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(54) **REPLACEMENT HEART VALVE**

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CPC ***A61F 2/2418*** (2013.01); ***A61F 2/2415*** (2013.01); *A61F 2220/0008* (2013.01); *A61F 2230/008* (2013.01); *A61F 2230/0054* (2013.01); *A61F 2230/0067* (2013.01); *A61F 2250/0029* (2013.01); *A61F 2250/0039* (2013.01)

(58) **Field of Classification Search**
None
See application file for complete search history.

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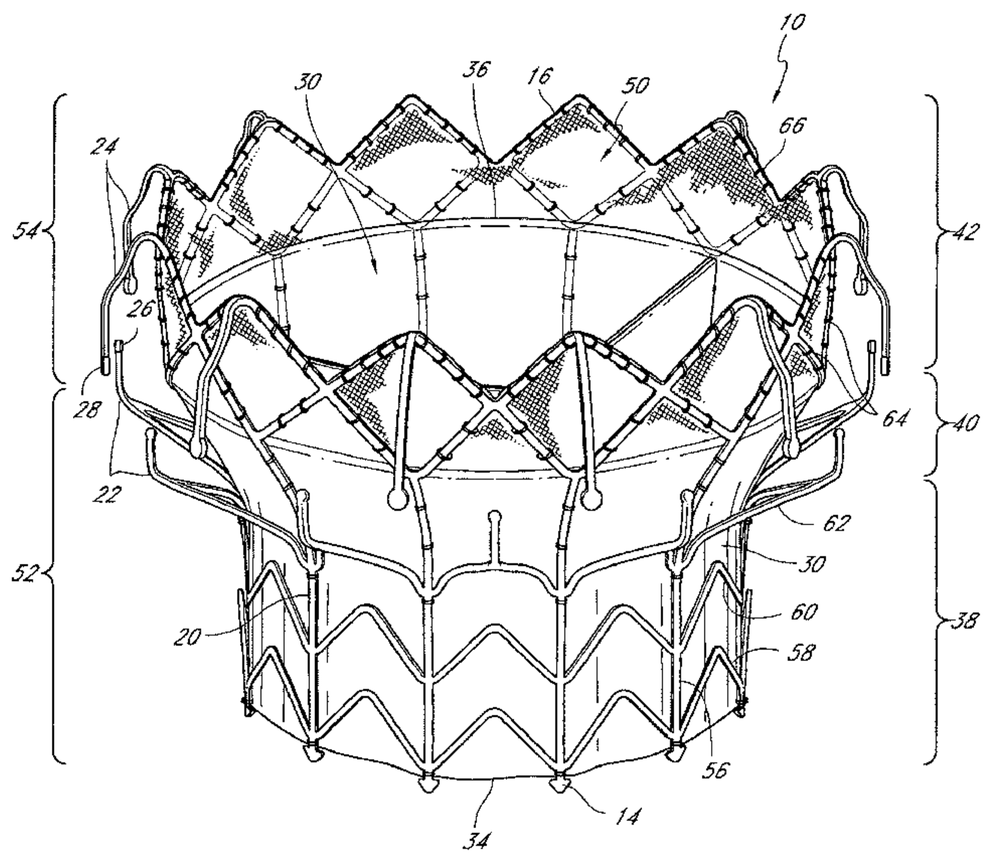
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(57) **ABSTRACT**

A replacement heart valve can have an expandable frame configured to engage a native valve annulus. A valve body can be mounted onto the expandable frame to provide functionality similar to a natural valve. The valve body has an upstream end and a downstream end, and a diameter at the downstream end is greater than a diameter at the upstream end.

17 Claims, 14 Drawing Sheets



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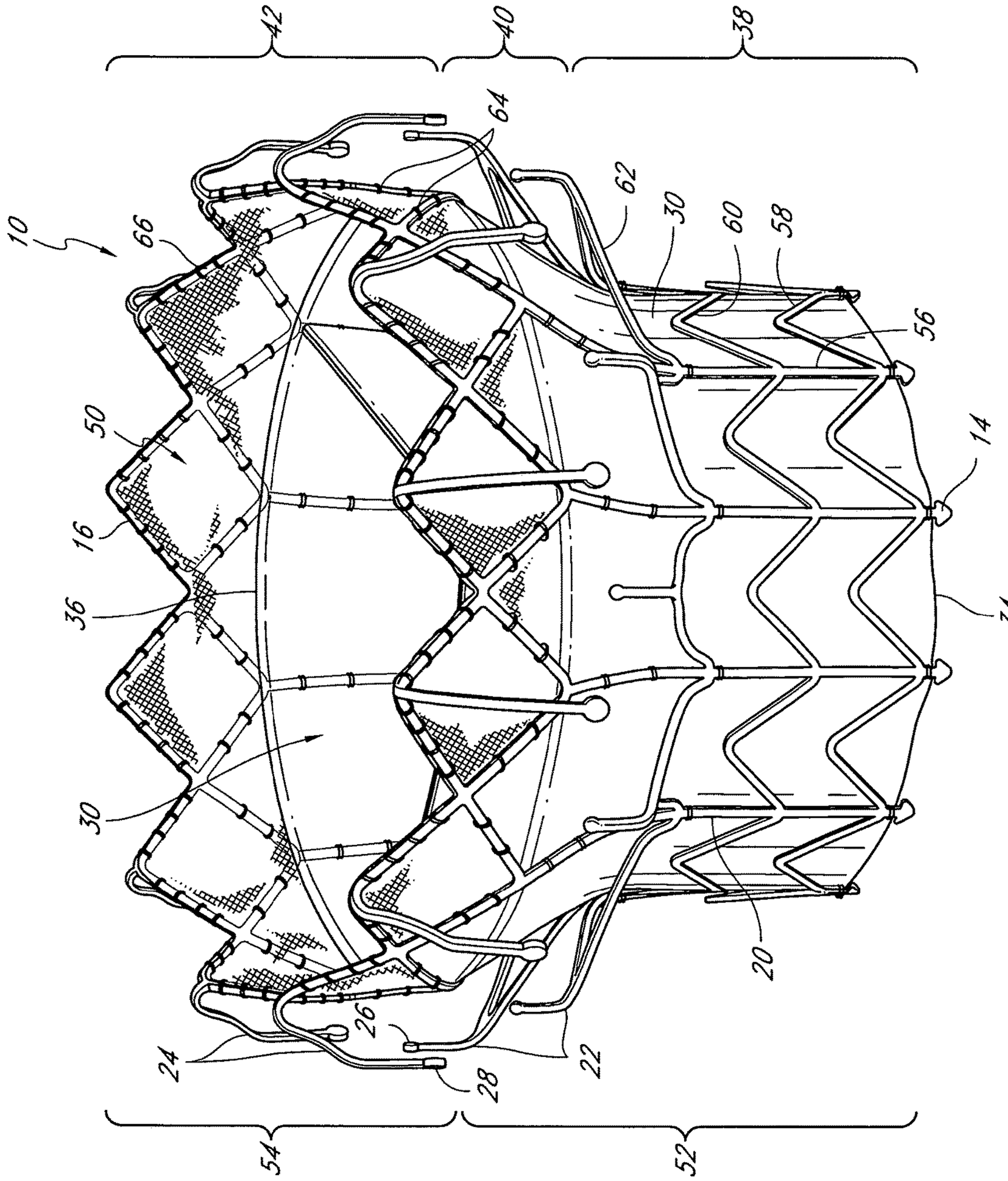


