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(54) **Titre :** SYSTEMES ET METHODES D'ABLATION A LA VAPEUR
(54) **Title:** VAPOR ABLATION SYSTEMS AND METHODS

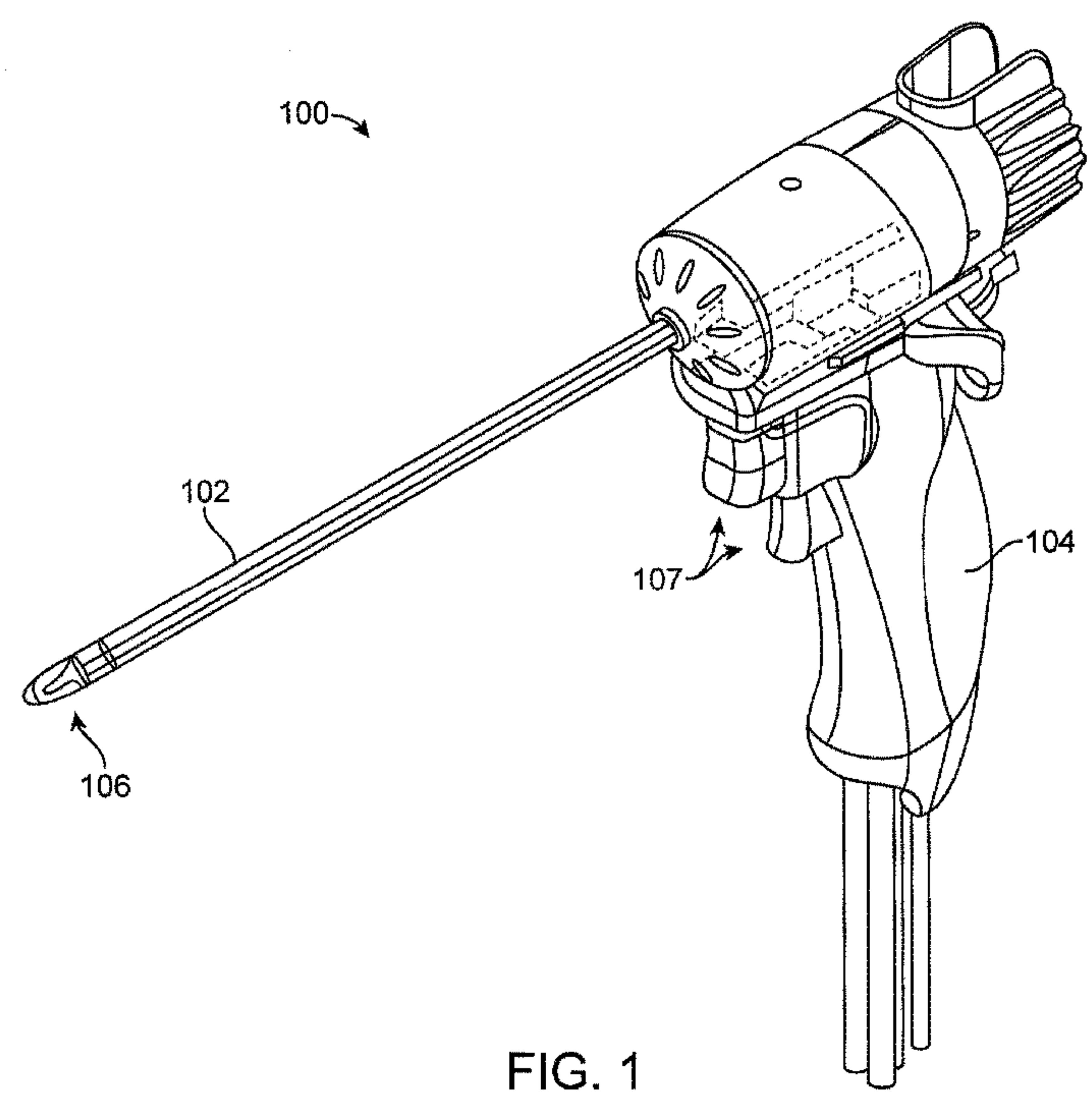

FIG. 1

(57) **Abrégé/Abstract:**
A vapor delivery system and method is provided that is adapted for treating prostate tissue. The vapor delivery system includes a vapor delivery needle configured to deliver condensable vapor energy to tissue. In one method, the vapor delivery system is advanced transurethrally into the patient to access the prostate tissue. The vapor delivery system includes a generator unit and an inductive heating system to produce a high quality vapor for delivery to tissue. Methods of use are also provided.

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(54) Title: VAPOR ABLATION SYSTEMS AND METHODS

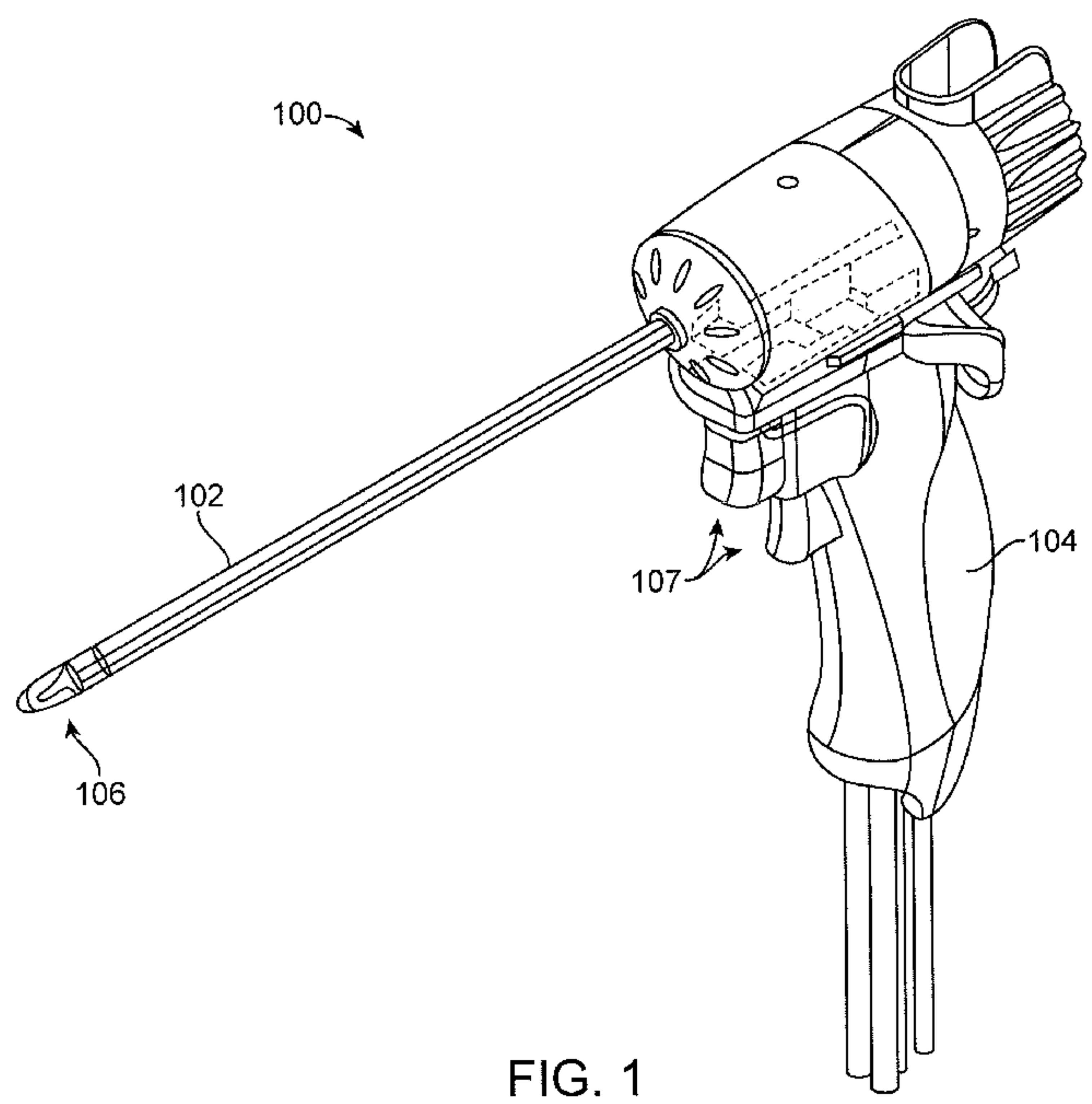

FIG. 1

(57) Abstract: A vapor delivery system and method is provided that is adapted for treating prostate tissue. The vapor delivery system includes a vapor delivery needle configured to deliver condensable vapor energy to tissue. In one method, the vapor delivery system is advanced transurethrally into the patient to access the prostate tissue. The vapor delivery system includes a generator unit and an inductive heating system to produce a high quality vapor for delivery to tissue. Methods of use are also provided.

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VAPOR ABLATION SYSTEMS AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of US Provisional Patent Application No. 62/109,540, filed January 29, 2015, titled "VAPOR ABLATION SYSTEMS AND METHODS", which is incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] The present invention relates to devices and related methods for treatment of benign prostatic hyperplasia using a minimally invasive approach. More specifically, the present disclosure relates to treating benign prostatic hyperplasia with vapor delivered to the prostate.

BACKGROUND

[0004] Benign prostatic hyperplasia (BPH) is a common disorder in middle-aged and older men, with prevalence increasing with age. At age 50, more than one-half of men have symptomatic BPH, and by age 70, nearly 90% of men have microscopic evidence of an enlarged prostate. The severity of symptoms also increase with age with 27% of patients in the 60-70 age bracket having moderate-to-severe symptoms, and 37% of patients in their 70's suffering from moderate-to-severe symptoms.

[0005] The prostate early in life is the size and shape of a walnut and prior to the enlargement resulting from BPH, weighs about 20 grams. Prostate enlargement appears to be a normal process. With age, the prostate gradually increases in size to twice or more its normal size. The fibromuscular tissue of the outer prostatic capsule restricts expansion after the gland reaches a certain size. Because of such restriction on expansion, the intracapsular tissue will compress against and constrict the prostatic urethra, thus causing resistance to urine flow.

