(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 October 2011 (27.10.2011)

PCT

(10) International Publication Number
WO 2011/133767 A1

(51) International Patent Classification:
A61B 18/14 (2006.01)

(21) International Application Number:
PCT/US2011/033423

(22) International Filing Date:
21 April 2011 (21.04.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/342,990 22 April 2010 (22.04.2010) US

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(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, CL, 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, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: FLEXIBLE ELECTROSURGICAL ABLATION AND ASPIRATION ELECTRODE WITH BEVELED ACTIVE SURFACE

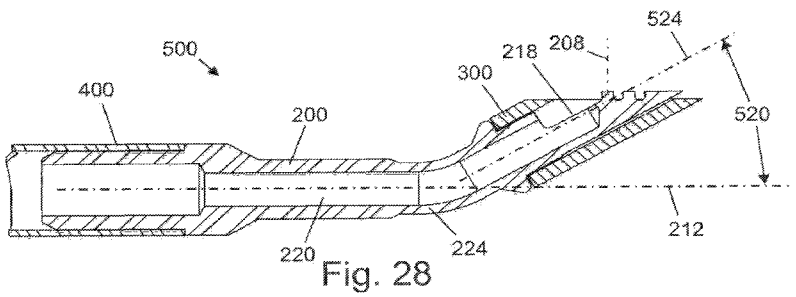

Fig. 28

(57) Abstract: Disclosed herein is a flexible single piece active element for use in connection with aspirating electrosurgical ablators, particularly those configured for bulk tissue vaporization. The active electrode elements of the present invention provide a simple construction suitable for use with a wide array of electrosurgical components and adjustable to wide range of angled positions to permit access to a variety of tissues, in an array of diverse environments and address a host of ablation needs. Additionally, the novel geometry and positioning of both ablation surface and aspiration ports permit aspiration flow to remove primarily waste heat rather than process heat, to thereby improve vaporization efficiency and reduce procedure time. Thus, active electrodes and ablation devices of the present invention maximize efficiency and adaptability while minimizing manufacturing cost and device profile.

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FLEXIBLE ELECTROSURGICAL ABLATION AND ASPIRATION ELECTRODE WITH BEVELED ACTIVE SURFACE

Priority

This application claims the benefit of U.S. Provisional Application Serial No. 61/342,990, filed April 22, 2010, the entire contents of which are hereby incorporated by reference herein.

Field of the invention

This invention relates to electrosurgical devices for use in a conductive fluid environment, and more specifically to aspirating ablation electrosurgical devices for bulk vaporization of tissue in a conductive fluid environment that may be manufactured at low cost and have increased efficiency through the minimization of process heat loss.

Background of the Invention

Minimally invasive surgical techniques have gained significant popularity due to their ability to accomplish desirable outcomes with reduced patient pain and accelerated recovery and return of the patient to normal activities. Arthroscopic surgery, wherein the intra-articular space is filled with fluid, allows orthopedic surgeons to efficiently perform procedures using special purpose instruments designed specifically for arthroscopy. Among these special purpose tools are various manual graspers and biters, powered shaver blades and burs, and electrosurgical devices. During the last several years specialized arthroscopic electrosurgical electrodes referred to in the art as "ablators" have been developed. Examples of such instruments includes ArthroWands manufactured by Arthrocare (Sunnyvale, California), VAPR electrodes manufactured by Mitek Products Division of Johnson & Johnson (Westwood, Massachusetts) and electrodes by Smith and Nephew, Inc. (Andover, Massachusetts). These ablator electrodes differ from conventional arthroscopic electrosurgical electrodes in that they are designed for the bulk removal of tissue by vaporization rather than the cutting of tissue or coagulation of bleeding vessels. While standard electrodes are capable of ablation, their geometries are generally not efficient for accomplishing this task. The tissue removal rates of ablator

electrodes are lower than those of arthroscopic shaver blades, however, electrosurgical ablators are used because they achieve hemostasis (stop bleeding) during use and are able to efficiently remove tissue from bony surfaces. Ablator electrodes are used in an environment filled with electrically conductive fluid.

During ablation, current flows from the ablator into the conductive fluid and heats the fluid to its boiling point. Heating of the conductive fluid is proportional to the density of electrical current flowing from the electrode into the fluid. Regions of high current density will experience higher rates of heating as compared to regions of low current density. In general, regions of high current density occur at the corners and edges of the electrode. Steam bubbles form first at the edges of an ablator but eventually cover virtually the electrode's entire surface. When a steam bubble reaches a critical size, arcing occurs within the bubble and enclosed portion of tissue. A train of sparks occurs within the bubble with the train ending when the bubble grows too large or the tissue enclosed in the bubble is evaporated and conditions within the bubble become unfavorable for sparking.

During ablation, water within the target tissue is vaporized. Because volumes of tissue are vaporized rather than discretely cut out and removed from the surgical site, the power requirements of ablator electrodes are generally higher than those of other arthroscopic electrosurgical electrodes. The efficiency of the electrode design and the characteristics of the Radio Frequency (RF) power supplied to the electrode also affect the amount of power required for ablation. Electrodes with inefficient designs and/or powered by RF energy with poorly suited characteristics will require higher power levels than those with efficient designs and appropriate generators. Because of these factors the ablation power levels of devices produced by different manufacturers vary widely, with some using power levels significantly higher than those commonly used by arthroscopists. Ablator electrode systems from some manufacturers may use up to 280 Watts, significantly higher than the 30 to 70 Watt range generally used by other arthroscopic electrosurgical electrodes.

During arthroscopic electrosurgery, all of the RF energy supplied to the electrode is converted into heat, thereby raising the temperature of the fluid within the joint and the temperature of adjacent tissue. Prior to the introduction of ablator electrodes, the

temperature of the fluid within the joint was not of concern to the surgeon. However, due to the higher power levels at which they generally operate and the longer periods of time that they are energized, fluid temperature is a major concern during the use of ablator electrodes. Standard arthroscopic electrosurgical electrodes are usually energized for only brief periods, generally measured in seconds, while specific tissue is resected or modified, or a bleeder coagulated. In contrast, ablator electrodes are energized for longer periods of time, often measured in minutes, while volumes of tissue are vaporized.

The temperature of the fluid within the joint is critical since cell death occurs at 45 °C, a temperature easily reached with high-powered ablators if fluid flow through the surgical site is insufficient. Patient injury may result. Such injuries have been documented.

The likelihood of thermal injury is strongly affected by the amount of power supplied to the ablator. This, in turn, is determined by the efficiency of the ablator and the speed with which the surgeon desires to remove tissue. A highly efficient ablator will allow the surgeon to remove tissue at desirably high rates while requiring low levels of power. Under these conditions, the likelihood of thermal injuries is reduced significantly.

Ablator electrodes are produced in a variety of sizes and configurations to suit a variety of procedures. Ablators for use in ankle, wrist or elbow arthroscopy, for instance, are smaller than those used in the knee or shoulder. In each of these sizes, a variety of configurations are produced to facilitate access to various structures within the joint being treated. These configurations differ in the working length of the electrode (the maximum distance that an electrode can be inserted into a joint), in the size and shape of their ablating surfaces and in the angle between the ablating face and the axis of the electrode shaft. Electrodes are typically designated by the angle between a normal to the ablating surface and the axis of the electrode shaft, and by the size of their ablating surface and any associated insulator.

Primary considerations of surgeons when choosing a particular configuration of ablator for a specific procedure are its convenience of use (the ease with which the instrument is able to access certain structures) and the speed with which the ablator will be able to complete the required tasks. When choosing between two configurations capable of accomplishing a particular task, surgeons will generally choose the ablator

with the larger ablating surface so as to remove tissue more quickly. This is particularly true for procedures during which large volumes of tissue must be removed. One such procedure is acromioplasty, the reshaping of the acromion. The underside of the acromion is covered with highly vascular tissue which may bleed profusely when removed by a conventional powered cutting instrument, such as an arthroscopic shaver blade. Ablator electrodes are used extensively during this procedure since they are able to remove tissue without the bleeding which obscures the surgeon's view of the site. Ablation in the area under the acromion is most efficiently accomplished using an electrode on which a line normal to the ablating surface is approximately perpendicular to the axis of the ablator shaft. Such an electrode is designated as a "90 Degree Ablator" or a "side effect" ablator. Examples of such electrodes include the "3.2 mm 90 Degree Three-Rib UltrAblator" by Linvatec Corporation (Largo, Florida), the "90 Degree Ablator" and "90 Degree High Profile Ablator" by Smith and Nephew (Andover, MA), the "Side Effect VAPR Electrode" by Mitek Products Division of Johnson and Johnson, and the "3.5 mm 90 Degree Arthrowand", "3.6 mm 90 Degree Lo Pro Arthrowand", and "4.5 mm 90 Deg. Eliminator Arthrowand" by Arthrocare Corporation.

Recently ablator electrodes have been configured with a means of aspiration to remove bubbles and debris from the surgical site. During electrosurgery in a conductive fluid environment, tissue is vaporized, thereby producing steam bubbles that may obscure the view of the surgeon or displace saline from the area of the intra-articular space that the surgeon wishes to affect. In the case of ablation (bulk vaporization of tissue), the number and volume of bubbles produced is even greater than when using other electrodes since fluid is continually boiling at the active electrode during use. Ideally, flow through the joint carries these bubbles away; however, in certain procedures this flow is insufficient to remove all of the bubbles. The aspiration means on an aspirating ablator removes some bubbles as they are formed by the ablation process, and others after they have collected in pockets within the joint. The ablator aspiration means is typically connected to an external vacuum source that provides suction for bubble evacuation.

Aspiration on currently available ablator products may be divided into two categories according to their level of flow. High-flow ablators have an aspiration tube, the axis of which is coaxial with the axis of the ablator rod or tube, that draws in bubbles

and fluid through its distal opening and/or openings cut into the tube wall near its distal tip. High-flow ablators may decrease the average joint fluid temperature by removing heated saline (waste heat since it is an undesirable byproduct of the process) from the general area in which ablation is occurring. The effectiveness of the aspiration, both for removal of bubbles and for removal of waste heat, will be affected by the distance between the aspiration opening and the active electrode. The distal tip of the aspiration tube is generally positioned several millimeters proximal to the active electrode so as to not to obstruct the surgeon's view of the electrode during use. Decreasing this distance is desirable since doing so will increase the effectiveness of the aspiration; however, this must be accomplished without limiting the surgeon's view or decreasing the ablator's ability to access certain structures during use. Examples of high-flow aspirating ablators systems include the Three Rib – Aspirating ablators by Linvatec Corporation and the 2.3 mm and 3.5 mm Suction Sheaths for the VAPR system by Mitek Products, the sheaths being used with standard VAPR ablation probes.

Arthrex, Incorporated (Naples, Florida) markets aspirating ablators in which the aspiration port is in the distal-most surface of the device, and the aspiration path runs through the device. These devices have higher flow rates than low-flow ablators, though less than the high-flow models previously herein described.

Low-flow ablators are characterized by the aspiration of bubbles and fluid through gaps in the ablating surfaces of the active electrode, conveying them from the surgical site via means in the elongated distal portion of the device. Because the low-flow aspiration tends to draw hot saline from the active site of a thermal process, current low-flow ablators require increased power to operate as effectively as a non-aspirating or high-flow aspirating ablators. In the case of low-flow ablators, the heat removed is necessary process heat rather than the waste heat removed by high-flow ablators. Because of this, aspirating ablators of the low-flow type generally require higher power levels to operate than other ablators thereby generating more waste heat and increasing undesirable heating of the fluid within the joint. Typical of low-flow aspirating ablators are those produced by Arthrocare and Smith and Nephew.

Each of these types of aspirating ablator electrodes has its drawbacks. In the case of high-flow aspirating ablators, the aspiration tube increases the diameter of the device,

thereby necessitating the use of larger cannulae. In the case of low-flow aspirating ablators, aspiration decreases the efficiency of the probes since process heat is removed from a thermal process. This decreased efficiency results in decreased rates of tissue removal for a given power level. In turn, this results in increased procedure times or necessitates the use of higher power levels to achieve satisfactory tissue removal rates. Both increased procedure time and high power level usage are undesirable as they cause increased heating of the fluid at the site and thereby the likelihood of thermal injury to the patient.

U.S. Patent Number 6,840,937 to Van Wyk discloses an aspirating ablator that minimizes the removal of process heat by placing aspiration ports at a distance from the active electrode, specifically in the distal end of the probe, and in the top surface of the ablator, the top aspiration port being surrounded by the insulator that surrounds the active electrode and the port being displaced a short distance from the active electrode. Aspiration ports positioned in this manner remove debris and aspiration byproducts from regions adjacent to the active electrode rather than through the active electrode in the manner of low-flow ablators thereby minimizing the loss of process heat. However, the construction taught by Van Wyk is not well suited to ablators other than 90-degree ablators, in which the aspirating surface is substantially parallel to the tube axis. The distal portion of the device may be bent to create other angles to the tube axis, however, the bend would be proximal to the distal end assembly and would have a relatively large radius such that the finished product would have to be used with large cannulae, an undesirable condition.

U.S. Patent No. 7,837,683 to Carmel, et al. (herein incorporated by reference in its entirety) describes an aspirating ablator that has an aspiration port in the center of the active electrode. The aspiration port is surrounded by a tubular portion (i.e., wall) that both restricts flow between protuberances surrounding the port and causes aspiration of liquids from regions above (distal to) the ablating surface. The efficiency of the Carmel ablator is increased since the amount of process heat removed is reduced; however, the construction of the device is somewhat complex. Producing ablators of various angles using the construction suggested by Carmel requires that the distal end of the ablator be

bent in the same manner as that of the Van Wyk embodiment. The resulting ablator is again too large to be used in small cannulae.

Many surgical procedures are not performed inside a natural or formed body cavity and as such are not performed on structures submerged under a conductive liquid. In laparoscopic procedures, for instance, the abdominal cavity is pressurized with carbon dioxide to provide working space for the instruments and to improve the surgeon's visibility of the surgical site. Other procedures, such as oral surgery, the ablation and necrosis of diseased tissue, or the ablation of epidermal tissue, are also typically performed in an environment in which the target tissue is not submerged. In such cases, it is necessary to provide a conductive irrigant to the region surrounding the active electrode(s), and frequently also to aspirate debris and liquid from the site. Such irrigant may be applied by a means external to the instrument; however, having an irrigation means internal or attached to the instrument generally provides better control and placement. This is also true for aspiration of fluid and debris. External means may be used for aspiration from the site; however, aspiration through the instrument distal end provides improved fluid control and may, in some cases, draw tissue toward the active electrode thereby enhancing performance. U.S. Pat. No. 7,566,333 to Van Wyk, et al. (herein incorporated by reference in its entirety) discloses an electrosurgical device for use in a dry or semi-dry environment.

Electrosurgical devices having means for irrigating a site, and/or means for aspirating fluid, bubbles and debris from a site are well known. Smith, in U.S. Pat. No. 5,195,959, disclose an electrosurgical device with suction and irrigation. Bales, et al., in U.S. Pat. No. 4,682,596 disclose a catheter for electrosurgical removal of plaque buildup in blood vessels, the catheter having lumens for supplying irrigant to the region of the instrument distal tip and for aspirating debris from the region. Hagen, in U.S. Pat. No. 5,277,696, discloses a high frequency coagulation instrument with means for irrigation and aspiration from the region of the instrument tip. Pao, in U.S. Pat. No. 6,674,499, discloses a coaxial bipolar probe with suction and/or irrigation. Eggers, in U.S. Pat. No. 6,066,134, discloses a method for electrosurgical cutting and coagulation which uses a bipolar probe having means for irrigating and aspirating from the region of the probe

distal tip. The Eggers device uses the irrigant flow to provide a return path to a return electrode recessed axially a distance away from the active electrode(s).

As in the case with ablators operating in a fluid filled cavity, for those operating in a dry or semi-dry environment with supplied irrigant, the placement and volume of aspiration flow through an electrosurgical instrument in the region of an active electrode, or even through the active electrode, may adversely affect the performance of the instrument. Electrosurgery, particularly procedures in which tissue is vaporized, is a thermal process. Aspiration which draws fluid through or around the active electrode surfaces draws away process heat, thereby decreasing heating of the conductive irrigant in the region so as to decrease bubble production and ablative arcing. This makes the device less efficient thereby requiring increased power to achieve acceptable performance.

The construction of aspirating ablator distal portions (those distal to the handle) may be divided into two types: complex construction in which power is conducted to the active electrode by wires housed within a tubular distal portion, and simple construction in which the elongated tubular structure conducts power to the active electrode.

Aspirating ablation devices with complex construction have a return electrode attached to the probe, the tubular portion conducting RF energy from the return electrode to the handle assembly, from which it is returned to the generator. This tubular return portion must be electrically isolated from the active electrode and wiring within the tubular portion which conducts power to the active electrode. Additionally, the tubular portion must house a dielectric tube for conducting the aspirated materials from the device distal tip to the handle, and therethrough to an external vacuum supply. Aspiration flow must be isolated from the tubular return structure since the conductive liquid contained in the flow is in contact with the active electrode and therefore at high potential. Ablation devices having complex construction are those from Arthrocare, Smith and Nephew, Mitek division of Johnson and Johnson, and Stryker.

Aspirating ablation devices with simple construction use a return electrode in the form of a dispersive pad which is removably applied to the patient's body remote to the surgical site. The distal portion of these device is a metallic tube, to the distal end of which is mounted an active electrode, the RF energy being conducted to the electrode by

the tube. Aspirated materials are conducted from the distal tip of the device to the handle, and therethrough to an external vacuum supply. Because the flow is at the same high potential as the tube, it is not necessary to electrically isolate it from the tube. Typical of aspirating ablators having a simple construction are the Lightwave Suction Ablator by Linvatec, and the 9800 series aspirating ablators by Arthrex.

Ablators having an ablating surface with a normal perpendicular to that of the device axis ("90 degree ablators") are the most popular configuration with surgeons, however, ablators are produced in a variety of configurations with the normal to the ablating surface inclined to the axis at angles ranging between thirty and ninety degrees. Ablators having a complex construction are formed to each unique angle using components specific to that geometry. For instance, the distal-end components used to create a 90-degree ablator are configured differently from those used to create a 60-degree ablator, which are different from those used to create a 30 degree ablator. Mitek produces a "VAPR-T Side-Effect ablator" and a "VAPR-T Reverse-angled Side-Effect ablator" from the same components, the tubular element being bent proximal to the distal electrode assembly, however, because of the bend in the tube the ablator cannot be inserted into a standard small-diameter cannula frequently used for fluid control in shoulder and knee surgery.

In the case of ablators having simple construction, non-aspirating ablators of various angles of a particular configuration (for example 3.4 mm 30-, 60- and 90-degree) may be constructed using common components. For instance, 30, 60 and 90 degree Ultrablators by Linvatec use a common active electrode component and insulator, the active electrode component being bent to the required angle to create the various products. Similarly, Arthrex 45 and 90 degree small joint and meniscectomy ablators have common active electrode components, the distal ablating surface of the component being beveled at 45 degrees to form the 45-degree ablator. The distal end of the element is bent 45 degrees to create a 90-degree ablator.

