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(54) **IMPLANTABLE PROSTHETIC VALVE**

(75) Inventors: **Kristian DiMatteo**, Watertown, MA (US); **Peter Marshall**, Newburyport, MA (US)

(73) Assignee: **Boston Scientific Scimed, Inc**, Maple Grove, MN (US)

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See application file for complete search history.

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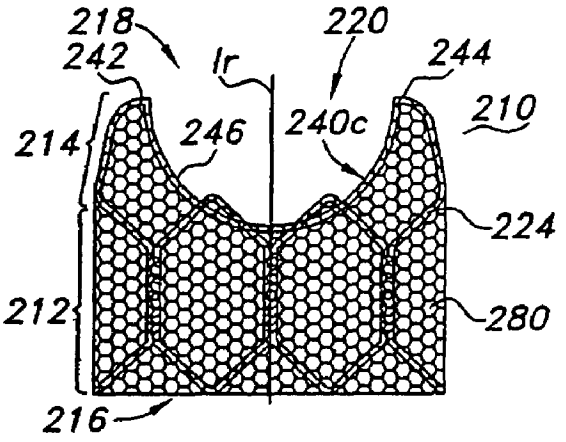
Primary Examiner—Suzette Gherbi
(74) *Attorney, Agent, or Firm*—Brooks, Cameron & Huebsch, PLLC

(57) **ABSTRACT**

A prosthetic valve for implantation within a fluid conducting lumen within a body includes an elongate generally cylindrical radially collapsible valve body scaffold defining a fluid passageway therethrough for retentive positioning within the lumen. A radially collapsible leaf valve member is supported by the scaffold includes a number of valve leafs deflectable between a closed position restricting fluid flow through the passageway and an open position permitting fluid flow through the passageway. The leaf valve member includes an interior leaf valve frame defining a valve leaf aperture which is sealed by a fluid impermeable non-thrombogenic lining to prevent fluid flow therethrough.

18 Claims, 7 Drawing Sheets



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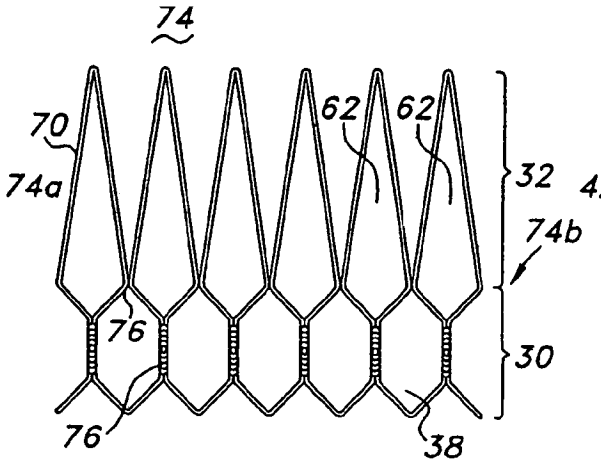

