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Apparatus and methods for delivering coiled prostheses

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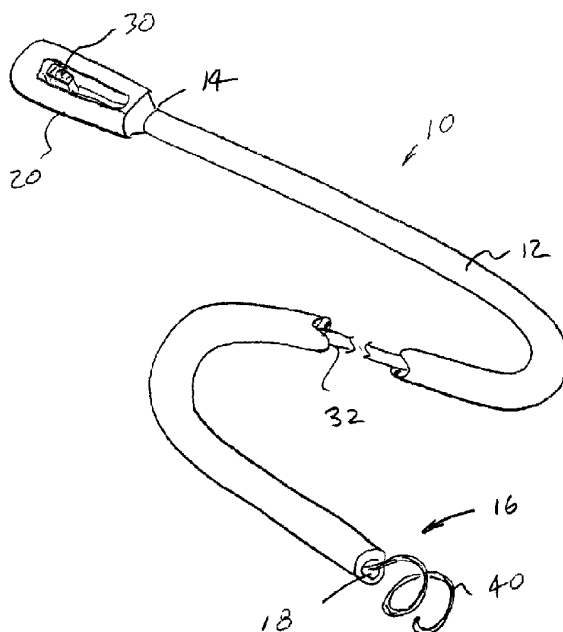
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(54) Title: APPARATUS AND METHODS FOR DELIVERING COILED PROSTHESES



(57) Abstract: Methods and apparatus for delivering prostheses to body lumens, such as stents and grafts to blood vessels, utilize a delivery device (10) which carries one or more linearized elements (40). The linearized elements (40) assume non-linear configurations, particularly helical configurations, when advanced and released from the delivery device (10). By selectively controlling the length and/or number of elements (40) delivered from the delivery device (10), extended and disseminated disease within the body lumens may be effectively treated.

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Apparatus And Methods For Delivering Coiled Prostheses

Field of the Invention

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to apparatus and methods for independently
5 delivering a plurality of luminal prostheses within a body lumen, such as a blood vessel.

Background of the Invention

Coronary artery disease is the leading cause of death and morbidity in the United States and Western society. In particular, atherosclerosis in the coronary arteries can cause myocardial infarction, commonly referred to as a heart attack, which can
10 immediately fatal or even if survived, cause damage to the heart which can incapacitate the patient.

While coronary artery bypass surgery can be an effective treatment for stenosed arteries resulting from atherosclerosis or other causes, it is a highly invasive, costly procedure, which typically requires substantial hospital and recovery time. Percutaneous
15 transluminal coronary angioplasty, commonly referred to as balloon angioplasty, is less invasive, less traumatic, and significantly less expensive than bypass surgery. Heretofore, however, balloon angioplasty has not been considered as effective a treatment as bypass surgery. The effectiveness of balloon angioplasty, however, has improved significantly with the introduction of stenting, which involves the placement of a scaffold structure
20 within the artery which has been treated by balloon angioplasty. The stent inhibits abrupt reclosure of the artery and has some benefit in inhibiting subsequent restenosis resulting from hyperplasia. Recently, experimental trials have demonstrated that coating stents with anti-proliferative drugs, such as paclitaxel, can significantly reduce the occurrence of hyperplasia in angioplasty treated coronary arteries which have been stented with the
25 coated stents.

While the combination of balloon angioplasty with drug-coated stents holds great promise, significant challenges still remain. Of particular interest is the treatment of extended or disseminated disease within an artery remains problematic. Most stents have a fixed length, typically in the range from 10 mm to 30 mm, and the placement of
30 multiple stents to treat disease over a longer length requires the successive use of multiple balloon stent delivery catheters. Moreover, it can be difficult to stent an angioplasty-treated region of a blood vessel with the optimum stent length.

