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Alkhatib

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(54) **PROSTHETIC AORTIC HEART VALVES**

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(73) Assignee: **St. Jude Medical, Inc.**, St. Paul, MN (US)

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 211 days.

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EP 1690515 8/2006

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International Search Report dated Dec. 2, 2009.

§ 371 (c)(1),
(2), (4) Date: **Feb. 24, 2010**

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(65) **Prior Publication Data**

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(57) **ABSTRACT**

Related U.S. Application Data

(60) Provisional application No. 60/966,113, filed on Aug. 24, 2007.

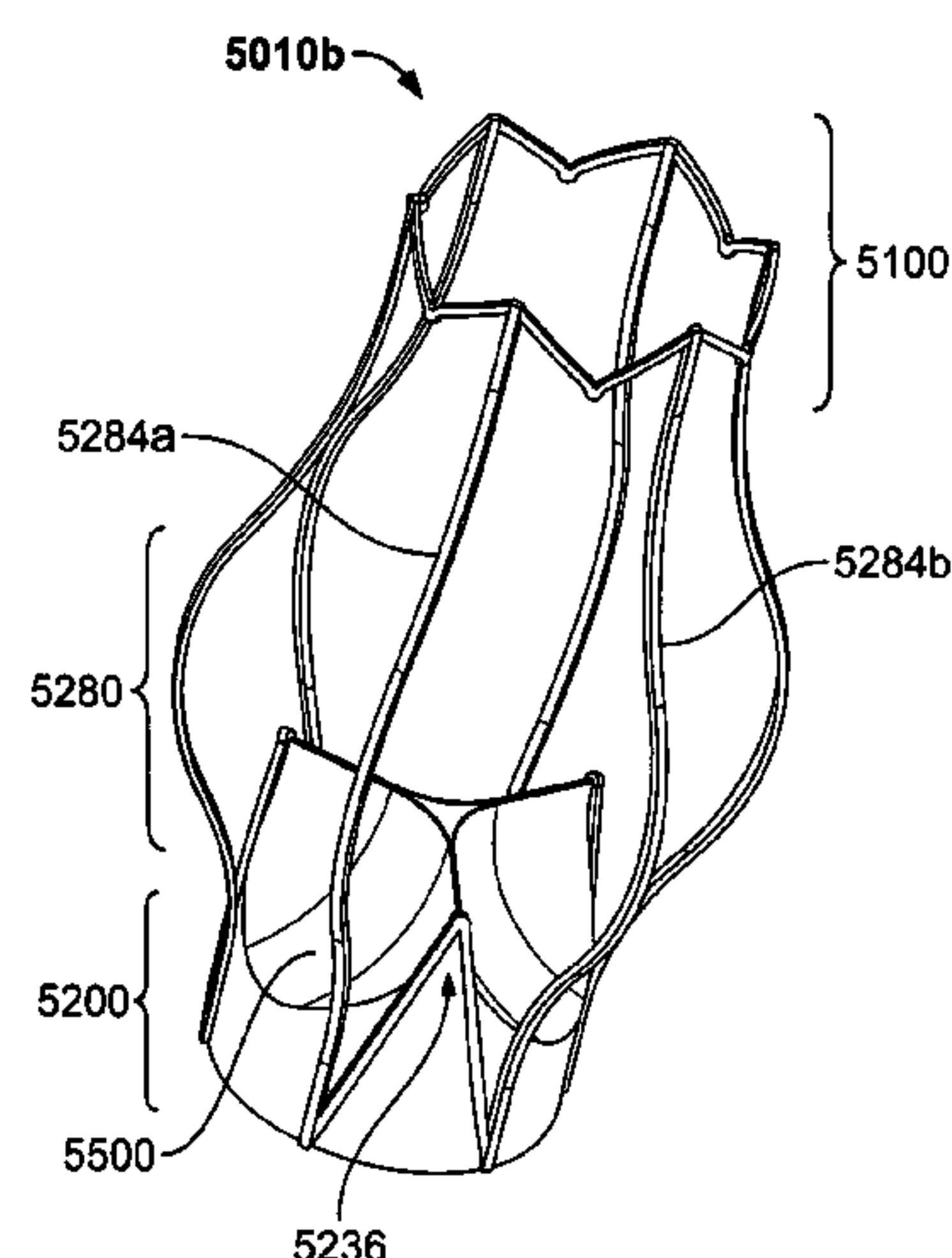
(51) **Int. Cl.**
A61F 2/24 (2006.01)
A61F 2/06 (2013.01)

(52) **U.S. Cl.**
USPC **623/2.17**; 623/1.24; 623/1.26

(58) **Field of Classification Search**
USPC 623/1.24, 1.26, 2.17, 2.18, 2.38
See application file for complete search history.

A prosthetic aortic valve includes an annular, annulus inflow portion that is designed to reside in or near the patient's native aortic valve annulus, and an annular, aortic outflow portion that is designed to reside in the patient's aorta downstream from at least a portion of the valsalva sinus. The annulus inflow portion and the aortic outflow portion are connected to one another by a plurality of connecting struts that are confined to regions near the commissures of the patient's native aortic valve. The connecting struts are designed to bulge out into the valsalva sinus to help anchor the prosthetic valve in place. The valve is circumferentially collapsible to a relatively small diameter for less-invasive delivery into the patient. The valve circumferentially expands to a larger operational diameter when deployed at the implant site.

