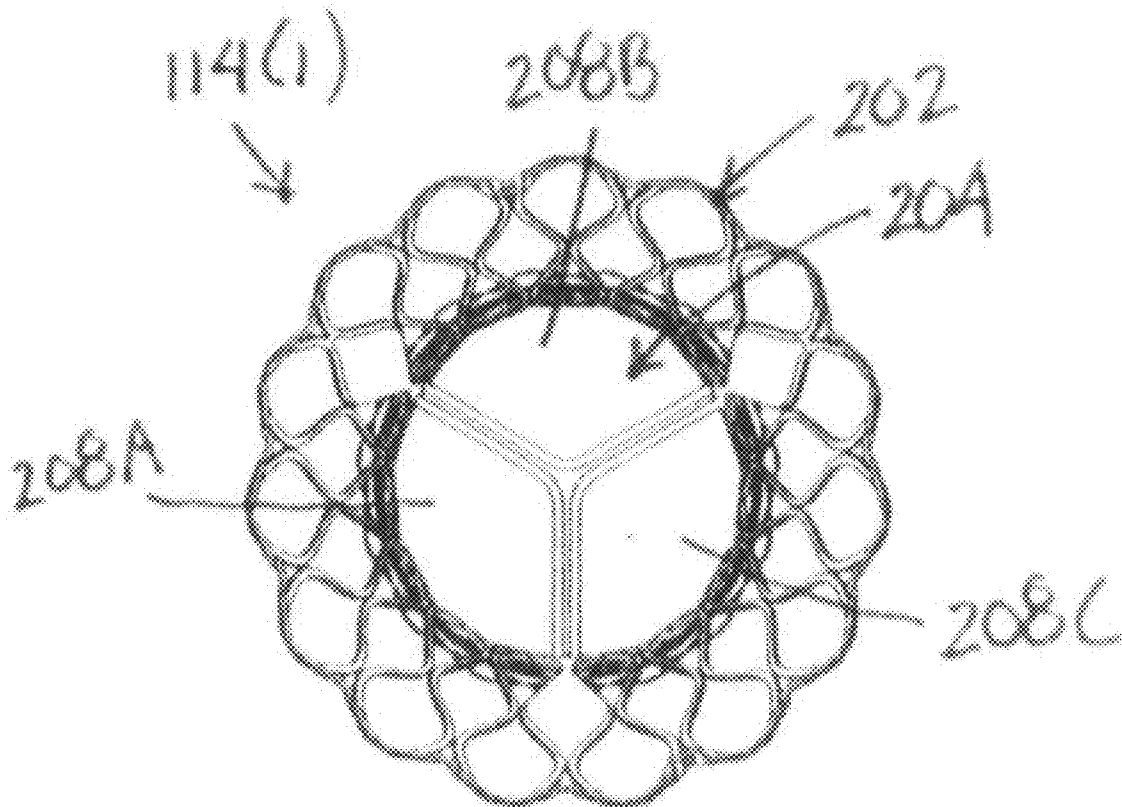




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(19) **United States**(12) **Patent Application Publication**
Tabor(10) **Pub. No.: US 2011/0208293 A1**(43) **Pub. Date: Aug. 25, 2011**(54) **CATHETER-BASED HEART VALVE
THERAPY SYSTEM WITH SIZING BALLOON****Publication Classification**(51) **Int. Cl.**
A61F 2/82 (2006.01)(52) **U.S. Cl.** **623/1.26**(57) **ABSTRACT**

A catheter-based heart valve therapy system, includes a stented heart valve prosthesis including a stent frame having a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient. A sizing balloon includes a first region having a shape in an inflated state that matches a shape of the valvular contact region of the stent frame in an expanded state. At least one catheter-based delivery system is configured to deliver the sizing balloon to the heart valve of the patient for a size determination, and deliver the prosthesis to the heart valve for implantation.

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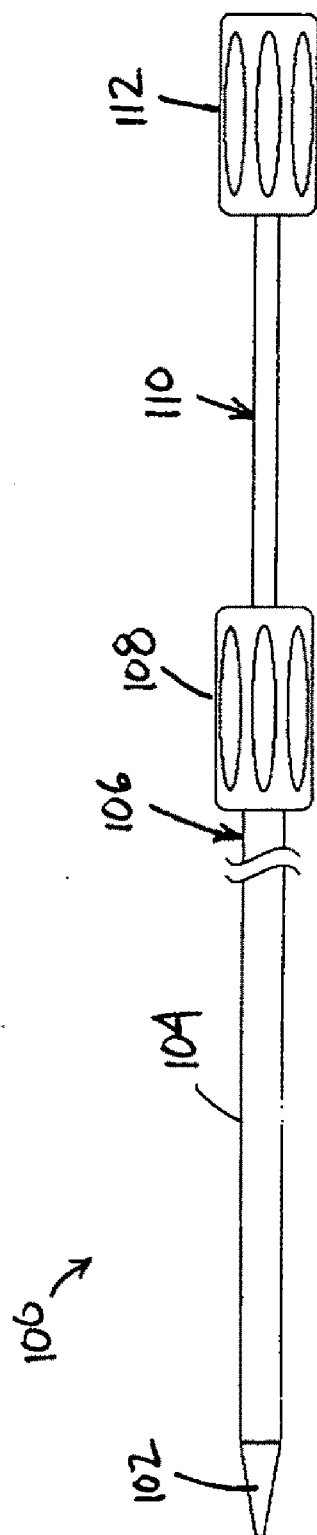


