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(54) Title: LEFT ATRIAL APPENDAGE SIZING AND ELIMINATION DEVICES AND RELATED METHODS

(57) Abstract: The present invention can be used in medical implant field, which provides excellent sizing for all left atrial appendage anatomies and it is related with left atrial appendage (LAA, Left Atrial Appendage) sizing and elimination devices and associated methods, that minimises the risk of shunt caused by undersizing or oversizing that may lead to the forming of non-occluded area that may occur from left atrial appendage to left atrium due to the perforation of left atrial appendage.

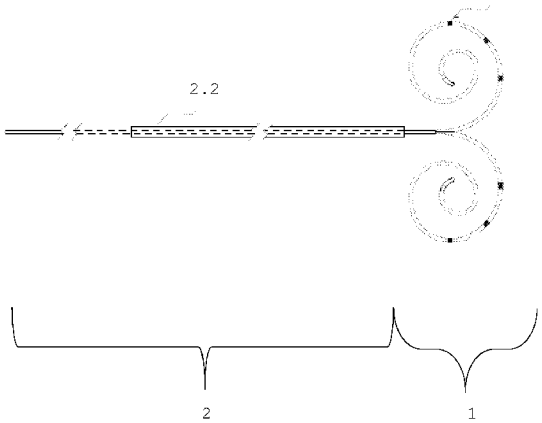

Figure 1

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LEFT ATRIAL APPENDAGE SIZING AND ELIMINATION DEVICES AND RELATED METHODS

Field of the Invention

The present invention can be used in medical implant field, which provides excellent sizing for all left atrial appendage anatomies and it is related with left atrial appendage (LAA, Left Atrial Appendage) sizing and elimination devices and associated methods, that minimizes the risk of shunt caused by under sizing or oversizing that may lead to the forming of non-occluded area that may occur from left atrial appendage to left atrium due to the perforation of left atrial appendage.

Background of the Invention

Atrial fibrillation (AF) is a cardiac arrhythmia, incidence of which is increased in parallel with the age, and decreases quality of life and exercise capacity. Heart rate and rhythm supervisions are performed initially for atrial fibrillation treatment. Ventricle speed is managed and it is tried to get back to the sinus rhythm. AF symptoms such as palpitation, shortness of breath and fatigue can be eased by medication. In addition, necessary treatment for the prevention of embolism must be carried out beside heart rate and rhythm supervision. Treatment with medication is provided to the patients with atrial fibrillation and who are in high-risk group for stroke but the dosage should be monitored.

In order to prevent from stroke in atrial fibrillation, treatment methods for left atrial appendage (LAA) which is the most important cause of embolism are being developed beside medication. Size, width and length of the LAA and LAA orifice, which hold on the left atrium with a neck and are formed by enlarging in the third week of pregnancy, varies depending on the factors such as gender and the age of the patience. On the other hand, size of the LAA orifice is not affected by body surface area.

Devices developed for left atrial appendage are used as the primary treatment method in closing the LAA with catheter techniques in patients with atrial fibrillation and high stroke ratio and those unsuitable for medication and the treatment carried out with these devices are more effective than medication.

LAA closing devices of the state of the art are not able to make the sizing of LAA orifice accurately, thereby increasing LAA volume and disrupting the natural anatomy. Increasing of volume may lead to clogging and clot formation; incorrect orifice sizing may cause the clot to reach the brain. In addition, LAA closure operations performed with surgical or hybrid interventions are risky operations for the patient. In application WO2007127664, it is mentioned about a ring shaped closure device used for LAA closure and it is explained that ring shaped closure device is implanted in LAA by a ring implementer.

The Problems Aimed To Be Solved By The Invention

Purpose of the invention is the development of the left atrial appendage (LAA, Left Atrial Appendage) sizing and elimination devices and related methods, that can be used in medical implant field, which provides excellent sizing for all left atrial appendage anatomies and minimizes the risk of shunt caused by under sizing or oversizing that may lead to the forming of non-occluded area that may occur from left atrial appendage to left atrium due to the perforation of left atrial appendage.

Another purpose of the invention is to reduce the total volume of LAA and to prevent from blockage and clog formation .

Brief Description of the Drawings

Figure 1. View of left atrial appendage (LAA) sizing device.

Figure 2. Cross section detail view of the pusher cable in the left atrial appendage (LAA) sizing device.

