

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
19 March 2009 (19.03.2009)

PCT

(10) International Publication Number
WO 2009/036346 A2

- (51) International Patent Classification:
A61B 18/14 (2006.01)
- (21) International Application Number:
PCT/US2008/076263
- (22) International Filing Date:
12 September 2008 (12.09.2008)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/993,790 14 September 2007 (14.09.2007) US
- (71) Applicants (for all designated States except US): **SYNERGETICS, INC.** [US/US]; 3845 Corporate Center, O'Fallon, Missouri 63368 (US). **EASLEY, James C.** [US/US]; c/o Synergetics, Inc., 3845 Corporate Center, O'Fallon, Missouri 63368 (US).

[US/US]; c/o Synergetics, Inc., 3845 Corporate Center, O'Fallon, Missouri 63368 (US). **NADOLSKI, Tim** [US/US]; c/o Synergetics, Inc., 3845 Corporate Center, O'Fallon, Missouri 63368 (US).

(74) Agents: **MUNSELL, Michael, G.** et al.; Armstrong Teasdale, LLP, One Metropolitan Square, 26th Floor, St. Louis, Missouri 63102 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

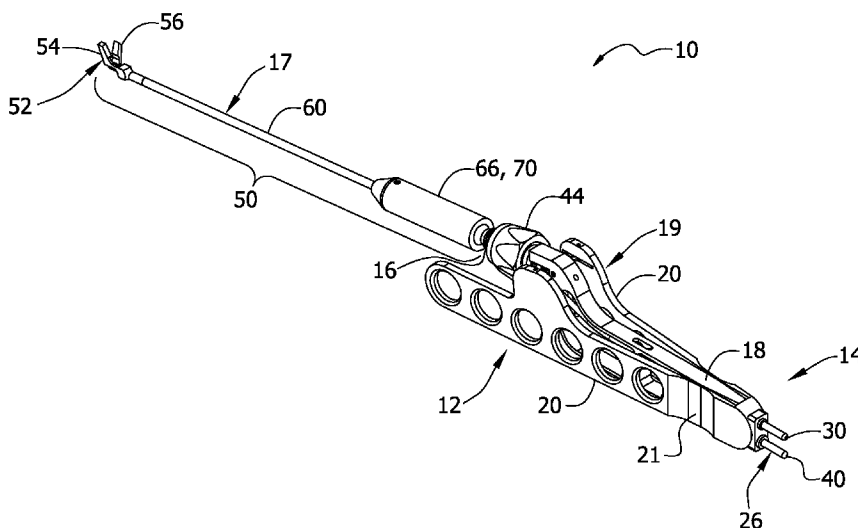
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **HANLON, Mathew A.** [US/US]; c/o Synergetics, Inc., 3845 Corporate Center, O'Fallon, Missouri 63368 (US). **SCHELLER, Gregg** [US/US]; c/o Synergetics, Inc., 3845 Corporate Center, O'Fallon, Missouri 63368 (US). **BOSWELL, John**

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

[Continued on next page]

(54) Title: BIPOLAR ELECTRO-SURGICAL INSTRUMENT

FIG. 1



(57) Abstract: A bipolar surgical instrument for passing current through tissue of a patient includes a handle, an actuator mounted on the handle, first and second shafts, first and second effectors mounted on distal ends of the respective first and second shafts, and a sleeve disposed around the shafts and slidable relative to the shafts from an actuated position to an open position. In the open position, the effectors are separated away from one another. The shafts and the effectors are resiliently biased outward away from one another.

WO 2009/036346 A2



FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished
upon receipt of that report*

BIPOLAR ELECTRO-SURGICAL INSTRUMENT

BACKGROUND

[0001] This invention relates generally to electro-surgical instruments in general and more specifically to electro-surgical forceps, clamps, or similar instruments having an actuator which provides bipolar coagulation, cauterization, dessication, cutting, sealing, or treatment of tissues.

[0002] One of two commonly used electrosurgical modalities is bipolar. In bipolar, voltage is applied to the patient using a special forceps, with one tine or effector connected to one pole of the A.C. voltage source and the other effector connected to the other pole of the voltage source. When a piece of tissue is held by the forceps and a foot pedal or other trigger is depressed, a high frequency electrical current flows from one effector to the other effector, through the intervening tissue. In this manner, the intervening tissue is heated.

[0003] Bipolar coagulation, cauterization, dessication, cutting, sealing, and treatment instruments are recognized as mature within the relevant surgical arts. Bipolar electro-surgical instruments utilize two generally opposing distal electrodes which are electrically coupled to a bipolar generator and are capable of accepting tissues there between. Bipolar generators, which are used in conjunction with bipolar surgical instruments as an excitation source, typically generate a modulated alternating current (AC) signal in the tens or hundreds of kilohertz or megahertz frequency

range and typically have an open circuit potential amplitude of tens to thousands of volts. The conductivity of the tissues treated by the bipolar instruments often vary due to the ionic content of the tissues which necessitates some type of current limiting, including passive saturation and active current control limiting. The root-mean-square (RMS) value of the treatment potential across the treated tissue multiplied by the RMS value of the treatment current through the tissue provides substantial resistive heating within the tissue supported or held by the bipolar surgical instrument. The heating is sufficient to coagulate blood, treat or cut blood vessels, or alter the biochemistry at the surgical site as desired by a surgeon.

[0004] Bipolar instruments typically have one or more distal end effectors or tips which are formed to provide the clamping, cutting, or other treatments required during surgery. When used as a bipolar surgical instrument, each end effector is electrically insulated from the other and each has a separate electrical current path through the instrument body and actuating handle, each of which typically terminate and connect with a distinct pin of a two or more pin electrical connector. The bipolar generator is electrically connected with the connector whereby electrocautery power is delivered to the effectors. When two end effectors are incorporated into or with a surgical instrument, often one effector remains stationary while an adjacent effector has an axial or angular displacement relative to the stationary effector.

[0005] For bipolar and non-bipolar instruments, axial or angular mechanical motion is often

imparted to the effectors via an actuating handle. Often the actuating handle provides an axial or a linear piston or shaft displacement in response to a surgeon's stimulus. The stimulus typically comprises the compression or movement of a trigger, lever, or one or more surfaces which are moveably or rotatably attached with the actuating handle. The piston or shaft axial or linear displacement is then transferred through an assembly or housing which imparts an axial or angular displacement onto the effectors. The assembly or housing design determines the precise type of movement imparted to the effectors.

BRIEF SUMMARY

[0006] In one aspect, a bipolar surgical instrument for passing current through tissue of a patient is provided. The instrument comprises: a handle, an actuator mounted on the handle, first and second shafts, first and second effectors mounted on distal ends of the respective first and second shafts, and a sleeve disposed around the shafts and slidable relative to the shafts from an actuated position to an open position. In the open position, the effectors are separated away from one another. The shafts and the effectors are resiliently biased outward away from one another so that when the sleeve moves from the actuated position to the open position, the effectors move away from one another.

[0007] In another aspect, a bipolar surgical instrument for passing current through tissue is provided. The instrument comprises: a handle, an actuator mounted on the handle, first and second shafts, and first and second effectors mounted on the first and second shafts

respectively and disposed at a distal end of the instrument. First and second electrical paths are separately routed from the connector through the handle and to the effectors. The paths are insulated from one another to maintain two poles. The paths extend coaxially and concentrically through the shafts.

[0008] Various refinements exist of the features noted in relation to the above-mentioned aspects. Further features may also be incorporated in the above-mentioned aspects as well. These refinements and additional features may exist individually or in any combination. For instance, various features discussed below in relation to any of the illustrated embodiments may be incorporated into any of the above-described aspects, alone or in any combination.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Fig. 1 is a rear perspective view of the single shafted bipolar surgical instrument having an effector assembly with an angular rotating translation mechanism. The effector assembly is shown slightly separated from the actuating handle.

[0010] Fig. 2 is a front perspective view thereof.

[0011] Fig. 3 is a right side plan view thereof.

[0012] Fig. 4 is a front side plan view thereof.

[0013] Fig. 5 is a rear side plan view thereof.

[0014] Fig. 6 is a top side plan view thereof.

[0015] Fig. 7 is a cross sectional view taken along lines 7 - 7 of Fig. 6.

[0016] Fig. 8 is a detailed cross sectional view taken along detail view Fig. 8 of Fig. 6.

[0017] Fig. 9 is a detailed cross sectional view taken along detail view Fig. 9 of Fig. 6.

[0018] Fig. 10 is a partially expanded assembly view of the effector assembly of Fig. 1.

[0019] Fig. 11 is a partially expanded assembly view of the housing of the effector assembly of Fig. 1.

[0020] Fig. 12 is an assembly view of the translational-to-rotational transmission mechanism of the effector assembly of Fig. 1.

[0021] Fig. 13 is an assembly view of the inner shaft, insulator, and second effector of the effector assembly of Fig. 1.

[0022] Fig. 14 is an assembly view of the outer shaft and first effector of the effector assembly of Fig. 1.

[0023] Fig. 15 is a left plan view of inner shaft and second effector of the effector assembly of Fig. 1.

[0024] Fig. 16 is a detailed view of the second effector taken along detail view Fig. 16 of Fig. 15.

[0025] Fig. 17 is a right, rear perspective view of the first effector of Fig. 1.

[0026] Fig. 18 is a right, front perspective view of the second effector of Fig. 1.

[0027] Fig. 19 is a top plan view of the case of the effector assembly of Fig. 1.

[0028] Fig. 20 is a cross sectional view taken along lines 20 - 20 of Fig. 19.

[0029] Fig. 21 is a right plan view of the insulating insert of the effector assembly of Fig. 1.

[0030] Fig. 22 is a cross sectional view taken along lines 22 - 22 of Fig. 21.

[0031] Fig. 23 an assembly view of the actuating handle of Fig. 1.

[0032] Fig. 24 is a cross sectional view taken along detail view Fig. 24 of Fig. 7.

[0033] Fig. 25 is a left plan view of the handle body of Fig. 1.

[0034] Fig. 26 is a top plan view of the handle body of Fig. 1.

[0035] Fig. 27 is a cross sectional view taken along lines 27 - 27 of Fig. 26.

[0036] Fig. 28 is a top plan view of the piston housing of Fig. 1 with internal bores shown in phantom.

[0037] Fig. 29 is a top plan view of the piston or shaft of Fig. 1 with retention pin holes shown in phantom.

[0038] Fig. 30 is a left plan view of the conductive bushing of Fig. 1 with internal bores shown in phantom.

[0039] Fig. 31 is a plan view of the first insulating bushing of Fig. 1 with internal bores shown in phantom.

[0040] Fig. 32 is a plan view of the second insulating bushing of Fig. 1 with internal bores shown in phantom.

[0041] Fig. 33 is a plan view of the insulating washer of Fig. 1.

[0042] Fig. 34 is a rear perspective view of the effector assembly retainer cap of Fig. 1.

[0043] Fig. 35 is a rear perspective view of the effector assembly retainer of Fig. 1.

[0044] Fig. 36 is a cross sectional view taken along detail view Fig. 36 of Fig. 7.

[0045] Fig. 37 is a rear perspective view of the effector assembly with an axial or linear translation mechanism.

[0046] Fig. 38 is a top plan view of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0047] Fig. 39 is a cross sectional view taken along lines 39 - 39 of Fig. 38.

[0048] Fig. 40 is a cross sectional view taken along detail view Fig. 40 of Fig. 39.

[0049] Fig. 41 is a cross sectional view taken along detail view Fig. 41 of Fig. 39.

[0050] Fig. 42 is an assembly view of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0051] Fig. 43 is an exploded assembly view taken along detail view Fig. 43 of Fig. 42.

[0052] Fig. 44 is a top plan view of the case of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0053] Fig. 45 is an enlarged end plan view of the insulating support of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0054] Fig. 46 is a cross sectional view taken along lines 46 - 46 of Fig. 45.

[0055] Fig. 47 is a top plan view of the insulating insert of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0056] Fig. 48 is a cross sectional view taken along lines 48 - 48 of Fig. 47.

[0057] Fig. 49 is a top plan view of the slotted body of the translational mechanism of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0058] Fig. 50 is a top plan view of the aft piston of the effector assembly with an axial or linear translation mechanism of Fig. 37.

[0059] Fig. 51 is a cross sectional view taken along lines 51 - 51 of Fig. 50.

[0060] Fig. 52 is a perspective view of the insulating insert of Fig. 21 assembled with an angular rotating translation mechanism.

[0061] Fig. 53 is a perspective view of an assembled angular rotating translation mechanism without the insulating insert of Fig. 21.

[0062] Fig. 54 is a perspective view of a bipolar surgical instrument of another embodiment.

[0063] Fig. 55 is a perspective view of the bipolar surgical instrument of Fig. 54 in an actuated position.

[0064] Fig. 56 is a perspective view of the instrument in an open or unactuated position.

[0065] Fig. 57 is a fragmentary top plan view of a pair of effectors of the instrument in the open position.

[0066] Fig. 58 is a fragmentary top plan view of pair of the effectors in the actuated position.

[0067] Fig. 59 is a fragmentary top plan view of the actuator of the instrument.

[0068] Fig. 60 is a perspective view of the instrument in the actuated position.

[0069] Fig. 61 is a perspective view like Fig. 60 but with the effectors rotated relative to the position shown in Fig. 60.

[0070] Fig. 62 is a cross-sectional view taken along lines 62 -- 62 of Fig. 61.

[0071] Fig. 63 is a cross-sectional view taken along line 63 -- 63 of Fig. 60.

[0072] Fig. 64 is a fragmentary top plan view of a pair of straight scissor effectors in an open position.

[0073] Fig. 65 is a fragmentary top plan view of the straight scissor effectors in an actuated position.

[0074] Fig. 66 is a top plan view of a pair of curved scissor effectors in an actuated position.

[0075] Corresponding reference characters indicate corresponding parts throughout the drawings.

DETAILED DESCRIPTION

[0076] Referring to Figures 1-3, a bipolar surgical instrument 10 of one embodiment generally includes an effector assembly 50 and an actuating handle 12. The effector assembly includes effectors 52 disposed at a distal end of the instrument 10. The actuating handle 12 (sometimes referred to as a bipolar N-handle)

includes an electrical connector 26 disposed at a proximal end 14, and an actuator 19.

[0077] Generally, the instrument 10 electrically connects the electrical connector 26 of the handle 12 to effectors 52 via a single shaft 17 of the assembly 50. The effector assembly includes a housing 66 holding nested shafts 60, 62 of the single shaft 51. The handle 12 conductively mates with the housing 66 yet maintains electrical isolation between the electrical poles. This embodiment enables removal and replacement of the effector assembly 50 (including effectors 52, shafts 60, 62, and housing 66), from the actuating handle 12 without a detrimental effect to the electrocautery properties of the surgical instrument 10. In other words, in this embodiment, the effector assembly is removable from the handle 12 and may be replaced so that it may be a disposable portion of the instrument 10.

[0078] Referring to Figs 2 and 23, an embodiment of the actuating handle 12 comprises a handle body 18, two pivoting plates including actuating surfaces 20 and a proximal electrical connector 26. Each of the surfaces 20 are proximally retained with the handle body 18 and medially connected via a pivoting linkage 22. The linkage 22 is connected to an actuating piston assembly 24 (broadly, a shaft) that is slidably placed within the handle body 18. In this embodiment, each actuating surface 20 has a reduced thickness portion 21 near or at the proximal end 14 which is preformed or bent to elastically bias each actuating surface 20 outward or away from the handle body 18. The reduced thickness portion 21 functions as a leaf spring whereby an outward force is

placed onto the linkage 22 and thereby a proximal retraction bias is imparted to the piston assembly 24. In this embodiment, each actuating surface 20 is retained proximally with the handle body 18 via welding or brazing. Alternative embodiments may have other retention methods, including but not limited to hinges, solders, fasteners, dovetails, or adhesives. The actuating surfaces 20 are positioned and configured so that a surgeon may "squeeze" one or both of the surfaces 20 and thereby impart motion to the effectors 52.

[0079] Referring to Figs. 23-24, the linkage 22 is pivotally retained relative to the surfaces 20 and the actuating piston assembly 24 as the surfaces 20 are displaced or moved. Retention pins 25 extend through each actuating surface 20 and a first end of each linkage 22, and are also placed through the actuating piston 24 and a second end of each linkage 22. The pins may be pressed into and retained within the actuating surfaces 20 and piston 24 while also having a pivotal clearance with a through hole of the linkage 22. Alternative embodiments may utilize a plurality of linkage pivotal retention methods, including but not limited to screws, springs, or living hinge mechanisms. In one embodiment, the actuating piston or shaft 24 displaces distally as the actuating surfaces 20 are displaced or squeezed. As described, the surfaces 20 bend or flex near or at the proximal end 14 of the handle body 18 yet may pivot via other mechanisms, including but not limited to a pin or hinge mechanism in alternative embodiments.

[0080] In one embodiment of the actuating handle 12, the piston 24 is slidably held within a piston

housing 23 (Fig. 28) which mates and seats within a piston housing bore 28 of the handle body 18. The piston housing 23 is held stationary with the handle body 18 via a retention screw 27 placed through a proximal end of the piston housing 23 and threaded into the handle body 18. Alternative embodiments may forego use of the piston housing 23 and slidably mate the piston 24 within the bore 28 or hold the piston housing 23 via a plurality of methods, including but not limited to press fits, pins, screws, or adhesives.

[0081] Referring to Fig. 1, 24 and 36, the electrical connector 26 connects with the effectors 52 via two separate electrical paths 32 and 42 that are routed through the actuating handle 12. A first electrical path 32 originates at a first pin 30 of the electrical connector 26 at or near the proximal end 14 of the actuating handle 12. A small diameter, optionally insulated, first conductor 34 is soldered, welded, or conductively bonded to the first pin 30 with a pin insulator 31 surrounding the interface. In this embodiment, the first pin 30 is hollow or tubular in shape whereby the first conductor 34 and bonding medium (such as solder) are held internally to the first conductor 34. Alternative embodiments may use or include a plurality of conductor and pin bonding techniques, including but not limited to crimps, ultrasonic bonds, and conductive adhesives. The conductor 34 is routed between the actuating surfaces 20 of the actuating handle 12, e.g., through the body 18, to a distal end 16 of the handle 12 and is further brazed, soldered, welded, or otherwise conductively bonded with a surface, recess, hole, or other portion of a conductive bushing 38. In this embodiment,

the bushing 38 is of a phosphorous bronze material but may comprise a plurality of other conductive materials in alternative embodiments. In this embodiment, the insulation 36 comprises a polyester, Kapton (polyimide), or Teflon (polytetrafluoroethylene) tubing while alternative embodiments may utilize a plurality of other substantially non-conductive coatings.