Prior art aspirating ablators of simple construction (that is, wherein the RF energy is conducted to the active electrode by the elongated tubular distal element) have an active electrode and distal aspiration path formed by an assembly of at least two elements, generally an active electrode element and an element to provide an aspiration

path from the aspiration port to the tubular element. This two-piece construction has two associated disadvantages: first, depending on the specific design, the complexity may increase manufacturing difficulty and cost; and second, the complexity may make it difficult to use common components to produce ablators having a range of angular displacement between ablating surface and tube device axis while maintaining a profile that allows use of the device in small diameter cannulas. For instance, Van Wyk in patent number 6,840,937, Carmel, et al. in co-pending application 11/431,515, teach aspirating ablators with distal electrode assemblies formed from an electrode element and a tubular element for providing an aspiration path, both elements being of a simple, easy to manufacture design that can be produced at low cost. However, if the assembly is bent in such a way that ablators having a range of angles between the surfaces can be formed with the same components, the resulting profile of the bent devices will be such that they cannot pass through small diameter cannulas. Gallo, et al. in co-pending applications 11/636,548 and 12/639,644 teaches assemblies of complex, difficult to machine components joined by laser welding. While these ablator assemblies can be bent to some degree to produce ablators having a range of angles between the ablating surfaces and the device axis and with the resulting ablators being able to pass through fairly small cannulas, the cost of manufacturing these assemblies is high.

There is a need for an aspirating ablator having a simple construction in which the aspiration flow removes primarily waste heat rather than process heat; and which is constructed so that a single component or set of components can be used to produce at low cost ablators of various angles which may be used with small cannulae for arthroscopy, or in a semi-dry environment.

Summary of the Invention

It is accordingly an objective of the present invention to provide a highly efficient aspirating electrosurgical ablator capable of overcoming the deficiencies discussed above. More particularly, in view of the ever-present need in the art for improvements in electrode design, it is an objective of the present invention to provide an effective, efficient aspirating ablator that has a simple form, may be produced at low cost and is suited to the bulk vaporization of a wide variety of tissue, in a wide array of environments. To that end, an additional objective of this invention to provide active electrode fabricated as a single machined component that can be flexed into a number of bent positions, to give rise to a range of ablating surface angles (i.e., the angle between the ablating surface and the axis of the ablation device).

Thus, in view of the above, the present invention provides an aspirating electrosurgical ablator for bulk vaporization of tissue characterized by a distal end active element of a unitary construction, preferably fabricated from a monolithic piece of homogeneous metallic material. The ablator preferably includes a proximal portion forming a handle, a distal portion that includes the active element and a central lumen extending from the proximal portion to the distal portion, stopping short of the distal end. In a particularly preferred embodiment, the active element is a closed-end tubular element having protuberances, grooves or other contours machined into its distal end to create regions of high current density and yield an angled or beveled ablating surface. The angle of the ablating surface is characterized by the angle a line normal to the ablating surface forms with the longitudinal axis of the distal portion of the tubular element. In a preferred embodiment, this angle ranges between 30 and 80 degrees, and more preferably between 40 and 70 degrees.

The active element is further characterized by cannulated lumen, preferably centralized and suited for aspiration extending therethough and terminating in a lateral opening (aspiration port) positioned just proximal and therefore adjacent to said ablating surface. This novel configuration of lateral aspiration port and beveled, contoured ablation surface permits ablation and vaporization to occur simultaneously, without significantly impacting process heat dispersal and/or negatively affecting ablation efficiency.

Accordingly, in a preferred embodiment, the present invention provides an active electrode for connection to an electrosurgical device for the bulk vaporization of tissue, the active electrode including a cannulated tubular element formed from a single piece of homogenous metallic material and characterized by an open proximal end, a closed distal end and a preferably centralized lumen extending therebetween, the active electrode further characterized by:

a) a tubular distal portion having a beveled distal-most ablation surface that forms an acute angle with the longitudinal axis of said distal portion,

b) a raised flange portion proximally adjacent to the tubular distal portion having a diameter greater than the diameter of the tubular distal portion and a flat distal-facing surface,

c) a tubular middle portion proximal adjacent to said flange portion, wherein the tubular middle portion and the tubular distal portion are not coaxial, further wherein the longitudinal axis of the tubular middle portion forms a pre-determined acute angle with the longitudinal axis of said tubular distal portion,

d) a tubular proximal portion configured for attachment to an elongate cannulated tubular member, and

e) a lateral opening formed in a side wall of the tubular distal portion and positioned proximally to said beveled ablation surface, said opening extending through the side wall of said distal portion into the central lumen.

The proximal end of the active electrode piece may be readily affixed to the distal end of the elongate tubular cannula element that constitutes the distal portion of an electrosurgical ablation device. The proximal portion of the ablation device includes a handle that may be, in turn, connected to a suitable vacuum source such that the aperture adjacent and just proximal to the beveled ablating surface, the central lumen of the active electrode piece, and the lumen of the cannula portion together form an aspiration path such that byproducts of ablation may be removed from the region surrounding the distal end of the device during use.

The unitary active element piece described above preferably further includes a tubular insulator having open proximal and distal ends and formed from a suitable dielectric material, the insulator configured to slide over and surround the distal end of the electrode. In use, the proximal end of the insulator abuts a raised or flanged, preferably radiused, portion of active element acting as a stop therefore. The distal end of the tubular insulator includes an angled planar surface analogous to and coordinating with the beveled ablation surface disposed on the distal end of the active element. When the insulator is assembled to the active electrode piece, the beveled ablating surface protrudes through the distal portion of the distal opening of the insulator a predetermined distance, and the open proximal end allows communication between the region distal to the insulator and the lateral aperture (i.e., aspiration port) disposed in the electrode piece. The beveled ablating surface is then parallel to the angled distal surface of the insulator.

Except for the portion of the electrode piece protruding beyond the insulator distal surface, the electrode piece and elongate tubular member are preferably insulated by a dielectric coating which overlaps the proximal end of the insulator. Additionally, with the exception of the distal insulator component and the proximal cannula component, the remainder of the active electrode component constitutes a unitary, integral construction, preferably fabricated from a homogenous single piece of metallic material.

Accordingly, in another preferred embodiment, the present invention provides an electrosurgical device for the bulk vaporization of tissue including an active electrode such as described above, including an elongate cannulated tubular element affixed to the proximal portion of the active electrode and further including a tubular insulator formed from a suitable dielectric material. In a particularly preferred embodiment, the insulator has an open proximal end characterized by a first proximal-most surface and an open distal end characterized by a second distal-most surface, such that when the insulator is positioned about the tubular distal portion of the active electrode, the first proximal-most surface of the insulator abuts the distal-facing surface of the flange portion and the second distal-most surface of the insulator is slightly proximal to the beveled ablation surface of the active electrode such that the lateral opening, the active electrode central lumen, and the cannulated tubular element provide a continuous aspiration path allowing the flow of vaporization by-products from the region adjacent to the beveled ablation

surface and to the proximal end of the electrode tubular element. The electrosurgical device may optionally further include a dielectric coating covering the exterior of the tubular element, the portion of the active electrode proximal to said insulator, and a proximal portion of said insulator.

The active element preferably includes a portion of reduced wall thickness disposed proximate to the proximal end of the insulator when assembled to the electrode piece, the reduced wall thickness affording flexibility to the active element, permitting it to be bent, the bend occurring primarily in the region of reduced wall thickness. Flexing and bending of the active electrode piece allows the distal end ablating surface to be oriented at a wide range of angles and therefore find utility in connection with a wide variety of electrosurgical products. For instance, bending the element to an angle that is the complement of the angle formed between a line normal to the ablating surface and the axis of the element distal portion in the direction of the aperture (hereinafter referred to as "upward") the normal to the ablating surface can be made perpendicular to the axis of the tubular element to form what is commonly referred to as a "90 degree ablator". As an example, if the first ablation surface angle (characterized by a line normal to the ablating surface and the longitudinal tube axis) is 60 degrees, in its unbent state the finished product would be referred to in the industry as a "60 degree ablator". Converting the active electrode piece to the upward configuration, such that the second angle is 30 degrees would result in the creation of a "90 degree ablator". Bending the electrode piece downward (away from the aperture) 15 degrees would make the angle between the normal to the ablating face and the tube axis 45 degrees so as to create a "45 degree ablator". In this fashion, a single unitary piece active element configured for connection to any number of conventional electrosurgical device can be used to produce a variety of ablator products appropriate for a range of tissues and procedures.

Because the active electrode piece is bent only moderately to form the various products (generally less than the complement of the first angle), and because the bend is localized at a distal location just proximate to the proximal end of the insulator, the ablators whether unbent or bent, fit into cannulae having relatively small inner diameters. In this manner, insertion trauma may be reduced.

Due to its location proximal to the ablating surface, the aspiration port primarily removes waste heat rather than process heat. The aspiration port may be made quite large relative to the size of the ablating surface so as to allow efficient removal of ablation byproducts without clogging. If clogging occurs, the size of the aspirating port and its readily accessible, unobstructed location allow easy clearing of the clogging tissue either by wiping on a suitable surface or by the insertion of a wire into the aspiration port.

The aspiration port allows substantial aspiration flow through the electrode piece thereby removing waste heat from the ablation process. Cooling of the electrode piece in this manner prevents failure of the dielectric coating which covers the assembly and also guards against overly high local temperatures which can, in turn, give rise to tissue injury.

A final objective of the present invention is to provide a method for forming an active electrode of the present invention, the method including the steps of:

(a) on a screw-machine, lathe or other suitable turning machine, forming a metal blank having a tubular distal portion of a predetermined length, a flange portion having a diameter greater than the diameter of said tubular distal portion and having a distal-facing surface, said flange portion being proximally adjacent to said tubular distal portion, a tubular middle portion proximal to said flange portion, a tubular proximal-most portion formed for attachment to an elongated cannulated member, and a central lumen extending from the proximal end of said active electrode to a predetermined depth;

(b) beveling the distal end of said blank to form an angled distal most surface on said blank;

(c) forming a lateral opening between the exterior surface of said tubular distal portion and the central lumen; and

(d) bending the tubular middle portion a pre-determined acute angle such that tubular distal portion and said tubular middle portion are not coaxial.

These and other objects are accomplished in the invention herein disclosed which is an aspirating electrosurgical ablator of simple construction. It will be understood by those skilled in the art that one or more aspects of this invention can meet certain of the above objectives, while one or more other aspects can meet certain other objectives. Each

objective may not apply equally, in all its respects, to every aspect of this invention. As such, the preceding objects should be viewed in the alternative with respect to any one aspect of this invention.

The above-noted objects and features of the invention will become more fully apparent when the following detailed description is read in conjunction with the accompanying figures and/or examples. However, it is to be understood that both the foregoing summary of the invention and the following detailed description are of a preferred embodiment and not restrictive of the invention or other alternate embodiments of the invention. In particular, while the invention is described herein with reference to a number of specific embodiments, it will be appreciated that the description is illustrative of the invention and is not constructed as limiting of the invention. Various modifications and applications may occur to those who are skilled in the art, without departing from the spirit and the scope of the invention, as described by the appended claims. Likewise, other objects, features, benefits and advantages of the present invention will be apparent from this summary and certain embodiments described below, and will be readily apparent to those skilled in the art having knowledge of electrode design. Such objects, features, benefits and advantages will be apparent from the above in conjunction with the accompanying examples, data, figures and all reasonable inferences to be drawn there-from, alone or with consideration of the references incorporated herein.

Brief Description of the Figures

Various aspects and applications of the present invention will become apparent to the skilled artisan upon consideration of the brief description of the figures and the detailed description of the present invention and its preferred embodiments which follows:

Figure 1 is a schematic representation of an electrosurgical system for bulk vaporization of tissue constructed in accordance with the principles of this invention.

Figure 2 depicts an electrosurgical device constructed in accordance with the principles of this invention

Figure 3 is a perspective view of the objects of Figure 2.

Figure 4 is a plan view of the distal portion of a prior art electrosurgical ablator.

Figure 5 is a side elevational view of the objects of Figure 1.

Figure 6 is an axial elevational view of the objects of Figure 1.

Figure 7 is a perspective view of the objects of Figure 1.

Figure 8 is a sectional view of the objects of Figure 1 at location A – A of Figure 1.

Figure 9 is a side elevational view of the prior art device objects of Figure 1 with the tubular element bent downward.

Figure 10 is an axial elevational view of the objects of Figure 6.

Figure 11 is a plan view of an electrode piece for an electrosurgical ablator formed in accordance with the principles of this invention.

Figure 12 is a side elevational view of the objects of Figure 8.

Figure 13 is a sectional view of the objects of Figure 8 at location A – A of Figure 8.

Figure 14 is an axial elevational view of the objects of Figure 8.

Figure 15 is a perspective view of the elements of Figure 8.

Figure 16 is a side elevational view of an insulator for an electrosurgical ablator formed in accordance with the principles of this invention.

Figure 17 is an axial elevational view of the objects of Figure 13.

Figure 18 is a perspective view of the objects of Figure 13.

Figure 19 is a plan view of the distal end assembly of an ablator formed in accordance with the principles of this invention.

Figure 20 is a side elevational view of the objects of Figure 16.

Figure 21 is a sectional view of the objects of Figure 16 at location A – A of Figure 16.

Figure 22 is an axial elevational view of the objects of Figure 16.

Figure 23 is a perspective view of the objects of Figure 16.

Figure 24 is a side elevational view of the objects of Figure 16 wherein the electrode piece has been bent downward to a predetermined angle.

Figure 25 is an axial elevational view of the objects of Figure 21.

Figure 26 is a plan view of the objects of Figure 16 in which the electrode piece has been bent upward to a predetermined angle.

Figure 27 is a side elevational view of the objects of Figure 23.

Figure 28 is a sectional view of the objects of Figure 23 at location A – A of Figure 23.

Figure 29 is an axial elevational view of the objects of Figure 23.

Figure 30 is a sectional view of the distal portion of the device during use.

Figure 31 is a plan view of an active electrode for an alternate embodiment of this invention.

Figure 32 is a side elevational view of the objects of Figure 31.

Figure 33 is a side elevational sectional view of the objects of Figure 31 at location A – A of Figure 31.

Figure 34 is a distal axial view of the objects of Figure 31.

Figure 35 is a perspective view of the objects of Figure 31.

Figure 36 is a plan view of an insulator for an alternate embodiment of this invention.

Figure 37 is a perspective view of the objects of Figure 36.

Figure 38 is a side elevational view of the objects of Figure 36.

Figure 39 is a distal axial view of the objects of Figure 36.

Figure 40 is a side elevational sectional view of the objects of Figure 36 at location A – A of Figure 36.

Figure 41 is a view of the objects of Figure 36 in direction A - A of Figure 36.

Figure 42 is a plan view of the distal assembly of an alternate embodiment of the invention herein disclosed.

Figure 43 is a side elevational view of the objects of Figure 42.

Figure 44 is a side elevational sectional view of the objects of Figure 42 at location C – C of Figure 42.

Figure 45 is a distal axial view of the objects of Figure 42.

Figure 46 is a perspective view of the objects of Figure 42.

Detailed Description of the Preferred Embodiment

The present invention constitutes a marked improvement in the field of electrosurgery, more particularly, to high efficiency surgical devices and methods which use radio frequency (RF) electrical power to vaporize and remove all or part of a tissue mass.

Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the present invention, the preferred methods, devices, and materials are now described. However, before the present materials and methods are described, it is to be understood that this invention is not limited to the particular compositions, methodologies or protocols herein described, as these may vary in accordance with routine experimentation and optimization. It is also to be understood that the terminology used in the description is for the purpose of describing the particular versions or embodiments only, and is not intended to limit the scope of the present invention which will be limited only by the appended claims.

Elements of the Present Invention:

In the context of the present invention, the following definitions apply:

The words "a", "an", and "the" as used herein mean "at least one" unless otherwise specifically indicated.

In common terminology and as used herein, the term “electrode” may refer to one or more components of an electrosurgical device (such as an active electrode or a return electrode) or to the entire device, as in an “ablator electrode” or “cutting electrode”. Such electrosurgical devices are often interchangeably referred to herein as electrosurgical “probes” or “instruments”.

The present invention is particularly concerned with the category of electrosurgical instruments referred to in the art as “ablators”, i.e., electrosurgical electrodes designed for the bulk removal of tissue by vaporization rather than the cutting of tissue or coagulation of bleeding vessels.

The present invention makes reference to an “active electrode” or “active element”. As used herein, the term “active electrode” refers to one or more conductive elements formed from any suitable metallic material, such as stainless steel, nickel,

titanium, tungsten, and the like, connected, for example via cabling disposed within the elongated proximal portion of the instrument, to a power supply, for example, an externally disposed electrosurgical generator, and capable of generating an electric field.

The present invention makes reference to a "return electrode". As used herein, the term "return electrode" refers to one or more powered conductive elements to which current flows after passing from the active electrode(s) back to the electrical RF generator. This return electrode may be located on the ablator device or in close proximity thereto and may be formed from any suitable electrically conductive material, for example a metallic material such as stainless steel, nickel, titanium, tungsten, aluminum and the like. Alternatively, one or more return electrodes, referred to in the art as "dispersive pads" or "return pads", may be positioned at a remote site on the patient's body.

The present invention makes reference to "fluid(s)". As used herein, the term "fluid(s)" refers to liquid(s), either electrically conductive or non-conductive, and to gaseous material, or a combination of liquid(s) and gas(as).

The term "proximal" refers to that end or portion which is situated closest to the user; in other words, the proximal end of an electrosurgical instrument of the instant invention will typically include the handle portion.

The term "distal" refers to that end or portion situated farthest away from the user; in other words, the distal end of an electrosurgical instrument of the instant invention will typically include the active electrode portion.

The present invention makes reference to the vaporization of tissue. As used herein, the term "tissue" refers to biological tissues, generally defined as a collection of interconnected cells that perform a similar function within an organism. Four basic types of tissue are found in the bodies of all animals, including the human body and lower multicellular organisms such as insects, including epithelium, connective tissue, muscle tissue, and nervous tissue. These tissues make up all the organs, structures and other body contents. The present invention is not limited in terms of the tissue to be treated but rather has broad application to the vaporization any target tissue with particular applicability to the ablation, destruction and removal of problematic joint tissues.

The instant invention has both human medical and veterinary applications. Accordingly, the terms "subject" and "patient" are used interchangeably herein to refer to the person or animal being treated or examined. Exemplary animals include house pets, farm animals, and zoo animals. In a preferred embodiment, the subject is a mammal.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. In case of conflict, the present specification, including definitions, will control.

Utilities of the Present Invention:

As noted above, the present invention is directed to high efficiency electrosurgical instruments and methods which utilize radio frequency (RF) energy to vaporize soft tissues, having particular utility in the context of arthroscopy and the removal of problematic joint tissues. However, the invention is not restricted thereto. Aspects are equally applicable to other uses, for example in connection with oncological, ENT, urological, gynecological, and laparascopic procedures, as well as in the context of general surgery.

Similarly, while some embodiments utilize the endogenous fluid of a "wet field" environment to transmit current to target sites, others require an exogenous irrigant. In certain embodiments, the "irrigant" (whether native or externally applied) is heated to the boiling point, whereby thermal tissue treatment arises through direct contact with either the boiling liquid itself or steam associated therewith. This thermal treatment may include desiccation to stop bleeding (hemostasis), and/or shrinking, denaturing, or enclosing of tissues for the purpose of volumetric reduction (as in the soft palate to reduce snoring) or to prevent aberrant growth of tissue, for instance, endometrial tissue or malignant tumors.

Liquids (either electrically conductive or non conductive) and gaseous irrigants, either singly or in combination may also be advantageously applied to devices for incremental vaporization of tissue. Normal saline solution may be used. Alternatively, the use of low-conductivity irrigants such as water or gaseous irrigants or a combination of the two allows increased control of the ablating environment.

The electrosurgical devices of the present invention may be used in conjunction with existing diagnostic and imaging technologies, for example imaging systems including, but not limited to, MRI, CT, PET, x-ray, fluoroscopic, thermographic, photo-acoustic, ultrasonic and gamma camera and ultrasound systems. Such imaging technology may be used to monitor the introduction and operation of the instruments of the present invention. For example, existing imaging systems may be used to determine location of target tissue, to confirm accuracy of instrument positioning, to assess the degree of tissue vaporization (e.g., sufficiency of tissue removal), to determine if subsequent procedures are required (e.g., thermal treatment such as coagulation and/or cauterization of tissue adjacent to the target tissue and/or surgical site), and to assist in the traumatic removal of the device.

