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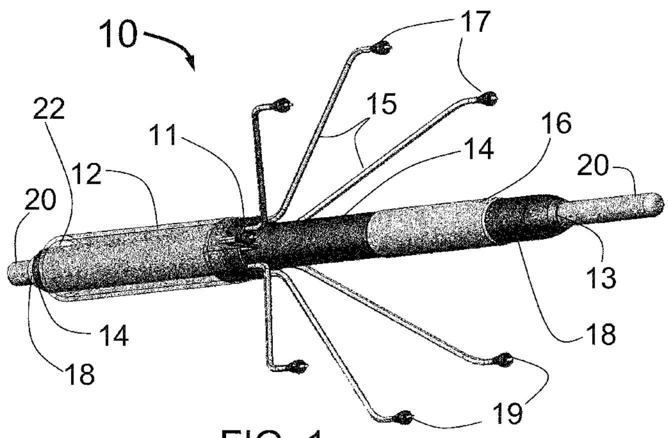

FIG. 1

(57) **Abstract**: At the present time, physicians often treat patients with atrial fibrillation (AF) using radiofrequency (RF) catheter systems to ablate conducting tissue in the wall of the Left Atrium of the heart around the ostium of the pulmonary veins. These systems are expensive and take time consuming to use. The present invention circular ablation system CAS includes a multiplicity of expandable needles that can be expanded around a central axis and positioned to inject a fluid like ethanol to ablate conductive tissue in a ring around the ostium of a pulmonary vein quickly and without the need for expensive capital equipment. The expansion of the needles is accomplished by self-expanding or balloon expandable structures. The invention includes centering means so that the needles will be situated in a pattern surrounding the outside of the ostium of a vein. Also included are members that limit the distance of penetration of the needles into the wall of the left atrium, or the aortic wall. The present invention also has an important application to ablate tissue around the ostium of one or both renal arteries, for the ablation of the sympathetic nerve fibers and/or other afferent or efferent nerves going to or from each kidney in order to treat hypertension.

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EXPANDABLE CATHETER SYSTEM FOR PERI-OSTIAL INJECTION AND MUSCLE AND NERVE FIBER ABLATION

REFERENCE TO RELATED APPLICATION

This Application is being filed as a Continuation-in-Part of Patent Application Serial #13/092,363, filed 22 April 2011, currently pending.

BACKGROUND OF THE INVENTION

This invention is in the field of devices to ablate muscle cells and nerve fibers for the treatment of cardiac arrhythmias and/or hypertension.

At the present time, physicians often treat patients with atrial fibrillation (AF) using radiofrequency (RF) catheter systems to ablate conducting tissue in the wall of the Left Atrium of the heart around the ostium of the pulmonary veins. Similar technology, using radiofrequency energy, has been used inside the renal arteries to ablate sympathetic and other nerve fibers that run in the wall of the aorta on the outside of the renal arteries, in order to treat high blood pressure. In both cases these are elaborate and expensive catheter systems that can cause thermal, cryoablative, or other injury to surrounding tissue. Many of these systems also require significant capital outlays for the reusable equipment that lies outside of the body, including RF generation systems and the fluid handling systems for cryoablative catheters.

Because of the similarities of anatomy, for the purposes of this disclosure, the term target vessel will refer here to either the pulmonary vein for AF ablation applications or the renal artery for hypertension therapy applications. The term ostial wall will refer to the wall of the Left Atrium surrounding a pulmonary vein for AF application and to the wall of the aorta for the hypertension application.

In the case of atrial fibrillation ablation, the ablation of tissue surrounding multiple pulmonary veins can be technically challenging and very time consuming. This is particularly so if one uses RF catheters that can only ablate one focus at a time. There is also a failure rate using these types of catheters for atrial fibrillation ablation. The failures of the current approaches are related to the challenges in creating reproducible circumferential ablation of tissue around the ostium (peri-ostial) of a pulmonary vein. There are also significant safety issues with current technologies related to very long fluoroscopy and procedure times that lead to high levels of radiation exposure to both the patient and the operator, and may increase stroke risk in atrial fibrillation ablation.

There are also potential risks using the current technologies for RF ablation to create sympathetic nerve denervation inside the renal artery for the treatment of hypertension. The long-term sequelae of applying RF energy inside the renal artery itself are unknown. This type of energy applied within the renal artery may lead to late restenosis, thrombosis, embolization of debris into the renal parenchyma, or other problems inside the renal artery. There may also be uneven or incomplete sympathetic nerve ablation, particularly if there are anatomic abnormalities, or atherosclerotic or fibrotic disease inside the renal artery, such that there is non-homogeneous delivery of RF energy. This could lead to treatment failures, or the need for additional and dangerous levels of RF energy to ablate the nerves that run along the adventitial plane of the renal artery.

Finally, while injection of ethanol as an ablative substance is used within the heart and other parts of the body, there has been no development of an ethanol injection system specifically designed for circular ablation of the ostial wall of a target vessel.

SUMMARY OF THE INVENTION

The present invention Circular Ablation System (CAS) is capable of producing damage in the tissue that surrounds the ostium of a blood vessel in a relatively short period of time using a disposable catheter requiring no additional capital equipment. The primary focus of use of CAS is in the treatment of cardiac arrhythmias and hypertension.

Specifically, there is a definite need for such a catheter system that is capable of highly efficient, and reproducible circumferential ablation of the muscle fibers and conductive tissue in the wall of the Left Atrium of the heart surrounding the ostium of the pulmonary veins which could interrupt atrial fibrillation (AF) and other cardiac arrhythmias.

This type of system may also have major advantages over other current technologies by allowing time efficient and safe circumferential ablation of the nerves in the wall of the aorta surrounding the renal artery (peri-ostial renal tissue) in order to damage the sympathetic nerve fibers that track from the peri-ostial aortic wall into the renal arteries, and thus improve the control and treatment of hypertension. Other potential applications of this approach may evolve over time.

The present invention is a catheter which includes multiple expandable injector tubes arranged circumferentially around the body of the CAS near its distal end. Each tube includes an injector needle at its distal end. There is a penetration limiting member proximal to the distal end of each needle so that the needles will only penetrate into the tissue of the ostial wall to a preset distance. This will reduce the likelihood of perforation of the ostial wall and will optimize the depth of injection for each application. The injector needles are in fluid communication with an injection lumen in the catheter body which is in fluid communication with an injection port at the proximal end of the CAS. Such an injection port would typically include a standard connector such as a Luer connector used to connect to a source of ablative fluid.

The expandable injector tubes may be self-expanding made of a springy material or a memory metal such as NITINOL or they may be expandable by mechanical means. For example, the expandable legs with distal injection needles could be mounted to the outside of an expandable balloon whose diameter is controllable by the pressure used to inflate the balloon.

The entire CAS is designed to be advanced over a guide wire in either an over the wire configuration where the guide wire lumen runs the entire length of the CAS or a rapid exchange configuration where the guide wire exits the catheter body at least 10 cm distal to the proximal end of the CAS and runs outside of the catheter shaft for its proximal section.

The distal end of the CAS also includes a centering means at or near its distal end. The centering means could be a mechanical structure or an expandable balloon. The centering means will help to ensure that the injector tubes will be engaged circumferentially around and outside of the ostium of the target vessel. If the injector tubes are expanded by a balloon, then it is envisioned that the distal portion of the balloon would have conical or cylindrical distal portions that would facilitate centering the CAS in the target vessel.

The CAS would also be typically packaged inside an insertion tube that constrains the self-expanding legs prior to insertion into a guiding catheter, and allows the distal end of the CAS to be inserted into the proximal end of a guiding catheter or introducer sheath.

The CAS might also be packaged to include an outer sheath that runs the entire length of the CAS so as to cover and protect the needles and also protect them from getting caught as the CAS is advanced distally to the desired location.

It is also envisioned that the injection needles could be formed from a radiopaque material such as tantalum or tungsten or coated with a radiopaque material such as gold or platinum so as to make them clearly visible using fluoroscopy.

It is also envisioned that one or more of the injector needles could be electrically connected to the proximal end of the CAS so as to also act as a diagnostic electrode(s) for evaluation of the electrical activity in the area of the ostial wall.

It is also envisioned that one could attach 2 or more of the expandable legs to an electrical or RF source to deliver electric current or RF energy around the circumference of a target vessel to the ostial wall to perform tissue ablation.

For use in the treatment of AF the present invention CAS would be used with the following steps:

- Access to the left atrium via a large peripheral vein, such as the femoral vein, typically with the insertion of a sheath.
- Use a transseptal approach to get into the left atrium, via the vein, to the right atrium, to enter the left atrium. This approach is a well known procedure.
- Advance a guide wire and guiding catheter across the inter-atrial septum into the left atrium.
- Using a guiding catheter with a shaped distal end or guiding sheath, engage the first targeted pulmonary vein. This can be confirmed with contrast injections as needed.
- Advance a guide wire through the guiding catheter into the pulmonary vein.
- Place the distal end of an insertion tube which constrains the distal end of the CAS into the proximal end of the guiding catheter.
- Advance the distal end of the CAS into and advance the CAS through the guiding catheter, and tracking over the guidewire, until it is just proximal to the distal end of the guiding catheter.
- Advance the CAS over the guidewire until the distal portion of its centering means is within the target vessel.
- Expand the centering means. If the centering means is cylindrical, expand it until it is just slightly less (1-4 mm less) than the diameter of the target vessel. This will ensure that the catheter will be roughly "centered" within the target vessel to enable the circumferential deployment of the legs of the CAS around the target vessel ostium so that injection will be centered around the ostium of the target vessel.
- Pull back the guiding catheter to leave space for the expanding injector tubes to open.
- Expand the injector tubes or let them expand if they are self-expanding. If balloon expandable, adjust the balloon pressure to get the desired diameter. If self-expanding, the circumference of the self-expansion can be adjusted in vivo by varying the distance of the pullback of the guiding catheter. That is, if one wants a smaller diameter (circumference) expansion to fit the ostial dimension of that specific target vessel, one can partially constrain the injector tube expansion by not fully retracting the guiding catheter all the way to the base of the tubes. However, the preferred method is to have the final opening distance be preset for the CAS, with the injector tubes fully expanded to their memory shape. Typically the CAS size would be pre-selected based on the anticipated or

measured diameter of the ablation ring to be created, such that the fully expanded injector tubes create the correctly sized ablation "ring."

- Advance the CAS until the injector needles at the distal end of the self-expanding injector tubes penetrate the ostial wall, with the penetration depth being a fixed distance limited by the penetration limiting member attached to each needle at a preset distance proximal to the distal end of the needle. If the centering means is conical, as the CAS is advanced distally, the cone will engage the ostium of the vein which will center the CAS.
- Attach a syringe or injection system to the injection connector at the CAS proximal end.
- Engagement of the ostial wall can be confirmed by injection of a small volume of iodinated contrast via a syringe, through the needles, prior to injection of the "ablative" fluid such as alcohol. If there is contrast "staining" of the tissue this will confirm that the needles are engaged into the tissue and not free floating in the left atrium or aorta.
- Inject an appropriate volume of ethanol (ethyl alcohol) or other appropriate cytotoxic fluid from the syringe or injection system through the catheter and out of the needles into the ostial wall. A typical injection would be 1-10 ml. This should produce a multiplicity of circles of ablation (one for each needle) that will intersect to form an ablative ring around the ostium of the target vessel. Contrast could be added to the injection to allow x-ray visualization of the ablation area.
- Once the injection is complete, retract the CAS back into the guiding catheter, which will collapse the self-expanding injector tubes. If the device is balloon expandable deflate the balloon and retract back into the guiding catheter.
- In some cases, one may rotate the CAS 20-90 degrees and then repeat the injection if needed to make an even more definitive ring of ablation.
- The same methods as per prior steps can be repeated to ablate tissue around the one or more of the other pulmonary veins during the same procedure, as indicated to ensure AF inhibition.
- Remove the CAS from the guiding catheter completely.
- When indicated, advance appropriate diagnostic electrophysiology catheters to confirm that the ablation has been successful.
- Remove all remaining apparatus from the body.

- A similar approach can be used with the CAS, via access from a peripheral artery such as the femoral artery, to treat hypertension, via ablation of tissue in the peri-ostial aortic wall tissue surrounding one or both of the renal arteries, with the goal of ablating afferent and/or efferent sympathetic nerve fibers entering or exiting the kidney.

It is also envisioned that two or more of the legs/injector tubes may be connected to an electrical or RF field source to allow for electrical discharge or RF ablation to enable tissue ablation of the tissue in the ostial wall.

It is also envisioned that one could mount injector tubes with needles on the outer surface of an expandable balloon on the CAS in order to deliver 2 or more needles around the circumference of the ostium of a target vessel to inject ablative fluid to the ostial wall. In this case, the distal portion of the balloon could include the centering means of a cylindrical or conical shape. This embodiment could also include an elastic band covering the injector tubes where the elastic band could both help maintain a smooth outer surface of the CAS to facilitate delivery as well as act as the penetration limiting member to limit the penetration of the injection needles.

Another preferred embodiment of the present invention CAS is to use a separate self-expanding structure to both expand the injector tubes to a desired diameter and to have a distal portion of the structure (e.g., conical or cylindrical) act to center the CAS about the target vessel. This embodiment could include a tubular sheath whereby the CAS would expand as the sheath is withdrawn and is collapsed down as the sheath is advanced back over the expanded structure. It is also conceived that instead of the sheath, the guiding catheter that is used to guide the delivery of the CAS to the target vessel site would act like a sheath such that the CAS will expand outward when pushed out the tip of the guiding catheter and collapsed own as it is retracted back into the guiding catheter. If the guiding catheter is used for this, then an introducer tube would be needed to load the CAS into the proximal end of the guiding catheter.

Thus it is an object of the present invention CAS is to have a percutaneously delivered catheter that can be used to treat atrial fibrillation with a one, or more injections of an ablative fluid into the wall of the left atrium surrounding one or more pulmonary veins.

Another object of the present invention CAS is to have a percutaneously delivered catheter that can be used to treat hypertension with one, or more injections of an ablative fluid into the wall of the aorta surrounding a renal artery.

Still another object of the present invention CAS is to have a percutaneously delivered catheter that includes a multiplicity of circumferentially expandable injector tubes, each tube having a needle at its distal end for injection of an ablative fluid into the ostial wall of a target vessel.

Still another object of the present invention CAS is to have a centering means located at or near the catheter's distal end. The centering means designed to allow the injector to be centered on the target vessel so that the injected ablative fluid will form an ablative ring outside of the ostium of the target vessel. The centering means can be fixed or expandable, and may include a cylindrical or conical portion.

Another object of the invention is to have a penetration limiting member or means attached to the distal potion of the injector leg or as part of the distal portion of the CAS in order to limit the depth of needle penetration into the ostial wall.

Yet another object of the present invention CAS is to have one or more of the injector needles act as diagnostic electrodes for measurement of electrical activity within the ostial wall of the target vessel.

