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(12) **United States Patent**
Lenker

(10) **Patent No.: US 10,485,579 B2**
(45) **Date of Patent: Nov. 26, 2019**

(54) **STEERABLE ENDOLUMINAL PUNCH**

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(73) Assignee: **Indian Wells Medical, Inc.**, Lake Forest, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 324 days.

(21) Appl. No.: **15/441,025**

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(65) **Prior Publication Data**

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Related U.S. Application Data

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(51) **Int. Cl.**

A61B 17/34	(2006.01)
A61B 34/30	(2016.01)
A61M 25/01	(2006.01)
A61M 25/06	(2006.01)
A61B 17/00	(2006.01)
A61B 17/3207	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/3421*** (2013.01); ***A61B 17/3478*** (2013.01); ***A61B 17/3498*** (2013.01); ***A61B 34/30*** (2016.02); ***A61M 25/0138*** (2013.01); ***A61M 25/0147*** (2013.01); ***A61M 25/0158*** (2013.01); ***A61M 25/06*** (2013.01); ***A61M 25/0662*** (2013.01); *A61B 17/320725* (2013.01); *A61B 2017/003* (2013.01); *A61B 2017/00247* (2013.01); *A61B 2017/00309* (2013.01); *A61B 2017/00327* (2013.01); *A61B 2017/00539* (2013.01); *A61B 2017/00544* (2013.01); *A61M 25/0108* (2013.01); *A61M 2210/125* (2013.01)

(58) **Field of Classification Search**

CPC . A61B 17/34; A61B 17/3403; A61B 17/3417; A61B 17/3421; A61B 17/3478; A61B 2017/00247; A61B 2017/00309; A61B 2017/00323; A61M 25/0105; A61M 25/0133; A61M 25/0138; A61M 25/0147; A61M 25/06; A61M 25/065

See application file for complete search history.

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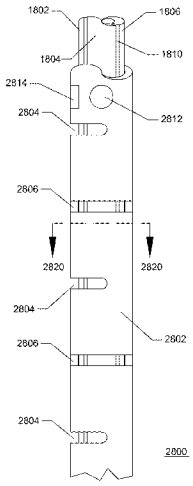
(57) **ABSTRACT**

A transseptal needle or punch wherein the distal end of the transseptal needle is able to articulate laterally out of the longitudinal axis of the steerable transseptal needle. The transseptal needle further comprise a blunted distal end configuration that is minimally traumatic. Under control by the user or a computer, at the proximal end of the transseptal needle can be articulated to generate various curves with high bending force. The transseptal needle is configured for use within a transseptal introducer.

22 Claims, 48 Drawing Sheets



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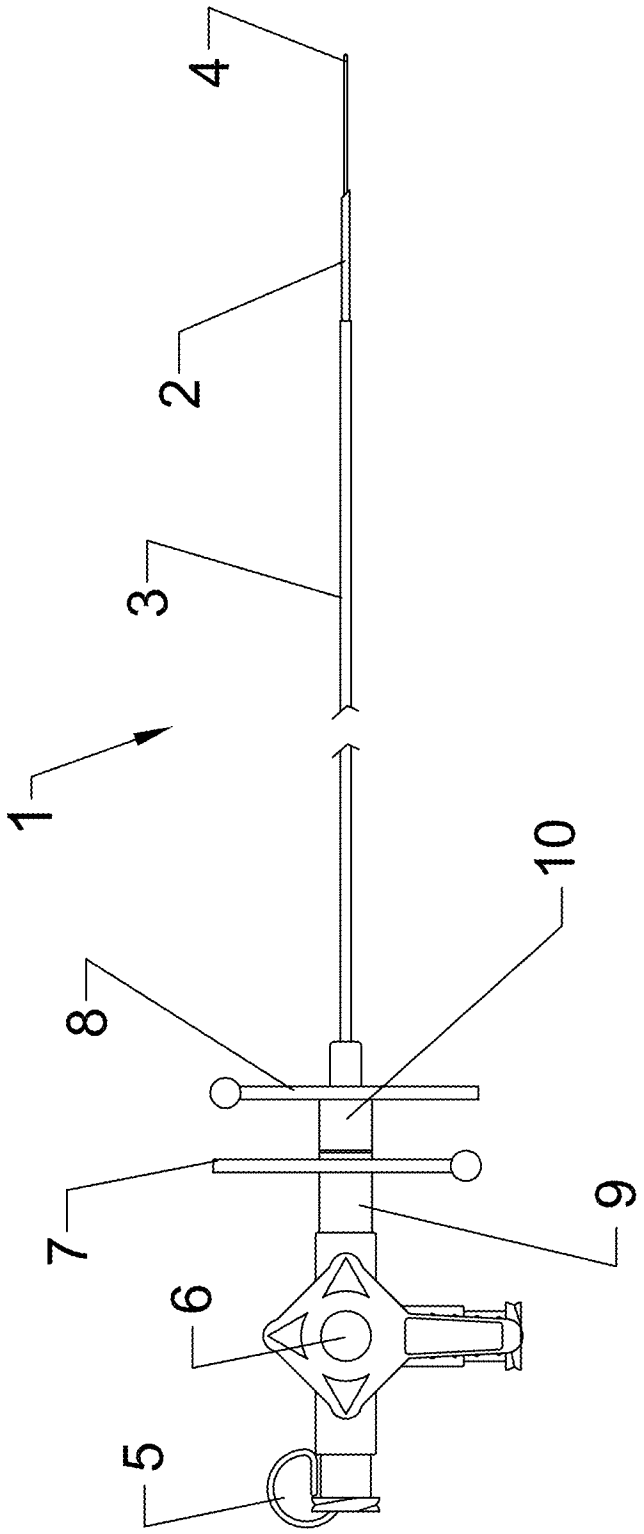

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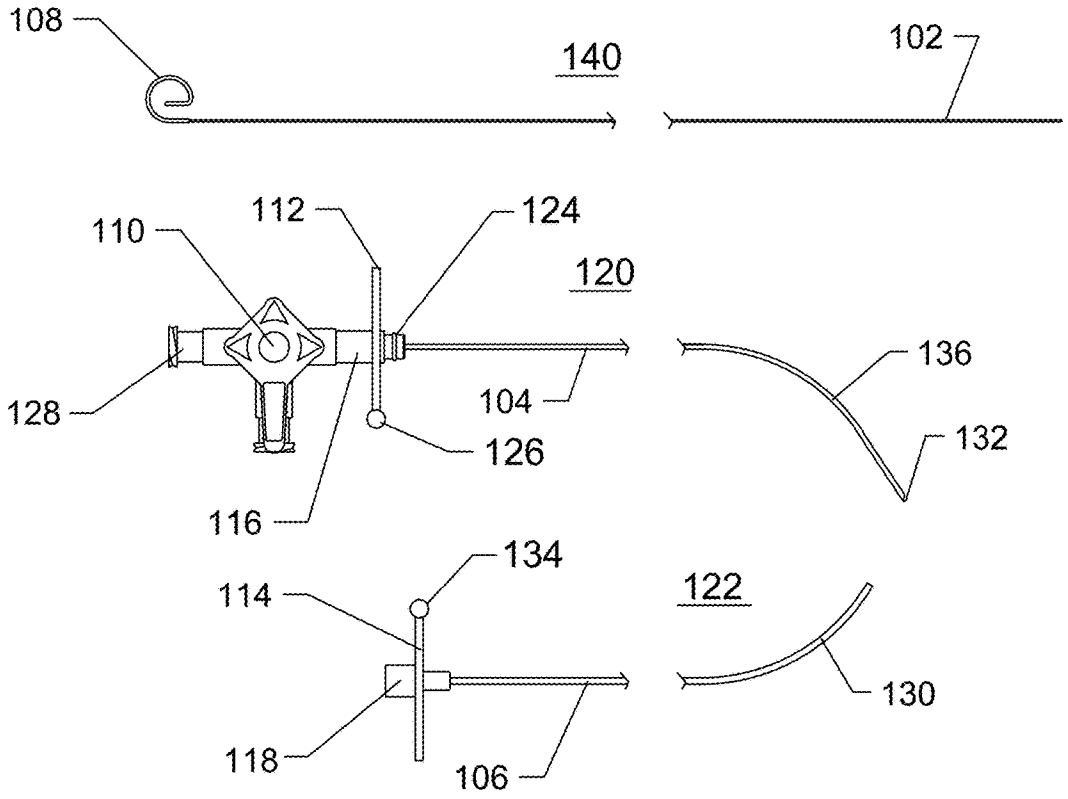
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Fig. 2

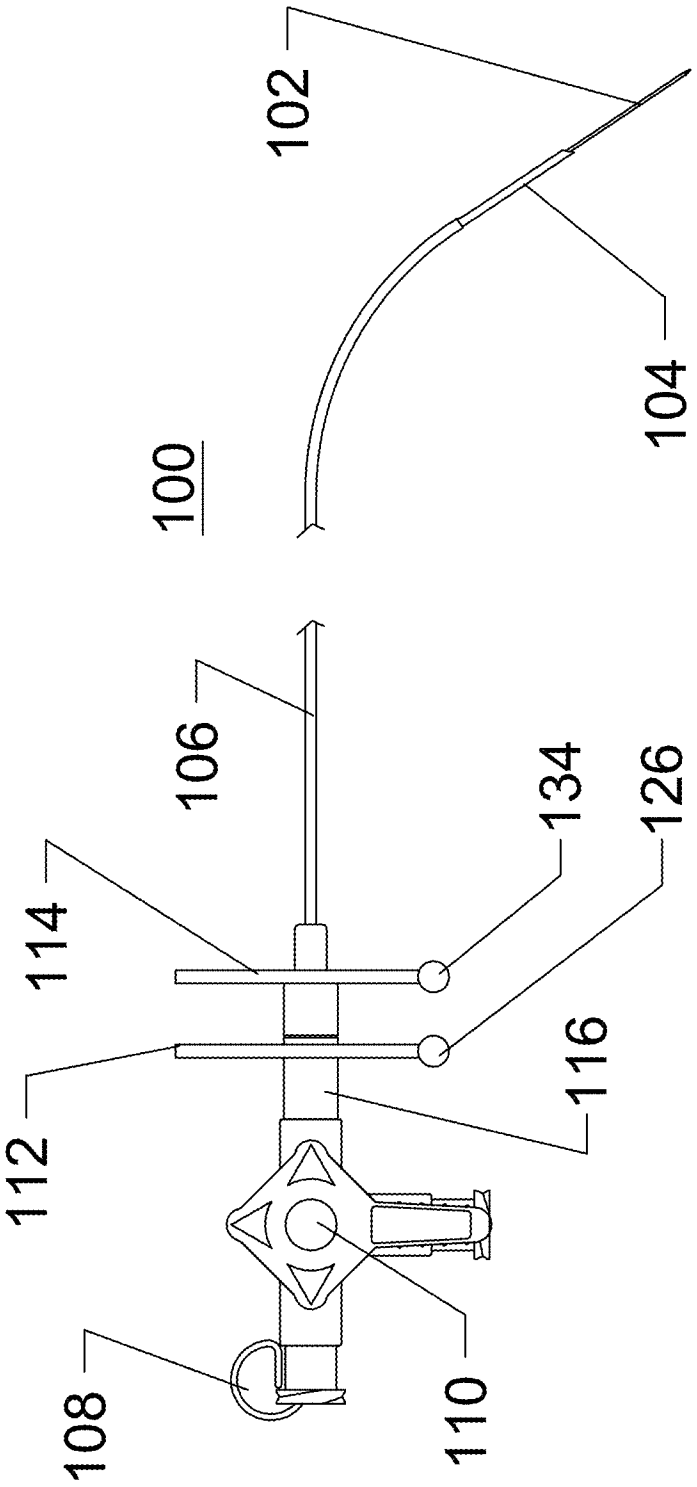

Fig. 3

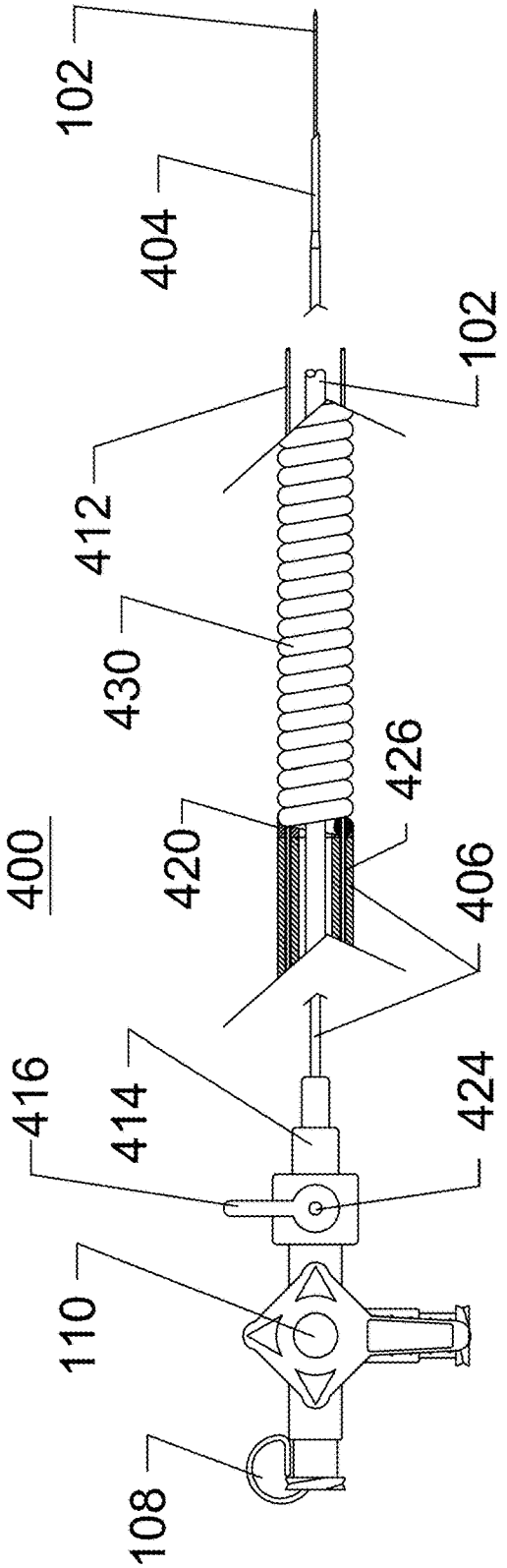

Fig. 4

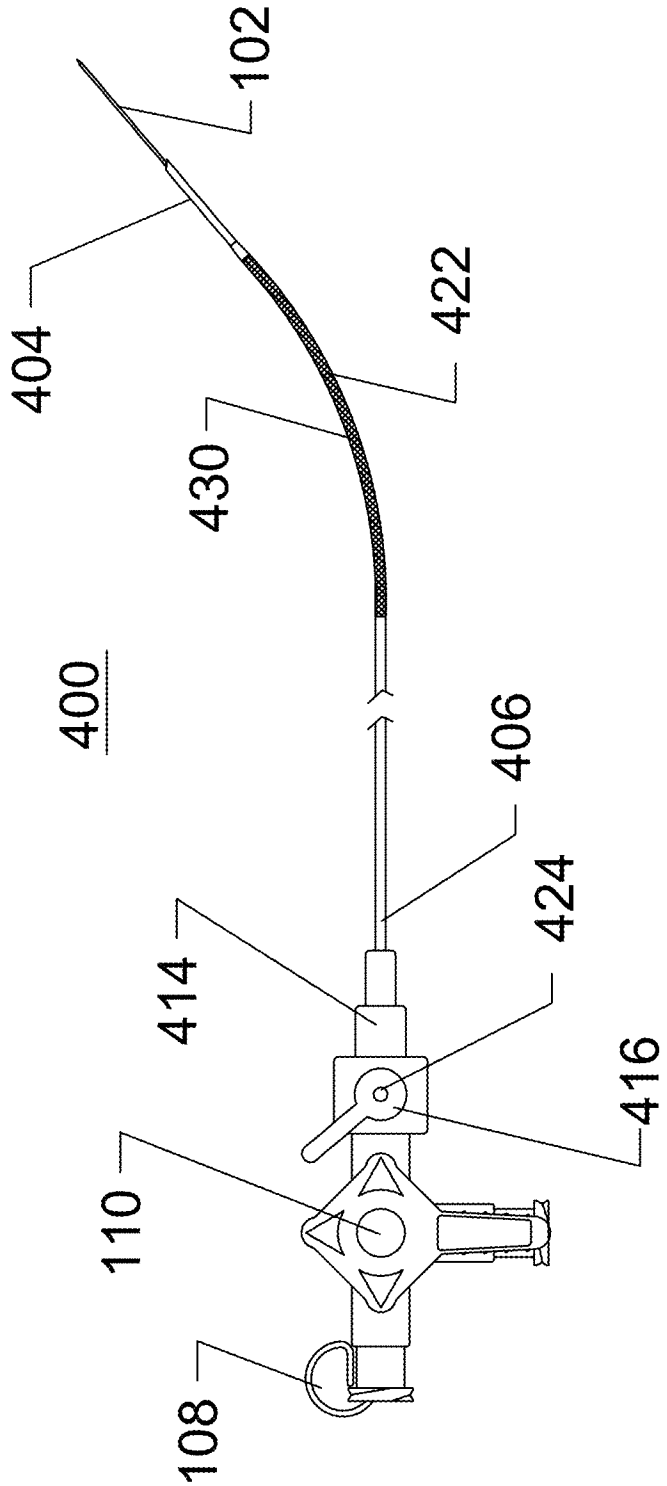

Fig. 5

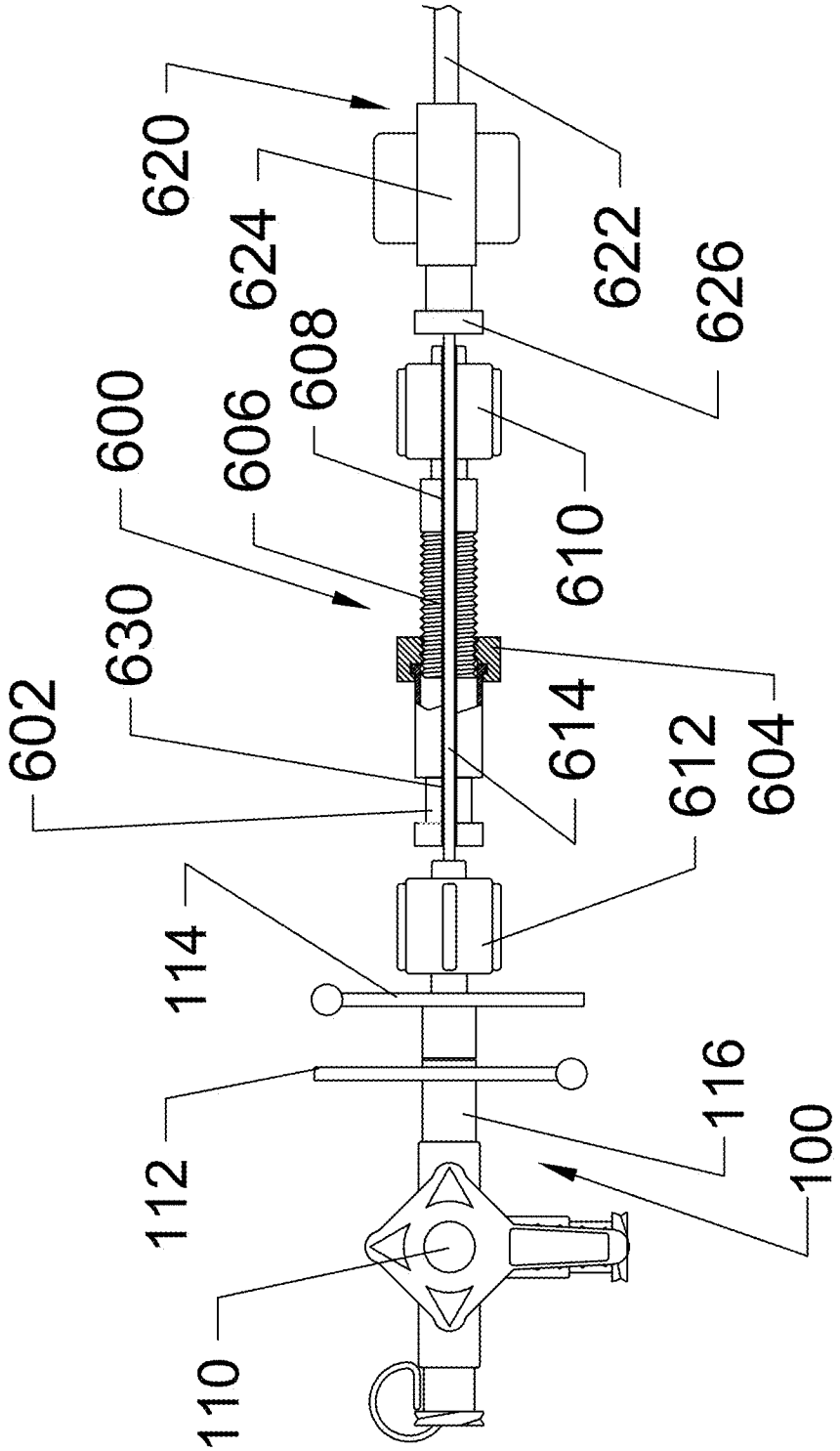
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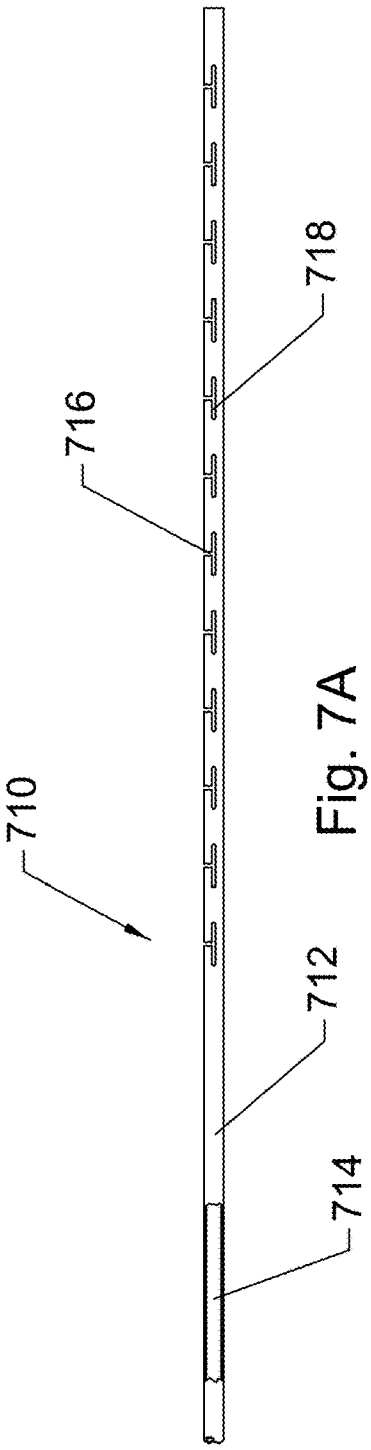
Fig. 6



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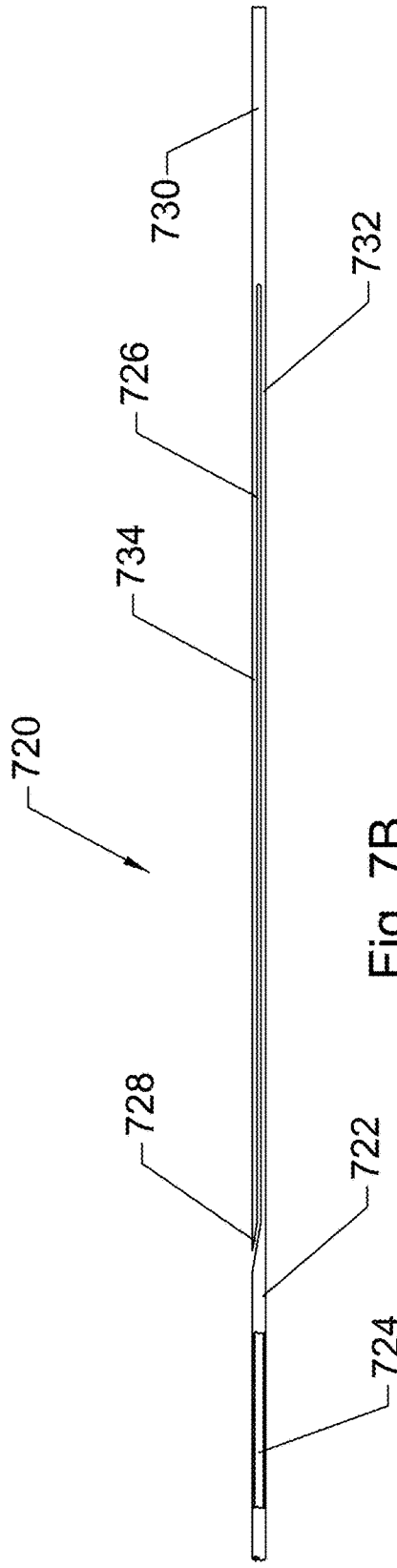

Fig. 7B

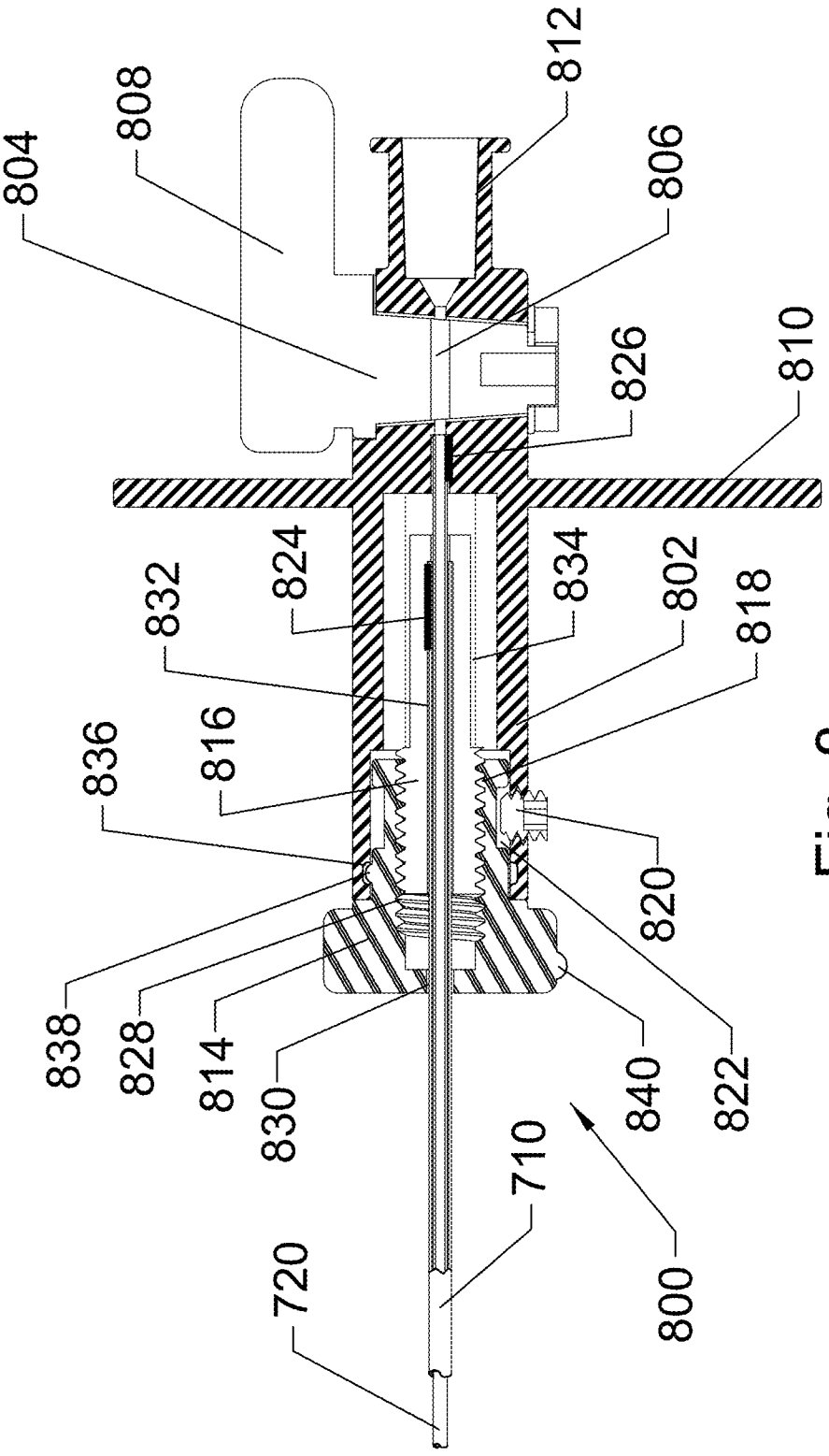
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Fig. 8

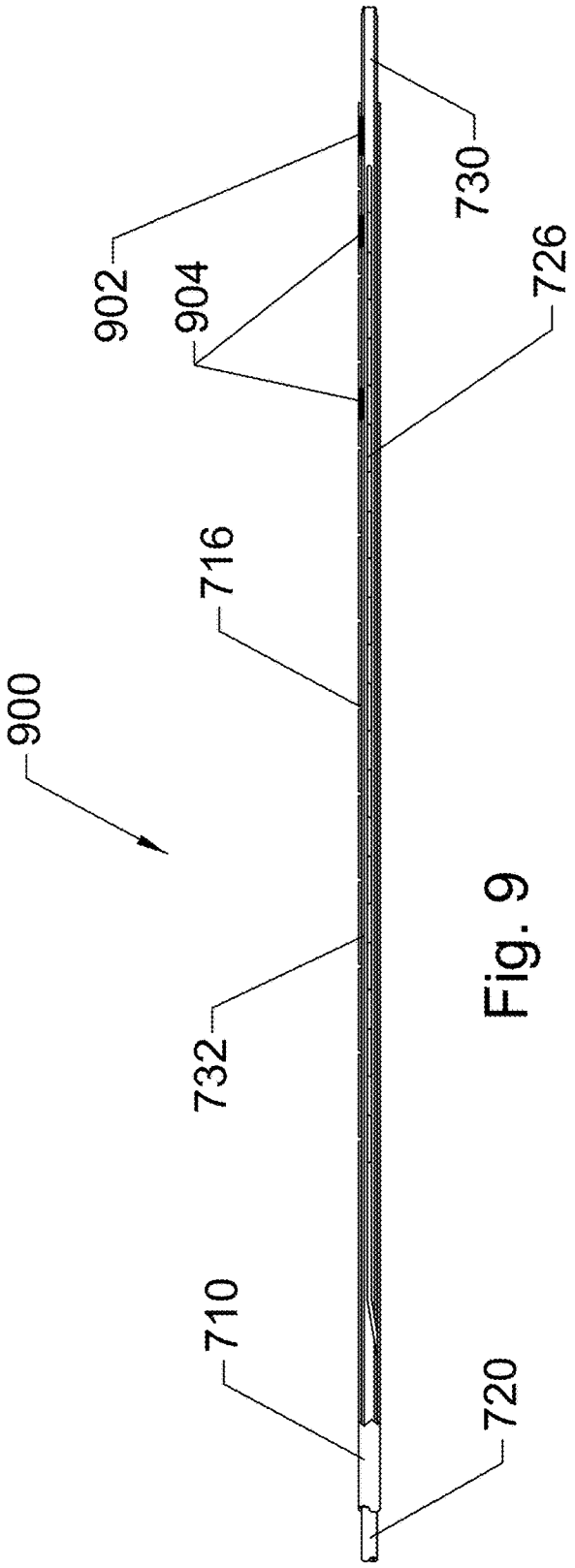


Fig. 9

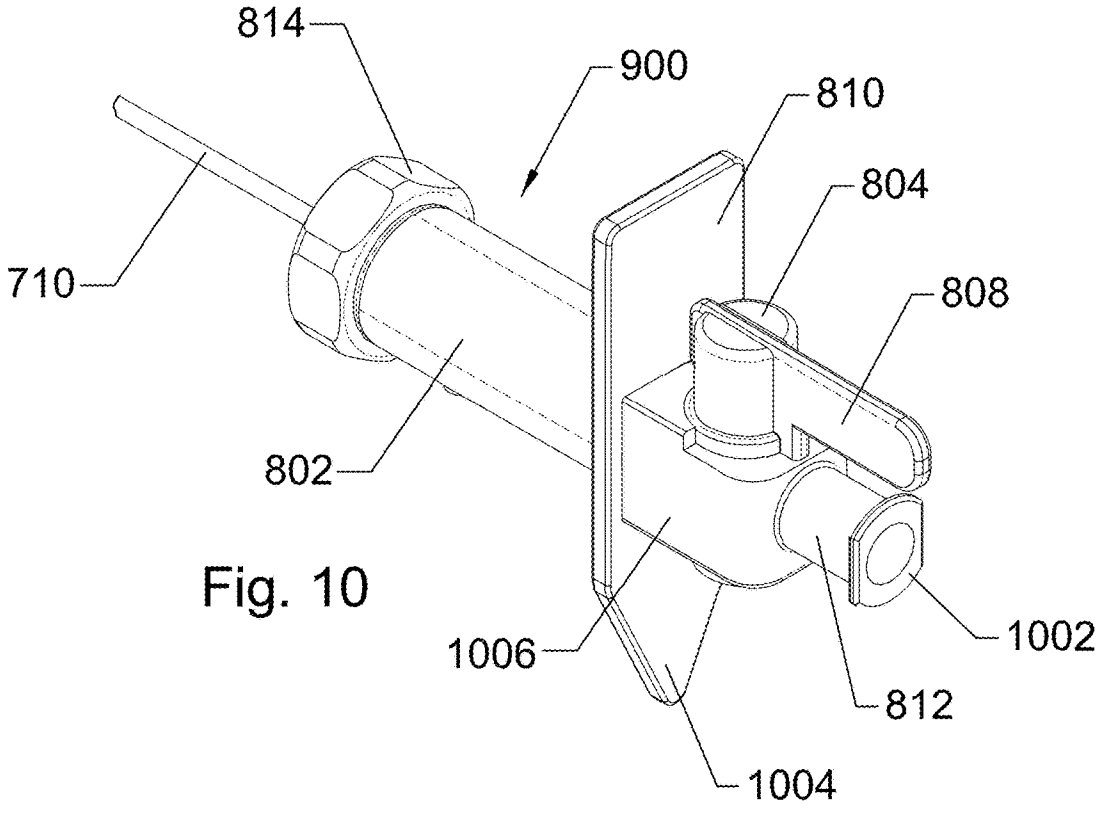
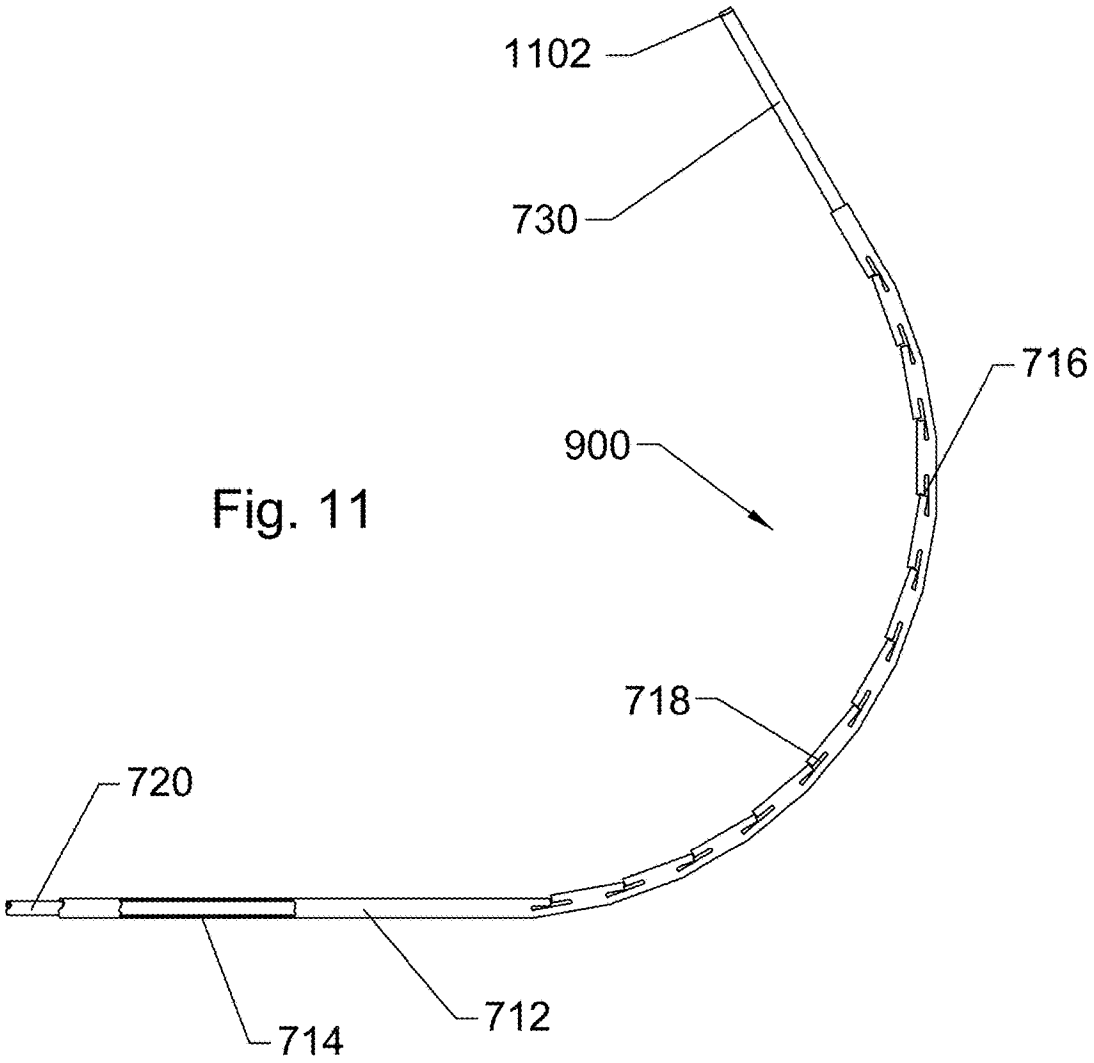


Fig. 10



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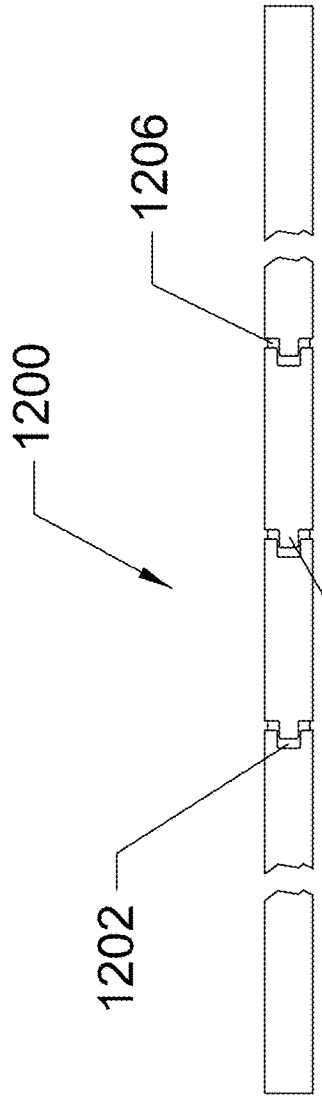


Fig. 12A

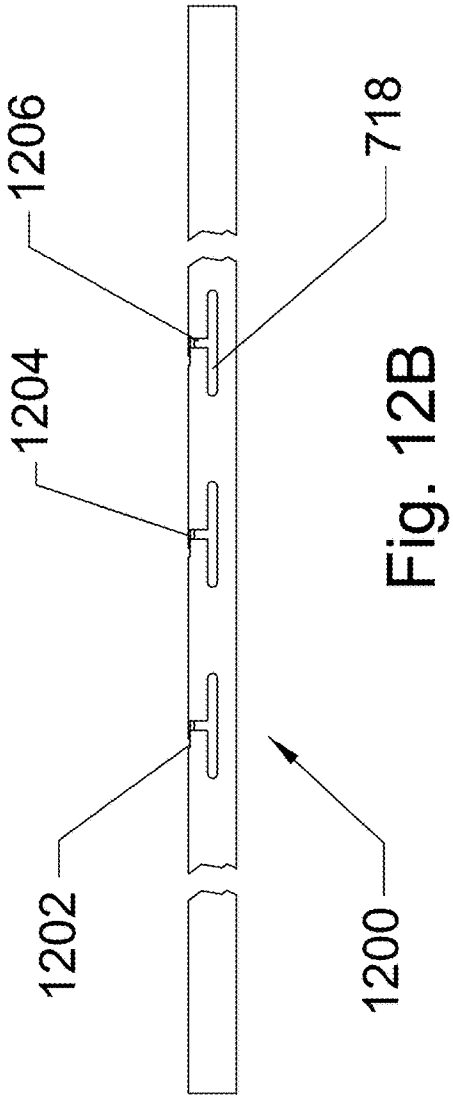
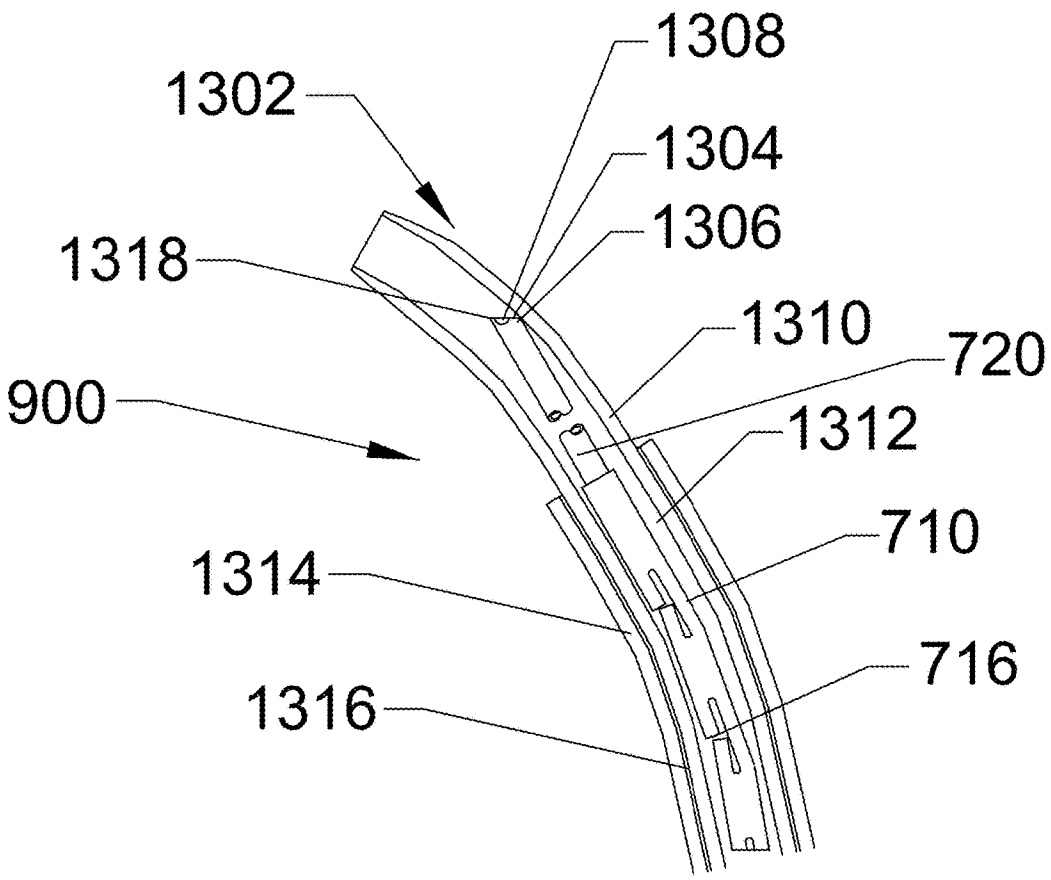


