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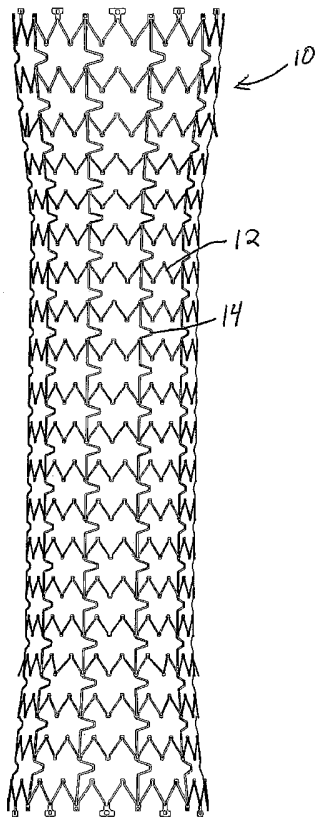
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(54) Title: STENT REMOVAL AND REPOSITIONING AID AND ASSOCIATED METHOD



(57) Abstract: A removable stent for placement within a portion of the anatomy of a patient is provided. The stent includes a scaffolding having struts that is configured to define a substantially cylindrical member having a proximal end and a distal end. The stent also includes a suture intertwined about at least a portion of the struts, wherein the suture includes at least one loop such that a force applied to the loop does not result in purse-stringing.

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STENT REMOVAL AND REPOSITIONING AID AND ASSOCIATED METHOD

BACKGROUND OF THE INVENTION

1) Field of the Invention

The present invention relates to stents, in particular, to a stent removal and repositioning aid that promotes removal or repositioning a stent within a lumen.

2) Description of Related Art

Stents are devices that are inserted into body lumens such as vessels or passages to keep the lumen open and prevent closure due to a stricture, external compression, or internal obstruction. In particular, stents are commonly used to keep blood vessels open in the coronary arteries and they are frequently inserted into the ureters to maintain drainage from the kidneys, the bile duct for pancreatic cancer or cholangiocarcinoma, or the airways and esophagus for strictures or cancer. Vascular as well as nonvascular stenting has evolved significantly; unfortunately there remain significant limitations with respect to the technology for positioning and removing stents following implantation into various portions of a patient's anatomy.

In various areas of application, *e.g.*, bronchus, biliary, trachea, or esophagus, the stents must be removable from the body or repositionable as a function of the course of the disease or treatment. This can be problematic since newly formed tissue can grow on the support frame of the stent and even grow through it, which can result in complications when removing a stent. In this regard, stents have been developed that include a support frame surrounded on the outside by a thread or wire. The support frame can be radially constricted by pulling on the thread ends that are each provided with a loop or the like, reducing a length of the thread engaged around the stent and creating a "purse-string" effect, which makes it possible for the frame to be removed or repositioned. However,

when the wire or thread is guided or braided in multiple windings around the support frame, a high degree of friction results between the two stent components, which has a disadvantageous effect on the explantation process. In addition, stents having eyelets for looping the thread therethrough may have sharp edges that cause the thread to tear or break during the removal process.

Alternatively, physicians have grasped the thread ends with forceps or a similar instrument to reposition or remove the stent from within the lumen. However, this can be complex at times when the tissue has grown over the suture thread. Also, the suture may not be strong enough to remove the stent. Grasping may lead to damage to the stent itself, as the forceps may have difficulty accessing or adequately gripping the thread to remove or reposition the stent. Physicians may also use grasping forceps to grab the struts of the stent at a proximal end and remove the stent from the deployment site, but this also risks damage to the lumen or the stent, as the proximal end of the stent may be difficult to access.

Thus, there is a need in the industry for a stent that reduces the risk of damage to the stent, thread or suture, and/or the surrounding tissue during removal or repositioning of the stent. In addition, there is a need for a stent that provides for greater accessibility, as well as promotes effective repositioning and/or removal of the stent from a lumen.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Having thus described the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

FIG. 1 is a plan view of a stent having an interstice geometry, according to one embodiment of the present invention;

FIG. 2 is an end view of the stent shown in FIG. 1;

FIG. 3 is a perspective view of a stent including a plurality of sutures and illustrating each suture arranged throughout interstices of the stent, according to one embodiment of the present invention;

