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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BOSTON SCIENTIFIC CORP.,)
BOSTON SCIENTIFIC SCIMED, INC.,)
SCIMED LIFE SYSTEMS, INC., and)
SCHNEIDER (EUROPE) GMBH,)

Plaintiffs,)

vs.)

JOHNSON & JOHNSON, INC. and)
CORDIS CORPORATION,)

Defendants.)

02 CV 10249 RCL

Civil Action No. _____

FILED
IN CLERKS OFFICE
2002 FEB 14 A 11:07
U.S. DISTRICT COURT
DISTRICT OF MASS.

COMPLAINT AND JURY DEMAND

NATURE OF ACTION

1. This is an action for patent infringement of United States Patents Nos. B1 4,762,129; 5,156,594; 5,217,482; and 5,395,334 (collectively "the patents-in-suit"). The plaintiffs are the owner of all rights in the patents-in-suit and the exclusive manufacturer and distributor of products covered by the patents-in-suit. The defendants are related companies who have infringed the patents-in-suit by making, using, selling and/or offering for sale balloon catheters for use in angioplasty and delivery of vascular stents.

PARTIES

2. Plaintiff Boston Scientific Corp. ("BSC") is a Delaware corporation with a principal place of business in Natick, Massachusetts.

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3. Plaintiff Boston Scientific Scimed, Inc. is a wholly owned subsidiary of BSC and a Minnesota corporation with a principal place of business in Maple Grove, Minnesota.

4. Plaintiff Scimed Life Systems, Inc. is a wholly owned subsidiary of BSC and a Minnesota corporation with a principal place of business in Maple Grove, Minnesota.

5. Plaintiff Schneider (Europe) GmbH is a wholly owned subsidiary of BSC and a Swiss corporation with a principal place of business in Switzerland.

6. Defendant Johnson & Johnson, Inc. is a New Jersey corporation with a principal place of business in New Brunswick, New Jersey.

7. Defendant Cordis Corporation is a Florida corporation with a principal place of business in Hialeah, Florida.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this district under 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

CLAIM FOR RELIEF

10. U.S. Patent No. 4,762,129 entitled "Dilation Catheter," a true copy of which is attached hereto as Exhibit A, duly issued on August 9, 1988. Following reexamination, Reexamination Certificate B1 4,762,129, also attached as Exhibit A, issued on July 2, 1991.

11. U.S. Patent No. 5,156,594 entitled "Balloon Catheter With Distal Guide Wire Lumen," a true copy of which is attached hereto as Exhibit B, duly issued on October 20, 1992.

12. U.S. Patent No. 5,217,482 entitled "Balloon Catheter With Distal Guide Wire Lumen," a true copy of which is attached hereto as Exhibit C, duly issued on June 8, 1993.

13. U.S. Patent No. 5,395,334 entitled "Balloon Catheter With Distal Guide Wire Lumen," a true copy of which is attached hereto as Exhibit D, duly issued on March 7, 1995.

14. Plaintiffs are the owner of all right, title and interest in United States Patent Nos. 5,156,594; 5,217,482; and 5,395,334 and the assignee of all rights of B1 4,762,129 by and through certain exclusive license agreements.

15. The defendants are infringing and have infringed, and contributed to and induced infringement of, one or more claims of the patents-in-suit by, without limitation, making, using, selling and/or offering for sale rapid exchange catheter systems including the Bx VELOCITY™ Rx Balloon Expandable Stent System. The defendants' infringement has been and continues to be willful and deliberate with respect to one or more of the patents-in-suit.

16. As a result of the defendants' infringement, the plaintiffs will suffer severe and irreparable harm, unless that infringement is enjoined by this Court, and have suffered substantial damages.

WHEREFORE, the plaintiffs request that this Court:

1. Permanently enjoin the defendants, their officers, directors, employees, agents, licensees, successors, and assigns, and all persons in concert with them, from further infringement of the patents-in-suit;
2. Award the plaintiffs compensatory damages under 35 U.S.C. § 284;
3. Treble the damages assessed under 35 U.S.C. § 284;
4. Adjudge this case an exceptional case and award the plaintiffs their costs and reasonable attorney's fees pursuant to 35 U.S.C. § 285; and
5. Award the plaintiffs such other relief as the Court deems just and proper.

PLAINTIFFS CLAIM A TRIAL BY JURY ON ALL ISSUES SO TRIABLE

BOSTON SCIENTIFIC CORP.,
BOSTON SCIENTIFIC SCIMED, INC.,
SCIMED LIFE SYSTEMS, INC, and
SCHNEIDER (EUROPE) GMBH

By their attorneys,

A handwritten signature in black ink, appearing to read "William F. Lee", written over a horizontal line.

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Dated: February 14, 2002

United States Patent [19]

[11] **Patent Number:** **4,762,129**

Bonzel

[45] **Date of Patent:** **Aug. 9, 1988**

[54] **DILATATION CATHETER**
 [76] **Inventor:** Tassilo Bonzel, Neumattenstrasse 27,
 D-7800 Freiburg, Fed. Rep. of
 Germany

[21] **Appl. No.:** 893,558

[22] **PCT Filed:** Nov. 15, 1985

[86] **PCT No.:** PCT/DE85/00479

§ 371 **Date:** Jul. 14, 1986

§ 102(e) **Date:** Jul. 14, 1986

[87] **PCT Pub. No.:** WO86/03129

PCT Pub. Date: Jun. 5, 1986

[30] **Foreign Application Priority Data**

Nov. 23, 1984 [DE] Fed. Rep. of Germany 3442736

[51] **Int. Cl.⁴** A61M 29/02

[52] **U.S. Cl.** 128/344; 604/96

[58] **Field of Search** 128/344, 325, 348.1,
 128/10, 656, 658, 772, 673, 675, 748, 207.15;
 604/96-103, 281, 282

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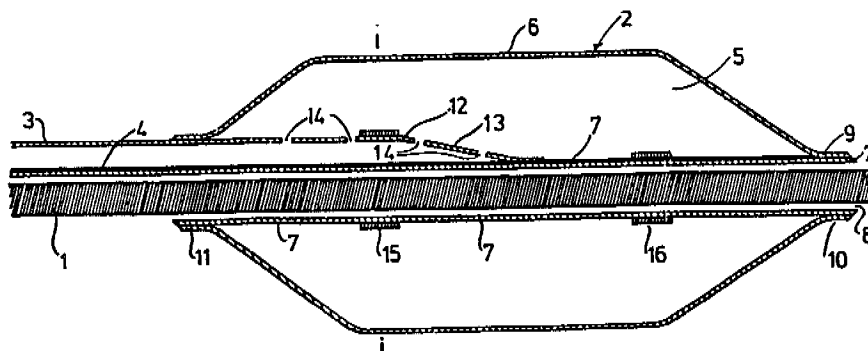
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Primary Examiner—Dalton L. Truluck
Assistant Examiner—Frank Wilkens
Attorney, Agent, or Firm—Charles J. Knuth; Peter C. Richardson; Lawrence C. Akers

[57] **ABSTRACT**

A dilatation catheter, in particular for expanding constrictions in coronary vessels, includes a balloon (2) capable of being enlarged by injecting a fluid through a tube (3). The tube (3) is arranged laterally offset from a segment of flexible tubing (7) by which a passage (8) for a guide wire (1) is formed in the balloon (2).

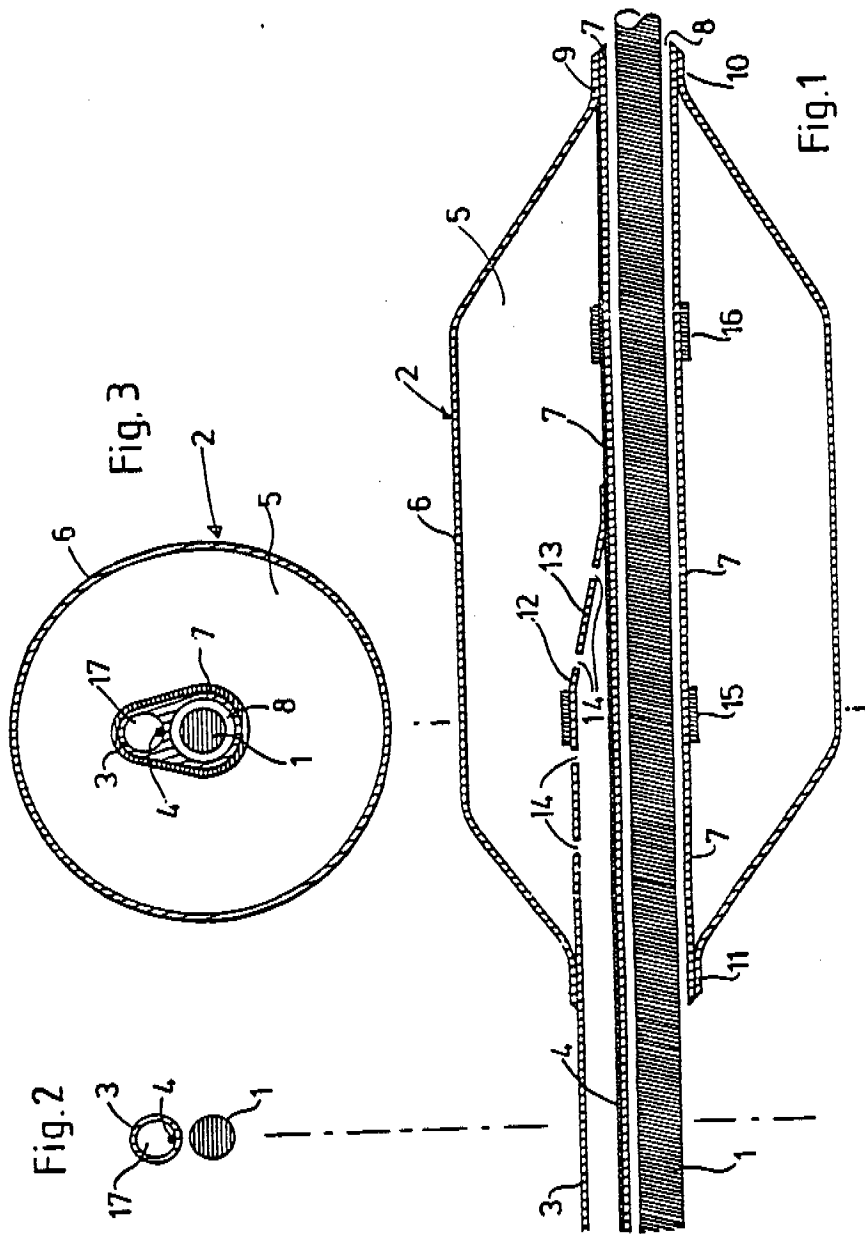
7 Claims, 1 Drawing Sheet



U.S. Patent

Aug. 9, 1988

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DILATATION CATHETER

BACKGROUND OF THE INVENTION

The invention relates to a dilatation catheter having a tube the operative end of which opens into an expandable balloon and a segment of flexible tubing traversing the balloon, sealingly connected to the distal end of the balloon, and capable of being threaded by a guide wire.

Such a dilatation catheter is described in *The American Journal of Cardiology*, Vol. 49, Apr. 1, 1982, pages 1216 to 1222, and is employed to enlarge constrictions in vessels and body cavities, in particular coronary arteries. At the tip of such a dilatation catheter, an inflatable balloon is disposed, capable of being filled or emptied by way of a lumen inside the catheter.

In the known dilatation catheter, a tube is provided that passes over into a balloon at its anterior end. Through the interior of the balloon and the tube, in the known dilatation catheter, a flexible tube extends, projecting beyond the anterior end of the balloon and sealingly connected to the anterior end of the balloon. Through the inside of the flexible tube, a guide wire is passed, capable of being displaced relative to the balloon during the operation, so that the dilatation catheter can be advanced or retracted along the guide wire. When replacing a dilatation catheter applied with the aid of a guide catheter, it is necessary that the guide wire protrude from the patient's body by a length greater than the length of the dilatation catheter with tube. For this reason, manipulation of the known dilatation catheter is difficult, especially since the forces of friction between the guide wire and the flexible tubing passing all the way through the balloon and the tube are great.

SUMMARY OF THE INVENTION

Departing from this prior art, the object of the invention is to create a dilatation catheter that can be passed easily along a guide wire and simply and easily replaced by another dilatation catheter.

This object is accomplished, according to the invention, in that the proximal end of the balloon is likewise sealingly attached to the length of flexible tubing, and in that the tube opens into the interior of the balloon laterally displaced from the segment of tubing.

Since the segment of tubing coming into contact with the surface of the guide wire is only about as long as the balloon and the tube no longer encloses the guide wire and the guide tubing enclosing it, manipulation of the dilatation catheter is facilitated. Control is improved because of the absence of frictional forces in a long segment of guide tubing. Furthermore, owing to the comparative shortness of the length of tubing, the guide wire need no longer protrude from the patient's body by about the same length as the length of the dilatation catheter.

Suitable embodiments and refinements of the invention are described elsewhere in the present application.

DETAILED DESCRIPTION OF THE INVENTION

The invention will now be illustrated with reference to the embodiment represented in the drawing by way of example. In the drawing,

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FIG. 1 shows the anterior portion of the dilatation catheter according to the invention, with tube opening into the balloon,

FIG. 2 shows a cross section of a dilatation catheter in the region of the tube, passing alongside the guide wire, and

FIG. 3 shows a cross section of the dilatation catheter in the region of a gold marker in the balloon.

In FIG. 1, the anterior portion of a dilatation catheter is represented, to be advanced with the aid of a guide catheter not shown in the drawing, having a diameter of some millimeters and a length of about one meter, for example from a patient's right groin throughout the length of the artery to the aorta and the coronary arteries. Through the guide catheter not shown in the drawing, first a guide wire 1 is advanced into the corresponding coronary. A segment of the guide wire 1, which is about 1 m in length, may be seen in FIG. 1. The guide wire 1 serves as instrumentation track to guide the dilatation catheter.

The dilatation catheter has a balloon tube and a tube 3, shown cut away in FIG. 1 and likewise on the order of 1 m in length.

FIG. 2 shows a section of the guide wire 1 and tube 3. The tube 3 serves firstly to transmit thrusts and tensions for pushing the balloon 2 to and fro and rotating it on the guide wire 1. For this reason, it is desirable for the tube 3 to be reinforced by a stabilizing wire 4 in the manner shown in FIGS. 1 to 3. Besides its function of transmitting forces, the tube 3 serves for injection of fluids into the interior 5 of the balloon 2 and for aspiration of fluids when the diameter of the balloon is to be decreased.

As may be seen in FIG. 1, the balloon consists of an envelope 6 and a length of flexible tubing 7, so that the balloon 2 has a passage 8 sealed off from the interior 5 of the balloon. The balloon passage 8 enables the balloon 2 to be thrust onto the guide wire 1 and thereby guided along the guide wire 1.

In FIG. 3, the substantially annular cross section of the balloon 2 is seen, together with the balloon passage 8 through which the guide wire 1 extends. For good transmission of the forces exerted upon the tube 3 to the balloon 2, the stabilizing wire 4 extends into the neighborhood of the distal end 9 of the balloon 2.

As is clearly seen in FIG. 1, at the distal end 9 of the balloon 2 the envelope 6 takes the form of a length of flexible tubing 10, tightly connected to the distal end of the segment of tubing 7. Similarly, the envelope 6 terminates at the proximal end in a segment of tubing 11, sealingly connected firstly to the proximal end of segment 7 and secondly to the tube 3.

The operative end 12 of tube 3, pointing to the right in FIG. 1, terminates in a taper 13 fixed to the tubing 7. Both in the taper 13 and elsewhere at the operative end 12, radial openings 14 are provided in the tube 3, whereby fluid injected into the tube 3 can pass from the tube 3 into the interior 5 of the balloon 2.

In FIGS. 1 and 3, gold stripes 15 and 16 are additionally represented, serving to mark the location of the dilatation catheter in X-ray views.

In FIG. 3, we see a cross section of the balloon 2 in the region of the gold strip 15. The tube 3 with its inner lumen 17 and the segment of tubing 7 with balloon passage 8 are made in one piece in the region shown in FIG. 3, so that the gold stripe 15 assumes a substantially oval form rather than that of a figure-eight.

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The guide wire 1 may have a central lumen, not shown in the drawing, for pressure measurement or to contain a contrast medium. To minimize frictional resistance between the interior of the balloon passage 8 and the surface of the guide wire 1, the inside of the tubing segment 7, reinforced by the stabilizing wire 4, and/or the top of the guide wire 1 may be provided with a lubricant coating.

For dilatation of coronary vessels, first the guide wire 1 is introduced through the guide catheter into the proper coronary artery. The guide wire 1 lies freely in the guide catheter and so may be conveniently rotated and controlled. For anatomical orientation, adequate additional doses of contrast medium may be supplied. When the guide wire 1 has passed the constriction in the coronary artery, the tip of the guide wire 1 remains on the far side of the stenosis in the coronary vessel. At this point, and not until, the dilatation catheter according to the invention is thrust onto the guide wire 1 outside the body and advanced through the guide catheter along the track formed by the guide wire 1 into the coronary artery and under the constriction. If the balloon 2 is to be replaced during the operation by a balloon 2 of larger size, it is a simple matter to retract the dilatation catheter according to the invention, leaving the anterior end of the guide wire 1 in the coronary vessel and permitting secure advancement of the replacement balloon with no need to overcome much friction or to relocate the stenosis a second time. If deficient stability of the result of dilatation is suspected, the guide wire 1 may even be left in place for several hours, with a view to renewed dilatation at a later time. The distal end 9 of the dilatation catheter is flattened in the manner described above for better insertability into vascular constrictions.

The invention permits the provision of balloons of various lengths, widths and wall thicknesses to accommodate various pressures, and they may be interchanged with ease. Depending on medical requirements, the dilatation catheters are equipped with tubes 3 of varying weight and flexibility, admitting of differential advance. For larger dilatation catheters, an additional inner lumen, not shown in the drawing, is provided, its anterior end extending to the distal end 9 of the balloon 2 and communicating with the interior of the vessel inside the patient's body. In this way, pressure measurements and injections of contrast medium may be performed. The guide wires 1 of a complete instrumentarium are likewise of different weights and flexibilities. The guide wires 1 have soft, flexible tips, which may be shorter or longer, as well as straight or bowed. If no additional inner lumen is provided in the balloon, a central lumen as above mentioned may be provided in the guide wires for pressure measurements and injections of contrast medium.

I claim:

1. A dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends and a lumen extending between said ends of uniform cross section along its length and free of obstructions adapted to receive a guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal

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end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter,

said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube, in combination with an elongated guide wire.

2. The combination of claim 1 wherein the guide wire is provided with a central lumen for pressure measurement and/or injection of contrast medium.

3. The combination of claim 1 wherein the first tube is reinforced by means of a longitudinally-extending stabilizing means.

4. A dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive a guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter,

said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube,

in combination with an elongated guide wire.

5. A method for opening a constricted region in the vascular system of a patient comprising the steps of:

(a) providing an elongated guide wire and a dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive said guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter, said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube;

(b) inserting said guide wire into the vascular system of the patient;

(c) positioning said catheter so that said guide wire is in a sliding fit within said second elongated hollow tube;

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- (d) advancing said catheter along said guide wire into and within said vascular system, with said expandable balloon in an unexpanded condition, until said expandable balloon is situated within said constricted region;
 - (e) expanding the expandable balloon to open the constricted region;
 - (f) contracting the expandable balloon; and
 - (g) withdrawing said catheter and said guide wire from the body of the patient.
6. A method for opening a constricted region in the vascular system of a patient comprising the steps of:
- (a) providing an elongated guide wire and a dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends and a lumen extending between said ends of uniform cross section along its length and free of obstructions adapted to receive a guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating

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- at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter, said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube, with said second elongated hollow tube being adapted to receive said guide wire in a sliding fit;
 - (b) inserting said guide wire into the vascular system of the patient;
 - (c) positioning said catheter so that said guide wire is in a sliding fit within said second elongated hollow tube;
 - (d) advancing said catheter along said guide wire into and within said vascular system, with said expandable balloon in an unexpanded condition, until said expandable balloon is situated within said constricted region;
 - (e) expanding the expandable balloon to open the constricted region;
 - (f) contracting the expandable balloon; and
 - (g) withdrawing said catheter and said guide wire from the body of the patient.
7. A method of claim 6 wherein the first tube is reinforced by means of a longitudinally-extending stabilizing means.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,762,129
DATED : August 9, 1988
INVENTOR(S) : Tassilo Bonzel

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

Change column 4, lines 10 and 11, from

" upon the first tube, in combination with an elongated guide wire." to

-- upon the first tube,
in combination with an elongated guide wire.--

Signed and Sealed this

Twenty-ninth Day of November, 1988

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks

REEXAMINATION CERTIFICATE (1501st)

United States Patent [19]

[11] **B1 4,762,129**

Bonzel

[45] **Certificate Issued Jul. 2, 1991**

[54] **DILATATION CATHETER**

[76] **Inventor: Tassilo Bonzel, Neumattenstrasse 27,
D-7800 Freiburg, Fed. Rep. of
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- No. 90/002,016, May 4, 1990

Reexamination Certificate for:

Patent No.: **4,762,129**
 Issued: **Aug. 9, 1988**
 Appl. No.: **893,558**
 Filed: **Nov. 15, 1985**

[22] **PCT Filed: Nov. 15, 1985**

[86] **PCT No.: PCT/DE85/00479**

§ 371 Date: **Jul. 14, 1986**

§ 102(e) Date: **Jul. 14, 1986**

[87] **PCT Pub. No.: WO86/03129**

PCT Pub. Date: Jun. 5, 1986

[30] **Foreign Application Priority Data**

Nov. 23, 1984 [DE] Fed. Rep. of Germany 3442736

[51] **Int. Cl.⁵ A61M 29/02**

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

[58] **Field of Search 604/96-103;
606/127, 159, 194, 200**

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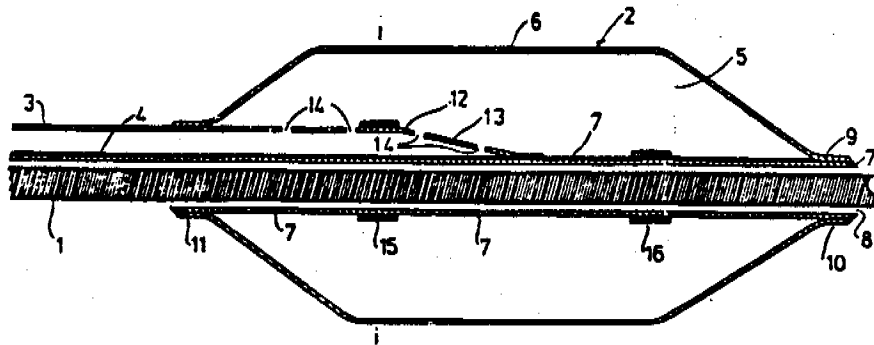
ABSTRACT

A dilatation catheter, in particular for expanding constrictions in coronary vessels, includes a balloon (2) capable of being enlarged by injecting a fluid through a tube (3). The tube (3) is arranged laterally offset from a segment of flexible tubing (7) by which a passage (8) for a guide wire (1) is formed in the balloon (2).

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REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS
INDICATED BELOW.

Matter enclosed in heavy brackets **[]** appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS
BEEN DETERMINED THAT:

Claim 2 is cancelled.

Claims 1 and 3-7 are determined to be patentable as amended.

New claims 8-27 are added and determined to be patentable.

1. A dilatation catheter comprising an expandable balloon having distal and proximal ends, *wherein the balloon is elongated in the longitudinal direction of the dilatation catheter and exhibits, upon expansion, a substantially cylindrical central working portion between said distal and proximal ends*, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends and a lumen extending between said ends of uniform cross section along its *entire* length and free of obstructions adapted to receive a guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter,

said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube, **[in combination with an elongated guide wire]**

in combination with an elongated guide wire received in a sliding fit within said second hollow tube,

said guide wire having a proximal portion and a distal portion with a flexible tip, and having sufficient stiffness that it can readily be advanced in use distally through a body lumen by exerting a pushing force upon its proximal portion, with the proximal end of said elongated guide wire adapted to be readily slid into and out of the distal end of said second hollow tube during a dilatation procedure.

3. The combination of claim **[1]** 8 wherein the first hollow tube is reinforced by means of **[a]** an integral non-removable longitudinally-extending stabilizing means.

4. A dilatation catheter comprising an expandable balloon having distal and proximal ends, *wherein the balloon is elongated in the longitudinal direction of the*

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dilatation catheter and exhibits, upon expansion, a substantially cylindrical central working portion between said distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive a guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, *and wherein the shortest distance between the substantially cylindrical working surface of the balloon upon expansion and the outer surface of the second elongated hollow tube is substantially greater than the width in cross-section of the second elongated hollow tube*, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter,

said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube,

in combination with an elongated guide wire received in a sliding fit within said second hollow tube,

said guide wire having a proximal portion and a distal portion with a flexible tip, and having sufficient stiffness that it can readily be advanced in use distally through a body lumen by exerting a pushing force upon its proximal portion, with the proximal end of said elongated guide wire adapted to be readily slid into and out of the distal end of said second hollow tube during a dilatation procedure.

5. A method for opening a **[constricted region]** constriction in the vascular system of a patient comprising the steps of:

(a) providing an elongated guide wire having distal and proximal ends and a dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive said guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter, said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube;

(b) inserting said guide wire into the vascular system of the patient;

(c) then positioning said catheter over the proximal end of said guide wire so that said guide wire is in a

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- sliding fit within said second elongated hollow tube;
- (d) advancing said catheter along said guide wire into and within said vascular system, with said expandable balloon in an unexpanded condition, until said expandable balloon is situated within said [constricted region] constriction;
- (e) expanding the expandable balloon situated within said constriction to open the [constricted region] constriction during the expansion of the balloon by the compressive force of the expanding balloon against said constriction;
- (f) contracting the expandable balloon while within the site of the opened constriction, said site remaining opened after the expandable balloon is contracted; and thereafter
- (g) withdrawing said catheter and said guide wire from the body of the patient.
6. A method for opening a [constricted region] constriction in the vascular system of a patient comprising the steps of:
- (a) providing an elongated guide wire having distal and proximal ends and a dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends and a lumen extending between said ends of uniform cross section along its length and free of obstructions adapted to receive a guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter, said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube,
- with said second elongated hollow tube being adapted to receive said guide wire in a sliding fit;
- (b) inserting said guide wire into the vascular system of the patient;
- (c) then positioning said catheter over the proximal end of said guide wire so that said guide wire is in a sliding fit within said second elongated hollow tube;
- (d) advancing said catheter along said guide wire into and within said vascular system, with said expandable balloon in an unexpanded condition, until said expandable balloon is situated within said [constricted region] constriction;
- (e) expanding the expandable balloon situated within said constriction to open the [constricted region] constriction during the expansion of the balloon by the compressive force of the expanding balloon against said constriction;
- (f) contracting the expandable balloon while within the site of the opened constriction, said site remaining opened after the expandable balloon is contracted; and thereafter

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- (g) withdrawing said catheter and said guide wire from the body of the patient.

7. [A] The method of claim 6 wherein the first tube is reinforced by means of a longitudinally-extending stabilizing means.

8. The combination of claim 4 wherein said elongated guide wire is a steerable guide wire.

9. The method of claim 5 wherein the expandable balloon is elongated in the longitudinal direction of the dilatation catheter and exhibits, upon expansion, a substantially cylindrical central working portion between the distal and proximal ends of said balloon.

10. The method of claim 5 wherein the first hollow tube is reinforced by means of an integral non-removable longitudinally-extending stabilizing means.

11. A coronary angioplasty dilatation catheter adapted for use in a coronary angioplasty procedure and dimensioned and configured for opening a constriction in a coronary artery, comprising an expandable balloon of a suitable material for opening said constriction by the exertion of compressive force when the balloon is expanded within said constriction during a coronary angioplasty procedure having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive a coronary angioplasty guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter,

said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube, in combination with an elongated coronary angioplasty guide wire received in a sliding fit within said second hollow tube,

said guide wire having a proximal portion and a distal portion with a flexible tip, and said guide wire adapted to be advanced during a coronary angioplasty procedure, by the manipulation of a portion of said guide wire extending from the body of a patient in the region of the groin, through the arterial system including the aorta into said coronary artery and across said constriction so that the distal tip of said guide wire is disposed on the far side of said constriction, and further adapted to guide said coronary angioplasty dilatation catheter through said arterial system into said coronary artery, and with the proximal end of said guide wire adapted to be readily slid into and out of the distal end of said second hollow tube during a coronary angioplasty procedure.

12. The combination of claim 11 wherein said coronary angioplasty guide wire has a solid, non-hollow cross-section in at least one transverse plane taken through said guide wire at a location displaced from the distal tip of said guide wire.

13. The combination of claim 11 wherein the expandable balloon is elongated in the longitudinal direction of the dilatation catheter and exhibits, upon expansion, a substantially cylindrical central working portion between said distal and proximal ends of said balloon.

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14. The combination of claim 11 wherein said dilatation catheter is about one meter in length.

15. The combination of claim 11 wherein said coronary angioplasty guide wire has a flexible, bowed distal tip.

16. The combination of claim 11 wherein said second tube has a lumen extending between said distal and proximal ends of said second tube of uniform cross section along its entire length and free of obstructions.

17. A method for opening a constriction in the vascular system of a patient, including the operation of readily exchanging dilatation catheters, comprising the steps of:

- (a) providing an elongated guide wire having distal and proximal ends and a first dilatation catheter comprising an expandable balloon having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive said guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter, said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube;
- (b) inserting said guide wire and said first dilatation catheter into the vascular system of the patient so that the distal tip of said guide wire has passed to the far side of the constriction and the length of the guide wire protruding from the body of the patient is less than the full length of the dilatation catheter, and said guide wire is in a sliding fit within said second elongated hollow tube;
- (c) withdrawing said first dilatation catheter from the body of the patient while maintaining said guide wire in said vascular system with its distal tip on the far side of said constriction;
- (d) then positioning a second dilatation catheter as described in step (a) over the proximal end of said guide wire so that said guide wire is in a sliding fit within the second elongated hollow tube of said second dilatation catheter;
- (e) advancing said second dilatation catheter along said guide wire into and within said vascular system, with its expandable balloon in an unexpanded condition, until said expandable balloon is situated within said constriction;
- (f) expanding the expandable balloon situated within said constriction to open the constriction during the expansion of the balloon by the compressive force of the expanding balloon against said constriction;
- (g) contracting the expandable balloon while within the site of the opened constriction, said site remaining opened after the expandable balloon is contracted; and thereafter
- (h) withdrawing said second dilatation catheter and said guide wire from the body of the patient.

18. The method of claim 17 wherein the expandable balloon of said second dilatation catheter is different in size

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from the expandable balloon of said first dilatation catheter.

19. The method of claim 18 wherein the expandable balloon of said second dilatation catheter is larger in size than the expandable balloon of said first dilatation catheter.

20. The method of claim 17 wherein said vascular system is the arterial system and said constriction is in a coronary artery, wherein said first and second dilatation catheters are coronary angioplasty dilatation catheters, and wherein said guide wire is a coronary angioplasty guide wire.

21. The method of claim 20 wherein in said step (b) said coronary angioplasty guide wire is inserted into said arterial system in the region of the groin through a guiding catheter and wherein said first coronary angioplasty dilatation catheter is advanced along said guide wire through said arterial system through said guiding catheter.