[0006] In the male urogenital anatomy, the prostate gland is located below the bladder and the bladder neck. The walls of the bladder can expand and contract to cause urine flow through the urethra, which extends from the bladder, through the prostate and penis. The portion of urethra that is surrounded by the prostate gland is referred to as the prostatic urethra. The prostate also surrounds the ejaculatory ducts which have an open termination in the prostatic urethra. During sexual arousal, sperm is transported from the testes by the ductus deferens to the prostate which provides fluids that combine with sperm to form semen during ejaculation. On each side of the prostate, the ductus deferens and seminal vesicles join to form a single tube called an ejaculatory duct. Thus, each ejaculatory duct carries the seminal vesicle secretions and sperm into the prostatic urethra.

[0007] The prostate glandular structure can be classified into three zones: the peripheral zone, transition zone, and central zone. Peripheral zone PZ comprises about 70% of the volume of a young man's prostate. This sub-capsular portion of the posterior aspect of the prostate gland surrounds the distal urethra and 70 to 80% of cancers originate in the peripheral zone tissue. The central zone CZ surrounds the ejaculatory ducts and contains about 20-25% of the prostate volume. The central zone is often the site of inflammatory processes. The transition zone TZ is the site in which benign prostatic hyperplasia develops, and contains about 5-10% of the volume of glandular elements in a normal prostate, but can constitute up to 80% of such volume in cases of BPH. The transition zone consists of two lateral prostate lobes and the periurethral gland region. There are natural barriers around the transition zone, i.e., the prostatic urethra, the anterior fibromuscular stroma, and a fibrous plane between the transition zone and peripheral zone. The anterior fibromuscular stroma or fibromuscular zone is predominantly fibromuscular tissue.

[0008] BPH is typically diagnosed when the patient seeks medical treatment complaining of bothersome urinary difficulties. The predominant symptoms of BPH are an increase in frequency and urgency of urination, and a significant decrease in the rate of flow during urination. BPH can also cause urinary retention in the bladder which in turn can lead to lower urinary tract infection (LUTI). In many cases, the LUTI then can ascend into the kidneys and cause chronic pyelonephritis, and can eventually lead to renal insufficiency. BPH also may lead to sexual dysfunction related to sleep disturbance or psychological anxiety caused by severe urinary difficulties. Thus, BPH can significantly alter the quality of life with aging of the male population.

[0009] BPH is the result of an imbalance between the continuous production and natural death (apoptosis) of the glandular cells of the prostate. The overproduction of such cells leads to increased prostate size, most significantly in the transition zone which traverses the prostatic urethra.

[0010] In early stage cases of BPH, pharmacological treatments can alleviate some of the symptoms. For example, alpha-blockers treat BPH by relaxing smooth muscle tissue found in the prostate and the bladder neck, which may allow urine to flow out of the bladder more easily.

Such drugs can prove effective until the glandular elements cause overwhelming cell growth in the prostate.

[0011] More advanced stages of BPH, however, can only be treated by surgical or less-invasive thermal ablation device interventions. A number of methods have been developed using electrosurgical or mechanical extraction of tissue, and thermal ablation or cryoablation of intracapsular prostatic tissue. In many cases, such interventions provide only transient relief, and these treatments often cause significant peri-operative discomfort and morbidity.

[0012] In one thermal ablation method, RF energy is delivered to prostate tissue via an elongated RF needle being penetrated into a plurality of locations in a prostate lobe. The elongated RF needle is typically about 20 mm in length, together with an insulator that penetrates into the lobe. The resulting RF treatment thus ablates tissue away from the prostatic urethra and does not target tissue close to, and parallel to, the prostatic urethra. The application of RF energy typically extends for 1 to 3 minutes or longer which allows thermal diffusion of the RF energy to ablate tissue out to the capsule periphery. Such RF energy delivery methods may not create a durable effect, since smooth muscle tissue and alpha adrenergic receptors are not uniformly ablated around the prostatic urethra or within the transition zone. As a result, tissue in the prostate lobes can continue to grow and impinge on the urethra thus limiting long-term effectiveness of the treatment.

SUMMARY OF THE DISCLOSURE

[0013] A vapor delivery system is provided, comprising a generator unit including a cradle, a syringe assembly disposed in the cradle and configured to interact with the cradle to deliver a fluid at a controlled rate, an inductive heating system fluidly coupled to the syringe assembly and configured to receive fluid from the syringe assembly, a force sensor disposed in the cradle and configured contact the cradle and/or syringe assembly to generate an electrical signal proportional to a force exerted on the force sensor by the cradle and/or syringe assembly, and an electronic controller configured control delivery of fluid and RF power to the inductive heating system for the production of vapor, the electronic controller being further configured to calibrate the electrical signal as representing a fluid pressure within the syringe assembly, the electronic controller being further configured to stop delivery of fluid and/or RF power to the inductive heating system when the fluid pressure falls outside of a desired range of fluid pressures.

[0014] In some embodiments, the cradle is arranged such that a distal end of the syringe assembly is held at a higher elevation than a proximal end of the syringe assembly when the syringe assembly is inserted into the cradle.

[0015] In one embodiment, the cradle is configured to purge any air from the syringe assembly during a priming procedure in which fluid is force from the syringe assembly through the vapor delivery system.

[0016] In another embodiment, the cradle further comprises a piston coupled to a linear motor, wherein the piston interacts with a plunger of the syringe assembly to delivery fluid from the syringe assembly.

[0017] In some embodiments, a contact switch is activated when the syringe assembly is inserted into the cradle.

[0018] In one embodiment, the inductive heating system comprises an inner fluid coil surrounded by an outer conductive coil.

[0019] A method of controlling a flow of vapor is provided, comprising receiving a syringe assembly into a cradle of a generator unit, delivering a fluid at a controlled rate from the syringe assembly to an inductive heating system fluidly coupled to the syringe assembly, measuring a force exerted on a force sensor that is disposed in the cradle and configured contact the cradle and/or syringe assembly during fluid delivery, and calibrating the measured force with an electronic controller to represent a fluid pressure within the syringe assembly, and stopping delivery of fluid to the inductive heating system when the fluid pressure falls outside of a desired range of fluid pressures.

[0020] A method of treating prostate tissue is provided, comprising inserting a vapor delivery system transurethrally into a patient to access the prostatic urethra of the patient, advancing a vapor delivery needle generally transverse to the vapor delivery system through the prostatic urethra and into a transition zone of the prostate, and delivering vapor through distally facing vapor delivery ports of the vapor delivery needle to direct the vapor distally from the device into the prostate.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] In order to better understand the invention and to see how it may be carried out in practice, some preferred embodiments are next described, by way of non-limiting examples only, with reference to the accompanying drawings, in which like reference characters denote corresponding features consistently throughout similar embodiments in the attached drawings.

[0022] FIG. 1 shows one embodiment of a vapor delivery system.

[0023] FIGS. 2A-2B show close-up views of a distal portion of the vapor delivery system including a vapor delivery needle.

[0024] FIGS. 2C-2D show a normal prostate and an enlarged prostate being treated with a vapor delivery system.

[0025] FIGS. 3A-3B show a vapor delivery system including an inductive heating system for producing high quality condensable vapor.

[0026] FIG. 4 shows a generator unit configured to control generation of vapor in the inductive heating system.

[0027] FIG. 5 shows one embodiment of a syringe assembly that interacts with the generator unit.

[0028] FIG. 6 shows a cross-sectional view of a syringe cradle and syringe assembly of the generator unit.

[0029] FIG. 7 is a cross-sectional view of a shaft of the vapor delivery system.

DETAILED DESCRIPTION OF THE INVENTION

[0030] In general, one method for treating BPH comprises introducing a heated vapor interstitially into the interior of a prostate, wherein the vapor controllably ablates prostate tissue. This method can utilize vapor for applied thermal energy of between 50 calories and 300 calories per each individual vapor treatment (and assumes multiple treatments for each prostate lobe) in an office-based procedure. The method can cause localized ablation of prostate tissue, and more particularly the applied thermal energy from vapor can be localized to ablate tissue adjacent the urethra without damaging prostate tissue that is not adjacent the urethra.

[0031] The present disclosure is directed to the treatment of BPH, and more particularly for ablating transitional zone prostate tissue without ablating central or peripheral zone prostate tissue. In one embodiment, the present disclosure is directed to treating a prostate using convective heating in a region adjacent the prostatic urethra. The method of ablative treatment is configured to target smooth muscle tissue, alpha adrenergic receptors, sympathetic nerve structures and vasculature parallel to the prostatic urethra between the bladder neck region and the verumontanum region to a depth of less than 2 cm.

[0032] The system can include a vapor delivery mechanism that delivers vapor media, including water vapor. The system can utilize a vapor source configured to provide vapor having a temperature of at least 60-140° C. In another embodiment, the system further comprises a computer controller configured to deliver vapor for an interval ranging from 1 second to 30 seconds.

[0033] In some embodiments, the system further comprises a source of a pharmacologic agent or other chemical agent or compound for delivery with the vapor. These agents include, without limitation, an anesthetic, an antibiotic or a toxin such as Botox®, or a chemical agent that can treat cancerous tissue cells. The agent also can be a sealant, an adhesive, a glue, a superglue or the like.

[0034] FIG. 1 shows one embodiment of a vapor delivery system. Vapor delivery system 100 can have an elongate shaft 102 configured for insertion into the urethra of a patient and a handle portion 104 for gripping with a human hand. The vapor delivery system 100 can include a vapor delivery needle 106 disposed in the shaft that is configured to extend from a distal portion of the elongate shaft 102. The vapor delivery needle can extend generally perpendicular to or transverse from the shaft, and can include one or more vapor delivery ports configured to deliver a flow of vapor media from the needle into prostate tissue. The vapor delivery system 100 can further include one or more triggers, buttons, levers, or actuation mechanisms 107 configured to actuate the various functions of the system. For example, the actuation mechanism can be configured to extend/retract the vapor delivery needle, and start/stop the flow of vapor, aspiration, and a cooling and/or irrigation fluid such as saline.