FIG. 1

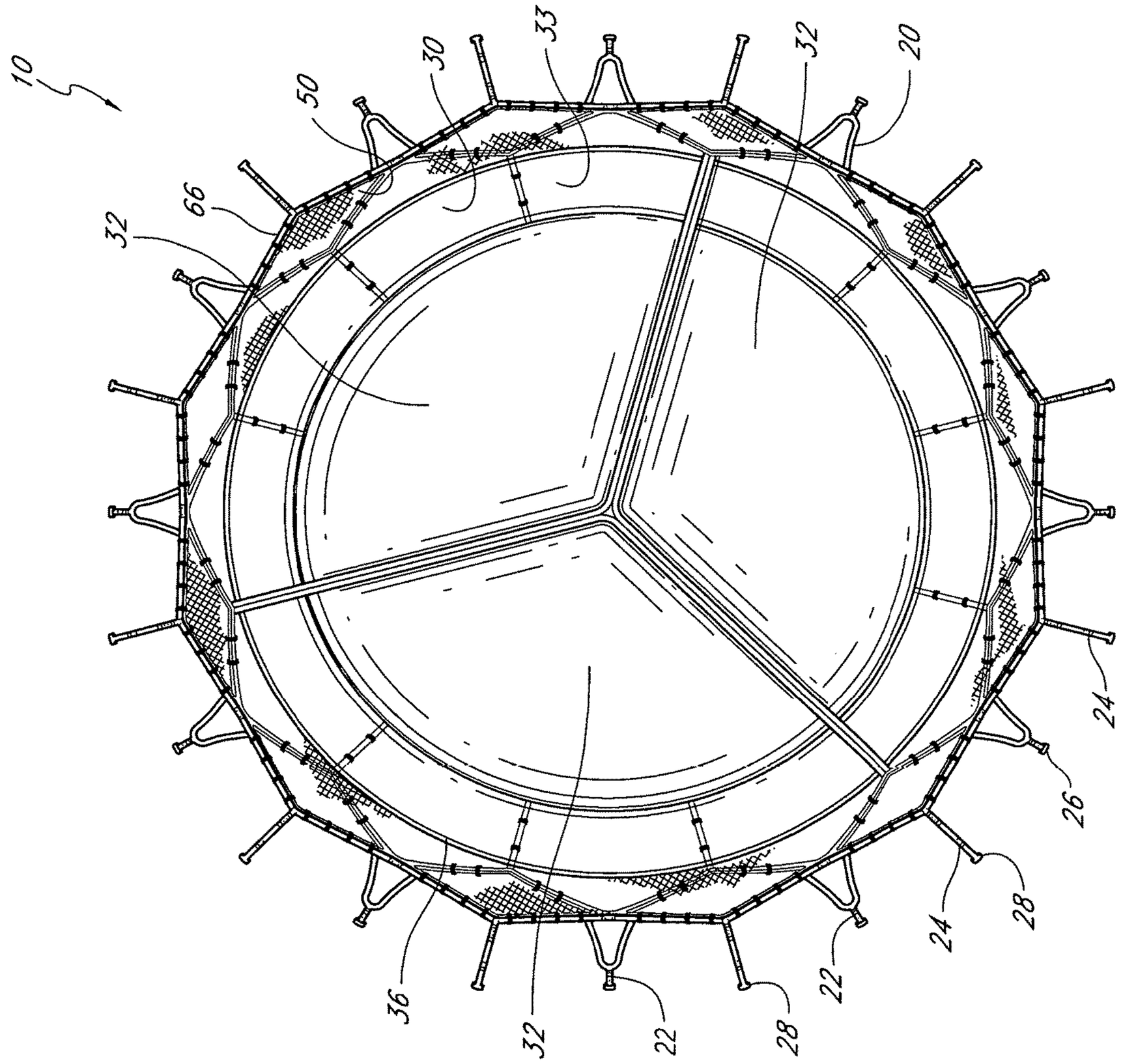


FIG. 2

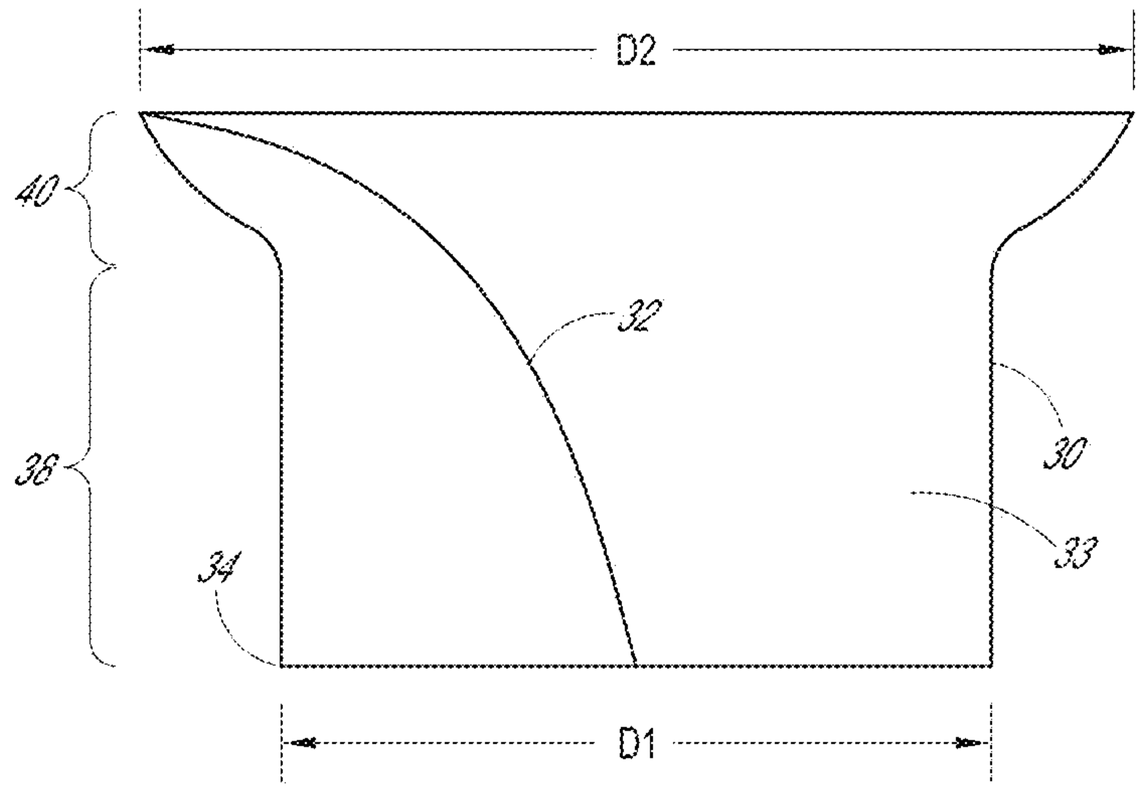


FIG. 3A

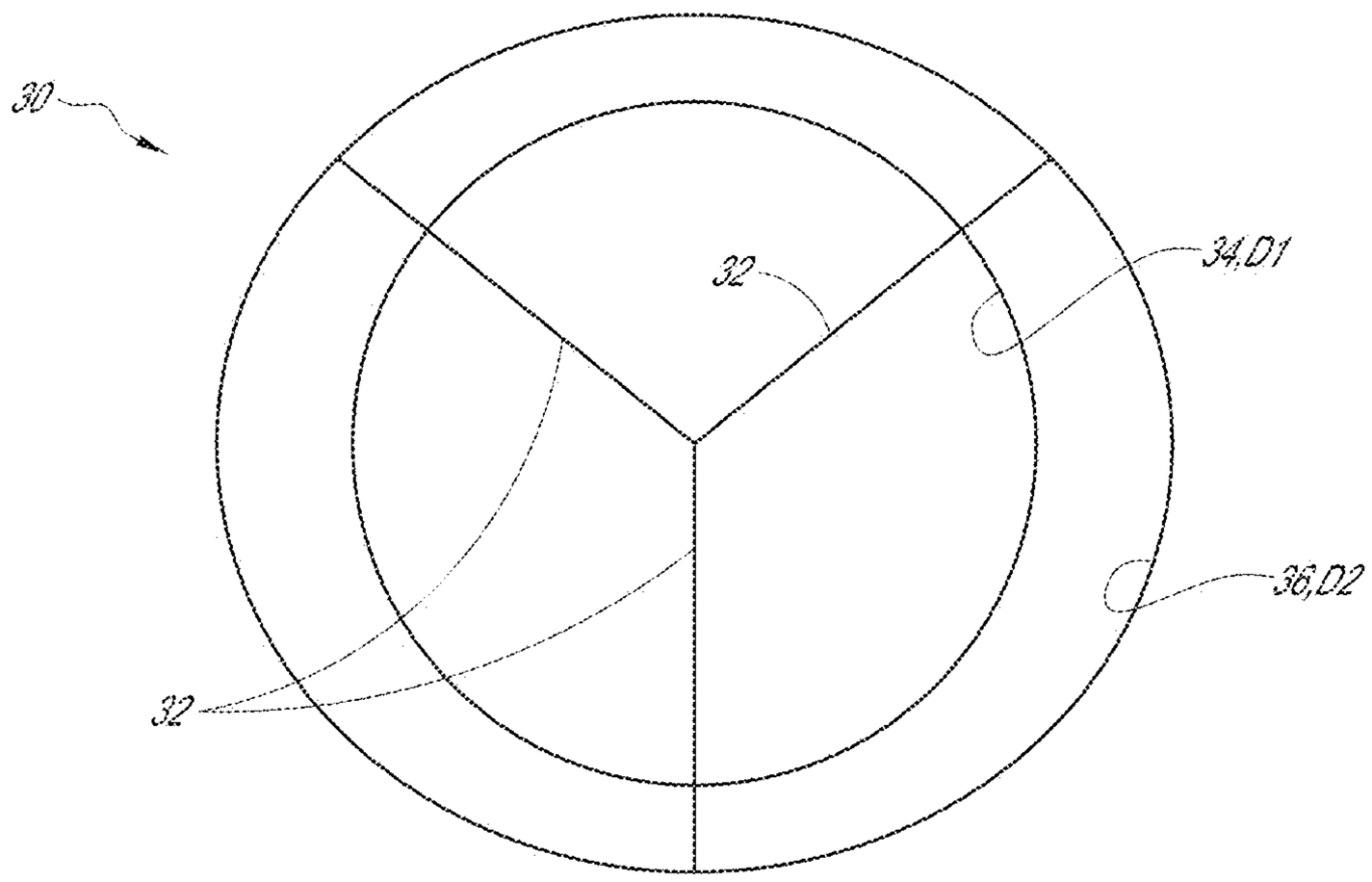


FIG. 3B

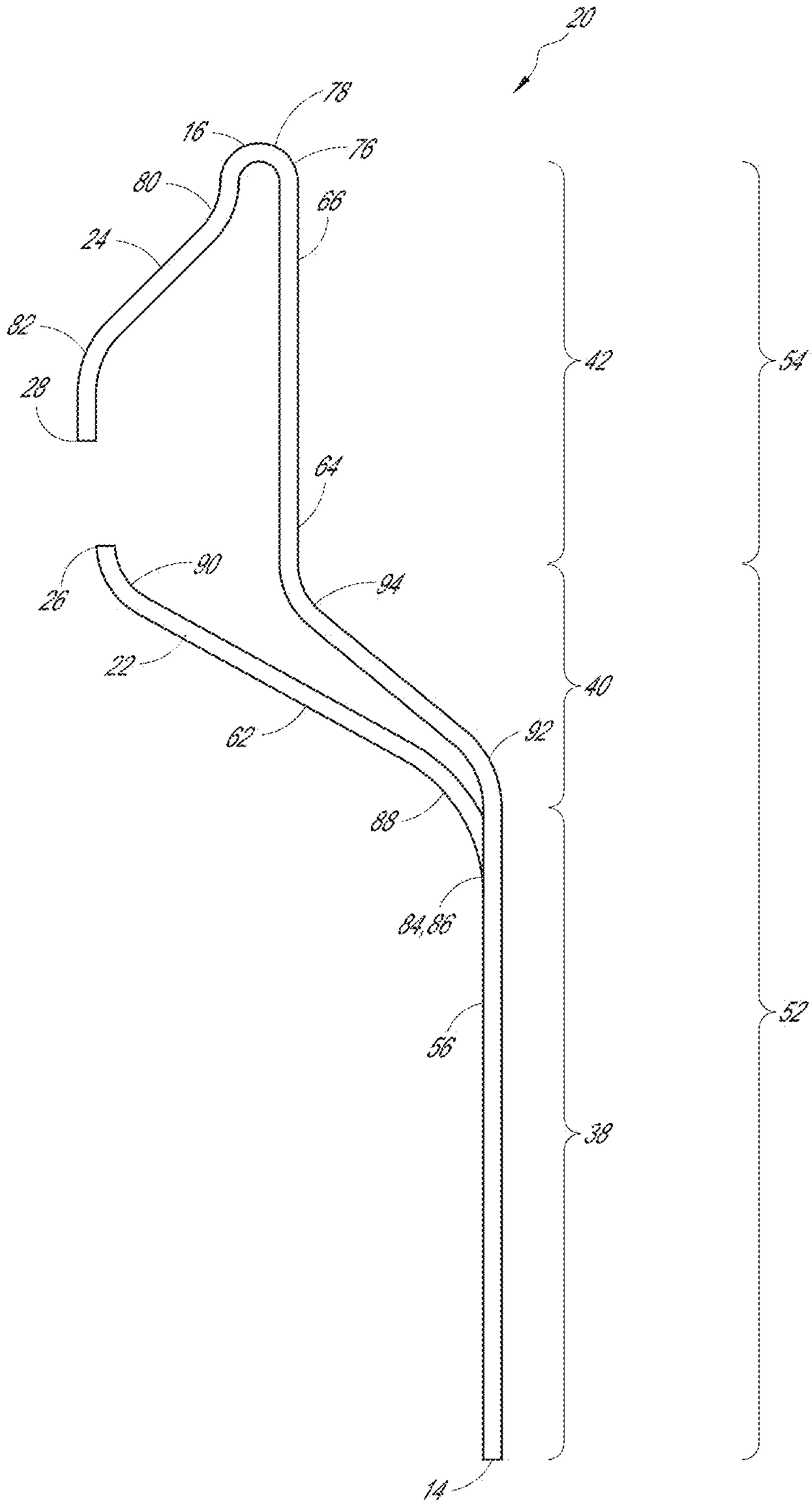

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FIG. 4

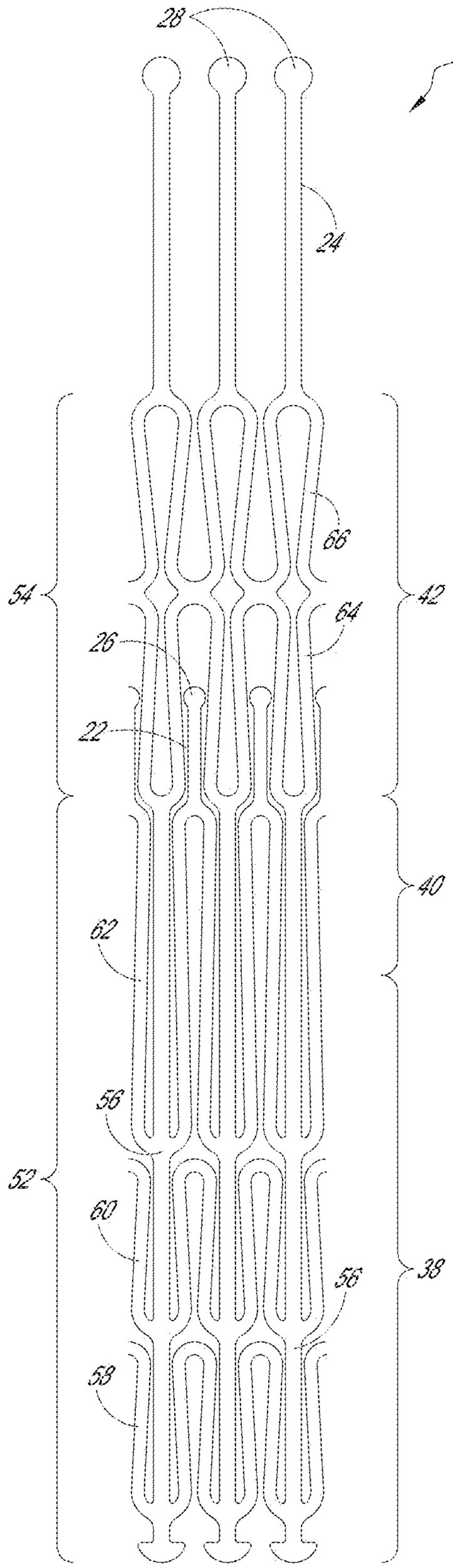


FIG. 5



FIG. 10

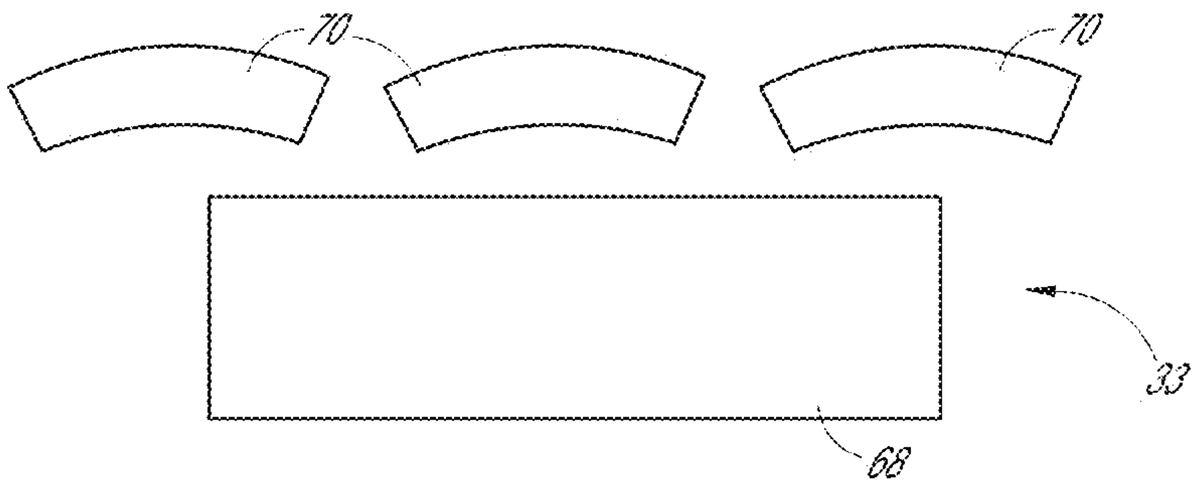


FIG. 7

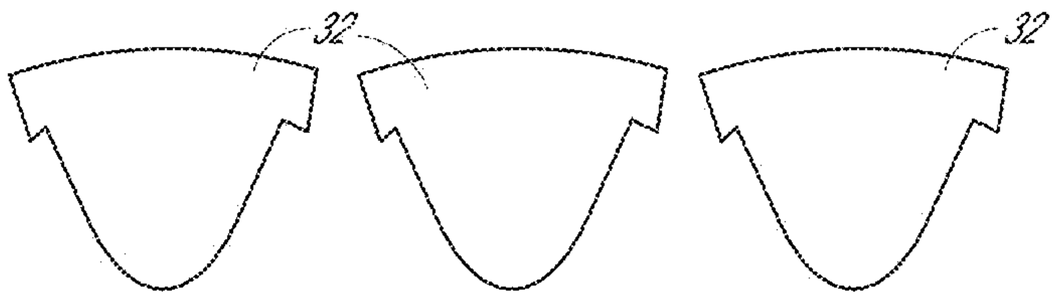


FIG. 6

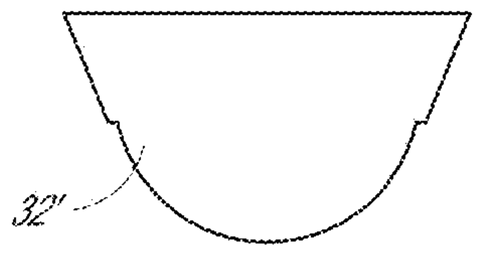


FIG. 6A

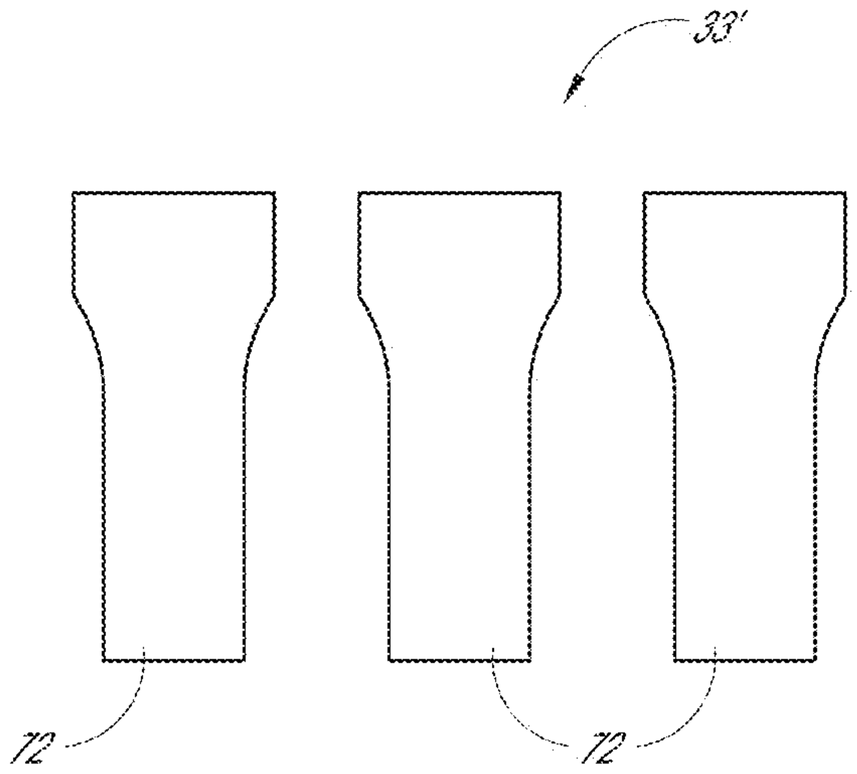


FIG. 8

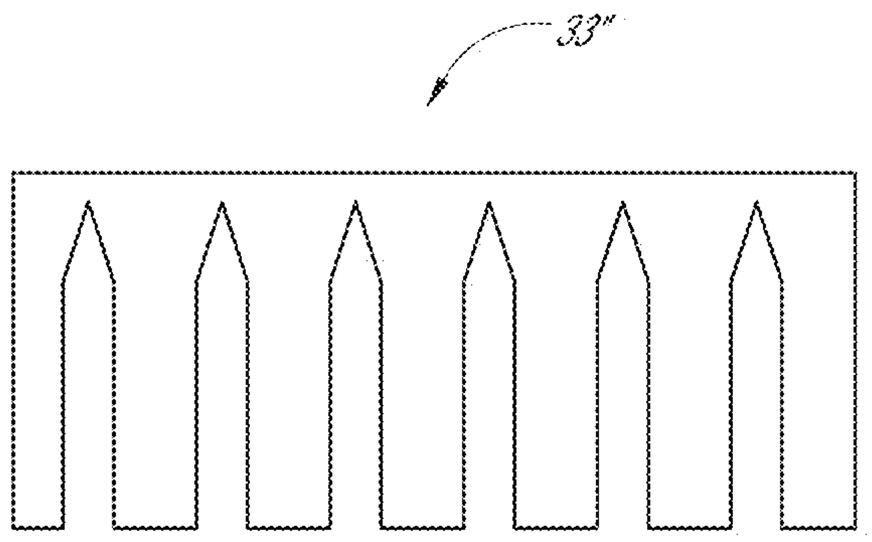


FIG. 9

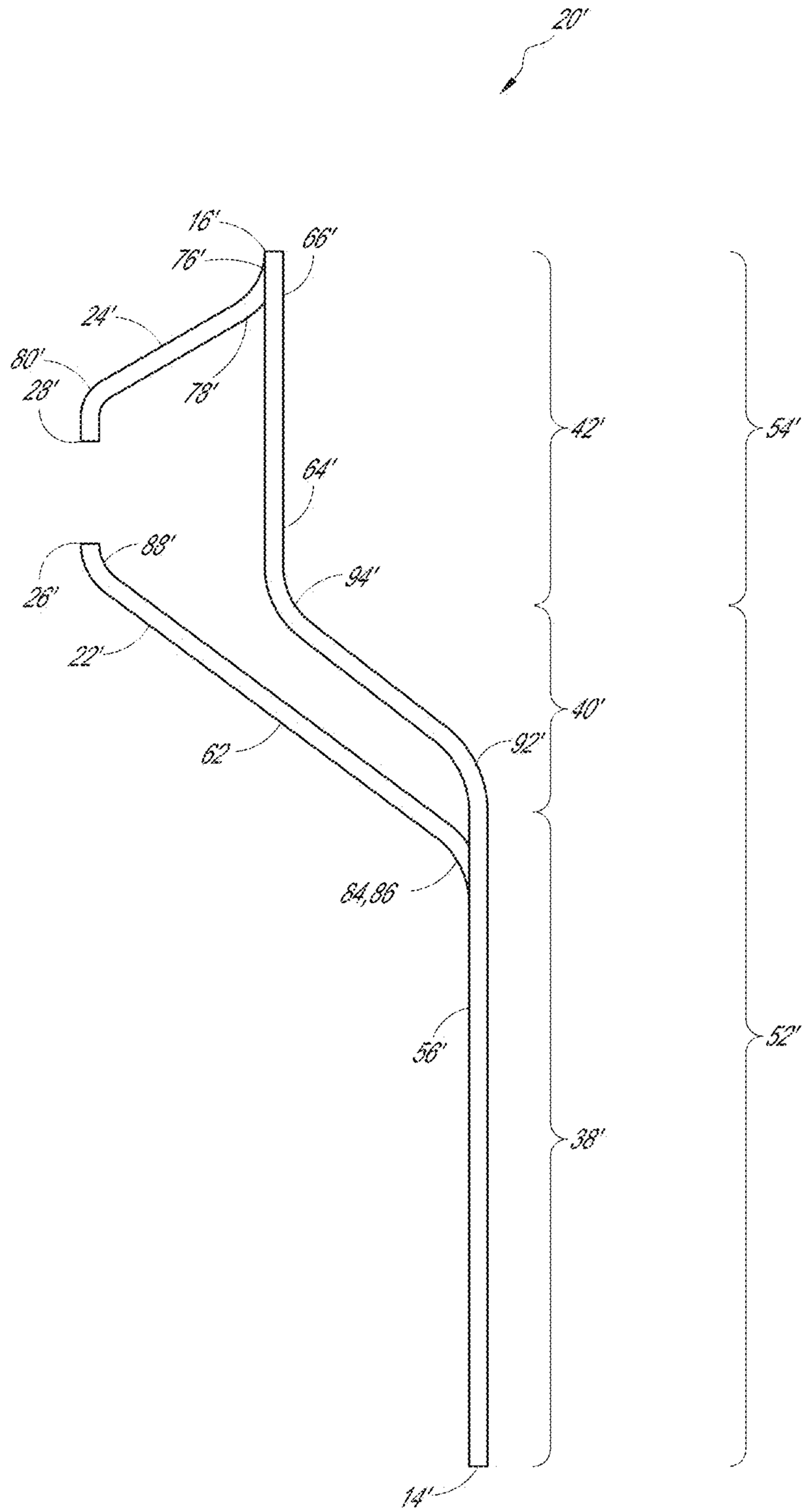


FIG. 11

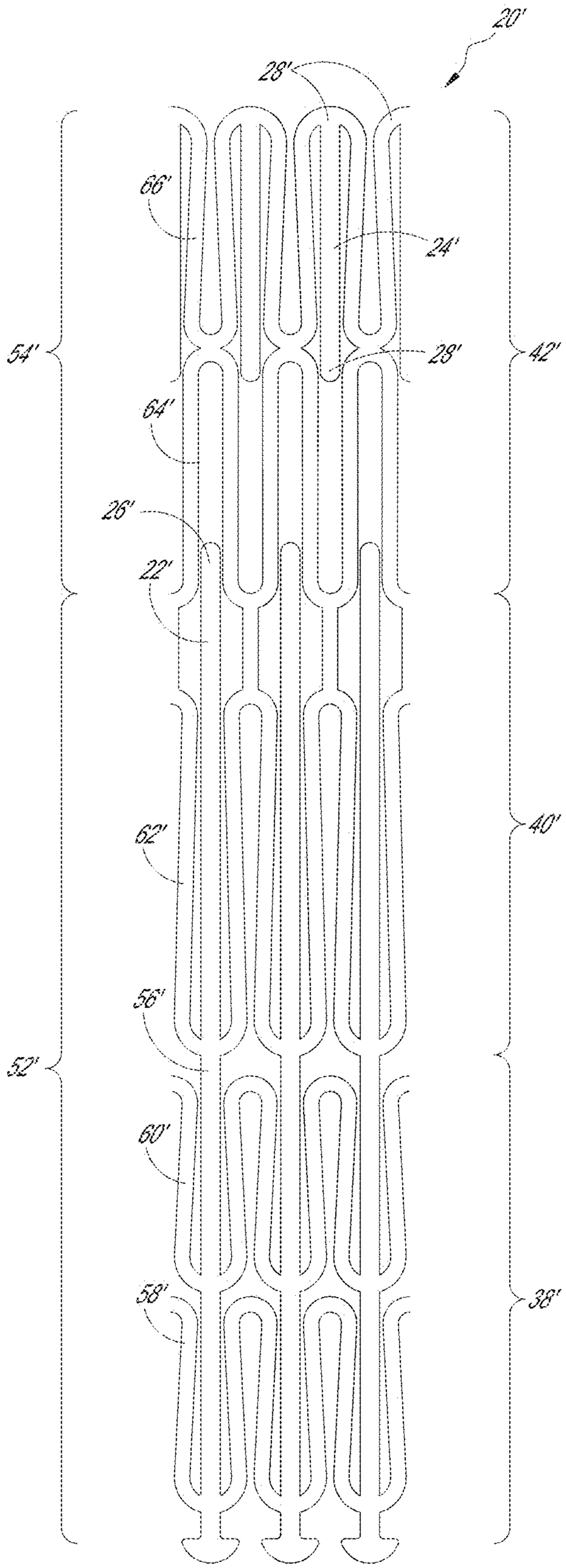


FIG. 12

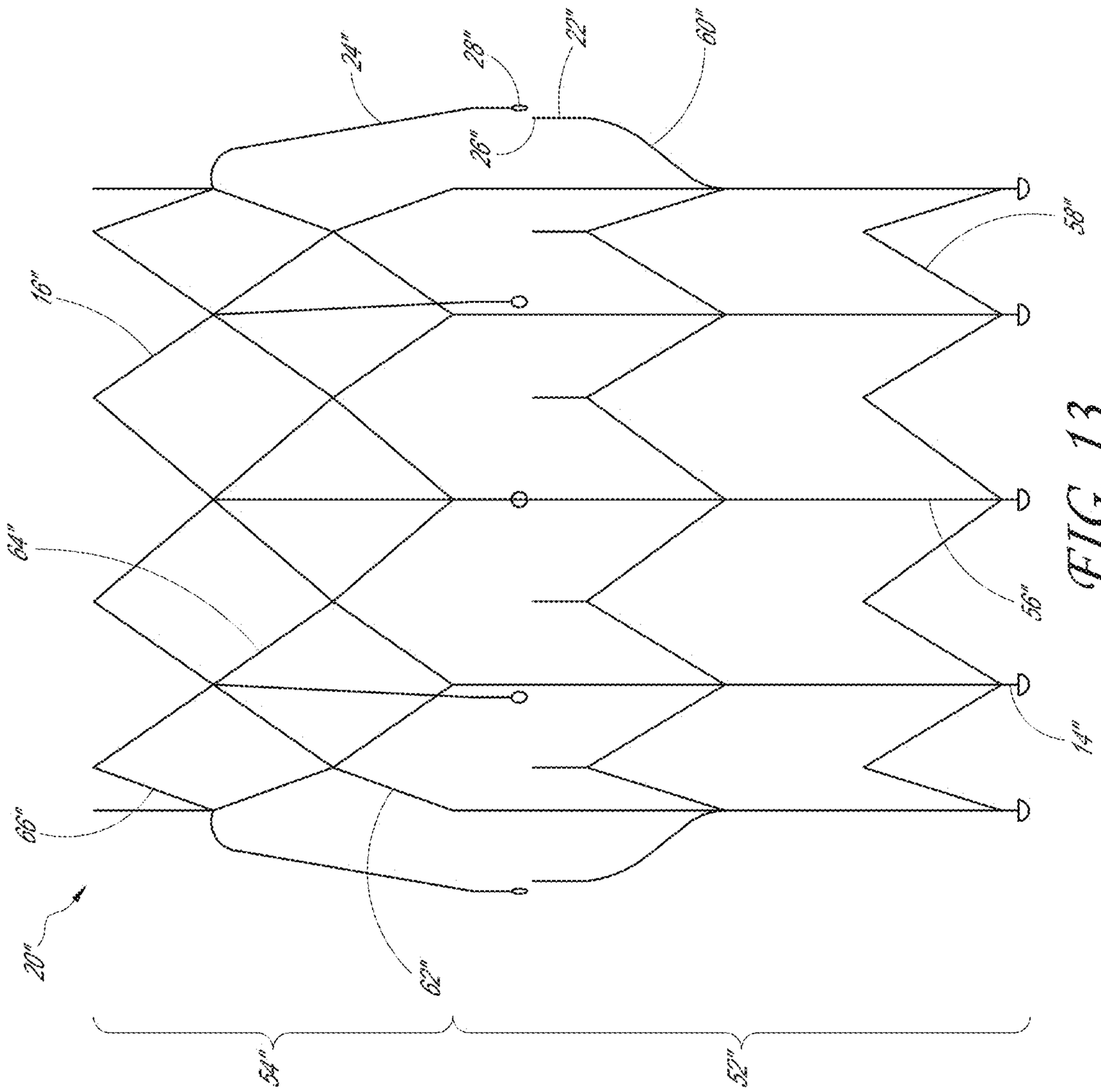


FIG. 13

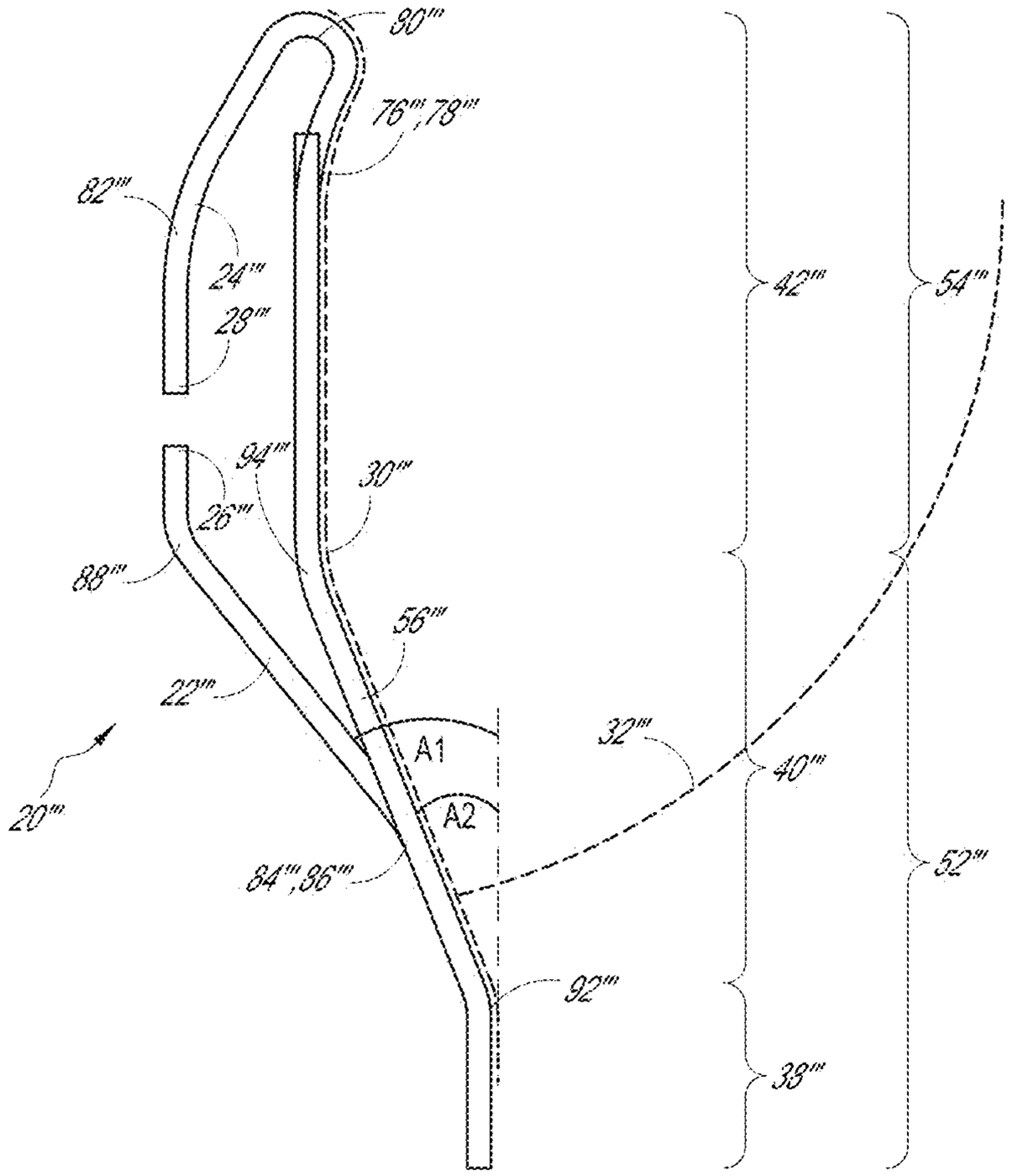


FIG. 14



FIG. 15

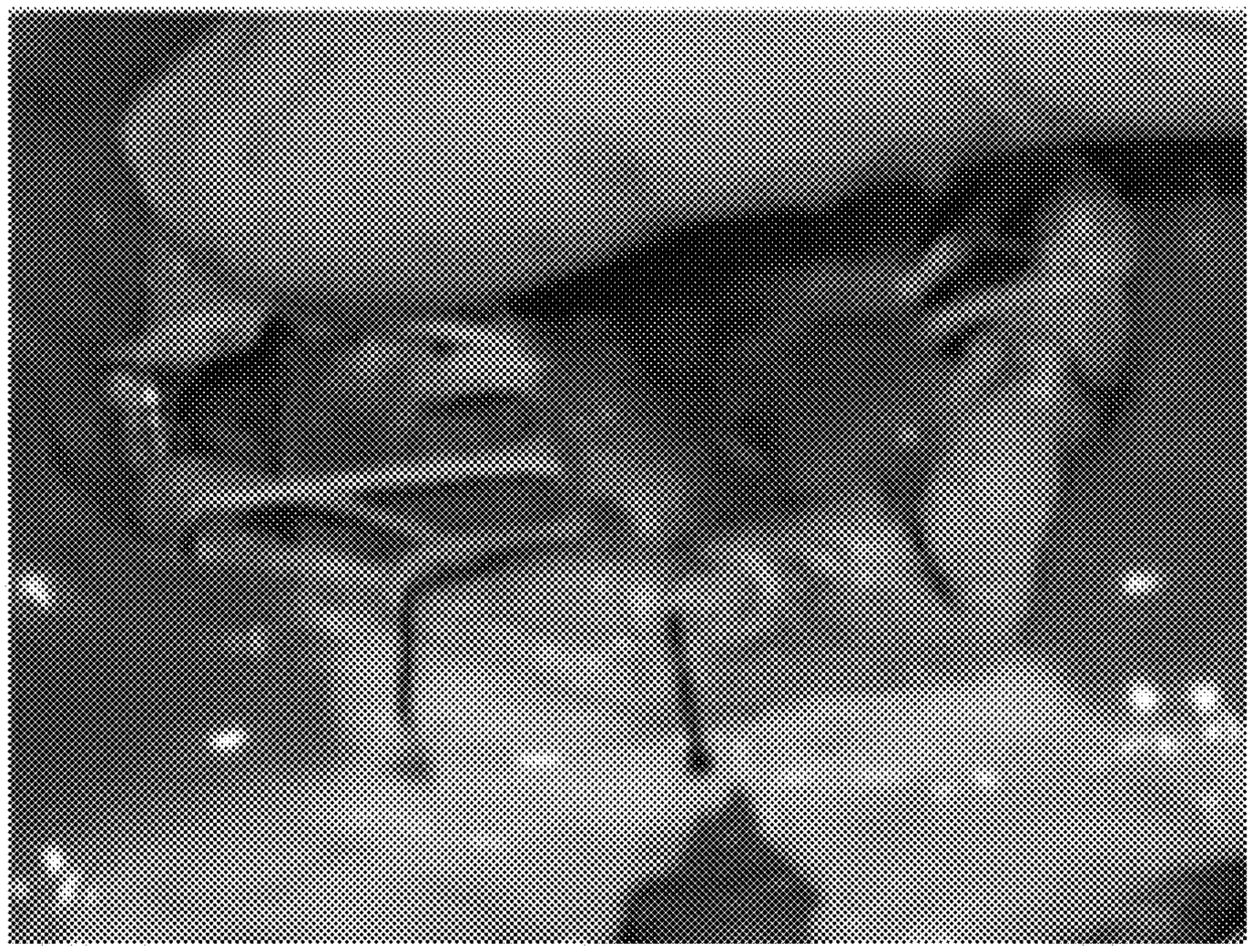


FIG. 16

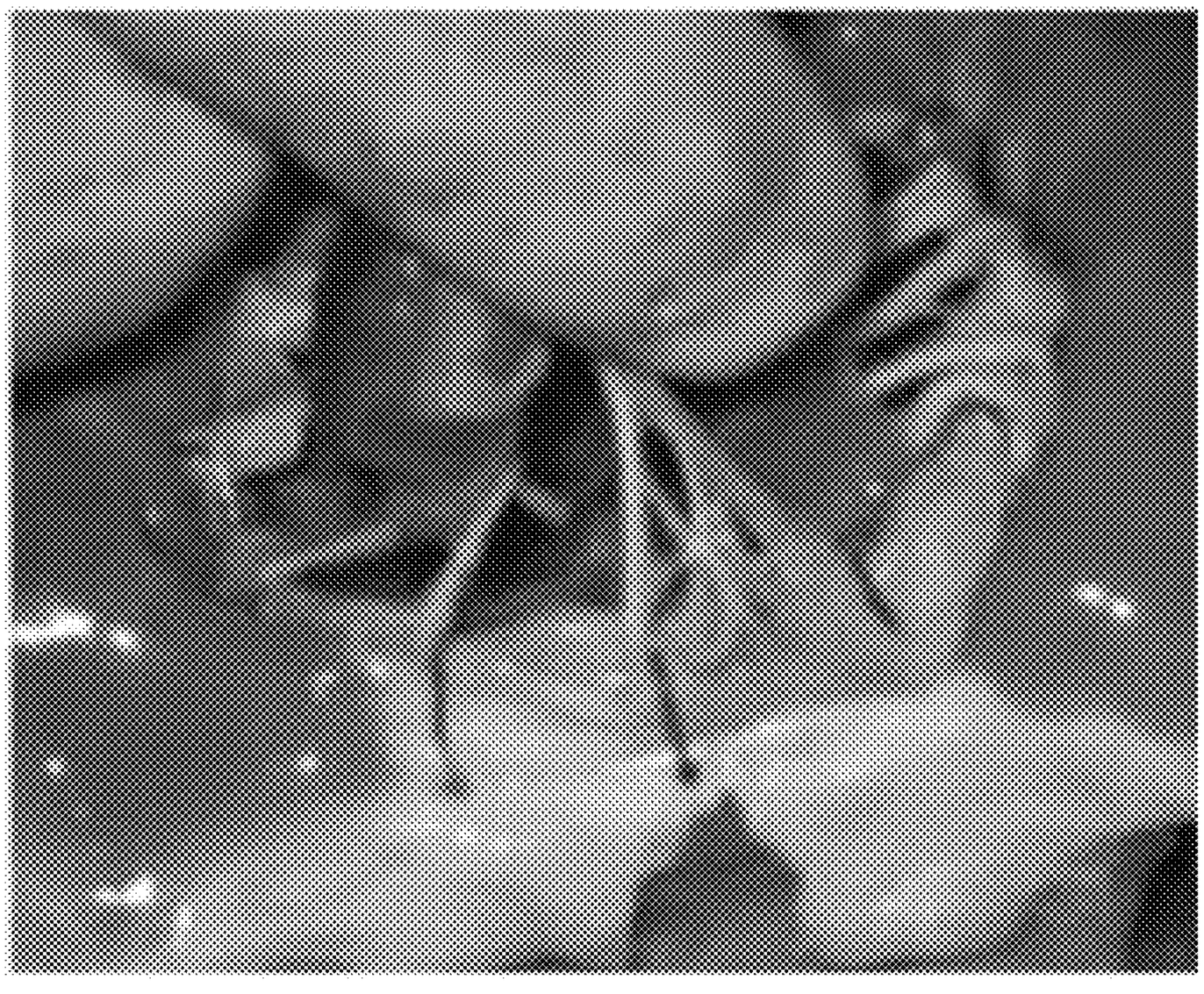


FIG. 17

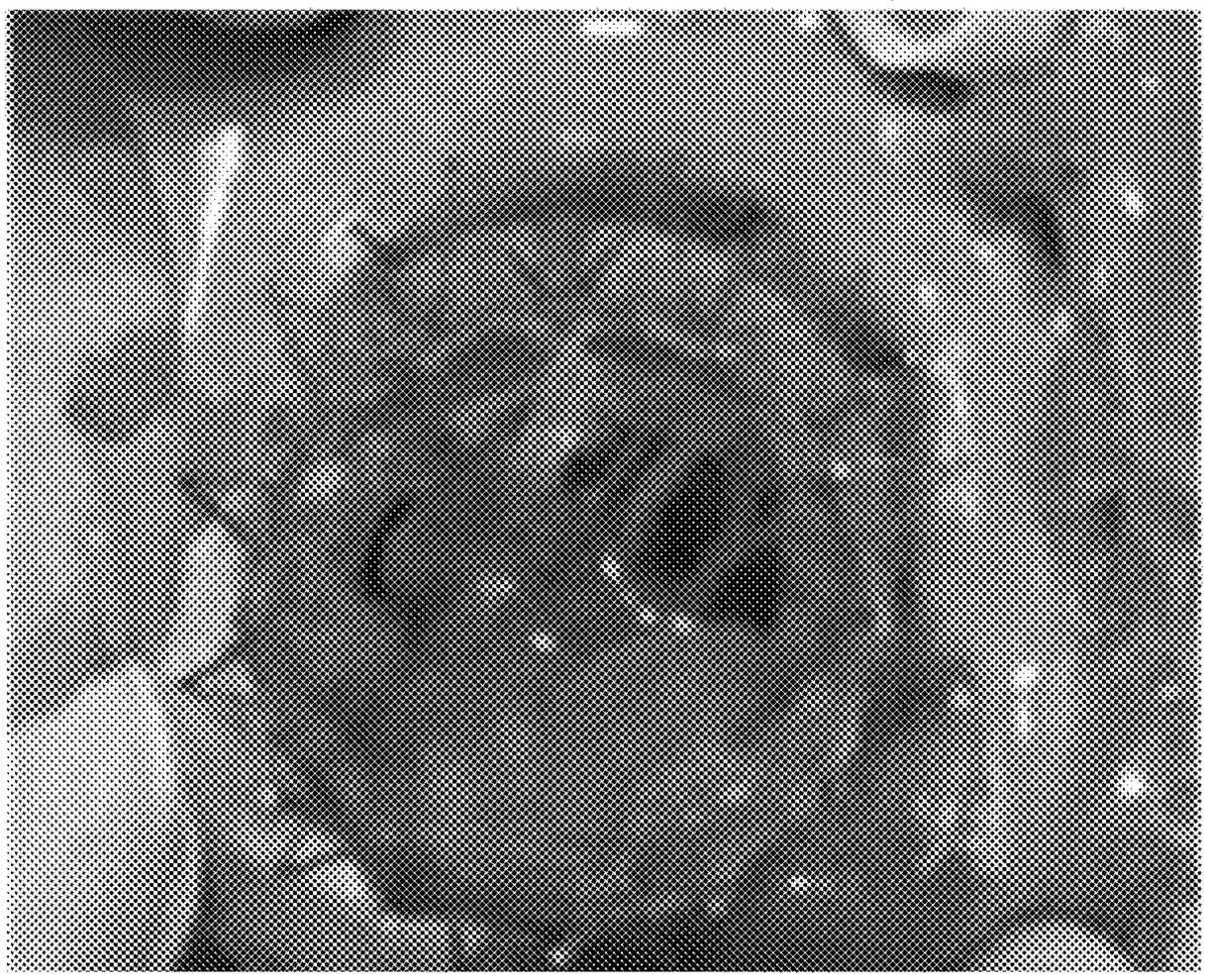


FIG. 18

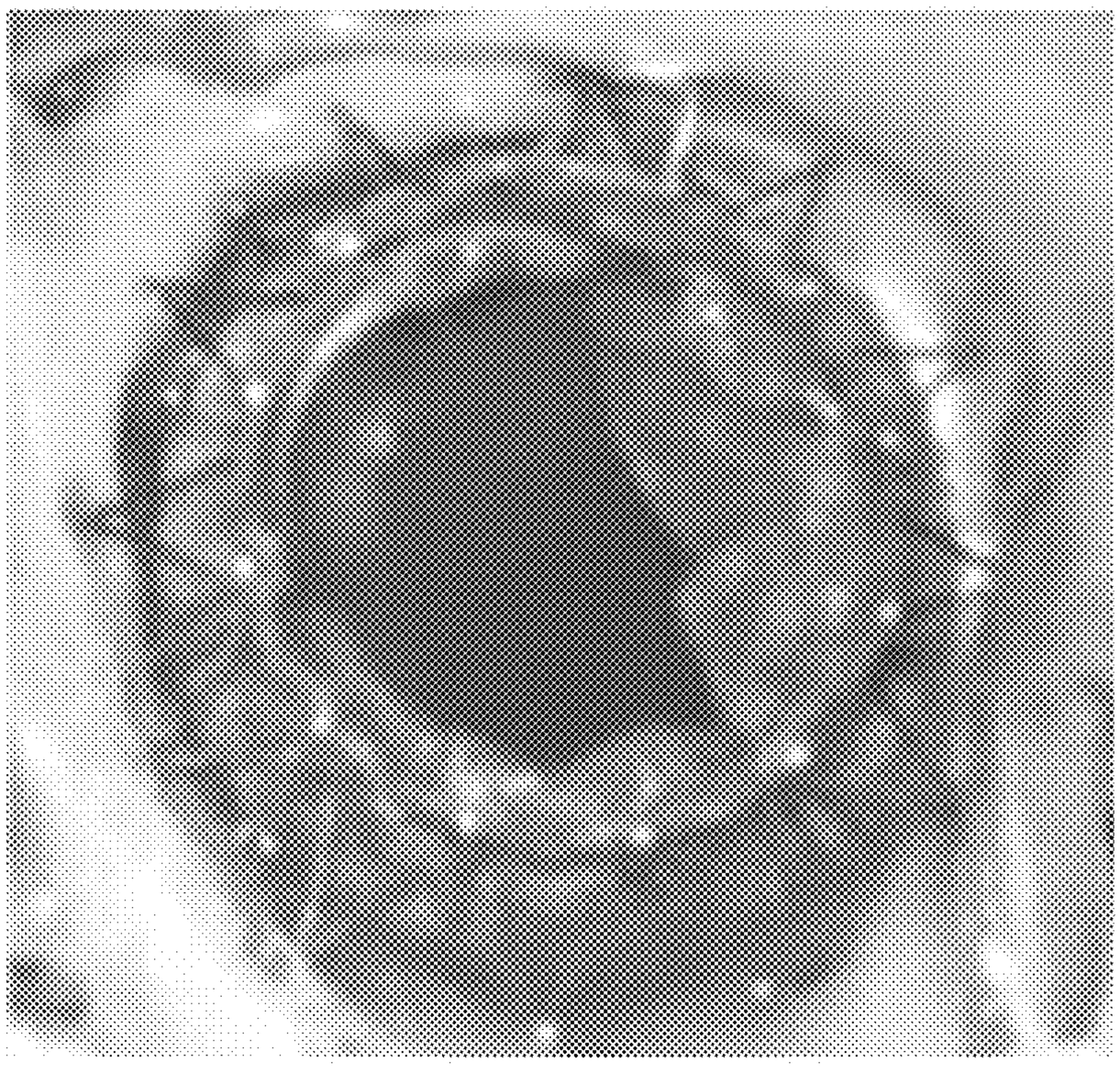


FIG. 19

REPLACEMENT HEART VALVE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 13/165,721, filed Jun. 21, 2011, which claims priority to U.S. Provisional Application No. 61/357,048, which was filed on Jun. 21, 2010. The entire contents of the above applications are hereby incorporated by reference herein. Further, Applicants' U.S. application Ser. No. 12/569,856, filed Sep. 29, 2009, and U.S. application Ser. No. 12/761,349, filed