Fig. 1A

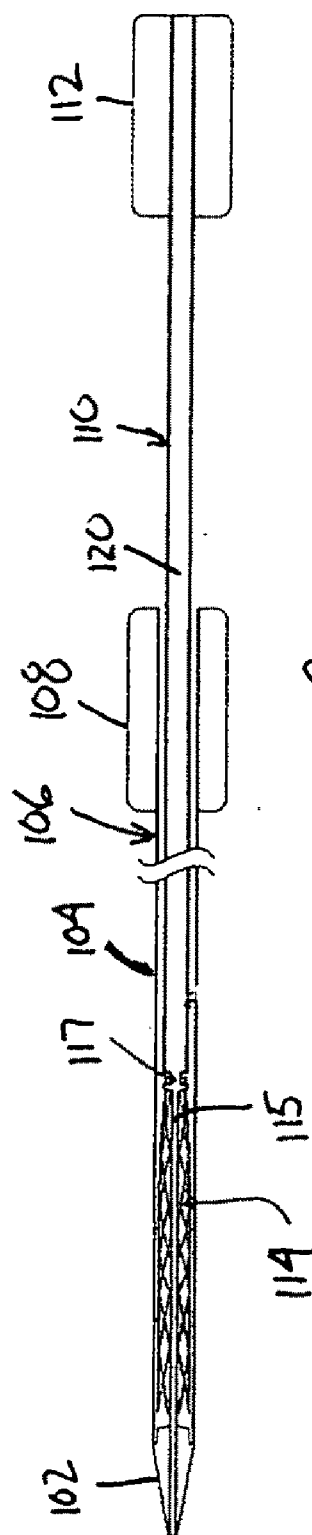
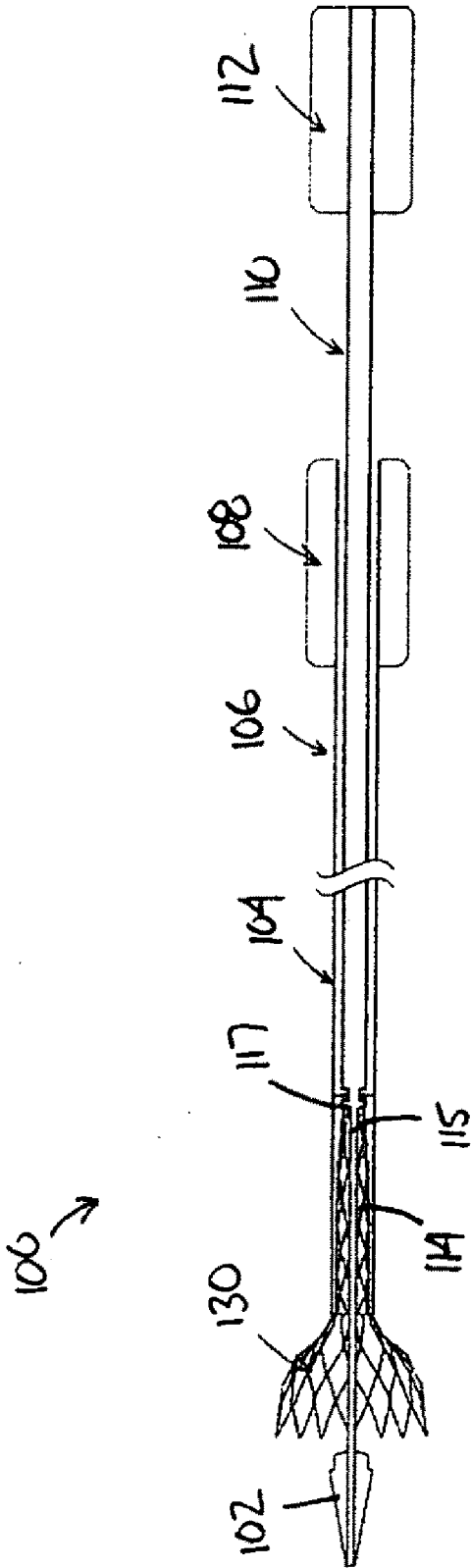
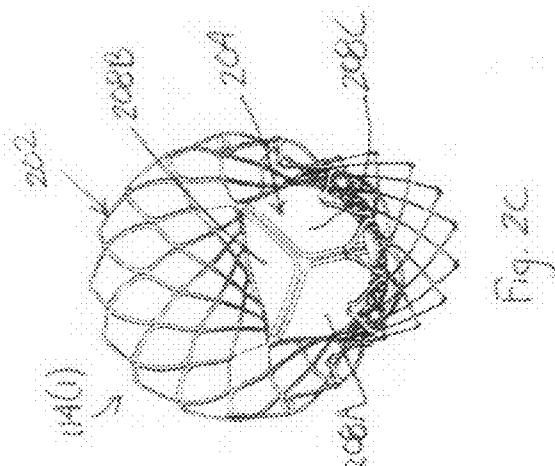
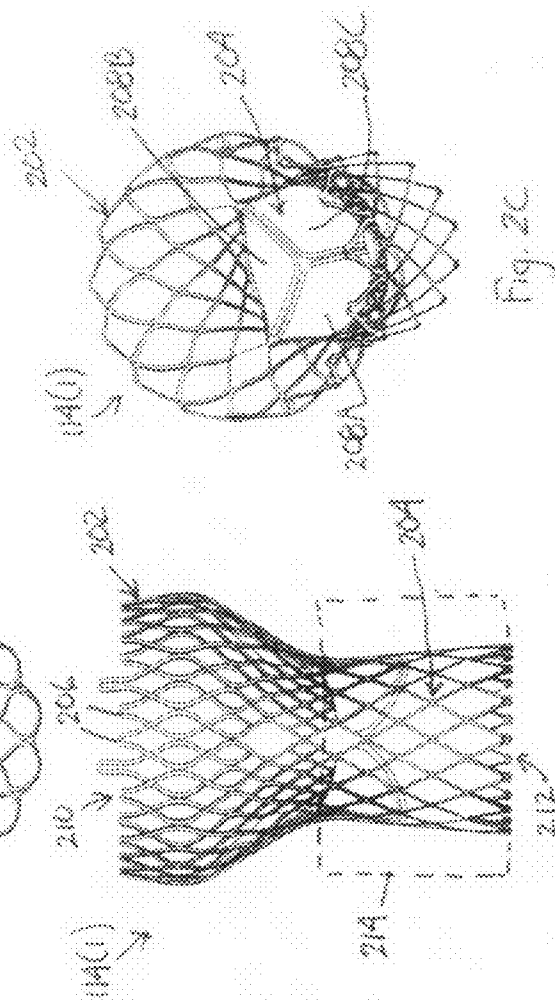
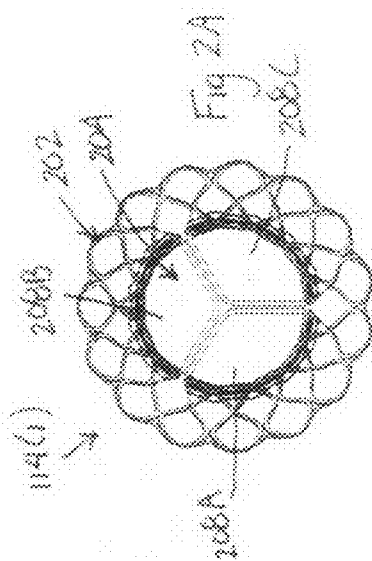


