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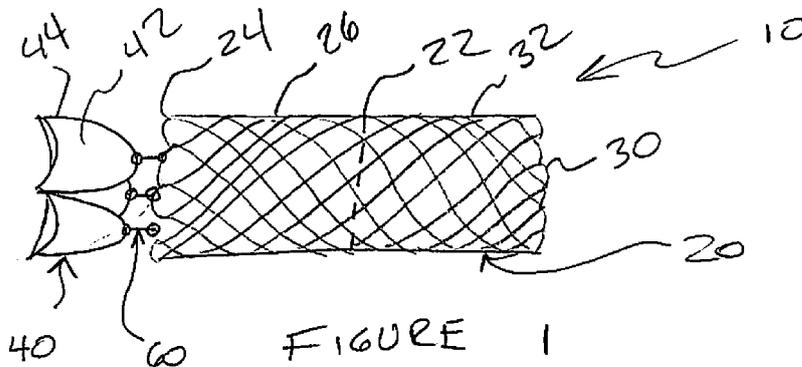
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(54) Title: LOW-PROFILE PROSTHETIC VALVE STRUCTURE



(57) Abstract: A prosthetic valve assembly that includes a stent, a tissue sleeve and an anchoring mechanism. By loading the three components of the valve assembly into a delivery catheter in a series formation, such that no two components are located within each other, the size of the delivery catheter can be reduced.

## LOW-PROFILE PROSTHETIC VALVE STRUCTURE

### RELATED APPLICATIONS

**[0001]** This application claims benefit of and priority to U.S. Provisional Application Serial No. 61/800,153 filed March 15, 2013 entitled *Low-Profile Prosthetic Valve Structure*, which is hereby incorporated herein by reference in its entirety.

### BACKGROUND OF THE INVENTION

**[0002]** Replacing heart valves with prosthetic valves was, until recently, a complicated surgical procedure that involved cutting open the chest, establishing blood flow through a blood pump, stopping the heart, etc. This complicated procedure, even when performed perfectly, required extensive recovery time due to the invasiveness and damage done to access the implantation site. Additionally, the risk of infection or other complications is extremely high.

**[0003]** Numerous advancements have been made to develop prosthetic valves that can be implanted percutaneously, using a catheter to snake the prosthetic valve through the vasculature to the implantation site. If successful, the recovery time is greatly minimized relative to conventional open-heart surgery.

**[0004]** A designer of a percutaneously-delivered prosthetic valve is faced with numerous challenges, however. First and foremost is designing a prosthetic valve that can be compressed enough to be inserted into a catheter small enough to be navigated to the valve site through the vasculature. Other challenges include anchoring the valve at the valve site so the valve does not migrate after release; including a support structure for the valve that is robust enough to push the native, often calcified valve out of the way and prevent it from later interfering with the function of the new valve; ensuring that the new valve allows proper flow in a desired direction and effectively stops flow in the opposite direction; ensuring that no blood flows around the sides of the implanted device (this is known as perivalvular leakage); designing a prosthetic valve device that does not fail due to fatigue after hundreds of thousands of cycles of leaflet function; designing a

valve that meets all of these criteria and can still be manufactured economically; and the list goes on.

**[0005]** These prosthetic valves, and their respective delivery catheters, are designed to replace a particular native valve, such as the aortic valve, for example. Percutaneous navigation to a valve is easiest, and least traumatic to the patient, when a smaller catheter is used. Smaller catheters, however, present challenges when designing effective prosthetic valves that can be compressed enough to fit, and slide, within the lumen of a small catheter, such as a 16 Fr or even a 14 Fr catheter. Significant strides have been made in recent years in designing prosthetic valves that have reduced profiles when in a catheter-loaded configuration. For example, the devices described in U.S. Patent Publication Number 2006/0271166 to Thill et al., the contents of which are incorporated by reference herein, can assume an elongated, unfolded configuration when loaded into a catheter and, when released from the catheter at a target site, resume a folded configuration. The present invention is directed to taking this innovative concept and presenting additional ways that the loaded configuration could present an even lower profile.

#### OBJECTS AND SUMMARY OF THE INVENTION

**[0006]** One aspect of the invention is directed to a prosthetic valve device that presents a low profile in a catheter-loaded configuration.

