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Walsh et al.

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(54) **PROSTHETIC HEART VALVE DELIVERY SYSTEM**

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A61F 2/95	(2013.01)
A61F 2/24	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/2418*** (2013.01); ***A61F 2/2439*** (2013.01); ***A61F 2/9517*** (2020.05); *A61F 2220/0016* (2013.01); *A61F 2220/0083* (2013.01)

(58) **Field of Classification Search**

CPC A61F 2/2418; A61F 2/2436; A61F 2/2439; A61F 2/243; A61F 2/2433; A61F 2/82; A61F 2/9517; A61F 2/966; A61F 2002/9665; A61F 2/24; A61F 2/962; A61F 2/95

See application file for complete search history.

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Primary Examiner — Seema Mathew

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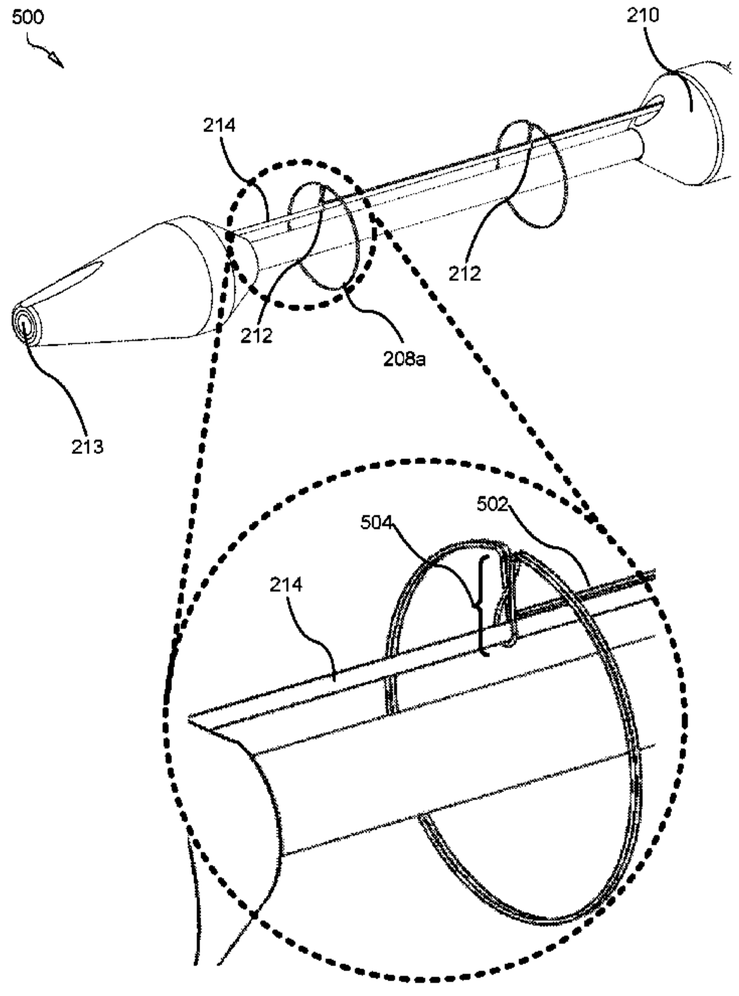
(57) **ABSTRACT**

A prosthetic heart valve and delivery system adapted to facilitate transapical or transfemoral implantation of a prosthetic heart valve, the delivery system comprising an elongated sheath or shaft have one or more loop stabilization wires adapted to circumscribe and crimp a metallic stent, the loop stabilization wires releasable with retraction of an engagement pin to expand the metallic stent and anchor the same in native tissue within the circulatory system of a patient.

12 Claims, 18 Drawing Sheets



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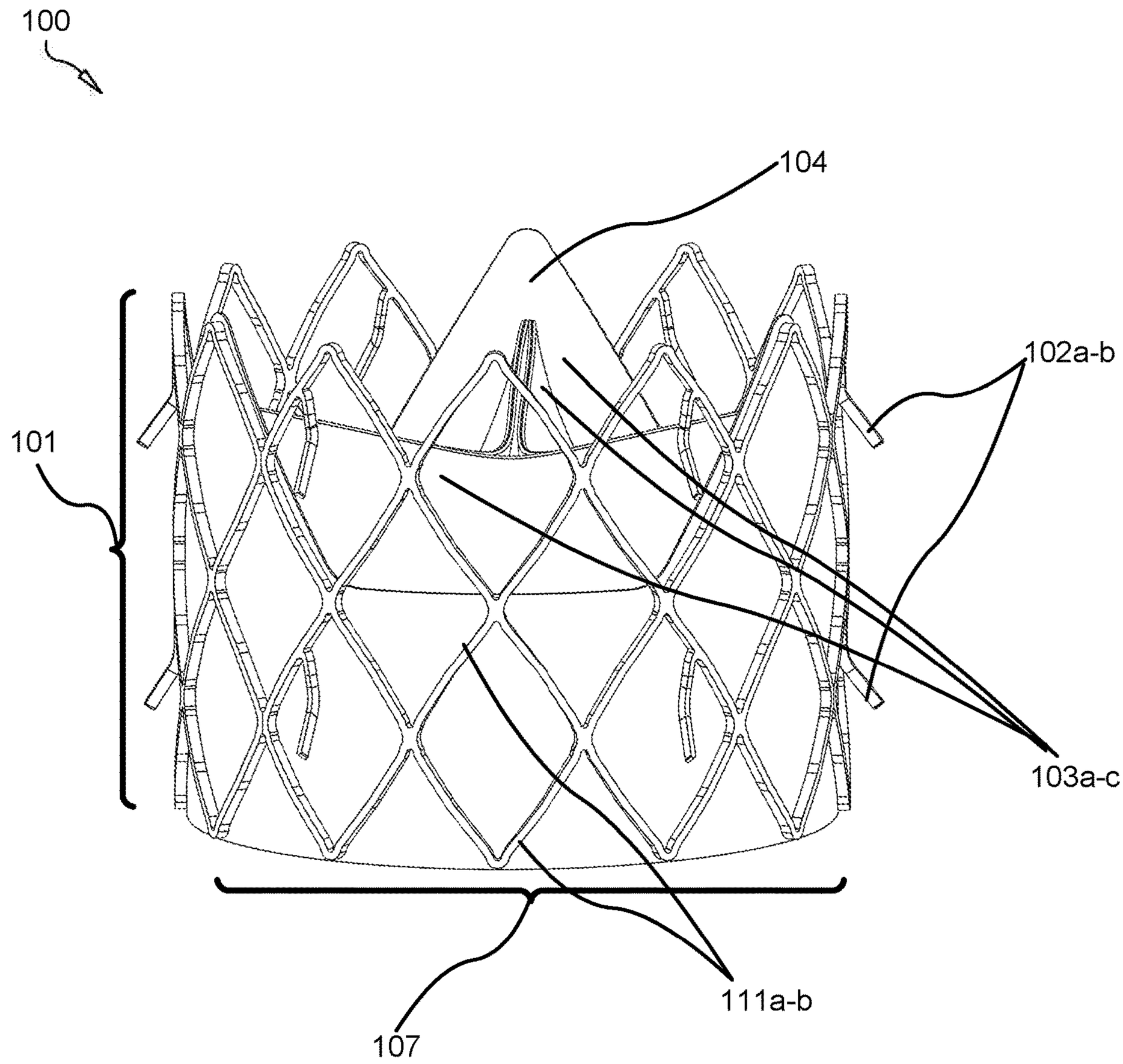