FIG 6

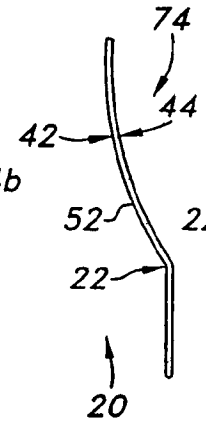

FIG 7

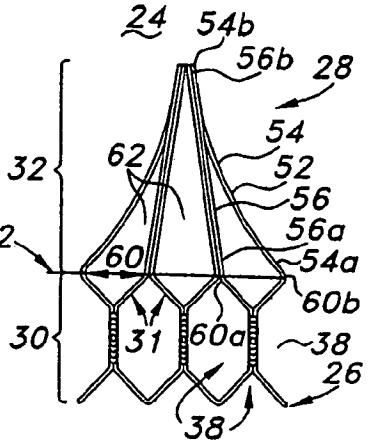

FIG 5

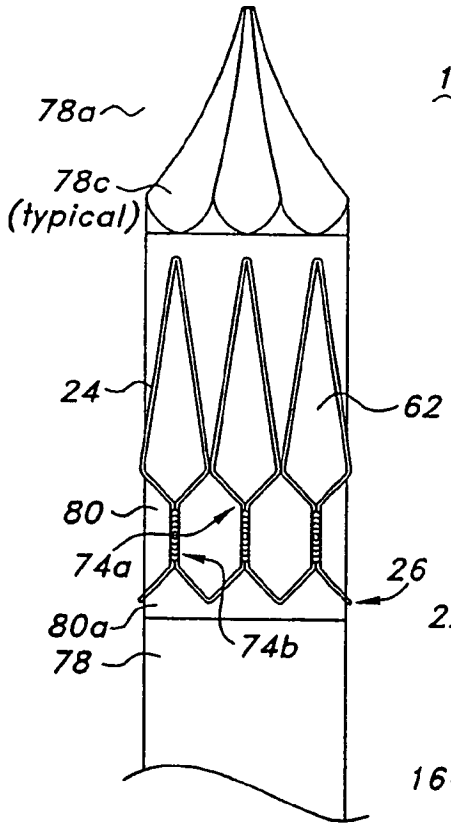

FIG 8

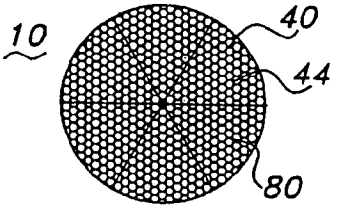

FIG 2

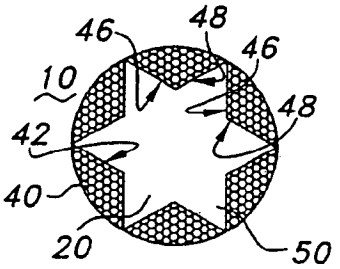

FIG 4

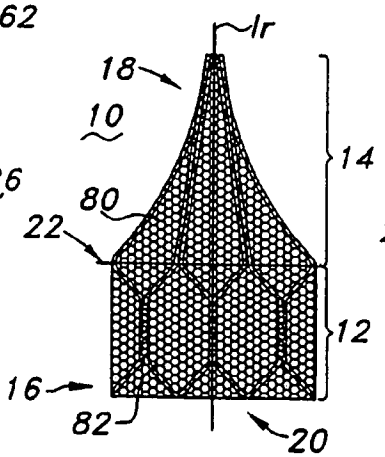

FIG 1

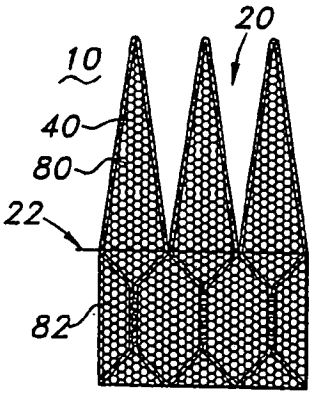

FIG 3

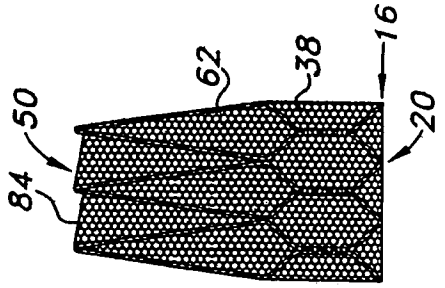

FIG 16

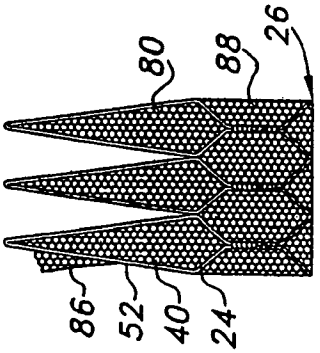

FIG 15

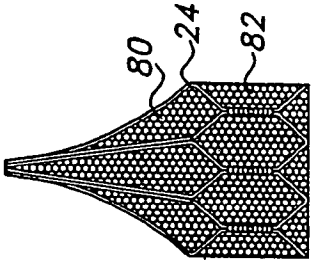

FIG 14

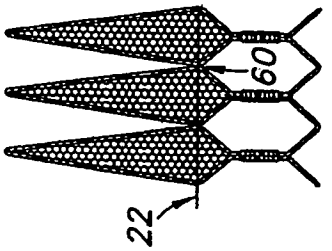

FIG 12

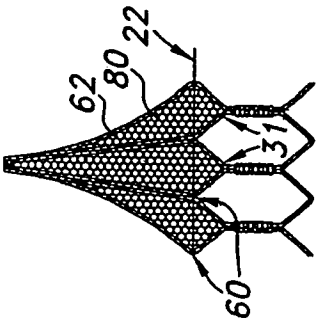

FIG 11

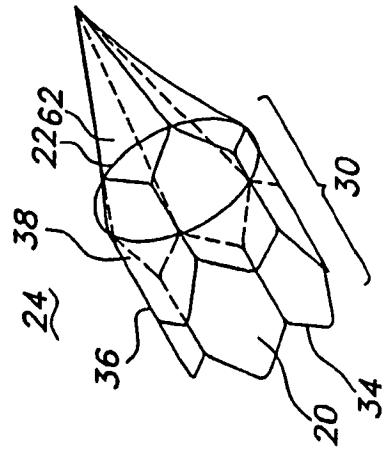

FIG 9

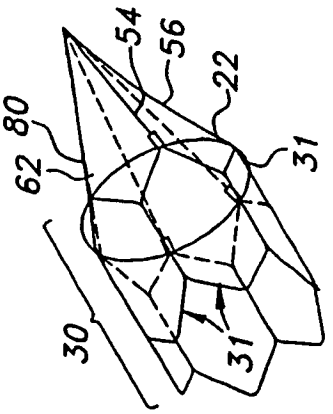

FIG 10

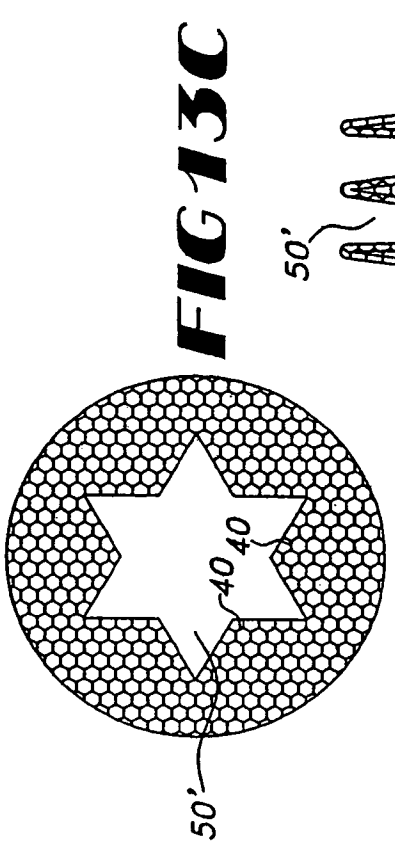

FIG 13C

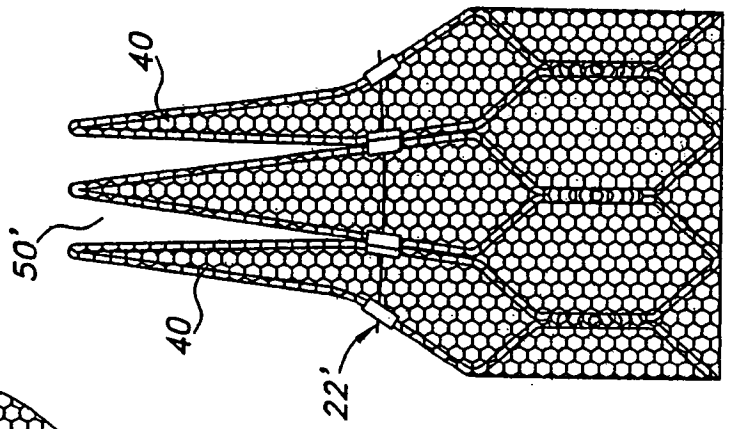

FIG 13B

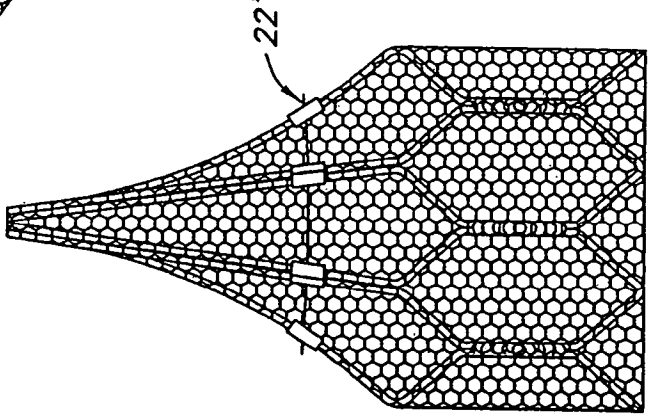

FIG 13A

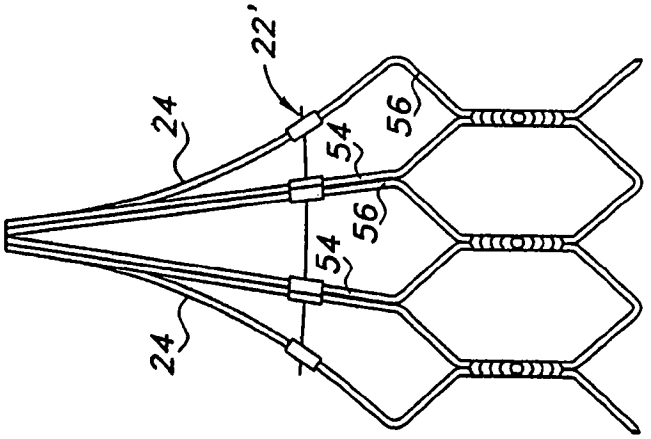

FIG 13D

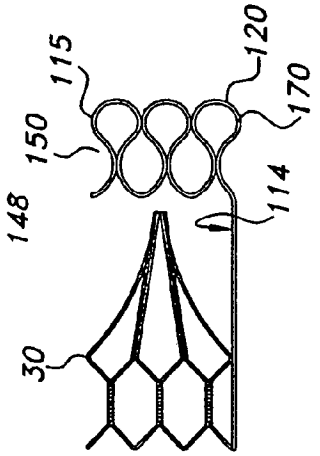

FIG 17

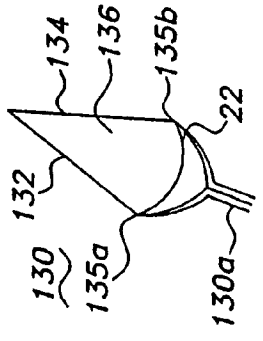

FIG 21

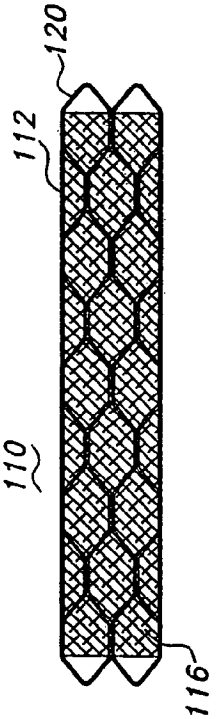

FIG 18

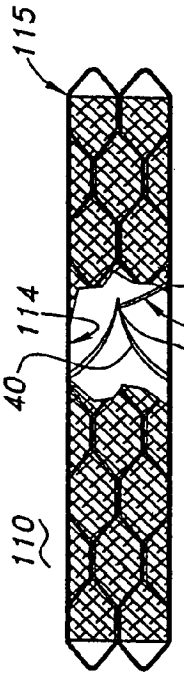

FIG 19

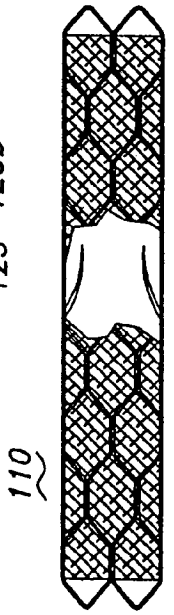

FIG 20

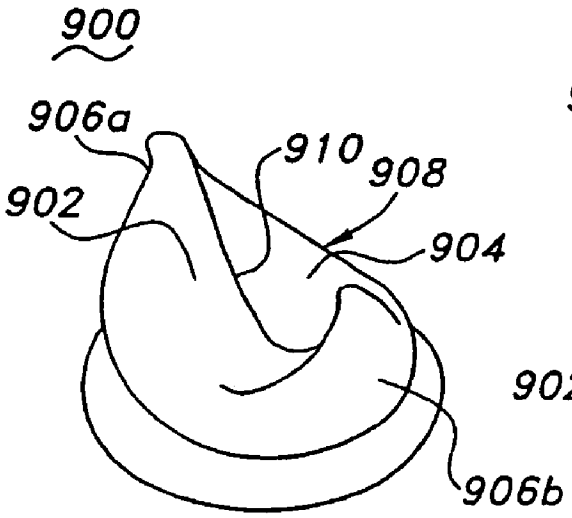

FIG 22
(PRIOR ART)

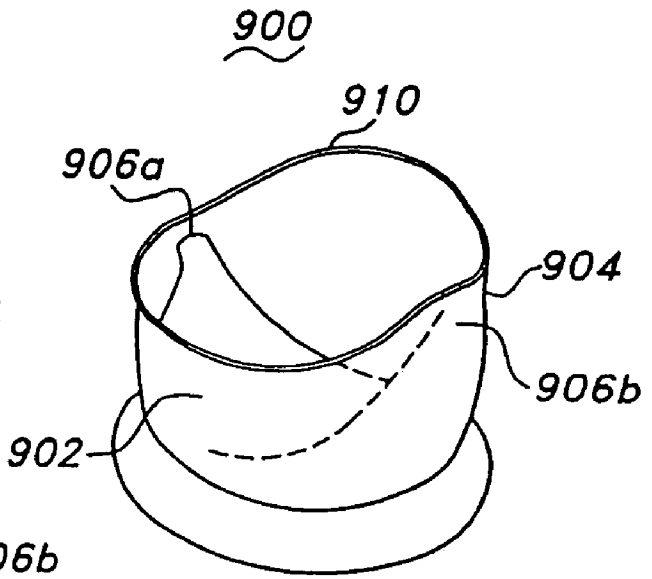

FIG 23
(PRIOR ART)

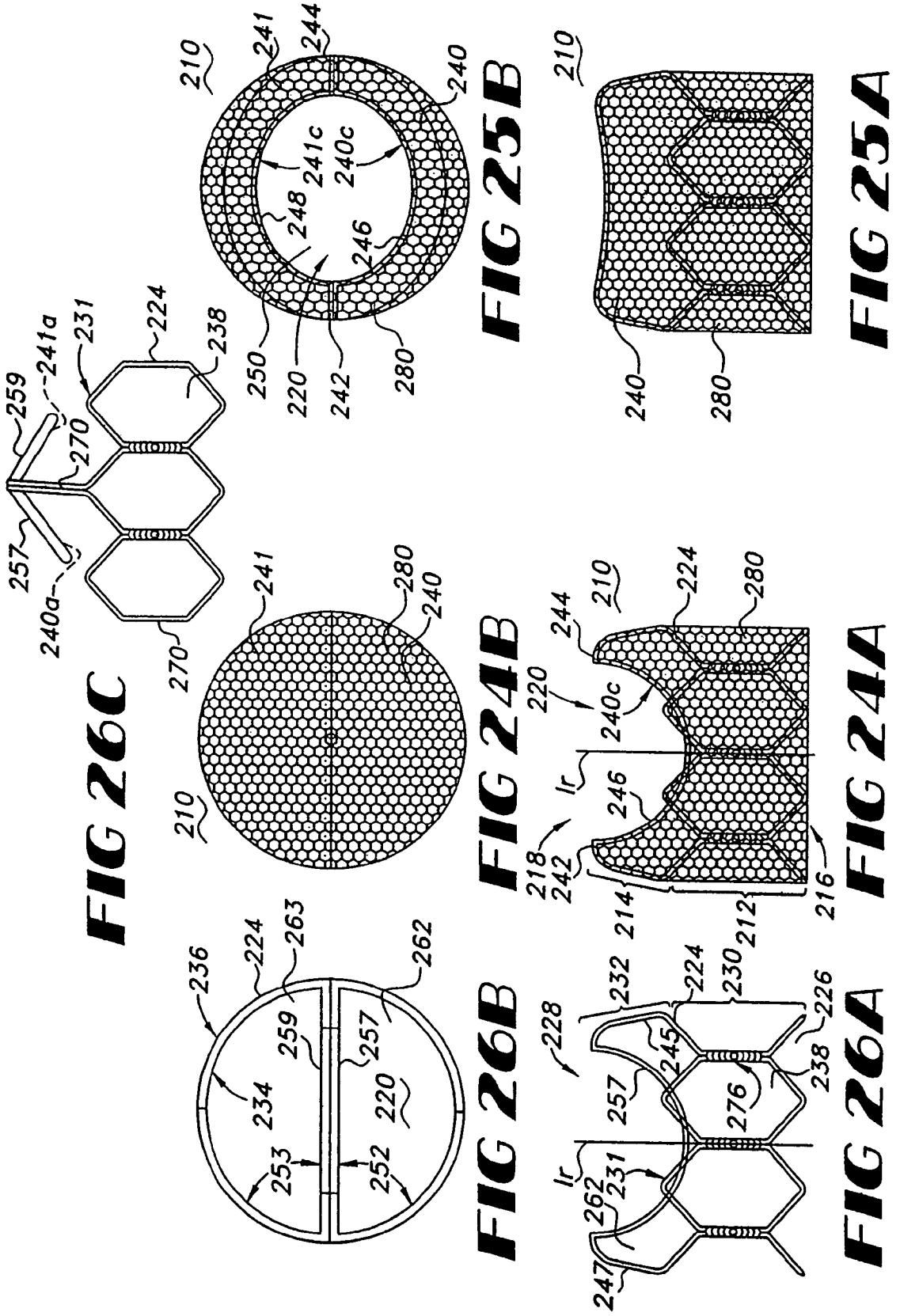
FIG 26C
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231
224
238
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240a
FIG 25B
210
241
244
240
241c
240c
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250
220
242
280
FIG 26B
236
224
263
262
259
257
234
220
253
252
FIG 24B
280
240
210
241
270
FIG 25A
210
240
280
FIG 24A
220
244
210
224
280
240c
lr
246
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214
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FIG 26A
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245
257
276
238
lr
262
231
247