**[0007]** Another aspect of the invention is directed to a prosthetic valve device that is sized to replace an aortic valve and capable of being delivered using a small, flexible catheter.

**[0008]** Another aspect of the invention is directed to a prosthetic valve device that comprises two components are connected but positioned in series (spaced apart axially) in a delivery catheter to reduce the size of the delivery catheter required.

**[0009]** One aspect of the invention provides a device for replacing a native valve comprising: a stent; a tissue sleeve; and, an anchoring mechanism usable to secure said tissue sleeve within said stent; wherein, in a configuration inside a delivery catheter, said

anchoring mechanism is not located within said stent; and wherein, in a deployed configuration, said tissue sleeve is located within said stent.

**[0010]** Another aspect of the invention provides prosthetic valve device that comprises a braided anchoring mechanism connected at a proximal end to a wireform.

**[0011]** Another aspect of the invention provides an implantable device that includes a support structure having an extended configuration and a folded configuration, the support structure having a first end, a second end and a preformed fold between said first end and said second end, wherein said preformed fold at least assists in inverting said first portion into said second portion when said support structure is released from a delivery device, and a prosthetic valve structure including a hinged end hingedly attached to said support structure first end, thereby allowing said support structure first portion to invert into said support structure second portion without inverting said prosthetic valve structure.

**[0012]** Another aspect of the invention provides an implantable prosthetic valve structure with a support structure that has a folded configuration in which the prosthetic valve structure extends, at least partially, into said support structure.

**[0013]** Another aspect of the invention provide a prosthetic valve device that includes a support structure that has inwardly curved sidewalls when it is in a folded configuration.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0014]** These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

**[0015]** Figure 1 is a side view of an embodiment of the invention;

**[0016]** Figures 2A-2D illustrate a delivery sequence for the embodiment of Figure 1;

**[0017]** Figures 3A-F illustrate a delivery sequence for an embodiment of the invention;

**[0018]** Figure 4 is a side view of an embodiment of the invention;

- [0019] Figure 5 is a side view of an embodiment of the invention;
- [0020] Figure 6 is a side view of an embodiment of the invention;
- [0021] Figures 7A-D illustrate a delivery sequence for an embodiment of the invention;
- [0022] Figures 8A-D illustrate a delivery sequence for an embodiment of the invention;  
and

### DESCRIPTION OF EMBODIMENTS

[0023] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0024] Referring first to Figure 1 there is shown a device 10 of the invention. Device 10 generally includes a support structure 20, a valve assembly 40, and a connection 60 between the support structure 20 and the valve assembly 40. Figure 1 shows the device 10 in an elongate configuration prior to being compressed in order to fit within the lumen of a delivery catheter. It can be seen that the support structure 20, the valve assembly 40, and the connection mechanism 60 are all linearly arranged along a longitudinal axis in a series configuration, with no overlapping of components.

[0025] With regard to the support structure, a dotted line 22 represents a preformed fold created in the support structure 20 that at least partially causes the device 10 to fold inwardly on itself when released from a delivery catheter. The support structure 20 can be described as having a first end 24, a first portion 26 between the first end 24 and the preformed fold 22, a second end 30, and second portion 32 between the second end 30 and the preformed fold 22.

**[0026]** The valve assembly 40 includes tissue valve 42 attached to a wireform 40. The wireform 40 gives structural integrity to the tissue valve 44.

**[0027]** The connection 60 between the valve assembly 40 and the support structure 20 is described in more detail below.

**[0028]** Figure 2 shows the device 10 of Figure 1 in a fully expanded, delivered configuration. The device 10 has folded inwardly on itself such that the fold 22 is now defining the proximal end of the support structure 20. As the device 10 folded, the wireform 40, which contains a tissue valve 42, is drawn into the support structure 20. Because the first portion 26 is now inverted, in other words, it is inside-out in comparison to its prefolded configuration of Figure 1, the connection mechanism 60 must hinge or pivot in order to maintain the orientation of the valve assembly 40. Because the connection mechanism 60 hinges, when the first portion 24 inverts into the second portion 32, the valve assembly 40 moves only linearly (axially) into the support structure 20, as shown by the arrow 100 in Figure 2. Thus, only one preformed fold 22 is needed in the support structure 20 to allow the valve assembly 40 to maintain its orientation while moving axially.