Fig. 12B



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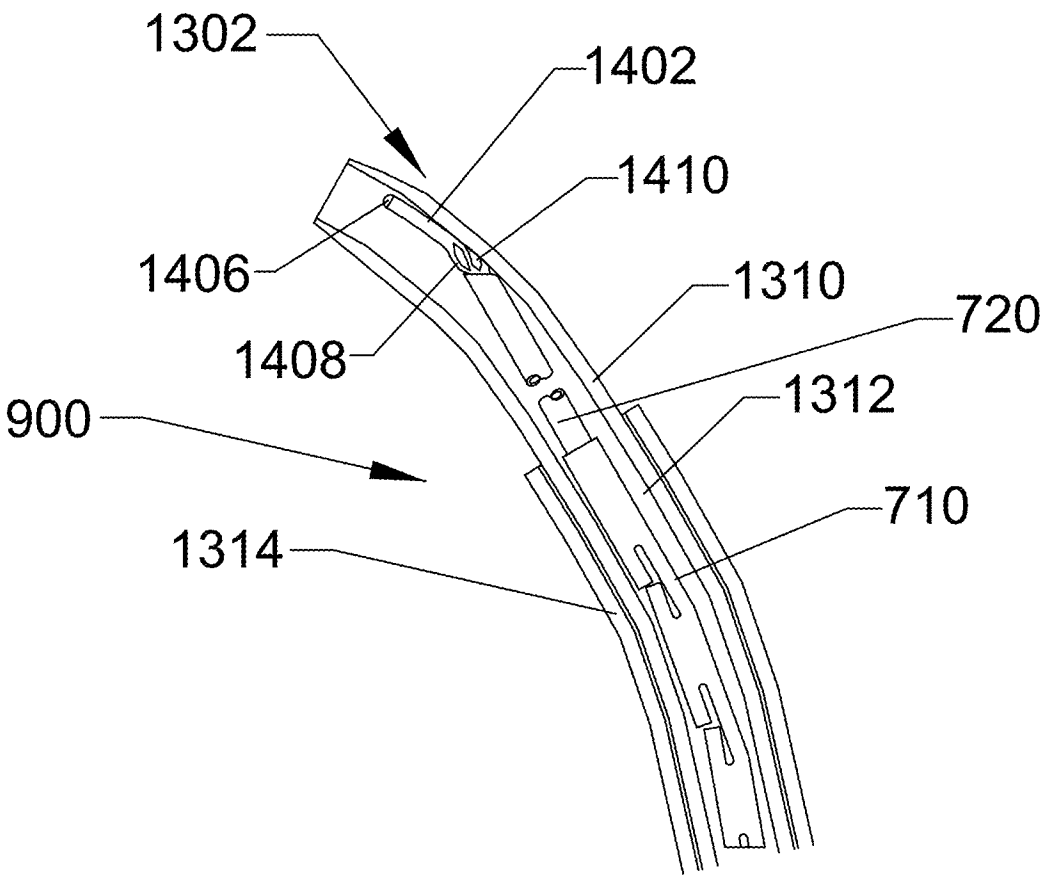

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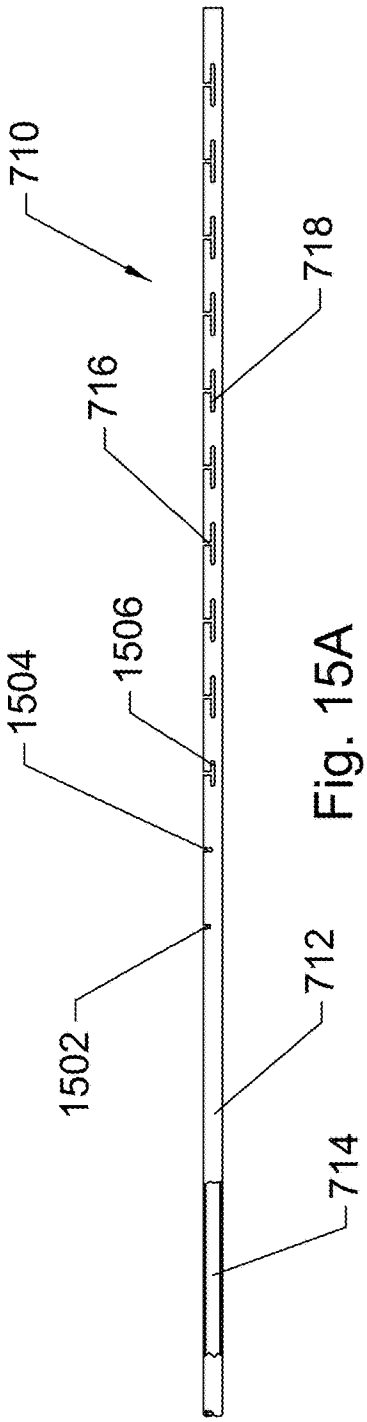


Fig. 15A

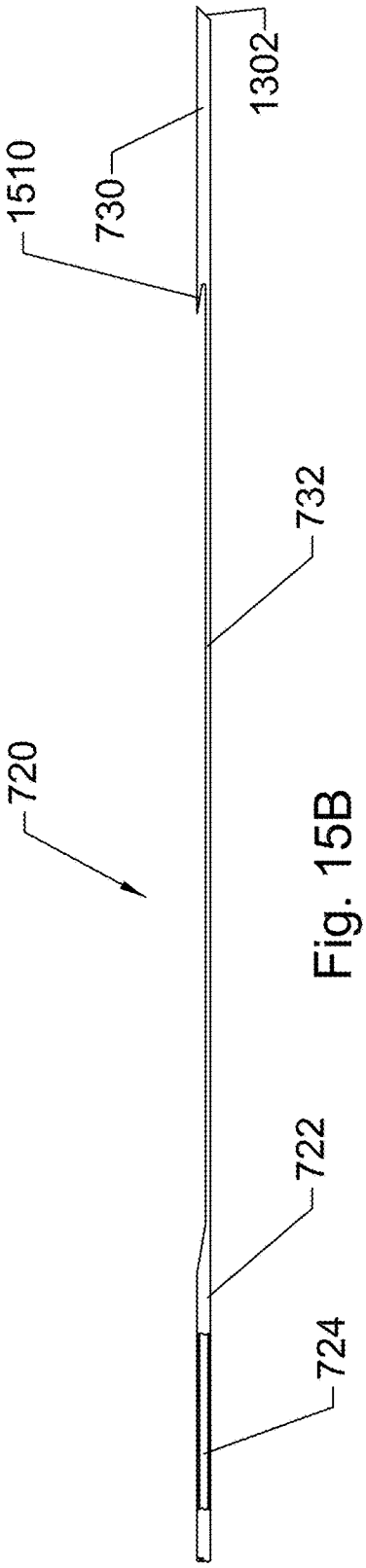


Fig. 15B

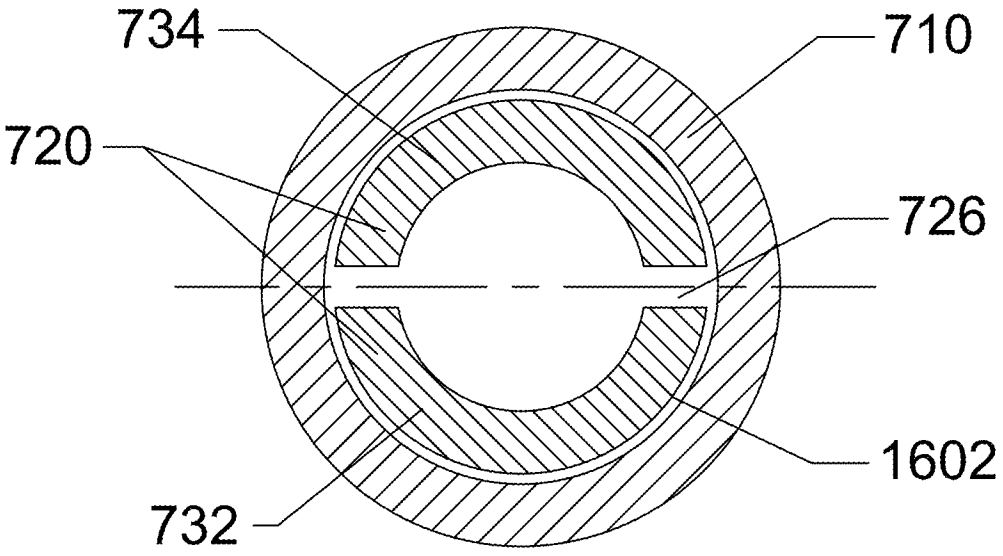


Fig. 16A

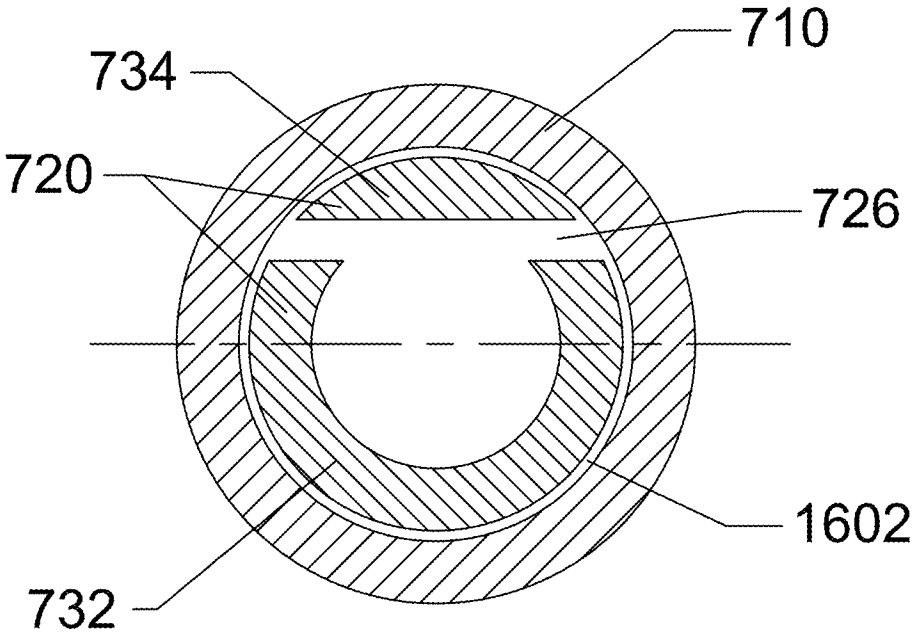


Fig. 16B

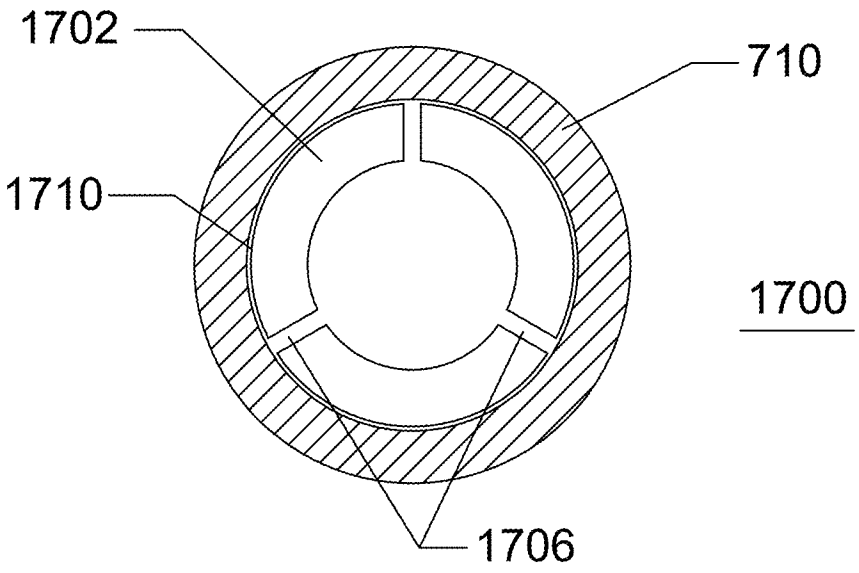


FIG. 17A

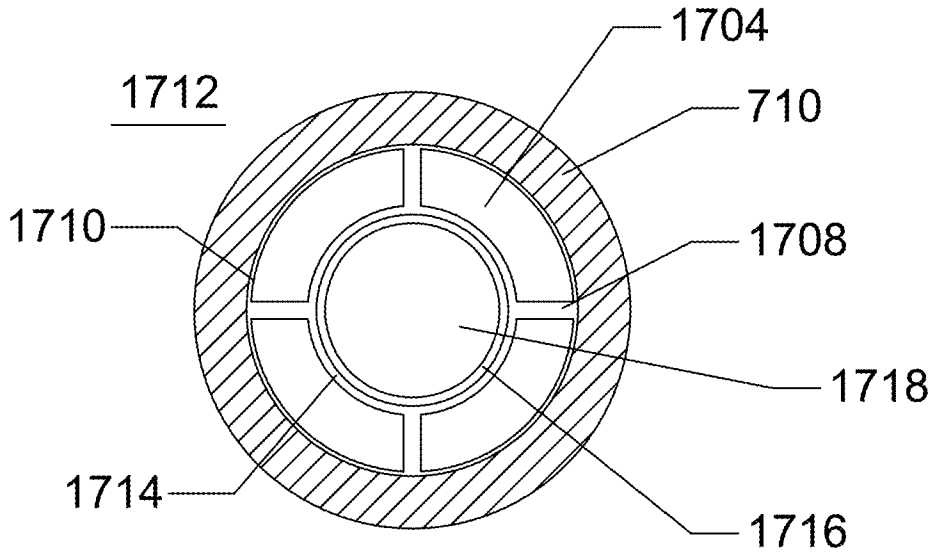


FIG. 17B

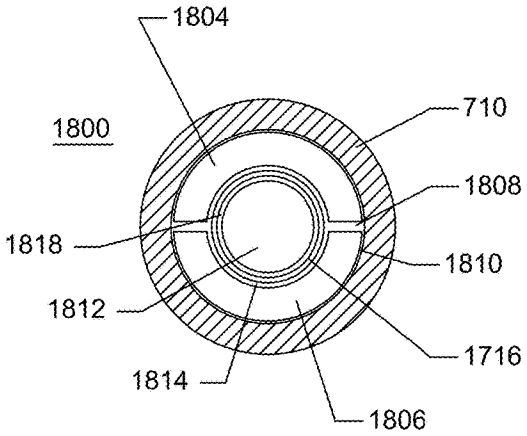


FIG. 18A

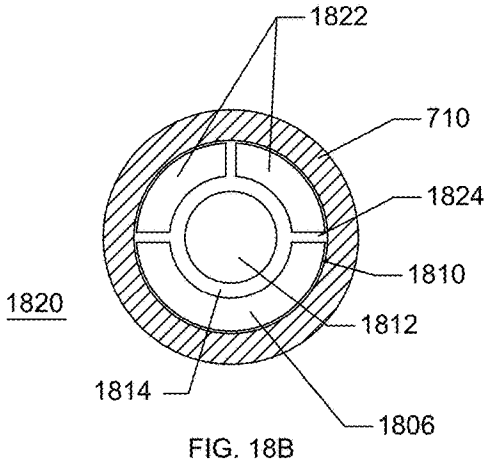


FIG. 18B

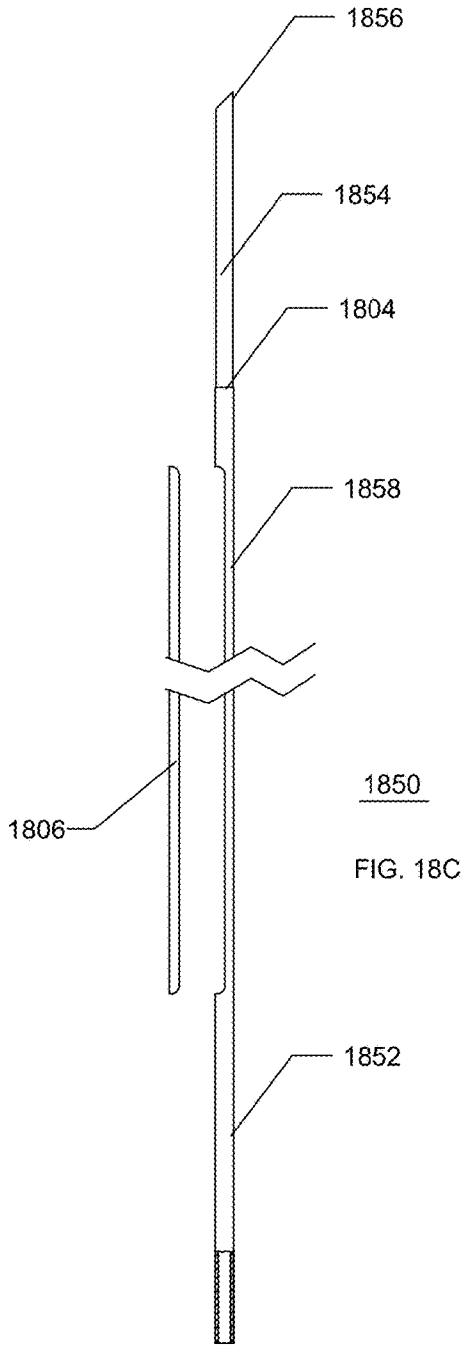


FIG. 18C

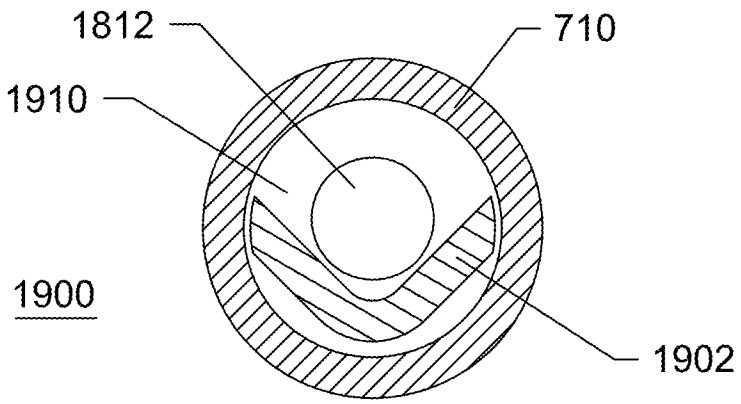


FIG. 19A

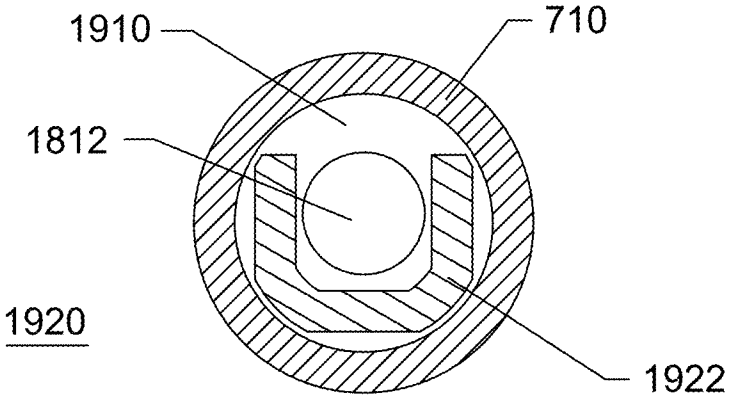
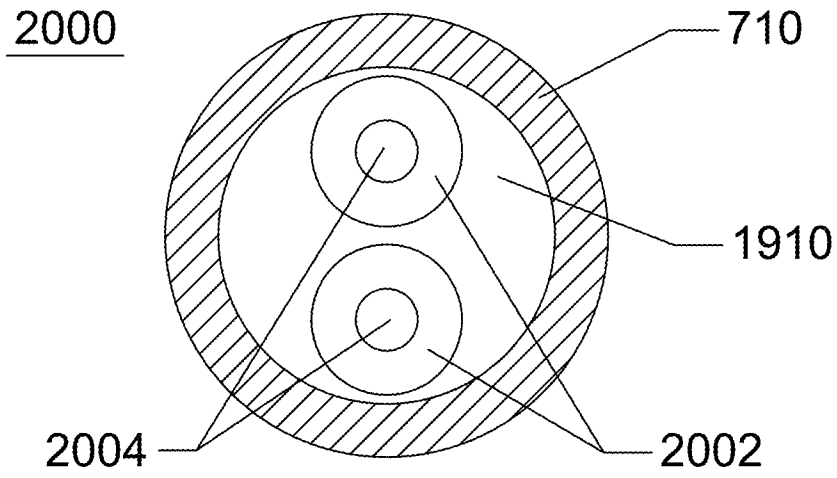


FIG. 19B



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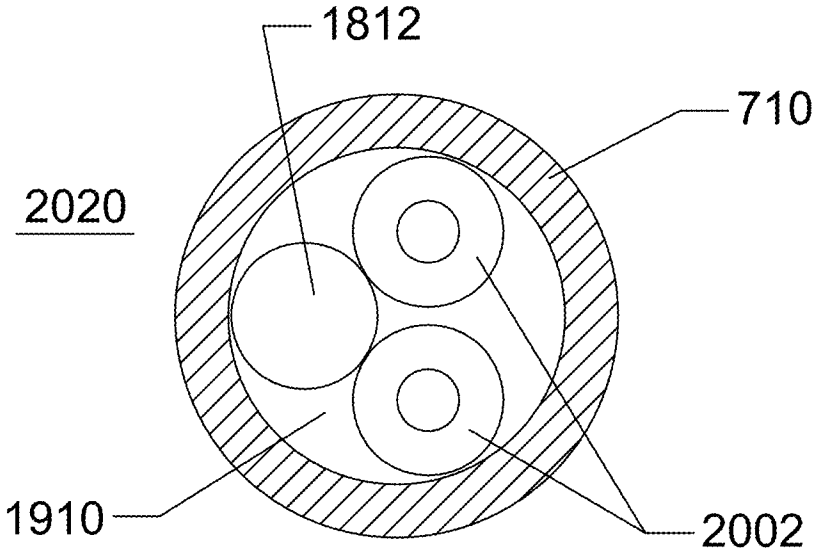


FIG. 20B

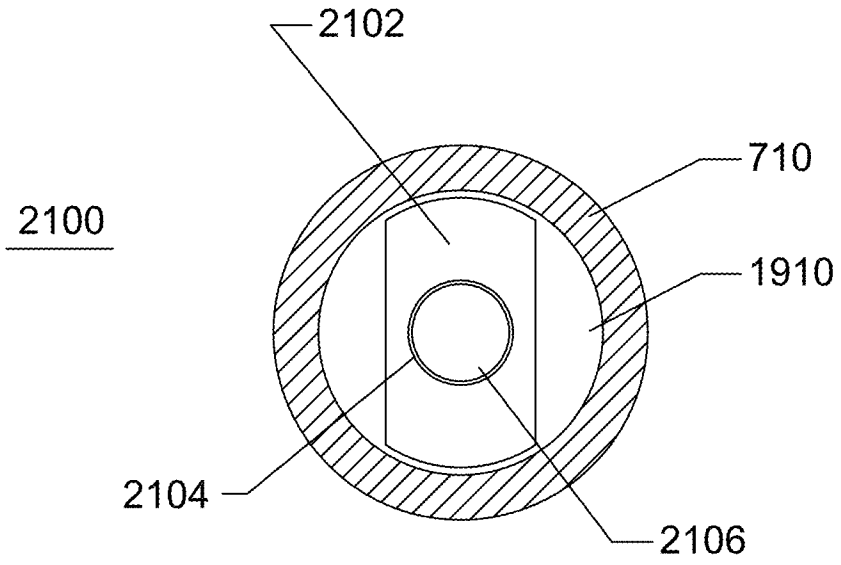
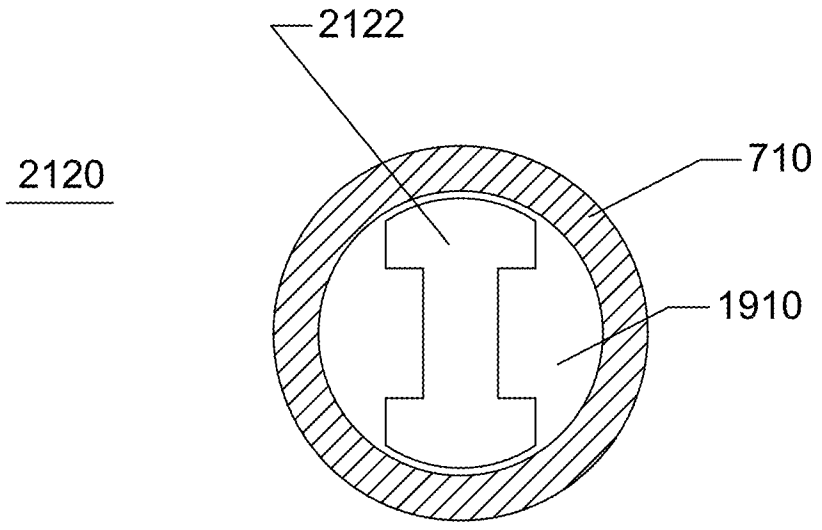


FIG. 21A



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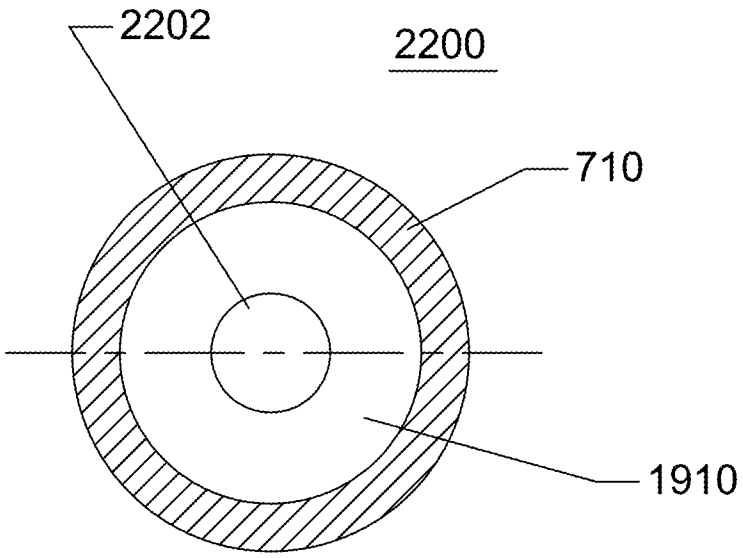
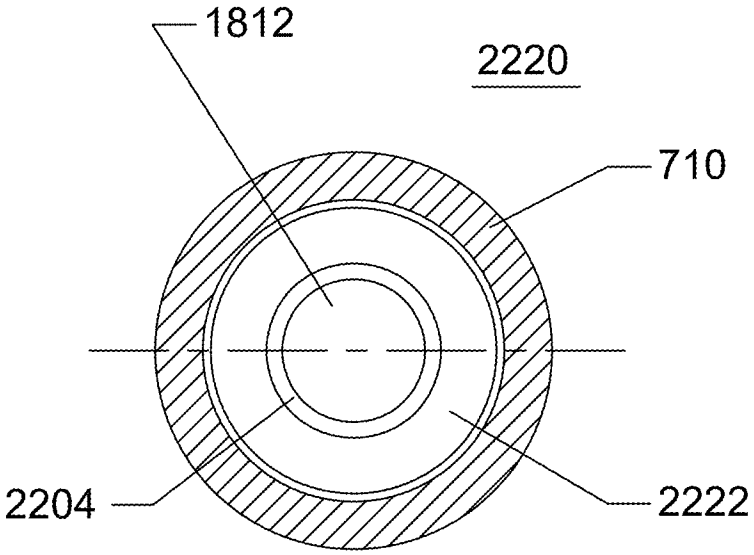


FIG. 22A



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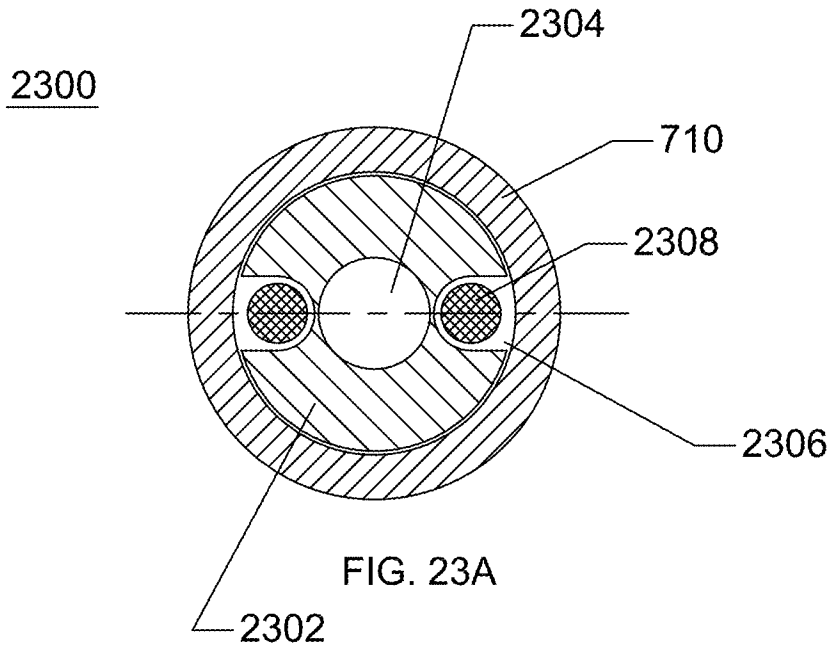

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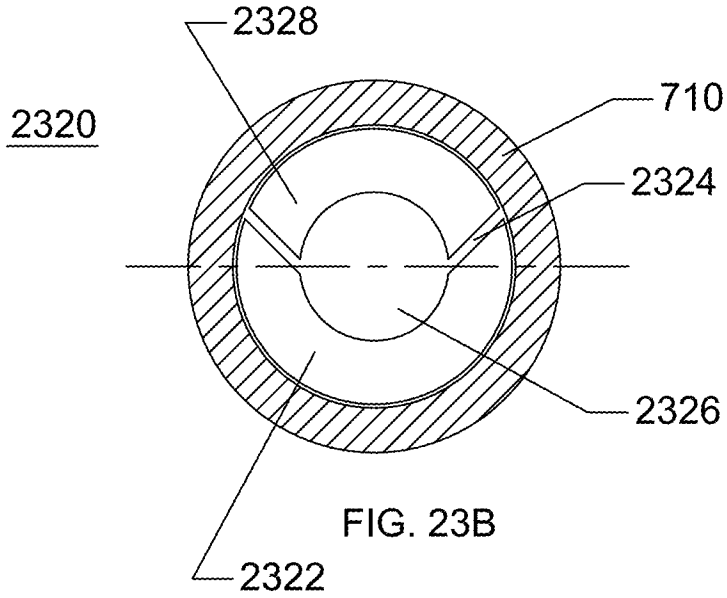
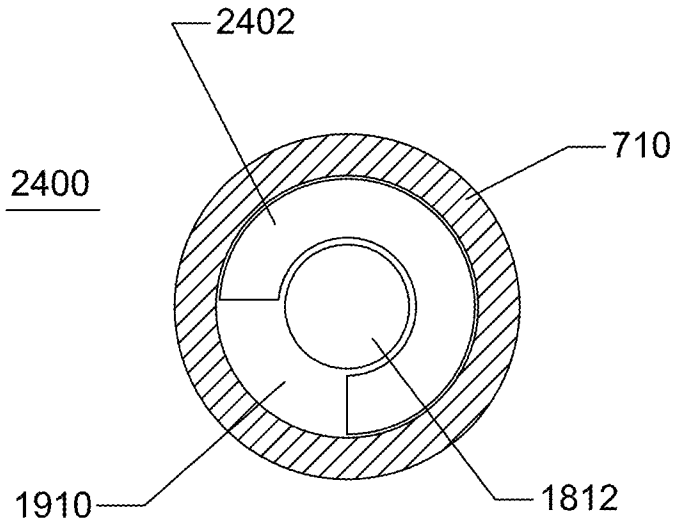


FIG. 23B



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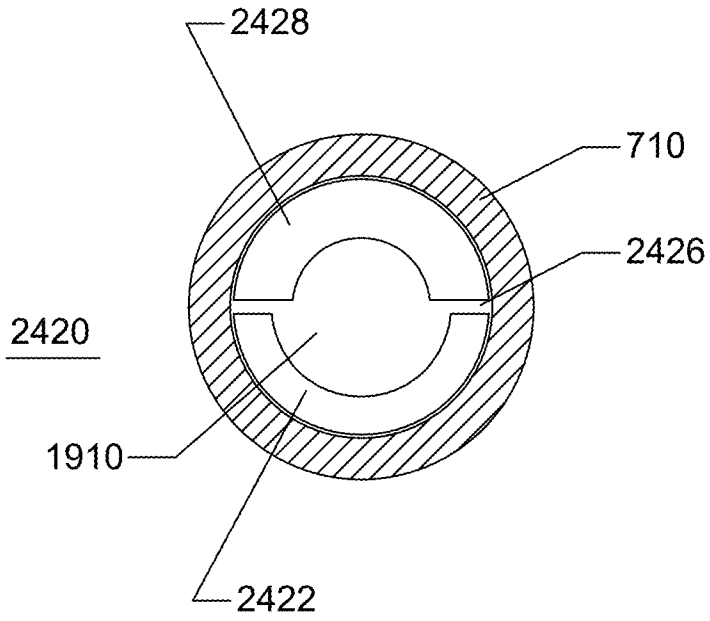

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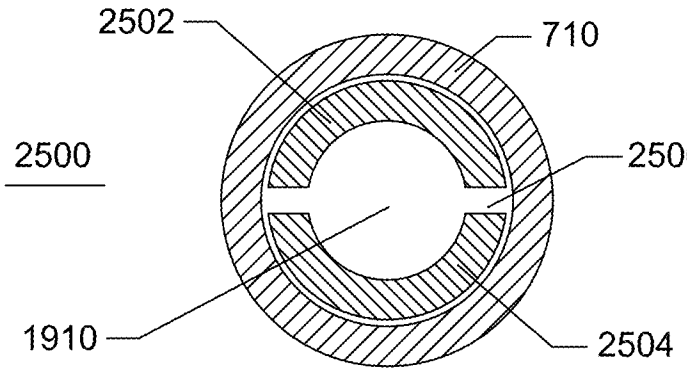
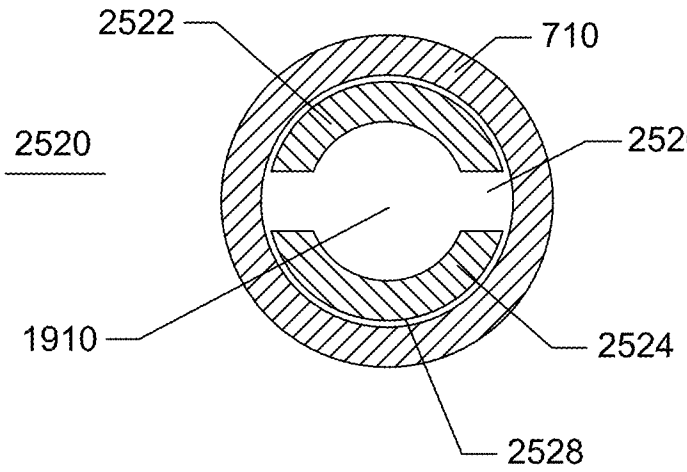


FIG. 25A



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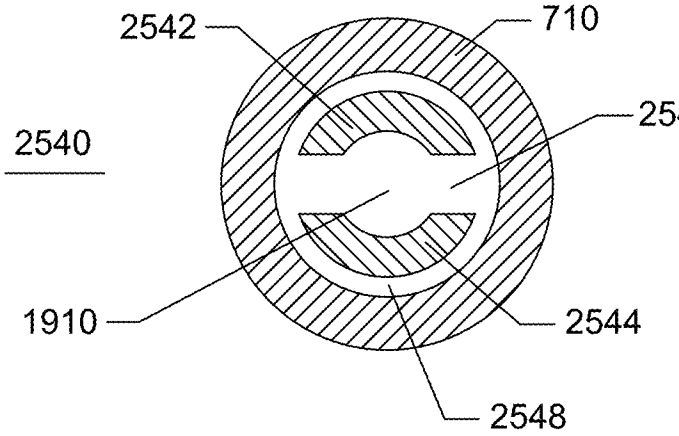

