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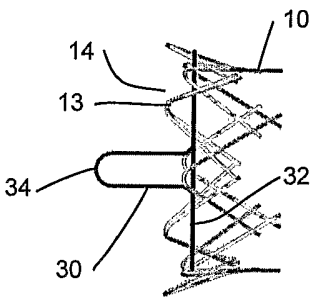
(54) Title: STENT RETRIEVAL MEMBER AND DEVICES AND METHODS FOR RETRIEVING OR REPOSITIONING A STENT



(57) Abstract: An implantable stent includes a stent retrieval member (30) for repositioning or retrieval of the stent after it has been implanted into a bodily lumen. The stent includes a distensible tubular stent (10) having a tubular structure having a tubular wall (16) defined by an interior surface and an exterior surface and having opposed open ends (12,14) ; and a stent retrieval member (30) comprising an elongate member comprising a generally circular perimetric base (32) and a shaped projection (34) having first and second spaced apart members (36,38) extending acutely or perpendicularly from the base (32) and connected by an apical portion (40) . Force exerted on the shaped projection causes contraction or expansion of the circular base. The circular base is securably attached to one of the open ends of the stent, and the shaped projection extends longitudinally beyond this open end of the stent.

STENT RETRIEVAL MEMBER AND DEVICES AND METHODS FOR RETRIEVING OR REPOSITIONING A STENT

CROSS-REFERENCE TO RELATED APPLICATIONS:

This application claims the benefit of U.S. Provisional Application No. 60/647,981, filed January 28, 2005, the contents of which are incorporated herein by reference.

FIELD OF THE INVENTION:

The present invention relates to devices, methods and systems for retrieval and/or repositioning of an implanted stent. More particularly, the present invention relates to implantable stents having a stent retrieval member or loop for easy for retrieval and/or repositioning of the implanted stent.

BACKGROUND OF THE INVENTION:

An intraluminal prosthesis is a medical device used in the treatment of diseased bodily lumens. One type of intraluminal prosthesis used in the repair and/or treatment of diseases in various body vessels is a stent. A stent is a generally longitudinal tubular device formed of biocompatible material which is useful to open and support various lumens in the body. For example, stents may be used in the vascular system, urogenital tract, esophageal tract, tracheal/bronchial tubes and bile duct, as well as in a variety of other applications in the body. These devices are implanted within the vessel to open and/or reinforce collapsing or partially occluded sections of the lumen.

Stents generally include an open flexible configuration. This configuration allows the stent to be inserted through curved vessels. Furthermore, this configuration allows the stent to be configured in a radially compressed state for intraluminal catheter implantation. Once properly positioned adjacent the damaged vessel, the stent is radially expanded so as to support and reinforce the vessel. Radial expansion of the stent may be accomplished by inflation of a balloon attached to the catheter or the stent may be of the self-expanding variety which will radially expand once deployed. Structures which have been used as intraluminal

vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from a heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern.

Various techniques or systems have been proposed for retrieving and/or repositioning an implanted stent. For example, U.S. Patent No. 5,643,277 to Soehendra et al. describes the use of a tapered, threaded cable for removal of an implanted stent. The threaded portion of the cable is described as being twisted to engage an implanted biliary stent, such as a polyethylene stent, and then pulled to remove the sent from the patient.

U.S. Patent No. 6,676,692 to Rabkin et al. describes a catheter system having stent-capturing hooks. The hooks are described as being useful for engaging the stent, thereby allowing repositioning and/or retrieval of the stent.

U.S. Patent Application Publication No. 2002/0188344 A1 to Bolea et al. describes the use of hinged hooks attached to interior portions of an implantable stent. Use of a retrieval tool is described as engaging the hooks, and, upon twisting of the retrieval tool, the stent is contracted thereby allowing retrieval of the stent. In another embodiment, a wire lasso is described as being secured to an implantable stent with the wire lasso having a small loop internally disposed within the open lumen of the stent. The loop of the lasso is described as being engaged by a retrieval tool, and, upon twisting of the retrieval tool, the stent is contracted thereby allowing retrieval of the stent. Other embodiments include a lasso wire threaded through eyelets at a stent end. A retrieval tool is described as engaging the lasso wire, and, upon twisting or axially pulling the lasso wire, the stent is contracted thereby allowing retrieval of the stent.

Prior retrieval systems may appear easy to use, but often require certain user-sensitive techniques, such as twisting or turning in order to reposition or remove the stent. Moreover, in smaller stents, such as biliary stents, the spacing between conventional stent segments is generally smaller than the size of standard forceps or graspers, making it even difficult to grab a hook or lasso.

SUMMARY OF THE INVENTION:

The present invention provides a stent retrieval system that allows for easy access to the retrieval member located on an implantable stent. Further, the stent removal member of the present invention avoids complicated twisting movements for retrieval or repositioning of the implanted stent.

In one aspect of the present invention, an implantable distensible band is provided. The band comprises an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base. The elongate member may be a strand, such as a wire strand, either a monofilament or multifilament strand. Desirably, such bands may function as retrieval members when used in conjunction with a stent or a graft.

In another aspect of the present invention, an implantable stent is provided. The stent comprises: (i) a distensible tubular stent having a tubular structure having a tubular wall defined by an interior surface and an exterior surface and having opposed open ends; and (ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base, wherein the circular base is securably attached to one of the open ends of the stent and further wherein the shaped projection extends longitudinally beyond the one open end of the stent.

In another aspect of the present invention, a method of retrieving or repositioning an implanted stent is provided. The method comprises the steps of (a) providing a tubular distensible stent comprising (i) a wall to define an interior surface and an exterior surface and having opposed open ends; and (ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on

the shaped projection causes contraction or expansion of the circular base, wherein the circular base is securably attached to one of the open ends of the stent and further wherein the shaped projection extends longitudinally beyond the one open end of the stent; (b) implanting the stent within a bodily lumen; and (c) pulling the shaped projection of the stent retrieval member to contract the first end of the stent and to move the stent.

In another aspect of the present invention, a method of retrieving or repositioning an implanted stent is provided. The method comprises the steps of (a) locating a distensible stent within a bodily lumen, the stent comprising a hollow tubular structure having a tubular wall to define an interior surface and an exterior surface and having opposed open ends and a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base, wherein the circular base is securably attached to one of the open ends of the stent and further wherein the shaped projection extends longitudinally beyond the one open end of the stent; and (b) pulling the shaped projection of the stent retrieval member to contract the first end of the stent and to move the stent.

