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An agency of Industry Canada

CA 2573181 C 2010/01/19

(11)(21) 2 573 181

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2005/07/13
(87) Date publication PCT/PCT Publication Date: 2006/01/19
(45) Date de délivrance/Issue Date: 2010/01/19
(85) Entrée phase nationale/National Entry: 2007/01/09
(86) N° demande PCT/PCT Application No.: CA 2005/001095
(87) N° publication PCT/PCT Publication No.: 2006/005188
(30) Priorité/Priority: 2004/07/13 (US10/890,364)

(51) Cl.Int./Int.Cl. *A61B 17/32* (2006.01), *A61B 17/125* (2006.01), *A61B 17/28* (2006.01), *A61B 18/02* (2006.01)

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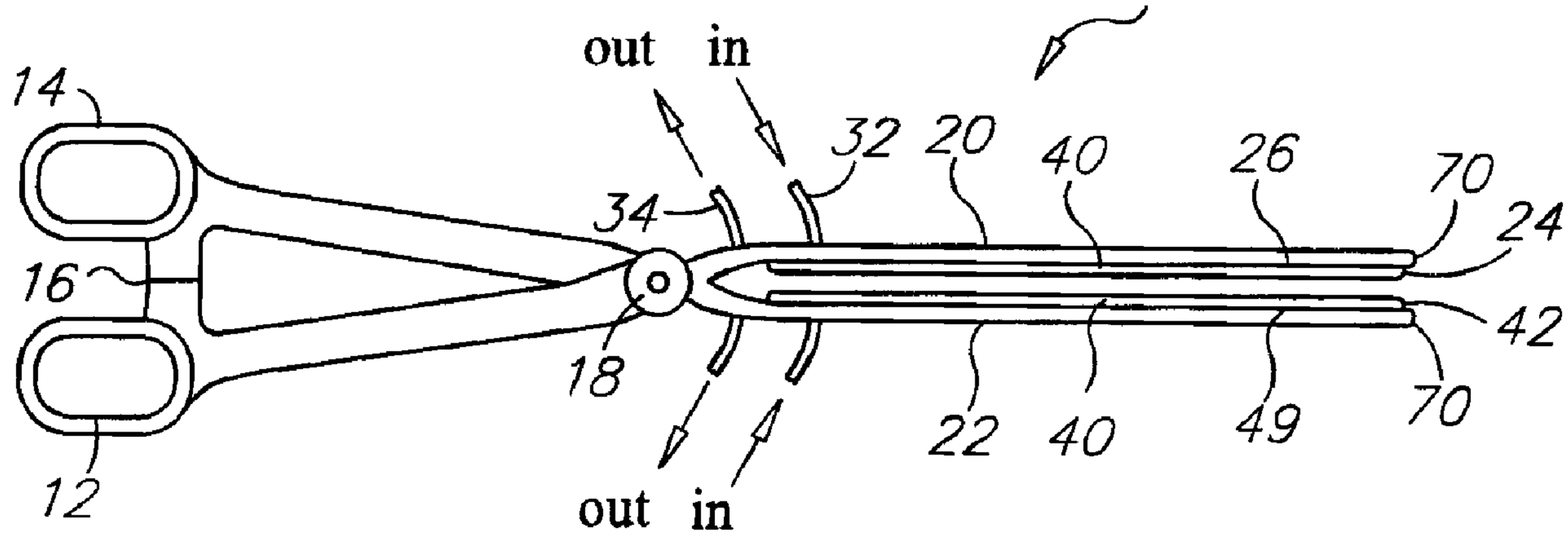
(54) Titre : PINCE CHIRURGICALE MINIMALEMENT INVASIVE COMPORTANT DES ELEMENTS DE TRAITEMENT
(54) Title: MINIMALLY INVASIVE SURGICAL CLAMP HAVING TREATMENT ELEMENTS



(57) Abrégé/Abstract:
A medical device is provided having a means for actuating a pair of opposing jaw members. The jaw members are movable relative to one another from a first position, wherein the jaw members are disposed in a spaced apart relation relative to one another, to a second position, wherein the jaw members cooperate to grasp tissue therebetween. An ablation tool is connected to at least one of the jaws members, such that the jaw members are capable of conducting ablation energy through the tissue grasped therebetween.

ABSTRACT

A medical device is provided having a means for actuating a pair of opposing jaw members. The jaw members are movable relative to one another from a first position, wherein the jaw members are disposed in a spaced apart relation relative to one another, to a second position, wherein the jaw members cooperate to grasp tissue therebetween. An ablation tool is connected to at least one of the jaws members, such that the jaw members are capable of conducting ablation energy through the tissue grasped therebetween.

MINIMALLY INVASIVE SURGICAL CLAMP HAVING TREATMENT ELEMENTS

FIELD OF THE INVENTION

The present invention relates to a method and system for ablating tissue, and more particularly to a medical device having a pair of opposing jaws used for tissue ablation.

BACKGROUND OF THE INVENTION

It is well documented that atrial fibrillation (AF), either alone or as a consequence of other cardiac disease, continues to persist as the most common type of cardiac arrhythmia. In the United States, AF currently affects an estimated two million people, with approximately 160,000 new cases being diagnosed each year. The cost of treatment for AF alone is estimated to be in excess of $400 million worldwide each year.

Although pharmacological treatment is available for AF, the treatment is far from perfect. For example, certain antiarrhythmic drugs, like quinidine and procainamide, can reduce both the incidence and the duration of AF episodes. Yet, these drugs often fail to maintain sinus rhythm in the patient. Cardioactive drugs, like digitalis, Beta blockers, and calcium channel blockers, can also be given to control AF by restoring the heart's natural rhythm and limiting the natural clotting mechanism of the blood. However, antiarrhythmic drug therapy often becomes less effective over time. In addition, antiarrhythmic drug can have severe side effects, including pulmonary fibrosis and impaired liver function.

Another therapy for AF is surgery. In a technique known as the "Maze" procedure, a surgeon makes several incisions through the wall of the atrium with a scalpel and then sews the cuts back together, creating a scar pattern. The scars isolate and contain the chaotic electrical impulses to control and channel the electrical signals. The Maze procedure is expensive, complicated to perform, and associated with long hospital stays and high morbidity.

An alternative to open heart or open chest surgery is a minimally invasive treatment in which ablation devices are used to form scars in various locations in the atrial tissue. Ablation devices that apply heat or cold to body tissue are known. Typically, these devices have an elongate, highly-flexible shaft with a steerable distal end for negotiating a path

through the body of a patient. Rigid shaft devices are used in more invasive procedures where a more local opening or direct access to a treatment site is available or created.

It is important to note that these devices are used in an attempt to ablate tissue through the full thickness of the cardiac wall, and thus create a risk associated with damaging structures within or on the outer surface of the cardiac wall. Accordingly ablation devices have been developed which include opposing jaw members to ablate tissue from both sides of the cardiac wall. For example, US Patent Nos. 6,161,543 to Cox; 5,733,280 to Avitall; and 6,517,536 to Hooven describe techniques for ablating tissue of organs or vessels having opposing walls and disclose ablation devices having clamping members to clamp a treatment site therebetween. Such devices include rigid members/shafts to facilitate reaching the tissue treatment site.

While rigid shafts may be useful in some applications, they have certain limitations as well. For example, without a preset shape for reaching a particular location in the body of a patient, the rigid nature of the shaft limits the area of tissue that can be reached and treated. Even where a relatively large incision is provided, tissue areas that are not at least somewhat directly accessible cannot be reached.

Although a rigid shaft can be provided with a predetermined shape, one must select a device with a rigid shaft that has the most appropriate shape for positioning the working portion of the device in contact with the treatment site in view of the particular anatomical pathway to be followed in the patient. It will be appreciated that a large inventory of devices having rigid shafts may be required to accommodate the various treatment sites and patient anatomies. As an example, U.S. Patent No. 6,161,543 to Cox el al. describes a variety of rigid probe shapes. Further, for a patient having a relatively uncommon anatomic configuration and/or a difficult to reach treatment site, all rigid devices of an existing set may have less than optimal shapes for positioning. This may impair the prospects of successfully carrying out the treatment procedure. For an ablation device which must bear against tissue at the remote region to create lesions, the contour followed by the device in reaching the target site will in general further restrict the direction and magnitude of the movement and forces which may be applied or exerted on the working portion of the device to effect tissue contact and treatment.

SUMMARY OF THE INVENTION

The present invention advantageously provides a surgical clamp having a pair of opposing jaw members that are movable relative to one another from a first position where

the jaw members are proximate each other thereby creating a minimally invasive insertion profile, to a second position where the jaw members cooperate to grasp tissue therebetween. A deflection mechanism remotely actuated from the handle assembly is coupled to a linkage assembly. The linkage assembly is operatively coupled to the jaws such that activation of the deflection mechanism serves to deflect the jaws in a substantially parallel motion with respect to each other. A remote unit controls the deflection mechanism.

In an exemplary embodiment, a medical device for ablating tissue is provided, having a pair of opposing jaws positionable from a first position to a second position, at least one of the opposing jaws including an ablation element, and a shaft assembly operable connected to the opposing jaws. The shaft assembly has a malleability such that the shaft assembly retains a first shape until manipulated to a second shape.

In another embodiment, a medical device for ablating tissue is provided, including a first jaw and a second jaw, where the first jaw includes a first jaw ablation tool having at least one first jaw ablation segment. A shaft assembly is also provided. The shaft assembly is operably connected to the first jaw and the second jaw, and is malleable such that the shaft assembly retains a first shape until manipulated to a second shape. The medical device also includes a handle assembly that is attached to the shaft assembly opposite the first jaw and the second jaw. The handle assembly is operably connected to the first jaw and the second jaw to move the first jaw and the second jaw from a first position to a second position.

In yet another exemplary embodiment, a medical device for ablating tissue is provided having a first jaw and a second jaw, the first jaw including a first jaw ablation tool configured to circulate cryogenic fluid therethrough and having at least one first jaw ablation segment. Also included is a shaft assembly operably connected to the first jaw and the second jaw. The shaft assembly has malleability such that the shaft assembly retains a first shape until manipulated to a second shape. The medical device further includes a handle assembly attached to the shaft assembly opposite the first jaw and the second jaw, where the handle assembly is operably connected to the first jaw and the second jaw to move the first jaw and the second jaw from a first position to a second position. An ablation control system is operably connected to the first ablation tool.

In another exemplary embodiment, a medical device is provided having an elongated shaft, a cooling element, and a second element movable with respect to the cooling element to define a clamp, wherein the movable element is selectively detachable from the shaft. This detachable feature would allow for ablating in two methods: firstly in a clamp made to ablate

tissue with two opposing walls, and secondly in a "wand" mode that would allow ablating from one surface only.

In an exemplary method, a method of ablating tissue includes the steps of: providing an ablating device having a pair of opposing jaws positionable from a first position to a second position, where at least one of said opposing jaws includes an ablation tool and a shaft assembly operable connected to the opposing jaws, the shaft assembly having a malleability such that the shaft assembly retains a first shape until manipulated to a second shape; manipulating the shaft assembly from the first shape to the second shape; positioning the opposing jaws in the first position such that the opposing jaws are in a spaced apart relation; placing the opposing jaws about the tissue to be treated; positioning the opposing jaws in the second position such that the opposing jaws grasp the tissue to be treated; and ablating the tissue to be treated.

In another exemplary method, a method for evaluating transmurality of a lesion is provided and includes the steps of positioning a first and a second jaw of an ablating device about tissue to be treated; applying a cooling element to at least the first jaw of the ablating element; and measuring temperature from a temperature sensor associated with the second jaw of the ablating device.

In still another exemplary embodiment, a medical device for ablating tissue is provided, having a first jaw and a second jaw, wherein at least one of the first jaw and the second jaw includes an ablation element. The device further includes a shaft assembly operably coupled to the first jaw and the second jaw, the shaft assembly having a malleability such that the shaft assembly retains a first shape until manipulated to a second shape, and a jaw actuation assembly operably coupled to the first jaw and the second jaw to move the first jaw and the second jaw selectively from a first position proximate each other to a second open position.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a plan view of a surgical clamp in accordance with the present invention;

FIG. 2 is a sectional view of an ablation segment of the surgical clamp of FIG. 1;

FIG. 3 is a sectional view of an ablation segment including multiple injection tubes of the surgical clamp of FIG. 1;

FIG. 4 is a sectional view of an ablation segment including orifices of the surgical clamp of FIG. 1;

FIG. 5 is a plan view of an alternative embodiment of the surgical clamp of FIG. 1;

FIG. 6 is a plan view of the surgical clamp of FIG. 1 including curved jaws;

FIG. 7 is a sectional view of an ablation segment including insulation sleeve of the surgical clamp of FIG; 1

FIG. 8 is a plan view of the surgical clamp of FIG. 1 including elongated shafts;

FIG. 9 is a sectional view of the elongated shaft and ablation segment of the surgical clamp of FIG. 8;

FIG. 10 is a surgical system for operating the surgical clamp in accordance with the present invention;

FIG. 11 a plan view of an alternative surgical clamp in accordance with the present invention;

FIG. 12 is a sectional view of an elongated shaft and ablation segment of the surgical clamp of FIG. 11;

FIGS. 13-17 illustrate additional configurations of a surgical clamp;

FIG. 18 illustrates still another surgical clamp configuration;

FIGS. 19 and 20 illustrate additional details of the jaw elements shown in FIG. 18;

FIGS. 21 and 22 show additional clamp configurations;

FIGS. 23A and 23B show a surgical clamp configuration utilizing a four-bar linkage mechanism to deflect the jaws of the clamp;

FIGS. 24A and 24B provide perspective views of the jaws of the surgical clamp configuration of FIGS. 23A and 23B;

FIGS. 25A and 25B show a surgical clamp configuration utilizing a three-bar linkage mechanism to deflect the jaws of the clamp;

FIGS. 26A and 26B show a surgical clamp configuration utilizing a two-bar linkage mechanism to deflect the jaws of the clamp; and

FIGS. 27 and 28 show an alternate embodiment of the surgical clamp of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides a medical device having a handle assembly for actuating a pair of opposing jaw members. The jaw members are movable relative to one another from a first position, wherein the jaw members are disposed in a spaced apart relation

relative to one another, to a second position, wherein the jaw members cooperate to grasp tissue therebetween. An ablation tool is connected to at least one of the jaw members, such that the jaw members are capable of conducting ablation energy through the tissue grasped therebetween.

Referring now to the figures in which like reference designators refer to like elements, there is shown in FIG. 1 a plan view of an exemplary embodiment of the medical device constructed in accordance with the principles of the present invention and designated generally as surgical clamp 10. The surgical clamp 10 includes a handle assembly having elongated handles 12 and 14 and may optionally include a lock mechanism 16, similar to a conventional surgical hemostat. The elongated handles 12, 14 are connected to one another by pivot or hinge 18, and continue distally in the form of a first elongated jaw 20 and a second elongated jaw 22. At least one of the elongated jaws 20, 22 includes an ablation tool. For example, the first elongated jaw 20 includes an ablation tool 24 positioned on the inner surface 26 of the first elongated jaw 20.

Referring to FIGS. 2-3, the ablation tool 24 includes an ablation segment 28 having a thermally-transmissive region 30, and defining a fluid path having at least one fluid inlet 32 and a fluid outlet 34 through the ablation tool 24 to the ablation segment 28, wherein the fluid inlet 32 is in fluid communication with a cryogenic fluid source. Also, even though many materials and structures can be thermally conductive or thermally transmissive if chilled to a very low temperature and/or cold soaked, as used herein, a "thermally-transmissive region" is intended to broadly encompass any structure or region of the ablation tool 24 that readily conducts heat.

For example, a metal structure exposed (directly or indirectly) to the cryogenic fluid path is considered a thermally-transmissive region 30 even if an adjacent polymeric or latex portion also permits heat transfer, but to a much lesser extent than the metal. Thus, the thermally-transmissive region 30 can be viewed as a relative term to compare the heat transfer characteristics of different catheter regions or structures, regardless of the material.

Furthermore, while the thermally-transmissive region 30 can include a single, continuous, and uninterrupted surface or structure, it can also include multiple, discrete, thermally-transmissive structures that collectively define a thermally-transmissive region that is elongate or linear. Depending on the ability of the cryogenic system, or portions thereof, to handle given thermal loads, the ablation of an elongate tissue path can be performed in a single or multiple cycle process without having to relocate the catheter one or more times or drag it across tissue.

In an exemplary embodiment, as shown in FIG. 4, the ablation segment 28 includes one or more orifices 36, where the orifices 36 define the thermally-transmissive region 30. The orifices 36 enable the application of cryogenic fluid directly onto the tissue to be treated.

Additionally, the second elongated jaw 22 can include an ablation tool 42 positioned on the inner surface 49 of the second jaw 22. The ablation tool 42 includes an ablation segment 46 having a thermally-transmissive region 30, and defines a fluid path having at least one fluid inlet 48 and a fluid outlet 50 through the ablation tool 42 and the ablation segment 46, wherein the fluid inlet 48 is in fluid communication with a cryogenic fluid source.

In an exemplary embodiment, as shown in FIG. 5, the handles 12 and 14 are at an acute angle to the first elongated jaw 20 and the second elongated jaw 22. Furthermore, as shown in FIG. 6, the first elongated jaw 20 and the second elongated jaw 22 include a curved portion.

Each of FIGS. 1,5, and 6 illustrate the various inlet ("in") and outlet ("out") ports for supplying and evacuating fluid to and from the jaws 20 and 22.

Additionally, the first elongated jaw 20 and the second elongated jaw 22 are malleable, each have a shape-holding deformability, that is, they have rigidity such that the first elongated jaw 20 and the second elongated jaw 22 each retain a first shape until manipulated to a further shape with the application of moderate pressure, and until reshaped. The first elongated jaw 20 and the second elongated jaw 22 retain their shape with sufficient rigidity to manipulate the ablation segment 28 against tissue, and push it past intervening tissue to a desired position.