FIG. 1

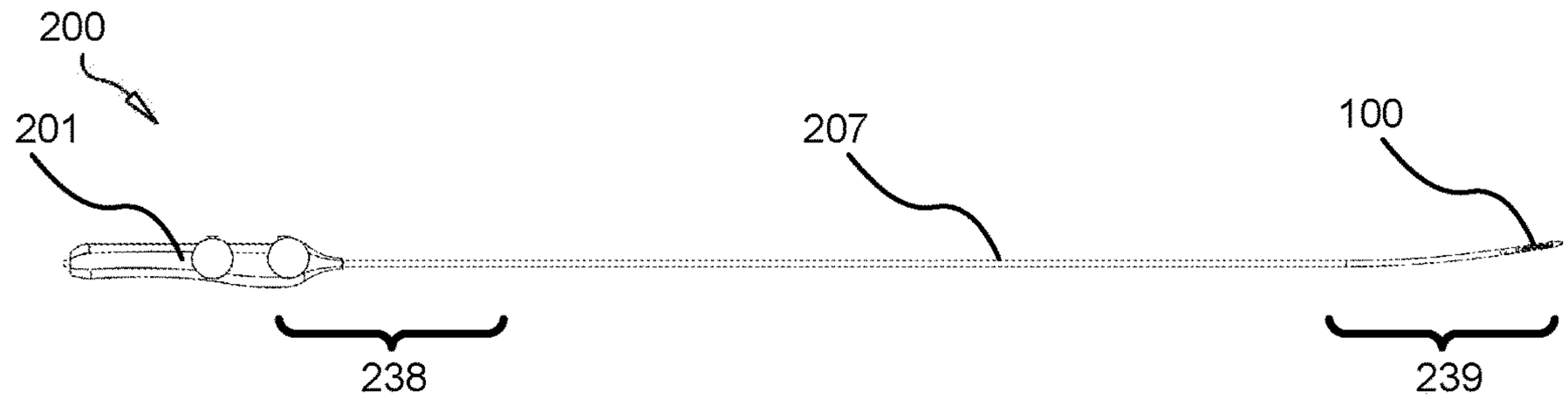


FIG. 2A

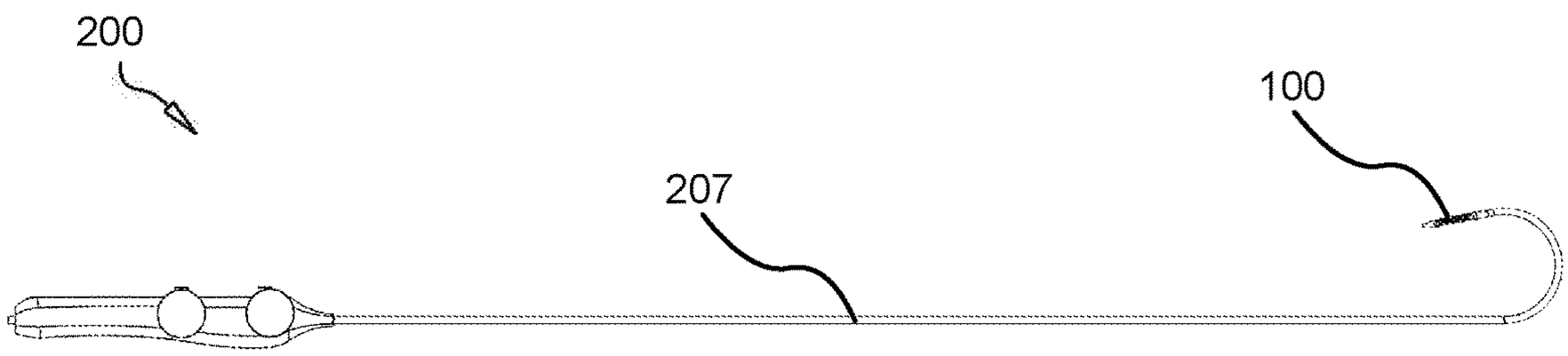


FIG. 2B

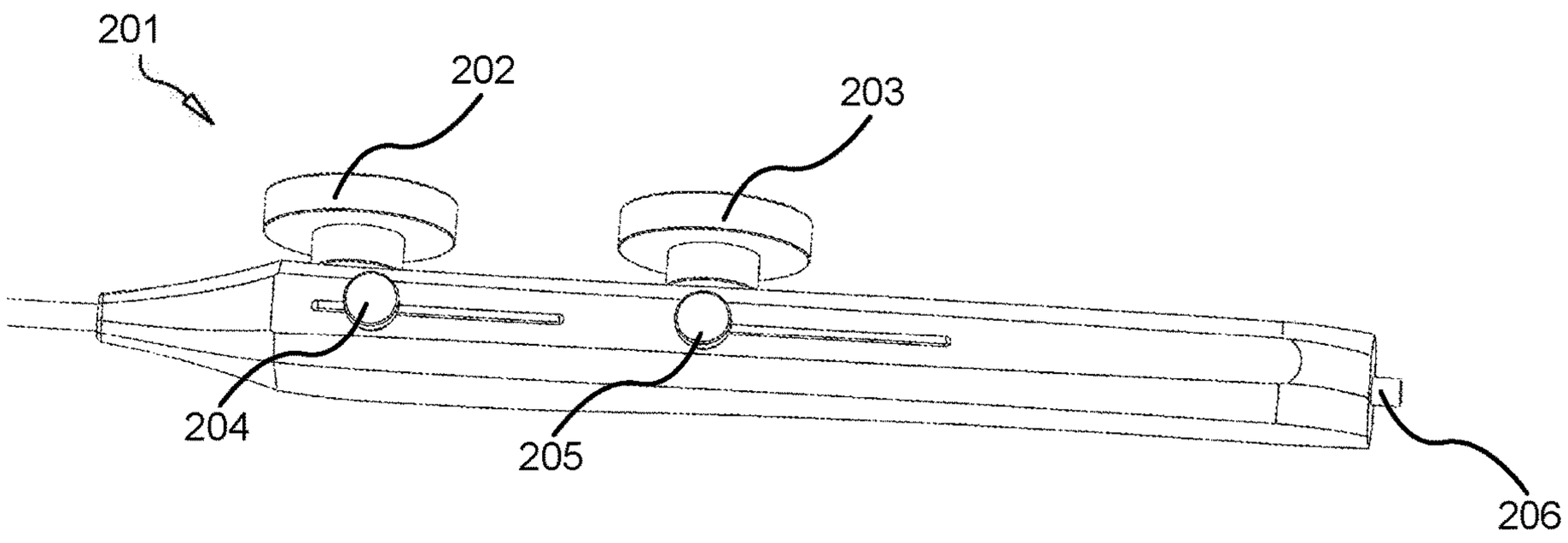


FIG. 2C

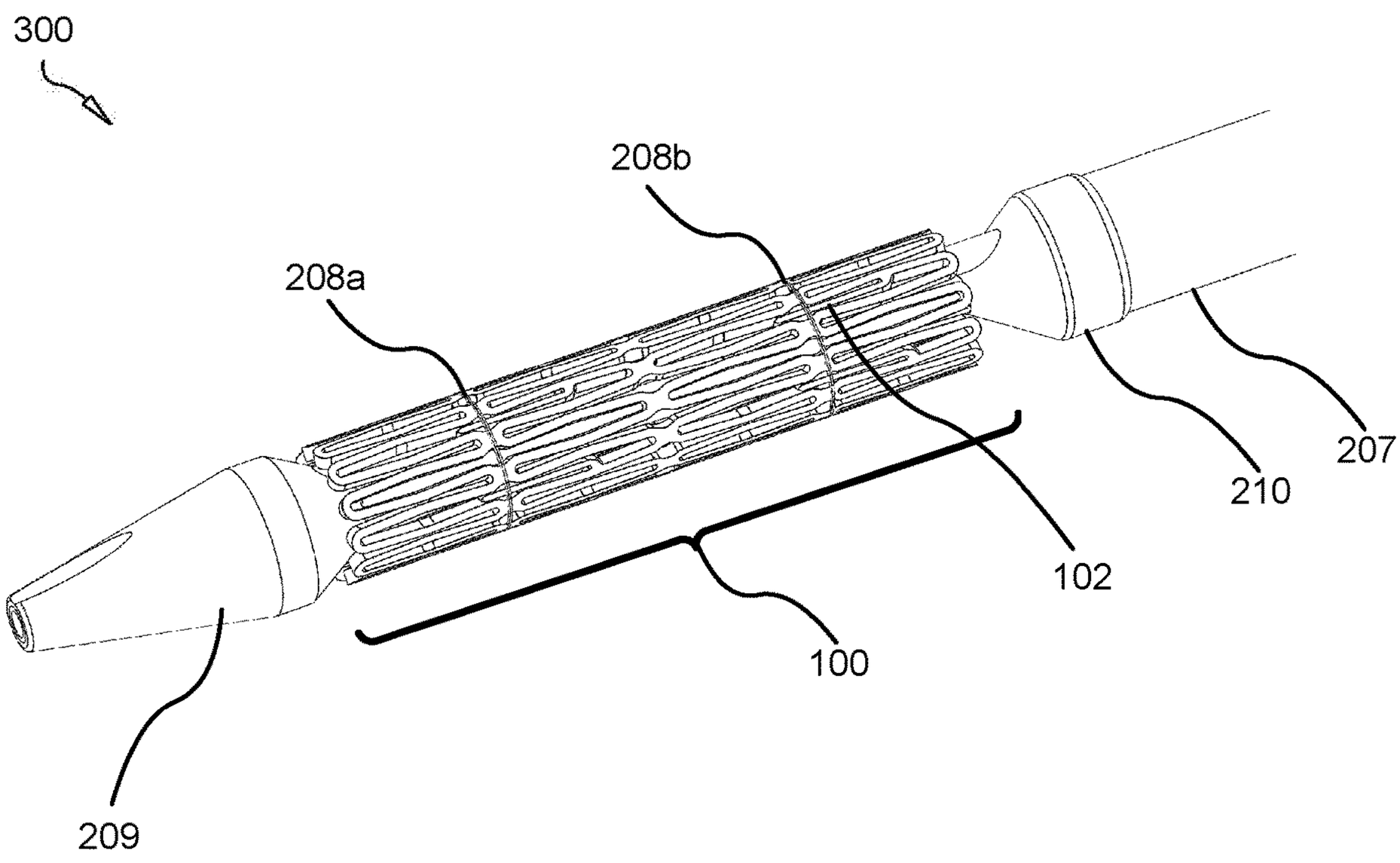
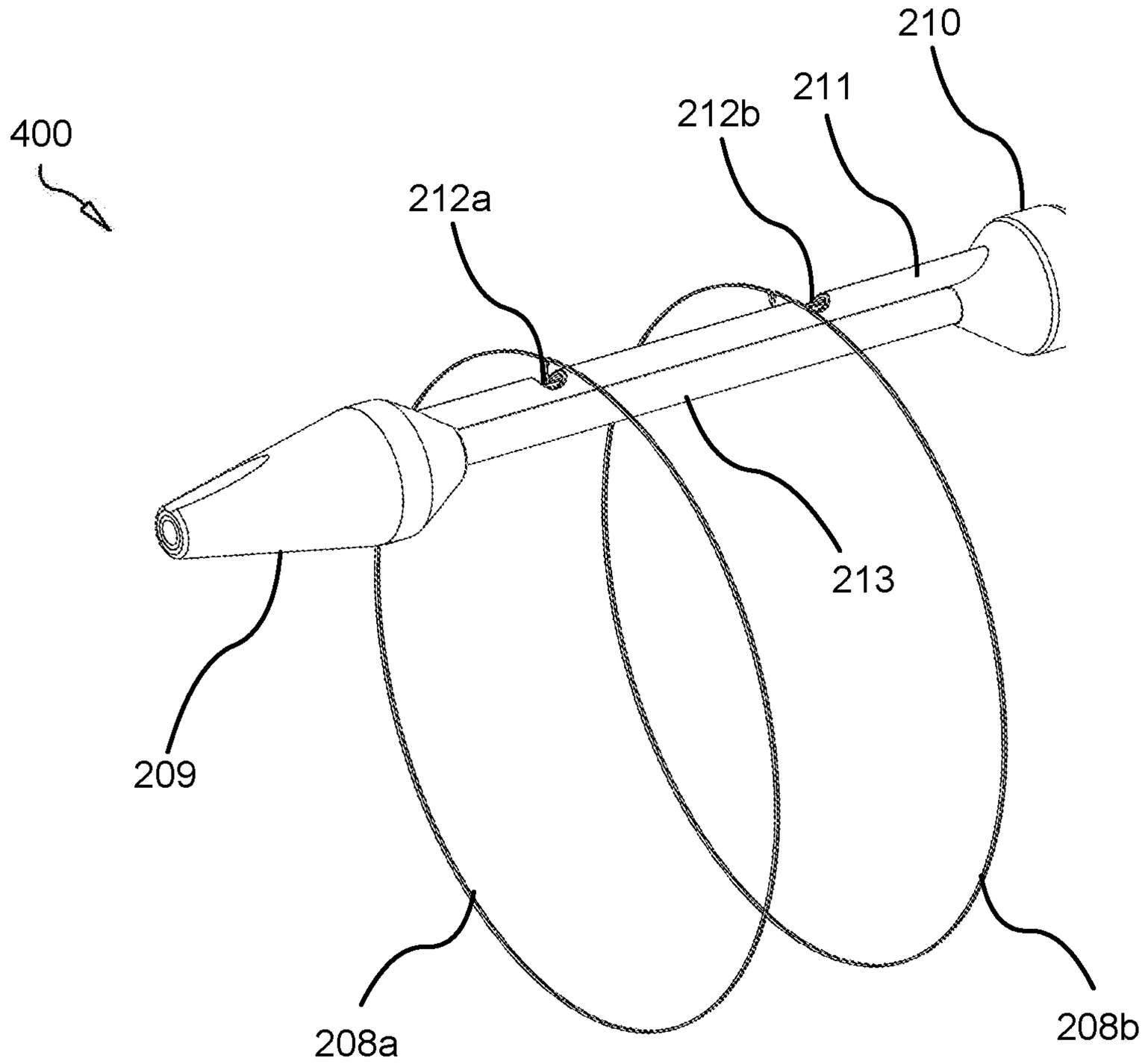


FIG. 3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208a
208b

FIG. 4A

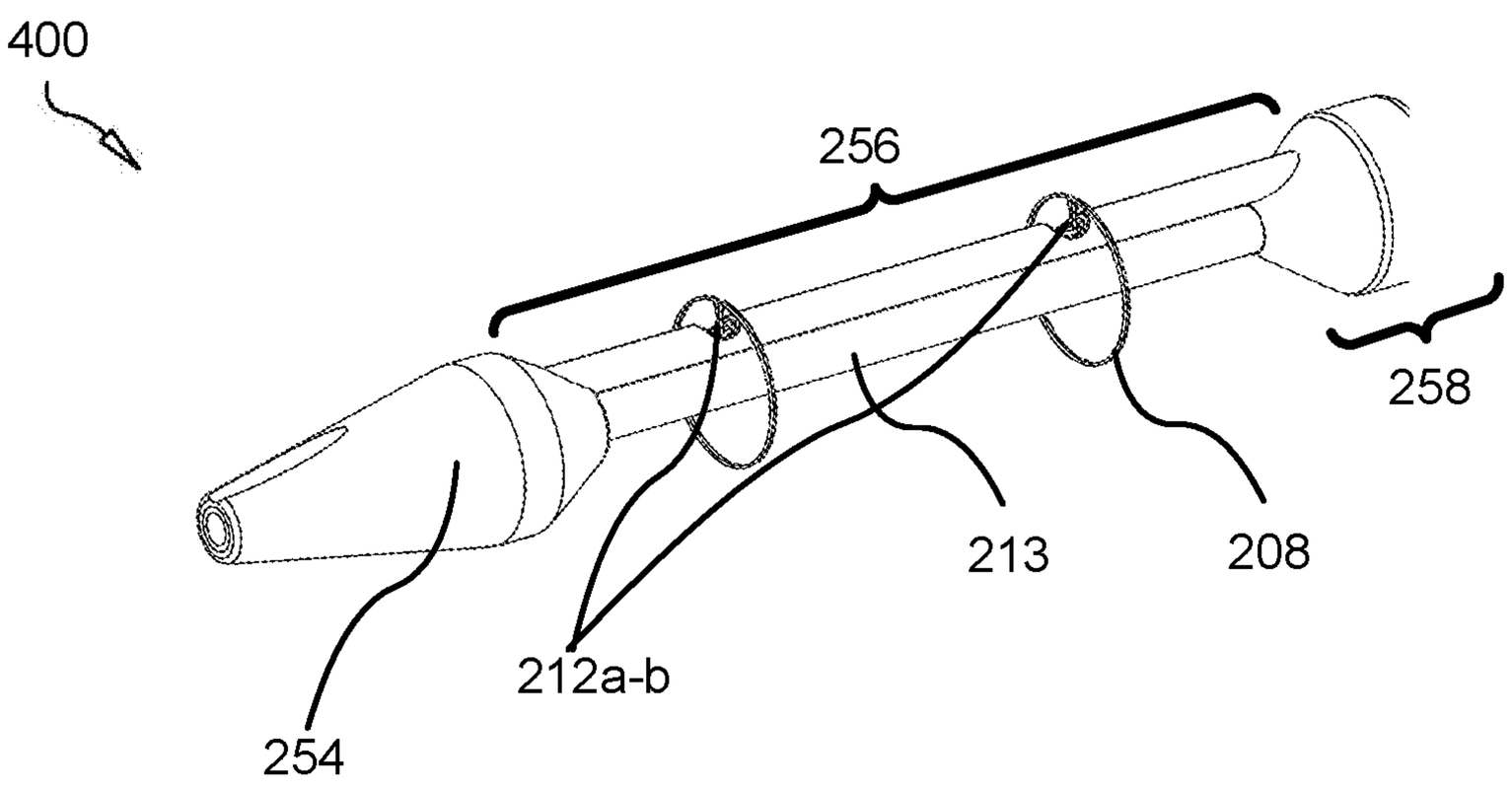
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FIG. 4B

