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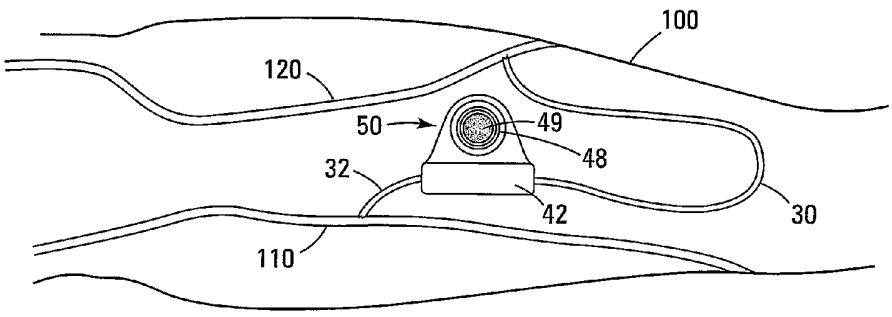

(57) Abstract: A dialysis valve includes a tube attached between an artery and a vein which, when elongated, simultaneously narrows in diameter at at least one location. The narrowed portion of the tube decreases the volume and velocity between the arterial and venous side of the patient to prevent damage or intimal hyperplasia on the venous side between dialysis treatments. When the valve is opened for dialysis, an unrestricted blood flow exists between the arterial and venous side, permitting a controlled, open blood flow during dialysis.

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DIALYSIS VALVE AND METHOD

FIELD OF THE INVENTION

The present invention relates to a valve useful for controlling blood flow in artificial dialysis fistulas or bypass grafts.

BACKGROUND

Dialysis involves connecting patients with insufficient kidney function to a dialysis machine which cleanses the blood of waste products and impurities. Put another way, the dialysis machine performs the same function as a normal, healthy kidney should. In other cases, dialysis is used to remove poisons and drugs from the blood more safely and quickly than the natural kidneys would. To properly connect a patient to a dialysis machine requires accessing, on a continuing basis, a blood vessel, to divert the flow of blood from the patient to the dialysis machine. This is normally accomplished by the implantation into the patient of an artificial fistula or bypass graft, which is usually made of expanded polytetrafluoroethylene (ePTFE). In the case of a graft, the graft is punctured with a needle and blood from patients requiring dialysis is transported to the dialysis machine whereupon the blood is diffused across a semipermeable membrane. Upon completion of this procedure, dialyzed blood is returned to the patient through a second needle in the graft. Dialysis is usually necessary every two to three days, which often results in the lumen of the graft becoming compromised. The more common problem related to dialysis grafts is intimal hyperplasia, which can occur when the higher pressure/volume of the arterial flow crosses the boundary from the relatively non-compliant graft to the more compliant outflow vein at the venous anastomosis. The resultant intimal hyperplasia in the vein adjacent to the anastomosis leads to progressive stenosis and eventually premature clotting and graft occlusion. Repairing a hemodialysis graft occlusion is currently accomplished by one of several techniques: open surgical revision (surgical thrombectomy), thrombolytic drugs (thrombolysis) or mechanical declotting via percutaneous techniques (percutaneous mechanical thrombectomy). Percutaneous mechanical thrombectomy techniques include suction thrombectomy, balloon

thrombectomy, clot maceration and mechanical thrombectomy. The goal of each of these therapies is the preservation of vascular access. In almost all cases, any technique which is used to declot the graft will also require angioplasty of the venous anastomotic stenosis in order to reestablish normal flow.

It is known that blood flow in excess of 300 cc per minute can cause intimal hyperplasia in the outflow vein near the anastomosis. The problem arises from the fact that blood flows less than 300 cc per minute have been associated with graft thrombosis. The solution to this dilemma appears to arise from a recognition that blood flows of less than 300 cc per minute are not intrinsically pro-thrombotic, but are a reflection of progressive stenosis that is likely to rapidly reach a level at which thrombosis can occur with any added insult. What would be ideal and what is clearly needed is a method for preventing high flows through the graft while it is not being used and thus reducing or eliminating the stimulus for intimal hyperplasia and yet allowing the high flows through the graft during dialysis that are required for a successful dialysis run.

SUMMARY

In one embodiment the invention comprises a method of controlling blood flow during dialysis. The method involves implanting a tube between a patient's vein and an artery, where the tube is capable of containing fluids and defines a longitudinal dimension, a diameter and an inner surface. The diameter of the tube is narrowed during dialysis at at least one location along the longitudinal dimension to control the volume and velocity of blood flow through the tube during dialysis. In another embodiment, the inner surface of the tube at the narrowed location is in a substantially circular configuration.

In another embodiment the invention comprises a dialysis valve, the valve comprising a tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface. A bellows capable of being held at varying lengths defines an interior chamber wherein the tube is mounted in the chamber so that when the bellows increases in length, the tube simultaneously increases in longitudinal dimension and at least a portion of the tube decreases in diameter. In a further

embodiment the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability.

In still another embodiment the invention comprises a dialysis valve, the valve comprising a tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface. A balloon contacts the tube so that when the balloon is inflated at least a portion of the tube decreases in diameter. In a further embodiment, the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability. In yet a further embodiment the balloon surrounds the tube.

In an alternative embodiment the invention comprises a valve, the valve comprising a tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface. A nitinol spring is attached to each end of the tube so that when the spring is actuated the tube decreases in longitudinal dimension and the tube increases in diameter. In a further embodiment the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a side view of the uncoated braid in the truncated, open configuration.

Fig. 1a shows an end view of the uncoated braid shown in Fig. 1.

Fig. 2 shows a side view of the uncoated braid in the elongated, decreased diameter configuration.

Fig. 2a shows an end view of the uncoated braid shown in Fig. 2.

Fig. 3 shows a side view of the coated braid assembly in the shortened, increased diameter configuration.

Fig. 3a shows an end view of the coated braid assembly shown in Fig. 3.

Fig. 4 shows a side view of the coated braid assembly in the elongated, decreased diameter configuration.

Fig. 4a shows an end view of the coated braid assembly shown in Fig. 4.

Fig. 5 shows a cross section of the coated braid assembly shown in Figs. 3, 3a, 4, and 4a.

Fig. 6 shows a cut away plan view of the dialysis valve actuated by an elongatable/compressible bellows in the elongated, closed position.

Fig. 6a shows a cut away plan view of the dialysis valve shown in Fig. 6 in the shortened, open position.

Fig. 6b shows a side view of the valve shown in Fig. 6.

Fig. 6c shows a plan view of the valve shown in Fig. 6.

Fig. 6d shows an end view of the valve shown in Fig. 6.