Fig. 1B





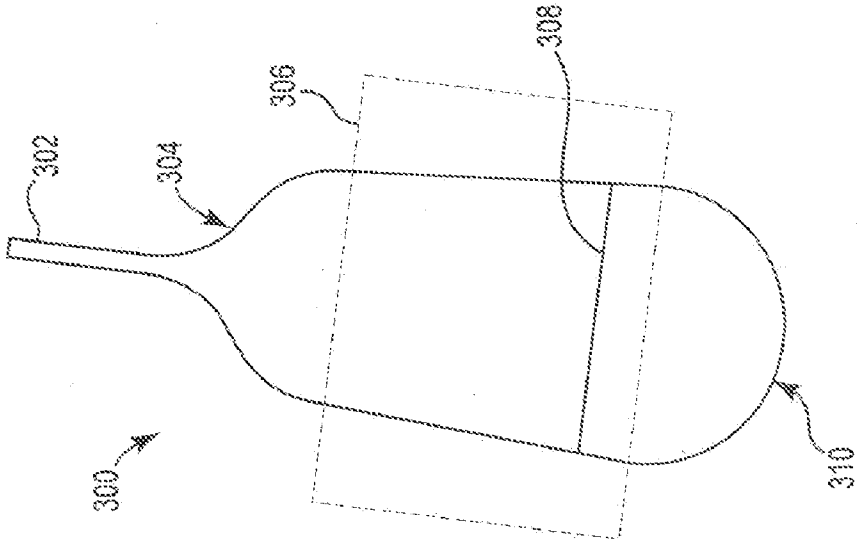
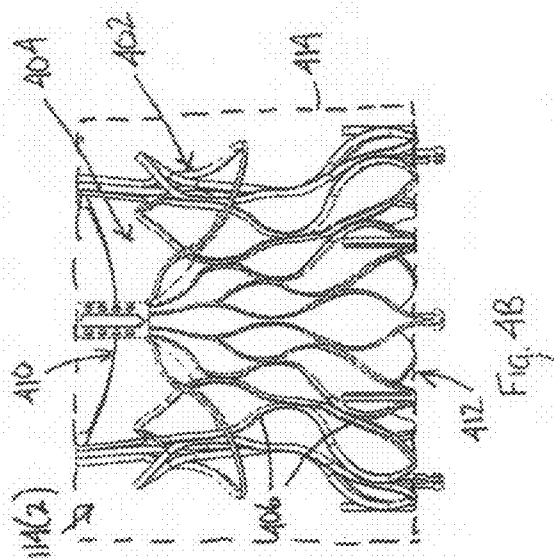
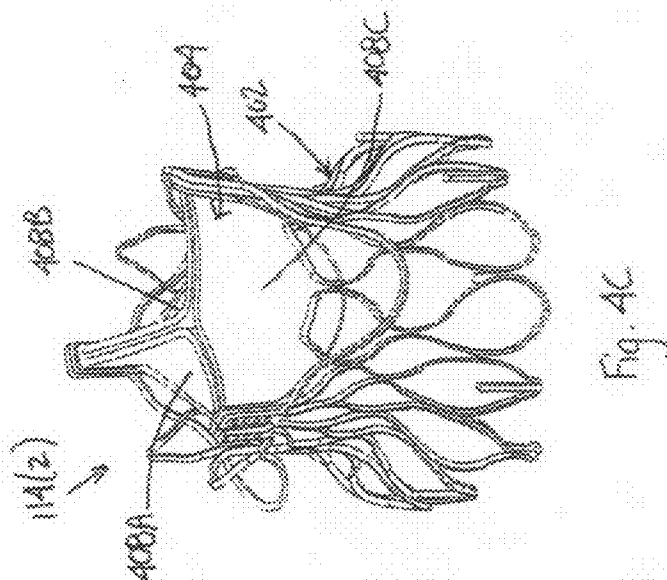
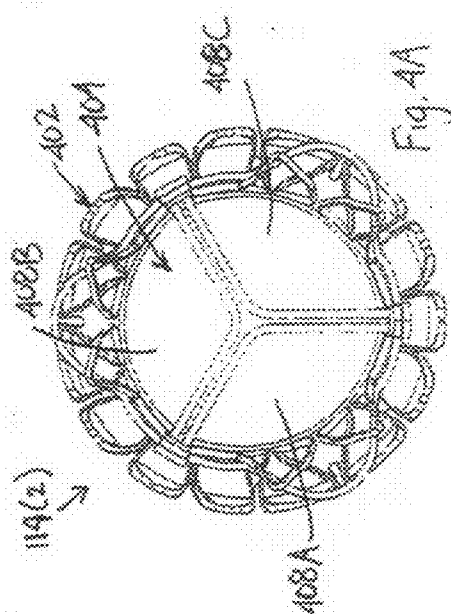