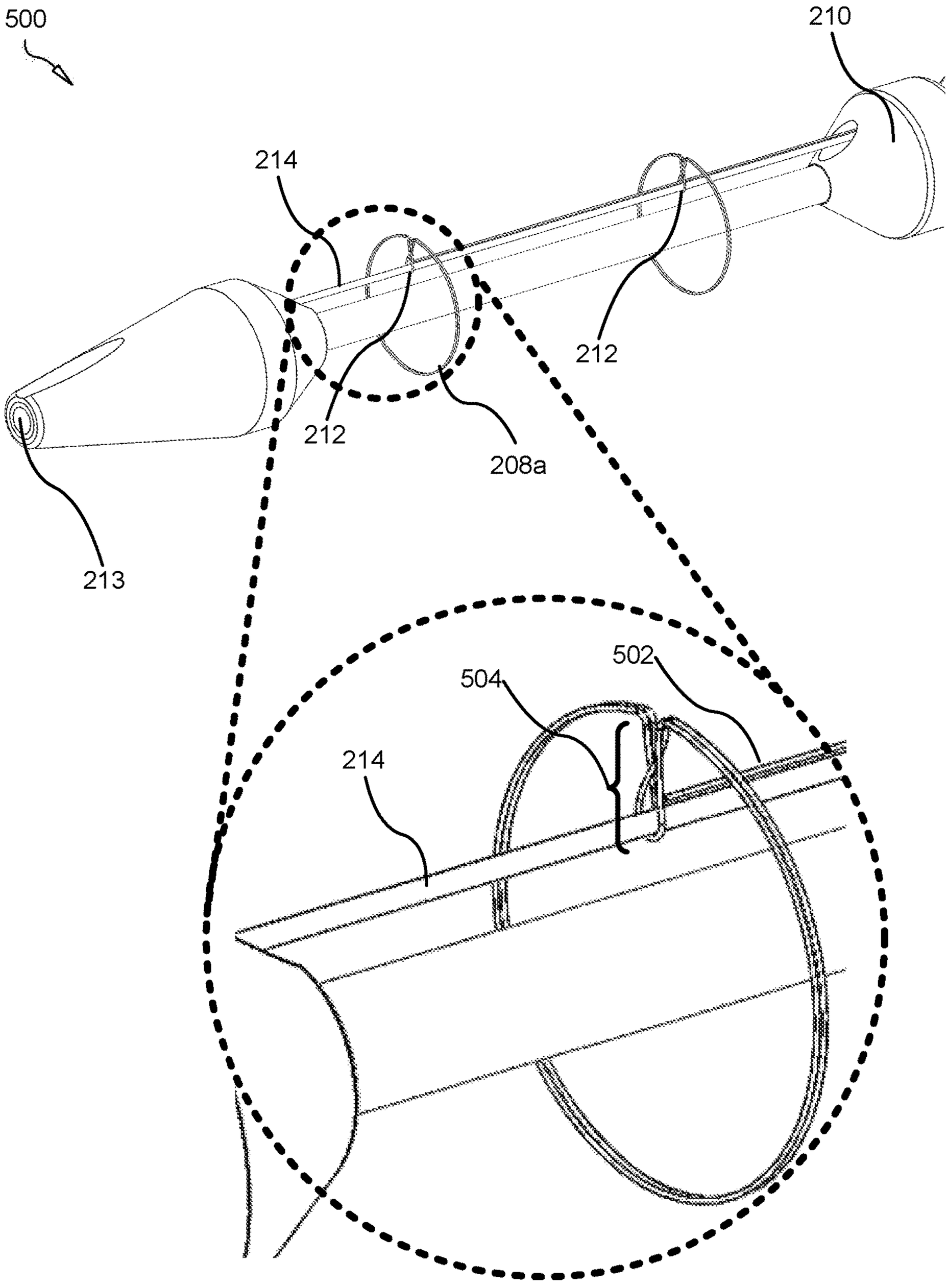

FIG. 5

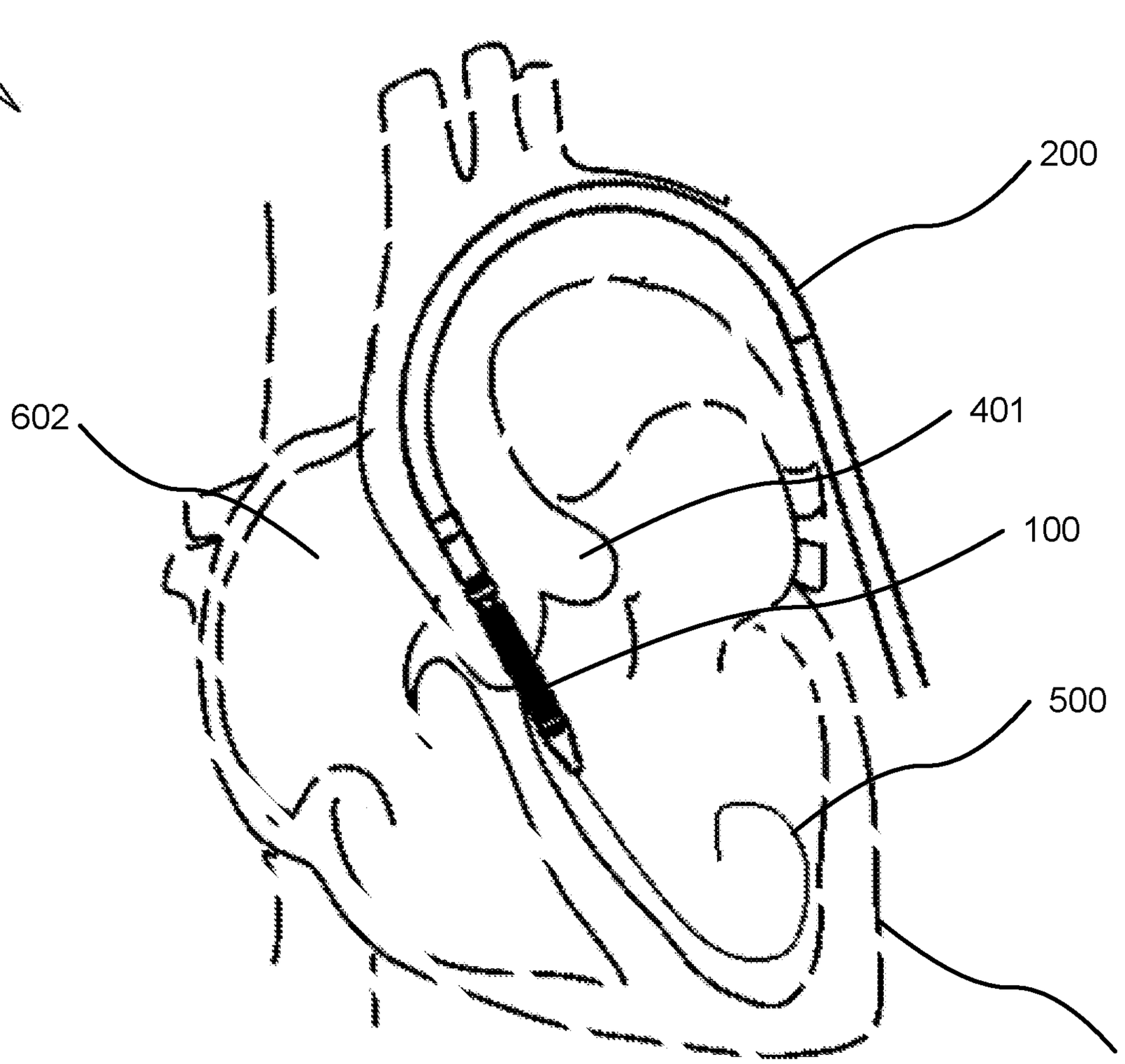

FIG. 6

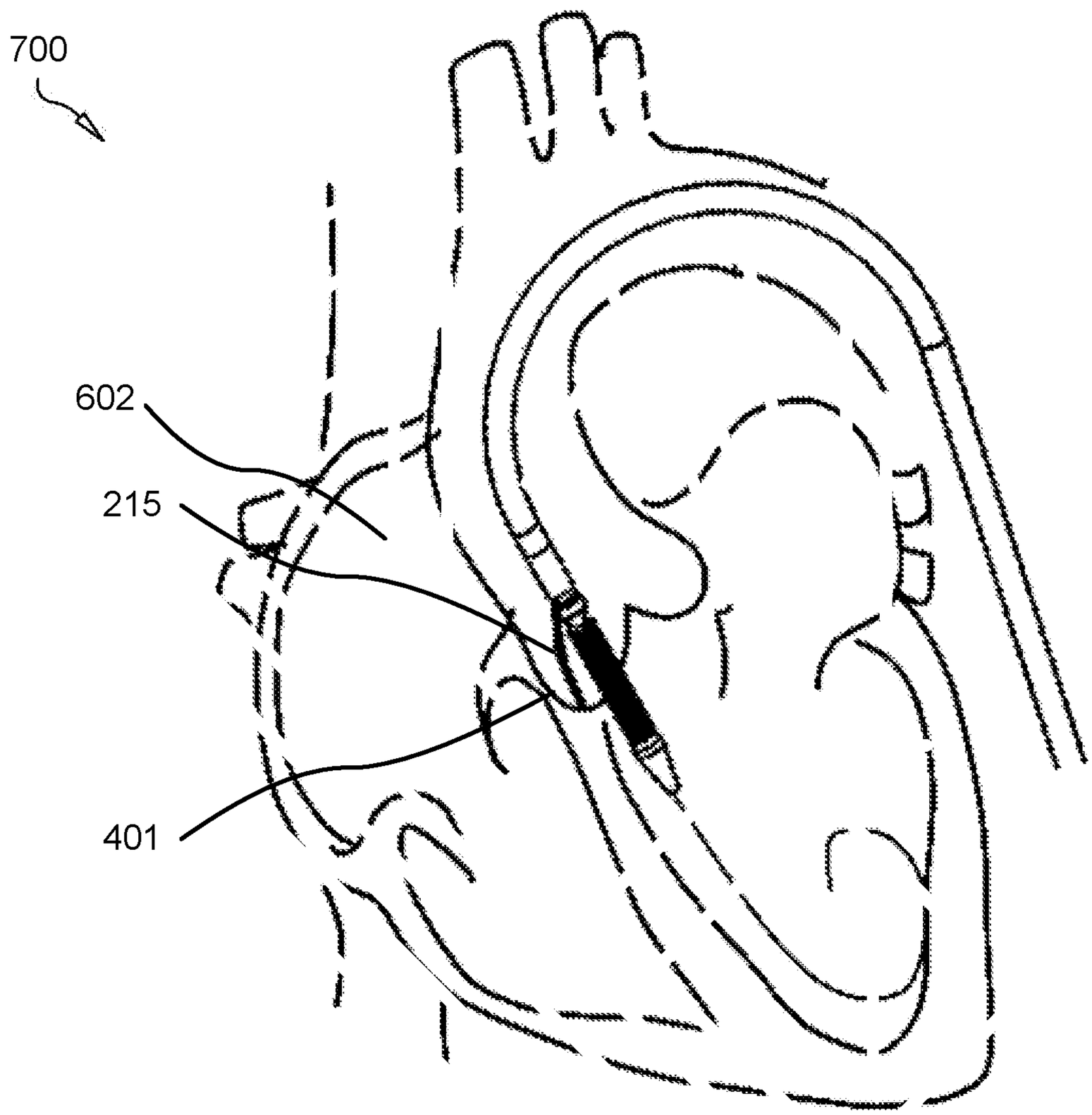

FIG. 7A

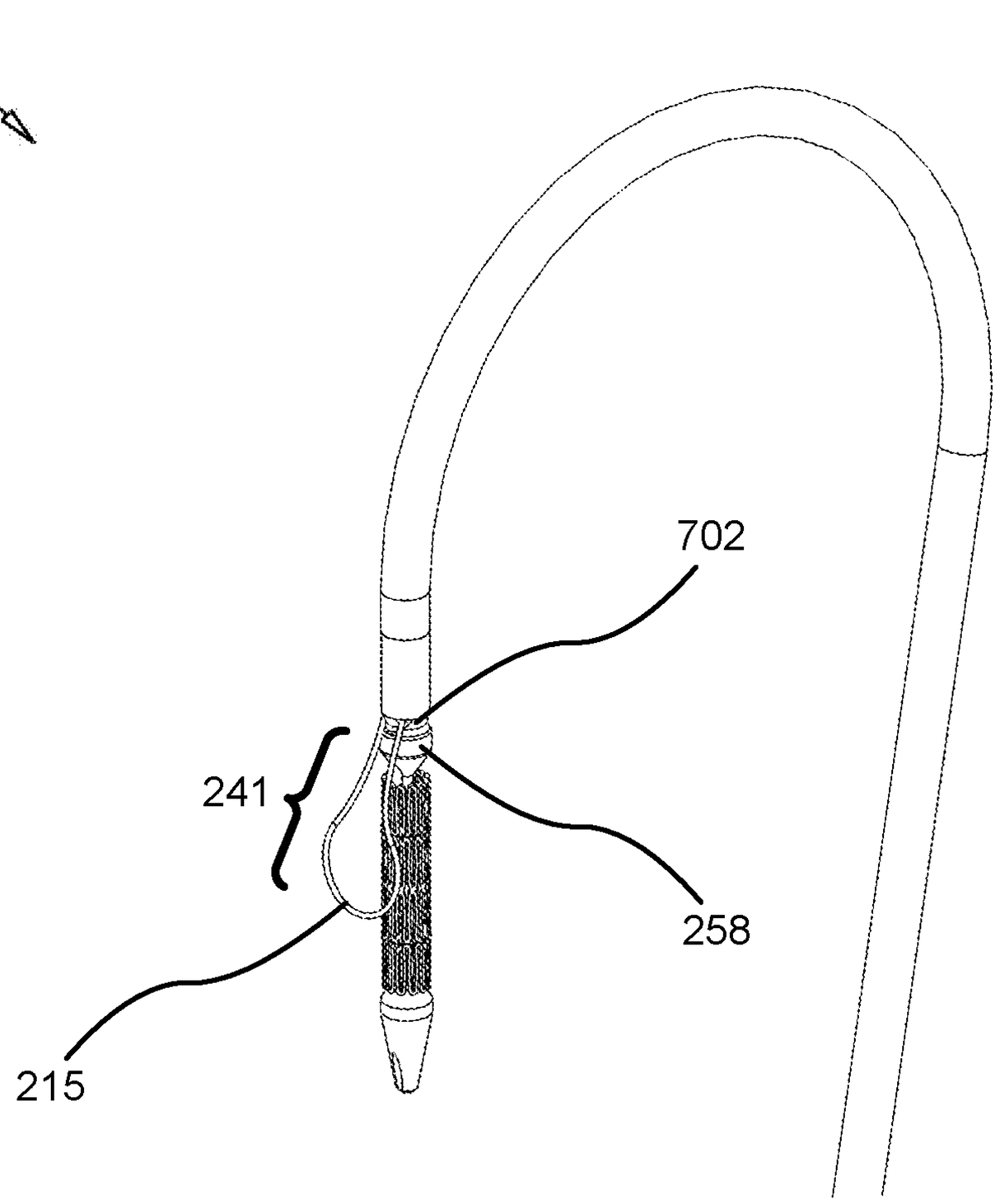

FIG. 7B

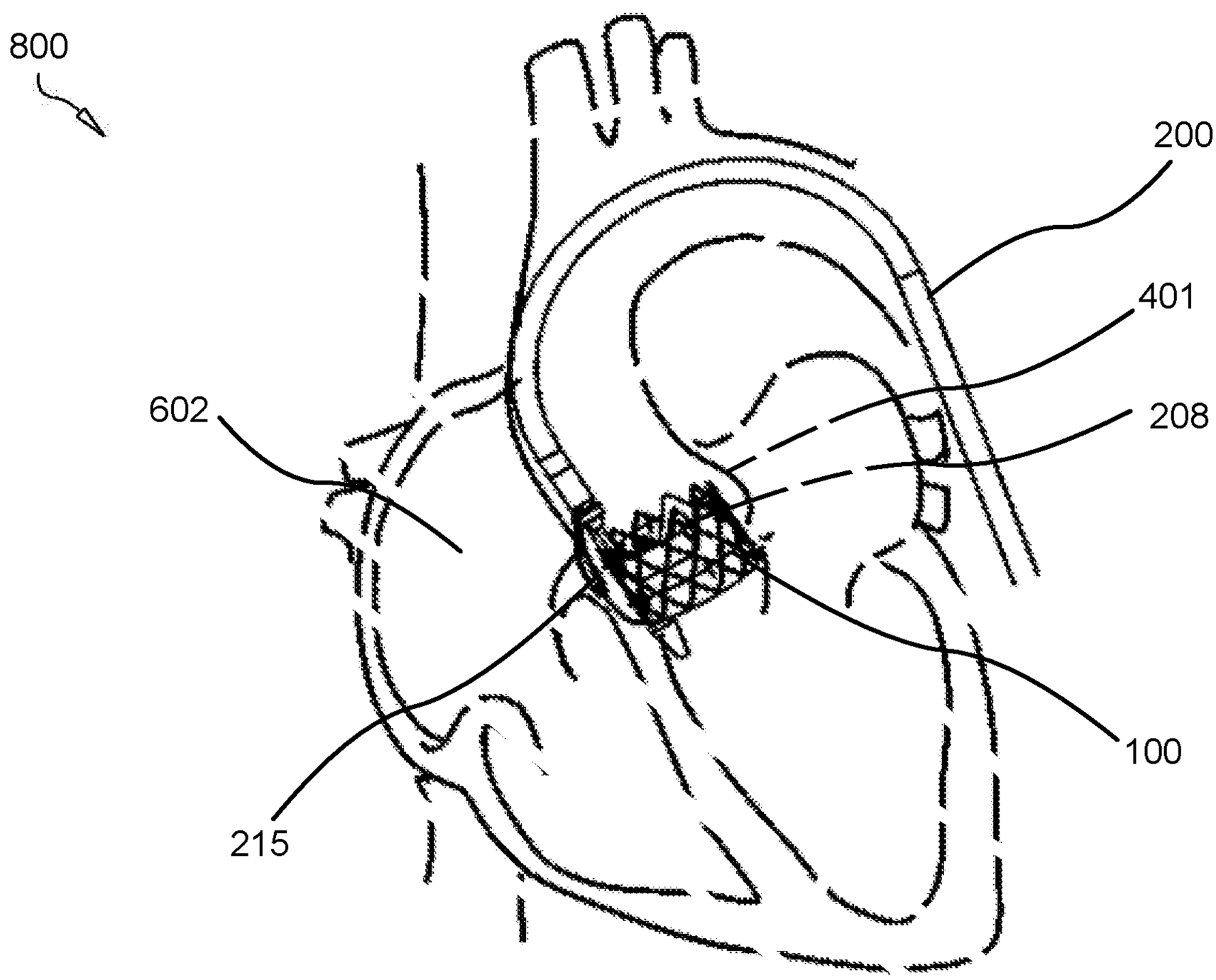

FIG. 8

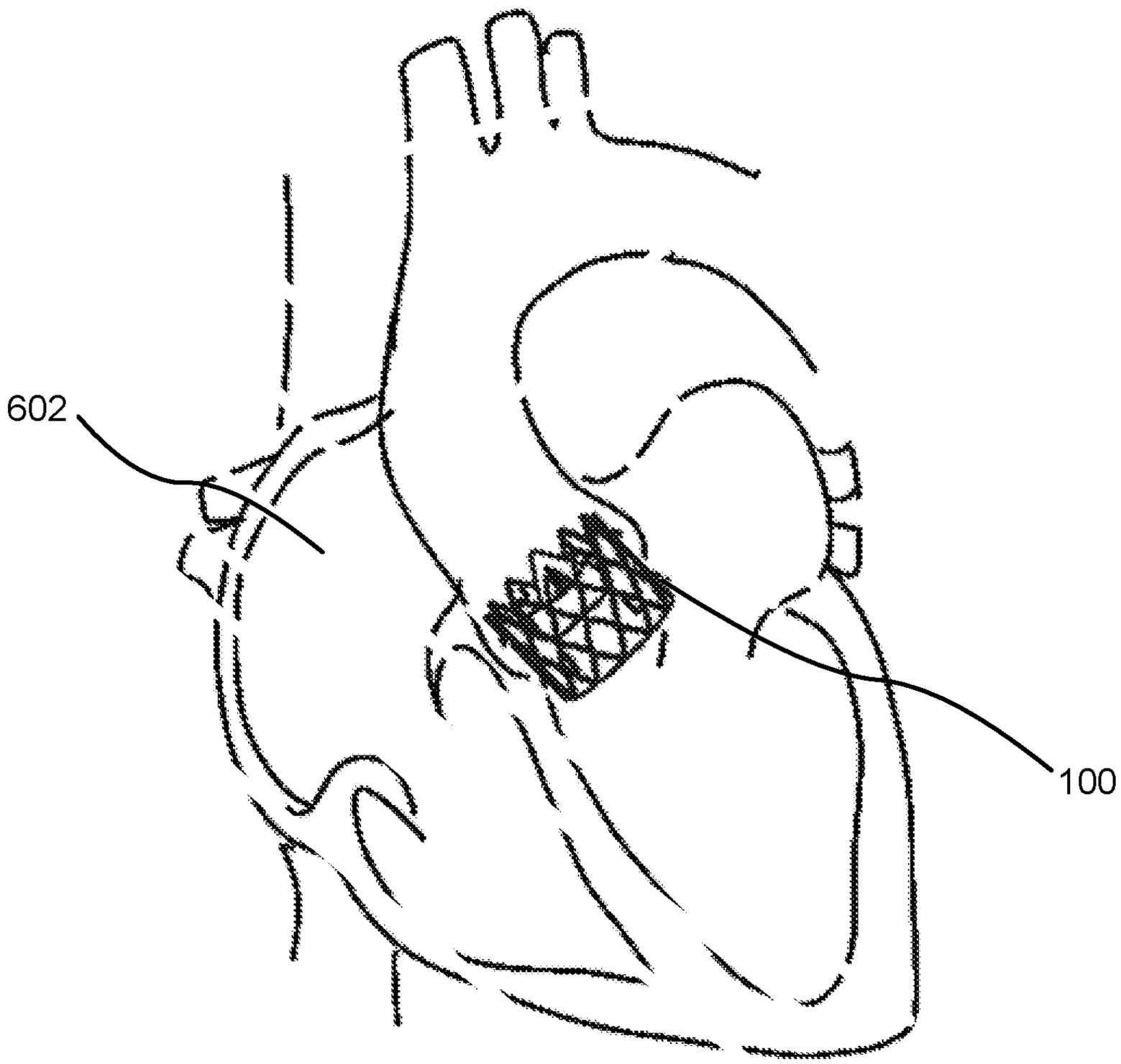

FIG. 9

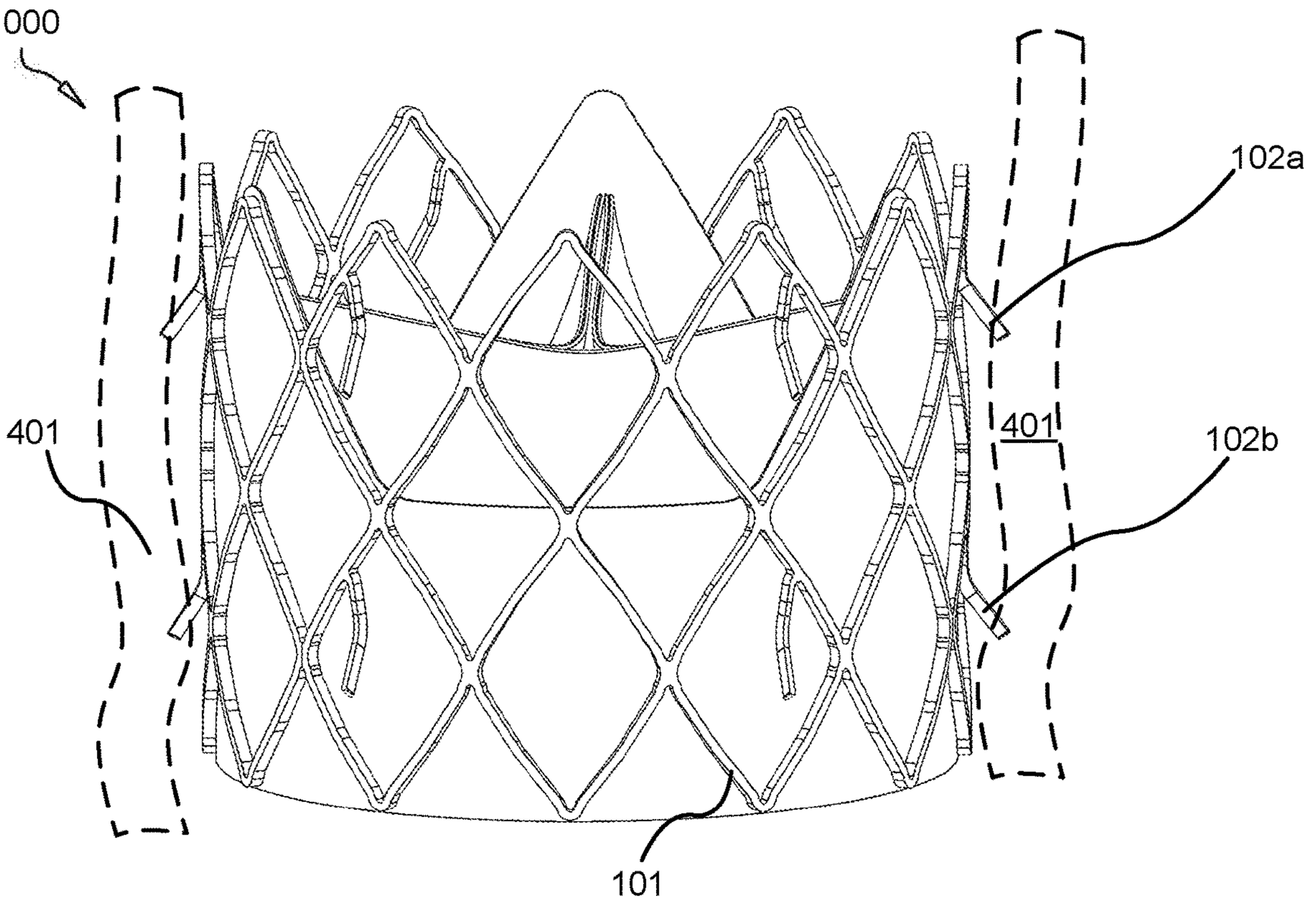

FIG. 10

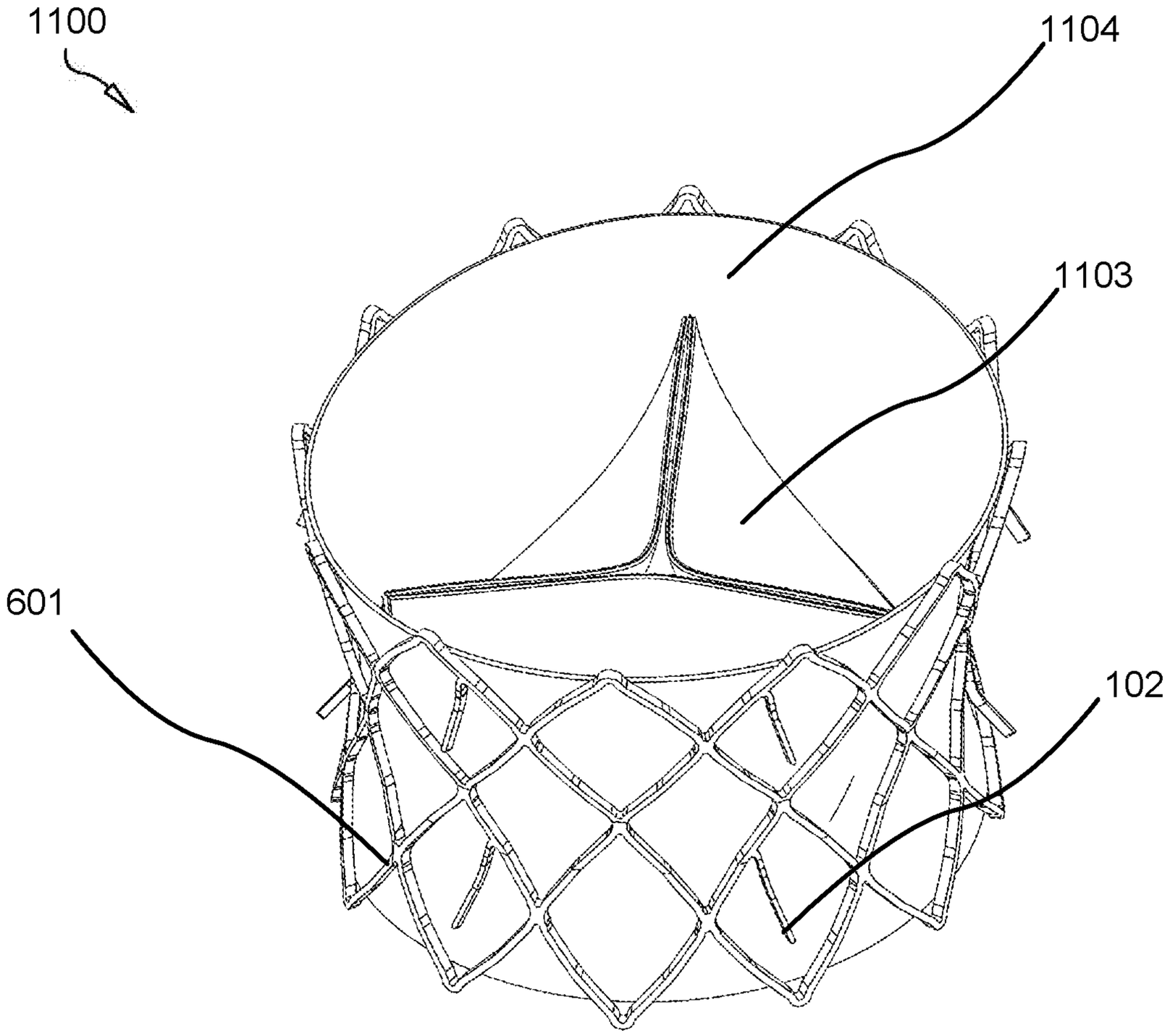

FIG. 11

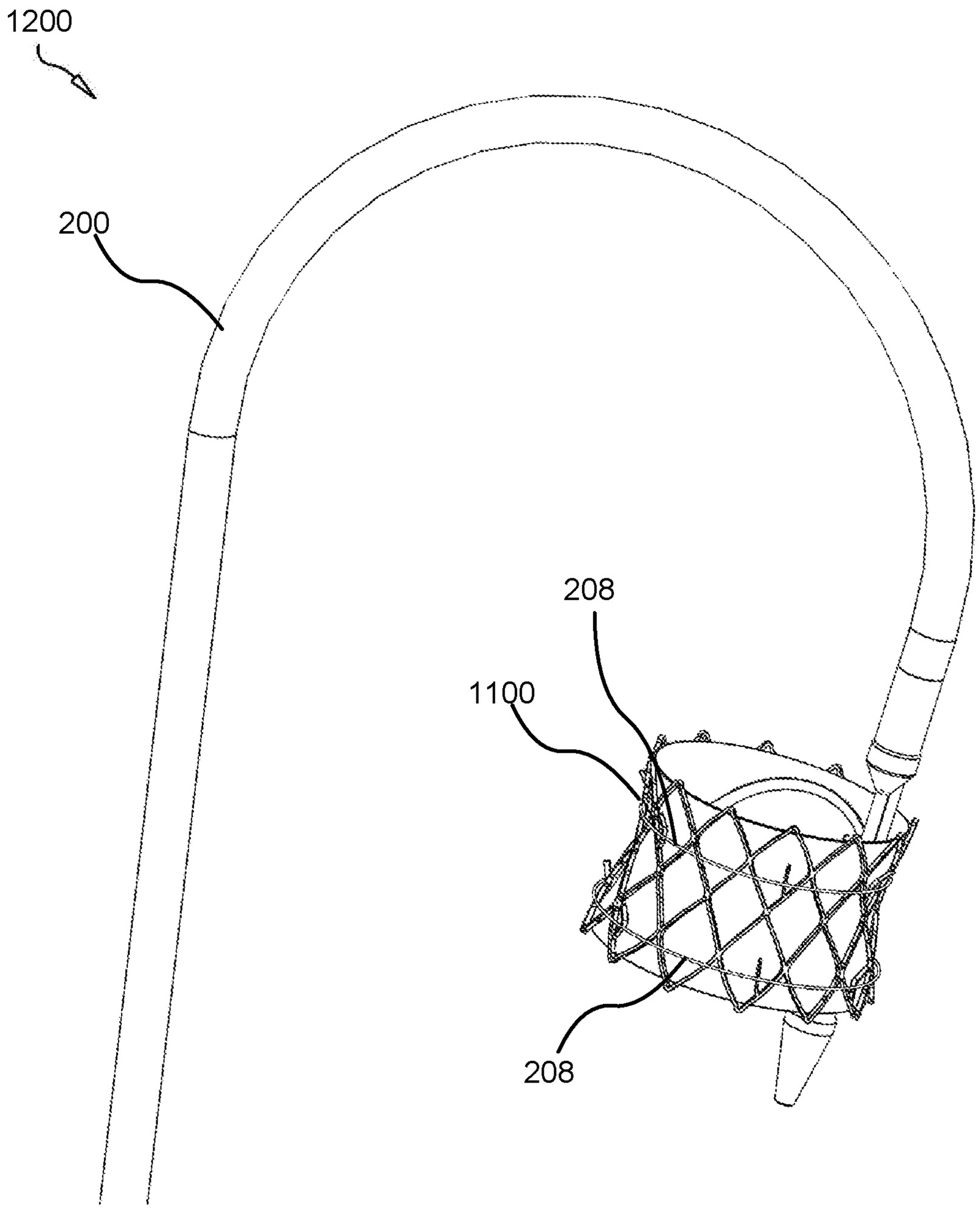

FIG. 12A

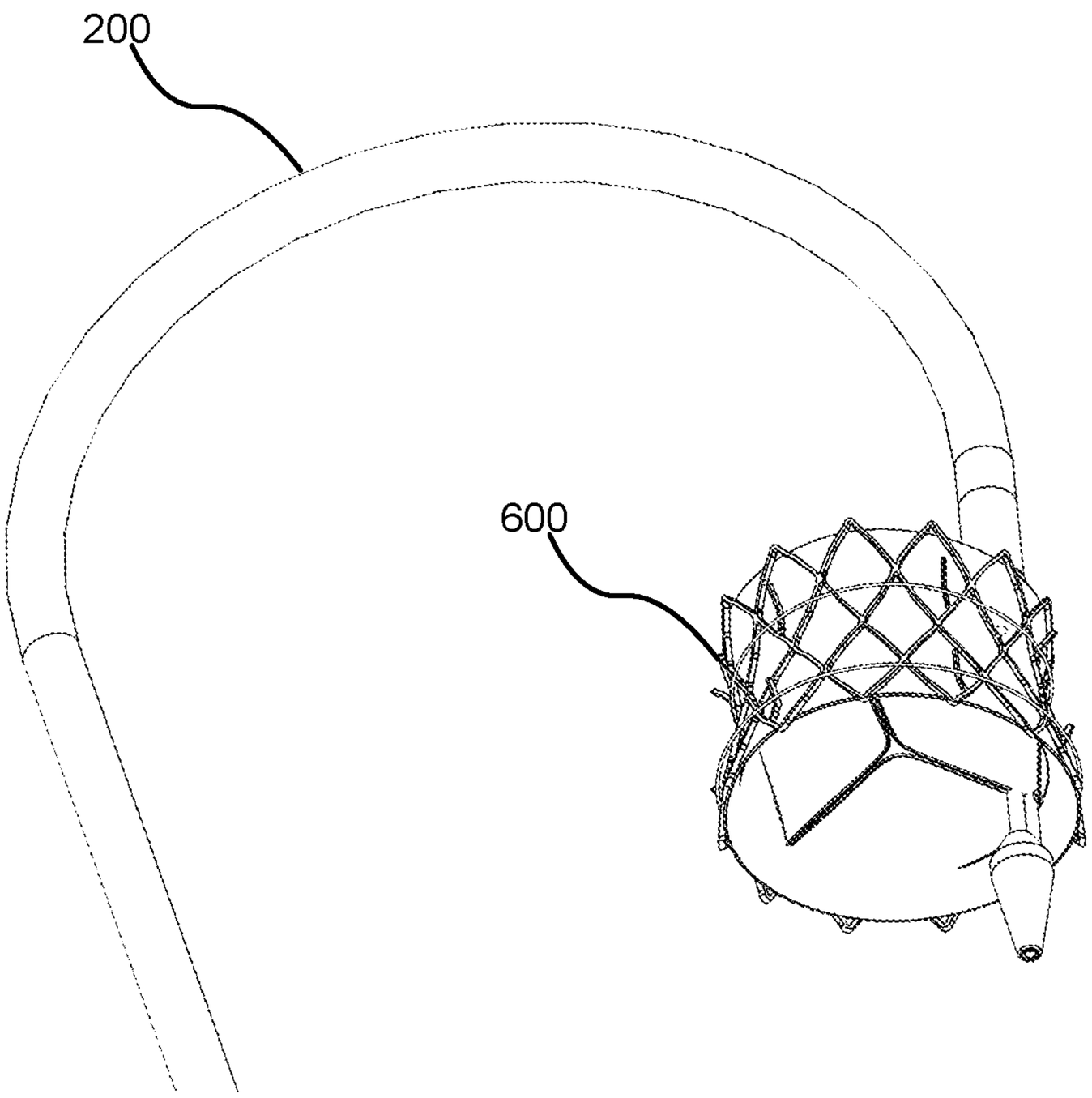

FIG. 12B

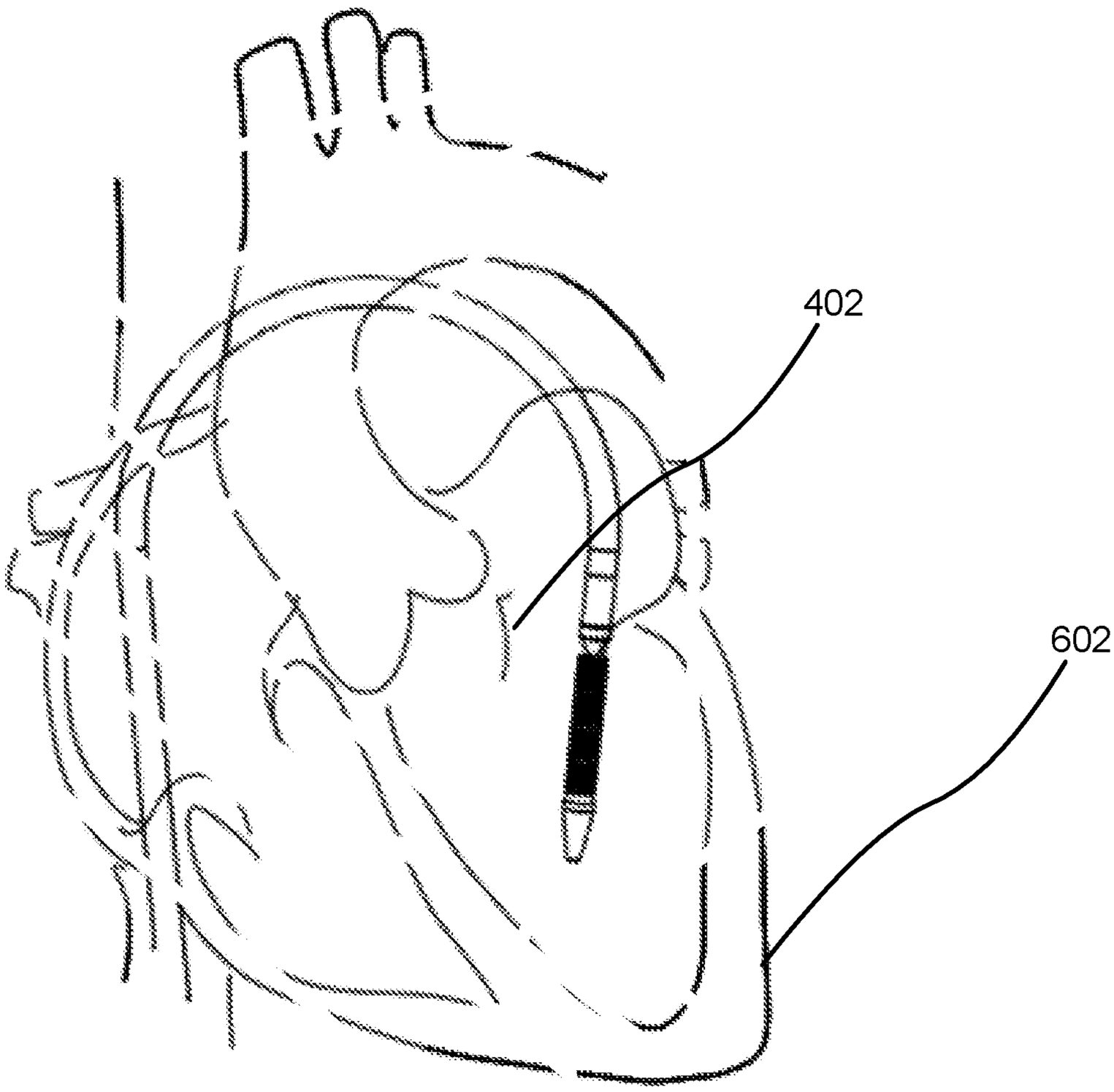

FIG. 13

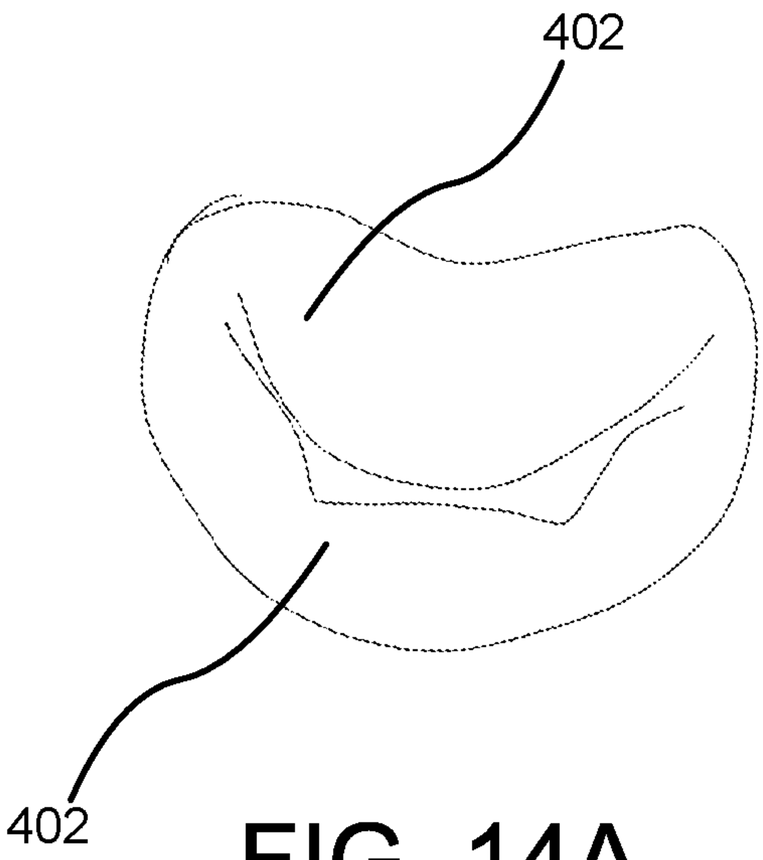

FIG. 14A

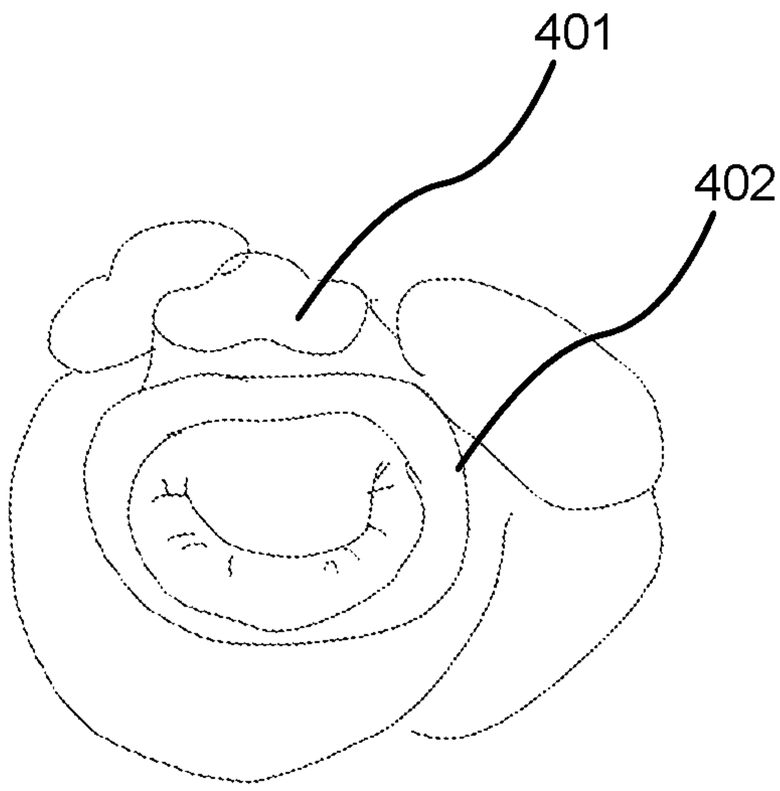

FIG. 14B

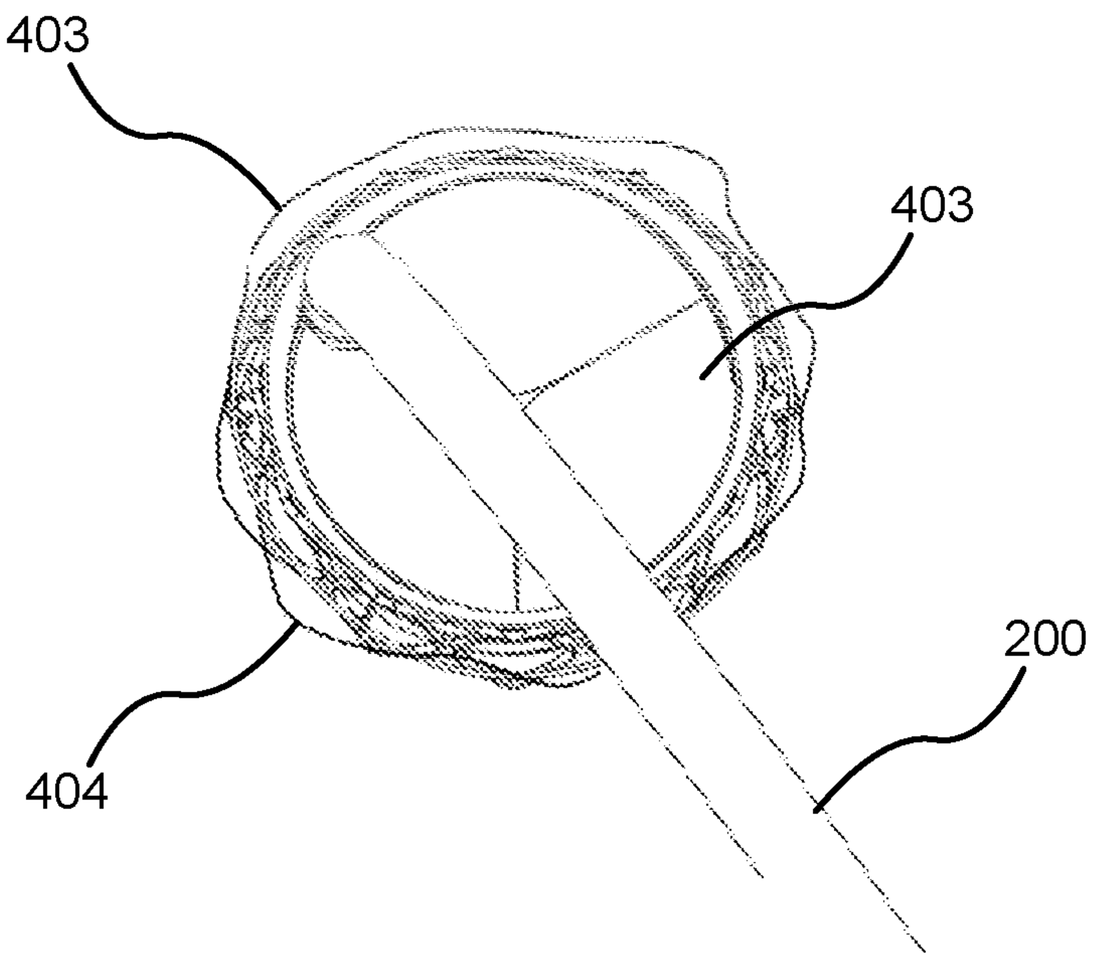

FIG. 14C

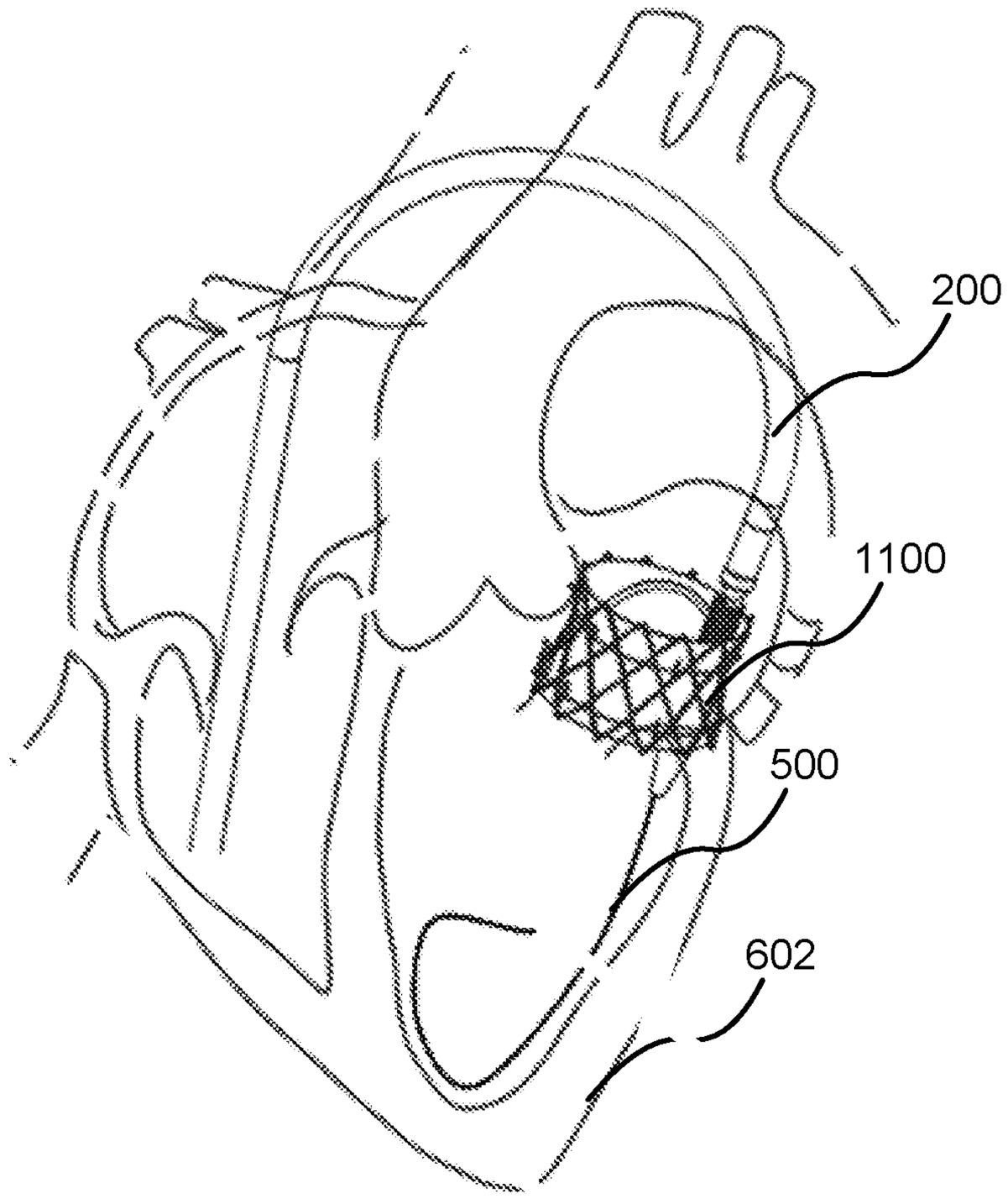

FIG. 15

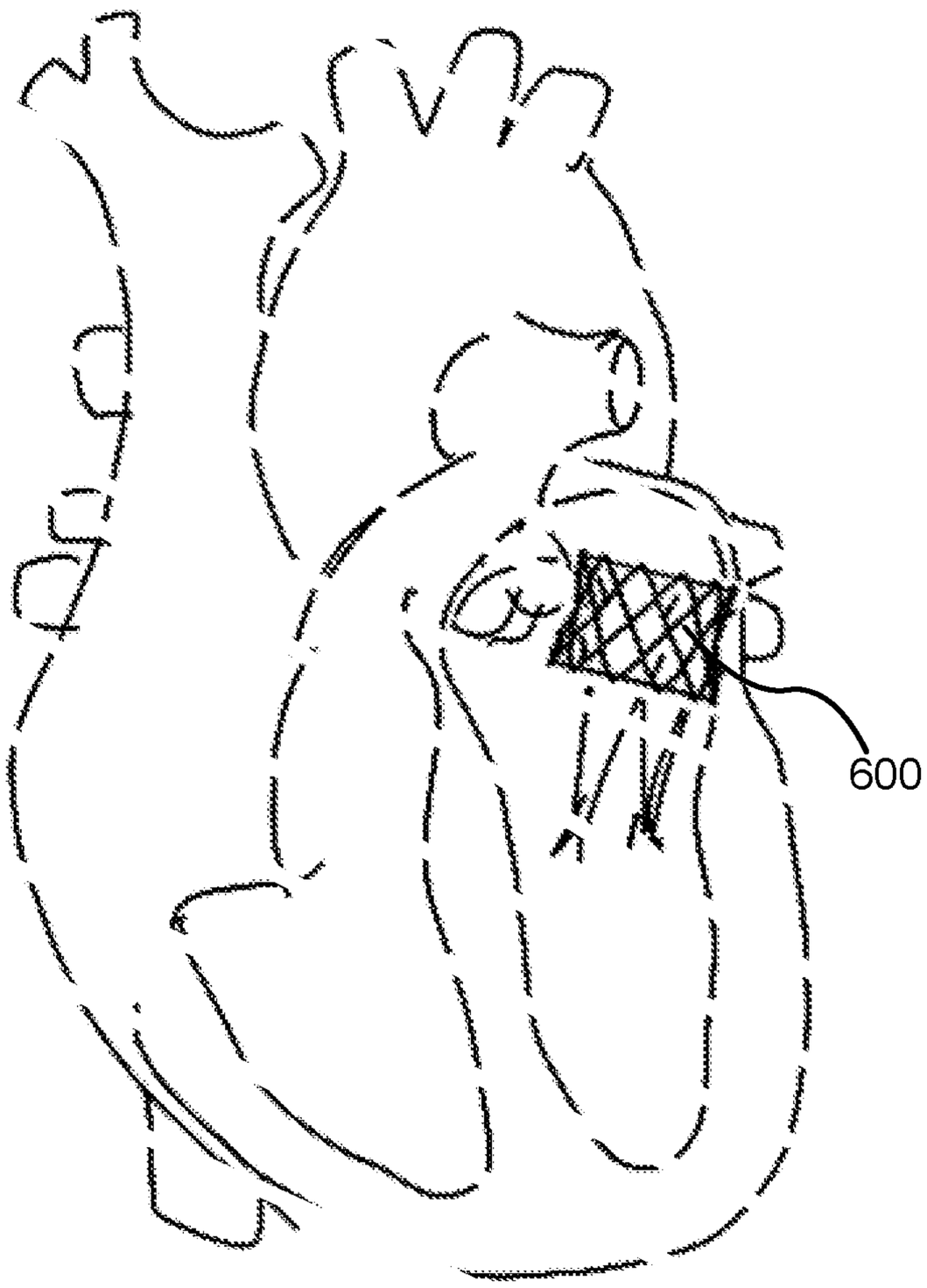

FIG. 16

PROSTHETIC HEART VALVE DELIVERY SYSTEM

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to the field of prosthetic heart valves and more specifically relates to a delivery system for prosthetic heart valves and a method of transcatheter delivery of a valve through the cardiovascular system.

Description of the Related Art