These and other objects and advantages of this invention will become obvious to a person of ordinary skill in this art upon reading of the detailed description of this invention including the associated drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a three dimensional sketch of the distal end of the present invention Circular Ablation System (CAS);

FIG. 2 is a longitudinal cross sectional drawing partially cut-away of the distal end of the CAS;

FIG. 3 is a longitudinal cross sectional drawing showing area 3 of FIG. 2 which is the distal end of the self-expanding injector leg, injector needle and penetration limiter;

FIG. 4 is a longitudinal cross sectional drawing partially cut-away showing area 4 of FIG. 2 which is the proximal end of the self-expanding injector legs and how they are in fluid communication with the injection lumen of the CAS;

FIG. 5 is a longitudinal elevational view of the CAS with centering balloon expanded;

FIG. 6A is a longitudinal elevational view of the CAS with legs collapsed inside the distal end of a guiding catheter as the distal end of the CAS is inserted into the target vessel;

FIG. 6B is a longitudinal elevational view of the CAS after the CAS centering means has been expanded and the guiding catheter has been pulled back (retracted) allowing the self-expanding legs to expand;

FIG. 6C is a longitudinal elevational view of the CAS now advanced in the distal direction until the injector needles penetrate the ostial wall and the penetration limiters on each needle limit the penetration as they touch the ostial wall. In this configuration an ablative substance such as alcohol is injected into the ostial wall through the needles causing a complete circular ablation of tissue in the ostial wall in a ring surrounding the target vessel;

FIG. 6D shows target vessel and ostial wall after the CAS and guiding catheter have been removed from the body and the ablated tissue in the ostial wall remains;

FIG. 6E is a schematic drawing showing the overlapping area of ablation in the ostial wall that form a circle around the ostium of the target vessel;

FIG. 7 is a longitudinal cross sectional drawing of the proximal end of the present invention CAS;

FIG. 8 is a longitudinal cross sectional drawing of an alternative version of the injector needle and penetration limiting means;

FIG. 9 is a longitudinal cross section of the CAS with the injector needle of FIG. 8 with the injector tubes shown collapsed inside the introducer tube used to insert the CAS into the proximal end of a guiding catheter or sheath;

FIG. 10 is a three dimensional sketch of another embodiment of the CAS that uses a balloon to expand the expandable injector tubes used to deliver the ablative substance to the ostial wall of the target vessel;

FIG. 11A is a longitudinal elevational view of a further embodiment of the CAS that uses self-expanding injector tubes connected circumferentially with one or more stabilizing structures to ensure uniform expansion of the injector tubes used to deliver the ablative substance to the ostial wall of the target vessel;

FIG. 11B is a longitudinal elevational view of the closed CAS of FIG. 11A as packaged and as it would appear when first advanced into the body of a human patient or finally removed from the body of a human patient;

FIG. 12 is a longitudinal cross section of the CAS of FIG. 11A.;

FIG. 13 is an enlarged view of the portion 114 of FIG. 11A;

FIG. 14 is a longitudinal cross-section of the enlarged view of the portion 114 of FIG. 12;

FIG. 15 is an enlarged view of the portion 115 of FIG. 12;

FIG. 16 is a longitudinal cross section of the proximal end of the CAS of FIGs. 11A and 12;

FIG. 17 is a longitudinal view of a circular ablation system;

FIG. 18 is a schematic drawing showing a radial cross-section of the embodiment of the circular ablation system shown in FIG. 17; and,

FIG. 19 is a schematic drawing of the circular ablation system showing needle tips penetrating the wall of an aorta.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 is a three dimensional sketch of the distal end of the present invention Circular Ablation System (CAS) 10 in its state before it is loaded into a guiding catheter or sheath for delivery over the guide wire 20 into a human being. The proximal portion of the CAS 10 includes three tubes, an outer tube 12, a middle tube 14 and an inner tube 18. The guidewire 20 can be slidably advanced or removed through the guide wire lumen 13 inside of the inner tube 18. An expandable cylindrical balloon 16 is attached at its proximal end to the middle tube 14 and at its distal end to the inner tube 18. The balloon inflation lumen is located between the inner tube 18 and the middle tube 14. The balloon 16 can be inflated by injection of a fluid through the balloon inflation lumen and deflated by applying suction to the balloon inflation lumen.

An injector transition manifold 11 is sealed onto the outside of the middle tube 14. The outer tube 12 is sealed at its distal end onto the outside of the injector transition manifold 11. The expandable injector tubes 15 are attached at their proximal end to or through the injector transition manifold 11 so that the proximal lumen of the injector tubes 15 are in fluid communication with the fluid injection lumen 22 that lies between the middle tube 14 and the outer tube 12. The injector tubes 15 could be made of a springy metal such as L605 or the preferred embodiment being made from a memory metal such as NITINOL. A plastic hub 17 is attached to the distal end of each injector tube 15. An injector needle 19 extends distally from the distal end of each plastic hub 17. The lumen of each injector needle 19 is in fluid communication with the lumen of the expandable injector tube (leg) 15. Each hub 17 acts as a penetration limiting member to limit the penetration of the distally attached needle 19 into the ostial wall of the target vessel. In this embodiment it is envisioned that the penetration of the needles 19 would be limited to pre-set distance, for example the distance might be between 0.5 mm and 1cm.

While the injector tubes 15 of FIG. 1 are self-expanding, it is also envisioned that if the injector tubes are not self-expanding, that a self-expanding structure could be attached either inside or outside of the injector tubes 15 to cause the injector tubes to expand to a predetermined diameter to facilitate circular ablation in the ostial wall of the target vessel. If such a self-expanding structure is used then the injector tubes could be made from a flexible material such as a plastic or silicone rubber.

FIG. 2 is a longitudinal cross sectional drawing of the distal end of the CAS 10 in its state before it is loaded into a guiding catheter or sheath for delivery over the guide wire 20 into a human being. The proximal portion of the CAS 10 includes three tubes, an outer tube 12, a middle tube 14 and an inner tube 18. The guidewire 20 can be advanced or removed through the guide wire lumen 13 inside of the inner tube 18. An expandable cylindrical balloon 16 is attached at its proximal end to the middle tube 14 and at its distal end to the inner tube 18. The balloon 16 may be either an elastic balloon or a folded inelastic balloon such as is used for angioplasty. The proximal end of the balloon 16 is attached to the middle tube 14 and the distal end of the balloon 16 is attached to the inner tube 18 such that the area under the balloon 16 is in fluid communication with the balloon inflation lumen 24 that lies between the middle tube 14 and the inner tube 18. The balloon 16 can be inflated by injection of a fluid or gas through the balloon inflation lumen 24 and deflated by applying suction to the balloon inflation lumen 24.

Normal saline solution including a fluoroscopic contrast agent would be the typical fluid used to inflate the balloon 16.

The injector transition manifold 11 is sealed onto the outside of the middle tube 14. The outer tube 12 is sealed at its distal end onto the outside of the injector transition manifold 11. The expandable injector tubes 15 are attached at their proximal end through the injector transition manifold 11 so that the proximal lumen of the injector tubes 15 are in fluid communication with the fluid injection lumen 22 that lies between the middle tube 14 and the outer tube 12. FIG. 4 shows an expanded version of the area 4 of FIG. 2. The injector tubes 15 could be made of a springy metal such as L605 or the preferred embodiment being made from a memory metal such as NITINOL. A plastic hub penetration limiter 17 with flattened distal end to act as a means of limiting the penetration of the needle 19 is attached over the distal end of each of the 8 expandable injector tubes 15. An injector needle 19 extends distally from the distal end of each plastic hub 17. The lumen of each injector needle is in fluid communication with the lumen of the expandable injector tube 15.

FIG. 3 is an enlarged longitudinal cross sectional drawing showing area 3 of FIG. 2 which is the distal end of the self-expanding injector tube 15 with injector tube lumen 21, injector needle 19 and penetration limiter 17. While FIG. 3 shows the limiters 17 as being symmetric around the injector tube 15, it is also envisioned that an asymmetric penetration limiter, for example a limiter with significant material only on the inside might be preferable as it would be less likely to catch on a guiding catheter when the CAS 10 is advanced through or retracted back into the guiding catheter at the end of the procedure.

FIG. 4 is an enlarged longitudinal cross sectional drawing of the CAS 10 showing area 4 of FIG. 2 which is the proximal end of the self-expanding injector tubes 15 with lumens 21. FIG. 4 shows detail on how the lumens 21 of the injector tubes 15 are in fluid communication with the injection lumen 22 of the CAS 10. Specifically, the proximal section of each injector tube 15 is inserted through a hole in the injector transition manifold 11 and fixedly attached and sealed to the manifold 11 so that the proximal end of the each tube 15 has its proximal end and opening in fluid communication with the injector lumen 22 that lies between the outer tube 12 and the middle tube 14 of the CAS 10. As another way of achieving this structure it is also conceived that the injector manifold 11 might be a single piece of plastic molded over the proximal ends of the injector tubes 15 in a molding operation prior to assembly.

FIG. 5 is the longitudinal elevational view of the CAS 10' with centering balloon 16' expanded. Also shown are the outer tube 12, middle tube`14 and inner tube 18 with guidewire 20. The injector tubes 15 protrude in the distal direction from the distal end of the injector manifold 11 and have hubs 17 (penetration limiting members) with injector needles 19 at their distal end. The expanded balloon 16' should be inflated to be just slightly less than the diameter of the target vessel. This will allow it to act as a centering means without causing undue injury to the target vessel wall. Ideally, the balloon 16' would be a low pressure elastic balloon where the diameter can be adjusted by using the appropriate pressure to inflate the balloon 16' through the balloon inflation lumen 24. It is also conceived that the CAS 10' would have a non-compliant or semi-compliant molded folded balloon with a limited diameter range vs. pressure such as is used in an angioplasty balloons.

FIG. 6A is the longitudinal elevational view of the CAS 10 with injector tubes 15 collapsed inside the distal end of a guiding catheter 30 as the distal end of the CAS 10 is inserted into the target vessel over the guide wire 20. The distal end of the guiding catheter 30 would normally first be placed inside of the ostium of the target vessel (engaged) and is shown here slightly back from the ostium as it would be during the first part of its distal retraction. From the position shown in FIG. 6A, the guiding catheter 30 is pulled back (retracted) in the proximal direction allowing the self-expanding injector tubes 15 to spring open to their open position. The extent of leg expansion could be adjusted (limited and smaller) in vivo by not fully retracting the guiding catheter, thus modestly constraining the expanded dimension of the expandable tubes 15.

FIG. 6B is the longitudinal elevational view of the CAS 10' after the guiding catheter has been pulled back and the inflatable balloon 16' has been expanded with the guide wire 20 still lying within the target vessel. From this state, the CAS 10' with expanded balloon 16' is advanced in the distal direction until the needles 19 penetrate the ostial wall surrounding the target vessel. Engagement of the ostial wall could be confirmed by injection of a small volume of iodinated contrast through the needles, prior to injection of the "ablative" fluid such as alcohol.

FIG. 6C is the longitudinal elevational view of the CAS 10'' now advanced in the distal direction with the injector needles 19 fully penetrating the ostial wall and the penetration limiting members (hubs) 17 on each needle limiting the penetration as they touch the ostial wall. In this configuration an ablative substance such as ethanol is injected into the ostial wall through the needles 19. The ablative fluid will disperse from the needles and as more ablative fluid is injected, the area of fluid dispersion shown in FIG. 6C will increase so as to eventually cause a complete circular ablation of tissue in the ostial wall in a ring surrounding the target vessel. The balloon 16' is then deflated and the CAS 10 is pulled back in the proximal direction until the needles 19 are no longer penetrating the ostial wall. The CAS 10 is then pulled back more in the proximal direction into the distal end of the guiding catheter 30 which will collapse the self-expanding injector tubes 15. At this point the guide wire 20 may be advanced into another target vessel and the ablation procedure repeated. After the last target vessel is treated, the CAS 10 can then be removed from the patient's body. At this point electrophysiology catheters may be introduced through the guiding catheter to verify the success of the procedure.

FIG. 6D shows target vessel and ostial wall after the CAS 10 and guiding catheter have been removed from the body and the ablated tissue in the ostial wall remains.

FIG. 6E is a schematic drawing showing a representation of the overlapping areas of ablation in the ostial wall from each needle 19 that form a ring around the ostium of the target vessel after the procedure using the CAS 10 has been completed. While FIG. 6E shows overlapping circles to highlight the ablation from each needle 19, in reality because ethanol disperses readily in tissue, the circles would actually blend together.

FIG. 7 is a longitudinal cross sectional drawing of the proximal end of the present invention CAS 10. The proximal end of the inner tube 18 is attached to a Luer fitting 38 that can be used to inject fluid to flush the guide wire lumen 13 inside of the inner tube 18. The guide wire 20 is inserted through the guide wire lumen 13. The proximal end of the middle tube 14 is attached to the side tube 34 with lumen 36. The proximal end of the side tube 34 is attached to the Luer fitting 36 which can be attached to a syringe or balloon inflation device to inflate and deflate the balloon 16 of FIGs. 1 and 2. The lumen 36 is in fluid communication with the balloon inflation lumen 24 that lies between the middle tube 14 and the inner tube 18. The proximal end of the outer tube 12 is connected to the distal end of the side tube 32 with lumen 33. The side tube 32 is connected at its proximal end to the Luer fitting 31 that can be connected to a syringe or fluid injector to inject an ablative substance such as ethanol through the lumen 33 into the injection lumen 22 through the injector tubes 15 and out the needles 19 into the ostial wall of the target vessel. Additional valves and stopcocks may also be attached to the Luer fittings 35 and 31 as needed.

FIG. 8 is a longitudinal cross sectional drawing of an alternative version of the injector needle 49 of the CAS 40 with two differences from that shown in FIG. 3. First, here the injector needle 49 is the sharpened distal end of the self–expanding tube 45 with injector tube lumen 41 while in FIG. 3 the self-expanding tube 15 was attached to a separate injector needle 19 with lumen 21. The penetration limiting means of this embodiment is the limiter 50 with tubular section 52 that is attached to the outside of the tube 45 with self-expanding legs 57A and 57B that will open up as the CAS 40 is deployed. The limiter 50 would typically be made from a single piece of NITINOL preset into the shape shown with at least 2 self-expanding legs. The major advantage if this design is that the penetration limiting means takes up very little space within the guiding catheter used for device delivery making it easier to slide the CAS 40 through the guiding catheter. Although two legs 57A and 57B are shown it is conceived that 1. 3, 4 or more legs could be attached to the tube 45 to act as a penetration limiting member or means when the needle 49 is advanced to penetrate the ostial wall of the target vessel.

FIG. 9 is a longitudinal cross section of the distal portion of the CAS 40 with the injector needle 49 and limiter 50 of FIG. 8 with the injector tubes 45 shown collapsed inside an insertion tube 60 with handle 65 used to insert the CAS 40 into the proximal end of a guiding catheter or sheath. This is how the CAS 40 would be typically packaged although the insertion tube 60 might be packaged proximal to the injector tubes 15 where the insertion tube 60 would be slid in the distal direction to collapse the injector tubes 15 just before the CAS 40 is inserted in the guiding catheter or sheath. Such an insertion tube 60 could be used with all of the embodiments of the present invention disclosed herein. The steps to prepare it for use would be as follows:

1. Remove the sterilized CAS 40 from its packaging in a sterile field.
2. Flush the guide wire lumen 13 with saline solution.
3. Access to the left atrium via a large peripheral vein, such as the femoral vein, typically with the insertion of a sheath.
4. Use a transseptal approach to get into the left atrium, via the vein, to the right atrium, to enter the left atrium. This approach is a well known procedure.
5. Advance a guide wire and guiding catheter across the inter-atrial septum into the left atrium.
6. Using a guiding catheter or guiding sheath with a shaped distal end, engage the first targeted pulmonary vein. This can be confirmed with contrast injections as needed.
7. Advance a guide wire through the guiding catheter into the pulmonary vein.

8. Insert the proximal end of the guide wire into the guide wire lumen 13 of the CAS 40 and bring the wire through the CAS 40 and out the proximal end Luer fitting 38 of FIG. 7.
9. Place the distal end of an insertion tube 60 which constrains the distal end of the CAS 40 into the proximal end of the guiding catheter. There is typically a Tuohy-Borst fitting attached to the distal end of a guiding catheter to constrain blood loss. The insertion tube 60 can be pushed through the opened Tuohy-Borst fitting and the Tuohy-Borst fitting closed on its outside to hold it in place.
10. Advance the distal end of the CAS 40 out of the insertion tube 60 and into the guiding catheter.
11. Advance the CAS 40 (or 10) through the guiding catheter 30 of FIG. 6A, and tracking over the guide wire 20, until the unexpanded tubes 45 (or 15) are located just proximal to the distal end of the guiding catheter 30. This is shown in FIG. 6A.
12. Advance the CAS 40 or 10 over the guide wire 20 until the balloon 16 used for centering is within the target vessel.
13. Expand the balloon 16 used for centering until it is just slightly less (1-4 mm less) than the diameter of the target vessel. This will ensure that the distal portion of the CAS 40 or 10 will be roughly "centered" within the target vessel to enable the circumferential deployment of the expandable tubes 45 or 15 centered around the target vessel ostium so that injection into the ostial wall will be centered around the ostium of the target vessel.
14. Pull back the guiding catheter 30 so that the self-expanding injector tubes 15 open. The circumference of the tube 15 expansion can be adjusted in vivo by varying the distance of the pullback of the guiding catheter 30. That is, if one wants a smaller diameter (circumference) of expansion to fit the ostial dimension of that specific target vessel, one

can partially constrain the injector tube 15 expansion by not fully retracting the guiding catheter 30 beyond the proximal end of the injector tubes 15. However, the preferred method is to have the final opening distance be preset for the CAS 40 or 10, with the injector tubes 45 (or 15) fully expanded to their maximum diameter governed by their memory shape. Typically the CAS 40 or 10 maximum diameter of the injector tubes 15 would be pre-selected based on the anticipated or measured diameter of the ablation ring to be created, such that the fully expanded injector tubes create the correctly sized ablation "ring." This step is portrayed in FIG. 6B.

15. Advance the CAS 40 or 10 until the injector needles in the self-expanding injector tubes 45 (or 15) penetrate the ostial wall, as seen in FIG. 6C with the penetration depth being a fixed distance limited by the penetration limiting members 17 of FIG 6C or 50 of FIGs. 8 and 9.
16. Attach a syringe or injection system to the Luer fitting 35 of FIG. 7.
17. Prior to injection of the "ablative" fluid such as alcohol engagement of the ostial wall could be confirmed by injection of a small volume of iodinated contrast via a syringe through the Luer fitting 35 and out of the needles 49 or 19 of FIG. 6C.. If there is contrast "staining" of the tissue this will confirm that the needles 49 or 19 are engaged into the tissue and not free floating in the left atrium or aorta.
18. Inject an appropriate volume of ethanol (ethyl alcohol) or other appropriate cytotoxic fluid from the syringe or injection system through the catheter and out of the needles 49 or 19 into the ostial wall. A typical injection would be 1-10 ml. This should produce a multiplicity of interlocking circles of ablation (one for each needle) that will run together

and intersect to form a ring or ablated tissue around the ostium of the target vessel as is seen in FIG. 6E.