**[0029]** Figure 3 shows an embodiment of a connection mechanism 60. The connection mechanism 60 may be a link 62 having two ring connectors 64 separated by a spacer 66. The spacer 66 is sized to ensure that, in the elongated configuration, the connection mechanism 60 adequately separates the support structure 20 from the valve assembly 40. The connection mechanism 60 may be constructed of a variety of bio-compatible material such as an alloy, including but not limited to stainless steel and Nitinol, or may be a polymer or other suitable non-metallic material.

**[0030]** Figure 4 shows another embodiment of a connection mechanism 60. This connection mechanism 60 may be a tether 70 having ends 72 that are tied to the wireform 44 of the valve assembly 40 and to the support structure 20. The tether may be constructed of any suture material or may be a wire having suitable flexibility to be tied in a knot. The length of the tether 70 between the tied ends 72 constitutes a spacer 74 that is sized to ensure adequate separation of the support structure 20 from the valve assembly 40 in the elongated configuration of Figure 1.

**[0031]** Figure 5 shows an embodiment of a connection mechanism 60 that is a single loop 80. The loop 80 extends around the wireform 44 and a strand of the support structure 20. The loop 80 is sized to ensure adequate separation of the support structure 20 from the valve assembly 40 in the elongated configuration of Figure 1.

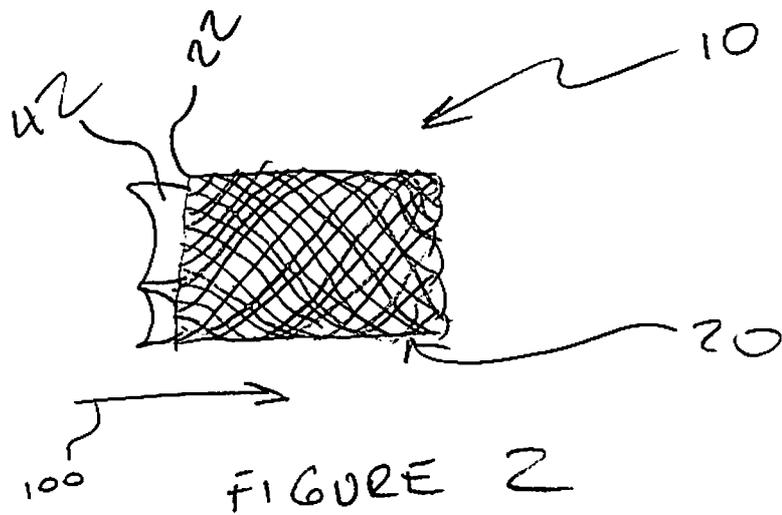
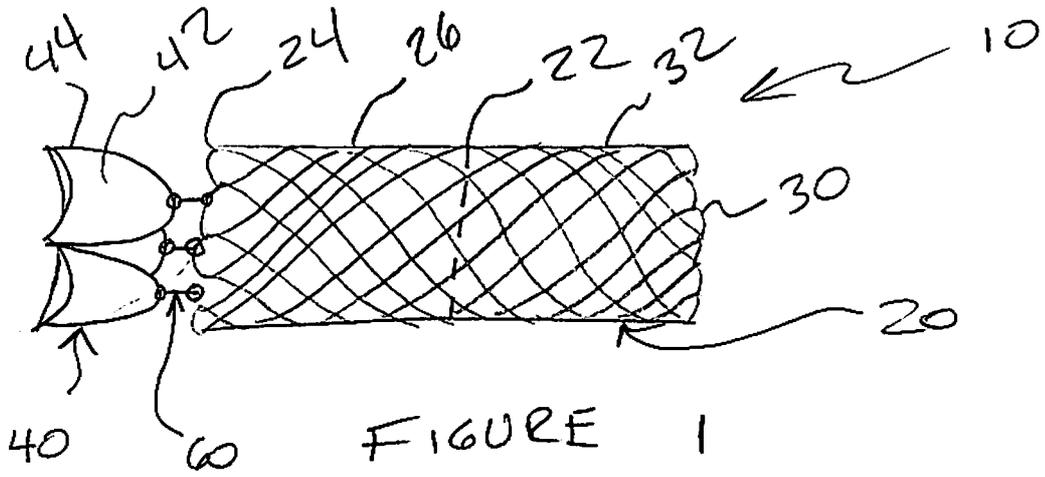
**[0032]** Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. An implantable device comprising:
  - a support structure having an extended configuration and a folded configuration and including:
    - a first end;
    - a second end;
    - a preformed fold between said first end and said second end;
    - a first portion between said first end and said preformed fold;
    - a second portion between said second end and said preformed fold;
  - wherein said preformed fold at least assists in inverting said first portion into said second portion when said support structure is released from a delivery device;
  - a prosthetic valve structure hingedly attached to said support structure first end, thereby allowing said support structure first portion to invert into said support structure second portion without inverting said prosthetic valve structure.
2. The implantable device of claim 1 wherein said hinged end is attached to said support structure first end with a connection mechanism.
3. The implantable device of claim 2 wherein said connection mechanism comprises a hinge.
4. The implantable device of claim 2 wherein said connection mechanism comprises a link.
5. The implantable device of claim 4 wherein said link comprises two ring connectors separated by a spacer.
6. The implantable device of claim 1 wherein, in said elongated configuration, said connection mechanism separates said support structure from said valve assembly.
7. The implantable device of claim 1 wherein said connection mechanism comprises a tether.