Fig. 3



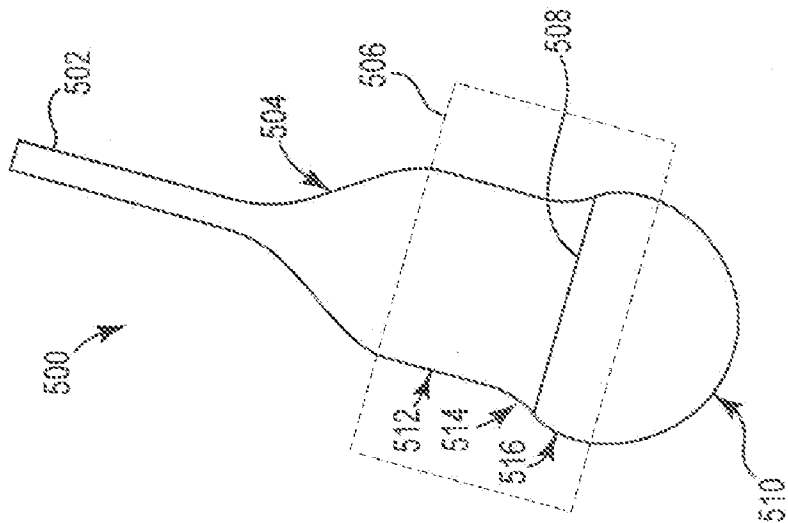


Fig. 5

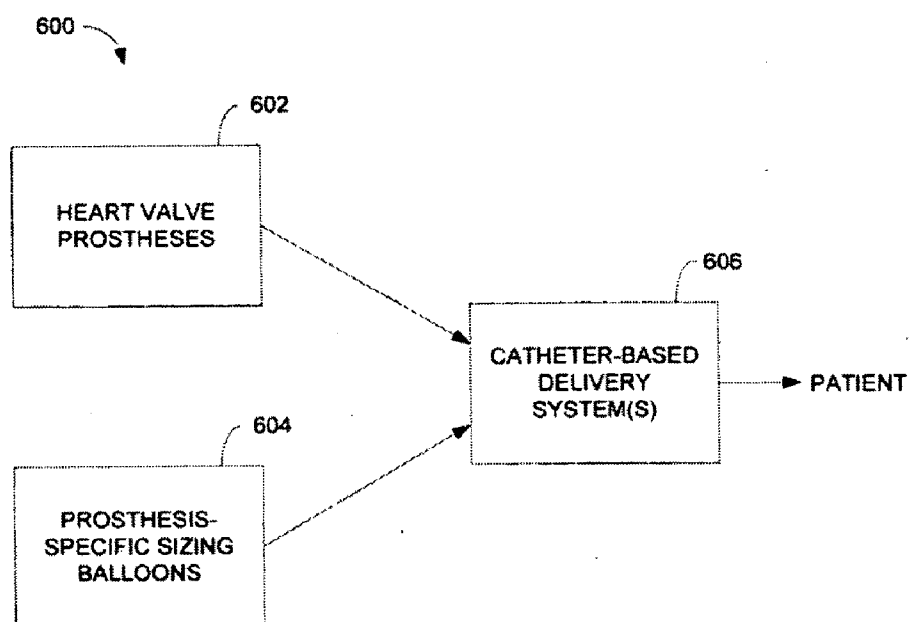


Fig. 6

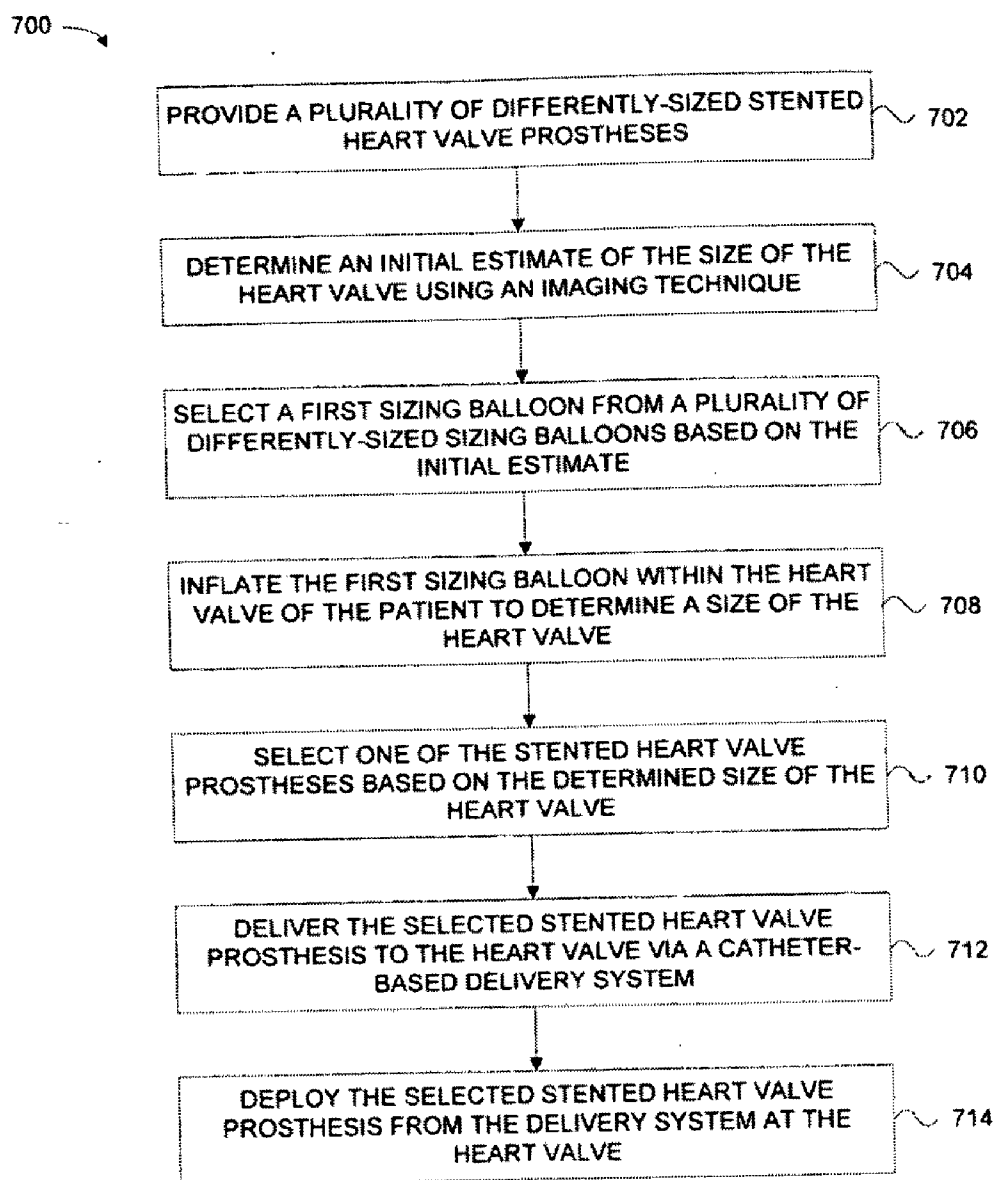


Fig. 7

CATHETER-BASED HEART VALVE THERAPY SYSTEM WITH SIZING BALLOON

BACKGROUND

[0001] The present disclosure relates to systems and methods for percutaneous implantation of a heart valve prosthesis. More particularly, it relates to systems and methods for transcatheter implantation of a stented heart valve prosthesis, including a balloon sizing procedure.

[0002] Heart valves, such as the mitral, tricuspid, aortic, and pulmonary valves, are sometimes damaged by disease or by aging, resulting in problems with the proper functioning of the valve. Heart valve problems generally take one of two forms: stenosis in which a valve does not open completely or the opening is too small, resulting in restricted blood flow; or insufficiency in which blood leaks backward across a valve when it should be closed.

[0003] Heart valve replacement has become a routine surgical procedure for patients suffering from valve regurgitation or stenotic calcification of the leaflets. Conventionally, the vast majority of valve replacements entail full sternotomy in placing the patient on cardiopulmonary bypass. Traditional open surgery inflicts significant patient trauma and discomfort, requires extensive recuperation times, and may result in life-threatening complications.

[0004] To address these concerns, within the last decade, efforts have been made to perform cardiac valve replacements using minimally-invasive techniques. In these methods, laparoscopic instruments are employed to make small openings through the patient's ribs to provide access to the heart. While considerable effort has been devoted to such techniques, widespread acceptance has been limited by the clinician's ability to access only certain regions of the heart using laparoscopic instruments.

[0005] Still other efforts have been focused upon percutaneous transcatheter (or transluminal) delivery of replacement cardiac valves to solve the problems presented by traditional open surgery and minimally-invasive surgical methods. In such methods, a valve prosthesis is compacted for delivery in a catheter and then advanced, for example through an opening in the femoral artery and through the descending aorta to the heart, where the prosthesis is then deployed in the valve annulus (e.g., the aortic valve annulus).

[0006] Various types and configurations of prosthetic heart valves are used in percutaneous valve procedures to replace diseased natural human heart valves. The actual shape and configuration of any particular prosthetic heart valve is dependent to some extent upon the valve being replaced (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve). In general, prosthetic heart valve designs attempt to replicate the function of the valve being replaced and thus will include valve leaflet-like structures used with either bioprostheses or mechanical heart valve prostheses. If bioprostheses are selected, the replacement valves may include a valved vein segment or pericardial manufactured tissue valve that is mounted in some manner within an expandable stent frame to make a valved stent. In order to prepare such a valve for percutaneous implantation, one type of valved stent can be initially provided in an expanded or uncrimped condition, then crimped or compressed around a balloon portion of a catheter until it is close to the diameter of the catheter. In other percutaneous implantation systems, the stent frame of the valved stent can be made of a self-expanding material. With these systems, the valved stent is crimped down to a desired

size and held in that compressed state with a sheath, for example. Retracting the sheath from this valved stent allows the stent to expand to a larger diameter, such as when the valved stent is in a desired position within a patient. With either of these types of percutaneous stent delivery systems, conventional sewing of the prosthetic heart valve to the patient's native tissue is typically not necessary.

[0007] Adverse effects can occur if an implanted transcatheter heart valve does not fit appropriately, including paravalvular leakage and damage to surrounding tissues (e.g., aorta, cardiac tissue). However, there are significant limitations associated with current imaging-based sizing procedures for transcatheter heart valves. Limitations associated with imaging-based sizing procedures include, for example, the following: (1) Measurements are only taken in two dimensions, and therefore do not account for annular ellipticity; (2) identifying the true leaflet basal hinge point can be difficult with calcification, imaging errors, and the non-orthogonal geometry of a tricuspid valve; (3) unknown annular compliance makes cross-sectional geometry of an implanted frame difficult to predict, which can lead to unacceptable stent aspect ratios and valve performance; and (4) variable calcification profiles may interact unpredictably with the frame.