[0035] In some embodiments, the triggers or actuation mechanisms 107 can be manipulated in such a way as to control varying degrees or flow rates of vapor and/or irrigation. In one specific embodiment, the triggers or actuation mechanisms 107 can comprise a first trigger configured to extend/retract the vapor delivery needle, a second trigger configured to start/stop the flow of vapor, and a third trigger configured to provide a cooling and/or irrigation fluid such as saline. In another embodiment, a single trigger or actuation mechanism can both extend/retract the vapor delivery needle and start/stop the flow of vapor. In one embodiment, a single press or depression of one of the triggers, such as a trigger that provides the cooling and/or irrigation fluid, may provide a standard irrigation flush, while a rapid double press or depression of the trigger may provide a "turbo" irrigation flush in which the flow rate of irrigation is increased over the standard flush flow rate. This feature may be useful, for example, if the physician encounters a blockage, needs additional cooling, or has reduced vision in the urethra and/or prostate due to accumulation of blood or other bodily fluids.

[0036] The fluid or irrigation source can provide a fluid, such as saline, through a separate lumen in the shaft to provide irrigation and flushing to tissue during insertion of the system and during vapor delivery to tissue. In some embodiments, the irrigation can be used to clear blood and debris from tissue lumens to increase visibility. The irrigation can also provide cooling to the urethra of the patient, both via direct contact of the irrigation fluid with the urethra as well as cooling the shaft of the vapor delivery system as the fluid flows from the irrigation source through the shaft and into contact with the tissue. Urethral flush can be used during the lesion formation. In one embodiment, the flush rate can be approximately 80 mL / minute, or ranging from 20 to 400 mL / minute. Changes in flush rate will change the amount of tissue cooling (depth) into the urethra and prostate, which can affect lesion size.

[0037] FIG. 2A shows a close-up view of the distal portion of the shaft of vapor delivery system 100, including the vapor delivery needle 106 extending beyond the shaft and exposing the vapor delivery ports 108. Vapor delivery ports 108 may be arranged in a pattern that optimizes the delivery of vapor to tissue in a given application. For example, in a system designed for treatment of BPH the delivery ports 108 comprise multiple rows of a plurality of vapor delivery ports. In one specific embodiment, the delivery ports 108 can be spaced at 120 degree intervals around the circumference of the needle, with one row of delivery ports facing distally from the front edge of the needle, as shown in Fig. 2B, to ensure ablation of tissue adjacent to the prostatic urethra. In general, the vapor delivery ports can each have a unique diameter. In one embodiment the vapor delivery ports all have the same diameter.

[0038] Fig. 2C shows a normal, healthy prostate, and Fig. 2D shows an enlarged prostate being treated with a vapor delivery system 100. In one embodiment, the vapor delivery system can be inserted into the urethra and advanced to the prostatic urethra through a transurethral approach. The vapor delivery needle 106 can be advanced generally transverse to the shaft of the vapor delivery system and into the prostate tissue. Vapor can be generated by the vapor delivery system and delivered into the prostate through the vapor delivery needle. As described above, the vapor delivery needle can include a row of vapor delivery ports that point distally away from the device when the vapor delivery needle is extended transverse to the shaft of the device. Referring to Fig. 2D, the vapor can be delivered to the prostate through this distally facing vapor delivery ports to ablate prostate tissue distal to the position of the vapor delivery needle in the prostate. The position of the vapor delivery needle and the vapor delivery ports can allow for ablation of transition zone tissue of the prostate extending distally from the position of the vapor delivery needle. For example, in Figure 2D transition zone tissue is treated that extends under bladder muscular tissue that cannot be safely penetrated by a delivery device needle.

[0039] The vapor delivery system 100 can include a vapor source, an aspiration source, a fluid cooling or irrigation source, a light source, and/or an electronic controller configured to control generation and delivery of vapor from the vapor source, through a lumen of the shaft, through the vapor delivery needle, and into prostate tissue. In some embodiments, the electronic controller can be disposed on or in the vapor delivery system, and in other embodiments the electronic controller can be disposed separate from the system.

[0040] A vapor source can be provided for generating and delivering a vapor media through the vapor delivery needle to ablate tissue. In one embodiment, the vapor source can be a vapor generator that can deliver a vapor media, such as water vapor, that has a precisely controlled quality to provide a precise amount of thermal energy delivery, for example measured in calories per second. In some embodiments, the vapor source can comprise an inductive heating system disposed in the vapor delivery system (e.g., in the handle) in which a flow media is inductively heated to generate a condensable vapor such as steam.

[0041] Figs. 3A-3B illustrate one embodiment of an inductive heating system 320, comprising an inner fluid coil 322 (shown in Fig. 3A) surrounded by an outer electrically conductive coil 324 (Fig. 3B). The inner fluid coil can be constructed from steel tubing which may be annealed. The inner fluid coil may be soldered or include a solder stripe to insure electrical conductivity between coil windings. The outer conductive coil can be a conductive material, such as electrically insulated copper Litz wire having an overall diameter ranging from 18 gauge to 22 gauge. As shown, the inductive heating system 320 can be disposed within the vapor delivery system, such as within the handle. An inlet portion 326 of the inner fluid coil 322 can receive a fluid, such as sterile water, from an external fluid source. The fluid can pass through the inner fluid coil 322 as AC or RF current is applied to the outer conductive coil 324 via electrical connections 325. Current flowing in the outer conductive coil can induce currents to flow in the inner fluid coil that resistively heat the fluid within the inner fluid coil so as to produce a high quality condensable vapor, which is then delivered to the vapor delivery needle via outlet portion 328.

[0042] Fig. 4 illustrates a generator unit 40 configured to provide power and fluid to the inductive heating system for the production of vapor. The generator unit also can connect to the vapor delivery system 100 described above to provide power and other components to the system vital for operation, such as irrigation/cooling fluid, suction, etc. The generator unit can include an electronic controller and a graphical user interface (GUI) 434 to provide operating parameters and controls to the user during vapor therapy. The generator unit can include a syringe cradle 430 adapted to hold syringe assembly 536 for providing fluid, such as sterile water, to the inductive heating system.

[0043] The generator unit can also include an electrical connector 432 which can provide rf current to the inductive heating system, electrical signals to and from the switches 107 of the vapor delivery system, measurements of, for example, the temperature of the inductive heating system, and electrical signals to/from a controller of vapor delivery system, for example in its electrical connector, to identify the vapor delivery system, track its history of vapor delivery, and prevent excessive use of a given vapor delivery system. Generator unit 40 may also contain the peristaltic pump 435 that provides a flow of cooling/irrigation fluid such as saline to the vapor delivery system. In operation, flexible tubing 437 can be routed from a bag of sterile saline, through the peristaltic pump, and through tubing into the vapor delivery system. Guides or markers can be provided on the peristaltic pump 435 to insure that the tubing is inserted in a path that provides flow in a direction from the saline bag into the vapor delivery system when the pump is activated normally.

[0044] Fig. 5 shows syringe assembly 536 that provides a precise amount of fluid such as sterile water to the vapor delivery system 100 for conversion into vapor. Syringe assembly 536 includes a syringe 537 having exit port 541 that is offset from the center line of the syringe, with luer fitting 542 that connects to sterile water tubing on the vapor delivery system, plunger 538 that moves forward in the syringe to eject water, and backward in the syringe to fill the syringe with water, and accessory rod 540 that removably attaches to plunger 538 during system set-up to fill syringe 537. When syringe 537 has been filled with fluid, accessary rod 540 is discarded, and filled syringe 537 is inserted into the cradle of the generator unit.

[0045] Fig. 6 shows a cross-sectional view of the syringe cradle 430 of Fig. 4, with the syringe assembly 536 of Fig. 5 inserted into cradle 430. A contact switch 654 is activated when syringe 537 is inserted into cradle 430 to insure that the syringe is in place when power is delivered to the vapor delivery system. The state of the contact switch is sensed through electrical leads 652. A force sensor 644 is disposed in the cradle such that it contacts and interacts with the cradle and/or syringe assembly 537. When the electronic controller is commanded to deliver sterile water to the vapor delivery system, piston 642 of the cradle engages syringe plunger 538, and a linear motor attached to piston 642 delivers sterile water at a precisely controlled rate from syringe 537 out through luer fitting 542 into fluid tubing connected to the inductive heating system. As sterile water is pushed, syringe 537 impinges on cradle 430, which is free to move laterally within generator 40. Forward movement of cradle 430 is prevented as it impinges upon force sensor 644. Microscopic lateral movement of force sensor 644 is translated into an electrical signal that is proportional to the force exerted on force sensor 644 by cradle 430. The electrical signal is conducted through leads 648 to the electronic controller and calibrated as the water pressure within syringe 537 and throughout the fluid tubing including within the inner coil of the inductive heating system. Water pressure is monitored by the electronic controller of the generator unit 40, and the electronic controller can be configured to stop delivery of RF power and fluid to the inductive heating system if the fluid pressure falls outside of a desired range of pressures, e.g., if the fluid pressure is too low (for example due to a leak in the water line), or too high (for example due to a blockage in the water line).

[0046] Cradle 430 is configured to purge any air from the fluid tubing during a priming procedure in which water is forced from the syringe and fills and flushes the system water and vapor lines, exiting from the vapor delivery ports of the vapor delivery device. As shown in Fig. 6, cradle 430 is designed so as to keep the distal end of syringe 537 at a higher elevation than its proximal end when inserted into the cradle, and to keep offset exit port 541 of the syringe at the top of the syringe. This design forces any air in the syringe to move under the influence of gravity to the upper distal end of the syringe and to exit the syringe to be purged from the fluid tubing during the priming procedure. Removal of air from the fluid tubing prevents over heating of the inductive heating system, and prevents loss of water volume and therefore loss of calories delivered to tissue.

[0047] The electronic controller of the generator unit can be set to control the various parameters of vapor delivery, for example, the controller can be set to deliver vapor media for a selected treatment interval at a selected flow rate, a selected pressure, or selected vapor quality. Further details on the vapor delivery system, the vapor generator, and how vapor and fluid are delivered to tissue can be found in US Patent No. 8,273,079 and PCT Publication No. WO 2013/040209, both of which are incorporated by reference. In some embodiments, the electronic controller can also control the aspiration and/or cooling irrigation functions of the vapor delivery system.