FIG. 25C

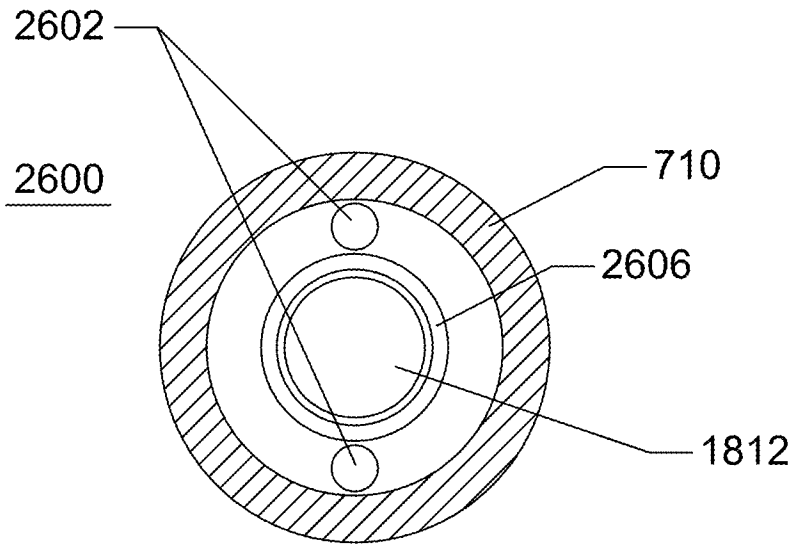

FIG. 26A

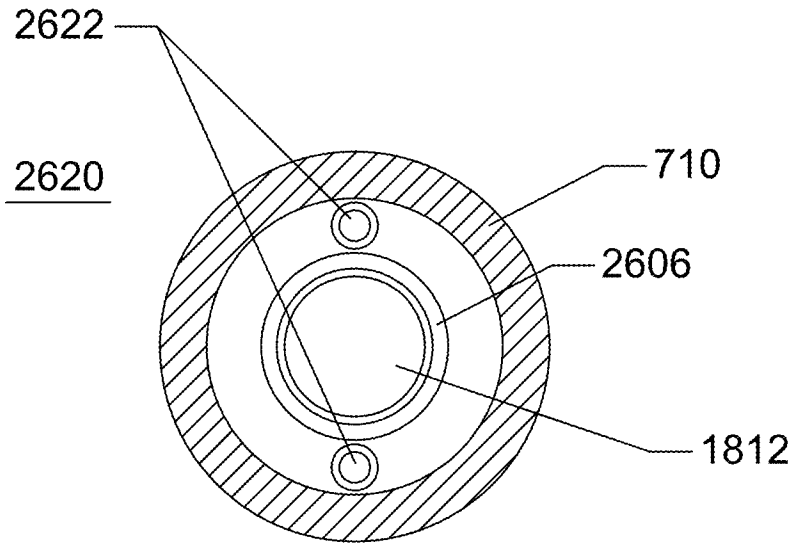

FIG. 26B

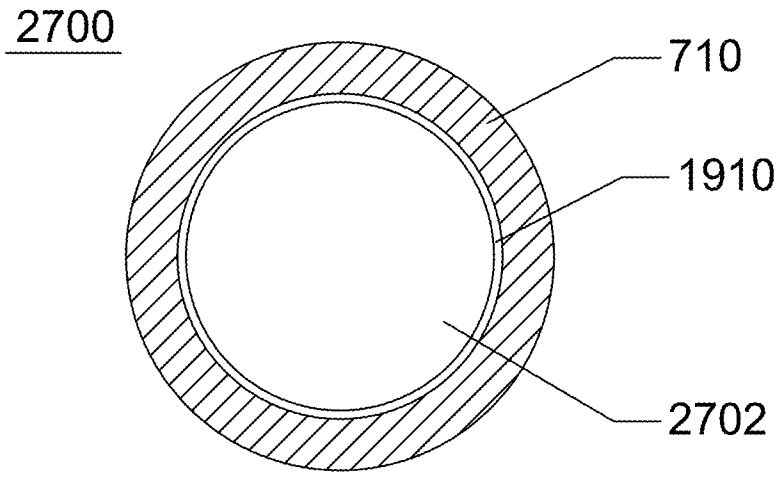

FIG. 27A

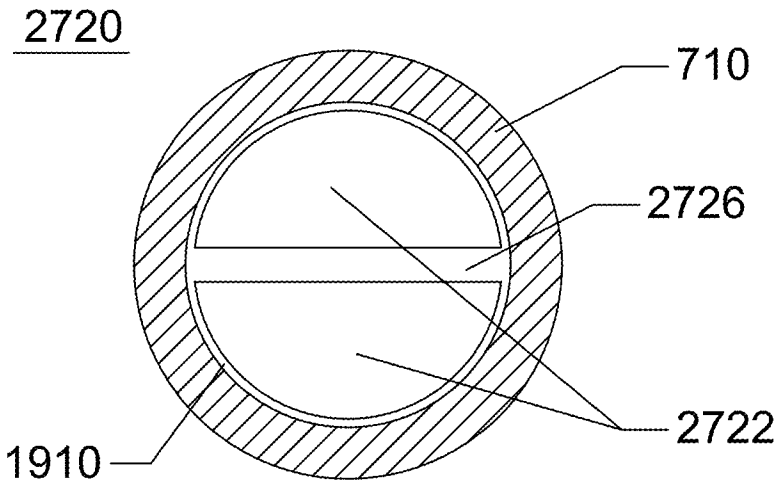

FIG. 27B

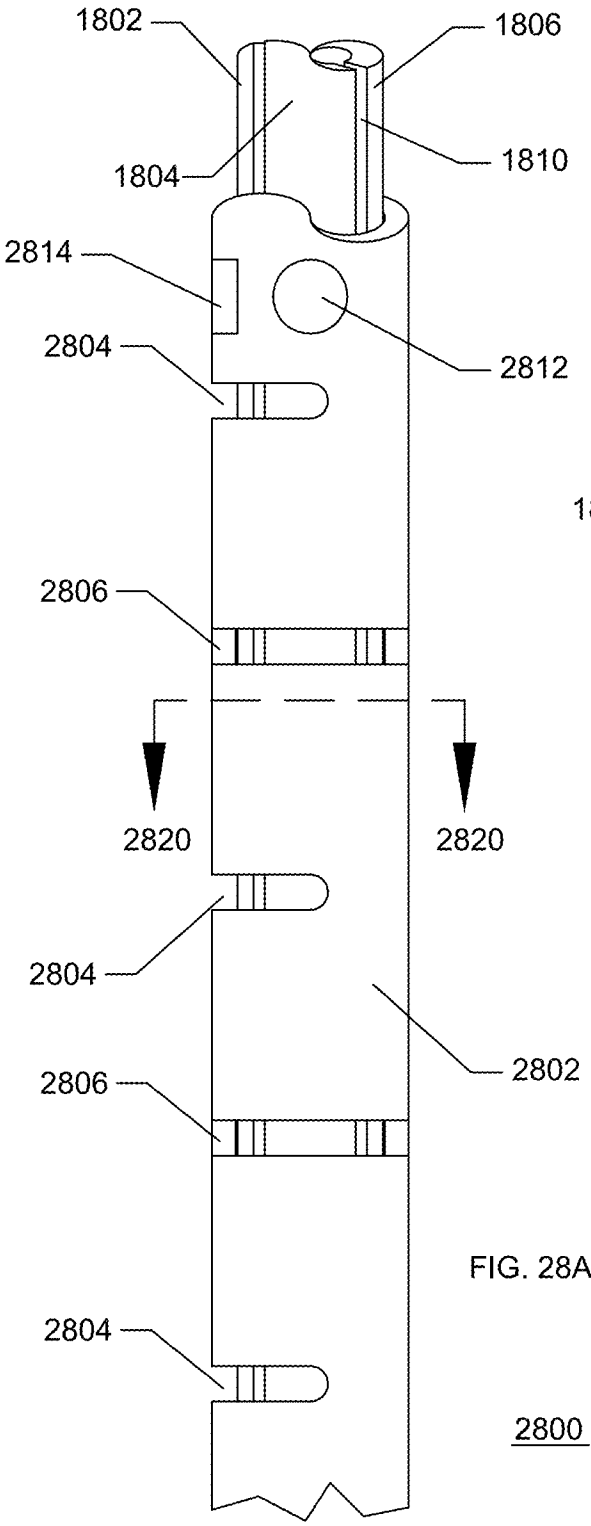

FIG. 28A

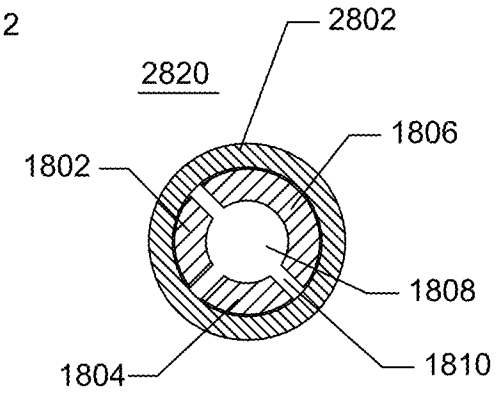

FIG. 28B

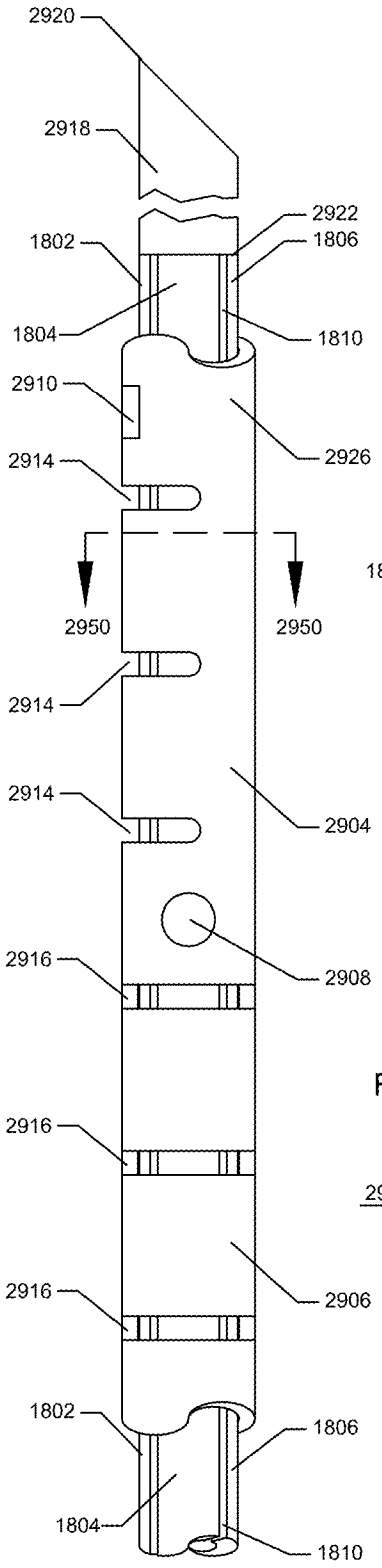

FIG. 29A

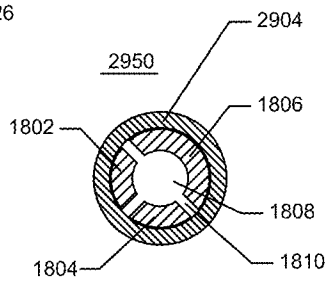

FIG. 29B

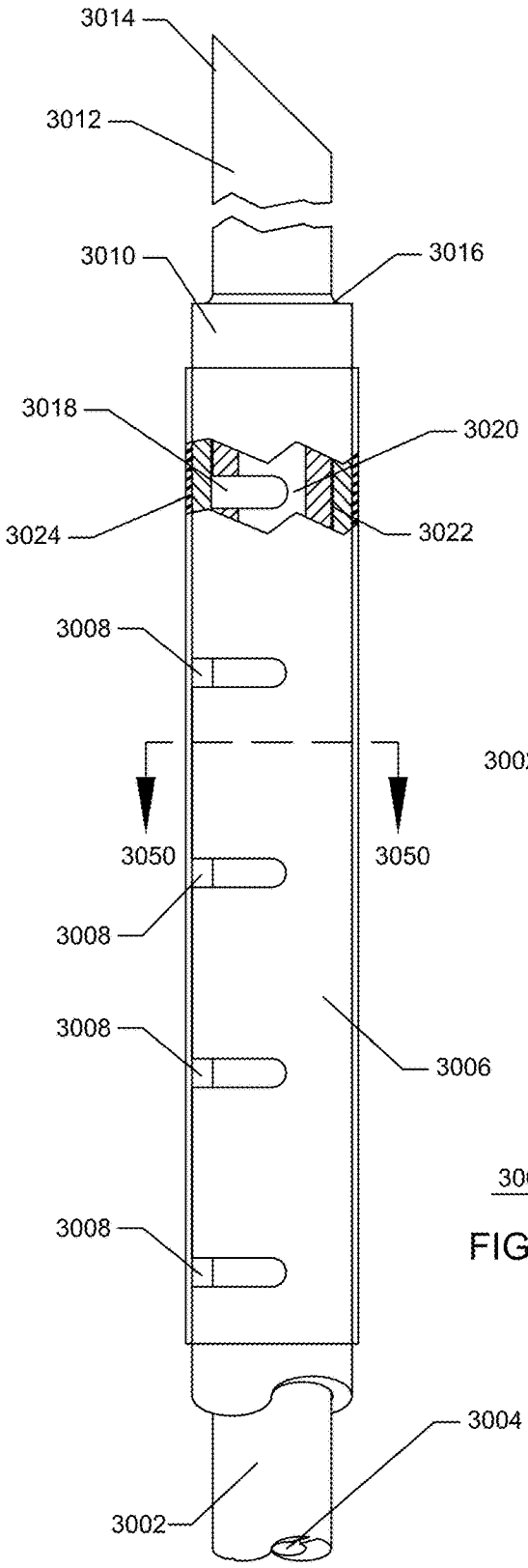

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FIG. 30A

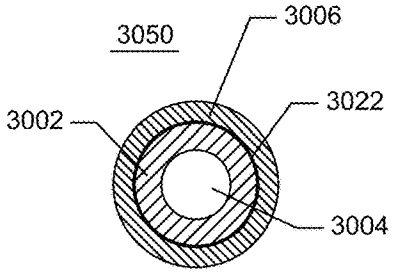

FIG. 30B

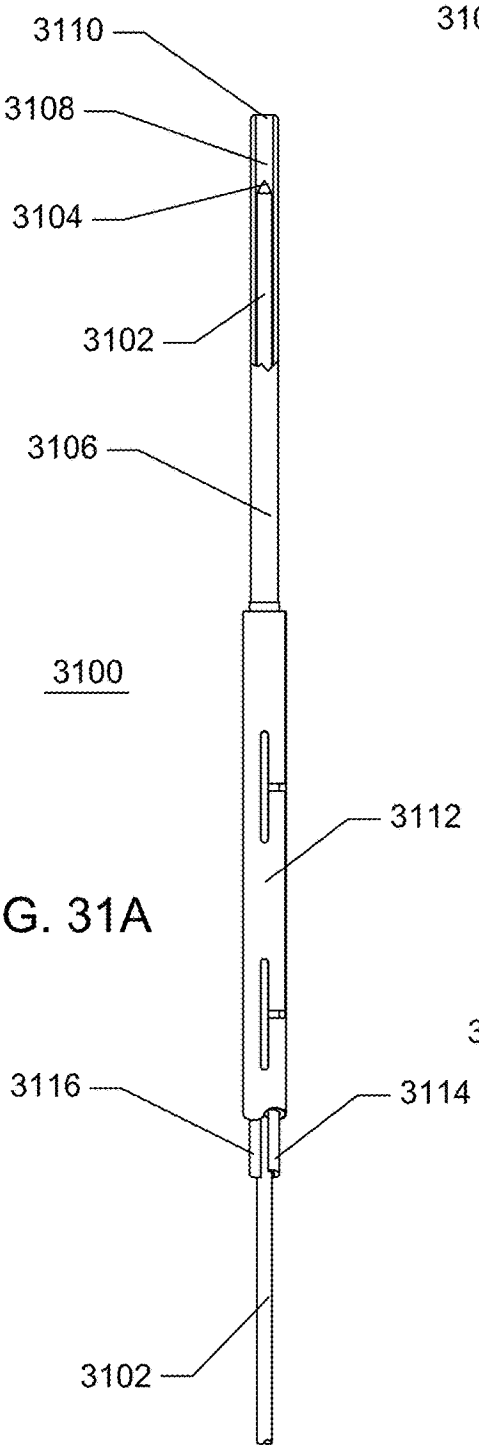

FIG. 31A

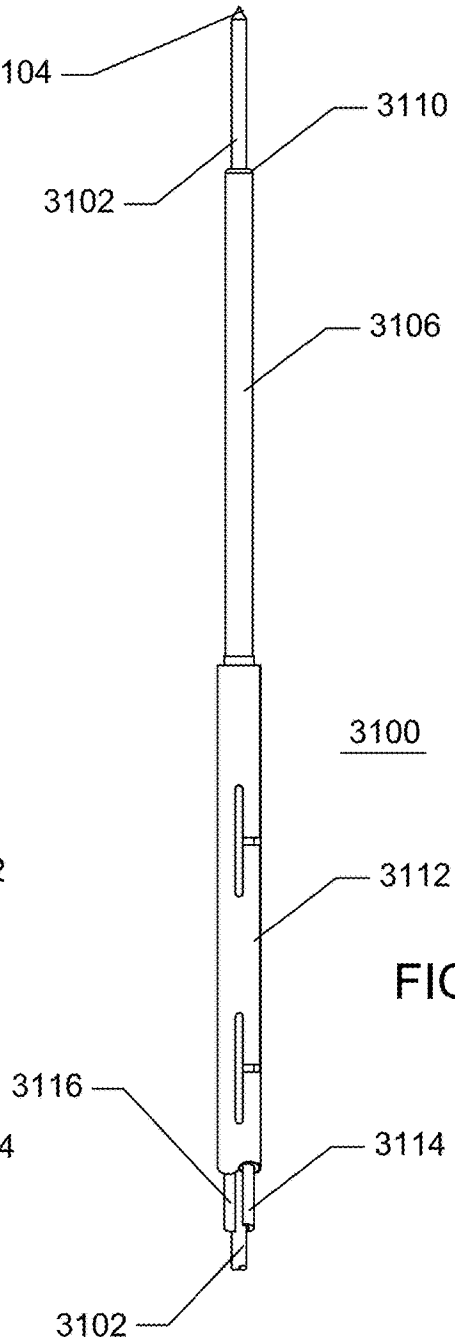

FIG. 31B

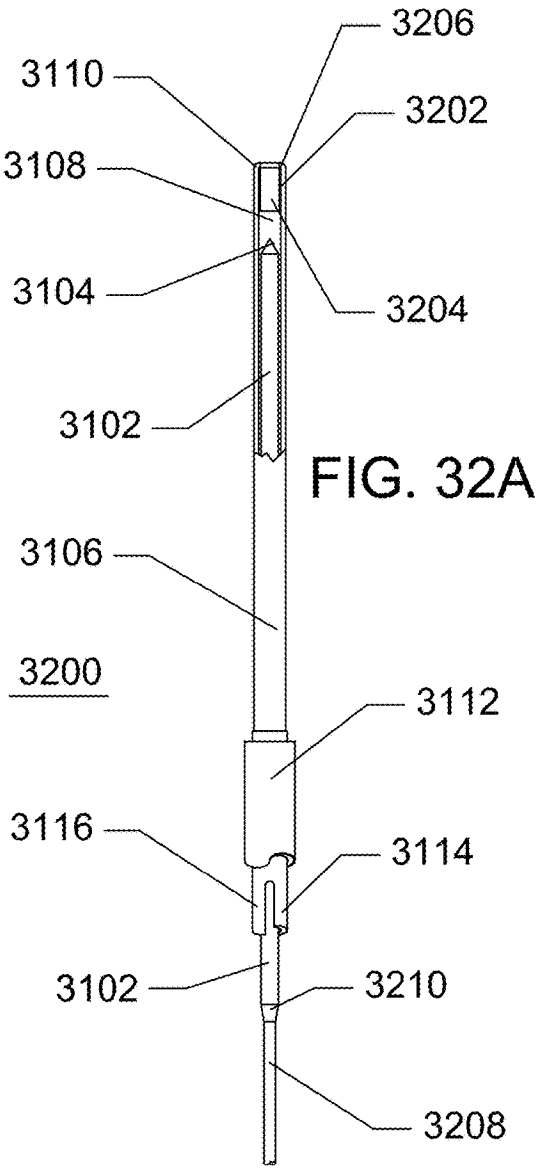

FIG. 32A

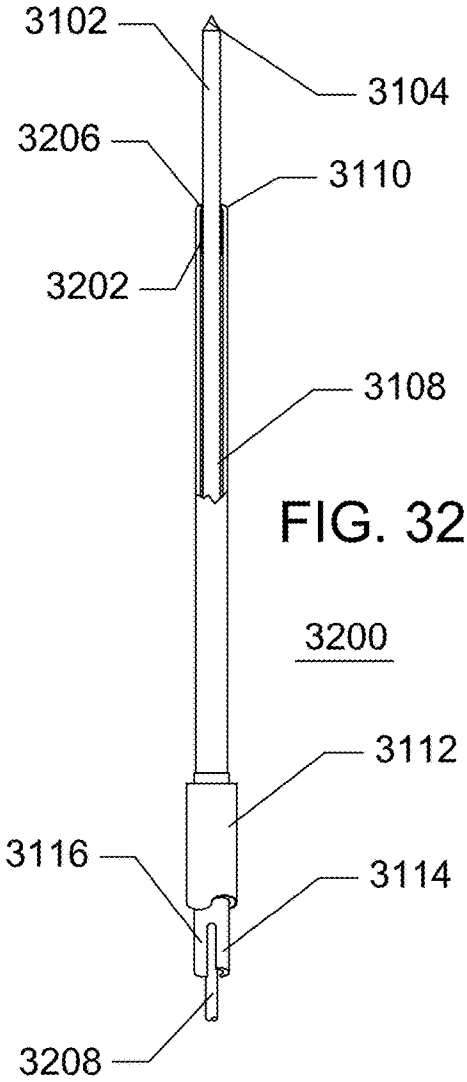

FIG. 32B

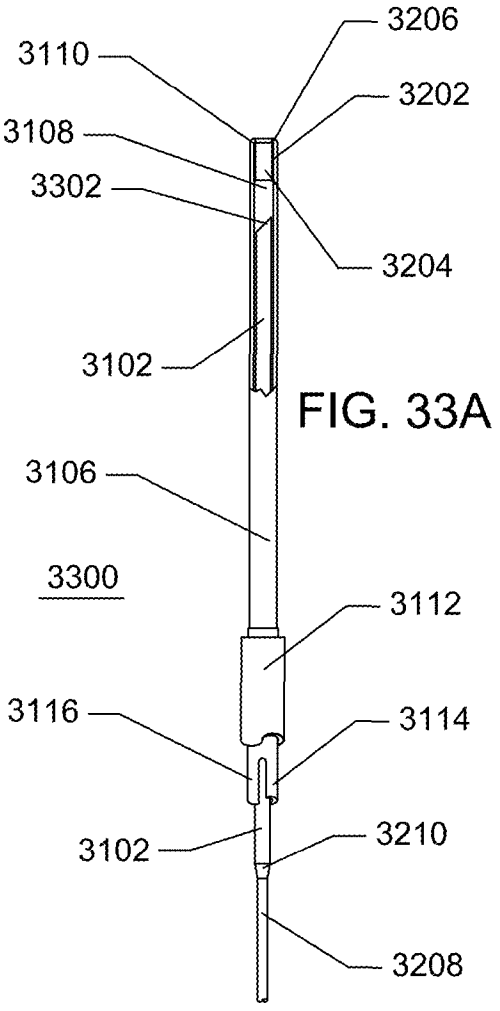

FIG. 33A

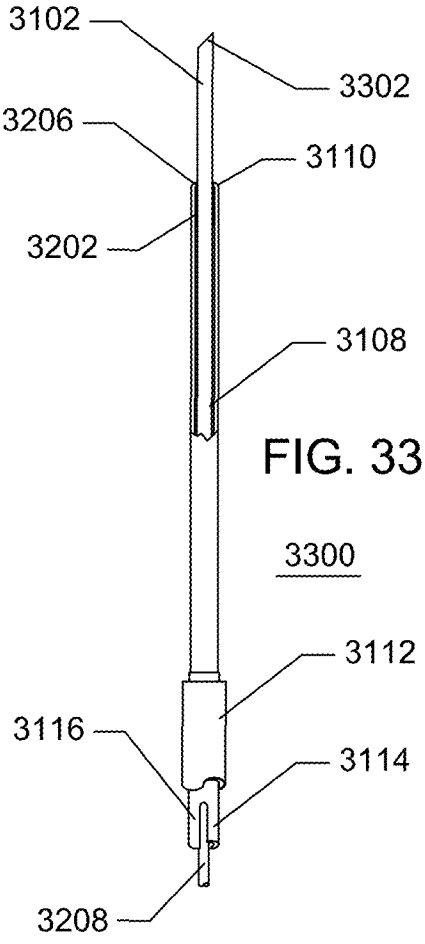

FIG. 33B

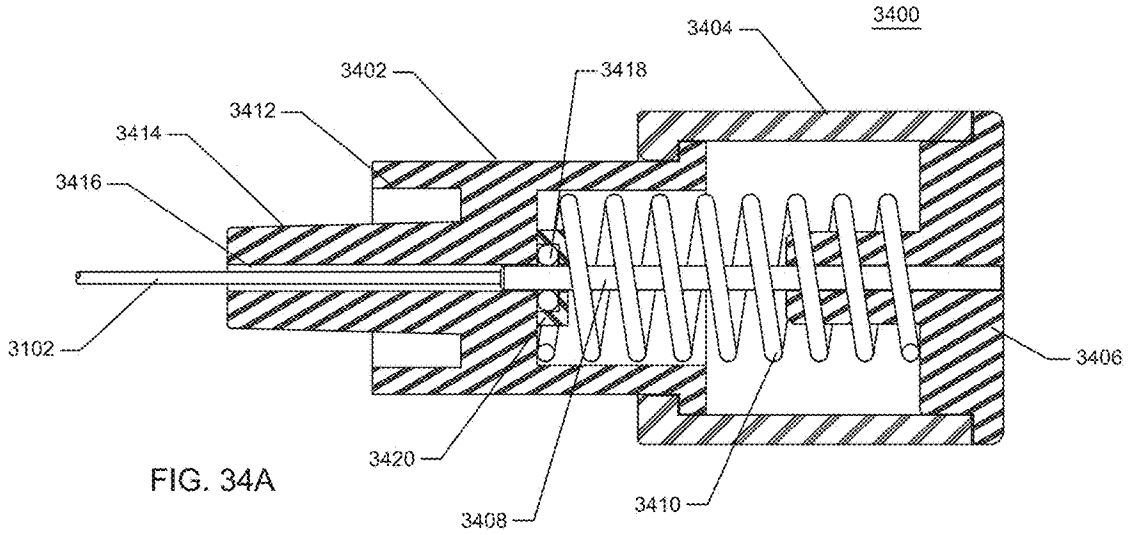

FIG. 34A

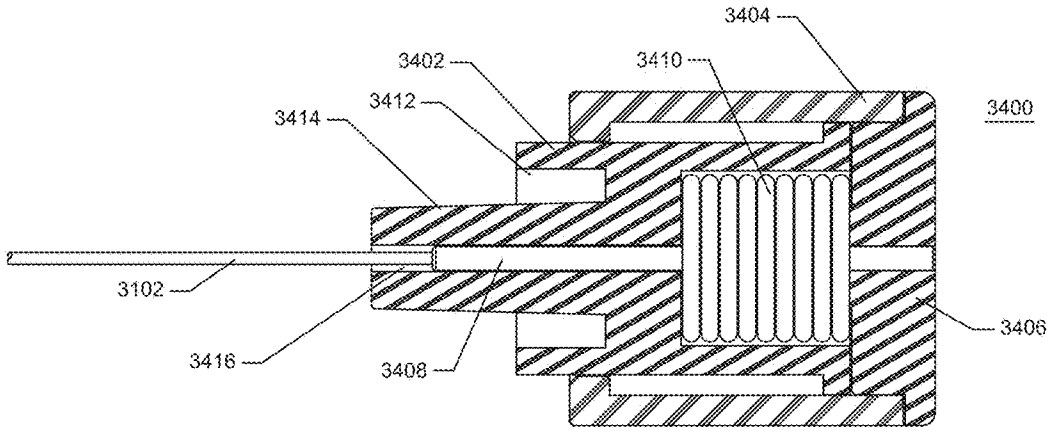

FIG. 34B

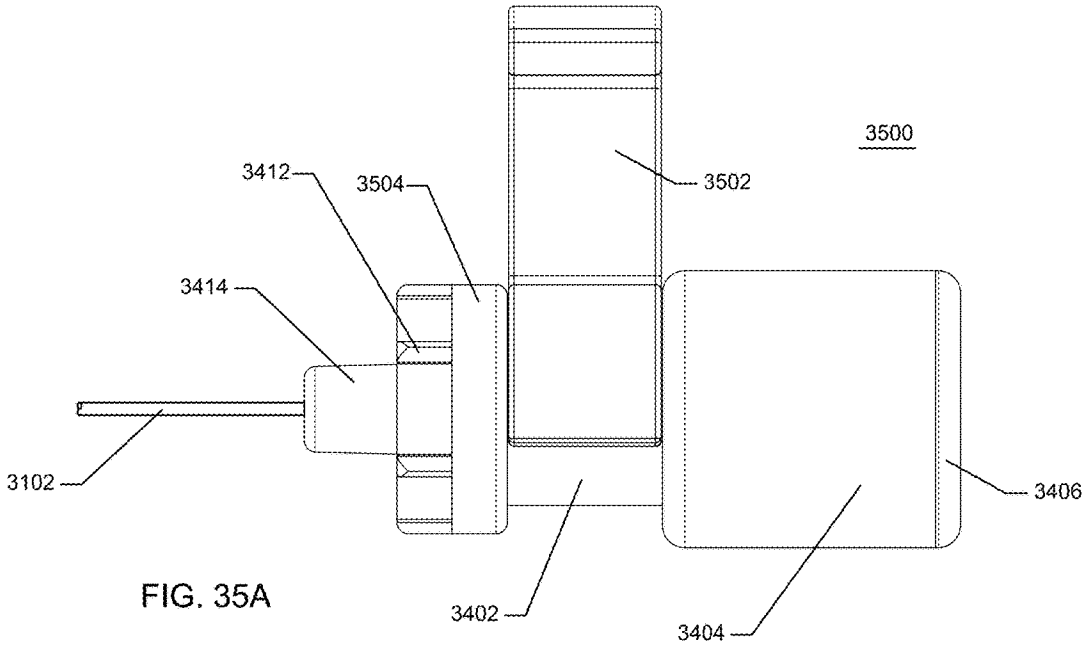

FIG. 35A

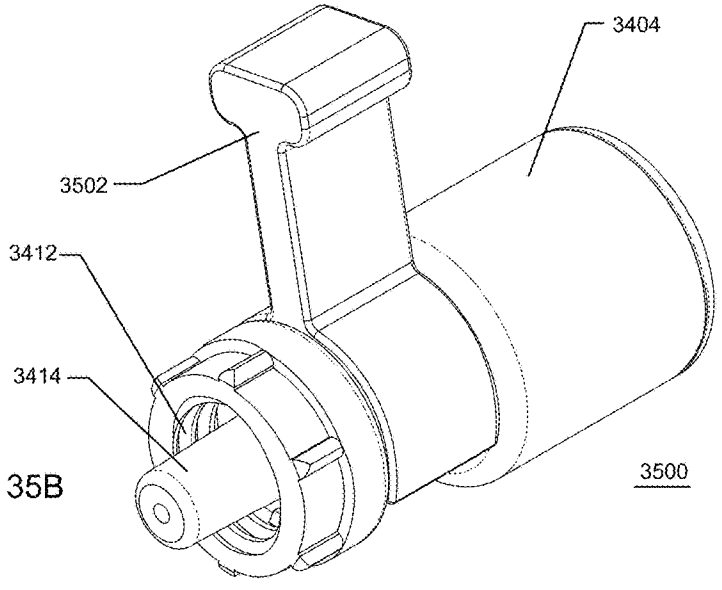

FIG. 35B

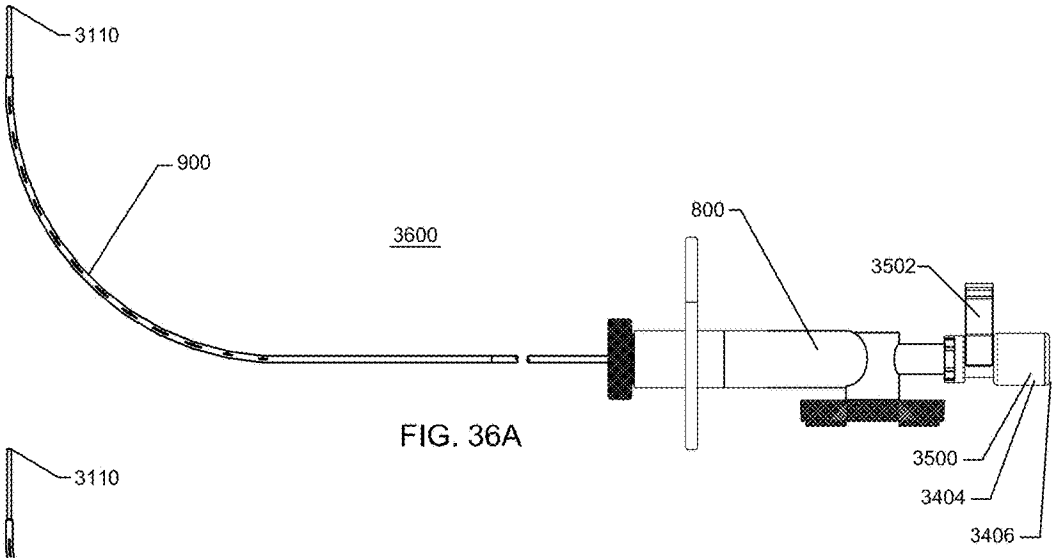

FIG. 36A

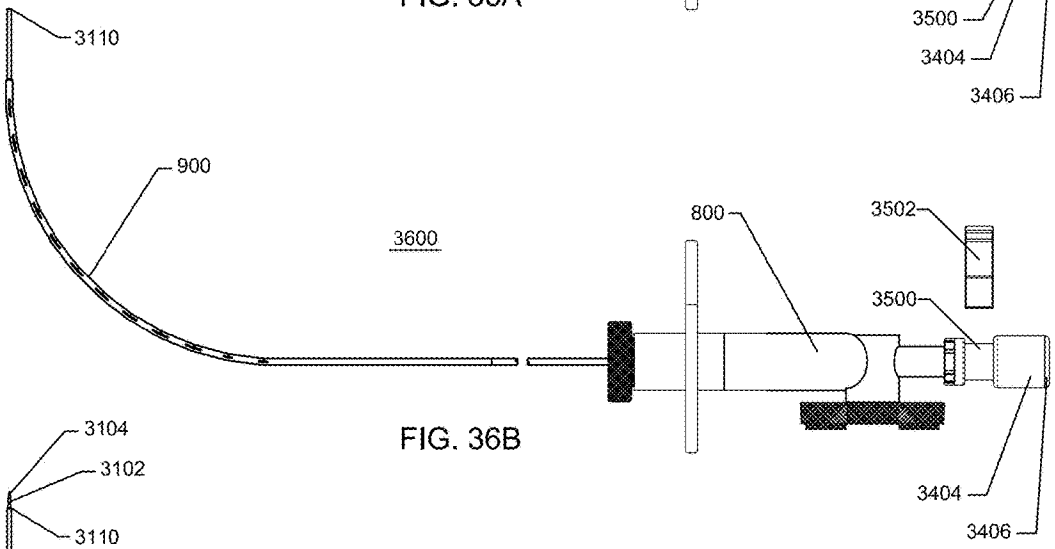

FIG. 36B

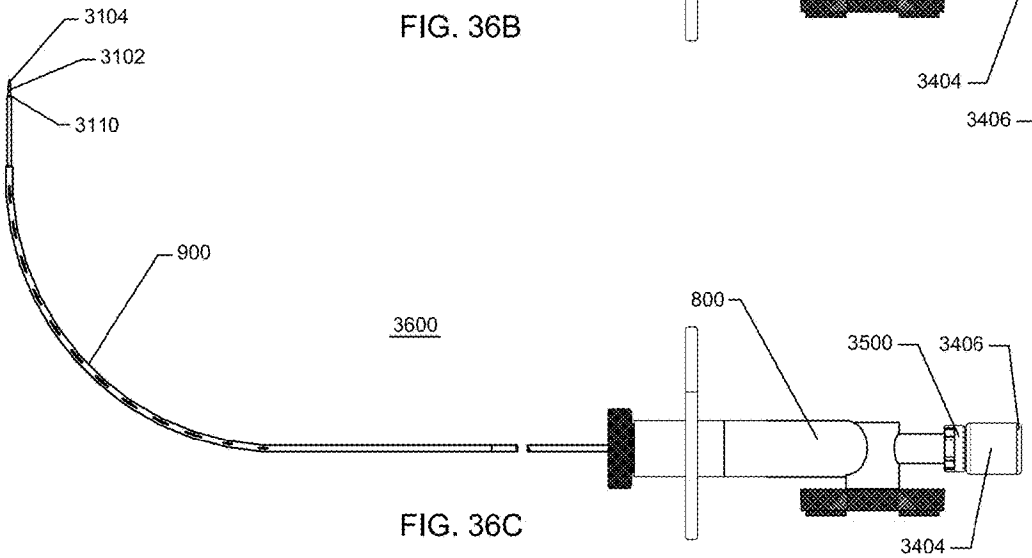

FIG. 36C

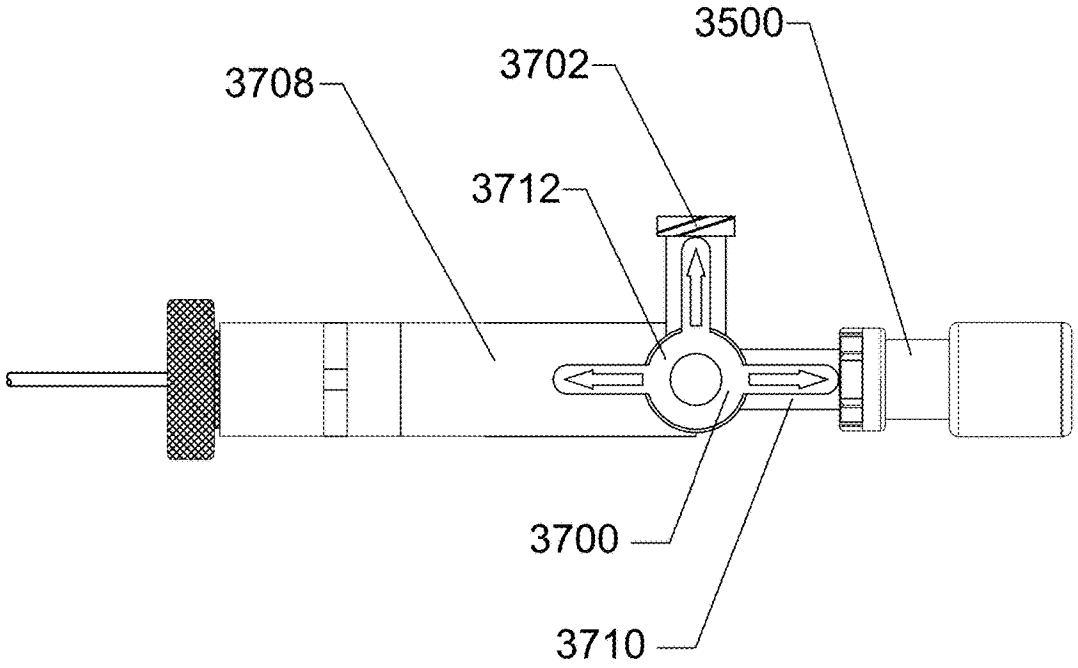

FIG. 37

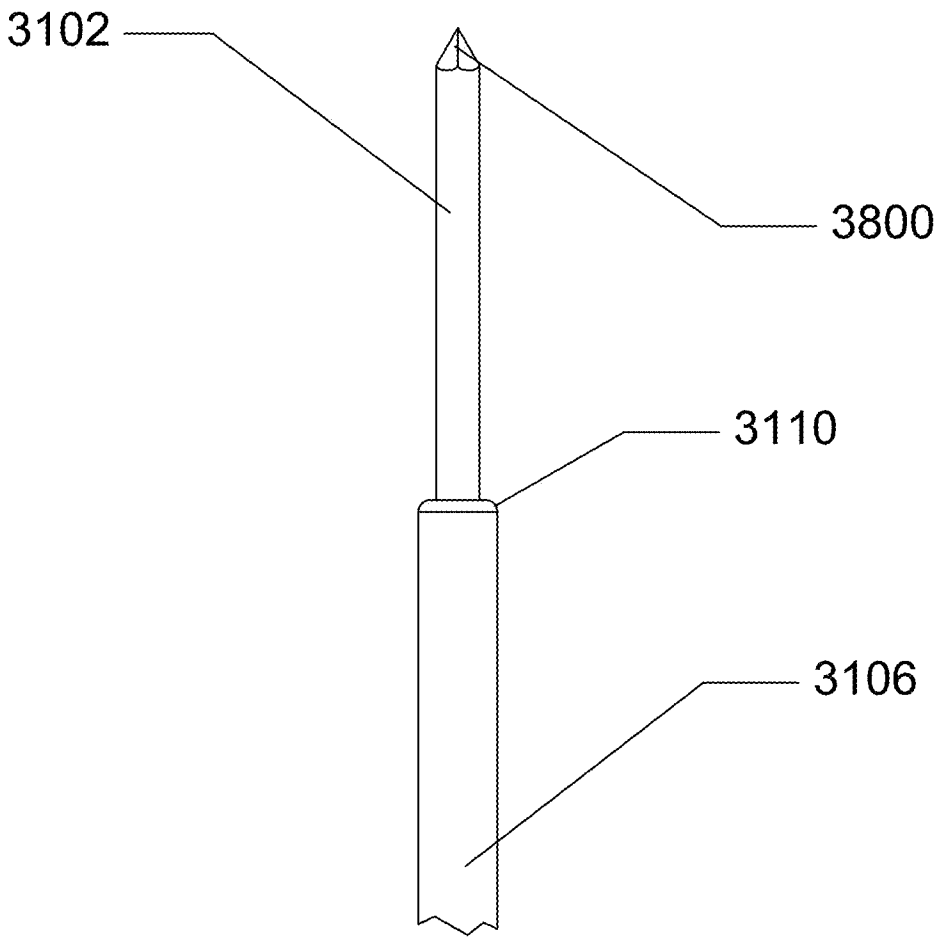

FIG. 38

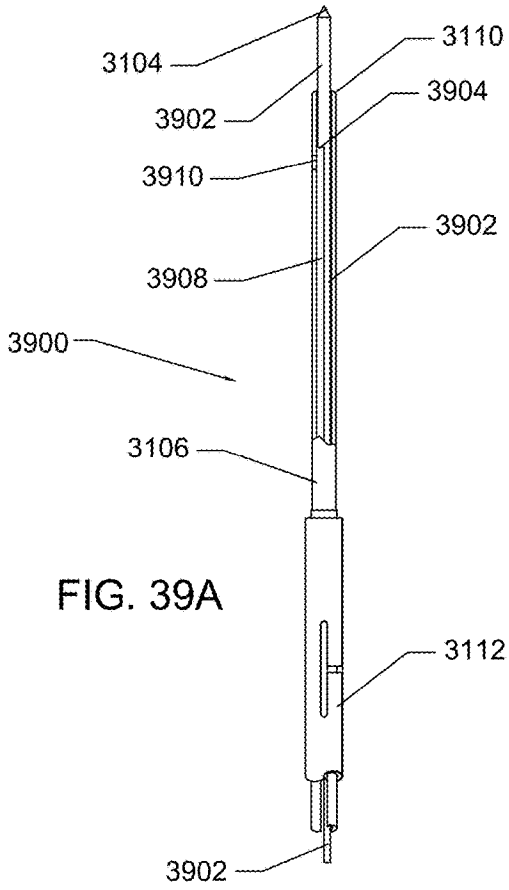

FIG. 39A

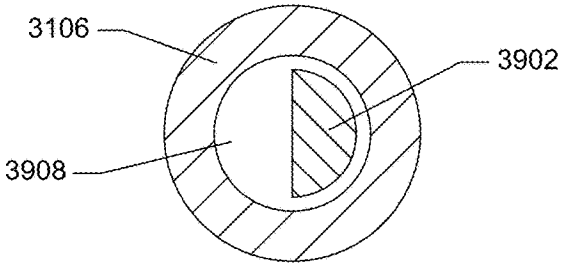

FIG. 39B

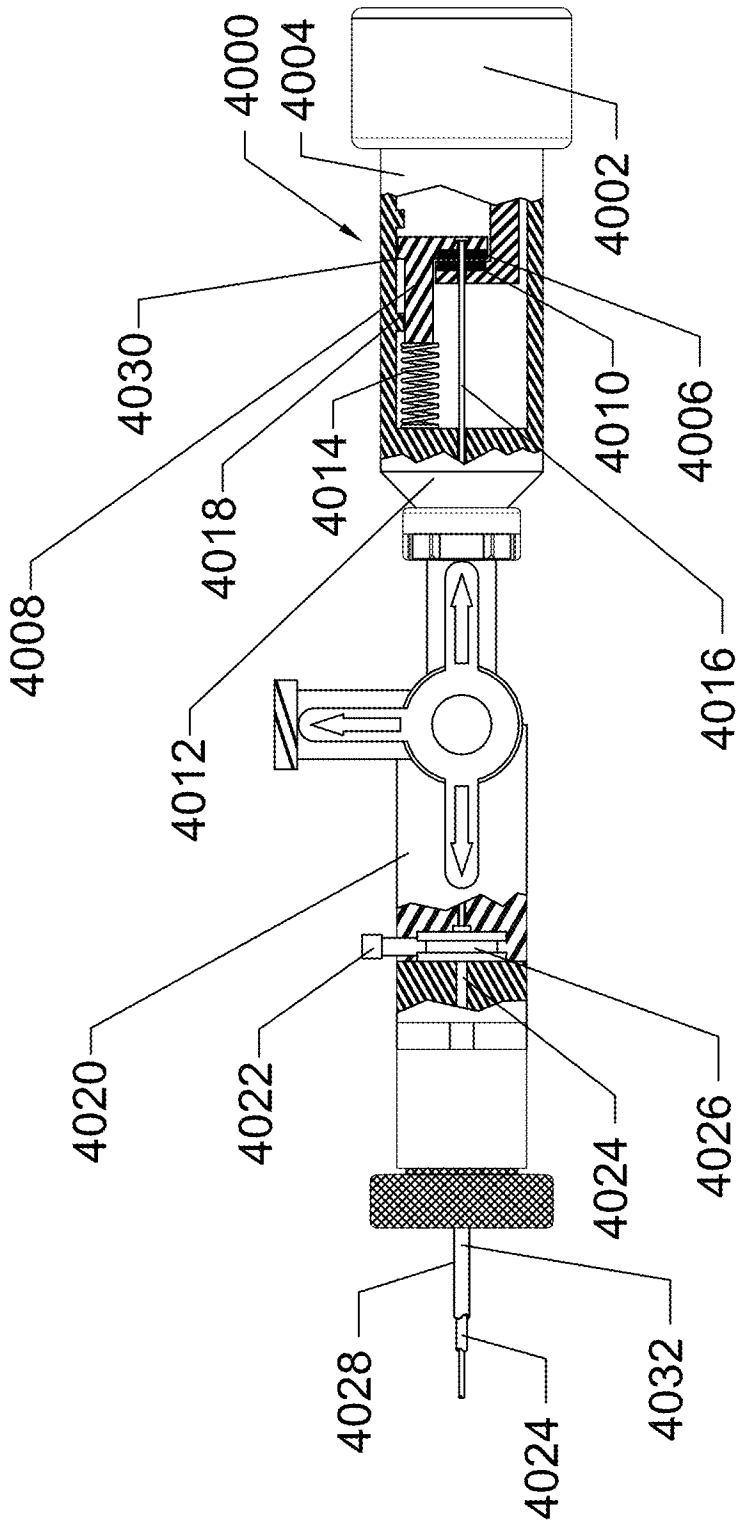
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FIG. 40