FIG. 4 is a perspective view of a stent including at least one suture and illustrating the suture arranged throughout interstices of the stent, according to another embodiment of the present invention;

FIG. 5 an enlarged perspective view of a suture arranged along the interstices of the stent shown in FIGS. 3-4, according to one embodiment of the present invention; and

FIG. 6 is a partial perspective view of a stent including a plurality of suture loops and a suture extending therethrough, according to yet another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, this invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

With reference to FIGS. 1-2, a stent **10** is shown having interstice geometry. The stent **10** includes a scaffolding of struts. The struts generally include a plurality of interconnected legs **12** and connectors **14**. As shown in FIG. 1, the stent **10** includes a series of legs **12** arranged circumferentially about the stent, as well as arranged in rows along the longitudinal axis of the stent, while a plurality of connectors **14** are arranged parallel to the longitudinal axis of the stent to connect the rows together. The stent **10** is formed of a memory metal that facilitates flexibility of the stent **10** such that the stent may be deformed and return to its original shape. As such, the legs **12** and connectors **14** of the stent **10** are preferably formed from a composite material such as Ni, C, Co, Cu, Cr, H, Fe, Nb, O, Ti and combinations thereof (*e.g.*, Nitinol). The composite material is generally formed into a compressed tube from which the stent is etched and is formed on a suitable shaping device to give the stent the desired external geometry.

The stent **10** is generally cylindrical, having openings at the proximal and distal ends. As illustrated in FIG. 1, the diameter of the proximal and distal ends is

slightly larger than the diameter of longitudinal portion of the stent extending therebetween. In the event the stent is to be shaped to the dimensions of a particular lumen, optical photography and/or optical videography of the target lumen may be conducted prior to stent formation. The interstice geometry of the stent then can be etched and formed in accordance with the requirements of that target lumen. For example, if the stent **10** were designed for the trachea, which has a substantially D shaped lumen and additionally the middle portion of the stent is preferably softer than the proximal or distal ends, the stent could be designed to those specifications. In particular, if the topography of the trachea of a particular patient is captured optically and the appropriate dimension provided, a patient specific prosthesis could be engineered. These techniques can be adapted to other non-vascular lumina but is very well suited for vascular applications where patient specific topography is a function of a variety of factors such as genetics, lifestyle, *etc.*

It should be pointed out that, unlike the use of differing shape memory materials to change regions of a stent **10**, stents in accordance with the present invention can take on an infinite number of characteristic combinations of interstice geometry by changing angles, segment lengths, and segment thicknesses during the etching and forming stages of stent engineering or during post formation processing and polishing steps. Moreover, by modifying the geometry of the connectors **14**, additional functionality may be achieved.

The stent could also include a cover, typically a polymer such as polyurethanes (*e.g.*, polycarbonate urethane, or Chronoflex® manufactured by Cardiotech International), that is applied between the legs **12** and connectors **14** to provide a predetermined shape for the stent **10**, as well as graft each of the legs and connectors into a unitary structure. The cover does not inhibit flexing or radial expansion of the stent **10**, although it is possible to design the cover so that it controls the physical properties of the stent.

The suture **16** may be any suitable suture material, as known to those skilled in the art, such as polypropylene. However, it is understood that the term "suture" as used herein could be any suitable thread or wire or other material having a preferably flexible, but possibly inflexible, elongate shape, as known to

those skilled in the art, capable of transferring force from forceps or a similar instrument to the stent **10** in alternative embodiments of the present invention.

Therefore, it is understood that any number of configurations of stents **10** could be incorporated and still be within the present scope of the invention. An exemplary embodiment of the interstice geometry of a stent **10** is disclosed in U.S. Patent Publication No. 20040127973 (Application No. 10/674,972), entitled "Removable Biliary Stent," which is assigned to the present assignee and is incorporated herein by reference. Thus, the interstice geometry of the stent **10** should not be limited to that depicted in the disclosed Figures, as any number of configurations of interstice geometry could be employed with the present invention to achieve various degrees of rigidity and functionality. U.S. Patent Publication No. 20040122511 (Application No. 10/669,450) entitled "Coated Stent with Geometry Determined Functionality and Method of Making the Same," which is assigned to the present assignee, is also incorporated herein by reference, and further describes a cover that may be employed with the present invention, including the types of materials and properties suitable for the cover, as well as the process of manufacturing the stent **10**.

