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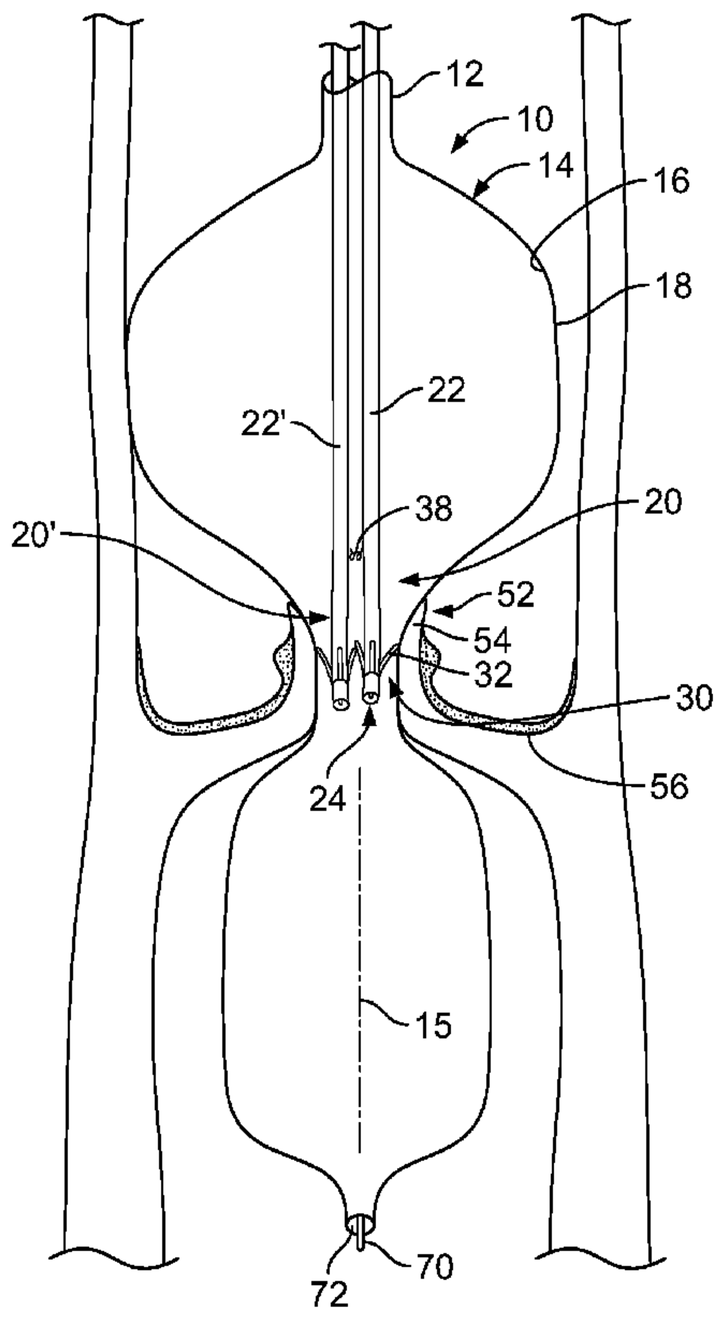
(54) **Titre : CATHETER A ONDE DE CHOC**
(54) **Title: SHOCKWAVE CATHETER**



(57) **Abrégé/Abstract:**
A catheter (10), for use, for example, in valvuloplasty, includes an elongated body (12) and an inflatable balloon (14) carried by the elongated body (12). The balloon (14) has an inner surface (16) and an outer surface (18). The catheter (10) further includes at least one shock wave source (20) within the inflatable balloon (14) and a follower arrangement (30) that maintains the at least one shock wave source (20) a substantially fixed distance from the inner surface (16).of the balloon.

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[Continued on next page]

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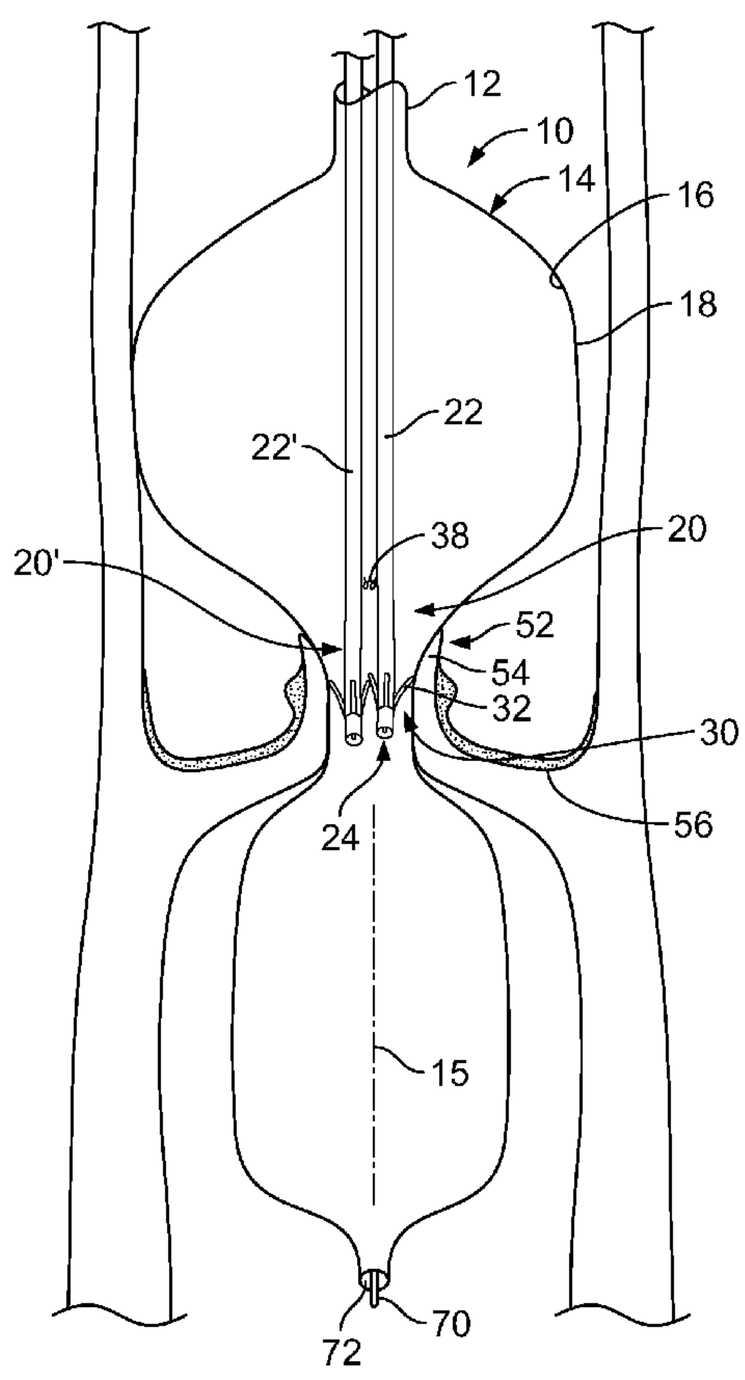