[0082] Referring to Figs. 23-24, the bushing 38 conductively contacts a conductive effector assembly retainer 44. The retainer 44 is mounted with, yet insulated from, the handle body 18 and may connect with the effector assembly housing 66 via distal threads 46 on the retainer 44 which mate with proximal threads 68 within or on the effector assembly housing 66. In this embodiment, the bushing 38 is at least partially surrounded by the retainer 44 with a remaining portion surrounded by an effector assembly retainer cap 45. The retainer cap 45 conductively attaches to the retainer 44, e.g., by threads, and sandwiches the conductive bushing 38 and associated insulating bushings 49, 53 between the retainer cap 45 and retainer 44. That is, in this embodiment, the piston housing 23 has a housing lip 28 against which a first insulating bushing 49 is pressed from a proximal location of the housing 23 and against which a second insulating bushing 53 is pressed from a distal portion of the housing 23. The conductive bushing 38 fits over at least a portion of the insulating bushings 49, 53 with all of the aforesaid sandwiched between the effector assembly retainer 44 and the effector assembly retainer cap 45. Since the housing 23 is secured with the handle body 18, the resultant effector assembly retainer 44 is rotatably held with the handle body 18, is insulated

from the handle body 18, and is able to retain electrical continuity with the case 70 of the effector assembly 50. Alternative embodiments may utilize a plurality of connection or mating methods including but not limited to tapered fits, press fits, pins, detent ball retention, or a rotating pin and groove slot arrangement. The retainer 44 may be of a titanium or stainless steel material but may comprise a plurality of conductive materials in alternative embodiments including but not limited to carbon impregnated composites, conductive polymers, or other conductive metals and alloys thereof. Within this embodiment, a counterbored or enlarged portion of the first insulating bushing 49 mates over the second insulating bushing 53 whereby the housing lip 28 is substantially surrounded. Also in this embodiment, an insulating washer 47 is placed proximally from the conductive bushing 38 between the conductive bushing 38 and the handle body 18. The washer 47 further assures electrical isolation between the first 32 and second 42 electrical paths.

[0083] Referring to Figs 24 and 36, a second electrical path 42 originates at a second pin 40 of the proximal electrical connector 26. In this embodiment, the second pin 40 is attached, for example, via threads, directly with the proximal end 14 of the handle body 18. As the handle body 18 is of a conductive material, typically titanium or stainless steel, the conductive path for the second pin 40 is through the handle body 18, through the conductive piston housing 23, and into and through the actuating piston or shaft assembly 24. The actuating piston or shaft 24 and housing 23, as an assembly, is electrically insulated from the effector

assembly retainer 44 via the aforesaid one or more insulating bushings 49, 53 between the actuating piston or shaft assembly 24 and the effector assembly retainer 44. In this embodiment, this provides a substantially coaxial and concentric electrical output connection with the effector assembly 50. That is, the threaded outer retainer 44 comprises a first electrical pole connected with the first pin 30 and the central actuating piston or shaft assembly 24 comprises a second electrical pole connected with the second pin 40 via the handle body 18. A coaxial configuration as described allows the effector assembly 50 to rotate or spin relative to the handle body 18 without a loss of electrical contact. Although this embodiment utilizes a conductive handle body 18 for the second electrical path 42, alternative embodiments may utilize a discrete conductor routed to or with the actuating piston or shaft assembly 24. Further alternative embodiments may use a handle body 18 comprising conductive or non-conductive material(s) including various metals and alloys thereof, composites, ceramics, and polymers with or without conductive impregnation. Yet further alternative embodiments may attach the second pin 40 via other methods, including but not limited to press fits, brazing, soldering, welding, or ultrasonic bonding.

[0084] Referring again to Figs. 1-3, the effector assembly 50 of this embodiment is quickly and conveniently removable from the actuating handle 12 and allows for single-use or disposable effector assembly 50 operation. This effector assembly 50 of this embodiment comprises one or more distal effectors 52, a proximal housing 66, and a shaft assembly 58 (having two shafts

which are nested) between the effector(s) 52 and the housing 66. In this embodiment, the effectors 52 are of a foot shape yet alternative embodiments may utilize effector shapes of any form, including but not limited to clamp shapes, scissor shapes, tweezer or cup shapes. Also in this embodiment, the shaft assembly 58 comprises two nested shafts, an inner shaft 62 and an outer shaft 60 with an insulator 64 there between. The insulator 64 is a Kapton or Teflon material (having an approximately .003 inch thickness in this embodiment) but may comprise other insulating material(s) in alternative embodiments, including but not limited to polymers, ceramics, phenolics, or air dielectrics of other thickness(es). The effectors 52 may be formed into other shapes and styles and move axially or angularly relative to the housing 66, or have substantially no movement. without departing from the scope and spirit of the present invention.

[0085] Referring to Figs. 10-12, the effector assembly 50 of this embodiment is capable of imparting an angular or rotary distal motion to the effectors 52 (angular effector assembly). The assembly 50 first comprises a housing 66 having a translation mechanism 76 comprising a slotted linearly or axially translating component 78 and a rotating component 82 (see also Fig. 53) conductively attached with the inner shaft 62. That is, the housing 66 translation mechanism 76 converts the linear or axial motion of the actuating piston or shaft assembly 24 to an inner shaft 62 rotary or angular motion when the instrument 10 is assembled. The rotary or angular motion of the inner shaft 62 allows a second distal effector 56 or foot attached with the inner shaft 62 to move angularly relative to a first effector 54 or

foot attached with the outer shaft 60. Both the rotating component 82 and the translating component 78 are housed within an insulating insert 72 which is further housed within a case 70 which in combination form the housing 66.

[0086] The rotating component has a substantially spiral surface groove 84 or surface cut around which the translating component 78 slidably mates. In this embodiment the spiral surface groove 84 is formed by twisting a partially flattened bar or shaft approximately 270 degrees while alternative embodiments may utilize milling, grinding, or molding methods to form the groove 84. Also in this embodiment, a return spring 88 is placed between the rotating component 82 and the linearly translating component 78 and serves to mechanically bias the effectors 52 into an open or non-contacting position, i.e. bias separation between the components 78, 82. As the translating component 78 axially or linearly moves over the rotating component 82 due to the force of the actuating piston 24, an extending ear or a slot 80 of the translating component 78, which is slidably mated with the groove 84, imparts an angular or rotary force upon the inner shaft 62. That is, the surface groove 84 fits within the slot 80 and a non-grooved proximal portion of the rotating component 82 fits and is held within a retention slot 79 of the translating component 78. The proximal non-grooved portion in combination with the retention slot 79 prohibits the components 78, 82 from separating due to the spring 88 bias.

[0087] The translation mechanism 76 is electrically isolated from the case 70 of the housing 66

via an insulating material, in the form of the insulating insert 72, there between. In this embodiment, the case 70 is conductive and electrically connected with the outer shaft 60 and one or more layers of insulation tape 105 is placed between the insulating insert 72 and the case 70. The insulation tape 105 is of a Kapton material in this embodiment, but may be of any insulating material or not used in alternative embodiments.

[0088] Referring to Figs. 21-22, the insulating insert 72 for the angular rotating translation mechanism 76 has a proximal guide ear slot 75 into which a linear guide ear 85 of the linearly translating component 78 slidably mates. The slot 75 allows movement of the linearly translating component 78 in an axial direction yet prohibits angular movement of the component 78, thereby allowing the rotating component 82 to move angularly as described. The linear guide ear 85 is a radial extension from the linearly translating component 78 in this embodiment yet in alternative embodiments may comprise one or more extensions or groove types which mate with a corresponding mirror image in or on the insulating insert 72 whereby angular movement of the translating component 78 is restricted.

[0089] Referring to Figs. 10-12 and Fig. 43, the rotating component 82 is conductively affixed to a proximal end of the inner shaft 62 via a set screw 90 extending therefrom and threaded into and through the rotating component 82. That is, the inner shaft 62 is mated with a rotating component bore 86 and the set screw 90 transitions through a threaded hole 83 into the bore 86 whereby the inner shaft 62 is compressively held.

Alternative embodiments may affix the inner shaft 62 with the rotating component 82 via other methods, including but not limited to soldering, welding, brazing, or frictional or press fits.

[0090] Referring to Figs 21-22, the insulating insert 72 for the angular rotating translation mechanism 76 also has a rotational guide slot 77 which axially contains or houses the set screw 90 extending from the rotating component 82. In this embodiment, the rotational guide slot 77 is a substantially semicircular cut or slot within the insulating insert 72 which serves as an angular stop. The stop limits the effector 52 angular displacement and further prevents the surgeon from applying excessive force to the effectors 52, thereby minimizing the probability of effector 52 deformation. The rotational guide slot 77 also limits or restricts axial movement of the inner shaft 62.

[0091] In this embodiment, a translating component adjusting screw 81 is proximally threaded into the linearly translating component 78. Proximal or distal adjustment of this screw 81 minimizes the interface gap between the actuating piston 24 and the screw 81 whereby actuating surface 20 play is minimized.

[0092] Referring again to Figs 24 and 36, an electrical conduction path is established between the rotating component 82 and the inner shaft 62. The second electrical path 42 from the handle 12 actuating piston 24 is conducted through the translation mechanism 76 via the translating 78 and rotating 82 components directly through the inner shaft 62 and onto a second effector 56 attached with the inner shaft 62. The first electrical path 32

from the effector assembly retainer 44 connects with the housing 66 case 70 (which is insulated from the translation mechanism 76) and conducts through the outer shaft 60 to a first effector 54 attached with the outer shaft. Throughout the actuating handle 12 and effector assembly 50, first 32 and second 42 electrical path isolation is maintained.

[0093] Referring to Figures 1, 8, 9, and 10, in this embodiment an effector assembly 50 is capable of imparting an angular or rotary motion. The first effector 54 (or foot) is stationary and attached with the outer shaft 60. The outer shaft 60 is tubular in shape and has an inside diameter of sufficient size to slidably house the inner shaft 62 and insulator 64 there between. The first effector 54 may be attached with outer shaft 60 via other techniques, including but not limited to welds, brazes, solders, adhesives, or press or frictional fits. The outer shaft 60 may be electrically connected and held with the case 70 via one or more set screws 91 which are radially threaded into and through one or more retention holes 93 within the case 70 and tightened onto the outer shaft 60. That is, the outer shaft 60 is mated with a bore 74 in the insulating insert 72 through which the set screws 91 transition and seat upon the outer shaft 60. The insulating insert 72 fits within the case 70 and further houses the translation mechanism 76. A conductive path is established from the effector assembly retainer 44 through the conductive case 70, the set screws 91, the outer shaft 60, to the first effector 54.

[0094] Referring to Figs. 40 - 43, an effector assembly 50 embodiment capable of imparting an

axial or linear distal motion to the effectors 52 (axial effector assembly) also comprises the housing 66 having the translation mechanism 92. The translation mechanism 92 attaches to the outer shaft 60 yet in combination with the housing 66 converts the linear or axial motion of the actuating piston or shaft assembly 24 to an outer shaft 60 axial or linear motion. In this embodiment, the effectors 52 are substantially aligned relative to the axis of the shafts 58 and move axially or linearly whereby a blood vessel or other tissue may be grasped therebetween. In this embodiment, the most distal effector 56 or foot is conductively attached with the inner shaft 62 and conductively held with the case 70 via one or more set screws 110 and insulated from the translation mechanism 92 via an insulating support 104.

[0095] The axial effector assembly 50 second electrical path 42 originates as described above but is routed to the outer shaft 60. The actuating piston or shaft assembly 24 conductively contacts the translation mechanism 92 and is conductively attached with the outer shaft 60. The outer shaft 60 is conductively attached with the distal first effector 54 which moves axially relative to the second effector 56. The translation mechanism 92 is also housed within an insulating insert 72 whereby electrical pole separation is maintained relative to the case 70. In this embodiment, the piston or shaft assembly 24 contacts and presses against a set screw 96 proximally attached to a spring loaded and linearly moving aft piston 94. A slotted body 98 is attached to the aft piston 94 via a threaded extension 100 which passes through the center of a return spring 108. In this embodiment, the return spring 108 seats between the aft piston 94 and a

reduced diameter portion 101 of the insulating insert 72 whereby a retraction bias force is imparted to the first effector 54. The outer shaft 60 is conductively attached distally to the slotted body 98 within a body bore 99, e.g., via brazing or welding. The conductive attachment may take other alternative forms including but not limited to conductive adhesives, frictional or press fits, pins, threads, or screws.

[0096] Referring to Figs. 43-48, an alignment screw 107 is threaded into the aft piston 94 and slidably seats within an alignment slot 103 of the insulating insert 72. The slidable alignment of the screw 107 and the slot 103 ensures proper orientation of the first effector 54 relative to the second effector 56 as the first effector moves axially due to the force of the actuating piston 24. Alternative embodiments may utilize a plurality of different alignment mechanisms on any of the moving components slidably held by the housing 66, including but not limited to pins and grooves, ears and grooves, component flats, or non-round cross sectional mates.

[0097] The axially moving effector assembly 50 first electrical path 32 originates as afore described yet is routed to the inner shaft 62. That is, the effector assembly retainer 44 first conductively and removably connects with the housing 66 case 70. For this embodiment of the axial effector assembly 50, the inner shaft 62 may be electrically connected and held substantially stationary with the case 70 via one or more set screws 110 which are radially threaded into and through the case 70 and tightened onto the inner shaft 62.

For optimum support and insulation, the inner shaft 62 is mated with an insulating support 104 also having a bore 106 into which the set screws 110 transition and seat upon the inner shaft 62. For example, the bore 106 is substantially perpendicular to a lengthwise axis of the insulating support 104. In this embodiment, the insulating support 104 fits within the case 70, within the slot 102 of the slotted body 98, and between the radially threaded portions of the case 70. A conductive path is established from the effector assembly retainer 44 through the conductive case 70, the set screws 110, the inner shaft 62, and onto the second effector 56. The insulating support 104 assures that the pole of the case 70 is insulated from the pole of the translation mechanism 92. The insulating support 104 may be manufactured from a plurality of substantially non-conductive materials, including but not limited to Kapton, Teflon, Polyetheretherketone (PEEK), polymers, ceramics, or composites. For the axial translation mechanism 92, placement of the insulating support 104 into the slot 102 of the slotted body 98 maintains a substantially axial or linear alignment of the inner 62 and outer 60 shafts.

[0098] Further alternative embodiments of the effector assemblies 50 may use two small gauge insulated wires threaded through the inner shaft 62 and terminated upon the distal effectors 52. The handle 12 paths remain as described with the wires proximally terminating at the case 70 and at an interface which conductively contacts the actuating piston or shaft assembly 24. The inner shaft 62 remains insulated from the outer shaft 60.

[0099] The actuating handle 12 and effector assemblies 50 uniquely provide bipolar coagulation, cauterization, dessication, cutting, sealing, or treatment of tissues heretofore not found with single shafted bipolar surgical instruments. These embodiments uniquely allow a plurality of removable effector assemblies 50 to provide a variety of cutting, grasping, or clamping functions while used with a single actuating handle 12 and while maintaining an electrical isolation between the effectors 52. The removable and disposable nature of the effector assemblies 50 promote a sterile surgical field and thereby minimize the risk of extraneous infection at the surgical site.

[00100] In another embodiment shown in Figs. 54-63, a bipolar surgical instrument 201 comprises a handle assembly and an actuator 203 mounted on the handle. The handle and actuator may be configured generally as already described, but with the variations described below. In this embodiment, the entire instrument 201 may be disposable, or alternatively, may be sterilizable for repeated use.

[00101] First and second effectors 211 are fixed to first and second shafts 213 respectively. The effectors are disposed at a distal end of the instrument 201. As shown in Figs. 57-58, Each effector 211 includes a relatively wide base 213 portion and curves away from a longitudinal axis LA of the sleeve 215 described below. Each effector 211 has a convex, curved outer surface and a concave, curved inner surface. The inner surface of each effector has a flat tip 219 for contacting a matching flat tip of the opposite effector. The effectors are shaped

symmetrically about a plane through the longitudinal axis of the sleeve. In other words, the effectors of this embodiment are mirror images of each other.

[00102] Other effector or tip shapes are contemplated within the scope of the invention. These alternatives may have any function or combination of functions such as are known or would be obvious to one of ordinary skill in the art. Alternate tip gripping surfaces are also contemplated including without limitation serrated surfaces, interlocking teeth, loops, cups, or others. Some embodiments may include effectors which are sharpened so as to provide mechanical cutting capability while simultaneously supplying electrical current for coagulation.

[00103] Figs. 64-66 depict some alternative embodiments. For example, Figs. 64 and 65 show a scissors effector including sharpened effector surface 249 that provides simultaneous mechanical cutting and coagulation. When the effectors are actuated into contact with each other, heating of the effectors occurs as the sharpened surface cuts tissue to cause coagulation or cauterization. Fig. 66 depicts a sharpened effector surface 259 similar to the sharpened effector surface 249, except that it is curved.

[00104] Referring to Fig. 63, a double-lumen or dual lumen tube 225 has lumens 227 that extend parallel to one another (side-by-side) and do not cross one another. The tube material is electrically insulating. The lumens are insulated from one another by the tube material so that the two shafts extending side-by-side therein are separate and electrically insulated. In an

embodiment, the tube is made of an alumina extrusion (broadly, a ceramic), though other materials, including other ceramics are contemplated. A suitable tube is available from distributor McMaster Carr (PN 87175k71) and from manufacturer LSP Ceramics PN ADB507 (.093 OD x .025 ID holes) and ADB510 (.125 OD x .040 ID holes). The tube may be smaller in size, subject to electrical clearance limits and the minimum mechanical strength necessary. LSP ceramics offers dual lumen tubing of three smaller outer diameter sizes including .062 x .016, .047 x .025, and .032 x .005.

[00105] Each lumen 227 receives one of the shafts therethrough. In some embodiments, the lumens are spaced apart a distance of about 0.5 mm, or at least about 0.2 mm. Other spacings may also be suitable, however.

[00106] Sleeve 215 receives the tube 225 and is thereby disposed around the shafts 213 such that the shafts also extend side-by-side through the sleeve. The sleeve is slidable relative to the shafts from an actuated position (Figs. 55, 58, 61, 63 to an open position (Figs 54, 57). The effectors are separated away from one another in the open position, and are in contact with each other when in the actuated position.

[00107] In this embodiment, the fit between the sleeve 215 and the tube 225 is loose enough that the tube is rotatable within the sleeve so that the effectors can be rotated through 360 degrees. A knob 231 of the handle facilitates rotating the sleeve and effectors. The knob of this embodiment has a star shape in cross-section and is joined to the tube by a set screw.

