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(54) **CRANIAL DRILL SYSTEM**

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(57) **ABSTRACT**

(21) Appl. No.: **16/444,089**

The invention concerns a cranial drill system comprising one or more surgical drill elements for drilling into the brain. The invention also concerns a cranial drilling system comprising a surgical drill element for drilling into the skull and an element for penetrating the dura. The surgical drill element may comprise a profile that forms an opening in the skull having a narrower diameter portion and a wider diameter portion and the piercing element may be arranged to be a close fit in the narrower diameter portion of the opening. The invention also concerns a cranial drill system comprising a guiding element to be located in a hole formed through the skull and a piercing element for piercing the dura. The guiding element may have a passageway or channel therein for receiving the piercing element such that the piercing element is movable relative to the guide element to pierce the dura.

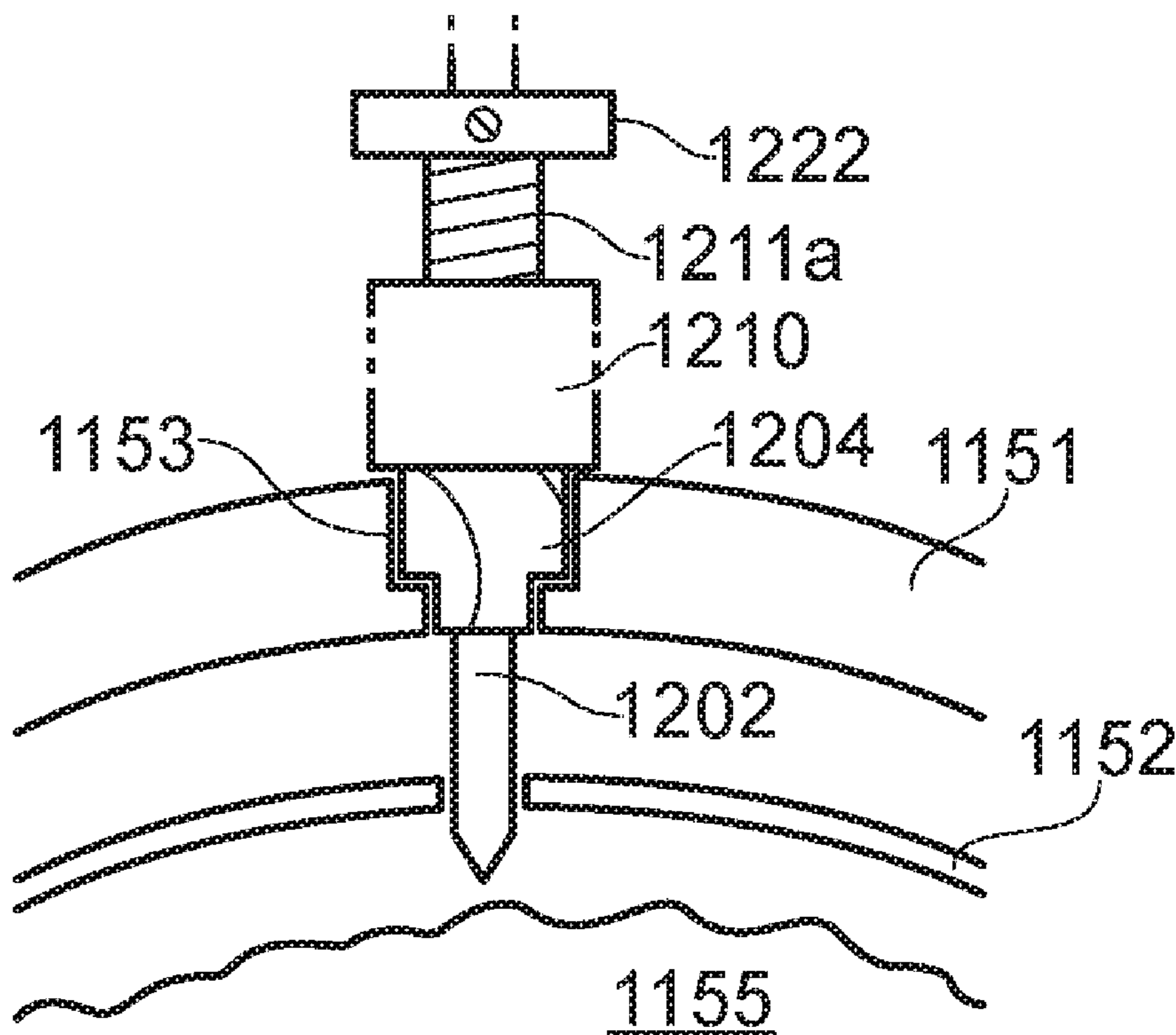
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(63) Continuation of application No. 14/403,862, filed on Nov. 25, 2014, now Pat. No. 10,363,049, filed as application No. PCT/GB2013/051451 on May 31, 2013.