8. An implantable device comprising:
- a support structure having a first portion and a second portion separated from said first portion by a preformed fold;
  - a valve assembly;
  - a connection mechanism connecting said valve assembly to said first portion of said support structure;
- wherein said implantable device has a first configuration and a second configuration;
- wherein in said first configuration, said support structure is unfolded and said support structure, said valve assembly, and said connection mechanism are axially arranged;
- wherein in said second configuration, said first portion is inverted into said second portion and said valve assembly is drawn at least partially into said first portion by said connection mechanism.
9. The implantable device of claim 8 wherein said connection mechanism pivots such that said when said first portion inverts, said valve assembly does not invert.
10. The implantable device of claim 8 wherein said connection mechanism comprises a hinge.
11. The implantable device of claim 8 wherein said connection mechanism comprises a link.
12. The implantable device of claim 11 wherein said link comprises two ring connectors separated by a spacer.
13. The implantable device of claim 8 wherein, in said elongated configuration, said connection mechanism separates said support structure from said valve assembly.
14. The implantable device of claim 8 wherein said connection mechanism comprises a tether.

15. The implantable device of claim 14 wherein said tether comprises a first end tied to the support structure and a second end tied to the valve assembly.
16. The implantable device of claim 8 wherein said connection mechanism comprises a loop.
17. A method of delivering an implantable device comprising:  
arranging a first component, a connector, and a second component axially in a delivery catheter, said connector connecting said first component and said second component such that said first and second components do not overlap;  
releasing said first component, said connector, and said second component at a target site from said catheter;  
allowing said first component to fold into itself while said connector pivots, thereby drawing said second component axially toward said first component.
18. The method of claim 17 wherein allowing said first component to fold into itself comprises creating a preformed fold in said first component prior to arranging, and unfolding said preformed fold during said arranging step such that said preformed fold causes said first component to fold into itself when released.
19. The method of claim 17 wherein arranging a first component, a connector and a second component axially in a delivery catheter comprises arranging a support structure, a connector, and a valve assembly in a delivery catheter.
20. The method of claim 17 wherein arranging a first component, a connector, and a second component axially in a delivery catheter, said connector connecting said first component and said second component such that said first and second components do not overlap, comprises arranging said first component, said connector, and said second component axially in said delivery catheter such that said first component and said second component are spaced apart from each other.