FIG. 3 illustrates a suture **16** intertwined about the legs **12** and connectors **14** of the stent **10**. The suture **16** preferably defines a plurality of loops **18** located proximate to, and circumferentially about, at least one opening of the stent **10**. However, in alternative embodiments there may be strands of suture **16** extending from the proximal and distal ends instead of loops **18** and, for example, the free end of the suture could have a knot that allows forceps or a similar instrument to grasp the end of the suture. The suture **16** typically extends along the longitudinal axis of the stent **10** from the proximal and/or distal end of the stent and stops three to four leg **12** segments along the connectors **14**. However, the suture **16** could extend along the entire longitudinal axis of the stent **10** from the proximal to distal end or could extend any number or leg **12** segments along a respective connector **14**. Each loop **18** is sized and configured to receive forceps or a similar instrument, and at least a portion of the remaining suture **16** opposite that of the loop is attached to the legs **12** and/or connectors **14** to prevent the suture from coming loose or completely disengaged from the stent **10**. Each loop **18** is

attached to the stent **10** such that a force applied through the suture **16** transfers force through the loops and to the stent. The suture **16** could include, for example, a knot that secures the suture to the stent, but an adhesive, a fastener, or similar technique could also be used that is capable of effectively transferring force. In addition, the suture **16** could also be held in place on the stent **10** by a cover and struts on a covered stent. For instance, the suture **16** could be formed integral with the cover and struts of the stent **10** such that knots and the like would not be required.

Therefore, when forceps or a similar instrument pulls on one or more of the loops **18** at the proximal end of the stent **10**, the stent is urged in the direction of pulling such that the stent may be repositioned within a lumen or completely removed. Moreover, the forceps could also be positioned through the axis of the stent **10** and through one or more loops to push the stent at the distal end of the stent, such that the stent is pushed to a different position or removed from the lumen. In this regard, pulling or pushing on the loops **18** does not create a purse-string effect and consequently, the expanded diameter of the stent **10** is unlikely to change during repositioning or explantation. Eliminating the purse-string effect reduces the risk of re-expansion failure, such as by plastic deformation of the stent, when the stent **10** is repositioned within the lumen.

FIG. 4 illustrates an alternative embodiment, wherein the suture **16** is arranged in a single loop, with the ends of the loop connected with a knot **20**. The loop extends from the proximal and/or distal end of the stent **10**, along one or more connectors **14**, along a series of legs **12**, and along one or more additional connectors. The loop could be arranged about any number of legs **12** and connectors **14**, and even along the entire longitudinal axis from the proximal to the distal end of the stent. In addition, there could be any number of loops about the circumference of the stent in alternative embodiments. The loop of suture **16** is typically intertwined about at least a portion of the legs **12** and connectors **14** and secured with a knot or similar fastening technique such that application of a force on the suture transfers the force to the stent **10**. However, as described above, the suture **16** could also be held in place on the stent **10** by a cover and struts on a covered stent. For instance, the suture **16** could be formed integral with the cover

and struts of the stent **10** such that knots and the like would not be required. As before with respect to FIG. 3, in alternative embodiments there may be strands of suture **16** extending from the proximal and distal ends instead of forming a loop **18** and, for example, the free ends of the suture could each have a knot that allows forceps or a similar instrument to grasp one or both ends of the suture.

Like the stent **10** shown in FIG. 3, the stent depicted in FIG. 4 also does not create a purse-string effect. Thus, when forceps or a similar instrument pulls on one or more of the loops **16** at the proximal end of the stent **10**, the stent is also pulled such that the stent may be repositioned within the lumen or completely removed without changing the expanded diameter of the stent. Similarly, the forceps could be positioned through the longitudinal axis of the stent **10** to engage a loop of suture **16** at the distal end of the stent to push the stent to a different position or to remove the stent from the lumen.

FIG. 5 illustrates that the suture **16** is preferably arranged about the connectors **14** in a spiral-like configuration. Arranging the suture **16** in a spiral-like configuration distributes the force along each connector **14** when forceps or a similar instrument pulls upwardly or pushes downwardly on each loop **18** shown in FIGS. 3 and 4. Therefore, the spiral-like configuration reduces the risk that the suture **16** will break or become dislodged during repositioning or removal of the stent **10**. It is understood that the suture **16** could be arranged about the legs **12** and/or connectors **14** in the configuration shown in FIG. 5, but is not required to have this particular configuration, as there may be alternative configurations in additional embodiments. In addition, the suture **16** in FIG. 5 is shown as being loosely arranged about the connector **14** for illustrative purposes only, as the suture will typically be in more intimate contact with the scaffolding of the stent **10** or tightly wound about the connector.

