US 20050143807A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2005/0143807 A1**

Pavcnik et al. (43) **Pub. Date: Jun. 30, 2005**

(54) **IMPLANTABLE VASCULAR DEVICE COMPRISING A BIOABSORBABLE FRAME**

(76) Inventors: **Dusan Pavcnik**, Portland, OR (US); **Frederick S. Keller**, Portland, OR (US); **Josef Rosch**, Portland, OR (US); **Thomas A. Osborne**, Bloomington, IN (US); **John A. Deford**, Bloomington, IN (US); **Joseph F. Obermiller**, Bloomington, IN (US); **Joe Roberts**, Bloomington, IN (US); **Paul Amarant**, Bloomington, IN (US)

Correspondence Address:
BRINKS HOFER GILSON & LIONE/CHICAGO/COOK
PO BOX 10395
CHICAGO, IL 60610 (US)

(21) Appl. No.: **10/910,490**

(22) Filed: **Aug. 3, 2004**

Related U.S. Application Data

(63) Continuation of application No. 09/777,091, filed on Feb. 5, 2001.

(60) Provisional application No. 60/180,002, filed on Feb. 3, 2000.

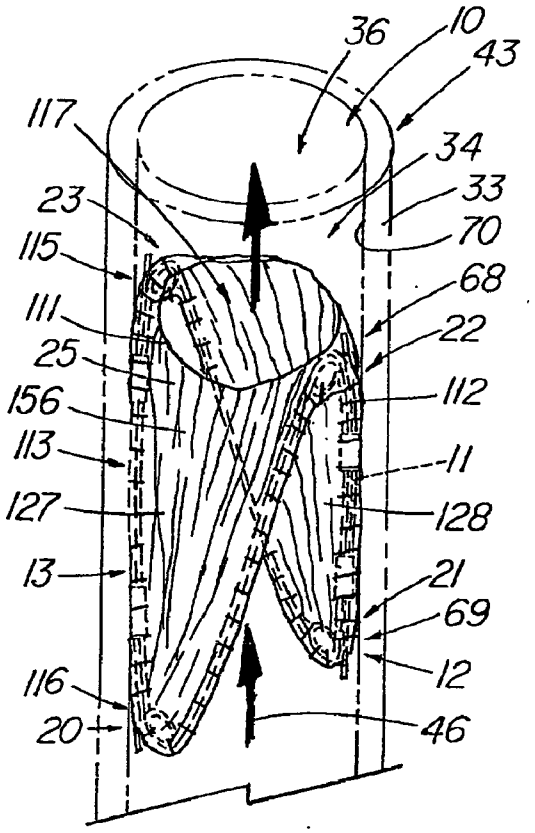
Publication Classification

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1.24**; 623/2.18

(57) **ABSTRACT**

A multiple-sided valve for implantation within a body vessel comprising a frame comprising a bioabsorbable material is provided. The devices can be pushed from a delivery catheter into the lumen of a duct or vessel and may include one or more barbs for anchoring purposes. A full or partial covering of fabric or other flexible material, or a bioabsorbable material, including a collagen-based material such as small intestinal submucosa (SIS), may be attached to the frame to form an occlusion device, a graft, or an implantable, intraluminal valve such as for correcting incompetent veins in the lower legs and feet.