19. In some cases, one may rotate the CAS 20-90 degrees and then repeat the injection to make an even more definitive ring of ablation.
20. Retract the CAS 40 or 10 back into the guiding catheter 30 which will collapse the self-expanding injector tubes 45 or 15.
21. The same methods as per steps 6-19 can be repeated to ablate tissue around the one or more of the other pulmonary veins during the same procedure, as indicated to ensure AF ablation or the 2nd Renal artery in the treatment of hypertension.
22. Remove the CAS 40 (or 10) from the guiding catheter 30 completely pulling it back into the insertion tube 60. Thus if the CAS 40 (or 10) needs to be put back into the body it is collapsed and ready to go.
23. When indicated, advance appropriate diagnostic electrophysiology catheters through the guiding catheter to confirm that the ablation has been successful.
24. Remove all remaining apparatus from the body.

A similar approach can be used with the CAS, via access from a peripheral artery such as the femoral artery, to treat hypertension, via ablation of tissue in the periostial aortic wall tissue surrounding one or both of the renal arteries, with the goal of ablating afferent and/or efferent sympathetic nerve fibers entering or exiting the kidney.

While the proximal end of the metallic injector tubes 15 and 45 shown here terminate in the injector manifold 11, it is also envisioned that these tubes could connect to wires that run to the proximal end of the CAS to allow the injector needles 19 and 49 to act as electrodes for sensing signals from the ostial wall of the target vessel as well as potentially delivering electrical stimulation or higher voltages and currents to ablate the tissue in the ostial wall by electrical or RF ablation.

FIG. 10 is a three dimensional sketch of another embodiment of the CAS 70 that uses a balloon 76 to expand the expandable injector tubes 75 used to deliver the ablative substance to the ostial wall of the target vessel through the injection needles 79. The 8 injector tubes 75 connect to the manifold 71 that is free to slide distally and proximally along the catheter outer tube 74 as the balloon 76 is inflated and deflated. The manifold 71 connects the lumens of the injector tubes 75 to the tube 72 with fluid injection lumen 81. The tube 72 connects to a fitting at the proximal end of the CAS 70 such as the Luer fitting 33 of FIG. 7. A source of ablative fluid would attached to the fitting and be used to inject the ablative fluid through the fluid injection lumen 81 of the tube 72 into the expandable tubes 75 and out the injection needles 79 into the ostial wall of the target vessel. The balloon 76 is inflated and deflated by delivery of a fluid through the lumen formed between the outer tube 74 and the inner tube 78. The proximal shaft 84 of the balloon 76 is attached to the outside of the outer tube 74 and the distal shaft 82 of the balloon 76 is attached to the outside of the inner tube 78. The inside of the inner tube 78 provides a guide wire lumen 85 for the guide wire 20. The distal end of the inner tube 78 includes a radiopaque marker 73 to assist in visualizing the distal end of the CAS 70 as it is inserted into the target vessel. The balloon 76 includes a distal shaft 82, a proximal shaft 84, a proximal conical section 87, a central cylindrical section 88, and a distal conical section 89. The injector tubes 74 are attached to the outside of the central cylindrical section 88 of the balloon 76 and are also held by the expandable band 77 that covers the outside of the injector tubes 75 and the central cylindrical section 88 of the balloon 76. While the expandable band 77 is shown in FIG. 10 as covering only the central cylindrical portion 88 of the balloon 76, it is envisioned that it might also extend in the proximal direction to cover the injector tubes 75 over their entire length proximal to the needles 79 which would make a smoother outer surface of the CAS 70 over this portion. The needles 79 extend in the distal direction from the distal end of the injector tubes 75 and may be made of a standard needle material such as stainless steel or a more radiopaque material such as tantalum or tungsten or plated with a radiopaque material such as gold or platinum. The expandable band 77 also serves the purpose for the CAS 70 of being the penetration limiting member located proximal to the distal end of each needle 70 that only allows each needle 70 to penetrate a preset distance into the ostial wall of the target vessel. In this embodiment the penetration limiting member 77 should limit needle penetration to a depth between 0.5 mm and 1cm. It is also envisioned that the entire CAS 70 could be covered by a sheath (not shown) that would protect the needles 79 from coming into contact with the inside of the guiding catheter used to delivery the CAS 70 to the target vessel. The sheath would be slid back in the proximal direction once the CAS 70 is positioned with the guide wire 20 within the target vessel. The CAS 70 can also be used with an insertion tube 60 as shown in FIG. 9.

The balloon 76 can be either an elastic balloon or a semi-compliant or non-compliant balloon such as used in angioplasty catheters. Such a balloon is typically inflated with normal saline solution including a contrast agent.

It is also envisioned that the best way to protect the needles 79 of the CAS 70 would be to have an elastic band (not shown in FIG. 10) attached to the distal shaft of the balloon 82 or the inner tube 78 (or both) cover the distal ends of the needles 79 in the pre-deployment condition. Inflation of the Balloon 76 would pull the needles 79 in the proximal direction out from under such an elastic band. Such an elastic band would prevent the needles 79 from catching on the inside of the guiding catheter as the CAS 70 is advanced into the body.

For this embodiment of the CAS 70, the method of use would be the following steps:

1. Remove the sterilized CAS 70 from its packaging in a sterile field.
2. Flush the guide wire lumen 85 with saline solution.
3. Access to the left atrium via a large peripheral vein, such as the femoral vein, typically with the insertion of a sheath.
4. Use a transseptal approach to get into the left atrium, via the vein, to the right atrium, to enter the left atrium. This approach is a well known procedure.
5. Advance a guide wire and guiding catheter across the inter-atrial septum into the left atrium.
6. Using a guiding catheter or guiding sheath with a shaped distal end, engage the first targeted pulmonary vein. This can be confirmed with contrast injections as needed.
7. Advance a guide wire through the guiding catheter into the pulmonary vein.
8. Insert the proximal end of the guide wire 20 into the guide wire lumen 85 of the CAS 70 and bring the wire 20 through the CAS 70 and out the proximal end Luer fitting 38 of FIG. 7.

9. Place the distal end of an insertion tube 60 of FIG. 9 which constrains the distal end of the CAS 70 into the proximal end of the guiding catheter. There is typically a Tuohy-Borst fitting attached to the distal end of a guiding catheter to constrain blood loss. The insertion tube 60 can be pushed through the opened Tuohy-Borst fitting and the Tuohy-Borst fitting closed on its outside to hold it in place.
10. Advance the distal end of the CAS 70 out of the insertion tube 60 and into the guiding catheter.
11. Advance the CAS 70 through the guiding catheter, and tracking over the guide wire 20, until the distal marker band 73 is located just proximal to the distal end of the guiding catheter.
12. Advance the CAS 70 over the guide wire 20 until the marker band 73 is within the target vessel and the distal shaft 82 of the balloon 76 is just proximal to the target vessel.
13. Pull the guiding catheter back so that the balloon 76 is now distal to the distal end of the guiding catheter.
14. Inflate the balloon 76 until it is the appropriate diameter which is between 1 and 10 mm larger in diameter than the target vessel.
15. Advance the CAS 70 until the injector needles 79 in the injector tubes 75 penetrate the ostial wall, with the penetration depth being a fixed distance limited by the expandable band 77. The distal conical section of the balloon 76 will act to center the CAS 70 as it is advanced into the target vessel.
16. Attach a syringe or injection system to the Luer fitting 35 of FIG. 7 that provides ablative fluid that will be injected into the ostial wall.

17. Engagement of the ostial wall could be confirmed by injection of a small volume of iodinated contrast via a syringe through the Luer fitting 35 and out of the needles 79 prior to injection of an "ablative" fluid such as alcohol. If there is contrast "staining" of the tissue this will confirm that the needles 79 are engaged into the tissue and not free floating in the left atrium or aorta.
18. Inject an appropriate volume of ethanol (ethyl alcohol) or other appropriate cytotoxic fluid from the syringe or injection system through the lumen 81 of the tube 82 and out of the needles 79 into the ostial wall. A typical injection would be 1-10 ml. This should produce a multiplicity of interlocking circles of ablation (one for each needle) that should intersect to form a ring around the ostium of the target vessel as is seen in FIG. 6E.
19. Deflate the balloon 76 and retract the CAS 70 back into the guiding catheter.
20. In some cases, one may rotate the CAS 70 between 20-90 degrees and then repeat the injection to make an even more definitive ring of ablation.
21. The same methods as per steps 6-20 can be repeated to ablate tissue around the one or more of the other pulmonary veins during the same procedure, as indicated to ensure AF ablation or the 2nd Renal artery in the treatment of hypertension.
22. Remove the CAS 70 from the guiding catheter completely pulling it back into the insertion tube 60. Thus if the CAS 70 needs to be put back into the body it is collapsed and ready to go.
23. When indicated, advance appropriate diagnostic electrophysiology catheters through the guiding catheter to confirm that the ablation has been successful.
24. Remove all remaining apparatus from the body.

A similar approach can be used with the CAS 70, via access from a peripheral artery such as the femoral artery, to treat hypertension, via ablation of tissue in the periostial aortic wall tissue surrounding one or both of the renal arteries, with the goal of ablating afferent and/or efferent sympathetic nerve fibers entering or exiting the kidney.

While the CAS 70 shows a separate tube 72 it is envisioned the fluid injection lumen of the CAS 70 catheter body could be constructed similar to that of the CAS 10 of FIGs. 1-5 where an additional outer tube would be placed with the fluid injection lumen being between the outer and middle tubes. It is also envisioned that instead of concentric tubes with lumens between the tubes, a multi-lumen catheter could be used with separate lumens formed during extrusion of the catheter body. Similarly, while the shape of the tubes and lumens shown here are cylindrical, other shapes are also envisioned.

While the present invention described here has an expandable balloon as a centering means, it is envisioned that a fixed diameter centering section could be used or a mechanical expandable structure could also facilitate centering of the CAS. For example, FIG. 11A and 12 show a self-expanding wire structure 96 to center the CAS.

FIG. 11A is a longitudinal elevational view of the fully open configuration of another embodiment of the CAS 90 that uses self-expanding injector tubes 95 connected circumferentially with one or more stabilizing structures to ensure uniform expansion of the injector tubes 95 used to deliver the ablative substance to the ostial wall of the target vessel. In this embodiment the stabilizing structures are the strings 93P and 93D that are attached to the proximal and distal ends of the injector hubs 97 which attach to the distal end of each injector tube 96 and the proximal end of each injector needle 99. It is envisioned that the strings 93P and 93D could be fixedly attached to each of the hubs 97 or they could constrain the injector tubes 96 by going through a hole in each injector hub 97 as shown in the enlargement of section 113 which is FIG. 13. The first approach of attachment has the advantage of ensuring that the length of the strings 93P and 93D between adjacent injector tubes 95 is uniform thus potentially having a more uniform circumferential deployment of the needles 99 of the CAS 90. The structure used for attachment could still involve the holes 111P and 111D of FIG. 13 only with a small amount of adhesive applied to attach the strings 93P and 93D inside of the holes 111P and 111D.

The CAS 90 of FIG. 11A also includes an inner tube 98 and outer tube 94 with an injector lumen 91 located between the inner and outer tubes 98 and 94. The lumen of the inner tube 98 facilitates the advancement of the CAS 90 over the guidewire 20. An injector manifold 107 attached between the inner tube 98 and outer tube 94 hold the injector tubes 95.

Distal to the distal end of the outer tube 94 and injector manifold 107 and attached to the inner tube 98 is a self-expanding centering structure 96 which here is shown in the expanded state as 4 wires attached at their proximal end to the ring 108 which is fixedly attached to the inner tube 98 and at their distal end to the ring 106 which is free to move longitudinally over the shaft of the inner tube 98. A radiopaque marker band 109 is attached to the inner tube 98 and marks the position of the injector needles 99. It is also envisioned that the injector hubs 97 could include a radiopaque marker or be made from a radiopaque material to enhance visualization during use of the CAS 90 under fluoroscopy. For example the injector assemblies could be formed from a plastic with a radiopaque metal filler such as tungsten filled urethane.

The distal tip 100 of the CAS 90 has a tapered distal tip 103 and a reduced diameter section 105 and central portion 104 that includes a radiopaque marker band. The proximal portion of the reduced diameter section 105 has a tapered shape to facilitate centering of the sheath 92 as it is advanced over the reduced diameter section 105 A retractable sheath 92 with radiopaque marker 102 lies coaxially outside of the outer tube 94 and when retracted in the proximal direction allows the centering structure 96 and self-expanding injector tubes 95 to expand to their preset diameters. The sheath 92 when advanced to its most distal location will fit over the reduced diameter section 105 and up against the proximal end of the central portion 104 of the distal tip 100. For the user the radiopaque marker in the central section 104 and the radiopaque marker band 102 will come together as the sheath 92 reached its most distal location and the CAS 90 is in its closed position.

In this closed position, the CAS 90 as shown in FIG. 11B will be advanced through the body to the desired location. Also in this closed position, the CAS 90 will be pulled out of the body. An important advantage of this design is that the injector needles 99 are constrained within the sheath 92 whenever the CAS 90 is outside of the body so that health care workers cannot be stuck by the needles 99 or infected by blood borne pathogens following the used of the CAS 90.

FIG. 12 is a longitudinal cross section of the CAS 90 of FIG. 11A. In this embodiment the strings 93P and 93D that stabilize the expanded injector tubes 95 are attached to the proximal and distal ends of the injector hubs 97 which attach to the distal end of each injector tube 96 and the proximal end of each injector needle 99. It is envisioned that the strings 93P and 93D could be fixedly attached to each of the hubs 97 or the could constrain the injector tubes 96 by going through a hole in each injector hub 97 as shown in the enlargement of section 114 which is FIG. 14. The first approach of attachment has the advantage of ensuring that the length of the strings 93P and 93D between adjacent injector tubes 95 is uniform thus potentially having a more uniform circumferential deployment for needles 99 of the CAS 90. The structure used for attachment could still involve the holes 111P and 111D of FIG. 13 only with a drop of adhesive applied to attach the strings 93P and 93D inside of the holes 111P and 111D.

The CAS 90 of FIG. 12 also includes an inner tube 98 and outer tube 94 with an injector lumen 91 located between the inner and outer tubes 98 and 94. The lumen of the inner tube 98 facilitates the advancement of the CAS 90 over the guide wire 20. An injector manifold 107 attached between the inner tube 98 and outer tube 94 hold the injector tubes 95. An enlarged view of the section 115 is shown in FIG. 15.

Distal to the distal end of the outer tube 94 and injector manifold 107 and attached to the inner tube 98 is a self-expanding centering structure 96 which here is shown in the expanded state as 2 of the 4 wires attached at their proximal end to the ring 108 which is fixedly attached to the inner tube 98 and at their distal end to the ring 106 which is free to move longitudinally over the shaft of the inner tube 98. While 4 self-expanding wires are shown here, it is envisioned that as few as 3 wires or as many as 16 wires could be used for centering. The self-expanding wires would typically be made of a springy material, for example a memory metal such as NITINOL.

A radiopaque marker band 109 is attached to the inner tube 98 and marks the position of the injector needles 99.

The distal tip 100 of the CAS 90 has a tapered distal tip 103 and a reduced diameter section 105 and central portion 104 that includes a radiopaque marker band. The proximal portion of the reduced diameter section 105 has a tapered shape to facilitate centering of the sheath 92 as it is advanced over the reduced diameter section 105 A retractable sheath 92 with radiopaque marker 102 lies coaxially outside of the outer tube 94 and when retracted in the proximal direction allows the centering structure 96 and self-expanding injector tubes 95 to expand to their preset diameters. The sheath 92 when advanced to its most distal location will fit over the reduced diameter section 105 and up against the proximal end of the central portion 104 of the distal tip 100. For the user the radiopaque marker in the central section 104 and the radiopaque marker band 102 will come together as the sheath 92 reached its most distal location. It is also envisioned that the entire distal tip 100 could be made from a radiopaque material, for example tungsten filled urethane.

FIG. 13 is an enlarged view of the portion 114 of FIG. 11A. Here the injector hub 97 includes a flattened distal end 112 that acts to limit the penetration of the needle 99. The injector hub 97 connects to the distal end of the injector tube 95 and the proximal end of the injector needle 99. The injector assembly includes proximal connector 111P with hole 116P through which the connecting string 93P is connected. The injector assembly also has distal connector 111D with hole 116D through which the string 93D is connected. In the preferred embodiment the strings 93P and 93D would be fixedly attached to the connectors 111P and 111D either by using an adhesive or by tying the string to each connector.