(30) **Foreign Application Priority Data**

Jun. 1, 2012 (GB) 1209772.1



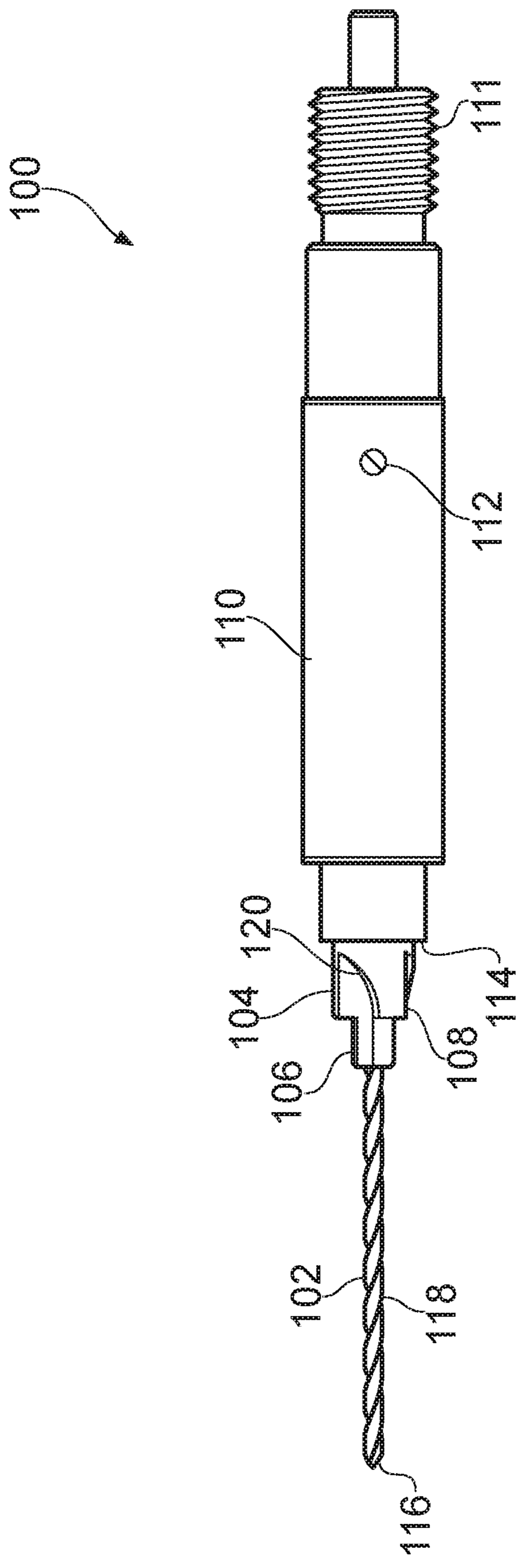


FIG. 1

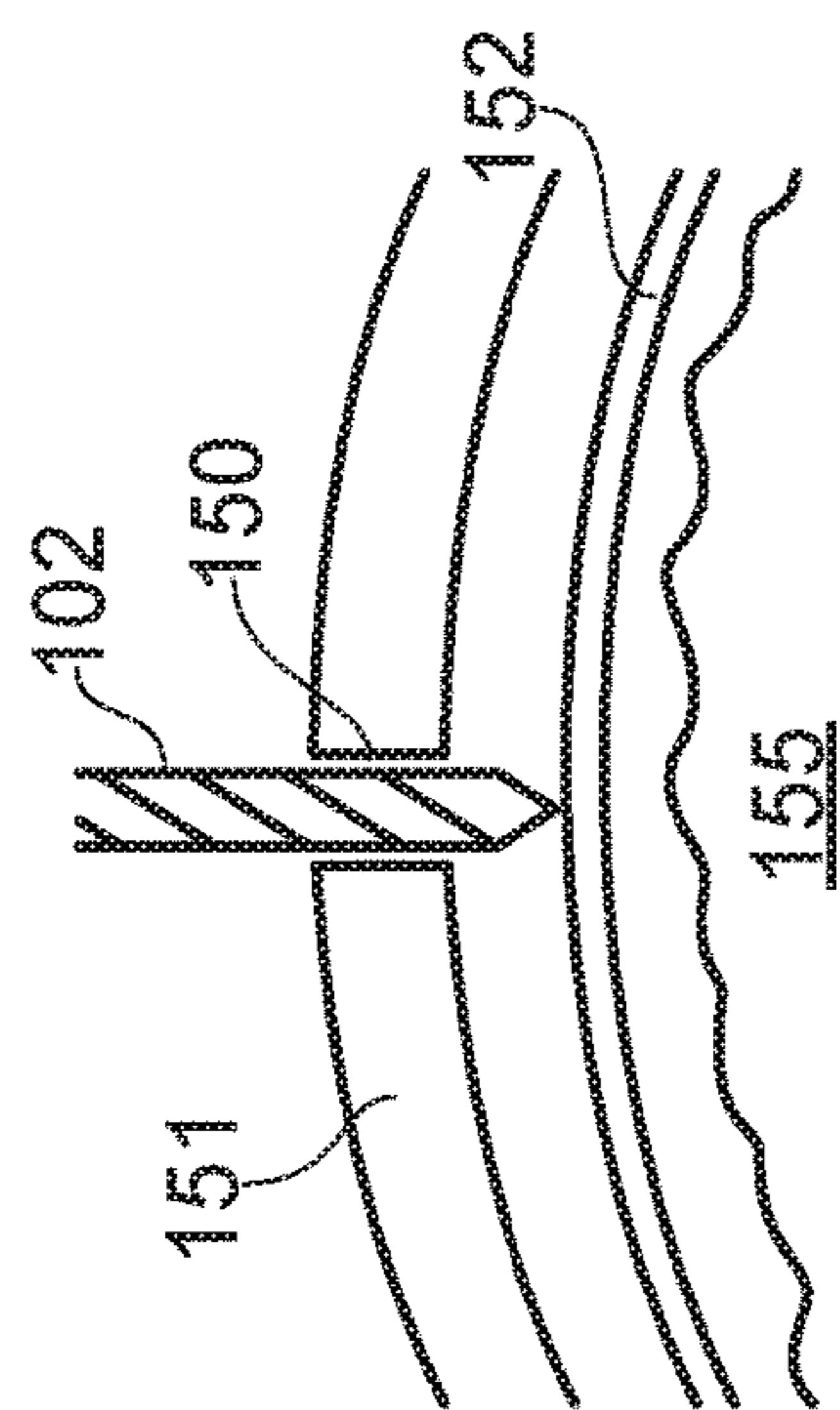


FIG. 2A

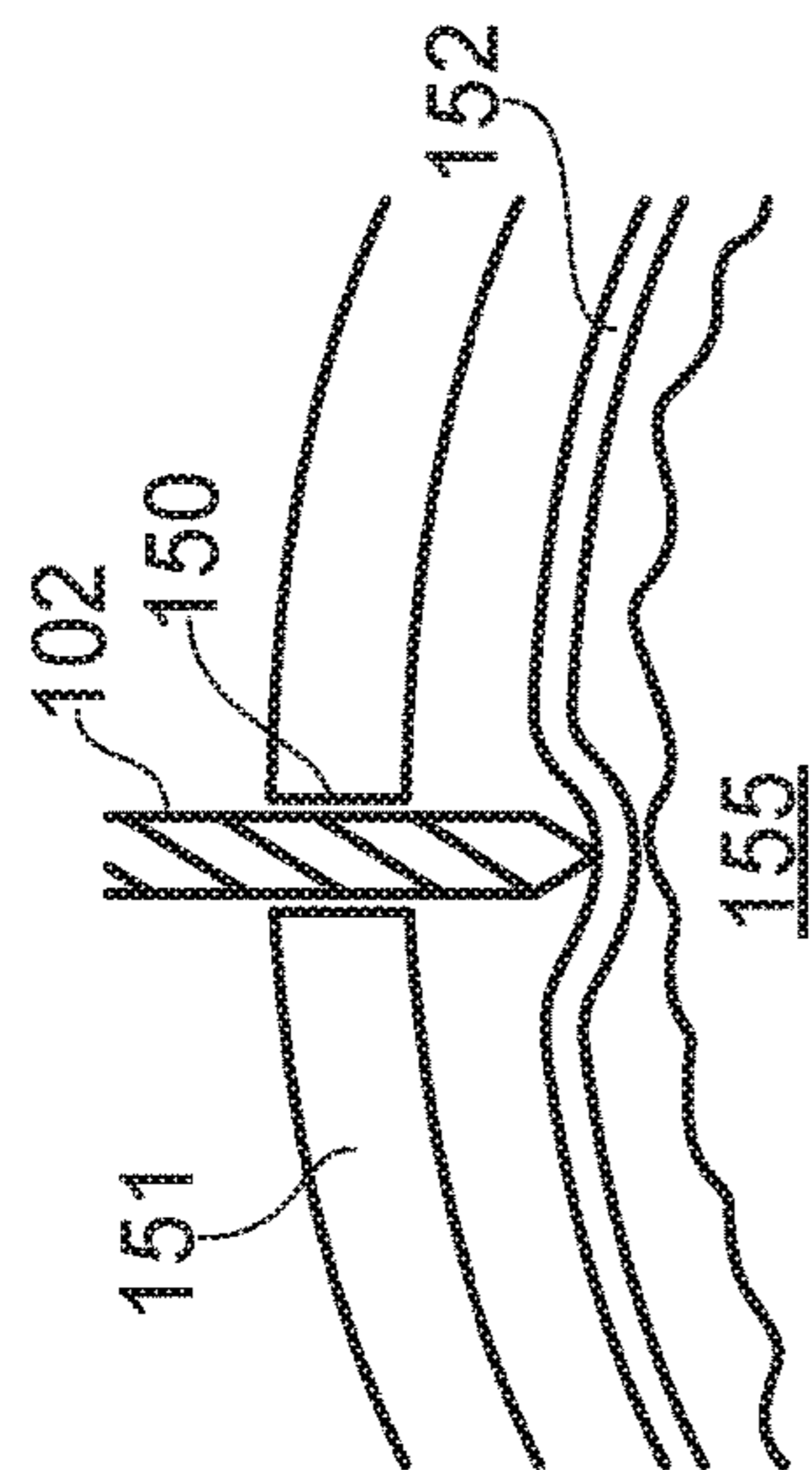