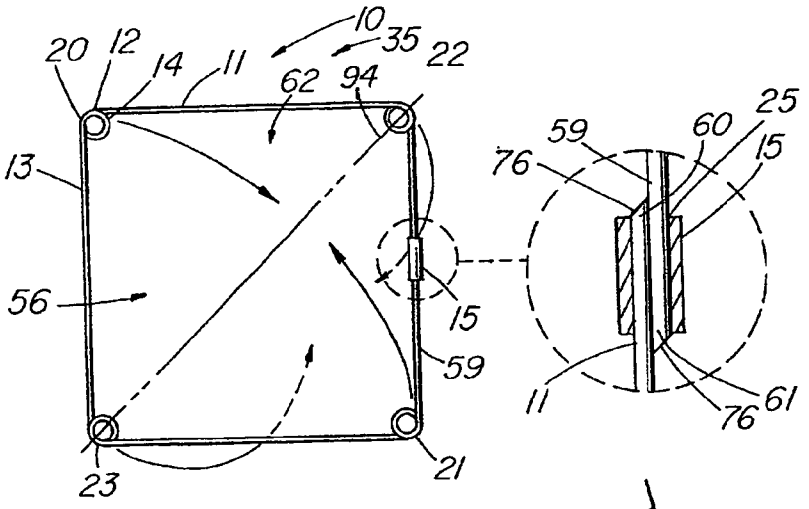


FIG. 1

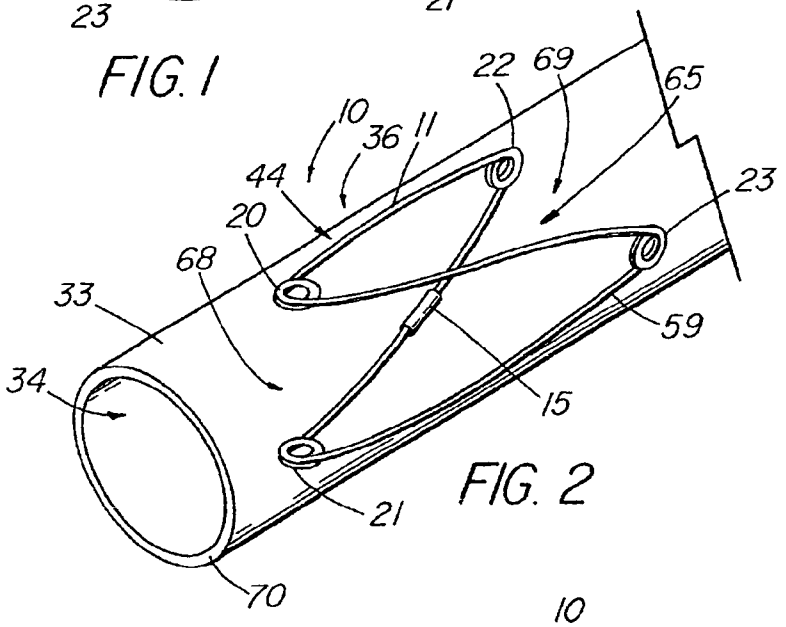


FIG. 2

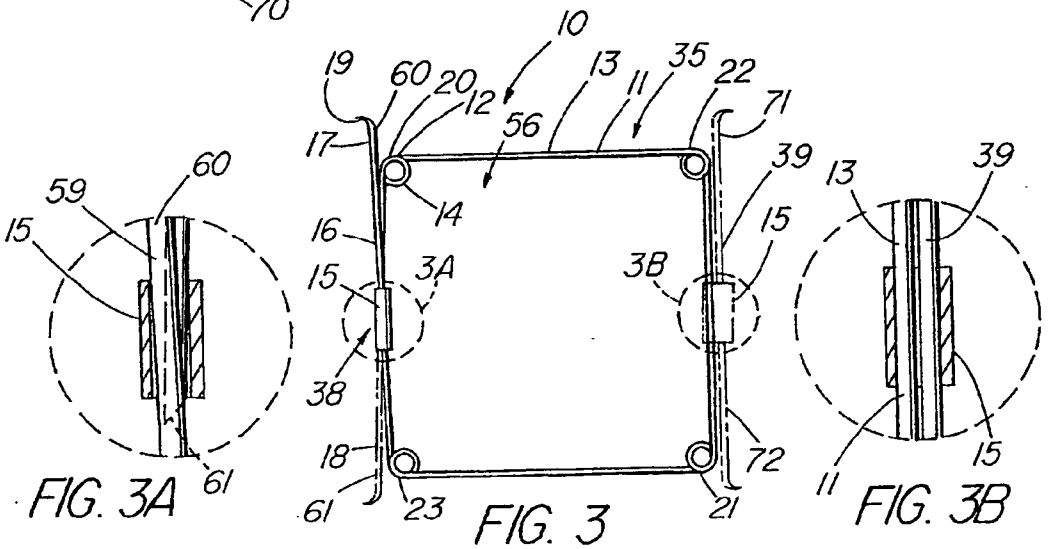


FIG. 3A

FIG. 3

FIG. 3B

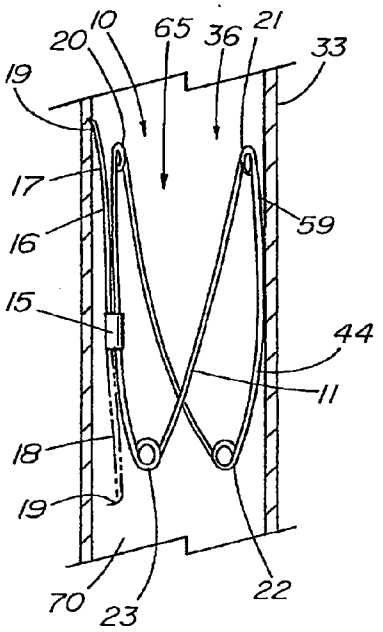


FIG. 4

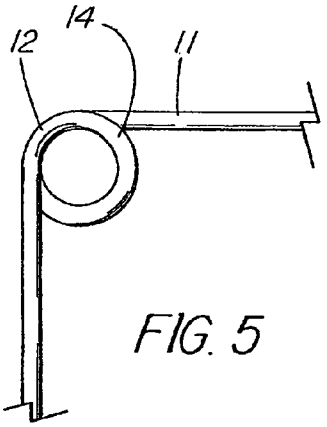


FIG. 5

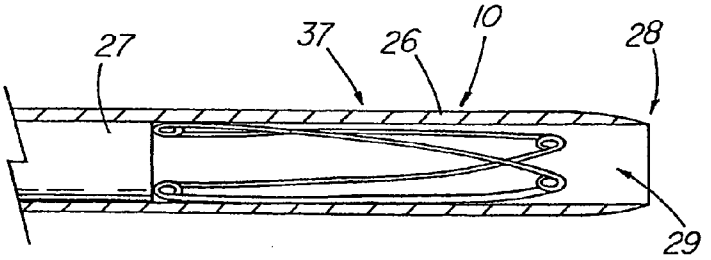


FIG. 6

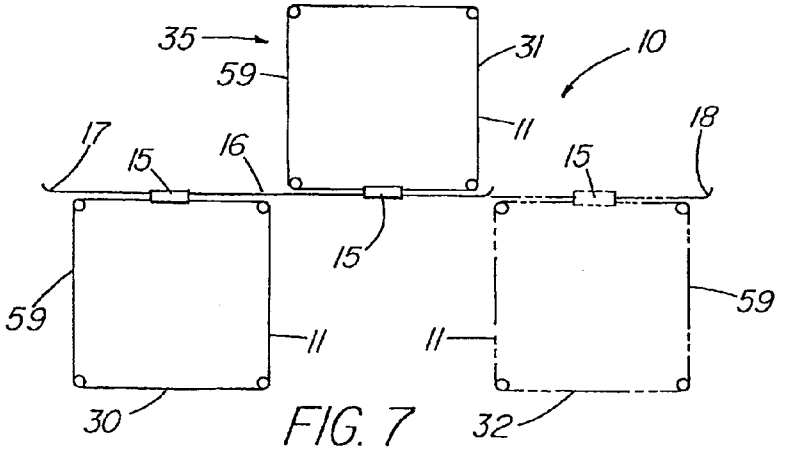


FIG. 7

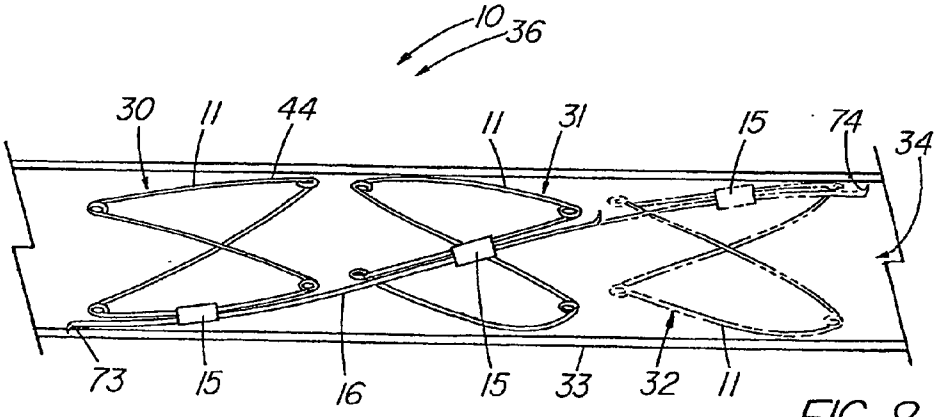


FIG. 8

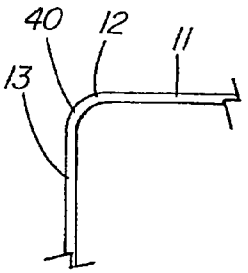


FIG. 9

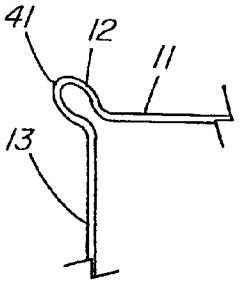


FIG. 10

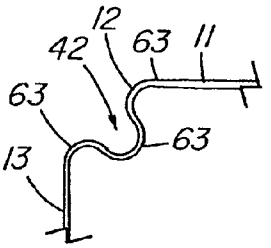


FIG. 11

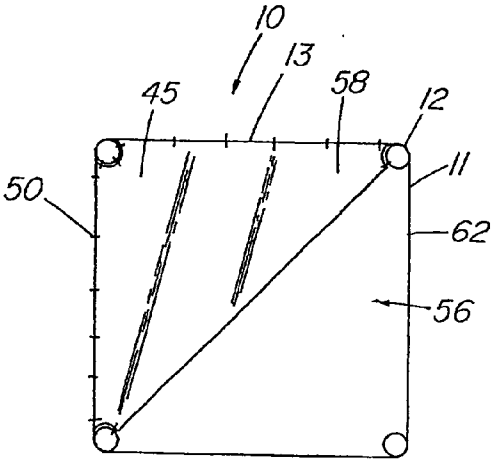


FIG. 12

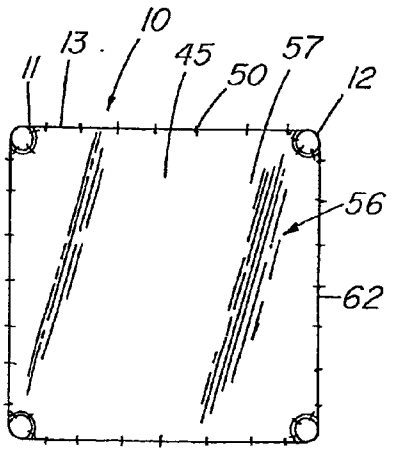


FIG. 15

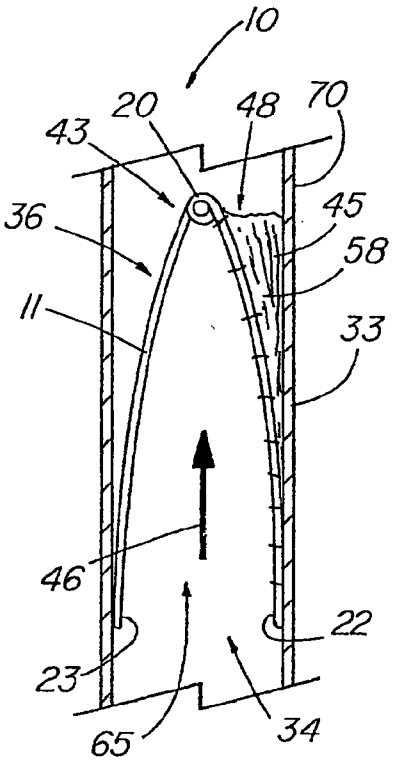


FIG. 13

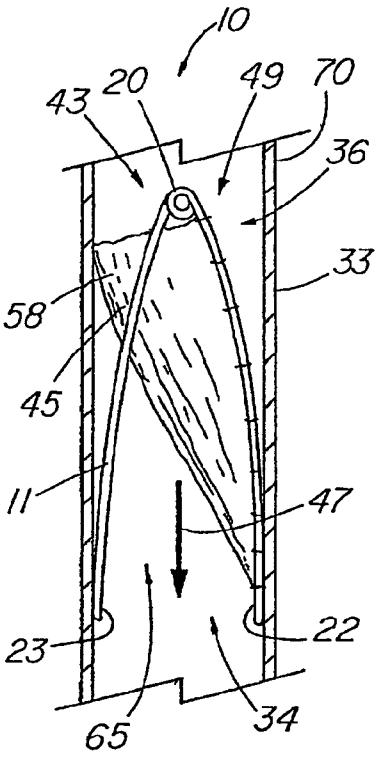


FIG. 14

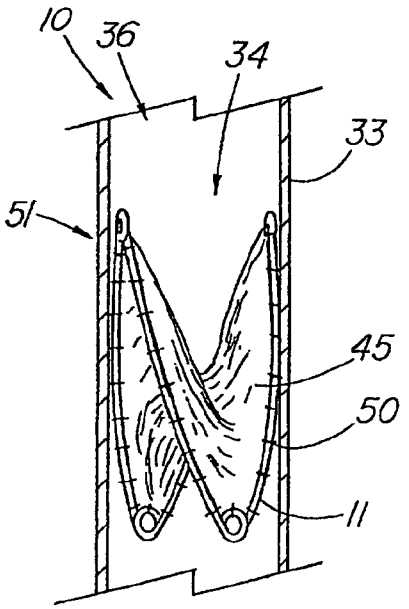


FIG. 16

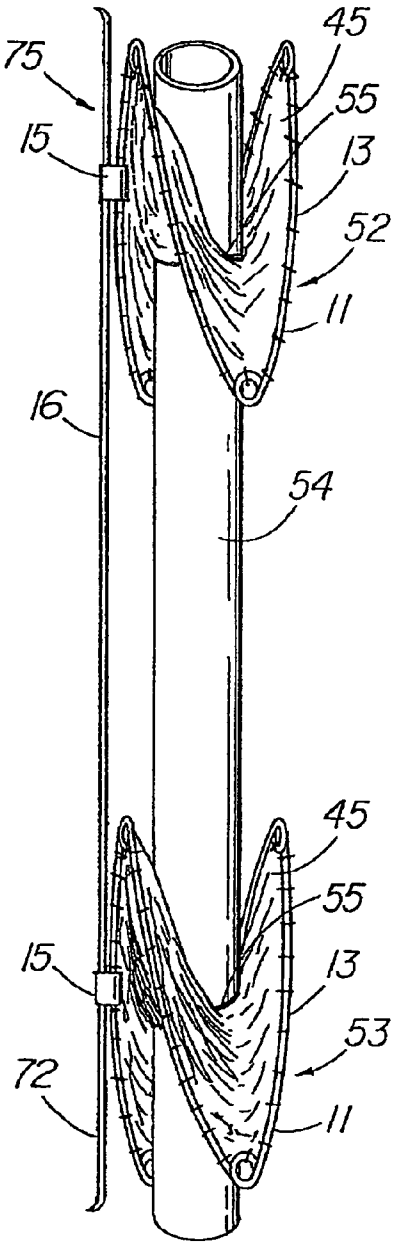


FIG. 17

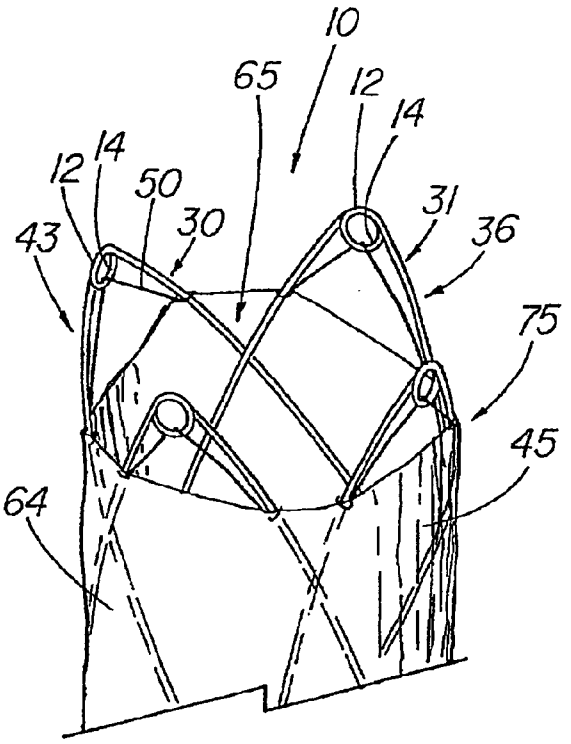


FIG. 18

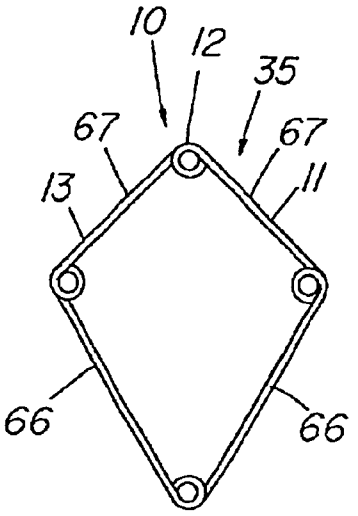


FIG. 19

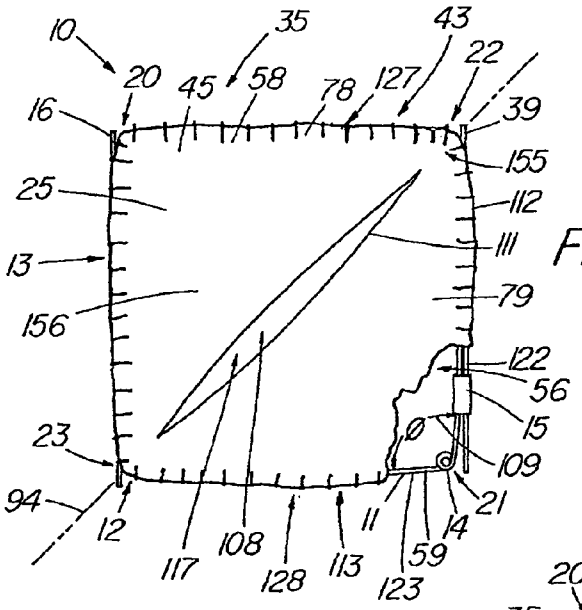


FIG. 20

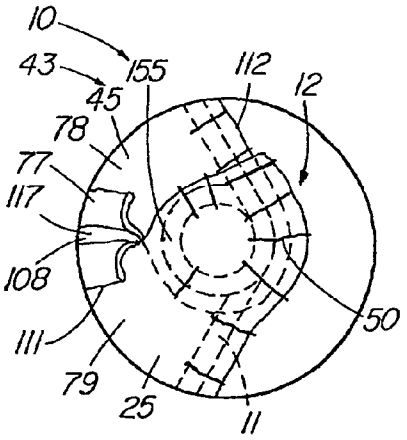


FIG. 21A

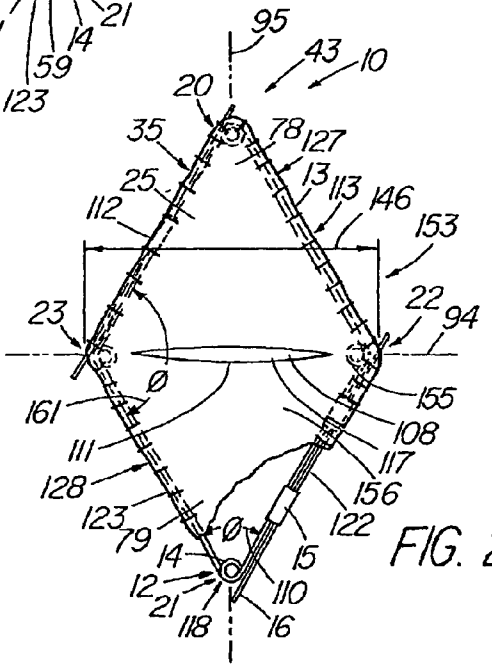


FIG. 21

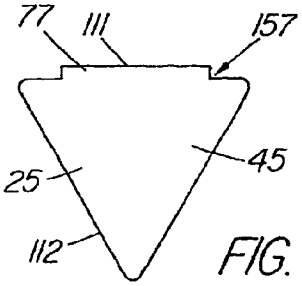


FIG. 21B

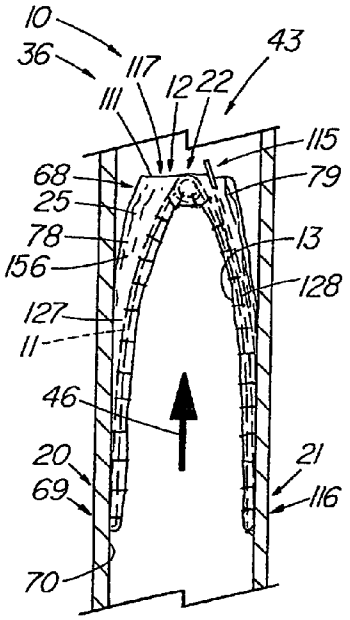


FIG. 22

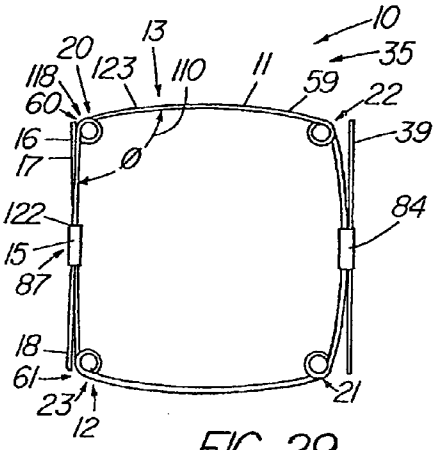


FIG. 29

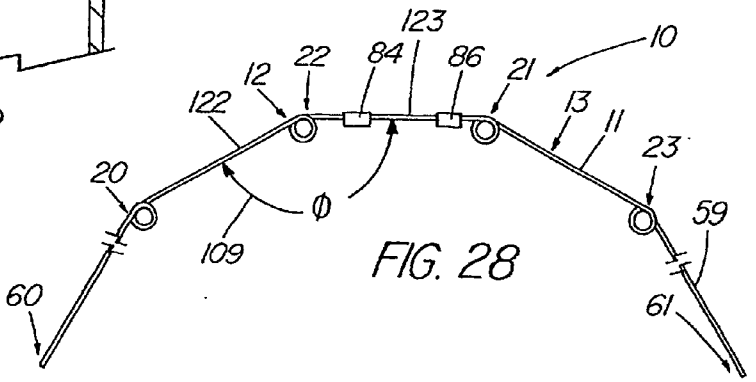


FIG. 28

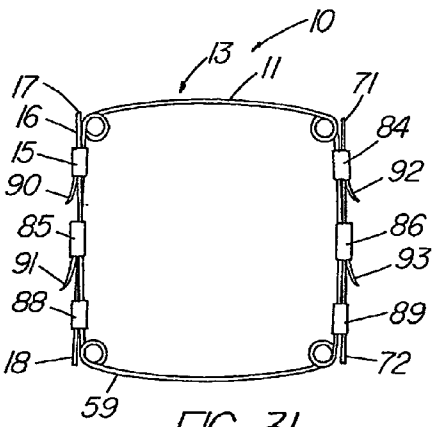


FIG. 31

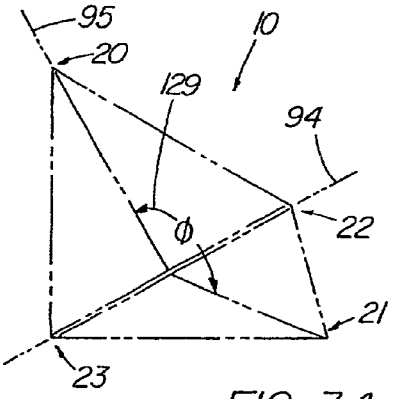


FIG. 34

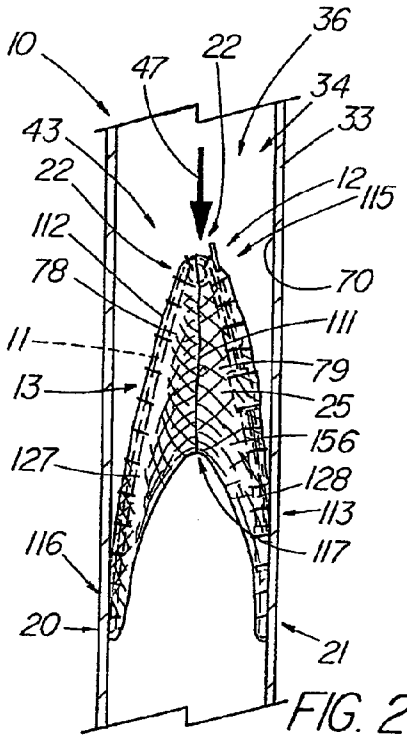


FIG. 23

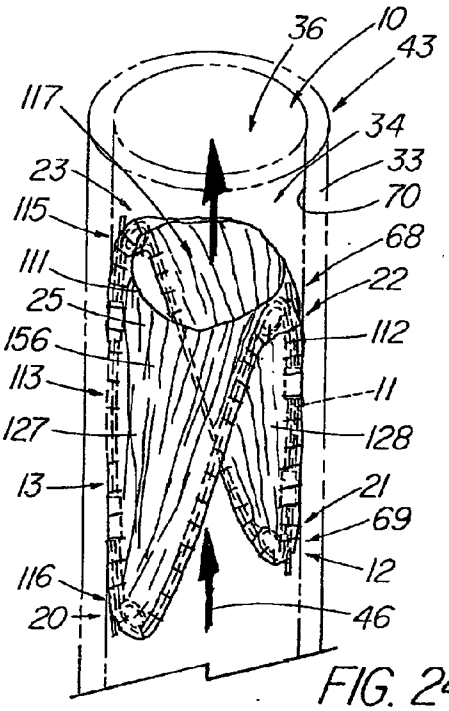


FIG. 24

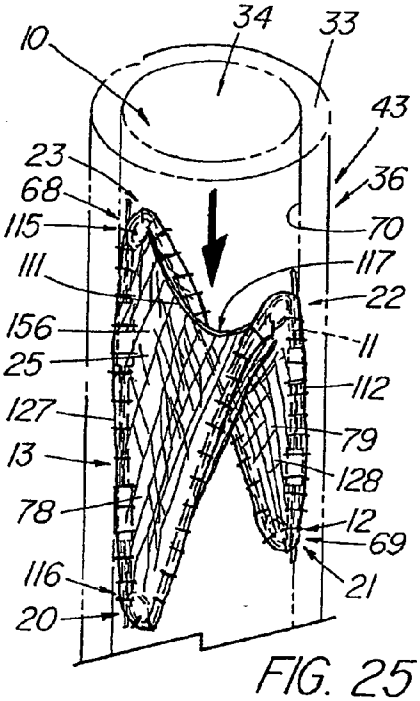


FIG. 25

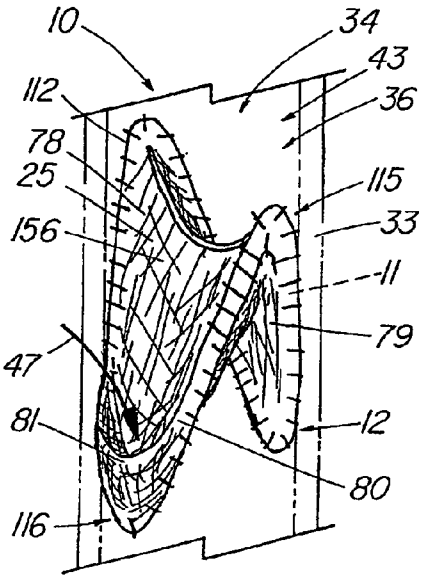


FIG. 27

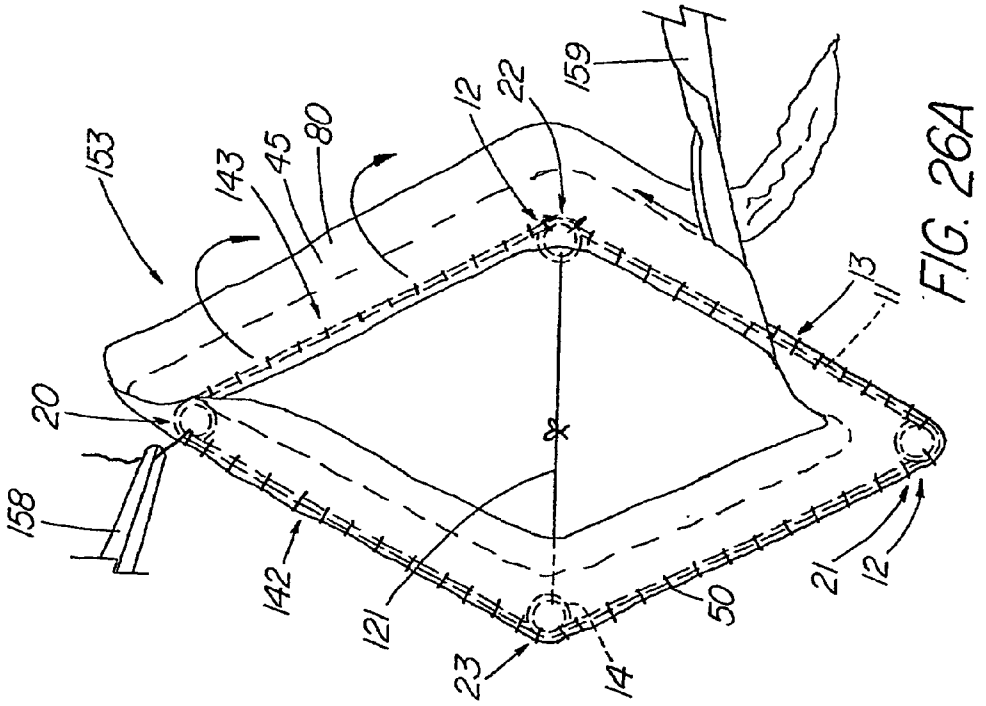


FIG. 26A

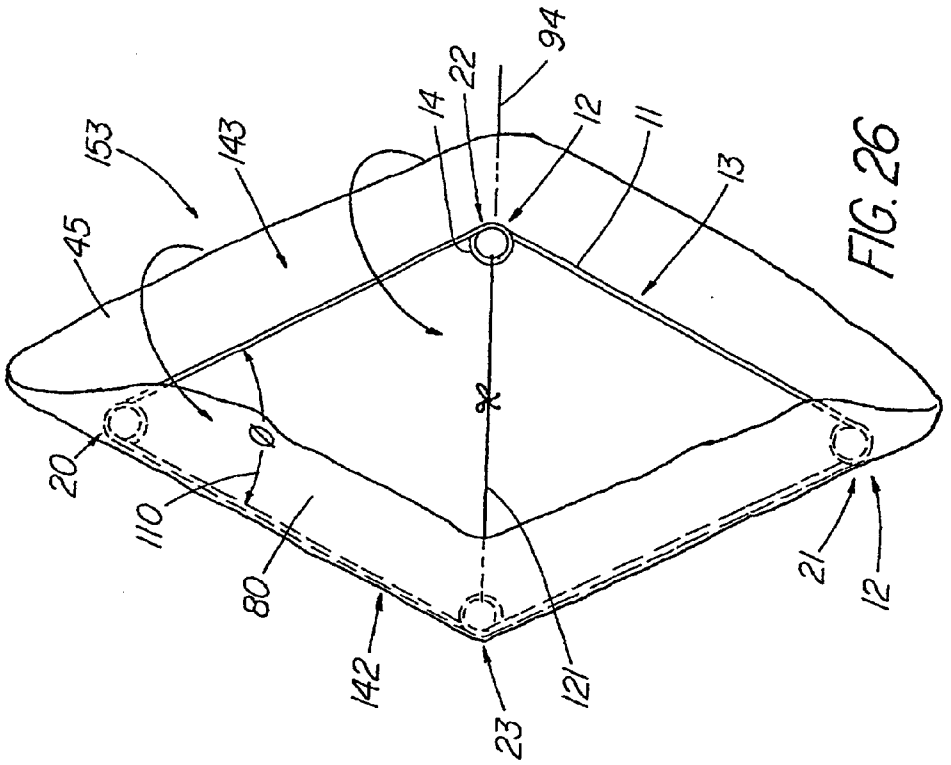


FIG. 26

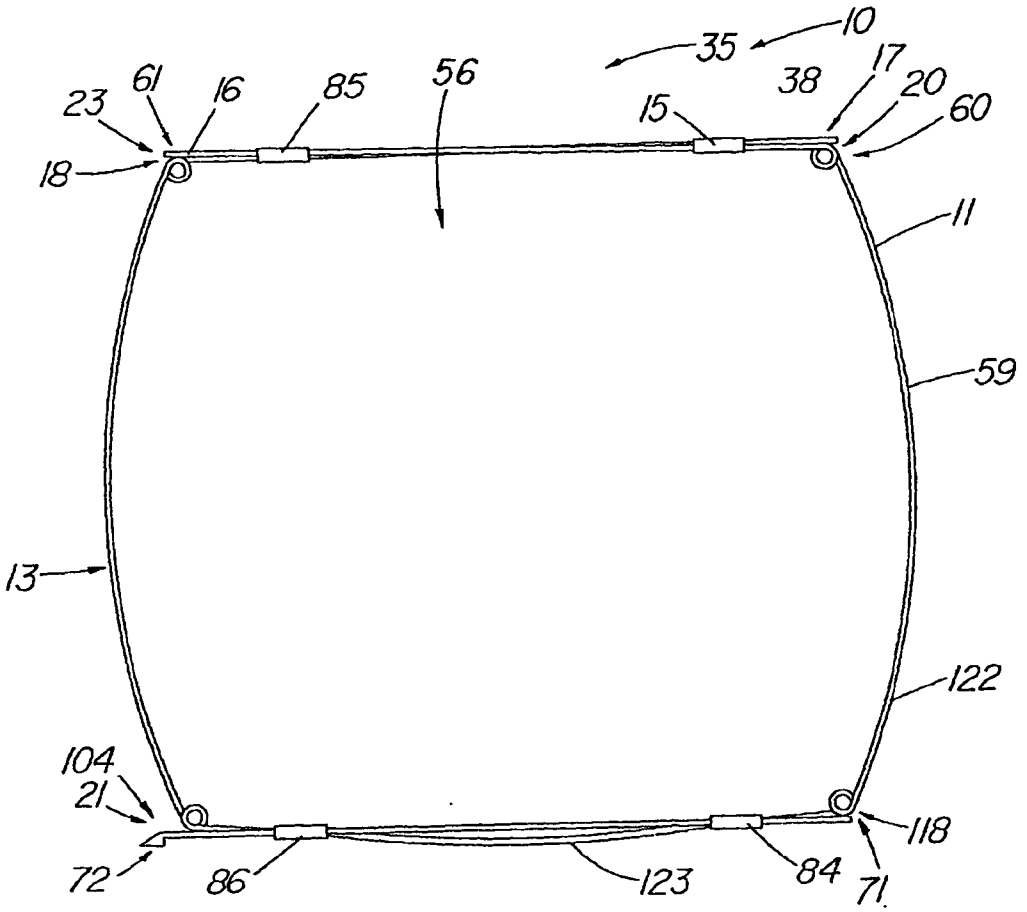

10
35
17
38
20
60
61
16
85
56
15
23
18
11
59
13
122
104
21
118
72
86
123
84
71

FIG. 30

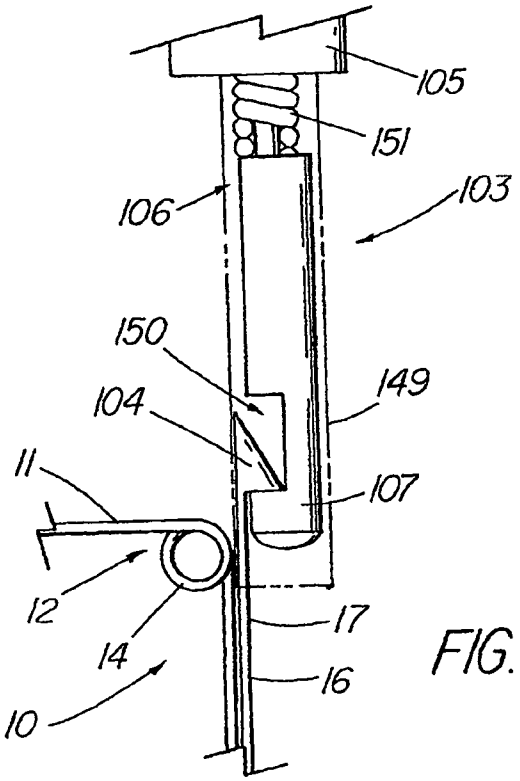

105
151
106
103
150
149
104
107
11
12
14
17
16
10

FIG. 33

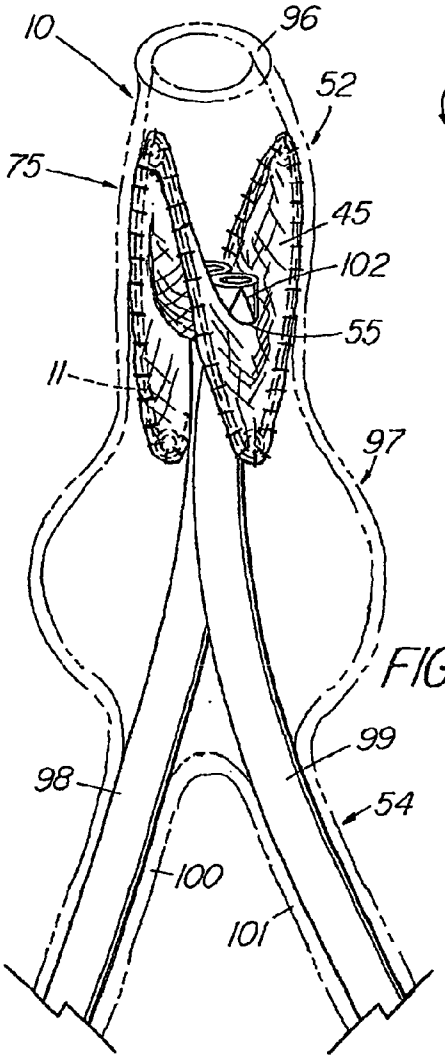


FIG. 32

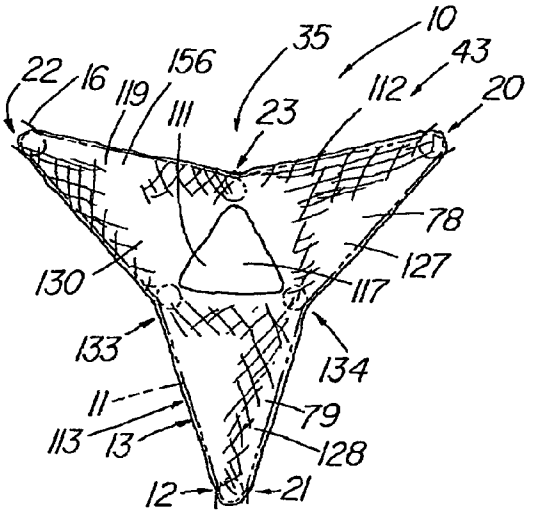


FIG. 35

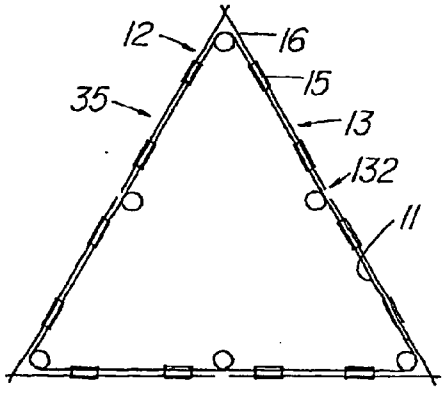


FIG. 36

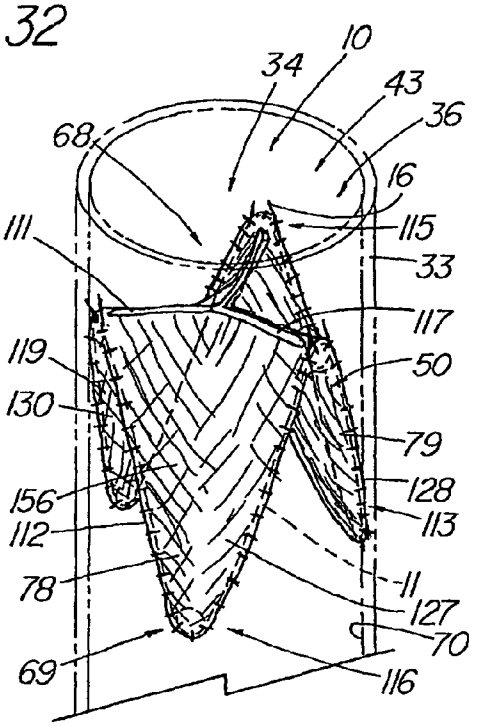


FIG. 37

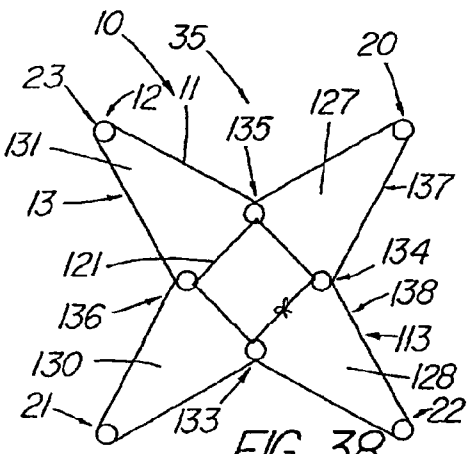


FIG. 38

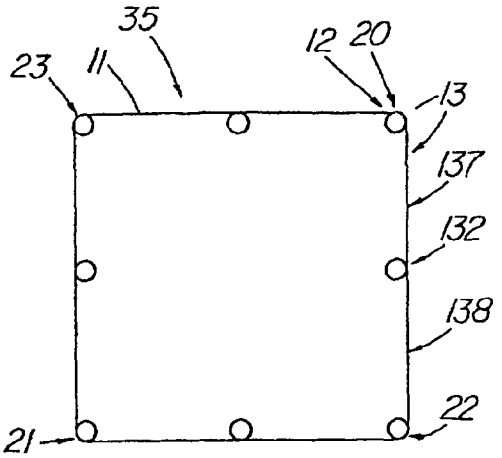


FIG. 39

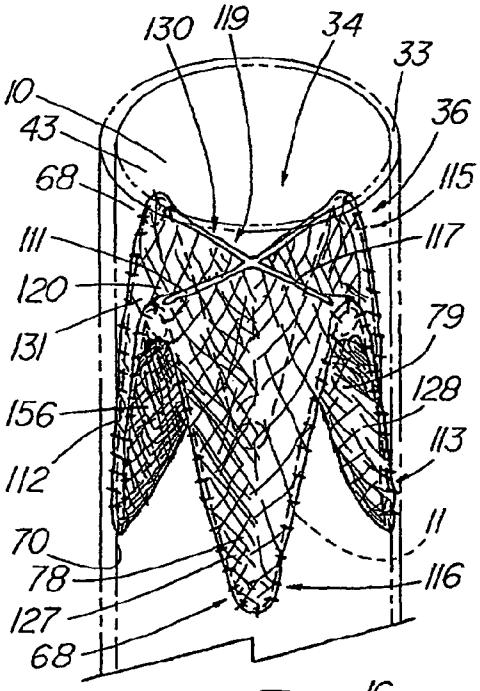


FIG. 40

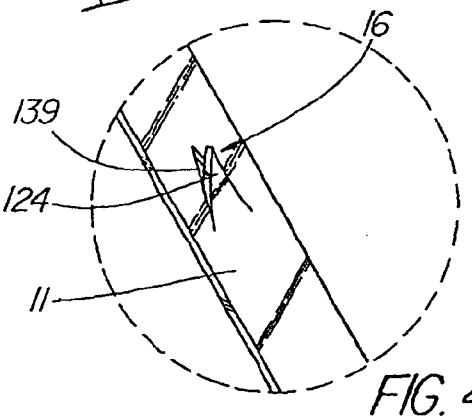


FIG. 41A

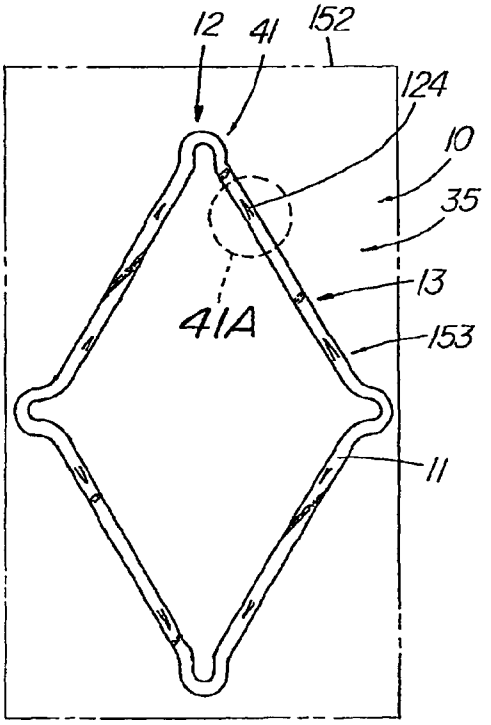


FIG. 41

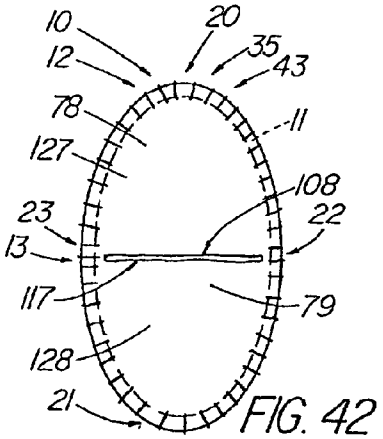


FIG. 42

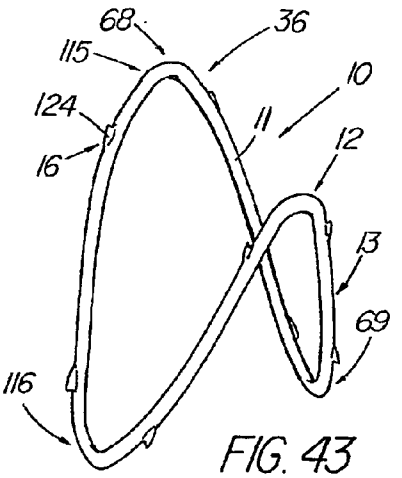


FIG. 43

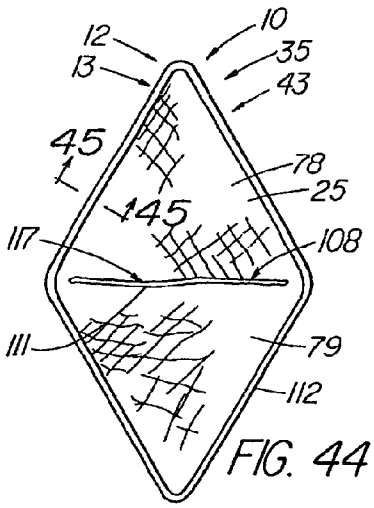


FIG. 44

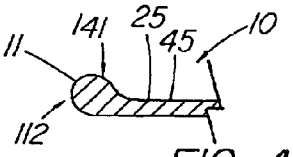


FIG. 45

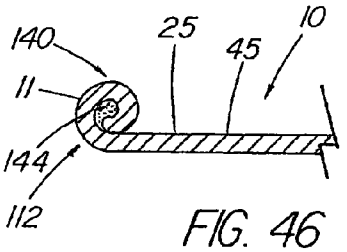


FIG. 46

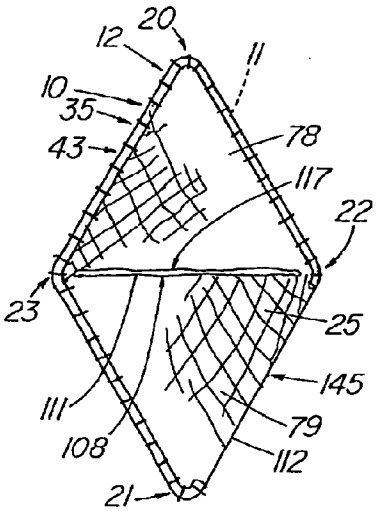


FIG. 47

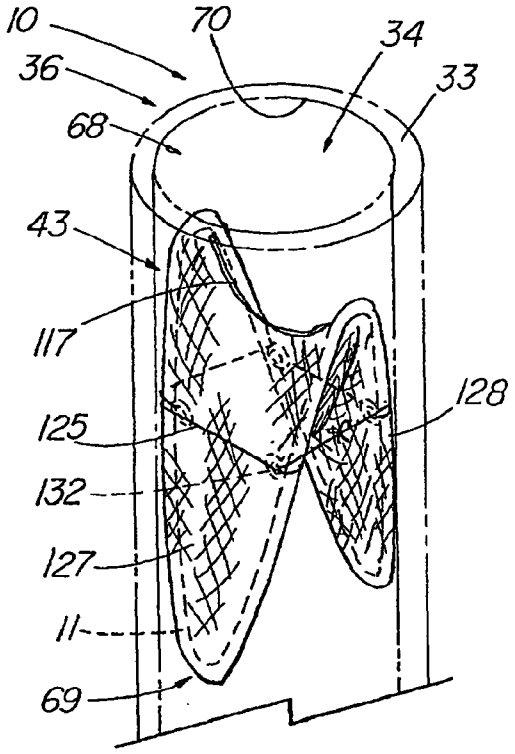


FIG. 48

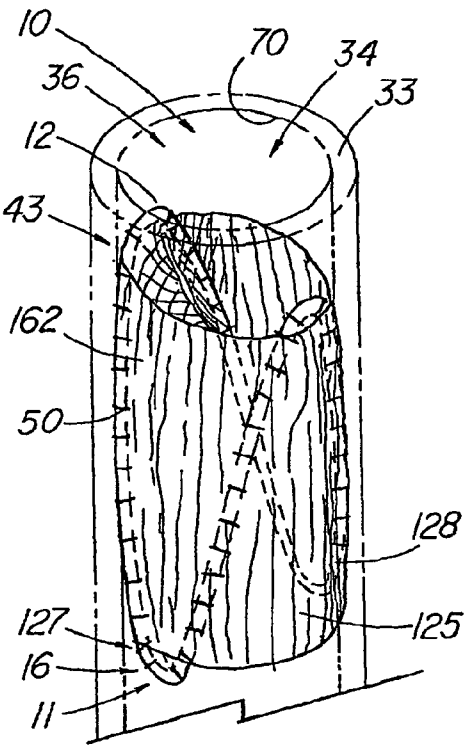


FIG. 49

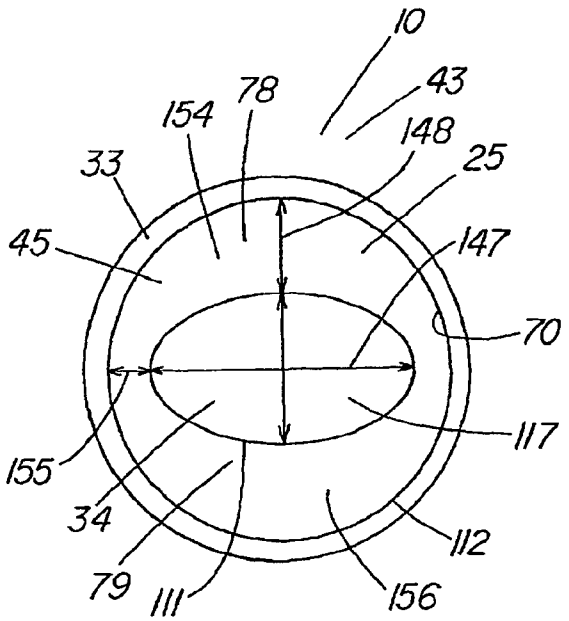


FIG. 50

IMPLANTABLE VASCULAR DEVICE COMPRISING A BIOABSORBABLE FRAME

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of, and fully incorporates by reference, U.S. utility patent application Ser. No. 09/777,091, filed Feb. 5, 2001, published as U.S. 2001-0039450 A1 on Nov. 8, 2001, which claims priority to Provisional U.S. Patent Application Ser. No. 60/180,002, filed Feb. 3, 2000 and regular utility application Ser. No. 09/324,382, filed Jun. 2, 1999, and issued as U.S. Pat. No. 6,200,336 on Mar. 13, 2001.

BACKGROUND

[0002] 1. Technical Field

[0003] This invention relates to medical devices, more particularly, to intraluminal devices.

[0004] 2. Background Information

[0005] As minimally invasive techniques and instruments for placement of intraluminal devices have developed over recent years, the number and types of treatment devices have proliferated as well. Stents, stent grafts, occlusion devices, artificial valves, shunts, etc., have provided successful treatment for a number of conditions that heretofore required surgery or lacked an adequate solution altogether. Minimally invasive intravascular devices especially have become popular with the introduction of coronary stents to the U.S. market in the early 1990s. Coronary and peripheral stents have been proven to provide a superior means of maintaining vessel patency. In addition, they have subsequently been used as filter, occluders, or in conjunction with grafts as a repair for abdominal aortic aneurysm, with fibers or other materials as occlusion devices, and as an intraluminal support for artificial valves, among other uses.

