, the tube being movable between a first retracted position and a second extended position;

a push rod having a proximal end and a distal end, the distal end of the push rod being coupled to the proximal end of the tube for slidably positioning the tube in the vessel; and

a fluid seal positioned at the proximal end of the tube and coupled between the tube and the guide catheter for fluidly sealing between the tube and the guide catheter when the tube is in the second extended position.

2. The guide catheter system of claim **1** wherein the relatively flexible tube of the intravascular device includes a coil spring extending along and defining at least a portion of the flexible tube.

3. The guide catheter system of claim **2** further including an inner layer and an outer layer of a polymer material surrounding the coil spring.

4. The guide catheter system of claim **1** wherein the inner diameter of the tube is sized to permit placement of a guide wire through the tube.

5. The guide catheter system of claim **1** wherein the inner diameter of the tube is sized to permit placement of an angioplasty balloon catheter through the tube.

6. The guide catheter system of claim **1** wherein the flexible tube of the intravascular device is 6 to 12 inches in length.

7. The guide catheter system of claim **1** wherein the push rod is a wire.

8. The guide catheter system of claim **1** wherein the push rod has a length of 40 to 45 inches.

9. The intravascular device of claim **1** wherein the push rod includes a visual marker on a proximal end thereof.

10. An improved intravascular device for use in combination with a guide catheter having a distal end, a proximal end and an internal diameter defining a central lumen, the improvement comprising:

a relatively flexible tube having an outer diameter sized for insertion through the central lumen of the guide catheter into a coronary vessel, the flexible tube being concentrically aligned with the guide catheter and the tube having an inner diameter defining an internal lumen therethrough, the tube having a proximal end and a distal end, the extent therebetween defining an extension length of the flexible tube, the length of the tube being sized so that the proximal end of the tube terminates adjacent the distal end of the the guide catheter and the distal end extends into the vessel to reach a treatment site;

a proximal funnel formed near the proximal end of the flexible tube, the proximal funnel having a distally tapered frusto-conical portion, the distally tapered frusto-conical portion defining an opening between the central lumen of the guide catheter and the internal lumen of the tube for allowing fluid communication therebetween, the distally tapered frusto-conical portion including a first proximal outer diameter and a second smaller distal outer diameter, the first outer diameter coinciding with the internal diameter of the guide catheter to provide a tight interaction therebetween; and

a push rod coupled to the proximal end of the tube for slidably positioning the tube for placement.

11. A guide wire placement system for placement of a guide wire into a coronary vessel of a patient, the guide wire placement system comprising:

a guide catheter having a proximal end, a distal end, and a central lumen extending therethrough;

a relatively flexible tube sized for insertion into a coronary vessel through the central lumen of the guide catheter into a coronary vessel, the flexible tube of the intravascular device being concentrically aligned with the guide catheter and having a proximal end and a distal end, the extent therebetween defining an extension length of the flexible tube, the length of the tube

being sized so that the proximal end of the tube terminates adjacent the distal end of the guide catheter and the distal end extends into the vessel to reach a treatment site, the tube defining an internal lumen being sized to receive the guide wire therethrough for placement of the guide wire into the patient, the tube having sufficient rigidity to support a pre-formed guide wire for advancement and placement into the vessel;

a push rod attached to the proximal end of the tube for slidably positioning the tube for placement with the guide wire, wherein the tube is slidable between a first retracted position and a second extended position; and

means for coupling the proximal end of the flexible tube adjacent to the distal end of the guide catheter when the tube is positioned in the second extended position, the means having an opening between the central lumen of the guide catheter and the internal lumen of the tube allowing fluid communication therebetween to form a continuous lumen from the proximal end of the guide catheter into the treatment site.

12. For use in combination with a guide catheter having an inner diameter defining a central lumen, a proximal end and a distal end, an improvement comprising:

a distal extension device including:

a relatively flexible tube defining an inner lumen and being sized for insertion through the central lumen of the guide catheter into a coronary vessel requiring treatment, the flexible tube being concentrically aligned with he guide catheter, the tube having a proximal end and a distal end, the extent therebetween defining an extension length of the flexible tube, the length of the tube being sized so that the proximal end of the tube terminates adjacent the distal end of the guide catheter and the distal end of the flexible tube extends into a vessel to reach a treatment site;

means extending between the proximal end of the tube and the inner diameter of the guide catheter for joining the central lumen and the inner lumen in fluid communication with one another to establish a continuous lumen beyond the distal end of the guide catheter into a coronary vessel; and

a push rod coupled to the proximal end of the flexible tube for placement of the tube into the vessel requiring treatment.

13. The distal extension device of claim **12** wherein the means for joining includes a proximal funnel formed at the proximal end of the flexible tube, the proximal funnel having a distally tapered frusto-conical portion, the distally tapered frusto-conical portion having an opening between the central lumen and the inner lumen to allow fluid communication therebetween and including a first outer diameter and a second smaller outer diameter, the first outer diameter coinciding with an internal diameter of a guide catheter to provide a tight interaction therebetween for sealing the guide catheter relative to the flexible tube of the drug delivery device.

14. The distal extension device of claim **13** wherein the distally tapered frusto-conical portion of the proximal funnel includes a recessed channel through which the push rod extends for attachment thereof to the flexible tube of the distal extension device.

15. The distal extension device of claim **14** wherein the proximal funnel includes an elongated tubular portion extending from the frusto-conical portion, the elongated tubular portion of the proximal funnel surrounding the flexible tube.

16. The distal extension device of claim **15** wherein a bond sleeve encloses the push rod and the elongated tubular portion of the proximal funnel to provide a smooth transitional surface.

17. The distal extension device of claim **12** wherein the flexible tube includes a coil spring extending along and defining at least a portion of the flexible tube.

18. The distal extension device of claim **17** further including an inner layer and an outer layer of polymer material about the coil spring.

19. The distal extension device of claim **12** wherein the push rod is a wire.

20. The distal extension device of claim **19** wherein the wire has a flattened distal end to provide an attachment surface for connection to the flexible tube.

21. A fluid delivery system for delivering fluid into and through a coronary vessel to a treatment site, the system comprising:

a guide catheter having a proximal end and a distal end;

a relatively flexible tube sized for insertion through the coronary vessel, the tube defining an inner lumen for fluid delivery, the length of the tube being sized so that the proximal end of the tube aligns with the distal end of the guide catheter and the distal end of the tube extends into the vessel to reach the treatment site;

a push rod coupled to the flexible tube and extending proximally therefrom for placement of the tube into the vessel, wherein the flexible tube is movable between a first retracted position and a second extended position; and

means adjacent a distal portion of the guide catheter for fluidly sealing between the tube and the guide catheter when the tube is extended into the second extended position.

22. 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 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, the tube having a proximal end and a distal end, the extent therebetween defining an extension length of the flexible tube, the length of the tube being sized so that the proximal end of the tube aligns with the distal end of the guide catheter and the distal end of the tube extends into the vessel to reach the treatment site; and

a push rod eccentrically coupled to the tube and extending proximally therefrom for placement of the tube, wherein 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.

23. An aspiration system for withdrawing blood clotting material from a treatment site within a coronary vessel, the aspiration system comprising:

a guide catheter having a proximal end, a distal end, a central lumen, and an internal diameter;

a relatively flexible tube sized for insertion through the central lumen of the guide catheter into a coronary vessel requiring treatment, the flexible tube being concentrically aligned with the guide catheter, the tube having a proximal end and a distal end, the extent therebetween defining an extension length of the flex-

ible tube, wherein the flexible tube is movable between a first retracted position and a second extended position, the length of the tube being sized so that the proximal end of the tube aligns with the distal end of the guide catheter and the distal end of the tube extends into a vessel to reach the treatment site when the flexible robe is in the second extended position;

a push rod coupled to the proximal end of the tube for slidably positioning the tube for placement, wherein the flexible tube is movable between a first retracted position and a second extended position; and

a seal at the proximal end of the tube and coupled between the tube and the guide catheter for sealing between the tube and the guide catheter when the distal end of the tube is extended into the second extended position.

24. The aspiration system of claim **23** wherein the proximal end of the tube terminates within the guide catheter and wherein the seal comprises:

a proximal funnel formed at the proximal end of the flexible tube, the proximal funnel having a distally tapered frusto-conical portion, the distally tapered frusto-conical portion having an opening between the central lumen of the outer tube and the internal lumen of the inner tube to allow fluid communication therebetween, the distally tapered frusto-conical portion defining a first proximal outer diameter and a second smaller distal outer diameter, the first outer diameter coinciding with the internal diameter of the guide catheter to provide a tight interaction therebetween for sealing the guide catheter relative to the flexible tube for aspiration treatment.

25. For use in combination with a guide catheter having a proximal end, a distal end, and a central lumen, an intravascular device comprising:

a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for insertion through the central lumen of the guide catheter so that the distal end of the tube may be positioned beyond the distal end of the guide catheter to extend the flexible tube to a treatment site; and

a push rod eccentrically coupled to the tube and extending proximally therefrom for slidably positioning the tube.

26. An intravascular system comprising:

a guide catheter having a proximal end, a distal end, a central lumen, and an internal diameter;

a relatively flexible tube having a proximal end, a distal end, an outer diameter and an internal lumen, wherein the outer diameter is sized for insertion through the central lumen of the guide catheter so that the distal end of the tube may be positioned beyond the distal end of the guide catheter to extend the flexible tube to the treatment site and wherein the proximal end of the tube terminates adjacent the distal end of the the guide catheter;

means for coupling the proximal end of the flexible tube relative to the distal end of the guide catheter, the means having an opening between the central lumen of the guide catheter and the internal lumen of the tube allowing fluid communication therebetween to form a continuous lumen from the proximal end of the guide catheter into a coronary vessel to the treatment site; and

a push rod eccentrically coupled to the proximal end of the tube for slidably positioning the tube.

27. The system of claim **26** wherein the means for coupling includes a proximal funnel formed at the proximal end of the flexible tube, the proximal funnel having a distally tapered frusto-conical portion, the distally tapered frusto-conical portion having an opening between the central lumen of the outer tube and the internal lumen of the inner tube to allow fluid communication therebetween, the distally tapered frusto-conical portion defining a first proximal outer diameter and a second smaller distal outer diameter, the first outer diameter coinciding with the internal diameter of the guide catheter to provide a tight interaction therebetween.

28. The system of claim **27** wherein the proximal funnel includes an elongated tubular portion extending from the frusto-conical portion, the elongated tubular portion of the proximal funnel surrounding the flexible tube.

29. The system of claim **28** wherein a bond sleeve encloses the push rod and the elongated tubular portion of the proximal funnel to provide a smooth transitional surface.

30. The system of claim **27** wherein the distally tapered frusto-conical portion of the proximal funnel includes a recessed channel through which the push rod extends for attachment thereof to the flexible tube of the device.

31. The system of claim **26** wherein the flexible tube includes a coil spring extending along and defining at least a portion of the flexible tube.

32. The system of claim **31** wherein an inner layer and an outer layer of polymeric material surround the coil spring.

33. The system of claim **26** wherein the push rod is a wire.

34. An intravascular system comprising;

a first main outer tube having a proximal end, a distal end, an inner diameter, an outer diameter, and a central lumen;

a second inner tube having a proximal end and a distal end, wherein the second inner tube is adapted to be positioned within and through the first main outer tube, the second inner tube including an internal lumen having a distal opening, wherein the internal lumen is in fluid communication with the central lumen of the guide catheter and wherein the second inner tube is flexible so that the inner tube may be directed through a coronary ostium to position the distal opening at a treatment site; and

a push rod coupled to the second inner tube for slidably positioning the second inner tube relative to the first main outer tube.

35. The system of claim **34** wherein the proximal end of the second inner tube terminates adjacent the distal end of the main outer tube, the system further including means for coupling the proximal end of the second inner tube to the distal end of the main outer tube, the means having an opening between the central lumen of the guide catheter and the internal lumen of the tube allowing fluid communication therebetween to form a continuous lumen beyond the distal end of the main outer tube into the ostium of the coronary vessel.

36. The system of claim **35** wherein the means for coupling includes a proximal funnel formed at the proximal end of the inner tube, the proximal funnel having a distally tapered frusto-conical portion, the distally tapered frusto-conical portion having an opening between the central lumen of the outer tube and the internal lumen of the inner tube to allow fluid communication therebetween, the distally tapered frusto-conical portion defining a first outer diameter

and a second smaller outer diameter, the first outer diameter coinciding with the internal diameter of the first main outer tube to provide tight interaction therebetween for sealing the main outer tube relative to the inner tube.

37. The system of claim **34** wherein the second inner tube includes a coil spring extending along and defining at least a portion of the inner tube.

38. The system of claim **37** further including a layer of polymeric material surrounding the coil spring.

39. The system of claim **34** wherein the push rod is coupled to a proximal end of the inner tube.

40. The system of claim **34** wherein the push rod is eccentrically coupled to the second inner tube so that the internal lumen of the second inner tube remains substantially unobstructed.

41. The system of claim **34** wherein the push rod is a wire.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,527,292
DATED : JUNE 18, 1996
INVENTOR(S) : DANIEL O. ADAMS, SCOTT P. THOME

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

Col. 21, line 30, delete "he", insert --the--

Col. 23, line 7, delete "robe", insert --tube--

Signed and Sealed this

Tenth Day of December, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

EXHIBIT C

US005234416A

United States Patent [19]

Macaulay et al.

[11] Patent Number: 5,234,416

[45] Date of Patent: Aug. 10, 1993

[54] **INTRAVASCULAR CATHETER WITH A NONTRAUMATIC DISTAL TIP**

[75] Inventors: **Patrick E. Macaulay**, Cupertino; **Lawrence D. Wasicek**, Sunnyvale; **Alfredo Bayot**, Newark; **Kurt Klemm**, Santa Clara, all of Calif.

[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

[21] Appl. No.: **711,045**

[22] Filed: **Jun. 6, 1991**

[51] **Int. Cl.**[5] **A61M 25/00**

[52] **U.S. Cl.** **604/282**; 604/264; 128/658

[58] **Field of Search** 604/96, 264, 280, 282; 128/656-658, 772; 138/120, 123-126

[56] **References Cited**

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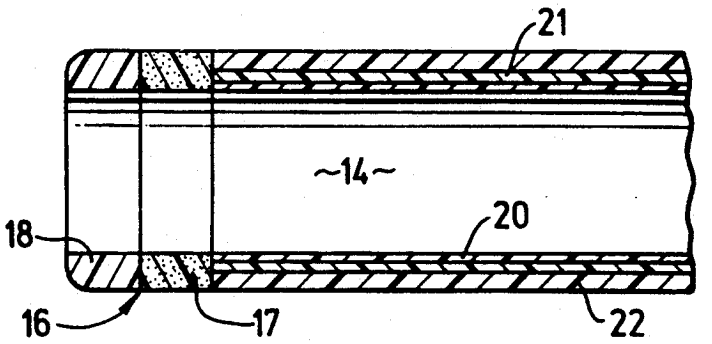
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—C. Maglione

[57] **ABSTRACT**

An intravascular catheter such as a guiding catheter of composite construction having a nontraumatic distal tip comprising a proximal elastomeric tubular element and a distal elastomeric tubular element formed of softer material that the proximal section. The proximal tubular section of the distal tip preferably has a radiopaque material incorporated therein to enable the distal tip to be fluoroscopically observable when in place within a patient. The shaft of the catheter, which exhibits excellent torquability and pushability, is formed with a very thin wall. The catheter shaft includes an inner tubular member of braided polymeric fibrous strands impregnated with a thermoset polyurethane and having an outer jacket or coating of thermoplastic polyurethane secured to the braided tubular member. In some embodiments it is preferred to include a lubricous liner within the braided tubular member.

19 Claims, 1 Drawing Sheet



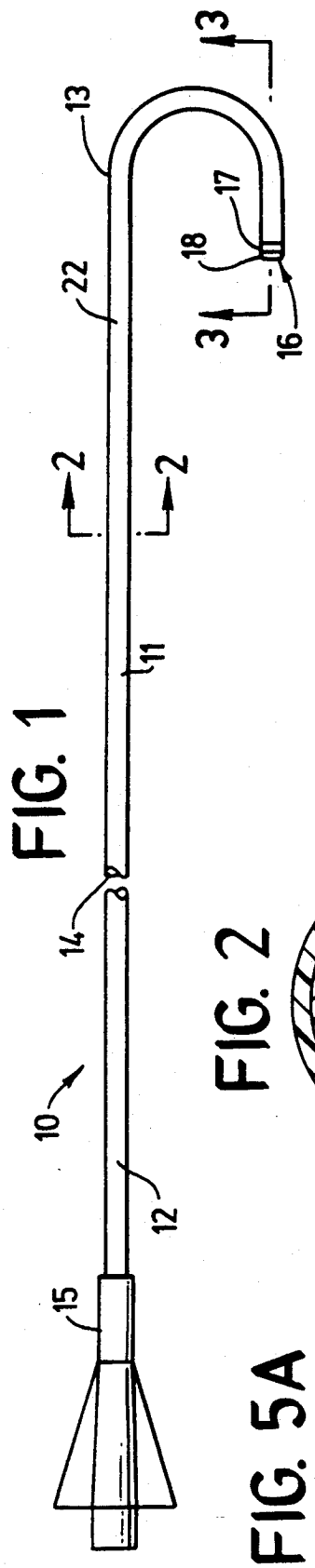


FIG. 1

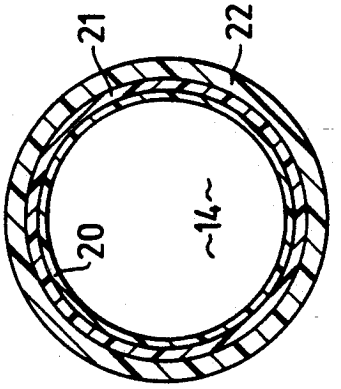


FIG. 2

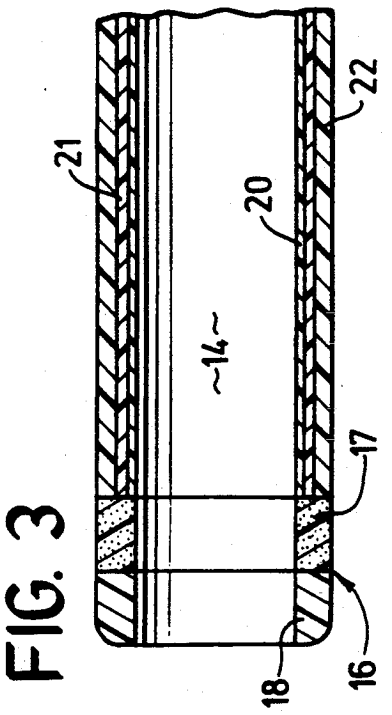


FIG. 3

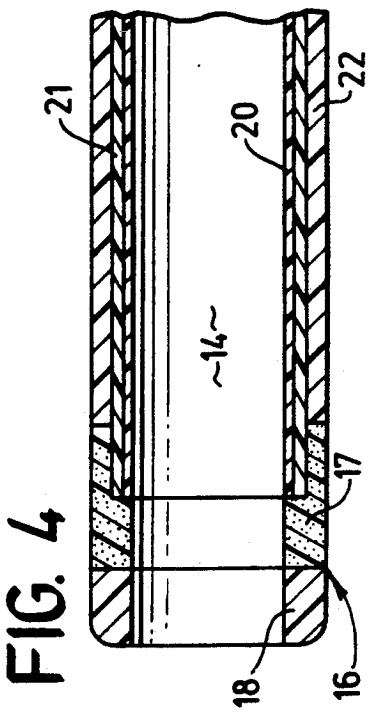


FIG. 4

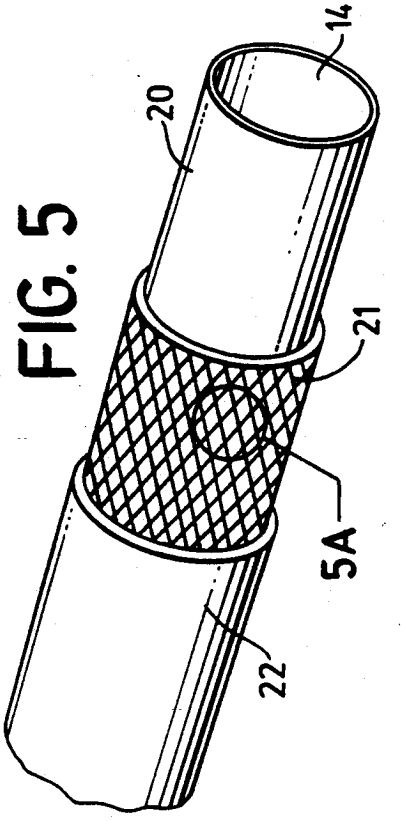


FIG. 5

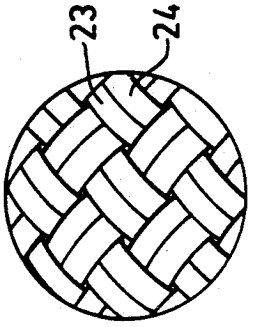


FIG. 5A

INTRAVASCULAR CATHETER WITH A NONTRAUMATIC DISTAL TIP

BACKGROUND OF THE INVENTION

This invention generally relates to guiding catheters for use in intravascular procedures such as percutaneous transluminal coronary angioplasty (PTCA).

In classic PTCA procedures, a guiding catheter having a preshaped distal tip is percutaneously introduced into the cardiovascular system of a patient and advanced therein until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium of the desired coronary artery. The guiding catheter is twisted or torqued from its proximal end which extends out of the patient to turn the distal tip of the guiding catheter so that it can be guided into the coronary ostium. A guidewire and a dilatation catheter having a balloon on the distal end thereof are introduced into and advanced through the guiding catheter to the distal tip thereof, with the guidewire slidably disposed within an inner lumen of the dilatation catheter. The guidewire is first advanced out the distal tip of the guiding catheter, which is seated in the ostium of the patient's coronary artery, until the distal end of the guidewire crosses the lesion to be dilated. The dilatation catheter is then advanced out of the distal tip of the guiding catheter, over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion. Once properly positioned, the balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressures (e.g., generally 4–12 atmospheres) to dilate the stenosed region of the diseased artery. The balloon is then deflated so that the dilatation catheter can be removed from the dilated stenosis and blood flow resumed therethrough.

Further details of guiding catheters, dilatation catheters, guidewires, and the like used in angioplasty procedures can be found in U.S. Pat. No. 4,323,071 (Simpson-Robert); U.S. Pat. No. 4,439,185 (Lundquist); U.S. Pat. No. 4,468,224 (Enzmann et al.); U.S. Pat. No. 4,516,972 (Samson); U.S. Pat. No. 4,438,622 (Samson et al.); U.S. Pat. No. 4,554,929 (Samson et al.); U.S. Pat. No. 4,582,185 (Samson); U.S. Pat. No. 4,616,652 (Simpson); U.S. Pat. No. 4,638,805 (Powell); U.S. Pat. No. 4,748,986 (Morrison et al.); and U.S. Pat. No. 4,898,577 (Badger et al.) which are hereby incorporated herein in their entirety by reference thereto.

Guiding catheters are frequently provided with soft distal tips in order minimize trauma to the arterial lining as the guiding catheter is advanced through an arterial passageway. See for example U.S. Pat. No. 4,385,635 (Ruiz) which is incorporated herein by reference. Soft distal tips may reduce arterial trauma, but they do not always provide a smooth transition between the distal tip and the catheter shaft proximal thereto. Additionally, the soft distal tips are very difficult to locate fluoroscopically by the physician when guiding the distal tip into the ostium of the desired coronary artery.

What has been needed and heretofore unavailable is a guiding catheter or other similar catheter with a nontraumatic distal tip which provides a smooth transition with the catheter shaft and is fluoroscopically observable by the physician in order to facilitate the advancement thereof through a patient's vasculature. The present invention satisfies that need.

SUMMARY OF THE INVENTION

The present invention is directed to a guiding catheter, and particularly to a guiding catheter with a nontraumatic distal tip.

The catheter of the invention generally includes an elongated, tubular shaft having proximal and distal ends, an inner lumen extending therein and a flexible nontraumatic distal tip which is significantly softer than the catheter shaft to which it is secured. The nontraumatic distal tip has at least two, relatively short elastomeric or rubber-like tubular elements which are coaxially secured to the distal end of the tubular shaft. The soft tip is designed with progressively stiffer elements in the proximal direction toward the tubular shaft so that when the tip contacts a blood vessel wall, the force thereof is transmitted to the tubular shaft in a transitionless manner, causing it to align with the flowline of the vessel. The most distal of the elastomeric tubular elements is softer and more pliable than the elastomeric tubular element proximally adjacent thereto and should have a durometer hardness of at least a Shore 10 A hardness less than the adjacent proximal tubular element. The proximal tubular element should have a durometer hardness of about a Shore 80 A to about a Shore 100 A and the distal tubular element should have a durometer hardness of about a Shore 70 A to about a Shore 90 A. The proximal elastomeric tubular element is formed with radiopaque material incorporated therein to facilitate the fluoroscopic observation thereof when disposed within a patient's body lumen such as an artery.

The tubular shaft of the catheter is preferably of composite construction with an elongated braided tubular member formed from radially compressive multifilament polymeric strands, which is impregnated with a thermoset polymer and provided with an outer jacket of thermoplastic polymer. An inner lubricous liner formed of suitable lubricous material such as fluorinated ethylene propylene or polytetrafluoroethylene (e.g., Teflon®, a registered trademark of E. I. du Pont, de Nemours & Co., Inc.) may be provided on the interior of the braided tubular member to thereby define the inner lumen extending within the catheter shaft.

To provide greater flexibility in the distal section of the catheter shaft, the distal section of the braided tubular member may be impregnated with a softer thermoset polymer than the thermoset polymer which impregnates the proximal section of the tubular braided member.

In one preferred embodiment the catheter of the invention is a highly torquable guiding catheter which is readily advanced within a patient's vascular system and, when torqued from the proximal end, it has little tendency to store energy along the length thereof and to release the stored energy by the sudden rotation of the distal end of the catheter, i.e. does not cause the distal end of the catheter to whip. Moreover, the composite structure of the catheter ensures that the circularity of the inner lumen thereof is maintained, so there is little likelihood that a guidewire or dilatation catheter will become bound-up within the lumen when the catheter passes through tortuous passageways. The elastomeric tubular elements forming the nontraumatic distal tip of the catheter are intended to minimize the risk of traumatic engagements with arterial linings and allows the distal tip to be fluoroscopically observable.

These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a guiding catheter embodying features of the invention.

FIG. 2 is a transverse cross-sectional view of the catheter shown in FIG. 1 taken along the lines 2—2.

FIG. 3 is an enlarged longitudinal centerline cross-sectional view of the distal tip of the catheter shown in FIG. 1 taken along the lines 3—3.

FIG. 4 is an enlarged longitudinal centerline cross-sectional view of an alternate construction of the distal tip of a catheter embodying features of the invention.

FIG. 5 is a perspective view of the shaft of the catheter shown in FIG. 1 with sections exposed.

FIG. 5A is an expanded view of the braided section circled in FIG. 5.

DETAILED DESCRIPTION OF THE INVENTION

FIGS. 1–5 and 5A schematically illustrate a guiding catheter 10 of the invention which generally includes an elongated catheter shaft 11 having a proximal section 12, a more flexible distal section 13, an inner lumen 14 extending therein, a Luer hub 15 on the proximal end of the shaft and a nontraumatic distal tip 16 comprising two relatively short elastomeric tubular elements 17 and 18 which are coaxially disposed. The distal section 13 of the shaft 11 is shaped to facilitate the entry thereof into the ostium of a desired coronary artery. As will be appreciated by those skilled in the art, the J-shape of the distal section 13 of the catheter shown in FIG. 1 is a schematic representation and a variety of shapes, such as the well-known Judkins and Amplatz configurations for both the right and left coronary arteries, may be employed to facilitate the entry of the distal tip of the guiding catheter into the ostium of the desired coronary artery. The relatively soft, nontraumatic distal tip 16 is intended to minimize traumatic engagement with arterial tissue.

FIGS. 2, 5 and 5A illustrate the composite construction of the shaft 11 of catheter 10. A thin-walled lubricous inner lining 20 is disposed within braided tubular element 21 and defines the inner lumen 14. The braided tubular element 21 is impregnated with a thermoset polymeric material and an outer jacket 22, preferably formed of a thermoplastic polymeric material, surrounds the exterior of the braided tubular element 21. The braided tubular element 21 is formed from a plurality of pairs of fibrous multifilament polymeric strands 23 and 24 which are radially compressed against the inner liner 20 when they are braided into the diamond-like pattern as shown in FIG. 5A.

The nontraumatic distal tip 16 of the catheter 10, as illustrated in FIG. 3, is comprised of two relatively short flexible tubular elements, a proximal element 17 and a distal element 18, and is butt joined to the distal end of shaft 11 by melt fusing or by a suitable adhesive, such as well-known cyanoacrylate-based adhesives, e.g. Loctite TM 405, sold by Loctite Corporation, Newington, Conn. Both tubular elements 17 and 18 are formed of elastomeric or rubber-like materials but the distal section 18 is softer and more flexible than proximal section 17. Additionally, the proximal section 17 has a radiopaque filler material incorporated therein such as bismuth trioxide in order to make the distal tip fluoroscopically observable within a patient. The short tubular sections 17 and 18 are also butt joined together by suitable means such as by heat fusing or by a suitable adhesive such as a cyanoacrylate-based adhesive, e.g. Loctite TM 405.

FIG. 4 illustrates a presently preferred construction for the nontraumatic distal tip 16 wherein the proximal tubular element 17 has a stepped construction which extends over a shoulder provided at the distal end of the shaft 11. Otherwise, the distal tip is the same as described above for the embodiment shown in FIG. 3.

In one presently preferred embodiment of the invention, the inner lubricous lining 20 has a wall thickness of about 0.002 inch (0.051 mm), the braided tubular member 21 and the thermoset polymer matrix into which it is disposed has a wall thickness of about 0.003 inch (0.076 mm) and the outer jacket 22 has a wall thickness of about 0.005 inch (0.13 mm). The diameter of the inner lumen 14 extending within the inner lining 20 may range from about 0.06 to about 0.09 inch (1.5–2.3 mm). The overall length of the catheter 10 for coronary angioplasty may range from about 80 to about 125 cm.

The catheter shaft 11 is preferably manufactured by braiding a plurality of pairs of fibrous strands 23 and 24 onto the tubular inner liner 20 or, in the alternative, a mandrel (not shown) and then impregnating the fibrous braid with a thermoset polymeric material to form a tubular element 21. The distal section 13, which may be the most distal 5 to 20 cm of the shaft 11, may be impregnated with a thermoset polymer which cures to a softer material than that impregnating the proximal section 12 to provide a greater degree of flexibility to the distal section 13. In a presently preferred method of forming the product, a thermoplastic tubular member or sleeve which forms the outer jacket 22 is fit onto the impregnated, braided tubular element 21, and then a heat shrinkable tubular element (not shown) is fit over the thermoplastic tube forming the outer jacket 22 and the assembly is then heated to shrink the heat shrinkable tube and press the thermoplastic jacket 22 against the exterior of the braided tubular element 21 to secure the jacket thereto. Upon cooling, the heat shrinkable tube is slit along its length and then peeled off the jacket 22.

The relatively short tubular elements 17 and 18 and the tip are butt joined together by suitable means such as fusion bonding to the distal end of the shaft 11. Luer hub 15 may be secured to the proximal end of the shaft 11. The distal section 13 of the catheter shaft 11 may be shaped to the desired configuration for its intended end use when the thermoset impregnate is cured or it may be heated and shaped after the catheter 10 has been made, for example, by the physician before the catheter is inserted into the patient.

One presently preferred thermoset polymer for impregnating the proximal section of the braided tubular element 21 is a polyurethane, such as two component polyurethane RP 6414-3 (resin and hardener) sold by the Ciba-Geigy Corporation and the presently preferred thermoset polymer for impregnating the distal end portion of the braided tubular element is also a polyurethane, such as two component polyurethane RP 6413-1 (resin and hardener) also sold by the same company. The resin/hardener ratios (by weight) for these polyurethane polymers are typically about 100/60. These polymers will cure at about 200 degrees F. or at room temperature. Preferably, the polymers are partially cured at an elevated temperature (e.g. 200 degrees

F.) and then are allowed to completely cure at room temperature. Other polymer systems such as epoxy based systems may also be used.

The thermoplastic jacket or coating **22** is preferably formed of a thermoplastic polyurethane made with a polytetramethylene glycol ether such 2363 55DE Pellethane which is available from the Dow Chemical Company or a polyurethane such as Texin-965 DM which is available from the Mobay Corporation.

The cured properties for the above polymers (7 days @ 77° F.) are set forth in the following table.

PROPERTY TESTED	METHOD OF TESTING (ASTM)	6413	6414	PELLETANE 2363-55DE
DENSITY	D-792	1.06	1.08	1.15
HARDNESS	D-2224D	90-95A	55-65D	55D
TENSILE STRENGTH	D-638 (D-412)	2500 psi	2500 psi	6500 psi
ULTIMATE ELONGATION	D-638 (D-412)	400%	250%	450%
TEAR STRENGTH	D-624	350 psi	550 psi	600 psi
COMP SET	D-395	68%	89%	75%
TABER WEAR	D-1044 (C-501)	4.0 mg	8.6 mg	70(H-22)

The relatively short tubular elements **17** and **18** of the non-traumatic distal tip **16** of the catheter are preferably formed from aliphatic polyurethanes which are available from Thermedics Inc. of Woburn, Mass. under the trade name Tecoflex. A radiopaque grade of the Tecoflex resin, EG93A-HT60, is preferably used for the proximal section **17** and a softer nonradiopaque grade, EG80A, is preferably used for the distal section **18**. Other grades of polyurethane, other elastomer systems and rubber-like materials may be employed.

The dimensions of the proximal and distal tubular sections of the non-traumatic distal tip varies depending upon the dimensions of the catheter. Generally, the length of the tubular sections **17** and **18** is less than the outside diameter thereof. For most guiding catheters the length of the proximal radiopaque section **17** will be about 1 to about 10 mm, typically about 2 to about 2.5 mm, and the length of the distal section will be about 0.5 to about 4 mm, typically about 0.5 to about 1 mm. The outside diameters of both sections range from about 0.09 to about 0.15 inch (2.3–3.7 mm), typically about 0.1 inch (2.54 mm), and the inside diameters thereof range from about 0.07 to about 0.09 inch (1.78–2.3 mm), typically about 0.08 inch (2.0 mm). Greater or lesser dimensions may be used depending upon the particular end use of the catheter.

The multifilament polymeric fibrous strands employed to form the braided tubular element are preferably about 50 to about 200 denier and may be formed from a fibrous polymeric material such as aramid (e.g. Kevlar 49 sold by du Pont) and a polyester (e.g. Vectran). Other polymeric materials may be suitable. A 2×2 braid pattern shown in FIG. **5A** is preferred and may be formed using 16 carriers with one bobbin per carrier. To facilitate the bonding of the polymer matrix which is incorporated into the braided tubular element **21** to a liner **20** formed of fluorinated ethylene propylene, the outer surface of the lining is etched with sodium naphthalene. In lieu of impregnating the braided tubular element after its formation with a thermoset plastic, in some instances it may be convenient to intermix thermoplastic fibers, such as polyester fibers, as adhesive with the multifilament fibers so that the tubular element is braided with the thermoset fibers incorporated therein. Heating of the braided tubular element will cure the incorporated polyester.

While the invention has been primarily described herein in terms of a guiding catheter with two relatively soft tubular elements forming the nontraumatic distal tip, it will be apparent to those skilled in the art that the distal tip may be formed from three or more of these relatively soft tubular elements with the durometer hardnesses thereof increasing in each element from the most distal element to the most proximal element. Moreover, the invention can be employed in a variety of intravascular catheters other than guiding catheters, such as peripheral guides and angiographic guides, other modifications and improvements can be made to the invention without departing from the scope thereof.

What is claimed is:

1. An intravascular catheter comprising:

a) a tubular shaft having proximal and distal ends with an inner lumen extending therein and comprising:

a braided tubular member formed of a plurality of multifilament strands which are impregnated with a thermoset polymeric resin, the thermoset polymer resin which is incorporated into a distal portion of the braided tubular member having a cured hardness less than the cured hardness of the thermoset polymer resin which is incorporated into a proximal portion of the braided tubular member;

a lubricous polymeric lining extending longitudinally through the braided tubular member and defining the inner lumen extending within the elongated shaft of the guiding catheter; and

a thermoplastic polymeric jacket on the exterior of the braided tubular member;

b) a relatively short and straight nontraumatic distal tip having at least two relatively short, coaxially disposed flexible tubular elements, including a first tubular element which is secured to the distal end of the catheter shaft, and a second tubular element which is secured to the first tubular element and which is softer than the first tubular element.

2. The intravascular catheter of claim **1** wherein the flexible tubular elements are formed of elastomeric or other rubber-like materials.

3. The intravascular catheter of claim **1** wherein the second tubular element has a durometer hardness of at least about Shore 10 A less than the Shore hardness of the first tubular element.

4. The intravascular catheter of claim **1** wherein the second tubular element has a durometer hardness of about Shore 70 A to about Shore 90 A.

5. The intravascular catheter of claim **1** wherein the first tubular element has a durometer hardness of about Shore 80 A to about Shore 100 A.

6. The intravascular catheter of claim **1** wherein the thermoset polymeric resin which is incorporated into the braided tubular member is a polyurethane.

7. The intravascular catheter of claim **1** wherein the thermoplastic polymeric jacket is a polyurethane.

8. The intravascular catheter of claim **1** wherein multifilament strands are formed of one or more materials selected from the group consisting of aramid and polyester.

9. The intravascular catheter of claim 1 wherein the braided tubular member has a double strand, diamond-shaped construction.

10. A torquable guiding catheter having an elongated tubular shaft with an inner lumen extending therein and having a preformed distal portion with a soft, relatively short and straight distal tip which facilitates a non-traumatic advancement through a patient's vasculature, comprising:

a) an elongated tubular shaft having proximal and distal ends, an inner lumen extending therein and a preformed distal portion, the shaft comprising:

a braided tubular member formed of a plurality of multifilament strands which are impregnated with a thermoset polymeric resin, the braided tubular member having a distal end which has impregnated with a thermoset polymer resin having a cured hardness less than the cured hardness of the thermoset polymer impregnating the braided tubular member proximal thereto,

a thermoplastic polymeric jacket on the exterior of the braided tubular member, and

b) a nontraumatic tip secured to the distal end of the elongated shaft comprising a relatively short elastomeric proximal tubular element and, in a coaxial configuration therewith, a relatively short elastomeric distal tubular element, with the distal tubular element being softer than the proximal tubular element.

11. The guiding catheter of claim 10 wherein the braided tubular member is formed of radially compressed multifilament polymeric strands impregnated with thermoset polymeric resin.

12. The guiding catheter of claim 10 wherein the thermoset polymeric resin which is incorporated into the braided multifilament polymeric strands is a polyurethane.

13. The guiding catheter of claim 10 wherein the thermoplastic polymeric jacket is a polyurethane.

14. The guiding catheter of claim 10 wherein the multifilament strands are formed of a material selected from the group consisting of aramid and polyester.

15. The guiding catheter of claim 10 wherein the multifilament polymeric strands are braided into a double strand, diamond shaped construction.

16. The guiding catheter of claim 10 including a lubricous polymeric lining extending longitudinally through the braided tubular member and defining the inner lumen extending within the elongated shaft of the guiding catheter.

17. The intravascular catheter of claim 10 wherein the distal tubular element has a durometer hardness of at least about Shore 10 A lower than the durometer hardness of the proximal tubular element.

18. The intravascular catheter of claim 10 wherein the distal tubular element has a durometer hardness of about Shore 70 A to about Shore 90 A.

19. The intravascular catheter of claim 10 wherein the proximal tubular element has a durometer hardness of about Shore 80 A to about Shore 100 A.

* * * * *

EXHIBIT D

US005658263A

United States Patent [19]

Dang et al.

[11] Patent Number: 5,658,263

[45] Date of Patent: Aug. 19, 1997

[54] **MULTISEGMENTED GUIDING CATHETER FOR USE IN MEDICAL CATHETER SYSTEMS**

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[73] Assignee: **Cordis Corporation**, Miami Lakes, Fla.

[21] Appl. No.: **443,727**

[22] Filed: **May 18, 1995**

[51] **Int. Cl.**[6] **A61M 25/00**

[52] **U.S. Cl.** **604/280**; 604/282; 604/264

[58] **Field of Search** 604/280, 281, 604/282, 283, 264; 138/123, 127, 129, 133, 138, 174; 128/656–658

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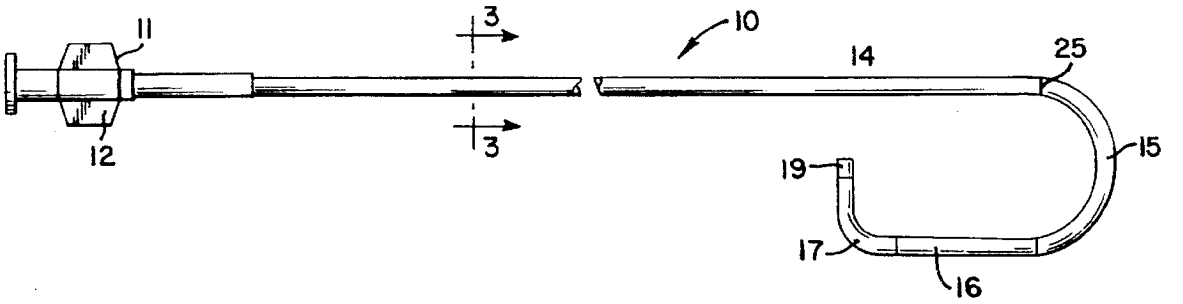
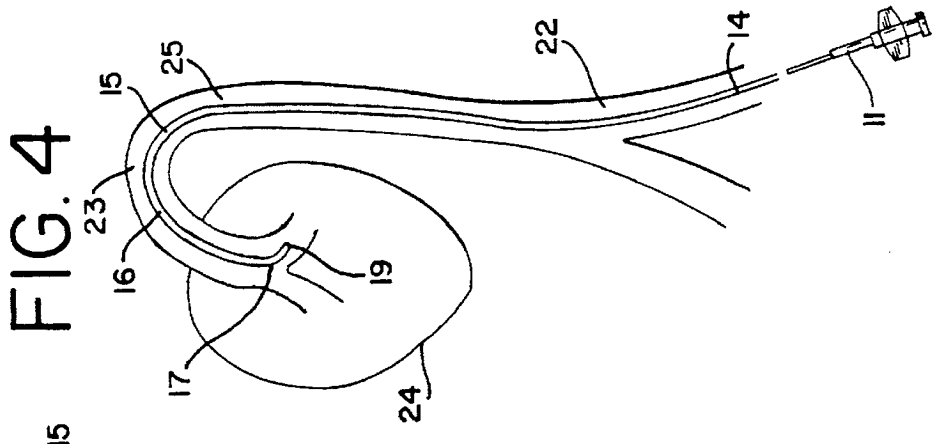
Primary Examiner—Corrine M. McDermott
Assistant Examiner—Ronald K. Stright, Jr.
Attorney, Agent, or Firm—Lockwood, Alex, Fitzgibbon & Cummings

[57] **ABSTRACT**

The present invention provides a significantly improved guiding catheter for use in catheter systems. It utilizes a segmented body to tailor the catheter strength and flexibility for optimal responsiveness at the distal end. The segmented body utilizes progressively softer materials in the distal direction in order to improve overall maneuverability. The longest and proximalmost segment is substantially straight and harder or stiffer than the rest of the catheter and than typical guiding catheter bodies. This segment performs the function of a handle having a platform at its distal end in order to improve response in the distal segments of the remainder of the catheter. This invention improves the transmission of torque, axial and lateral forces and reduces the likelihood of kinking both laterally and radially. Achieved is improved control of the distal portion through input from the hub at the proximal end of the elongated stiff handle segment. The distal portion provides a softer shaft for transmitting torque over the aortic arch to the tip of the catheter. Guiding is optimized by segment. The softer material portion of the catheter, when inserted, generally coincides with the aortic arch and allows for optimal torque and push force transmission over the arch. Backup support is enhanced, the amount of backup activity being limited more by the ability of the operator to transmit manual input to the tip of the guiding catheter, rather than to tip construction.

16 Claims, 2 Drawing Sheets

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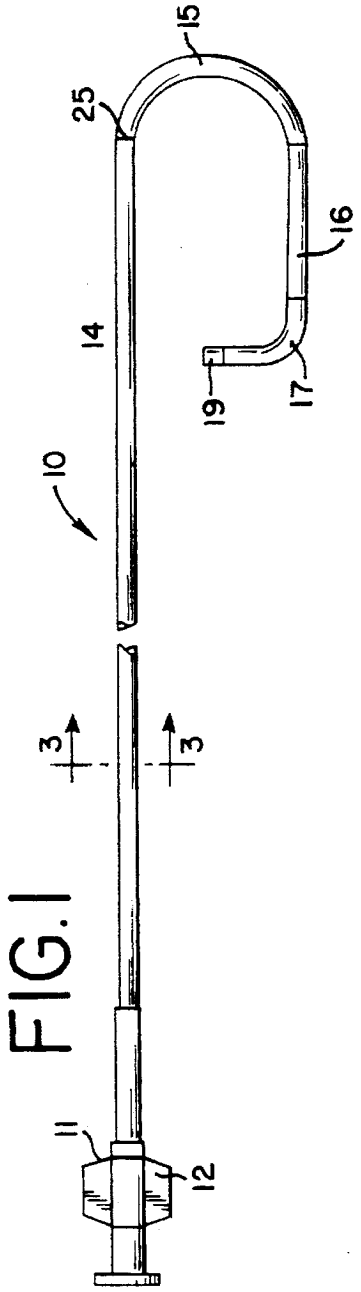
FIG. 1
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12

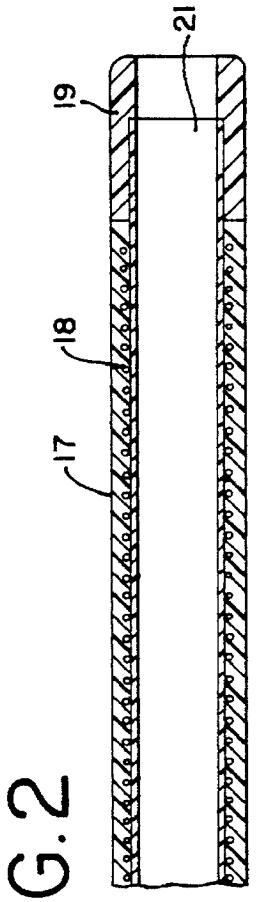
FIG. 2
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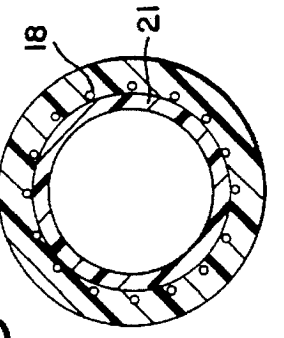
FIG. 3
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FIG.5

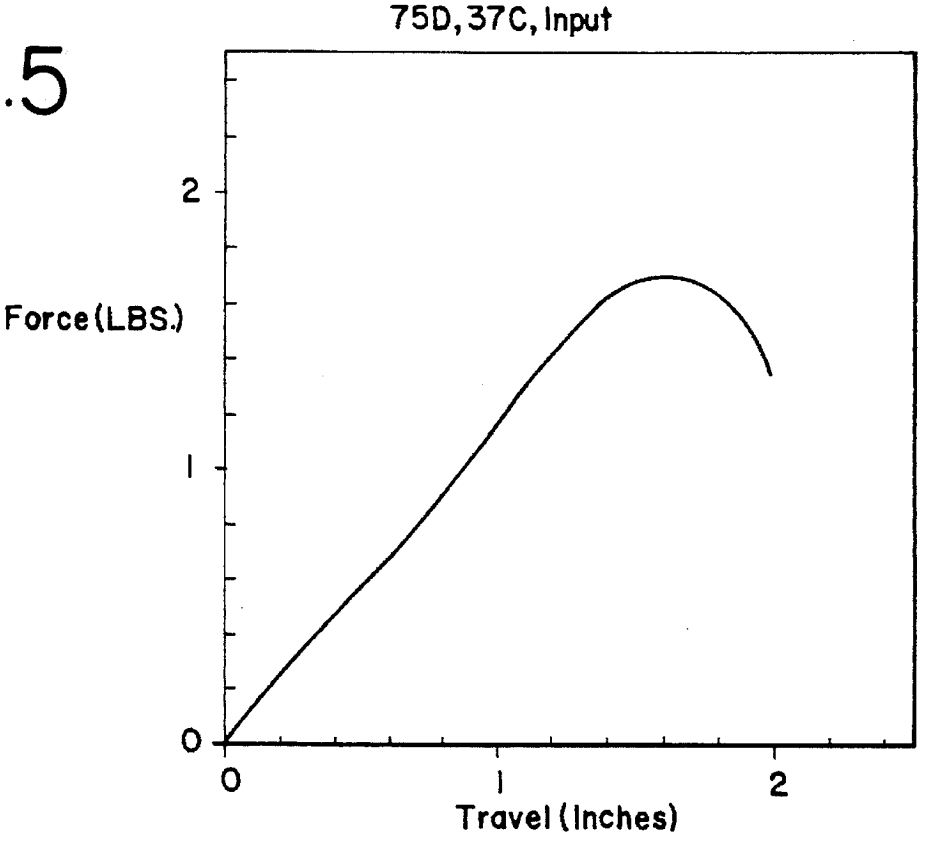
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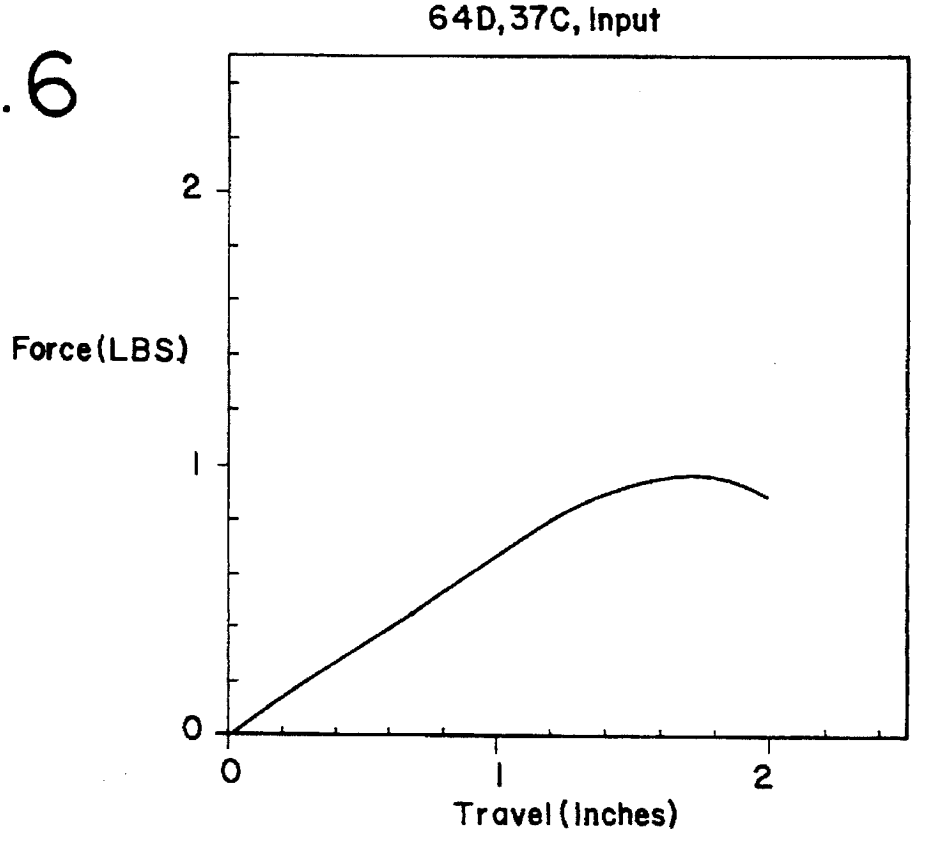
FIG.6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Travel (Inches)

MULTISEGMENTED GUIDING CATHETER FOR USE IN MEDICAL CATHETER SYSTEMS

BACKGROUND OF THE INVENTION

The present invention generally relates to procedures and devices for diagnostic and therapeutic medical procedures requiring use of intravenous catheters, such as those used in cardiac angioplasty. More specifically, the invention relates to guiding catheters such as those suitable for use as a part of catheter systems including those which are used for radiopaque dye injection, for the deployment of laser catheters or other therapeutic devices.

Guiding catheters are used for placing balloon and laser catheters and other medical devices into the desired body vessel, typically a blood vessel such as an artery. Such an artery may be located in or near the heart, brain, abdomen, or peripheral regions. Often, the catheter is inserted into an artery of the arm or leg and threaded to the desired location. The guiding catheter thus becomes the pathway for the other therapeutic or diagnostic medical device.

Since guiding catheters have maneuverability limitations, a guidewire is sometimes inserted first. In these instances, the guiding catheter is inserted over the guidewire. Usually, the guidewire then is withdrawn and the diagnostic or therapeutic catheter introduced through a lumen of the guiding catheter.

Characteristically, the end of the guiding catheter is often formed with a desired curvature to conform to the shape of the location to be treated such as in an artery or to improve maneuverability. The tip is often soft to substantially lessen the risk of trauma to the vessel walls during insertion and/or treatment.

In a typical guiding catheter, the main length, or body, of the guiding catheter is designed for a balance of strength and flexibility. Flexibility improves the ability of the body of the catheter to negotiate the tortuous paths of branching, curving, and narrowing arteries. Those practiced in the art also try to make the body strong by giving it a high torsion modulus and column strength. It has been determined that a strong body reduces the undesirable characteristics called kinking and "whipping" and increases the desirable characteristic called "backup" support.

Catheters sometimes demonstrate "whipping," which is caused by spring torsion. With high spring torsion, the physician experiences a lag in rotational response followed by rotational acceleration. It has been determined that a high torsion modulus reduces the spring torsion and hence the whip. High column strength has been found to improve the ability of the catheter body to withstand lateral forces, axial forces and improve "backup" support. Backup refers to the guiding catheter's ability to provide a reference or backboard for the therapeutic or diagnostic catheter. High column strength also improves the ability of the catheter body to withstanding kinking, and to reduce the angle of kinking when it does occur.