22. A coronary angioplasty dilatation method for opening a constriction in a coronary artery of a patient comprising the steps of:

- (a) providing an elongated coronary angioplasty guide wire having distal and proximal ends and a coronary angioplasty dilatation catheter comprising an expandable balloon having distal and proximal ends, wherein the balloon is elongated in the longitudinal direction of the dilatation catheter and exhibits, upon expansion, a substantially cylindrical central working portion between said distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the expandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive said guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter, said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube;
- (b) inserting said guide wire into the arterial system of the patient and advancing said guide wire, by the manipulation of a portion of said guide wire extending from the body of the patient, through said arterial system, including the aorta, into said coronary artery and across said constriction so that the distal tip of said guide wire is disposed on the far side of said constriction;
- (c) then positioning said catheter over the proximal end of said guide wire so that said guide wire is in a sliding fit within said second elongated hollow tube;
- (d) advancing said catheter along said guide wire into and within said vascular system, with said expandable balloon in an unexpanded condition, until said expandable balloon is situated within said constriction;
- (e) expanding the expandable balloon situated within said constriction to open the constriction during the expansion of the balloon by the compressive force of the expanding balloon against said constriction;
- (f) contracting the expandable balloon while within the site of the opened constriction, said site remaining

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opened after the expandable balloon is contracted; and thereafter

(g) withdrawing said catheter and said guide wire from the body of the patient.

23. The method of claim 22 wherein in said step (b) said coronary angioplasty guide wire is inserted into said arterial system through a guiding catheter and wherein said dilatation catheter is advanced along said guide wire through said arterial system through said guiding catheter.

24. The method of claim 22 wherein said elongated coronary angioplasty guide wire provided in step (a) has a solid, non-hollow cross-section in at least one transverse plane taken through said guide wire at a location displaced from the distal tip of said guide wire.

25. The method of claim 22 wherein in said step (b) said guide wire is inserted into the arterial system in the region of the groin and is advanced therefrom through said arterial system into said coronary artery.

26. The method of claim 25 wherein in said step (b) said coronary angioplasty guide wire is inserted into said arterial system through a guiding catheter and wherein in said step (d) said coronary angioplasty dilatation catheter is advanced along said guide wire through said arterial system through said guiding catheter.

27. A coronary angioplasty dilatation catheter adapted for use in a coronary angioplasty procedure and dimensioned and configured for opening a constriction in a coronary artery, comprising an expandable balloon of a suitable material for opening said constriction by the exertion of compressive force when the balloon is expanded within said constriction during a coronary angioplasty procedure having distal and proximal ends, a first, relatively long, elongated hollow tube having distal and proximal ends and opening adjacent its distal end into the interior of the ex-

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pandable balloon, the first tube being sealingly connected to the proximal end of the balloon, and a second, relatively short, elongated hollow tube integral with said first tube, having distal and proximal ends, and adapted to receive a coronary angioplasty guide wire in a sliding fit, the second tube traversing the interior of the expandable balloon from the distal end to the proximal end of the balloon and being sealingly connected to the distal end of the balloon, and the second tube terminating at its proximal end substantially distally of the proximal end of the first tube in an aperture open to the exterior of the catheter,

said first tube having sufficient stiffness that the second tube and expandable balloon can readily be advanced or withdrawn together in use along the guide wire by exerting a pushing or pulling force upon the first tube, in combination with an elongated coronary angioplasty guide wire received in a sliding fit within said second hollow tube,

said guide wire having a proximal portion and a distal portion with a flexible tip, and said guide wire adapted to be advanced during a coronary angioplasty procedure, by the manipulation of a portion of said guide wire extending from the body of a patient, through the arterial system including the aorta into said coronary artery and across said constriction so that the distal tip of said guide wire is disposed on the far side of said constriction, and further adapted to guide said coronary angioplasty dilatation catheter through said arterial system into said coronary artery, and with the proximal end of said guide wire adapted to be readily slid into and out of the distal end of said second hollow tube during a coronary angioplasty procedure.

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United States Patent [19]

[11] Patent Number: **5,156,594**

Keith

[45] Date of Patent: **Oct. 20, 1992**

- [54] **BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN**
- [75] Inventor: **Peter T. Keith, Edina, Minn.**
- [73] Assignee: **SciMed Life Systems, Inc., Maple Grove, Minn.**
- [21] Appl. No.: **574,265**
- [22] Filed: **Aug. 28, 1990**
- [51] Int. Cl.⁵ **A61M 29/00**
- [52] U.S. Cl. **604/96; 606/194; 604/282**
- [58] Field of Search **606/192, 194; 604/95-103, 282, 204**

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Assistant Examiner—Adam J. Cermah
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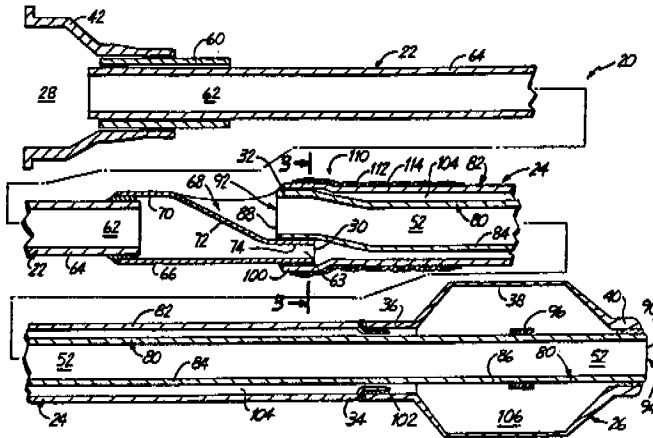
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[57] **ABSTRACT**

An over-the-wire balloon dilatation catheter has a stainless steel hypotube catheter shaft, an intermediate sleeve section bonded to the shaft and a distal balloon section connected to the sleeve section. The sleeve section is formed from relatively flexible polymer materials and includes an inner core tube which defines a guide wire lumen extending only through a distal portion of the catheter (including its sleeve and balloon sections) to facilitate fast balloon catheter exchanges. A distal end of the hypotube shaft is crimped laterally and the core tube is nested and bonded within the crimp to provide a proximal outlet for the guide wire lumen. The hypotube shaft provides an inflation lumen for the balloon, with the inflation lumen being continued as an annular inflation lumen through the sleeve section where an outer sleeve is bonded about the core tube and extends from the distal end of the hypotube shaft to the balloon section. A kink-resistant coil structure extends distally from the distal end of the hypotube shaft to provide a gradual change in stiffness along the length of the catheter from the relatively stiff hypotube shaft to the relatively flexible distal portion of the catheter.

56 Claims, 6 Drawing Sheets



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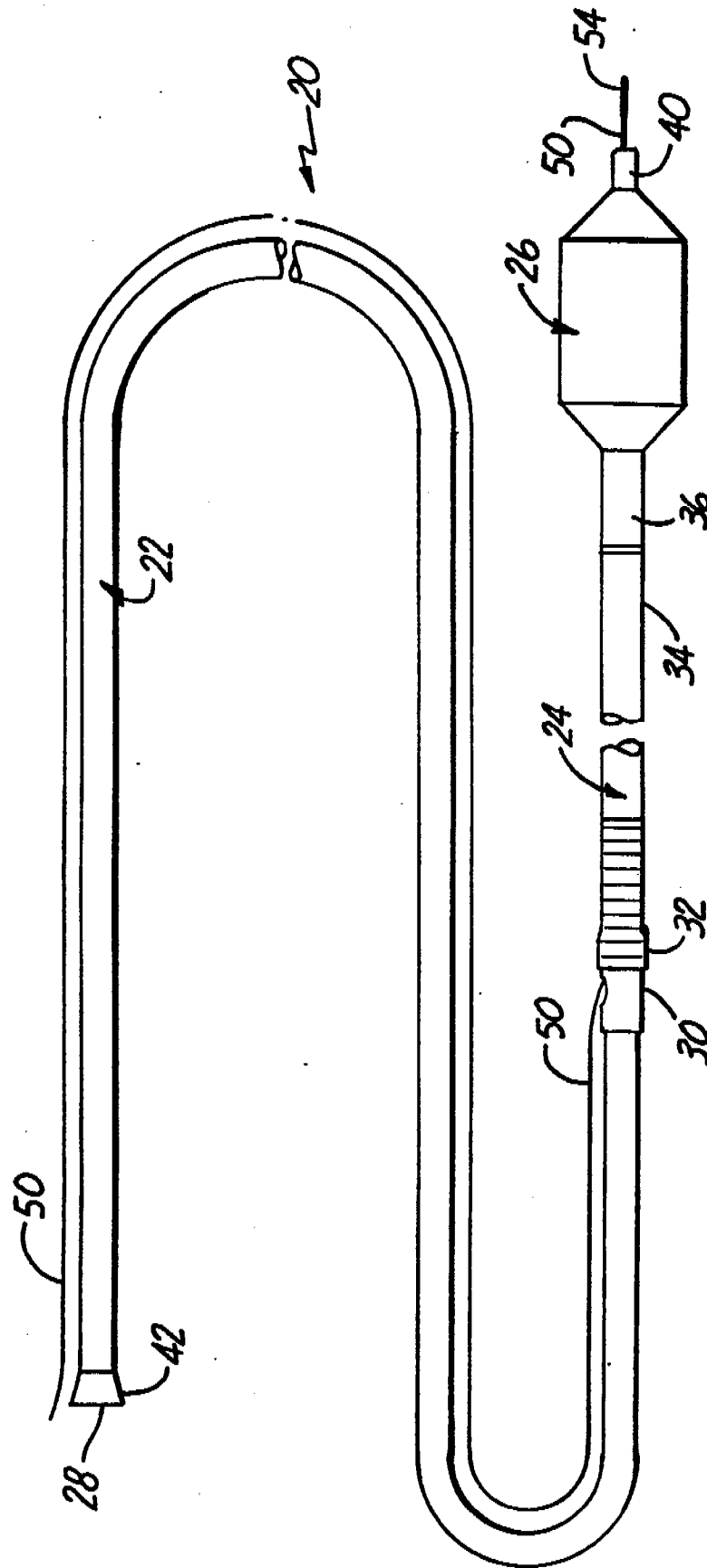
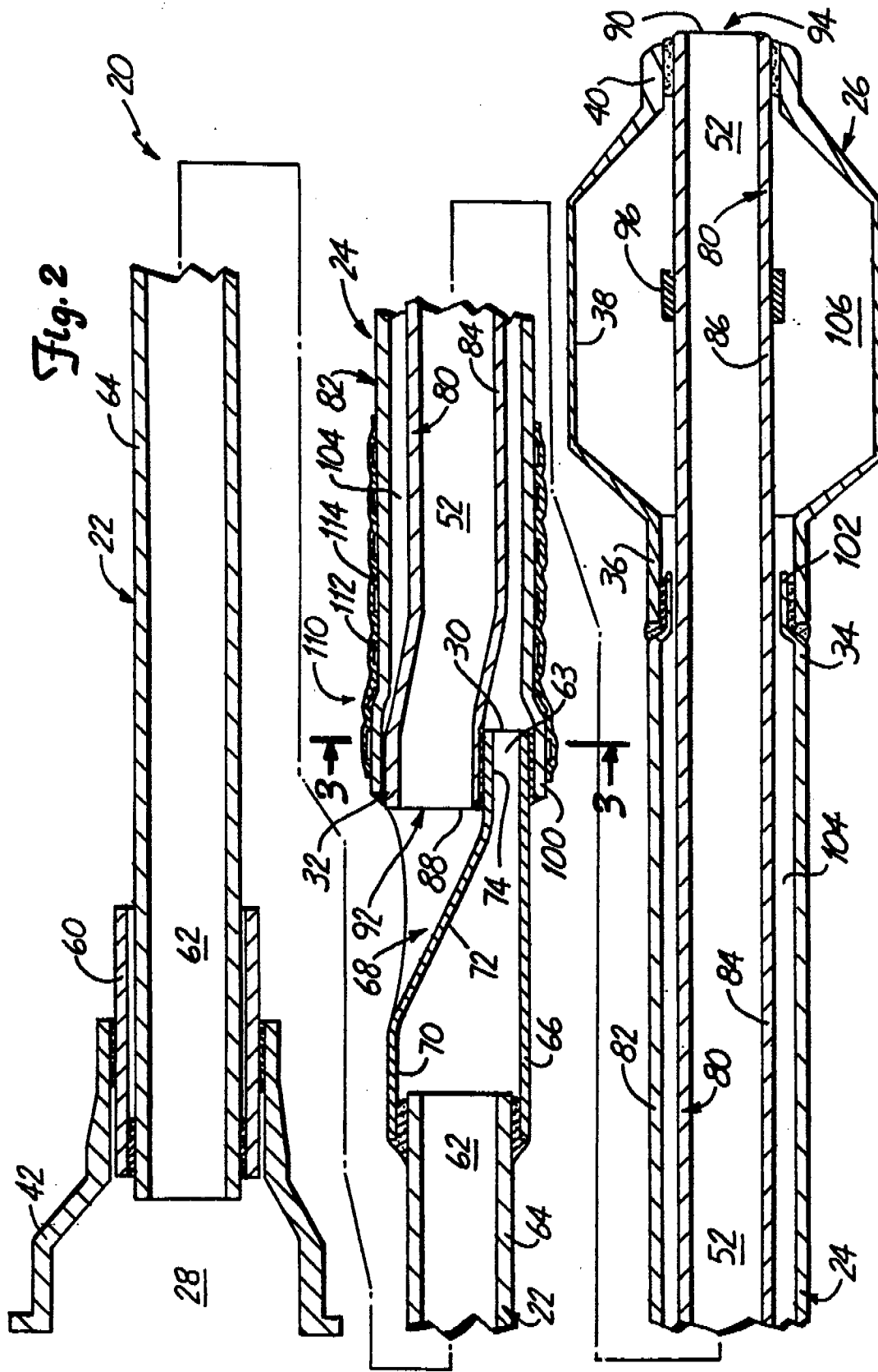
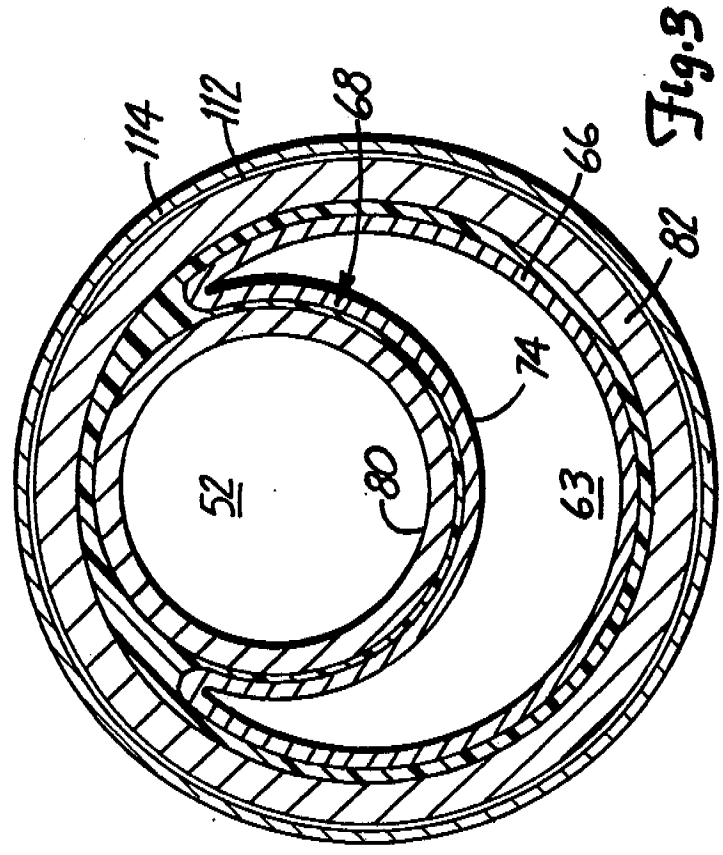
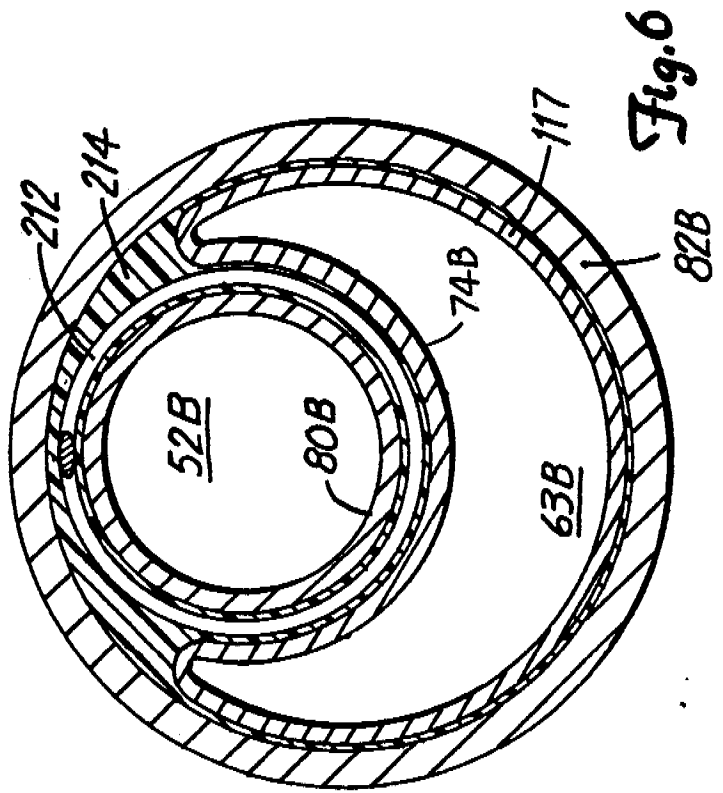
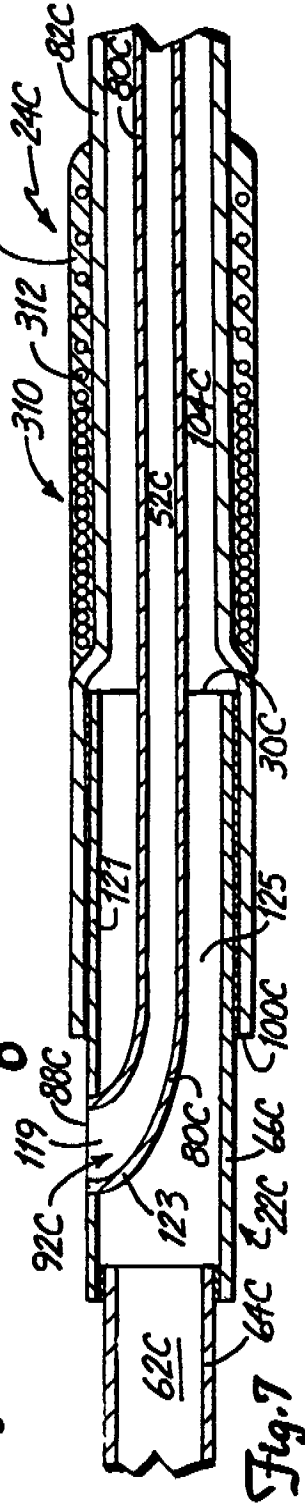
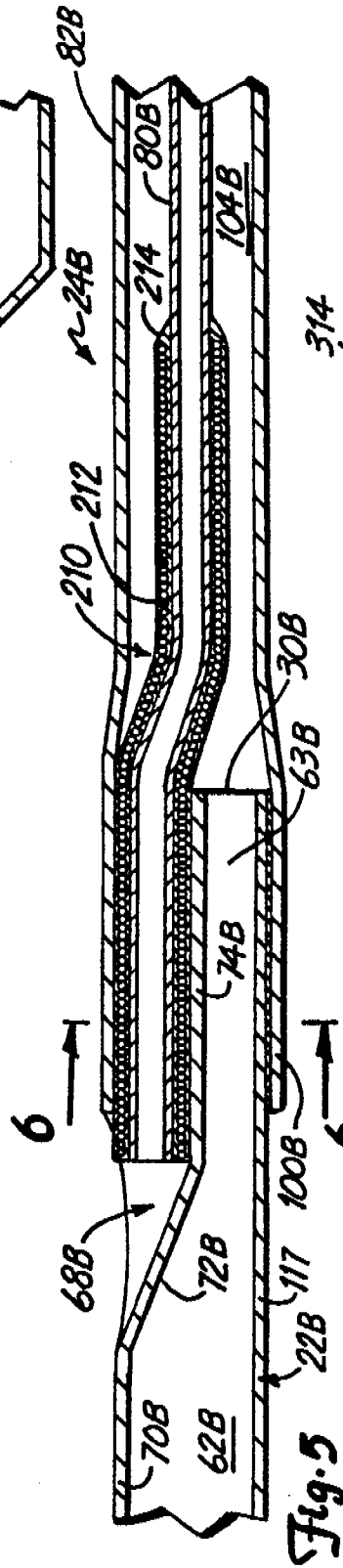
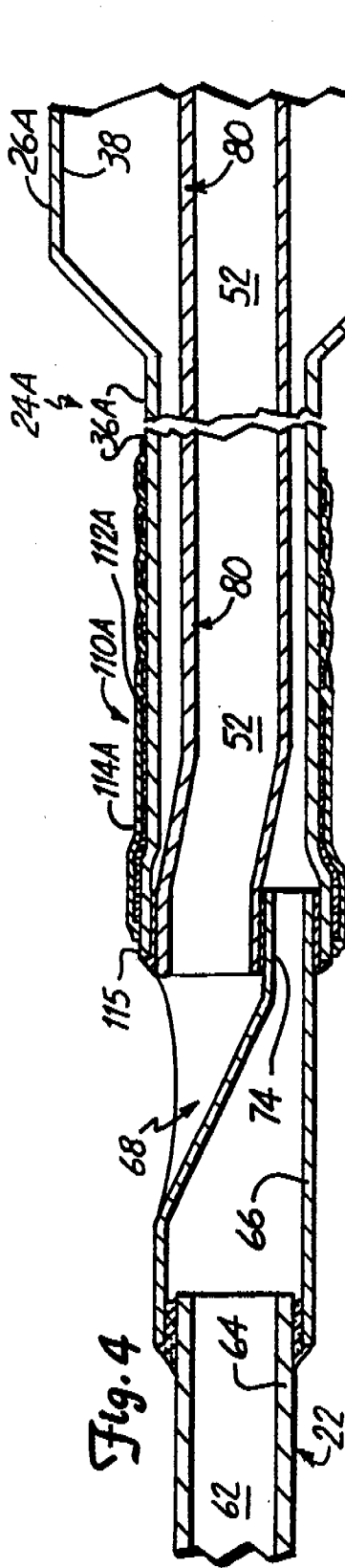
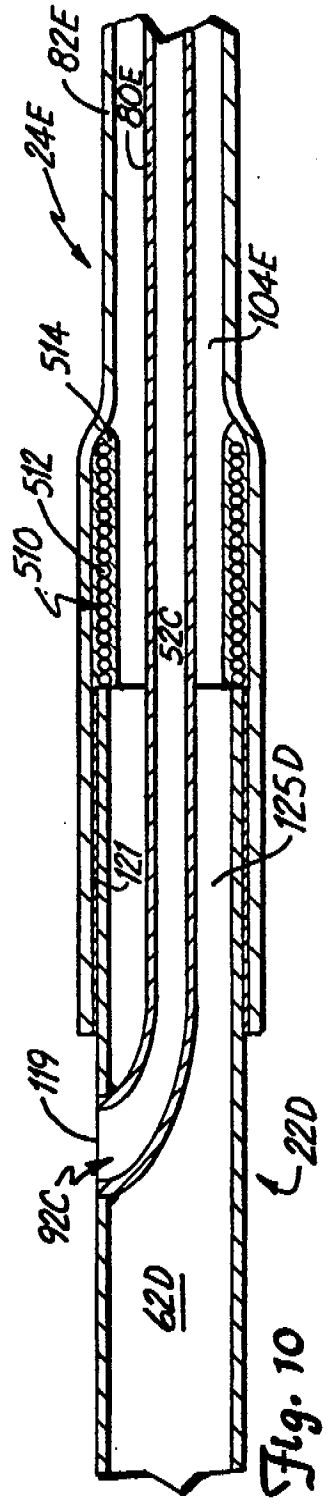
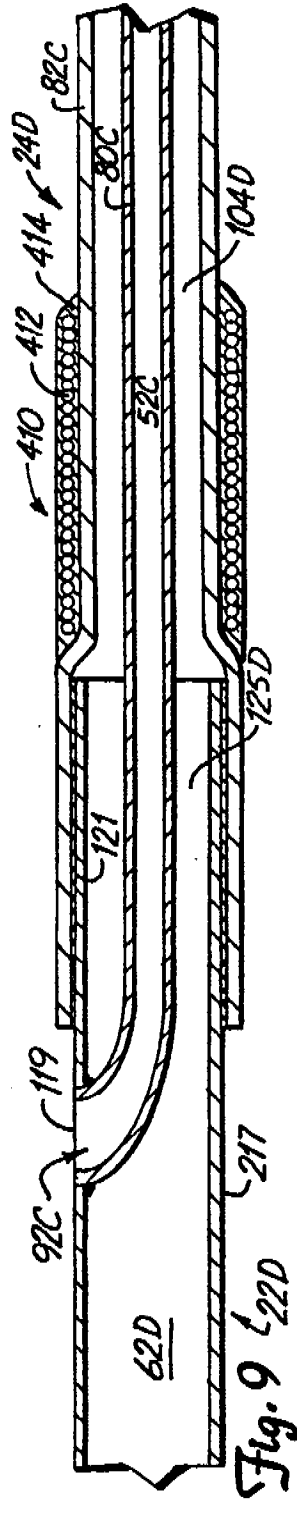
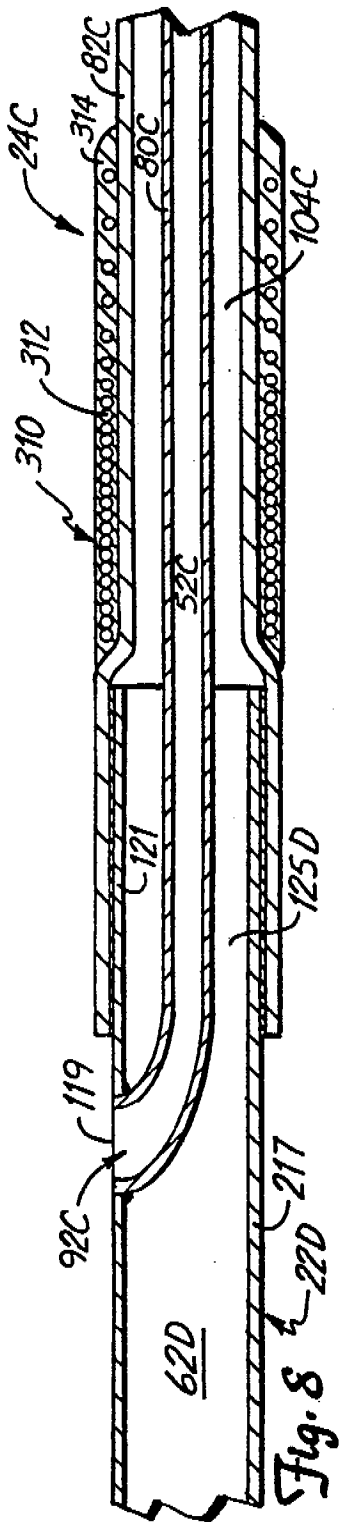


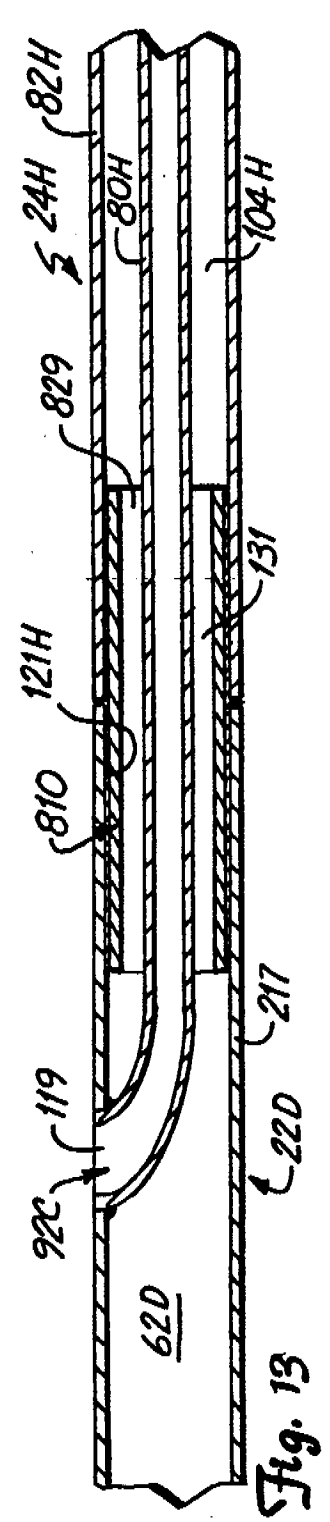
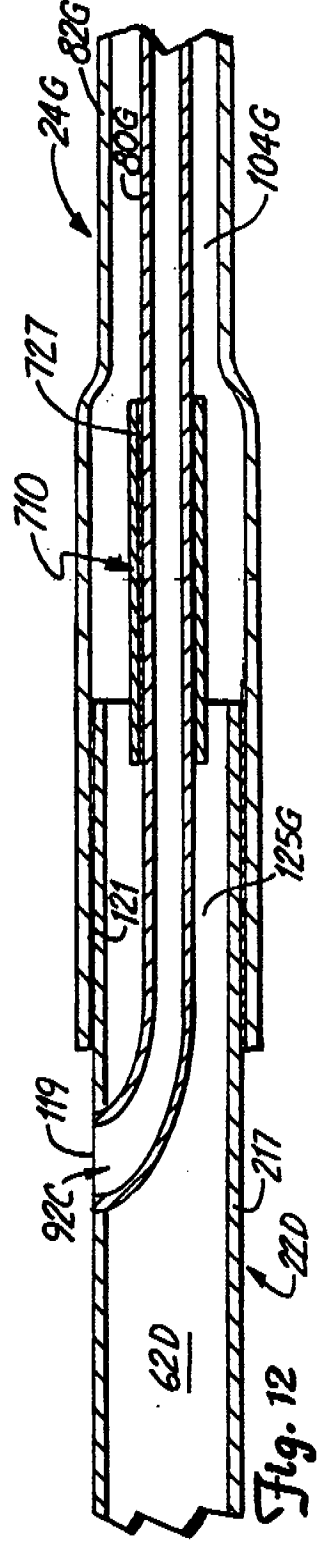
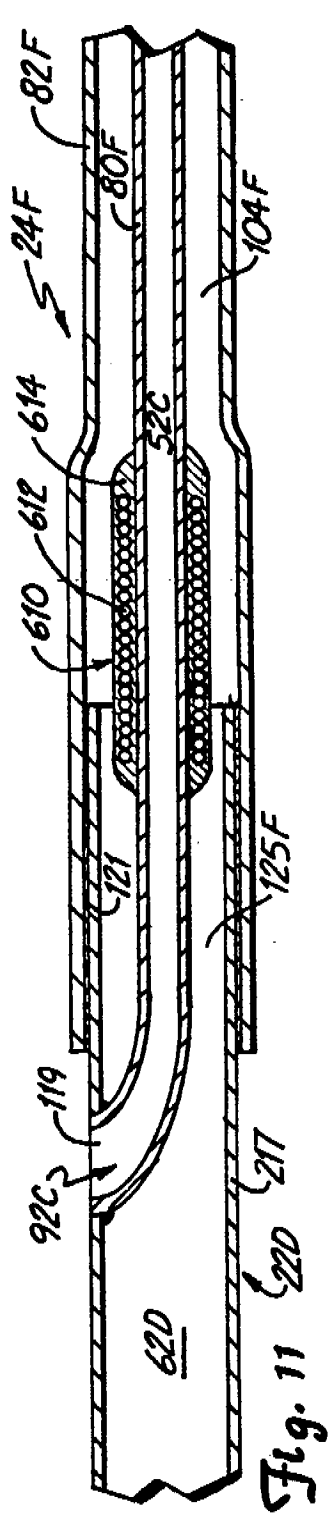
Fig. 1











BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN

BACKGROUND OF THE INVENTION

The present invention relates to the field of angioplasty. In particular, the present invention relates to a dilatation balloon catheter of the "over-the-wire" type having a relatively short distal guide wire lumen extending through the balloon of the catheter.

