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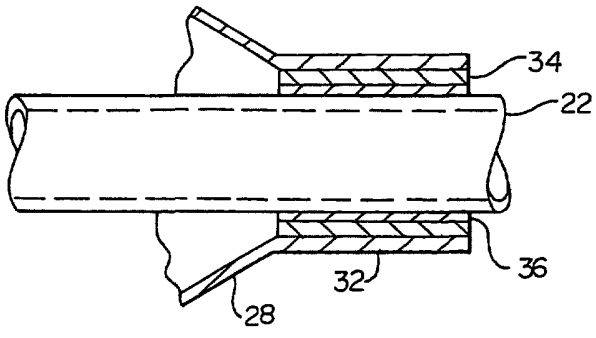
(54) Title: CATHETER HAVING AN IMPROVED BALLOON-TO-CATHETER BOND



(57) Abstract: A tie layer insert is disclosed to aid in bond formation between an expandable balloon and a distal portion of a catheter shaft. The tie layer insert can be a single layer applied directly to the structural surfaces, or alternatively, the tie layer may be incorporated into a preformed polymeric insert. In the latter embodiment, the polymeric insert may include several layers of polymeric material. During the manufacturing process, the preformed polymeric insert is positioned between the distal portion of the expandable balloon and the catheter shaft. The entire distal region is then processed to form a sealably bonded expandable balloon to the distal end of the catheter shaft.

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CATHETER HAVING AN IMPROVED BALLOON-TO-CATHETER BOND

Technical Field

The present invention relates generally to the field of medical devices having an expandable balloon disposed proximate the distal portion of a shaft. More specifically, the present invention relates to improved physical properties, processing and performance of a bond formed between the waist of an expandable balloon and the portion of the tubular member of a catheter shaft to which it is bonded.

Background of the Invention

Intravascular diseases are commonly treated by relatively non-invasive techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA). These therapeutic techniques are well known in the art and typically involve the use of a balloon catheter with a guidewire, possibly in combination with other intravascular devices such as stents. A typical balloon catheter has an elongate shaft with a balloon attached proximate the distal end and a manifold attached to the proximal end. In use, the balloon catheter is advanced over the guidewire such that the balloon is positioned adjacent a restriction in a diseased vessel. The balloon is then inflated and the restriction in the vessel is opened.

There are three basic types of intravascular catheters for use in such procedures including fixed-wire (FW) catheters, over-the-wire (OTW) catheters and single-operator-exchange (SOE) catheters. The general construction and use of FW, OTW and SOE catheters are all well known in the art. An example of an OTW catheter may be found in commonly assigned U.S. Patent No. 5,047,045 to Arney et al. An example of an SOE balloon catheter is disclosed in commonly assigned U.S. Patent No. 5,156,594 to Keith.

Manufacturers are constantly in search of materials and designs that enhance the performance of their intravascular catheters. One particular source of improvement has been the incorporation of performance enhancing polymeric materials into their intravascular catheter designs. Certain polymeric materials enable the catheter to be more lubricious, thereby aiding the advancement of a guidewire within the body of the catheter. Other polymeric materials make particular sections of the catheter more rigid, thereby aiding the catheter in its advancement through the

patient's anatomy. The primary drawback to using specialized polymeric materials is that often the individual polymers forming the structural components are incompatible with one another. This is a particular problem for manufacturers who must combine the individual components to form a single operable intravascular catheter.

One solution to the use of incompatible polymers has been to place a layer between the two incompatible polymeric structural components that is sufficiently bondable to either component. In effect, this distinct layer "ties" the two structural components together, thereby receiving its commonly referred to name as a tie layer. Tie layers have been extruded over the length of intravascular catheters. This added layer, regardless of its thickness, affects the performance characteristics of an intravascular catheter shaft incorporating the tie layer.

Several performance characteristics that are important to intravascular catheters include pushability, trackability and crossability. Pushability refers to the catheter's ability to transmit force from the proximal end of the catheter to the distal end of the catheter. Trackability refers to the catheter's ability to navigate tortuous vasculature. Crossability refers to the catheter's ability to navigate the balloon catheter across narrow restrictions in the vasculature, such as stenosed vessels or fully and partially deployed stents. All of the above performance characteristics are interrelated and depend on the design of the catheter shaft over its length.

