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United States Patent Application Publication

20250255719

Kind Code

A1

Publication Date

August 14, 2025

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METHOD FOR DEPLOYING A PROSTHETIC HEART VALVE

Abstract

A method for deploying an expandable prosthetic heart valve in a patient includes introducing a guidewire into a patient and advancing the guidewire through a vasculature of a patient to a deployment site. A distal end portion of a delivery apparatus and the prosthetic heart valve mounted in a radially compressed configuration on an expandable member of the distal end portion are advanced over the guidewire. The prosthetic heart valve is positioned at the deployment site. The expandable member is radially expanded, causing the prosthetic heart valve to radially expand to a radially expanded configuration. The prosthetic heart valve comprises an expandable metal frame and one or more leaflets attached to the frame, wherein the frame comprises a plurality of struts arranged to form two circumferentially extending rows of hexagonal shaped cells.

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Appl. No.: 19/192708

Filed: April 29, 2025

Related U.S. Application Data

parent US continuation 17460183 20210828 parent-grant-document US 12310851 child US 19192708

parent US continuation 16130726 20180913 parent-grant-document US 11103346 child US 17460183

parent US continuation 14880616 20151012 parent-grant-document US 10076412 child US 16130726

parent US continuation 14338001 20140722 parent-grant-document US 9161834 child US

14880616
parent US continuation 13910348 20130605 parent-grant-document US 8784480 child US
14338001
parent US continuation 12396378 20090302 parent-grant-document US 8460368 child US
13910348
us-provisional-application US 61032851 20080229

Publication Classification

Int. Cl.: **A61F2/24** (20060101); **A61F2/95** (20130101); **A61F2/97** (20130101)

U.S. Cl.:

CPC **A61F2/243** (20130101); **A61F2/2418** (20130101); **A61F2/2439** (20130101); **A61F2/95** (20130101); **A61F2/97** (20130101); A61F2/2412 (20130101); A61F2230/0076 (20130101); A61F2250/0008 (20130101); A61F2250/0029 (20130101); A61F2250/0036 (20130101); A61F2250/0059 (20130101)

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation of U.S. patent application Ser. No. 17/460,183, filed Aug. 28, 2021, which is a continuation of U.S. patent application Ser. No. 16/130,726, filed Sep. 13, 2018, now U.S. Pat. No. 11,103,346, which is a continuation of U.S. patent application Ser. No. 14/880,616, filed Oct. 12, 2015, now U.S. Pat. No. 10,076,412, which is a continuation of U.S. patent application Ser. No. 14/338,001, filed Jul. 22, 2014, now U.S. Pat. No. 9,161,834, which is a continuation of U.S. patent application Ser. No. 13/910,348, filed Jun. 5, 2013, now U.S. Pat. No. 8,784,480, which is a continuation of U.S. patent application Ser. No. 12/396,378, filed Mar. 2, 2009, now U.S. Pat. No. 8,460,368, which claims the benefit of U.S. Provisional Application No. 61/032,851, filed Feb. 29, 2008, all which are hereby incorporated by reference.

FIELD

[0002] The present invention relates generally to medical devices and methods. More particularly, the present invention provides minimally invasive methods and devices for percutaneous transcatheter implantation of expansible prosthetic heart valves within or adjacent a valved anatomic site within the heart.

BACKGROUND

[0003] When treating certain medical conditions, it is sometimes desirable to expand a frame or other radially expandable member in an orifice or conduit of a patient's body. For example, expandable tubes called stents are commonly inserted into a natural conduit of a patient's body and expanded inside the conduit to hold the conduit in an open position. Such expandable stents can be used to expand, widen, or otherwise provide structural support to various conduits of the human body, including, for example, arteries, veins, bile ducts, the esophagus, and the colon. In other treatment procedures, prosthetic heart valves that include a frame member are implanted into the body at a treatment site (e.g., a heart valve annulus). These prosthetic heart valves can be positioned in the heart valve annulus by expanding the frame member to roughly the size of the valve annulus.

[0004] Such frames or stents can be self-expanding or expanded using an expansion balloon. One conventional method involves positioning a frame on a balloon of a balloon catheter, maneuvering

the balloon and frame to the treatment site, and inflating the balloon with a fluid to expand the frame or stent to the desired size. Such an approach, however, can have drawbacks. For example, during the expansion of the balloon the orifice or conduit is usually at least partially, if not completely, occluded, which can cause certain undesirable effects. Accordingly, it is desirable to provide methods and delivery systems that eliminate or reduce these and other potential drawbacks.

SUMMARY

[0005] In the deployment of prosthetic devices in the aortic arch or in the intracranial arteries, blockage of the lumen by the balloon during the implantation process, even for a short period of time, can introduce complications to the medical procedure. The apparatuses and methods described in various embodiments herein can reduce and/or substantially eliminate the occlusion of the lumen (e.g., artery or other passageway) during expansion of a prosthetic device therein.

[0006] The apparatuses and methods described in various embodiments herein can prolong prosthetic device deployment time, eliminate pacing and its associated risks, as well as permitting repositioning of the prosthetic device during deployment.

