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(54) Title: MICROCATHETER STENT

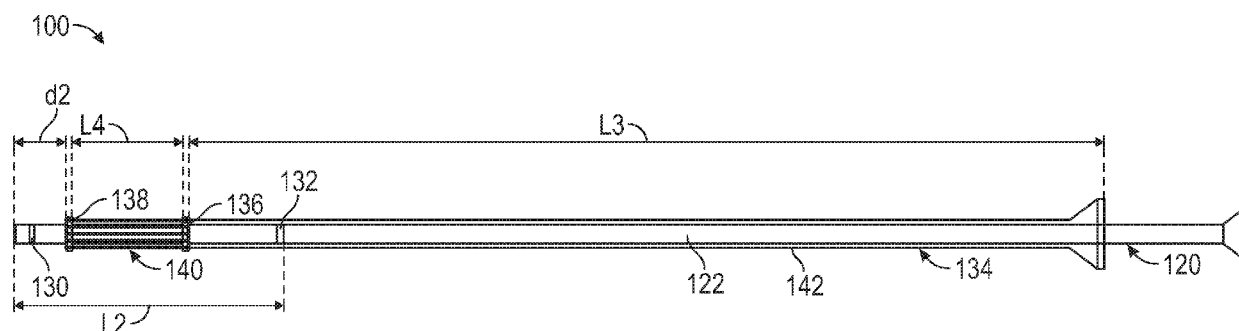


FIG. 1

(57) Abstract: Apparatus and methods of use of a microcatheter are described herein. The microcatheter can be used in the deployment and placement of a coil within a wide neck intracranial aneurysm. In some embodiments, a microcatheter includes an inner catheter movably disposed within an outer catheter. An expandable stent is coupled to both the inner catheter and outer catheter for deployment to a neck of an aneurysm. The expandable stent can have a variety of different configurations and be fabricated with microwires. The expandable stent can have an elongate collapsed or delivery configuration and be moved to an expanded configuration creating a web in the shape of, for example, sunflower leaflets. The stent in the expanded configuration creates a strut that allows for coil placement in a wide neck intracranial aneurysm without the need of the assistance of a laser cut stent, flow diverter, or balloon.

TITLE: MICROCATHETER STENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This claims priority to Provisional Application U. S. Serial No. 62/338,875, filed
5 on May 19, 2016, which is herein incorporated by reference in its entirety.

FIELD OF THE INVENTION

The invention relates to microcatheters and, more particularly, to a microcatheter
for use in the placement of a coil within a wide neck of an intracranial aneurysm
10

BACKGROUND OF THE INVENTION

A cerebral aneurysm (also known as an intracranial or intracerebral aneurysm) is a
weak or thin spot on a blood vessel in the brain that balloons out and flows with blood.
The bulging aneurysm can put pressure on a nerve or on surrounding brain tissue. The
15 aneurysm may also leak or rupture (hemorrhage), thus spilling blood into the surrounding
tissue. Some cerebral aneurysms, particularly those that are small, do not bleed or cause
other problems. Cerebral aneurysms can occur anywhere in the brain, but most often are
located along a loop of arteries that run between the underside of the brain and the base of
the skull. The most common sites for an intracranial aneurysm is the interior
20 communicating artery (30%), the posterior communicating artery (25%), and the middle
cerebral artery (20%).

Microcatheters are typically used to access the lumen of an intracranial aneurysm
by tracking the microcatheter along a micro wire. One purpose of such microcatheters is to
allow deployment of coils that can occlude the lumen of an intracranial aneurysm and
25 isolate the aneurysm from the circulation of blood flow and facilitate thrombosis over time.
For example, such use and deployment of a coil can be feasible if the neck of the
intracranial aneurysm is favorable; meaning the width of the neck of the intracranial
aneurysm is short and does not allow herniation of the coil into the parent vessel causing
occlusion or partial occlusion, and potential thromboembolic events leading to ischemic
30 stroke. In certain cases, however, the neck of the aneurysm is wide and requires, for
example, the assistance of using a balloon, laser cut stent, and/or flow diverter. Using
these devices as adjunctive to the use of the microcatheter can allow for the coverage of the

neck of the intracranial aneurysm and prevent herniation of the coils into the lumen of the parent vessel.

Such use of these adjunctive devices, however, can carry potential unwanted side effects and can add additional cost. For example, using a stent or flow diverter may
5 require the patient to be on aspirin and Plavix for a period of time. In addition, these stents typically cannot be used in the acute stenting of ruptured aneurysms, making their use limited to special cases. Using a balloon can lead to arrest of blood flow in the parent artery and potential rupture of the vessel itself if the balloon was expanded to a diameter bigger than the original diameter of the blood vessel. To minimize risks, reduce additional
10 expensive costs, and reduce the necessary steps to coil wide neck aneurysms, devices and methods as described herein are needed to overcome these shortcomings from current techniques.

Accordingly, a primary objective of the present invention is the provision of a microcatheter stent assembly which overcomes the problems of the prior art.

15 Another objective of the present invention is the provision of a microcatheter for use in placing a coil inside an intracranial aneurism.

A further objective of the present invention is the provision of a catheter and stent assembly which quickly and safely allows the stent to be positioned adjacent the neck of an aneurism.

20 Still another objective of the present invention is the provision of a dual catheter assembly having a stent which can be collapsed for movement through an artery and expanded at the site of aneurism.

Yet another objective of the present invention is the provision of a medical device having a pair of elongated inner and outer catheters slidably nested for extension and
25 retraction relative to one another with a stent mounted on the catheters to collapse and expand as the catheters are extended and retracted, respectively.

A further objective of the present invention is the provision of a microcatheter stent having one or more radiopaque markers.

Another objective of the present invention is the provision of a catheter assembly
30 having a variable wall thickness from the proximal end to the distal end.

A further objective of the present invention is the provision of a microcatheter assembly having variable flexibility from the proximal end to the distal end.

These and other objectives will become apparent from the following description of the invention.

SUMMARY OF THE INVENTION

5 A microcatheter stent includes a pair of inner and outer nested catheters which are slidable relative to one another. An expandable stent has a front end attached to the inner catheter and a rear end attached to the outer catheter. The catheters are directed through a patient's artery in an extended position with the stent collapsed. Once the tip of the inner catheter reaches the neck of an aneurism, the catheters are retracted so as to expand the
10 stent in the aneurism neck so as to retain the catheters in position. Then a coil can be extended into the aneurism through the catheters.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of a microcatheter assembly, according to a first embodiment.
15 FIG. 2 is a side view of an inner catheter of the microcatheter assembly of FIG. 1.
FIG. 2A is an end elevation view of the microcatheter stent shown in Figure 2.
FIG. 3 is a side view of a microcatheter assembly according to a second embodiment.
FIG. 4 is an enlarged view of a distal end portion of a microcatheter assembly,
20 according to a third embodiment.
FIG. 5A is a side view of a distal end portion of a microcatheter assembly, according to a fourth embodiment, shown with the stent in an expanded configuration.
FIG. 5B is a distal end view of the microcatheter assembly of FIG. 5A.
FIG. 6A is a side view of a distal end portion of a microcatheter assembly,
25 according to a fifth embodiment, shown with the stent in an expanded configuration.
FIG. 6B is a distal end view of the microcatheter assembly of FIG. 6A.
FIG. 7A is a side view of a microcatheter assembly, according to a sixth embodiment, shown in an undeployed, delivery configuration.
FIG. 7B is a distal end view of the microcatheter assembly of FIG. 7A, shown in
30 the undeployed, delivery configuration.
FIG. 7C is a perspective view of the microcatheter assembly of FIG. 7A, shown in the undeployed, delivery configuration.

FIG. 8A is a distal end view of the microcatheter assembly of FIG. 7A, shown in a deployed, expanded configuration.

FIG. 8B is a side view of the microcatheter assembly of FIG. 7A, shown in the deployed, expanded configuration.

5 FIG. 8C is a perspective view of the microcatheter assembly of FIG. 7A, shown in the deployed, expanded configuration.

FIG. 9A is a side view illustration of an aneurysm with a portion of the microcatheter assembly of FIGS. 7A-7C, shown in the undeployed, delivery configuration.

10 FIG. 9B is a view similar to FIG. 9A showing the stent extended further into the neck of the aneurism.

FIG. 10A is a side view illustration of the aneurysm and microcatheter of FIG. 9 and the portion of the microcatheter assembly of FIGS. 7A-7C, shown in the deployed, expanded configuration within a neck of the aneurysm and a coil being delivered into the aneurysm.

15 FIG. 10B is a view similar to FIG. 10A showing the stent expanded at the location of FIG. 9B.

FIG. 11 is a perspective illustration of the aneurysm and microcatheter of FIG. 9 and the portion of the microcatheter assembly of FIGS. 7A-7C, shown in the deployed, expanded configuration within a neck of the aneurysm and a coil being delivered into the aneurysm.

FIG. 12 is a side elevation view of an alternative embodiment of the microcatheter and stent assembly according to the present invention.

FIG. 13 is an enlarged side elevation view taken along circle A of FIG. 12.

FIG. 14 is a sectional view taken along lines 14-14 of FIG. 13.

25 FIG. 15 is a perspective view of distal end of the assembly shown in FIG. 12.

FIG. 16 is a perspective view of the proximal end of the assembly shown in FIG. 12.

FIG. 17 is a distal end elevation view of the assembly shown in FIG. 12.

30 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Apparatus and methods of use of a microcatheter are described herein. The microcatheter (also referred to herein as “microcatheter assembly”) can be used in the

deployment and placement of a coil within a wide neck intracranial aneurysm. In some embodiments, a microcatheter includes an inner catheter movably disposed within an outer catheter. An expandable stent is coupled to both the inner catheter and outer catheter for deployment to a neck of an aneurysm. The expandable stent can have a variety of different configurations and be fabricated with microwires. The expandable stent can have an elongate collapsed or delivery configuration and be moved to an expanded configuration creating a web in the shape of, for example, sunflower leaflets. To move the stent to the expanded configuration, the outer catheter is moved distally relative to the inner catheter as described in more detail herein. The stent in the expanded configuration creates a strut that allows for coil placement in a wide neck intracranial aneurysm without the need of the assistance of a laser cut stent, flow diverter, or balloon.

In all of the embodiments, the microcatheter assembly of the invention includes an inner catheter disposable within a lumen of an outer catheter, and an expandable stent coupled to the inner catheter and to the outer catheter. The inner catheter can include an elongate tubular shaft with a distal portion, an intermediate portion and a proximal portion. The inner catheter can define a lumen through which a guidewire can be disposed and used during delivery of the stent to an aneurysm. In some embodiments, the distal portion, the intermediate portion and/or the proximal portion of the elongate tubular shaft can include an outer layer of material that can transition the stiffness of the elongate tubular shaft along its length. In some embodiments, each of the shaft portions may comprise a material having a different durometer that transitions the stiffness of the shaft from a relatively stiff configuration along the proximal shaft portion to a relatively flexible configuration along the distal shaft portion. In some embodiments, the elongate tubular shaft may include an inner layer or coating of lubricious material adapted to reduce friction within the interior lumen. Other features relating to the performance and radiopacity characteristics of the catheter are also described herein.

FIG. 1 is a side view of a microcatheter assembly 100 according to one embodiment. The microcatheter assembly 100 (also referred to herein as “microcatheter”) is a low profile catheter having a small diameter inner lumen. The microcatheter 100 can be used in neurovascular and peripheral interventions. The microcatheter 100 includes an inner catheter 120 movably disposed within a lumen of an outer catheter 134. The inner catheter 120 (see FIG. 2) includes an elongate tubular shaft 122 defining an inner lumen

and having a proximal shaft section, an intermediate shaft section, and a distal shaft section. The diameter D3 of the inner lumen (see FIG. 2) can be, for example, 0.42 mm (1.65 inches), and extend between a proximal end and a distal end of the inner catheter 120. The inner lumen of the elongate shaft 122 can be configured to slidably receive a guidewire (not shown) and coil(s) (not shown) that can be used to track other therapeutic devices to target a lumen of an intracranial aneurysm.

The proximal shaft section can include a hub 126 and strain relief assembly 128 that can be used as an aid to manipulate the microcatheter 100 from a location outside of the body. The hub 126 may include a main body having a number of fins 129 that can be used to improve gripping and to facilitate labeling for product identification. The strain relief assembly 128 can include a strain relief member (not shown) that can be adapted to provide additional column strength and rigidity to the proximal shaft section.