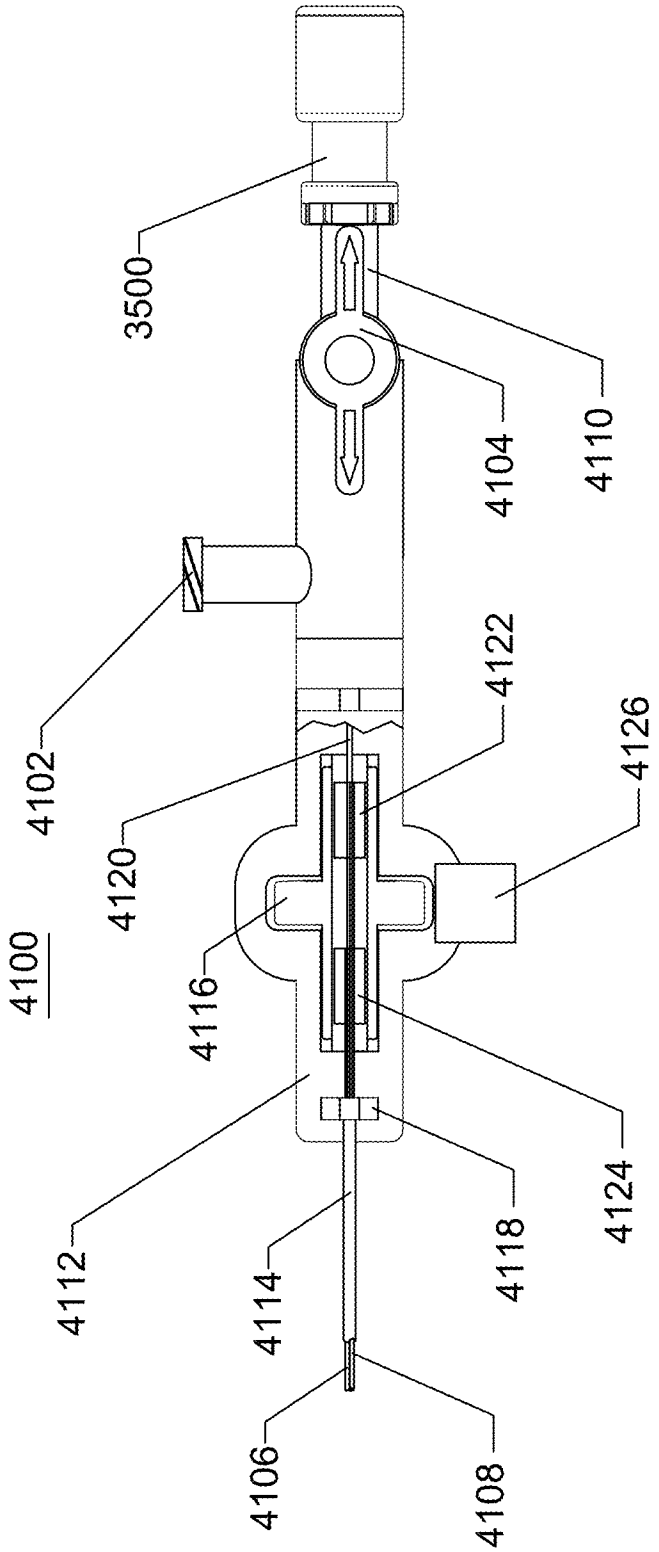
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FIG. 41

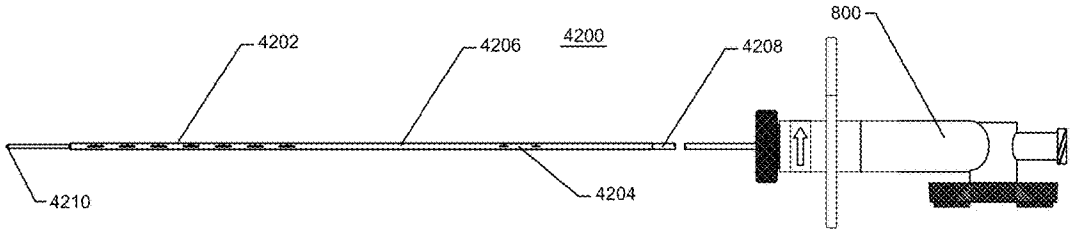

FIG. 42A

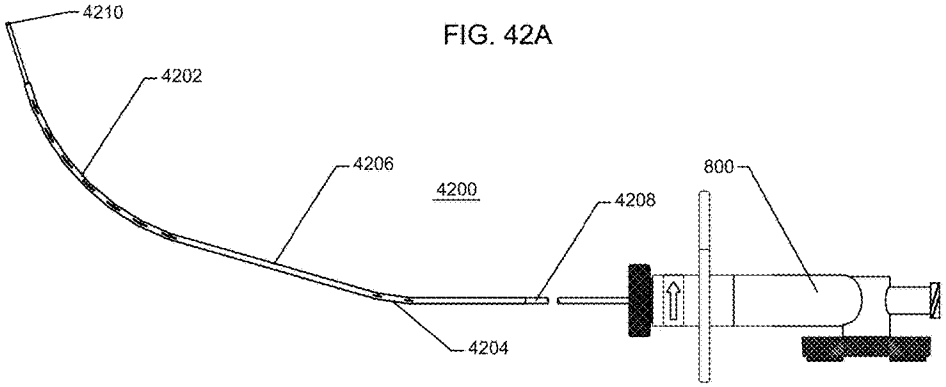

FIG. 42B

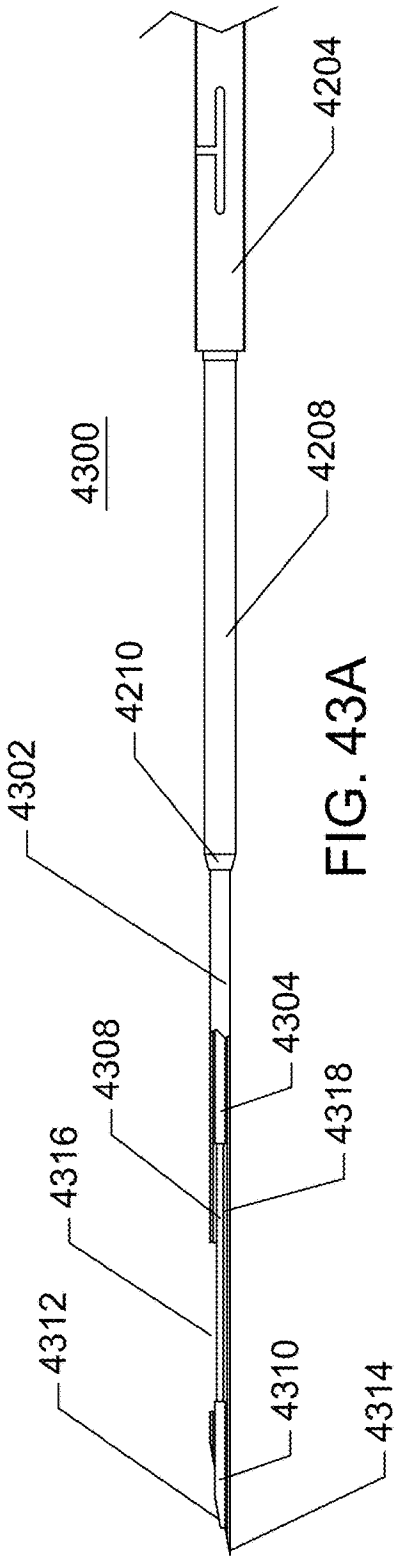

FIG. 43A

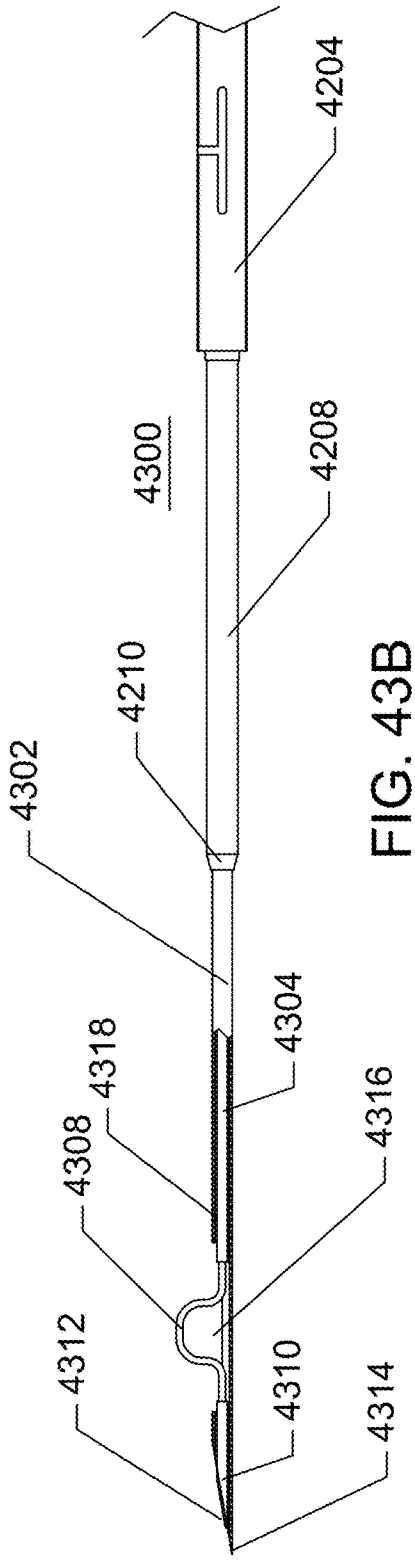

FIG. 43B

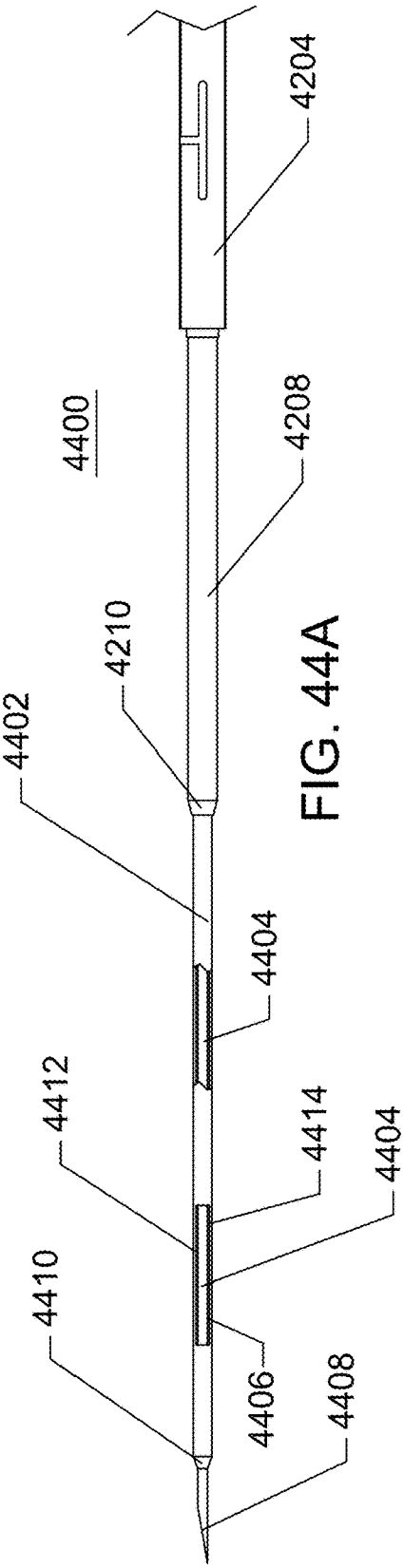

FIG. 44A

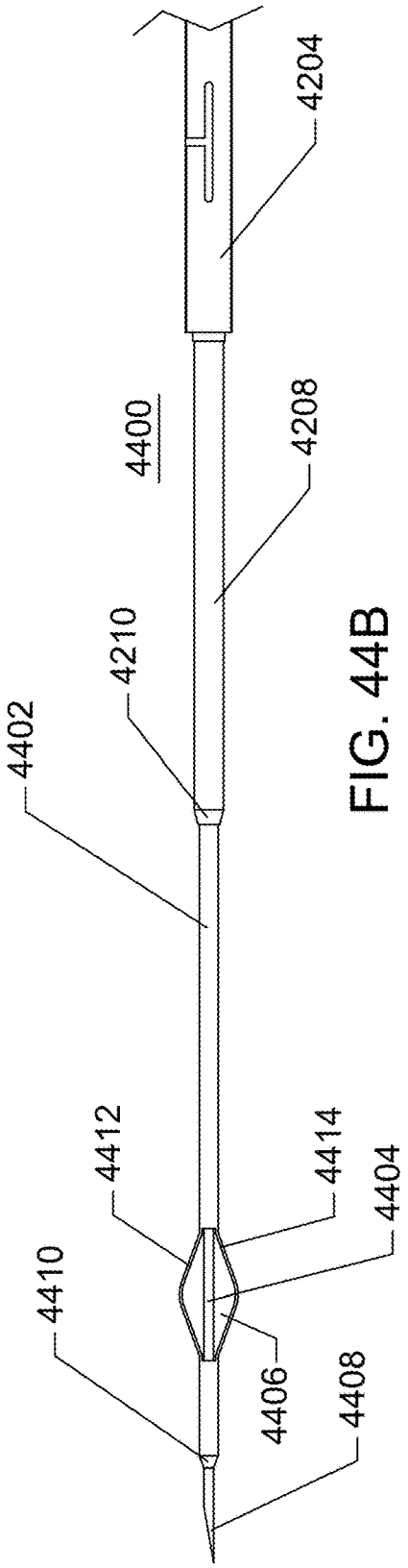

FIG. 44B

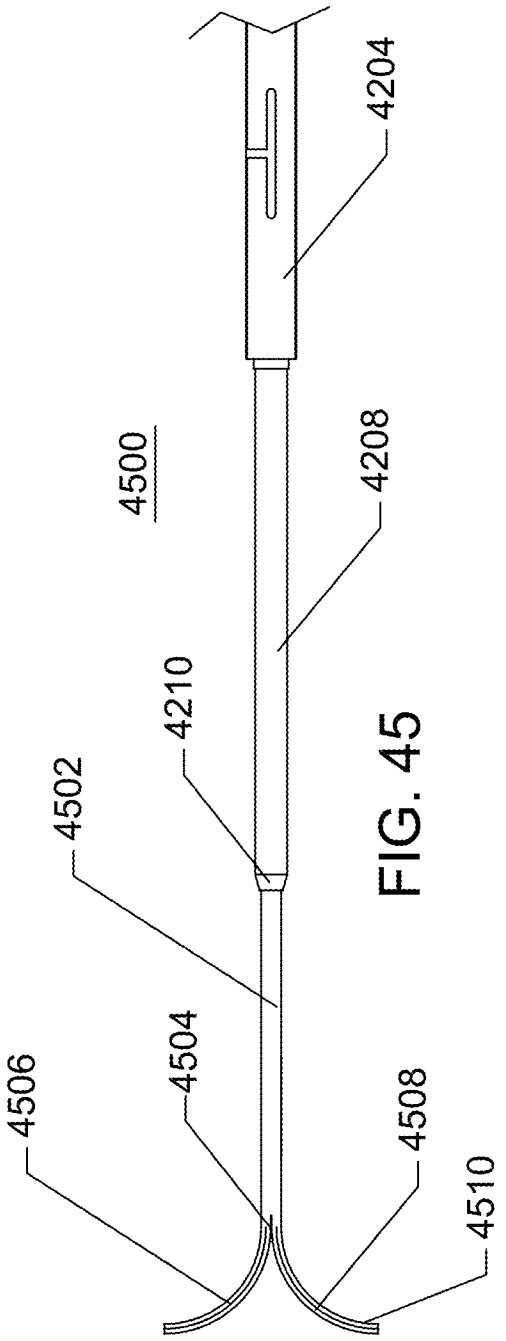

FIG. 45

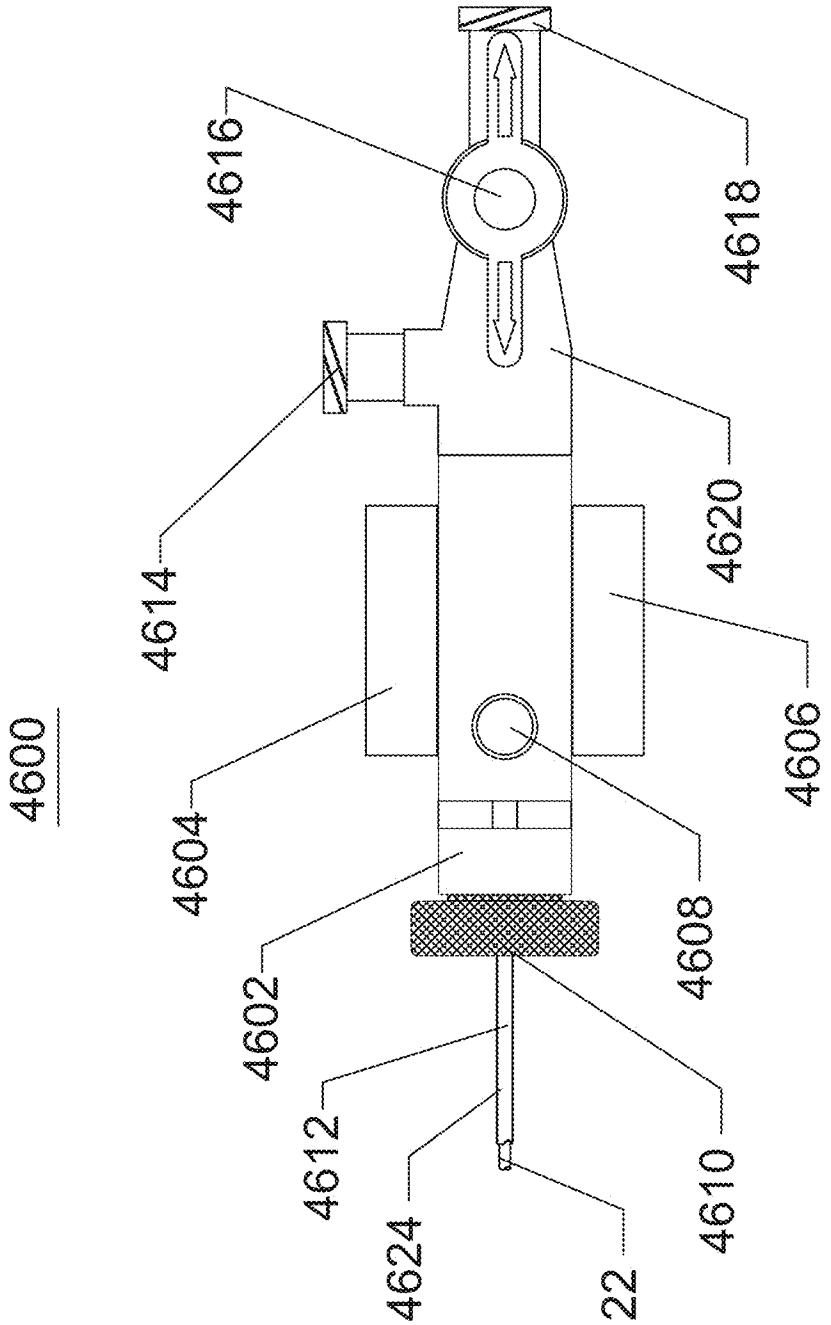
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FIG. 46

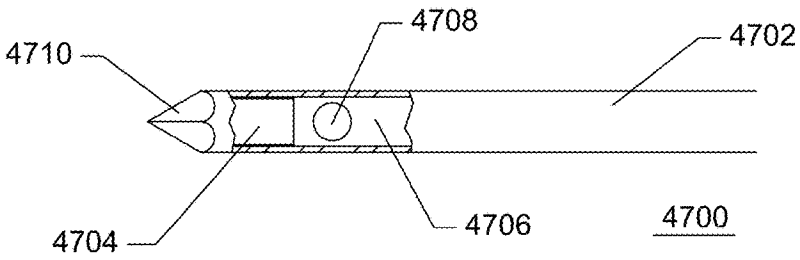

FIG. 47A

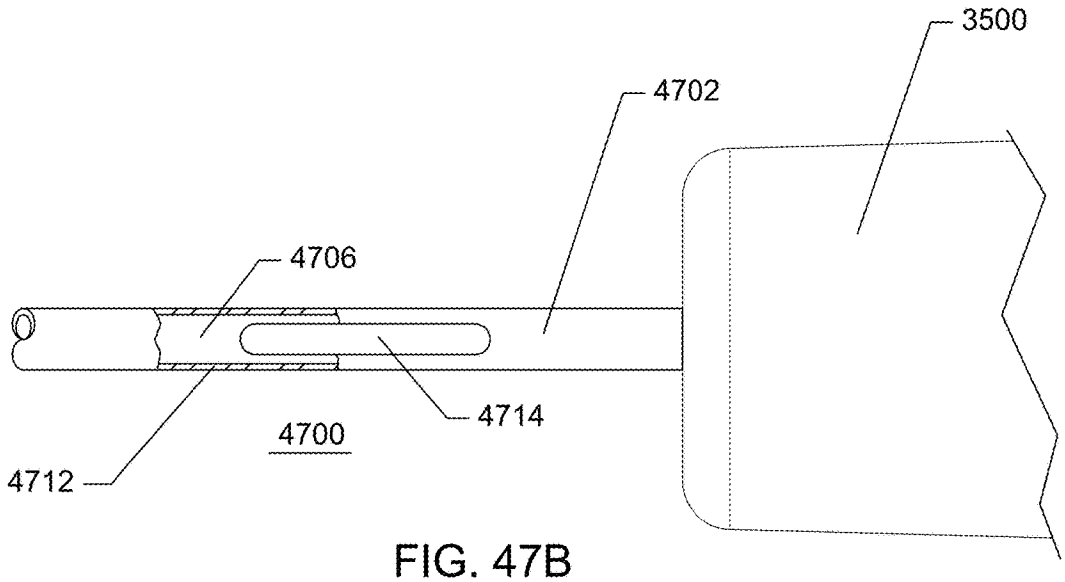

FIG. 47B

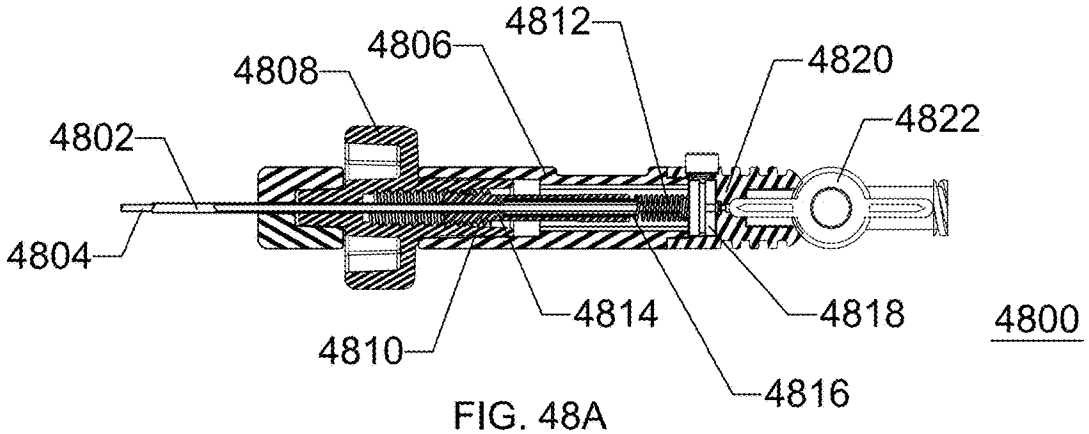

FIG. 48A

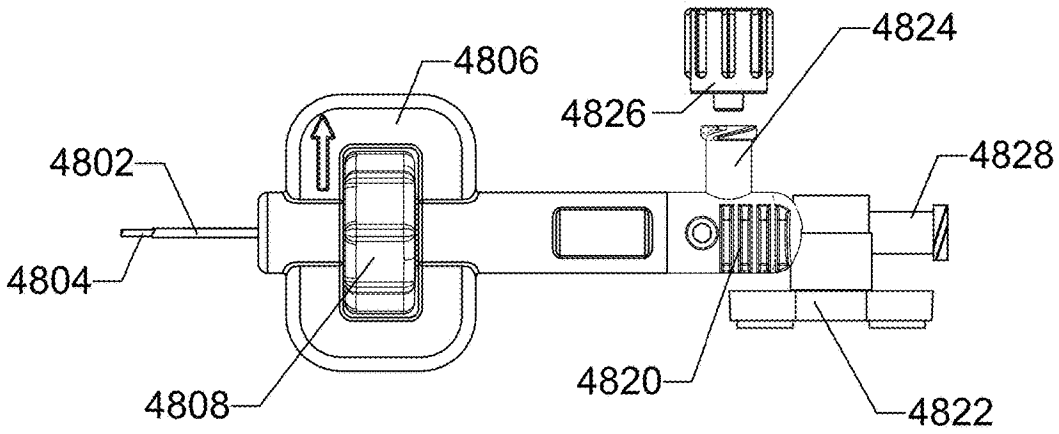

FIG. 48B

STEERABLE ENDOLUMINAL PUNCH

This application claims priority to U.S. Provisional Application 62/299,963, filed Feb. 25, 2016.

FIELD OF THE INVENTION

The inventions described below relate to endoluminal punches and needles.

BACKGROUND

The currently accepted procedure for left atrial access involves routing a needle called a Brockenbrough needle into the right atrium with the Brockenbrough needle pre-placed within a guiding catheter. The guiding catheter specifically preferred for use with a Brockenbrough needle is called a Mullins catheter or transseptal introducer. The Brockenbrough needle is a long, small diameter punch, generally formed from a stainless steel wire stylet that is surrounded by a stainless steel tube.

The Brockenbrough needle, a relatively rigid structure, is operated by advancing the device, with its stylet wire advanced to blunt the sharp tip, within its guiding catheter through the inferior vena cava and into the superior vena cava. Under fluoroscopic guidance, the Brockenbrough needle, retracted inside the distal tip of the Mullins catheter, is withdrawn caudally into the right atrium until it falls or translates medially into the Fossa Ovalis. The Brockenbrough needle can then be advanced out the tip of the Mullins catheter to punch the cardiac tissue.

A main disadvantage of this system is that the Brockenbrough needle system is pre-curved at its distal end and is relatively rigid. This pre-curving, rigidity, and necessary distal sharpness causes the Brockenbrough needle system to carve material from the interior wall of the otherwise straight guiding catheter when the Brockenbrough needle assembly is inserted therethrough. The material carved from the guide catheter could potentially be released into the cardiovascular system and generate emboli with any number of serious clinical sequelae. Should this embolic catheter material enter the left atrium it could flow into and block important arterial vasculature such as the coronary arteries or cerebrovasculature. Furthermore, advancing a pre-curved, rigid punch through the cardiovascular system is difficult and could potentially damage the vessel wall or any number of significant cardiovascular structures, during the advancement.

SUMMARY

It is desirable to have a Brockenbrough needle system that is initially straight and then becomes curved under user control after being inserted into the guiding catheter. Such a straight Brockenbrough configuration is advantageous during ex-vivo insertion as well as insertion after the guide catheter has already been placed into the cardiovascular system. During ex-vivo insertion, the debris can be flushed from the lumen of the guide catheter but complete removal is not assured and emboli can still be generated by the device. However, if the guide catheter has already been inserted into the cardiovascular system, the debris cannot be flushed out ahead of time and could easily flow toward or be released into the cardiovascular system with potentially catastrophic or fatal results. Furthermore, the needle or punch can be more easily advanced into the body lumen if it were not pre-curved. Furthermore, it is beneficial that the needle comprise an adjustable curvature once it is located within the vasculature so that the user can modify the curve, in situ. This ability to articulate the distal end of the transseptal needle can be termed articulation. The device can be termed a steerable needle. In other embodiments, the device can be configured, with or without a sharpened tip, as a catheter, biopsy punch, guidewire, medical or surgical instrument, transcatheter instrument, borescope, axially elongate medical instrument, or the like.

In some embodiments, the steerability, deflection, or articulation, of a distal region of the device can be accomplished using the inner tube and outer tube, concentrically arranged and radially constrained together. The inner tube outer diameter is a close tolerance fit to the inside diameter of the outer tube but the inner tube is free to translate along a longitudinal axis of the tubes relative to the outer tube. Thus, only translational motion along the longitudinal axis is used to generate the articulation. The inner tube is modified in a region proximate the distal end such that the inner tube is divided, weakened, or split, into two or more parts. Only a portion of these divided parts of the inner tube are affixed, at their proximal end, to the more proximal portion of the inner tube. The parts of the inner tube not affixed at their proximal end can be optionally affixed near their distal end to the portions of the inner tube that are also affixed at their proximal end. The outer tube is rendered flexible by cutting slots or gaps generally having a lateral or radial orientation, although there can be some projection at an angle or along the longitudinal axis of the outer tube. These lateral slots do not pass completely through the outer tubing so a spine with ribs is formed in the outer tubing. The inner tube is affixed to the outer tube at a region distal to the lateral slots in the outer tube. The portion of the inner tube that is affixed to the outer tube is that portion of the split inner tube that is connected at its proximal end to the more proximal portions of the inner tube.

The articulation is generated by an outer tube that is modified to increase flexibility within a pre-determined longitudinal region. The articulation is controlled by one or more control rods disposed within the lumen of the tube. The control rod or rods can run the entire length of the exposed device distal to the hub, or the control rod or rods can run at least a portion of the distance of the pre-determined longitudinal region of increased flexibility, the bending zone. The control rod or rods can be integral to, or affixed, at their proximal ends to the hub, to an anchor within the hub, to a control mechanism comprising mechanical advantage, or to an intermediate member that transfers energy to the control rod or rods. The control rod or rods can be affixed to a point substantially distal to the bending zone or they can be integral or affixed to an intermediate member that is then affixed to the outer tube at a location distal to the bending zone.

Thus, articulation can also be generated using a plurality of (two or more) nested, radially constrained, substantially concentric axially translating tubes, wherein a first tube is weakened on one side to increase flexibility and limit final curvature and shape while a second tube is split substantially longitudinally and broken off on one side within the region where the first tube is also weakened. In certain embodiments, both tubes are substantially in place to maintain hoop strength, column strength, kink resistance, and orientation of discreet structures, such as breaks or slots exist within the plurality of tubes.

In certain embodiments, the steerable transseptal needle can comprise a stylet that comprises a sharp distal end. The sharp distal end can comprise a conical or beveled distal tip.

The conical tip embodiment can comprise an angle of about 5 degrees to about 60 degrees from the longitudinal axis with a preferred angle of about 15 to about 30 degrees. The beveled tip embodiment can comprise an angle of about 5 degrees to about 60 degrees from the longitudinal axis. The sharp tip can, in other embodiments, comprise facets, pyramidal shapes, or the like.

In the embodiments that include a sharp stylet distal tip, the distal end of the inner tube and outer tube are generally blunted to the extent possible to render them minimally traumatic. The transition between the outer tube and the inner tube can comprise a tapered conical fairing, or it can comprise a rounded fillet, or the like. The distal end of the inner tube can also comprise a bevel or other configuration which is sharp. The distal end of the inner tube can comprise a rounded fillet, a blunted taper, or the like. The blunted taper can comprise angles ranging from about 45 degrees to about 90 degrees from the longitudinal axis.

The stylet can be routed through the central lumen of the inner tube and any control rods and keepers comprised within the outer tube. The stylet can comprise wire having a diameter of about 0.013 to about 0.030 inches in diameter with a preferred diameter of about 0.015 to about 0.025 inches in diameter with a more preferred diameter of about 0.016 to 0.022 inches in diameter. The stylet can comprise an area of reduced diameter within the region where the steerable transseptal needle is articulated, this reduced diameter reducing the bending resistance of the stylet in the bendable region.

The stylet shaft, since it runs through the bendable region of the transseptal needle, advantageously comprises a wire or tube diameter that does not impinge on the collapse of any structures radially within the bendable region. Thus, the stylet shaft outer diameter or dimension is advantageously smaller than the minimum diameter to which the control rods, keepers, stays, and the like, can collapse. The tip of the stylet, however, since it does not reside within the bendable region of the transseptal needle, can be a closer tolerance fit to the inside diameter of the distal most portion of the needle, which is generally the inner tube, but not necessarily. The closer the fit to the ID of the inner tube (minimized gap), the less force will be required to force the entire assembly through fibrous tissue. A preferred radial gap between the sharp stylet head and the ID of the inner tube can range between about 0.0005 inches and about 0.003 inches for an 18 gauge steerable needle.

The diameter of the stylet wire can be configured to permit fluid to be injected around the stylet but through the steerable transseptal needle internal lumen, even while the stylet wire is in place within the lumen. Furthermore, the annular lumen around the stylet can be configured to be sufficient to permit pressure measurements to be made through the central lumen of the steerable transseptal introducer while the stylet is in place. These pressure measurements and fluid injections can be facilitated by removal of the stylet from the steerable transseptal introducer. In a preferred embodiment, a central lumen of 0.023 inches diameter can surround a stylet shaft having a diameter of about 0.016 to 0.020 inches in diameter. Thus, a lumen of about 0.035 to about 0.015 inches, radially, can exist within the steerable transseptal needle while the stylet is in place.

The stylet can also comprise a tubular shaft with a pointed, or sharpened, distal end. The distal end can be integral to, or affixed to, the tubular shaft. The exit of the tubular shaft can be comprised within the distal tip structure, or somewhere in the side wall of the tubular shaft. The proximal end of the tubular shaft can be operably connected to a side-port within the hub of the transseptal needle or another port operably connected to the central lumen of the transseptal needle. The proximal end of the tubular stylet shaft can, in other embodiments, be operably connected to a fluid port on the hub of the stylet and not the transseptal needle. The ports can be advantageously configured as female Luer locks, quick connects, bayonet mounts, threaded connectors, or the like.

In other embodiments, the stylet wire can retain a reduced area, cross sectional shape comprising, but not limited to, half (or partial) circle, C-shape, cross-shape, or the like. The stylet wire can comprise these shapes to reduce the area of the lumen within the inner tube, control rods, and keepers, which are configured to maximize flow rate of fluids injected around the stylet wire. The reduced cross-sectional area of the stylet wire can continue along its entire length, or a portion thereof. In some embodiments, the reduced cross-section is eliminated and transitions to a full (or nearly full) circular cross-section at or near the distal end such that any protrusion outside of the inner tube lumen is substantially round and able to dilate tissue being punctured.

The stylet can comprise structures at its distal end that expand radially outward and provide for cutting incisions, which are larger than those which the basic stylet can create, in tissue. These structures can be passively or actively activated by user control at the proximal end of the stylet. The incision cutting mechanisms comprised by the stylet can include apparatus such as, but not limited to, cutting wire that is bent outward from a tubular stylet by providing compression or tension on control rods within the stylet. The incision cutting mechanism can also include apparatus that is actuated by rotating a control mechanism at the proximal end of the stylet which then causes outward projection of a cutting mechanism at the tip of the stylet. The cutting mechanism can comprise systems such as, but limited to, a thin wire, a thin heated wire, a wire sharpened to create a thin, cutting cross-section, a thin wire emanating radio frequency (RF) energy, a thin wire emanating high frequency ultrasound energy (HIFU), or the like.

The cutting stylet can comprise an axially elongate tubular structure, having a central lumen, which is affixed at its distal end to a stylet hub or control button comprised by the hub. A wire can be slidably disposed within the lumen of the axially elongate tubular structure. The wire can be affixed, at its distal end to the axially elongate tubular structure using fasteners, welds, adhesives, a combination of the aforementioned, or the like. An elongate window or opening can be created in the distal end of the axially elongate tubular structure. In other embodiments, the axially elongate tubular structure can comprise a "C" or "U"-shaped distal end or half-pipe. The wire can be affixed to a control mechanism at its proximal end such that distal advancement of the wire causes the wire, which is restrained at or near the distal end, to bulge outward through the half-pipe or window. The wire can be sharpened at least in the region where it bulges radially outward and the sharpened wire can be used to generate an incision in tissue surrounding the stylet. In other embodiments, the wire can be bent into a loop which is restrained within the tubular stylet and upon proximal tension on the wire, is pulled proximally to where it can bulge out through the window or half pipe. The amount of radial bulging or protrusion beyond the outside diameter of the stylet tubing can range from about 0.010 inches to about 0.50 inches with a preferred range of about 0.04 inches to about 0.30 inches. In the embodiment where the wire is rotated for activation, a jackscrew structure can be comprised within the stylet to cause axial tension or compression

on the stylet wire in response to this rotational activation. It is beneficial that the system comprise some sort of safety or interlock to prevent inadvertent radial outward protrusion of the cutting wire except at a desired time. In yet other embodiments, the activation mechanism can comprise use of shape memory materials that are activated by body temperature or fluid temperature infusions to move the material from martensitic to austenitic and thus cause the bulging effect. Retraction of the bulge can be accomplished using axial motion imposed on the wire relative to the tube.

In yet other embodiments, retraction or advance of the wire within the tube of the stylet can actuate cutting blades disposed within the stylet tube and hinged so that these blades, or a single blade, can be rotated radially outward to cut tissue. In all embodiments, the stylet is retracted within the lumen of the steerable transseptal needle until it is controllably advanced distally by the user, at which time the cutting elements can be restrained by a secondary safety, or not.

The hub at the proximal end of the stylet can preferably be removably affixed to the proximal female Luer lock connector on the steerable transseptal needle with a male Luer lock, quick disconnect, or other fastener. The stylet hub can comprise a spring-loaded actuator which is biased to withdraw the stylet tip proximally so it does not project out the distal end of the steerable transseptal needle. When the spring loaded button is depressed, or actuated, by the user, the sharp stylet tip protrudes out the distal end of the steerable transseptal needle sufficiently to penetrate tissue. Release of the spring-loaded button or actuator causes retraction of the sharp stylet distal tip within the blunted distal end of the steerable transseptal needle.

The hub of the steerable transseptal introducer can comprise a side port with a female Luer lock fitting to permit infusion or withdrawal of fluids or measurement of pressure while the stylet hub is locked in place and protruding axially through the steerable transseptal needle. The side port lumen is operably connected to the central lumen in the hub of the steerable transseptal needle. The side port can further comprise a valve such as a stopcock or a hemostasis valve to prevent unwanted fluid ingress or egress from the central lumen of the steerable transseptal needle. In some embodiments, the stopcock, preferably comprised by the hub of the steerable transseptal needle, can be configured as a three-way or four-way stopcock rather than a one-way stopcock to allow for the presence of a side port, operably connected to the lumen of the steerable transseptal needle with minimal required real estate. The side port, in other embodiments, can be affixed to the hub of the steerable transseptal needle at a location other than at the stopcock.

In another embodiment, the hub of the stylet can comprise a quick release or safety catch that prevents the sharp stylet tip from projecting out the distal end of the steerable transseptal needle inner tube lumen more than momentarily. This system includes a release that is activated upon full advancement of the stylet out the distal end, whereby the release activates and allows spring-biased withdrawal of the stylet proximally.