FIG. 14 is a cross-sectional section of an enlarged view of the portion 114 of FIG. 12. Here the injector hub 97 includes a flattened distal end 112 that acts to limit the penetration of the needle 99. The injector hub 97 connects to the distal end of the injector tube 95 and the proximal end of the injector needle 99. The injector assembly includes proximal connector 111P with hole 116P through which the connecting string 93P is connected. The injector assembly also has distal connector 111D with hole 116D through which the string 93D is connected. In this cross section, it can clearly be seen how the lumen 117 of the injector tube 95 is in fluid communication with the lumen 119 of the injector needle 99 inserted into the distal end of the injector hub 97.

FIG. 15 is an enlarged view of the portion 115 of FIG. 12. This view clearly shows the details of the manifold 107 attached between the inner tube 98 and outer tube 94. The manifold 107 is also attached to each injector tube 95 at its proximal end which passes through the manifold so as to allow fluid communication between the injector lumen 91 and the lumen 117 of the injector tubes 95. Also shown in FIG. 15 is the radiopaque marker ring 102 attached to the distal end of the sheath 92. This ring would typically be made from a radiopaque metal such at tantalum. The inner tube 98, outer tube 94 and sheath 92 would typically be made from a plastic material, although any of these tubes could have two sections and use a metal hypotube for their proximal section. The self-expanding injector tubes would typically be made from NITINOL heat treated so that their transition temperature is sufficiently low so that the tubes are in their memory super-elastic state when in the body. Also shown in FIG. 15 is the guide wire lumen 118 inside of the inner tube 98 and the lumen 122 between the outer tube 94 and the sheath 92.

FIG. 16 is a longitudinal cross section of the proximal end of the CAS 90 of FIGs. 11A and 12 with the sheath 92 in its most proximal position corresponding to the total expansion of both the injector tubes 92 and centering structure 96 of FIGs. 11A and 12. The proximal end of the inner tube 98 is attached to a Luer fitting 138 that can be used to inject fluid to flush the guide wire lumen 118 inside of the inner tube 98. The guide wire 20 is inserted through the guide wire lumen 118. The proximal end of the middle tube 94 is attached to the side tube 134 with lumen 136. The proximal end of the side tube 134 is attached to the Luer fitting 136 which can be attached to inject an ablative substance such as ethanol through the lumen 136 that is in fluid communication with the injection lumen lumen 91 that lies between the outer tube 94 and the inner tube 98. Thus ablative fluid injected through the Luer fitting 135 will be pushed through the injection lumen 91 into the injector tubes 95 and out of the needles 99 of FIGs. 11A and 12 into the ostial wall of the target vessel. The proximal end of the sheath 92 is connected to the distal end of the side tube 132 with lumen 133. The side tube 132 is connected at its proximal end to the Luer fitting 131 that can be connected to a syringe used to flush the lumen 122 between the outer tube 94 and the sheath 92. The sheath 92 is slideable over the outer tube 94 and would be advanced in the distal direction from the configuration of FIG. 16 to close the CAS 90 before it is moved to another location or removed from the body of a human patient. Additional valves and stopcocks may also be attached to the Luer fittings 135 and1 31 as needed. It is also envisioned that a Tuohy-Borst fitting could be built into the distal end of the sheath 92 to allow the sheath to be locked down onto the outer tube 94 during insertion into the body as well as to reduce any blood leakage when the sheath 92 is pulled back as shown in FIG. 16.

While the CAS 90 embodiments of FIGs. 11A through 16 uses a sheath to both protect the sharp needles during delivery and after removal from the body, it is also envisioned that the CAS 90 could be used without the sheath 92 where the guiding catheter would act as the sheath 92 to allow expansion and contraction of the injector tubes 95. Having the sheath 92 is advantageous however because of the added protection for the sharp needles.

For this embodiment of the CAS 90, the method of use for hypertension would be the following steps:

1. Remove the sterilized CAS 90 from its packaging in a sterile field.
2. Flush the guide wire lumen 118 with saline solution.
3. Access the aorta via a femoral artery, typically with the insertion of an introducer sheath.
4. Using a guiding catheter or guiding sheath with a shaped distal end, engage the first targeted renal artery through the aorta. This can be confirmed with contrast injections as needed.
5. Advance a guide wire through the guiding catheter into the renal artery.
6. Insert the proximal end of the guide wire 20 into the guide wire lumen 118 of the CAS 90 and bring the wire 20 through the CAS 90 and out the proximal end Luer fitting 138 of FIG. 16.

7. Place the distal end of the CAS 90 in its closed position of FIG. 11B into the proximal end of the guiding catheter. There is typically a Tuohy-Borst fitting attached to the distal end of a guiding catheter to constrain blood loss.
8. The closed CAS 90 can be pushed through the opened Tuohy-Borst fitting into the guiding catheter.
9. Advance the CAS 90 through the guiding catheter, and tracking over the guide wire 20, until the distal marker band 104 is within ostium of the renal artery and the sheath distal marker band 102 aligns with the end of the guiding catheter.
10. Lock the guiding catheter to the sheath 92 by tightening the Tuohy-Borst fitting at the proximal end of the guiding catheter.
11. Pull the guiding catheter and sheath back together in the proximal direction while holding the proximal end of the CAS 90 fixed. This will first release the centering basket 96 and then release the expandable injector tubes 95.
12. When the injector tubes 95 have been completely expanded as shown in FIG. 11A, advance the CAS 90 until the injector needles 99 in the injector tubes 95 penetrate the ostial wall, with the penetration depth being a fixed distance limited by the hubs 97. The wire basket 96 will act to center the CAS 90 so that the injector needles 99 will inject in a circle centered on the renal artery.
13. Attach a syringe or injection system to the Luer fitting 135 of FIG. 16 that provides ablative fluid that will be injected into the ostial wall of the aorta.
14. Engagement of the ostial wall could be confirmed by injection of a small volume of iodinated contrast via a syringe through the Luer fitting 135 and out of the needles 99 prior to injection of an "ablative" fluid such as alcohol. If there is contrast "staining"

of the tissue this will confirm that the needles 99 are engaged into the tissue and not free floating in the aorta.

15. Inject an appropriate volume of ethanol (ethyl alcohol) or other appropriate cytotoxic fluid from the syringe or injection system through the lumen 98 and out of the needles 99 into the wall of the aorta. A typical injection would be 1-10 ml. This should produce a multiplicity of interlocking circles of ablation (one for each needle) that should intersect to form a ring around the ostium of the target vessel as is seen in FIG. 6E.
16. Pull the system in the proximal direction until the needles 99 pull out of the wall of the aorta.
17. Put the CAS 90 back into the closed position of FIG. 11B by pulling the proximal end of the CAS 90 in the proximal direction so as to pull the open distal end of the CAS 90 back into the sheath 92 thus collapsing first the injector tubes 95 and then the centering structure wire basket 96. To reach the closed position of FIG. 11B one could instead push the sheath 92 in the distal direction while holding the proximal end of the CAS 90 to accomplish the same thing.
18. In some cases, one may rotate the CAS 90 between 20-90 degrees and then repeat the injection to make an even more definitive ring of ablation. This would be advantageous if the CAS 90 has fewer than 6 injector tubes and should not be needed with the 8 injector tubes shown in herein.
19. The same methods as per steps 6-20 can be repeated to ablate tissue around the other renal artery during the same procedure.
20. Loosen the Tuohy-Borst to unlock the sheath 92 from the guiding catheter.

21. Remove the CAS 90 in its closed position from the guiding catheter. Being in the closed position, the needles 99 are enclosed and cannot harm the health care workers.
22. When indicated, advance appropriate diagnostic electrophysiology catheters through the guiding catheter to confirm that the ablation has been successful.
23. Remove all remaining apparatus from the body.

A similar approach can be used with the CAS 90, to treat Atrial Fibrillation through a guiding catheter inserted through the septum into the left atrium with the ostial wall of the target vessel being the atrial wall surrounding one of the pulmonary veins.

FIG. 17 shows a longitudinal elevational view of the distal portion of yet another embodiment of the CAS 120 scaled for use in the treatment of hypertension by ablation of nerve fibers in or near the ostial wall of the renal arteries. The CAS 120 has an inner tube 128 with guide wire lumen 131 and outer tube 124 with ablative solution injection lumen 121 between the inner tube 128 and outer tube 124. A centering tip 130 is attached to the distal end of the inner tube 128. The tip 130 has a distal flexible section 133, a radiopaque marker 134 and a proximal shelf section 135.

This embodiment of the CAS 120 has 6 injection tubes 125 that have sharpened needle distal ends 129. The proximal ends of the injection tubes 125 connect through a manifold 137 located between the inner tube 128 and outer tube 124. Such a manifold would be similar to the manifold 107 of the CAS 90 detailed in FIG. 15. A penetration limiting cord 123 is attached with adhesive 127 to the outside of each of the injector tubes 125. The cord 123 can be either a polymeric material like nylon or a metal wire. If a thin radiopaque wire of a material such as platinum, gold or tantalum is used then the cord 123 can more easily be visualized under fluoroscopy. An optional radiopaque band 138 may also be used to mark the location of the cord 123 along the length of the CAS 120 when the CAS 120 is in its open position. A sheath 122 with distal radiopaque marker 126 is coaxially outside of the outer tube 124.

The sheath 122 is initially packaged all the way distal so that the radiopaque marker 126 comes up against the radiopaque marker 134 of the distal tip 130. FIG. 18 shows a radial cross section of the CAS 120 looking in the proximal direction at a location just distal to the cord 123. FIG. 18 shows the injector tubes 125 collapsed down against the inner tube 128 inside the sheath 122. Once the CAS 120 is in position with the distal tip 130 just inside a renal artery, the sheath 122 is pulled back in the proximal direction allowing the injector tubes 125 to expand outward to the position shown in FIG. 17. The entire CAS 120 is then advanced to have the needle tips 120 penetrate the ostial wall with the penetration limited by the cord 123.

The CAS 120 uses the widened distal tip 130 to provide centering of the injector tubes 125 with respect to a renal artery. While the CAS 120 does not include an expandable centering apparatus such as the basket 96 of the CAS 90 of FIG. 11B, or the balloon 16 of FIG. 1, it is envisioned a centering apparatus could be incorporated with the other features of the design of the CAS 120.

FIG. 19 is a sketch of the CAS 120 shown with its needle tips 129 penetrating the wall of the aorta outside of the ostium of a renal artery. In this sketch, the penetration into the wall of the aorta by the needle tips 129 is limited by the cord 123. The guiding catheter 140 and sheath 122 are both shown pulled back with the injector tubes 125 fully expanded. The entire CAS 120 is shown having been advanced over the guide wire 20 with distal flexible tip 103.

While the versions of the CAS shown here is an over the wire design, it is also envisioned that a rapid exchange guide wire system where the wire exits the catheter body at a location between the proximal end and the fluid injection ring would be feasible here. In addition, a fixed wire design such as that shown by Fischell et al in U.S. Patent number 6,375,660 for a stent delivery catheter would also work here.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims the invention may be practiced otherwise than as specifically described herein.

WHAT IS CLAIMED IS:

1. A circumferential ablation system for ablating tissue in the ostial wall of a target vessel comprising:

a catheter body having a central axis extending in a longitudinal direction and a fluid injection lumen;

at least two expandable injector tubes secured to said catheter body, each of said injector tubes having an injector tube lumen in fluid communication with the catheter body fluid injection lumen, said injector tubes having an injection needle with injector needle lumen, the injector needle being connected to the distal end of the injector tube and the injector needle lumen being in fluid communication with the injector tube lumen;

a penetration limiting member located at least 0.5 mm proximal to the distal end of each injector needle; and,

an external source of ablative fluid in fluid communication with each of said injector tube lumens.

2. The circumferential ablation system as recited in Claim 1 where said catheter body includes:

(a) an outer tube; and

(b) an inner tube in concentric alignment with said outer tube defining said catheter body fluid injection lumen.

3. The circumferential ablation system as recited in Claim 1 where each of said injector tubes is fixedly coupled to said inner tube at a proximal end of each of said injector tubes.

4. The circumferential ablation system as recited in Claim 3 where each of said injector tubes is fixed to said inner tube by a manifold.

5. The circumferential ablation system as recited in Claim 4 where said manifold is substantially annular in contour having at least two through openings passing in said longitudinal direction, each of said injector tubes being insertable within a respective one of said through openings in fluid communication with fluid flowing through said fluid injection lumen.

6. The circumferential ablation system as recited in Claim 5 where said manifold is adhesively coupled to said inner tube.

7. The circumferential ablation system as recited in Claim 5 where said manifold is molded in one piece formation with said inner tube.

8. The circumferential ablation system as recited in Claim 1 further including a sheath located coaxially outside of the outer tube.

9. The circumferential ablation system of claim 8 where said sheath has a first closed position and a second open position, where the sheath in the closed position extends in the distal direction so as to completely cover the injector needles.

10. The circumferential ablation system of claim 8 where said injector tubes are radially displaceable with respect to said central axis responsive to a relative longitudinal displacement of said sheath with respect to said outer tube.

11. The circumferential ablation system as recited in Claim 9 where expandable injector tubes are expanded when the sheath is in its open position.

12. The circumferential ablation system as recited in Claim 1 where said penetration limiter member is a hub member fixedly attached to each of said injector tubes.

13. The circumferential ablation system as recited in Claim 1 including an inner tube extending in said longitudinal direction being in substantially concentric alignment with said catheter body, said inner tube having a guide wire lumen.

14. The circumferential ablation system as recited in Claim 1 including a system centering mechanism secured to said inner tube for centering said circumferential ablation system within said vessel.

15. The circumferential ablation system as recited in Claim 14 where the centering mechanism is a self-expanding structure.

16. The circumferential ablation system as recited in Claim 14 further including a middle tube that concentrically surrounds the inner tube, and is concentrically surrounded by the outer

tube, where the system centering mechanism is an expandable balloon having a proximal shaft, a distal shaft and a central expandable portion with expandable space coaxially under the expandable portion, the distal shaft of the balloon being attached to the inner tube and the proximal shaft of the balloon being attached to the middle tube, the system further including a balloon inflation lumen located between the inner tube and the middle tube, the inflation lumen being in fluid communication with the space under the expandable balloon.

17. The circumferential ablation system as recited in Claim 16 wherein said radially expandable balloon is expandable in a radial direction with respect to said longitudinal direction when a fluid composition is inserted into said balloon inflation lumen.

18. The circumferential ablation system as recited in Claim 14 wherein said system centering mechanism has a predetermined deployed cross-sectional diameter less than a diameter of said target vessel for centering of the circumferential ablation system within said vessel.

19. The circumferential ablation system of Claim 16 where the balloon has a distal conical or cylindrical portion within the central expandable portion, the distal portion serving to center the balloon on the target vessel as the distal end of the circumferential ablation system is advanced into the target vessel.

20. The circumferential ablation system as recited in Claim 16 wherein said balloon is formed of an elastic composition.

21. The circumferential ablation system as recited in Claim 16 wherein said balloon is has low compliance and is formed by molding the balloon and then folding it into its pre-deployment shape.

22. The circumferential ablation system as recited in Claim 13 including a guide wire insertable through a guide wire lumen defined by said inner tube.

23. The circumferential ablation system of claim 22 having an over-the-wire configuration where the guide wire lumen runs the entire length of the catheter body.

24. The circumferential ablation system of claim 21 having a rapid exchange configuration where the proximal end of the guide wire lumen exits from the catheter body at a location at least 10 cm distal to the proximal end of the catheter body.

25. The circumferential ablation system as recited in Claim 1 where said injector tubes are self-expanding.

26. The circumferential ablation system as recited in Claim 25 where said injector tubes are formed of a nickel titanium alloy.

27. The circumferential ablation system as recited in Claim 25 further including one or more stabilizing structures that constrain the movement of the injector tubes.

28. The circumferential ablation system of claim 1 where injector tubes are expandable by inflation of an inflatable balloon.

29. The circumferential ablation system of claim 28 further including an elastic membrane having a proximal end and a distal end, the elastic membrane being mounted coaxially over the expandable injector tubes.

30. The circumferential ablation system of claim 29 where the distal end of the elastic membrane functions as the penetration limiting member.

31. The circumferential ablation system as recited in Claim 1 where said ablative fluid is an ethanol composition.

32. The circumferential ablation system as recited in Claim 1 including a fixed wire delivery mechanism.

33. A method of treating atrial fibrillation, the method including the steps of:

a. Advancing a guiding catheter until its distal end is situated in the ostium of a pulmonary vein,

b. Advancing a circular ablation system catheter through a guiding catheter until the distal end of the circular ablation system lies within the pulmonary vein, the circular ablation system including a distal portion with expandable tubes having injection needles at their distal end, the circular ablation system designed to allow injection of ablative fluid through the injection needles,

c. Retracting the guiding catheter in the proximal direction,

d. Causing the expandable tubes with distal injection needles to expand outward,

e. Advancing the circular ablation system in the distal direction until the injection needles penetrate the wall of the left atrium,

f. Delivering ablative fluid through the injection needles into the wall of the left atrium,

g. Retracting the circular ablation system in the proximal direction to pull the injection needles out of the wall of the left atrium,

h. Retracting the circular ablation system into the guiding catheter,

i. Repeating steps a through h for additional pulmonary veins as needed,

j. Removing the circular ablation system from the body of the patient.