Fig. 7 shows a cut away plan view of the valve activated by an inflatable balloon.

Fig. 7a shows a side view of the dialysis valve shown in Fig. 7, with the infusion needle penetrating the membrane.

Fig. 8a shows a cut away side view of the valve with a nitinol coil spring in the elongated, narrowed configuration.

Fig. 8b shows a cut away side view of the valve with a nitinol coil spring in the shortened, open configuration.

Fig. 8c is a partial breakaway side view of the nipple and threaded member attached to the coated braid assembly.

Fig. 9 shows a plan view of an embodiment of the valve sutured between a vein and an artery.

DETAILED DESCRIPTION

Definitions

"Braid Assembly" refers to a tubular structure comprised of overlapping flexible strands.

"ePTFE" refers to Expanded Polytetrafluoroethylene.

Nomenclature

10	Uncoated Braid
11	Strand
12	Diameter
14	Longitudinal Dimension
20	Coated Braid Assembly
22	Diameter
24	Longitudinal Dimension
25	Inner Surface
26	Elastomeric Coating

28 Anti-Thrombogenic Coating
30 Fistula Graft (Arterial Side)
31 Bonding Area
32 Fistula Graft (Venous Side)
41 Aperture
42 Outer Housing
43 Chamber
44 Bellows
45 Inter-Wall Space of Bellows
46 Hydraulic Line
47 Inner Wall of Bellows
48 Port
49 Membrane
50 Dialysis Valve (Hydraulic Bellows Actuated)
51 Outer Wall of Bellows
52 Infusion Needle
53 Nipple
54 Floating Connector
55 Fixed Connector
56 Compressible Section
60 Dialysis Valve (Hydraulic Balloon Actuated)
62 Balloon
64 Hydraulic Line
80 Valve
82 Nitinol Spring
83 O Ring
84 Controller
84a Electrical Wire (Signal)
84b Electrical Wire (Ground)
85 Threaded Connector
86 Outer Housing
100 Arm
110 Artery
120 Vein

Construction

The valve of the present invention applies the principles of fluid dynamics so that as the lumen of a tube is narrowed, the dynamic pressure and volume of fluids passing through it will decrease. Thus, when the principles of fluid dynamics are applied to blood flow, a controlled narrowing in a synthetic dialysis graft decreases arterial dynamic pressure and decreases blood volume in the coated braid assembly **20** before it can impact the lower pressure venous volume in the receiving vein **120**. It has been medically documented that a blood flow rate of below 300 cc per minute will, in most cases, prevent intimal hyperplasia from occurring. An additional advantage of reducing blood flow rate to below 300 cc per minute is that it further reduces the likelihood of problems with peripheral "stealing" of blood from the extremity (e.g., the hand) during the dialysis procedure.

Figs. 1, 1a, 2 and 2a show an uncoated tubular braid **10** which defines a diameter **12** and a longitudinal dimension **14**. The braid **10** comprises a plurality of individual strands **11** that are crossed over each other to form a cylinder as shown in Fig. 1 when in an unstressed or relaxed state. The diameter **12** and longitudinal dimension **14** of the braid **10** are inversely proportional to each other, wherein as shown in Fig. 2 the braid **10** upon being increased in its longitudinal dimension **14** decreases in at least some portion of its diameter **12**. Conversely, as shown in Fig. 1, when the braid **10** is decreased in longitudinal dimension **14** the diameter **12** increases. The braiding pattern as shown in Figs. 1, 1a, 2 and 2a shows bilateral symmetry wherein a center portion (unnumbered) of the braid **10** decreases in diameter with an increased longitudinal dimension **14**. It should be noted, however, that other braiding techniques exist which would cause a different portion (not shown) of the braid **10** to decrease in diameter **12** with an increased longitudinal dimension **14**, resulting in a different symmetry. In a preferred embodiment, the braid **10** is made of nitinol strands **11**. Nitinol is preferred because of its excellent biocompatibility and more importantly its ability to be repeatedly deformed and reformed without taking a permanent set or kink or breaking due to fatigue resistance. Other materials contemplated by and therefore within the scope of the invention include various grades of stainless steel and composite materials.

Figs. 3, 3a, 4, 4a and 5 show a coated braid assembly **20** which defines a diameter **22** and a longitudinal dimension **24**. The coated braid assembly **20** comprises a plurality of individual strands **11** that are crossed over each other to substantially form a cylinder as shown in Fig. 3 when in an unstressed or relaxed state. In a preferred embodiment, the coated braid assembly **20** is made of individual strands **11** of nitinol which is processed to display superelasticity at some point below normal human body temperature of 37 degrees C. Additional materials such as carbon fibers, stainless steel and composite materials would also work and are therefore within the scope of the invention. The coated braid assembly **20** is coated with an elastomeric coating **26** which serves to form a sealed tube capable of containing and conveying fluids. The diameter **22** and longitudinal dimension **24** of the coated braid assembly **20** are inversely proportional to each other, wherein as shown in Fig. 4 the coated braid assembly **20** upon being increased in its longitudinal dimension **24** decreases in at least some portion of its diameter **22**. Inversely, as shown in Fig. 3, when the coated braid assembly **20** is decreased in longitudinal dimension **24** the diameter **22** of the previously narrowed portion (unnumbered) increases. The braiding pattern as shown in Figs. 3, 3a, 4 and 4a shows bilateral symmetry wherein a center portion (unnumbered) of the coated braid assembly **20** decreases in diameter with an increased longitudinal dimension **24**. It should be noted that other braiding techniques and materials exist which would cause a different portion (not shown) of the coated braid assembly **20** to decrease in diameter **22** with an increased longitudinal dimension **24**, resulting in a different symmetry.

Fig. 5 shows a cross section of the coated braid assembly **20**. The individual strands **11** of the coated braid assembly **20** are embedded in the elastomeric coating **26** which serves to bind the individual strands **11** together as well as sealing the cylinder formed by the strands **11** to form a sealed tube (unnumbered) capable of containing and conveying fluids. The interior surface **25** of the coated braid assembly **20** is further coated with an anti-thrombogenic coating **28** or a pro-endothelialization coating (not shown) which mimics the endothelialization which is part of the blood vessel's initmal lining and prevents or reduces blood clotting. Various substances can be used as anti-thrombogenic coating **28** in the present invention, including but not limited to heparin complex solutions, benzalkonium heparinate, tridodeclymethylammonium heparinate, chlorhexidine-silver sulfadiazine,

mycocycline and rifampin. The elastomeric coating **26** can comprise many materials, such as a urethane, ePTFE or silicone material, which provide great strength and flexibility while remaining thin. The elastomeric coating **26** is applied to the uncoated braid **10** by any of several coating methods well known to those having ordinary skill in the art, including but not limited to, dipping, spraying, injection molding and coating over a mandrel to produce a smooth inner surface **25** of the coated braid assembly **20** prior to applying the anti-thrombogenic coating **28**. Similarly, the anti-thrombogenic coating **28** can be applied by coating, spraying, dipping or vapor deposition processes.