Apr. 15, 2010 disclose several embodiments of replacement heart valves. In some instances the present disclosure describes embodiments and principles that build upon and improve embodiments disclosed in these previous applications. As such, the entirety of each of these prior applications is incorporated by reference into this disclosure.

BACKGROUND

Field of the Invention

The present invention relates generally to replacement heart valves.

Description of Related Art

Human heart valves, which include the aortic, pulmonary, mitral and tricuspid valves, function essentially as one-way valves operating in synchronization with the pumping heart. The valves allow blood to flow in a downstream direction, but block blood from flowing in an upstream direction. Diseased heart valves exhibit impairments such as narrowing of the valve or regurgitation. Such impairments reduce the heart's blood-pumping efficiency and can be a debilitating and life threatening condition. For example, valve insufficiency can lead to conditions such as heart hypertrophy and dilation of the ventricle. Thus, extensive efforts have been made to develop methods and apparatus to repair or replace impaired heart valves.

Prostheses exist to correct problems associated with impaired heart valves. For example, mechanical and tissue-based heart valve prostheses can be used to replace impaired native heart valves. More recently, substantial effort has been dedicated to developing replacement heart valves, particularly tissue-based replacement heart valves, that can be delivered with less trauma to the patient than through open heart surgery. Replacement valves are being designed to be delivered through minimally invasive procedures and even percutaneous procedures. Such replacement valves often include a tissue-based valve body that is connected to an expandable frame that is then delivered to the native valve's annulus.

Development of replacement heart valves that can be compacted for delivery and then controllably expanded for controlled placement has proven to be particularly challenging.

SUMMARY OF THE INVENTION

Accordingly, there is in the need of the art for an improved replacement heart valve.

In accordance with one embodiment, the present invention provides a replacement heart valve that comprises an expandable frame and a valve body mounted onto the expandable frame. The expandable frame may have an engagement system configured to engage a native valve annulus at an engagement zone along the length of the frame. The frame can have an upstream portion, a downstream portion, and a transition portion between the upstream and downstream portions, where a diameter of the downstream portion is greater than a diameter of the upstream portion. The valve body can have a plurality of valve leaflets configured to move between an open condition and a closed condition. A diameter of the valve body at a downstream end of the leaflets can be greater than a diameter of the valve body at an upstream end of the leaflets and the upstream end of each leaflet can be positioned upstream of the frame engagement zone.

In some embodiments, the engagement system comprises a set of upstream anchors and a set of downstream anchors, each anchor comprising an anchor tip, and the frame engagement zone is defined between the tips of the upstream and downstream anchors.

The anchors can include one of many features. For example, a diameter defined by the tips of the upstream anchors can be approximately equal to a diameter defined by the tips of the downstream anchors. As another example, the downstream anchors can extend from the downstream portion of the expandable frame and the upstream anchors can extend from an area of the frame having a diameter less than the downstream portion, such as the upstream portion or the transition portion of the expandable frame.

In some embodiments, a replacement heart valve comprises an expandable frame configured to engage a native valve annulus at an engagement zone along the length of the frame and a valve body attached to the expandable frame. The expandable frame can include a foreshortening portion configured to longitudinally contract as the frame radially expands from a compacted to an expanded condition, a plurality of first anchors and a plurality of second anchors.