[0007] In one embodiment, an apparatus for delivering a prosthetic device through the vasculature of a patient comprises an elongate shaft having a distal end and a radially expandable member coupled to the distal end of the elongate shaft. The expandable member can comprise a distal end portion and a proximal end portion that are movable relative to one another between a first orientation and a second orientation. A plurality of struts can be coupled to at least one of the distal end and proximal end portions of the expandable member and can have a prosthetic device receiving area. In the first orientation the distal end and proximal end portions are a first distance apart, and in the second configuration the distal end and proximal end portions are a second distance apart. The second distance can be less than the first distance. Movement of the distal end and proximal end portions from the first orientation to the second orientation can cause connecting members to expand radially outwards from a first configuration to a second configuration to expand the prosthetic device

[0008] In specific implementations, the expandable member can comprise a screw member that extends between the distal end portion and the proximal end portion, and rotation of the screw member can cause the distal end and proximal end portions to move from the first to the second orientation. In other specific implementations, the expandable member can comprise a wire that extends between the distal end portion and the proximal end portion, and movement of the wire can cause the distal end and proximal end portions to move from the first to the second orientation.

[0009] In other specific implementations, one or more of the plurality of struts can extend from the distal end portion to the proximal end portion. In other specific implementations, the expandable member can comprise a cover that at least partially surrounds the plurality of struts. In other specific implementations, the cover can be configured to open to permit fluid to flow through the expandable member from the distal end portion to the proximal end portion and to close to substantially prevent fluid from flowing through the expandable member from the proximal end portion to the distal end portion. In other specific implementations, the cover can have at least one slit near the proximal end portion to allow the cover to open.

[0010] In specific implementations, one or more of the plurality of struts can be configured to expand in a predetermined manner. In other specific implementations, one or more of the plurality of struts can have a notch at an internal face of a desired bending point to facilitate expansion of the expandable member in the predetermined manner.

[0011] In other specific implementations, some of the plurality of struts can extend from the distal end portion and some of the plurality of struts can extend from the proximal end portion. The prosthetic device can be removably coupled at a first end to the struts that extend from the distal end portion and at a second end to the struts that extend from the proximal end portion.

[0012] In another embodiment, an apparatus for delivering a prosthetic device through the vasculature of a patient comprises an elongate shaft having a distal end and a radially expandable

member coupled to the distal end of the elongate shaft. The expandable member can have an open frame configuration and an outer mounting surface for mounting the prosthetic device in a collapsed state thereon. The expandable member can be configured to expand radially outwards from a first configuration to a second configuration to expand the prosthetic device.

[0013] In specific implementations, the expandable member can comprise a screw member that extends between the distal end portion and the proximal end portion, and rotation of the screw member can cause the distal end and proximal end portions to move closer together and cause the plurality of struts to expand radially.

[0014] In other specific implementations, the expandable member can comprise a plurality of longitudinally extending struts that extend between a distal end portion and a proximal end portion. In other specific implementations, one or more of the plurality of struts are configured to expand in a predetermined manner.

[0015] In other specific implementations, the expandable member can comprise a cover that at least partially surrounds the plurality of struts. The cover can be configured to open to permit fluid to flow through the expandable member from the distal end portion to the proximal end portion and to close to substantially prevent fluid from flowing through the expandable member from the proximal end portion to the distal end portion. In specific implementations, the cover has at least one slit near the proximal end portion to allow the cover to open.

[0016] In another embodiment, a method for delivering a prosthetic device through the vasculature of a patient is provided. The method can comprise providing an expandable member at a distal end of an elongate shaft, coupling the prosthetic device to the plurality of struts, and expanding the expansion device from a first configuration to a second configuration to expand the prosthetic device. The expandable member can have plurality of struts that form an open frame configuration.

[0017] In other specific implementations, the expandable member can comprise a plurality of struts that extend from a distal end portion of the expandable member to a proximal end portion of the expandable member and the method can further comprise the act of reducing the distance between the distal end portion and the proximal end portion to cause the plurality of struts to radially expand.

[0018] In other specific implementations, at least some of the plurality of struts can extend from a distal end portion of the expandable member and at least some of the plurality of struts extend from a proximal end portion of the expandable member, and the prosthetic device can be releasably coupled at a first end to the struts that extend from the distal end portion and at a second end to the struts that extend from the proximal end portion. The method can further comprise releasing the prosthetic device from the plurality of struts. In other specific implementations, after expanding the prosthetic device, the expandable member can be collapsed back to the first configuration and retracted from the body.

[0019] The foregoing and other advantages of the various embodiments disclosed herein will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1 is a perspective view of an expandable member for implanting a prosthetic device within the body.

[0021] FIG. 2 is a side view of the expandable member of FIG. 1.

[0022] FIG. 3 is an end view of the expandable member of FIG. 1.

[0023] FIG. 4 is a side view of a portion of an expandable member.

[0024] FIG. 5 is a view of an expandable member, shown in a collapsed configuration and with

portions removed for clarity.

[0025] FIG. **6** is a view of an expandable member, shown in a partially collapsed configuration and with portions removed for clarity.

[0026] FIG. **7** is a view of an expandable member, shown in an expanded configuration and with portions removed for clarity.

[0027] FIG. **8** is a cross-sectional view of a delivery system with an expandable member.

[0028] FIG. **9** is a partial cross-sectional view of a delivery system with an expandable member and a prosthetic device mounted thereon.

[0029] FIG. **10** is a view of a delivery system with an expandable member and a prosthetic device mounted thereon, shown with a cover and with the expandable member in an expanded configuration.

[0030] FIG. **11** is a partial cross-sectional view of an expandable member with a cover at least partially surrounding the expandable member.

[0031] FIG. **12** is a view of an expandable member with a cover at least partially surrounding the expandable member, with the cover shown in an open configuration.

[0032] FIG. **13** is a partial cross-sectional view of a prosthetic device being expanded within the body by an expandable member.