In some embodiments, the quick release, or safety stylet, can comprise an intermediate component that rotates or changes diameter to cause disengagement of the stylet from the button being pushed, such that a spring or other forcing mechanism can withdraw the safety stylet proximally such that it is sheathed and no longer protrudes beyond the distal end of the inner tube. This quick release can be reset by the user, for example, by releasing a button being pushed so that it can return to its initial, loaded, position. In yet other embodiments, the safety stylet hub can comprise magnets that cause the stylet tip to follow a control button or actuator until such time the magnetic force is exceeded by the force of the return spring, tissue resistance, or the like. Once a pre-set force is reached, the magnets pull apart and the stylet can return to its initial, retracted position. The Control handle, once released, likewise can return to its initial, armed position.

In some embodiments, the hub of the steerable transseptal needle piercing stylet can comprise a safety catch or release that prevents actuation of the piercing stylet until such actuation is desired. The safety catch can comprise a pin lock, a C-collar, a safety switch, a removable fastener, a breakaway member, or the like.

In other embodiments, the distal end of the steerable transseptal needle can comprise a cylindrical radiopaque marker band that reduces the diameter of the inner tube and provides for additional Radiopacity and visibility under fluoroscopy. This radiopaque marker band can be used to reduce the annulus around the stylet tip as it protrudes through the distal end of the steerable transseptal needle. However, when the stylet is retracted, the distal orifice of the central lumen of the steerable transseptal introducer is not significantly restricted because the lumen at the center of the RO marker is not blocked by the stylet, whose tip resides proximal to the RO marker sufficiently to allow for fluid flow therethrough.

In other embodiments, the steerable transseptal needle can comprise an electrical plug, operably connected to the inner tube, the central stylet or wire, or the outer tube. The electrical plug can be affixed to the hub of the steerable transseptal needle. The plug can be configured for releasable attachment to the cable of a radio frequency (RF) power supply or "Bovie". The plug can be used to conduct electrical energy to one or more of the tubes or wires of the steerable transseptal needle. The plug can comprise conductive materials such as, but not limited to, stainless steel, cobalt nickel alloy, titanium, brass, copper, nitinol, or the like. The steerable transseptal needle, in these embodiments, can comprise an outer jacket, which has electrical insulating properties, which surrounds the outer tube of the steerable transseptal needle, along some or the entirety of the exposed length of the outer tube, inner tube, or both. The insulating jacket can be fabricated from materials such as, but not limited to, polyester (PET), polyimide, FEP, PFA, PTFE, polyamide, Hytrel, Pebax, PEEK, PVC, polyurethane, polyethylene, polypropylene, or the like. In some embodiments, the insulating jacket can be the same as the pressure shroud surrounding the slots or openings in the tubing at the distal end of the steerable transseptal needle. The insulating jacket can be heat shrunk around the outer tubing, applied as a liquid that dries, slipped over the outer tubing and affixed, or the like.

In other embodiments, the steerable needle, catheter, or other axially elongate instrument, may be required in situations where high bending stresses are incurred. In the case of a transseptal needle, once articulated to the desired curvature, the needle tip should be resistant to further bending caused by off-axis forces acting during longitudinal or axial advancement of the needle through tissue structures. This stiffness is important since not only the needle, but surrounding catheter, dilator, obturator, or other instruments must also be pushed through the hole in the tissue, which is created by the steerable needle. These extra structures possess increased cross sectional area and thus increased forces

are required to advance through tissue. Such tissue may be easy to penetrate, or otherwise scarred, tough, and structurally difficult to penetrate.

Certain embodiments of the steerable needle configured for increased bending strength include providing for the tightest possible fit between the ID of the outer tube and the outside diameter of the inner tube, which is still consistent with longitudinal relative motion between the inner tube and its control rods and keepers and the outer tube. A radial gap of less than about 0.001 inches can beneficially reduce slop in the system, which can lead to buckling of the control rods and keepers.

In other embodiments, use of the maximum possible wall thickness for the inner tube, outer tube, control rods, keepers, and the like can enhance the area moment of inertia and resistance to external lateral or off-axis forces.

In other embodiments, some or all of the outer tube lateral openings can be configured to close upon bending to increase resistance to further bending once the openings have closed. Thus, control over the maximum permitted amount of articulation of the distal end can increase the flexural modulus of the bendable region structure. The lateral openings or slots can have widths ranging from about 0.001 inches to about 0.020 inches. Control over the slot or opening width as well as the number of slots or openings can be adjusted to regulate the flexural modulus of the bendable region. Placement of the slots or openings in the outer tube can be optimized to maximize stiffness in specific anatomic geometries. Regions of non-articulating outer tube can be dispersed within articulating regions to maximize transmission of longitudinal forces in the structure and maximize flexural modulus.

The distance between the control rod and its complimentary keeper, or stay, should be as small as possible given manufacturing constraints. Reducing the distance between the control rods reduces slop in the system, prevents buckling, and increases hoop strength. In some embodiments, the gap between the control rod and its complimentary keeper can range from about 0.0005 inches to about 0.010 inches, given an overall system diameter of about 0.050 inches. Larger system diameters can comprise larger gaps. In preferred embodiments, the gap between the control rod and keeper can be vanishingly small, as long as the two parts are disconnected and able to move longitudinally relative to each other with minimum friction.

In other embodiments, a plurality of control rods can be configured to act in opposition to provide for a push-pull actuation within the bendable region of the device. Instead of a control rod and complimentary keeper to retain the control rod as close as possible to the outer tube and off-center, the keeper can be replaced by another control rod. The distance between the two control rods should be as small as possible given manufacturing constraints. Reducing the distance between the control rods reduces slop in the system, prevents buckling, and increases hoop strength.

In some embodiments, the push-pull control rod system comprises at least a pair control rods affixed to the outer tube distal to the bendable region of the outer tube. The control rods extend separately through the bendable region and the non-bendable proximal region of the device all the way into the hub. Within the hub, the two or more control rods can be affixed to structures, such as, but not limited to, threaded jackscrew devices, which provide sufficient mechanical advantage and control to move the two or more control rods axially relative to each other and the outer tube. The jackscrew devices can be separately controlled or they can be linked so that operation of a single control knob, lever, motor, stepper motor, hydraulic actuator, or the like, causes tension on one control rod and compression on another control rod. The outer tube can also be affixed to the hub of the device.

In other embodiments, the hub can be configured to be removable from the steerable apparatus or needle. The hub can be configured to clamp onto the outer tube and to clamp onto the control rods or inner tube. Mechanisms within the hub can be configured to move the control rods, inner tube, or outer tube to provide for distal end articulation. In certain removable hub embodiments, the hub can be re-attachable. In other removable hub embodiments, the hub is not re-attachable. In certain embodiments, when the hub is removed, control over the inner tube, outer tube, control rods, and the like is removed so internal tensioning is relieved and the distal end is relatively limp and not forced into any particular curve except that generated by any spring biasing within the device. This configuration is described in the steerable guidewire patents filed by the same inventor group and assigned to Indian Wells Medical, Inc. In other embodiments, when the hub is removed, the bend or articulation generated in the distal end of the device can be maintained by an internal catch mechanism that is spring loaded and keeps the outer tube and inner tube (or control rods) in the same relative locations at the proximal end of the device. In an embodiment, the catch mechanism can comprise a plurality of fenestrations in the outer tube longitudinally arranged and configured to engage with complementary protrusions in the inner tube or control rods which are spring biased outwardly. In other embodiments, the catch mechanism can comprise a plurality of fenestrations, longitudinally arranged, on the inner tube or control rods, or attachments thereof, and configured to engage with complementary protrusions, which are spring biased inward from the outer tube. Reattachment of the hub, in either case results in the protrusions being retracted so that the hub can be used to control the relative longitudinal alignment of the inner tube, outer tube, and control rods.

For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention are described herein. It is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves one advantage or group of advantages as taught herein without necessarily achieving other advantages as may be taught or suggested herein. These and other objects and advantages of the present invention will be more apparent from the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

A general architecture that implements the various features of the invention will now be described with reference to the drawings. The drawings and the associated descriptions are provided to illustrate embodiments of the invention and not to limit the scope of the invention. Throughout the drawings, reference numbers are re-used to indicate correspondence between referenced elements.

FIG. **1** illustrates a side view of a trans-septal punch assembled so that the intermediate tube is bent in a direction 180 degrees opposite that of the outer tube, resulting in a substantially straight punch configuration, according to an embodiment of the invention;

FIG. **2** illustrates a side view of the disassembled trans-septal punch showing the central core wire or stylet, the intermediate tube bent in one direction and the outer tube bent in another direction, according to an embodiment of the invention;

FIG. **3** illustrates a side view of the trans-septal punch assembled so that the intermediate tube bend is aligned in the same direction as the outer tube bend, resulting in a curved distal end on the punch assembly, according to an embodiment of the invention;

FIG. **4** illustrates a side view of a trans-septal punch comprising a flexible region proximal to the distal end and pull-wires disposed between the distal end and the proximal end of the punch, according to an embodiment of the invention;

FIG. **5** illustrates a side view of the trans-septal punch of FIG. **4** wherein one of the pull-wires is placed in tension causing the distal flexible region of the punch to deflect into an arc away from the longitudinal axis of the punch, according to an embodiment of the invention;

FIG. **6** illustrates an adjustable, spacer, which sets and maintains the distance between the distal end of the punch hub and the proximal end of a guide catheter hub, according to an embodiment of the invention;

FIG. **7**A illustrates a side, partial breakaway, view of an outer tube of an articulating trans-septal punch comprising a plurality of slots near the distal end to generate a region of increased flexibility, according to an embodiment of the invention;

FIG. **7**B illustrates a side, partial breakaway, view of an intermediate, or inner, tube of an articulating trans-septal punch comprising a longitudinal slot dividing the tube into two axially oriented parts which are connected at the distal end of the inner tube, according to an embodiment of the invention;

FIG. **8** illustrates a cross-sectional view of the proximal end of the articulating trans-septal punch comprising a stopcock and a bend adjusting mechanism, according to an embodiment of the invention;

FIG. **9** illustrates a partial breakaway view of the distal end of the articulating trans-septal punch comprising the outer tube and the intermediate tube arranged concentrically and oriented circumferentially, according to an embodiment of the invention;

FIG. **10** illustrates an oblique view of the proximal end of the articulating trans-septal punch, according to an embodiment of the invention;

FIG. **11** illustrates a side view of the distal end of the articulating trans-septal punch incorporating a control rod and a control rod retainer, separated from each other, and the outer T-slotted tube with the inner tube being pulled proximally relative to the outer tube causing the outer tube to deform into a curve having very stiff, or rigid, mechanical properties, according to an embodiment of the invention;

FIG. **12**A illustrates a top view of a portion of the distal flexible region of an outer tube comprising dovetails or interlocking grooves to reduce torque or side-to-side motion, according to an embodiment of the invention;

FIG. **12**B illustrates a side view of a portion of the outer tube distal flexible region of an outer tube comprising dovetails or locking grooves to reduce torque or side-to-side motion, according to an embodiment of the invention;

FIG. **13** illustrates the distal end of an articulating septal punch advanced nearly to the distal end of an obturator or dilator, which is coaxially, removably assembled into the central lumen of a guide catheter sheath, according to an embodiment of the invention;

FIG. **14** illustrates the distal end of an articulating trans-septal punch further comprising a removable obturator having a collapsible distal shield, according to an embodiment of the invention;

FIG. **15**A illustrates an outer tube cut in its flexible regions with shorter lateral slots and with reduced or complete elimination of some T-slots to improve resistance to bending in that region, according to an embodiment of the invention;

FIG. **15**B illustrates a control rod without any control rod retainer leaving only the c-shaped control rod and the distal end, according to an embodiment of the invention;

FIG. **16**A illustrates a cross-sectional view of a control rod configuration in a steerable transseptal punch within the flexible region, wherein the separation between the control rod and a control rod retainer is substantially at the midpoint or center of the outer tubing, according to an embodiment of the invention;

FIG. **16**B illustrates a lateral cross-section of a tubing configuration of a steerable transseptal punch within the flexible distal region, with an off-center slot, according to an embodiment of the invention;

FIG. **17**A illustrates a cross-sectional view of a steerable transseptal punch comprising an outer tube and three control rods, each subtending approximately ⅓ of the internal circumference of the outer tube, some or all of which can be functional and each of which is separated from the other by the spacing and all residing within the central lumen of the outer tube, according to an embodiment of the invention;

FIG. **17**B illustrates a cross-sectional view of a steerable transseptal punch comprising an outer tube and four control rods, each subtending approximately ¼ of the internal circumference of the outer tube, some or all of which can be functional and each of which is separated from the other by the spacing and all residing within the central lumen of the outer tube, and further including an innermost tube to control the fluid path and prevent ingress of egress of fluid from the central lumen of the punch assembly, according to an embodiment of the invention;

FIG. **18**A illustrates a lateral cross-section of a steerable transseptal punch comprising an outer tube, a control rod, a control rod retainer, an internal pressure sleeve to prevent ingress or egress of fluids, and a stylet, according to an embodiment of the invention;

FIG. **18**B illustrates a lateral cross-section of a steerable transseptal punch comprising an outer tube, two control rods subtending ½ of the internal circumference of the inner lumen and a control rod retainer subtending ½ of the internal circumference of the outer tube, along with a central stylet, according to an embodiment of the invention;

FIG. **18**C illustrates a side view of a control rod and keeper system comprising a c-shaped control rod and a c-shaped control rod guide, retainer, or keeper configured to maintain the control rod against the inside diameter of an outer tube and further comprising ends configured for welding and providing a fluid-tight seal with other structures within a punch, according to an embodiment of the invention.

FIG. **19**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube and a control rod in the shape of a "V" or "L", according to an embodiment of the invention;

FIG. **19**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube and a control rod in the shape of a open ended box or "U", according to an embodiment of the invention;

FIG. **20**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube and two hollow control rods, each of which having a circular cross-section, according to an embodiment of the invention;

FIG. **20**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube, two hollow control rods, and a stylet, each of which comprising a circular cross-section, according to an embodiment of the invention;

FIG. **21**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube, a rectangular control rod with rounded ends and a round stylet within a lumen of the control rod, according to an embodiment of the invention;

FIG. **21**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube and an I-beam shaped control rod, according to an embodiment of the invention;

FIG. **22**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen and a control rod disposed within the central lumen, according to an embodiment of the invention;

FIG. **22**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube, a hollow control rod disposed within the lumen of the outer tube, and a stylet disposed within the lumen of the control rod, according to an embodiment of the invention;

FIG. **23**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen and a control rod disposed within the central lumen, the control rod having a central lumen and two channels to retain the one or more control wires or rods, according to an embodiment of the invention;

FIG. **23**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube, a control rod, and a control rod guide, the guide and the control rod being separated by slots formed at an angle other than radial, according to an embodiment of the invention;

FIG. **24**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a control rod disposed within the central lumen of the outer tube, the control rod having a central lumen and subtending less than a full circle circumferentially, and a central stylet, according to an embodiment of the invention;

FIG. **24**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube, a c-shaped control rod, and a control rod guide having thinner wall than the control rod, the guide and the control rod being separated by slots formed radially, according to an embodiment of the invention;

FIG. **25**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a c-shaped control rod disposed within the central lumen of the outer tube, a c-shaped control rod retainer, and narrow slots separating the control rod and the retainer, according to an embodiment of the invention;

FIG. **25**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a c-shaped control rod disposed within the central lumen of the outer tube, a c-shaped control rod retainer, and medium width slots separating the control rod and the retainer, according to an embodiment of the invention;

FIG. **25**C illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a c-shaped control rod disposed within the central lumen of the outer tube, a c-shaped control rod retainer, extremely wide slots separating the control rod and the retainer, and a large gap between the OD of the control rod and retainer and the ID of the outer tube, according to an embodiment of the invention;

FIG. **26**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a plurality of control rods or wires, an intermediate tube, and a central stylet, according to an embodiment of the invention;

FIG. **26**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a plurality of hollow tubular control rods or wires, an intermediate tube, and a central stylet, according to an embodiment of the invention;

FIG. **27**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen and a solid central control rod slidably disposed therein, according to an embodiment of the invention;

FIG. **27**B illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen, a semi-circular first solid control rod, and a semi-circular solid control rod retainer or second control rod, according to an embodiment of the invention;

FIG. **28**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen and a plurality of radially oriented cuts or grooves disposed in two generally orthogonal directions, the different cuts or grooves being interdigitated between each other along the length of a flexible region, a plurality of control rods and a control rod retainer, according to an embodiment of the invention;

FIG. **28**B illustrates a lateral cross section of the steerable transseptal punch comprising an outer tube having a central lumen, two quarter-circular arcuate control rods, and a semi-circular hollow control rod retainer, according to an embodiment of the invention;

FIG. **29**A illustrates a lateral cross section of a steerable transseptal punch comprising an outer tube having a central lumen and a plurality of radially oriented cuts or grooves disposed in two generally orthogonal directions, the different cuts or grooves being placed in order with the grooves in the first direction in a different axial region of the tube than the grooves in the second direction and each defining a flexible region in a specific direction, a plurality of control rods, a plurality of distal weld points, and a control rod retainer, according to an embodiment of the invention;

FIG. **29**B illustrates a lateral cross section of the steerable transseptal punch comprising an outer tube having a central lumen, two quarter-circular arcuate control rods, and a semi-circular hollow control rod retainer, according to an embodiment of the invention;

FIG. **30**A illustrates a lateral cross section of a steerable transseptal needle comprising an outer tube having a central lumen and a plurality of radially oriented openings, cuts, or grooves disposed in a single direction, defining a flexible region in a specific direction, a hollow circular control rod, a distal weld point between the control rod and the outer tube, a pressure jacket over the openings in the outer tube to prevent fluid leakage or ingress, and a distal hinge on the control rod, according to an embodiment of the invention;

FIG. **30**B illustrates a lateral cross section of the steerable transseptal punch comprising an outer tube having a central lumen and a hollow circular, tubular control rod having a central lumen, according to an embodiment of the invention;

FIG. **31**A illustrates a side view of a steerable transseptal needle comprising a blunt distal end and a sharp, tissue piercing stylet or obturator, in its retracted state, according to an embodiment of the invention;

FIG. **31**B illustrates a side view of the steerable transseptal needle of FIG. **31**A with the sharp stylet or obturator advanced distally beyond the distal end of the inner tube to form a sharp, tissue punch, according to an embodiment of the invention;

FIG. **32**A illustrates a steerable transseptal needle comprising a radiopaque marker at the distal end of the inner tube as well as a small diameter segment of the stylet wire, according to an embodiment of the invention;

FIG. **32**B illustrates the steerable transseptal needle of FIG. **32**A with the stylet advanced out the distal end of the inner tube, according to an embodiment of the invention;

FIG. **33**A illustrates a steerable transseptal needle comprising a beveled tip, sharp stylet, according to an embodiment of the invention;

FIG. **33**B illustrates the steerable transseptal needle of FIG. **33**A with the beveled sharp stylet advanced out the distal end of the inner tube;

FIG. **34**A illustrates a hub configured for use with a piercing stylet or obturator in its retracted state, according to an embodiment of the invention;

FIG. **34**B illustrates the hub of FIG. **34**A actuated such that the stylet or obturator is advanced a controlled distance, according to an embodiment of the invention;

FIG. **35**A illustrates a side exterior view of a stylet hub further comprising a removable safety clip, according to an embodiment of the invention;

FIG. **35**B illustrates the hub of FIG. **35**A in oblique view, according to an embodiment of the invention;

FIGS. **36**A, **36**B and **36**C illustrate side views of a steerable transseptal needle with a piercing stylet hub removably affixed to the proximal end of the needle hub, according to an embodiment of the invention;

FIG. **37** illustrates a top view of a steerable transseptal needle comprising a three-way stopcock affixed to its hub, rather than the standard one-way stopcock, according to an embodiment of the invention;

FIG. **38** illustrates a faceted sharp distal end of a piercing stylet, according to an embodiment of the invention;

FIG. **39**A illustrates a side, partial breakaway view of the distal end of a steerable transseptal needle wherein a portion of the stylet shaft has been cut away to facilitate fluid flow within the central lumen of the steerable transseptal needle, according to an embodiment of the invention;

FIG. **39**B illustrates a lateral cross-section of a stylet wire configured to facilitate fluid flow or pressure measurement while the stylet wire is in place within the steerable transseptal needle lumen, according to an embodiment of the invention;

FIG. **40** illustrates a hub of a steerable transseptal needle safety piercing stylet wherein the hub comprises magnetic latches to actuate the stylet, according to an embodiment of the invention;

FIG. **41** illustrates the hub of a steerable medical device wherein the hub comprises two separate jackscrews, affixed to separate control rods, and moving axially in opposite directions under the control of a knob and an optional stepper motor, according to an embodiment of the invention;

FIG. **42**A illustrates a steerable needle or medical device, in its straightened configuration, comprising two regions of flexibility separated by a non-flexible segment, according to an embodiment of the invention;

FIG. **42**B illustrates the steerable needle or medical device of FIG. **42**A in a curved or articulated orientation, according to an embodiment of the invention;

FIG. **43**A illustrates a side view, in partial cutaway, of the distal end of a steerable needle further comprising a stylet that is configured to cut tissue but with the cutting element retracted, according to an embodiment of the invention;

FIG. **43**B illustrates a side view, in partial cutaway, of the distal end of the steerable needle further comprising the cutting stylet as shown in FIG. **43**A but with the cutting element of the stylet actuated so as to project radially outward, according to an embodiment of the invention;

FIG. **44**A illustrates a side view, in partial cutaway, of the distal end of a steerable needle further comprising a cutting stylet comprising a window and a plurality of retracted expandable blades, according to an embodiment of the invention;

FIG. **44**B illustrates a side view, in partial cutaway, of the distal end of the steerable transseptal needle of FIG. **44**A with the plurality of cutting blades radially expanded, according to an embodiment of the invention;

FIG. **45** illustrates a side view of the distal end of a steerable transseptal needle comprising a cutting stylet wire that is split into two blades biased radially outward so as to project laterally when the stylet wire is exposed beyond the end of the steerable transseptal needle, according to an embodiment of the invention;

FIG. **46** illustrates the proximal end of a steerable transseptal needle with a hub, wherein the hub includes a radiofrequency generator, a power supply, and a switch to actuate the system, according to an embodiment of the invention;

FIG. **47**A illustrates the distal end of a piercing stylet for use with a transseptal needle, wherein the piercing stylet comprises a hollow tubular construction to permit flow therethrough as well as a radiopaque marker positioned near the distal tip of the stylet, according to an embodiment of the invention;

FIG. **47**B illustrates the proximal end of the piercing stylet of FIG. **47**A, showing the hollow tubular structure and a window disposed near the proximal end to allow for infusion or withdrawal of fluids within the hollow tubular structure, according to an embodiment of the invention

FIG. **48**A illustrates a side partial cross-sectional view of the proximal end of a steerable transseptal needle with a side port and a disengaging jackscrew traveler, according to an embodiment of the invention; and

FIG. **48**B illustrates a to view of the proximal end of the steerable transseptal needle of FIG. **48**A, according to an embodiment of the invention.

DETAILED DESCRIPTION

In accordance with current terminology pertaining to medical devices, the proximal direction will be that direction on the device that is furthest from the patient and closest to the user, while the distal direction is that direction closest to the patient and furthest from the user. These directions are applied along the longitudinal axis of the device, which is generally an axially elongate structure having one or more lumens or channels extending through the proximal end to the distal end and running substantially the entire length of the device.

In an embodiment, the invention is an endoluminally, transvascularly, or endovascularly placed tissue punch, with internal deflectability or the ability to articulate, at its distal end, in a direction away from its longitudinal axis. The punch can also be termed a catheter, needle, or cannula. The punch is generally fabricated from stainless steel and comprises an outer tube, an intermediate tube, a central stylet wire, and a distal articulating region. The deflecting or articulating mechanism is integral to the punch. The punch,

needle, or catheter is sufficiently rigid, in an embodiment, that it can be used as an internal guidewire or internal guide catheter. The punch is useful for animals, including mammals and human patients and is routed through body lumens or other body structures to reach its target destination.

In an embodiment, the punch comprises an inner core wire or stylet, an intermediate tube and an outer tube. In an embodiment, the stylet can be removable or non-removable. The punch further comprises a hub at its proximal end which permits grasping of the punch and also includes a stopcock or valve to serve as a lock for the stylet, or inner core wire, as well as a valve for control of fluid passage into and out from the innermost lumen within which the stylet or inner core wire resides. The proximal end further comprises one or more control handles to manipulate the amount of articulation at the distal end of the catheter. The proximal end further is terminated with a female Luer or Luer lock port, which is suitable for attachment of pressure monitoring lines, dye injection lines, vacuum lines, a combination thereof, or the like.

The punch is fabricated so that it is substantially straight from its proximal end to its distal end. Manipulation of a control mechanism at the proximal end of the punch causes a distal region of the punch to bend or curve away from its longitudinal axis. The bending, steering, or articulating region is located near the distal end of the punch and can be a flexible region or structure placed under tension or compression by pull wires or control rods routed from the control handle at the proximal end of the punch to a point distal to the flexible region. In another embodiment, the bending or articulating mechanism can also be created by pre-bending the outer tube in one direction and bending the intermediate tube in another direction. The two tubes can be rotated relative to each other, about their longitudinal axis, by turning knobs or grips at the proximal end of the punch. When the curvatures of both tubes are aligned, the tubes will generally cooperate and not oppose each other, thus, maximum curvature or deflection is generated. When the tubes are rotated so their natural curvatures are aligned 180 degrees from each other, the curves will oppose each other or cancel out. Thus, the nested tubes will be substantially straight when the curvatures of the two concentric tubes oppose each other. Alignment marks or graduations at the proximal end can be used to assist with proper rotational alignment of the two tubes. The central core wire or stylet is generally straight and flexible and does not contribute to the curvature. In another embodiment, however, the stylet can be imparted with a curvature to assist with steering or articulation. Rotation of the two concentric tubes at relative angles between about 180 degrees and 0 degrees will result in intermediate amounts of deflection so the amount of deflection can be increased or decreased in an analog, continuously variable, digital, or stepwise fashion. The stepwise or digital response can be generated using detents or interlocks that weakly engage at specific pre-determined locations. A locking mechanism can be further utilized to hold the two tubes in rotational alignment once the desired amount of curvature has been achieved.

In another embodiment, steerability can be obtained using actuators on the surface or within the interior of the cannula to force bending of the cannula. These actuators can be typically electrically powered. In an embodiment, an actuator can comprise electrical leads, a power source, a compressible substrate, and shape memory materials such as nitinol. Such actuators may be distributed along the length of the cannula. The actuators may be placed so as to oppose each other. Opposing actuators are activated one at a time and not simultaneously and can generate a steering effect or back and forth motion.

Other embodiments of the inventions comprise methods of use. One method of use involves inserting the central core wire or stylet so that it protrudes out the distal end of the punch. A percutaneous or cutdown procedure is performed to gain access to the vasculature, either a vein or an artery. An introducer and guidewire are placed within the vasculature and the guidewire is routed proximate to the target treatment site. The introducer can be removed at this time. A guiding catheter, preferably with a removable central obturator or dilator, with a tapered distal tip pre-inserted, is routed over the guidewire to the target site. In some embodiments, the guide catheter is routed through from a femoral vein, through the inferior vena cava, and into the right atrium of the heart. In an embodiment, the target site can be the atrial septum of the heart in the region of the Fossa Ovalis. In some embodiments, the guide catheter distal tip is routed past the right atrium and into the superior vena cava. The guidewire can be removed at this time. The punch is adjusted so that it assumes a substantially straight configuration. The punch can be advanced through the central lumen of the already placed catheter, sheath, introducer, or guide catheter. By making the punch as straight as possible, there is no curvature to force the sharpened distal edges of the punch to scrape the inside of the catheter lumen as the punch is advanced distally inside the guide catheter and potentially dislodge or skive away debris or material which could cause embolic effects to the patient. Carefully ensuring that the punch does not protrude beyond the distal end of the catheter or its obturator, the punch is next deflected so that it forms a curve. The distal end of the punch is sufficiently radiopaque that it is observable clearly under fluoroscopy or X-ray imaging. The location of the punch and the amount of deflection and curvature of the distal end are observed and controlled using the aforementioned fluoroscopy or X-ray imaging, or other imaging method such as MRI. The curve is oriented so that it is medially directed toward the atrial septum. Alignment with any curvature of the catheter can be completed at this time. The punch and guide catheter/obturator are withdrawn caudally, as a unit, into the right atrium from the superior vena cava. The punch and guide catheter are positioned using fluoroscopy or other imaging system against the Fossa Ovalis. The Fossa Ovalis is a relatively thin structure and the force of the punch will tent the Fossa Ovalis toward the left atrium. In one embodiment, the central core wire or stylet, initially advanced, can next be withdrawn to expose the sharp distal edge of the punch. When correctly positioned under fluoroscopy, ultrasound, or other imaging system, dye can be injected into the central lumen of the punch at its proximal end and be expelled out of the distal end of the punch and obturator to paint or mark the Fossa Ovalis. A generally "V-shaped" mark can be observed under fluoroscopy, which denotes the location of the Fossa Ovalis. The curvature of the punch can be increased or decreased by articulation to gain optimal alignment with the Fossa Ovalis. This steering function can be very beneficial in device placement.

Maintaining the position of the guiding catheter against the Fossa Ovalis, the punch is advanced distally against and through the atrial septum, in the region of the Fossa Ovalis, so that it penetrates and protrudes into the left atrium. In order to stabilize the atrial septal tissue prior to coring, a distally protruding corkscrew tipped wire or a vacuum head operably connected to the proximal end of the punch, can be used to grasp and retract the septal tissue. Once the initial

penetration is completed, the guide catheter is next advanced, with its tapered obturator leading the way, across the atrial septum until it resides within the left atrium. The tapered obturator or dilator along with the punch can be removed at this time to allow for catheter placement through the guiding catheter. In another embodiment, a calibrated spacer can be used between the guide catheter hub and the punch hub to ensure that the punch does not protrude beyond the distal end of the guide catheter tip until the desired time for punching the hole. At this point, the spacer is unlocked and removed from the punch or catheter. In some embodiments, the punch is removed from the guide catheter and the same punch is routed through a second guide catheter to provide access to the left atrium for the second guide catheter. Two guide catheters are often necessary for ablation procedures because one guide catheter is used to route mapping and diagnostic devices into the left atrium while the second guide catheter is used to route therapeutic catheters into the left atrium. Thus, the punch can be used more than once on a given patient but, for prevention of contamination, the same punch should not be used on different patients because cleaning and sterilization after use is nearly impossible given the small distances between the moving inner and outer tubes which can hide contamination from cleaning or sterilization by the user.

In another embodiment, the core wire, obturator or stylet is sharpened and serves as a tissue punch. In this embodiment, the distal end of the hollow tubes of the punch are blunted and made relatively atraumatic. Once the core wire punch has completed tissue penetration, the outer tubes are advanced over the central punch wire through the penetration and into the left atrium. In another embodiment, a pressure monitoring device such as a catheter tip pressure transducer, or a pressure line terminated by a pressure transducer, can be affixed to a quick connect, generally a Luer fitting, at the proximal end of the punch hub. By monitoring pressure, it is possible to determine when the distal end of the punch has passed from, for example, the right atrium into the left atrium, because the pressure versus time curves in these two chambers are measurably, or visually, different. The proximal end of the hub further has provision for attachment to a dye injection line for use in injecting radiographic contrast media through the central lumen of the punch. Typically a manifold can be attached to the Luer fitting on the proximal end of the hub, the manifold allowing for pressure monitoring, for example on a straight through port, and for radiopaque dye injection, for example through a side port. A stopcock, or other valve, can be used to control which port is operably connected to the central lumen of the punch.

In some embodiments, the inner tube, the outer tube, or both can have slots imparted into their walls to impart controlled degrees of flexibility. The slots can be configured as "snake cuts" to form a series of ribs with one or more spines. The spines can be oriented at a given circumferential position on the outer tube, the inner tube, or both. The spines can also have non-constant orientations. In some embodiments, only the outer tube is slotted. The slots can be generated within the distal portion of the outer tube where the curve is generated. This distance can range between 3-cm and 15-cm of the end and preferably between 7-cm and 12-cm of the distal end. The slot widths can range between 0.001 inches and 0.100 inches with a preferable width of 0.003 to 0.025 inches. In exemplary embodiments, the slot widths are about 0.010 inches. In some embodiments, it is desirable to have the outer tube bend in one direction only but not in the opposite direction and not in either lateral direction. In this embodiment, cuts can be made on one side of the outer tubing within, for example, the distal 10-cm of the tube length. Approximately 10 to 30 cuts can be generated with a width of approximately 0.010 to 0.040 inches. The cut depth, across the tube diameter from one side, can range between 0.1 and 0.9 of the tube diameter. In an embodiment, the cut depth can be approximately 0.4 to 0.6 of the tube diameter with a cut width of 0.025 inches. A second cut can be generated on the opposite side of the tube wherein the second cut is approximately 0.005 inches or less. In an embodiment, the outer tube can be bent into an arc first and then have the slots generated such that when the tube is bent back toward the 0.005 inch wide cuts, the tube will have an approximately straight configuration even through each tube segment between the cuts is slightly arced or curved.

FIG. **1** illustrates a side view of a punch, needle, or catheter assembly **100**, with an integral articulating or bending mechanism. The punch assembly **100** comprises a stylet or obturator wire **102**, an intermediate tube **104**, an outer tube **106**, an obturator grasping tab **108**, a stopcock **110**, an intermediate tube pointer **112**, an outer tube pointer **114**, an intermediate tube hub **116**, and an outer tube hub **118**.

Referring to FIG. **1**, the obturator wire **102** is affixed to the obturator grasping tab **108**. The stylet or obturator wire **102** is inserted through the central lumen of the intermediate tube **104** and is slidably disposed therein. The stopcock **110** is affixed to the intermediate tube hub **116** and the through lumen of the stopcock **110** is operably connected to the central lumen of the intermediate tube **104**. The intermediate tube pointer **112** is affixed to the intermediate tube hub so that it is visible to the user. The outer tube pointer **114** is affixed to the outer tube hub **118** so that it is visible to the user. The intermediate tube hub **116** and the intermediate tube **104** are able to rotate about the longitudinal axis within the outer tube hub **118** and the outer tube **106**. In an embodiment, the intermediate tube **104** is restrained from longitudinal motion relative to the outer tube **106**. In another embodiment, the intermediate tube **104** can be advanced distally relative to the outer tube **106**. In this latter embodiment, advancement of the inner tube **104** can be used to facilitate punching. The distal end of the intermediate tube **104** can be sharpened and serve as a punch. The distal end of the intermediate tube **104** is sheathed inside the outer tube **106** to protect the tissue from the sharp distal edge of the intermediate tube **104** until the intermediate tube **104** is advanced distally outside the distal end of the outer tube **106**. A releasable lock can be used to maintain the axial or longitudinal position of the intermediate tube **104** relative to the outer tube **106** until punching is required. A releasable lock can further be used to maintain the rotational position of the intermediate tube hub **116** and thus the intermediate tube **104** relative to the outer tube hub **118** and the outer tube **106**.

All components of the punch assembly **100** can be fabricated from metals such as, but not limited to, stainless steel, Elgiloy™, cobalt nickel alloy, titanium, nitinol, or the like. The nitinol can be shape-memory or it can be superelastic. The metals used in the obturator wire **102**, the intermediate tube **104** and the outer tube **106** are advantageously cold rolled, heat treated, or otherwise processed to provide a full spring hardness. The intermediate tube **104**, the outer tube **106**, or both, are relatively rigid, resilient structures. Polymeric materials, such as, but not limited to, polycarbonate, ABS, PVC, polysulfone, PET, polyamide, polyimide, and the like, can also be used to fabricate the stopcock **110**, the intermediate tube hub **116**, the outer tube

hub **118**, the intermediate tube pointer **112**, and the outer tube pointer **114**. The materials are beneficially radiopaque to maximize visibility under fluoroscopy during the procedure. Additional radiopaque markers fabricated from tantalum, platinum, iridium, barium sulfate, and the like can be added to improve visibility if needed. The intermediate tube **104** is curved or bent near its distal end into a gentle curve, preferably with a radius of between 1 to 5 inches and so that the distal tip is deflected through an angle of approximately 10 to 90 degrees from the longitudinal axis of the intermediate tube **104**. The outer tube **106** is curved or bent near its distal end into a gentle curve, preferably with a radius of between 1 to 5 inches and so that the distal tip is deflected through an angle of approximately 10 to 90 degrees from the longitudinal axis of the outer tube **106**. The intermediate tube hub **116** is welded, silver soldered, bonded, crimped, or otherwise fastened to the proximal end of the intermediate tube **104** so that the intermediate tube pointer **112** points in the direction of the bend in the intermediate tube **104**. The outer tube hub **118** is welded, silver soldered, bonded, crimped, or otherwise fastened to the proximal end of the outer tube **106** so that the outer tube pointer **114** points in the direction of the bend in the outer tube **106**. When the intermediate tube pointer **112** is oriented 180 degrees away from the direction of the outer tube pointer **114**, the bend in the intermediate tube **104** substantially counteracts or opposes the bend of the outer tube **106** and the coaxial assembly **100** is substantially straight, as shown in FIG. **1**. The stopcock **110** can also be a ring seal, Tuohy-Borst valve, membrane valve, hemostasis valve, gate valve, or other valve, generally, but not necessarily manually operated. The stiffness of the intermediate tube **104** and the outer tube **106** are sufficient that the punch can be used as a guide for other catheters through which the punch **100** is passed and will deflect those catheters, even ones that have thick walls and high resistance to bending.

FIG. **2** illustrates a side view of a stylet or obturator **140** further comprising the obturator wire **102** and the obturator-grasping tab **108**. The obturator wire **102** is blunted at its distal end to render it as atraumatic as possible. In another embodiment, the obturator wire **102** can be tapered in diameter to render it very flexible and therefore atraumatic at its distal end. The obturator wire **102**, in another embodiment, can be sharpened and serve as a needle or primary punching mechanism. FIG. **2** also illustrates an intermediate punch assembly **120** further comprising the intermediate tube **104**, the stopcock **110**, the intermediate tube pointer **112**, the intermediate tube hub **116**, an intermediate tube seal **124**, an intermediate tube pointer ball **126**, a through lumen port **128**, a beveled distal tip **132**, and a pre-set curve **136**. FIG. **2** further illustrates an outer tube assembly **122** further comprising the outer tube **106**, the outer tube hub **118**, the outer tube pointer **114**, an outer tube distal curve **130**, and an outer tube pointer ball **134**.

Referring to FIG. **2**, the obturator-grasping tab **108** is affixed, either integral to, silver soldered, welded, crimped, adhered, pinned, or otherwise attached, to the proximal end of the obturator wire **102**. The intermediate tube **104** is affixed to the intermediate tube hub **116** by silver soldering, welding, potting, crimping, setscrew, pin, or other fixation method, such that the hub **116** rotates 1 to 1 with the intermediate tube **104**. An optional intermediate tube pointer ball **126** is affixed to the intermediate tube pointer **112** and provides additional visual and tactile rotational positioning sense for the intermediate punch or needle assembly **120**. A curve or bend **136** is heat set, or cold worked into the intermediate tube **104** at or near its distal end. The distal end of the intermediate tube **104** comprises a bevel **132** which helps serve as a punch or cutting edge for the intermediate tube **104**. The angle of the bevel **132** can range between 20 and 70 degrees from the direction perpendicular to the longitudinal axis of the intermediate tube **104**. In another embodiment, the bevel is removed and the distal tip of the intermediate tube **104** is a gentle inward taper or fairing moving distally that serves as a dilator should the obturator wire **102** be used as the punching device rather than the blunt distal tip obturator of the intermediate tube **104**.

In yet another embodiment, the distal tip can comprise a conic section that can be further beveled. For example a 5 degree conic can be applied to the distal tip of the inner tube such that a very thin flat edge exists at the distal tip. This cone angle can range between about 1 degree to about 10 degrees. This flat edge can be beneficially set at between 0.001 and 0.005 inches with a preferred dimension of between 0.001 and 0.003 inches. This distal tip can then be further beveled to create a controlled amount of sharpness. In certain embodiments, the wall thickness of the tubing ranges from about 0.002 to 0.010 inches with a preferred range of about 0.003 and 0.007 inches. The conic section moves the sharp region of the distal tip radially inward so that it is not directly at the exterior of the tube and thus, the inner tube distal end is less likely to scrape on the interior walls of any catheters through which it is inserted. The heel or most proximal part of the beveled tubing can further be buffed or rounded to minimize sharpness at that location. The other edges of the beveled end, other than at the pointed tip can also be beveled to reduce sharpness in all areas except for the distal most portion of the bevel.

The intermediate tube hub **116** further comprises a circumferential groove with an "O" ring **124** affixed thereto. The "O" ring **124** serves to form a fluid (e.g. air, blood, water) tight seal with the inner diameter of the outer sheath hub **118** central lumen and allows for circumferential rotation of the intermediate tube hub **116** within the outer tube hub **118**. The "O" ring **124** can be fabricated from rubber, silicone elastomer, thermoplastic elastomer, polyurethane, or the like and may be lubricated with silicone oil or similar materials. The stopcock **110** can be a single way or a three-way stopcock without or with a sideport, respectively.

The outer punch assembly **122** comprises the bend **130**, which is heat set or cold worked into the outer tube **106** in the same longitudinal location as the bend **136** of the intermediate tube. The wall thicknesses of the intermediate tubing **104** and the outer tubing **106** are chosen to provide bending forces that cancel out when the curves **136** and **130** are oriented in opposite directions and the intermediate tubing **104** is inserted fully into the outer tubing **106**. The wall thickness of the outer tube **106** and the intermediate tube **104** can range between 0.003 inches and 0.20 inches, preferably ranging between 0.004 and 0.010 inches. The outer diameter of the outer tube **106** can range between 0.014 and 0.060 inches and preferably between 0.025 and 0.050 inches. In a most preferred embodiment, the outside diameter of the outer tube **106** is about 0.048 inches. The outer diameter of the obturator wire **102** can range between 0.005 and 0.030 inches and preferably range between 0.010 and 0.020 inches.