FIG. 2B

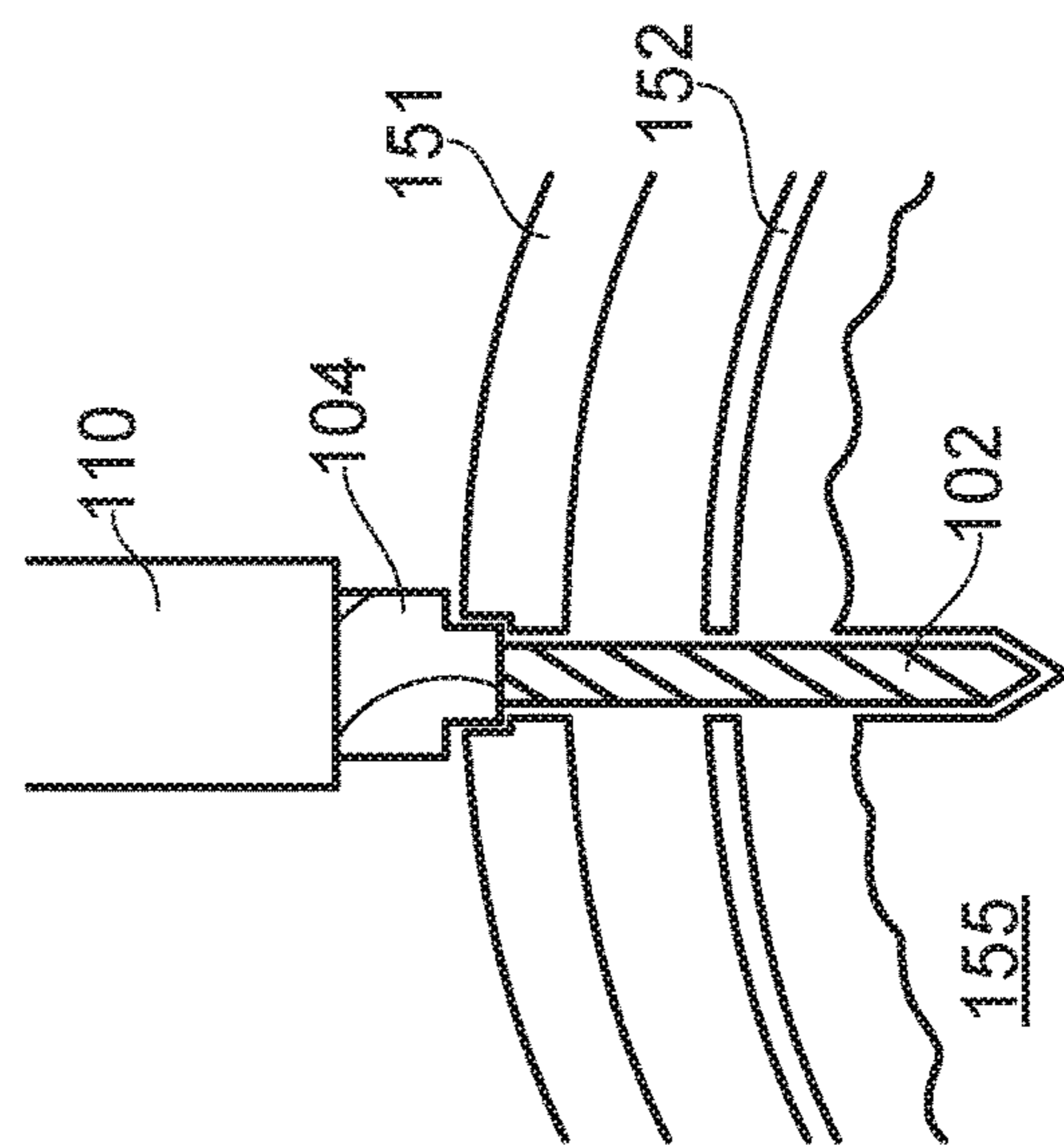


FIG. 2C

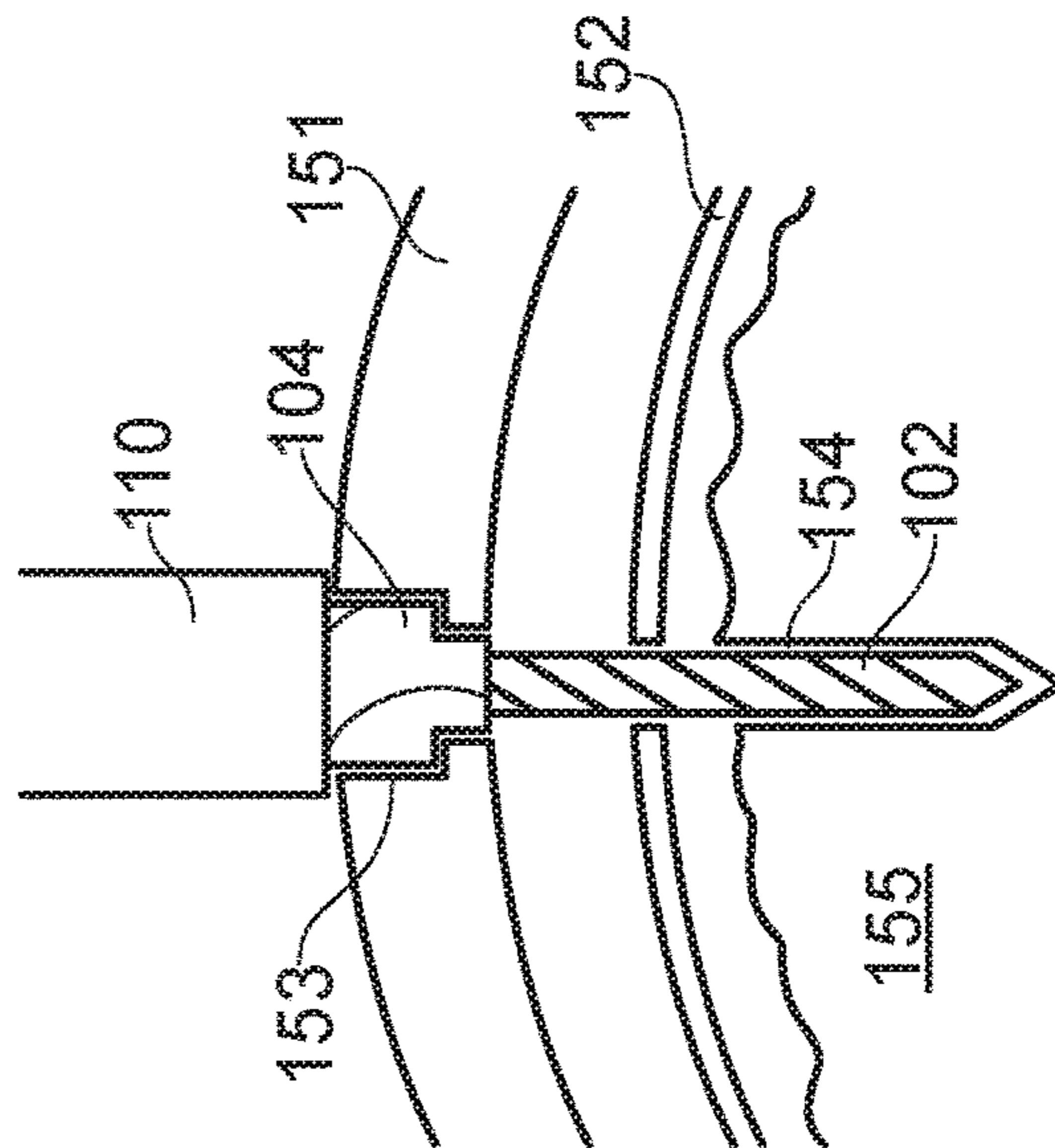


FIG. 2D

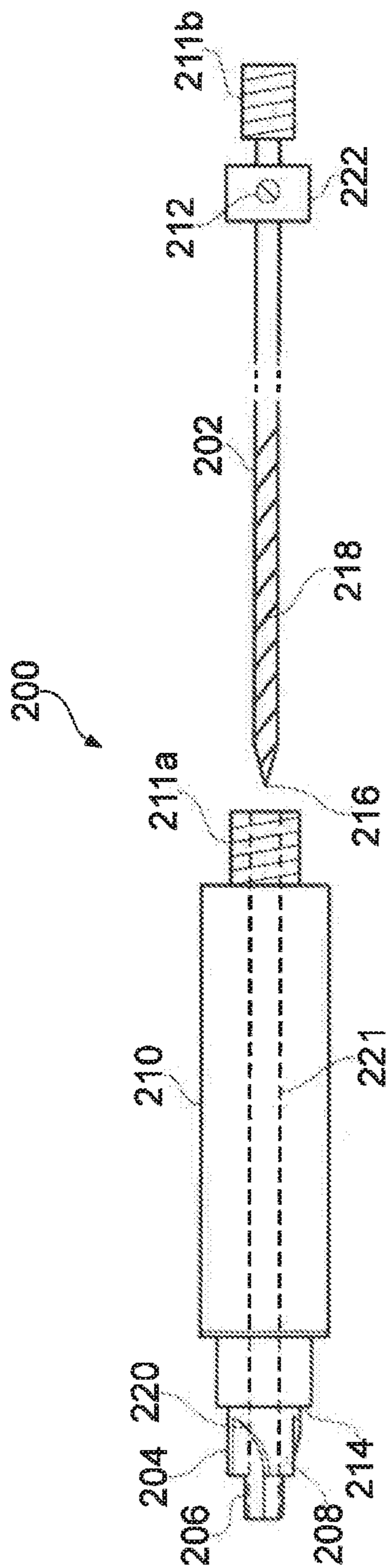


FIG. 3

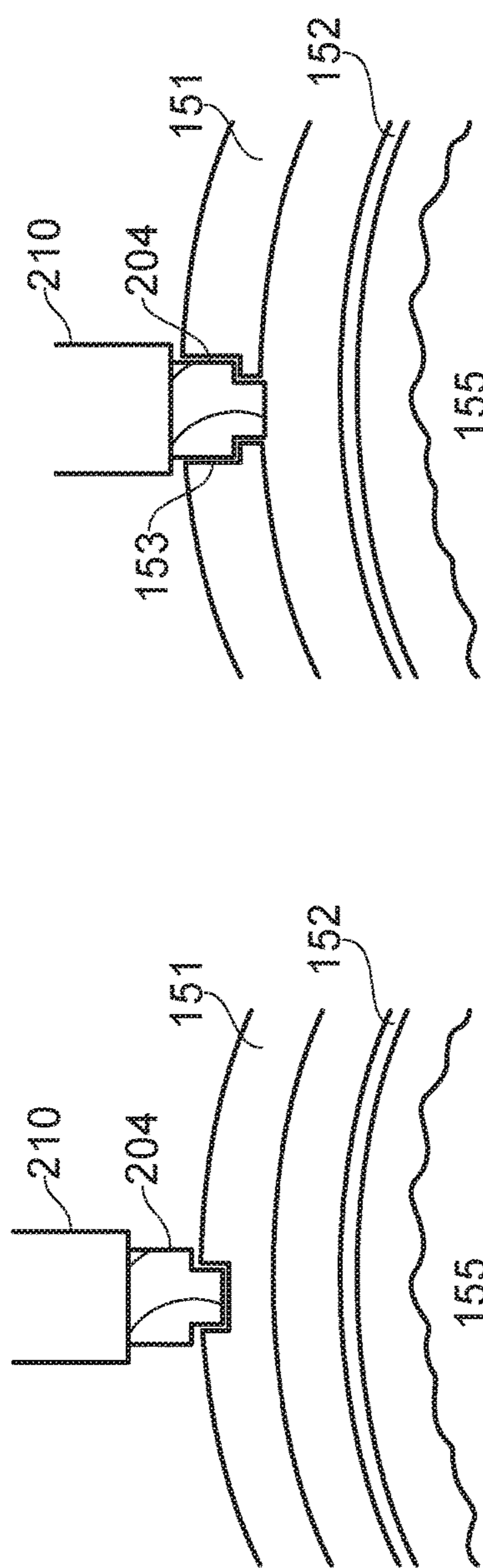


FIG. 4A