The inner catheter 120 can have a length L1 (FIG. 2) that can be, for example, 130-160 cm (51-63 inches). The inner catheter 120 can include an inner layer or coating that may include a hydrophilic polymer material that reduces friction within the interior lumen. An example of such lubricious material is polytetrafluoroethylene (PTFE), which is commercially available from Dupont under the trademark TEFLON®. Other materials such as polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), ethylvinylacetate (EVA), polyurethanes, polyamides, polyethyleneterephthalate (PET), ethylene-chlorofluoroethylene (ECTFE), fluorinated ethylenepropylene (FEP), polychlorotrifluoroethylene (PCTFE), polyvinylfluoride (PVF), polyvinylidene fluoride (PVDF), and their mixtures and/or copolymers thereof may also be employed, if desired.

The inner lumen of the elongate tubular shaft 122 can be uniform along the proximal, intermediate, and distal shaft sections of the catheter 120, or may vary in dimension at one or more locations along the length of the shaft 122. In the embodiment of FIG. 2, the inner lumen is substantially uniform along the entire length of the shaft 122 and has an inner diameter D3 that can be, for example, 0.42 mm (1.65 inches), which is sufficiently large to permit one or more conventional microwires and/or coils to be inserted and advanced through the interior lumen.

The elongate tubular shaft 122 also includes an outer layer that can be made of a combination of different polymeric materials (e.g., REBAX 7233, 2533, 5533, 4033) to facilitate the transition of a stiffness of the elongate tubular shaft 122 from relatively stiff at

a proximal end portion to very malleable at a distal end portion. The various shaft sections (e.g., proximal, intermediate, distal) of the elongate tubular shaft 122 may have a wall thickness in the range of, for example, about 0.25 mm to 0.5 mm (0.01 to 0.02 inch), and in some embodiments can be, for example, 0.38 mm (0.015 inch). In some embodiments, the distal shaft section may have a smaller wall thickness in the range of, for example, about 0.10 mm to 0.15 mm (0.004 to 0.006 inches), and in some embodiments can be, for example, 0.14mm (0.0055 inch). In some embodiments, the shaft 122 may have an outer diameter that transitions from a diameter D1 of about 2.4 Fr (0.792 mm, 0.03 inch) to a diameter D2 of about 1.7 Fr (0.561mm, 0.02 inch) (see, FIG. 2). In some embodiments, a reinforcement member (e.g., a braid, weave, etc.) (not shown) can be provided along all or a portion of the length of the shaft 122, to provide additional stiffness and torsional rigidity to the inner catheter 120.

The inner catheter 120 also includes two radiopaque features that permit the catheter 120 to be visualized within the body of a patient using a fluoroscope or other suitable imaging device. More specifically, a first radiopaque marker 130 encased within the distal shaft section, or disposed on an exterior thereof, can be provided to permit the physician to radiographically visualize the distal end of the microcatheter 100 as it is advanced through the body of a patient. The first radiopaque marker 130 may include a suitable material such as platinum, gold, or tantalum, or a combination of materials such as platinum/iridium that can be used to radiographically determine the location and/or orientation of the microcatheter 100 within the artery and lumen of an aneurysm sac. The first radiopaque marker 130 can be placed at or near the distal end of the shaft 122 to permit the physician to accurately determine the location of the distal tip of the catheter 100. The first radiopaque marker 132 can be positioned at a spaced distance from the distal end of the inner catheter 120, for example, at a distance of 0.75 mm from the distal end. A second radiopaque marker 132 is encased with the distal shaft section at a location proximal to the first radiopaque marker 130. In the treatment of brain aneurysms, for example, such second (or proximal) radiopaque marker 130 can be used to align the coil delivery wire (not shown) used in many endovascular coiling procedures. As with the first (or distal) radiopaque marker 130, the second radiopaque marker 132 can include a radiopaque material or combination of radiopaque materials that provide sufficient contrast to permit fluoroscopic visualization. The placement location of the second radiopaque

marker 132 can be, for example, at a distance d_1 from the distal end of the shaft 122. In some embodiments, the distance d_1 can be, for example, 30 mm – 60 mm (1.18-2.36 inches).

An outer layer of the shaft 122 can be coated with lubricious materials that facilitate the tracking of the microcatheter 100 through the tortuous anatomy intracranially. Examples of suitable lubricious materials may include hydrophilic polymers such as polyarylene oxides, polyvinylpyrrolidones, polyvinylalcohols, hydroxy alkyl cellulotics, aligns, saccharides, caprolactones, and the like, or mixtures and combinations thereof. Lubricious materials such as that described above with respect to the inner layer or coating can also be utilized. In some embodiments, an AET coating can be used. A fixed circumferential outer ring 138 is disposed on the distal portion of the shaft 122 at a location or distance d_2 from the distal end of the shaft 122. For example, in some embodiments, the distance d_2 can be, 2 mm (0.08 inch). The circumferential outer ring 138 can also be radiopaque as described above for the first and second radiopaque markers 130, 132 described above.

The outer catheter 134 can be constructed with the same or similar materials as the inner catheter 120 described above and can include the same or similar features. The outer catheter 134 includes an elongate tubular shaft 142 defining an inner lumen and having a proximal shaft section, an intermediate shaft section, and a distal shaft section. The outer catheter 134 can have a length L_3 that can be, for example, 120 cm - 150 cm (47.24-59.06 inches). The inner lumen of the elongate shaft 142 can have a diameter that can vary, for example, in the range of 0.9 mm (0.04 inch) at a proximal end portion to 0.7 mm (0.03 inch) at a distal end portion. The diameter of the inner lumen of the outer catheter 134 can be sized to allow for the inner catheter 120 to be movably received within the inner lumen of the outer catheter 134. The outer catheter 134 can also include one or more radiopaque markers. The outer catheter 134 includes an outer circumferential ring 136 that can be embedded within the shaft of the outer catheter 134 or disposed on an exterior thereof. The outer circumferential ring 136 can also be radiopaque as described for ring 138 of inner catheter 120.

The expandable stent 140 can be formed with microwires having, for example, a thickness of 25 μ m. A distal end portion of the expandable stent 140 is coupled to the outer ring 138 of inner catheter 120 and a proximal end portion of the expandable stent 140

is coupled to the outer ring 136 of outer catheter 134 as shown in FIG. 1. The expandable stent 140 can be moved between a delivery, elongate configuration as shown in FIG. 1 to an expanded configuration. When in the expanded configuration, the expandable stent 140 forms a structure having, for example, a flower petal shape or configuration with leaflets
5 (see, e.g., the embodiments of FIGS. 5A-6B). A length of each leaflet can be, for example, 0.5 mm to 4 mm (0.02-0.16 inch). When in the delivery configuration, the stent 140 can have a length L4 of, for example, between 1 and 6 mm (0.04-0.24 inch) (see, e.g., FIG. 1). In some embodiments, the stent 140 has a length of 4 mm (0.16 inch). The microwires of the stent 140 can, for example, be straight lines (see, e.g., FIGS. 1 and 4), be helically
10 wrapped around the outer surface of the inner catheter, be a braided or mesh configuration, or other suitable configuration as desired. The number of microwires that form the stent 140 can vary. For example, the stent 140 can include 2-52 microwires. The stent 140 can include one or more groups of microwires. For example, 2 to 8 microwires can be arranged in a group or bundle and connected with 1-4 cross links spaced along the length
15 of the microwires. In some embodiments, the cross links can be spaced equally along the length of the microwires. An example stent with bundles of microwires is shown in FIG. 4.

In use, with the stent 140 in the delivery or elongate configuration as shown in FIG. 1, the microcatheter 100 is placed within a lumen or neck of an intracranial aneurysm. The
20 outer catheter 134 can then be moved distally relative to the inner catheter 120 which causes the microwires of the stent 140 to collapse or fold upon themselves and move the stent 140 to the expanded configuration (e.g., flower shaped) within the neck of the aneurysm. Examples of a stent in the expanded configuration are shown in the embodiments of FIGS. 5A-6B and described below. For example, as the outer catheter 134
25 is moved distally, because the proximal end of the stent 140 is attached to the ring 136 on the outer catheter 134 and the distal end of the stent is attached to the inner catheter 120, the proximal end of the stent 140 is moved distally with the outer catheter 134, while the distal end of the stent 140 remains fixed on the inner catheter 120. With the stent 140 expanded within the neck of the aneurysm, a coil or other therapeutic device can be
30 deployed within the aneurysm. After deployment of the coil or other therapeutic device, the microcatheter 100 can be moved back to a delivery configuration with the stent 140 in an elongate configuration. For example, the outer catheter 134 can be moved proximally

relative to the inner catheter 120, which in turn pulls the proximal end of the stent 140 proximally and stretches or elongates the stent 140. The microcatheter 100 can then be removed from the body of the patient.

FIG. 3 illustrates a microcatheter that includes an alternative embodiment of a stent. A microcatheter 200 can be constructed the same as or similar to microcatheter 100 and can function in the same or similar manner as microcatheter 100. For example, the microcatheter 200 includes an inner catheter 220 movably disposed within an outer catheter 234 and an expandable stent 240. In this embodiment, the stent 240 includes a braided or mesh tubular member. The inner catheter 120 includes an elongate tubular shaft 222, radiopaque markers 230 and 222 and outer circumferential ring 238. The outer catheter 234 includes an elongate tubular shaft 242, one or more radiopaque markers (not shown) and outer circumferential ring 236. A proximal end of the stent 240 is coupled to the outer ring 236 of the outer catheter 234 and a distal end of the stent 240 is coupled to the outer ring 238 of the inner catheter 220. The microcatheter 200 can be used in the same manner as described above for microcatheter 100.

FIG. 4 illustrates a distal end portion of a microcatheter 300. The microcatheter 300 can be constructed the same as or similar to microcatheter 100 and can function in the same or similar manner as microcatheter 100. For example, the microcatheter 300 includes an inner catheter 320 movably disposed within an outer catheter 334 and an expandable stent 340. In this embodiment, the stent 340 includes multiple bundles or groups of microwire 344 connected by cross link members 346 spaced along a length of the microwires. The inner catheter 320 includes an elongate tubular shaft 322, radiopaque markers 330 and 332 and outer circumferential ring 338. The outer catheter 334 includes an elongate tubular shaft 342, one or more radiopaque markers (not shown) and outer circumferential ring 336. A proximal end of the stent 340 is coupled to the outer ring 336 of the outer catheter 334 and a distal end of the stent 340 is coupled to the outer ring 338 of the inner catheter 320. The microcatheter 300 can be used in the same manner as described above for microcatheter 100.

FIGS. 5A and 5B illustrate a microcatheter 400 shown in the expanded configuration. In other words, the outer catheter has been moved distally relative to the inner catheter, which in turn moves the proximal end of the stent distally toward the distal end of the stent and to an expanded configuration. The microcatheter 400 can be

constructed the same as or similar to microcatheter 100, and can function in the same or similar manner as microcatheter 100. For example, the microcatheter 400 includes an inner catheter 420 movably disposed within an outer catheter 434 and an expandable stent 440. The inner catheter 420 includes an elongate tubular shaft 422, radiopaque markers 430 and 432 and outer circumferential ring 438. The outer catheter 434 includes an elongate tubular shaft 442, one or more radiopaque markers (not shown) and outer circumferential ring 436. A proximal end of the stent 440 is coupled to the outer ring 436 of the outer catheter 434 and a distal end of the stent 440 is coupled to the outer ring 438 of the inner catheter 420. The microcatheter 400 can be used in the same manner as described above for microcatheter 100. As best shown in FIG. 5B, when the stent 440 has been moved to the expanded configuration, the stent 440 has a flower shape with leaflets 448. The stent 440 has an overall outer diameter D3 when in the expanded configuration and the leaflets 448 have a length L5. In some embodiments, the length L5 of each leaflet can be, for example, 0.5 mm to 4 mm (0.02-0.16 inch). In some embodiments, the diameter D3 can be, for example, about 4 mm (0.16 inch).

