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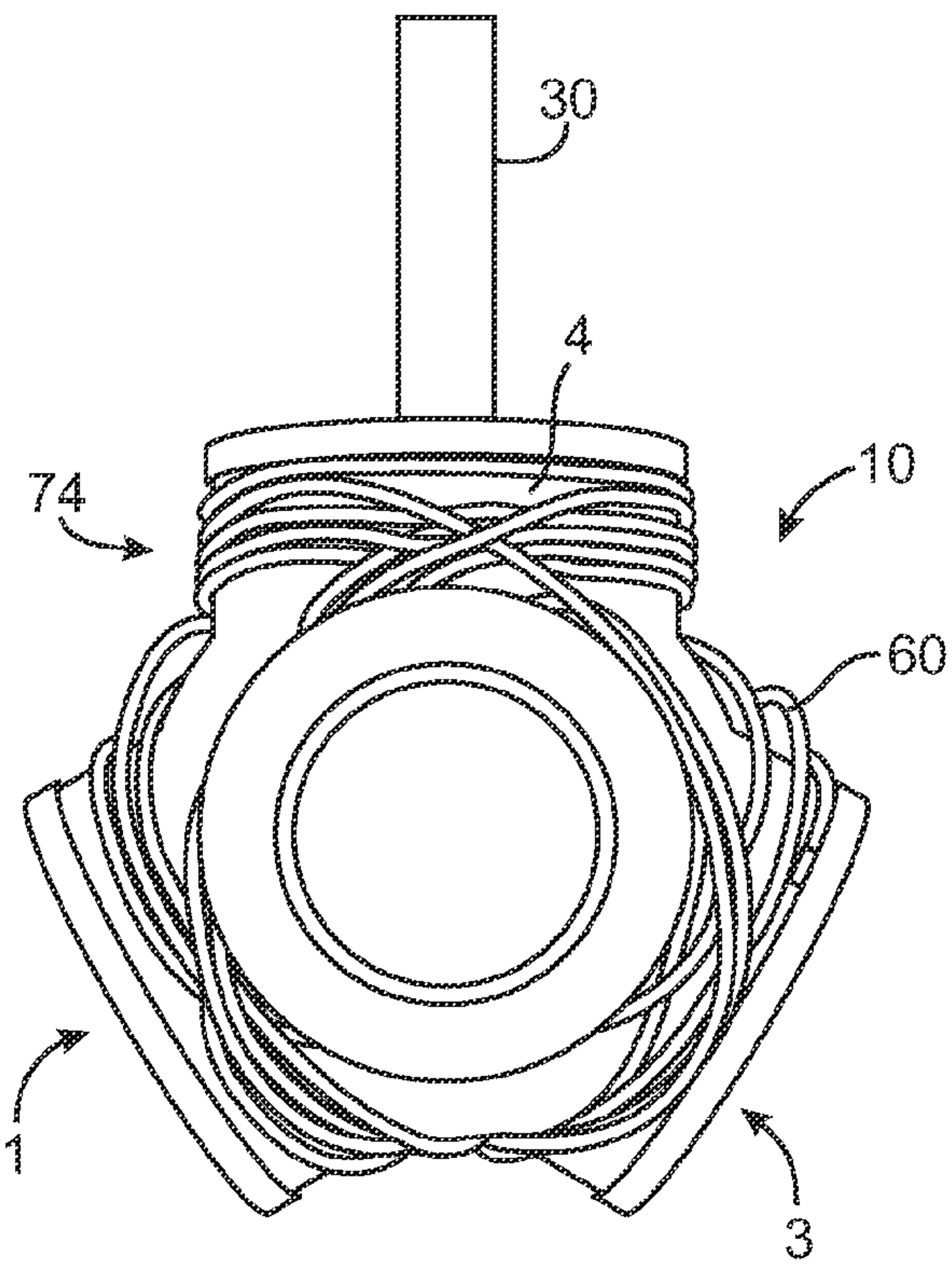

(57) **Abrégé/Abstract:**
This invention is directed to an implant having a coil (60) for embolizing a vascular site, such as aneurysm. The coil has a specific three-dimensional shape that is achieved by winding the coil around a mandrel (10) in a specific pattern and then heat setting the coil and the mandrel, another aspect of the invention. The three-dimensional shape resembles unclosed mobius loops. Also provided are methods of making the coil and methods of embolizing vascular site.

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(54) **Title:** AN IMPLANT, A MANDREL, AND A METHOD OF FORMING AN IMPLANT

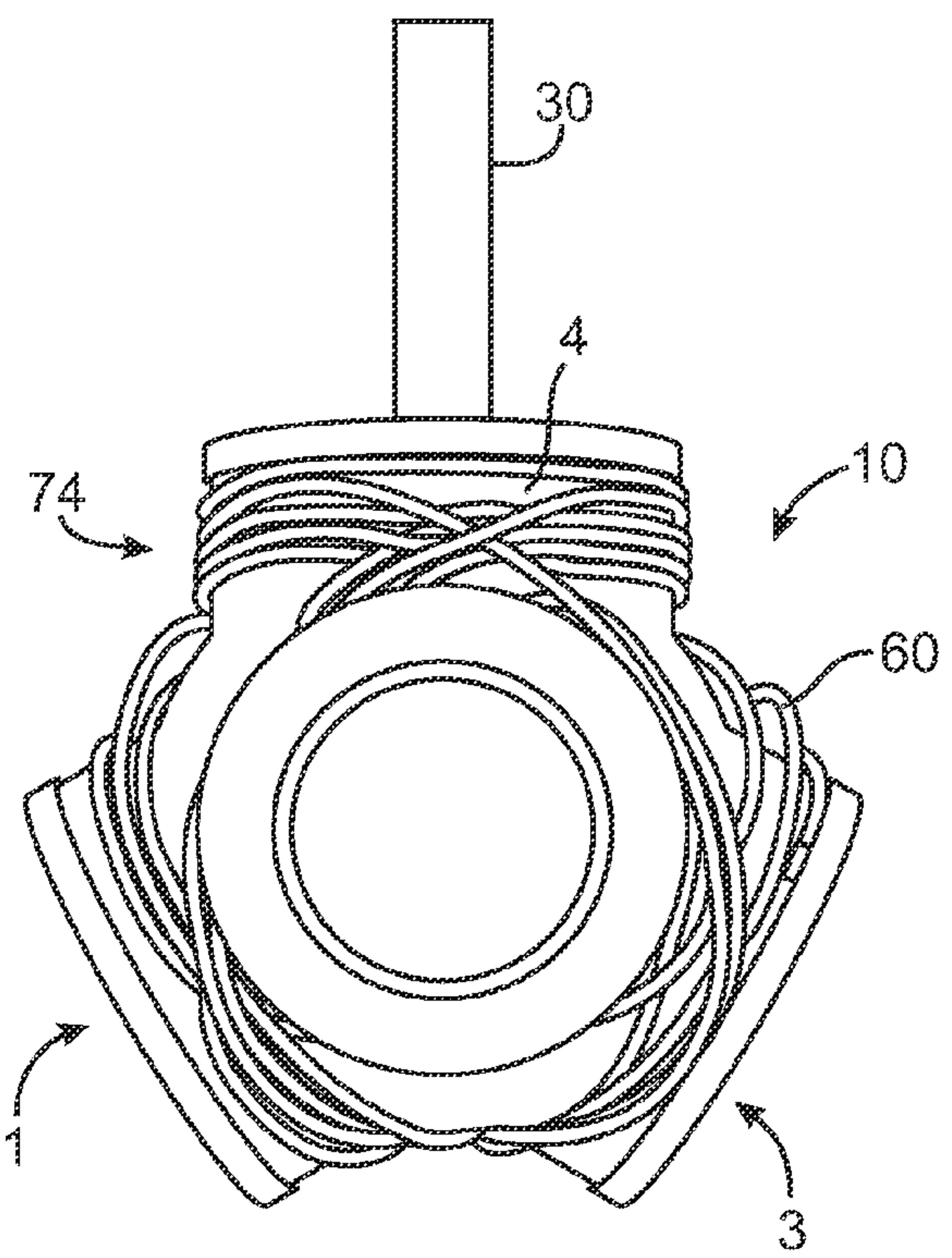

FIG. 9

(57) Abstract: This invention is directed to an implant having a coil (60) for embolizing a vascular site, such as aneurysm. The coil has a specific three-dimensional shape that is achieved by winding the coil around a mandrel (10) in a specific pattern and then heat setting the coil and the mandrel, another aspect of the invention. The three-dimensional shape resembles unclosed mobius loops. Also provided are methods of making the coil and methods of embolizing vascular site.

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AN IMPLANT, A MANDREL, AND A METHOD OF FORMING AN IMPLANT

FIELD OF THE INVENTION

This invention relates to the forming of implantable coils and to coils formed by such methods as well as to a mandrel used to form the shape of a coil implant, a method of forming a coil implant, and a coil implant formed by such method or with such mandrel.

BACKGROUND OF THE INVENTION

Implants are delivered to a vascular site, such as an aneurysm, of a patient via a microcatheter to occlude or embolize the vascular site. Typically, the implant is engaged at the distal end of either the delivery microcatheter or the guidewire contained within the microcatheter and controllably released therefrom into the vascular site to be treated. The clinician delivering the implant must navigate the microcatheter or guide catheter through the vasculature and, in the case of intracranial aneurysms, navigation of the microcatheter is through tortuous microvasculature. This delivery may be visualized by fluoroscopy or another suitable means. Once the distal tip of the catheter or guidewire is placed in the desired vascular site, the clinician must then begin to articulate the implant in the vascular site to ensure that the implant will be positioned in a manner to sufficiently embolize the site. Once the implant is appropriately positioned, the clinician must then detach the implant from the catheter or guidewire without distorting the positioning of the implant. Detachment may occur through a variety of means, including, electrolytic detachment, chemical detachment, mechanical detachment, hydraulic detachment, and thermal detachment.

Previously, there had been provided 3-dimensional coils which are formed from a straight wire by detachment from the catheter or guidewire. The 3-dimensional coil is typically formed from a metal which upon detachment (e.g., *in vivo)* reconfigures from the straight wire into a coil shape or confirmation having a secondary structure (i.e., an extended or helically coil confirmation) which under ideal circumstances will comport to the shape of the vascular site to be embolized. However, the *in vivo* formed coils of the prior art invariably failed to provide shapes which comport to the vascular site and this results in the ineffective embolization of the vascular site. Even when the 3-dimensional coils of the prior art initially comport to the vascular site, the secondary structure of the resulting coils may not be sufficiently stable to retain their comportment with the vascular site. For example, 3-dimensional *in vivo* formed spherical coils tend to fold upon themselves which leads to secondary structure different from that of the vascular site. Likewise, 3-dimensional *in vivo* formed cubic coils often collapse on themselves, similar to a "stack of coins" rather than retaining their cubic shape.

In light of the above, there exists a need for a coil implant which substantially conforms to the vascular site to be embolized.

SUMMARY OF THE INVENTION

One aspect is directed to an implant comprising a 3-dimensional coil designed to optimize packing into a vascular site, such as an aneurysm. It is contemplated that the implant, due to its secondary shape, may be able to substantially conform to a vascular site thereby providing a more effective embolization. In particular, the shape of the 3-dimensional coil may be composed of one or more unclosed mobius loops.

In another aspect, a 3-dimensional vascular coil is provided comprising one or more unclosed mobius loops. The coil is biased to form a pattern corresponding to the winding pattern around a mandrel when released from the catheter or guidewire. The bias disposes the coil into a 3-dimensional shape that conforms with the exterior of a sphere. The winding pattern has at least one unclosed mobius loop distributed over the shape. In other embodiments, the winding pattern has at least two or three unclosed mobius loops distributed over the shape.

