US008348999B2

(12) **United States Patent**
Kheradvar et al.

(10) **Patent No.: US 8,348,999 B2**
(45) **Date of Patent: Jan. 8, 2013**

(54) **IN-SITU FORMATION OF A VALVE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/372,392**

(22) Filed: **Feb. 13, 2012**

(65) **Prior Publication Data**

US 2012/0143319 A1 Jun. 7, 2012

Related U.S. Application Data

(62) Division of application No. 12/008,109, filed on Jan. 8, 2008, now Pat. No. 8,133,270.

(60) Provisional application No. 60/879,288, filed on Jan. 8, 2007, provisional application No. 60/930,458, filed on May 16, 2007.

(51) **Int. Cl.**
A61F 2/24 (2006.01)
A61F 2/06 (2006.01)

(52) **U.S. Cl.** **623/2.11**; 623/1.26

(58) **Field of Classification Search** 623/2.11, 623/2.12, 2.13, 2.14, 2.15, 2.16, 2.17, 2.18, 623/1.19, 1.26, 23.68, 1.24; 606/191, 192, 606/194

See application file for complete search history.

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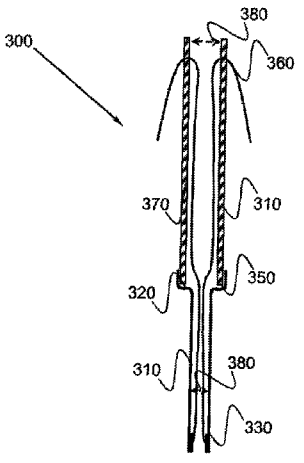
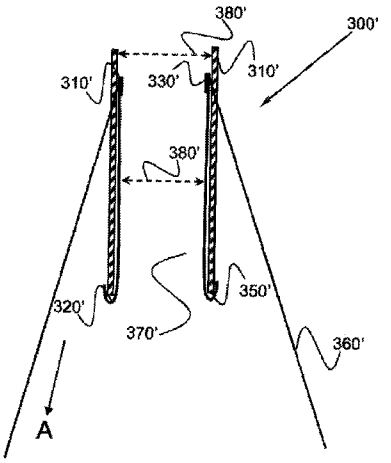
(57) **ABSTRACT**

The present invention satisfies the long felt need for a more compact and durable valve which may be formed in situ. The present invention provides a self-deployable valve system, a method of delivery, and a method of manufacturing for the self-deployable valve system. The present invention delivers the necessary components for forming a complete valve system in situ. The collapsed subcomponents of the system lack any functional characteristics commonly associated with a valve before being expanded. However, once expanded, the system is transformed into a competent valve for use in a wide variety of applications.

8 Claims, 10 Drawing Sheets





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PCT International Search Report and the Written Opinion of the International Searching Authority.
PCT International Preliminary Report on Patentability.

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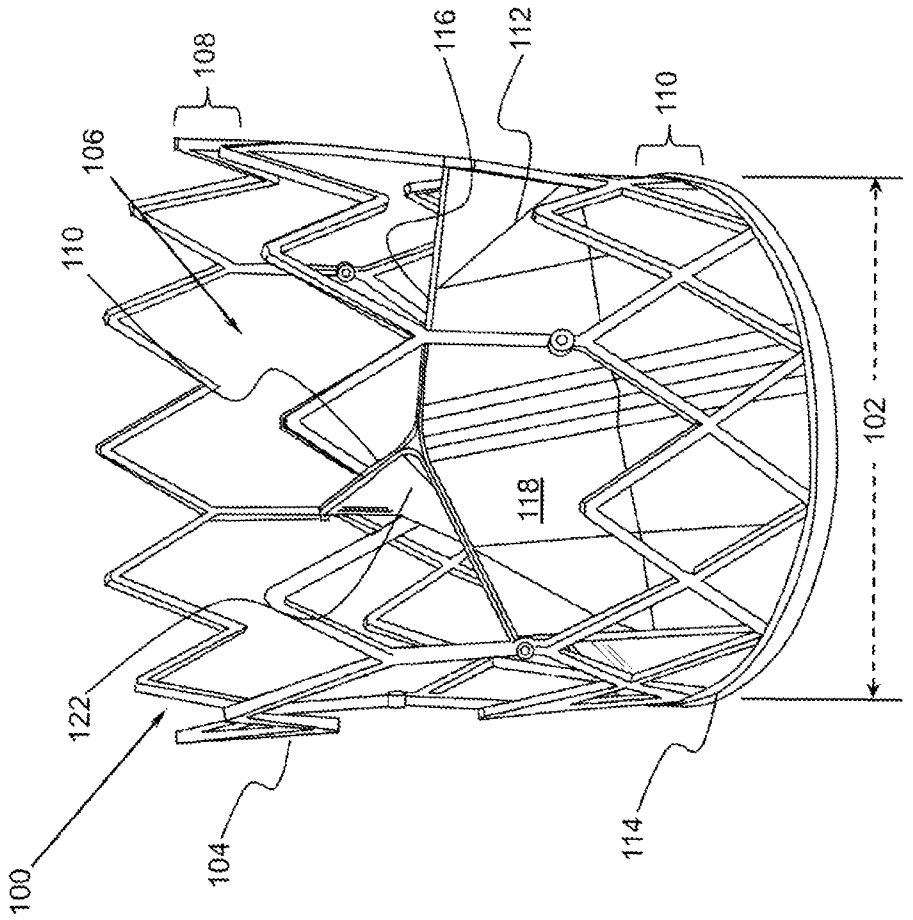
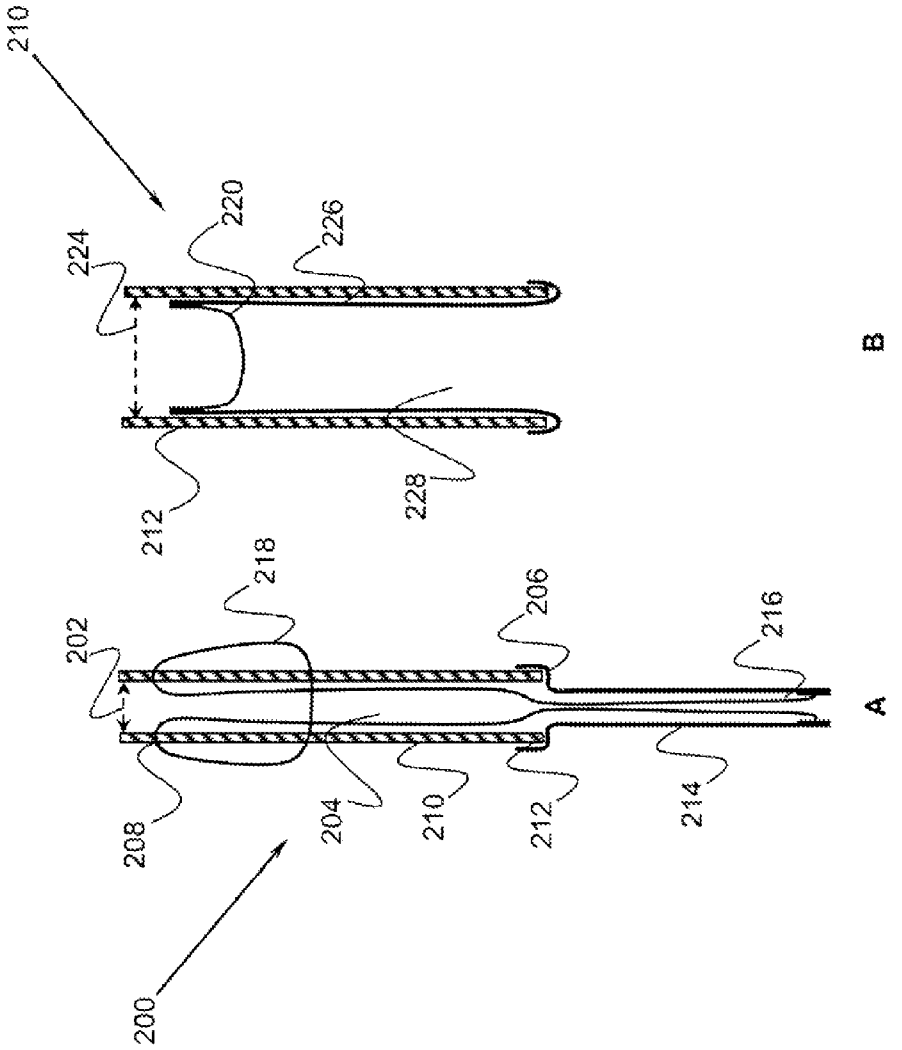


FIG. 1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B
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216
202
208
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212
214
200
A