As noted above, the electrosurgical instruments of the present invention find utility in bulk tissue vaporization. The flexible design permits the distal active end to exhibit a wide array of angled profiles. Certain configurations will have particular utility in the treatment of protruding or projecting tissues while others will be optimized for tissue surface treatment. Accordingly, the present invention is not particularly limited to the treatment of any one specific disease, body part or organ or the removal of any one specific type of tissue, the components and instruments of the present invention.

Illustrative Embodiments of the Present Invention:

Hereinafter, the present invention is described in more detail by reference to the exemplary embodiments. However, the following examples only illustrate aspects of the invention and in no way are intended to limit the scope of the present invention. As such, embodiments similar or equivalent to those described herein can be used in the practice or testing of the present invention.

Referring to the figures, Figure 1 depicts an electrosurgical system constructed in accordance with the principles of this invention. Ablator electrode **900** is connected by electrical cable **908** to electrosurgical generator **911**, and by tube **920** to an external vacuum source. A return electrode (not shown) is connected to the electrosurgical generator to provide a return path for the RF energy. The return electrode may be a

dispersive pad attached to the patient at a site remote from the surgical site, or may be in proximity to the active electrode in contact with tissue or the conductive liquid.

Figures 2 and 3 further depict the details of electrosurgical instrument **900** constructed in accordance with the principles of this invention. Instrument **900**, also referred to herein as an "ablator", has a proximal portion **902** forming a handle and an elongated distal portion **904**. Handle **902** has passing from its proximal end **906** electrical cable **908** which is connected to electrosurgical generator **911**, and flexible tube **910** which is connected to tube **920** and thereby to external vacuum source **913**. Near distal end **912** of handle **902**, first activation button **914** labeled "ablate" and second activation button **916** labeled "coagulate", protrude from top surface **918** of handle **902**. Elongated distal portion **904** has a proximal end **920** which is mounted to distal end **912** of handle **902**, and a distal end **922**.

To best understand the principles of this invention, it is necessary to consider a prior art aspirating ablator. The distal portion **100** of a prior art aspirating device is depicted in Figures 4 through 8. Tube **102** is affixed to active electrode **104** which is affixed to distal end **108** of tubular elongate element **106**, the proximal end **116** of which is assembled to the distal end **110** of tube **112**. Insulator **114** surrounds the upper portion of active electrode **104**. Lumen **120** of tube **102**, lumen **122** of active electrode **104**, lumen **124** of tubular elongate element **106**, and lumen **126** of tube **112** together form an aspiration path for removal of heated fluid, bubbles and debris products of ablation during use, lumen **126** of tube **112** being in communication with a vacuum source. Tube **102** prevents flow of liquid through grooves **130** between ribs **132** thereby minimizing removal of process heat so as to increase the efficiency of the prior art ablator. Distal portion **100** is covered with a suitable dielectric material except for the upper portions of active electrode **104** and insulator **114**. Dotted line **118** is normal to the ablating surface.

As shown in Figures 4 through 8, distal end **100** forms a "90 degree" ablator, a normal **118** to the upper, ablating surface **119** of active electrode **104** being normal to the axis of tubular member **106** and tube **110**. Figures 9 and 10 depict a distal portion **108** of tubular elongate element wherein the distal end is bent, formed downward so that line **118** normal to ablating surface **119** forms an angle **113** with axis **111** of member **106**. Bending in this manner increases the overall height of distal portion **100** to height **115**.

A distal-end element (active electrode) for an electrosurgical ablator formed in accordance with the principles of this invention is depicted in Figures 11 through 15. Active element **200** is formed from a single monolithic metallic material. Active element **200** combines the functions of elongate element **106** and active electrode **104** of prior art assembly **100**, such that proximal end **202** of element **200** is configured for mounting to directly the distal end of a tube. Distal portion **204** has an ablating surface **206** formed thereon, wherein a line **208** normal to ablating surface **206** forms an angle **210** with axis **212** of element **200**. Ablating surface **206** has integral grooves **214** formed therein. A lateral port or opening **206** that intersects lumen **220** of active element **200** is positioned just proximal to ablating surface **206**. Proximal to opening **218**, portion **219** of element **200** has an external diameter of **221**. Middle portion **224** of element **200** has at its distal end flange **226** having a distal surface **228** perpendicular to the device axis **212**, a conical proximal surface **230**, and a radiused edge **232** disposed between the distal and proximal surfaces. Sharpened edges increase the electric field on an RF device. Edge **232** is radiused to minimize intensification of the electric field so as to prevent breakdown of the dielectric coating that will cover the completed assembly. Proximal to flange **226**, middle portion **224** includes cylindrical portion **234** of diameter **236** that extends distance **238**. The proximal end **240** of middle portion **224** has formed thereon a flange **242** having a proximal planar surface **244** to which device axis **212** is normal, and a conical distal surface **246**. Distal to distal surface **246**, cylindrical portion **248** of diameter **250** extends distally to cylindrical portion **234**. Diameter **250** of cylindrical portion **248** is larger than diameter **236** of portion **234** such that bending of element **200** occurs primarily in portion **234**. Portion **234** is fabricated to have a reduced resistance to bending as compared to portion **248**; for example, portion 234 may be manufactured to have one or more regions of reduced wall thickness. In other embodiments, cylindrical portion **234** of middle portion **224** is eliminated such that middle portion **224** has a constant diameter throughout its entire length. In such embodiments, the length of middle portion **224** is minimized so that bending of portion **224** results in a tight bend radius. Element **200** may be manufactured at low cost using standard machine tools. For instance, a type of lathe commonly referred to as a Swiss-style screw machine may be

used to form a cylindrical blank after which a wire electrical discharge machine (wire EDM) may be used to form ablating surface **206**, grooves **214** and lateral opening **218**.

Figures 16 through 18 depict an insulator for an electrosurgical ablator formed in accordance with the principles of this invention. Insulator **300**, formed from a suitable dielectric material such as, for instance, alumina, is tubular in form having a lumen **301** with a diameter **302** slightly larger than diameter **221** of portion **219** of element **200**, and an outside diameter **304**. Insulator **300** has a proximal end **306** with a planar proximal face having a normal parallel to axis **310** of insulator **300**. Insulator **300** has a distal end **312** forming a planar surface **314** having a normal **316** angularly displaced from axis **310** angle **318**, angle **318** being approximately equal to angle **210** of element **200**. Lumen **301** intersects surface **314** to form distal opening **320**.

Referring to Figures 19 through 23 depicting the distal end assembly **500** of an electrosurgical ablator constructed in accordance with the principles of this invention. Proximal end **202** of active element **200** is mounted to the distal end **402** of tube **400**. Insulator **300** is mounted to distal end **204** of element **200**, proximal face **308** of insulator **300** being adjacent to distal face **228** of flange **226** which acts as a stop for insulator **300**. Lumen **301** of insulator **300** is centered by portion **219** of active element **200** such that the outer cylindrical surface of portion **204** of active element **200** does not contact the inner surface of lumen **301**. Distal face **314** of insulator **300** is parallel to ablating surface **206** and is displaced from ablating surface **206** distance **502**. Tubular member **400** is assembled to proximal end **240** of middle portion **224** of active element **200**, with distal end **402** of member **400** abutting proximal surface **244** of flange **242** of active element **200**. Distal opening **320** and lumen **301**, lumen **220** of element **200**, and lumen **404** of tubular member **400** provide an aspiration path between the region distal to distal surface **314** and a vacuum source connected via means within the handle to lumen **404** of tubular member **400**. A dielectric coating covers assembly **500** proximal to line **510**.

Active element **200** may be bent or flexed as needed. For example, active element **200** may be bent downward, to thereby decrease the angle between the axis of the device and the ablating surface. As depicted in Figures 24 and 25, when active element **200** is bent downward, axis **524** of the distal portion of assembly **500** forms angle **520** with axis **212** of tubular member **400**, the bend being localized in portion **224**

of element **200**. Ablating surface **206** forms angle **522** with axis **212** of tubular member **400**, said angle typically being on the order of 30 to 80, more preferably 40 to 70. Bent assembly **500** has an overall height of **515**, said height typically being on the order of 3 mm (0.12 inches) to 8 mm (0.32 inches) ., more preferably 3 mm (0.12 inches) to 6 mm (0.24 inches).

Active element **200** may also be bent upward, to increase the angle between the ablating surface and the axis of the elongate tubular member. Figures 26 through 29 depict distal portion **500** in which region **224** of active element **200** has been bent upward, whereby the axis **524** of distal portion **204** of active element **200** forms angle **520** with axis **212** of the proximal portion of element **200** and tubular element **400**. Angle **520** is the complement of angle **210** (Figure 13) between line **208** normal to ablating surface **206** and axis **212**. As depicted in Figure 28, normal line **208** may be made perpendicular to axis **212** to convert distal portion **500** into a "90 degree" ablator. Assembly **500** when formed as shown if Figures 26 through 29 has an overall height **515**.

It will be understood that, as shown in the figures, singly constructed active element **200** may be flexed to a variety of angled positions, characterized by a range of angles formed between the ablating surface and the axis of the tubular portion, so as to permit introduction of assembly **500** into a wide variety of environments and facilitate application to a wide variety of tissues. Because the bend is concentrated in region **224** of electrode element **200**, the overall height **515** is small regardless of the bend. In this manner, the angle will not interfere with or unduly restrict device insertion and manipulation.

During use, RF energy is supplied via tubular element **400** to electrode element **200** to ablating surface **206**, which in turn heats the conductive liquid adjacent to and surrounding surface **206**. Heating of the liquid continues until boiling of the liquid occurs at surface **206**, the boiling occurring first around the edges. Bubbles formed at the surface by the boiling grow until they reach a critical size at which arcing through the bubbles occurs. If ablating surface **206** is brought sufficiently close to the tissue, some of the bubbles will intersect the surface of the tissue, and arcing within these bubbles will pass from the ablating surface **206** to the tissue, each arc vaporizing a discreet volume of

tissue. Bubbles and debris created by the tissue vaporization process may then be aspirated from the site.

Figure 30 depicts this ablation process using assembly **500** formed as shown in Figures 26 through 29. Arcs **540** between ablating surface **206** and the tissue vaporize tissue. The ablation byproducts and bubbles are removed by the aspiration path provided by aperture **218** and lumen **220** of electrode element **200** and lumen **404** of tubular element **400**. Because the aperture **218** is proximally adjacent to the ablating surface **206** but not does not pass directly through surface **206** or intersect grooves **214** in the ablating surface, the amount of process heat removed is minimized. In this manner, aspiration does not interfere with or significantly decrease the efficiency of the ablating process.

An alternate embodiment of a distal end active element for an electrosurgical ablator formed in accordance with the principles of this invention is depicted in Figures 31 through 35. Active element **600** is identical in form and function to active element **200** except for the placement and configuration of opening **618** compared to opening **218** of active element **200**. Proximal end **602** of active element **600** is configured for mounting to the distal end of a standard electrosurgical shaft or tube. Distal end **604** has an ablating surface **606** formed thereon, wherein a line **608** normal to surface **606** forms an angle **610** with axis **612** of active element **600**. Surface **606** has grooves or contours **614** formed or machined therein. Just proximal to surface **606**, a lateral opening – aspiration port **618** – is disposed, said opening stemming from central lumen **620** of element **600**. Proximal to opening **618** is tubular active element portion **619** having an external diameter of **621**. Continuing in the proximal direction, one finds middle portion **624** of element **600**, a portion having at its distal end flange **626** having a distal surface **628** perpendicular to axis **612**, a conical proximal surface **630**, and a radiused edge **632** disposed between distal and proximal surfaces. Proximal to flange **626** in middle portion **624** is cylindrical portion **634** of diameter **636** and extending distance **638**. The proximal end **640** of middle portion **624** has formed thereon a flange **642** having a proximal planar surface **644** to which axis **612** is normal, and a conical distal surface **646**. Distal to distal surface **646**, cylindrical portion **648** of diameter **650** extends distally to cylindrical portion **634**. Diameter **650** of cylindrical portion **648** is larger than diameter **636** of portion **634**.

Figures 36 through 41 depict an insulator suitable for use in connection with an alternate embodiment of the present invention. Insulator **700**, formed from a suitable dielectric material such as, for instance, alumina, is tubular in form, has a lumen **701** with a diameter **702** sized to be slightly larger than diameter **621** of portion **619** of element **600**, and a distal portion **703** with an outside diameter **704**. The proximal portion **706** of insulator is characterized by a planar proximal face **708** having a normal parallel to axis **710** of insulator **700**. Proximal portion **706** has a maximum diameter **730**, which is greater than diameter **704** of distal portion **703**, and angled distal and proximal surfaces **732** and **734** respectively. Distal portion **703** has a distal end planar surface **714** having a normal **716** angularly displaced from axis **710** angle **718**, angle **718** being approximately equal to angle **610** of element **600**. Lumen **701** intersects surface **714** to form distal opening **720**. At the proximal end of opening **720**, recess **738** is formed, recess **738** having a proximal wall **740**.

Figures 42 through 46 depict the distal end assembly **800** of an electrosurgical ablator constructed in accordance with the principles of this invention. Proximal end **602** of active element **600** is mounted to the distal end **402** of tube **400**. Insulator **700** is mounted to distal end **604** of active element **600**, with proximal face **708** of insulator **700** positioned to be adjacent to distal face **628** of flange **626**. Distal face **714** of insulator **700** is parallel to ablating surface **606** and is displaced from ablating surface **606** distance **802**. Recess **738**, opening **618** and lumen **620** of element **600**, and lumen **404** of tubular member **400** together provide an aspiration path between the region distal to distal surface **714** and a vacuum source connected via means within the handle to lumen **404** of tubular member **400**. A dielectric coating covers assembly **500** and tubular member **400** proximal to line **510**.

Industrial Applicability:

The flexible single piece active element of the present invention, as well as the aspirating ablators formed therewith, find utility in the field of bulk tissue vaporization, providing a simple construction suitable for use with a wide array of electrosurgical components and adjustable to wide range of angled positions to permit access to a variety of tissues, in an array of diverse environments and address a host of ablation needs.

Additionally, the novel geometry and positioning of both ablation surface and aspiration port permits aspiration flow to remove primarily waste heat rather than process heat, to thereby improve vaporization efficiency and reduce procedure time. Thus, present invention maximizes efficiency and adaptability while minimizing manufacturing costs and device profile.

All patents and publications mentioned herein are incorporated by reference in their entirety. Nothing herein is to be construed as an admission that the invention is not entitled to antedate such disclosure by virtue of prior invention.

While the invention has been described in detail and with reference to specific embodiments thereof, it is to be understood that the foregoing description is exemplary and explanatory in nature and is intended to illustrate the invention and its preferred embodiments. Through routine experimentation, one skilled in the art will readily recognize that various changes and modifications can be made therein without departing from the spirit and scope of the invention.

Other advantages and features will become apparent from the claims filed hereafter, with the scope of such claims to be determined by their reasonable equivalents, as would be understood by those skilled in the art. Thus, the invention is intended to be defined not by the above description, but by the following claims and their equivalents.

WHAT IS CLAIMED:

1. An active electrode for connection to an electrosurgical device for the bulk vaporization of tissue, said active electrode comprising a cannulated tubular element formed from a single piece of homogenous metallic material and characterized by an open proximal end, a closed distal end and a central lumen extending therebetween, said active electrode further comprising:
    a) a tubular distal portion having a beveled distal-most ablation surface that forms an acute angle with the longitudinal axis of said distal portion,
    b) a raised flange portion proximally adjacent to said tubular distal portion having a diameter greater than the diameter of said tubular distal portion and a flat distal-facing surface,
    c) a tubular middle portion proximal adjacent to said flange portion, wherein said tubular middle portion and said tubular distal portion are not coaxial, further wherein the longitudinal axis of the tubular middle portion forms a pre-determined acute angle with the longitudinal axis of said tubular distal portion,
    d) a tubular proximal portion configured for attachment to an elongate cannulated tubular member, and
    e) a lateral opening formed in a side wall of said tubular distal portion and positioned proximally to said beveled ablation surface, said opening extending through the side wall of said distal portion into said central lumen.
2. The active electrode of claim 1 in which said lateral opening intersects said beveled ablation surface.
3. The active electrode of claim 1 in which said lateral opening is immediately adjacent to said distal-most surface.
4. The active electrode of claim 1 in which said lateral opening is displaced proximally a predetermined distance from said beveled ablation surface.
5. The active electrode of claim 1, wherein said beveled ablation surface is configured with machined contours.

6. The active electrode of claim 5, wherein said machined contours comprise a series of parallel grooves.
7. The active electrode of claim 5, wherein said machined contours comprise an array of protruding pins.
8. The active electrode of claim 5, wherein said machined contours comprise an array of raised ribs.
9. An electrosurgical device for the bulk vaporization of tissue comprising the active electrode of Claim 1 and further comprising:
    a) a tubular insulator formed from a suitable dielectric material, said insulator an open proximal end characterized by a first proximal-most surface, an open distal end characterized by a second distal-most surface, such that when said insulator is positioned about the tubular distal portion of said active electrode, the first proximal-most surface of said insulator abuts the distal-facing surface of said flange portion, and said second distal-most surface of said insulator is slightly proximal to said beveled ablation surface of said active electrode, and
    b) an elongate cannulated tubular element affixed to the proximal portion of said active electrode, and
    c) an optional dielectric coating covering the exterior of the tubular element, the portion of the active electrode proximal to said insulator, and a proximal portion of said insulator,

wherein said lateral opening, said active electrode central lumen, and the cannulated tubular element provide a continuous aspiration path allowing the flow of vaporization by-products from the region adjacent to the beveled ablation surface and to the proximal end of the electrode tubular element.