It is understood that shape, as used herein, is to be construed broadly to include any contour which is needed to configure the first elongated jaw 20 and the second elongated jaw 22 for positioning the active or distal portion of the ablation tool 24, and may include successive bends or segments having more than one curve, angle, deformation or other non-linear configuration. The shape-retaining feature of the first elongated jaw 20 and the second elongated jaw 22 allows an operator to bend the first elongated jaw 20 and the second elongated jaw 22 to a shape or contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the first elongated jaw 20 and the second elongated jaw 22 based upon the particular anatomy of a patient and the location of the treatment site.

Further, the stiffness of first elongated jaw 20 and the second elongated jaw 22 is such that the surgeon can form the first elongated jaw 20 and the second elongated jaw 22 by hand

to a desired shape without undue effort, and yet the first elongated jaw 20 and the second elongated jaw 22 retain the set shape as the surgical clamp 10 is maneuvered to and held in position at the treatment site. The first elongated jaw 20 and the second elongated jaw 22 should also be sufficiently rigid such that the surgeon can place the ablation segment 28 of the ablation tool 24 in pressured contact with the tissue treatment site. That is, the first elongated jaw 20 and the second elongated jaw 22 are sufficiently stiff to enable the surgeon to press the ablation segment 28 against the tissue to be treated without inducing a further deformation in the shape of the first elongated jaw 20 and the second elongated jaw 22. The first elongated jaw 20 and the second elongated jaw 22 may in some embodiments deflect slightly, and yet have sufficient stiffness to transfer an effective level of lateral force at their distal end.

In an exemplary embodiment, the first elongated jaw 20 and the second elongated jaw 22 are configured so that they are deformable in a single plane, where the first elongated jaw 20 and the second elongated jaw 22 remain substantially rigid in all other planes. For example, the first elongated jaw 20 and the second elongated jaw 22 can be manipulated in a first plane from a first shape to a second shape, wherein the first elongated jaw 20 and the second elongated jaw 22 are sufficiently rigid to retain the second shape. The first elongated jaw 20 and the second elongated jaw 22 also have sufficient rigidity such that the first elongated jaw 20 and the second elongated jaw 22 cannot be manipulated in a second plane orthogonal to the first plane, such that the first elongated jaw 20 and the second elongated jaw 22 are deformable only in the first plane. As such, the first elongated jaw 20 and the second elongated jaw 22 are deformable in only one plane.

In accordance with yet another aspect of the invention, as shown in FIG. 7, particularly directed to the ablative properties of ablation segments 28, 46, the energy distribution during treatment of tissue is further controlled by an adjustable insulation sleeve 52, wherein one each extends over and partially envelops the ablation segments 28, 46. A slotted segment in the insulation sleeve 52 forms a partial circumferential blanket or insulating sleeve which prevents the ablation segments 28,46 from affecting tissue on one side of the ablation segments 28, 46, whi1e leaving the other side of the ablation segments 28, 46 exposed for contact with tissue.

In a further exemplary embodiment, as shown in FIG. 8, the surgical clamp 10 includes a shaft assembly having a first shaft 56 and a second shaft 58 interposed between the handles 12 and 14 and the first elongated jaw 20 and the second elongated jaw 22. The first shaft 56 and a second shaft 58 operably connect the first elongated jaw 20 and the second

elongated jaw 22 to the handles 12 and 14 such that the first elongated jaw 20 and the second elongated jaw 22 are movable relative to one another from a first position, wherein the first elongated jaw 22 and the second elongated jaw 20 are disposed in a spaced apart relation relative to one another, to a second position, wherein the first elongated jaw 20 and the second elongated jaw 22 cooperate to grasp tissue therebetween.

Referring to FIG. 9, the first shaft 56 is substantially hollow, defining a first lumen 60 having at least one input lumen 62 positioned therein, wherein the first lumen 60 and the at least one lumen 62 define a fluid path to the ablation tool 24 on the first elongated jaw 20. The first lumen 60 and the at least one lumen 62 are in fluid communication with the ablation fluid outlet 34 and the ablation fluid inlet 32.

Additionally, similar to the first shaft 56, the second shaft 58 can be substantially hollow, defining a first lumen having at least one input lumen positioned therein, wherein the first lumen 60 and the at least one lumen 62 define a fluid path to the ablation tool 42 on the second elongated jaw 22. The first lumen and the at least one lumen 62 are in fluid communication with the ablation fluid outlet 50 and the ablation fluid inlet 48 .

The first shaft 56 and the second shaft 58 are malleable, each have a shape-holding deformability, that is, they have a rigidity such that the first shaft 56 and the second shaft 58 each retain a first shape until manipulated to a further shape with the application of moderate pressure, and until reshaped. The first shaft 56 and the second shaft 58 retain their shape with sufficient rigidity to close the first elongated jaw 20 and the second elongated jaw 22 to grasp the tissue, and push it past intervening tissue to a desired position.

It is understood that shape, as used herein, is to be construed broadly to include any contour which is needed to configure the surgical clamp 10 for positioning the active or distal portion of the ablation tool 24, and may include successive bends or segments having more than one curve, angle, deformation or other non-linear configuration. The shape-retaining feature of the first shaft 56 and the second shaft 58 allows an operator to bend the first shaft 56 and the second shaft 58 to a shape or contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the surgical clamp 10 based upon the particular anatomy of a patient and the location of the treatment site.

Further, the stiffness of the first shaft 56 and the second shaft 58 is such that the surgeon can form the first shaft 56 and the second shaft 58 by hand to a desired shape without undue effort, and yet the first shaft 56 and the second shaft 58 retain the set shape as the surgical clamp 10 is maneuvered to and held in position at the treatment site. The first shaft

56 and the second shaft 58 should also be sufficiently rigid such that the surgeon can place the ablation segment 28 of the ablation tool 24 in pressured contact with the tissue treatment site. That is, the first shaft 56 and the second shaft 58 are sufficiently stiff to enable the surgeon to press the ablation segment 28 against the tissue to be treated without inducing a further deformation in the shape of the first shaft 56 and the second shaft 58. The first shaft 56 and the second shaft 58 may in some embodiments deflect slightly, and yet have sufficient stiffness to transfer an effective level of lateral force at their distal end.

In an embodiment, the first shaft 56 and the second shaft 58 are configured so that they are deformable in a single plane, where the first shaft 56 and the second shaft 58 remain substantially rigid in all other planes. For example, the first shaft 56 and the second shaft 58 can be manipulated in a first plane from a first shape to a second shape, wherein the first shaft 56 and the second shaft 58 are sufficiently rigid to retain the second shape. The first shaft 56 and the second shaft 58 also have sufficient rigidity such that the first shaft 56 and the second shaft 58 cannot be manipulated in a second plane orthogonal to the first plane, such that the first shaft 56 and the second shaft 58 are deformable only in the first plane. As such the first shaft 56 and the second shaft 58 are deformable in only one plane.

In another embodiment the cryoablating element which is in fluid communication with the control system is removable from the movable clamp jaws. The shaft connecting the ablating element is flexible and has a deflection system actuated from the handle. In allowing the ablating element to be removable, the device can be used in two modes: clamp and wand type modes giving the user greater flexibility in carrying out the procedure.

In an exemplary embodiment, as shown in FIG. 10, the present invention includes an ablation control system 64. The ablation control system 64 includes a supply of cryogenic or cooling fluid 66 in communication with the surgical clamp 10. A fluid controller 68 is interposed or is in-line between the cryogenic fluid supply 66 and the surgical clamp 10 for regulating the flow of cryogenic fluid 66 into the surgical clamp 10 in response to a controller command. Controller commands can include programmed instructions, sensor signals, and manual user input. For example, the fluid controller 68 can be programmed or configured to increase and decrease the pressure of the fluid by predetermined pressure increments over predetermined time intervals.

In another exemplary embodiment, the fluid controller 68 can be responsive to input from a user input device to permit flow of the cryogenic fluid 66 into the surgical clamp 10. As also shown in FIG. 1, one or more temperature sensors 40 in electrical communication with the fluid controller 68 can be provided to regulate or terminate the flow of cryogenic

fluid 66 into the surgical clamp 10 when a predetermined temperature at a selected point or points on or within the ablation segment 28 is/are obtained. For example a temperature sensor 40 can be placed at a point proximate the ablation tool 24 distal end and other temperature sensors 40 can be placed at spaced intervals between the ablation tool 24 distal end and another point that is between the distal end and the proximal end.

In another exemplary embodiment, one or more sensors, such as a ECG leads, in electrical communication with the controller can be provided to regulate or terminate the flow of cryogenic fluid 66 into the ablation tool 24 depending on the electrical activity in the tissue being treated. For example, the first elongated jaw 20 and second elongated jaw 22 may provide feedback that permits a user to gauge the completeness of the ablation. Specifically, a lesion blocks electrical signals because it is non-conductive scar tissue. The first elongated jaw 20 and second elongated jaw 22 can be used to measure the ability of the lesion to block an electrical signal. Referring to FIG. 1, an electrode 70 is affixed one each to the distal ends of the first elongated jaw 20 and second elongated jaw 22. In an exemplary use, the electrodes 70 are used to verify electrical isolation of the lesion created by the ablation tool 24. For example, the first elongated jaw 20 and the second elongated jaw 22 are opened to position an electrode 70 on each side of the lesion. An electrical signal is transmitted from one electrode, through the lesion, to the opposite electrode. The lesion is considered electrically isolated if the receiving electrode is electrically silent to the signal.

Alternatively, the electrical sensors can be replaced or supplemented with pressure sensors. The pressure sensors can be used to determine when the ablation segment is in physical contact with the tissue to be treated.

The cryogenic fluid can be in a liquid or a gas state, or combination thereof. An extremely low temperature can be achieved within the medical device, and more particularly at the ablation segment by cooling the fluid to a predetermined temperature prior to its introduction into the medical device, by allowing a liquid state cryogenic fluid to boil or vaporize, or by allowing a gas state cryogenic fluid to expand. Exemplary liquids include chlorodifluoromethane, polydimethylsiloxane, ethyl alcohol, HFC's such as AZ-20 (a 50--50 mixture of difluoromethane & pentafluoroethane sold by Allied Signal), and CFC's such as DuPont's Freon. Exemplary gasses include argon, nitrous oxide, and carbon dioxide.

Referring now to FIG. 11, there is shown a plan view of an exemplary embodiment of a medical device constructed in accordance with the principles of the present invention and designated generally as surgical clamp 100. The surgical clamp 100 includes a shaft assembly having opposing jaw assemblies 102, 104 with jaw assembly 102 being fixed and

jaw assembly 104 being movable between a first position, wherein the jaw assemblies 102 and 104 are disposed in a spaced apart relation relative to one another, to a second position, wherein the jaw assemblies 102 and 104 cooperate to grasp tissue therebetween.

The fixed jaw assembly 102 includes a fixed extension shaft 106 and an ablation tool 108 disposed on the distal end of the fixed extension shaft 106, at an acute angle to the fixed extension shaft 106. As shown in FIG. 12, the fixed extension shaft 106 defines a first lumen 110 having at least one input lumen 112 positioned therein, wherein the first lumen 110 and the at least one input lumen 112 define a fluid path to the ablation tool 108, wherein the at least one input lumen 112 is in fluid communication with a cryogenic fluid source. The ablation tool 108 includes an ablation segment 114 with a thermally-transmissive region 116, defines a fluid path through the ablation tool 108 to the ablation segment 112, wherein the fluid path is in fluid communication with the first lumen 110 and the at least one input lumen 112.

The moveable jaw assembly 104 includes a movable extension shaft 118 and a moveable jaw 120 disposed on the distal end of the moveable extension shaft 118 at an acute angle to the moveable extension shaft 118. The moveable extension shaft 118 is operably connected to the fixed extension shaft 106, such that the moveable extension shaft 118 slides along the fixed extension shaft 106 to move the moveable jaw 120 between a first position, wherein the moveable jaw 120 and the ablation tool 108 are disposed in a spaced apart relation relative to one another, to a second position, wherein the moveable jaw 120 and the ablation tool 108 cooperate to grasp tissue therebetween.

In an exemplary embodiment, the ablation tool 108 and the moveable jaw 120 are malleable, each having a shape-holding deformability, that is, they have rigidity such that the ablation tool 108 and the moveable jaw 120 each retain a first shape until manipulated to a further shape with the application of moderate pressure, and until reshaped. The ablation tool 108 and the moveable jaw 120 retain their shape with sufficient rigidity to manipulate the ablation segment 114 against the tissue, and push it past intervening tissue to a desired position.

It is understood that shape, as used herein, is to be construed broadly to include any contour which is needed to configure the ablation tool 108 and the moveable jaw 120 for positioning the active or distal portion of the ablation tool 104, and may include successive bends or segments having more than one curve, angle, deformation or other non-linear configuration. The shape-retaining feature of the ablation tool 108 and the moveable jaw 120 allows an operator to bend the ablation tool 108 and the moveable jaw 120 to a shape or

contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the ablation tool 108 and the moveable jaw 120 based upon the particular anatomy of a patient and the location of the treatment site.

Further, the stiffness of the ablation tool 108 and the moveable jaw 120 is such that the surgeon can form the ablation tool 108 and the moveable jaw 120 by hand to a desired shape without undue effort, and yet the ablation tool 108 and the moveable jaw 120 retain the set shape as the surgical clamp 100 is maneuvered to and held in position at the treatment site. The ablation tool 108 and the moveable jaw 120 should also be sufficiently rigid such that the surgeon can place the ablation tool 108 and the moveable jaw 120 in pressured contact with the tissue treatment site. That is, the ablation tool 108 and the moveable jaw 120 are sufficiently stiff to enable the surgeon to press the ablation segment 114 against the tissue to be treated without inducing a further deformation in the shape of the ablation tool 108 and the moveable jaw 120. The ablation tool 108 and the moveable jaw 120 may in some embodiments deflect slightly, and yet has sufficient stiffness to transfer an effective level of lateral force at its distal end.

In an exemplary embodiment, the ablation tool 108 and the moveable jaw 120 are configured so that they are deformable in a single plane, where the ablation tool 108 and the moveable jaw 120 remain substantially rigid in all other planes. For example, the ablation tool 108 and the moveable jaw 120 can be manipulated in a first plane from a first shape to a second shape, wherein the ablation tool 108 and the moveable jaw 120 are sufficiently rigid to retain the second shape. The ablation tool 108 and the moveable jaw 120 also have sufficient rigidity such that the ablation tool 108 and the moveable jaw 120 cannot be manipulated in a second plane orthogonal to the first plane, such that the ablation tool 108 and the moveable jaw 120 are deformable only in the first plane. As such the ablation tool 108 and the moveable jaw 120 are deformable in only one plane.

In an exemplary embodiment, the fixed extension shaft 106 and the moveable extension shaft 118 are malleable, each have a shape-holding deformability, that is, they have a rigidity such that the fixed extension shaft 106 and the moveable extension shaft 118 shaft each retain a first shape until manipulated to a further shape with the application of moderate pressure, and until reshaped. The fixed extension shaft 106 and the moveable extension shaft 118 retain their shape with sufficient rigidity to close the ablation tool 108 and the moveable jaw 120 to grasp the tissue, and push it past intervening tissue to a desired position. The shape-retaining feature of the fixed extension shaft 106 and the moveable extension shaft 118

allows an operator to bend the fixed extension shaft 106 and the moveable extension shaft 118 to a shape or contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the surgical clamp 100 based upon the particular anatomy of a patient and the location of the treatment site.

It is understood that shape, as used herein, is to be construed broadly to include any contour which is needed to configure the fixed extension shaft 106 and the moveable extension shaft 118 for positioning the active or distal portion of the ablation tool 104, and may include successive bends or segments having more than one curve, angle, deformation or other non-linear configuration. The shape-retaining feature of the fixed extension shaft 106 and the moveable extension shaft 118 allows an operator to bend the fixed extension shaft 106 and the moveable extension shaft 118 to a shape or contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the fixed extension shaft 106 and the moveable extension shaft 118 based upon the particular anatomy of a patient and the location of the treatment site.

Further, the stiffness of the fixed extension shaft 106 and the moveable extension shaft 118 is such that the surgeon can form the fixed extension shaft 106 and the moveable extension shaft 118 by hand to a desired shape without undue effort, and yet the fixed extension shaft and the moveable extension shaft retains the set shape as the surgical clamp 100 is maneuvered to and held in position at the treatment site. The fixed extension shaft 106 and the moveable extension shaft 118 should also be sufficiently rigid such that the surgeon can place the ablation segment of the ablation segment 114 in pressured contact with the tissue treatment site. That is, the fixed extension shaft 106 and the moveable extension shaft 118 are sufficiently stiff to enable the surgeon to press the ablation segment 114 against the tissue to be treated without inducing a further deformation in the shape of the fixed extension shaft 106 and the moveable extension shaft 118. The fixed extension shaft 106 and the moveable extension shaft 118 may in some embodiments deflect slightly, and yet haves sufficient stiffness to transfer an effective level of lateral force at its distal end.

In an embodiment, the fixed extension shaft 106 and the moveable extension shaft 118 are configured so that they are deformable in a single plane, where the fixed extension shaft 106 and the moveable extension shaft 118 remain substantially rigid in all other planes. For example, the fixed extension shaft 106 and the moveable extension shaft 118 can be manipulated in a first plane from a first shape to a second shape, wherein the fixed extension shaft 106 and the moveable extension shaft 118 are sufficiently rigid to retain the second

shape. The fixed extension shaft 106 and the moveable extension shaft 118 also have sufficient rigidity such that the fixed extension shaft 106 and the moveable extension shaft 118 cannot be manipulated in a second plane orthogonal to the first plane, such that the fixed extension shaft 106 and the moveable extension shaft 118 are deformable only in the first plane. As such the fixed extension shaft 106 and the moveable extension shaft 118 are deformable in only one plane.

Referring to FIG. 12, the moveable extension shaft 118 defines a first lumen 122 having at least one input lumen 124 positioned therein, the first lumen 122 and the at least one input lumen 124 defining a fluid path to the moveable jaw 120, wherein the at least one fluid input lumen 124 is in fluid communication with a cryogenic fluid source. The moveable jaw 120 is an ablation tool including an ablation segment 126 with a thermally-transmissive region 128, and defining a fluid path through the moveable jaw 120 to the ablation segment 126, wherein the fluid path is in fluid communication with the first lumen 122 and the at least one input lumen 124.