Angioplasty procedures have gained wide acceptance in recent years as efficient and effective methods for treating types of vascular disease. In particular, angioplasty is widely used for opening stenoses in the coronary arteries, although it is also used for the treatment of stenoses in other parts of the vascular system.

The most widely used form of angioplasty makes use of a dilatation catheter which has an inflatable balloon at its distal end. Typically, a hollow guide catheter is used in guiding the dilatation catheter through the vascular system to a position near the stenoses (e.g., to the coronary artery ostia). Using fluoroscopy, the physician guides the dilatation catheter the remaining distance through the vascular system until a balloon is positioned to cross the stenoses. The balloon is then inflated by supplying fluid under pressure through an inflation lumen in the catheter to the balloon. The inflation of the balloon causes stretching of the artery and pressing of the lesion into the artery wall, to reestablish acceptable blood flow through the artery.

There has been a continuing effort to reduce the profile and shaft size of the dilatation catheter so that the catheter not only can reach but also can cross a very tight stenosis. A successful dilatation catheter must also be sufficiently flexible to pass through tight curvatures, especially in the coronary arteries. A further requirement of a successful dilatation catheter is its "pushability". This involves the transmission of longitudinal forces along the catheter from its proximal end to its distal end so that a physician can push the catheter through the vascular system and the stenoses.

Two commonly used types of dilatation catheters are referred to as "over-the-wire" catheters and "non-over-the-wire" catheters. An over-the-wire catheter is one in which a separate guide wire lumen is provided in the catheter so that a guide wire can be used to establish the path through the stenoses. The dilatation catheter can then be advanced over the guide wire until the balloon on the catheter is positioned within the stenoses. One problem with the over-the-wire catheter is the requirement of a larger profile and a generally larger outer diameter along the entire length of the catheter in order to allow for a separate guide wire lumen therethrough.

A non-over-wire catheter acts as its own guide wire, and thus there is no need for a separate guide wire lumen. One advantage of a non-over-the-wire catheter is its potential for a reduced outer diameter along its main shaft since no discrete guide wire lumen is required. However, one disadvantage is the inability to maintain the position of the guide wire within the vascular system when removing the catheter and exchanging it for a catheter having a smaller (or larger) balloon diameter. Thus, to accomplish an exchange with a non-over-the-wire catheter, the path to the stenoses must be reestablished when replacing the catheter with one having a different balloon diameter.

In an effort to combine the advantages of an over-the-wire catheter with a non-over-the-wire catheter, cath-

eters have been developed which have guide wire lumens which extend from a distal end of the catheter through the dilatation balloon and then exit the catheter at a point proximal of the dilatation balloon. The guide wire thus does not extend through the entire length of the catheter and no separate guide wire lumen is required along a substantially proximal section of the catheter. That proximal section can thus have a smaller outer diameter since it is only necessary to provide an inflation lumen therethrough for catheter operation. A further advantage of this type of modified over-the-wire catheter is that the frictional forces involved between the guide wire and the shortened guide wire lumen are reduced, thereby reducing resistance to catheter pushability and enhancing the "feel" and responsiveness of the catheter to a physician.

Perhaps the most significant advantage of using a shortened guide wire lumen is in the ease of exchange of the catheter over the guide wire. In performing an angioplasty procedure using such a catheter, the catheter is "back loaded" over the guide wire by inserting the proximal tip of the guide wire into a distal opening of the guide wire lumen in the catheter. The catheter is then advanced by "feeding" the catheter distally over the guide wire while holding the guide wire stationary. The proximal end of the guide wire will then emerge out of the proximal opening of the guide wire lumen (which is substantially space distally from the proximal end of the catheter itself) and is accessible again for gripping by the physician. The catheter can be pre-loaded onto the guide wire in this manner before the guide wire is inserted into the guide catheter or after. In either case, the guide wire is steered and passed through the guide catheter, coronary vessels and across a lesion. The exposed portion of the guide wire is then grasped while the catheter is advanced distally along the guide wire across the lesion. Using this procedure, little axial movement of the guide wire occurs during catheter loading and positioning for angioplasty.

If the dilatation balloon is found to be inadequate (too small or too large), the catheter can be similarly withdrawn without removing the guide wire from across the lesion. The guide wire is grasped while the catheter is withdrawn, and when the proximal opening of the guide wire lumen is reached, the grasping hand must be moved incrementally away from the proximal opening as the catheter is incrementally withdrawn, until the catheter is fully removed from the guide catheter and the guide wire is thus again exposed and accessible adjacent to the proximal end of the guide catheter.

This shortened guide wire lumen type of dilatation catheter design thus offers the advantages associated with the rapid exchangeability of catheters. The design also presents the potential to provide a smaller catheter shaft, since the guide wire is not contained within the proximal portion of the catheter shaft. The smaller catheter shaft thus allows for better contrast media injection and, as a result, better visualization. In addition, because of the rapid exchangeability features, standard non-extendable guide wires of approximately 175 centimeters in length may be used. Further, because the guide wire is contained in only a distal shorter guide wire lumen of the catheter, free wire movement is enhanced when compared to a standard over-the-wire catheter where the guide wire extends through a guide wire lumen extending along the entire length of the catheter.

While several structures for such shortened guide wire lumen dilatation catheter have been proposed these structures suffer from several disadvantages. Such catheters have been one piece polyethylene catheters having dual lumen configurations adjacent their distal regions. Typically, such catheters have larger than necessary shaft sizes and are stiffer in their distal regions than would be desired, including those portions bearing the dilatation balloon. A further disadvantage is that the proximal shaft portion of such catheters is relatively flexible, and has low column strength shaft, so that it tends to "bunch" and buckle when advanced across a lesion. To counteract this deficiency in such designs, additional stiffener elements have been provided in the shaft, which necessarily require a larger catheter shaft to accommodate the stiffener element structure. The known dilatation balloon catheter designs which include shortened guide wire lumens extending through the distal portion of the catheter suffer from the disadvantages mentioned above and do not take advantage of the unique opportunities presented by the possibilities of such designs in construction and application.

SUMMARY OF THE INVENTION

The present invention is an over-the-wire dilatation balloon catheter which has a guide wire lumen extending through only a distal portion of the catheter. The guide wire lumen extends from a distal end of the catheter proximally through a balloon of the catheter and exits the catheter at a point proximal of the balloon, but substantially distally from a proximal end of the catheter itself.

The present invention for a balloon dilatation catheter includes a thin-walled, high strength metallic tube having a longitudinal inflation lumen extending therefrom from its proximal end to its distal end. An intermediate sleeve section extends distally from the metallic tube. The sleeve section is more flexible than the metallic tube, and includes a proximal segment of inner core tube which has a longitudinal guide wire lumen extending therethrough and an outer sleeve which extends over the proximal segment of the core tube to define a longitudinally extending annular inflation lumen therebetween that is in fluid communication with the inflation lumen of the metallic tube. The guide wire lumen has an outlet at a proximal end of the proximal segment of the core tube, and the core tube has a distal segment which extends distally beyond the distal end of the outer sleeve. Means are provided for exposing the guide wire lumen outlet to the exterior of the catheter adjacent and proximal to the distal end of the metallic tube, without compromising the integrity of the inflation lumens extending through the catheter. An inflatable balloon extends over the distal segment of the core tube and has its proximal end connected to the distal end of the outer sleeve. A distal end of the balloon is connected to the core tube so that an interior of the balloon is in fluid communication with the annular inflation lumen in the sleeve section. Means are provided for preventing significant closure of the guide wire lumen and annular inflation lumen in the sleeve section adjacent the distal end of the metallic tube when the more flexible sleeve section is bent laterally relative to the metallic tube.

In a preferred embodiment of the present invention, the metallic tube is formed from a proximal relatively long stainless steel tube and a distal relatively short stainless steel tube bonded thereto. The outer diameter

of the proximal tube is smaller than the outer diameter of the distal tube, thus providing a catheter structure which is highly trackable and has a generally small shaft outer diameter, yet is very pushable and responsive to a doctor controlling movement of the catheter from its proximal end. Preferably, the means for exposing includes a longitudinal crimp adjacent the distal end of the distal stainless steel tube. The crimp extends laterally inwardly from one side of the distal tube, and has a proximal transition region and distal bonding region. The proximal end of the inner core tube is nested within the distal bonding region of the crimp and bonded thereto. The outer sleeve extends over at least a distal portion of the bonding region and is sealably affixed thereabout.

The means for preventing closure of a present invention may take a number of different forms. In a preferred embodiment, the means for preventing closure comprises a coil member affixed to the sleeve section adjacent the distal end of the metallic tube. As such, the coil member may be affixed about the outer sleeve to extend distally from the metallic tube or about the inner core tube to extend distally from the metallic tube. Such a coils member further may have its coil spaced uniformly apart or spaced increasingly apart as it extends distally from the metallic tube. Preferably, the coil member is formed from a spirally shaped ribbon. A compression sheath is provided to envelope the coil member and maintain the coil member in secure engagement to the sleeve section. In an alternative embodiment, the means for preventing closure comprises a tubular member affixed to the sleeve section adjacent the distal end of the metallic tube, with the tubular member being formed from a polyimide material.

Such closure preventing means thus provide a bending relief design between the relatively stiff metallic tube and more flexible distal region of the balloon dilatation catheter, to prevent kinking during catheter preparation work and handling (prior to insertion of the dilatation catheter into the guide catheter and patient). Such kinking or "crimping" of the catheter can result in a binding on the guide wire as it extends through the guide wire lumen or a reduction in size of the annular inflation lumen between the metallic tube and balloon or a compromise in strength of the catheter tubings, all of which will compromise the utility and responsiveness of the dilatation catheter. In addition, the closure preventing means reduces the possibility of a failure or separation of the bonds adjacent the distal end of the metallic tube which may be caused by excess strain placed on such bonds during catheter preparation or handling.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of a balloon dilatation catheter of the present invention having a distal guide wire lumen therethrough and showing a guide wire.

FIG. 2 is a sectional side elevational view of the balloon dilatation catheter of FIG. 1.

FIG. 3 is an enlarged sectional view as taken along lines 3—3 in FIG. 2.

FIG. 4 is a sectional side elevational view of a portion of the catheter of the present invention, illustrating an alternative structure for a reinforcing coil member thereon.

FIG. 5 is a sectional side elevational view of a portion of the catheter of the present invention, illustrating an

alternative structure for a reinforcing coil member thereon.

FIG. 6 is an enlarged sectional view as taken along lines 6-6 in FIG. 5.

FIG. 7 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 8 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 9 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 10 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 11 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 12 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 13 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

Although the above-identified drawing figures set forth various embodiments of the invention, other embodiments of the 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 will fall within the scope and spirit of the principles of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overall Catheter Structure

A balloon dilatation catheter 20 of the present invention is illustrated generally in FIG. 1. The catheter 20 has a proximal main shaft section 22, an intermediate sleeve section 24 and a distal balloon section 26. The main shaft section 22 has a proximal end 28 and a distal end 30. Likewise, the intermediate sleeve section 24 has a proximal end 32 and a distal end 34. The distal balloon section 26 has a proximal waist 36, an intermediate expandable segment 38 and a distal waist 40.

As illustrated in FIG. 1, the distal end 30 of the main shaft section 22 is connected to the proximal end 32 of the sleeve section 24, and the distal end 34 of the sleeve section 24 is connected to the proximal waist 36 of the balloon section 26. In use, the catheter 20 is coupled to an inflation device (not shown) by a luer manifold 42 connected to the proximal end 28 of the main shaft section 22. The inflation device thus provides or removes inflation solution from the catheter 20 to selectively inflate or deflate the intermediate expandable segment 38 of the distal balloon section 26 (in FIG. expandable segment 38 is shown in its inflated configuration).

The catheter 20 of the present invention is designed for use in combination with a catheter guide element such as a guide wire 50. In use in a coronary application, both the guide wire 50 and the catheter 20 are fed through and guided to an arterial lesion by means of a tubular guide catheter (not shown). Both the catheter 20 and guide wire 50 are therefore longer than the guide catheter, with a typical catheter length of approxi-

mately 135 cm and a typical guide wire length of approximately 175 cm. As illustrated in FIG. 1, the guide wire 50 extends longitudinally along the exterior of the main shaft section 22 of the catheter 20. Adjacent the distal end 30 of the main shaft section 22, the guide wire 50 enters the structure of the catheter 20 and extends distally therethrough until it exits the catheter structure adjacent the distal waist 40 of the distal balloon segment 26. As seen FIG. 2, a separate guide wire lumen 52 is provided in the catheter 20 through the intermediate sleeve section 24 and distal balloon section 26 thereof. The guide wire 50 thus is only entrained within the catheter 20 within this guide wire lumen 52, which is much shorter than the total length of the catheter 20 (e.g., the guide wire lumen 52 is approximately 30 cm long). The guide wire 50 has a proximal end 53 and a distal end 54 and is of a typical structure for guiding angioplasty catheters. At its distal end 54, the guide wire 50 preferably has a coiled and rounded tip structure which is bendable for steerability of the guide wire.

Referring now to FIG. 2, which shows the catheter 20 in greater detail, it is seen that the proximal end 28 of the main shaft section 22 further has a strain relief tube 60 disposed between the luer manifold 42 and shaft section 22. The strain relief tube 60 is larger than the main shaft section 22, and thus provides a step-wise strain relief function between the inflexible luer manifold 42 and the more flexible main shaft section 22. The main shaft section 22, tubular member 60 and luer manifold 42 are secured together respectively by suitable adhesive means, such as epoxy or cyanoacrylate.

Main Shaft Section

The main shaft section 22 is preferably formed as a thin-walled, high strength stainless steel tube structure, which is referred to as hypodermic tubing or hypotube. As a tubular structure the main shaft section 22 thus has a longitudinally extending inflation lumen 62 extending therethrough from its proximal end 28 to its distal end 30, which provides a means for the movement and pressurization of inflation fluid through the catheter 20 to and from the distal balloon section 26.

In a preferred embodiment, the main shaft section 22 is formed from two stainless steel tube sections, a proximal relatively long shaft section 64 and a distal relatively short shaft section 66. A distal end of the proximal shaft section 64 and a proximal end of the distal shaft section 66 are sealably affixed together by suitable means, such as by a solder joint. The proximal end of the distal shaft section 66 fits coaxially over the distal end of the proximal shaft section 64, as seen in FIG. 2, thereby allowing the proximal shaft section 64 to assume a smaller outer diameter than the distal shaft section 66. The main shaft section 22 is provided with a lubricious coating (such as polytetrafluoroethylene) to lessen frictional resistance (at least to the extent that the proximal shaft section 64 is so coated). The use of a thin-walled (e.g., 0.003 inch wall thickness), metallic tube structure for the main shaft section 22 thus provides a stiff enough shaft for pushability yet allows for a relatively small diameter shaft, thereby enhancing catheter visualization via fluoroscopy and catheter versatility. The inherent high strength nature of such a structure also allows it to withstand the fluid pressures necessary for proper catheter operation, which in a plastic shaft structure would require thicker walls. The high column strength and thickness of a hypotube shaft

also gives improved responsiveness to the catheter. Thus, the balloon and distal regions of the catheter move definitively (in a 1:1 relationship) with motions imparted at the catheter's proximal end by a physician. This feature allows the physician to actually "sense" the pathway as the catheter is tracked, which gives valuable information in the passage of the catheter to and through the lesion.

In the distal shaft section 66 of the main shaft section 22, a longitudinal crimp 68 is provided which extends laterally inwardly from one side of the distal section 66. The distal shaft section 66 has three sections, a proximal tubular region 70, a transition region 72, and a distal bonding region 74. The crimp 68 extends from its proximal origin in the transition region 72 to its greatest lateral depth in the bonding region 74. The crimp 68, as further illustrated in FIG. 3, does not seal off or close the inflation lumen 62, but does transform the inflation lumen from a circular lumen 62 to a crescent shape through the bonding region 74, as seen at 63 in FIG. 3.

Catheter Intermediate Sleeve Section

The intermediate sleeve section 24 extends distally from the main shaft section 22, and is bonded thereto adjacent the bonding region 74 of the distal shaft section 66. The intermediate sleeve section 24 has two primary longitudinal components, an inner core tube 80 and an outer sleeve or tube 82. The inner core tube 80 has a proximal segment 84 within the sleeve section 24 and a distal segment 86 within the distal balloon section 26. The inner core tube 80 and outer sleeve 82 are both preferably formed from thin-walled high density polyethylene.

The inner core tube 80 has a proximal end 88 and a distal end 90. At its proximal end 88, the core tube 80 is nested within the bonding region 74 of the distal shaft section 66 and bonded thereto by suitable means, such as epoxy or cyanoacrylate. The core tube 80 is thus affixed to the main shaft section 22 in an "off-axis" alignment at the bonding region 74. However, as seen in FIG. 2, as the core tube 80 extends distally from the main shaft section 22, it is aligned generally coaxially with the shaft section 22.

The core tube 80 defines the guide wire lumen 52 extending through the catheter 20. The guide wire lumen thus has a proximal outlet 92 adjacent the proximal end of the core tube 80 and a distal outlet 94 adjacent the distal end 90 of the core tube 80. At least one marker band 96 is provided about the core tube 80 (preferably centered within the expandable segment 38 of the distal balloon section 26) to aid in illuminating the position of the catheter 20 via fluoroscopy during an angioplasty procedure.

The outer sleeve 82 is generally tubular in form, and has a proximal end 100 and a distal end 102. The outer sleeve 82 is bonded about the distal shaft section 66 and the core tube 80 adjacent the bonding region 74, as seen in FIGS. 2 and 3 and is held in place thereto by suitable means, such as epoxy or cyanoacrylate. The outer sleeve 82 extends distally from the main shaft section 22 over the proximal segment 84 of the core tube 80, and as such, defines a distal continuation of the inflation lumen of the catheter 20. A longitudinally extending annular inflation lumen 104 is formed between the core tube 80 and outer sleeve 82. Of course, the proximal end 100 of the outer sleeve 82 is securely sealed about the distal shaft section 66 and the core tube 80 so that the longitudinal inflation lumens 62 and 104 through the catheter

20 are not compromised to the exterior of catheter 20, but are in fluid communication therethrough.

The intermediate sleeve structure defined above is the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein—namely, an inner core tube bonded to a distal portion of the main catheter shaft, with an outer sleeve forming an annular continuation of the inflation lumen through the main shaft between the core tube and outer sleeve. As discussed below and illustrated herein, various configurations of the connections and components relative to the formation of the distal guide wire lumen, including the coupling of the main shaft to the intermediate sleeve section, are contemplated.

Catheter Distal Balloon Section

The distal balloon section 26 is connected to the components of the intermediate sleeve section 24. The proximal waist 36 of the balloon section 26 is connected to the distal end 102 of the outer sleeve 82 by suitable means, such as by epoxy or cyanoacrylate. The distal waist 40 of the balloon section 26 is bonded to the core tube 80 adjacent its distal end 90 by suitable means, such as by epoxy or cyanoacrylate. An interior 106 of the balloon section 26 is thus sealed and in fluid communication with the annular inflation lumen 104 within the sleeve section 24. In a preferred embodiment, the balloon section 26 is formed from a compliant balloon material (e.g., polyolefin), although a balloon formed from thin-walled non-compliant material (e.g., PET—polyethylene terephthalate) is also contemplated.

Kink-resistant Structure

The metallic main shaft section 22 is relatively stiff compared to the polyethylene intermediate sleeve section 24. This creates a rather abrupt change in the flexibility of the materials for the catheter 20 adjacent the distal end 30 of the main shaft section 22 (at the bonding region 74). The use of a hypotube for the main shaft section 22 in the catheter 20 creates a catheter which is considerably stiffer than most previous over-the-wire angioplasty balloon catheter designs. Such stiffness is not a concern as long as the metallic main shaft section 22 remains in the relatively straight guide catheter within the patient, and indeed such stiffness provides distinct benefits in use of the catheter 20, as described above. In the distal portions of the catheter 20 (intermediate sleeve section 24 and distal balloon section 26), the catheter 20 must be very trackable and flexible in order to negotiate the tortuous coronary anatomy to and across the lesion. The relatively sharp transition in stiffness as the catheter structure changes from the metallic main shaft section 22 to the much more flexible polymer intermediate sleeve section 24 creates two concerns. First, during handling of the catheter prior to usage, there is a potential to kink the catheter structure at that flexibility transition point. Secondly, when the catheter is in vivo, the distal end 30 of the main shaft section 22 could potentially "dig in" to the guide catheter and create excessive friction due to the lack of bending support from the more flexible intermediate sleeve section 24.

To address these concerns, a kink-resistant structure 110 is provided to prevent kinking and possible damage to the intermediate sleeve section 24 during catheter preparation, handling and use. In its simplest form, this kink-resistant structure 110 provides a member of inter-

mediate stiffness or transitory stiffness and kink-resistant nature between the relatively stiff main shaft section 22 and the relatively flexible intermediate sleeve section 24. The kink-resistant structure 110 includes a coil member 112 affixed to the intermediate sleeve section 24 adjacent the distal end 30 of the main shaft section 22. The coil member 112 creates an intermediate stiffener element between the relatively stiff main shaft section 22 and the relatively flexible intermediate sleeve section 24 to allow bending of the catheter without kinking. The coil member 112 preferably has its coils spaced uniformly apart, and is preferably formed from a spiral ribbon of stainless steel placed about the outer sleeve 82 along that portion thereof extending over the bonding region 74 and distally therefrom. The coil member 112 is secured to the outer sleeve 82 by suitable adhesive means, such as by epoxy. To further secure the coil member 112 to the intermediate sleeve section 24, a heat-shrinkable sheath 114 is fitted over the coil member 112. Preferably the sheath 114 is formed from a polyimide or polyolefin material which is expanded radially outwardly and then shrunk down over the coil member 112 and outer sleeve 82 to secure the coil member 112 thereto. To further secure the sheath 114 and coil member 112 in place, some adhesive is provided between the sheath 114 and the intermediate sleeve section 24. By covering the ends of the coil member 112, the sheath 114 also lessens the chances of those ends providing a rough edge or catch as the catheter is advanced through the guide catheter or artery.

Although the kink-resistant structure is described and illustrated in connection with a balloon dilatation catheter, it is contemplated that such a structure be employed in any catheter shaft as a transition from a first thin-walled, high strength metallic tube structure to a second tube structure which is more flexible than the metallic tube structure. Such a kink-resistant structure, as described above (and also below in various embodiments), may be employed in a single lumen catheter shaft, or in multiple lumen catheter shaft having a central core tube such as the multi-lumen shaft illustrated by the intermediate sleeve section of the catheter disclosed in FIGS. 1-4.

Alternative Catheter Embodiment

Numerous alternative embodiments of the catheter of the present invention are contemplated. For example, several alternative arrangements for the main shaft section and intermediate sleeve structure portion of the catheter are illustrated and discussed herein, but it is not intended that the illustrated embodiments are all inclusive of those structures and designs which are included within the spirit and scope of the present invention. In the following discussion of further alternative embodiments of the present invention, to the extent a component is identical to that of a previously described embodiment, like reference numerals are used.

FIG. 4 illustrates an alternative embodiment for the distal portion of a catheter according to the present invention. Specifically, the outer sleeve (of the intermediate sleeve section) and the distal balloon section are formed from the same component, as a unitary member. Thus, proximal waist 36A of distal balloon section 26A is elongated proximally and acts as the outer sleeve for intermediate sleeve section 24A. A proximal end 115 of the proximal waist 36A is sealably fixed about the core tube 80 and main shaft section 22 adjacent the bonding region 74 thereof. It should be understood that the pros-

pect of having a unitary outer sleeve and balloon member is applicable to all embodiments disclosed herein and contemplated, although it is only illustrated and discussed with respect to the catheter structure of FIG. 4.

FIG. 4 also shows another variation for the catheter's structure illustrated in FIGS. 1-3. In FIG. 4, kink-resistant structure 110A includes coil member 112A which is defined as a spiral ribbon of stainless steel placed about a proximal portion of the proximal waist 36A along the bonding region 74 and distally therefrom. The coil member 112A does not have its coils uniformly spaced apart, but rather has its coils spaced increasingly further apart as the coil member extends distally from the main shaft section 22. This results in a coil member 112A which becomes increasingly more flexible, thereby "feathering out" the change in relative stiffness and strain or kink relief between the relatively inflexible main shaft section 22 and the relatively flexible intermediate sleeve section 24A. As before, a heat-shrinkable sheath 114A is fitted over the coil member 112A to further secure the coil member 112A to the sleeve section 24A.

In FIG. 5, a modified main shaft section 22B is illustrated. The main shaft section 22B is formed as a thin-walled, high strength stainless steel tube or hypotube, but is defined as a single tubular shaft 117 from its proximal end to its distal end 30B. The single shaft 117 has a longitudinally extending inflation lumen 62B there-through, and at its proximal end (not shown) the single shaft 117 is mounted to an inflation device in a manner such as that illustrated for the catheter of FIG. 2. Adjacent its distal end 30B, the single shaft 117 has a longitudinal crimp 68B which extends laterally inwardly from one side of the single shaft 117. The single shaft 117 thus has three sections, a proximal, relatively elongated tubular region 70B, a relatively short distal transition region 72B and a relatively short distal bonding region 74B. The crimp 68B extends from its proximal origin in the transition region 72B to its greatest lateral depth in the bonding region 74B. The crimp 68B does not seal or close off the inflation lumen 62B, but rather transforms the inflation lumen 62B from a circular lumen to a half-moon lumen through the bonding region 74B, as seen at 63B in FIG. 6. It is again understood that the use of a single tube to define the main shaft section of the catheter of the present invention is applicable to the other alternative embodiments of the catheter structures disclosed herein.

FIGS. 5 and 6 also illustrate an alternative arrangement for the kink-resistant structure of the inventive catheter. Kink-resistant structure 210 includes coil member 212. The sleeve section 24B includes an outer sleeve 82B and an inner core tube 80B, with the core tube 80B adapted to be nested within and bonded to the main shaft section 22B in its distal bonding region 74B. The coil member 212 of the kink-resistant structure 210 is positioned about the core tube 80B within the distal bonding region 74B and extending distally therefrom. The coil member 212 is preferably formed from stainless steel (either from a wire or ribbon) and may have uniform coil spacing or increasingly spaced coils as the coil member 212 extends distally from the main shaft section 22B. The coil member 212 is secured to the core tube 80B by suitable means, such as by embedding the coil member 212 in an epoxy layer 214 about the core tube 80B. A proximal end 100B of the outer sleeve 82B is bonded about the main shaft section 22B and inner tube

80B and coil structure 210 in the bonding region 74B thereof, as seen in FIGS. 5 and 6. In the intermediate sleeve section 24B, the inner core tube 80B thus provides a guide wire lumen 52B therethrough, and an annular inflation lumen 104B is provided between the inner tube 80B and outer sleeve 82B. Although the kink-resistant structure 210 is within the annular inflation lumen 104 and the outer sleeve 82B necks down distally from the main shaft section 22B, the size of the annular inflating lumen 104 is sufficient to provide proper fluid flow to and from the catheter's balloon.

FIGS. 7-13 illustrate an alternative configuration for that portion of the catheter adjacent the proximal inlet of the guide wire lumen. Instead of providing a crimp structure in the distal end of the main shaft section, an aperture is provided adjacent to and proximal of the distal end of the main shaft section. The aperture is aligned and sealably coupled to the inner tube to define the guide wire lumen proximal outlet. In all disclosed embodiments, the main shaft section is preferably formed from a hypotube-like material.

As seen in FIG. 7, an alternative embodiment of the catheter of the present invention has a proximal main shaft section 22C formed from thin-walled, high strength stainless steel tubing. A longitudinally extending inflation lumen 62C extends therethrough from a proximal end of the main shaft section 22C to its distal end 30C. In the embodiment seen in FIG. 7, the main shaft 22C is formed from two stainless steel tube sections, a proximal relatively long shaft section 64C and a distal relatively short shaft section 66C bonded to the distal end of the proximal section 64C. This two-part main shaft section structure thus allows a substantial length of the main shaft section 22C to be formed from the proximal shaft section 64C which has a smaller diameter than the distal shaft section 66C.

The distal shaft section 66C has an oval-shaped aperture 119 extending through its wall, with the oval being elongated in the longitudinal direction of the main shaft section 22C. The aperture 119 is spaced proximally from a distal end of the distal shaft section 66C (the distal end 30C of the main shaft section 22C). The space between the aperture 119 and distal end 30C thus defines in part a bonding region 121 for connecting the main shaft section 22C to a distally extending intermediate sleeve section 24C.

As before, the intermediate sleeve section 24C includes an inner core tube 80C and an outer sleeve 82C. A proximal end 88C of the core tube 80C is sealably bonded about the aperture 119 to align the proximal end 88C and aperture 119 and thereby define a proximal outlet 92C for a guide wire lumen 52C extending through the core tube 80C. As seen in FIG. 7, a proximal portion 123 of the core tube 80C extends laterally from the aperture 119 into the distal shaft section 66C and turns longitudinally and distally relative thereto to be aligned generally coaxially therewith. As such, the inflation lumen 62C is continued distally past the aperture 119 as a generally annular inflation lumen 125, between the core tube 80C and distal shaft section 66C (along the bonding region 121). Proximal end 100C of the outer sleeve 82C is bonded about the distal shaft section 66C in the bonding region 121 by a suitable means, such as by epoxy or cyanoacrylate. As seen in FIG. 7, the outer sleeve 82C extends distally from the main shaft section 22C over the core tube 80C and defines a longitudinally extending annular inflation lumen 104C between the core tube 80C and outer sleeve

82C. The proximal end 100C of the outer sleeve 82C is sealed about the distal shaft section 66C so that the longitudinal inflation lumens 62C, 125 and 104C are not compromised to the exterior of the catheter, but are in fluid communication therethrough.

In FIG. 7, kink-resistant structure 310 includes coil member 312 (of a wire or ribbon-like structure) which is bonded about the outer sleeve 82C to extend distally from the distal end 30C of the main shaft section 22C. In this embodiment, the coil member 312 does not extend about any portion of the main shaft 22C. The coil member 312 is secured to the outer sleeve 82C by suitable adhesive means, such as epoxy 314, and is embedded therein to firmly hold the coil member 312 in place about the intermediate sleeve section 24C. In the embodiment of FIG. 7, the coil member 312 is illustrated with its coils being spaced increasingly longitudinally apart as the coil member 312 extends distally along the catheter.