[0006] Some of the chief goals in designing stents and related devices include providing sufficient radial strength to supply sufficient force to the vessel and prevent device migration. An additional concern in peripheral use, is having a stent that is resistant to external compression. Self-expanding stents are superior in this regard to balloon expandable stents which are more popular for coronary use. The challenge is designing a device that can be delivered intraluminally to the target, while still being capable of adequate expansion. Self-expanding stents usually require larger struts than balloon expandable stents, thus increasing their profile. When used with fabric or other coverings that require being folded for placement into a delivery catheter, the problem is compounded.

[0007] There exists a need to have a basic stent, including a fabric or biomaterial covering, that is capable of being delivered with a low profile, while still having a sufficient expansion ratio to permit implantation in larger vessels, if desired, while being stable, self-centering, and capable of conforming to the shape of the vessel. There is a further need to have a intraluminal valve that can be deployed in vessels to replace or augment incompetent native valves, such as in the lower extremity venous system to treat patients with venous valve insufficiency. Such a valve should closely simulate the normal functioning valve and be capable of permanent implantation with excellent biocompatibility.

SUMMARY OF THE INVENTION

[0008] The foregoing problems are solved and a technical advance is achieved in an illustrative implantable valve that is deployed within a bodily passage, such as a blood vessel or the heart, to regulate or augment the normal flow of blood or other bodily fluids. The valve includes a covering having oppositely facing curvilinear-shaped surfaces (upper and lower) against which fluid traveling in a first or second direction within the bodily passage exerts force to at least partially open or close the valve. At least one outer edge of the covering resiliently engages and exerts force against the wall of the vessel and has arcuate shape that provides at least a partial seal against the wall.

[0009] In one aspect of the invention, the covering comprises a plurality of leaflets, each leaflet having a body extending from a wall-engaging outer edge to a free edge which is cooperable with one or more opposing leaflets to prevent flow in one direction, such as retrograde flow, while at least a portion of the leaflets having sufficient flexibility, when in situ to move apart, thereby creating a valve orifice that permits flow in the opposite direction, such as normal blood flow. The outer edge of each leaflet is adapted to engage and resilient exert force against a wall of the bodily passage such that it extends in both a longitudinal and circumferential directions along the vessel wall to at least partially seal a portion of the vessel lumen, while the free edge of each leaflet traverses the passageway across the diameter of the vessel.

[0010] In another aspect of the invention, the valve includes a frame that is covered by a piece of biocompatible material, preferably an Extracellular Collagen Matrix (ECM) such as small intestinal submucosa (SIS) or another type of submucosal-derived tissue. Other potential biomaterials include allographs such as harvested native valve tissue. The material is slit or otherwise provided with an opening along one axis to form two triangular valve leaflets over a four-sided frame. In the deployed configuration, the leaflets are forced open by normal blood flow and subsequently close together in the presence of backflow to help eliminate reflux. Other configurations include a two-leaflet valve having an oval or elliptically shaped frame, and valves having three or more legs and associated leaflets, which provide a better distribution of the load exerted by the column of fluid acting on the leaflets.

[0011] In still another aspect of the invention, the frame of the device is modified by placing one or more of the bends under tension which results in the frame assuming a second shape that has superior characteristics of placement within the vessel. One method of adjusting the shape includes forming the bends in the wire at an initial angle, e.g., 150□, that is larger than the desired final angle, e.g., 90□ for a four-sided valve, so when the frame is constrained into the final configuration, the sides are arcuate and bow outward slightly. The curvature of the sides allows the sides to better conform to the rounded countours of the vessel wall when the valve is deployed. In devices having a full or partial covering of material over the frame, a second method of modifying the shape is to use the material to constrain the frame in one axis. One such embodiment includes a four-sided valve with two triangular-shaped halves of material, such as SIS, where the material constrains the frame in a diamond shape. This puts the bend of the frame under stress