Designs which attempt to balance flexibility with strength generally provide a compromise in performance. Prior approaches designed to improve catheter performance include blending polymers to create desired harnesses (U.S. Pat. No. 4,898,591), multiple layers of polymers (U.S. Pat. No. 4,636,346 and U.S. Pat. No. 4,596,563), and molding polymers over metal braiding (U.S. Pat. No. 4,898,591). Thus, catheters may tend to be designed for maximum rigidity while allowing their minimum acceptable maneuverability. Some prior art has utilized a two segment design which permits better matching of catheter performance for artery location. U.S. Pat. No. 5,342,386 features a more flexible distal segment to improve distal maneuverability in a therapeutic balloon catheter. U.S. Pat. No. 5,171,232 utilizes a braided body and an unbraided transition proximal of the atraumatic tip, giving this therapeutic, diagnostic or guiding catheter greater flexibility in a distal segment.

The present invention is a guiding catheter comprised of several segments which are tailored to meet the maneuverability and firmness needs which vary along the length of a blood vessel. Thus, this invention is firmest at its elongated proximal end portion and most maneuverable at its distal end portion. It is the intent of the invention to have the firm elongated proximal end portion create a firm platform location for the more flexible portion of the catheter at a location which is distally remote and generally coincides with the beginning of a curved or arched area within the vessel. This will provide the greatest controllability at the distal end.

For example, when performing many angioplasty procedures, the guiding catheter is inserted at the leg in the femoral artery about 36 inches (about 90 cm) from the heart artery requiring dilation. Most patients have a substantially straight length of blood vessel, perhaps 29 inches (about 73 cm) in length. This straight length of blood vessel is ideal for a firm catheter body that provides a guiding catheter segment which resembles a "broom handle". In this example, the catheter would then need to maneuver through the aortic arch and perhaps even subsequently smaller vessels with sharper turns. It is not until the aortic arch that the catheter requires considerable flexibility, but the distance from the arch to the coronary arteries is only about 6 to 12 inches (about 15 cm to 30 cm). It is the intent of this invention to design the first or proximalmost segment to be substantially rigid and thus improve the maneuverability of the more flexible distal segments secured thereto.

The firmer catheter segment which extends to an optimum location acts as a relatively long handle that provides more efficient transmission of torque, axial and lateral loads from the hub location to the distal tip location. Thus, with the present invention, the physician experiences improved response when turning the catheter at the tube, when pushing it into the blood vessel and when bending it, all actuated from the hub at the proximal end, as well as when proceeding with diagnostic or treatment catheter backup maneuvers to facilitate passage through a lesion or stenosis.

It is a general object of this invention to provide a catheter more maneuverable and more responsive to the physician's manipulation at the proximal end than are prior guiding catheters.

Another object of this invention is to provide an improved guiding catheter having an in-body platform location therealong in order to provide greater control of more flexible catheter segments distal of this platform location.

Another object of the present invention is to provide an improved guiding catheter having more efficient transmission of torque from the proximal end to the distal end.

Another object of this invention is to provide more efficient transmission of axial loads from the proximal end to the distal end of a guiding catheter.

Another object of this invention is to provide more efficient transmission of lateral loads from the proximal end to the distal end of a guiding catheter.

Another object of the present invention is to provide a firmer guiding catheter surface on which a balloon catheter or the like can be supported when maneuvering it through tight turns or stenoses.

Another object of the present invention is to reduce the likelihood of kinking due to torque, axial or lateral loads applied to a guiding catheter.

Another object of this invention is to reduce the angle of kinking when it does occur during insertion of a guiding catheter.

SUMMARY OF THE INVENTION

The guiding catheter of this invention is generally comprised of a hub at the proximal end, at least three catheter segments which are progressively more flexible in the distal direction, and an atramatic tip at the distal end. It is intended to be inserted through the vascular system or the like and to a location at or near a stenosis or other treatment area. The profile of a guiding catheter according to this invention is substantially the same as other guiding catheters.

The present invention recognizes that improved maneuverability of guiding catheters can decrease the time required to perform an angioplasty or other stenosis treatment procedure, benefitting the physician and the patient. This improvement may be manifested in several ways. Improved maneuverability can decrease the time required to insert the guiding catheter to the desired location. Improved maneuverability may permit the physician to omit the use of a guidewire in some instances. The feature of the invention of a stiff column or "handle" improves the maneuverability of the guiding catheter to the point that a one-to-one type of responsiveness action is approached, if not fully achieved in at least some instances. Time and effort reductions can also be realized in improved maneuverability for the balloon catheter or the like by providing a properly positioned guiding catheter that provides a relatively rigid base for the treatment catheter, especially with respect to improved backup support. These manifestations of improvement all can reduce risk to the patient by potentially shortening the procedure time while also utilizing the physician's time more efficiently. In some instances, the invention may dramatically reduce risk to the patient by eliminating the need for procedures such as coronary bypass surgery because the catheter can negotiate to a stenosis which heretofore may have been unreachable and provide a pathway for the treatment to adequately dilate the artery.

This invention tailors flexibility by utilizing segments of different polymers which vary in hardness. For example, four segments are utilized in the illustrated embodiment, which is suitable for many coronary procedures. Such varying hardness can be conveniently quantified by the Shore hardness system which is used and is widely known by those in the art. The first segment, located at the proximal end, may be likened to a still or rigid handle. It is the hardest segment, preferably having a hardness of about Shore 75 D. The second segment in the distal direction preferably has a hardness of about Shore 64 D. The third segment has a preferable hardness of about Shore 55 D, and the fourth segment has a preferable hardness of about Shore 40 D. The tip is even softer, generally approximately that of a sponge, as will be appreciated to those skilled in the art.

The segments are joined together with a butt weld or other form of heat weld or through the use of an adhesive to form a smooth, continuous assembly. The segments of polymer preferably are molded about a braid of stainless steel or the like. Such braid is commonly used by those skilled in the art to enhance rigidity. It is preferred to line the inside of all segments of the catheter with a lubricious polymer sleeve for facilitating passage of the balloon catheter or other therapeutic device therethrough.

BRIEF DESCRIPTION OF THE DRAWINGS

In the course of this description, reference will be made to the attached drawing, wherein:

FIG. **1** is an elevational view, partially broken away, showing a preferred guiding catheter according to the invention, incorporating a hub, four sections and an atramatic tip;

FIG. **2** shows the distal end of the guiding catheter of FIG. **1** in longitudinal cross-section, including the distalmost section and atramatic tip;

FIG. **3** is an axial cross-section of the guiding catheter of FIG. **1**;

FIG. **4** is a somewhat schematic view which demonstrates implementation of the FIG. **1** guiding catheter in a coronary angioplasty or angiography procedure;

FIG. **5** is a plot of force versus travel illustrating longitudinal rigidity of the proximalmost elongated column shaft according to the invention; and

FIG. **6** is a plot as in FIG. **5**, except it is for a proximalmost elongated guiding catheter tube having a stiffness less than that of the tube which is the subject of FIG. **5**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** shows a guiding catheter, generally designated as **10**. A hub **11** is positioned on the proximal end of the guiding catheter. The hub **11**, in accordance with generally known principles, facilitates connection of guiding catheter **10** to equipment for carrying out desired medical procedures. Also, the hub **11** cooperates with the rest of the guiding catheter in steering the catheter, enabling the physician to easily grasp the distal end of the catheter **10** when guiding it through the arterial branches and to the stenosis. Hub **11** can also serve as a chamfered guide for the balloon catheter. The hub may be of a design similar to those commonly used, allowing for connection to pressurized fluid sources and diagnostic measuring equipment, for example.

Preferably, the hub **11** includes wings **12** which aid maneuverability. A therapeutic or diagnostic catheter or other medical device (not shown) is intended to be inserted into the proximal hole of the hub **11**. Hub **11** is sealingly connected to the proximal end of the catheter body and is made of a substantially rigid material, a polycarbonate being an illustrative material.

Distal of the hub **11** is a segmented guiding catheter tube. Typically, it is comprised of at least three segments of progressively softer materials in the distal direction. The proximalmost section is a stiff elongated proximal column tube, while the remaining sections form a modulated-stiffness tube assembly. The embodiment of FIG. **1** shows four segments **14**, **15**, **16** and **17**, and it is a preferable embodiment of the invention and one which is suitable for performing coronary angioplasty.

The first segment **14** is the hardest. It is also the longest segment, being an elongated proximal column tube which extends from the hub to a location which is between about 15 cm and about 30 cm from the distal tip of the catheter. In a typical catheter, this segment **14** extends at least 70 cm, perhaps up to on the order of 90 cm. It preferably possesses a Shore hardness of between about 70 D and about 80 D. A Shore hardness of on the order of about 75 D is preferred. It is intended to be as stiff as possible through the path of the blood vessels when inserted at body temperature. It is stiffer than the body of a typical guiding catheter. Properties as discussed are provided by materials such as nylon or polya-

mide homopolymers. Especially preferred nylons include Nylon 12. The Nylon 12 can be a homopolymer. Usually this segment, as well as all of the other segments, will be molded about braiding **18**, typically of stainless steel.

First segment **14** functions as a stiff column or handle on "top" of which more flexible segments of the catheter rest. An important goal of the invention, through the use of this harder material in the first, elongated proximal column tube segment, is to increase the efficiency of torque transmission, longitudinal load transmission and lateral load transmission for the whole guiding catheter assembly. This segment will also exhibit reduced deleterious effects of kinking by increasing the force necessary to cause kinking and by reducing the kinking angle when it does occur. Enhanced backup support as discussed herein is also achieved.

Turning now to the modulated-stiffness tube assembly, the illustrated embodiment is a three-segment assembly. It is made up of a proximalmost tube section **15** of the modulated-stiffness tube assembly, followed distally by an intermediate tube section **16** and then a distalmost tube section **17**.

This proximalmost tube section or segment **15** is intended to be more flexible than the first segment. Segment **15** preferably has a Shore hardness ranging from about 58 D to about 70 D. A Shore hardness of about 64 D is preferred. This second segment **15** is affixed to the harder, column segment **14** by means of a butt weld or other type of heat weld, or by an adhesive or the like. These stiffness properties can be provided by materials such as nylon or polyamide homopolymers having a hardness less than that of the elongated proximal column tube **14**. Especially preferred nylons include Nylon 12. The nylon can be a Nylon 12 homopolymer. This polymer would have hardness properties different from those of tube **14**, although both could be of the same type of polymer or nylon.

Intermediate tube section **16**, when included, is more flexible than the second or proximalmost tube section **15**. It has a Shore hardness ranging between about 45 D and about 65 D, preferably about 55 D. Assembly to its adjoining segments is by means of a heat weld, an adhesive, or the like. Stiffness properties within this range are preferably provided by a polymer blend of a stiffer homopolymer and a softer copolymer. Especially useful are blends of polyamide homopolymer and polyamide-containing copolymer. The blend can be of a nylon homopolymer and a nylon copolymer. Preferred is a blend of Nylon 12 (such as one having a Shore hardness of 64 D) with a polyether block amide copolymer, for example a PEBAX (such as one having a Shore hardness of 40 D).

A fourth or distalmost tube section **17** of the modulated-stiffness tube assembly is typically provided. It is secured by heat welding or adhesive means to an adjacent section of the catheter. It is again more flexible than all of the segments positioned proximal thereto. This section **17** has a Shore hardness ranging between about 30 D and about 50 D, preferably about 40 D. This section, as well as any of the other sections of the modulated-stiffness assembly, can be preformed to the shape of the artery section within which insertion is intended so that, once that location is reached, the curve will manifest itself in manner generally shown in FIG. **4**. This segment **17** will exhibit these properties when made of a polyamide-containing copolymer such as a PEBAX type of polymer discussed herein. It can be a nylon copolymer.

In a preferred arrangement, the proximalmost tube section can be a nylon homopolymer, the distalmost tube section being a nylon copolymer, and the intermediate tube section being a blend of a nylon homopolymer and a nylon copolymer. Also, the modulated-stiffness tube can have a construction wherein the proximalmost segment **15** is a nylon homopolymer, the distalmost segment **17** is a nylon-containing copolymer, and the intermediate segment **16** is a blend of a nylon homopolymer and a nylon-containing copolymer.

At the distal end of the segmented catheter **10** is an atraumatic tip **19** that possesses softness or even elastic properties as will be generally appreciated by those skilled in the art. A preferred material is a polyurethane such as Pellethane 80AE. Usually tip **19** includes radiopaque material for visibility during the procedure with the aid of X-ray fluoroscopy or other suitable imaging equipment.

With reference to FIG. **2**, the longitudinal cross-section shown therein is of the distal end length of the guiding catheter **10**. Shown intrinsically within the segment **17** is the braid **18**. It will be noted that the polymer material has been molded over the braid. Also shown in FIG. **2** and in FIG. **3** is a liner **21** which preferably runs substantially the entire length of the guiding catheter. It is preferably constructed of a lubricious type material such as a polytetrafluoroethylene material or a Teflon polymer. Such provides a lubricious surface to facilitate insertion of the therapeutic catheter or other treatment device therethrough.

FIG. **4** illustrates use of the invention during a cardiac angioplasty or angiography procedure. The first segment **14** is routed from the femoral artery, up through the descending aorta **22**, through the aortic arch **23** and into the heart **24**. More specifically, the column-like first segment or handle extends from the insertion point at the femoral artery through the aorta to the aortic branch. This is a substantially straight segment of blood vessel which accommodates the stiff elongated proximal column tube. The second segment **15** is routed through the aortic arch, the interface **25** between the second segment **15** and the first or stiffest and longest segment or handle **14** being positioned at or near the beginning of the aortic arch. In an exemplary illustration, the interface **25** is located about 15 to about 30 cm proximal of the distal tip **19**. The distalmost tube segment **17** will extend about 3 cm to about 8 cm from the distal tip. In this way, the second segment **15** is routed through the aortic arch, the catheter accommodating this shape by its greater flexibility. When provided, the intermediate tube segment **16** is routed very near the heart, requiring greater flexibility, and the fourth segment **17** is routed into the smaller coronary arteries, requiring the greatest flexibility.

EXAMPLE 1

FIGS. **5** and **6** illustrate longitudinal load bending tests for elongated proximal column tubes made of two different types of polymers. Catheter tubings of a size suitable for use in making the elongated proximal column tube **14** were tested at typical body temperature, 37° C. A constant force was exerted on the proximal end of each tube, and the reaction force which was measured with a gauge sensor is reported and is plotted against the travel of the catheter tube. A comparison of FIG. **5**, which reports these data for catheter tubing made of 75 D Nylon 12, with FIG. **6**, which reports these data for 64 D Nylon 12, shows that the 75 D material holds its shape under these elevated temperature conditions more so than does the 64 D material. This illustrates the improved longitudinal stiffness or column strength of the 75 D catheter length when compared with the 64 D catheter length. This also illustrates the improved

responsiveness and handling quickness of the 75 D material from the point of view of longitudinal or axial stresses.

EXAMPLE 2

Lateral stiffness testing was carried out. Two types of catheter tubings as generally discussed in connection with Example 1 were clamped at one end. Force was applied at the other end in generally cantilevered fashion. The force was increased until kinking occurred. The maximum force required to kinking was noted. In the case of the 75 D tubing, the maximum force indicating lateral stiffness was 242 gm-cm^2, while the maximum force for the 64 D tube was 183 gm-cm^2. In addition, the kink angle measured for the 75 D tube was 32°, while that for the 64 D tube was 45°. The conclusion is reached that the 75 D elongated proximal column tube or handle **14** of the invention is improved over a more conventional guiding catheter tube material such as that having a hardness of 64 D in that more force is required to bend the column tube **14** and same does not bend as much or kink as much when subjected to lateral forces.

EXAMPLE 3

Tubes as tested in Examples 1 and 2 were subjected to torque testing. One end of the tube was clamped, while the other end was attached to a motorized device for exerting radial or twisting forces onto the tube. The torque required to kink the tube was measured. In the case of the 75 D tube, the 75 D tube withstood a torque of 59.368N-mm, the movement being through a radial angle of 8.13N-mm per radian. For the 64 D tube, the torque required for initial twisting was 42.294 N-mm, the amount of twisting being 8.268N-mm per radian. This illustrates the improved torque resistance of the elongated proximal column tube **14** of the present invention when compared with more conventional 64 D guiding catheter tubes. This, as well as the other tests reported herein, illustrate the improved one-to-one responsiveness, both in terms of movement and time.

It will be understood that the embodiments of the present invention which have been described are illustrative of some of the applications of the principles of the present invention. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

We claim:

1. A guiding catheter having enhanced control characteristics and a distal portion adapted to be shaped into a curved configuration for use within a body vessel, the guiding catheter comprising:

an elongated catheter tube assembly, said tube assembly having a proximal end portion, a distal end portion having a tip member, and a lumen extending between said proximal and said distal end portions;

a hub connected to said proximal end portion of the tube assembly;

said elongated catheter tube assembly including an elongated proximal column tube extending from said proximal end portion to a proximalmost interface location along said elongated catheter tube assembly, said elongated proximal column tube having a stiffness ranging between Shore 70 D and about Shore 80 D;

said elongated catheter tube assembly including a modulated-stiffness tube assembly extending from said proximalmost interface location to said tip member, said modulated-stiffness tube assembly having a plurality of tube sections each of which has different stiffness properties such that these tube sections are of decreasing stiffness in the distal direction;

said elongated proximal column tube has a length substantially greater than and has a stiffness significantly greater than the total length and the maximum stiffness, respectively, of said modulated-stiffness tube assembly and of each individual section of the modulated-stiffness tube assembly;

said modulated-stiffness tube assembly has a proximalmost tube section, a distalmost tube section, and an intermediate tube section;

said proximalmost one of said tube sections of the modulated-stiffness tube assembly has a stiffness ranging between about 58 D and 70 D and always less than said stiffness of the elongated proximal column tube;

said proximalmost tube section is nylon homopolymer, said distalmost tube section is nylon copolymer, and said intermediate tube section is a polymer which is a blend of nylon homopolymer and nylon copolymer; and

wherein said nylon homopolymer has a stiffness of between about Shore 58 D and about Shore 70 D, and wherein said nylon copolymer has a stiffness of between about Shore 30 D and about Shore 50 D.

2. The guiding catheter according to claim **1**, wherein said elongated proximal column tube has a nylon tube extending its length.

3. The guiding catheter according to claim **2**, wherein said nylon is Nylon 12.

4. The guiding catheter according to claim **2**, wherein said nylon is Nylon 12 homopolymer.

5. The guiding catheter according to claim **1**, wherein said proximalmost interface location is an assembly location between said elongated proximal column tube and said modulated-stiffness tube assembly.

6. The guiding catheter according to claim **5**, wherein said assembly location welds together respective end surfaces of said elongated proximal column tube and a proximalmost tube section of said modulated-stiffness tube assembly.

7. The guiding catheter according to claim **1**, wherein said plurality of tube sections of the modulated-stiffness tube assembly are joined together at one or more assembly locations.

8. The guiding catheter according to claim **7**, wherein said assembly locations weld together respective end surfaces of said tube sections of the modulated-stiffness tube assembly.

9. The guiding catheter according to claim **1**, wherein said stiffness of the elongated proximal column tube is about Shore 75 D.

10. The guiding catheter according to claim **9**, wherein said proximalmost one of said tube sections of the modulated-stiffness tube assembly has a stiffness of about Shore 64 D.

11. The guiding catheter according to claim **1**, wherein said nylon homopolymer is Nylon 12.

12. The guiding catheter according to claim **1**, wherein said stiffness of the nylon homopolymer is about Shore 64 D, and said stiffness of the nylon copolymer is about Shore 40 D.

13. The guiding catheter according to claim **1**, further including a lubricious liner defining said lumen of said elongated catheter tube assembly along at least a major length thereof.

14. The guiding catheter according to claim **1**, further including a braid within said elongated catheter tube assembly along at least a major length thereof.

15. The catheter according to claim 1, wherein said intermediate segment has a stiffness of between about 45 D and about 65 D, and said distalmost segment has a stiffness of between about 30 D and about Shore 50 D, and wherein said proximalmost segment stiffness is greater than that of said intermediate segment and said intermediate segment stiffness is greater than that of said distalmost segment.

16. A guiding catheter having enhanced control characteristics and a distal portion adapted to be shaped into a curved configuration for use within a body vessel, the guiding catheter comprising:

an elongated catheter tube assembly, said tube assembly having a proximal end portion, a distal end portion having a tip member, and a lumen extending between said proximal and said distal end portions;

a hub connected to said proximal end portion of the tube assembly;

said elongated catheter tube assembly including an elongated proximal column tube extending from said proximal end portion to a proximalmost interface location along said elongated catheter tube assembly, said elongated proximal column tube having a stiffness ranging between Shore 70 D and about Shore 80 D;

said elongated catheter tube assembly including a modulated-stiffness tube assembly extending from said proximalmost interface location to said tip member, said modulated-stiffness tube assembly having a plurality of tube sections each of which has different stiffness properties such that these tube sections are of decreasing stiffness in the distal direction;

said elongated proximal column tube has a length substantially greater than and has a stiffness significantly greater than the total length and the maximum stiffness, respectively of said modulated-stiffness tube assembly and of each individual section of the modulated-stiffness tube assembly;

a proximalmost one of said tube sections of the modulated-stiffness tube assembly has a stiffness of about Shore 64 D;

said proximalmost tube section is nylon homopolymer, a distalmost tube section of the modulated-stiffness tube assembly is nylon copolymer, and an intermediate tube section of the modulated-stiffness tube assembly is a polymer which is a blend of nylon homopolymer and nylon copolymer.

* * * * *

EXHIBIT E

US006591472B1

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

(10) **Patent No.: US 6,591,472 B1**
(45) **Date of Patent: Jul. 15, 2003**

(54) **MULTIPLE SEGMENT CATHETER AND METHOD OF FABRICATION**

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(*) 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.: **09/207,644**

(22) Filed: **Dec. 8, 1998**

(51) **Int. Cl.**[7] **B23P 17/00**

(52) **U.S. Cl.** **29/417**; 29/527.2; 264/171.13; 264/171.18; 604/523

(58) **Field of Search** 29/417, 527.2, 29/460; 264/103, 171.12, 171.13, 171.16, 171.17, 171.18, 171.27; 604/523, 524, 526, 527

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Primary Examiner—Gregory Vidovich
Assistant Examiner—Essama Omgba
(74) *Attorney, Agent, or Firm*—Sterne, Kessler, Goldstein & Fox P.L.LC.

(57) **ABSTRACT**

Methods of fabricating medical vascular catheters adapted to be inserted into a blood vessel from an incision through the skin of a patient for introducing other devices or fluids for diagnostic or therapeutic purposes and particularly methods for fabricating such catheters with catheter bodies having catheter sections of differing flexibility are disclosed. Such catheter bodies having a proximal catheter body end and a distal catheter body end and formed of a proximal section and at least one distal section that have differing flexibilities are formed in a process comprising the steps of: (1) forming a continuous tubular inner jacket preferably of an inner liner and a reinforcement layer; (2) forming initial layer segments having an initial layer thickness along the length of the inner jacket from a material of first durometer hardness, whereby each initial layer segment is separated by a separation distance: (3) forming a final layer of a material of second durometer hardness with a second layer thickness over the tubular inner jacket along the separation distances and over and/or against the proximal and distal initial layer ends of the initial layer segments to form a continuous catheter body tubing; (4) severing the continuous catheter body tubing into catheter body lengths including a proximal catheter section formed of the material of second hardness and a distal catheter section of the material of first hardness; and (5) completing the catheter fabrication at the proximal catheter body end and the distal catheter body end. Centerless grinding of the catheter body or body tubing, formation of Intermediate catheter body sections, distal soft tips, and discontinuities in the reinforcement layer formed prior to step (2) are also disclosed.

25 Claims, 16 Drawing Sheets

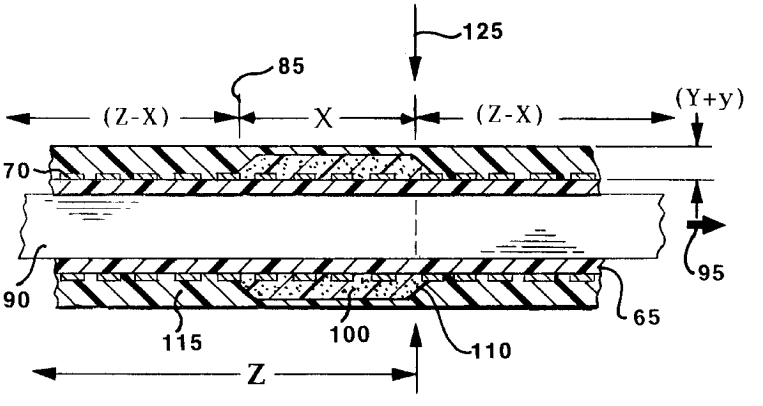

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FIG.1

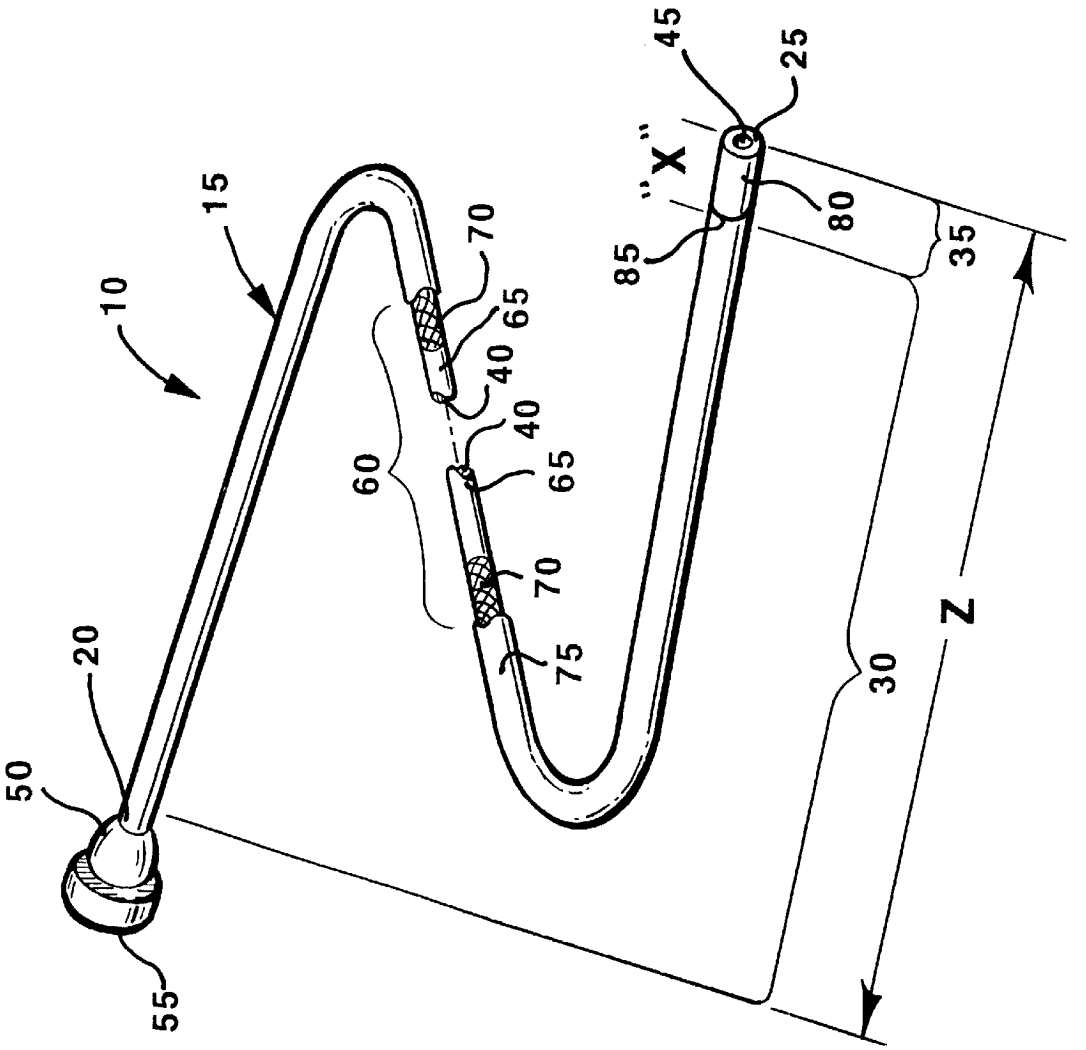


FIG.2

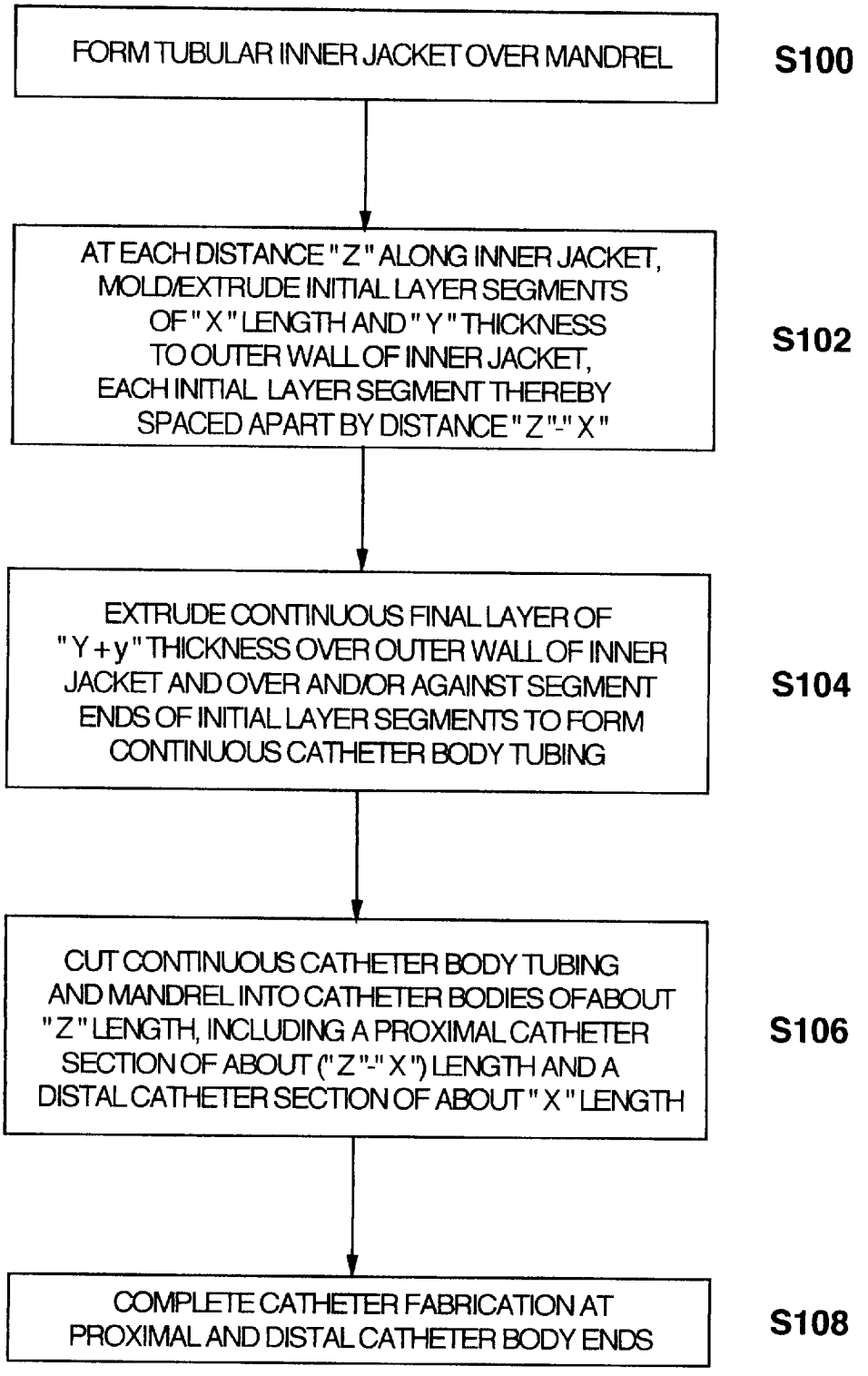

FORM TUBULAR INNER JACKET OVER MANDREL
S100
AT EACH DISTANCE "Z" ALONG INNER JACKET, MOLD/EXTRUDE INITIAL LAYER SEGMENTS OF "X" LENGTH AND "Y" THICKNESS TO OUTER WALL OF INNER JACKET, EACH INITIAL LAYER SEGMENT THEREBY SPACED APART BY DISTANCE "Z"-"X"
S102
EXTRUDE CONTINUOUS FINAL LAYER OF "Y+y" THICKNESS OVER OUTER WALL OF INNER JACKET AND OVER AND/OR AGAINST SEGMENT ENDS OF INITIAL LAYER SEGMENTS TO FORM CONTINUOUS CATHETER BODY TUBING
S104
CUT CONTINUOUS CATHETER BODY TUBING AND MANDREL INTO CATHETER BODIES OF ABOUT "Z" LENGTH, INCLUDING A PROXIMAL CATHETER SECTION OF ABOUT ("Z"-"X") LENGTH AND A DISTAL CATHETER SECTION OF ABOUT "X" LENGTH
S106
COMPLETE CATHETER FABRICATION AT PROXIMAL AND DISTAL CATHETER BODY ENDS
S108

FIG.3

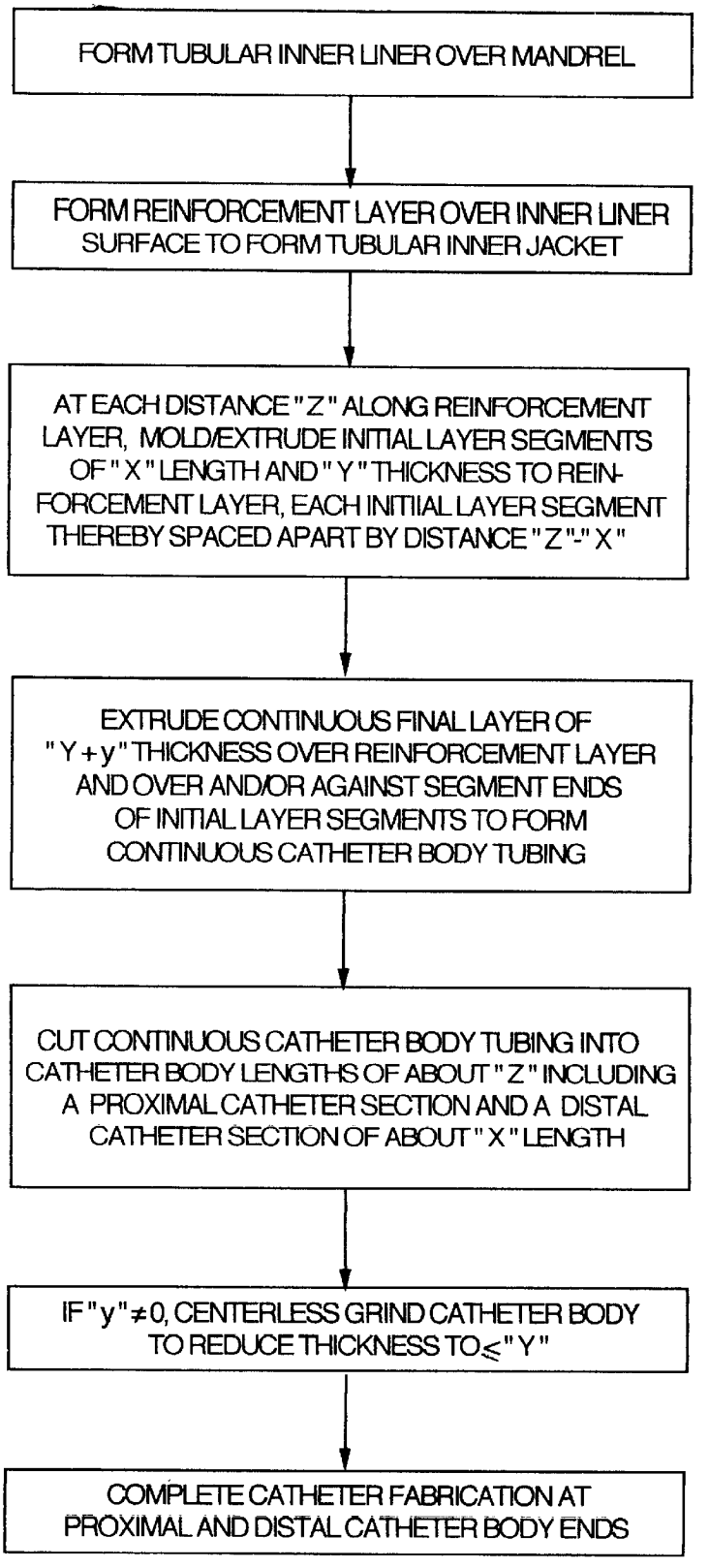

FORM TUBULAR INNER LINER OVER MANDREL
S200
FORM REINFORCEMENT LAYER OVER INNER LINER SURFACE TO FORM TUBULAR INNER JACKET
S202
AT EACH DISTANCE "Z" ALONG REINFORCEMENT LAYER, MOLD/EXTRUDE INITIAL LAYER SEGMENTS OF "X" LENGTH AND "Y" THICKNESS TO REINFORCEMENT LAYER, EACH INITIAL LAYER SEGMENT THEREBY SPACED APART BY DISTANCE "Z"-"X"
S204
EXTRUDE CONTINUOUS FINAL LAYER OF "Y+y" THICKNESS OVER REINFORCEMENT LAYER AND OVER AND/OR AGAINST SEGMENT ENDS OF INITIAL LAYER SEGMENTS TO FORM CONTINUOUS CATHETER BODY TUBING
S206
CUT CONTINUOUS CATHETER BODY TUBING INTO CATHETER BODY LENGTHS OF ABOUT "Z" INCLUDING A PROXIMAL CATHETER SECTION AND A DISTAL CATHETER SECTION OF ABOUT "X" LENGTH
S208
IF "y" ≠ 0, CENTERLESS GRIND CATHETER BODY TO REDUCE THICKNESS TO ≤ "Y"
S210
COMPLETE CATHETER FABRICATION AT PROXIMAL AND DISTAL CATHETER BODY ENDS
S212

FIG.4

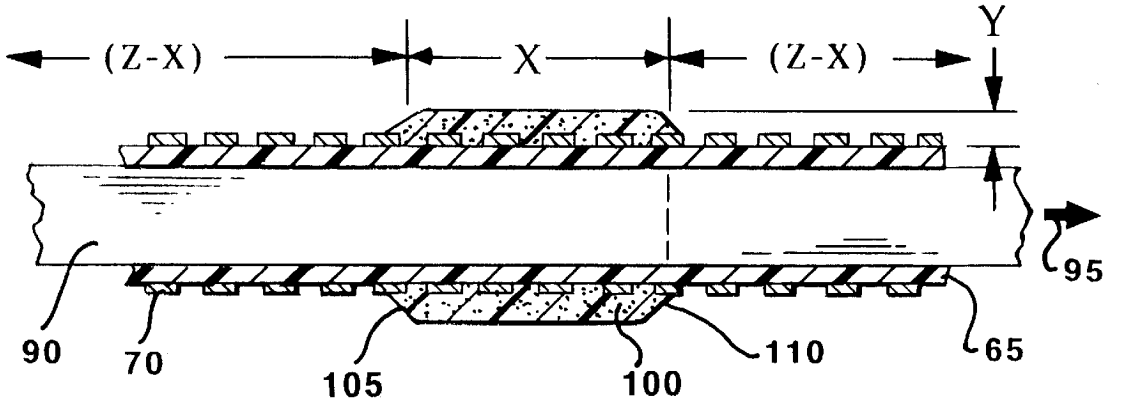

(Z-X)
X
(Z-X)
Y
95
90
70
105
100
110
65

FIG.5

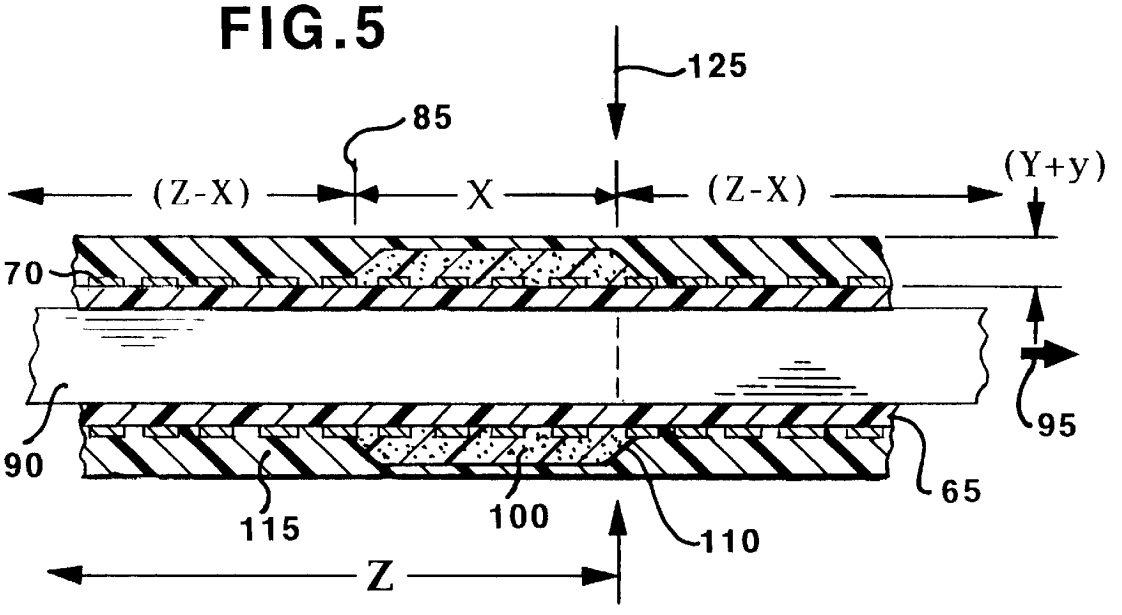

125
85
(Z-X)
X
(Z-X)
(Y+y)
70
95
90
115
100
110
65
Z

FIG.6

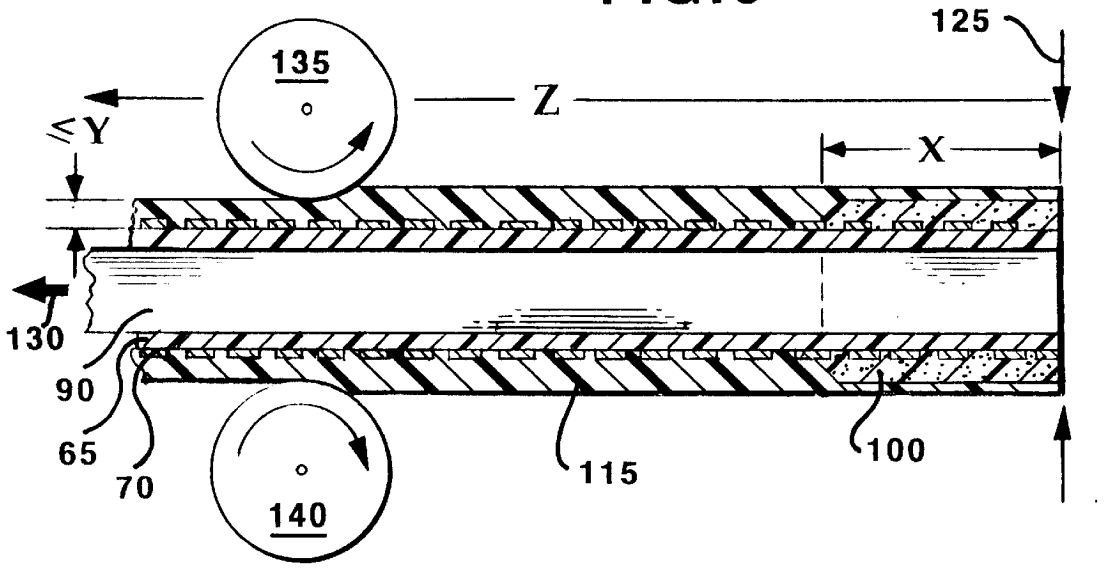


FIG.7

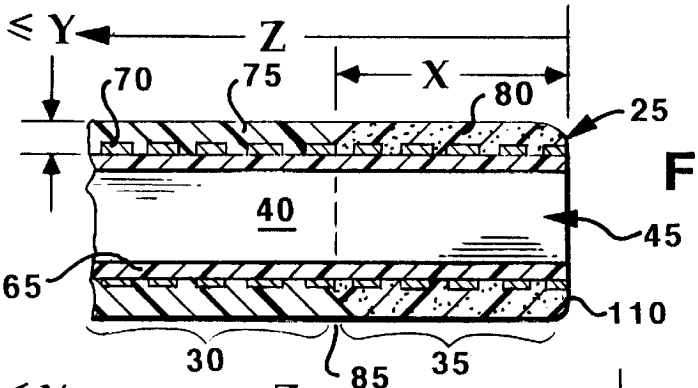


FIG.8

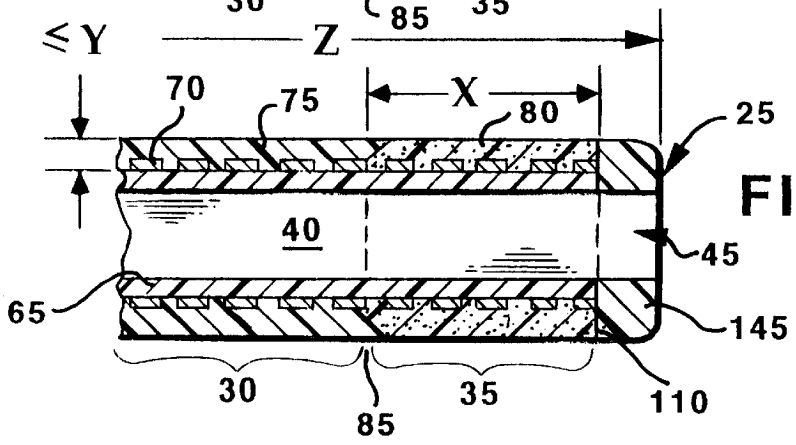
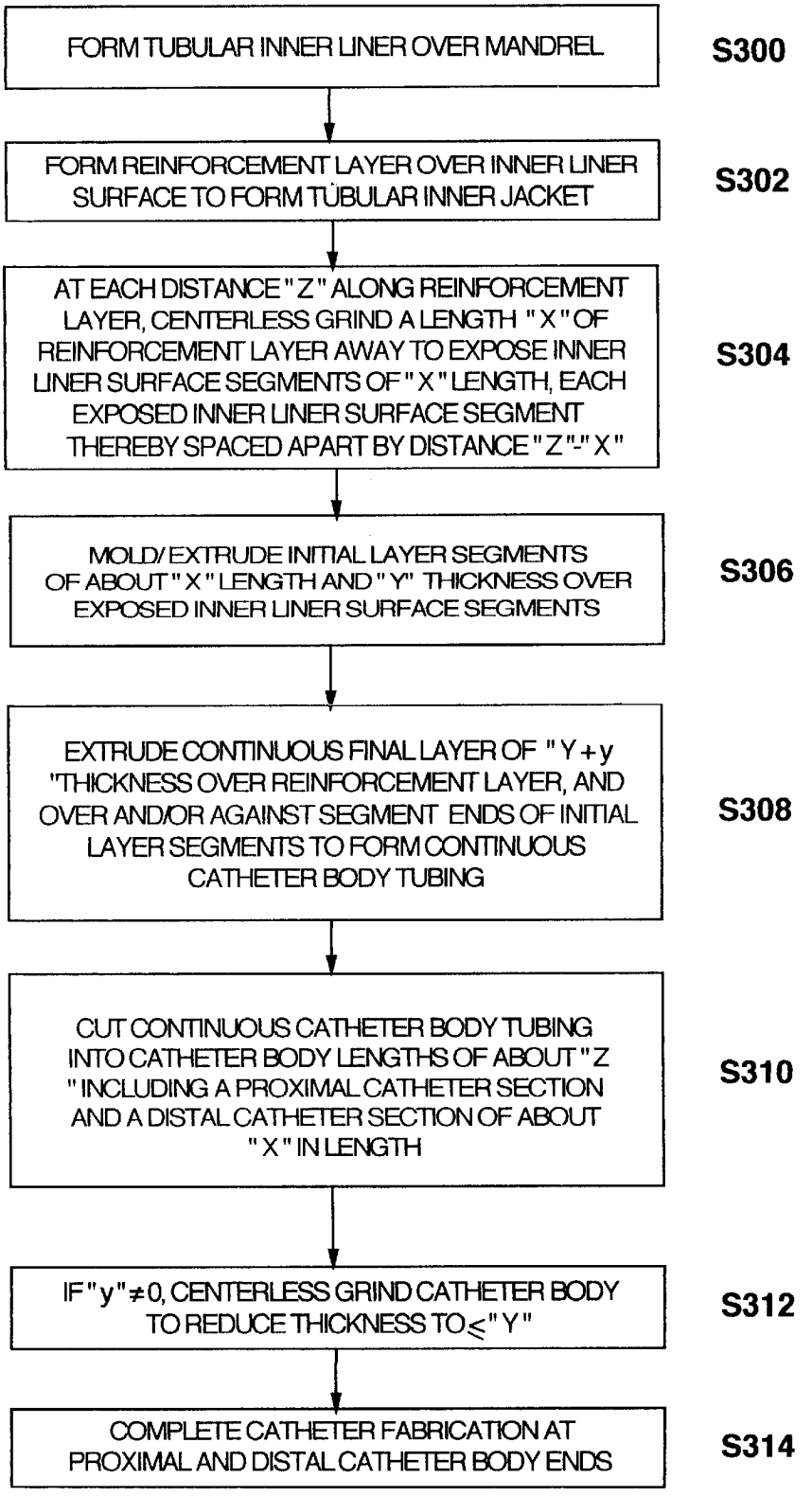


FIG.9


FORM TUBULAR INNER LINER OVER MANDREL
S300
FORM REINFORCEMENT LAYER OVER INNER LINER SURFACE TO FORM TUBULAR INNER JACKET
S302
AT EACH DISTANCE "Z" ALONG REINFORCEMENT LAYER, CENTERLESS GRIND A LENGTH "X" OF REINFORCEMENT LAYER AWAY TO EXPOSE INNER LINER SURFACE SEGMENTS OF "X" LENGTH, EACH EXPOSED INNER LINER SURFACE SEGMENT THEREBY SPACED APART BY DISTANCE "Z"-"X"
S304
MOLD/EXTRUDE INITIAL LAYER SEGMENTS OF ABOUT "X" LENGTH AND "Y" THICKNESS OVER EXPOSED INNER LINER SURFACE SEGMENTS
S306
EXTRUDE CONTINUOUS FINAL LAYER OF "Y+y "THICKNESS OVER REINFORCEMENT LAYER, AND OVER AND/OR AGAINST SEGMENT ENDS OF INITIAL LAYER SEGMENTS TO FORM CONTINUOUS CATHETER BODY TUBING
S308
CUT CONTINUOUS CATHETER BODY TUBING INTO CATHETER BODY LENGTHS OF ABOUT "Z "INCLUDING A PROXIMAL CATHETER SECTION AND A DISTAL CATHETER SECTION OF ABOUT "X" IN LENGTH
S310
IF "y" ≠ 0, CENTERLESS GRIND CATHETER BODY TO REDUCE THICKNESS TO ≤ "Y"
S312
COMPLETE CATHETER FABRICATION AT PROXIMAL AND DISTAL CATHETER BODY ENDS
S314