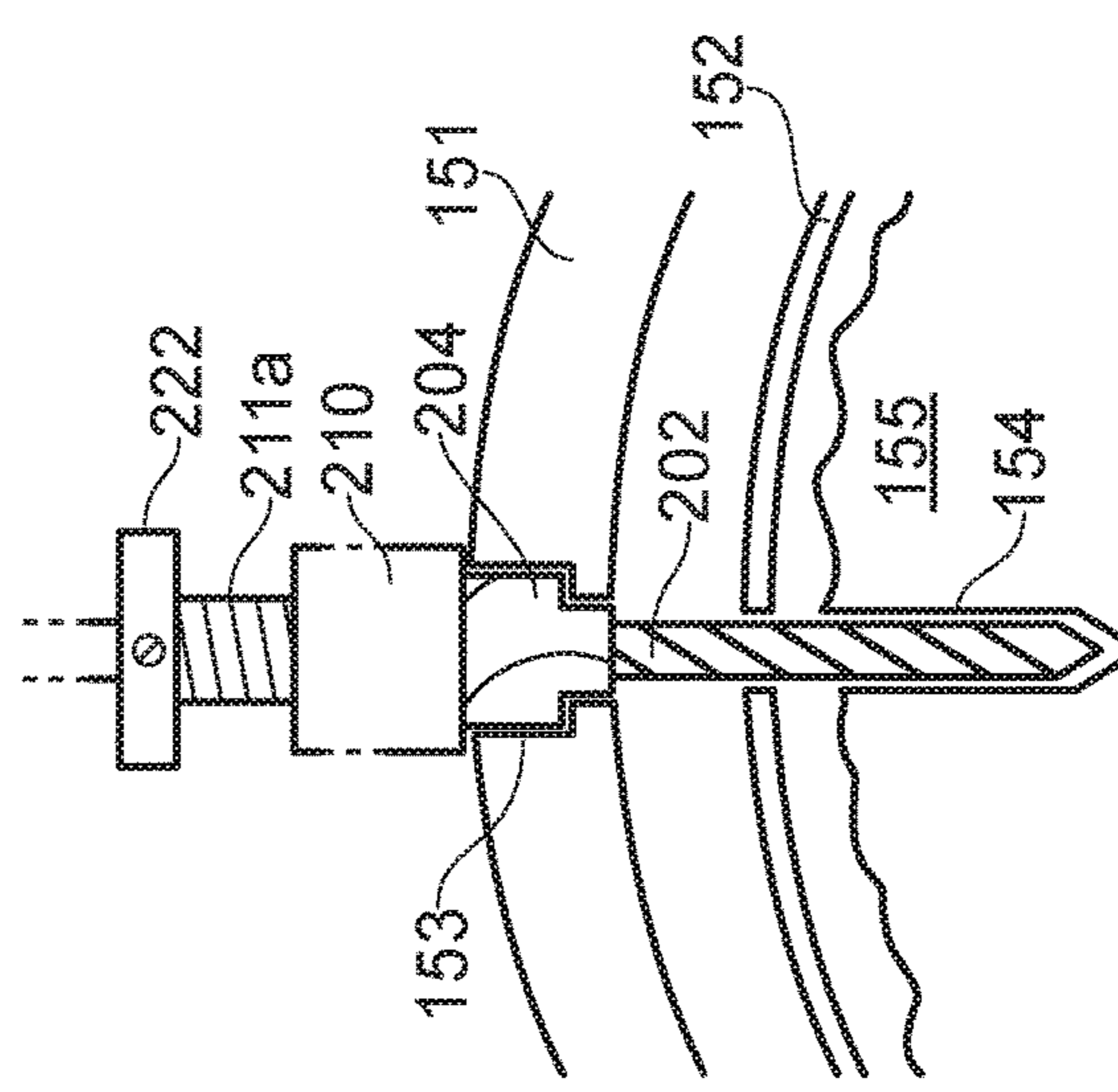


FIG. 4B

FIG. 4D

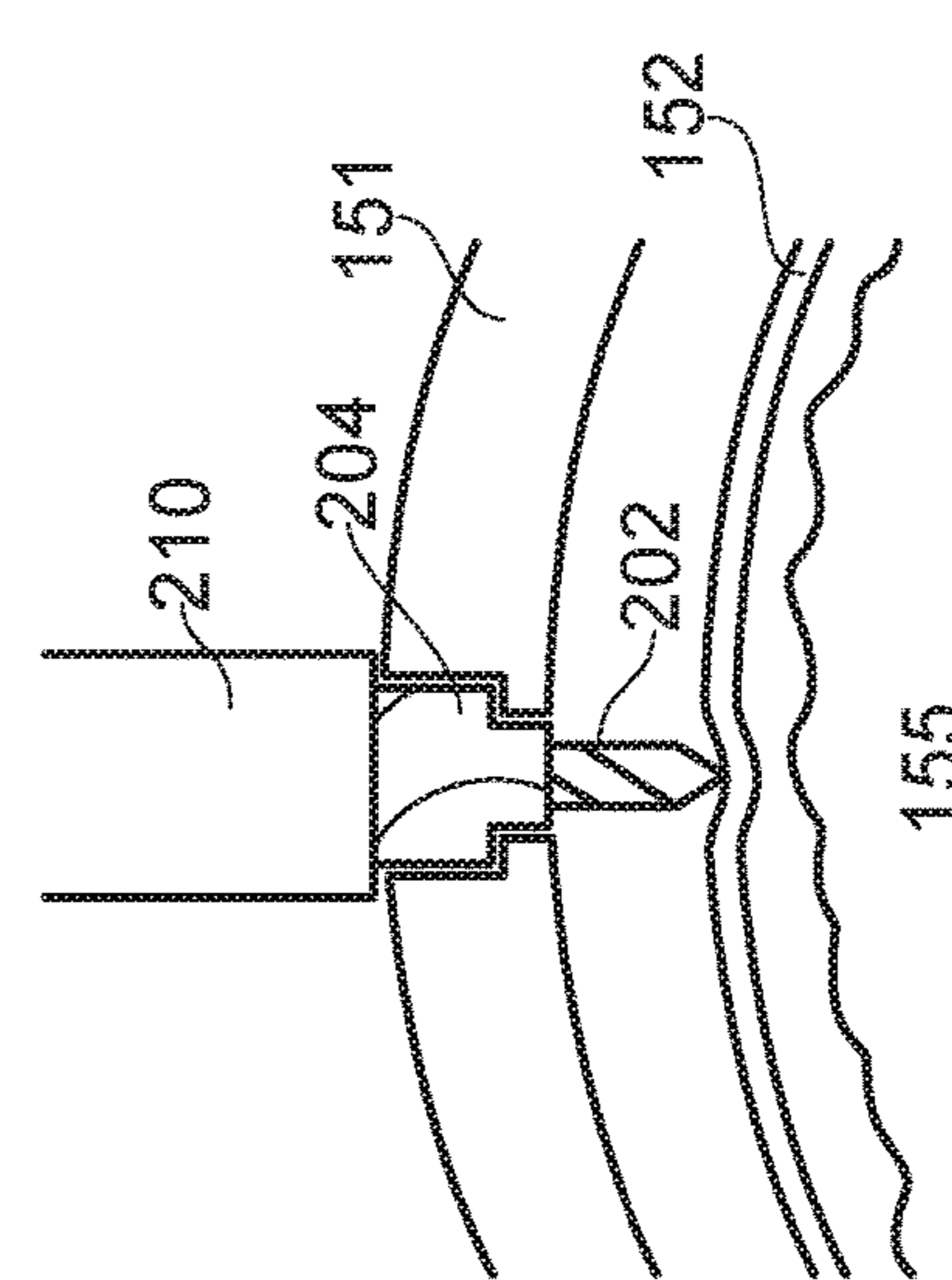


FIG. 4C

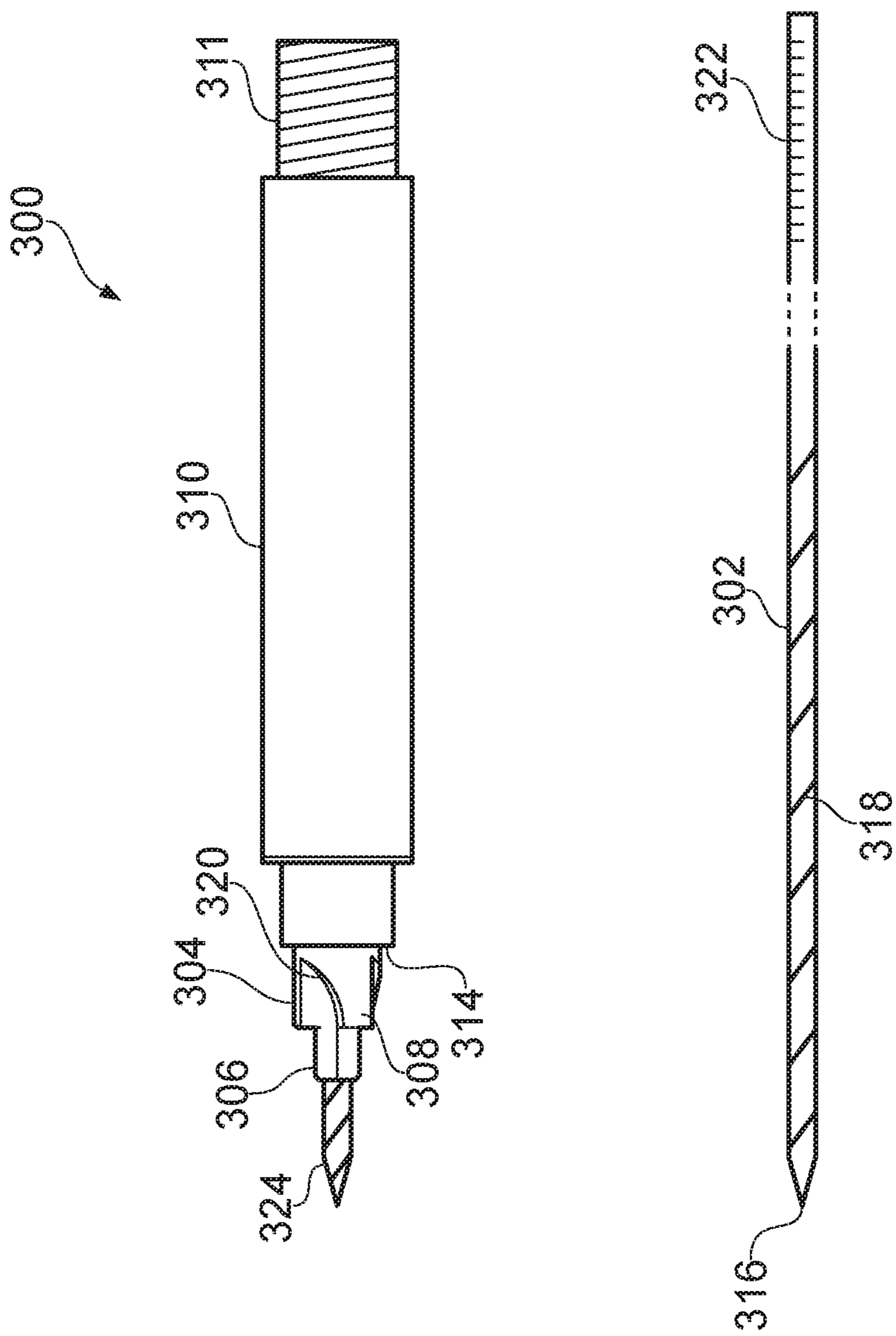


FIG. 5

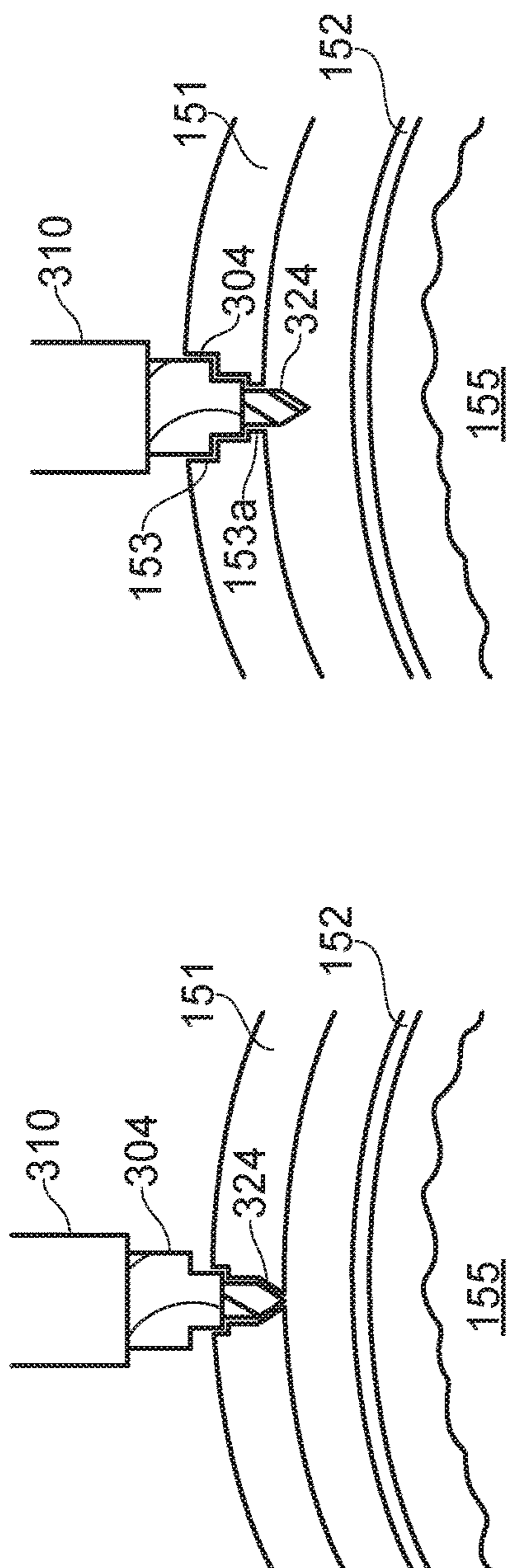


FIG. 6A