It is a manufacturing goal to reduce the profile of a manufactured intravascular catheter. A reduced profile catheter is less likely to positively engage the surrounding vascular walls. Additionally, a reduced profile catheter is also more likely to cross and re-cross over a stenosed region or a deployed stent.

Summary of the Invention

The present invention maximizes the benefits of a tie layer in a balloon catheter by utilizing only a discreet length of tie layer where needed on the catheter. In particular to the present invention, a discreet length tie layer is disclosed to aid in bond formation between an expandable balloon and a distal portion of a catheter shaft. However, the discreet tie layer can be utilized at any bond on the catheter shaft where improved bonding is needed. The tie layer disclosed in the present invention can be a single layer applied directly to the structural surfaces, or alternatively, the tie layer may be incorporated into a preformed polymeric insert. In the latter embodiment, the

polymeric insert may include several layers of polymeric material, each acting as or including the tie layer.

During the manufacturing process, the preformed polymeric insert is positioned around the outside surface of the catheter shaft proximate the distal end of the shaft, and a proximal or distal portion of a waist of the balloon overlays the preformed polymeric insert. The entire region is then processed to sealably bond the portion of the expandable balloon to the portion of the catheter shaft.

Brief Description of the Drawings

The appended claims particularly point out and distinctly claim the subject matter of this invention. The various objects, advantages and novel features of this invention will be more fully apparent from a reading of the following detailed description in conjunction with the accompanying drawings in which like reference numerals refer to like parts, and in which:

Figure 1 is a plan view of a balloon dilatation catheter in accordance with the present invention having a distal tip region;

Figure 2 is an enlarged partial cross-sectional view of the distal tip region of the balloon dilatation catheter of Figure 1;

Figure 3 is an enlarged partial cross-sectional view of the area surrounding the distal balloon waist of the balloon dilatation catheter of Figure 1; and

Figure 4 is perspective view of a cut away portion of tubular material depicting a series of coaxially disposed layers.

Detailed Description of the Preferred Embodiments

The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered identically. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Examples of construction, materials, dimensions, and manufacturing processes are provided for selected elements.

Referring now to the drawings, Figure 1 is a plan view of an over-the-wire (OTW) balloon catheter, which is representative of one type of catheter that can incorporate the present invention. Other intravascular catheter embodiments are additionally suitable without deviating from the spirit and scope of the present invention. For example, intravascular catheters suitable for incorporating the present

invention also include fixed-wire (FW) catheters and single-operator-exchange (SOE) catheters.

The balloon catheter 10 includes a shaft assembly 12 and a balloon assembly 14 connected proximate the distal end of the shaft assembly 12. A conventional OTW-type manifold assembly 16 is connected to the proximal end of the shaft assembly 12. The proximal end of the shaft assembly 12 extends into the manifold assembly 16 and is bonded to the shaft assembly 12. Manifold ports 18 and 20 extend from the manifold assembly 16 for attaching and fluidly connecting ancillary apparatus to a lumen extending through the balloon catheter 10. Each manifold port includes a lumen terminating into either a common lumen or a dedicated lumen extending within the shaft assembly 12 (e.g., a guidewire lumen). Functionally, the manifold assembly 16 additionally provides a convenient place for a physician to apply longitudinal or rotational forces in order to manipulate the catheter 10 during a medical procedure.

Referring specifically to Figure 1, the manifold assembly 16 illustrated includes two luer-type manifold ports 18 and 20. In alternative embodiments, the union between the manifold assembly 16 and ancillary medical devices (not shown) is completed using alternative connectors. A polymeric strain relief 24 can be snap-fit to the manifold assembly 16 in a preferred embodiment, and the shaft assembly 12 extends into the manifold assembly 16 through the strain relief 24.

In a preferred embodiment, the shaft assembly 12 comprises an outer tubular member 26 which is co-axially disposed about an inner tubular member 22 to define an annular inflation lumen therebetween over a substantial portion of the length of the catheter 10. Generally, the outer tubular member 26 in preferred embodiments has an outer diameter ranging from 0.040 inches to 0.045 inches with a wall thickness ranging from 0.0028 inches to 0.0044 inches. Materials used to form the outer tubular member 26 may vary to achieve the stiffness desired for the shaft assembly 12. Nylon and polyamides such as DURETHAN (available from Bayer) are particularly suitable for rigid outer tubular members. Other suitable materials for a rigid outer tubular member include polyetheretherketone (PEEK), polyimide (PI), and polyetherimide (PEI). Rigidity may additionally be imparted to the outer tubular member 26 by incorporating a braid on or within the tubular member. Polyether block amide (PEBA) is a relatively flexible polymeric material having a durometer of approximately 70D and could also be utilized for portions of the shaft assembly 12.