FIGS. 6A and 6B illustrate a microcatheter 500 shown in the expanded configuration. In other words, the outer catheter has been moved distally relative to the inner catheter, which in turn moves the proximal end of the stent distally toward the distal end of the stent and to an expanded configuration. The microcatheter 500 can be constructed the same as or similar to microcatheter 100 and can function in the same or similar manner as microcatheter 100. For example, the microcatheter 500 includes an inner catheter 520 movably disposed within an outer catheter 534 and an expandable stent 540. The inner catheter 520 includes an elongate tubular shaft 522, radiopaque markers 530 and 532 and outer circumferential ring 538. The outer catheter 534 includes an elongate tubular shaft 542, one or more radiopaque markers (not shown) and outer circumferential ring 536. A proximal end of the stent 540 is coupled to the outer ring 536 of the outer catheter 534 and a distal end of the stent 540 is coupled to the outer ring 538 of the inner catheter 520. The microcatheter 500 can be used in the same manner as described above for microcatheter 100. As best shown in FIG. 5B, when the stent 540 has been moved to the expanded configuration, the stent 540 has a flower shape with leaflets 548. The stent 540 has an overall outer diameter D3 when in the expanded configuration and the leaflets 548 have a length L5. In some embodiments, the length L5 of each leaflet can be,

for example, 0.5 mm to 4 mm (0.02-0.16 inch). In some embodiments, the diameter D3 can be, for example, about 4 mm (0.16 inch).

FIGS. 7A-8C illustrate a portion of a microcatheter assembly 600, according to another embodiment, and FIGS. 9-11 illustrate the microcatheter assembly 600 in use to
5 deliver a coil into an aneurysm. The microcatheter assembly 600 (also referred to as “microcatheter”) can be constructed the same as or similar to microcatheter 100 and can function in the same or similar manner as microcatheter 100. The microcatheter 600 includes an inner catheter 620 movably disposed within an outer catheter 634 and an expandable stent 640. In this embodiment, the stent 640 includes multiple bundles or
10 groups of microwire 644. As described above for previous embodiments, the bundles of microwires 644 can be connected by cross link members (not shown) spaced along a length of the microwires. The inner catheter 620 includes an elongate tubular shaft 622 that defines an inner lumen 650. A radiopaque marker 630 is disposed on the shaft 622 and an outer circumferential ring 638. Additional radiopaque markers can also be disposed on the
15 shaft 622 as desired and the outer circumferential ring 638 can also be radiopaque. The outer catheter 634 includes an elongate tubular shaft 642 that defines a lumen to receive the inner catheter 620. The outer catheter 634 can also include one or more radiopaque markers (not shown) disposed on the shaft 642 and an outer circumferential ring 636. A proximal end of the stent 640 is coupled to the outer ring 636 of the outer catheter 634 and
20 a distal end of the stent 640 is coupled to the outer ring 638 of the inner catheter 620. Each of the inner catheter 620 and outer catheter 634 can be formed with a material to provide flexibility to the inner catheter 620 and/or outer catheter 634, such that the inner catheter 620 and/or outer catheter 634 can be maneuvered through tortuous blood vessels. For example, as shown in FIGS. 8A-8C, 10 and 11, a distal end portion of the inner catheter
25 620 can move or flex into a curved shape as desired.

The stent 640 has an undeployed, delivery configuration (also referred to as “first configuration”) as shown in FIGS. 7A-7C and 9), and can be moved to a deployed, expanded configuration (also referred to as “second configuration”) during use, as shown in FIGS. 8A-8C, 10 and 11. When in the first configuration, an outer diameter of the stent
30 640 is smaller than when in the second configuration. To move the stent 640 to the second configuration, the outer catheter 634 is moved distally relative to the inner catheter 620, such that the outer ring 636 on the outer catheter 634 is moved distally closer to the outer

ring 638 on the inner catheter 620 (which remains stationary or fixed) as best shown, for example, in FIGS. 8B and 8C. This in turn causes the stent 640 to collapse upon itself and move to the second configuration. Thus, when the stent 640 is in the first configuration, the microcatheter 600 is in a first or delivery configuration and when the stent 640 is
5 moved to its second configuration (i.e., deployed, expanded), the microcatheter 600 is in a second or deployed configuration.

In use, with the microcatheter 600 in the first, delivery configuration (i.e., the stent 640 is in the first configuration), at least a distal end portion of the microcatheter 600 can be inserted into a body lumen, such as a blood vessel V, shown in FIG. 9. As shown in
10 FIG. 9, the distal end portion of the microcatheter 600 can be placed at or within a neck N of an aneurysm An. For example, a distal end of the stent 640 can be placed at the neck N. The outer catheter 634 can then be moved distally relative to the inner catheter 620 to move the stent 640 to its second configuration (i.e., deployed, expanded) within the neck N. The stent 640 thus can maintain the neck N in an open position and a coil 645 (or other
15 therapeutic agent or device) can be introduced into the aneurysm through the lumen 650 of the inner catheter 620, as shown in FIGS. 10 and 11. When the coil 645 has been fully deployed into the aneurysm, the stent 640 can be moved back to its first configuration (undeployed, collapsed) such that the microcatheter 600 can be removed from the blood vessel V of the patient.

FIGS. 12-16 show yet another embodiment of the microcatheter stent assembly according to the present invention. In this embodiment, the assembly 700 includes an inner catheter 720 and an outer catheter 734, with a braided stent 740 on the distal end of the assembly 700, similar to previously described embodiments. In RHV assembly 750 is mounted on the outer catheter 734, along with a Luer taper 760 at the proximal end of the
25 outer catheter 734. As seen in Figure 14, the inner catheter 720 includes an inner shaft 722 preferably made of PTFE, and a PEBAX inner shaft, with an SR wire 725 between the shafts 722 and 724. One or more radiopaque marker bands 730 may be provided on the inner and outer catheters 720, 734, similar to previously described embodiments. The outer catheter 734 comprises a shaft 742, as in prior embodiments. Preferred dimensions for the
30 assembly 700 are provided in FIG. 12-14, in inches, as well as millimeters (bracketed dimensions).

The following table provides an example of dimensions for the components of the assembly 700.

REF NO.	PART NUMBER	DESCRIPTION
722	D2.0; Microcatheter, Inner Shaft, PTFE	PTFE Liner, .0165" x .0175"
725	D2.1; Microcatheter, Inner Shaft, SR Wire	Stretch Resistant Wire, SS, .0005" x .003"
742	D2.2 Microcatheter, Outer Shaft	63D Pebax, .0026" x .03799"
724	D2.2; Microcatheter, Inner Shaft, Pebax	63D Pebax, .0175" x .02358"
734	D2.1; Microcatheter, Inner Marker Band	Marker Band for Inner Shaft, .022" x .026" x .005"L
734	D2.1; Microcatheter, Outer Marker Band	Marker Band for Outer Shaft, .0345" x .0365" x .060"L
734	D2.1; Microcatheter, Tip Marker Band	Marker Band for Tip, .018" x .022" x .005"L
740	D2.3; Microcatheter, Outer Shaft, Braid ASSEMBLY	24 Wire Braid, .002" NiTi #1, 75-80 PPI for Proximal End and 20 PPI where exposed
750	D2.0 - RHV Assembly	Generic RHV Bonded to .038" Outer Shaft, and Tightens onto a .026" Shaft
760	D2.0 - Luer Taper	Generic Luer for .026" Shaft and .016" ID

Although not shown and described for each embodiment, any of the embodiments of a microcatheter described herein can be coupled to or include a handle assembly that can include controls and actuators to operate the microcatheter. For example, a handle assembly can include actuators that can be actuated by a user to cause the inner catheter and/or outer catheter to curve or flex. A handle assembly can also include one or more actuators that can be used to actuate the outer catheter to move distally and proximally relative to the inner catheter to move the stent between the undeployed, delivery configuration and the deployed, expanded configuration. Further, as described for microcatheter 100, any embodiment of a microcatheter described herein can include a hub (e.g., hub 126) and strain relief assembly (e.g., strain relief assembly 128) that can be used as an aid to manipulate the microcatheter 100 from a location outside of the body.

Thus, the dual, nested catheter and stent assembly for deploying a stent at the site of an aneurysm, according to the present invention, accomplishes at least all of the state objectives. It is understood that this assembly is primarily intended for use in intracranial aneurysms, but can also be employed with aneurysms located in other parts of the body.

While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods

described above indicate certain events occurring in certain order, the ordering of certain events may be modified. Additionally, certain of the events may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.

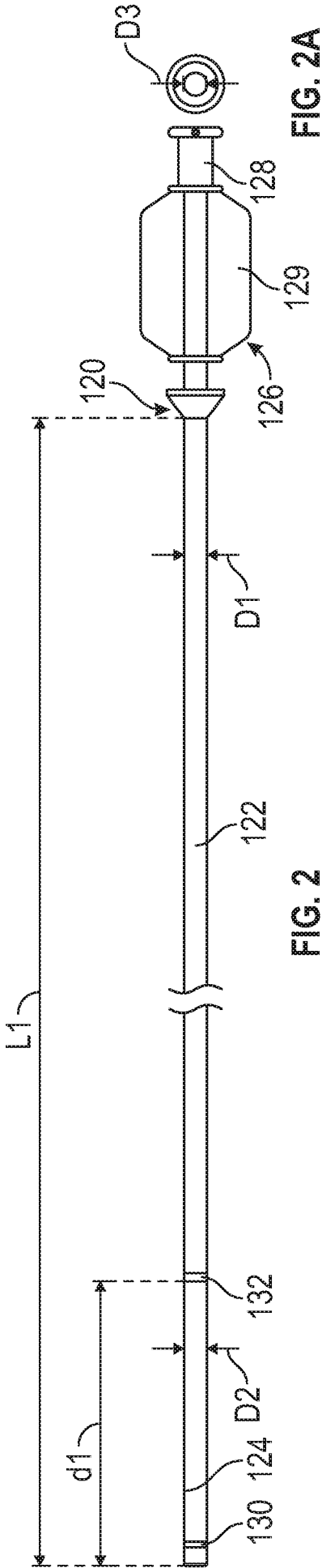
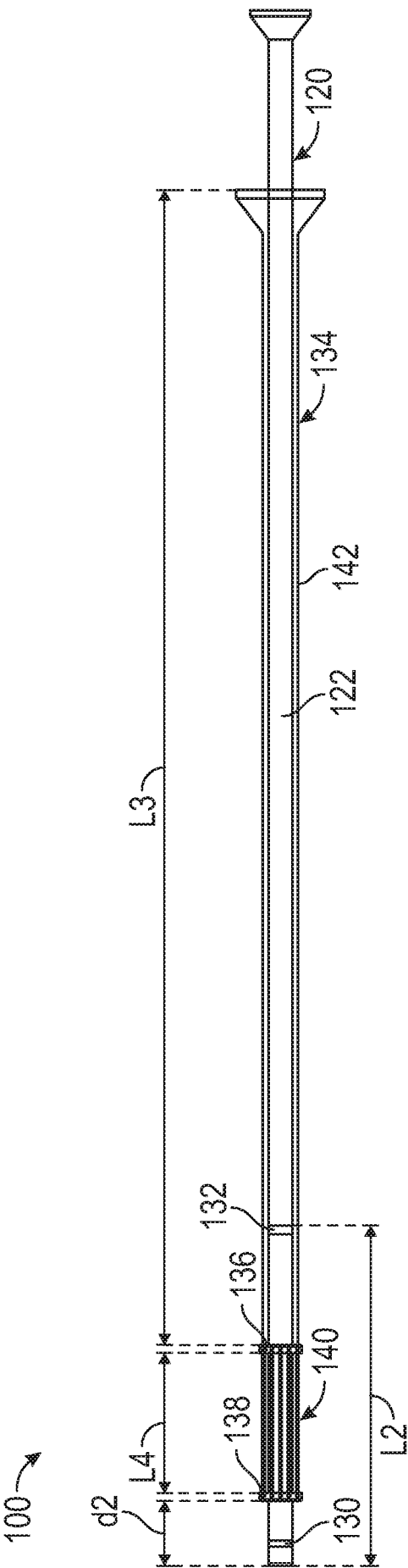
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What is claimed is:

1. A catheter and stent assembly, comprising:
an outer catheter;
5 an inner catheter extending through the outer catheter;
the inner and outer catheters being slidable relative to one another between
extended and retracted positions;
a stent having a first end attached to the inner catheter and a second end attached to
the outer catheter;
10 the stent being configurable from a collapsed condition for insertion into a patient
and an expanded condition at a selected site in the patient.
2. The catheter and stent assembly of claim 1 further comprising a microwave
extending through the inner catheter.
- 15 3. The catheter and stent assembly of claim 1 wherein the stent is formed by
microwires.
4. The catheter and stent assembly of claim 1 wherein the stent includes cross link
20 members extending between the microwires.
5. The catheter and stent assembly of claim 1 wherein the inner catheter includes a
radiopaque marker.
- 25 6. The catheter and stent assembly of claim 5 wherein the outer catheter includes a
radiopaque marker.
7. The catheter and stent assembly of claim 1 wherein the inner and outer catheters
each have a distal end with a circumferential ring, and the first and second ends of
30 the stents are connected to the rings of the inner and outer catheters, respectively.