25 Claims, 12 Drawing Sheets



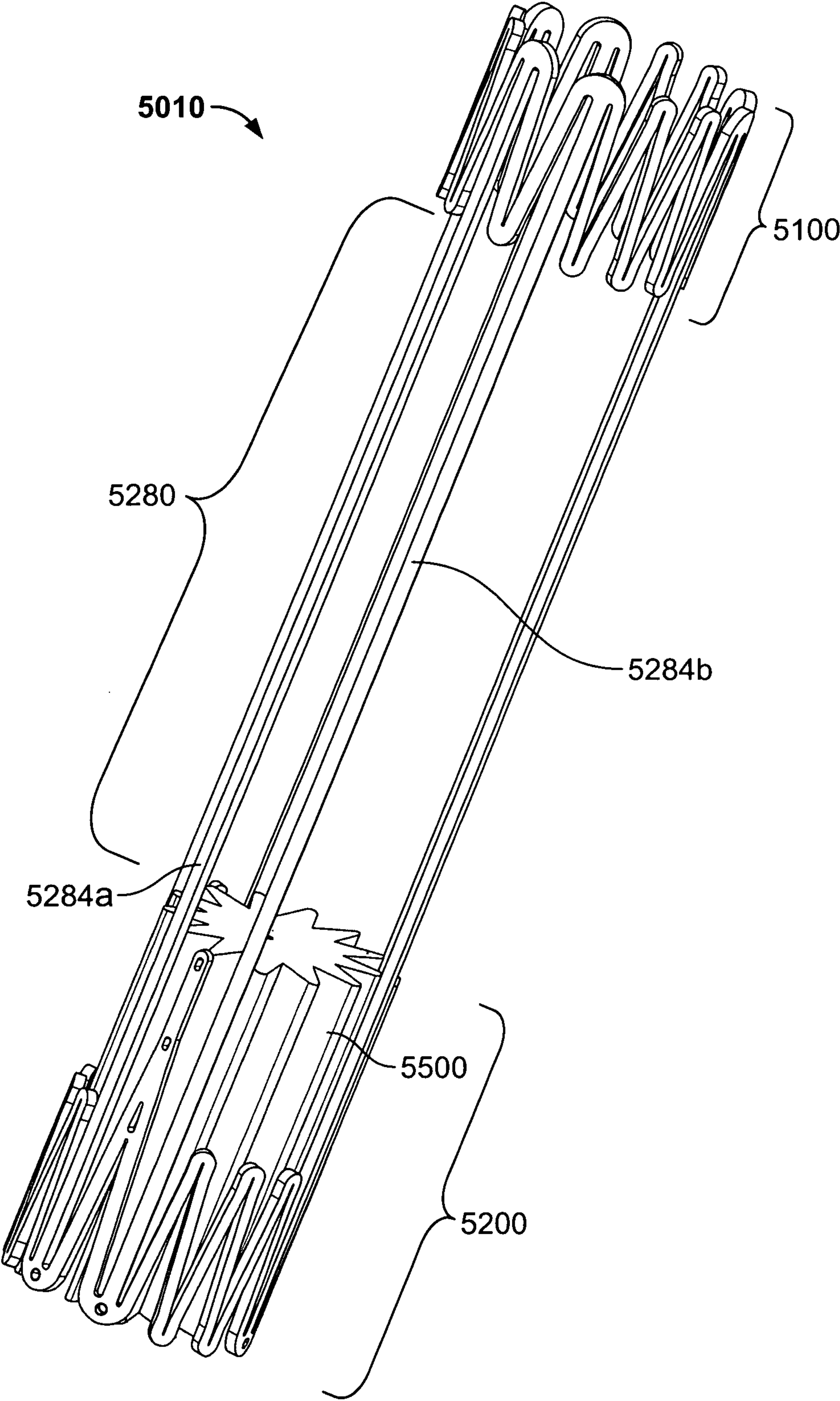


FIG. 1

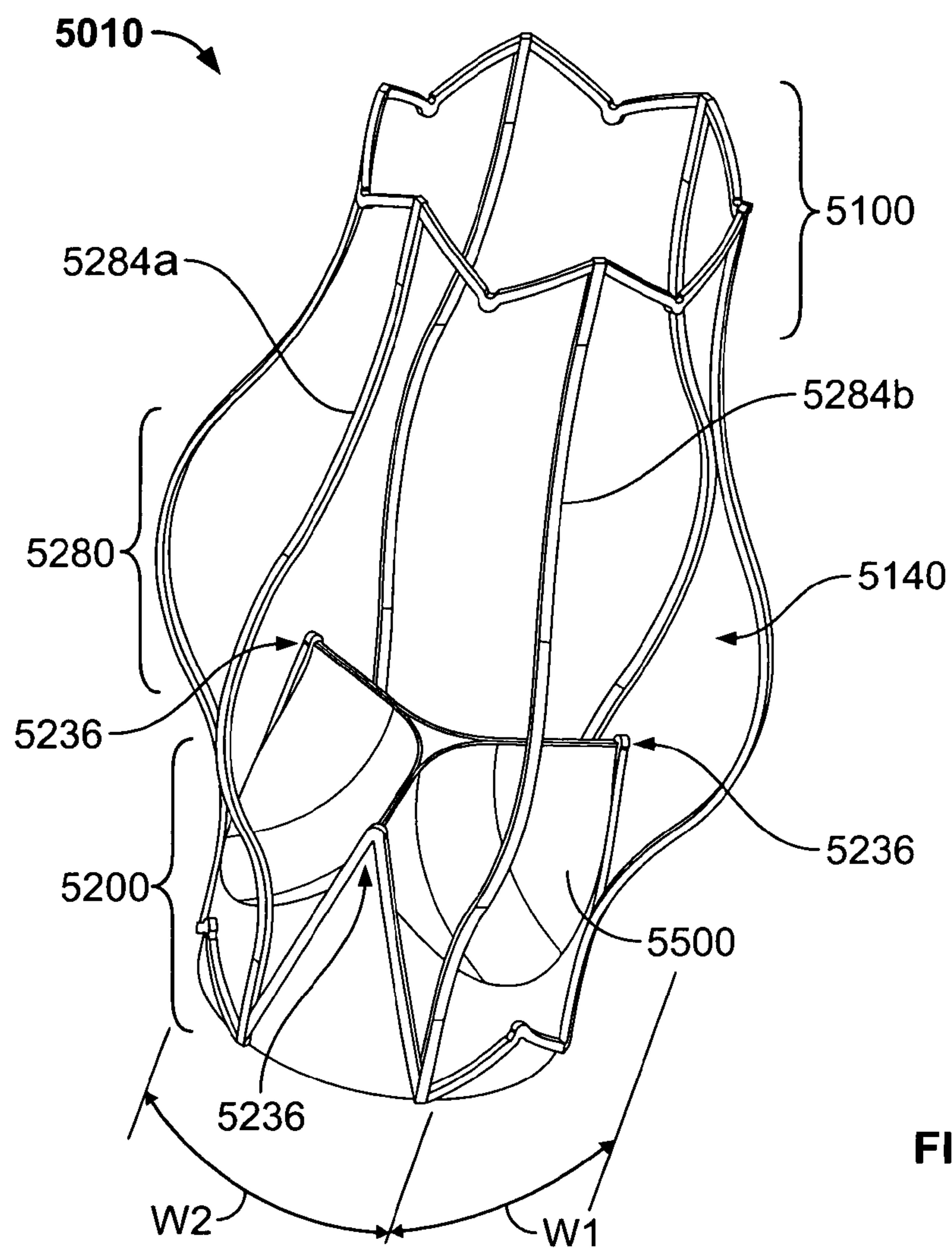


FIG. 2

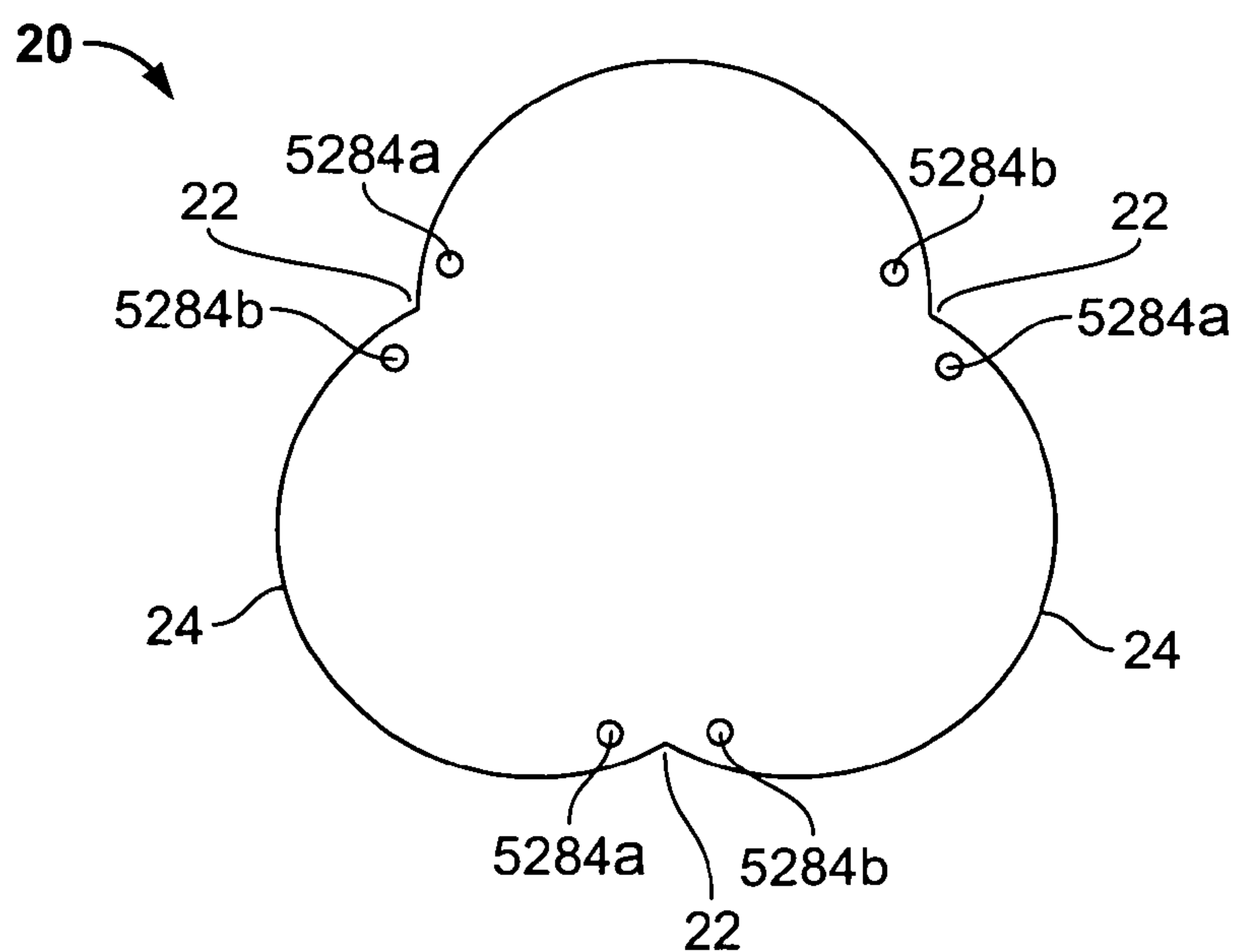


FIG. 3