FIG. **3** illustrates a side view of the punch assembly **100** fully assembled and aligned so that both the intermediate tube distal curve **136** (Refer to FIG. **2**) and the outer tube distal curve **130** are aligned in the same direction resulting in a natural bend out of the axis of the punch **100**. The punch assembly **100** comprises the obturator wire **102**, the intermediate tube **104**, the outer tube **106**, the obturator grasping

tab **108**, the stopcock **110**, the intermediate tube pointer **112**, the outer tube pointer **114**, the intermediate tube hub **116**, the intermediate tube pointer ball **126**, and the outer tube pointer ball **134**.

Referring to FIG. **3**, the outer tube pointer **114** and intermediate tube pointer **112** are aligned together and in this configuration, the tubing assembly possesses its maximum curvature, which is oriented in the same directions as the pointers **112** and **114**. The pointer balls **126** and **134** are aligned together to provide additional tactile and visual indices of curvature direction. In an embodiment, the curvature of the tube assembly **104** and **106** is unbiased with no net force exerted therebetween and an angle of approximately 45 degrees is subtended by the device in the illustrated configuration. Further curvature can also occur out of the plane of the page so that the curvature takes on a 3-dimensional shape, somewhat similar to a corkscrew. In another embodiment, the curvature of the aligned inner tube **104** and the outer tube **106** subtends an angle of 90-degrees or greater. Again, the intermediate tube **104** and the outer tube **106** have stiffness sufficient that the assembly is capable of guiding any catheter through which the punch **100** is passed. In another embodiment, the intermediate tube **104** and the outer tube **106** have different degrees of curvature so that when they are aligned, a net force still is generated between the two tubes, although a maximum curvature configuration is still generated. This embodiment can be advantageous in permitting articulation in a direction away from the direction of primary curvature. The radius of curvature of the punch **100** can range from substantially infinity, when straight, to as little as 0.5-cm, with a preferred range of infinity to as little as 2-cm radius when fully curved or articulated. One embodiment permits a substantially infinite to a 3-cm radius of curvature. The overall working length of the punch, that length from the proximal end of the outer tube hub to the distal most end of the punch, can range from 10 to 150-cm and preferably between 60 and 100-cm, with a most preferred range of between 70 and 90-cm. A preferred curve has a radius of about 3-cm and is bent into an arc of about 45 to 90 degrees.

FIG. **4** illustrates a side view of another embodiment of a needle or punch assembly **400** comprising an obturator wire **102**, an obturator wire grasping tab **108**, a stopcock **110**, an intermediate tube **404**, an outer tube **406**, a plurality of deflecting wires **412**, an outer tube hub **414**, a deflecting lever **416**, a weld **420**, an axis cylinder **424**, a plurality of deflecting wire channels **426**, and a flexible region **430**. The distal end of the region just proximal to the flexible region **430** is shown in breakaway view. Furthermore, the distal end of the region just proximal to the flexible region **430** as well as the flexible region **430** has been expanded in scale so that certain details are more clearly visible.

Referring to FIG. **4**, the flexible region **430** is affixed to the outer tube **406** by a weld **420**. The flexible region **430** can also be fixed to the outer tube **406** by a crimp, pin, setscrew, adhesive bond, interference fit, mechanical interlock, thread, or the like. The attachment between the flexible region **430** and the outer tube **406** is made at the proximal end of the flexible region **430** and a second attachment or weld **420** can be made at the distal end of the flexible region **430** so as to attach to a length of distal outer tube **406**. The flexible region **430** can comprise a length of coiled wire such as that used in guidewires, it can be a tube that comprises cutouts to provide a backbone configuration to impart flexibility, it can be a length of polymeric tube with elastomeric characteristics, or it can be another type of structure that is known in the art as providing flexibility. These preferred structures also advantageously provide column strength and kink resistance to the flexible region **430**. The center of the flexible region **430** is hollow and comprises a lumen, which is operably connected to the central lumen of the outer tube **406** at both the proximal and distal end of the flexible region **430**. The stopcock **110** is affixed, at its distal end, to the outer tube hub **414**. The outer tube hub **414** further comprises a deflecting lever **416** that is affixed to the axis cylinder **424**, which serves as an axle or rotational pin, and can be moved proximally or distally by manual action on the part of the operator or by a motor or other electromechanical actuator (not shown). The deflecting lever **416** is operably connected to the proximal ends of the deflecting wires **412**. In an exemplary embodiment, one of the deflecting wires **412** is affixed to the top of the axis cylinder **424** and the other deflecting wire is affixed to the bottom of the axis cylinder **424**. When the deflecting lever is pulled proximally, for example, the top wire **412** is placed under tension and the tension on the bottom wire is relieved causing tension to be exerted on the distal end of the punch **400**. The deflecting wires **412** are slidably routed through the deflecting wire channels **420** within the outer tube **406**. The deflecting wires **412** also run through the deflecting wire channels **420** within the flexible region **430**. The deflecting wires **412** can also be routed through the internal lumen of the outer tube **406** and the flexible region **430**.

Referring to FIG. **4**, the outer tube hub **414** is affixed to the proximal end of the outer tube **406** by a crimp, pin, setscrew, adhesive bond, interference fit, mechanical interlock, thread, or the like. The intermediate tube **404** is affixed to the distal end of the outer tube **406** by a crimp, pin, setscrew, adhesive bond, interference fit, mechanical interlock, thread, or the like. In another embodiment, the intermediate tube **404** is routed throughout the length of the outer tube **406**. In this embodiment, the intermediate tube can comprise grooves (not shown) that serve as deflecting wire channels **420** when the intermediate tube **404** is inserted inside the outer tube **406**. Such grooves can also be disposed on the interior surface of the outer tube **406**, rather than on the exterior surface of the inner tube **404**. The obturator wire **102** and the attached grasping loop **108** are slidably disposed within the inner lumen of the outer tube **406**, or the intermediate tube **404**. The intermediate tube **404** is gently tapered up to the outer tube **406** at the distal end of the outer tube **406** in a transition region so that a dilator effect can be created during distal advancement of the punch **400**. The distal end of the intermediate tube **404** can comprise a bevel **132** (FIG. **2**) or other sharp point for punching through biological tissue. The distal end of the intermediate tube **404** preferably forms a non-coring needle or punch that does not excise a tissue sample. The non-coring punch feature is achieved by keeping the central lumen closed or very small. The non-coring punch **400** embodiment can comprise filling the lumen of the intermediate tube **404** with the obturator or stylet wire **102** to prevent the sharp edge of the intermediate tube from functioning as a trephine.

FIG. **5** illustrates a side view of the punch assembly **400** wherein the deflecting lever **416** has been withdrawn proximally causing increased tension in one of the deflecting wires **412**, causing the flexible region **430** to bend **422** out of the longitudinal axis. The punch assembly **400** further comprises the obturator wire **102**, the obturator wire grasping tab **108**, the stopcock **110**, the deflecting lever **416**, an axis cylinder **424**, the hub **414**, the outer tubing **406**, the intermediate tubing **404**, and the bend **422**.

Referring to FIG. **5**, the deflecting lever **416** has been moved proximally and the axis cylinder **424** causing the top

deflecting wire **412** to be placed in tension while the bottom deflecting wire **412** is relaxed. The deflecting wires **412** are affixed at their distal end to the outer tubing **406** or the intermediate tubing **404** at a point substantially at or beyond the distal end of the flexible region **420**. The distal fixation point (not shown) of the deflecting wires **412** is off-center from the axis of the outer tubing **406** or intermediate tubing **404**. When uneven tension is created in the opposing deflecting wires **412**, the uneven tension on the distal end of the punch **400** causes the bendable region **430** to undergo deflection into a curve or bend **422**. Similarly, forward movement of the deflecting lever **416** will place the bottom deflecting wire **412** in tension while the upper deflecting wire **412** will be relaxed, causing the punch **400** to undergo a bend in the opposite direction (downward). The deflecting lever **416** can further comprise a ratchet and lock, a friction lock, a spring-loaded return, or other features to hold position or cause the lever and the bendable region **430** to return to a neutral deflection configuration (substantially straight). The spring nature of the outer tube **406** and the bendable region **430** can advantageously be used to cause a return to neutral once the deflection force is removed from the deflecting lever **416**. The stylet or obturator wire **102** can be withdrawn or extended to expose or protect (respectively) the distal end of the intermediate tube **404** which can be sharpened or blunted. The obturator wire **102** can further be used as the primary punch, especially if the distal tip of the obturator wire **102** is sharpened. If the obturator wire **102** is used as the primary punch, the proximal end of the intermediate tube hub is fitted with a Tuohy-Borst or other hemostatic valve to permit the obturator wire **102** to remain in place. In this embodiment, sidearms affixed proximal to the proximal end of the punch, and operably connected to the central lumen, serve to permit pressure monitoring and dye contrast injection without compromising hemostasis or air entry into the punch assembly **400**.

FIG. **6** illustrates a side view of an adjustable spacer **600** interconnecting a guide catheter **620** and a punch assembly **100**. The spacer **600** further comprises a proximal connector **602**, a rotating nut **604**, an inner telescoping tube **608**, a threaded region **606**, a distal locking connector **610**, and an outer telescoping tube **614**. The guide catheter further comprises a tube **622**, a hub **624**, and a proximal connector **626**. The punch assembly **100** further comprises the stopcock **110**, the distal rotating locking connector **612**, the intermediate tube pointer **112**, the outer tube pointer **114**, and the intermediate tube hub **116**. The spacer **600** can comprise an optional slot **630**.

Referring to FIG. **6**, the punch assembly **100** is inserted through the central lumen of the adjustable spacer **600**. The distal end of the punch assembly **100** is then inserted through the central lumen of the guide catheter **620**. The hub **624** of the guide catheter **620** is affixed to the proximal end of the guide catheter tube **622**. The distal end of the hub **624** comprises a female luer lock connection, which is bonded to, or integrally affixed to the hub **624**. The hub **624** can further comprise a seal or hemostasis valve such as a Tuohy-Borst fitting. The punch **100** hub **116** is terminated at its distal end by a swivel male luer lock connector **612**. The adjustable spacer **600** comprises an outer telescoping tube **614**, shown in partial cutaway view that is terminated at its proximal end with a female luer lock **602**. The proximal end of the outer telescoping tube **614** has a flange that permits rotational attachment of the rotating nut **604**, shown in partial cutaway view, so that the rotating nut is constrained in position, longitudinally, relative to the outer telescoping tube **614** but is free to rotate. The inner telescoping tube **608** is affixed at its distal end with a swivel male luer connector **610**, or equivalent. The proximal end of the inner telescoping tube **608** is affixed to, or comprises, the integral threaded region **606**. The threaded region **606** mates with the internal threads on the rotating nut **604**. As the rotating nut **604** is rotated, either manually or by an electromechanical device, it moves forward or backward on the inner telescoping tube **608** and threaded region **606** thus changing the space between the hub **116** of the punch **100** and the proximal end of the hub **624** of the guide catheter **620**. The system is preferably set for spacing that pre-sets the amount of needle or stylet travel. In an embodiment, the rotating nut **604** comprises a quick release that allows disengagement of the inner telescoping tube **608** from the outer telescoping tube **614** so that collapse is permitted facilitating the tissue punching procedure of advancing the punch **100** distally relative to the hub **624**. The system further comprises hemostatic valves at some, or all, external connections to prevent air leaks into the punch **100**. The telescoping tube **608** can be set to disengage from the outer telescoping tube **614** to allow for longitudinal collapse so that the punch **100** can be advanced distally to provide its tissue punching function. In another embodiment, the spacer **600** comprises the slot **630** that permits the spacer to be removed sideways off the punch **100**. The slot **630** is wide enough to allow the outer tube **106** to fit through the slot **630** so the spacer **600** can be pulled off, or removed from, the punch **100** prior to the punching operation. Thus, the slot **630** can be about 0.048 to 0.060 inches wide and extend the full length of the spacer **600**. With the slot **630**, the spacer **600** comprises a generally "C-shaped" lateral cross-section. The spacer **600** can further comprise a slot closure device (not shown) to prevent inadvertent removal of the punch **100**.

In another embodiment, the threaded region **606** and the rotating nut **604** are replaced by a friction lock on telescoping tubes, a ratchet lock, or other suitable distance locking mechanism. In yet another embodiment, a scale or series of markings (not shown) is incorporated into the adjustable spacer **600** to display the exact distance between the proximal end and the distal end of the spacer **600**. In another embodiment, the proximal end and the distal end of the spacer **600** do not comprise one or both of the female luer lock **602** or the rotating male luer lock **610**. In this embodiment, the spacer **600** provides positional spacing but does not affix the punch **100** to the guide catheter **620** so that the two devices move longitudinally as a unit. In another embodiment, the pull wires **412** of FIG. **4**, which are strong in tension but cannot support compression are replaced by one or more control rods, which are flexible but which have column strength. Thus, deflection can be generated by imparting either tension on the control rod or compression and such tension and compression is capable of deflecting the distal tip of the punch **400** without the need of a separate control rod to impart tension in the other direction. The intermediate tube hub **116** is terminated at its proximal end by a female luer, luer lock, threaded adapter, bayonet mount, or other quick release connector. The quick connect or female luer can be releasably affixed to a hemostasis valve, other stopcock, pressure transducer system, "Y" or "T" connector for pressure and radiopaque contrast media infusion, or the like.

In another embodiment, a vacuum line can be connected to a port affixed to the proximal end of the punch. The port can be operably connected to a bell, cone, or other structure at the distal end of the punch by way of a lumen, such as the central lumen of the intermediate tube or an annulus between the intermediate and outer tube, within the punch.

By application of a vacuum at the proximal end of the punch, the distal structure can be releasably secured to the atrial septum prior to punching through. In another embodiment, a corkscrew structure projects out the distal end of the punch and is operably connected to a knob or control at the proximal end of the punch by way of a control rod slideably or rotationally free to move within a lumen of the punch. The corkscrew structure can be screwed into tissue to releasably secure the distal end of the punch to the tissue, for example, to enhance stability of the punch prior to, during, or after the punching operation.

Referring to FIG. **1**, in another embodiment, the intermediate tube **104**, the outer tube **106**, or both, are fabricated from shape memory nitinol. In this embodiment, electrical energy can be applied to the pre-bent regions of the inner tube **104**, the outer tube **106**, or both. Upon application of electrical energy, Ohmic or resistive heating occurs causing temperature of the tubes to increase. The nitinol changes its state from martensitic to austenitic, with the increase in temperature, and can assume a pre-determined configuration or stress state, which is in this case curved. The austenite finish temperature for such a configuration is approximately 40 degrees centigrade or just above body temperature. In yet another embodiment, the austenitic finish temperature can be adjusted to be approximately 28 to 32 degrees centigrade. The punch **100** can be maintained at room temperature where it is substantially martensitic and non-rigid. Upon exposure to body temperatures when it is inserted into the core lumen of the guide catheter, it will assume its austenitic shape since body temperature is around 37 degrees centigrade. This can cause the punch **100** to curve from substantially straight to substantially curved. In this configuration, only a single tube, either the intermediate tube **104** or the outer tube **106** is necessary, but both tubes, while potentially beneficial, are not required.

FIG. **7**A illustrates a side view, in partial breakaway, of the distal end of an axially elongate outer tube **710**, comprising a lumen **714**, a proximal, uncut portion **712**, a plurality of lateral partial cuts **716**, and a plurality of longitudinal "T" cuts **718**, according to an embodiment.

Referring to FIG. **7**A, the outer tube **710** serves as the outer tube of an articulating septal punch such as that illustrated in FIG. **5**. The plurality of partial lateral cuts **716** serve to render the region of the outer tube **710** in which the lateral cuts **716** are located more flexible than the proximal region **712**. The plurality of longitudinal "T" cuts, serve to further render the region of the outer tube **710**, in which the "T" cuts **718** reside, more flexible than in tubes where such "T" cuts **718** were not present. The longitudinal "T" cuts **718** are optional but are beneficial in increasing the flexibility of the outer tube **710** in the selected bend region. The partial lateral slots **716** can be spaced apart by about 0.02 to about 1.0 inches with a preferred range of about 0.1 inches to about 0.8 inches and a further preferred range of about 0.15 inches to about 0.5 inches. In an exemplary embodiment, the partial lateral slots **716** are spaced about 0.17 inches apart. The spacing between the partial lateral slots **716** can vary. In some embodiments, for example, the spacing between the partial lateral slots toward the proximal end of the outer tube **710** can be about 0.3 inches while those partial lateral slots **716** nearer the distal end of the outer tube **710** can be spaced about 0.15 inches apart. The spacing can change in a step function, it can change gradually moving from one end of the outer tube **710** to the other, or it can increase and decrease one or more times to generate certain specific flexibility characteristics. Increased spacing increases the minimum radius of curvature achievable by compression of the partial lateral slots **716** while decreased spacing allows for a smaller minimum radius of curvature.

The number of lateral cuts **716** or, optionally, the number of lateral cuts **716** with T-cuts **718** can number between about four and about 50 with a preferred number being between about six and about 25 and a more preferred number of about eight to about fifteen. In the illustrated embodiment, there are 12 partial lateral cuts **716**, each modified with a "T" slot **718**. In other embodiments, the partial lateral cuts **716** can be shaped differently. For example, the partial lateral cuts **716** can be at angles other than 90 degrees to the longitudinal axis, curved, V-shaped, Z-shaped, W-shaped or the like. In other embodiments, the 'T' slots **718** can have, for example, further cuts approximately lateral to the longitudinal axis, along any portion of the "T" cut **718**.

The outer tube **710** can have an outer diameter of about 0.020 to about 0.1 inches with a preferred outside diameter of about 0.040 to about 0.060 inches and a more preferred diameter of about 0.045 inches to about 0.055 inches. In the illustrated embodiment, the outside diameter is about 0.048 inches while the inner diameter is about 0.036 inches. The inside diameter of the outer tube **710** can range from about 0.0.010 inches to about 0.090 inches.

FIG. **7**B illustrates an embodiment of a side view, in partial breakaway, of the distal end of an axially elongate intermediate tube **720**, comprising a lumen **724**, a proximal, uncut portion **722**, a longitudinal slot **726** further comprising an angled lead in **728**, a free side **734**, a pusher or connected side **732**, and a distal tip **730**.

Referring to FIG. **7**B, the distal tip **730** interconnects the free side **734** and the pusher side **732**. The distal tip **730** further comprises a tapered distal end that can be beveled or otherwise shaped into a sharp edge such as by circumferentially forming a trephine-like (cylindrical) blade or even a pointed end that is closed or partially closed. The free side **734** and the pusher side **732** are generally integrally formed but can also be affixed to each other by welding, adhesives, fasteners, or the like.

The lead in **728** to the longitudinal slot **726** is beneficially angled to prevent guidewires, stylets, or other catheters, which are inserted through the central lumen **724** from being caught or bumping against an edge. The angled lead in **728** serves a guide to assist with traverse of a stylet, obturator, or guidewire past the lead in **728** and into the distal region of the steerable transseptal needle. The lead in **728** can be angled from between about −80 degrees (the angle can be retrograde) from the longitudinal axis (fully lateral) to about +2 degrees and preferably from about +5 degrees to about +20 degrees with a most preferred angle of about +8 degrees and about +15 degrees. In the illustrated embodiment, the angle of the lead in slot **728** is about 10 degrees from the longitudinal axis. A second feature of the lead in **728** is that it be positioned or located proximally to the most proximal "T" slot **718** in the outer tube **710** when the two tubes **710**, **720** are affixed to each other (see FIG. **9**). The lead in **728** is located at least 1-cm proximal to the proximal most "T" slot **718** and preferably at least 2-cm proximal to the proximal most "T" slot **718** so that bending in the distal region does not distort the lead in **728** and cause kinking, misalignment, or pinching of the internal lumen **724**.

The inner or intermediate tube **720** can have an outside diameter that is slightly smaller than the inside diameter of the outer tube **710** so that the intermediate tube **720** can be constrained to move longitudinally or axially within the outer tube **710** in a smooth fashion with relatively little force exerted. In the illustrated embodiment, the outside diameter

of the intermediate tube **720** is about 0.033 inches giving about a 0.0015 inch radial clearance between the two tubes **710** and **720**. The inside diameter of the intermediate tube **720** can range from about 0.002 to about 0.015 inches less than the outside diameter of the intermediate tube **720**. In the illustrated embodiment, the wall thickness of the intermediate tube is about 0.006 inches so the inside diameter of the intermediate tube is about 0.021 inches. The lumen **724** of the intermediate tube **720** can be sized to slidably accept a stylet or obturator **140** such as illustrated in FIGS. **1** and **2**. A typical stylet wire **140** can range in diameter from about 0.01 to about 0.23 inches with a preferred diameter range of about 0.012 to about 0.020 inches. In another embodiment, the outer tube **710** has an outside diameter of about 0.050 inches and an inside diameter of about 0.038 inches. In this embodiment, the inner tube **720** has an outside diameter of about 0.036 inches and an inside diameter of about 0.023 inches. The radial wall clearance between the inner tube **710** and the outer tube **720** is about 0.001 inches and the diametric clearance is about 0.002 inches. The annulus between the two tubes must be substantially smooth, free from burrs, and free from contamination because the two tubes **710**, **720** beneficially need to translate along their longitudinal axis relative to each other over relatively long axial distances of about 50 to about 150-cm.

The inner tube **720** transmits force along its proximal non-slotted region **722** from the proximal end of the inner tube **720** to the lead in **728** where the force continues to be propagated along the connected side **732** to the distal end **730**. The outer tube **710** transmits force along its proximal non-slotted region **712**. Longitudinal forces applied to the distal, flexible region with the slots **716** cause deformation of the outer tube in an asymmetrical fashion with the side of the outer tube **710** comprising the partial lateral slots **716** forming an outer curve if the slots **716** are expanded and an inside curve if the slots **716** are compressed. Forces to cause bending are preferably exerted such that the partial lateral slots **716** are compressed up to the point where the gap closes, but no further, however forces can also be exerted to expand the slots **716**, however limits on curvature are not in place because the lateral slots **716** can open in an unrestrained fashion except for the material properties of the outer tube **710**.

The disconnected side **734** of the inner tube **720**, separated from the connected side **732** by the longitudinal slot **726** and the lead in **728**, serves to maintain an undistorted tube geometry and provide resistance to deformation while helping to maintain the inner lumen **724** in a round configuration and provide a shoehorn or funnel effect to guide an obturator, guidewire, or stylet **140** therethrough as they are advanced distally. The disconnected side **734**, being separated from the force transmitting member **722** cannot provide any substantial longitudinal load bearing structure, although at its distal end, where it is integral or affixed to the distal end **730**, some tension load carrying capability exists. The intermediate tube **720** can be considered a split tube and does not carry a load in compression or tension along substantially the entire length of the disconnected side **734**.

The partial lateral slot **716** in the inner, or intermediate, tube **720** and the T-Slot **718** in the outer tube **710**, as well as the longitudinal slot **726** in the inner or intermediate tube **720**, and the lead in slot **728** can be fabricated by methods such as, but not limited to, electron discharge machining (EDM), wire EDM, photoetching, etching, laser cutting, conventional milling, or the like. In other embodiments, different slot configurations can also be employed, such as curved slots, complex slots, zig-zag slots, or the like. In some embodiments, the partial lateral slot **716** can be configured with a tongue and groove or dovetail design to prevent or minimize lateral movement or torquing of the outer tube **710** in the flexible region. In some embodiments, the tongue and groove or dovetail (not shown) can be generally centered between two "T" slots, for example. The parts can be ganged and fixture such that, using wire EDM, for example, a plurality of tubes can be cut to reduce manufacturing costs. As many as 20 to 30 tubes, or more, can be fixtured, secured, and etched by the aforementioned methods.

FIG. **8** illustrates a side, cross-sectional view of an embodiment of a hub end **800** of an articulating septal punch. The hub end **800** comprises the outer tube **710**, the intermediate tube **720**, a hub body **802**, a stopcock petcock **804** further comprising a petcock handle **808** and a petcock through bore **806**, a Luer lock fitting **812**, an arrow pointer **810**, a keyed lumen **834**, a setscrew or pin **820**, a jackscrew body **816** further comprising a plurality of threads **828** and a central lumen **832**, a control knob **814** further comprising a plurality of threads **818**, a central lumen **830**, the protrusion **838**, and a circumferential recess **822**, an outer tube weld **824**, an orientation mark **840**, and an intermediate tube weld **826**. The hub body **802** can further comprise a plurality of recesses or complementary structures **836**.

Referring to FIG. **8**, the petcock **804** is affixed to the petcock handle **808** by welding, integral fabrication, fasteners, adhesives, or the like. The petcock **804** is retained within a lateral through bore in the hub body **802**, which is in the illustrated embodiment, tapered, using a locking "C" washer, fastener, screw, pin, or the like (not shown). The petcock **804** can be rotated about its longitudinal axis to align the through bore **806** with the axis and central lumen of the hub body **802** or it can be rotated sideways to shut off and seal the lumen against the flow of fluids. The Luer lock **812** can be affixed to, or integrally fabricated with, the hub body **802**. The knob **814** is retained within the hub body **802** by the setscrew of pin **820** which prevents axial movement but permits rotational movement as constrained by the setscrew, projection, or pin **820** riding within the circumferential recess **822** which is integrally formed or affixed to the knob **814**. The jackscrew body **816** is capable of axial movement within the hub body **802** but is restrained from rotation about the long axis by flats or features on the exterior of the jackscrew body **816** which are constrained by flats or features in the keyed lumen **834**. The knob **814** comprises threads **828** on its internal lumen which engage with external threads **818** on the jackscrew body **816**. Rotation of the knob **814** thus causes the jackscrew body **816** to move axially proximally or distally with mechanical advantage. Rotation of the knob **814** can be forced using manual action or using a motor or other mechanism (not shown). The outer tube **710** is affixed to the jackscrew body **816** by the outer tube weld **824**. The intermediate tube **720** (which can also be called the inner tube) is affixed to the hub body **802** by the intermediate tube weld **826**. The central lumen **724** of the inner tube **720** is operably connected to a central lumen of the hub body **802**, the petcock through bore **806**, and the lumen of the Luer fitting **812**.

The knob **814** can comprise markings **840** to permit the user to visualize its rotary or circumferential position with respect to the hub body **802**. These markings **840** can comprise structures such as, but not limited to, printed alphanumeric characters (not shown), a plurality of geometric shapes such as dots, squares, or the like, or the markings can comprise raised or depressed (embossed) characters of similar configuration as described for the printed markings.

In an embodiment, the knob **814** can comprise a number on each of the facets so the facets can be numbered from one to 6, in the illustrated embodiment. The knob markings **840** can further comprise raised structures, as illustrated, which can further be enhanced with contrasting colors for easy visualization.

The knob **814** can further comprise one or more complementary structures affixed or integral thereto, such as a plurality of protrusions **838** that fit into detents **836** affixed or integral to the proximal end of the hub body **802**. Such protrusions extending into detents in the hub body **802** can provide a ratcheting or clicking sound as well as providing resistance to inadvertent movement of the knob **814** once it is rotated to the correct location. The knob **814**, in some embodiments, can be biased toward the hub body **802** to ensure that complementary structures such as the protrusions and detents come into correct contact. In other embodiments, the knob **814** can comprise a ratchet system to further control its rotary movement with respect to the hub body **802**. In other embodiments, the knob **814** can comprise one or more detents (not shown) while the hub body **802** can comprise one or more complementary protrusions (not shown). It is beneficial that the knob **814** be moved only when required by the user and not by accident or not when it is required to maintain its rotary position and, by consequence, the curvature at the distal end of the tubing. The number of ratchet locations, or low energy positions or setpoints, can range from about 2 per 360 degree rotation to about 20 with a preferred number of ratchet locations ranging from about 4 to about 12.

The hub body **802** can be fabricated from biocompatible metals such as, but not limited to, stainless steel, titanium, nickel coated brass, cobalt nickel alloy, and the like, although it could also be fabricated from polymeric materials in a less expensive format. The knob **814** can be fabricated from the same metals as the hub body **802** but it can beneficially be fabricated from biocompatible polymers such as, but not limited to, polyamide, polyimide, polyvinyl chloride (PVC), acrylonitrile butadiene styrene (ABS), acetal polymers, polycarbonate, polysulfone, PEEK, Hytrel®, Pebax®, and the like. The petcock **804** and petcock handle **808** can be fabricated from the same materials as the knob **814**, or it can be different materials. The jackscrew body **816** can be fabricated from the same materials as the hub body **802**, or from different materials, but must be able to be strongly affixed to the outer tube **710**.

FIG. **9** illustrates a side view, in partial breakaway, of an embodiment of a distal end **900** of an articulating transseptal punch with any stylets removed. The distal end **900** comprises the outer tubing **710** further comprising the lateral partial slits **716** and the intermediate (or inner) tubing **720** further comprising the longitudinal slit **726** and the distal tip **730**. A weld **902** affixes the distal end of the outer tubing **710** to the connected side **732** of the intermediate tubing. The distal end **900** can further comprise one or more separate radiopaque markers **904**.

Referring to FIG. **9**, outer tube **710** and the intermediate tubing **720** are rotated about the longitudinal axis such that the connected side **732** of the intermediate tube **720** is generally aligned with, and affixed or welded **902** to, the outer tubing **710** on the side comprising the partial lateral slits **716**. The width of the partial lateral slits **716**, the T-slots **718**, and the longitudinal slot **726** can range from about 0.001 to about 0.050 inches with a preferred range of about 0.005 to about 0.020 inches. In the illustrated embodiment, the slits **716**, **718**, and **726** are about 0.010 inches. The width of the partial lateral slits **716** on the outer tube **710** can be used, in compression to provide at least some limit to how much the outer tube **710** can bend in compression along the side comprising the partial lateral slits **716**. Note that the intermediate tube **720** extends beyond the distal end of the outer tube **710**. In the illustrated embodiment, the intermediate tube **720** extends about 10 mm to about 20 mm beyond the distal end of the outer tube **710**. This construction provides for reduced device complexity, increased reliability of operation, and reduced manufacturing costs relative to other steerable devices. The system also provides for high stiffness when the distal end **900** is straight, as illustrated, curved as in FIG. **11**, or curved, bent, deflected, steered, or otherwise deformed in any configuration between straight and maximally curved. The articulating trans-septal punch is necessarily stiff, has high column strength, and has significant resistance to bending from external sources because it needs to force an incision through tissue at the end of a very long, 2 to 4 foot length, of very small diameter punch tubing. Thus, the all-metal tubing punch can translate forces from its proximal end to its distal end that a polymeric catheter could not come close to equaling. Catheters carrying such a punch would be less effective for the specific purpose of transseptal puncturing than would the articulating trans-septal needle.

The distal end **900** of the articulating trans-septal punch is generally fabricated from metals with sufficient radiopacity or radio-denseness that they are clearly visible under fluoroscopic or X-ray imaging. However, if this is not the case, additional radiopaque markers **904** can be affixed to the outer tube **710**, the inner tube **720**, or both. These radiopaque markers can comprise materials such as, but not limited to, tantalum, gold, platinum, platinum iridium, barium or bismuth compounds, or the like.

Close tolerances between the internal diameter of the outer tube **710** and the outside diameter of the inner tube **720**, ranging from a radial gap of between about 0.0005 inches to about 0.008 inches, depending on diameter cause the two tubes **710** and **720** to work together to remain substantially round in cross-section and not be ovalized, bent, kinked, or otherwise deformed. This is especially important in the flexible distal region comprising the partial lateral cuts **716** on the outer tube **710** and the longitudinal slot **726** in the inner or intermediate tube **720**. The two tubes **710** and **720** can be fabricated from the same materials or the materials can be different for each tube **710**, **720**. Materials suitable for tube fabrication include, but are not limited to, stainless steel, nitinol, cobalt nickel alloy, titanium, and the like. Certain very stiff polymers may also be suitable for fabricating the tubes **710**, **720** including, but not limited to, polyester, polyimide, polyamide, polyether ether ketone (PEEK), and the like. The relationship between the inner tube **720**, the outer tube **710**, and the slots **716**, **718**, **726**, **728** serve to allow flexibility and shaping in high modulus materials such as those listed above, which are not normally suitable for flexibility. The internal and external surface finishes on these tubes **710**, **720** are preferably polished or very smooth to reduce sliding friction between the two tubes **710**, **720** because of their very small cross-sections and their relatively long lengths. Lubricants such as, but not limited to, silicone oil, hydrophilic hydrogels, hydrophilic polyurethane materials, PFA, FEP, or polytetrafluoroethylene (PTFE) coatings can be applied to the inner diameter of the outer tube **710**, the outer diameter of the inner tube **720**, or both, to decrease sliding friction to facilitate longitudinal relative travel between the two tubes which is necessary for articulating the flexible, slotted region near the distal end **900** of the articulating transseptal sheath. The exterior surface of the outer tube **710** can be covered with a poly-

meric layer, either substantially elastomeric or not, which can cover the slots **716**, **718**, etc. and present a smoother exterior surface to the environment. The exterior surface can be affixed or configured to slip or slide over the exterior of the outer tube **710**.

The weld **902** affixes the outer tube **710** to the intermediate or inner tube **720** such that they cannot move relative to each other along the longitudinal axis at that point. However, since the two tubes **710**, **720** are affixed to each other on the side of the outer tube **710** containing the partial lateral slots or gaps **716**, compression or expansion of those gaps **716** can be accomplished by moving the weld **902** by relative movement of the inner tube **720** and the outer tube **710**. The weld transmits the force being carried by the connected side **732** of the inner or intermediate tube **720** to the slotted side of the outer tube **710**. Note that the terms intermediate tube **720** and inner tube **720** are used interchangeably, by definition. The inner tube **720** becomes an intermediate tube **720** if another tube or catheter is passed through its internal lumen **724**.

In other embodiments, since the inner or intermediate tube **720** is split **726** lengthwise in the flexible region, a portion, or the entirety, of the distal end of the intermediate tube **720** can be affixed, adhered, welded, fastened, or otherwise attached to the outer tube **710** and functionality can be retained. The distal end **730** of the intermediate tube **720** can, in some embodiments be retained so as to create a cylindrical distal region **730** in the intermediate tube **720** and this entire cylindrical distal region **730**, or a portion thereof that does not project distally of the distal end of the outer tube **710** can be welded to the outer tube **710** around a portion, or the entirety of the circumference of the outer tube **710**. If only a portion of the inner tube **720** is welded to the outer tube **710**, then the weld is beneficially located, approximately centered, on the side of the outer tube **710** comprising the partial lateral slots **716**. The cylindrical distal region **730** is a beneficial construction, rather than completely cutting the inner tube **720** away on one side, since the distal region **730** projects distally of the distal end of the outer tube **710** to form the tip of the punch further comprising a sharpened tip **1102**, **1302** configured to punch through myocardial tissue (refer to FIGS. **11** and **13**).

In some embodiments, one of the welds, all of the welds, or a portion of the welds can be completed using techniques such as, but not limited to, TIG welding, laser welding, silver soldering, fasteners, adhesives, plasma welding, resistance welding, interlocking members, or a combination thereof. Laser welding is beneficial because it is highly focused and can be located with high accuracy. These welds include the weld **902** at the distal end that connects the inner tube **720** and the outer tube **710** as well as the welds at the proximal end connecting the inner tube **720** to the hub and the outer tube **710** to the traveler of the jack-screw **816**.

FIG. **10** illustrates an oblique external view of an embodiment of the proximal end **800** of the steerable trans-septal needle comprising the outer tube **710**, the knob **814**, the hub body **802**, the arrow pointer **810** further comprising the pointed end **1004**, a stopcock body **1006**, the petcock **804**, the petcock handle **808**, and the Luer fitting **812** further comprising a locking flange **1002**.

Referring to FIG. **10**, the pointed end **1004** can be integrally formed with the arrow pointer **810**, or it can be affixed thereto. The arrow pointer **810** can be integrally formed with the hub body **802**, or it can be affixed thereto using fasteners, welds, adhesives, brazing, soldering, or the like. The stopcock body **1006** can be integrally formed with the hub body **802** or it can be affixed thereto using fasteners, welding, soldering, brazing, adhesives, threads, bayonet mounts, or the like. Referring to FIGS. **8** and **10**, the lumen of the Luer fitting **812** is operably connected to the through bore of the petcock **804** if the petcock **804** is aligned therewith (as illustrated), or the petcock **804** can be rotated about an axis to misalign the through bore of the petcock **804** with the Luer fitting **812** and prevent fluid flow or passage of solid material therethrough. The knob **814** can be round, shaped as a lever, it can comprise knurls, facets (as illustrated), or it can comprise a plurality of projections which facilitate grabbing and rotation by the user. Circumferential motion of the knob **814** about is longitudinal axis is preferably and beneficially smooth but with sufficient friction to maintain its position in any desired configuration.

FIG. **11** illustrates an embodiment of the distal end **900** of the articulating trans-septal needle in a curved configuration. The distal end **900** comprises the outer tube **710**, the intermediate tube **720**, the outer tube lumen **714**, the distal end of the proximal region of outer tube **712**, the distal end **730** of the intermediate tube **720** further comprising the sharpened distal tip **1102**, the plurality of outer tube longitudinal cuts or slots **718**, and the plurality of outer tube partial lateral cuts **716**.

Referring to FIG. **11**, the outer tube partial lateral cuts **716** represent spaces that close up when the side of the tube in which the lateral cuts **716** are located is placed in compression. Such compression is generated by pushing the outer tube **710** distally relative to the intermediate tube **720**. When the partial lateral cuts **716** gaps close, further compression is much more difficult because the outer tube **710** stiffens substantially when no further gap exists for compression. The composite structure, with the intermediate tube **720** nested concentrically inside the outer tube **710** is relatively stiff and resistant to kinking no matter what amount of curvature is being generated. Such stiffness is essential when using the articulating trans-septal needle to bend or steer another catheter such as a Mullins introducer, or other guide catheter.

Preferred radius of curvatures for the distal end can range from about 1 inch to about 6 inches, with a preferred range of about 2 inches to about 4 inches and a more preferred range of about 2.5 to about 3.5 inches for the purpose of puncturing the atrial septum. Even smaller radius of curvatures would be appropriate in, for example, the cerebrovasculature, the arteries of the heart, and the like. The radius of curvature need not be constant. In some embodiments, the proximal end of the flexible region can have the partial lateral cuts spaced more widely than those at the distal end of the flexible region, causing the distal end to bend into a tighter radius than, the proximal end of the flexible region. In other embodiments, the distal region can be less flexible than the proximal end of the flexible region.

The partial lateral cuts **716**, and the "T"-slots in the outer tube **710** are beneficially treated using etching, electropolishing, passivation, sanding, deburring, machining, or other process to round the external edges of the partial lateral cuts **716**. Thus, the edges are blunted or rounded so they are not sharp such as to cause the articulating trans-septal needle to dig, skive, or shave material from the inside of a polymer guide catheter since that is a primary benefit of using the articulating trans-septal needle rather than a pre-curved, non-articulating, trans-septal needle or other punch that, when advanced distally through a polymeric sheath, can scrape or skive material from the inner diameter of the sheath or introducer.

The distal end **1102** can be sharp in some embodiments but it can also be somewhat or completely blunted. In the

case of partially or completely blunted distal construction, the distal end can be operably connected to a source of electrical or radiofrequency (RF) energy and puncture holes can be created using the electrical or RF energy. The energy is carried by the intermediate tube **720**, which is preferably electrically insulated from the outer tube **710**, from the hub **900** into which electrical or RF energy can be applied to the distal tip **1102**.

FIG. **12**A illustrates a top view of another embodiment of an outer tube **1200** in the region of the distal, flexible section, wherein the outer tube **1200** comprises a plurality of partial lateral cuts or slots **1206** further comprising a dovetail **1202**. The dovetail **1202** creates a groove **1202** and further comprises a peg or projection **1204** that rides or is circumferentially constrained within the groove **1202** as long as the outer tube **1200** is neutrally forced, or forced in compression on the side of the partial lateral cuts or slots **1206**. The projection **1204** riding within the dovetail groove **1202** provides for torque resistance and torsional rigidity in the area of the dovetail **1202**.

FIG. **12**B illustrates a side view of the outer tube **1200** in the region of the distal, flexible section, wherein the outer tube **1200** comprises the partial lateral slots **1206**, the dovetail **1202** further comprising the projection **1204**, and the "T" slots **718**. The T-slots **718** are optional or they can be configured differently.

The punch can be used to create holes in various structures in the body. It is primarily configured to serve as an articulating or variable deflection Brockenbrough needle. However, the steerable punch can be used for applications such as transluminal vessel anastomosis, biopsy retrieval, or creation of holes in hollow organs or lumen walls. The punch can be used in the cardiovascular system, the pulmonary system, the gastrointestinal system, or any other system comprising tubular lumens, where minimally invasive access is beneficial. The punch can be configured to be coring or non-coring in operation, depending on the shape of the distal end and whether an obturator or the circular hollow end of the punch is used to perform the punching operation. In the coring configuration, a plug of tissue is removed using, for example, a cylindrical cutting blade at the distal end, while in the non-coring configuration, substantially no tissue is removed from the patient. The punch facilitates completion of transseptal procedures, simplifies routing of the catheters, minimizes the chance of embolic debris being dislodged into the patient, and improves the ability of the cardiologist to orient the punch for completion of the procedure. The punch of the present invention is integral and steerable. It is configured to be used with other catheters that may or may not be steerable, but the punch disclosed herein does not require external steerable catheters or catheters with steerability to be steerable as it is steerable or articulating on its own. The punch is capable of bending and unbending a practically unlimited number of times. The punch is especially useful with catheters that are not steerable since the punch comprises its own steering system.