Figure 3. Front view of left atrial appendage (LAA) elimination device.

Figure 4. Perspective view of left atrial appendage (LAA) elimination device.

Figure 5. Side view of left atrial appendage (LAA) elimination device.

Figure 6. Top view of the simulation that shows the volume reduction in LAA with left atrial appendage (LAA) elimination device.

Figure 7. Side view of the simulation that shows the volume reduction in LAA with left atrial appendage (LAA) elimination device.

Figure 8. Top view of the left atrial appendage (LAA) elimination device in the natural, anatomic LAA.

Description of the References in the Drawings

Parts in drawings are numbered and explanations are given below:

1 : First component

1.1 : Radiopaque marker

2 : Second component

2.1 : Pusher cable

2.2 : Pusher sheath

3 : Third component

3.1 : Bracelet

3.1.1 : Joint position

3.2 : Filament

4 : Braided sealing element

4.1 : Connection / transition section

4.2 : Distal circle

4.3 : Proximal circle

5 : Metallic wire

6 : Patch material

Detailed Description of the Invention

The present invention can be used in medical implant field, which provides excellent sizing for all left atrial appendage anatomies and it is related with left atrial appendage (LAA, Left Atrial Appendage) sizing and elimination devices and associated methods, that minimises the risk of shunt caused by under sizing or oversizing that may lead to the forming of non-occluded area that may occur from left atrial appendage to left atrium due to the perforation of left atrial appendage.

Subject of the invention is related to; the LAA sizing device consisting of a first component (1) consisting of at least one or two spiral metallic wires (5), which is radiopaque marked seen under fluoroscopy (1.1), and preformed, and a second component (2) having a pusher cable (2.1) longitudinal part of which is in the form of tube or wire, and located in the pusher sheath (2.2) which allows the first element (1) to travel in the ostium, and a braided sealing element (4) that allows the LAA elimination device to be anchored in the LAA anatomy without damaging the tissue and a third component (3) comprising at least two metallic wires (5), preformed, with a certain length and shape, coming from the ring (3.1) divided in two opposite direction and consisting of at least one filament (3.2), bracelet (3.1) which includes the third component's (3) and braided sealing element's joint position (3.1.1) and LAA elimination device shaped as at least two braided sealing elements connected to each other, the dimensions of which are different, preferably monolithic or at least one connecting / transition part (4.1) .

The metallic wires (5) of the first element (1) in the LAA sizing device (the field of invention) advances and enters to the LAA ostium with pusher sheath (2.2) and it is released by pusher cable (2.1) in LAA.

LAA sizing device is positioned at the largest diameter of the LAA orifice at the size of ellipsoid.

At least four radiopaque markers (1.1) located at a certain distance from each other in the first item (1) calculate the narrowest throat of the LAA under fluoroscopy.

Thus, full sizing of the LAA orifice is achieved. Figures 1 and 2 show the cross-section detailed views of the LAA sizing device and the pusher cable (2.1), respectively.

Then, the LAA elimination device is positioned at the left atrial appendage and while third component (3) and proximal circle (4.3) are placed in LAA, distal circle (4.2) remains outside of the LAA.

The proximal circle (4.3) in the braided sealing element (4) closes the LAA ostium from the inner side of LAA and connection / transition part (4.1) is easily placed in the LAA orifice without applying radial power to the tissue which is in contact with LAA elimination device.
The distal circle (4.2) in the braided sealing element (4) is in the shape of the left atrial ostium but has a somewhat larger surface area than the proximal circle (4.3) in order to ensure complete occlusion of the atrial part of the LAA.

Thus, LAA is eliminated by providing complete closure. Figures 3, 4 and 5 show the front, perspective and side views of the LAA elimination device.

In terms of safety, metallic wires (5) are preformed at least to be more than 5% of the LAA orifice size, as supported by clinical findings; and filaments (3.2) in the metallic wires (5) are shaped to be rounded at the tips of each other atraumatically for the purpose of not damaging the tissue.

With the LAA elimination device, sufficient tension is provided at LAA boundary section and when oval braided sealing element (4) is placed in LAA orifice, minimum tension that doesn't damage natural anatomy is provided.

Thus, by reducing the total volume of LAA, it can be placed in the main anatomy without creating possible residual shunt .