[0033] FIG. **14** is a view of a delivery system with an expandable member, shown with a prosthetic device mounted thereon.

[0034] FIG. **15** is a view of a delivery system with an expandable member and prosthetic device mounted there, shown in an expanded configuration.

[0035] FIG. **16** is a view of a delivery system with an expandable member at a treatment site in the body, with a prosthetic device shown in an expanded configuration.

[0036] FIG. **17A** is a delivery system with an expandable member and a collapsed prosthetic device mounted thereon.

[0037] FIG. **17B** is a cross-sectional view taken at line **17B-17B** of FIG. **17A**.

[0038] FIG. **18** is a view of a strut of an expandable members and a connection means for connecting the strut to a prosthetic device.

[0039] FIG. **19** shows a view of an anchoring device.

[0040] FIG. **20** shows a view of the anchoring device of FIG. **19** positioned within the body to hold a prosthetic device in position relative to the anchoring device.

[0041] FIG. **21A** shows a cross-sectional view of a delivery system with the anchoring device shown in FIG. **19**, with the anchoring device shown in a non-deployed state.

[0042] FIG. **21B** shows a cross-sectional view of a delivery system with the anchoring device shown in FIG. **19**, with the anchoring device shown in a deployed state.

[0043] FIG. **22** shows an illustration of a delivery system that has an expandable member that is deployable by a ratchet mechanism.

[0044] FIG. **23** shows an illustration of a shaft suitable for use with the delivery system of FIG. **22**.

[0045] FIG. **24** shows an illustration of a mechanism for use with a delivery system of the type shown in FIG. **22**.

[0046] FIG. **25** shows an illustration of a delivery system with an expandable member that is operable using an actuation device positioned adjacent the expandable member.

DETAILED DESCRIPTION

[0047] The following description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Various changes to the described embodiment may be made in the function and arrangement of the elements described herein without departing from the scope of the invention.

[0048] As used in this application and in the claims, the singular forms “a,” “an,” and “the” include the plural forms unless the context clearly dictates otherwise. Additionally, the term “includes” means “comprises.” Further, the terms “coupled” and “associated” generally means electrically,

electromagnetically, and/or physically (e.g., mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items. [0049] Although the operations of exemplary embodiments of the disclosed method may be described in a particular, sequential order for convenient presentation, it should be understood that disclosed embodiments can encompass an order of operations other than the particular, sequential order disclosed. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Further, descriptions and disclosures provided in association with one particular embodiment are not limited to that embodiment, and may be applied to any embodiment disclosed.

[0050] Moreover, for the sake of simplicity, the attached figures may not show the various ways (readily discernable, based on this disclosure, by one of ordinary skill in the art) in which the disclosed system, method, and apparatus can be used in combination with other systems, methods, and apparatuses. Additionally, the description sometimes uses terms such as “produce” and “provide” to describe the disclosed method. These terms are high-level abstractions of the actual operations that can be performed. The actual operations that correspond to these terms can vary depending on the particular implementation and are, based on this disclosure, readily discernible by one of ordinary skill in the art.

[0051] In certain embodiments, the delivery systems and methods disclosed herein can be used to deploy a frame member or stent without an expansion balloon. Thus, many of the difficulties associated with the use of such expansion balloons for delivering intraluminal devices, particularly intravascular devices, can be avoided or substantially eliminated. The delivery systems and methods disclosed herein can be substantially the same as those used in traditional methods, except that the expansion of the prosthetic devices can be achieved by effecting relative movement between mechanical elements, rather than by the expansion and contraction of a balloon member.

[0052] FIGS. 1-3 disclose an illustrated embodiment of an expandable member (expandable basket) **100** with an open-frame configuration. Expandable member **100** can comprise a plurality of longitudinally-extending, circumferentially-spaced struts **102** terminating and joined together at opposite ends of the expandable member. As shown in FIG. 1, for example, struts **102** can extend between the distal end **104** and proximal end **106** of the expandable member **100**. Struts **102** can be formed of a variety of materials and in a variety of shapes, as long as the shape and structure is sufficiently strong to cause expansion of a prosthetic device, as described in more detail below. For example, each strut **102** can be formed of a tubular structure of elastic material, such as stiff plastic or metal. In addition, the expandable member **100** can be formed of a variety of number of struts **102**, so long as the struts are of sufficient number, strength, and/or shape so as to provide sufficient force to surfaces and/or contact points of the prosthetic device to expand the device as described herein.

[0053] The plurality of struts **102** can define an annular supporting surface for an expandable intraluminal device to be delivered. Each strut **102** in the annular array can be laterally deformable to radially expand or radially contract the annular array of struts **102**, and the annular supporting surface defined by them.

[0054] The expandable member **100** can be expandable between a first or non-expanded configuration (FIG. 5) to a second or expanded configuration (FIG. 1). The expandable member **100** is desirably configured so that shape defined by the annular supporting surface of the expandable member in its expanded configuration (FIG. 1) is substantially predetermined and known. Thus, when the expandable member **100** is expanded, the annular supporting surface of the expandable member **100** will push against the prosthetic device mounted thereon to expand the prosthetic device to a predetermined shape (i.e., a shape that is complementary to the shape of the expandable member **100** in its expanded configuration).

[0055] The expandable member **100** can be configured so that it will expand to a predetermined expanded configuration in a variety of ways. For example, struts **102** can be pre-formed or “heat-

set” into a desired expanded configuration prior to deployment. The pre-formed struts **102** of perfusion basket **100** may then be stretched down or collapsed into a deployable configuration. By pre-forming struts **102** in this manner, upon expansion of the expandable member **100**, the struts **102** will conform to the predetermined shape into which they have been pre-formed.