FIG. 2B

FIG. 2A

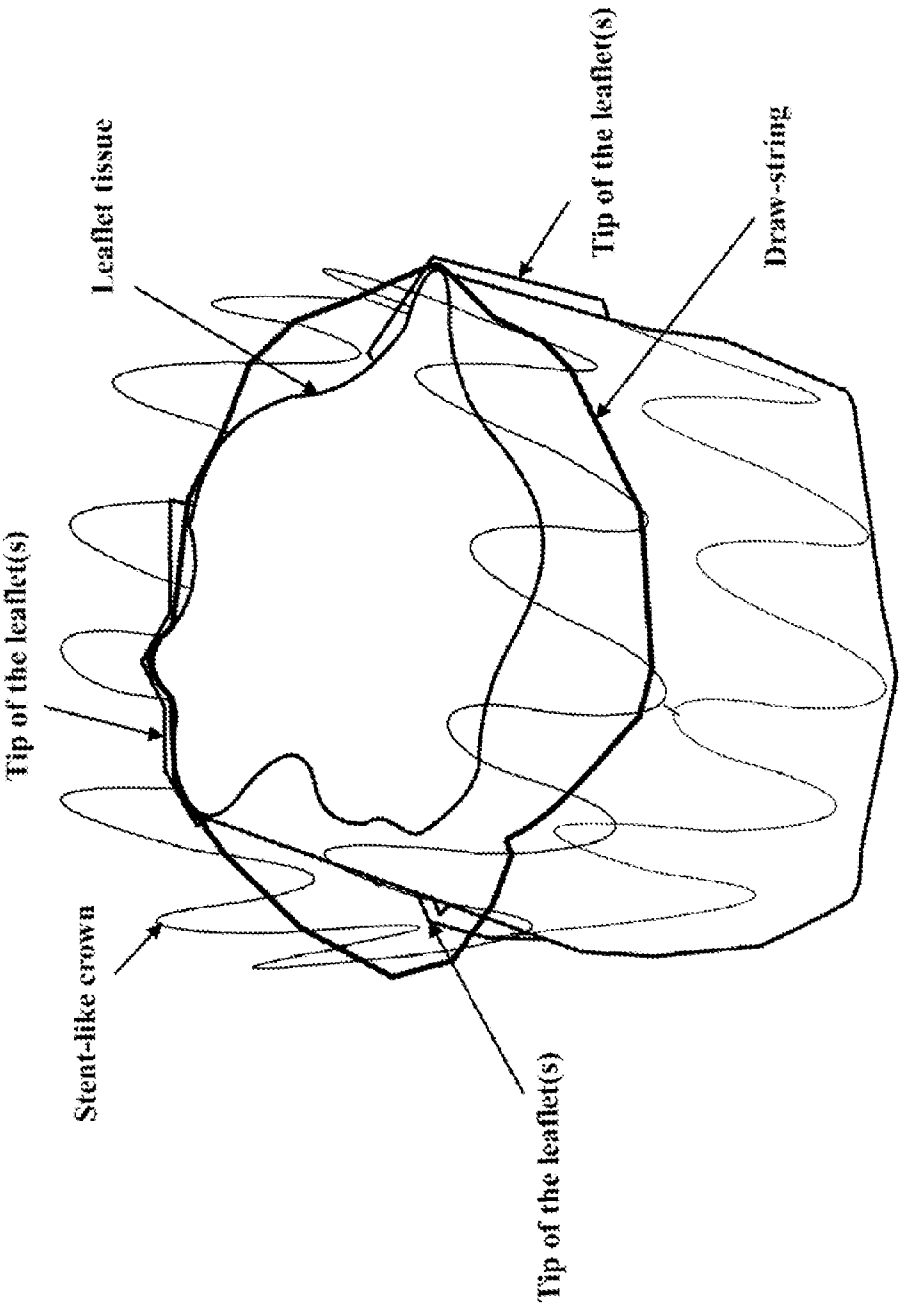

Leaflet tissue
Tip of the leaflet(s)
Draw-string
Tip of the leaflet(s)
Stent-like crown
Tip of the leaflet(s)

FIG. 2C

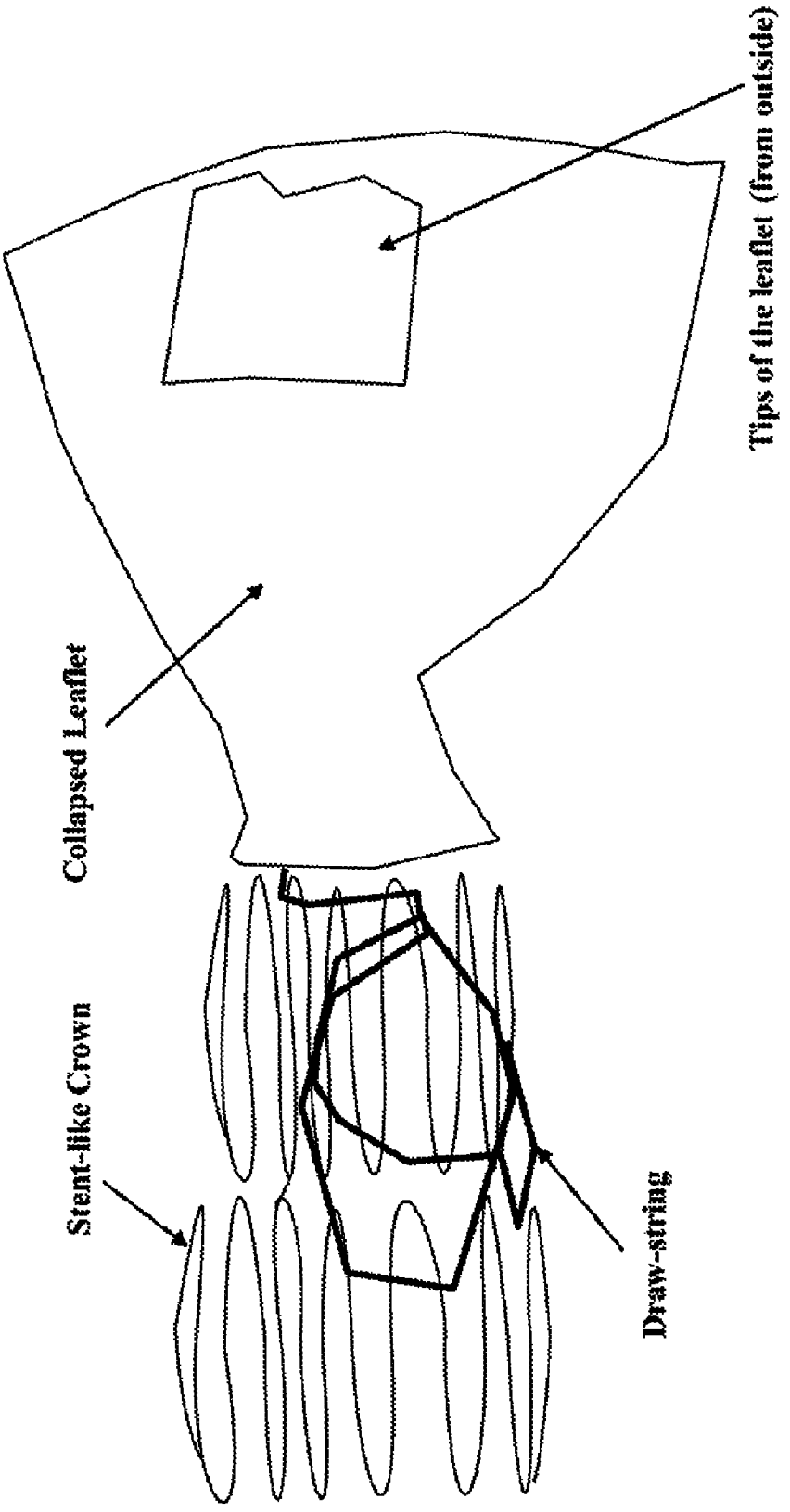
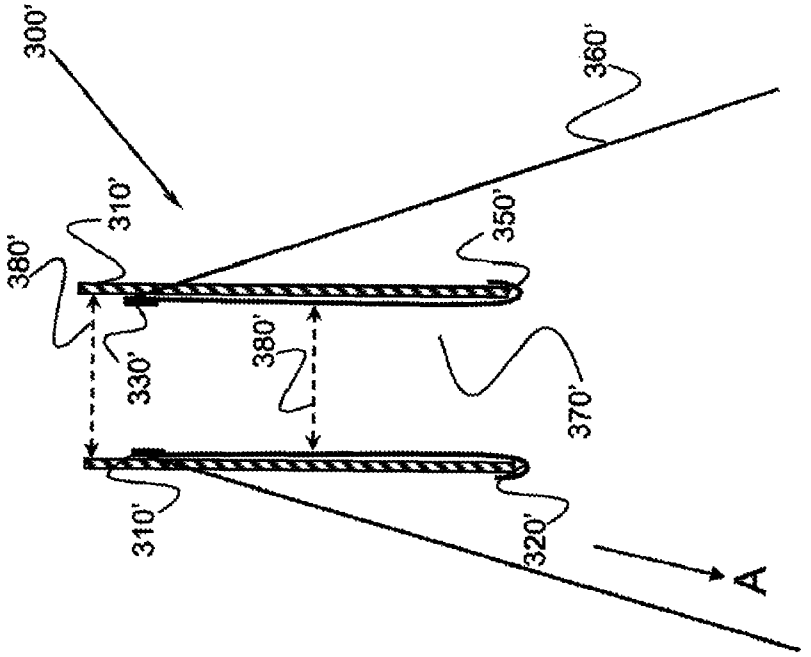

Tips of the leaflet (from outside)
Collapsed Leaflet
Stent-like Crown
Draw-string

FIG. 2D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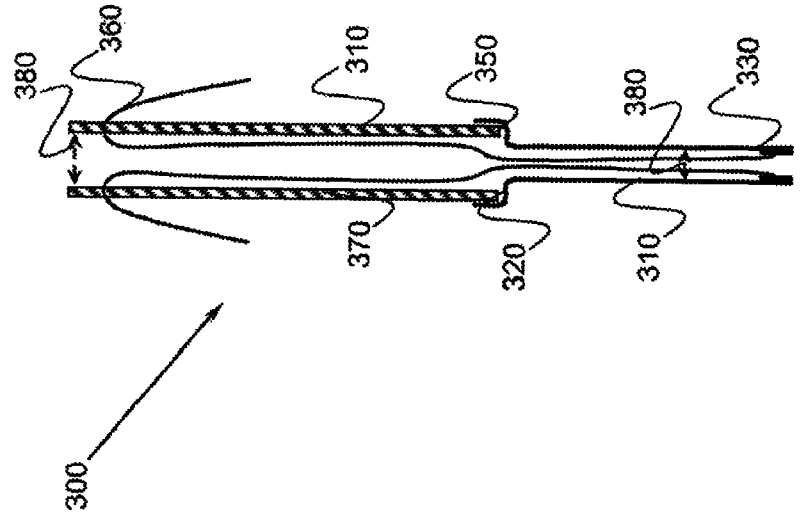
380'
370'
310'
320'
A