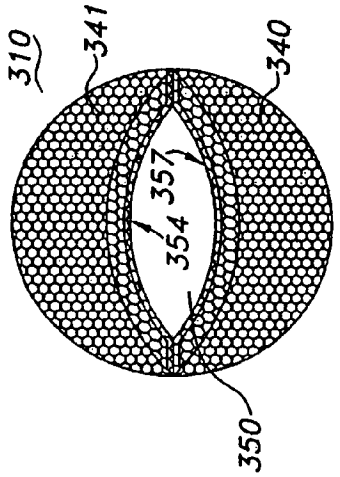

FIG 28B

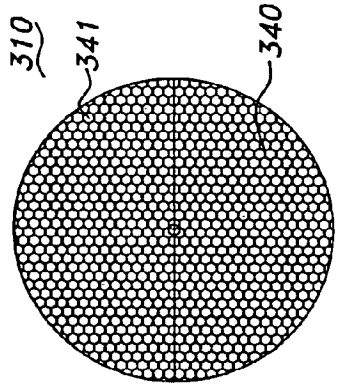

FIG 27B

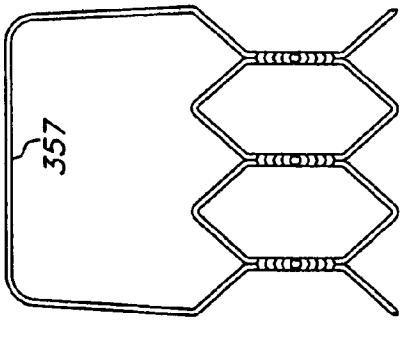

FIG 29B

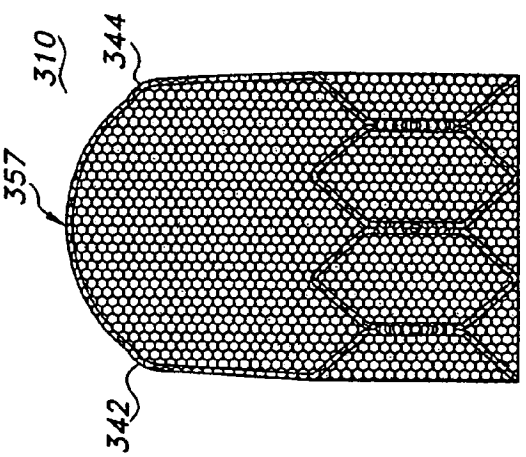

FIG 28A

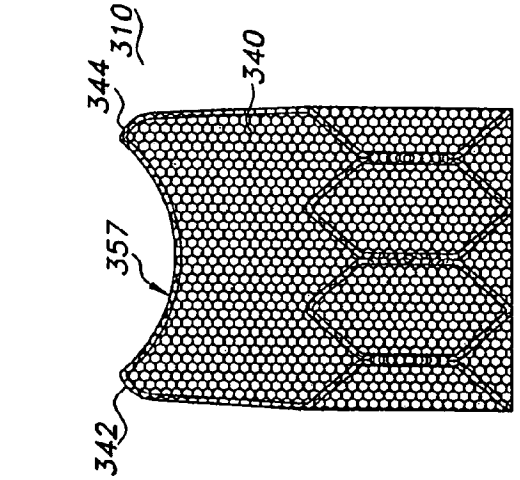

FIG 27A

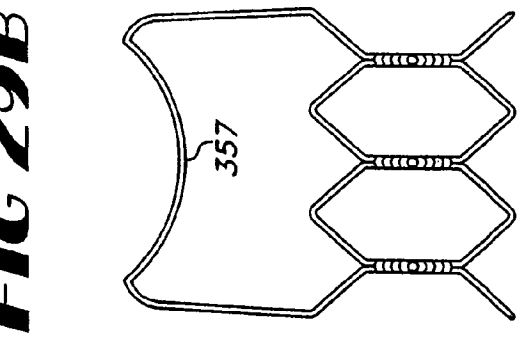

FIG 29A

IMPLANTABLE PROSTHETIC VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 10/714,034, filed Nov. 14, 2003, now U.S. Pat No. 6,840,957, which is a continuation of U.S. application Ser. No. 10/191,667, filed Jul. 9, 2002, and now U.S. Pat. No. 6,685,739, which is a division of U.S. application Ser. No. 09/425,142, filed Oct. 21, 1999, now U.S. Pat. No. 6,440,164 B1.

FIELD OF THE INVENTION

The present invention relates to the field of implantable prostheses. More specifically, the present invention relates to implantable prosthetic cardiac, aortic, and venous valves.

BACKGROUND OF THE INVENTION

In human pathology, the proper functioning of both cardiac and venous valves is of paramount importance. Disorders of cardiac valves cause significant morbidity and mortality. These disorders affect persons of all ages and can result from congenital or degenerative conditions, as well as from the sequelae of infections. Stenosis and insufficiency of the aortic or mitral valves have a greater incidence than stenosis and insufficiency of the tricuspid and pulmonary valves. Venous insufficiency is believed to contribute to various maladies, including edema, varicose veins, aching leg pain while standing, lipodermatosclerosis, and ulcerations. Venous insufficiency is essentially caused by venous hypertension and chronic venous stasis due to valvular incompetence both of an idiopathic nature and of a secondary nature following past illnesses of the venous systems.

A prosthetic cardiac or venous valve may regulate the direction of the pulsating blood flow so as to limit the occurrence of blood stasis in the region about the valve. By maintaining the direction of blood flow therethrough, a prosthetic cardia, aortic, or venous valve may alleviate the maladies resulting from valve disorders or venous insufficiency. A prosthetic valve should therefore permit blood flow in the proper predetermined direction to limit or prevent backflow of the blood in a reverse direction.

The art has seen several attempts for providing a prosthetic valve to alleviate the consequences of cardiac valve disorders and of venous insufficiency. These attempts generally fall into two categories, biologic valves and mechanical valves. Biologic valves are comprised of a stent supporting a number of circumferential leaflets made of a flexible material. If the material is biologic in nature, it may be either a xenograft, that is, harvested from a non-human cadaver, or an allograft, that is, harvested from a human cadaver. For example, it is known in the art to apply a pericardium biological tissue layer covering, for providing the valve leaflets, to a stent which provides structural annular integrity to the prosthesis. Non-biologic material such as polyurethane has also been used. The second category of prosthetic valves, mechanical valves, usually comprise a rigid annulus supporting up to three rigid leaflets. The annulus and leaflets are frequently formed in pyrolitic carbon, a particularly hard and wear resistant form of carbon. The annulus is captured within a sewing ring so that the valve may be attached to tissue at the location of the replaced valve. Unfortunately, surgically positioning these implants typically requires suturing or sewing the device into the blood vessel, increasing the risk of thrombosis due to the resulting suturing or anastomoses of the body vessel.

These attempts typically provide a valve structure having a relatively rigid tubular body structure which supports a flexible valve leaf structure. That is, any structural rigidity imparted to the tubular body structure is separated from the valve leaf structure. For example, U.S. Pat. No. 4,759,759 discloses a prosthetic valve having a solid stent member having a diametrically-opposed upstanding posts and a substantially cylindrical flexible cover. The two portions of the cover extending between the upstanding stent posts may be collapsed against each other in sealing registry over a fluid passageway defined by the stent. The stent, being a solid member, limits the radial collapsing thereof for endoscopic delivery within a body lumen. The cover, being unsupported by the stent within the fluid passageway of the valve, must itself provide sufficient strength and resiliency to optimally regulate fluid flow. Alternatively, U.S. Pat. No. 5,855,691 discloses a prosthetic valve having a radially expandable covered stent which defines an elongate fluid passageway therethrough. A flexible valve is disposed within the fluid passageway to regulate fluid flow therethrough. The valve is formed of a flexible and compressible material formed into a disc with at least three radial incisions to form deflectable leaflets. While the stent circumferentially supports the valve body, the leaflets are not supported by any other structure within the fluid passageway. There is therefore a need in the art for a unitary prosthetic valve construction which provides structural reinforcement to both the tubular body portion of the valve and to the valve leafs supported thereon.

SUMMARY OF THE INVENTION

The present invention is directed to providing a fully prosthetic valve having valve leafs formed from a covered valve leaf frame and which may be implanted using a minimally-invasive, endoscopic technique.

The present invention provides a prosthetic valve for implantation within a body lumen. The prosthetic valve of the present invention provides a device for regulating and maintaining the direction of a pulsating fluid flow through the body lumen. The valve includes a radially-collapsible scaffold portion and a radially-collapsible leaf valve portion. The scaffold portion includes a tubular open body scaffold defining a fluid passageway therethrough. The leaf valve portion is deflectable between a closed configuration in which fluid flow through the valve passageway is restricted and an open configuration in which fluid flow through the valve passageway is permitted.

