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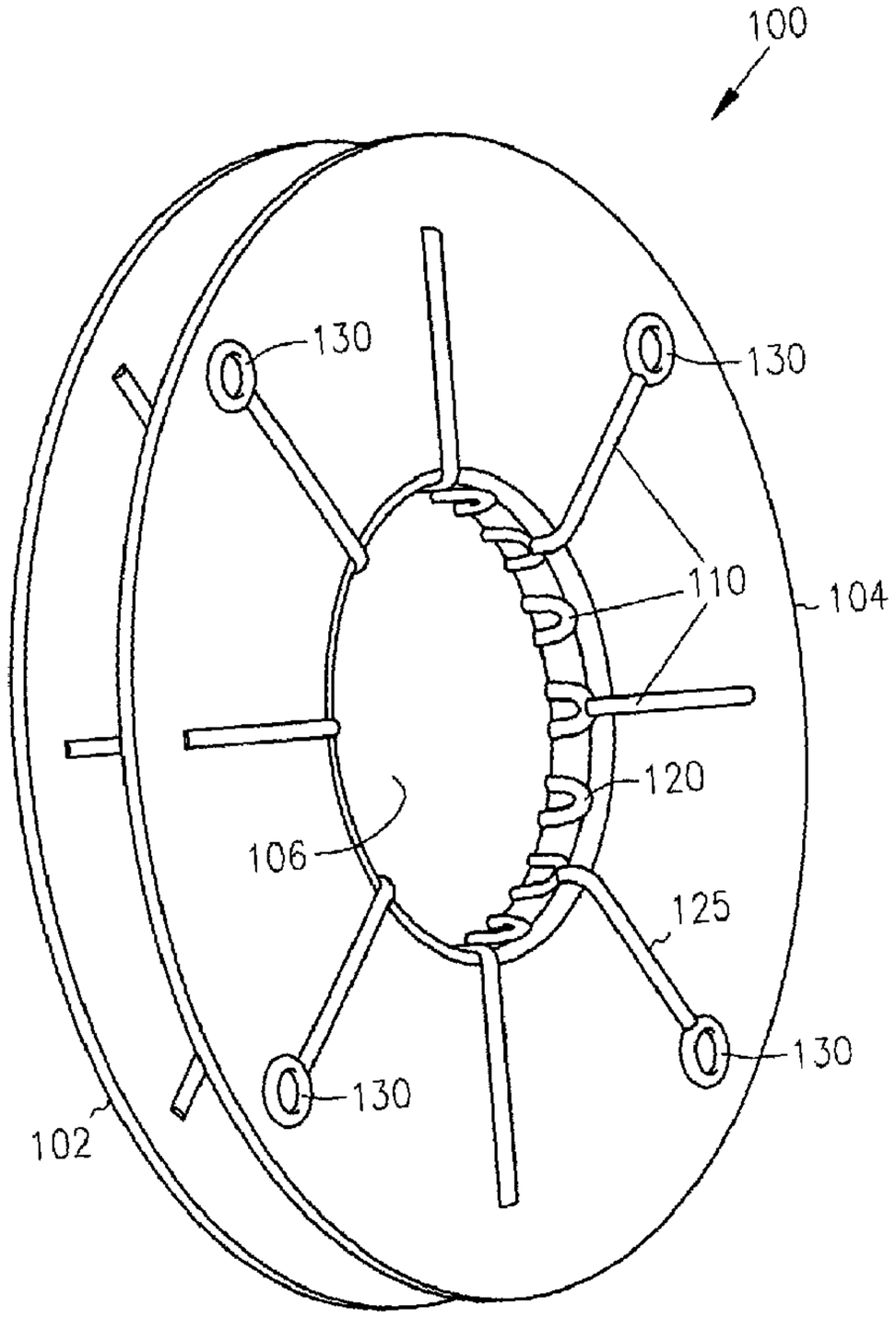
(54) Titre : DISPOSITIF D'OCCLUSION VASCULAIRE
(54) Title: VASCULAR OCCLUSION DEVICE



(57) Abrégé/Abstract:
An occlusion device includes a pair of connected members configured for being situated on opposing sides of a hole in a tissue, wherein the pair of connected members are formed of a material which is bioadsorbable to the tissue. The pair of connected members can include a non-metallic skeleton.

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(54) Title: VASCULAR OCCLUSION DEVICE

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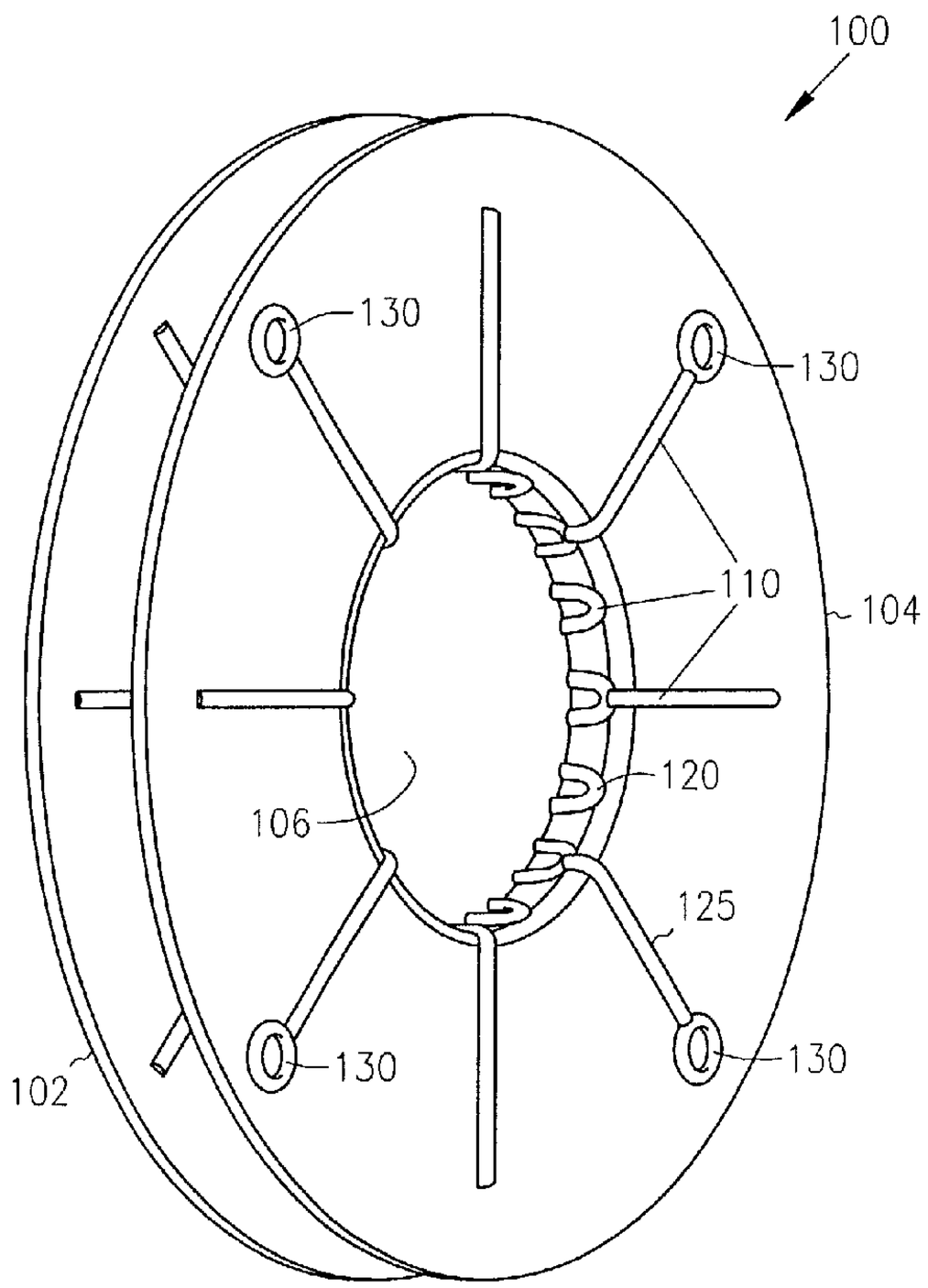

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VASCULAR OCCLUSION DEVICE

Field of the Invention

This invention relates to the field of medical devices, and more specifically to an apparatus for vascular occlusion.

Background

Vascular occlusion devices such as atrial septal defect closure devices are used for closing defects or holes in the vascular system of a body. Such devices usually include an occluding member which is dimensioned larger than the hole, and some technique for mounting the occluding member to the tissue proximate the defect or hole.

The devices are typically made of a wire frame or skeleton which can become fatigued or perforate the tissue wall. It is also desirable to center the device within the hole and provide a stable technique for keeping the device securely mounted to the tissue.

Brief Description of the Drawings

Figure 1A shows a front view of a vascular occlusion device according to one embodiment.

Figure 1B shows a perspective view of the vascular occlusion device of Figure 1A.

Figure 1C shows a side view of the vascular occlusion device of Figure 1A with the flanges folded outward.

Figure 1D shows side view of the vascular occlusion device of Figure 1A.

Figure 1E shows a side section view along line E-E of Figure 1B.

Figure 2 shows a detail of area 2 of Figure 1E.

Figure 3 shows a front perspective view of the vascular occlusion device of Figure 1A.

Figure 4 shows a side view of the vascular occlusion device of Figure 1A.

Figure 5 shows a detail of a front portion of the vascular occlusion device of Figure 1A.

Figure 6 shows a detail of a front portion of the vascular occlusion device of Figure 1A.

Figure 7 shows a rear perspective view of the vascular occlusion device of Figure 1A.

Figure 8A shows a front view of a vascular occlusion device according to one embodiment.

Figure 8B shows a side sectional view along line B-B of the vascular occlusion device of Figure 8A.

Figure 8C shows a sectional view along line C-C of Figure 8A.

Figure 8D shows a view of the vascular occlusion device of Figure 8A.

Figure 8E shows a front perspective view of the vascular occlusion device of Figure 8A.

Figure 9 shows a front view of the vascular occlusion device of Figure 8A.

Figure 10 shows a rear perspective view of the vascular occlusion device of Figure 8A.

Figures 11A-11C show side, top and bottom view of a device according to one embodiment.

Figure 12A shows a device in accordance with one embodiment.

Figure 12B shows a top view of a portion of the device of Figure 12A.

Figure 12C shows a cross section of line C-C of Figure 12B.

Figure 12D shows a cross-section of line D-D of Figure 12B.

Figures 13A-13D show the device of Figure 12A being deployed in accordance with one embodiment.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the present invention. Therefore, the following detailed description is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

The present system provides a device that can be used to occlude defects in the vascular system by minimally invasive means. Patients are often born with congenital defects in the heart commonly alluded to as "holes in the heart." This may be between the upper chambers in the heart called "atrial septal defects" or between the lower chambers of the heart called "ventricular septal defects." In other instances, it may be "patent ductus arteriosii" when it is a communication between the aorta and pulmonary artery. In addition, there may be arterio-venous fistulae at several sites within the body, or the presence of collateral arteries to the lungs that bring excessive amounts of blood and require closure.

In recent years, after diagnostic or therapeutic cardiac catheterization, it has become possible to close the arterial puncture site with devices, and because of the anticoagulation they receive, the potential for bleeding and prolonged bed rest can be avoided. However the devices for the closure of heart defects or femoral hemostatic devices have clinical problems and there is a need for a more optimal method of closure.

In the case of cardiac septal defects, some present devices are made of metallic frameworks with single or multiple metallic wires in different geometries. These have the potential of erosion into surrounding structures and corrosion as these implants in children will remain in place for 70 years and more. Some self-centering devices have decreased the potential for residual

leaks and permit the almost complete occlusion of these defects. However some of these devices are bulky, and made of several bulky wires.

In some embodiments, the present system includes a vascular occlusion device that can be self-centering, can completely occlude defects, and can also be retrieved back into the delivery catheter in case of sub-optimal deployments. In one embodiment, a vascular occlusion device can include no metallic components. For example, the device can be made from bio-compatible plastic materials that permit it to be injection molded, vacuum formed, or extruded. This makes the manufacturability of such a device quite simple and large quantities can be manufactured quite easily. In one embodiment, the device is made from a bio-adsorbable polymer or a bio-degradable polymer. After deployment of the device, such a polymer is gradually replaced by fibrous tissue and resorbed over a period of months. No metallic components remain and this permits the most desirable form of repair of such defects. In other instances, where a bio-adsorbable material is not appropriate, for fear of aneurysm formation in high pressure shunts, silicone elastomers, polyurethanes or combinations of the two can be used.

Figure 1A-7 show a vascular occlusion device 100 according to one embodiment. Device 100 includes a double disk device, with two flanges 102 and 104 that extend outwards from a central area 106. In one embodiment, the central area 106 is dimensioned to act as a self-centering mechanism to allow the flanges and the device to be substantially centered over the defect. The central area occludes the defect and extends to the double flanges circumferentially. In one embodiment, central area 106 has a diameter of approximately 12 mm, with the flanges 102 and 104 having a diameter of approximately 30 mm.

Device 100 includes a self-expanding skeleton structure 110 that provides the major structural strength of the device. Skeleton structure 110 includes a plurality of ribs 125. Between each of the ribs 125 are thinner membrane portions 127. In one example, the membrane portions 127 can be approximately 0.01 inches thick, or less. Ribs 125 can be approximately 0.025 inches thick. Skeleton 110 supports a main body structure which includes the flanges 102 and 104. As seen in Figures 1C, 1D, 3, 4, 5, 6 and 7, the skeleton

has a sinuous structure around the central rim 120 that permits the rim area to be collapsed down. From this, there are the plurality of spoke-like projections or ribs 125 that permit folding of the flanges. In one example, ribs 125 extend radially along each disk. On one of the disks, one or more holes 130 are incorporated whose function is to be the sites to tether it to the release mechanism (see Figure 5) with a tether 139. In one embodiment, holes 130 are located at the ends of ribs 125 with a section of rib encircling the hole.

Device 100 is flexible, compressible, and self-expandable and can be used in a manner known in the art. In one example use, the device 100 can be collapsed into a catheter by folding the flanges 102 and 104 outwards and collapsing the central rim 120. The catheter is then passed through an atrial or ventricular septal defect, or other hole in a body. The first disk 102 of device 100 is pushed out of the catheter and springably opens on one side of the defect. The rib configuration of the skeleton structure of each flange automatically expands the flange to its original dimensions on release from the confines of the catheter. The expanded disk 102 is then drawn back to the defect. The catheter is pulled back, and second disk 104 then springably opens on the second side of the defect. The central rim area 120 also expands to its original size and abuts the inner diameter surface of the defect. This acts as a centering mechanism to center the flanges of the device on each side of the defect. Referring to Figure 4, the outer surface of rim 120 diametrically extends from a first surface 121 to a second surface 123. These surfaces and the rest of the expanded rim surface are biased towards and can contact the inner surface of the defect to help center the device.