8. The catheter and stent assembly of claim 1 further comprising a layer of lubricious material between the inner and outer catheters.
9. The catheter and stent assembly of claim 1 wherein the outer catheter has a thicker wall at a proximal end and a thinner wall at a distal end.
10. The catheter and stent assembly of claim 1 wherein the outer catheter has a flexibility which decreases from a proximal end to a distal end.
11. A medical device, comprising:
a pair of elongated inner and outer catheters slidably nested for extension and retraction;
a stent mounted on the catheters to collapse when the catheters are extended and expand when the catheters are retracted.
12. The medical device of claim 11 wherein the stent comprises microwires.
13. The medical device of claim 11 wherein the stent has opposite ends connected to the inner and outer catheters, respectively.
14. The medical device of claim 11 wherein the stent is on the exterior of the catheters.
15. The medical device of claim 11 wherein the catheters have varying durometer along their length.
16. The medical device of claim 11 further comprising a strain relief assembly on each catheter.
17. The medical device of claim 11 wherein the inner catheter has a hub at a proximal end.

18. The medical device of claim 17 wherein the hub includes at least one fin for gripping.
- 5 19. The medical device of claim 11 further comprising a microwire extending through the inner catheter.
- 10 20. The medical device of claim 19 wherein the microwire terminates in a coil at a distal end.