For these reasons, it would be desirable to provide improved stents, stent delivery systems, stenting methods, and the like, for the treatment of patients having

coronary artery disease, as well as other occlusive diseases of the vasculature. In particular, it would be desirable to provide stents, delivery systems, and methods for the treatment of disseminated and variable length stenotic regions within the vasculature. For example, it would be desirable to provide methods which permit a physician to optimize
5 the length of the treated vessel which is stented according to the nature of the disease, either by adjusting the stent length *in situ* or by placing multiple stents of the same or different lengths over the treatment region.

U.S. Patent No. 6,190,402B1, describes a self-forming vasculature implant. U.S. Patent No. 6,258,117, describes a multiple section stent structure; and U.S. Patent No.
10 5,895,398, describes a clot retrieval device having a deployable helical clot snare.

Object of the Invention

It is an object of the present invention to overcome or ameliorate some of the disadvantages of the prior art, or at least to provide a useful alternative.

Brief Summary of the Invention

15 The present invention at least in a preferred embodiment provides for improved methods, apparatus, and systems for delivering prostheses to body lumens, particularly stents and grafts to blood vessels in the arterial and venous vasculature. The prostheses preferably comprise scaffold structures formed from linearized elements, typically metal wires having a round diameter, but also including ribbons, multifilar cables, braided
20 structures, composite structures, wires having non-circular cross-sections, and the like. By "linearized element", it is meant that the structural component will be capable of assuming a linearized configuration while the scaffold is being delivered. Most simply, the linearized element will have a non-linear configuration when unconstrained and will assume the linearized configuration when subjected to radial or axial constraint. In such
25 instances, the linearized element will be formed so that it has a "memory" of the non-linear configuration but can be linearized by applying compressive or axial stress. In the exemplary embodiment, the linearized element has a helical memory. When constrained within the lumen of a delivery device, the linearized element assumes a generally straight configuration. When advanced outwardly from the constrained lumen, however, the
30 linearized element returns to its helical configuration. A number of metals will have efficient elasticity to be able to shift between the linearized and non-linear configurations. Some of the metals include spring stainless steels, such as MP35N, Elgiloy, as well as superelastic alloys, such as nickel-titanium alloys, e.g. Nitinol™ alloy.

While the presently preferred linearized element will be formed from an elastic metal, one skilled in the art will appreciate that a variety of other metal and non-metal materials could be used to form such elements. For example, the elements could be formed from malleable metals, such as malleable stainless steel alloys, where the linearized element is then deformed into the non-linear configuration as it is advanced from the delivery device, e.g., by passing the linearized element over a shaping mandrel in the delivery device. Alternatively, the linearized element could be formed from a heat memory alloy, where the element is heated *in situ* after deployment in order to effect the change in shape from linear to non-linear. In addition, resilient and malleable polymeric and other non-metal materials might find use. These technologies, as well as others, for changing the shape of metal and non-metal structures within body lumens, are well described in the technical and medical literature.

The linearized elements of at least a preferred embodiment of the present invention will be capable of assuming a variety of non-linear configurations. While helical non-linear configurations are presently preferred, it will be appreciated that serpentine, zigzag and other irregular configurations would also be suitable for at least some of the intended purposes of at least the preferred embodiment of the present invention. Moreover, while it will generally be preferred to form the linearized elements from wire, most usually wire having a circular cross-section, it will also be possible to form the linearized elements from ribbons, flat sheets of material, and other conventional techniques. For example, serpentine or zigzag non-linearized elements could be formed from flat sheets of appropriate metal, e.g. by laser cutting, chemical etching, or the like. For example, a flat sheet could be configured to assume a desired tubular geometry.

Methods according to at least a preferred embodiment of the present invention for delivering prosthesis to a body lumen comprise introducing a delivery device to an interior of the body lumen, typically the lumen of a blood vessel, where the device carries the linearized element, as discussed above. The element is preferably deployed by advancing the element relative to the delivery device within the interior of the body lumen so that the element assumes its non-linear configuration across the surface region of the interior as the element is advanced. The element is then released from the delivery device after it has assumed its non-linear configuration. Release may be effected by selectively severing the element after a desired length of the element has been reached. Alternatively, the delivery device may carry a plurality of linearized elements, each having a desired length so that each individual element is released after its entire length has been advanced from the delivery device.