The shape of the coil can also conform with a pattern of eight substantially triangular shapes distributed over the surface of a sphere. In one embodiment, the eight substantially triangular shapes include four substantially triangular shapes with sides that bow outwards (convex) away from the center of the respective triangular shape, and four substantially triangular shapes with sides that bow inwards (concave) towards the center of the respective triangular shape. The shape of the coil can also have loops that conform with a path between the substantially triangular shapes, with a path that curves around the center of the sphere while also curving around at least four points corresponding to the triangular shapes, or with a path that can be described as generally following the contour of a hyperbolic parabloid or the contour of a saddle. Depending on the length of the coil, at least one and preferably multiple wraps of the coil will be made around the mandrel according to the winding pattern.

In another aspect there is provided a method of embolizing a vascular site of a patient comprising delivering the implant just described to the vascular site. The implant is delivered with a delivery device. The delivery device can be a microcatheter optionally including a guidewire and/or a positioner.

Another aspect is directed to a mandrel. The mandrel includes a sphere and a plurality of markers, such as four markers, disposed on the exterior surface of the sphere. Optionally, one of the markers includes a stem. Each of the four markers define a pathway between adjacent markers, and the pathway preferably defines a winding pattern for a coil that is to be wrapped around the outer surface of the sphere. The winding pattern includes a series of sequential turns across the surface of the sphere corresponding to points where the pathway is disposed adjacent to a marker. The winding pattern also includes a series of sequential crossing points that correspond to midpoints between adjacent markers on the surface of the sphere.

In another aspect there is provided a method of forming the implant of the invention. The method of forming the coil includes the process of wrapping the coil over the mandrel according to the winding pattern. The method further includes subjecting the mandrel and wrapped coil to heat. The method also includes additional processing steps that form a finished coil from the wrapped coil.

According to an aspect, there is provided an implant comprising: a coil having a coil length that is biased to conform to a winding pattern, the coil comprising a primary, substantially linear configuration for delivery of the coil to a vascular site, and a secondary, substantially spherical configuration in an unrestrained state for positioning at the vascular site, the winding pattern approximately conforming to an outer surface of a sphere, the winding pattern consisting of only substantially triangular shapes, each triangular shape having a center, four of the triangular shapes having sides that bow outward away from the center, four of the triangular shapes having sides that bow inward towards the center, the coil comprising a proximal end, a distal end, and a longitudinal axis that, when the coil is in the linear configuration, extends from the proximal end to the distal end, the coil formed by winding about a mandrel and twisting the proximal end at least a half a turn with respect to the distal end about the longitudinal axis.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate exemplary embodiments of the invention, and, together with the general description given above and the detailed description given below, serve to explain the features of the invention.

Figure 1A is a plan view of a positioning system used to deliver a coil of the invention.

Figure 1B is a closer view of a portion of Fig. 1A showing the positioning system in partial cross-section and an exemplary coil in a position within the human body prior to deployment of the coil.

Figure 1C is a closer view of a portion of Fig. 1A showing the positioning system in partial cross-section and an exemplary implant in another position within the human body after deployment but before detachment.

Figure 1D is a shows the layup of the coil in the vascular site.

Figure 2 is a plan view of a mandrel.

Figure 3 is a top view of the mandrel of Fig. 2.

Figure 4 is a close-up view of a portion of Fig. 2.

Figure 5 is an isometric exploded view of the mandrel of Fig. 2.

Figure 6 is a schematic view of the winding pattern followed by a coil across the surface of the mandrel of Fig. 2, with a portion of the coil and the stem omitted.

Figure 7A is the schematic view of Fig. 6 with the mandrel omitted.

Figure 7B shows the schematic of Fig. 7A with the rearward portion of the winding pattern omitted.

Figure 7C shows a perspective of an unclosed mobius loop.

Figure 8 is a representation of the winding pattern of Fig. 6.

Figure 9 and Figure 10 are plan views of the mandrel of Fig. 2 showing the winding pattern of the coil around the mandrel.

DETAILED DESCRIPTION OF THE INVENTION

Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, the preferred methods, devices, and materials are now described. Nothing herein is to be construed as an admission that the invention is not entitled to antedate such disclosure by virtue of prior invention.

It must be noted that as used herein and in the appended claims, the singular forms "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

Methods of Embolizing a Vascular Site

The implant of the invention may be used to embolize a vascular site. This is best illustrated in Figs. 1A, 1B, 1C, and 1D, which are described below. It should be noted that this method of delivery is one contemplated embodiment and that the implant of the invention may be delivered by a variety of other methods known by one of skill in the art.

In the embodiment illustrated in Fig. 1A, an operator uses a guide catheter 112 to position a microcatheter 114 in a patient's vasculature. The procedure involves inserting the guide catheter 112 into the patient's vasculature through an access point such as the groin, and directing the distal end 112a of the guide catheter 112 through the vascular system until it reaches the carotid artery. After removing a guide wire (not shown) from the guide catheter 112, a microcatheter 114 is inserted into the guide catheter 112 and the distal end 114a of the microcatheter 114 subsequently exits the guide catheter distal end 112a and is positioned near the target site 116, such as an aneurysm in the patient's brain. As illustrated in Figs. 1B and 1C, the microcatheter 114 includes microcatheter markers 115 and 115a that facilitate imaging of the distal end 114a of the microcatheter 114 with common imaging systems and, in the illustrated embodiment, the microcatheter markers 115 and 115a are made of a radiopaque material. After the distal end 114a reaches the target site 116, the positioning system (not shown) of the illustrated embodiment is then inserted into the microcatheter 114 to position the implant interface 180 at the distal end of the positioner 140 near the target site 116, as illustrated in Fig. 1C. If the implant 190 is being delivered in the procedure, the implant 190 is attached to the implant interface 180 prior to inserting the positioning system into the microcatheter 114. This mode of implant delivery is illustrated in Figs. 1A, 1B, and 1C.

The delivery of the implant 190 is facilitated by disposing the microcatheter marker 115a near the target site 116, and aligning the microcatheter marker 115 with a positioner marker 164 in the positioner 140 which, when the two markers (markers 115 and 164) are aligned with each other as illustrated in Fig. 1C, indicates to the operator that the implant interface 180 is in the proper position for the release of the implant 190 from the positioning system (not shown). After depositing the implant 190 at the target site 116, a second implant 190 can be deposited at the target site 116 by removing the positioning system from the microcatheter 114 and inserting a second positioning system with an attached second implant 190 into the microcatheter 114 in a manner similar to the method used with the insertion of the first implant 190. The same procedure can be used for a third implant 190 and subsequent implants if clinically necessary. If the implant 190 is already in the patient's body to be retrieved or repositioned, the positioning system is inserted into the microcatheter 114 without the implant 190.

The Mandrel, the Implant, and the Method of Making the Implant

The invention, in one embodiment, is directed to an implant having a coil length that is biased to conform to a winding pattern, the winding pattern approximately conforming to a shape of an outer surface of a sphere. The winding pattern has at least one unclosed mobius loop (or a plurality of unclosed mobius loops) distributed over the shape. A mobius loop is formed by bringing the ends of that same coil around and twisting one end half of a turn before joining the ends. In this invention, the mobius loop is unclosed meaning the ends are not joined. This is best illustrated in Fig. 7C. A mobius loop is a strip having a single surface and is chiral.

To achieve the mobius loop, a mandrel is employed. The mandrel 10 illustrated in Figs. 2 and 3 includes a sphere 20, four markers, and optionally a stem 30. The markers are mounted on the external surface of the sphere 20 at four locations. Each marker is designated with a numeric identifier of 1, 2, 3, or 4 as illustrated in Figs. 2 and 3.

Specifically, the stem 30 extends from marker 4. Marker 1 is on the left side of Figs. 2 and 3 and is identifiable because it includes a starter tube 40. Marker 3 is to the right of marker 1 in Fig. 2 and to the bottom right in Fig. 3. Marker 2 is not viewable in Fig. 2 because it is on the rearward side of the figure, and is illustrated on the top right side in Fig. 3. Fig. 5 illustrates an isometric assembly view of the mandrel 10 without the starter tube 40.

The markers 1, 2, 3, and 4 are cylindrical and define longitudinal axes 11, 12 (not shown, but refers to the axis through marker 2), 13, and 14 for markers 1, 2, 3, and 4, respectively. Each axis 11, 12, 13, and 14 passes through the center of the sphere 20. The longitudinal axis 14 also passes through the center of the stem 30. The axes 11, 12, and 13 are at a vertical angle 50 to a plane 52 that is orthogonal to the axis 14, as illustrated in Fig. 2, which is about 19.5 degrees $\pm$ 2.5 degrees. The axes 11, 12, and 13 are also at a horizontal angle 54 relative to each other, as illustrated in Fig. 3, which is about 120 degrees $\pm$ 5 degrees.

On the radial extreme of each marker 1, 2, 3, and 4, relative to the center of the sphere 20, is optionally a cap 21, 22, 23, and 24. Each cap 21, 22, 23, and 24 has an outer diameter that is greater than the outer diameter of the corresponding marker 1, 2, 3, and 4. The outer diameter dimensions of the markers and caps and the outer diameter of the sphere 20 preferably vary according to the size of the mandrel 10. The size of the mandrel 10 corresponds to the size of the coil 60 that is to be formed with the mandrel 10.

The markers 1, 2, 3, and 4 are disposed on the outer surface of the sphere 20, and each marker 1, 2, 3, and 4 has an outer diameter that is smaller than the outer diameter of the sphere 20, which provides a spacing 70 between each marker 1, 2, 3, and 4 upon the surface of the sphere 20. This spacing 70 between each marker 1, 2, 3, and 4 provides a pathway 72 (Fig. 6) across the surface of the sphere 20 between each marker 1, 2, 3, and 4. The pathway 72 defines the winding pattern 74 (Figs. 7A and 7B) for a coil 60 that is to be wrapped around the external surface of the sphere 20 in the spacing 70 between each marker 1, 2, 3, and 4.

The diameter of the marker 1, 2, 3, and 4 is selected to provide a coil of a desired softness and strength. The softness of the coil determines the coil's ability to conform to the vascular site. The larger the diameter of the marker 1, 2, 3, and 4, the larger the loop, the softer the coil, and the better the coil is able to conform to the vascular site. In one embodiment of the invention, the ratio of the diameter of the marker 1, 2, 3, and 4 to the diameter of the sphere is from about 0.5 to about 0.75, or 0.55 to about 0.75, or about 0.61 to about 0.65, or about 0.63.

The winding pattern 74 is initiated at the starter tube 40 on marker 1 as shown in Fig. 5. In one embodiment, an end of the coil 60 to be wound is inserted through the starter tube 40 in order to fix the coil 60 relative to the start tube 40. The initial wrap of the coil 60 is made around the outer diameter surface of the marker 1 until achieving a single wrap. A single wrap refers to a wrap that is from 270 circumferential degrees to 360 circumferential degrees. After achieving a single wrap, the coil 60 is wrapped along the pathway 72 disposed along the surface of the sphere 20 in the spacing 70 between adjacent markers 1, 2, 3, and 4, and the pathway 72 is not disposed along the outer diameter surfaces of the markers after the initial wrap.

The winding pattern 74 used for the wrapping of the coil 60 follows the pathway 72 on the external surface of the sphere 20. As illustrated in Fig. 6, the pathway 72 sequentially runs adjacent to each marker 1, 2, 3, and 4 until approaching a midpoint 80 on the surface of the sphere between adjacent markers. As illustrated in Fig. 6, the midpoint 1-3 is disposed at the midpoint 80 between markers 1 and 3 (80 (1-3)). Similar midpoints 80 are located on the sphere between each marker, with a total of six midpoints designated as follows: 1-2 (between markers 1 and 2), 1-3 (between markers 1 and 3), 1-4 (between markers 1 and 4), 2-3 (between markers 2 and 3), 2-4 (between markers 2 and 4), and 3-4 (between markers 3 and 4). When the pathway 72 approaches each midpoint 80, the pathway 72 moves away from a position adjacent to one marker and towards a position adjacent to a different marker. As illustrated in Fig. 6, the pathway 72 travels from a first position 82 adjacent to marker 3 to the midpoint 1-3 and then to a second position 84 adjacent to marker 2.