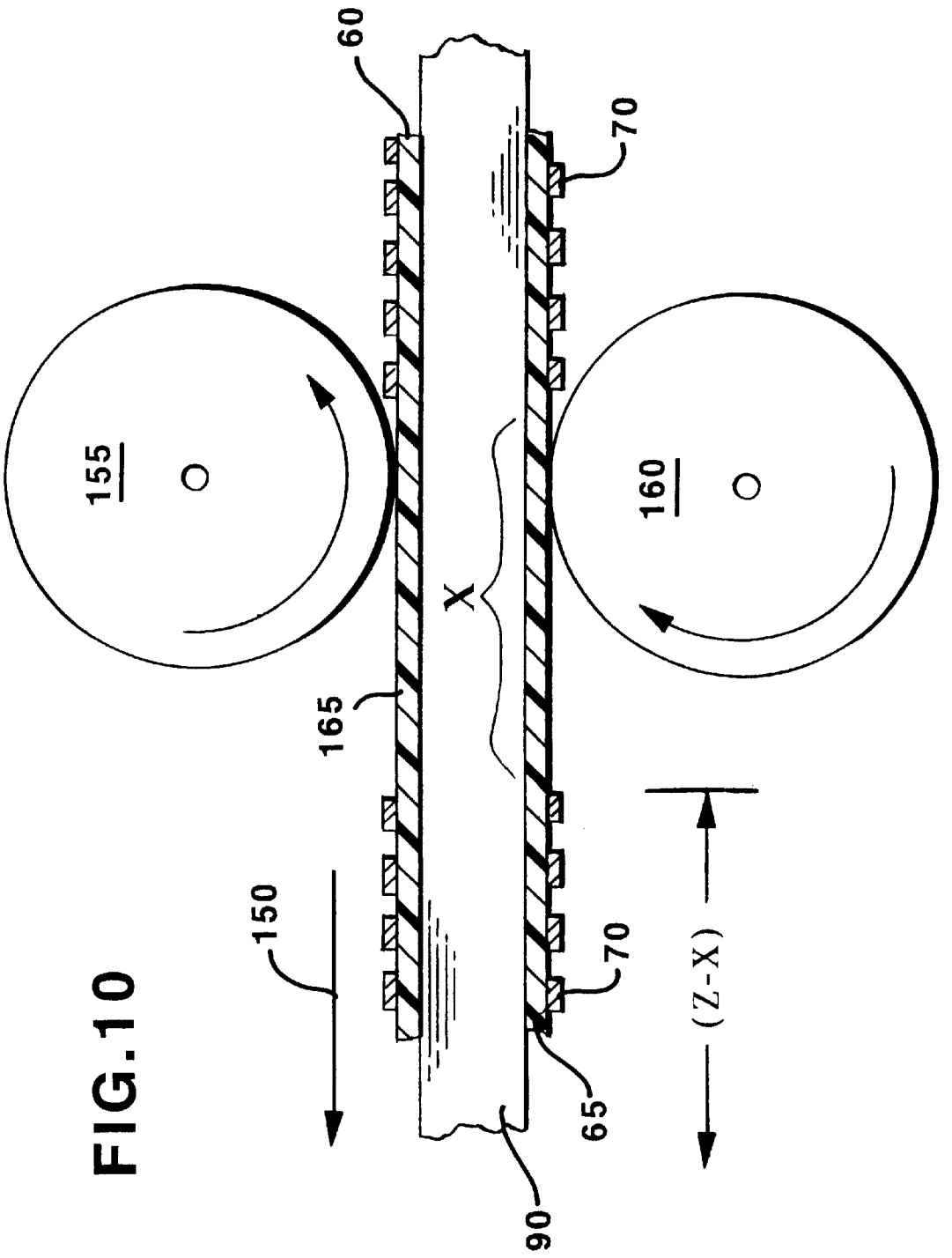


FIG.10

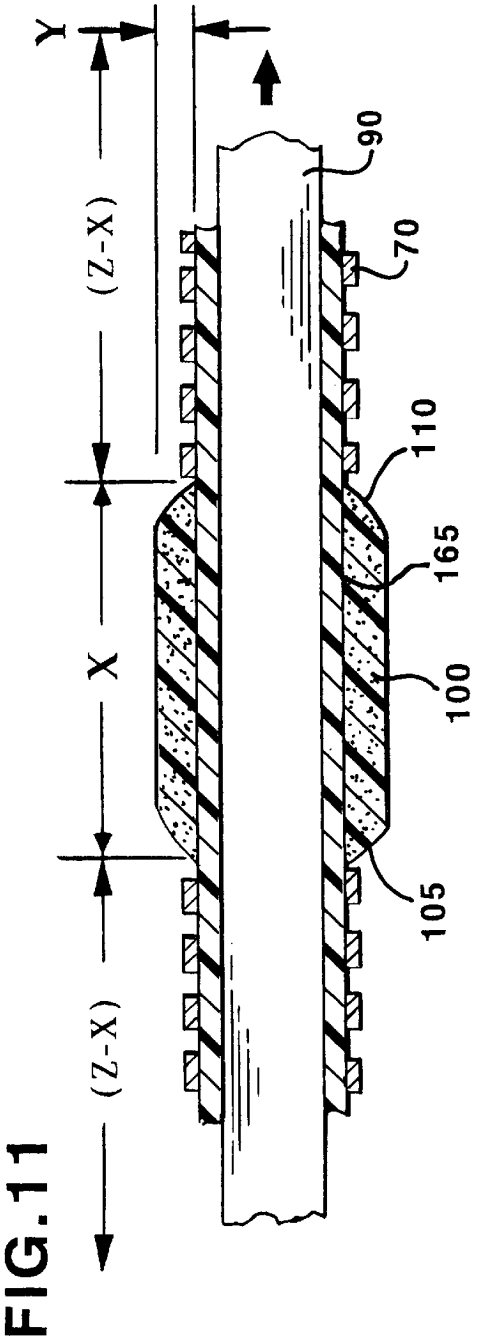

Y
(Z-X)
X
(Z-X)
90
70
110
165
100
105

FIG.11

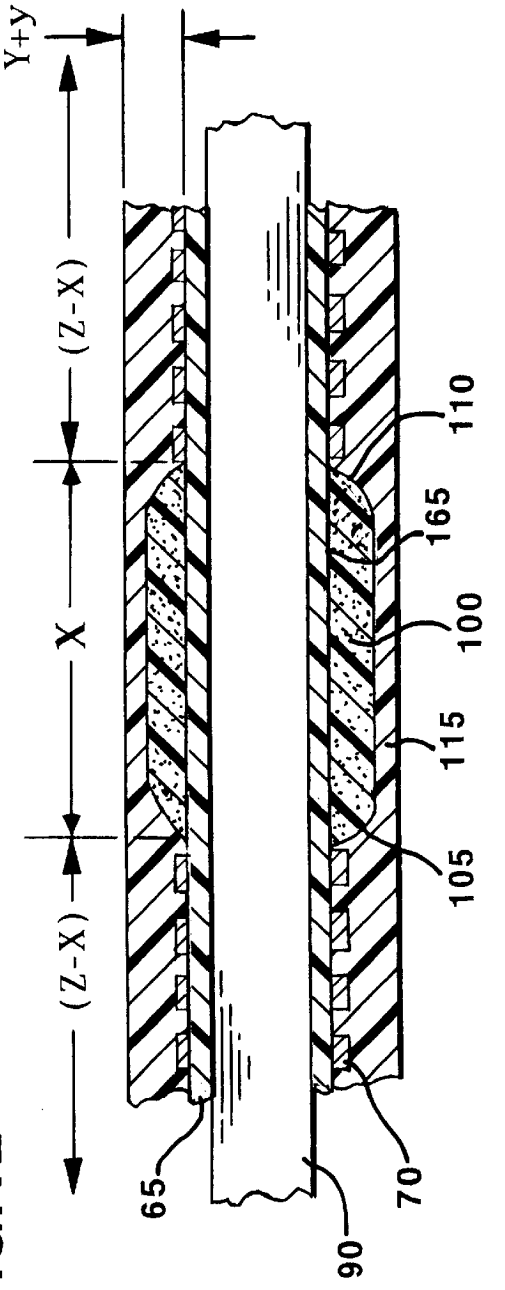
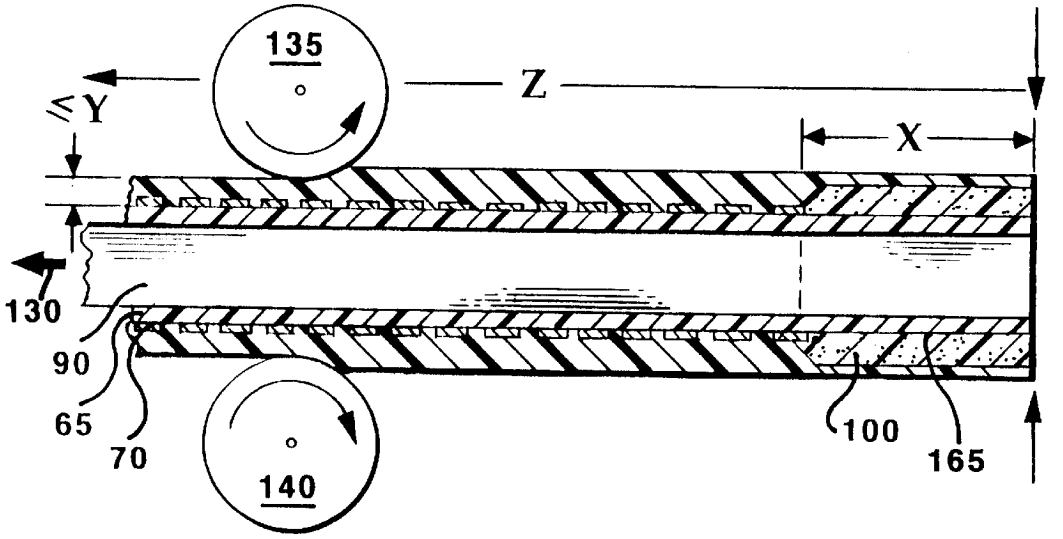

Y+y
(Z-X)
X
(Z-X)
110
165
100
115
105
65
90
70

FIG.12

FIG. 13


135
Z
Y
X
130
90
65
70
100
165
140

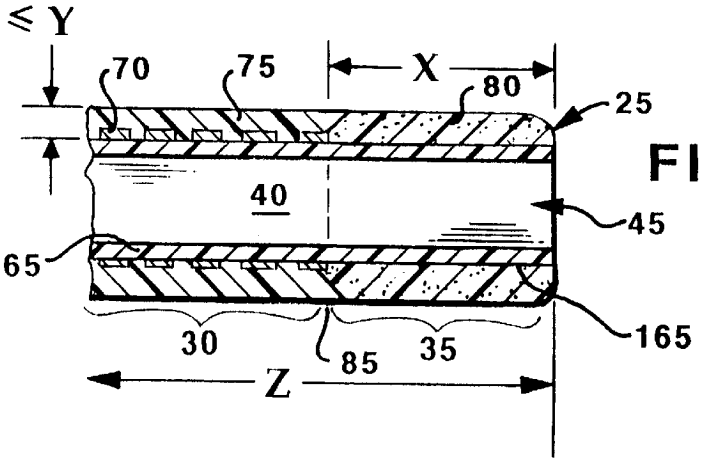

Y
70
75
X
80
25
40
45
65
165
30
85
35
Z

FIG. 14

FIG.15

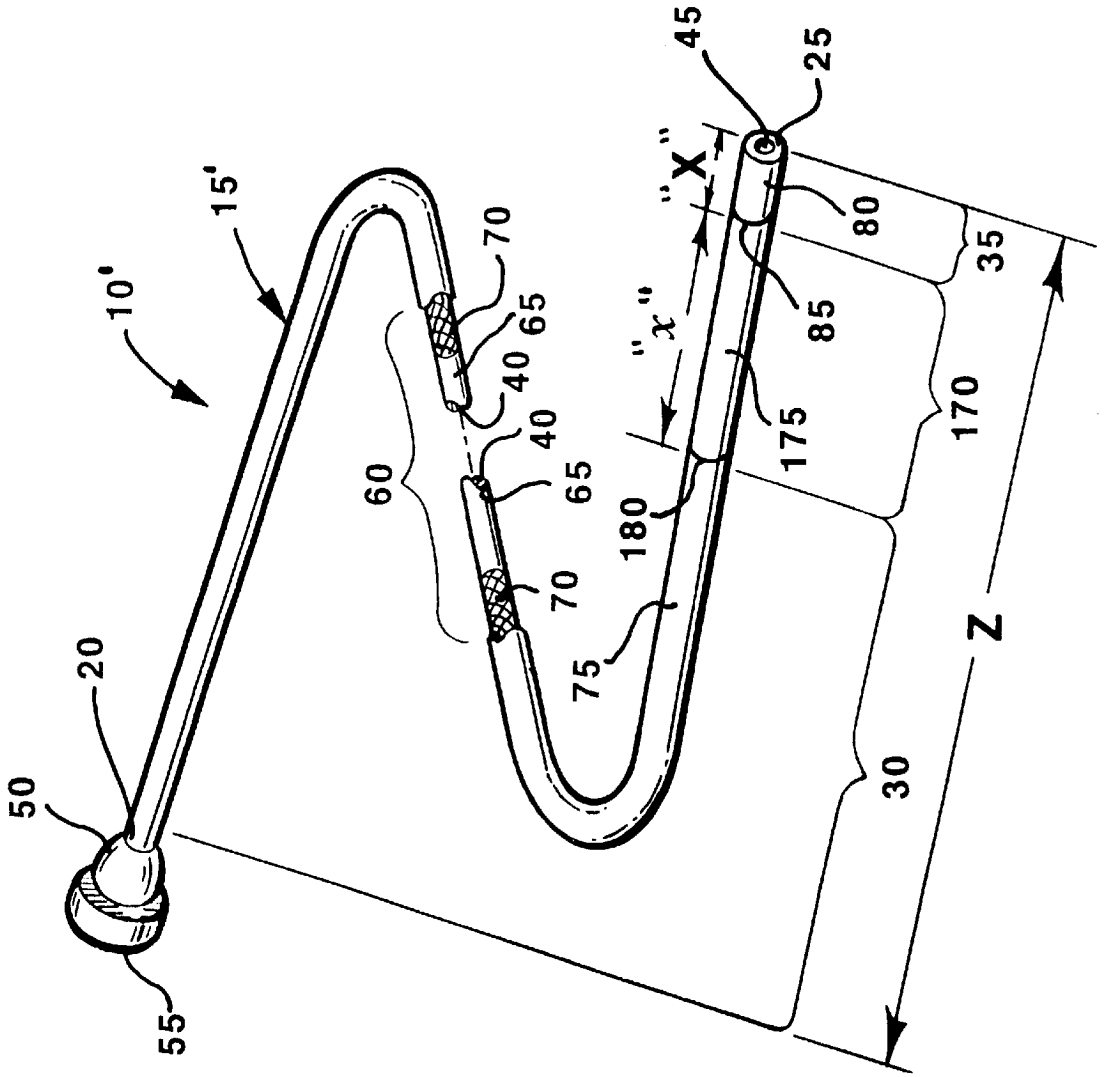
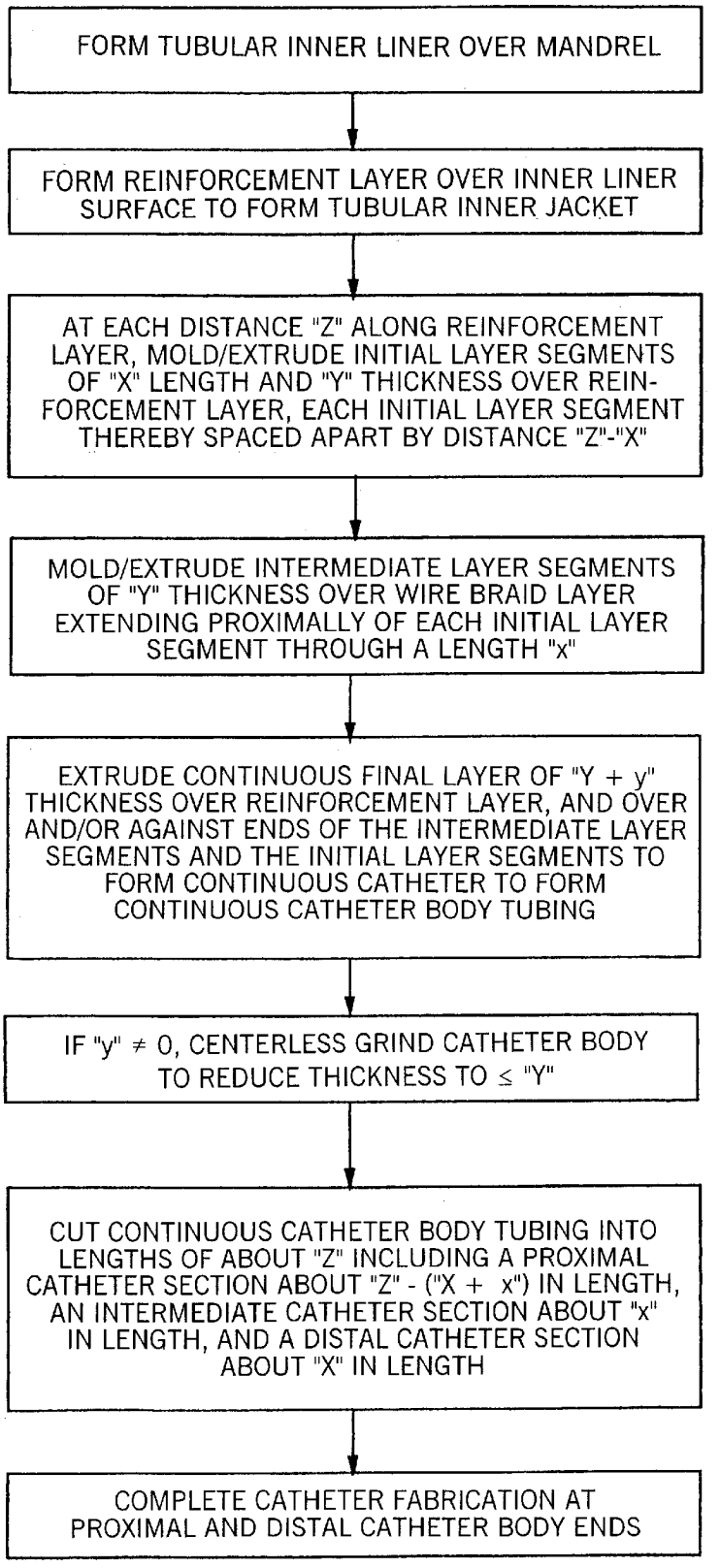

10'
15'
20
25
30
35
40
40
45
50
55
60
65
65
70
70
75
80
85
170
175
180
"X"
"x"
Z

FIG.16


FORM TUBULAR INNER LINER OVER MANDREL
S400
FORM REINFORCEMENT LAYER OVER INNER LINER SURFACE TO FORM TUBULAR INNER JACKET
S402
AT EACH DISTANCE "Z" ALONG REINFORCEMENT LAYER, MOLD/EXTRUDE INITIAL LAYER SEGMENTS OF "X" LENGTH AND "Y" THICKNESS OVER REINFORCEMENT LAYER, EACH INITIAL LAYER SEGMENT THEREBY SPACED APART BY DISTANCE "Z"-"X"
S404
MOLD/EXTRUDE INTERMEDIATE LAYER SEGMENTS OF "Y" THICKNESS OVER WIRE BRAID LAYER EXTENDING PROXIMALLY OF EACH INITIAL LAYER SEGMENT THROUGH A LENGTH "x"
S406
EXTRUDE CONTINUOUS FINAL LAYER OF "Y + y" THICKNESS OVER REINFORCEMENT LAYER, AND OVER AND/OR AGAINST ENDS OF THE INTERMEDIATE LAYER SEGMENTS AND THE INITIAL LAYER SEGMENTS TO FORM CONTINUOUS CATHETER TO FORM CONTINUOUS CATHETER BODY TUBING
S408
IF "y" ≠ 0, CENTERLESS GRIND CATHETER BODY TO REDUCE THICKNESS TO ≤ "Y"
S410
CUT CONTINUOUS CATHETER BODY TUBING INTO LENGTHS OF ABOUT "Z" INCLUDING A PROXIMAL CATHETER SECTION ABOUT "Z" - ("X + x") IN LENGTH, AN INTERMEDIATE CATHETER SECTION ABOUT "x" IN LENGTH, AND A DISTAL CATHETER SECTION ABOUT "X" IN LENGTH
S412
COMPLETE CATHETER FABRICATION AT PROXIMAL AND DISTAL CATHETER BODY ENDS
S414

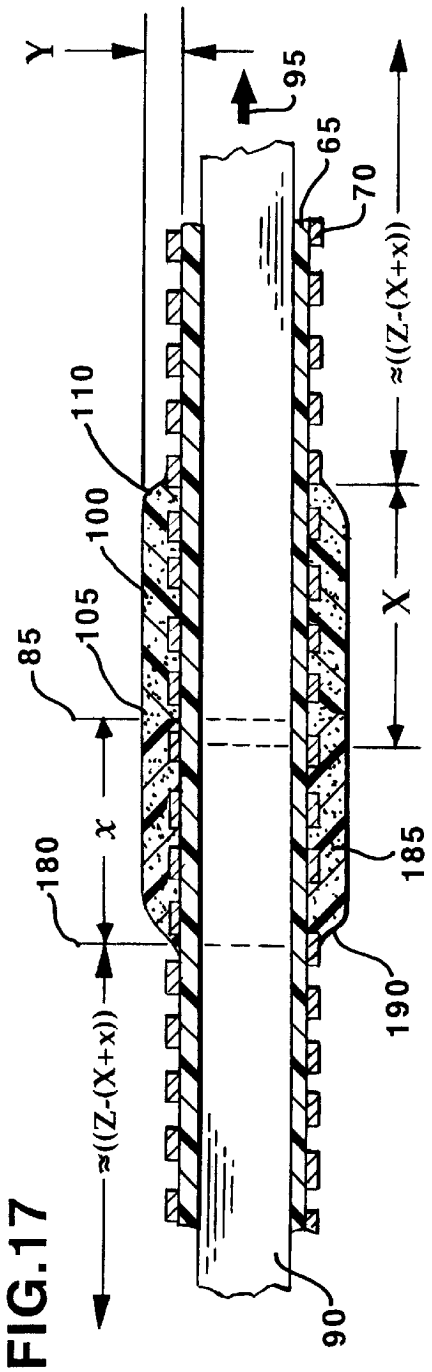

Y
95
65
70
≈((Z-(X+x))
X
110
100
105
85
x
180
185
190
90

FIG.17

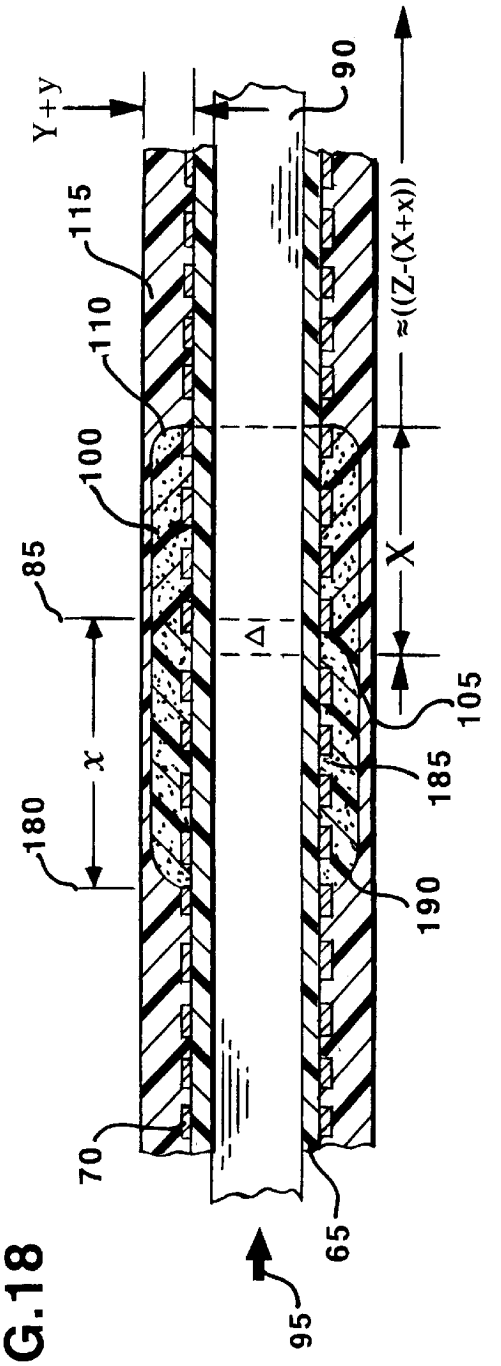
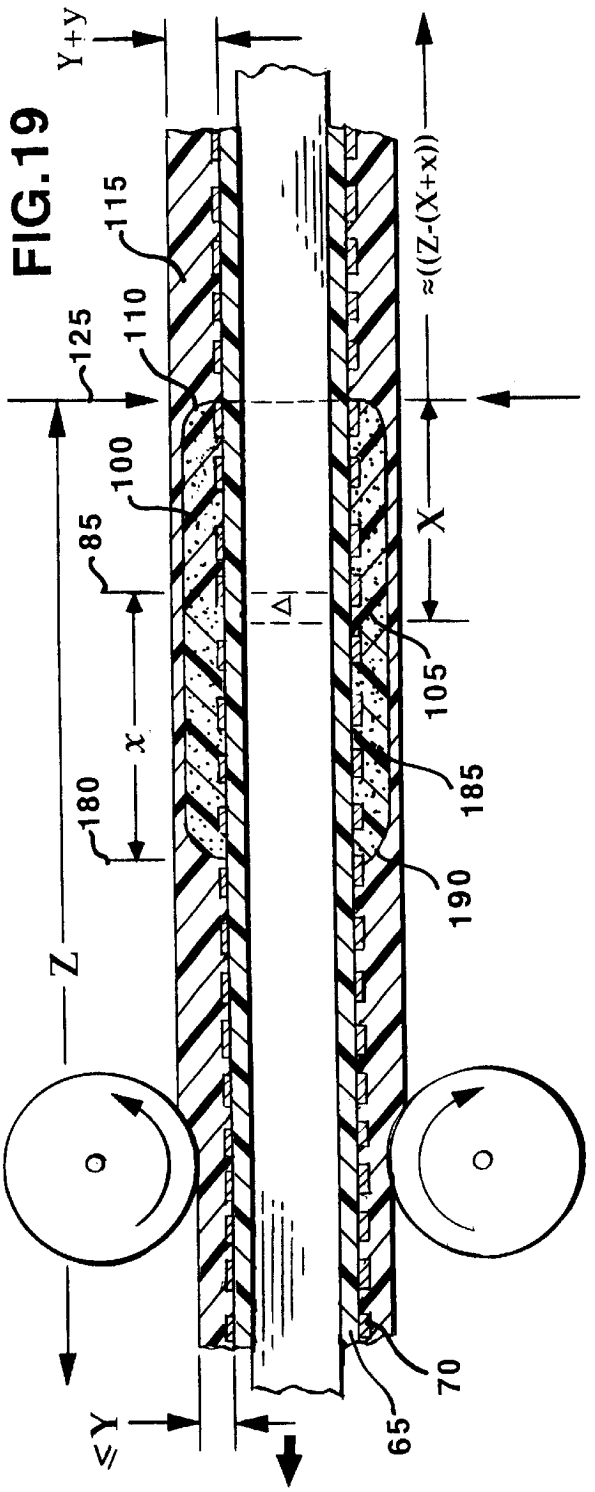

Y+y
90
115
110
100
85
x
180
Δ
X
≈((Z-(X+x))
105
185
190
70
65
95

FIG.18

FIG.19


Y+y
115
125
110
100
85
180
Z
x
Δ
X
≈((Z-(X+x))
105
185
190
70
65
≤Y

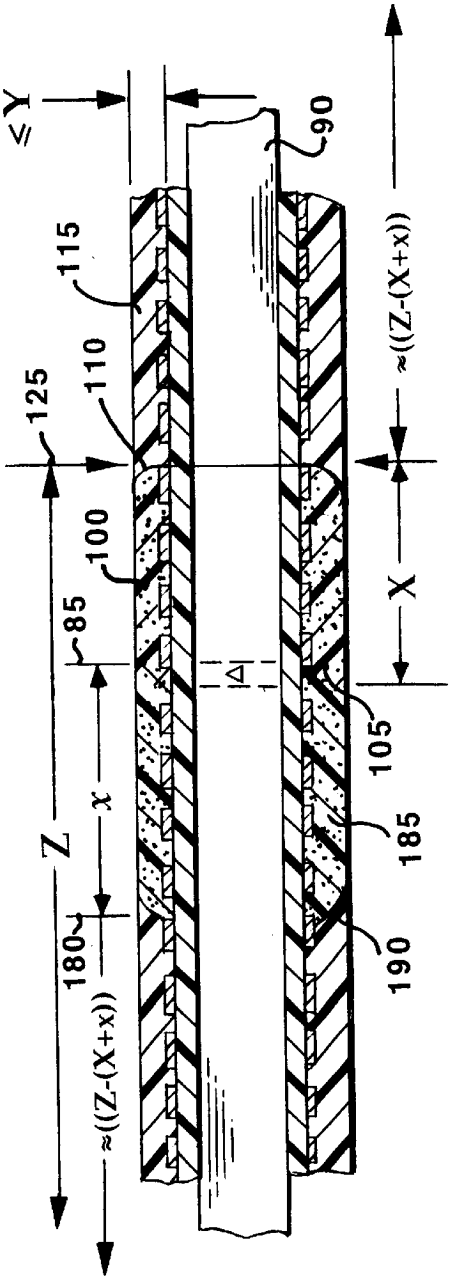
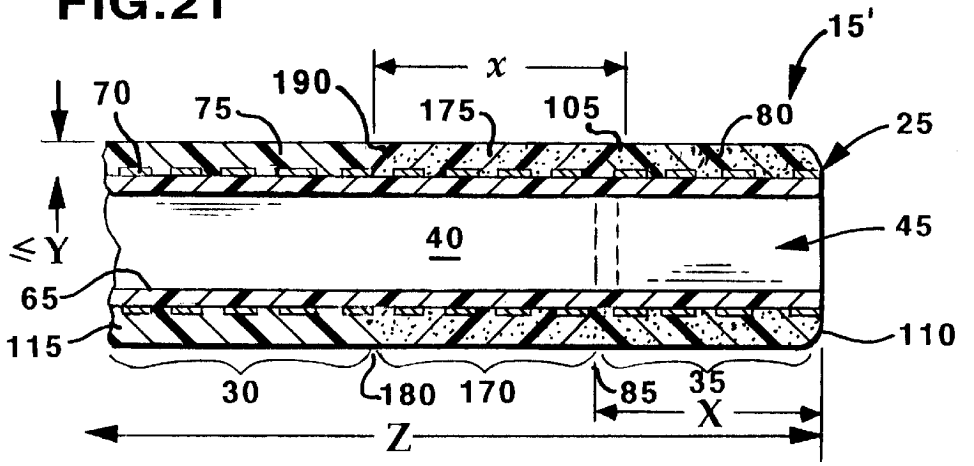

≤Y
90
115
125
110
100
85
Z
x
Δ
X
≈((Z-(X+x))
105
185
180
190
≈((Z-(X+x))

FIG.20

FIG.21



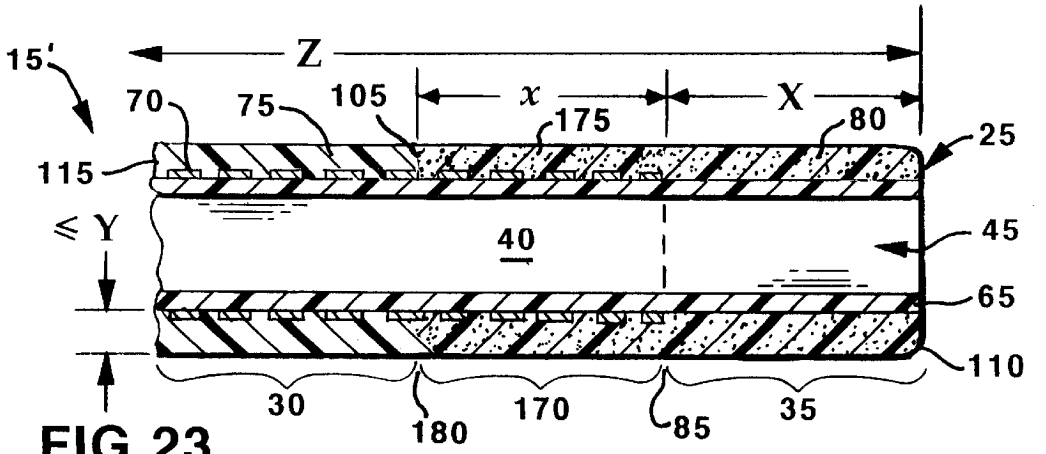


FIG.23

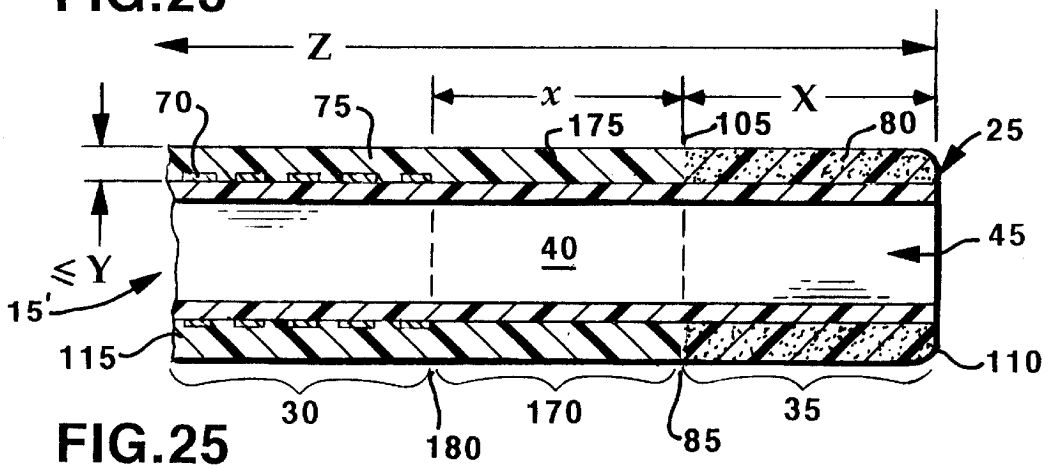


FIG.25

FIG.22

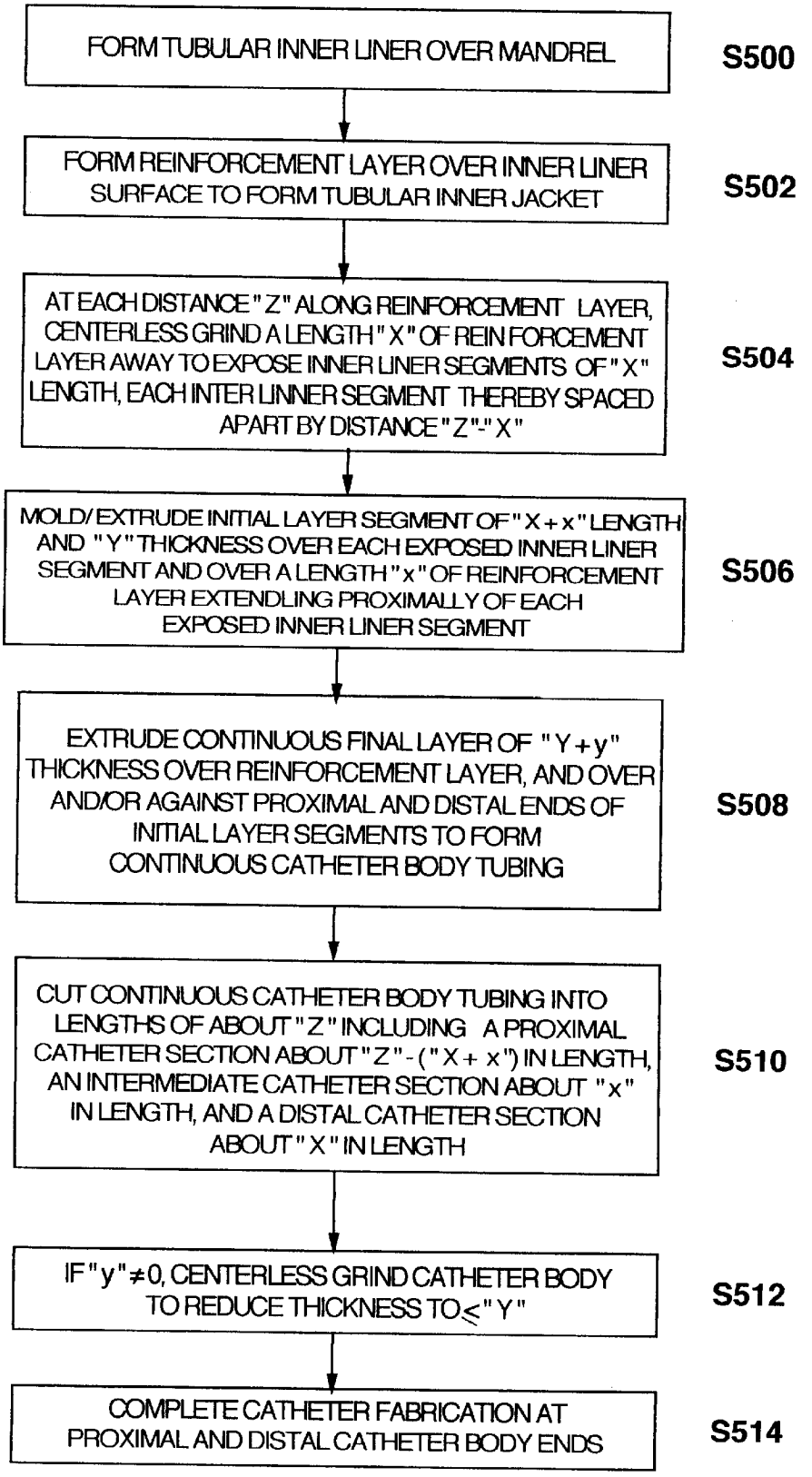
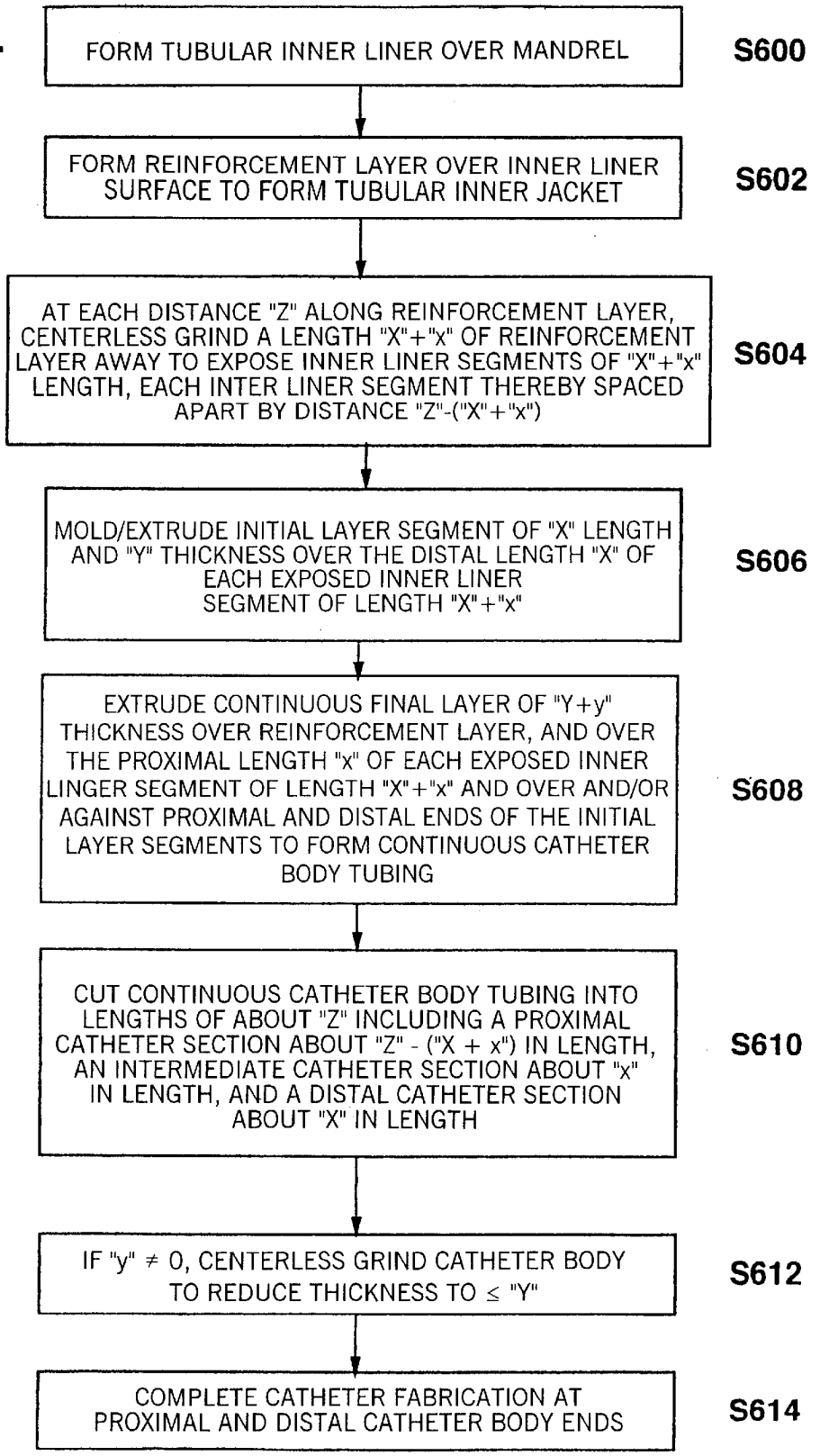

FORM TUBULAR INNER LINER OVER MANDREL
S500
FORM REINFORCEMENT LAYER OVER INNER LINER SURFACE TO FORM TUBULAR INNER JACKET
S502
AT EACH DISTANCE "Z" ALONG REINFORCEMENT LAYER, CENTERLESS GRIND A LENGTH "X" OF REIN FORCEMENT LAYER AWAY TO EXPOSE INNER LINER SEGMENTS OF "X" LENGTH, EACH INTER LINNER SEGMENT THEREBY SPACED APART BY DISTANCE "Z"-"X"
S504
MOLD/EXTRUDE INITIAL LAYER SEGMENT OF "X+x" LENGTH AND "Y" THICKNESS OVER EACH EXPOSED INNER LINER SEGMENT AND OVER A LENGTH "x" OF REINFORCEMENT LAYER EXTENDLING PROXIMALLY OF EACH EXPOSED INNER LINER SEGMENT
S506
EXTRUDE CONTINUOUS FINAL LAYER OF "Y+y" THICKNESS OVER REINFORCEMENT LAYER, AND OVER AND/OR AGAINST PROXIMAL AND DISTAL ENDS OF INITIAL LAYER SEGMENTS TO FORM CONTINUOUS CATHETER BODY TUBING
S508
CUT CONTINUOUS CATHETER BODY TUBING INTO LENGTHS OF ABOUT "Z" INCLUDING A PROXIMAL CATHETER SECTION ABOUT "Z"-("X+x") IN LENGTH, AN INTERMEDIATE CATHETER SECTION ABOUT "x" IN LENGTH, AND A DISTAL CATHETER SECTION ABOUT "X" IN LENGTH
S510
IF "y" ≠ 0, CENTERLESS GRIND CATHETER BODY TO REDUCE THICKNESS TO ≤ "Y"
S512
COMPLETE CATHETER FABRICATION AT PROXIMAL AND DISTAL CATHETER BODY ENDS
S514

FIG.24


FORM TUBULAR INNER LINER OVER MANDREL
S600
FORM REINFORCEMENT LAYER OVER INNER LINER SURFACE TO FORM TUBULAR INNER JACKET
S602
AT EACH DISTANCE "Z" ALONG REINFORCEMENT LAYER, CENTERLESS GRIND A LENGTH "X"+"x" OF REINFORCEMENT LAYER AWAY TO EXPOSE INNER LINER SEGMENTS OF "X"+"x" LENGTH, EACH INTER LINER SEGMENT THEREBY SPACED APART BY DISTANCE "Z"-("X"+"x")
S604
MOLD/EXTRUDE INITIAL LAYER SEGMENT OF "X" LENGTH AND "Y" THICKNESS OVER THE DISTAL LENGTH "X" OF EACH EXPOSED INNER LINER SEGMENT OF LENGTH "X"+"x"
S606
EXTRUDE CONTINUOUS FINAL LAYER OF "Y+y" THICKNESS OVER REINFORCEMENT LAYER, AND OVER THE PROXIMAL LENGTH "x" OF EACH EXPOSED INNER LINGER SEGMENT OF LENGTH "X"+"x" AND OVER AND/OR AGAINST PROXIMAL AND DISTAL ENDS OF THE INITIAL LAYER SEGMENTS TO FORM CONTINUOUS CATHETER BODY TUBING
S608
CUT CONTINUOUS CATHETER BODY TUBING INTO LENGTHS OF ABOUT "Z" INCLUDING A PROXIMAL CATHETER SECTION ABOUT "Z" - ("X + x") IN LENGTH, AN INTERMEDIATE CATHETER SECTION ABOUT "x" IN LENGTH, AND A DISTAL CATHETER SECTION ABOUT "X" IN LENGTH
S610
IF "y" ≠ 0, CENTERLESS GRIND CATHETER BODY TO REDUCE THICKNESS TO ≤ "Y"
S612
COMPLETE CATHETER FABRICATION AT PROXIMAL AND DISTAL CATHETER BODY ENDS
S614

MULTIPLE SEGMENT CATHETER AND METHOD OF FABRICATION

CROSS-REFERENCE TO RELATED PENDING APPLICATIONS

Reference is made to commonly assigned U.S. patent application Ser. No. 09/046,241 filed Mar. 23, 1998, for CATHETER HAVING EXTRUDED RADIOPAQUE STRIPES EMBEDDED IN SOFT TIP AND METHOD OF FABRICATION, in the names of Nasser Rafiee. et al.

FIELD OF THE INVENTION

The present invention relates to methods of fabricating medical vascular catheters adapted to be inserted into a blood vessel from an incision through the skin of a patient for introducing other devices or fluids for diagnostic or therapeutic purposes and particularly methods for fabricating such catheter bodies with catheter sections of differing flexibility.

BACKGROUND OF THE INVENTION

Catheters are tube-like medical instruments that are inserted into a body cavity, duct, tract, organ or blood vessel for a wide variety of diagnostic or therapeutic reasons, including delivery of diagnostic radiopaque materials, infusion of therapeutic drugs, performance of other interventional procedures, drainage of body cavities, organs or vessels, perfusion, and the like. Medical vascular catheters for each of these purposes can be introduced to numerous target sites within a patient's body by guiding the catheter through an incision made in the patient's skin and a blood vessel and then through the vascular system to the target site. Certain vascular catheters are introduced over a previously introduced guide wire or infusion wire and/or within a previously introduced guiding catheter or are advanced by blood flow in the vessel.

Medical vascular catheters generally comprise an elongated, flexible catheter tube or body with a catheter side wall enclosing a catheter lumen extending between a proximal catheter body end coupled to a relatively more rigid catheter hub to a distal catheter body end. The catheter body may be relatively straight or inherently curved or curved by insertion of a curved stiffening wire or guide wire through the catheter lumnen. The catheter body and catheter side wall are typically fabricated and dimensioned to minimize the catheter body outer diameter and side wall thickness and to maximize the catheter lumen diameter while retaining sufficient side wall flexibility and strength characteristics to enable the catheter to be used for the intended medical purpose.

Such medical catheters may be designed and used for diagnostic or therapeutic purposes in a wide range of catheter body sizes, lengths and configurations for accessing relatively large blood vessels, tracts, ducts or organs of the body or relatively small cardiac, neural or peripheral blood vessels that are frequently tortuous.

Guiding catheters are used to access a site in a patient's body and are formed to have a high degree of directional control and to provide a guiding catheter lumen through which smaller diameter, therapeutic catheters having little or no directional control are advanced to the site. In the field of vascular intervention, guiding catheters are particularly useful to guide angioplasty and atherectomy catheters through the vasculature to a site of a blockage, such as, coronary, cerebral and renal sites. Typically guiding catheters have a

specific distal section shape adapted and sized to facilitate insertion to the site of interest.

The requirements of a good guiding catheter include high torque transmission and pushability for advancement through the vasculature, high catheter lumen lubricity to facilitate insertion of catheters and other devices therethrough, low kinking characteristics, and good distal shape memory. Additionally it is desirable to provide a smooth and relatively soft distal tip leading surface to prevent damage to the vascular vessels during advancement. It is also desirable to provide a radiopaque marker near the distal tip of the catheter to enhance its visibility by fluoroscopy. A wide variety of guiding catheters have been developed that address these design requirements as set forth for example in U.S. Pat. No. 4,817,613 to Jaraczewski et al. A number of distal soft tips and radiopaque markers are also described in the above-referenced, commonly assigned, '241 patent application and in commonly assigned U.S. Pat. Nos. 5,509,910 to Lunn and 5,545,149 to Brin et al. and in U.S. Pat. Nos. 4,283,447 to Flynn, 5,078,702 to Pomeranz, 5,234,416 to Macauley et al. and 5,221,270 to Parker.

Such guiding catheter bodies are typically formed with relatively long and stiff proximal sections or shafts and relatively short and soft distal tips, although short intermediate bonding segments or sections can be employed to assist bonding the soft distal tip to,the distal end of the proximal shaft as disclosed in the above-referenced '910 and '149 patents. Typically, the proximal section or shaft is formed of an inner tube, metal or polymeric filaments braided overlying the inner tube, and an outer tube over the braid, thereby providing a reinforced catheter shaft as disclosed in the above-referenced '910, '416, and '149 patents. The distal soft tip is either formed separately and adhered to the distal end of the catheter shaft through a variety of techniques or is formed integrally as an extension of one of the outer or inner liners as disclosed in the above-referenced '613 patent, for example. Butt welding techniques are disclosed in the above-referenced '910, '416, and '149 patents, and lap joint techniques are disclosed in U.S. Pat. Nos. 4,531,943 to Van Tassel et al. and 4,551,292, issued to Fletcher et al. and in the above-referenced '270 patent The exterior surface of the distal end of the catheter shaft is ground circumferentially using a "centerless" grinder to reduce the distal shaft wall thickness. The tip member is then fitted over the distal end of the catheter shaft to form a lap joint with the distal shaft and is then bonded to the distal shaft using an adhesive or other bonding technique.

Angiographic catheters of the type disclosed in U.S. Pat. No. 5,738,742 to Stevens are also formed with a wire braid reinforced proximal catheter section or shaft and a distal soft tip that is attached-thereto. In one approach characterized as prior art, a distal end portion of the proximal catheter shaft is centerless ground to a shape accommodating attachment of a separately formed soft distal tip that is then attached thereto. In a further approach presented by Stevens, a continuous reinforced tubing is first fabricated wherein an inner tube is formed over a mandrel, wire braid is applied over the inner tube outer wall during a continuous fabrication process, periodic sections of the wire braid are centerless ground away to expose the inner tube in those sections, and a continuous elastomeric coating is applied over the wire braid and exposed inner tube sections. The continuous reinforced tubing is cut to catheter body lengths including the sections without the wire braid, and the outer layer and inner layer of the section without wire braid are thermally fused together and shaped to form an integral soft distal tip. A very similar technique is disclosed in U.S. Pat. No.

4,321,226 to Markling for fabrication of catheters of unspecified types. Other angiographic catheters employ relatively stiff polymeric materials, e.g., certain nylon blends, polyamides, polyesters, etc., to provide a relatively rigid proximal catheter shaft and other softer blends of like materials in the distal end section or distal soft tip as disclosed, for example, in U.S. Pat. No. 4,563,181 to Wijayarathna et al.

Small diameter medical catheters or "microcatheters" having a catheter body outer diameter in the range of one, French (1F; 0.33 mm) to three French (3F; 1.00 mm), are typically used in tortuous vascular passageways for diagnostic and interventional neurological techniques, such as the imaging and treatment of aneurysms, tumors, arteriovenous malformations/fistulas, and the like, in the blood vessels in the brain. Such neurological catheters must be very flexible, particularly in distal sections thereof, to pass through the tortuous regions. Difficulties in endovascular positioning, however, make it desirable to impart high tensile and column strength over at least the proximal portion of the catheter. Additionally, the blood vessels of the brain are relatively fragile, so it is desirable that the catheter have a soft, non-traurmatic exterior to prevent injury. U.S. Pat. Nos. 4,464,176 to Wijayrathna and 4,739,768 to Engelson describe such catheters consisting of an inner layer and an outer layer, where the inner layer terminates proximally of the outer layer to form a relatively more flexible distal catheter section in the range of 4.0 cm in length. A large number of designs of neurological catheters for introduction over a guidewire or that are intended to be flow directed have been described in the prior art wherein the catheter body is formed of two or three or more sections of increasing flexibility distally and terminating in a distal soft tip. Such flow directed catheters are described, for example, in U.S. Pat. No. 5,336,205 to Zenzon et al. Commonly assigned U.S. Pat. No. 5,676,659 to McGurk, discloses a microcatheter body having a continuous outer layer overlying a wire braid formed over a tubular inner liner or layer to form a reinforced proximal catheter section, a more flexible intermediate section formed of the inner and outer layer without the wire braid, and terminating in a distal soft tip or distal catheter section formed only of the outer layer. It is also suggested that the pitch or characteristics of the wire braid can be varied through the proximal catheter section to increase the flexibility of the proximal catheter section distally. The formation of these catheter sections on a discrete catheter body involves use of discrete outer tubes placed over the inner jacket, heat shrink tubes placed over the outer tubes, baking the assembly in an oven, and removing the heat shrink tubes.

Finally, infusion wires have been developed that combine the functions of a guidewire with the capability of delivering an infusate while the guidewire is positioned in a blood vessel to allow introduction of other catheters or medical devices over the infusion wire. Such infusion wires are typically formed of wire reinforced proximal catheter sections that are relatively stiff to aid in pushability and torqueability and more flexible distal catheter sections that can be curved to make turns in tortuous vasculature. One such open ended infusion wire is disclosed in U.S. Pat. No. 5,178.158 to de Toledo.

As can be seen from the prior art, many common techniques, materials and constructions are employed in the fabrication of medical catheters and infusion wires of a wide range of sizes for the various medical diagnostic and therapeutic procedures. In almost all cases, medical catheter bodies need to have relatively stiff proximal catheter sections to aid in advancing the catheter distal tip to the site of interest and a relatively soft or otherwise atraumatic distal tip to avoid damage to the vasculature, tract, duct, or cavity wall it is advanced through or to. Most such catheters for vascular use now employ one or more intermediate catheter sections of intermediate flexibility or some manner of increasing flexibility of the catheter body distally so that the distal end catheter section can be advanced through a tortuous pathway. The fabrication of these catheters can be complicated and expensive. There remains a need for a fabrication technique that simplifies fabrication steps and reduces cost while retaining desirable characteristics of the catheter body.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to simplify and reduce the cost of fabrication of medical catheters of the type described above.

The present invention provides improved fabrication methods for catheters of the type having an elongated catheter body and catheter hub at the proximal catheter body end with at least one catheter lumen extending through the catheter hub and body and to a distal catheter body end thereof, and catheters formed thereby. The catheter body is formed of at least a proximal catheter section coupled at its proximal end to the catheter hub and a distal catheter section coupled at a junction with the distal end of the proximal catheter section and terminating at a distal end of the distal catheter sections. One or more intermediate catheter sections are optionally formed between the proximal and distal catheter section. The distal catheter section can comprise a relatively short distal soft tip or a separately formed distal soft tip can be attached to the distal end of the distal catheter section.

Catheters constructed in accordance with the principles of the present invention comprise a catheter body having a proximal catheter body end and a distal catheter body end and formed of a proximal section and at least one distal section that have differing flexibilities, wherein the catheter body is formed in a process comprising the steps of: (1) forming a continuous tubular inner jacket; (2) forming short initial layer segments of an initial segment thickness along the length of the inner jacket from a material of first durometer hardness, whereby each initial layer segment is separated apart by a separation distance; (3) forming a final layer of a material of second durometer hardness in a layer thickness over the tubular inner jacket along the separation distances and over and/or against the proximal and distal initial layer ends of the initial layer segments to form a continuous catheter body tubing; (4) severing the continuous catheter body tubing into catheter body lengths including a proximal catheter section formed of the material of second durometer hardness and a distal catheter section formed of the material of first hardness; and (5) completing the catheter fabrication at the proximal catheter body end and the distal catheter body end.

In step (3), the thickness of the final layer can be less than, equal to or greater than the thickness of the initial layer segments. In step (5) or in an intermediate step between steps (3) and step (4), centerless grinding can be employed to render the catheter body diameter uniform and/or to reduce the final outer diameter of the catheter body or catheter body tubing, respectively, to remove any final layer material overlying the proximal catheter section of the catheter body.