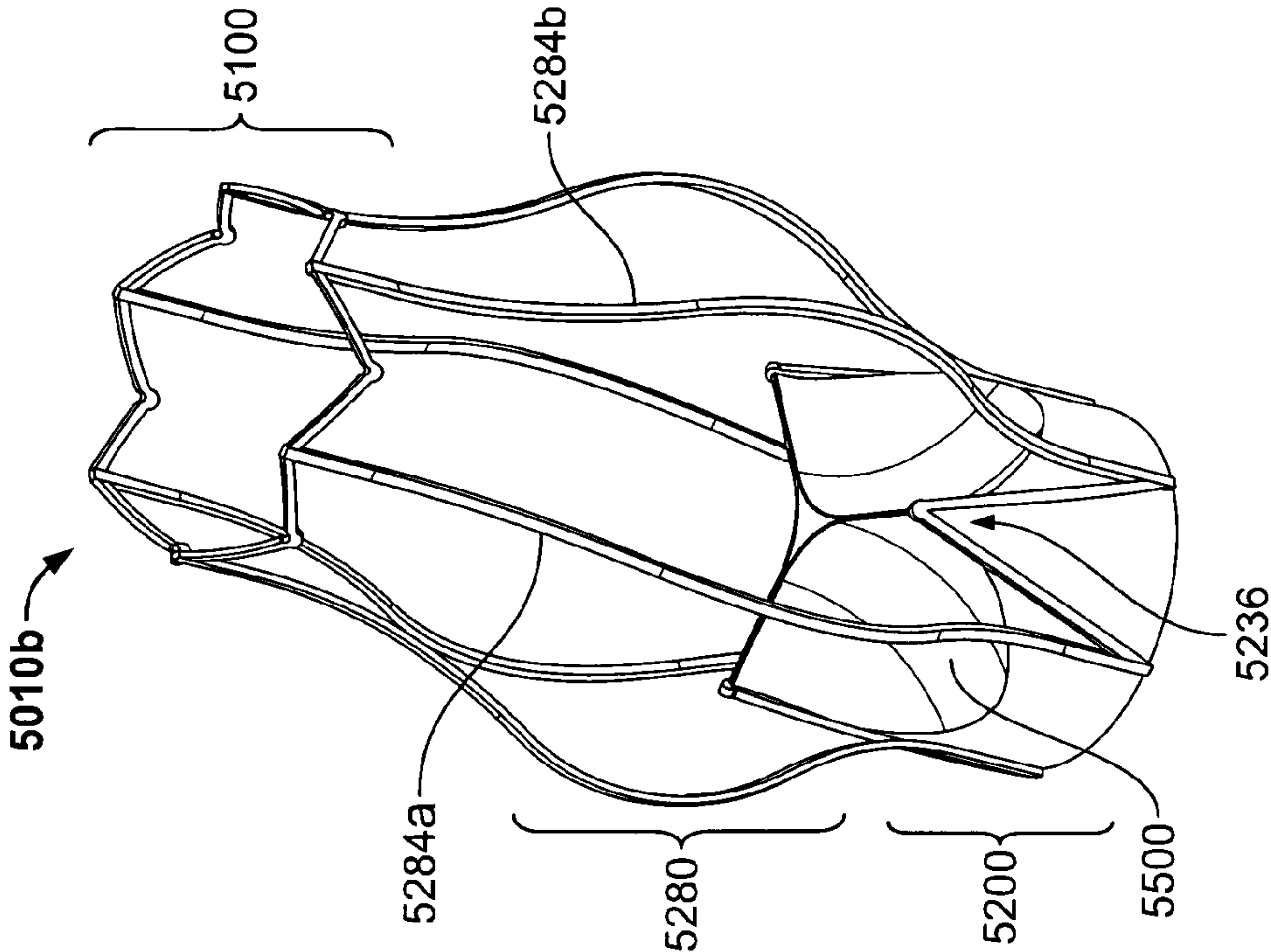


FIG. 5

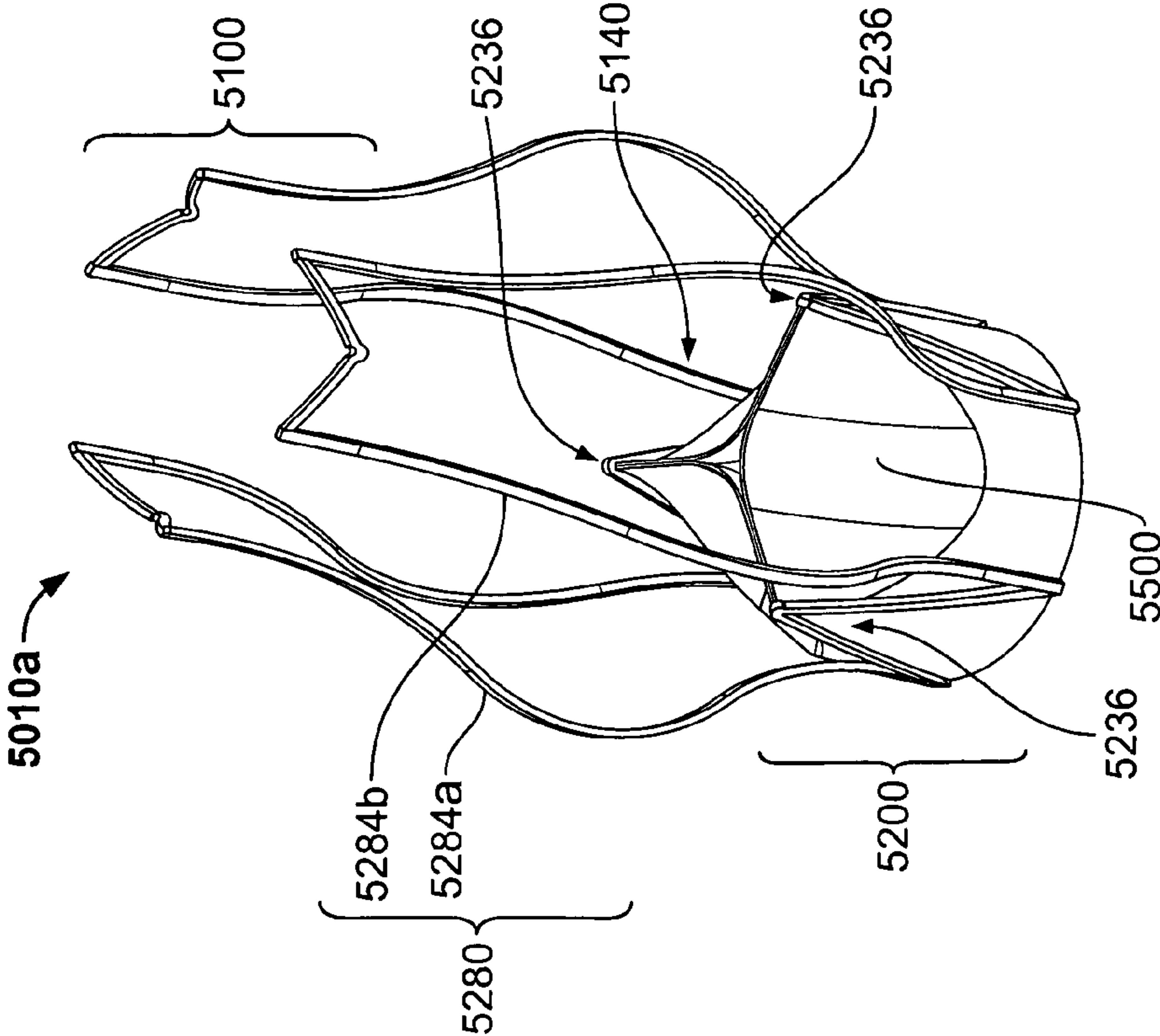


FIG. 4

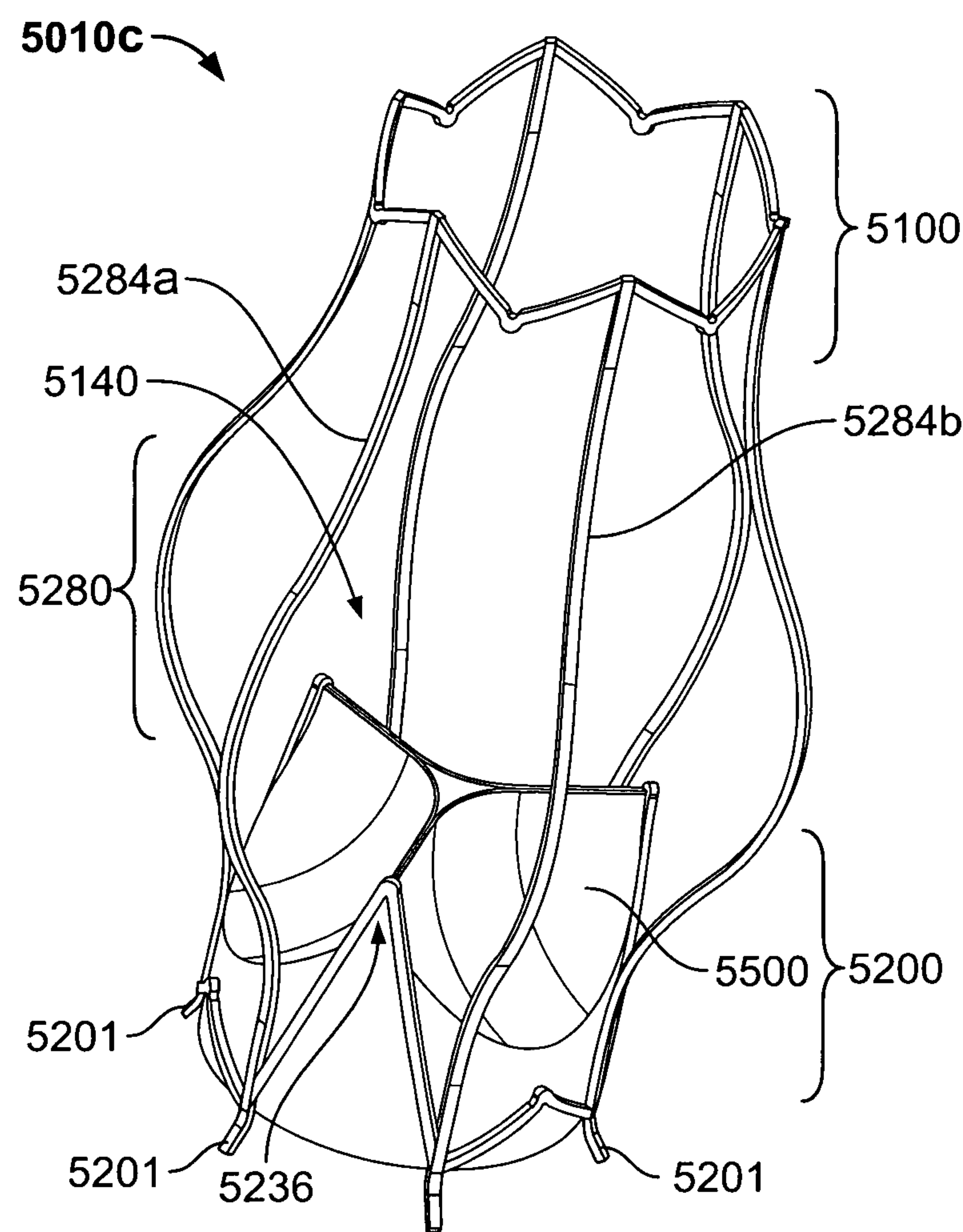
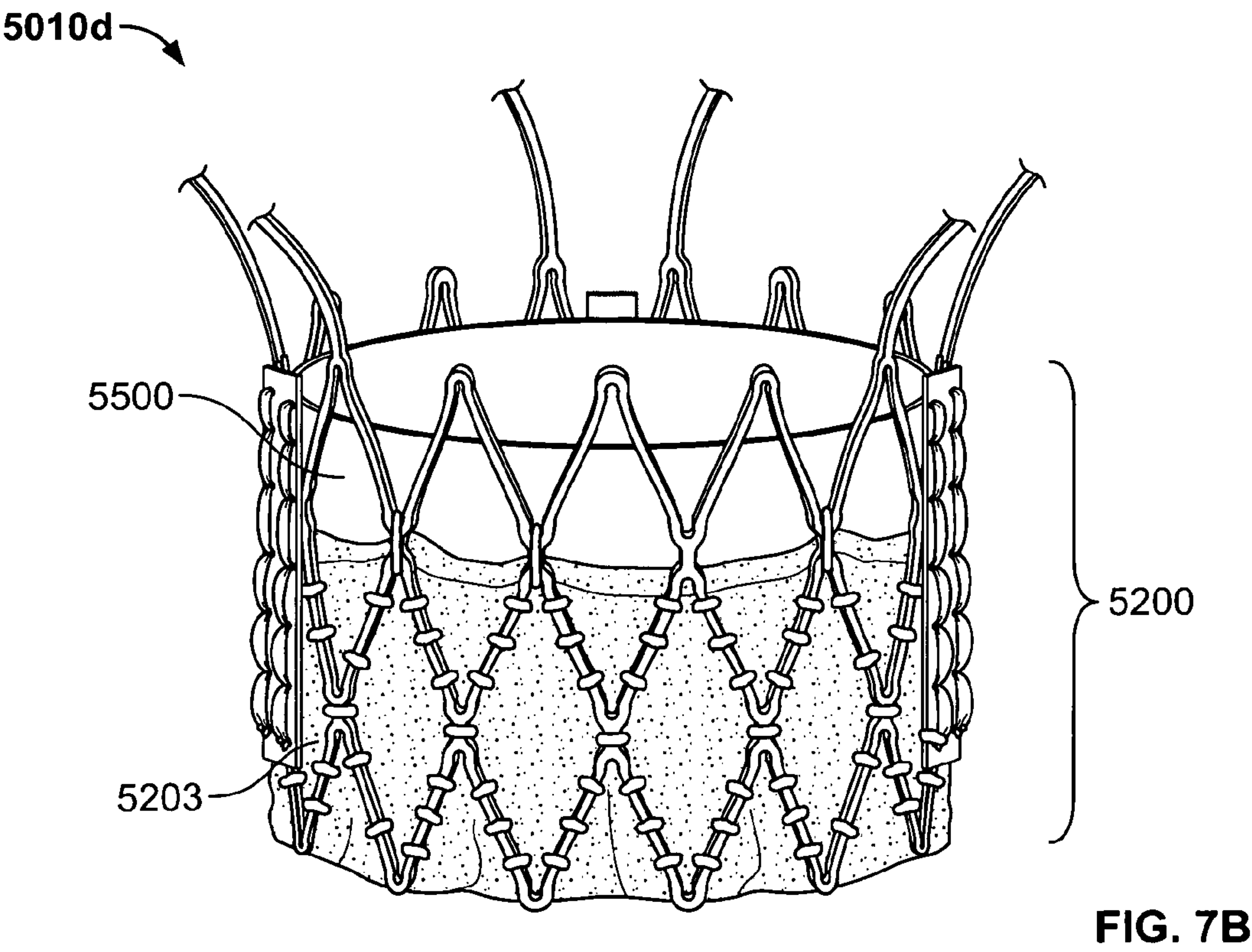
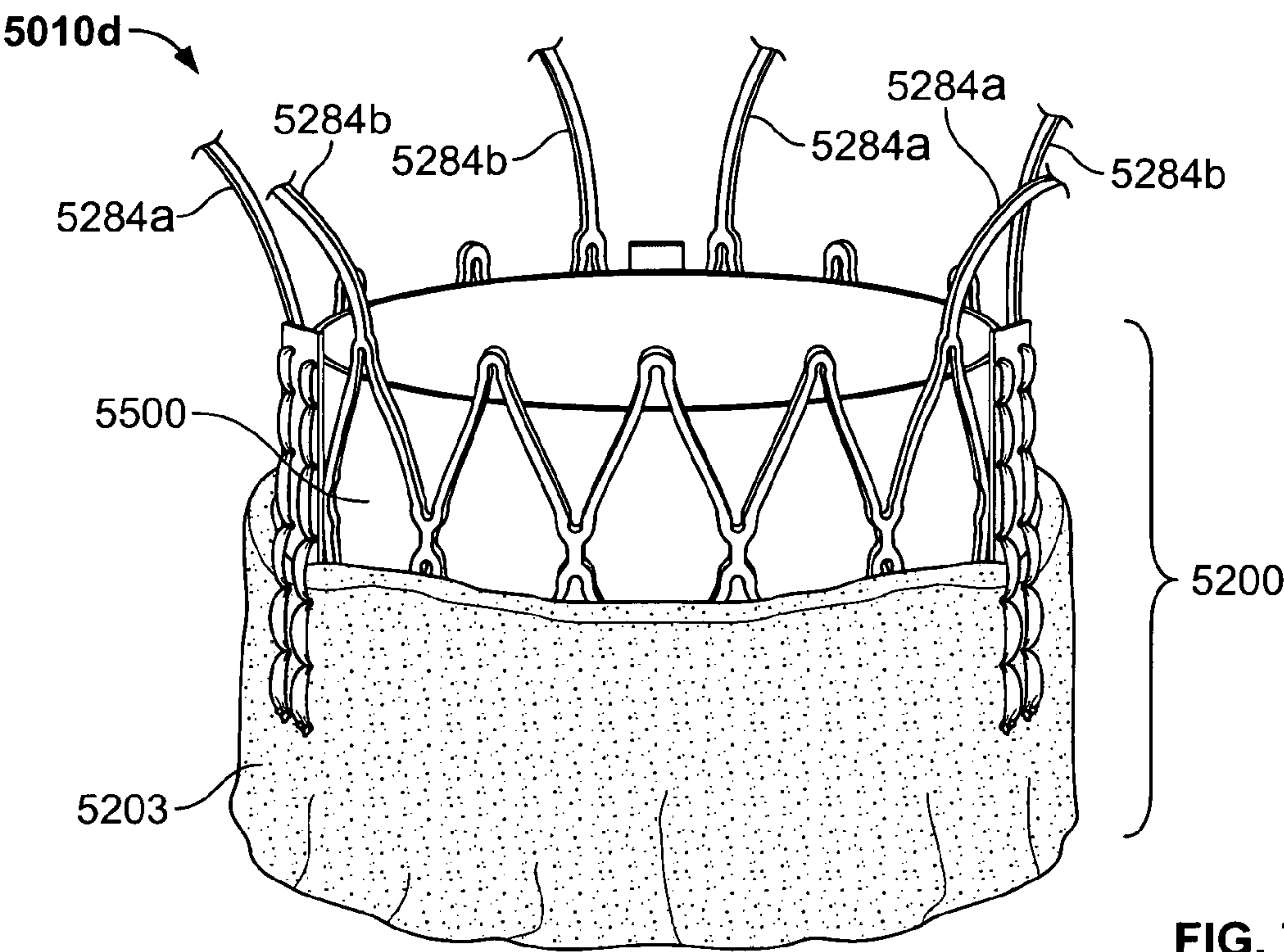