The fixed jaw assembly 102 and the moveable jaw 104 assembly are operably connected to a handle assembly 103. The handle assembly 103 includes a fixed handle 132 attached to the fixed extension shaft 106 and a lever arm 134 pivotally connected to the fixed handle 132. The lever arm 134 is attached to the movable extension shaft, 118 such that as the lever arm 134 pivots about the fixed handle 132 from a start position, the moveable jaw 120 moves from a first position to a second position.

Referring now to FIG. 13, there is shown a plan view of an exemplary embodiment of a medical device constructed in accordance with the principles of the present invention and designated generally as surgical clamp 200. The surgical clamp 200 includes a jaw assembly having a first jaw 202, and a second jaw 204 in opposing relation. The first jaw 202 and the second jaw 204 are movable between a first position, wherein the first jaw 202 and the second jaw 204 are disposed in a spaced apart relation relative to one another, to a second position, wherein the first jaw 202 and the second jaw 204 cooperate to grasp tissue therebetween. The first jaw 202 and the second jaw 204 are connected to an elongated shaft assembly 206, wherein a handle assembly 208 is connected to the elongated shaft assembly 206 opposite the first jaw 202 and the second jaw 204. At least one of the first jaw 202 and the second jaw 204 includes an ablation tool. For example, the first jaw 202 includes an ablation tool 210 positioned on the inner surface 212 of the first jaw 202.

The elongated shaft assembly 206 defines a first lumen having at least one input lumen positioned therein (not shown). The first lumen and the at least one input lumen

define a fluid path to the ablation tool 210, wherein the at least one input lumen is in fluid communication with a cryogenic fluid source. The ablation tool 210 includes an ablation segment with a thermally-transmissive region, and defines a fluid path through the ablation tool to the ablation segment, wherein the fluid path is in fluid communication with the first lumen and the at least one input lumen.

Additionally, the second jaw 204 can include an ablation tool 220 having an ablation segment with a thermally-transmissive region similar to that of ablation tool 210 disposed on first jaw 202.

In an exemplary embodiment, the first jaw 202 and the second jaw 204 are malleable, each have a shape-holding deformability, that is, they have rigidity such that the first jaw 202 and the second jaw 204 each retain a first shape until manipulated to a further shape with the application of moderate pressure, and until reshaped. The first jaw 202 and the second jaw 204 retain their shape with sufficient rigidity to manipulate the ablation segment 210 against tissue, and push it past intervening tissue to a desired position.

It is understood that shape, as used herein, is to be construed broadly to include any contour which is needed to configure the first jaw 202 and the second jaw 204 for positioning the active or distal portion of the ablation tool, and may include successive bends or segments having more than one curve, angle, deformation or other non-linear configuration. The shape-retaining feature of the first jaw 202 and the second jaw 204 allows an operator to bend the first jaw 202 and the second jaw 204 to a shape or contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the first jaw 202 and the second jaw 204 based upon the particular anatomy of a patient and the location of the treatment site.

Further, the stiffness of the first jaw 202 and the second jaw 204 is such that the surgeon can form the first jaw 202 and the second jaw 204 by hand to a desired shape without undue effort, and yet the first jaw 202 and the second jaw 204 retain the set shape as the surgical clamp 200 is maneuvered to and held in position at the treatment site. The first jaw 202 and the second jaw 204 should also be sufficiently rigid such that the surgeon can place the ablation segment of the ablation tool in pressured contact with the tissue treatment site. That is, the first jaw 202 and the second jaw 204 are sufficiently stiff to enable the surgeon to press the ablation segment against the tissue to be treated without inducing a further deformation in the shape of the first jaw 202 and the second jaw 204. The first jaw 202 and the second jaw 204 may in some embodiments deflect slightly, and yet have sufficient stiffness to transfer an effective level of lateral force at its distal end.

In an exemplary embodiment, the first jaw 202 and the second jaw 204 are configured so that they are deformable in a single plane, where the first jaw 202 and the second jaw 204 remain substantially rigid in all other planes. For example, the first jaw 202 and the second jaw 204 can be manipulated in a first plane from a first shape to a second shape, wherein the first jaw 202 and the second jaw 204 are sufficiently rigid to retain the second shape. The first jaw 202 and the second jaw 204 also have sufficient rigidity such that the f first jaw 202 and the second jaw 204 cannot be manipulated in a second plane orthogonal to the first plane, such that the first jaw 202 and the second jaw 204 are deformable only in the first plane. As such the first jaw 202 and the second jaw 204 are deformable in only one plane.

In an exemplary embodiment, the elongated shaft assembly 206 is malleable, having a shape-holding deformability, that is, it has rigidity such that the elongated shaft assembly 206 retains a first shape until manipulated to a further shape with the application of moderate pressure, and until reshaped. The elongated shaft assembly 206 retains its shape with sufficient rigidity to close the first jaw 202 and the second jaw 204 to grasp the tissue, and push it past intervening tissue to a desired position.

It is understood that shape, as used herein, is to be construed broadly to include any contour which is needed to configure the surgical clamp 200 for positioning the active or distal portion of the ablation tool, and may include successive bends or segments having more than one curve, angle, deformation or other non-linear configuration. The shape-retaining feature of the elongated shaft assembly 206 allows an operator to bend the elongated shaft assembly 206 to a shape or contour, for example around an organ or tissue structure, and have an optimal configuration for positioning and or orienting the active or distal region of the surgical clamp 200 based upon the particular anatomy of a patient and the location of the treatment site.

Further, the stiffness of the elongated shaft assembly 206 is such that the surgeon can form the elongated shaft assembly 206 by hand to a desired shape without undue effort, and yet the elongated shaft assembly 206 retains the set shape as the surgical clamp 200 is maneuvered to and held in position at the treatment site. The elongated shaft assembly 206 should also be sufficiently rigid such that the surgeon can place the ablation segment of the ablation tool in pressured contact with the tissue treatment site. That is, the elongated shaft assembly 206 is sufficiently stiff to enable the surgeon to press the ablation segment against the tissue to be treated without inducing a further deformation in the shape of the elongated shaft assembly 206. The elongated shaft assembly 206 may in some embodiments deflect

slightly, and yet has sufficient stiffness to transfer an effective level of lateral force at its distal end.

In an embodiment, the elongated shaft assembly 206 is configured so that it is deformable in a single plane, where the elongated shaft assembly 206 remains substantially rigid in all other planes. For example, the elongated shaft assembly 206 can be manipulated in a first plane from a first shape to a second shape, wherein the elongated shaft assembly 206 is sufficiently rigid to retain the second shape. The elongated shaft assembly 206 also has sufficient rigidity such that the elongated shaft assembly 206 cannot be manipulated in a second plane orthogonal to the first plane, such that the elongated shaft assembly 206 is deformable only in the first plane. As such the elongated shaft assembly 206 are deformable in only one plane.

Referring now to FIG. 14, an exemplary tool is shown having a handle portion 208 from which extends a probe 211 having a cooling segment 212. As with all disclosed embodiments, the cooling segment 212 can be provided with a smooth or textured tissue engaging surface 214. In FIG. 14, the tissue-engaging surface 214 is textured to have "teeth." A second element 216 is movable relative to the probe to define a tissue capture zone 218. A distal region 220 of the second element 216 can have a complementary shape to the cooling segment 212 and be smooth (as shown) or textured. As the probe 211 and the second element 216 are moved axially with respect to each other, the tissue capture zone 218 increases or decreases in size. In the illustrated embodiment, the second element 216 is secured to the probe 211 and is axially slidable with respect thereto by axially moving a proximal portion 222 of the second element 216.

With respect to FIG. 15, a different actuating mechanism is shown in an exemplary tool having a handle portion 224 from which extends a probe 226 having a cooling segment 228. A second element 230 is movable relative to the probe 226 to define a tissue capture zone 232. As the probe 226 and the second element 230 are moved axially with respect to each other, the tissue capture zone 232 increases or decreases in size. In the illustrated embodiment, the second element 230 is secured to the probe 226 and is axially slidable with respect thereto by axially moving a proximal portion 234 of the second element by pulling a handle, lever, or trigger 236 that is engaged with the proximal portion of the second element. A spring 238 or other bias means can be provided to either urge the second element 230 in either the distal or proximal direction.

FIG. 16 shows yet another configuration wherein a cooling element 240 is juxtaposed with a second element 242 and wherein the elements are biased apart. A sleeve or handle

element 244 is slidable with respect to the elements so that as it is moved distally it urges the elements together.

Referring to FIG. 17 another clamping tool is disclosed that includes a handle portion 246 having an actuator 248 that pivots or rotates fore and aft. The actuator 248 is coupled to a pull or push wire 250 that is secured to a distal portion of an elongate shaft structure 252 to cause the shaft structure to clamp tissue 254. As shown, the shaft structure 252 includes an insulating distal portion 256, a bellows or coil portion 258 that provides a clamping effect, and a cooling segment 260. A coolant injection tube 262 introduces coolant into the cooling segment 260. The elongate shaft structure 252 can be transitioned from a substantially linear configuration to the configuration shown or it can be preformed to substantially the configuration shown and actuated to tighten the space between the insulating distal portion 256 and the cooling segment 260 which can further be insulated on its outward face. As shown, the wire 250 is secured at its distal end to a shim 264.

FIG. 18 illustrates yet another configuration of a tool including a handle 266, actuator 268, insulated shaft 270, first jaw 272, and second jaw 274, wherein manipulation of the actuator 268 causes the jaws to open and close or move relative to each other. The figure depicts the jaws in both the open and clamped state. Coolant can flow to and/or through one or both jaws and both jaws can be insulated except at the point where they meet. One or both jaws can be provided with temperature and/or impedance measurement devices to monitor and evaluate lesion formation and characteristics. In an embodiment a temperature sensor is associated with a jaw that does not have a cooling element. The jaws are clamped together with tissue therebetween. The transmurality of a lesion could be ascertained when the temperature sensor detects a temperature of –40 degrees Centigrade for two minutes. Of course, time and temperature may be different for different types, conditions and thickness of tissue.

FIGS. 19 and 20 show additional details of the first jaw 272 and the second jaw 274, respectively; wherein the first jaw made of an insulating material defines a recess 276 shaped to receive an elongate cooling element 278 affixed to insulating material.

Although the device of FIG. 18 may include two jaws, one jaw can be removable so that a single jaw with a cooling segment is provided. Thus, the device can be convertible from a clamping tool to a "wand" type device for use in procedures not requiring clamping.

FIG. 21 illustrates yet another configuration for the clamping device. Here, cooling segment 260 can be deflected from its normal position to a variety of deflection positions via use of actuator 248 (not shown). Cooling segment 260 may be deflected to an angle of

choice by manipulation of the actuator. Coolant can then be introduced to cooling segment 260 via the internal injection tube (not shown).

FIG. 22 illustrates yet another configuration for a clamping device wherein a cooling element 280 is slidably disposed within an insulating sheath 282. The distal portion of the cooling element 281 and the distal portion of the sheath 283 are angled with respect to their proximal portion so that extension and retraction of the cooling element with respect to the sheath opens and closes a tissue-clamping zone 284.

Although generally shown as a cryogenic ablation tool, it is understood that in other embodiments the ablation segment applies other types of energy or combination of energies, to the tissue to be treated, including, but not limited to, cryogenic energy, radio frequency (RF) energy, microwave energy, ultrasound energy, laser energy, and contact heating energy. It is further understood that other devices can be coupled to the guide distal end, for example, cameras, video devices, probes and other components can be affixed to the guide for various applications. For example, pacing/sensing electrodes can be affixed to points on the slotted segment.

FIG. 23A illustrates another embodiment of the surgical clamping device of the present invention. Because typical surgical ablation procedures require an open chest operation due to the large size of the surgical probe, the present invention provides a surgical device that allows cryosurgical ablation of cardiac tissue via a minimally invasive process. FIG 23A shows a minimally invasive clamping mechanism as part of a surgical clamp. Shaft assembly 285 includes a first jaw 286 and a second jaw 287 extending therefrom. Initially, jaws 286 and 287 are proximate each other and in a "closed" position as shown in FIG. 23A in order to provide a very low profile at the time of insertion. Typically, the profile is less than 12 mm in diameter at the point of insertion in the target tissue.

Jaw 287 includes a cooling element while jaw 286 may include a temperature sensor to assess the transmuraility of a lesion, or may be comprised of insulation material. Although the device of FIG. 23A may include two jaws, one jaw can be removable so that a single jaw with a cooling segment is provided. Thus, the device can be convertible from a clamping tool to a "wand" type device for use in procedures not requiring clamping. Further, one or both jaws may include an ablation element and/or a sensing element.

Included within shaft 285 is a jaw actuation mechanism 288. Mechanism 288 includes a four-bar linkage operatively coupled to a deflection wire 290. The four-bar linkage includes upper linkage bars 291 and 292 joined at upper linkage coupling 293, and lower linkage bars 289 and 294 joined at lower linkage coupling 295. Jaws 286 and 287 are

operatively coupled to and extend from upper linkage junction 293 and lower linkage junction 295 respectively.

Deflection wire is controlled via a remote unit (not shown) in order to apply a closing force to jaws 286 and 287 (shown in FIG. 23A) or an opening force (shown in FIG. 23B). In FIG. 23A, the application of a force in the direction of the arrow collapses the upper linkage bars 288 and 292 and the lower linkage bars 293 and 294, bringing opposing jaws 286 and 287 in a side-by-side parallel position. This is the jaw positioning used at the insertion point in the surgical procedure in order to minimize the clamp profile resulting in a small incision diameter. An opposite force is necessary to open the jaws in order to clamp the target tissue.

In FIG. 23B, the direction of the arrow indicates the opening force upon deflection wire 290. The deflection wire 290 is operatively coupled to proximal coupling 296. The pushing force upon the near coupling 296 separates the upper linkage bars 288 and 292 from the lower linage bars 293 and 294 thus also separating the upper jaw 286 from the lower jaw 287. A distal anchor 297 is fixed within shaft 285. In the open orientation shown in FIG. 23B, the clamp has already been inserted within the body, in the minimally invasive orientation of FIG. 23A, and the jaws can now be controllably separated to create a clamping area indicated by A. Therefore the four-bar linkage 289 used in conjunction with the surgical clamp having a malleable and/or deflectable shaft 285 can be effectively used to perform both PV clamp isolation and linear epicardial ablations via a small incision diameter.

FIGS. 24A and 24B are representations of the jaw configurations of FIGS. 23A and 23B. Malleable shaft 285 contains actuation mechanism 288 and deflection wire 290 (not shown). Jaws 286 and 287 extend from shaft 285 and are controlled via the actuation mechanism as described above. Jaw 287 includes an ablation element 298. In the open configuration of FIG. 24B, a clamping area A is created between the jaws. In FIG. 24A, the jaws are closed and in a parallel, side-by-side orientation.

FIG. 25A and FIG. 25B illustrate an alternate configuration of the actuation mechanism 288 described above. In this configuration, a three-bar linkage 299 is used to actuate and configure jaws 286 and 287. FIG. 25A illustrates an asymmetrical 3-bar linkage clamping mechanism used in conjunction with the surgical clamp of the present invention. Once again, jaws 286 and 287 can be opened and closed by application of a direct force indicated by the arrow in FIG. 25B or an opposite, pulling force shown by the arrow in FIG. 25A. Anchor point 300 remains fixed within the shaft assembly (not shown). Near coupling 301 is connected to jaw 286 and, upon activation of the displacement wire 302, upper jaw 286 can be opened in an offset, asymmetrical orientation with respect to jaw 287, as shown in

FIG. 25B. While the movement of the jaws relative to each other in the configuration of FIG. 23A using a four-bar linkage 289 is substantially parallel, the movement of the jaws in FIG. 25A utilizing the three-bar linkage are non-parallel and results in an open configuration where jaw 286 is offset from jaw 287. This jaw-configuration may be useful where the surgical clamp is inserted within difficult-to-reach endocardial locations.

FIGS. 26A and 26B illustrate yet another embodiment of the present invention. In this embodiment, a two-bar linkage mechanism 303 is used to displace the opposing jaws in the manner shown. This configuration, like the configuration shown in FIGS. 25A and 26B results in an asymmetrical displacement of the jaws. Anchor 304 remains fixed within the shaft assembly (not shown) while upper coupling 305 is operatively coupled to upper jaw 286 and lowered coupling 306 is operatively coupled to lower jaw 287.

Like the embodiments described above, one of the jaws may include an ablation element and the other jaw may include a temperature or impedence sensor for assessing the transmurality of a lesion. Alternately, both jaws may include ablation elements. The jaws are again controlled by a jaw displacement wire 307. A control unit controls wire 307 and results in either a closing (pulling) force upon the two-bar linkage 303 (FIG. 26A) resulting in the closing of jaws 286 and 287 or an opening (pushing) force upon two-bar linkage 303 resulting in the asymmetrical displacement of jaws 286 and 287.

FIG. 27 is yet another embodiment of the cyrosurgical clamping device of the present invention. Jaw 308 is an "active" jaw that includes an ablation element 310 capable of delivering cryogenic fluid to an ablation site. Jaw 309 is typically a "passive" jaw that does not contain an ablation element and may instead include a temperature or impedence sensor for transmurality assessment. Alternately, jaw 309 may also be an active jaw with an ablation element. FIG. 27 shows the jaws in an "open" configuration with a clamping space C illustrated between opposing jaws 308 and 309. When the jaws are brought together via a jaw activation mechanism (described above) the profile of the surgical clamp is very small, typically between 10 and 12 mm in diameter.

A pair of members 311 extend from a tubular shaft 312 and are each operatively coupled to one of the jaws. Members 311 are elastic and may be pre-molded to a certain shape in order to properly position jaws 308 and 309 around its intended target tissue region. Alternately, members 311 may be profiled Nickel Titanium tubes that allow for the transfer and return of refrigerant to and from the ablation elements on jaws 308 and/or 309. The axial movement of activation wires within tube 12 control the displacement of the jaws and the

displacement can be controlled by wires, motors, wireless remote or any other conventional control devices.