FIGS. 8-13 also illustrate embodiments of the catheter of the present invention wherein an aperture is provided through the main shaft section wall to accommodate the proximal outlet for the relatively short, distal guide wire lumen. As opposed to the embodiment of FIG. 7, however, the embodiments illustrated in FIGS. 8-13 show the main shaft section as a single shaft rather than as a multi-part shaft. Indeed, FIG. 8 illustrates a catheter structure identical to that of FIG. 7, except that the main shaft section 22D is shown as a single shaft 217, rather than having proximal and distal shaft sections 64C and 66C as seen in FIG. 7. As such, the catheter inflation lumen includes longitudinally extending inflation lumens 62D, 125D and 104D.

FIG. 9 is an embodiment of the catheter of the present invention otherwise similar to FIG. 8, except that kink-resistant structure 410 has coil member 412 with uniformly spaced coils along the entire length. Again, the entire coil member 412 is fixed to the outer sleeve 82C of the intermediate sleeve section 24C by embedding the coil member 412 within a suitable material such as epoxy or cyanoacrylate 414.

In the catheter structure of FIG. 10, intermediate section 24E has an inner core tube 80E and an outer sleeve 82E. The structure of the catheter is otherwise the same as the catheter of FIG. 9, except that the kink-resistant structure thereof is positioned inside the outer sleeve 82E rather than outside of the outer sleeve. Kink-resistant structure 510 is affixed to an inner surface of the outer sleeve 82E distally of the main shaft section 22D by a suitable means, such as embedded adhesive 514. The kink-resistant 510 includes coil member 512 which provides an intermediate stiffener between the relatively stiff main shaft section 22D and the relatively flexible intermediate sleeve section 24E. As seen, the outer sleeve 82E necks down distally from the kink-resistant structure 510 to provide a lower profile for the catheter in its distal regions. An annular inflation lumen 104E formed between the inner tube 80E and outer sleeve 82E (and at a proximal end thereof, between the inner tube 80E and the kink-resistant structure 510) is not comprised by such a necked-down sleeve design but maintained at sufficient size to provide for adequate and quick inflation and deflation of the balloon.

In FIG. 11 intermediate sleeve section 24F includes an inner core tube 80F and an outer sleeve 82F. Kink-resistant structure 610 is mounted about the inner tube 80F along the bonding region 121 and extending distally from the main shaft section 22D into the intermediate

sleeve section 24F. The kink-resistant structure includes coil member 612 which is affixed about the core tube 80F by suitable means such as being embedded in epoxy or another suitable adhesive 614. As seen in FIG. 11, the outer sleeve 82F has an enlarged diameter at its proximal end to accommodate the main shaft section 22D and the kink-resistant structure 610, and so that the annular inflation lumens 125F and 104F about the core tube 80F remain sufficiently large to provide proper inflation and deflation pressures to the balloon of the catheter.

FIGS. 12 and 13 illustrate a further variation of the kink-resistant structure of the present invention. In the embodiments of FIGS. 12 and 13, the kink-resistant structure does not include a coil member, is formed from a polymer tube which is of intermediate stiffness between the main shaft section and intermediate sleeve section. In FIG. 12, kink-resistant structure 710 is provided which is formed from a polyimide or other stiff polymer tube 727. The tube 727 is bonded about an inner core tube 80G of the intermediate sleeve section 24G by a suitable adhesive, such as epoxy or cyanoacrylate. The tube 727 extends through a distal portion of the bonding region 121 and distally beyond the main shaft section 22D into the intermediate sleeve section 24G. Again, an outer sleeve 82G of the sleeve section 24G has an enlarged diameter at its proximal end to accommodate the main shaft section 22D and the kink-resistant structure 710, and so that the components are dimensioned such that annular inflation lumens 125G and 104G are not comprised.

In FIG. 13, kink-resistant structure 810 is illustrated, as formed from a polyimide or other stiff polymer tube 829 which is bonded to the inner surfaces of both the main shaft section 22D and an outer sleeve 82H of an intermediate sleeve section 24H at a bonding region 121H. The tube 829 thus provides not only a kink-resistant structure to accommodate the change in stiffness of the main shaft section and intermediate sleeve section, but also provides a substrate for bonding the two catheter sections together by a suitable adhesive, such as epoxy or cyanoacrylate. A core tube 80H of the sleeve section 24H extends through the interior of the tube 829 to the aperture 119 on the main shaft section 22D. Thus, an annular longitudinally extending inflation lumen 131 is formed as a "bridge lumen" (between the core tube 80H and tube 829) from the inflation lumen 62D to an annular inflation lumen 104H within the sleeve section 24H.

As mentioned above, various combinations of these alternative component and catheter structures are contemplated and are intended to be considered, although not explicitly shown. For example, it is contemplated that a two-part main shaft section structure (such as illustrated in FIGS. 2, 4 and 7) may be combined with any one of the kink-resistant structure such as that illustrated in FIGS. 8-13. By way of example and not limitation, a further example of such a combination may include the use of a distal balloon section having an elongated proximal waist (such as shown in FIG. 4) with any of the alternative kink-resistant structures disclosed herein.

CONCLUSION

The balloon dilatation catheter of the present invention is an over-the-wire catheter structure with a distal guide wire lumen which optimizes the features of such a catheter in a way not previously considered or

achieved. The use of a hypotube-type main shaft for the catheter allows the attainment of a high strength, pushable shaft having thin walls and small diameter. The further use of a two-part hypotube shaft structure allows an even smaller diameter for the proximal elongated section of the main catheter shaft. Employing a crimp as a means for aligning and creating a proximal outlet for the relatively short guide Wire lumen also serves to provide a transition region for exit of the guide wire from the catheter itself which is relatively gradual. The crimped shaft design also provides additional stiffness in the transition region where the guide wire enters and exits the catheter proximally of the balloon thereof, thereby creating a more rigorous catheter structure. Because the catheter of the present invention is based upon a relatively stiff proximal main shaft section, and such a catheter must have a relatively flexible distal portion for working through the tortuous arterial anatomy, a strain relief or kink-resistant structure is provided to make a more gradual transition between the relatively stiff main catheter shaft and the relatively flexible distal portion of the catheter. Various configurations of strain relief and kink-resistant structures are disclosed herein, and all are believed suitable to accomplish the desired end of preventing significant closure of the guide wire lumen and annular inflation lumen in the more flexible distal portions of the catheter, especially adjacent the distal end of the main catheter shaft.

Although the present invention has been described with reference to preferred 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.

What is claimed is:

1. A balloon dilatation catheter comprising:
 - a thin-walled, high strength metallic tube having a longitudinal inflation lumen extending there-through from a proximal end to a distal end;
 - an intermediate sleeve section extending distally from the metallic tube, the sleeve section being more flexible than the metallic tube and including an inner core tube which has a longitudinal guide wire lumen extending therethrough and an outer sleeve which extends over a proximal segment of the core tube to define an annular inflation lumen between the inner core tube and the outer sleeve that is in fluid communication with the inflation lumen of the metallic tube, with the guide wire lumen having an outlet at a proximal end of the proximal segment of the core tube and with the core tube having a distal segment which extends distally beyond a distal end of the outer sleeve;
 - means for exposing the guide wire lumen outlet at the proximal end of the core tube to an exterior of the catheter adjacent and proximal to the distal end of the metallic tube;
 - an inflatable balloon extending over the distal segment of the core tube, the balloon having its proximal end connected to the distal end of the outer sleeve and having its distal end connected to the core tube so that an interior of the balloon is in fluid communication with the annular inflation lumen in the intermediate sleeve section; and
 - a coil member affixed about the outer sleeve of the intermediate sleeve section adjacent the distal end of the metallic tube, the coil member having its coils spaced increasingly apart as it extends distally from the metallic tube.

2. The balloon dilatation catheter of claim 1 wherein the means for exposing includes a longitudinal crimp adjacent the distal end of the metallic tube which extends laterally inwardly from one side of the metallic tube, the crimp having a proximal transition region and a distal bonding region, the proximal end of the inner core tube being nested within the distal bonding region of the longitudinal crimp of the metallic tube and bonded thereto, and with the outer sleeve extending over at least a distal portion of the bonding region and sealably affixed thereabout.

3. The balloon dilatation catheter of claim 2 wherein the metallic tube is formed from a proximal relatively long stainless steel tube and a distal relatively short stainless steel tube bonded thereto, with the longitudinal crimp being in the distal tube.

4. The balloon dilatation catheter of claim 3 wherein the outer diameter of the proximal tube is smaller than the outer diameter of the distal tube.

5. The balloon dilatation catheter of claim 1 wherein the coil member is formed from a spirally-shaped ribbon.

6. The balloon dilatation catheter of claim 1, and further comprising:
a sleeve enveloping the coil member to maintain the coil member in secured engagement to the intermediate sleeve section.

7. The balloon dilatation catheter of claim 1 wherein the metallic tube is formed from a proximal relatively long stainless steel tube and a distal relatively short stainless steel tube affixed thereto.

8. The balloon dilatation catheter of claim 7 wherein the outer diameter of the proximal tube is smaller than the outer diameter of the distal tube.

9. The balloon dilatation catheter of claim 1 wherein the outer sleeve is formed integrally with the balloon.

10. The balloon dilatation catheter of claim 1 wherein the inner core tube is formed from high density polyethylene.

11. The balloon dilatation catheter of claim 1 wherein the outer sleeve is formed from high density polyethylene.

12. The balloon dilatation catheter comprising:
a first thin-walled, high strength, relatively inflexible tube having a longitudinal inflation lumen extending therethrough from a proximal end to a distal end, the first tube having, at the distal end thereof, a longitudinal crimp extending laterally inwardly from one side of the first tube with the crimp having a proximal transition region and a distal bonding region;
a second relatively flexible core tube having a longitudinal guide wire lumen extending therethrough from a proximal end to a distal end, with the proximal end of the second tube being nested within the distal bonding region of the longitudinal crimp of the first tube and bonded thereto so that the second tube extends distally from the first tube;
a balloon assembly having an elongated proximal waist segment, an intermediate expandable segment and a distal waist segment, the proximal segment extending over at least a distal portion of the distal bonding region and sealably affixed thereabout so that the inflation lumen is in fluid communication with an interior of the balloon assembly through the proximal segment, with the balloon assembly extending distally from the distal bonding region over the second tube to a second bonding

region where the distal waist segment is sealably affixed about the second tube; and
a coil member affixed about at least a proximal portion of the proximal waist segment to extend distally from the distal bonding region.

13. The balloon dilatation catheter of claim 12 wherein the coil member is formed from a spirally-shaped ribbon.

14. The balloon dilatation catheter of claim 12, wherein the coil member has its coils spaced increasingly apart as it extends distally from the first tube.

15. The balloon dilatation catheter of claim 12, and further comprising:
a sheath enveloping the coil member and maintaining the coil member about the proximal waist segment of the balloon assembly.

16. The balloon dilatation catheter of claim 12 wherein the first tube is formed from a proximal, relatively long stainless steel tube and a distal relatively short stainless steel tube bonded thereto, with the longitudinal crimp being in the distal tube.

17. The balloon dilatation catheter of claim 16 wherein the outer diameter of the proximal tube is smaller than the outer diameter of the distal tube.

18. The balloon dilatation catheter of claim 12 wherein the second tube is formed from high density polyethylene.

19. In an elongate dilatation catheter of the type that can be slidably moved along a guide wire that can extend past a distal end of the catheter, wherein the guide wire is received in a guide wire lumen of the catheter, the guide wire extending from a distal guide wire lumen opening to a proximal guide wire lumen opening disposed in a portion of the catheter that is spaced distally from a proximal end of the catheter, the dilatation catheter including an inflatable balloon and an inflation lumen extending through the catheter separate from the guide wire lumen, an improvement comprising:
a first proximal shaft section of the catheter defined by a relatively rigid metallic tube;
a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section; and
a transition section disposed between the first shaft section and the second shaft section, the transition section including a transition member comprising a metallic element of gradually diminished dimension, the transition member extending adjacent to the proximal guide wire lumen opening, and the transition member having gradually decreasing rigidity in the distal direction to provide a relatively smooth transition between the first shaft section and the second shaft section.

20. The improved catheter of claim 19 in which the transition member is adapted to impart a tapering transition in flexibility between the relatively rigid proximal portion and the relatively more flexible second section.

21. The improved catheter of claim 19 in which the transition member extends at least in part across the guide wire lumen proximal opening.

22. The improved catheter of claim 19 in which the transition member extends at least in part distally of the guide wire lumen proximal opening.

23. The improved catheter of claim 19 in which the transition member comprises:
a coil spring located in a wall of the relatively more flexible portion of the catheter distally of the proximal lumen opening.

24. The improved catheter of claim 23 in which the coil spring is of gradually greater flexibility in a distal direction.

25. The improved catheter of claim 23 in which the coil spring is located around the guide wire lumen.

26. The improved catheter of claim 19 in which the transition member is located at least in part around the inflation lumen.

27. The improved catheter of claim 19 in which the transition member is connected to the first shaft section.

28. In an elongate dilatation catheter of the type that can be slidably moved along a guide wire that can extend past a distal end of the catheter, wherein the guide wire is received in a guide wire lumen of the catheter, the guide wire extending from a distal guide wire lumen opening to a proximal guide wire lumen opening located in a portion of the catheter that is spaced distally from a proximal end of the catheter, the dilatation catheter including an inflatable balloon and an inflation lumen extending through the catheter separate from the guide wire lumen, an improvement comprising:

a first proximal shaft section of the catheter defined by a relatively rigid metallic tube;

a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section; and

a transition section disposed between the first shaft section and the second shaft section, the transition section including a transition member extending adjacent to the proximal guide wire lumen opening, the transition member having gradually decreasing rigidity in the distal direction to provide a relatively smooth transition between the first section of the shaft and the second section of the shaft.

29. The improved catheter of claim 28 in which the transition member is adapted to impart a tapering transition in flexibility between the relatively rigid first section and the relatively more flexible second section of the shaft.

30. The improved catheter of claim 28 in which the transition member extends at least in part across the guide wire lumen proximal opening.

31. The improved catheter of claim 28 in which the transition member extends at least in part distally of the guide wire lumen proximal opening.

32. The improved catheter of claim 28 in which the transition member extends at least in part around the inflation lumen.

33. The improved catheter of claim 28 in which the transition member is connected to the first shaft section.

34. A balloon dilatation catheter comprising:

a metallic tube defining a first shaft section having a proximal end and a distal end;

a second shaft section, more flexible than the metallic tube, disposed distally of the first shaft section;

the first and second shaft sections having an inflation lumen defined therethrough which extends from the proximal end of the metallic tube to the distal end of the second shaft section;

a dilatation balloon attached to the distal end of the second shaft section, the dilatation balloon being in fluid communication with the inflation lumen such that inflation pressure may be provided to the balloon therethrough;

a transition section interposed between the first shaft section and the second shaft section, the transition section including a transition member including a crimp defining the proximal guide wire outlet and

configured to provide stiffness which gradually decreases distally from the stiffness of the first shaft section to the stiffness of the second shaft section; and

a guide wire tube extending through the interior of the balloon, the guide wire tube defining a second separate and shorter lumen than the inflation lumen, the second lumen having a proximal guide wire opening at its proximal end and a distal guide wire opening at its distal end, with the proximal guide wire opening being disposed adjacent the distal end of the first shaft section, and wherein the second lumen receives a guide wire therein such that the catheter may be slidably moved on the guide wire.

35. The catheter of claim 34 wherein the transition member comprises a metallic element of gradually diminished dimension.

36. The catheter of claim 34 wherein the transition member extends at least in part across the guide wire lumen proximal opening.

37. The catheter of claim 34 wherein the transition member extends at least in part distally of the guide wire lumen proximal opening.

38. The catheter of claim 34 wherein the transition member is adapted to impart a tapering transition in flexibility between the metallic tube of the first shaft section and the more flexible second shaft section.

39. The catheter of claim 34 wherein the transition member extends at least in part around the inflation lumen.

40. In an elongate dilatation catheter which has an inflatable balloon and an inflation lumen extending through the catheter, wherein the catheter is of the type that can be slidably moved along a guide wire that can extend past a distal end of the catheter through a guide wire lumen of the catheter, wherein the guide wire lumen is separate from the inflation lumen and extends from a distal guide wire lumen opening to a proximal guide wire lumen opening located in a portion of the catheter that is spaced distally from a proximal end of the catheter so that the guide wire lumen is shorter than the inflation lumen, an improvement comprising:

a first proximal shaft section of the catheter defined by a relatively rigid metallic tube;

a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section; and

a transition section disposed between the first shaft section and the second shaft section, the transition section including a transition member comprising a metallic element of gradually diminished dimension, the transition member extending adjacent to the proximal guide wire lumen opening, and the transition member having gradually decreasing rigidity in the distal direction to provide a relatively smooth transition between the first shaft section and the second shaft section.

41. The improved catheter of claim 40 in which the transition member is adapted to impart a tapering transition in flexibility between the relatively rigid proximal portion and the relatively more flexible distal portion.

42. The improved catheter of claim 40 in which the transition member extends at least in part across the guide wire lumen proximal opening.

43. The improved catheter of claim 40 in which the transition member extends at least in part distally of the guide wire lumen proximal opening.

44. The improved catheter of claim 40 in which the transition member extends at least in part around the inflation lumen.

45. The improved catheter of claim 40 in which the transition member is connected to the first shaft section.

46. In an elongate dilatation catheter which has an inflatable balloon and an inflation lumen extending through the catheter, wherein the catheter is of the type that can be slidably moved along a guide wire which can extend past a distal end of the catheter through a guide wire lumen of the catheter, wherein the guide wire lumen is separate from the inflation lumen and extends from a distal guide wire lumen opening to a proximal guide wire lumen opening disposed in a portion of the catheter that is spaced distally from a proximal end of the catheter so that the guide wire lumen is shorter than the inflation lumen, an improvement comprising:

- a first proximal shaft section of the catheter defined by a relatively rigid metallic tube;
- a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section; and
- a transition section disposed between the first shaft section and the second shaft section, the transition section including a transition member extending adjacent to the proximal guide wire lumen opening, the transition member having gradually decreasing rigidity in the distal direction to provide a relatively smooth transition between the first section of the shaft and the second section of the shaft.

47. The improved catheter of claim 46 in which the transition member is adapted to impart a tapering transition in flexibility between the relatively rigid proximal portion and the relatively more flexible distal portion.

48. The improved catheter of claim 46 in which the transition member extends at least in part across the guide wire lumen proximal opening.

49. The improved catheter of claim 46 in which the transition member extends at least in part distally of the guide wire lumen proximal opening.

50. The improved catheter of claim 46 in which the transition member extends at least in part around the inflation lumen.

51. The improved catheter of claim 46 in which the transition member is connected to the first shaft section.

52. In an elongate dilatation catheter of the type that has a first relatively long proximal shaft section, a second shorter distal shaft section disposed distally of the

first shaft section, an inflatable balloon attached to the distal end of the second shaft section wherein the first and second shaft sections have an inflation lumen defined therethrough so that the balloon is in fluid communication with the inflation lumen, and wherein the catheter is of the type that can be slidably moved along a guide wire which can extend through a guide wire lumen of the catheter, the guide wire lumen being separate from the inflation lumen and extending from a distal guide wire lumen opening at the distal end of the catheter to a proximal guide wire lumen opening adjacent the proximal end of the second shaft section so that the guide wire lumen is shorter than the inflation lumen, an improvement comprising:

- the first proximal shaft section of the catheter defined by a relatively rigid metallic tube;
- the second shaft section of the catheter being relatively more flexible than the metallic tube and having a relatively short reinforced proximal portion and a relatively long non-reinforced distal portion, and
- the reinforced proximal portion including a transition member disposed adjacent to the proximal lumen opening and extending distally along the second shaft section to provide a reinforcement therefor, the transition member including a metallic element which decreases gradually in dimension as it extends distally along the catheter to provide gradually decreasing rigidity in the distal direction, the transition member having a distal terminal end spaced from the balloon by the length of the non-reinforced distal portion of the second shaft section.

53. The improved catheter of claim 52 wherein the transition member is adapted to impart a tapering transition in flexibility between the relatively rigid first shaft section and the relatively more flexible second shaft section.

54. The improved catheter of claim 52 wherein the transition member is located at least in part around the inflation lumen.

55. The improved catheter of claim 52 wherein the transition member extends at least in part across the guide wire lumen proximal opening.

56. The improved catheter of claim 52 wherein the transition member extends at least in part distally of the guide wire lumen proximal opening.

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United States Patent [19]

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Keith

[45] **Date of Patent:** **Jun. 8, 1993**

- [54] **BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN**
- [75] **Inventor:** Peter T. Keith, Edina, Minn.
- [73] **Assignee:** SciMed Life Systems, Inc., Maple Grove, Minn.
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- [22] **Filed:** Nov. 15, 1991

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- [52] **U.S. Cl.** 606/194; 604/102; 604/282
- [58] **Field of Search** 604/96-103, 604/170; 606/192-196; 600/18

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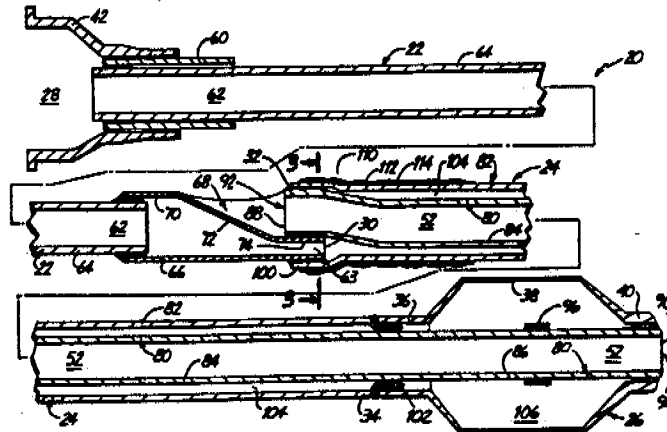
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[57] **ABSTRACT**

An over-the-wire balloon dilatation catheter has a stainless steel hypotube catheter shaft, an intermediate sleeve section bonded to the shaft and a distal balloon section connected to the sleeve section. The sleeve section is formed from relatively flexible polymer materials and includes an inner core tube which defines a guide wire lumen extending only through a distal portion of the catheter (including its sleeve and balloon sections) to facilitate fast balloon catheter exchanges. A distal end of the hypotube shaft is crimped laterally and the core tube is nested and bonded within the crimp to provide a proximal outlet for the guide wire lumen. The hypotube shaft provides an inflation lumen for the balloon, with the inflation lumen being continued as an annular inflation lumen through the sleeve section where an outer sleeve is bonded about the core tube and extends from the distal end of the hypotube shaft to the balloon section. A kink-resistant coil structure extends distally from the distal end of the hypotube shaft to provide a gradual change in stiffness along the length of the catheter from the relatively stiff hypotube shaft to the relatively flexible distal portion of the catheter.