Finally, the use of a polyamide such as CRISTAMID (available from Elf Atochem) imparts a slightly less rigid durometer than the rigid polyamides and slightly greater than the PEBA material, making it suitable for certain applications.

The inner tubular member 22 defines a guidewire lumen, which provides a passage for a guidewire (not shown). The inner tubular member 22 is generally made of polyethylene such as Marlex HDPE in preferred embodiments. In alternative embodiments, the inner tubular member 22 is made from or lined with a lubricious material such as polytetrafluoroethylene (PTFE). In one preferred embodiment, at the proximal end of the inner tubular member 22, the inner tubular member 22 has an outside diameter ranging from 0.024 inches to 0.026 inches, and most preferably about 0.025 inches. The inner diameter of the inner tubular member 22 preferably measures approximately 0.018 inches to 0.0195 inches, allowing for use of a 0.014-inch guidewire. The inner tubular member 22 has a wall thickness ranging from 0.0026 inches to 0.004 inches, and most preferably about 0.0032 inches. The outside diameter to wall thickness ratio must be sufficiently small to minimize the propensity for the shaft assembly 12, and more specifically, the inner tubular member 22 from kinking.

At the distal end of the shaft assembly 12 is a balloon assembly 14. The balloon assembly 14 includes an expandable balloon 28 having a proximal balloon waist 30 and a distal balloon waist 32. The proximal balloon waist 30 affixes the expandable balloon 28 to the outer tubular member 26 near its distal end by means of an adhesive, or alternatively, or in combination with, RF, laser or other thermal bonding. The distal balloon waist 32, as shown best in Figure 2, similarly affixes the expandable balloon 28 to the inner tubular member 22 near its distal end by means of an adhesive bond and/or an RF, laser or other thermal bond. This particular balloon assembly 14 arrangement allows the expandable balloon 28 to be in fluid communication with the annular inflation lumen defined between the outer tubular member 26 and the inner tubular member 22. In preferred embodiments, a portion of the inner tubular member 22 extends distally beyond the distal balloon waist 34.

As described in detail above, the inner tubular member 22 is preferably made of a polyethylene material such as Marlex HDPE. The expandable balloon 28, on the other hand, is preferably made of a PEBA material such as PEBAX. These two materials are sufficiently dissimilar in chemical composition to affect the bonding between them. In particular, the dissimilarities between the two material

compositions may affect certain thermal bonding procedures. As a result, the effectiveness of the bond between the two structural components having been formed from these certain thermal bonding procedures may be structurally compromised. Likewise, similar bonding effects may be seen if materials such as nylon, Hytrel, Arnitel or other polymers are selected as the balloon material.

Under certain circumstances, bonding failure may result in the separation of a portion of the distal balloon waist 32 from the inner tubular member 22. During a procedure, such separation may result in an inflation fluid leak when such fluid is supplied. The balloon dilation catheter 10 is deployed once the catheter is properly advanced and positioned across a targeted site within a patient's anatomy. When in position, inflation fluid is directed through the catheter's annular inflation lumen into the expandable balloon 28. As the pressure within the expandable balloon 28 increases, fluid trapped within the expandable balloon 28 causes the expandable balloon's inflation. A fissure in the bond sealing the distal balloon waist 32 to the inner tubular member 22 would result in a leak, thereby decreasing the inflation efficiency of the expandable balloon 28.

As with the distal balloon waist bond, bonding may be more difficult between the proximal balloon waist 30 and the portion of shaft to which it is affixed depending upon the selection of each polymeric material. The present invention is discussed in detail with respect to the distal waist bond, but is understood to be equally applicable to the proximal waist bond when dissimilar polymers are selected for the balloon and portion of the shaft to which the proximal waist is affixed.

With current manufacturing processes, the bonds formed between the distal balloon waist 32 and the inner tubular member 22 or proximal waist 30 and outer tubular member 26 are sufficiently strong to ensure a patient's safety during a medical procedure. The bonding between these two structural components, however, is a subject of constant improvement. Achieving the strongest bond possible when two dissimilar materials form their respective structural components is imperative to the success of the medical device and the safety of the patient. As such, an improved bond is desired to further curb the concerns of both practitioners and patients alike regarding the functionality and safety of catheters using this design.