FIG. 28 illustrates an alternate design of the embodiment of FIG. 27. Jaw 308 is an active jaw with an ablation element capable of releasing cryogenic fluid. Jaw 309 can be a passive jaw without cryoablation capability or an active jaw with an ablation element. Jaw 308 is fixed and substantially rigid while jaw 309 is initially in position A, proximate jaw 308 in a parallel arrangement in order to present a low diameter profile. Movement of an actuation mechanism (not shown) within tube 312 in the direction of the OPEN arrow deflects jaw 309 downward in the direction of arrow D resulting in jaw 309 at position B. Movement of an actuation mechanism in tube 312 in the direction of the CLOSE arrow closes the jaws, bringing lower jaw 309 upward resulting in the jaws being in a substantially closed and parallel relationship. Therefore, the actuation mechanism controls only the lower jaw 309, while the upper jaw 308 remains fixed.

The medical device of the present invention is well suited for treating tissue in a variety of locations in the body during invasive surgical procedures. Illustrative applications include open thoracic and peritoneal surgery as well as endoscopic procedures, e.g., treating tissue located at or near the heart, intestines, uterus, and other regions for which surgical or endoscope assisted surgical access and topical tissue treatment, or cauterization or ablation is appropriate, as well as ophthalmic surgery, and tumor ablation and various applications preparatory to further surgical steps.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.

IN THE CLAIMS

1. A medical device for ablating tissue comprising:

a first jaw and a second jaw, wherein at least one of the first jaw and the second jaw includes an ablation element;

a shaft assembly operably coupled to the first jaw and the second jaw, and

a jaw actuation assembly operably coupled to the first jaw and the second jaw to move the first jaw and the second jaw selectively from a first position proximate each other to a second open position, wherein the jaw actuation assembly includes a deflection mechanism; and

a linkage assembly operatively coupled to the deflection mechanism, wherein activation of the deflection mechanism displaces at least the first and the second jaw in a substantially parallel orientation.

2. The medical device of claim 1, wherein at least one of the first jaw and the second jaw includes a sensing element for transmurality assessment.

3. The medical device of claim 2, wherein the sensing element is a temperature sensor.

4. The medical device of claim 2, wherein the sensing element is an impedance sensor.

5. The medical device of claim 1, wherein the linkage assembly comprises:

a first coupling connected to the deflection mechanism;

an anchor affixed to the shaft assembly; and

a pair of jaw couplings movable upon activation of the deflection mechanism, wherein each jaw coupling is connected to a corresponding jaw such that a force

applied to the deflection mechanism results in the jaws being in the first position and an opposing force applied to the deflection mechanism deflects the first and the second jaws resulting in the jaws being in the second position thereby creating a tissue clamping region.

6. The medical device of claim 1, wherein the deflection mechanism is controlled by a remote unit.

7. The medical device of claim 1, wherein the first position of the jaws results in an insertion diameter between 10 and 12 millimeters.

8. The medical device of claim 1, wherein the first jaw is fixed, the deflection mechanism displaces the second jaw.

9. The medical device of claim 1, wherein the linkage assembly comprises:

a first coupling connected to the deflection mechanism;

an anchor affixed to the shaft assembly, the anchor coupled to the second jaw; and

a second coupling connected to the first coupling and to the first jaw, the second coupling movable upon activation of the deflection mechanism such that a force applied to the deflection mechanism results in the jaws being in the first position and an opposing force applied to the deflection mechanism results in the first jaw being obliquely separated from the second jaw resulting in the jaws being in an offset open position.

10. The medical device of claim 1, wherein the linkage assembly comprises:

a first coupling connected to the deflection mechanism, the first coupling connected to the first jaw;

an anchor affixed to the shaft assembly; and

a second coupling connected to the second jaw, the first and the second coupling movable about the anchor upon activation of the deflection mechanism such that a force applied to the deflection mechanism results in the jaws being in the first position and an opposing force applied to the deflection mechanism deflects the first and the second jaws resulting in the jaws being in an offset open position.

11. A medical device for ablating tissue comprising:

a first jaw and a second jaw, wherein at least one of the first jaw and the second jaw includes an ablation element;

a shaft assembly operably coupled to the first jaw and the second jaw, and

a jaw actuation assembly operably coupled to the first jaw and the second jaw to move the first jaw and the second jaw selectively from a first position proximate each other to a second open position; and wherein the ablation element is removable from the jaw.