Once deployment of the device is considered optimal, the device is released. If deployment is sub-optimal, tethers 139, which are attached at one or more of holes 130 can be used to retrieve the device. By pulling back on the tethers, the device can be re-collapsed into the catheter. Again, holes 130 are structurally connected to ribs 125. Thus, when the tethers are pulled back, the force against the ribs of the skeleton structure force flange 104 to collapse. The device can then be drawn back into the catheter to be re-deployed.

Figure 2 shows one example of a distal end of a rib 125 of device 100. In this example, the end 141 of rib 125 is thinner (approximately 0.01 inches) than the inner portion 143 (approximately 0.025 inches) of the rib. This provides that the periphery area of each flange is a little more flexible and softer than the middle regions. This can help eliminate tissue erosion by the device once it is implanted.

Again, in one embodiment device 100 is molded from a non-metallic material. Such an occlusion device has better tolerance than prior devices and has better long-term stability. Possible materials include: silicone elastomers, polyurethanes, or combinations of the two, and other compatible materials. In one example, device 100 is a one-piece, completely integrated device formed of a single material with ribs 110 being thicker parts of the material. This allows for fast manufacturability since the device can be molded or otherwise formed in a single process. In some embodiments, the ribs are formed of one type of material and the membrane portion from a different type of material.

In one embodiment, the device includes a bio-adsorbable material. Possible bio-adsorbable material include: polyglycolic acid, polydioxanone, polylactic acid, and polycaprolactone, etc. Some embodiments use other bio-degradable and bioabsorbable plastics. Again, in some embodiments, these poly materials can be used to form the device as a single integrated unit formed of a single, moldable material. Using a bioadsorbable material as described above allows the device to slowly be resorbed into the body while the poly material is replaced by tissue. This results in a closed defect and leaves no metallic parts in a body.

Figures 8A-10 show a vascular occlusion device 200 according to one embodiment. Device 200 includes a pair of disk members defining a pair of flange members 202 and 204 connected by a central area 206. The skeleton structure 210 of occlusion device 200 includes an appearance of the petals of a flower. The skeleton 210 of device 200 runs across from one side to the other through a central area 206. In this example, skeleton 210 includes rib portions 225 running towards and around the periphery of each flange of the device. Holes 230 are provided similar to holes 130 described above. Again, the central

area 206 can be dimensioned to provide a self-centering device by having an outer rim surface 220 to abut the defect. While the disk shape shown is square-shaped, it may be round, oval, rectangular, or any other desirable shape. The thickness of the skeleton is variable and is determined by the occlusive pressures that will force the device from the defect. The thickness of the membrane can be variable. In one example, the membrane portion can be about 0.010 inches or less, with the ribs being about 0.020 inches to 0.025 inches. The membrane in both the flanges can be perforated, and sieve like, to reduce the bulk of the device, so that it can be more easily loaded into a catheter. It would be desirable for the central area to be free of perforations for the shunt to be occluded. In one embodiment, the central area 206 is about 10 mm in diameter and each flange has a diameter of approximately 28 mm.

Device 200 can be constructed of the same material as for device 100.

Figures 11A-11C show a device 300 for closure of patent ductus arteriosii (PDA), according to one embodiment. Device 300 includes only one disk 302. There is a central tubular area 306 that is sized to fit into the patent ductus arteriosus. The circular ring 310 is for the release mechanism. Device 300 can be loaded into a catheter and this is used to cross the PDA. The circular disk 302 and the tubular section 306 are opened in the aorta and then it is pulled back into the PDA, so that the disk occludes the defect, and the tubular section seated in the PDA, keeps it in place and centered. If required, the device can be drawn back into the catheter for retrieval in case of sub-optimal deployment.

Device 300 can be constructed of the same material as for device 100.

Device 300 can include ribs 320 extending outwardly along a face of the disk 302. Again, in one embodiment, device 300 can be formed as an integral, one-piece design. For example, device 300 can be molded from a plastic material, such as a bioadsorbable material as discussed above.

Figures 12A-13D show a device 400 that can be used to occlude puncture sites in the femoral artery or vein after percutaneous interventions, in accordance with one embodiment. In one example, device 400 includes a bio-adsorbable

polymer. It has an intra-vascular member 402 that is rectangular in shape or oval. This is connected by a wide "waist" 404 to the extra-vascular member 406, that leads to a ring 408. One feature of this device is that the waist is designed to be slightly larger than the puncture hole in the artery or vein. For instance, with 6, 8 or 10 French catheter systems, the hole in the vessel can be as large as 1.98, 2.64, or 3.3 mm. The occluder is designed in different sizes so that the waist between the intravascular and extravascular disks are 2, 2.75 or 3.5 mm in diameter. This allows the present device to fit into the hole and tightly occlude it.

Figures 12B-12D show the shape of intra-vascular member 402 according to one embodiment. In this example, member 402 has a rectangle shape of approximately 6 mm by 8 mm, and which is curved to form a partial cylindrical shape. This allows the member to sit flush against an inner surface along the axis of the artery (See Figure 13D).

The external disk 406 is structured to prevent device 400 from prolapsing back into the artery and producing a total occlusion of the artery. Device 400 can be constructed of the same material as for device 100.

Figures 13A-13D show one example of device 400 in use. For example, after a percutaneous procedure, an angiogram is obtained to identify the site of puncture, to ensure that it is above the bifurcation of the femoral artery. Device 400 is loaded into its sheath and this is passed through the previous sheath into the common iliac artery. The device is partially extruded until the intravascular disk 402 opens inside the artery. The whole unit is withdrawn, until the intravascular disk is snug against the artery. The device is held in place, using the release device 430, and the sheath 440 is drawn back so that the extravascular disk is opened. The sheaths are drawn back. The "self-centering" mechanism of the device permits the device to tightly occlude the defect. The intravascular disk prevents the device from being blown out by the intra-arterial pressure. Once hemostasis is confirmed, the device is released. It is anticipated that the bioadsorbable polymer would resorb over the course of a few weeks and heal with no foreign bodies remaining in the site.

Moreover, in one or more embodiments discussed above, the material of a device can be modified as necessary to prolong or shorten the resorption period to allow for predictable resorption times.

It is understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

What is claimed is:

1. An occlusion device comprising:

first and second disk members which are connected together, each of the first and second disk members having a self-expanding, non-metallic structure including a plurality of integral rib members which are flexible so as to be compressible within a catheter and are biased towards an open position to expand the disk members when removed from the catheter.

2. The occlusion device of claim 1, wherein the occlusion device includes a bioadsorbable material.

3. The occlusion device of claim 2, wherein the bioadsorbable material includes polyglycolic acid.

4. The occlusion device of claim 2, wherein the bioadsorbable material includes polydioxanone.

5. The occlusion device of claim 2, wherein the bioadsorbable material includes polylactic acid.

6. The occlusion device of claim 2, wherein the bioadsorbable material includes polycaprolactone.

7. The occlusion device of claim 1, wherein the first and second disk members are connected together at a central area having a periphery and a plurality of ribs are located around the periphery of the central area.

8. The occlusion device of claim 1, wherein each of the plurality of ribs are radially oriented on the first and second disk members.

9. The occlusion device of claim 1, wherein at least a portion of the plurality of ribs define a petal-shaped configuration.

10. The occlusion device of claim 1, wherein the first and second disk members have a central area therebetween, the central being dimensioned to extend across a hole in a tissue, wherein the central portion includes an outer periphery having a plurality of ribs to bias the periphery against the tissue.

11. The occlusion device of claim 1, further including one or more holes formed in one of the disk members proximate a periphery of the disk member.

12. The occlusion device of claim 11, wherein each of the one or more holes are encircled by a portion of the rib members.

13. The occlusion device of claim 1, wherein one or more of the rib members are thinner towards an outer end of the rib member.

14. The occlusion device of claim 1, wherein the occlusion device is a one-piece integral device.

15. An occlusion device comprising:

a pair of disk members connected together at a central area, the pair of disk members having integral rib sections extending radially towards a periphery of the disk members, and one or more holes formed proximate the periphery of one of the disk members.

16. The occlusion device of claim 15, wherein each of the disk members are adapted to be self-expanding.

17. The occlusion device of claim 15, wherein the occlusion device includes a bioadsorbable material.

18. The occlusion device of claim 15, wherein the central area includes a periphery and a plurality of ribs are located around the periphery of the central area.

19. The occlusion device of claim 15, wherein each of the one or more holes are encircled by a portion of the rib members.

20. The occlusion device of claim 1, wherein the occlusion device is a one-piece integral device formed of a non-metallic material.

21. An occlusion device comprising:

a one-piece integral device including a disk member and a tubular member connected to the disk member, the device having a self-expanding, non-metallic structure including a plurality of ribs running along the disk member.

22. The occlusion device of claim 21, wherein the device includes a bioadsorbable material.

23. The occlusion device of claim 21, wherein the device is adapted to be compressible within a catheter and expands when removed from the catheter.

24. An occlusion device comprising:

an intravascular portion and an extravascular portion connected by a waist, wherein the intravascular portion includes a partially cylindrical shape such that an upper surface of the intravascular portion rests flush against an inner surface of an artery.