FIG. 3B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300

FIG. 3A

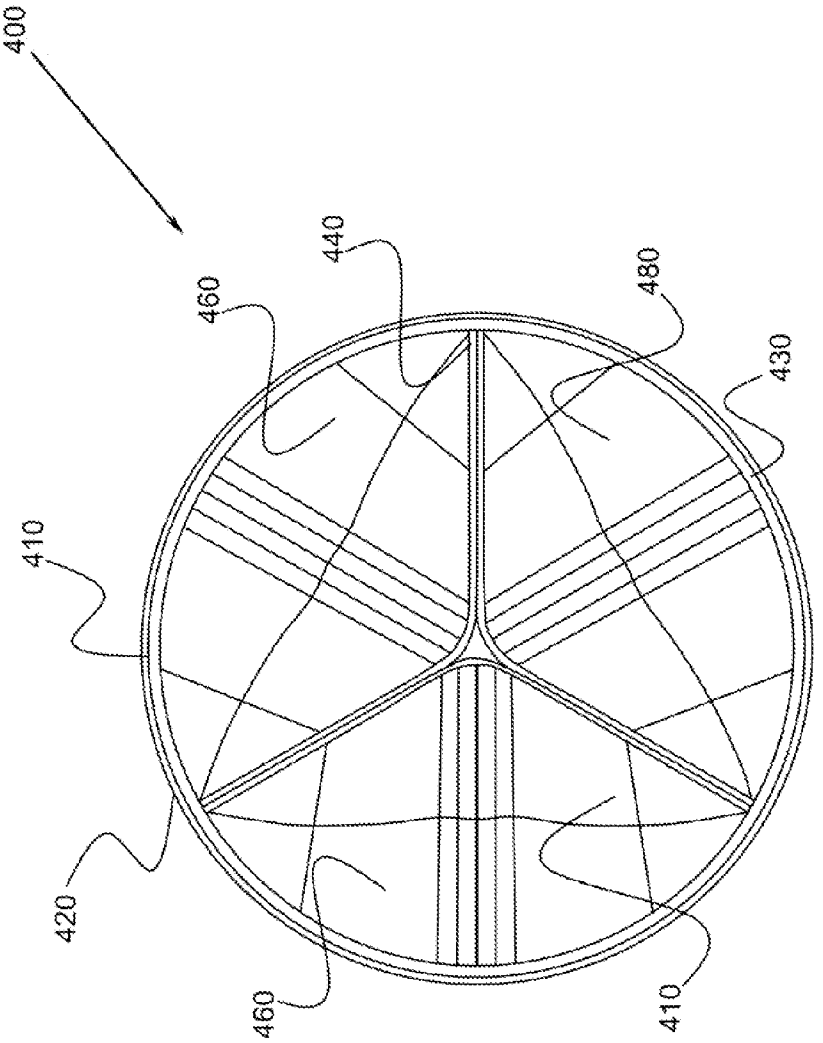

FIG. 4

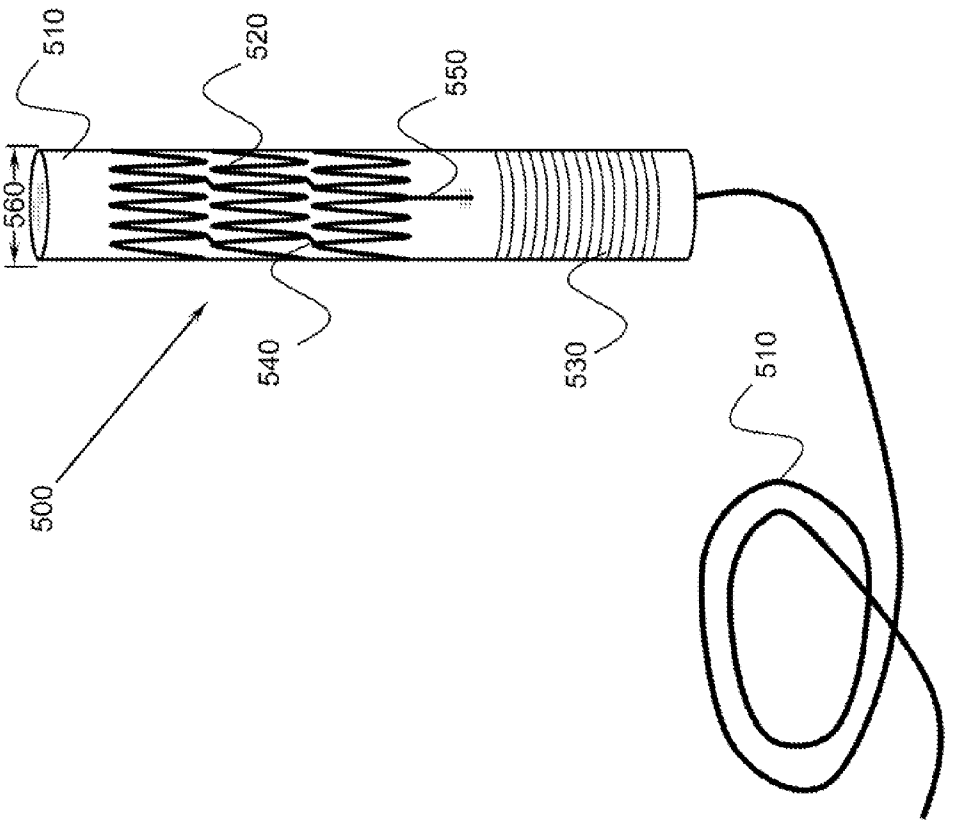

FIG. 5

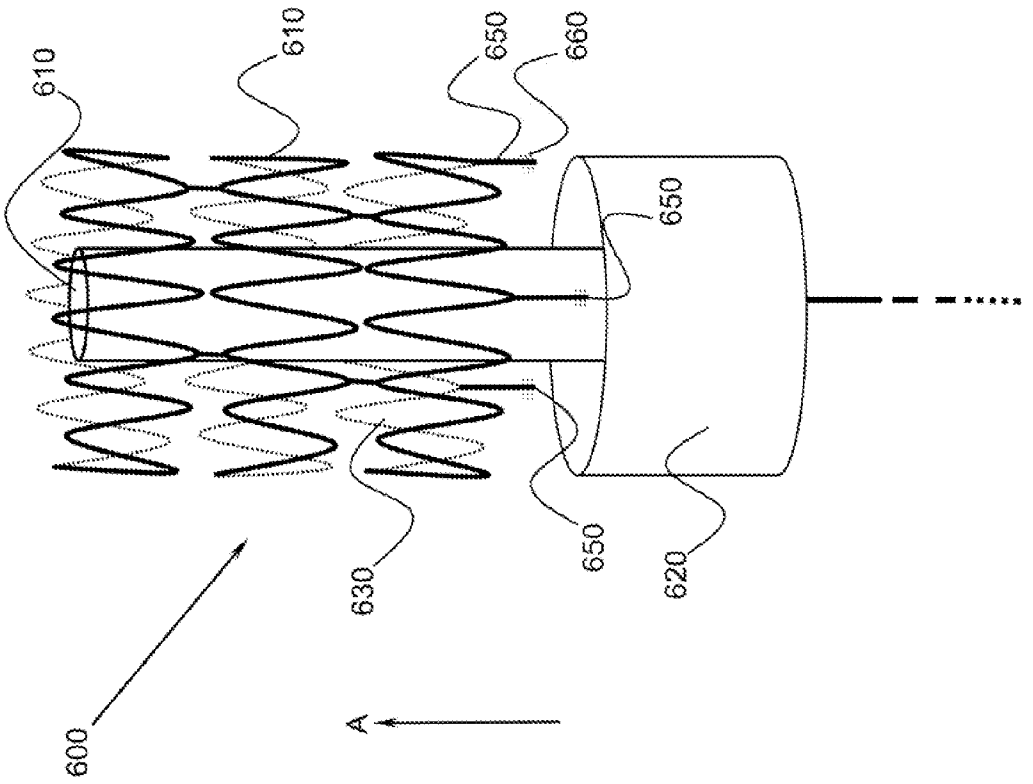

FIG. 6

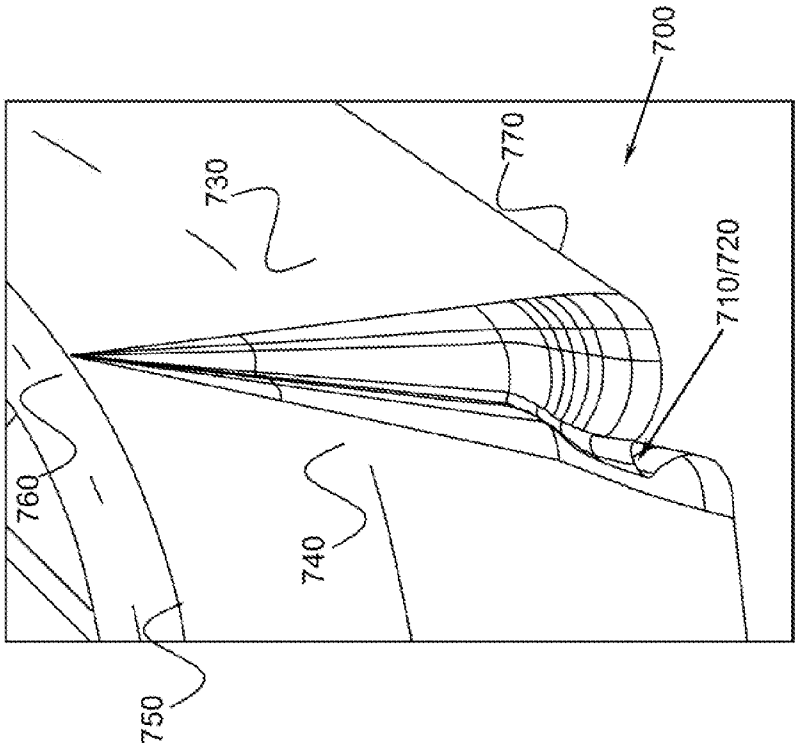

FIG. 7

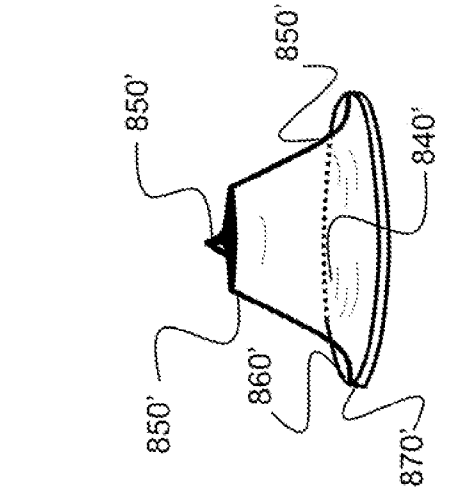

FIG. 8C

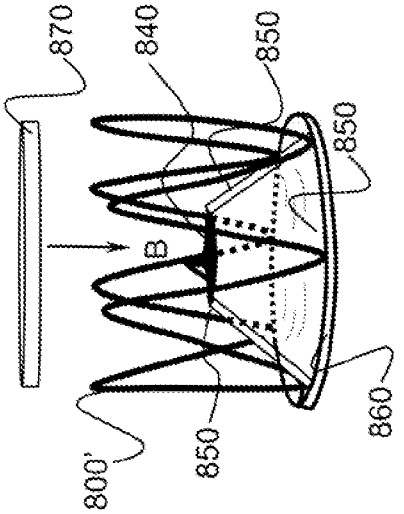

FIG. 8B

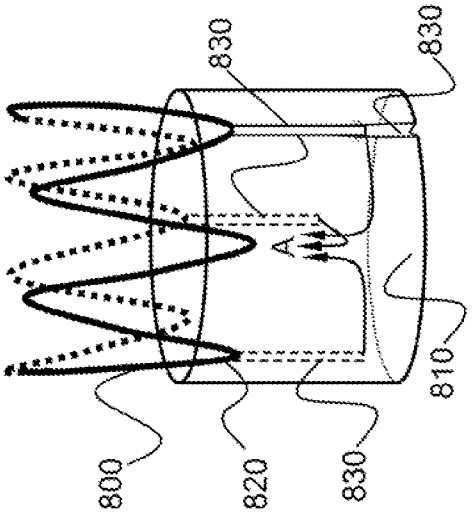

FIG. 8A

IN-SITU FORMATION OF A VALVE

PRIORITY CLAIM

This is a Divisional Application of U.S. patent application Ser. No. 12/008,109, now U.S. Pat. No. 8,133,270 filed on Jan. 8, 2008, which is a non-provisional patent application of U.S. Provisional Patent Application No. 60/879,288, filed Jan. 8, 2007, titled, "In-situ formation of a valve by infolding leaflets and its method of delivery;" and U.S. Provisional Patent Application No. 60/930,458, filed May 16, 2007, titled, "Deployable forming heart valve system and its percutaneous method of delivery."

BACKGROUND OF THE INVENTION

(1) Technical Field

The present invention is related to a prosthetic valve and a method for implantation in a body channel, and methods of delivery.

(2) Description of Related Art

Human heart valves under the conditions of normal physiological functions are organs that open under the changes in pressure gradient inside the cardiac chambers. Four valves in the heart serve to direct the flow of blood through all chambers in a forward direction. In addition to the four heart valves (tricuspid valve, mitral valve, aortic valve, and pulmonary valve), a patient has other flow-regulatory valves, such as venous valves, sphincter valves, and the like.

When disease conditions affect the structure or the materials of the native valve, the valve itself will decay, degenerate or disrupt and requires repair or replacement to restore proper function necessary for the continuation of life.

U.S. Pat. No. 4,451,936 to Carpentier et al., entire contents of which are incorporated herein by reference, discloses an aortic prosthetic valve for supra-annular implantation comprising a valve body of generally annular configuration and a valve element movably mounted on the valve body for opening and closing the valve, and a scalloped suture ring circumscribing the valve body adjacent the base surface and configured to approximately fit the contour of the Sinuses of Valsalva at the base of the aorta.

U.S. Pat. No. 4,790,843 to Carpentier et al., entire contents of which are incorporated herein by reference, discloses a prosthetic heart valve assembly that includes an artificial annulus, a prosthetic valve and a retaining ring for releasably retaining the prosthetic valve on the artificial annulus. By removing the retaining ring, the valve can be replaced with another valve.

U.S. Pat. No. 4,994,077 to Gabbay, entire contents of which are incorporated herein by reference, discloses an improved prosthetic heart valve comprising a support body or stent covered by a layer of biological tissue having only the smooth surfaces thereof presented outwardly. The valve cusp is made of pericardial tissue that has been doubled over such that the rough side thereof is folded inwardly.

U.S. Pat. No. 4,994,077 to Dobben, entire contents of which are incorporated herein by reference, discloses a valve system consisting of a cylindrical or crown shaped stent that is made by bending wire into a zigzag shape to anchor the device and attach the flow regulator flap of a valve. The device presents significant hemodynamic, delivery, fatigue and stability disadvantages.

U.S. Pat. No. 5,163,953 to Vince, entire contents of which are incorporated herein by reference, discloses a valve system consisting of a flow-regulation mechanism of a flap of biologic material that is mounted inside a stent comprised of a toroidal body formed of a flexible coil of wire. The main shortcoming of this design is the profile and configuration, thus making the device clinically ineffective as a minimally invasive technique.

U.S. Pat. No. 5,332,402 to Teitelbaum, entire contents of which are incorporated herein by reference, discloses a valve system consisting of shape memory Nitinol and a flow-regulating valve. The stent-like support is comprised of a meshwork or braiding of Nitinol wire with trumpet-like distal and proximal flares. The flared ends are intended to maintain the position of the stent component across the valve thereby anchoring the device. The disadvantages of the device are the reduced valve orifice and sub-optimal hemodynamic characteristics.

