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(54) **COMBINED SHAPED BALLOON AND STENT PROTECTOR**

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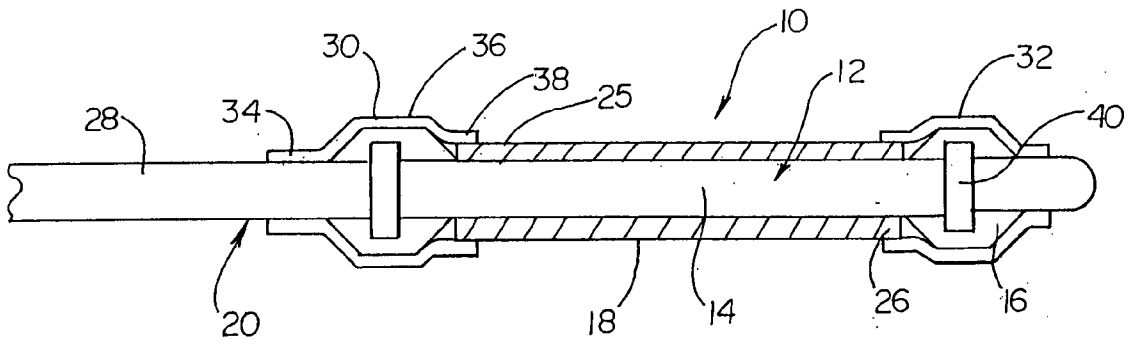
(52) **U.S. Cl.** **623/1.12**

(57) **ABSTRACT**

A stent delivery catheter comprising a catheter shaft and balloon engaged thereto. The balloon being inflatable from a first inflation state to a first expanded state as well as to a second expanded state. The balloon having a stent mounting region for retaining and delivery of a stent therefrom, and at least one adjacent region. The stent mounting region having a first diameter and the at least one adjacent region having a second diameter. In the first inflation state the first diameter being less than the second diameter. In the first expanded state the first diameter being no greater than the second diameter. In the second expanded state the first diameter being greater than the second diameter. The stent being retained on the stent mounting region by engagement of the at least one adjacent portion and at least one retractable stent retaining sleeve.