FIG. 1

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SHOCKWAVE CATHETER

[0001]

BACKGROUND

[0002] Patients suffering from aortic valve stenosis often have calcified aortic valve leaflets. Shockwave therapy for the treatment of aortic valve stenosis has been previously described in, for example U.S. Pat. Pub. No. 2010/0114020A1. As described therein, a valvuloplasty catheter includes a balloon that is inflatable with a fluid. When the balloon is inflated, it is configured to be adjacent valve leaflets, such as the valve leaflets of an aortic valve. Within the balloon, there is disposed a shock wave generator. The shock wave generator includes at least two electrodes. When a high voltage pulse is applied across the electrodes, an electrical arc is formed. The electrical arc creates a shock wave within the fluid that propagates to the balloon walls to impinge upon the valve leaflets and the calcification on the valve. Repeated shock waves cause the calcification to break-up.

[0003] The distance between the shock wave generator (the electrodes) and the valve leaflets of the catheter described above is variable and not controlled. It has been found that shock wave therapy designed to break calcium deposits is most effective at certain distances from a radiating shock wave source. This is particularly the case when the source is a point source without a reflector. Generally, the effectiveness of the shock waves falls off or decreases with the square of the distance from the source.

[0004] When a valvuloplasty balloon and a shock wave generator are combined as described above, the distance between the shock wave generator and the balloon walls generally increases as the valve is opened by balloon expansion occasioned by effective treatment and valvuloplasty pressure. As the distance changes and becomes greater, the effectiveness of the therapy decreases. This increases both the time and the number of shock waves required for complete

and effective treatment. Hence, there is a need for a shock wave valvuloplasty catheter that maintains therapy effectiveness at a desired level until the valve being treated is dilated the desired amount.

SUMMARY

[0005] According to embodiments shown and described herein, a catheter, which may find use, for example, in valvuloplasty, includes an elongated body and an inflatable balloon carried by the elongated body. The balloon has an inner surface and an outer surface. The catheter further includes at least one shock wave source within the inflatable balloon and a follower arrangement that maintains the at least one shock wave source a substantially fixed distance from the inner surface of the balloon.

[0006] The follower arrangement may be carried by the at least one shock wave source within the inflatable balloon. The at least one shock wave source may be an arc generator including an electrode pair.

[0007] The follower arrangement may include at least one stand-off extending from the electrode pair. The stand-off may be formed of flexible material.

[0008] The arc generator may include an elongated lead. The electrode pair may be carried by the elongated lead, and the elongated lead may be biased in a direction towards the inner surface of the inflatable balloon. The elongated lead may include at least one bend that biases the elongated lead towards the inner surface of the inflatable balloon.

[0009] The catheter may further include a biasing member carried by the elongated lead that biases the elongated lead towards the inner surface of the inflatable balloon. The biasing member may be a spring.

[0010] The at least one shock wave source may include an arc generator. The follower arrangement may include a stand-off carried by the arc generator and the arc generator may be biased towards the inner surface of the inflatable balloon.

[0011] The catheter may further include a frame structure that carries the at least one shock wave source. The frame structure may be arranged to expand with inflation of the inflatable balloon to maintain the at least one shock wave source a substantially fixed distance from the

inner surface of the balloon. The frame structure may include at least one stand-off adjacent the at least one shock wave source to maintain the at least one shock wave source a substantially fixed distance from the inner surface of the balloon.

[0012] In other embodiments, a method includes the steps of providing a catheter including an elongated body, an inflatable balloon carried by the elongated body and having an inner surface and an outer surface, and at least one shock wave source within the inflatable balloon. The method further includes the steps of inserting the catheter into a vein or artery of a patient and placing the balloon adjacent to an anatomical structure to be treated, inflating the balloon with a fluid, causing the shock wave source to provide shock waves within the balloon that propagate through the liquid to treat the anatomical structure, and maintaining the at least one shock wave source a substantially fixed distance from the inner surface of the balloon while the shock waves are provided by the at least one shock wave source.