In a first variation of the method of the present invention, in a further step between steps (2) and (3), an intermediate

segment layer of a material having a further durometer hardness is formed over the tubular inner jacket in an intermediate segment length and an intermediate segment thickness in proximity to each initial layer segment. The final layer forming step (3) further comprises forming the final layer over the tubular inner jacket along the separation distances and over the initial and intermediate segment layers to form the continuous catheter body tubing. The severing step (4) further comprises severing the continuous catheter body tubing into catheter body lengths including a proximal catheter section formed of the material of second hardness an intermediate catheter section formed of the material of intermediate hardness, and a distal catheter section formed of the material of first hardness over the inner jacket.

More particularly, the first material preferably is a softer durometer material than the second material (and the intermediate material, if present) whereby the resulting distal catheter section is more flexible than the proximal catheter section, although it is possible to selectively employ a first material that is harder than the second material to provide a less flexible distal section.

The first material (and the intermediate material, if present) is preferably molded over the continuous catheter body tubing in a cylinder, although it may be molded in a linear band, e.g., as a half cylinder section. The second material is preferably molded as a cylinder over the tubular inner jacket along the separation distances and over the first layer segments (and intermediate segment layers, if present) to form a continuous, cylindrical, catheter body tubing. The first and any intermediate segment layers are preferably molded or extruded to the inner jacket with tapered end edges so that they mutually engage one another (if both are present) and the second layer in a tapered edge manner.

The tubular inner jacket can be of any construction but is preferably formed in the first step of an inner tubular layer or liner composed of a lubricious material continually formed over a wire or plastic mandrel in a coating or continuous extrusion process. The use of such materials provides a very smooth lumen surface after the mandrel is removed for introducing devices and high velocity fluids through the lumen. The tubular inner jacket is preferably reinforced by any of the reinforcement processes, including use of multiple wall layers, including preferably the use of a reinforcement layer disposed over the outer surface of the tubular inner liner. Thus, the first step further preferably comprises continuously forming a reinforcement layer over the outer surface of the tubular inner liner. The reinforcement layer preferably comprises a braided reinforcement layer composed of a filament braid, preferably employing stainless steel or polymeric filaments, which is tightly braided over the outer surface of the tubular inner liner. The other layer segments and the final layer are then formed over the braided reinforcement layer. The flexibility of the catheter body is controlled by selecting the relative lengths and mechanical characteristics of each of these components.

The invention can be practiced using further tubular inner jackets. For example, the reinforcement of the tubular inner jacket, e.g., the reinforcement layer, can be either not formed or can be selectively removed in the first step (1) to expose inner liner surface lengths along the length of the inner tubular jacket are separated apart by the separation distance. Then, the initial material layer is formed over the exposed length. If a transition or intermediate catheter section is to be formed, the intermediate hardness material layer can be formed over the reinforcement adjacent to the initial material layer as described above. Alternatively, the exposed inner liner surface can be extended to an exposed length, and the initial material and the intermediate material can be formed in adjacent layer segments over that entire length. Again, however, the intermediate hardness material layer may be alternatively formed over the exposed length.

Larger diameter angiography and guide catheters formed in accordance with the present invention can have a separately formed distal soft tip segment attached to the distal catheter body end in the final fabrication step as a distal soft tip in any of the manners described above in the prior art. In such cases, a single transition from the tubular inner liner lumen to the contiguous lumen defined by the distal soft tip exists. However, the single transition can be eliminated in catheters formed in accordance with the methods of the present invention wherein the second material and the inner jacket material are suitably selected to be soft and flexible.

Employing these techniques in the different sections of the catheter body, flexibility, tensile strength, column strength, and hoop strength may be varied as desired by selectively controlling the mechanical characteristics of one or more of the formed catheter sections. Moreover, the fabrication process of forming the segment layers over prescribed segment lengths of the tubular inner jacket and then forming the continuous catheter body tubing enhances the uniformity of the characteristics of the catheter bodies cut from the continuous catheter body tubing. Costs of fabrication are also reduced.

In the exemplary embodiments, the major proximal section of the catheter body extending from its proximal end to the distal or intermediate catheter section is the least flexible, but has excellent torque transmission and hoop strength characteristics. The distal catheter section possesses the greatest flexibility with the minimum torqueability and hoop strength. The distal and any intermediate catheter section has or have greater flexibility while retaining adequate torqueability and hoop strength to permit guiding of the catheter by itself or over a guide wire and prevent kinking and collapse of the catheter lumen.

The methods of construction involve molding and extrusion techniques that result in a continuous catheter body tubing having the catheter sections formed thereon in repetitive patterns along the length thereof. Each junction of adjoining catheter sections is integrally formed and secure from fracture in use. Catheter bodies are cut from the continuous catheter body tubing, and the catheter fabrication is completed by trimming and finishing steps. The fabrication methods are therefore efficient and less costly and result in uniform product.

This summary of the invention and the objects, advantages and features thereof have been presented here simply to point out some of the ways that the invention overcomes difficulties presented in the prior art and to distinguish the invention from the prior art and is not intended to operate in any manner as a limitation on the interpretation of claims that are presented initially in the patent application and that are ultimately granted.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects, advantages and features of the invention will become apparent from the following detailed description of the preferred embodiments of the invention, in which:

FIG. **1** is a schematic illustration of a typical catheter formed in accordance with the methods of fabrication of the present invention to have a proximal catheter section and a distal catheter section that can comprise a distal soft tip;

FIG. **2** is a flow chart of a simplified fabrication process for forming a catheter of the type depicted in FIG. **1**;

FIG. **3** is a flow chart of a further simplified fabrication process for forming a catheter of the type depicted in FIG. **1**;

FIGS. **4–7** are partial cross-section views of a catheter body distal portion in the stages of fabrication of the flow charts of FIGS. **2** and **3**;

FIG. **8** is a partial cross-section view of a distal catheter body end formed in accordance with the fabrication steps of FIGS. **1** and **2** and having a distal soft tip attached thereto in the final fabrication step;

FIG. **9** is a flow chart of a still further simplified fabrication process for forming a catheter of the type depicted in FIG. **1**;

FIGS. **10–14** are partial cross-section views of a catheter body distal portion in the stages of fabrication of the flow chart of FIG. **9**;

FIG. **15** is a schematic illustration of a typical catheter formed in accordance with the methods of fabrication of the present invention to have a proximal catheter section, an intermediate catheter section, and a distal catheter section that can comprise a distal soft tip;

FIG. **16** is a flow chart of a simplified fabrication process for forming a catheter of the type depicted in FIG. **15**;

FIGS. **17–21** are partial cross-section views of a catheter body distal portion in the stages of fabrication of the flow chart of FIG. **16**;

FIG. **22** is a flow chart of a further simplified fabrication process for forming a catheter of the type depicted in FIG. **15**;

FIG. **23** is a partial cross-section view of a catheter body distal portion formed in accordance with the method of FIG. **22**;

FIG. **24** is a flow chart of a further simplified fabrication process for forming a catheter of the type depicted in FIG. **15**; and

FIG. **25** is a partial cross-section view of a catheter body distal portion formed in accordance with the: method of FIG. **24**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS OF THE INVENTION

FIG. **1** illustrates a two section embodiment of a medical catheter **10** constructed in accordance with the principles of the present invention having a catheter body **15** extending between a proximal catheter body end **20** and a distal catheter body end **25** and formed of a proximal catheter section **30** and a distal catheter section **35** that have differing flexibilities. The flexibility of the catheter body **15** is controlled by selecting the relative lengths and mechanical characteristics of each of these components. A catheter lumen **40** extends through the length "Z" of the catheter body **15** from a catheter lumen distal end opening **45** to a proximal connector **50** and then extends proximally through connector **50** to a catheter lumen proximal end opening **55**. The catheter lumen **45** is provided within an inner liner of a tubular inner jacket **60** described below and allows for the passage of a diagnostic or therapeutic fluid or other device through it and/or allows for the catheter body **15** to be advanced in an OTW manner over a guidewire or infusion wire previously advanced to a site of interest in a patient's body.

Proximal hub or connector **50** can be any standard medical interconnection device that provides for the introduction of a diagnostic or therapeutic fluid or other device through the catheter lumen **40** and out of the lumen distal end opening **45**. The proximal connector **50** can be a luer fitting, for example, wherein the diagnostic or therapeutic fluid or other device is introduced through lumen proximal end opening **55** into the catheter lumen **40** in the illustrated case. Alternatively, the proximal connector **50** can optionally include one or more side port extensions for infusion or withdrawal of fluids through the catheter lumen **45**. In such a case, a penetrable seal mechanism can be formed across the lumen proximal end opening to seal against a guidewire or infusion wire or other medical device advanced through it and into the catheter lumen **45** to inhibit backflow of blood or body fluids and any infused fluids.

The catheter body **15** is denoted as having an overall length "Z" and includes a proximal catheter shaft or section **30** of length approximately "Z"–"X" between the proximal catheter end **20** to the junction **85** and a distal catheter section **35** of length "X" extending between the junction **85** and the distal catheter body end **25**. These length terms are employed in the fabrication process described below and are somewhat approximate due to overlapping and trimming variables as described below.

The proximal catheter section **30** and certain embodiments of the distal catheter section **35** of the catheter body **15** are formed of a tubular inner jacket **60** that is preferably reinforced by any of the reinforcement processes known in the catheter art. Such reinforced tubular inner jackets can be formed of multiple continuous wall layers e.g. polyamide tube or hypotube coated by a softer tubular layer or the like, or of a tubular inner liner **65** covered by a reinforcement layer **70** disposed over the outer surface of the tubular inner liner **65** as illustrated in FIG. **1**. The tubular inner liner **65** is composed of a lubricious material, such as a fluorocarbon polymer, a polyamide (e.g., Nylon), polyether block amides (PEBA), a polyolefin, a polyimide, or the like. In one preferred embodiment, the inner liner **65** is extruded of Shore 70D PEBAX® polyether block-polyamide. In another preferred embodiment, the tubular inner liner is formed of polytetrafluoroethylene (PTFE). The inner liner is continually formed over a wire or plastic mandrel in a coating or continuous extrusion process. The use of such materials provides a very smooth catheter lumen surface after the mandrel is removed for introducing devices and high velocity fluids through the catheter lumen. It would also be possible to form the inner liner **65** as a laminate structure comprising a non-lubricious outer layer and an inner lumen surrounding layer or coating of a more lubricious material.

The reinforcement layer **70** is preferably formed of metal wire filaments or plastic filaments braided together in the manner described above. The reinforcement layer preferably comprises a reinforcement layer composed of a filament braid, preferably employing stainless steel or polymeric filaments, which is tightly braided over the outer surface.of the tubular inner liner. Preferably, rectangular wire filaments of stainless steel, a shape memory alloy (e.g., Nitinol), polymeric fibers, or the like, are used. The other layer segments and the final layer are then formed over the reinforcement layer or over exposed tubular inner liner surface segments as described below.

In one embodiment of the invention, the catheter body is formed with the reinforcement, e.g., the reinforcement layer **70**, extending all the way to the catheter body distal tip **45** or only to the junction **85**. The braid structure is preferably square cut or otherwise smoothed in the fabrication process, so that it terminates cleanly at the desired termination location and is free from protrusions, burrs, and other

discontinuities which could extend out of the catheter body and subject the patient to injury. In one form of a guide or angiographic catheter formed in accordance with a method of the invention, the reinforcement layer **70** extends to the catheter body distal tip **45** and a further distal soft tip is butt or lap joined thereto in a manner well known in the art. In a further form of such a large diameter catheter, the reinforcement layer **70** terminates at the junction **85**, and the distal catheter section **35**, trimmed to a suitable length "X", constitutes an integrally formed distal soft tip.

In the proximal catheter section **30**, the illustrated reinforcement layer **70** of the tubular inner jacket **60** is covered by a proximal outer layer **75**. Similarly, in the distal catheter section **35**, either the reinforcement layer **70** of the tubular inner jacket **60** or the inner liner **65** of the tubular inner jacket **60** is covered by a distal outer layer **80**, depending on whether the reinforcement layer **70** is present or not. The distal outer layer **80** is formed of a material of first hardness, and the proximal outer layer **75** is formed preferably of a material of second hardness. The first material preferably is a softer material than the second material, whereby the resulting distal catheter section **35** is more flexible than the proximal catheter section **30**, although it is possible to selectively employ a first material that is harder than the second material to reverse the flexibility change. The catheter **10** of FIG. **1** thus preferably has a catheter lumen **40** with a uniform lumen diameter through its length and catheter outer layers **75** and **80** that have a common, uniform outer diameter.

The catheter body **15** of an angiography catheter can be "straight" as depicted in FIG. **1** or can be pre-curved into an Amplatz-type shape, a Judkins-type left shape or a pigtail shape, for example, wherein the distal catheter section is curved to the shape. The methods of the present invention can be employed to reinforce the curvature by employing a soft durometer material along the inside of the curve and a hard durometer material along the outside of the curve.

The catheter of FIG. **1** is formed in accordance with the methods of the present invention illustrated in FIGS. **2–14**. FIG. **2** sets forth the steps of the invention in a more general manner applicable to any form of tubular inner jacket, and without certain finishing steps, and FIG. **3** sets forth the preferred steps of forming the catheter of FIG. **1**. FIGS. **4–7** illustrate these steps in greater detail, and FIG. **8** illustrates an optional addition to the final fabrication step. FIG. **9** sets forth a further method of forming the catheter of FIG. **1**, and FIGS. **10–14** illustrate those steps.

In FIG. **1**, the catheter body **15** comprising the proximal catheter section **30** and the distal catheter section **35** is formed in a continuous process wherein the tubular inner jacket may take any of the forms known in the art and include continuous tubular reinforcement layers or spiral wound, circular or flattened, reinforcement layers of the typed disclosed in the above-referenced '158 patent to de Toledo, for example. A continuous tubular inner jacket of indeterminate length is formed in step **S100**, preferably over a continuous wire or plastic mandrel.

A plurality of initial layer segments having a length "X" and thickness "Y" are formed each distance "Z" along the length of the inner jacket from a material of first durometer hardness in step **S102**. For a wide range of catheters, "X" can be selected in a range between 0.2 cm and 20 cm, and "Z" can be selected in a range between 60 cm and 200 cm. For example, where "X"=10 cm and "Z"=100 cm, the separation between successive initial layer segments is "Z"–"X" or 90 cm.

The initial layer segment can be cylindrical extending all the way around the circumference of the inner jacket or it can be formed in stripes along one side of the inner jacket. In this case, the material of first durometer hardness is preferably a relatively "soft" durometer material that is injection molded or extruded over the inner jacket so that each initial layer segment is a relatively flexible layer segment of thickness "Y". The materials of first durometer hardness can be selected from the group consisting of polyamide polyether block amides, (PEBAX® or VESTAMID®), polyurethane, polyethylene, silicone rubber, polyimides, nylon, fluorinated hydrocarbon polymers and the like in a hardness range from 30 A to 75 D, and the materials of second durometer hardness can be selected from the same group in a greater hardness than the materials of first durometer hardness.

However, in one particular example related to a shaped distal catheter section, materials of differing durometer hardness can be formed in lines on opposite sides of the inner jacket over a length "X". When a shape is to be formed, in the distal catheter section in the final step of fabrication, e.g. the Amplatz-type shape, a Judkins-type left shape or a pigtail shape, for example, a soft durometer material can be molded or extruded in a line along the inside of the curve to be formed and a hard durometer material can be molded or extruded along the outside of the curve. The shape in the distal catheter section is then formed in step **S108** by inserting a shaped mandrel through the catheter lumen and then heating and cooling it. The resulting curved shape is more flexible on the interior side of the curve than on the outer side of the curve, tending to reinforce the maintenance of the shaped distal catheter section.

Radiopaque materials can be incorporated into the material of first hardness as described, for example, in the above-referenced '447 patent to Flynn and '270 patent to Parker.

Then, in step **S104**, a continuous catheter body tubing is formed from which catheter bodies can be cut to specified length "Z". A final layer of a material of second hardness is continuously formed over the tubular inner jacket along the separation distances "Z"–"X" between and preferably extending over the initial layer segments of length "X" to form a continuous catheter body tubing outer layer formed by one or the other or both of the materials of first and second hardness. The final layer is preferably formed by extrusion of a continuous layer with a thickness "Y"+"y", which is preferably equal to or greater than "Y". In this way, a continuous outer layer of "Y"+"y" thickness is formed overlying the outer wall of the inner jacket between the initial layer segments and extending between or preferably overlying the initial layer segments. The final layer material has a second durometer hardness that is preferably harder than the initial material, so that a relatively stiff continuous outer layer of the continuous catheter body tubing is formed in this step.

In step **S106**, the continuous catheter body tubing and the mandrel are cut into catheter bodies of about "Z" length, including a proximal catheter section of about "Z"–"X" length formed of the material of second hardness and a distal catheter section of about "X" length. The proximal catheter section is formed of the layer of the final material of second hardness and the tubular inner jacket, and the distal catheter section is formed of the layer of the initial material of first hardness and the tubular inner jacket and a layer of thickness "y" of the final material of second hardness, if "y">0. In this case, the material of second hardness is harder than the material of first hardness, and consequently, the distal catheter body section is more flexible than the proximal catheter body section.

In step **S108**, fabrication of the catheter is completed by removing the mandrel from the catheter lumen, trimming and dressing the catheter body and the distal catheter body end and attaching the proximal connector **50** to form the catheter **10** as it appears in FIG. **1**. The junction **85** constitutes the area of intimate contact of the initial layer segment material with the final layer material. These materials are selected to be compatible and capable of adhering together in the extrusion of the final layer over the inner jacket and against or over the initial layer segment.

A preferred embodiment of the method is illustrated further in FIGS. **3–7** wherein the particular tubular inner jacket **60** illustrated in FIG. **1** is formed in steps **S200** and **S202** over a wire or plastic mandrel **90** employing fabrication techniques described, for example, in the above-referenced '659 patent to McGurk or the '416 patent to Macauley et al. However, in those cases, each catheter body is separately formed by placing or forming a length of the tubular inner liner over a mandrel and then forming the reinforcement layer over that length. In the fabrication methods of the present invention, the mandrel **90** is of an indeterminate length well exceeding the length of the catheter bodies to be formed.

The tubular inner liner **65** is first formed by deposition or extrusion over the mandrel **90** of the aforementioned PTFE material, for example, and the reinforcement layer **70** is formed over its exterior surface to provide a continuous tubular inner jacket **60** in a manner similar to that disclosed in the above-referenced '226 patent to Markling and the '742 patent to Stevens, prior to the removal of sections of the reinforcement layer. While the reinforcement layer **70** is depicted in FIGS. **4–7** as formed of flattened metal or plastic filaments, it will be understood that it can be formed of round metal or plastic filaments as disclosed, for example, in the above-referenced '270 patent to Parker, or in any of the forms described above with respect to FIG. **2**.

FIG. **4** illustrates a length of the tubular inner jacket **60**, comprising the reinforcement layer **70** overlying the tubular inner liner **65**, that is formed over mandrel **90** in steps **S200** and **S202**. FIG. **4** also illustrates the advancement of the tubular inner jacket **60** and mandrel **90** distance "Z" in the direction of the arrow **95** to locate a section of length "X" thereof in a molding or extrusion cavity (not shown). At this point in step **S204**, the cylindrical initial layer segment **100** of length "X" is formed over the section of length "X" as shown in FIG. **4**. After each such initial layer segment **100** is formed, the tubular inner jacket **60** over the mandrel **90** is advanced in the direction of advancement **95** a distance "Z", and the process is repeated, resulting in a plurality of such initial layer segments **100** formed over the tubular inner jacket **60** and each separated from its neighbor by a separation distance "Z"–"X", The initial layer segment proximal end **105** and the initial layer segment distal end **110** are preferably tapered in the molding or extrusion process to provide for an overlapping of the: initial layer segment **100** with the final layer (or an intermediate segment layer) as described below.

FIG. **5** depicts the continuous formation of a final layer **115** of a material of second hardness, the final layer formed with "Y"+"y" thickness over the tubular inner jacket **60** along the separation distances "Z"–"X" and over the initial layer segments **100** (if "y">0) to form a continuous catheter body tubing **120** in accordance with step **S206**. The continuous extrusion process results in an overlapping, ring shaped, layer of the material of the final layer **115** extending over the tapered initial layer segment proximal end **105** and initial layer segment distal end **110**. Strong adhesion of the melted material of second hardness with the solid material of first hardness used in the initial layer sigment is accomplished by selecting compatible materials that have close melting temperatures, whereby at least a surface layer of the material of first hardness melts upon contact with the molten material of second hardness and subsequently cools and solidifies forming an integral bond.

Thus, a continuous catheter body tubing of indeterminate length is formed in this manner. Catheter bodies **15** are then or later cut from the continuous catheter body tubing and formed into a catheter **10**. In step **S208**, the continuous catheter body tubing is cut into catheter body lengths of about "Z" at the catheter body cut lines **125** shown in FIG. **5**. At this point, if "y"=0, then the final step **S212** can be followed to complete the fabrication of the catheter as described above with respect to step **S108** of FIG. **2**. If "y" is not equal to 0, then it is desirable to follow step **S210** of FIG. **3** to make the outer diameters of the proximal catheter section and the distal catheter section the same. Regardless of the value of "y", following step **S210** is preferred, and it is illustrated in FIG. **6** for the case where "y">0.

In this case, the catheter body length supported by the mandrel **90** is advanced in a centerless grinding advance direction **130** through a centerless grinding machine illustrated schematically by the grinding wheels **135** and **140** to reduce the thickness of the initial layer segment **100** and the final layer **115** to ≦"Y" as shown in FIG. **6**. The centerless grinding process exposes the outer surface of the initial layer segment **100**. Although this step **S210** is depicted and described as occurring after the continuous catheter body tubing is cut into catheter body lengths, it could also be conducted before the cuts are made along catheter body cut lines **125**.

In step **S212**, the cut section of the mandrel **90** is removed, and final fabrication of the catheter **10** is completed. The catheter distal tip **25** is shaped and any protrusions, burrs, discontinuities, or the like, which may result from the termination of the braid at the cut lines **125** are trimmed. As shown in FIG. **7**, the distal outer layer **80** is formed by the initial layer segment **100**, and the proximal outer layer **75** is formed by the final layer **115**. The resulting catheter **10** thus has proximal and distal catheter sections **30** and **35** of differing flexibility, and in the typical case, the distal catheter section **35** is more flexible than the proximal catheter section **30** by virtue of the selection of the materials of the initial layer segment **100** and the final layer **115**. It will be understood that the length "X" is not necessarily to scale and can be substantially longer or shorter than illustrated depending on the intended use and characteristics of the catheter body **15**

FIG. **8** is a partial cross-section view of a distal catheter body end formed in accordance with the fabrication steps of FIGS. **1** and **2** and having a discrete distal soft tip **45** attached thereto in the final fabrication step **S212**. The discrete distal soft tip **145** can also be formed at the distal catheter body end **25** of the other embodiments of the invention described hereafter. The distal soft tip **145** can be formed with radiopaque material encased therein and can be shaped and attached to form the distal catheter body end **25** in a manner disclosed in the above-referenced '910 patent to Lunn or the '149 patent to Brin et al. or in the above-referenced copending '241 patent application.

FIG. **9** is a flow chart of a still further simplified fabrication process for forming a catheter **10** of the type depicted in FIG. **1**, wherein the reinforcement layer **70** is removed along the lengths "X" where the initial segment layers **100**

are to be formed. FIGS. **10–14** are partial cross-section views of a catheter body distal portion in the stages of fabrication of the flow chart of FIG. **9**. In FIG. **9**, steps S**300** and S**302** correspond to steps S**200** and S**202** of FIG. **3** to form the tubular inner jacket **60**. In this alternative method for forming a two section catheter body **15**, the reinforcement of the tubular inner jacket **60**, e.g., the reinforcement layer **70**, can be either not formed or can be selectively removed, exposing a length "X" of the tubular inner liner **65** in step S**304**. In a continuous removal process also illustrated in FIG. **10**, the lengths "X" of exposed inner liner surface **165** along the length of the inner tubular jacket **60** are removed by a centerless grinding machine schematically illustrated by grinding wheels **155** and **160**. Each exposed inner liner surface **165** of length "X" is separated from one another by the distance "Z"−"X" along the continuous tubular inner jacket **60**. The centerless grinding methods disclosed in the above referenced '226 patent to Markling and the '742 patent to Stevens can be employed in step S**304**.

In step S**306**, illustrated in FIG. **11**, the initial layer segments **100** of length "X" are formed over the exposed inner liner surface segments **165**, in substantially the same manner as step S**204** and FIG. **4**. In step S**308**, illustrated in FIG. **12**, the continuous final layer **115** of a material of second hardness and in a thickness "Y"+"y" is extruded along the separation distances "Z"−"X" and over the initial layer segments **100** (if "y">0). A continuous catheter body tubing is formed thereby in substantially the same manner as step S**206** and FIG. **5** as described above.

Again, after the continuous catheter body tubing is formed in this manner, it is cut into catheter body lengths of about "Z" in accordance with step S**310** at the catheter body cut lines similar to lines **125** shown in FIG. **5**. At this point, if "y"=0, then the final step S**314** can be followed to complete the fabrication of the catheter as described above with respect to step S**108** of FIG. **2**. If "y" is not equal to 0, then it is desirable to follow step S**312** of FIG. **9** to make the outer diameters of the proximal catheter section and the distal catheter section the same. Regardless of the value of "y", following step S**312** is preferred, and it is illustrated in FIG. **13** for the case where "y">0.

Again, the catheter body length supported by the mandrel **90** is advanced in a centerless grinding advance direction **130** through a centerless grinding machine illustrated schematically by the grinding wheels **135** and **140** to reduce the thickness of the initial layer segment **100** and the final layer **115** to ≦"Y" as shown in FIG. **13**. The centerless grinding process exposes the outer surface of the initial layer segment **100**.

Note that this step S**312** is depicted and described as occurring after the continuous catheter body tubing is cut into catheter body lengths of about "Z" in step S**310**. However, step S**312** could alternatively be conducted before the cuts are made along catheter body cut lines **125**, so that the continuous catheter body tubing **120** is formed with the thickness of the initial layer segment **100** and the final layer **115** reduced to ≦"Y".

In step S**314**, the cut section of the mandrel **90** is removed from catheter lumen, and final fabrication of the catheter **10** is completed. The catheter distal tip **25** shown in FIG. **14** is shaped as described above with reference to FIG. **7**. As shown in FIG. **14**, the distal outer layer **80** is formed by the initial layer segment **100** overlying the exposed inner liner surface segment **165**, and the proximal outer layer **75** is formed by the final layer **115** overlying the reinforcement layer **70**. The resulting catheter **10** thus has proximal and distal catheter sections **30** and **35** of differing flexibility, and in the typical case, the distal catheter section **35** is more flexible than the proximal catheter section **30** by virtue of the selection of the materials of the initial layer segment **100** and the final layer **115** as well as the removal of the reinforcement layer **70** It will be understood that the length "X" is not necessarily to scale and can be substantially longer or shorter than illustrated depending on the intended.use and characteristics of the catheter body **15**. The discrete distal soft tip **145** of FIG. **8** can also be attached to form the distal catheter body end **25** as described above with respect to FIG. **8**.

These fabrication techniques result in a catheter body **15** of FIG. **1** that is formed of proximal and distal catheter sections optionally including a further distal soft tip. The principals of the present invention can be applied to the fabrication of medical catheters having one or more further intermediate catheter sections intermediate the proximal and distal catheter sections. FIG. **15** illustrates a three section embodiment of a medical catheter **10'** constructed in accordance with the principles of the present invention also having a three section catheter body **15'** extending between a proximal catheter body end **20** and a distal catheter body end **25** and formed of the proximal catheter section **30**, the distal catheter section **35** and an intermediate catheter section **170**, each having differing flexibilities. The flexibility of the catheter body **15'** is controlled by selecting the relative lengths and mechanical characteristics of each of these components. A catheter lumen **40** extends through the length "Z" of the catheter body **15'** from a catheter lumen distal end opening **45** to a proximal connector **50** and then extends proximally through connector **50** to a catheter lumen proximal end opening **55**. The catheter lumen **40** is provided within an inner liner of a tubular inner jacket **60** preferably formed of a tubular inner liner **65** and a reinforcement layer **70** of any of the types described above. Although the catheter body **15'** is shown in a straight configuration, it will be understood that it can be formed in a pre-curved configuration, where the curve extends through the distal catheter section **35** and/or the intermediate catheter section **170** and possibly a distal portion of the proximal catheter section **30**.

The intermediate catheter section **170** is formed of an intermediate outer layer **175** and is of a length "x" that extends proximally from junction **85** to a proximal junction **180** with the proximal outer layer **75**. In accordance with the preferred methods of fabrication described below, the intermediate catheter section **170** can be formed many different ways to provide a flexibility that differs from the flexibility of the proximal and distal catheter sections **30** and **35**, respectively. In the typical case, the proximal catheter section **30** is formed to have sufficient column strength and hoop strength for advancement through the incision in the patient's skin and blood vessel and through the tortuous vasculature. The proximal catheter section side wall is formed to be relatively stiff to provide good torqueability and pushability, as these terms are understood in the art. The side wall of the intermediate catheter section **170** is formed to be more flexible than the proximal catheter section to provide for better maneuverability of the catheter through tortuous passageways. The side wall of the distal catheter section **35** is formed to have even greater flexibility to provide a soft distal tip and/or to allow OTW (over-the-wire) or flow advancement of the catheter body **15'** through the tortuous passageways.

In the guide catheter context, the intermediate stiffness of the intermediate catheter section **170**, which is typically

pre-curved, provides backup support of the distal most segment that is introduced into a blood vessel. It inhibits the straightening of the curve and dislodgment of the distal segment from the previously accessed vessel when a further catheter is introduced through the catheter lumen.

Generally speaking, the catheter body **15'** can be formed with a single initial layer segment and a final layer as described above formed over a tubular inner jacket **60**, where the reinforcement layer **70** is removed to form exposed inner liner surface segments of length "X" or length "X+x" as further described below. In this approach, only two molding or extrusion steps are required, but the centerless grinding step is required to alter the flexibility of the underlying tubular inner jacket in these sections. A further intermediate segment layer can be formed of length "x" after or before formation of the initial layer segment of length "X", thereby requiring an additional molding or extrusion step. In this case, the centerless grinding step can still optionally be employed to selectively expose inner liner surface segments of length "X" or length "X+x".

A first fabrication method is set forth in the flow chart of FIG. **16** and illustrated in FIGS. **17–21** whereby the proximal, intermediate and distal outer layers **75**, **175**, and **80**, respectively, are formed of materials of different durometer hardness overlying the reinforcement layer **70** that extends the full length "Z" of the catheter body **15'**. Steps **S400–S404** are the same as steps **S200–S204** of FIG. **3**, resulting in the initial layer segment **100** illustrated in FIG. **4**. In step **S406**, illustrated in FIG. **17**, the intermediate segment layer **185** of thickness "Y" is extruded or molded over a length "x" of the reinforcement layer **70** proximal to the initial layer segment **100** such that it extends from the intermediate segment layer proximal end **190** into overlying contact with the tapered initial layer segment proximal end **105** of the initial segment layer **100**. Because of this overlap, the lengths "x" and "X" overlap by a distance "Δ", and the distance along the exposed reinforcement layer **70** between the contiguously molded distal and intermediate segment layers **100** and **185** is approximately ("Z"–("X+x")). It should be noted that the order of steps **S404** and **S406** can be reversed or that both steps can be performed in a single molding or co-extrusion operation.

Step **S408** illustrated in FIG. **18** is performed in substantially the same manner as step **S206** described above. Steps **S410** and **S412**, illustrated in FIGS. **19** and **20**, respectively, are performed in substantially the same manner as steps **S210** and **S208**, respectively, described above. However, the steps are reversed in order so that the catheter body outer layer is ground to the thickness ≦"Y" before the continuous catheter body tubing is cut along cut lines **125** into catheter body lengths. This reversal of these steps simply illustrates this possible order for each of the methods of the invention, and it will be understood that the order can be reversed in the practice of the method illustrated in FIG. **16**. Finally, step **S414** corresponds to step **S212** to form the three section catheter **10'** of FIG. **15**. FIG. **21** illustrates the resulting distal segment of the catheter body **10'** comprising the distal catheter section **35**, the intermediate catheter section **170** and a distal portion of the proximal catheter section **30**. It will be understood that the lengths "X" and "x" are not necessarily to scale and can be substantially longer or shorter than illustrated depending on the intended use and characteristics of the catheter body **15'**. The discrete distal soft tip **145** of FIG. **8** can also be attached to form the distal catheter body end **25** as described above with respect to FIG. **8**.

The method of FIGS. **16–21** can also be altered by the addition of the step **S304** of FIG. **9**, to remove the reinforcement layer **70** through the distal section length "X" to provide the exposed inner liner surface segment **165** illustrated in FIG. **10**. This method is set forth in FIG. **22** where steps **S500–S504** are the same as steps **S300–S304** of FIG. **9** and illustrated in FIG. **10**. In step **S506**, the initial layer segment of thickness "Y" is extruded or molded over a length "x" of the reinforcement layer **70** proximal to the exposed inner layer liner segments and over the length "X" of the exposed inner layer liner segment. Steps **S508–S514** correspond to steps **S408–S414** of FIG. **16**. Thus, only two materials of differing durometer hardness are employed, and the three catheter sections differ in flexibility due to the underlying reinforcement layer in the intermediate catheter section of length "x". As shown in view of the resulting distal catheter body segment of FIG. **23**, the reinforcement layer **70** is terminated at the distal junction **85**. The distal outer layer **80** overlying the exposed inner liner surface of the distal catheter section length "X" and the intermediate outer layer **175** overlying the reinforcement layer **70** within the intermediate catheter section length "x" are formed at the same time of the continuous initial layer segment of a material of first hardness. The distal catheter section **35** is therefore more flexible than the reinforced intermediate catheter section **170**. The proximal outer layer **75** is then formed as a final layer **115** of a material of second hardness, preferably of a greater durometer hardness than the durometer hardness of the initial layer segment. Consequently, the proximal catheter section **30** is less flexible than the intermediate catheter section **170** and the distal catheter section **35**.

FIG. **24** sets forth the alternative approach of removing lengths "X"+"x" of the reinforcement layer **70**, applying the initial layer segment **100** only over the length "X", and applying the final layer **115** over the reinforcement layer **70** and the remaining length "x" of the exposed inner liner surface segment. The resulting distal end segment of the catheter body **15'** is shown in FIG. **25**. Steps **S600–S602** are the same as the first two steps of FIGS. **3**, **9**, **16** and **22**. In step **S604**, the reinforcement layer is removed in the manner of step **S304** of FIG. **9** as illustrated in FIG. **10**, except that the removed length corresponds to the intended lengths of both the distal catheter segment and the intermediate catheter segment, that is a length "X" +"x". The separation distance between adjacent exposed inner liner segments of length "X"+"x" is "Z"–("X"+"x"). In step **S606**, the initial layer segment of thickness "Y" is extruded or molded only over the length "X" of the exposed inner layer liner segment. In step **S608**, the final layer segment is applied or formed over the reinforcement layer and the length "x" of the exposed inner liner surface segment between the adjacent initial layer segments. Steps **S610–S614** correspond to the final three steps of each of the methods depicted in FIGS. **3**, **9**, **16**, and **22**. In this method depicted in FIG. **24**, only two materials of differing durometer hardness are employed, and the three catheter sections differ in flexibility due to the lack of the underlying reinforcement layer in the intermediate catheter section of length "x". The resulting distal end, segment of the catheter body **15'** is shown in FIG. **25**.

It will also be understood that the lengths "X" and "x" of the distal and intermediate catheter segments depicted in FIGS. **23** and **25** are not necessarily to scale and can be substantially longer or shorter than illustrated depending on the intended use and characteristics of the catheter body **15'**. In each case, the discrete distal soft tip **145** of FIG. **8** can also be attached to form the distal catheter body end **25** as described above with respect to FIG. **8**.

The steps of the methods of FIGS. **16**, **22**, and **24** can be selectively combined using three materials of differing

durometer hardness applied in an initial segment layer and an intermediate segment layer and a final layer over selected lengths of exposed inner liner surface segments to create a catheter body of four catheter sections.

In all of the above-described methods, the first material (and the intermediate material, if present) is preferably molded over the continuous catheter body tubing in a cylinder, although it may be molded in a linear band, e.g., as a half cylinder section along the length "Z". The second material is preferably molded as a cylinder over the tubular inner jacket along the separation distances "Z"–"X" and over the first layer segments (and intermediate segment layers, if present) to form a continuous, cylindrical, catheter body tubing.

In each case, where the thickness "y"≠0, the tubular catheter body outer layer is preferably centerless ground to grind away the thickness of the layers overlying the jacket to ≦"Y". The centerless grinding step provides a catheter body of uniform diameter over its length exposing the outer surface of the initial layer segment and any intermediate segment layers.

The catheter body sections can be fabricated in accordance with any of the above-described methods in any selected lengths. The distal catheter section formed by any of the above-described processes has a typical length in the range from about 0.1 cm to 10 cm depending on the nature and use of the catheter. If the distal catheter section constitutes a distal soft tip of a guide catheter or angiographic catheter, its length can be in the range of 0.05 cm to 0.4 cm and typically between about 0.1 cm to 0.25 cm long for example, after distal end trimming. The intermediate catheter section formed by any of the above-described processes can be of any length suitable for the application. In over-the-wire (OTW) or flow directed microcatheters, the intermediate catheter section length can be formed range of about 1.0 cm to 20.0 cm, or even longer, and the distal catheter section can be between 1.0–10.0 cm, preferably about 4.0 cm. In this way, up to three distinct regions of flexibility, tensile strength, column strength, and hoop strength may be provided in a small diameter catheter. In certain cases, the intermediate catheter section or the distal catheter section can be formed of a material that is loaded with a radiopaque material to form a radiopaque ring just at or proximal to the distal catheter end. The intermediate section length can in this case be about 0.1 cm to 1.0 cm to provide high definition of the location of the radiopaque ring.

The fabrication methods of the present invention are particularly useful for forming medical vascular catheters in a wide range catheter body lengths and outer diameters and a wide range of catheter sections and section lengths. Such catheters include relatively large diameter guiding catheters and angiography catheters and medical catheters used to access various body cavities, ducts, tracts and organs having catheter body outside diameters of 2.67 mm (8 F) to 4 mm (12 F) or more. The fabrication methods of the present invention, however, are not limited to such large diameter catheters, and will be useful for smaller diameter vascular catheters, preferably below 2.67 mm (8 F), and frequently as small as 1 mm (3 F), and below, such as those used in neurological diagnostic and interventional procedures. Such small diameter vascular catheters will also be useful for other procedures, such as gynecological procedures, cardiac procedures, general interventional radiology procedures, and the like, for access to the small vasculature as necessary.

Although particular embodiments of the invention have been described herein in some detail, this has been done for the purpose of providing a written description of the invention in an enabling manner and to form a basis for establishing equivalents to structure and method steps not specifically described or listed. It is contemplated by the inventors that the scope of the limitations of the following claims encompasses the described embodiments and equivalents thereto now known and coming into existence during the term of the patent. Thus, it is expected that various changes, alterations, or modifications may be made to the invention as described herein without departing from the spirit and scope of the invention as defined by the appended claims.

PART LIST FOR FIGS. **1–25**

medical catheter **10**
catheter body **15**
proximal catheter body end **20**
distal catheter body end **25**
proximal catheter section **30**
distal catheter section **35**
catheter lumen **40**
catheter lumen distal end opening **45**
proximal connector **50**
catheter lumen proximal end opening **55**
tubular inner jacket **60**
tubular inner liner **65**
reinforcement layer **70**
proximal outer layer **75**
distal outer layer **80**
junction **85**
mandrel **90**
advancement direction **95**
initial layer segment **100**
initial layer segment proximal end **105**
initial layer segment distal end **110**
final layer **115**
catheter body cut lines **125**
centerless grinding advancement direction **130**
centerless grinding wheel **135**, **140**
discrete distal soft tip **145**
centerless grinding advancement direction **150**
centerless grinding wheel **155**, **160**
exposed inner liner surface segment **165**
intermediate catheter section **170**
intermediate outer layer **175**
proximal junction **180**
intermediate segment layer **185**
intermediate segment layer proximal end **190**

What is claimed is:

1. A method of fabricating medical catheter bodies of length "Z" from continuous catheter body tubing, comprising the steps of:

extruding a continuous inner jacket having an outer surface and a catheter lumen extending therethrough;

forming initial layer segments on the outer surface of the continuous inner jacket, each segment having a length "X" and a thickness "Y" and being separated by a length "Z–X" along the length of the continuous inner jacket, wherein the initial layer segments are formed of a first material;

subsequently forming a final layer of a second material having a thickness "Y+y" over at least a portion of the inner jacket, thereby forming a continuous catheter body tubing; and

severing the continuous catheter body tubing into catheter bodies of length "Z", the catheter bodies each having a proximal portion and a distal portion, wherein the distal portion has a distal end, a distal outer layer, and a length of approximately "X", and wherein the distal portion is substantially formed of the first material.

2. The method of claim **1**, wherein the first material is softer than the second material, such that the distal portion is more flexible than the proximal portion.

3. The method of claim **1**, wherein the initial layer segments have tapered proximal ends and tapered distal ends, and wherein the final layer overlies at least a portion of the tapered proximal and distal ends of the initial layer segments.

4. The method of claim **1**, wherein the continuous inner jacket is formed of a lubricious material.

5. The method of claim **1**, wherein the distal outer layer of the distal portion is formed of the first material.

6. The method of claim **1**, further comprising the steps of:

forming a distal soft tip segment; and

attaching the distal soft tip segment to the distal end of the distal portion of each catheter body.

7. The method of claim **1**, wherein the step of forming initial layer segments further comprises the step of forming the initial layer segments as linear lines of thickness "Y" and length "X" along at least a portion of the inner jacket, thereby leaving the remaining portion of the inner jacket exposed;

and wherein the step of forming the final layer further comprises the step of forming the final layer over the exposed portion of the inner jacket and along the linear lines of the initial layer segments.

8. The method of claim **1**, wherein the step of forming a continuous inner jacket further comprises the step of:

forming a reinforcement layer overlying the outer surface of the continuous inner jacket.

9. The method of claim **8**, wherein the reinforcement layer is a wire braid.

10. A method of fabricating medical catheter bodies of length "Z" from continuous catheter body tubing, comprising the steps of:

extruding a continuous inner jacket having an outer surface and a catheter lumen extending therethrough;

forming initial layer segments on the outer surface of the continuous inner jacket, each initial layer segment having a length "X" and a thickness "Y" and being separated by a length "Z–X" along the length of the continuous inner jacket, wherein the initial layer segments are formed of a first material;

subsequently forming intermediate layer segments adjoining the initial layer segments along the length of the continuous inner jacket, each intermediate layer segment having a length "x" such that the contiguously formed initial and intermediate layer segments are separated by a length of approximately "Z–(X+x)", wherein the intermediate layer segments are formed of an intermediate material;

thereafter forming a final layer of a second material and having a thickness "Y+y" over at least a portion of the inner jacket, thereby forming a continuous catheter body tubing; and

severing the continuous catheter body tubing into catheter bodies of length "Z", the catheter bodies each having a proximal portion, an intermediate portion and a distal portion, wherein the distal portion has a distal end, a distal outer layer, and a length of approximately "X", and wherein the distal portion is substantially formed of the first material.

11. The method of claim **10**, wherein the hardness of the first material is less than the hardness of the second material, such that the distal portion is more flexible than the proximal portion.

12. The method of claim **11**, wherein the hardness of the intermediate material is different from both the hardness of the first material and the hardness of the second material.

13. The method of claim **10**, wherein the initial layer segments have tapered proximal ends and tapered distal ends, and wherein the final layer overlies at least a portion of the tapered distal end of each initial layer segment, and wherein each intermediate layer segment overlies at least a portion of the proximal end of each initial layer segment.

14. The method of claim **10**, wherein the continuous inner jacket is formed of a lubricious material.

15. The method of claim **10**, wherein the distal outer layer of the distal portion is formed of the first material.

16. The method of claim **10**, further comprising the steps of:

forming a distal soft tip segment; and

attaching the distal soft tip segment to the distal end of the distal portion of each catheter body.

17. The method of claim **10**, wherein the step of forming initial layer segments further comprises the step of forming the initial layer segments as linear lines of thickness "Y" and length "X" along at least a portion of the inner jacket, thereby leaving the remaining portion of the inner jacket exposed;

and wherein the step of forming the final layer further comprises the step of forming the final layer over the exposed portion of the inner jacket and along the linear lines of the initial layer segments.

18. The method of claim **10**, wherein the step of forming a continuous inner jacket further comprises the step of:

forming a reinforcement layer overlying the outer surface of the continuous inner jacket.

19. The method of claim **18**, wherein the reinforcement layer is a wire braid.

20. A method of fabricating medical catheter bodies of length "Z" from continuous catheter body tubing, comprising the steps of:

extruding a continuous inner jacket having an outer surface and a catheter lumen extending therethrough;

forming initial layer segments on the outer surface of the continuous inner jacket, each initial layer segment having a length "X" and thickness "Y" and being separated by a length "Z–X" along the length of the continuous inner jacket, wherein the initial layer segments are formed of a first material;

subsequently forming a final layer of a second material and having a thickness "Y+y" over at least a portion of the inner jacket, thereby forming a continuous catheter body tubing; and

severing the continuous catheter body tubing into catheter bodies of length "Z", the catheter bodies each having a proximal portion and a distal portion, wherein the distal portion has a distal end, and a distal outer layer formed of the first material.

21. The method of claim **20**, wherein the first material is softer than the second material, such that the distal portion is more flexible than the proximal portion.

22. The method of claim **20**, wherein the continuous inner jacket is formed of a lubricious material.

23. The method of claim **20**, further comprising the steps of:

forming a distal soft tip segment; and

attaching the distal soft tip segment to the distal end of the distal portion of each catheter body.

24. The method of claim **20**, wherein the step of forming a continuous inner jacket further comprises the step of:

forming a reinforcement layer overlying the outer surface of the continuous inner jacket.

25. The method of claim **24**, wherein the reinforcement layer is a wire braid.

* * * * *

EXHIBIT F

US005690613A

United States Patent [19]

Verbeek

[11] Patent Number: 5,690,613

[45] Date of Patent: Nov. 25, 1997

[54] **RAPID EXCHANGE HIGH PRESSURE TRANSITION FOR HIGH PRESSURE CATHETER WITH NON-COMPLIANT BALLOON**

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[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[21] Appl. No.: **759,696**

[22] Filed: **Dec. 6, 1996**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **604/103**; 604/96; 606/194

[58] **Field of Search** 604/96–104, 282; 128/898; 606/191–200, 108; 600/201, 204, 207

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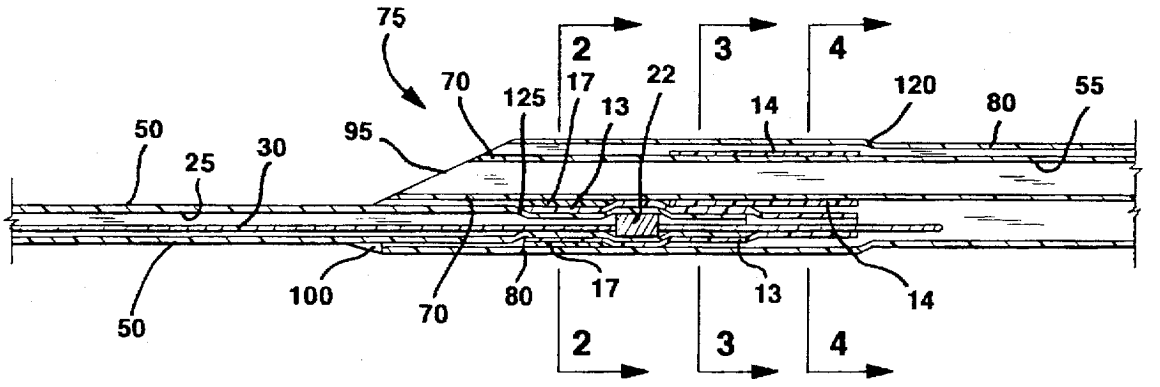
Primary Examiner—Glenn K. Dawson

Attorney, Agent, or Firm—Dianne M.F. Plunkett; Harold R. Patton

[57] **ABSTRACT**

A medical catheter is provided which includes a core wire extending longitudinally through inflation tubing. The inflation tubing defines an inflation lumen. The distal end of the inflation tubing extends longitudinally through a tubular first reinforcement band which terminates distal to the distal end of the inflation tubing. An inner lumen tube defines a guidewire lumen, the inner lumen tube being biaxial with the inflation tubing and running longitudinally along the outer diameter of the inflation tubing. The inner lumen tube extends longitudinally through a shim tube which has a longitudinal slit running along its top side. The inner lumen tubing which has the shim coaxially bonded thereon extends longitudinally through a shaft tube. The inflation tube with the first reinforcement band coaxially bonded thereon also extends longitudinally through the shaft tube. The shaft tube is bonded to the inner lumen tube and to the inflation tube. A metal piece may be bonded to the inflation tube. An inflatable balloon is mounted at the distal end of the shaft tube, the balloon is in fluid communication with the inflation lumen.

22 Claims, 3 Drawing Sheets



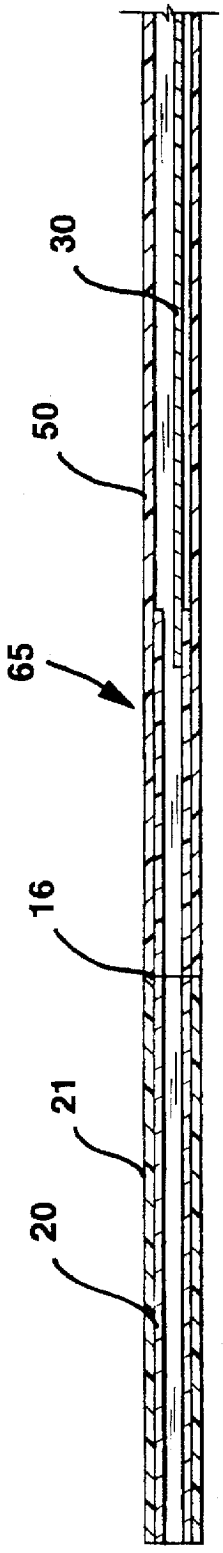


FIG.1A

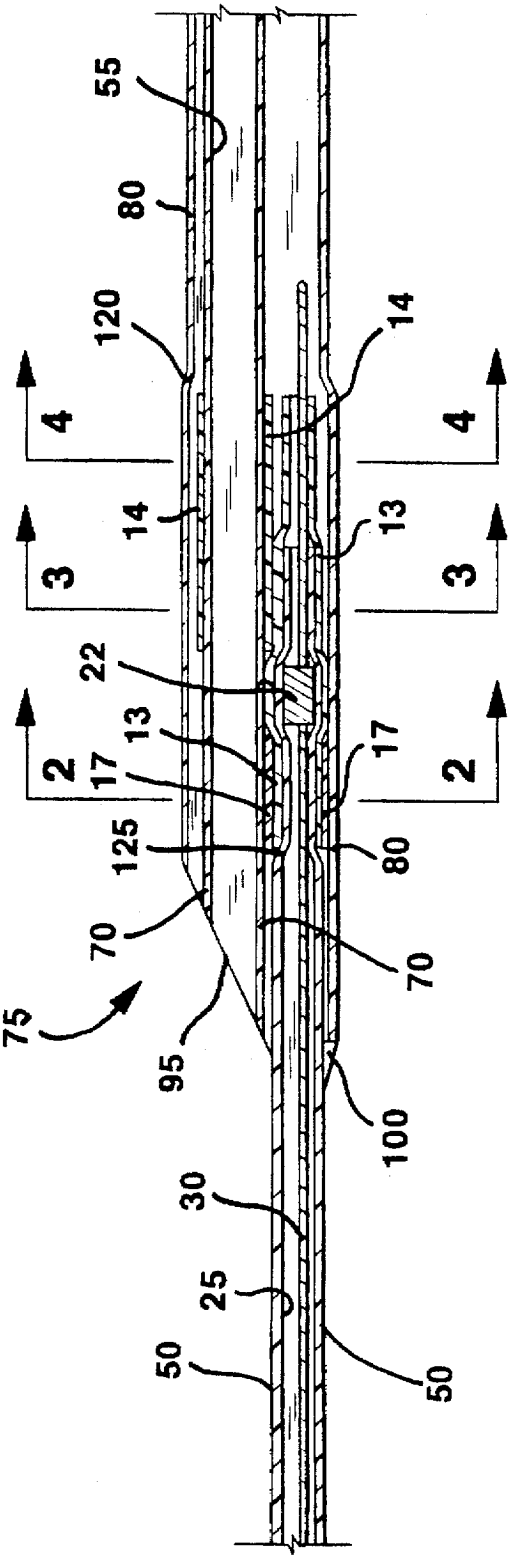


FIG. 1B

FIG.1 FIG.1A FIG.1B FIG.1C

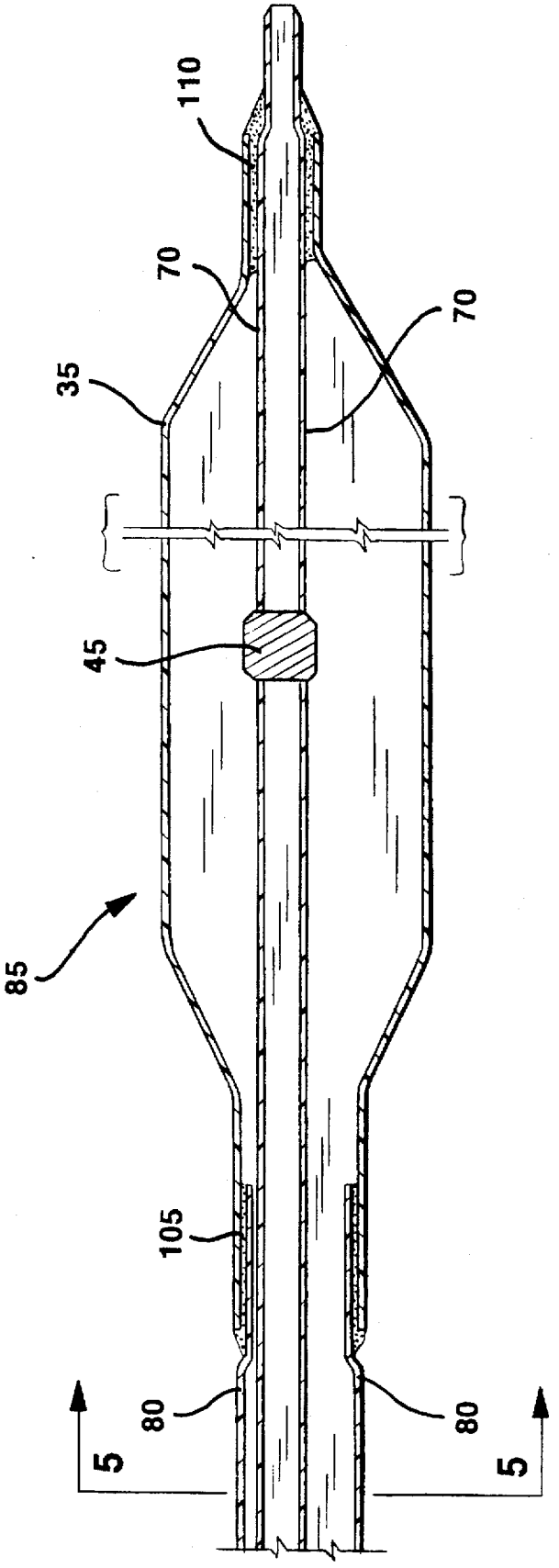


FIG. 1C

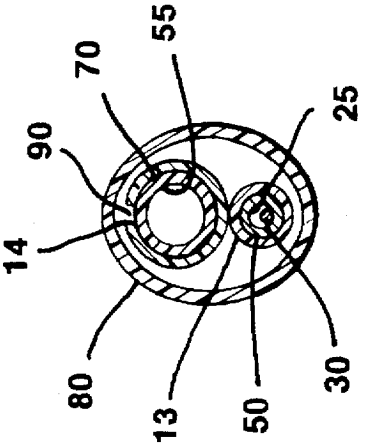


FIG. 3

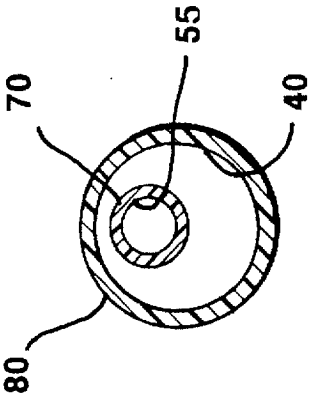


FIG.5

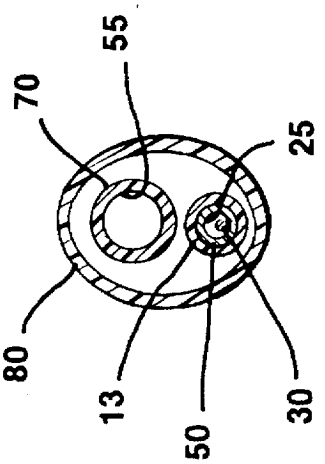


FIG. 2

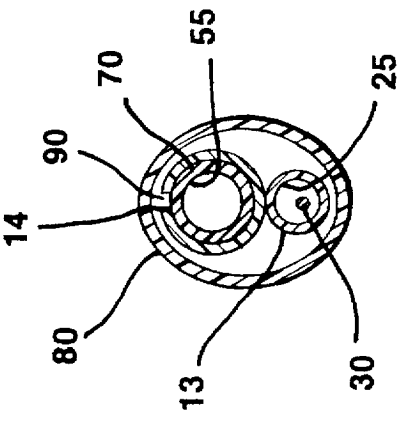


FIG. 4

RAPID EXCHANGE HIGH PRESSURE TRANSITION FOR HIGH PRESSURE CATHETER WITH NON-COMPLIANT BALLOON

FIELD OF THE INVENTION

The present invention relates to angioplasty catheters, and more particularly, to a shaft transition section for a rapid exchange high pressure balloon catheter.