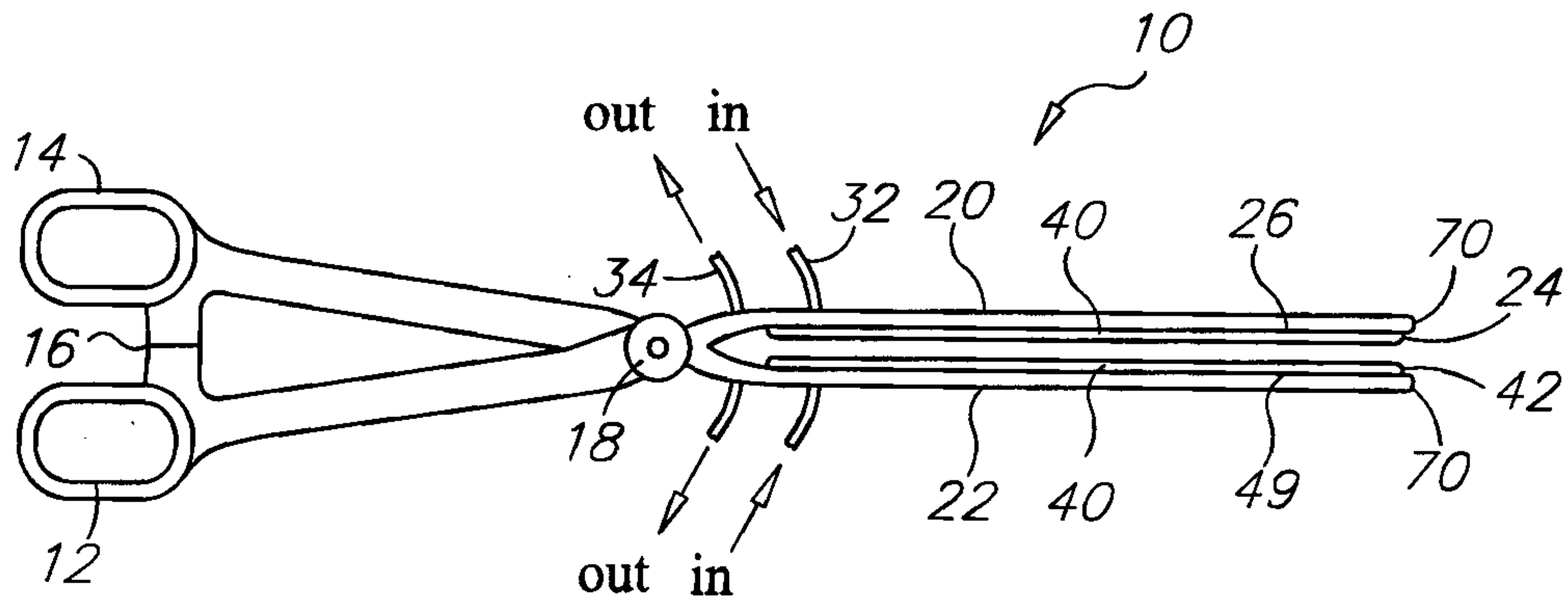


FIG. 1

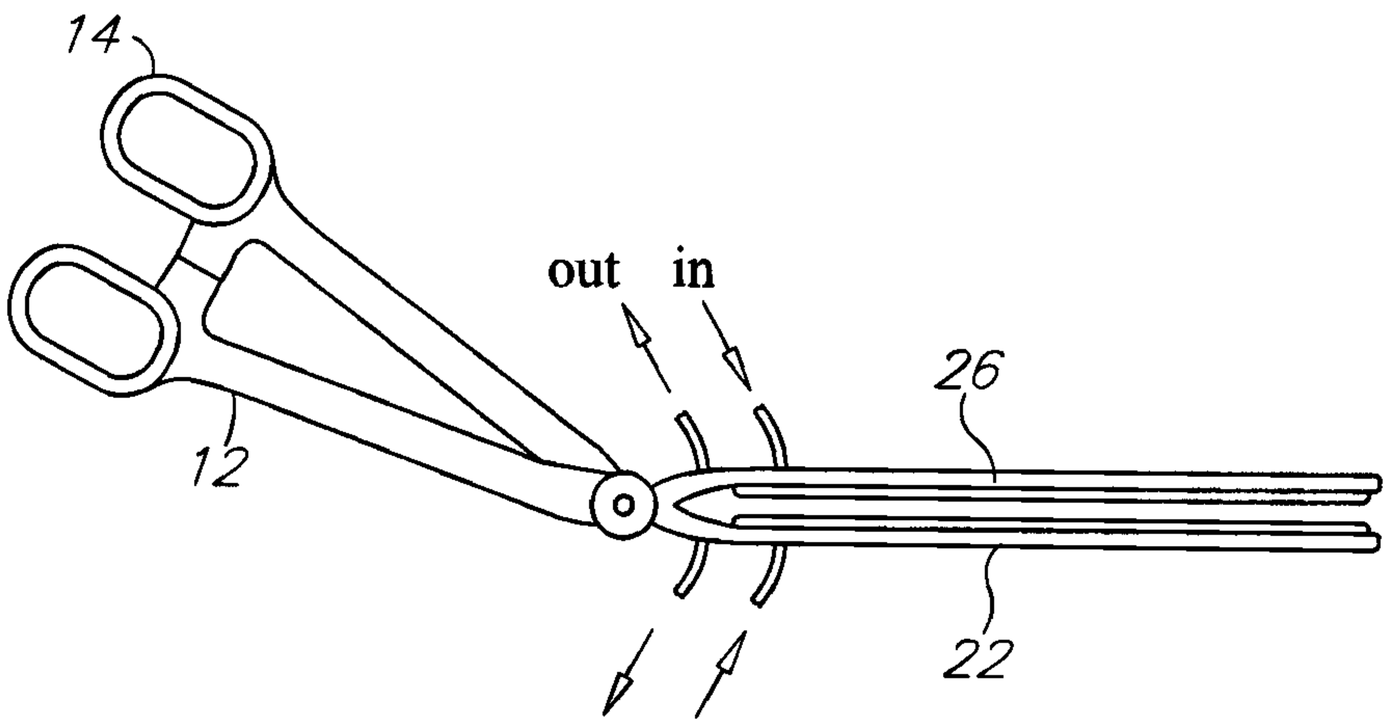


FIG. 5

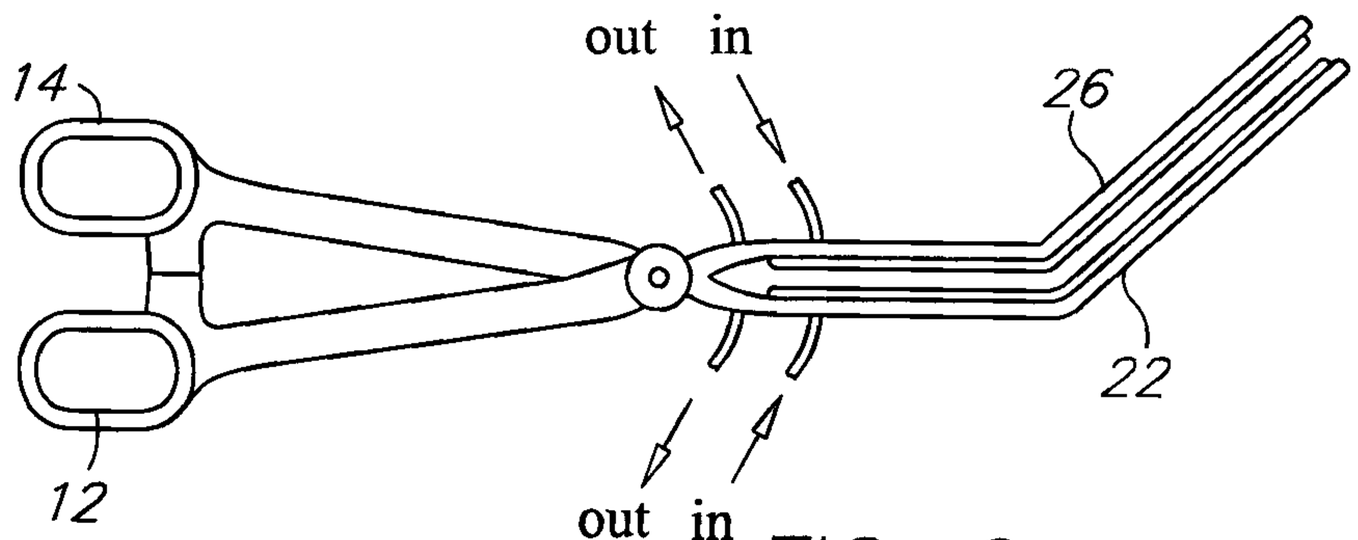


FIG. 6

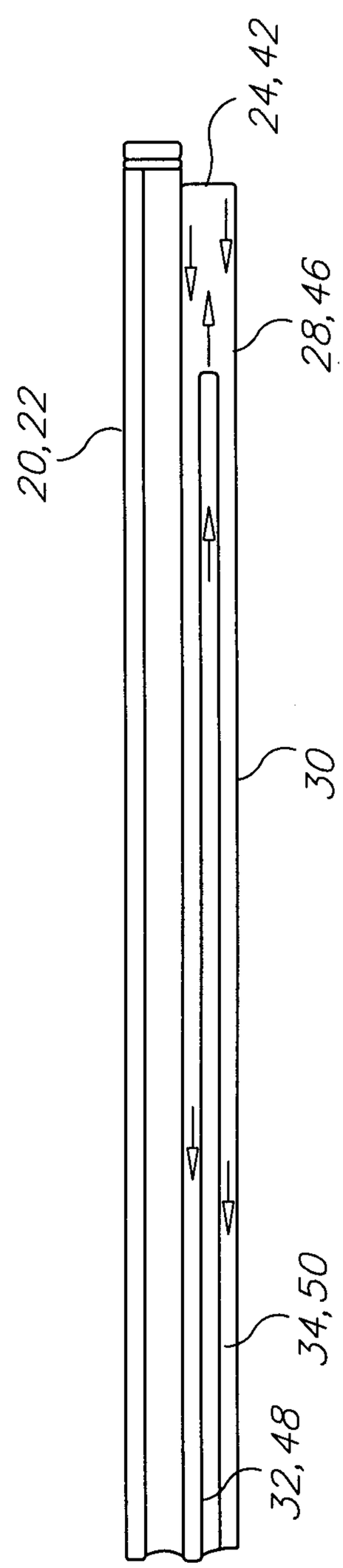


FIG. 2

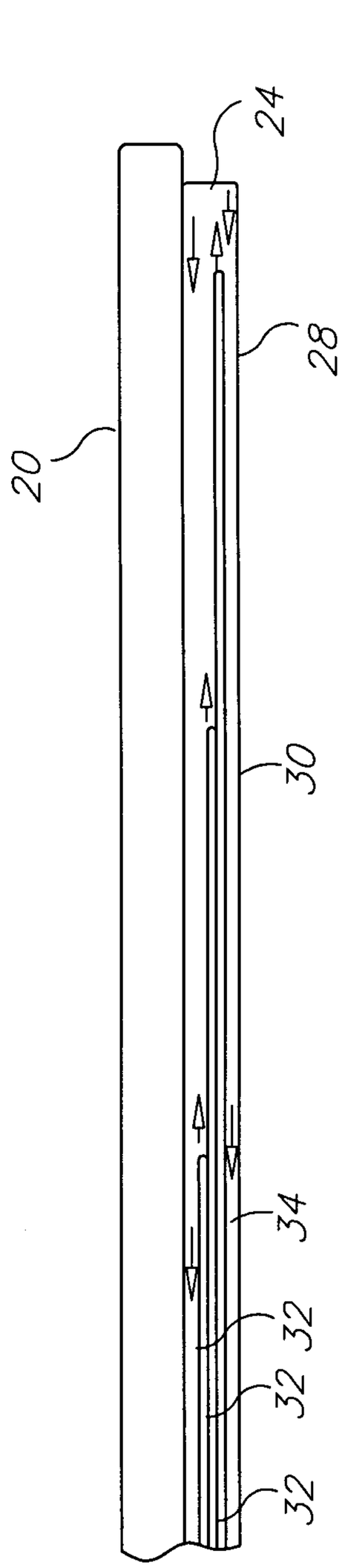


FIG. 3

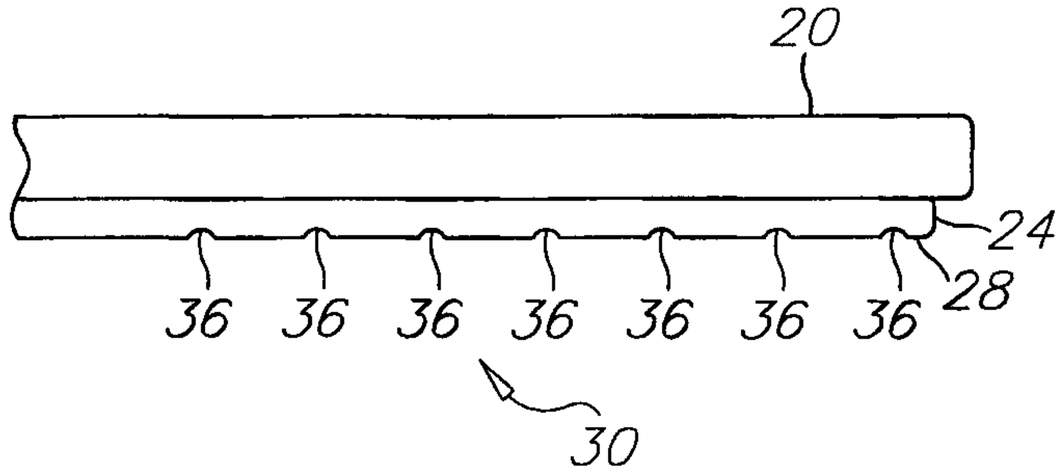


FIG. 4

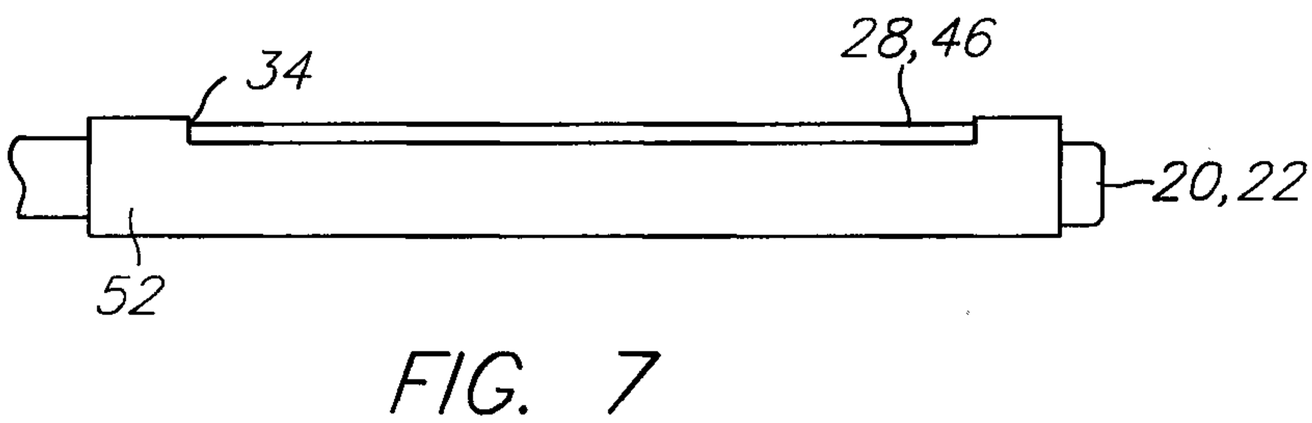


FIG. 7

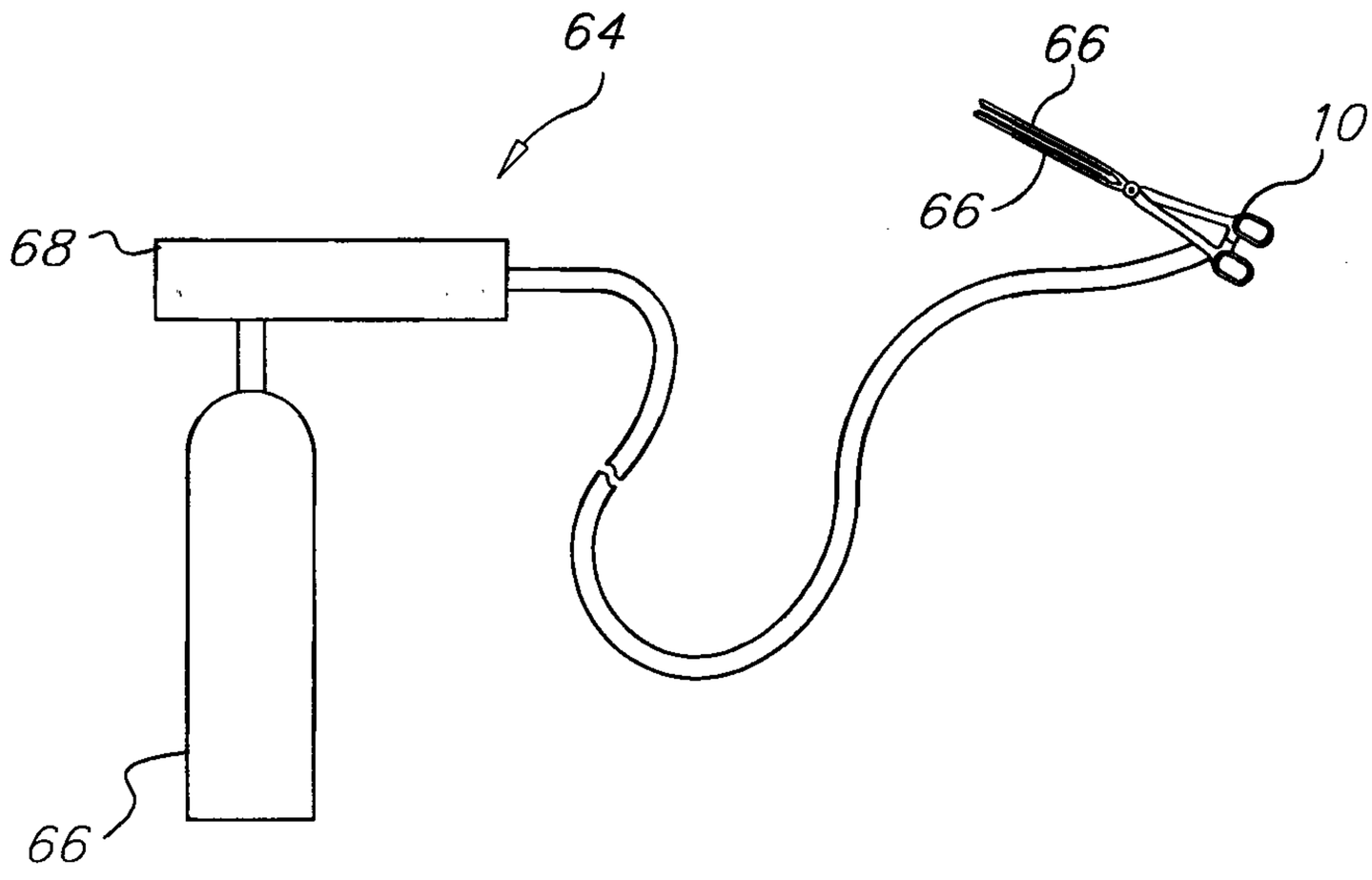


FIG. 10

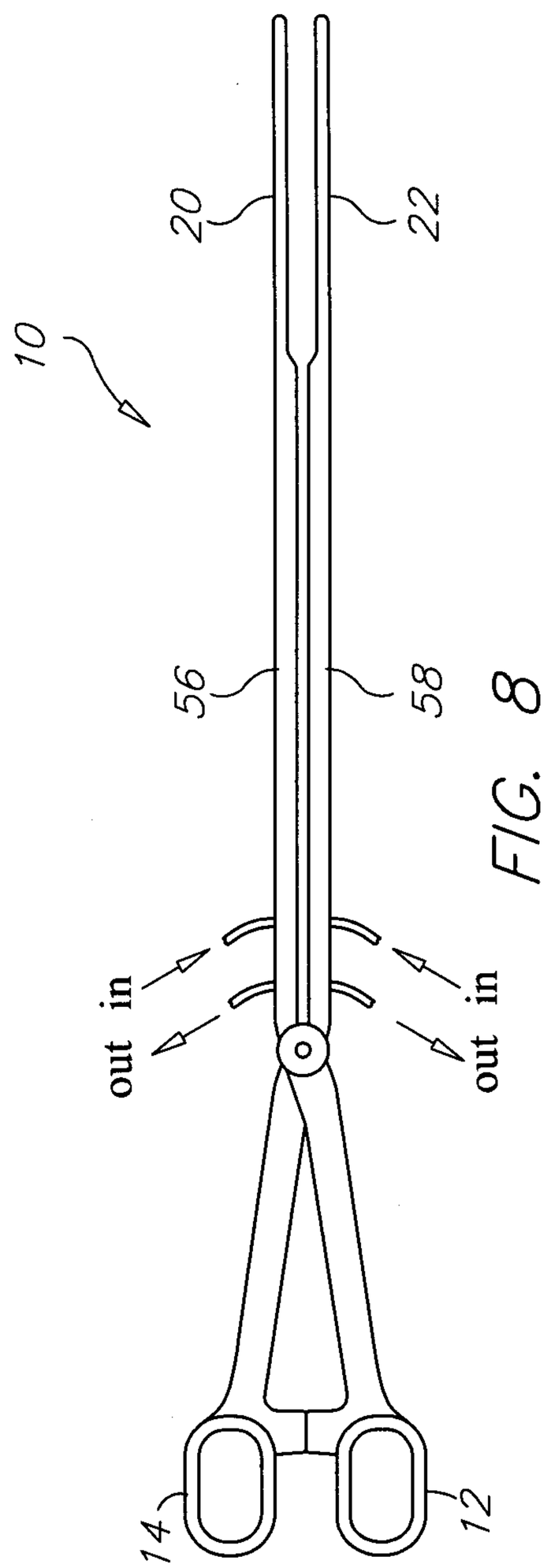


FIG. 8

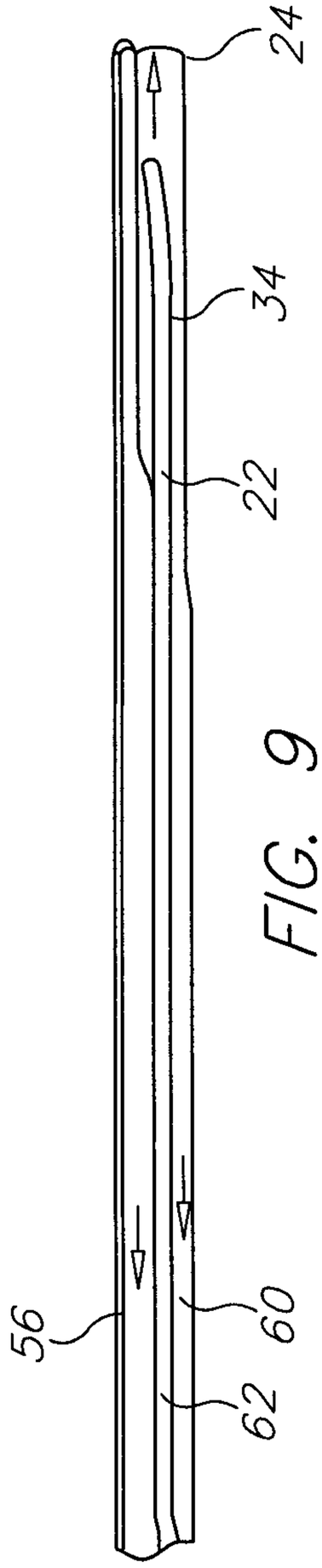


FIG. 9

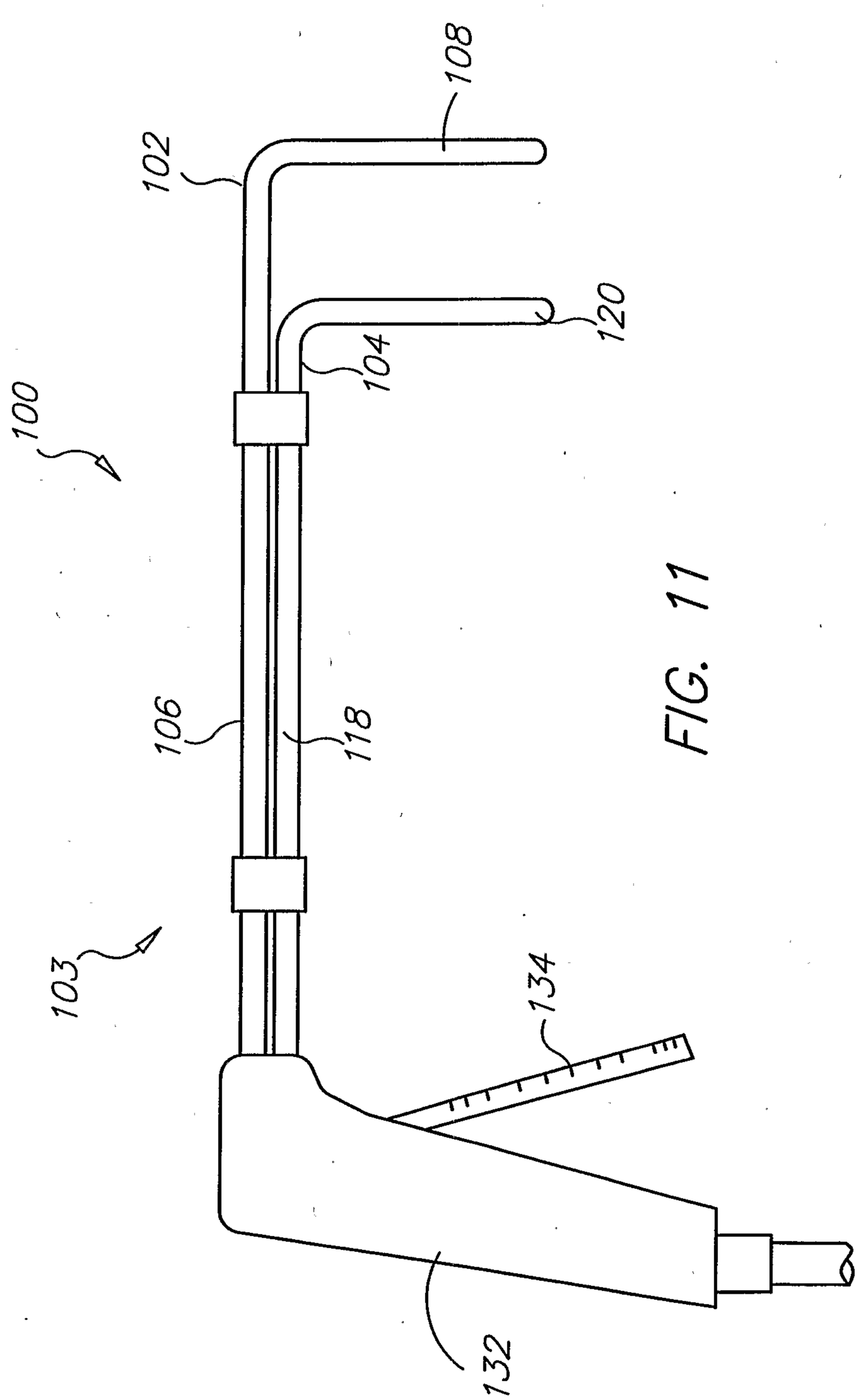
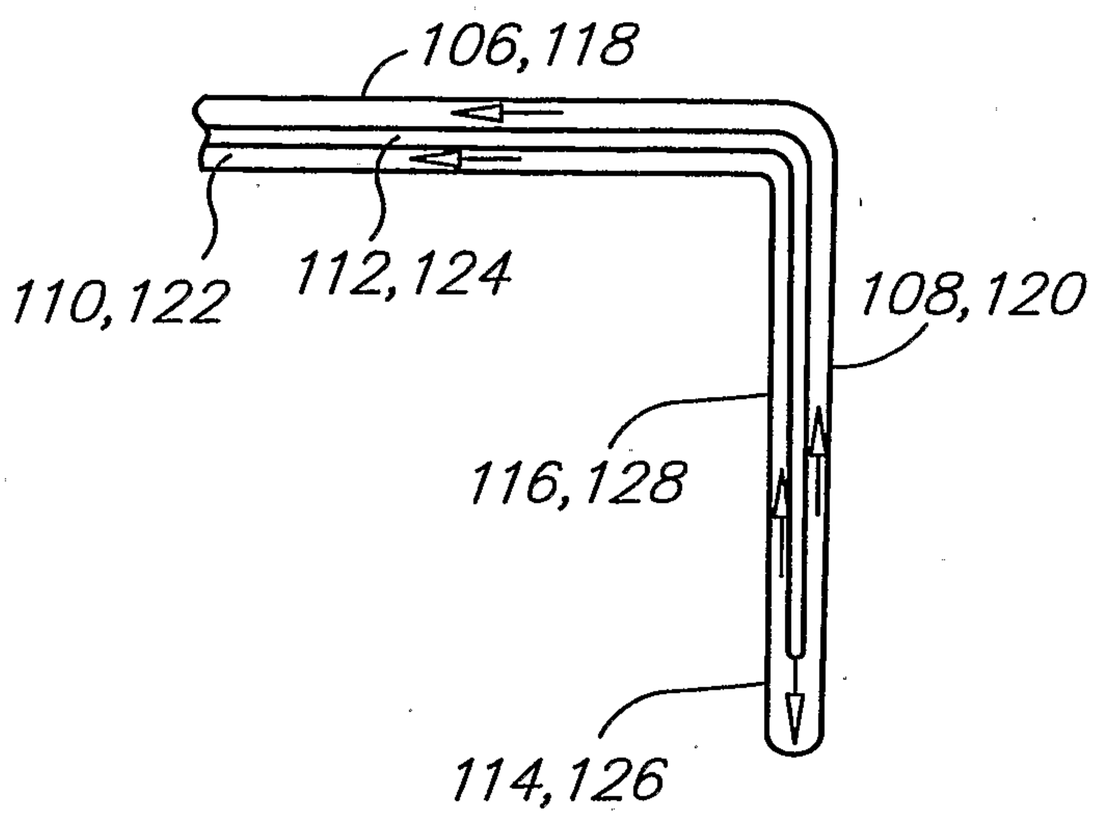