[00108] In this embodiment, the sleeve 215 includes a main portion 235 and a band 237 at its distal end. The main portion is suitably made of extra thin wall 304 Stainless Steel Hypodermic Tubing, and the band is made of plastic such as PEEK, Delrin, ABS, Teflon, etc. A slider 239 of the handle is mounted at a proximal end of the sleeve for sliding the sleeve and thereby forcing or actuating the effectors together. In the actuated position, the circuit is completed and heating is effected to cause coagulation or other effects described above.

[00109] The shafts 213 and the effectors 211 are resiliently biased outward away from one another so that when the sleeve 215 moves from the actuated position to the open position, the effectors move away from one another. In other words, when the end of the sleeve is not contacting the effectors or the shafts (in the open position), the effectors automatically move away from one another.

[00110] The effectors 211 may be suitably made of metal, such as 17-4 stainless steel having a yield strength greater than 100,000 psi. The effectors are suitably machined or turned on a lathe to the shape depicted. The effectors are then joined, e.g., by brazing, to the respective shaft. Alternative tip materials may be considered, especially metals with high thermal conductivities and medium to high yield strengths including but not limited to copper, aluminum, silver, gold, tungsten, zinc, and alloys, composites, or mixtures thereof.

[00111] A proximal end of the tube 225 is received in a handle sleeve 245, and in a holder 247 at

the proximal end of the handle. The shafts are electrically connected (e.g., soldered or otherwise joined) to ends of insulated wires 251. The wires include plugs 253 generally at an opposite end for connection to a bipolar generator (not shown). In this embodiment, the generator generates a signal of about 1 Mhz, though other signals may be used.

[00112] In this embodiment, there are first and second electrical paths 261, 262 routed from the generator, through the wires to the shafts. The paths proceed through the shafts to the effectors at respective ends thereof. The paths are insulated from one another to maintain two separate electrical poles.

[00113] Using alumina or similar stiff material for the tube is advantageous because it enhances the stiffness of the assembly. Using a dual lumen tube is advantageous because it insulates the wires, paths or poles and the proximal wire termination points. The dual lumen tube also maintains parallelism between the end effectors (i.e. the tips). These various tube constructions also simplify manufacturing.

[00114] In other embodiments, however, designs employing such tubes may be constrained by the small number of commercially available extrusion sizes, and the material costs may be prohibitive in some markets.

[00115] An alternative embodiment replaces the dual lumen tube with a composite structure of insulating media, shrink tubing, and a hypodermic tube. The insulating media may be one or more of an epoxy, plastic, adhesive, or other insulating media, and may be

hardenable once in place. The shrink tubing may be a polyimide tubing or polyester shrink tubing, for example. The tube suitably has a thin wall thickness, for example of .0005" to .003". The hypodermic tube is suitably made of very thin wall metal and has a predetermined outer diameter.

[00116] In a method of manufacturing this embodiment, each conducting shaft is first shrouded by or inserted into the shrink tube. The shafts are then placed through the hypodermic tube. Using custom fixtures (not shown) to maintain a parallel configuration of the two shafts inside the hypodermic tube and to establish a predetermined separation distance, free space between the polyimide or polyester insulation and the inside wall of the hypodermic tube is filled or injected with the insulating media. In one embodiment, the composite thus formed contains two metallic cores, a thin layer of plastic insulation around each core, an irregular cavity filled with epoxy, plastic, etc, and an outer metallic, glass, ceramic, or plastic shell.

[00117] In an additional embodiment, the hypodermic tube used as an outer mold cavity in the embodiment above is eliminated. An injection mold tool has a cylindrical cavity of the desired outer diameter of the core structure. The main shafts could then be insert-molded into a structure of plastic, epoxy, or ceramic, thereby eliminating the need for the polyimide/polyester insulation and the hypodermic shell tube.

[00118] All of the embodiments described herein may be manufactured from a variety of material(s) including but not limited to steels including stainless

steels, copper, brass, bronze, aluminum, tungsten, titanium, nitinol and other metals, composites, and polymers. The conductive path elements require the material of manufacture to have a conductive character. The aforesaid insulating components further require the material of manufacture to have a low electrical conductivity.

[00119] Embodiments of the present invention may be used in or with many types of surgical procedures, including but not limited to intracranial neurosurgery, endo-nasal neurosurgery, anterior-cervical spine surgery, and other minimally invasive procedures often in conjunction with endoscope viewing systems.

[00120] When introducing elements of the present invention or the embodiment(s) thereof, the articles "a", "an", "the" and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements.

[00121] As various changes could be made in the above constructions and methods without departing from the scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawing[s] shall be interpreted as illustrative and not in a limiting sense.

WHAT IS CLAIMED IS:

1. A bipolar surgical instrument for passing current through tissue of a patient comprising:

a handle,

an actuator mounted on the handle,

first and second shafts,

first and second effectors, each mounted on respective first and second shafts, the effectors disposed at a distal end of the instrument,

a sleeve disposed around the shafts and slidable relative to the shafts from an actuated position to an open position, the effectors being separated away from one another in the open position,

wherein the shafts and the effectors are resiliently biased outward away from one another so that when the sleeve moves from the actuated position to the open position, the effectors move away from one another.

2. The bipolar surgical instrument of claim 1 wherein the effectors do not move longitudinally when moving from the actuated position to the open position.

3. The bipolar surgical instrument of claim 1 wherein the effectors move only laterally toward one another and rotationally about a single axis.

4. The bipolar surgical instrument of claim 1 wherein each effector includes a relatively wide base portion and curves away from a longitudinal axis of the shaft.

5. The bipolar surgical instrument of claim 1 wherein at least one of the effectors has a sharpened edge configured to cause mechanical cutting and simultaneous coagulation upon movement from the open position to the actuated position.

6. The bipolar surgical instrument of claim 1 wherein the shafts extend side-by-side through the sleeve, and further comprising first and second electrical paths routed through the shafts and to the effectors, the paths being insulated from one another to maintain two electrical poles.

7. The bipolar surgical instrument of claim 1 further comprising a composite structure of insulating media surrounding the shafts.

8. The bipolar surgical instrument of claim 7 wherein each shaft is shrouded by a plastic shrink tube.

9. The bipolar surgical instrument of claim 8 wherein the shrouded shafts are surrounded by insulating media encapsulated within a rigid tube.

10. The bipolar surgical instrument of claim 7 wherein each shaft is surrounded by insulating media, wherein said insulating media forms a rigid structure surrounding the shafts.

11. The bipolar surgical instrument of claim 1 further comprising a double-lumen tube wherein the lumens extend parallel side-by-side and do not cross one another.

12. The bipolar surgical instrument of claim 11 wherein each shaft extends through one of the lumens of the double-lumen tube.

13. The bipolar surgical instrument of claim 12 wherein the sleeve receives the tube therein.

14. The bipolar surgical instrument of claim 13 wherein the tube is rotatable within the sleeve so that the effectors can be rotated through 360 degrees.

15. The bipolar surgical instrument of claim 12 wherein the lumens of the tube are spaced apart a distance of at least 0.2 millimeters so that the electrical paths are separate.

16. The bipolar surgical instrument of claim 11 wherein the tube is made of alumina.

17. A bipolar surgical instrument for passing current through tissue of a patient comprising:

a handle,

an actuator mounted on the handle,

first and second shafts,

first and second effectors mounted on the first and second shafts respectively, the effectors disposed at a distal end of the instrument,

an electrical connector mounted on a proximal end of the instrument,

first and second electrical paths separately routed from the connector through the handle, and to the

effectors, the paths being insulated from one another to maintain two poles,

wherein the paths extend coaxially and concentrically through the shafts.

18. The bipolar surgical instrument of claim 17 wherein the effectors and shafts are removably attached to the handle.

19. The bipolar surgical instrument of claim 18 wherein the effectors are adapted for at least one of cutting, grasping, or clamping.

20. The bipolar surgical instrument of claim 17 wherein the shafts are mounted in a housing.

21. The bipolar surgical instrument of claim 18 wherein the shafts are nested such that one shaft is nested within the other.

22. The bipolar surgical instrument of claim 20 wherein the effectors have a foot shape.

23. The bipolar surgical instrument of claim 17 wherein one or both of the effectors rotate from an open to an actuated position.

24. The bipolar surgical instrument of claim 17 wherein at least a portion of the handle is of a conductive material, and wherein one of the electrical paths is through the conductive material of the handle.

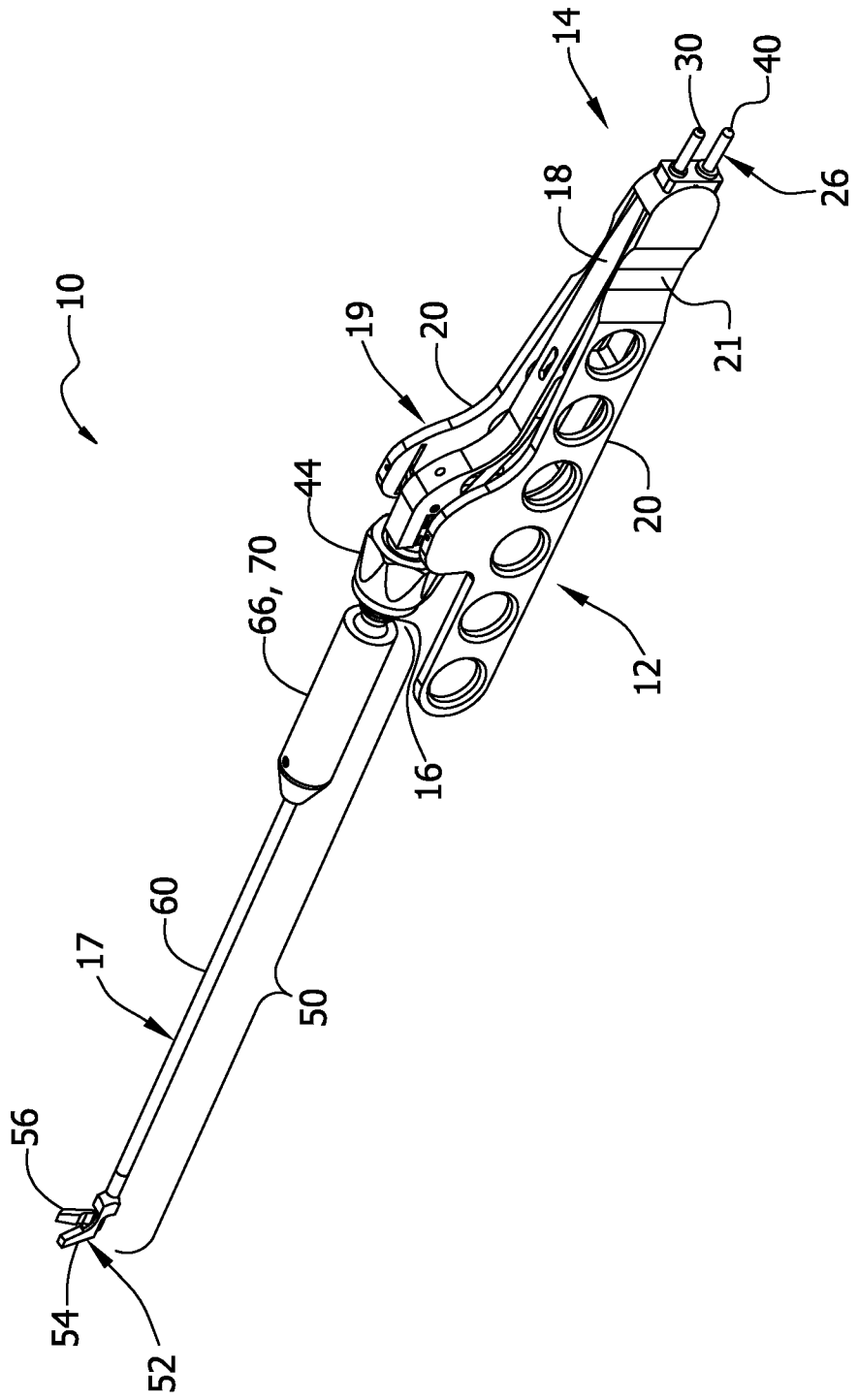


FIG. 1

FIG. 2

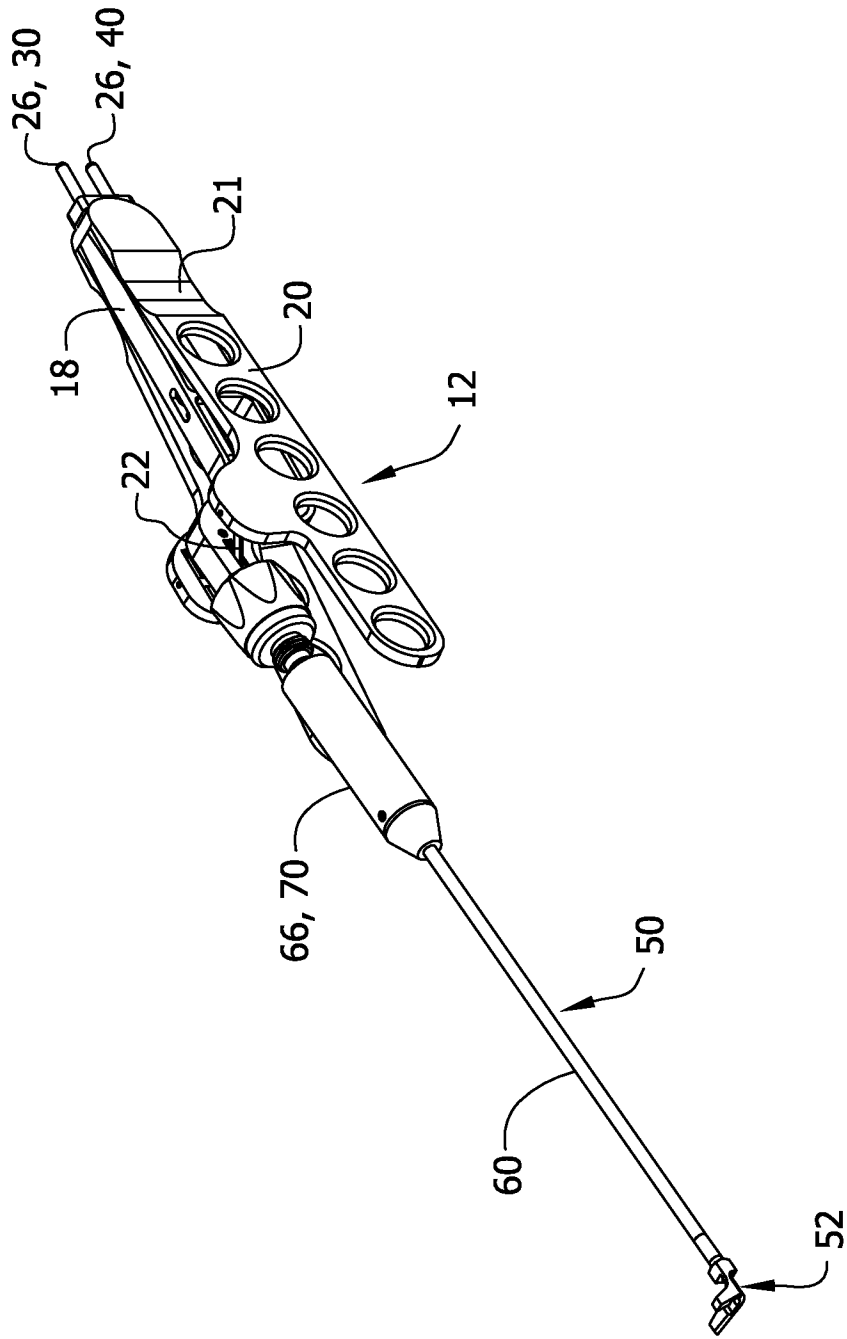


FIG. 3

3/40

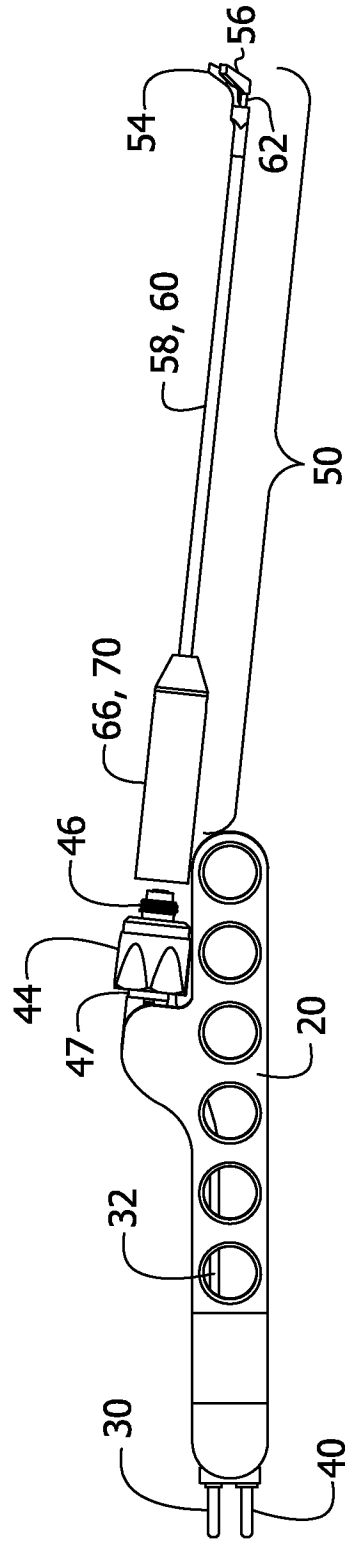


FIG. 4

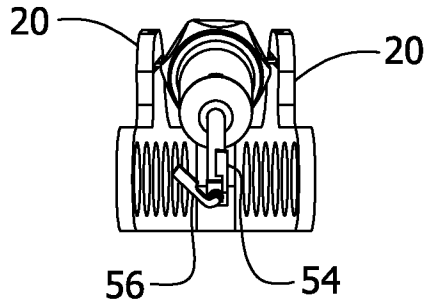
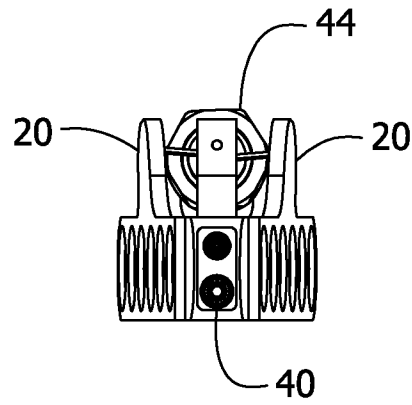