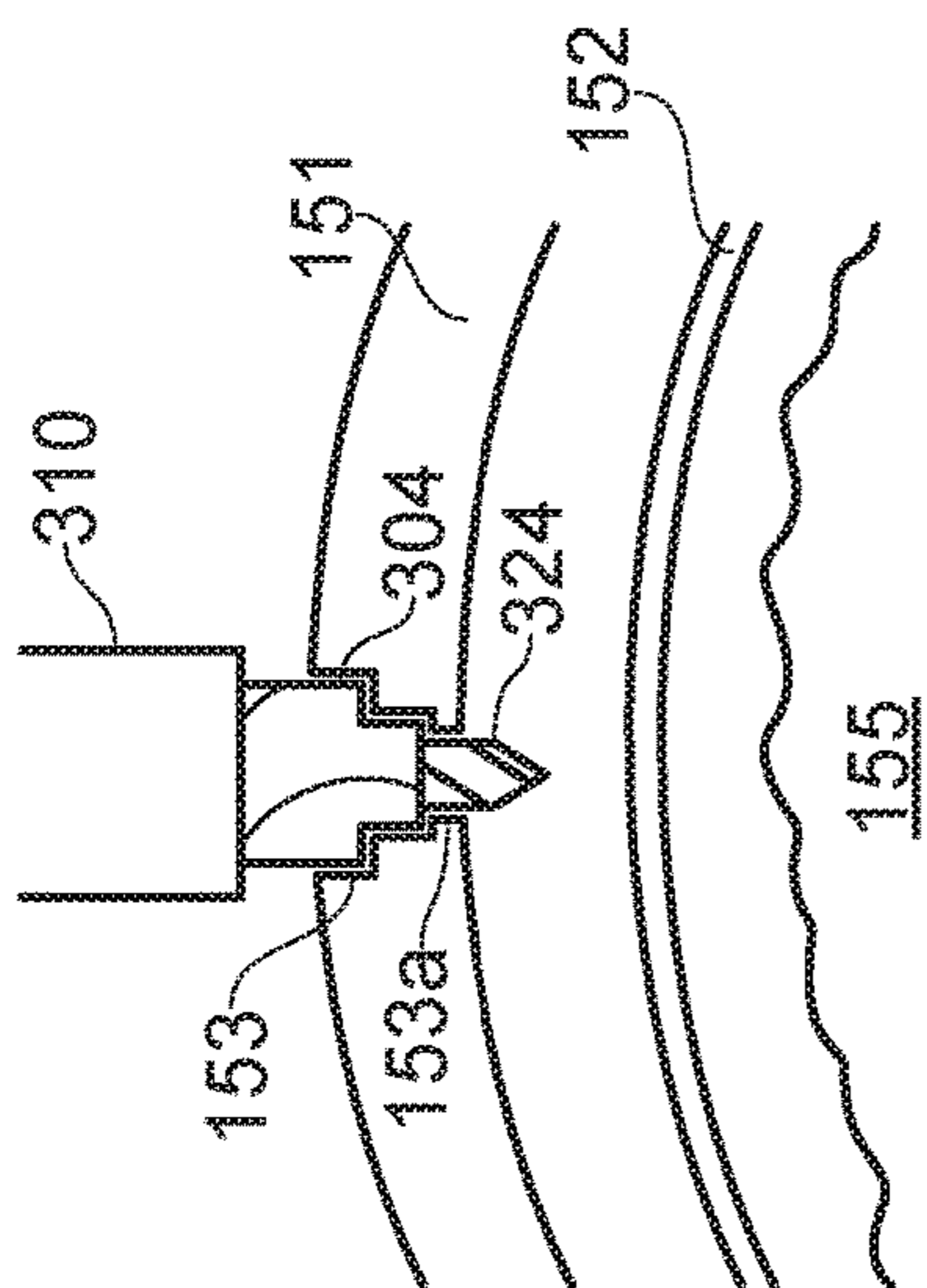


FIG. 6B

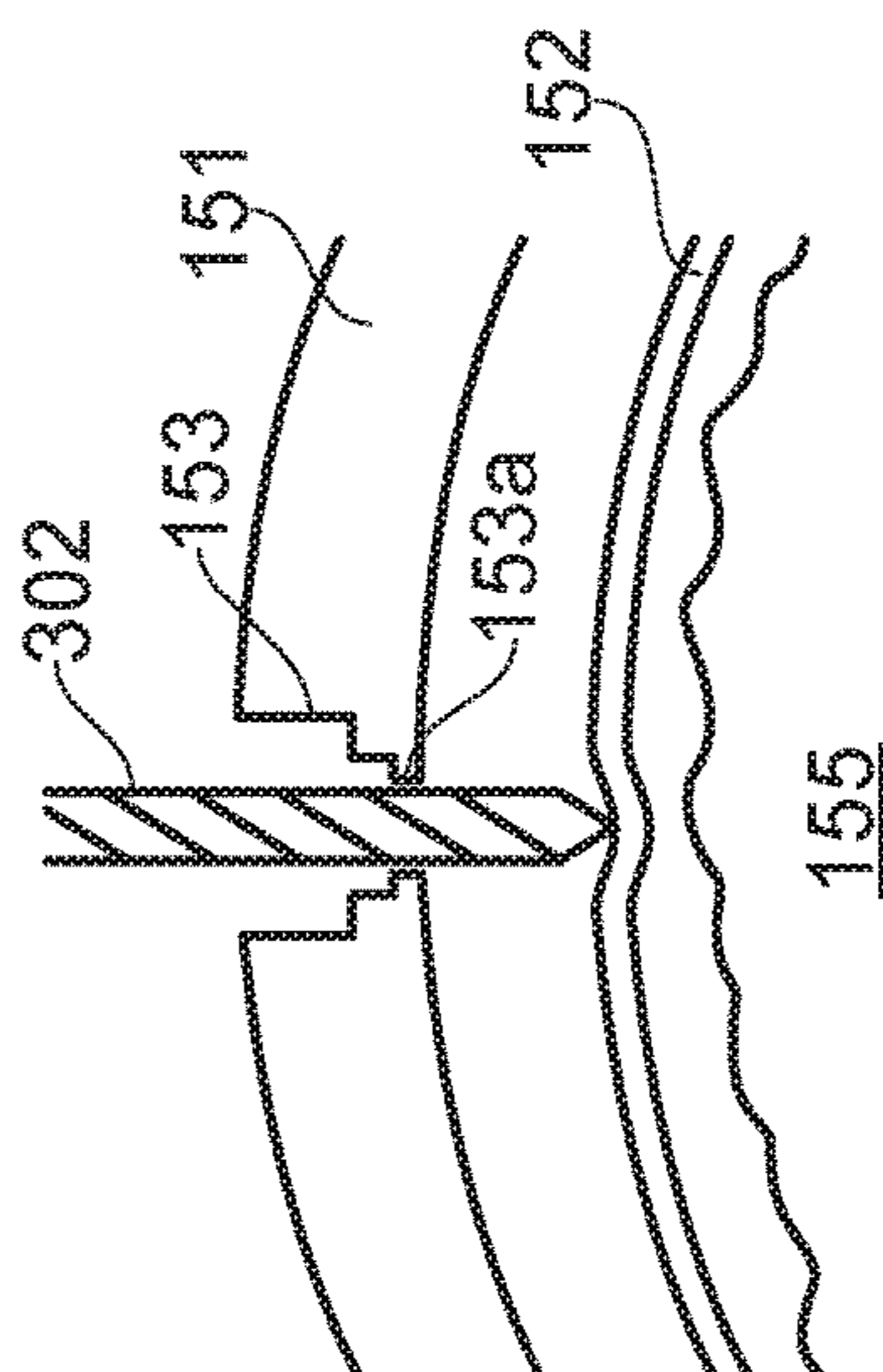


FIG. 6C

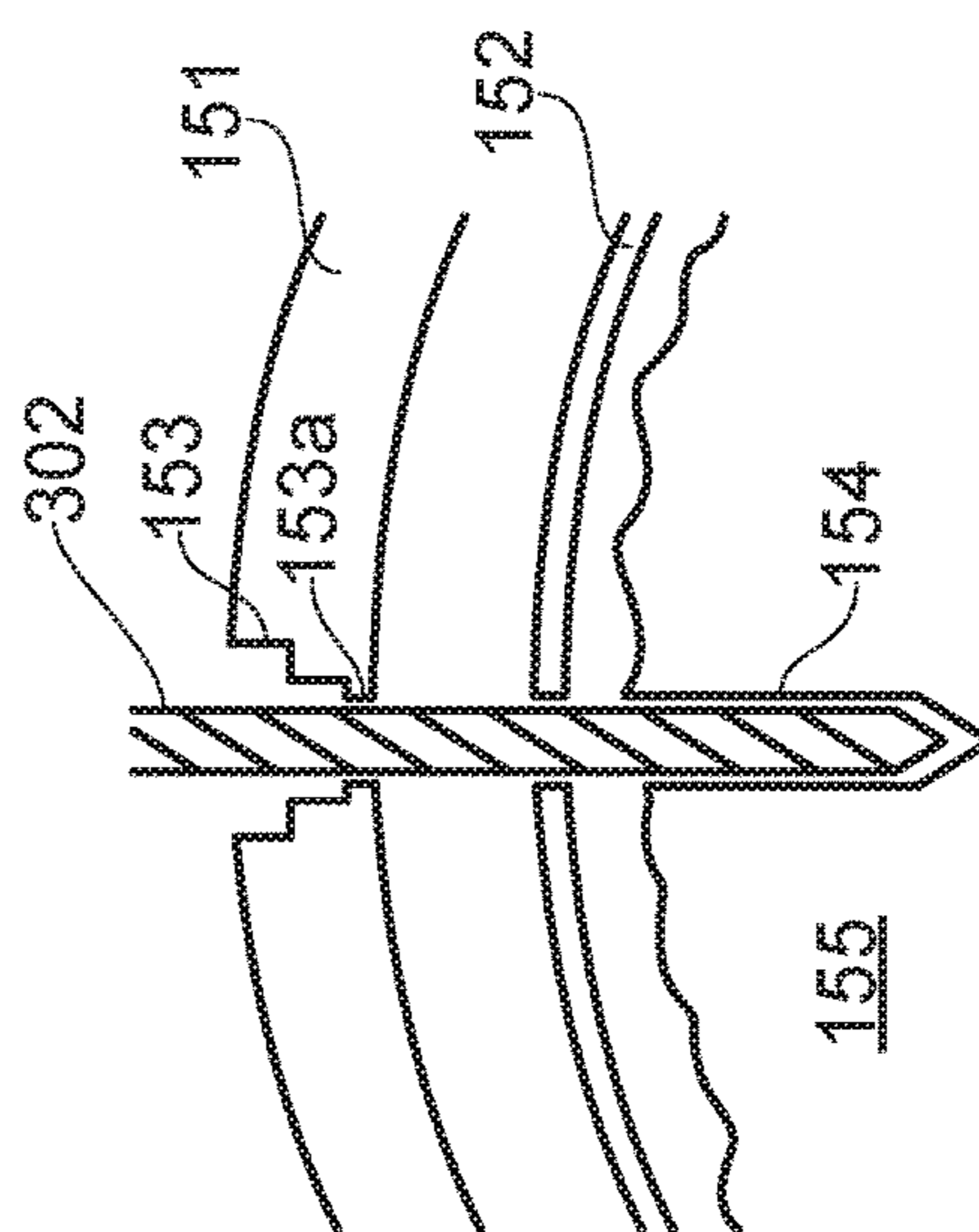


FIG. 6D

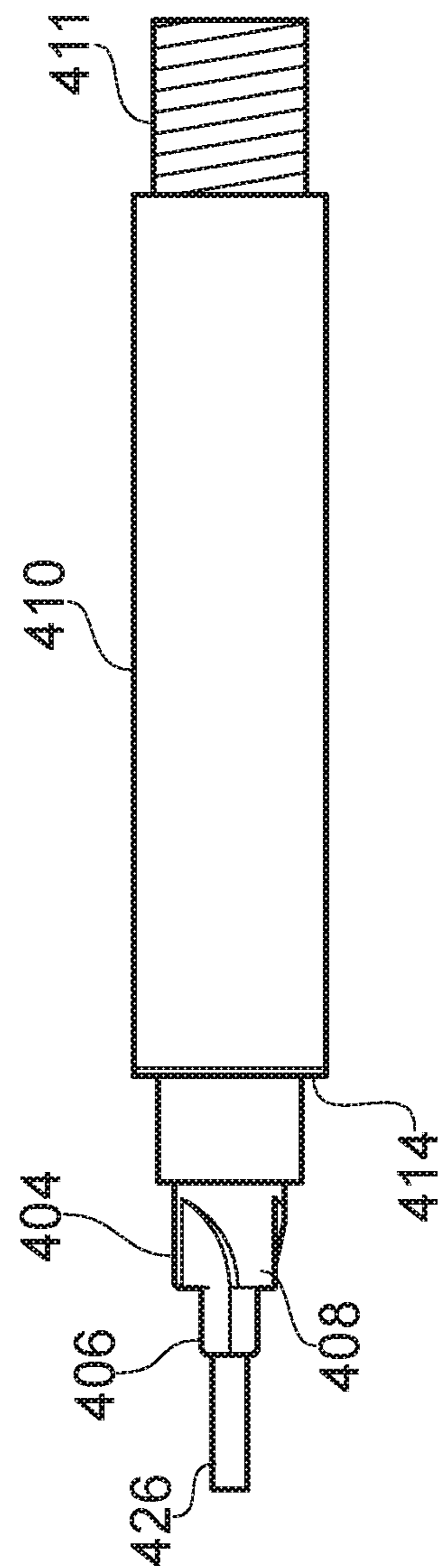
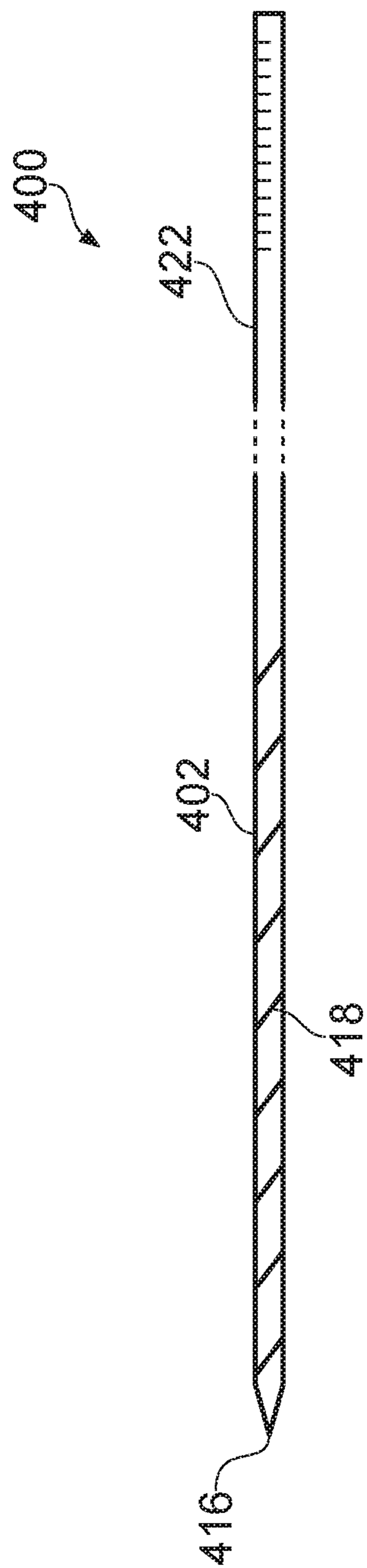