The punch can be removed from the lumen of a catheter after it completes perforation of the hollow organ or vessel wall, through which it is placed, so as to maximize the size of said lumen and allow for advancement of devices such as diagnostic mapping catheters, ablation catheters, catheters to place atrial appendage closure devices, mitral valve repair devices, mitral valve replacement devices, annuloplasty rings, and the like. Without removal of the punch, the lumen is compromised and the capacity of the sheath to introduce catheters is reduced, given a certain outside diameter. Minimizing the outside diameter of the sheath is important in preventing a damaged fossa Ovalis. This device is intended for use with catheters and is not intended for use as integral to a catheter. This device steers itself and can steer a catheter but is not a replacement for a steerable catheter. For instance, an introduction sheath or guide catheter can be steered and bendable but if the trans-septal punch is not steerable and is pre-bent, advancement of the pre-bent trans-septal punch through the sheath or guide catheter and its obturator, steerable or not, will cause the sharp distal end of the trans-septal punch to shave or skive off debris or material from the inside diameter of the obturator of the sheath or guide catheter or the catheters themselves. This shaving or skiving can occur even when the trans-septal punch is protected by a central obturator, stylet, inner tube, or guidewire. Use of a steerable obturator does not help the situation because a pre-bent, trans-septal punch, advanced through a straight, steerable obturator will still shave off or skive material from the inside diameter of the obturator.

The steering mechanism disclosed herein in FIGS. **7**A & **7**B through-FIG. **11** can be used to steer other types of catheters, guide catheters, introducers, sheaths, guidewires, or even obturators that are placed within the aforementioned devices, with high degree of control over long lengths up to 250 cm or more while requiring less wall thickness and thus allowing for larger internal lumens than steerable devices of the prior art with the same outside diameter. Typical sheaths can have internal lumens with capacities of, for example, 6-Fr to 12-Fr and still maintain very thin walls of around 1-Fr. While smaller catheters or guide catheters with lumens in the range of about 2-Fr to 5-Fr can have even smaller wall thicknesses, depending on the materials used to construct the walls of the sheath. Some sheath constructions can comprise composite materials such as an inner tube fabricated from metal and an outer tube fabricated from metal with a polymeric exterior coating. The inner tube can further be coated with an interior liner of, for example PTFE, or other fluoropolymers (PFA, FEP), Parylene, Pebax®, Hytrel®, polyimide, polyamide, PET, or the like, to create certain reduced frictional properties, electrically insulating properties, or both. These coatings or liners can range in thickness from about 0.0001 to about 0.005 inches, with a preferred thickness range of about 0.0005 to 0.002 inches. Electrical insulating properties are important if electrically conductive catheters are inserted through one or more lumens of a guide catheter or introducer whose mechanical properties are derived from high strength materials such as, in certain embodiments, conductive metal. Electrical insulating properties are also important should the device itself be used for electrical purposes such as, but not limited to, RF Ablation, RF hole puncturing, RF coagulation, and the like.

The steering mechanism disclosed herein, comprising two or more nested axially elongate cylindrical tubes moving relative to each other only along the longitudinal axis, can provide a high degree of precision, repeatability, force, column strength, torsional control, and the like, in a configuration with extremely thin walls and large inside diameter (ID) to outside diameter (OD) ratio. One of the tubes comprises partial lateral cuts or complex lateral gaps and the other tube comprising a split running substantially the length of the flexible region. The disconnected side of the slit tube can be removed so that only a partially formed, connected side remains. However, in preferred embodiments, the disconnected side, which is actually retained at the distal end, is not removed but serves to fill space within the lumen of the outer tube **710** to prevent kinking, improve column strength, prevent lumen collapse and provide for guiding of central stylets or catheters. Prior art devices require greater

wall thickness, which reduces the size of the internal lumen relative to a given outside diameter, or they do not have the same degree of precise movement at the distal tip under control from the proximal end of the device.

FIG. **13** illustrates a side view of the distal end **900** of an articulating transseptal punch advanced through a central lumen **1312** of a dilator or obturator **1310** of a guide catheter **1314**. The articulating transseptal punch distal end **900** comprises the outer tube **710**, comprising the plurality of partial lateral cuts **716**, and the inner tube **720**, comprising a sharpened distal tip **1302**. The sharpened distal tip **1302** comprises a bevel **1304**, one or more facets **1308**, a point **1318**, and a rounded or blunted outside edge **1306**. The obturator **1300** further comprises the central lumen **1312**. The guide catheter **1314** further comprises a central lumen **1316**.

Referring to FIG. **13**, the guide catheter **1314** and its obturator **1310** are generally curved near the distal end. When the distal end **900** is advanced distally through the lumen **1312** of the obturator **1310**, scraping of the inner wall of the obturator **1310** is prevented by inclusion of a rounded edge **1306** of the distal end **1302** toward the outside of the curvature. The distal sharp end **1302** comprises a bevel **1304** to create a sharpened tissue punch with a point **1318**. The facets **1308** are optional but can be provided in numbers ranging from one to about 10. The bevel **1304** can be generated at a single angle, or with a complex curvature. In some embodiments, the bevel **1304** can be generated at an angle of about 20 to about 80 degrees from lateral to the axis of the tube with a preferred range of about 30 to about 60 degrees from lateral, and a most preferred range of about 40 to about 50 degrees. The point **1318** can be a point in three dimensions or in two dimensions, such as the point **1318** illustrated herein.

FIG. **14** illustrates the distal end **900** of an articulating transseptal punch further comprising a stylet **1400**. The stylet comprises the core wire **1402**, the proximal lock **1404** (not shown), a collapsing shield **1408**, and the rounded distal tip **1406**.

Referring to FIGS. **13** and **14**, the stylet **1400** is slidably and removably inserted through the central lumen of the inner tube **720** to assist with blunting the sharpened distal end. Stylets sufficiently small to fit through these central lumens of the inner tube **720** are generally quite small, having a diameter of about 0.012 to 0.015 inches and are necessarily very weak. They are subject to bending and kinking and cannot hide a sufficient amount of the distal pointed end **1302** to prevent damage to the inside of a polymeric guide catheter **1314** or its obturator **1310**. Because the inner tube **720** has a very thick wall relative to its overall diameter, a wire inserted through the central lumen of the inner tube **720** cannot protect or shield the distal end **1302** adequately. Thus, a regular stylet **1400** is only partially useful in preventing skiving material from the inside of the guide catheter **1314** or obturator **1310** unless it includes the collapsing shield **1408**. A radially collapsing feature **1408** of the obturator **1400** can be beneficial in protecting the distal end with more completeness than a non-collapsing version. The collapsing feature **1408** is collapsed radially, laterally, or diametrically by withdrawing the obturator **1400** inside the inner tube **720** and it expands on its own using self expansion under spring bias, shape memory recovery, or the like. The obturator **1400** can be fabricated from materials such as, but not limited to, stainless steel, nitinol, cobalt nickel alloy, titanium, and the like using methods such as cold rolling or tempering to achieve substantial spring conditions. In the illustrated embodiment, the collapsing shield feature **1408** is created by means of a split tube of spring stainless steel, comprising a plurality of slots or openings **1410** which are biased outward to create a bulge when unrestrained. The slotted tube shield **1408** is integral or affixed to the core wire **1402**. The amount of outward bulge of the shield **1408** is not large but is sufficient to substantially equal or exceed the wall thickness of the inner tube **720**.

In some embodiments, the outer tube **710** can be modified to adjust stiffness. It can be preferential to increase the resistance to bending moving distally to proximally on the outer tube **710**. This increase in bending resistance contravenes the tendency of the outer tube to bend more severely at the proximal end of the flexible region than in the distal region. It is possible to configure the bending so that the bend radius is approximately constant or such that a greater curvature (smaller radius of bending) is generated moving toward the distal end of the bendable region. The partial lateral slots **716** can be cut with reduced depth more proximally to increase the resistance to bending imparted by the outer tube **710**. The partial lateral slots **716** can be cut more narrowly in the more proximal regions to reduce the distance the slot **716** can close. The T-slots **718** can be reduced in length or removed in the more proximal regions of the flexible region of the outer tube **710**. Elastomeric bumpers or fillers can be added to some of the partial lateral slots **716** to reduce the amount the partial lateral slots **716** can compress. Once the partial lateral slots **716**, associated with the T-slots **718** have closed under bending of the outer tube **710**, further bending is resisted and is substantially arrested. By tailoring the width and spacing of the partial lateral slots **716**, a specific final curvature can be tailored for a given catheter.

FIG. **15**A illustrates an the outer tube **710** comprising the lumen **714**, the proximal tube wall **712**, the plurality of partial lateral slots **716**, the plurality of T-slots **718**, a short partial lateral slot **1502**, a slightly longer partial lateral slot **1504**, and a standard length lateral slot **716** but with a shortened T-slot **1506**.

Referring to FIG. **15**A, the most proximal partial lateral slot **1502** penetrates less than the standard partial lateral slots **716**. The second (moving distally) partial lateral slot **1504** is slightly longer than slot **1502** and therefore is more flexible in that region and requires less force to generate bending. The third partial lateral slot comprises the shortened T-slot **1506** which reduces the ability of the tubing to bend given a constant bending force.

FIG. **15**B illustrates the inner tube **720** comprising the lumen **724**, the proximal region **722**, the connected side **732**, the distal end **730**, the sharpened tip **1302**, and a beveled lead-in **1510** at the proximal end of the distal end **730**.

Since, during use of the steerable transseptal needle, the needle is advanced distally through an already placed introducer, sheath, or guide catheter, it is beneficial that the straight steerable transseptal needle be capable of advancing through any curvatures in the already placed introducer, sheath, or guide catheter. Thus. In certain embodiments, the bevel is oriented such that the pointed point of the sharpened tip **1302** is oriented toward the direction of bending. In this way, the steerable transseptal needle, when in its straight configuration, can be pushed against into the curved region of the introducer, sheath, or guide catheter and not have the sharp point dig into the wall of the introducer, sheath, or guide catheter. The side of the sharpened tip **1302** away from the sharp point can further be rounded somewhat to make it even more atraumatic and smooth so it can skate or sled along the curvature of the introducer, sheath, or guide

catheter without digging out any material from the wall of the introducer, sheath, or guide catheter.

Referring to FIG. **15**B, the proximal end of the disconnected region can be moved distally to increase the stiffness of the inner tube **720** in a specific region, generally the most proximal part of this distal, flexible region.

In certain preferred embodiments, it is beneficial that the inner tube **720** can sustain compression to generate bending of the outer tube **710** at the distal end back to straight after being curved and even to bend beyond straight in the other (or opposite) direction. In order to sustain compression, it is beneficial that the disconnected side **734** be separated from the connected side **732** at or near substantially the center or midpoint of the tubing. Depending on the width of the slot **726** separating the disconnected side **734** from the connected side **732**, the location of the slot can be offset from the midpoint but this is dependent on the wall thickness of the inner tube **720** and the angle of the slotting. In a preferred embodiment, interference exists between the disconnected side **734** and the connected side **732** such that the disconnected side and force transmitting member cannot move substantially inward, a situation that would have negative effects of obstructing the lumen, restricting fluid flow therethrough, trapping stylets or other catheters that need to move longitudinally therein, or buckling sufficiently to prevent application of longitudinal compression forces on the connected side **732**.

FIG. **16**A illustrates a lateral cross-sectional view an inner tube **720** nested inside an outer tube **710** and separated from the outer tube **720** by a radial gap **1602** in the flexible region of an articulating septal punch wherein the inner tube **720** is separated by a split or gap **726** into two approximately or substantially equal parts, a connected side **732** and a disconnected side **734**, approximately (or substantially) at the midline or centerline of the cross-section.

FIG. **16**B illustrates a lateral cross-sectional view an inner tube **720** nested inside an outer tube **710** and separated from the outer tube **720** by a radial gap **1602** in the flexible region of an articulating septal punch wherein the inner tube **720** is separated by a split or gap **726** into two substantially unequal parts, a connected side **732** and a disconnected side **734**, substantially offset from the midline or centerline of the cross-section.

Referring to FIGS. **16**A and **16**B, the disconnected side **734** is retained in close proximity to the outer tube **710** by its stiffness and its inability to deform such that the edges of the disconnected side **734** can pass beyond the edges of the connected side **732** and thus the two sides **732** and **734** are retained radially displaced from centerline. If the gap **726** were too large or either side **732**, **734** were small enough to fit within the edges of the other side, then displacement of one side toward the centerline and confounding of the off-center orientation of the connected side **732** or **734** would occur leading to buckling of the connected side **732** in compression and inability to straighten out a bent transseptal needle. Another problem might be loss of torqueability and predictability of the direction of bending. Both embodiments shown in FIGS. **16**A and **16**B maintain circumferential and radial orientation of the inner tube connected side **732** relative to the disconnected side **734** and promote high precision deflection of the distal tip.

In preferred embodiments, the radial gap **1602** is minimized and is retained between about 0.0005 to 0.002 inches when the needle is about 0.050 in outside diameter. Furthermore, the split or gap **726** should be as minimal as possible and in preferred embodiments can range from about 0.002 inches to about 0.015 inches with a gap of about 0.004 to 0.010 inches being most preferable.

The embodiments presented in FIGS. **7** through **16** describe a system that does not use pull wires or push rods. There are no side lumens required in either the outer tube or the inner tube. Such side lumens, as found in certain prior art catheters, require extensive cross-sectional area be used to surround the side lumens and take away from the potential area for the central lumen since the outside extent of the catheter is limited. The use of control rods or pull wires requires such as those in certain prior art catheters, retaining these structures along one side of the outer tube so it does not obstruct the lumen, which is needed for stylets, fluid injection, radiopaque dye injection, and the like. Side lumens or channels are necessary to retain a pull wire or control rod in the correct location so as to provide correct off center forces to bend the distal end. The side lumens are also necessary to keep the control rod or pull wires out of the central lumen which needs to remain open and substantially circular. The system disclosed herein, however, retains a high degree of column strength, maximum torqueability, the largest possible central lumen, and a very strong control and steering function or capability. Furthermore, the side lumens or channels are necessary to maintain spatial (rotational orientation) for the articulating distal end of the device. Without the side lumens or channels permitting axial slidability but generating radial retention, the pull wires or pushrods would be free to migrate around within the central lumen of the device and could bend the device in an unwanted direction. Long catheters or needles with relatively small cross-sectional areas are highly subject to torque and rotational misalignment and some method must be employed to retain the correct circumferential location of the articulating apparatus.

Furthermore, a pull-wire as used in prior art devices is incapable of generating compression against the distal end of the device so a pull-wire could not, under compression, move or articulate the distal end of the device. The pull-wire, under tension, can move or articulate the distal end and would require some sort of counterforce such as an opposing pull-wire, shape memory metal, or spring return biasing to move the distal end in the reverse direction. A pull-wire with a diameter of about 0.010 inches (0.0000785 square inches) would sustain tension loads of about 500,000 PSI, to generate a pull force of 40 pounds or 250,000 PSI to generate a pull force of 20 pounds, beyond the capability of most known metals or polymers. Forces exceeding 20 pounds can be necessary to cause bending and stiffening of a Brockenbrough needle to generate the appropriate column strength and bending resistance such that the fossa Ovalis can be penetrated by the needle. A unconstrained push-rod or control rod of almost any diameter will buckle under these types of loads and be unable to generate oppositional forces under compression to articulate the distal end in the reverse direction sufficiently to make the device clinically acceptable.

However, a tubular or cylindrical central control device can maintain its structure in compression, maintain circumferential location within the outer cylindrical, axially elongate tube, maintain precise control, maintain sufficient tensile strength to exert forces up to and exceeding 40 pounds, and maintain a central lumen larger than any other type of steerable device. The resistance to buckling occurs even when the inner tube is slotted longitudinally because the inner tube is constrained within the outer tube using very tight tolerances that will not let the inner tube bend out of its straight orientation, even under compression.

FIG. **17**A illustrates a lateral cross-sectional view of the shaft **1700** of a steerable needle or punch. The shaft comprises an outer tube **710** further comprising a lumen **1710**, a plurality of control rods **1702**, a plurality of control rod spaces **1706**, and a resultant central lumen **1712**.

Referring to FIG. **17**A, the control rods **1702** are slidably disposed within the lumen **1710** outer tube **710**, as well as relative to each other. The illustrated embodiment shows three control rods **1702**, which can also be termed push rods, pull rods, or linkages, all of which include the mechanical properties to be able to exert compression as well as tension, and optionally torque, on an object being controlled. In some embodiments, one or more of the plurality of control rods **1702** can serve as a control rod retainer and not be affixed to any specific item. The control rods **1702** are affixed at their distal end to the outer tube, distal to a region of increased flexibility or bendability relative to a more proximal region of the outer tube **710**. The plurality of control rods **1702**, are retained away from the resultant central lumen **1712** and substantially against the inner diameter of the outer tube **710** by the narrow spacing **1706**. The three control rods **1702** are configured to provide for steering, deflection, or articulation of the distal end of the steerable needle or punch about multiple axes. Each control rod **1702** can be moved independently, or in concert, along the longitudinal axis under the influence of different actuators, controllers, hydraulic actuators, electrical actuators, pneumatic actuators, levers, knobs, jackscrews, or the like.

The outer tube **710**, the control rods **1702**, or both, can be fabricated from materials such as, but not limited to, polyimide, polyamide, polyester, polyurethane, silicone, PEEK, PTFE, PFA, FEP, stainless steel, nitinol, titanium, cobalt nickel alloys, and the like.

FIG. **17**B illustrates a lateral cross-sectional view of another embodiment of the shaft **1712** of a steerable needle or punch. The shaft **1712** comprises an outer tube **710** further comprising a lumen **1710**, a plurality of control rods **1704**, a plurality of control rod spaces **1708**, and a resultant central lumen **1714**. The shaft **1712** further comprises an intermediate or inner tube **1716** which can serve as a keeper and as a fluid-tight barrier, or liner, to prevent the migration of fluids, gas or liquid, across so as to maintain the central lumen leak-free and fluid impermeable central lumen **1718**.

Referring to FIG. **17**B, the inner tube **1716** can be fabricated from materials such as, but not limited to, polyimide, polyamide, polyester, polyurethane, silicone, PEEK, PTFE, PFA, FEP, stainless steel, nitinol, titanium, cobalt nickel alloys, and the like. The wall thickness of the inner tube can range from about 0.0005 inches to about 0.010 inches, with a preferred range of about 0.0007 to about 0.005 inches. The inner tube **1716** can be affixed to the hub (not shown) at the proximal end and to the distal end of the outer tube **710**, either directly or through an intermediary structure which could include a bonding ring or at least one of the control rods **1702**.

FIG. **18**A illustrates a lateral cross-sectional view of another embodiment of the shaft **1800** of a steerable needle or punch. The shaft **1800** comprises the outer tube **710** further comprising a lumen **1810**, a control rod **1804**, a control rod retainer **1806**, guide, or keeper, a plurality of control rod spaces **1808**, and a resultant central lumen **1814**. The shaft **1800** further comprises an intermediate or inner tube **1716** which can serve as a keeper and as a fluid-tight barrier, or liner, to prevent the migration of fluids, gas or liquid, across so as to maintain a central lumen leak-free and fluid impermeable central lumen **1818**. A stylet **1812** is slidably disposed within the fluid impermeable central lumen **1818**.

Referring to FIG. **18**A, the control rod **1804** is slidably disposed within the lumen **1810** and retained against or near the internal wall of the outer tube **710** by the control rod retainer **1806**. The plurality of control rod spaces **1808** between the control rod **1804** and the control rod retainer **1806** are intentionally kept as small as possible without generating excessive friction that would hinder longitudinal relative movement between the control rod **1804** and the control rod retainer **1806**, as well as between the control rod **1804** and the outer tube **710**. In the illustrated embodiment, the plurality of control rod spaces **1806** are about 0.002 inches wide while the radial distance between the outer wall of the control rod and the inner wall of the inner tube is about 0.001 inches. These spaces could be increased up to, but not beyond, the point where the retaining function of the control rod retainer **1806** is defeated and the control rod **1804** can move laterally into the center of the lumen **1814**. The outer tube **710** is shown with a 0.050 inch OD and a wall thickness of about 0.006 inches with a range of about 0.001 to 0.020 inches. The control rod **1804** is illustrated with a wall thickness of about 0.008 inches but can range from about 0.001 to about 0.020 inches.

FIG. **18**B illustrates a lateral cross-sectional view of another embodiment of a shaft **1820** of a steerable needle or punch. The shaft **1820** comprises the outer tube **710** further comprising the lumen **1810**, two control rods **1822**, a control rod retainer **1806**, guide, or keeper, a plurality of control rod spaces **1824**, and a resultant central lumen **1814**. A stylet **1812** is slidably disposed within the central lumen **1814**.

Referring to FIG. **18**B, the control rod retainer **1806** can be affixed at the distal end of the outer tube **710**, it can be affixed at a hub (not shown), or it can be affixed to the outer tube at a point intermediate the hub and a bendable region in the outer tube **710**. In a preferred embodiment, the control rod retainer **1806** is affixed to the outer tube at one axial location only. In another embodiment the control rod retainer **1806** is not affixed to the outer tube or the inner tube, but rather rides loosely within the outer tube **710** held in place by the control rods **1822**. This structure applies to all the control rods and control rod retainers described within this specification.

The two control rods **1822** are affixed at their proximal end to a hub (not shown) or a control mechanism within a hub (not shown) allowing the control rods **1822** to be independently moved longitudinally, or axially, relative to the outer tube **710**, under manual or assisted control. Such assisted control includes, but is not limited to, rotational electric motors, pneumatic actuators, stepping motors, linear electric motors, hydraulic actuators, and the like and may further be controlled by computers, robotic devices, or other automated control systems. The two control rods **1822** can, in other embodiments, be one or both affixed directly to the hub, or through an intermediary member, such that any relative motion between the control rods and the outer tube is brought about by moving the outer tube by an actuator while the control rods, one or both, remain affixed to the hub, directly or through an intermediary member such as another tube, anchor, fastener, or the like. Affixation can be performed using methods and devices such as, but not limited to, welds, laser welds, silver solder, fasteners, adhesives, mechanical interlock, ultrasonic welds, or the like.

At the distal end, the control rods **1822** can be affixed directly to the outer tube **710** distal to a region of enhanced flexibility or through an intermediary such as a separate

tube, linkage, control rod, fastener, or the like. The control rods **1822** can be affixed at a same point or at different locations along the circumference or longitudinal axis of the outer tube **710**.

FIG. **18**C illustrates a side view of a control rod and keeper system **1850** comprising a c-cross-sectional shaped control rod **1804** and a c-cross-sectional shaped control rod keeper, guide, or retainer **1806**. This configuration is shown in lateral cross-section in FIG. **18**A. The control rod **1804** can extend or run substantially the entire working length of the steerable needle between a hub (not shown) and a region distal to any deflectable or steerable regions of the outer tube **710** (refer to FIGS. **18**A and **18**B). The control rod **1804** can also be configured to retain its C-shape only within the approximate region of a bendable or articulating region of the outer tube **710**. In other areas, proximal and distal to the bendable region, the control rod **1804** can be affixed or integral to a pusher rod, which can be solid or hollow, or other tubular structure. The control rod **1804** is affixed, or integral to a distal tubing extension **1854**, which can be optionally terminated with a sharp point, as shown, or with a rounded blunt end, with a tapered dilator, or the like. The distal tubing extension **1854** steps up, in the illustrated example, to a larger diameter at the point **1860**. The distal tubing extension **1854** can be integral, or affixed to the control rod **1804** or the control rod guide **1806** by a weld, adhesive bond, mechanical fastener, solder joint, brazing joint, or the like.

Referring to FIG. **18**C, the c-shaped control rod guide or retainer **1806** can be completely disconnected from the control rod **1804**, or it can be affixed at a point distal to the flexible region, at a point proximal to the flexible region, but not both proximal and distal. In other embodiments, the control rod retainer **1806** can be affixed to the outer tube **710** but not to the control rod **1804**. The control rod retainer **1806** serves the function of forcing the control rod **1804** laterally off-center to maintain off-center within the outer tube **710** and for filling the lumen of the outer tube **710** to prevent collapse of the lumen and kinking during articulation or bending.

FIG. **19**A illustrates a lateral cross-sectional view of another embodiment of a shaft **1900** of a steerable needle or punch. The shaft **1900** comprises the outer tube **710** further comprising the lumen **1910**, one or more "V" shaped control rod **1902**, a resultant central lumen **1910**. A stylet **1812** can be slidably disposed within the central lumen **1910**.

Referring to FIG. **19**A, the V-shaped control rod **1902** can be slidably disposed within the lumen **1910** of the outer tube **710** such that it can be axially displaced without substantial resistance, yet it is still constrained against substantial lateral movement due to the space restrictions within the lumen **1910**.

FIG. **19**B illustrates a lateral cross-sectional view of another embodiment of a shaft **1920** of a steerable needle or punch. The shaft **1920** comprises the outer tube **710** further comprising the lumen **1910**, one or more "U" shaped control rod **1922**, a resultant central lumen **1910**. The stylet **1812** can be slidably disposed within the central lumen **1910**.

Referring to FIG. **19**B, the U-shaped control rod **1922** can be slidably disposed within the lumen **1910** of the outer tube **710** such that it can be axially displaced without substantial resistance, yet it is still constrained against substantial lateral movement due to the space restrictions within the lumen **1910**.

Referring to all the control rods disclosed herein, these control rods can extend the entire length of the device from the hub or handle to a region distal to any flexible regions or regions of enhanced bendability in the outer tube. The control rods can also be affixed or integral to rods, tubing, or other structures extending part way through the device but not traversing the flexible regions or regions of enhanced bendability. The control rods can be affixed to the hub or handle by way of an anchor, weld, adhesive, mechanical interlock, actuator, or the like. The control rods can further comprise hinges or areas of substantially increased flexibility proximate one or both of the ends, proximal and distal.

FIG. **20**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2000** of a steerable needle or punch. The shaft **2000** comprises the outer tube **710** further comprising the lumen **1910**, one or more hollow, round control rods **2002**, the control rods further comprising a resultant central lumen **2004**. This arrangement does not leave room for a large diameter, round stylet but it does provide for a substantial lumen for fluid flow **1910** within the outer tube **710**.

FIG. **20**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2020** of a steerable needle or punch. The shaft **2020** comprises the outer tube **710** further comprising the lumen **1910**, one or more hollow, round control rods **2002**, and an off-center but full size stylet **1812**. This arrangement does provide for a lumen for fluid flow **1910** within the outer tube **710** and the stylet **1812** further provides the function of the control rod retainer, when the stylet **1812** is in place within the lumen **1910**.

FIG. **21**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2100** of a steerable needle or punch. The shaft **2100** comprises the outer tube **710** further comprising the lumen **1910**, a rectangular control rod **2102**, the control rod **2102** further comprising a central lumen **2104**. A round stylet can be retained within the lumen **2104** and it does provide for a substantial lumen **1910** for fluid flow within the outer tube **710**.

Referring to FIG. **21**A, the distal end of the control rod **2102** can be affixed to the outer tube **710** on one side or another thus generating some offset forces to bend the outer tube **710**.

FIG. **21**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2120** of a steerable needle or punch. The shaft **2200** comprises the outer tube **710** further comprising the lumen **1910**, and an I-Beam shaped control rod **2122**. A round stylet cannot be retained within the lumen **1910** but it does provide for a substantial lumen **1910** for fluid flow within the outer tube **710**, even greater than that for the embodiment shown in FIG. **21**A. Note that the edges of the control rods **2122** and **2102** in FIGS. **21**A and **21**B are rounded to provide a smoother fit within the lumen **1910**, but this rounding, or even part of it, is optional.

FIG. **22**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2200** of a steerable needle or punch. The shaft **2200** comprises the outer tube **710** further comprising the lumen **1910**, and a round, solid control rod **2202**. A round stylet (shown in FIG. **22**B) can be retained within the lumen **1910** by moving the control rod **2202** off-center and it does provide for a substantial lumen **1910** for fluid flow within the outer tube **710** but little control over the radial or circumferential position of the control rod within the outer tube **710** is provided.

FIG. **22**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2220** of a steerable needle or punch. The shaft **2220** comprises the outer tube **710** further comprising the lumen **1910**, and a round, hollow control rod **2222** further comprising a lumen **2204**. The stylet **1812** is retained within the lumen **2204** of the hollow control rod **2222**.

FIG. **23**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2300** of a steerable needle or punch. The shaft **2300** comprises the outer tube **710** further comprising the lumen **1910**, and a round, hollow control rod retainer **2302** further comprising a central lumen **2304** and a plurality of retainer grooves **2306**, and a plurality of control rods or pull wires **2308**. A round stylet (shown in FIG. **22**B) can be retained within the lumen **2304** but is left out of this illustration.

Referring to FIG. **23**A, the control rods or pull wires **2308** are illustrated as solid but can comprise structures such as, but not limited to, stranded, tubular, circularly braided, flat braided, continuous tubular, slotted tubular, or the like. The grooves **2306**, which can be termed channels, slots, or the like, are beneficially cut or formed into the exterior of the control rod retainer **2302**. In other embodiments, these grooves **2306** could be replaced by one or more off-center lumens (not shown) within the cross-section of the control rod retainer **2302**. The control rod retainer **2302** can be affixed at one or more points within the outer tube **710** or it can be free floating. The central lumen **2304** is capable of accepting another wire or control rod, a stylet, or fluid.

FIG. **23**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2320** of a steerable needle or punch. The shaft **2320** comprises the outer tube **710** further comprising the lumen **1910**, an arcuate or curved, c-shaped control rod retainer **2322** and an arcuate or c-shaped cross-section control rod **2328**. The control rod **2328** and the control rod retainer **2322** are separated by a plurality of gaps or spaces **2324**. A round stylet (not shown here but shown in FIG. **22**B) can be retained within the remaining lumen **2326**.

Referring to FIG. **23**B, the spaces **2324** between the control rod retainer **2322** and the control rod **2328** do not radiate from the center in a radial direction but rather at an angle from the radial direction. The spaces **2324** between the control rod retainer **2322** and the control rod **2328** are drawn at about 0.002 inches spacing but that spacing could be between about 0.0005 and 0.015 inches with a preferable spacing of between about 0.001 and 0.008 inches.

FIG. **24**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2400** of a steerable needle or punch. The shaft **2400** comprises the outer tube **710** further comprising the lumen **1910**, an arcuate or curved control rod **2402** which subtends approximately 270 degrees of circumference on the inside diameter of the outer tube **710**. A round stylet **1812** is illustrated as slidably, and removably, retained within the remaining lumen **1910** which is defined by the curvature in the center of the arcuate control rod **2402**.

Referring to FIG. **24**A, the arcuate control rod **2402** is retained against the side wall of the outer tube **710** by its shape, being greater than 180 degrees in circumference. Because the arcuate control rod **2402** is not a full 360 degree control rod, it will have somewhat increased bending and decreased resistance, relative to a fully circular control rod, to lateral forces imposed thereupon.

FIG. **24**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2420** of a steerable needle or punch. The shaft **2420** comprises the outer tube **710** further comprising the lumen **1910**, an arcuate or curved control rod **2428** which subtends approximately 180 degrees of circumference on the inside diameter of the outer tube **710**, along with an arcuate control rod retainer **2422** which further subtends approximately 180 degrees within the outer tube **710**. A plurality of slits, or slots, 2426 separate the control rod **2428** and the control rod retainer **2422**.

The control rod retainer **2422** of FIG. **24**B is smaller in wall thickness than that of the control rod **2428** to permit greater fluid flow rates therein and still keep the control rod **2428** against the inside wall of the outer tube **710** and offset from the centerline.

FIG. **25**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2500** of a steerable needle or punch. The shaft **2500** comprises the outer tube **710** further comprising the lumen **1910**, an arcuate or curved control rod **2502** which subtends approximately 180 degrees of circumference on the inside diameter of the outer tube **710**, along with an arcuate control rod retainer **2504** which further subtends approximately 180 degrees within the outer tube **710**. A plurality of slits, or slots, **2506** separate the control rod **2502** and the control rod retainer **2504**. This configuration is similar to that shown in FIG. **18**A except that the control rod **2502** and the control rod retainer **2504** subtend a greater arc than the device of FIG. **18**A and thus, the gaps **2506** are much smaller, in this case about 0.002 inches and leaving very little room for lateral displacement of the control rod **2502**. The outer tube **710**, as shown, is an 18 gauge tube with an outside diameter of about 0.050 inches and an inside diameter of about 0.038 inches. This diameter can change to suit the occasion but the concept of tight tolerances between the inner and outer structures is important in retaining alignment and off-center positioning.

FIG. **25**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2520** of a steerable needle or punch. The shaft **2520** comprises the outer tube **710** further comprising the lumen **1910**, an arcuate or curved control rod **2522** which subtends approximately 180 degrees of circumference on the inside diameter of the outer tube **710**, along with an arcuate control rod retainer **2524** which further subtends approximately 180 degrees within the outer tube **710**. A plurality of slits, or slots, **2526** separate the control rod **2522** and the control rod retainer **2524**. This configuration is similar to that shown in FIG. **25**A except that the control rod **2522** and the control rod retainer **2524** subtend a significantly reduced arc than the device of FIG. **25**A and thus, the gaps **2526** are much larger, in this case about 0.009 inches and leaving much more room for lateral displacement of the control rod **2522**. As in FIG. **25**A, the outside arc of the control rod **2522** and the control rod retainer **2524** is a close fit with the inside diameter of the outer tube **710**, having only a gap of about 0.001 inches. Since the materials used in all the elements can be metallic, friction from longitudinal relative translation is low and is not a major factor relative to the forces needed to bend the structure.

FIG. **25**C illustrates a lateral cross-sectional view of another embodiment of a shaft **2540** of a steerable needle or punch. The shaft **2540** comprises the outer tube **710** further comprising the lumen **1910**, an arcuate or curved control rod **2542** which subtends approximately 180 degrees of circumference on the inside diameter of the outer tube **710**, along with an arcuate control rod retainer **2544** which further subtends approximately 180 degrees within the outer tube **710**. A plurality of slits, or slots, **2546** separate the control rod **2542** and the control rod retainer **2544**. This configuration is similar to that shown in FIG. **25**B, with approximately the same slot width **2546**, except that the control rod **2542** and the control rod retainer **2544** comprise a significantly reduced outside diameter than the device of FIG. **25**B, and thus, the gap **2548** between the control rod **2542** and the inside diameter of the outer tube **710**, as well as that of the control rod retainer and the inside diameter of the outer tube **710** are much larger and leave much more room for lateral displacement of the control rod **2542** and the retainer **2544**.

FIG. **26**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2600** of a steerable needle or

punch. The shaft **2600** comprises the outer tube **710** further comprising the lumen **1910**. The shaft **2600** further comprises a plurality of solid control rods or wires **2602**, an intermediate or inner tube **2606**, and a stylet **1812**. The plurality of control rods or wires **2602** ride within the annulus **2610** comprised between the outside of the intermediate or inner tube **2606** and the inside of the outer tube **710**.

FIG. **26**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2620** of a steerable needle or punch. The shaft **2620** comprises the outer tube **710** further comprising the lumen **1910**. The shaft **2620** further comprises a plurality of hollow control rods or wires **2622**, an intermediate or inner tube **2606**, and a stylet **1812**. The plurality of control rods or wires **2622** ride within the annulus **2610** comprised between the outside of the intermediate or inner tube **2606** and the inside of the outer tube **710**. The hollow control rods or wires **2622** can be tubular in configuration and either solid wall or fenestrated, woven, braided, or the like.

Referring to FIGS. **26**A and **26**B, the inner tube **1606** restrains the control wires or rods **1606**, **2622** radially off-center but does not provide much resistance against circumferential misalignment.

FIG. **27**A illustrates a lateral cross-sectional view of another embodiment of a shaft **2700** of a steerable needle or punch. The shaft **2700** comprises the outer tube **710** further comprising the lumen **1910** and a solid, full diameter control rod **2702** that is slidably disposed or constrained within the lumen **1910** with adequate wall clearance such that minimal friction is encountered but maximum bracing against kinking of the outer tube **710** is provided.

FIG. **27**B illustrates a lateral cross-sectional view of another embodiment of a shaft **2720** of a steerable needle or punch. The shaft **2720** comprises the outer tube **710** further comprising the lumen **1910** and a plurality of solid, partial diameter control rods **2722** that are slidably disposed within the lumen **1910** with adequate wall clearance, and comprise gaps or space **2726** from each other, such that minimal friction is encountered but maximum bracing against kinking of the outer tube **710** is provided. The plurality of control rods **2722** can be hollow or solid. They can be fabricated from tubes, and filling the center, or from a round, solid bar. The central gap **2726** can be fabricated by slotting a tube or bar or by forming the two parts separately.

FIG. **28**A illustrates a lateral (side) view of a distal, deflectable region **2800** of a steerable needle or punch. The distal deflectable region **2800** comprises the outer tube **2802**, with a first plurality of radially directed, partial cuts or gaps **2804** oriented in a first direction, and a second plurality of radially directed partial cuts or gaps **2806** oriented in a second direction. The gaps **2802** and **2804** are formed in the wall such that not all cu **2802** cuts are grouped together but are, in at least one case, interleaved with the cuts **2804**. The distal deflect able region **2800** further comprises a first control rod **1802**, a second control rod **1804**, and a control rod retainer or keeper **1806**, each separated by a plurality of slots **1810**. The deflectable region **2800** further comprises the first weld **2814** and the second weld **2812**.

Referring to FIG. **28**A, the two control rods **1802** and **1804** are able to separately apply off-center forces on the outer tube **2802** and, due to the selective ability of the outer tube to bend in the first and second directions, cause the outer tube to flex or articulate in these two directions. The stability of the control rod **1802** allows the second control rod **1804** to flex the tube without closing or opening the gaps **2804** but instead closing or opening the gaps **2806**. The same condition is true for the control rod **1804** stabilizing longitudinal movement of the outer tube against opening or closing of the gaps **2806** in a specific direction so that the control rod **1802** can flex the outer tube in the direction of the gaps **2804**.

The control rods **1802** and **1804** can be separately affixed to the outer tube **2802** distal to the articulating region or they can be affixed together and to the outer tube **2802** distal to the articulating region. The control rods can be affixed together, to the outer tube, or to an intermediary structure such as another tube using methods such as, but not limited to, welding, soldering, fasteners, mechanical interlock, adhesive bonding, and the like. In the illustrated embodiment, the first control rod **1802** is affixed to the outer tube by the first weld **2814** and the second control rod **1804** is affixed to the outer tube by the second weld **2812**. These welds **2812**, **2814** can preferably be laser welds or silver soldered joints although the other listed methods can also be used.

FIG. **28**B illustrates a cross-section **2820** of the tubing **2800** in the distal articulating region as viewed in the direction shown. The cross-section **2820** comprises the outer tube **2802**, the central lumen **1808**, the first control rod **1802**, the second control rod **1804**, the control rod retainer **1806**, and the plurality of gaps **1810**.

FIG. **29**A illustrates a lateral (side) view of a distal, bi-directionally deflectable region **2900** of a steerable needle or punch. The distal bi-directionally deflectable region **2900** comprises a first outer tube region **2906**, with a first plurality of radially directed, partial cuts or gaps **2916** oriented in a first direction, a second outer tube region **2904** comprising and a second plurality of radially directed partial cuts or gaps **2914** oriented in a second direction. The cuts or fenestrations **2914** and **2816** are formed in the wall such that all cuts or gaps **2914** or **2916** are grouped together in their respective outer tube regions **2904** and **2906**. The distal deflect able region **2900** further comprises a first control rod **1802**, a second control rod **1804**, and a control rod retainer or keeper **1806**, each separated by a plurality of slots **1810**. The deflectable region **2900** further comprises the first weld **2908** and the second weld **2910**, which are located at different axial locations along the tubing. The distal end of the outer tubing **2918**, located axially distal to the deflectable region, is terminated distally by a sharp point **2920** and affixed to one or more of the control rods **1802**, **1804**, the control retainer **1806**, the distal-most outer tube **2926**, or one or more of these by a fixation point, arc, or ring **2922**, which can be a weld, adhesive bond, solder joint, mechanical fastener, integral fabrication, intermediary structure or the like.

Referring to FIG. **29**A, the two control rods **1802** and **1804**, affixed to the outer tube at different locations immediately distal to their respective articulating regions **2904**, **2906** by welds **2910** and **2908**, are able to separately apply off-center forces on the outer tube regions **2904** and **2906** and cause the outer tube to flex or articulate in these two directions within their specific locations **2906**, **2904**. The stability of the control rod **1802**, in both compression and tension, allows the second control rod **1804** to flex the **2906** tube without closing or opening the gaps **2914** but instead closing or opening the gaps **2916**. The same condition is true for the control rod **1804** stabilizing longitudinal movement of the outer tube against opening or closing of the gaps **2916** in a specific direction so that the control rod **1802** can flex the outer tube in the direction of the gaps **2914**.

The control rods **1802** and **1804** are separately affixed to the outer tube distal to their respective articulating. The control rods can be affixed to the outer tube, or to an

intermediary structure such as another tube using methods such as, but not limited to, welding, soldering, fasteners, mechanical interlock, adhesive bonding, and the like. In the illustrated embodiment, the first control rod **1802** is affixed to the outer tube by the first weld **2910** and the second control rod **1804** is affixed to the outer tube by the second weld **2908**. These welds **2908**, **2910** can preferably be laser welds or silver soldered joints although the other listed methods can also be used.

FIG. **28**B illustrates a cross-section **2950** of the tubing region **2904** in the distal articulating region as viewed in the direction shown. The cross-section **2950** comprises the outer tube **2904**, the central lumen **1808**, the first control rod **1802**, the second control rod **1804**, the control rod retainer **1806**, and the plurality of gaps **1810**.

FIG. **30**A illustrates a lateral (side) view of a distal, bi-directionally deflectable region **3000** of a steerable needle or punch. The distal bi-directionally deflectable region **3000** comprises an outer tube **3006**, with a plurality of radially directed, partial cuts or gaps **3008** oriented in a first direction, and further comprising a distal end **3010**. The distal region **3000** further comprises a hollow tubular control rod **3002**, a central lumen **3004**, a distal weld **3016**, a tubing extension **3012** optionally terminated by a sharp point **3014**, and a hinge region **3020** created, in this embodiment, by a cut **3018** in the control rod **3002**.