[0048] FIG. 7 provides a cross sectional view of elongate shaft 102 of vapor delivery system 100 from FIGS. 1-2. Lumen 148 can be configured to accommodate the vapor delivery needle described above and in FIGS. 1-2, to allow for the vapor delivery needle to be advanced from the shaft during vapor delivery. Lumen 115 formed within tube 112 can have a diameter ranging from about 2 to 5 mm for accommodating various endoscopes 118, while at the same time providing an annular space 138 for allowing an irrigation fluid to flow within lumen 115 and outwardly from the shaft into the distal urethra and bladder. The lumen 115 can be sized to accommodate an endoscope or camera to provide additional viewing and feedback to the physician. This endoscope or camera can provide a view of the distal end of the shaft, including a view of the vapor delivery needle when deployed. As can be seen in FIG. 7, the lumen 115 is dimensioned to provide a space 138 for fluid irrigation flow around the endoscope 118. In some embodiments, the annular space 138 can be a separate concentric lumen around the endoscope for irrigation fluid flow. The annular space 138 allows for flow of irrigation fluid from the vapor delivery system into tissue, and also provides cooling to the shaft when vapor is delivered from the vapor delivery needle (disposed in lumen 148) into tissue. Material 144 in FIG. 7 can conduct heat from the vapor delivery needle to the irrigation/cooling fluid flowing in annular space 138, or alternatively, can conduct cooling from the irrigation/cooling fluid to the vapor delivery needle, to prevent over-heating of the patient (particularly the urethra) during vapor therapy.

[0049] Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of illustration and the above description of the invention is not exhaustive. Specific features of the invention are shown in some drawings and not in others, and this is for convenience only and any feature may be combined with another in accordance with the invention. A number of variations and alternatives will be apparent to one having ordinary skills in the art. Such alternatives and variations are intended to be included within the scope of the claims. Particular features that are presented in dependent claims can be combined and fall within the scope of the invention. The invention also encompasses embodiments as if dependent claims were alternatively written in a multiple dependent claim format with reference to other independent claims.

CLAIMS

What is claimed is:

1. A vapor delivery system, comprising:

a generator unit including a cradle;

a syringe assembly disposed in the cradle and configured to interact with the cradle to deliver a fluid at a controlled rate;

an inductive heating system fluidly coupled to the syringe assembly and configured to receive fluid from the syringe assembly;

a force sensor disposed in the cradle and configured contact the cradle and/or syringe assembly to generate an electrical signal proportional to a force exerted on the force sensor by the cradle and/or syringe assembly; and

an electronic controller configured control delivery of fluid and RF power to the inductive heating system for the production of vapor, the electronic controller being further configured to calibrate the electrical signal as representing a fluid pressure within the syringe assembly, the electronic controller being further configured to stop delivery of fluid and/or RF power to the inductive heating system when the fluid pressure falls outside of a desired range of fluid pressures.

2. The system of claim 1, wherein the cradle is arranged such that a distal end of the syringe assembly is held at a higher elevation than a proximal end of the syringe assembly when the syringe assembly is inserted into the cradle.

3. The system of claim 2, wherein the cradle is configured to purge any air from the syringe assembly during a priming procedure in which fluid is force from the syringe assembly through the vapor delivery system.

4. The system of claim 1, wherein the cradle further comprises a piston coupled to a linear motor, wherein the piston interacts with a plunger of the syringe assembly to delivery fluid from the syringe assembly.

5. The system of claim 1, wherein a contact switch is activated when the syringe assembly is inserted into the cradle.

6. The system of claim 1, wherein the inductive heating system comprises an inner fluid coil surrounded by an outer conductive coil.

7. A method of controlling a flow of vapor, comprising:

receiving a syringe assembly into a cradle of a generator unit;

delivering a fluid at a controlled rate from the syringe assembly to an inductive heating system fluidly coupled to the syringe assembly;

measuring a force exerted on a force sensor that is disposed in the cradle and configured contact the cradle and/or syringe assembly during fluid delivery; and

calibrating the measured force with an electronic controller to represent a fluid pressure within the syringe assembly; and

stopping delivery of fluid to the inductive heating system when the fluid pressure falls outside of a desired range of fluid pressures.

8. A method of treating prostate tissue, comprising:

inserting a vapor delivery system transurethrally into a patient to access the prostatic urethra of the patient;

advancing a vapor delivery needle generally transverse to the vapor delivery system through the prostatic urethra and into a transition zone of the prostate; and

delivering vapor through distally facing vapor delivery ports of the vapor delivery needle to direct the vapor distally from the device into the prostate.