As can be appreciated from Figs. 6 and 7A and 7B, the winding pattern 74 follows a pathway 72 that traces a pattern of substantially triangular shapes 90 over the surface of the sphere 20, with each apex 91 of each triangular shape 90 disposed at a midpoint 80. As can be further appreciated, two types of substantially triangular shapes 90 are apparent. One type of substantially triangular shape encloses each marker 1, 2, 3, and 4 and has sides that bow out away from the axes 11, 12, 13, and 14 of the markers. The other type of substantially triangular shape is disposed between the markers 1, 2, 3, and 4 and has sides that correspondingly bow in towards the center of the triangular shape and away from the axes of the markers. As illustrated in Fig. 7A with dashed lines, a total of four outwardly-bowed triangular shapes 92 and a total of four inwardly-bowed triangular shapes 94 are formed, which altogether follow the shape of the outer surface of the sphere 20.

It should be noted that the term “substantially triangular shape” refers to a 3-sided shape wherein the lines defining any or all of the sides are straight, concave or convex. In addition, when the substantially triangular shape is placed on the surface of a sphere, it is understood that the shape so formed will not be 2-dimensional but will otherwise comport to the 3-dimensional surface configuration of the underlying sphere.

Fig. 8 representatively illustrates the winding pattern 74 in regard to the markers 1, 2, 3, and 4 that are passed by the pathway 72. As indicates at the top left corner of Fig. 7A the winding pattern 74 is initiated at marker 1 at the starter tube 40, which is represented by a circle with a number 1, and the initial wind is shown wrapping around marker 1. Subsequent to the initial wind around marker 1, the winding pattern 74 travels to a position adjacent to marker 4, and then to a position adjacent to marker 2, and so on as illustrated. The winding pattern 74 subsequently repeats until the entire coil 60 is wrapped around the mandrel 10. The length of the wrap is dependent on the size of the coil.

The winding pattern 74 can also be represented by reference to the midpoints 80 that are sequentially traversed after the initial wind around marker 1. An initial portion of the winding pattern represented by Fig. 8 can thus be represented by the following pattern of midpoints traversed by winding pattern 74 after the initial wrap around marker 1: 1-4, 2-4, 2-3, 3-4, 2-4, 1-2, 1-3, 3-4, and so on.

When forming the coil 60, the coil is wrapped around the mandrel 10 according to the winding pattern 74, with the beginning of the coil 60 disposed at the starter tube 40 (not shown). When the end the coil 60 is reached in the wrapping process, a portion of the coil 60 is sometimes not wrapped around the sphere 20 and is instead wrapped around the stem 30 (not shown) and stretched to secure the end of the coil in place. Figs. 9 and 10 show the mandrel 10 and the wrapped coil 60. The wrapped coil 60 is subsequently subjected to a heat treatment process, similar to processes known in the art, that causes the coil 60 to thereafter have a bias to the winding pattern 74 of the mandrel 20, i.e., to have the predisposition to coil in a pattern similar to the winding pattern 74 of the mandrel 20. After the coil 60 has been subjected to the heat treatment process, the coil is removed from the mandrel 20 and further processed. This further processing preferably includes modification described in the next section. Additionally, the coil 60 may comprise a primary structure that is helical.

A coil 60 formed with the mandrel 10, applying the winding pattern 74, and the heat treatment process will have the loop pattern illustrated in Figs. 7A and B. Preferably, the coil 60 will be biased to form a shape corresponding to the winding pattern 74, with a pattern of eight substantially triangular shapes evenly distributed and spherically curved so as to approximately form the outer diameter shape of the sphere 20, as schematically represented in Fig. 7A. The pattern of the coil 60 will also preferably form a series of four outwardly-bowed substantially triangular shapes corresponding to shapes 92 and a total of four inwardly-bowed substantially triangular shapes corresponding to shapes 94. Depending on the length of the coil 60, at least one and preferably multiple wraps of the coil will be made around the mandrel 10 according to the winding pattern 74, as illustrated in Figs. 9 and 10.

As illustrated in Fig. 7B, which shows a forward-facing portion of the winding pattern 74 of Fig. 7A with the rearward-facing portion omitted for clarity, the winding pattern 74 includes three loops designated as loop 1, loop 2, and loop 3 that correspond with shapes 92 and 94. As can be appreciated from Fig. 7B, the loop 1, loop 2, and loop 3 portions of the winding pattern 74 follows a path that is disposed between adjacent shapes 92 and 94 that alternate position along the path of loop 1. In the path of loop 1, at point 96, the loop 1 is between a shape 92 on one side and a shape 94 on the other side. Farther along the path of loop 1, at point 98, the relative positions of shapes 92 and 94 to loop 1 have alternated so that loop 1 is between a shape 94 on one side and a shape 92 on the other side. As can also be appreciated from Figs. 6 and 10, the same alternations of shapes 92 and 94 occur on the rearward-facing portion of the winding pattern 74, and the same alternations of shapes 92 and 94 occur with the loop 2 and loop 3 portions of the winding pattern 74. Yet another thing that can be appreciated from Figs. 6 and 7A-B, is that the loops 1, 2, and 3 of winding pattern 74 follow paths that curve around the center of the sphere 20 while also curving around at least four points corresponding to shapes 92 and 94, which can be described as generally following the contour of a hyperbolic parabloid or the contour of a saddle. This is shown in Fig. 7B.

Materials

In one embodiment, the coil 60 may be made from a biocompatible metal that does not react adversely with the tissues and fluids when used in the body. The wire may be round, square, oval, triangular, or another shape. In certain embodiments the wire commonly has a diameter of from about 0.025 to about 0.09 mm, from about 0.03 to about 0.08 mm from about 0.04 to about 0.06 mm. In certain specific embodiments, the wire has a diameter of about 0.05 mm. In some embodiments the wire may be comprised only of a primary shape e.g., a simple single helix. In some embodiments the wire component may comprise a primary shape e.g., helical coil and a secondary shape.

In one embodiment, the material of the coil 60 is made of a material that may be heat set at a temperature of approximately 400 °C to about 700 °C. In some embodiments, the coil is heat set at about 650 °C. The metal or metal alloy can be radiopaque so that the position and location of the implant in the body can be monitored with radiological techniques. Suitable metals include, but are not limited to the noble metals such as the platinum group metals which include platinum, palladium, rhodium and rhenium as well as iridium, gold, silver, tungsten, and tantalum and alloys of these metals with one another. Additional metals include the super elastic metals such as "Nitinol" and the like. In one embodiment, the coil 60 is made of platinum alloy.

The mandrel of the invention may be made from a variety of materials, such as steel, so long as the material selected can withstand the heat set of the coil.

Modifications and Delivery of the Coil

As mentioned above, the coil of the invention may also undergo further processing, including being modified and used with an implant comprising other components. In one embodiment, the implant is modified to include a stretch-resistant member as described in "An Implant Including a Coil and a Stretch Resistant Member," United States Patent Serial Number 8,328,860 B2 issued December 11, 2012.

In another embodiment, the coil is coupled with a delivery device. Any delivery device suitable for delivering a coil to a vascular site may be employed. Suitable microcatheters are described in WO 2007/121405 entitled "System and Method For Mechanically Positioning Intravascular Implants".

Regardless of the delivery device employed, after delivery of the implant to the vascular site, the implant substantially conform to the vascular site due to its three-dimensional shape. This is illustrated in Fig. 1D.

EXAMPLES

Example 1 - Method of Making the Implant

An implant of the invention may be made by the following procedure.

1. Under microscope insert the distal end of the wire or coil into the starter tube.

2. Wind coil around mandrel as described above and in Fig. 8.

3. Heat set the coil and the mandrel. The temperature is from about 550 °C to about 650 °C.

Example 2 - Comparison of other three-dimensional shapes

The coil of the invention was tested and compared with coils having a cubic three-dimensional (3-D) shape and a spherical (or spheroidal) 3-D shape. The clinicians assessed the ability of the coil to compact into the vascular site and the ability of the coil to conform to the shape of the vascular site.

Protocol

The coils of the invention were obtained according to Example 1. The mobius loop coils of the invention were made on a 10 millimeter (mm) sphere with four 8 mm markers. The coils having a cubic 3-D were made by winding wire around a mandrel having six markers (rather than the four to obtain the coils of the invention), one on each face of the cube. One marker was 5 mm and the other five markers were 8 mm. The sphere was 10 mm. The spherical coil were obtained by winding wire around a base mandrel with eight markers. The sphere was again 10 mm and the markers were about 5 mm.

Once the coils were wound according to the patterns above, the coils were heat set at the temperature provided below.

In swine, 10 millimeter aneurysms were created. A 10 millimeter x 30 centimeter coil was placed into the aneurysm several times without detaching it and then removing it from the catheter and deploying the next coil. This is illustrated in Fig. 1D.

The clinicians, who tested these coils in a blinded format, then delivered the coil to the aneurysm and provided qualitative feedback regarding the coil. Independent observers then translated each comment into a +1 (good), 0 (neutral), -1 (bad) scale. Some coils were marked with a score higher due to the comments of the doctors. Three of the coils of the mobius loop coils, three of the spherical coils and one of the cubic coils were assessed. Some of the coils tested contained stretch-resistant members as indicated below. The results are presented in Table 1.

Table 1

Design	**Stretch Resistant Member**	**Heat Set Temp. (°C)**	**Observer 1**			**Observer 2**			**Observer 3**				
			1	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**	**Avg.**	**St. Dev.**
Cubic	--	670	0	0	1	1	0	-1	-1	1	0	0.11	0.78
Cubic	Nitinol	550	0	0	1	0	1	1	0	1	1	0.56	0.53
Cubic	--	550	1	1	1.5	0	1	0	1	1	1	0.83	0.50
Cubic	Poly-propylene	650	1	0.5	1	1	1	0	1	1	0	0.72	0.44
Mobius Loop	--	650	0	1	1	1	-1	1	1	1		0.63	0.74
Mobius Loop	--	650	1	1	0.5			1	0	1	1	0.79	0.39

Mobius Loop	--	550	1	1	1.5	1	0	1	1	1	1	0.94	0.39
Spherical	Nitinol	550	-1	-1	0	-1	-1	0	-1	-1	1	-0.56	0.73
Spherical	--	550	0	0	0.5	-1			-1	-1	1	-0.21	0.81

The test was then repeated except the stretch resistant member was varied as indicated. Also, the score were evaluated on a score of 0 (bad) to 5 (good). The results are in Table 2 below.

Table 2

Design	**Stretch-Resistant Member**	**Overall Performance**	**Standard deviation**
Cubic	Nitinol	3.0	0.50
Spherical	Nitinol	3.25	0.29
Cubic	Polypropylene	3.67	0.29
Mobius loop	Nitinol	3.75	0.87
Mobius loop	Polypropylene	4.17	0.58

As can be seen in Table 1 and 2, the mobius loop coil is preferred for its overall performance and repeatability over the cubic and spherical coils.

While the present invention has been disclosed with reference to certain embodiments, numerous modifications, alterations, and changes to the described embodiments are possible without departing from the sphere and scope of the present invention, as defined in the appended claims. Accordingly, it is intended that the present invention not be limited to the described embodiments, but that it has the full scope defined by the language of the following claims, and equivalents thereof.

We claim:

1. An implant comprising:

a coil having a coil length that is biased to conform to a winding pattern, the coil comprising a primary, substantially linear configuration for delivery of the coil to a vascular site, and a secondary, substantially spherical configuration in an unrestrained state for positioning at said vascular site, the winding pattern approximately conforming to an outer surface of a sphere, the winding pattern consisting of only substantially triangular shapes, each triangular shape having a center, four of the triangular shapes having sides that bow outward away from the center, four of the triangular shapes having sides that bow inward towards the center, the coil comprising a proximal end, a distal end, and a longitudinal axis that, when the coil is in the linear configuration, extends from the proximal end to the distal end, the coil formed by winding about a mandrel and twisting the proximal end at least a half a turn with respect to the distal end about the longitudinal axis.