1 Claim, 6 Drawing Sheets



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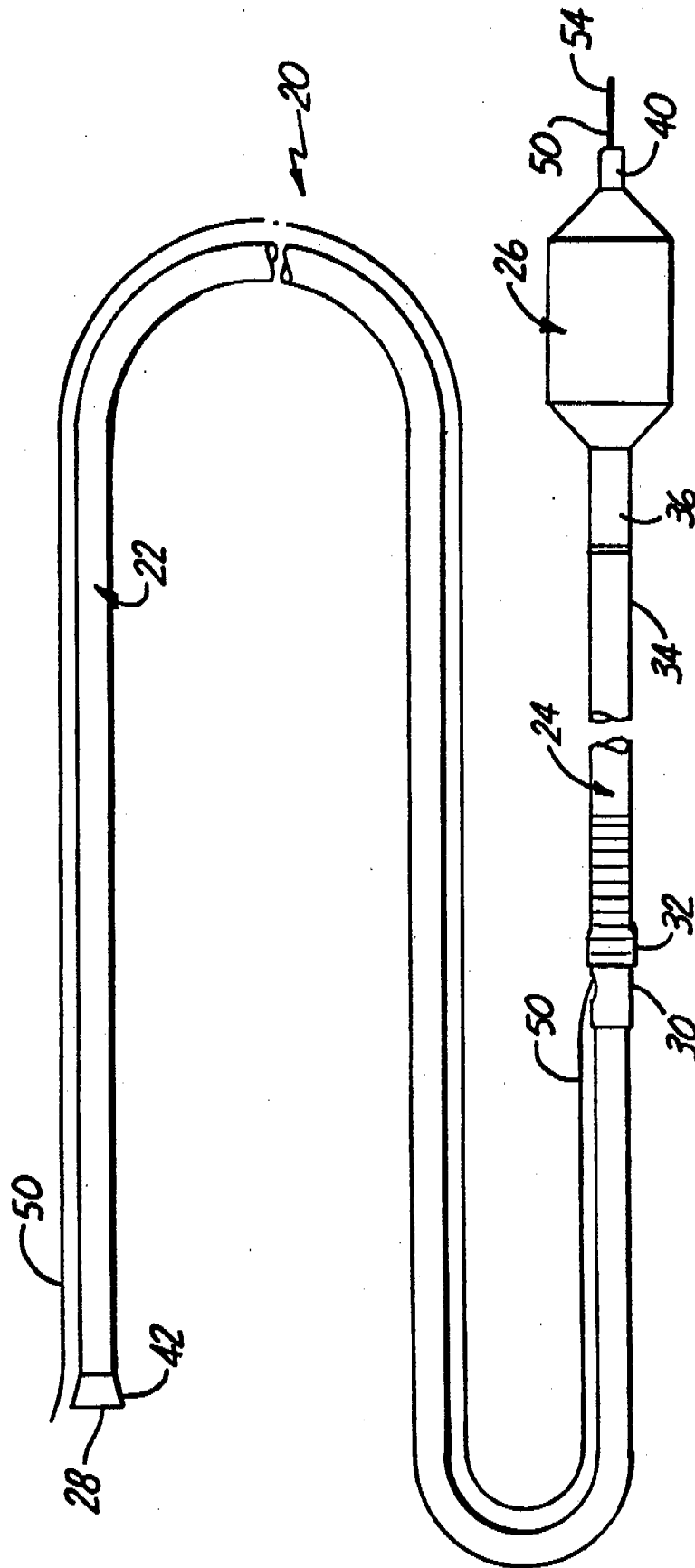
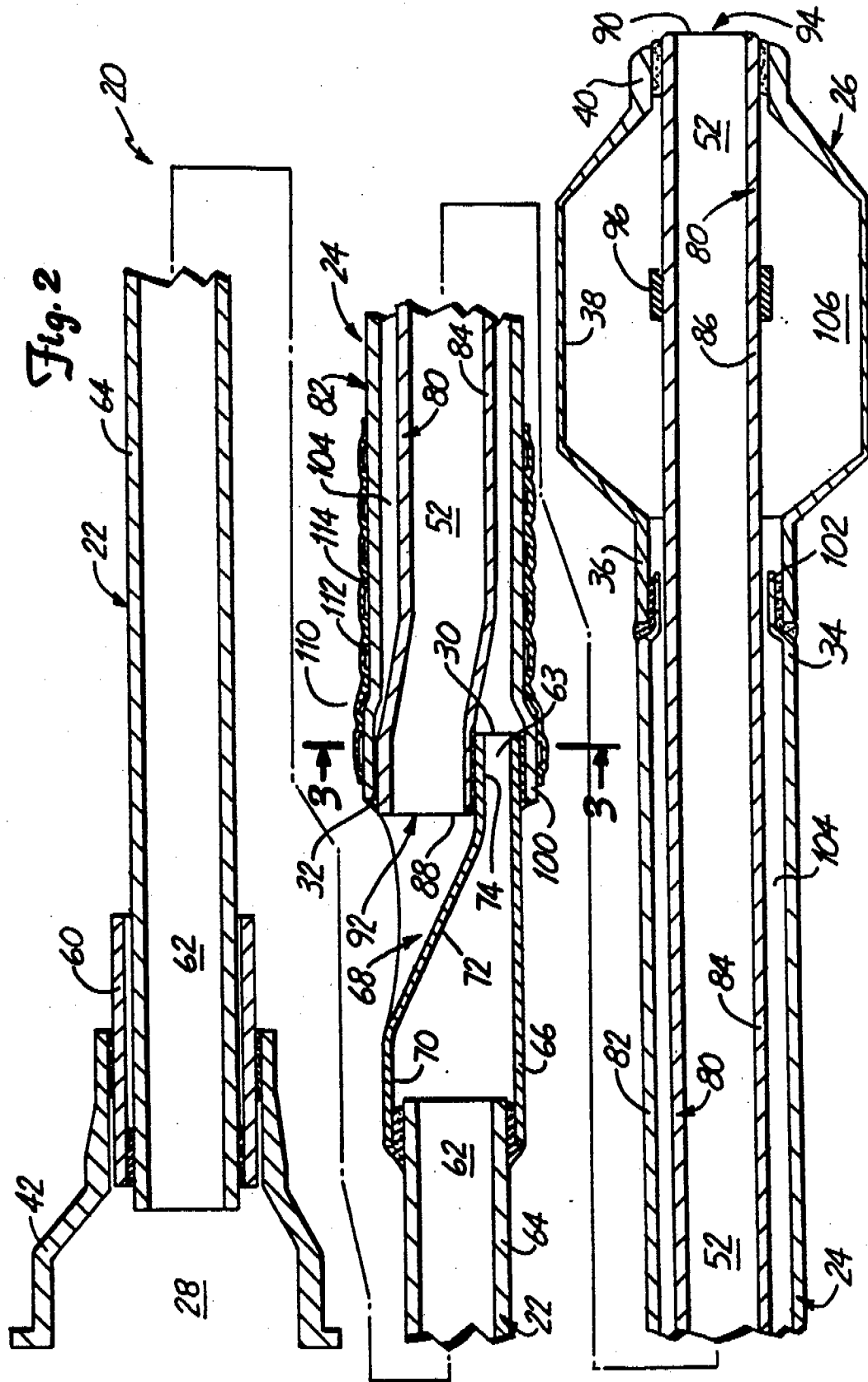
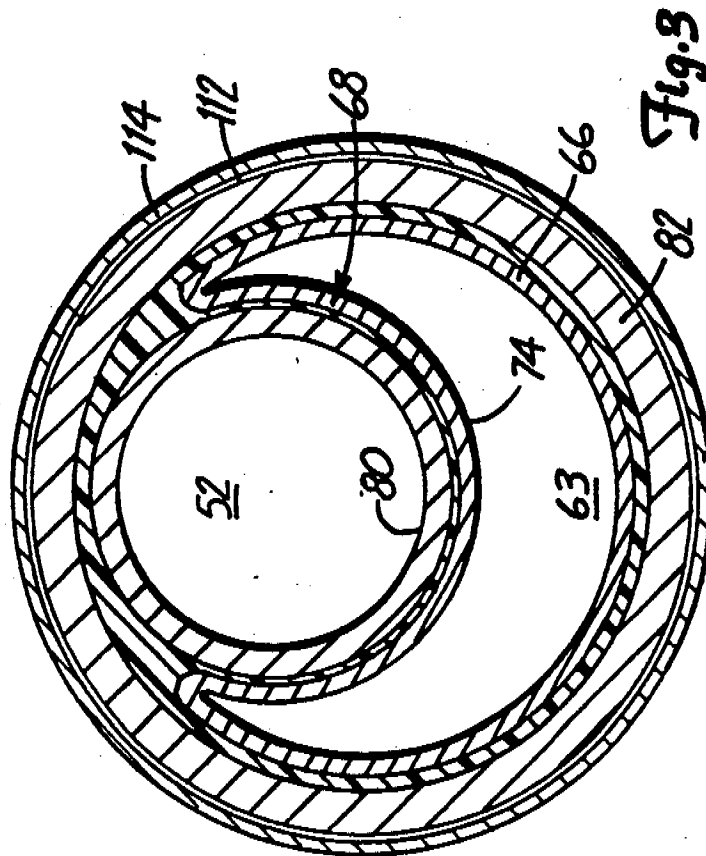
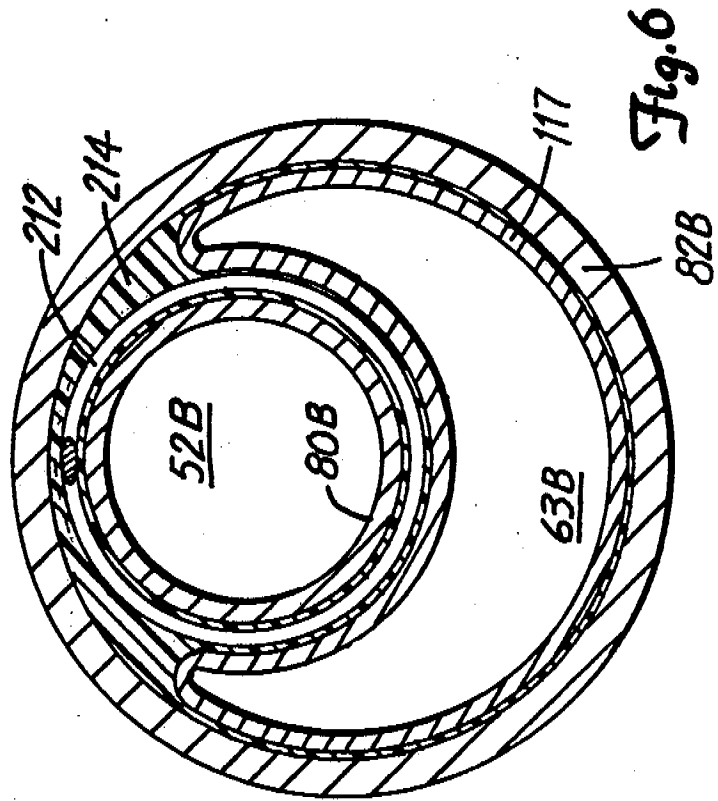
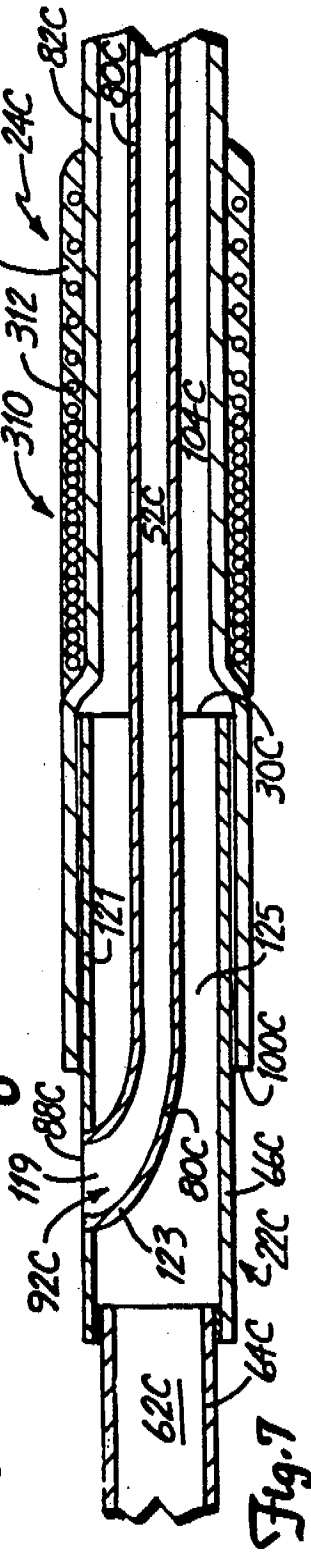
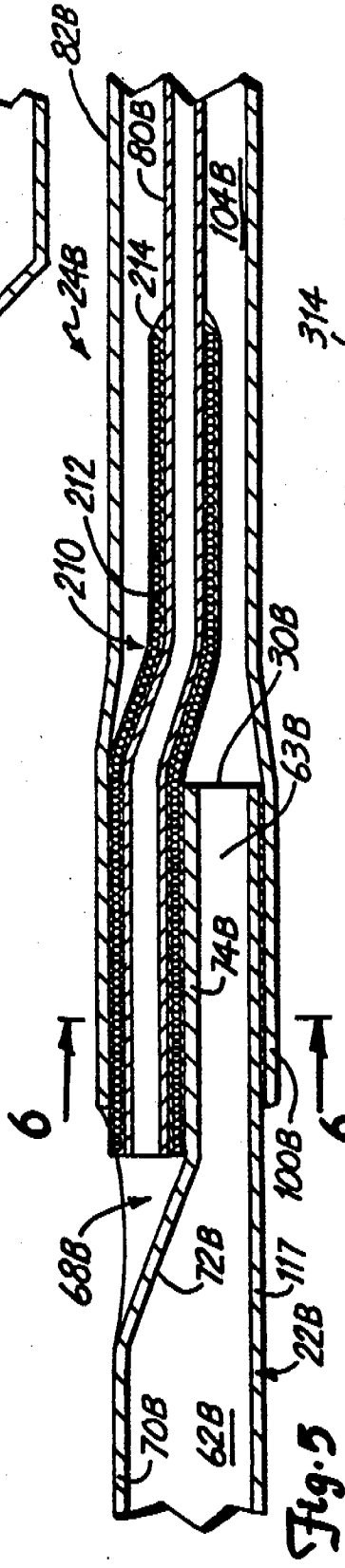
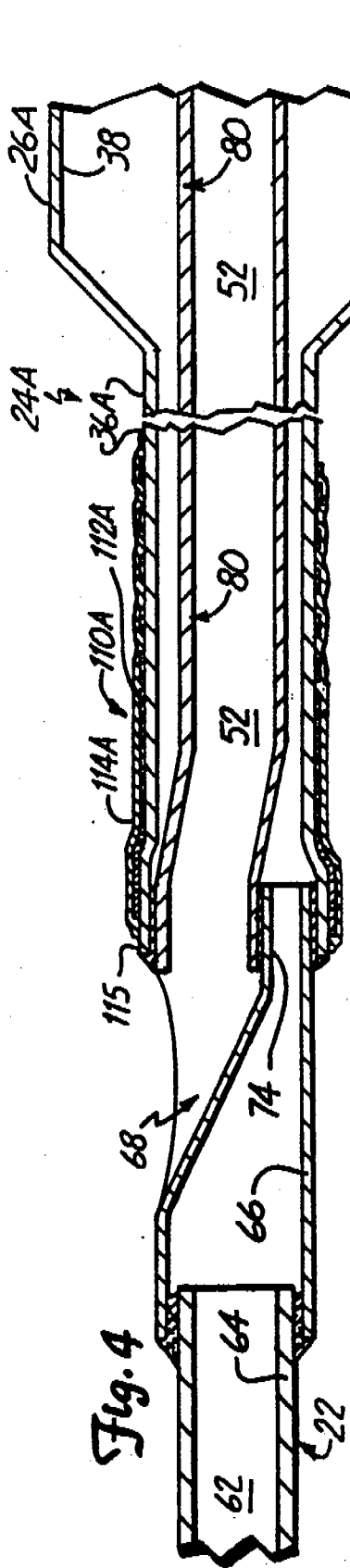
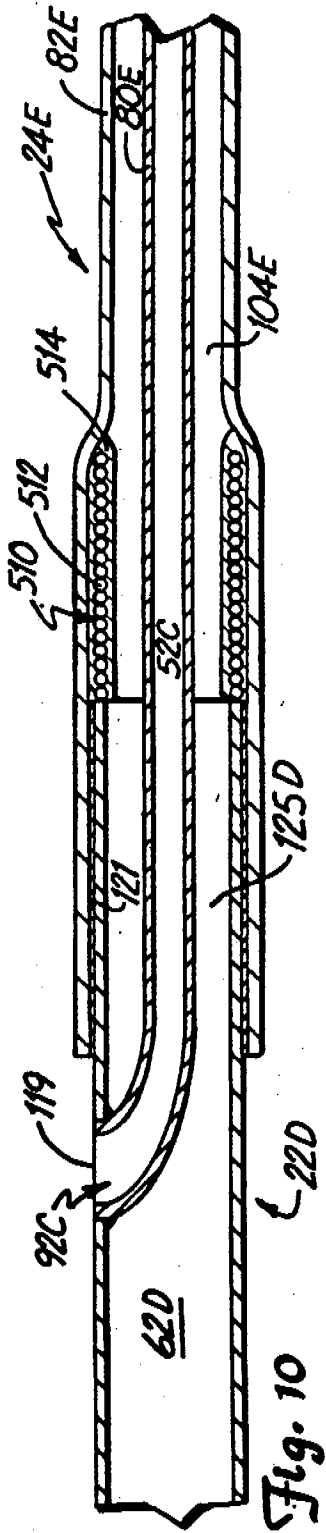
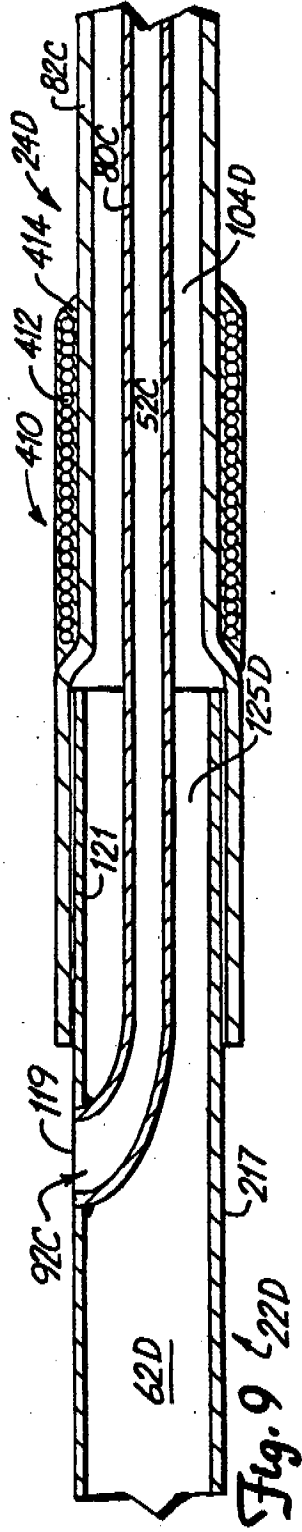
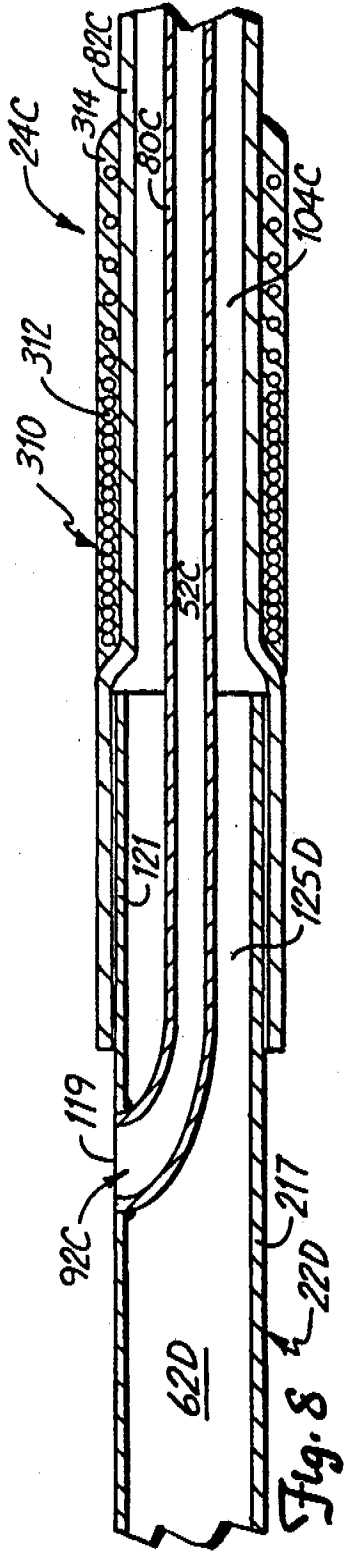


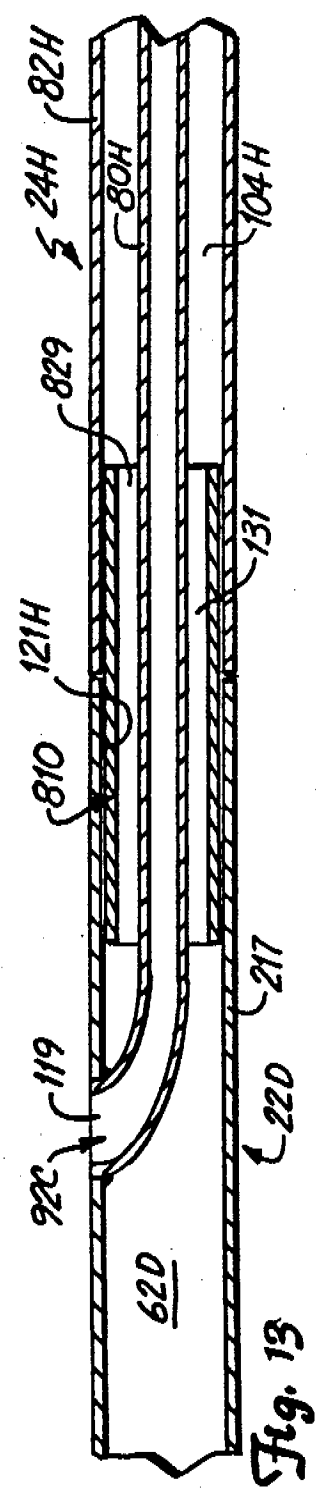
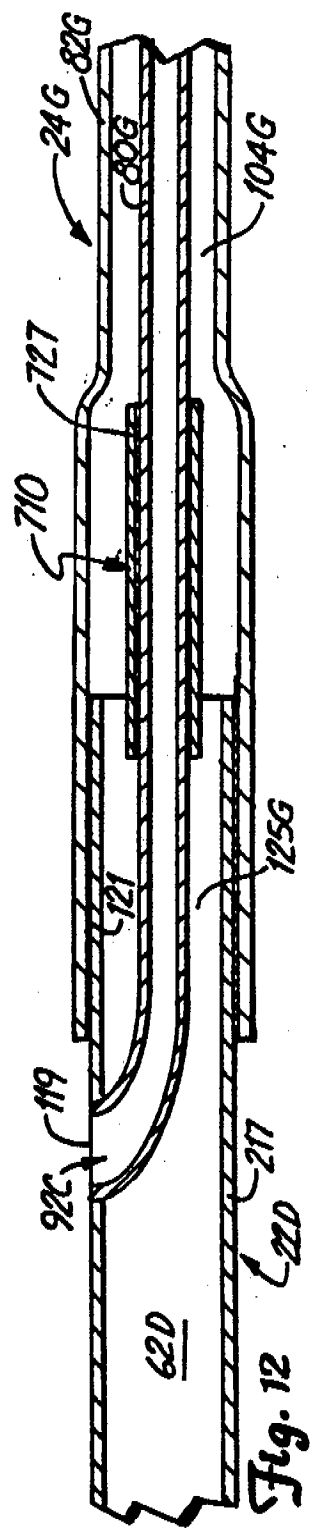
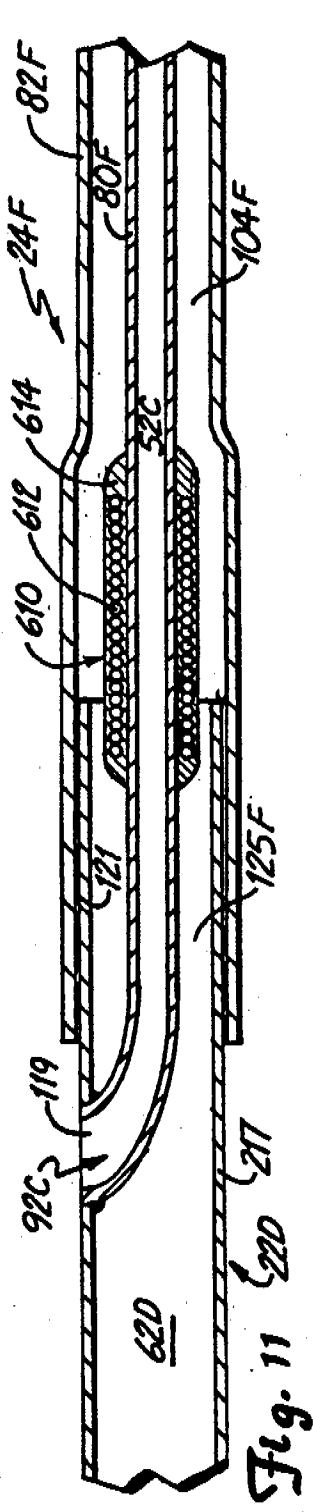
Fig. 1











BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN

This is a continuation of application Ser. No. 07/574,265, filed Aug. 28, 1990, now U.S. Pat. No. 5,156,594.

BACKGROUND OF THE INVENTION

The present invention relates to the field of angioplasty. In particular, the present invention relates to a dilatation balloon catheter of the "over-the-wire" type having a relatively short distal guide wire lumen extending through the balloon of the catheter.

Angioplasty procedures have gained wide acceptance in recent years as efficient and effective methods for treating types of vascular disease. In particular, angioplasty is widely used for opening stenoses in the coronary arteries, although it is also used for the treatment of stenoses and other parts of the vascular system.

The most widely used form of angioplasty makes use of a dilatation catheter which has an inflatable balloon at its distal end. Typically, a hollow guide catheter is used in guiding the dilatation catheter through the vascular system to a position near the stenoses (e.g., to the coronary artery ostia). Using fluoroscopy, the physician guides the dilatation catheter the remaining distance through the vascular system until a balloon is positioned to cross the stenoses. The balloon is then inflated by supplying fluid under pressure through an inflation lumen in the catheter to the balloon. The inflation of the balloon causes stretching of the artery and pressing of the lesion into the artery wall, to reestablish acceptable blood flow through the artery.

There has been a continuing effort to reduce the profile and shaft size of the dilatation catheter so that the catheter not only can reach but also can cross a very tight stenosis. A successful dilatation catheter must also be sufficiently flexible to pass through tight curvatures, especially in the coronary arteries. A further requirement of a successful dilatation catheter is its "pushability". This involves the transmission of longitudinal forces along the catheter from its proximal end to its distal end so that a physician can push the catheter through the vascular system and the stenoses.

Two commonly used types of dilatation catheters are referred to as "over-the-wire" catheters and "non-over-the-wire" catheters. An over-the-wire catheter is one in which a separate guide wire lumen is provided in the catheter so that a guide wire can be used to establish the path through the stenoses. The dilatation catheter can then be advanced over the guide wire until the balloon on the catheter is positioned within the stenoses. One problem with the over-the-wire catheter is the requirement of a larger profile and a generally larger outer diameter along the entire length of the catheter in order to allow for a separate guide wire lumen therethrough.

A non-over-wire catheter acts as its own guide wire, and thus there is no need for a separate guide wire lumen. One advantage of a non-over-the-wire catheter is its potential for a reduced outer diameter along its main shaft since no discrete guide wire lumen is required. However, one disadvantage is the inability to maintain the position of the guide wire within the vascular system when removing the catheter and exchanging it for a catheter having a smaller (or larger) balloon diameter. Thus, to accomplish an exchange with a non-over-the-wire catheter, the path to the stenoses must be reestab-

lished when replacing the catheter with one having a different balloon diameter.

In an effort to combine the advantages of an over-the-wire catheter with a non-over-the-wire catheter, catheters have been developed which have guide wire lumens which extend from a distal end of the catheter through the dilatation balloon and then exit the catheter at a point proximal of the dilatation balloon. The guide wire thus does not extend through the entire length of the catheter and no separate guide wire lumen is required along a substantially proximal section of the catheter. That proximal section can thus have a smaller outer diameter since it is only necessary to provide an inflation lumen therethrough for catheter operation. A further advantage of this type of modified over-the-wire catheter is that the frictional forces involved between the guide wire and the shortened guide wire lumen are reduced, thereby reducing resistance to catheter pushability and enhancing the "feel" and responsiveness of the catheter to a physician.

Perhaps the most significant advantage of using a shortened guide wire lumen is in the ease of exchange of the catheter over the guide wire. In performing an angioplasty procedure using such a catheter, the catheter is "back loaded" over the guide wire by inserting the proximal tip of the guide wire into a distal opening of the guide wire lumen in the catheter. The catheter is then advanced by "feeding" the catheter distally over the guide wire while holding the guide wire stationary. The proximal end of the guide wire will then emerge out of the proximal opening of the guide wire lumen (which is substantially spaced distally from the proximal end of the catheter itself) and is accessible again for gripping by the physician. The catheter can be preloaded onto the guide wire in this manner before the guide wire is inserted into the guide catheter or after. In either case, the guide wire is steered and passed through the guide catheter, coronary vessels and across a lesion. The exposed portion of the guide wire is then grasped while the catheter is advanced distally along the guide wire across the lesion. Using this procedure, little axial movement of the guide wire occurs during catheter loading and positioning for angioplasty.

If the dilatation balloon is found to be inadequate (too small or too large), the catheter can be similarly withdrawn without removing the guide wire from across the lesion. The guide wire is grasped while the catheter is withdrawn, and when the proximal opening of the guide wire lumen is reached, the grasping hand must be moved incrementally away from the proximal opening as the catheter is incrementally withdrawn, until the catheter is fully removed from the guide catheter and the guide wire is thus again exposed and accessible adjacent to the proximal end of the guide catheter.

This shortened guide wire lumen type of dilatation catheter design thus offers the advantages associated with the rapid exchangeability of catheters. The design also presents the potential to provide a smaller catheter shaft, since the guide wire is not contained within the proximal portion of the catheter shaft. The smaller catheter shaft thus allows for better contrast media injection and, as a result, better visualization. In addition, because of the rapid exchangeability features, standard non-extendable guide wires of approximately 175 centimeters in length may be used. Further, because the guide wire is contained in only a distal shorter guide wire lumen of the catheter, free wire movement is enhanced when compared to a standard over-the-wire catheter

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where the guide wire extends through a guide wire lumen extending along the entire length of the catheter.

While several structures for such shortened guide wire lumen dilatation catheter have been proposed these structures suffer from several disadvantages. Such catheters have been one piece polyethylene catheters having dual lumen configurations adjacent their distal regions. Typically, such catheters have larger than necessary shaft sizes and are stiffer in their distal regions than would be desired, including those portions bearing the dilatation balloon. A further disadvantage is that the proximal shaft portion of such catheters is relatively flexible, and has low column strength shaft, so that it tends to "bunch" and buckle when advanced across a lesion. To counteract this deficiency in such designs, additional stiffener elements have been provided in the shaft, which necessarily either require a larger catheter shaft to accommodate the stiffener element structure. The known dilatation balloon catheter designs which include shortened guide wire lumens extending through the distal portion of the catheter suffer from the disadvantages mentioned above and do not take advantage of the unique opportunities presented by the possibilities of such designs in construction and application.

SUMMARY OF THE INVENTION

The present invention is an over-the-wire dilatation balloon catheter which has a guide wire lumen extending through only a distal portion of the catheter. The guide wire lumen extends from a distal end of the catheter at a point proximal of the balloon, but substantially distally from a proximal end of the catheter itself.

The present invention for a balloon dilatation catheter includes a thin-walled, high strength metallic tube having a longitudinal inflation lumen extending there-through from its proximal end to its distal end. An intermediate sleeve section extends distally from the metallic tube. The sleeve section is more flexible than the metallic tube, and includes a proximal segment of inner core tube which has a longitudinal guide wire lumen extending therethrough and an outer sleeve which extends over the proximal segment of the core tube to define a longitudinally extending annular inflation lumen there-between that is in fluid communication with the inflation lumen of the metallic tube. The guide wire lumen has an outlet at a proximal end of the proximal segment of the core tube, and the core tube has a distal segment which extends distally beyond the distal end of the outer sleeve. Means are provided for exposing the guide wire lumen outlet to the exterior of the catheter adjacent and proximal to the distal end of the metallic tube, without compromising the integrity of the inflation lumens extending through the catheter. An inflatable balloon extends over the distal segment of the core tube and has its proximal end connected to the distal end of the outer sleeve. A distal end of the balloon is connected to the core tube so that an interior of the balloon is in fluid communication with the annular inflation lumen in the sleeve section. Means are provided for preventing significant closure of the guide wire lumen and annular inflation lumen in the sleeve section adjacent the distal end of the metallic tube when the more flexible sleeve section is bent laterally relative to the metallic tube.

In a preferred embodiment of the present invention. The metallic tube is formed from a proximal relatively long stainless steel tube and a distal relatively short

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stainless steel tube bonded thereto. The outer diameter of the proximal tube is smaller than the outer diameter of the distal tube, thus providing a catheter structure which is highly trackable and has a generally small shaft outer diameter, yet is very pushable and responsive to a doctor controlling movement of the catheter from its proximal end. Preferably, the means for exposing includes a longitudinal crimp adjacent the distal end of the distal stainless steel tube. The crimp extends laterally inwardly from one side of the distal tube, and has a proximal transition region and distal bonding region. The proximal end of the inner core tube is nested within the distal bonding region of the crimp and bonded thereto. The outer sleeve extends over at least a distal portion of the bonding region and is sealably affixed thereabout.

The means for preventing closure of a present invention may take a number of different forms. In a preferred embodiment, the means for preventing closure comprises a coil member affixed to the sleeve section adjacent the distal end of the metallic tube. As such, the coil member may be affixed about the outer sleeve to extend distally from the metallic tube or about the inner core tube to extend distally from the metallic tube. Such a coil member further may have its coil spaced uniformly apart or spaced increasingly apart as it extends distally from the metallic tube. Preferably, the coil member is formed from a spirally shaped ribbon. A compression sheath is provided to envelope the coil member and maintain the coil member in secure engagement to the sleeve section. In an alternative embodiment, the means for preventing closure comprises a tubular member affixed to the sleeve section adjacent the distal end of the metallic tube, with the tubular member being formed from a polyimide material.

Such closure preventing means thus provide a bending relief design between the relatively stiff metallic tube and more flexible distal region of the balloon dilatation catheter, to prevent kinking during catheter preparation work and handling (prior to insertion of the dilatation catheter into the guide catheter and patient). Such kinking or "crimping" of the catheter can result in a binding on the guide wire as it extends through the guide wire lumen or a reduction in size of the annular inflation lumen between the metallic tube and balloon or a compromise in strength of the catheter tubings, all of which will compromise the utility and responsiveness of the dilatation catheter. In addition, the closure preventing means reduces the possibility of a failure or separation of the bonds adjacent the distal end of the metallic tube which may be caused by excess strain placed on such bonds during catheter preparation or handling.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of a balloon dilatation catheter of the present invention having a distal guide wire lumen therethrough and showing a guide wire.

FIG. 2 is a sectional side elevational view of the balloon dilatation catheter of FIG. 1.

FIG. 3 is an enlarged sectional view as taken along lines 3—3 in FIG. 2.

FIG. 4 is a sectional side elevational view of a portion of the catheter of the present invention, illustrating an alternative structure for a reinforcing coil member thereon.

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FIG. 5 is a sectional side elevational view of a portion of the catheter of the present invention, illustrating an alternative structure for a reinforcing coil member thereon.

FIG. 6 is an enlarged sectional view as taken along lines 6—6 in FIG. 5.

FIG. 7 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 8 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 9 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 10 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 11 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 12 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 13 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

Although the above-identified drawing figures set forth various embodiments of the invention, other embodiments of the 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 will fall within the scope and spirit of the principles of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overall Catheter Structure

A balloon dilatation catheter 20 of the present invention is illustrated generally in FIG. 1. The catheter 20 has a proximal main shaft section 22, an intermediate sleeve section 24 and a distal balloon section 26. The main shaft section 22 has a proximal end 28 and a distal end 30. Likewise, the intermediate sleeve section 24 has a proximal end 32 and a distal end 34. The distal balloon section 26 has a proximal waist 36, an intermediate expandable segment 38 and a distal waist 40.

As illustrated in FIG. 1, the distal end 30 of the main shaft section 22 is connected to the proximal end 32 of the sleeve section 24, and the distal end 34 of the sleeve section 24 is connected to the proximal waist 36 of the balloon section 26. In use, the catheter 20 is coupled to an inflation device (not shown) by a luer manifold 42 connected to the proximal end 28 of the main shaft section 22. The inflation device thus provides or removes inflation solution from the catheter 20 to selectively inflate or deflate the intermediate expandable segment 38 of the distal balloon section 26 (in FIG. 1, expandable segment 38 is shown in its inflated configuration).

The catheter 20 of the present invention is designed for use in combination with a catheter guide element such as a guide wire 50. In use in a coronary application, both the guide wire 50 and the catheter 20 are fed through and guided to an arterial lesion by means of a

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tubular guide catheter (not shown). Both the catheter 20 and guide wire 50 are therefore longer than the guide catheter, with a typical catheter length of approximately 135 cm and a typical guide wire length of approximately 175 cm. As illustrated in FIG. 1, the guide wire 50 extends longitudinally along the exterior of the main shaft section 22 of the catheter 20. Adjacent the distal end 30 of the main shaft section 22, the guide wire 50 enters the structure of the catheter 20 and extends distally therethrough until it exits the catheter structure adjacent the distal waist 40 of the distal balloon segment 26. As seen FIG. 2, a separate guide wire lumen 52 is provided in the catheter 20 through the intermediate sleeve section 24 and distal balloon section 26 thereof. The guide wire 50 thus is only entrained within the catheter 20 within this guide wire lumen 52, which is much shorter than the total length of the catheter 20 (e.g., the guide wire lumen 52 is approximately 30 cm long). The guide wire 50 has a proximal end 53 and a distal end 54 and is of a typical structure for guiding angioplasty catheters. At its distal end 54, the guide wire 50 preferably has a coiled and rounded tip structure which is bendable for steerability of the guide wire.

Referring now to FIG. 2, which shows the catheter 20 in greater detail, it is seen that the proximal end 28 of the main shaft section 22 further has a strain relief tube 60 disposed between the luer manifold 42 and shaft section 22. The strain relief tube 60 is larger than the main shaft section 22, and thus provides a step-wise strain relief function between the inflexible luer manifold 42 and the more flexible main shaft section 22. The main shaft section 22, tubular member 60 and luer manifold 42 are secured together respectively by suitable adhesive means, such as epoxy or cyanoacrylate.

Main Shaft Section

The main shaft section 22 is preferably formed as a thin-walled, high strength stainless steel tube structure, which is referred to as hypodermic tubing or hypotube. As a tubular structure the main shaft section 22 thus has a longitudinally extending inflation lumen 62 extending therethrough from its proximal end 28 to its distal end 30, which provides a means for the movement and pressurization of inflation fluid through the catheter 20 to and from the distal balloon section 26.

In a preferred embodiment, the main shaft section 22 is formed from two stainless steel tube sections, a proximal relatively long shaft section 64 and a distal relatively short shaft section 66. A distal end of the proximal shaft section 64 and a proximal end of the distal shaft section 66 are sealably affixed together by suitable means, such as by a solder joint. The proximal end of the distal shaft section 66 fits coaxially over the distal end of the proximal shaft section 64, as seen in FIG. 2, thereby allowing the proximal shaft section 64 to assume a smaller outer diameter than the distal shaft section 66. The main shaft section 22 is provided with a lubricious coating (such as polytetrafluoroethylene) to lessen frictional resistance (at least to the extent that the proximal shaft section 64 is so coated). The use of a thinwalled (e.g., 0.003 inch wall thickness), metallic tube structure for the main shaft section 22 thus provides a stiff enough shaft for pushability yet allows for a relatively small diameter shaft, thereby enhancing catheter visualization via fluoroscopy and catheter versatility. The inherent high strength nature of such a structure also allows it to withstand the fluid pressures

necessary for proper catheter operation, which in a plastic shaft structure would require thicker walls. The high column strength and thickness of a hypotube shaft also gives improved responsiveness to the catheter. Thus, the balloon and distal regions of the catheter move definitively (in a 1:1 relationship) with motions imparted at the catheter's proximal end by a physician. This feature allows the physician to actually "sense" the pathway as the catheter is tracked, which gives valuable information in the passage of the catheter to and through the lesion.