In an additional embodiment of the present invention, FIG. 6 depicts a stent **10** having a series of loops **18** arranged about the circumference of the stent at the proximal and/or distal end. The loops **18** are preferably a suture material, and there may be any number of loops about the circumference of the stent **10**. The stent **10** also includes a loop of suture **16** that extends about the circumference of the loop, through the loops **18**, and connects to itself with a knot **20**. The loops **18**

could be connected to the stent **10** in the manner described above in conjunction with FIGS. 3-5, or the loops could be attached to the outer periphery of the proximal and/or distal end of the stent. Furthermore, the loops **18** could be a single piece of suture circumferentially disposed about the proximal and/or distal end of the stent **10**, or one or more loops could be a single suture. The loops **18** are attached to the stent **10** such that a force applied through the suture **16** transfers force through the loops and to the stent.

Unlike the embodiments shown in FIGS. 3 and 4, the stent **10** shown in FIG. 6 creates a purse string effect. As such, pulling or pushing on the suture **16** with forceps or a similar instrument causes the proximal and/or distal end of the stent **10** to purse string. Thus, forceps or a similar instrument could be used to purse string the proximal end of the stent **10** by pulling on the suture **16**, while pushing on the suture at the distal end of the stent will cause the distal end to purse string. Purse stringing the suture **16** crimps the proximal or distal end of the stent **10** to promote repositioning or removal of the stent from the lumen. Once the suture **16** is released, the proximal or distal end of the stent **10** will expand.

The present invention provides several advantages. Providing one or more loops from a suture material allows forceps or a similar instrument to engage the loops rather than the stent **10** itself. Therefore, the embodiments of the present invention facilitate easier removal or repositioning of the stent **10** without increasing the likelihood of damage to the stent and/or the lumen. Furthermore, the suture is arranged about the stent **10** to distribute the forces applied during repositioning or removal of the stent, which reduces the risk that the suture and/or stent will be damaged or dislodged.

Many modifications and other embodiments of the invention set forth herein will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

THAT WHICH IS CLAIMED:

1. A removable stent for placement within a lumen comprising:

a scaffolding of struts configured to define a substantially cylindrical member having a proximal end and a distal end; and

at least one element intertwined about at least a portion of the struts, wherein the element comprises at least one engageable member such that a force applied to the engageable member does not result in purse-stringing.

2. The stent according to Claim 1, wherein the struts comprise a plurality of interconnected legs arranged circumferentially about the stent and a plurality of connectors interconnecting the legs and extending along a longitudinal axis of the stent.

3. The stent according to Claim 2, wherein at least a portion of each element is intertwined longitudinally along a plurality of connectors in a spiral-like configuration.

4. The stent according to Claim 2, wherein at least a portion of the element extends circumferentially along a plurality of legs in a spiral-like configuration.

5. The stent according to Claim 2, wherein each element is intertwined about a plurality of legs and connectors, and wherein free ends of each element are joined together to define an engageable member.

6. The stent according to Claim 1, wherein at least a portion of each element is intertwined proximate to the proximal or distal ends of the scaffolding.

7. The stent according to Claim 6, wherein a free end of each element proximate to the proximal or distal ends is configured as an engageable member.

8. The stent according to Claim 1, wherein at least a portion of the engageable member extends proximally from the proximal end or distally from the distal end.

9. The stent according to Claim 1, wherein the at least one element comprises a suture material.

10. The stent according to Claim 1, wherein the at least one engageable member comprises a loop.

11. A removable stent for placement within a lumen comprising:

a scaffolding of struts configured to define a substantially cylindrical member having a proximal end and a distal end; and

a plurality of engageable members arranged circumferentially about at least one of the proximal and distal ends; and

at least one element disposed within each of the engageable members and about the circumference of the proximal or distal end, wherein a force applied to the element at the proximal or distal end causes the proximal or distal end to reduce in diameter.