U.S. Pat. No. 5,370,685 to Stevens, entire contents of which are incorporated herein by reference, discloses a percutaneous valve replacement system for the endovascular removal of a malfunctioning valve followed by replacement with a prosthetic valve. The valve replacement system may include a prosthetic valve device comprised of a stent and cusps for flow-regulation such as a fixed porcine aortic valve, a valve introducer, an intraluminal procedure device, a procedure device capsule and a tissue cutter. The valve device disclosed requires a large delivery catheter and intraluminal-securing means such as suturing to anchor the device at the desired location.

U.S. Pat. No. 5,397,351 to Pavcnik et al., entire contents of which are incorporated herein by reference, discloses a self-expanding percutaneous valve comprised of a poppet, a stent and a restraining element. The valve stent has barbed means to anchor to the internal passageway. The device includes a self-expanding stent of a zigzag configuration in conjunction with a cage mechanism comprised of a multiplicity of criss-crossed wires and a valve seat. The disadvantages of the device include large delivery profile, reduced effective valvular orifice, and possible perivalvular leakage.

U.S. Pat. No. 5,411,552 to Andersen et al., entire contents of which are incorporated herein by reference, discloses various balloon expandable percutaneous prosthetic valves. One embodiment discloses a valve prosthesis comprised of a stent made from an expandable cylindrical structure and an elastically collapsible valve mounted to the stem. The device is placed at the desired location by balloon expanding the stent and the valve. The main disadvantage to this design is the 20+ French size delivery catheters.

U.S. Pat. No. 5,445,626 to Gigante, entire contents of which are incorporated herein by reference, discloses a valve operated catheter for urinary incontinence and retention comprising a flexible duct designed to be inserted in the patient's urethra, the catheter provided with a spiral shaped end portion, having a plurality of holes for the passage of urine. The duct is provided, at its other end, with a seat in which there is housed a valve made of elastic material, the valve being usually closed because of the elastic action.

U.S. Pat. No. 5,500,014 to Quijano et al., entire contents of which are incorporated herein by reference, discloses a biological valvular prosthesis comprising a chemically fixed conduit derived from a harvested vein segment bearing at least one integrally formed venous valve, and a restriction means positioned about the conduit at either side of the venous for restricting the venous valve from expanding outwardly.

U.S. Pat. No. 5,824,064 to Taheri, entire contents of which are incorporated herein by reference, discloses an aortic valve replacement system combined with an aortic arch graft. The devices and percutaneous methods described require puncture of the chest cavity.

U.S. Pat. No. 5,840,081 to Andersen et al., entire contents of which are incorporated herein by reference, discloses a valve prosthesis for implantation in the body by use of a catheter. The valve prosthesis is formed of a stent with a pre-formed collapsible valve mounted on the stent.

U.S. Pat. No. 5,855,597 to Jayaraman, entire contents of which are incorporated herein by reference, discloses a device comprising a star-shaped stent, a replacement valve and a replacement graft for use in repairing a damaged cardiac valve. The device is comprised of a chain of interconnected star-shaped stent segments in the center of which sits a replacement valve. The flow-regulation mechanism consists of three flaps cut into a flat piece of graft material that is rolled to form a conduit in which the three flaps may be folded inwardly in an overlapping manner.

U.S. Pat. No. 5,855,601 to Bessler et al., entire contents of which are incorporated herein by reference, discloses methods and devices for the endovascular removal of a defective heart valve and the replacement with a percutaneous cardiac valve. The device is comprised of a self-expanding stent member with a flexible valve disposed within. The stent member is of a self-expanding cylindrical shape made from a closed wire in a zigzag configuration that can be a single piece, stamped, extruded or formed by welding the free ends together. The flow-regulation mechanism is comprised of an arcuate portion that contains a slit to form leaflets and a cuff portion that is sutured to the stent and encloses the stent. The preferred flow regulator is a porcine pericardium with three cusps.