In another aspect of the present invention, a system is provided. The system comprises (a) a distensible stent, said stent comprises (i) a hollow tubular structure having a tubular wall to define an interior surface and an exterior surface and having opposed open ends; and (ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base, wherein said circular base is securably attached to one of said open ends of said stent and further wherein said shaped projection extends longitudinally beyond said one open end of said stent; and (b) a delivery catheter for implanting said stent.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIG. 1 is a perspective view of a hollow, tubular stent according to the present invention.

FIG. 2 is an expanded view of a wall portion of the stent of FIG. 1 taken along the 2-2 axis showing a plurality of stent wires.

FIG. 3 depicts a braided stent with a closed-end loop design at both stent ends.

FIG. 4 is a perspective view of a stent retrieval loop according to the present invention having a circular base and a projecting member.

FIG. 5 is a top view of the stent retrieval loop of FIG. 4 taken along the 5-5 axis.

FIG. 6 is a front elevational view of the stent retrieval loop of FIG. 4 taken along the 6-6 axis.

FIG. 7 is a side elevational view of the stent retrieval loop of FIG. 4 taken along the 7-7 axis.

FIG. 8 is an expanded view of the projecting member of FIG. 4.

FIG. 9 is an expanded view of a first alternative design for the projecting member of FIG. 8.

FIG. 10 is an expanded view of a second alternative design for the projecting member of FIG. 8.

FIG. 11 is an expanded view of a third alternative design for the projecting member of FIG. 8.

FIG. 12 is an expanded view of a fourth alternative design for the projecting member of FIG. 8.

FIG. 13 is an expanded view of a fifth alternative design for the projecting member of FIG. 8.

FIG. 14 is a side elevational view of the stent of FIG. 3 having the stent retrieval loop of FIG. 4 at one of the ends of the stent.

FIG. 15 is a front elevational view of the stent of FIG. 3 having the stent retrieval loop of FIG. 4 at one of the ends of the stent.

FIG. 16 is a perspective view of the stent of FIG. 3 having the stent retrieval loop of FIG. 4 at one of the ends of the stent.

FIGS. 17 is a side elevational view of the stent of FIG. 14 having an inwardly projecting stent retrieval loop.

FIG. 18 is a side elevational view of the stent of FIG. 14 having an inwardly and acutely projecting stent retrieval loop.

FIG. 19 depicts a stent having a covering of silicone according to the present invention.

FIG. 20 is a cross-sectional view of the stent of FIG. 19 showing an outer covering of silicone about the stent.

FIG. 21 is a cross-sectional view of the stent of FIG. 19 showing an inner covering of silicone about the stent.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:

FIG. 1 depicts stent **10** of the present invention. Stent **10** is a hollow tubular structure having opposed open ends **12**, **14** and having a tubular wall **16** therebetween. A portion of the tubular wall **16** is depicted in FIG. 2 as having a plurality of elongate wires **18** formed into the tubular wall **16**. The elongate wires **18** traverse the length of the stent **10** in a

direction traverse to the longitudinal length of the stent **10**. The elongate wires **18** may be formed into the tubular wall **16** by braiding the wires **18**, winding the wires **18**, knitting the wires **18**, and combinations thereof. Preferably, the wires **18** are braided to form the tubular wall **16**.

As depicted in FIG. 3, stent **10** is desirably an atraumatic stent having no sharp terminating members at one or both of the opposed open ends **12, 14**. The elongate wires **18** terminating at open end **12** are mated to form closed loops **13** and adjacently mated wires are secured to one and the other by mechanical means, such as welds **20**. The positioning of adjacently mated wires to form closed-loop end designs is further described in U.S. Application No. 60/472,929, filed May 23, 2003, the contents of which are incorporated herein by reference. Desirably, the elongate wires **18** terminating at open end **12** are in a cathedral type arch or loop configuration. Further details of the cathedral type of arch or closed-loop configuration may be found in U.S. Application No. 10/845,844, filed May 15, 2004, the contents of which are incorporated herein by reference.

The stent wires **18** at the open end **14** are bent to form closed loop ends **15** thereat. As depicted in FIG. 3, the loop ends **15** are substantially angular having approximately or about a 90° bend. The radius of curvature at the point of the bend is desirably minimized. In other words, the loop end **15** desirably has an angularly bent portion between substantially straight wire portions that do not otherwise have a portion with a significant radius of curvature. The loop ends **15**, however, are not limited to angular bends of 90° and other bend angles may suitably be used. For example, angular bends with a bend angle from about 30° to about 150° are also useful. Other useful bend angles include from about 60° to about 120°, from about 70° to about 110°, from about 80° to about 100°, from about 85° to about 95°, and the like.

The stent **10** depicted in FIG. 3 includes multiple wires, such as 24 wires **18** as depicted in FIG. 3, of nitinol or nitinol-containing material. The wires are relatively thin at a diameter of about 0.011 inches. The number of wires and the diameters of the wires, which may be the same or different, depicted in FIG. 3 are not limiting, and other numbers of wires and other wire diameters may suitably be used.

Desirably, the wires **18** are made from any suitable implantable material, including without limitation nitinol, stainless steel, cobalt-based alloy such as Elgiloy®, platinum, gold,

titanium, tantalum, niobium, polymeric materials and combinations thereof. Useful and nonlimiting examples of polymeric stent materials include poly(L-lactide) (PLLA), poly(D,L-lactide) (PLA), poly(glycolide) (PGA), poly(L-lactide-co-D,L-lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLLA/PGA), poly(D,L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), polydioxanone (PDS), Polycaprolactone (PCL), polyhydroxybutyrate (PHBT), poly(phosphazene) poly(D,L-lactide-co-caprolactone) PLA/PCL), poly(glycolide-co-caprolactone) (PGA/PCL), poly(phosphate ester) and the like.

Further, the wires **18** may have a composite construction, such as described found in U.S. Patent Application Publication 2002/0035396 A1, the contents of which is incorporated herein by reference. For example, the wires **18** may have an inner core of tantalum gold, platinum, iridium or combination of thereof and an outer member or layer of nitinol to provide a composite wire for improved radiocapicity or visibility. Preferably, the wires **18** are made from nitinol.