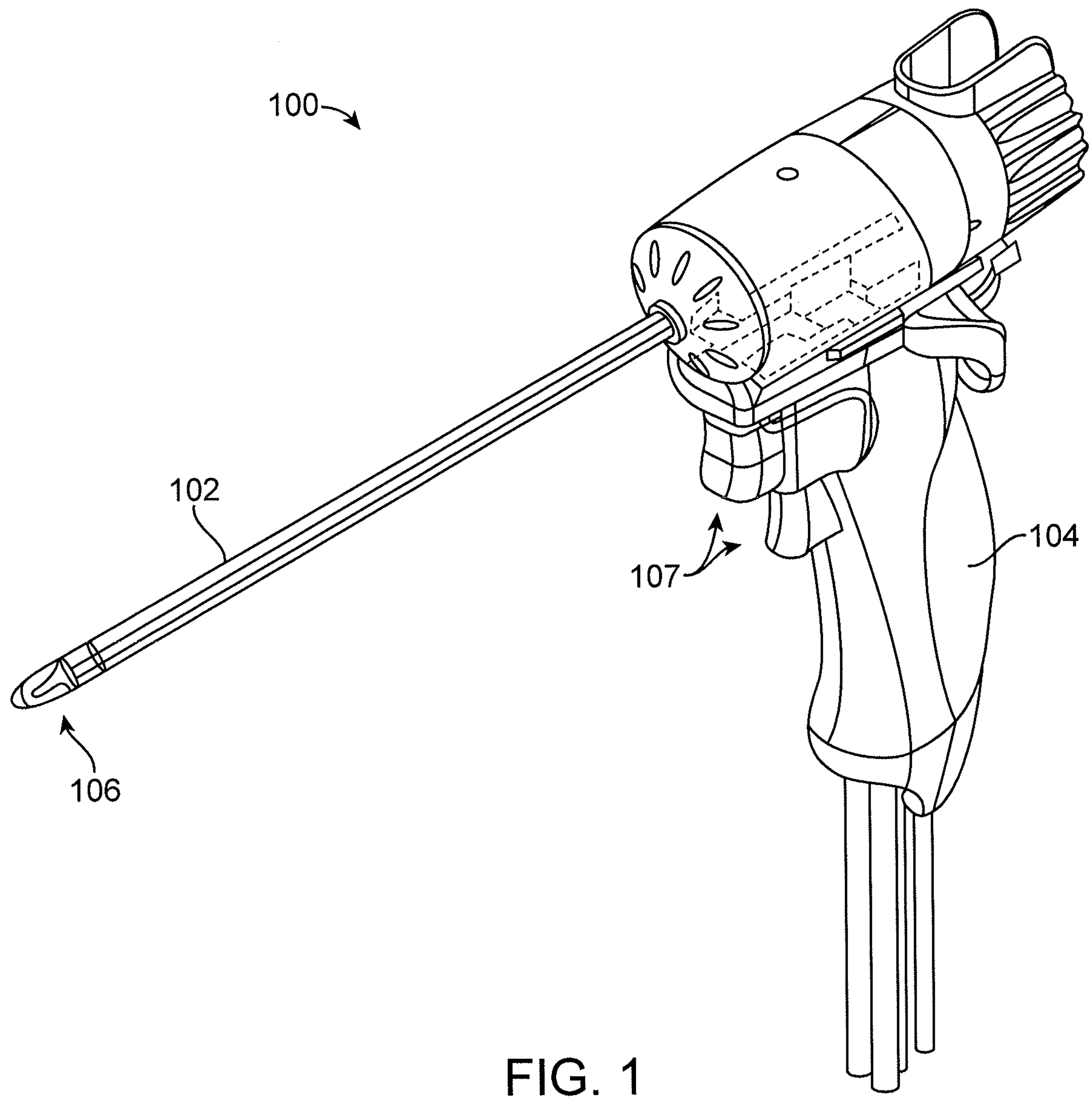

FIG. 1

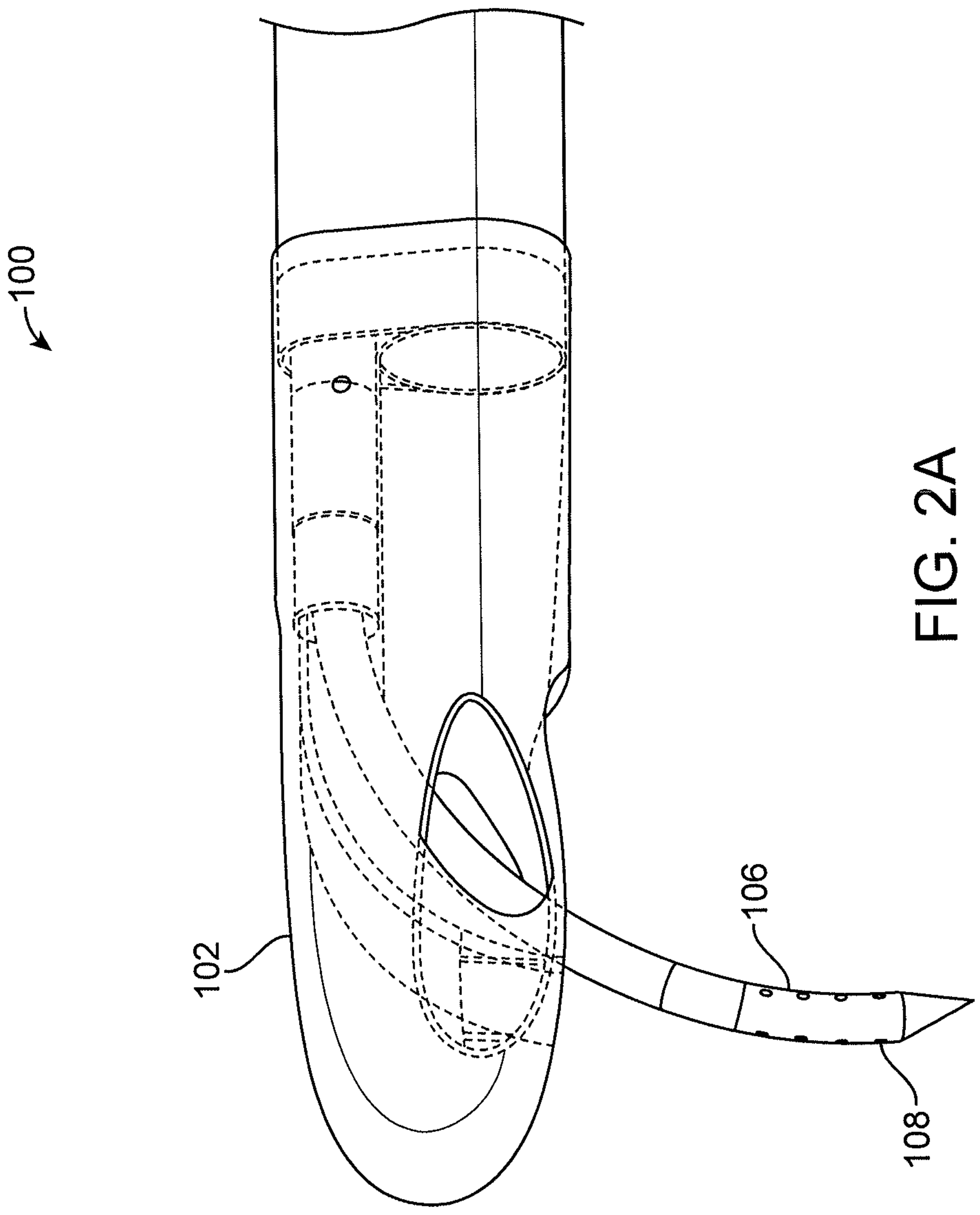

FIG. 2A

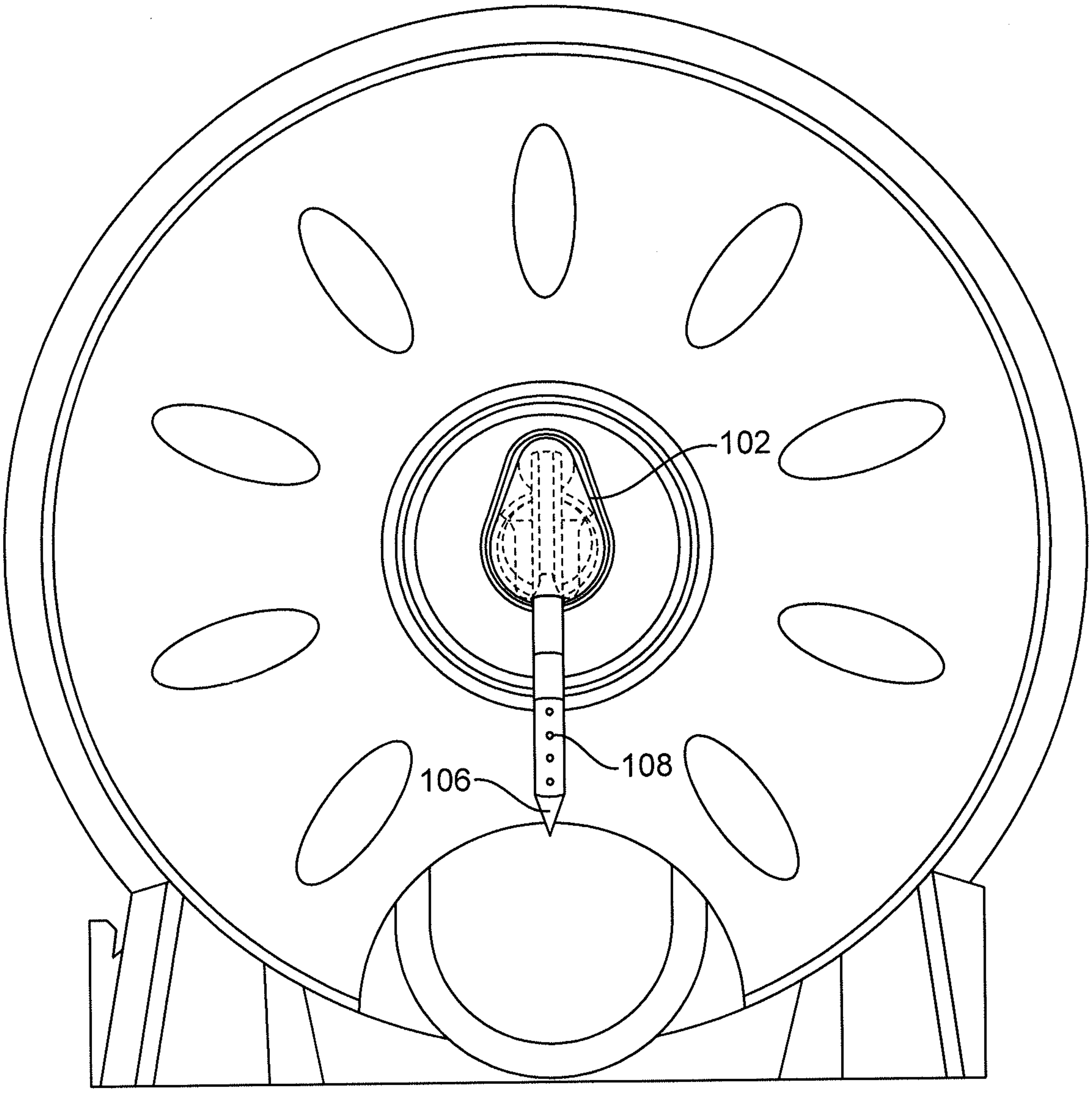

FIG. 2B