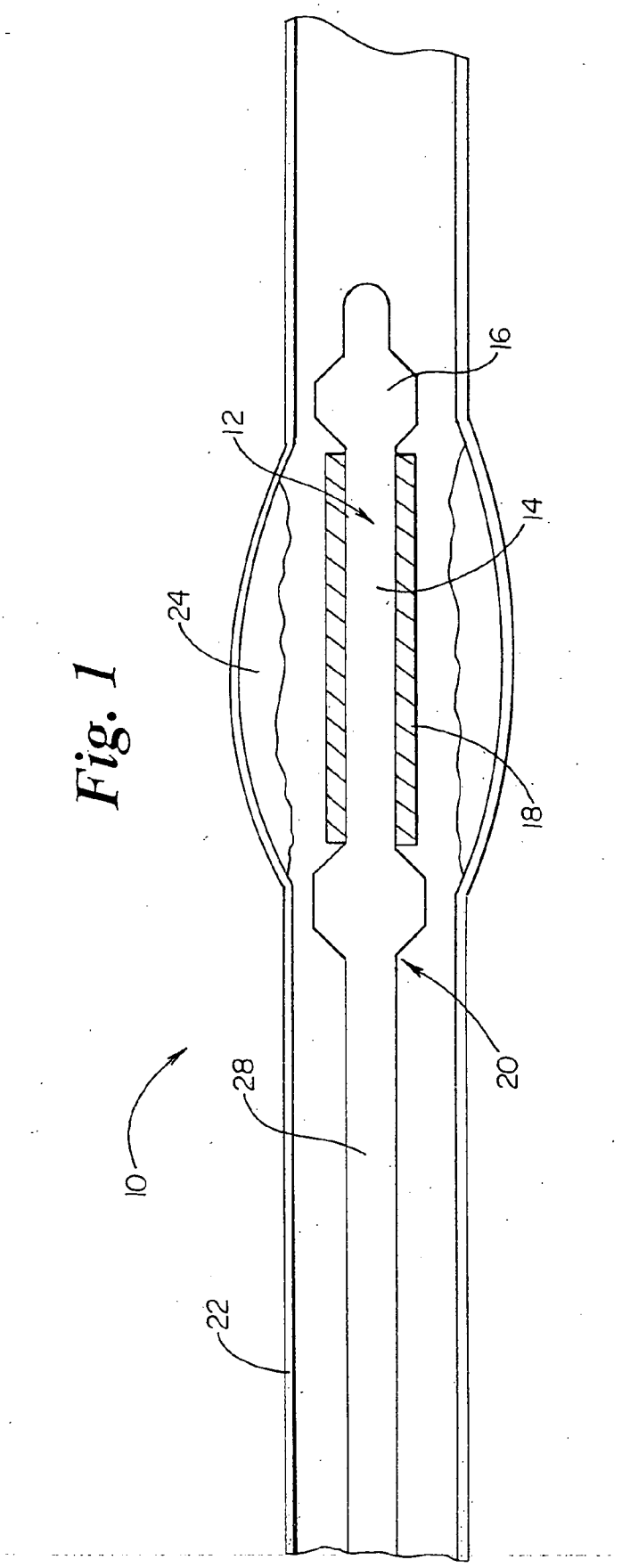


Fig. 1

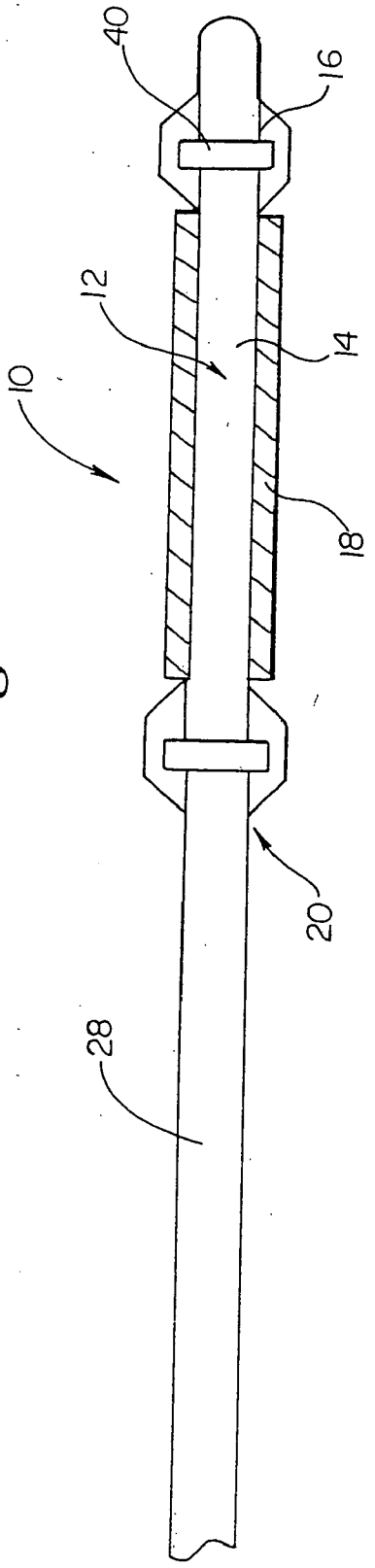


Fig. 2

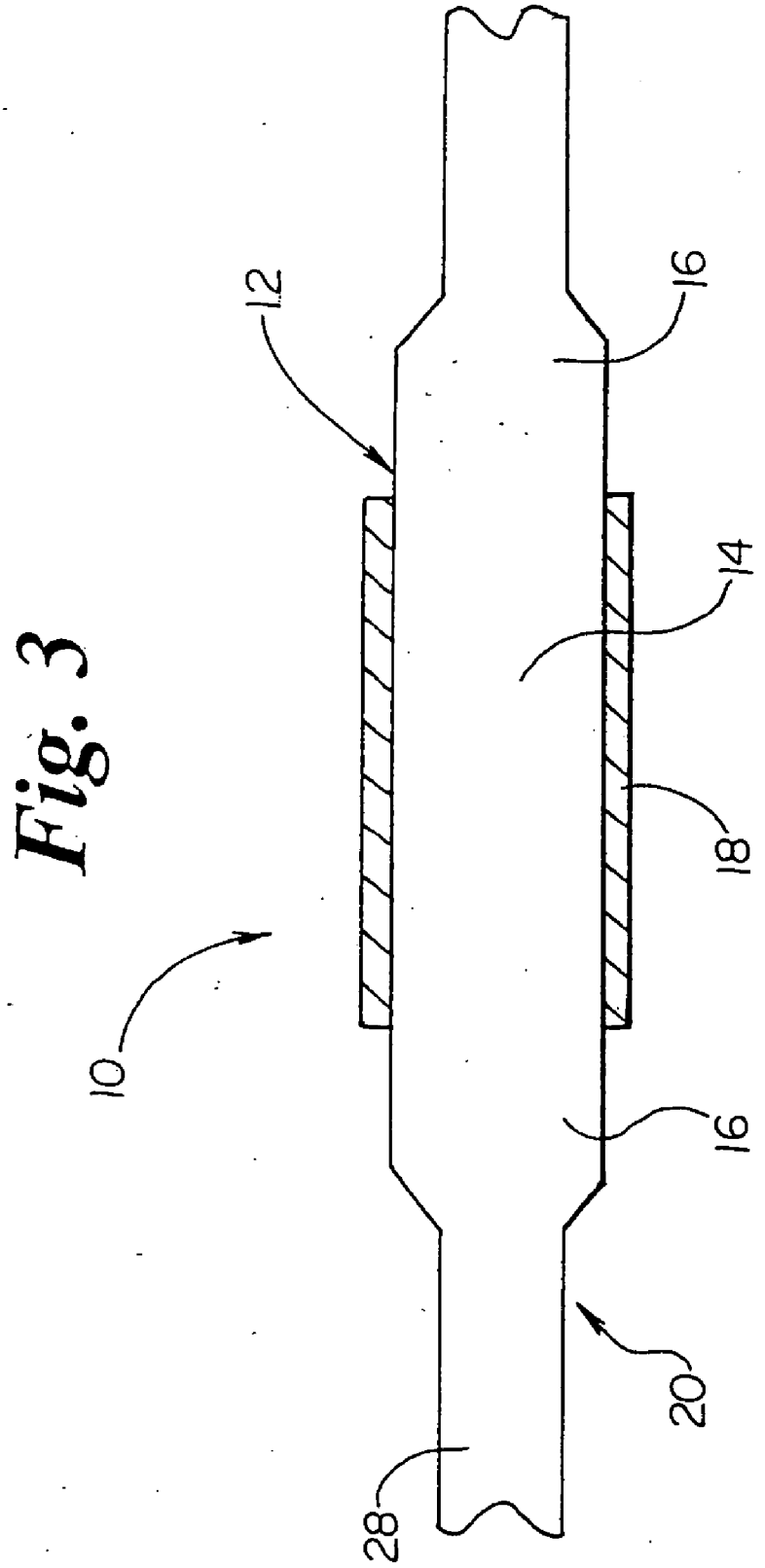


Fig. 3