Fig. 6 shows a cut away plan view of an embodiment of the dialysis valve **50** actuated by a hydraulically actuated double walled metal bellows **44**. The bellows **44** can be made of such materials as platinum, gold or stainless steel and can be made by vapor deposition over a wax mandrel. Two separate sized mandrels are used to produce a (smaller diameter) inner wall **47** and a (slightly larger diameter) outer wall **51**. Silicone or urethane glue (not shown) is applied to a nipple **53** at a bonding area **31** extending from a floating connector **54** and/or fixed connector **55.** The coated braid assembly **20** is then attached to the floating connector **54** and/or fixed connector **55** by inserting the coated braid assembly **20** over the nipple **53** extending from the floating connector **54** and/or fixed connector **55**. The surface (unnumbered) of the nipple **53** may be knurled or have concentric grooves to facilitate attachment and sealing. An "O" ring **83** may be placed over the end (unnumbered) of the coated braid assembly **20** contacting the nipple **53** to further facilitate attachment and sealing. The coated braid assembly **20** with attached floating connector **54** and/or fixed connector **55** is then mounted inside a chamber **43** formed by the inner wall **47** of the bellows **44**. At least one end (unnumbered) of the coated braid assembly **20** is attached to a floating connector **54**. The floating connector **54** and/or fixed connector **55** provide that the ends (unnumbered) of the coated braid assembly **20** are maintained in an open configuration irrespective of the diameter of other portions of the coated braid assembly **20**. It is contemplated to have both ends (unnumbered) of the coated braid assembly **20** attached to a floating connector **54**. Alternatively, one end (unnumbered) of the coated braid assembly **20** can be attached to a floating connector **54** while the other end (unnumbered) is attached to a fixed connector **55**. The inner wall **47** is inserted into the outer wall **51** and then laser-welded at the end

(unnumbered) to a floating connector **54** at each end or a floating connector **54** at one end and a fixed connector **55** at the other end to seal the bellows **44**. The floating connector **54** and fixed connector **55** are made of the same material as the inner wall **47** and outer wall **51** of the bellows **44**. A hydraulic line **46** is attached to an aperture **41** extending through the outer wall **51** only. An inter-wall space **45** exists between the inner wall **47** and outer wall **51** of the bellows **44**. In the view shown in Fig. 6 the coated braid assembly **20** and floating connectors **54** are disposed inside the chamber **43**. In Fig. 6 the bellows **44** is longitudinally extended, which correspondingly increases the longitudinal dimension of the internally attached coated braid assembly **20**. As shown in Fig. 4 when the coated braid assembly **20** is longitudinally extended at least a portion of it will assume a lesser diameter **22**. It should be mentioned that the diameter **22** of the coated braid assembly **20** is dependent on its degree of longitudinal extension. The double walled bellows **44** is mounted in an outer housing **42** which is configured to provide space for the coated braid assembly **20** to elongate or shorten during actuation of the valve **50**. Due to the varying longitudinal dimensions **24** the coated braid assembly **20** can assume, a compressible section **56** made of ePTFE is attached to the at least one floating connector **54**. Alternately, if two floating connectors **54** are used, a second compressible section **56** will be used. One end (unnumbered) of the coated braid assembly **20** and attached floating connector **54** or fixed connector **55** is attached to compressible section **56** which is attached to the fistula graft (arterial) **30** while the other end (unnumbered) is attached to the fistula graft (venous) **32** or to a second compressible section **56**. A bonding area **31** exists where an adhesive is alternatively used to further facilitate the attachment. The fistula grafts **30, 32** are made of ePTFE. A hydraulic line **46** is in fluid communication with the inner wall space **45** of the bellows **44** via the aperture **41** and extends to a port **48** which is covered by a membrane **49** which is made of a self-sealing material such as an implantable latex, urethane or silicone. The outer housing **42** is preferably injection molded implantable high durometer urethane plastic (Carbothane®) or machined stainless steel or other biocompatible plastic and metal materials could also be used. During actuation of the dialysis valve **50** a saline solution (not shown) is injected into the bellows **44** by means of a pressurizing infusion needle **52** which is inserted by a physician through the membrane **49** covering the port **48** via the hydraulic line **46**. The bellows **44** is adjustable corresponding to the amount of saline injected and can thus be fully extended or

assume any intermediate position. This causes the bellows **44** to extend longitudinally, thus simultaneously causing the coated braid assembly **20** to increase in longitudinal dimension **24** and at least a portion to decrease in its diameter **22**, resulting in a controlled, reduced blood volume through the valve **50**. The normal, default condition of the bellows **44** is in the foreshortened or open configuration as shown in Fig. 6a. Thus, should control of blood flow through the dialysis valve **50** fail for any reason, normal blood flow would resume.

Fig. 6a shows a cut away plan view of the dialysis valve **50** shown in Fig. 6 but with the coated braid assembly **20** in the shortened, open configuration.

Fig. 6b shows a side view of the dialysis valve **50**. Fig. 6c shows a top view of the dialysis valve **50**. Fig. 6d shows an end view of the dialysis valve **50**.

Fig. 7 shows a cut away plan view of an embodiment of the dialysis valve **60** which is actuated by means of a hydraulic balloon **62** which extends around the coated braid assembly **20** in a cuff-like manner. The balloon **62** can be made from elastomeric latex, silicone or urethane. In this embodiment of the dialysis valve **60** the coated braid assembly **20** is attached at each end to a floating connector **54**. The floating connector **54** provides that the ends (unnumbered) of the coated braid assembly **20** are maintained in an open configuration regardless of the diameter of other portions of the coated braid assembly **20**. The floating connector **54** is attached at at least one end to a compressible section **56** made of ePTFE within the outer housing **42**. The compressible section **56** is attached to the floating connector **54** and provides for the increase or decrease of the longitudinal dimension **24** of the coated braid assembly **20** within the outer housing **42** during actuation of the valve **60**. It should be mentioned that both ends of the coated braid assembly **20** may be provided with floating compressible sections **56**. A port **48** is attached to the outer housing **42** and is covered by a membrane **49** which is made of a self-sealing material such as silicone or urethane. The outer housing **42** is preferably injection molded implantable high durometer urethane plastic or machined stainless steel, however, other biocompatible plastic and metal materials could also be used. A hydraulic line **64** connects balloon **62** to the port **48** which is covered by membrane **49**. Actuation of the dialysis valve **60** is accomplished as shown in Fig. 7a by inserting an infusion

needle **52** through the membrane **49** and injecting a pressurized saline solution (not shown) through the port **48** via the hydraulic line **64**. The balloon **62** is adjustable corresponding to the amount of saline injected and can thus be fully inflated or assume any intermediate position. When the balloon **62** is mounted within the outer housing **42** this results in the balloon **62** radially expanding as well as elongating, which causes at least a portion of the coated braid assembly **20** to assume a decreased diameter **22**, thus controlling the flow of blood through the dialysis valve **60**. Radial compression is thus increased, precisely controlling the inward force of the inflated balloon **62** against the hemo-dynamic forces exerted against the inner surface **25** of the coated braid assembly **20**. It should also be mentioned that in another embodiment, the balloon **62** and coated braid assembly **20** could be integrally attached at one or a plurality of locations (not shown).