FIG. 11


106,118
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114,126

FIG. 12

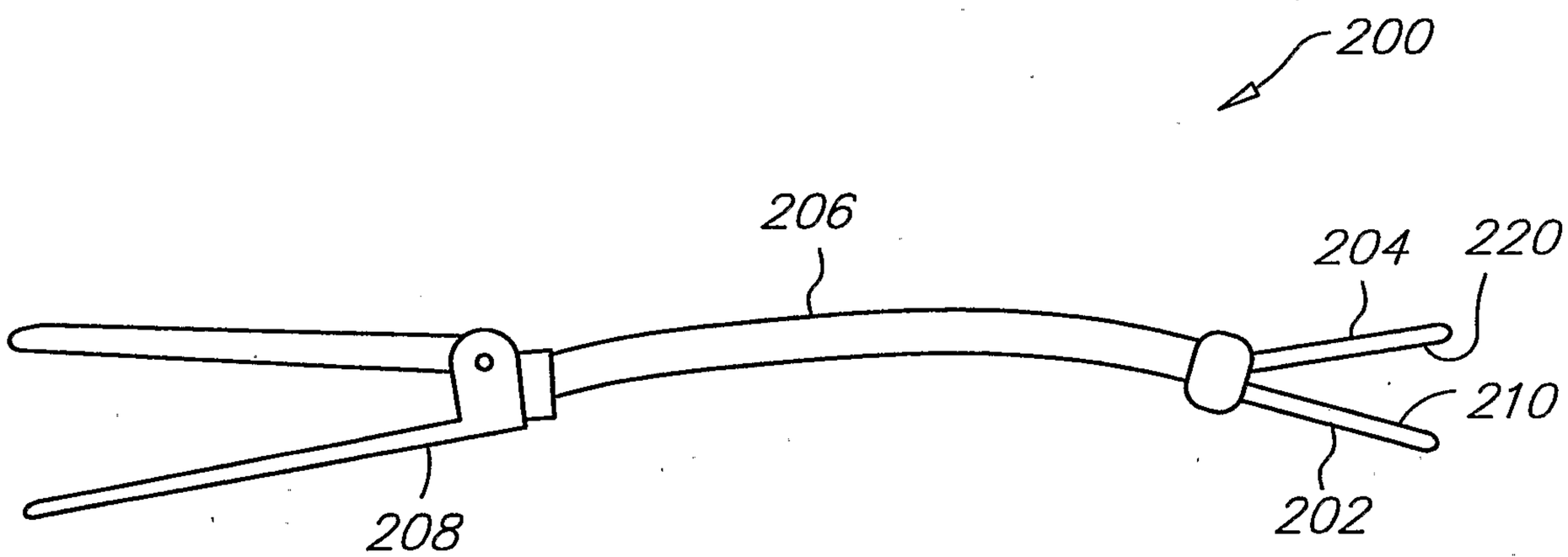
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FIG. 13