The human heart is the muscular organ which pumps blood through the circulatory system. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. The four chambers of the heart are identified as the upper left, the right atria, the lower left, and right ventricle. This combination of chambers and valves allows only one-way blood flow during the complete pumping cycle of the heart.

Prosthetic heart valves are used to replace damaged or diseased heart valves, commonly in the aortic and mitral valves. These heart valves can be damages or x underdeveloped by congenital, inflammatory, or infectious conditions, or simple old age. Typically, a surgeon accesses the heart through the thoracic cavity via a sternotomy. The patient is placed on cardiopulmonary bypass, thereafter, allowing access to the heart and the replacement of heart valves.

The percutaneous delivery of heart valves as an alternative to conventional valve replacement is known in the art and referred to as percutaneous aortic valve replacement (PAVR) or percutaneous aortic valve implantation (PAVI). Transcatheter valves can be provided via a transfemoral (via the upper leg), subclavian (beneath the collar bone), transvenous, or transcardia routes. The valve prothesis may be attached to calcified leaflets of heart valves within the valve annuli. Accessing native valves in this manner typically allows for reduced trauma, less hospital stay and improved patient recovery, over alternatives method of delivery such as sternotomy.

Patients and surgeons attempting PAVI face a number of challenges, including stenosed (contracted or narrowed) blood vessels too small in diameter to accommodate through passage of traditional delivery systems and prosthetic heart valves, often caused by plaque, previous surgeries, or tortuosity of path. Additionally, aortic valve are typically delivered using a balloon-expandable delivery system in which crimped prosthetic heart valves (or compressed stents) are advanced through blood vessels to the target site and mounted in place within the annulus using an inflatable balloon adapted to expand the prosthetic heart valve to its functional size.

Careful deployment of the valve prosthesis is critical to allow secure attachment and anatomical alignment, allowing optimal valve performance. Native valves with stenosis (i.e., calcification) can provide a surface that aids in attachment of the valve prostheses. In aortic regurgitation, leaflets may not have the amount of calcification needed for secure engagement of the valve prosthesis.

Because of the difficult in placing a stent, many stents are misplaced. There exists no efficient means in the art of slightly adjusting a stent about to be deployed at the delivery site. For this reason, new stents must periodically replace, or

be implanted within, older stents. These older stents may lack the surface morphology necessary for new valve implantation. There is a need in the art for a prothesis which may be placed into prosthetic valves previously put in place.

The valves and delivery systems known in the art lack features which overcome these difficulties presented by challenging anatomical conditions.

These balloon delivery systems suffer from a number of drawbacks, including insufficient expansive force of the balloon to properly place the prothesis, and insufficient resistance once placed with the leaflets. The annulus in which the prothesis is placed may expand over time and result in displacement of the prothesis and migration away from the ventricle.

Systems and methods which address controlled deployment and attachment of the prosthesis is critical to optimal prosthetic valve performance. Accordingly, it is desirable to devise additional systems to allow transcatheter delivery of a valve prosthesis.

The foregoing examples of the related art and limitations related therewith are intended to be illustrative and not exclusive. Other limitations of the related art will become apparent to those of skill in the art upon a reading of the specification and a study of the drawings.