[0056] Alternatively, or in addition to pre-forming struts **102**, struts **102** may each include at least one notch **108** formed at an internal face of a desired bending point **110** on struts **102**. Notching the appropriate bending points **110** as shown in FIG. 4, facilitates the bending of struts **102** and can provide greater control over the shape of the expandable member **100** during deployment. Also, notches **108** can allow the struts **102** to be deployed using less actuating (e.g., compressive) force. The size and depth of notches **108** can vary depending on the strength to formability ratio desired for each strut **102**.

[0057] A variety of different mechanisms can be used to expand and/or collapse expandable member **100**. In one embodiment, as shown in FIGS. 5-7, the mechanism for expanding and/or collapsing the expandable member **100** can comprise a screw mechanism **120** configured to apply a longitudinal force to expand or collapse expandable member **100**. For clarity, FIGS. 5-7 illustrate expandable member **100** with all but one strut **102** removed. Referring to FIG. 5, a prosthetic device (not shown) can be mounted on the expandable member **100** while it is in a collapsed configuration. Then the expandable member **100** can be expanded from the collapsed configuration to the expanded configuration shown in FIG. 7. FIG. 6 illustrates a partially collapsed configuration, which the expandable member **100** can pass through during expansion of the expandable member **100**. Alternatively, the partially collapsed configuration (FIG. 6) can be the initial configuration of the expandable member **100**. In other words, the expandable member **100** can be expandable from any first configuration (e.g., the completely collapsed configuration of FIG. 5, the partially collapsed configuration of FIG. 6, or another partially collapsed configuration) to a second, expanded configuration (e.g., FIG. 7).

[0058] When in the lowest profile configuration (i.e., the initial collapsed or partially collapsed configuration), the proximal end **106** of the expandable member **100** and the distal end **104** of the expandable member are furthest apart and screw mechanism **120** is in an extended position. To expand the expandable member **100** and deploy the prosthetic device mounted thereon, the expandable member **100** can be expanded by actuating an external mechanism. Actuation of the external mechanism (for example, rotation of actuating member **130** on an external handle as shown in FIG. 8) causes screw mechanism **120** to rotate about the longitudinal axis of the expandable member **100**, as shown by arrow **122** in FIG. 7. As shown in FIG. 8, screw mechanism **120** can have an externally threaded portion **136** that is received in an internally threaded portion **134** of distal end **104**. The rotation of screw mechanism **120** causes the externally threaded portion **136** of screw mechanism **120** to extend further into the internally threaded portion **134** of distal end **104**, causing distal end **104** to move toward proximal end **106**. As the distance between the two ends of the expandable member **100** shortens, struts **102** are axially compressed (as shown by arrows **121**, **124**) and forced to radially expand (FIG. 7).

[0059] After the prosthetic device is expanded, the expandable member **100** can be collapsed back to a lower profile configuration for removal from the treatment site through the patient's vasculature. To return expandable member **100** to the collapsed configuration (FIG. 5) or partially collapsed configuration (FIG. 6), the rotation of screw mechanism **120** can be reversed, causing the distance between the proximal end **106** and distal end **104** of the expandable member **100** to increase and the struts to radially contract.

[0060] FIG. 8 illustrates an embodiment of a delivery system that comprises an expandable member **100** at a distal end. A rotatable actuating member **130** can be coupled to the screw mechanism **120**. Screw mechanism **120** can extend longitudinally through one or more shafts **132** and attach to a distal end of expandable member **100**. As discussed above, distal end **104** of expandable member **100** is preferably coupled to an internally threaded member **134** that is in

threaded engagement with an externally threaded portion **136** of screw mechanism **120**. Rotation of actuating member **130** causes screw mechanism **120** to rotate, shortening the distance between the proximal end **106** and distal end **104** of expandable member **100** as discussed above.

[0061] FIG. **9** illustrates an exemplary embodiment of a delivery system **150** for deploying a prosthetic device **152** using expandable member **100**. Prosthetic device **152** can be any expandable intraluminal device, such as an expandable prosthetic heart valve. In this exemplary embodiment, delivery system **150** can include an outer member (shaft) **154** and an inner member (shaft) **156**, with outer member **154** coaxially disposed around inner member **156**. Outer member **154** and inner member **156** can be made from any number of suitable materials, such as a polymeric or metallic material.

[0062] Inner member **156** can comprise an expandable member **100** attached near the distal end of inner member **156**. Inner member **156** can also have a guide wire lumen so that the delivery system **150** can be advanced over a guide wire **158**, with the guide wire passing through the lumen. Guide wire **158** can be introduced into a body lumen and guided to the proper location in accordance with the conventional methods that used with balloon-type catheters. The expandable member **100** and prosthetic device **152** can track the guide wire **158** to the target location for deployment of the prosthetic device **152**.

[0063] FIG. **9** shows struts **102** of the expandable member **100** in a substantially unexpanded configuration. FIG. **9** illustrates the expandable member **100** in a partially collapsed configuration (as shown in FIG. **6**); however, as discussed above, expandable member **100** could be further collapsed (as shown in FIG. **5**) to achieve a lower profile configuration. Prosthetic device **152** is shown mounted on the outer surfaces of struts **102**, which collectively define an annular surface for receiving prosthetic device **152** in a contracted state. As shown in FIG. **9**, expandable member **100** can be collapsed into and constrained by the distal end of outer member **154**, which forms a sheath extending over the valve. Thus, prosthetic device **152** can be constrained and/or positioned in a contracted condition between outer member **154** and the annular surface defined by struts **102**. Prosthetic device **152** can be maneuvered through the patient's vasculature to the treatment site while mounted on expandable member **100**, as shown in FIG. **9**.