BACKGROUND OF THE INVENTION

One of the therapeutic procedures applicable to the present invention is known as percutaneous transluminal coronary angioplasty (PTCA). This procedure can be used, for example, to reduce arterial build-up of .cholesterol fats or atherosclerotic plaque. Typically a first guidewire of about 0.038 inches in diameter is steered through the vascular system to the site of therapy. A guiding catheter, for example, can then be advanced over the first guidewire to a point just proximal of the stenosis. The first guidewire is then removed. A balloon catheter on a smaller 0.014 inch diameter second guidewire is advanced within the guiding catheter to a point just proximal of the stenosis. The second guidewire is advanced into the stenosis, followed by the balloon on the distal end of the catheter. The balloon is inflated causing the site of the stenosis to widen. The original catheter can then be withdrawn and a catheter of a different size or another device such as an atherectomy device can be inserted.

Conventional angioplasty balloons fall into high, medium, and low pressure ranges. Low pressure balloons are those that have burst pressures below 6 atmospheres (6.1×10^5 Pascals). Medium pressure balloons are those that have burst pressures between 6 and 12 atm (6.1×10^5 and 1.2×10^6 Pa). High pressure balloons are those that have burst pressures above 12 atm (1.2×10^6 Pa). Burst pressure is determined by such factors as wall thickness and tensile strength, for example.

High pressure balloons are desirable because they have the ability to exert more force and crack hard lesions. High pressure balloons are also useful in stent deployment. A biocompatible metal stent props open blocked coronary arteries, keeping them from reclosing after balloon angioplasty. A balloon of appropriate size and pressure is first used to open the lesion. The process is repeated with a stent crimped on a high pressure balloon. The stent is deployed when the balloon is inflated. A high pressure balloon is useful for stent deployment because the stent must be forced against the artery's interior wall so that it will fully expand thereby precluding the ends of the stent from hanging down into the channel encouraging the formation of thrombus.

Rapid exchange catheters are those which have shorter guidewire lumens passing from the distal end of the catheter through the balloon and opening to the exterior of the catheter somewhere proximal to the balloon. Catheter exchanges over the guidewire are easier to accomplish because they can be done with a single operator rather than two operators as required by over-the-wire catheters.

The catheter shaft area where the proximal end of the guidewire lumen begins is known as the transition area. Maintaining flexibility, a low profile and a strong bond in the transition area is difficult when high pressures of greater than 450 psi (31 bar) are used. With such pressures, parts could delaminate and separate. Typically, the area having the least bond strength, with the exception of the balloon area, is at the transition section where components meet and the tubing is necked down and/or weakened by heat.

U.S. Pat. Nos. 5,328,472 and 5,410,797 to Steinke et at. disclose flexible biaxial tubes which form the transition region. The rated burst pressure for this product is 10 bar with a transition area capable of 14 bar.

U.S. Pat. No. 5,545,134 to Hilaire et al. discloses a tube which comprises in its upper part a channel with a substantially circular cross-section which, once drawn, constitutes the second inner duct for the passage of a guide-wire, and in its lower part a second channel with a cross-section having substantially the shape of a crescent or kidney, which progressively disappears by stretching.

U.S. Pat. No. 5,549,556 to Ndondo-Lay et al in FIG. 6 and U.S. Pat. No. 5,549,557 to Steinke et al in FIG. 2 disclose a biaxial guidewire and inflation lumen. The inflation lumen being defined by a spring coil and an inflation lumen jacket with a central core wire. Such a transition construction withstands pressures of up to 400 psi.

What is needed is a rapid exchange catheter with a shaft transition that can reliably withstand internal pressure of at least 450 psi (31 bar) without leaking or rupturing which is relatively easy, consistent and reliable to manufacture.

SUMMARY OF THE INVENTION

The above features and advantages of the present invention, as well as others, are accomplished by providing a medical catheter comprising a core wire extending longitudinally through inflation tubing. The inflation tubing defines an inflation lumen. The distal end of the inflation tubing extends longitudinally through a tubular first reinforcement band which terminates distal to the distal end of the inflation tubing. An inner lumen tube defines a guidewire lumen, the inner tureen tube being biaxial with the inflation tubing and running longitudinally along the outer diameter of the inflation tubing. The inner lumen tube extends longitudinally through a shim tube which has a longitudinal slit running along its top side. The inner lumen tubing which has the shim coaxially bonded thereon extends longitudinally through a shaft tube. The inflation tube with the first reinforcement band coaxially bonded thereon also extends longitudinally through the shaft tube. The shaft tube is bonded to the inner lumen tube and to the inflation tube. A metal piece may be bonded to the inflation tube. An inflatable balloon is mounted at the distal end of the shaft tube, the balloon is in fluid communication with the inflation lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a longitudinal cross section of the proximal end of the shaft of the present invention;

FIG. 1B is a longitudinal cross-section of the transition section;

FIG. 1C is a longitudinal cross-section of the balloon;

FIG. 2 is a cross-section taken along the lines 2—2 of FIG. 1B before heat shrinking;

FIG. 3 is a cross-section taken along the lines 3—3 of FIG. 1B before heat shrinking;

FIG. 4 is a cross-section taken along the lines 4—4 of FIG. 1B before heat shrinking; and

FIG. 5 is a cross-section taken along the lines 5—5 of FIG. 1C.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a 6 French compatible, rapid exchange catheter with a transition that can reliably

withstand internal pressure of at least 450 psi (31 bar) pressure without leaking or rupturing which is relatively easy, consistent and reliable to manufacture. FIG. 1A–1C are longitudinal cross-sectional views of a high pressure balloon catheter adapted for use in percutaneous transluminal coronary angioplasty (PTCA). FIG. 1A represents the proximal section **65**. FIG. 1B represents the transition section **75**. FIG. 1C represents the balloon section **85**. With the addition of a metal piece such as a marker band **22**, an irradiated reinforcement band of at least 8 mm in length and a shim **14** with a longitudinal slit **90** along the top side, the transition section **75** can withstand 2.44 Lbf or 10.8 N, which is over twice the typical catheter 5N minimum requirement.

The proximal section **65** of the shaft seen in FIG. 1A is made of a stainless steel 0.0232 inch (0.58 mm) outer diameter hypotube **20**, a stainless steel core wire **30** tapering down from a 0.305 mm proximal end to a 0.102 mm distal end for flexibility, a 0.026 inch (0.66 mm) outer diameter clear laminate irradiated shaft tubing **21** and polyimide tubing **50** with essentially the same outer diameter as the shaft **21**, or a minimal variance such as an 0.029 inch (0.74 mm) outer diameter. The distal end of the irradiated shaft tubing **21** is adhesively bonded to the proximal end of the polyimide tubing **50** using polyimide shaft adhesive **16**.

The transition section **75** shown in FIG. 1B is designed to handle at least 450 psi (31 bar) pressure and still remain flexible enough to navigate torturous paths. The transition section **75** of the shaft seen in FIG. 1B adds the following components to the assembly, an exit marker band **22** made of radiopaque metal such as Pt/Ir or stainless steel, a reinforcement band **13** of a clear material such as irradiated Linear Low Density Polyethylene (LDPE), inner lumen tubing **70** defining a guidewire lumen made of High Density Polyethylene (HDPE), and an inner lumen shim **14** made of LDPE.

The balloon section **85** seen in FIG. 1C comprises distal shaft tubing **80** made of 50% HDPE/50% LDPE, a balloon **35** made of any material suitable for high pressures above 12 atm such as PET, PET blends or Nylon, and a balloon marker band **45** made of any suitable radiopaque metals such as platinum/iridium.

Begin the assembly process by preparing the polyimide tubing **50**. Neck and trim the polyimide tubing **50** by inserting the distal end of polyimide tubing **50** having an outer diameter of 0.029 inches (0.74 mm) and an inner diameter of 0.0249 inches (0.63 mm) into the 0.022 inch diameter of the stepped mandrel. The stepped mandrel consists of a 0.022 inch outside diameter hypotube having an internal diameter to allow insertion of a 0.012 inch mandrel, which after insertion forms the stepped mandrel. Locate 9 mm of the tubing **50** onto the 0.012 inch section of the stepped mandrel.

Bonding a metal piece such as a marker band **22** into the transition section **75**, and preferably to the inner diameter of the polyimide tubing **50** increases the pull strength of the transition section **75** thereby reducing the likelihood of separation under high inflation pressures. Greater force can be applied in the proximal direction without the polyimide tubing **50** separating from the reinforcement band **13**. A radiopaque metal can be used for the marker band **22**. This permits the marker band **22** to perform the function of allowing the physician to visualize with fluoroscopy the location of the guidewire exit at the proximal end of the inner lumen tubing **70**. To accomplish the dual purpose of visualization and greater pull strength, slide an marker band **22** with an outside diameter of 0.56 mm and an inside diameter of 0.43 mm inside the polyimide tubing **50** and onto the 0.012 inch section of the stepped mandrel 5 mm distal from the distal end of the 0.022 inch section of the stepped mandrel. Pull back the 0.012 inch section mandrel far enough to be able to grasp the distal end of the tubing **50** with needle nose pliers. To anchor the marker band **22** within the transition section **75**, perform necking by locating the tubing **50** which is over the 0.012 portion of the mandrel, over a heat source. Neck the distal end of the tubing **50** down to a 0.012 inch inner diameter for a trim length of 11.0 mm. This length is just long enough for anchoring and bonding. Trim the polyimide tubing **50** on the proximal side to a 20 cm length while inserted into a 0.022 inch mandrel.

Without a metal piece such as a marker band **22** in the transition section **75**, the polyimide tubing **50** can be pulled out of the reinforcement band **13** with less effort because the weakest part of the bonding is between the polyimide tubing **50** and the reinforcement band **13**. Adding the metal marker band **22** means that the marker band **22** must push aside all the material in the transition section **75** much like pulling a Ping-Pong ball through a tube with a smaller diameter than the diameter of the Ping-Pong ball.

Expand a 30 mm section of reinforcement band **13** to a diameter which is suitable for fitting over the polyimide tubing **50**. The reinforcement band **13** must be irradiated to prevent the walls from melting and thinning. The wall formed by the reinforcement band **13** must be preserved because the wall from the inner lumen tubing **70** melts away and the reinforcement band **13** wall is then the last barrier for the pressure. For optimal pull strength the portion of the polyimide tubing **50** beyond the neck **125** where the reinforcement band **13** is crimped onto must be at least 10 mm. Testing showed reinforcement band **13** lengths of 6 mm was too short while a length of more than 12 mm was unnecessary. Locate the reinforcement band **13** over the distal end of the polyimide tubing **50** subassembly. Verify that the proximal end of the reinforcement band **13** is aligned with the polyimide tubing necking **125**. The reinforcement band **13** will overlap the 0.433 inch (11 mm) length of the necked down distal end of the polyimide tubing **125**, and will extend distally from the tubing **50** for a minimum length of 3 mm.

The distal end of the reinforcement band **13** will extend 0.315 inches (8 mm preferably with a range of 7 mm to 9 mm) beyond the distal end of the polyimide tubing **50**. The proximal end of the reinforcement band **13** terminates at the neck **125** of the polyimide tubing so as to maintain a minimum profile. Using a heat source, shrink the reinforcement band **13** onto the polyimide tubing **50**. The shim **14** length may range between approximately 9 mm and 11 mm. The distance between the polyimide tubing neck **125** and the distal end of the inner lumen shim **14** is approximately 0.748 inches (19.00 mm). The purpose of the inner lumen shim **14** is to fill the gap between the reinforcement band **13**, inner lumen tubing **70** and distal shaft **80** distally from the exit marker band **22** and proximally from the distal shaft neck **120** with a material which has a melt compatibility with the material in both the LDPE reinforcement band **13** and the HDPE inner lumen tubing **70** so as to bond the pieces together and prevent leakage at high pressures.

Slit and trim the shim **14** into 10 mm lengths and cut a straight slit **90** from one end to the other. When positioned in the transition prior to melting, it is important that the slit **90** in shim **14** is on top. This is because melting shrinkage occurs in the opposite direction of the slit, i.e., downwards. The top of the distal shaft tubing **80** will shrink onto and bond with the top of the inner lumen tubing **70**. The ends of the inner shim **14** (left and right from the slit **90**) will pull

down and fill in the cavities between the distal shaft tubing **80** and the inner tureen **70** and the reinforcement band **13**. A mandrel in the guidewire lumen **55** and also in the inflation tureen **25** prevents these lumens from collapsing during heat shrinking and bonding of the transition section **75**. The inflation/core wire lumen **25** empties into the inflation lumen **40** which is defined by the shaft **80**. The inner lumen tubing **70** defines the guidewire lumen **55** and should have an inner diameter suitable for passing a standard 0.014 inch guidewire, as for example, 0.017 inches (0.43 mm). Neck the inner lumen tubing **70** within a 3 mm section to an outside diameter of approximately 0.457 mm to 0.559 mm. Cut the inner lumen tubing **70** to approximately 208–212 mm and preferably to 210 mm.

When no marker band **22** is used but adhesive is used to bond the polyimide tubing **50** to the reinforcement band **13** it is important that all surfaces are clean so as to reduce impurities contributing to separation failures. Clean and activate the surfaces with plasma treating. Ultraviolet (UV) curable adhesive could be used to bond the polyimide tubing **50** and reinforcement band **13** together. Put UV-curable adhesive on the polyimide tubing neck **125** and shrink the reinforcement band **13** around it. Cure the UV adhesive.

As seen in FIG. 1B, an optional second reinforcement band **17** with a length of 1.5 mm (0.06 inch) and a preshrunk wall thickness of 0.03 mm (0.001 inch), could also be placed proximal to the marker band **22** and coaxially over the proximal end of the reinforcement band **13**. The second reinforcement band **17** would be placed proximal to the marker band **22** so that circumferential rigidity is increased. To increase the pull strength still further in the transition section **75**, the material proximal to the marker band **22** could be made even more rigid. This can be done by using polyester tubing for the second reinforcement band **17**. Polyester is more rigid than the LDPE. The second reinforcement band **17** could be used in conjunction with the marker band **22** or without the marker band **22**. Pull strength is greatest with both the marker band **22** and the second reinforcement band **17**. Pull strength is less with the marker band **22** only. Having the second reinforcement band **17** without the marker band **22** would not significantly increase pull strength. Omitting the marker band **22** simplifies manufacturing and reduces cost.

Assemble the distal shaft tubing **80** and the inner lumen tubing **70** as follows. Expand the proximal end of the distal shaft tubing **80** such that it will fit over the many layers of tubing within, including the inner lumen tubing **70**, inner lumen shim **14**, polyimide tubing **50**, reinforcement band **13** and exit marker band **22**. Assemble the shim **14** slit **90** face up onto the inner lumen tubing **70** such that the distal end of the shim **14** is 21.5 mm to 22.5 mm (0.846 inch to 0.886 inch) away from the proximal end of the inner lumen tubing **70**. A mandrel with 0.0165 inch (0.42 mm) diameter is inserted in the inner lumen tubing **70**. Locate the shim **14** assembly in the proximal end of the distal shaft **80** such that the distal end of the shim **14** is aligned with the distal shaft neck **120**. Insert the two stepped mandrel of 0.022/0.012 inch inside the polyimide tubing **50** in such a way that the 0.012 section of the mandrel will extend from the distal end of the reinforcement band **13** with 5.0 to 10.0 mm (0.20 inch–0.39 inch). Insert the distal end of the polyimide tubing **50** into the proximal end of the distal shaft tubing **80**. The distal end of the clear reinforcement band **13** preferably extends past the polyimide tubing **50** by 8 mm. Locate the distal end of the clear reinforcement band **13**, in alignment with the distal end of the shim **14**. After fitting the expanded distal shaft tubing **80** over these layers, heat shrink the distal shaft tubing **80** tightly down using a conventional heat source. The resulting distal shaft tubing **80** in the transition section **75** will have a major outer diameter of 0.048 inches (1.22 mm) and a minor outer diameter of 0.038 inches (0.97 mm).

Trim the excess proximal end of the distal shaft tubing **80** to just proximal to the proximal end of the inner lumen **70** tubing. Remove the 0.0163 inch mandrel from the transition section **75**. Skive **95** the proximal end of the inner lumen tubing **70** at an angle of approximately 10 degrees for a length of 2 mm. Use a suitable medical grade cyanoacrylate adhesive such as Loctite® 420 preferably or 421 (manufactured by Loctite Corp. in Hartford Conn.) to create a polyimide shaft adhesive **100** fillet at the proximal end of the trimmed area of the inner lumen tubing **70** on the distal shaft tubing **80** perimeter. The purpose of the adhesive fillet **100** is to smooth the transition from the polyimide tubing **50** to the larger outer diameter of the distal shaft tubing **80** and to provide a secondary pressure seal for the inflation lumen **25**. Remove the 0.022/0.012 inch stepped mandrel from the polyimide tubing **50**.

Various visual markers can be applied onto the hypotube **20** and the polyimide shaft tubing **50**. The markers can be used for physician end marks without the need for angiography; such end marks include the brachial approach or the femoral approach and the guidewire exit marker band **22**. Markers should be approximately 2 mm to 4 mm wide around the polyimide tubing **50**. Bond the balloon marker band **45** to the inner lumen tubing **70** using conventional adhesives.

Trim the balloon **35** tails to 2 mm at the distal neck end and to 4.5 mm at the proximal neck end. Neck down a 2 mm length of the distal end of the distal shaft tubing **80** for 1.5 mm diameter balloons. Balloons larger than a 1.5 mm diameter need not be necked down. Bonding surfaces may be treated to facilitate bonding. Bond the proximal balloon tall to the distal end of the distal shaft tubing **80** with any conventional manner such as adhesive **105**. Bond the distal balloon tail to the distal end of the inner lumen tubing **70** with any conventional manner such as adhesive **110**.

Prepare the hypotube assembly. Cut a hypotube **20** with an outer diameter of 0.0232 inches and an inner diameter of 0.010 to 0.012 inches to 42.13 inches in length. Braze the core wire **30** to the hypotube **20**. The core wire **30** provides push and prevents the polyimide tubing **50** and transition area **75** from kinking when bent. Place the proximal end of the core wire **30** into the distal end of the hypotube **20** such that there is about a 7.0 mm to 9.0 mm overlap, and braze. Heat shrink the clear laminate irradiated shaft tubing **21** onto the hypotube and trim such that approximately 1.575 inches (40.0 mm) of the distal end of the hypotube **20** extends beyond the irradiated shaft tubing **21** on the distal end and approximately 50.0 mm extends on the proximal end. Insert the polyimide tubing **50** assembly onto the hypotube Align the core wire **30** through the transition section **75**. Apply a suitable medical grade cyanoacrylate adhesive such as Loctite® 420 (manufactured by Loctite Corp. in Hartford Conn.) to the hypotube **20** and abut the proximal end of the polyimide tubing **50** with the distal end of the irradiated shaft tubing **21**.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the appended claims.

No.	Component
13	First Reinforcement Band
14	Inner Lumen Shim
16	Polyimide Shaft Adhesive
17	Second Reinforcement Band
20	Hypotube
21	Irradiated Shaft Tubing
22	Marker Band
25	Core Wire Lumen/ Inflation Lumen
30	Core Wire
35	Balloon
40	Inflation Lumen
45	Balloon Marker Band
50	Polyimide Tubing
55	Guidewire Lumen
65	Proximal Section
70	Inner Lumen Tubing
75	Transition Section
80	Distal Shaft Tubing
85	Balloon Section
90	Slit
95	Skive
100	Adhesive Fillet
105	Proximal Bond Adhesive
110	Distal Bond Adhesive
120	Distal Shaft Neck
125	Polyimide Tubing Neck

What is claimed is:

1. A medical catheter comprising:

a proximal section having a proximal end and a distal end;

a transition section having a proximal end and a distal end;

a balloon section having a proximal end and a distal end, the distal end of the proximal section being affixed to the proximal end of the transition section, the distal end of the transition section being affixed to the proximal end of the balloon section, the balloon section having a balloon mounted at the distal end, the transition section further comprising:

an inflation tube defining an inflation lumen, the inflation tubing having an inner diameter, an outer diameter, a proximal end and a distal end, the balloon being in fluid communication with the inflation lumen;

a first reinforcement band having a distal end and a proximal end, the distal end of the inflation tube extending longitudinally through the first reinforcement band, the distal end of the first reinforcement band terminating distal to the distal end of the inflation tube;

an inner lumen tube defining a guidewire lumen, the inner lumen tube being biaxial with the inflation tubing and running longitudinally along the outer diameter of the inflation tubing;

a shim tube, the inner lumen tube extending longitudinally through the shim tube, the shim tube having a proximal end and a distal end;

a shaft tube defining a shaft lumen; and

the inner lumen tube having the shim tube coaxially bonded thereon extending longitudinally through the lumen of the shaft tube, the inflation tube with the first reinforcement band coaxially bonded thereon also extending longitudinally through the lumen of the shaft tube, the shaft tube being bonded to the inner lumen tube and to the inflation tube.

2. A catheter according to claim 1 wherein the inflation tube has a core wire extending longitudinally therethrough.

3. A catheter according to claim 1 wherein the shim tube has a longitudinal slit running along a top portion of the shim tube.

4. A catheter section according to claim 1 wherein the first reinforcement band is necked down over the distal end of the inflation tube such that the distal end of the shim tube is aligned with the distal end of the first reinforcement band.

5. A catheter according to claim 1 wherein the inflation tube is necked down proximal to the proximal end of the first reinforcement band, the necked down portion of the inflation tube abuts the proximal end of the first reinforcement band.

6. A catheter according to claim 1 wherein the shaft is necked down distal to and abutting the distal end of the shim.

7. A catheter according to claim 1 wherein a metal piece having a proximal end and a distal end is bonded to an inner surface of the inflation tube.

8. A catheter according to claim 7 wherein the proximal end of the shim tube is distal to the distal end of the metal piece.

9. A catheter according to claim 7 wherein the metal piece is made of a radiopaque material.

10. A catheter according to claim 1 wherein the first reinforcement band extends beyond the inflation tube by at least 5 mm.

11. A catheter according to claim 1 wherein the first reinforcement band is made of irradiated LDPE.

12. A catheter according to claim 1 wherein the shim tube is at least about 10 mm long.

13. A catheter according to claim 1 having a second reinforcement band, the second reinforcement band having a distal end and a proximal end, the inflation tube extending longitudinally through the second reinforcement band, the second reinforcement band distal end being proximal to the first reinforcement band proximal end.

14. A medical catheter comprising:

a proximal section having a proximal end and a distal end;

a transition section having the proximal end and a distal end;

a balloon section having a proximal end and a distal end, the distal end of the proximal section being affixed to the proximal end of the transition section, the distal end of the transition section being affixed to the proximal end of the balloon section, the balloon section having a balloon mounted at the distal end, the transition section further comprising:

an inflation tube, the inflation tube defining an inflation lumen, the inflation tube having an inner diameter, an outer diameter, a proximal end and a distal end, the balloon being in fluid communication with the inflation tube;

a first reinforcement band having a distal end and a proximal end, the distal end of the inflation tube extending longitudinally through a first reinforcement band, the distal end of the first reinforcement band terminating distal to the distal end of the inflation tube, the first reinforcement band being necked down over the distal end of the inflation tube, the inflation tube being necked down proximal to the proximal end of the first reinforcement band, the necked down portion of the inflation tube abutting the proximal end of the first reinforcement band;

an inner lumen tube defining a guidewire lumen, the inner lumen tube being biaxial with the inflation tubing and running longitudinally along the outer diameter of the inflation tubing;

a shim tube, the inner lumen tube extending longitudinally through the shim tube, the shim tube having a proximal end and a distal end, the distal end of the shim tube being aligned with the distal end of the first

reinforcement band, the shim tube having a longitudinal slit running along a top portion of the shim tube;

a shaft tube defining a shaft lumen; and

the inner lumen tube having the shim tube coaxially bonded thereon extending longitudinally through the shaft tube, the inflation tube with the first reinforcement band coaxially bonded thereon also extending longitudinally through the shaft tube, the shaft tube being bonded to the inner lumen tube and to the inflation tube, the shaft being necked down distal to and abutting the distal end of the shim tube.

15. A transition section according to claim **14** wherein a core wire extends longitudinally through the inflation lumen.

16. A transition section according to claim **14** wherein the first reinforcement band and the shim tube are made of LDPE.

17. A transition section according to claim **14** wherein the inner lumen tube is made of HDPE.

18. A transition section according to claim **14** wherein a metal piece is bonded to the inflation tube.

19. A transition section according to claim **14** wherein the proximal end of the shim tube is distal to the distal end of the metal piece.

20. A transition section according to claim **14** having a second reinforcement band, the second reinforcement band having a distal end and a proximal end, the inflation tube extending longitudinally through the second reinforcement band, the second reinforcement band distal end being proximal to the first reinforcement band proximal end.

21. A medical catheter comprising:

a proximal section, a balloon section and a transition section therebetween, the transition section further comprising:

a shaft tube;

inflation lumen means for fluid communication with the balloon section, the inflation lumen means within the shaft tube;

metal reinforcing means for interior reinforcement of the inflation lumen means;

band reinforcing means for exterior reinforcement of the inflation lumen means at a distal end of the inflation lumen means, the band reinforcing means bonded to the inflation lumen means and to the shaft tube;

guidewire lumen means within the shaft tube in side-by side relation with the inflation lumen means; and

shim means for filling the space between the guidewire lumen means, the shaft tube and the band reinforcing means; the shim means bonded to the guidewire tureen means, the shaft tube and the band reinforcing means.

22. A method for making a medical catheter comprising the steps of:

providing an inflation lumen tube;

providing a reinforcing tube;

applying the reinforcing tube to the inflation lumen tube by shrinking the reinforcing tube into contact with an end of the inflation lumen tube;

providing a guidewire lumen tube;

providing a shim of material having a melting temperature which is less than the melting temperature of the guidewire lumen tube and less than the melting temperature of the reinforcing tube;

applying the shim around the guidewire lumen tube;

providing a heat shrinkable shaft tube;

inserting the guidewire lumen tube and shim and the inflation lumen tube and reinforcing tube into the shaft tube; and

heating the shaft tube to a temperature such that the shaft tube shrinks and the shim melts to bond the guidewire lumen tube, the shaft and reinforcing tube.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : **5,690,613**

DATED : **Nov. 25, 1997**

INVENTOR(S) : **Maurice T.Y. Verbeek**

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

C. 10 L. 11 **"guidewire tureen" to be changed to "guidewire lumen"**

Signed and Sealed this

Nineteenth Day of October, 1999

Attest:

Attesting Officer

Q. TODD DICKINSON

Acting Commissioner of Patents and Trademarks

EXHIBIT G

US005328472A

United States Patent [19]

Steinke et al.

[11] **Patent Number: 5,328,472**

[45] **Date of Patent: Jul. 12, 1994**

[54] **CATHETER WITH FLEXIBLE SIDE PORT ENTRY**

[75] Inventors: **Thomas A. Steinke**, San Diego; **Leonard F. Briggs**, Chula Vista; **Garry E. Rupp**, San Diego, all of Calif.

[73] Assignee: **Medtronic, Inc.**, Minneapolis, Minn.

[21] Appl. No.: **919,672**

[22] Filed: **Jul. 27, 1992**

[51] **Int. Cl.**[5] **A61M 29/00**

[52] **U.S. Cl.** **604/102**; 604/96; 604/282; 606/194

[58] **Field of Search** 604/96, 102, 280, 282; 128/656-658, 772; 606/191, 192, 194

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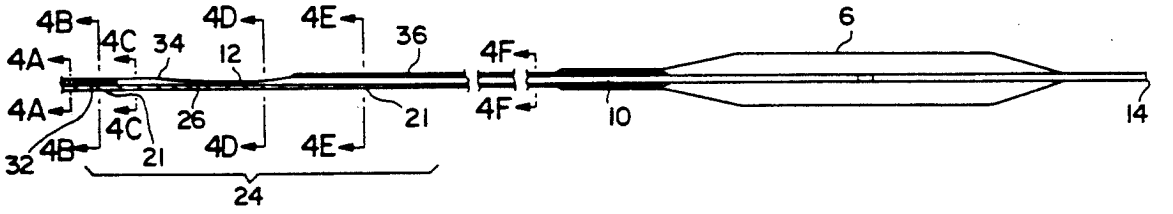
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Corrine Maglione
Attorney, Agent, or Firm—Dianne M. F. Plunkett; Harold R. Patton

[57] **ABSTRACT**

An improved balloon catheter is disclosed which is comprised of two jacketed spring coils placed end-to-end and joined by a linking element which contains a lumen communicating between the inflation lumens formed by the two spring coils. A side port entry to a guidewire lumen, which extends through the distal coil to the distal end of the catheter, is located in the transition region formed by the linking element. The linking element may include two polyimide tubes or may be a multilumen insert. The catheter is stiffened by a core wire which is bonded directly to the spring coils. A catheter comprised of a single spring coil with a side port entry in the coil is also disclosed, and a method and apparatus for crimping the coil to create the entry.

12 Claims, 7 Drawing Sheets



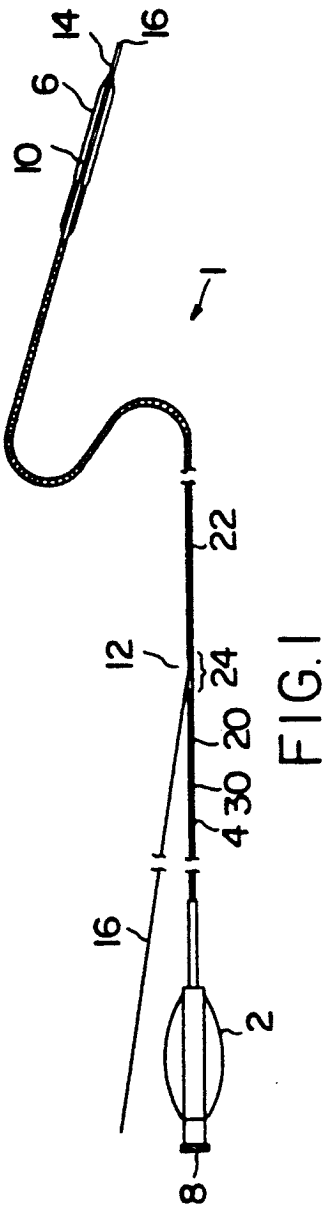


FIG. 1

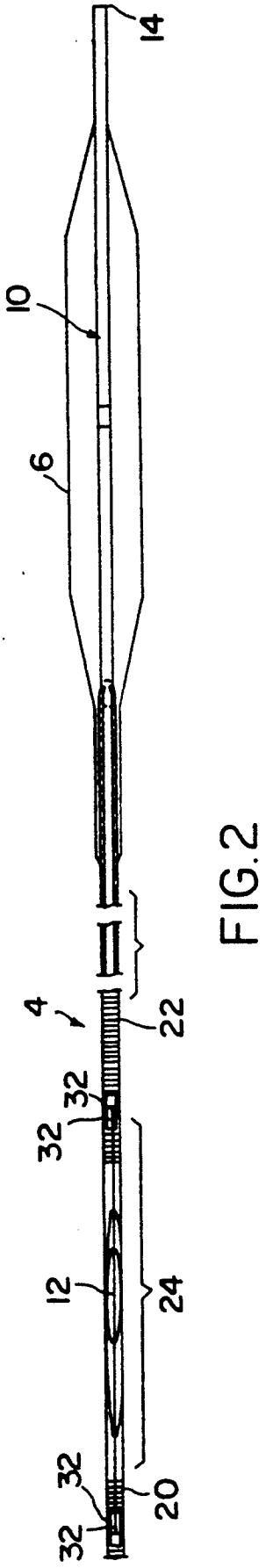


FIG. 2

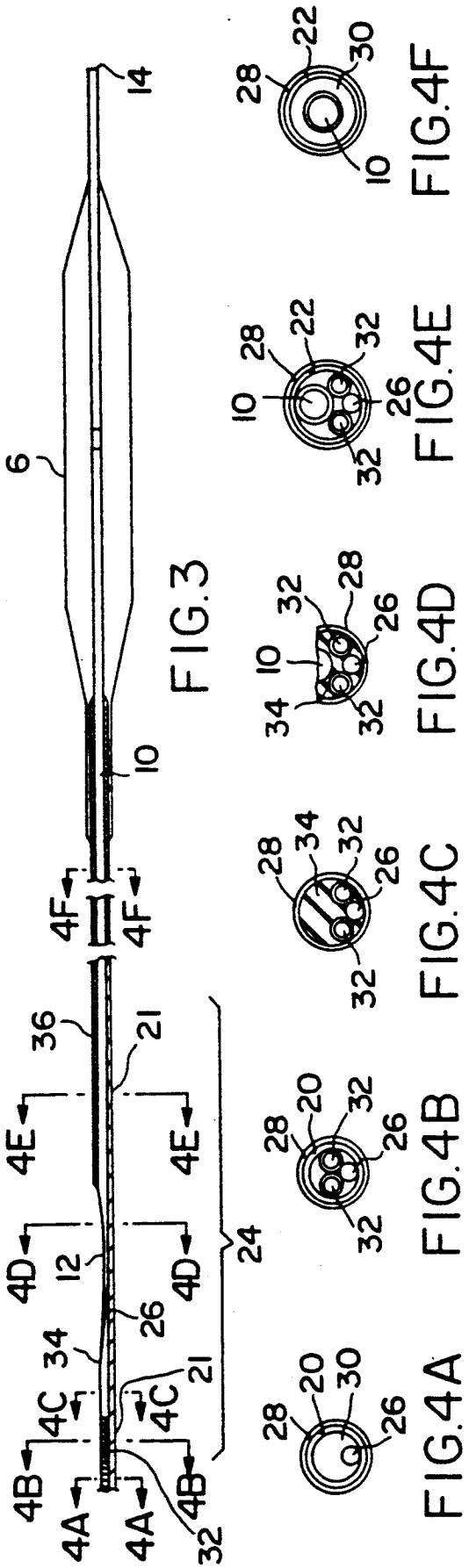


FIG.3

FIG.4F

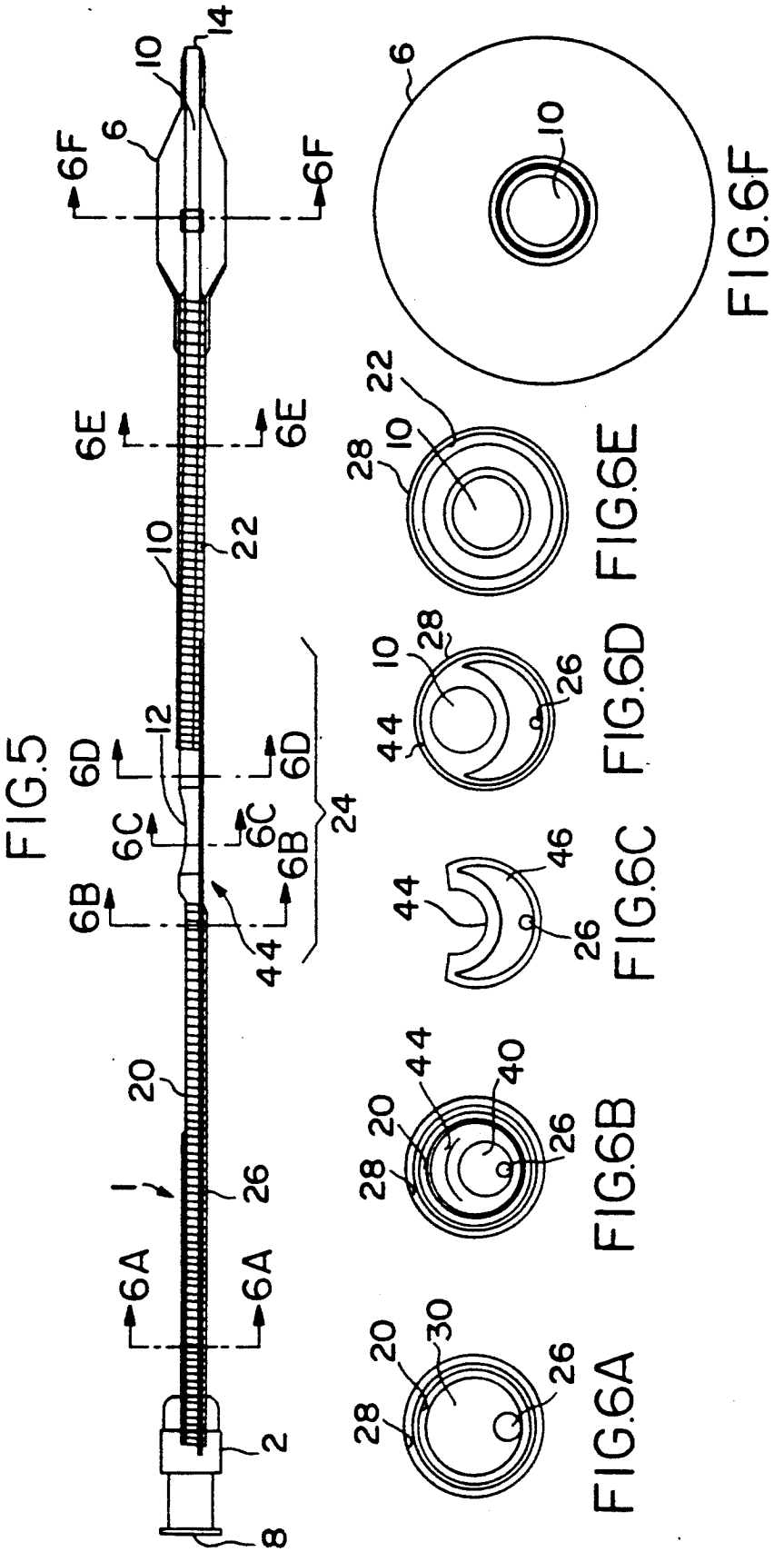
FIG.4E

FIG.4D

FIG.4C

FIG.4B

FIG.4A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20
26
1
6A
6A
2
8
6
10
FIG.6F
22
28
10
FIG.6E
10
28
26
44
FIG.6D
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FIG.6A
FIG.5

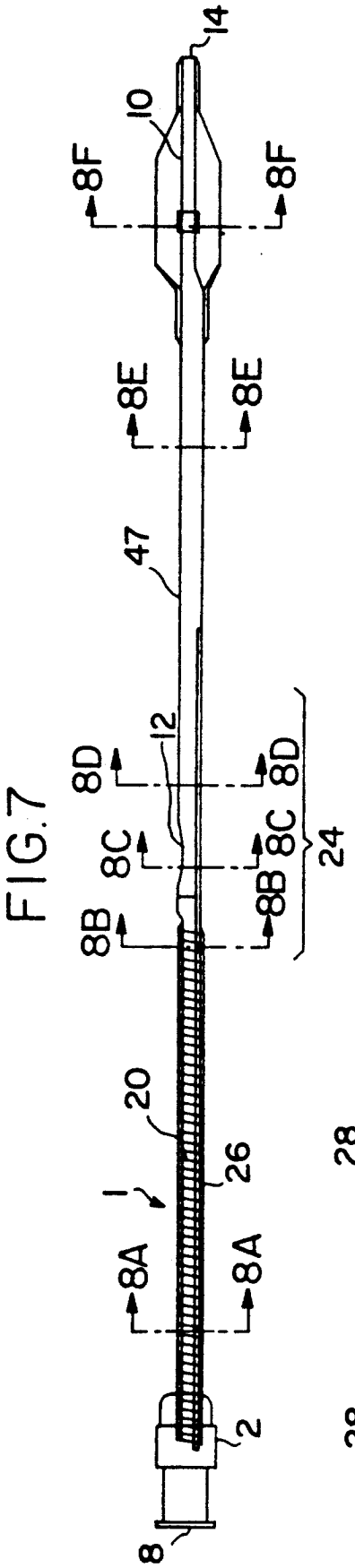

FIG.7

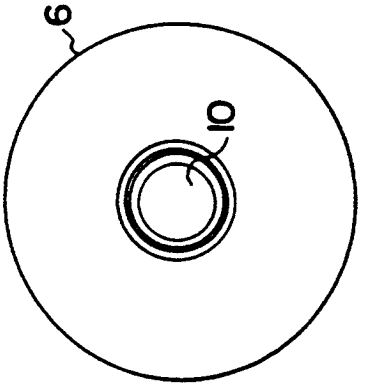

FIG.8F

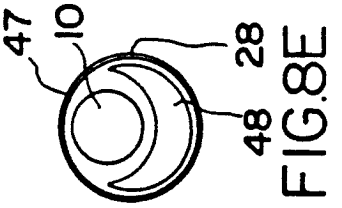

FIG.8E

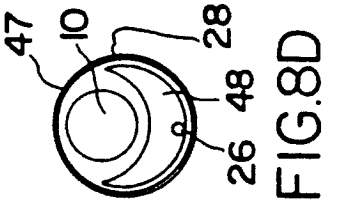

FIG.8D

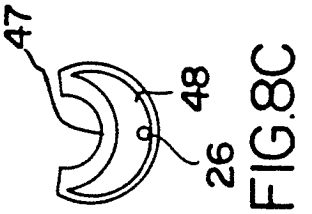

FIG.8C

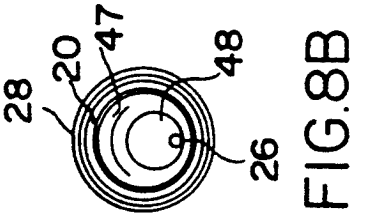

FIG.8B

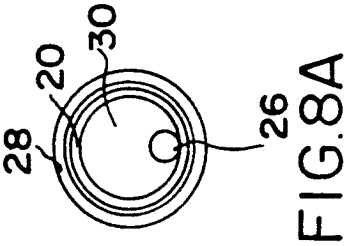

FIG.8A

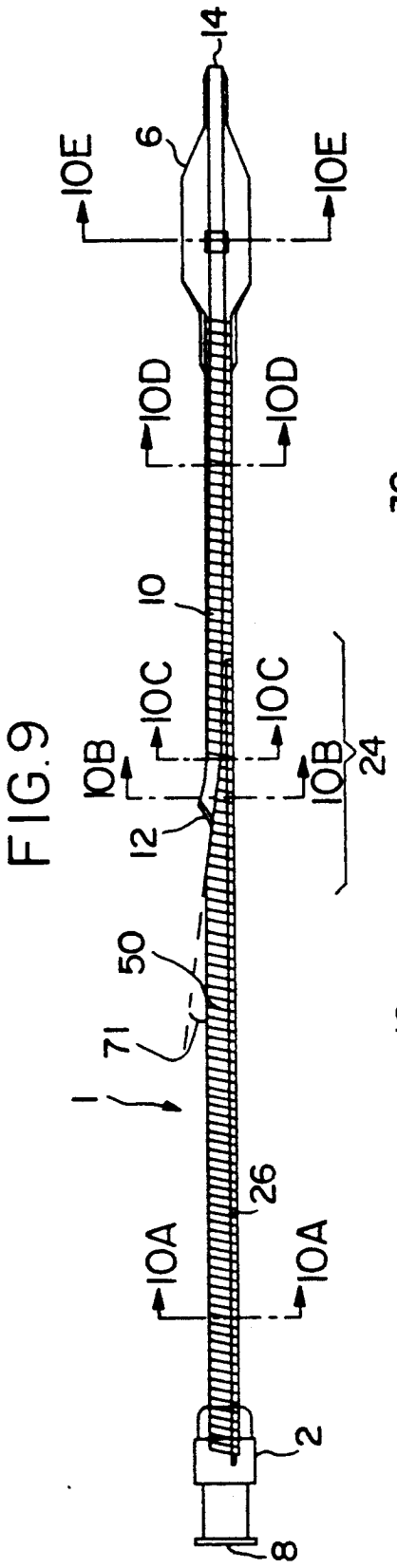

FIG. 9

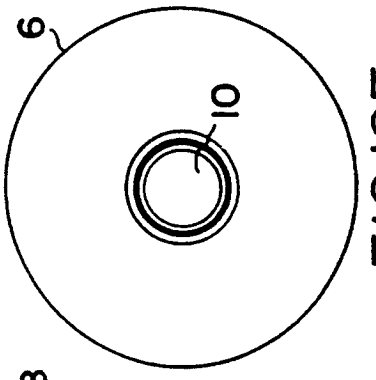

FIG. 10E

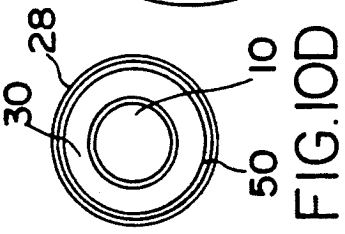

FIG. 10D

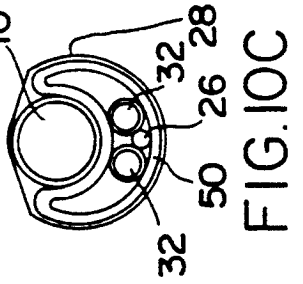

FIG. 10C

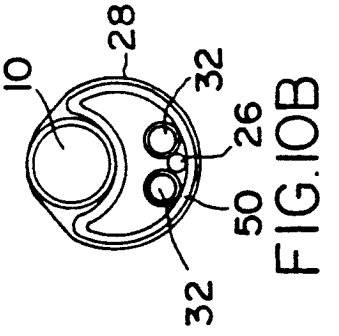

FIG. 10B

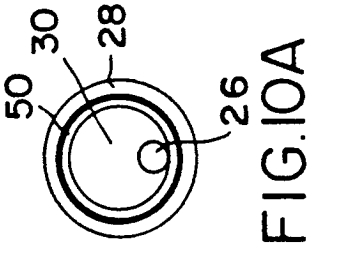

FIG. 10A

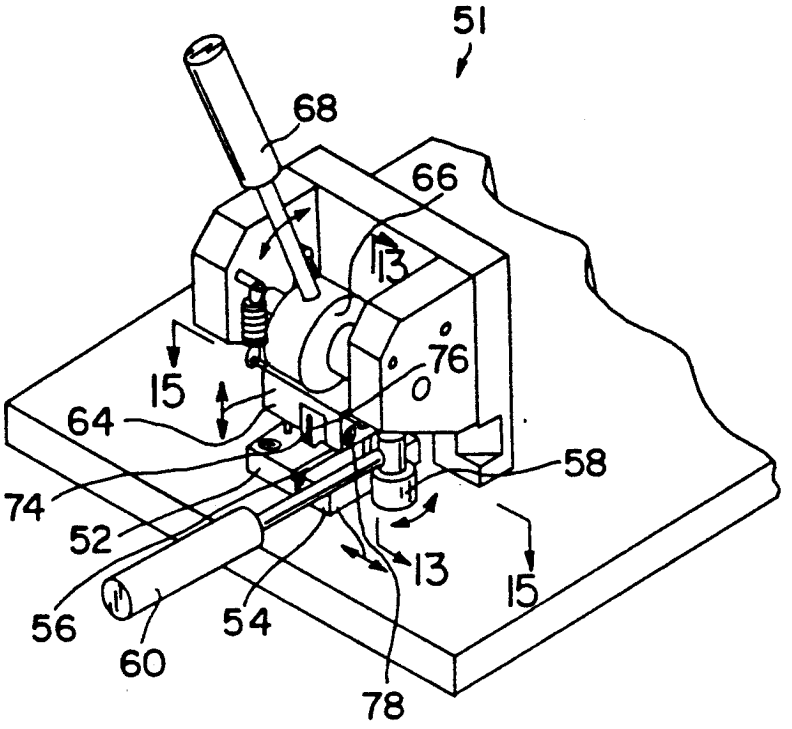
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FIG. 11

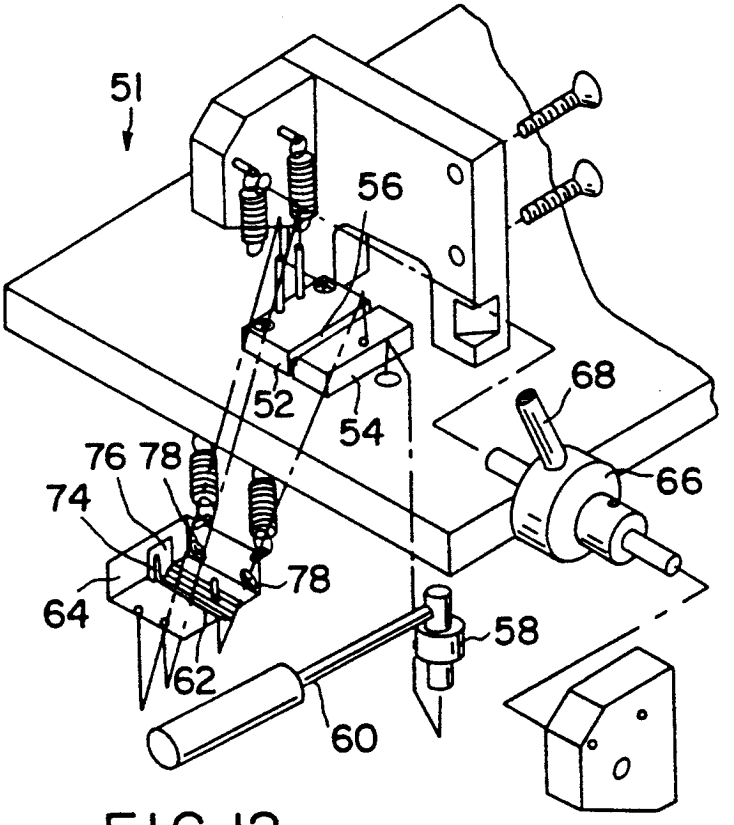
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FIG. 12

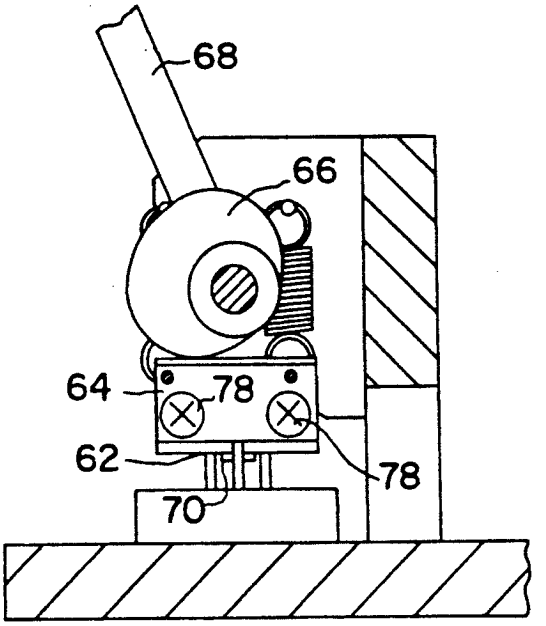

FIG.13

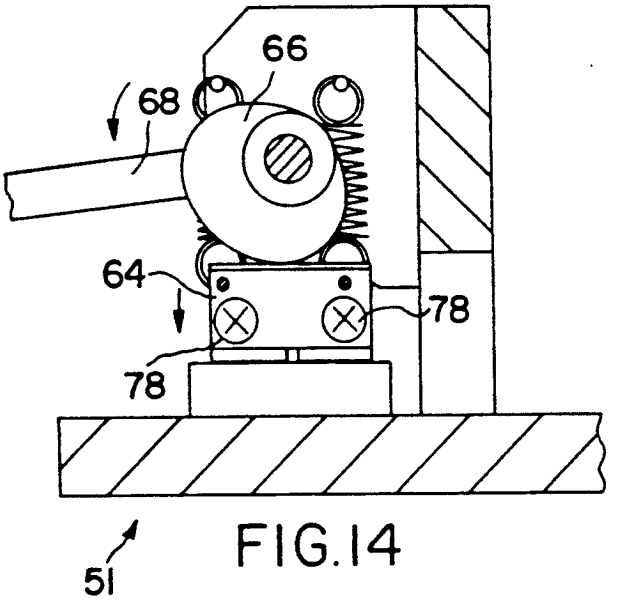

FIG.14

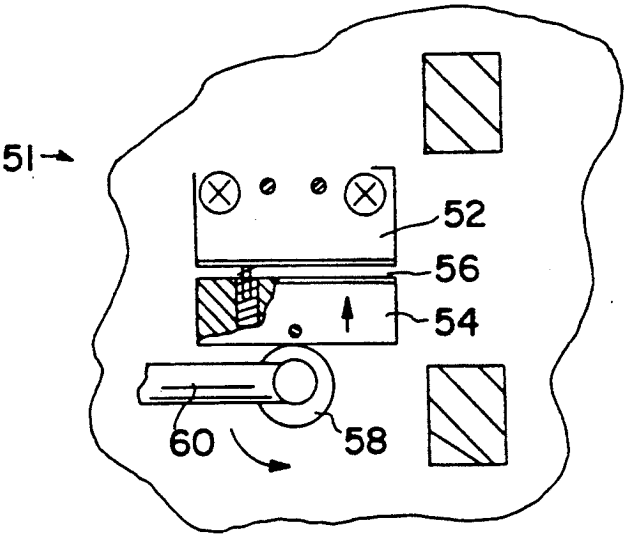

FIG.15

CATHETER WITH FLEXIBLE SIDE PORT ENTRY

BACKGROUND OF THE INVENTION

The technique of eliminating a vascular stenosis by dilating a balloon on a catheter placed within the stenosis was developed by Dr. Andreas Gruntzig. The first marketable catheters for angioplasty were "fixed wire" catheters, in which a core or guidewire was fixed within the catheter to stiffen it so that it could be pushed into position in the vascular system.