34. The method of claim 33 further adding a step before the final step j, the step being to advance a protective sheath that is part of the circular ablation system in the distal direction so as to completely cover the needles and protect healthcare workers from inadvertent needle sticks form the circular ablation system after it has been removed from the body of the patient.

35. A method of treating hypertension, the method including the steps of:

a. Advancing a circular ablation system catheter through a guiding catheter until the distal end of the circular ablation system lies within a renal artery, the circular ablation system including a distal portion with expandable tubes having injection needles at their distal end, the circular ablation system designed to allow injection of ablative fluid through the injection needles,

b. Retracting the guiding catheter in the proximal direction,

c. Causing the expandable tubes with distal injection needles to expand outward,

d. Advancing the circular ablation system in the distal direction until the injection needles penetrate the wall of the aorta surrounding the renal artery,

e. Delivering ablative fluid through the injection needles into the wall of the left atrium,

f. Retracting the circular ablation system in the proximal direction to pull the injection needles out of the wall of the aorta,

g. Retracting the circular ablation system into the guiding catheter,

h. Repeating steps a through h for the other renal artery as needed,

i. Removing the circular ablation system from the body of the patient.

36. The method of claim 35 further adding a step before the final step j, the step being to advance a protective sheath that is part of the circular ablation system in the distal direction so as to completely cover the needles and protect healthcare workers from inadvertent needle sticks form the circular ablation system after it has been removed from the body of the patient.