[0064] Alternatively, as described in U.S. Patent Publication No. 2008/0065011 and U.S. patent application Ser. No. 12/247,846, the prosthetic device **152** can be initially mounted in a collapsed (crimped) state at a location that is either distal or proximal to expandable member **100**. The entire disclosures of U.S. Patent Publication No. 2008/0065011 and U.S. patent application Ser. No. 12/247,846 are incorporated by reference herein. After the prosthetic device is advanced through narrow portions of the patient's vasculature (for example, the iliac artery which is typically the narrowest portion of the relevant vasculature), the prosthetic device can be positioned on (or over) the expandable member **100**. If the prosthetic device has not yet been advanced to the deployment site when the expandable member is repositioned underneath the prosthetic device, then the prosthetic device and expandable member can be advanced to the treatment site together and the expandable member can be expanded to deploy the prosthetic device at the treatment site. In this manner, prosthetic device can be crimped to an even smaller diameter and the profile of the delivery system can be further reduced.

[0065] Once the prosthetic device **152** and expandable member **100** reach the desired deployment location, outer member **154** can be retracted proximally, exposing the prosthetic device **152** for deployment. FIG. **10** illustrates the expandable member **100** in an expanded configuration after the outer member **154** has been retracted relative to the expandable member **100**. The expansion of expandable member can be caused (as discussed above) by actuating screw mechanism **120** to compress the expandable member **100** longitudinally and force struts **102** to expand radially. As shown in FIG. **10**, the delivery system can have an actuating member **130** positioned on or around an external handle member **128**. External handle member **128** can have visual indicia **131** which indicate the amount of expansion of expandable member. The rotation of the actuating member **130**

(as discussed above, for example, with regard to FIG. 8) forces struts 102 on expandable member 100 to longitudinally contract and radially expand, causing prosthetic device 152 to be expanded and anchored at the target location.

[0066] The delivery system 150 shown in FIGS. 9 and 10 desirably also comprises a cover 160 that at least partially surrounds expandable member 100. As shown in FIGS. 11 and 12, cover 160 can be disposed over a working length (prosthetic device mounting area) 162 of the expandable member 100, with cover 160 extending the length of prosthetic device 152 and over a proximal end portion 164 of expandable member 100. For clarity, FIG. 11 shows cover 160 partially cut-away, showing the location of struts 102 beneath cover 160 at the working length 162 and proximal end portion 164. Desirably, distal end portion 166 remains uncovered as shown in FIG. 11. Cover 160 is desirably attached to the outer surface of struts 102 along the working length 162. Cover 160 is desirably includes one or more slits 170 and is at least partially detached from the outer surface of struts 102 at proximal end portion 164.

[0067] Slits 170 can be arranged approximately 120 degrees about the circumference of cover 160 at proximal end portion 164. Slits 170 allow proximal end portion 164 of cover 160 to act as temporary leaflets 168, which may open (second configuration) when fluid flows through expandable member 100 from the distal end 104 to the proximal end 106 as indicated by arrows 172 (FIGS. 10 and 12) and close (first configuration) as when fluid tries to pass through expandable member 100 from the proximal end 106 to the distal end 104 as indicated by arrows 174 (FIG. 11).

[0068] By providing a cover 160 that permits fluid flow in one direction, but restricts it in the other, the delivery system can mimic a native valve while the prosthetic device 152 is being deployed. In conventional systems, for example, a balloon member can occlude the orifice (such as the aortic valve) causing difficulties. The pressure drop across the aortic valve when the valve is closed and the flow across the valve (~5 L/min) is so great that occlusion of the annulus may result in the ventricle ejecting the occluding member (e.g., expandable balloon) into the aorta. By permitting flow through the expandable member, pressure build-up during prosthetic device deployment can be avoided.

[0069] Also, by allowing fluid to flow through the orifice during deployment of the prosthetic device, the need for pacing the heart can be reduced or entirely eliminated. Although current pacing procedures are effective, they still require rapid deployment of prosthetic devices. For example, in certain procedures, the prosthetic device should be deployed in about 3 to 5 seconds. Since the deployment systems described herein permit flow across the orifice during deployment of the prosthetic device, the prosthetic device can be deployed more slowly, and can be repositioned and/or moved by an operator during deployment. In contrast, pacing procedure do not generally allow for any repositioning or movement of the prosthetic device during deployment. Additionally, by eliminating pacing, the procedure can be greatly simplified and variations in patient anatomy and systems (e.g., ventricular pressure and flow) for the purpose of pacing need not be considered.

[0070] FIG. 13 illustrates a specific embodiment where the prosthetic device 152 is a prosthetic heart valve that is to replace the native aortic valve. The embodiments disclosed herein permit blood to flow from the left ventricle 182 through the expandable member 100 and into the aorta 184. As the prosthetic device 152 is moved into position at the aortic annulus 180, blood can flow from the left ventricle 182 through the aortic annulus 180 into the aorta 184 (as shown by arrow 185). However, when the flow of blood is reversed, cover 160 closes (as shown in FIG. 11) and at least substantially blocks blood from flowing from the aorta 184 back into the left ventricle 182. Thus, while prosthetic device 152 is being deployed cover 160 (and its leaflets 168) open (as shown in FIGS. 10, 13, and 13) allowing blood to flow into the aorta. When the ventricles finish contracting and begin to relax, however, cover 160 (and its leaflets 168) move against struts 102 at the proximal end portion 164 (FIG. 11) and substantially prevent blood from flowing back into the left ventricle.