or tension which permits better positioning within the vessel. It also allows the diagonal axis of the frame with the slit or orifice to be adjusted to the optimal length to properly size the frame for the vessel such that the leaflets open to allow sufficient flow, but do not open to such a degree that they contact the vessel wall. The potential benefits of both adding tension to the bends to bow the sides and constraining the frame into a diamond shape using the covering, can be combined in a single embodiment or employed separately.

[0012] In still another aspect of the present invention, the device includes a frame that in one embodiment, is formed from a single piece of wire or other material having a plurality of sides and bends each interconnecting adjacent sides. The bends can be coils, fillets, or other configurations to reduce stress and improve fatigue properties. The single piece of wire is preferably joined by an attachment mechanism, such as a piece of cannula and solder, to form a closed circumference frame. The device has a first configuration wherein the sides and bends generally lie within a single, flat plane. In an embodiment having four equal sides, the frame is folded into a second configuration where opposite bends are brought in closer proximity to one another toward one end of the device, while the other opposite ends are folded in closer proximity together toward the opposite end of the device. In the second configuration, the device becomes a self-expanding stent. In a third configuration, the device is compressed into a delivery device, such as a catheter, such that the sides are generally beside one another. While the preferred embodiment is four-sided, other polygonal shapes can be used as well. The frame can either be formed into a generally flat configuration, or into the serpentine configuration for deployment. Besides rounded wire, the frame can comprise wires of other cross-sectional shapes (e.g., oval, delta, D-shape), or flat wire. Additionally, the frame can be molded from a polymer or composite material, or formed from a bioabsorbable material such as polyglycolic acid and materials with similar properties. Another method is to laser cut the frame out of a metal tube, such as stainless steel or nitinol. Still yet another method is to spot weld together, or otherwise attach, a series of separate struts that become the sides of a closed frame. In further alternative embodiments, the frame can be left with one or more open gaps that are bridged by the material stretched over the remainder of the frame. The frame can also be formed integrally with the covering, typically as a thickened or strengthened edge portion that gives the device sufficient rigidity to allow it to assume the deployed configuration in the vessel. To prevent the frame from radially expanding within the vessel beyond the point which would be considered safe or desirable, the device can be formed into the serpentine configuration and a circumferentially constraining mechanism, such as a tether, strut, sleeve, etc., placed around the device, or built into the frame, to expand or unfold during deployment of the device to limit its expansion to a given diameter, such as that which is slightly larger than the vessel into which it is placed to allow anchoring, but not permit the device to exert to great a force on the vessel wall.

[0013] In another aspect of the present invention, one or more barbs can be attached to the frame for anchoring the device in the lumen of a vessel. The barbs can be extensions of the single piece of wire or other material comprising the frame, or they can represent a second piece of material that is separately attached to the frame by a separate attachment mechanism. An elongated barb can be used to connect additional devices with the second and subsequent frames attached to the barb in a similar manner. Additional barbs can be secured to the device from cannulae placed over the frame. In embodiments in which the frame is formed as a single piece, such as when cut from a sheet of material or injection molded, the barbs can be formed as integral extensions of the frame.