FIG. 6



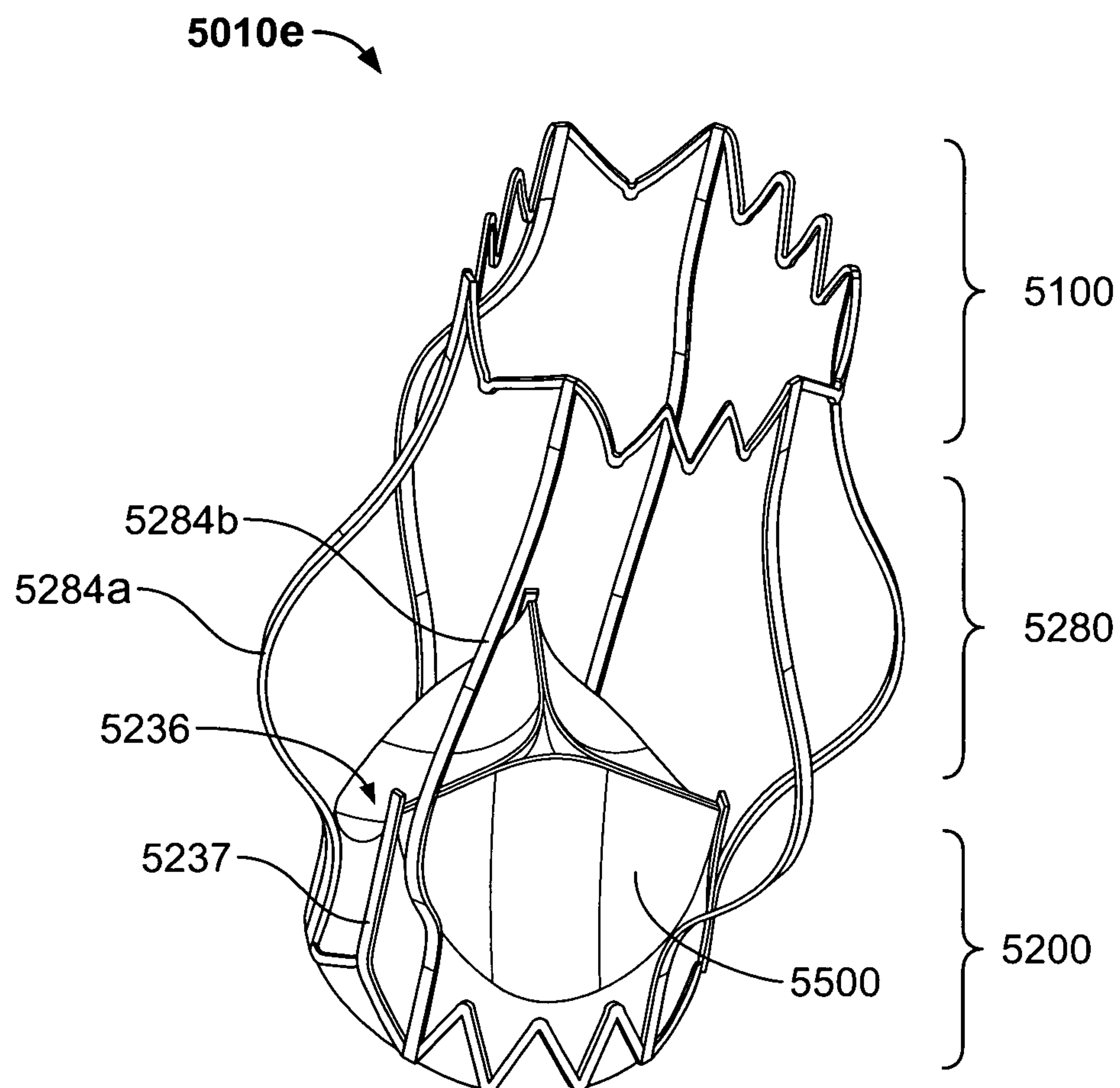


FIG. 8

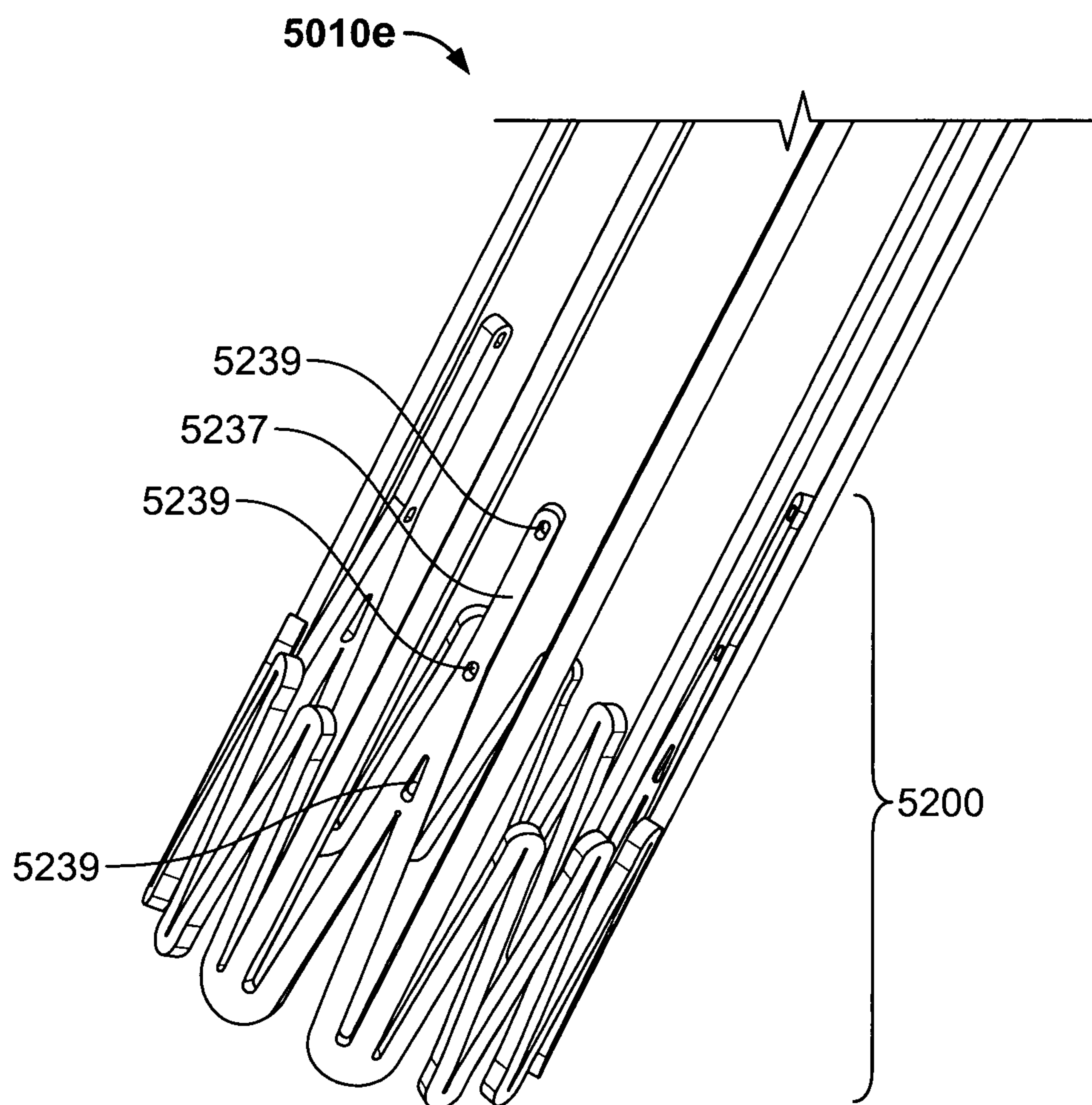


FIG. 9

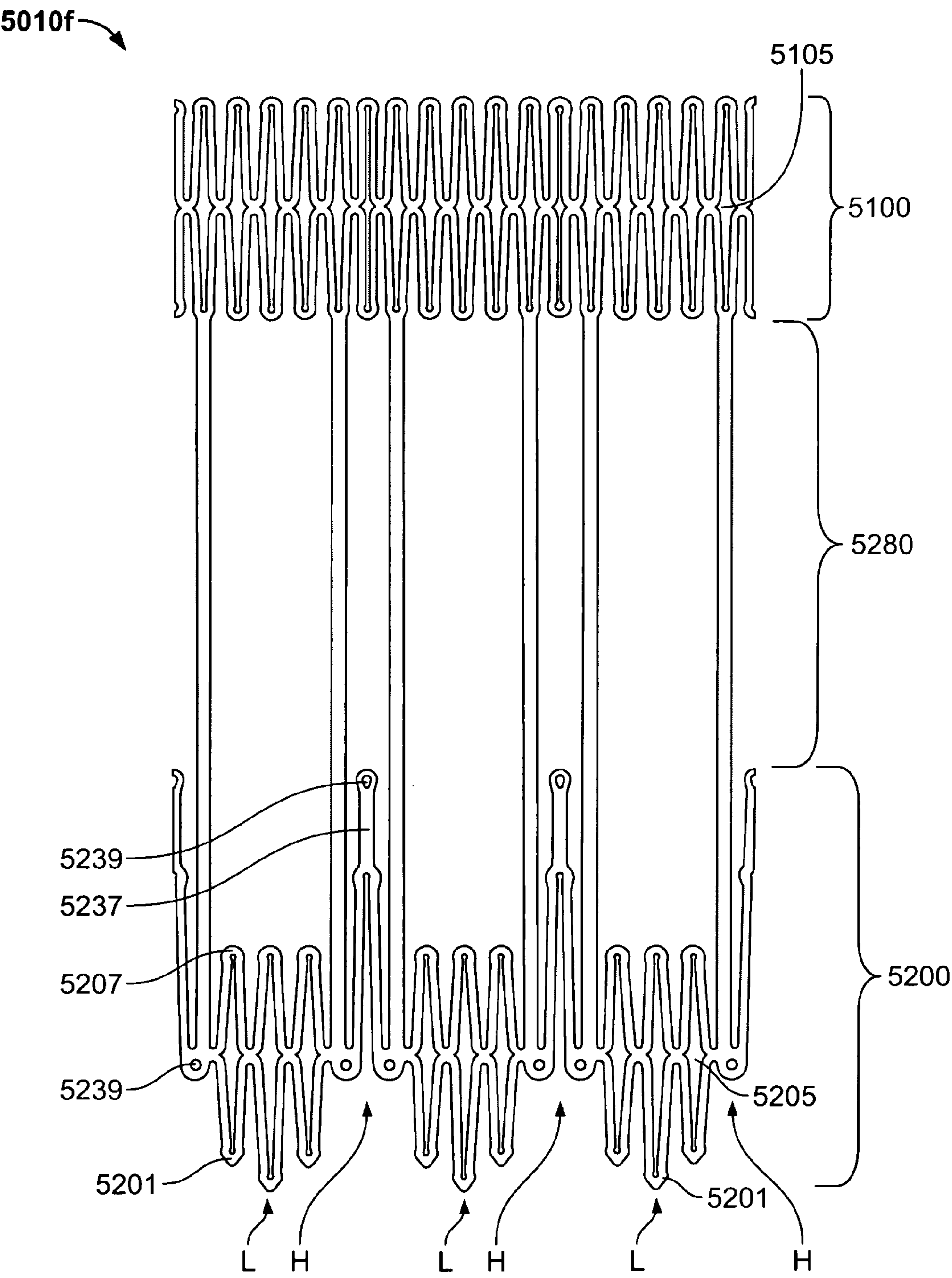


FIG. 10

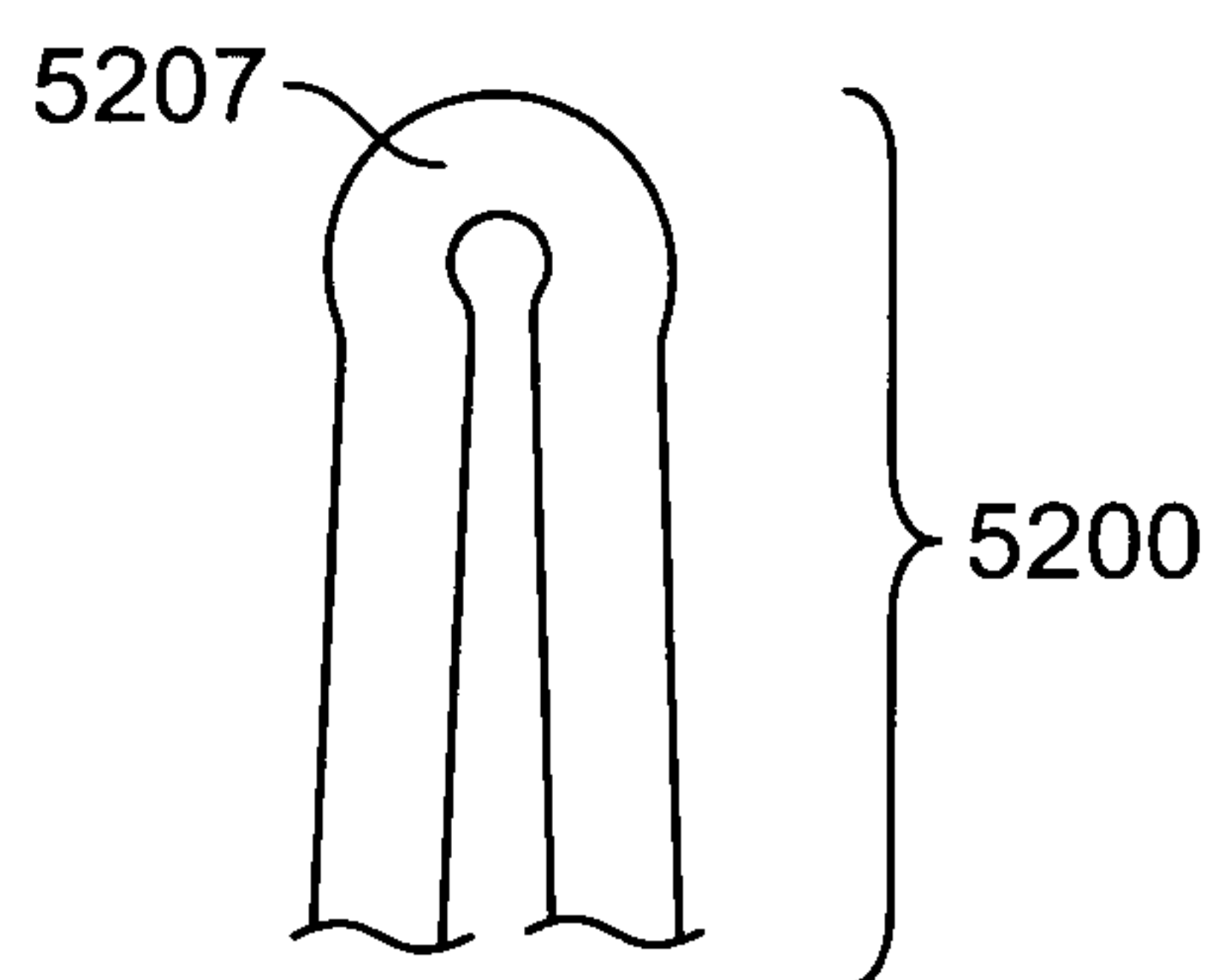


FIG. 11

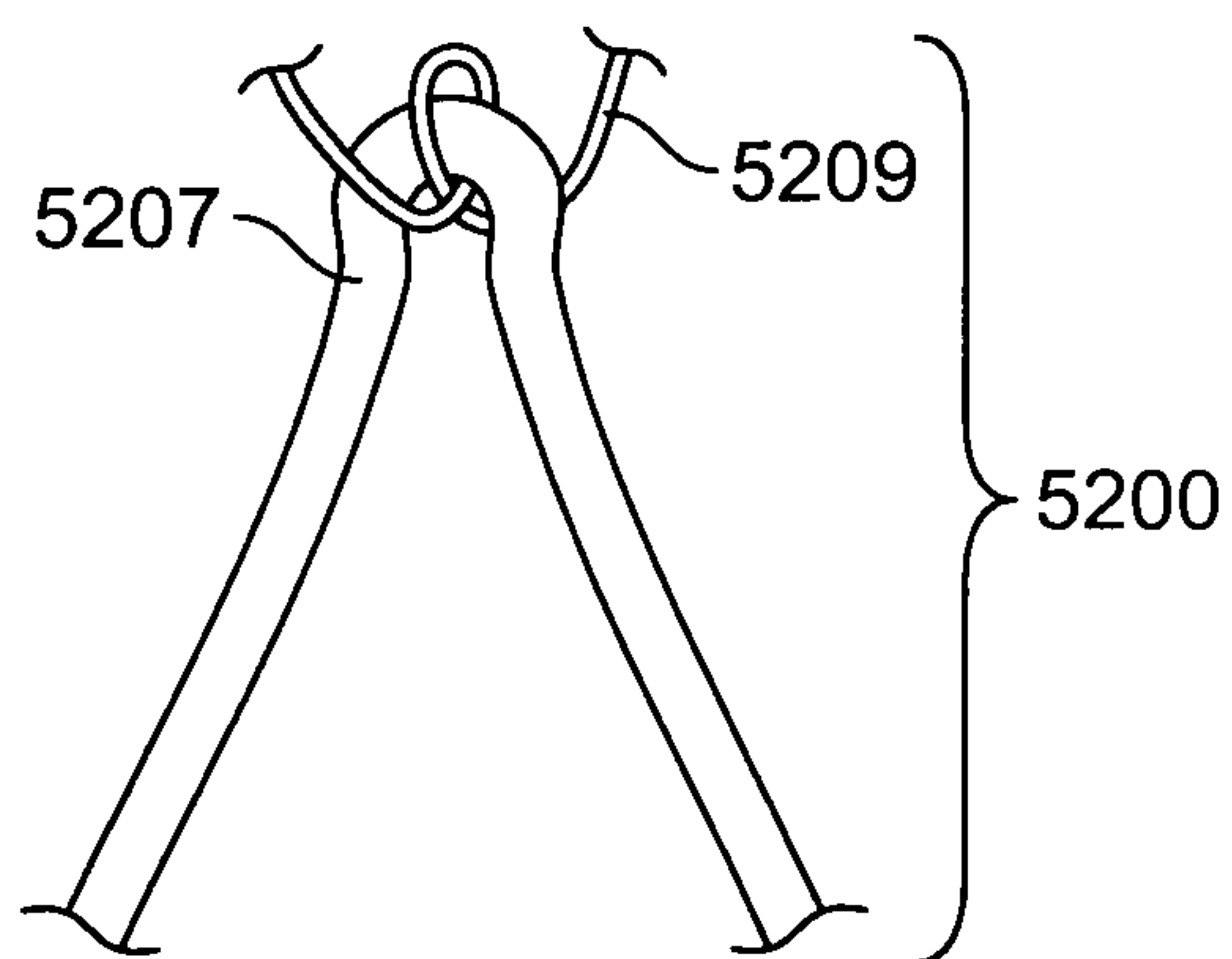


FIG. 12

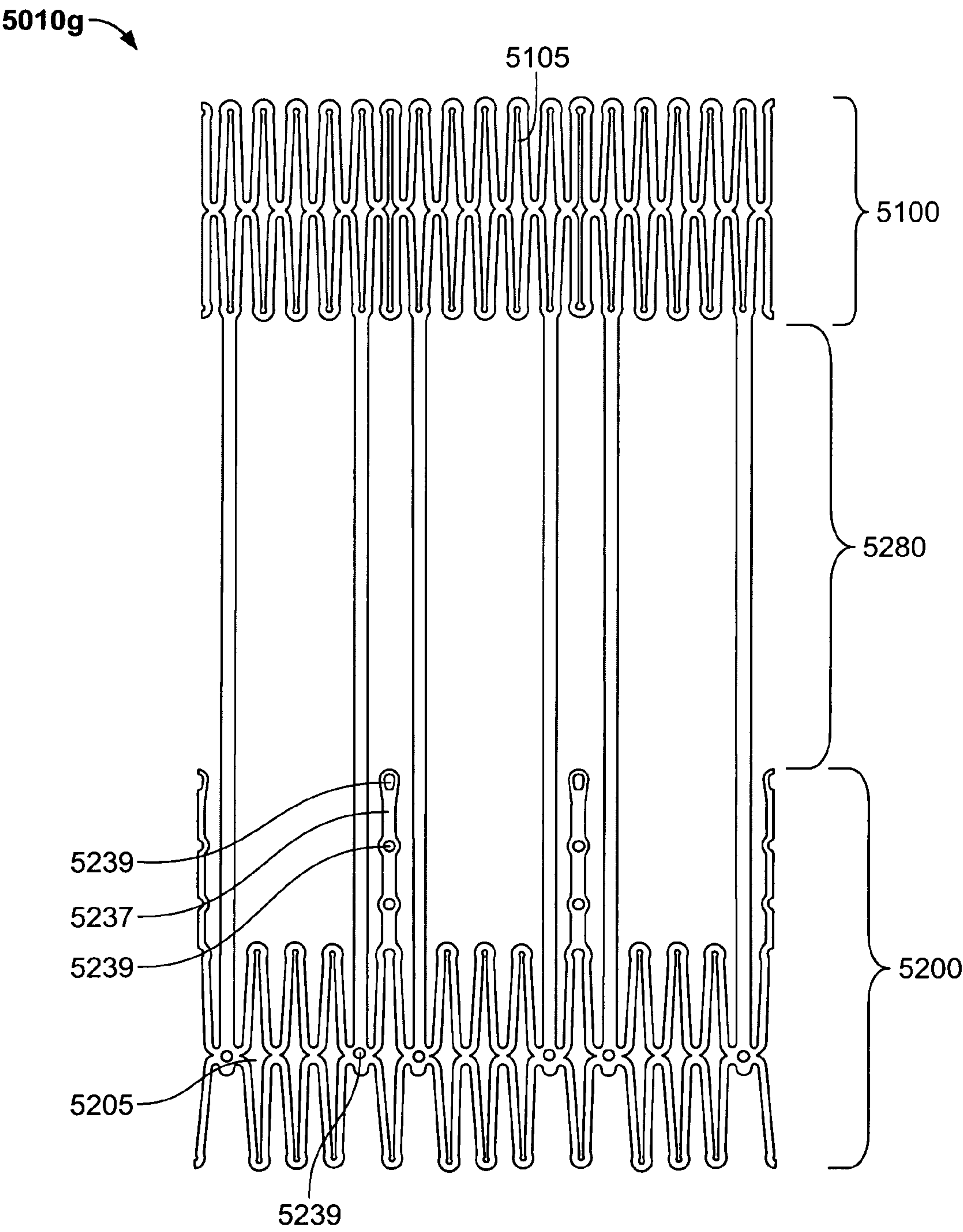


FIG. 13

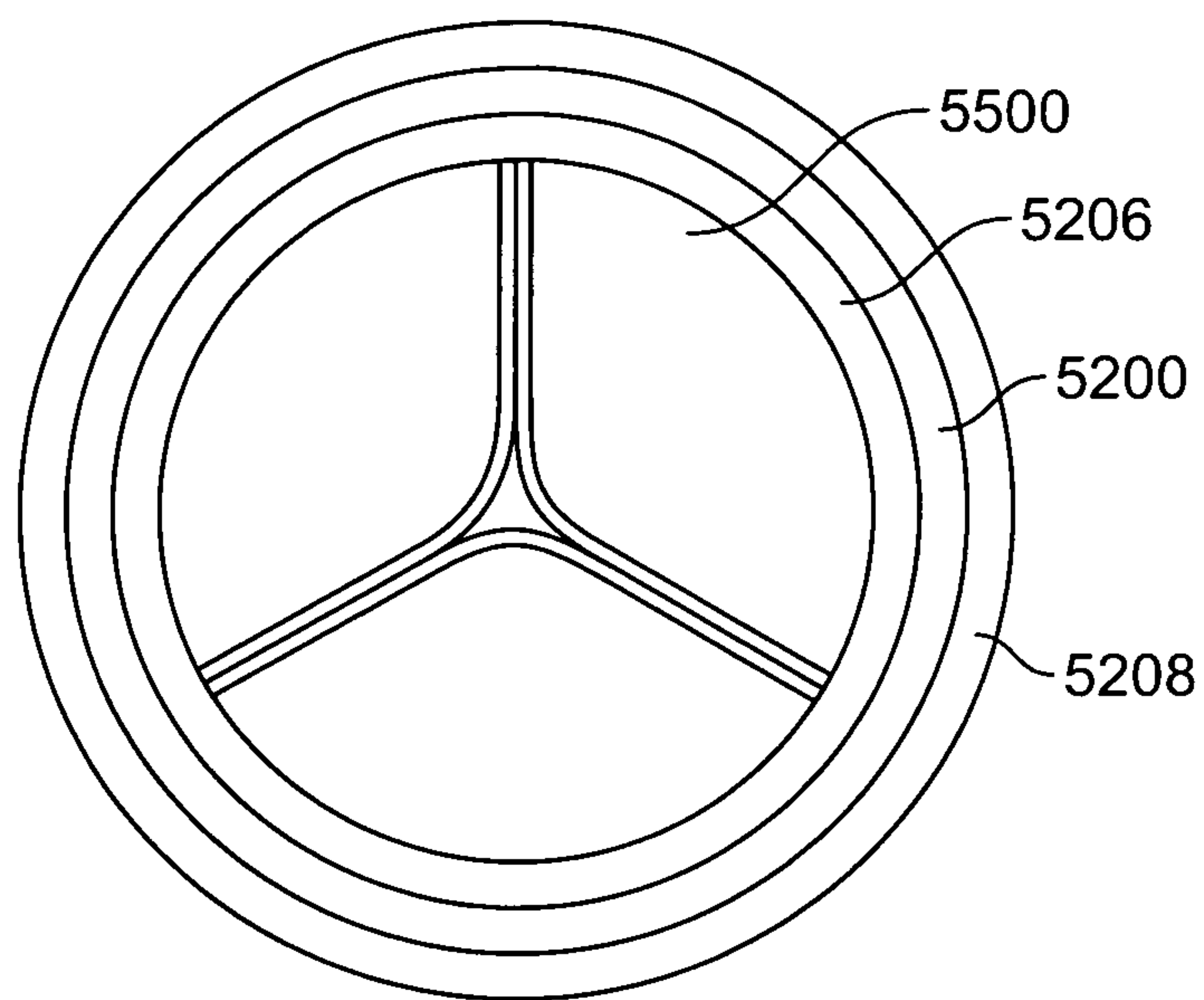


FIG. 14

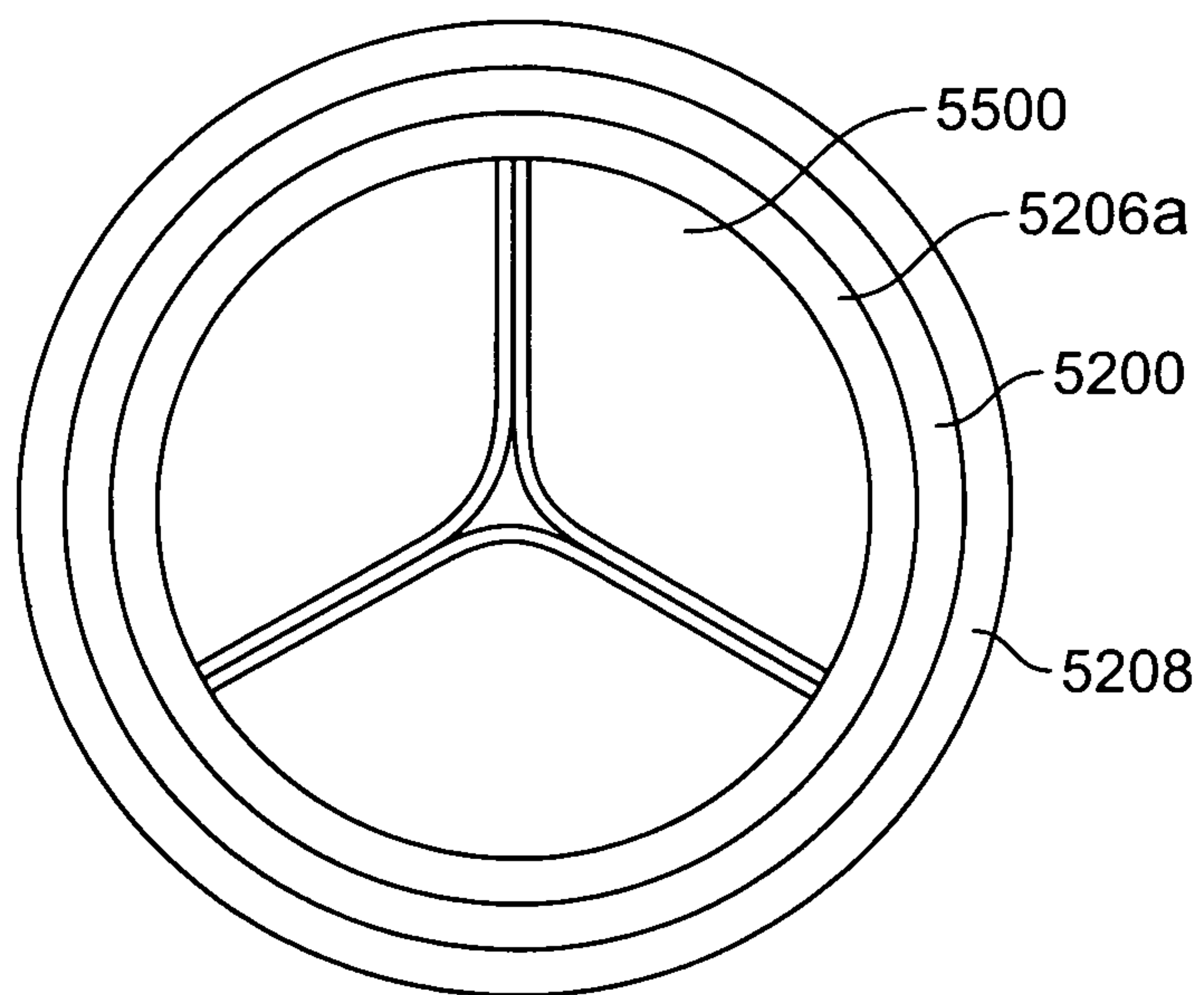


FIG. 15

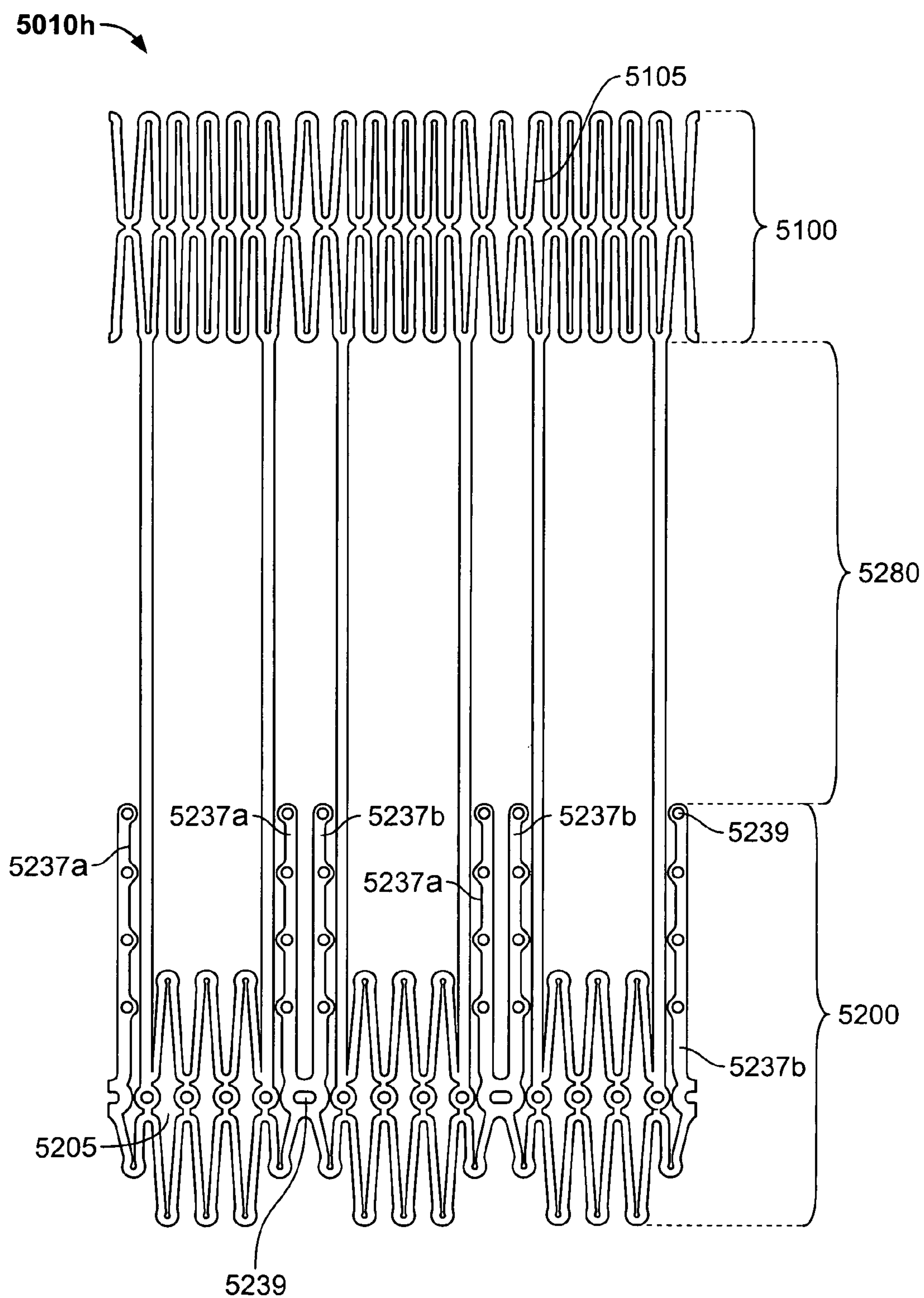


FIG. 16

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PROSTHETIC AORTIC HEART VALVES

This application claims the benefit of U.S. provisional patent application No. 60/966,113, filed Aug. 24, 2007, which is hereby incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

PCT patent application No. PCT/US08/07015, filed Jun. 4, 2008, shows prosthetic heart valves that are annularly collapsible for delivery into a patient, and then re-expandable at the implant site in the patient. (The above document will be referred to hereinafter as the above-mentioned reference, and it is hereby incorporated by reference herein in its entirety.) The prosthetic heart valves shown and described in the above-mentioned reference typically include an annular supporting structure or stent frame (e.g., of a highly elastic metal such as nitinol). This stent frame or stent typically includes an annulus inflow portion and an aortic outflow portion that is generally coaxial with the annulus inflow portion and spaced downstream (in terms of blood flow through the implanted valve) from the annulus inflow portion. The annulus inflow and aortic outflow portions are preferably connected to one another substantially solely by connecting struts that extend between the annulus inflow and aortic outflow portions adjacent to the commissure regions (also known as commissure posts having commissure tips) of the valve. By confining these connecting struts between the annulus inflow and aortic outflow portions to close proximity to the commissure tip regions, the circumferential space between annularly adjacent commissure tips is left relatively open, which (in the case of aortic valve use) helps the prosthesis avoid occluding the ostia of the coronary arteries.