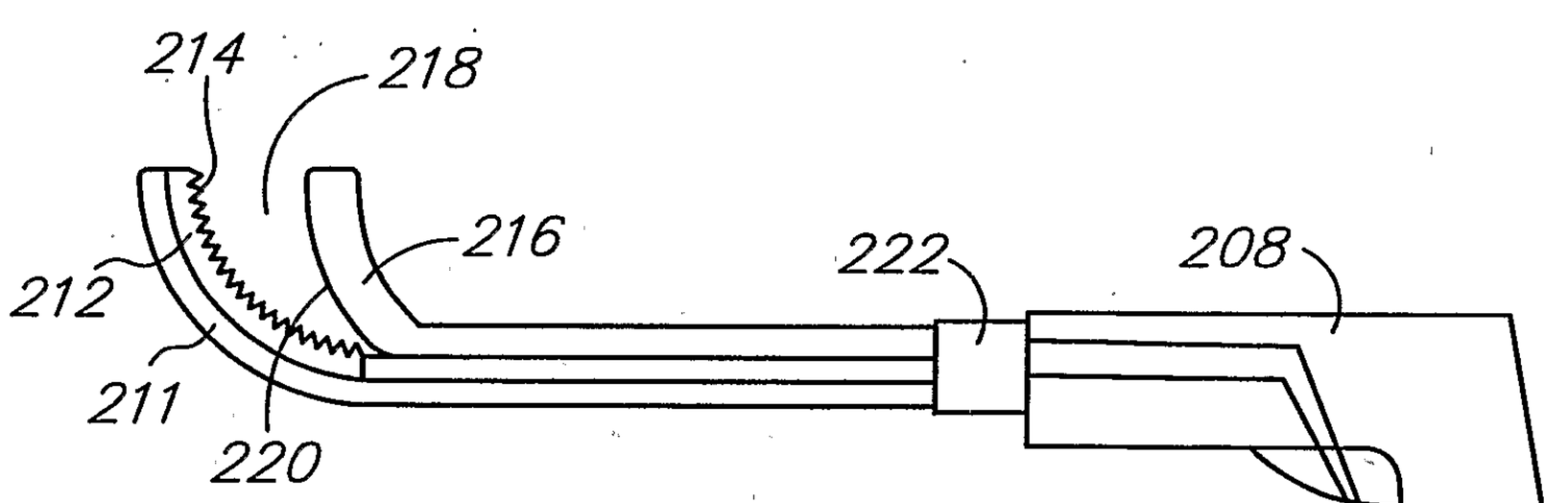


FIG. 14

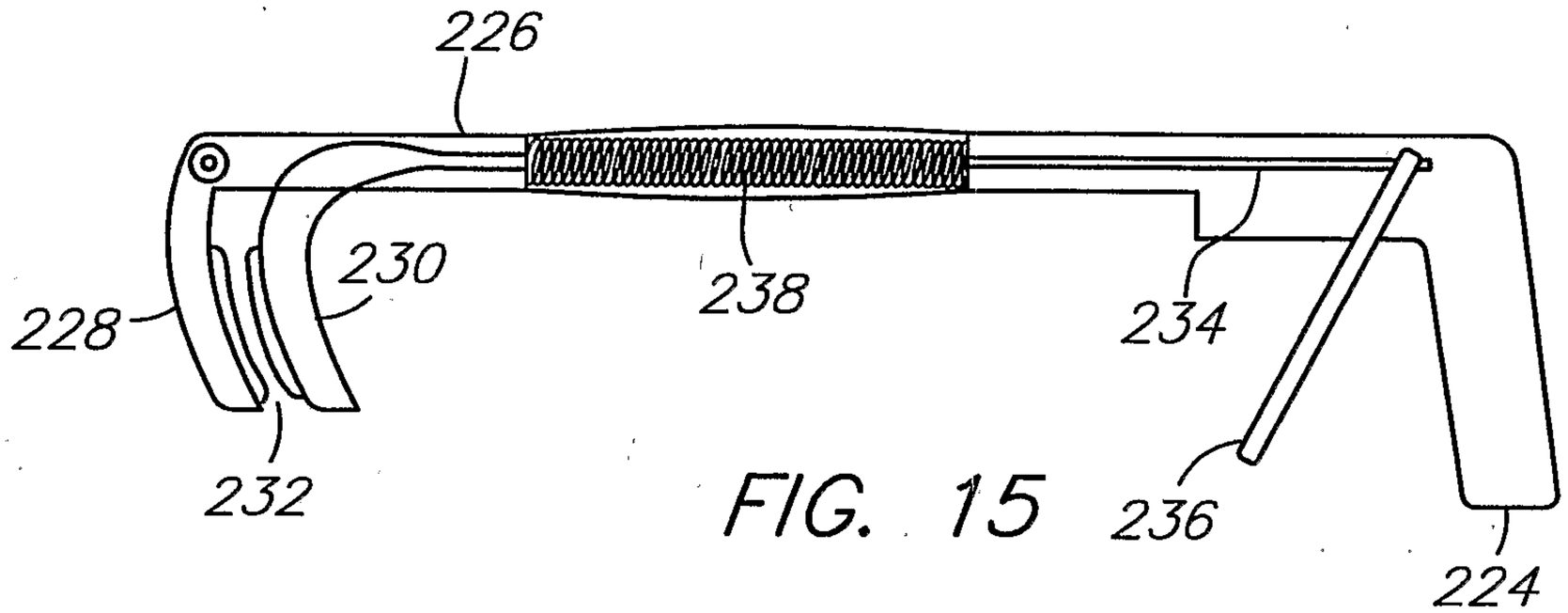


FIG. 15

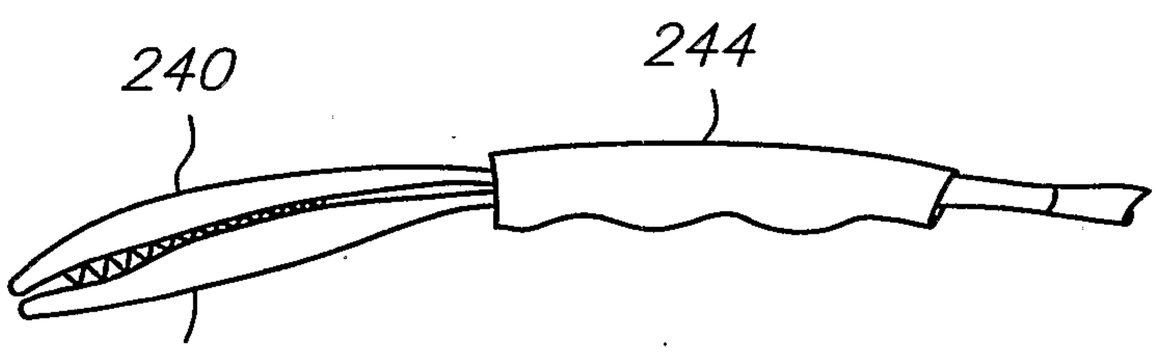


FIG. 16

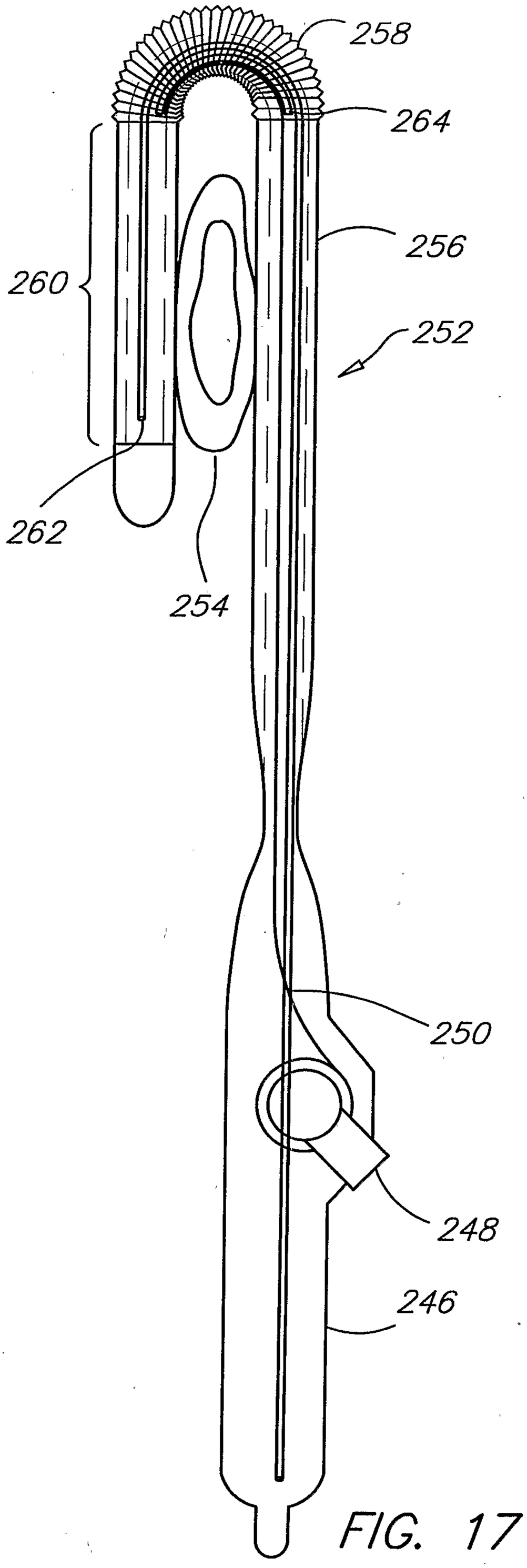


FIG. 17

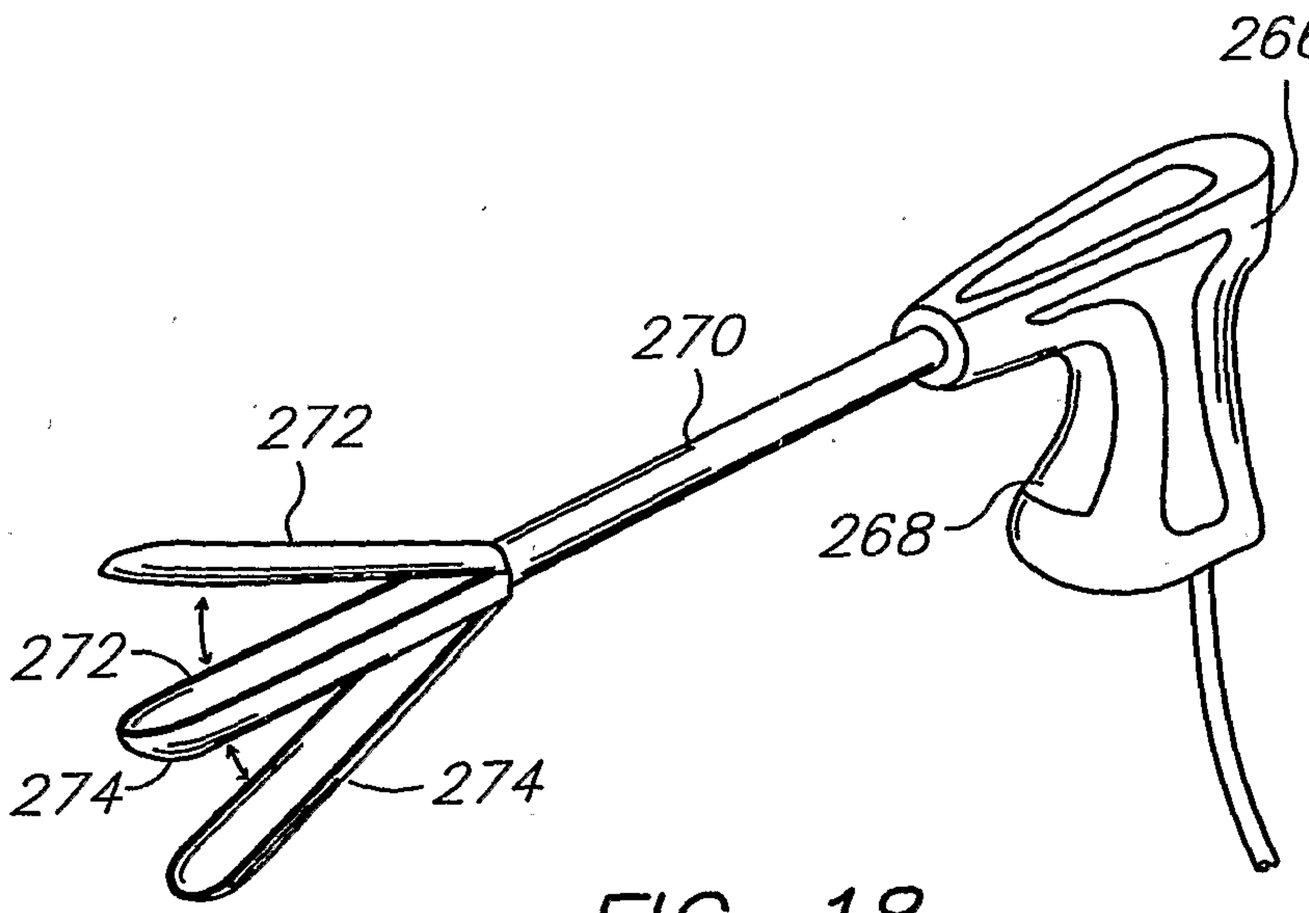


FIG. 18

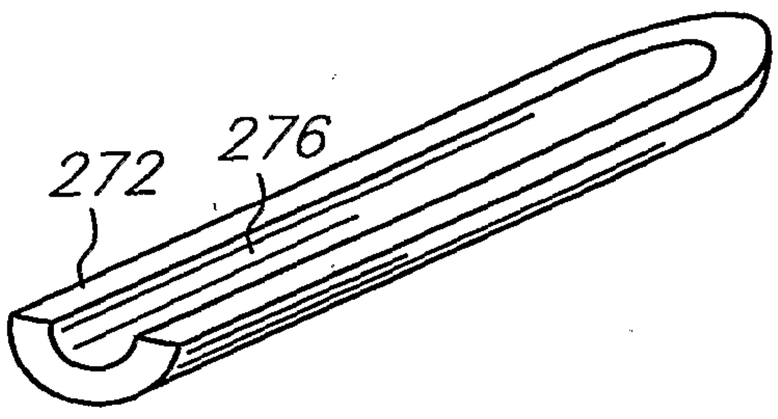


FIG. 19

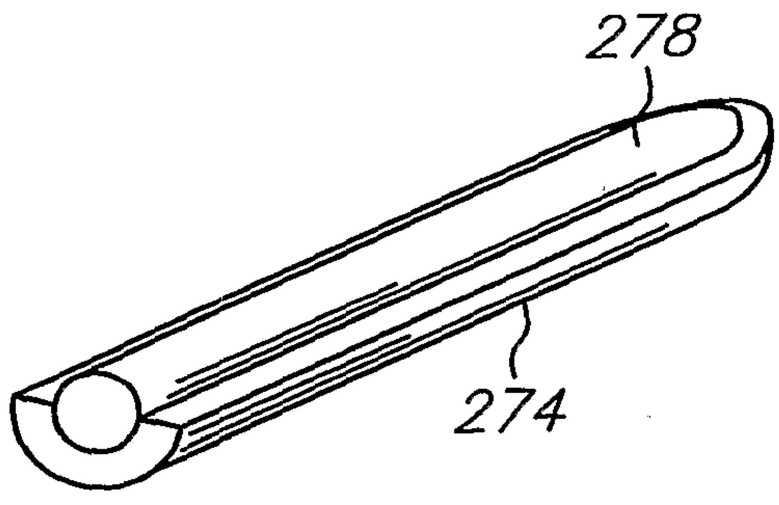


FIG. 20

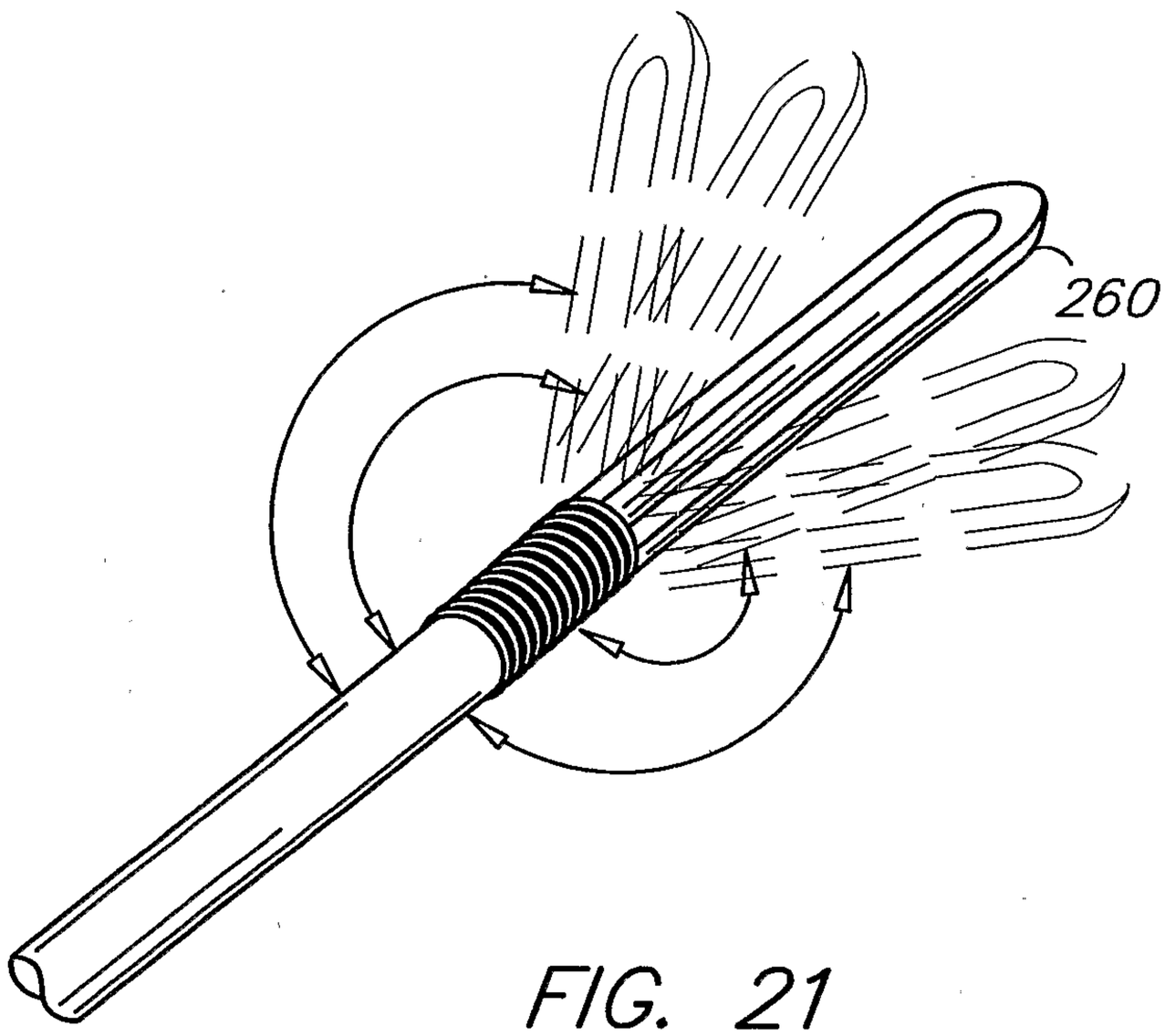


FIG. 21

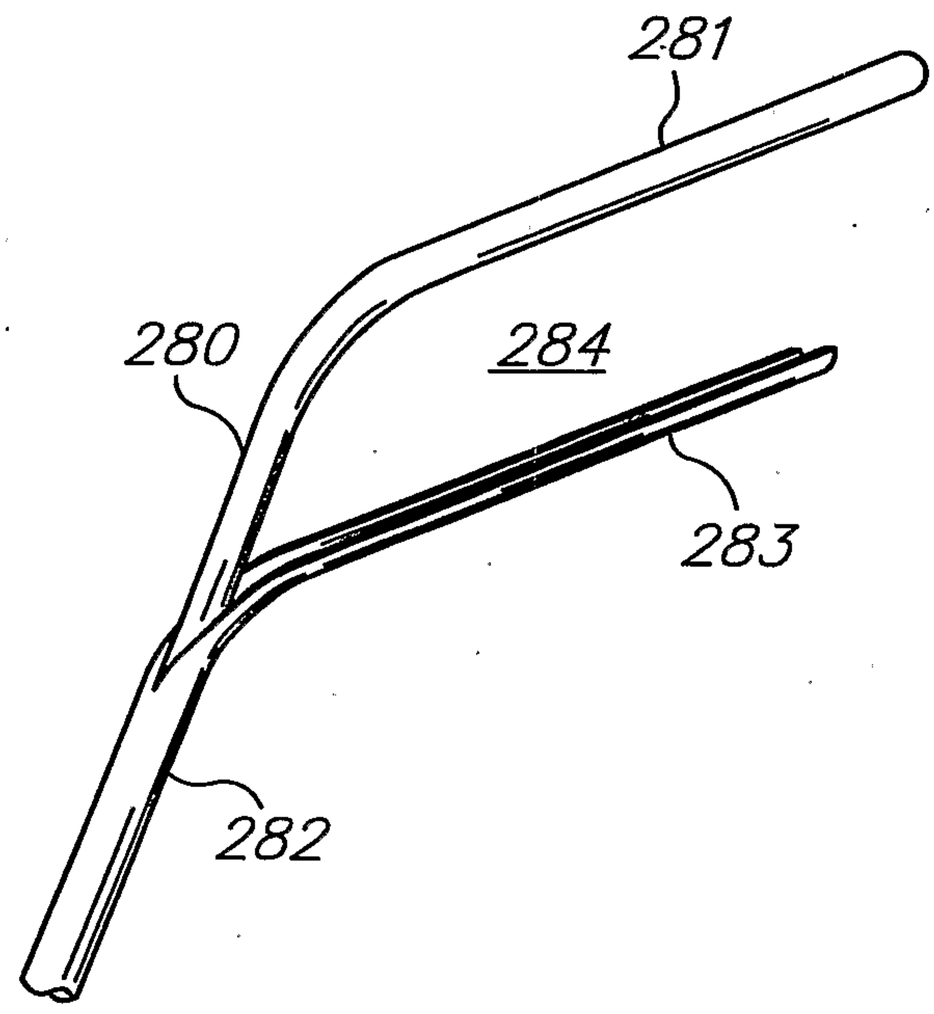


FIG. 22

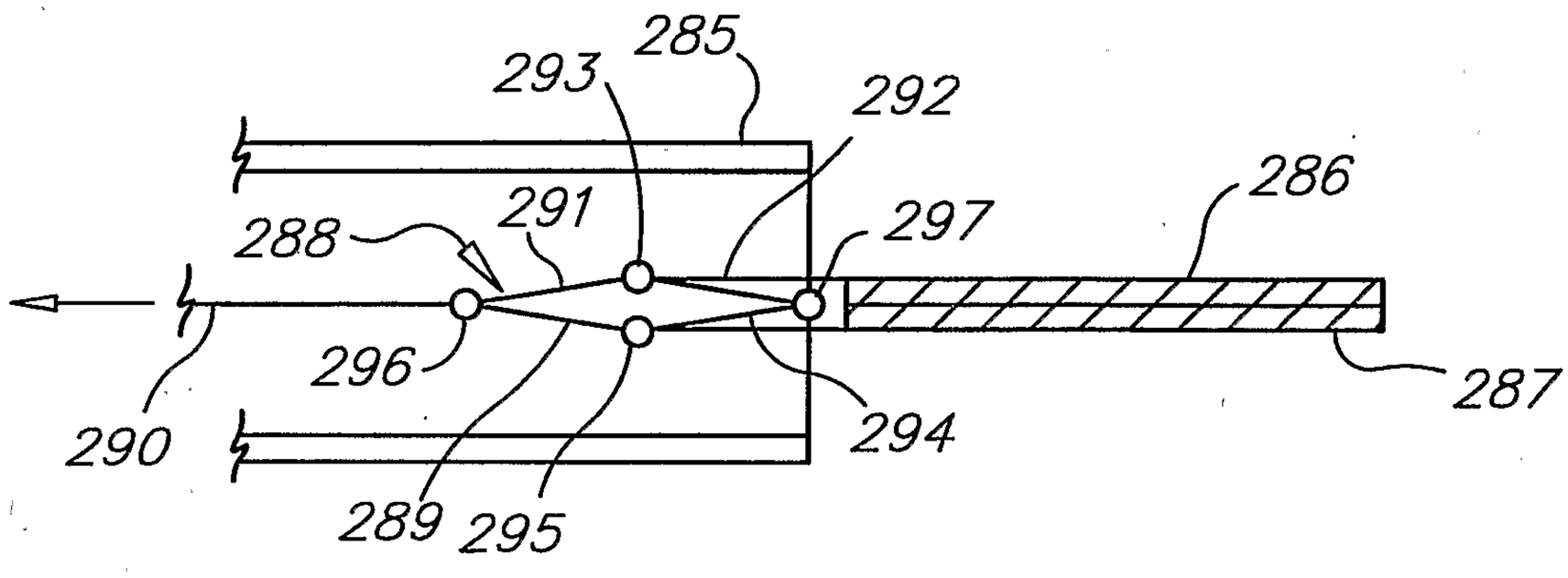


FIG. 23A

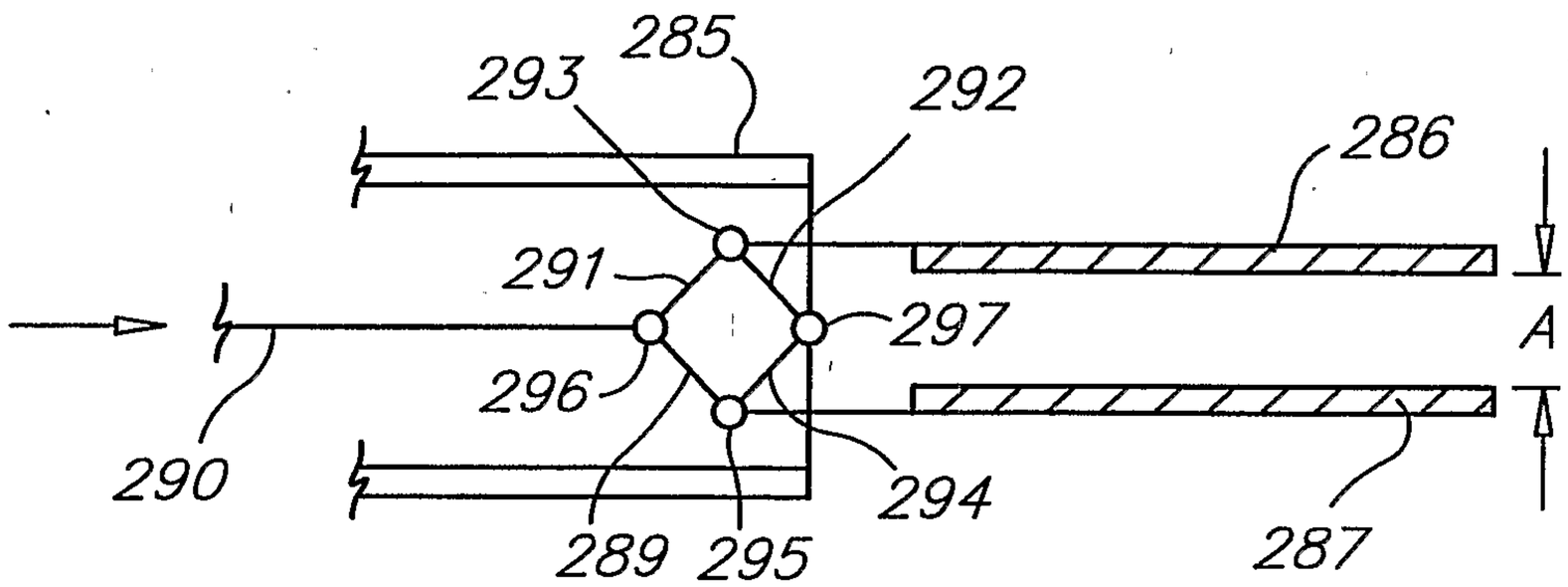