U.S. Pat. No. 5,925,063 to Khosravi, entire contents of which are incorporated herein by reference, discloses a percutaneous prosthetic valve comprised of a coiled sheet stent to which a plurality of flaps are mounted on the interior surface to form a flow-regulation mechanism that may be comprised of a biocompatible material. The disadvantages of this design include problematic interactions between the stent and flaps in the delivery state, and the lack of a detailed mechanism to ensure that the flaps will create a competent one-directional valve.

U.S. Pat. No. 5,954,766 to Zadano-Azizi et al., entire contents of which are incorporated herein by reference, discloses a device in which flow-regulation is provided by a flap disposed within a frame structure capable of taking an insertion state and an expanded state. The preferred embodiment of the flow-regulation mechanism is defined by a longitudinal valve body made of a sufficiently resilient material with a slit that extends longitudinally through the valve body.

U.S. Pat. No. 5,957,949 to Leonhardt et al., entire contents of which are incorporated herein by reference, discloses a prosthetic valve comprised of a tubular graft having radially compressible annular spring portions and a flow regulator, which is preferably a biological valve disposed within. In addition to oversizing the spring stent by 30%, anchoring means is provided by a light-activated biocompatible tissue adhesive that is located on the outside of the tubular graft and seals to the living tissue. Disadvantages of this device include those profile concerns, a large diameter complex delivery system, and feasibility of the light actuated anchoring means.

U.S. Pat. No. 6,106,550 to Magovern et al., entire contents of which are incorporated herein by reference, discloses an implantable apparatus for receiving a heart valve, comprising an annular ring having an inner wall and an outer wall, a plurality of channels displaced circumferentially about the ring, each channel extending from the inner wall to the outer wall, and a plurality of tissue attachment pins each pin being movable in a respective one of the channels between a first position during implantation, and a second position wherein the first end of each pin extends beyond the outer wall for tissue attachment.

U.S. Pat. No. 6,168,614 to Andersen et al., entire contents of which are incorporated herein by reference, discloses a method of endovascularly delivering a valve through a blood vessel, comprising the steps of providing a tissue valve and an expandable support structure, connecting the tissue valve to the support structure, and securing the tissue valve and the support structure to a desired valve location with the support structure in the expanded shape.

U.S. Pat. No. 6,206,911 to Milo, entire contents of which are incorporated herein by reference, discloses an expandable stent that is created so as to undergo essentially no axial foreshortening when expanded from an unexpanded or compressed configuration to an operative configuration. Attachment to the surrounding tissue may be via pairs of needle-like projections or prongs that may be bent to have a radial orientation during the deployment phase.

U.S. Pat. No. 6,283,127 to Sterman et al., entire contents of which are incorporated herein by reference, discloses a device system and methods facilitating intervention within the heart or a great vessel without the need for a median sternotomy or other form of gross thoracotomy, substantially reducing trauma, risk of complication, recovery time, and pain for the patient. Using the device systems and methods of the invention, surgical procedures may be performed through percutaneous penetrations within intercostal spaces of the patient's rib cage, without cutting, removing, or significantly displacing any of the patient's ribs or sternum.

U.S. Pat. No. 6,530,952 to Vesely, entire contents of which are incorporated herein by reference, discloses a cardiovascular valve system including a permanent base unit that is affixed to the patient using conventional sutures or staples, and a collapsible valve having a collapsible frame that mates with the permanent base unit, and supports valve leaflets. An installed collapsible frame may be re-collapsed and disengaged from the permanent housing whereas a new collapsible valve is then installed, to resume the function of the prosthesis.

U.S. Pat. No. 6,569,196 to Vesely, entire contents of which are incorporated herein by reference, discloses a system for minimally invasive insertion of a bioprosthetic heart valve. The system includes a collapsible tissue-based valve system, a catheter-based valve delivery system, a surgical platform and a device tracking and visualization system, wherein the collapsible valve system includes a permanent outer frame that is affixed to the patient using conventional sutures or staples and a collapsible valve having a collapsible inner frame that mates with the outer frame.

U.S. Pat. No. 6,582,462 to Andersen et al., entire contents of which are incorporated herein by reference, discloses a valve prosthesis for implantation in a body channel by way of catheterization, the prosthesis comprising a radially collapsible and expandable cylindrical stent and a collapsible and expandable valve having commissural points wherein the valve is mounted to the stent at the commissural points.

U.S. Pat. No. 6,652,578 to Bailey et al., entire contents of which are incorporated herein by reference, discloses a catheter system with minimally invasive techniques for percutaneous and transluminal valvuloplasty and prosthetic valve implantation.

U.S. Pat. No. 6,830,584 to Seguin, entire contents of which are incorporated herein by reference, discloses a device for replacing, via a percutaneous route, a heart valve located in a bodily vessel, comprising an elongated support element, two series of elongated blades arranged around the circumference

of the elongated elements, where the blades have opposite cutting edges and can be extended corolla-shaped such that their cutting edges are set in the extension of one another thereby forming circular cutting edges to cut the native valve so as to separate it from the corporeal duct.

U.S. Pat. No. 6,830,585 to Artof et al., entire contents of which are incorporated herein by reference, discloses a percutaneously deliverable heart valve with a plurality of valvular leaflets, the plurality of leaflets being sewn together at least a potion of their side edges to form an annulus at about the in-flow edge and a plurality of commissure tissues.

U.S. Pat. No. 6,896,690 to Lambrecht et al., entire contents of which are incorporated herein by reference, discloses a device for performing intravascular procedures wherein at least a portion of the device is configured for placement in a flowpath of a blood vessel. The device comprises a valve means configured to allow greater antegrade flow than retrograde flow through the vessel and a filter operative to restrict the passage of emboli while allowing blood flow through the vessel.

U.S. Pat. No. 6,908,481 to Cribier, entire contents of which are incorporated herein by reference, discloses a valve prosthesis comprising a collapsible, elastic valve member, an elastic stent member in which the valve member is mounted, and a support coupled to the valve member and positioned between the valve member and the stent member, wherein the stent member forms a continuous surface and comprises strut members that provide a structure sufficiently rigid to prevent eversion.

U.S. Pat. No. 6,951,571 to Srivastava, entire contents of which are incorporated herein by reference, discloses a valve-implanting device comprising a collapsible frame, inner and outer guide wires removably connected to the collapsible frame, and a plurality of valve flaps attached to the collapsible frame.

U.S. Pat. No. 6,974,476 to McGuckin, Jr. et al., entire contents of which are incorporated herein by reference, discloses a valve system comprising a first substantially annular portion adapted to be positioned on a proximal side of the annulus of a patient and a second substantially annular portion adapted to be positioned on a distal side of the annulus of a patient, wherein at least one of the first and second substantially annular portions is movable towards the other portion to a clamped position to clamp around the annulus. The second portion has a flow restricting apparatus.

Each of the prior art stent valve designs has certain disadvantages which are resolved by the present embodiments. The prior art valve prosthesis generally consists of a support structure with a tissue valve connected to it, wherein the support structure is delivered in a collapsed shape intraluminally and secured to a desired valve location with the support structure in the expanded shape. However, the support structure tends to compressively impinge a portion of the leaflets of the tissue valve at the structure struts when the support structure is expanded by an inflatable balloon for positioning endovascularly. The impinged leaflets tend to deteriorate and calcify, making the valve useless. Moreover, recent studies showed that there is an imperfect apposition of the stent against the native valve which resulted in paravalvular leak and obstruction of coronary Ostia at the coronary sinuses. Additionally, existing stent designs set a limit for a minimum catheter size and cannot be delivered with small enough catheters. As a result, one direct disadvantage of the size limitation is the exclusion of children from the beneficiaries of this technology. Thus, a continuing need exists for a new and improved expanding valve structure that is formed in-situ and that can be used with tiny catheters.

SUMMARY OF THE INVENTION

It is an objective of the present invention to provide a valve prosthesis which is formed in situ. It is also an objective of the present invention to permit implantation of the prosthetic valve without surgical intervention in the body.

In one aspect the present invention is an in-situ forming valve, comprising: an expandable component comprising a hollow portion, a distal end, and a proximal end; a sheet component comprising a distal circumference and a proximal circumference, the distal circumference held in at least partial contact with the distal end of the expandable component, the proximal end of the sheet component further comprising at least two pinched regions; and an at least one link detachably attached to at least one point of the proximal end of the sheet, the link configured to position the proximal end of the sheet component into the hollow portion of the expandable component thereby forming a functional valve in situ.

In another aspect of the present invention, the sheet component comprises a single tubular sheet.

In another aspect of the present invention, the sheet component is a multitude of sheet components sealed together.

In another aspect of the present invention, the at least one link is further attached to at least one point above the distal end of the expandable component such that the expansion of the expandable component is configured to position the proximal end of the sheet component into the hollow portion of the expandable component thereby forming a functional valve in situ.

In another aspect of the present invention, the expandable component is at least partially comprised of a shape memory material.

In another aspect of the present invention, the expandable component is at least partially comprised of an elastic material.

In another aspect of the present invention, the expandable component is equipped with at least one bioactive agent selected from a group consisting of analgesics/antipyretics, antiasthamatics, antibiotics, antidepressants, antidiabetics, antifungal agents, antihypertensive agents, anti-inflammatories, antineoplastics, antianxiety agents, immunosuppressive agents, antimigraine agents, sedatives/hypnotics, antipsychotic agents, antimanic agents, antiarrhythmics, antiarthritic agents, antigout agents, anticoagulants, thrombolytic agents, antifibrinolytic agents, platelet aggregation inhibitor agents, antibacterial agents, antiviral agents, antimicrobials, and anti-infectives.