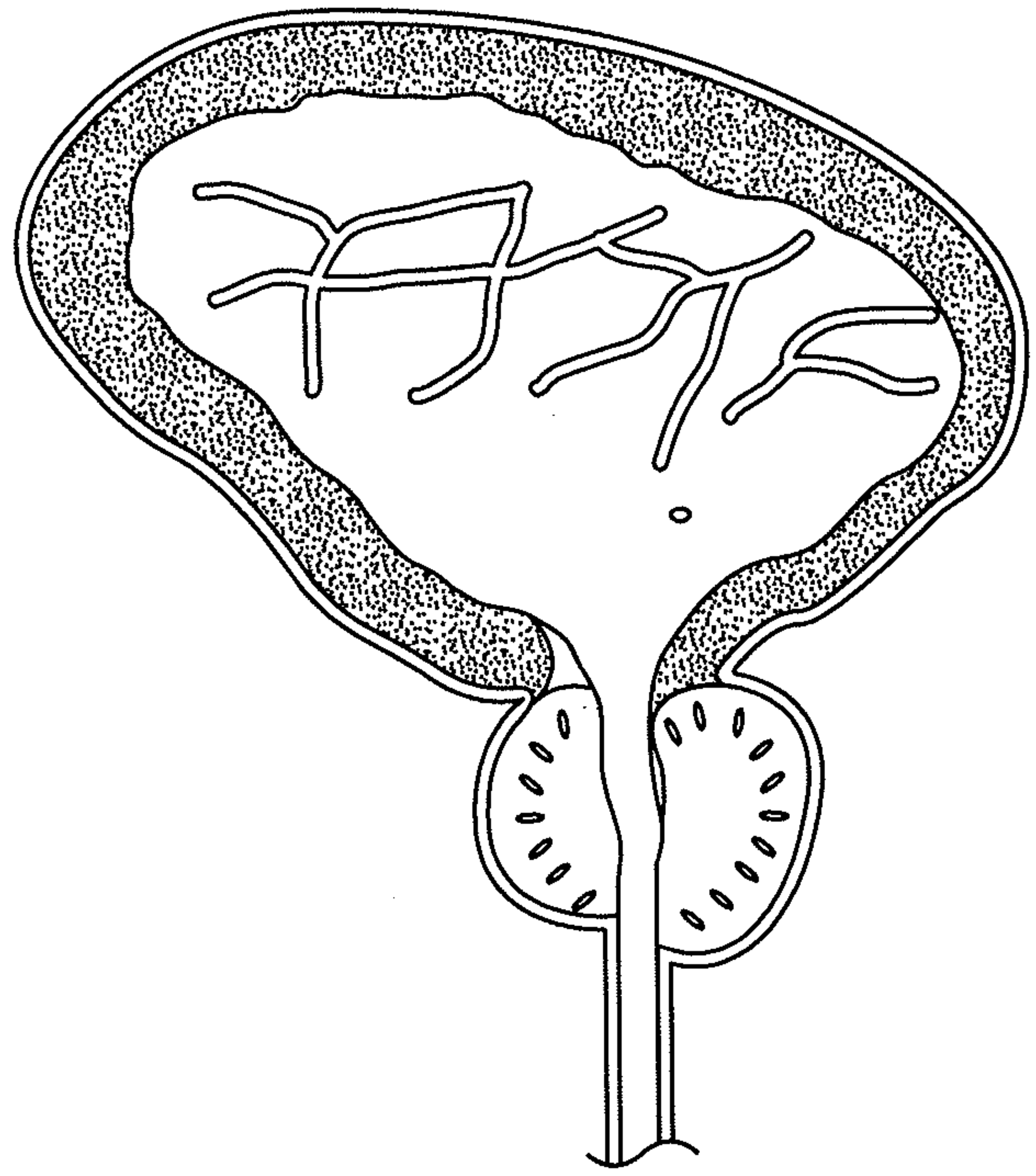

FIG. 2C

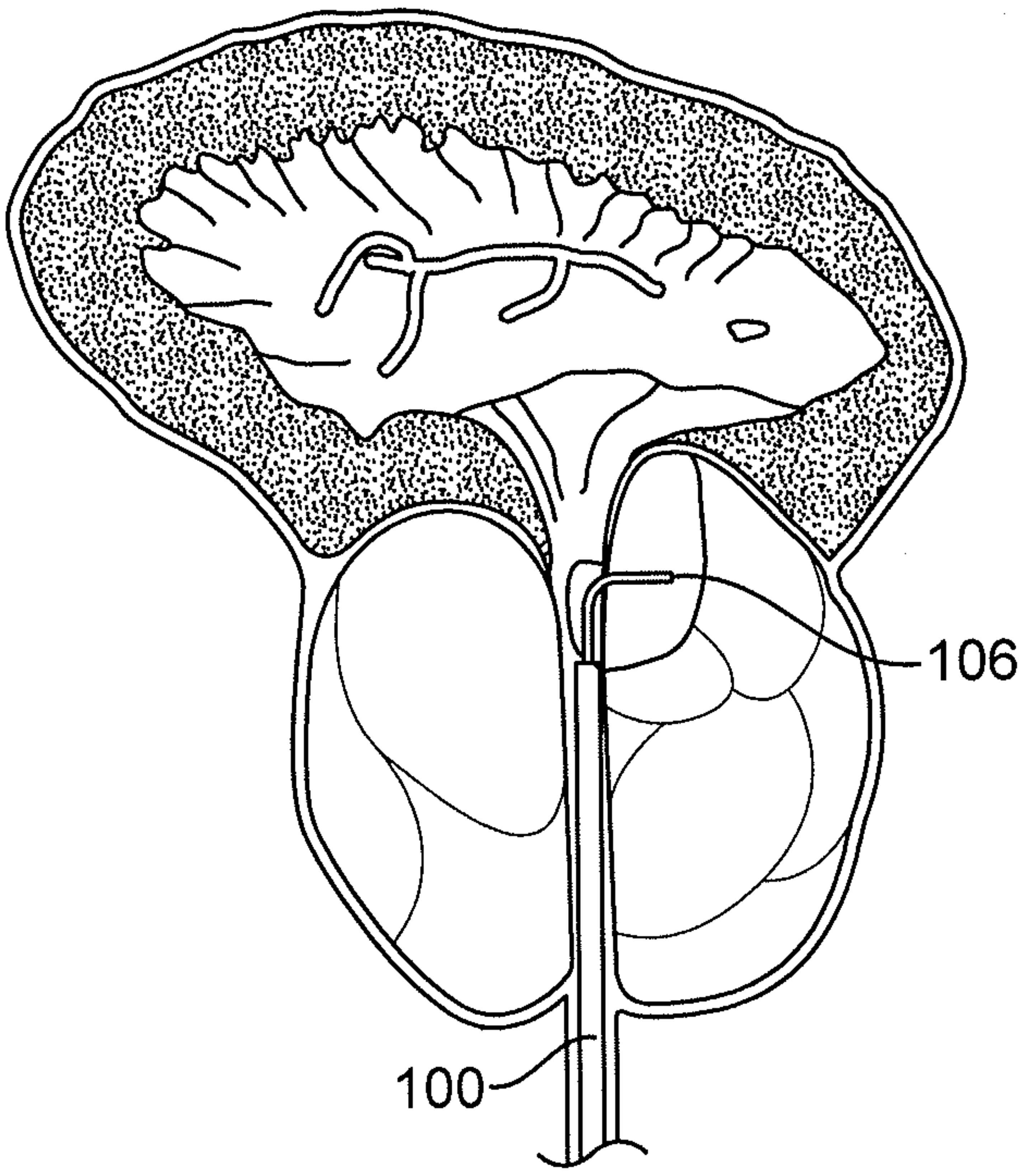

FIG. 2D

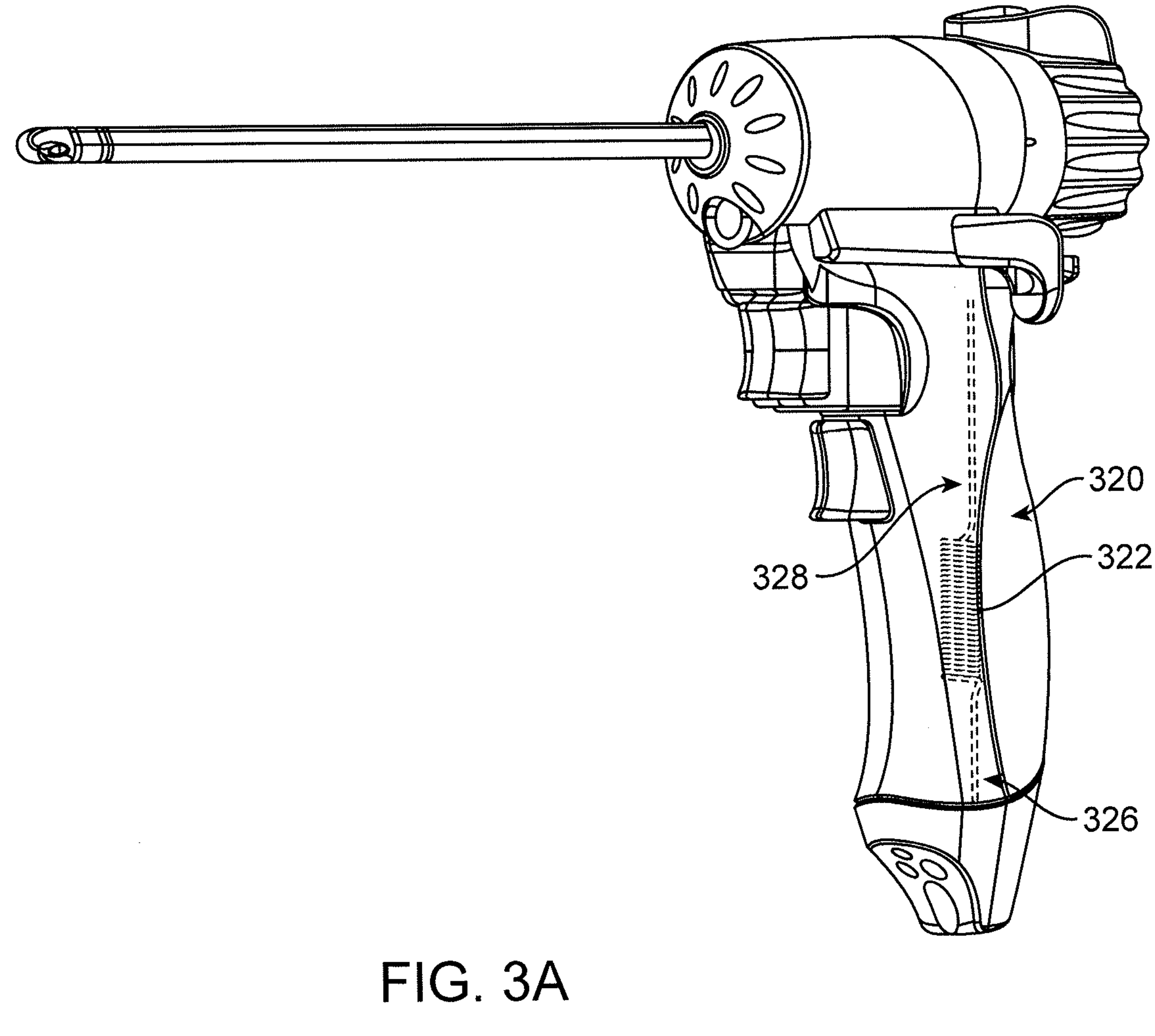

FIG. 3A