Advancing the linearized element relative to the delivery device may comprise drawing the delivery device proximally relative to the body lumen while pushing the linearized element from the delivery device, typically using an internal pusher element. In such instances, the pusher rod will usually be held in a generally stationary relationship to the body lumen, while the delivery device is retracted proximally relative to both the body lumen and the pusher rod. In this way, the linearized element will deploy within the body lumen, while assuming its non-linear configuration, with little or no relative movement relative to the luminal wall. That is desirable since any movement of the linearized element against the luminal wall may cause injury, particularly in arteries and other blood vessels.

In order to even further reduce movement of the deploying linearized element against the vessel wall, and thus reducing the risk to trauma to the vessel wall, it will often be desirable to control the deployment to offset the foreshortening of the linearized element as it is deployed. It will be appreciated that when a linearized element assumes a non-linear configuration, such as a helical configuration, the absolute length of the element will shorten. In the case of helical elements, the shortening will be quite significant, typically from 80 percent to 99 percent, depending on the pitch of the helix which is released. In order to minimize motion of the element against the vessel wall as it is deployed, it is therefore desirable to move the delivery device approximately at a rate substantially equal to the axial progress of the deployed helix within the body lumen (which will be much less than the absolute length of the linearized element which is being expelled). Thus, the pusher rod will be moving in a distal direction which is more rapid than the proximal withdrawal of the delivery device. Moreover, it will be further desirable to rotate the delivery device so that the deploying "helical" element is not caused to rotate within the vessel. Thus, three separate parameters of the deployment will need to be controlled to minimize the relative motion of the helical element against the blood vessel wall. First, the delivery device will be withdrawn proximally at a rate equal to the axial rate of deployment of the helix within the blood vessel. Second, the pusher rod will be distally advanced at a rate equal to the liner deployment rate of the helix within the deployment device. Finally, rotation of the delivery device will be controlled to counteract any tendency of the delivery device to rotate the helix as it is being deployed. All three of these deployment parameters may be manually controlled by the physician by observing the deployment under fluoroscopic imaging. Alternatively, programmable systems may be provided to automatically deploy and control the element deployment.

In a specific aspect of the method of the present invention, the pitch of the helical element may be controlled by adjusting the rate of drawing the delivery device proximally and/or advancing the linearized element from the delivery device. While the helical configuration of the linearized device will usually have a preferred or natural pitch, the actual pitch within the blood vessel or the body lumen may be controlled to a certain degree by adjusting its rate of advancement and the withdrawal rate of the delivery device to adjust the pitch. Usually, the delivery device will be rotated in order to further control the release geometry of the linearized element.

In other specific aspects of the method of the present invention, the prostheses are selectively deployed to transverse desired lengths of the vasculature or other body lumen. The covered length can be controlled in either or both of two ways. First, when the delivery device has the ability to sever the linearized element, the treating physician can control the length of the prostheses by simply stating at a first target limitation, deploying the prostheses as described above (optionally with control of pitch in a helical prostheses), and severing the prostheses from the delivery device when a desired end location has been reached.

Additionally, the length of the vessel to be treated may be controlled by delivering multiple helical or other prostheses at selected and distributed portions of the luminal wall. Again, the treating physician will choose a beginning point within the body lumen and then deliver a prostheses over a selected length of the body lumen from that point. One, two, three, four or more additional segments of the prostheses may then be deployed.

Thus, the methods and apparatus of at least a preferred embodiment of the present invention can be used to treat both short and long diseased segments within the vasculature and other body lumens. Usually, the treated regions will have a length of at least 10 mm and may have a length up to 60 mm and in some instances 100 mm or longer. Typically, when using only a single deployed prostheses, the treated lengths will be from 10 mm to 50 mm, usually from 10 mm to 30 mm. When using multiple prostheses, the lengths may be much greater, typically from 20 mm to 100 mm, more often from 20 mm to 60 mm.