Fig. 7a shows a side view of the dialysis valve **60** with the infusion needle **52** penetrating the membrane **49**. Also shown in Fig. 7a is the connection of the hydraulic line **64** to the balloon **62**.

Fig. 8a shows a cut away side view of an embodiment of the valve **80** that is actuated by a nitinol spring **82** attached to at least one floating connector **54**. The floating connector(s) **54** and/or fixed connector **55** is/are attached to each end (unnumbered) of the coated braid assembly **20** and serve as attachment points for the nitinol spring **82** as well as keeping the ends (unnumbered) of the coated braid assembly **20** in an open configuration at all times. Silicone or urethane glue (not shown) is applied at a bonding area **31** to a nipple **53** extending from the floating connector **54** and/or fixed connector **55.** The coated braid assembly **20** is then attached to the floating connectors **54** by inserting the coated braid assembly **20** over the nipple **53** extending from the floating connector **54** and/or fixed connector **55**. The surface (unnumbered) of the nipple **53** may be knurled or have grooves to facilitate attachment and sealing. A slip ring or "O" ring **83** may further be placed over the end (unnumbered) of the coated braid assembly **20** contacting the nipple **53** to further facilitate attachment and sealing. At least one end of the nitinol spring **82** and attached floating connector **54** is attached to a compressible section **56** of ePTFE to provide for longitudinal movement of the coated braid assembly **20** during actuation within the outer housing **86**. At least one floating connector **54** is

threadably engaged with a threaded connector **85** which serves to provide a means of adjustment for the amount of closure of the valve **80**. A controller **84** which comprises an electrical power supply (not shown), regulator (not shown) and timer (not shown) is in electrical connection by means of signal wire **84a** and ground wire **84b** to respective ends of the nitinol spring **82**. In a preferred embodiment, the electrical energy needed for actuating the nitinol spring **82** is supplied by a battery (not shown). Battery power is preferred because of portability, safety and low cost. When an appropriate amount of electrical energy is sent from the controller **84** to the nitinol spring **82** it will shorten from its default elongated (closed) configuration as shown in Fig. 8a, to its shortened (open) configuration as shown in Fig. 8b, thus causing a increased diameter **22** of the coated braid assembly **20** and an open flow through the valve **80**.

Fig. 9 shows a plan view of the dialysis valve **50** implanted into the arm **100** of a patient between an artery **110** and vein **120** to perform dialysis. While the dialysis valve **50** is shown in Fig. 9, the other embodiments disclosed in the specification, to wit the dialysis valve **50** and valve **60** would be implanted in the patient in an identical manner.

Nitinol is an approximate stoichiometric alloy of nickel and titanium and is used in the invention for two different purposes, as discussed above. Other elements, however, such as vanadium are sometimes added in small amounts to alter the mechanical characteristics of the alloy. Chemical composition and processing history primarily determine the particular mechanical properties of a shape memory/superelastic metallic alloy. In general, such an alloy will exist in either one or the other, or combinations of two crystallographic phases. Austenite is the parent crystallographic phase and exists at higher temperatures. Martensite is the other phase and is formed by either subjecting the alloy to lower temperatures, electrical stress or by placing mechanical or physical stress on the alloy while it is in the austenitic phase. Transition temperatures between these two phases can be experimentally determined for a particular alloy. Processing history includes high temperature annealing as well as low temperature forming and deformation. Following standard material and processing specifications, the transitional temperatures that define the alloy's mechanical characteristics are predictable and

controllable. Standard transitional temperature designations are given as: M_s for the start of the transition to the martensitic phase, M_f for completion of the transition to martensite, A_s for the start of the transition to the austenitic phase, and A_f for the completed transition to austenite.

Nitinol is trained into a desired shape by restraining the alloy into the desired shape, then baking the restrained alloy at relatively high temperatures for a specified period of time. Due to the variability in composition, desired mechanical characteristics and size of alloy used, temperatures and times will vary and overlap.

Superelasticity is based on the stress-induced phase transition from austenite to martensite. Stress-induced induced phase transition from austenite to martensite occurs when the alloy temperature is above A_f and a physical restraint is applied to the alloy. As long as the restraint is in place, the portion of the alloy receiving the stress reverts to the martensitic phase, which remains as long as the stress is maintained. Unless the shape recovery limits are exceeded, when the restraint is removed and the stress is released the alloy returns to its original austenitic phase and trained shape as long as the temperature is maintained above A_f. Thus, when the austenitic, trained shape of the alloy is deformed and held by stress in a new shape, a certain amount of force is exerted by the alloy against the restraint as it resists the new, untrained shape.

The thermal shape memory effect of these alloys has been known much longer than superelasticity. Thermal shape memory occurs as the result of a piece of shape memory alloy metal being deformed while in the lower temperature martensitic phase and then being reheated to a temperature somewhere above A_s which causes the alloy to reform in the austenitic phase. When the crystallographic nature of the alloy is completely austenitic, the alloy's shape returns to the previously trained shape. Shape memory training occurs when a thermal shape memory/superelastic metallic alloy is annealed (heat treated) while restrained in a certain shape. The trained shape will then be maintained unless it is deformed while in the low temperature martensitic phase. Upon reheating the alloy to the austenitic phase, the original shape, which was "learned" in the annealing process, will be "remembered" and returned to. Thus, temperature change is one way of controlling the crystallographic phase of a shape memory/superelastic metallic alloy. The nitinol spring **82** is actuated by electrical

energy heating the alloy to resume the austenitic phase and thus its originally trained shape.