Either of both of the opposed open ends **12, 14** of the stent **10** may have a stent retrieval member **30** securably disposed thereat. A perspective view of a stent retrieval member **30** is depicted in FIG. 4. The stent retrieval member **30**, which may also be referred to as a stent retrieval loop, is useful for repositioning and/or retrieval of an implanted or deployed stent **10**. The stent retrieval member **30** allows the practitioner to contract and move the stent **10** within the implanted lumen. The stent retrieval member may be made from a memory shape alloy, such as the above described materials, including nitinol. The use of a shape memory material, as compared other convention materials such as suture thread, has numerous advantages. For example, the self-supporting nature of the shape memory material facilitates the locating of the stent retrieval member **30**, particularly since it does not sag or flop, but remains substantially stationary once implanted. A memory shape alloy member **30** will not tangle, a potential problem with suture loops, and will also aid in opening the stent **10**. Another advantage from using a memory shape alloy material is the wire loop defining the member **30** would be less likely to break than a plastic or polymeric loop when a pulling force is applied, such as required for repositioning or removal of the stent **10**.

As depicted in FIG. 4 the stent retrieval member **30** includes a generally circular base **32** and a shaped projection **34**. The circular base **32** is a generally circular perimetric base,

i.e., in the form of an elongate wire disposed in a generally circular configuration. The circular base **32** may also be described as a generally circular ring. The projection **34** includes first and second spaced apart members **36, 38**. The spaced apart members **36, 38** extend from the circular base **32** at a parted region **33** of the circular base **32** and are connected by an apical portion **40** opposed from the circular base **32**. The parted region **33** may be described as an interrupted portion of the circular base **32** and is further defined by opposed parted wire ends **35** and **37**. The projection **34** extends from the circular base **32** in a substantially perpendicular fashion. The present invention, however, is not limited to a perpendicularly extending projection **32**, and as described below other extending orientations may suitably be used.

FIG. 5 depicts a top view of the stent retrieval member **30** of FIG. 4 taken along the 5-5 axis. As depicted in FIG. 5, the stent retrieval member **30** has a circular or a substantially circular base **32**. The present invention, however, is not so limited and other shaped bases may suitably be used. Desirably, the shape of the base **32** matches or substantially matches the cross-sectional shape of the stent **10** at either of its opposed open ends **12, 14**.

FIG. 6 is a front elevational view of the stent retrieval member **30** of FIG. 4 taken along the 6-6 axis. As depicted in FIG. 6, the shaped projection **32** extends from a substantially planar base **32**. FIG. 7 is a right elevational view of the stent retrieval member **30** of FIG. 4 taken along the 7-7 axis. As depicted in FIG. 7, the shaped projection **34** may extend in a substantially perpendicular fashion from the base **32**. Further, the shaped projection **34** may also be substantially planar from a side view to reduce the overall profile of the member.

The present invention, however, is not limited to the shaped projection **34** as depicted in FIGS. 4 and 6, and other suitably shaped projections may suitably be used. For example, as depicted in FIG. 8, the length or spacing between the spaced apart members **36, 38** may be increased to form a wider shaped loop with a less pointed or more rounded apical region **40**. The shaped projection **34** as depicted in FIG. 8 may also be described as being "U-shaped". Such U-shaped projections may include straight or substantially straight spaced apart members **36, 38** and a curved apical region **40**. The present invention, however, is not limited to straight or substantially straight members **36, 38** and other shapes, such as curved

or slightly curved, may suitably be used. Such shaped projections **34** may be described as being or lobed-shaped, generally lobed-shaped or substantially lobed-shaped.

Further, as depicted in FIG. 8, the spaced apart members **36, 38** of the shaped projection **34** define an open base, B, of the shaped projection **34**. The base B is further defined by a length L_1, which is the distance between the members **36, 38** thereat. Further, the apical region **40** defines a height, H_1, from base B to the apex or summit of the apical region **40**. Desirably, the height, H_1, is greater than the length, L_1.

As depicted in FIG 9, a stent retrieval member **42** may include two substantially straight spaced apart members **44, 46**. The spaced apart members **44, 46** may be formed from separate members and joined together at the apical region **48** so that the member **48** is in the form of or substantially in the form of a triangle with an open base. Alternatively, the spaced apart members **44, 46** may be formed from a single elongate member and sharply bent at the apical region **48** to form the open triangular shape. Desirably, the members **44** and **46** are of substantially equal lengths. Such a stent retrieval member **42** may also be described as being generally V-shaped. While the apical region **48** is depicted as having a relatively sharp bend, the present invention is not so limited. For example, the apical region **48** may have a curved portion with a radius of curvature.

In another embodiment, a shaped projection **50** may be in the form of a trapezoid. As depicted in FIG. 10, members **52** and **54** of shaped projection **50** as substantially straight segments joined at a planar apical region **56**. The lengths of the members **52** and **54** are depicted as being substantially equal in FIG. 10. In such a case, the shaped projection **50** is formed in the shape of an isosceles trapezoid, or a shape substantially representing an isosceles trapezoid, but having an open base opposed from the apical region **56**. While the intersection of the members **52** and **54** with the apical region **56** are depicted by sharp bends in FIG. 10, the present invention, however, is not so limited. The bends may be some what rounded, i.e., having some curvature or radius of curvature.

In yet other embodiments as depicted in FIGS. 11 and 12, the shaped projection may be semi-circular, such as shaped projection **58**, or semi-elliptical, such as shaped projection **60**. Further, as depicted in FIG. 13, shaped projection **62** may include straight members **64** and **66** that are joined by a rounded or curved apical region **68**. Further, as depicted in FIG.

13, the spaced apart members **64, 66** of the shaped projection **62** define an open base, B, of the shaped projection **62**. The base, B, is further defined by a length L_1, which is the distance between the members **64, 66** thereat. Further, the apical region **68** defines a width, W_1, which is a distance between the spaced apart members **64, 66** at the apical region **68**. Desirably, as depicted in FIG. 13, the length, L_1 is greater than the width, W_1. Such spaced apart members **64, 68** may also be described as being obliquely disposed to one and the other. The present invention, however, is not so limited, and the width, W_1, at the apical region **68** may be greater than the length, L_1, between the spaced apart members **64, 66** at the base, B. Further, while the members **64, 66** are depicted in FIG. 13 as being straight or substantially straight, the present invention is not so limited. The members **64, 66** may be curved or slightly curved.