In yet another aspect of the present invention, the sheet component is made from a material selected from a group consisting of natural membranes, synthetic material, engineered biological tissue, biological valvular leaflet tissue, pericardial tissue, and cross-linked pericardial tissue.

In another aspect of the present invention, the invention further comprises an elongate delivery apparatus, wherein the in-situ formed valve is collapsibly mounted onto the elongate delivery apparatus.

In another aspect of the present invention, the distal end of the at least one hollow sheet component at least partially extends out from the hollow portion and over the distal end of the expandable component.

In another aspect of the present invention, the at least one link is detachably attached to at least three points of contact along the proximal end of the sheet, the link configured to position the proximal end of the sheet component into the hollow portion of the expandable component, thereby forming a three flap valve in situ.

In another aspect of the present invention, the at least one link is made of a dissolvable material.

In a still further aspect of the present invention, the invention is an in-situ forming valve, comprising: an expandable component comprising a hollow portion, a distal end, and a proximal end; and a sheet component at least partially enveloping the distal end of the expandable component, the sheet component having a first pre-implantation configuration and a second functional valvular configuration, the first pre-implantation configuration is configured to transform to the second functional valvular configuration.

In another aspect of the present invention, the second functional valvular configuration is reversibly transformable back to the first pre-implantation configuration.

In a still further aspect of the present invention, the invention is a method comprising acts of delivering an expandable component distally attached to a distal end of a sheet component to a target area; expanding the expandable component; and positioning the sheet component into the expandable component, such that the positioning induces the sheet component to form a functional valve within the expandable component.

In a still further aspect of the present invention, the act of expanding the expandable component automatically induces the sheet component to position within the expandable component thereby forming a functional valve.

In another aspect of the present invention, the act of positioning the sheet component into the expandable component is manually induced.

In another aspect of the present invention, the method further comprises an act of selectively suturing a proximal end of the sheet.

In another aspect of the present invention, the at least one link is attached to the at least one point of the proximal end of the sheet component by folding, sowing, pinching, suturing, gluing, chemical sealing, mechanically fastening, heat sealing, and any combination thereof.

In another aspect of the present invention, the method further comprises an act of replacing a preexisting natural valve or an artificial valve.

In a still further aspect of the present invention, the invention is a method for manufacturing a valve formed in situ comprising acts of: attaching at least a portion of an expandable component to a distal end of a sheet; fixedly attaching a plurality of portions of a proximal end to itself; and adjoining the distal portion of the sheet component to the distal end of the expandable component.

In another aspect of the present invention, the distal end of the sheet component is adjoined to a distal end of the expandable component by a fiber.

In a still further aspect of the present invention, the invention is an in-situ forming valve, comprising: an expandable component comprising a hollow portion, a distal end, and a proximal end; a plurality of prongs pivotally attached with the distal end of the expandable component; and a sheet component comprising a distal end and a proximal end, the proximal end of the sheet component adjustably attached with the each of the plurality of prongs, the prongs configured to position the proximal end of the sheet component within the hollow portion of the expandable component thereby forming a functional valve in situ.

In a still further aspect of the present invention, the invention is a method for forming a valve in situ comprising acts of placing a compliant sheet component in contact with a plurality of prongs of an expandable component; using the prongs to pinch the proximal end at the point of contact between each of the prongs and the sheet; expanding the sheet component and expandable component; and inverting the sheet component to form a valve in situ.

In a still further aspect the present invention, the invention is a method for forming a valve in situ comprising acts of placing a sheet component in contact with a plurality of apexes of an expandable component; fastening the proximal end of the sheet component to itself in at least two locations; expanding the sheet component and expandable component; and turning the sheet component inside out thereby forming a valve in situ.

In another aspect of the present invention, the act of turning the sheet component inside out is automatically triggered by the expansion of the expanding the sheet.

In another aspect of the present invention is an in-situ forming valve, comprising: an expandable component comprising a hollow portion, a distal end, and a proximal end; and a sheet component at least partially attached with the distal end of the expandable component, the sheet component having a first pre-formed configuration and a second functional valvular configuration, the first pre-implantation configuration is configured to transform to the second functional valvular configuration and reversibly transform into the first pre-formed configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

The objects, features and advantages of the present invention will be apparent from the following detailed descriptions of the disclosed aspects of the invention in conjunction with reference to the following drawings, where:

FIG. **1** is a side perspective view of a formed tri-leaflet valve prosthesis;

FIG. **2**A is a partial side view of a collapsed deployable forming valve system;

FIG. **2**B is a partial side view of an expanded, formed valve system;

FIG. **2**C is the illustration of an example of an expanded component with the leaflet(s);

FIG. **2**D is the illustration of an example of a collapsed expandable component with the attached compressed leaflet(s)

FIG. **3**A is the partial side-view diagram of one example of a collapsed valve;

FIG. **3**B is the partial side-view diagram of one example of an expanded, formed valve;

FIG. **4** is a top perspective view of an expanded tri-leaflet valve prosthesis;

FIG. **5** is a side-view of a collapsed a pre-formed valve prosthesis;

FIG. **6** is a side view of a stage of an expanding forming valve prosthesis;

FIG. **7** is a zoomed in view of a valve leaflet(s)' membrane;

FIG. **8**A is an enhanced view of an expanded crown and an unformed sheet;

FIG. **8**B is an illustration of one example of an expanded crown and a functional valve; and

FIG. **8**C is an illustration of an example of an expanded tri-leaflet valve and its annular ring.

Appendix A is an additional description of the present invention, entitled, "Deployable forming heart valve system and its percutaneous method of delivery," and

Appendix B is a further description of the present invention, entitled, "In-situ formation of a valve by infolding leaflets and its method of delivery."

DETAILED DESCRIPTION

The present invention satisfies the long felt need for a more compact and durable valve which may be formed in situ. The

present invention provides a self-deployable valve system, a method of delivery, and a method of manufacturing for the self-deployable valve system. The present invention delivers the necessary components for forming a complete valve system in situ.

In the following detailed description, numerous specific details are set forth in order to provide a more thorough understanding of the present invention. However, it will be apparent to one skilled in the art that the present invention may be practiced without necessarily being limited to these specific details. In other instances, well-known structures and devices are shown in block diagram form, rather than in detail, in order to avoid obscuring the present invention.

The reader's attention is directed to all papers and documents which are filed concurrently with this specification and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference. All the features disclosed in this specification, (including any accompanying claims, abstract, and drawings) may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

Furthermore, any element in a claim that does not explicitly state "means for" performing a specified function, or "step for" performing a specific function, is not to be interpreted as a "means" or "step" clause as specified in 35 U.S.C. Section 112, Paragraph 6. In particular, the use of "step of" or "act of" in the claims herein is not intended to invoke the provisions of 35 U.S.C. 112, Paragraph 6.

Below, an introduction to the present invention is provided to give an understanding of the specific aspects. Then specific embodiments of the present invention are provided.

(1) Introduction

The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Further, the dimensions of layers and other elements shown in the accompanying drawings may be exaggerated to more clearly show the details. The present invention should not be construed as being limited to the dimensional relations shown in the drawings, nor should the individual elements shown in the drawings be construed to be limited to the dimensions shown.

(1.1) In Situ Formed Valve

Referring to FIG. **1**, a side perspective view of a second configuration, or expanded state tri-leaflet valve **100** is shown. The valve **100** is a functional, one-way valve which may be fully deployed and assembled in situ. The expandable component **102** of the valve **100** is in a collapsed state as a part of the pre-valve prior to the delivery inside the body. During in situ deployment of the valve **100**, the expandable component **102** transforms to an expanded state.

Although shown as a collapsible stent-like frame, the expandable component **102** may take on a variety of forms and may be made from a variety of materials. Non-limiting examples of suitable expandable components **102** include but are not limited to shape-memory materials, stainless steel, polymers, plastic, etc. Further, the expandable component **102** may be made from any number of materials suitable for in vivo and industrial applications. Non-limiting examples of suitable materials include but are not limited to shape memory material, self-expanding Nitinol, or thermal shape memory Nitinol.

The expandable component **102** may also be equipped with at least one bioactive agent. For biologically inspired applications, the expandable component **102** may be equipped with a bioactive agent selected from a group consisting of analgesics/antipyretics, antiasthamatics, antibiotics, antidepressants, antidiabetics, antifungal agents, antihypertensive agents, antiinflammatories, antineoplastics, antianxiety agents, immunosuppressive agents, antimigraine agents, sedatives/hypnotics, antipsychotic agents, antimanic agents, antiarrhythmics, antiarthritic agents, antigout agents, anticoagulants, thrombolytic agents, antifibrinolytic agents, platelet aggregation inhibitor agents, and antibacterial agents, antiviral agents, antimicrobials, anti-infective agents, and any combination thereof.

The expandable component **102** includes a hollow portion **106**, a proximal end **108**, and distal end **110**. In the case of the assembled, formed valve **100** shown, the distal circumference **114** of the sheet component **112** may extend out from the hollow portion **106** and attached over the distal end **110** of the expandable component **102**. Distal circumference **114** overlap of the distal end **110** functionally prevents leakage of fluid such as but not limited to blood along the border of the valve **100**. Although the distal end **110** of the expandable component **102** may be a continuous annulus, a continuous shape is not necessary for either deployment or seepage prevention.

The sheet component **112** of the valve **100** is formed into a functional first leaflet **118**, second leaflet **110**, and third leaflet **122**. The first leaflet **118**, second leaflet **110**, and third leaflet **122** are formed by selectively shaping the proximal circumference **116** at a first shaping point **124**, second shaping point **126**, and third shaping point **128**. In one embodiment, the sheet component **112** may be a single continuous structure. As shown, the proximal circumference **116** is pinched or folded onto itself at the first shaping point **124** and second shaping point **126** to form the first leaflet **118** therebetween. The second leaflet **110** is formed by pinching or folding the proximal circumference **116** at the second shaping point **126** and the third shaping point **128**. Similarly, the third leaflet **122** is formed by pinching or folding the proximal circumference **116** at the first shaping point **124** and the third shaping point **128**. A shaping point may be temporarily or permanently held in position by either active or passive means. Non-limiting examples of methods by which the shape of the shaping point may be maintained include but are not limited to sutures, bends, fibers, ties, etc.