As a further option, the linearized elements of at least a preferred embodiment of the present invention may be coated, loaded, or otherwise coupled to or with an active substance intended to enhance the selected therapy. Linearized elements intended for treating blood vessels and other body lumens may be coated with substances intended to inhibit cellular proliferation, inflammation, or other conditions. Exemplary active

substances include anti-neoplastic drugs such as paclitaxel, methotrexate, and batimastat; antibiotics such as doxycycline, tetracycline, rapamycin, and actinomycin; immunosuppressants such as dexamethasone, methyl prednisolone, nitric oxide sources such as nitroprussides; estrogen; estradiols; and the like.

5 The present invention at least in a preferred embodiment further comprises catheters and other apparatus for delivering helical prostheses. The catheters preferably comprise a catheter body having a proximal end, a distal end, and at least one lumen through at least a portion thereof. A linearized element is preferably disposed in the lumen, and the mechanism for advancing and releasing at least one length of the
10 linearized element from the lumen is provided. As described above, the linearized elements will assume a non-linear configuration when advanced and released from the catheter body. Usually, the advancing and releasing mechanism will comprise a severing mechanism to selectively cut the linearized element after a desired length has been released. Alternatively, the catheter may carry a plurality of linearized elements which
15 are divided or cut into discrete lengths prior to deployment. Thus, the discrete lengths may be released after they are fully advanced from the lumen of the catheter body. In the latter case, the catheter body may carry from two to twenty discrete elements, typically from three to ten discrete elements.

Brief Description of the Drawings

20 A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 is a perspective view of a catheter capable of delivering helical elements constructed in accordance with the principles of the present invention.

25 Figs. 1A and 1B illustrate alternatively non-linearized element geometries according to the present invention.

Fig. 2 is a detailed view of the distal end of the catheter of Fig. 1, shown in section.

Fig. 3 is an alternative view of the distal end of the catheter of Fig. 1, shown in section.

30 Fig. 4 is a second alternative view of the distal end of the catheter of Fig. 1, shown in section.

Figs. 5A-5E illustrates use of the catheter of Fig. 1 for delivering multiple, helical prostheses at distributed points in the blood vessel.

DETAILED DESCRIPTION OF THE INVENTION

- [0026] Referring to Fig. 1, a delivery device comprising a catheter 10 includes a catheter body 12 having a proximal end 14 and a distal end 16. The catheter will include at least one lumen 18 (Fig. 2) extending over at least a portion thereof, and will further include a proximal
- 5 hub 20 attached to the proximal end 14. Hub 14 will include a mechanism for advancing a linearized element 26 from the lumen 18, such as a thumb slide 30. In the exemplary embodiment, the thumb slide will be attached to a push rod 32 which extends through the lumen 18 and engages the linearized element(s) 40 to be advanced from the catheter. As shown in Fig. 1, the linearized element 40 assumes a helical non-linear configuration as it is advanced from the
- 10 lumen 18 of the catheter body 12.
- [0027] Referring now to Fig. 1A, an alternative linearized element 42 is illustrated which will assume a serpentine non-linear configuration when advanced from the catheter or other delivery device. Fig. 1A shows the serpentine structure in its flattened or "rolled-out" configuration. It will be appreciated that the scaffold provided by the serpentine structure will be
- 15 rolled into a generally tubular configuration, as indicated by the arrows in Fig. 1A. When linearized, the element 42 will still assume a generally straight configuration, as shown in Fig. 2. A second alternative non-linear geometry comprises the zigzag pattern shown in Fig. 1B. Again, Fig. 1B illustrates this pattern in its flattened or rolled-out configuration. The actual device would be rolled as indicated by the arrows into a generally tubular configuration to serve as a
- 20 scaffold structure in the present invention.
- [0028] As illustrated in Fig. 2, a single linearized element 40 is pushed by the pusher rod 32 to assume its helical or rather non-linear configuration when fully released from the catheter body 12. Since the linearized element 40 and the pusher rod 42 are not connected, there is no need to provide a severing or other release mechanism in the embodiment of Fig. 2.
- 25 [0029] Fig. 3, in contrast, shows a linearized element 46 having an indeterminate length. That is, the linearized element 46 will be sufficiently long so that it may be divided into two, three, four, or an even larger number of discrete non-linearized elements upon release from the catheter body 12. In order to effect such release, a severing device 50, such as an actuatable blade, electrochemical, or other severing mechanism, is provided at the distal end of the delivery
- 30 device. In this way, once a non-linear structure having a sufficient length has been delivered, the transition point between the linearized element and the non-linearized element will be severed using the device 50. Additional non-linear scaffold devices may then be delivered using the same catheter over regions space-part within the vasculature or other body lumens.