25. The occlusion device of claim 24, wherein the occlusion device includes a bioadsorbable material.

26. The occlusion device of claim 24, wherein the device is a one-piece integral unit.

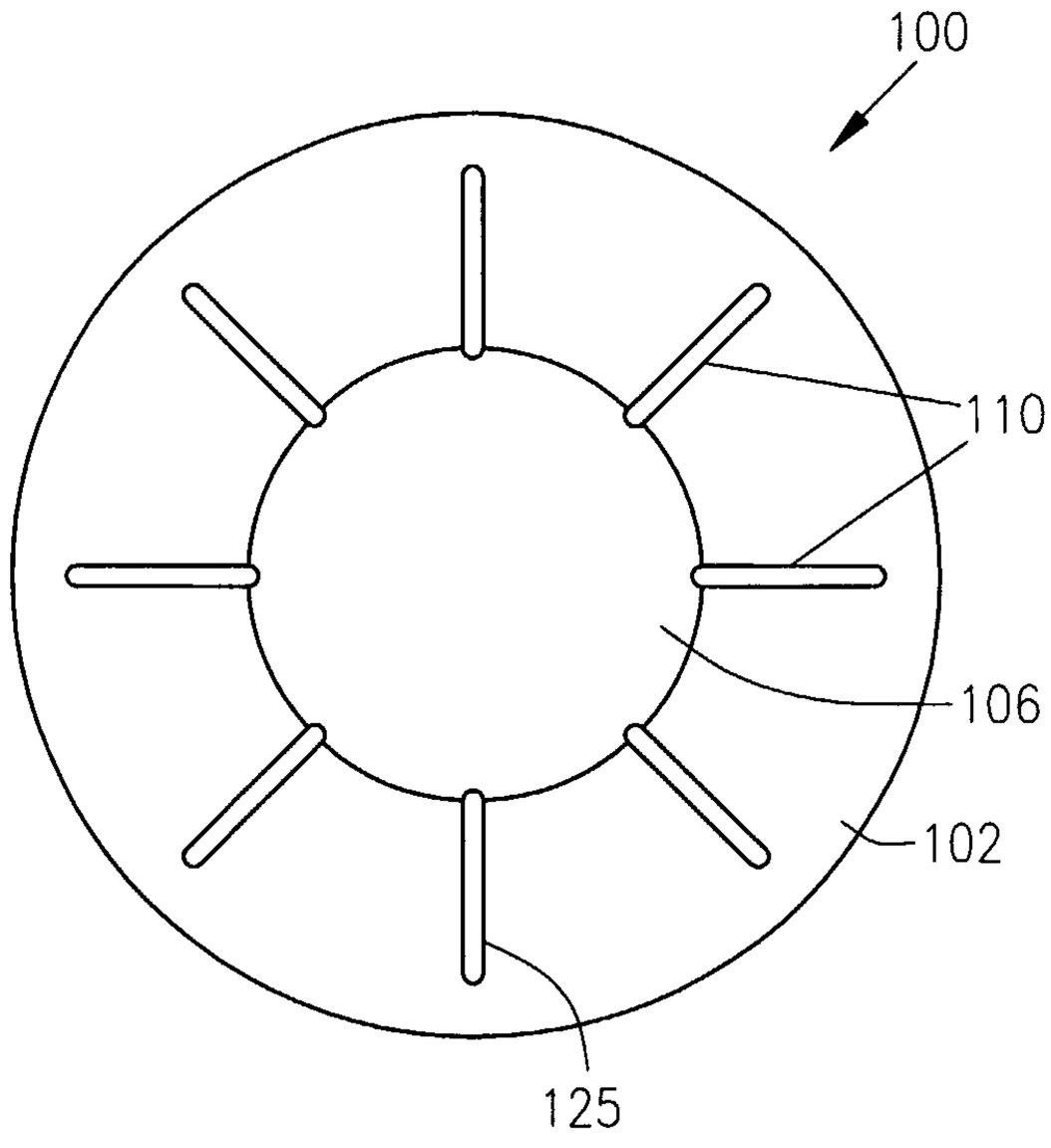


FIG. 1A

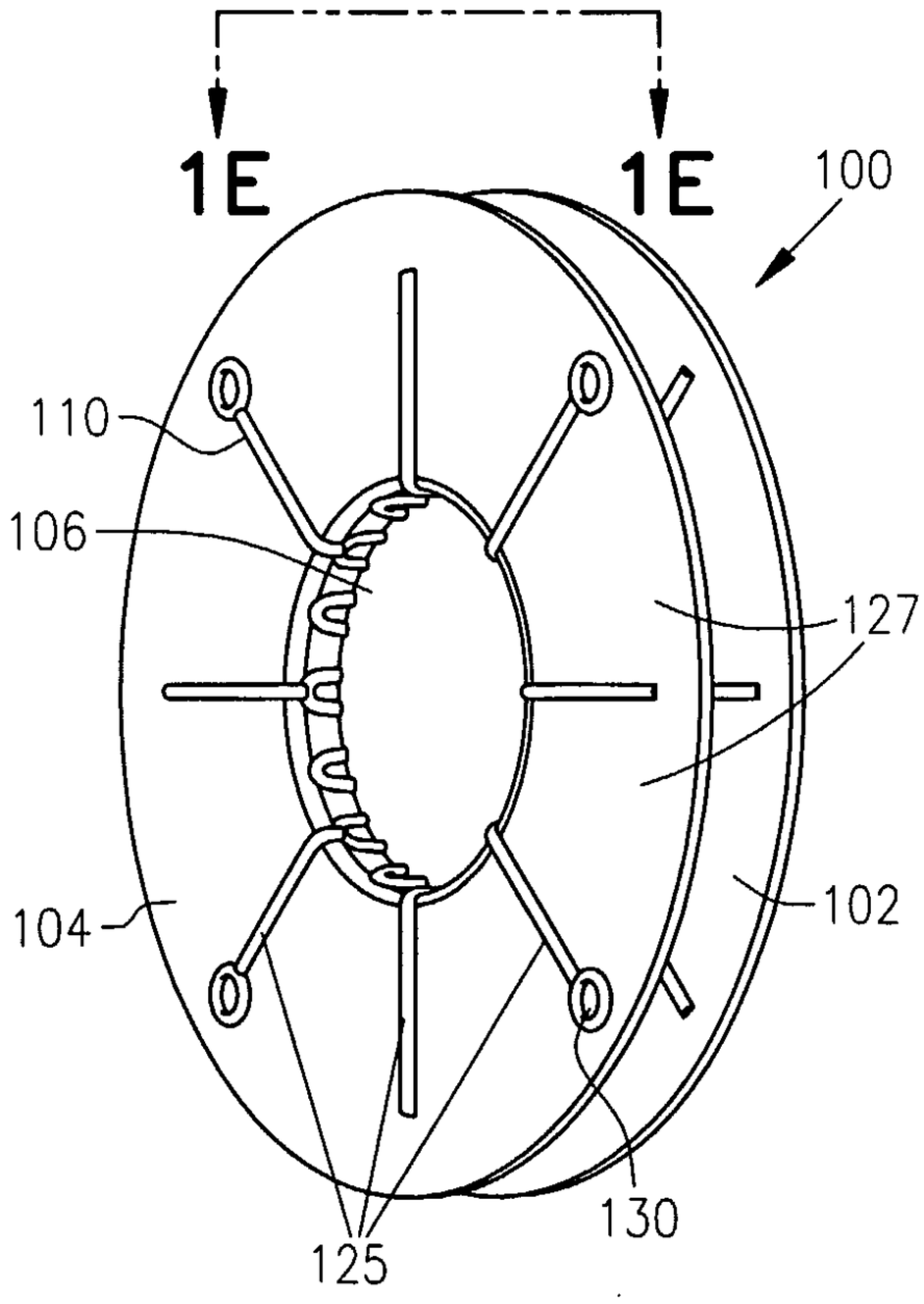


FIG. 1B