Dr. John Simpson and Dr. Edward Robert subsequently developed an "over-the-wire" catheter in which a guidewire was slidably placed within a lumen of the catheter. This system provided reasonably easy placement of the catheter because the guidewire was first positioned beyond the stenosis and the catheter was then slid into place over it. Although over-the-wire catheters generally have a larger profile than fixed wire catheters, the guidewire can be much more easily positioned in the vascular system than a fixed wire catheter.

Both over-the-wire and fixed wire catheters are usually made using polymer tubing to form the catheter body. In some catheters, however, the catheter shaft is formed of a spring coil (a helically wound wire) jacketed on the outside or inside so that it is sealed to form a lumen. For example, U.S. Pat. Nos. 4,976,689, 4,944,740, 4,917,666 and 4,723,936 issued to the assignee of the present invention describe such catheters. Although more expensive and more complicated to make than polymer catheters, spring coil catheters have certain advantages. They allow flexibility in the catheter while providing greater axial stiffness than a typical polymer extrusion. As a result, the catheter is very "pushable", i.e., axial force at one end is transmitted to the other end. In addition, kinking of the catheter as it bends around curves is minimized. The use of flat wire rather than round wire is preferred because it has greater resistance to compression and less tendency to deform.

An advantage of over-the-wire catheters is that if a catheter has to be exchanged for a larger or smaller catheter, the guidewire can be left in place and the catheter withdrawn over it and another catheter slid into place over it. A difficulty with the exchange procedure is that it is difficult to keep the guidewire in place, because removing the catheter requires removal of the guidewire and subsequent recrossing of the stenosis. To avoid this problem, very long "exchange" guidewires, more than twice the length of the catheter, are used so that they can be separately held in place while the catheter is withdrawn. In addition, shorter guidewires have been made, which are lengthened by attachment of an extension wire during the exchange process in order to render them the length of a long exchange wire. Unfortunately, such long guidewires and extension wires require an additional person to hold the guidewire during the catheterization process and are somewhat difficult to use.

This problem was solved by the development of catheters which have shorter guidewire lumens, so that the guidewire exits from the catheter closer to the balloon than to the proximal end of the catheter. Thus the guidewire can be anchored or held by the physician as he or she removes the catheter from the body and the exchange occurring over the shorter guidewire lumen.

One version of such a catheter is shown in U.S. Pat. No. 4,762,129 (and B1 4,762,129) issued to Bonzel,

where the guidewire lumen passes through the balloon and exits immediately proximal to the balloon. The guidewire lumen and inflation lumen are of a "bilumen" or "biaxial" configuration in which the guidewire lumen runs parallel to the inflation lumen. A similar system is shown in U.S. Pat. No. 4,748,982 issued to Horzewski, et al., and in U.S. Pat. No. 4,988,356 issued to Crittenden, in which the guidewire lumen, which runs parallel to the inflation lumen, contains a slit extending its length so that the guidewire can be removed from the lumen through the slit at a point immediately proximal to the balloon.

These bilumen designs can be relatively easy to manufacture because they can be made from a single extrusion of the shaft and guidewire lumen together. In addition, they allow use of a slit guidewire lumen. Sometimes, however, they have a larger profile than might be desired and poor guidewire movement.

Examples of bilumen rapid exchange catheters on the market are ACS' Alpha TM catheter and ACS' RX TM catheter. In the Alpha TM catheter, a hypotube (stainless steel tube) forms the proximal end of the catheter and a bilumen extrusion the distal portion. The bilumen portion is slit so that the guidewire can be removed from it at varying positions as shown in the Horzewski, et al., patent mentioned above. In the RX TM catheter, the entire catheter is a single bilumen extrusion, the proximal portion of which contains a core wire. A side entry is cut into the guidewire lumen near the balloon.

In rapid exchange catheter designs such as those in Yock, U.S. Pat. Nos. 5,040,548 and 5,061,273, the short guidewire lumen is coaxial with respect to the inflation lumen, but exits (or enters) in a side port at least 10 centimeters from the distal tip of the catheter. (The Yock disclosure suggests a lumen of 10 or more centimeters; in catheters on the market, the coaxial lumen varies from about 9 to about 35 centimeters in length.) Coaxial construction has provided certain advantages such as smaller profile catheters and better guidwire movement.

However, in these catheters, the construction of the distal guidewire entry area or "transition region" has posed a challenge. The inflation lumen must be isolated from the distal port to prevent exit of the inflation fluid to the exterior. In some designs, the transition region is not strong enough to avoid distal kinking. In others, abrupt changes in stiffness from one part of the catheter to another may occur. In yet others, the transition region may be too stiff, preventing its placement in the coronary arteries.

An example of a coaxial rapid exchange catheter on the market is Schneider's Piccolino TM . In this catheter, the entire inflation lumen appears to be formed of one piece, and a core wire extends through the proximal portion, through the transition region and into the distal portion. The guidewire lumen is located in the distal end of the inflation lumen and appears to be fused into position in the transition area. An entry is cut into the proximal end of the guidewire and adjacent fused area.

In SciMed's Express TM catheter, a hypotube forms the proximal segment and a separate hypotube segment formed into a crescent shape is attached to the distal end of the proximal hypotube, creating a trough in which the guidewire lumen is located. A short coil jacketed by the inflation lumen surrounds the guidewire lumen, reinforcing the transition. The remaining distal segment of the catheter is made of standard coaxial extrusions.

It would be desirable to develop a catheter which allows rapid exchange, has the benefits of a coaxial guidwire lumen, has the advantages of a spring coil design, and which can be designed for appropriate but varying flexibility along the length of the catheter, without abrupt changes in stiffness, or an undesirably stiff transition region.

SUMMARY OF THE INVENTION

The present invention is directed to an improved catheter and method of making and using same which can be manufactured with variable stiffness characteristics, appropriate flexibility, and desired amounts of axial stiffness.

In one aspect, the invention is a method of making a catheter including the following steps:

selecting two tubular members for the catheter body, each defining a lumen;

placing the tubular members end-to-end;

spacing the ends of the tubular members from each other to create a transition region therebetween; and

providing a linking element in the transition region defining a lumen to communicate between the lumens of the two tubular members, so that by varying the characteristics of the tubular members and the linking element, the handling characteristics of the catheter can be controlled.

In another aspect, the invention is a catheter body comprised of two tubular members having lumens placed end-to-end and spaced apart by a linking element having a lumen communicating between the lumens of the two tubular members. Generally, the method also includes the steps of providing a side port entry in the transition region and a third tubular member within the distal tubular member to act as a guidewire lumen. The catheter also preferably includes such a third tubular member. The first two tubular members are preferably formed of spring coils and the linking element is a flexible tube, sometimes two flexible tubes, usually formed of polyimide. Sometimes the linking element is a single multilumen element comprising both the guidewire lumen and a lumen communicating between the inflation lumens of the spring coils.

In another aspect, the invention is a catheter having a spring coil shaft defining a lumen and a side port and having a distal and proximal end. The catheter preferably includes a balloon located generally at the distal end of the shaft, the balloon having a distal and a proximal end, and a lumen extending from the distal end to the side port, the lumen adapted to receive a guidewire in a sliding fit. The distal end of the balloon is sealed to the lumen and the proximal end of the balloon is sealed to the shaft. The shaft is usually jacketed with polyethylene and a core wire is bonded to the shaft to stiffen the catheter. Preferably the spring coil shaft is formed of two spring coils placed end-to-end to define a transition region therebetween; the side port entry located in the transition region, as described in more detail above. Alternately, the entry may be located in a single spring coil shaft, and one or more flexible tubes, preferably polyimide, sealed adjacent the entry to communicate between the distal and proximal ends of the coil.

In another aspect, the invention is a method of using a catheter including the following steps:

providing a catheter including a spring coil shaft defining a lumen and a side port and having a distal and proximal end, a lumen extending from the distal end to the side port, said lumen adapted to receive a guidewire in a sliding fit and a treatment region located at the distal end of the shaft;

providing a guiding catheter;

providing a guidewire;

inserting the guiding catheter into a vascular system having a stenosis;

threading the guidewire through the vascular system and through the stenosis;

threading the catheter over the guidewire to locate the treatment means with respect to the stenosis; and

withdrawing the catheter.

Preferably, the method also includes the following steps:

providing a second catheter including a spring coil shaft defining a lumen and a side port and having a distal and proximal end, a lumen extending from the distal end to the side port, said lumen adapted to receive a guidewire in a sliding fit and a treatment region located at the distal end of the shaft;

inserting the second catheter over the guidewire;

treating the stenosis; and

withdrawing the second catheter.

Generally, the treatment means of the catheter is a dilatation balloon having a distal end sealed to the lumen and a proximal end sealed to the shaft, and the step of treating the stenosis includes inflating the balloon to dilate the stenosis. The spring coil shaft of the catheter is preferably formed of two spring coils located end-to-end and defining a transition region therebetween; the side port located in the transition region, and the catheter most preferably has one or more of the additional features already described above.

In another aspect, the invention is a catheter including an elongated shaft defining a lumen and a core wire for stiffening the shaft, where the core wire is bonded directly to the shaft. Preferably the shaft is a spring coil and the core wire is brazed to it. Most preferably, the shaft is comprised of two spring coils spaced end-to-end and the core wire is fixed to both spring coils, and the catheter has one or more of the additional features already mentioned.

In another aspect, the invention is a method of creating a side entry along the length of the shaft of a catheter having the following steps:

providing a spring coil shaft;

connecting the coils together in an area of the shaft;

crimping some of the connected coils sufficiently to create an entrance to the shaft while maintaining a lumen through the crimped coils.

The step of connecting the coils generally includes brazing the coils to render them more shapable and may include welding them to a core wire extending through the coil. One or more core wires may be inserted through the coils to be crimped to maintain a lumen through the crimped coils. The core wire is usually 0.014" in diameter and may be a hypotube mandrel shaped in a "U" or crescent. One or more flexible shafts may be inserted into the lumen to carry the inflation fluid. A guidewire lumen is usually inserted in the distal portion of the coils and opens to the exterior of the catheter at the side port entry.

In yet another aspect, the invention is apparatus for creating a side port entry in a spring coil shaft including means for retaining the spring coil in a fixed position, means for crimping a length of spring coil, and means

for adjusting the crimping means between crimping and non-crimping position.

The means for retaining the spring coil in a fixed position are usually two blocks forming a space therebetween for holding the spring coil. The crimping means is a tongue having a lower edge extending lengthwise with respect to the coil. The two blocks are movable relative to each other, via an arm attached to an eccentric cam, so that coils of different sizes can be accommodated. The tongue can be variably positioned with respect to the spring coil via an arm attached to an eccentric cam. The tongue is removable and tapered lengthwise to provide a desired entry angle (of about 6 degrees) for the side port entry.

Other aspects and advantages of the invention will be apparent to those of ordinary skill in the art.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of the preferred embodiment of the catheter of the present invention.

FIG. **2** is a top plan view, partially cut away, of the preferred catheter of the present invention, showing the transition zone and side port entry.

FIG. **3** is a cross-section, taken lengthwise, of the preferred catheter of the present invention, taken lengthwise, showing the balloon, the transition zone, and the side port entry.

FIGS. **4A**, **4B**, **4C**, and **4D**, **4E**, and **4F** are cross-sections of the catheter taken at lines **4A**, **4B**, **4C**, **4D**, **4E**, and **4F**, of FIG. **3**, respectively.

FIG. **5** is a cross-section of the transition region and adjacent shaft, taken lengthwise, of another embodiment of the present invention.

FIGS. **6A**, **6B**, **6C**, **6D**, **6E** and **6F** are cross-sections of the transition region and shaft of the present invention taken at lines **6A**, **6B**, **6C**, **6D**, **6E** and **6F** of FIG. **5**.

FIG. **7** is a cross-section of the transition region and adjacent shaft, taken lengthwise, of another embodiment of the present invention.

FIGS. **8A**, **8B**, **8C**, **8D**, **8E** and **8F** are cross-sections of the transition region and shaft, taken at lines **8A**, **8B**, **8C**, **8D**, **8E** and **8F**, respectively, of FIG. **7**.

FIG. **9** is a cross section of the transition region and adjacent shaft, taken lengthwise, of another embodiment of the present invention.

FIGS. **10A**, **10B**, **10C**, **10D**, and **10E** are cross-sections of the transition region and shaft, taken at lines **10A**, **10B**, **10C**, **10D**, and **10E** of FIG. **9**, respectively.

FIG. **11** is a side elevation of apparatus used to create the side port entry in the transition region of the embodiment of the present catheter shown in FIG. **9**.

FIG. **12** is an exploded view of the apparatus of FIG. **11**.

FIGS. **13** and **14** are side elevational views, in cross-section, of the apparatus of FIG. **11**, in non-crimping and crimping positions, respectively.

FIG. **15** is a top view in cross-section of the device of FIG. **11**, showing the variably-positioned holder for the catheter.

DETAILED DESCRIPTION OF THE SPECIFIC EMBODIMENTS

An angioplasty catheter **1** of the present invention is shown schematically in FIG. **1**. It includes an adapter **2**, a catheter body **4** defining an inflation lumen **30**, and a balloon **6** disposed at the distal end of the catheter body. The balloon is inflated by fluid passing through the inflation lumen from the proximal end **8** of the catheter into the balloon. An inner lumen **10** located within the catheter body extends through the balloon, and the distal end of the balloon is sealed to the inner lumen near the distal end of the lumen.

The inner lumen exits to the exterior of the catheter through a side port entry **12** distal to the proximal end of the catheter **8**, but proximal to the balloon. Preferably the side port entry is located about 20 centimeters from the distal tip **14** of the catheter. A guidewire **16** can be slidingly received within the inner lumen. The length of the balloon will vary but, in the preferred embodiment, it is about 20 mm long and blow-molded from a polyethylene tube in a manner known to those in the art.

Details of the preferred embodiment are shown in FIGS. **2** and **3** and cross-sections are shown in FIGS. **4A** through **4F**. In the preferred embodiment, the catheter body **4** is formed of jacketed spring coil, preferably a proximal **20** and distal **22** coil placed end-to-end and spaced apart so that a linking element (here formed of flexible tubes **32**) can form the transition region **24** therebetween. (The spring coils are of a flat wire type and are made of a biocompatible material such as stainless steel.) The spring coil provides the catheter with flexibility while providing axial stiffness.

The coils are jacketed with polyethylene **28** and define an inflation lumen **30** which passes through the proximal coil, the transition region, and the distal coil into balloon **6** so that the fluid can be passed through the lumen to inflate the balloon for an angioplasty procedure.

A core wire **26** extends through the proximal coil **20** into the distal coil **22** and is bonded directly to both at points **21**. The core wire is also formed of stainless steel and is brazed, welded or soldered to the coil. (Laser welding is preferred.) The bond avoids the necessity of melting or otherwise creating a separate lumen for the core wire and imparts stability and stiffness to the catheter.

The core wire stiffens the catheter in the area where the guidewire runs exterior to the catheter body, provides additional axial support, and also forms a safety wire to anchor the distal coil to the proximal coil. The diameter of the core wire in the preferred embodiment tapers from about 0.016 in. at the proximal end to about 0.010 in. at the transition region to about 0.0025 in. at its distal end, but can vary depending on grade of material.

The transition region **24** is formed in this catheter of a linking element (here flexible tubes **32**) which provides a bridge between the two spring coils forming the catheter body. It serves in this catheter to locate the guidewire entry **12** (also referred to as the distal entry or side port entry). The use of a linking element such as that described herein to create a three-part catheter shaft provides great flexibility in manufacturing the catheter; by varying the materials and design of the linking element and the shaft, different catheter characteristics can be obtained. In the preferred embodiment, the linking element is formed from one or more, preferably two, parallel flexible tubes **32** which link the inflation lumens of the two adjacent coils. (In another embodiment described in more detail below, it is formed of a multilumen insert.)

The tubes **32** are formed of a flexible biocompatible material. The material should be heat resistant and will retain its shape during the heating operation. The material used in the preferred embodiment is a polyimide. The advantage of a polyimide is that polyethylene or

other materials needed to seal off the remainder of the inflation lumen or anchor the flexible tubes in place will bond to it. Teflon TM can be used but does not bond well without special surface treatment; polyethylene may be used but has a lower melting point and will require the use of a mandrel during manufacture to maintain the patency of the lumen due to its heat sensitivity.

The flexible tubes must also be large enough to provide adequate balloon inflation and deflation times while maintaining a small cross-section. For a catheter with a transition region diameter of about 0.43 in., polyimide tubes having an outer diameter of 0.012 in. and an inner diameter of 0.010 in. are preferred.

The polyimide tubes are anchored in place by a polyethylene plug **34** which also serves to seal the coils' inflation lumen from the exterior of the catheter at the side port entry. The transition zone is preferably about 1.5 cm. in length and the flexible tubes about 2.0 cm. in length.

The inner lumen **10** is formed of a high density polyethylene tube; in the preferred embodiment, it is about 0.017 in. in inner diameter and 0.022 in. in outer diameter. It is located within the catheter body and extends through the balloon to form, at its distal end, the distal end of the catheter, **14**. It is anchored in place at its proximal end by polyethylene plug **34**; at its distal end, it is sealed to balloon **10** and simultaneously anchored.

The catheter is made by first welding the core wire to the appropriately positioned spring coils. The polyimide tubes are sleeved with polyethylene (which will ultimately form the polyethylene plug) and positioned in the transition zone. The guidewire lumen, containing a mandrel tapered at its underside at the proximal end, is positioned in the transition region also. The tapered mandrel is desirable because it provides a smooth ramp at the side port entry. An alternate approach to the tapered mandrel is to offset the two spring coils slightly during manufacture, and use a standard mandrel.

The polyethylene jacket (which jackets the coil and the transition region) is positioned over the catheter and heat shrunk in place. The transition region is heated to assure that the polyethylene plug has formed and sealed the transition region. The guidewire port is cut using methods known in the art. The balloon and manifold are then attached in a conventional manner.

Other ways of manufacturing are to form the linking element or transition region in advance, preferably by molding a multilumen polyethylene unit or element **44** shown in the catheter of FIGS. **5** and **6a** through **6F**. This catheter also contains two jacketed spring coils **20** and **22** placed end-to-end and linked by a linking element, here in the form of the molded multilumen element **44**. This multilumen linking element has a crescent shaped lumen **46** instead of the flexible polyimide tubes (for more economical use of space), and includes the guidewire lumen **10**, although the guidewire lumen **10** may be formed separately from the multilumen insert and bonded to it.

The multilumen element can be molded of polyimide or polyethylene and anchored to the jacketing polyethylene and the spring coils during the heat shrinking operation. Wire (not shown) from the distal end of the proximal coil **20** or the proximal end of the distal coil **22** wound helically about the multilumen transition region may be added as a safety wire. A disadvantage of polyethylene for the multilumen insert is that mandrels have to be placed during manufacture in the lumens during the heating operation so that they do not collapse.

Another version of the catheter is shown in FIGS. **7** and **8A** through **8F**. This embodiment retains the spring coil **20** and its advantages at the proximal end of the catheter, but uses a multilumen extrusion **47** for the distal portion. The multilumen extrusion can be formed of polyethylene, polyimide or other flexible material, and bonded to the proximal lumen during the heat shrinking operation. The multilumen extrusion is a single bilumen extrusion and contains both the guidewire lumen **10** and a crescent shaped inflation lumen **48** for economical use of space; it is inserted at its proximal end into the proximal coil **20** and anchored in a fashion similar to that described above.

Although the extrusion in this embodiment is generally convenient to manufacture, mandrels are necessary during the heat shrinking operation to keep the lumens open. A disadvantage, of course, is that the distal segment of the catheter lacks the handling characteristics of the spring coil, i.e., axial stiffness with flexibility, and that it is very difficult to bond a core wire to the extrusion, further reducing the stability and axial stiffness of the catheter. This drawback can be overcome, however, by reinforcing the extrusion with a braid or fibers. For example, fibers in an extrudable matrix such as Vectra TM made by Hoechst Celanese might be suitable for this extrusion (and, indeed, the proximal segment of this or the other embodiments of the catheter as well).

In yet another embodiment of the present invention, shown in FIGS. **9** and **10A** through **10F**, the entire catheter shaft is made of one spring coil **50**. The side port entry **12** in the transition region is formed by first connecting adjacent coils together in what will be the transition zone **24**. Connecting adjacent coils together helps to hold the spring coil steady during crimping; brazing or another high temperature treatment is preferred over welding because it makes the coils more ductile and therefore more amenable to shaping. Additional strength can be obtained by laser welding each adjacent coil to the core wire as well.

The group of adjacent connected coils in zone **24** are then carefully crimped using a crimping tool such as a machinist's scribe or the specially designed tool of FIGS. **11** through **15**. The crimping is controlled to provide a gradual, smooth transition into the spring coil shaft, while retaining the inflation lumen. As shown in FIG. **9**, the desired entry angle **71** is about 6 degrees, and the entry can be hand-crimped to provide the desired angle, or a device such as that shown in FIG. **11** can be used to easily create the crimping angle.

To maintain the inflation lumen during crimping, a core wire, (preferably two of about 0.014" in diameter) is placed in the lumen during the crimping. In the preferred embodiment, a hypotube mandrel split lengthwise to form a crescent or U, is inserted during crimping to maintain and shape the inflation lumen.

After crimping, one or more, preferably two, short flexible tubes, specifically polyimide shafts **32** such as those described earlier, are inserted by mandrel into the inflation lumen in the transition zone to transport inflation fluid between the distal and proximal portion of the spring coil shaft. A seal, preferably of a polymer such as polyethylene, or an adhesive such as a cyanoacrylate, a UV-cured adhesive, or an epoxy, is then inserted to seal the polyimide shafts in place and block the remainder of the inflation lumen from fluid flow.

The guidewire lumen itself is then inserted and fixed to the side port entry, and the remainder of the catheter is finished.

In the preferred version of this embodiment of the invention, the spring coil outer diameter is about 0.034 in., the length of crimp is about 0.200 in. (200 mm), and the angle 71 of taper is 6 degrees.

The crimping apparatus 51 illustrated in FIGS. 11 through 15 is a prototype designed to crimp spring coils of various sizes. As shown in particular in FIG. 15, the device includes two blocks 52 and 54 spaced from each other to create a groove 56 therebetween for retaining the coil during crimping. The two blocks are preferably movable with respect to each other, so that the spring coil can be easily put in place, and so that coils of different sizes can be accommodated. An eccentric cam 58 together with an arm 60 attached thereto is included for variably spacing the blocks.

A tongue 62 for crimping the coils is placed in another block 64 mounted above the two spaced blocks. This block, too, is movable with respect to the coil to position the tongue in crimping and non-crimping positions, as shown in particular detail in FIGS. 13 and 14. The positioning means is an eccentric cam 66 with an arm 68 attached to it so that the block can be positioned with the tongue at various depths to provide different amounts of crimp for different coils. The tongue preferably has a lower edge 70 which is tapered lengthwise, preferably at an angle of about 6 degrees, to create the 6-degree entry angle mentioned above.

The tongue is held in a slot 74 in fixture 76 fitted in block 64. The fixture can be removed from the block and the tongue from the slot in the fixture, by removing screws 78, so that a tongue of a different length or a different taper can be inserted into the fixture and block.

In use, a tongue of selected size and taper is placed in fixture 76 and upper block 64 is assembled with the tongue and fixture. Block 54 is positioned with respect to block 52 using arm 60 and the spring coil to be crimped is placed in groove 56. Arm 60 is repositioned to fixedly retain the spring coil. Crimping is completed by using arm 68 to adjust the position of block 64 and tongue 62 to crimp the coil.

From the foregoing detailed description of specific embodiments of the present invention, it should be apparent that a catheter with a side port entry and method for making and using same have been described. Although particular embodiments of the invention have been described herein in some detail, this has been done for the purposes of illustration only and is not intended to be limiting with respect to the scope of the invention. It has been contemplated by the inventors that various changes, alterations, or modifications may be made to the invention as described herein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A catheter comprising:
a spring coil shaft and having an inflation lumen;
a side port;
a distal and proximal end;
a balloon located generally at the distal end of the shaft, the balloon having a distal end and a proximal end; and
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, wherein the distal end of the balloon is sealed to the inflation lumen.

2. A catheter according to claim 1 and wherein the shaft is jacketed with polyethylene.

3. A catheter according to claim 1 and wherein the spring coil shaft is formed of two spring coils placed end to end with a transition region therebetween, said transition region formed of a flexible tube, the side port entry located in the transition region, and each spring coil having an inflation lumen.

4. A catheter according to claim 3 and wherein the flexible tube located within the transition region defines an inflation lumen in fluid communication with the inflation lumens of the two coils.

5. A catheter according to claim 4 and wherein two flexible tubes are located within the transition region.

6. A catheter according to claim 3 and wherein a core wire extending through the inflation lumen of the shaft is affixed to the two coils.

7. A catheter according to claim 1 and further comprising a first flexible tube sealed into the spring coil shaft adjacent the side port and said first flexible tube in fluid communication with the inflation lumen in the spring coil shaft.

8. A catheter according to claim 7 and further comprising a second flexible tube sealed into the spring coil shaft parallel to the first tube and the tubes are formed of polyimide, said second flexible tube being in fluid communication with the inflation lumen in the spring coil shaft.

9. A catheter body comprising:
a distal tubular member having
a longitudinal distal inflation lumen throughout and
a longitudinal inner guidewire lumen throughout;
a proximal tubular member, the proximal tubular member being formed of a jacketed spring coil and having
a longitudinal proximal inflation lumen throughout; and
a transition region formed of a flexible tube and having
at least one flexible transition inflation lumen allowing the distal inflation lumen and the proximal inflation lumen to be in fluid communication, the distal and proximal inflation lumens being placed end to end and the transition region being affixed to the proximal tubular member and to the distal tubular member;
a side port entry in the transition region from which the guidewire lumen exits to the catheter exterior; and
a seal surrounding the transition inflation lumen and filling the transition region to seal the side port from the distal inflation lumen and from the proximal inflation lumen.

10. A catheter body comprising:
a distal tubular member having
a longitudinal distal inflation lumen throughout and
a longitudinal inner guidewire lumen throughout;
a proximal tubular member, the proximal tubular member being formed of a jacketed spring coil and having
a longitudinal proximal inflation lumen throughout; and
a transition region formed of a flexible tube and having

at least one flexible transition inflation lumen allowing the distal inflation lumen and the proximal inflation lumen to be in fluid communication, the distal and proximal inflation lumens being placed end to end and the transition region being affixed to the proximal tubular member and to the distal tubular member;

a side port entry in the transition region from which the guidewire lumen exits to the catheter exterior; and

wherein the transition region includes a second flexible tube.

11. A catheter according to claim **10** and wherein the transition inflation lumen is formed of polyimide.

12. A catheter body comprising:

a distal tubular member having

a longitudinal distal inflation lumen throughout and

a longitudinal inner guidewire lumen throughout;

a proximal tubular member, the proximal tubular member being formed of a jacketed spring coil and having

a longitudinal proximal inflation lumen throughout; and

a transition region formed of a flexible tube and having

at least one flexible transition inflation lumen allowing the distal inflation lumen and the proximal inflation lumen to be in fluid communication, the distal and proximal inflation lumens being placed end to end and the transition region being affixed to the proximal tubular member and to the distal tubular member;

a side port entry in the transition region from which the guidewire lumen exits to the catheter exterior; and

further comprising a core wire affixed to each of the distal and proximal tubular members.

* * * * *

EXHIBIT H

US005102403A

United States Patent [19]

Alt

[11] Patent Number: 5,102,403

[45] Date of Patent: Apr. 7, 1992

[54] **THERAPEUTIC MEDICAL INSTRUMENT FOR INSERTION INTO BODY**

[76] Inventor: **Eckhard Alt**, Eichendorffstrasse 52, 8012 Ottobrunn, Fed. Rep. of Germany

[21] Appl. No.: **539,153**

[22] Filed: **Jun. 18, 1990**

[51] **Int. Cl.**[5] **A61M 25/00**

[52] **U.S. Cl.** **604/280;** 604/96; 128/772

[58] **Field of Search** 604/96-101, 604/280, 264; 606/191, 194, 195; 128/207.15, 673, 675, 692, 772

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,850,358	7/1985	Millar	128/675
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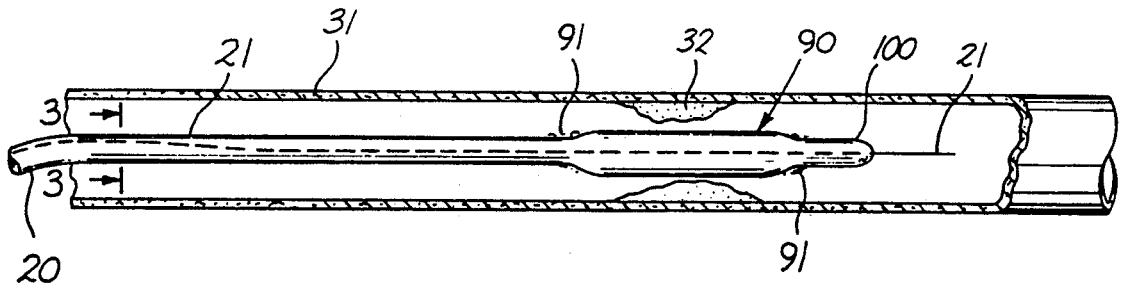
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—William Lewis
Attorney, Agent, or Firm—Laurence R. Brown

[57] **ABSTRACT**

This invention provides a cylindrical plastic catheter of the type having a distal end portion movable over a guide wire to a treatment site such as a stenosis in the cardiovascular system, wherein the catheter shape gradually changes from a tubular configuration with a cylindrical skin defining an interior inflating lumen. The skin configuration and internal lumen changes shape gradually along the catheter length for insertion of the wire into a resident guide lumen resident only in the distal end portion without bends or kinks in the wire and retaining a generally parallel disposition to the catheter axis from which it departs to penetrate the catheter. Thus a guiding groove in the skin gradually transforms into a crescent partly surrounding the guide wire before changing into a toroidal body defining a guide wire lumen. The diameter of the catheter is thus kept constant and small with consistent axial stiffness throughout its length for supporting withdrawal and intrusion from external axial forces. The balloon mounts on the catheter body cylinder for a better, more secure seal and the axial forces along the catheter are balanced about the axis so that there is no tendency to buckle or veer with entry or withdrawal forces. By supplying a groove along the length of the catheter body to receive nested therein a parallel guide wire, the outer circumferencial dimension of the combination guide wire-catheter body may be reduced for entry into vessels of restricted size.

24 Claims, 1 Drawing Sheet



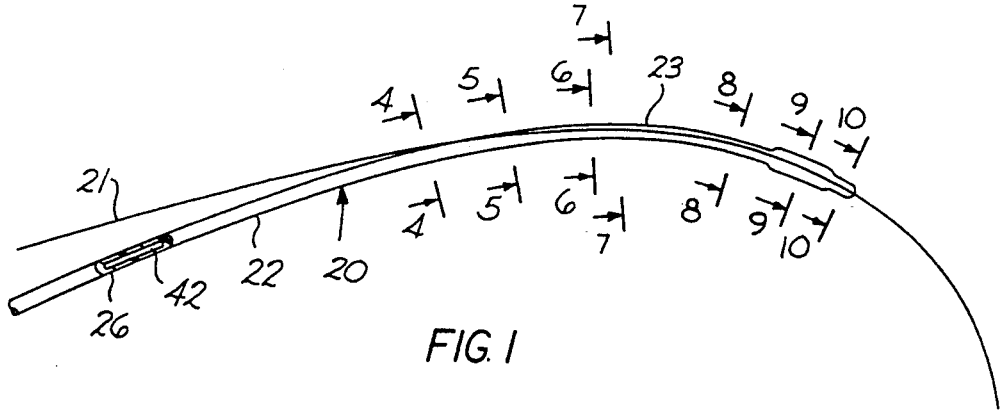


FIG. 1

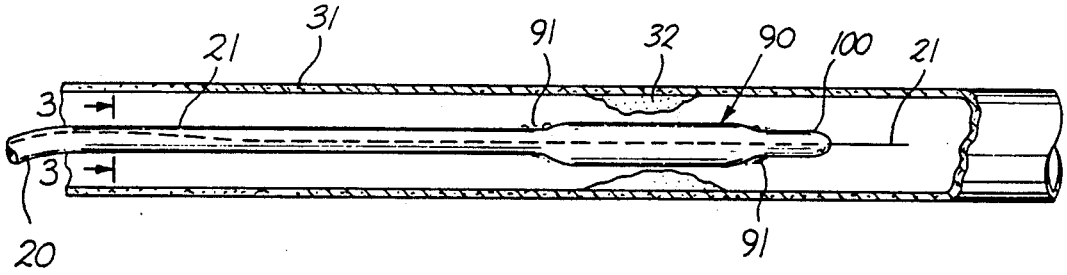


FIG. 2

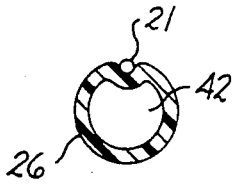


FIG. 3

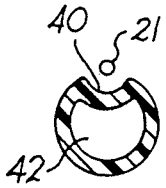


FIG. 4

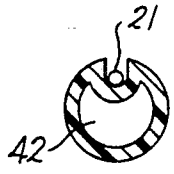


FIG. 5

FIG. 6

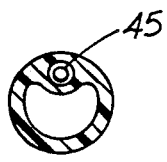


FIG. 7

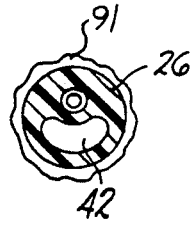


FIG. 8

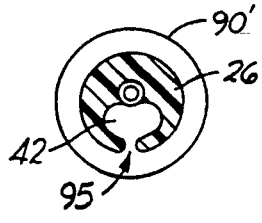


FIG. 9

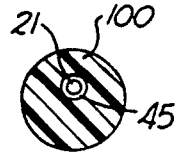


FIG. 10

THERAPEUTIC MEDICAL INSTRUMENT FOR INSERTION INTO BODY

TECHNICAL FIELD

This invention relates to instruments and methods of therapeutic treatment of the body at internal body sites and more particularly it relates to dilatation catheters movable along coronary blood vessels upon a guide wire to position an uninflated balloon at a site for treating stenosis by subsequent inflation of the balloon, or the like.

BACKGOUND ART

The art balloon dilatation catheters for treatment of stenosis in coronary blood vessels is well developed. Representative U.S. patented art includes the following briefly discussed catheters:

G. T. Schejeldahl, et al., U.S. Pat. No. 4,413,989 Nov. 8, 1983 was concerned with long treatment periods in a balloon catheter inserted over a guide wire and thus provides for dilation without interruption of the blood supply with a lumen for bypassing blood.

A. Kuhl, U.S. Pat. No. 4,439,186 provides for pulsating pressure for expansion and contraction of the balloon to permit blood flow past the balloon.

J. J. Leary, U.S. Pat. No. 4,545,390 is concerned with steering the balloon and thus provides a steerable end to the guide wire upon which the balloon rides.

M. J. Horzewski, et al., U.S. Pat. No. 4,748,982 June 7, 1988 provides a balloon dilatation catheter with a short distal end portion moving along a guide wire with the feature of decreasing stiffness of the catheter body from the proximal extremity to the distal extremity in order to overcome difficulties in pushing prior catheters to a treatment site.

T. Bonzel, U.S. Pat. No. 4,762,129, Aug. 9, 1988 provides a stiffener wire in a separate balloon dilating lumen positioned parallel to the guide wire except at the distal end to aid in pushing the balloon to the treatment site.

There still reamin many unsolved problems in the art of treatment of a site within the body with instrumentation located in part outside the body. In the dilatation catheter art, for example, there are problems of pushing catheters into position at the treatmenmt site through restricted body vessels. Any unbalance of thrust forces or bends or kinks in te catheter can interfere with insertion or withdrawal. Critical is the friction encountered in moving a catheter along a guide wire. While considerable friction is removed by inserting the guide wire only at a distal end region of the catheter, the adds criticality by introducing a tendency to tilt or veer in the presence of slightly off axis thrust forces or unbalances of size, strength or axial stiffness of the catheter body. This is particularly evident at entrance point of the wire into the catheter body, where it is common to bend or distort the path of the guide wire, thereby adding unwanted friction and guiding problems. An example of this is given by the sharp bending zone in the guidewire set forth in the Horzewski patent.

Furthermore with dilatation balloon structure affixed to the catheter body and subjected to dilating by means of injecting fluid at high pressure, there are sealing and inflation problems. Thus, because of the high inflation pressures, any attempt to seal on a non-cylindrical surface produces a tendency to either produce leakage by tearing away the sealing joint or an uneven inflation of the balloon structure causing weak points or misshaping. Shaping is critical for passage into stenosis areas, and leakage or pressure limitations critical to the treatment and safety of the patient.

Another problems area is the abrupt transition of a catheter tubing body or lumen at transition areas for entry of a guide wire or mounting of a balloon. This can for example tend to cause damage to vesel sidewalls or as heretofore discussed by causing the short distal end rider type of catheter geneally preferable to reduce friction on insertion between the catheter and the guide wire or its connection tubing to bend, veer, buckle or bind on the guide wire in response to pushing or pulling axial forces exerted along the catheter axis to insert or withdraw the catheter.

The distal end profile of a balloon is critical particularly if it needs to be forced through a stenosis. The flexibility of the balloon for dilation is inconsistent with the initial need for penetration of restricted passageways to position the balloon at a treatment site for dilation. As a matter of fact any abrupt transition from one material to another or from one shape to another as it occurs if two separate lumens—one for inflation of the balloon and one for guidance of the wire—cause an abrupt joint between the lumens such as in the catheter suggested by Bonzel, supra, such abrupt changes provide problems of insertion, positioning and reliability.

Particularly for coronary blood vessel treatment, small diameters, known as low profile, for insertion into branch vessels and flexibility to bend around sharp corners is critical. Thus balloons attached to stiff tubings or those unadapted to bend around a vessel curve are of limited use as well as those requiring significant room resulting in greater diameters of the catheter body for mounting elements affixing the balloon structure upon the catheter.

Very critical to coronary vessel treatment is the quick interchange of dilatators of different size. Thus a smaller diameter dilatator balloon may be used for penetration of the stenosis and enlargement enough to accommodate a larger diameter balloon necessary to restore a reasonably normal working diameter in the vessel.

It is therefore a particular object of this invention to provide an improved dilatation catheter particularly adapted for angioplasty and treatment of coronary vessels that resolves the foregoing problems in the prior art.

A more general object is to provide improved instrumentation and treatment methods for therapeutic treatment at sites within the body from the outside.

Other objects, features and advantages of the invention will be found throughout the following description, and in the accompanying drawings and claims.

DISCLOSURE OF THE INVENTION

This invention provides therapeutic instrumentation and treatment methods for treatment inside the body of the type that is passed over a guide wire of positioning at the treatment site. A specific example is an inflatable dilatation catheter specially adapted for arteriosclerotic vessel treatment of stenosis or angioplasty. The catheter is of the type riding on a guide wire only at a short distal end portion. Novel features of this catheter include the transition of the catheter tubing, typically plastic having a cylindrical thin skin-like wall surrounding a single inflation lumen for dilating and accompanying balloon

to accommodate a second guide wire lumen at a predetermined length of the catheter body near the distal end.

Thus the configuration of a conventional cylindrical catheter tubing with outer plastic wall defining a single internal lumen changes gradually while passing through successive configurations at the more distal (balloon) end. Thus the generally substantially cylindrical outer wall, becomes grooved to guide a substantially parallel guide wire alongside toward the interior of the catheter without any substantial bending of the wire. The catheter groove then progressively leads into a crescent shaped wall-lumina configuration which partially encompasses the guide wire before becoming cylindrical to surround the guide wire as a toroid. In parallel to this grooving and encompassing process, the inner lumen of the catheter changes its shape as well from round towards more of a C-shaped configuration. This unique and novel feature contributes significantly to smaller total diameter of dilatation catheters despite the same mechanical strength for pushing the catheter forward, compared to conventional arrangement with two parallel cylindrical lumens. The distal end lumen and body structure finally tapers into a low profile solid nose adapted for working its way through stenosis before the balloon affixed to the cylindrical length of the catheter body is placed at the stenosis. The wall of the inflating-deflating tube is apertured at the site of the balloon to connect the balloon via the inflating-deflating lumen within the catheter body to the outside of the human body for operation of the balloon by fluid injection under pressure. This provides a short low friction rider of limited length and of small diameter substantially cylindrical. This cylindrical diameter extends along the entire length of the distal catheter body that it can be introduced into smaller vessels in the coronary system for treatment.

The novel structure permits construction at the entry position of the guide wire into the catheter body at a position having a common shape and consistent still axial strength with the rest of the catheter body to facilitate feeding into a treatment site. A lateral modulus of elasticity sufficient to permit bending about sharp curves is provided within the plastic catheter body devoid of stiffener wires. The bending is enhanced around curves by the novel form of the inflating lumen as a C-shaped lumen, which bends readily as the catheter is inserted. It also readily permits withdrawal and replacement of small diameter catheters in small passagesways with progressively increasing balloon sizes when needed.

When a catheter and a guide wire are inserted into an arterial vessel of sufficient size over an introducer sheet, the diameter of the dilatation catheter plus that of a guide wire lying outside the catheter is not critical to the possibility to introduce the system into the human body. But there are conditions where severely diseased and narrowed vessels make the size of the introducer sheet critical to the success of insertion. In those cases, the overall diameter of the dilation catheter and the guide wire together can be decreased if a groove is present along the entire catheter structure forwards of the outside of the body. By this means the guide wire is situatied within the circumferential groove in the dilation catheter enabling small size introducer sheets.

BRIEF DESCRIPTION OF THE DRAWINGS

Like reference characters are used to identify similar features throughout the drawings, wherein:

FIG. **1** is a sketch of a distal end portion of a dilatation catheter of this invention showing a low friction saddle rider portion of the catheter merging into and surrounding a substantially parallel guide wire upon which the catheter distal end rides;

FIG. **2** is a broken away fragmental sketch of the dilatation catheter functioning at a treatment site inside a body vessel at a stenosis treatment site; and

FIGS. **3** to **10** are respective cross sectioned portions of the catheter at corresponding positions **3**—**3**, etc. shown on FIG. **1**.

THE PREFERRED EMBODIMENT

In the present invention , the catheter can be given special and critical properties by means of treatment of plastic materials from which the catheter is formed. For example, silicones, polyethylenes, polyurethanes, polyvinylchlorides and like synthetic plastic materials are readily formed into desired shapes by injection molding techniques, and may be after treated by thermal molding.

The distal rider end of the catheter afforded by a preferred embodiment of this invention also is molded from a suitable plastic material to have a gradual transformation along the axial length from an initial substantially round cylindric shape to a modified shape of the dilatation fluid lumen without abrupt changes from a generally cylindrical configuration of constant diameter for penetration of a guide wire into a gradually created second guide wire lumen formed inside the catheter body. The catheter body comprises an outer body skin defining an internal cylindrical dilation fluid lumen which is gradually conformed along a predetermined portion of the length into a riding saddle over the guide wire.

Along this length, which permits the guide wire to remain along its length with a substantially parallel axis with the catheter body, the catheter body wall gradually progresses from a groove into a crescent shaped wall and internal lumen which at least partly surrounds the guide wire. The crescent closes toroidally about the guide wire to form a guide wire lumen which gradually extends toward the axis of the catheter body as the dilating lumen and outer configuration tapers into a terminal nose of solid plastic material. The generally cylindrical body shape is maintained at a constant diameter, with a cylindrical outer region positioned between the entry point of the guide wire and the nose for attachment of a circumferential dilatation balloon. Communication between the balloon and dilation fluid in the dilation lumen results from apertures in the body wall.

Throughout the transition portion of the length catheter axial stiffness is maintained constant to facilitate entry and withdrawal of the catheter. Lateral bending elasticity is provided by the material and shaping of the lumen without substantially departing from the initial cylindric shape in order to facilitate bending in conformation with body vessels.

The balloon or balloon mounting vicinity of the catheter may be radiation tempered. The C-shaped lumen may be reinforced by shaping or adding reinforcement means internal to the lumen at any points of critical stress under pressure caused by non-round lumen shaping. The tempered portions of the catheter can be treated to give a lateral bending modulus for similarly bending around curves without significant effect to the axial pushing stiffness required for positioning and withdrawing the catheter over a substantially parallel guide

wire. Preferably the balloon at the distal end terminates near a solid plastic nose section tapered to provide less friction in penetrating a stenosis area for example to position the balloon for dilatation. Also preferably the balloon exterior perimeter tapers at both ends and has no disruptions.

By having a common circumferential plastic body about the dilatation lumen cavity smoothly an progressively changing along the catheter length into an interior guide wire lumen without abutments or steps in the catheter diameter, many problems of exerting distortion forces on the catheter or balloon surface for reaching treatment sites are eliminated. This all results in a more reliable, low friction, easy to insert balloon dilation catheter with a smaller diameter catheter in the region of the balloon than known in the prior art.

As may be seen in FIGS. **1** and **2**, the catheter of this invention is ideally suited for treament of cardiac disease such as stenosis **32** of arterial vessel wall **31**. The catheter **20** is inserted into the cardiovascular system typified by vessel **31** over a previously inserted guide wire **21** which runs parallel outside the catheter until it reaches a distal end region **23** for guiding the catheter to carry instrumentation such as a dilatation balloon located near its distal end to a treatment site **32**.

This catheter is of the type that as it nears the distal end **23**, the guide wire **21** is gradually more and more encompassed and thus little friction between the guide wire and catheter is present to impede insertion or withdrawal of the catheter from a position outside the body. The catheter at region **2—2** of this embodiment is generally of cylindrical shape having an internal inflation lumen **42** for fluid under pressure to expand a dilatation balloon in the distal end region **22**. The catheter body is formed of a plastic material **26** having enough axial stiffness to push the distal end **23** over the guide wire **21** and through small or stenosis restricted cardiovascular blood vessels into a treatment site without buckling or restricting the lumen **42** diameter, as aforesaid.

The catheter throughout the distal end regions **4—4** to **10—10**, as shown in cross section in corresponding FIG. **4** through **10**, undergoes smoothly progressing changes of shape of the wall **26** and lumen **42**. The distal terminal end at FIG. **10** is of solid plastic which tapers to a penetration shape, which helps to advance the balloon more easily over an already positioned guide wire through high degree narrowings so that the balloon section of FIG. **9** may be placed into position for dilatation as shown in FIG. **2** within the blood vessel **31** at stenosis site **32**. The guide wire facilitates withdrawal of the catheter **20** along the guide wire **21** and allows its replacement with one having a larger diameter head end portion allowing a greater degree of dilatation. Because of the easy insertion of the guide wire into the novel guiding lanes and of the limited length of guidance of the wire in the balloon possible with this invention, initial treatment with a smaller balloon can readily be followed by a subsequent treatment with a larger balloon without the need for extensive guiding of the new catheter over a guide wire of more than double the length of the catheter.

The smoothly changing shape of the catheter along its axial length at the balloon site critical to this invention allows for an exchange of catheters without significant friction thus facilitating easy and fast pull back and advance of subsequent catheter structure over a guide wire. This can be visualized as related to the cross sections of FIGS. **3** to **10**. Thus the catheter plastic body wall **26** becomes more deeply grooved at **40** for guiding the guide wire toward its final position, in this embodiment coaxial with the balloon as shown in FIG. **10**. Thus guide wire **21** enters the catheter body axially from left to right (FIG. **1**) through a groove, a crescent shaped semi-enveloping configuration, FIGS. **5** and **6**, and then completely surrounded as in FIGS. **7** through **10**. Thus the catheter is transformed from a single lumen catheter into two lumens, adding one for the guide wire, all without changing substantially the outer cylindrical body configuration or its diameter. Furthermore, the guide wire gradually enters its new guiding lumen through several changes of guidance within a groove, and thus incurs no kinking or sharp bending as mandatory for low friction removal or advance of the catheter over the guide wire.

Also the lumen shape changes gradually within the catheter **20** as seen through the progression of FIGS. **3** to **9**, for this embodiment. Note that the balloon **90** has an outer skin **91** which is distendable in the presence of fluid in the inflating lumen **42** under increased pressure into an expanded diameter **90** shown in phantom view. This balloon is affixed to the outer cylindrical catheter surface at each end. That is critical in that high internal pressures are minimized and equalized about the joint, resulting in more reliability and operation at greater safety margins.

The small diameter of the catheter **20**, especially at zone **23**, permits good lateral flexibility to bend around curves in the cardiovascular vessels. At the tip **100**, a special material with some pliability is preferred for use in penetration of a stenosis region and this may be achieved by thermal or radiation treatment.

The smooth progressive change of shape of the catheter body **26** and its internal inflating lumen **25** to convert the single lumen catheter to one having an additional internal guide wire lumen **45** without substantially changing the direction of travel of the guide wire and the constant outer catheter diameter throughout is typified by the sequence in the FIGS. **3** to **10**. Thus the catheter body **26** of FIG. **3** becomes grooved at FIG. **4**, with the body **26** and internal lumen **42** becoming crescent shaped at FIGS. **4** and **5**. The internal lument **415** is formed at FIG. **7** so that the balloon **90** may be glued or otherwise affixed to the outer cylindrical periphery of the catheter body **26** at **91** in FIGS. **2** and **8**. The aperture **95** in the catheter body **26** of FIG. **9** permits balloon **90** to be dilated from fluid in lumen **42** to the inflated balloon condition **90**. The lumen **42** is tapered toward the nose **100** shown in FIG. **10** to provide a low profile solid penetrating probe end. During this entire transition, the catheter maintains its cylindrical shape and diameter.

Accordingly it is seen heretofore and in the appended claims that this invention has advanced the state of the art with those novel features defined in the claims for examplifying the nature and spirit of the invention.

I claim:

1. A catheter with distal end structure for forming a lumen to encompass and ride along a guide wire comprising in combination:

a substantially cylindrical catheter body with an outer wall about a first lumen with the outer wall gradually changing in shape along the catheter body length toward the distal end from an entrance groove shaped as a path for guiding the wire inwardly into the cylindrical body along the catheter length to form initially a crescent shaped catheter

body configuration partly surrounding the wire and which thereafter changes into a closed cylinder wall surrounding a second guide lumen for encompassing the guide wire.

2. The catheter distal end structure of claim 1 wherein the outer wall of the catheter body over the length in which the catheter changes gradually and smoothly from a single lumen configuration to a two lumen configuration is substantially cylindrical in shape forming with the accompanying guide wire an extension of the cylindrical catheter body.

3. The catheter distal end structure of claim 1 wherein the path of the wire through the groove and crescent shaped configuration into the second quide lumen is substantially parallel with the catheter body.

4. The catheter distal end structure of claim 1 wherein the catheter body consists of a plastic material having a substantially constant axial stiffness throughout the distal end structure length corresponding substantially to that of the cylindrical catheter body, for permitting the catheter to be inserted into or withdrawn from body vessels of small dimension from a position outside the body.

5. The catheter structure of claim 1 wherein the catheter body along the length of the change from one to two lumens thereby presenting the initial lumen in a crescent shape is reinforced to prevent the generally cylindrical catheter body from distorting in shape in response to internal fluid pressures used for dilatation.

6. The catheter of claim 1 having a distal end portion formed with a substantially cylindrical outer wall along a predetermined length to which a balloon dilatation structure is affixed at two spaced positions along the cylindrical outer wall for dilation by means of fluid under pressure in the initial lumen.

7. The catheter of claim 6 wherein the dilatation balloon structure when dilated under fluid pressure has a cylindrical configuration tapering gradually down to the catheter body at two ends.