Top and side views of simulation that shows the volume reduction in LAA by using LAA elimination device are given in Figure 6 and Figure 7 . Figure 8 shows top view of the LAA elimination device positioned in natural, anatomic LAA.

The LAA elimination device, which is more flexible than the first component (1); due to its elastic design, is suitable for systolic and diastolic motion of LAA even during atrial fibrillation attack.

Braided sealing element (4) which is made out of shape memory alloys like nickel-titanium (nitinol) also includes patch material (6) which can be poly (tetraf luoroethylene) (PTFE) , poly (vinyl chloride) (PVC) , dacron or any biocompatible fabric. Radiopaque markers (1.1) are produced from gold / platinum- iridium.

In the LAA elimination device (subject of invention), there are rounded joints (3.1.1) located at the ends of the braided sealing element (4) and third component (3) in the bracelet (3.1); and these joints (3.1.1) changes direction by moving both directions in the cross sectional's planar direction of braided sealing element (4) LAA orifice. Metallic wires (5) can move as the angle a which is variable in the range of 0° to 90°.

Industrial Application of the Invention:

Field of invention, accurate and precise determination of necessary measurements for LAA sizing and elimination devices and related methods; which can be used in medical

implant field, which provides excellent sizing for all left atrial appendage anatomies, and minimises the risk of shunt caused by under sizing or oversizing that may lead to the forming of non-occluded area that may occur from left atrial appendage to left atrium due to the perforation of left atrial appendage, is superior to other methods used to close left atrial appendage.

CLAIMS

1. The invention relates to left atrial appendage sizing device **characterized in that** it comprises a first component (1) consisting of at least one or two spiral metallic wires (5), which is radiopaque marked seen under fluoroscopy (1.1), and preformed, and a second component (2), consisting of pusher cable (2.1), the longitudinal part of which is in the form of a tube or a wire, and which is located in the pusher sheath (2.2), and which allows the first element (1) to travel in the ostium.

2. Invention relates to left atrial appendage elimination or closure device and its properties are characterized as; allowing the LAA elimination device to be fixed in the LAA anatomy without damaging the tissue, having a third component (3) comprising at least two spiral metallic wires (5), preformed, having a certain length and shape, consisting of at least one filament (3.2), comes from the bracelet (3.1) with the braided sealing element (4) and separates into two in the reverse direction; also having bracelet (3.1) which includes the third component's (3) and braided sealing element's joint position (3.1.1) and having braided sealing element (4) shaped as at least two braided sealing elements connected to each other, the dimensions of which are different, preferably monolithic or has at least one connection / transition part (4.1) .

3. Invention is related to left atrial appendage sizing and elimination method and its property can be characterized with these ***process*** steps;

- Moving of the metallic wires (5) in the first component (1) of the LAA sizing device to the ostium with the pusher sheath (2.2) ,
- Entering of LAA sizing device in the ostium and its release in the ostium with pusher cable (2.1),
- Positioning of the LAA sizing device at the largest diameter of the LAA orifice at the size of ellipsoid and sizing of left atrial appendage with calculation of the narrowest throat of LAA under fluoroscopy via radiopaque markers (1.1) found in the first component (1),
- Arrangement of the metallic wires (5) in the third component (3) to be more than at least 5% of the LAA orifice size,
- Positioning of LAA elimination device in the left atrial appendage,
- Eliminating the LAA by placing the third component (3) and proximal circle (4.3) in LAA, and keeping the distal circle outside of the LAA.

4 .It is related to left atrial appendage elimination and closure device, which is mentioned in claim 2, and its property can be characterized by the fact that the distal circle (4.2) from the metallic circles in the braided sealing element (4) is larger than the proximal circle (4.3) .

5 . It is related to left atrial appendage elimination and closure device, which is mentioned in claim 2, and its property can be characterized by the fact that filaments (3.2) of the third component (3) are rounded for the purpose of not damaging the tissue.

6 . It is related to left atrial appendage elimination and closure device, which is mentioned in claim 2, and its property can be characterized by the fact that braided sealing element (4) includes patch material (6) which can be

poly (tetrafluoroethylene) (PTFE), poly (vinyl chloride) (PVC), dacron or biocompatible fabric.

7. It is related to left atrial appendage elimination and closure device, which is mentioned in claim 2, and its property can be characterized by the fact that tips of joint positions (3.1.1) in the bracelets (3.1) are rounded.