Each of the anchors, according to some embodiments, can extend radially outwardly from the frame at an anchor base and terminate at an anchor tip. At least part of the foreshortening portion can be disposed between the first and second anchor bases and the engagement zone can be defined between the first and second anchor tips. Further, the first anchors can comprise first, second and third spaced apart bending stages along the length of each upstream anchor, and wherein the first anchor is bent radially outwardly in the first and second bending stages, and is bent in an opposite direction in the third bending stage.

The anchors may include additional features. For example, the portion of the first anchor between the third bending stage and the anchor tip can be generally parallel to an axis of the frame. The second anchor can comprise first, second and third spaced apart bending stages, and wherein in the first bending stage the anchor is bent radially inwardly, in the second bending stage the anchor is bent radially outwardly, and in the third bending stage the anchor is bent radially inwardly. The second bending stage of the first anchor can be bent about 180 degrees.

According to some embodiments, a replacement heart valve comprises an expandable frame configured to engage a native valve annulus at an engagement zone along the length of the frame, and a valve body attached to the expandable frame. The valve body can comprise a plurality of valve leaflets configured to open to allow flow in a first direction and engage one another so as to close and not allow flow in a second direction opposite the first direction. The expandable frame can comprise an upstream portion, a downstream portion, a transition portion, a plurality of upstream anchors and a plurality of downstream anchors.

The downstream portion can have a diameter different than a diameter of the upstream portion. The transition portion can be between the upstream and downstream por-

tions. Each anchor can extend radially outwardly from the frame at an anchor base and terminate at an anchor tip. At least part of a foreshortening portion disposed between the upstream and downstream anchor bases. The engagement zone defined between the upstream and downstream anchor tips. The bases of the upstream anchors can be disposed at a location along the length of the frame having a first diameter, and the bases of the downstream anchors can be disposed at a location along the length of the frame having a second diameter, and the first diameter is different than the second diameter.

In some embodiments, the diameter of the downstream portion is greater than the diameter of the upstream portion. In addition, in some embodiments, the bases of the upstream anchors are disposed in the upstream portion, and the bases of the downstream anchors are disposed in the downstream portion or the bases of the upstream anchors are disposed in the transition portion, and the bases of the downstream anchors are disposed in the downstream portion.

In some embodiments, a replacement heart valve comprises an expandable frame configured to engage a native valve annulus and a valve body mounted onto the expandable frame. The valve body can comprise a plurality of valve leaflets configured to open to allow flow in a first direction and engage one another so as to close and not allow flow in a second direction opposite the first direction. The valve body can have an upstream end and a downstream end where a diameter at the downstream end is greater than a diameter at the upstream end.

In some embodiments, a replacement heart valve comprises an expandable frame configured to engage a native valve annulus and a valve body mounted onto the expandable frame. The valve body can include a plurality of valve leaflets configured to open to allow flow in a first direction and engage one another so as to close and not allow flow in a second direction opposite the first direction. The expandable frame can have an upstream portion, a downstream portion, a first set of anchors, and a second set of anchors. A diameter of the expandable frame at the downstream portion can be greater than a diameter of the expandable frame at the upstream portion. Further, each anchor can comprise an anchor tip. The first set of anchors can extend from the downstream portion of the expandable frame and the second set of anchors can extend from an area of the frame having a diameter less than the downstream portion. The anchor tips of the first set of anchors can be configured to be positioned generally opposed to the anchor tips of the second set of anchors when the expandable frame is engaged to the native valve annulus.

Other inventive embodiments and features are disclosed below.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects and advantages are described below with reference to the drawings, which are intended to illustrate but not to limit the invention. In the drawings, like reference characters denote corresponding features consistently throughout similar embodiments.

FIG. **1** is a perspective view of one embodiment of a replacement heart valve.

FIG. **2** is a view looking upstream through the replacement heart valve of FIG. **1**.

FIGS. **3**A and **3**B are schematic views of one embodiment of a valve body.

FIG. **4** is a schematic side view of one embodiment of a frame for supporting a valve body.

FIG. **5** is a partial flat pattern depiction of the pattern from which the frame of FIG. **4** is cut.

FIGS. **6** and **6**A show valve leaflets configured in accordance with one embodiment.

FIG. **7** illustrates components of an outer valve skirt configured in accordance with one embodiment.

FIG. **8** illustrates components of another embodiment of an outer valve skirt.

FIG. **9** illustrates components of still another embodiment of an outer valve skirt.

FIG. **10** shows an embodiment of a connection skirt.

FIG. **11** is a schematic side view of another embodiment of a frame.

FIG. **12** is a partial flat pattern depiction of the pattern from which the frame of FIG. **11** is cut.

FIG. **13** is a side view of still another embodiment of a frame.

FIG. **14** shows a schematic side view of yet another embodiment of a frame.

FIGS. **15-19** are photographs filed in U.S. Provisional Application No. 61/357,048, filed on Jun. 21, 2010, which has been incorporated herein by reference. FIG. **15** is an image, from the perspective of the left ventricle, of one embodiment of a replacement heart valve positioned within a native mitral valve.

FIG. **16** is another image, from the perspective of the left ventricle, of the replacement heart valve of FIG. **15** positioned within a native mitral valve.

FIG. **17** is another image, from the perspective of the left ventricle, of the replacement heart valve of FIG. **15** positioned within a native mitral valve.

FIG. **18** is an image, from the perspective of the left atrium, of the replacement heart valve of FIG. **15** positioned within a native mitral valve.

FIG. **19** is an image, from the perspective of the left atrium, of the replacement heart valve of FIG. **15** positioned within a native mitral valve.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The present specification and drawings disclose aspects and features of the invention in the context of several embodiments of replacement heart valves and portions thereof that are configured for replacement of natural heart valves in a patient. These embodiments may be discussed in connection with replacing specific valves such as the patient's aortic or mitral valve. However, it is to be understood that the context of a particular valve or particular features of a valve should not be taken as limiting, and features of any one embodiment discussed herein can be combined with features of other embodiments as desired and when appropriate.

With initial reference to FIGS. **1** and **2**, an embodiment of a replacement heart valve **10** is shown. The illustrated replacement heart valve **10** is designed to replace a diseased native mitral valve. In this embodiment, the replacement heart valve **10** is made up of a self-expanding frame **20** to which a valve body **30** is attached. As best seen in FIG. **2**, the valve body **30** includes flexible leaflets **32** that open and close. The valve body **30** can include two, three or more leaflets **32**. The valve body **30** has an inflow end **34** and an outflow end **36**. The replacement heart valve **10** is shown with an upstream portion **38**, a transition portion **40** adjacent the upstream portion **38** and a downstream portion **42** disposed adjacent the other side of the transition portion **40**.

The valve body **30** can extend the length of the frame **20** or it can extend along only part of the length of the frame **20**. For example, the valve body **30** shown in FIGS. **1** and **2** extends along the upstream portion **38** and the transition portion **40**. The valve body **30** also extends along the non-foreshortening zone **52**. In another embodiment the valve body **30** also extends along the downstream portion **42** and/or the foreshortening zone **54**. As shown, in the illustrated embodiment a connection skirt **50** extends along the length of the downstream portion **42**. In some embodiments, the ends **14**, **16** of the replacement heart valve **10** can coincide with the inflow end **34** of the valve body **30** and the outflow end **36** of the valve body. In the illustrated embodiment, the inflow end **34** substantially coincides with one end **14** of the replacement heart valve **10** while the other end **16** of the replacement heart valve **10** extends past the outflow end **36** of the valve body.

The valve body **30** can be implanted within a heart to replace a damaged or diseased heart valve such as a mitral valve. The valve leaflets **32** can function in a manner similar to the natural mitral valve. For example, a plurality of valve leaflets **32** can open to allow flow in a first direction and engage one another so as to close and not allow flow in a second direction opposite the first direction. The replacement heart valve **10** can be constructed so as the open naturally with the beating of the heart.

Additional example replacement heart valves with valve bodies and leaflets are discussed in detail in Applicants' U.S. application Ser. No. 12/569,856, filed Sep. 29, 2009, incorporated by reference herein in its entirety and with particular reference to FIGS. 1-3C, 5-13 and 17-25 and the accompanying discussion including paragraphs [0063]-[0070], [0083]-[0101], [0110]-[0114], [0118], [0124]-[0128], and [0130]-[0137].

With continued reference to FIGS. **1-2**, in this embodiment, the frame **20** is elongate with different diameter sections. For example, the upstream end **14** of replacement heart valve **10** or frame **20** has a first diameter that is substantially less than a second diameter at the downstream end **16**. The frame **20** maintains the first diameter along its length in the upstream portion **38**. In the transition portion **40** between the upstream **38** and downstream **42** portions, the frame **20** flares outwardly so that the diameter increases to the second diameter. The downstream portion **42** disposed adjacent the transition portion **40** preferably maintains the second diameter along its length.

The frame **20** is constructed from a metal tube, such as a nitinol tube. As such, the frame **20** can be expanded and/or compressed and/or otherwise worked to have the desired introduction and implantation configurations.

The frame **20** is constructed so that part of the frame foreshortens as the frame is radially expanded from a collapsed configuration. In the illustrated embodiment a foreshortening zone **54** generally corresponds with the downstream portion **42**. A non-foreshortening zone **52** extends upstream from the foreshortening zone **54**, and generally corresponds to the upstream **38** and transition **40** portions.

Opposing anchors **22**, **24** are constructed on the frame **20** so that preferably their tips **26**, **28** are in the downstream portion **42**. The anchors **22**, **24** are configured to grasp opposite sides of the native mitral annulus. In some embodiments, one or more of the anchor tips **26**, **28** are in the downstream portion **42**, the upstream portion **38**, the transition portion **40**, or at or near the border of the transition portion **40** and the downstream portion **42** or the border of the transition portion **40** and the upstream portion **38**. Preferably, each of the anchors **22**, **24** also extends generally radially outwardly from the frame **20** so that the anchor tips **26**, **28** are generally spaced away from the rest of the frame **20**. In some embodiments, all or part of the structure connected to the anchor tip and extending radially from the frame, including one or more rings and/or struts, can be considered part of the anchor. The anchors can include a base located on the anchor on a side opposite the tip. The base can be for example where the anchor begins to extend away from the frame **20**.

As shown, the anchors **22** extend from the downstream portion **42** of the frame **20**. For example, the anchors **22** can extend from the end **16** of the frame **20**. In some embodiments the anchors **22** can extend from other parts of the downstream portion **42** of the frame. The illustrated anchors **24** extend from the upstream portion **38** of the frame **20**. As such, the anchors **24** and the anchors **22** both extend from regions having different diameters. As an additional example, the anchors **24** can extend from the downstream portion **42** and the anchors **22** can extend from the transition portion **40**. Alternatively, both set of anchors **22**, **24** can extend from the transition portion **40**.

The anchors **22**, **24** can also extend from regions having the same diameter. For example both sets of anchors can extend from the downstream portion **42**.

The anchors **22**, **24** can be one of many different lengths. For example, the anchors can be shorter than, as long as or longer than any of the upstream **38**, transition **40**, and downstream **42** portions. As shown, the anchors **24** are shorter than the downstream portion **42** and the anchors **22** are longer than the transition portion **40**. The anchors **22** extend from the upstream portion **38**, through the transition portion **40** and into the downstream portion **42**. Other configurations are also possible.

The anchor tips **26**, **28** can have one of many shapes. For example, the shape can be configured to increase the amount of surface area of the tip that is in contact with tissue. The tips **26**, **28** are shown as round or elliptical disks but can have other shapes as well, such as tear drop, rectangular, rectangular with a curved end, etc.

In preferred embodiments, the replacement heart valve **10** may be deployed into a heart valve annulus, and positioned when compacted so that the anchor tips **26**, **28** of the opposing anchors **22**, **24** are disposed on opposite sides of the native annulus. As the replacement heart valve **10** is expanded, the opposing anchors are drawn closer together so as to grasp opposite sides of the native annulus with the anchor tips **26**, **28** and securely hold the replacement heart valve **10** in position. As such, the replacement heart valve **10** can be held securely in position without requiring a substantial radial force against the native annulus. The foreshortening zone **54** can be used to move the anchor tips **26**, **28** closer together as the replacement heart valve **10** moves to the expanded position to thereby engage the native valve annulus.

Applicant's U.S. patent application Ser. No. 12/084,586, which was published on Aug. 27, 2009 as U.S. Publication No. 2009/0216314, discusses embodiments of foreshortening stents with anchors, and can be referred to for further discussion of certain aspects of the illustrated embodiments. The above application is incorporated in its entirety by reference herein with particular reference to the discussion concerning structure and operation of embodiments of a foreshortening stent, particularly a foreshortening stent having anchors.