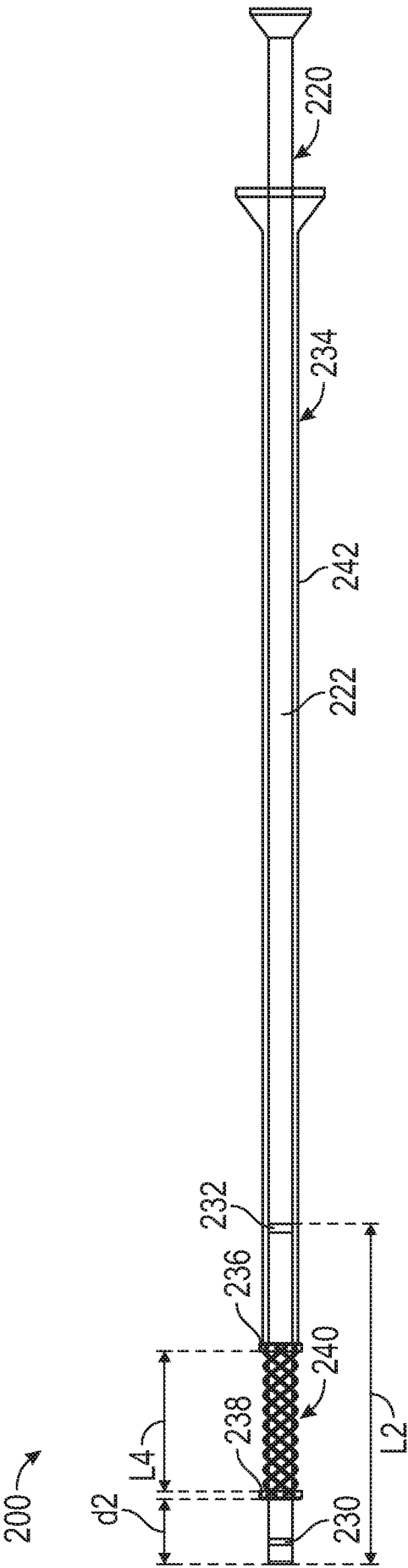


FIG. 3

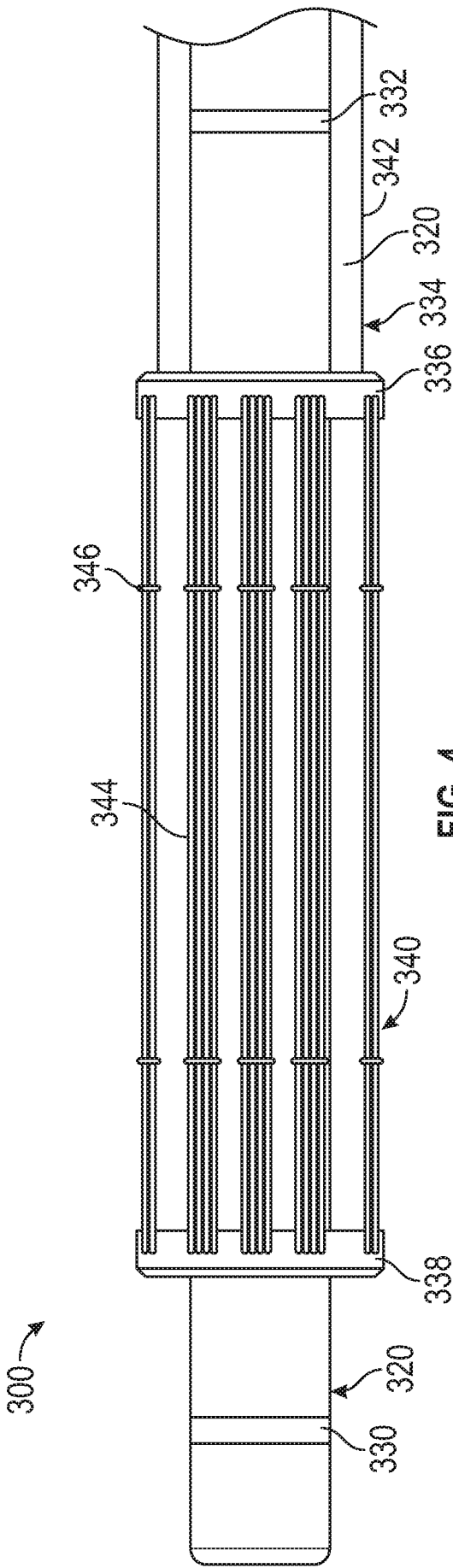


FIG. 4

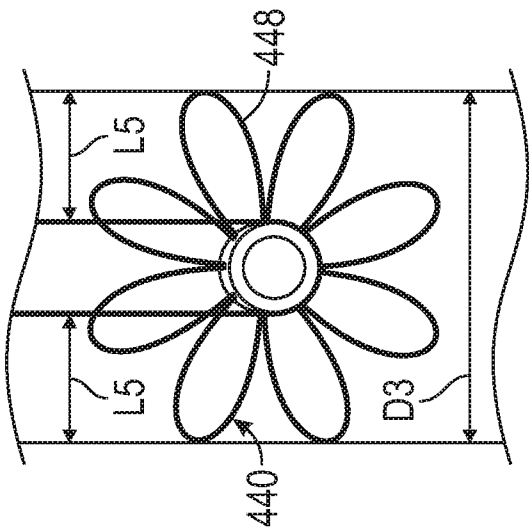


FIG. 5B

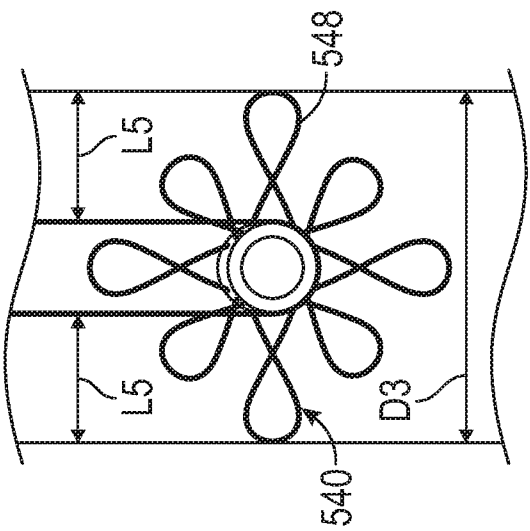


FIG. 6B

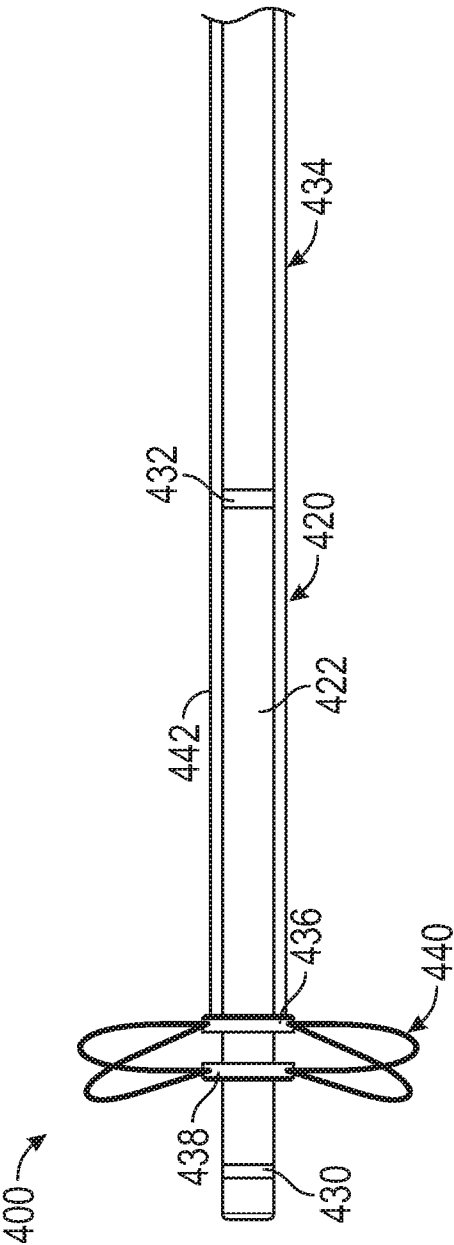


FIG. 5A

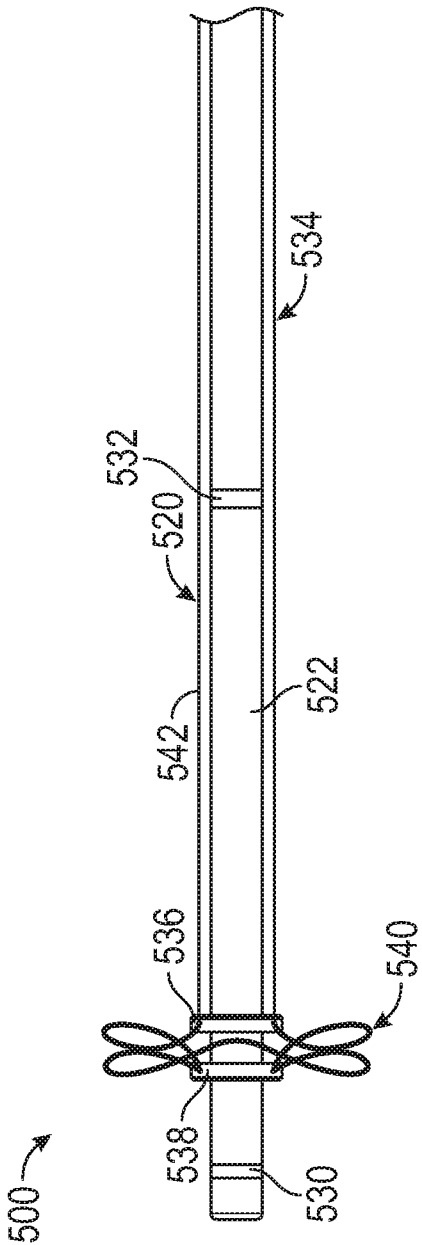


FIG. 6A

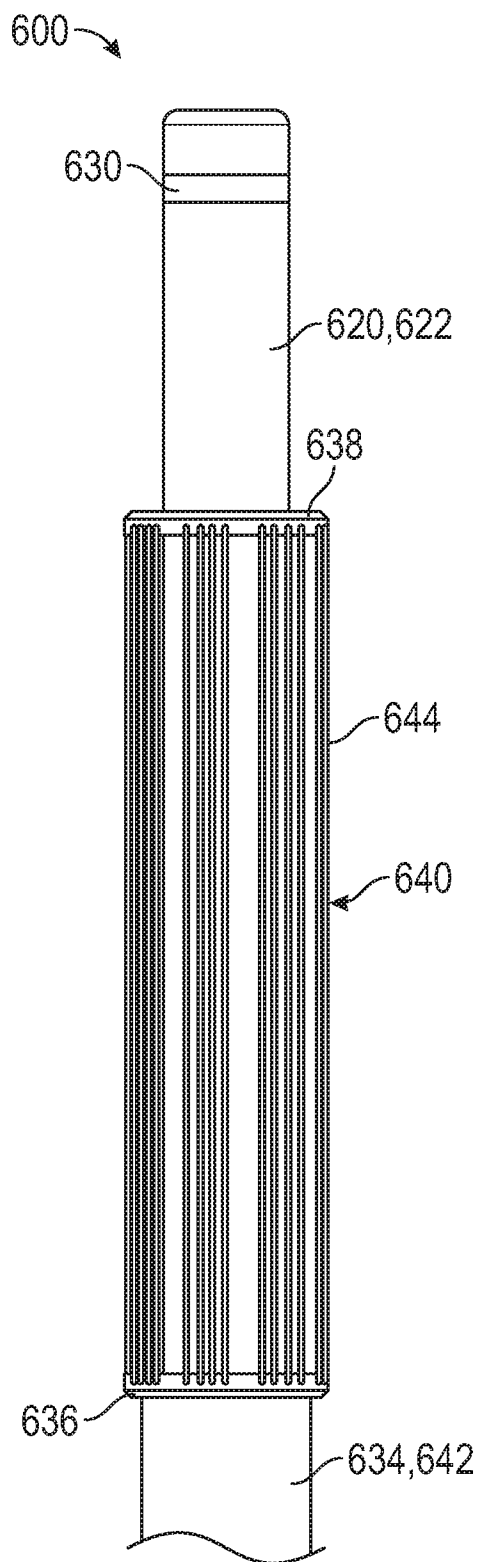


FIG. 7A

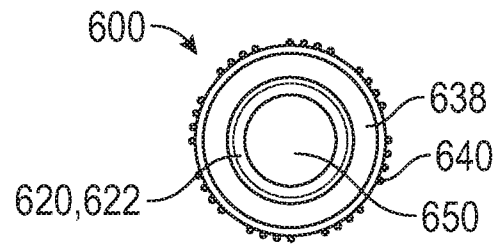


FIG. 7B

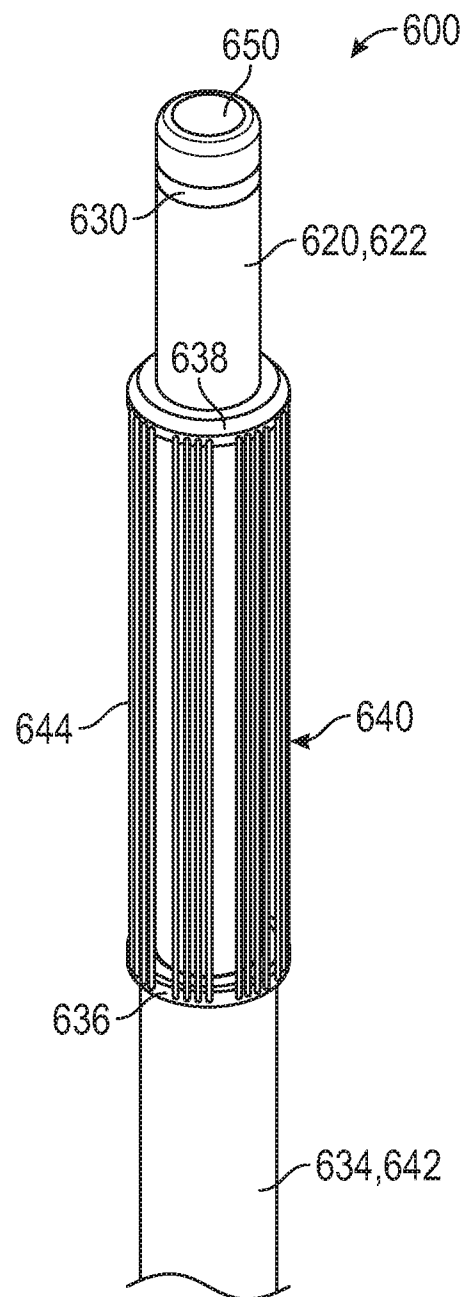


FIG. 7C

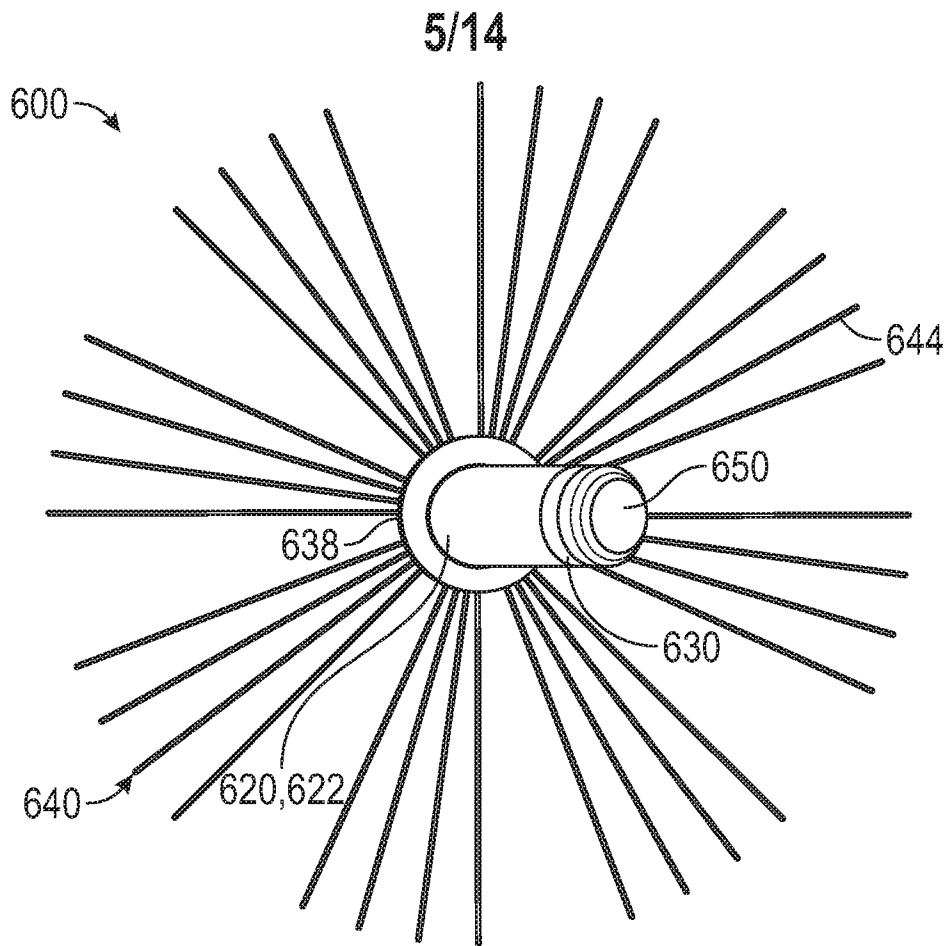


FIG. 8A

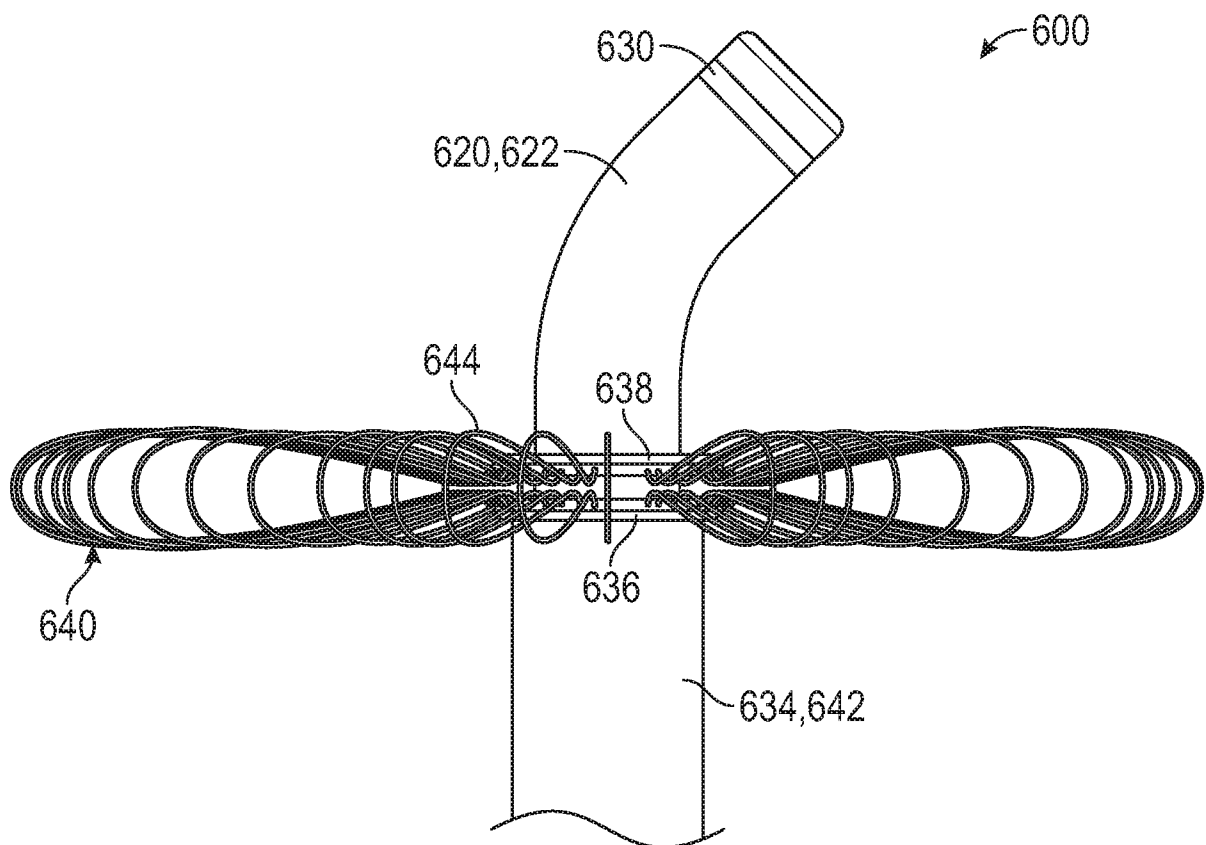
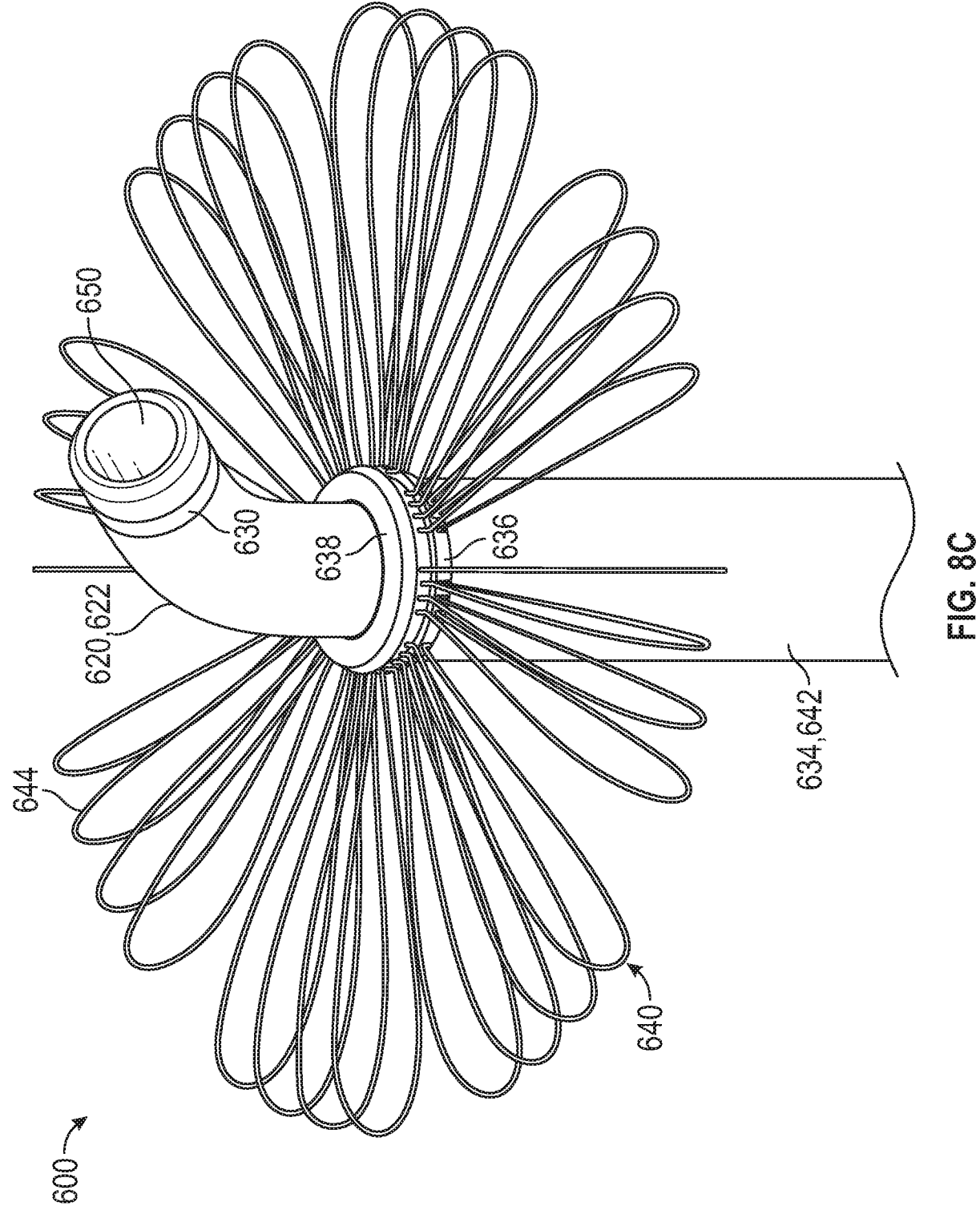