8. It is related to left atrial appendage elimination and closure device, which is mentioned in claim 2, and its property can be characterized by the fact that the joints (3.1.1) located in the bracelet (3.1) changes direction as the angle a which is in the range of 0° to 90° on both sides in the cross sectional's planar direction of braided sealing element (4) LAA orifice.

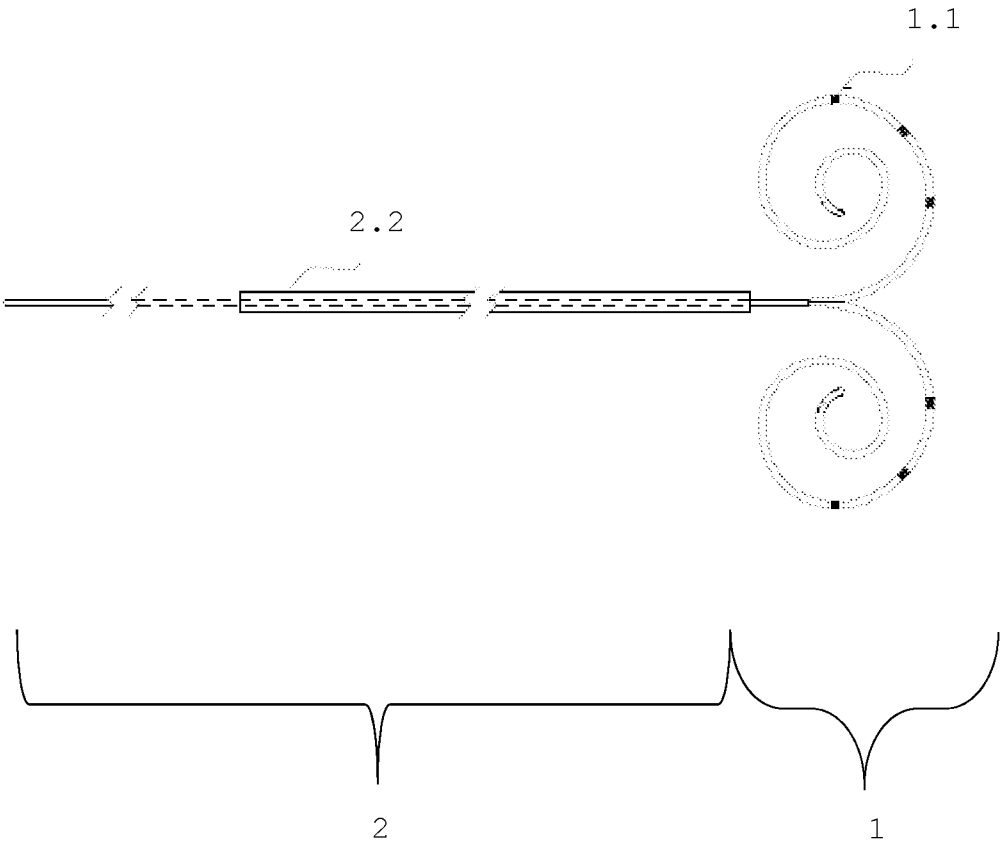


Figure 1

Figure 2

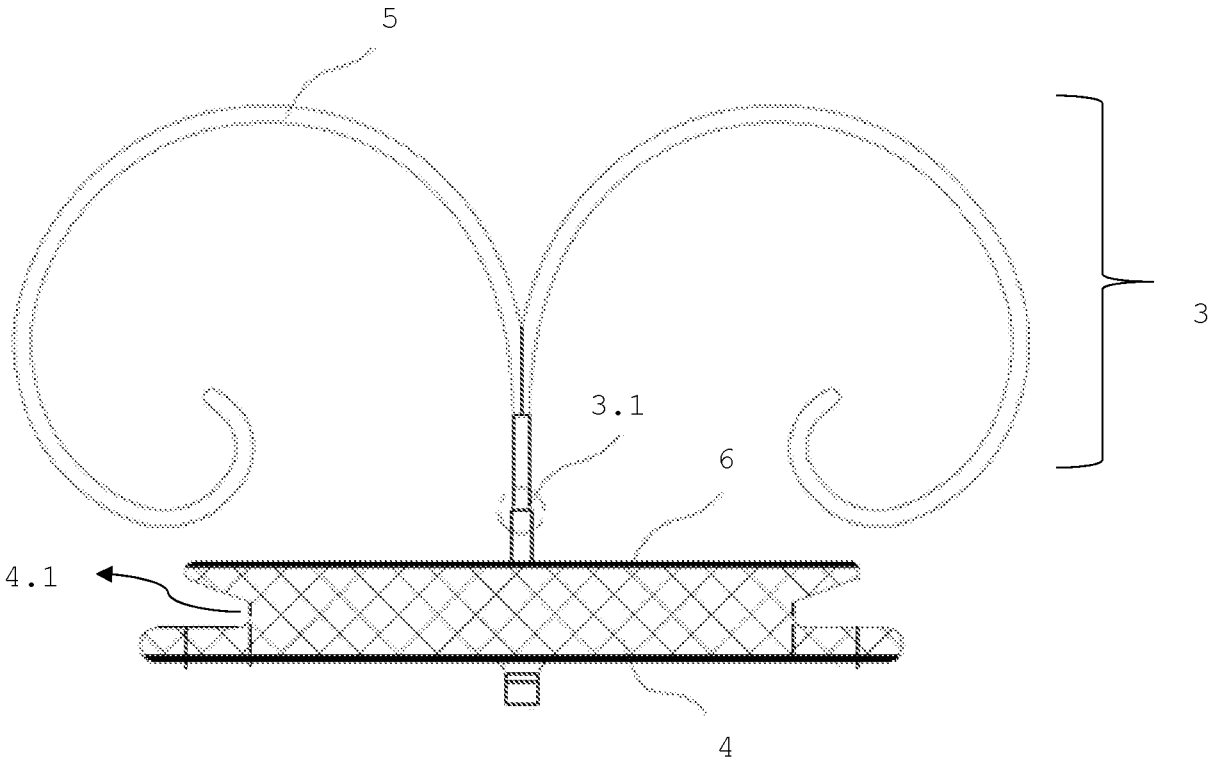


Figure 3

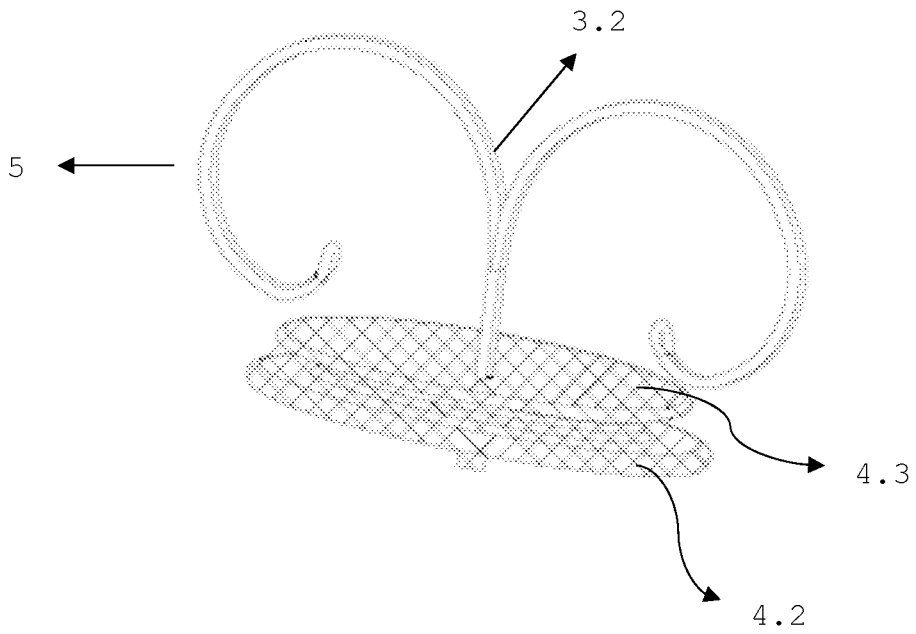
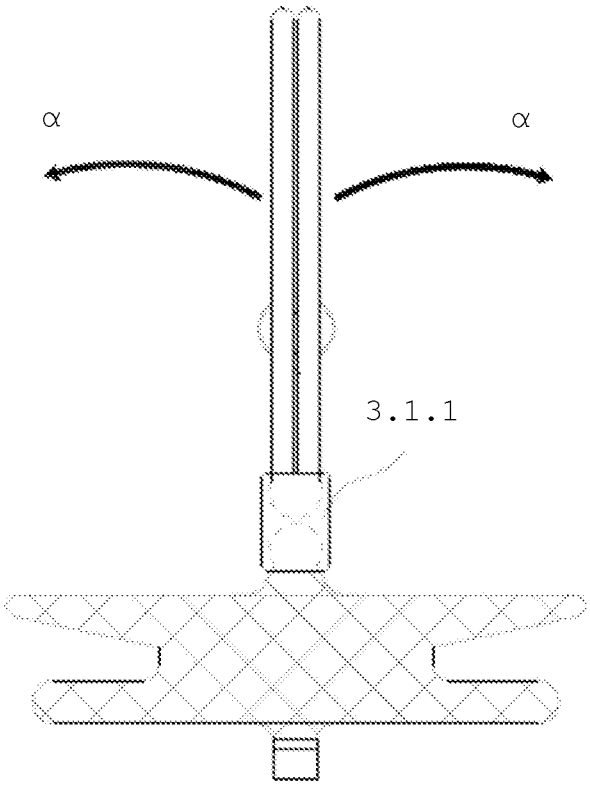