2. The implant of claim 1, wherein the coil substantially conforms to a vascular site.

3. The implant of claim 1, wherein the coil is comprised of a metal wire.

4. The implant of claim 3, wherein the wire is comprised of a metal selected from the group consisting of platinum, palladium, rhodium, rhenium, iridium, gold, silver, tungsten, tantalum, an alloy of two or more of these metals, or a super elastic metal.

5. The implant of claim 4, wherein the wire is a platinum alloy.

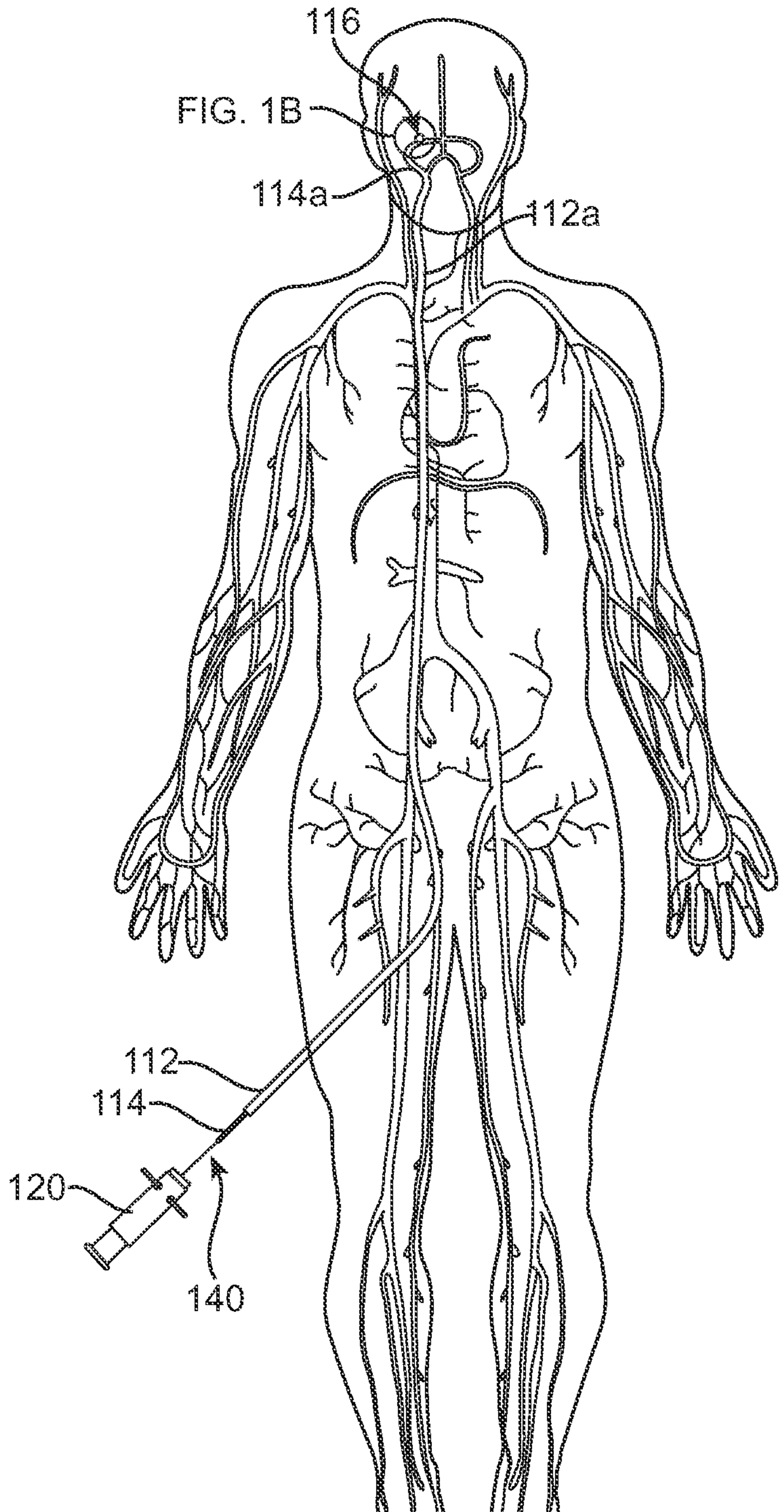


FIG. 1A

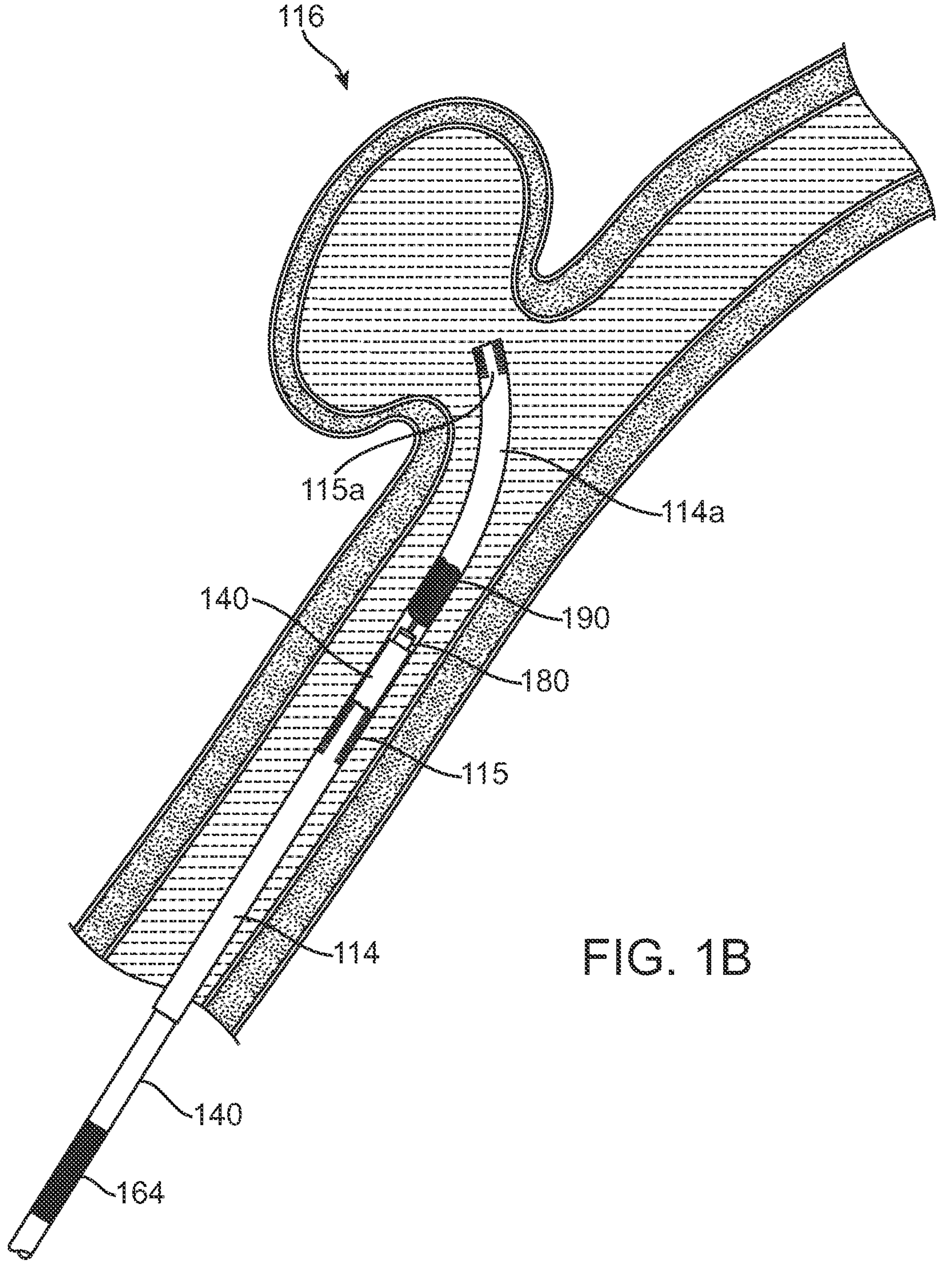


FIG. 1B

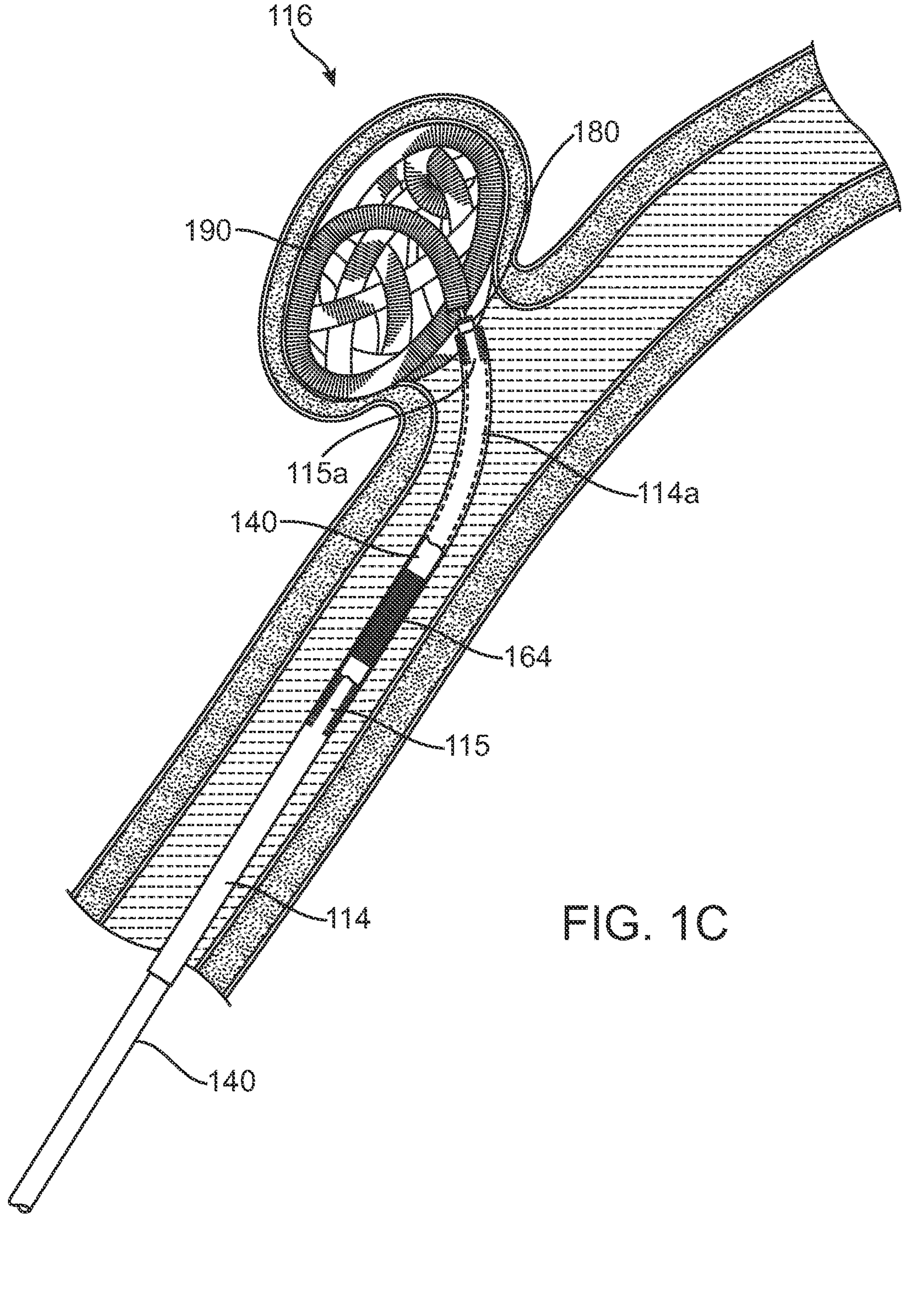


FIG. 1C

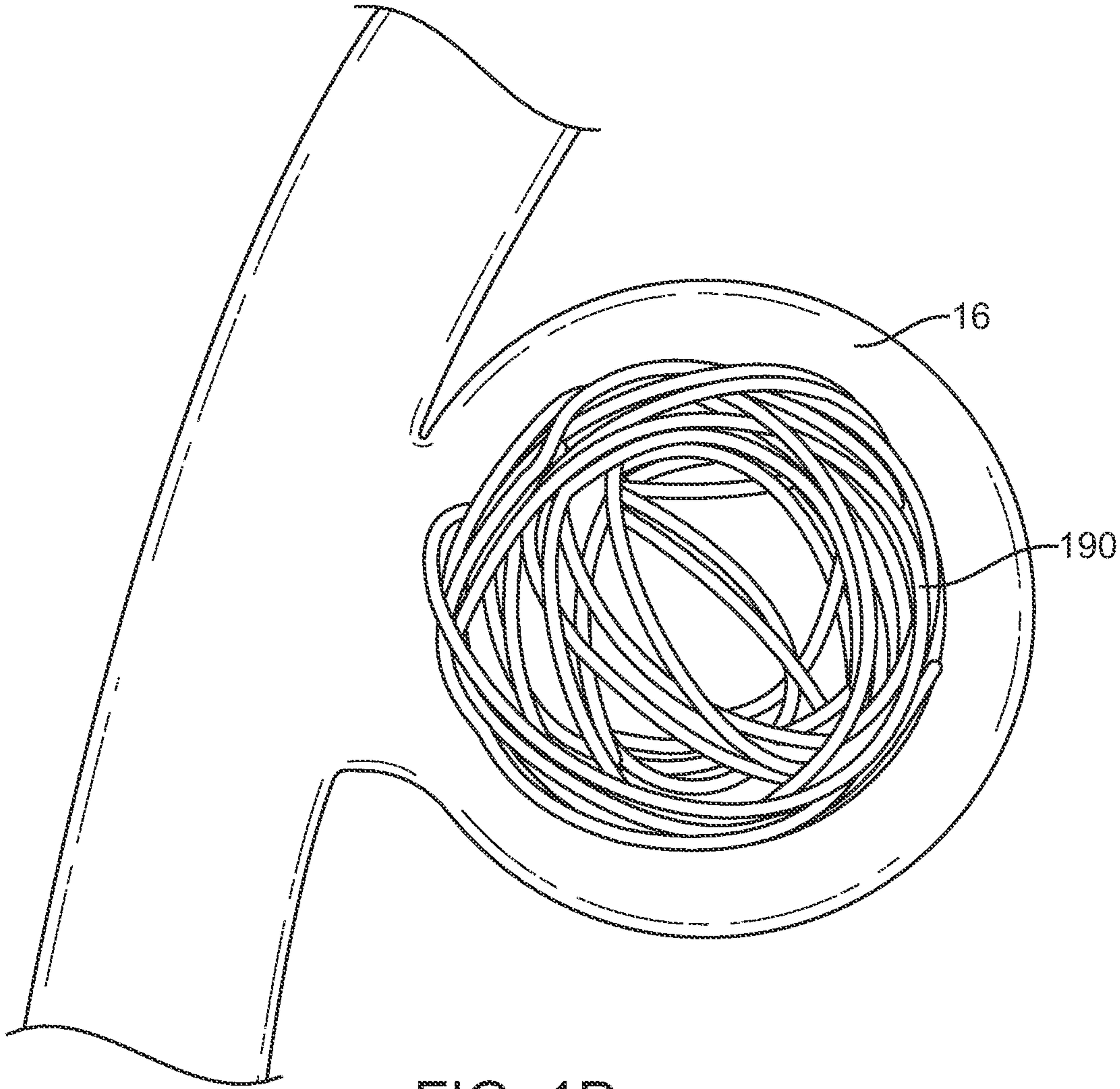


FIG. 1D

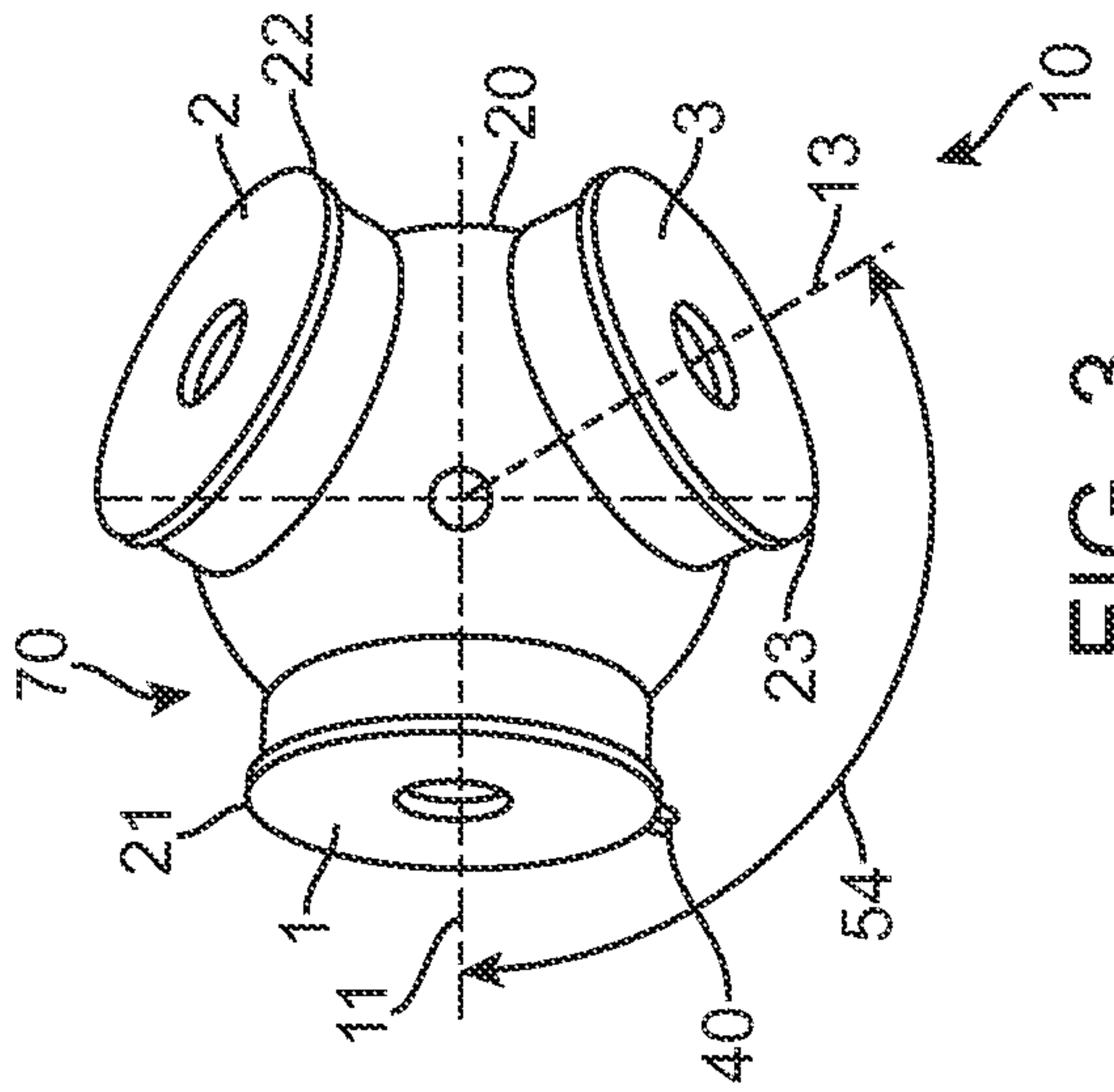


FIG. 3

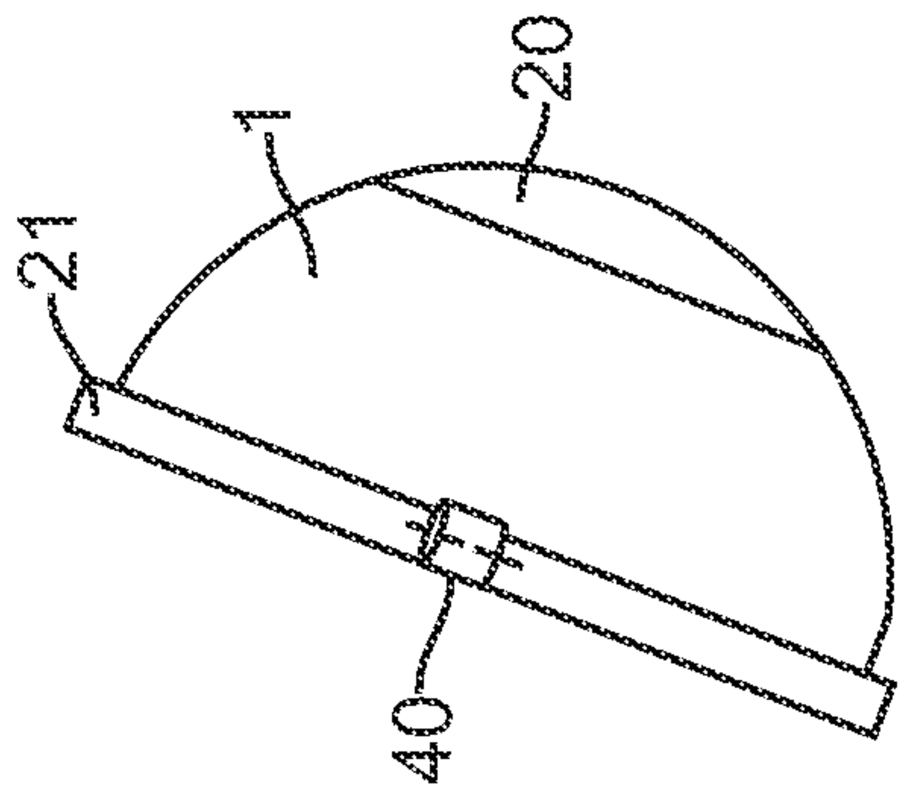


FIG. 4

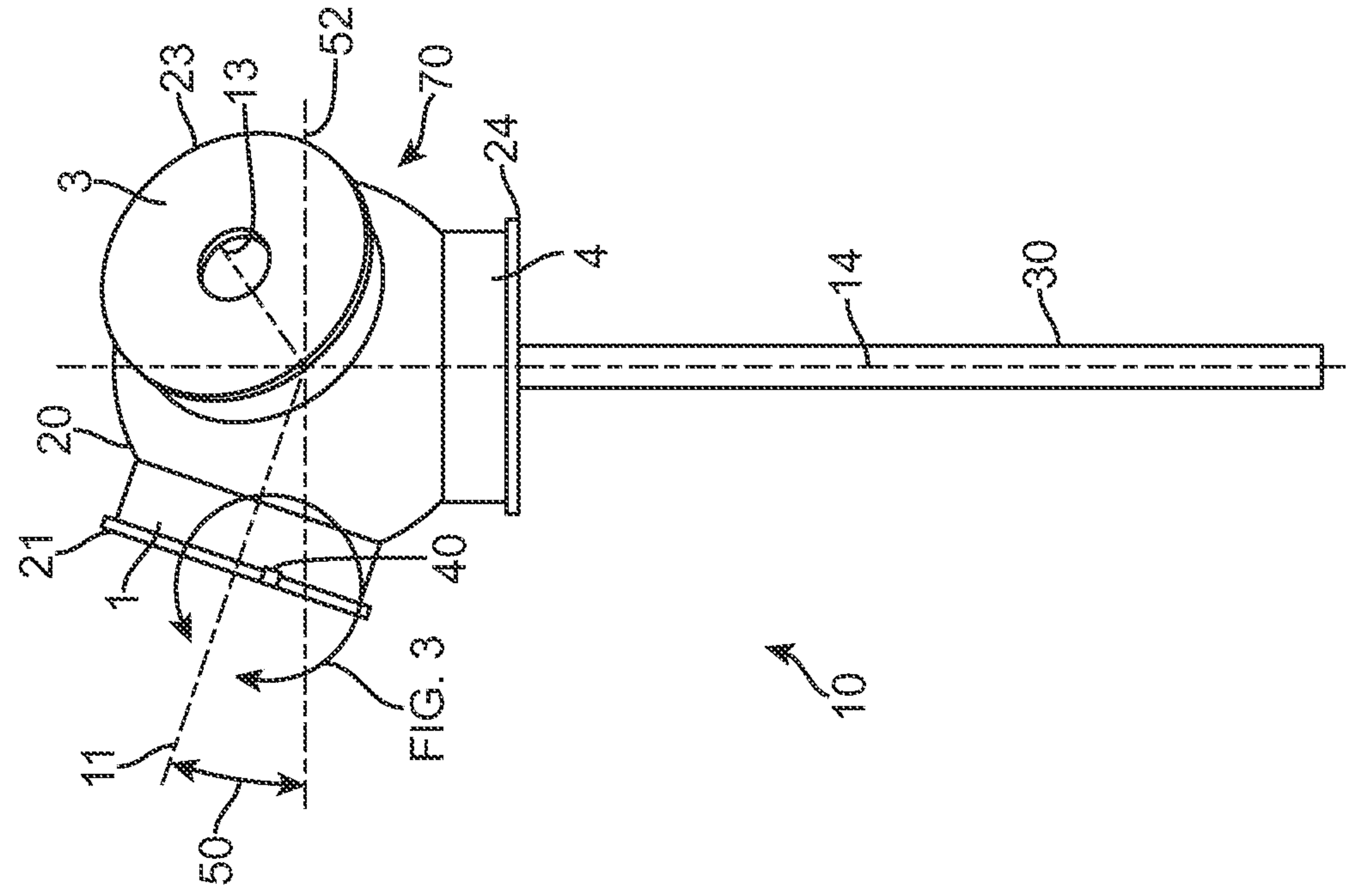


FIG. 2

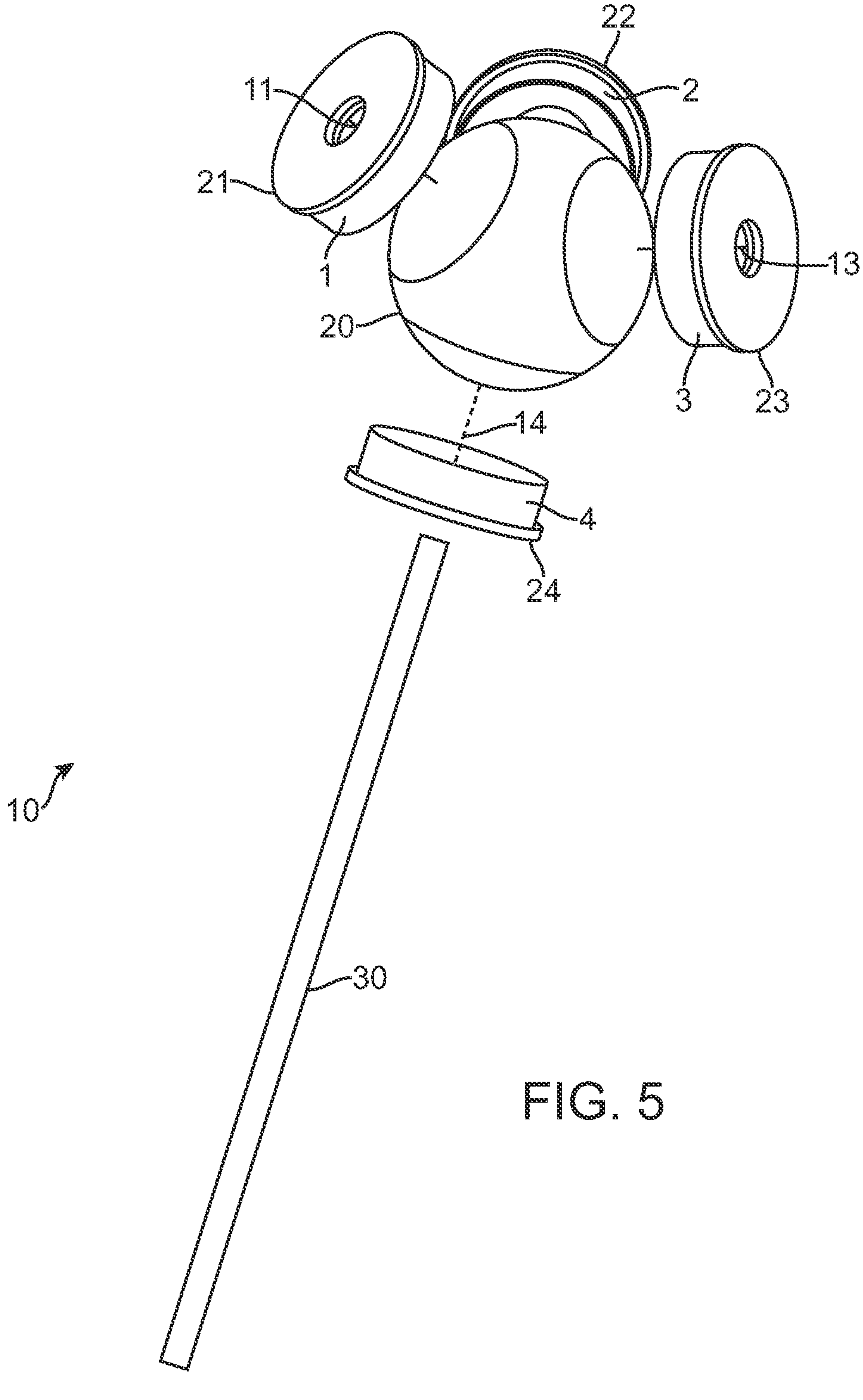
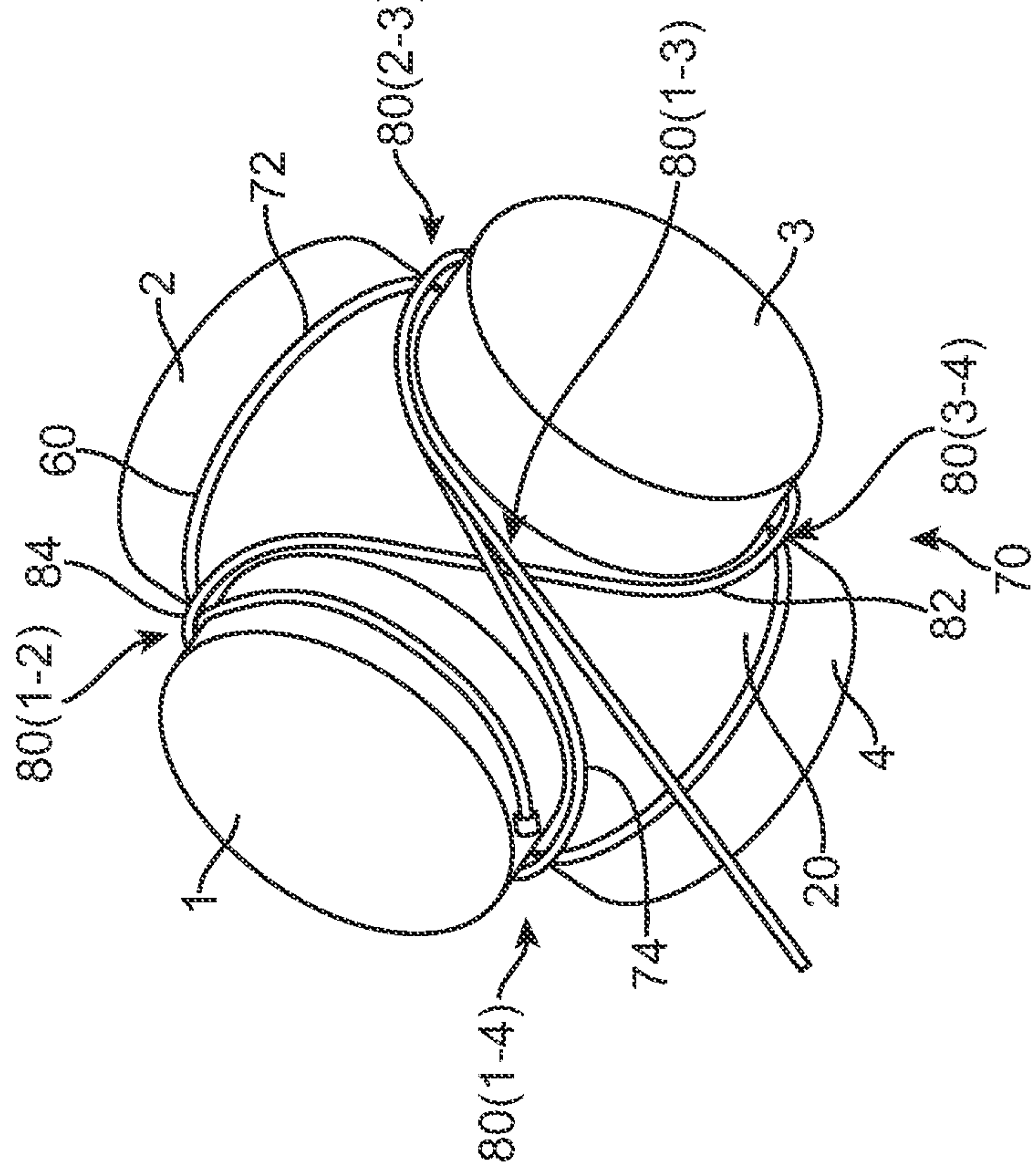