FIGS. **3**A-B show an embodiment of the valve body **30** separate from the other components of the replacement heart

valve **10**. The valve body **30** preferably is shaped to accommodate the transition portion **40** of the frame **20**. More specifically, the valve body transition portion **40** is generally conical, where the upstream portion **38** is generally cylindrical. In embodiments where the valve body **30** extends into the downstream portion **42**, the downstream portion can also be generally cylindrical. In some embodiments, one or more of the upstream portion **38** and the downstream portion **42** can be generally conical. In the illustrated embodiment, the upstream portion **38** of the valve body **30** has an inflow diameter D_1. A downstream, or outflow end **36** of the valve body **30** has a diameter D_2 that is greater than the upstream portion diameter D_1. Approaching the outflow end **36** of the valve body **30**, the valve body flares outwardly to the larger diameter. As such, the inflow diameter D_1 of the valve body **30** is less than the outflow diameter D_2 of the valve body **30**. The inflow D_1 and outflow D_2 diameters can vary greatly, in some embodiments, the inflow diameter D_1 can be approximately 30 mm and the outflow diameter D_2 can be approximately 40 mm.

The valve leaflets **32** extend along all or part of the length of the valve body **30**, and including all or part of the reduced and increasing diameter portions of the valve body, i.e. the upstream **38** and transition **40** portions, as shown. In some embodiments, the leaflets **32** can also span all or part of the length of the downstream portion **42**.

As best shown in FIGS. **1** and **2**, the replacement heart valve **10** can also include a connection skirt **50**. The connection skirt **50** can be a flexible fabric, preferably a knit polyester fabric. The connection skirt **50** can be attached to one or both of the frame **20** and the valve body **30**. As shown, the connection skirt **50** is attached to the distal end of the valve body **30** and also attached to the frame **20** in the foreshortening zone. In the illustrated embodiment, the valve body **30** is attached to the frame **20** so that it is contained within the non-foreshortening zone. In other embodiments, the valve body **30** may be partially contained in both the non-foreshortening zone **52** and the foreshortening zone **54**. Some embodiments may not include the connection skirt **50**.

With additional reference to FIGS. **4** and **5**, a schematic side view of the frame **20** is shown, along with a flat pattern depiction of the pattern from which the frame **20** is cut from a metal tube, such as a nitinol tube. As mentioned previously, the frame **20** has a non-foreshortening zone **52** and a foreshortening zone **54**. As shown, longitudinal struts **56** span the length of the non-foreshortening zone **52**. Distal or downstream portions of the longitudinal struts **56** make up the transition portion **40**, in which the struts **56** bend so as to flare radially outwardly and then bend again so as to stop expanding in radius and attach to the foreshortening zone **54** of the frame **20**. As such, the frame **20** is generally divided into an upstream portion **38** made up of the first diameter, a transition portion **40** at which the diameter is expanding, and a downstream portion **42** which includes the foreshortening zone **54** and which is adapted to engage the native valve annulus.

First **58**, second **60**, and third **62** rings made up of undulating struts are connected to the longitudinal struts **56** in the non-foreshortening zone **52**. The illustrated first **58** and second **60** rings are of generally the same size, however, the struts in the third ring **62** are substantially larger and longer than the struts in the first **58** and second **60** rings. For example, the struts of the first **58** and second **60** rings can be about twice as long as the struts of the third ring **62**, or longer. Additionally, upstream anchors **22** extend from the free apices of the struts in the third ring **62**. As best shown in FIG. **4**, the struts in the third ring **62** preferably are flared radially out at a more dramatic angle than is the longitudinal strut **56** at the transition portion **40**. In the illustrated embodiment, the third ring struts **62** can be considered part of the upstream anchors **22**.

Referring to FIGS. **4** and **5**, a fourth ring **64** is attached to the distal end of the longitudinal struts **56** at an apex of the fourth ring **64**. A fifth ring **66** attaches to the fourth ring **66** on the side opposite the longitudinal struts **56**. The fifth ring **66** can be a mirror image of the fourth ring **64**. As illustrated, the fourth **64** and fifth **66** rings are of generally the same size. The fourth **64** and fifth **66** rings are made up of undulating struts and make up the foreshortening zone **54**. Expansion of the replacement heart valve **10** causes the struts of the fourth ring **64** to move farther apart such that they are at a greater angle relative to one another. Thus, they move from a relatively vertical orientation to a more horizontal orientation. This also causes the ring to shrink in vertical height. The fifth ring exhibits similar behavior when the valve **10** expands. This movement of the fourth **64** and fifth **66** rings results in foreshortening of the frame **20**.

Additionally, downstream anchors **24** extend from the free apices of the fifth ring **66**. As best shown in FIG. **4**, the downstream anchors **24** are bent down and flared radially out from the struts of the fourth **64** and fifth **66** rings. The upstream anchors **22** on the third ring **62** are bent so as to generally oppose the downstream anchors **24** that extend from the foreshortening zone **54**. A tip **26** of each upstream anchor **22** is downstream of the transition portion **40**. As such, the downstream anchors **24** extend from the distal or outflow end **16** of the valve **10**, and the upstream anchors **22** extend outwardly from the upstream portion of the valve **10**, upstream of the transition portion **40**.

The shape of each of the anchors will now be described in more detail with reference to FIG. **4**. Each anchor **22**, **24** can have one or more bending stages to position the anchor tip in the desired location. Preferably, each anchor has at least two bending stages.

The downstream anchor **24** has a base **76** that is connected to a free apex of the fifth ring **66**. After the base **76** there is a first bending stage **78** so that the anchor is radially spaced outwardly from the frame **20**. As shown, the anchor at the first bending stage **78** is bent approximately 180 degrees. A large bend such as a bend of approximately 180 degrees, or between around 150-200 degrees, can provide structural support and strength to the anchor. Such a large bend can also be located at other points in the anchor and at other bending stages. A second bending stage **80** is shown used to flare the anchor radially outwardly from the frame **20**. In a third bending stage **82** the anchor bends in a radially inward direction so as to direct the anchor tip **28** towards the opposing anchor **22** and position the portion of the anchor between the tip and the third bending stage parallel or substantially parallel to the frame **20**. In some embodiments more or fewer bending stages can be used. In addition, the various bending stages can be used to different purposes and to provide different positions of the anchor than those described above.

The upstream anchor **22** can also have one or more bending stages. The anchor **22** has a base **84** where the strut of the third ring **62** connects to the longitudinal strut **56**. A first bending stage **86** of the anchor **22** can be located at the base to move the anchor **22** radially outwardly from frame **20**. A second bending stage **88** can further move the anchor **22** radially outwardly from frame **20**. In this way, the anchor **22** can be bent in a gradual manner away from the frame **20**. In some embodiments, one bending stage can be used to

move the anchor **22** away from the frame. The anchor **22** can also include a large bend similar to the approximately 180 degree bend in the first bending stage **78** of anchor **24**. Finally, anchor **22** is also shown with a third bending stage **90**. The third bending stage **90** can direct the anchor tip **26** towards the opposing anchor **24** and position the tip parallel or substantially parallel to the frame **20**.

The transition portion **40** can also include one or more bending stages, such as bending stages **92**, **94** shown in FIG. **4**.

Notably, in this embodiment the native annulus which is intended to be gripped between the anchor tips **26**, **28** will be engaged by the foreshortening zone **54** of the frame **20**, and will not engage the transition portion **40** of the frame **20**. Rather, in a mitral placement, the upstream **38** and transition **40** portions of the replacement valve **10** will not necessarily be disposed within the annulus but mostly or entirely in the atrium.

In the embodiment illustrated in connection with FIGS. **1-5**, the valve body **30** is a two-layer valve comprising an outer valve skirt **33** and inner leaflets **32** (see FIGS. **2** and **3**A). The outer valve skirt **33** is disposed between the leaflets **32** and the frame **20**. It is to be understood, however, that in other embodiments, a single-layer valve body **30** not having an outer valve skirt **33** may be employed.

With particular reference next to FIG. **6**, an embodiment of conical valve leaflet **32** is shown. This figure shows one embodiment of a pattern for cutting the leaflets **32** from a flat, tissue material such as pericardium. Preferably, upstream portions of the leaflets are generally curved and commissures are disposed along downstream side edges of the leaflets. The curvature and size of the pattern cuts, and particularly the curvature of the side edges, is chosen so that the valve fits within the generally conical shape defined by the frame **20**. In the illustrated embodiment, the side edges at and adjacent the downstream end are angled relative to a longitudinal axis of the valve. As such, the valve as defined by the leaflets **32** has an outflow diameter that is greater than its inflow diameter. In addition, as discussed previously, the leaflets can extend between different diameter sections of the valve body, thus the leaflets are generally positioned at a smaller diameter at the upstream end than at the downstream end. FIG. **6**A shows another embodiment of a conical leaflet pattern **32'**.

In the illustrated embodiments, the outer valve skirt **33** is attached to the frame **20** and the leaflets **32** are attached to the outer valve skirt **33**. Preferably, the outer valve skirt **33** is also formed of a pericardium tissue similar to the leaflets **32**. The outer valve skirt **33** can be constructed in multiple different ways. For example, with reference next to FIGS. **7** and **8**, embodiments show that an outer valve skirt **33**, **33'** can be made by cutting multiple pieces of flat tissue material and sewing the tissue together to form the outer valve skirt with the flared transition portion. In FIG. **7**, a generally rectangular piece **68** makes up the constant-diameter upstream portion **38** of the outer valve skirt **33**, and three or more curving pieces **70** that can be sewn together to approximate the shape of the flared transition portion **40** are cut, sewn together, and sewn to the downstream end of the upstream portion **38** to construct the outer valve skirt **33**.

In FIG. **8**, multiple pieces **72**, each having a constant-width upstream portion, an expanding-width transition portion, and a constant-width downstream portion can be employed to form an outer valve skirt **33'**. In the illustrated embodiment, three such pieces are shown and can be sewn together to create the flared valve skirt. However, it is to be understood that in other embodiments, six, nine, or 12 pieces, or even other numbers of pieces can be employed to construct a flared outer valve skirt **33'**.

With reference next to FIG. **9**, an embodiment of a pattern for forming an outer valve skirt **33"** out of a single piece of flat tissue is shown. In this embodiment, the downstream end is generally contiguous, but cavities are cut from an upstream end down to a point adjacent the downstream end. Upstream portions of the cavities are generally constant in width so as to approximate the upstream portion of the outer valve skirt **33"**, and transition portions of the pattern progressively reduce in width until forming a point so as to correspond to the transition portion. In constructing the outer valve skirt **33"**, the opposing edges of the cavities are sewn together so that the valve skirt takes on the flared shape generally corresponding to the frame **20**. In the illustrated embodiment, six cavities are used. However, in other embodiments, more or less cavities such as three, nine, or 12, can be employed.

Preferably, the outer valve skirt **33** is constructed of a tissue that is flexible, but not particularly expansive and stretchy. As such, in the illustrated embodiments, the outer valve skirt **33** extends through the non-foreshortening zone **52** of the frame **20**, but does not extend into the foreshortening zone **54** of the frame **20**. However, in other embodiments, a portion of the outer valve skirt **33** may extend into the foreshortening zone **54**.

Referring back to FIGS. **1** and **2**, in a preferred embodiment a downstream end of the outer valve skirt **33** is sewn to a connection skirt **50**. The connection skirt **50** can be made of knit polyester or another stretchable fabric. The connection skirt **50** can be made to move with the foreshortening portion **54** of the frame **20**.

With additional reference next to FIG. **10**, one embodiment of a flat pattern for a connection skirt **50** is illustrated. In this embodiment, an upstream edge of the connection skirt **50** is generally straight so as to correspond to the downstream edge of the outer valve skirt **33** and contribute to an advantageous seam structure. A downstream end of the connection skirt, **50** however, undulates. Preferably, the undulations are patterned to generally correspond to undulations of struts in the foreshortening zone **24** of the frame **20**, such as struts of the fifth ring **66**. The undulations can match the curvature of the struts, and the connection skirt **50** is sewn along the edges of its undulations to the corresponding foreshortening cell struts, as shown in FIGS. **1** and **2**. It is to be understood that other configurations of connection skirts **50** can be employed. For example, a connection skirt **50** can have a generally straight downstream end or can have undulations that do not correspond with the end **16** of the frame **20**.

With reference next to FIGS. **11** and **12**, a schematic side section view and flat pattern cutout view of a frame **20'** in accordance with another embodiment is shown. As with the embodiment in FIGS. **1-5**, the illustrated frame **20'** has an upstream portion **38'** of generally constant diameter, a transition portion **40'** of expanding diameter and a downstream or annulus-engagement portion **42'** of generally constant diameter, which diameter is greater than the upstream portion diameter. In this embodiment, longitudinal struts **56'** extend distally beyond the transition portion **40'**, and define the upstream anchors **22'**. More specifically, the longitudinal struts **56'** bend radially outwardly from the upstream portion **38'** upstream of the transition portion **40'**, and extend downstream beyond the transition portion **40'** so that a downstream tip of each strut defines an anchor tip **26'**. The transition portion **40'** in this embodiment is made up of the undulating struts in the third ring **62'**. The transition portion

40' also includes two bending stages 92', 94'. Downstream apices in the third ring 62' have second longitudinal struts 74 extending therefrom, which connect each downstream apex to an apex of closed foreshortening cells defined by the fourth 64' and fifth 66' rings.