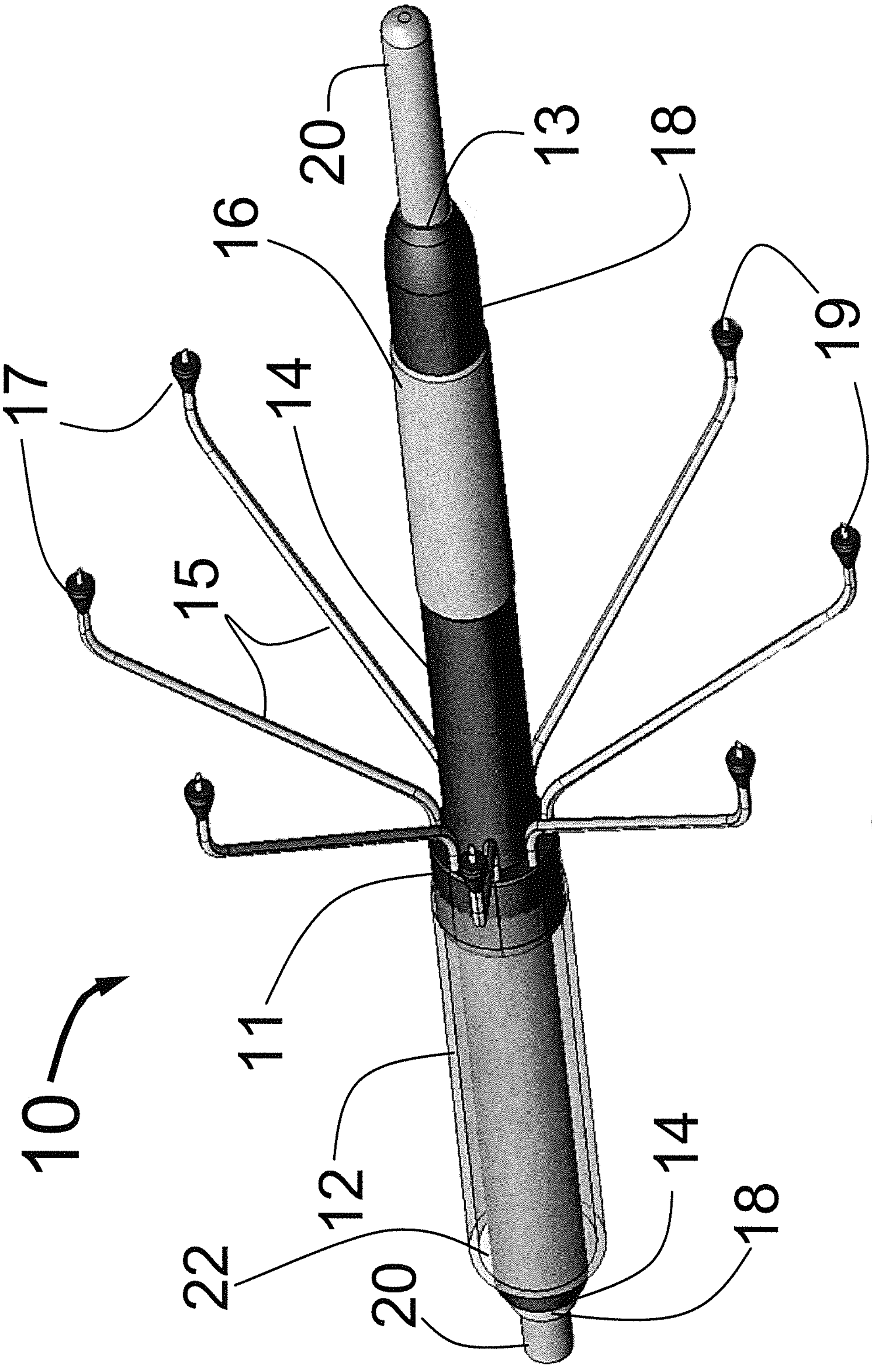

FIG. 1

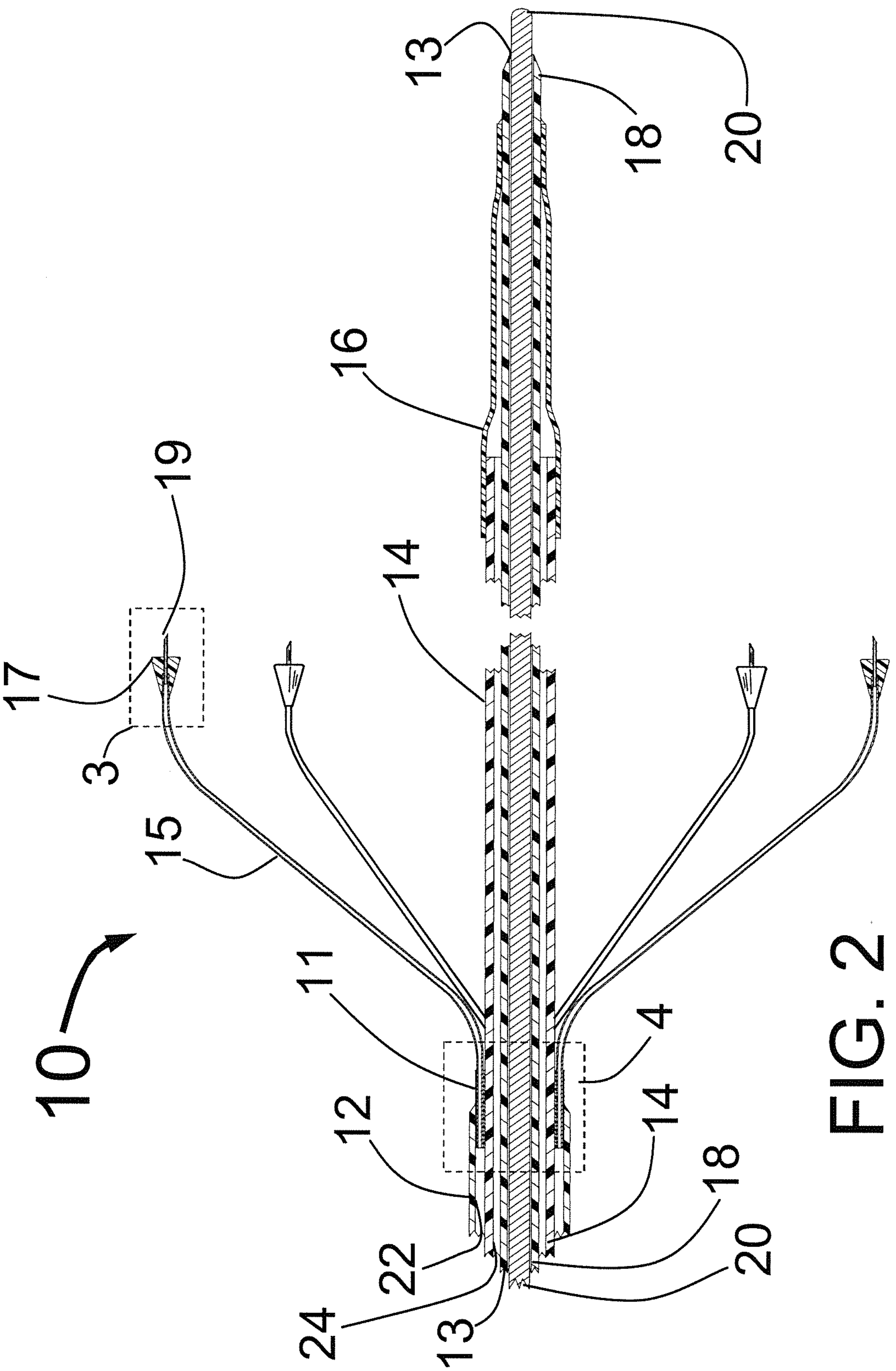

FIG. 2

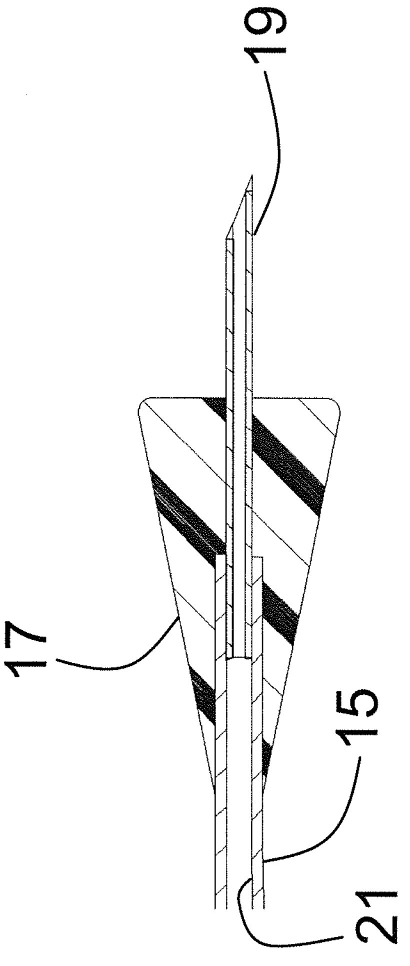

FIG. 3

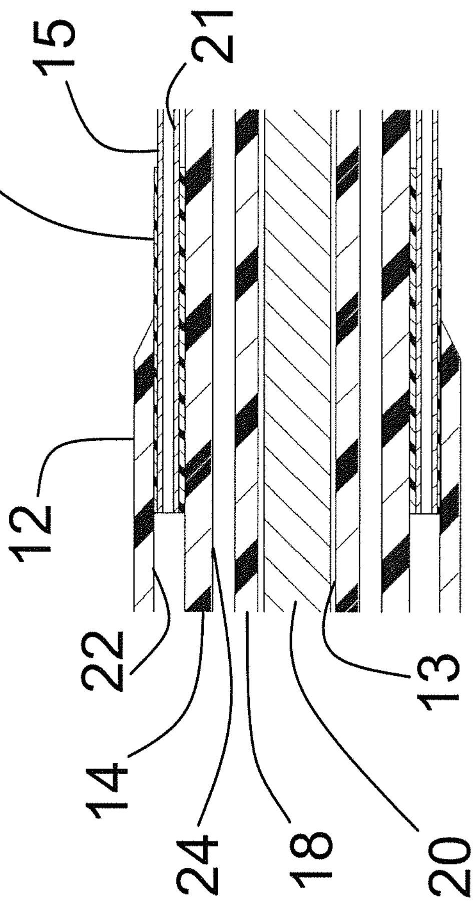

FIG. 4

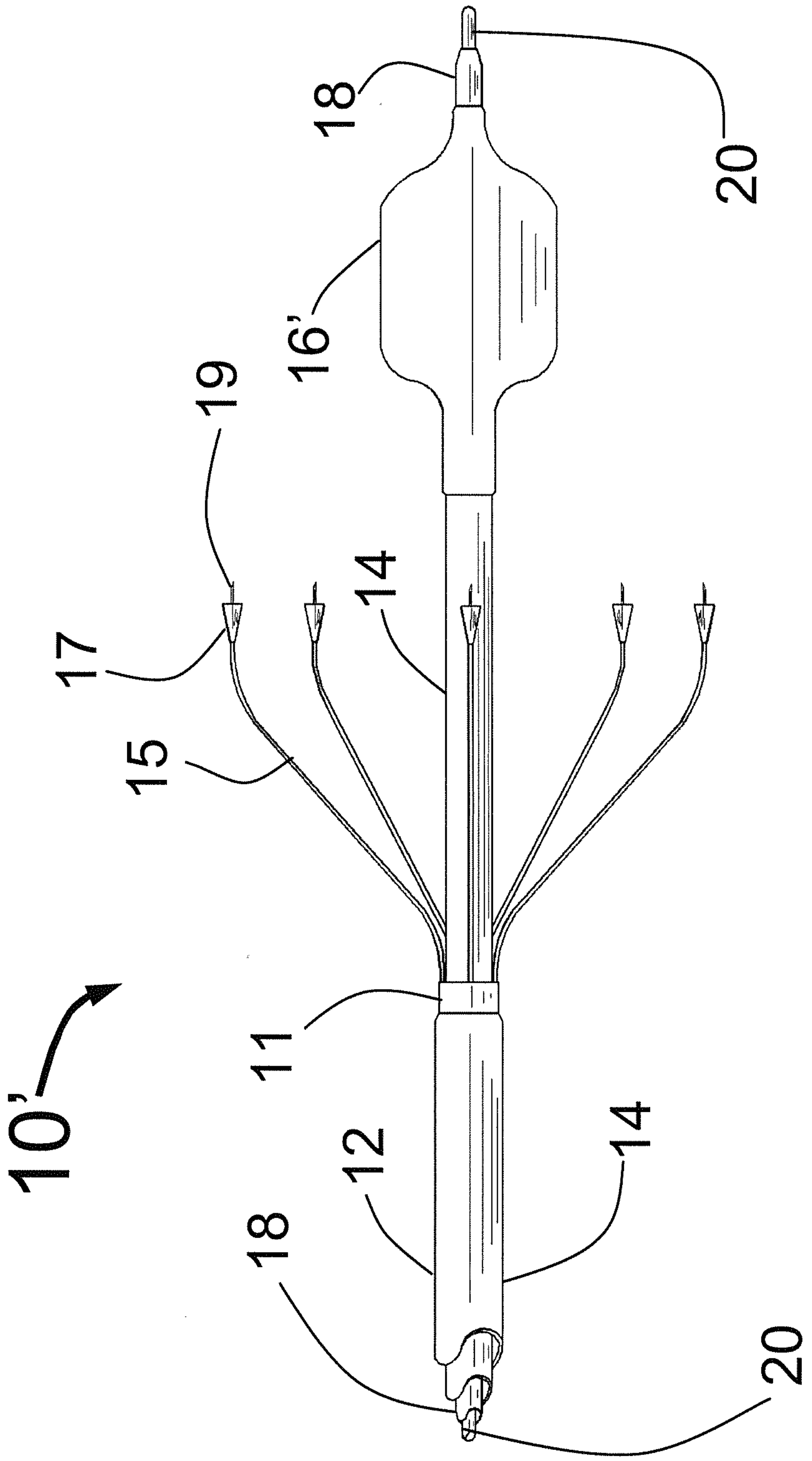

FIG. 5

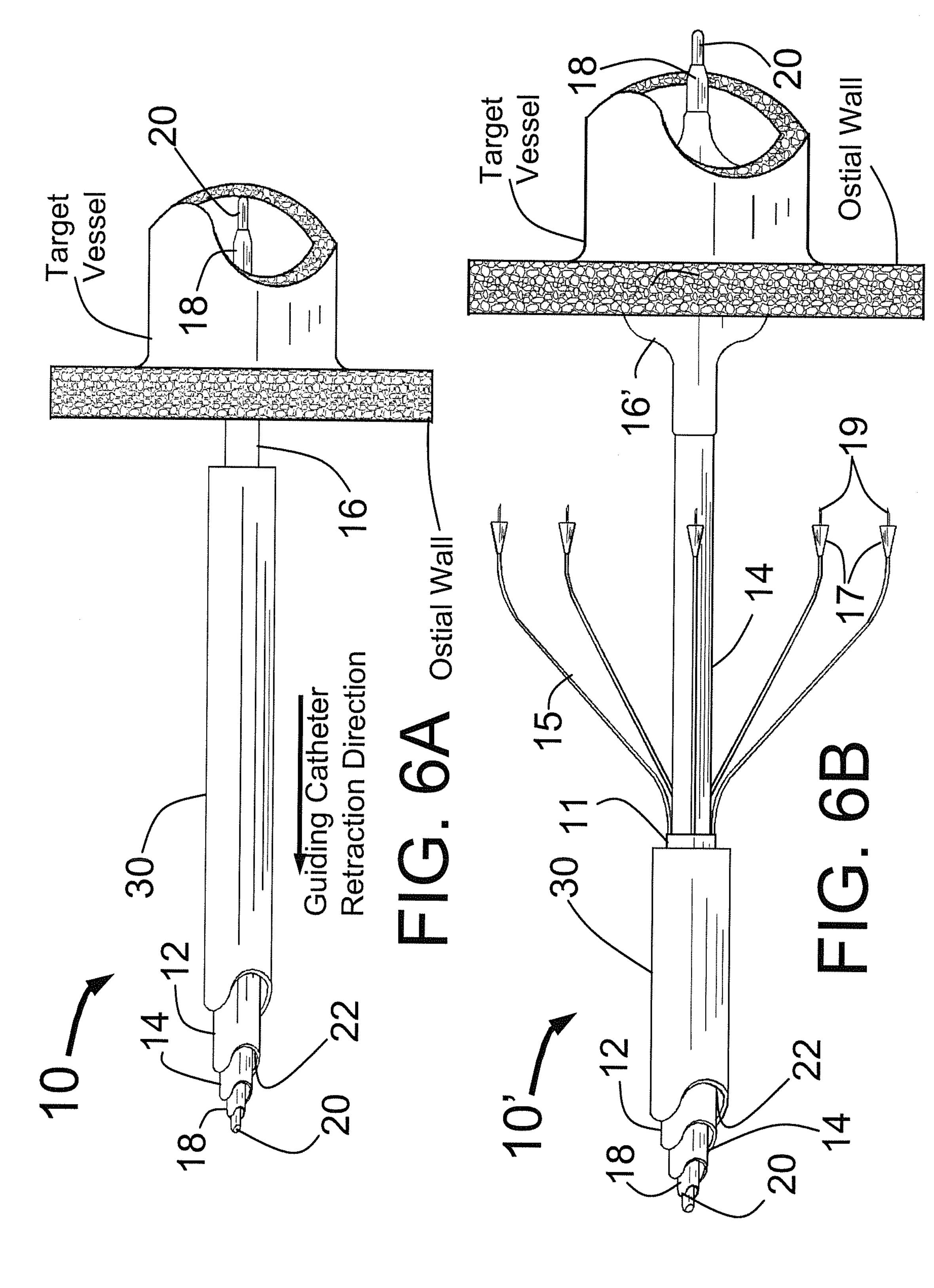
Target Vessel
Ostial Wall
Guiding Catheter Retraction Direction
10
10'
11
12
14
15
16
16'
17
18
19
20
22
30