Figure 4



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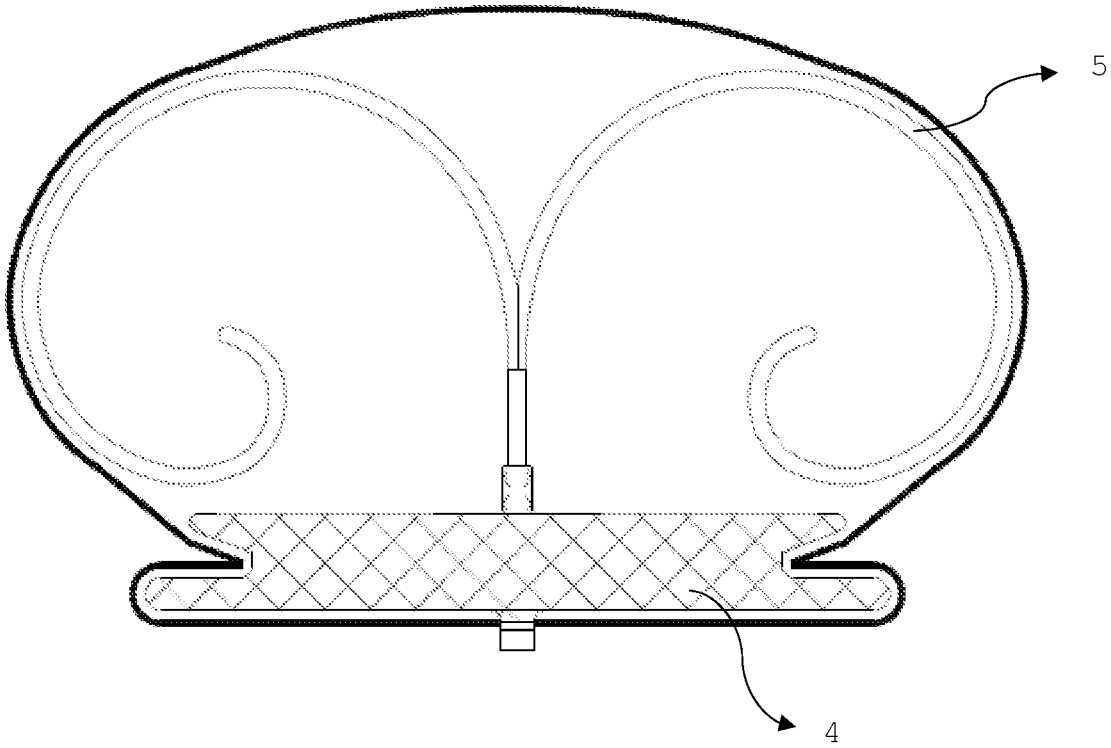