As described above, any of the above-described stent retrieval members, such as but not limited to stent retrieval member **30**, may be securably disposed or securably attached to either or both of the opposed open ends **12, 14** of the stent **10**. As depicted in FIG. 14 stent retrieval member **30** is disposed at the open end **14** of the stent **10**. As depicted in FIGS. 14 and 15, the shaped projection **34** extends longitudinally beyond the open end **14** of the stent **10**. Such longitudinal projection of the stent retrieval member **30** facilitates grasping of the member **30** by a user for retrieval or repositioning of the stent **10** from a bodily lumen. The closed stent loops **13** at stent end **14** may be equally longitudinally extending or may be longitudinally offset as depicted in FIGS. 14 and 15. The longitudinal offsetting of the stent loops **13** reduces stent deployment force. Such offsetting is described in additional detail in U.S. Provisional Application No. 60/626,729, filed November 10, 2004 and entitled "Atraumatic Stent With Reduced Deployment Force, Method For Making The Same And Method And Apparatus For Deploying And Positioning The Stent", the contents of which is incorporated herein by reference.

As depicted in FIG. 16, the stent retrieval member **30** may be securably attached to the stent end **14** by looping the generally circular base **32** through the closed stent loops **13**. The elongate wire forming the stent retrieval member **30** may be welded onto itself to form a unitary structure. The present invention, however, is not limited to the use of welding to form a unitary structure, and other joining techniques or methods may suitably be used. For example, portions of the elongate wire forming the stent retrieval member **30** may be joined

together through the use of a hypotube (not shown). Alternatively, the elongate wire portions may be crimped or tied in a knot to form a unitary structure.

As described above, the shaped projection **34** may extend perpendicularly or substantially perpendicularly from the generally circular base **32** of the stent retrieval member **30** and generally longitudinally parallel to the wall **16** of the stent **10**. The present invention, however, is not so limited. For example, as depicted in FIGS. 17 and 18, shaped projection **34'** may be inwardly disposed relative to the interior of the stent **10**. For example, the shaped projection **34'** of the stent retrieval member **30'** may include an inwardly projecting region **70** from which other portions **72** and **74** of the stent retrieval member **34'** may be suitably be disposed. The present invention is not limited to the use of the inwardly projecting region **70** for an inwardly projecting stent retrieval member **30'**. For example, as depicted in FIG. 18, stent retrieval member **30''** may include a shaped projection **34''** which is acutely disposed from the base **32''** of the stent retrieval member **30''**.

The memory shape alloy retrieval member or loop **30** may be used with any metal or polymeric stents. The main purpose of the retrieval member or loop **30** is to facilitate movement of the stent once the stent has been deployed. When the projection **34** is pulled along an axis of the stent **10**, such as the longitudinal axis of the stent **10**, the circular base **32** contracts in diameter to pull the end **14** of the stent **10** radially inward. This action removes the contact force of the end of the stent on the lumen and reduces the profile of the stent for a safe and easy maneuvering of the stent. Once the pulling force on the retrieval loop is removed, the stent self-expands against the lumen in its new position. Desirably, the pulling force excludes any twisting force. Further, the retrieval member **30** desirably does not include any barbs, eyelets or the like so that the member **30** has a low profile and does not interfere with the intended purpose or function of the stent **10**.

The stent retrieval member or loop **30** may be made from Nitinol wire wound on a mandrel of the same diameter or larger than the diameter of the end of the stent **10**. A larger diameter retrieval loop **30** will have more spring force when placed in or onto a smaller diameter stent. A higher spring force may be desirable because it can facilitate in radially expanding the stent **10**, as well as preventing the loop **30** from tangling on the stent. The retrieval member **30** may be shaped with a single protruding projection **34** or with multiple protruding projections **34** (not shown). As described above, the shape of the protruding

projection **34**, which may also be referred to as an access loop, may vary in size, angle and wire diameter.

As depicted in FIG. 19, the stent **10** may be fully, substantially or partially covered or lined with a polymeric material **102**. The stent **10** may also be embedded in a polymeric coating. The covering may be in the form of a tubular structure. Nonlimiting examples of useful polymeric materials include polyesters, polypropylenes, polyethylenes, polyurethanes, polynaphthalenes, polytetrafluoroethylenes, expanded polytetrafluoroethylene, silicone, and combinations and copolymers thereof. Desirably, the polymeric material **102** is silicone. The polymeric material and/or silicone **102** may be disposed on external surfaces **104** of the stent **10**, as depicted in FIG. 20, or disposed on the internal surfaces **106** of the stent **10**, as depicted in FIG. 21, or combinations thereof.

With any embodiment, the stent **10** may be used for a number of purposes including to maintain patency of a body lumen, vessel or conduit, such as in the coronary or peripheral vasculature, esophagus, trachea, bronchi colon, biliary tract, urinary tract, prostate, brain, and the like. The devices of the present invention may also be used to support a weakened body lumen or to provide a fluid-tight conduit for a body lumen.

Also, the stent **10** may be treated with any known or useful bioactive agent or drug including without limitation the following: anti-thrombogenic agents (such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents (such as enoxaprin, angiopeptin, or monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid); anti-inflammatory agents (such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine); antineoplastic/antiproliferative/anti-miotic agents (such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors); anesthetic agents (such as lidocaine, bupivacaine, and ropivacaine); anti-coagulants (such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides); vascular cell growth promotors (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promotors); vascular cell

growth inhibitors (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin); cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vascoactive mechanisms.

Further, with any embodiment of the stent **10** the general tubular shape may be varied. For example, the tubular shape may have a varied diameter, may be tapered, and may have an outwardly flared end and the like. Further, the ends of the stent may have a larger diameter than the middle regions of the stent. In one particularly useful embodiment, at least one of the ends of the stent transition from one diameter to another diameter. Desirably, both ends transition in this manner to yield "flared" ends, as depicted in FIG. 19.

The stent may be coated with a polymeric material. For example, the stent wires may be partially or fully covered with a biologically active material which is elutably disposed with the polymeric material. Further, the polymeric coating may extend over or through the interstitial spaces between the stent wires so as to provide a hollow tubular liner or cover over the interior or the exterior surface of the stent. The polymeric material may be selected from the group consisting of polyester, polypropylene, polyethylene, polyurethane, polynaphthalene, polytetrafluoroethylene, expanded polytetrafluoroethylene, silicone, and combinations thereof.

In one aspect of the present invention, an implantable distensible band is provided. The band comprises an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base. The elongate member may be a strand, such as a wire strand, either a monofilament or multifilament strand. Desirably, such bands may function as retrieval members when used in conjunction with a stent or a graft.

Desirably, the elongate member comprises a biocompatible material selected from the group consisting of nitinol, cobalt-based alloy, stainless steel, platinum, gold, titanium,

tantalum, niobium, polymeric materials and combinations thereof. Moreover, the elongate member comprises a biocompatible, shape-memory material, such as a super-elastic material. Desirably, The elongate member comprises nitinol.