[0013] The catheter may further include a follower carried by the shock wave generator, and the maintaining step may include biasing the follower against the inner wall of the balloon.

[0014] The catheter may include a frame structure that carries the at least one shock wave source. The maintaining step may include expanding the frame structure with inflation of the inflatable balloon to maintain the at least one shock wave source the substantially fixed distance from the inner surface of the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The various described embodiments of the invention, together with representative features and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like reference numerals identify identical elements, and wherein:

[0016] FIG. 1 is a partial cut away view of a heart and a catheter embodying aspects of the invention within the aortic valve of the heart;

[0017] FIG. 2 is a side view of a shock wave generator which may be used to advantage within the catheter of FIG. 1 and which embodies aspects of the invention;

[0018] FIG. 3 is a partial cut away view of the heart of FIG. 1 illustrating the catheter as it is delivering therapy to the aortic valve of the heart;

[0019] FIG. 4 is a partial cut away view of the heart of FIG. 1 illustrating the catheter upon completion of therapy to the aortic valve of the heart;

[0020] FIG. 5 is a partial cut away view of another heart and another catheter embodying further aspects of the invention within the aortic valve of the heart; and

[0021] FIG. 6 is a partial view to an exploded scale illustrating particular aspects of the catheter of FIG. 5.

DETAILED DESCRIPTION

[0022] Referring now to FIG. 1, it is a partial cut away view of the aorta 50 of a heart and a catheter 10 embodying aspects of the invention within the aortic valve 52 of the heart. The catheter 10 generally includes an elongated body 12, an inflatable balloon 14 carried by the elongated body 12, at least one shock wave source 20 within the inflatable balloon 14, and a follower arrangement 30. The balloon includes an inner surface 16 and an outer surface 18. The follower arrangement 30 is carried by the shock wave source 20. As will be seen subsequently, the follower arrangement maintains the at least one shock wave source 20 a substantially fixed distance from the inner surface 16 of the balloon.

[0023] The balloon 14 is inflatable through the elongated body 12 with a fluid such as, for example, saline. The balloon is configured so that when positioned within the aortic valve 52, its outer surface 18 substantially conforms to and is immediately adjacent to or in contact with the aortic valve leaflets 54 and the calcification 56 thereon.

[0024] The shock wave source 20 preferably is an arc generator that produces electrical arcs that form rapidly expanding and contracting steam bubbles within the balloon 14. The rapidly expanding and contracting steam bubbles form shock waves within the balloon 14 that propagate through the fluid within the balloon and impinge upon the inner surface 16 of the balloon 14 and the calcification 56. After repeated shock waves, the calcification is broken up to permit the aortic valve 52 to function. The follower arrangement 30 maintains the shock wave source a substantially fixed distance from the inner surface 16 of the balloon 14 and hence the valve

leaflets 54 to maintain full effectiveness of the shock waves during the shock wave application procedure.

[0025] FIG. 1 also shows that the catheter 10 is arranged to accept a guide wire 70. The guide passes through a guide wire lumen 72 and serves to guide the catheter into an artery or vein to place the balloon adjacent an anatomical structure to be treated such as an aortic valve. Once the balloon is thus positioned, it may be inflated and the shock wave therapy begun.

[0026] As may be seen in FIG. 2, the shock wave source or generator 20 includes an elongated lead 22 and an electrode pair 24 carried by the lead 22. The electrode pair 24 is formed by a pair of coaxially disposed electrodes including a ring electrode 26 and a center electrode 28. Voltage pulses are applied across electrodes 26 and 28 through the lead 22 to cause the arcs which produce the shock waves.

[0027] The catheter 10 of FIG. 1 includes two shock wave sources 20 and 20'. The shock wave source 20' may be identical to the shock wave source 20. Each shock wave source carries a follower arrangement. In the embodiment of FIG. 1, a spring 38 is attached to and in between the leads 22 and 22' of the shock wave sources 20 and 20', respectively. The spring 38 serves as a biasing member to force the electrode pairs of the shock wave sources and the follower arrangements off of the center axis 15 of the balloon 14 towards the inner surface 16 of the balloon 14.

[0028] Alternatively, or in addition, as may be seen in FIG. 2, the lead 22 may have permanent bends 34 and 35 formed therein. The bends bias the electrode pair 24 in the direction indicated by arrow 36 towards the inner surface 16 of the balloon 14.

[0029] Hence, FIG. 1 shows a valvuloplasty system having a catheter 10 according to some aspects of the invention that includes a valvuloplasty balloon 14 with two electrodes (electrode pair 24) disposed therein. The system is shown within an aortic valve 52 for treating calcification 56 on the valve leaflets 54. The electrodes are urged away from the center axis 15 of the balloon 14 toward the perimeter of the balloon 14 by a spring member 38. As may be appreciated, the spring member may be replaced by spring loading or biasing the leads 22 and 22' that carry the electrodes outwardly. The balloon 14 is shown within a severely stenosed valve 52. Stand offs 32 carried on electrodes maintain a substantially constant distance between

electrodes and the walls of the balloon 14 and hence between the electrodes and the valve leaflets 54.