FIG. 8B



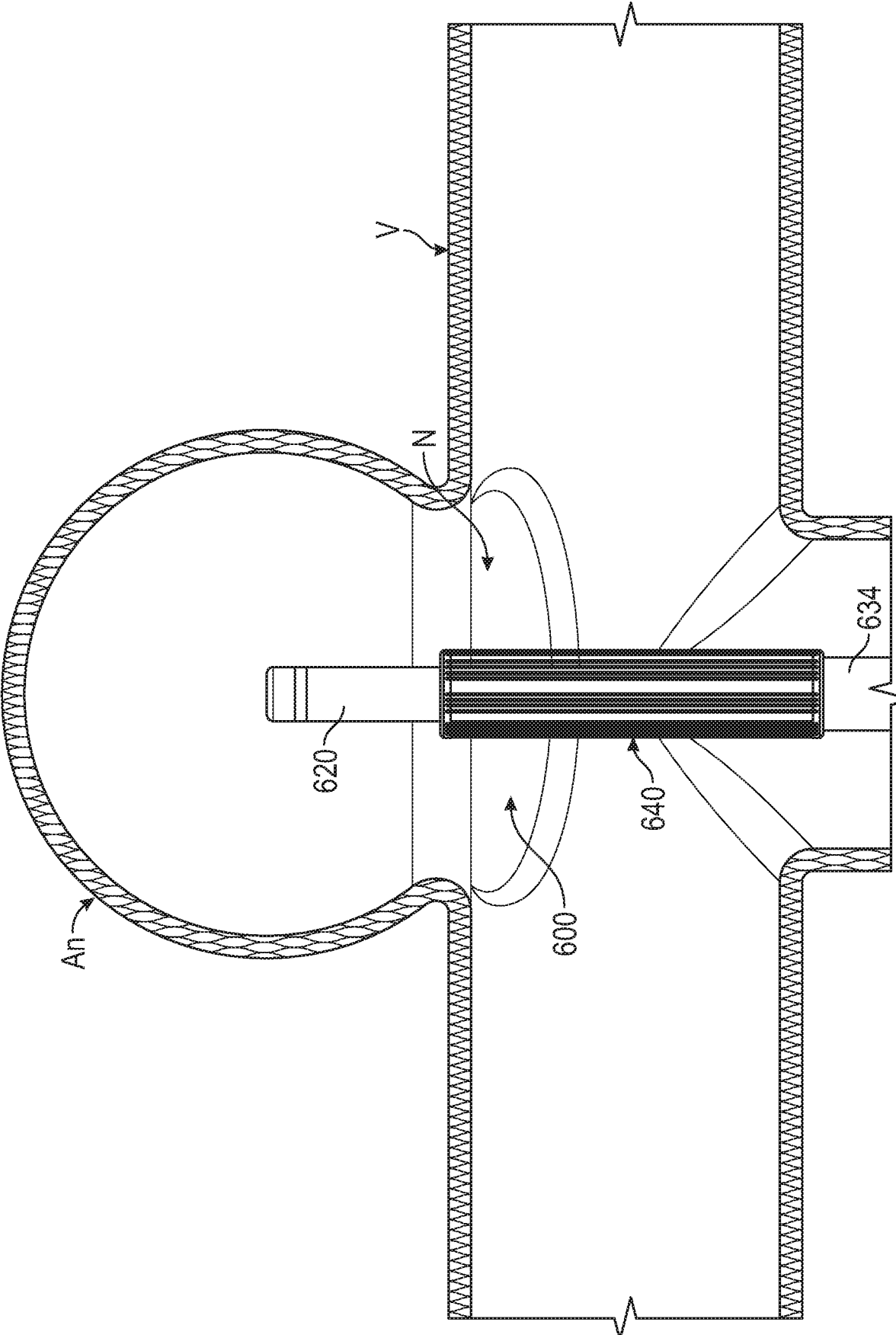


FIG. 9A

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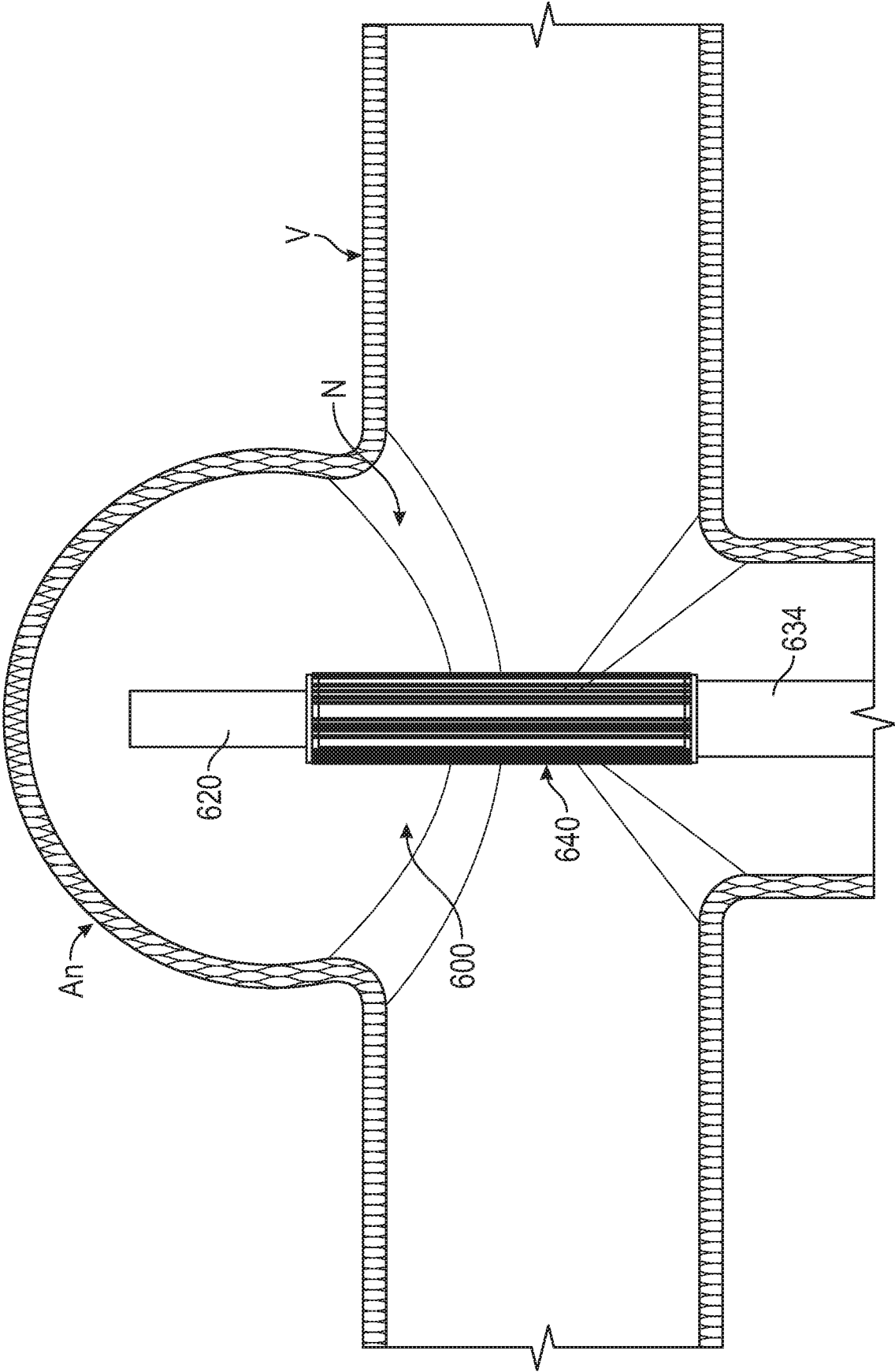