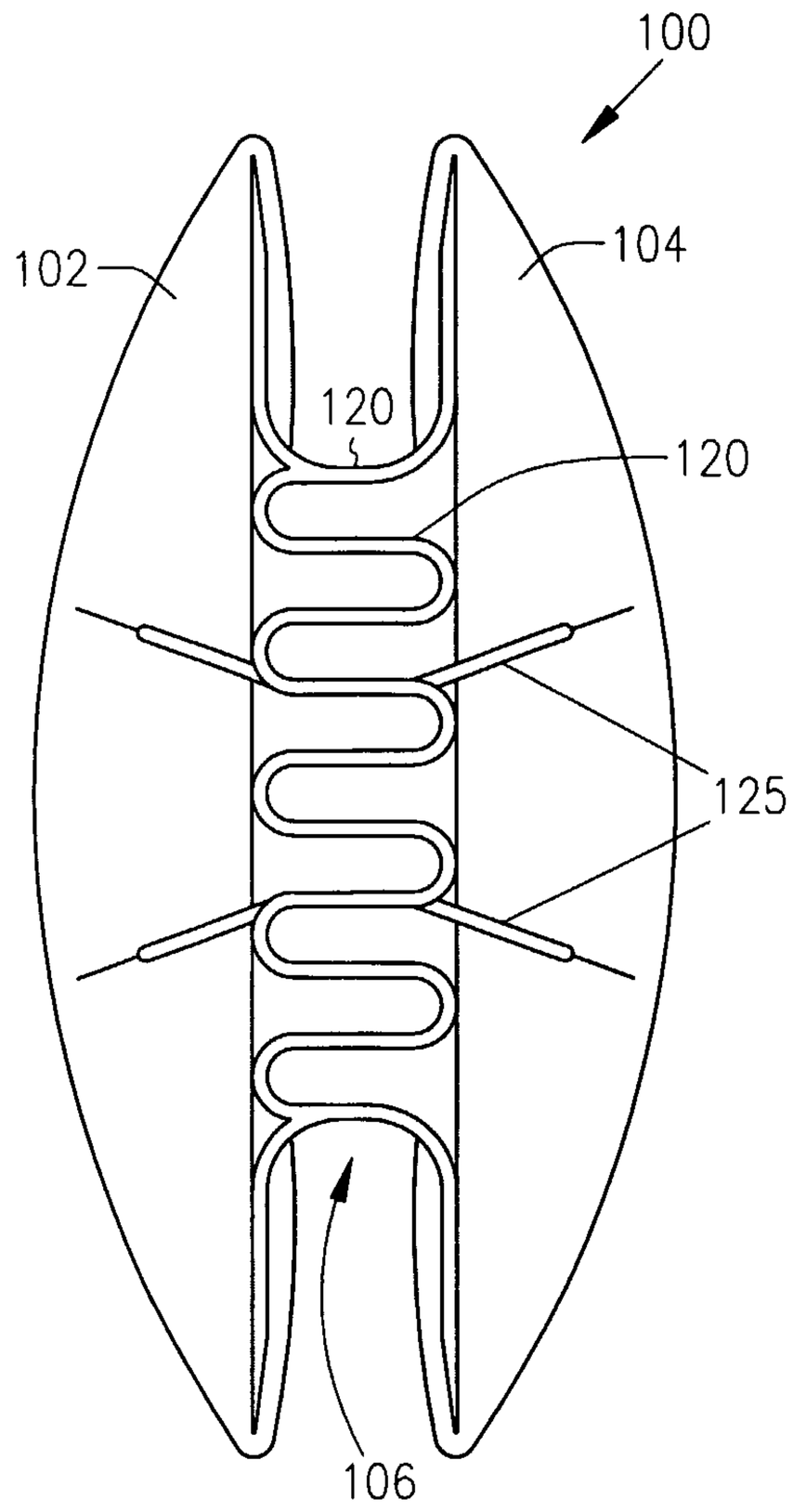


FIG. 1C

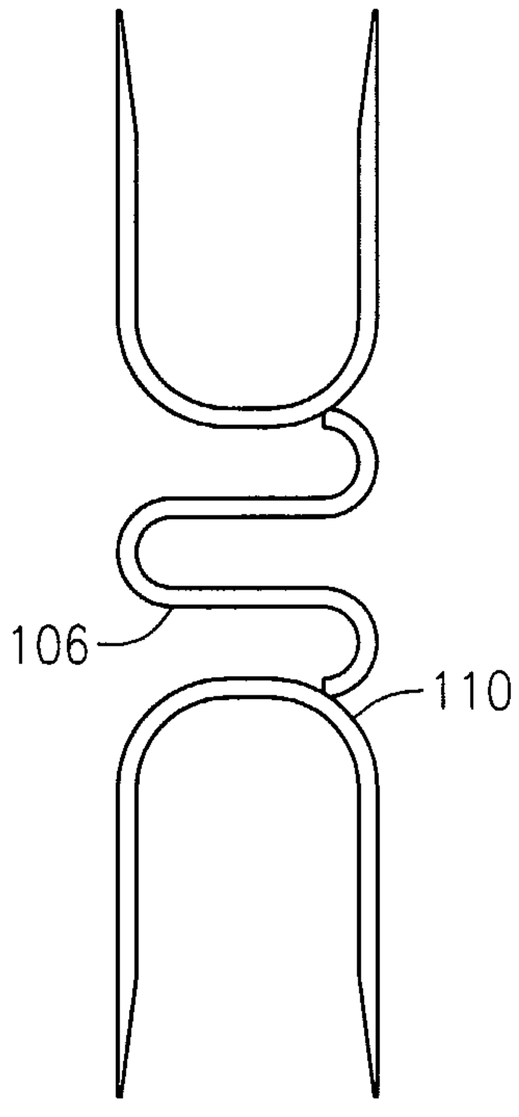


FIG. 1D

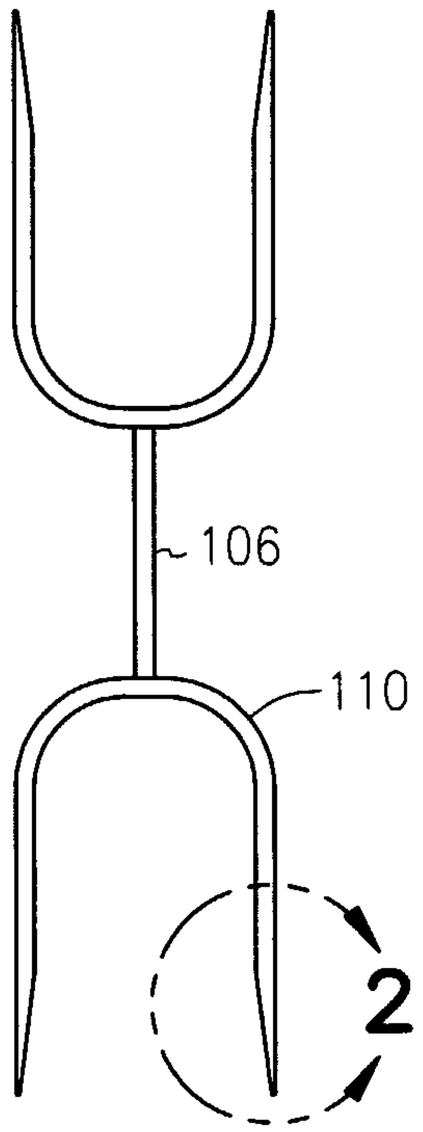


FIG. 1E

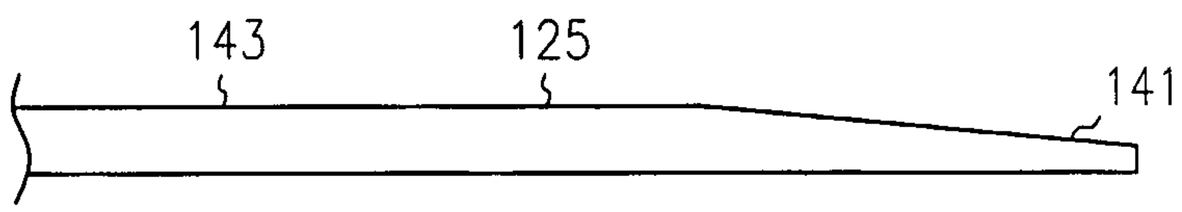


FIG. 2

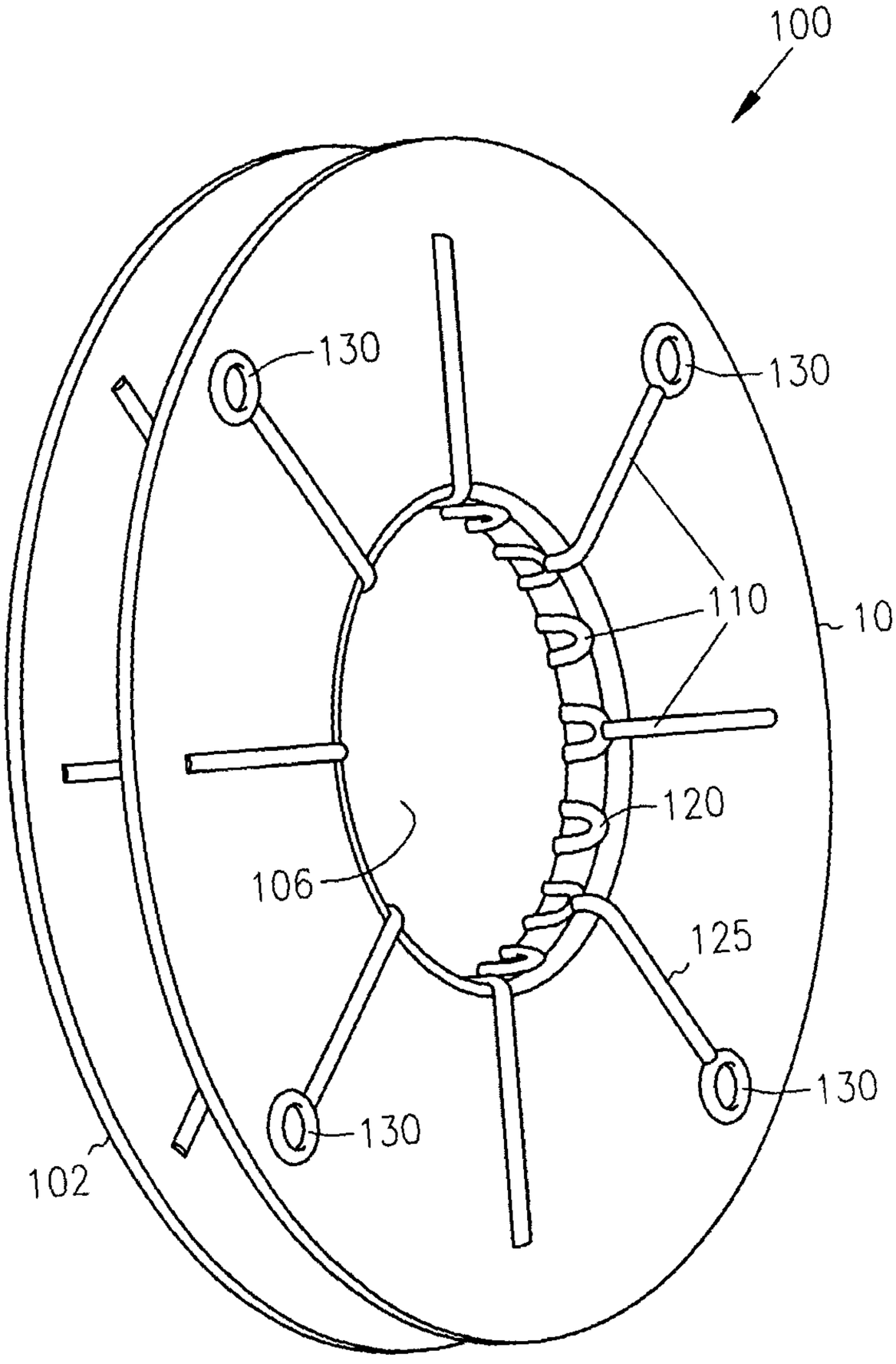


FIG. 3

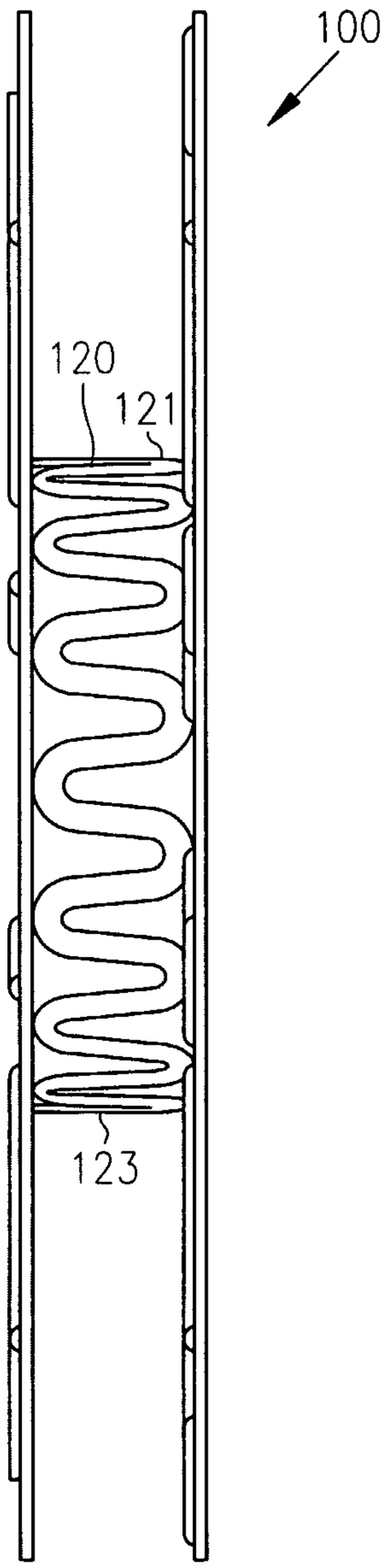