[0008] In light of the above, a need exists for a catheter-based heart valve therapy system that can make a more accurate size determination, and deliver an appropriately sized heart valve prosthesis to the heart valve.

SUMMARY

[0009] One embodiment is directed to a catheter-based heart valve therapy system, which includes a stented heart valve prosthesis including a stent frame having a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient. The system includes a sizing balloon including a first region having a shape in an inflated state that matches a shape of the valvular contact region of the stent frame in an expanded state. The system also includes at least one catheter-based delivery system configured to deliver the sizing balloon to the heart valve of the patient for a size determination, and deliver the prosthesis to the heart valve for implantation.

[0010] Another embodiment is directed to a method of performing a therapeutic procedure on a heart valve, which includes providing a plurality of differently-sized stented heart valve prostheses. Each of the prostheses includes a stent frame with a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient. The valvular contact regions of the plurality of prostheses have a common shape in an expanded state. The method includes inflating a first sizing balloon within the heart valve of the patient to determine a size of the heart valve, wherein the inflating of the first sizing balloon causes a first portion of the first sizing balloon to assume a shape that matches the common shape. One of the stented heart valve prostheses is selected based on the determined size of the heart valve. The selected stented heart valve prosthesis is delivered to the heart valve via a catheter-based delivery system, and the selected stented heart valve prosthesis is deployed from the delivery system at the heart valve.

[0011] Yet another embodiment is directed to a catheter-based heart valve therapy system, which includes a plurality of differently-sized stented heart valve prostheses. Each of the prostheses includes a stent frame with a valvular contact region that is configured to make contact with a heart valve

and nearby anatomy of a patient. The valvular contact regions of the plurality of prostheses have a common shape in an expanded state. The system includes a prosthesis-specific sizing balloon that corresponds to a prosthesis type of the plurality of prostheses and corresponds to a prosthesis size of a first subset of the plurality of prostheses. The sizing balloon includes a first region having a shape in an inflated state that is the same as the common shape. The system includes at least one catheter-based delivery system configured to deliver the sizing balloon to the heart valve of the patient for a size determination, and deliver one of the prostheses from the first subset to the heart valve for implantation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIGS. 1A-1C are diagrams illustrating a system for delivering a transcatheter prosthetic heart valve to an implantation site according to one embodiment.

[0013] FIGS. 2A-2C are diagrams illustrating one embodiment of the stented heart valve prosthesis shown in FIGS. 1B and 1C.

[0014] FIG. 3 is a diagram illustrating a prosthesis-specific sizing balloon corresponding to the stented heart valve prosthesis shown in FIGS. 2A-2C according to one embodiment.

[0015] FIGS. 4A-4C are diagrams illustrating another embodiment of the stented heart valve prosthesis shown in FIGS. 1B and 1C.

[0016] FIG. 5 is a diagram illustrating a prosthesis-specific sizing balloon corresponding to the stented heart valve prosthesis shown in FIGS. 4A-4C according to one embodiment.

[0017] FIG. 6 is a block diagram illustrating a catheter-based heart valve therapy system according to one embodiment.

[0018] FIG. 7 is a flow diagram illustrating a method of performing a therapeutic procedure on a heart valve according to one embodiment.

DETAILED DESCRIPTION

[0019] The terms “distal” and “proximal” are used herein with reference to the treating clinician during the use of the catheter system; “Distal” indicates an apparatus portion distant from, or a direction away from the clinician and “proximal” indicates an apparatus portion near to, or a direction towards the clinician. The term “therapy” or “therapeutic procedure” as used herein in the context of heart valves is intended to include the repair of a heart valve, the replacement of a heart valve, or a combination of repair and replacement of a heart valve. While some of the description herein may refer specifically to therapy of aortic valves, the systems and methods disclosed herein can also generally be used for therapy of native or bioprosthetic mitral, pulmonic, or tricuspid valves.

[0020] FIGS. 1A-1C are diagrams illustrating a system **100** for delivering a transcatheter prosthetic heart valve to an implantation site according to one embodiment. In the illustrated embodiment, the system **100** includes a shaft assembly **110** and a sheath assembly **106**. The shaft assembly **110** includes a carrier shaft **120**, a connector shaft **115**, a nose cone **102**, and a handle device **112**. The connector shaft **115** interconnects the carrier shaft **120** and the nose cone **102**, and in some constructions has a reduced-sized diameter to permit placement of the stented heart valve prosthesis **114** over the connector shaft **115**. Though not shown in FIGS. 1A-1C, a guide wire lumen can be formed through the shafts **115** and **120**.

[0021] Carrier shaft **120** is sized to be slidably received within a portion of the sheath assembly **106**, and is configured in the illustrated embodiment for releasable coupling with the stented heart valve prosthesis **114**. The carrier shaft **120** forms or includes a coupling device **117**. The coupling device **117** is configured to selectively retain a proximal portion of the stented heart valve prosthesis **114**. The coupling device **117** is configured to releasably mount the stented heart valve prosthesis **114** to the shaft assembly **110** when the prosthesis **114** is forced to a collapsed state within the sheath assembly **106**. In this collapsed state, then, the stented heart valve prosthesis **114** will longitudinally move with movement of the shaft assembly **110**. The sheath assembly **106** is configured to permit deployment of the stented heart valve prosthesis **114** from the loaded state shown in FIGS. 1A and 1B.

[0022] The nose cone **102** can assume a variety of forms, and is generally constructed to facilitate atraumatic placement of the delivery system **100** through a patient's vasculature and heart. The handle device **112** is mounted or connected to a proximal end of the carrier shaft **120**, and provides a convenient surface for grasping by a clinician.

[0023] The sheath assembly **106** generally includes a sheath **104** and a handle device **108**. The sheath **104** can be of a conventional catheter-like configuration (e.g., biocompatible polymer with or without an encapsulated wire braiding). In some constructions, the sheath **104** can further incorporate various steering features. Regardless, the sheath **104** is generally compliant, and is able to traverse the tortuous pathways associated with transcatheter heart valve implantation. The handle device **108** can assume a wide variety of forms, and is generally mounted or connected to a proximal end of the sheath **104**. The sheath **104** defines a lumen sized to slidably receive the carrier shaft **120**, as well as the stented heart valve prosthesis **114** in the collapsed state.

[0024] The delivery system **100** is operable to deliver or implant the stented heart valve prosthesis **114** as described in further detail below. FIGS. 1A and 1B illustrate the system **100** loaded with the stented heart valve prosthesis **114** prior to deployment. In particular, the stented heart valve prosthesis **114** is connected to the carrier shaft **120**, for example via the coupling device **117**, and is radially constrained within the sheath **104**.

[0025] The loaded delivery system **100** is then advanced toward the implantation target site, for example in a retrograde manner through a cut-down to the femoral artery and into the patient's descending aorta. The delivery system **100** is then advanced, under fluoroscopic guidance, over the aortic arch, through the ascending aorta, and midway across the defective aortic valve (for aortic replacement). After positioning of the delivery system **100**, the sheath **104** is partially retracted relative to the prosthesis **114** as shown in FIG. 1C. For example, the handle device **108** provided with the sheath assembly **106** is retracted toward the handle device **112** of the shaft assembly **110**. As shown, a distal region **130** of the prosthesis **114** is thus exteriorly exposed relative to the sheath **104**, and begins to self-deploy. This proximal retraction of the sheath **104** continues, with a continually increasing length of the prosthetic **114** being exposed and thus partially deployed, until the prosthetic **114** is fully deployed at the native heart valve.