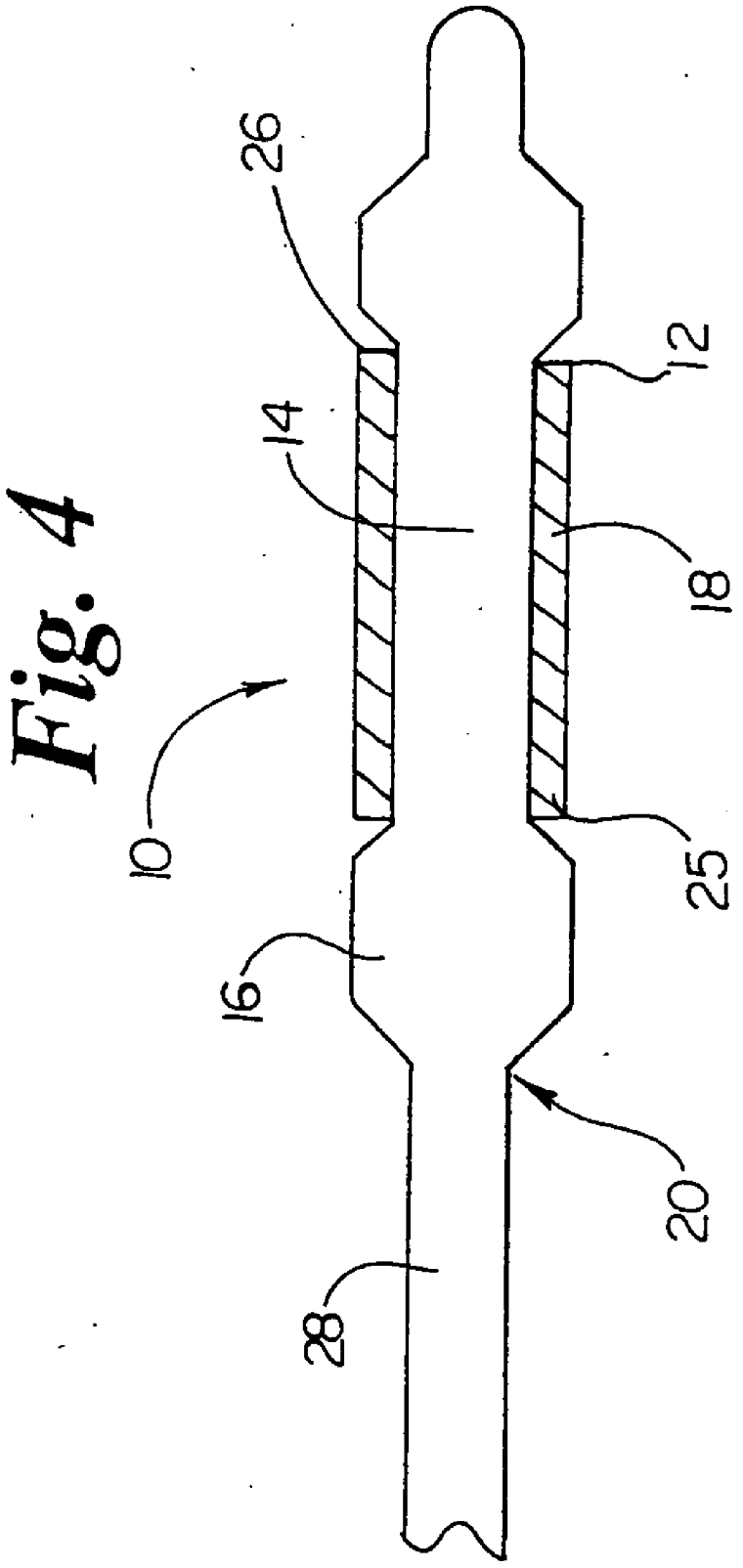


Fig. 4

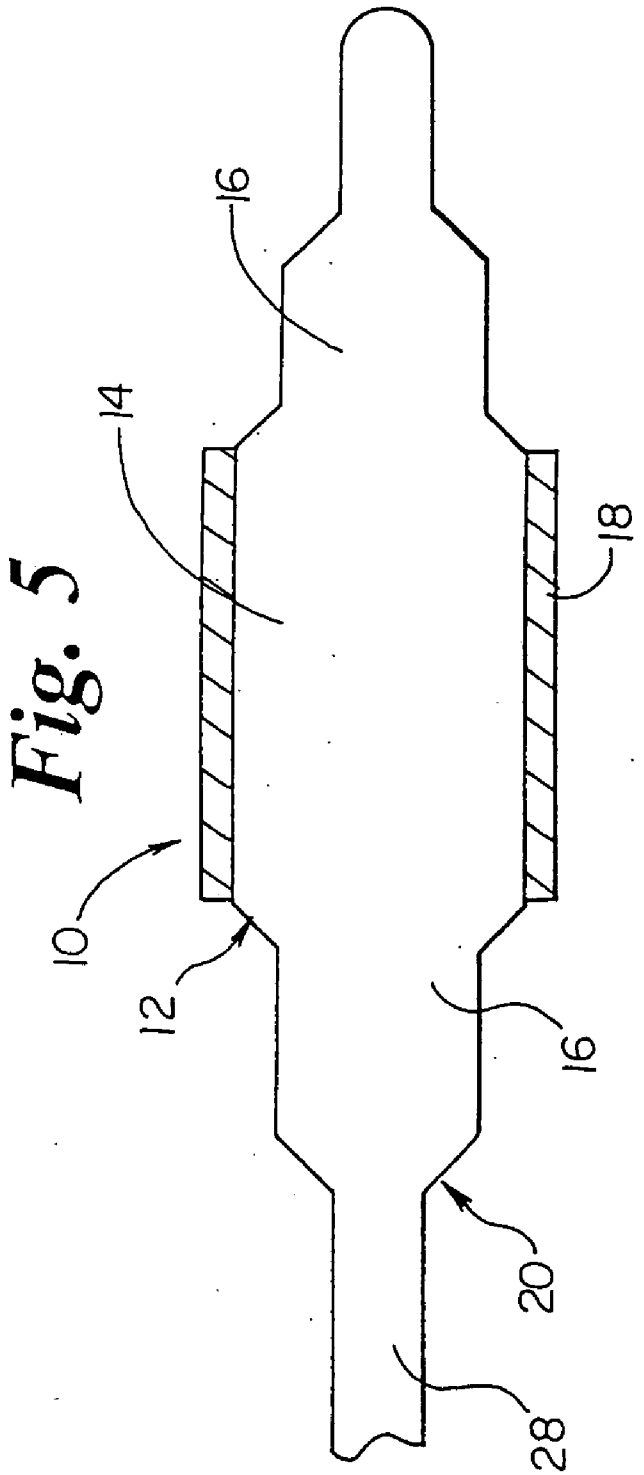


Fig. 5

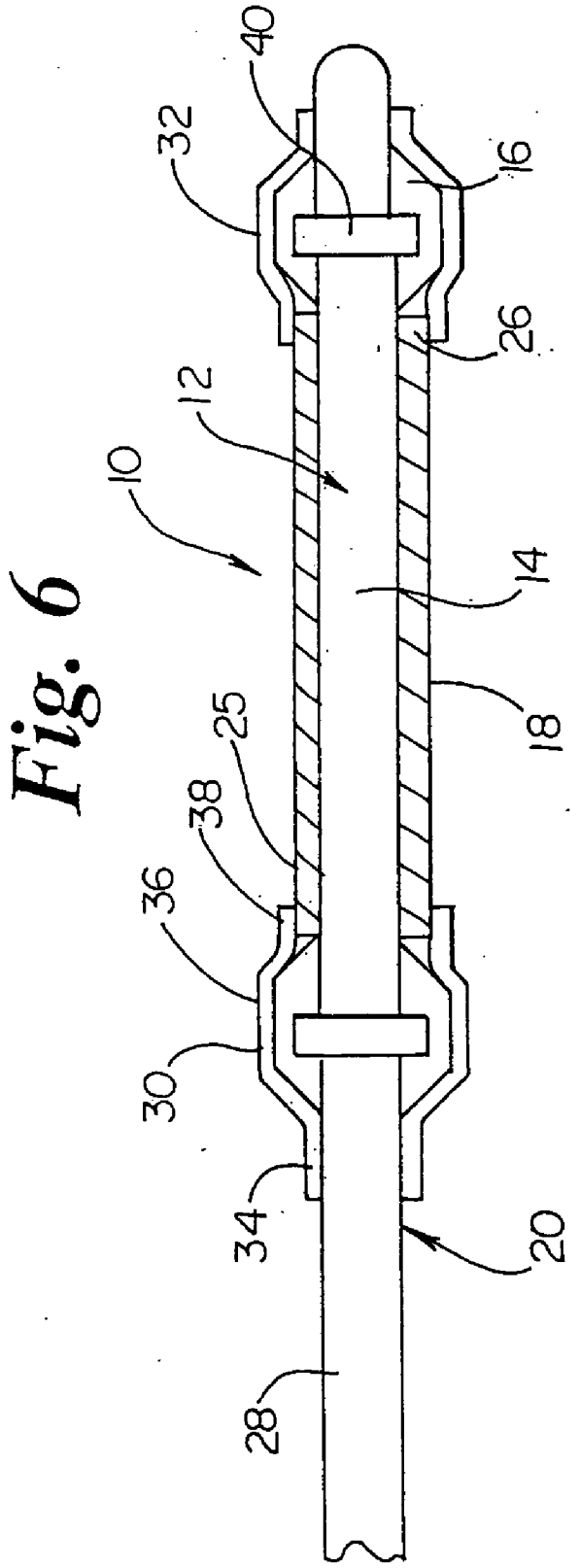
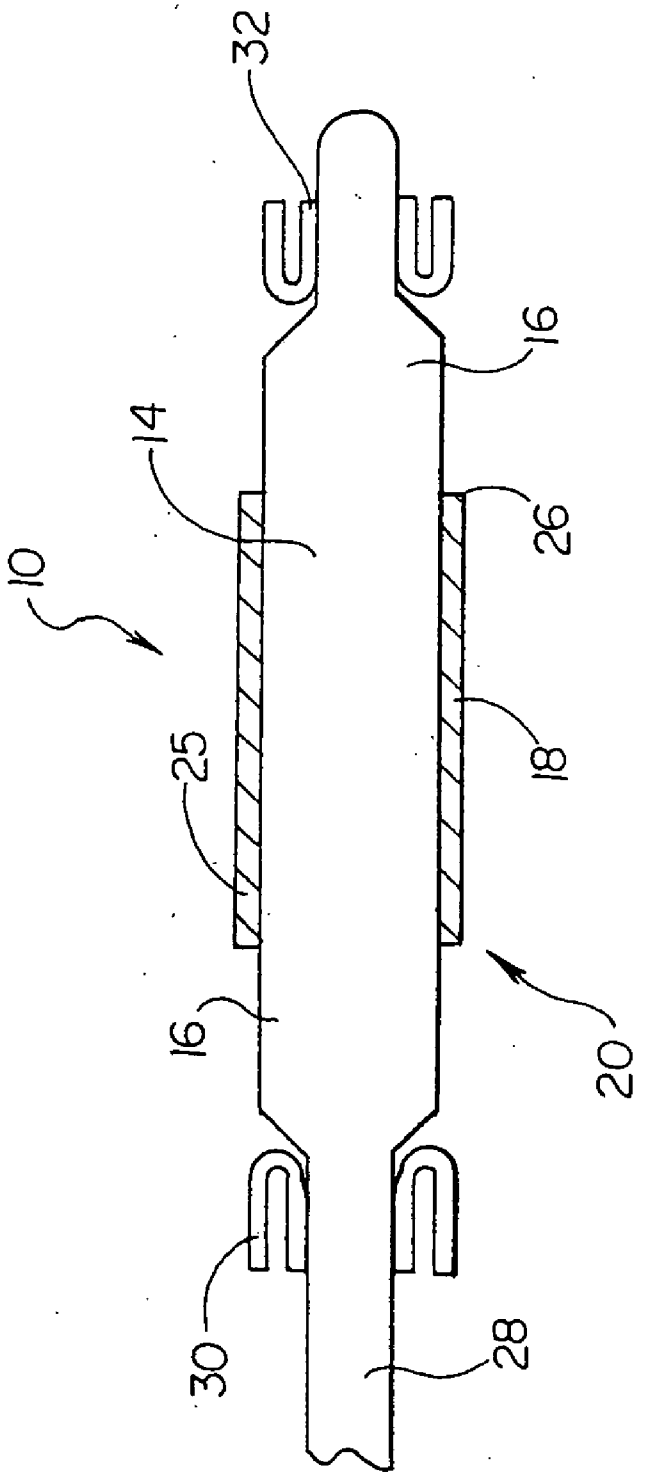