Valves of this general type are intended for delivery into a patient at an implant site to which the surgeon may not have direct open access, e.g., for suturing the implanted valve in place. Good self-anchoring of the valve at the implant site is therefore important, and there may be self-anchoring improvements that can be made relative to embodiments that are shown in the above-mentioned reference.

SUMMARY OF THE INVENTION

A prosthetic aortic valve in accordance with the invention typically includes an annular stent frame and a plurality of valve leaflets supported by a portion of the stent. The stent typically includes an annulus inflow portion configured for disposition adjacent a patient's native aortic valve annulus. The leaflets are typically supported by the annulus inflow portion. The stent typically further includes an aortic outflow portion configured for disposition in the patient's native aorta downstream from at least a portion of the patient's native valsalva sinus (also sometimes called the sinus of valsalva). The stent typically still further includes a plurality of connecting struts that constitute substantially the sole connection between the annulus inflow portion and the aortic outflow portion. The annulus inflow portion typically defines a plurality of commissure tips that are spaced from one another in the annular direction around the annulus inflow portion. The commissure tips are the features of the annulus inflow portion that are closest to the aortic outflow portion. Each of the above-mentioned connecting struts is connected to the annulus inflow portion only at points that are farther from the aortic outflow portion than the commissure tips. In addition, each of the connecting struts is adjacent to an associated one of the commissure tips, and at least one of the struts is positioned for disposition adjacent each side of each of the patient's native

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aortic valve commissure tips. Each of the connecting struts is constructed to bulge radially outwardly like (and into) the valsalva sinus when the valve is in use in a patient.

Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a simplified perspective or isometric view of an illustrative embodiment of some components of a prosthetic heart valve in accordance with the invention, in a first possible operating condition of those components.

FIG. 2 is a simplified perspective or isometric view of a structure like that shown in FIG. 1, in another possible operating condition of that structure.

FIG. 3 is a simplified cross-sectional view of a patient's native tissue, with some components of an implanted valve of this invention visible in that native tissue structure.

FIG. 4 is a view similar to FIG. 2 for another illustrative embodiment in accordance with the invention.

FIG. 5 is a view similar to FIG. 2 for yet another illustrative embodiment in accordance with the invention.

FIG. 6 is a view similar to FIG. 2 for still another illustrative embodiment in accordance with the invention.

FIG. 7a is a view similar to part of FIG. 2 for yet another illustrative embodiment in accordance with the invention. FIG. 7a shows the leaflets of the valve open but greatly simplified. FIG. 7a also shows other possible components added.

FIG. 7b is a view similar to FIG. 7a for another illustrative embodiment in accordance with the invention.

FIG. 8 is a view similar to FIG. 2 for still another illustrative embodiment in accordance with the invention.

FIG. 9 shows a portion of the FIG. 8 embodiment in another operating condition of the apparatus.

FIG. 10 is a simplified elevational view of a portion of yet another illustrative embodiment in accordance with the invention. FIG. 10 shows the depicted component after it has been cut along an axis that is vertical in FIG. 10 and then laid out flat in the plane in which FIG. 10 is drawn.

FIG. 11 is an enlargement of a representative portion of what is shown in FIG. 10.

FIG. 12 shows the FIG. 11 structure in another operating condition.

FIG. 13 is a view similar to FIG. 10 for another illustrative embodiment in accordance with the invention.