FIG. 7

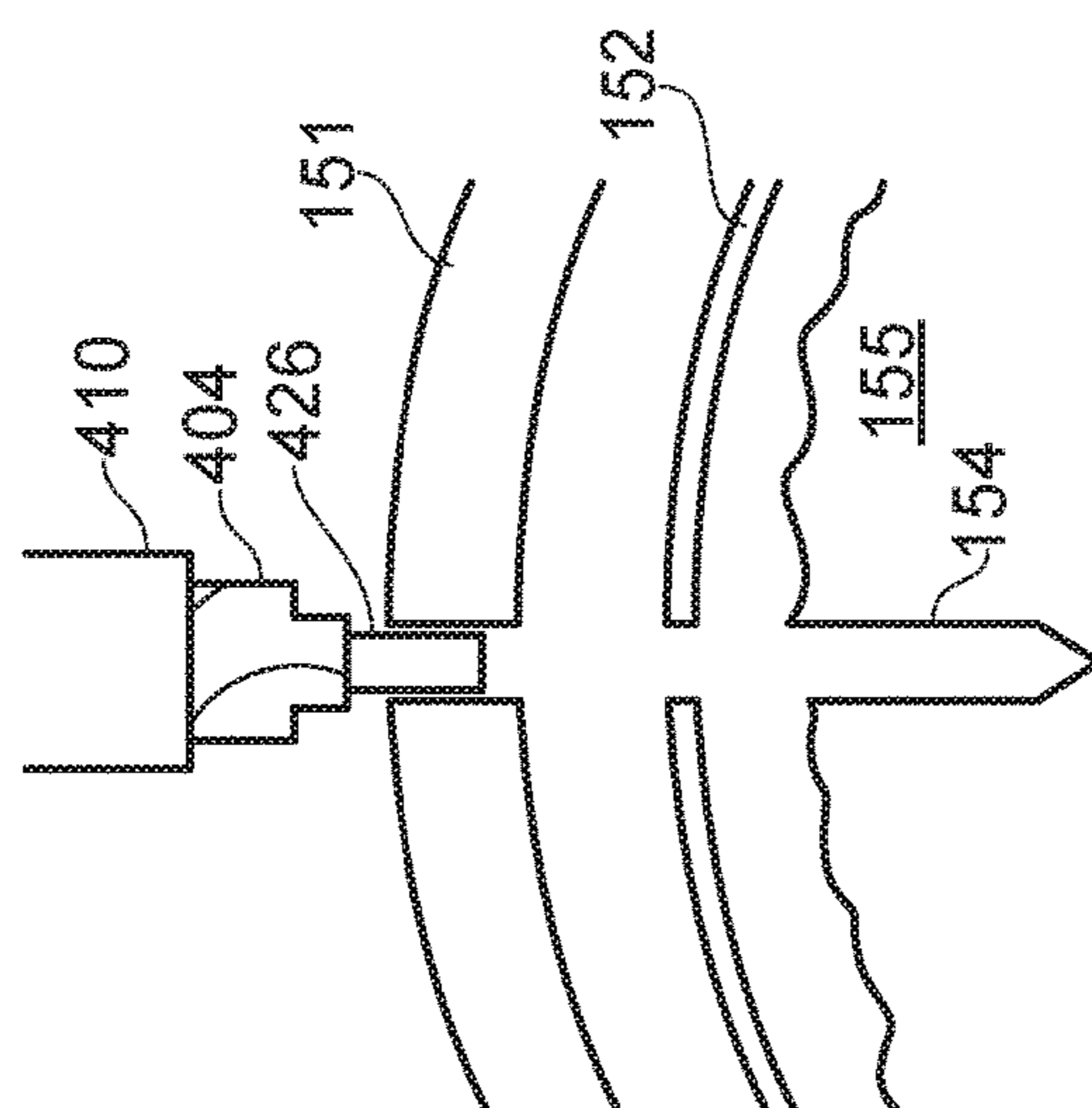


FIG. 8B

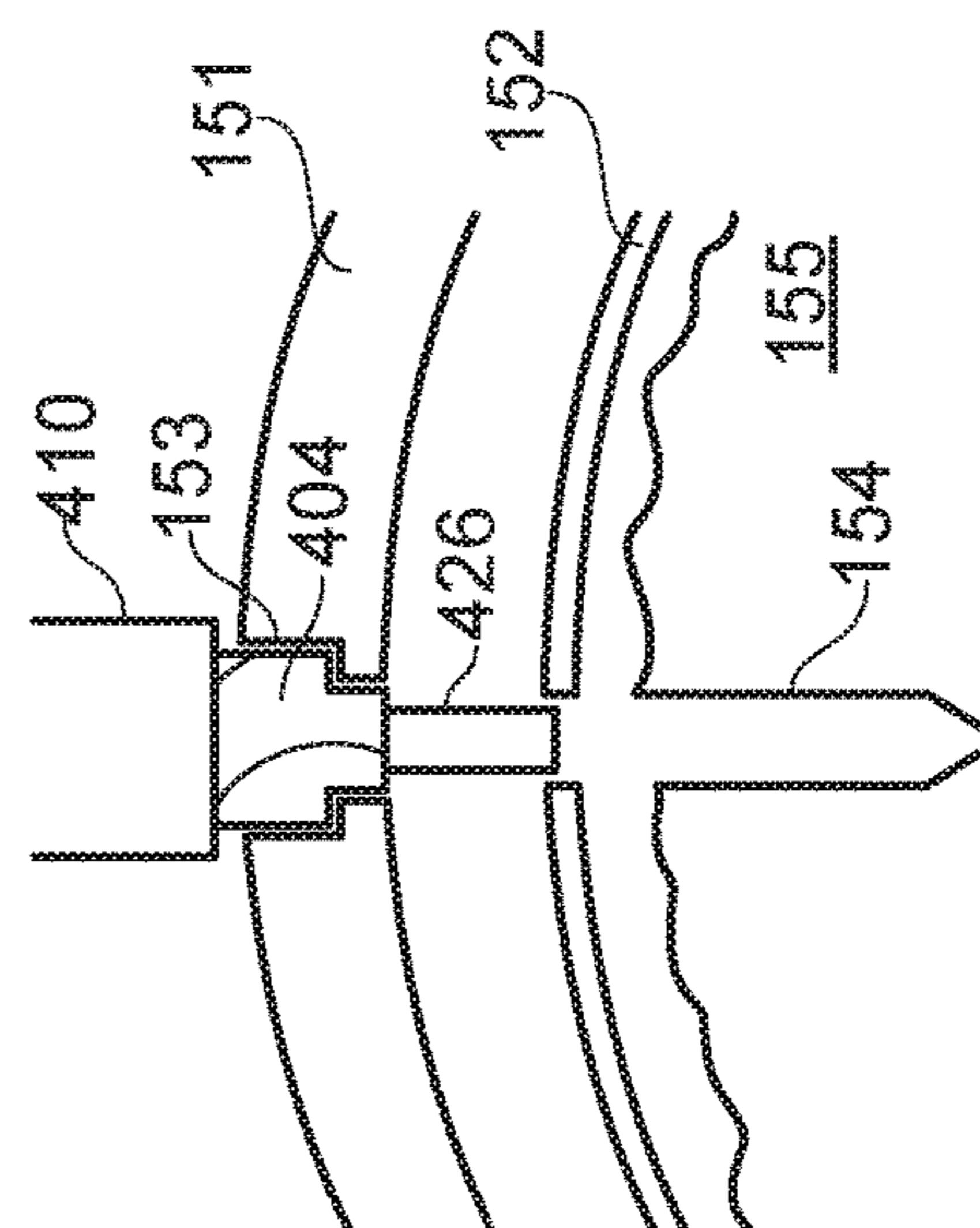


FIG. 8D

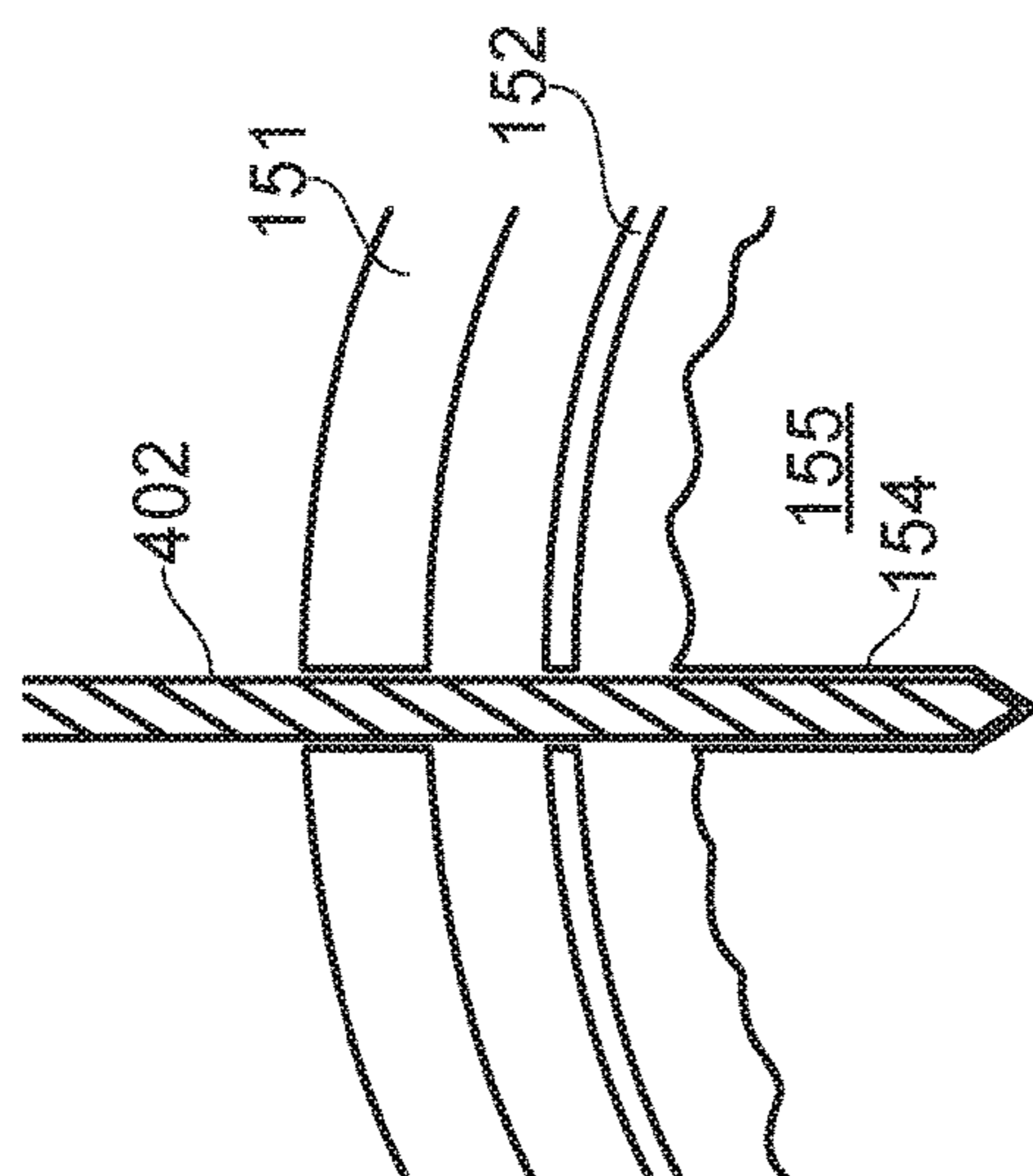


FIG. 8A

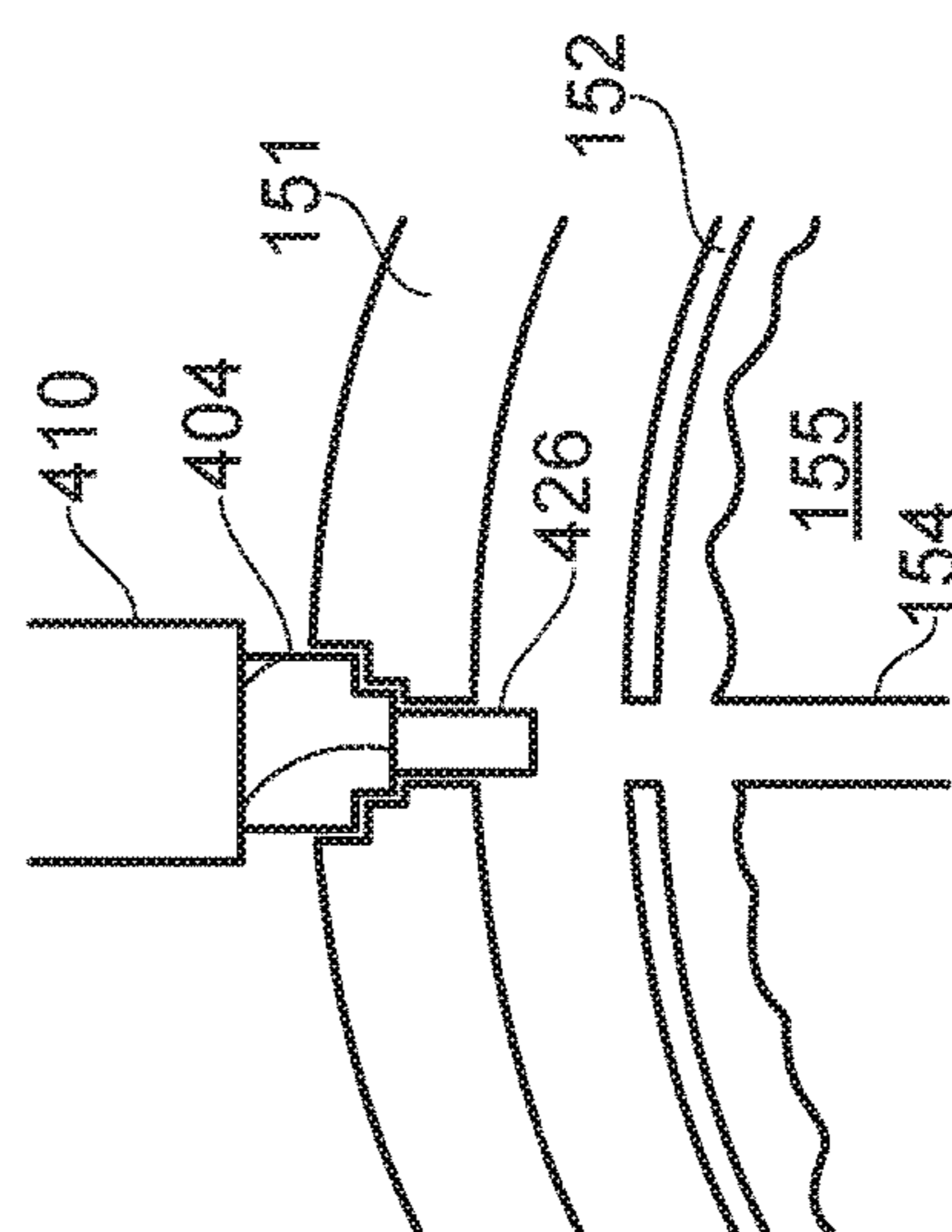


FIG. 8C

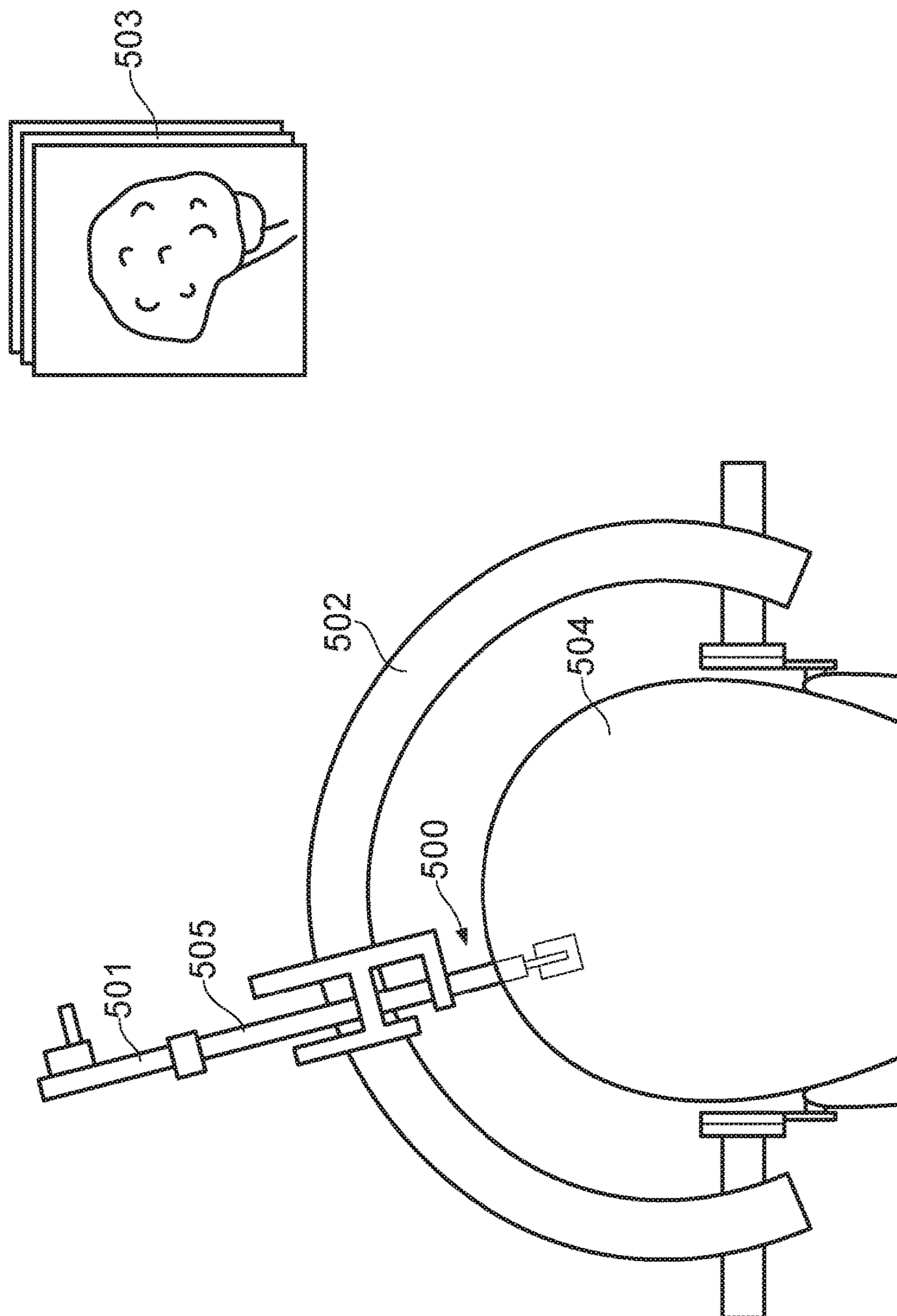