Each of the valve leafs desirably includes a valve leaf frame having an open construction so as to facilitate radially-collapsing or -expanding the leaf valve portion of the valve. Each valve leaf frame defines a valve leaf aperture with the scaffold. The present invention seals each valve leaf aperture to prevent fluid flow therethrough. The material used to seal each valve leaf aperture is sufficiently thin and pliable so as to permit radially-collapsing the leaf valve portion for delivery by catheter to a location within a body lumen. A fluid-impermeable biocompatible non-thrombogenic valve leaf cover may be positioned on each valve leaf frame so as to seal the valve leaf aperture. The valve leaf cover may be formed from a surgically-useful textile such as Dacron, polyethlylene (PE), polyethylene terephthalate (PET), silk, Rayon, or the like. The valve leaf cover may also be formed of a surgically-useful polymeric material such as urethane, polytetrafluoroethylene (PTFE) or expanded poly-

tetrafluoroethylene (ePTFE). The valve leaf cover may also coated with a cellular growth-inhibiting drug such as Heparin or Taxol or another such composition.

Similarly, each of the valve leaf apertures may be covered with cultured tissue cells derived from a either a donor or the host patient which are attached to the valve leaf frames. The cultured tissue cells may be initially positioned to extend either partially or fully into each valve leaf aperture. In order to provide additional support to the attached cultured tissue cells, a microfilter-type support mesh spanning the valve leaf aperture may also be provided. The present invention further contemplates that the supporting scaffold and valve leaf frames may be formed of either a bioabsorbable material or a non-bioabsorbable material. It is contemplated that the scaffold and valve leaf frames which are formed from a bioabsorbable material will eventually be displaced by the tissue cells as the tissue cells mature. Eventually the cells alone will provide the fully functioning valve. Alternatively, when the scaffold and valve leaf frames are formed from a non-bioabsorbable material, the cultured cells provide a means for reducing any undesirable biological response by the host.

The leaf valve member is normally spring biased towards the closed configuration. The present invention also contemplates biasing the leaf valve member towards the open configuration to simulate known anatomical mechanics of a valve in which the leaf valve portion would close upon experiencing sufficient back flow pressure from the direction downstream from the valve.

The leaf valve portion desirably includes a number of valve leafs which are deflected between the closed and open configurations when the fluid pressure differential thereacross exceeds a predetermined threshold. That is, the fluid pressure differential acts to open the valve when the fluid pressure upstream of the valve leaf portion is greater than the fluid pressure downstream of the valve leaf portion.

Each of the valve leafs is deflectably supported by the scaffold at a flexible hinge. The present invention contemplates that the open and closed configurations of the valve may be defined either downstream or upstream of the flexible hinges. It is desired that the scaffold portion of the valve will eventually provide fluid-tight engagement with the body lumen although it is contemplated that some leaking or fluid flow between the scaffold portion and the body lumen is still acceptable. Just as it is preferred, but not required, that the valve leafs prevent fluid flow in the closed configuration, it is recognized that substantial restriction of fluid flow past the scaffold-lumen interface may still provide a prosthetic valve exhibiting acceptable performance characteristics.

The present invention shows and describes both a bicuspid valve and a six-leaf valve, although designs employing a different number of valve leafs are clearly within the scope of the present invention. The bicuspid valve includes a pair of leaf frames which deflect about a hinge positioned downstream of the closable valve opening. The six-leaf variant includes valve leafs which deflect about hinges positioned upstream of the closable valve opening.

The abutting engagement between adjacent valve leafs, while desirably providing a fluid-tight seal, is contemplated to significantly restrict backflow past the valve leafs. The abutting engagement between adjacent valve leafs may therefore provide less than complete fluid integrity while still achieving the desired performance parameters.

The scaffold of the valve includes a first end defining a first opening, a second end defining a second opening, a substantially cylindrical interior face, a substantially cylindrical exterior face, and at least one radially-extending scaffold opening communicating between interior and exterior faces. The interior face generally defines the fluid passageway. The scaffold and leaf valve member are formed to be expandable from a first diameter permitting delivery through the body lumen to a second radially-expanded diameter for retentively engaging the body lumen at a desired location. The scaffold may be formed having a shape memory favoring radial self-expansion or may be formed so as to permit radial expansion by a delivery balloon which is deflated and withdrawn after scaffold expansion against the body lumen. The scaffold may further provide at least one radially outwardly projecting hook member for retentively engaging the fluid conduit when expanded thereagainst.

The present invention also contemplates forming both the scaffold and the valve leaf frames as a unitary support trellis. The unitary trellis may be formed by a single undulating wire bent to form both the radially expandable scaffold portion and the radially expandable valve leaf frames. While various configurations for the unitary support trellis of the present invention are contemplated, one preferred configuration bends a wire along a longitudinally extending and retracting undulating path so as to alternately define a collapsible and expandable leaf frame aperture and then a collapsible and expandable scaffold aperture. The wire may be laid along a flat surface so as to form a planar trellis preform. The trellis preform may then be wrapped about an elongate cylindrical mandrel. The valve leaf frames may be deflected about their respective hinges to establish a shape memory in either the open or closed configuration either prior to or after wrapping the trellis preform about the mandrel.

The trellis is desirably formed from a biocompatible metal or polymeric material. The trellis may additionally be formed from a shape-memory material to more reliably provide the required geometry to function effectively within the valve once radially expanded at a site within a lumen. The trellis may be formed from an alloy of nickel and titanium in specific proportions known in the art as nitinol. Alternatively, the trellis may be formed from a polymeric material which allows the trellis to be radially collapsed for delivery to a site in a lumen but then radially expands to return to an undeflected shape so as to function effectively within the valve.

The present invention also contemplates attaching an elongate generally cylindrical first biocompatible non-thrombogenic liner to the trellis. The first liner may be positioned on either the interior or exterior face of the scaffold. The first liner may also provide the sealing cover for the valve leaf frame apertures. The first liner may be trimmed to span between adjacent valve leafs in the open configuration so as to provide a larger surface area for the body fluid to act upon when urging the valve leafs between the open and closed configuration. The first liner may also be trimmed to provide at least one flap extending in the downstream direction beyond each valve leaf. Each flap may then be folded over the adjacent valve leaf frame and laminated through a valve leaf aperture to the liner.

Furthermore, an elongate generally cylindrical second biocompatible non-thrombogenic liner may be positioned on the scaffold opposite the first liner. The second liner may desirably extend only along a portion of the scaffold or fully along scaffold. The first and second liners may be joined so as to fully encase either just the scaffold or the entire trellis. It is contemplated that the first and second liners may be laminated together through one or more openings defined by the trellis. Additionally, the second liner may be formed by

folding the first liner over the first end of the scaffold so as to extend at least partially along the opposite face of the scaffold as the first lining.

Each liner positioned on the trellis may inhibit thrombus formation and facilitate tissue ingrowth therethrough for assimilating the valve of the present invention into the body lumen. Towards this latter goal, one or both of the liners may be formed from a porous textile or polymeric material. It is further contemplated that either liner may be formed from an xenograft of cellular tissue from a donor such as bovine cardial tissue, or homograft of cellular tissue formed from the host patient.

It is also contemplated by the present invention that the prosthetic valve may also be attached to the interior surface of a second radially collapsible prosthetic fluid conduit. The second fluid conduit may be selected from many known stent and covered stent designs known in the art. The second fluid conduit further maintains the patency of the lumen to either side of the valve and may also include a biocompatible fluid impermeable non-thrombogenic lining on either or both of its own inner or outer surfaces. The materials used to form the second fluid conduit may also be selected to be either bioabsorbable or non-bioabsorbable as may be desired.

The present invention is also directed to methods of making the prosthetic valve of the present invention.

While the present invention has been described generally, the present invention will be more readily appreciated in a reading of the "Detailed Description of the Invention" with reference to the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows side elevational view of a prosthetic venous valve of the present invention in a closed, flow restricting configuration.

FIG. **2** shows a top elevational view of the prosthetic venous valve of FIG. **1** in the closed configuration.

FIG. **3** shows a side elevational view of the prosthetic venous valve of FIG. **1** in an open, flow conducting configuration.

FIG. **4** shows a top elevational view of the prosthetic venous valve of FIG. **1** in the open configuration.

FIG. **5** shows the unitary support trellis of the prosthetic venous valve of FIG. **1**.

FIG. **6** shows a front elevational view of the unitary support trellis of the present invention in a flat trellis preform configuration.

FIG. **7** is a side elevational view of the unitary support scaffolding and valve leaflet frames upon being stressed to provide for a self-closing valve.

FIG. **8** depicts one step in a method of constructing the prosthetic valve of the present invention by wrapping the unitary support scaffolding and valve leaflet frames about a non-thrombogenic lining positioned about a mandrel.

FIG. **9** shows an isometric view of a unitary support trellis for a prosthetic valve of the present invention.

FIG. **10** shows a perspective view of a prosthetic valve of the present invention in an open configuration and in which the scaffold portion of the valve is substantially uncovered.

FIG. **11** shows a side elevational view of the prosthetic valve of FIG. **10**.

FIG. **12** shows a side elevational view of the prosthetic valve of FIG. **10** in an open configuration.

FIGS. **13**A-D depict a further embodiment of the present invention in which adjacent leaf frames are joined at a location therealong to reduce the size of the valve flow opening.

FIG. **14** shows an embodiment a prosthetic valve of the present invention in which a unitary support trellis is positioned over a liner.

FIG. **15** shows an alternate embodiment of a prosthetic valve of FIG. **14** in which a second liner is positioned on the trellis to extend across the proximal end of the scaffold portion.

FIG. **16** is a side elevational view of an alternate embodiment of a prosthetic valve of the present invention in an open, flow-conducting configuration in which a non-thrombogenic webbing spans between each adjacent leaflet of the valve.

FIG. **17** shows an alternate embodiment of the present invention in which a secondary support scaffolding is formed to the downstream side of the valve leaflets.

FIG. **18** shows a still further embodiment of the present invention in which a number of deflectable valve leafs are attached within the fluid-conducting passageway to a radially-expandable prosthetic support structure.

FIG. **19** is a partial cut-away of the embodiment of FIG. **10** depicting the valve leaflets in a closed, flow-restricting configuration.