Success in bonding the distal balloon waist 32 to the inner tubular member 22 or the proximal waist 30 to the outer tubular member 26 has been traditionally achieved using an adhesive. In these traditional methods, the adhesive is first applied

between the two components. The two components are then bonded together to form the completed sealed union. There exist drawbacks, however, to using adhesives in such bonding procedures. For example, adhesives that are suitable for joining the two catheter components are commonly associated with long curing times, sensitivity to ambient conditions (including humidity and temperature), and the need for extensive surface treatment. As a result, bonding between the distal balloon waist 32 and the inner tubular member 22 and the proximal balloon waist 30 and outer tubular member 26 is typically time and labor intensive.

Adhesives common in catheter manufacturing also often take hours to cure. Moreover, procedures for bonding the balloon waist to the tubular member are highly dependent on operator skill. Assemblers must initially apply the appropriate amount of adhesive between the two catheter components to insure proper adhesion. In certain embodiments, the assembler may then sculpt a backfill onto the bond using additional adhesive to provide a smooth transition. Assembler errors and curing times may result in substantial delays. Delays in catheter production increase the manufacturer's costs.

The present invention identifies the use of a selected group of polymeric materials that aid in bonding the distal balloon waist 32 to the inner tubular member 22 or the proximal balloon waist 30 to the outer tubular member 26. In effect, the selected group of polymeric materials "ties" the two structural components having differing material compositions together. Therefore, hereinafter, the layer of polymeric material disposed between either the distal balloon waist 32 and the inner tubular member 22 or the proximal waist 30 and the outer tubular member 26 is called a tie layer.

Tie layers suitable for the present invention possess a bonding affinity to both materials forming the distal balloon waist 32 of the expandable balloon 28 and the inner tubular member 22. More specifically, in preferred embodiments, the tie layer material of the present invention is selected because it has a bonding affinity to polyethylene, PTFE, polyamide, PEBA, nylon, Hytrel, Arnitel or other suitable polymers used in a catheter's construction. The first two materials are preferred materials for forming the inner tubular member 22 and the latter materials are preferred materials for forming the distal balloon waist 32. Tie layer materials particularly suitable for the present invention include a linear low density polyethylene such as Plexar. The tie layer material may be heat-shrinkable and first

heat shrunk to conform to the shaft, followed by bonding of the balloon waist. Alternative tie layer materials suitable for bonding materials forming the inner tubular member 22 to materials forming the distal balloon waist 32, being known in the art, are also incorporated as within the spirit and scope of the present invention.

Although the difficulty in bonding the distal balloon waist 32 to the inner tubular member 22 has been highlighted, other bonding areas along the catheter may be aided through tie layers. For example, a segment of tie layer may be placed between the proximal balloon waist 30 and the outer tubular member 26 to aid in bonding the expandable balloon 28 to the catheter shaft 12. As with the bonding between the distal balloon waist 32 and the inner tubular member 22, there may exist some bonding incompatibility between the materials comprising the proximal balloon waist 30 and the outer tubular member 26. A discreet section of tie layer material positioned between these two structural components may alleviate these bonding difficulties. Thus, the following sections discuss the bonding incompatibility between the distal balloon waist 32 and the inner tubular member 22 for illustrative purposes only, as other portions experiencing bonding difficulties may also be treated with the specific and precise placement of a tie layer.

Unlike traditional bonding procedures, discussed in detail above, a tie layer permits manufacturers to form a secured bond between the distal balloon waist 32 and the inner tubular member 22 using thermal bonding processing alone. Adhesives, although they may still be used, are not required to form a secure bond. Thus, the inclusion of a tie layer when attaching the balloon assembly to the catheter shaft may decrease consumer costs by reducing the errors and curing times associated with traditional bond processing procedures.

Figure 3 shows an enlarged cross-sectional view of a distal tip region of a balloon dilation catheter 10 having a tie layer disposed therein. More specifically, two polymeric layers, a first layer 34 and a second layer 36, are shown disposed between the distal balloon waist 32 and the inner tubular member 22. Although two layers are specifically illustrated, a single tie layer is sufficient to form a sealably secure bond between the distal balloon waist 32 and the inner tubular member 22. Likewise, more than two tie layers may be disposed between the distal balloon waist 32 and the inner tubular member 22 in order to achieve a particular bonding and style configuration. Choosing the appropriate layer configuration often depends upon the

specific materials utilized for the various structural components, as well as the desired shape for the distal tip of the catheter.