The circular base of the implantable distensible band may be parted defining opposed parted ends, wherein the first spaced apart member extends from one of the opposed ends and the second spaced apart member extends from the other the opposed end.

The shaped projection of the implantable distensible band may be U-shaped, V-shaped, shaped as an isosceles trapezoid, shaped as a loop, lobe-shaped, semicircular-shaped, semi-elliptical-shaped, or the like, and combinations thereof.

Desirably, the shaped projection of the implantable distensible band has an open base defined by a length between the spaced apart members and a height of the apical region defined by a length from the open base and the apical region, wherein the height of the apical region is greater that the length of the open base. The shaped projection of the implantable distensible band may also have an open base defined by a length between the spaced apart members and a width of the apical region defined by a lateral length between the spaced apart members at the apical region, wherein the length of the open base is greater than the width of the apical region.

Desirably, the apical region of the implantable distensible band is curved.

Desirably, the spaced apart members of the shaped projection of the implantable distensible band are obliquely disposed to one and the other.

Desirably, the force on the implantable distensible band is a pulling force for contraction of the band, preferably, a pulling force without any twisting force.

In another aspect of the present invention, an implantable stent is provided. The stent comprises: (i) a distensible tubular stent having a tubular structure having a tubular wall defined by an interior surface and an exterior surface and having opposed open ends; and (ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base and a shaped projection having first and second spaced apart members

extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base, wherein the circular base is securably attached to one of the open ends of the stent and further wherein the shaped projection extends longitudinally beyond the one open end of the stent. Desirably, the stent comprises one or more elongate strands braided to form the stent. The plurality of elongate strands may be braided in a series of closed stent loops at the first open end to define an atraumatic stent end, i.e., a stent end having no sharp terminating wires. The circular base of the stent retrieval loop may be securably attached to the closed stent loops at the atraumatic stent end. The circular base may be interlooped with the closed stent loops. Alternatively, or in addition to, portions of the circular base may be welded to the closed stent loops, may be clamped to the closed stent loops, or the like, and combinations thereof.

In this aspect of the present invention, the stent retrieval member may be similarly shaped and made of similar materials as the above-described implantable distensible band. Further, prior to attachment of the stent retrieval member to the stent, the diameter of the circular base of the stent retrieval member may be greater than the diameter of the first open end of the stent. The circular base may contract the open end of the stent upon application of a pulling force upon the shaped projection of the stent retrieval member. Desirably, the force is a pulling force for contraction of the circular base and the first open end of the stent. The force may be a pulling force without any twisting force. The shaped projection of the stent retrieval member may be longitudinally parallel to the wall of the stent or in other words may extend from the stent while being approximately parallel to the stent wall. Alternatively or additionally, the apical region of the shaped projection of the stent retrieval member may be inwardly disposed relative to the interior surface of the stent.

In another aspect of the present invention, a method of retrieving or repositioning an implanted stent is provided. The method comprises the steps of (a) providing a tubular distensible stent comprising (i) a wall to define an interior surface and an exterior surface and having opposed open ends; and (ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base, wherein the

circular base is securably attached to one of the open ends of the stent and further wherein the shaped projection extends longitudinally beyond the one open end of the stent; (b) implanting the stent within a bodily lumen; and (c) pulling the shaped projection of the stent retrieval member to contract the first end of the stent and to move the stent.

In another aspect of the present invention, a method of retrieving or repositioning an implanted stent is provided. The method comprises the steps of (a) locating a distensible stent within a bodily lumen, the stent comprising a hollow tubular structure having a tubular wall to define an interior surface and an exterior surface and having opposed open ends and a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from the base and connected by an apical portion, whereby force exerted on the shaped projection causes contraction or expansion of the circular base, wherein the circular base is securably attached to one of the open ends of the stent and further wherein the shaped projection extends longitudinally beyond the one open end of the stent; and (b) pulling the shaped projection of the stent retrieval member to contract the first end of the stent and to move the stent. Desirably, the step of pulling the shaped projection excludes twisting of the shaped projection.

In another aspect of the present invention, a system is provided. The system comprises (a) a distensible stent, said stent comprises (i) a hollow tubular structure having a tubular wall to define an interior surface and an exterior surface and having opposed open ends; and (ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base, wherein said circular base is securably attached to one of said open ends of said stent and further wherein said shaped projection extends longitudinally beyond said one open end of said stent; and (b) a delivery catheter for implanting said stent. The system may further comprise forceps for engaging the shaped projection of the stent retrieval member.

Various stent types and stent constructions may be employed in the invention. Among the various stents useful include, without limitation, self-expanding stents and balloon expandable extents. The stents may be capable of radially contracting, as well and in this sense can best be described as radially distensible or deformable. Self-expanding stents include those that have a spring-like action which causes the stent to radially expand, or stents which expand due to the memory properties of the stent material for a particular configuration at a certain temperature. Nitinol is one material which has the ability to perform well while both in spring-like mode, as well as in a memory mode based on temperature. Other materials are of course contemplated, such as stainless steel, platinum, gold, titanium and other biocompatible metals, as well as polymeric stents. The configuration of the stent may also be chosen from a host of geometries. For example, wire stents can be fastened into a continuous helical pattern, with or without a wave-like or zig-zag in the wire, to form a radially deformable stent. Individual rings or circular members can be linked together such as by struts, sutures, welding or interlacing or locking of the rings to form a tubular stent. Tubular stents useful in the present invention also include those formed by etching or cutting a pattern from a tube. Such stents are often referred to as slotted stents. Furthermore, stents may be formed by etching a pattern into a material or mold and depositing stent material in the pattern, such as by chemical vapor deposition or the like. Examples of various stent configurations are shown in U.S. Patent Nos. 4,503,569 to Dotter; 4,733,665 to Palmaz; 4,856,561 to Hillstead; 4,580,568 to Gianturco; 4,732,152 to Wallsten, 4,886,062 to Wiktor, and 5,876,448 to Thompson, all of whose contents are incorporated herein by reference.

The invention being thus described, it will now be evident to those skilled in the art that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications are intended to be included within the scope of the following claims.

WHAT IS CLAIMED IS:

1. An implantable distensible band comprising:

an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base.

2. The implantable distensible band of claim 1, wherein said elongate member is a strand.

3. The implantable distensible band of claim 1, wherein said elongate member comprises a biocompatible material selected from the group consisting of nitinol, cobalt-based alloy, stainless steel, platinum, gold, titanium, tantalum, niobium, polymeric materials and combinations thereof.