12. The stent according to Claim 11, wherein at least a portion of each of the engageable members is intertwined about at least a portion of the struts.

13. The stent according to Claim 11, wherein each of the engageable members is attached to an outer periphery of the proximal or distal end.

14. The stent according to Claim 11, wherein each of the engageable members extends proximally from the proximal end or distally from the distal end.

15. The stent according to Claim 11, wherein the plurality of engageable members and at least one element comprise a suture material.

16. The stent according to Claim 11, wherein the plurality of engageable members comprise loops.

17. A method for removing or repositioning a stent within a lumen comprising:

engaging at least one engageable member defined by an element interwined about at least a portion of the stent; and

applying a force to the engageable member such that the force does not result in purse-stringing.

18. The method according to Claim 17, wherein engaging comprises engaging a plurality of engageable members.

19. The method according to Claim 17, wherein applying comprises pulling the at least one engageable member proximally at a proximal end of the stent.

20. The method according to Claim 17, wherein applying comprises pushing the at least one engageable member distally at a distal end of the stent.

21. A method for removing or repositioning a stent within a lumen, the stent comprising a plurality of engageable members arranged circumferentially about at least one of a proximal end and a distal end of the stent, the method comprising:

engaging at least one element disposed within each of the engageable members and about the circumference of the proximal or distal end; and

applying a force to the element at the proximal or distal end such that the proximal or distal end reduces in diameter.

22. The method according to Claim 21, wherein applying comprises pulling the at least element proximally at a proximal end of the stent.

23. The method according to Claim 21, wherein applying comprises pushing the at least one element distally at a distal end of the stent.