[0030] Referring now to Fig. 4, a third alternative advancement and release mechanism is illustrated. The embodiment of Fig. 4 is similar to that of Fig. 2, except that a plurality of discrete linearized elements 48a, 48b, and 48c, are carried within lumen 18 and advanced using pusher rod 32. It will be appreciated that since these linearized elements 48a - 48c are separate, and unconnected, they may be released sequentially by advancing the pusher rod (and optionally retracting and/or rotating the catheter body 12) to deliver each non-linearized element. There is no need to provide for a severing mechanism as with the embodiment of Fig. 3. While three discrete linearized elements 48a - 48c are illustrated, it will be appreciated that anywhere from two to 10 linearized elements, or more, could be accommodated using the approach of Fig. 4.

10 [0031] Referring now to Figs. 5A - 5C, use of the delivery catheter 10 of Fig. 1 and Fig. 3 or Fig. 4 will be illustrated. Catheter 10 is initially delivered so that its proximal end 16 lies past a first target region TR1, as shown in Fig. 5A. The catheter 10 may be introduced over a guide wire GW. The catheter may be an over-the-wire design. In some instances, however, it will be preferable to provide a rapid exchange design having a side guide wire port 60 spaced a short distance from its distal end, as shown in Fig. 2. In this way, the catheter may be introduced by withdrawing the pusher rod 32 and linearized elements approximately so that they lie behind the side guide wire port 60. The catheter may then be introduced over the conventional guide wire GW without the need to completely remove and/or exchange the pusher rod and linearized element assembly with the guide wire. Of course, for catheters having larger diameters, it would be possible to provide a separate guide wire lumen extending the entire length of the catheter for an over-the-wire introduction.

25 [0032] Once the catheter 10 is in place, the pusher rod 32 will be advanced so that the first non-linearized element 48 is advanced from the distal end 16, as illustrated in Fig. 5B. The pusher rod is pushed in the direction of the arrow and a leading end of the element 48c engages the luminal wall of the blood vessel BV.

[0033] After the element 48c engages the luminal wall, it is desirable to begin retracting the catheter body in the direction of arrow 70 while advancing the pusher rod 32 in the direction of arrow 72 while preferably rotating the catheter body to counteract the relative rotation of the element 48c. The catheter body is thus rotated in the direction of arrow 74. By appropriately controlling each of these three motions, the coil will deploy helically with minimal motion relative to the luminal wall.

30 [0034] The first prostheses 48a will be completely delivered when it is advanced fully from the distal end 16 of catheter 10, as illustrated in Fig. 5D. The catheter 10 may continue to be withdrawn through the vasculature or other body lumen until a second region is reached where it

is desired to deliver the second element 48b. The steps of delivering the second linearized element 48b from the catheter are analogous to those described in Figs. 5A - 5C for the first element 48a. A complete deployment of the first linearized element 48a into its helical configuration and the second linearized element 48b into its helical configuration are illustrated in Fig. 5E.