4. The implantable distensible band of claim 1, wherein said elongate member comprises a biocompatible, shape-memory material.

5. The implantable distensible band of claim 4, wherein said biocompatible, shape-memory material is a super-elastic material.

6. The implantable distensible band of claim 1, wherein said elongate member comprises nitinol.

7. The implantable distensible band of claim 1, wherein said circular base is parted defining opposed parted ends and further wherein said first spaced apart member extends from one of said opposed ends and said second spaced apart member extends from the other said opposed end.

8. The implantable distensible band of claim 7, wherein said shaped projection is U-shaped.

9. The implantable distensible band of claim 7, wherein said shaped projection is V-shaped.

10. The implantable distensible band of claim 7, wherein said shaped projection is shaped as an isosceles trapezoid.

11. The implantable distensible band of claim 7, wherein said shaped projection is shaped as a loop.

12. The implantable distensible band of claim 7, wherein said shaped projection is lobe-shaped.

13. The implantable distensible band of claim 7, wherein said shaped projection is semicircular-shaped.

14. The implantable distensible band of claim 7, wherein said shaped projection is semi-elliptical-shaped.

15. The implantable distensible band of claim 7, wherein said shaped projection has an open base defined by a length between said spaced apart members and a height of said apical region defined by a length from said open base to said apical region, wherein said height of said apical region is greater that said length of said open base.

16. The implantable distensible band of claim 7, wherein said shaped projection has an open base defined by a length between said spaced apart members and a width of said apical region defined by a lateral length between said spaced apart members at said apical region, wherein said length of said open base is greater than said width of said apical region.

17. The implantable distensible band of claim 1, wherein said apical region is curved.

18. The implantable distensible band of claim 1, wherein said spaced apart members of said shaped projection are obliquely disposed to one and the other.

19. The implantable distensible band of claim 1, further comprising a second projection extending from said base and extending longitudinally beyond the end of the stent.

20. The implantable distensible band of claim 1, wherein said force is a substantially non-twisting pulling force for contraction of said band.

21. An implantable stent comprising:

a distensible tubular stent having a tubular structure having a tubular wall defined by an interior surface and an exterior surface and having opposed open ends; and

a stent retrieval member comprising an elongate member comprising a generally circular perimetric base and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base, wherein said circular base is securably attached to one of said open ends of said stent and further wherein said shaped projection extends longitudinally beyond said one open end of said stent.

22. The stent of claim 21, further comprising one or more elongate strands braided to form said stent.

23. The stent of claim 22, wherein said plurality of elongate strands are braided in a series of closed stent loops at said first open end to define an atraumatic stent end.

24. The stent of claim 23, wherein said circular base of said stent retrieval loop is securably attached to said closed stent loops at said atraumatic stent end.

25. The stent of claim 24, wherein said circular base is interlooped with said closed stent loops.

26. The stent of claim 24, wherein portions of said circular base are welded to said closed stent loops.

27. The stent of claim 24, wherein portions of said circular base are clamped to said closed stent loops.

28. The stent of claim 21, wherein said elongate member of said stent retrieval member is a strand.

29. The stent of claim 21, wherein said elongate member of said stent retrieval member comprises a biocompatible material selected from the group consisting of nitinol, cobalt-based alloy, stainless steel, platinum, gold, titanium, tantalum, niobium, polymeric materials and combinations thereof.

30. The stent of claim 21, wherein said elongate member of said stent retrieval member comprises a biocompatible, shape-memory material.

31. The stent of claim 30, wherein said biocompatible, shape-memory material is a super-elastic material.

32. The stent of claim 21, wherein said elongate member of said stent retrieval member comprises nitinol.

33. The stent of claim 21, wherein said circular base is parted defining opposed parted ends and further wherein said first spaced apart member extends from one of said opposed ends and said second spaced apart member extends from the other said opposed end.

34. The stent of claim 33, wherein said shaped projection of said stent retrieval member is U-shaped.

35. The stent of claim 34, wherein said shaped projection of said stent retrieval member is V-shaped.

36. The stent of claim 33, wherein said shaped projection of said stent retrieval member is shaped as an isosceles trapezoid.

37. The stent of claim 33, wherein said shaped projection of said stent retrieval member is shaped as a loop.

38. The stent of claim 33, wherein said shaped projection of said stent retrieval member is lobe-shaped.

39. The stent of claim 33, wherein said shaped projection of said stent retrieval member is semicircular-shaped.

40. The stent of claim 33, wherein said shaped projection of said stent retrieval member is semi-elliptical-shaped.

41. The stent of claim 33, wherein said shaped projection of said stent retrieval member has an open base defined by a length between said spaced apart members and a height of said apical region defined by a length from said open base to said apical region, wherein said height of said apical region is greater that said length of said open base.

42. The stent of claim 33, wherein said shaped projection of said stent retrieval member has an open base defined by a length between said spaced apart members and a width of said apical region defined by a lateral length between said spaced apart members at said apical region, wherein said length of said open base is greater than said width of said apical region.

43. The stent of claim 21, wherein said apical region is curved.

44. The stent of claim 21, wherein said spaced apart members of said shaped projection are obliquely disposed to one and the other.

45. The stent of claim 33, wherein, prior to attachment of said stent retrieval member to said stent, the diameter of said circular base of said stent retrieval member is greater than the diameter of said first open end of said stent.

46. The stent of claim 33, wherein said circular base contracts said first open end of said stent upon application of a pulling force upon said shaped projection of said stent retrieval member.

47. The stent of claim 21, wherein said shaped projection of said stent retrieval member extends from the stent and is approximately parallel to the stent wall.

48. The stent of claim 21, wherein said apical region of said shaped projection of said stent retrieval member has is inwardly disposed relative to said interior surface of said stent.

49. The stent of claim 21, further comprising a second shaped projection extending from said base and extending longitudinally beyond said first open end.

50. The stent of claim 21, wherein said force is a substantially non-twisting pulling force for contraction of said circular base and said first open end of said stent.

51. A method of retrieving or repositioning an implanted stent comprising:

(a) providing a tubular distensible stent comprising:

a wall to define an interior surface and an exterior surface and having opposed open ends; and

a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base, wherein said circular base is securably attached to one of said open ends of said stent and further wherein said shaped projection extends longitudinally beyond said one open end of said stent;

(b) implanting said stent within a bodily lumen; and

(c) pulling said shaped projection of said stent retrieval member to contract said first end of said stent and to move said stent.