FIG. 14 is a simplified view looking down on the inflow portion of an illustrative embodiment of a prosthetic heart valve in accordance with the invention.

FIG. 15 is a simplified view looking down on the inflow portion of another illustrative embodiment of a prosthetic heart valve in accordance with the invention.

FIG. 16 is a view similar to FIG. 13 for another illustrative embodiment in accordance with the invention.

DETAILED DESCRIPTION

Many of the principles employed in the prosthetic valves that are shown and described in the above-mentioned reference can be employed in valves in accordance with this invention. Accordingly, the descriptions of some features herein can be somewhat abbreviated because more complete information is already available from the above-mentioned reference. To facilitate comparison, the reference numbers that are used herein for components that are at least generally similar to components in the above-mentioned reference are often

(although perhaps not always) related by integer multiples of 1000 to the reference numbers used for those generally similar components in the above-mentioned reference. Thus, for example, component **5010** herein is generally similar to any of components **10**, **1010**, **2010**, **3010**, **4010**, **5010**, etc., in the above-mentioned reference.

FIG. 1 shows some components of an illustrative prosthetic heart valve in accordance with the invention in an annularly or circumferentially collapsed condition for delivery into a patient via relatively small-diameter delivery apparatus. (FIG. 1 has been simplified as explained in more detail in the next paragraph.) Such small-diameter delivery can be used to avoid full open-chest/open-heart surgery. FIG. 2 shows a valve generally like the valve shown in FIG. 1 (although with some differences from what is shown in FIG. 1) after annular or circumferential re-expansion (e.g., via the use of highly-elastic, self-expansion). FIG. 2 thus shows a valve in its deployed condition (i.e., the condition it has when implanted in a patient).

All of the many embodiments shown and described in this specification are annularly or circumferentially collapsible to a delivery condition like that generally illustrated by FIG. 1, and then annularly or circumferentially re-expandable to an implanted or deployed condition like that generally illustrated by FIG. 2.

The valves shown in FIGS. 1 and 2 are intended for implanting within a patient's native aortic valve to mitigate impaired functioning of the native valve. FIGS. 1 and 2 do not necessarily show all features or components of complete valves. For example, some layers of material (e.g., fabric and/or tissue) that may be used around the outside of certain portions of these valves are not shown in FIGS. 1 and 2 to better reveal possible constructional features of other components of the valves. In particular, FIGS. 1 and 2 primarily show the collapsible/expandable, metal, stent frame **5010** of the depicted valves, and the flexible leaflets **5500** of these valves. (Again, fabric material (not shown) can be used outside or inside stent frame **5010** at the inflow section of the stent.) Examples of suitable materials for leaflets **5500** include biological tissue, polymer, thin metal, reinforced polymer, etc. As used herein, the term "biological tissue" includes such things as actual harvested porcine valves, bovine pericardium, and the like.

As in the above-mentioned reference, stent **5010** includes an aortic outflow portion **5100** and an annulus inflow portion **5200**. Portions **5100** and **5200** are connected to one another substantially solely by at least one connecting strut **5284**. All of these structures (**5100**, **5200**, and **5284**) are annularly or circumferentially collapsible (FIG. 1) and re-expandable (FIG. 2). This includes leaflets **5500**. When the valve is in place in a patient's native aortic valve, the prosthetic valve is re-expanded as shown in FIG. 2. When the valve is thus re-expanded at the implant site in the patient, annulus inflow portion **5200** is typically adjacent the patient's native aortic valve annulus, aortic outflow portion **5100** is in the aorta downstream from the valsalva sinus (or downstream from at least part of the valsalva sinus), and connecting struts **5284** pass through the valsalva sinus (or through at least part of the valsalva sinus). In addition, respective connecting struts **5284** preferably pass near and on each side of each of the patient's native valve commissures. This last point will be described in greater detail later in this specification. Because portion **5100** thus resides in the patient's aorta when the valve is implanted, portion **5100** is generally referred to herein as the aortic outflow portion.

Annulus inflow portion **5200** includes three commissure posts or tip regions **5236** that are equally spaced from one

another around the valve. In the FIG. 2 embodiment, for example, each of the commissure tips **5236** is at the free apex of a V-shaped commissure post structure that extends down from the tip as viewed in FIG. 2. Each of these V-shaped commissure post structures is cantilevered from at least an associated pair of annularly spaced points on remaining structure of annulus inflow portion **5200**. Cantilevering the commissure posts in this way facilitates giving the commissure posts desirable flexibility, which includes flexibility in a direction that is radial of the valve at the location of the tip or free end of each commissure post.

Adjacent each of commissure tips **5236**, there is an associated pair of connecting struts **5284a** and **5284b**. One of these struts **5284a** is on one side of the associated commissure tip **5236** in a circumferential direction around the valve, and the other strut **5284b** is on the other side of the associated commissure tip in a circumferential direction around the valve. Each of these struts **5284** connects to the annulus inflow portion **5200** at a point that is well below the associated commissure tip **5236**. As in the above-mentioned reference, this makes it possible for the commissure post structure below each tip **5236** to be desirably flexible relatively independently of struts **5284**. It also facilitates giving commissure post structures **5236** and struts **5284** shapes in the radial direction (i.e., inwardly and outwardly of the valve as a whole) that can be relatively independent of one another. For example, commissure post structures **5236** can go relatively straight up from the base of annulus inflow portion **5200**, while struts **5284** can bulge radially out from the geometric cylindrical surface in which the commissure post structures lie. (The entire population of connecting struts **5284** in a valve may sometimes be referred to collectively by reference number **5280**.)

The connecting struts **5284a** and **5284b** that are adjacent to each commissure tip **5236** can remain relatively close to one another and to that commissure tip as they extend to aortic outflow portion **5100**. Thus, for example, in the annular (circumferential) direction around the expanded valve (e.g., as in FIG. 2), and at the level (in the axial direction along the valve) of commissure tips **5236**, the struts **5284a** and **5284b** that are associated with each commissure tip **5236** tend to be closer to one another than they are to the circumferentially nearest strut **5284** that is associated with another commissure tip. This helps to give the valve relatively large openings **5140** between the struts **5284** that are associated with annularly adjacent ones of the commissure tips. This may be desirable to help the valve avoid occluding the coronary ostia of the patient's coronary arteries. These ostia are located in the valsalva sinus approximately midway between axial projections of certain of the native aortic valve commissures (see FIG. 3, which is discussed in more detail later in this specification).

To quantify an aspect of what is said above, at the level of commissure tips **5236** in the circumferentially expanded valve shown in FIG. 2, the width **W1** of the opening **5140** between the struts **5284** associated with two annularly (or circumferentially) adjacent commissures is preferably greater than the width **W2** between the struts associated with a given commissure. More preferably **W2** is less than about one-half of **W1**.

FIG. 3 shows the approximate cross-sectional shape of a typical native valsalva sinus **20**. Axial projections of the commissures of the native aortic valve are indicated at **22**. Locations of coronary artery ostia are indicated at **24**. Between each annularly adjacent pair of commissure projections **22**, valsalva sinus **20** has an outwardly bulging lobe. The two connecting struts **5284a** and **5284b** associated with each prosthetic valve commissure pass axially through the valsalva sinus on respective opposite sides of the commissure projec-

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tion **22** that is associated with the prosthetic valve commissure **5236** that is aligned with that projection **22**. These struts **5284a** and **5284b** also bulge radially out to follow the bulge of the adjacent valsalva sinus tissue (see again FIG. 2). From this it will be appreciated that the shape and locations of struts **5284a** and **5284b** can help to anchor the prosthetic valve in the desired axial and angular location in the patient. The presence of a pair of struts **5284a** and **5284b** adjacent to each side of each commissure projection **22** can help prevent the prosthetic valve from rotating in the patient about the longitudinal axis of the valve. In addition, the outward bulging of struts **5284** into the outward bulging of the valsalva sinus lobes can help prevent the prosthetic valve from moving in either direction along the longitudinal axis of the valve. These anchoring aspects of connecting struts **5284** passing through valsalva sinus **20** can be in addition to other anchoring aspects that the prosthetic valve may have (e.g., as shown and described in the above-mentioned reference).

When deployed in a patient, all of the various prosthetic valve embodiments that are shown and described in this specification have outwardly bulging connecting struts **5284** like those shown in FIG. 2, with spacing (e.g., W1 and W2) like that shown in FIG. 2, and with positioning of the struts relative to native valve commissure projections **22** like that shown in FIG. 3.

FIG. 4 shows an alternative embodiment of stent frame **5010** (now labelled **5010a** in FIG. 4). Although there are some differences between stent **5010a** and stent **5010**, the same reference numbers are generally used for generally similar parts of both embodiments (i.e., the embodiment of FIG. 4 and the earlier-described embodiment of FIGS. 1 and 2). Whereas in the embodiment of FIGS. 1 and 2 both of aortic outflow portion **5100** and annulus inflow portion **5200** are annularly continuous all the way around stent **5010**, in the FIG. 4 embodiment stent **5010a** is annularly continuous as a whole, but each of portions **5100** and **5200** has several interruptions in the annular (circumferential) direction. In particular, where portion **5100** extends between two annularly adjacent connecting struts **5284**, portion **5200** does not extend between those two struts; and where portion **5200** extends between two annularly adjacent struts **5284**, portion **5100** does not extend between those two struts. In other respects the prosthetic heart valve shown in FIG. 4 can be similar to what is shown in FIGS. 1 and 2, and it can implant in a patient similarly to what is shown in FIG. 3.

An embodiment like that shown in FIG. 4 may fit better in certain patients. For example, it may fit better in an irregular native aortic valve annulus (e.g., an annulus that is made irregular by a congenital defect or by the presence of calcified native leaflet material). A purpose for this embodiment is to provide flexibility in sizing of the distal section (e.g., aortic outflow portion **5100**). The intention of the inflow side is not to conform to native geometry, but rather to remodel that geometry to allow the prosthetic valve to function optimally. The presence of hard calcification can impact the final deployed shape. This design allows some balance between remodeling and conforming.

FIG. 5 shows another alternative embodiment of stent frame **5010** (now referenced **5010b** in FIG. 5). Again, the same reference numbers used earlier are used again for generally similar elements of FIG. 5. In FIG. 5 aortic outflow portion **5100** is annularly continuous (as in FIGS. 1 and 2), but annulus inflow portion **5200** is annularly interrupted in the same way that the annulus inflow portion is interrupted in FIG. 4. In other respects the FIG. 5 embodiment may be similar to the previously described embodiments, and it can be implanted in a patient as illustrated in part in FIG. 3. Like

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the embodiment of FIG. 4, the embodiment of FIG. 5 may fit better in certain patients, such as patients with an irregular native aortic valve annulus.

Note that in any of the embodiments shown and described herein, the stent frame can be provided with eyelets, apertures, or other features that facilitate attachment of the leaflets and other materials to the stent. Examples will be shown and described later in this specification.

FIG. 6 shows yet another alternative embodiment of stent frame **5010** (now numbered **5010c** in FIG. 6). Once again, the same reference numbers used earlier are used again for generally similar elements in FIG. 6. Stent **5010c** is basically the same as stent **5010**, with the addition of a plurality of anchor members **5201** that are resiliently biased to incline outwardly from annulus inflow portion **5200**. During delivery of the valve into a patient in an annularly compressed or collapsed condition, anchor members **5201** can be deflected substantially parallel to the longitudinal axis of the valve. When the valve is released from such annular compression for deployment in the patient (e.g., by pushing the valve out of the distal end of a delivery tube that keeps the valve annularly compressed), anchor members **5201** spring out as shown in FIG. 6. In this condition anchor members **5201** engage (e.g., penetrate) the adjacent native tissue of the patient and thereby help to hold the valve in place in the patient. (FIG. 3 again applies to the deployed condition of the FIG. 6 embodiment.)

It will be appreciated that anchors like **5201** can be used at any of many different locations on the stent frame **5010**, etc., of any of the embodiments shown herein. As just one example of other possible locations for anchors like **5201**, such anchors could be alternatively or additionally located on the upper (outflow) edge of any of the stent frame shown herein.