FIG. **20** is a partial cut-away of the embodiment of FIG. **11** depicting the valve leafs in an open, flow-conducting configuration.

FIG. **21** depicts an alternate embodiment of a covered valve leaf of the present invention to be attached to a radially expandable outer conduit.

FIGS. **22** and **23** depict a prosthetic bicuspid valve of the prior art in the open and closed configurations, respectively.

FIGS. **24**A-B are respective side and top elevational views of a prosthetic bicuspid valve of the present invention in the closed configuration.

FIGS. **25**A-B are respective side and top elevational views of a prosthetic bicuspid valve of the present invention in the open configuration.

FIGS. **26**A-B depict a unitary scaffold for the prosthetic bicuspid valve of FIG. **24** in the closed configuration.

FIG. **26**C depicts the scaffold for the prosthetic bicuspid valve of FIG. **24** in the open configuration.

FIGS. **27**A-B are respective side and top elevational views of another embodiment of the prosthetic bicuspid valve of FIG. **24**, having a larger valve leaf and shallower valve cusp, in the closed configuration.

FIGS. **28**A-B are respective side and top elevational views of the prosthetic bicuspid valve of FIG. **27**A in the open configuration.

FIGS. **29**A-B are side elevational views of the scaffold of the prosthetic bicuspid valve of FIG. **27**A and FIG. **28**A, respectively.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates generally to method and apparatus for providing a fluid flow check valve for a body lumen. A preferred embodiment of the present invention is particularly suitable for forming an endoluminal prosthetic valve for vascular applications. The prosthetic valve of the present invention regulates and maintains the direction of a pulsating fluid flow through a body lumen. The prosthetic valve of the present invention is configured to open and close in response to the fluid pressure differential across the

valve. The valve includes a radially-collapsible scaffold portion and a radially-collapsible leaf valve portion which allows the valve to be delivered via catheter through the body lumen in which it will be emplaced. The scaffold portion includes a tubular open body scaffold defining a fluid passageway therethrough. The leaf valve portion is deflectable between a closed configuration in which fluid flow through the valve passageway is restricted and an open configuration in which fluid flow through the valve passageway is permitted.

The preferred embodiment of the prosthetic valve of the present invention is designed to be biased towards a closed, flow-restricting configuration. The valve opens when sufficient fluid pressure is applied to the leaflets from the upstream direction. Desirably the valve will open when the pressure differential across the leaflets reaches about 1-20 mm Hg. When the pressure differential is too low, the valve closes to prevent back flow. The valve desirably withstands up to about 100 mm Hg of back flow pressure. When the pressure differential from blood flowing the desired direction is removed, the valve returns to the closed configuration.

As will be described in further detail hereinbelow for the six-leaf variant of the present invention, the leaf valve portion is connected to the scaffold portion so that the valve leafs are deflectable about an annularly extending hinge line. The location of the hinge line along the length of the leaf valve portion influences the fluid pressure required to open and close the valve. In the closed configuration, the valve leaf portion substantially restricts fluid flow through the valve by providing a biocompatible impermeable non-thrombogenic covering. extending from the hinge line in registry with the passageway.

Referring now to the drawings, FIGS. **1-5** depict a prosthetic valve **10** of the present invention. Valve **10** provides a radially-collapsible trellis **24** having an open construction. Trellis **24** includes an elongate tubular body scaffold **30** supporting a number of deflectable valve leaf frames **52** deflectable about a hinge line **22**. Each valve leaf frame **52** defines a leaf frame aperture **62** which is sealed by a valve cover **80** positioned on trellis **24**. The remainder of trellis **24** may also be covered with one or more liners **82** and **88**, or may be left uncovered altogether. The covered leaf frames **52** form the deflectable valve leafs **40** which **16** may be moved out of abutting engagement with each other so as to permit fluid flow through valve **10** in response to the fluid pressure upstream thereof.

Valve **10** is provided for implantation within the fluid passageway of a body lumen, such as for replacement of a cardial, arterial, or venous valve, to regulate the flow of a bodily fluid therethrough in a single direction. Valve **10** is constructed from biocompatible materials so as to minimize any adverse body reaction to the implantation of valve **10**. Valve **10** includes an elongate tubular body portion **12** and a leaf valve portion **14**. Valve **10** includes an upstream end **16**, a downstream end **18**, and an elongate fluid passageway **20** extending therebetween along a valve axis $\mathbf{1}_v$. Leaf valve portion **14** is connected to body portion **12** to extend in overlying registry with passageway **20**. Leaf valve portion **14** includes one or more valve leafs **40** which are deflectable with respect to body portion **12** about a hinge line **22** between a closed configuration, shown in FIGS. **1** and **2**, restricting fluid flow through passageway **20**, and an open configuration, shown in FIGS. **3** and **4**, permitting fluid flow through passageway **20**. As shown in FIGS. **13**A-D, hinge line **22** may be alternatively formed along the length of valve portion **14** by joining adjacent valve leafs **40** at a midway location **22'**. Locating hinge line **22** further downstream from body portion **12** increases the required higher fluid pressure differential to deflect the valve leafs to the open configuration.

Leaf valve portion **14** may provide any number of valve leafs **40**. While six valve leafs are provided and discussed by reference to FIGS. **1-4**, a bicuspid valve configuration is also contemplated and will be further discussed hereinbelow. Still referring to FIGS. **1-4**, each of the valve leafs **40** are similarly-sized and -shaped and include opposed first and second major surfaces **42** and **44**, respectively. Each first major surface **42** of a valve leaf **40** is oriented in facing opposition towards upstream end **16** of valve **10**. Each of the valve leafs **40** provide a sawtooth perimetrical edge formed by a first and second leaf edge **46** and **48**, respectively, which are positionable in abutting engagement with a leaf edge of an adjacent valve leaf **40** to define the closed configuration of valve **10**. Similarly, as best shown in FIG. **4**, the leaf edges **46** and **48** define a valve leaf opening **50** when in the open configuration. Valve leaf opening **50** is in fluid communication with passageway **20**.

All of the valve leafs **40** are formed having a spring bias towards either the open or the closed configuration. When all of the valve leafs **40** are spring biased towards the closed configuration, the open configuration may be attained when the fluid pressure acting on the first major surfaces **42** of the valve leafs **40** overcomes both the fluid pressure acting on the second major surfaces **44** of the valve leafs **40** of valve **10** and any spring bias closing force imparted to the valve leafs **40** acting to close the valve leafs. Should the fluid pressure from the downstream end **28** of valve **10** become too great relative to the upstream fluid pressure, the valve leafs **40** will also be urged towards the closed configuration. Each valve leaf **40** desirably curves inward such that the second major surface **44** has a concave shape to better collect backflow and urge the valve leafs **40** towards the closed configuration. The prosthetic valve **10** of the present invention thereby provides a device for regulating and maintaining the direction of a pulsating fluid flow through the body lumen. While leaf valve portion **14** is normally spring biased towards the closed configuration, it is also contemplated, however, to bias leaf valve portion **14** towards the open configuration in order to simulate known anatomical mechanics of certain valves. Thus, when biased towards the open configuration, leaf valve portion **14** would close upon experiencing sufficient back flow pressure from the downstream end **28** of valve **10**.

FIG. **5** shows the unitary support trellis **24** employed by valve **10**. Trellis **24** may be formed from a material exhibiting shape memory characteristics or from a material which is readily expandable by a balloon catheter. Trellis **24** is generally an elongate tube being coaxial with valve axis $\mathbf{1}_v$. Trellis **24** has opposed upstream and downstream ends **26** and **28**. Upstream end **26** of trellis **24** is further defined by a radially collapsible body scaffold **30**. Downstream end **28** of trellis **24** is further defined by a radially-collapsible leaf valve framework **32**.

Trellis **24** may be formed from a wide variety of materials and in a wide variety of configurations. Radially-expandable endovascular stents known in the art provide useful basic designs for modification into a support trellis of the present invention and may be formed in a wide variety of configurations. One example of a stent useful in the present invention is a slotted tubular stent which is designed to radially expand either by balloon catheter or by forming the stent from a temperature-sensitive memory alloy which changes shape at a designated temperature or temperature range.

Other stent types, such as tubular-shaped wire stents and self-expandable spring-biased stents are also contemplated. Trellis **24** may therefore be formed from a variety of materials including stainless steel, titanium, platinum, gold and other bio-compatible metals. Shape memory plastics, polymers, and thermoplastic materials which are inert in the body may also be employed to form trellis **24**. Shaped memory alloys having superelastic properties generally made from specific ratios of nickel and titanium, commonly known as nitinol, are among the preferred trellis materials,

With additional reference to FIG. **9**, scaffold **30** is a substantially cylindrical member having an interior face **34**, an exterior face **36** and defines at least one radially-extending scaffold opening **38** communicating therebetween. Interior face **34** of scaffold **30** generally defines passageway **20**. It is contemplated by the present invention that scaffold opening **38** need not be completely perimetrically bounded by scaffold **30**. Scaffold **30** is formed to have a generally open configuration including a plurality of openings **38** communicating between interior face **34** and exterior face **36**. These openings **38** provide for longitudinal flexibility of valve **10** as well as to permit valve **10** to be radially collapsed for delivery through, and radially expanded for deployment in, a body lumen such as a blood vessel. Furthermore, scaffold **30** preferably maintains a substantially coaxial alignment with the body lumen as leaf valve portion **14** deflects between the open and closed configurations so as to better seal passageway **20** when valve **10** is closed.

Leaf valve framework **32** includes a leaf frame **52** corresponding to each valve leaf **40** of leaf valve portion **14**. Each leaf frame **52** includes a first and second elongate component legs **54** and **56**, respectively. Each leaf frame **52** also has a length which is greater than the radius of the radially-expanded scaffold when implanted so as to minimize the risk of a valve leaf **40** over-deflecting about hinge line **22** towards upstream end **16** of valve **10**. Each component leg **54** and **56** includes a proximal end **54***a* and **56***a*, and an opposed distal end **54***b* and **56***b*, respectively. Each leaf frame **52** is joined to scaffold **30** at a flexible hinge **60** defined by the junction of the proximal ends **54***a* and **56***a* of each leg component with scaffold **30**. For each valve leaf **40**, hinge **60** includes space-apart hinge components **60***a*, and **60***b*. Additionally, the distal ends **54***b* and **56***b* are contiguously formed. Each hinge component **60***a*, **60***b* may be respectively joined to the adjacent hinge component **60***b*, **60***a* of the adjacent leaf frame **52** in order to provide improved sealing of valve **10** in the closed configuration. The joining of the hinge components **60***a* and **60***b* of adjacent valve leafs **40** further defines annular hinge line **22**.