8. The catheter of claim 1 with a body consisting of plastic having a characteristic of axial stiffness and a shear characteristic permitting the catheter body to readily bend around curves.

9. A substantially cylindrical catheter body structure adapted to receive, direct, and envelop a substantially parallel disposed guide wire along a portion of the catheter's length thereby forming an internal catheter guide wire lumen by changes of shape of the cylindrical catheter body gradually over said length from a guide wire entry groove indented on the catheter outer surface into the internal lumen encompassing the guide wire.

10. The catheter structure of claim 9 wherein the catheter body shape configuration about the lumen is constructed to preserve a substantially constant longitudinal stiffness along the catheter body.

11. A therapeutic medical instrument for insertion into the body for treatment at an internal body site, comprising in combination:

guide wire means for insertion into the body to a treatment site for guiding therapeutic means thereover into the treatment site;

treatment means for insertion into the treatment site having a proximal end for employment outside the body including treatment lumen structure providing a communication path from outside the body to the treatment site, guide wire lumen structure within said treatment means for movement of the instrument along the guide wire to a treatment site, and a distal end instrument for movement inside the body to a treatment site;

treatment means structure for inserting the guide wire means into the guide wire lumen confined to a short length low friction coupling region near the distal end of the treatment means at a linear portion having a substantially cylindrical body of substantially constant diameter, whereat the treatment lumen configuration changes in shape gradually along said coupling region to receive the guide wire and fully encompass the guide wire, and

wherein the coupling region structure in the instrument for introducing the guide wire into the guide wire lumen without substantial change of direction of the guide wire from a parallel position alongside the treatment means body providing a smooth progressive transition from cylindrical shape, to indented cylindrical shape provides a groove for guiding the guide wire, to substantially cresent shape for partly surrounding the wire, to the guide lumen.

12. A catheter for use with a companion guide wire having means for retention of the guide wire substantially within the catheter outer perimeter for insertion into a body vessel of restricted size, comprising in combination, a catheter body having a longitudinal groove internally indented in the outer periphery along a portion of the catheter length adapted to nest a guide wire therein and structure gradually changing the groove into a lumen within the catheter body for retaining the guide wire to thus produce a reduced outer perimeter for the catheter and guide wire.

13. A catheter as defined in claim 12 having a guide wire nested in said groove thereby producing a substantially cylindrical outer perimeter of the combined catheter body and guide wire.

14. A combination of a guide wire and catheter adapted for insertion into a body vessel comprising in combination, a catheter body having a longitudinal groove along a predetermined length of the catheter near its distal end to be inserted into a body vessel of restricted size, said groove having a shape for receiving nested therein alongside the catheter body a substantially parallel guide wire, said groove changing into a lumen within the catheter for thereby receiving and surrounding the guide wire thereby to reduce an outer peripheral dimension of the catheter body-guide wire combination residing within the vessel.

15. The method of inserting a guide wire into the distal end of a catheter so that the catheter may ride along the guide wire with low friction comprising the steps of:

producing a hollow cylindrical catheter with a circumferential wall surrounding a lumen,

gradually changing the circumferential wall configuration to provide structure for inserting the guide wire to structurally change the circumferential wall along its length into a second lumen formed within the catheter with the initial cylindrical hollow catheter circumferential wall changing along its length to form (a) an entrance groove for guiding the wire into a crescent shaped wall section partly surrounding the wire and (b) transition structure closing the cresent to produce a guiding lumen about the wire, and

inserting a guide wire disposed substantially parallel with the catheter into the groove to follow the transition structure and enter the guiding lumen

without departing substantially from the parallel disposition of the guide wire and catheter.

16. The method of introducing a guide wire into a substantially cylindrical catheter body near its distal end while maintaining the diameter of the cylindrical catheter body substantially constant along its length to a position disposed around a guiding wire in a distal end region having a dilatation balloon structure positioned circumferentially about the catheter body perimeter, comprising the steps of:

indenting the cylindrical catheter body to provide a shaped groove along the length of the body for entry of the guiding wire, changing the groove in shape along said length into a lumen surrounding the guide wire without a substantial change in diameter of the catheter body, and

inserting a guide wire disposed substantially parallel to the catheter body gradually into the dilatation catheter body along its length to dispose the guide wire substantially concentrically within the balloon without substantially changing the diameter of the catheter body.

17. The method of claim 16 further comprising the step of changing an internal dilation lument shape initially disposed within the cylindrical catheter body from substantially circular to a non-round shape to accommodate the groove for insertion of the guide wire.

18. The method of transforming a distal end of a substantially cylindrical catheter body having an internal lumen to produce an additional internal guide wire lumen therein by the steps of retaining the cylindrical body outer peripheral dimension substantially constant along its length and changing the shape of said cylindrical body and internal lumen along tbe length of the body to form an indented guide groove on the catheter body outer surface thereby changing the shape of the internal lumen and changing the cylindrical body shape over the length of the catheter body from the groove into said internal guide wire lumen.

19. The method of creating in a substantially cylindrical plastic catheter body, having internal lumen means, a structure for encompassing and riding over a guide wire comprising the steps of modifying the outer peripheral shape of the catheter body while substantially retaining its cylindrical configuration into an indented groove for gradually enveloping the guide wire along a predetermined length of the catheter body to produce a further internal lumen within the cylindrical body to fully surround the guide wire.

20. The method of claim 19 including the step of tapering the lumen means and the cylindrical body gradually along a distal end length of the catheter body beyond said predetermined length.

21. The method of claim 19 including the steps of affixing a dilatation balloon structure over a length of the cylindrical body behind said predetermined length having a substantially constant diameter and producing aperture means to communicate with said lumen means for dilation of the balloon structure.

22. The method of inserting into and withdrawing from a treatment site a catheter consisting of a plastic material comprising a dilatation balloon assembly having a dilating lumen and structure for riding concentrically about a guide wire along a portion of its length at a distal end position of the catheter, comprising the steps of: inserting into the treatment site a guide wire, positioning a distal end portion of the catheter substantially parallel to the guide wire, merging the external substantially parallel guide wire into a groove in an outer catheter surface portion near the distal end gradually changing into an internal lumen positioned within the catheter along a predetermined portion of the catheter surrounding the guide wire without substantially bending the guide wire, forming a catheter body over its length having a similar axial stiffness and catheter peripheral shape so that the catheter movement forces are substantially axially balanced along the body of the catheter throughout its length, and imposing both insertion and withdrawal forces at a proximal end of the catheter in a direction along the length of the catheter for inserting and withdrawing the catheter from the treatment site.

23. The method of claim 22 further comprising the step of grooving the outer periphery of the catheter along a portion of its length to conform with and receive nested therein said guided wire with the catheter body substantially constant in diameter over a merge area between the groove and internal lumen.

24. The method of decreasing the overall volume required for the combination of a catheter body and a parallel guide wire for insertion into a restricted size body tubing such as a cardiovascular vessel for treatment comprising the steps of providing a longitudinal groove along a portion of the length of the catheter body conformed with the guide wire dimensions changing the groove gradually into a lumen within the catheter body surrounding the guide wire, and feeding the guide wire and catheter into the body with the guide wire resting in the lumen.

* * * * *

EXHIBIT I

US005911715A

United States Patent [19]

Berg et al.

[11] Patent Number: 5,911,715

[45] Date of Patent: *Jun. 15, 1999

[54] **GUIDE CATHETER HAVING SELECTED FLEXURAL MODULUS SEGMENTS**

[75] Inventors: **Todd A. Berg**, Lino Lakes; **Jason A. Galdonik**, Bloomington, both of Minn.

[73] Assignee: **SciMed Life Systems, Inc.**, Maple Grove, Minn.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/800,927**

[22] Filed: **Feb. 13, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/703,635, Aug. 27, 1996, which is a continuation-in-part of application No. 08/195,222, Feb. 14, 1994, Pat. No. 5,569,218.

[51] **Int. Cl.**[6] **A61M 25/00**

[52] **U.S. Cl.** **604/525**; 604/527; 138/125

[58] **Field of Search** 604/264, 280, 604/281, 282; 600/433–435; 138/130–132, 125, 129, 144

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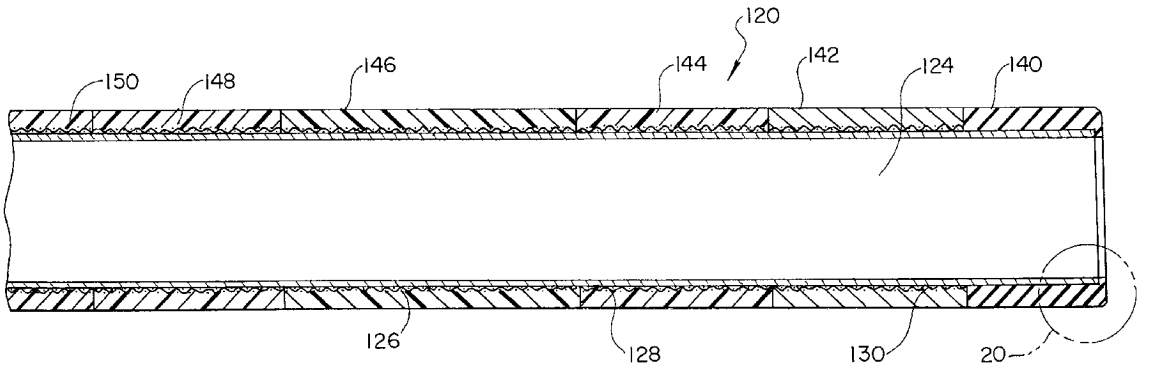
Primary Examiner—Ronald Stright, Jr.

Attorney, Agent, or Firm—Crompton, Seager & Tufte, LLC

[57] **ABSTRACT**

A guiding catheter for use in coronary angioplasty and other cardiovascular interventions which incorporates a plurality of segment of selected flexural modulus in the shaft of the device. The segments which have a different flexibility than the sections immediately proximal and distal to them, creating zones in the catheter shaft which are either more or less flexible than other zones of the shaft. The flexibility and length of the shaft in a given zone is then matched to its clinical function and role. A mid-shaft zone is significantly softer than a proximal shaft or distal secondary curve to better traverse the aortic arch shape without storing too much energy. A secondary zone section is designed to have maximum stiffness to provide optimum backup support and stability.

26 Claims, 15 Drawing Sheets



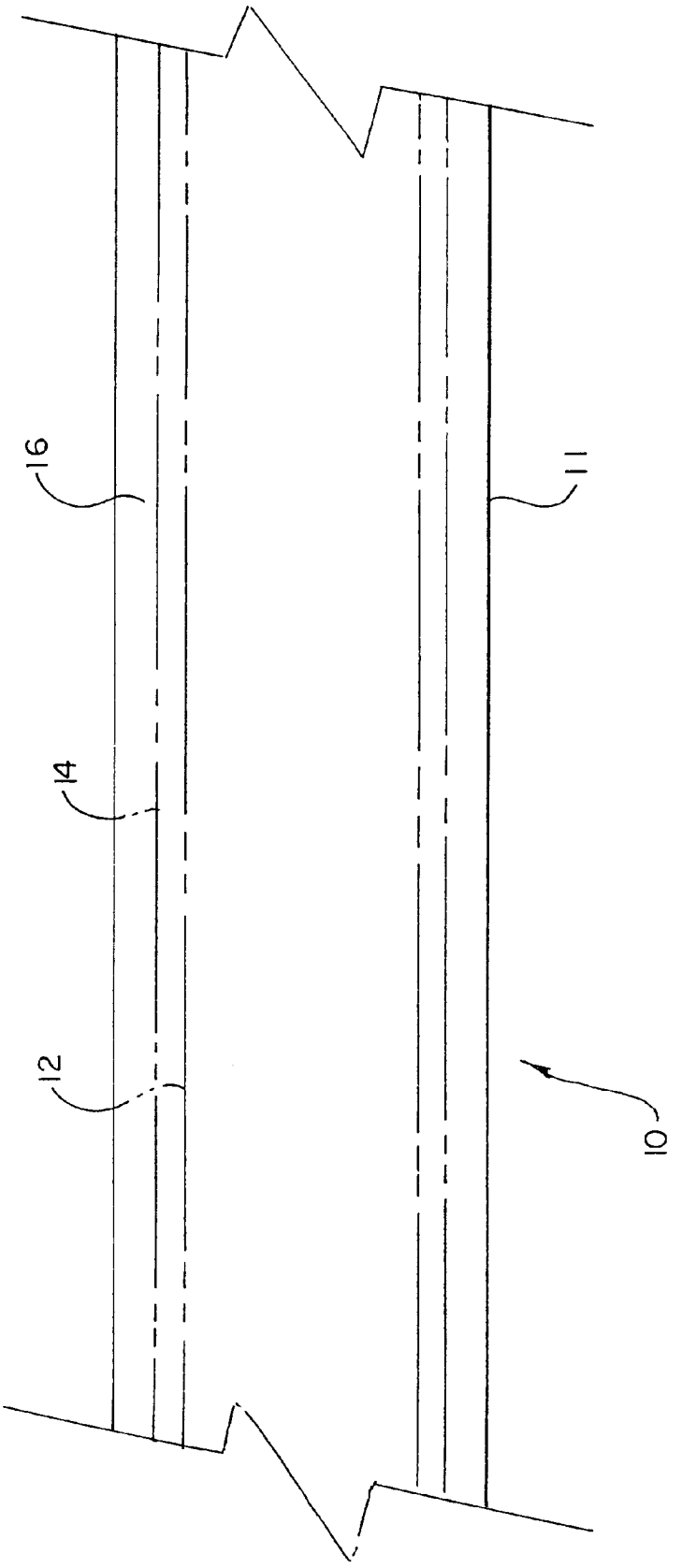


Fig. 1

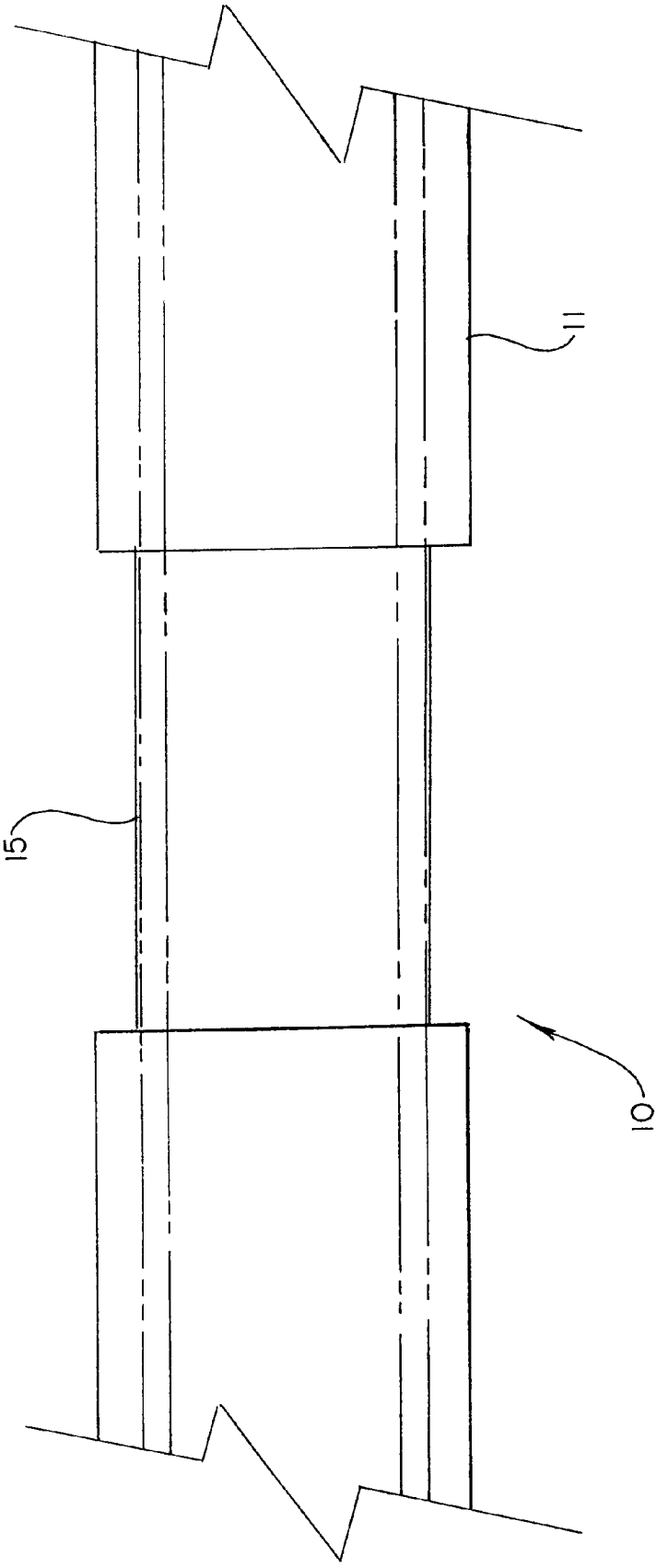


Fig. 2

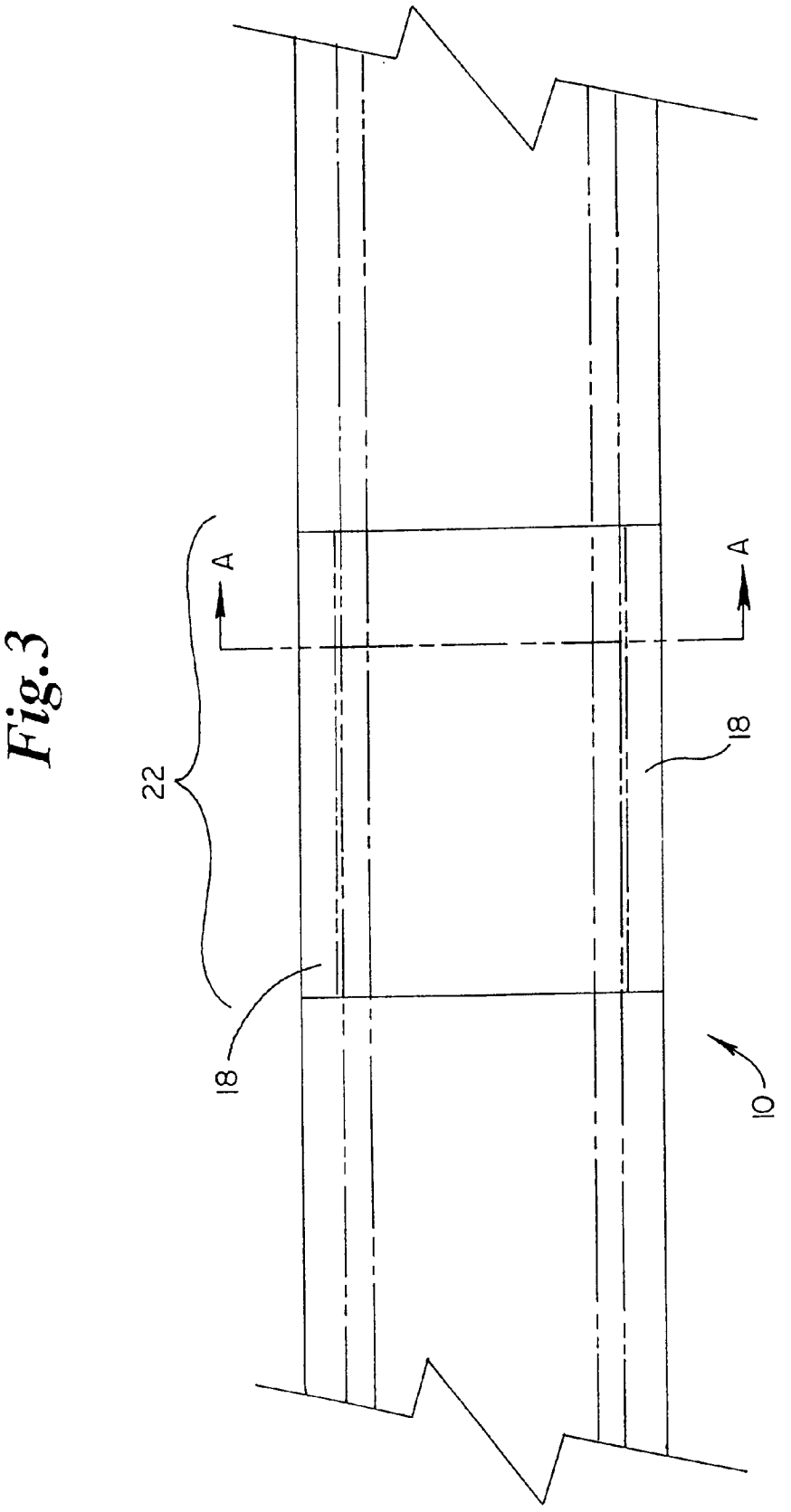


Fig.3

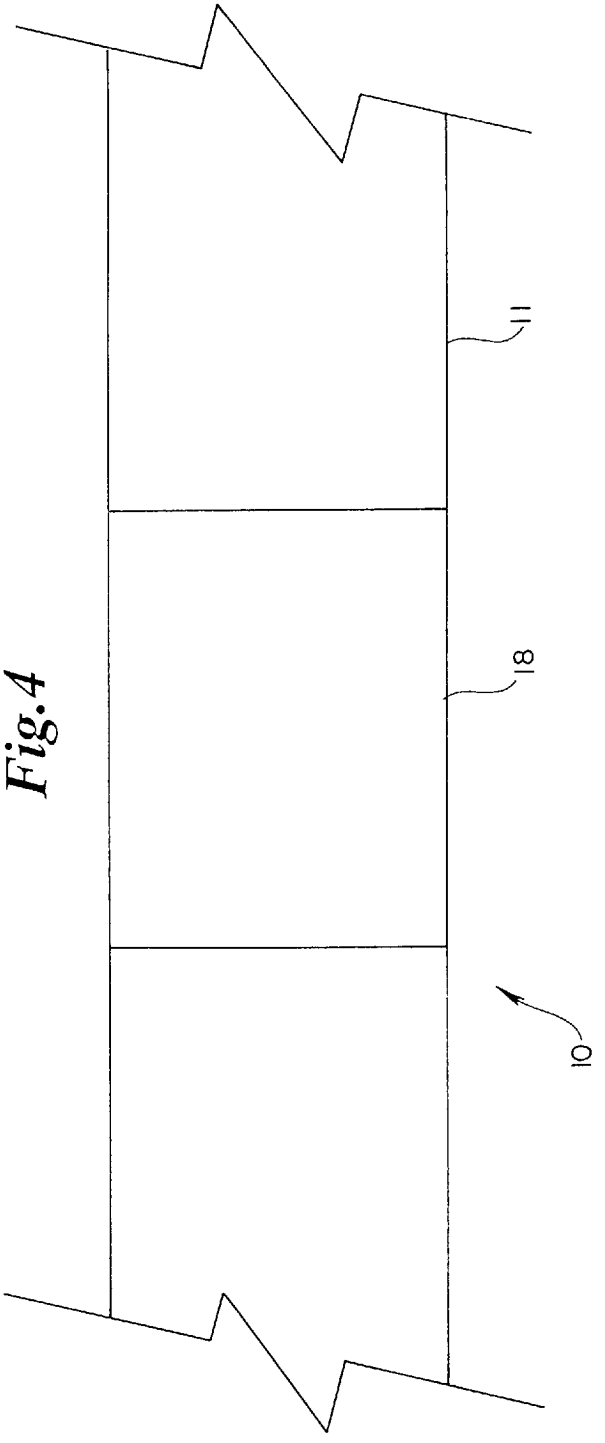
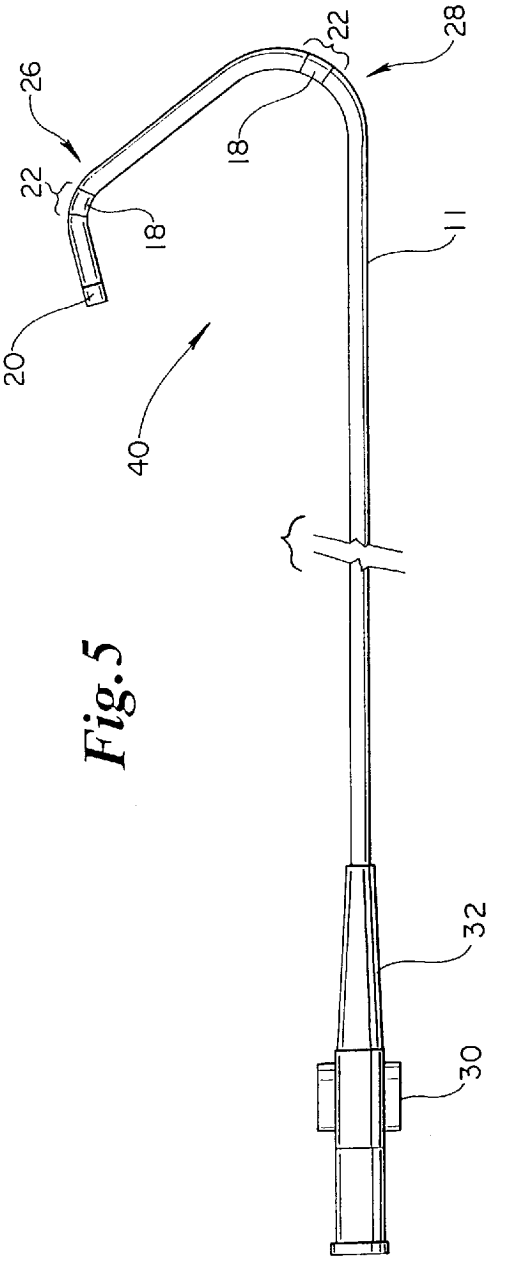


Fig.4



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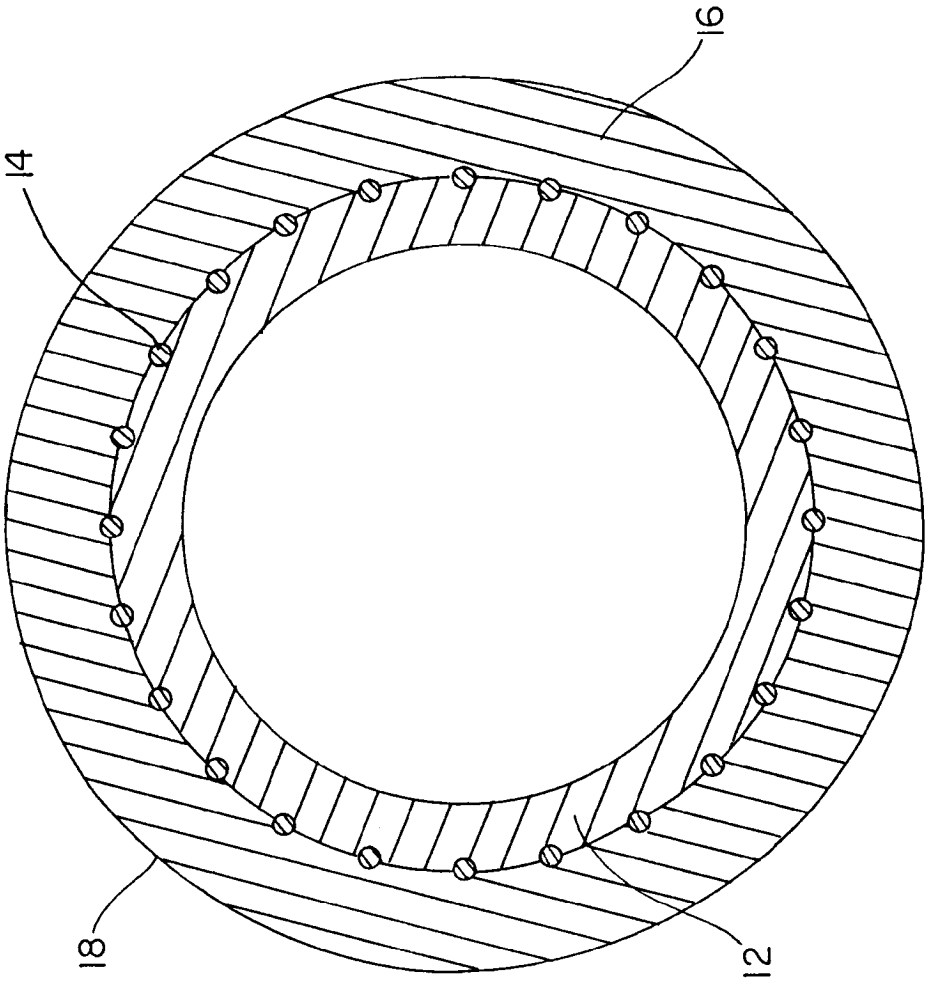

Fig.6

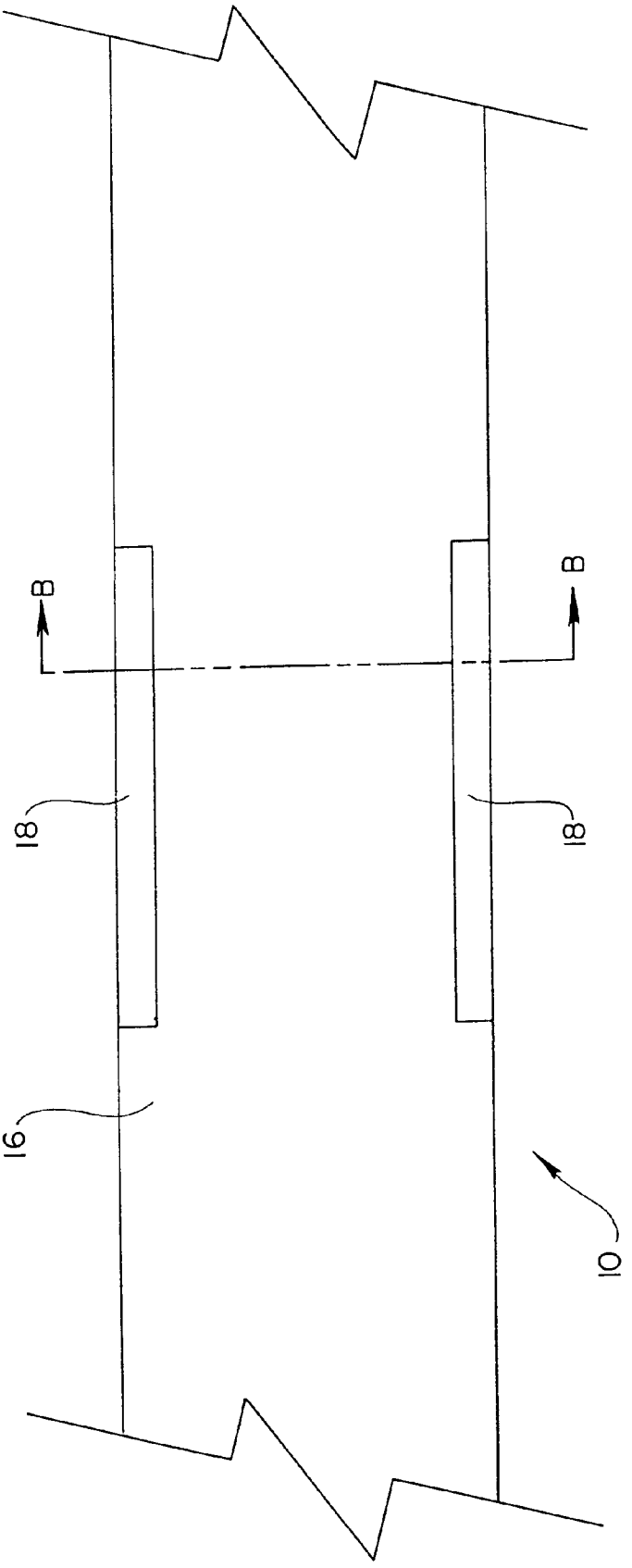

Fig. 7

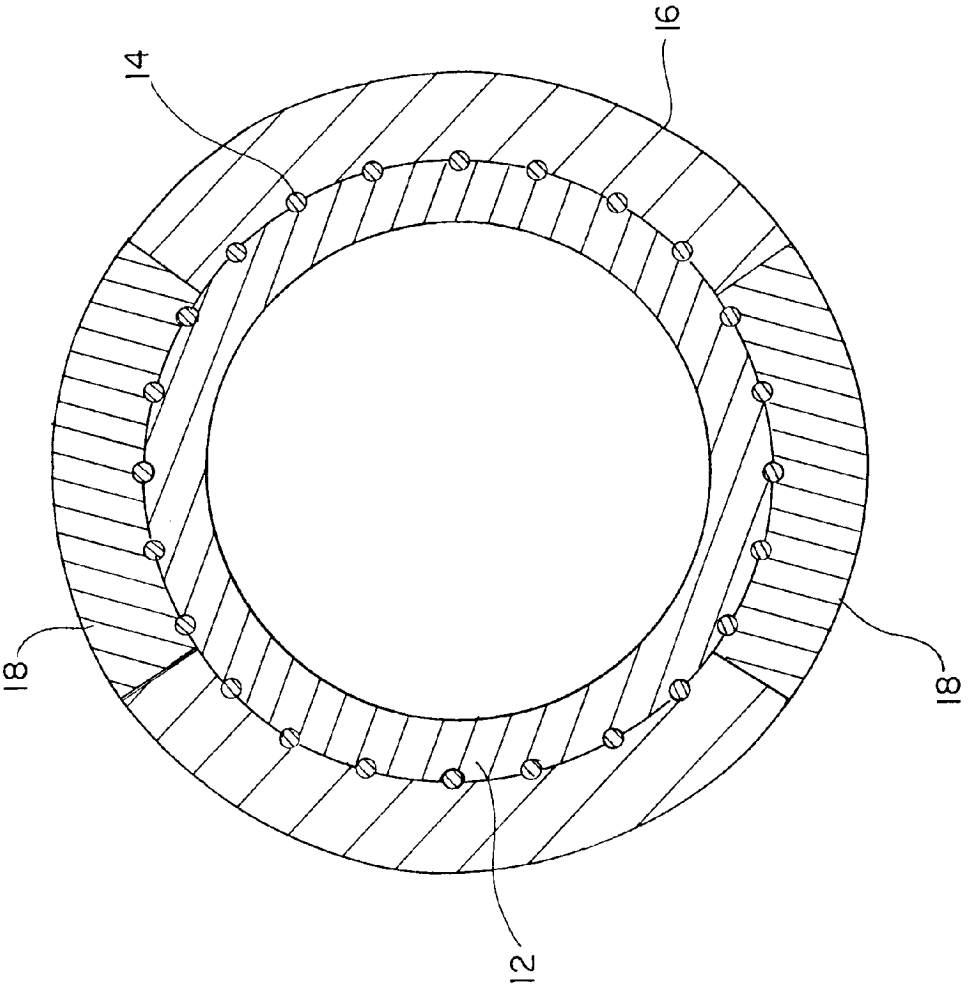

Fig. 8

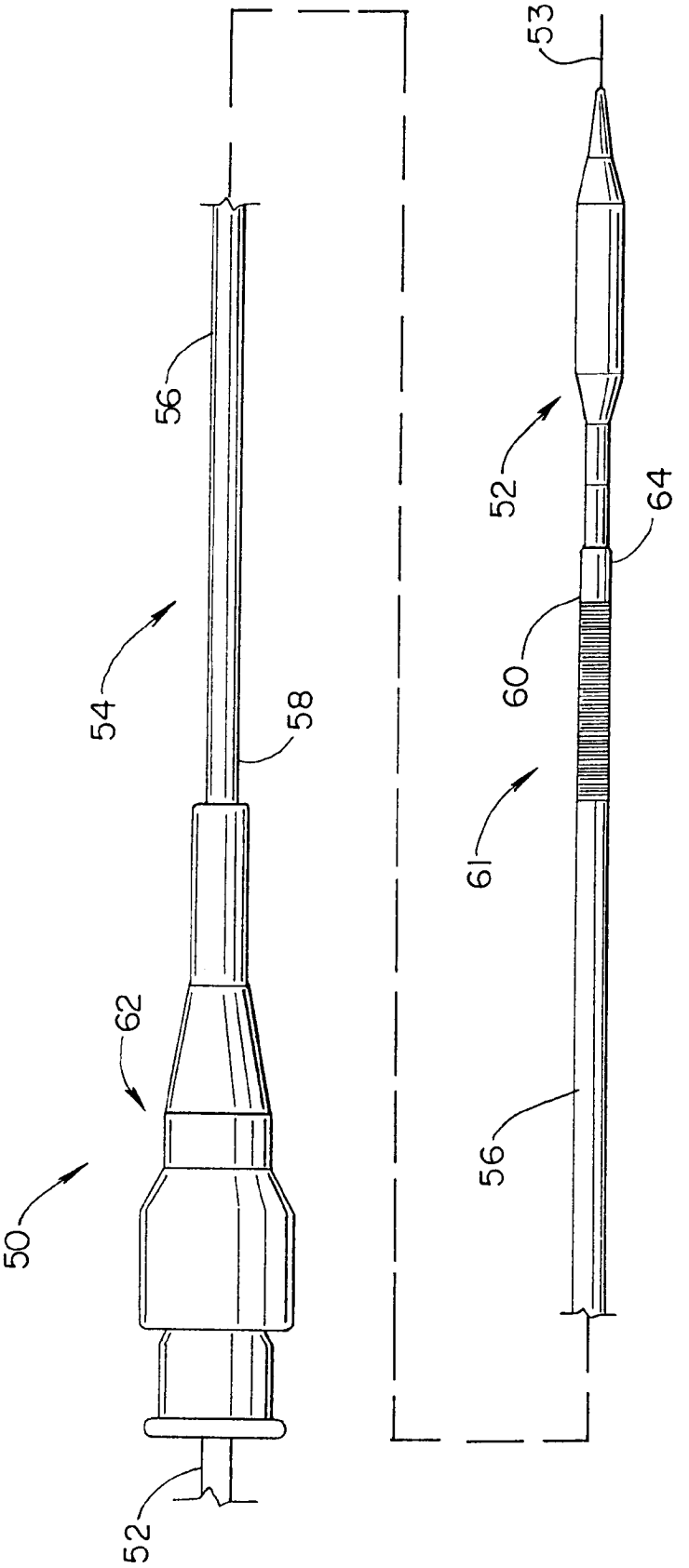

Fig. 9

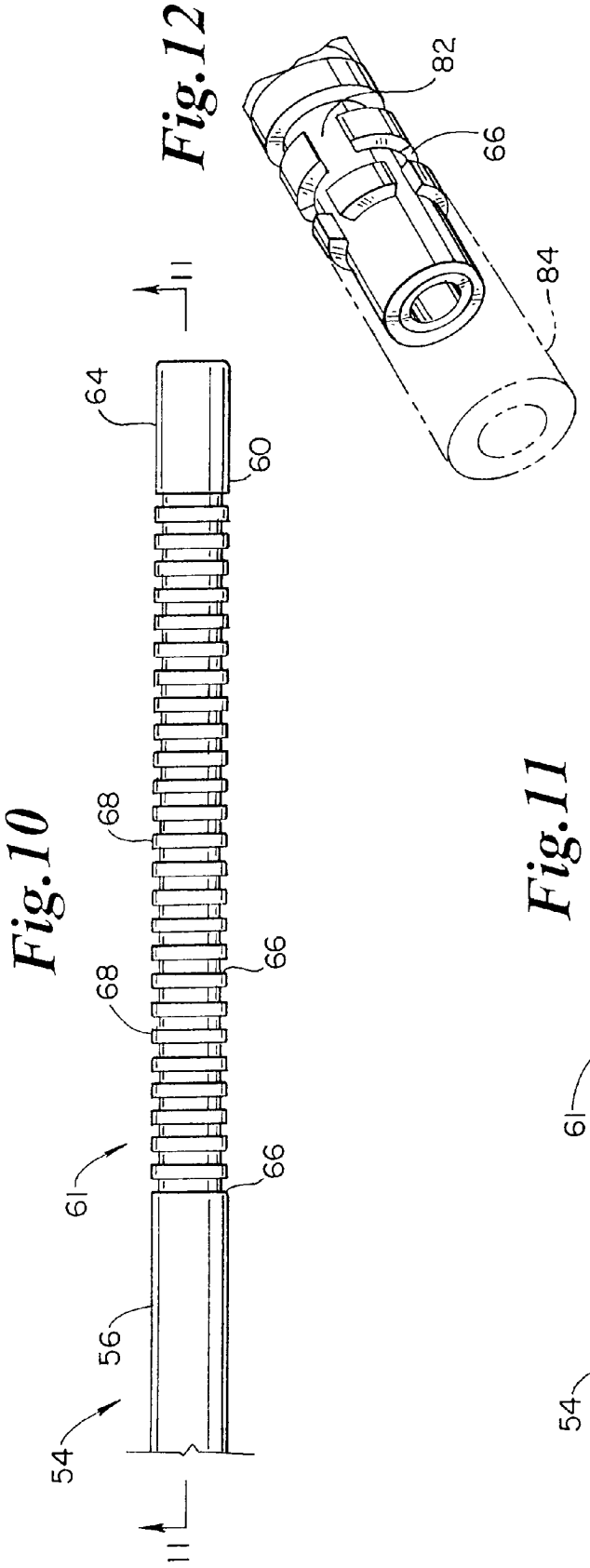
Fig. 12
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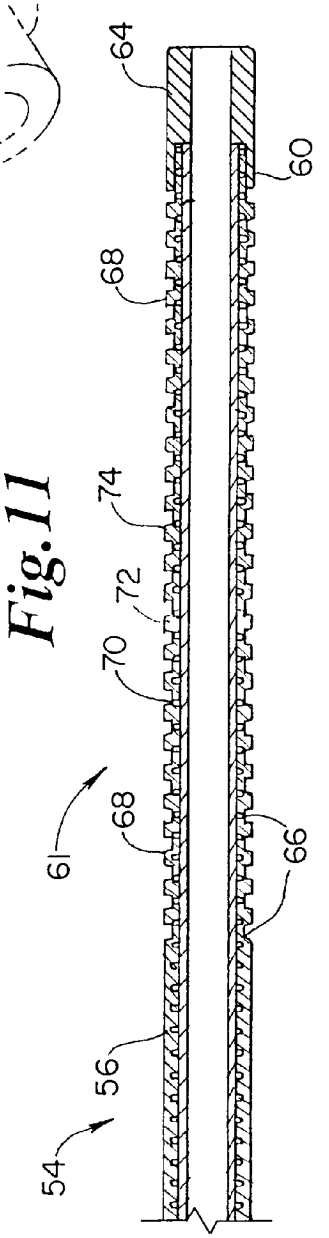
Fig. 11
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Fig.11A

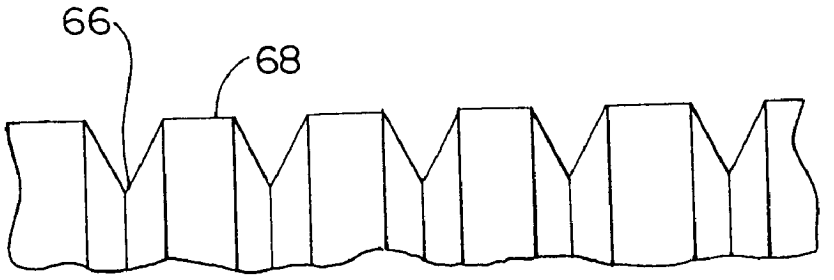


Fig.11B

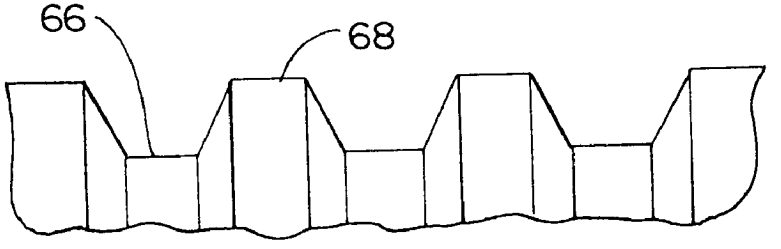
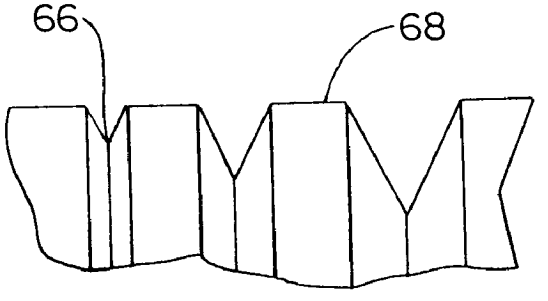


Fig.11C



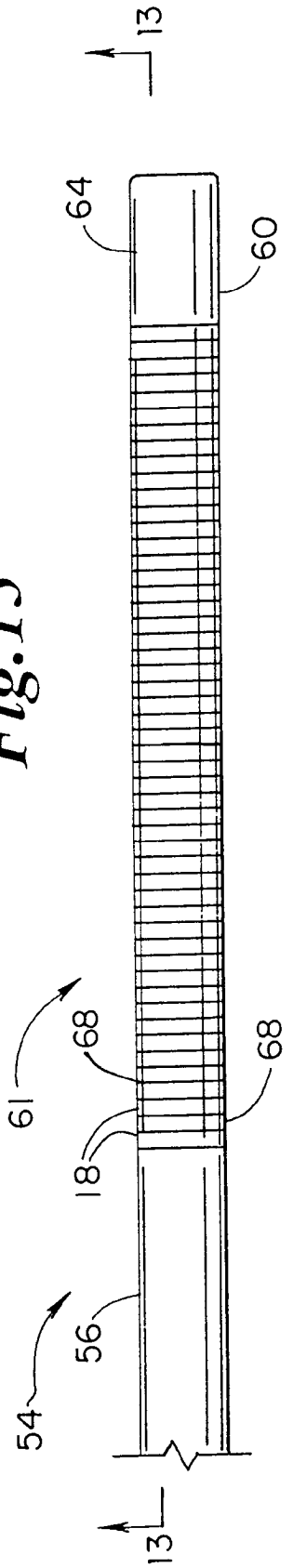


Fig. 13

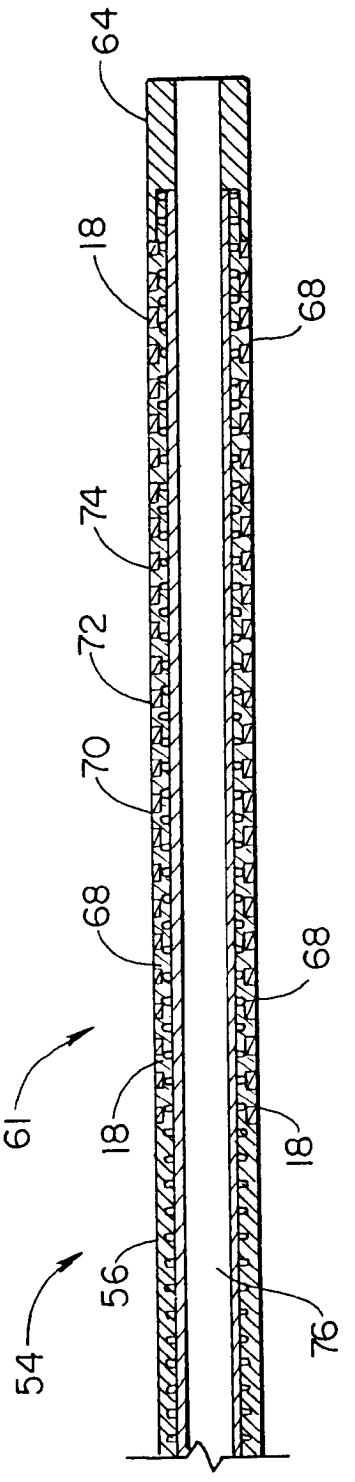


Fig. 14

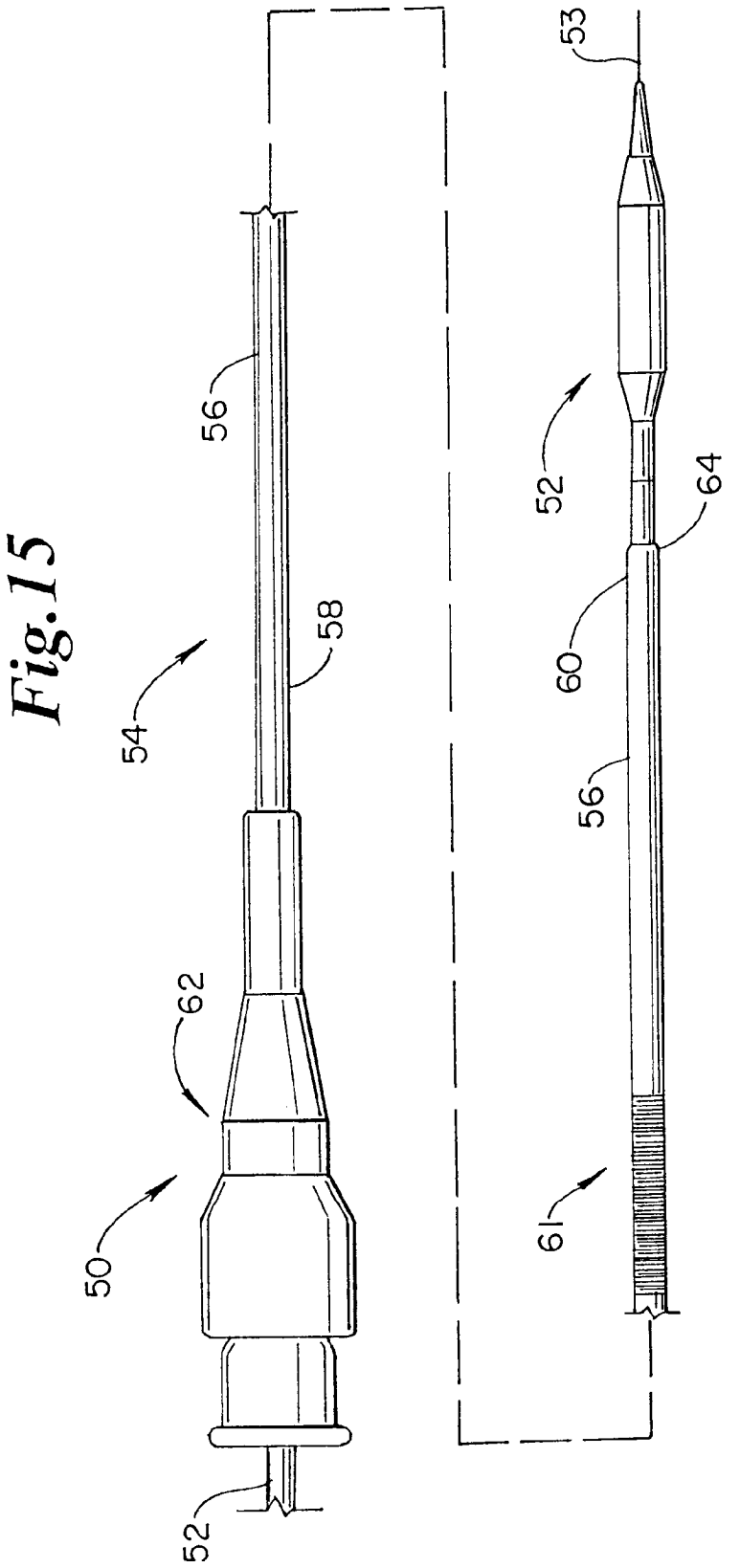


Fig. 15

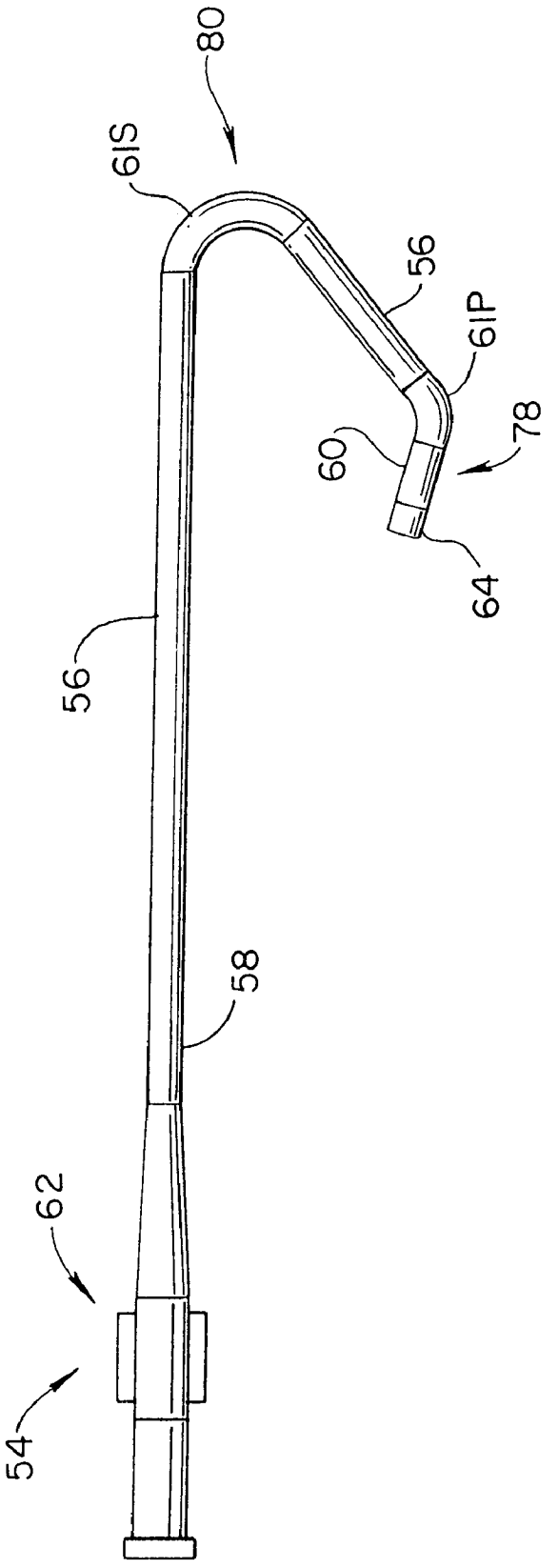
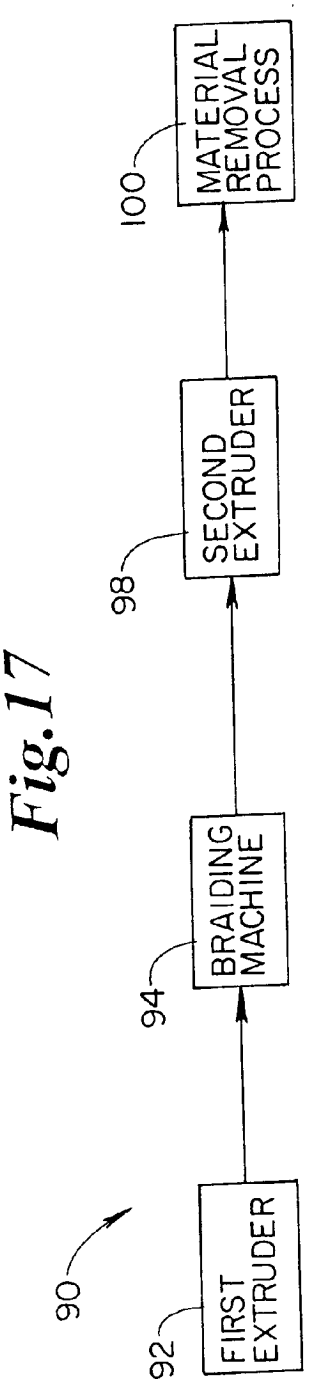


Fig. 16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FIRST EXTRUDER
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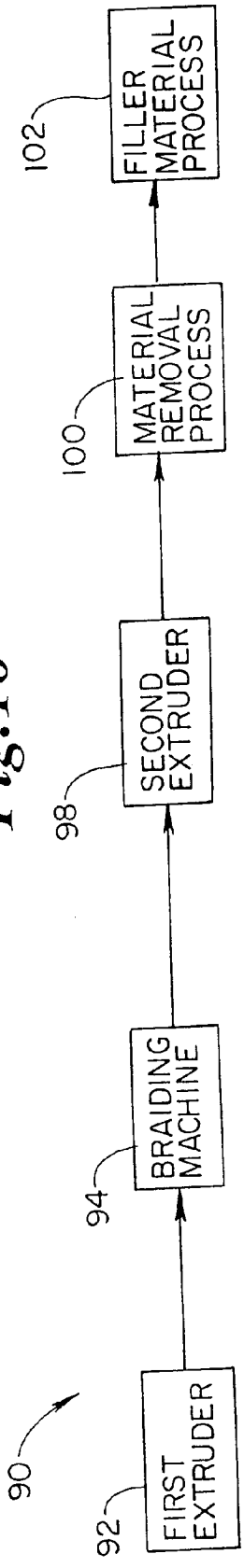
BRAIDING MACHINE
98
SECOND EXTRUDER
100
MATERIAL REMOVAL PROCESS

Fig. 17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FILLER MATERIAL PROCESS

Fig. 18

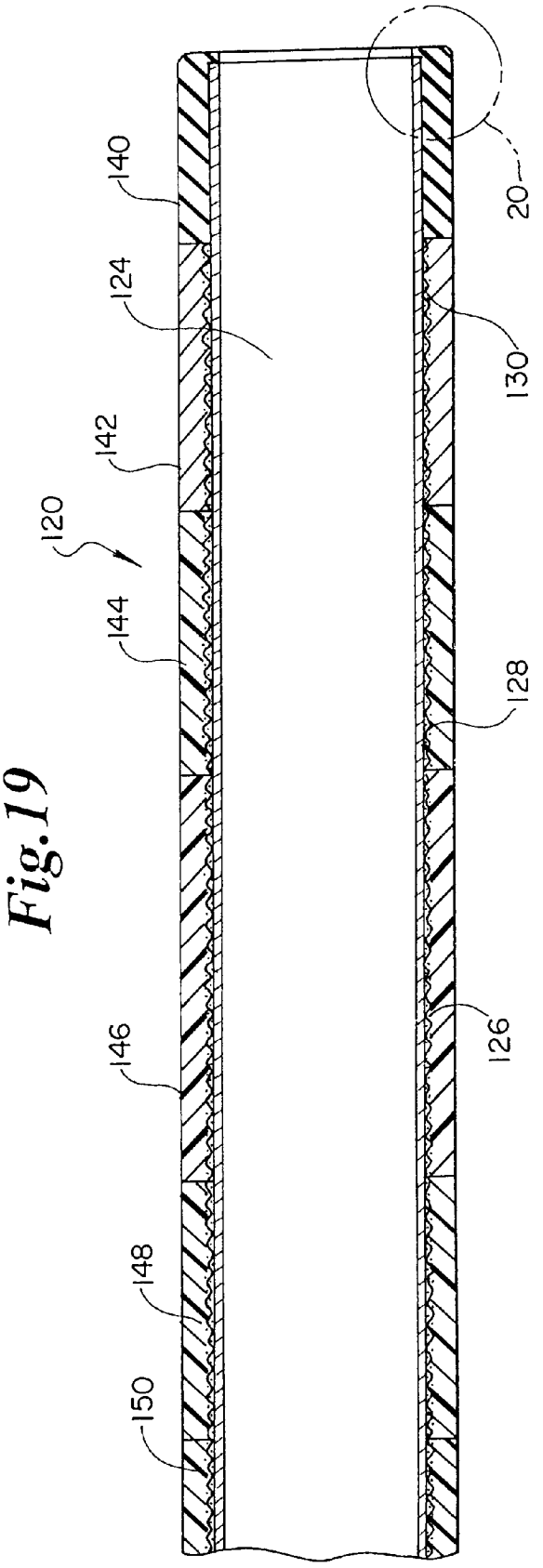

Fig. 19

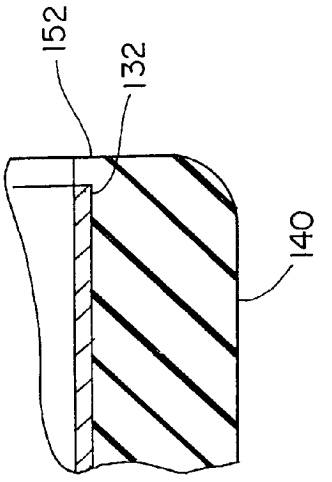

Fig. 20

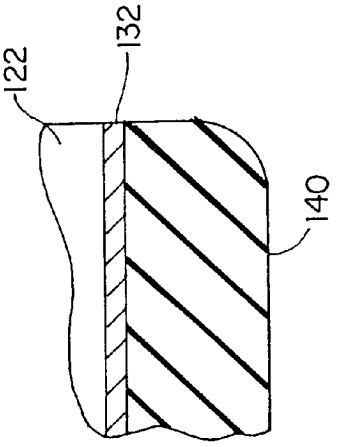

Fig. 21

GUIDE CATHETER HAVING SELECTED FLEXURAL MODULUS SEGMENTS

CROSS-REFERENCES TO CO-PENDING APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 08/703,635, filed Aug. 27, 1996, entitled "Guide Catheter Having a Plurality of Filled Distal Grooves", which is a continuation-in-part of U.S. patent application Ser. No. 08/195,222, filed Feb. 14, 1994, entitled "Elastic Guide Catheter Transition Element" now issued as U.S. Pat. No. 5,569,218, both to the same assignee.