FIG. 4

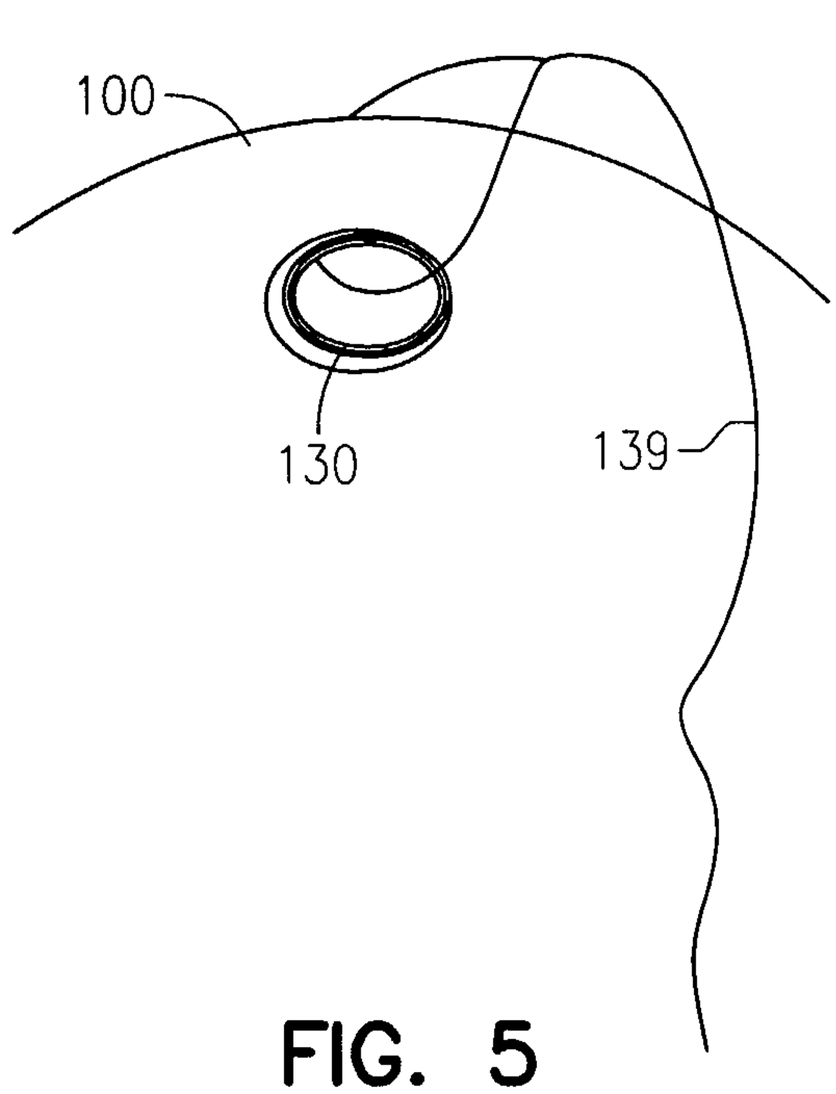


FIG. 5

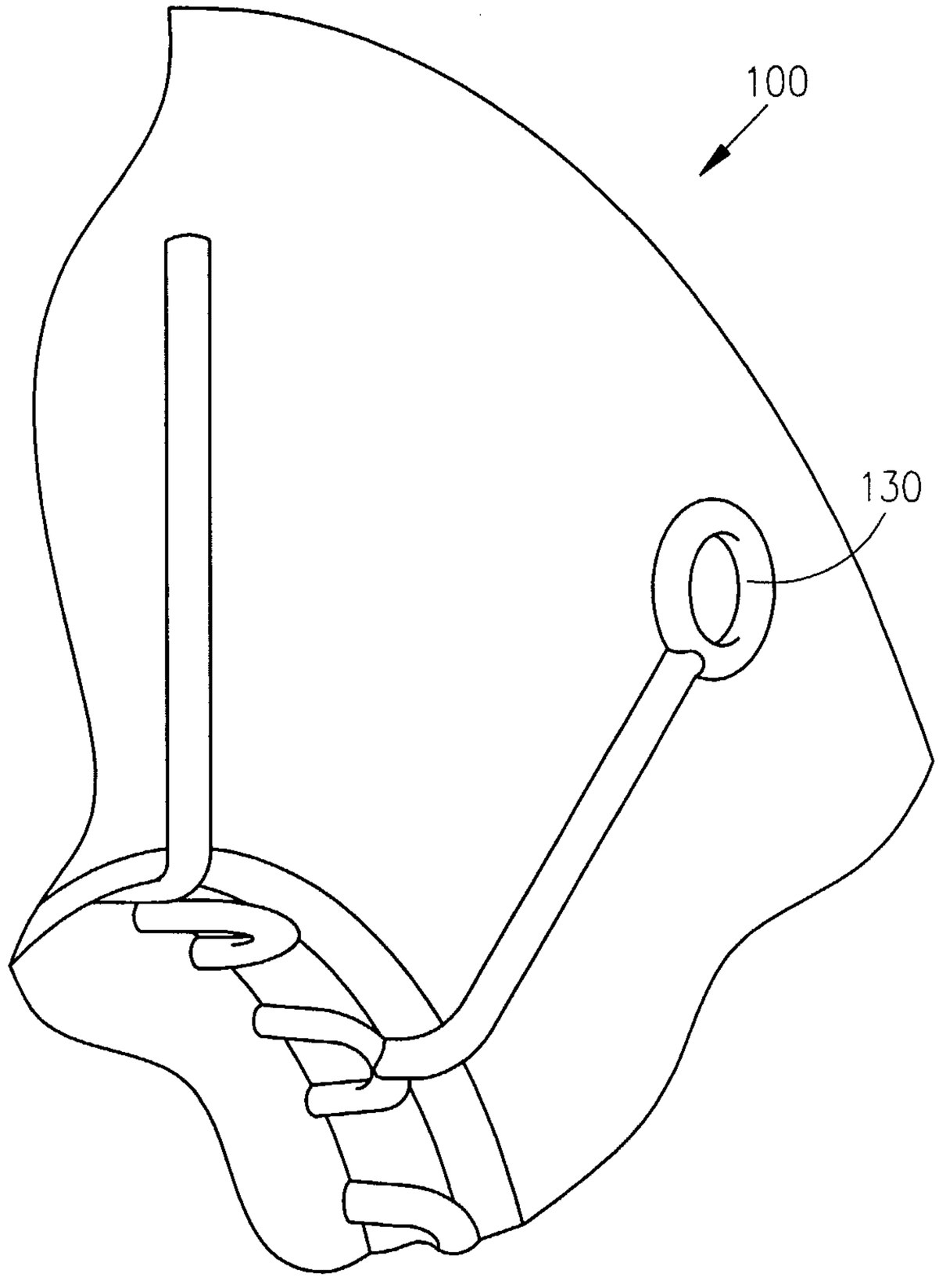


FIG. 6

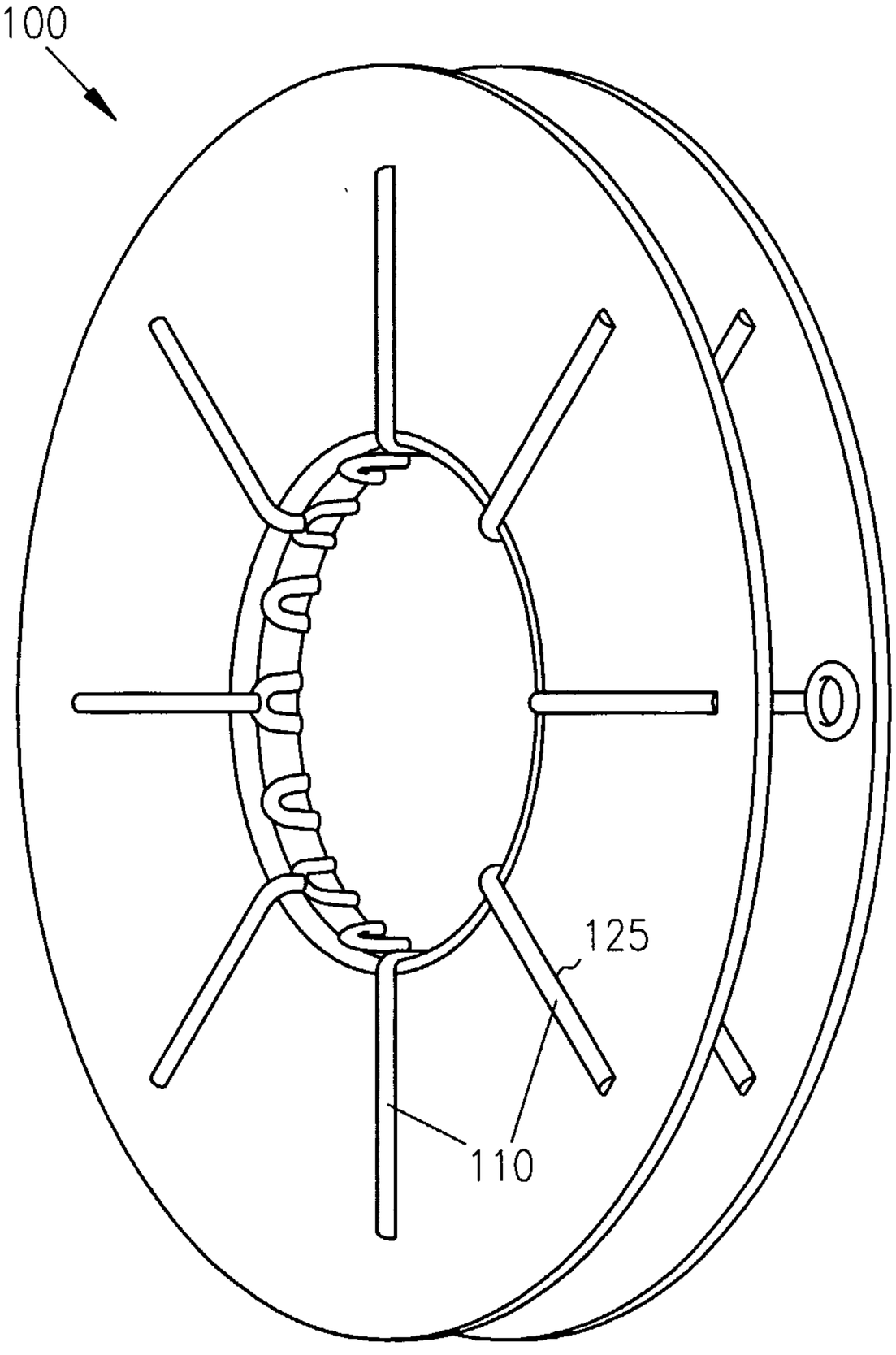


FIG. 7

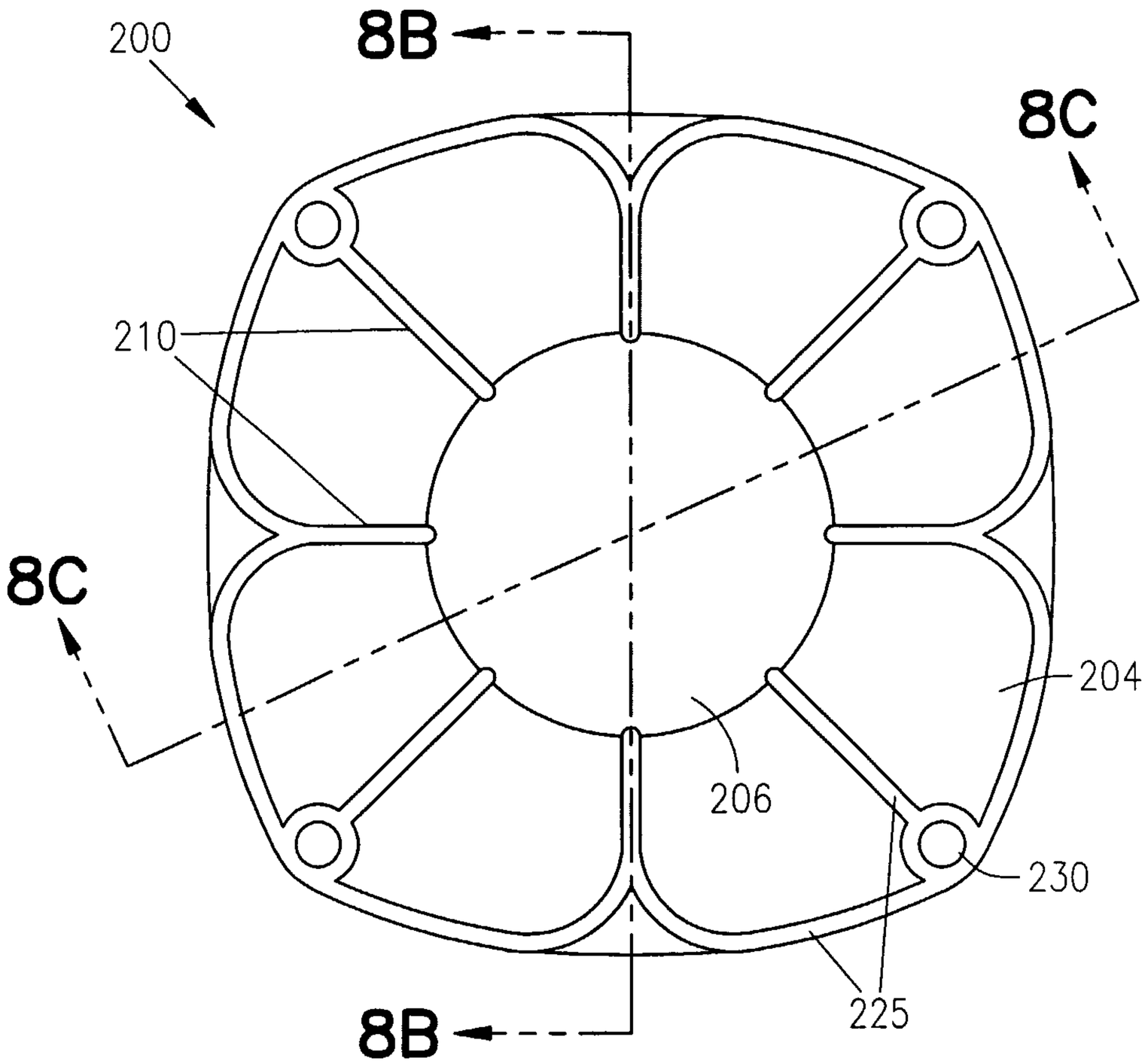


FIG. 8A

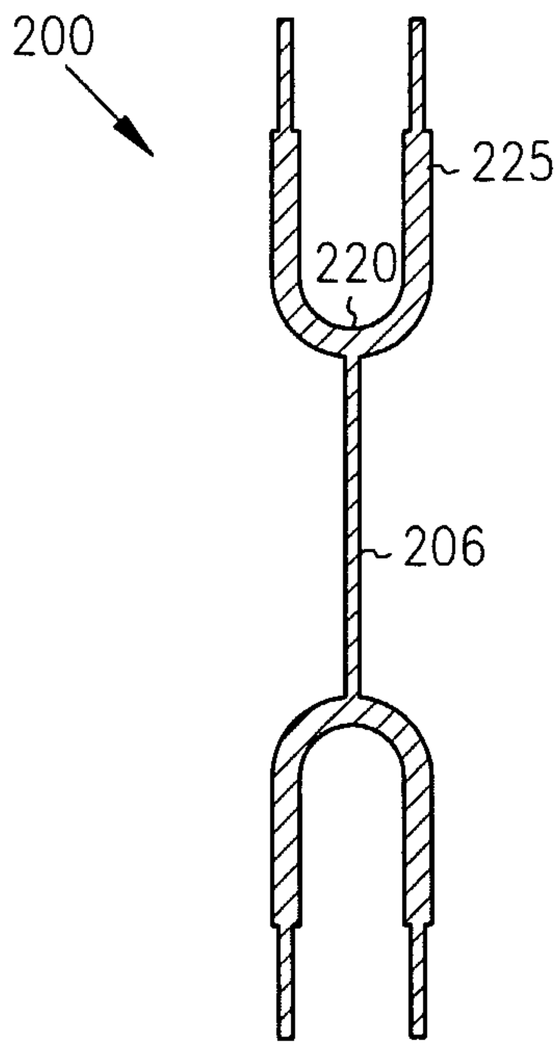


FIG. 8B

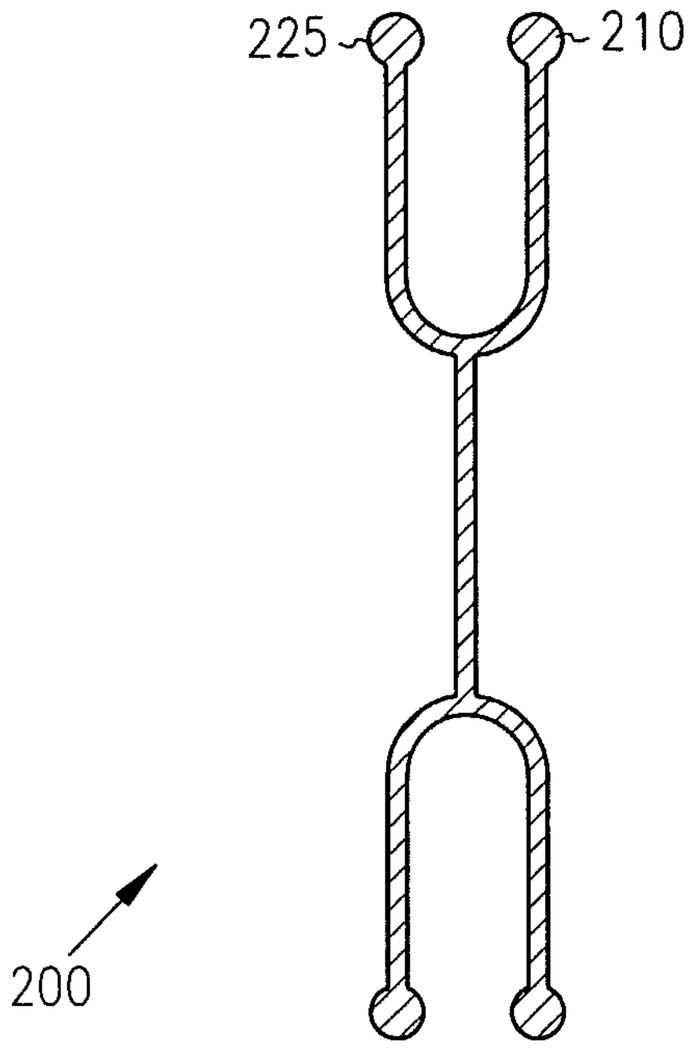