Fig. 6

Fig. 7



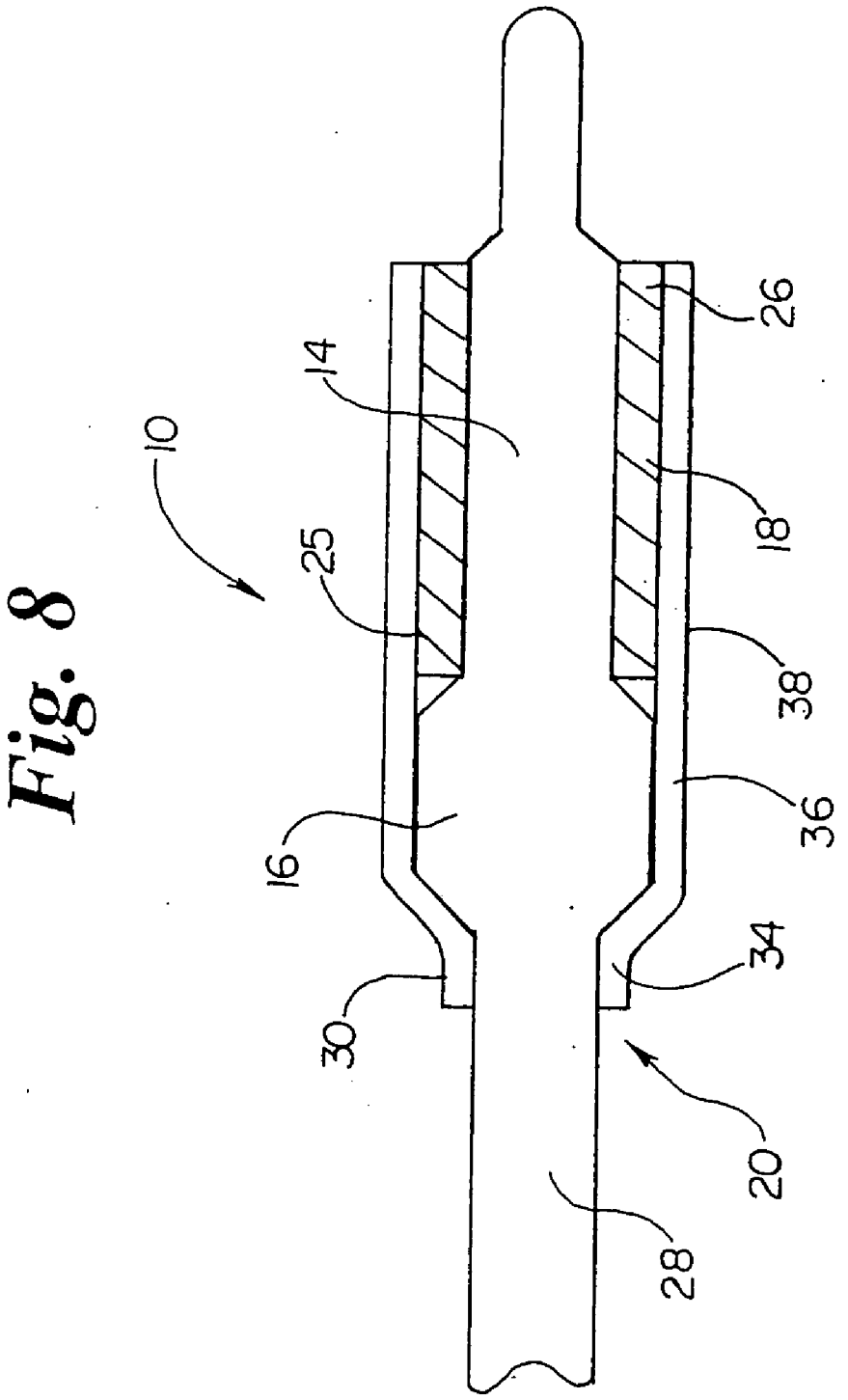


Fig. 8

Fig. 9

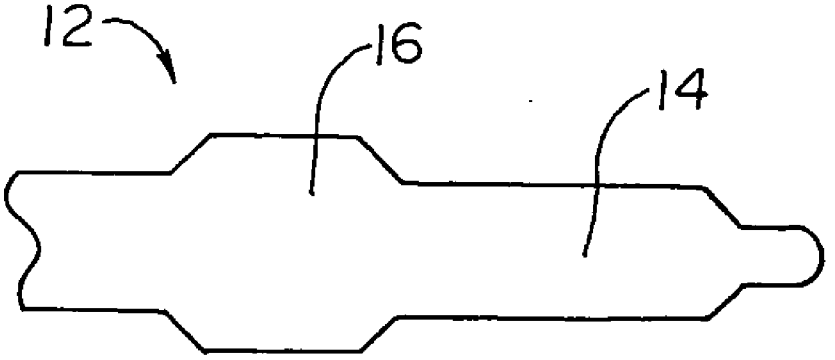


Fig. 10

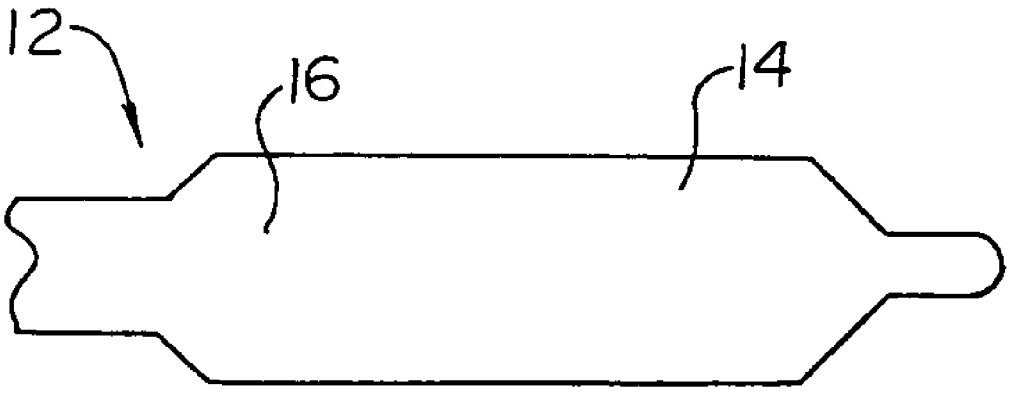


Fig. 11

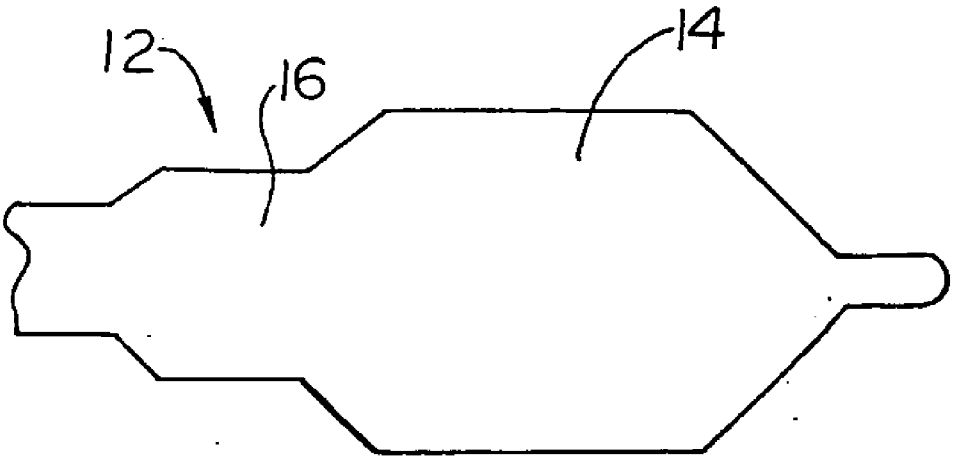


Fig. 12

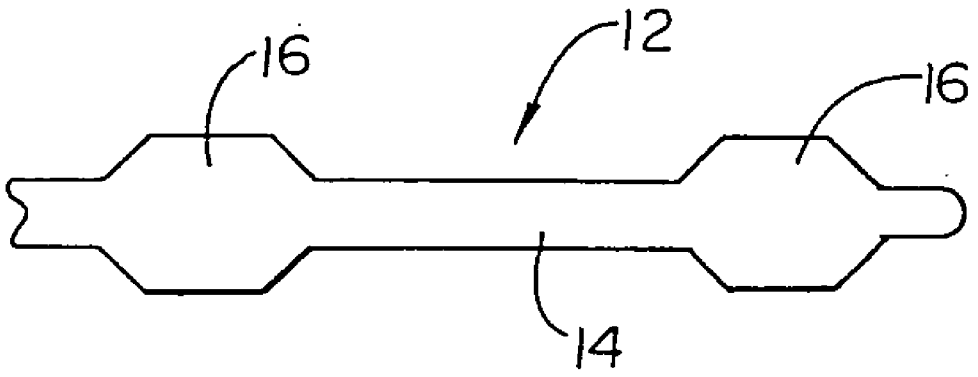


Fig. 13

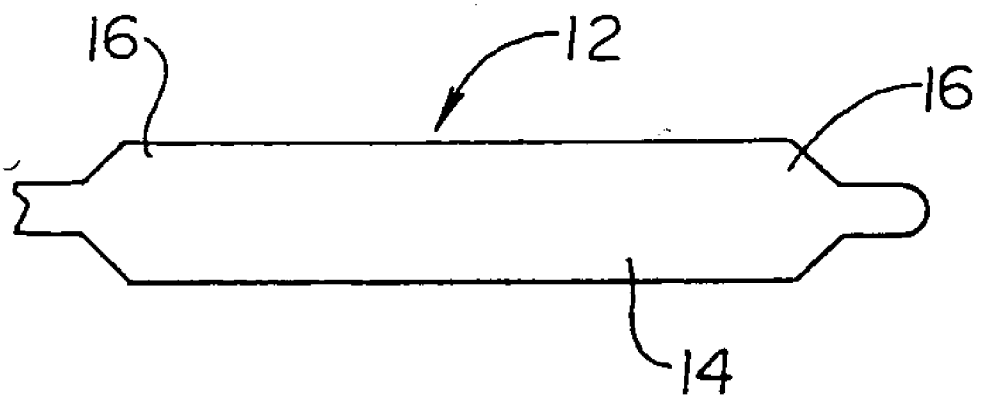
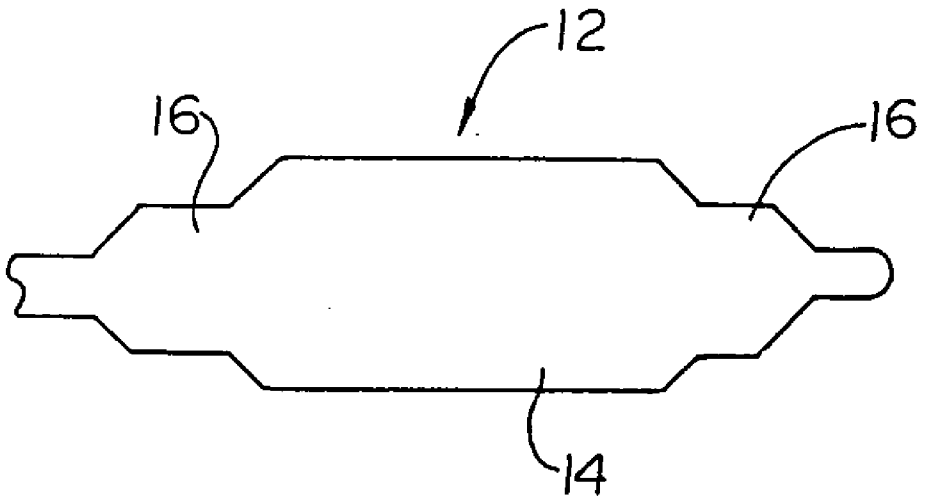