One practical advantage of a shape memory/superelastic alloy over non-superelastic materials is that it can be deformed to a far greater degree without taking a permanent set or kink. In the case of superelastic alloys (i.e., alloys processed to exhibit superelasticity at body temperature), assuming the alloy is above the A_f temperature, removal of the restraint alone is sufficient to resume the original, trained shape. When the alloy is processed to have shape memory characteristics, the martensitic phase alloy need only be subjected to temperatures somewhere above A_f and the alloy will eventually return to its original, trained shape. It is also possible to use a restraint in conjunction with alloys trained to exhibit thermal shape memory characteristics.

Thus, the uncoated braid **10** that forms the reinforcement of the coated braid assembly **20** made of nitinol is processed to exhibit superelastic characteristics at human body temperature. More specifically, superelasticity (stress-induced martensite) allows the coated braid structure **20** to repeatedly increase and decrease its longitudinal dimension **24** while simultaneously decreasing and increasing its diameter **22** without taking a permanent set or kink. Finally, breaking as a result of metal fatigue is virtually unknown with superelastic nitinol.

Use

The dialysis valve **50, 60** is incorporated into a dialysis fistula system to close or limit the flow of blood during periods when dialysis is not taking place. Using techniques which are well known, the fistula is inserted between a vein **120** and an artery **110**. The dialysis valve **50, 60** is only open when dialysis is occurring. As explained above, between dialysis treatments the dialysis valve **50, 60** may be constricted allowing a limited, increased velocity blood flow thereby preventing the formation of thrombus or clotting in the fistula. In other instances, the valve **50, 60** may be completely closed, preventing any blood flow between dialysis treatments.

Using the dialysis valve **50, 60** following successful surgical implantation first requires the physician locating the port **48** and membrane **49** which are located beneath the patient's skin. Between dialysis treatments an infusion needle **52** loaded with a saline solution first punctures the patient's skin followed by puncturing the membrane **49**. The saline solution (not shown) is then injected under pressure through the port **48**, hydraulic line **46, 64** and finally into the bellows **44** or balloon **62**. Saline is continued to be injected until the desired degree of closure of the coated braid assembly **20** is achieved. When the next dialysis treatment is to occur, the physician locates the port **48** and membrane **49**, inserts an infusion needle **52** and withdraws the saline solution, resulting in the coated braid assembly **20** decreasing in its longitudinal dimension **24** and increasing in diameter, thus resuming its open, default configuration.

Although the present invention has been described in considerable detail with reference to certain preferred versions thereof, other versions are also possible. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

What is claimed is:

1. A method of controlling blood flow between and during dialysis treatments, comprising:
   a. implanting a tube between a patient's vein and an artery, the tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface;
   b. narrowing the diameter of the tube in an adjustable manner between dialysis treatments at at least one location along the longitudinal dimension; and
   c. opening the diameter of the tube during dialysis.

2. The method of claim 1 wherein the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability.

3. The method of claim 2 wherein the inner surface of the tube at the narrowed location is in a substantially circular configuration.

4. The method of claim 1 wherein the inner surface of the tube is substantially smooth.

5. A dialysis valve, comprising:
   a. a tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface; and
   b. a bellows capable of being held at varying lengths, the bellows defining an interior chamber wherein the tube is mounted in the chamber so that when the bellows adjustably increases in length, the tube simultaneously increases in longitudinal dimension and at least a portion of the tube decreases in diameter.

6. The dialysis valve of claim 5 wherein the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability.

7. The dialysis valve of claim 6 wherein the inner surface of the tube is further coated with an anti-thrombogenic coating.

8. The dialysis valve of claim 5 further comprising at least the decreased diameter portion of the tube having a substantially circular configuration.

9. The dialysis valve of claim 5 wherein the inner surface of the tube is substantially smooth.

10. The dialysis valve of claim 5 wherein the bellows is double walled so as to define an inner wall space; a hydraulic line is in fluid connection with the inner wall space so when a pressurized fluid is pumped into the inner wall space, the bellows increases in length, simultaneously increasing the longitudinal dimension of the tube.

11. The dialysis valve of claim 10 wherein the bellows is contained in a housing.

12. The dialysis valve of claim 11 wherein a port is attached to the housing, a resealable membrane covers the port and the port is in fluid communication with the hydraulic line.

13. A dialysis valve, comprising:

a. a tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface; and

b. a balloon adjustably capable of varying degrees of inflation contacting the tube so that when the balloon is inflated at least a portion of the tube decreases in diameter.

14. The dialysis valve of claim 13 wherein the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability.

15. The dialysis valve of claim 14 wherein the inner surface of the tube is further coated with an anti-thrombogenic coating.

16. The dialysis valve of claim 13 further comprising at least the decreased diameter portion of the tube having a substantially circular configuration.

17. The dialysis valve of claim 13 wherein the inner surface of the tube is substantially smooth.

18. The dialysis valve of claim 13 wherein the balloon surrounds the tube.

19. The dialysis valve of claim 18 wherein inflating the balloon simultaneously causes at least a portion of the tube to decrease in diameter

20. The dialysis valve of claim 13 wherein the bellows is contained in a housing.

21. The dialysis valve of claim 20 wherein a port is attached to the housing, a resealable membrane covers the port, the port is in fluid communication with the hydraulic line and the hydraulic line in fluid communication with the balloon.

22. A valve, comprising:

a. a tube capable of containing fluids and defining a longitudinal dimension, a diameter and an inner surface; and

b. a nitinol spring adjustably attached to each end of the tube so that when the spring is actuated the tube decreases in longitudinal dimension and the tube increases in diameter.

23. The valve of claim 22 wherein the tube comprises a braided nitinol structure processed to exhibit superelasticity below normal human body temperature coated with an elastomer allowing the tube to be repeatedly altered in longitudinal dimension and in diameter and still maintain fluid containing capability.

24. The valve of claim 23 wherein the inner surface of the tube is further coated with an anti-thrombogenic coating.

25. The valve of claim 23 further comprising at least the decreased diameter portion of the tube having a substantially circular configuration.