52. The method of claim 51, wherein the step of pulling said shaped projection excludes twisting of said shaped projection.

53. A method of retrieving or repositioning an implanted stent comprising:

(a) locating a distensible stent within a bodily lumen, said stent comprising a hollow tubular structure having a tubular wall to define an interior surface and an exterior surface and having opposed open ends and a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base, wherein said circular base is securably attached to one of said open ends of said stent and further wherein said shaped projection extends longitudinally beyond said one open end of said stent; and

(b) pulling said shaped projection of said stent retrieval member to contract said first end of said stent and to move said stent.

54. The method of claim 53, wherein the step of pulling said shaped projection excludes twisting of said shaped projection.

55. A system comprising:

(a) a distensible stent, said stent comprising:

(i) a hollow tubular structure having a tubular wall to define an interior surface and an exterior surface and having opposed open ends; and

(ii) a stent retrieval member comprising an elongate member comprising a generally circular perimetric base implantable within a bodily lumen and a shaped projection having first and second spaced apart members extending acutely or perpendicularly from said base and connected by an apical portion, whereby force exerted on said shaped projection causes contraction or expansion of said circular base, wherein said circular base is securably attached to one of said open ends of said stent and further wherein said shaped projection extends longitudinally beyond said one open end of said stent; and

(b) a delivery catheter for implanting said stent.

56. The system of claim 55 further comprising:

forceps for engaging said shaped projection of said stent retrieval member.