FIG. 9

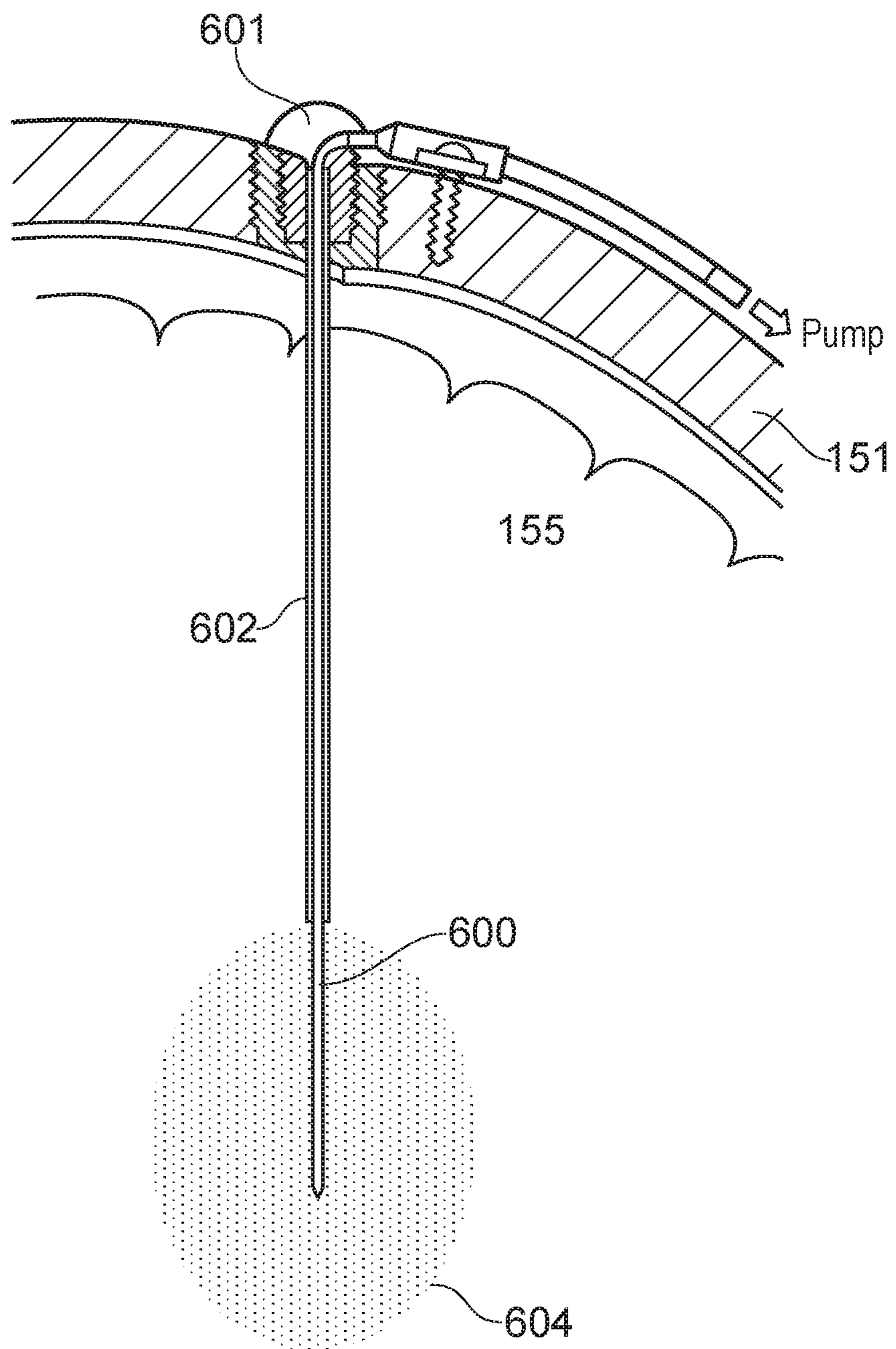


FIG. 10

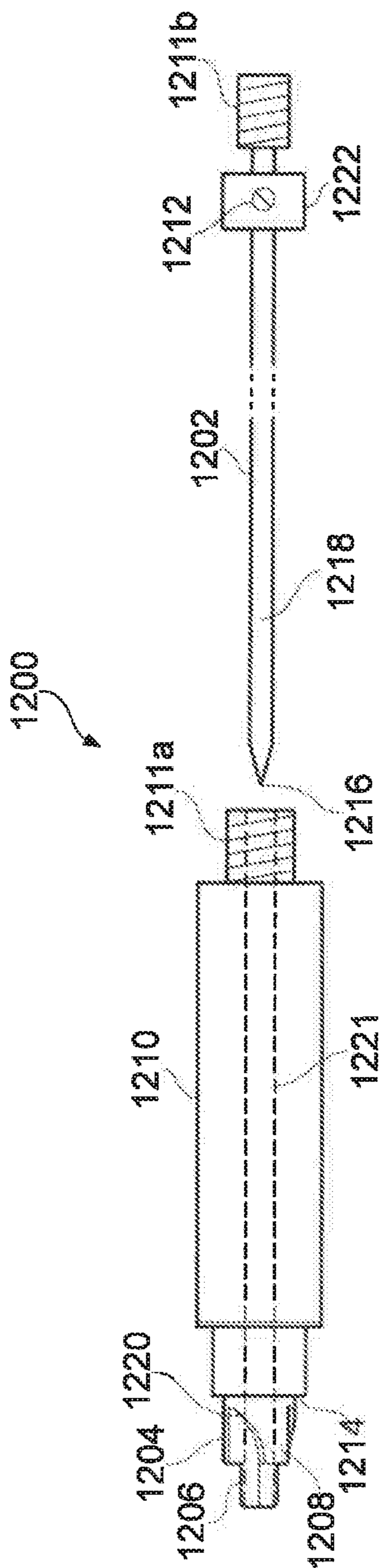


FIG. 11

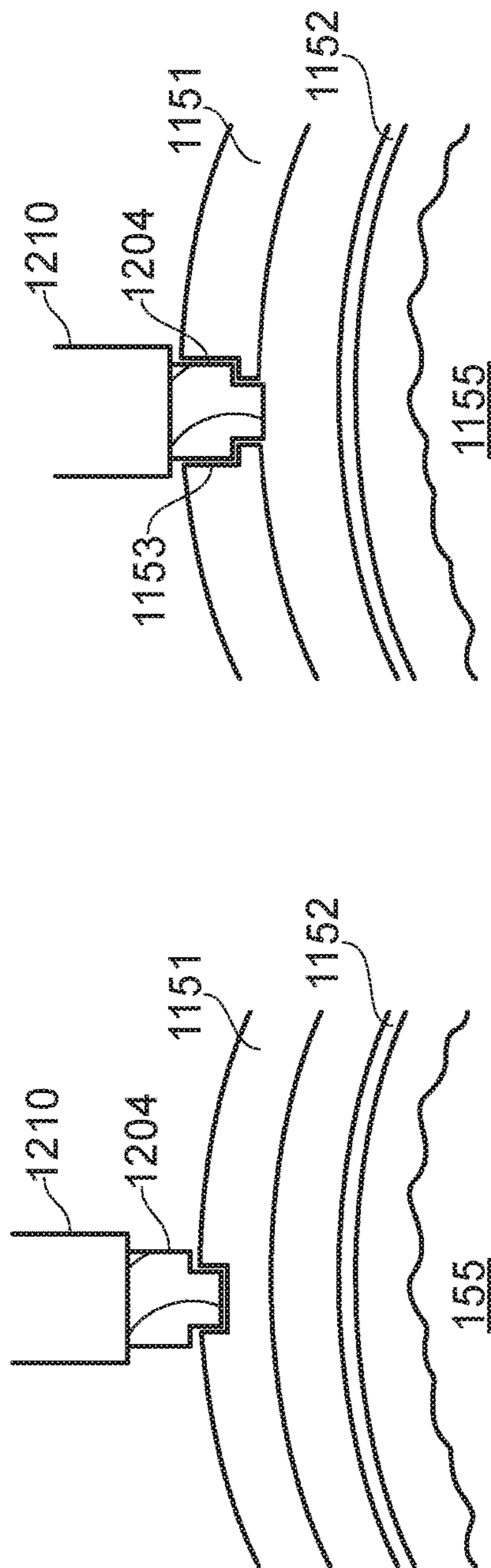


FIG. 12A

FIG. 12B

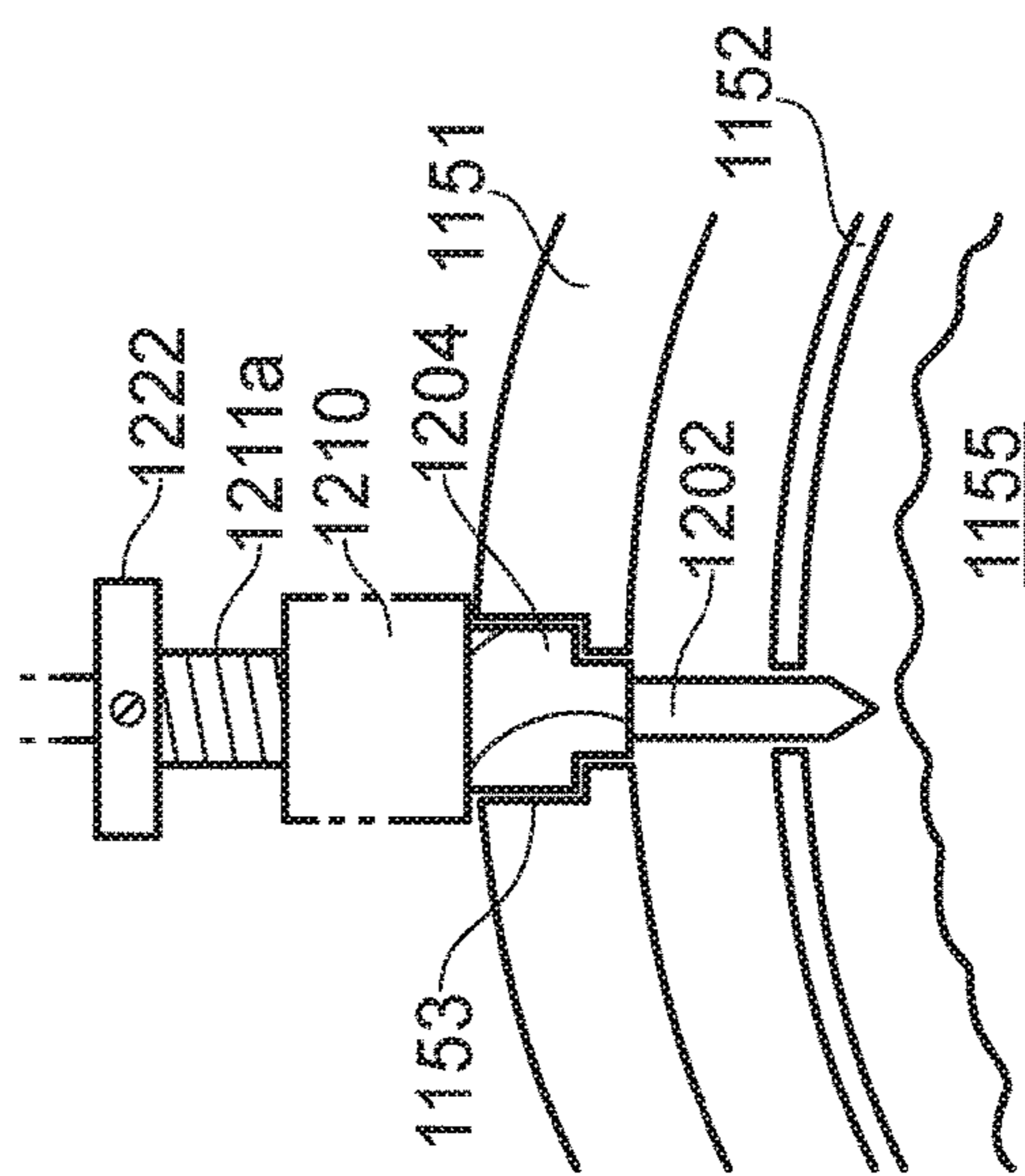


FIG. 12D