Each leaf frame **52** defines a leaf frame aperture **62** with the distal extent **31** of scaffold **30**. Leaf frame aperture **62** communicates between the first and second major surfaces **42** and **44** of valve leaf **40**. The shape of leaf frame **52** is selected so as to assist and not inhibit the radial contraction of valve **10** for delivery via catheter through a body lumen. Additionally, leaf frame **52** is formed having a curve imparted thereto so as to provide a concave shape to second major surface **44** of leaf **40**. Each leaf frame **52** is imparted with a shape memory so as to extend over passageway **20** in either the open or closed configuration.

Trellis **24** is preferably formed by a single wire **70** contoured to form both scaffold **30** and leaf valve frame **32**. As shown in FIG. **6**, wire **70** may trace a pattern on a flat surface so as to form a trellis preform **74**. Wire **70** may be longitudinally extended and retracted in an undulating pattern such that a valve leaf frame aperture **62** is formed and then a scaffold opening **38** is formed, although other paths are possible. Each leaf frame aperture **62** and each scaffold opening **38** are perimetrically defined by a segment of wire **72** which allows trellis **24** to be radially-collapsible to allow delivery of valve **10** through a body lumen and then radially-expanded at a selected lumen site. Moreover, wire **70** may be welded, fused, crimped, sutured, or otherwise, joined together at strategic locations such as at a scaffold joint **76** defined between circumferentially-adjacent scaffold openings **38**. Additionally, wire **70** may be joined at or about hinge joints **76** where adjacent hinge portions **60***a* and **60***b* of adjacent valve leaf frames abut.

Referring to FIGS. **7** and **8**, trellis preform **74** is bent into the shape of trellis **24** by wrapping preform **74** about an elongate cylindrical mandrel **78** and joining trellis perform ends **74***a* and **74***b* together, and then deflecting the leaf frames **52** about hinge line **22** into overlying registry with passageway **20**. Trellis **24** may be heat set in this configuration by a method as is typically known for the material which forms trellis **24**.

The present invention seals each leaf frame aperture **62** to prevent fluid flow therethrough. The material used to seal each leaf frame aperture **62** is sufficiently thin and pliable so as to permit radially-collapsing the leaf valve portion for delivery by catheter to a location within a body lumen. Referring to FIGS. **10-12**, a fluid-impermeable biocompatible non-thrombogenic valve leaf cover **80** may be positioned on trellis **24** so as to seal the leaf frame apertures **62**. Preferably, valve leaf cover **80** seals the entire expanse of each leaf frame aperture **62** prior to implantation although it is recognized that the lumen wall will also assist in sealing leaf frame aperture **62** in the region about scaffold **30** adjacent hinge line **22**. Therefore, valve leaf cover **80** should minimally seal leaf frame aperture **62** between component legs **54** and **56** and hinge line **22** so that as scaffold **30** becomes embedded in the lumen wall, valve **10** will fully seal at hinge line **22**. Valve leaf cover **80** may be formed from a thin layer of, by way of illustration and not by limitation, PE, Pellethane, Urethane, bovine pericardial tissue, and the like. Alternatively, Valve leaf cover may be formed from a surgically-useful textile including, by way of illustration and not by limitation, Dacron, Polyethylene terephthalate (PET), Polyethlylene (PE), silk, Rayon, or the like. Valve leaf cover **80** may also be formed of a surgically-useful polymeric material including, by way of illustration and not by limitation, polytetrafluoroethylene (PTFE) or expanded polytetrafluoroethylene (ePTFE). Valve leaf cover **80** is desirably coated with a cellular growth-inhibiting drug such as Heparin or Taxol or the like.

Similarly, each valve leaf aperture **62** may be covered with cultured tissue cells derived from a either a donor or the host patient. The cultured tissue cells may be attached to each leaf frame **52** to the distal extent **31** of scaffold **30** so as to seal each valve leaf aperture **62**. The cultured tissue cells may be initially positioned on a micro filter type mesh so as to extend either partially or fully into each valve leaf aperture **62**. Scaffold **30** and leaf frames **52** may be formed of either a bioabsorbable material or a non-bioabsorbable material so that each will eventually be displaced by the tissue cells as the tissue cells mature. Eventually, then, the cells alone will provide the fully functioning valve, Alternatively, when scaffold **30** and leaf frames **52** are formed from a non-bioabsorbable material, the cultured cells provide a means for reducing any undesirable biological response by the host.

FIGS. **13**A-D depict a still further embodiment of the present invention in which adjacent valve leaf frames **24** are

joined at a location along the length thereof so as to provide a smaller opening **50'** in the open configuration. Adjacent component legs **54** and **56** may be joined by welding or other techniques so as to form a hinge line **22'** at a location downstream from the distal extent **31** of scaffold **30**. As the size of opening **50** affects the required actuation pressure differential acting upon the valve leafs **40**, it is contemplated that the precise location at which adjacent valve leaf frames **24** are joined may be selected in accordance with the fluid flow pressure parameters at the site within the body in which the valve of the present invention is emplaced.

Referring again to FIGS. **1-4** and with additional reference to FIGS. **14-16**, an elongate generally cylindrical first biocompatible non-thrombogenic liner **82** is attached to trellis **24**. First liner **82** may be positioned over either of interior face **34** or exterior face **36** of scaffold **30**. First liner **82** may also be provided in addition to, or in place of, valve leaf cover **80** for sealing the leaf frame apertures **62**. FIG. **15** depicts first liner **82** positioned on the interior **34** of scaffold **30**. Furthermore, first liner **82** may be trimmed to conform closely to the valve leaf frames, as shown in FIG. **15**. As shown by FIG. **16**, first liner **82** may include a valve webbing **84** trimmed to span between the edges of adjacent valve leafs in the open configuration so as to provide a larger surface area for the body fluid to act upon when urging the valve leafs **40** between the open and closed configuration. First liner **82** may also be trimmed to provide at least one flap **86** extending in the downstream direction beyond each valve leaf **40**. Each flap **86** may then be folded through the adjacent valve leaf aperture **62** and laminated to the first liner spanning the other major surface.

Similarly, an elongate generally cylindrical second biocompatible non-thrombogenic liner **88** may be positioned on scaffold **30** opposite first liner **82**. Second liner **88** may extend only along a portion of scaffold **30**, as shown in FIG. **15**, or fully along trellis **24**, as shown in FIG. **16**. The first and second liners may be joined so as to fully encase either just scaffold **30** or all of trellis **24**. Numerous techniques may be employed to laminate or bond first liner **82** to second liner **88** through the scaffold openings **38** and the leaf frame apertures **62** of trellis **34** including heat setting, adhesive welding, application of uniform force and other bonding techniques. Additionally, second liner **88** may be formed by folding an extended length of first liner **82** over upstream end **26** of scaffold **30** so as to extend at least partially along the opposite face of scaffold **30** as first liner **82**.

Each of liners **82** and **88** may be capable of inhibitting thrombus formation. Additionally, liners **82** and **88** may either prevent or facilitate tissue ingrowth therethrough, as the particular application for the valve may dictate. For example, liner **88** may be formed from a porous material to facilitate tissue ingrowth therethrough while liner **80** is formed from a material or a treated material which inhibits tissue ingrowth. Liners **80** and **88** may be formed from a surgically-useful textile including, by way of illustration and not by limitation, Dacron, Polyethylene terephthalate (PET), Polyethlylene (PE), silk, Rayon, or the like, Valve leaf cover **80** may also be formed of a surgically-useful polymeric material including, by way of illustration and not by limitation, polytetrafluoroethylene (PTFE) or expanded polytetrafluoroethylene (ePTFE). It is further contemplated that either liner **82** and **88** may be formed from an xenograft of cellular tissue from a donor such as bovine cardial tissue, or homograft of cellular tissue formed from the host patient.

The polymeric liners **82** and **88** and valve cover **80** of the present invention may be formed by a variety of methods. For example, extrusion processes such as ram extrusion; polymeric casting techniques such as solvent casting and film casting; molding techniques such as blow molding, injection molding and rotational molding; and other thermoforming techniques useful with polymeric materials may be employed and chosen to best serve the type of material used and specific characteristics of the liner or cover desired.

While either or both of the polymeric liners **80** and **88** may be provided directly in tubular form, i.e as an extruded tube, either one or both can also be formed from extruded sheets of material which can be wrapped around all or a portion of the support scaffold to form a cover or liner. Combinations of sheets and tubes are also contemplated and may be applied to the support scaffold in a manner essentially as taught by U.S. patent application Ser. No. 09/035,501, which is herein incorporated by reference. For example, in one embodiment a sheet may be first formed and wrapped externally about the support scaffold and seamed along the longitudinal axis to form a cover. Such a sheet may be made with a high degree of uniaxial orientation. The relative axis of orientation of the stent may vary depending on the material used to form the liner or cover and the orientation and size of its pore structure. For example, in applicants' aforementioned copending U.S. application Ser. No. 08/721,834, the extruded material used to form the liner or cover may be formed from unsintered ePTFE sheets which have been expanded longitudinally and aligned generally longitudinally along the longitudinal stent axis, transverse to the longitudinal direction, or in an off-axis angle therebetween. In another example, a sheet or tube of ePTFE may be stretched and sintered several times to create a preformed ePTFE having expansion memory, such as shown in PCT Publication No. WO 96/00103 (Application No. U.S./95/07326), which is herein incorporated by reference. This publication is based on U.S. priority application Ser. No. 08/265,794, filed Jun. 27, 1994, which is also herein incorporated by reference. The preformed ePTFE allows for further expansion once the stent is implanted and radially deployed. Other embodiments of the present invention include the use of one or more tubes, providing a tube and a sheet formed into a tubular structure, or providing a plurality of sheets formed into a tubular structure on either surface of the stent.

Various bioeffecting agents may also be included in the liners by well known methods. For example, anti-infective agents and/or antithrombogenic agents may be coated on the liner or disposed within some of the pores of the polymeric cover or conformal layer prior to implantation. Additionally, such bioeffecting agents may also be employed on the stent or in the anchoring material used thereon. One example is shown in commonly assigned International Patent Application No. WO 95/29647, published on Nov. 9, 1995 and its 27 U.S. priority applications Ser. No. 235,300, filed Apr. 29, 1994, and Ser. No. 350,233, filed Dec. 1, 1994, which are incorporated herein by reference.