In certain embodiments, both the first layer 34 and the second layer 36 may comprise tie layer materials. For example, the first tie layer 34, because of its positioning, may possess a greater bonding affinity to materials forming a distal balloon waist 32. Whereas the second tie layer 36 may possess a greater bonding affinity to materials forming an inner tubular member 22. Although either the first 34 or the second 36 tie layer may possess a bonding affinity to both the distal balloon waist 32 and the inner tubular member 22, the layer distribution as described may provide the maximum bonding efficiency for the region as a whole.

Manufacturing a catheter distal tip in accordance with the present invention begins by first inserting a mandrel (not shown) into the distal end of the inner tubular member 22. The insertion of the mandrel insures against deformation of the catheter tip during the subsequent thermal processing events. Once the mandrel is inserted, the tie layers, preferably preformed as an insert, are disposed between the inner tubular member 22 and the distal balloon waist 32. In one embodiment, each tie layer is disposed over the inner tubular member 22, or alternatively, upon a preceding tie layer. The properly positioned tie layer is then thermally processed individually. In preferred embodiments, the tie layer insert is substantially the same length as the distal waist of the balloon, although it can be slightly longer or shorter and still provide adequate bonding. The short segment tie layer discreet to the balloon waist area provides a distinct advantage over the user of a tie layer over a greater length of the shaft in that the tie layer affects stiffness of the area in which it is used.

In an alternative embodiment, multiple individual tie layers are disposed between the inner tubular member 22 and the distal balloon waist 32. Once the individual tie layers are properly positioned, they are all then thermally processed together, forming an effective fluid tight seal in the distal tip region of the catheter 10.

In yet another embodiment, a single polymeric insert 40 comprising a plurality of tie layers is disposed between the inner tubular member 22 and the distal balloon waist 32. The tie layers within this polymeric insert 40 are thermally bonded during their extrusion process. In a preferred embodiment, the polymeric insert 40 is formed by extruding the plurality of tie layers into a tubular form. Multiple polymeric inserts 40 are then derived from the single tubular extrusion 42 by cutting the tubular

extrusion 42 at appropriate increments. Further, the polymeric inserts may be sized to fit the shaft utilizing a necking process after extrusion.

Figure 4 depicts a segment of the tubular extrusion 42 in phantom. Along the length of the tubular extrusion 42, a cut away portion of the tubular extrusion 42 is highlighted. This highlighted portion depicts a resulting polymeric insert 40 having a plurality of coaxially disposed tie layers 34 and 36. This polymeric insert 40 is then disposed between the inner tubular member 22 and the distal balloon waist 32. Once properly positioned, the distal balloon waist 32, the polymeric insert 40 and the inner tubular member 22 are thermally processed together to form a fluid tight seal in the distal tip region of a catheter 10.

Numerous characteristics and advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size and ordering of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

WHAT IS CLAIMED IS:

1. A balloon catheter assembly comprising:

a first tubular member having a proximal portion and a distal portion with a lumen extending the length therein;

a discreet length of tie layer insert disposed over a portion of the distal segment of the first tubular member; and

a balloon having a proximal portion, a distal portion and an expandable region therebetween, wherein at least one of the proximal portion or the distal portion of the balloon is affixed to the discreet length of tie layer.

2. The balloon catheter assembly of claim 1, wherein a second tubular member is disposed within the lumen of the first tubular member and includes a distal portion extending distally beyond the first tubular member with the proximal portion of the balloon affixed to the distal portion of the first tubular member and the distal portion of the balloon is affixed to the distal portion of the second tubular member.

3. The balloon catheter assembly of claim 2, wherein the first tubular member is disposed within at least a portion of a second tubular member having a distal portion terminating proximal of a distal end of the first tubular member with the proximal portion of the balloon affixed to the distal portion of the second tubular member and a distal portion of the balloon affixed to the distal portion of the first tubular member.