26. The valve of claim 25 wherein the inner surface of the tube is substantially smooth.

27. The valve of claim 22 further comprising the nitinol spring being in electrical connection with a controller.

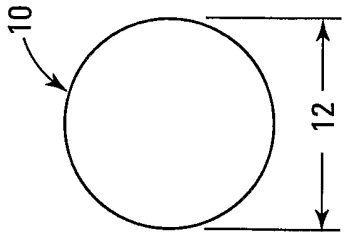

Fig. 1a

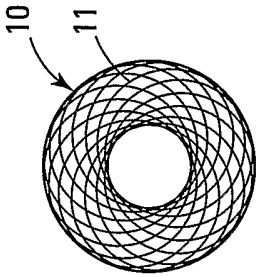

Fig. 2a

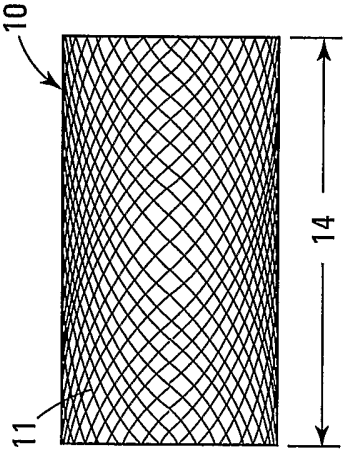

Fig. 1

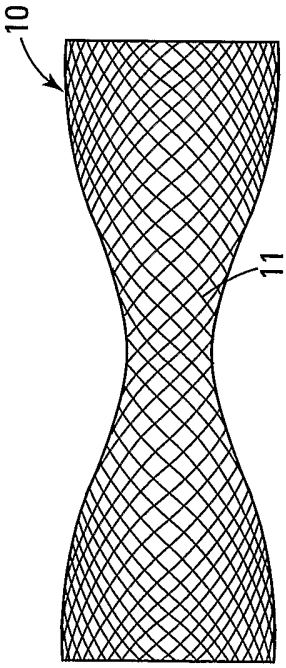

Fig. 2

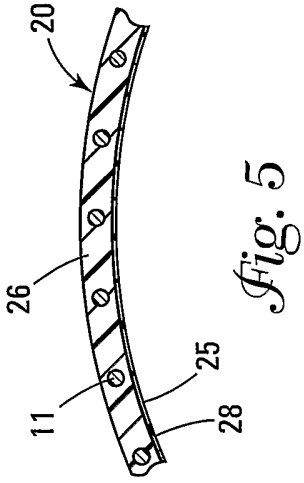

Fig. 5

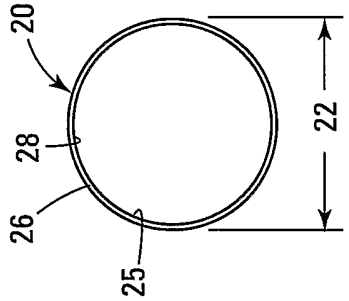

Fig. 3a

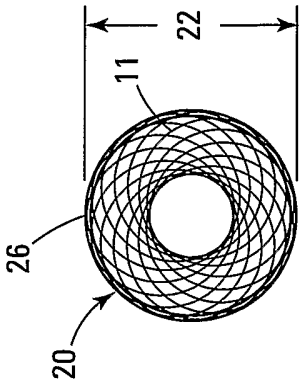

Fig. 4a

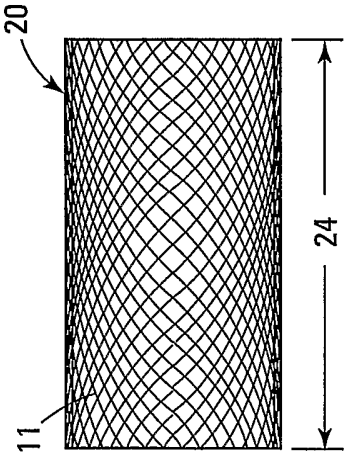

Fig. 3

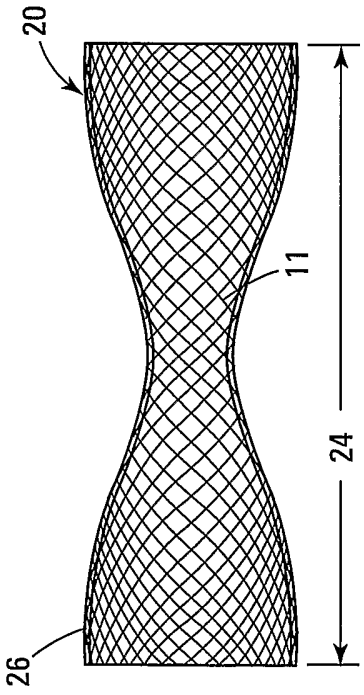

Fig. 4

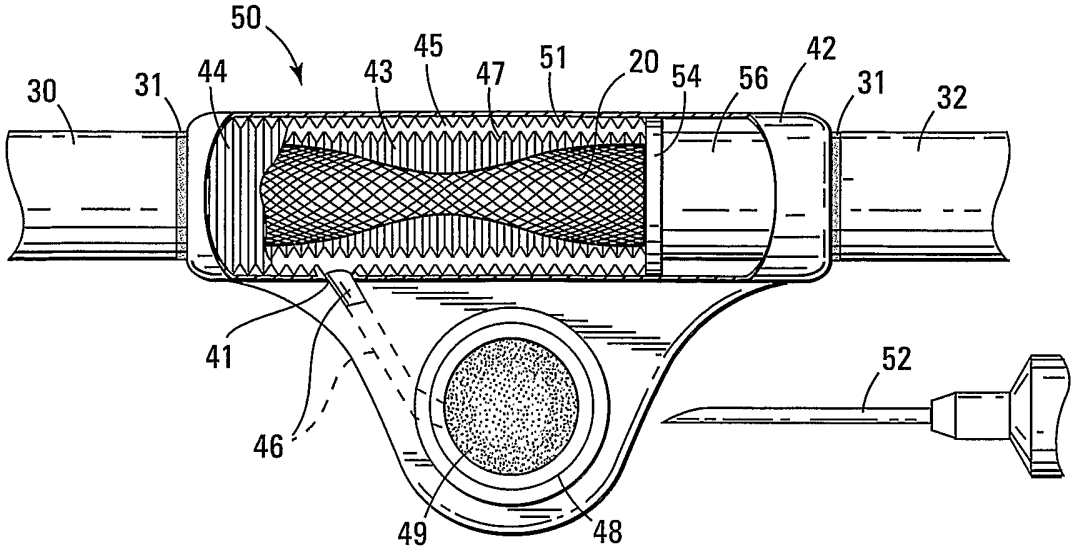
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Fig. 6