Referring again to FIG. **8**, a method of forming a composite endoluminal device of the present invention includes the steps of providing an inner liner **82** on an elongate cylindrical mandrel **78**. Trellis **24** is positioned over liner **82**. Trellis **24** may be positioned over liner **82** such that an extent **80***a* of liner **82** may be folded over the upstream end **26** of trellis **24** and positioned over an extent of the exterior face of scaffold **30**, as shown in FIG. **15**. Extent **80***a* may be affixed to liner **82** through the scaffold openings **38** or affixed to scaffold **30** itself. Extend **80***a* may be positioned over the entire length of trellis **24**, as shown in FIGS. **1** and **3**. Alternatively, a second liner **88** may be positioned on trellis **24** opposite first liner **82**.

Still referring to FIG. **8**, mandrel **78** may be formed to include a shaped end **78***a* to serve as a die for shaping the closed configuration of the valve. Shaped end **78***a* includes a contoured impression **78***c* for each valve leaf **40**. Each valve leaf **40** may be deflected against its contoured impression **78***c* to provide abutting engagement between the adjacent valve leafs. Trellis **24** may be shaped by shaped end **78***a* either prior to or after covering with liners **80** or **88**. It may be desirable to impart the shape memory to trellis **24** prior attaching the liners. Additionally, while the leaf valve framework **32** is conformed to shaped end **78***a*, the valve leafs **40** may be joined in accordance with the embodiment of FIGS. **13**A-D, either before or after attaching one or both of liners **80** and **88**. It is further contemplated that each impression **78***c* may itself provide a contoured surface for imparting a curve to the deflected valve leafs **40**.

The present invention further contemplates positioning trellis **24** about mandrel **78** without an underlying lining. Trellis **24** may then receive first lining over only the exterior face **36** of scaffold **30**. Lining **80** may further be extended so as to cover the leaf frame apertures **62** of leaf valve frame **52**, although it is contemplated using a different material to cover the leaf frame apertures **62**. Lining **80** may also provide a valve webbing spanning between adjacent valve leafs **40**.

It is additionally contemplated by the present invention to leave scaffold **30** substantially uncovered and to seal each leaf frame aperture **62** to the extent required to provide an acceptable degree of flow restriction in the closed configuration. While leaf frame apertures **62** are desirably fully sealed prior to implantation, it is contemplated that only that portion of leaf frame aperture **62** which extends in registry with fluid passageway **20** be sealed by one or more liners **80**. The embedding of scaffold **30** into the body lumen would thereby provide valve **10** with an acceptable degree of fluid-integrity about the lumen wall. In such an embodiment, valve leaf cover **80** may be applied to trellis **24** to fully seal leaf frame aperture **62**. The preferred method includes attaching a cover to both frame component legs **54** and **56** and to the segment of distal scaffold extent **31** between the corresponding hinges.

Liners **82** and **88** may be formed of a polymeric material which may be fused by various techniques such as heat sealing, solvent bonding, adhesive bonding, or use of coatings. It is also contemplated that liners **80** and **88** may be formed of a textile material, or that each could include a homograft or xenograft tissue retained by the intermediate member to seal the openings in same. The formation, application, and orientation of liners **80** and **88** may be accomplished by the techniques described in commonly-assigned and copending U.S. patent application Ser. No. 09/035,501, entitled "Conformal Laminate Stent Device", which is incorporated by reference herein.

FIG. **17** shows an alternate embodiment of a trellis **148** for valve **110** in which trellis **30** of valve **10** is mechanically joined to a second radially collapsible scaffold **150**. It is also contemplated that trellis **30** of valve **10** may be continuously formed by the same wire **170** which forms second scaffold **150**. The present invention contemplates that elongate portions **170***a* of wire **170** may be employed between sections of scaffolds to allow the prosthetic valve **10** to be emplaced within tortuously-extending sections of body lumen.

FIGS. **18-21** depict yet another embodiment of the present invention in which the valve leafs of an implantable prosthetic valve **110** are attached to the interior luminal surface **114** of a second radially collapsible tubular fluid conduit **112**. Second conduit **112** may be selected from many known stent and covered stent designs known in the art. Second conduit **112** further maintains the patency of the body lumen to either side of valve **10** and may also include a biocompatible fluid impermeable non-thrombogenic lining **116** on either or both of its own interior or exterior lumenal surfaces, **114** and **115**, respectively. The materials used to form the second tubular fluid conduit may also be selected to be either bioabsorbable or non-bioabsorbable as previously described for liners **80** and **88**.

Second conduit **112** includes a radially collapsible skeleton **120** which may be formed from a shape memory alloy, an elastic metal, or a polymer. Second conduit **112** may also be formed of a bioabsorbable material. Outer surface **115** of second conduit **112** need not be covered as skeleton **120** will eventually embed into the lumen wall, but a lining **116** may be preferable so as to limit flow-around until that time.

As shown in FIG. **19**, a non-absorbable tether line **125** may have ends **125***a* and **125***b* affixed between second conduit **112** and each valve leaf **40** to prevent the leafs from inverting towards the upstream end **126** of secondary conduit should the back flow pressure become sufficient to over-deflect the leafs past hinge line **22**. Tether line **125** is desirably affixed at ends **125***a* and **125** to non-bioabsorbable components of valve **110**.

With additional reference to FIG. **21**, it is also contemplated by the present invention to mechanically attach a number of covered leaf frames **130** to the interior luminal surface **114** of second conduit **112**. Covered leaf frames **130** are similar in construction to valve leafs **40** of valve **10**. Each covered leaf frame **130** includes a first and second elongate component leg **132** and **134** welded or otherwise affixed to skeleton **120** at a hinge portion **135** comprising hinges **135***a* and **135***b* where the component legs attach. Covered leaf frame **130** defines a leaf frame aperture **136** with skeleton **120** between the associated hinges **135***a* and **135***b*. A leaf cover **140** is desirably affixed over each leaf frame aperture **136** by spanning from each component leg **132** and **134** to skeleton **120** between the hinges **135***a* and **135***b* so as to provide a fluid integrity to the valve in the closed configuration. Alternatively, the covered leaf frames could be attached to surface **114** along a leaf frame stem **130***a*.

Referring now to FIGS. **22** and **23**, a prosthetic bicuspid valve **900** of the prior art is depicted. Valve **900** is typical of a bubble valve design which provides first and second valve leafs, **902** and **904**. Valve **900** is formed having a solid interior stent frame which provides a pair of opposed raised posts which form raised hubs **906***a* and **906***b*. The interior stent is covered with a generally cylindrical cover **908** which itself is formed of a flexible material. Valve flaps **902** and **904** are formed by the portion of cover **908** extending unsupported beyond the interior stent structure. Valve flaps **902** and **904** must therefore rely on the resiliency and shape memory of the material of the cover **908** for any bias towards the open or closed configurations, As shown in FIG. **23**, cover **908** terminates at a flap edge **910** which, in the open configuration, defines a substantially circular opening through valve **900**. In the closed configuration, shown in FIG. **22**, flap edge **910** extends along a substantially catenary path between raised hubs **906***a* and **906***b* to seal valve **900**.

FIGS. **24**A-**26** depict a prosthetic bicuspid valve **210** of the present invention. With like numbers indicating like components to other embodiments of the present invention, bicuspid valve **210** is a bubble valve including a support trellis **224** and a fluid impermeable non-thrombogenic lining **280**. Valve **210** is contemplated as a replacement aortic

valve. Valve **210** is constructed from biocompatible materials so as to minimize any adverse body reaction to its implantation.

Valve **210** includes an elongate tubular body portion **212** and a leaf valve portion **214**. Valve **210** includes an upstream end **216**, a downstream end **218**, and an elongate fluid passageway **220** extending therebetween along a valve axis $\mathbf{1}_v$. Leaf valve portion **214** extends in overlying registry with passageway **220** and includes first and second valve leafs **240** and **241** which are deflectable between a closed configuration, shown in FIGS. **24**A and **24**B, restricting fluid flow through passageway **220**, and an open configuration, shown in FIGS. **25**A and **25**B, permitting fluid flow through passageway **220**. Valve **210** also includes a pair of diametrically-opposed valve hinge hubs **242** and **244** about which valve leafs **240** and **241** deflect between the open and closed configurations. Hinge hubs **242** and **244** are located downstream of valve leafs **240** and **241** when valve **210** is in the closed configuration.

Valve leafs **240** and **241** are similarly-sized and -shaped and include opposed first and second major surfaces **240***a*, **241***a* and **240***b*, **241***b*, respectively. Each first major surface **240***a*, **241***a* of a valve leaf **240** is oriented in facing opposition towards upstream end **216** of valve **210**. Valve leafs **240** and **241** further include an arcuate leaf edge **240***c* and **241***c*, respectively, which are positionable in abutting engagement along a substantially catenary curve between hinge hubs **242** and **244** to define the closed configuration of valve **210**. Similarly, as best shown in FIG. **4**, the leaf edges **240***c* and **241***c* define an eye-shaped valve leaf opening **250** when in the open configuration. Valve leaf opening **250** is in fluid communication with passageway **220**. Whereas the valve leafs of the sawtooth valves of the present invention desirably had a longitudinal length greater than the radius of the implanted scaffold, valve leafs of the bicuspid valves of the present invention may be formed having a longitudinal length dimension 1 which is smaller than the radius of the implanted scaffold portion.

Valve leafs **240** and **241** are desirably formed having a spring bias about hinge hubs **242** and **244** towards the closed configuration. The open configuration may be attained when the fluid pressure acting on the first major surfaces **240***a* and **241***a* of the valve leafs **240** and **241** overcomes both the fluid pressure acting on the second major surfaces **240***b* and **241***b* of the valve leafs **240** of valve **210** and the spring bias imparted to the valve leafs **240** acting to close the valve leafs. Similarly, when the fluid pressure from the downstream end **218** of valve **210** become too great relative to the upstream fluid pressure, the valve leafs **240** will be urged towards the closed configuration to thwart fluid flow through the valve back towards the upstream end **228**.