[0030] Further, FIG. 2 shows a detailed view of one electrode pair 24 and its lead 22. The standoffs 32 are formed by soft flexible arms that are designed to hold the electrode pair 24 off the balloon wall in non-touching relation to the balloon material. They are also designed to hold the tip of the electrode pair 24 a substantially constant distance, for example, 1-2 mm, from the balloon wall. At the same time, according to this embodiment, the elongated lead 22 has bends 34 and 35 to provide a predetermined bias toward the outside (away from the center axis) of the balloon.

[0031] FIG. 3 is a partial sectional view showing the valvuloplasty balloon 14 placed in an aortic valve 52 and after providing some treatment to break up or sever the calcium deposits 56 on the valve leaflets 52. The electrode pairs 24 have been held a substantially constant distance, for example about 1-2 mm, from the tissue by the stand offs since the electro-hydraulic shock therapy began. As the shock waves break the calcium, the opening 60 in the valve 52 slowly widens. Even though the valve is being opened wider, the distance between the electrode pairs 24 and the tissue of the leaflets 54 remains substantially constant, controlled by the stand offs 32 and the bends 34 and 35 in the electrode leads.

[0032] FIG. 4 shows a fully opened opening 60 of valve 52 expanded by the combination valvuloplasty balloon 14 and the shock wave therapy. The bias in the catheter and the standoffs hold the electrode pairs a substantially constant distance from the tissue of the valve being treated. For simplicity, only two electrode pairs are shown. However, in actual practice, as many as 3-9 electrode pair may typically be used. The electrode pairs 24 can be fired (provided with arc forming voltage) alternately or simultaneously. The calcium on the valve 52 and its softened valve leaflets 54 (and valve cusps) is now cracked making the valve much better prepared for the placement of a TAVI (Transcatheter Aortic-Valve Implantation) valve. In addition, the native valve 52 may function on its own without a replacement.

[0033] FIG. 5 shows an alternate embodiment. Here, a catheter 110 includes an elongated body 112 and an inflatable balloon 114, as in previous embodiments. Here, however, the shock wave sources 120, which may be electrode pairs, are mounted on a basket or frame structure 122 having basket arms or frame elements 124. The basket arms 124 may be formed of Nitinol and

may be set to expand with the balloon 114 as the stenosis of the aortic valve being treated is softened and expanded by the shock waves.

[0034] FIG.6 shows the Nitinol arms 124 in greater detail with respect to the shock wave sources 120. Here it may be seen that the arms 124 may be configured with bumps or stand offs 132 to hold the shock wave sources 120 away from the balloon and tissue a substantially fix distance during the shock wave treatment.

[0035] FIG. 6 also shows that, as in previous embodiments, the catheter 112 may accommodate a guide wire 170. The guide wire 170 may be received within a guide wire lumen 172 and used, as previously described, to guide the catheter into proper position.

[0036] While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended to cover in the appended claims all such changes and modifications which fall within the true spirit and scope of the invention.

CLAIMS:

1. A catheter comprising:

an elongated body;

an inflatable balloon carried by the elongated body, the balloon having an inner surface and an outer surface;

an elongated lead carrying at least one shock wave source located within the inflatable balloon;

means for biasing the shock wave source towards the inner surface of the balloon; and

a stand-off attached to the lead and configured to space the shock wave source a fixed distance from the inner surface of the balloon.

2. The catheter of claim 1, wherein said stand-off is formed from a flexible material.

3. The catheter of claim 1 or 2, wherein the biasing means comprises at least one bend in the lead.

4. The catheter of claim 1 or 2, wherein the biasing means is a spring.

5. The catheter of claim 1 or 2, wherein the biasing means comprises a frame structure attached to the lead and carrying the shock wave source, wherein the frame structure expands with inflation of the inflatable balloon to move the shock wave source towards the inner surface of the balloon, and wherein the stand-off is formed as part of the frame structure.