FIGS. 7a and 7b show illustrative embodiments in which an inflow-end cuff **5203** (e.g., of fabric) is included. Except for the addition of inflow cuff **5203**, the embodiments shown in FIGS. 7a and 7b can be similar to any of the other embodiments shown herein. (FIGS. 7a and 7b include greatly simplified depictions of the leaflet structure **5500** in the open condition.) Inflow cuff **5203** preferably extends annularly all the way around the valve adjacent to its inflow edge. (As always throughout this specification, “inflow” refers to the direction of blood flow through the valve after it has been implanted and is in use in a patient.) The cuff fabric material can be attached to the outside (FIG. 7a), the inside (e.g., between stent frame **5010d** and leaflets **5500** as shown in FIG. 7b), or directly below the stent frame in another embodiment. Inside and outside are preferred because this allows for better integration of the leaflet material **5500** onto the stent **5010d**, because the leaflet materials utilize the presence of the cuff fabric material during assembly and integration. This also provides a more durable design. When the valve is in the expanded state, the cuff fabric material should lie flat on the inside or outside of the stent frame **5010d**. The presence of the fabric **5203** helps promote tissue in-growth after the valve has been implanted. This helps to seal the valve against perivalvular leakage. (FIG. 3 again applies to the deployed condition of the FIGS. 7a and 7b embodiments.)

FIGS. 8 and 9 show another illustrative embodiment in which stent frame **5010e** includes commissure regions that are somewhat more post-like, as at reference number **5237**. (FIG. 8 shows the apparatus in its annularly expanded, deployed condition. FIG. 9 shows part of the same apparatus in its annularly collapsed, delivery condition.) Making each prosthetic valve commissure region more like a single upstanding post **5237** may enhance each such commissure region’s independent flexibility (i.e., its ability to flex independently of other parts of supporting structure **5010e**).

Amplifying the description of this aspect of FIGS. 8 and 9 somewhat, in embodiments of this type, each commissure tip **5236** of the valve is at the free end of a respective single structural member **5237** that is cantilevered from a respective single point on remaining structure of annulus inflow portion **5200**.

FIGS. 8 and 9 also show examples of how stent frame **5010e** may be provided with apertures **5239** for facilitating attachment of other components (e.g., leaflets **550**) to the stent frame. Another possible use for apertures like **5239** is for helping to releasably secure a prosthetic valve in accordance with the invention to delivery system apparatus for the valve. For example, wires or suture material may pass through apertures like **5239** from and/or to delivery apparatus to help releasably hold the valve in the delivery apparatus until the valve is ready to be deployed into the patient. FIG. 3 again applies to deployment of the FIG. 8-9 embodiment.

FIG. 10 shows an example of a stent frame **5010f** that (solely for purposes of illustration herein) has been cut along a longitudinal axis and then flattened. In the FIG. 10 embodiment the inflow edge of the stent frame (toward the bottom of FIG. 10) is scalloped or recessed so that it is relatively "high" in the vicinity of each commissure region **5236** and relatively "low" between each annularly adjacent pair of commissure regions. The high areas are pointed out by reference characters H, and the low areas are pointed out by reference characters L. Making the inflow edge of stent frame **5010f** relatively high adjacent the aortic valve commissures helps the prosthetic aortic valve avoid possibly impinging on the patient's native mitral valve, and may also have other advantages.

FIG. 10 also illustrates some other possible variations. For example, FIG. 10 shows another possible arrangement of apertures **5239** like those mentioned above. FIG. 10 shows another arrangement of the circumferentially collapsible/expandable ring structures that can be used in areas **5100** and **5200**. In this example these ring structures include four-sided, open-centered cells (e.g., **5105** and **5205**) that can expand in the left-right direction as viewed in FIG. 10 to annularly expand the stent frame for deployment in the patient, or that can shrink in the left-right direction as viewed in FIG. 10 to annularly collapse the stent frame for delivery into the patient. FIG. 10 shows these cells **5105** and **5205** in their annularly collapsed condition. A row of such cells can be thought of as two side-by-side serpentine or undulating rings that are 180° out of phase with one another and that have been joined together at adjacent peaks in their undulations. FIG. 10 also shows another example of use of barbs **5201** like those described earlier in this specification.

FIGS. 11 and 12 show a representative detail from FIG. 10. It will be understood that this type of feature can be used at any suitable location(s) in any of the embodiments shown herein. The feature detailed in FIGS. 11 and 12 is a rounded corner **5207** between otherwise relatively straight members of cells like **5205** or other similar serpentine or undulating ring structures. (Again, this feature can also be used elsewhere such as in region **5100**.) FIG. 11 shows one representative rounded corner **5207** in an annularly collapsed structure. Note that in FIG. 11 rounded corner **5207** preferably has an overall C shape. FIG. 12 shows the same rounded corner after annular expansion of the structure. Now (i.e., in FIG. 12) corner **5207** has opened up somewhat to have a more nearly U shape. Use of these rounded corners helps to avoid stress concentration where the members of the cellular or serpentine structure change direction. This can improve the performance and extend the life of the structure. Also, upon expansion, these rounded corners tend to open up slightly (e.g., from a C

shape to a U shape). This can facilitate leaflet attachment by providing locations through which suture material **5209** can be passed (e.g., as shown in FIG. 12).

FIG. 13 shows (using the same general type of depiction as in FIG. 10) yet another alternative embodiment in which aortic outflow portion **5100** has more closed cells **5105** than annulus inflow portion **5200**. This may facilitate annular expansion of aortic outflow portion **5100** to a larger diameter than annulus inflow portion **5200**. FIG. 13 also shows another example of how and where aperture **5239** may be provided in stent frame **5010g** to facilitate attachment of leaflets and other materials to the stent frame. (FIG. 3 again applies to deployment of embodiments like those shown in FIGS. 10 and 13.)

FIG. 14 shows that a valve in accordance with the invention may have fabric **5206** mounted internally of any portion of stent frame **5010** (the FIG. 14 example shows fabric **5206** between annulus inflow portion **5200** and leaflets **5500**). FIG. 14 also shows that a valve in accordance with the invention may have fabric **5208** mounted externally of any portion of stent frame **5010** (again, the FIG. 14 example shows fabric **5208** around the outside of annulus inflow portion **5200**). Although FIG. 14 shows fabric around both the inside and outside of a portion of stent frame **5010**, it will be understood that fabric may be used in only one of these locations if desired. Some or all of the fabric like **5206** and/or **5208** may form the cuff **5203** shown in FIG. 7a or 7b.

FIG. 15 shows that a valve in accordance with the invention may have tissue material **5206a** as a buffer between the stent frame **5010** and coapting leaflets **5500** to prevent abrasion of the leaflets by the stent frame and provide longer durability performance for the valve. In the example shown in FIG. 15, tissue material **5206a** is between annulus inflow portion **5200** and leaflets **5500**. Tissue material **5206a** is preferably thinner than the material used for leaflets **5500**.

FIG. 16 shows (using the same general type of depiction as in FIG. 13) another illustrative embodiment of stent frame **5010h** in which each commissure post region **5237** is bifurcated into two, substantially parallel, independently cantilevered post members **5237a** and **5237b**.

In general, it is preferred that the circumferential (annular, radial) collapse and re-expansion of prosthetic valves in accordance with this invention is elastic or at least mostly elastic. However, part or all of such collapse and/or re-expansion may alternatively or additionally result from use of shape-memory properties of the material of the stent frame (e.g., **5010**) of the valve. As still another possibility, some or all of the collapse and/or re-expansion of the valve may be plastic. For example, such plastic re-expansion may be produced by inflation of a balloon (e.g., on a catheter) inside the valve.

It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, the number of undulations or cells used in aortic outflow portion **5100** and/or annulus inflow portion **5200** can be different (more or less) than the numbers shown in the FIGS. that form part of this disclosure.

What is claimed is:

1. A prosthetic aortic valve, comprising:

an annular stent frame including (1) an annulus inflow portion configured for disposition, in use, adjacent a patient's native aortic valve annulus, the annulus inflow portion having an inlet end and an outlet end and including a plurality of sections spaced from one another in the annular direction, the annulus inflow portion being devoid of structure between adjacent ones of the sections

so as to define at least one gap in the annular direction around the annulus inflow portion between one of the sections of the annulus inflow portion and another of the sections of the annulus inflow portion, the at least one gap extending from the inlet end to the outlet end, (2) an aortic outflow portion configured for disposition, in use, in the patient's native aorta downstream from at least a portion of the patient's valsalva sinus, and (3) a plurality of connecting struts connecting the annulus inflow portion to the aortic outflow portion, the annulus inflow portion defining a plurality of commissure tips that are spaced from one another in the annular direction around the annulus inflow portion, the commissure tips being the features of the annulus inflow portion that are closest to the aortic outflow portion, each of the connecting struts being connected to the annulus inflow portion only at points that are farther from the aortic outflow portion than the commissure tips, each commissure tip having an associated pair of the connecting struts disposed on opposite sides of the commissure tip in the annular direction, and each of the connecting struts, in use, bulging radially outwardly between the annulus inflow portion and the aortic outflow portion; and a plurality of valve leaflets supported by the annulus inflow portion.

2. The prosthetic aortic valve defined in claim 1 wherein the aortic outflow portion is integrally connected to the annulus inflow portion via the connecting struts.

3. The prosthetic aortic valve defined in claim 1 wherein the stent frame is elastically, annularly compressible to a first relatively small size.

4. The prosthetic aortic valve defined in claim 3 wherein the stent frame is elastically, annularly re-expandable from the first size to a second relatively large size.

5. The prosthetic aortic valve defined in claim 4 wherein the second size is suitable for use of the valve in and by the patient.

6. The prosthetic aortic valve defined in claim 3 wherein the first size is suitable for delivery of the valve into the patient.

7. The prosthetic aortic valve defined in claim 1 wherein the connecting struts in the pair are spaced apart from one another by a distance in the annular direction that is less than the distance in the annular direction between one of the connecting struts in the pair and a next adjacent connecting strut not in the pair, all of the distances being measured at the level of the commissure tips.

8. The prosthetic aortic valve defined in claim 1 wherein the aortic outflow portion is annularly continuous all the way around the valve.

9. The prosthetic aortic valve defined in claim 1 wherein the aortic outflow portion has at least one interruption in the annular direction.

10. The prosthetic aortic valve defined in claim 1 further comprising a plurality of anchor members that are resiliently biased to incline outwardly from the stent frame, the anchor members being connected to the stent frame only at positions that are not between the annulus inflow portion and the aortic outflow portion.

11. The prosthetic aortic valve defined in claim 1 further comprising an annular cuff that is mounted on the annulus inflow portion.

12. The prosthetic aortic valve defined in claim 1 wherein each of the commissure tips is at a free end of a respective single structural member that is cantilevered from at least a respective single point on remaining structure of the annulus inflow portion.

13. The prosthetic aortic valve defined in claim 1 wherein each of the commissure tips is at a free apex of a V-shaped structure that is cantilevered from at least a respective pair of points on remaining structure of the annulus inflow portion.

14. The prosthetic aortic valve defined in claim 1 wherein the stent frame defines a plurality of apertures for use in securing the leaflets to the stent frame.

15. The prosthetic aortic valve defined in claim 1 wherein the stent frame defines a plurality of apertures for use with a delivery system for the valve.

16. The prosthetic aortic valve defined in claim 1 wherein the annulus inflow portion includes a pair of structural members that are integral with one another at a curved corner that is initially C-shaped and that becomes more U-shaped when the structural members move away from one another in a direction that is annular of the valve.

17. The prosthetic aortic valve defined in claim 1 wherein both the aortic outflow portion and the annulus inflow portion include structure that undulates as one proceeds in an annular direction around the valve.

18. The prosthetic aortic valve defined in claim 17 wherein the structure of the aortic outflow portion that undulates has approximately a same number of undulations as the structure of the annulus inflow portion that undulates.

19. The prosthetic aortic valve defined in claim 17 wherein the structure of the aortic outflow portion that undulates has more undulations than the structure of the annulus inflow portion that undulates.

20. The prosthetic aortic valve defined in claim 1 wherein the inlet end of the annulus inflow portion includes a recessed edge portion aligned in a longitudinal direction of the stent frame with at least one of the commissure tips, no other portion of the inlet end being closer to the aortic outflow portion than the recessed edge portion.

21. The prosthetic aortic valve defined in claim 1 further comprising fabric inside at least a portion of the stent frame.

22. The prosthetic aortic valve defined in claim 1 further comprising fabric outside at least a portion of the stent frame.

23. The prosthetic aortic valve defined in claim 1 further comprising tissue material between the stent frame and the leaflets.

24. The prosthetic aortic valve defined in claim 23 wherein the tissue material is thinner than the leaflets.

25. The prosthetic aortic valve defined in claim 1 wherein the leaflets are made of a material selected from the group consisting of biological tissue, polymer, thin metal, and reinforced polymer.