Fig. 14



COMBINED SHAPED BALLOON AND STENT PROTECTOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not Applicable

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention

[0004] The present invention relates generally to a method of installing a stent utilizing a balloon catheter to perform an initial angioplasty and to seat the stent after it has been located in the vessel. The invention also relates to novel balloon structures which have particular use in the method of the invention. More specifically, this invention relates to a stent delivery system wherein at least a portion of the balloon is step compliant which provides the balloon with the ability to expand specific portions of the balloon at different times according to a variety of inflation pressures. In addition the unique shape of the balloon may be configured to engage the stent throughout the insertion as well as the delivery procedures which in turn reduces longitudinal movement of an associated medical device such as a stent, stent-graft, graft or vena cava filter mounted on the balloon both prior to and during balloon expansion.

[0005] 2. Description of the Related Art

[0006] Expandable, implantable medical devices such as stents are utilized in a number of medical procedures and situations as are stent delivery assemblies. As such, their structure and function are well known. A stent is a generally cylindrical prosthesis introduced via a catheter into a lumen of a body vessel in a configuration having a generally reduced diameter and then expanded to the diameter of the vessel. The stent may be self-expanding, such as a NITINOL shape memory stent, or it may be expandable by means of an inflatable portion of the catheter, such as a balloon. In its expanded configuration, the stent supports and reinforces the vessel walls while maintaining the vessel in an open, unobstructed condition.

[0007] Self-expanding, inflation assisted expandable and inflation expandable stents are well known and widely available in a variety of designs and configurations. Inflation expandable and inflation assisted expandable stents are expanded via outward radial pressure such as that provided by a balloon disposed underneath the stent during inflation of the balloon.

[0008] Medical device delivery balloons may have a variety of shapes, sizes, inflation characteristics and a variety of other performance attributes. Some examples of balloons which may be used for the expansion and delivery of a medical device are described in U.S. Pat. No. 5,556,383; U.S. Pat. No. 5,738,901; U.S. Pat. No. 6,024,752; and U.S. Pat. No. 6,048,350.

[0009] In advancing an inflation expandable stent through a body vessel to the deployment site, there are a number of important considerations. The stent must be able to securely maintain its axial position on the delivery catheter, without translocating proximally or distally, and especially without becoming separated from the catheter. Furthermore, it may be desirable to protect the distal and proximal ends of the stent to prevent distortion of the stent and to prevent abrasion and/or to reduce potential trauma to the vessel walls.

[0010] To address the concerns stated above, one approach has been identified which utilizes a retractable sheath or sheaths which are disposed about the distal end of the catheter and cover the stent and balloon. In such devices the sheath is retracted prior to the inflation of the balloon and subsequent delivery of the stent. Another solution involves the utilization of one or more stent retaining means such as elastomeric sleeves or socks. The socks are disposed about the ends of the stent and the respective adjacent portions of the catheter shaft. Socks may be constructed such that during balloon inflation the socks release the stent as a result of the forces and change in geometry resulting from the expanding balloon. It is also known that socks may be constructed to retract or be pulled off of the stent as a result of their construction and the expansion of the balloon.

[0011] Inflation expandable stent delivery and deployment assemblies are known which utilize restraining means that overlie the stent during delivery. U.S. Pat. No. 4,950,227 to Savin et al., relates to an inflation expandable stent delivery system in which a sleeve overlaps the distal or proximal margin (or both) of the stent during delivery. During inflation of the stent at the deployment site, the stent margins are freed of the protective sleeve(s). U.S. Pat. No. 5,403,341 to Solar, relates to a stent delivery and deployment assembly which uses retaining sheaths positioned about opposite ends of the compressed stent. The retaining sheaths of Solar are adapted to tear under pressure as the stent is radially expanded, thus releasing the stent from engagement with the sheaths. U.S. Pat. No. 5,108,416 to Ryan et al., describes a stent introducer system which uses one or two flexible end caps and an annular socket surrounding the balloon to position the stent during introduction to the deployment site. The content of all references, including patents and patent applications are respectively incorporated it their entirety herein by reference.

[0012] Providing a means for containing and securing the stent or other medical device on the balloon catheter prior to inflation is but one problem facing stent delivery systems. An additional concern is the shifting or sliding of the stent relative to the balloon during balloon expansion. Numerous attempts have been made to reduce or prevent translocation of the stent on the balloon during balloon expansion. For example: copending U.S. patent application Ser. No. 09/667,916, filed Sep. 22, 2000 and entitled Coated Stents with Better Gripping Ability, describes a stent coating which provides the stent with improved ability to adhere to the balloon during the expansion process. Another example is U.S. Pat. No. 5,836,965 which describes a process wherein a balloon is expanded and heat set then allowed to cool in order to adhere the balloon to the stent. Yet another example is co-pending U.S. patent application Ser. No. 08/740,727, filed Nov. 1, 1996 and entitled Selective Coating Of A Balloon Catheter With Lubricous Material For Stent Deployment, which describes a balloon having a tacky coating for securing a stent to a balloon prior to delivery.

[0013] Angioplasty, an accepted and well known medical practice involves inserting a balloon catheter into the blood vessel of a patient, maneuvering and steering the catheter through the patient's vessels to the site of the lesion with the balloon in an uninflated form. The uninflated balloon portion of the catheter is located within the blood vessel such that it crosses the lesion or reduced area. Pressurized inflation fluid is metered to the inflatable balloon through a lumen formed in the catheter to thus dilate the restricted area. The inflation fluid is generally a liquid and is applied at relatively high pressures, usually in the area of six to twenty atmospheres. As the balloon is inflated it expands and forces open the previously closed area of the blood vessel. Balloons used in angioplasty procedures such as this are generally fabricated by molding and have predetermined design dimensions such as length, wall thickness and nominal diameter. Balloon catheters are also used in other systems of the body for example the prostate and the urethra. Balloon catheters come in a large range of sizes and must be suitably dimensioned for their intended use.

[0014] Recently the use of a catheter delivered stent to prevent an opened lesion from reclosing or to reinforce a weakened vessel segment, such as an aneurism, has become a common procedure. A typical procedure for stent installation involves performing an initial angioplasty to open the vessel to a predetermined diameter sufficient to permit passage of a stent delivery catheter across the lesion, removal of the angioplasty balloon catheter, insertion of a delivery catheter carrying the stent and a stent deploying mechanism, deploying the stent across the opened lesion so as to separate the stent from the catheter and bring it into contact with the vessel wall, usually with dilation to a lager diameter using a balloon larger than the balloon of the predilation catheter, and then removing the delivery catheter (after deflating the balloon if used). In many cases it has become the practice to then "retouch" the dilation by deploying a third catheter carrying a balloon capable of dilating at a substantially higher pressure to drive the stent into the vessel wall, thereby to assure that there is no risk of the stent later shifting its position and to reduce occurrence of restenosis or thrombus formation. This third "retouch" dilation is often considered necessary when the balloon used to seat the stent is made of a compliant material because such balloons generally cannot be safely pressurized above 9-12 atm., and higher pressures are generally considered necessary to assure full uniform lesion dilation and seating of the stent.