FIG. 8C

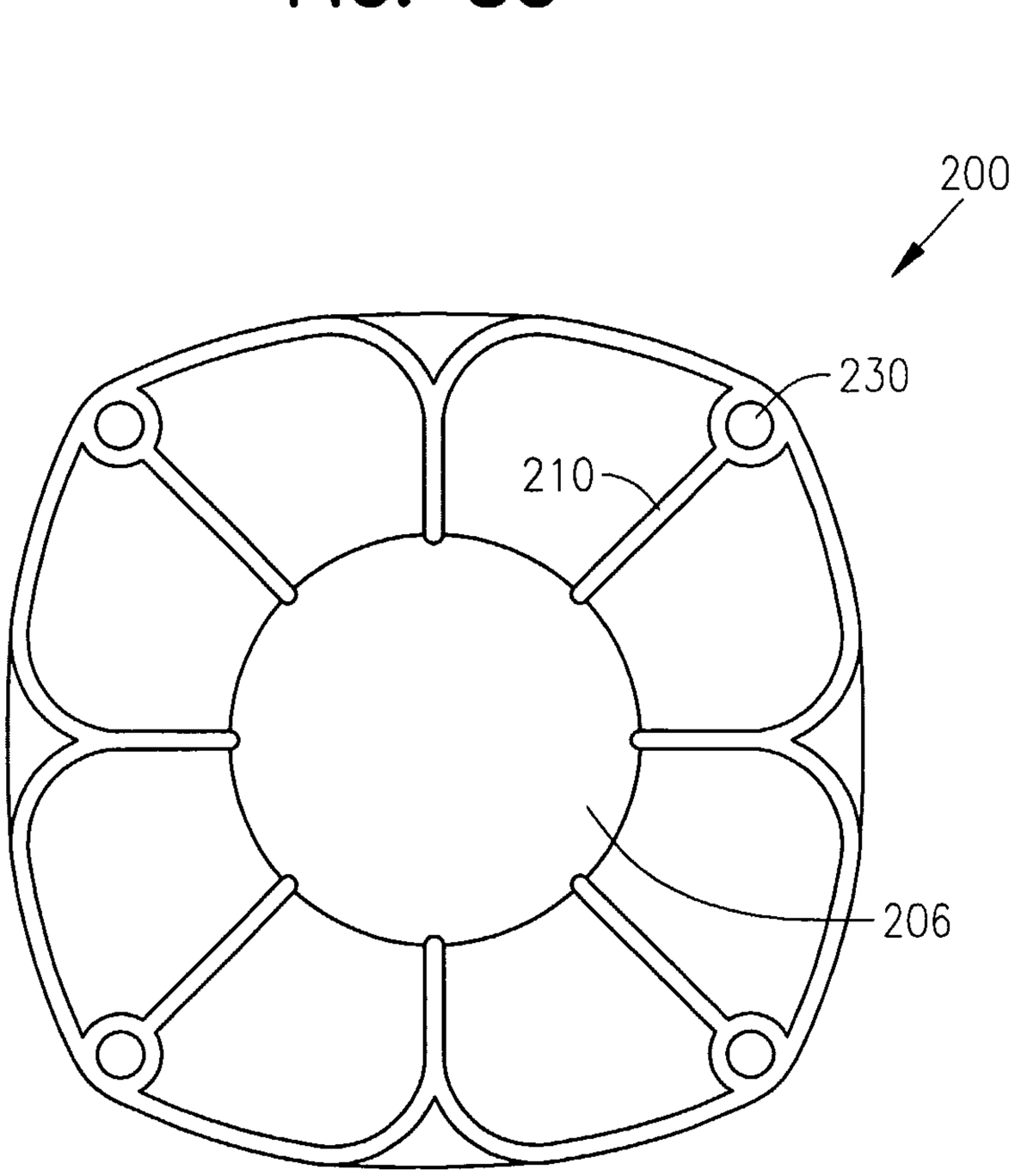


FIG. 8D

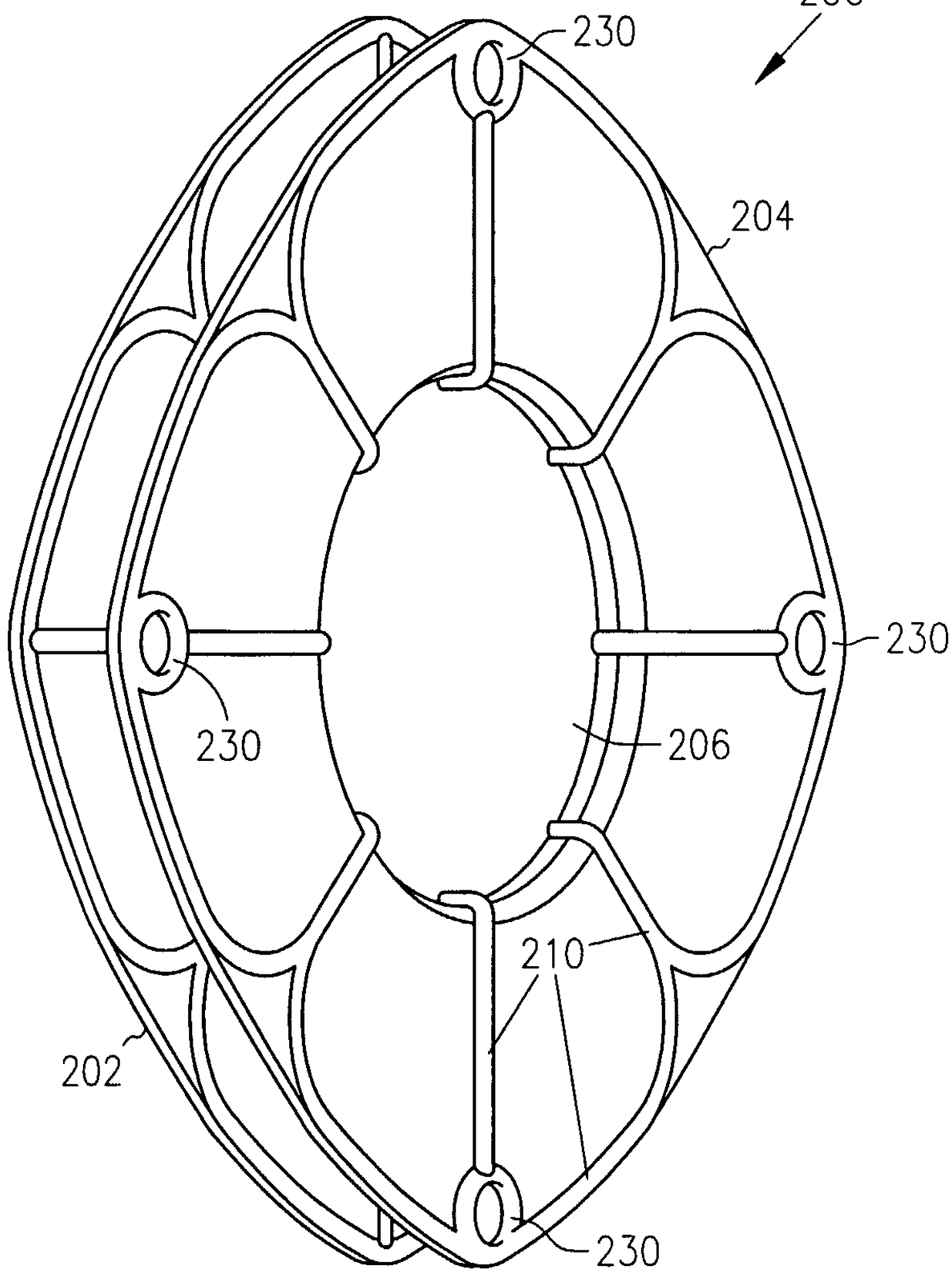


FIG. 8E

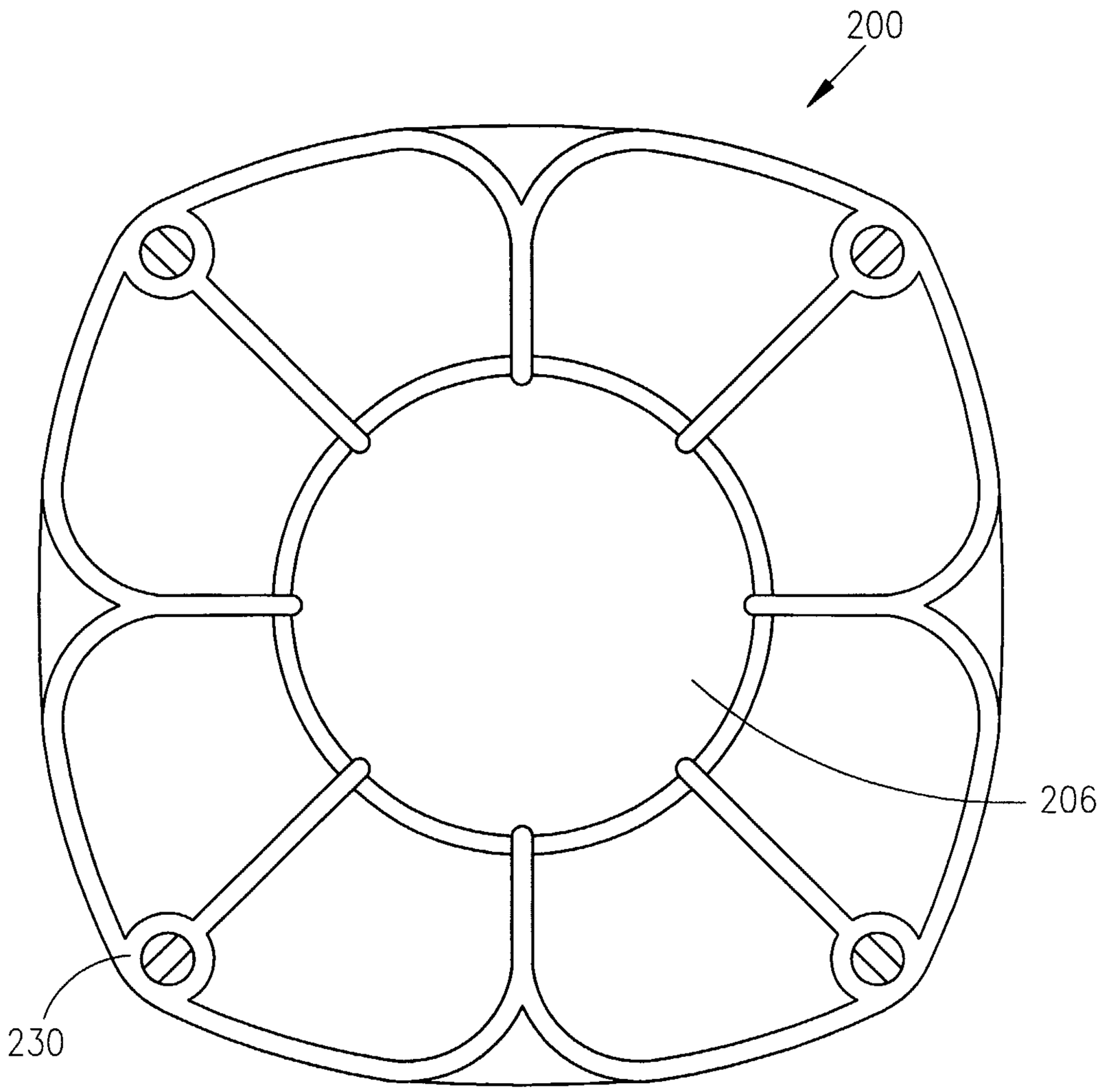


FIG. 9

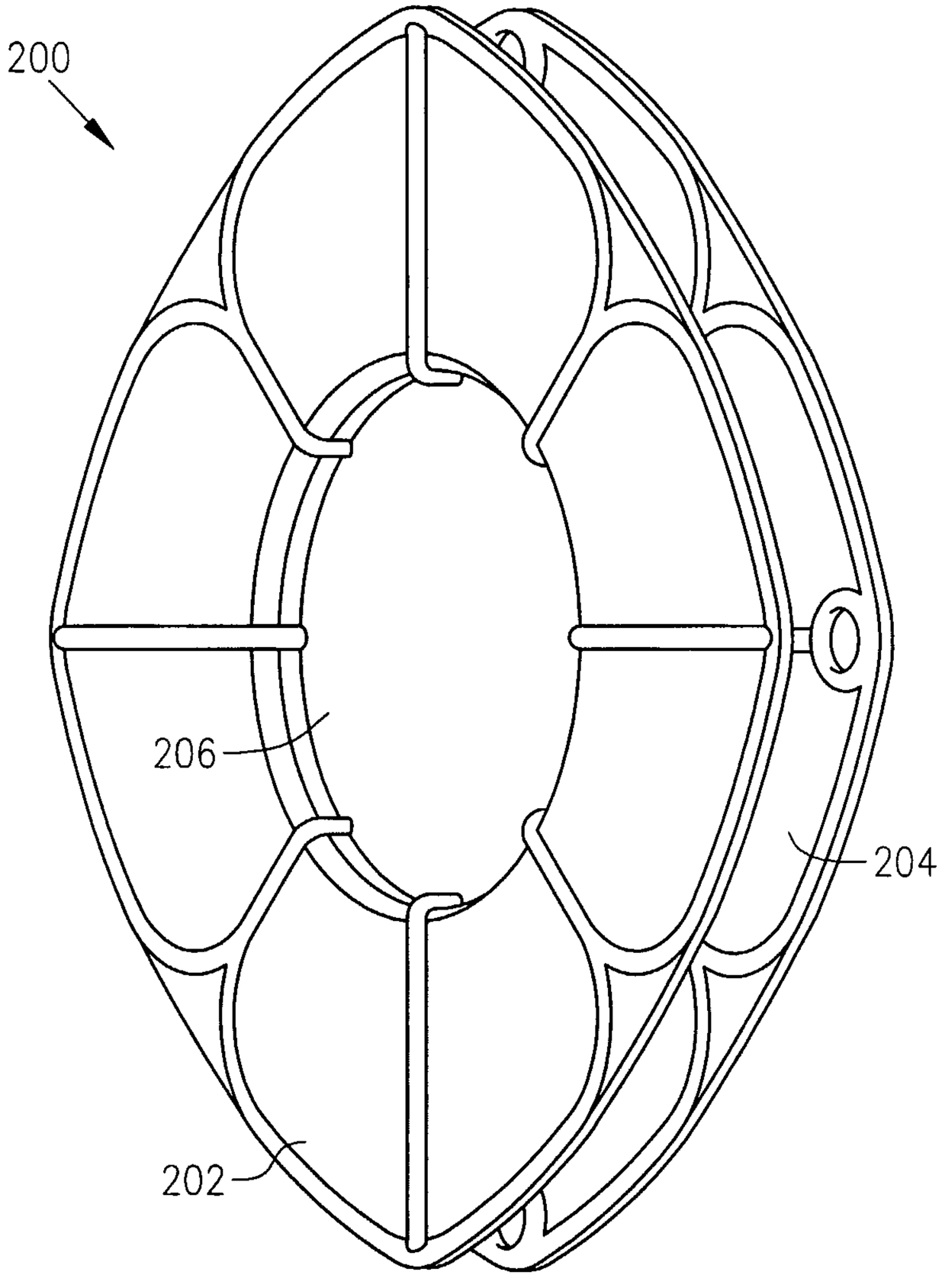


FIG. 10

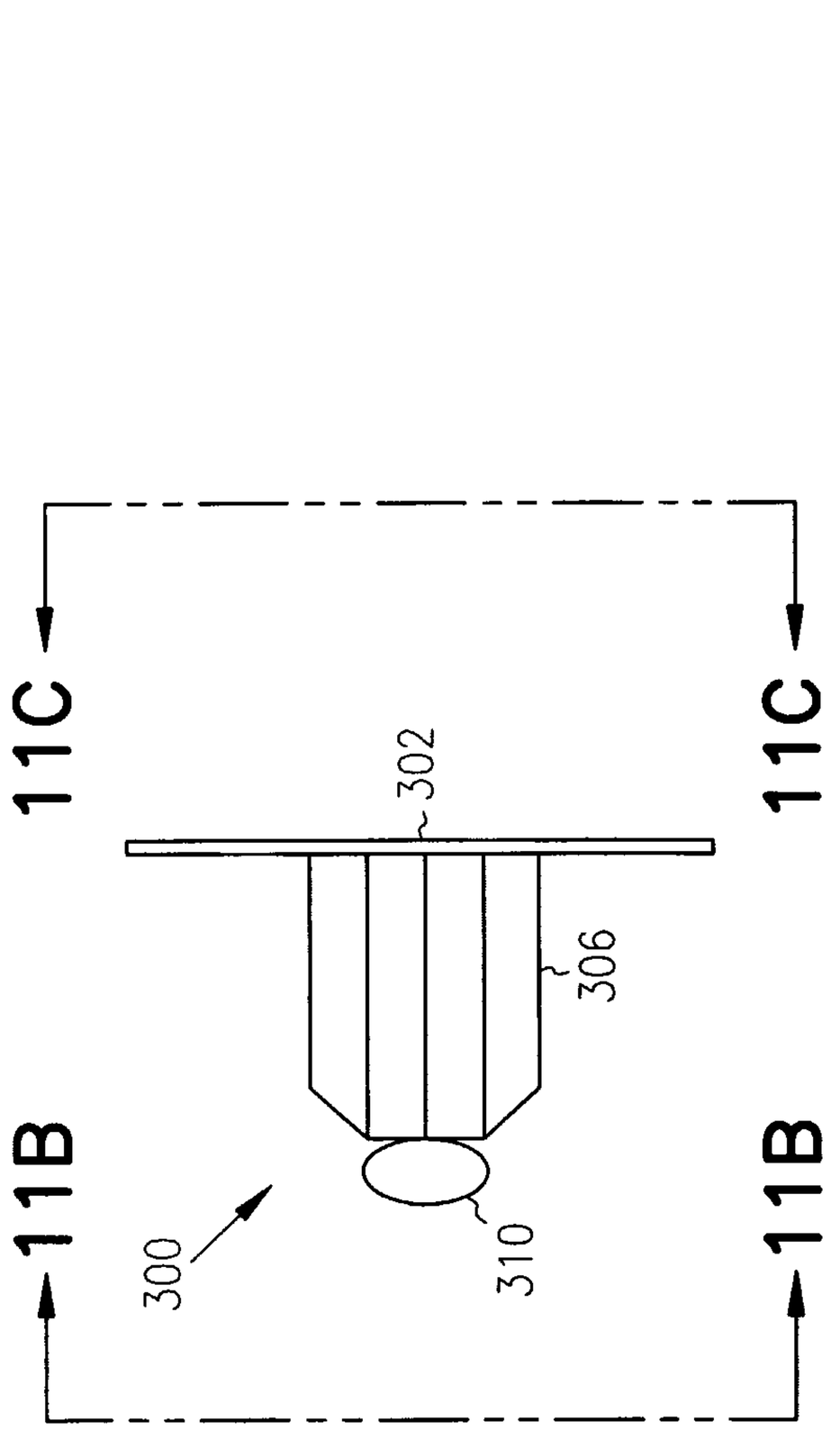


FIG. 11A

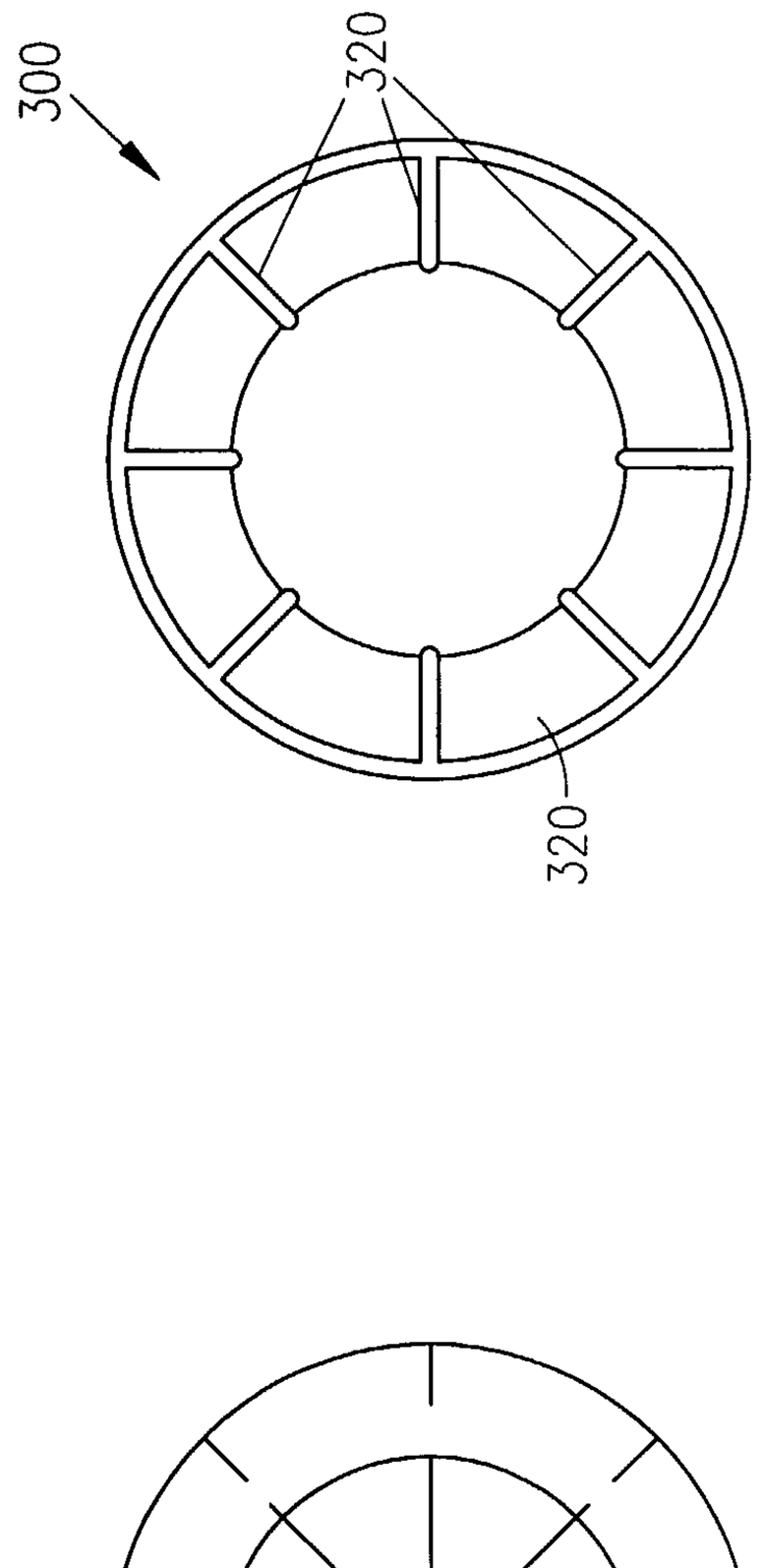