FIG. 9B

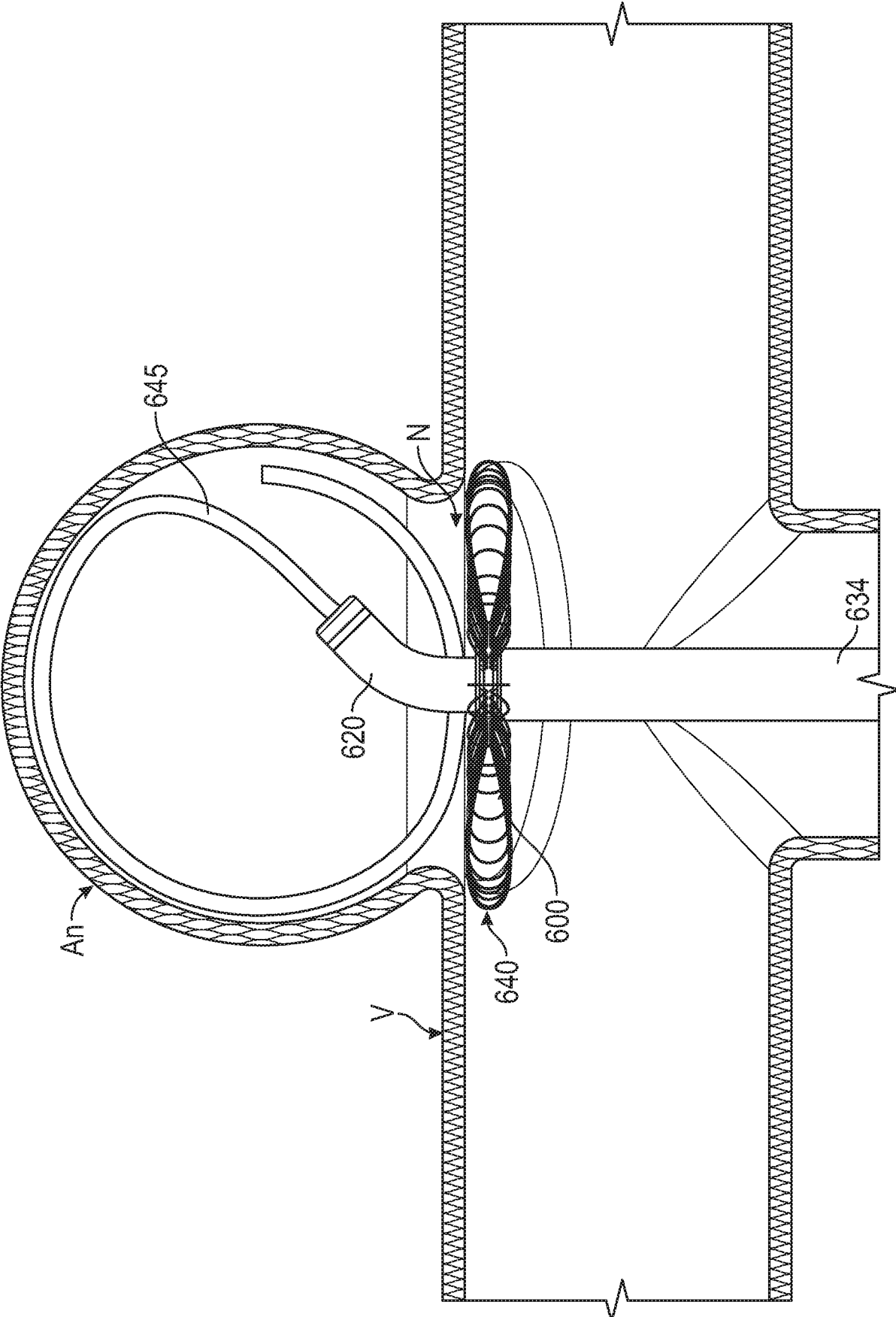


FIG. 10A

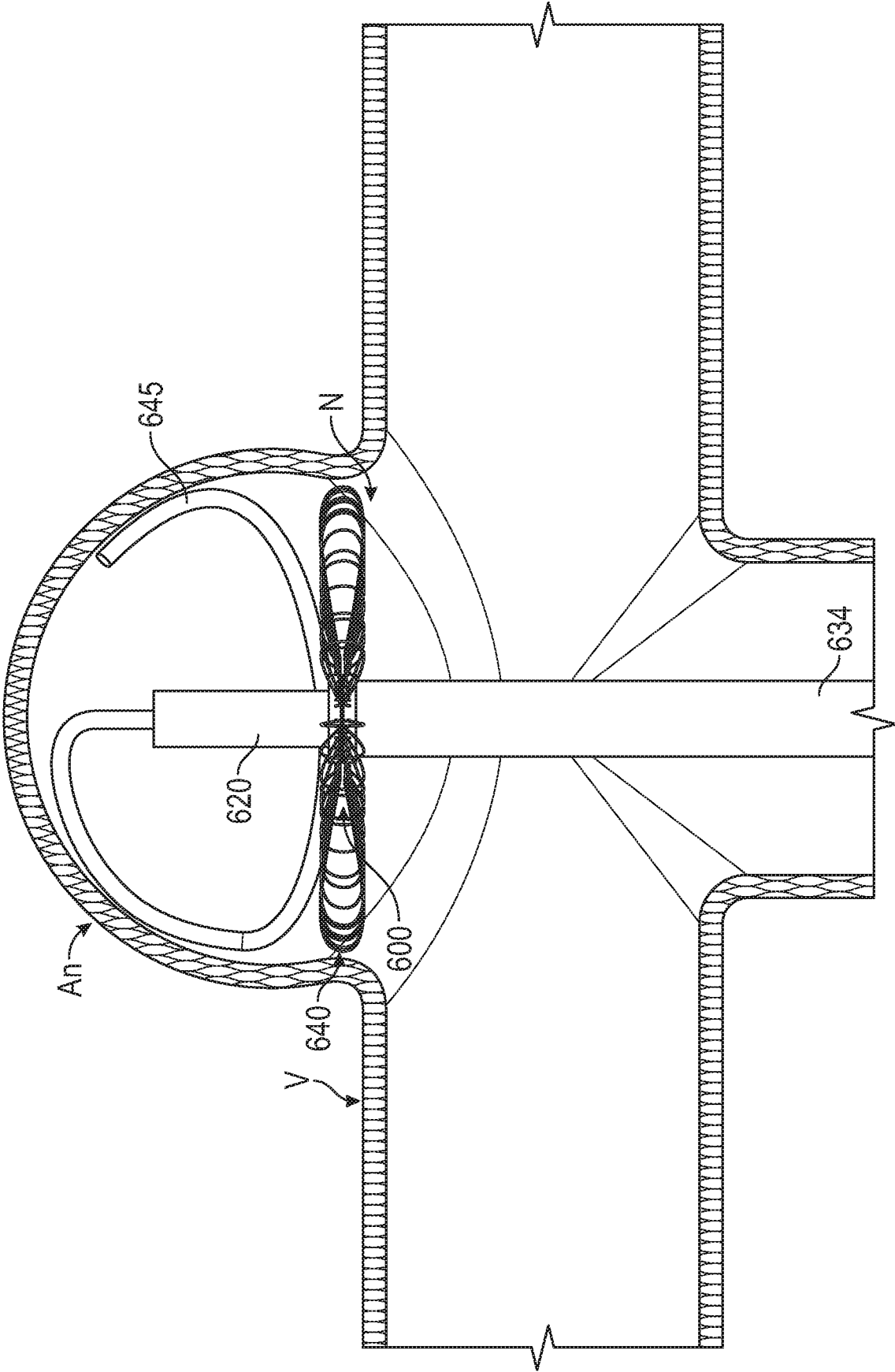


FIG. 10B

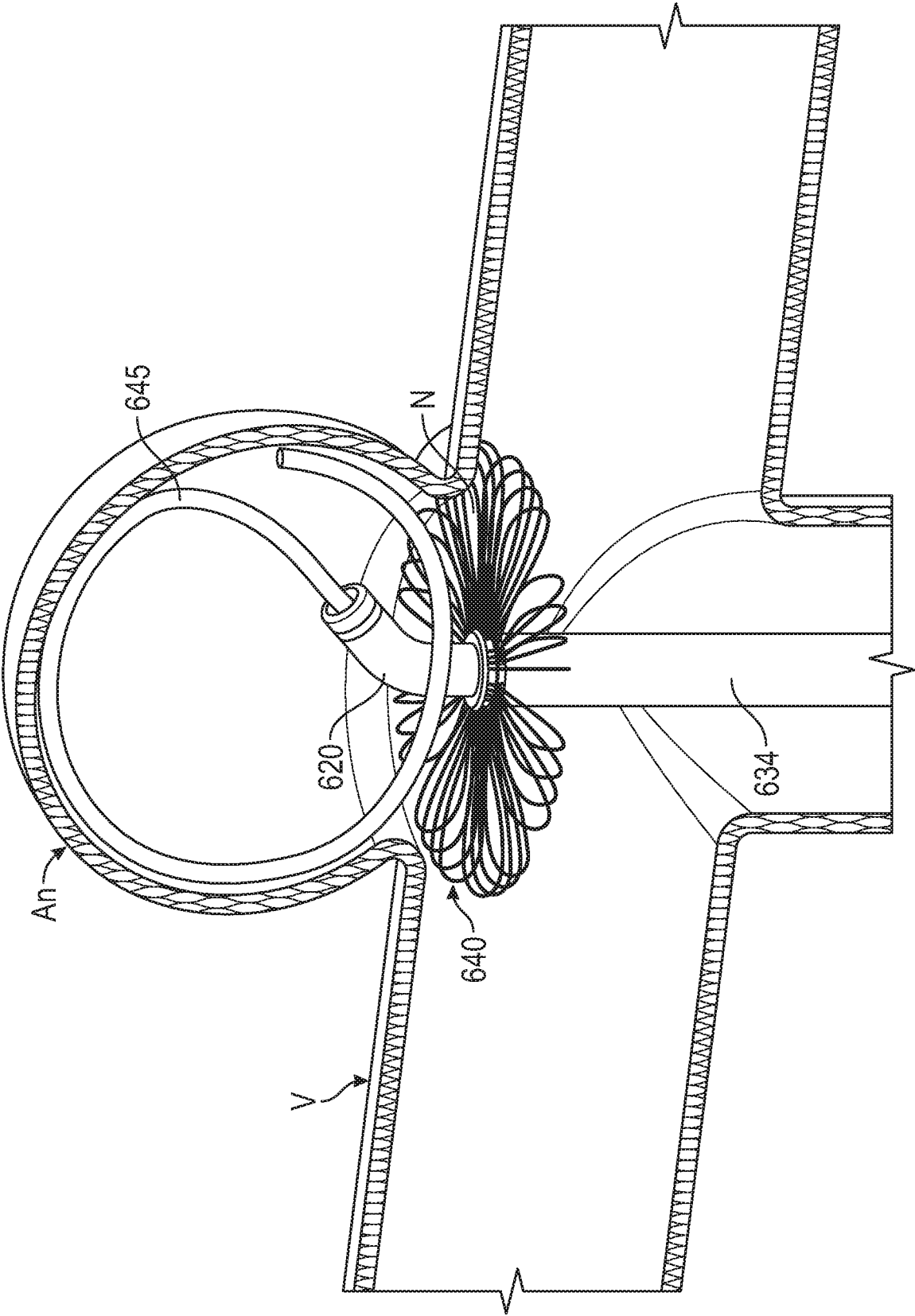
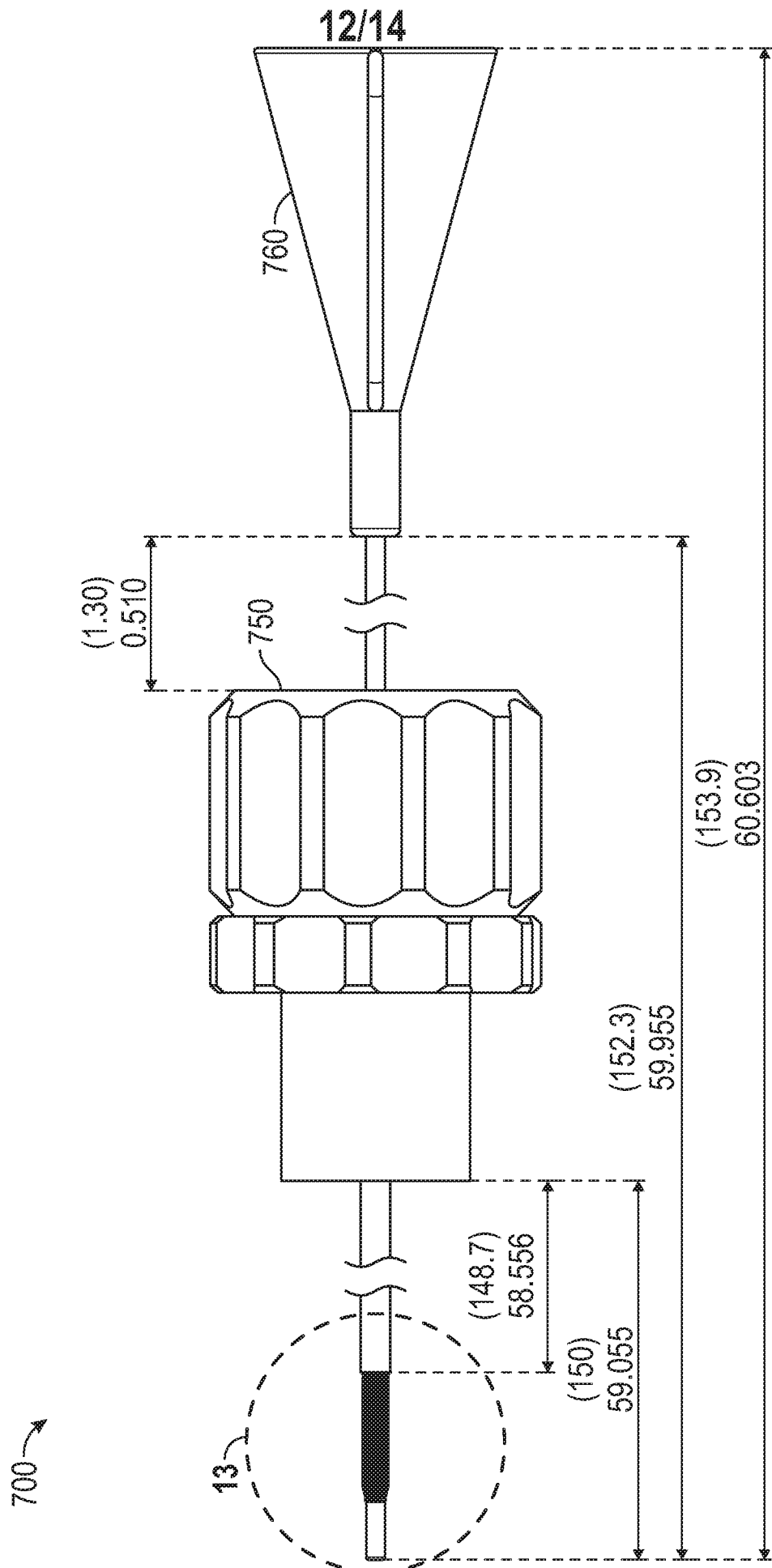