FIG. 5



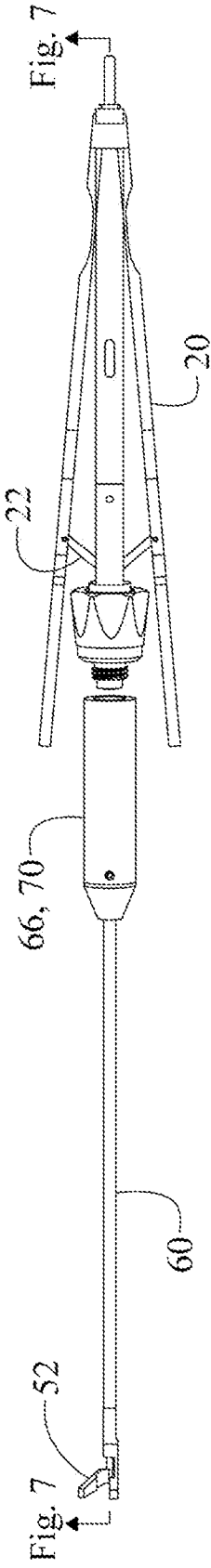


Fig. 6

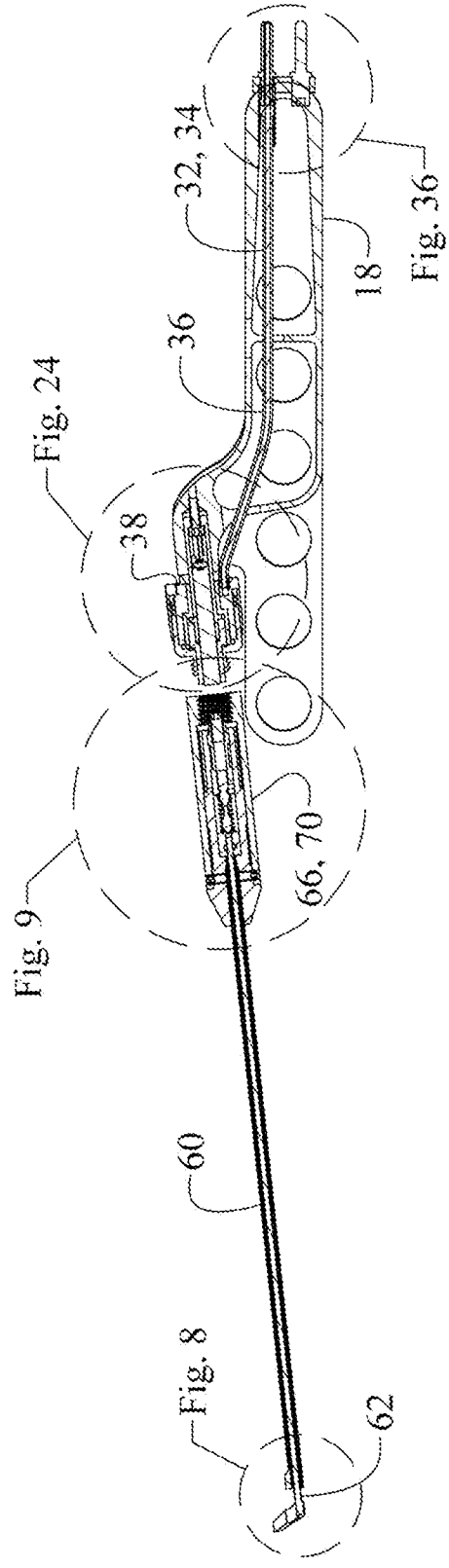


Fig. 7

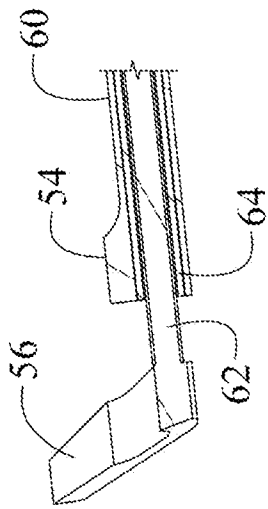


Fig. 8

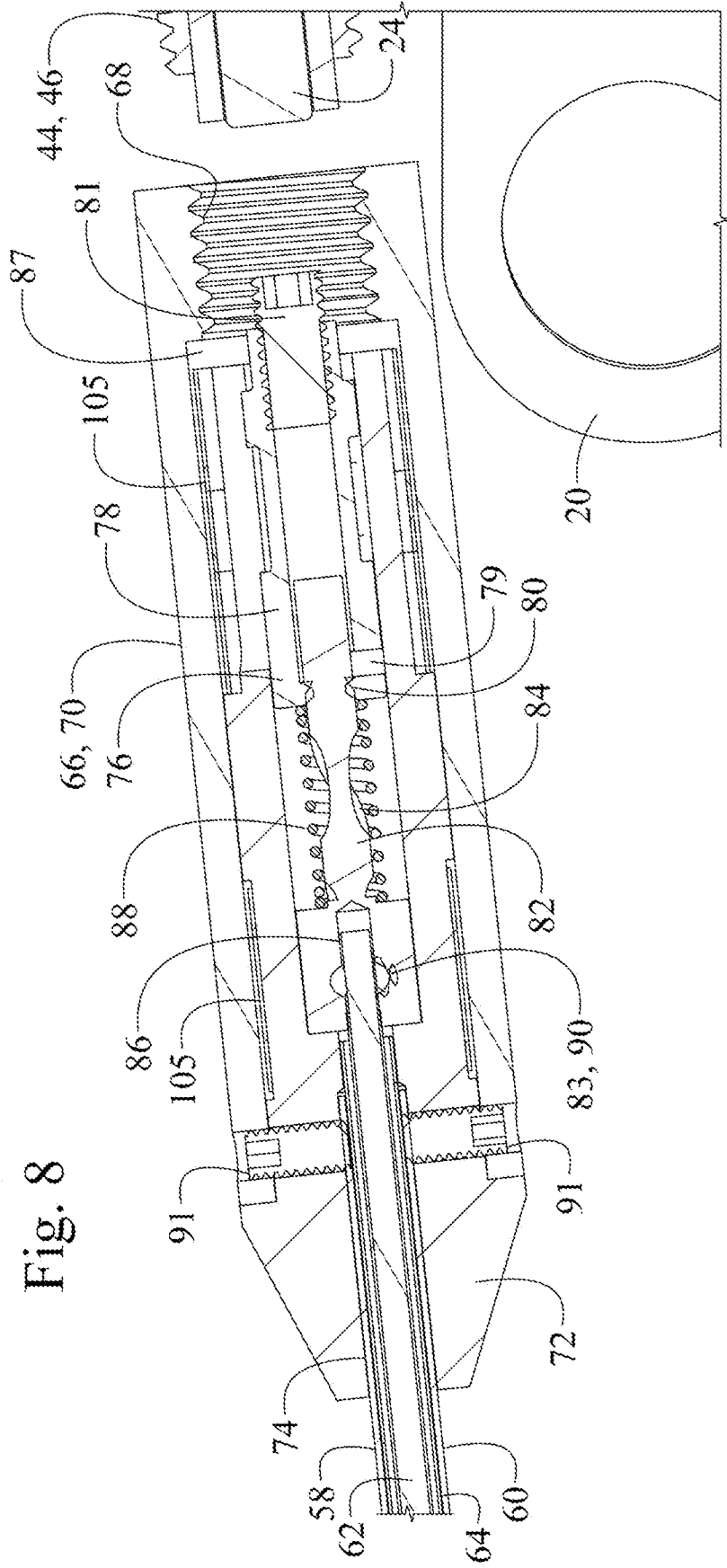


Fig. 9

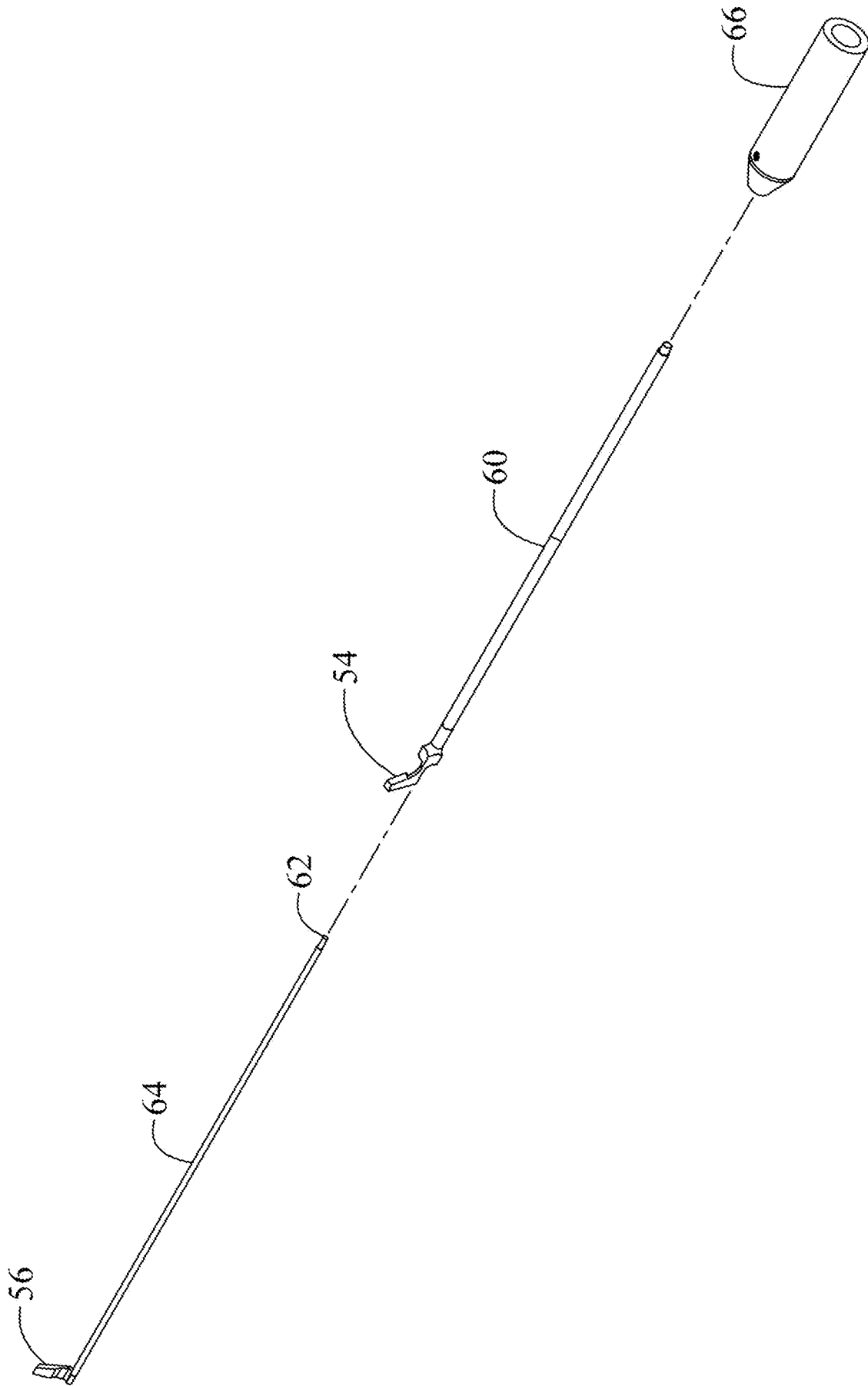


Fig. 10

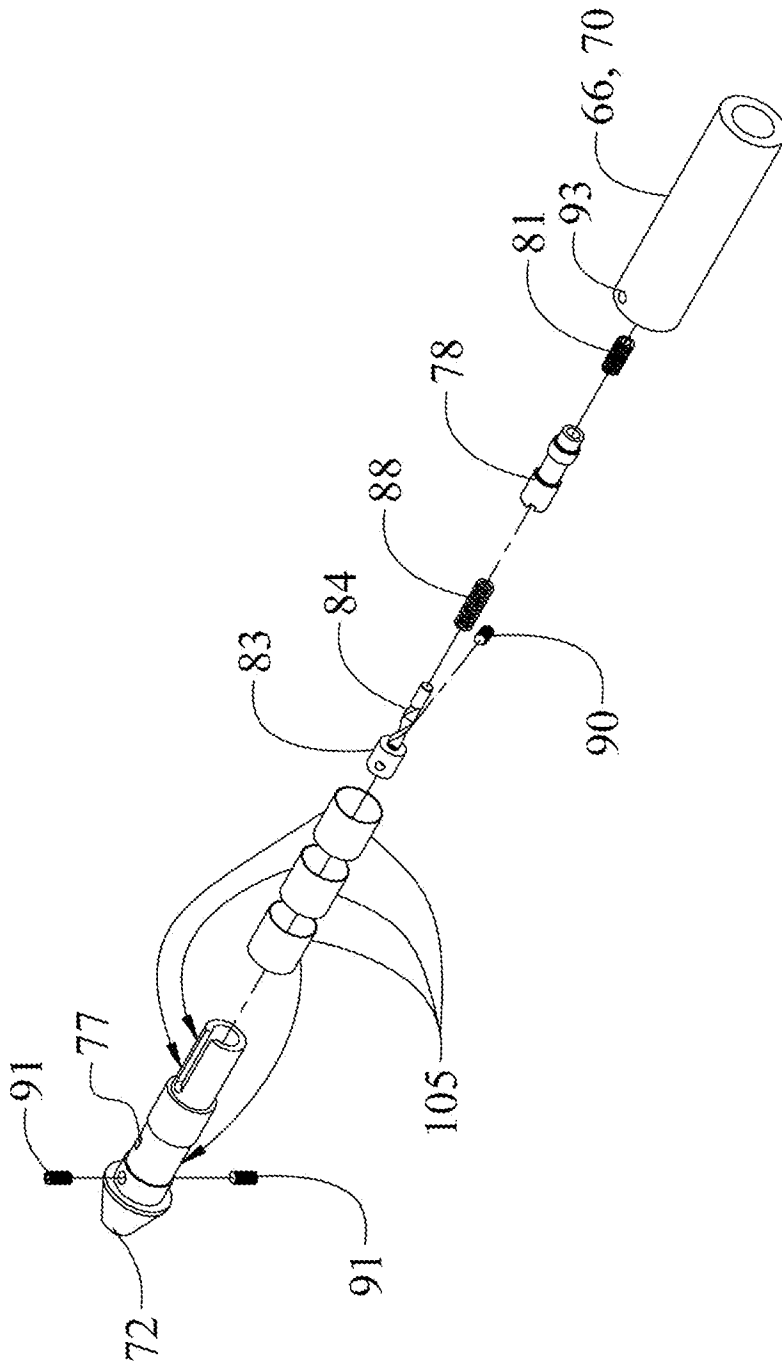


Fig. 11

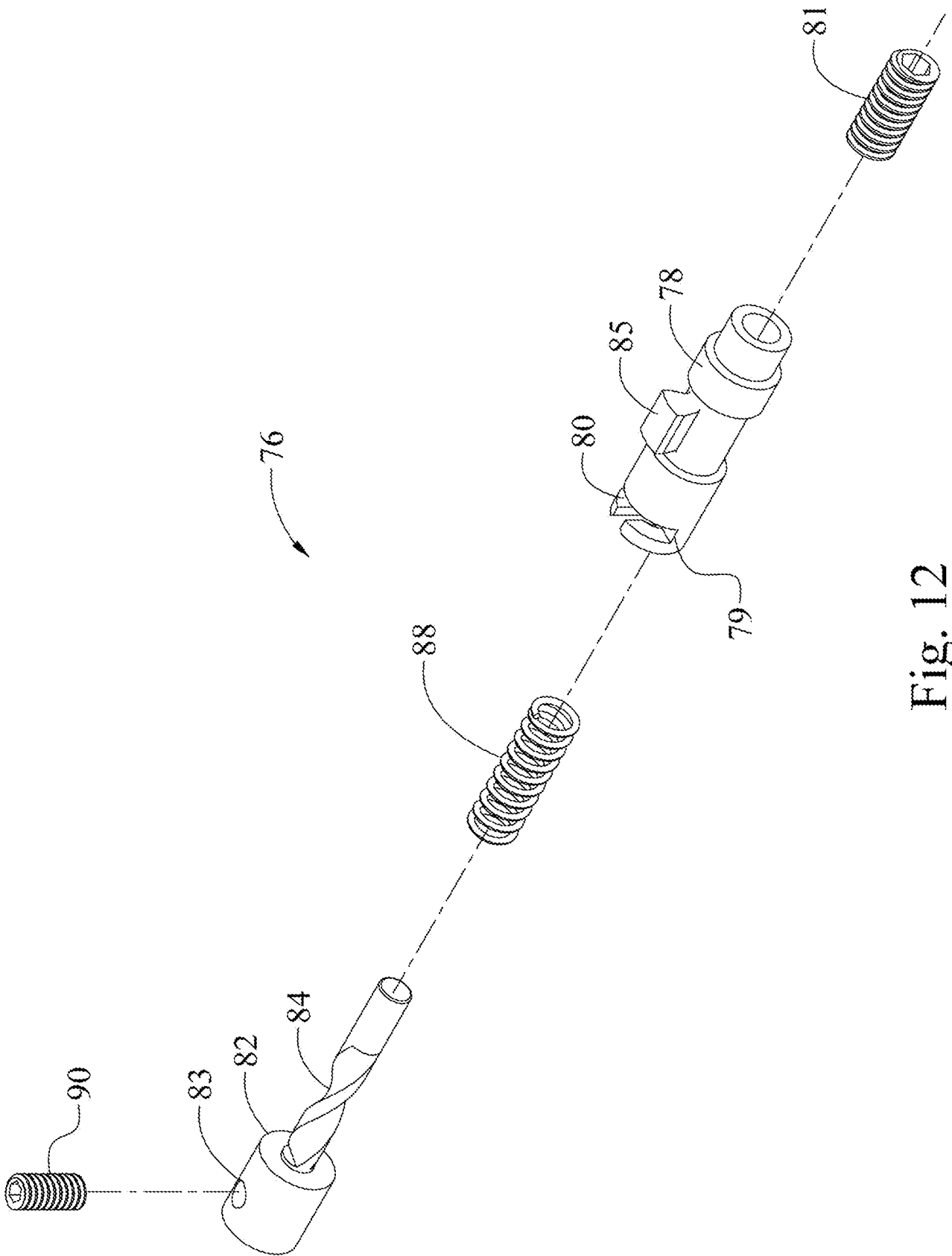


Fig. 12

10/40

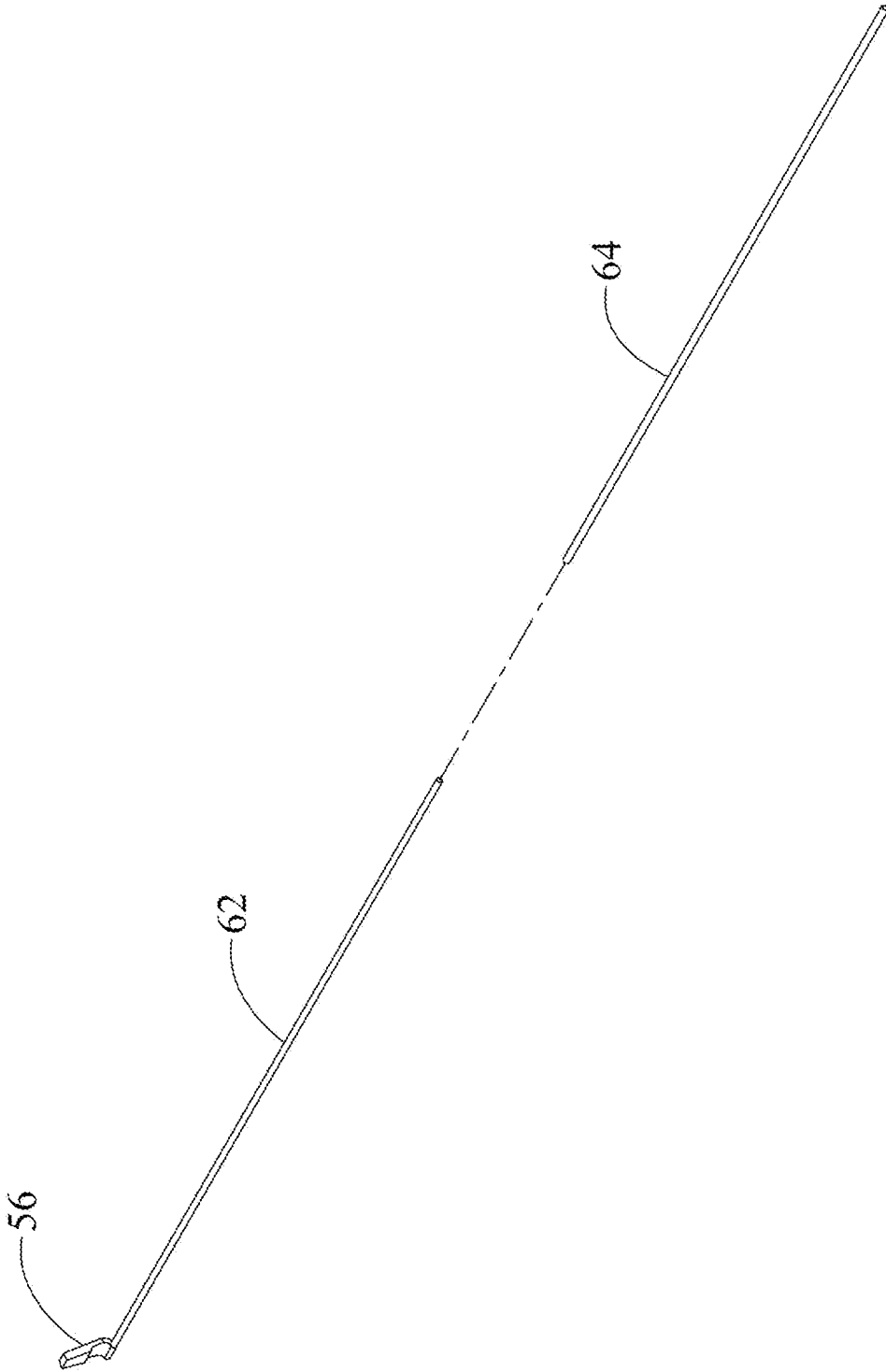


Fig. 13

11/40

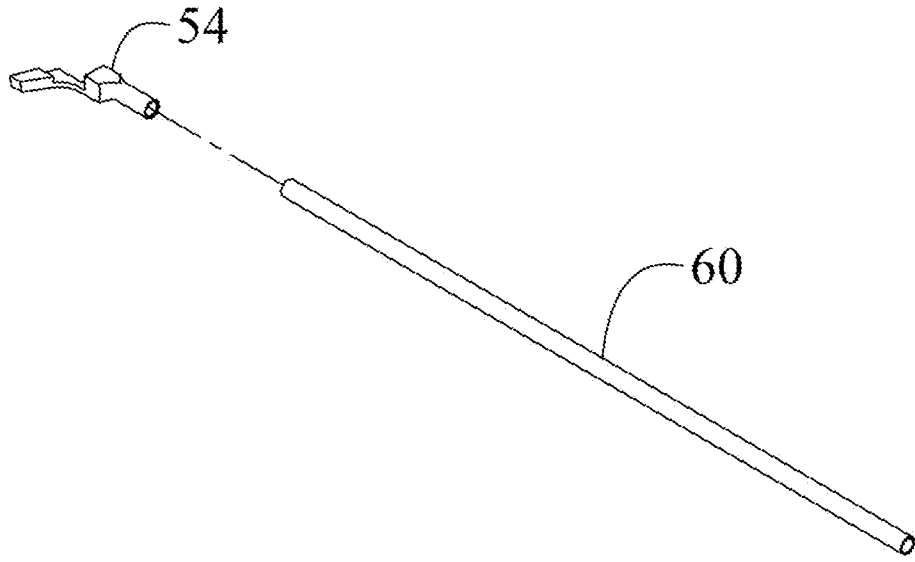


Fig. 14