[0026] The delivery system **100** is useful with a variety of different configurations of a stented heart valve prostheses. In general terms, the prosthetic heart valve **114** includes a stent frame maintaining a valve structure (tissue or synthetic), with

the stent frame having a normal, expanded state and collapsible to a collapsed state for loading within the system **100**. The stent frame can be constructed to self-deploy or expand when released from the delivery system **100**, or a separate expansion member can be provided (e.g., an expansion balloon). For example, the stented heart valve prosthesis **114** can be a prosthetic sold under the trade name CoreValve® available from Medtronic CoreValve, LLC. Other non-limiting examples of transcatheter heart valve prostheses useful with the system **100** are described in U.S. Publication Nos. 2006/0265056; 2007/0239266; and 2007/0239269; the teachings of each of which are incorporated herein by reference.

[0027] FIG. 2A is a diagram illustrating a top view of one embodiment of the stented heart valve prosthesis **114** shown in FIGS. 1B and 1C. FIG. 2B is a diagram illustrating a side view of the stented heart valve prosthesis **114** shown in FIG. 2A according to one embodiment. FIG. 2C is a diagram illustrating a perspective view of the stented heart valve prosthesis **114** shown in FIG. 2A according to one embodiment. The embodiment of the stented heart valve prosthesis **114** shown in FIGS. 2A-2C is identified by reference number **114(1)**. Prosthesis **114(1)** is compressible to a relatively small diameter for percutaneous delivery to the heart of a patient, and is then self-expandable via removal of external compressive forces.

[0028] As shown in FIGS. 2A-2C, stented heart valve prosthesis **114(1)** includes a stent frame **202** and a valve structure **204**. The stent frame **202** is a self-expanding support structure that includes a number of strut or wire portions **206** arranged relative to each other to provide a desired compressibility and strength to the prosthesis **114(1)**. Stent frame **202** includes a valvular contact region **214** that is configured to make contact with a heart valve and nearby anatomy of a patient. Stent frame **202** can be made from a shape memory material, such as Nitinol. Valve structure **204** is mounted inside of the stent frame **202**, and includes a plurality of leaflets **208A-208C** (collectively referred to as leaflets **208**). In the illustrated embodiment, valve structure **204** includes three leaflets **208**. In other embodiments, valve structure **204** may include more or less than three leaflets **208**. FIG. 2B also shows a proximal outflow end **210** and a distal inflow end **212** of prosthesis **114(1)**. Valvular contact region **214** in the illustrated embodiment extends from the bottom end of the valve structure **204** (adjacent to the distal inflow end **212** of the stent frame **202**) to the top end of the valve structure **204** (which corresponds to the position of the sinotubular junction).

[0029] As discussed above in the Background section, it is important for stented heart valve prostheses to be sized appropriately to help ensure a proper fit with the patient's anatomy, but there are several limitations associated with current imaging-based sizing procedures. One embodiment provides a heart valve therapy system that uses prosthesis-specific sizing balloons to facilitate identification of an appropriately sized heart valve prosthesis. Different types of stented heart valve prostheses typically have different shapes, and each type typically includes multiple sizes. In one embodiment, a differently-shaped balloon is used for each different type of prosthesis, and a different sized balloon is used for each different prosthesis size. The specific shape of the sizing balloons varies based on the prosthesis shape. In one embodiment, the sizing balloons disclosed herein are configured to be delivered, inflated, and deflated, using a conventional catheter-based delivery system.

[0030] FIG. 3 is a diagram illustrating a prosthesis-specific sizing balloon **300** corresponding to the stented heart valve prosthesis **114(1)** shown in FIGS. 2A-2C according to one embodiment. Sizing balloon **300** includes a tube **302**, a proximal end **304**, a valvular contact region **306**, a visually detectable marker **308**, and a distal end **310**. Tube **302** is configured to be fluidly connected to an inflation/deflation source (not shown) for inflating and deflating the sizing balloon **300**. Valvular contact region **306** is configured to make contact with a heart valve of a patient when sizing balloon **300** is in an expanded state. Sizing balloon **300** according to one embodiment is a non-compliant balloon that is configured to be used to estimate the size of the aortic annulus in a patient to facilitate the identification of an appropriately sized heart valve prosthesis.

[0031] In one embodiment, valvular contact region **306** of balloon **300** has an inflated shape and size that matches (e.g., is identical to or substantially identical to) the shape and size of the valvular contact region **214** (FIG. 2B) of stented heart valve prosthesis **114(1)** in the expanded state. In the expanded state, both regions **214** and **306** are gradually tapered such that the diameter of these regions gradually increases going from the proximal end to the distal end. Thus, the diameter of these regions is larger at the distal end (e.g., flared at the inflow end) than at the proximal end. This taper helps keep the balloon **300** in place during the sizing procedure.

[0032] The use of a balloon **300** with a valvular contact region **306** that matches the shape and size of the valvular contact region **214** of the prosthesis **114(1)** provides numerous benefits. For example, anterior mitral leaflet and coronary ostia interactions can be predicted for the prosthesis **114(1)** by monitoring these interactions during use of the balloon **300**. As another example, balloon **300** according to one embodiment has a compliance or radial flexibility that is the same as or substantially the same as that of the stent frame **202**, and the balloon **300** is configured to generate the same or substantially the same radial force as the stent frame **202**. This allows the balloon **300** to simulate the radial force of the stent frame **202** on the native anatomy and predict how the frame **202** would interact with and be deformed by the native anatomy, such as predicting paravalvular leakage, heart block, and post-installation aspect ratio of the stent frame **202**. For example, if the balloon sizing procedure indicated that the stent frame **202** would be deformed to an unacceptable degree by the native anatomy, a different size and/or type of stent frame may be chosen for the procedure. The use of sizing balloon **300** also allows the size of the perimeter of the valve annulus to be determined, as opposed to just a diameter measurement (which may not be an accurate indicator of size if the valve annulus is highly elliptical or irregular).

[0033] In one embodiment, a conventional imaging technique (e.g., CT, MRI, echocardiography) is used to make an initial estimate of the size of the native heart valve, and a sizing balloon **300** with a size corresponding to the initial estimate is chosen for the sizing procedure. After inflation of this sizing balloon **300** within the native heart valve of a patient, a conventional imaging technique is employed to assess the fit of the expanded balloon **300** within the heart valve. After a determination is made regarding the fit of the expanded balloon **300** within the heart valve, an appropriately sized version of the stented heart valve prosthesis **114(1)** is selected based on this determination. If the expanded balloon

300 is substantially over-sized or under-sized, a differently-sized balloon **300** may be selected and the sizing procedure repeated.