FIG. 11C

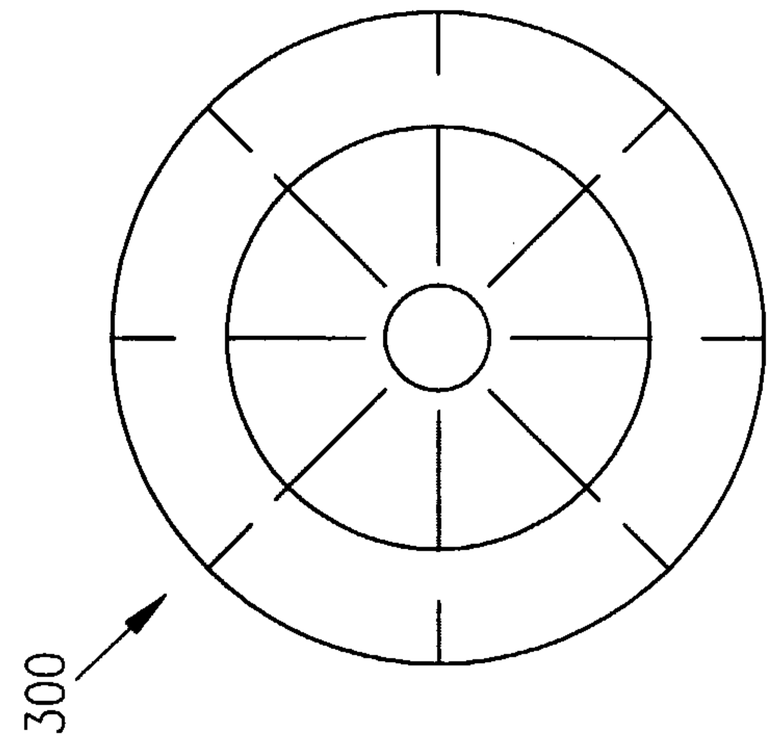


FIG. 11B

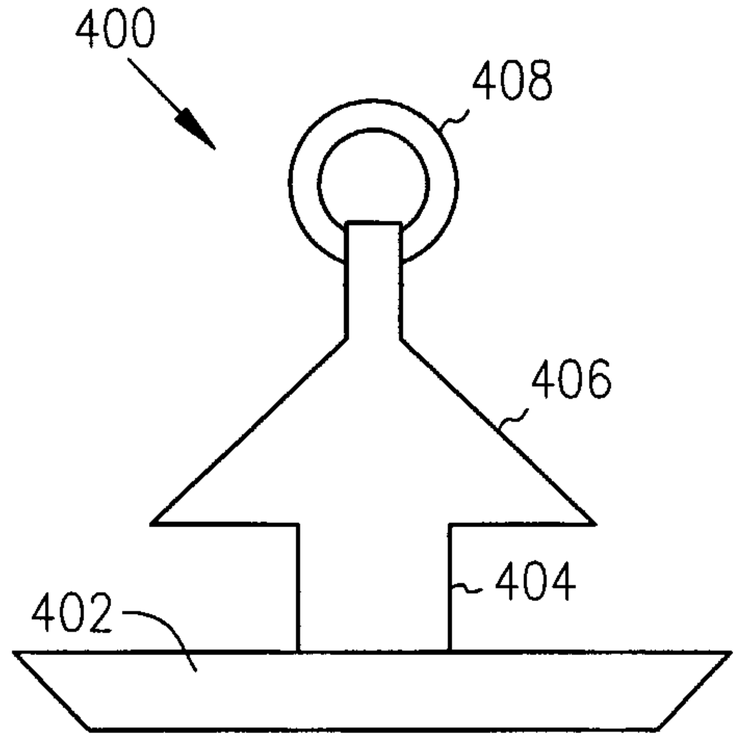


FIG. 12A

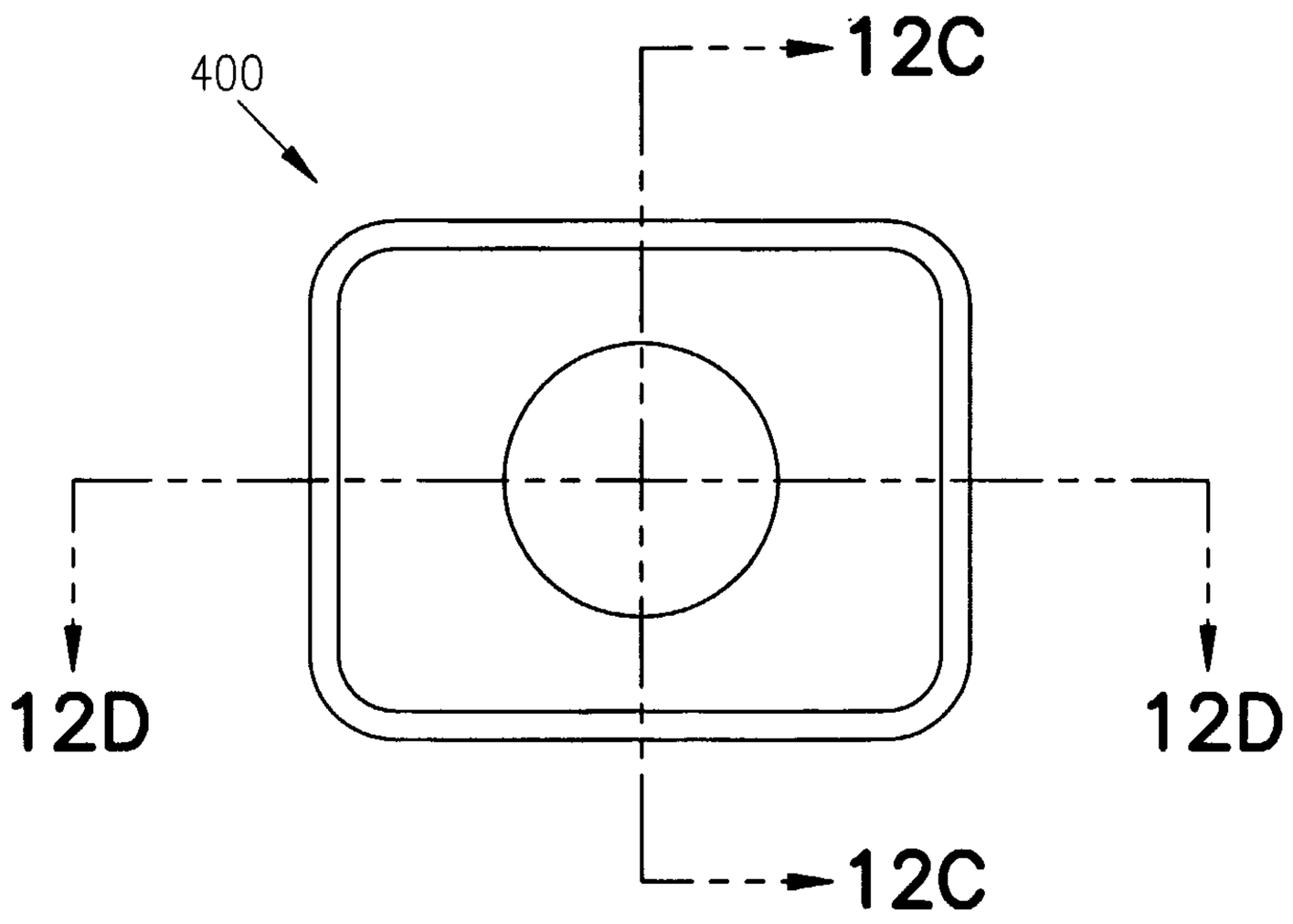


FIG. 12B

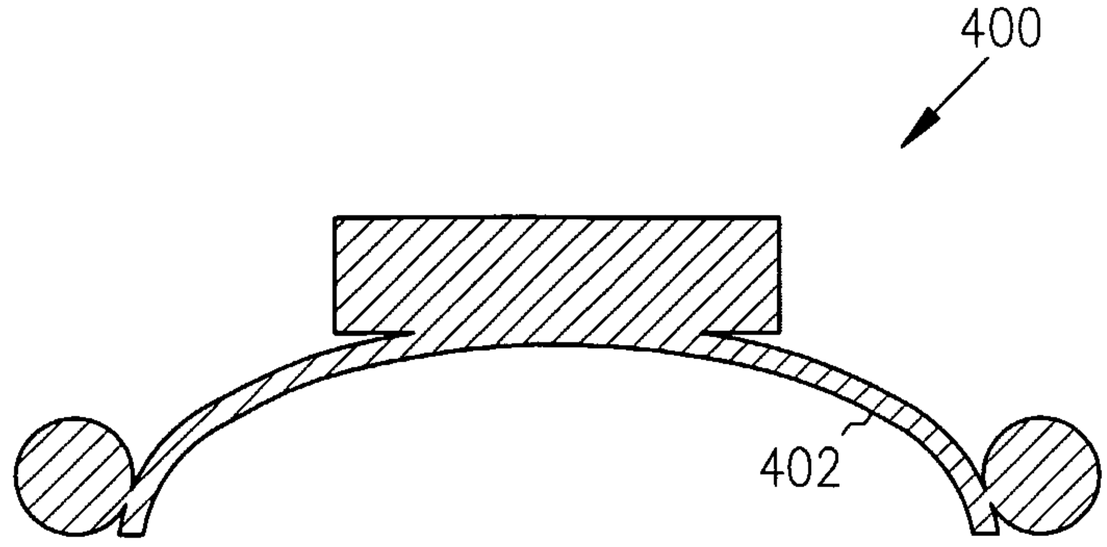


FIG. 12C

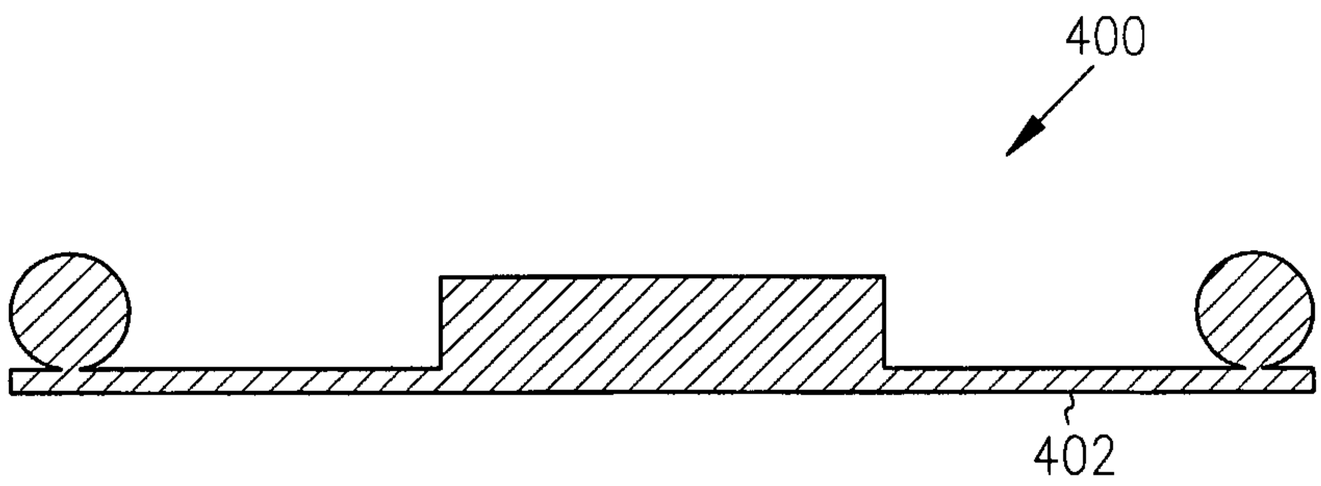


FIG. 12D