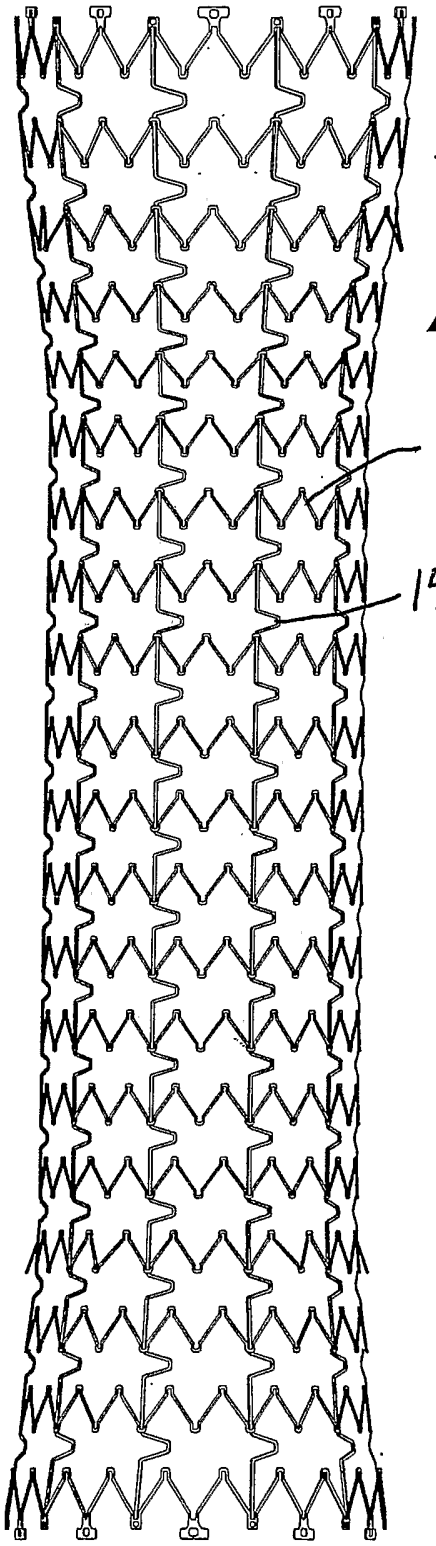


Fig. 1

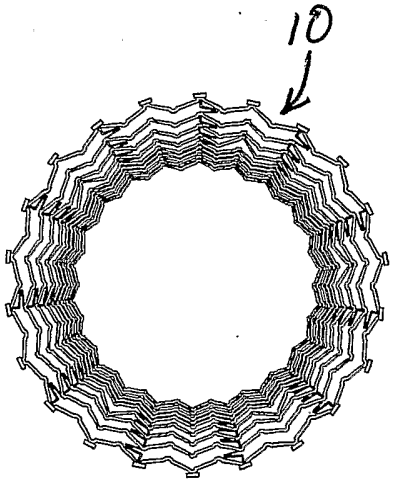


Fig. 2

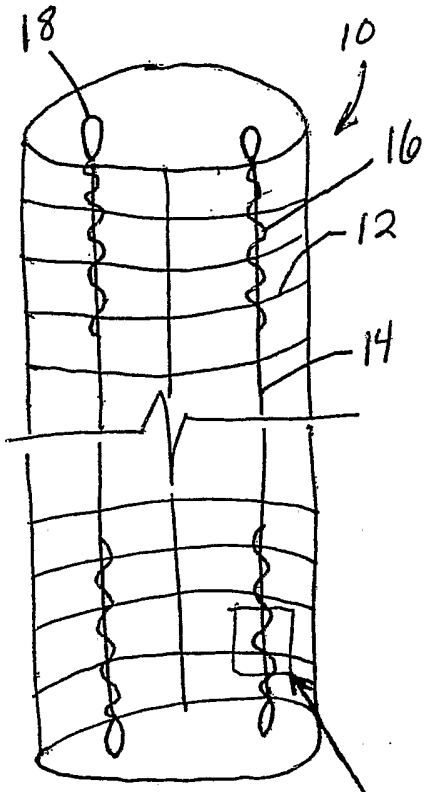


Fig. 3

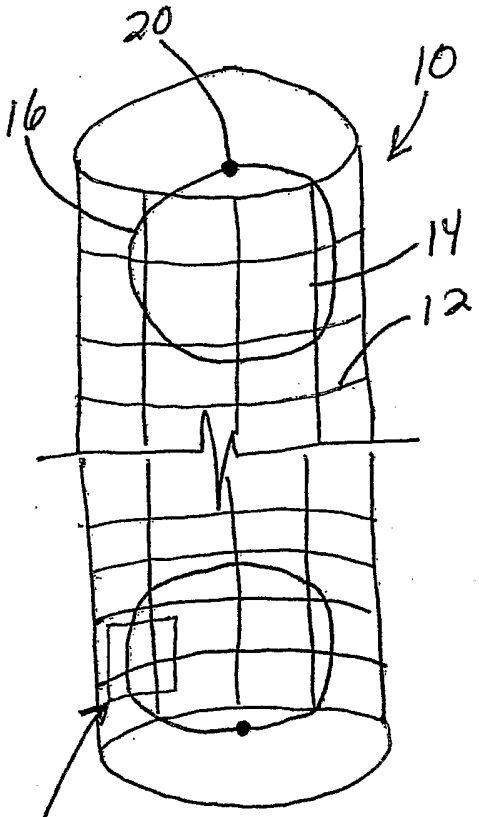


Fig. 4

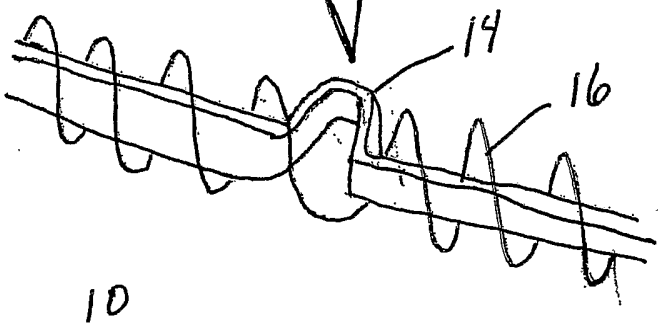


Fig.

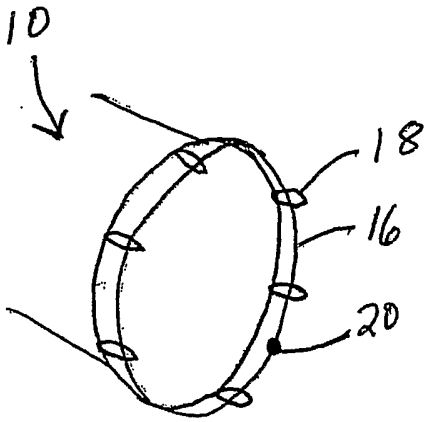


Fig. 6