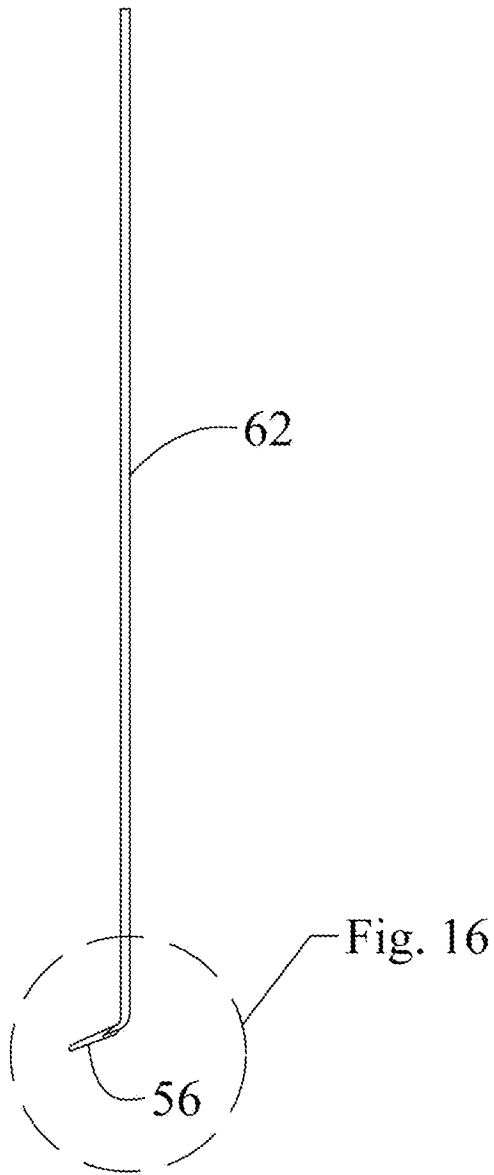


Fig. 15

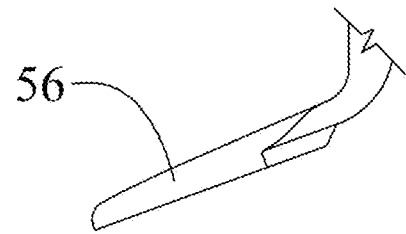


Fig. 16

FIG. 17

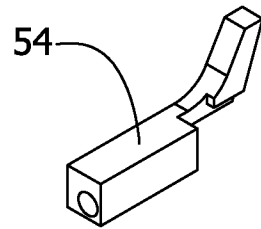


FIG. 18

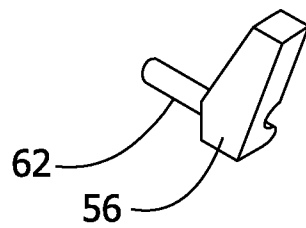


FIG. 19

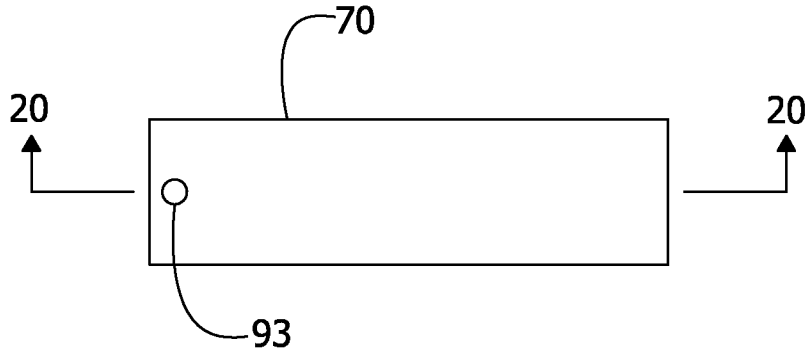
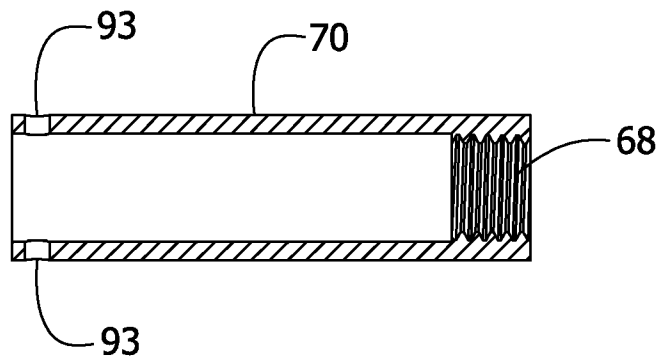


FIG. 20



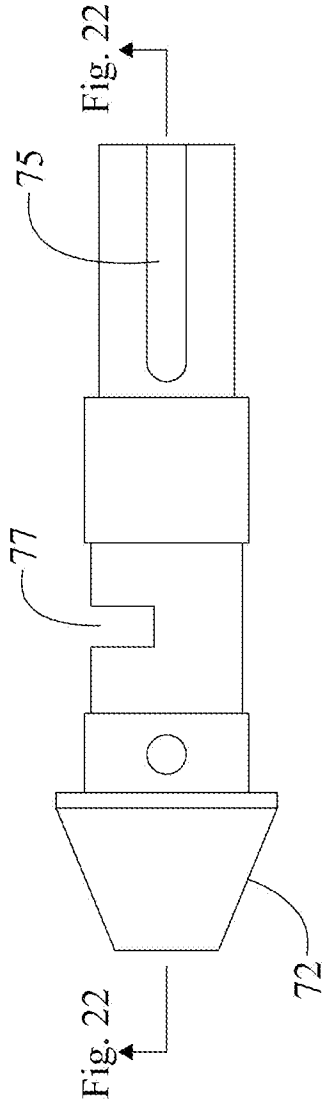


Fig. 21

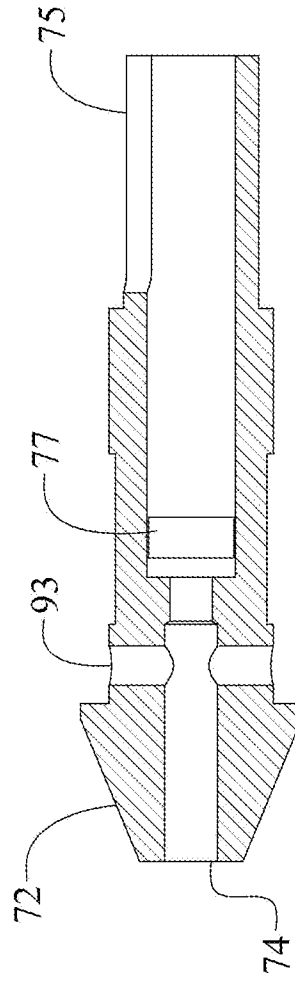


Fig. 22

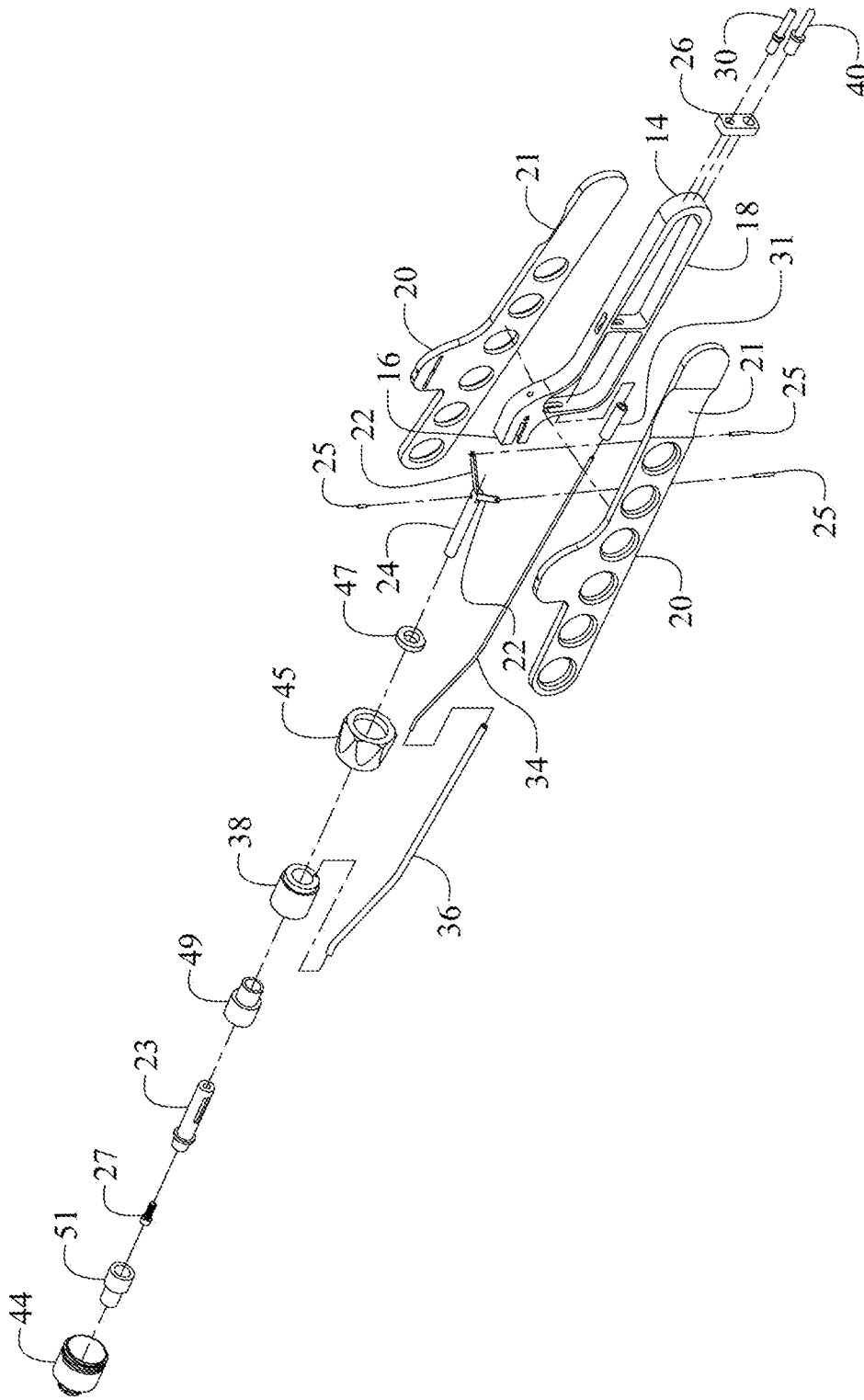
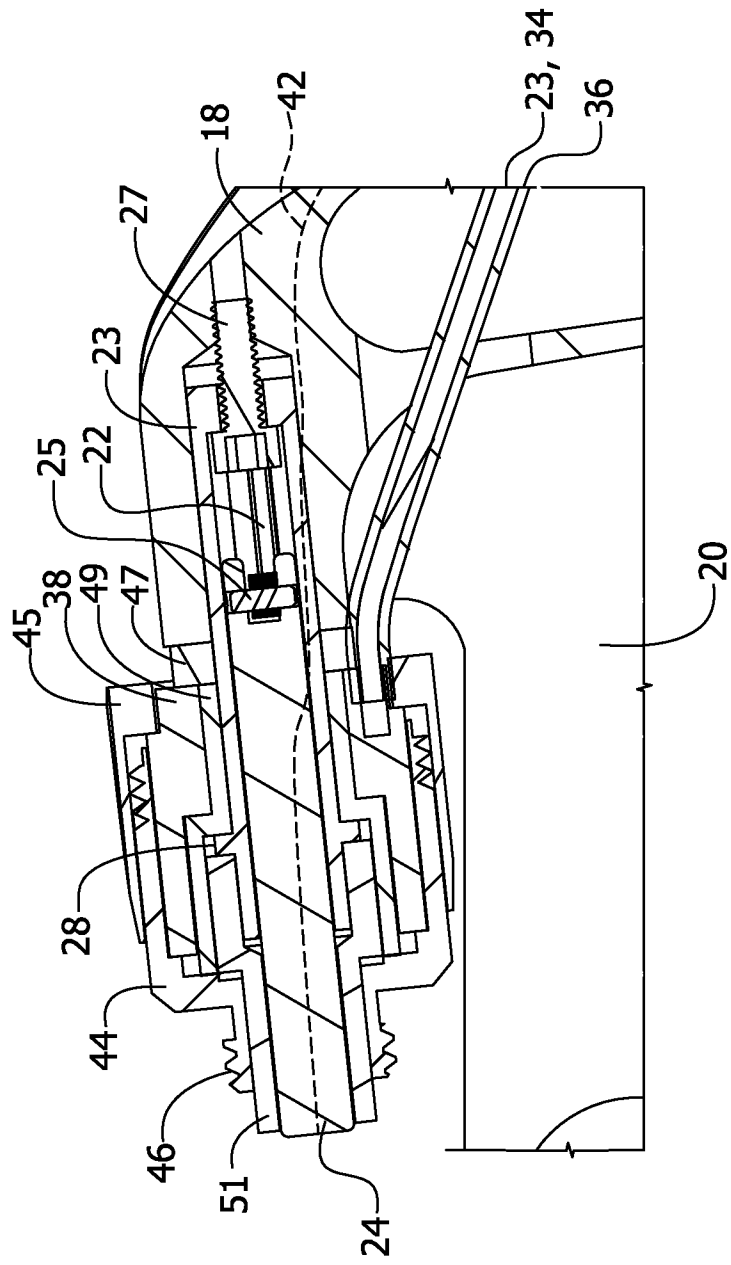