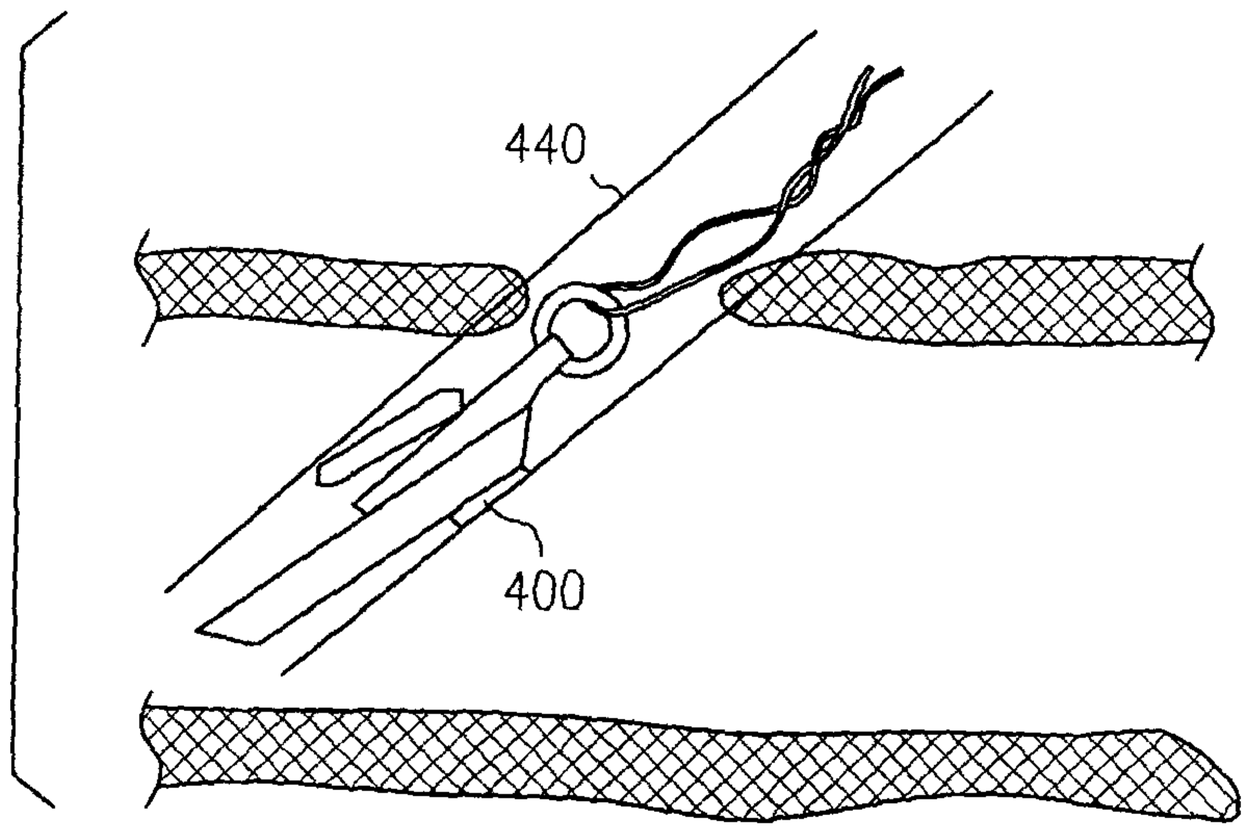


FIG. 13A

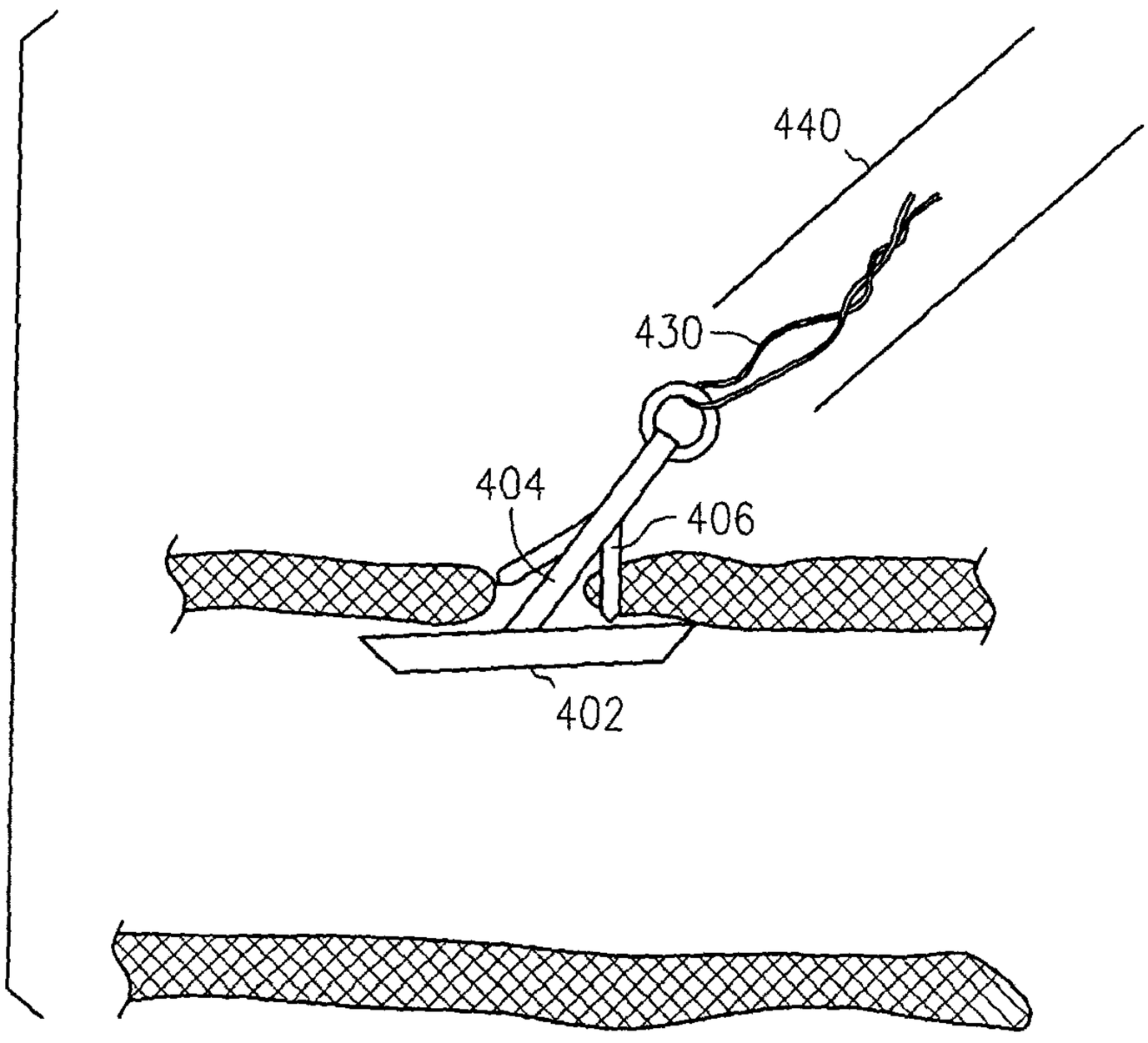


FIG. 13B

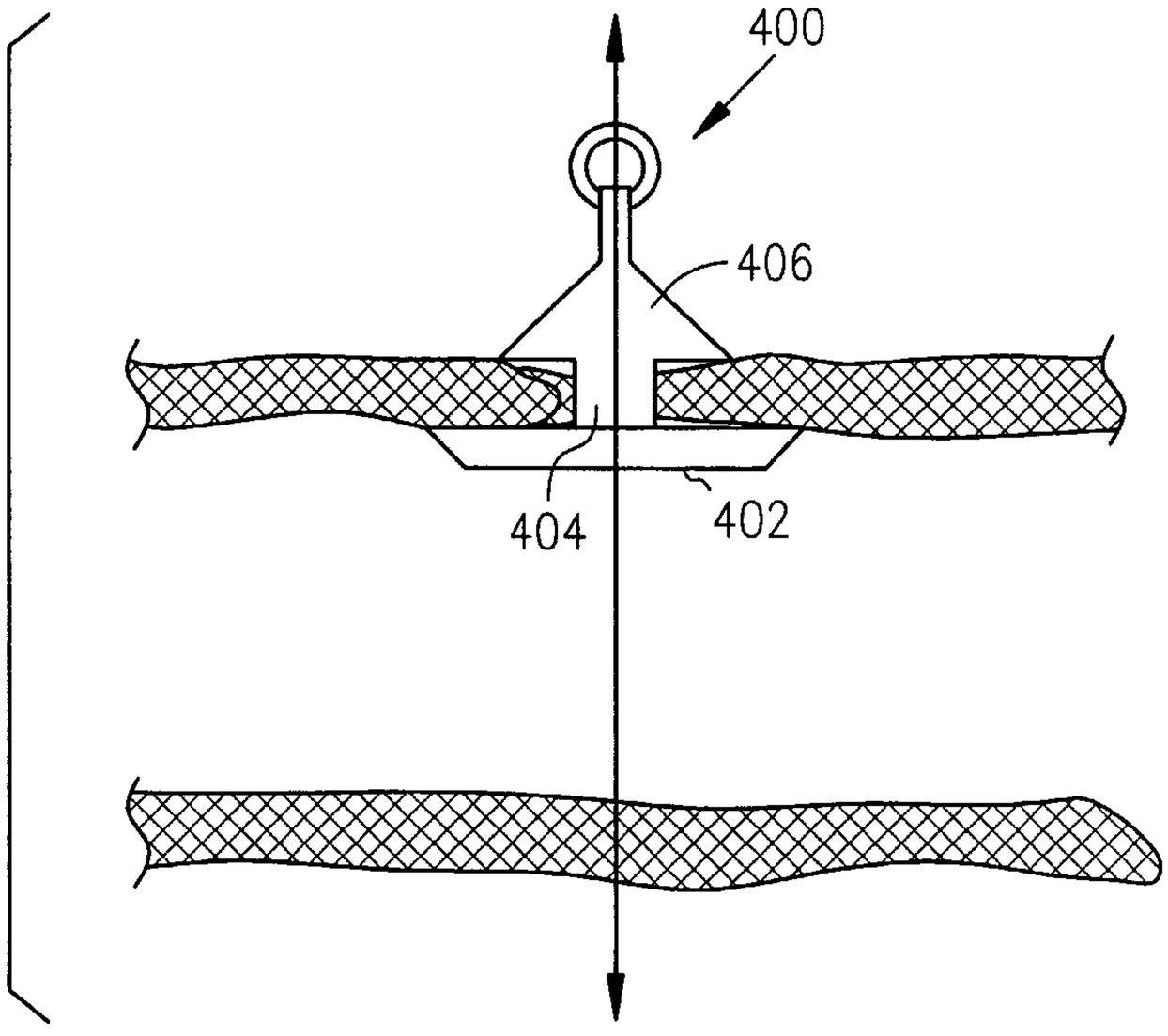


FIG. 13C

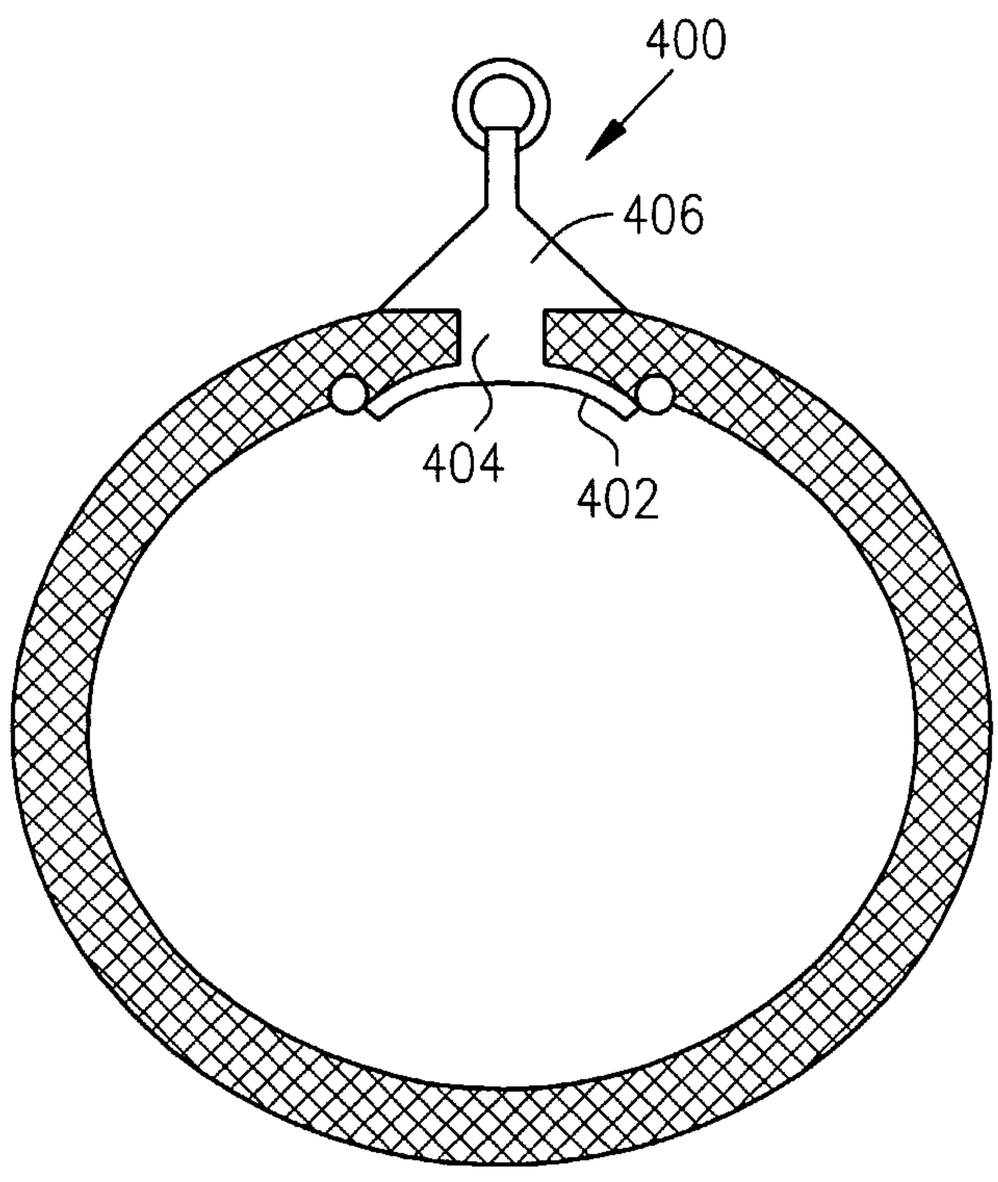
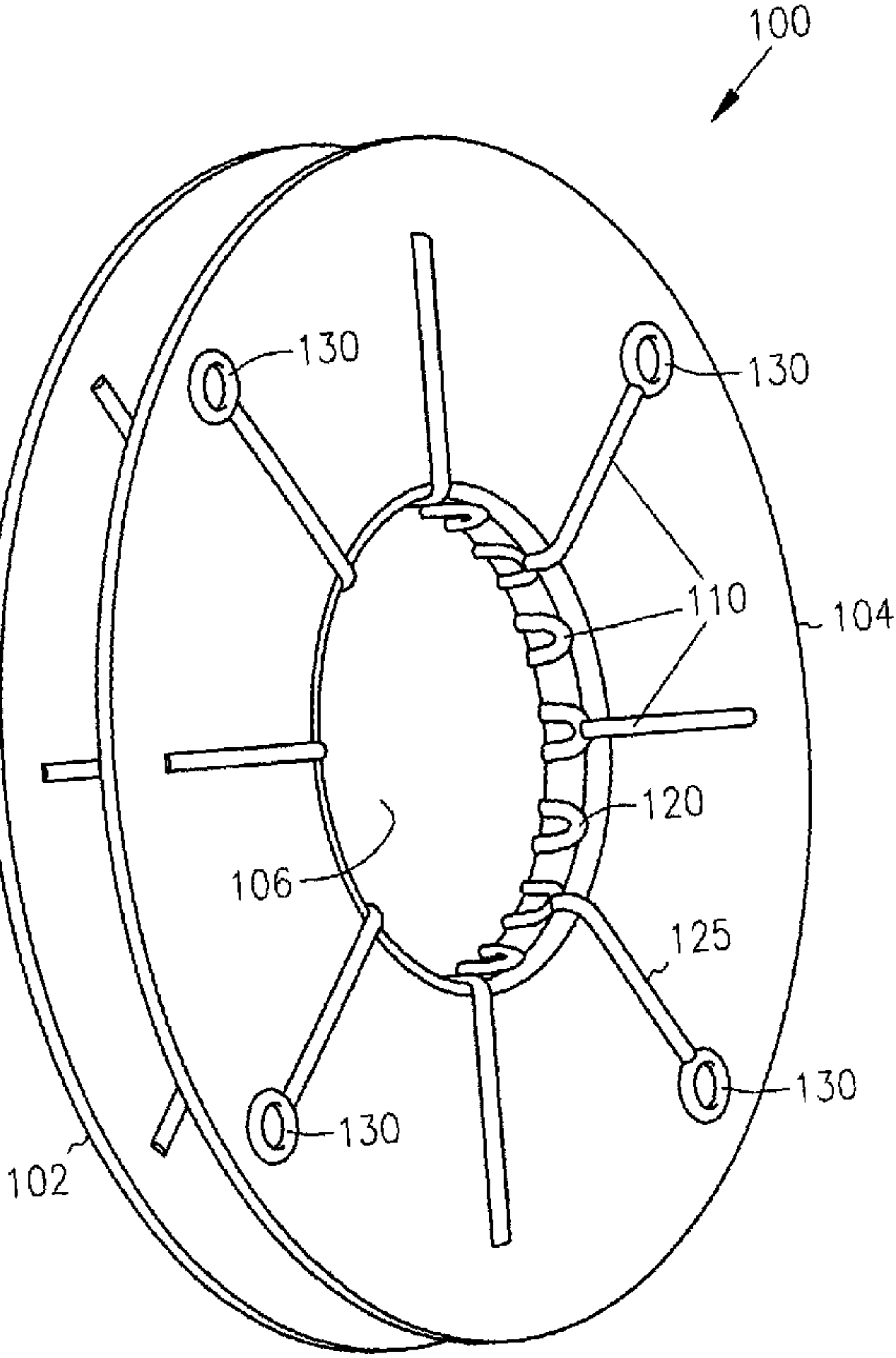


FIG. 13D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