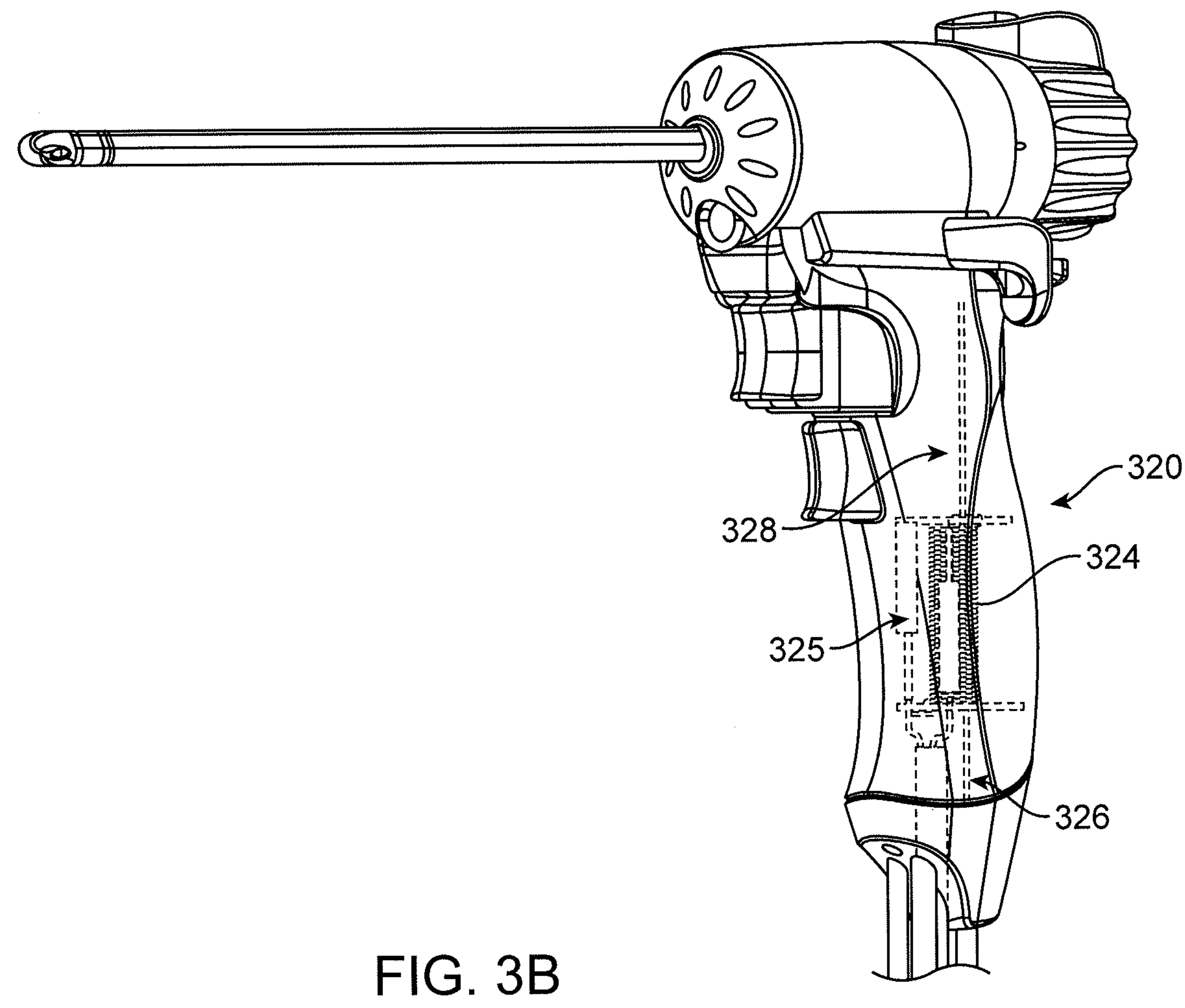

FIG. 3B

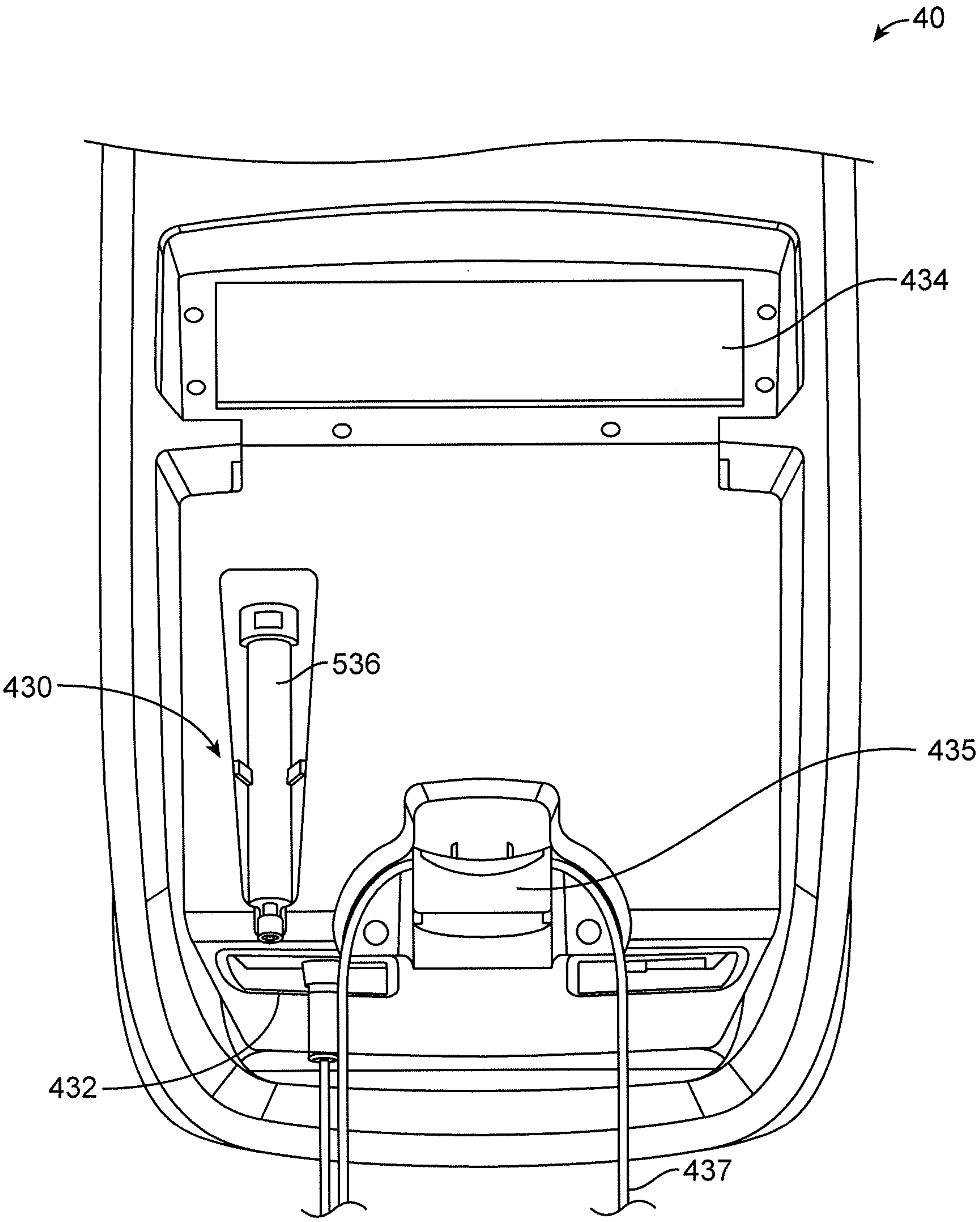

FIG. 4

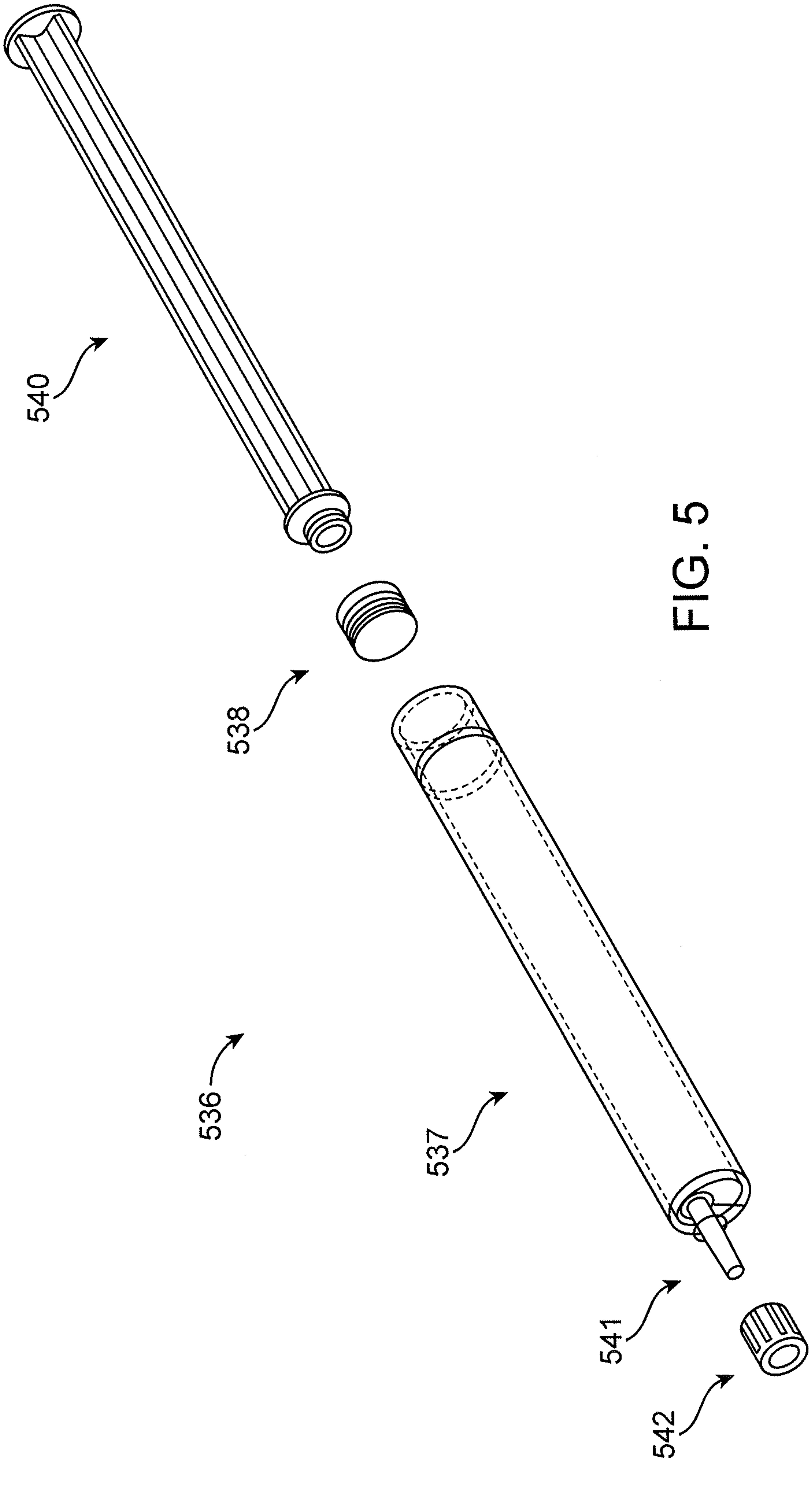

FIG. 5