Referring to FIG. **30**A, the cuts or fenestrations **3008** are formed in the wall such that all cuts or gaps extend and transect approximately 50% of the diameter of the tube. This transection or cut can range from about 10% to about 90% of the diameter with a preferred range of about 30% to about 70% of the diameter. The transaction can be a simple cut with a rounded end, as illustrated, it can have substantially no rounding, or it can comprise T-slots at the end to facilitate bending depending on the strength of the material and resistance to bending. The transection can comprise a width of about 0.001 to about 0.020 inches with a preferred range of about 0.005 to about 0.015 inches and a most preferred range of about 0.007 to about 0.012 inches. The control rod **3002** can be affixed to the distal-most outer tube **3010**, distal to any flexibility enhancing features such as the transections **3008**, by a fixation point, arc, or ring **3016**, which can be a weld, adhesive bond, solder joint, mechanical fastener, integral fabrication, intermediary structure or the like.

This configuration retains the internal lumen as mostly fluid-tight and leak free, except in the region of the hinge cutout **3018** in the control rod **3002**. To prevent leakage through the slots **3008** from the slot **3018**, a pressure shroud **3018** is affixed around the exterior of the outer tube. This pressure shroud can comprise, for example, a shrink wrapped or bonded tube of polyester, polyurethane, PTFE, **1**-EP, PFA, or the like. The wall thickness of the pressure shroud **3018** can range from about 0.00025 inches to about 0.010 inches with a preferred range of about 0.0005 to about 0.005 inches and a most preferred range of about 0.0007 to about 0.002 inches.

The central lumen **3004** is capable of serving as a leak-free channel for infusion and withdrawal of fluids, both liquid and gas, and can serve as a pressure monitoring lumen, for example, without concern for migration of materials out of, or into, the sides of the device.

The hinge **3020**, generated by cutting a notch **3018** in the control rod **3002** is optional. The hinge **3020** could also be fabricated using more standard hinge construction comprising a pin and loops or by the inclusion of materials of elastomeric nature to permit flexing.

FIG. **30**B illustrates a cross-section **3050** of the tubing region **3006** in the distal articulating region as viewed in the direction shown. The cross-section **3050** comprises the outer tube **3006**, the central lumen **3004**, the hollow control rod **3002**, and the gap **3522** between the control rod **3002** and the outer tube **3006**.

Referring to FIG. **30**B, the gap **3522** needs to be enough to prevent binding of the control rod **3002** against the outer tube **3006** during bending. The gap **3006** can be sized radially between about 0.001 and 0.025 inches with a preferred gap of about 0.005 to about 0.020 inches, with a most preferred gap of about 0.010 to 0.015 inches.

FIG. **31**A illustrates a side view, in partial breakaway, of the distal end of a steerable transseptal needle **3100** comprising an outer tube **3112**, an inner tube **3106**, further comprising a lumen **3108** and a blunted distal end **3110**, a stylet **3102** further comprising a sharp, pointed, distal end **3104**, which is shown retracted inside the lumen **3108**, a control rod **3114**, and a keeper or stay **3116**.

Referring to FIG. **31**A, the sharp tip **3104** can be formed integrally to the stylet **3102**. The sharp tip **3104** can be conical and be sharpened to angles ranging from about 10 degrees to about 60 degrees from the longitudinal axis, per side. The blunted distal end **3110** of the inner tube **3106** can comprise a full round approximately equal to the wall thickness, a taper, a chamfer, or the like. The inner tube **3106** is small in diameter and is difficult to make completely non-sharp but it is blunted to the extent possible. The control rod **3114** is illustrated and extends within the bendable region of the steerable transseptal needle. Sufficient space can exist around the stylet shaft **3102** and within the lumen **3108** to permit fluids to be injected and withdrawn or pressure measurements to be taken. In another embodiment, the stylet wire shaft **3102** can comprise one or more longitudinal slots (not shown) to increase fluid flow area therethrough. The stylet wire or shaft **3102** can also have a star shaped cross-section, a C-shaped cross-section, or the like. The sharp tip **3104** is retracted sufficiently inside the blunted end **3110** that there is no risk of unwanted tissue or guide catheter shaft puncture or damage while the steerable transseptal needle is being advanced or positioned.

FIG. **31**B illustrates a side view of the distal end of the steerable transseptal needle **3100** with the stylet **3102** advanced beyond the blunted distal end of the inner tube **3110** to expose the sharp tip **3104**. The steerable transseptal needle comprises the outer tube **3112**, the inner tube **3106** with the blunted distal end **3110**, the stylet **3102**, shown advanced, further comprising the sharp, pointed, distal end **3104**, the control rod **3114**, and the keeper or stay **3116**.

Referring to FIG. **31**B, the sharp tip **3104** is advanced sufficiently to provide for a clean tissue puncture and so that the pierced tissue can ride over the stylet shaft **3102**, over the blunted distal end **3110**, and onto the outside of the inner tube **3106**. Projection of the inner tube **3106** beyond the outer tube **3112** is traditionally about 1.5 cm. This distal projection distance of the inner tube **3106** can be maintained so that the sharp tip **3104** projects beyond the 1.5 cm or the inner tube **3106** projection can be reduced so that the sharp tip **3104** is positioned at approximately 1.5 cm (or less) from the outer tube **3112**, when the stylet is fully advanced.

FIG. **32**A illustrates a side view, in partial breakaway, of the distal end of a steerable transseptal needle **3200** comprising the outer tube **3112**, the inner tube, **3106** further comprising the lumen **3108** and the blunted distal end **3110**, the stylet **3102** further comprising a neck down **3210** to a smaller diameter more proximal stylet shaft **3208**, the sharp, pointed, distal end **3104**, which is shown retracted inside the

lumen **3108**, the control rod **3114**, the keeper or stay **3116**, a radiopaque marker **3202** further comprising a radiopaque marker lumen **3204**, and a radiopaque marker retainer **3206**.

Referring to FIG. **32**A, the radiopaque marker **3202** can comprise materials such as, but not limited to, tantalum, platinum, gold, platinum iridium, or the like. The radiopaque marker **3202** is preferably affixed within the lumen **3108** but can, in other embodiments, be affixed to the exterior of the inner tube **3106**. The radiopaque marker **3202** can be affixed to the wall of the inner tube **3106**, as is, or the inner tube **3106** wall can be machined to create an increased diameter on the ID or a decreased diameter on the OD to accept the radiopaque marker **3202**. The radiopaque marker **3202** can be affixed to the inner tube **3106** by welding, adhesive bonding, swaging, a combination thereof, or the like. In an embodiment, the inner tube **3106** can be formed down to a smaller diameter after the radiopaque marker is installed to prevent the radiopaque marker from ever being dislodged.

FIG. **32**B illustrates a side, partial breakaway view of the distal end of the steerable transseptal needle **3200** with the stylet **3102** advanced to expose the sharp end **3104** distal to the distal end **3210** of the inner tube **3202**. The steerable transseptal needle **3200** comprises the outer tube **3112**, the inner tube **3106**, further comprising the lumen **3108** and the blunted distal end **3110**, the stylet **3102**, further comprising the smaller diameter more proximal stylet shaft **3208**, the sharp, pointed, distal end **3104**, which is shown advanced and exposed beyond the end of the inner tube **3106**, the inner tube lumen **3108**, the control rod **3114**, the keeper or stay **3116**, the radiopaque marker **3202** further comprising the radiopaque marker lumen **3204**, and the radiopaque marker retainer **3206**.

Referring to FIG. **32**B, the lumen **3204** of the RO marker **3202** is sufficiently large that the stylet wire **3102** can slidably project therethrough with no appreciable drag or binding. The RO marker lumen **3204** should be at least approximately 0.002 inches larger in diameter than the OD of the stylet shaft **3102**.

FIG. **33**A illustrates a side view, in partial breakaway, of the distal end of a steerable transseptal needle **3300** comprising all the elements of the steerable transseptal needle **3200** of FIGS. **323**A and **32**B, but wherein the sharp pointed end **3104** of the stylet **3102** is replaced by a beveled, sharp end **3302**. The beveled end **3302** can be angled at about 10 degrees to about 60 degrees from the longitudinal axis of the stylet wire **3102**. The beveled end **3302** can further comprise one or more facets, not shown.

FIG. **34**A illustrates a side view of a stylet hub **3400** comprising the proximal length of stylet wire **3102**, the hub body **3402**, further comprising a hub lumen **3416**, a male Luer taper **3414**, and a male Luer lock feature **3412**, a spring housing **3404**, a push cap **3406**, a wire retaining tube **3408**, a spring **3410**, an O-Ring **3418**, and an O-ring retainer **3420**. The stylet hub **3400** is shown with the push cap **3406** and its spring container retracted, as biased by the spring **3410**.

Referring to FIG. **34**A, the hub body **3402**, the spring housing **3404**, the cap **3406**, and the O-ring retainer **3420** can comprise plastic such as, but not limited to, polycarbonate, polysulfone, PEEK, PVC, ABS, or the like. The parts can be assembled using adhesive bonding, solvent bonding, ultrasonic welding, interference snap fits, or the like. The spring housing **3404** slides axially over the OD of the hub body **3402** and these two parts are not bonded together. The cap **3406** is affixed to the wire holding tube **3408** using adhesive bonding, a mechanical interference, or the like. The stylet wire **3102** can be affixed to the holding tube **3408** using laser welds, silver solder, crimping, mechanical fasteners, or the like. The O-ring **3418** prevents fluid leakage through the lumen **3416** into the interior of the spring housing **3404** where it could escape and cause patient hemorrhage. Air ingress through the lumen **3416** could also lead to an air embolism and thus needs to be prevented by this O-ring. The spring **3410** can be fabricated from materials such as, but not limited to, stainless steel, nitinol, titanium, cobalt nickel alloy, or the like. In the illustrated embodiment, the spring **3410** is an open coil, when relaxed, but could also be a leaf spring or other spring structure. The spring **3410** biases the hub **3400** to keep the stylet **3102** fully retracted except when activation is required. In the illustrated embodiment, the spring **3410** is fabricated from stainless steel and comprises an OD of 0.25 inches and a wire diameter of about 0.01 to 0.03 inches, with a preferred wire diameter of about 0.015 to 0.014 inches.

FIG. **34**B illustrates a side view of the stylet hub **3400** with the spring compressed and the push cap **3406** and its spring housing **3404** fully advanced to compress the spring **3410**. The stylet hub **3400** comprises the proximal length of stylet wire **3102**, the hub body **3402**, further comprising the hub lumen **3416**, the male Luer taper **3414**, and a male Luer lock feature **3412**, the spring housing **3404**, the push cap **3406**, the wire retaining tube **3408**, a the spring **3410**. The stylet wire **3102** is now advanced distally due to distal relative motion of the push cap **3406**.

FIG. **35**A illustrates a side view of a stylet hub **3500** comprising the hub body **3402** further comprising the Luer lock feature **3412**, the male Luer taper **3414**, an enlarged diameter grip **3504** around the male Luer lock feature **3412**, the spring housing **3404**, the push cap **3406**, and a safety clip **3502**.

Referring to FIG. **35**A, the safety clip **3502** resides within the depression created by the spring housing **3404** and the enlargement **3504**. The safety clip **3502** comprises a grip region and a c-shaped section that removably snaps around the barrel of the hub body **3402**. Thus, the C-shape comprise sufficient opening to permit easy attachment and release of the C-clip **3502** by grasping the grip region or handle. The safety clip **3502** prevents the user from advancing the spring housing **3404** and cap **3406** distally. Once the safety clip is removed, the spring housing **3404** and cap **3406** can move distally, under spring compression, to force the stylet shaft **3102** distally. The safety can comprise other structures that permit such a safety feature. Such safety features can comprise integral switches, control knobs, mechanical interlocks, or the like.

FIG. **35**B illustrates an oblique view of the stylet hub **3500**, comprising the spring housing **3404**, the Male Luer lock feature **3412**, the male Luer taper **3414**, and the removable safety clip **3502**. The threads forming the male Luer lock feature **3412** can be clearly seen. These threads interlock with threads on the flange of a female Luer lock connector to form a bayonet mount or screw mount to securely maintain attachment. When fully secured, the hub **3500** or **3400** are positioned precisely with relation to the hub **3500** or **3400** on the steerable transseptal needle (FIG. **36**), thus providing for precise locating and function of the stylet tip protrusion distance.

FIG. **36**A illustrates an exterior side view of a steerable transseptal needle **3600** with its distal end curved 90 degrees. The steerable transseptal needle comprises the stylet **3102** (not shown because it is retracted), the stylet hub **3500**, further comprising the stylet hub button **3404** and cap **3406**, the safety clip **3502**, the bendable region of the needle **900**, the steerable transseptal needle hub **800**, and the blunted distal end **3110**.

Note that the stylet hub **3500** can be released and removed from the hub **800** of the steerable transseptal needle **3600**. Although a Luer lock is shown as the preferred attachment, any type of quick connect can be used such as, but not limited to, mechanical fastener, bayonet mount, screw mount, or the like.

FIG. **36**B illustrates the steerable transseptal needle of FIG. **36**A with the safety clip **3502** removed but the activation button **3404**, **3406** on the stylet hub **3500** has not been advanced or depressed.

FIG. **36**C illustrates the steerable transseptal needle of FIG. **36**B with the activation button **3404**, **3406** on the stylet hub **3500** having been depressed and causing the stylet **3102**, and its sharp tip **3104**, to be exposed distally beyond the end **3110** of the inner tube.

In other embodiments, the stylet hub can comprise a quick release feature for the spring. In these embodiments, when a control button is pushed, an intermediate structure is engaged and forces the stylet shaft **3102** distally until a certain point is reached, wherein the intermediate structure is disengaged and the spring forces the stylet shaft **3102** proximally. This disengagement can result from mechanical action that spreads holding features apart sufficiently to release the stylet shaft **3102** and spring **3410**. The disengagement can also occur by means of a rotary intermediate device that turns such that the stylet shaft **3102** and spring **3410** lose engagement and are allowed to be biased proximally. In this embodiment, the stylet sharp tip **3104** is never advanced for very long and inadvertent advancement of the structure has less risk of causing damage to critical tissues because the sharp stylet tip **3104** retracts faster than a human can push the device forward.

In yet other embodiments, the hub of the steerable transseptal needle can comprise a side port that is operably connected to the central lumen of the steerable transseptal needle. This side port can be terminated with a female Luer lock and optionally a hemostasis valve or stopcock. This side port can be used to inject or withdraw fluids or to measure pressure while the piercing stylet system is in place and locked onto the proximal end of the steerable transseptal needle.

FIG. **37** illustrates a top view of a steerable transseptal needle hub body **3708** affixed to a three-way stopcock **3700**. The stopcock **3700** comprises a side port **3702** further comprising a lumen (not shown), which is operably connected to the other lumens of the stopcock through the petcock **3712**, which allows both the side port **3702** and the proximal through port **3710** to be operably connected to a central lumen (not shown) of the hub **3708**. The ends of the stopcock lumens are preferably female Luer lock ports, but could also be regular threaded mounts, quick connects, bayonet mounts, or the like. The piercing stylet hub **3500** is affixed to the Luer threads of the proximal through port **3710**.

FIG. **38** illustrates a side view of a faceted sharp distal end **3800** of a piercing stylet **3102**. Also illustrated in FIG. **38** are the outer tube **3106** and the blunted, generally laterally cut and rounded distal end **3110** of the outer tube. The number of facets can range from 1 to 10 or more with a preferred number of 2 to 4. Where the stylet tip is not faceted, it can comprise a simple cone or bevel as Illustrated elsewhere. The facets can be cut at an angle of between about 5 and about 45 degrees relative to the longitudinal axis of the stylet **3102**.

FIG. **39**A illustrates a side, partial breakaway view of a steerable transseptal needle comprising a piercing stylet **3900** further comprising a distal shaft **3902**, the sharp distal tip **3104**, a transition zone **3904**, a cutout or cutaway section **3908**, and a central shaft **3902**. The steerable transseptal needle comprises the inner tube **3106**, the outer tube **3112**, and the blunted distal end **3110** of the inner tube **3106**, and one or more, optional, fenestration, window, opening, or hole **3910**. The cutaway region **3908** can run the entire length of the stylet wire or it can terminate at a transition, as shown, to a substantially, completely rounded distal end **3902**. The cutaway region **3908** can project out the distal end of the inner tube **3106** or it can fully reside within the inner tube **3106** when retracted, extended, or both. The window **3910** can permit pressure measurement and fluid injection or removal therethrough when operably in communication with the cutaway region **3908**.

FIG. **39**B illustrates a lateral cross-section of a stylet wire **3900** configured to facilitate fluid flow or pressure measurement while the stylet wire **3900** is in place within the lumen of a steerable transseptal needle. The stylet wire **3900** has had its cross section reduced thus creating a half-moon shaped shaft and creating a half-moon shaped lumen **3908** within the inner tube **3106**. The cross-section can be half-moon shaped, as illustrated, or it can be C-shaped, S-shaped, D-Shaped, U shaped, or the like.

FIG. **40** illustrates a hub of a steerable transseptal needle safety piercing stylet wherein the hub of the stylet comprises a quick release to actuate, and then retract the stylet. The stylet hub **4000** comprises a push button **4002**, a first transmission arm **4004** further comprising a first magnet **4006**, a second transmission arm **4008** further comprising a second magnet **4010** and a catch **4030**, a stylet hub body **4012** further comprising a stop **4018**, a stylet wire **4016** and a return spring **4014**. The hub **4020** of the steerable transseptal needle further comprises an electrical connector **4022**, operably connected to the inner tubing **4024** or its anchor **4026**. The outer tubing of the needle is covered with an insulating jacket **4028**.

The stylet wire **4016** is affixed to the first transmission arm **4004**. First magnet **4006** is affixed to the first transmission arm **4004** and the second magnet **4010** is affixed to the second transmission arm **4008**. The return spring **4014** is operably connected to the first transmission arm **4004** to bias the first transmission arm **4004** proximally away from the second transmission arm **4008**. The first **4004** and second **4008** transmission arms as well as the spring **4014** reside with, and are radially constrained within a cavity within the stylet hub body **4012**. The spring **4014**, as well as the first and second transmission arms **4004** and **4008** can move longitudinally within the cavity of the stylet hub body **4012**. The spring **4014** is affixed at one end to the stylet hub body **4012** and to the second transmission arm **4008** such that the spring **4014**, at rest, is uncompressed and distal movement of the second transmission arm **4008** forces the spring **4014** into compression from which it wants to recover. The spring **4014** can also be used in tension using an alternative layout. The stop **4018** within the stylet hub body **4012** prevents unwanted distal motion of the second transmission arm **4008** because of the stop **4030** interferes with the catch **4030**. This interference forces the first and second transmission arms and their magnets **4006** and **4010** apart after a predetermined travel.

The magnets **4010** and **4006** can comprise materials such as, but not limited to, samarium cobalt, neodymium iron boron, iron, or the like. The magnets can comprise magnifier structures to optimize the magnetic fields. The magnets can be configured, in a preferred embodiment, so that opposite

poles come together to provide attraction between the magnets, or wherein like poles come together to provide for repulsive forces.

The electrical connector **4022** is integral or affixed to the anchor **4026** or it can be operably connected and affixed to another metal component, such as the jackscrew traveler (not shown). Application of electrical RF power to the electrical connector **4022** is in electrical communication with the inner tube **4024**. A separate ground wire can be applied to the patient. The electrical insulator jacket **4028** is optional but is preferably affixed around the outer tube for its full length or substantially so. Thus the inner tube **4024** ultimately receives the RF energy and is the component that can burn or cauterize tissue. The inner tube **4024** can be blunted, partially, or completely closed off at its distal end to render it maximally atraumatic.

FIG. **41** illustrates a steerable needle or axially elongate medical device **4100** comprising a hub **4112**, a fluid injection sideport **4102**, a stopcock **4104**, a first control rod **4106**, a second control rod **4108**, a proximal port **4110**, a piercing stylet **3500**, an outer tube **4114**, a control knob **4116** further comprising a pair of internal threads, an outer tube anchor **4118**, an inner fluid tube or sleeve **4120**, a second jackscrew traveler **4122**, a first jackscrew traveler **4124**, and an optional drive system **4126**.

Referring to FIG. **41**, the first control rod **4106** and the second control rod **4108** are slidably, axially movably, constrained within the outer tube **4114** and extend to or beyond the end of a distal bendable region of the outer tube **4114** (not shown). The outer tube is affixed to the outer tube anchor **4118**. The fluid-tight sleeve **4120** is a tube that is constrained within the first control rod **4106** and second control rod **4108**. The proximal end of the fluid tight sleeve **4120** is operably connected to the sideport **4102** and the proximal port **4110** and is affixed to the hub **4112**. The distal end of the fluid tight sleeve **4120** terminates at or near the distal end of the device **4100**. The hub **4112** is affixed or integral to the stopcock **4104**. The proximal end of the first control rod **4106** is affixed or integral to the first jackscrew traveler **4124** and the proximal end of the second control rod **4108** is affixed or integral to the second jackscrew traveler **4122**. The first jackscrew traveler **4124** comprises external threads that comprise a right hand helix. The second jackscrew traveler **4122** comprises external threads that comprise a left-hand helix. The control knob **4116** comprises distal and proximal extensions that further comprise internal threads configured to engage with the threads on the jackscrew travelers **4122** and **4124**. Thus, the distal threads on the control knob **4116** comprise a right hand helix and the proximal threads on the control knob **4116** comprise a left hand helix. The threads can, of course be reversed so that the proximal threads are right hand helices and the distal threads are left hand helices. The two control rods **4106** and **4108** and their jackscrew travelers **4124** and **4122** can also be controlled with separate control rod. However, the configuration illustrates provides for a push-pull arrangement that allows a single control movement to actuate the control rods for simplest operation. The actuator **4126** can comprise a stepper motor and controller, a geared actuator, hydraulic pistons, pneumatic pistons, linear motor, and the like.

FIG. **42**A illustrates a steerable medical device **4200**, in its straight, unarticulated configuration, comprising a hub **800**, a distal tip **4210**, a distal bendable region **4202**, a proximal bendable region **4204**, a non-bendable intermediate region **4206**, and a non-bendable proximal region **4208**.

Referring to FIG. **42**A, the inner control rods or rods and keepers (not shown) preferably run substantially at least the entire length of the bendable regions **4202**, **4204**, and the intermediate non-bendable region **4206**. The proximal bendable region **4204** comprises two T-slots which are configured so that the lateral cuts in the outer tube close down and increase flexural modulus in that area. The intermediate non-bendable region **4206** retains a high flexural modulus. The distal bendable region **4202** is configured with seven T-slots but this number can vary between 1 and 20 with a preferred number of between 4 and 15. The width of the laterally formed slots can be adjusted so as to maximize bending strength or flexural modulus. The T-slots in the proximal bendable region **4204** are approximately 0.005 inches wide but can range from about 0.001 inches to about 0.020 inches with a preferred range of about 0.001 to about 0.010 inches, in the case of a 0.050 inch outer tube outside diameter.

FIG. **43**A illustrates a steerable needle or catheter comprising a cutting stylet **4300**. The cutting stylet **4300** is illustrated with its cutting element retracted so as not to extend radially outward beyond the boundary of the cutting stylet **4300**. The steerable needle or catheter comprises the outer tube **4204**, the distal end of the inner tube **4208**, the distal tip **4210** of the inner tube **4208**, a cutting stylet tube **4302** further comprising a cutting stylet lumen **4318**, a proximal cutting stylet wire **4304**, a sharp cutting wire segment **4308**, a cutting stylet tube window **4316**, a cutting stylet wire distal end **4310**, a sharp distal tip **4314** of the cutting stylet tube **4302**, and a distal weld **4312**.

FIG. **43**B illustrates a steerable needle or catheter comprising a cutting stylet **4300**. The cutting element is illustrated as advanced or activated radially outward so as to cut a larger incision in tissue than is possible with an axially elongate stylet. The steerable needle or catheter comprises the outer tube **4204**, the distal end of the inner tube **4208**, the distal tip **4210** of the inner tube **4208**, the cutting stylet tube **4302** further comprising the cutting stylet lumen **4318**, the proximal cutting stylet wire **4304**, the sharp cutting wire segment **4308**, the cutting stylet tube window **4316**, the cutting stylet wire distal end **4310**, the sharp distal tip **4314** of the cutting stylet tube **4302**, and the distal weld **4312**.

The cutting wire **4304** is actuated by distal advance of the cutting stylet wire **4304** by actuation at the proximal end of the cutting stylet system **4300**. The weakened portion or segment **4308** selectively bends and the window **4316** assists in guiding weakened portion **4308** radially outward in a predictable direction. The cutting stylet system **4300** can be fabricated from stainless steel, nitinol, titanium, cobalt nickel alloy, or the like. The cutting stylet system **4300** can further comprise radiopaque markers to assist with visualization of its operation and extent of position and advancement.

The cutting stylet **4300** can be actuated radially outward and it can be retracted radially inward and stowed for subsequent maneuvers including advancement and withdraw from the patient.

FIG. **44**A illustrates the distal end of a steerable transseptal needle **4400** further comprising a cutting stylet tube **4402**, a window **4406** in the cutting stylet tube **4402**, an actuator element **4404** further comprising a sharp distal tip **4408**, at least one expandable sharp elements **4412** and **4414**, the steerable transseptal needle distal end **4210**, the distal tubing projection **4208**, and the outer tube **4204**. The control or actuator element **4404** is advanced and thus, the at least one expandable sharp elements **4412** and **4414** are not radially expanded because the distal end **4410**, to which they are attached is advanced distally.

The expandable sharp elements **4412** and **4414** can number from about 1 to about 10 with a preferred number of between about 2 and about 4. The expandable sharp elements **4412** and **4414** are affixed at their distal end to the distal tip **4410** or a length of tubing affixed thereto. The expandable sharp elements **4412** and **4414** are affixed, or integral, at their proximal end to the cutting stylet tubing **4402**. The expandable sharp elements can comprise malleable materials, spring biased materials, or shape memory materials. Materials of manufacture of the expandable sharp elements **4412** and **4414** can include but not be limited to, nitinol, titanium, stainless steel, tantalum, gold, platinum, platinum iridium, and the like, the latter four of which include enhanced radiopaque properties.

FIG. **44**B illustrates the distal end of the steerable transseptal needle **4400** further comprising the cutting stylet tube **4402**, the window **4406** in the cutting stylet tube **4402**, the actuator element **4404** further comprising the sharp distal tip **4408**, the expandable sharp elements **4412** and **4414**, the steerable transseptal needle distal end **4210**, the distal tubing projection **4208**, and the outer tube **4204**. The control or actuator element **4404** is retracted, thus pulling the distal end **4410** proximally and thus, the at least one expandable sharp elements **4412** and **4414** are radially expanded. The at least one expandable sharp elements **4412** and **4414** are configured with sharp exterior edges capable of cutting animal tissue.

The advantage of this system **4400** is that it cuts an incision in tissue and not a puncture hole. The incision is capable of superior healing to a puncture hole and is also capable of expanding to permit passage of larger instruments than would a puncture hole, especially in fibrous or scarred tissue.

FIG. **45** illustrates a steerable transseptal needle **4500** comprising the inner tube **4208**, the outer tube **4204**, and a piercing stylet system further comprising a core structure **4502**, a first cutting element **4506**, a second cutting element **4508** and at least one cutting edge **4510** disposed on the exterior of one or all of the cutting elements **4506** and **4508**. The cutting elements **4506** and **4508** are separated by the gap **4504** which permits movement of one cutting element **4506** in a direction different from that of the other cutting element **3508**.

There can be one cutting element, two cutting elements as shown, or more. Some or all of the cutting elements can comprise the sharpened edge **4510**. The cutting elements **4506** and **4508** can be fabricated from materials such as but not limited to, nitinol, stainless steel, nitinol, and the like. Nitinol elements can be superelastic or shape memory in performance.

The core structure **4502** translates longitudinally and slides within the inner tube **4208**. The core structure **4502** can be manipulated by a user since it extends from the proximal end of the steerable transseptal needle **4500** to the expandable cutting elements **4506** and **4508**. Retraction of the core structure **4502** can retract the cutting elements **4506** and **4508** within the inner tube distal end **4210** completely. Advancement of the core structure **4502** exposes the cutting elements **4506** and **4508** beyond the distal end **4210** and allows them to spring or move radially outward to cut an incision larger than the diameter of the core structure **4502**, itself. The core structure can comprise a solid wire, tubular, or other cross-section.

FIG. **46** illustrates the proximal end of a steerable transseptal needle **4600** comprising a hub **4602**, a power supply **4604**, a radiofrequency generator **4606**, a switch **4608**, a control knob **4610**, an inner tube **4622**, an outer tube **4624**, an insulating cladding **4612**, an adapter **4620** further comprising a side port **4614**, a stopcock **4616** and a proximal port **4618**.

The power supply **4604** can comprise batteries or it can be wired to an external source of electrical power. The radiofrequency (RF) generator **4606** is powered by the power supply **4604** by way of a bus (not shown) and can be turned on or off with the switch **4608**. The output of the radiofrequency generator **4606** can be monopolar or bipolar and is operably connected to the outer tube **4624**, the inner tube **4622**, or both. The insulating cladding **4612** surrounds the outer tube **4624** and can also surround the projecting part of the inner tube **4622** leaving a small region at the distal tip of the inner tube **4622** uninsulated so that the electrical energy can be applied to tissue for cutting or cauterizing purposes. In the case of a monopolar system, the patient can have an electrode affixed to their skin, usually on their back to form a closed circuit. The insulating cladding **4612** can be fabricated from materials such as, but not limited to, polyester, fluoropolymers, and the like. The steerable transseptal needle **4600** can be useful in cutting through scarred tissue that resists normal needle punctures. The power supply can be integral to the system **4600**, as illustrated, or it can be external and wired to inner **4622** or outer tube **4624** through a bus residing within the hub **4602**.

FIG. **47**A illustrates a piercing stylet **4700** comprising an axially elongate tube **4702**, a central lumen **4706**, a sharp distal tip **4710**, a radiopaque marker **4704**, distal side openings **4708**.

The radiopaque marker **4704** is encapsulated within the distal end of the stylet tubing **4702** to minimize the risk of being dislodged. The radiopaque marker **4704** can be welded, silver soldered, crimped, swaged, bonded, or otherwise fastened, to the stylet tubing **4702**. The side openings or windows **4708** comprise perforations that permit fluid communication between the central lumen **4704** and the exterior of the tubing **4702**. The radiopaque marker **4704** preferably resides distal to the one or more side windows **4708**. The radiopaque marker **4704** can comprise a cylindrical rod, or other geometric shape, of materials such as, but not limited to, platinum, tantalum, platinum iridium, gold, barium or bismuth compounds, and the like. The stylet tube **4702** can be swaged or crimped at its distal end to cover the radiopaque marker **4704**, to grip a depression in the radiopaque marker **4704**, or both, to prevent dislodgement of the radiopaque marker **4704** from the tube **4702**. The distal end of the stylet tube **4702**, following having been reduced in diameter, can be further welded to provide material for creating the sharp tip **4710**. The tube **4702**, the marker **4704**, or both, can be ground or otherwise formed into a sharp tip with, for example, a conic, a faceted trocar, a bevel, or the like.

Fluid injected through the central lumen **4706** can escape the central lumen through the side windows, ports, or fenestrations **4708**. Furthermore, the side windows **4708** can allow for pressure measurement by means of a pressure transducer operably connected to the central lumen **4706** at the proximal end of the stylet or another location.

FIG. **47**B illustrates the piercing stylet **4700** comprising the tube **4702**, further comprising the central lumen **4706** and a tubing wall **4712**, the hub **3500**, and one or more proximal windows **4714** to allow for fluid communication between into the piercing stylet central lumen **4702** from an exterior port (not shown), which can, for example, be affixed and operably connected to a hub (not shown) of a transseptal needle (not shown). The one or more windows **4714** can be formed into the tubing wall **4712** by standard machining

methods, such as, but not limited to, laser cutting, EDM, standard milling, photochemical etching, or the like.

Use of the system, as illustrated in FIGS. **47**A and **47**B, allows the central lumen of a transseptal needle to contain a large cutting or piercing stylet without compromising the ability to measure pressure, inject fluid or withdraw fluid from a patient. The radiopaque marker **4704** further permits the operator to visualize the distal-most cutting part of the system under fluoroscopy, which enhances the ability to prevent the system from cutting unwanted perforations in the patients anatomy.

FIG. **48**A illustrates a proximal end of a steerable transseptal needle **4800**, in partial side cross-section, wherein the steerable transseptal needle **4800** comprises an inner tube **4804**, an outer tube **4802**, a hub **4806**, a control knob **4808**, a jackscrew traveler **4810**, a spring **4812**, an O-ring **4814**, an O-ring retainer **4816**, an inner tube anchor **4818**, a hub to stopcock adapter **4820**, and a stopcock **4822** (not sectioned).

The jackscrew traveler **4810** comprises threads on its exterior that engage internal threads within the control knob **4808**. The jackscrew traveler **4810** is keyed such that it cannot rotate within the hub **4806**. Thus rotation of the control knob **4808** causes the jackscrew traveler **4810** to advance either proximally or distally. In the illustrated embodiment, the jackscrew traveler **4810** engages three threads within the control knob **4808**. Rotation of the control knob **4806** in a first direction causes the jackscrew traveler **4810** to advance distally. The outer tube **4802** is affixed to the jackscrew traveler and thus moves distally relative to the inner tube **4804**, which is affixed to the anchor **4818**, which is affixed to the hub **4806** and the adapter **4820**. Rotation of the control knob **4808** in a second direction causes the jackscrew traveler **4810** to move proximally relative to the inner tube **4804**. Since only three threads are engaged, once the jackscrew traveler **4810** moves three thread pitches proximally, its threads disengage from the threads of the control knob **4808**. Further rotation of the control knob **4808** does not result in any further proximal movement of the jackscrew traveler **4810**. Rotation of the control knob **4806** in the first direction, following thread disengagement, causes re-engagement of the threads of the jackscrew traveler **4010** to the threads of the control knob **4808**, coerced by the spring **4812**, which has become increasingly compressed by the proximal motion of the jackscrew traveler **4810**. This system is advantageous relative to a hard stop because the jackscrew traveler **4810** and control knob **4808** generate a large mechanical advantage that could rip the hub **4806** and the adapter **4820** apart in the situation where a hard stop, or motion limiter, is employed.

FIG. **48**B illustrates the proximal end of the steerable transseptal needle **4800**, in top view, wherein the steerable transseptal needle **4800** comprises the inner tube **4804**, the outer tube **4802**, the hub **4806**, the control knob **4808**, the hub to stopcock adapter **4820** further comprising the side port **4824** and a sealing cap **4826**, and the stopcock **4822** further comprising the proximal through port **4828**. The proximal through port **4828** and the side port **4824** are in fluid communication with each other but can be separated by the stopcock **4822**, as shown in the illustrated embodiment.

The steerable needle, in other embodiments, can comprise monitoring systems to measure, display, announce, record, or evaluate operating parameters of the steerable transseptal needle. In an embodiment, the steerable transseptal needle can comprise strain gauges to measure the force being applied by the user to bend the needle. A torque gauge can also be comprised by the system to measure torque being applied to the control knob or the torque being applied by the distal curvature movement. The strain gauge or torque gauge can be affixed within the hub or elsewhere within the steerable transseptal needle to measure compression or tension forces. This information can be displayed in the form of a readout device, such as a digital display of the force or torque. The number of turns can be counted and displayed by, for example, a Hall-Effect sensor, mechanical counter, or the like. In an embodiment, the force or toque can be correlated to the angle of deflection at the distal end, the number of turns applied to the control knob, or both. The readout can be digital or analog and can be affixed to the hub or can be wirelessly received and displayed on external equipment such as a smart phone, computer, tablet computer, panel display, or the like. The wireless technology can, for example, comprise Wi-Fi, Bluetooth®, or other standardized protocols. The human interface can, in other embodiments, comprise audible feedback such as a simple beep or tone, or it can be more sophisticated and provide information using language callouts such as force, turns, torque, or the like.

In operation, the system operates similarly to the standard steerable transseptal needle with a few exceptions. The procedure is to advance a steerable transseptal needle, with a tissue piercing stylet affixed in place, through a transseptal introducer that has already been placed. The steerable transseptal needle is articulated to generate the proper curve, as determined under fluoroscopic or ultrasound guidance. The steerable transseptal needle transseptal introducer assembly is withdrawn caudally out of the superior vena cava and into the right atrium of the heart. Proper location, orientation, tenting, and other features are confirmed. Radiopaque dye can be injected through the steerable transseptal needle to facilitate marking of the fossa ovalis or blood flow around the distal end of the steerable transseptal needle. Pressure measurements can also be taken through the lumen of the steerable transseptal needle to confirm tracings consistent with the right or left atrium of the heart. Once proper positioning has been confirmed, a safety is removed from the stylet hub and a button on the stylet hub is depressed or actuated to cause the sharpened stylet tip to advance out beyond the distal end of the steerable transseptal needle. This sharpened stylet punches through the fossa ovalis and the septal tissue pulls over the stylet, over the inner tube, and over the obturator or dilator of the transseptal introducer. At this point, the sharp stylet is released and retracts proximally within the steerable transseptal needle. The transseptal introducer is now within the left atrium of the heart and the steerable transseptal introducer can be withdrawn from the lumen of the obturator.

While the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. The elements of the various embodiments may be incorporated into each of the other species to obtain the benefits of those elements in combination with such other species, and the various beneficial features may be employed in embodiments alone or in combination with each other. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims

What is claimed is:

1. An apparatus adapted for punching a hole in a body lumen or hollow organ of a mammal comprising:

an outer tube having a proximal end, a distal end, a longitudinal axis, and a lumen extending therethrough;

an inner tube having proximal end, a distal end, a longitudinal axis, and a lumen extending therethrough, said

inner tube disposed within the distal end of the outer tube, with a portion of said inner tube projecting distally from the distal end of the outer tube;

a first control rod and a second control rod disposed within the lumen of the outer tube,

a plurality of laterally oriented slits extending partway into the outer tube within a bendable region but not completely transecting the outer tube;

a connection point between the first control rod and the outer tube such that the first control rod is affixed to the outer tube on a side of the outer tube comprising the laterally oriented slits and distally to the bendable region,

a connection point between the second control rod and the outer tube such that a distal end of the second control rod is affixed to the outer tube on a side of the outer tube opposite the laterally oriented slits and distally to the bendable region,

a needle hub affixed to the proximal end of the inner tube, wherein said needle hub comprises an internal lumen capable of receiving a control mechanism, wherein the outer tube is longitudinally constrained relative to the needle hub; and

the control mechanism is operable to tension one of (1) the first control rod or the second control rod and (2) the outer tube to the other of (1) the first control rod or the second control rod and (2) the outer tube.

2. The apparatus of claim **1** wherein said needle hub comprises a valve at its proximal end.

3. The apparatus of claim **1** further comprising a control rod retainer configured to maintain the first control rod and the second control rod off center within the lumen of the outer tube.

4. The apparatus of claim **3** wherein:

the first control rod and the second control rod have arcuate transverse cross sections, and the control rod retainer has an arcuate transverse cross section, and the first control rod and the second control rod and the control rod retainer are disposed between the outer tube and the inner tube.

5. The apparatus of claim **1** wherein longitudinal movement of the first control rod and the second control rod relative to the outer tube causes distortion of the outer tube in a region of the laterally oriented slits and results in selective bending of the outer tube and the first control rod and the second control rod in the region of the laterally oriented slits.

6. The apparatus of claim **1** wherein the first control rod is integral, or affixed to, the second control rod in a region distal to the bendable region.

7. The apparatus of claim **1** wherein the first control rod is not affixed to the second control rod in a region distal to the bendable region.

8. The apparatus of claim **1** wherein the first control rod and the second control rod are affixed to an intermediate structure, which is, in turn, affixed to a hub.

9. The apparatus of claim **1** wherein the first control rod and the second control rod are affixed to a distal length of tubing which extends distal to the outer tube.

10. The apparatus of claim **1** wherein the first control rod and the second control rod are affixed to a distal length of tubing which extends distal to the outer tube and is terminated in a sharp point.

11. The apparatus of claim **1** wherein the distal end of the outer tube can controllably curve between about 0 and at least about 60 degrees from the longitudinal axis.

12. The apparatus of claim **1** wherein axial advancement of the first control rod and the second control rod relative to each other and the outer tube curves the distal end of the apparatus.

13. The apparatus of claim **1** further comprising a pressure jacket disposed exterior to the outer tube wherein the pressure jacket prevents ingress or egress of fluid through the laterally oriented slits.

14. The apparatus of claim **1** further comprising an innermost tube, further comprising a proximal end, a distal end, and a lumen therethrough, disposed interior to the first control rod and the second control rod and preventing the ingress or egress of fluid from the interior lumen of the innermost tube.

15. The apparatus of claim **1** further comprising a removable obturator or stylet slidably disposed within a central lumen defined by the first control rod and the second control rod, wherein the obturator or stylet can be advanced forward out the distal end of the apparatus or it can be removed from the apparatus by withdrawal through the proximal end of the apparatus.

16. The apparatus of claim **1** wherein the first control rod and the second control rod are operably moved by electrical motors, pneumatic actuators, or hydraulic pistons.

17. The apparatus of claim **1** further comprising one or more radiopaque markers capable of enhanced visibility under fluoroscopy.

18. The apparatus of claim **1** wherein the first control rod and the second control rod comprise a substantially solid, semicircular cross-section, rather than being hollow, and C-shaped.

19. The apparatus of claim **1** wherein movement of the first control rod and the second control rod is determined by commands generated by a computer or robotic device.

20. The apparatus of claim **1** wherein the first control rod and the second control rod comprise a V-shaped lateral cross-section.

21. The apparatus of claim **1** wherein:

the first control rod and the second control rod are disposed between the outer tube and the inner tube.

22. The apparatus of claim **21** wherein:

the first control rod and the second control rod have arcuate transverse cross sections.

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