FIG. 5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80(1-3)
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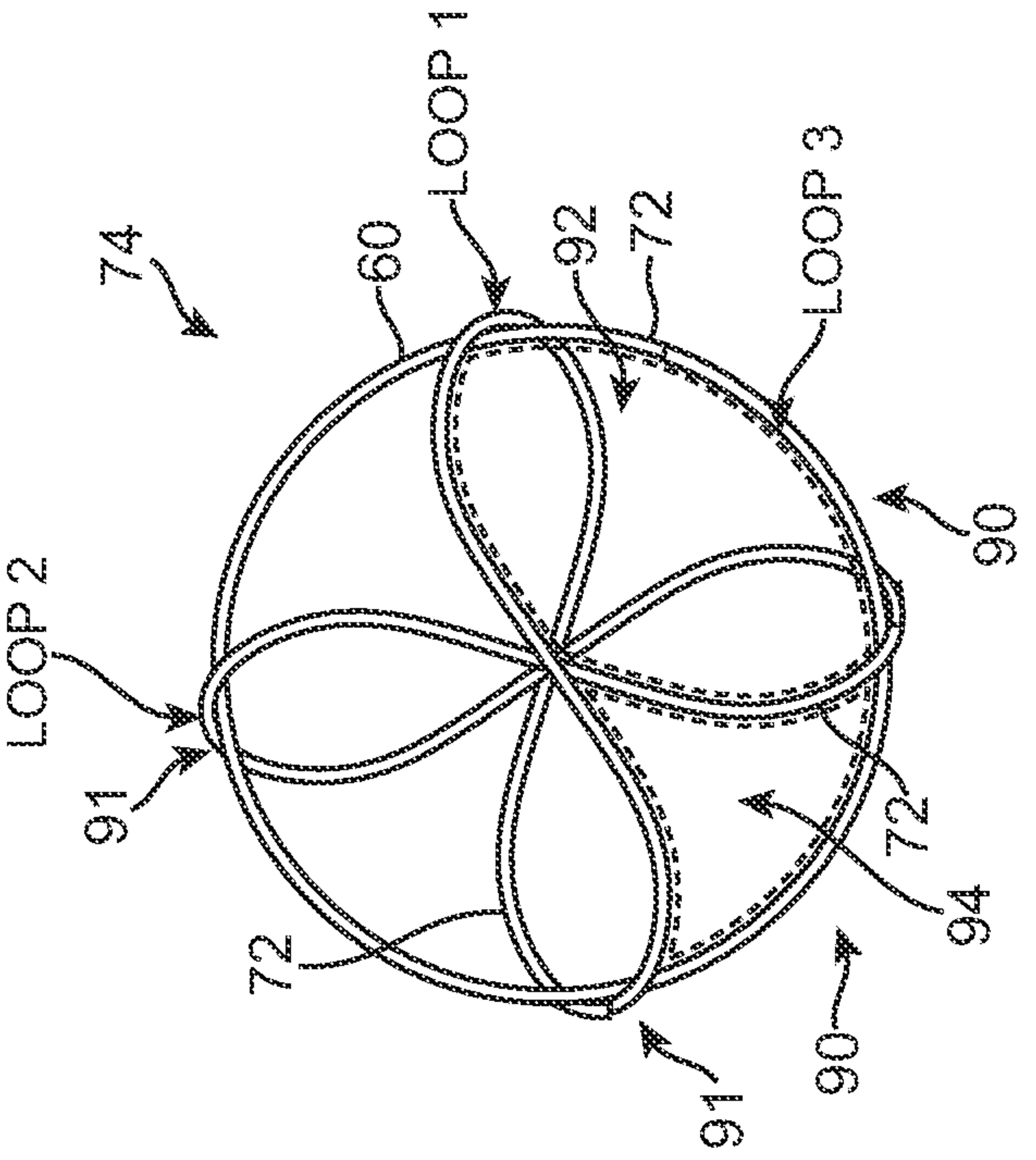
FIG. 6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LOOP 1
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72
LOOP 3
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90
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FIG. 7A