FIG. 11



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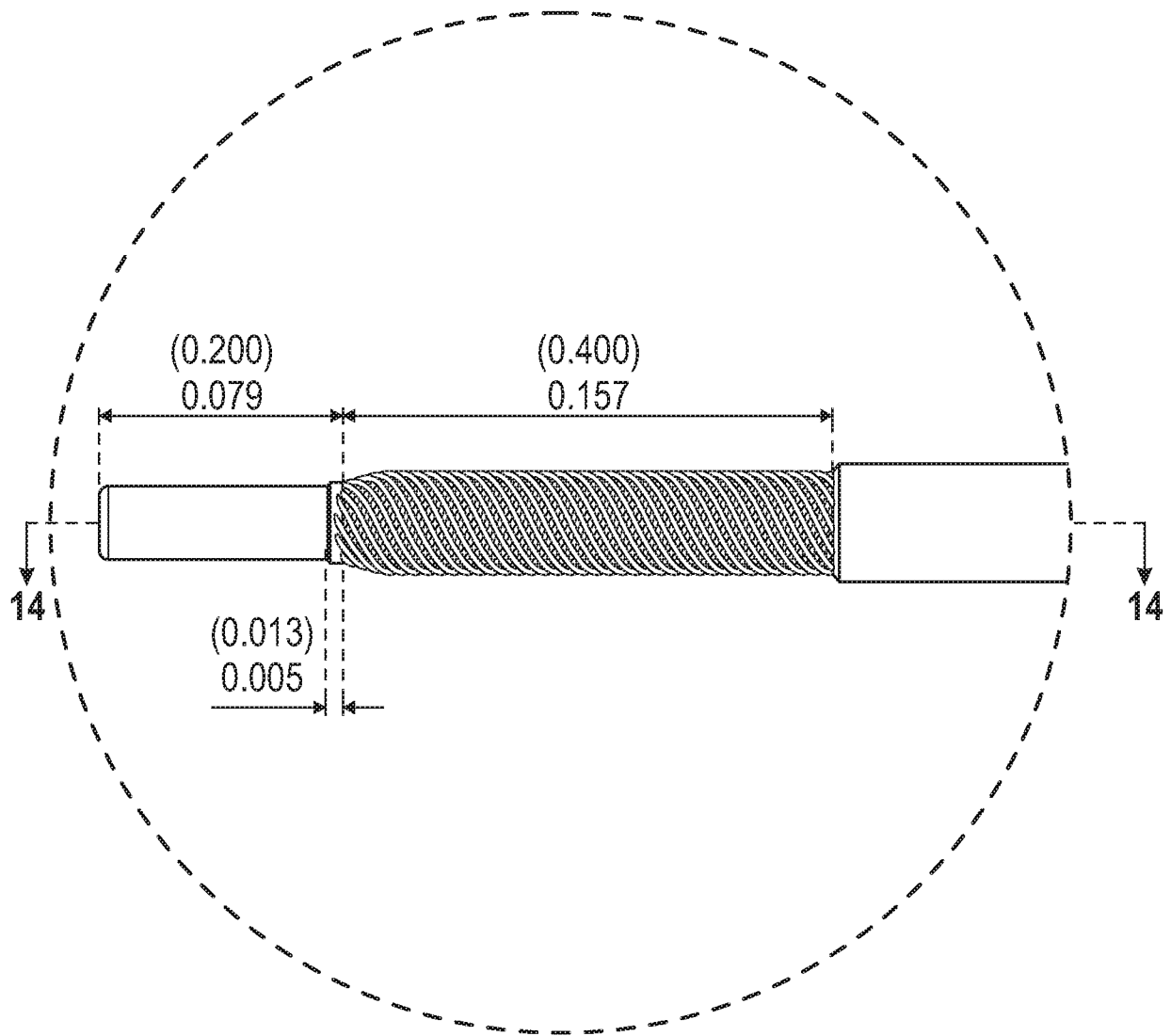


FIG. 13

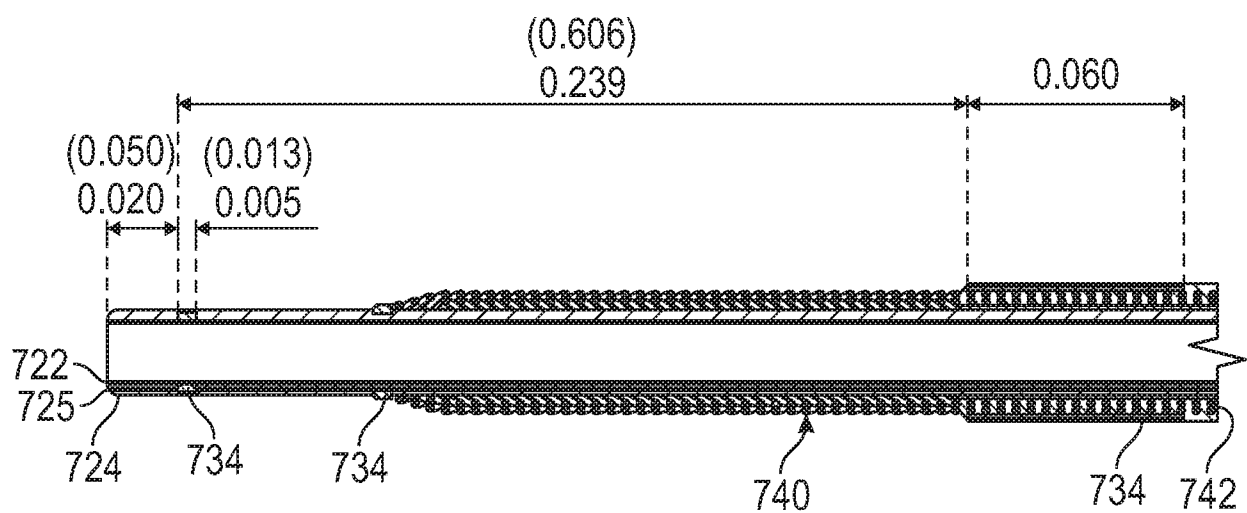


FIG. 14

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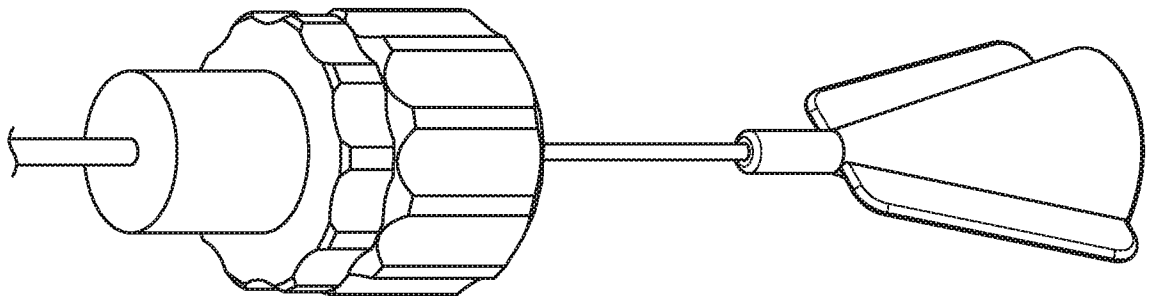


FIG. 15

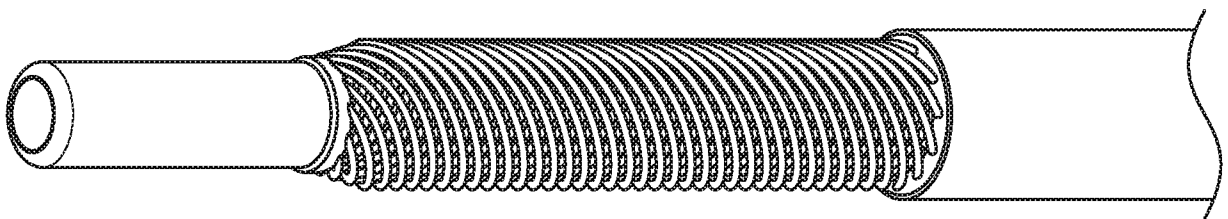


FIG. 16

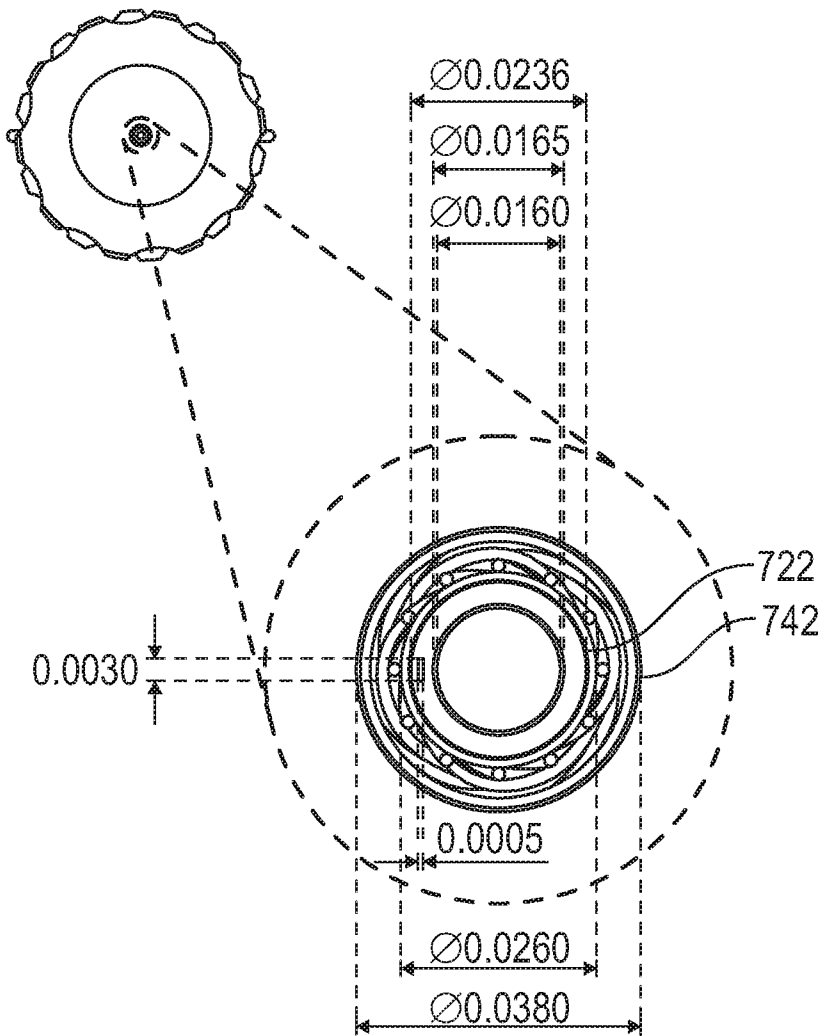


FIG. 17

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 17/33296

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 29/00 (2017.01)

CPC - A61B 17/1204, A61B 17/12109, A61B 17/1214, A61B 17/12145, A61B 17/12168, A61B 17/12172, A61B 17/12022, A61B 17/12113, A61B 17/12118

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,449,372 A (SCHMALTZ et al.) 12 September 1995 (12.09.1995) Entire document, especially abstract, col 4, ln 34-38, col 5, ln 49- col 6, ln 26, col 8, ln 30-53, col 12, ln 55- col 13, ln 15 and FIGS. 1-6, 11-13.	1-3, 5-7, 9, 11-14, 16-20
X	US 2015/0164512 A1 (CHIN et al.) 18 June 2015 (18.06.2015) Entire document, especially Abstract, para[0010]- para[0012], para[0037]- para[0041], para[0055]- para[0060] and FIGS. 1-4.	1, 3-4, 8, 10-15
A	US 2016/0030023 A1 (HAYAKAWA et al.) 04 February 2016 (04.02.2016) Entire document.	1-20
A	US 8,574,258 B2 (BRAUN et al.) 05 November 2013 (05.11.2013) Entire document.	1-20
A	US 9,247,930 B2 (COLEMAN et al.) 02 February 2016 (02.02.2016) Entire document.	1-20

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search

12 July 2017

Date of mailing of the international search report

10 AUG 2017

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