6. The catheter of any one of claims 1 to 5, wherein the at least one shock wave source is an arc generator.

7. The catheter of claim 6, wherein the arc generator comprises an electrode pair.

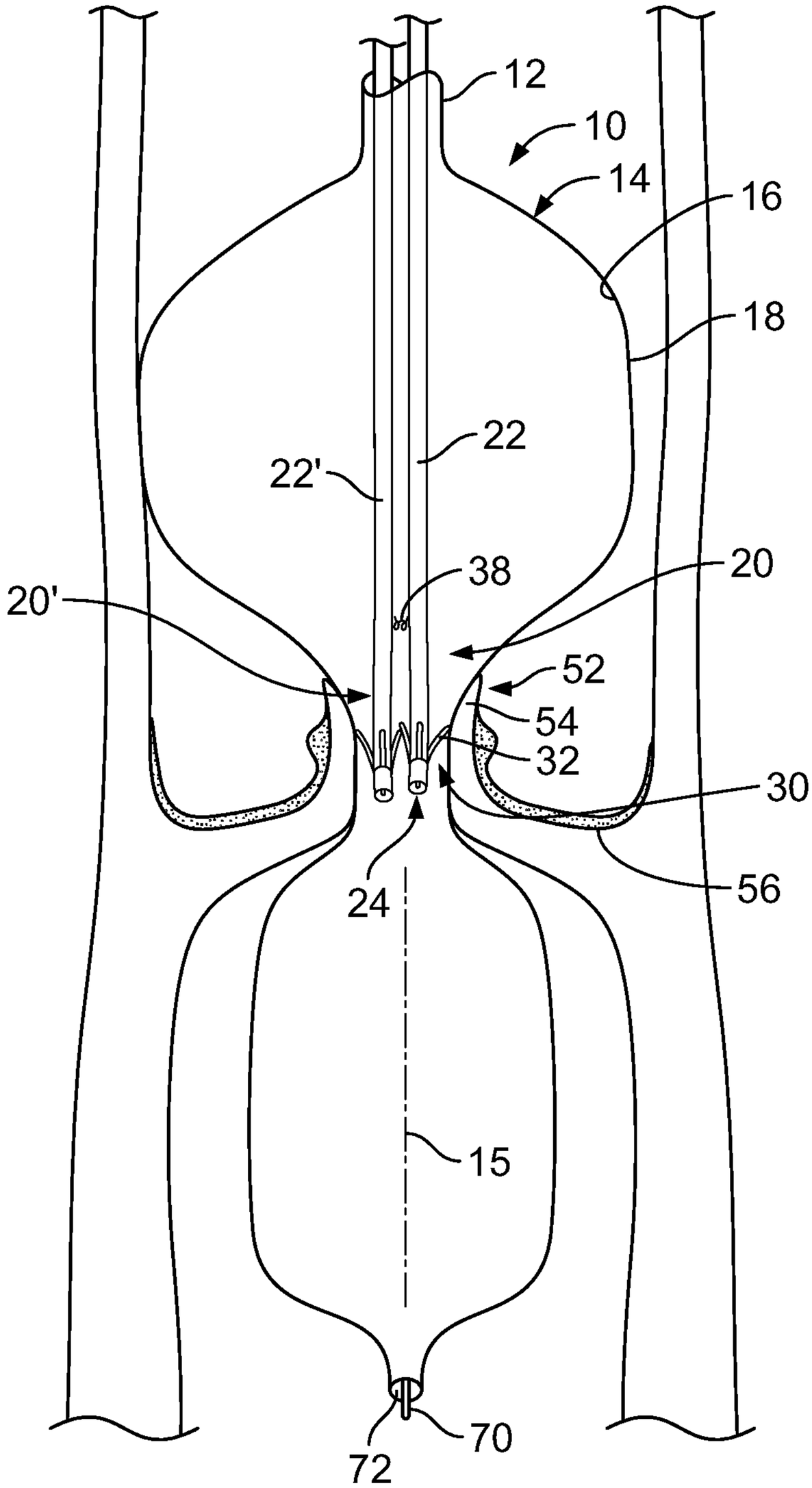
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FIG. 1

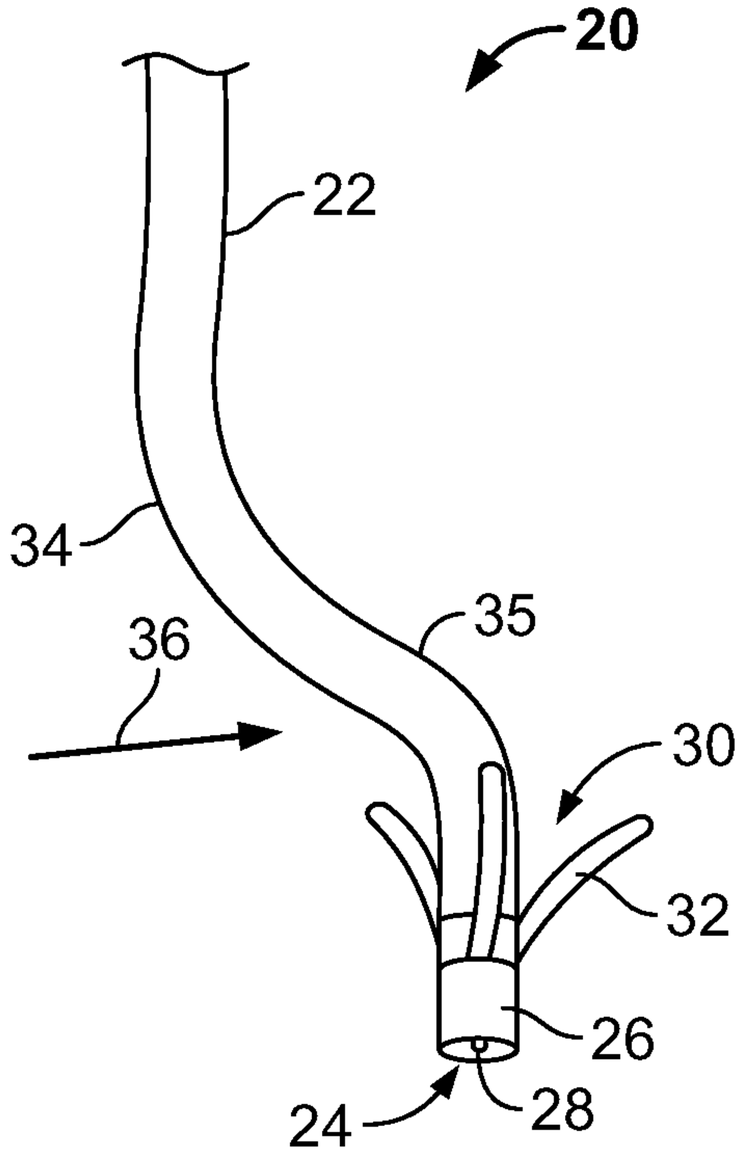
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FIG. 2