[0015] A wide variety of stent configurations and deployment methods are known. For instance, stent configurations include various forms of bent wire devices, self-expanding stents; stents which unroll from a wrapped configuration on the catheter; and stents which are made of a deformable material so that the device may be deformed on deployment from a small diameter to a larger diameter configuration. References disclosing stent devices and deployment catheters include:

U.S. Pat. No. 4733665	Palmaz
U.S. Pat. No. 4776337	Palmaz
U.S. Pat. No. 5195984	Schatz
U.S. Pat. No. 5234457	Andersen

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U.S. Pat. No. 5116360	Pinchuck et al
U.S. Pat. No. 5116318	Hillstead
U.S. Pat. No. 4649922	Wiktor
U.S. Pat. No. 4655771	Wallsten
U.S. Pat. No. 5089006	Stiles
U.S. Pat. No. 5007926	Derbyshire
U.S. Pat. No. 4705517	DiPisa, Jr.
U.S. Pat. No. 4740207	Kreamer
U.S. Pat. No. 4877030	Beck et al
U.S. Pat. No. 5108417	Sawyer
U.S. Pat. No. 4923464	DiPisa, Jr
U.S. Pat. No. 5078726	Kreamer
U.S. Pat. No. 5171262	MacGregor
U.S. Pat. No. 5059211	Stack et al
U.S. Pat. No. 5104399	Lazarus
U.S. Pat. No. 5104404	Wolff
U.S. Pat. No. 5019090	Pinchuk
U.S. Pat. No. 4954126	Wallsten
U.S. Pat. No. 4994071	MacGregor
U.S. Pat. No. 4580568	Gianturco
U.S. Pat. No. 4681110	Wiktor
U.S. Pat. No. 4800882	Gianturco
U.S. Pat. No. 4830003	Wolff et al
U.S. Pat. No. 4856516	Hillstead
U.S. Pat. No. 4922905	Strecker
U.S. Pat. No. 4886062	Wiktor
U.S. Pat. No. 4907336	Gianturco
U.S. Pat. No. 4913141	Hillstead
U.S. Pat. No. 5092877	Pinchuk
U.S. Pat. No. 5123917	Lee
U.S. Pat. No. 5116309	Coll
U.S. Pat. No. 5122154	Rhodes
U.S. Pat. No. 5133732	Wiktor
U.S. Pat. No. 5135536	Hillstead
U.S. Pat. No. 5282824	Gianturco
U.S. Pat. No. 5292331	Boneau
U.S. Pat. No. 5035706	Gianturco et al
U.S. Pat. No. 5041126	Gianturco
U.S. Pat. No. 5061275	Wallsten et al
U.S. Pat. No. 5064435	Porter
U.S. Pat. No. 5092841	Spears
U.S. Pat. No. 5108416	Ryan et al
U.S. Pat. No. 4990151	Wallsten
U.S. Pat. No. 4990155	Wilkoff
U.S. Pat. No. 4969890	Sugita et al
U.S. Pat. No. 4795458	Regan
U.S. Pat. No. 4760849	Kropf
U.S. Pat. No. 5192297	Hull
U.S. Pat. No. 5147385	Beck et al
U.S. Pat. No. 5163952	Froix

[0016] In U.S. Pat. No. 5,348,538, the entire contents of which being incorporated herein by reference, there is described a single layer balloon which follows a stepped compliance curve. The stepped compliance curves of these balloons has a lower pressure segment following a first generally linear profile, a transition region, typically in the 8-14 atm range, during which the balloon rapidly expands yielding in elastically, and a higher pressure region in which the balloon expands along a generally linear, low compliance curve. The stepped compliance curve allows a physician to dilate different sized lesions without using multiple balloon catheters.

[0017] Stepped compliance curve catheter balloon devices using two different coextensively mounted balloon portions of different initial inflated diameter, are also described in U.S. Pat. No. 5,447,497 and in U.S. Pat. No. 5,358,487 to Miller. These dual layer balloons are designed with the outer balloon portion larger than the inner portion so that the compliance curve follows the inner balloon portion until it

reaches burst diameter and then, after the inner balloon bursts, the outer balloon becomes inflated and can be expanded to a larger diameter than the burst diameter of the inner balloon.

[0018] A polyethylene ionomer balloon with a stepped compliance curve is disclosed in EP 540 858. The reference suggests that the balloon can be used on stent delivery catheters. The disclosed balloon material of this reference, however, yields a compliant balloon and therefore a stent delivered with such a balloon would typically require "retouch."

[0019] Balloons having a stepped compliance curve have also been described for use in stent delivery. Two examples of such stent delivery balloons and methods of their use are described in U.S. Pat. No. 5,749,851 and U.S. Pat. No. 5,980,532, respectively incorporated in their entirety herein by reference.

[0020] The entire content of all of the patents and patent applications listed within the present patent application are respectively incorporated in their entirety herein by reference.

BRIEF SUMMARY OF THE INVENTION

[0021] The invention in one aspect is directed to a medical balloon. More specifically, the present invention is directed to a stent delivery system employing a unique stepped compliant balloon which is shaped to retain a stent about a stent mounting region of the balloon prior to and during stent delivery. The balloon is capable of providing low pressure predilation at a relatively small diameter to open the lesion sufficiently to allow insertion and deployment of the stent across the lesion and for subsequent high pressure embedding of the stent in the vessel wall. The same balloon catheter may also be employed to insert and deploy the stent. Thus at least one catheter may be eliminated from what may otherwise be a two or three catheter installation process.

[0022] In at least one embodiment of the invention, the balloon of the invention may be made by molding a balloon into a configuration in which the second portion has a larger diameter than the first portion and then shrinking the second portion to the diameter of the first portion or less than the diameter of the first portion. The method of making such balloons comprises yet another aspect of the invention.

[0023] In at least one embodiment of the invention the, the balloon may be incorporated into a stent delivery catheter, wherein a stent mounting region of the balloon has a diameter less than the diameter of the balloon ends, whereby the stent is prevented from longitudinal migration relative to the catheter as a result of interference provided by the balloon ends. The balloon may be configured to expand so that the stent remains held in place during balloon expansion.

[0024] In at least one embodiment of the invention the balloon is configured to have a first inflation state, a second inflation state, and a third or fully inflated state.

[0025] In yet another embodiment of the invention the balloon may be configured to expand such that the balloon ends maintain a larger diameter than the stent mounting region until a predetermined inflation pressure is achieved, whereupon the stent mounting region may expand to a diameter greater than the diameter of the balloon ends.

[0026] In yet another aspect of the invention a stent delivery catheter may employ a stepped compliant balloon and one or more stent retaining sleeves. The balloon may be configured such that the balloon ends inflate sufficiently to cause the sleeves to retract, whereupon the stent mounting region expands to release the stent.

[0027] These and other more detailed and specific objectives and an understanding of the invention will become apparent from a consideration of the following Detailed Description of the Invention in view of the Drawings. Other embodiments may also be apparent, but which are not described in detail, from the following description.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0028] A detailed description of the invention is hereafter described with specific reference being made to the drawings in which:

[0029] **FIG. 1** is a side view of an embodiment of the invention as depicted within a body vessel;

[0030] **FIG. 2** is a side view of an embodiment of the invention wherein the balloon is depicted in a first inflation state;

[0031] **FIG. 3** is a side view of the embodiment of the invention shown in **FIG. 2**, wherein the balloon is depicted in the second inflation state;

[0032] **FIG. 4** is a side view of an alternative embodiment of the invention, wherein the balloon is depicted in the second inflation state;

[0033] **FIG. 5** is a side view of an embodiment of the invention wherein the balloon is shown in the third inflation state;

[0034] **FIG. 6** is a side view of an embodiment of the invention which includes a pair of retractable stent retaining sleeves;

[0035] **FIG. 7** is a side view of the embodiment of the invention shown in **FIG. 6** wherein the balloon is in the second inflation state and the sleeves are retracted;

[0036] **FIG. 8** is a side view of an embodiment of the invention which includes a single retractable stent retaining sleeve;

[0037] **FIG. 9** is a side view of the balloon shown in **FIG. 8** shown in the first inflation state;

[0038] **FIG. 10** is a side view of the balloon shown in **FIG. 9** shown in the second inflation state;

[0039] **FIG. 11** is a side view of the balloon shown in **FIG. 10** shown in the third inflation state;

[0040] **FIG. 12** is a side view of an embodiment of the balloon shown in the first inflation state;

[0041] **FIG. 13** is a side view of the balloon shown in **FIG. 12** shown in the second inflation state; and

[0042] **FIG. 14** is a side view of the balloon shown in **FIG. 13** shown in the third inflation state.

DETAILED DESCRIPTION OF THE INVENTION

[0043] The catheters employed in the practice of the present invention are most conveniently constructed as over-the-wire balloon catheters of conventional form for use in angioplasty, except that the balloon has a stepped compliance curve. However it should be understood that the present invention can be applied, in addition to over-the-wire catheters, to fixed-wire catheters, to shortened guide wire lumens or single operator exchange catheters, and to non over-the-wire balloon catheters. Furthermore this invention can be used with balloon catheters intended for use in any and all vascular systems of cavities of the body.

[0044] As may be seen in **FIG. 1**, the present invention is directed to a stent delivery catheter, indicated generally at **10**, which employs a balloon **12** which is mounted to a distal portion **20** of the catheter shaft **28**. In the present invention, the balloon **12** includes a stent mounting region **14** and a pair of adjacent end portions **16**.