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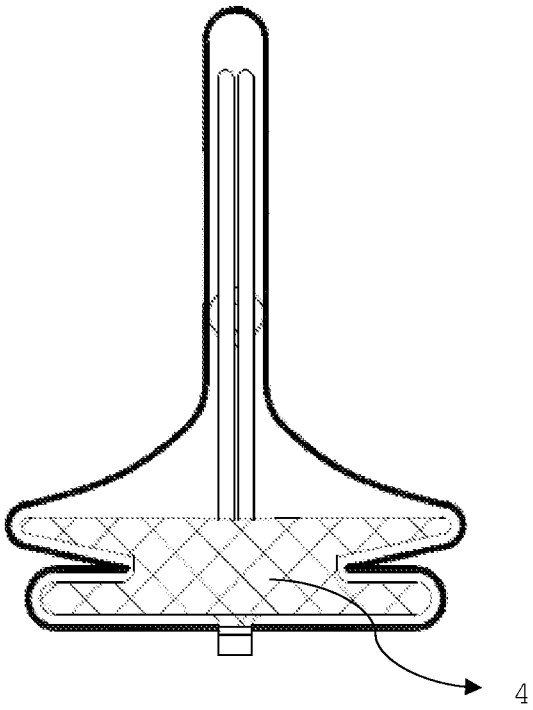

Figure 7

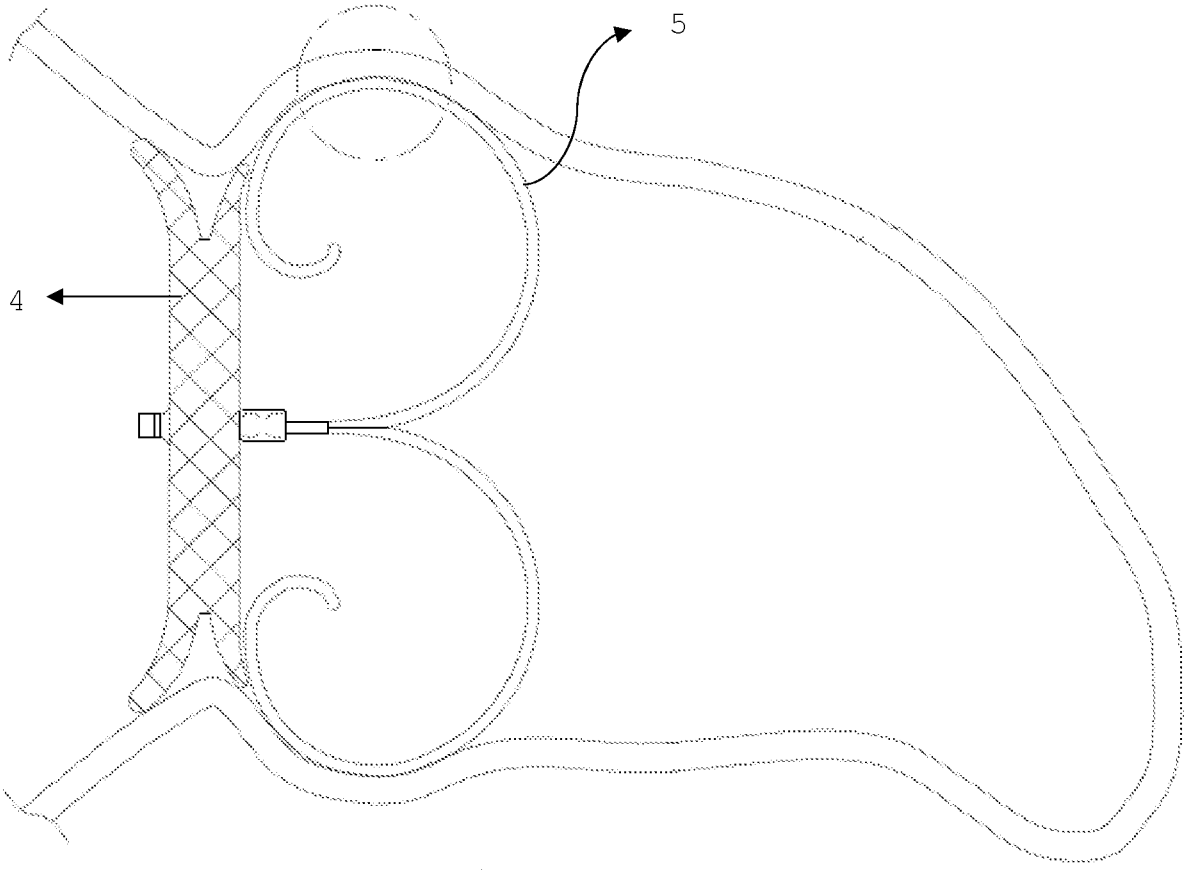

Figure 8