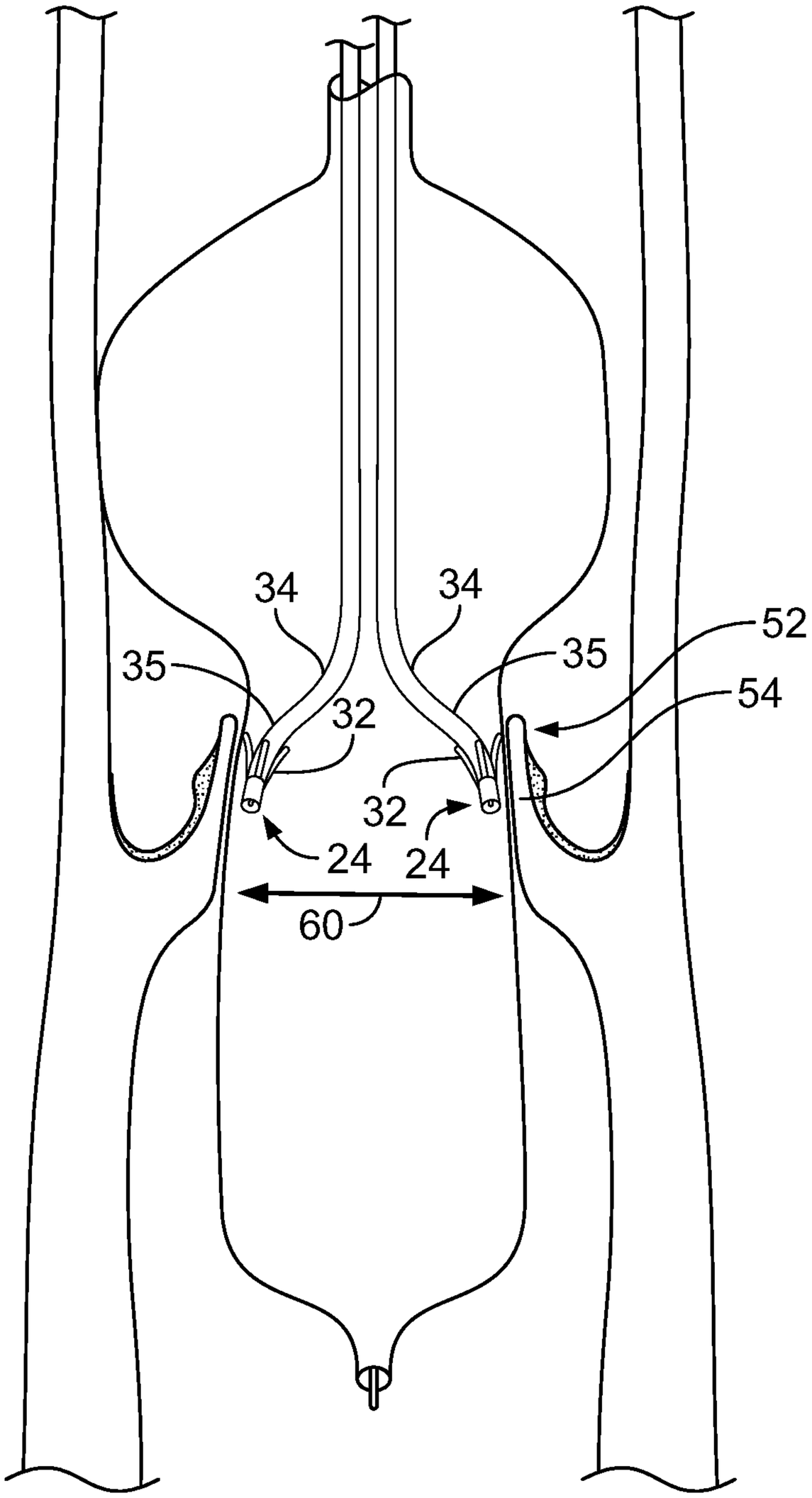


FIG. 3

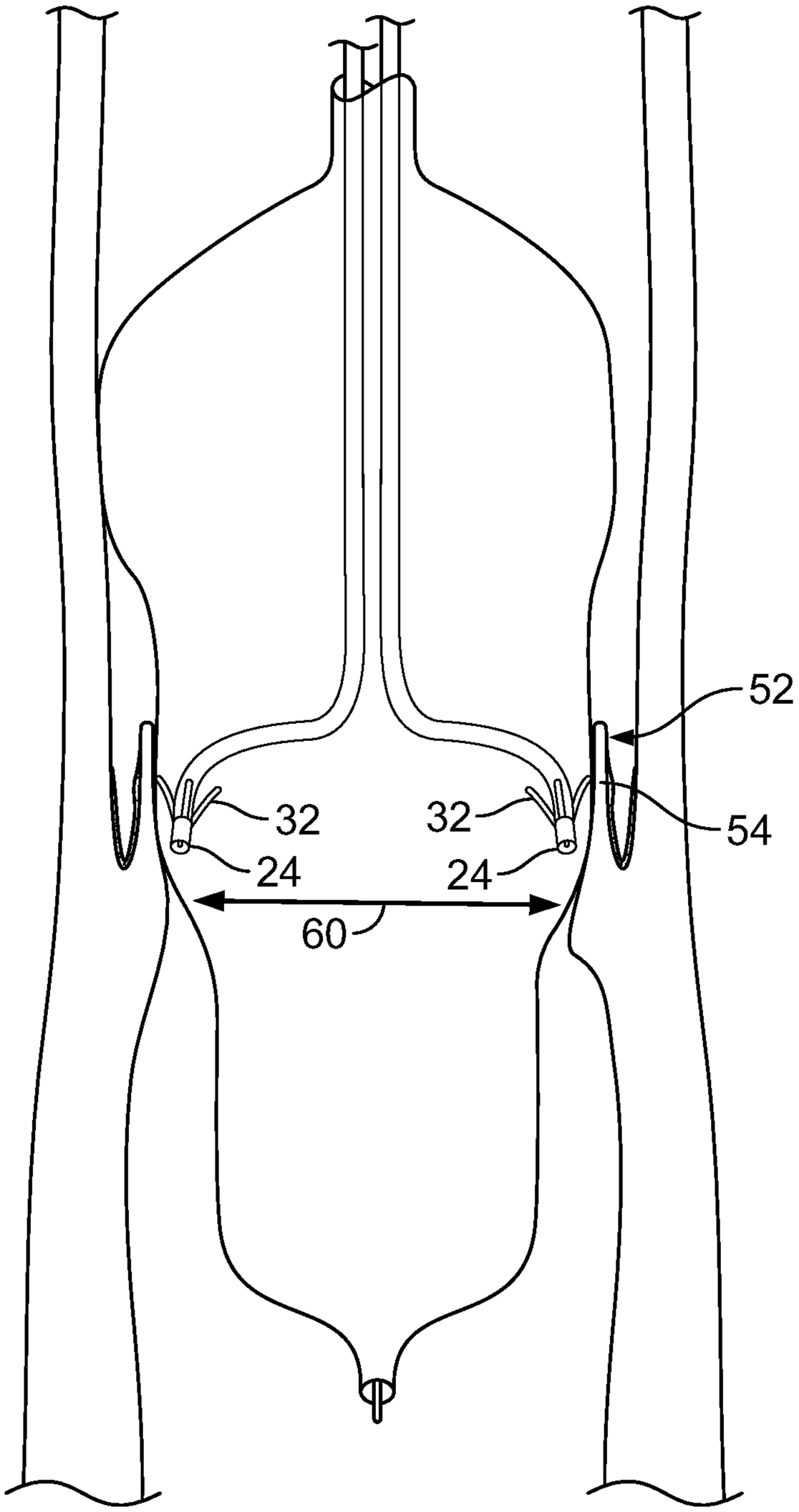


FIG. 4