[0045] A stent **18** is disposed about the stent mounting region **14** prior to stent delivery. The stent **18** is delivered by advancing the distal portion **20** of the catheter **10** through a body lumen or vessel **22** to a legion site **24**. The balloon **12** is then inflated to predetermined pressure to expand the stent to a fully expanded state.

[0046] As is know to those of skill in the art, when a medical balloon of catheter is in the non-inflated state, the balloon will typically include one or more folds. The folded configuration of the balloon provides numerous benefits to the catheter device. An example of a folded balloon is described in U.S. Pat. App. 09/335,361, filed Jun. 17, 1999 and entitled Stent Securement By Balloon Modification, the entire contents of which being incorporated herein by reference. The balloon **12** depicted in **FIG. 1** is shown in what is referred to herein as the first inflation state. However, the first inflation state is considered for purposes of this application to be an inflation state wherein the balloon **12** has been unfolded by an internal inflation pressure of about 1 to about 3 atmospheres. Despite, being "unfolded" by such pressure, the balloon **12** as shown in **FIG. 1** is not yet expanded and is thus may be characterized as being unexpanded or nominally inflated.

[0047] As may be seen in **FIGS. 2-5** the balloon **12** may be characterized as having at least two inflation states in addition to the first inflation state shown in **FIG. 1**. In **FIG. 2**, the balloon **12** is shown in the first inflation state; in **FIGS. 3 and 6**, the balloon **12** is respectively shown in alternative second inflation states, and in **FIG. 5**, the balloon **12** is shown in a third inflation state.

[0048] As may be seen in **FIG. 2**, when the balloon **12** is in the first inflation state, the catheter as a whole has a low profile sufficient for allowing the distal portion **20** of the catheter **10** to advance through a body lumen. In the first inflation state the stent mounting region **14** of the balloon **12** will typically have a diameter less than about 2.5 mm. The diameter of the stent mounting region may also range from about 1.5 mm to about 2.5 mm. In the first inflation state, the diameter of the end region(s) **16** will be greater than the diameter of the stent mounting region **14**. The end region(s) **16** will typically be between about 1.65 mm to about 2.65 mm in diameter depending on the diameter of the stent mounting region **14**.

[0049] The balloon **12** is inflated by injecting a fluid or other inflation means into the balloon **12**. Typically the catheter **10** will be equipped with one or more inflation lumens (not shown) which are in fluid communication with the balloon and the proximal end of the catheter (not shown). Lumens as well as inflation means for balloons, including the present catheter balloon are well known in the art.

[0050] It may also be seen that in the embodiment shown in **FIG. 2**, the catheter **10** is equipped with marker bands **40**. Marker bands may be used to denote the location of the stent on the catheter as well as to serve as a means of determining the location of the distal end of the catheter as it advances through the body. The marker bands are typically constructed of radiopaque materials. Examples of suitable marker bands are described in U.S. application Ser. No. 09/327,234 entitled Radiopaque Bands and filed Jun. 7, 1999, the entire contents of which being incorporated herein by reference.

[0051] As the balloon **12** is inflated, the balloon **12** will expand the stent **18**. As may be seen in **FIG. 3**, the balloon **12** has been inflated to a second inflation or inflated state. In the second inflation state the balloon **12** may be configured to provide the stent mounting region **14** and the end regions **16** with substantially the same diameter such as is shown. However, in the embodiment illustrated in **FIG. 4**, when the balloon **12** is in the second inflation state, the diameter of the stent mounting region **14** remains less than the diameter of the end regions **16**. In the second inflation state the diameter of the stent mounting region may range from about 3.0 to about 3.6 mm, in alternative embodiments however, the diameter may be less. Where the balloon is configured to have end regions **16** which have diameters greater than the diameter of the stent mounting region **14** the diameter of the end portions will typically be about 0.1 mm to about 1 mm greater than the diameter of the stent mounting region **14**.

[0052] By providing the balloon **12** with end regions **16** that have a greater diameter than that of the stent mounting region **14**, the end portions may be utilized to engage the ends **25** and **26** of the stent **18** thereby ensuring that the stent **18** does not migrate longitudinally relative to the balloon **12**. By providing such enlarged end regions in both the first inflation state, such as is shown in **FIG. 2** as well as in the second inflation state, such as is shown in **FIG. 4**, the position of the stent **18** remains constant on the balloon **12** during insertion and advancement of the catheter **10** as well as during balloon inflation.

[0053] Subsequent to inflating the balloon **12** to a second inflation state, such as is shown in **FIGS. 3 and 4**, the balloon **12** may be further inflated to a third inflation state, such as is shown in **FIG. 5**.

[0054] As previously described the balloon **12** may be at least partially stepped compliant. In the embodiments discussed thus far the stent mounting region **14** is characterized as having a stepped compliance curve where as the adjacent end region(s) may be characterized as having a substantially linear compliance curve. Examples and description of a stepped compliant curves as well as a substantially linear compliance curve are described in U.S. Pat. No. 5,632,760 and U.S. Pat. No. 5,980,532, both of which are incorporated in their respective entireties herein by reference. Typically, a stepped compliance curve may be characterized by a first or low pressure segment defined by a low inflation pressure

range. In the present invention, the low pressure segment of the stepped compliance curve of the stent mounting region **14** is generally collinear with a corresponding segment of the generally linear compliance curve of the end portions **16** which is defined by said low inflation pressure range. The stepped compliance curve of the stent mounting regions **16** may also include a transition segment during which the balloon expands rapidly relative to the at least one adjacent region and a high pressure segment during which the compliance curve of the stent mounting region expands slowly relative to the transition segment.

[**0055**] In the third inflation state the balloon **12** is inflated with pressure from about 12 to about 16 atmospheres. The greater pressure of the third inflation state corresponds to the high pressure segment of the compliance cure. The balloon **12** is constructed such that when the balloon **12** is inflated to the third inflation state, only the diameter of the stent mounting region **14** will continue to expand according to the high pressure segment of the stepped compliance curve. The diameter of the end regions **16** will exhibit only nominal expansion if at all when the balloon **12** is inflated to the third inflation state.

[**0056**] Alternatively, the balloon **12** may be characterized as having a stent mounting region **14** which has a higher rate of expansion than the rate of expansion of the end regions **16**. Such that when the balloon **12** is inflated with a predetermined inflation pressure, the stent mounting region **14** will inflate to a greater degree than the end portions **16**. Numerous methods could be applied to the balloon of the present invention to achieve different inflation rates. For example the end regions **16** could incorporate a relatively hard coating and/or additional materials such as the relatively stiff high pressure polymeric materials, such as thermoplastic polymers and thermoset polymeric materials, poly(ethylene terephthalate) (commonly referred to as PET), polyimide, thermoplastic polyimide, polyamides, polyesters, polycarbonates, polyphenylene sulfides, polypropylene and rigid polyurethanes. Such materials or coatings could be applied to a portion of the end region **16** to provide the region(s) **16** with a reduced rate of inflation relative to the stent mounting region **14**. In addition, one or both expansion rates may also be characterized as being stepped compliant as described above.

[**0057**] In an alternative embodiment shown in **FIG. 6**, the catheter **10** may be equipped with retractable stent retaining sleeves **30** and **32**. Each of the sleeves **30** and **32** have three portions: a catheter engagement portion **34**, an balloon end region overlaying portion **36**, and a stent end overlaying portion **38**. The catheter engagement portion **34** is engaged to a portion of the catheter shaft **28** adjacent to the balloon **12**. The sleeves **30** and **32** may be engaged to the catheter in any manner known. For example the sleeves may be frictionally engaged, adhesively bonded, chemically or heat welded or other wise attached to the catheter shaft **28**. The end overlaying portion **36** of each sleeve is slidingly disposed about the end region **16** of the balloon **12**. The stent end overlaying region **38** of each sleeve **30** and **32**, extends on to the stent mounting region **14** of the balloon **12** and respectively overlays stent ends **25** and **26**. The stent end overlaying region **38** of each sleeve **30** and **32** retains the stent **18** on the stent mounting region **14** of the balloon **12** prior to stent delivery.

[**0058**] As may be seen in **FIG. 7**, when the balloon **12** is inflated to the second inflation state, the sleeves **30** and **32** are retracted off of the respective stent ends **25** and **26** to release the stent.

[**0059**] In the embodiments shown in **FIGS. 3, 4** and **7**, the balloon **12** may be inflated to the third inflation state as is shown in **FIG. 5**. In addition the sleeves **30** and **32** may be configured to retract off of the stent ends **25** and **26** when the balloon **12** is in the third inflation state rather than the second inflation state.

[**0060**] Alternatively, the catheter **10** may include a single sleeve **30** such as may be seen in **FIG. 8**.