The sheet component **112** may be made from a variety of materials which may be varied to suit the needs of a particular application. Non-limiting examples of suitable materials include but are not limited to natural membranes, synthetic material, engineered biological tissue, biological valvular leaflet tissue, pericardial tissue, or crosslinked pericardial tissue. In one embodiment, the pericardial tissue may be procured from human, bovine, equine, porcine, ovine, or other animals. In another embodiment, the crosslinked pericardial tissue is crosslinked with a crosslinking agent selected from the group consisting of formaldehyde, glutaraldehyde, dialdehyde starch, antibiotics, glyceraldehydes, cyanamide, diimides, diisocyanates, dimethyl adipimidate, neomycin, carbodiimide, epoxy compound, and any mixture thereof. In an alternative embodiment, the sheet component **112** may be a complex of individual sheets affixed together to form a substantially continuous and leak proof structure. Multiple sheets may be sealed together in a variety of ways. Non-limiting examples of which include but are not limited to glue, epoxy, polymers, latex, etc.

(1.2) Functionality of a Biologically Inspired Prosthetic Valve

The valve **100** may be used in a wide variety of applications. The valve **100** is well suited for a wide variety of industrial applications in which a competent one way valve is needed. The valve **100** is also well suited for biologically inspired valve prosthesis applications. For example, the valve **100** may be used to replace an existing natural valve in the body such as but not limited to heart valves, an existing prosthetic valve, or the valve may be placed in a location where a valve previously did not exist.

When used as a heart valve prosthesis, the valve **100** seamlessly works in place of a natural heart valve. Similar to a natural heart valve, the valve **100** is able to maintain the unidirectional flow of blood from one heart chamber to the next by selectively opening in response to a pressure gradient from one side of the valve to the other.

(1.3) In Situ Formation of a Valve from a Deployable Forming Valve System

Referring to FIG. **2**A, a collapsed partial side view of a deployable forming valve system **200** is shown. The deployable forming valve system **200** is in a collapsed pre-formed configuration. Importantly, the deployable forming valve system **200** lacks the functionality of a valve while in the pre-formed or radially collapsed state. Further, in the non-functional pre-formed state, the deployable forming valve system lacks the structural characteristics of a valve.

The deployable forming valve system **200** includes an expandable component **210**. The expandable component **210** of the deployable forming valve system **200** includes a hollow center or hollow portion **204**, a distal end **206**, and a proximal end **208**. A non-limiting example of a suitable expandable component **210** includes a tube that is shaped into a collapsible/expandable stent-like crown, although in general any piece with suitable attachment points, a hollow center, and the ability to radially expand would be considered a viable alternative. Further, although shown as an elongate and radially collapsed cylinder, the dimensions of the expandable component **210** may be varied to suit a variety of applications.

Attached with and overlapping the bottom circumference, or distal end **206**, of the expandable component **210** is the bottom edge or distal end **212** of an unformed leaflet or compliant sheet component **214**. The distal end **212** of the compliant sheet component **214** is shown as at least partially overlaping or enveloping the distal end **206** of the expandable component **210**.

In the first pre-formed configuration, the proximal end **216** of the compliant sheet component **214** extends downward and beneath the expandable component **210**. Although the expandable component **210** and compliant sheet component **214** of the deployable forming valve system **200** are attached, the valve aspect of deployable forming valve system **200** has not been formed and therefore does not function as an operable valve. When the deployable forming valve system **200** is deployed inside the heart, a blood vessel, a lymphatic vessel, or other body channel, the deployable forming valve system **200** is configured to transform to a second functional valvular configuration. Once deployed to the target site and manually or automatically activated, do the pre-valve components of the deployable forming valve system **200** become a fully functional valve. The deployable forming valve system **200** may optionally be removable from the implant site by transforming the device from the second functional valvular configuration back to the first pre-formed configuration of FIG. **2**A.

In order to automatically transform the first pre-formed configuration to a second functional valvular configuration, a variety of mechanisms may be used. A non-limiting example of a suitable mechanism includes using a link **218**. The link **218** may accomplish this task with a minimal number of attachment points. Non-limiting examples of suitable link **218** materials include but are not limited to natural or synthesized fiber, metal, or plastic, and elastic/non-elastic fibers such as but not limited to silk, Nitinol, and polymeric materials. When using a link **218**, the proximal end **208** of the expandable component **210** is attached to one end of a link **218**, such as a string, while the other end of the link **218** is attached to the proximal end **216** of the compliant sheet component **214**. By radially expanding the diameter **202** of the expandable component **210**, the link **218**, attached with the proximal end **216** of the compliant sheet component **214**, positions or draws the compliant sheet component **214** into the hollow portion **204** of the expandable component **210**. As the proximal end **216** of the compliant sheet component **214** is drawn or positioned into the hollow portion **204** proximally, the compliant sheet component **214** is pulled inside-out.

The collapsed state of the deployable forming valve system **200** is suitable for delivery to a desired target area. While in the first pre-formed configuration, the diameter **202** of the deployable forming valve system **200** is compressed to the lower limit of the deployable forming valve system **200**. Although the deployable forming valve system **200** is non functional, the compressed diameter **202** facilitates the difficult task of traveling along narrow tubular, channels, veins, or arteries as the valve prosthesis is moved towards the target area.

Further information regarding a deployable forming heart valve system and its percutaneous method of delivery can be found in Appendix A, which is incorporated by reference as though fully set forth herein. Appendix A is the content of a provisional application to which this application claims priority.

Referring to FIG. **2**B, a partial side view of an expanded valve prosthesis **220** is shown. While the expandable component **222** is expanding, the diameter **224** increases, turning the compliant sheet component **226** inside out and into the hollow portion **228** of the expandable component **222**. By synchronizing the expansion of the expandable crown with the position of the compliant sheet component **226** via a contraction system such as a link **220**, the formation of the second functional valvular configuration may be completely automated. While the expandable component **222** is expanded at the designated position, the draw-string at the proximal section of the crown pulls the compliant sheet component **226** inside out through the expandable component **222**. Examples of a suitable expansion mechanism include but are not limited to an expandable component **222** made from shape memory material or an inflatable balloon.

The automated or programmed formation of the functional valvular configuration from primary pre-valve configuration may be enhanced by an expandable component **222** which is forcibly compressed while in transit to the target deployment site. Once at the target site, the expandable component **222** is allowed to return to its natural expanded state, for example the formed, functional valvular configuration of FIG. **2**B. Such activation transform may be accomplished by removing a physical restraint securing the first pre-implantation configuration **200**. Automatic activation of the expandable component may be accomplished by modifying the characteristics of the materials used in the expandable component **222**. Non-limiting examples of suitable expandable component **222** materials include but are not limited to stainless steel, shape-memory materials, superelastic materials and magnetic-shape-memory materials.

Referring to FIG. **3**A, a partial side view of a collapsed manually deployable valve **300** is shown. The manually deployable valve **300** consists of two major components: a superior stent-like crown **310**, and an inferior leaflet membrane **320**. In the collapsed state, the crown **310** is constricted over a delivery catheter/guide-wire while the leaflet membrane **320** is wrinkled at the distal end **330** and proximal end **330**. The manually deployable valve **300** is deliverable to its designated position transapically or via major vessels such as but not limited to femoral artery, carotid artery, and jugular vein.

The distal end **350** of the stent-like crown or expandable component **310** is connected to the distal end **330** of the leaflet membrane **320**. The proximal end **330** of the unformed leaflet membrane **320** is proximally anchored to a contraction system such as a link **360** in the form of a draw-string or combination of pulling strings. Further, the link **360** may be a singular link **360** detachably attached to at least one point of contact along the proximal end **330** of the unformed leaflet membrane **320**. Ultimately the formation of the leaflets, such as those shown in FIG. **1**, may be manually performed or triggered independent of the expansion of the stent-like crown **310**. For example, as the diameter **380** of the stent-like crown **310** is increasing, the diameter **390** of the leaflet membrane **320** also increases. Unlike the automatic formation of the second functional valvular configuration depicted in FIG. **3**B, the proximal end **330** of the leaflet membrane **320** is manually positioned into the hollow portion **370** of the stent-like crown **310** by pulling the link **360**. The link **360** is configured to position the proximal end **330** of the leaflet membrane **320** into the hollow portion **370** of the stent-like crown **310** thereby forming a tri-leaflet valve in situ.

Referring to FIG. **3**B, a partial side view of the expanded, manually deployable valve **300'** is shown. The stent-like crown **310'** of the valve **300'** may be expanded by any number of methods including but not limited to balloon catheters and other suitable expansion instruments. The stent-like crown **310'** may also be made of a shape memory material or elastic material. Once the collapsed stent-like crown **300'** has been delivered to the target site, the collapsed stent-like crown **300'** is transformed to its expanded configuration **310**. Attached to the distal end **350'** of the stent like crown **310'** is a portion of the leaflet membrane **320'**. As the diameter **380'** of the stent-like crown **310'** increases, the diameter **390'** of the leaflet membrane **320'** also increases until the distal end **330'** and proximal end **330'** are fully opened (not shown in the picture). Once fully deployed, a contraction system, such as a link **360'**, is pulled downward in the direction of A. By pulling the link **360'** in the direction of A, the open leaflet membrane **320'** is positioned into the hollow portion **370'**, thereby forming a fully functional valve **300'**.