[0071] Cover **160** can also provide protection to flexible membranes or other components of the expandable prosthetic device to be delivered by forming a barrier between struts **102** and the prosthetic device during delivery and deployment of the prosthetic device at the treatment site. Cover **160** can be formed of any suitable material, including, for example urethane and the like. Moreover, instead of the slits **170** and leaflets **168** shown in the illustrated embodiments, cover **160** can comprise any suitable shape and configuration, so long as that shape and configuration is suitable to restrict flow in one direction and permit flow in the other direction during placement and deployment of the prosthetic device.

[0072] Various prosthetic devices are suitable for deployment with the delivery systems disclosed herein, including, for example, heart valves that comprise expandable frame members and one or more leaflet members attached to the expandable frame members. After deployment of the prosthetic device, the expandable member can be radially contracted as discussed above and the expandable member can be retracted from the body.

[0073] In other embodiments, the prosthetic device itself can comprise at least a portion of the expandable member. FIG. **14** is an illustration of a delivery system **200** where the open-frame expandable member comprises a prosthetic device. In the illustrated embodiment, delivery system **200** comprises an implantable prosthetic device **202** (hereinafter “valve **202**”) that is suitable for percutaneous deployment and that is releasably coupled to expansion struts **216** to form an expandable member. Valve **202** is preferably adapted to be radially crimped and radially expanded, which simplifies navigation through the narrow passages of the patient's vasculature during delivery and positioning of valve **202**. Valve **202** preferably also comprises a flexible membrane **204** and a collapsible support structure (frame) **206**.

[0074] After deployment at a treatment location, flexible membrane **204** can be positioned in a flow path through valve **202** to permit flow in a first direction, and substantially resist flow in a second direction. In one embodiment, flexible membrane **204** can include a collapsible pliant material formed as flexible leaflets **208**, which can be arranged to collapse in, for example, a mono cusp, bicuspid, or tricuspid arrangement.

[0075] In the illustrated embodiment, collapsible support structure **206** can be expandable from a first diameter to a second diameter, and can have a flow path through the collapsible support structure **206** along its structural axis. Collapsible support structure **206** can include a generally cylindrical expandable framework of frame members **210**, which primarily secure valve **202** at or adjacent to the defective valve annulus. Collapsible support structure **206** can provide stability to the valve **202** and help to prevent valve **202** from migrating after it has been implanted.

[0076] Prosthetic valves of this type are usually implanted in one of the channels of the body to replace a native valve. In the illustrated embodiment, the prosthetic valve will be explained in connection with a cardiac valve prosthesis configured for implantation at the aortic annulus; however, it should be understood that the delivery systems disclosed herein can be used with other expandable members and prosthetic devices.

[0077] Collapsible support structure **206** may be a support stent configured to crimp evenly so as to present a relatively low profile or narrow configuration. The collapsible support structure **206** can also be radially deployable from the low profile configuration so as to extend to occupy the passage at the target location for implantation in a body duct. In one embodiment, collapsible support structure **206** can comprise a series of frame members (struts) **210** arranged and connected to define a geometrical structure that causes collapsible support structure **206** to expand radially as the structure is compressed axially. For example, frame members **210** can define substantially diamond shaped cells **212** that when axially compressed force collapsible support structure **206** to expand radially. Valve **202** can be releasably coupled to connecting struts (linkages) **216** at attachment areas **214** located at proximal and distal ends of valve **202**.

[0078] In operation, a delivery catheter advances valve **202** while coupled to expansion struts **216** through a sheath over a guidewire to a target location in a body duct, for example, the aortic valve.

As shown in FIG. 14, when in a collapsed position, connecting struts 216 can be disposed substantially axially relative to the deployment system. To expand valve 202, the distance between distal end 104 and proximal end 106 can be shortened by rotating screw mechanism 120. As discussed above, the rotation of screw mechanism causes distal end 104 to move closer to proximal end 106, which forces connecting struts 216 to extend radially. To facilitate the radial expansion of connecting struts 216, the connecting struts can have hinge or bend areas 217, about which the connecting struts bend. These bend areas can be pre-formed or notched, or otherwise configured so that connecting struts 216 will radially extend at the bend area 217 when they are axially compressed.

[0079] Because connecting struts 216 are connected to frame members 210 at attachment areas 214, the radial expansion of connecting struts 216 applies radially directed forces to the valve 202 via frame members 210. The radially movement of connecting struts 216 causes valve 202 to radially expand (deploy). As shown in FIG. 16, once valve 202 begins to expand, leaflets 204 may be immediately activated and begin to regulate flow through the annulus. Once valve 202 is completely deployed, connecting struts 216 may be disengaged from attachment areas 214 and removed from the target location.

[0080] In a specific implementation shown in FIGS. 17A, 17B, and 18, connecting struts 216 can be pivotably coupled to a portion of annular members 230, 232 at pivot connection areas (bending areas) 234. For example, in one embodiment, the proximally located connecting struts can be coupled to a first annular member 230 at the proximal end and distally located connecting struts can be coupled to a second annular member 232 at the distal end. Annular members 230 and 232 can comprise a plurality of adjacent, circumferentially spaced extending members 236 with spaces located between adjacent extending members 236 for receiving connecting struts 216. Connecting struts 216 can be positioned and captured between extending members 236 and configured to pivot or bend about pivot connection area 234. A ring member 219 can pass through each of the connecting struts 216 to hold each connecting strut 216 in position at one of the annular members 230 and 232.