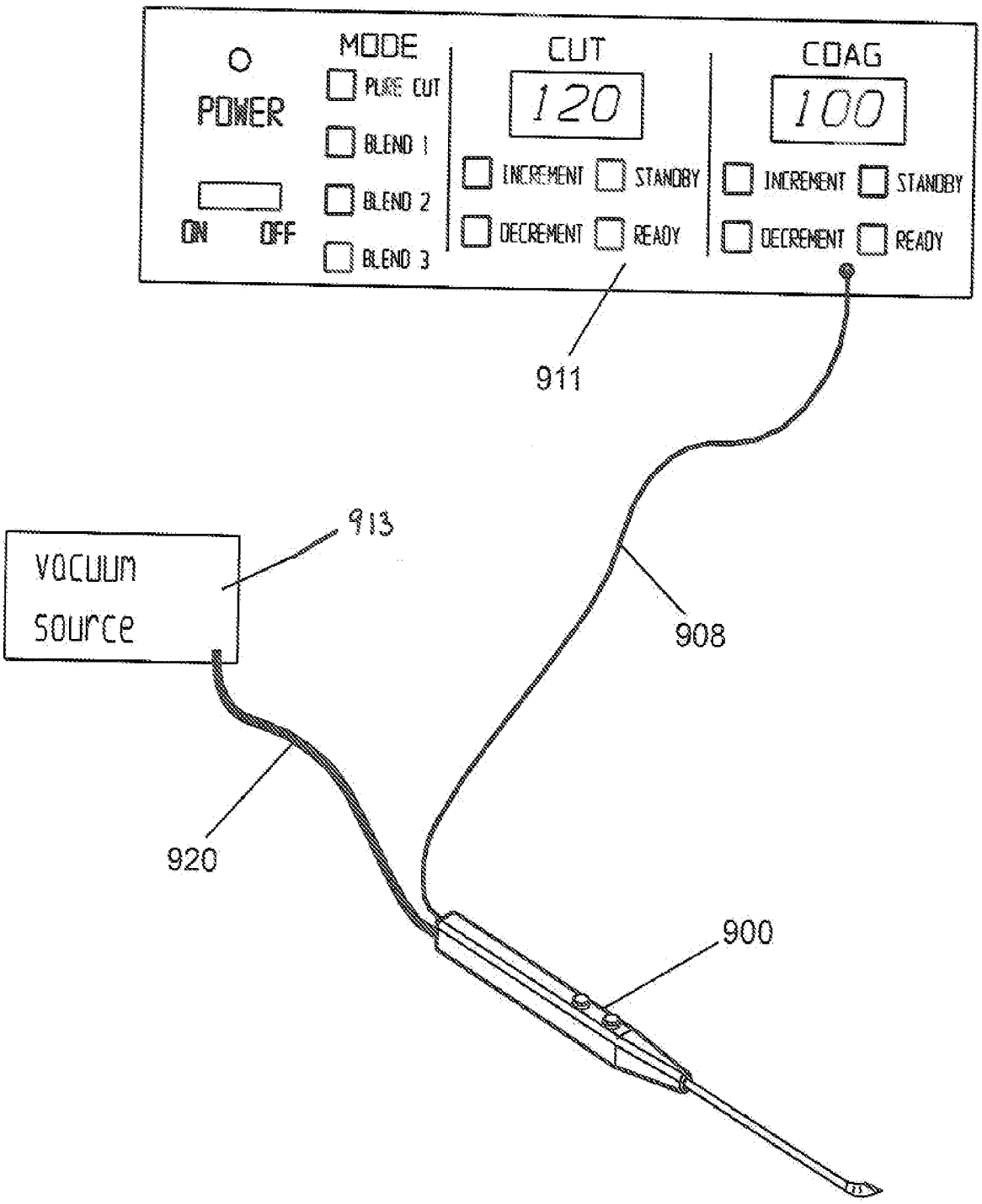
10. A method for forming the active electrode of claim 1, said method comprising the steps of:

(a) on a screw-machine, lathe or other suitable turning machine, forming a metal blank having a tubular distal portion of a predetermined length, a flange portion having a diameter greater than the diameter of said tubular distal portion and having a distal-facing surface, said flange portion being proximally adjacent to said tubular distal portion, a tubular middle portion proximal to said flange portion, a tubular proximal-most portion formed for attachment to an elongated cannulated member, and a central lumen extending from the proximal end of said active electrode to a predetermined depth;

(b) beveling the distal end of said blank to form an angled distal most surface on said blank;

(c) forming a lateral opening between the exterior surface of said tubular distal portion and the central lumen; and

(d) bending the tubular middle portion a pre-determined acute angle such that tubular distal portion and said tubular middle portion are not coaxial.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VACUUM
SOURCE
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Fig. 1

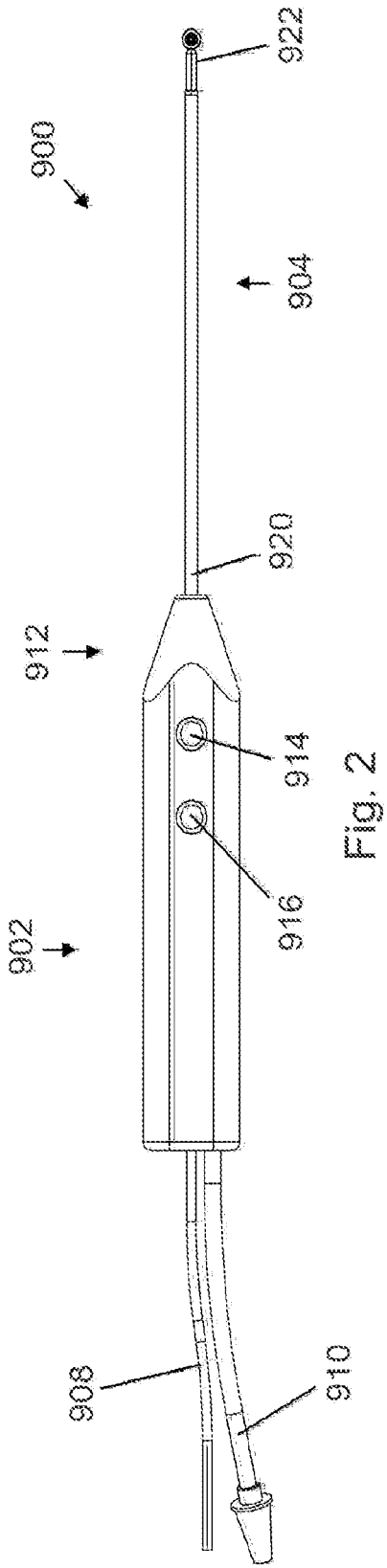
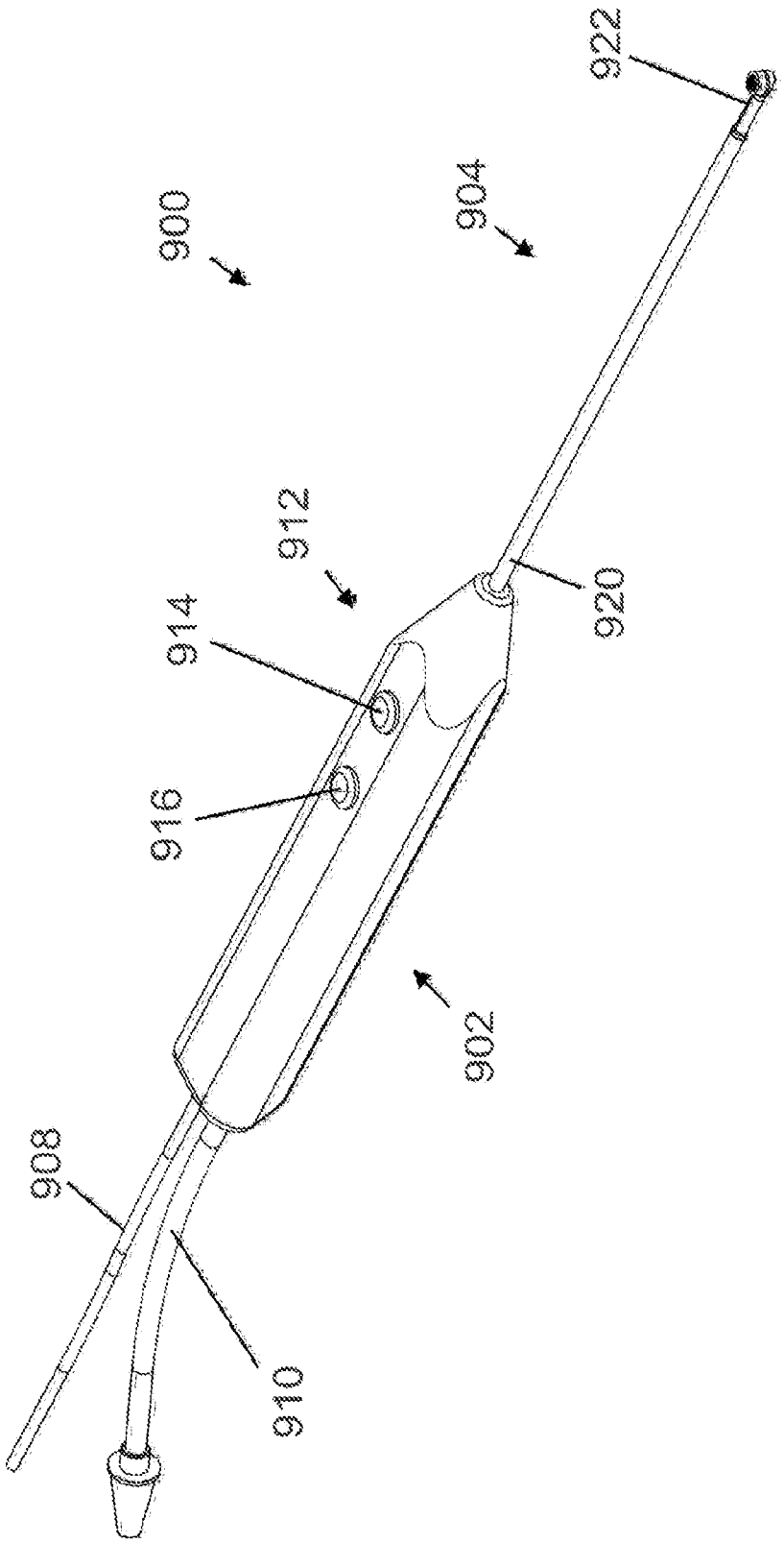


Fig. 2



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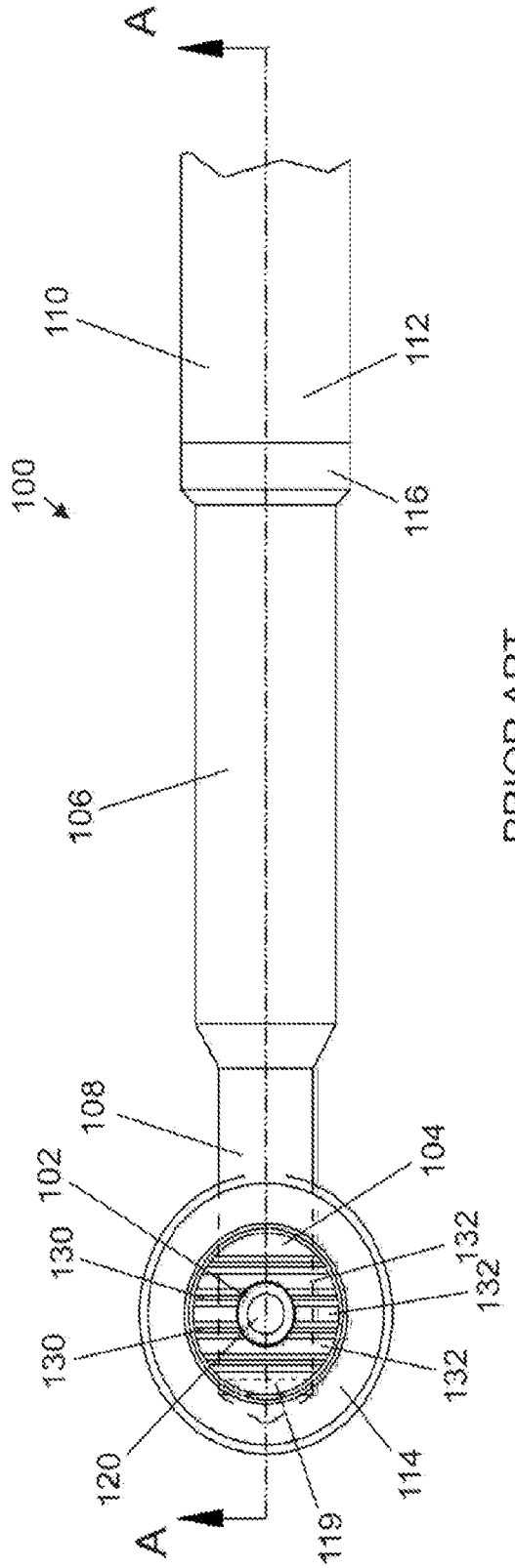
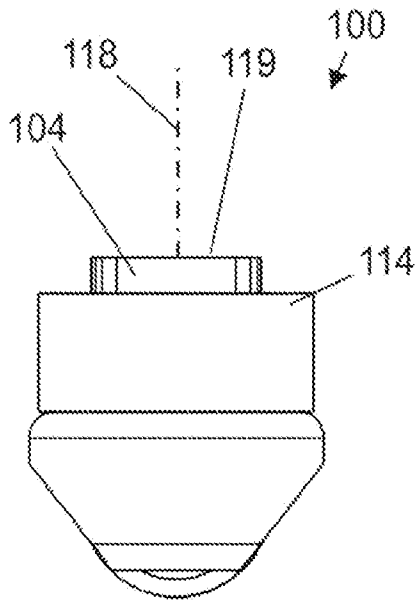
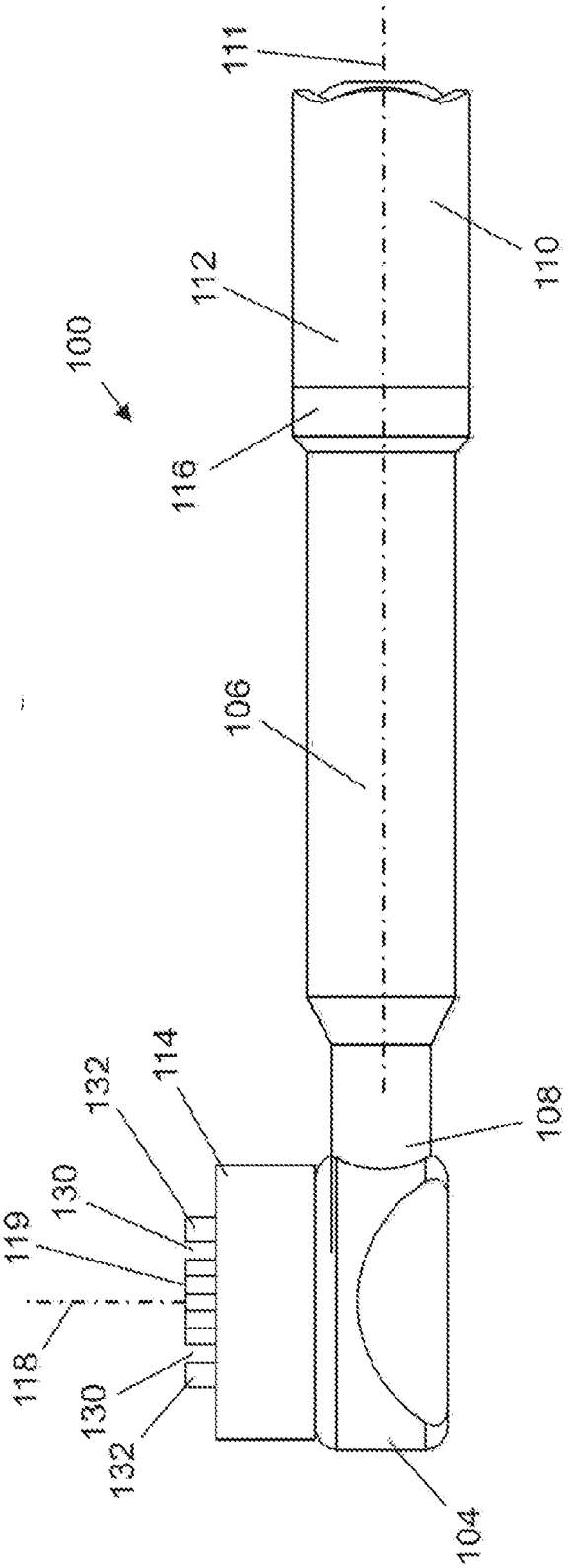