The anchor 24' is shown with a base 76' connected to the fifth ring 66'. The anchor 24' includes first 78' and second 80' bending stages. The first bending stage 78' positions the anchor 24' away from the frame 20' and the second bending stage 80' positions the tip 28'. The anchor 22' also has first 86' and second 88' bending stages. The first bending stage 86' is located at and near the base 84' and positions the anchor 22' away from frame 20'. The second bending stage 88' positions the anchor tip 26' towards the opposing anchor 24' and positions the tip parallel or substantially parallel to the frame 20'.

In the frame 20' embodiment of FIGS. 11 and 12, since the third ring 62' is attached to the longitudinal struts 56' only at the upstream apices, at least some foreshortening can be anticipated in the transition portion 40' due to expansion of the third ring struts. In a preferred embodiment, a greater proportion of foreshortening takes place in the closed foreshortening cells of the downstream fourth 64' and fifth 66' rings than in the third ring 62'. In some embodiments, a greater proportion of the outer valve skirt or all of the outer valve skirt can be constructed of flexible fabric so that the outer valve skirt can accommodate and move with the foreshortening third ring 62', while the leaflets can continue to be made of a generally nonelastic material such as pericardium. In further embodiments, a pericardium outer valve skirt can be relatively-loosely stitched or otherwise attached to a connection skirt and the frame 20' along, for example, the second longitudinal struts 74 so that during the radial expansion process, the distal end of the outer valve skirt can move relative to the frame 20' so that the outer valve skirt and the leaflets maintain optimal geometry and placement as the frame length changes. In still further embodiments, the struts of a third ring 62' can be configured so that any foreshortening during radial expansion is sufficiently minor or small so as to not substantially affect tissue-based valve members such as the outer valve skirt and/or leaflets.

FIG. 13 shows yet another embodiment of a frame 20". The frame 20" has a substantially constant inner diameter, such that the diameter is substantially the same at the two opposing ends 14" and 16". This embodiment employs longitudinal struts 56" in the non-foreshortening portion 52" and first 58" and second 60" rings of expansible struts connected to the longitudinal struts 56". The second rings 60" flare radially outwardly as part of the anchors 22". The foreshortening zone 54" has two rows of closed foreshortening cells made by third 62", fourth 64" and fifth 66" rings. The downstream anchors 24" extend from points adjacent the downstream end 16" of the frame 20", but portions of some of the foreshortening cells are downstream of the anchor bases. In the illustrated embodiment, the downstream anchors are longer than the upstream anchors.

Referring to FIG. 14, a schematic side view of a frame 20'" is shown. As mentioned previously, the frame 20 has a non-foreshortening zone 52'" and a foreshortening zone 54'". Longitudinal struts 56'" span all or part of the length of the non-foreshortening zone 52'". Distal or downstream portions of the longitudinal struts 56'" make up all or part of the transition portion 40'", in which the struts 56'" bend at bending stage 92'" so as to flare radially outwardly and then bend again at bending stage 94'" so as to stop expanding in radius and attach to the foreshortening zone 54'" of the frame 20'". As such, the frame 20'" is generally divided into an upstream portion 38'" made up of the first diameter, a transition portion 40'" at which the diameter is expanding, and a downstream portion 42'" which includes the foreshortening zone 54'" and which is adapted to engage the native valve annulus.

One, two, three, or more rings made up of undulating struts can be connected to the longitudinal struts 56'" in the non-foreshortening zone 52'". One, two, three, or more rings made up of undulating struts can also be used to form the foreshortening zone 54'".

Downstream anchors 24'" can extend from a portion of the downstream portion 42'" or foreshortening portion 54'" as shown. The downstream anchors 24'" are bent down or bent out from the frame 20'" and flared radially out from the frame 20'". Anchor 24'" is shown with a base 76'" connected to the frame 20'". The anchor 24'" includes first 78'", second 80'" and third 82'" bending stages. The first bending stage 78'" is a radially inward bend. The inward bend can be between about 5-30 degrees, for example. The second bending stage 80'" can have a large bend, such as an approximately 180 degree radially outwardly extending bend, or between around 150-200 degrees, as has been described. After the second stage bend the anchor extends in an upstream and radially outward direction. The first 78'" and second 80'" bending stages can position the anchor 24'" away from the frame 20'". The third bending stage 82'" can position the tip 28'", such as to position the tip 28'" to oppose the anchor tip 26'" and/or position the tip 28'" parallel or substantially parallel with the frame 20'". The bend at the third bending stage can be, for example, between about 5-30 degrees.

Upstream anchors 22'" preferably extend from the non-foreshortening portion 52'". For example, upstream anchors 22'" and/or the ring(s) or struts to which they are attached, are shown extending from the transition portion 40'". As can be seen in FIG. 14, the upstream anchors 22'" are flared radially out at a more dramatic angle than is the longitudinal strut 56'". As has been mentioned above, the transition portion 40'" has a first bending stage 92'" and a second bending stage 94'" which changes the diameter of the frame 20'" between the upstream portion 38'" and the downstream portion 42'". The anchor 22'" also has first 86'" and second 88'" bending stages. The first bending stage 86'" is located near or at the base 84'" and directs the anchor 22'" away from frame 20'". The second bending stage 88'" directs the anchor tip 26'" towards the opposing anchor 24'" and preferably positions the tip parallel or substantially parallel to the frame 20'".

In this embodiment, the anchors 22'" extend from the frame 20'" at the transition portion 40'" rather than at the upstream portion 38'". This allows the anchors 22'" to have a smaller bend or angle at the first bending stage 86'" because some of the desired bend is already provided by the first bending stage 92'" of the transition at portion 40'". For example, where it is desired to position the anchor 22'" an angle A_1 from the upstream portion, the first bending stage 92'" of the transition portion 40'" can be bent an angle A_2 and then the first bending stage 86'" of the anchor 22'" can be bent the remaining amount to provide the angle A_1. For example, where the anchor 22'" is positioned an angle A_1 of approximately 40 degrees from the frame of the upstream portion 38'", the transition portion can be positioned at an angle A_2 of approximately 20 degrees or 30 degrees and then the anchor 22 can be positioned an additional amount from frame at the transition portion to make up the entire 40 degrees.

In another embodiment, the anchor **22'''** can extend from the upstream portion of the frame, and can have a first bending stage at which the anchor bends approximately the same as the first bending stage of the transition portion. The anchor **22'''** can have a second bending stage spaced from the first stage and which directs the anchor **22'''** further radially outwardly to the desired angle A_1. The anchor **22'''** has a third bending stage to position the anchor tip **26'''**.

The upstream anchors **22'''** are bent so as to generally oppose the downstream anchors **24'''** that extend from the foreshortening zone **54'''**. A tip **26'''** of each upstream anchor **22'''** is downstream of the transition portion **40'''**. As such, the anchor tips **26**, **28** of the opposing anchors **22**, **24** can be disposed on opposite sides of the native annulus of a heart valve and used to engage the valve to thereby replace the valve with a replacement heart valve as has been described herein.

As can also be seen in FIG. **14**, the valve body **30'''** can be attached to the frame **20'''**. The valve body **30'''** can be positioned in the upstream **38'''**, transition **40'''**, and/or downstream **42'''** portions. The valve body **30'''** can also be positioned in both the foreshortening **54'''** and the non-foreshortening **52'''** zones. An example leaflet **32'''** is also illustrated. In this embodiment, the leaflet **32'''** is within the transition portion **40'''** and the downstream portion **42'''** but is not within the upstream portion **38'''**.

In some embodiments, the implant can be delivered via a transvenous, transseptal, or an antegrade approach.

FIGS. **15-19** are photographs filed in U.S. Provisional Application No. 61/357,048, filed on Jun. 21, 2010, which has been incorporated herein by reference. These images are of post-implant examination which showed engagement of an implant with native leaflets and annulus. Referring next to FIGS. **15-19**, an embodiment of a valve **10''''** having a frame **20''''** and valve body **30''''** is shown deployed within a native mitral valve. FIGS. **15-17** are shown from within the left ventricle and FIGS. **18** and **19** are shown from within the left atrium.

With reference first to FIGS. **15-17**, the downstream anchors **24''''** can extend around the native mitral valve leaflets. As shown, the downstream anchors **24''''** extend between chordae tendineae coupling the native mitral valve leaflet and papillary heads of papillary muscle. The tips **28''''** of the downstream anchors **24''''** can engage the native mitral valve annulus. As shown in the illustrated embodiment, in some instances tips **28''''** of the downstream anchors **24''''** can engage the fibrous trigones of the native mitral valve. With reference next to FIGS. **18** and **19**, the tips **26''''** of the upstream anchors **22''''** can engage the native mitral valve annulus.

What is claimed is:

1. A method of delivering a replacement valve to a native mitral valve of a heart and securing the replacement valve relative to a native mitral valve annulus, the native mitral valve positioned between a left atrium and a left ventricle, the method comprising:

delivering the replacement valve to the native mitral valve annulus while the replacement valve is in a radially compacted state, the replacement valve comprising:

an expandable frame having a proximal end ending at a proximalmost end and a distal end ending at a distalmost end;

a valve body positioned within a lumen of the expandable frame; and

one or more distal anchors extending from the distal end of the expandable frame and sized to contact tissue on a ventricular side of the native mitral valve when the replacement valve is deployed within the native mitral valve; and

deploying the replacement valve within the native mitral valve annulus such that:

the replacement valve is in an expanded configuration with a cross-sectional diameter of the distalmost end of the expandable frame being greater than a cross-sectional diameter of the proximalmost end of the expandable frame, the replacement valve only decreasing or remaining constant in cross-sectional diameter from the distalmost end to the proximalmost end;

the one or more distal anchors are positioned radially outwardly from the frame;

tips of the one or more distal anchors extend substantially parallel to a longitudinal axis of the expandable frame; and

at least one of the distal anchors extends between chordae tendineae of the native mitral valve.

2. The method of claim **1**, wherein:

the expandable frame further comprises a proximal anchoring portion sized to contact tissue on an atrial side of the native mitral valve when the replacement valve is deployed within the native mitral valve; and

deploying the replacement valve within the native mitral valve annulus comprises expanding the replacement valve such that the proximal anchoring portion is positioned radially outwardly from the frame.

3. The method of claim **2**, wherein the proximal anchoring portion comprises a plurality of free apices each connected to the expandable frame at a first base and at a second base, the first and the second bases located distal of the proximal end of the expandable frame.

4. The method of claim **2**, wherein each distal anchor extends from a portion of the expandable frame having a greater cross-sectional diameter than a portion from which the proximal anchoring portion extends.

5. The method of claim **1**, wherein deploying the replacement valve within the native mitral valve annulus comprises engaging at least a first of the one or more distal anchors with a first fibrous trigone of the native mitral valve.

6. The method of claim **5**, wherein deploying the replacement valve within the native mitral valve annulus comprises disposing a native leaflet of the native mitral valve between at least the first distal anchor and the expandable frame.

7. The method of claim **5**, wherein deploying the replacement valve within the native mitral valve annulus comprises engaging at least a second of the one or more distal anchors with the native mitral valve annulus.

8. The method of claim **1**, wherein delivering the replacement valve to the native mitral valve annulus while the replacement valve is in the radially compacted state comprises delivering the replacement valve from a region outside the heart to the left ventricle of the heart.

9. The method of claim **8**, wherein delivering the replacement valve to the native mitral valve annulus while the replacement valve is in the radially compacted state comprises transseptally delivering the replacement valve.

10. The method of claim **1**, wherein the expandable frame further comprises an engagement zone, and wherein expanding the replacement valve comprises radially expanding the engagement zone of the expandable frame to engage the native mitral valve annulus.

11. The method of claim **1**, wherein the valve body comprises a plurality of valve leaflets.

12. The method of claim **11**, wherein the replacement valve comprises a plurality of commissures disposed along downstream side edges of the valve leaflets.

13. The method of claim **11**, wherein the valve body comprises three leaflets.

14. The method of claim **11**, wherein the plurality of valve leaflets are configured to open to allow flow in a first direction from the left atrium to the left ventricle and engage one another so as to close and not allow flow in a second direction opposite the first direction.

15. The method of claim **1**, wherein each of the one or more distal anchors is formed by a single strut.

16. The method of claim **1**, wherein the tips of the one or more distal anchors are enlarged relative to a remainder of the one or more distal anchors to increase a surface area of the tips in contact with the tissue on the ventricular side of the native mitral valve when the replacement valve is expanded and deployed within the native mitral valve.

17. The method of claim **1**, wherein the expandable frame comprises a plurality of cells, and wherein the valve body is fully located radially within the plurality of cells of the expandable frame.

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