[0081] In this and in the other embodiments, the number of connecting struts 216 can vary. For example, FIG. 17B illustrates four circumferentially spaced connecting struts 216; however, more or fewer connecting struts 216 can be used, so long as the outwardly directed force generated by the connecting struts 216 as they undergo compression is sufficient to expand valve 202 from an unexpanded configuration with a smaller diameter to an expanded configuration with a greater diameter. In the illustrated embodiment, FIG. 17B shows eight different locations between extending members 236 into which connecting struts 216 can be located.

[0082] Relative movement of annular members 230 and 232 can be caused by a screw mechanism or other axially applied forces (as described in more detail above), causing connecting struts 216 to expand radially. To expand valve 202 uniformly, it can be desirable to space connecting struts 216 annularly around annular members 230 and 232. In addition, it may be desirable to connect struts 216 to the valve at areas where the valve has structural supports or posts so that the valve has sufficient rigidity at the area where struts 216 contact valve 202.

[0083] Various means for attaching connecting struts 216 to valve 202 can be used. For example, connecting struts 216 can have a first end pivotably coupled to annular members 230 and 232, and a second end that comprises a securing mechanism for securing the valve 202 to the connecting strut as shown in FIG. 18. For example a wire member 238 can pass through connecting strut 216 and a portion of the valve 202 can be captured between wire 238 and a holding area 240 of connecting strut 216 (e.g., wire member 238 can pass through a loop or opening formed in one of struts 210 and positioned in area 240). The valve 202 can be released from connecting strut 216 by pulling wire 238 towards a proximal end (in the direction of arrow 242) a distance great enough to release valve 202 from the holding area 240.

[0084] FIGS. 19-21 show an embodiment of an expandable anchoring device 300 that can be used

to hold a valve **302** in a desired position during deployment of valve **302**. As shown in FIG. **19**, anchoring device **300** can include a plurality of flexible members, or fingers, **304**. These flexible members **304** can be used to anchor the delivery system in place during deployment of valve **302**. As shown in FIG. **20**, for example, during deployment of a prosthetic device (valve **302**) at an aortic annulus, flexible members **304** can be expanded in the left ventricle, where flexible members **304** can be configured to contact a portion of tissue surrounding the native aortic valve **310**. Once deployed, anchoring device **300** can fix the position of valve **302** relative to the native valve **310**. Thus, valve **302** can then be expanded in the native valve **310** without concern for positioning error caused by, for example, movement of the beating heart or the blood pressure through the native valve **310**.

[0085] In addition, anchoring device **300** can help hold the valve in the proper position by preventing the delivery system from moving proximally during deployment. For example, after expansion of anchoring device **300** within the left ventricle, the delivery system can be moved proximally until the anchoring device **300** contacts the ventricle walls near the aortic annulus, effectively preventing the delivery system from moving any further proximally. After the anchoring device **300** secures the relative position of the prosthetic device (valve), the prosthetic device can be expanded at the aortic annulus.

[0086] Referring to FIGS. **21A** and **21B**, the anchoring device **300** can be delivered to the treatment site (or anchoring location) constrained in an outer member (cover) **314**. To deploy anchoring device **300**, outer member **314** can be retracted, exposing flexible members **304**. Flexible members **304** can be biased outwards and upon retraction of the cover member **314**, flexible members **304** radially expand and can be placed in contact with tissue near the native annulus **310**. The expandable portion of the anchoring device can be formed in a variety of shapes. For example, if desired, flexible members **304** can be replaced with an expandable braided cup. After positioned appropriately, valve **302** can be expanded using a member **315**, which can be, for example, an expandable member as described herein or a balloon member.

[0087] To remove anchoring device **300** from the treatment location, a retraction collar **308** can be utilized to “recapture” flexible members **304**. In one embodiment, a pull wire **312** can be attached to a collar **308** that is located near the distal ends of flexible members **304** of anchoring device **300**. By pulling pull wire **312** proximally, the collar **308** can move proximally over flexible members **304**, causing them to radially collapse along the axis of the delivery system. Once collapsed, the anchoring device **300** can be removed from the treatment site by being retracted from the body through a catheter of the delivery system.

[0088] Screw mechanism **120** is a particularly desirable mechanism for expanding the expandable member, since it can provide significant compressive force at a local area (e.g., the expandable member), thereby forcing the expandable member to radially expand without imparting significant forces throughout other locations of the delivery system. However, as discussed above, other mechanisms for expanding the expandable member can be utilized. For example, FIG. **22** illustrates another embodiment of a deployment system where the distance between the distal end **104** and proximal end **106** of an expandable member **100** can be adjusted to expand a valve or other prosthetic device.

[0089] In this embodiment, the distance between the two ends of the expandable member can be adjusted by applying a longitudinal (non-rotational) force the length of the deployment system **400**. As with the other deployment systems described herein, deployment system **400** can be used for delivering a prosthetic device, such as a heart valve, but is not limited thereto, and may be adapted to stent delivery systems as well. In one embodiment, deployment system **400** can include a shaft **402** that can track through the vasculature and yet have sufficient “longitudinal” compressive strength to allow a wire or cable **404** to be pulled through a center lumen defined through shaft **402** with sufficient force to deploy, for example, expandable member **100** (shown with some struts **102** removed for clarity).