5 [0035] It will be appreciated that the lengths, pitches, adjacent spacings, and the like, of the helical and other elements deployed according to the methods of the present invention can be controlled at the discretion of the treating physician. Thus, the methods and apparatus of the present invention provide useful flexibility for the treating physician to treat extended and
10 disseminated disease in the vasculature and other body lumens.

[0036] Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

The claims defining the invention are as follows:-

1. A method for delivering a prosthesis to a stenotic region of a blood vessel, the method comprising:

introducing an elongate catheter shaft having a proximal end, a distal end and a lumen therebetween into the blood vessel, the shaft carrying a self-expandable prosthetic element disposed in the lumen in a linearized configuration while constrained in the lumen and adapted to radially expand into a helical configuration upon deployment, and wherein the prosthetic element is separable into a first prosthesis having a first length and second prosthesis having a second length prior to release from the catheter shaft;

advancing the first lumen of the prosthetic element from the lumen while the second length is retained in the lumen in the linearized configuration; and

separating the first prosthesis from the second prosthesis with a separating element coupled to the catheter shaft such that the first prosthesis resiliently expands to the helical configuration outside the lumen while the second prosthesis is retained in the catheter shaft in the linearized configuration, the helical configuration being generally tubular with an open longitudinal passage therein adapted to provide a scaffold to inhibit closure of the blood vessel without substantially inhibiting blood flow through the longitudinal passage, wherein the first prosthesis continuously engages a wall of the blood vessel along substantially all of the first length.

2. A method according to claim 1, wherein separating comprises severing the first prosthesis from the second prosthesis after the first prosthesis has traversed the stenotic region.

3. A method according to claim 1, further comprising viewing the first prosthesis relative to the length of the stenotic region.

4. A method according to claim 1, wherein advancing comprises drawing the catheter shaft relative to the blood vessel and pushing the first prosthesis from the lumen as the catheter shaft is drawn.

5. A method according to claim 4, wherein the rate of drawing the catheter shaft is varied relative to the rate of pushing the first prosthesis from the catheter shaft in order to control the pattern in which the first prosthesis is laid on the stenotic region.

6. A method according to claim 4, wherein the rate of drawing the delivery catheter is varied relative to the rate of pushing the first prosthesis from the delivery catheter in order to control the pitch of the first prosthesis

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7. A method according to claim 4, further comprising rotating the catheter shaft as the first prosthesis is pushed.

8. A method according to claim 1, wherein the prosthetic element is at least partially malleable and wherein advancing comprises deforming the first prosthesis into the helical configuration as the first prosthesis is advanced.

9. A method according to claim 1, wherein the prosthetic element is pre-shaped with a spring memory and wherein advancing comprising releasing the first prosthesis from a linearized constraint.

10. A method according to claim 9, wherein the constraint is the lumen and wherein advancing comprises pushing the first prosthesis from the lumen as the catheter shaft is drawn relative to the body lumen.

11. A method according to claim 10, wherein the rate of drawing the catheter shaft is varied relative to the rate of pushing the first prosthesis in order to control the pattern in which the first prosthesis is laid on the stenotic region.

12. A method according to claim 11, wherein the first prosthesis is advanced so that it traverses the stenotic region with diffuse disease over a length of at least 10 mm.

13. A method according to claim 10, wherein the element is coated or loaded with an active substance which inhibits hyperplasia after the first prosthesis has been placed in the blood vessel.

14. A method according to claim 1, wherein the prosthetic element is composed at least partly of a bioabsorbable material.

15. A method according to claim 14, wherein the prosthetic element comprises a metal scaffold covered with a polymeric layer.