SUMMARY

From the foregoing discussion, it should be apparent that a need exists for an improved prosthetic heart valve and delivery system. The present invention has been developed in response to the present state of the art, and in particular, in response to the problems and needs in the art that have not yet been fully solved by currently available inventions. Accordingly, the present invention has been developed to provide a prosthetic heart valve and delivery system comprising: a spring-biased, metallic stent adapted to radially expand and contract comprising: a plurality of crisscrossing laths forming a cylindrical body, and a flexible check valve formed from one or more compressible valvular elements mounted within an interior recess formed by the crisscrossing laths; a plurality of declined stabilization prongs protruding laterally from one or more laths in the expanded metallic stent configuration; a selectively steerable delivery system comprising: a handle comprising a plurality of controls adapted to apply tensile force to one or more pull wires, the handle defining a hollow through passageway, an elongated sheath affixed at a proximal end to the handle, the elongated sheath comprising a flexible tubular member; wherein the one or more pull wires longitudinally traverse a lumen within the delivery system; one or more stabilization wire(s) forming annular rings at a distal end of the sheath, the annular rings adapted to receive, circumscribe and crimp the metallic stent, the stabilization wires protruding from one or more apertures on the distal end, the stabilization loops forming one or more subloops within one of the sheath and a lumen; an engagement pin detachably inserted into the subloop(s) of the stabilization wire(s), the engagement pin connected with a pull wire to a control on the handle, the engagement pin adapted to retract proximally out of the subloop(s) when the control is activated, the engagement pin adapted to release the annular rings and allow the metallic stent to expand; a frustoconical tip; wherein the sheath defines an annular recess at a distal end behind the frusto-

conical tip, the annular recess adapted to receive the metallic stent in compressed configuration.

The lumen may be the elongated sheath.

The elongated sheath may be between 60 and 150 cm long on a longitudinal axis. The one or more loop stabilization wire(s) may be positioned within the annular recess. The metallic stent may be detachably circumscribed by the loop stabilization wires.

The prosthetic heart valve and delivery system may further comprise a tapered hub at the distal end behind the frustoconical tip. The frustoconical tip may define a hollow nose cone passageway traversing the frustoconical tip longitudinally.

The one or more loop stabilization wire(s) may form subloops within the annular recess. The compressed metallic stent may be between 3 mm and 10 mm in diameter and the expanded metallic stent is between 10 mm and 40 mm in diameter.

A second prosthetic heart valve and delivery system is provided comprising: a spring-biased, metallic stent adapted to radially expand and contract comprising: a plurality of crisscrossing laths, and a flexible check valve formed from one or more compressible valvular elements mounted within an interior recess formed by the crisscrossing laths; a plurality of stabilization prongs protruding laterally from one or more laths in the expanded metallic stent configuration; a selectively steerable delivery system comprising: a handle comprising a plurality of controls adapted to apply tensile force to one or more pull wires, the handle defining a hollow through passageway, an elongated sheath affixed at a proximal end to the handle, the elongated sheath comprising a flexible tubular member; wherein the one or more pull wires longitudinally traverse a lumen within the delivery system; one or more stabilization wire(s) forming annular rings at a distal end of the sheath, the annular rings adapted to receive, circumscribe and crimp the metallic stent, the stabilization wires protruding from one or more apertures on the distal end, the stabilization loops forming one or more subloops within one of the sheath and a lumen; an engagement pin detachably inserted into the subloop(s) of the stabilization wire(s), the engagement pin connected with a pull wire to a control on the handle, the engagement pin adapted to retract proximally out of the subloop(s) when the control is activated, the engagement pin adapted to release the annular rings and allow the metallic stent to expand; a tapered tip; a tapered hub forming a second annular recess through which a rigid stabilization loop protrudes; a rigid stabilization loop adapted to telescope relative to the frustoconical tip, the rigid stabilization loop declining laterally and toward the distal end, the rigid stabilization loop adapted to engage soft tissue and adjust positioning of the delivery system within a patient's circulatory system; wherein the sheath defines an annular recess at a distal end behind the frustoconical tip, the annular recess adapted to receive the metallic stent in compressed configuration; wherein the one or more loop stabilization wire(s) form subloops within the annular recess.

The elongated sheath may be between 60 and 150 cm long on a longitudinal axis. The metallic stent, in some embodiments, may be detachably circumscribed by the loop stabilization wires.

In various embodiments, the prosthetic heart valve and delivery system further comprises a tapered hub at the distal end behind the frustoconical tip. The frustoconical tip may define a hollow nose cone passageway traversing the frustoconical tip longitudinally.

A third prosthetic heart valve and delivery system is provided comprising: a spring-biased, metallic stent; a selectively steerable delivery system comprising: a handle comprising a plurality of controls adapted to apply tensile force to one or more pull wires, the handle defining a hollow through passageway, an elongated sheath affixed at a proximal end to the handle, the elongated sheath comprising a flexible tubular member; wherein the one or more pull wires longitudinally traverse one or more of a lumen and the sheath; one or more stabilization wire(s) forming annular rings at a distal end of the sheath, the annular rings adapted to receive, circumscribe and crimp the metallic stent, the stabilization wires protruding from one or more apertures on the distal end, the stabilization wires adapted to expand at a delivery point in a patient's vascular system and deploy the metallic stent; a frustoconical tip; wherein the sheath defines an annular recess at a distal end behind the frustoconical tip, the annular recess adapted to receive the metallic stent in compressed configuration.

Reference throughout this specification to features, advantages, or similar language does not imply that all of the features and advantages that may be realized with the present invention should be or are in any single embodiment of the invention. Rather, language referring to the features and advantages is understood to mean that a specific feature, advantage, or characteristic described in connection with an embodiment is included in at least one embodiment of the present invention. Thus, discussion of the features and advantages, and similar language, throughout this specification may, but do not necessarily, refer to the same embodiment.

Furthermore, the described features, advantages, and characteristics of the invention may be combined in any suitable manner in one or more embodiments. One skilled in the relevant art will recognize that the invention may be practiced without one or more of the specific features or advantages of a particular embodiment. In other instances, additional features and advantages may be recognized in certain embodiments that may not be present in all embodiments of the invention.

These features and advantages of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

In order that the advantages of the invention will be readily understood, a more particular description of the invention will be rendered by reference to specific embodiments that are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings, in which:

FIG. **1** illustrates a forward perspective view of an aortic valve prosthesis assembly with self-expanding frame in accordance with the present invention.

FIG. **2**A illustrates a side perspective view of a delivery system with contracted valve frame assembly in accordance with the present invention;

FIG. **2**B illustrates a side perspective view of a delivery system with contracted valve frame assembly in accordance with the present invention;

FIG. **2**C illustrates a top perspective view of a delivery system in accordance with the present invention;

FIG. **3** illustrates a top perspective view of a valve frame assembly and delivery system in accordance with the present invention;

FIG. **4**A illustrates a side perspective view of a distal end of a delivery system with a lasso in an extruded configuration in accordance with the present invention;

FIG. **4**B illustrates a side perspective view of a distal end of a delivery system with a lasso in a semi-extruded configuration in accordance with the present invention;

FIG. **5** illustrates a cutaway side perspective view of a distal end of a delivery system, with zoomed view thereof, in accordance with the present invention;

FIG. **6** illustrates an environmental side perspective view of a contracted valve frame assembly tracked to the aortic position using a delivery system in accordance with the present invention;

FIG. **7**A illustrates an environmental side perspective view of a contracted valve frame assembly and delivery system with a stabilization loop deployed in at least one aortic sinus in accordance with the present invention;

FIG. **7**B illustrates a side perspective view of a contracted valve frame assembly and delivery system with a stabilization loop deployed in accordance with the present invention;

FIG. **8** illustrates an environmental side perspective view of a valve frame assembly and delivery system deployed at the native aortic valve in accordance with the present invention;

FIG. **9** illustrates an environmental perspective view of a deployed valve frame assembly in accordance with the present invention;

FIG. **10** illustrates a valve with stabilization prongs engaging native tissue in accordance with the present invention;

FIG. **11** illustrates a top forward perspective view of a mitral valve assembly in accordance with the present invention.

FIG. **12**A illustrates a side perspective view of a mitral valve attached to a delivery system in accordance with the present invention;

FIG. **12**B illustrates a side perspective view of a mitral valve attached to a delivery system in accordance with the present invention;

FIG. **13** illustrates a contracted mitral valve tracked to a general mitral valve position on a delivery system prior to deployment in accordance with the present invention;

FIG. **14**A illustrates the atrial side of the mitral valve;

FIG. **14**B illustrates a sectioned perspective view of the atrial side of the mitral valve;

FIG. **14**C illustrates an inflow view of the valve positioned into a mitral valve in accordance with the present invention;

FIG. **15** illustrates an environmental perspective view of a deployed mitral valve still connected to the delivery device in accordance with the present invention; and

FIG. **16** illustrates an environmental perspective view of a deployed mitral valve with the delivery system withdrawn in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Reference throughout this specification to "one embodiment," "an embodiment," or similar language means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Appearances of the phrases "in one embodiment," "in an embodiment," and similar language throughout this specification may, but do not necessarily, all refer to the same embodiment.

The described features, structures, or characteristics of the invention may be combined in any suitable manner in one or more embodiments. In the following description, numerous specific details are provided. One skilled in the relevant art will recognize, however, that the invention may be practiced without one or more of the specific details, or with other methods, components, materials, and so forth. In other instances, well-known structures, materials, or operations are not shown or described in detail to avoid obscuring aspects of the invention.

Objects of the Present Invention

It is an object of the present invention to provide an apparatus, system, and method for valve replacement, preferably using a minimally invasive surgical technique. While the systems and methods will have application in a number of different vessels in various parts of the body, they are particularly well suited for replacement of a malfunctioning cardiac valve, and in particular an aortic valve. The systems and methods will also have application in other malfunctioning cardiac valves, e.g., a pulmonary valve or a mitral valve. The systems and methods are particularly advantageous in their ability to provide a more flexible prosthetic heart valve delivery system, ensure accurate and precise placement of the prosthetic heart valve or valve prosthesis with reduced reliance on imaging, and provide additional attachment of the valve prosthesis, reducing the incidence of valve migration. Another advantage is the delivery and implantation of the valve prosthesis through the aorta, which has a smaller diameter than the inferior vena cava, through which surgeons typically proceed to access the heart.

It is further an object of the present invention to provide improved systems and methods for implanting a prosthetic heart valve. In particular, improved minimally invasive methods and systems are provided for retrograde implantation of expansible prosthetic heart valves within or adjacent a valved anatomic site within the heart. In particular, the improved prosthetic heart valve delivery systems and methods of the present disclosure provide more flexibility in the valve replacement procedure, ensure accurate and precise placement of the prosthetic heart valve with reduced reliance on imaging, and provide additional attachment of the prosthetic valve, reducing the incidence of valve migration or misalignment.

Various embodiments now will be described more fully hereinafter. Such embodiments may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey its scope to those skilled in the art.

It is additionally an object of the present invention to provide a valve prosthesis delivery system which facilitates delivery of a valve prosthesis to the heart while minimizing trauma or damage to the vessels and tissues of a patient. The various embodiments described herein provide a means for both pushing and pulling the valve prosthesis delivery system through the tight turns presented by the heart chambers. It is noted that for the purposes of describing the disclosed systems and methods, the term "proximal" refers to a relative position closer to a control unit whereas the term "distal" refers to a relative position further away from a control unit.

FIG. **1** illustrates a forward perspective view of an aortic valve prosthesis **100** with self-expanding frame in accordance with the present invention. The aortic valve prosthesis **100** is interchangeable referred to hereinafter as a valve frame assembly **100**. The prosthesis **100** is spring-biased to apply expansive radial forces in opposition to the native anatomy of a patient thus securing the prosthesis **100** in position when deployed. The prothesis **100** comprises a frame **101**, which may comprise a plurality of crisscrossing metal laths **111** forming a lattice-like cylindrical structure, or stent, which circumscribes one or more interiorly-disposed leaflets **103**.

In the shown embodiments, the prosthesis is in a radially-dilated (or expanded) configuration but is delivered in a radially-contracted (or compressed configuration).

The prothesis **100** comprises a plurality of protuberating stabilization prongs **102**, barbs, or hooks. These prongs **102** jut laterally from the frame **101** and may be declined toward a bottom of the frame **101**. The prongs **102** are adapted to engage with the native anatomy surrounding a deployed prothesis **100** and reduce embolization or migration of the prosthesis **100** post PAVI within a patient. The prosthesis may include as few as one or as many of as 100 prongs **102**. The prongs **102** in typical embodiments decline from the top of the prothesis **100**, but may incline in some embodiments. In still further embodiments, prongs **102** positioned near the top of the prothesis **100** incline or decline while prongs **102** positioned near the bottom of the prothesis **100** angle in a opposing direction.

When the prothesis is correctly positioned in the native aortic valve, the prongs **102** may hook or barb the aortic commissures and/or cusps of the aortic valve. The aortic valve is typically composed of three leaflets with cusps at the inflow (ventricular) portion of the valve and commissures at the outflow portion. These commissures are the structure of the adjoining leaflets. It is common after PAVI for the seal which a prothesis formed within the annulus to leak at the commissures. The prongs **102** help pull the commissures together around the outer circumference of the prothesis **100**, helping to seal the prothesis **100** in place and prevent leakage and regurgitant blood.

The prothesis **100** comprises a plurality of leaflets **103** coupled to the frame **101** and disposed within a hollow interior recess **107** formed by the frame **101**. The leaflets **103** may be formed from a flexible or semi-rigid bioinert material, including polymeric materials. The leaflets **103** form a check valve which prevents regurgitation of blood back into the ventricle. In other embodiments, the leaflets **103** comprise a homograft from a cadaver or autograft. The leaflets **103** may be formed as a single integrated piece, or valvular structure.

FIGS. **2A-5** illustrates perspective views of a delivery system **200** with contracted valve frame assembly in accordance with the present invention, including a handle **201**. The delivery device **200** is adapted to facilitate mounting of any aortic valve prosthesis **100** in any axial orientation (outflow of the valve positioned in the direction of either the distal or proximal side). The contracted (or crimped) prosthesis **100** is mounted at the distal end **239** of a delivery sheath **207** that can be between 60 cm and 150 cm long. A proximal side **238** of the delivery system **200**, **300**, **400**, **500**, comprises a user handle **201**. The contracted prothesis **100** may be between 3 mm and 10 mm in diameter. The expanded prothesis **100** may be between 15 and 40 mm in diameter. The sheath diameter **207** may be between 3 and 10 mm in diameter.

The distal end **239** of the delivery device **200** comprises a frustoconical tip **254** behind which the crimped prothesis **100** is mounted. The prothesis **100** is mounted, or inserted onto the sheath **207**, to rest within a recess **256** defined between the frustoconical tip **254** and a tapered hub **258** on the sheath **207**. The tapered hub **258** may comprise a frustocone with a hollow interior passage. A plurality of apertures **212** (or bores) form on a surface (such as the top surface) of the sheath **207** within the recess **256**.