[0014] In still another aspect of the present invention, a covering, which can be a flexible synthetic material such as DACRON, or expanded polytetrafluorethylene (ePTFE), or a natural or collagen-based material, such as an allographic tissue (such as valvular material) or a xenographic implant (such as SIS), can be attached to the device with sutures or other means to partially, completely, or selectively restrict fluid flow. When the covering extends over the entire aperture of the frame, the frame formed into the second configuration functions as an vascular occlusion device that once deployed, is capable of almost immediately occluding an artery. An artificial valve, such as that used in the lower legs and feet to correct incompetent veins, can be made by covering half of the frame aperture with a triangular piece of material. The artificial valve traps retrograde blood flow and seals the lumen, while normal blood flow is permitted to travel through the device. In related embodiments, the device can be used to form a stent graft for repairing damaged or diseased vessels. In a first stent graft embodiment, a pair of covered frames or stent adaptors are used to secure a tubular graft prosthesis at either end and seal the vessel. Each stent adaptor has an opening through which the graft prosthesis is placed and an elongated barb is attached to both frames. In another stent graft embodiment, one or more frames in the second configuration are used inside a sleeve to secure the device to a vessel wall.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] **FIG. 1** depicts a top view of one exemplary embodiment of the present invention;

[0016] **FIG. 2** depicts a pictorial view of the embodiment of **FIG. 1**;

[0017] **FIGS. 3, 3A** and **3B** depict a top view and enlarged, partial cross-sectional views of a second exemplary embodiment of the present invention;

[0018] **FIG. 4** depicts a side view of the embodiment of **FIG. 3** deployed in a vessel;

[0019] **FIG. 5** depicts a enlarged partial view of the embodiment of **FIG. 1**;

[0020] **FIG. 6** depicts a partially-sectioned side view of the embodiment of **FIG. 1** inside a delivery system;

[0021] **FIG. 7** depicts a top view of a third embodiment of the present invention;

[0022] **FIG. 8** depicts a side view of the embodiment of **FIG. 7** deployed in a vessel;

[0023] **FIGS. 9, 10** and **11** depict enlarged partial views of other embodiments of the present invention;

[0024] **FIG. 12** depicts a top view of a fourth embodiment of the present invention;

[0025] **FIGS. 13 and 14** depicts side views of the embodiment of **FIG. 12**;

[0026] **FIG. 15** depicts a top view of a fifth embodiment of the present invention;

[0027] **FIG. 16** depicts a side view of the embodiment of **FIG. 15**;

[0028] **FIG. 17** depicts a side view of a sixth embodiment of the present invention;

[0029] **FIG. 18** depicts an enlarged pictorial view of a seventh embodiment of the present invention;

[0030] **FIG. 19** depicts a top view of an eighth embodiment of the present invention;

[0031] **FIG. 20** depicts a top view of a first embodiment of a multi-leaflet intraluminal valve of the present invention;

[0032] **FIG. 21** depicts a top view of a second embodiment of a multi-leaflet intraluminal valve;

[0033] **FIG. 21A** depicts a partial top view of another embodiment of leaflets of the present invention;

[0034] **FIG. 21B** depicts a top view of another embodiment of leaflet of the present invention;

[0035] **FIGS. 22 and 23** depict side views of the embodiment of **FIG. 21** when deployed in a vessel;

[0036] **FIGS. 24 and 25** depict pictorial views of the embodiments of **FIG. 21** when deployed in a vessel;

[0037] **FIGS. 26 and 26**A depict the method of attaching the covering to the embodiment of **FIG. 21**;

[0038] **FIG. 27** depicts a pictorial view of the basic valve of **FIG. 21** upon deployment with an alternative leaflet embodiment;

[0039] **FIGS. 28, 29, 30** and **31** depict top views of selected embodiments of the present invention, made using the method shown in **FIG. 28**;

[0040] **FIG. 32** depicts a pictorial view of an embodiment of a stent graft that includes stent adaptors of the present invention;

[0041] **FIG. 33** depicts a delivery system for deploying an embodiment of the present invention; and

[0042] **FIG. 34** depicts a pictorial view of the present invention having returned to the first configuration following formation into the second configuration;

[0043] **FIGS. 35 and 36** depict top views of a three-leg valve embodiment of the present invention, before and after being constrained;

[0044] **FIG. 37** depicts a pictorial view of the embodiment of **FIG. 35** in the deployed configuration;

[0045] **FIGS. 38 and 39** depict top views of four-leg valve embodiments of the present invention, before and after being constrained;

[0046] **FIG. 40** depicts a pictorial view of the embodiment of **FIG. 38** in the deployed configuration;

[0047] **FIG. 41** depicts a top view of a frame formed from a sheet of material;

[0048] **FIG. 41A** depicts a detail view of the embodiment of **FIG. 41**;

[0049] **FIG. 42** depicts a top view of a third embodiment of an intraluminal valve;

[0050] **FIG. 43** depicts a pictorial view a frame embodiment formed into a deployed configuration;

[0051] **FIG. 44** depicts a top view of an embodiment of implantable valve having an integrally formed frame and covering;

[0052] **FIG. 45** depicts a cross-sectional view taken along line **45-45** of **FIG. 44**;

[0053] **FIG. 46** depicts a cross-sectional view of a second embodiment of valve having an integrally formed frame and covering;

[0054] **FIG. 47** depicts a top view of an intraluminal valve embodiment having an open frame;

[0055] **FIGS. 48 and 49** depict a pictorial views of an intraluminal valve embodiments that includes a circumferentially constraining mechanism; and

[0056] **FIG. 50** depicts a top view of the embodiment of **FIG. 22**.

DETAILED DESCRIPTION OF THE DRAWINGS AND THE PRESENTLY PREFERRED EMBODIMENTS

[0057] The invention is further illustrated by the following (preceding) pictorial embodiments, which in no way should be construed as further limiting. The present invention specifically contemplates other embodiments not illustrated but intended to be included in the appended claims. FIGS. **1-11,18-19** are directed to a basic stent frame; **FIGS. 12-14** are directed to a single-leaflet valve; **FIGS. 15-16** are directed to an occluder (or filter); **FIGS. 17 and 32** are directed to a stent adaptor for a stent graft, **FIG. 20-27, 35-40, 42-50** are directed to a multi-leaf valve; and **FIG. 28-31** are directed to a constrained frame which can be used to form any of the other embodiments.

[0058] **FIG. 1** depicts a top view of one embodiment of the medical device **10** of the present invention comprising a frame **11** of resilient material, preferably metal wire made of stainless steel or a superelastic alloy (e.g., nitinol). While round wire is depicted in each of the embodiments shown herein, other types, e.g., flat, square, triangular, D-shaped, delta-shaped, etc. may be used to form the frame. In the illustrative embodiment, the frame comprises a closed circumference **62** of a single piece **59** of material that is formed into a device **10** having a plurality of sides **13** interconnected by a series of bends **12**. The depicted embodiment includes four sides **13** of approximately equal length. Alternative embodiments include forming a frame into any polygonal shape, for example a pentagon, hexagon, octagon, etc. One alternative embodiment is shown in **FIG. 19** that includes a four-sided frame **11** having the general shape of a kite with two adjacent longer sides **66** and two adjacent shorter sides **67**. In the embodiment of **FIG. 1**, the bends **12** interconnecting the sides **13** comprise a coil **14** of approximately one and a quarter turns. The coil bend produces superior bending fatigue characteristics than that of a simple bend **40**, as shown in **FIG. 9**, when the frame is formed from stainless steel and most other standard materials. The embodiment of **FIG. 9** may be more appropriate, however, if the frame is formed from nitinol (NiTi) or other superelastic alloys, as

forming certain type of bends, such as coil **14**, may actually decrease fatigue life of a device of superelastic materials. Therefore, the bend **12** should be of a structure that minimizes bending fatigue. Alternative bend **12** embodiments include an outward-projecting fillet **41** as shown in **FIG. 10**, and an inward-projecting fillet **42** comprising a series of curves **63**, as shown in **FIG. 11**. Fillets are well known in the stent art as a means to reduce stresses in bends. By having the fillet extend inward as depicted in **FIG. 11**, there is less potential trauma to the vessel wall.

[**0059**] When using stainless steel wire, the size of the wire which should be selected depends on the size of device and the application. An occlusion device, for example, preferably uses 0.010" wire for a 10 mm square frame, while 0.014" and 0.016" wire would be used for 20 mm and 30 mm frames, respectively. Wire that is too stiff can damage the vessel, not conform well to the vessel wall, and increase the profile of the device when loaded in the delivery system prior to deployment.

[**0060**] Returning to **FIG. 1**, the single piece **59** of material comprising the frame **11** is formed into the closed circumference **62** by securing the first and second ends **60,61** with an attachment mechanism **15** such as a piece of metal cannula. The ends **60,61** of the single piece **59** are then inserted into the cannula **15** and secured with solder **25**, a weld, adhesive, or crimping to form the closed frame **11**. The ends **60,61** of the single piece **59** can be joined directly without addition of a cannula **15**, such as by soldering, welding, or other methods to join ends **61** and **62**. Besides joining the wire, the frame could be fabricated as a single piece of material **59**, by stamping or cutting the frame **11** from another sheet (e.g., with a laser), fabricating from a mold, or some similar method of producing a unitary frame.

[**0061**] The device **10** depicted in **FIG. 1** is shown in its first configuration **35** whereby all four bends **20,21,22,23** and each of the sides **13** generally lie within a single flat plane. To resiliently reshape the device **10** into a second configuration **36**, shown in **FIG. 2**, the frame **11** of **FIG. 1** is folded twice, first along one diagonal axis **94** with opposite bends **20** and **21** being brought into closer proximity, followed by opposite bends **22** and **23** being folded together and brought into closer proximity in the opposite direction. The second configuration **36**, depicted in **FIG. 2**, has two opposite bends **20,21** oriented at the first end **68** of the device **10**, while the other opposite bends **22,23** are oriented at the second end **69** of the device **10** and rotated approximately 90□ with respect to bends **20** and **21** when viewed in cross-section. The medical device in the second configuration **36** can be used as a stent **44** to maintain an open lumen **34** in a vessel **33**, such as a vein, artery, or duct. The bending stresses introduced to the frame **11** by the first and second folds required to form the device **10** into the second configuration **36**, apply force radially outward against the vessel wall **70** to hold the device **10** in place and prevent vessel closure. Absent any significant plastic deformation occurring during folding and deployment, the device in the second configuration **36** when not with the vessel or other constraining means, will at least partially return to the first configuration **25**, although some deformation can occur as depicted in **FIG. 34**, depending on the material used. It is possible to plastically form the stent into this configuration which represents an intermediate condition between the first configuration (which it also can obtain) and the second configuration. It is also possible to plastically deform the device **10** into the second configuration **36**, such that it does not unfold when restraint is removed. This might be particularly desired if the device is made from nitinol or a superelastic alloy.

[**0062**] The standard method of deploying the medical device **10** in a vessel **33**, depicted in **FIG. 6**, involves resiliently forming the frame **11** into a third configuration **37** to load into a delivery device **26**, such as a catheter. In the third configuration **37** the adjacent sides **13** are generally beside each other in close proximity extending generally along the same axis. To advance and deploy the device from the distal end **28** of the delivery catheter **26**, a pusher **27** is placed into the catheter lumen **29**. When the device **10** is fully deployed, it assumes the second configuration **36** within the vessel as depicted in **FIG. 2**. The sides **13** of the frame, being made of resilient material, conform to the shape of the vessel wall **70** such that when viewed on end, the device **10** has a circular appearance when deployed in a round vessel. As a result, sides **13** are arcuate or slightly bowed out to better conform to the vessel wall.

[**0063**] A second embodiment of the present invention is depicted in **FIG. 3** wherein one or more barbs **16** are included to anchor the device **10** following deployment. As understood, a barb can be a wire, hook, or any structure attached to the frame and so configured as to be able to anchor the device **10** within a lumen. The illustrative embodiment includes a first barb **16** with up to three other barbs **17,71,72**, indicated in dashed lines, representing alternative embodiments. As depicted in detail view A of **FIG. 3**, the barb combination **38** that comprises barbs **17** and **18**, each barb is an extension of the single piece **59** of material of the frame **11** beyond the closed circumference **59**. The attachment cannula **15** secures and closes the single piece **59** of material into the frame **11** as previously described, while the first and second ends **60,61** thereof, extend from the cannula **15**, running generally parallel with the side **13** of the frame **11** from which they extend, each preferably terminating around or slightly beyond respective bends **20,23**. To facilitate anchoring, the distal end **19** of the barb **16** in the illustrative embodiment contains a bend or hook.

[**0064**] Optionally, the tip of the distal end **19** can be ground to a sharpened point for better tissue penetration. To add a third and fourth barb as shown, a double ended barb **39** comprising barbs **71** and **72** is attached to the opposite side **13** as defined by bends **21** and **22**. Unlike barb combination **38**, the double barb **39**, as shown in detail view B of **FIG. 3**, comprises a piece of wire, usually the length of barb combination **38**, that is separate from the single piece **59** comprising the main frame **11**. It is secured to the frame by attachment mechanism **15** using the methods described for **FIG. 1**. **FIG. 4** depicts barb **17** (and **18**) engaging the vessel wall **70** while the device **10** is in the second, deployed configuration **36**. While this embodiment describes up to a four barb system, more than four can be used.

[**0065**] **FIG. 7** depicts a top view of a third embodiment of the present invention in the first configuration **35** that includes a plurality of frames **11** attached in series. In the illustrative embodiment, a first frame **30** and second frame **31** are attached by a barb **16** that is secured to each frame by their respective attachment mechanisms **15**. The barb **16** can be a double-ended barb **39** as shown in **FIG. 3** (and detail

view B) that is separate from the single pieces **59** comprising frames **30** and **31**, or the barb may represent a long extended end of the one of the single pieces **59** as shown in detail view A of **FIG. 3**. Further frames, such as third frame **32** shown in dashed lines, can be added by merely extending the length of the barb **16**. **FIG. 8** depicts a side view of the embodiment of **FIG. 7** in the second configuration **36** as deployed in a vessel **33**.

[**0066**] **FIGS. 12-18** depict embodiments of the present invention in which a covering **45** comprising a sheet of fabric, collagen (such as small intestinal submucosa), or other flexible material is attached to the frame **11** by means of sutures **50**, adhesive, heat sealing, A weaving@ together, crosslinking, or other known means. **FIG. 12** depicts a top view of a fourth embodiment of the present invention while in the first configuration **35**, in which the covering **45** is a partial covering **58**, triangular in shape, that extends over approximately half of the aperture **56** of the frame **11**. When formed into the second configuration **36** as shown in **FIGS. 13-14**, the device **10** can act as an artificial valve **43** such as the type used to correct valvular incompetence. **FIG. 13** depicts the valve **43** in the open configuration **48**. In this state, the partial covering **58** has been displaced toward the vessel wall **70** due to positive fluid pressure or flow in a first direction **46**, e.g., normal venous blood flow, thereby opening a passageway **65** through the frame **11** and the lumen **34** of the vessel **33**. As the muscles relax, producing flow in a second, opposite direction **47**, e.g., retrograde blood flow **47**, as shown in **FIG. 14**, the partial covering **58** acts as a normal valve by catching the backward flowing blood and closing the lumen **34** of the vessel. In the case of the artificial valve **43**, the partial covering **58** is forced against the vessel wall to seal off the passageway **65**, unlike a normal venous valve which has two leaflets, which are forced together during retrograde flow. Both the artificial valve **43** of the illustrative embodiment and the normal venous valve, have a curved structure or cusp that facilitates the capture of the blood and subsequent closure. In addition to the triangular covering, other possible configurations of the partial covering **58** that result in the cupping or trapping of fluid in one direction can be used.

[**0067**] Selecting the correct size of valve for the vessel ensures that the partial covering **58** properly seals against the vessel wall **70**. If the lumen **34** of the vessel is too large for the device **10**, there will be retrograde leakage around the partial covering **58**.

[**0068**] **FIG. 15** depicts a top view of a fifth embodiment of the present invention in the first configuration **35**, whereby there is a full covering **57** that generally covers the entire aperture **56** of the frame **11**. When the device **10** is formed into the second configuration **36**, as depicted in **FIG. 16**, it becomes useful as an occlusion device **51** to occlude a duct or vessel, close a shunt, repair a defect, or other application where complete or substantially complete prevention of flow is desired. As an intravascular device, studies in swine have shown occlusion to occur almost immediately when deployed in an artery or the aorta with autopsy specimens showing that thrombus and fibrin which had filled the space around the device. The design of the present invention permits it to be used successfully in large vessels such as the aorta. Generally, the occlusion device should have side **13** lengths that are at least around 50% or larger than the vessel diameter in which they are to be implanted.

[**0069**] **FIGS. 17-18** depict two embodiments of the present invention in which the device **10** functions as a stent graft **75** to repair a damaged or diseased vessel, such as due to formation of an aneurysm. **FIG. 17** shows a stent graft **75** having a tubular graft prosthesis **54** that is held in place by a pair of frames **11** that function as stent adaptors **52,53**. Each stent adaptor **52,53** has a covering attached to each of the frame sides **13** which includes a central opening **55** through which the graft prosthesis **54** is placed and held in place by friction or attachment to prevent migration. One method of preventing migration is placement of a stent adaptor **52,53** according to the present invention at each end and suturing the graft prosthesis **54** to the covering of the stent adaptors **52,53**. The stent adaptors **52,53** provide a means to seal blood flow while centering the graft prosthesis in the vessel. A long double-ended barb **39** connects to each stent adaptor **52,53** and assists to further anchor the stent graft **75**. In the embodiment depicted in **FIG. 18**, the covering **45** comprises a outer sleeve **64** that is held in place by first and second **30,31** frames that function as stents **44** to hold and seal the sleeve **64** against a vessel wall and maintain an open passageway **65**. In the illustrative embodiment, the stents **44** are secured to the graft sleeve **64** by sutures **50** that are optionally anchored to the coils **14** of the bends **12**. If the embodiment of **FIG. 18** is used in smaller vessels, a single frame **11** can be used at each end of the stent graft **75**. Another stent graft **75** embodiment is depicted in **FIG. 32** for repairing a vessel defect **97**, such as an aneurysm in a bifurcated vessel. The stent adaptor **52** of the present invention is placed in the common vessel **96** such as the abdominal aorta. Two tubular grafts **54** are secured within an aperture **55** in the covering **45** of the frame **11** by one or more internal stent adapters **102**, or another type of self-expanding stent, that bias the opening of the grafts **54** against the surrounding covering **45** to provide an adequate seal. Each leg **98,99** of the stent graft prosthesis **75** transverses the vessel defect **97** and feeds into their respective vessel branches **100,101** such the right and left common iliac arteries. As with the embodiment of **FIG. 17**, a second stent adapter **53** can be used to anchor the other end of the tubular graft **54** in each vessel branch **100,101**.