Fig. 23

FIG. 24



18/40

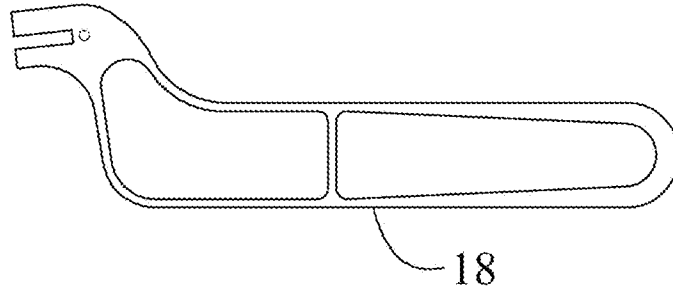


Fig. 25

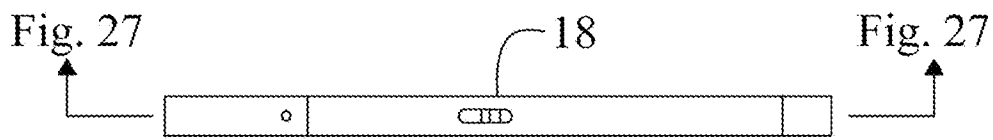


Fig. 26

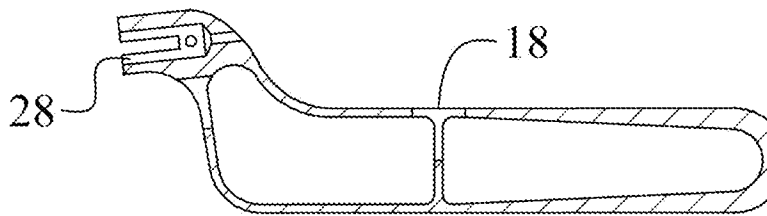


Fig. 27

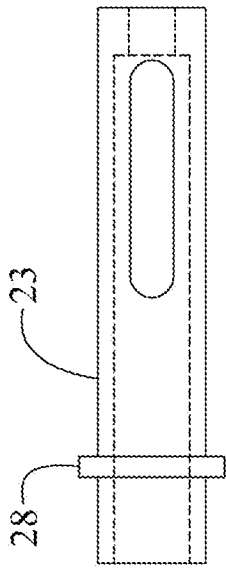


Fig. 28

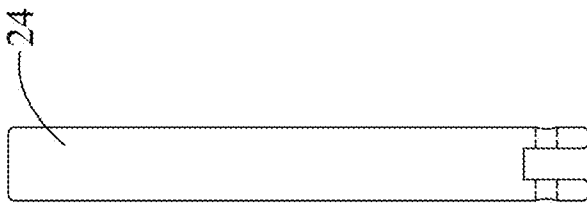


Fig. 29

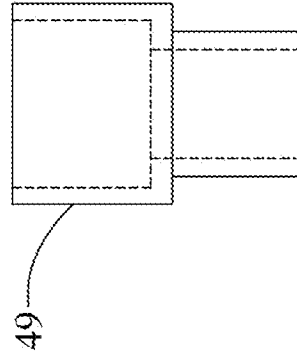


Fig. 30

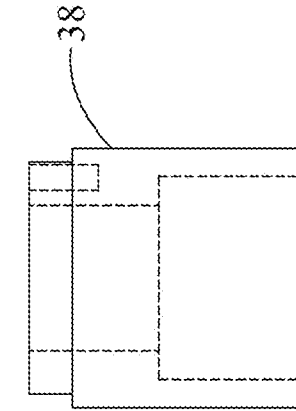


Fig. 31

28

23

24

49

38

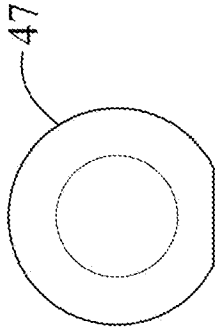


Fig. 33

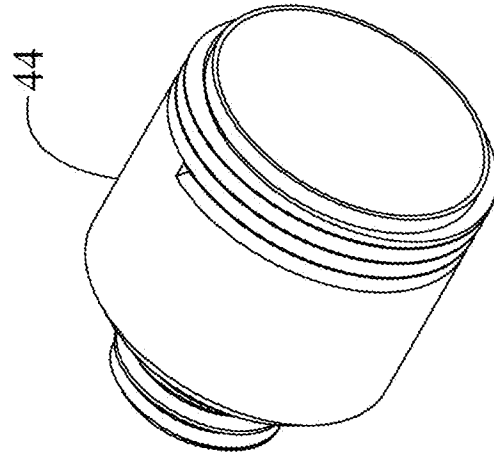


Fig. 35

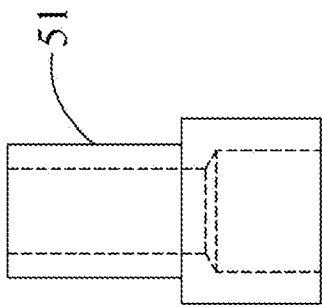


Fig. 32

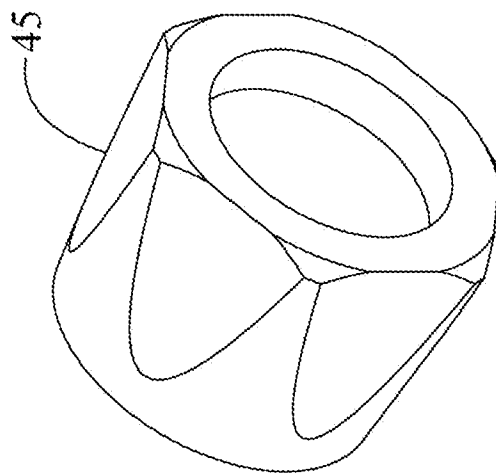
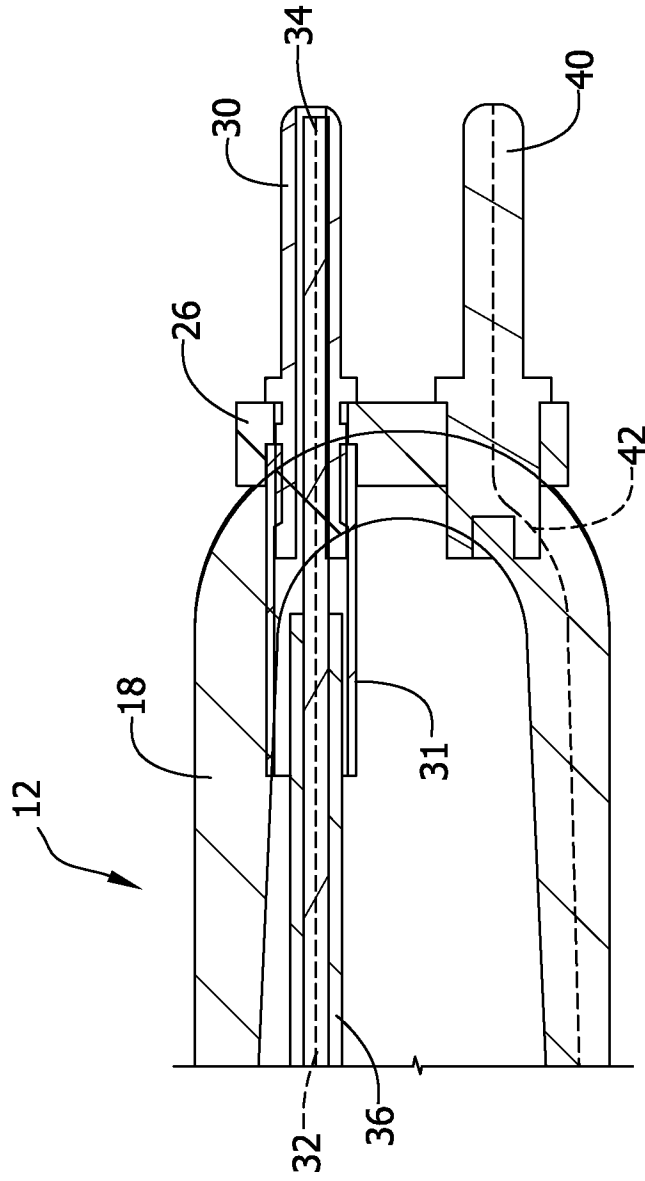


Fig. 34

FIG. 36



22/40

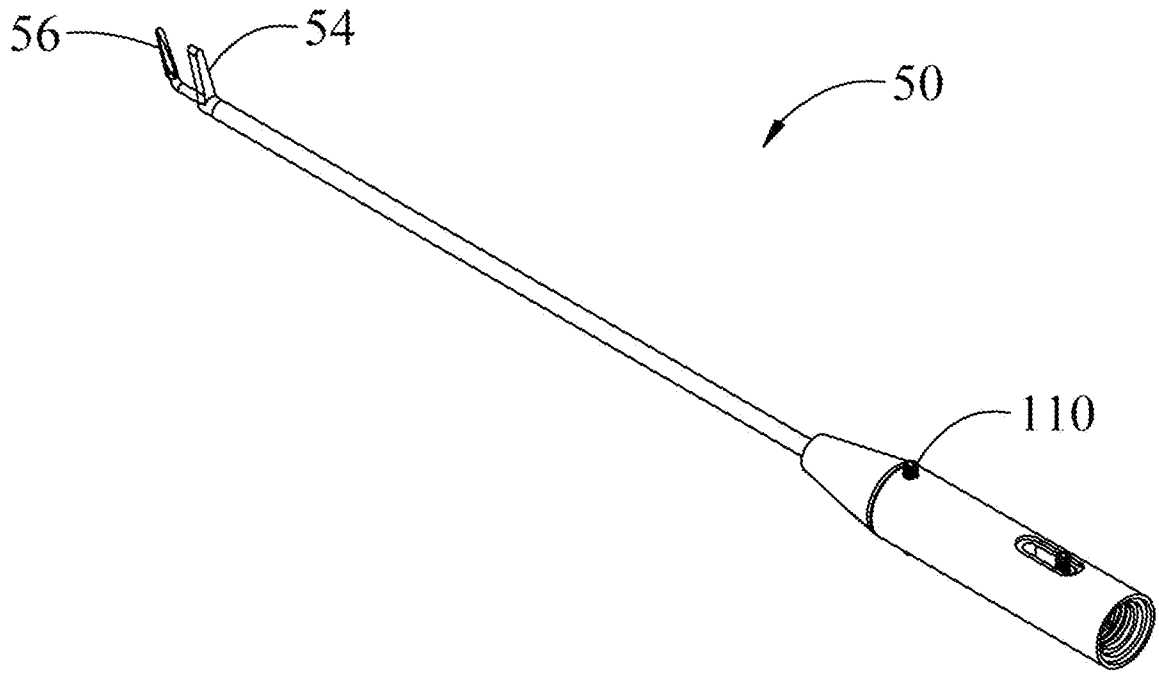


Fig. 37

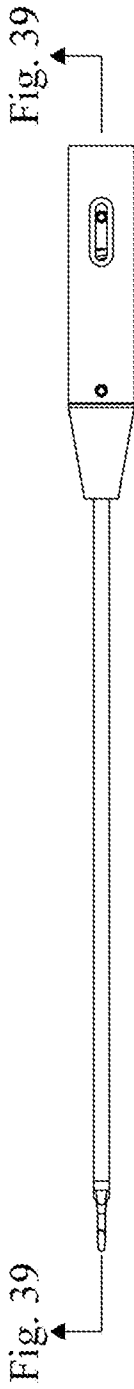
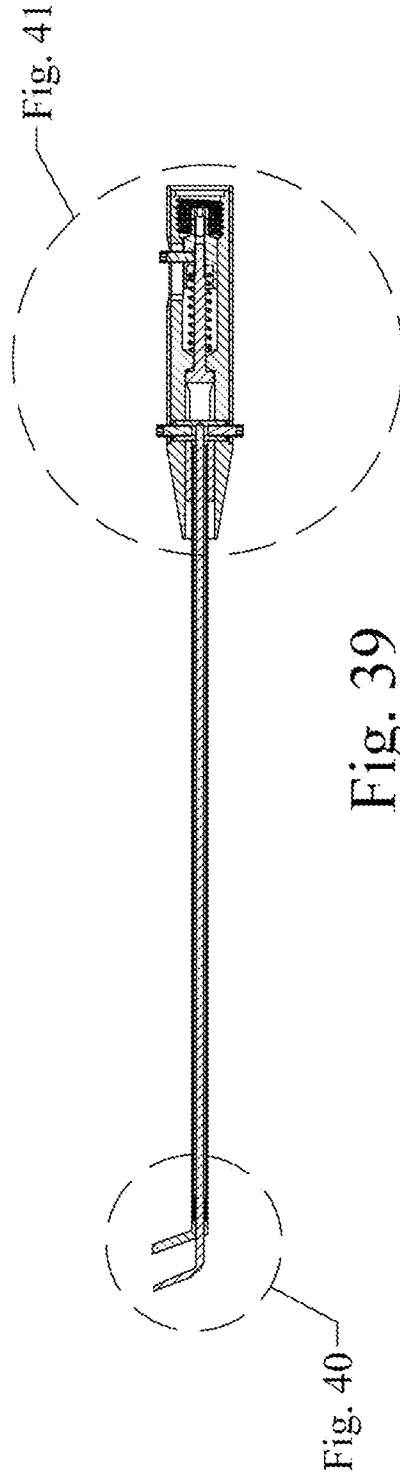