In the distal shaft section 66 of the main shaft section 22, a longitudinal crimp 68 is provided which extends laterally inwardly from one side of the distal section 66. The distal shaft section 66 has three sections, a proximal tubular region 70, a transition region 72, and a distal bonding region 74. The crimp 68 extends from its proximal origin in the transition region 72 to its greatest lateral depth in the bonding region 74. The crimp 68, as further illustrated in FIG. 3, does not seal off or close the inflation lumen 62, but does transform the inflation lumen from a circular lumen 62 to a crescent shape through the bonding region 74, as seen at 63 in FIG. 3.

Catheter Intermediate Sleeve Section

The intermediate sleeve section 24 extends distally from the main shaft section 22, and is bonded thereto adjacent the bonding region 74 of the distal shaft section 66. The intermediate sleeve section 24 has two primary longitudinal components, an inner core tube 80 and an outer sleeve or tube 82. The inner core tube 80 has a proximal segment 84 within the sleeve section 24 and a distal segment 86 within the distal balloon section 26. The inner core tube 80 and outer sleeve 82 are both preferably formed from thin-walled high density polyethylene.

The inner core tube 80 has a proximal end 88 and a distal end 90. At its proximal end 88, the core tube 80 is nested within the bonding region 74 of the distal shaft section 66 and bonded thereto by suitable means, such as epoxy or cyanoacrylate. The core tube 80 is thus affixed to the main shaft section 22 in an "off-axis" alignment at the bonding region 74. However, as seen in FIG. 2, as the core tube 80 extends distally from the main shaft section 22, it is aligned generally coaxially with the shaft section 22.

The core tube 80 defines the guide wire lumen 52 extending through the catheter 20. The guide wire lumen thus has a proximal outlet 92 adjacent the proximal end of the core tube 80 and a distal outlet 94 adjacent the distal end 90 of the core tube 80. At least one marker band 96 is provided about the core tube 80 (preferably centered within the expandable segment 38 of the distal balloon section 26) to aid in illuminating the position of the catheter 20 via fluoroscopy during an angioplasty procedure.

The outer sleeve 82 is generally tubular in form, and has a proximal end 100 and a distal end 102. The outer sleeve 82 is bonded about the distal shaft section 66 and the core tube 80 adjacent the bonding region 74, as seen in FIGS. 2 and 3 and is held in place thereto by suitable means, such as epoxy or cyanoacrylate. The outer sleeve 82 extends distally from the main shaft section 22 over the proximal segment 84 of the core tube 80, and as such, defines a distal continuation of the inflation lumen of the catheter 20. A longitudinally extending annular inflation lumen 104 is formed between the core tube 80 and outer sleeve 82. Of course, the proximal end 100 of

the outer sleeve 82 is securely sealed about the distal shaft section 66 and the core tube 80 so that the longitudinal inflation lumens 62 and 104 through the catheter 20 are not compromised to the exterior of catheter 20, but are in fluid communication therethrough.

The intermediate sleeve structure defined above is the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein—namely, an inner core tube bonded to a distal portion of the main catheter shaft, with an outer sleeve forming an annular continuation of the inflation lumen through the main shaft between the core tube and outer sleeve. As discussed below and illustrated herein, various configurations of the connections and components relative to the formation of the distal guide wire lumen, including the coupling of the main shaft to the intermediate sleeve section, are contemplated.

Catheter Distal Balloon Section

The distal balloon section 26 is connected to the components of the intermediate sleeve section 24. The proximal waist 36 of the balloon section 26 is connected to the distal end 102 of the outer sleeve 82 by suitable means, such as by epoxy or cyanoacrylate. The distal waist 40 of the balloon section 26 is bonded to the core tube 80 adjacent its distal end 90 by suitable means, such as by epoxy or cyanoacrylate. An interior 106 of the balloon section 26 is thus sealed and in fluid communication with the annular inflation lumen 104 within the sleeve section 24. In a preferred embodiment, the balloon section 26 is formed from a compliant balloon material (e.g., polyolefin), although a balloon formed from thin-walled non-compliant material (e.g., PET--polyethylene terephthalate) is also contemplated.

Kink-resistant Structure

The metallic main shaft section 22 is relatively stiff compared to the polyethylene intermediate sleeve section 24. This creates a rather abrupt change in the flexibility of the materials for the catheter 20 adjacent the distal end 30 of the main shaft section 22 (at the bonding region 74). The use of a hypotube for the main shaft section 22 in the catheter 20 creates a catheter which is considerably stiffer than most previous over-the-wire angioplasty balloon catheter designs. Such stiffness is not a concern as long as the metallic main shaft section 22 remains in the relatively straight guide catheter within the patient, and indeed such stiffness provides distinct benefits in use of the catheter 20, as described above. In the distal portions of the catheter 20 (intermediate sleeve section 24 and distal balloon section 26), the catheter 20 must be very trackable and flexible in order to negotiate the tortuous coronary anatomy to and across the lesion. The relatively sharp transition in stiffness as the catheter structure changes from the metallic main shaft section 22 to the much more flexible polymer intermediate sleeve section 24 creates two concerns. First, during handling of the catheter prior to usage, there is a potential to kink the catheter structure at that flexibility transition point. Secondly, when the catheter is in vivo, the distal end 30 of the main shaft section 22 could potentially "dig in" to the guide catheter and create excessive friction due to the lack of bending support from the more flexible intermediate sleeve section 24.

To address these concerns, a kink-resistant structure 110 is provided to prevent kinking and possible damage to the intermediate sleeve section 24 during catheter

preparation, handling and use. In its simplest form, this kink-resistant structure 110 provides a member of intermediate stiffness or transitory stiffness and kink-resistant nature between the relatively stiff main shaft section 22 and the relatively flexible intermediate sleeve section 24. The kink-resistant structure 110 includes a coil member 112 affixed to the intermediate sleeve section 24 adjacent the distal end 30 of the main shaft section 22. The coil member 112 creates an intermediate stiffener element between the relatively stiff main shaft section 22 and the relatively flexible intermediate sleeve section 24 to allow bending of the catheter without kinking. The coil member 112 preferably has its coils spaced uniformly apart, and is preferably formed from a spiral ribbon of stainless steel placed about the outer sleeve 82 along that portion thereof extending over the bonding region 74 and distally therefrom. The coil member 112 is secured to the outer sleeve 82 by suitable adhesive means, such as by epoxy. To further secure the coil member 112 to the intermediate sleeve section 24, a heat-shrinkable sheath 114 is fitted over the coil member 112. Preferably the sheath 114 is formed from a polyimide or polyolefin material which is expanded radially outwardly and then shrunk down over the coil member 112 and outer sleeve 82 to secure the coil member 112 thereto. To further secure the sheath 114 and coil member 112 in place, some adhesive is provided between the sheath 114 and the intermediate sleeve section 24. By covering the ends of the coil member 112, the sheath 114 also lessens the chances of those ends providing a rough edge or catch as the catheter 20 is advanced through the guide catheter or artery.

Although the kink-resistant structure is described and illustrated in connection with a balloon dilatation catheter, it is contemplated that such a structure be employed in any catheter shaft as a transition from a first thin-walled, high strength metallic tube structure to a second tube structure which is more flexible than the metallic tube structure. Such a kink-resistant structure, as described above (and also below in various embodiments), may be employed in a single lumen catheter shaft, or in multiple lumen catheter shaft having a central core tube such as the multi-lumen shaft illustrated by the intermediate sleeve section of the catheter disclosed in FIGS. 1-4.

Alternative Catheter Embodiment

Numerous alternative embodiments of the catheter of the present invention are contemplated. For example, several alternative arrangements for the main shaft section and intermediate sleeve structure portion of the catheter are illustrated and discussed herein, but it is not intended that the illustrated embodiments are all inclusive of those structures and designs which are included within the spirit and scope of the present invention. In the following discussion of further alternative embodiments of the present invention, to the extent a component is identical to that of a previously described embodiment, like reference numerals are used.

FIG. 4 illustrates an alternative embodiment for the distal portion of a catheter according to the present invention. Specifically, the outer sleeve (of the intermediate sleeve section) and the distal balloon section are formed from the same component, as a unitary member. Thus, proximal waist 36A of distal balloon section 26A is elongated proximally and acts as the outer sleeve for intermediate sleeve section 24A. A proximal end 115 of the proximal waist 36A is sealably fixed about the core

tube 80 and main shaft section 22 adjacent the bonding region 74 thereof. It should be understood that the prospect of having a unitary outer sleeve and balloon member is applicable to all embodiments disclosed herein and contemplated, although it is only illustrated and discussed with respect to the catheter structure of FIG. 4.

FIG. 4 also shows another variation for the catheter's structure illustrated in FIGS. 1-3. In FIG. 4, kink-resistant structure 110A includes coil member 112A which is defined as a spiral ribbon of stainless steel placed about a proximal portion of the proximal waist 36A along the bonding region 74 and distally therefrom. The coil member 112A does not have its coils uniformly spaced apart, but rather has its coils spaced increasingly further apart as the coil member extends distally from the main shaft section 22. This results in a coil member 112A which becomes increasingly more flexible, thereby "feathering out" the change in relative stiffness and strain or kink relief between the relatively inflexible main shaft section 22 and the relatively flexible intermediate sleeve section 24A. As before, a heat-shrinkable sheath 114A is fitted over the coil member 112A to further secure the coil member 112A to the sleeve section 24A.

In FIG. 5, a modified main shaft section 22B is illustrated. The main shaft section 22B is formed as a thin-walled, high strength stainless steel tube or hypotube, but is defined as a single tubular shaft 117 from its proximal end to its distal end 30B. The single shaft 117 has a longitudinally extending inflation lumen 2B there-through, and at its proximal end (not shown) the single shaft 117 is mounted to an inflation device in a manner such as that illustrated for the catheter of FIG. 2. Adjacent its distal end 30B, the single shaft 117 has a longitudinal crimp 68B which extends laterally inwardly from one side of the single shaft 117. The single shaft 117 thus has three sections, a proximal, relatively elongated tubular region 70B, a relatively short distal transition region 72B and a relatively short distal bonding region 74B. The crimp 68B extends from its proximal origin in the transition region 72B to its greatest lateral depth in the bonding region 74B. The crimp 68B does not seal or close off the inflation lumen 62B, but rather transforms the inflation lumen 62B from a circular lumen to a half-moon lumen through the bonding region 74B, as seen at 63B in FIG. 6. It is again understood that the use of a single tube to define the main shaft section of the catheter of the present invention is applicable to the other alternative embodiments of the catheter structures disclosed herein.

FIGS. 5 and 6 also illustrate an alternative arrangement for the kink-resistant structure of the inventive catheter. Kink-resistant structure 210 includes coil member 212. The sleeve section 24B includes an outer sleeve 82B and an inner core tube 80B, with the core tube 80B adapted to be nested within and bonded to the main shaft section 22B in its distal bonding region 74B. The coil member 212 of the kink-resistant structure 210 is positioned about the core tube 80B within the distal bonding region 74B and extending distally therefrom. The coil member 212 is preferably formed from stainless steel (either from a wire or ribbon) and may have uniform coil spacing or increasingly spaced coils as the coil member 212 extends distally from the main shaft section 22B. The coil member 212 is secured to the core tube 80B by suitable means, such as by embedding the coil member 212 in an epoxy layer 214 about the core tube

80B. A proximal end 100B of the outer sleeve 82B is bonded about the main shaft section 22B and inner tube 80B and coil structure 210 in the bonding region 74B thereof, as seen in FIGS. 5 and 6. In the intermediate sleeve section 24B, the inner core tube 80B thus provides a guide wire lumen 52B therethrough, and an annular inflation lumen 104B is provided between the inner tube 80B and outer sleeve 82B. Although the kink-resistant structure 210 is within the annular inflation lumen 104 and the outer sleeve 82B necks down distally from the main shaft section 22B, the size of the annular inflating lumen 104 is sufficient to provide proper fluid flow to and from the catheter's balloon.

FIGS. 7-13 illustrate an alternative configuration for that portion of the catheter adjacent the proximal inlet of the guide wire lumen. Instead of providing a crimp structure in the distal end of the main shaft section, an aperture is provided adjacent to and proximal of the distal end of the main shaft section. The aperture is aligned and sealably coupled to the inner tube to define the guide wire lumen proximal outlet. In all disclosed embodiments, the main shaft section is preferably formed from a hypotube-like material.

As seen in FIG. 7, an alternative embodiment of the catheter of the present invention has a proximal main shaft section 22C formed from thin-walled, high strength stainless steel tubing. A longitudinally extending inflation lumen 62C extends therethrough from a proximal end of the main shaft section 22C to its distal end 30C. In the embodiment seen in FIG. 7, the main shaft 22C is formed from two stainless steel tube sections, a proximal relatively long shaft section 64C and a distal relatively short shaft section 66C bonded on the distal end of the proximal section 64C. This two-part main shaft section structure thus allows a substantial length of the main shaft section 22C to be formed from the proximal shaft section 64C which has a smaller diameter than the distal shaft section 66C.

The distal shaft section 66C has an oval-shaped aperture 119 extending through its wall, with the oval being elongated in the longitudinal direction of the main shaft section 22C. The aperture 119 is spaced proximally from a distal end of the distal shaft section 66C (the distal end 30C of the main shaft section 22C). The space between the aperture 119 and distal end 30C thus defines in part a bonding region 121 for connecting the main shaft section 22C to a distally extending intermediate sleeve section 24C.

As before, the intermediate sleeve section 24C includes an inner core tube 80C and an outer sleeve 82C. A proximal end 88C of the core tube 80C is sealably bonded about the aperture 119 to align the proximal end 88C and aperture 119 and thereby define a proximal outlet let 92C for a guide wire lumen 52C extending through the core tube 80C. As seen in FIG. 7, a proximal portion 23 of the core tube 80C extends laterally from the aperture 119 into the distal shaft section 66C and turns longitudinally and distally relative thereto to be aligned generally coaxially therewith. As such, the inflation lumen 62C is continued distally past the aperture 119 as a generally annular inflation lumen 125, between the core tube 80C and distal shaft section 66C (along the bonding region 121). Proximal end 100C of the outer sleeve 82C is bonded about the distal shaft section 66C in the bonding region 121 by a suitable means, such as by epoxy or cyanoacrylate. As seen in FIG. 7, the outer sleeve 82C extends distally from the main shaft section 22C over the core tube 80C and

defines a longitudinally extending annular inflation lumen 104C between the core tube 80C and outer sleeve 2C. The proximal end 100C of the outer sleeve 82C is sealed about the distal shaft section 66C so that the longitudinal inflation lumens 62C, 125 and 104C are not compromised to the exterior of the catheter, but are in fluid communication therethrough.

In FIG. 7, kink-resistant structure 310 includes coil member 312 (of a wire or ribbon-like structure) which is bonded about the outer sleeve 82C to extend distally from the distal end 30C of the main shaft section 22C. In this embodiment, the coil member 12 does not extend about any portion of the main shaft 2C. The coil member 312 is secured to the outer sleeve 2C by suitable adhesive means, such as epoxy 314, and is embedded therein to firmly hold the coil member 312 in place about the intermediate sleeve section 24C. In the embodiment of FIG. 7, the coil member 312 is illustrated with its coils being spaced increasingly longitudinally apart as the coil member 312 extends distally along the catheter.

FIGS. 8-13 also illustrate embodiments of the catheter of the present invention wherein an aperture is provided through the main shaft section wall to accommodate the proximal outlet for the relatively short, distal guide wire lumen. As opposed to the embodiment of FIG. 7, however, the embodiments illustrated in FIGS. 8-13 show the main shaft section as a single shaft rather than as a multi-part shaft. Indeed, FIG. 8 illustrates a catheter structure identical to that of FIG. 7, except that the main shaft section 22D is shown as a single shaft 217, rather than having proximal and distal shaft sections 64C and 66C as seen in FIG. 7. As such, the catheter inflation lumen includes longitudinally extending inflation lumens 62D, 125D and 104D.

FIG. 9 is an embodiment of the catheter of the present invention otherwise similar to FIG. 8, except that kink-resistant structure 410 has coil member 412 with uniformly spaced coils along the entire length. Again, the entire coil member 412 is fixed to the outer sleeve 82C of the intermediate sleeve section 24C by embedding the coil member 412 within a suitable material such as epoxy or cyanoacrylate 414.

In the catheter structure of FIG. 10, intermediate section 24E has an inner core tube 80E and an outer sleeve 82E. The structure of the catheter is otherwise the same as the catheter of FIG. 9, except that the kink-resistant structure thereof is positioned inside the outer sleeve 82E rather than outside of the outer sleeve. Kink-resistant structure 510 is affixed to an inner surface of the outer sleeve 82E distally of the main shaft section 22D by a suitable means, such as embedded adhesive 514. The kink-resistant 510 includes coil member 512 which provides an intermediate stiffener between the relatively stiff main shaft section 22D and the relatively flexible intermediate sleeve section 24E. As seen, the outer sleeve 82E necks down distally from the kink-resistant structure 510 to provide a lower profile for the catheter in its distal regions. An annular inflation lumen 104E formed between the inner tube 80E and outer sleeve 82E (and at a proximal end thereof, between the inner tube 80E and the kink-resistant structure 510) is not compromised by such a necked-down sleeve design but maintained at sufficient size to provide for adequate and quick inflation and deflation of the balloon.

In FIG. 11 intermediate sleeve section 24F includes an inner core tube 80F and an outer sleeve 82F. Kink-resistant structure 610 is mounted about the inner tube

80F along the bonding region 121 and extending distally from the main shaft section 22D into the intermediate sleeve section 24F. The kink-resistant structure includes coil member 612 which is affixed about the core tube 80F by suitable means such as being embedded in epoxy or another suitable adhesive 614. As seen in FIG. 11, the outer sleeve 82F has an enlarged diameter at its proximal end to accommodate the main shaft section 22D and the kink-resistant structure 610, and so that the annular inflation lumens 125F and 104F about the core tube 80F remain sufficiently large to provide proper inflation and deflation pressures to the balloon of the catheter.

FIGS. 12 and 13 illustrate a further variation of the kink-resistant structure of the present invention. In the embodiments of FIGS. 12 and 13, the kink-resistant structure does not include a coil member, is formed from a polymer tube which is of intermediate stiffness between the main shaft section and intermediate sleeve section. In FIG. 12, kink-resistant structure 710 is provided which is formed from a polyimide or other stiff polymer tube 727. The tube 727 is bonded about an inner core tube 80G of the intermediate sleeve section 24G by a suitable adhesive, such as epoxy or cyanoacrylate. The tube 727 extends through a distal portion of the bonding region 121 and distally beyond the main shaft section 22D into the intermediate sleeve section 24G. Again, an outer sleeve 82G of the sleeve section 24G has an enlarged diameter at its proximal end to accommodate the main shaft section 22D and the kink-resistant structure 710, and so that the components are dimensioned such that annular inflation lumens 125G and 104G are not compromised.

In FIG. 13, kink-resistant structure 810 is illustrated, as formed from a polyimide or other stiff polymer tube 829 which is bonded to the inner surfaces of both the main shaft section 22D and an outer sleeve 82H of an intermediate sleeve section 24H at a bonding region 121H. The tube 829 thus provides not only a kink-resistant structure to accommodate the change in stiffness of the main shaft section and intermediate sleeve section, but also provides a substrate for bonding the two catheter sections together by a suitable adhesive, such as epoxy or cyanoacrylate. A core tube 80H of the sleeve section 24H extends through the interior of the tube 829 to the aperture 119 on the main shaft section 22D. Thus, an annular longitudinally extending inflation lumen 131 is formed as a "bridge lumen" (between the core tube 80H and tube 829) from the inflation lumen 62D to an annular inflation lumen 104H within the sleeve section 24H.

As mentioned above, various combinations of these alternative component and catheter structures are contemplated and are intended to be considered, although not explicitly shown. For example, it is contemplated that a two-part main shaft section structure (such as illustrated in FIGS. 2, 4 and 7) may be combined with any one of the kink-resistant structure such as that illustrated in FIGS. 8-13. By way of example and not limitation, a further example of such a combination may include the use of a distal balloon section having an elongated proximal waist (such as shown in FIG. 4) with any of the alternative kink-resistant structures disclosed herein.

Conclusion

The balloon dilatation catheter of the present invention is an over-the-wire catheter structure with a distal guide wire lumen which optimizes the features of such a catheter in a way not previously considered or achieved. The use of a hypotube-type main shaft for the catheter allows the attainment of a high strength, pushable shaft having thin walls and small diameter. The further use of a two-part hypotube shaft structure allows an even smaller diameter for the proximal elongated section of the main catheter shaft. Employing a crimp as a means for aligning and creating a proximal outlet for the relatively short guide wire lumen also serves to provide a transition region for exit of the guide wire from the catheter itself which is relatively gradual. The crimped shaft design also provides additional stiffness in the transition region where the guide wire enters and exits the catheter proximally of the balloon thereof, thereby creating a more rigorous catheter structure. Because the catheter of the present invention is based upon a relatively stiff proximal main shaft section, and such a catheter must have a relatively flexible distal portion for working through the tortuous arterial anatomy, a strain relief or kink-resistant structure is provided to make a more gradual transition between the relatively stiff main catheter shaft and the relatively flexible distal portion of the catheter. Various configurations of strain relief and kink-resistant structures are disclosed herein, and all are believed suitable to accomplish the desired end of preventing significant closure of the guide wire lumen and annular inflation lumen in the more flexible distal portions of the catheter, especially adjacent the distal end of the main catheter shaft.

Although the present invention has been described with reference to preferred 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.

What is claimed is:

1. A balloon dilatation catheter comprising:

- a metallic tube defining a first shaft section having a proximal end and a distal end;
- a second shaft section, more flexible than the first shaft section, disposed distally of the first shaft section;
- the first and second shaft sections having an inflation lumen defined therethrough;
- a dilatation balloon attached to the distal end of the second shaft section, the dilatation balloon being in fluid communication with the inflation lumen such that inflation pressure may be provided to the balloon therethrough;
- an intermediate section disposed between the first shaft section and the second shaft section, the intermediate section configured to have a stiffness between the stiffness of the first shaft section and the stiffness of the second shaft section; and
- a guide wire tube extending through the interior of the balloon, the guide wire tube defining a second and shorter lumen than the inflation lumen, the second lumen having a proximal guide wire opening at its proximal end and a distal guide wire opening at its distal end, the proximal guide wire opening being disposed along the intermediate section between the first and second shaft sections and the second lumen being formed and aligned to receive a guide wire therein such that the catheter may be slidably moved on the guide wire.

* * * * *

United States Patent [19]

[11] **Patent Number:** 5,395,334

Keith et al.

[45] **Date of Patent:** Mar. 7, 1995

- [54] **BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN**
- [75] **Inventors:** Peter T. Keith, Fridley; Charles L. Euteneuer, St. Michael, both of Minn.
- [73] **Assignee:** SciMed Life Systems, Inc., Maple Grove, Minn.
- [21] **Appl. No.:** 35,254
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 "Until someone does it, no one thinks it can be done," C. R. Bard, Inc., 1988.

Related U.S. Application Data

- [63] Continuation of Ser. No. 792,786, Nov. 15, 1991, Pat. No. 5,217,482, which is a continuation of Ser. No. 574,265, Aug. 28, 1990, Pat. No. 5,156,594.
- [51] **Int. Cl.⁶** A61M 29/00; A61M 25/00
- [52] **U.S. Cl.** 604/102; 604/282; 606/194
- [58] **Field of Search** 604/96-103, 604/282; 606/192-196; 600/18

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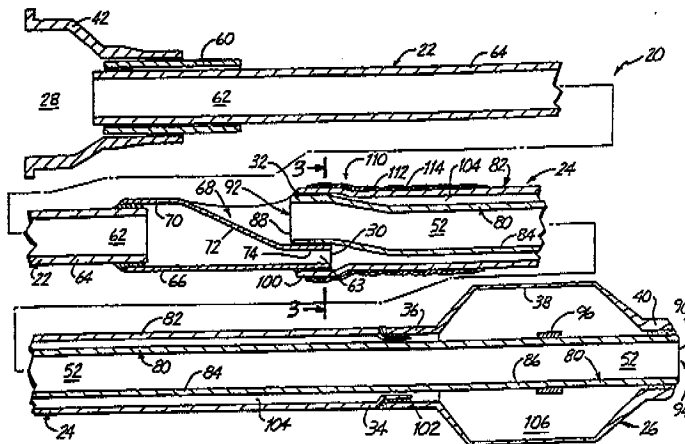
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[57] **ABSTRACT**

An over-the-wire balloon dilatation catheter has a stainless steel hypotube catheter shaft, an intermediate sleeve section bonded to the shaft and a distal balloon section connected to the sleeve section. The sleeve section is formed from relatively flexible polymer materials and includes an inner core tube which defines a guide wire lumen extending only through a distal portion of the catheter (including its sleeve and balloon sections) to facilitate fast balloon catheter exchanges. A distal end of the hypotube shaft is crimped laterally and the core tube is nested and bonded within the crimp to provide a proximal outlet for the guide wire lumen. The hypotube shaft provides an inflation lumen for the balloon, with the inflation lumen being continued as an annular inflation lumen through the sleeve section where an outer sleeve is bonded about the core tube and extends from the distal end of the hypotube shaft to the balloon section. A kink-resistant coil structure extends distally from the distal end of the hypotube shaft to provide a gradual change in stiffness along the length of the catheter from the relatively stiff hypotube shaft to the relatively flexible distal portion of the catheter.