FIG. 6A

FIG. 6B

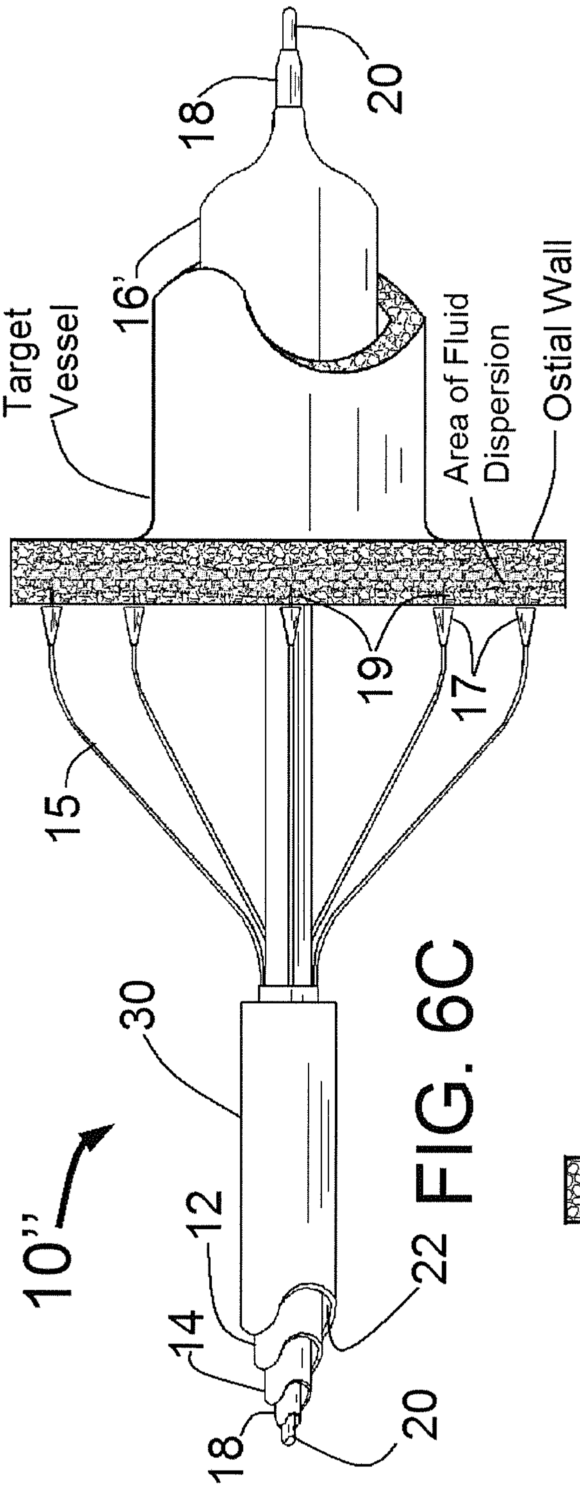

FIG. 6C

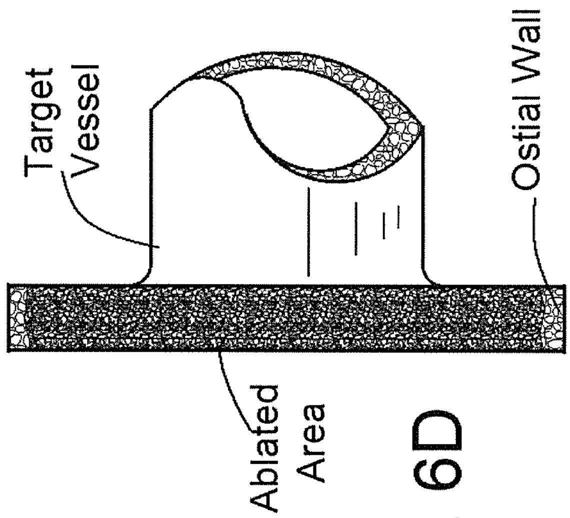

FIG. 6D

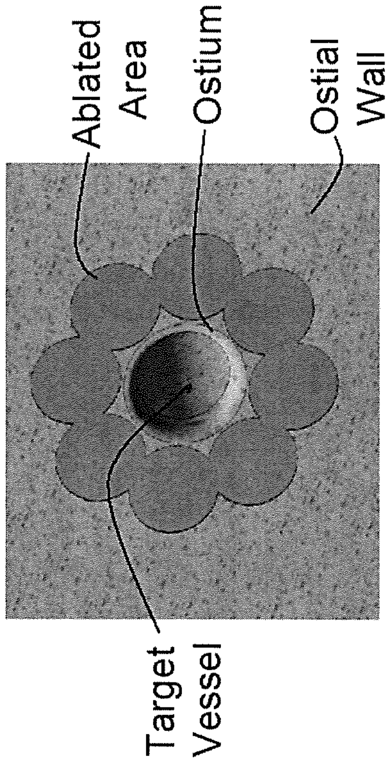

FIG. 6E

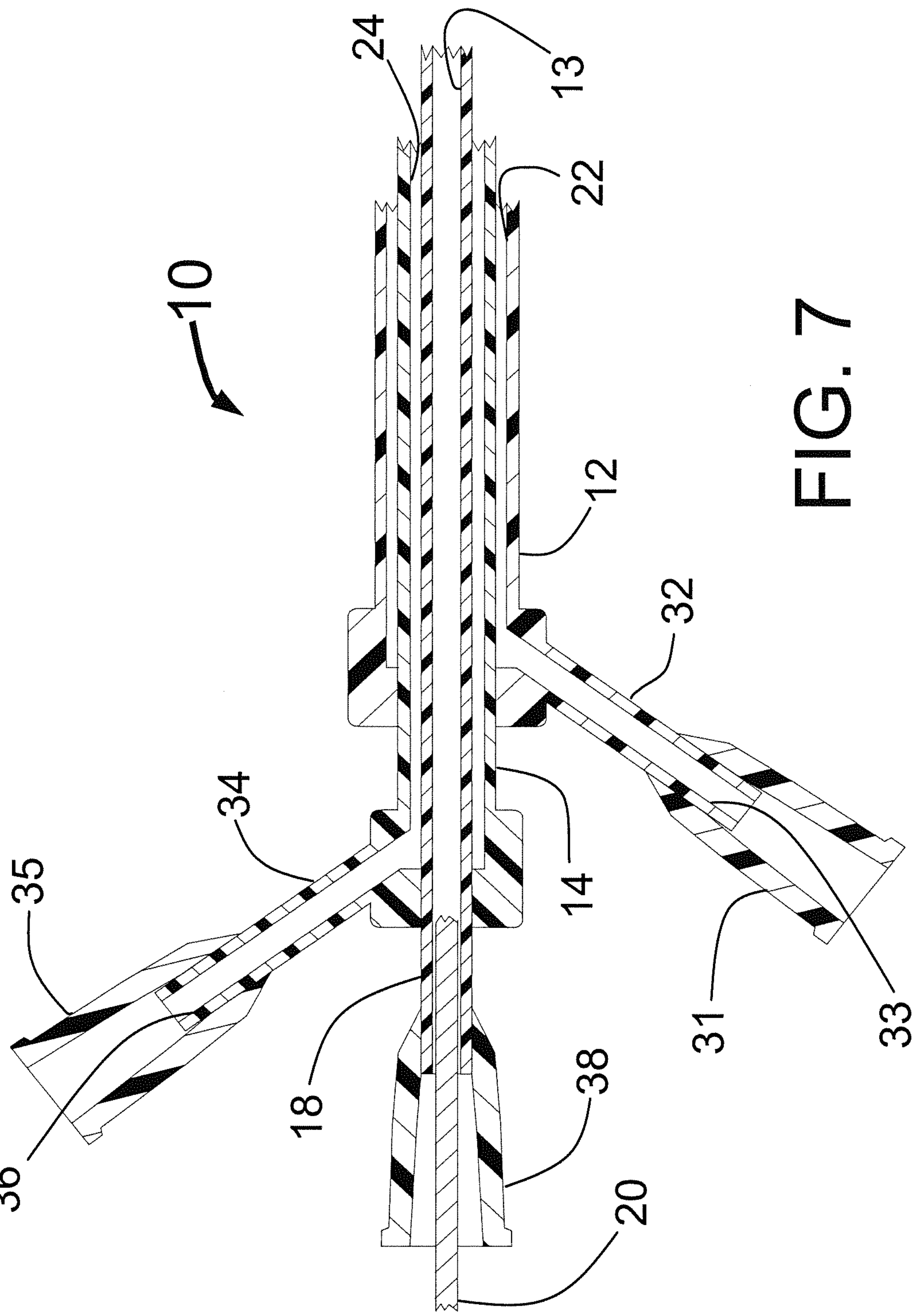

FIG. 7

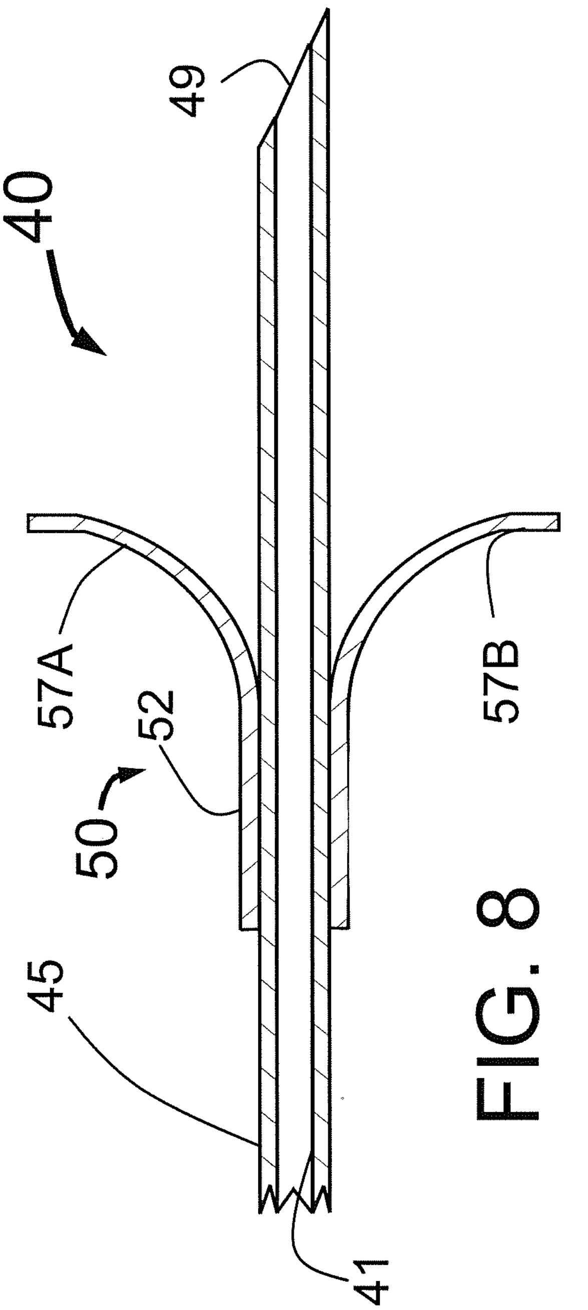

FIG. 8

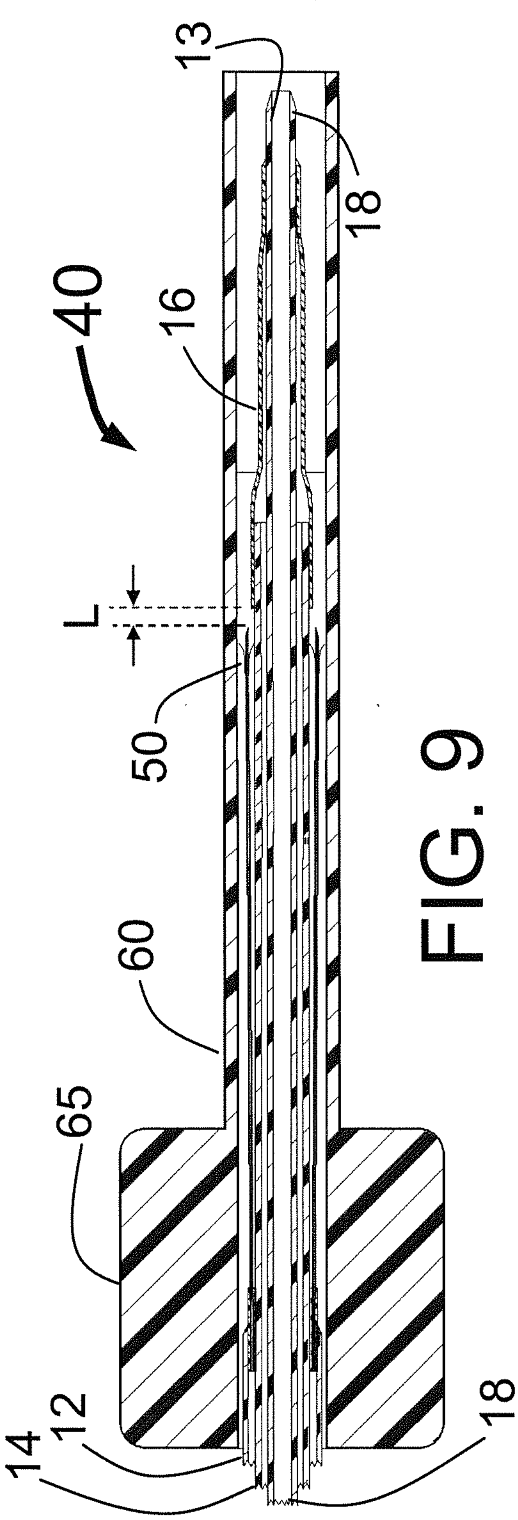

FIG. 9

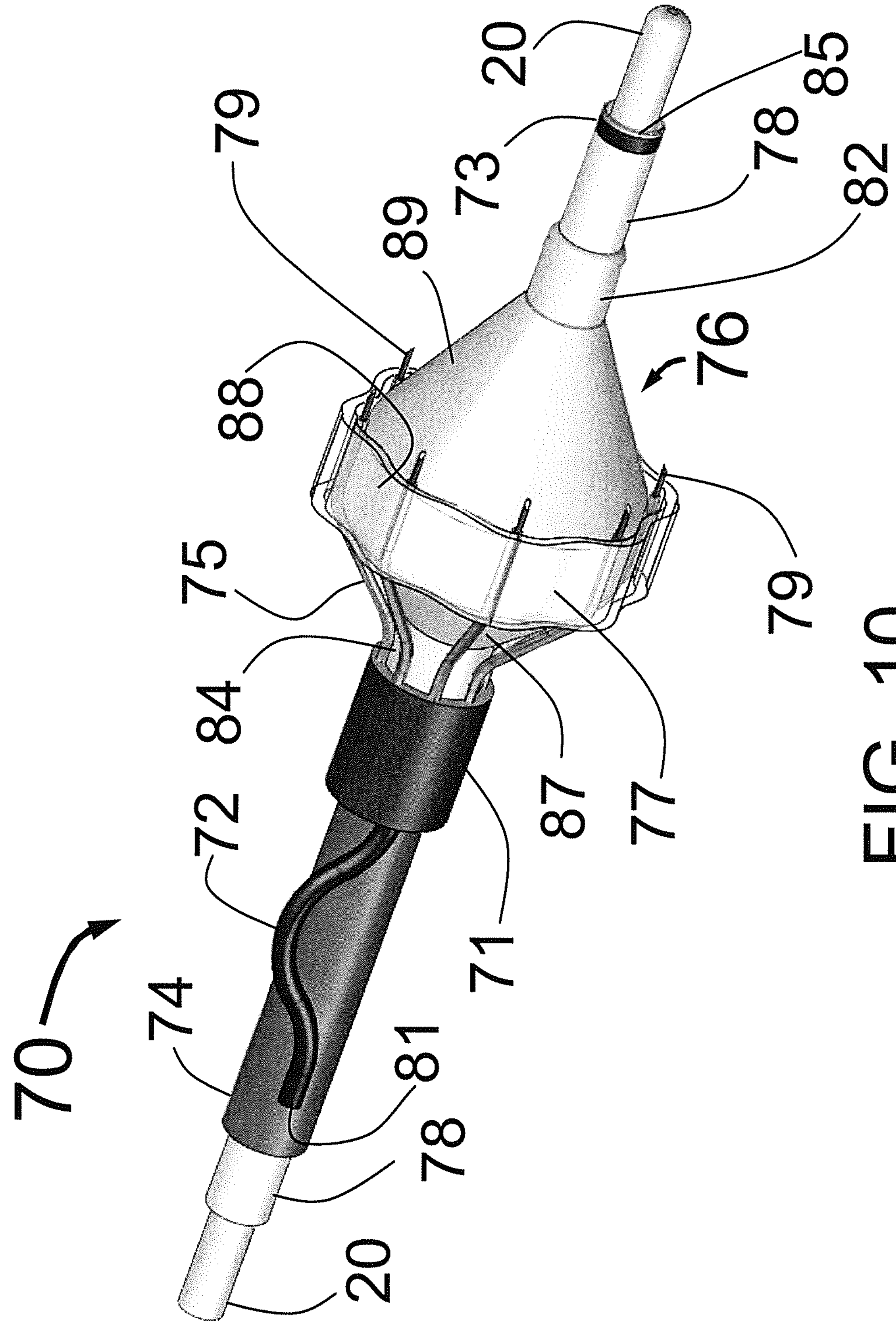

FIG. 10

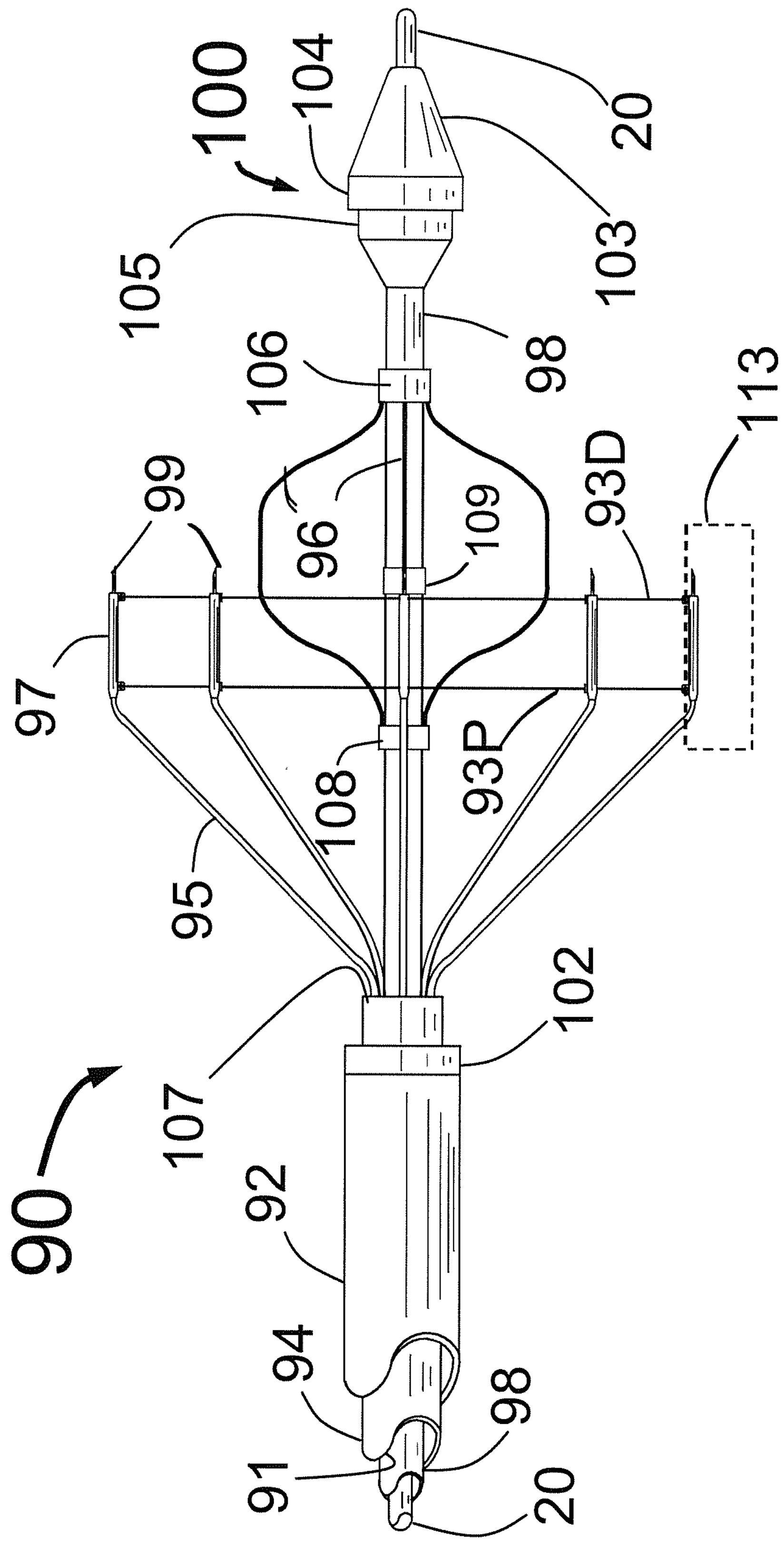
100
104
20
103
105
106
98
113
99
93D
96
109
97
108
93P
95
102
107
90
92
94
98
91
20

FIG.11A

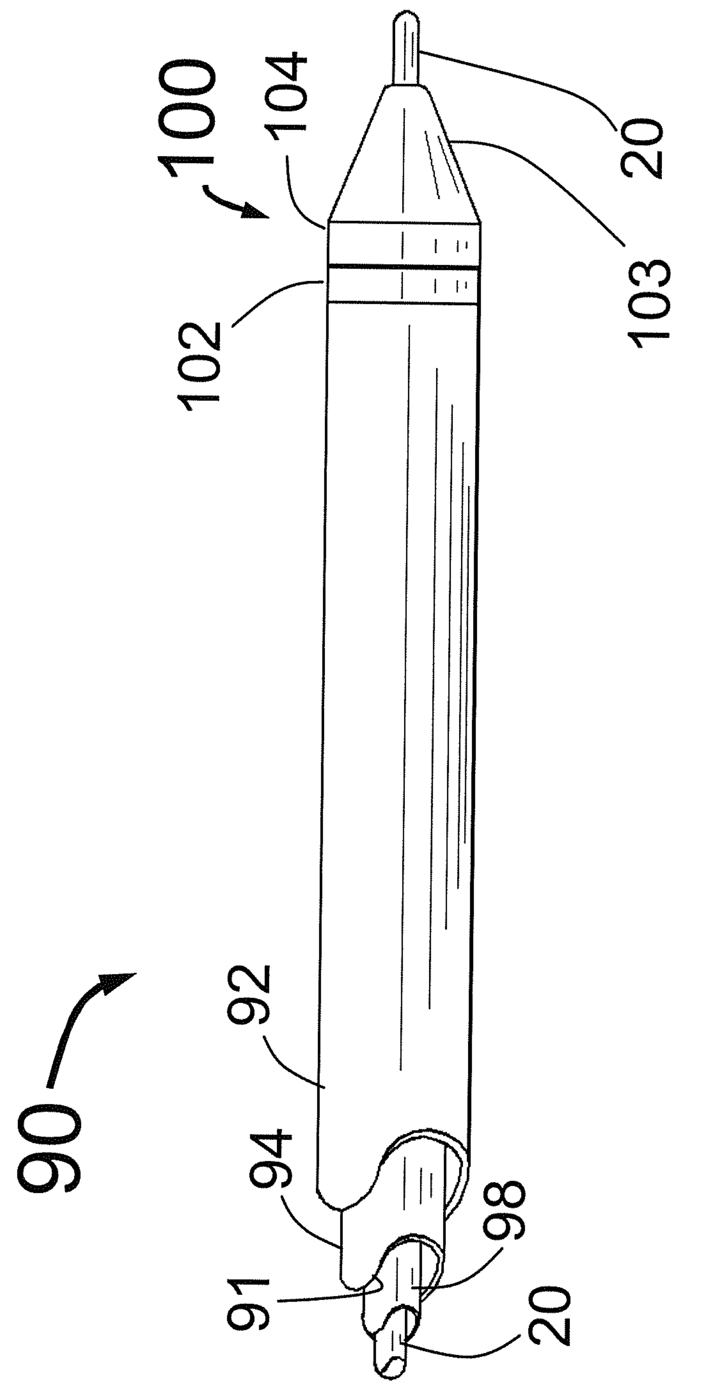

FIG.11B

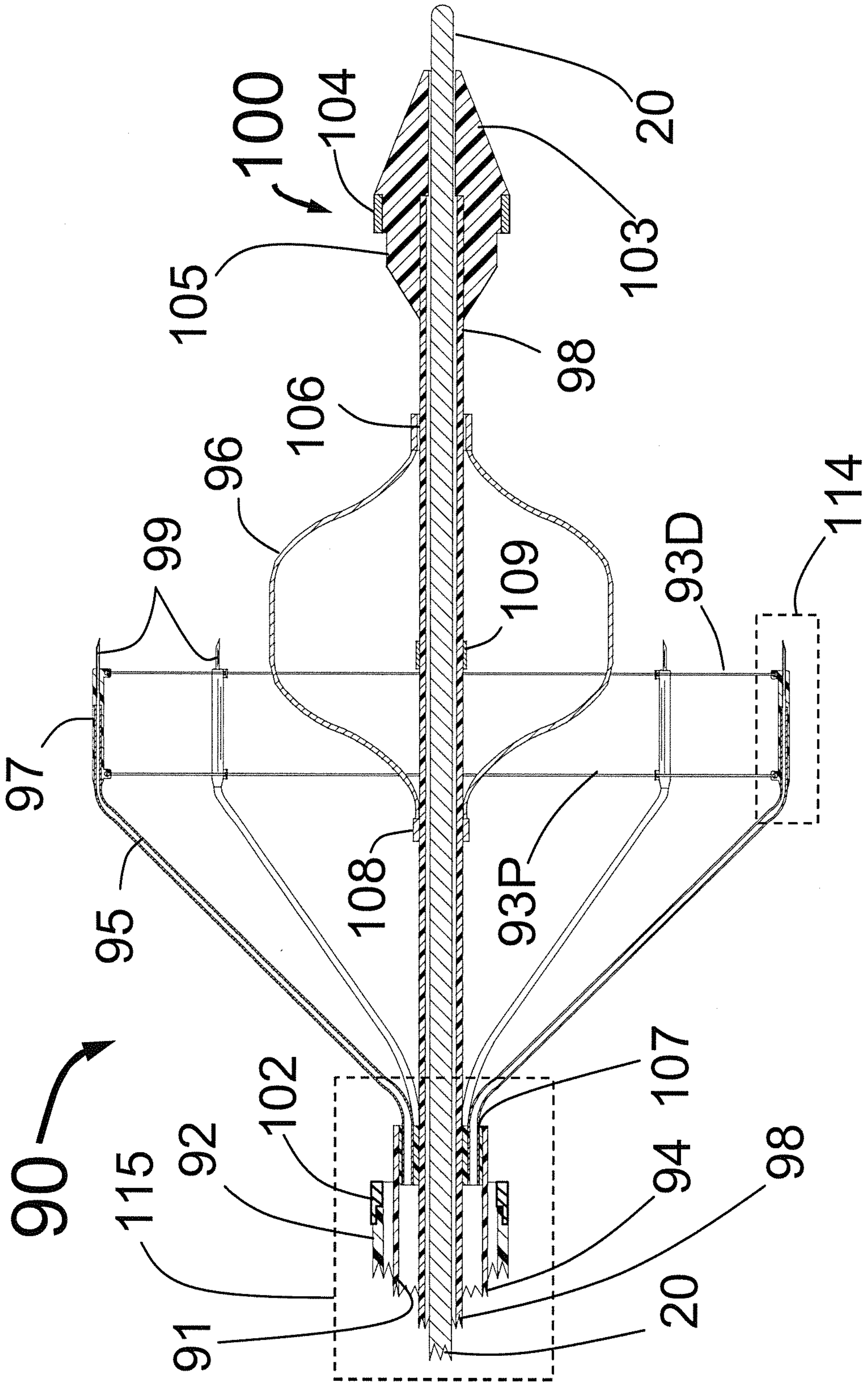
100
104
20
103
105
98
106
96
109
99
93D
114
97
95
108
93P
90
115
92
102
107
94
98
91
20

FIG.12

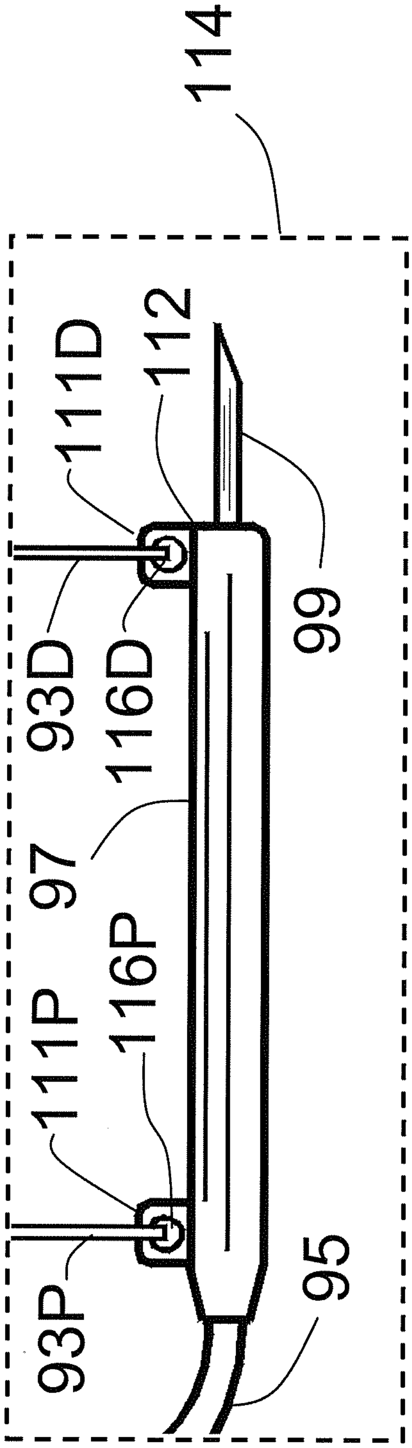
114
111D
112
93D
116D
99
97
116P
111P
93P
95