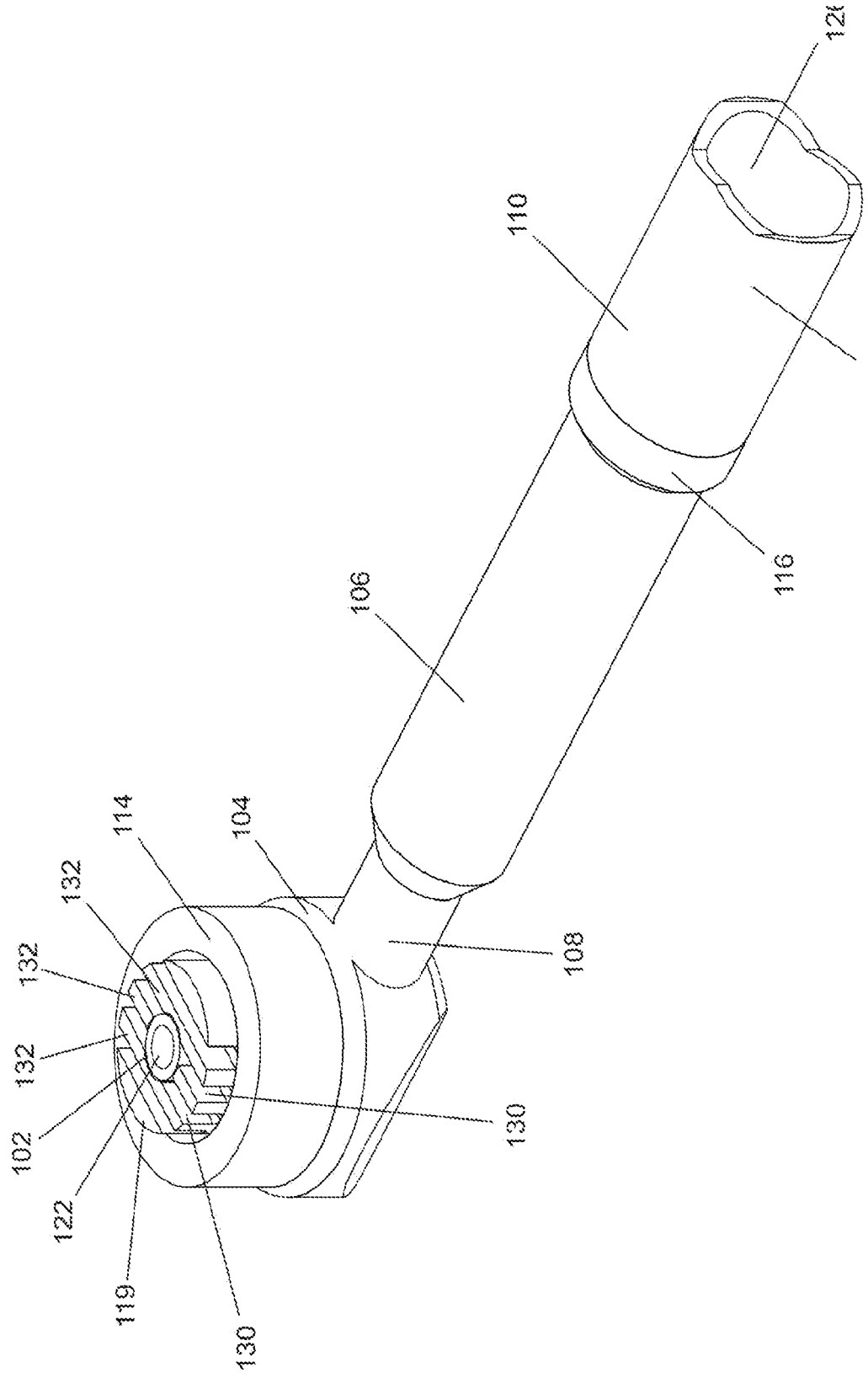
PRIOR ART
Fig. 4



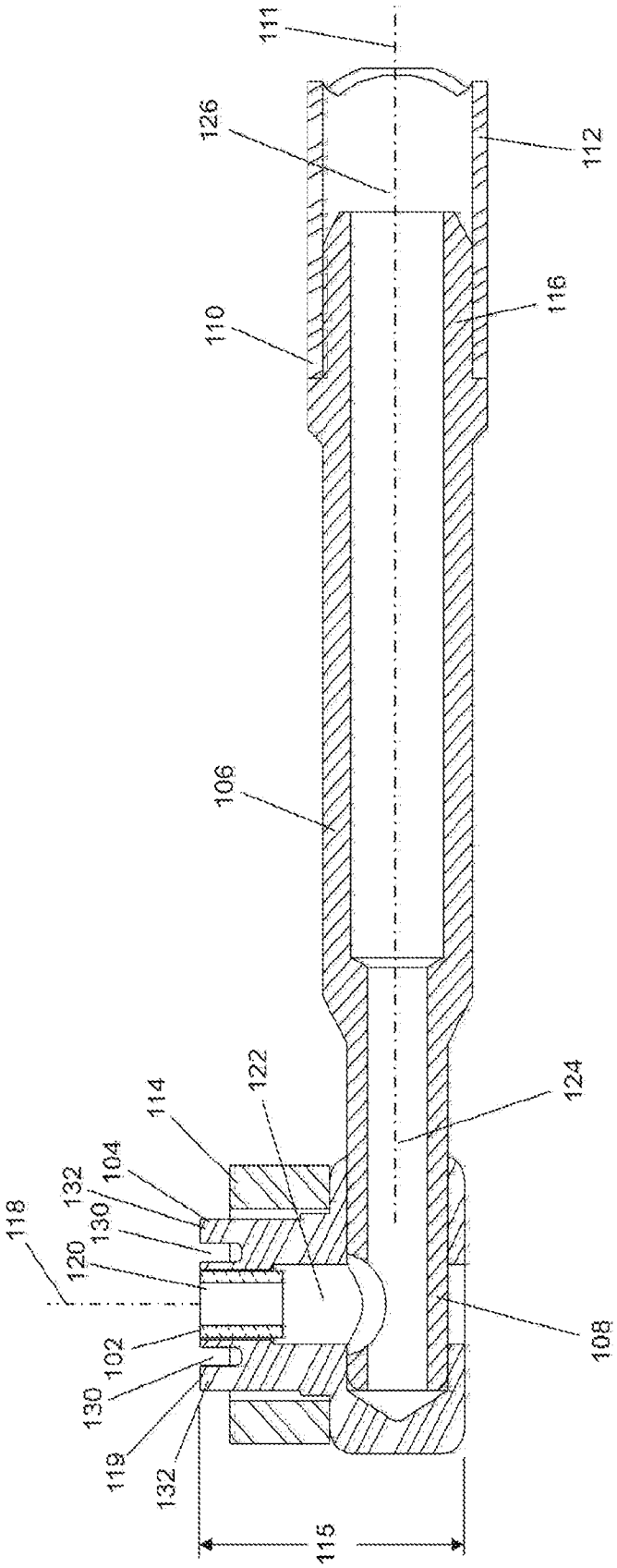
PRIOR ART
Fig. 5



PRIOR ART
Fig. 6



PRIOR ART
Fig. 7



PRIOR ART
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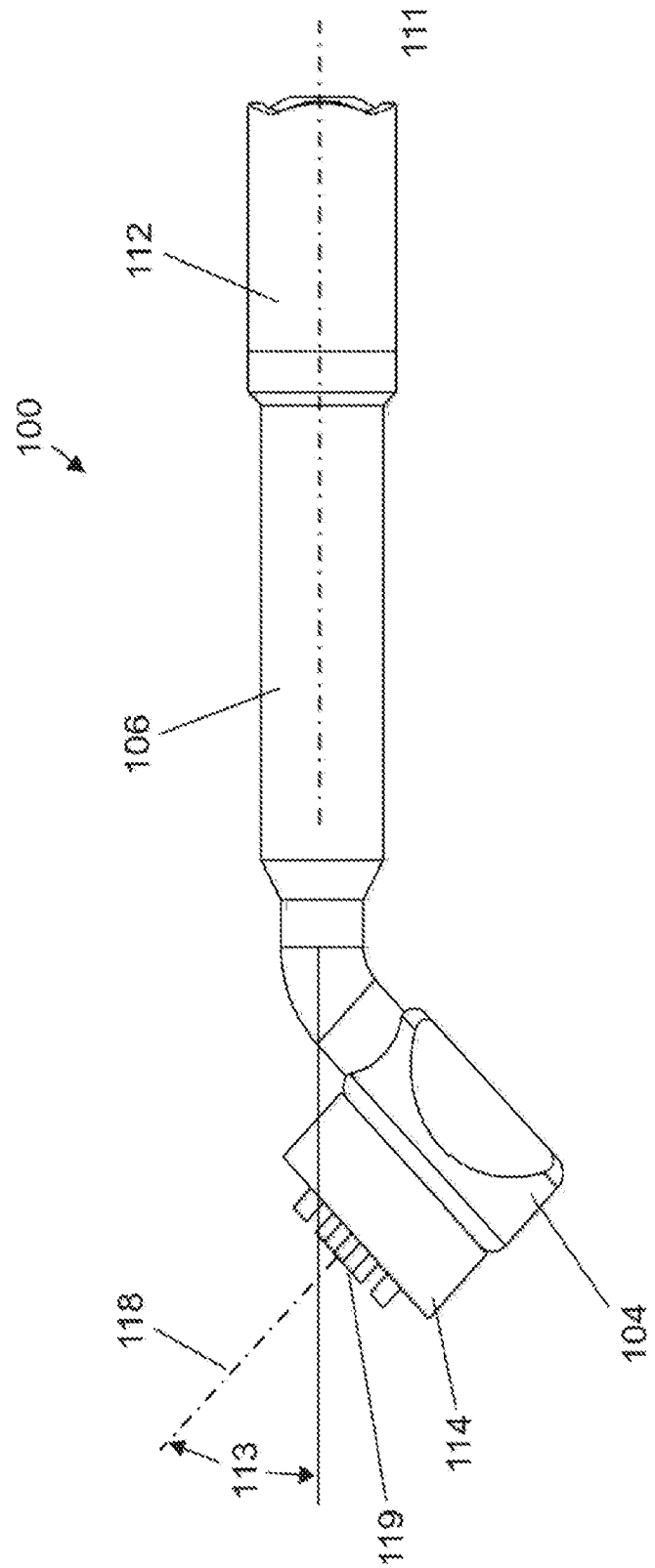

PRIOR ART
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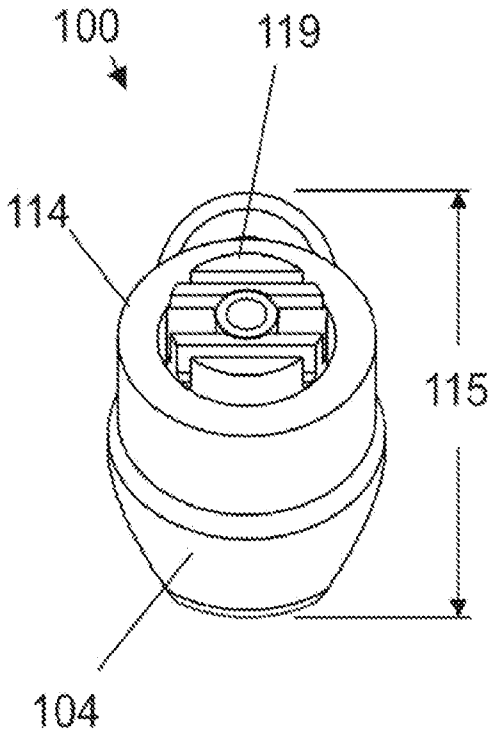

PRIOR ART
Fig. 10

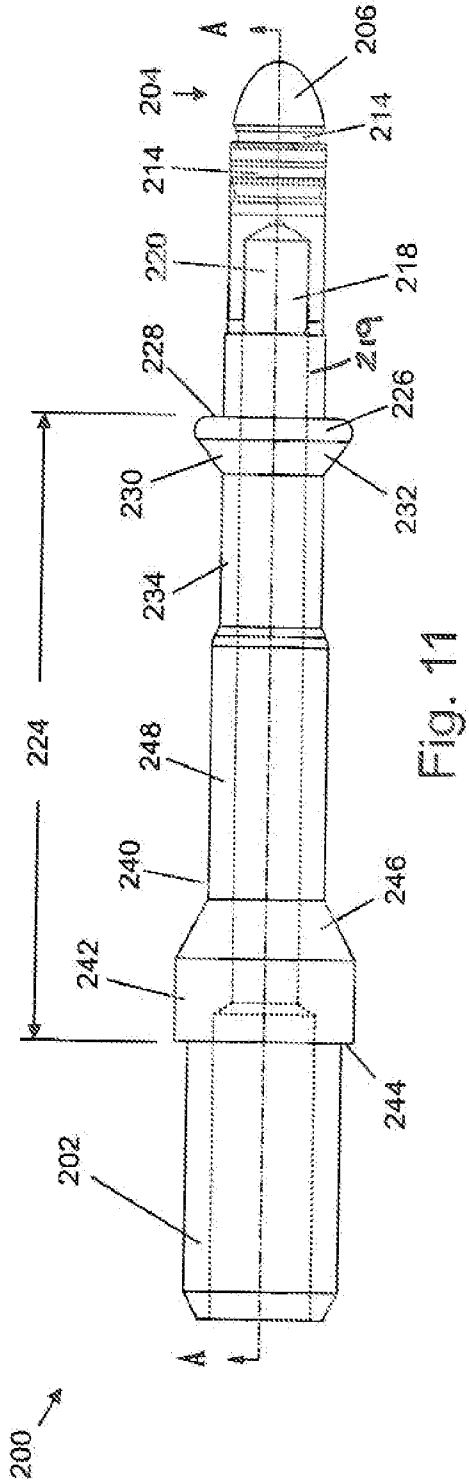
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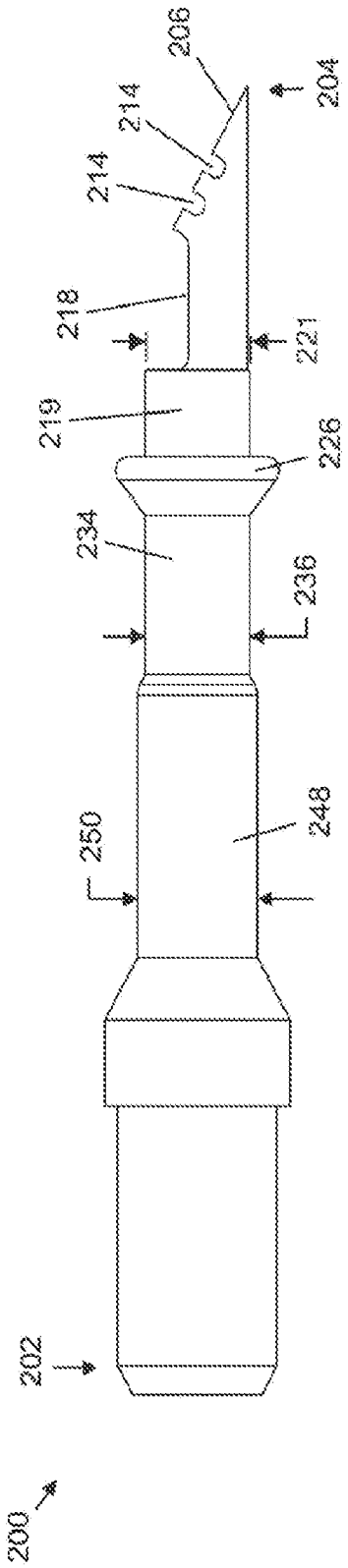
Fig. 11



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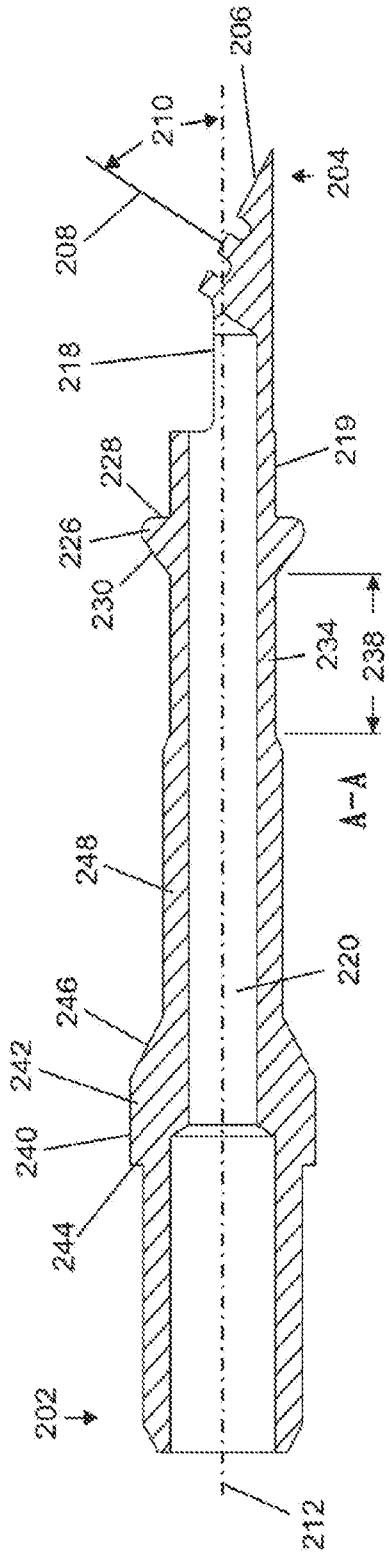
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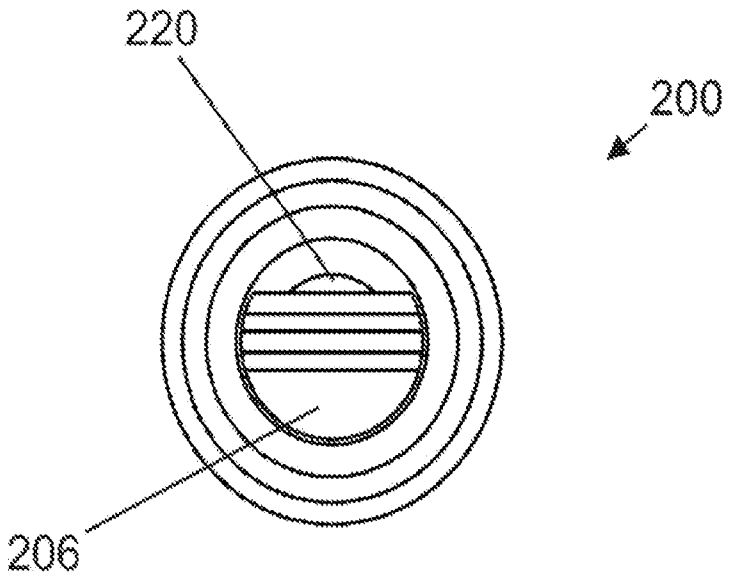
Fig. 13



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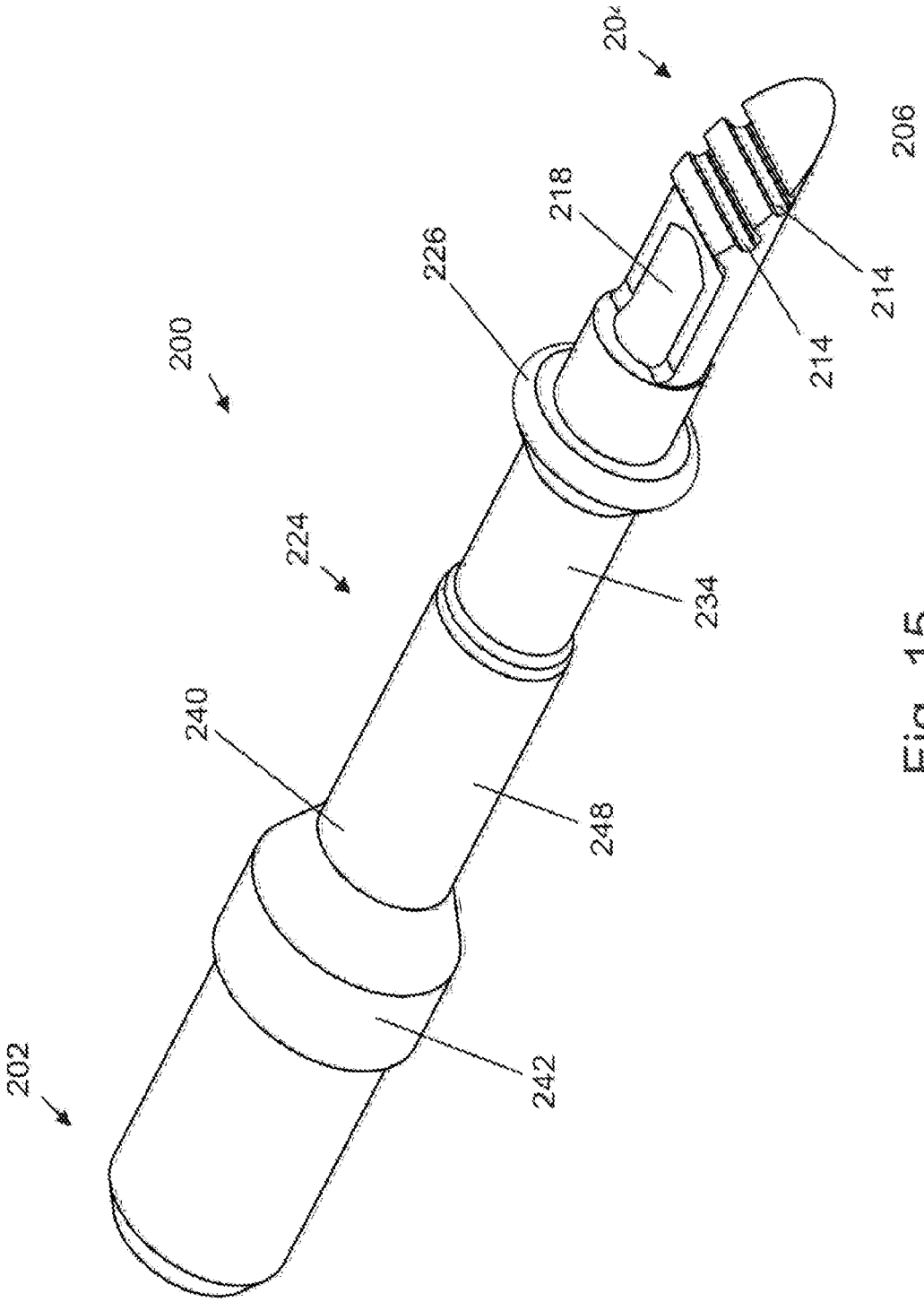

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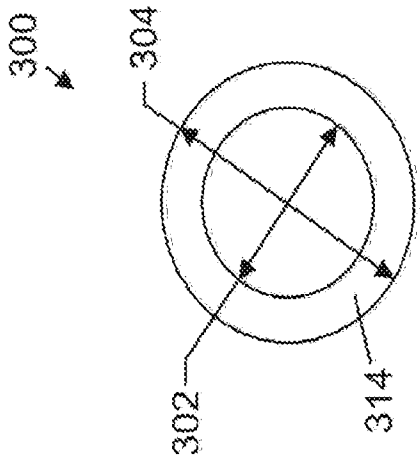

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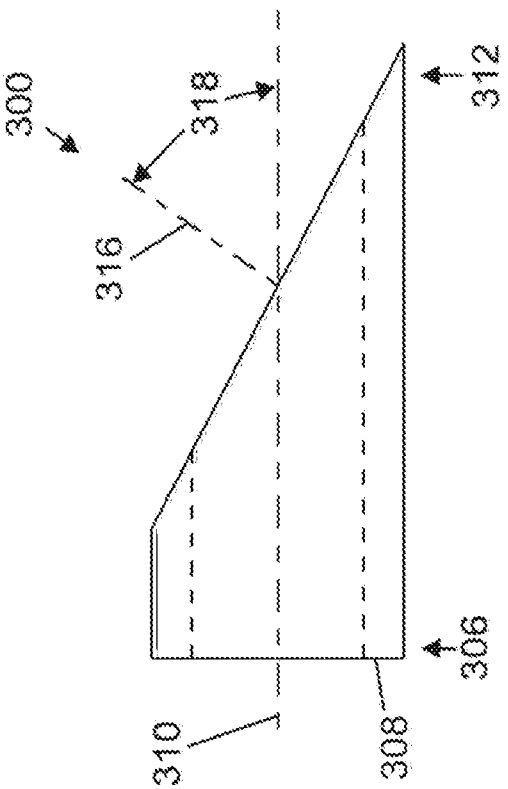