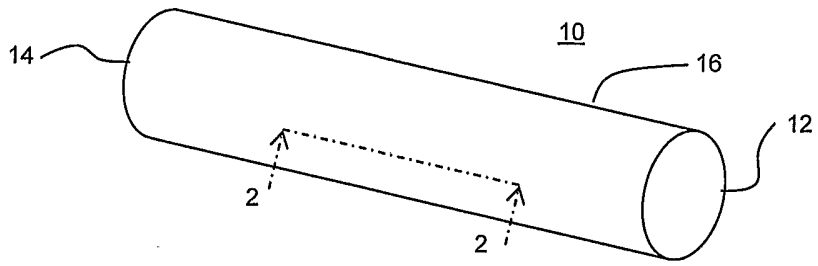


FIG. 1

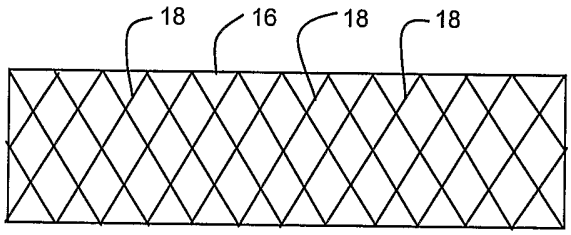


FIG. 2

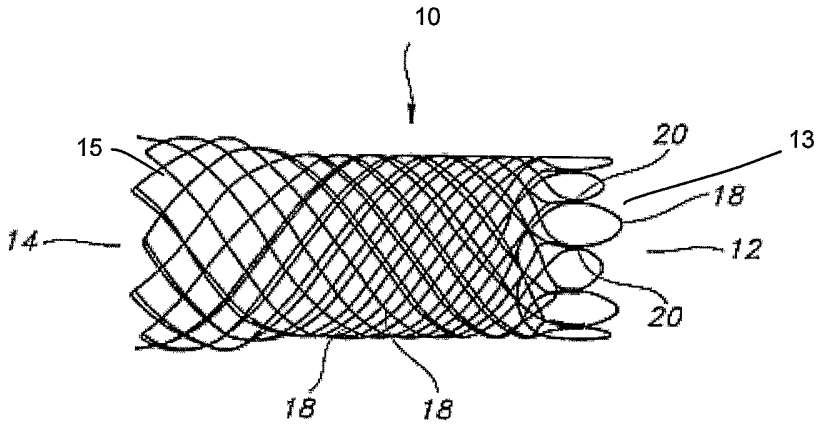


FIG. 3

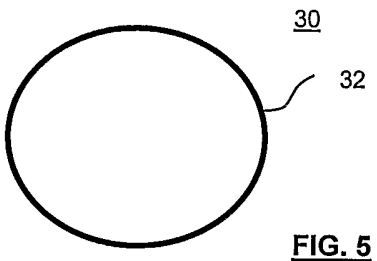


FIG. 5

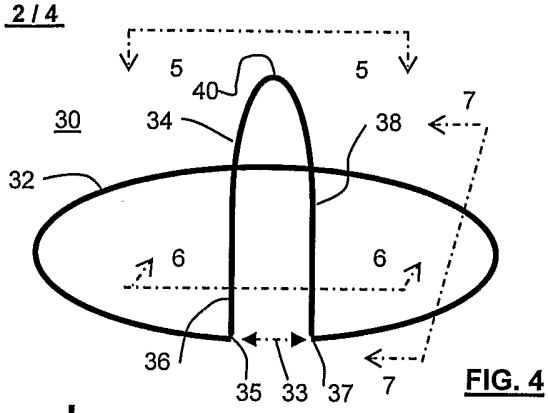


FIG. 4

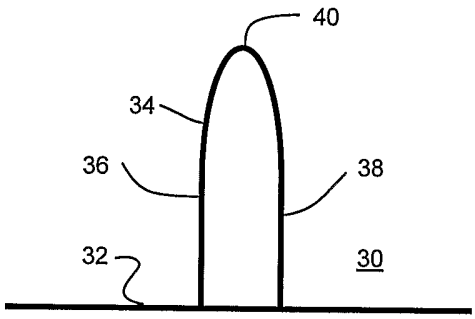


FIG. 6

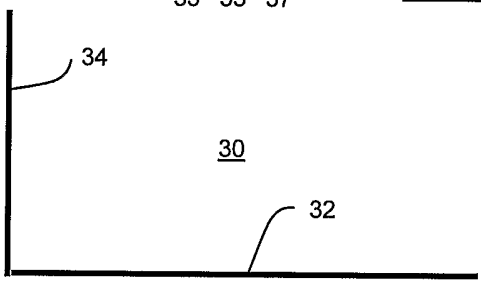


FIG. 7

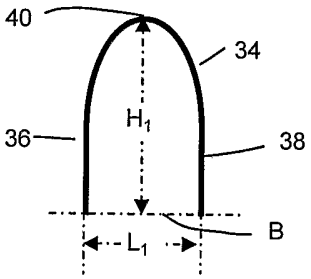


FIG. 8

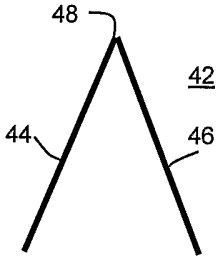


FIG. 9

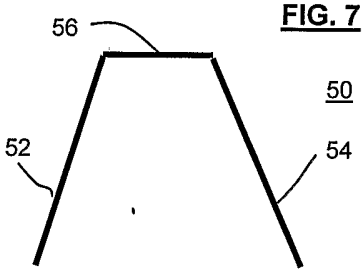


FIG. 10

FIG. 11

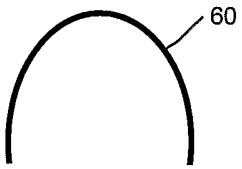


FIG. 12

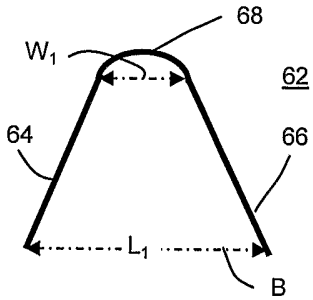


FIG. 13

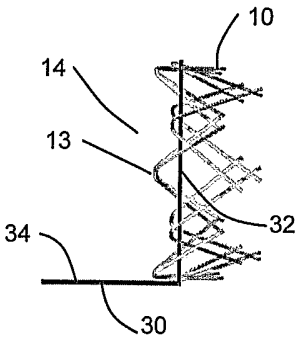


FIG. 14

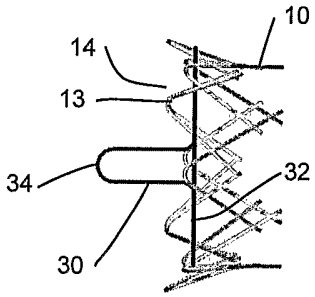


FIG. 15

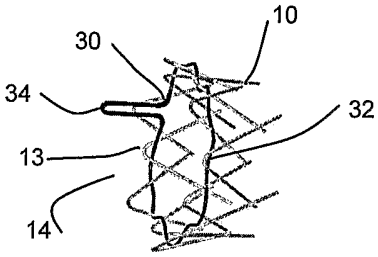


FIG. 16

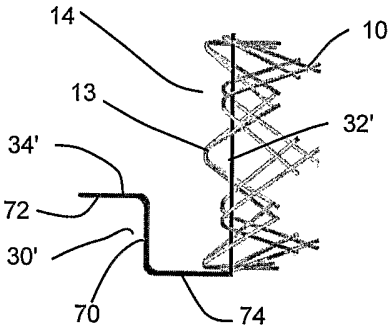


FIG. 17

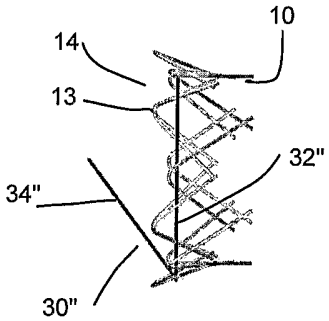


FIG. 18

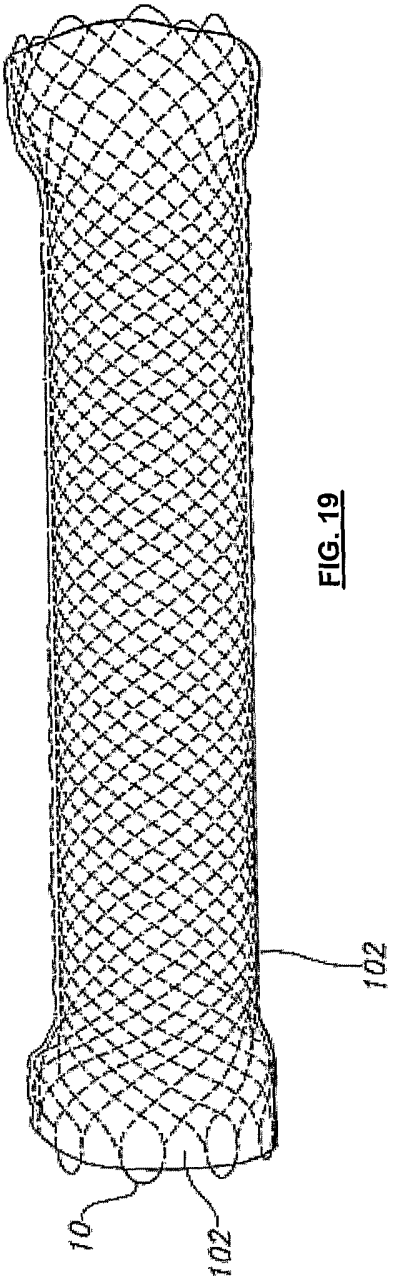


FIG. 19

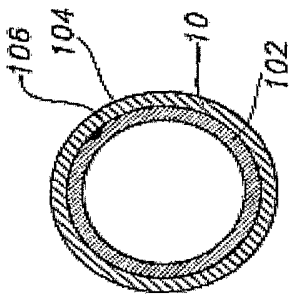


FIG. 21

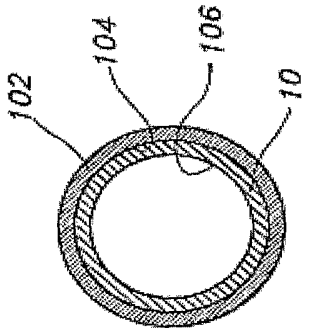


FIG. 20

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/002984

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/06

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)
A61F

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 2002/188344 A1 (BOLEA STEPHEN L ET AL) 12 December 2002 (2002-12-12) paragraph [0049] - paragraph [0051] figures 8-11	1-50,55, 56
A	US 2004/116996 A1 (FREITAG LUTZ) 17 June 2004 (2004-06-17) paragraph [0016]; figure 1	1,21,47, 49,50
A	US 5 755 777 A (CHUTER ET AL) 26 May 1998 (1998-05-26) column 7, line 60 - line 61 column 8, line 1 - line 4 figure 6	21-23

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 May 2006	02/06/2006

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	Amaro, H

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/002984

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 51-54
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2006/002984

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002188344 A1	12-12-2002	US 2005080480 A1	14-04-2005
US 2004116996 A1	17-06-2004	CA 2443899 A1	24-10-2002
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		JP 2004530472 T	07-10-2004
		MX PA03009424 A	15-10-2004
		RU 2257870 C1	10-08-2005
US 5755777 A	26-05-1998	NONE	