A top perspective view of a tri-leaflet valve **400** is shown in FIG. **4**. As shown, both the crown **410** and membrane(s) **420** have been expanded and formed into a fully functional tri-leaflet valve prosthesis **400**. The distal end **430** of the membrane **420** is shown overlapping the distal end and side walls of the crown **410**. The proximal end **440** of the crown **410** and the proximal end **440** of the membrane **420** are also clearly visible. The proximal end **440** of the membrane **420** defines the first leaflet **460**, the second leaflet **470**, and the third leaflet **480**. The distal end **430** of the membrane **420** may be attached to the distal end of the crown **410** by mechanisms including, but not limited to, sewing, sutures or stitches, adhesives, or frictional fit depending on the particular application.

(1.4) Delivery of an In Situ Formed Valve Prosthesis

FIG. **5** demonstrates another embodiment of the present invention referred to asthe pre-formed valve system **500**, deliverable and consequently deployable inside the target site within a body chamber, vessel, etc. Referring to FIG. **5**, the subcomponents of a pre-valve system **500** over a partial segment of a delivery catheter are shown. The pre-valve system **500** is deliverable into a chamber in a collapsed state and transforms into a second functional valvular configuration. Although shown as a catheter **510** and guide-wire **520** assembly, a variety of instruments may be used to deliver and deploy the collapsed configuration of the valve inside the target site.

The pre-valve system **500** includes an expandable component, shown as a compressed crown **530**, and a sheet component in the form of a compressed and compliant membrane **540**. The compliant membrane **540** may be made of thin sheet component which is appended over the catheter **510**. The compressed crown **530** is comprised of multiple segments held together with joints **550**. A contraction system, such as a plurality of prongs **550** may be attached at the proximal end of the compressed crown **530**. The prongs **550** act as a link which may be attached to at least one point of the proximal end of the compliant membrane **540**. The prongs **550** may be attached to at least one point of the compliant membrane **540** by folding, sowing, pinching, suturing, gluing, chemical sealing, mechanically fastening, heat sealing, or any combination thereof.

The compliant membrane **540** may be made from compliant tissue membranes, which can be a single sheet component or a compound manifold. The compliant membrane **540** may also be made from a variety of materials such as but not limited to polymeric materials or obtained from bovine, porcine or equine pericardial tissue, depending on the type of usage.

In a first step the subcomponents of the unassembled pre-valve system **500** are placed on the catheter **510** or a reasonable assembly or delivery system alternative. The compressed crown **530** and compliant membrane **540** are placed unassembled on the catheter **510**. The diameter **570** of the unassembled pre-valve system **500** is sufficiently small to suite a wide variety of applications. Further the relatively small diameter **570** of the unassembled pre-valve system **500** eases the task of traversing great distances in confined channels while the unassembled pre-valve system **500** is delivered towards the target site.

FIG. **6** is a transitional time-point during the transformation process of the pre-valve configuration to expanded valve configuration. Once at the target site, the subcomponents of the pre-valve configuration **600** are expanding from the catheter **610** as shown in FIG. **6**. The fenestrated shape of the crown **620** provides an adequate attachment surface for deployment in soft substrates such as but not limited to calcified tissue, normal, tissue, etc. Although a fenestrated crown **620** is shown, a variety of mechanisms may be used in addition to or in place of a fenestrated crown **620**. Non-limiting examples of which include, but are not limited to a monolithic stent-like component, a structure mainly made of multitude of woven wires, etc. Once the fenestrated component **620** is secured to the target site, the sheet component or unformed leaflets **630** are moved in the direction of A over the circumference of the crown **620** and over the prongs **650**. The unformed leaflets **630** are comprised of a skirt, a role or a tubular sheet component of compliant membrane folded over the catheter **610** beside or adjacent the fenestrated crown **620**. The prongs **650** along the fenestrated crown **620** will act as the support for valve's leaflets **630**.

Each of the three prongs **650** is adapted with a series of grips **660** adapted to secure at least a portion of the sheet component or unformed leaflets **630** within their grasp. The grips **660** are configured to secure and fasten the shaping

points along the perimeter of the unformed leaflets **630**. The shaping points are folded onto themselves, such that when the prongs **650** are activated, the shaping points induce the unformed leaflets **630** to form a functional valve.

An enhanced view of a sheet component **700** with a fold **710** is shown in FIG. **7**. The fold **710** of the sheet component **700** is formed at the forming point **720**. The fold **710** at the forming point **720** may be induced by a link **260** (See FIG. **2**B) or a prong **550** (See FIG. **5**) in contact with the sheet component **700**. As the sheet component **700** is positioned within an expandable component or ring (not shown), the sheet component **700** to the left and right of the fold **710** become a first leaflet **730** and second leaflet **740** respectively. In order to form the first leaflet (or a segment of a single piece leaflet) **730** and second leaflet (or another segment of the same single piece leaflet) **740**, the distal end **750** is brought into contact with the expandable component **760** thereby securing the distal end **750** of the sheet component **700** in place. Once the distal end **750** of the sheet component **700** is secured in place, a link or prong pulls or positions the proximal end **770** of the sheet component **700** into the expandable component **760** thereby forming a bicuspid valve within the hollow part of the expandable component **860** (or crown) at the target site.

The expanding non-functional configuration is sequentially transitioned towards a second functional valvular configuration. The transition begins with the expansion of the crown **620** and sheet component **730** (See FIG. **7**), the prongs **650** are used to create a fold, such as the fold **710** depicted in FIG. **7** and to secure the leaflets preventing valve prolapse. An enhanced view of an expanded crown **800** and unformed sheet component **810** in contact with the prongs **820** is depicted in FIG. **8**A. Each of the three prongs **820** attached to the unformed sheet component **810** creates a fold **830** in the material. The prongs **920** may be used to carry and deliver permanent sutures or fasteners to hold or grip the fold **830** of the sheet component **810**. The prongs **820** may either be removably or permanently affixed to the sheet component **810** at the fold **830** by shape memory and/or regular sutures. Once the folds **830** have been secured, the prongs **820** push or position the sheet component **810** into the expanded crown **800** in the direction of A, ultimately forming the valve **840** depicted in FIG. **8**B.

Referring to FIG. **8**B, the expanded crown **800'** and fully functional valve **840** are shown. The functional valve **840** is shown with three leaflets (or a tubular leaflet with three pinches) **850**. The expanded crown **800'** fits within the channel of the target area, while fluids are selectively allowed to pass through the valve **840**. The expanded crown **800'** resists the recoil force preventing wall collapse, secures the position of the valve **840** placement, and may prevent or minimize the process of tissue overgrowth and its impact on the functionality of the implanted valve **840** through drug and/or gene coating. The distal end overlap **860** of the valve **840** extends over the expanded crown **800'** and functions akin to an O-ring to prevent seepage along the wall of the expanded crown **800'**. For example, when used to replace an existing heart valve in body, the distal end overlap **860** of the valve **840** prevents paravalvular leakage and regurgitation. In one embodiment, a hollow annulus or support structure **870** may be placed inside the expanded crown **800'** and over the valve **840**. For applications in which the expanded crown **800'** are not needed, the support structure **870** may be placed over the valve **840** and secured within the distal end overlap **860**.

FIG. **8**C is an illustration of an expanded tri-leaflet valve **840'** having three leaflets or a single tubular leaflet with 3 pinches **850'** supported by an annular ring **870'** enveloped by a distal end overlap **860'**. An annular ring **870'** may be secured to at least one location to the distal end overlap **860'**. The annular ring **870'** would aide the valve **840'** in resisting recoil and provides a structure by which the valve **840'** could be secured to the target position.

Further description of the in situ formation of a valve and its method of delivery can be found in Appendix B, which is incorporated by reference as though fully set forth herein. Appendix B is also the content of a provisional application to which this application claims priority.

What is claimed is:

1. A method for forming a valve in situ, comprising acts of:
- delivering an expandable component attached to a distal end of a sheet component to a target area;
- expanding the expandable component;
- positioning the sheet component into the expandable component, such that the positioning induces the sheet component to form a functional valve within the expandable component; and
- wherein the act of expanding the expandable component induces the sheet component to position into the expandable component thereby forming the functional valve.

2. The method for forming a valve in situ as in claim **1**, further comprising an act of selectively suturing a proximal end of the sheet.

3. The method for forming a valve in situ as in claim **1**, wherein the sheet component includes a proximal end and wherein at least one link is attached to at least one point of the proximal end of the sheet component by folding, sowing, pinching, suturing, gluing, chemical sealing, mechanically fastening, heat sealing, and any combination thereof.

4. The method for forming a valve in situ as in claim **1**, further comprising an act of replacing a preexisting natural valve or an artificial valve.

5. A method for manufacturing a valve formed in situ comprising acts of:
- attaching at least a portion of an expandable component to a distal end of a sheet component;
- fixedly attaching a plurality of portions of a proximal end of the sheet component to itself; and
- adjoining the distal portion of the sheet component to the distal end of the expandable component, such that expansion of the expandable component draws the sheet component into the expandable component to form a valve.

6. The method for manufacturing a valve in situ as in claim **5**, wherein the distal end of the sheet component is adjoined to a distal end of the expandable component by a fiber.

7. A method for forming a valve in situ comprising acts of:
- placing a compliant sheet component in contact with a plurality of prongs of an expandable component;
- using the prongs to pinch the proximal end at a point of contact between each of the prongs and the sheet;
- expanding the sheet component and expandable component; and
- inverting the sheet component to forth a valve in situ, wherein the act of inverting the sheet component is triggered by expansion of the expandable component.

8. A method for forming a valve in situ comprising acts of:
- placing a sheet component in contact with a plurality of apexes of an expandable component;
- flustering the proximal end of the sheet component to itself in at least two locations;
- expanding the sheet component and expandable component; and
- turning the sheet component inside out thereby forming a valve in situ, wherein the act of turning the sheet component inside out is triggered by expansion of the expandable component.

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