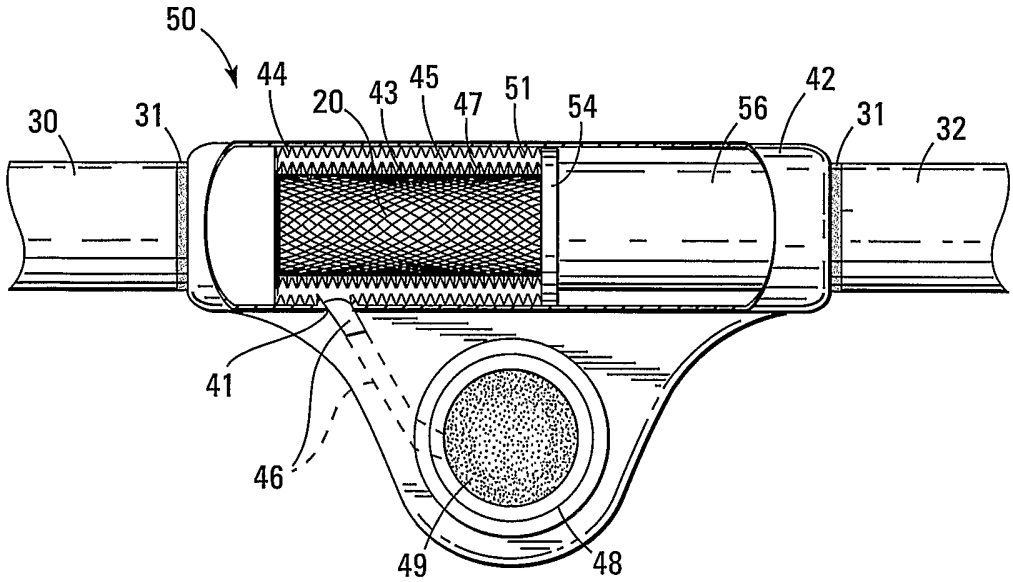
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Fig. 6a

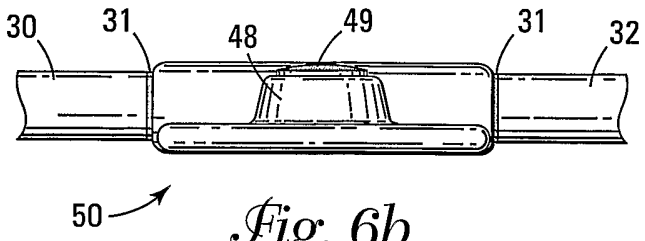

Fig. 6b

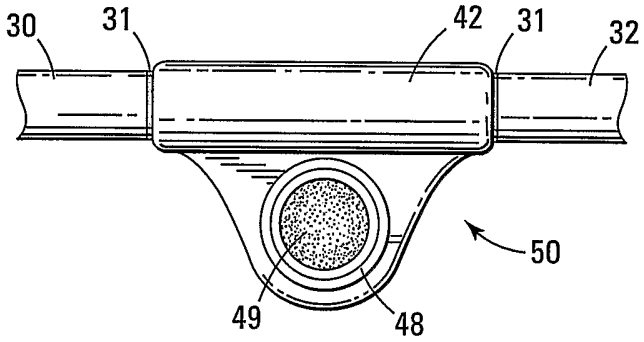

Fig. 6c

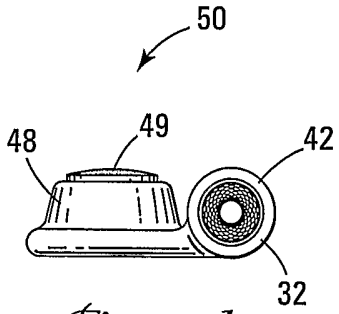

Fig. 6d

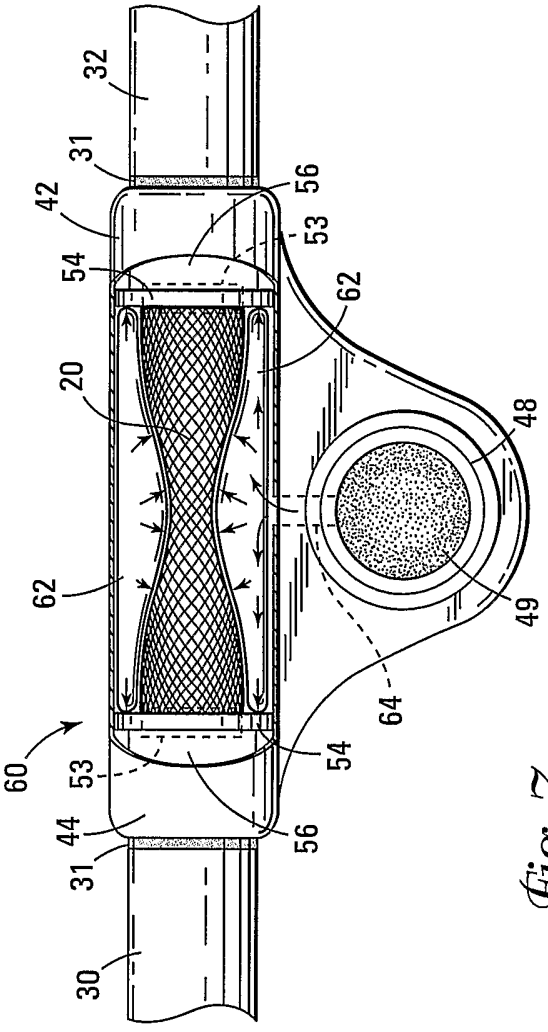
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Fig. 7

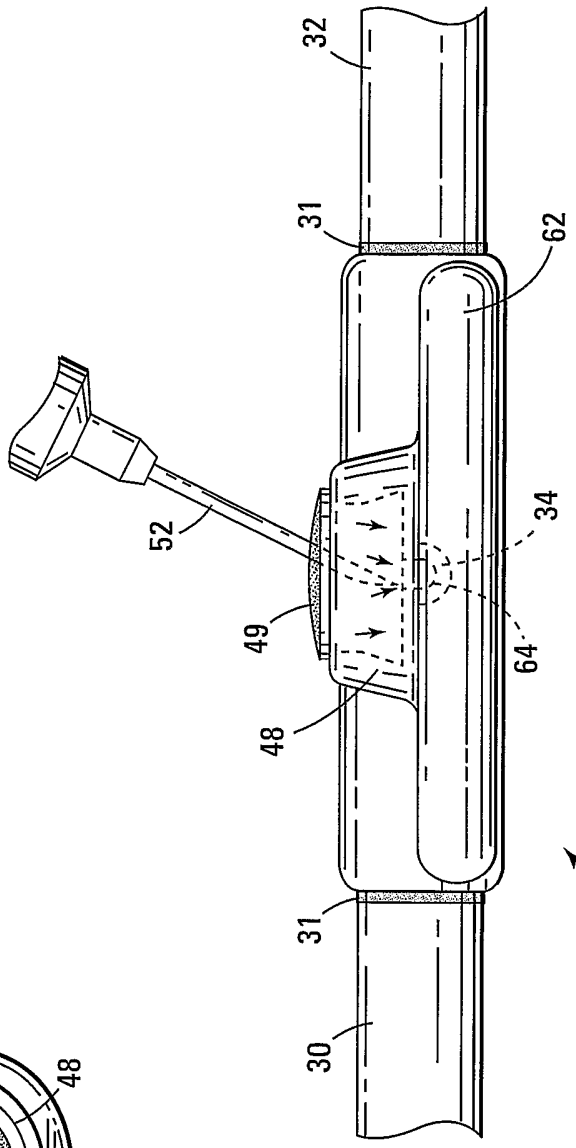
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Fig. 7a