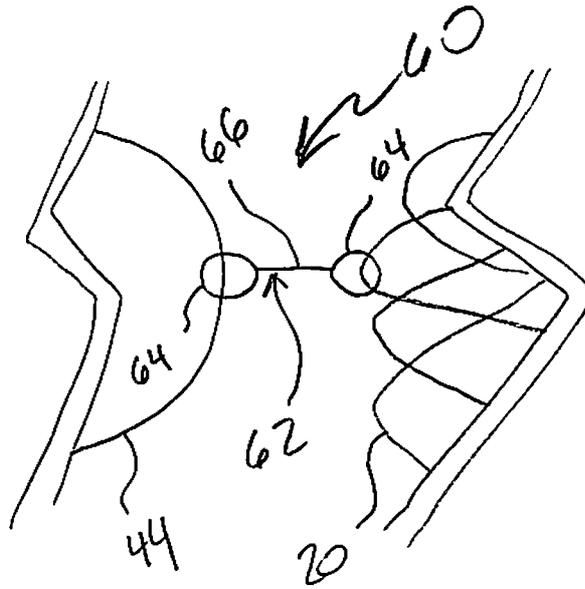


FIGURE 3

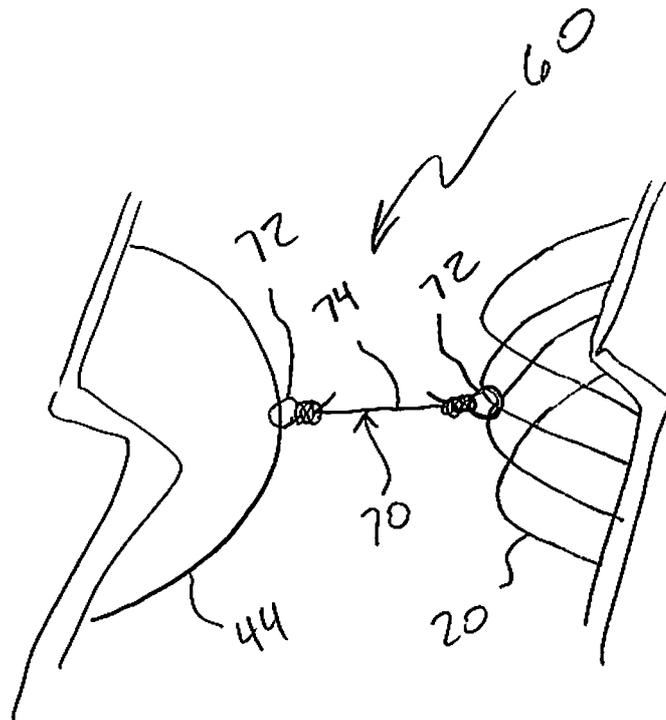


FIGURE 4

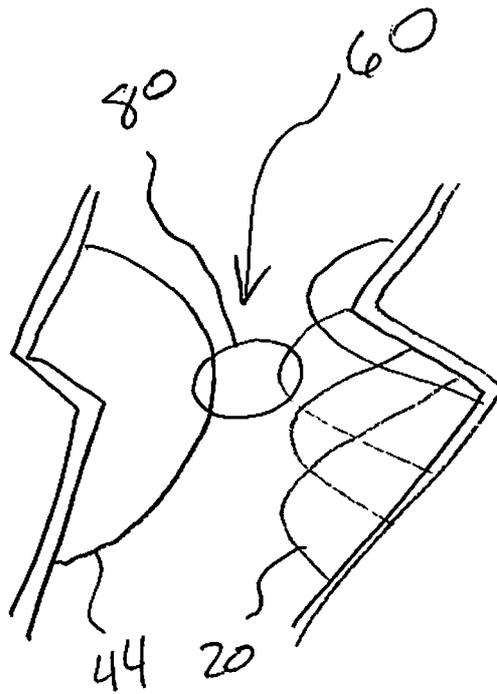


FIGURE 5

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC(8) - A61F 2/24 (2014.01) USPC - 623/1.26 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61F 2/24 (2014.01) USPC - 623/1.24, 1.26, 1.51, 1.53, 2.1, 2.11, 2.13, 2.14, 2.18, 900 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched CPC - A61F 2/2427 (2014.06) Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Delphion, Orbit, Google		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2012/0209370 A1 (THILL et al) 16 August 2012 (16.08.2012) entire document	1-20
A	US 7,267,686 B2 (DIMATTEO et al) 11 September 2007 (11.09.2007) entire document	1-20
A	US 8,021,420 B2 (DOLAN) 20 September 2011 (20.09.2011) entire document	1-20
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
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Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774