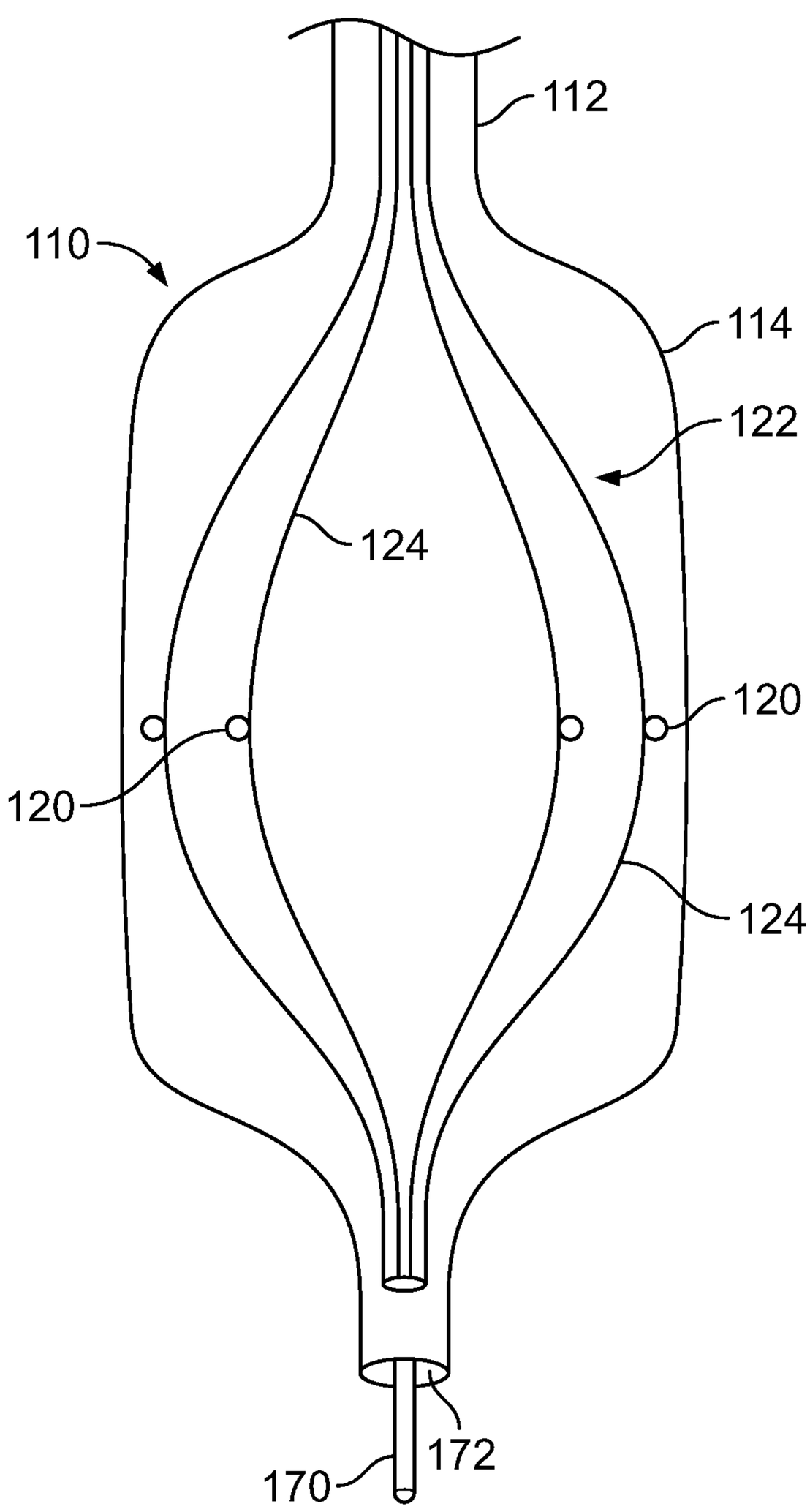


FIG. 5

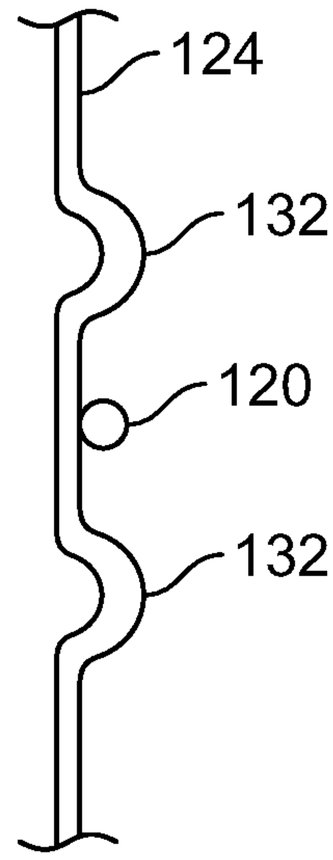