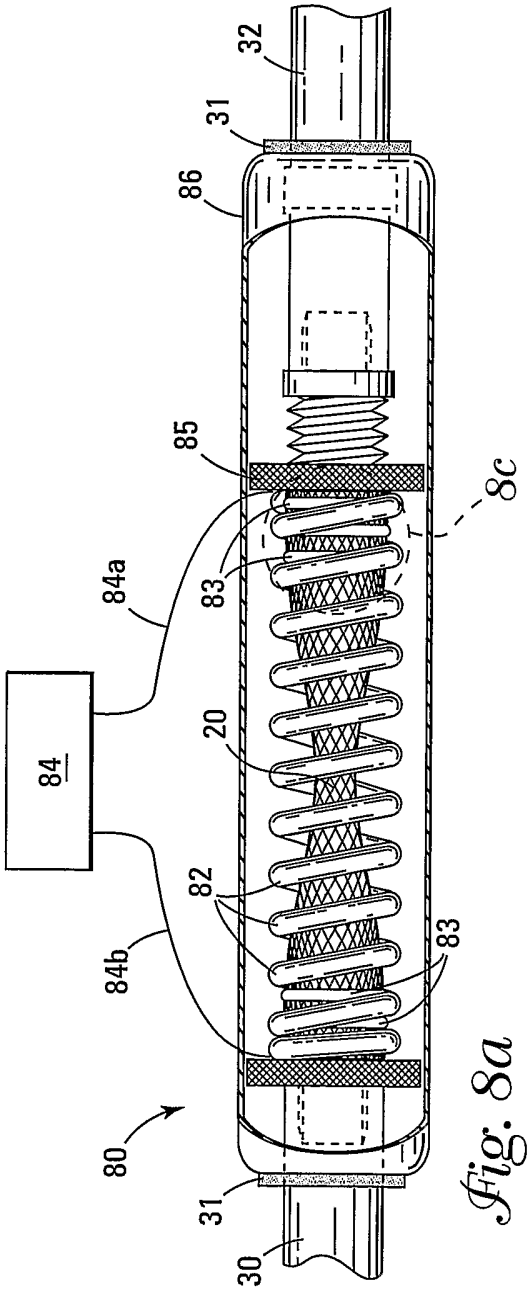

Fig. 8a

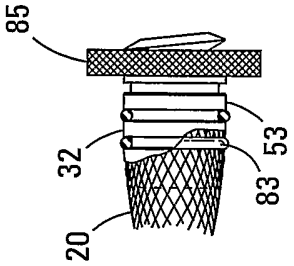

Fig. 8c

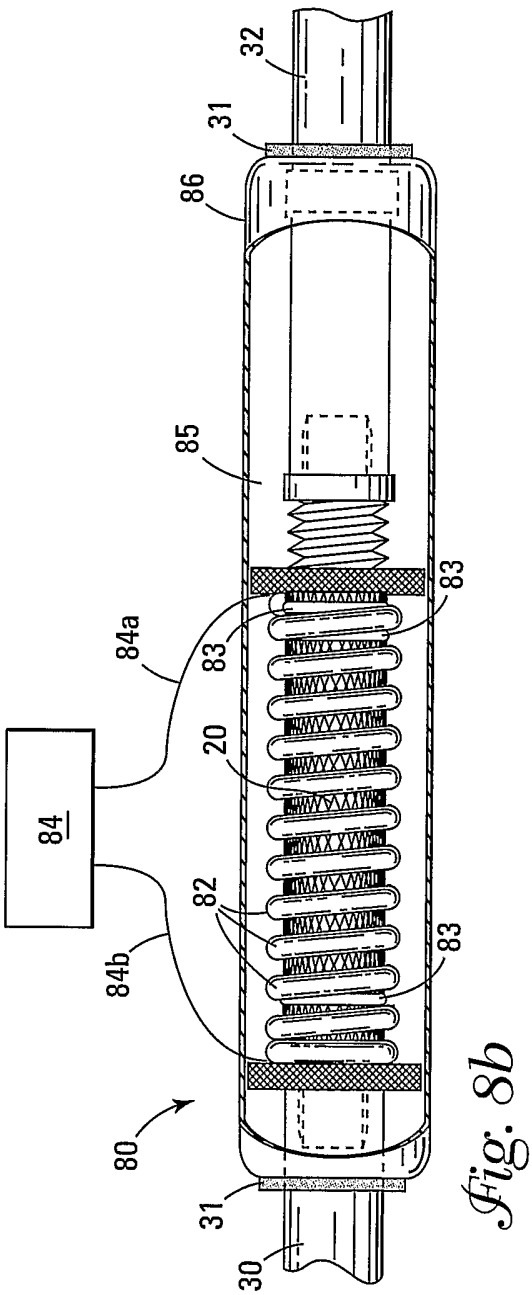

Fig. 8b

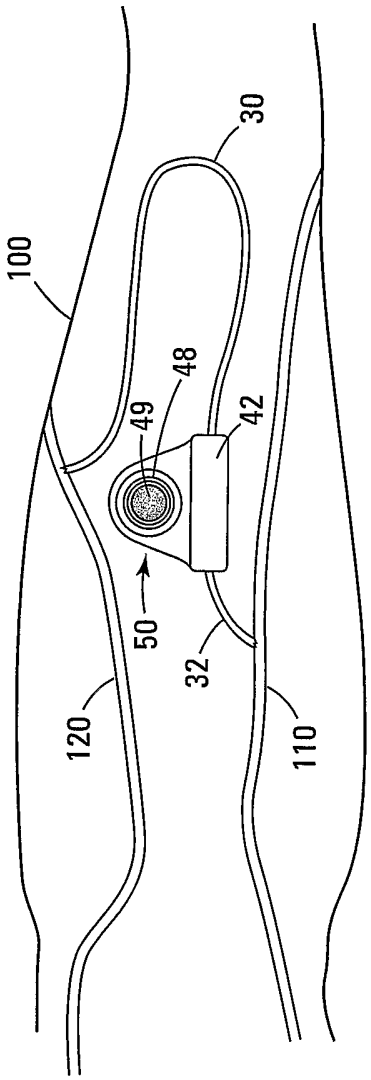

Fig. 9