TECHNICAL FIELD

The present invention generally relates to the field of intravascular medical devices, and more specifically refers to the field of catheters such as guiding catheters used for the placement of medical devices and diagnostic catheters used to inject radiopaque fluids within the body for treatment and diagnosis of vascular diseases. In particular, the present invention relates to an improved guide or diagnostic catheter of a braided or braidless catheter design, having a transition zone with a different flexibility than adjacent portions of the catheter shaft for improved catheter performance.

BACKGROUND OF THE INVENTION

The use of intravascular catheters for the treatment of cardiovascular disease is well known in the field of medicine. The need for a greater variety of devices to treat different types of circumstances has grown tremendously as the techniques for the use of such devices has progressed.

Prior art guiding catheters are generally comprised of a shaft which is hollow, defining an inner lumen. The shaft is generally comprised of two tubes congruent to each other with a support member therebetween. A hub is connected to the proximal end of the shaft to provide a means for connecting another device such as a syringe to inject fluids, or for providing a means to direct the device in order to place it within the vessel. A tip of a desired shape is provided at the distal end of the shaft.

An example of a prior art guide catheter as described above is located in PCT publication No. WO 92/15356, published Sep. 17, 1992, to Nita et al., for CARDIOVASCULAR CATHETER HAVING DISCRETE REGIONS OF VARYING FLEXIBILITY, which teaches a guide catheter that has varying flexibilities along its length.

In order for the physician to place the catheter at the correct location in the vessel, the physician must apply longitudinal and rotational forces. In order for the catheter to transmit these forces from the proximal end to the distal end, the catheter must be rigid enough to push through the blood vessel, but yet flexible enough to navigate the bends in the blood vessel. The catheter must also be torsionally rigid to transmit the applied torque. To accomplish this balance between longitudinal rigidity, torsional rigidity, and flexibility, there is often a support member added to the shaft. This support member is often comprised of a metal braid or coil embedded in the shaft. This support wire is often embedded in the shaft between the two layers of tubing that comprise the shaft.

A guiding catheter is guided through the aorta over the aortic arch and down to the ostium of the vessel which is to be treated. It is preferable to have a soft tip or flexible section engage the ostium. Therefore, it is advantageous to have the proximal section be rigid to transmit the forces applied, but

to have the distal end more flexible to allow for better placement of the guide catheter. Having the distal section more flexible also creates a less traumatic section to the blood vessel. The distal end of the catheter is rotated, through the transmission of torque from the proximal end, until the tip of the guiding catheter is in the desired position. With the variations of different bend shapes available on the distal ends of these devices and with variations in patient anatomy, each device may need to be torqued more or less in order to correctly place it.

One problem that has surfaced is that as more flexible distal sections are placed on these catheters, the incidence of guide catheter back-out is increased. Guide catheter back-out occurs when the guide disengages from its preferred positioning (e.g., coronary ostium), thereby creating the need for the physician to reposition the guiding catheter. Many different guide catheter curve shapes have been designed to overcome this problem, with each giving different levels of support. However, as the flexibility of the distal most section is increased, the tendency for back-out again increases.

It is possible to construct a device that is very rigid to obtain the correct amount of back-out support. However, the resulting device would be very traumatic to the patient's arteries due to its rigidity. Similarly, it is possible to construct a very flexible device to limit the trauma the device imparts to the blood vessels. However, the device then becomes too flexible and does not provide any back-out support.

Another problem that is seen in current devices is that devices are constructed such that they are equally flexible in all planes. That feature is not always desired.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages associated with the prior art by providing a transition element in the material. The present invention allows for flexibility of a guiding catheter to be increased, while maintaining its ability to prevent guide catheter back-out. The present invention also allows for the rigidity of a guiding catheter to be increased in a discrete segment, thereby increasing the back-out resistance while maintaining the flexibility. The present invention provides a manner in which a device of varying flexibility may be made very inexpensively. The present invention also provides a manner in which differential flexibility may be imparted to a guide catheter.

A preferred embodiment of the present invention includes a tubular member for a guide catheter and a guide catheter which incorporates an inner tubular member, a wire braid disposed over at least a portion of the inner tubular member and a plurality of discrete segments of outer tubular member overlying the braid and inner tubular member. The discrete segments of outer tubular member are of selected flexibility or durometer to selectively vary the flexural modulus of the catheter tube or guide catheter distal region to match identified functions of the particular segment of the catheter shaft in specific intravascular procedures. Unlike prior art catheters, this preferred design incorporating distinct segments, does not necessarily follow the current standard of each section of a catheter becoming more flexible as you move proximal to distal along a catheter shaft. Thus, each discrete segment of the catheter shaft of the present embodiment is matched to its clinical role and function. Each section has a specific flexural modulus, length and location along the catheter tube or guide catheter.

In a preferred embodiment of a catheter incorporating discrete segments of varying flexibility, the catheter shaft

includes at least two, but preferably six zones of controlled flexural modulus due to the discrete segments of outer tubular member thereon. These include a proximal shaft zone of flexural modulus greater than 49 Kpsi, a mid-shaft zone of flexural modulus from 29–67 Kpsi, a secondary curve zone of flexural modulus greater than 49 Kpsi, a transition zone of flexural modulus from 13–49 Kpsi, a distal section zone of flexural modulus from 2–49 Kpsi, and a soft tip zone of flexural modulus between 1 and 15 Kpsi. A preferred embodiment can also include a very short distal bumper zone of flexural modulus of less than 7 Kpsi. These zones are preferably created by utilizing a discrete segment of outer tubular member manufactured from a polyether block amide having a selected stiffness or durometer rating to achieve the desired flexural modulus of the shaft when the discrete outer tubular segment functions in combination with the inner tubular member and braid if disposed thereunder.

In another preferred embodiment of the invention, the catheter shaft material is removed in the transition section. The outer tube of the shaft is removed down to the braid of the catheter. This is done by a grinding process. The removal of this material creates a band in which there is no material present. That band is then filled with a material having different physical properties than the material which was removed, thereby changing that section's properties.

If the filler material substituted in the band is a more flexible material, the transition section will have the flexibility of both the remaining inner tube layer, the braid, and the new outer material. It is clearly seen that while this catheter section becomes a new combination, it will still be more flexible than the sections immediately proximal and distal to it. If the filler material substituted in the band is a more rigid material, the combination of the materials in this transition section will be more rigid than the sections immediately proximal and distal to it.

In another embodiment of the present invention, a transition zone is formed by removing catheter shaft material from the catheter shaft distal portion, forming one or more annular grooves, and further forming one or more longitudinal grooves contiguous with the annular grooves and contiguous with the shaft distal end. Softer, more flexible material suitable for forming an atraumatic tip is used as the filler material. The soft filler material extends distally, extending past the transition zone and forming the atraumatic tip itself. In this manner, the transition zone and tip are formed of the same material and in the same step.

Another embodiment of the present invention includes an improved intravascular catheter for use in catheter procedures. The catheter includes a shaft having a proximal end, a distal end, and a lumen extending longitudinally therethrough. The catheter shaft includes a first layer and a second layer overlying the first layer. The improvement includes a transition zone located along the catheter shaft having a different degree of flexibility than an adjacent portion of the shaft. The transition zone includes a high density of grooves.

The grooves may be generally annular grooves. The grooves may include micro-grooves. In one embodiment, the annular grooves have a density greater than 5 grooves per inch, with preferably 5 to 50 grooves per inch.

The grooves may be located within the second layer. The grooves may be generally annular, but extending less than 360° degrees about the catheter shaft to form a bending plane.

The transition zone may be located proximal of the distal end. The catheter shaft may be curved, and the transition zone may be located along the curve of the shaft. The catheter shaft may include a primary curve, wherein the transition section is located along the primary curve.

The catheter may further include a support layer overlying the first layer. The grooves may be located within the second layer and not extend down to the support layer.

The catheter may further include material located within the grooves, having a different shore hardness than the second layer. The material may be relatively softer than the second layer. Alternatively, the material may be relatively stiffer than the second layer.

In another embodiment, the present invention is an intravascular catheter for use in catheter procedures. The catheter includes a shaft having a proximal end, a distal end, and a lumen extending longitudinally therethrough. The shaft includes a first layer with a second layer overlying the first layer.

The catheter shaft includes a first curve. The improvement includes a transition zone located along the catheter shaft first curve having a different degree of flexibility than an adjacent portion of the shaft. The second layer within the transition zone has a high density of surface contours located therein.

The surface contours may be micro-contours. The surface contours may include a plurality of generally annular grooves. The catheter may further include material located within the surface contours having a different shore hardness relative to the second layer. The material may be softer relative to the second layer. Alternatively, the material may be stiffer relative to the second layer.

The catheter may include a second curve along its shaft, and a second transition zone may be located along the second curve. The catheter may further include material located within the surface contours of the second transition zone, having a different shore hardness relative to the second layer. The catheter may further include material located within the surface contours of the transition zone located along the first curve, having a greater shore hardness rating relative to the material located within the second transition zone located along the second curve.

The present invention includes a method of manufacturing a catheter for use in intravascular catheter procedures. The method includes providing a mandrel and forming a first layer over the mandrel. A second layer is overlayed or coupled to the first layer. A portion of the second layer is removed to form a high density of grooves in the surface of the second layer.

The portion of the second layer may be removed using an abrasion process. The grooves may be generally annular grooves. The abrasion process may further include the steps of rotating the catheter about its longitudinal axis. A grinding wheel having a pattern corresponding to the generally annular grooves is rotated. The catheter is moved into the grinding wheel to a desired depth. The grooves may be V-shaped.

The grooves may be micro-grooves. The density of the grooves may be greater than 5 grooves per inch, with 5 to 50 grooves per inch preferred. The grooves may be filled with a material having a different hardness rating relative to the second layer. The material may be softer relative to the second layer. Alternatively, the material may be harder relative to the second layer. The method may further include the step of grinding the catheter to a uniform outside diameter.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be further described with reference to the accompanying drawings where like numbers refer to like parts in several views and wherein:

FIG. **1** is a plan view showing a section of the catheter shaft;

FIG. **2** is another plan view of the catheter shaft with a length of the shaft ground down to create a band;

FIG. **3** is a plan view of FIG. **2** after the filler material has been added;

FIG. **4** is a perspective view of the catheter shaft of FIG. **3**;

FIG. **5** is one embodiment of the present invention;

FIG. **6** is a cross section of FIG. **3** along line **6—6**;

FIG. **7** is another embodiment of the present invention;

FIG. **8** is a cross section of FIG. **7** along line **8—8**;

FIG. **9** is a plan view of another embodiment of the present invention, including a transition zone located along the catheter shaft;

FIG. **10** is a partial enlarged perspective view showing the transition zone along the catheter shaft;

FIG. **11** is a longitudinal cross section of FIG. **10** taken along line **11—11**;

FIG. **11A** is a partial view of the longitudinal cross section of FIG. **11** depicting an alternative V-shaped annular groove;

FIG. **11B** is a partial view of the longitudinal cross section of FIG. **11** depicting a second alternative annular groove configuration;

FIG. **11C** is a partial view of the longitudinal cross section of FIG. **11** depicting annular grooves of varying depth and width along the longitudinal length of the catheter;

FIG. **12** is an enlarged perspective view of an embodiment wherein the transition zone includes annular and longitudinal grooves and is contiguous with the catheter distal tip;

FIG. **13** is an enlarged perspective view of yet another embodiment of the transition zone located along the catheter shaft;

FIG. **14** is a longitudinal cross section of FIG. **13** along line **13—13**;

FIG. **15** is a perspective view of a guide catheter showing an application of the present invention;

FIG. **16** is a perspective view of a guide catheter showing another application of the present invention;

FIG. **17** is a schematic block diagram showing one method of manufacturing a catheter in accordance with the present invention;

FIG. **18** is a schematic block diagram showing yet another method of manufacturing the present invention;

FIG. **19** is a partial cross-sectional view of a distal portion of a catheter tube or guide catheter depicting a preferred distal construction;

FIG. **20** is a detailed partial cross-sectional view of the tip region indicated in FIG. **19** showing a preferred tip construction; and

FIG. **21** is a detailed partial cross-sectional view of an alternative embodiment of the tip configuration of FIG. **20** depicting the inner tubular member extending to the distal end of the catheter tube.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** shows a section of a catheter **10** which is preferably a guiding catheter. Catheter shaft **11** is comprised of an inner tube **12** which is surrounded by a support member **14**. Support member **14** is then surrounded by an outer tube **16**. Inner tube **12** is represented in FIG. **1** by dashed lines and the support member **14** is represented by a dotted line.

In the preferred embodiment, inner tube **12** is a thin walled PTFE (polytetrafluoroethylene) tube. This creates a smooth, friction-free surface for the passage of other devices through the inner tube. Support member **14** is a 304 stainless steel wire, wound in a braided pattern around inner tube **12**. Alternatively, support member **14** could also be comprised of polymer fibers. Outer tube **16** is a polymer jacket which is placed through an extrusion process onto combined layers of inner tube **12** and support member **14**. Preferably, outer tube **16** is comprised of PEBAX®, a polyether block amide (PEBA) available from ATOMCHEM POLYMERS, Birdsboro, Pa. FIG. **6** shows a cross section of this construction.

FIG. **2** is a drawing of a portion of catheter **10**. Catheter shaft **11** is shown having a section ground or abraded away to create a band **15** in which no material exists. As shown in FIG. **2**, outer shaft **16** is removed to expose the support member **14**, and to create a band **15** which will be filled later with a different material.

In the preferred embodiment, outer tube **16** is removed through an abrasion process. Specifically, the section in which the band **15** to be created is brought in contact with a grinding wheel. Catheter shaft **11** is then rotated 360 degrees to remove material circumferentially around the device. The grinding wheel is slowly advanced to increase the depth of the cut until the support member **14** is exposed. Although abrasion is the preferred mode of processing, the band **15** can be created in many different ways, some of which include alternate extrusion methods, cutting, and thermal processing.

FIG. **3** is a plan view of the device depicted in FIG. **2** after the different material, filler material **18**, has been placed in the band **15** to create the transition section **22**. Filler material **18** is an element which has different physical properties than the outer tube **16**. For example, if the catheter shaft **11** is comprised of a flexible polymer, the filler material **18** may be either a rigid polymer, a rigid metal, or an even more flexible polymer. Likewise, if the catheter shaft **11** is comprised of a rigid polymer, the filler material **18** may be a more flexible polymer material.

Filler material **18** is preferably a circular polymer tube with a diameter equal to the diameter of the band **15** and a length equal to the length of the band. The filler material **18** is cut longitudinally to allow it to be placed over the catheter shaft **11** and onto the band **15**. A processing sleeve is then loaded over both the catheter shaft and the band. The entire transition section **22** is then subjected to a heating source to cause the materials to flow together. The processing sleeve allows for a smooth outer surface following thermal processing.

In a preferred embodiment, the outer tube **16** is comprised of PEBAX having a durometer of 67D. Although 67D is preferred, the outer tube could be on the order of 40–72D. The filler material **18** is also comprised of PEBAX, but has a durometer of 25D. Although 25D is preferred, the outer tube could be on the order of 5–72D. In a preferred embodiment, the band **15** length is in the order of 0.1 to 0.75 inches. The thickness of the band **15** varies with the amount of outer tube **16** material which is removed. For example, in an 8F guiding catheter, the diameter of the outer tube is in the order of 0.102–0.106 inches. After the material is removed, the diameter of the band **15** is on the order of 0.092–0.096 inches. The diameter of the catheter shaft **11**, or outer tube **16**, also varies with the desired end use for the product. A guiding catheter may be on the order of five to ten French, while a balloon angioplasty catheter will be on the order of two to five French.

FIG. **4** shows the perspective view of the device when completed. Band **15** is replaced with filler material **18** in a circumferential pattern around the catheter shaft **11**.

FIG. **5** shows a specific application of this invention in the area of guiding catheters. Guiding catheter **40** is comprised of a catheter shaft **11** which is constructed as described above. Connected to the proximal end of the catheter shaft **11** is a hub **30** and strain relief **32**. The connection of these elements allows the physician to connect other devices to the guiding catheter **40** and to manipulate the device through the application of longitudinal or rotational forces. Connected to the distal end of the catheter shaft **11** is a distal tip **20**. Distal tip **20** generally consists of a softer, more flexible polymer which is connected to the catheter shaft **11** through a thermal process. In a preferred embodiment, distal tip **20** is comprised of a PEBAX polymer tube having a durometer of 35–40D. Distal tip **20** generally does not contain either the inner tube **12** or the support member **14**. However, it is possible for these elements to be present in a portion of the distal tip **20**.

The most distal section of the guiding catheter **40** is formed to correspond to a desired geometrical shape. This shape is determined by the specific anatomy of the patient, and the amount of guide catheter back-out support that is needed for the procedure. Generally, the guiding catheter has at least two bends at the distal end of the catheter shaft **11**. These are the primary curve **26** and the secondary curve **28**. These curves assist the physician in the placement of the device for treatment of the vessels.

In order to simultaneously maximize the amount of guide catheter back-out support and the flexibility of the distal end of the device, the present invention can be used. The present invention utilizes a catheter shaft which is relatively rigid to provide for good guide catheter back-out support, and combines that with a filler material **18** which is relatively flexible. Therefore, a transition section **22** is created which is more flexible to allow for easier and less traumatic guide catheter placement. Flexible transition sections **22** can be located where tight radiuses are created due to the shape of the guide catheter to allow larger devices to pass through the curve with greater ease. The transition sections **22** act as elastic joints which better accommodate devices by allowing the shaft to straighten. In this embodiment, the transition sections **22** are created at the primary curve **26** or the secondary curve **28**. This placement of the transition sections **22** provides the benefits of a flexible distal section and the benefits of a rigid distal section simultaneously. The transition sections **22** can be located strategically within the guide catheter shaft. Ideal locations include: a flexible transition section **22** at the primary curve radius to allow safer deep seating of the guide, flexible transition sections **22** at radius locations within the curve style to improve ease of device passage as it remains coaxial within the vessel lumen and a rigid transition section **22** at the secondary curve to provide maximum back-out support.

Transition sections **22** can be applied to the main shaft in as many locations as needed. Because the support member **14** and the inner tube **12** are continuous through the transition section **22**, a stronger bond is created. This is a key advantage over butt joints as described and used in the prior art. Most catheter shafts are made to be rigid the entire length of the catheter shaft to ensure that correct stiffness occurs at the desired locations. The catheter shaft does not need to be rigid the entire length to provide back-out support. The present invention allows for the rigidity or flexibility to be added only where it is needed.

In an alternative embodiment of the present invention, it is desired to start with a more flexible catheter shaft **11** and create zones of rigidity through the use of the present invention. Bands **15** can be created in the catheter shaft **11** and filled with a more rigid filler material **18**, thereby creating a transition section **22** which is more rigid.

FIGS. **7** and **8** represent another embodiment in which it is desired to create bending planes within the catheter shaft **11**. This also can be accomplished through the use of the present invention. The catheter can be processed as described above, but instead of grinding the band **15** in a 360 degree manner, opposing sides of the catheter shaft **11** may be ground down and then filled with a more flexible filler material **18** to create a plane in which the transition element may bend. Alternatively, a flexible catheter shaft **11** can be ground down on opposing sides and then filled with a more rigid filler material **18**, to create planes in which the catheter may not bend.

In another embodiment of the present invention, the filler material **18** may be a composite or a blend of two different substances. Specifically, it may be comprised of a polymer tube which has a spring coil embedded therein to impart different flexibility in that section. It may also be comprised of two or more polymer sections that have physical properties that are different from each other and from the catheter shaft **11**.

Yet another embodiment of the present invention is shown in FIG. **9**. FIG. **9** shows a catheter assembly generally at **50**, which includes a dilatation catheter **52** positioned over guide wire **53**, within guide catheter **54**. Guide catheter **54** can be similar to the catheter **10** as previously described herein.

Catheter **54** includes a shaft **56** having a proximal end **58** and a distal end **60**. Operably connected to the proximal end **58** of the shaft **56** is a hub assembly **62**. Operably connected to the distal end **60** of the shaft **56** is a soft tip **64**. Located with respect to the distal end **60** is transition zone **61**.

FIG. **10** is a partial enlarged perspective view of transition zone **61**. Transition zone **61** can be similar to transition section **22** as previously described herein. With transition zone **61**, the performance of catheter **54** is changed using mechanical properties (such as the use of surface contours or annular grooves shown), rather than changing catheter materials. Transition zone **61** is used to change the flexibility of guide catheter **54** at desired locations along shaft **56**, improving catheter performance. U.S. Pat. No. 5,358,493 to Schweich, Jr. et al. disclose a catheter shaft having a proximal section, an intermediate section, and a distal section having different degrees of flexibility, which is herein incorporated by reference.

In one embodiment, transition zone **61** includes a plurality of alternating sections, consisting of annular grooves **66** and raised portions (or rings) **68**. The alternating grooves **66** and raised portions **68** extend radially about the catheter shaft **56**. With this embodiment, the transition zone **61** is more flexible relative to the adjacent portions of shaft **56**, even though transition zone **61** and shaft **56** may be constructed of similar materials.

Referring to FIG. **11**, a longitudinal cross-sectional view of guide catheter **54** is shown. Guide catheter **54** is multi-layered, and includes an inner layer **70**, a support layer **72**, and an outer layer **74**. The inner layer **70** is in the form of a tubular member defining a lumen **76** extending longitudinally therethrough. Support layer **72** is formed over the inner layer **70** and includes helically braided strands. The strands may be metallic or non-metallic and may be formed over inner layer **70** or partially embedded within the inner layer **70**.

Outer layer **74** is formed over support layer **72** and inner layer **70**. Outer layer **74** is formed of a material which has

a similar stiffness or durometer relative to inner layer **70**. Alternatively, it is recognized that outer layer **74** may be formed of a material which has a different stiffness or durometer relative to inner layer **70**. Along transition zone **61**, portions of outer layer **74** are removed to form grooves **66** and raised portions **68**. With this construction, transition zone **61** is more flexible relative to the remaining portions of catheter shaft **56**.

In one embodiment, inner layer **70** is formed of an extruded polymeric material, such as polyether block amide, having a durometer between 60D and 72 D. Support layer **72** is formed of braided stainless steel strands. Outer layer **74** is formed of an extruded Nylon, also having a durometer between 60 and 72 D.

In one embodiment (shown in FIGS. **10** and **11**), transitional zone **61** is approximately 0.5 inches long and located proximal to the distal end **60** of shaft **56**. The transition zone **61** is formed of a "micro-groove" construction. The transition zone **61** includes a high density of grooves.

In one preferred embodiment, the density is greater than 5 grooves per inch, with each groove **66** and raised portion **68** being approximately 0.010 inches wide and 0.005 inches deep for an 8-French diameter device. The micro-groove construction allows flexibility to be added to guide catheter **54** at desired locations along its shaft **56**, or along the entire length of the guide catheter shaft **56**, without the use of bonded catheter segments. The micro-groove construction allows for improved catheter performance within a patient's vascular system.

In one preferred embodiment, grooves **66** extend into a portion of outer layer **74**, but do not extend down to support layer **72**. The "micro-groove" construction of the present invention allows the flexibility of catheter shaft **56** to be changed at desired areas or "transition zones" along the catheter shaft **56** without sacrificing the structural integrity of the catheter shaft through bonding, fusing, or similar procedures. For braided catheter construction, a continuous support layer **72** extends through the extension of catheter shaft **56** proximal of transition zone **61**, through transition zone **61**, and through the portion of the catheter shaft which is distal of transition zone **61**.

As depicted in FIG. **11**, each of the microgrooves has a generally rectangular cross section. FIGS. **11A**, **11B** and **11C** depict alternative cross sections for the microgrooves which allow further variability in the flexibility of the micro-grooved section of the shaft. FIG. **11A** depicts multiple V-shaped microgrooves **66** separated by generally flat raised portions **68**. The V-shaped groove allows for varying the flexibility of the shaft radial within a given longitudinal section. As depicted in FIG. **11B**, the microgroove **66** may be of a generally trapezoidal shape. Finally, the width and depth of the microgrooves **66** may be varied along a given longitudinal section of a catheter. This allows variation in flexibility over such section from groove to groove.

The micro-groove construction provides an economical, yet effective method for improving catheter performance. By using micro-groove construction within transition zone **61**, changes in catheter material are not necessary, nor sacrifices in structural integrity, for changing the flexibility along desired locations of catheter shaft **56**. With micro-groove construction, additional filler materials are not necessary within transition zone **61**. The micro-groove construction limits the patient's exposure to catheter procedure problems, such as embolism and ischemia, while providing improved catheter performance during the catheter procedure.

It is recognized that inner layer **70**, support layer **72**, and outer layer **74** may be formed of other materials. In one embodiment, the inner layer **70** is formed of polytetrafluoroethylene having a durometer between 60 and 72 D, and outer layer **74** is formed of polyether block amide having a durometer between 60 D and 72 D. It is recognized that guide catheter **54** may be a braidless guide catheter, without support layer **72**.

Transition zone **61** has a different flexibility than the portion of catheter shaft **56** proximal of transition section **61** and the portion of catheter shaft **56** distal of transition zone **61**. In one embodiment, transition zone **61** is relatively more flexible than the portion of catheter shaft **56** proximal of transition zone **61** and the portion of catheter shaft **56** distal of transition zone **61**. In another application, transition zone **61** is relatively more stiff than the portion of catheter shaft **56** which is proximal of transition zone **61** and the portion of catheter shaft **56** which is distal of transition zone **61**.

Referring to FIG. **13**, guide catheter **54** may further include filler material **18** located within grooves **66**. Referring also to FIG. **14**, filler material **18** is located within grooves **66** such that guide catheter **54** has a generally uniform outside diameter. Filler material **18** is a material having a durometer which is softer relative to the durometer of inner layer **70** and outer layer **74**. In one embodiment, inner layer **70** is formed of polyether block amide having a durometer between 60 D and 72 D, outer layer **74** is formed of Nylon having a durometer between 60 D and 72 D, and filler material **18** is formed of a relatively softer polyether block amide having a durometer between 75 A and 40 D. Alternatively, it is recognized that filler material **18** may be formed of other soft, flexible materials, which includes flexible adhesives, such as urethane oligomer/methacrylate monomer blends which can be ultraviolet curable such as Dymax 138-M std. A preferred viscosity is about 350 cps. with a 40D durometer.

Since filler material **18** has a durometer which is softer relative to outer layer **74** and inner layer **70**, transition zone **22** is more flexible relative to the remaining portion of the guide catheter **54** shaft **56**. Additionally, filler material **18** allows transition zone **61** and guide catheter **54** to have a smooth, generally uniform outside diameter. By using transition zone **61** at desired locations along shaft **56**, catheter performance is improved by creating and controlling catheter flexibility in sections independent of the shaft stiffness.

Alternatively, if it is desired for transition zone **61** to be stiffer (or less flexible) relative to inner layer **70** and outer layer **74**, filler material **18** may consist of a material having a higher durometer relative to inner layer **70** and/or outer layer **74**. In one embodiment, filler material **18** is formed of polyether block amide or nylon, having a durometer between 70 D and 80 D.

Now referring to FIG. **12**, an embodiment of the present invention is illustrated, wherein the transition zone includes one or more annular groove **66** contiguous with a plurality of longitudinal grooves **82** contiguous with a catheter distal tip **84**. In this embodiment, the catheter distal tip **84** may be made of the same filler material as that filling the annular groove **66** and longitudinal groove **82**. By using the same material in annular grooves **66**, longitudinal grooves **82**, and catheter distal tip **84**, the tip **84** may be made in the same step as the step filling the grooves **66** and **82**. This creates a transition zone between catheter shaft **56** and catheter distal tip **84**, as well as reducing manufacturing cost by eliminating a separate additional step for tip creation. The invention disclosed by the embodiment of FIG. **12** is discussed further

in co-pending U.S. patent application Ser. No. 08/703,641, filed Aug. 27, 1996, entitled "Insert Molded Catheter Tip" to the same assignee.

Referring to FIG. **15**, it is recognized that transition zone **61** may be located at different locations along catheter shaft **56** to improve catheter performance as desired for specific catheter procedures. In each application, the section of catheter shaft proximal to transition zone **61** and the portion of catheter shaft distal of transition zone **61** has a different degree of flexibility than transition zone **61**. In one embodiment, transition zone **61** is relatively more flexible than the catheter shaft section proximal to transition zone **61** and/or relatively more flexible than the portion of catheter shaft **56** distal of transition zone **61**. Alternatively, transition zone **61** may be relatively stiffer than the portion of catheter shaft which is proximal to transition zone **61** and/or relatively stiffer than the portion of the catheter shaft which is distal to the transition zone **61**.

Referring to FIG. **16**, one application of the present invention is shown. Guide catheter **54** is curved to a desired geometrical shape for accessing a desired anatomical location during a catheter procedure. As shown, guide catheter **54** includes a primary curve **78** and a secondary curve **80**. A transition zone **61** (labeled **61P**) is located at the primary curve **78** and a transition zone **61** (labeled **61S**) is located at the secondary curve **80**.

In this embodiment, it is desirable to have a relatively flexible transition zone **61** located at primary curve **78** to aid in seating guide catheter **54** tip **64** within the ostium of the coronary receiving treatment. Therefore, the primary curve transition zone **61** is contoured, and may include "micro-grooves" having grooves **66** and raised portions **68** as shown in FIGS. **10** and **11**. Transition zone **61** may further include filler material **18** located within grooves **66**, as shown in FIGS. **13** and **14**, wherein the filler material **18** is of a softer durometer than inner layer **70** and/or outer layer **74**.

It is also desirable that transition zone **61** located at the secondary curve **80** be stiffer relative to the remaining portions of guide catheter shaft **56** for improving back-out support of guide catheter **54** during coronary treatment. Secondary curve transition zone **61** includes filler material **18** located within grooves **66**. Filler material **18** is a material having a durometer which is stiffer relative to the durometer of the material forming inner layer **70** and outer layer **74**. This construction increases the stiffness of transition zone **61** located at secondary curve **80** relative to the remaining portion of the guide catheter **56**.

Referring to FIG. **17**, a process of manufacturing catheter **54** having transition zone **22** is shown generally in schematic form at **90**. A mandrel (not shown) passes through a first extruder **92** for extruding inner layer **70**. After cooling, the coated mandrel is next passed through braiding machine **94** for braiding support layer **72** over inner layer **70**. The braided catheter construction may pass through a heated dye (not shown) for partially embedding the support layer **72** within the inner layer **70**. Next, guide catheter **54** is passed through second extruder **98** for extruding the outer layer **74** over the support layer **72** and inner layer **70**. As previously described herein, the extruded inner layer **70** and outer layer **74** are formed of materials having a generally similar durometer. In one embodiment, extruded inner layer **70** and extruded outer layer **74** have a relatively stiff durometer in the range between 60 D and 72 D to maximize catheter response during a coronary procedure.

Guide catheter **54** passes through material removal process **100** to form transition zone **61** having a contoured, grooved (or micro-grooved) construction. In one embodiment, the material removal process **100** is an abrasion process similar to that previously described herein. In one embodiment, the abrasion process uses a grinding wheel having notches corresponding with the desired transition zone **61** pattern. The grinding wheel is rotated, and positioned adjacent the catheter **54** shaft which is simultaneously rotated. The rotating catheter shaft is moved slowly into the rotating grinding wheel for grinding grooves within the catheter **54** shaft to a desired depth, forming the grooved construction of transition zone **61**. In one preferred embodiment, the material removal process removes a portion of outer layer **74**, but does not remove material down to support layer **72**. Alternatively, it is recognized that the material removal process may remove material from the outer layer **74** at a depth down to (and exposing) support layer **72**.

The rotating catheter shaft is moved away from the rotating grinding wheel, and may be moved longitudinally along its rotating axis relative to the grinding wheel for forming larger areas of transition zone **61**, or multiple transition sections **22**. Catheter **54** may be provided with a grooved outer layer **74** at desired locations, or along the entire guide catheter **54** shaft **56**.

Referring to FIG. **18**, the manufacturing process **90** may further include a filler material process **102** for positioning filler material **18** within grooves **66**. The filler material **18** may be of a greater or lower durometer than the material forming inner layer **70** and/or outer layer **74** to form relatively stiffer or relatively more flexible transition zone **61** as desired.

In one embodiment, the filler material process **102** includes placing a sleeve over the transition zone **61** similar to the process previously described herein. The sleeve and the transition zone **61** are exposed to a heating source to cause the materials to flow together, resulting in filler material **18** being located within groove **66**. The catheter shaft may then be subjected to a secondary grinding process to provide the guide catheter **54** with a uniform outer diameter through transition zone **61**.

In another embodiment, the filler material process may include an insert molding process. The portion of guide catheter **54** having transition zone **61** may be placed into an insert mold. The desired filler material **18** is then injected into the mold and the mold is cooled. The transition zone **61** is then removed from the mold and subjected to a secondary grinding process providing a constant outside diameter to the guide catheter shaft.

Alternatively, filler material **18** may be a flexible adhesive, as previously described herein. The flexible adhesive is applied to transition zone **61**, filling in grooves **66**. The excess adhesive is wiped away, leaving the catheter shaft **56** with a generally uniform outside diameter.

It is recognized that transition zones **61** may be located along catheter shaft **56** to create "bending planes" as previously described herein. In this application, the grooves, contours, or generally annular "micro-grooves" do not extend 360° about the catheter shaft. The grooves are located on opposing sides of the catheter shaft **56**. With this construction, the catheter more readily bends in a first plane about the grooved portions, relative to a second plane which does not include the grooved portions.

As previously described herein, the opposing sides of catheter shaft **56** may include grooves by methods as previously described herein, and then be filled with a relatively more flexible filler material **18**, creating a plane in which the

transition zone **61** may bend. Alternatively, the catheter shaft **56** may be ground down on opposing sides and then filled with a relatively more rigid filler material **18**, to create planes in which the catheter shaft resist bending relative to the opposing side which do not include grooves.

Now referring to FIGS. **19–21**, a preferred embodiment of a distal portion **120** of a catheter tube is depicted incorporating a plurality of discrete outer tubular member segments **140**, **142**, **144**, **146**, **148** of preselected flexibility. In combination with the inner tubular member **122** and support member **126**, the outer tubular member segments **140**, **142**, **144**, **146**, **148** achieve a preferred flexural modulus in the selected segments of the assembled distal catheter shaft **120**. The overall design of the distal catheter shaft portion **120** can be used in conjunction with a straight or curved catheter similar to that depicted in FIG. **16**. In preferred embodiments, the catheter shaft section **120** does not follow current standards of design, wherein each section becomes more flexible as you move proximal to distal along the catheter shaft. Rather, the catheter shaft is designed so that each segment incorporates a flexural modulus which matches its clinical role and function. Thus, the length, location and degree or magnitude of flexibility for any segment is selected for preferred applications.

As depicted in FIG. **19**, the distal catheter shaft section **120** includes an inner tubular member **122** having a lumen **124** extending therethrough. The inner tubular member **122** is preferably a polytetrafluoroethylene tubular member. A support member **126** overlies the outside longitudinal surface **128** of the inner tubular member **122** over a portion thereof. In preferred embodiments, the support member **126** is a braided wire support of stainless steel which extends from the proximal end of the catheter and has a distal end **130** which terminates proximal of a distal end **132** of the inner tubular member **122**. A preferred method of manufacturing the inner tubular member **122** having the braid member **126** overlying the outer longitudinal surface **128** of the inner tubular member **122** with the distal end **130** of the braid member **126** restrained for further processing is disclosed in co-pending application Ser. No. 08/800,926, filed on the same date as this application, entitled "Catheter Having an Adhesive Braid Wire Constraint and Method of Manufacture", the disclosure of which is incorporated herein by reference.

The inner tubular member **122** is preferably a thin-walled tube having a wall thickness of about 0.0015–0.002 inches. The support member **126** has preferably a braided stainless steel braid of high tensile strength. A preferred stainless steel is a high tensile 304 Stainless Steel having a tensile strength of about 340 Kpsi. A preferred wire has a 0.0025 inch diameter which is braided at 65 PIC per inch using 16 strands.

As illustrated in FIG. **19**, the distal catheter shaft section **120** incorporates a plurality of discrete outer tubular member segments **140**, **142**, **144**, **146**, **148** and **150**. In this embodiment, six discrete segments are illustrated. This number can be varied to satisfy a pending clinical application. The discrete outer tubular member segments are preferably manufactured from a polymeric material, such as a polyether block amide. Each segment is manufactured with selected physical properties to give a desired durometer as a measure of flexibility, which when in combination with the inner tubular member **120** and support member **126** upon assembly, give a desired flexibility of the shaft within that segment.

In a preferred embodiment, a distal catheter shaft section includes a soft tip zone **140** which is about 0.075 to about 0.150 inches in length. This portion of the catheter shaft does not include a braid or support member **126** to provide an atraumatic end to the catheter shaft for navigating vasculature and engaging the coronary vessels. A preferred flexural modulus for the combined outer tubular member **140** and inner shaft extending therethrough is about 1 to about 15 Kpsi. A polyether block amide having a 35 D durometer rating can be used in this section.

As depicted in FIG. **20**, the distal end of the inner tubular member **132** terminates slightly proximal of the distal end of the soft tip zone outer tubular segment **140**. This creates a super soft distal bumper zone **152** and provides a super soft interface between the catheter tip and vessel walls without increasing the chance that the tip of the catheter may prolapse. In preferred embodiments, the distal bumper zone **152** is less than 0.025 inches and has a flexural modulus of less than 7 Kpsi. Alternatively, as depicted in FIG. **21**, the inner tubular member **122** can run co-extensive with the outer tubular segments with the distal end **132** terminating at the same point as the soft tip zone outer tubular segment **140**.

Referring again to FIG. **19**, a distal section zone outer tubular segment **142** is illustrated extending in a proximal direction adjacent the soft tip zone outer tubular segment **140**. In preferred embodiments, the distal segment zone outer tubular segment **142** extends proximally for about 0.3 inches to about 1.0 inches. A preferred overall flexural modulus for this region of the distal catheter shaft section **120** is between about 2 and about 49 Kpsi. This section provides coaxial tip positioning and allows active intubation and less traumatic contact. This section would include the primary curve section discussed with respect to FIG. **16** above. In preferred embodiments, a polyether block amide of 40 D Durometer is utilized in this section of the catheter.

Adjacent to the distal section zone outer tubular segment **142** is a transition zone outer tubular segment **144** which extends proximally from the proximal end of the distal section zone outer tubular segment **142**. This segment of the distal catheter shaft portion **120**, when assembled, has a flexural modulus of between about 13 and about 49 Kpsi to provide a smooth flexible transition between secondary and primary curves in the catheter. The length of this segment is about 0.3 to 2.0 inches. A polyether block amide polymer having a 55 D Durometer can be utilized in this section.

A secondary curve zone outer tubular segment **146** extends proximally from the transition zone outer tubular segment **144**. In preferred embodiments, this section has an overall flexural modulus of greater than 49 Kpsi. This section of the catheter shaft and curve geometry provides backup support and is modified to have maximum stiffness for support and stability of the catheter. The length of the secondary curve zone outer tubular segment **146** is preferably about 1 to about 6 inches in length. A polyether block amide having a 70 D Durometer can be utilized in this segment.

A mid-shaft zone outer tubular segment **148** extends proximally from the proximal end of the secondary curve zone outer tubular segment **146**. This section of the distal portion of the catheter shaft **120** has a preferred flexural modulus of about 29 to about 67 Kpsi. This section of the catheter traverses the aortic arch and includes increased flexibility to minimize stored energy from bending over the arch. This reduces whipping and increases stability of the catheter. The preferred length of the mid-shaft zone outer tubular segment **148** is about 5 to about 10 inches. A polyether block amide polymer having a 63 D Durometer can be utilized in this section.

A proximal shaft zone outer tubular segment **150** extends proximally from the proximal end of the mid-shaft zone outer tubular segment **148**. This segment extends to the proximal end of the catheter. A preferred flexural modulus for this section of the catheter is greater than 49 Kpsi to provide maximum stiffness for push and control. A polyether block amide polymer of 70 D Durometer can be utilized in this segment. The length of this segment is determined by the desired overall length of the catheter.

The above selected flexural modulus for specific segments of the distal catheter shaft section **120** can be applied to each component of a curve in preformed curved catheters. Since each curve shape can be broken down into specific function, each curve function can be assigned a specific flexibility relevant to its function. With the present invention, the component of curve shape which provides support is isolated from the rest of the catheter shaft. This isolated section is made to be very stiff. Stiffness can be derived as described above or may be provided with other materials such as segments of Nitinol, hypotube, articulated stainless steel or fiber filled polymer. In this way, in-vitro curve shapes can be made to match in vivo shapes. This improves the predictability and reliability of curve performance and does not require the curve to open up to adjust to the anatomy and to provide enough spring for backup support. The stiffness is increased and located specific to each curve shape to eliminate the need for elastic shape memory. The resulting stiffer fixed catheter curve shape and design provides a stable platform for devices to pass into the coronary anatomy.

A preferred method of manufacturing a catheter incorporating a distal catheter shaft portion **122**, as depicted in FIG. **19**, includes first providing an inner tubular member **122** having a support member **126** disposed over a portion thereof. As previously stated, a preferred method of manufacturing this subassembly is disclosed in co-pending application Ser. No. 08/800,926, filed on the same date as this application, entitled "Catheter Having an Adhesive Braid Wire Constraint and Method of Manufacture", which is incorporated herein by reference. Outer tubular segments of selected length and flexibility are than slidably received over the subassembly and abutted to one another as depicted in FIG. **19**. A heat shrink sleeve which can be manufactured from an FEP resin is placed over the whole assembly. The assembly is then heated or baked to adhere and fuse the components of the final catheter assembly. The heat shrink sleeve is then removed.

Although the present invention is described in terms of the preferred embodiment above, it should be noted that alterations and modifications of this invention will be possible without departing from the spirit and scope of this invention.

What is claimed is:

1. A tubular assembly for a guide catheter comprising:

a. an inner tubular member having a proximal end, a distal end and a longitudinal surface;

b. a support member disposed over a substantial portion of said longitudinal surface and conforming thereto, said support member having a distal end terminated proximal of said distal end of said inner tubular member; and

b. a support member disposed over a substantial portion of said longitudinal surface and conforming thereto, said support member having a distal end terminated proximal of said distal end of said inner tubular member; and

c. a plurality of discrete outer tubular member segments disposed over said inner tubular member and said support member in abutting relationship, wherein said plurality includes at least a first, second and third outer tubular member segment with said second outer tubular member segment between said first and third outer tubular member segment and having a flexural modulus greater than said first and third outer tubular member segments, and wherein in combination said plurality of discrete outer tubular members form an outer tubular member extending over at least a substantial portion of the length of said inner tubular member.

2. The tubular member of claim **1**, wherein said second outer tubular member segment has a flexural modulus greater than 49 Kpsi.

3. The tubular member of claim **2**, wherein said inner tubular member is manufactured from polytetrafluoroethylene.

4. The tubular member of claim **3**, wherein said support member is a braided metallic member.

5. The tubular member of claim **1**, wherein all of said discrete outer tubular member segments are manufactured from a polymeric material.

6. The tubular member of claim **5**, wherein said polymeric material is a polyether block amide.

7. The tubular member of claim **1**, wherein at least one of said discrete outer tubular member segments is manufactured from a polymeric material.

8. A guide catheter comprising:

a. an inner tubular member having a proximal end, a distal end and a longitudinal surface;

b. a support member disposed over a substantial portion of said longitudinal surface and conforming thereto, said support member having a distal end terminated proximal of said distal end of said inner tubular member;

c. a plurality of discrete outer tubular member segments disposed over said inner tubular member and said support member in abutting relationship, wherein in combination said plurality of discrete outer tubular members form an outer tubular member extending the length of said inner tubular member, said plurality of discrete outer tubular member segments include a soft tip zone outer tubular member, at least a portion of which extends proximally from said distal end of said inner tubular member, a distal section zone outer tubular member extending proximally from said soft tip zone outer tubular member, a transition zone outer tubular member extending proximally from said distal section zone outer tubular member, a secondary curve zone outer tubular member extending proximally from said transition zone outer tubular member, a mid-shaft zone outer tubular member extending proximally from said secondary curve zone outer tubular member and a proximal shaft zone outer tubular member extending proximally from said mid-shaft zone outer tubular member; and,

d. wherein said secondary curve zone outer tubular member has a flexural modulus greater than said mid-shaft zone outer tubular member and said transition zone outer tubular member.

9. The guide catheter of claim **8**, wherein the flexural modulus of said catheter in the portion having said secondary curve zone outer tubular member thereon is greater than about 49 Kpsi.

10. The guide catheter of claim **9**, wherein the flexural modulus of said catheter in the portion having said mid-shaft zone outer tubular member thereon is between about 30 and about 60 Kpsi.

11. The tubular member of claim **8**, wherein all of said discrete outer tubular member segments are manufactured from a polymeric material.

12. The tubular member of claim **11**, wherein said polymeric material is a polyether block amide.

13. The tubular member of claim **8**, wherein said inner tubular member is manufactured from polytetrafluoroethylene.

14. The tubular member of claim **13**, wherein said support member is a braided metallic member.

15. The tubular member of claim **8**, wherein at least one of said discrete outer tubular member segments is manufactured from a polymeric material.

16. The tubular member of claim **8**, wherein at least some of said plurality of discrete outer tubular member segments have different flexibility characteristics so that when disposed over said inner tubular member, the flexibility of said tubular members varies over its length due to said differences in outer tubular member segments.

17. A guide catheter comprising:

a. an inner tubular member having a proximal end, a distal end and a longitudinal surface;

b. a support member disposed over a substantial portion of said longitudinal surface and conforming thereto, said support member having a distal end terminated proximal of said distal end of said inner tubular member; and

c. a plurality of discrete outer tubular member segments disposed over said inner tubular member and said support member in abutting relationship, wherein in combination said plurality of discrete outer tubular members form an outer tubular member extending the length of said inner tubular member, said outer tubular member segments having different flexibility characteristics so that as assembled said guide catheter has discrete segments of selected flexural modulus which are not progressively more flexible in the distal direction, over the entire length thereof.

18. The guide catheter of claim **17** wherein said plurality of discrete outer tubular member segments include a soft tip zone outer tubular member, at least a portion of which extends proximally from said distal end of said inner tubular member, a distal section zone outer tubular member extending proximally from said soft tip zone outer tubular member, a transition zone outer tubular member extending proximally from said distal section zone outer tubular member, a secondary curve zone outer tubular member extending proximally from said transition zone outer tubular member, a mid-shaft zone outer tubular member extending proximally from said secondary curve zone outer tubular member and a proximal shaft zone outer tubular member extending proximally from said mid-shaft zone outer tubular member.

19. The guide catheter of claim **18**, wherein the flexural modulus of said catheter in the portion having said secondary curve zone outer tubular member thereon is greater than about 49 Kpsi.

20. The guide catheter of claim **19**, wherein the flexural modulus of said catheter in the portion having said mid-shaft zone outer tubular member thereon is between about 29 and about 67 Kpsi.

21. The guide catheter of claim **20**, wherein the flexural modulus of said catheter in the portion having said soft tip zone outer tubular member thereon is between about 1 and about 15 Kpsi.

22. The guide catheter of claim **21**, wherein the flexural modulus of said catheter in the portion having said distal section zone outer tubular member thereon is between about 2 and about 49 Kpsi.

23. The guide catheter of claim **22**, wherein the flexural modulus of said catheter in the portion having said transition zone outer tubular member thereon is between about 13 and about 49 Kpsi.

24. The guide catheter of claim **23**, wherein the flexural modulus of said catheter in the portion having said proximal shaft zone outer tubular member thereon is greater than about 49 Kpsi.

25. The tubular member of claim **18**, wherein said inner tubular member is manufactured from polytetrafluoroethylene.

26. The tubular member of claim **25**, wherein said support member is a braided metallic member.

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