[0034] In another embodiment, rather than using imaging techniques, or in addition to using imaging techniques, the fit of the expanded balloon **300** within the heart valve is assessed using intraballoon pressure information. In one form of this embodiment, prior to delivery of the balloon **300** inside the patient, the balloon **300** is inflated to a predetermined intraballoon pressure and the diameter of the inflated balloon **300** is measured along with the volume of liquid injected into the balloon **300**. After insertion of the balloon **300** into the heart valve, the balloon **300** is again inflated using the same volume of fluid, and the intraballoon pressure is measured again. A measured pressure that is greater than the predetermined pressure indicates that the native heart valve is exerting force on the balloon **300**, and the balloon **300** may be of the correct size. A measured pressure that is the same as the predetermined pressure indicates that the native heart valve is not exerting force on the balloon **300**, and the balloon **300** may be too small.

[0035] In one embodiment, the visually detectable marker **308** on the sizing balloon **300** is configured to be aligned with the heart valve annulus (e.g., aortic basal annulus) of the native heart valve. The visually detectable marker **308** on the balloon **300** facilitates accurate placement of the balloon **300** within the native valve. In the illustrated embodiment, marker **308** is a circular line drawn around the circumference of the balloon **300**.

[0036] In one embodiment, in addition to being used for sizing purposes, balloon **300** is also configured to be used for balloon aortic valvuloplasty (BAV) for relief of aortic valvular stenosis. In one form of this embodiment, a BAV procedure is performed using balloon **300** by applying a high radial force to break open fused commissures in the native valve, and then a reduced radial force is applied to approximate the radial force of the stent frame to assess sizing. In one embodiment, the BAV procedure is performed using a single balloon. In another embodiment, the BAV procedure is performed using a balloon-in-balloon system. In one form of this embodiment, balloon **300** is configured as a balloon-in-balloon system including an inner balloon and an outer balloon with different radial forces (e.g., a higher radial force outer balloon and a lower radial force inner balloon, or vice versa).

[0037] As mentioned above, in one embodiment, a differently-shaped balloon **300** is used for each different type of prosthesis **114** (with a balloon shape that corresponds to the shape of the particular type of prosthesis being used), and a different sized balloon is used for each different prosthesis size. In one embodiment, each balloon **300** and each prosthesis **114** correspond to a single size (e.g., 23, 26, 29, or 31 mm). In another embodiment, each balloon **300** corresponds to and is inflatable to a range of sizes (e.g., one balloon **300** with a range of 20-24 mm, another balloon **300** with a range of 25-29 mm, and another balloon **300** with a range of 30-34 mm). Thus, for example, in one form of this embodiment, if the native valve had an actual size of 23 mm, and a balloon **300** with a range of 20-24 mm was being used, the balloon **300** would gradually be expanded to 20 mm, 21 mm, 22 mm, etc., as it was being monitored with a conventional imaging technique. Interference may begin to be seen when the balloon **300** was expanded to about 23 mm, and the shape of the balloon **300** may begin to be deformed as it is expanded to 24

mm. Thus, the sizing procedure may result in a determination that the native valve size is between about 23 mm and 24 mm.

[0038] FIG. 4A is a diagram illustrating a top view of another embodiment of the stented heart valve prosthesis **114** shown in FIGS. 1B and 1C. FIG. 4B is a diagram illustrating a side view of the stented heart valve prosthesis **114** shown in FIG. 4A according to one embodiment. FIG. 4C is a diagram illustrating a perspective view of the stented heart valve prosthesis **114** shown in FIG. 4A according to one embodiment. The embodiment of the stented heart valve prosthesis **114** shown in FIGS. 4A-4C is identified by reference number **114(2)**. Prosthesis **114(2)** is compressible to a relatively small diameter for percutaneous delivery to the heart of a patient, and is then self-expandable via removal of external compressive forces.

[0039] As shown in FIGS. 4A-4C, stented heart valve prosthesis **114(2)** includes a stent frame **402** and a valve structure **404**. The stent frame **402** is a self-expanding support structure that includes a number of strut or wire portions **406** arranged relative to each other to provide a desired compressibility and strength to the prosthesis **114(2)**. Stent frame **402** includes a valvular contact region **414** that is configured to make contact with a heart valve and nearby anatomy of a patient. Stent frame **402** can be made from a shape memory material, such as Nitinol. Valve structure **404** is mounted inside of the stent frame **402**, and includes a plurality of leaflets **408A-408C** (collectively referred to as leaflets **408**). In the illustrated embodiment, valve structure **404** includes three leaflets **408**. In other embodiments, valve structure **404** may include more or less than three leaflets **408**. FIG. 4B also shows a proximal outflow end **410** and a distal inflow end **412** of prosthesis **114(2)**. Valvular contact region **414** according to the illustrated embodiment extends from the bottom end of the valve structure **404** (adjacent to the distal inflow end **412** of the stent frame **402**) to the top end of the valve structure **404** (which corresponds to the position of the sinotubular junction).

[0040] FIG. 5 is a diagram illustrating a prosthesis-specific sizing balloon **500** corresponding to the stented heart valve prosthesis **114(2)** shown in FIGS. 4A-4C according to one embodiment. Sizing balloon **500** includes a tube **502**, a proximal end **504**, a valvular contact region **506**, a visually detectable marker **508**, and a distal end **510**. Tube **502** is configured to be fluidly connected to an inflation/deflation source (not shown) for inflating and deflating the sizing balloon **500**. Valvular contact region **506** is configured to make contact with a heart valve of a patient when sizing balloon **500** is in an expanded state. Sizing balloon **500** according to one embodiment is a non-compliant balloon that is configured to be used to estimate the size of the aortic annulus in a patient to facilitate the identification of an appropriately sized heart valve prosthesis.

[0041] In one embodiment, valvular contact region **506** of balloon **500** has an inflated shape and size that matches (e.g., is identical to or substantially identical to) the shape and size of the valvular contact region **414** (FIG. 4B) of stented heart valve prosthesis **114(2)** in the expanded state. In the expanded state, both regions **414** and **506** have a first portion (indicated at **512** in FIG. 5) with a constant or substantially constant diameter and a second portion (indicated at **516**) with a different constant or substantially constant diameter, which are connected by a tapered portion (indicated at **514**) with a varying diameter. As shown in FIG. 5, the second portion **516** has a larger diameter than the first portion **512**, and the tapered portion **514** is at an angle of about forty-five degrees. The

diameter of the regions **414** and **506** is larger at the distal end (e.g., flared at the inflow end) than at the proximal end, which helps keep the balloon **500** in place during the sizing procedure. In one embodiment, balloon **500** is configured to be used in the same manner as described above with respect to balloon **300**.

[0042] FIG. **6** is a block diagram illustrating a catheter-based heart valve therapy system **600** according to one embodiment. System **600** includes a plurality of heart valve prostheses **602**, a plurality of prosthesis-specific sizing balloons **604**, and at least one catheter-based delivery system **606**. In one embodiment, the prostheses **602** comprise a plurality of differently-sized stented heart valve prostheses, and each of the prostheses **602** includes a stent frame having a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient. The valvular contact regions of the plurality of prostheses **602** according to one embodiment have a common shape in an expanded state. The common shape in one embodiment has a varying diameter. In one embodiment, the prosthesis-specific sizing balloons **604** each include a first region having a shape in an inflated state that matches the common shape. In one embodiment, each prosthesis-specific sizing balloon **604** corresponds to a prosthesis type of the prostheses **602** and corresponds to a prosthesis size of a subset of the prostheses **602**. The at least one catheter-based delivery system **606** is configured to deliver one or more of the sizing balloons **604** to the heart valve of a patient for a size determination, and deliver one of the prostheses **602** to the heart valve of the patient for implantation.