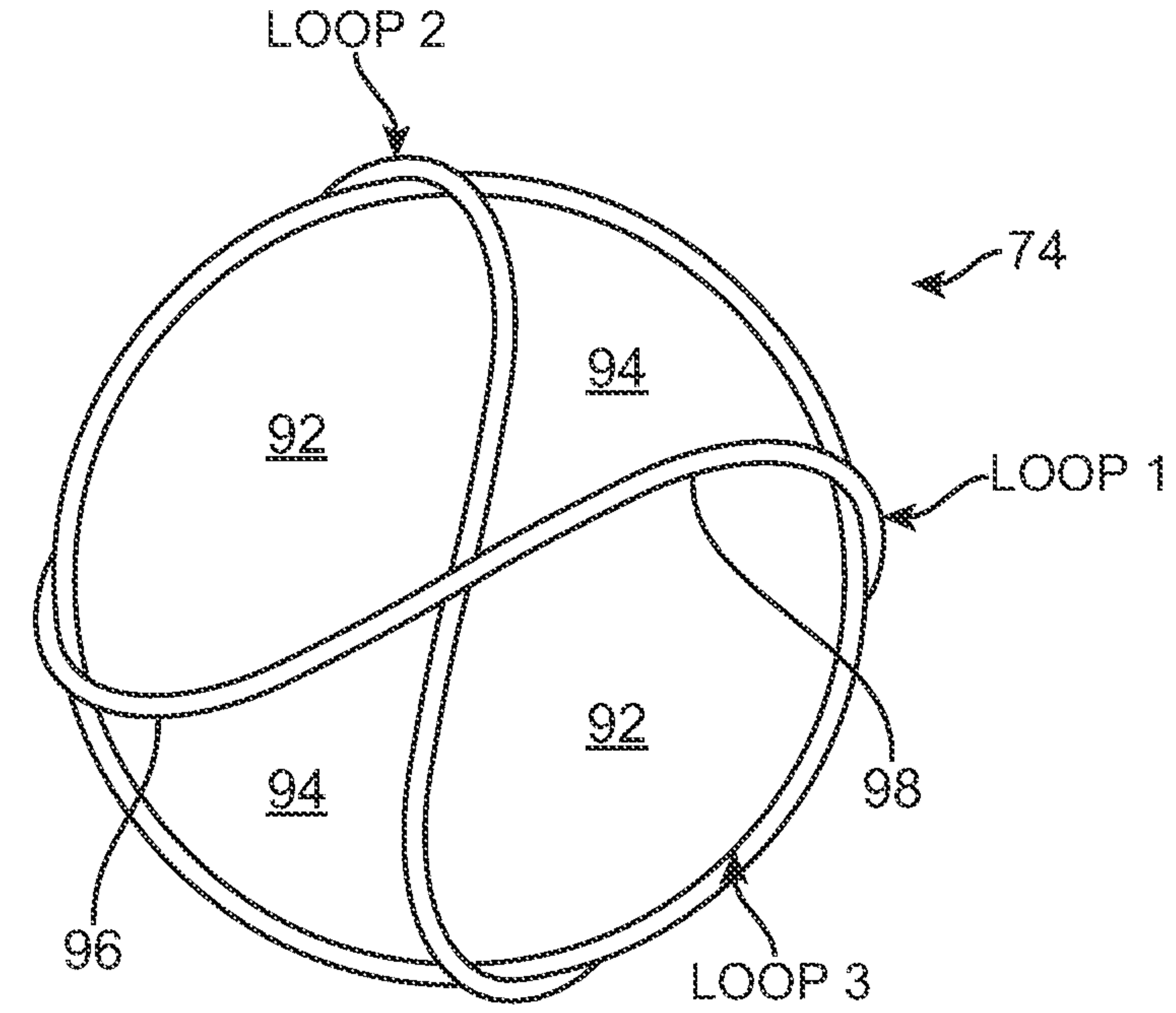


FIG. 7B

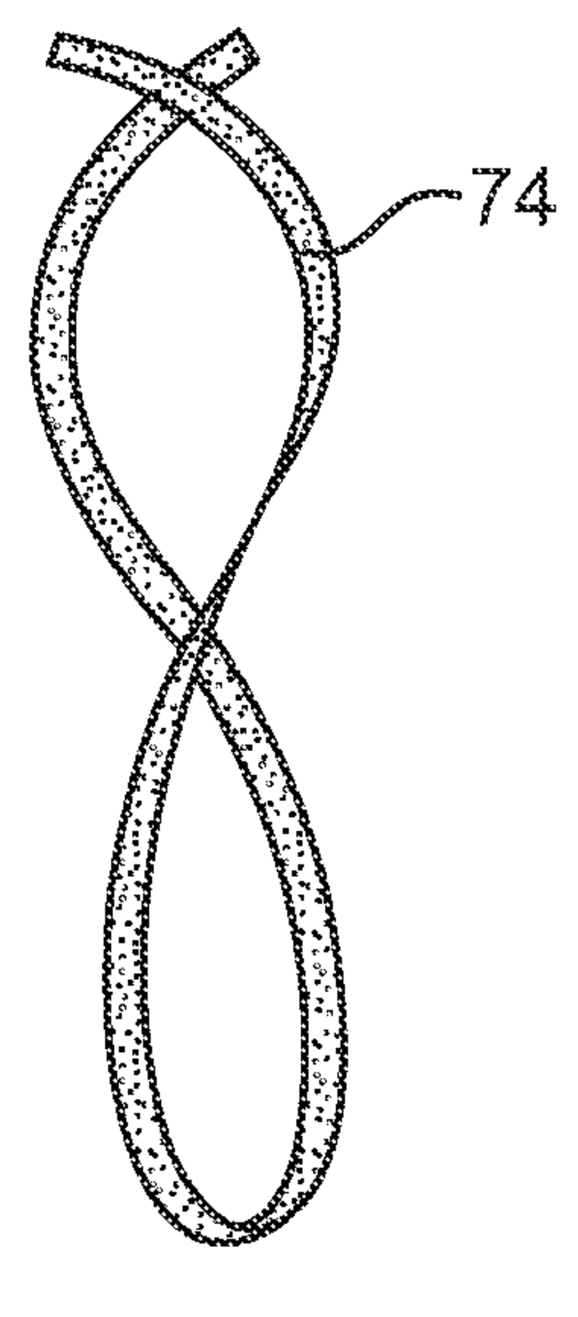


FIG. 7C

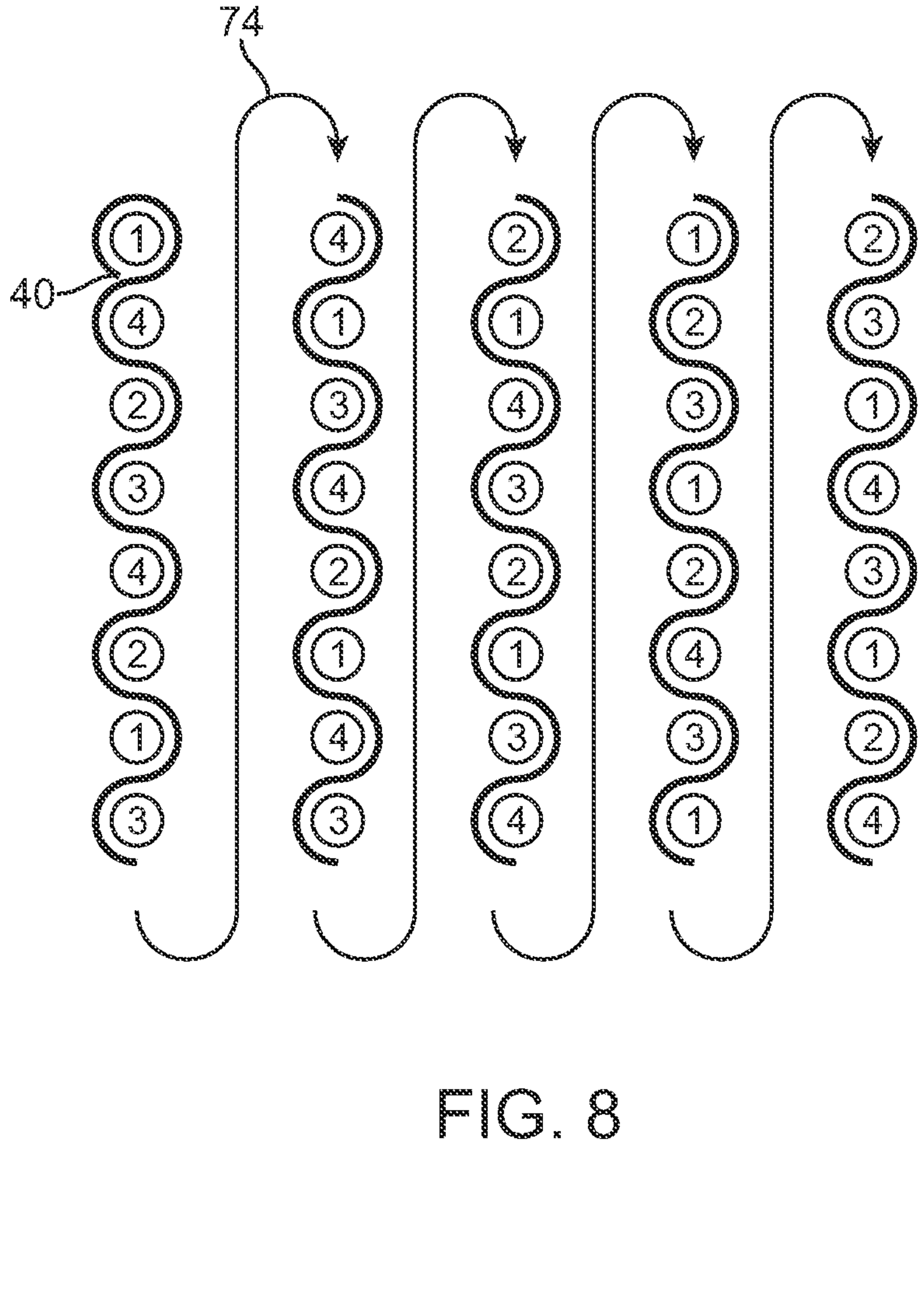


FIG. 8