[0090] In one embodiment, one end of wire **404** extends through expandable member **100** and is coupled to distal end **104** of expandable member **100**. A proximal end of wire **404** is operatively coupled to a handle **406** to interface with a ratcheting mechanism **420** (shown in FIG. **24**).

[0091] Ratcheting mechanism **420** may be activated, for example, by gripping and squeezing handles **408** and **410** (FIG. **22**) to cause wire **404** to be pulled proximally through the center lumen of shaft **402** and locked into place by opposing locking wheels **422**, **424** (FIG. **24**) in a manner well known by those of ordinary skill in the art. Other locking elements **439** can be provided to at least temporarily secure the position of wire **404** relative to shaft **402**. A release knob **412** may also be included on handle **406** and used to release locking wheels **422**, **424** and the tension on wire **404** as desired.

[0092] FIG. **23** is a cross sectional view along the longitudinal length of flexible shaft **402**. In one embodiment, flexible shaft **402** is composed of a circular cross section closed wound coil **430** interposed with a triangular cross section closed wound coil **432**. Each coil **430** and **432** is confined within a tubular cover **434**, which can be made of vinyl or a similar material. Coils **430** and **432** define a lumen extending the length of flexible shaft **402** with wire **404** disposed therein.

[0093] In operation, once expandable member **100** is positioned as desired in the vasculature, ratcheting mechanism **420** of handle **406** can be activated. Ratcheting mechanism **420** pulls proximally (in the direction of arrow **438**) on wire **404**, this in turn, pulls distal end **104** of expandable member **100** toward proximal end **106** to cause expandable member **100** to “deploy” in a manner previously described. The resulting force (shown by arrow **440**) used to pull on wire **404** is transferred to shaft **402**, which is configured to absorb the compressive load and resist compression (shown by arrow **442**) without significant buckling or shape distortion of shaft **402**.

[0094] Since shaft **402** provides a stable mounting platform, in an alternative embodiment, instead of deploying expandable member **100** by pulling on wire **404**, a rotation actuator **450** can be used. Advantageously, since rotation actuator **450** is mounted to a “rigid” platform, the twisting actuation is acceptable.

[0095] The mechanisms described herein can also be actuated by a variety of power sources. For example, the screw mechanisms described above can be actuated using a power source such as a motor or battery. In the illustrated embodiment shown in FIG. **25**, a rotation actuator **450**, such as DC motor or equivalent, is coupled to the distal end **452** of shaft **402**. In this embodiment, rotation actuator **450** may be coupled to a drive shaft **454**, such as a threaded rod. Drive shaft **454** can be operatively engaged with a threaded receptacle **456** positioned on a distal end **104** of expandable member **100** (some struts **102** removed). Operationally, rotation actuator **450** makes drive shaft **454** rotate causing threaded receptacle **456** to traverse linearly upon drive shaft **454**. The linear movement of threaded receptacle **456** toward proximal end **106** causes distal end **104** to move toward proximal end **106** to deploy expandable member **100**.

[0096] In one embodiment, a gear reduction mechanism **460** can be added to rotation actuator **450** to create a higher output torque and also allow for fine tuning of the placement procedure. It should be understood that variations in motor voltage (DC only), gearbox ratios, and screw thread pitch may be used to obtain the required or desired torque needed to deploy expandable member **100**.

[0097] The apparatuses and methods described herein can improve what currently is one of the most critical stages of the deployment procedure by allowing a physician to more accurately position and deploy a prosthetic device without disrupting patient hemodynamics.

[0098] Although the specific embodiments discussed above describe methods and apparatuses for expanding various prosthetic devices, it should be understood that the devices and methods disclosed herein can be used for other purposes. For example, the expandable members disclosed herein can be used to replace expandable balloon members in a variety of medical procedures. Thus, the expandable members described herein can be used, for example, for angioplasty (e.g., opening clogged coronary arteries), valvuloplasty (e.g., dilating a stenotic heart valve), and other procedures in which expanding balloon members are conventionally utilized.

[0099] The invention has been disclosed in an illustrative manner. Accordingly, the terminology employed throughout should be read in an exemplary rather than a limiting manner. Although minor modifications of the invention will occur to those of ordinary skill in the art, it shall be understood that what is intended to be circumscribed within the scope of the patent warranted hereon are all such embodiments that reasonably fall within the scope of the advancement to the art hereby contributed, and that scope shall not be restricted, except in light of the appended claims and their equivalents.

Claims

1. A method for deploying an expandable prosthetic heart valve in a patient, the method comprising: introducing a guidewire into a patient and advancing the guidewire through a vasculature of a patient to a deployment site; advancing over the guidewire a distal end portion of a delivery apparatus and the prosthetic heart valve mounted in a radially compressed configuration on an expandable member of the distal end portion of the delivery apparatus; positioning the prosthetic heart valve at the deployment site; and radially expanding the expandable member, causing the prosthetic heart valve to radially expand from the radially compressed configuration to a radially expanded configuration, wherein the prosthetic heart valve comprises an expandable metal frame and one or more leaflets attached to the frame, wherein the frame comprises a plurality of struts arranged to form two circumferentially extending rows of hexagonal shaped cells.
 2. The method of claim 1, wherein the delivery apparatus comprises a handle that includes visual indica that indicates an amount of expansion of the prosthetic heart valve.
 3. The method of claim 1, further comprising releasing the prosthetic heart valve from the delivery apparatus after radially expanding the prosthetic heart valve.
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