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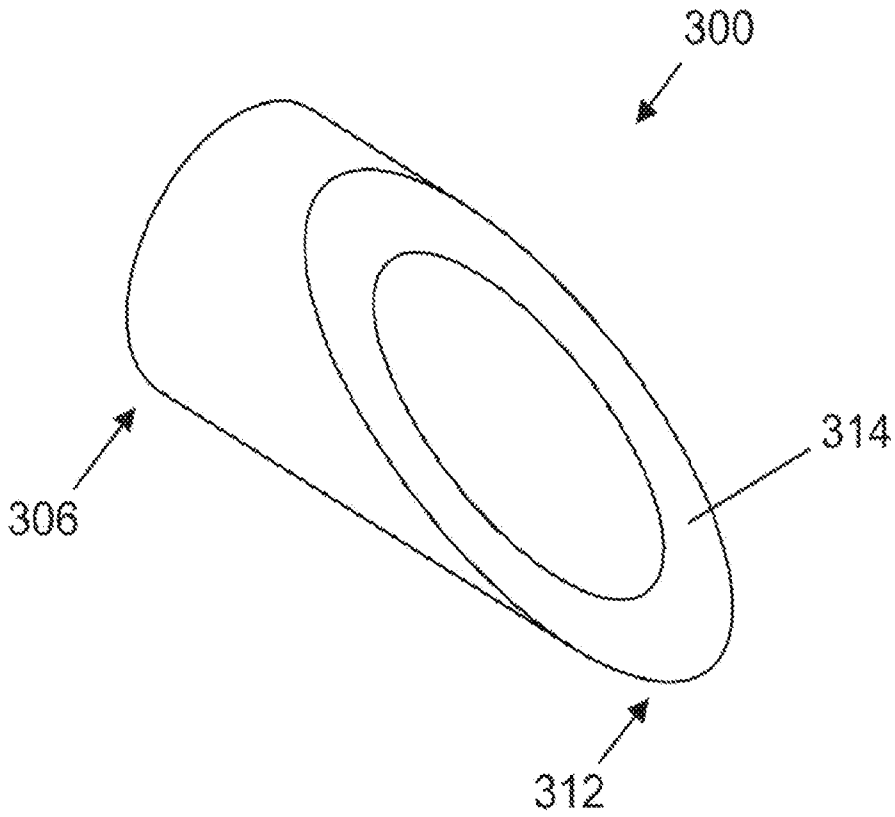

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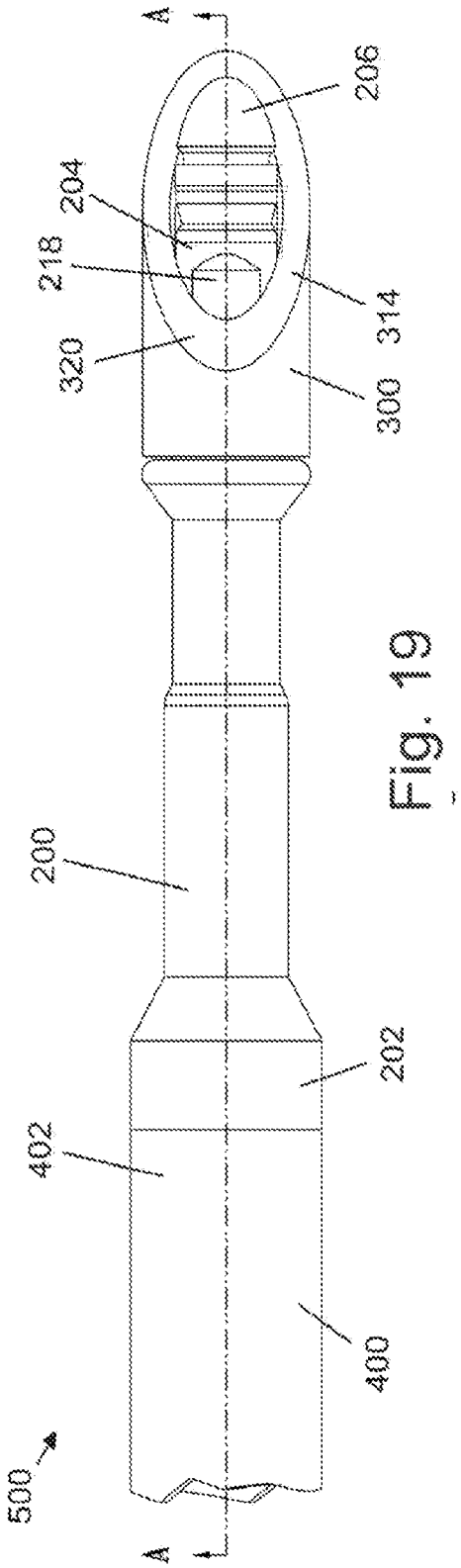

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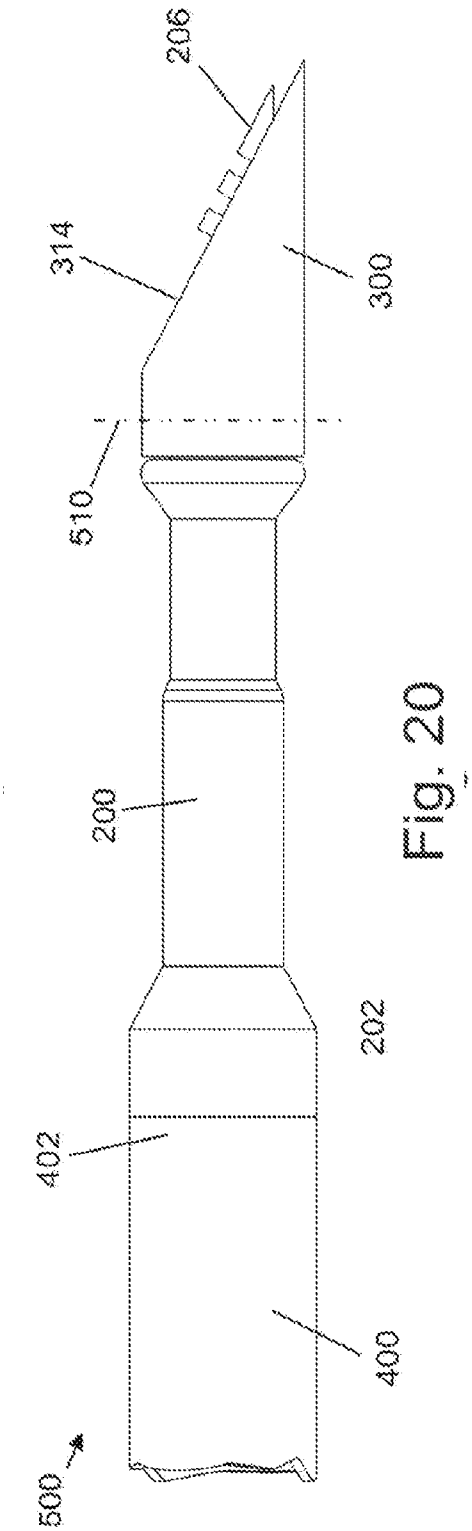

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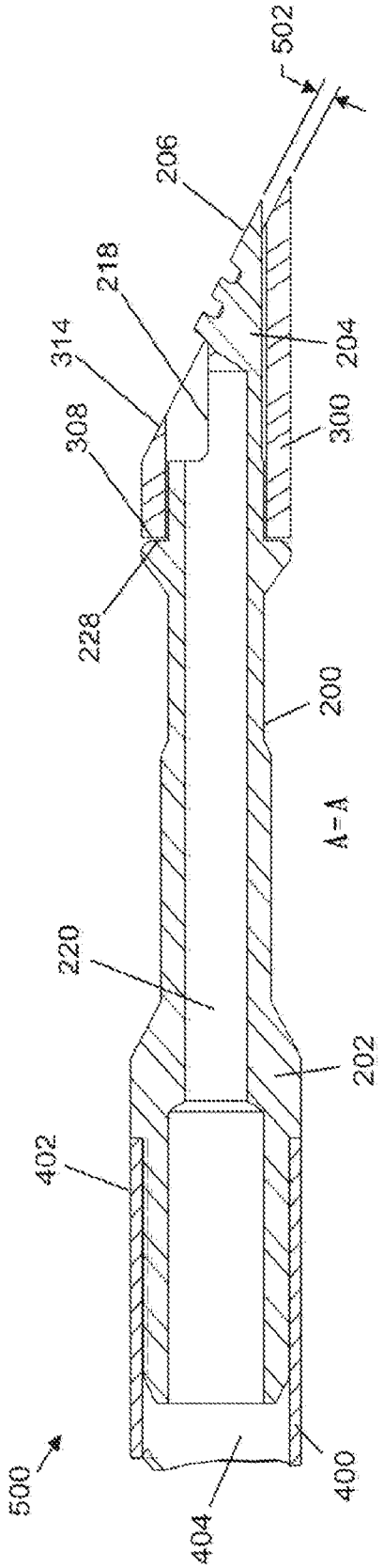

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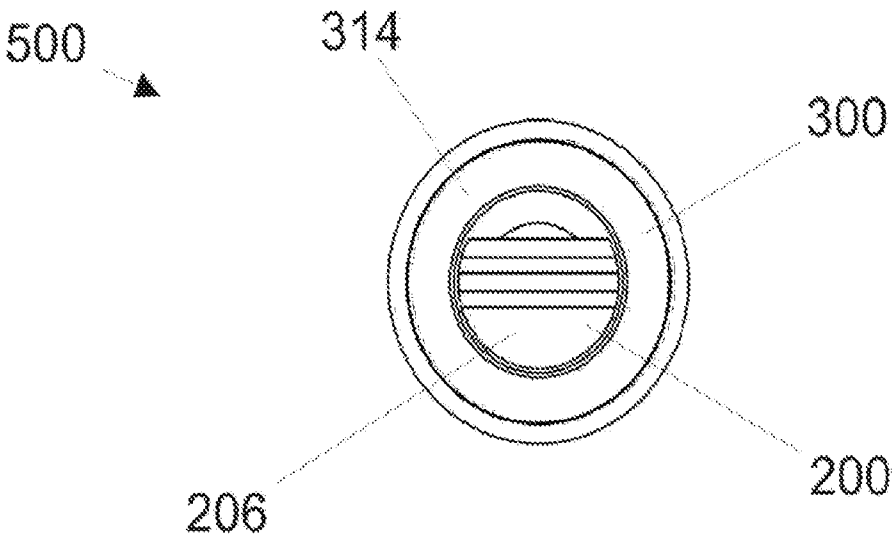

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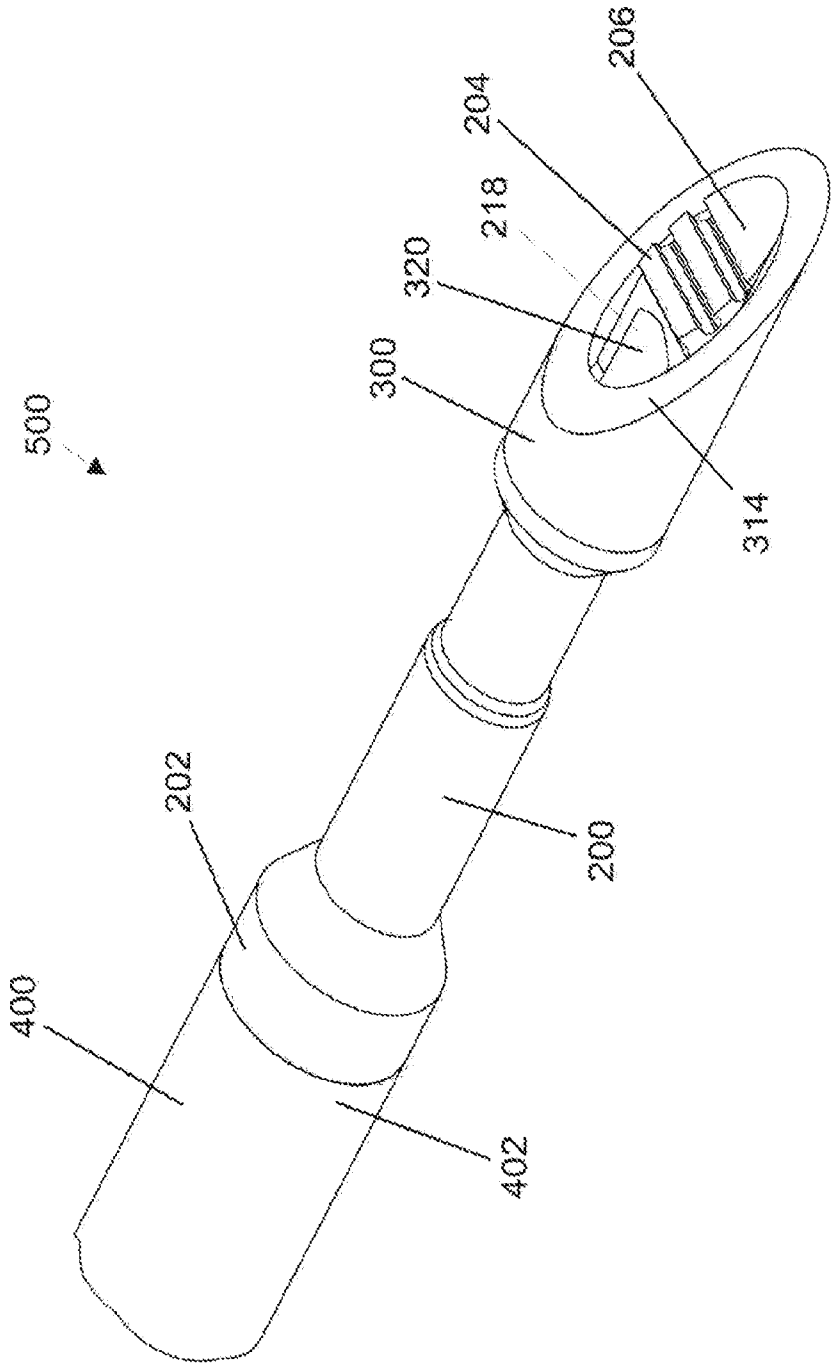

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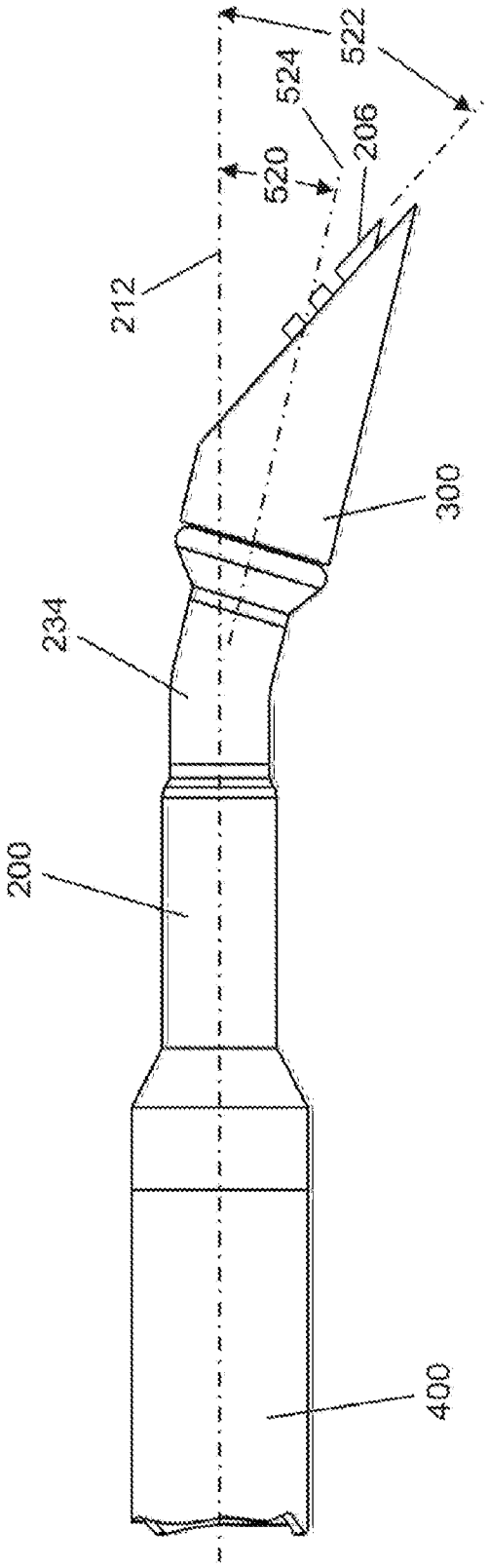

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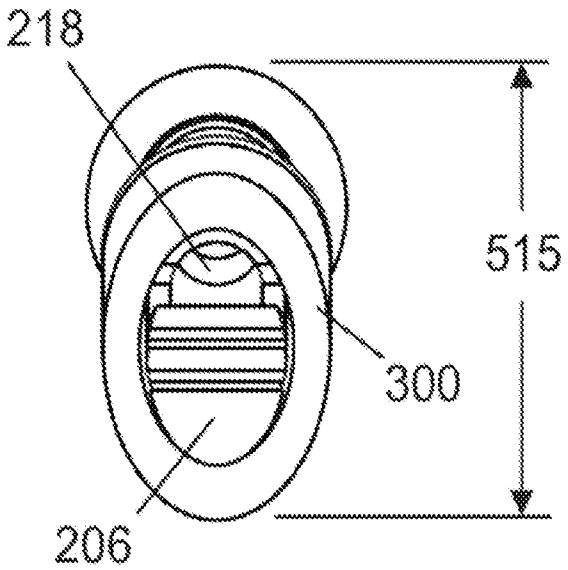

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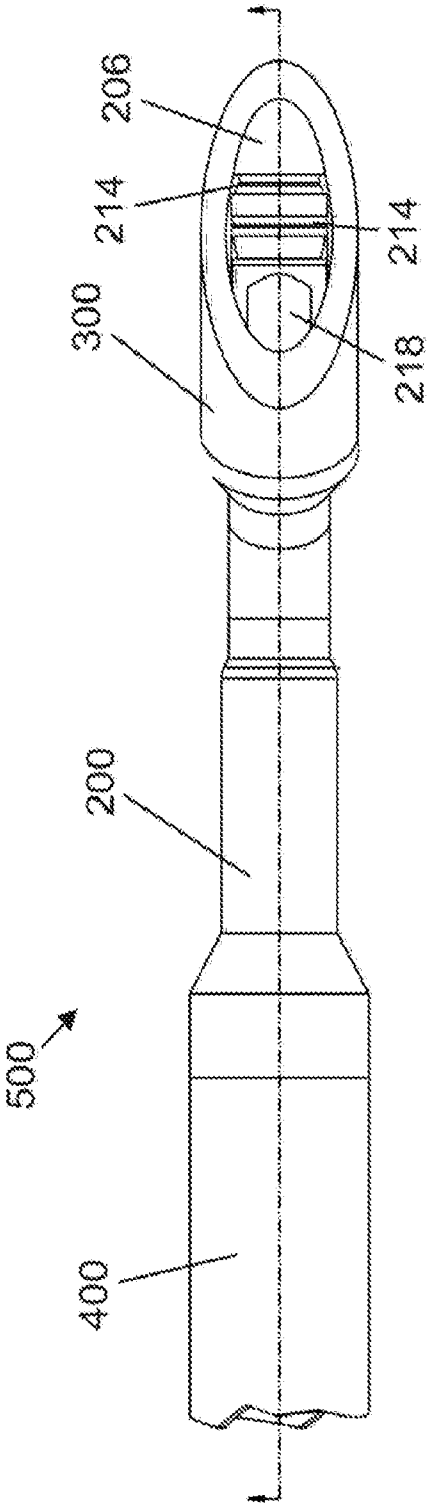