16. A method according to claim 1, wherein the first length is different than the second length.

17. A catheter for delivering a prosthesis to a blood vessel, said catheter comprising:

an elongate shaft having a proximal end, a distal end and a lumen therebetween;
a self-expanding prosthetic element carried by the shaft and disposed in the lumen in a linearized configuration while constrained in the lumen and adapted to radially expand into a helical configuration upon deployment, wherein the prosthetic element is separable into a first prosthesis having a first length and a second prosthesis having a second length prior to release from the shaft; and

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a separating element coupled with the shaft adapted to separate the first prosthesis from the second prosthesis such that the first prosthesis resiliently expands to the helical configuration outside the lumen while the second prosthesis is retained in the shaft in the linearized configuration, the helical configuration being generally tubular with an open longitudinal passage therein adapted to provide a scaffold to inhibit closure of the blood vessel without substantially inhibiting blood flow through the longitudinal passage, wherein the first prosthesis continuously engages a wall of the blood vessel along substantially all of its first length.

18. A catheter as in claim 17, wherein the prosthesis carries a therapeutic agent.

19. A catheter as in claim 18, wherein the therapeutic agent comprises an anti-restenosis agent.

20. A catheter as in claim 17, wherein the prosthetic element is composed at least partly of a bioabsorbable material.

21. A catheter as in claim 17, wherein the prosthetic element comprises a metal scaffold covered with a polymeric layer.

22. A catheter as in claim 17, wherein the first length is different than the second length.

23. A method of delivering a prosthesis to a body lumen, said method substantially as herein described with reference to any one of the embodiments of the invention as shown in the accompanying drawings.

24. A catheter, substantially as herein described with reference to any one of the embodiments of the invention shown in the accompanying drawings.

Dated 7 February, 2008

Xtent, Inc.

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON

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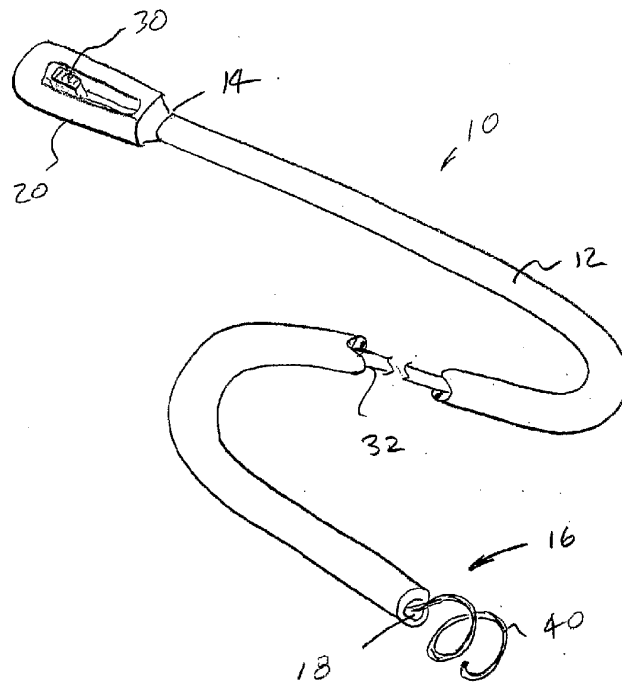