[**0070**] **FIGS. 20-27** and **35-41** depict embodiments of present inventions in which the device **10** comprises an implantable valve having multiple leaflets **25** that act together to regulate and augment the flow of fluid through a duct or vessel **33**, or within the heart to treat patients with damaged or diseased heart valves. The covering **45** of each of these embodiments includes one or a series of partial coverings **58** that form the leaflets **25** of the valve. As with the other embodiments, the covering **45** may comprise a biomaterial or a synthetic material. While DACRON, expanded polytetrafluoroethylene (ePTFE), or other synthetic biocompatible materials can be used to fabricate the covering **45**, a naturally occurring biomaterial, such as collagen, is highly desirable, particularly a specially derived collagen material known as an extracellular matrix (ECM), such as small intestinal submucosa (SIS). Besides SIS, examples of ECM=s include pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa, and dura mater. SIS is particularly useful, and can be made in the fashion described in Badylak et al., U.S.

Pat. No. 4,902,508; Intestinal Collagen Layer described in U.S. Pat. No. 5,733,337 to Carr and in 17 Nature Biotechnology 1083 (November 1999); Cook et al., WIPO Publication WO 98/22158, dated 28 May 1998, which is the published application of PCT/US97/14855. Irrespective of the origin of the valve material (synthetic versus naturally occurring), the valve material can be made thicker by making multilaminate constructs, for example SIS constructs as described in U.S. Pat. Nos. 5,968,096; 5,955,110; 5,885,619; and 5,711,969. Animal data show that the SIS used in venous valves of the present invention can be replaced by native tissue in as little as a month=s time. In addition to xenogenic biomaterials, such as SIS, autologous tissue can be harvested as well, for use in forming the leaflets of the valve. Additionally Elastin or Elastin Like Polypetides (ELPs) and the like offer potential as a material to fabricate the covering or frame to form a device with exceptional biocompatibility. Another alternative would be to used allographs such as harvested native valve tissue. Such tissue is commercially available in a cryopreserved state.

[**0071**] To more completely discuss and understand the multi-leaflet valve **43** embodiments of FIGS. **20-27**,**35-41**, it is useful to now add certain supplemental terminology which in some instances, could be applied to the embodiments depicted in the earlier figures. In the illustrative multi-leaflet embodiments, the valve **43** is divided into a plurality of legs **113**, each of which further comprises a leaflet **25**. To anchor, support, and provide the proper orientation of the leaflets **25**, a separate or integral frame **11** is included, such as the wire frame **11** depicted in **FIG. 1**. Ideally, the wire used to construct the frame is made of a resilient material such as **302**,**304** stainless steel; however, a wide variety of other metals, polymers, or other materials are possible. It is possible for the frame to be made of the same material as the leaflets **25**. One other example of a suitable frame material would be a superelastic alloy such as nitinol (NiTi). Resiliency of the frame **11**, which provides radial expandability to the valve **43** when in the second configuration **36** for deployment, is not necessarily an essential property of the frame. For example, optional barbs **16** can provide the means to anchor the valve **43** after delivery, even if the valve **43** lacks sufficient expansile force to anchor itself against the vessel wall. Additionally, the frame can comprise a ductile material with the device **10** being designed to be balloon expandable within the vessel.

[**0072**] Typically, when used as a valve to correct venous insufficiency in the lower extremities, the valve **43** in situ comprises a plurality of bends **12** of the frame, that provide the majority of the outward radial force that helps anchor the device to vessel wall **70**, as depicted in **FIGS. 22-27**. When deployed, the frame assumes the undulating or serpentine configuration characteristic of the invention with a first series of bends **115** of the first or proximal end alternating with a second series of bends **116** of the second or distal end, with the second or distal bends **116** being located at the bottom of the valve distal to the heart and the first or proximal bends **115** being located at the top of the valve proximal to the heart. It should be understood that the valve can assume other orientations, depending on the particular clinical use, and thus, any directional labels used herein (>distal=, >top=, etc.) are merely for reference purposes. The leaflet **25**, which generally covers the valve leg **113** and therefore, assumes the same roughly triangular >U=or >V=shape of that portion of the frame **11** perimeter, includes an resilient arcuate outer edge **112** that conforms to and/or seals with the contours of the vessel wall **70**, and an inner edge **11** that traverses the vessel lumen **34**. The central portion or body **156** of the leaflet **25** extends inward from the vessel wall **70** and outer edge **112** in an oblique direction toward the first end **68** of the valve **43** where it terminates at the inner edge **111** thereof. The valve leaflets that come in contact with the vessel wall can also be arcuate as the supporting frame to better conform to and seal wit the vessel wall. The leaflets **25** assume a curvilinear shape when in the deployed configuration **36**. The portion of the body **156** proximate the inner edge **111** is sufficiently flexible such that is can move in and out of contact with the inner edge **111** the opposite or other leaflets **25**; however, the remainder of the body **156**, particular that near the outer edge **112** or second end **69** of the device **10**, can be made less flexible or even rigid in some instances, essentially functioning more for support, similar to the function of the frame **11**, rather than to cooperate with other leaflet(s) **25**. **FIGS. 20-27** depict the present invention as an implantable, intraluminal, vascular adapted for use as a implantable multi-leaflet valve **43** including a stent **44** or frame **11** with at least a partial covering **58**. The covering comprises a first and a second valve leaflets **78**,**79** that at least partially seal the aperture **56** within the frame **11** while the valve **43** is in the deployed configuration **36** and forms the opening **117** or valve orifice which regulates the flow of fluid **46**,**47** through the valve. **FIG. 20** shows the device **10** in the first, generally planar configuration **35** where the frame **11** is generally rectangular or in particular square in shape. The partial covering **58** forming the leaflets **78**,**79** generally extends across the entire frame **11** with the aperture **56** comprising a slit **108** that extends across the first axis **94** of the frame **11**, the first axis being defined as traversing diagonally opposite bends (**22** and **23** in this example) that are in line with the valve orifice **117** that forms the valve **43**. The covering **45** is therefore divided into at least first and second portions (making it a partial covering **58**) which define the first and second valve leaflets **78**,**79**. To form the leaflets **78**,**79**, a complete covering **45** can be slit open along the axis after it is affixed to the frame, or at least first and second adjacent triangular portions (partial coverings **58**) can be separately attached, eliminating the need for mechanically forming a slit **108**. In the embodiment of **FIG. 20**, the slit **108** is made in the covering **45** such that the slit terminates a few millimeters from each of the corner bends **22**,**23**, creating a pair of corner gaps **155**, thereby eliminating two of the most likely sources of leakage around the valve **43**. In the illustrative embodiments, the outer edge **112** of the partial covering **58** that comprises the leaflet **25** is stretched over the frame **11** comprising the valve leg **113** and sutured or otherwise attached as disclosed herein. The leaflet **25** is secured in place such that the material is fairly taut, such that when the valve **43** is situated in the vessel **33** and its diameter constrained to slightly less than the valve width **146**, the leaflet **25** assumes a relatively loose configuration that gives it the ability to flex and invert its shape, depending on the direction of fluid flow. The inner edge **111** of the leaflet **25** is generally free and unattached to the frame and generally extends between the bends **22** and **23** (the bends **115** of the first end) of the valve leg **113**. The inner edge **111** may be reinforced by some means, such as additional material or thin wire, that still would allow it to be sufficiently pliable to be able to seal against another leaflet **25** when retrograde

flow **47** forces the leaflets **78,79** together. The leaflet **25** is sized and shaped such that the inner edge **111** of one leaflet **78** can meet or overlap with the inner edge **111** of the opposing leaflet **79** (or leaflets, e.g., **119,120**), except when degree of normal, positive flow **46** is sufficient to force the leaflets **25** open to permit fluid passage therethrough.

[**0073**] The embodiments of **FIGS. 21-27** are configured into an elongated diamond shape **153** in the planar configuration **35** with the distance between the two bends **22,23** aligned with the valve orifice **117** and first axis **94** being less than the distance between bends **20** and **21** along the second, perpendicular axis **95**. This diamond configuration **153** can be accomplished by forming the frame **11** into that particular shape, or constraining a square frame into a diamond shape **153**, which will be discussed later. By configuring the valve **43** into the diamond shape **153**, the valve legs **127,128** become more elongated in shape, which can help add stability when positioning the device **10** during deployment, provides more surface area to receive retrograde flow, and more closely mimics a natural venous valve. In the deployed configuration **36** of the embodiment of **FIG. 21**, which is shown in **FIGS. 22-25**, the valve leaflets **78,79** are forced apart by the normal pulsatile blood flow **46** (**FIGS. 22,24**). The respective valve leaflets **78,79** naturally move back into closer proximity following the pulse of blood. Retrograde blood flow **47** forces the valve leaflets **78,79** against one another, as depicted in **FIGS. 23 and 25** thereby closing off the lumen **34** of the vessel **33** and the valve orifice **117**.

[**0074**] **FIGS. 21A-21B** depict embodiments of the valve **43** in which each leaflet **78,79** includes a flap **77** of overhanging material along the slit edge **111** to provide advantageous sealing dynamics when the valve **43** is in the deployed configuration **36** as depicted in **FIGS. 22-25**. The flaps **77** are typically formed by suturing two separate pieces of covering **45** material to the frame such that the inner edge **111** is extendable over the slit **108** and inner edge **111** of the adjacent leaflet **25**. By overlapping with an adjacent flap **77** or leaflet **25**, the flap **77** can provide additional means to help seal the valve orifice **117**. Two embodiments of leaflets **25** with flaps **77** are shown. In **FIG. 21A**, the inner edge **111** is basically straight and extends over the first axis **94** of the frame **11**. The flaps **77** can be cut to create a corner gap **155** that covers and seals the corner region around the bend **22,23**. In the embodiment of **FIG. 21B**, the flap **77** is cut such that there is a notch **157** in the leaflet where the leaflet meets the corner bends **22,23**. While these flaps **77** may provide benefit in certain embodiments, the optional flaps **77** shown in **FIG. 21** are not necessary to provide a good seal against backflow **47** if the valve **43** and leaflets **25** are properly sized and configured.

[**0075**] **FIGS. 26-26A** depict one method of affixing a covering **45** comprising a biomaterial, such as SIS, to the frame **11** which has been constrained using a temporary constraining mechansim **121**, such as a suture, to acheive the desired frame configuration. As shown in **FIG. 26**, the covering **45** is cut larger than the frame **11** such that there is an overhang **80** of material therearound, e.g, 5-10 mm. The frame **11** is centered over the covering **45** and the overhang **80** is then folded over from one long side **142**, with the other long side **143** subsequently being folded over the first. As shown in **FIG. 26A**, the covering **45** is sutured to the frame along one side **142**, typically using forceps **158** and needle, thereby enclosing the frame **11** and the coiled eyelet **14** with the overhang **80** along side **142**. The covering **45** is sutured to the frame with resorbable or non-resorbable sutures **50** or some other suitable method of attaching two layers of biomaterials can be used. In the case of SIS, a single ply sheet, usually about 0.1 mm thick, is used in the hydrated condition. In the illustrative embodiments, 7-0 Prolene suture is used, forming a knot at one bend (e.g., bend **20**), then continuing to the next bend (e.g., **22**) with a running suture **50**, penetrating the layers of SIS around the frame at about 1-2 mm intervals with loops formed to hold the suture **50** in place. When the next coil turn **14** is reached, several knots are formed therethrough, and the running suture **50** continues to the next coil turn **14**. If barbs are present, such as shown in the embodiment of **FIG. 21**, the suture **50** is kept inside of the barbs **16** located about each coil turn **14**. In the illustrative example, the covering **45** is affixed to the frame **11** such that one side of the overhang **80** is not sutured over the other side in order to maintain the free edge of the overhang **80**, although the alternative condition would be an acceptable embodiment. Alternative attachment methods include, but are not limited to, use of a biological adhesive, a cross-linking agent, heat welding, crimping, and pressure welding. For synthetic coverings, other similar methods of joining or attaching materials are available which are known in the medical arts. The covering **45**, whether made from a biomaterial or synthetic material, can be altered in ways that improve its function, for example, by applying a coating of pharmacologically active materials such as heparin or cytokines, providing a thin external cellular layer, e.g., endothelial cells, or adding a hydrophilic material or other treatment to change the surface properties.

[**0076**] Once the covering **45** has been sutured into place or otherwise attached to the frame, the overhang **80** is folded back away from the frame, as shown on the second side **143** of the frame of **FIG. 26A**, and part of the excess overhang **80** is trimmed away with a scalpel **159** or other cutting instrument to leave a 2-4 mm skirt around the frame **11**. The overhang **80** or skirt provides a free edge of SIS (or material with similar remodeling properties) to help encourage more rapid cell ingrowth from the vessel wall, such that the SIS replaces native tissue as quickly as possible. An unattached edge of the overhang **80** can also form a corner flap **81** or pocket as depicted in **FIG. 27**. This corner flap **81** can serve to catch retrograde blood flow **47** to provide a better seal between the device **10** and the vessel wall **70** as well as providing an improved substrate for ingrowth of native intimal tissue from the vessel **33**, if made of SIS or another material with remodeling properties.

[**0077**] Referring now to **FIGS. 28-31**, the frame **11** used to form the valve **43** embodiments, e.g., **FIGS. 20-27**, that are placed in the legs or other deep veins as replacement for incompetent venous valves, is sized according to the size of the target vessel. For example, a typical venous valve might be made of 0.0075" 304 stainless steel mandril wire with an attachment mechanism **15** comprising 23 to 24 gauge thin-wall stainless steel cannula or other tubing. Larger wire (e.g., 0.01") and attachment cannula **15** are typically used for valves **43** of the larger diameter (greater than 15 mm). Selection of the attachment cannula **15** depends on competing factors. For example, use of larger gauge attachment cannula **15** results in a slightly increased device **10** profile, yet it includes additional room for flux when the attachment mechanism **15** is soldered over the continuous wire **59** comprising the frame **11**. **FIG. 30** best depicts an uncovered

frame **11** used to form a venous valve **43**, wherein the length of the sides **13** typically range from about 15 to 25 mm. For larger frames, heavier gauge wire is typically used. For example, 25 mm frames might use 0.01" wire, with larger diameter embodiments such as stent occluders used for femoral bypass or stent adaptors, such as shown in **FIGS. 17 and 32**, requiring an even heavier gauge. The appropriate gauge or thickness of the frame wire also depends on the type of alloy or material used. As previously disclosed, the frame is typically formed in a generally flat configuration and then manipulated into its characteristic serpentine configuration and loaded into a delivery system. Therefore, the frame usually will tend to reassume the first or generally flat configuration if the restraint of the delivery system or vessel is removed. Deformation of the frame **11** can occur after it has been manipulated into the second configuration, however, such that it no longer will lie completely flat, as depicted in **FIG. 34**. This angle of deformation **129**, which varies depending on the frame thickness and material used, generally does not compromise the function of the device **10**, which can be reconfigured into the serpentine configuration (of the second, deployed configurations) without loss of function.

[**0078**] The frame **11** of the present invention can be made either by forming a series of bends in a length of straight wire and attaching the wire to itself, as previously discussed, to form a closed configuration, or the frame **11** can be formed in the deployment (second) configuration **35** as depicted in **FIGS. 41-41A** by cutting it out of a flat sheet **152** of material, e.g., stainless steel or nitinol. Further finishing procedures can then be performed after it has been cut or formed, such as polishing, eliminating sharp edges, adding surface treatments or coatings, etc. In addition to metal, the frame **11** can comprise one or more polymers, composite materials, or other non-metallic materials such as collagen with the frame either being cut from a thin sheet of the material, or molded into the deployment configuration **36** as depicted in **FIG. 43**. Unlike the majority of the depicted embodiments, the frame **11** of **FIG. 43** does not naturally assume a flattened configuration **35** when the device **10** is unconstrained by the vessel or delivery system.

[**0079**] The illustrative embodiments of **FIGS. 41-41A** and **43** include integral barbs **124** that extend from the frame **11**, which being formed as a closed frame, does not have free ends **60,61** that can be used to serve as barbs **16** as depicted in **FIG. 3** and other embodiments. **FIGS. 41-41A** depict a series of integral barbs **124** comprising V-shaped cuts **139** transversing the thickness of the flat metal frame **11**, which are bent outward to form the barb **16**. In the embodiment of **FIG. 43**, the integral barbs **124** are formed along with the frame **11** with two extending from the frame at either side of each bend **12**. These integral barbs **124** can be designed into the mold if the frame **11** is formed out of a polymer material. The number, arrangement, and configuration of the integral barbs **124** is generally not critical and can vary according to design preference and the clinical use of the device. The barbs **16** may or may not penetrate the covering, depending on their design and other factors, including the thickness and type of covering used.