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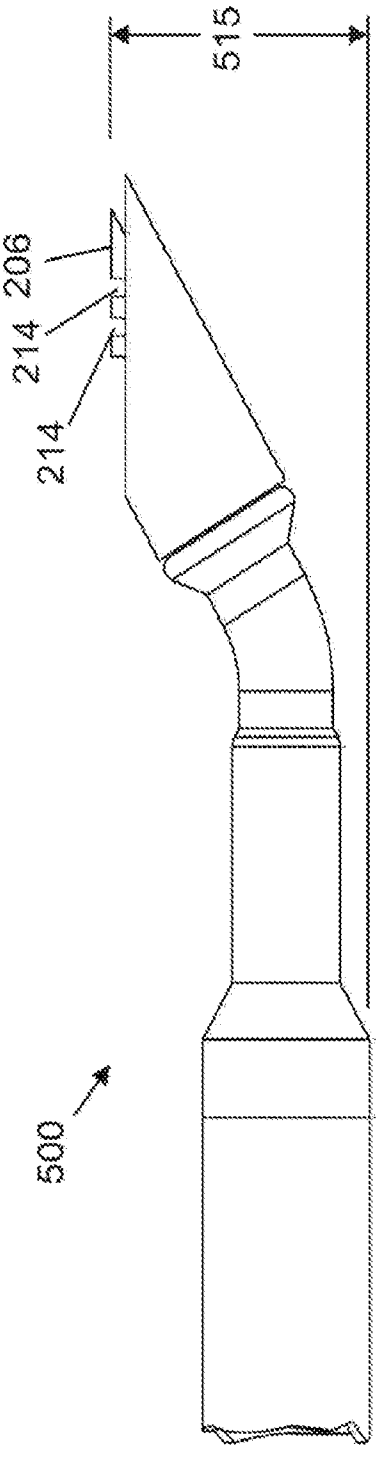

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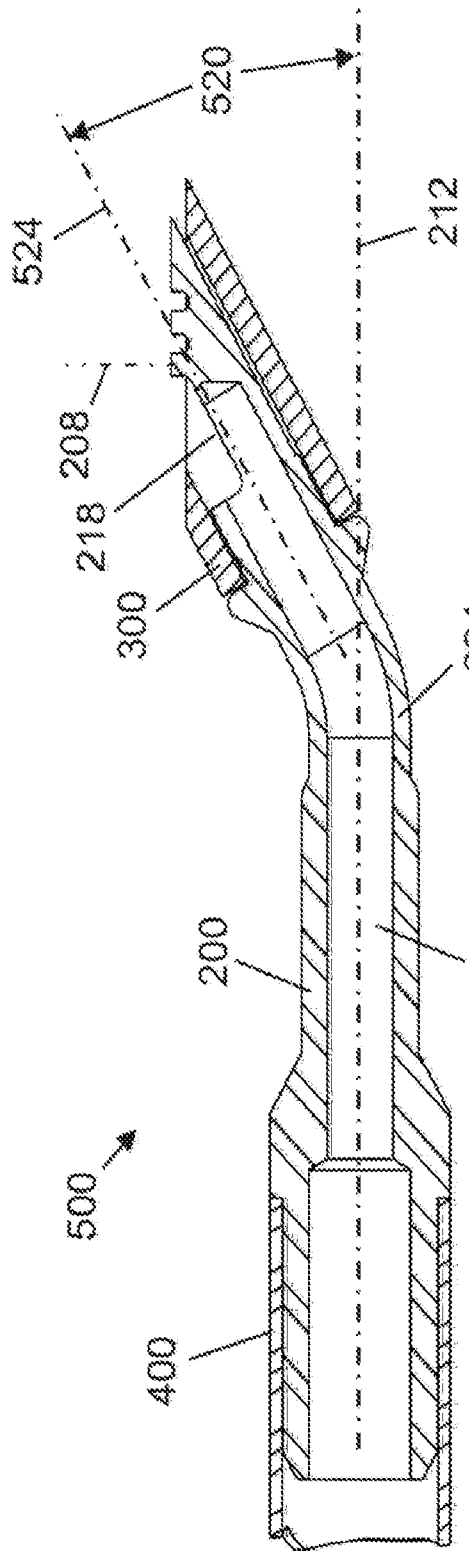

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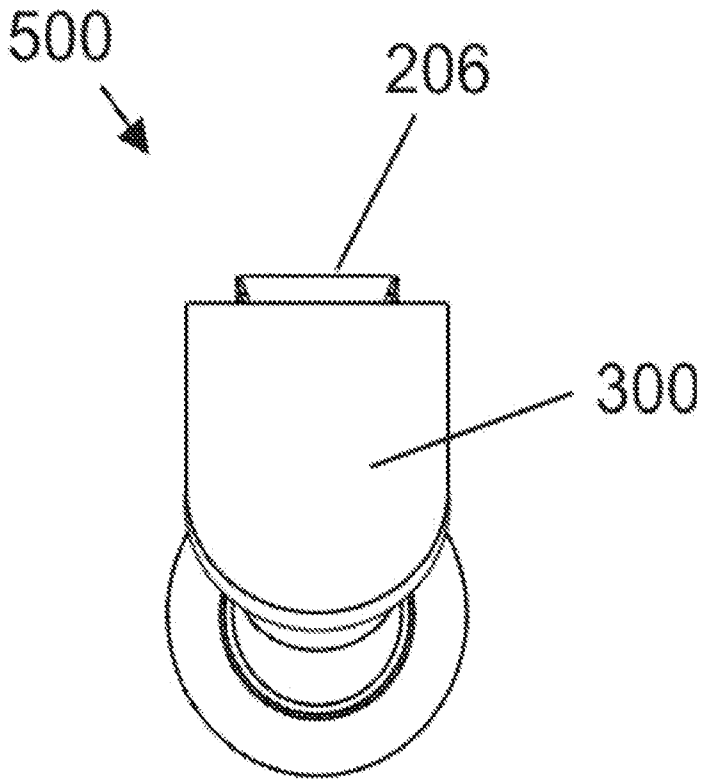
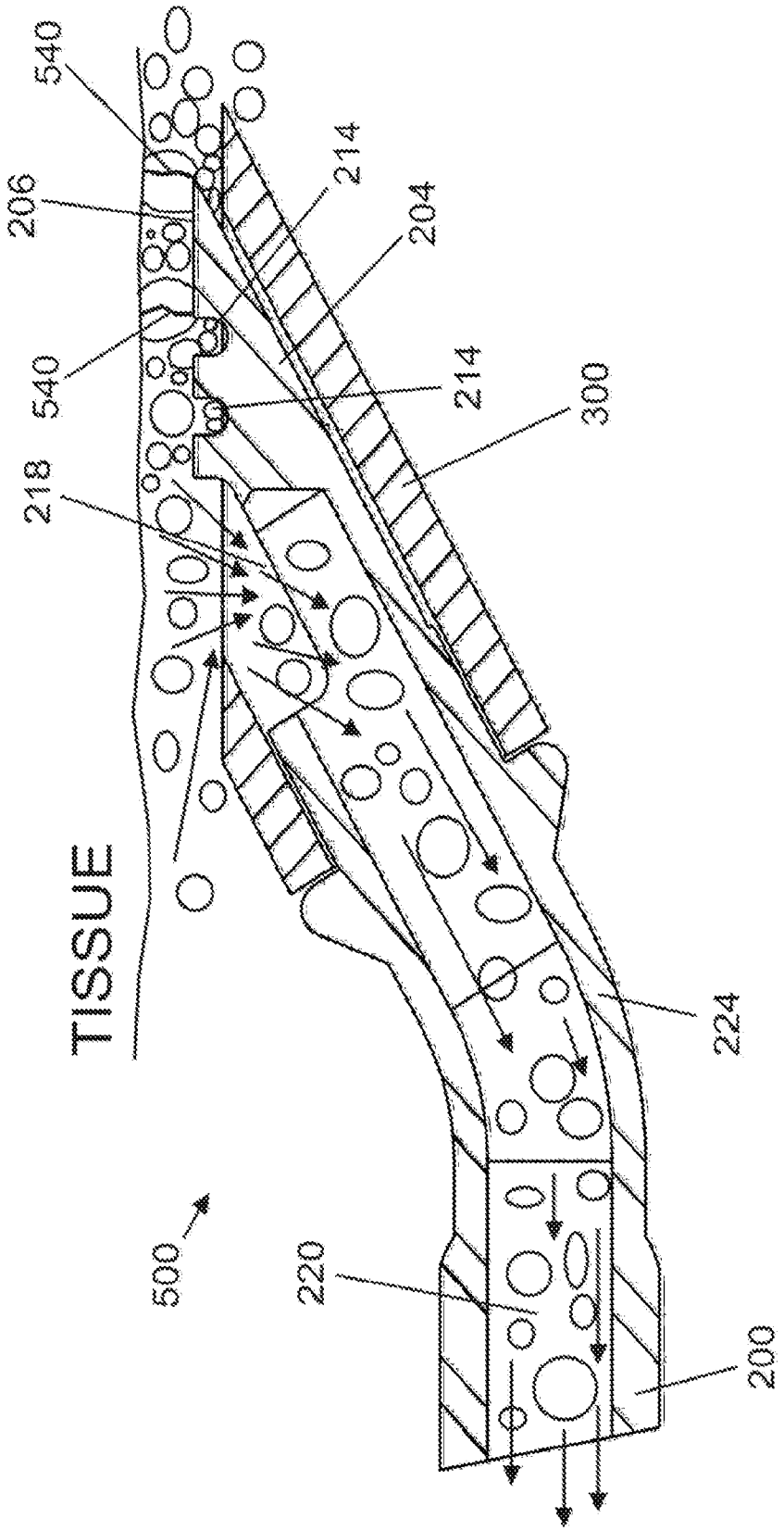


Fig. 29



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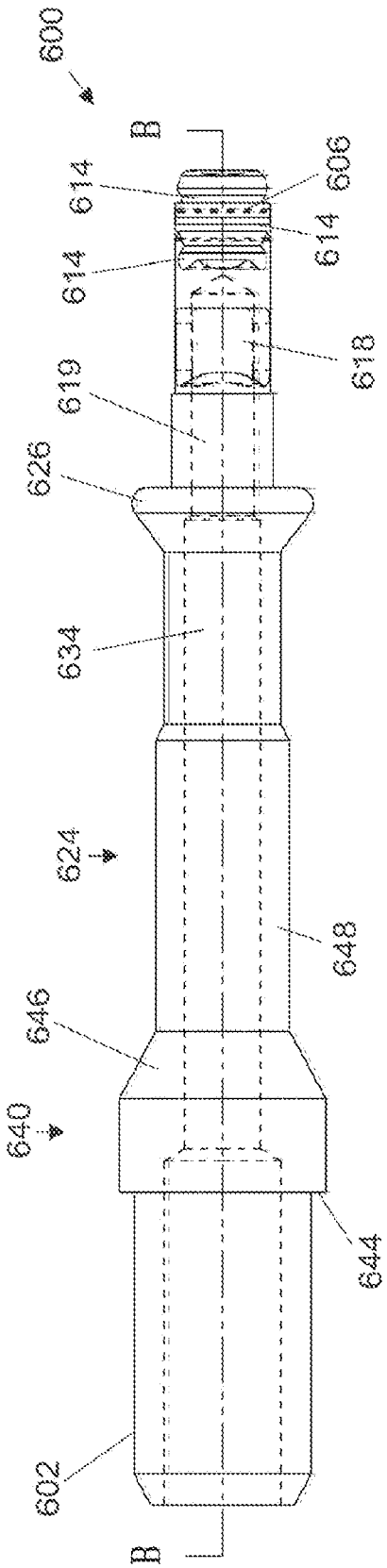

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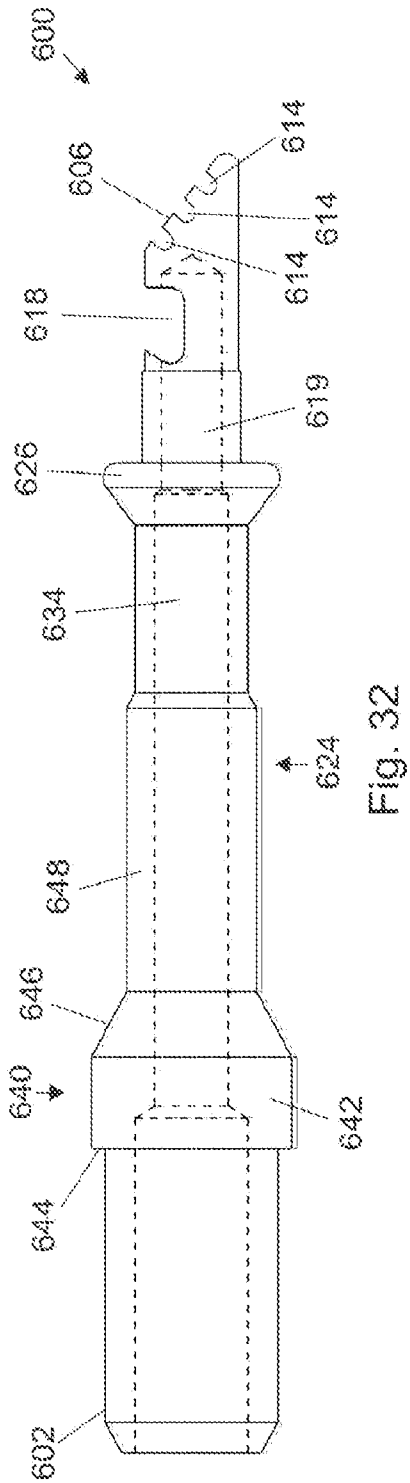

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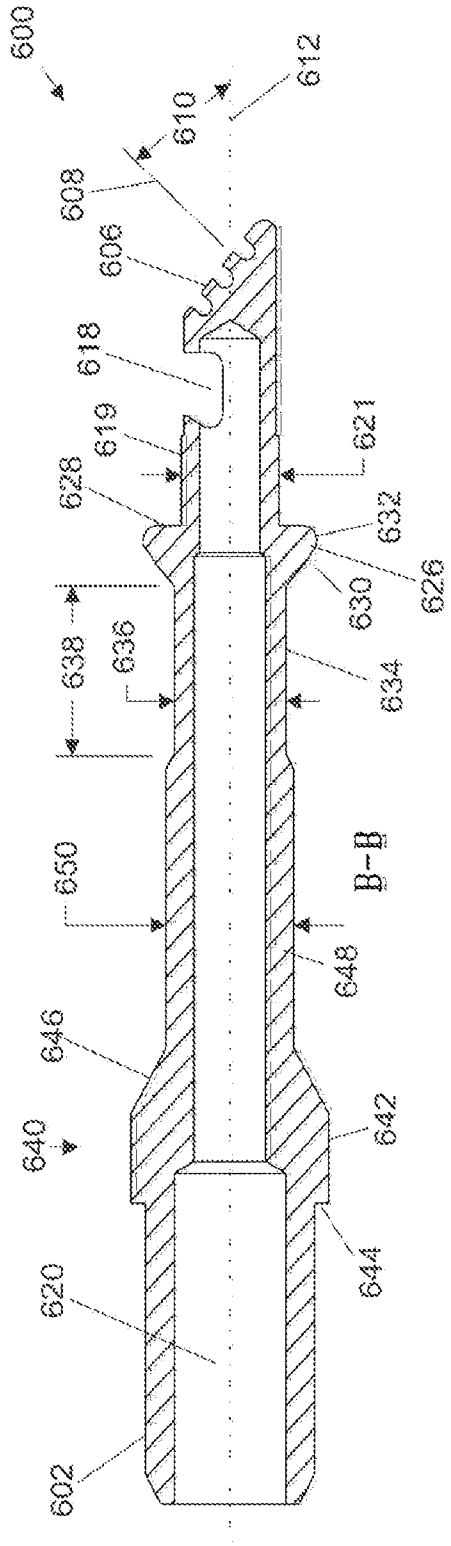
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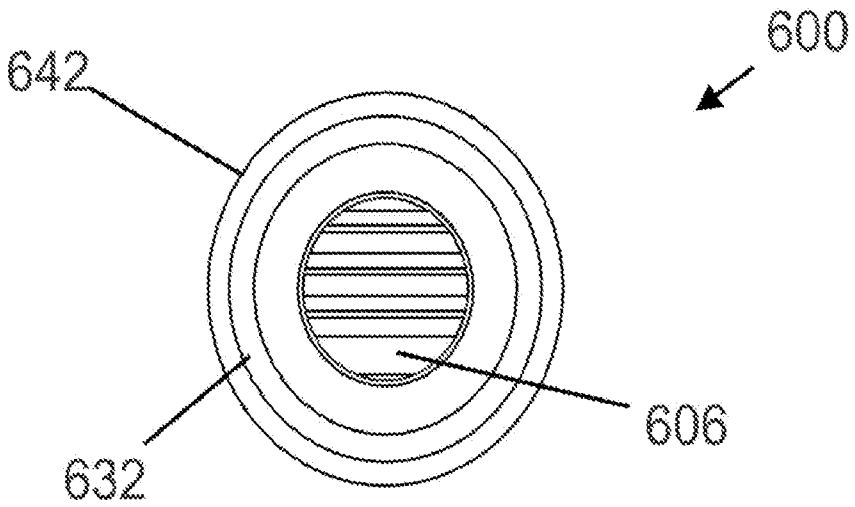
Fig. 33



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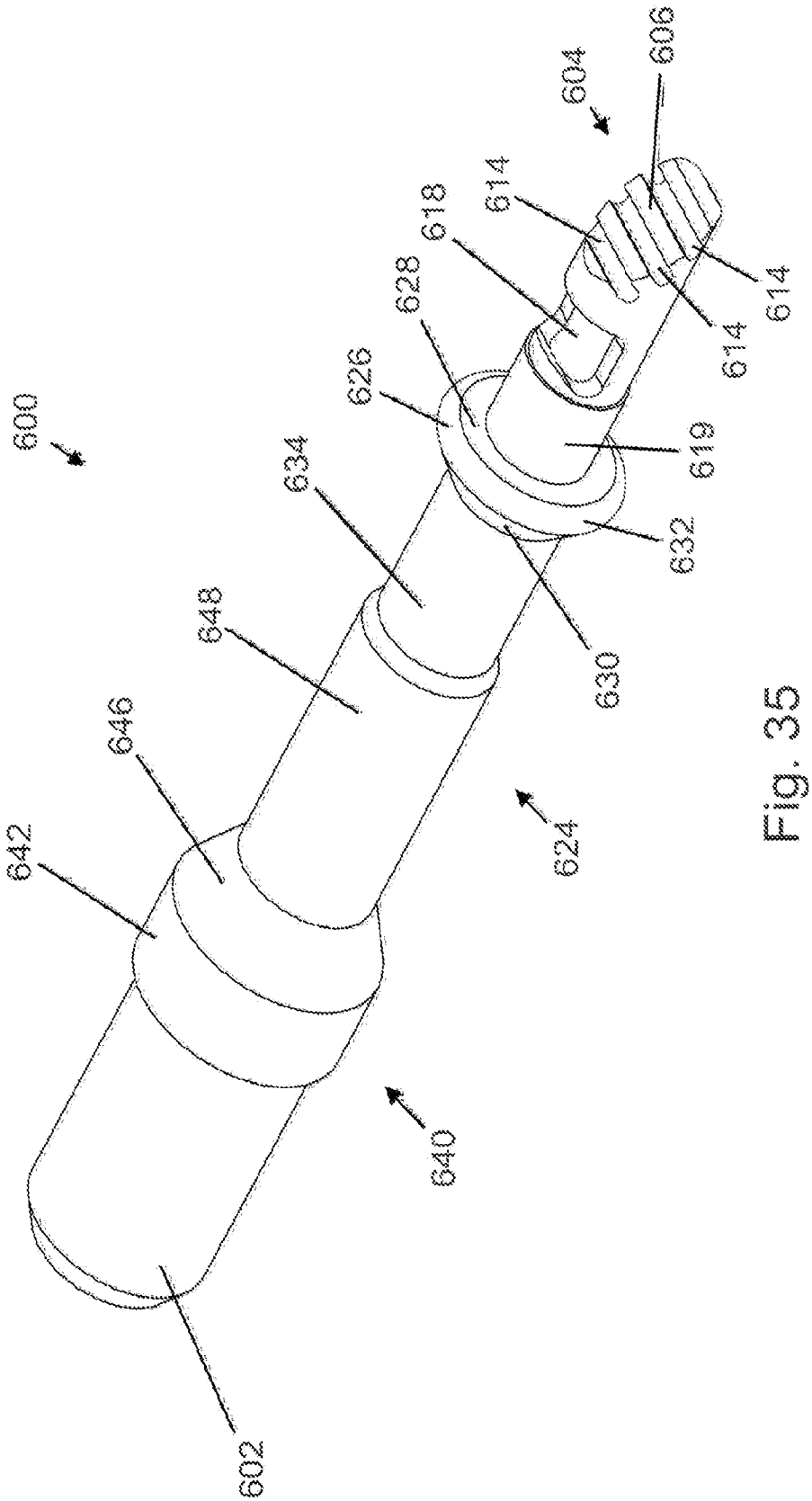
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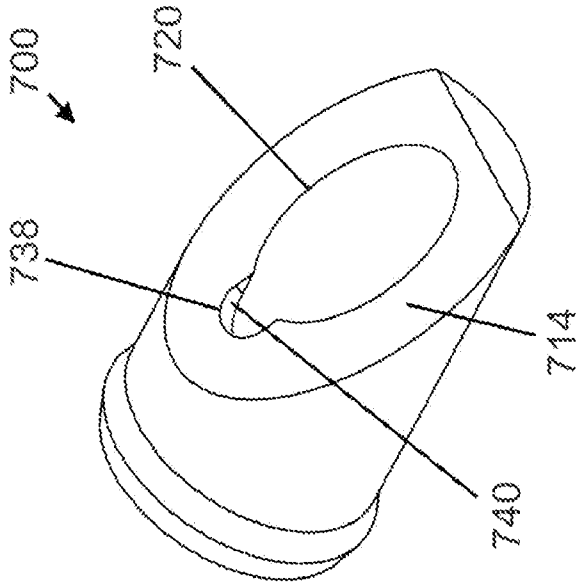
Fig. 35