FIG. 23B

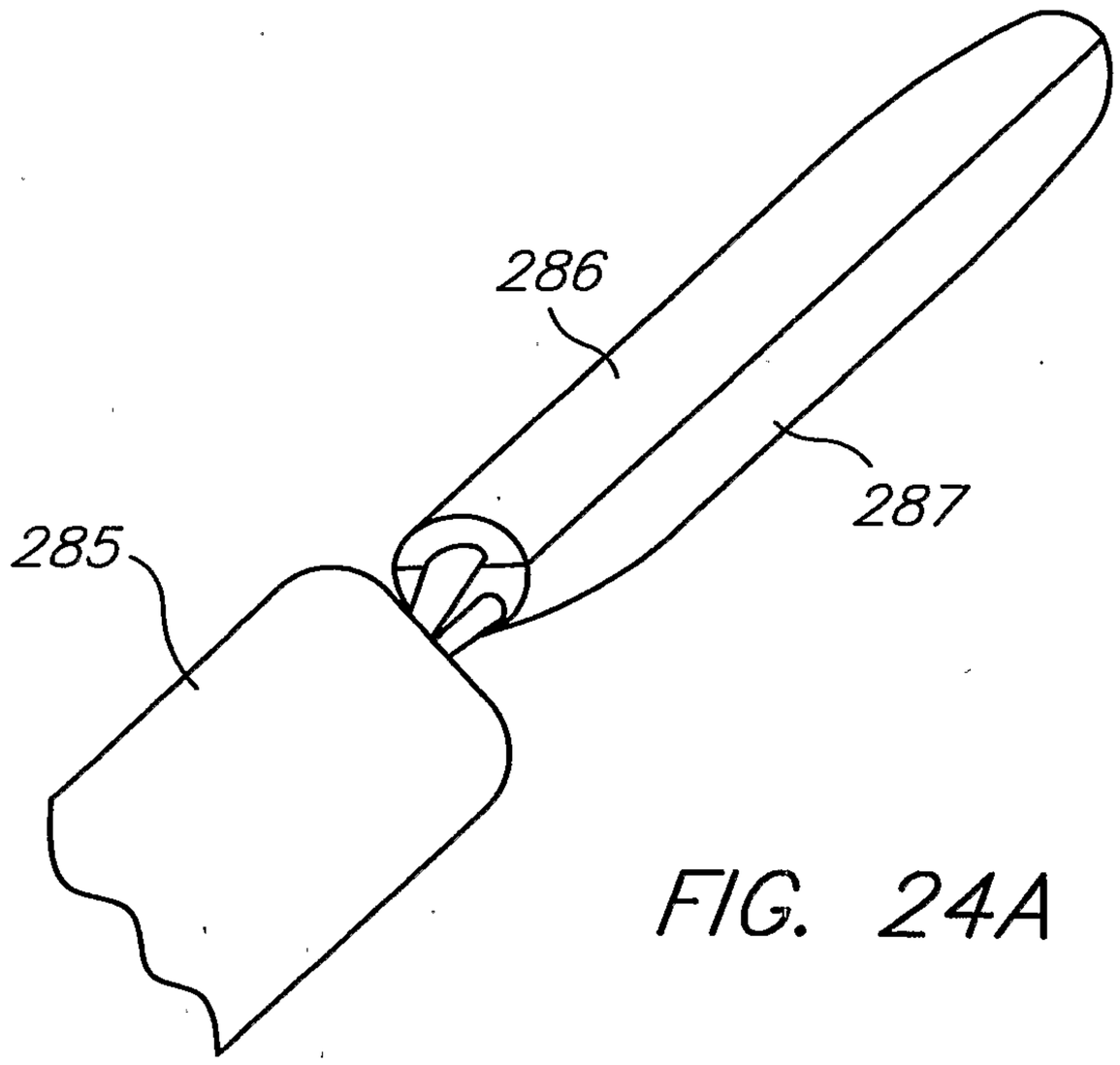


FIG. 24A

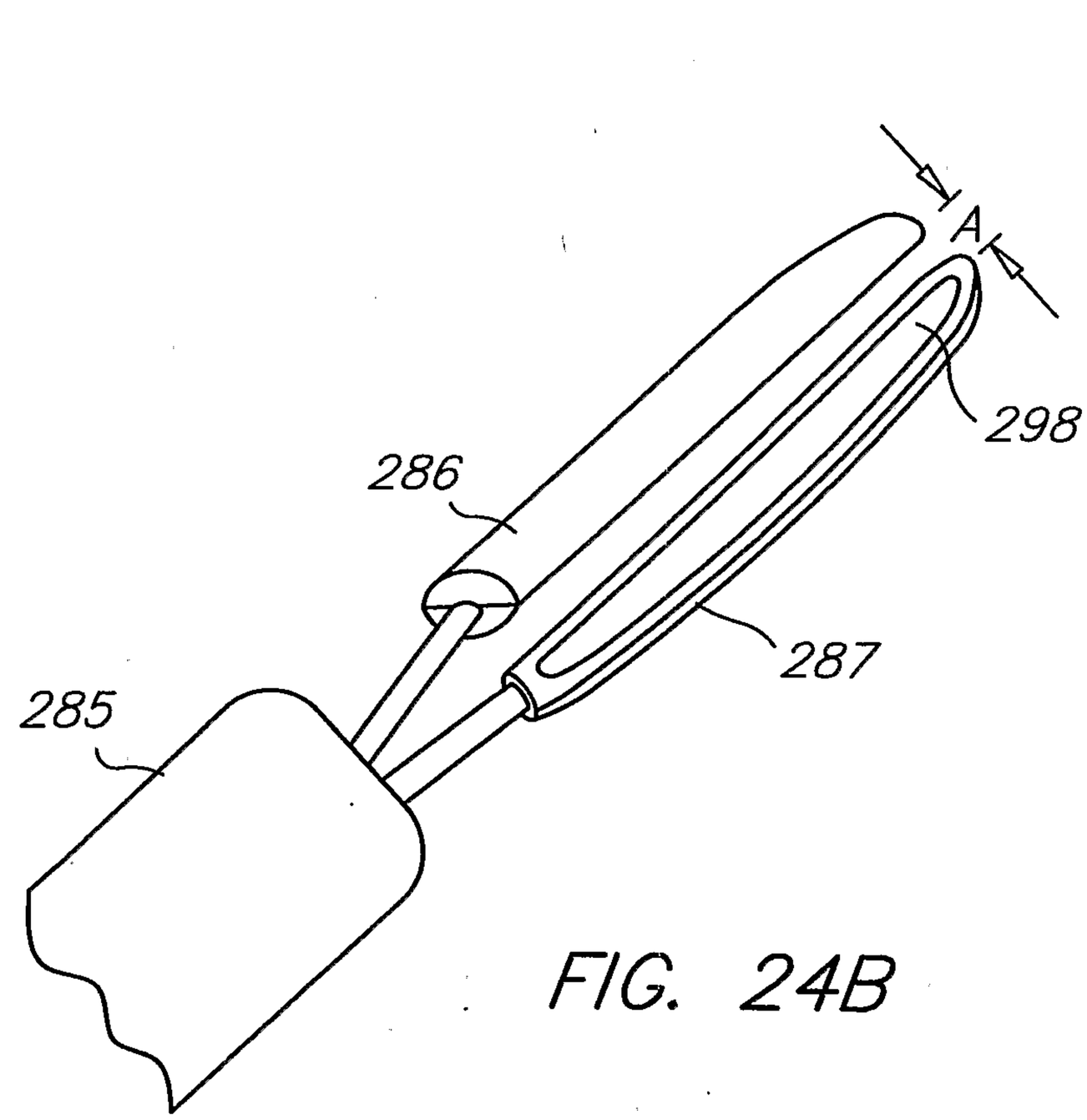


FIG. 24B

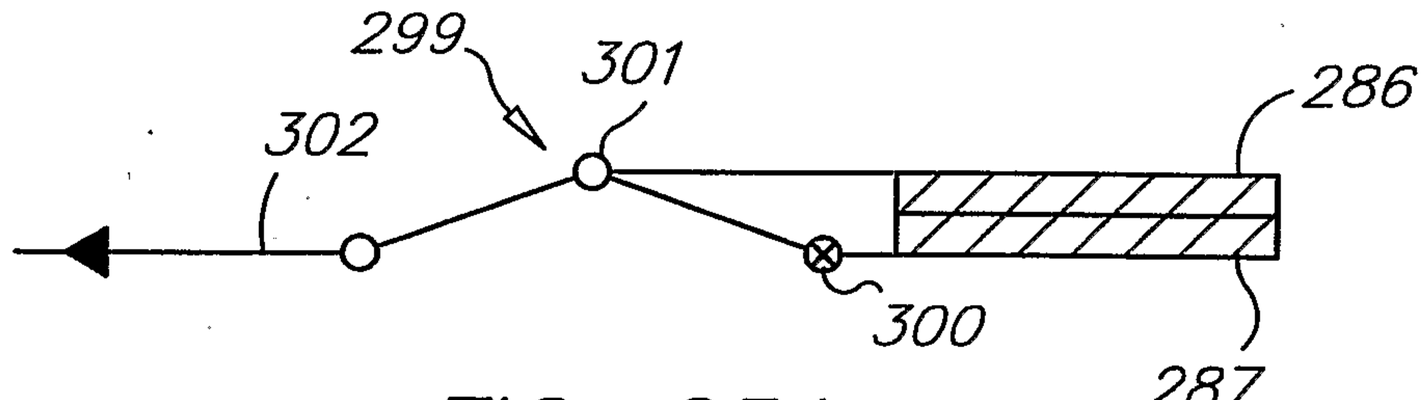


FIG. 25A

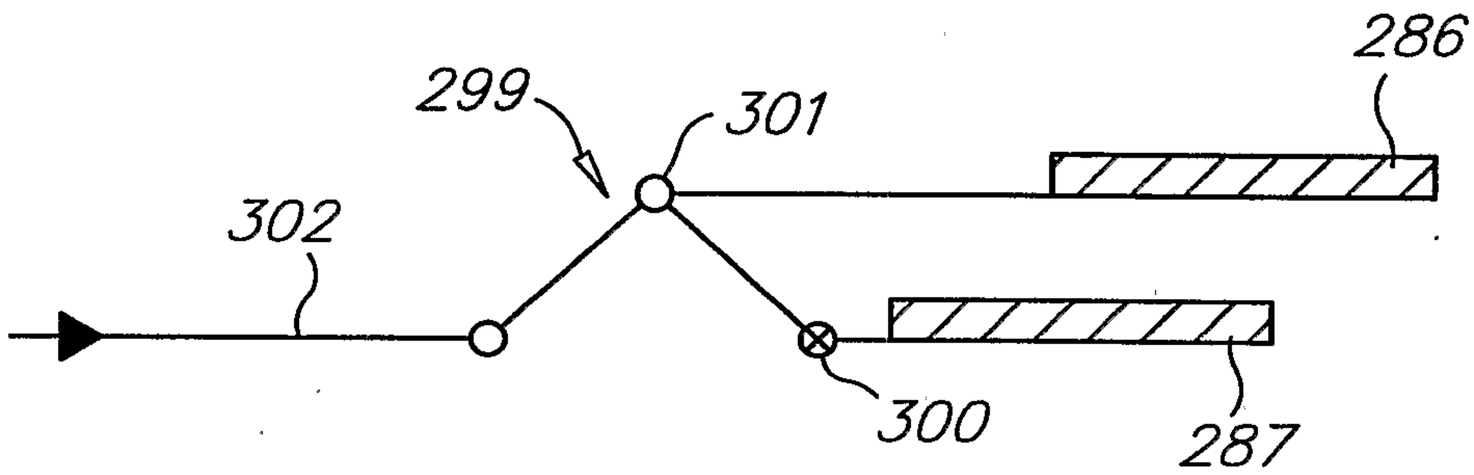


FIG. 25B

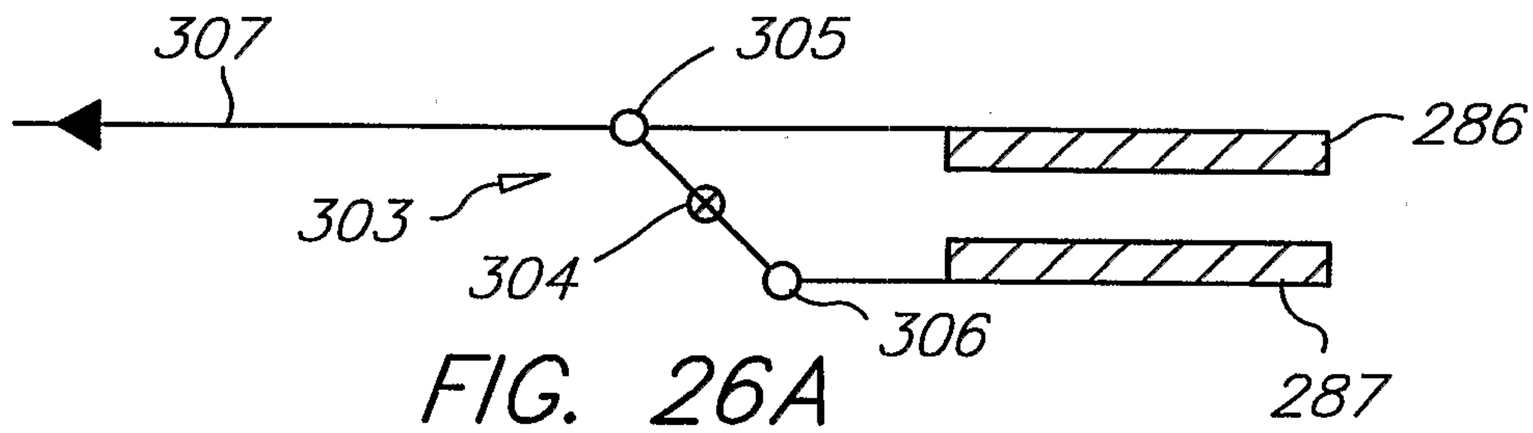


FIG. 26A

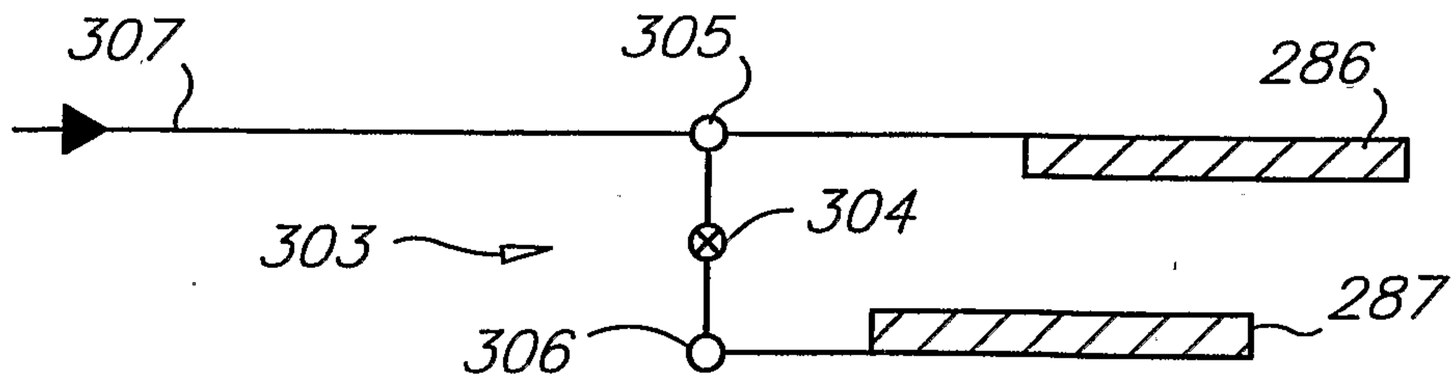


FIG. 26B

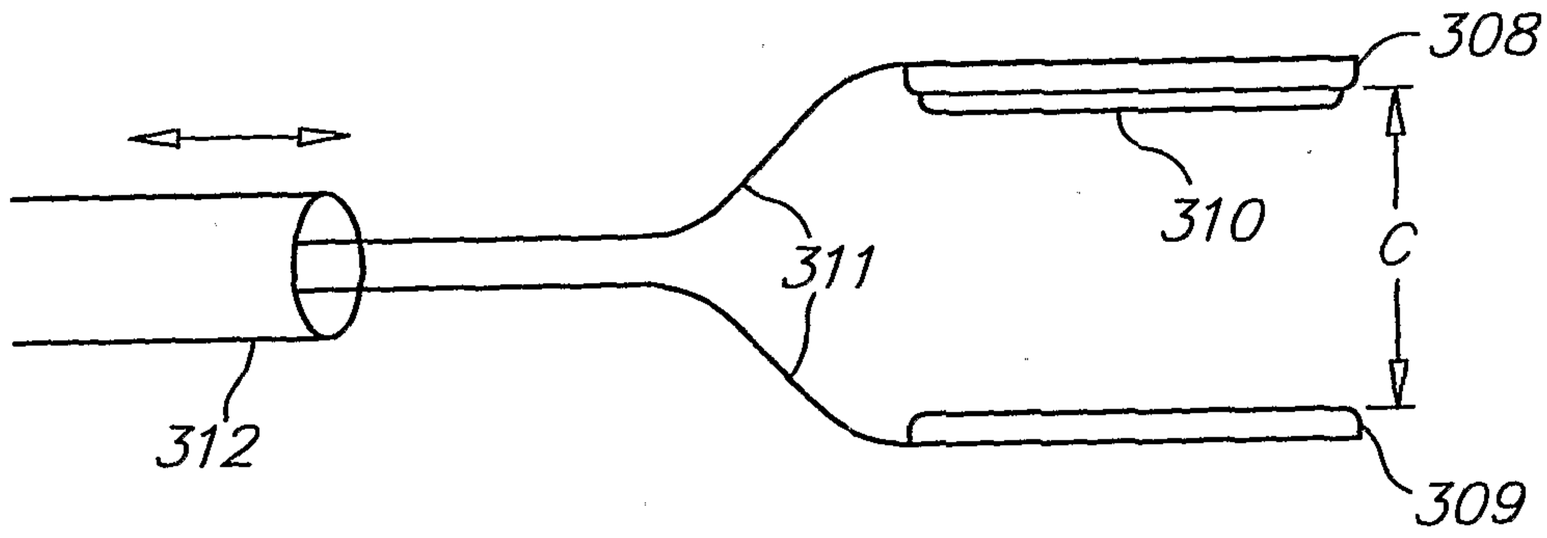


FIG. 27

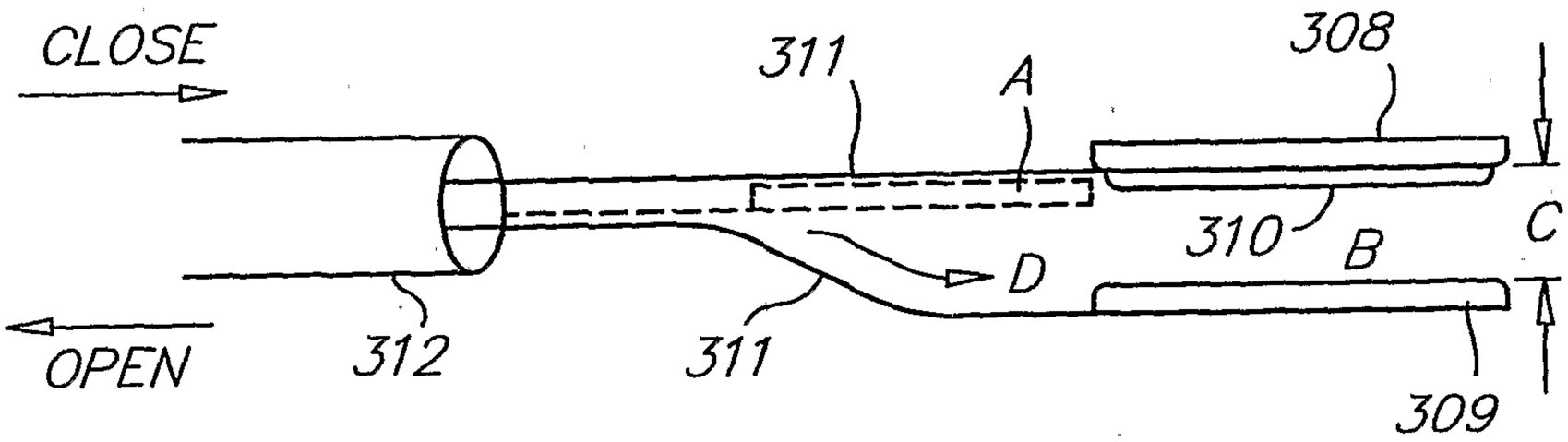
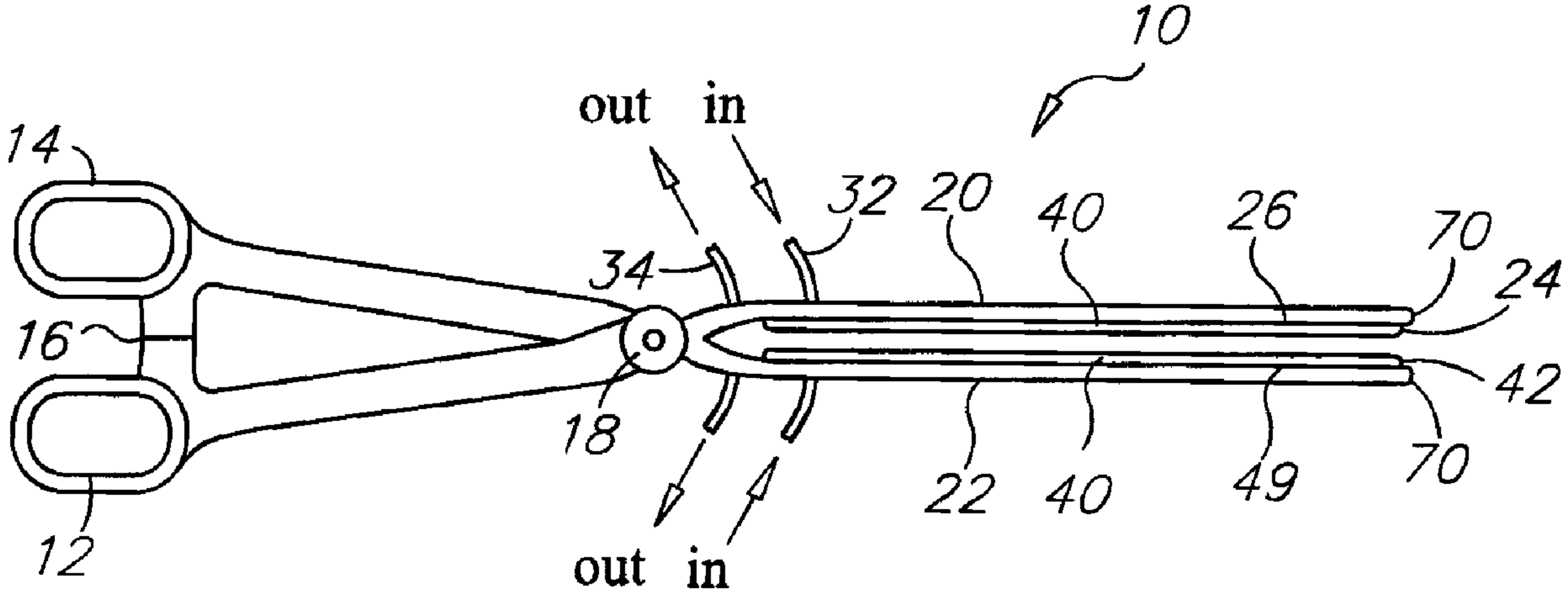


FIG. 28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