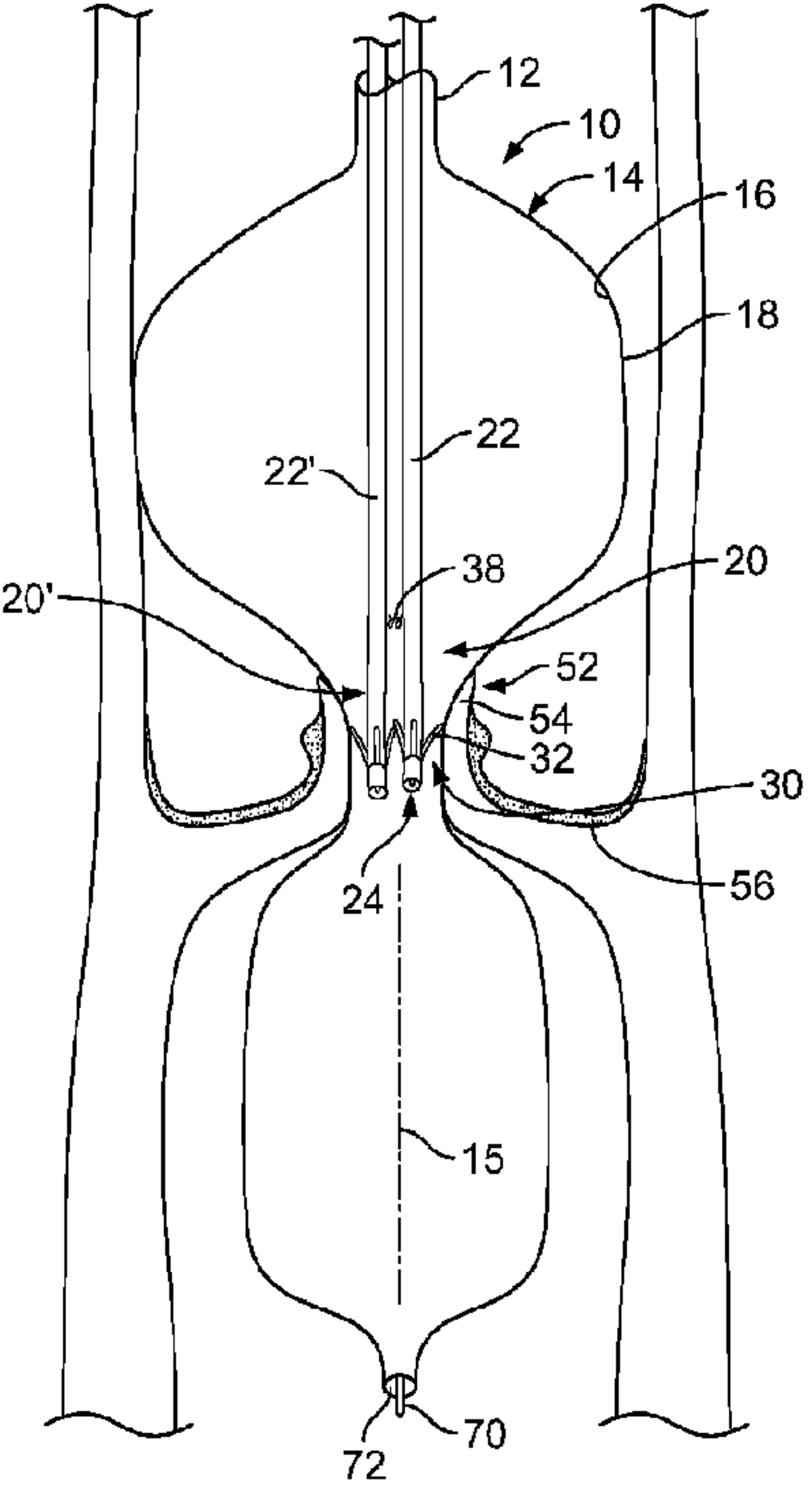


FIG. 6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