[0043] FIG. **7** is a flow diagram illustrating a method **700** of performing a therapeutic procedure on a heart valve according to one embodiment. At **702**, a plurality of differently-sized stented heart valve prostheses are provided. In one embodiment, each of the prostheses provided at **702** includes a stent frame with a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient. The valvular contact regions of the plurality of prostheses have a common shape in an expanded state in one embodiment. At **704**, an initial estimate of the size of the heart valve is determined using an imaging technique. At **706**, a first sizing balloon is selected from a plurality of differently-sized sizing balloons based on the initial estimate. At **708**, the first sizing balloon is inflated within the heart valve of the patient to determine a size of the heart valve. In one embodiment, the inflating of the first sizing balloon at **708** causes a first portion of the first sizing balloon to assume a shape that matches the common shape. In one embodiment, the size of the heart valve is determined at **708** based on imaging the inflating of the first sizing balloon. In another embodiment, the size of the heart valve is determined at **708** based additionally on intraballoon pressure information. At **710**, one of the stented heart valve prostheses is selected based on the determined size of the heart valve. At **712**, the selected stented heart valve prosthesis is delivered to the heart valve via a catheter-based delivery system. At **714**, the selected stented heart valve prosthesis is deployed from the delivery system at the heart valve. In one embodiment of method **700**, a balloon aortic valvuloplasty (BAV) procedure is performed with the first sizing balloon prior to determining the size of the heart valve.

[0044] The sizing balloon techniques help provide an optimized fit of the implanted heart valve prosthesis, thereby reducing device-related complications associated with inap-

propriate sizing. Although the systems and methods disclosed herein have been primarily described in the context of stented heart valve prostheses, it will be understood that embodiments of the balloon sizing techniques may also be applied to other devices and other portions of a patient's anatomy, including sizing catheter-delivered annuloplasty rings/bands. **[0045]** Although the present disclosure has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes can be made in form and detail without departing from the spirit and scope of the present disclosure.

What is claimed is:

1. A catheter-based heart valve therapy system, comprising:
 - a stented heart valve prosthesis including a stent frame having a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient;
 - a sizing balloon including a first region having a shape in an inflated state that matches a shape of the valvular contact region of the stent frame in an expanded state; and
 - at least one catheter-based delivery system configured to deliver the sizing balloon to the heart valve of the patient for a size determination, and deliver the prosthesis to the heart valve for implantation.
2. The heart valve therapy system of claim 1, wherein the sizing balloon is a prosthesis-specific sizing balloon that corresponds to a prosthesis type and a prosthesis size of the stented heart valve prosthesis.
3. The heart valve therapy system of claim 1, wherein the valvular contact region of the prosthesis and the first region of the sizing balloon each have a shape that is tapered such that a diameter of these regions increases going from a proximal end of these regions to a distal end of these regions.
4. The heart valve therapy system of claim 3, wherein the distal end of the prosthesis corresponds to an inflow end of the prosthesis.
5. The heart valve therapy system of claim 1, wherein the valvular contact region of the prosthesis and the first region of the sizing balloon each have a shape that includes a first portion with a first substantially constant diameter and a second portion with a second substantially constant diameter, wherein the first and second diameters are different.
6. The heart valve therapy system of claim 5, wherein the valvular contact region of the prosthesis and the first region of the sizing balloon each have a shape that further includes a tapered portion with a varying diameter that connects the first portion and the second portion.
7. The heart valve therapy system of claim 5, wherein the second portion corresponds to distal ends of the prosthesis and balloon, and wherein the second substantially constant diameter is larger than the first substantially constant diameter.
8. The heart valve therapy system of claim 1, wherein the sizing balloon is configured to generate a radial force on the heart valve that is substantially similar to an amount of radial force that is generated by the prosthesis.
9. The heart valve therapy system of claim 1, wherein the sizing balloon has a compliance that is substantially similar to a compliance of the stent frame.
10. The heart valve therapy system of claim 1, wherein the sizing balloon includes a visually detectable marker that is configured to facilitate accurate placement of the balloon within the heart valve.

11. The heart valve therapy system of claim **10**, wherein the visually detectable marker is configured to be aligned with an annulus of the heart valve.

12. A method of performing a therapeutic procedure on a heart valve, comprising:

providing a plurality of differently-sized stented heart valve prostheses, each of the prostheses including a stent frame with a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient, the valvular contact regions of the plurality of prostheses having a common shape in an expanded state;

inflating a first sizing balloon within the heart valve of the patient to determine a size of the heart valve, wherein the inflating of the first sizing balloon causes a first portion of the first sizing balloon to assume a shape that matches the common shape;

selecting one of the stented heart valve prostheses based on the determined size of the heart valve;

delivering the selected stented heart valve prosthesis to the heart valve via a catheter-based delivery system; and

deploying the selected stented heart valve prosthesis from the delivery system at the heart valve.

13. The method of claim **12**, and further comprising:

determining an initial estimate of the size of the heart valve using an imaging technique; and

selecting the first sizing balloon from a plurality of differently-sized sizing balloons based on the initial estimate.

14. The method of claim **12**, wherein the size of the heart valve is determined based on imaging the inflating of the first sizing balloon.

15. The method of claim **14**, wherein the size of the heart valve is determined based additionally on intraballoon pressure information.

16. The method of claim **12**, and further comprising: performing a balloon aortic valvuloplasty (BAV) procedure with the first sizing balloon prior to determining the size of the heart valve.

17. The method of claim **16**, and further comprising: applying a high radial force to the heart valve with the first sizing balloon during the BAV procedure; and reducing the radial force to the heart valve to determine the size of the heart valve.

18. The method of claim **16**, wherein the first sizing balloon comprises a balloon-in-balloon system including an inner balloon and an outer balloon having different radial forces.

19. The method of claim **12**, wherein the first sizing balloon is a prosthesis-specific sizing balloon that corresponds to a particular prosthesis type and a particular prosthesis size.

20. A catheter-based heart valve therapy system, comprising:

a plurality of differently-sized stented heart valve prostheses, each of the prostheses including a stent frame with a valvular contact region that is configured to make contact with a heart valve and nearby anatomy of a patient, the valvular contact regions of the plurality of prostheses having a common shape in an expanded state;

a prosthesis-specific sizing balloon that corresponds to a prosthesis type of the plurality of prostheses and corresponds to a prosthesis size of a first subset of the plurality of prostheses, wherein the sizing balloon includes a first region having a shape in an inflated state that is the same as the common shape; and

at least one catheter-based delivery system configured to deliver the sizing balloon to the heart valve of the patient for a size determination, and deliver one of the prostheses from the first subset to the heart valve for implantation.

21. The heart valve therapy system of claim **20**, wherein the common shape has a varying diameter.

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