4. A balloon catheter comprising:

a first tubular member having a lumen extending the length therein;

a second tubular member coaxially disposed within at least a portion of the first tubular member with a distal segment extending distally beyond a distal end of the first tubular member;

a tie layer insert disposed over a portion of the distal segment of the second tubular member; and

a balloon having a proximal portion, a distal portion and an expandable region therebetween, the expandable region of the balloon being in fluid communication with the lumen of the first tubular member, further wherein at least a portion of the

proximal portion of the balloon is affixed to the first tubular member and at least a portion of the distal portion of the balloon is affixed to the tie layer.

5. The balloon catheter of claim 4, wherein the balloon is manufactured from polyether block amide.

6. The balloon catheter of claim 5, wherein the second tubular member is manufactured from high density polyethylene.

7. The balloon catheter of claim 4, wherein the first tubular member and the second tubular member extend co-axially over substantially the entire length of the balloon catheter.

8. The balloon catheter of claim 4, wherein the material of the tie layer insert has a bonding affinity with both the first tubular member and the second tubular member.

9. The balloon catheter of claim 8, wherein the tie layer insert is manufactured from linear low density polyethylene.

10. The balloon catheter of claim 4, wherein the tie layer insert has more than one layer.

11. A balloon catheter comprising:

a first tubular member having a lumen extending the length therein;

a second tubular member coaxially disposed within at least a portion of the first tubular member with a distal segment extending distally beyond a distal end of the first tubular member;

a polymeric insert disposed over and affixed to only a portion of the distal segment of the second tubular member; and

a balloon having a proximal portion, a distal portion and an expandable region therebetween, the expandable region of the balloon being in fluid communication with the lumen of the first tubular member, further wherein the proximal portion of the balloon is affixed to the first tubular member at a first attachment site and the distal portion of the balloon is affixed to the polymeric insert at a second attachment site.

12. The balloon catheter of claim 11, wherein the balloon is manufactured from polyether block amide.

13. The balloon catheter of claim 12, wherein the second tubular member is manufactured from high density polyethylene.

14. The balloon catheter of claim 11, wherein the polymeric insert is cylindrical in shape.

15. The balloon catheter of claim 14, wherein the polymeric insert comprises more than one layer.

16. The balloon catheter of claim 14, wherein the polymeric insert is manufactured from a functional polymer.

17. A balloon catheter comprising:

a first tubular member having a lumen extending the length therein;

a second tubular member coaxially disposed within at least a portion of the first tubular member with a distal segment extending distally beyond a distal end of the first tubular member;

a polymeric insert disposed over at least a portion of the distal segment of the second tubular member; and

a balloon having a proximal balloon waist, a distal balloon waist and an expandable region therebetween, the balloon further comprising a polymeric material having a bonding affinity with both the first tubular member and the polymeric insert while lacking a bonding affinity with the second tubular member, further wherein the proximal balloon waist of the balloon is affixed to the first tubular member and the distal balloon waist of the balloon is affixed to the polymeric insert.

18. The balloon catheter of claim 17, wherein the balloon is manufactured from polyether block amide.

19. The balloon catheter of claim 18, wherein the second tubular member is manufactured from high density polyethylene.

20. The balloon catheter of claim 17, wherein the polymeric insert comprises more than one layer.

21. The balloon catheter of claim 20, wherein the polymeric insert comprises linear low density polyethylene.

22. A process for improved bonding between an expandable balloon and a catheter shaft, the process comprising the steps of:

providing a catheter shaft having an outer tubular member and an inner tubular member, wherein the inner tubular member has a proximal end, a distal end and a lumen extending therein, and further wherein the inner tubular member is coaxially disposed within at least a portion of the outer tubular, with a portion of the inner tubular member extending distally beyond the distal end of the outer tubular member;

providing a polymeric insert;

disposing the polymeric insert over a portion of the inner tubular member extending distally beyond the distal end of the outer tubular member;

providing an expandable balloon having a first end, a second end and an expandable region therebetween;

affixing the first end of the expandable balloon to a portion of the outer tubular member; and

affixing the second end of the expandable balloon to a portion of the polymeric insert.