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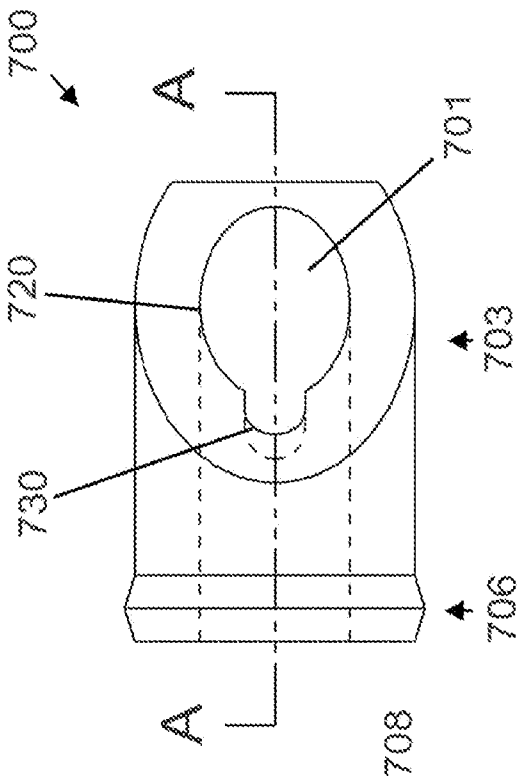

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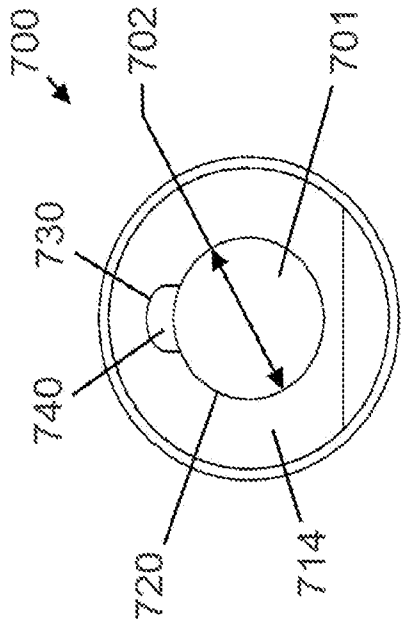

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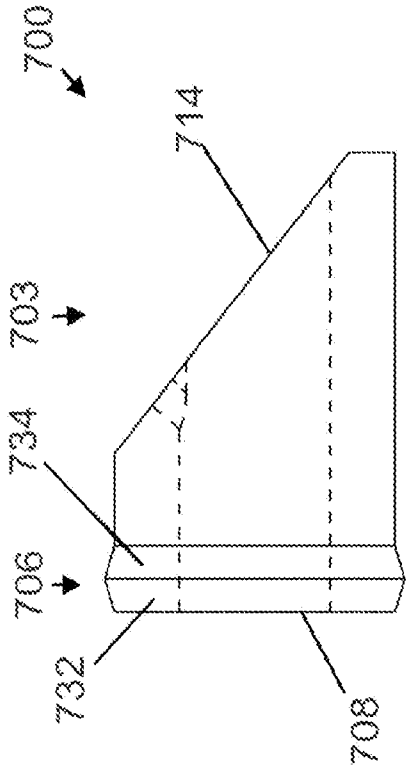

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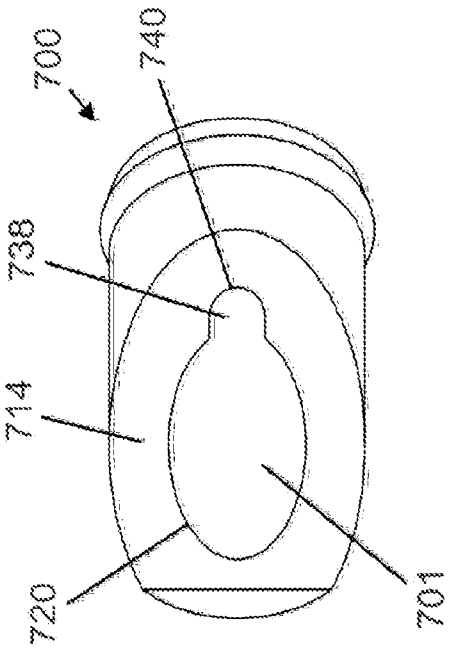
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Fig. 41

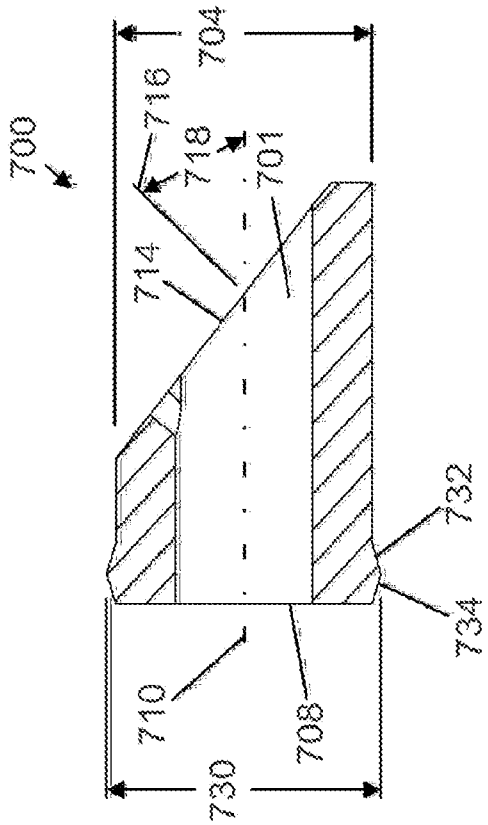
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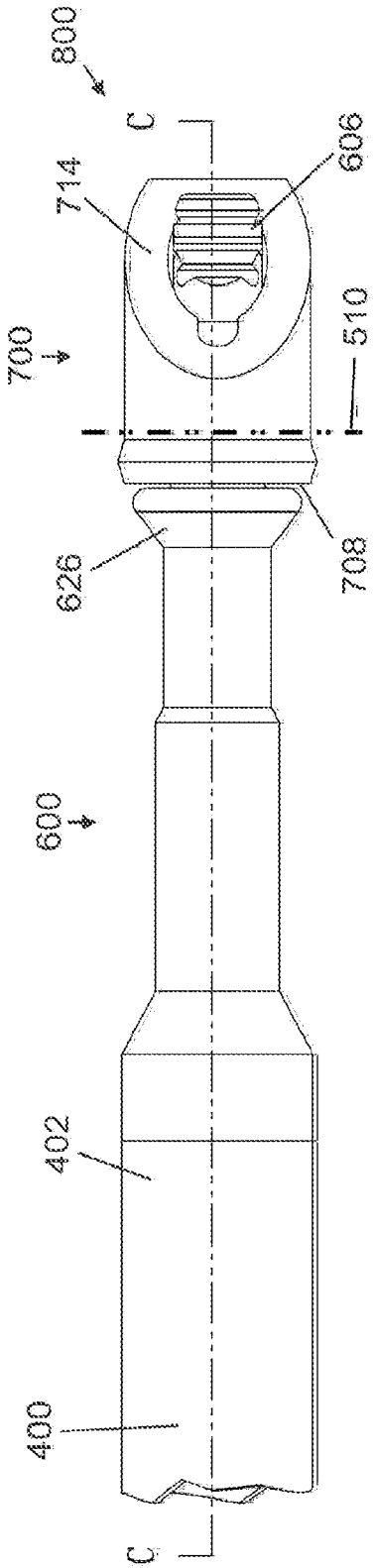
Fig. 40



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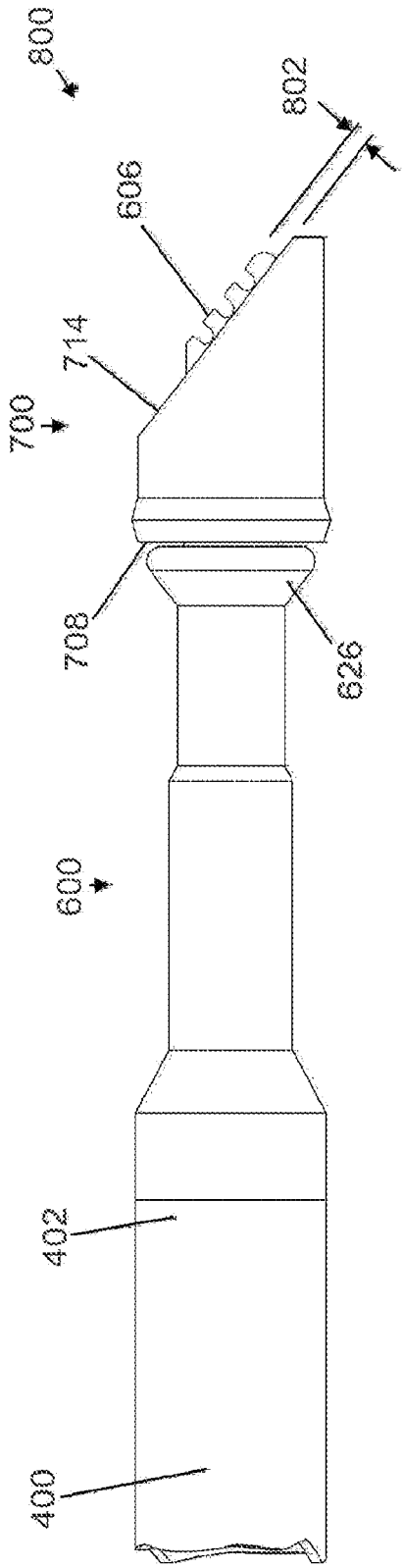

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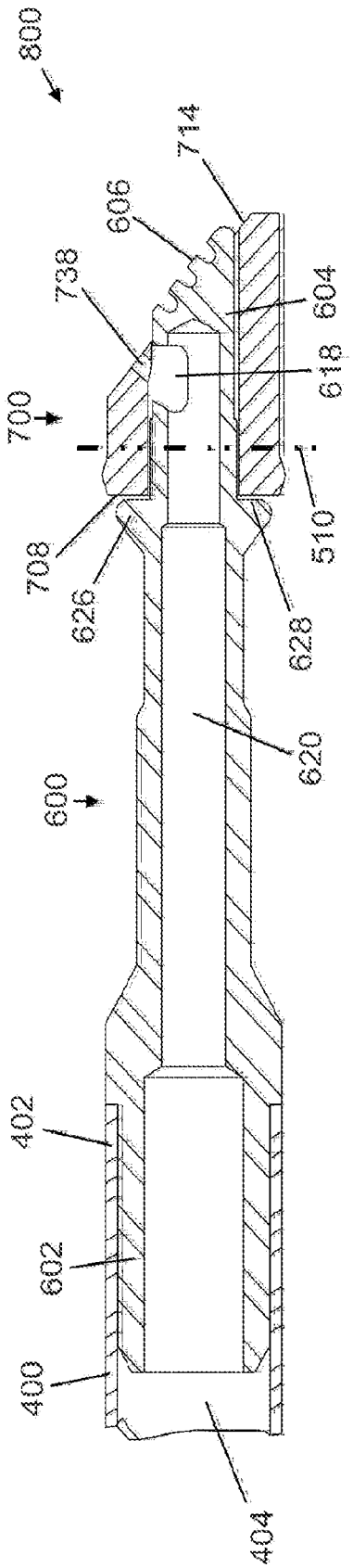
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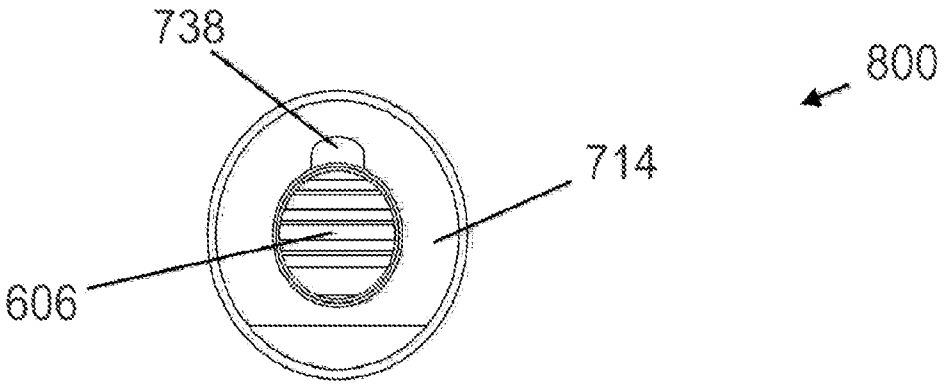
Fig. 44



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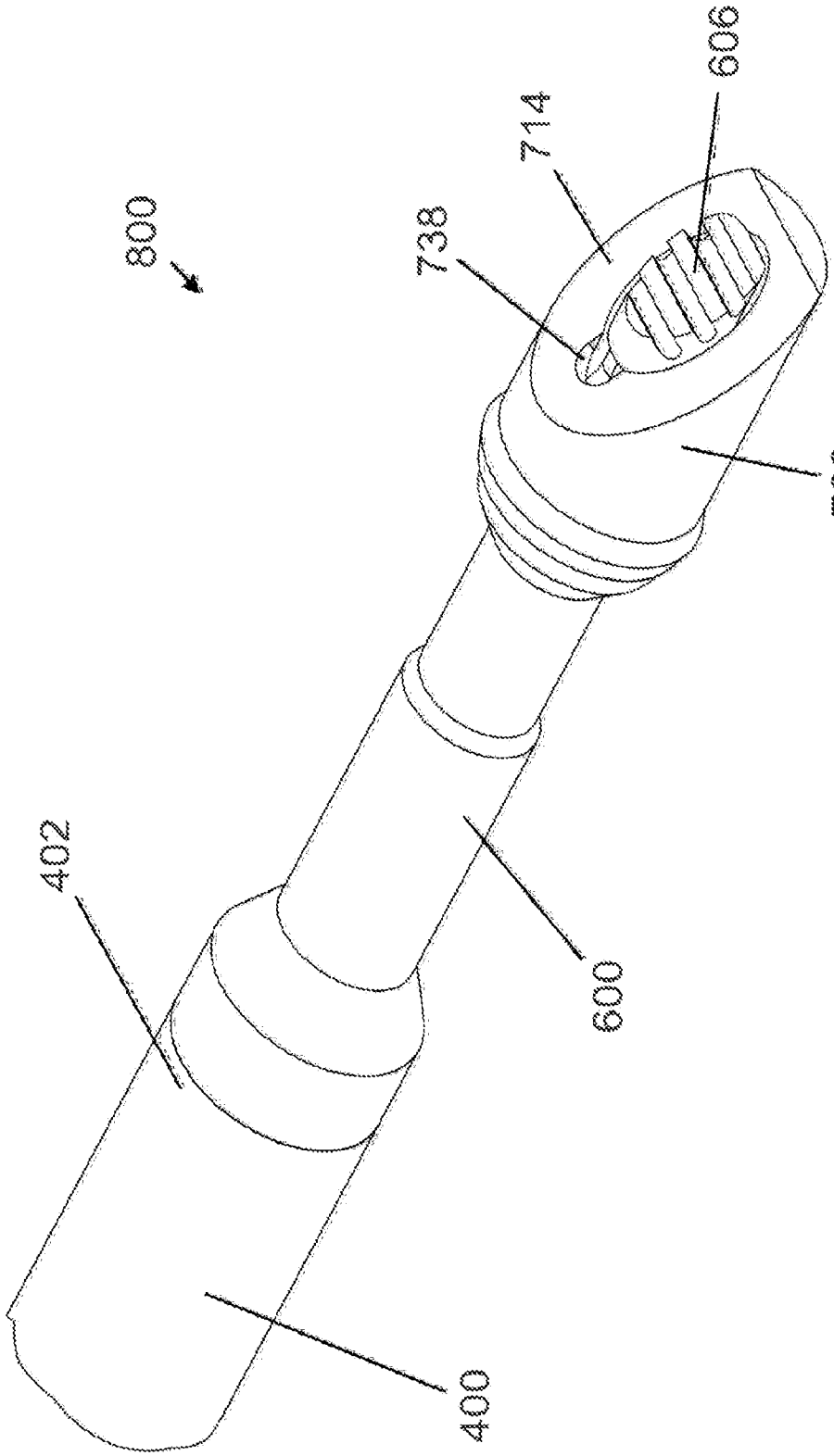

Fig. 46

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/033423

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/14 (2011.01)
USPC - 606/41
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 18/14 (2011.01)
USPC - 604/35, 105, 113, 114; 606/41, 45, 46, 49; 607/99, 105, 113

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0293653 A1 (VAN WYK) 28 December 2006 (28.12.2006) entire document	1-3, 5, 6, 8, 9
Y		4, 7, 10
Y	US 6,949,096 B2 (DAVISON et al) 27 September 2005 (27.09.2005) entire document	4, 7
Y	US 6,823,218 B2 (BERUBE) 23 November 2004 (23.11.2004) entire document	10
A	US 2008/0058821 A1 (MAURER et al) 06 March 2008 (06.03.2008) entire document	1-10
A	US 2003/0130655 A1 (WOLOSZKO et al) 10 July 2003 (10.07.2003) entire document	1-10
A	US 2006/0235377 A1 (EARLEY et al) 19 October 2006 (19.10.2006) entire document	1-10

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
01 September 2011	15 SEP 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)