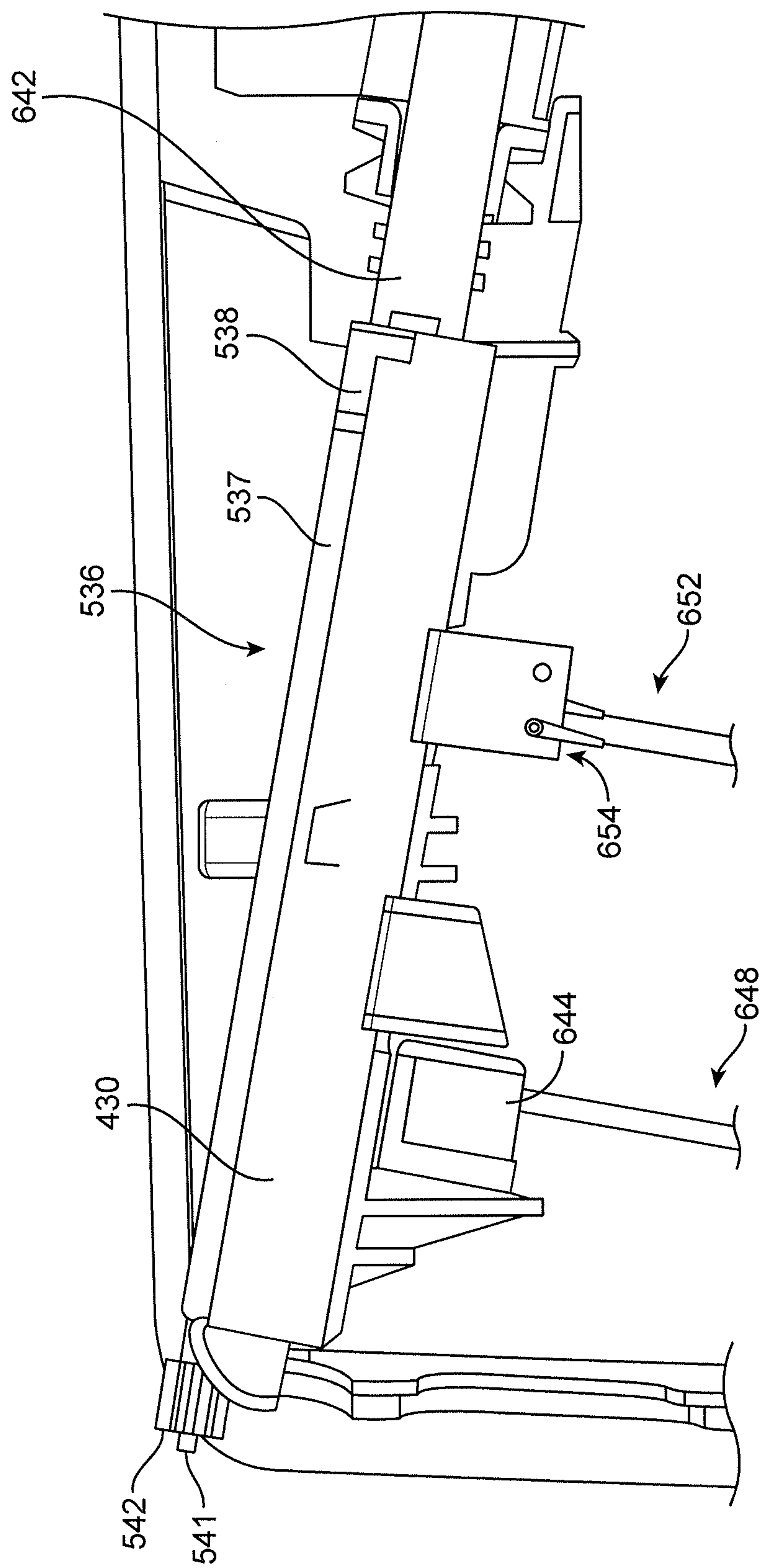

FIG. 6

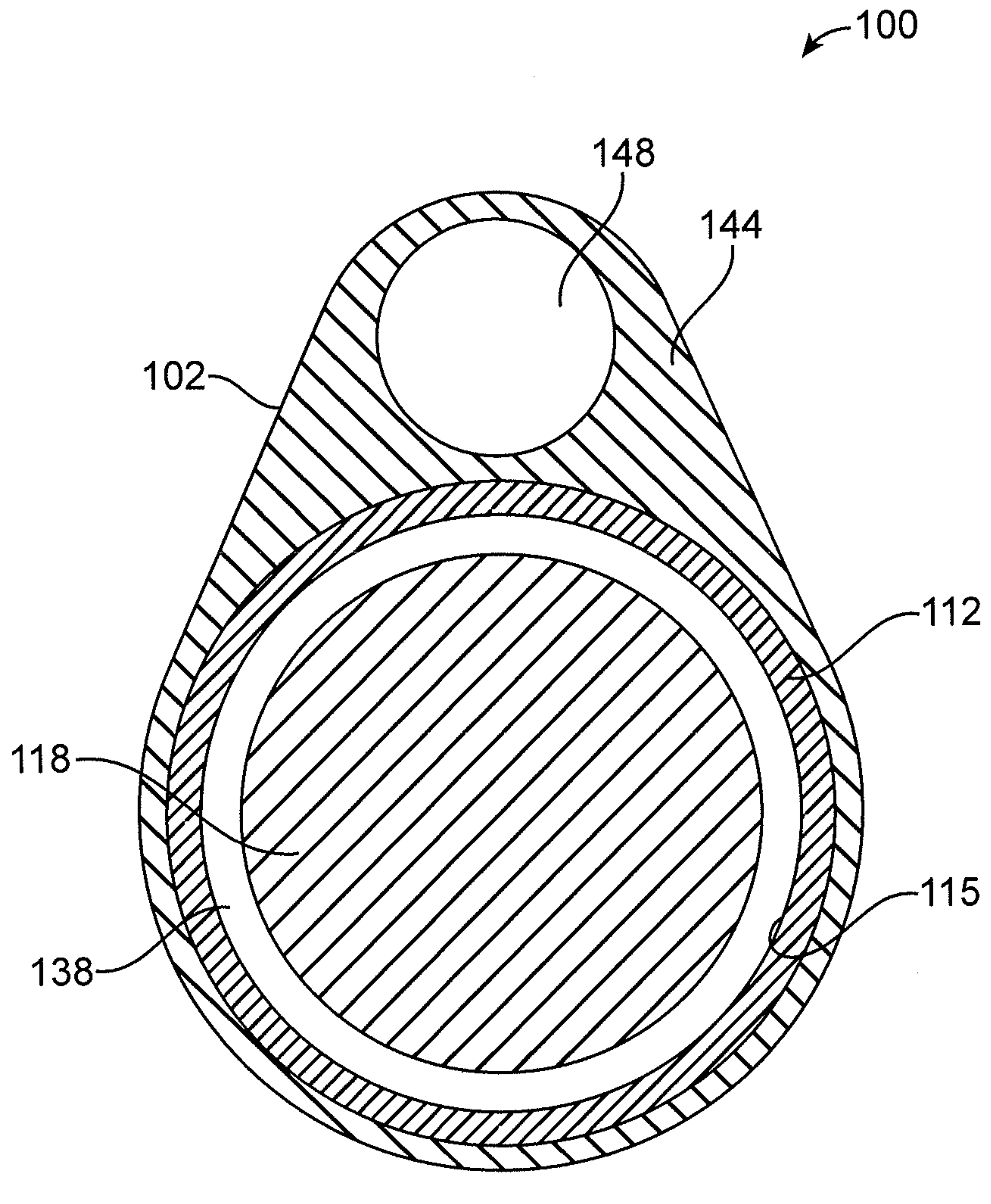

FIG. 7

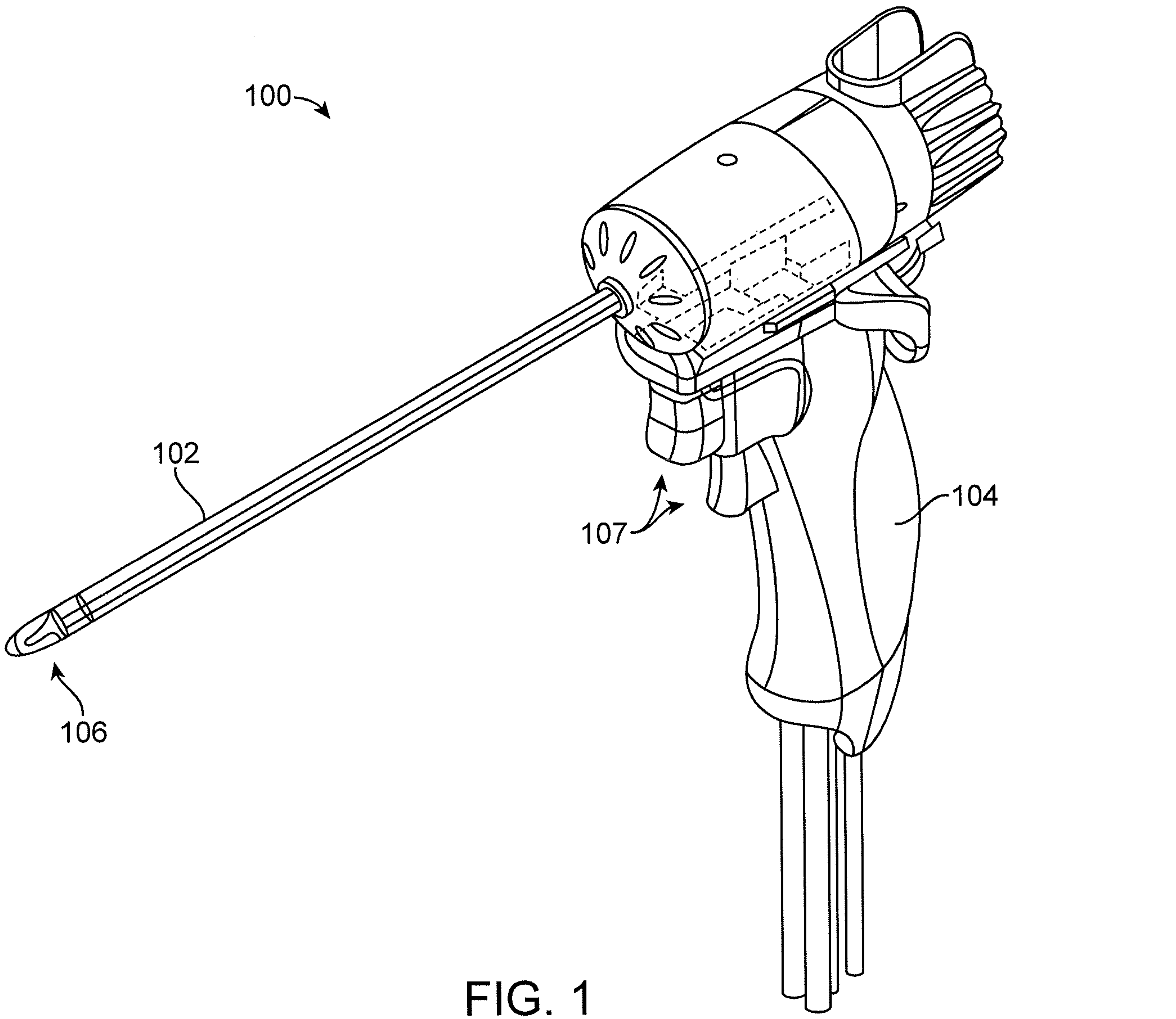

FIG. 1