[**0080**] While the frame embodiment of **FIG. 43** can be formed from a variety of medical grade polymers having properties that permit the frame to function as a supporting structure for the valve leaflets **78,79**, it should be noted that for some uses, it may be desirable to form the frame **11** from a material that can be degraded and adsorbed by the body over time to advantageously eliminate a frame structure can would remain in the vessel as a foreign body and that could possibly fracture and/or cause perforation of the vessel wall. A number of bioabsorbable homopolymers, copolymers, or blends of bioabsorbable polymers are known in the medical arts. These include, but are not necessarily limited to, poly-alpha hydroxy acids such as polyactic acid, polylactide, polyglycolic acid, or polyglycolide; trimethlyene carbonate; polycaprolactone; poly-beta hydroxy acids such as polyhydroxybutyrate or polyhydroxyvalerate; or other polymers such as polyphosphazines, polyorganophosphazines, polyanhydrides, polyesteramides, polyorthoesters, polyethylene oxide, polyester-ethers (e.g., polydioxanone) or polyamino acids (e.g., poly-L-glutamic acid or poly-L-lysine). There are also a number of naturally derived bioabsorbable polymers that may be suitable, including modified polysaccharides such as cellulose, chitin, and dextran or modified proteins such as fibrin and casein.

[**0081**] **FIGS. 44-46** depicts two exemplary embodiments in which the frame **11** is integral with the covering **45**. In the embodiment of **FIG. 44**, the valve **43** is formed as a single piece of material, such as a flexible polymeric or collagen-based material, whereby there is a thin, compliant central portion comprising the covering **45** or leaflets **78,79**, and a thickened edge **141** portion that comprises the frame **11**. The valve **43**, shown in the generally flat configuration **35**, can be also formed into the deployment configuration **36** (see **FIG. 43**). Optionally, the material of the frame **11** portion can be subjected to treatments or processes that add rigidity or other desired characteristics that permit the frame to better support the covering **45** portion or anchor the device **10** to the vessel wall. As with the embodiment of **FIG. 43**, optional intergral barbs **124** can be included along the frame **11**. In addition to forming a thickened edge **141** to serve as the frame **11**, other layers of different materials can be laminated to or blended with the edge portion to provide the desired properties. As another alternative to the thickened edge **141** portion of **FIGS. 44-45**, the outside edge **112** of the covering **45** can be folded over itself to form a rolled edge **140** (**FIG. 46**) that adds rigidity to serve as a frame **11**. The rolled edge **140** can be held in placed with a glue, resin, or similar bonding agent **144**. For example, the covering **45** and rolled edge **140** can comprise a sheet of SIS with a bonding agent **144** such as collagen glue or other bioabsorbable material used to secure the rolled portion and after hardening, to add the necessary degree of rigidity for the valve **43** (or occluder, filter, stent adaptor, etc.) to assume the deployment configuration within the vessel. Excess of the bonding agent **144** can be fashioned to structural elements that can serve to help anchor the device **10** within the vessel. It is also within the scope of the invention to eliminate a discernable frame **11** by changing the material or material properties along the outer edge **112** of the leaflets, by adding or incorporating one or more different material or agents along the outer edge **112** of covering **45** such that the stiffness and/or resiliency increased, thereby allowing the frame to hold a desired shape during deployment, while still allowing the adjacent covering material to be sufficiently flexible to function as a leaflet **25**. If the illustrative valve **43** lacks the radial expandability to anchor itself to the vessel wall, it may be mounted on a balloon to expand the valve **43** and anchor the barbs, if present, into the vessel wall.

[0082] The illustrative embodiments of the present invention generally include a closed frame **11** to give the device **10** its form. **FIG. 47** depicts an example in which the frame **11** portion is not a closed structure. Rather, a portion of the covering **45** used to span a gap **145** in the frame such that a portion of the outside edge **112** (of leaflet **79** in this example) is unsupported therealong. The length of the gaps **145** and their distribution can vary as long as the frame **11** is still able to fulfill its role to support and define the shape of the valve **43** or device **10**.

[0083] **FIGS. 21-31** depict various embodiments in which the bends **20**,**21**,**22**,**23** are placed in a resiliently tensioned or stressed state after being initially formed such that the bends were not under tension. The term >tension=, as used herein, is meant to describe generally a forced applied to a resilient material or structure against the natural tendency of the material or structure, whether or not the force is in fact tensile, compression, or torsional. Further incremental forces applied will generally encounter greater resistance than would otherwise be exhibited by the material or structure, such as a compression spring, which exerts a force (resilience) resisting compression proportional to the distance the spring has already been compressed. The addition of tension to one or more bends **12** of the device frame **11** can alter the properties of the frame **11** and result in improved sealing characteristics or the ability of the device **10** to impinge upon the vessel wall **70** to prevent migration or shifting. In the illustrative embodiments, the coil turn **14** is formed as previously disclosed whereby each bend **12** is in a untensioned state with the adjacent sides **13** having an initial angle after formation of the bend **12**. For example, in the embodiment of **FIG. 20**, the initial angle **109** after the bends are formed and the final angle **110** after the frame **11** is assembled are both approximately 90□. Therefore, the bends **12** of the embodiment of **FIG. 20** are not placed under any significant degree of tension. In the embodiments of **FIGS. 21-31**, the frame is restrained to permanently place the bends **12** under tension such that the angle between the sides **122**,**123** adjacent to the bend **12** is increased or decreased by some method of manipulation to produce a resiliently tensioned bend **118** (**FIGS. 26 and 29**) having a final angle **110** different than the initial angle **109** (e.g., **FIG. 28**).

[0084] Referring particularly to **FIGS. 21-28**, the covering **45** (including a full or a partial covering **58**) can be attached to the frame **11** of the valve **43** or other embodiment of the present invention, to constrain a generally untensioned square frame **11** (such as in **FIG. 1**) and subsequently form an altered shape **82**, such as a diamond **153**, in which the distance between bends **20** and **21** is lengthened and the distance between bends **22** and **23** is shortened. By way of example, and using **FIG. 21** as reference, the angle **110** measured between the adjacent sides **13** from bends **20** and **21** might decrease to 70-80□ with a increase in the corresponding angles **161** measured at bends **22** and **23** to 100-110□. This manipulation of the frame **11** shape serves to add tension in each of the bends, which allows better positioning of the device **10** against the vessel wall **70** while in the deployed configuration, as shown in **FIGS. 22-25**. Additionally, constraining the frame **11** along the first axis **94** of the slit **108** allows that distance **146** to be adjusted to provide the optimum size for the vessel **33** into which the valve **43** is to be implanted. Assuming a resilient frame **11** is being used that makes the valve **43** radially expandable, it would normally be preferential to slightly oversize the valve **43** along at the width **146** of the frame **11** (along first axis **94**) when the valve **43** is in the generally flattened configuration **35**, thereby causing the leaflets **78**,**79** to relax slightly when the valve **43** is in the deployed configuration **36** and being constrained slightly by the vessel **33**. The proper length of the constrained frame **11** as measured diagonally between bends **22** and **23** is calculated such that the leaflets **78**,**79** open by an effective amount in the presence of blood flow **46** that most closely mimics that found in a normal functioning valve.

[0085] Dog studies by Karino and Motomiya (Thrombosis Research 36: 245-257) have demonstrated that there is about a 60 to 70% constriction of blood flow through the natural valve. In the valve **43** of the present invention, the leaflets **25** should ideally span about 30-60% of the vessel **33** diameter across. If it is much less than 30%, blood flow **46** may be impeded to an unacceptable degree, while if the leaflets **78**,**79** are allowed to fully open, they can adhere to the vessel wall **70** and therefore, not close properly in the presence of retrograde flow **47**. The frame **11** can be formed or constrained such that the distance **146** between points **22**,**23** lies between πr, which would allow the valve to open to the full extent that the vessel allows, and 2 r in which the valve **43** is stretched tight across the frame **11** and is very limited in the amount of blood that will allow to pass through. To give the leaflets the flexibility and compliance to open to permit flow and then close to seal against backflow, the slit axis distance **146** of the valve **43** should be oversized with respect to the diameter of the vessel into which it is to be placed. Constraining the valve **43** along the first axis **94** such that it sized a few mm larger than the lower extreme (2 r) or a few mm larger than the upper extreme (πr), not only allows the leaflets to function in a more optimal manner, but also allows the valve **43** to safely and effectively impinge on the vessel wall to seal and reduce the possibility of migration. The ideal amount of oversize is largely dependent on the size and diameter of the frame **11** prior to resizing. **FIG. 49** depicts a schematic top view of the valve of **FIG. 22** showing the length **147** of the orifice, the width **148** of the orifice, the portion **154** of the vessel occluded by a leaflet **25**, and the corner gaps **155** than exist between each lateral edge **156** of the valve orifice **117** and the outer edge **112** of the leaflet **25** (or the frame **11**). The following formula can be to approximate the elliptic circumference (C) of the valve orifice **117**, where a=one half the length **147** of the orifice, and b=one half the width **148** of the orifice **117**:

[0086] Assuming that we wish to size the valve **43** to produce an orifice **117** that opens approximately 30-60% of the vessel lumen **34** (with the occluded portions **154** comprising 40-70% of the same), the preceding formula can be used to determine the amount of oversize that produces the desired characteristics. The amount of oversize (valve width **146** in the flat configuration minus the diameter of the vessel lumen **34**) would generally range from 1-2 mm for smaller valves (those placed in 8-9 mm vessels) up to 3-4 mm for valves intended for larger vessels (17-21 mm). For example, a valve intended for a 14 mm vessel should ideally have a 2-3 mm oversize if the range of 30-60% opening is to be maintained. If the frame **11** of a valve **43** having 20 mm sides is constrained such that the distance between bends **22** and **23** is adjusted to approximately 16 mm, the valve **43** opens approximately 43%, which is well within the most desired range. If constrained to 17 mm, the valve **43** is able to open

up to approximately 55% of the vessel diameter. In contrast, oversizing the valve **43** by 6 mm, produces a large orifice **117** of 83% which lies outside the target range, although it would certainly produce a valve **43** capable of opening and closing in response to fluid flow **46,47**. To produce a valve **43** in which the valve width in the generally flattened configuration **35** is 17-18 mm, which would be a valve **43** sized to accommodate a 14-15 mm vessel, the 20 mm frame **11** should be constrained such that the distance between bends **22** and **23** is 15 mm prior to addition of the covering **45**, if a compliant material such as SIS is used. As depicted in **FIG. 26**, the frame **11** is constrained across the first axis **94** using a temporary constraining mechanism **121**, such as by tying a suture through the coil turns **14** of bends **22** and **23** to pull them toward one another until a distance of 15 mm is reached. After the covering **45** has been attached, such as by the method previously disclosed, the temporary constraining suture **121** is cut, which results in a slight expansion in the width of the frame **11** as the SIS stretches under the tension of the constrained frame, resulting in the desired final width of 17-18 mm. The amount of expansion varies with the compliance of the particular covering **45** as well as the resiliency of the frame **11**. Although the desired final width **146** of the constrained frame **11** can result from a relatively wide range of initial frame **11** sizes, depending on how much the frame is constrained, generally, larger sized frames (e.g., sides measuring about 25 mm) are most suitable for larger vessels (e.g., 16-21 mm in diameter), while smaller frames (e.g., 15 mm) are most suitable for smaller diameter vessels (e.g., 8-9 mm). While this range represents the most common sizes used for correcting venous valve insufficiency in the lower legs, valves **43** of the present invention can be made in a much larger range of sizes to treat veins or other vessels elsewhere in the body.

[**0087**] **FIGS. 28-31** depict another embodiment of the present invention in which a open frame **11**, such as depicted in **FIG. 28**, is assembled into a square frame (**FIGS. 29-31**) such the bends **12** are put under tension. The resiliently tensioned bends **118** in the assembled device (as shown in **FIGS. 29-31**) result from the initial angle **109** formed in wire frame **11** before being assembled into a closed circumference **62** (**FIG. 28**), being greater than the final angle **110**. To form the embodiment of **FIG. 1**, for example, the wire is wrapped around a pin to form the coil turns **14** with the sides **13** generally lying about 90□ with respect to one another. The attachment mechanism **15** then secures and closes the frame **11** to form the final square shape. In the embodiments of **FIGS. 28-31**, the first angle **109** is made approximately 150□, rather than 90═, which is the desired final angle **110**. While the wire is not under stress after the bends **12** are initially formed, the bends **12** and sides **13** are stressed when the device **10** is constrained during assembly to form the four-sided, generally square shape. In particular reference to **FIG. 30**, the sides **122,123** adjacent to a resiliently tensioned bend **118** becomes somewhat deformed when the bend **12** is put under stress, generally assuming a bowed shape between the adjacent bends. By creating this >rounded square=with tensioned or stressed bends **118**, the sides **13** of the frame **11** are able to better conform to the rounded vessel wall **70** than would a side **13** that is initially straight prior to deployment. Additionally, by rounding the distal bends **116** of the valve legs **113**, it may also reduce the potential for the valve legs **113** to cause trauma to the vessel **33** as they continue to exert force thereupon.

[**0088**] An additional method of constraining the valve **43**, or similar type device **10** (e.g., occluder, filter, stent, stent adaptor), is depicted in **FIG. 48** in which a circumferentially constraining mechanism **125**, is added to at least partially encircle the frame **11** while it is in both the delivery configuration **37** (**FIG. 6**) and the deployed configuration **36** such that the device **10** is limited in its ability to radially expand. Once the device reaches its maximal radial expansion, the outward force the device **10** places on the vessel wall **70** is eliminated, thereby reducing potential damage thereto (e.g., from an improperly sized valve), such as tissue erosion possibly resulting in eventual perforation of the vessel **33**. In the illustrative embodiment, the circumferentially constraining mechanism **125** comprises a suture that is affixed to and completely encircles the frame **11** to limit the outward expansion of the valve legs **127,128**. The sides **13** of the valve legs **127,128** include an intermediate coil turn **126**, also illustrated in **FIG. 39** fulfilling a different function, that provides an effective attachment point through which to feed and/or affix the suture restraint **125**. In the illustrative embodiment, the suture restraint **125** is in a relaxed state when the device **10** is loaded in the delivery system. Then, as the device **10** is deployed, it expands within the vessel **33** until it is constrained by the suture restraint **125** if the device **10** has been properly sized such that vessel **33** does not provide constraining forces sufficient to prevent the device **10** from fully expanding to its predetermined maximum diameter. If the device is undersized for the diameter of the vessel, it may be subject to migration due to insufficient expansion. The illustrative embodiment is merely exemplary of the numerous available circumferentially constraining mechanisms **125**. It is not necessary that the circumferentially constraining mechanism **125** completely encircle the device **10**. For example, short pieces of suture or another type of tethering mechanism, such as a section of webbing or other material, can be affixed between the sides of the valve legs to limit their expansion, or the frame can include an integral circumferentially constraining mechanism, such as an expandable strut formed as part of the frame. The strut would unfold as the frame radially expands and limits how far the sides of the valve leg to which is attached, can spread apart relative to each other, thereby limiting the outward radial force from the device against the vessel wall.

[**0089**] Another possibility is for circumferentially constraining mechanism **125** to comprise a sleeve **162** of flexible material, such as SIS around the valve **43**, as depicted in **FIG. 50**, which is of a diameter appropriate for deployment within the target vessel **33** (typically, being slightly larger than the target vessel diameter) that allows the valve to anchor thereto. The sleeve **162** could be affixed to the frame **11** with sutures **50** or by some other means as the valve **43** is held in a collapsed condition prior to loading the device **10**, including the sleeve **162**, into a delivery system. The sleeve **162** enclosed the length of the valve **43**, or the bends **12** and barbs **16** can be left uncovered, as shown. To reduce resiliency of the sleeve **162**, tethers and other types of circumferentially constraining mechanism **125** can be used in combination with the sleeve **162** to limit radial expandability of the valve **43**. It should be noted that if the circumferentially constraining mechanism **125** itself is a resilient member, it will only serve to reduce the outward force of the device **10** against the vessel wall **70** until maximum expansion is reached.