15 Claims, 6 Drawing Sheets



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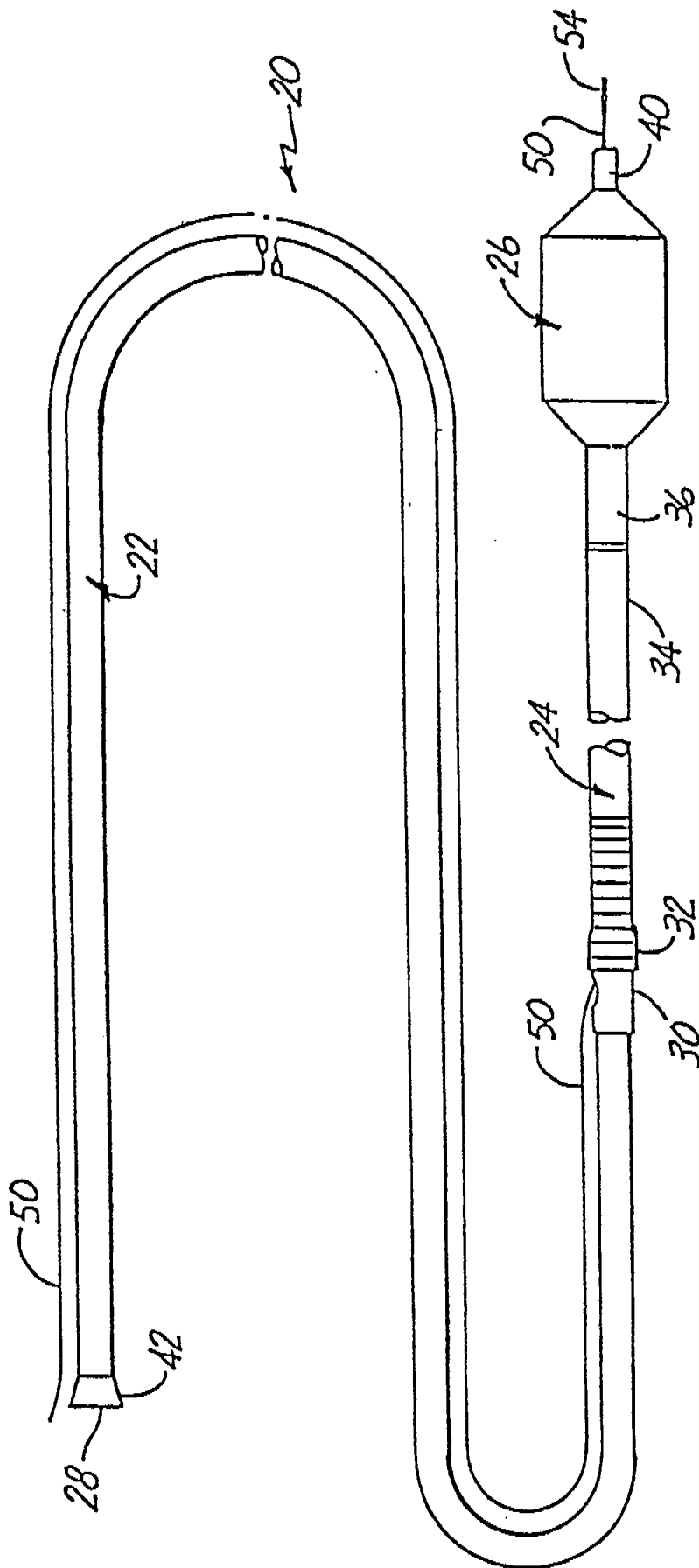
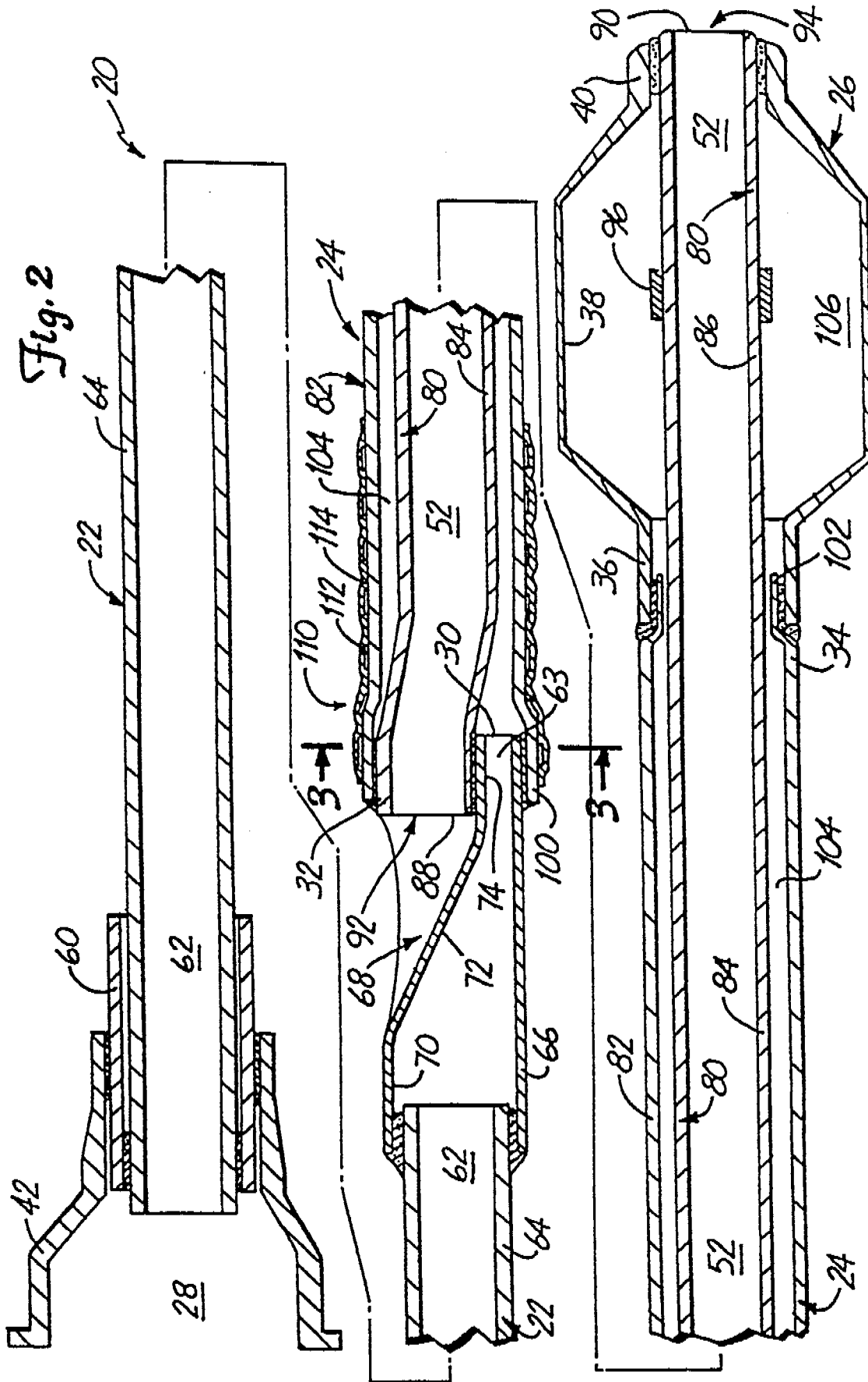
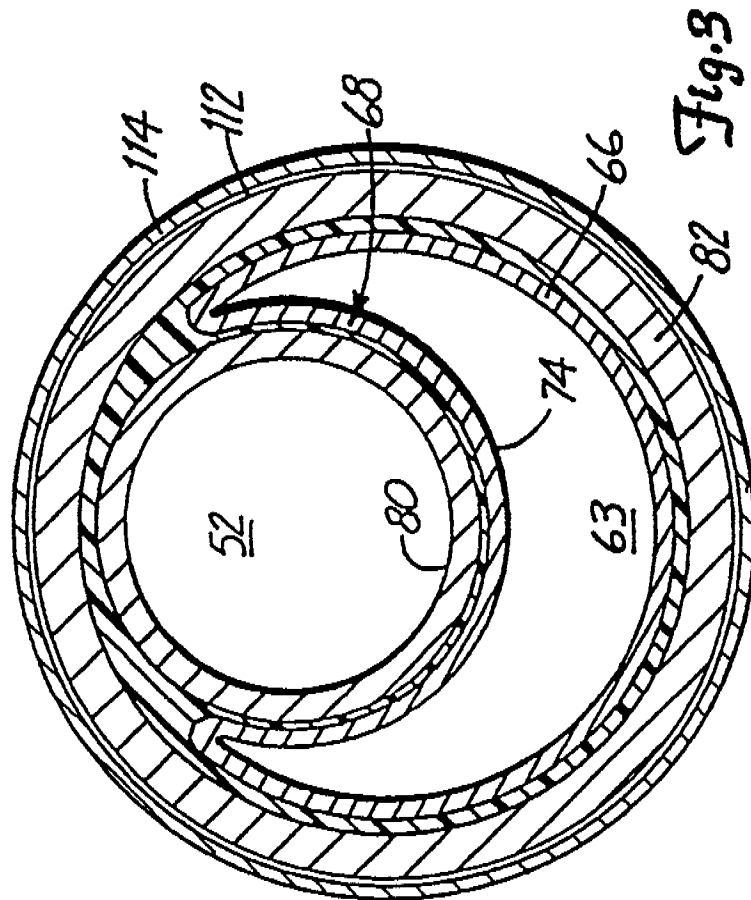
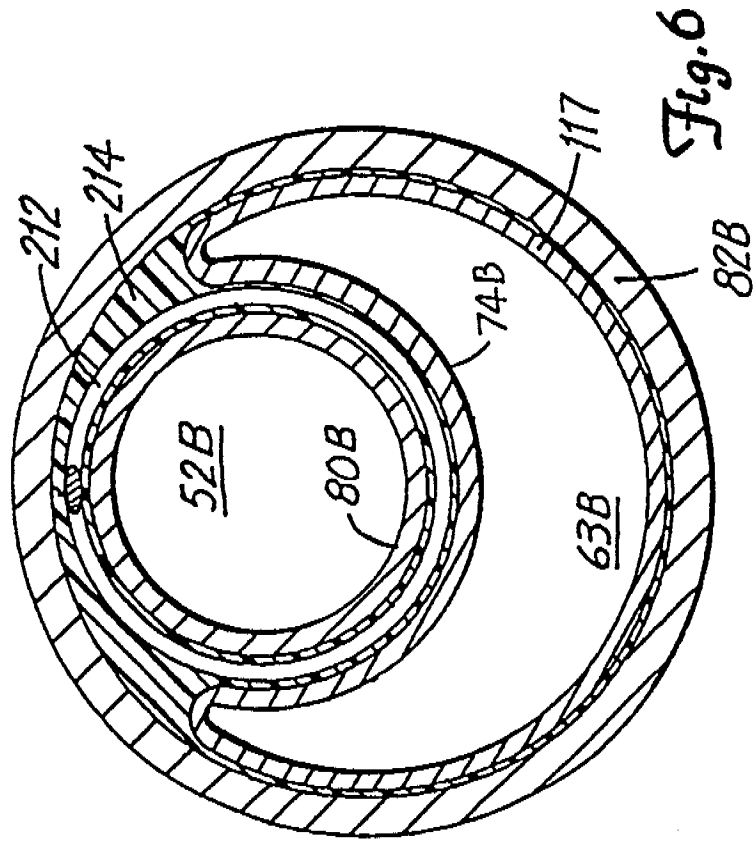
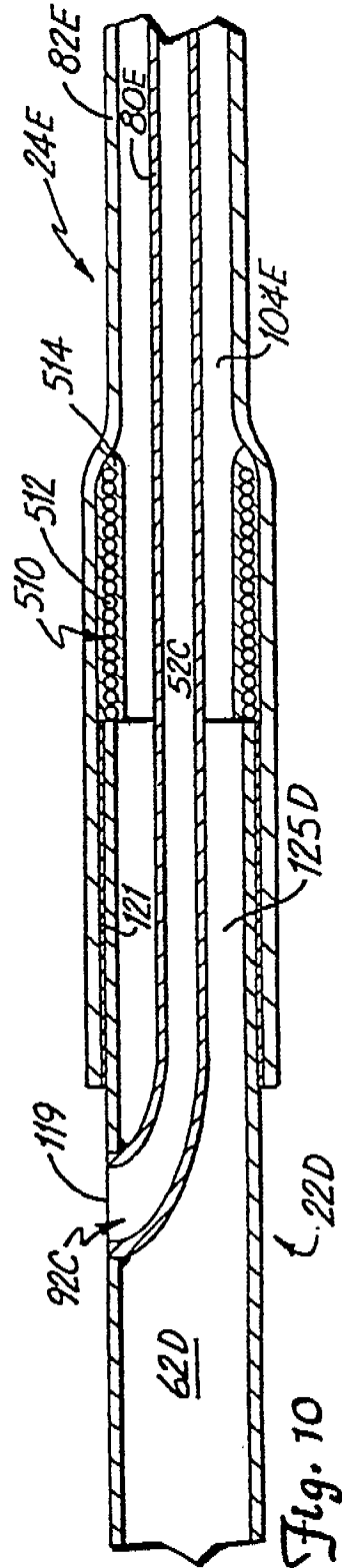
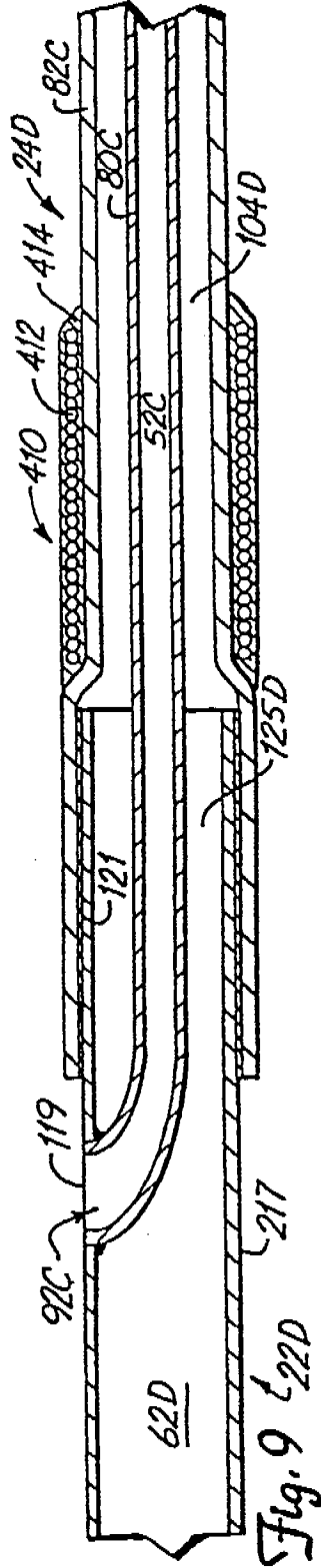
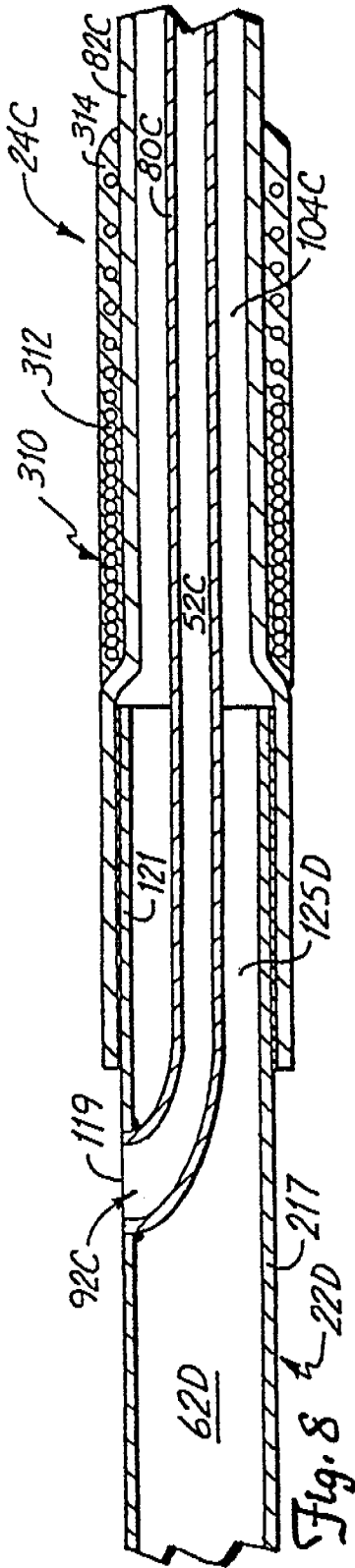


Fig. 1







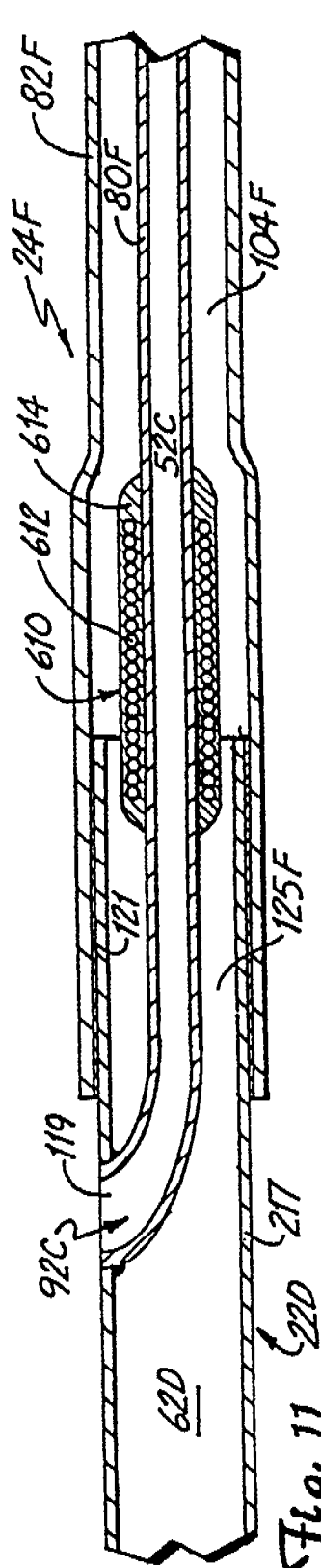


Fig. 11

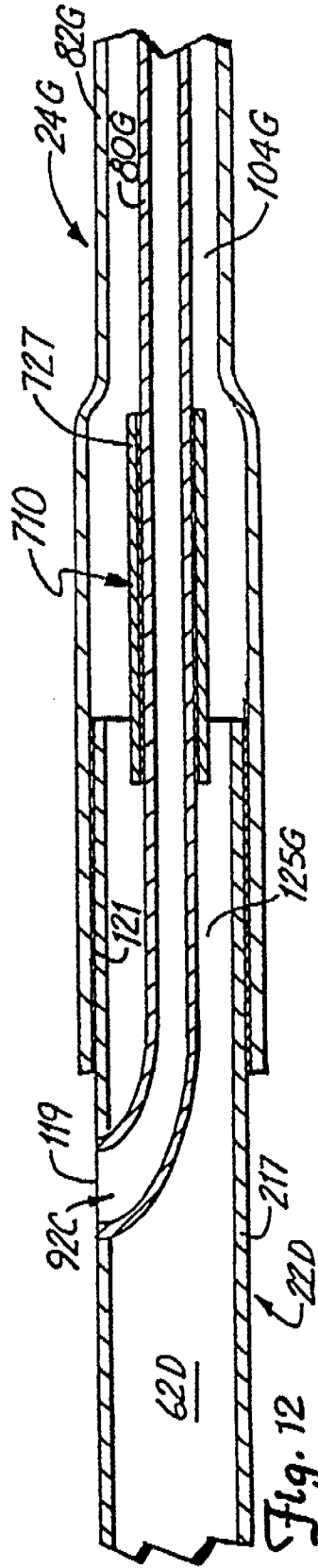


Fig. 12

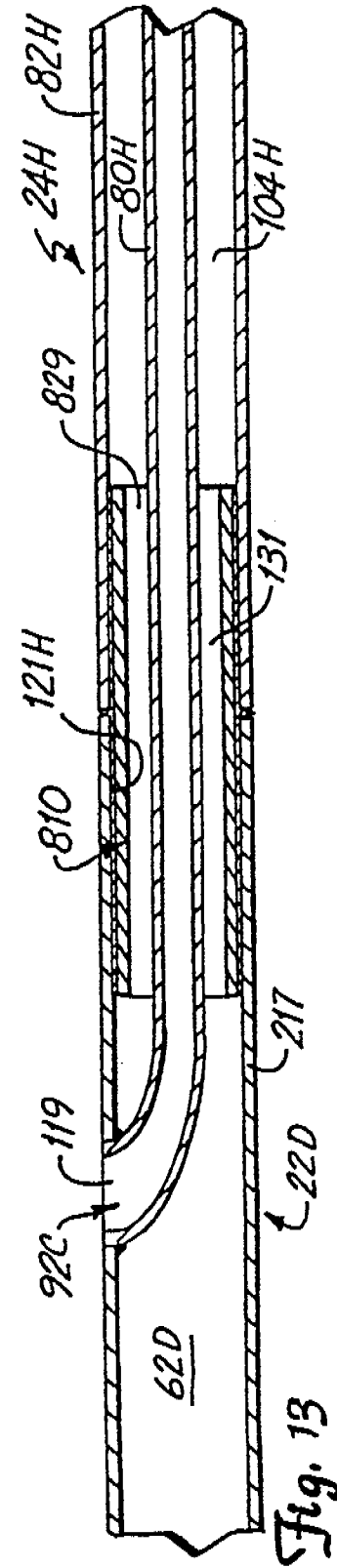


Fig. 13

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BALLOON CATHETER WITH DISTAL GUIDE WIRE LUMEN

RELATED APPLICATIONS

This is a continuation application of pending prior application Ser. No. 07/792,786, filed on Nov. 15, 1991, now U.S. Pat. No. 5,217,482, which is a continuation of prior application Ser. No. 07/574,265, filed on Aug. 28, 1990, which issued as U.S. Pat. No. 5,156,594, on Oct. 20, 1992.

BACKGROUND OF INVENTION

The present invention relates to the field of angioplasty. In particular, the present invention relates to a dilatation balloon catheter of the "over-the-wire" type having a relatively short distal guide wire lumen extending through the balloon of the catheter.

Angioplasty procedures have gained wide acceptance in recent years as efficient and effective methods for treating types of vascular disease. In particular, angioplasty is widely used for opening stenoses in the coronary arteries, although it is also used for the treatment of stenoses in other parts of the vascular system.

The most widely used form of angioplasty makes use of a dilatation catheter which has an inflatable balloon at its distal end. Typically, a hollow guide catheter is used in guiding the dilatation catheter through the vascular system to a position near the stenoses (e.g., to the coronary artery ostia). Using fluoroscopy, the physician guides the dilatation catheter the remaining distance through the vascular system until a balloon is positioned to cross the stenoses. The balloon is then inflated by supplying fluid under pressure through an inflation lumen in the catheter to the balloon. The inflation of the balloon causes stretching of the artery and pressing of the lesion into the artery wall, to reestablish acceptable blood flow through the artery.

There has been a continuing effort to reduce the profile and shaft size of the dilatation catheter so that the catheter not only can reach but also can cross a very tight stenosis. A successful dilatation catheter must also be sufficiently flexible to pass through tight curvatures, especially in the coronary arteries. A further requirement of a successful dilatation catheter is its "pushability". This involves the transmission of longitudinal forces along the catheter from its proximal end to its distal end so that a physician can push the catheter through the vascular system and the stenoses.

Two commonly used types of dilatation catheters are referred to as "over-the-wire" catheters and "non-over-the-wire" catheters. An over-the-wire catheter is one in which a separate guide wire lumen is provided in the catheter so that a guide wire can be used to establish the path through the stenoses. The dilatation catheter can then be advanced over the guide wire until the balloon on the catheter is positioned within the stenoses. One problem with the over-the-wire catheter is the requirement of a larger profile and a generally larger outer diameter along the entire length of the catheter in order to allow for a separate guide wire lumen therethrough.

A non-over-wire catheter acts as its own guide wire, and thus there is no need for a separate guide wire lumen. One advantage of a non-over-the-wire catheter is its potential for a reduced outer diameter along its main shaft since no discrete guide wire lumen is required. However, one disadvantage is the inability to maintain the position of the guide wire within the vascular sys-

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tem when removing the catheter and exchanging it for a catheter having a smaller (or larger) balloon diameter. Thus, to accomplish an exchange with a non-over-the-wire catheter, the path to the stenoses must be reestablished when replacing the catheter with one having a different balloon diameter.

In an effort to combine the advantages of an over-the-wire catheter with a non-over-the-wire catheter, catheters have been developed which have guide wire lumens which extend from a distal end of the catheter through the dilatation balloon and then exit the catheter at a point proximal of the dilatation balloon. The guide wire thus does not extend through the entire length of the catheter and no separate guide wire lumen is required along a substantially proximal section of the catheter. That proximal section can thus have a smaller outer diameter since it is only necessary to provide an inflation lumen therethrough for catheter operation. A further advantage of this type of modified over-the-wire catheter is that the frictional forces involved between the guide wire and the shortened guide wire lumen are reduced, thereby reducing resistance to catheter pushability and enhancing the "feel" and responsiveness of the catheter to a physician.

Perhaps the most significant advantage of using a shortened guide wire lumen is in the ease of exchange of the catheter over the guide wire. In performing an angioplasty procedure using such a catheter, the catheter is "back loaded" over the guide wire by inserting the proximal tip of the guide wire into a distal opening of the guide wire lumen in the catheter. The catheter is then advanced by "feeding" the catheter distally over the guide wire while holding the guide wire stationary. The proximal end of the guide wire will then emerge out of the proximal opening of the guide wire lumen (which is substantially spaced distally from the proximal end of the catheter itself) and is accessible again for gripping by the physician. The catheter can be pre-loaded onto the guide wire in this manner before the guide wire is inserted into the guide catheter or after. In either case, the guide wire is steered and passed through the guide catheter, coronary vessels and across a lesion. The exposed portion of the guide wire is then grasped while the catheter is advanced distally along the guide wire across the lesion. Using this procedure, little axial movement of the guide wire occurs during catheter loading and positioning for angioplasty.

If the dilatation balloon is found to be inadequate (too small or too large), the catheter can be similarly withdrawn without removing the guide wire from across the lesion. The guide wire is grasped while the catheter is withdrawn, and when the proximal opening of the guide wire lumen is reached, the grasping hand must be moved incrementally away from the proximal opening as the catheter is incrementally withdrawn, until the catheter is fully removed from the guide catheter and the guide wire is thus again exposed and accessible adjacent to the proximal end of the guide catheter.

This shortened guide wire lumen type of dilatation catheter design thus offers the advantages associated with the rapid exchangeability of catheters. The design also presents the potential to provide a smaller catheter shaft, since the guide wire is not contained within the proximal portion of the catheter shaft. The smaller catheter shaft thus allows for better contrast media injection and, as a result, better visualization. In addition, because of the rapid exchangeability features, standard non-

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extendable guide wires of approximately 175 centimeters in length may be used. Further, because the guide wire is contained in only a distal shorter guide wire lumen of the catheter, free wire movement is enhanced when compared to a standard over-the-wire catheter where the guide wire extends through a guide wire lumen extending along the entire length of the catheter.

While several structures for such shortened guide wire lumen dilatation catheter have been proposed these structures suffer from several disadvantages. Such catheters have been one piece polyethylene catheters having dual lumen configurations adjacent their distal regions. Typically, such catheters have larger than necessary shaft sizes and are stiffer in their distal regions than would be desired, including those portions bearing the dilatation balloon. A further disadvantage is that the proximal shaft portion of such catheters is relatively flexible, and has low column strength shaft, so that it tends to "bunch" and buckle when advanced across a lesion. To counteract this deficiency in such designs, additional stiffener elements have been provided in the shaft, which necessarily require a larger catheter shaft to accommodate the stiffener element structure. The known dilatation balloon catheter designs which include shortened guide wire lumens extending through the distal portion of the catheter suffer from the disadvantages mentioned above and do not take advantage of the unique opportunities presented by the possibilities of such designs in construction and application.

SUMMARY OF THE INVENTION

The present invention is an over-the-wire dilatation balloon catheter which has a guide wire lumen extending through only a distal portion of the catheter. The guide wire lumen extends from a distal end of the catheter proximally through a balloon of the catheter and exits the catheter at a point proximal of the balloon, but substantially distally from a proximal end of the catheter itself.

The present invention for a balloon dilatation catheter includes a thin-walled, high strength metallic tube having a longitudinal inflation lumen extending therethrough from its proximal end to its distal end. An intermediate sleeve section extends distally from the metallic tube. The sleeve section is more flexible than the metallic tube, and includes a proximal segment of inner core tube which has a longitudinal guide wire lumen extending therethrough and an outer sleeve which extends over the proximal segment of the core tube to define a longitudinally extending annular inflation lumen therebetween that is in fluid communication with the inflation lumen of the metallic tube. The guide wire lumen has an outlet at a proximal end of the proximal segment of the core tube, and the core tube has a distal segment which extends distally beyond the distal end of the outer sleeve. Means are provided for exposing the guide wire lumen outlet to the exterior of the catheter adjacent and proximal to the distal end of the metallic tube, without compromising the integrity of the inflation lumens extending through the catheter. An inflatable balloon extends over the distal segment of the core tube and has its proximal end connected to the distal end of the outer sleeve. A distal end of the balloon is connected to the core tube so that an interior of the balloon is in fluid communication with the annular inflation lumen in the sleeve section. Means are provided for preventing significant closure of the guide wire lumen and annular inflation lumen in the sleeve section adja-

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cent the distal end of the metallic tube when the more flexible sleeve section is bent laterally relative to the metallic tube.

In a preferred embodiment of the present invention, the metallic tube is formed from a proximal relatively long stainless steel tube and a distal relatively short stainless steel tube bonded thereto. The outer diameter of the proximal tube is smaller than the outer diameter of the distal tube, thus providing a catheter structure which is highly trackable and has a generally small shaft outer diameter, yet is very pushable and responsive to a doctor controlling movement of the catheter from its proximal end. Preferably, the means for exposing includes a longitudinal crimp adjacent the distal end of the distal stainless steel tube. The crimp extends laterally inwardly from one side of the distal tube, and has a proximal transition region and distal bonding region. The proximal end of the inner core tube is nested within the distal bonding region of the crimp and bonded thereto. The outer sleeve extends over at least a distal portion of the bonding region and is sealably affixed thereabout.

The means for preventing closure of a present invention may take a number of different forms. In a preferred embodiment, the means for preventing closure comprises a coil member affixed to the sleeve section adjacent the distal end of the metallic tube. As such, the coil member may be affixed about the outer sleeve to extend distally from the metallic tube or about the inner core tube to extend distally from the metallic tube. Such a coil member further may have its coils spaced uniformly apart or spaced increasingly apart as it extends distally from the metallic tube. Preferably, the coil member is formed from a spirally shaped ribbon. A compression sheath is provided to envelope the coil member and maintain the coil member in secure engagement to the sleeve section. In an alternative embodiment, the means for preventing closure comprises a tubular member affixed to the sleeve section adjacent the distal end of the metallic tube, with the tubular member being formed from a polyimide material.

Such closure preventing means thus provide a bending relief design between the relatively stiff metallic tube and more flexible distal region of the balloon dilatation catheter, to prevent kinking during catheter preparation work and handling (prior to insertion of the dilatation catheter into the guide catheter and patient). Such kinking or "crimping" of the catheter can result in a binding on the guide wire as it extends through the guide wire lumen or a reduction in size of the annular inflation lumen between the metallic tube and balloon or a compromise in strength of the catheter tubings, all of which will compromise the utility and responsiveness of the dilatation catheter. In addition, the closure preventing means reduces the possibility of a failure or separation of the bonds adjacent the distal end of the metallic tube which may be caused by excess strain placed on such bonds during catheter preparation or handling.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of a balloon dilatation catheter of the present invention having a distal guide wire lumen therethrough and showing a guide wire.

FIG. 2 is a sectional side elevational view of the balloon dilatation catheter of FIG. 1.

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FIG. 3 is an enlarged sectional view as taken along lines 3—3 in FIG. 2.

FIG. 4 is a sectional side elevational view of a portion of the catheter of the present invention, illustrating an alternative structure for a reinforcing coil member thereon.

FIG. 5 is a sectional side elevational view of a portion of the catheter of the present invention, illustrating an alternative structure for a reinforcing coil member thereon.

FIG. 6 is an enlarged sectional view as taken along lines 6—6 in FIG. 5.

FIG. 7 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 8 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 9 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 10 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 11 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 12 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

FIG. 13 is a sectional view of a portion of an alternative embodiment of the catheter of the present invention.

Although the above-identified drawing figures set forth various embodiments of the invention, other embodiments of the 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 will fall within the scope and spirit of the principles of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overall Catheter Structure

A balloon dilatation catheter 20 of the present invention is illustrated generally in FIG. 1. The catheter 20 has a proximal main shaft section 22, an intermediate sleeve section 24 and a distal balloon section 26. The main shaft section 22 has a proximal end 28 and a distal end 30. Likewise, the intermediate sleeve section 24 has a proximal end 32 and a distal end 34. The distal balloon section 26 has a proximal waist 36, an intermediate expandable segment 38 and a distal waist 40.

As illustrated in FIG. 1, the distal end 30 of the main shaft section 22 is connected to the proximal end 32 of the sleeve section 24, and the distal end 34 of the sleeve section 24 is connected to the proximal waist 36 of the balloon section 26. In use, the catheter 20 is coupled to an inflation device (not shown) by a luer manifold 42 connected to the proximal end 28 of the main shaft section 22. The inflation device thus provides or removes inflation solution from the catheter 20 to selectively inflate or deflate the intermediate expandable segment 38 of the distal balloon section 26 (in FIG. 1,

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expandable segment 38 is shown in its inflated configuration).

The catheter 20 of the present invention is designed for use in combination with a catheter guide element such as a guide wire 50. In use in a coronary application, both the guide wire 50 and the catheter 20 are fed through and guided to an arterial lesion by means of a tubular guide catheter (not shown). Both the catheter 20 and guide wire 50 are therefore longer than the guide catheter, with a typical catheter length of approximately 135 cm and a typical guide wire length of approximately 175 cm. As illustrated in FIG. 1, the guide wire 50 extends longitudinally along the exterior of the main shaft section 22 of the catheter 20. Adjacent the distal end 30 of the main shaft section 22, the guide wire 50 enters the structure of the catheter 20 and extends distally therethrough until it exits the catheter structure adjacent the distal waist 40 of the distal balloon segment 26. As seen FIG. 2, a separate guide wire lumen 52 is provided in the catheter 20 through the intermediate sleeve section 24 and distal balloon section 26 thereof. The guide wire 50 thus is only entrained within the catheter 20 within this guide wire lumen 52, which is much shorter than the total length of the catheter 20 (e.g., the guide wire lumen 52 is approximately 30 cm long). The guide wire 50 has a proximal end 53 and a distal end 54 and is of a typical structure for guiding angioplasty catheters. At its distal end 54, the guide wire 50 preferably has a coiled and rounded tip structure which is bendable for steerability of the guide wire.

Referring now to FIG. 2, which shows the catheter 20 in greater detail, it is seen that the proximal end 28 of the main shaft section 22 further has a strain relief tube 60 disposed between the luer manifold 42 and shaft section 22. The strain relief tube 60 is larger than the main shaft section 22, and thus provides a step-wise strain relief function between the inflexible luer manifold 42 and the more flexible main shaft section 22. The main shaft section 22, tubular member 60 and luer manifold 42 are secured together respectively by suitable adhesive means, such as epoxy or cyanoacrylate.

Main Shaft Section

The main shaft section 22 is preferably formed as a thin-walled, high strength stainless steel tube structure, which is referred to as hypodermic tubing or hypotube. As a tubular structure the main shaft section 22 thus has a longitudinally extending inflation lumen 62 extending therethrough from its proximal end 28 to its distal end 30, which provides a means for the movement and pressurization of inflation fluid through the catheter 20 to and from the distal balloon section 26.

In a preferred embodiment, the main shaft section 22 is formed from two stainless steel tube sections, a proximal relatively long shaft section 64 and a distal relatively short shaft section 66. A distal end of the proximal shaft section 64 and a proximal end of the distal shaft section 66 are sealably affixed together by suitable means, such as by a solder joint. The proximal end of the distal shaft section 66 fits coaxially over the distal end of the proximal shaft section 64, as seen in FIG. 2, thereby allowing the proximal shaft section 64 to assume a smaller outer diameter than the distal shaft section 66. The main shaft section 22 is provided with a lubricous coating (such as polytetrafluoroethylene) to lessen frictional resistance (at least to the extent that the proximal shaft section 64 is so coated). The use of a thin-walled (e.g., 0.003 inch wall thickness), metallic

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tube structure for the main shaft section 22 thus provides a stiff enough shaft for pushability yet allows for a relatively small diameter shaft, thereby enhancing catheter visualization via fluoroscopy and catheter versatility. The inherent high strength nature of such a structure also allows it to withstand the fluid pressures necessary for proper catheter operation, which in a plastic shaft structure would require thicker walls. The high column strength and thickness of a hypotube shaft also gives improved responsiveness to the catheter. Thus, the balloon and distal regions of the catheter move definitively (in a 1:1 relationship) with motions imparted at the catheter's proximal end by a physician. This feature allows the physician to actually "sense" the pathway as the catheter is tracked, which gives valuable information in the passage of the catheter to and through the lesion.