FIG.13

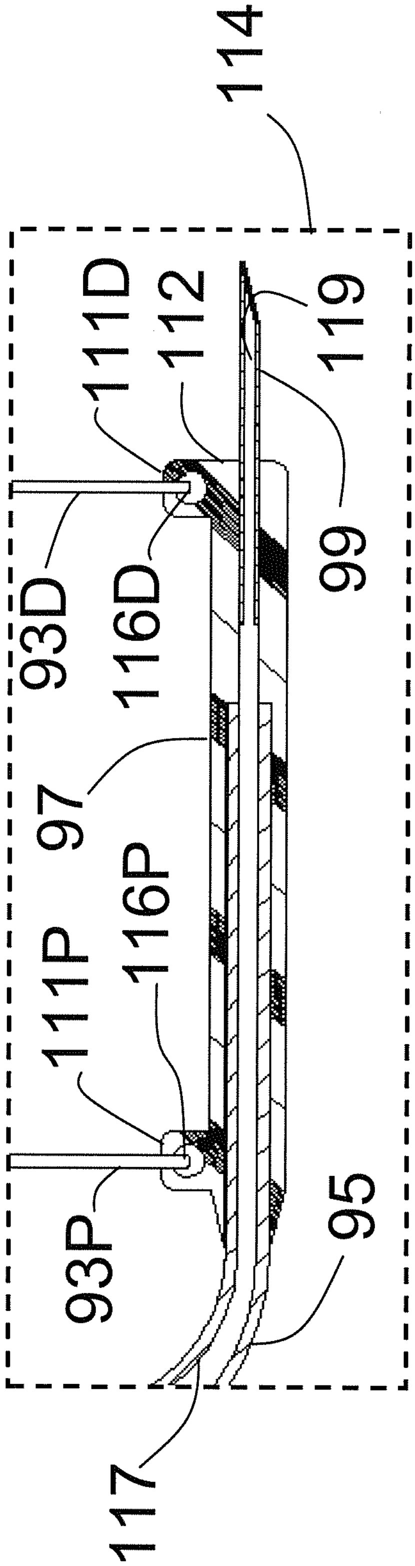
114
111D
112
119
93D
116D
99
97
116P
111P
93P
95
117

FIG.14

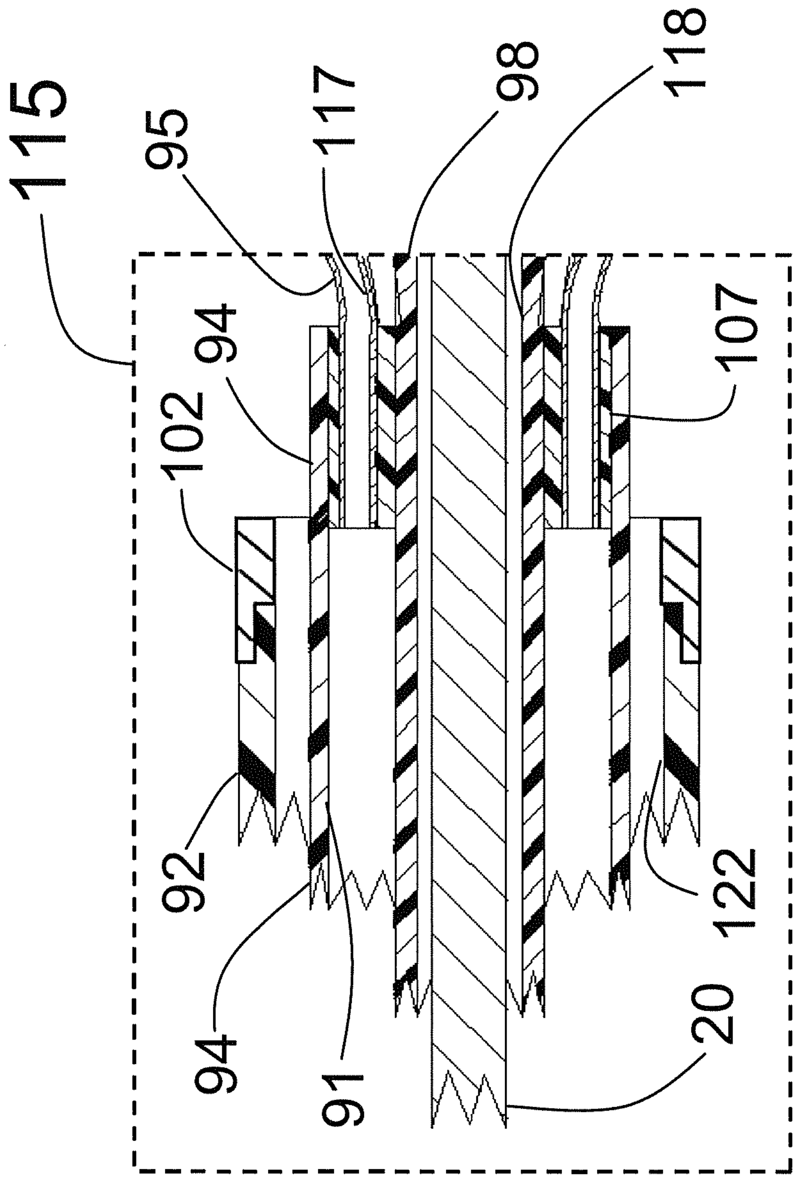

FIG.15

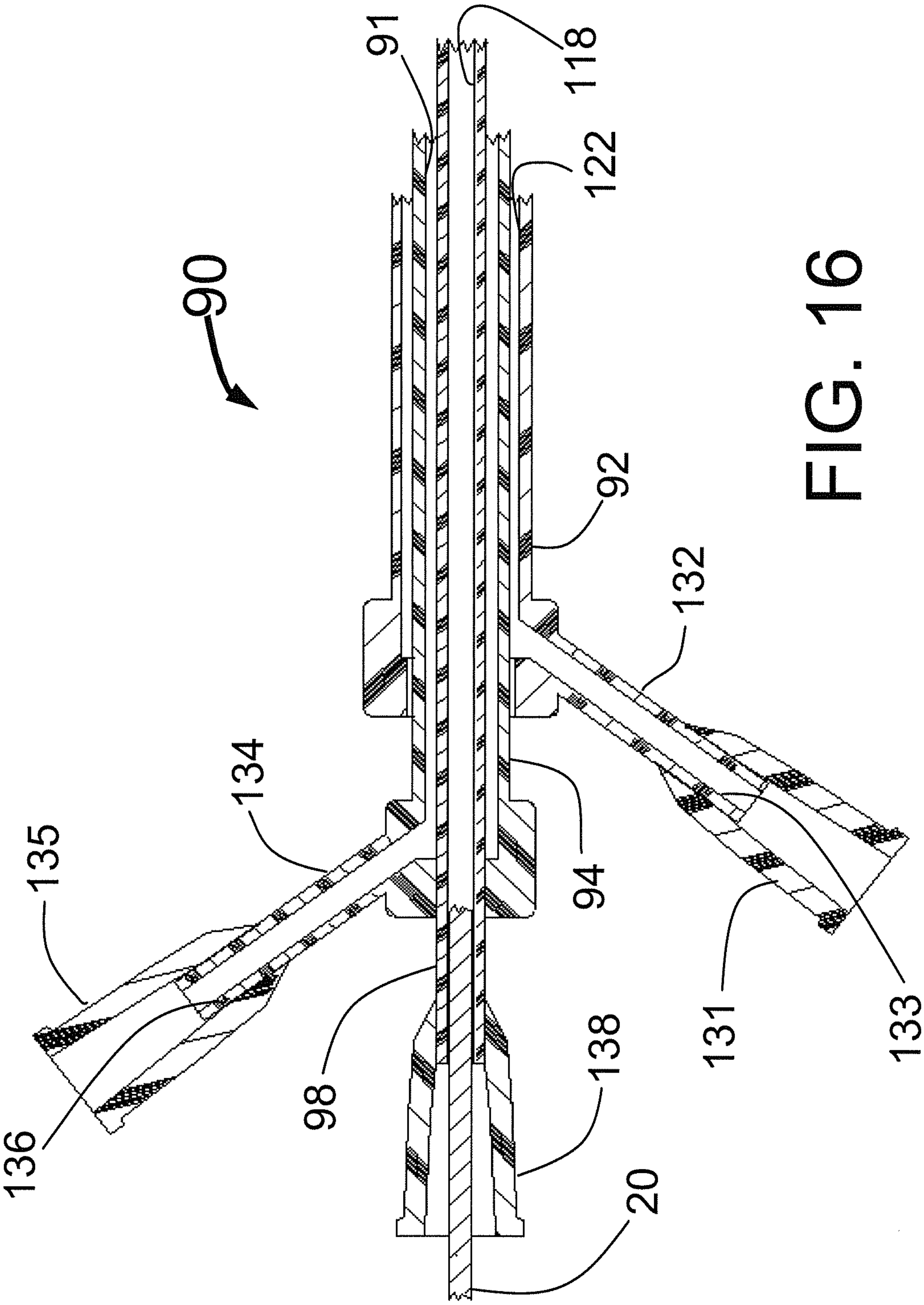

FIG. 16

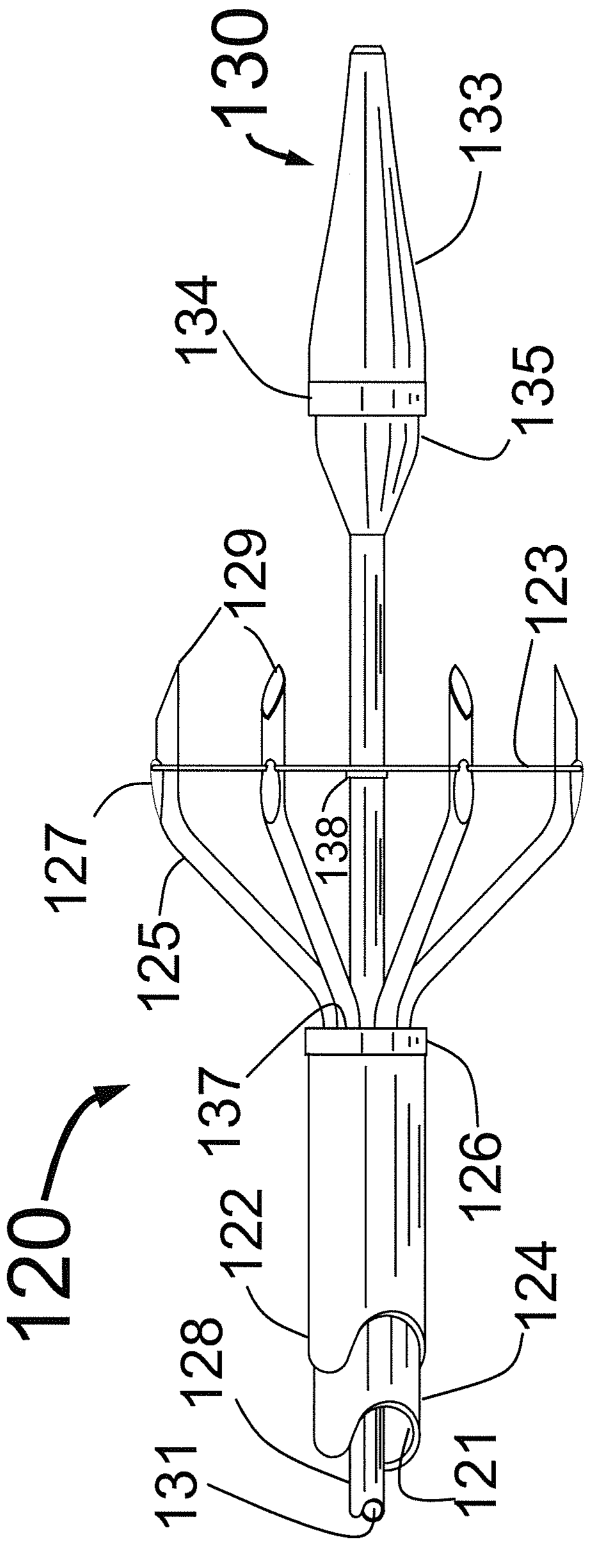
130
133
134
135
129
123
127
138
125
120
137
126
122
124
128
121
131

FIG. 17

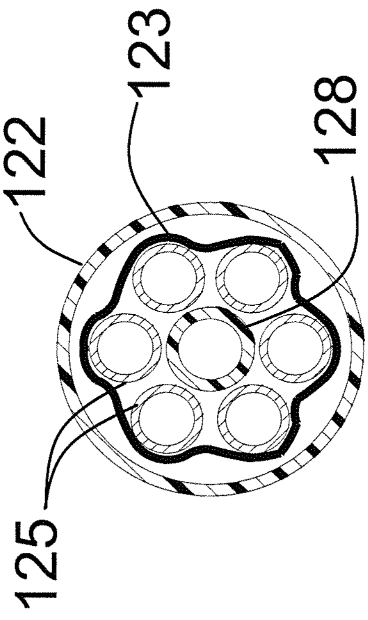
122
123
128
125

FIG. 18

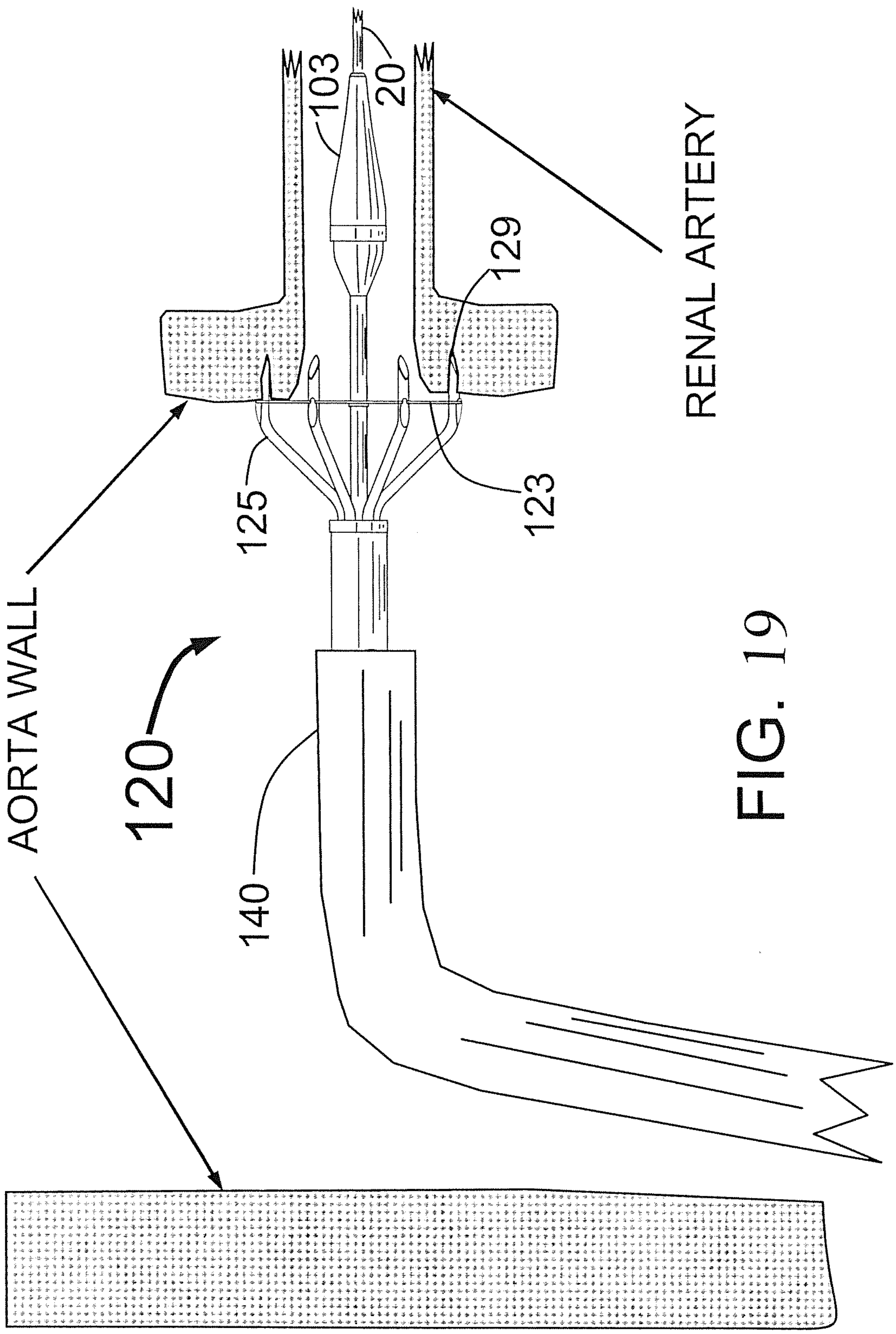

FIG. 19