[0090] **FIGS. 30-31** depict alternative methods of forming the frame **11** and attaching barbs thereto. In the embodiment shown in **FIG. 30**, attachment mechanisms **15,85** and **84,86**, per side rather than a single cannula as shown in previous embodiments, such as **FIG. 29**. Rather than placing the attachment mechanisms **15** at the point **87** where the respective ends **60,61** of the wire frame **11** cross to form the square shape, two attachment mechanisms **15,85** are placed on either side of the cross point **87**. Having an additional attachment mechanism **84,85,86** on a side **13** provides better fixation of the frame with little additional metal and helps prevent twisting of the frame **11**. On the opposite side which contains the double ended barb **39**, the double attachment mechanisms **84,86** arrangement provides a similar function. In the embodiment of **FIG. 31**, three attachment mechanisms **15,85,88** and **84,86,89**, are used per side which provide better fixation of the frame **11** as well as serving as attachment points for including supplemental barbs **90,91, 92,93** to provide a more secure anchoring of the device **10** to the vessel wall **70**. The illustrative barbs **16** are typically configured such that they extend only a short distance (less than 1-2 mm) beyond the bends **12**; however, the barbs **16** can be made virtually any practical length, such as extending them more than 1 cm beyond the bends **12** to aid in stabilizing the device **10** upon deployment such that it does not shift laterally and end up being cockeyed within the vessel. To assist in this function, the barbs can be shaped accordingly, rather than be limited to a substantially straight configuration.

[0091] The present invention is not limited to a two-leaflet valve **43** (or two-leg occluder or stent adaptor, etc.). **FIGS. 35-40** depict multi-leaflet valves **43** having three or four valve legs **113** and leaflets **25**. The addition of additional leaflets reduces the load produced by the fluid column upon each individual leaflet **25**. This in turn, puts less stress upon the sutures or attachment points of the covering **45**, thereby allowing the valve **43** to function under higher pressures than would otherwise be possible. For example, these valves **43** could prove advantageous for use on the arterial side, such as to augment pulmonary valves, or within the heart itself, where pressures exerted on the leaflets can be significantly higher than normally found on the venous side. **FIG. 35** depicts a valve **43** which in the generally flattened configuration **35**, has a three legs **127,128,130** that lie approximately 120□ with respect to one another. The respective leaflets are arranged such that the inner edges **111** thereof, define a triangular-shaped valve orifice **117**. When the illustrative valve **43** is placed in the vessel **33** for which it has been properly sized, as depicted in **FIG. 37**, the leaflets **78,79,119** are able to close against one another to seal the valve. The concept of adding additional legs **113** to distribute the load over a larger number of attachment points **50** (e.g., sutures) and add positional stability to the device **10**, can be applied to occluders and stent adaptors as well.

[0092] One method of forming the embodiment of **FIG. 35**, involves constructing a triangular-shaped frame **1**, as shown in **FIG. 36**, that includes an intermediate coiled eyelet **132** formed at the midpoint of each of the three sides **13**. A temporary constraining suture **121**, such as that shown in **FIG. 38**, is threaded through each of the intermediate eyelets **132**, drawing them inward to form three additional bends **133,134,135** forming three legs **127,128,130** of a desired shape (**FIG. 35**), depending how tightly the constraining suture **121** is drawn. At this point, the covering **45** is attached to the frame **11**, either as three separate leaflets **78,79,119**, or a single piece through which the triangular-shaped valve orifice **117** is formed. After the covering **45** has been secured to the frame **11**, the constraining suture **121** is cut and removed. As depicted, the barbs **16** are affixed to the triangular shaped frame of **FIG. 36**, two per side, such that they terminate on either side of intermediate eyelet **132**. Thus, when the intermediate eyelets **132** are drawn inward to create six sides **13**, each includes a barb **16**.

[0093] The embodiment of **FIGS. 38-40**, which includes four legs **127,128,130,131**, is formed in a similar manner to that of the embodiment of **FIGS. 35-37**. The frame **11** is initially formed in a square configuration (**FIG. 39**) with intermediately placed coiled eyelets **132** at the midpoint of each side **13**, dividing the side into a first and second side portion **137,138**. As depicted in **FIG. 38**, the temporary constraining suture **121** is used to draw the eyelets inward where they form the four additional bends **133,134,135,136** such that four valve legs **127,128,130,131** are formed with the first and second sides portions **137,138** becoming sides **13** of adjacent valve legs **127,128**. A square-shaped valve orifice **117** is created when the four leaflets **78,79,119,120** are attached to the legs **127,128,130,131** of frame **11**. One should appreciate that valves with more than four legs would be made in a similar manner to the embodiments above with a five-sided valve being formed from a pentagon, a six-sided valve being formed from a hexagon, etc.

[0094] Delivery of the device **10** of the present invention can be accomplished in a variety of ways. One method, depicted in **FIG. 33**, involves the use of a delivery system **103** similar to that used to deliver embolization coils. The delivery system **103** comprises an outer member **105**, such as a cannula or catheter, and an coaxial inner member **105** that includes a tethering tip **107**, such as a notched cannula, adapted to receive a barb **17** extending from the frame **11**. The tip **104** of the barb is configured such that it can positively engage with the tethering tip **107**. This can be accomplished by adding a projection, such as a secondary barb, hook, spine, etc. to the tip **104**, or otherwise enlarging the diameter thereof such that it can be releasably secured by the tethering tip **107** until deployment. The coaxial inner member **106** also includes an outer sheath **149** that retains and the locks the barb tip **104** within the tethering tip **107** until it is advanced or retracted by manipulation of a proximal handle (not shown) to expose the notch **150** in the tethering tip, which releases the barb **17** and deploys the device **10**. The device **10** is preloaded within the outer member **105**. The coaxial inner member **106** and attached device **10** are then advanced together from the outer member **106** at the target site. Further manipulation of the proximal handle, advances the tethering tip **107**, which in this particular embodiment, includes a coiled spring **151**, relative to the outer sheath **149**. After the device **10** has been released from the tethering tip **107**, the spring-activated handle is released and the outer sheath **149** slides back over the tethering tip **107**. The coaxial inner member **106** is withdrawn into the outer member **105** and the entire delivery system **103** is removed from the patient. As shown in **FIG. 33**, the barb tip **104** extends just beyond the coil turn **14** of the frame **11** so as to have sufficient room to engage with the coaxial inner member **106**. The barb tip **104** must be positioned to account for whether the device **10** is to be placed using a femoral approach or a superior approach.

[0095] The illustrative delivery system **103** represents only one of many possibilities. For example, the device **10** can be attached to a delivery device using screws, clips, magnets, or some other tethering mechanism, or can be deployed by applying electrical current, heat, or some other means to cause detachment with a carrying mechanism. As previously disclosed, rather than making the device **10** self-expanding, where it is pushed from some sort tubular device, it can be formed from a ductile material, mounted over a balloon or other inflatable or expandable delivery mechanism, and deployed by expanding the device in that manner.

[0096] It is thus seen that the present invention includes devices having a number of configurations with regard to the frame, covering, barbs, etc. Futhermore, it has been seen that the invention and can be formed in a variety of ways using a different types of medical grade materials, and has utility to treat a wide range of medical problems. The embodiments contained herein should be considered merely exemplary as one skilled in the medical arts would appreciate that further modifications would be possible that would be included within the spirit of the invention.

What is claimed is:

1. A device for implantation within a bodily passage comprising:

a bioabsorbable frame; and

at least one leaflet formed by a covering having remodelable properties that is attached to a portion of the frame;

wherein the leaflet has a flexible free edge that defines at least a portion of a valve orifice.

2. The device for implantation within a body passage of claim 1, wherein the flexible free edge is an outer body edge of the leaflet.

3. The device for implantation within a body passage of claim 1, wherein the leaflet has an arcuate shape.

4. The device for implantation within a body passage of claim 1, wherein the flexible free edge at least partially opens in response to force exerted by a fluid traveling in a first direction within a bodily passage.

5. The device for implantation within a body passage of claim 1, wherein the frame is formed integrally with the covering.

6. The device for implantation within a body passage of claim 1, wherein the frame is moveable between a deployed configuration and a compressed delivery configuration.

7. The device for implantation within a body passage of claim 6, wherein the frame in the deployed configuration assumes a serpentine configuration.

8. The device for implantation within a body passage of claim 1, wherein the frame further comprises a means for anchoring the device in the lumen of a body passage.

9. The device for implantation within a body passage of claim 1, wherein the frame further comprises one or more barbs.

10. The device for implantation within a body passage of claim 1, wherein the material with remodeling properties is an extracellular matrix material.

11. The device for implantation within a body passage of claim 10, wherein the extracellular matrix material is selected from the group consisting of: small intestine submucosa, pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa and dura mater.

12. The device for implantation within a body passage of claim 1, wherein the material with remodeling properties is small intestine submucosa.

13. The device for implantation within a body passage of claim 1, wherein the bioabsorbable material is selected from the group consisting of: poly-alpha hydroxyl acid, trimethylene carbonate, polycaprolactone, poly-beta hydroxyl acid, polyphosphazine, polyorganophosphazine, polyanhydride, polyesteramide, polyorthoester, polyethylene oxide, polyester-ether and polyamino acid.

14. The device for implantation within a body passage of claim 1, wherein the bioabsorbable material is polyacetic acid, polylactide, polyglycolic acid or polyglycolide.

15. The device for implantation within a body passage of claim 1, wherein the bioabsorbable material is polyhydroxybutyrate, polyhydroxyvalerate or a polydioxanone polyester-ether.

16. The device for implantation within a body passage of claim 1, wherein the bioabsorbable material is poly-L-glutamic acid or poly-L-lysine.

17. The device for implantation within a body passage of claim 1, wherein the bioabsorbable material is a modified polysaccharide, fibrin or casein.

18. The device for implantation within a body passage of claim 1, wherein the bioabsorbable material is cellulose, chitin or dextran.

19. A valve for implantation within a body passage, comprising:

a bioadsorbable frame, and two or more leaflets,

wherein each leaflet is formed by a covering having remodelable properties that is attached to one or more portions of the frame;

wherein each leaflet has a flexible free edge, and

wherein each flexible free edge of each leaflet meets to cooperably define an opening.

20. Te valve of claim 19, wherein the valve has two leaflets.

21. The valve of claim 19, wherein the valve has three leaflets.

22. The valve of claim 19, wherein the covering with remodelable properties is an extracellular matrix material.

23. The valve of claim 19, wherein the bioabsorbable frame comprises a material selected from the group consisting of: poly-alpha hydroxyl acid, trimethylene carbonate, polycaprolactone, poly-beta hydroxyl acid, polyphosphazine, polyorganophosphazine, polyanhydride, polyesteramide, polyorthoester, polyethylene oxide, polyester-ether and polyamino acid.

24. A device for implantation within a body passage comprising:

a single frame having two or more sides, the frame formed into two or more legs and comprised of a bioabsorbable material;

a covering attached to at least two sides of a first leg to form a body of a first leaflet, the covering comprising a material with remodeling properties;

the first leaflet having an inner body edge and an outer body edge; and

wherein the inner body edge of the first leaflet is a flexible free edge that defines at least a portion of a valve orifice.

25. The valve for implantation within a body passage of claim 24 wherein the inner body edge of the first leaflet and the inner body edge of the second leaflet are sufficiently flexible to move apart in response to fluid flow through the valve orifice in a first direction.

26. The valve for implantation within a body passage of claim 25 wherein the inner body edge of the first leaflet is cooperable with the inner body edge of the second leaflet to substantially prevent retrograde fluid flow in a second direction that is opposite the first direction.

27. The valve for implantation within a body passage of claim 24 wherein the material with remodeling properties is an extracellular matrix material.

28. The valve for implantation within a body passage of claim 24 wherein the extracellular matrix material is selected from the group consisting of:

small intestine submucosa, pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa and dura mater.

29. The valve for implantation within a body passage of claim 24, wherein the material with remodeling properties is small intestine submucosa.

30. The valve for implantation within a body passage of claim 24, wherein the bioabsorbable material is selected from the group consisting of: poly-alpha hydroxyl acid, trimethylene carbonate, polycaprolactone, poly-beta hydroxyl acid, polyphosphazine, polyorganophosphazine, polyanhydride, polyesteramide, polyorthoester, polyethylene oxide, polyester-ether and polyamino acid.

31. The valve for implantation within a body passage of claim 24, wherein the bioabsorbable material is polyacetic acid, polylactide, polyglycolic acid or polyglycolide.

32. The valve for implantation within a body passage of claim 24, wherein the bioabsorbable material is a polydioxanone polyester-ether, polyhydroxybutyrate or polyhydroxyvalerate.

33. The valve for implantation within a body passage of claim 24, wherein the bioabsorbable material is poly-L-glutamic acid or poly-L-lysine.

34. The valve for implantation within a body passage of claim 24, wherein the bioabsorbable material is fibrin, casein or a modified polysaccharide.

35. The valve for implantation within a body passage of claim 24, wherein the bioabsorbable material is cellulose, chitin or dextran.

36. A valve for implantation within a body passage comprising:

a single frame having two or more sides, the frame formed into two or more legs and comprised of a bioabsorbable material;

a covering attached to at least two sides of a first leg to form the body of a first leaflet, the covering comprising a material with remodeling properties;

the first leaflet having a first inner body edge and a first outer body edge;

wherein the first inner body edge of the first leaflet is a first flexible free edge that defines at least a portion of a valve orifice;

the covering attached to at least two sides of a second leg to form the body of a second leaflet, the covering comprising a material with remodeling properties;

the second leaflet having a second inner body edge and a second outer body edge; and

wherein the second inner body edge of the second leaflet is a second flexible free edge that defines at least a portion of the valve orifice.

37. A valve for implantation within a body passage comprising:

a single frame having two or more sides, the frame formed into three or more legs and comprising a bioabsorbable material;

a covering attached to at least two sides of a first leg to form the body of a first leaflet, the covering comprising a material with remodeling properties;

the first leaflet having a first inner body edge and a first outer body edge;

wherein the first inner body edge is a first flexible free edge that defines at least a portion of a valve orifice;

the covering attached to at least two sides of a second leg to form the body of a second leaflet, the covering comprising a material with remodeling properties;

the second leaflet having a second inner body edge and a second outer body edge; and

wherein the second inner body edge is a second flexible free edge that defines at least a portion of the valve orifice; and

the covering attached to at least two sides of a third leg to form the body of a third leaflet, the covering comprising a material with remodeling properties;

the third leaflet having a third inner body edge and a third outer body edge; and

wherein the third inner body edge is a third flexible free edge that defines at least a portion of the valve orifice.

38. The device for implantation within a body passage of claim 37 wherein the first inner body edge, the second inner body edge, and the third inner body edge, are sufficiently flexible to move apart in response to fluid flow through the valve orifice in a first direction.

39. The device for implantation within a body passage of claim 37, wherein the first inner body edge is cooperable with the second inner body edge of the second leaflet and the third inner body edge to substantially prevent retrograde fluid flow in a second direction that is opposite the first direction.

40. The device for implantation within a body passage of claim 37 wherein the material with remodeling properties is an extracellular matrix material.

41. The device for implantation within a body passage of claim 37, wherein the extracellular matrix material is selected from the group consisting of: small intestine submucosa, pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa and dura mater.

42. A valve for implantation within a body passage comprising:

a single frame having two or more sides, the frame formed into two or more legs and comprising a bioabsorbable material;

wherein the bioabsorbable material is selected from the group consisting of: polyacetic acid, polylactide, polyglycolic acid, polyglycolide, trimethylene carbonate, polycaprolactone, polyhydroxybutyrate, polyhydroxyvalerate, polyphosphazine, polyorganophosphazine, polyanhydride, polyesteramide, polyorthoester, polyethylene oxide, polyester-ether, poly-L-glutamic acid, poly-L-lysine, cellulose, chitin, dextran, fibrin and casein;

a covering attached to at least two sides of a first leg to form a body of a first leaflet, the covering comprising a material with remodeling properties;

wherein the material with remodeling properties is an extracellular matrix material selected from the group consisting of: small intestine submucosa, pericardium, stomach submucosa, liver basement membrane, urinary bladder submucosa, tissue mucosa and dura mater;

the first leaflet having a first inner body edge and a first outer body edge;

wherein the first inner body edge of the first leaflet comprises a first flexible free edge that defines at least a portion of a valve orifice.

the covering is attached to at least two sides of a second leg to form a body of a second leaflet, the covering comprising a material with remodeling properties;

the second leaflet having a second inner body edge and a second outer body edge;

wherein the second inner body edge comprises a second flexible free edge that defines at least a portion of the valve orifice;

the first flexible free edge and the second flexible free edge are sufficiently flexible to move apart in response to fluid flow through the valve orifice in a first direction;

the first inner body edge is cooperable with second the inner body edge to substantially prevent retrograde fluid flow within a body vessel in a second direction that is opposite the first direction;

wherein the first outer body edge has an arcuate shape;

wherein the frame is moveable between a deployed configuration and a compressed delivery configuration; and

wherein the frame comprises one or more barbs.

* * * * *