In the distal shaft section 66 of the main shaft section 22, a longitudinal crimp 68 is provided which extends laterally inwardly from one side of the distal section 66. The distal shaft section 66 has three sections, a proximal tubular region 70, a transition region 72, and a distal bonding region 74. The crimp 68 extends from its proximal origin in the transition region 72 to its greatest lateral depth in the bonding region 74. The crimp 68, as further illustrated in FIG. 3, does not seal off or close the inflation lumen 62, but does transform the inflation lumen from a circular lumen 62 to a crescent shape through the bonding region 74, as seen at 63 in FIG. 3.

As shown in FIG. 2, the tube forming distal section 66 can have a thinner wall than the tube forming proximal shaft section 64. Additionally, as crimp 68 progresses distally through distal section 66, the latitudinal cross section of section 66 can become generally progressively more compact as shown in FIGS. 2 and 3.

Catheter Intermediate Sleeve Section

The intermediate sleeve section 24 extends distally from the main shaft section 22, and is bonded thereto adjacent the bonding region 74 of the distal shaft section 66. The intermediate sleeve section 24 has two primary longitudinal components, an inner core tube 80 and an outer sleeve or tube 82. The inner core tube 80 has a proximal segment 84 within the sleeve section 24 and a distal segment 86 within the distal balloon section 26. The inner core tube 80 and outer sleeve 82 are both preferably formed from thin-walled high density polyethylene.

The inner core tube 80 has a proximal end 88 and a distal end 90. At its proximal end 88, the core tube 80 is nested within the bonding region 74 of the distal shaft section 66 and bonded thereto by suitable means, such as epoxy or cyanoacrylate. The core tube 80 is thus affixed to the main shaft section 22 in an "off-axis" alignment at the bonding region 74. However, as seen in FIG. 2, as the core tube 80 extends distally from the main shaft section 22, it is aligned generally coaxially with the shaft section 22.

The core tube 80 defines the guide wire lumen 52 extending through the catheter 20. The guide wire lumen thus has a proximal outlet 92 adjacent the proximal end of the core tube 80 and a distal outlet 94 adjacent the distal end 90 of the core tube 80. At least one marker band 96 is provided about the core tube 80 (preferably centered within the expandable segment 38 of the distal balloon section 26) to aid in illuminating the position of the catheter 20 via fluoroscopy during an angioplasty procedure.

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The outer sleeve 82 is generally tubular in form, and has a proximal end 100 and a distal end 102. The outer sleeve 82 is bonded about the distal shaft section 66 and the core tube 80 adjacent the bonding region 74, as seen in FIGS. 2 and 3 and is held in place thereto by suitable means, such as epoxy or cyanoacrylate. The outer sleeve 82 extends distally from the main shaft section 22 over the proximal segment 84 of the core tube 80, and as such, defines a distal continuation of the inflation lumen of the catheter 20. A longitudinally extending annular inflation lumen 104 is formed between the core tube 80 and outer sleeve 82. Of course, the proximal end 100 of the outer sleeve 82 is securely sealed about the distal shaft section 66 and the core tube 80 so that the longitudinal inflation lumens 62 and 104 through the catheter 20 are not compromised to the exterior of catheter 20, but are in fluid communication therethrough.

The intermediate sleeve structure defined above is the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein—namely, an inner core tube bonded to a distal portion of the main catheter shaft, with an outer sleeve forming an annular continuation of the inflation lumen through the main shaft between the core tube and outer sleeve. As discussed below and illustrated herein, various configurations of the connections and components relative to the formation of the distal guide wire lumen, including the coupling of the main shaft to the intermediate sleeve section, are contemplated.

Catheter Distal Balloon Section

The distal balloon section 26 is connected to the components of the intermediate sleeve section 24. The proximal waist 36 of the balloon section 26 is connected to the distal end 102 of the outer sleeve 82 by suitable means, such as by epoxy or cyanoacrylate. The distal waist 40 of the balloon section 26 is bonded to the core tube 80 adjacent its distal end 90 by suitable means, such as by epoxy or cyanoacrylate. An interior 106 of the balloon section 26 is thus sealed and in fluid communication with the annular inflation lumen 104 within the sleeve section 24. In a preferred embodiment, the balloon section 26 is formed from a compliant balloon material (e.g., polyolefin), although a balloon formed from thin-walled non-compliant material (e.g., PET-polyethylene terephthalate) is also contemplated.

Kink-resistant Structure

The metallic main shaft section 22 is relatively stiff compared to the polyethylene intermediate sleeve section 24. This creates a rather abrupt change in the flexibility of the materials for the catheter 20 adjacent the distal end 30 of the main shaft section 22 (at the bonding region 74). The use of a hypotube for the main shaft section 22 in the catheter 20 creates a catheter which is considerably stiffer than most previous over-the-wire angioplasty balloon catheter designs. Such stiffness is not a concern as long as the metallic main shaft section 22 remains in the relatively straight guide catheter within the patient, and indeed such stiffness provides distinct benefits in use of the catheter 20, as described above. In the distal portions of the catheter 20 (intermediate sleeve section 24 and distal balloon section 26), the catheter 20 must be very trackable and flexible in order to negotiate the tortuous coronary anatomy to and across the lesion. The relatively sharp transition in stiffness as the catheter structure changes from the metallic main shaft section 22 to the much more flexible polymer

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intermediate sleeve section 24 creates two concerns. First, during handling of the catheter prior to usage, there is a potential to kink the catheter structure at that flexibility transition point. Secondly, when the catheter is in vivo, the distal end 30 of the main shaft section 22 could potentially "dig in" to the guide catheter and create excessive friction due to the lack of bending support from the more flexible intermediate sleeve section 24.

To address these concerns, a kink-resistant structure 110 is provided to prevent kinking and possible damage to the intermediate sleeve section 24 during catheter preparation, handling and use. In its simplest form, this kink-resistant structure 110 provides a member of intermediate stiffness or transitory stiffness and kink-resistant nature between the relatively stiff main shaft section 22 and the relatively flexible intermediate sleeve section 24. The kink-resistant structure 110 includes a coil member 112 affixed to the intermediate sleeve section 24 adjacent the distal end 30 of the main shaft section 22. The coil member 112 creates an intermediate stiffener element between the relatively stiff main shaft section 22 and the relatively flexible intermediate sleeve section 24 to allow bending of the catheter without kinking. The coil member 112 preferably has its coils spaced uniformly apart, and is preferably formed from a spiral ribbon of stainless steel placed about the outer sleeve 82 along that portion thereof extending over the bonding region 74 and distally therefrom. The coil member 112 is secured to the outer sleeve 82 by suitable adhesive means, such as by epoxy. To further secure the coil member 112 to the intermediate sleeve section 24, a heat-shrinkable sheath 114 is fitted over the coil member 112. Preferably the sheath 114 is formed from a polyimide or polyolefin material which is expanded radially outwardly and then shrunk down over the coil member 112 and outer sleeve 82 to secure the coil member 112 thereto. To further secure the sheath 114 and coil member 112 in place, some adhesive is provided between the sheath 114 and the intermediate sleeve section 24. By covering the ends of the coil member 112, the sheath 114 also lessens the chances of those ends providing a rough edge or catch as the catheter 20 is advanced through the guide catheter or artery.

Although the kink-resistant structure is described and illustrated in connection with a balloon dilatation catheter, it is contemplated that such a structure be employed in any catheter shaft as a transition from a first thin-walled, high strength metallic tube structure to a second tube structure which is more flexible than the metallic tube structure. Such a kink-resistant structure, as described above (and also below in various embodiments), may be employed in a single lumen catheter shaft, or in multiple lumen catheter shaft having a central core tube such as the multi-lumen shaft illustrated by the intermediate sleeve section of the catheter disclosed in FIGS. 1-4.

Alternative Catheter Embodiment

Numerous alternative embodiments of the catheter of the present invention are contemplated. For example, several alternative arrangements for the main shaft section and intermediate sleeve structure portion of the catheter are illustrated and discussed herein, but it is not intended that the illustrated embodiments are all inclusive of those structures and designs which are included within the spirit and scope of the present invention. In the following discussion of further alternative embodi-

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ments of the present invention, to the extent a component is identical to that of a previously described embodiment, like reference numerals are used.

FIG. 4 illustrates an alternative embodiment for the distal portion of a catheter according to the present invention. Specifically, the outer sleeve (of the intermediate sleeve section) and the distal balloon section are formed from the same component, as a unitary member. Thus, proximal waist 36A of distal balloon section 26A is elongated proximally and acts as the outer sleeve for intermediate sleeve section 24A. A proximal end 115 of the proximal waist 36A is sealably fixed about the core tube 80 and main shaft section 22 adjacent the bonding region 74 thereof. It should be understood that the prospect of having a unitary outer sleeve and balloon member is applicable to all embodiments disclosed herein and contemplated, although it is only illustrated and discussed with respect to the catheter structure of FIG. 4.

FIG. 4 also shows another variation for the catheter's structure illustrated in FIGS. 1-3. In FIG. 4, kink-resistant structure 110A includes coil member 112A which is defined as a spiral ribbon of stainless steel placed about a proximal portion of the proximal waist 36A along the bonding region 74 and distally therefrom. The coil member 112A does not have its coils uniformly spaced apart, but rather has its coils spaced increasingly further apart as the coil member extends distally from the main shaft section 22. This results in a coil member 112A which becomes increasingly more flexible, thereby "feathering out" the change in relative stiffness and strain or kink relief between the relatively inflexible main shaft section 22 and the relatively flexible intermediate sleeve section 24A. As before, a heat-shrinkable sheath 114A is fitted over the coil member 112A to further secure the coil member 112A to the sleeve section 24A.

In FIG. 5, a modified main shaft section 22B is illustrated. The main shaft section 22B is formed as a thin-walled, high strength stainless steel tube or hypotube, but is defined as a single tubular shaft 117 from its proximal end to its distal end 30B. The single shaft 117 has a longitudinally extending inflation lumen 62B there-through, and at its proximal end (not shown) the single shaft 117 is mounted to an inflation device in a manner such as that illustrated for the catheter of FIG. 2. Adjacent its distal end 30B, the single shaft 117 has a longitudinal crimp 68B which extends laterally inwardly from one side of the single shaft 117. The single shaft 117 thus has three sections, a proximal, relatively elongated tubular region 70B, a relatively short distal transition region 72B and a relatively short distal bonding region 74B. The crimp 68B extends from its proximal origin in the transition region 72B to its greatest lateral depth in the bonding region 74B. The crimp 68B does not seal or close off the inflation lumen 62B, but rather transforms the inflation lumen 62B from a circular lumen to a half-moon lumen through the bonding region 74B, as seen at 63B in FIG. 6. It is again understood that the use of a single tube to define the main shaft section of the catheter of the present invention is applicable to the other alternative embodiments of the catheter structures disclosed herein.

FIGS. 5 and 6 also illustrate an alternative arrangement for the kink-resistant structure of the inventive catheter. Kink-resistant structure 210 includes coil member 212. The sleeve section 24B includes an outer sleeve 82B and an inner core tube 80B, with the core

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tube 80B adapted to be nested within and bonded to the main shaft section 22B in its distal bonding region 74B. The coil member 212 of the kink-resistant structure 210 is positioned about the core tube 80B within the distal bonding region 74B and extending distally therefrom. The coil member 212 is preferably formed from stainless steel (either from a wire or ribbon) and may have uniform coil spacing or increasingly spaced coils as the coil member 212 extends distally from the main shaft section 22B. The coil member 212 is secured to the core tube 80B by suitable means, such as by embedding the coil member 212 in an epoxy layer 214 about the core tube 80B. A proximal end 100B of the outer sleeve 82B is bonded about the main shaft section 22B and inner tube 80B and coil structure 210 in the bonding region 74B thereof, as seen in FIGS. 5 and 6. In the intermediate sleeve section 24B, the inner core tube 80B thus provides a guide wire lumen 52B therethrough, and an annular inflation lumen 104B is provided between the inner tube 80B and outer sleeve 82B. Although the kink-resistant structure 210 is within the annular inflation lumen 104 and the outer sleeve 82B necks down distally from the main shaft section 22B, the size of the annular inflating lumen 104 is sufficient to provide proper fluid flow to and from the catheter's balloon.

FIGS. 7-13 illustrate an alternative configuration for that portion of the catheter adjacent the proximal inlet of the guide wire lumen. Instead of providing a crimp structure in the distal end of the main shaft section, an aperture is provided adjacent to and proximal of the distal end of the main shaft section. The aperture is aligned and sealably coupled to the inner tube to define the guide wire lumen proximal outlet. In all disclosed embodiments, the main shaft section is preferably formed from a hypotube-like material.

As seen in FIG. 7, an alternative embodiment of the catheter of the present invention has a proximal main shaft section 22C formed from thin-walled, high strength stainless steel tubing. A longitudinally extending inflation lumen 62C extends therethrough from a proximal end of the main shaft section 22C to its distal end 30C. In the embodiment seen in FIG. 7, the main shaft 22C is formed from two stainless steel tube sections, a proximal relatively long shaft section 64C and a distal relatively short shaft section 66C bonded on the distal end of the proximal section 64C. This two-part main shaft section structure thus allows a substantial length of the main shaft section 22C to be formed from the proximal shaft section 64C which has a smaller diameter than the distal shaft section 66C.

The distal shaft section 66C has an oval-shaped aperture 119 extending through its wall, with the oval being elongated in the longitudinal direction of the main shaft section 22C. The aperture 119 is spaced proximally from a distal end of the distal shaft section 66C (the distal end 30C of the main shaft section 22C). The space between the aperture 119 and distal end 30C thus defines in part a bonding region 121 for connecting the main shaft section 22C to a distally extending intermediate sleeve section 24C.

As before, the intermediate sleeve section 24C includes an inner core tube 80C and an outer sleeve 82C. A proximal end 88C of the core tube 80C is sealably bonded about the aperture 119 to align the proximal end 88C and aperture 119 and thereby define a proximal outlet 92C for a guide wire lumen 52C extending through the core tube 80C. As seen in FIG. 7, a proximal portion 123 of the core tube 80C extends laterally

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from the aperture 119 into the distal shaft section 66C and turns longitudinally and distally relative thereto to be aligned generally coaxially therewith. As such, the inflation lumen 62C is continued distally past the aperture 119 as a generally annular inflation lumen 125, between the core tube 80C and distal shaft section 66C (along the bonding region 121). Proximal end 100C of the outer sleeve 82C is bonded about the distal shaft section 66C in the bonding region 121 by a suitable means, such as by epoxy or cyanoacrylate. As seen in FIG. 7, the outer sleeve 82C extends distally from the main shaft section 22C over the core tube 80C and defines a longitudinally extending annular inflation lumen 104C between the core tube 80C and outer sleeve 82C. The proximal end 100C of the outer sleeve 82C is sealed about the distal shaft section 66C so that the longitudinal inflation lumens 62C, 125 and 104C are not compromised to the exterior of the catheter, but are in fluid communication therethrough.

In FIG. 7, kink-resistant structure 310 includes coil member 312 (of a wire or ribbon-like structure) which is bonded about the outer sleeve 82C to extend distally from the distal end 30C of the main shaft section 22C. In this embodiment, the coil member 312 does not extend about any portion of the main shaft 22C. The coil member 312 is secured to the outer sleeve 82C by suitable adhesive means, such as epoxy 314, and is embedded therein to firmly hold the coil member 312 in place about the intermediate sleeve section 24C. In the embodiment of FIG. 7, the coil member 312 is illustrated with its coils being spaced increasingly longitudinally apart as the coil member 312 extends distally along the catheter.

FIGS. 8-13 also illustrate embodiments of the catheter of the present invention wherein an aperture is provided through the main shaft section wall to accommodate the proximal outlet for the relatively short, distal guide wire lumen. As opposed to the embodiment of FIG. 7, however, the embodiments illustrated in FIGS. 8-13 show the main shaft section as a single shaft rather than as a multi-part shaft. Indeed, FIG. 8 illustrates a catheter structure identical to that of FIG. 7, except that the main shaft section 22D is shown as a single shaft 217, rather than having proximal and distal shaft sections 64C and 66C as seen in FIG. 7. As such, the catheter inflation lumen includes longitudinally extending inflation lumens 62D, 125D and 104D.

FIG. 9 is an embodiment of the catheter of the present invention otherwise similar to FIG. 8, except that kink-resistant structure 410 has coil member 412 with uniformly spaced coils along the entire length. Again, the entire coil member 412 is fixed to the outer sleeve 82C of the intermediate sleeve section 24C by embedding the coil member 412 within a suitable material such as epoxy or cyanoacrylate 414.

In the catheter structure of FIG. 10, intermediate section 24E has an inner core tube 80E and an outer sleeve 82E. The structure of the catheter is otherwise the same as the catheter of FIG. 9, except that the kink-resistant structure thereof is positioned inside the outer sleeve 82E rather than outside of the outer sleeve. Kink-resistant structure 510 is affixed to an inner surface of the outer sleeve 82E distally of the main shaft section 22D by a suitable means, such as embedded adhesive 514. The kink-resistant 510 includes coil member 512 which provides an intermediate stiffener between the relatively stiff main shaft section 22D and the relatively flexible intermediate sleeve section 24E. As seen, the

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outer sleeve 82E necks down distally from the kink-resistant structure 510 to provide a lower profile for the catheter in its distal regions. An annular inflation lumen 104E formed between the inner tube 80E and outer sleeve 82E (and at a proximal end thereof, between the inner tube 80E and the kink-resistant structure 510) is not compromised by such a necked-down sleeve design but maintained at sufficient size to provide for adequate and quick inflation and deflation of the balloon.

In FIG. 11 intermediate sleeve section 24F includes an inner core tube 80F and an outer sleeve 82F. Kink-resistant structure 610 is mounted about the inner tube 80F along the bonding region 121 and extending distally from the main shaft section 22D into the intermediate sleeve section 24F. The kink-resistant structure includes coil member 612 which is affixed about the core tube 80F by suitable means such as being embedded in epoxy or another suitable adhesive 614. As seen in FIG. 11, the outer sleeve 82F has an enlarged diameter at its proximal end to accommodate the main shaft section 22D and the kink-resistant structure 610, and so that the annular inflation lumens 125F and 104F about the core tube 80F remain sufficiently large to provide proper inflation and deflation pressures to the balloon of the catheter.

FIGS. 12 and 13 illustrate a further variation of the kink-resistant structure of the present invention. In the embodiments of FIGS. 12 and 13, the kink-resistant structure does not include a coil member, is formed from a polymer tube which is of intermediate stiffness between the main shaft section and intermediate sleeve section. In FIG. 12, kink-resistant structure 710 is provided which is formed from a polyimide or other stiff polymer tube 727. The tube 727 is bonded about an inner core tube 80G of the intermediate sleeve section 24G by a suitable adhesive, such as epoxy or cyanoacrylate. The tube 727 extends through a distal portion of the bonding region 121 and distally beyond the main shaft section 22D into the intermediate sleeve section 24G. Again, an outer sleeve 82G of the sleeve section 24G has an enlarged diameter at its proximal end to accommodate the main shaft section 22D and the kink-resistant structure 710, and so that the components are dimensioned such that annular inflation lumens 125G and 104G are not compromised.

In FIG. 13, kink-resistant structure 810 is illustrated, as formed from a polyimide or other stiff polymer tube 829 which is bonded to the inner surfaces of both the main shaft section 22D and an outer sleeve 82H of an intermediate sleeve section 24H at a bonding region 121H. The tube 829 thus provides not only a kink-resistant structure to accommodate the change in stiffness of the main shaft section and intermediate sleeve section, but also provides a substrate for bonding the two catheter sections together by a suitable adhesive, such as epoxy or cyanoacrylate. A core tube 80H of the sleeve section 24H extends through the interior of the tube 829 to the aperture 119 on the main shaft section 22D. Thus, an annular longitudinally extending inflation lumen 131 is formed as a "bridge lumen" (between the core tube 80H and tube 829) from the inflation lumen 62D to an annular inflation lumen 104H within the sleeve section 24H.

As mentioned above, various combinations of these alternative component and catheter structures are contemplated and are intended to be considered, although not explicitly shown. For example, it is contemplated that a two-part main shaft section structure (such as

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illustrated in FIGS. 2, 4 and 7) may be combined with any one of the kink-resistant structure such as that illustrated in FIGS. 8-13. By way of example and not limitation, a further example of such a combination may include the use of a distal balloon section having an elongated proximal waist (such as shown in FIG. 4) with any of the alternative kink-resistant structures disclosed herein.

Conclusion

The balloon dilatation catheter of the present invention is an over-the-wire catheter structure with a distal guide wire lumen which optimizes the features of such a catheter in a way not previously considered or achieved. The use of a hypotube-type main shaft for the catheter allows the attainment of a high strength, pushable shaft having thin walls and small diameter. The further use of a two-part hypotube shaft structure allows an even smaller diameter for the proximal elongated section of the main catheter shaft. Employing a crimp as a means for aligning and creating a proximal outlet for the relatively short guide wire lumen also serves to provide a transition region for exit of the guide wire from the catheter itself which is relatively gradual. The crimped shaft design also provides additional stiffness in the transition region where the guide wire enters and exits the catheter proximally of the balloon thereof, thereby creating a more rigorous catheter structure. Because the catheter of the present invention is based upon a relatively stiff proximal main shaft section, and such a catheter must have a relatively flexible distal portion for working through the tortuous arterial anatomy, a strain relief or kink-resistant structure is provided to make a more gradual transition between the relatively stiff main catheter shaft and the relatively flexible distal portion of the catheter. Various configurations of strain relief and kink-resistant structures are disclosed herein, and all are believed suitable to accomplish the desired end of preventing significant closure of the guide wire lumen and annular inflation lumen in the more flexible distal portions of the catheter, especially adjacent the distal end of the main catheter shaft.

Although the present invention has been described with reference to preferred 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.

What is claimed is:

1. In an elongate dilatation catheter of the type that can be slidably moved along a guide wire that can extend past a distal end of the catheter, wherein the guide wire is received in a guide wire lumen of the catheter, the guide wire extending from a distal guide wire lumen opening to a proximal guide wire lumen opening disposed in a portion of the catheter that is spaced distally from a proximal end of the catheter, the dilatation catheter including an inflatable balloon and an inflation lumen extending through the catheter separate from the guide wire lumen, an improvement comprising:

- a tube formed from a relatively stiff material composition, the tube defining a first shaft section having a proximal end and a distal end;
- a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section and having the guide wire lumen extending through a portion thereof; and

a transition section generally disposed between the first shaft section and the second shaft section, the transition section including a portion which is of diminished dimension relative to the tube such that at least the portion of the transition section is more flexible than the first shaft section, less flexible than the second shaft section, and extends at least in part across the proximal guide wire lumen opening.

2. The improved catheter of claim 1 wherein the tube is formed from a metallic material.

3. The improved catheter of claim 1 wherein the proximal guide wire lumen opening is disposed adjacent the proximal end of the second shaft section.

4. The improved catheter of claim 1 wherein the proximal guide wire lumen opening is disposed adjacent the distal end of the first shaft section.

5. In an elongate dilatation catheter which has an inflatable balloon and an inflation lumen extending through the catheter, wherein the catheter is of the type that can be slidably moved along a guide wire which can extend past a distal end of the catheter through a guide wire lumen of the catheter, wherein the guide wire lumen is separate from the inflation lumen and extends from a distal guide wire lumen opening to a proximal guide wire lumen opening disposed in a portion of the catheter that is spaced distally from a proximal end of the catheter so that the guide wire lumen is shorter than the inflation lumen, an improvement comprising:

a first proximal shaft section of the catheter defined by a tubing of relatively rigid material;

a second shaft section disposed distally of the first shaft section, the second shaft section being relatively more flexible than the first shaft section; and

a transition section generally disposed between the first shaft section and the second shaft section and extending adjacent to the proximal guide wire lumen opening, the transition section having decreased rigidity intermediate the first and second shaft sections, to provide a stepped transition in flexibility between the first shaft section and the second shaft section, the transition section having a distal terminal end spaced proximally from the balloon.

6. The improved catheter of claim 5 in which the tubing is formed from a metallic material.

7. The improved catheter of claim 5 in which the transition section extends at least in part around the inflation lumen.

8. The improved catheter of claim 5 in which the proximal guide wire lumen opening is disposed adjacent the proximal end of the second shaft section.

9. The improved catheter of claim 5 in which the proximal guide wire lumen opening is disposed adjacent the distal end of the first shaft section.

10. In an elongate dilatation catheter of the type that has a relatively long proximal shaft section, a second shorter distal shaft section disposed distally of the first shaft section, an inflatable balloon attached to the distal end of the second shaft section wherein the first and second shaft sections have an inflation lumen defined therethrough so that the balloon is in fluid communication with the inflation lumen, and wherein the catheter is of the type that can be slidably moved along a guide wire which can extend through a guide wire lumen of the catheter, the guide wire lumen being separate from the inflation lumen and extending from a distal guide wire lumen opening at the distal end of the catheter to a proximal guide wire lumen opening adjacent the proximal end of the second shaft section so that the guide wire lumen is shorter than the inflation lumen, an improvement comprising:

the first proximal shaft section of the catheter defined by a tubing of relatively rigid material;

the second shaft section of the catheter being relatively more flexible than the first shaft section and having a relatively short reinforced proximal portion and a relatively long nonreinforced distal portion; and

the reinforced proximal portion including a transition member disposed adjacent to the proximal guide wire lumen opening and extending distally along the second shaft section to provide a reinforcement therefor, the transition member including a metallic element having a uniform reduced dimension relative to the tubing as it extends distally along the catheter to provide a stepped transition in rigidity in the distal direction, the transition member having a distal terminal end spaced from the balloon by the length of the nonreinforced distal portion of the second shaft section.

11. The improved catheter of claim 10 in which the tubing is formed from a metallic member.

12. The improved catheter of claim 10 in which the transition member extends at least in part distally of the proximal guide wire lumen opening.

13. The improved catheter of claim 10 in which the transition member extends at least in part around the inflation lumen.

14. The improved catheter of claim 10 in which the transition member comprises a coil.

15. The improved catheter of claim 10 in which the proximal guide wire lumen opening is disposed adjacent the distal end of the first shaft section.

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CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Boston Scientific Corp.,
Boston Scientific Scimed, Inc.
Scimed Life Systems, Inc., and
Schneider (Europe) GMBH

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Middlesex
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

Johnson & Johnson, Inc. and
Cordis Corporation

02 CV 10249 RCL
COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Hale and Dorr LLP
60 State Street
Boston, MA 02109-9987
(617) 526-5000

ATTORNEYS (IF KNOWN)

FILED
IN CLERK'S OFFICE
2002 FEB 14 10 00 AM
U.S. DISTRICT COURT
DISTRICT OF MASSACHUSETTS

II. BASIS OF JURISDICTION (PLACE AN "X" IN ONE BOX ONLY)

- 1 U.S. Government Plaintiff
- 3 Federal Question (U.S. Government Not a Party)
- 2 U.S. Government Defendant
- 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (For Diversity Cases Only)

- | | | | | | |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| | PTF | DEF | | PTF | DEF |
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (PLACE AN "X" IN ONE BOX ONLY)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury — Med. Malpractice <input type="checkbox"/> 365 Personal Injury — Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes <input type="checkbox"/> 890 Other Statutory Actions
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence HABEAS CORPUS: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS — Third Party 26 USC 7609

V. ORIGIN

(PLACE AN "X" IN ONE BOX ONLY)

- 1 Original Proceeding
- 2 Removed from State Court
- 3 Remanded from Appellate Court
- 4 Reinstated or Reopened
- 5 Transferred from another district (specify)
- 6 Multidistrict Litigation
- 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

(CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE BRIEF STATEMENT OF CAUSE. DO NOT CITE JURISDICTIONAL STATUTES UNLESS DIVERSITY.)

Action for Patent Infringement under 35 U.S.C. #271

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: YES NO

VIII. RELATED CASE(S) IF ANY

JUDGE

DOCKET NUMBER

DATE

2/14/02

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

02 CV 10249 RCL

1. TITLE OF CASE (NAME OF FIRST PARTY ON EACH SIDE ONLY)
Boston Scientific Corp. v. Johnson & Johnson, Inc.

2. CATEGORY IN WHICH THE CASE BELONGS BASED UPON THE NUMBERED NATURE OF SUIT CODE LISTED ON THE CIVIL COVER SHEET. (SEE LOCAL RULE 40.1(A)(1)).

- I. 160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.
- II. 195, 368, 400, 440, 441-444, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950. *Also complete AO 120 or AO 121 for patent, trademark or copyright cases
- III. 110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.
- IV. 220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.
- V. 150, 152, 153.

FILED
IN CLERKS OFFICE
2002 FEB 14 11:07
U.S. DISTRICT COURT
DISTRICT OF MASS.

3. TITLE AND NUMBER, IF ANY, OF RELATED CASES. (SEE LOCAL RULE 40.1(G)). IF MORE THAN ONE PRIOR RELATED CASE HAS BEEN FILED IN THIS DISTRICT PLEASE INDICATE THE TITLE AND NUMBER OF THE FIRST FILED CASE IN THIS COURT.

4. HAS A PRIOR ACTION BETWEEN THE SAME PARTIES AND BASED ON THE SAME CLAIM EVER BEEN FILED IN THIS COURT?

YES NO

5. DOES THE COMPLAINT IN THIS CASE QUESTION THE CONSTITUTIONALITY OF AN ACT OF CONGRESS AFFECTING THE PUBLIC INTEREST? (SEE 28 USC §2403)

YES NO

IF SO, IS THE U.S.A. OR AN OFFICER, AGENT OR EMPLOYEE OF THE U.S. A PARTY?

YES NO

6. IS THIS CASE REQUIRED TO BE HEARD AND DETERMINED BY A DISTRICT COURT OF THREE JUDGES PURSUANT TO TITLE 28 USC §2284?

YES NO

7. DO ALL OF THE PARTIES IN THIS ACTION, EXCLUDING GOVERNMENTAL AGENCIES OF THE UNITED STATES AND THE COMMONWEALTH OF MASSACHUSETTS ("GOVERNMENTAL AGENCIES"), RESIDING IN MASSACHUSETTS RESIDE IN THE SAME DIVISION? - (SEE LOCAL RULE 40.1(D)).

YES NO

A. IF YES, IN WHICH DIVISION DO ALL OF THE NON-GOVERNMENTAL PARTIES RESIDE?

EASTERN DIVISION CENTRAL DIVISION WESTERN DIVISION

B. IF NO, IN WHICH DIVISION DO THE MAJORITY OF THE PLAINTIFFS OR THE ONLY PARTIES, EXCLUDING GOVERNMENTAL AGENCIES, RESIDING IN MASSACHUSETTS RESIDE?

EASTERN DIVISION CENTRAL DIVISION WESTERN DIVISION

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Dominic E. Massa, Esq.

ADDRESS Hale and Dorr LLP, 60 State Street, Boston, MA 02109-9987

TELEPHONE NO. (617) 526-6386