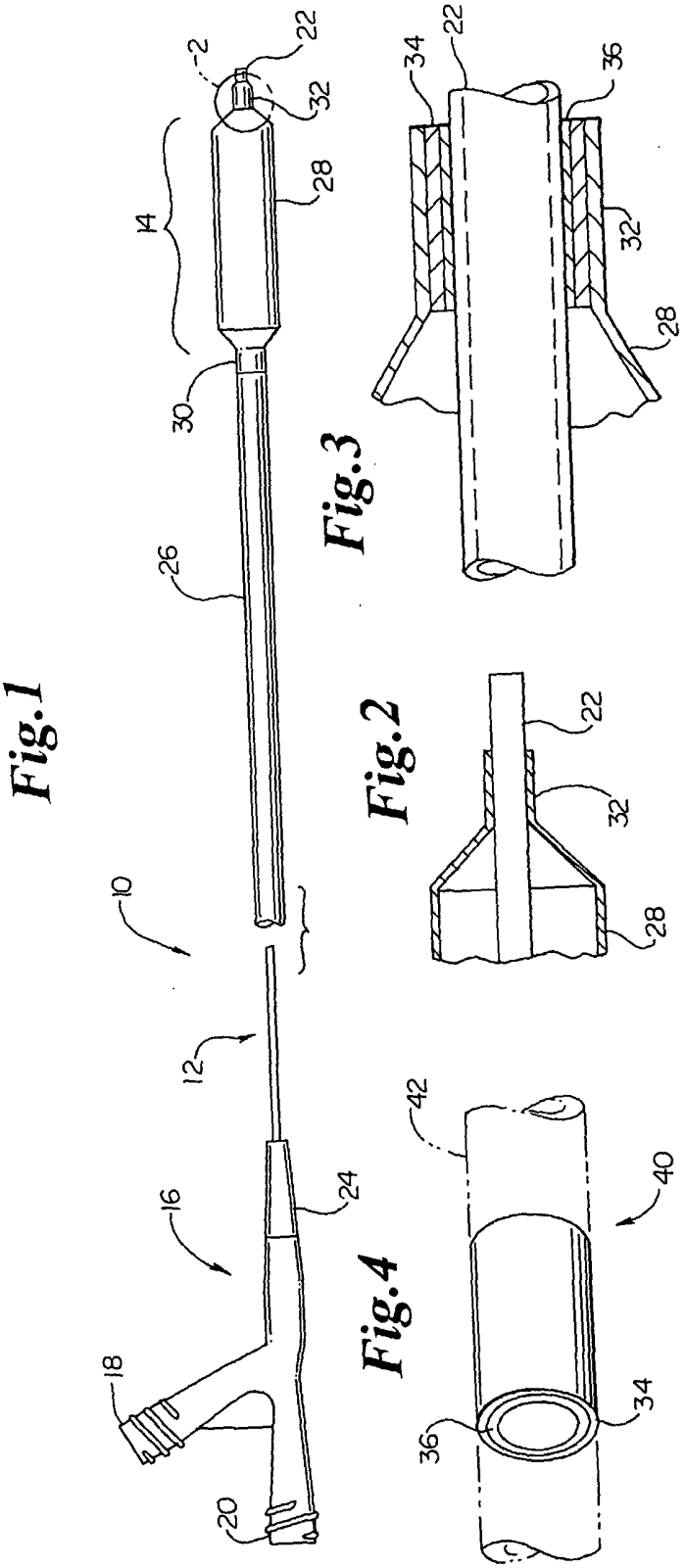

Fig.1

Fig.2

Fig.3

Fig.4

INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/US 02/30404

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/10 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 179 811 B1 (FUGOSO MAURICIO L ET AL) 30 January 2001 (2001-01-30) column 2, line 66 -column 3, line 15; figures 1,2,5	1-4,7,8, 11,14
X	EP 0 846 472 A (MEDTRONIC INC) 10 June 1998 (1998-06-10) column 3, line 49 -column 7, line 2; figures 1,2	1-4,7,8, 11,14
X	US 6 325 814 B1 (DUSBABEK ANDREW J ET AL) 4 December 2001 (2001-12-04) figures 13,14	1-4,7,8, 11,14
X	US 5 047 045 A (BURNS MATTHEW M ET AL) 10 September 1991 (1991-09-10) column 3, line 50 -column 4, line 8	1-4,7,8, 11,14
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
17 April 2003	07/05/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Cuiper, R

INTERNATIONAL SEARCH REPORT

In tional Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 553 960 A (ADVANCED CARDIOVASCULAR SYSTEM) 4 August 1993 (1993-08-04) column 5, line 15 - line 26; figures 1,2 ---	1
A	US 5 769 819 A (SCHWAB SHARON ET AL) 23 June 1998 (1998-06-23) figure 1 -----	1-16

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int[illegible]onal Application No
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