FIG-1

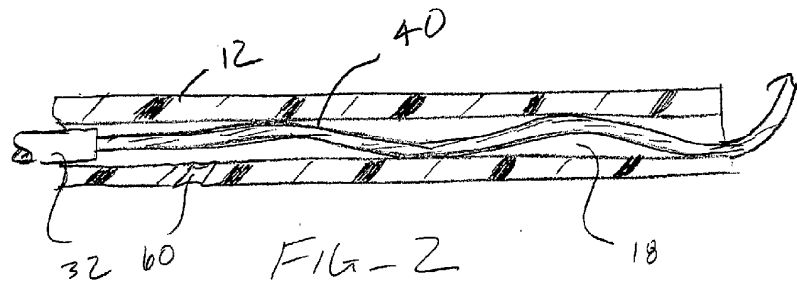


FIG-2

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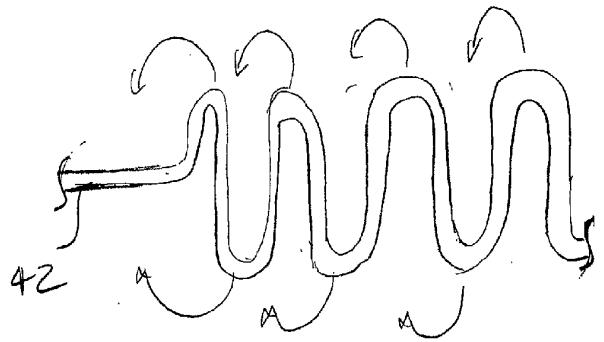


FIG-1A

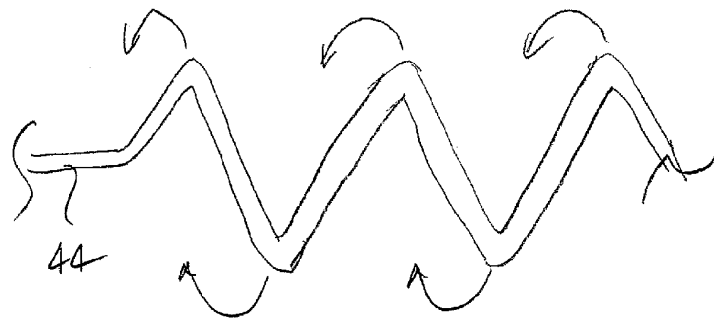
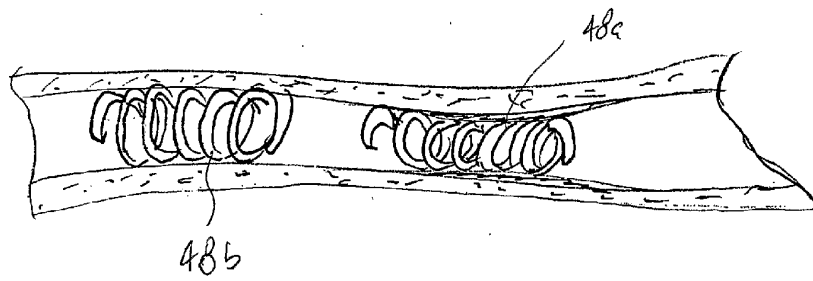
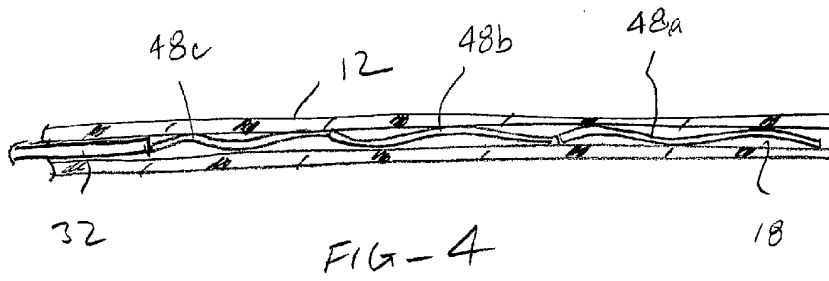
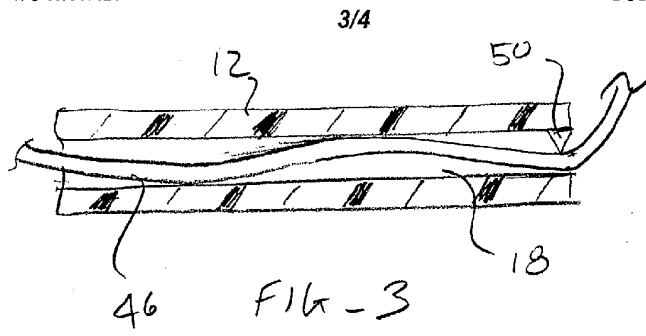


FIG-1B



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