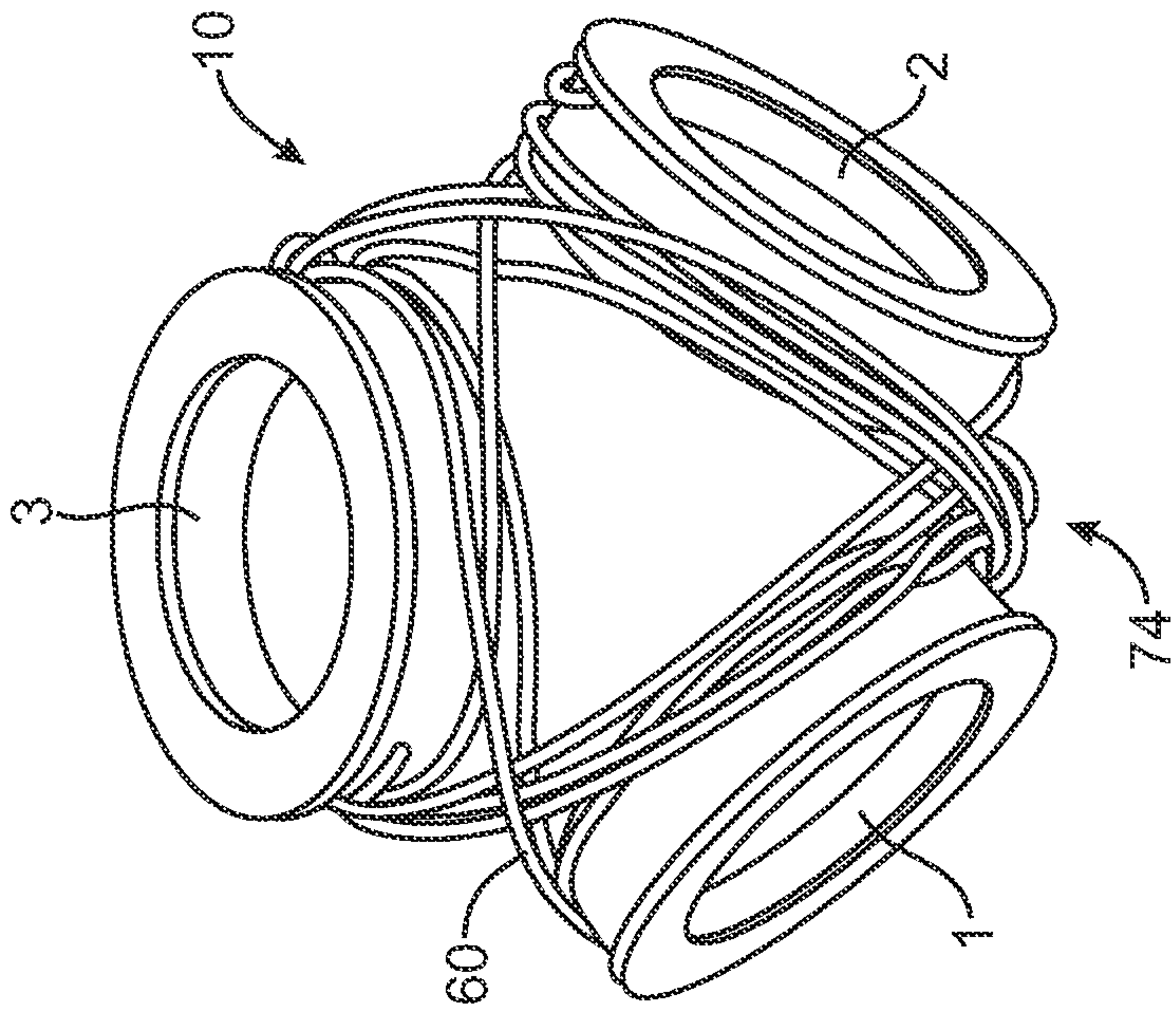


FIG. 10

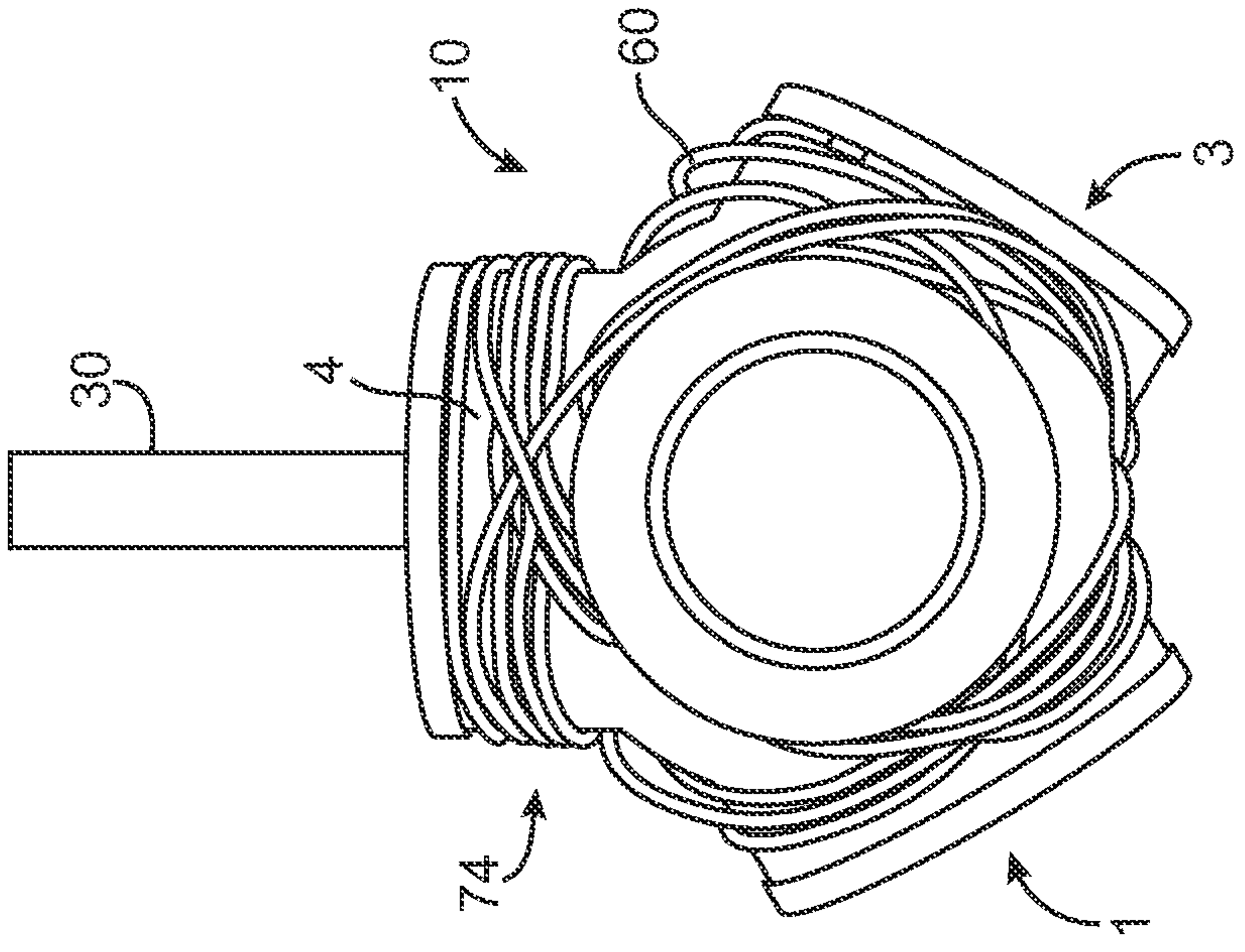
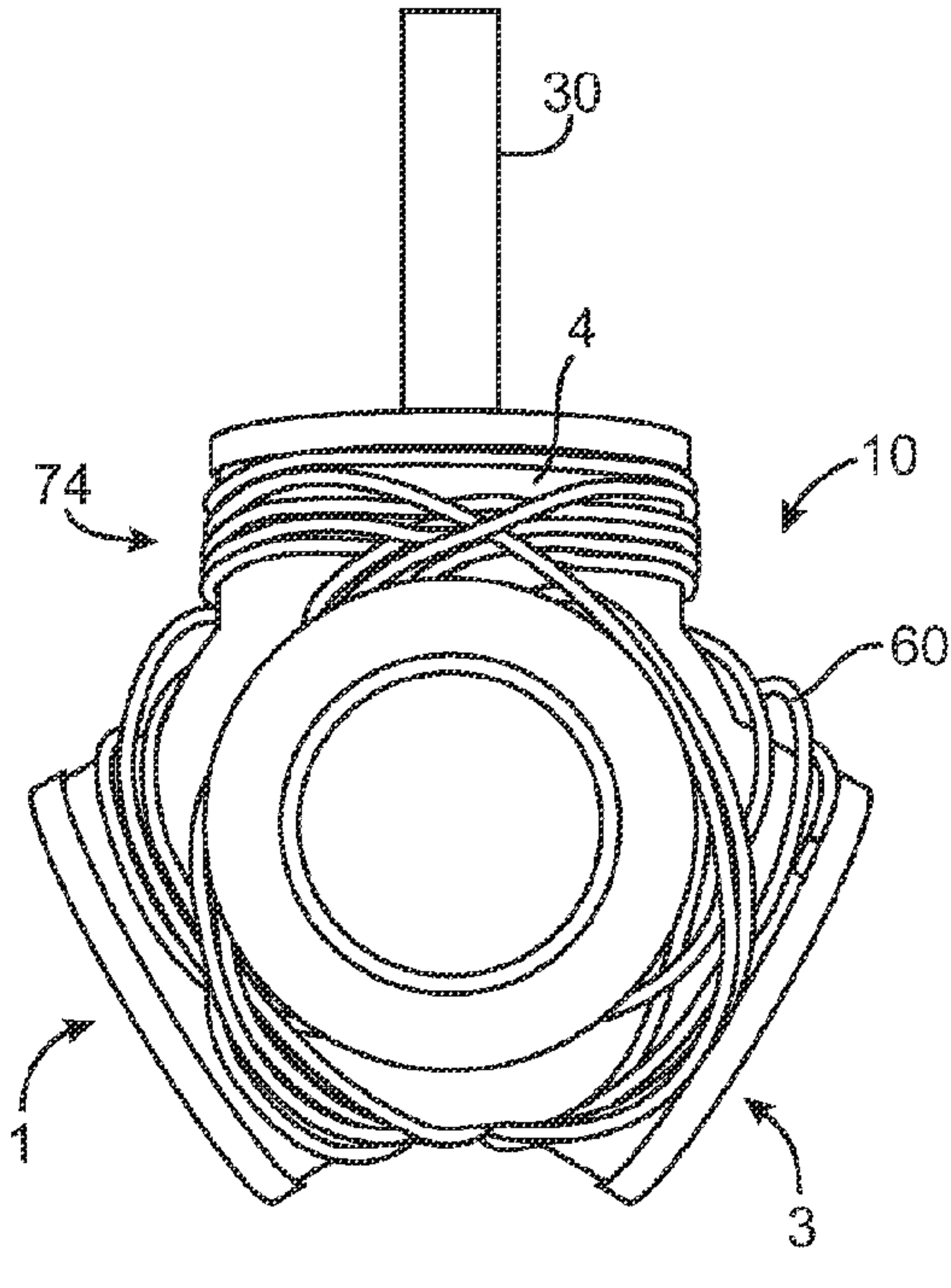


FIG. 9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