FIGS. **26**A-C show the support trellis **224** employed by valve **210**. Trellis **224** may be formed from a material exhibiting shape memory characteristics or from a material which is readily expandable by a balloon catheter. Trellis **224** is generally an elongate tube being coaxial with valve axis $\mathbf{1}_v$. Trellis **224** has opposed upstream and downstream ends **226** and **228**. Upstream end **226** of trellis **224** is further defined by a radially collapsible body scaffold **230**. Downstream end **228** of trellis **224** is further defined by a radially-collapsible leaf valve framework **232**.

Trellis **224** may be formed from a wide variety of materials and in a variety of configurations. Radially-expandable endovascular stents known in the art provide useful basic designs for modification into a support trellis of the present invention and may be formed in a wide variety of configurations. One example of a stent useful in the present invention is a slotted tubular stent which is designed to radially expand either by balloon catheter or by forming the stent from a temperature-sensitive memory alloy which changes shape at a designated temperature or temperature range. Other stent types, such as tubular-shaped wire stents and self-expandable spring-biased stents are also contemplated. Trellis **224** may therefore be formed from a variety of materials including stainless steel, titanium, platinum, gold and other bio-compatible metals. Shape memory plastics and thermoplastic materials which are inert in the body may also be employed to form trellis **224**. Shaped memory alloys having superelastic properties generally made from specific ratios of nickel and titanium, commonly known as nitinol, are among the preferred trellis materials.

Scaffold **230** is a substantially cylindrical member having an interior face **234**, an exterior face **236** and defines at least one radially-extending scaffold opening **238** communicating therebetween. Interior face **234** of scaffold **230** generally defines passageway **220**. It is contemplated by the present invention that scaffold opening **238** need not be perimetrically bounded by scaffold **230**. Scaffold **230** is formed to have a generally open configuration including a plurality of openings **238** communicating between interior face **234** and exterior face **236**. These openings **238** provide for longitudinal flexibility of valve **210** as well as to permit valve **210** to be radially collapsed for delivery through, and radially expanded for deployment in, a body lumen such as a blood vessel. Furthermore, scaffold **230** preferably maintains a substantially coaxial alignment with the body lumen as leaf valve portion **214** deflects between the open and closed configurations so as to better seal passageway **220** when valve **210** is closed.

Leaf valve framework **232** includes leaf frames **252** and **253** corresponding to valve leafs **240** and **241**. Leaf frames **252** and **253** define leaf frame apertures **262** and **263** with the distal extent **231** of scaffold **230**. Leaf frame apertures **262** and **263** communicate between first and second major surfaces **240***a* and **240***b* of valve leaf **240**, and first and second major surfaces **241***a* and **241***b* of valve leaf **241**, respectively. Leaf frames **252** and **253** may be radially contracted towards valve axis $\mathbf{1}_v$ for delivery via catheter through a body lumen. Leaf frames **252** and **253** are imparted with a shape memory so as to extend over passageway **220** once implanted in a body lumen.

Leaf valve framework **232** further includes diametrically opposed hinge posts **245** and **247** extending from distal end **231** of scaffold **230** towards hinge hubs **242** and **244**, respectively. Hinge hubs **242** and **244** extend transversely to valve axis $\mathbf{1}_v$. Arcuate frame portions **257** and **259** of valve leafs **240** and **241** extend between hinge hubs **242** and **244** along a substantially catenary path. As shown in FIGS. **25**B and **26**C, arcuate frame portions **257** and **259** deflect about hinge hubs **242** and **244** and swings towards and away from each other as valve leafs **240** and **241** are urged between the closed and open configurations.

Each leaf frame aperture **262** and each scaffold opening **238** are perimetrically defined by a segment of wire **270** which allows trellis **224** to be radially-collapsible so as to allow delivery of valve **210** through a body lumen and then radially-expanded at a selected lumen site. Moreover, wire **270** may be welded, fused, crimped, sutured, or otherwise, joined together at strategic locations, such as at a scaffold joint **276** defined between circumferentially-adjacent scaffold openings **238**.

Trellis **224** is preferably formed by a single wire **270** contoured to form both scaffold **230** and leaf valve frame **232**. Wire **270** may be longitudinally extended and retracted

in an undulating pattern such that one half of scaffold **230** is formed and a then a portion or all of valve leaf frame **232** prior to completing scaffold **230**, although other paths are possible. Alternatively still, trellis **224** may be formed in constituent components which are then joined. Other methods for forming trellis **224** as a unitary member will thus be apparent to those skilled in the art.

Liner **280** may be formed in accordance with the description for liner **80** hereinabove. Liner **280** may be applied to trellis **224** at either interior face **234**, exterior face **236**, or at both faces. Liner **280** may further be affixed only to trellis **224** or may include portions which are adhered to itself through the scaffold openings **238** and/or the leaf frame apertures **262** and **263**. It is contemplated that one of inner liner **280***a* and outer liner **280***b* may be forced though trellis **224** to be affixed to the other or both may be joined together within the scaffold openings **238** or the leaf frame apertures **262**, **263**.

The present invention further contemplates that the liner **280** forming the major surfaces of valve leafs **240** and **241** are urgable into a concave shape so as to better collect backflow and urge the valve leafs towards the open or closed configuration. The major surfaces of valve leafs **240** and **241** have complex shapes which are a function of the longitudinal spacing of catenary frame portion from distal end **23 1** of scaffold **230**. Furthermore, the material forming the major surfaces need not taughtly-extend across the leaf frame openings of valve leafs **240** and **241**. The present invention contemplates providing sufficient excess material spanning leaf frame apertures **262** and **263** such that overwhelming fluid pressure acting on one major surface of a valve leaf forces the covering through the valve leaf opening. When excess material is applied across valve leaf apertures **262** and **263**, then the first major surfaces of each valve leaf **240** and **241** may assume a concave shape so as to favor the opening the valve leafs and the second major surfaces may assume a concave shape so as to favor closing the valve leafs.

FIGS. **27**A-**29**B depict an alternate embodiment of a bicuspid valve of the present invention. Valve **310** is similar in most respects to valve **210** described hereinabove but includes valve leafs **340** and **341** defined by leaf frame edges **357** and **359** having larger radius of curvature between hinge hubs **342** and **344** than is shown in FIGS. **2**-**5**. The larger radius of curvature along leaf frame edges **357** and **359** results in larger major surfaces for the opposed valve leafs **340** and **341** and defines a smaller opening **350** in the open configuration, as shown in FIG. **28**B. It is contemplated that leaf frame edges **357** and **359** are deflectable to a position coextensive with hinge hubs **342** and **344**, as shown in FIG. **29**B, or to a position downstream of hinge hubs **342** and **344**, as shown in FIG. **28**B. It is also contemplated that the first major surfaces **340***a* and **341***a* may come into contact when valve leafs **340** and **341** are in the closed configuration.

While the present invention has been shown and described in detail above, it will be clear to the person skilled in the art that changes and modifications may be made without departing from the spirit and scope of the invention. That which is set forth in the foregoing description and accompanying drawings is offered by way of illustration only and not as a limitation. The actual scope of the invention is intended to be defined by the following claims.

What is claimed:

1. A valve, comprising:

a radially-elastic scaffold with valve leaflet frames having an open-frame construction; and

an elongate liner adjacent the radially-elastic scaffold and valve leaflet frames to provide a fluid passageway, where the elongate liner includes excess material to provide a concave shape to the elongate liner extending into the open-frame construction, and where the valve leaflet frames with the elongate liner move between a closed position to restrict fluid flow through the fluid passageway and an open position to allow fluid flow through the passageway.

2. The valve of claim **1**, further including a microfilter support mesh over the open-frame construction of the valve leaflet frames to support cultured tissue cells seeded on to the elongate liner.

3. The valve of claim **1**, wherein the valve leaflet frames of the radially-elastic scaffold are mechanically biased towards the open position.

4. The valve of claim **1**, wherein the valve leaflet frames of the radially-elastic scaffold are mechanically biased towards the closed position.

5. The valve of claim **1**, wherein the elongate liner is positioned over the radially-elastic scaffold and a second liner is positioned on the radially-elastic scaffold opposite the elongate liner.

6. The valve of claim **1**, wherein the radially-elastic scaffold attaches to an interior surface of a second radially collapsible prosthetic fluid conduit.

7. The valve of claim **6**, wherein the second radially collapsible prosthetic fluid conduit is a stent.

8. A valve, comprising:

a radially deformable unitary open-frame scaffold having a tubular body and valve leaflet frames; and

a liner at least partially encasing the radially deformable unitary open-frame scaffold to provide a fluid passageway, where the liner includes excess material to provide a concave shape to the liner extending into the open-frame scaffold, and where the valve leaflet frames with the liner move between a closed position to restrict fluid flow through the fluid passageway and an open position to allow fluid flow through the passageway.

9. The valve of claim **8**, further including a flexible hinge supporting each of the valve leaflet frames on the tubular body.

10. The valve of claim **8**, wherein the radially deformable unitary open-frame scaffold expands from a first diameter to a second radially-expanded diameter.

11. The valve of claim **10**, wherein the radially deformable unitary open-frame scaffold expands through the use of a delivery balloon.

12. The valve of claim **10**, wherein the radially deformable unitary open-frame scaffold is formed from a shape memory material that self-expands from the first diameter to the second radially-expanded diameter.

13. The valve of claim **8**, wherein the elongate liner is positioned over the radially deformable unitary open-frame scaffold and a second liner is positioned on the radially deformable unitary open-flame scaffold opposite the elongate liner.

14. A medical system, comprising:

a valve having:

a radially-elastic scaffold with valve leaflet frames having an open-frame construction; and

an elongate liner adjacent the radially-elastic scaffold and valve leaflet frames to provide a fluid passageway, where the elongate liner includes excess material to provide a concave shape to the elongate liner extending into the open-frame construction, and where the valve leaflet frames with the elongate liner move between a

closed position to restrict fluid flow through the fluid passageway and an open position to allow fluid flow through the passageway; and

a second radially collapsible prosthetic fluid conduit, wherein the radially-elastic scaffold attaches to an interior surface of the second radially collapsible prosthetic fluid conduit.

15. The medical system of claim **14**, wherein the second radially collapsible prosthetic fluid conduit is a stent.

16. The medical system of claim **14**, wherein the valve leaflet frames of the radially-elastic scaffold are mechanically biased towards the open position.

17. The medical system of claim **14**, wherein the valve leaflet frames of the radially-elastic scaffold are mechanically biased towards the closed position.

18. The medical system of claim **14**, wherein the elongate liner is positioned over the radially-elastic scaffold and a second liner is positioned on the radially-elastic scaffold opposite the elongate liner.

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