Fig. 38



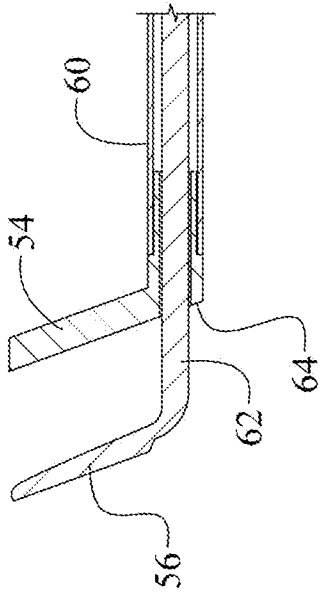


Fig. 40

50

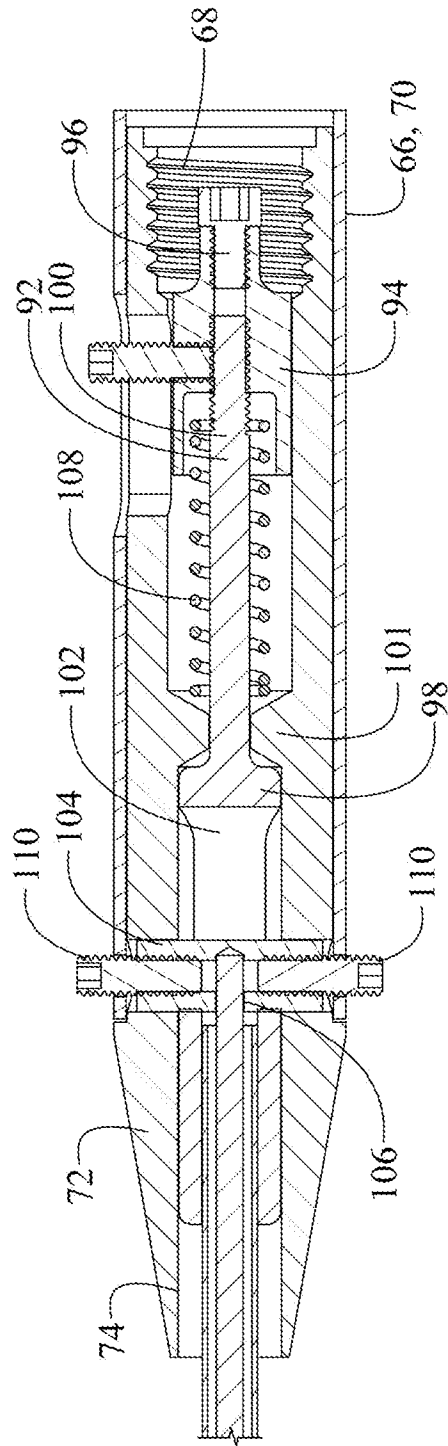


Fig. 41

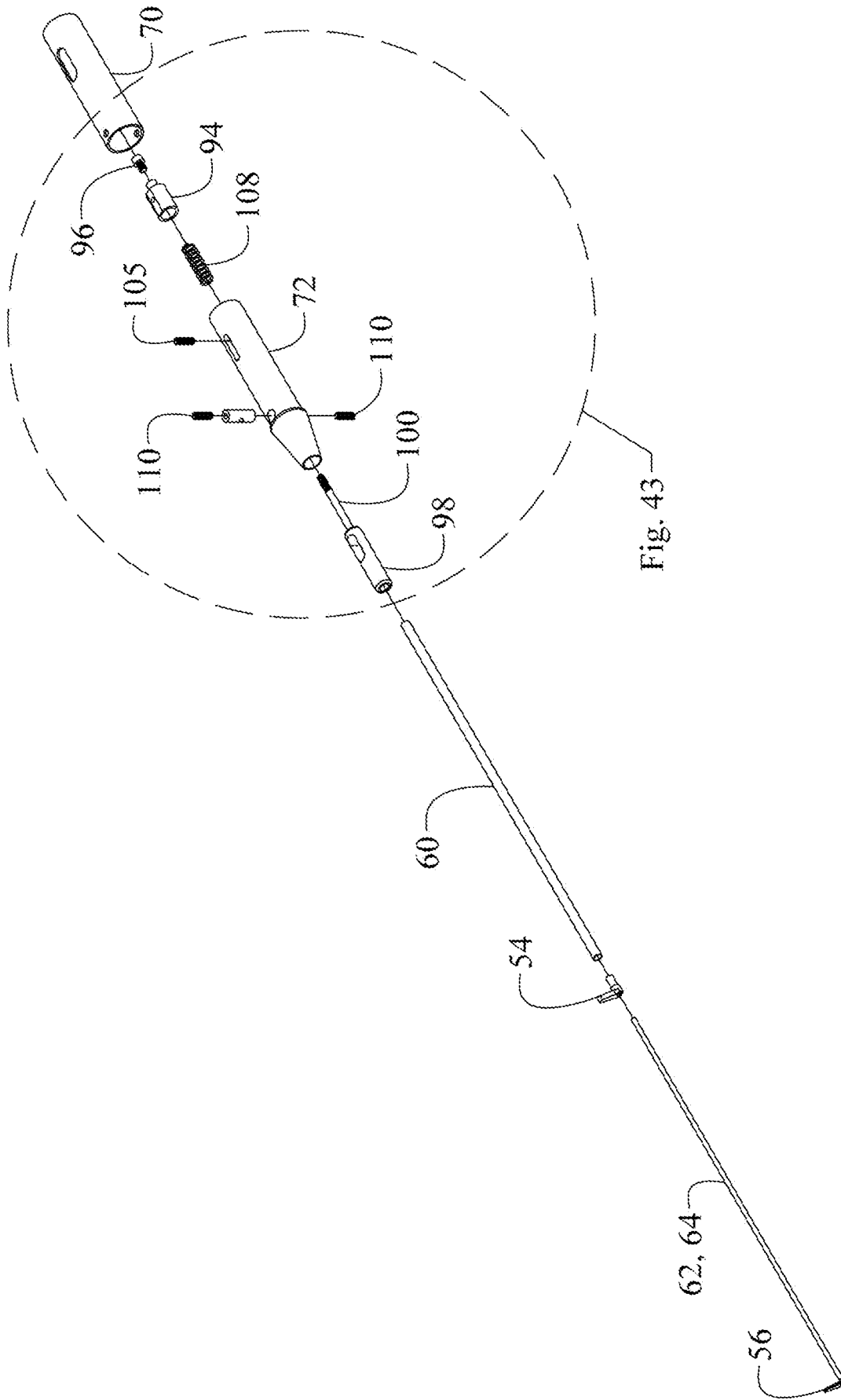


Fig. 42

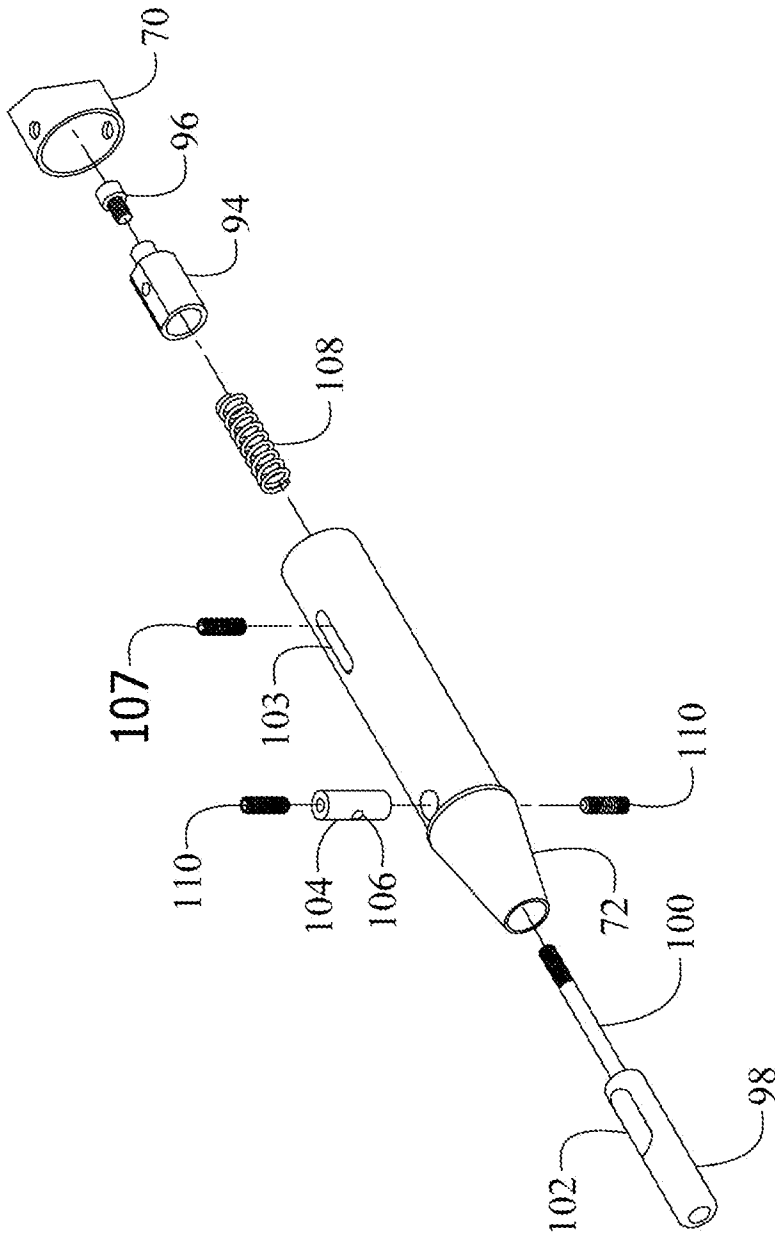


Fig. 43

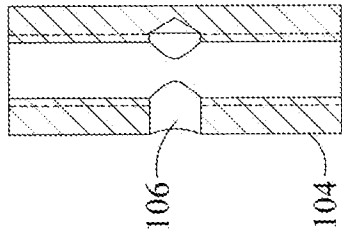


Fig. 46

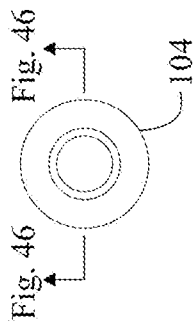


Fig. 45

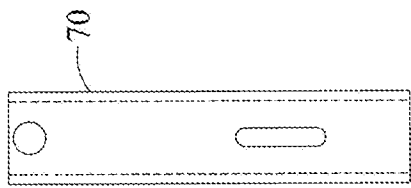


Fig. 44

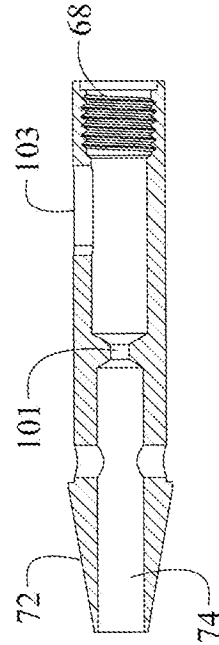


Fig. 48

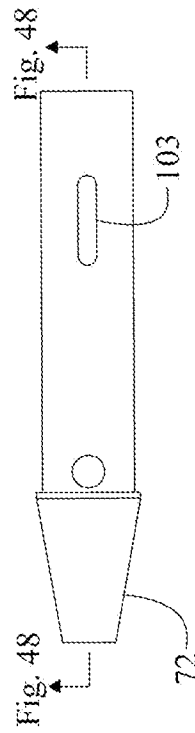


Fig. 47

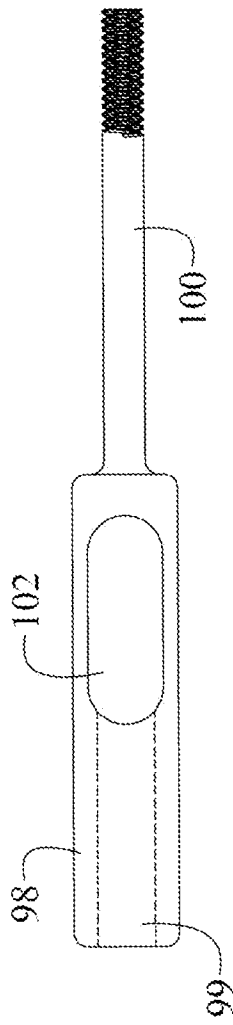


Fig. 49

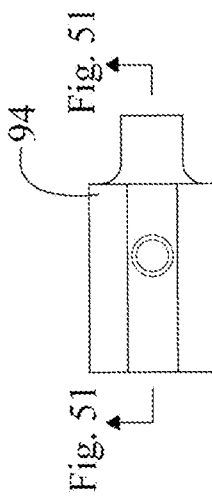


Fig. 50

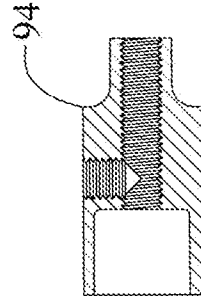


Fig. 51

29/40

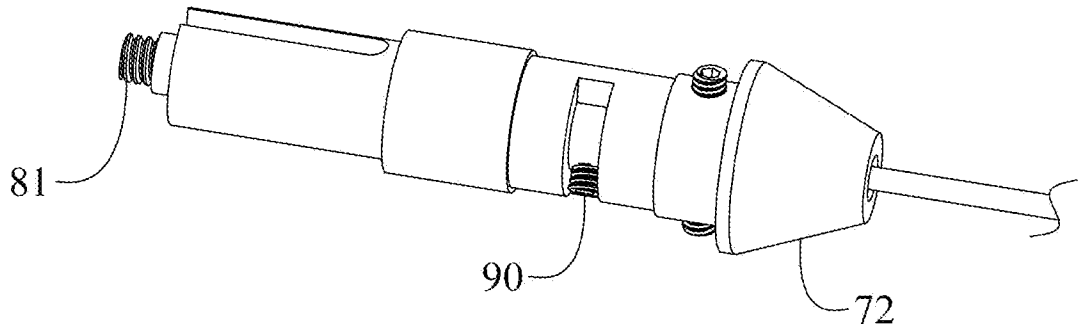


Fig. 52

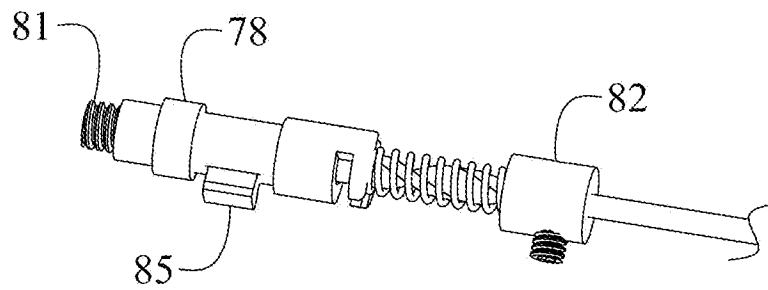


Fig. 53

30/40

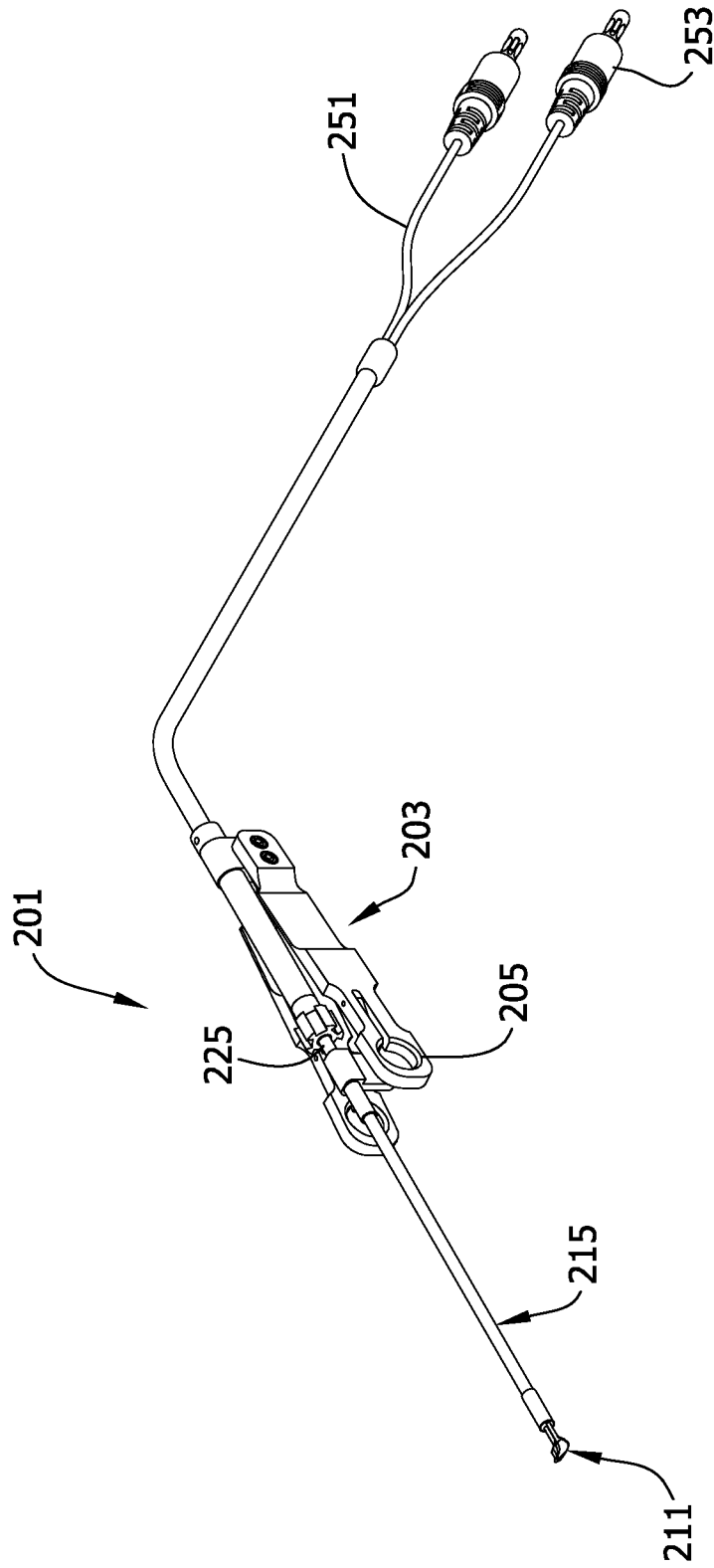
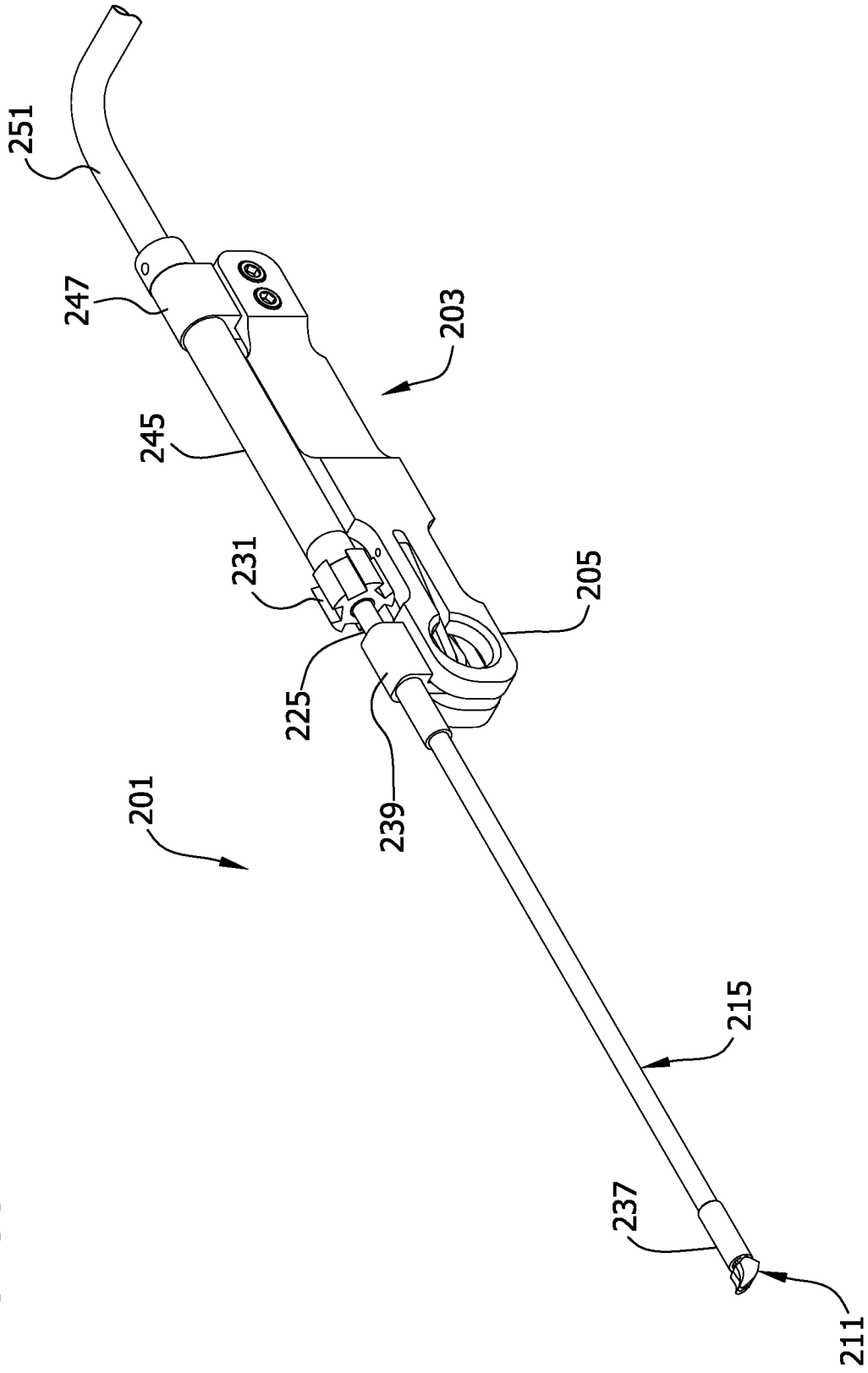