[**0061**] In another alternative embodiment of the invention may be seen in **FIGS. 9-11**, the invention may be directed exclusively to the inventive balloon **12** such as balloon **12** shown in **FIG. 1**. In the present embodiment, the balloon **12** is shown with a stent mounting region **14** distally adjacent to a single end portion **16**, such as may also be seen in **FIG. 8**. In **FIGS. 9-11** the balloon **12** is shown respectively in the first inflation state, the second inflation state and the third inflation state. The balloon **12** may be incorporated into a balloon catheter or a stent delivery catheter such as those previously shown and described above, or as may be known in the art.

[**0062**] Similar to the embodiments shown in **FIGS. 9-11**, the alternative embodiments shown in **FIGS. 12-14** are directed to the balloon **12** portion of the catheter such as is shown in **FIGS. 2-4** above. In the embodiments shown in **FIGS. 12-14**, the balloon **12** has a distal adjacent end **16** and a proximal adjacent end **17** which surround the stent mounting region **14**. As with the previous embodiments, the embodiments shown in **FIGS. 12-14** may be incorporated into any type of balloon catheter or stent delivery catheter especially those described herein. The balloon **12** of **FIGS. 9-14** may include the same inflation characteristics as the balloons **12** of the various embodiments of the invention previously described.

[**0063**] In all of the embodiments described herein, if a stent is utilized with the balloon **12** the stent may be deployed from the second inflation state by simply collapsing the balloon subsequent to achieving the second inflation state, such as is depicted in **FIGS. 3, 4** and **7**. However, the stent may be further expanded by inflating the balloon **12** to the third inflation state. By further expanding the stent **18** in this manner the balloon **12** may be used to predilate a vessel by expanding to the second inflation state, and then seating the stent in place by expanding the balloon **12** to the third inflation state such as is shown in **FIG. 5**.

[**0064**] The balloon **12** of the various embodiments discussed herein should be made of a thermoplastic polymer material which has a high strength, and gives a low compliance balloon at pressures above about 15 atmospheres. For purposes of this application "low compliance" is considered to correspond to a diameter increase of no more than 0.1 mm per increased atmosphere of pressure, preferably less than 0.06 mm/atm. Suitably the balloon polymer is poly(ethylene terephthalate) (PET) of initial intrinsic viscosity of at least 0.5, more preferably 0.7-0.9. Other high strength polyester materials, such as poly(ethylene naphthalenedicarboxylate) (PEN), nylons such as nylon 11 or nylon 12, thermoplastic polyimides and high strength engineering

thermoplastic polyurethanes such as Isoplast 301 sold by Dow Chemical Co., and Pebax™ (a block copolymer polyamide and polyether) made by Elf Atochem. are considered suitable alternative materials. Desirably the balloon is blown in a way which will give a wall strength of at least 18,000 psi, preferably greater than 20,000 psi. Techniques for manufacturing balloons with such wall strengths are well known.

[0065] After being blown, the stent mounting region **14** of the balloon **12** is provided with a stepped compliance curve by annealing the balloon for a short time after blowing at a pressure at or only slightly above ambient and at a temperature which causes the blown balloon to shrink. The process is described in U.S. Pat. No. 5,348,538, incorporated in its entirety herein by reference. However, the balloons of the invention are desirably constructed with a greater difference between the low pressure and high pressure linear regions of the compliance curve so that the transition between the two regions results in a step-up of diameter of the balloon of at least 0.4 mm. This is accomplished by blowing the balloon to the larger diameter and then shrinking to a greater extent than was done in the specific illustrative examples of U.S. Pat. No. 5,348,538. The amount of shrinkage is controlled by the pressure maintained in the balloon during annealing and the temperature and time of the annealing. For a balloon made from 0.74 intrinsic viscosity PET, the blowing pressure is suitably in the range 200-400 psi, and temperature is suitably in the range of 90-100° C., and the annealing pressure is in the range of 0-20, preferably 5-10 psi at 90-100° for 3-10 seconds.

[0066] In a further aspect of the invention, the balloons employed in the inventive process are configured so that the stent mounting region **14** of the balloon **12** has a stepped compliance curve and the remainder of the balloon, specifically the end region(s) **16** have an unstepped or substantially linear compliance curve, the low pressure regions of the compliance curves of both the stent mounting region **14** and the end region(s) **16** being generally collinear.

[0067] The invention may also be practices by use of dual layer balloons such as described in co-pending U.S. application Ser. No. 08/243,473, filed May 16, 1994 as a continuation of now abandoned U.S. application Ser. No. 07/927,062, filed Aug. 8, 1992, incorporated herein by reference, and in U.S. Pat. No. 5,358,487, incorporated herein by reference. Suitably both balloons of the dual layer balloons are low compliance balloons designed with the outer balloon portion larger by at least 0.25 mm than the inner portion and the inner balloon designed to burst at a pressure below about 15 atm so that the compliance curve follows the inner balloon portion until it reaches burst diameter and then, after the inner balloon bursts, the outer balloon becomes inflated and can be expanded to a larger diameter than the burst diameter of the inner balloon.

[0068] Although the present invention has been described in terms of specific embodiments, it is anticipated that alterations and modifications thereof will no doubt be come apparent to those skilled in the art. It is therefore intended that the following claims be interpreted as covering all such alterations and modifications as fall within the true spirit and scope of the invention.

[0069] In addition to being directed to the embodiments described above and claimed below, the present invention is further directed to embodiments having different combinations of the features described above and claimed below. As such, the invention is also directed to other embodiments having any other possible combination of the dependent features claimed below.

[0070] The above examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

1-33. (Cancelled)

34. A medical balloon comprising:

a stent mounting region and a pair of adjacent end regions,

the balloon being inflatable from a first inflation state to a second inflation state, in the first inflation state the stent mounting region having a diameter less than that of the adjacent end regions,

the stent mounting region having a first rate of expansion and the at adjacent region having a second rate of expansion, the first rate of expansion being greater than the second rate of expansion, whereby when the balloon is inflated from the first inflation state to the second inflation state by a predetermined inflation pressure the diameter of the stent mounting region is at least as large as the diameter of the adjacent and regions.

35. The medical balloon of claim 34 wherein when the balloon is expanded from the first inflation state to the second inflation state the balloon is pressurized to a pressure sufficient to expand a stent mounted over the stent mounting region to a first stent expanded state.

36. The medical balloon of claim 34 wherein the stent mounting region has a stepped compliance curve and each of the end regions have a substantially linear compliance curve, the stepped compliance curve being characterized by a low pressure segment defined by a low inflation pressure range, said low pressure segment being generally collinear with a corresponding segment of the generally linear compliance curve of the end regions which is defined by said low inflation pressure range, a transition segment during which the balloon expands rapidly relative to the end regions and a high pressure segment during which the compliance curve of the stent mounting region expands slowly relative to the transition segment.

37. The medical balloon of claim 36 wherein when the balloon is inflated to the second inflation state the stent mounting region is expanded according to the transition segment of the stepped compliance curve.

38. The medical balloon of claim 36 wherein when the balloon is inflated to the second inflation state the stent mounting region is expanded according to the low pressure segment of the stepped compliance curve.

39. The medical balloon of claim 34 wherein the balloon further comprises a third inflation state, in the third inflation state the diameter of the stent mounting region is greater than the diameter of the at least one adjacent region.

40. The medical balloon of claim 39 wherein when the balloon is inflated to the third inflation state the stent

mounting region is expanded according to a transition segment of the stepped compliance curve.

41. The medical balloon of claim 39 wherein when the balloon is inflated to the third inflation state the stent mounting region is expanded according to the high pressure segment of the stepped compliance curve.

42. The medical balloon of claim 34 wherein when the balloon is in the first inflation state the diameter of the stent mounting region is about 1.5 mm to about 2.5 mm.

43. The medical balloon of claim 34 wherein when the balloon is in the first inflation state the end regions have a diameter of about 1.65 mm to about 2.65 mm.

44. The medical balloon of claim 34 wherein when the balloon is in the second inflation state the end regions have a diameter of about 2.0 mm to about 3.75 mm.

45. The medical balloon of claim 34 wherein when the balloon is in the third inflation state the diameter of the stent mounting region is about 2.75 mm to about 4.25 mm and the end regions have a diameter of about 2.0 mm to 3.75 mm.

46. The medical balloon of claim 34 wherein the stent mounting region has a hardness value greater than that of the adjacent end regions.

47. The medical balloon of claim 34 further comprising a coating, the coating being positioned on at least a portion of the adjacent end regions of the balloon and not on the stent mounting region, the coating effective to restrict expansion of the end regions at the predetermined inflation pressure.

48. The medical balloon of claim 47 wherein the coating is selected from at least one member of the group consisting of: poly(ethylene terephthalate) (commonly referred to as PET), polyimide, thermoplastic polyimide, polyamides, polyesters, polycarbonates, polyphenylene sulfides, polypropylene and rigid polyurethanes.

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