One or more lasso elements **208** exit, and protrude from, the apertures **212**. The lasso elements **208** are shown in a contracted configuration (or state) in FIG. **3**, in an expanded configuration in FIG. **4**A, and in a semi-expanded configuration in FIG. **4**B.

The lasso elements **208** protrude from the apertures **212** in the sheath **207** or lumen **211**. FIG. **5** is a cutaway omitting the lumen **211** from view and showing an engagement pin **214** which traverses the lumen **211** longitudinally. The engagement pin **214** may be retracted using one or more of the controls **202** at the handle **201**. The engagement pin **214** is interconnected to the handle **201** using a pull wire **502**.

The pull wire **502** may be a separate flexible wire attached to the lasso elements **208** or integrated as a single piece therewith. The engagement pin **214** is inserted into one or more subloops **504** formed by the lasso elements **214** within the lumen **211**.

Alternatively, the lasso elements **208** (and the pull wire **502**) may traverse the hollow interior recess of the sheath **207** rather than a separate lumen. A nose cone shaft **213** that connects the nose cone to the user handle also provides a lumen for a guidewire **500** (further described below in relation to FIG. **6**). FIG. **4***b* illustrates the state of the lasso **208** after an actuation of control **203** on the user handle **201** to reduce the diameter of lassos **208***a-b*.

The lasso elements **208** are adapted to circumscribe the prothesis **100** and crimp, or compress, the prothesis **100** when the control **203** is actuated. The lasso elements **208** pull the prothesis **100** inwardly radially into a contracted configuration. When the engagement pin **214** is retracted toward the proximal end of the delivery system **400**, the lasso elements **208** are freed to expand, and thus allow the prothesis to expand, at the target location.

In various embodiments, the lasso elements **208** are formed from sutures, metallic braids, polyethylene, or other flexible materials known to those of skill in the art. The lasso elements **208** may be retracted after the prothesis **100** is deployed back into the sheath **207** in some embodiments. In other embodiments, the lasso elements **208** are cut at one end and the uncut end pulled out through the handle **201** after the prothesis **100** is deployed. In still further embodiments, the lasso elements **208** form part of the prothesis **100** itself, and are left in situ after the expanded prothesis **100** is deployed. Thus, the lasso elements **207** may form part of the prothesis **100** or the delivery system **200**.

As illustrated in FIG. **2**C a user handle **201** may consist of steering actuation control **202** and a surrounding lasso element control **203**. The lasso element **208** may comprise suture, wire, monofilament, or other materials known to those of skill in the art. In some embodiments, friction or ratcheting elements may be incorporated into the handle **201** to further enhance operator control.

The controls **202-205** provide a selectively steerable delivery sheath **207** adapted to advance the crimped prothesis **100** through major vessels and/or arteries of the patient's circulatory system, including through the femoral artery and around one or more aortic arches.

The sheath **207** comprises a flexible, hollow, elongated tubular member forming an interior recess, or lumen, for housing one or more pull wires (or guidewires) traversing the sheath **207** longitudinally and affixed at proximal ends to the controls **202-205**. Through the application of tensile force to the control wires using the controls **202-205**, the curvature of the sheath **207** may be selectively manipulated during surgery and the prothesis **100** guided through the circulatory system to the target location within the patient's heart **602**.

Control of the loop stabilization wire **215** (further described below) is realized via a sliding interface **204** to release or contract the annular loop **241** (or annular ring) formed by the loop stabilization wire **215**. To disengage the prosthesis **100** from the delivery device **200**, the sliding interface **205** is retracted to pull back the engagement pin **214** on the surrounding lasso element loop **208**. The user handle **201** also defines a passage for common guidewires, and pull wires. The handle **201** includes a guide wire access point **206**.

FIG. **2**B illustrates a configuration of the delivery device **200** in a steered position after actuation of the steering control **202** which determines the degree and radius of flex of the distal portion **239** of the delivery device **200**.

The delivery system **100** can be configured such that the heart valve prosthesis **100** is advanced through the vascular system while being movably coupled to the sheath **207**, minimizing friction of the tip **209** and cross section of the delivery system **200**, **300**, **400**, **500** with the tunica intima, tunica media and tunica adventitia of the blood vessels. The controls **202-205** and guidewires impart motion control and articulation to the sheath **207**, providing a surgeon with control over the direction of travel of the contracted prosthesis **100** to the target location.

The sheath **207**, in the shown embodiment, comprises a tip **209**, which may be round or tapered. In those embodiments in which the tip **209** is frustoconical, the tip **209** is a frustoconical tip **254**. In some embodiments, the delivery system **200** lacks a tip **209** altogether. In other embodiments, a cylindrical sleeve may telescope on the sheath **207** and be adapted to envelope the crimped prothesis **100** as it travels to the delivery point before the cylindrical sleeve is retracted telescopically using controls on the handle **201** to expose the crimped prothesis **100**.

FIG. **6** illustrates an environmental side perspective view of a contracted valve frame assembly **600** tracked to the aortic position using a delivery system in accordance with the present invention. The native aortic valve may be diseased, stenotic and/or regurgitant.

FIG. **7**A illustrates an environmental side perspective view of a contracted valve frame assembly and delivery system **700** with a stabilization loop **215** deployed in at least one aortic sinus of the heart **602** in accordance with the present invention. The stabilization loop **215** may be stabilized in at least one aortic sinus **401**. The stabilization loop **215** is retractable to aid in aligning the prothesis **100** within the native valve anatomy.

FIG. **7**B illustrates a side perspective view of a contracted valve frame assembly and delivery system **700** with a stabilization loop **215** deployed in accordance with the present invention.

A second annular recess **702** may form behind the tapered hub **258**, from which the stabilization loop **215** protrudes. The stabilization loop **215** juts at a declined angle from the sheath **207** and is adapted to engagement the soft tissue of the blood vessels. The stabilization loop **215** telescopes into and out of the sheath **207**, applying both lateral and downward forces against the walls of the blood vessels and/or leaflets and/or ventricles of the heart **602**. The stabilization loop **215** is connected to one or more controls **202-205** on the handle **201**. The stabilization loop **215** is adjusted to position the prothesis **100** within the annulus **401** before final deployment of the prothesis **100** at the target area.

FIG. **8** illustrates an environmental side perspective view of a contracted valve frame assembly and delivery system deployed at the native aortic valve in accordance with the present invention. The lasso element **208** may be actuated to partially or completed reduce the valve diameter to remove or adjust the position of the prothesis **100**.

FIG. **9** illustrates an environmental perspective view of a deployed valve frame assembly in accordance with the present invention. Once the prothesis **100** is positioned and deployed, the deployment system **200** is removed leaving the prothesis **100** in place in the annulus **401**.

FIG. **10** illustrates a valve **100** with stabilization prongs **102** engaging native tissue of the annulus **401** in accordance with the present invention. The radial force of the metallic stent **101** and the prongs **102** anchor the prothesis **100** within the annulus **401**.

FIG. **11** illustrates a top forward perspective view of a mitral valve assembly **1100** in accordance with the present invention. The mitral valve assembly **1100** may have a waisted shape as shown (i.e., more narrow through the center between the top and bottom) to aid in axial location and anchoring in the native mitral valve position. The embodiment shown in FIG. **11** may be a mitral valve prothesis with a self-expanding frame which has sufficient radial expansion force to oppose the native anatomy and aid in securing its position. The frame **601** features a plurality of stabilization prongs **102** which further engage with the native anatomy to reduce embolization or migration of the valve prothesis. A plurality of flexible leaflets **1103** are attached to the frame **601** (or frame **102**) via a membrane **1104**. The membrane **1104** may be fabric, or made or organic, synthetic or polymeric materials. The membrane **1104** is also attached to the frame **601** and acts as a sealing surface against regurgitant blood flow.

FIG. **12**A illustrates a side perspective view of a mitral valve **1100** attached to a delivery system **200** in accordance with the present invention. The valve **1100** is surrounded by lasso elements **208**.

FIG. **12**B illustrates a side perspective view of a mitral valve **1100** attached to a delivery system **200** in accordance with the present invention. The outflow view of the valve **1100** is shown. This position represents the valve **1100** and delivery system **200** as it is routed through the inferior vena cava, transseptal atrial cross and crossing the mitral valve of the heart **602**.

FIG. **13** illustrates a cross section of the heart **602** showing the mitral valve **1100** tracked to a general mitral valve position using a delivery system **200** prior to deployment in accordance with the present invention.

FIG. **14**A illustrates the atrial side of the mitral valve in accordance with the prior art. The anterior leaflet **403** and the posterior leaflet **404** are shown.

FIG. **14**B illustrates a sectioned perspective view of the atrial side of the mitral valve in accordance with the prior art.

FIG. **14**C illustrates an inflow view of the valve positioned into a mitral valve in accordance with the present invention;

FIG. **15** illustrates an environmental perspective view of a deployed mitral valve still connected to the delivery device in accordance with the present invention. User control can be used to partially or completely retract the valve **1100**.

FIG. **16** illustrates an environmental perspective view of a deployed mitral valve **1100** with the delivery system **200** withdrawn in accordance with the present invention.

Reference throughout this specification to features, advantages, or similar language does not imply that all of the features and advantages that may be realized with the present invention should be or are in any single embodiment of the invention. Rather, language referring to the features and advantages is understood to mean that a specific feature, advantage, or characteristic described in connection with an embodiment is included in at least one embodiment of the present invention. Thus, discussion of the features and advantages, and similar language, throughout this specification may, but do not necessarily, refer to the same embodiment.

Furthermore, the described features, advantages, and characteristics of the invention may be combined in any suitable manner in one or more embodiments. One skilled in the relevant art will recognize that the invention may be practiced without one or more of the specific features or advantages of a particular embodiment. In other instances, additional features and advantages may be recognized in certain embodiments that may not be present in all embodiments of the invention.

These features and advantages of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A prosthetic heart valve and delivery system comprising:

a spring-biased, metallic stent adapted to radially expand and contract comprising:

a plurality of crisscrossing laths forming a cylindrical body, and

a flexible check valve formed from one or more compressible valvular elements mounted within an interior recess formed by the crisscrossing laths;

a plurality of declined stabilization prongs protruding laterally from one or more laths in the expanded metallic stent configuration;

a selectively steerable delivery system comprising:

a handle comprising a plurality of controls adapted to apply tensile force to one or more pull wires, the handle defining a hollow through passageway,

an elongated sheath affixed at a proximal end to the handle, the elongated sheath comprising a flexible tubular member;

wherein the elongated sheath is between 60 and 150 cm long on a longitudinal axis;

wherein the one or more pull wires longitudinally traverse a lumen within the delivery system;

one or more stabilization wire(s) forming annular rings at a distal end of the sheath, the annular rings adapted to receive, circumscribe and crimp the metallic stent, the stabilization wires protruding from one or more apertures on the distal end, the stabilization loops forming one or more subloops within one of the sheath and a lumen;

an engagement pin detachably inserted into the subloop(s) of the stabilization wire(s), the engagement pin connected with a pull wire to a control on the handle, the engagement pin adapted to retract proximally out of the subloop(s) when the control is activated, the engagement pin adapted to release the annular rings and allow the metallic stent to expand;

a frustoconical tip;

wherein the sheath defines an annular recess at a distal end behind the frustoconical tip, the annular recess adapted to receive the metallic stent in compressed configuration.

2. The prosthetic heart valve and delivery system comprising of claim **1**, wherein the lumen is the elongated sheath.

3. The prosthetic heart valve and delivery system comprising of claim **1**, wherein the one or more loop stabilization wire(s) are positioned within the annular recess.

4. The prosthetic heart valve and delivery system comprising of claim **1**, wherein the metallic stent is detachably circumscribed by the loop stabilization wires.

5. The prosthetic heart valve and delivery system comprising of claim **1**, further comprising a tapered hub at the distal end behind the frustoconical tip.

6. The prosthetic heart valve and delivery system comprising of claim **1**, wherein the frustoconical tip defines a hollow nose cone passageway traversing the frustoconical tip longitudinally.

7. The prosthetic heart valve and delivery system comprising of claim **1**, wherein the one or more loop stabilization wire(s) form subloops within the annular recess.

8. The prosthetic heart valve and delivery system comprising of claim **1**, wherein the compressed metallic stent is between 3 mm and 10 mm in diameter and the expanded metallic stent is between 10 mm and 40 mm in diameter.

9. A prosthetic heart valve and delivery system comprising:

a spring-biased, metallic stent adapted to radially expand and contract comprising:

a plurality of crisscrossing laths, and

a flexible check valve formed from one or more compressible valvular elements mounted within an interior recess formed by the crisscrossing laths;

a plurality of stabilization prongs protruding laterally from one or more laths in the expanded metallic stent configuration;

a selectively steerable delivery system comprising:

a handle comprising a plurality of controls adapted to apply tensile force to one or more pull wires, the handle defining a hollow through passageway,

an elongated sheath affixed at a proximal end to the handle, the elongated sheath comprising a flexible tubular member;

wherein the elongated sheath is between 60 and 150 cm long on a longitudinal axis;

wherein the one or more pull wires longitudinally traverse a lumen within the delivery system;

one or more stabilization wire(s) forming annular rings at a distal end of the sheath, the annular rings adapted to receive, circumscribe and crimp the metallic stent, the stabilization wires protruding from one or more apertures on the distal end, the stabilization loops forming one or more subloops within one of the sheath and a lumen;

an engagement pin detachably inserted into the subloop(s) of the stabilization wire(s), the engagement pin connected with a pull wire to a control on

the handle, the engagement pin adapted to retract proximally out of the subloop(s) when the control is activated, the engagement pin adapted to release the annular rings and allow the metallic stent to expand;

a tapered tip;

a tapered hub forming a second annular recess through which a rigid stabilization loop protrudes;

a rigid stabilization loop adapted to telescope relative to the frustoconical tip, the rigid stabilization loop declining laterally and toward the distal end, the rigid stabilization loop adapted to engage soft tissue and adjust positioning of the delivery system within a patient's circulatory system;

wherein the sheath defines an annular recess at a distal end behind the frustoconical tip, the annular recess adapted to receive the metallic stent in compressed configuration;

wherein the one or more loop stabilization wire(s) form subloops within the annular recess.

10. The prosthetic heart valve and delivery system comprising of claim **9**, wherein the metallic stent is detachably circumscribed by the loop stabilization wires.

11. The prosthetic heart valve and delivery system comprising of claim **9**, further comprising a tapered hub at the distal end behind the frustoconical tip.

12. The prosthetic heart valve and delivery system comprising of claim **9**, wherein the frustoconical tip defines a hollow nose cone passageway traversing the frustoconical tip longitudinally.

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