FIG. 54

31/40

FIG. 55



32/40

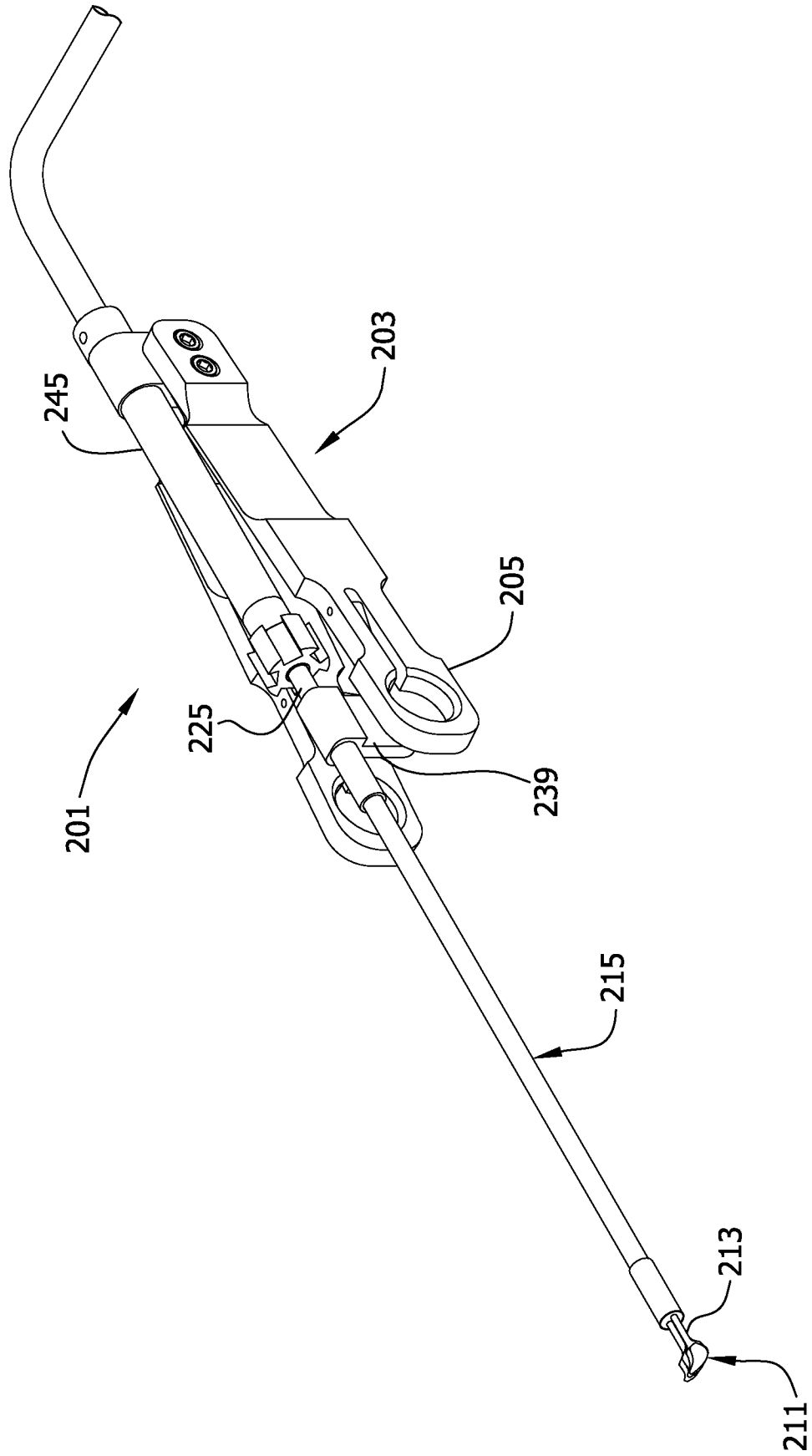


FIG. 56

33/40

FIG. 57

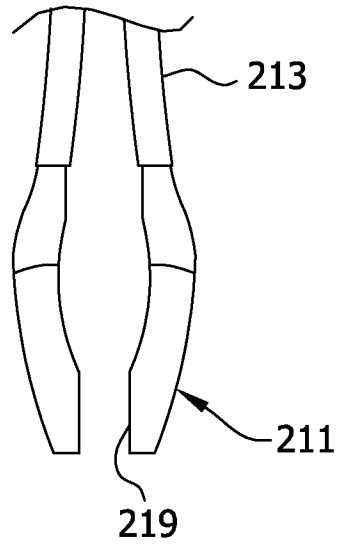
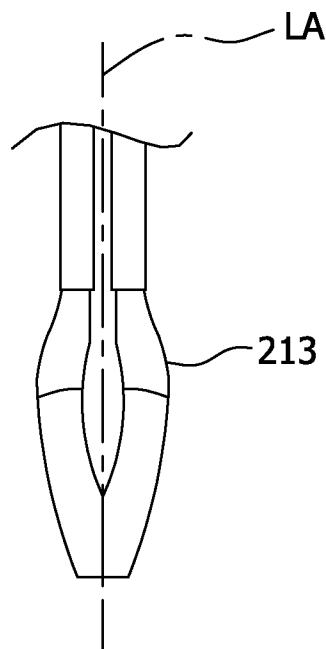
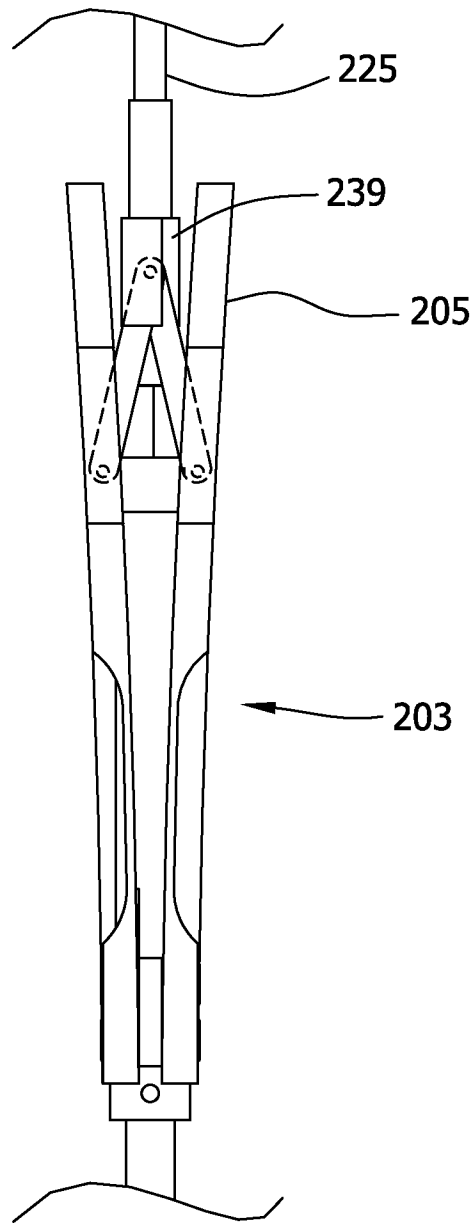


FIG. 58



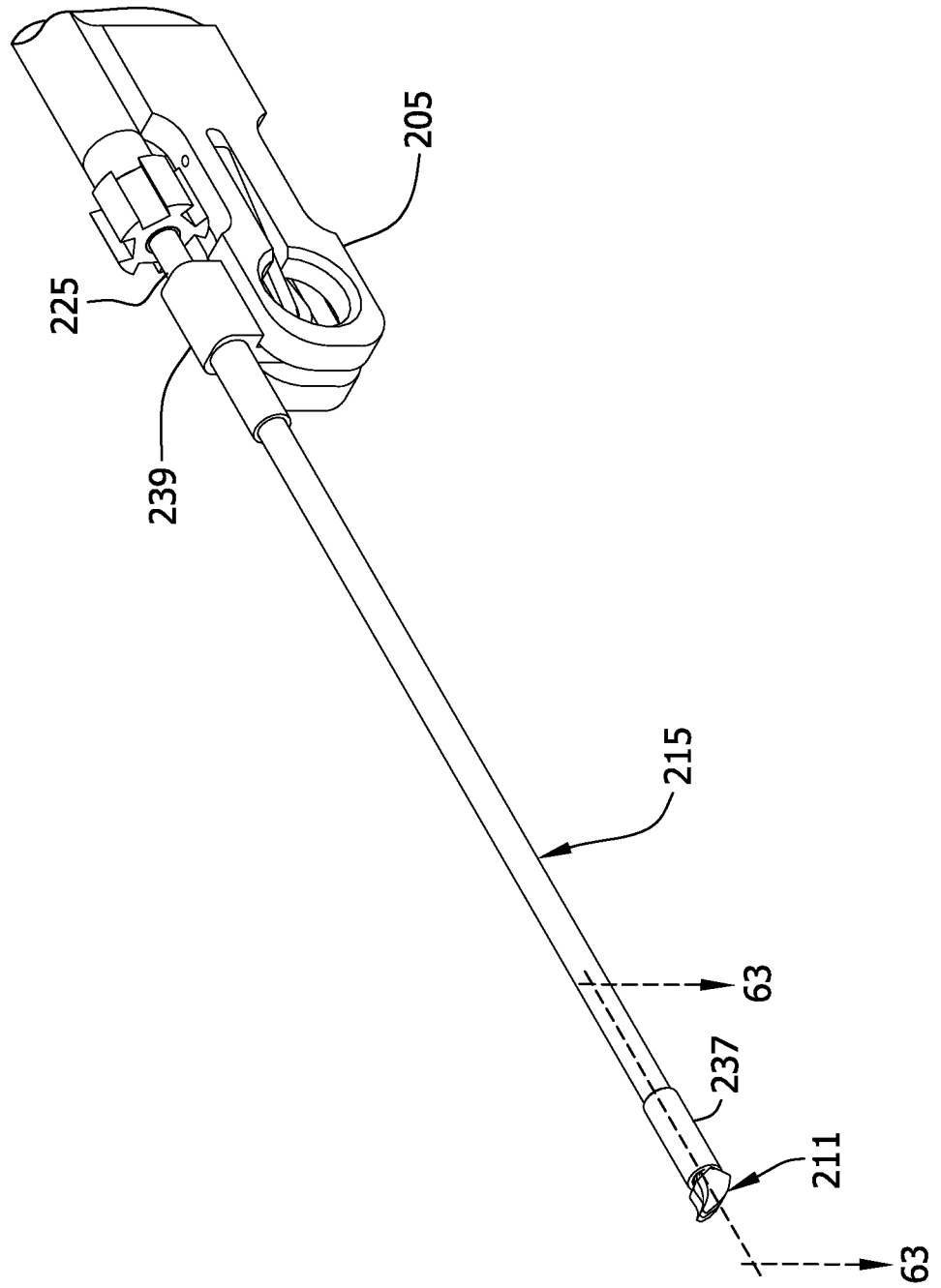
34/40

FIG. 59



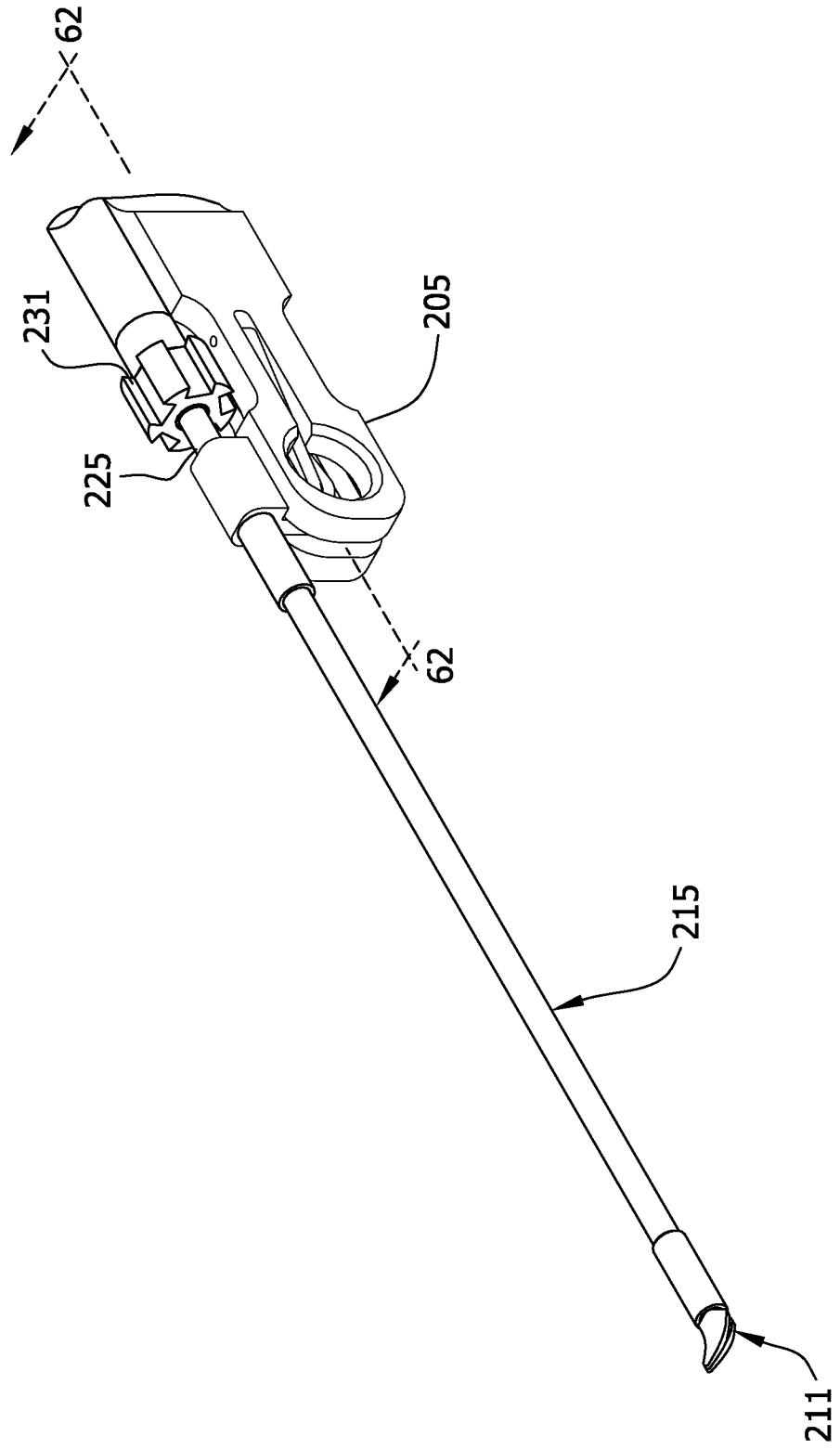
35/40

FIG. 60



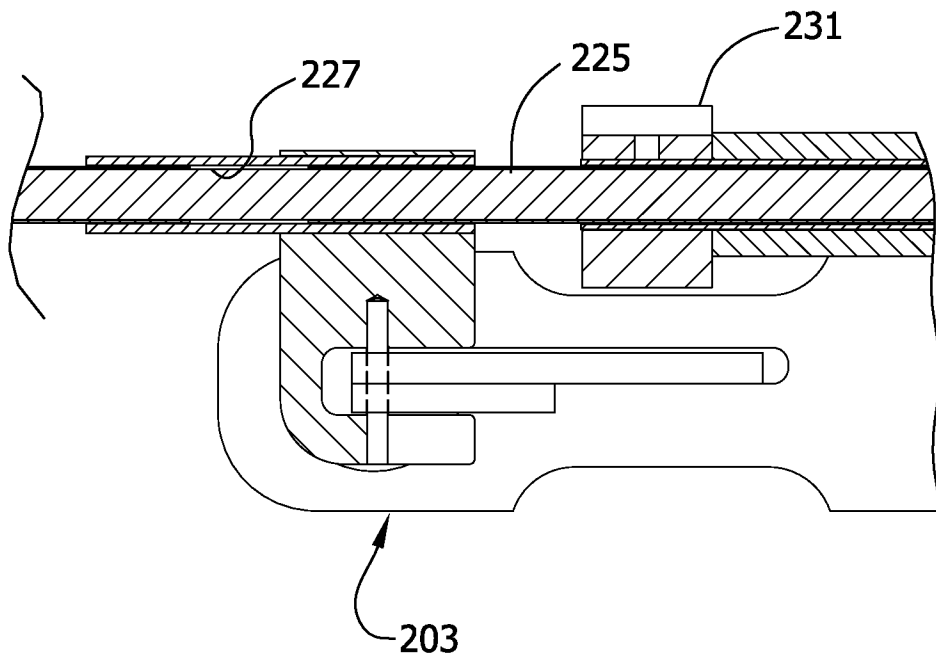
36/40

FIG. 61



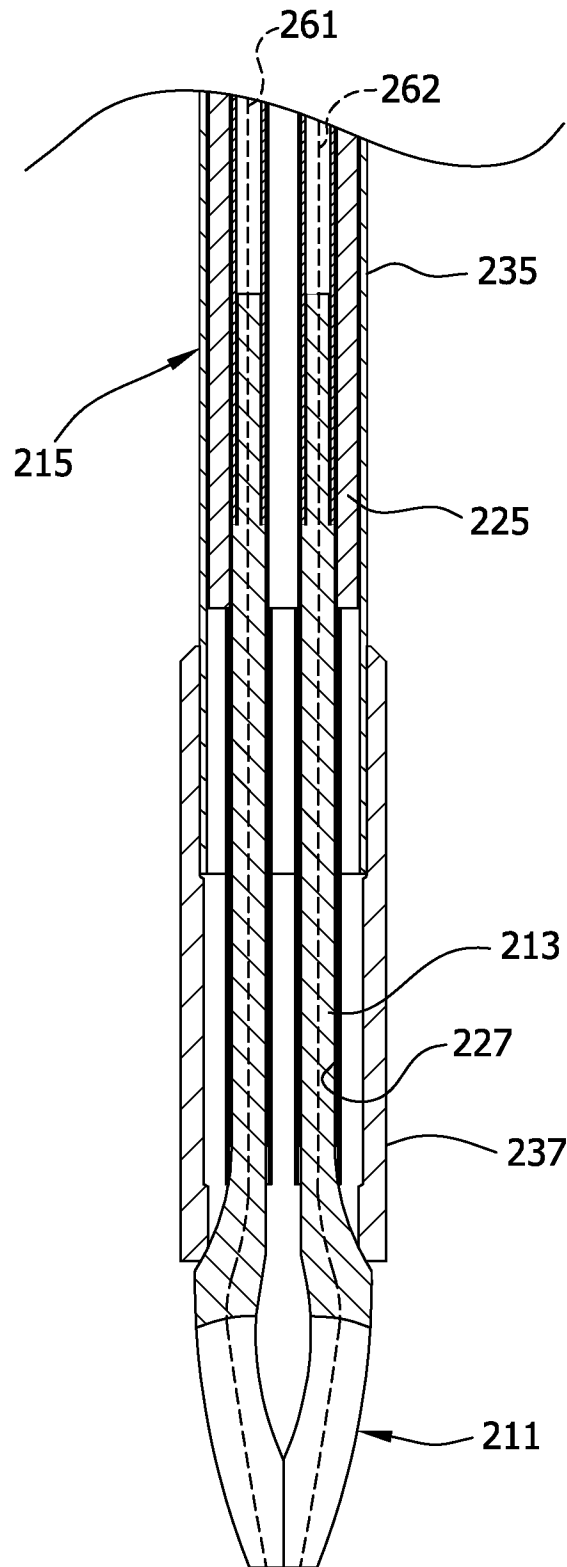
37/40

FIG. 62



38/40

FIG. 63



39/40

FIG. 64

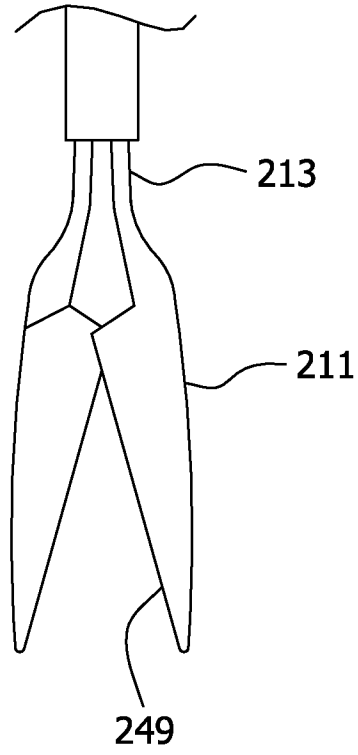
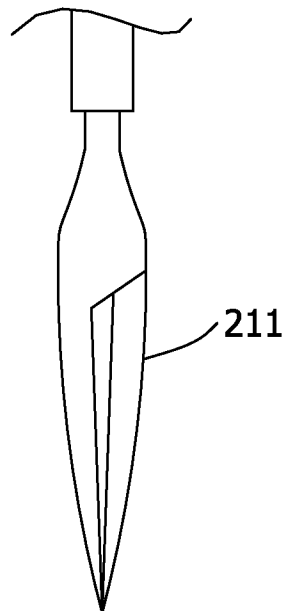


FIG. 65



40/40

FIG. 66