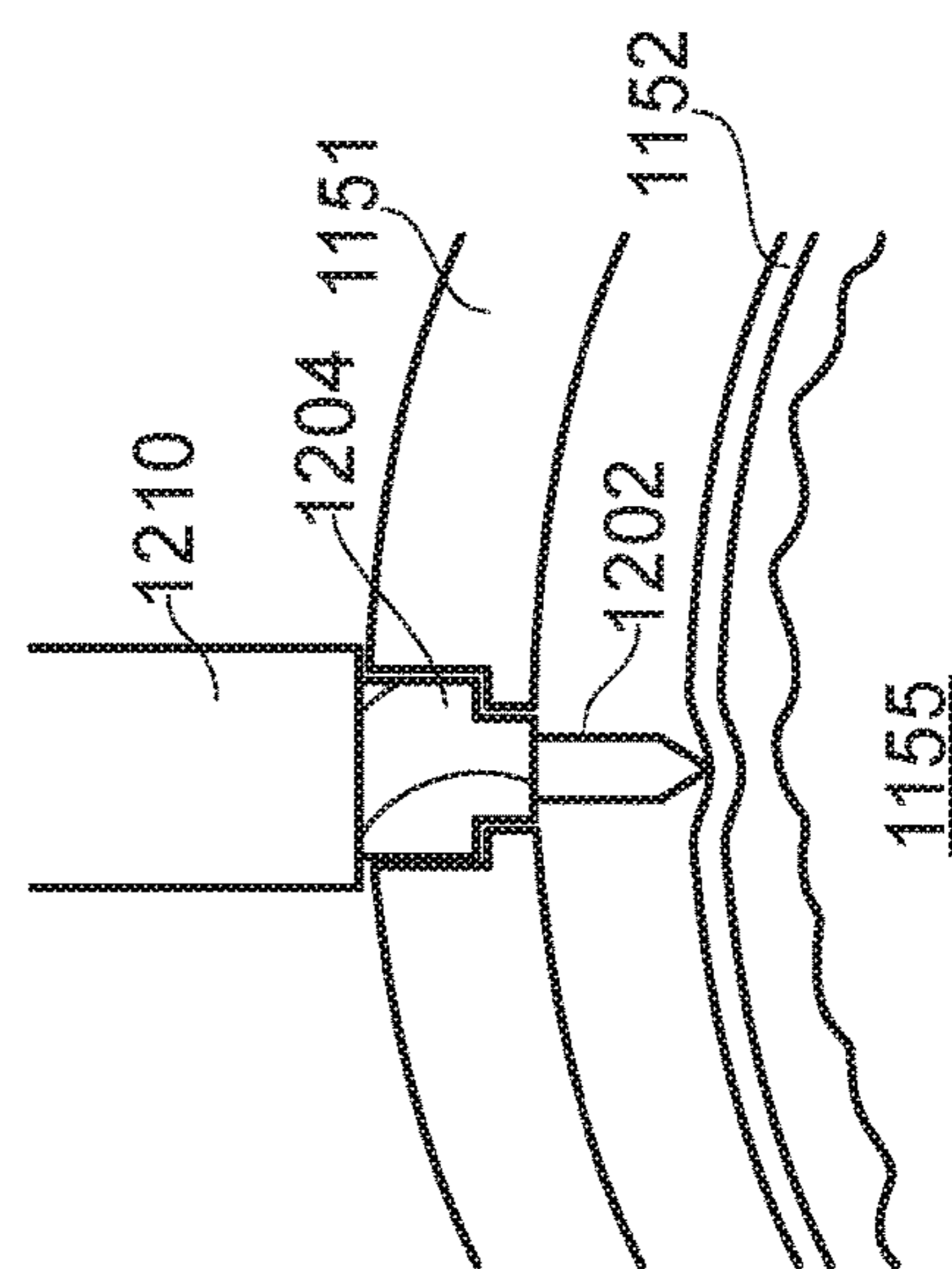


FIG. 12C

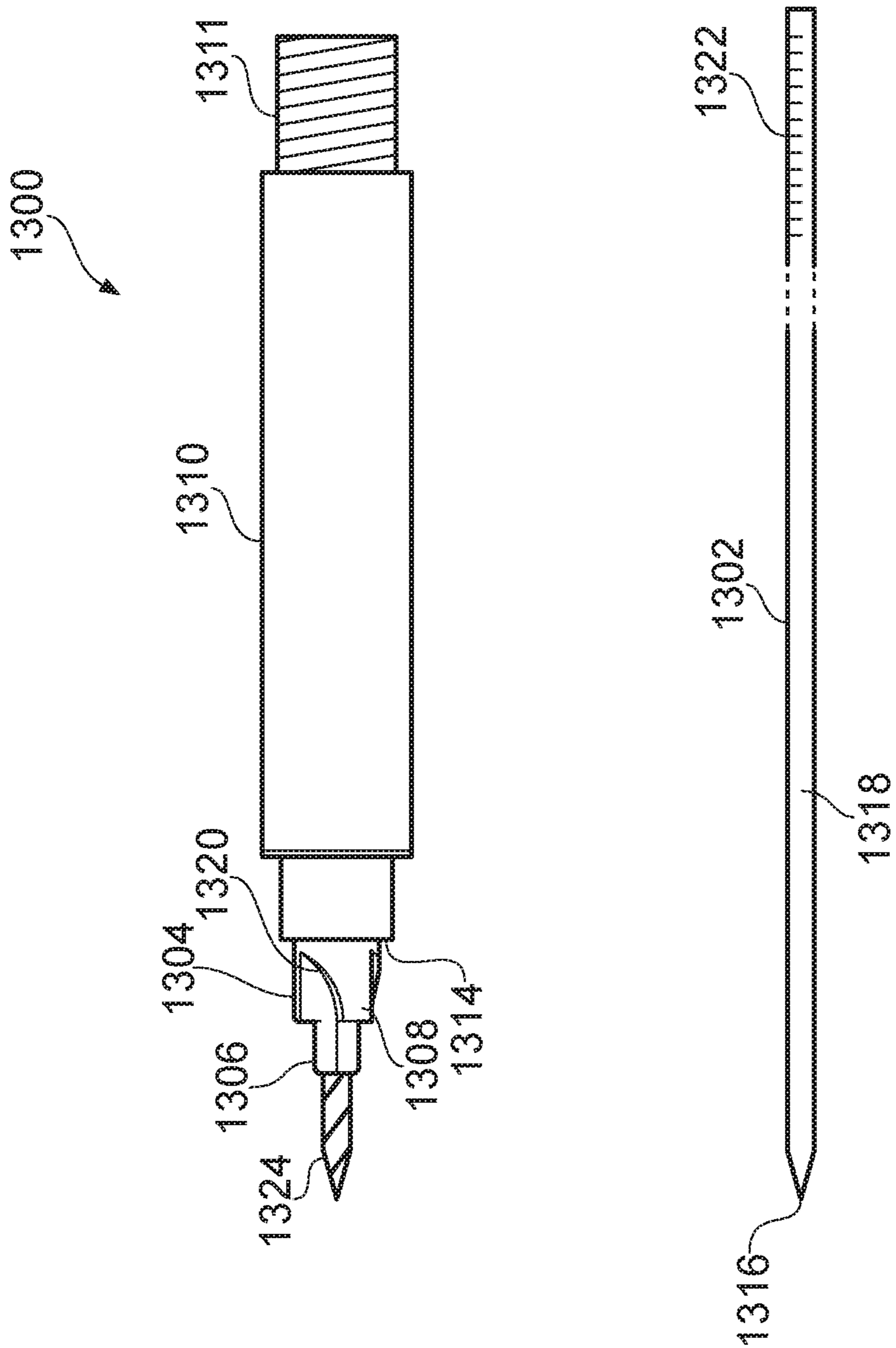


FIG. 13

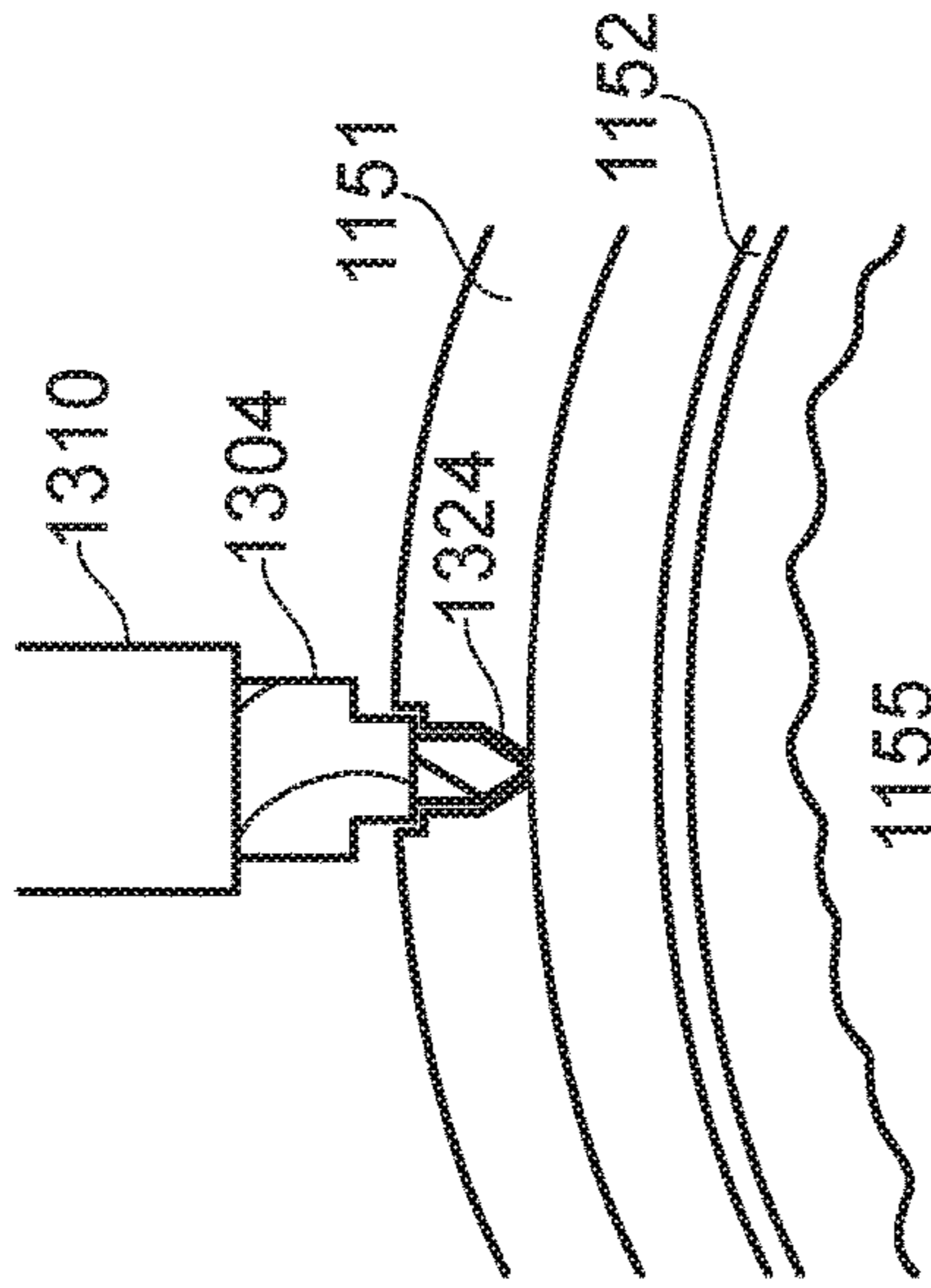


FIG. 14A

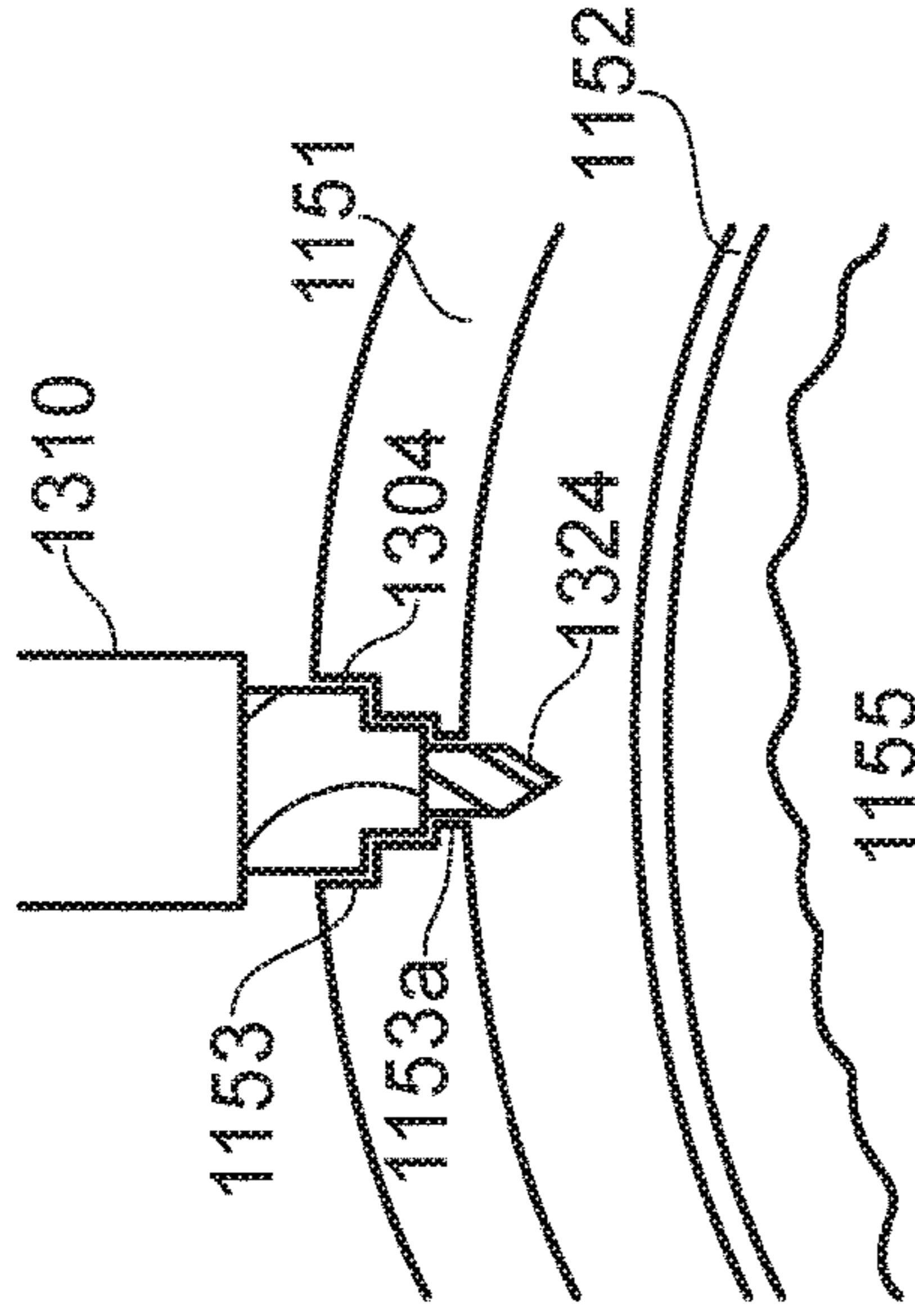


FIG. 14B

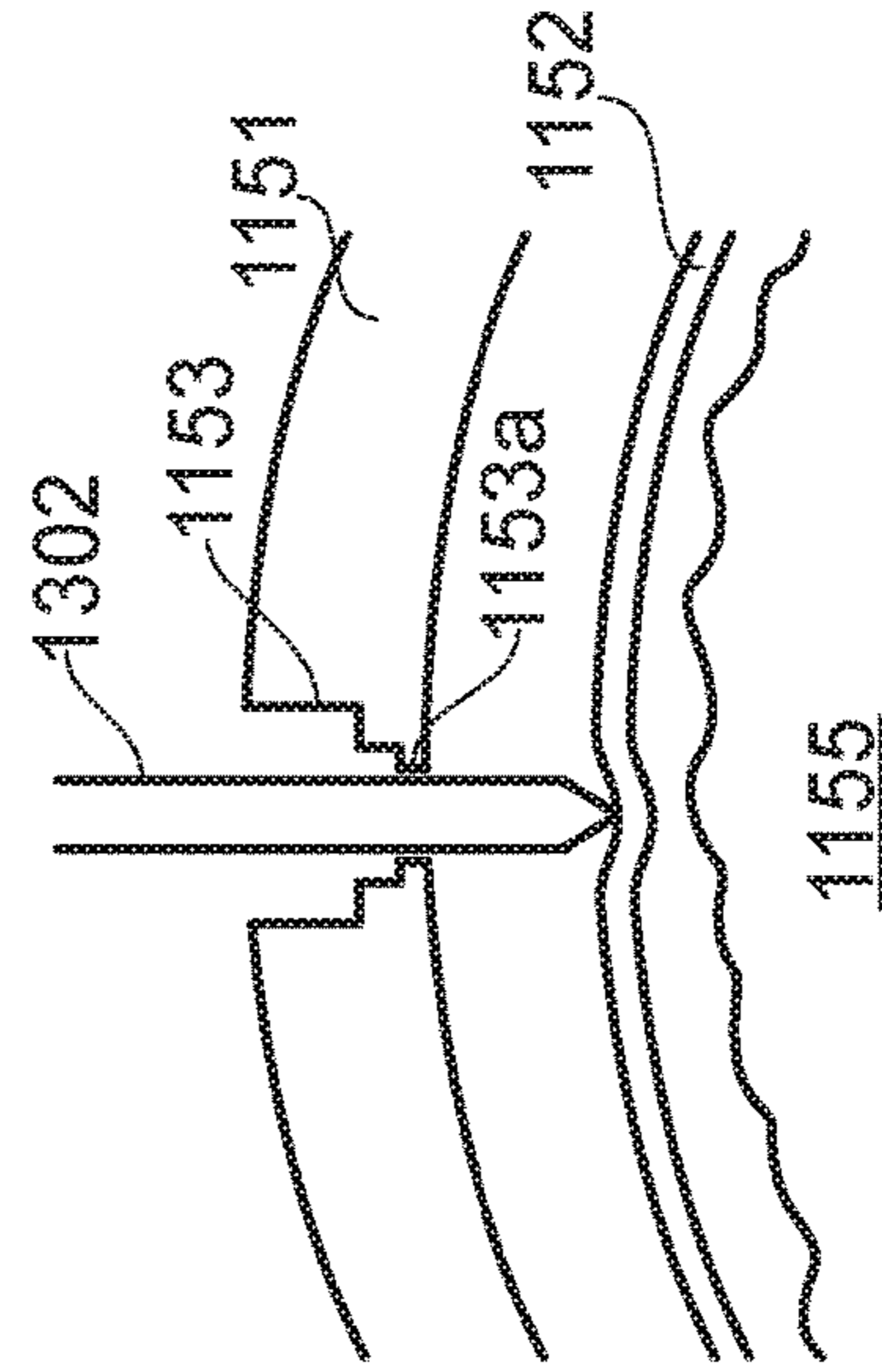


FIG. 14C

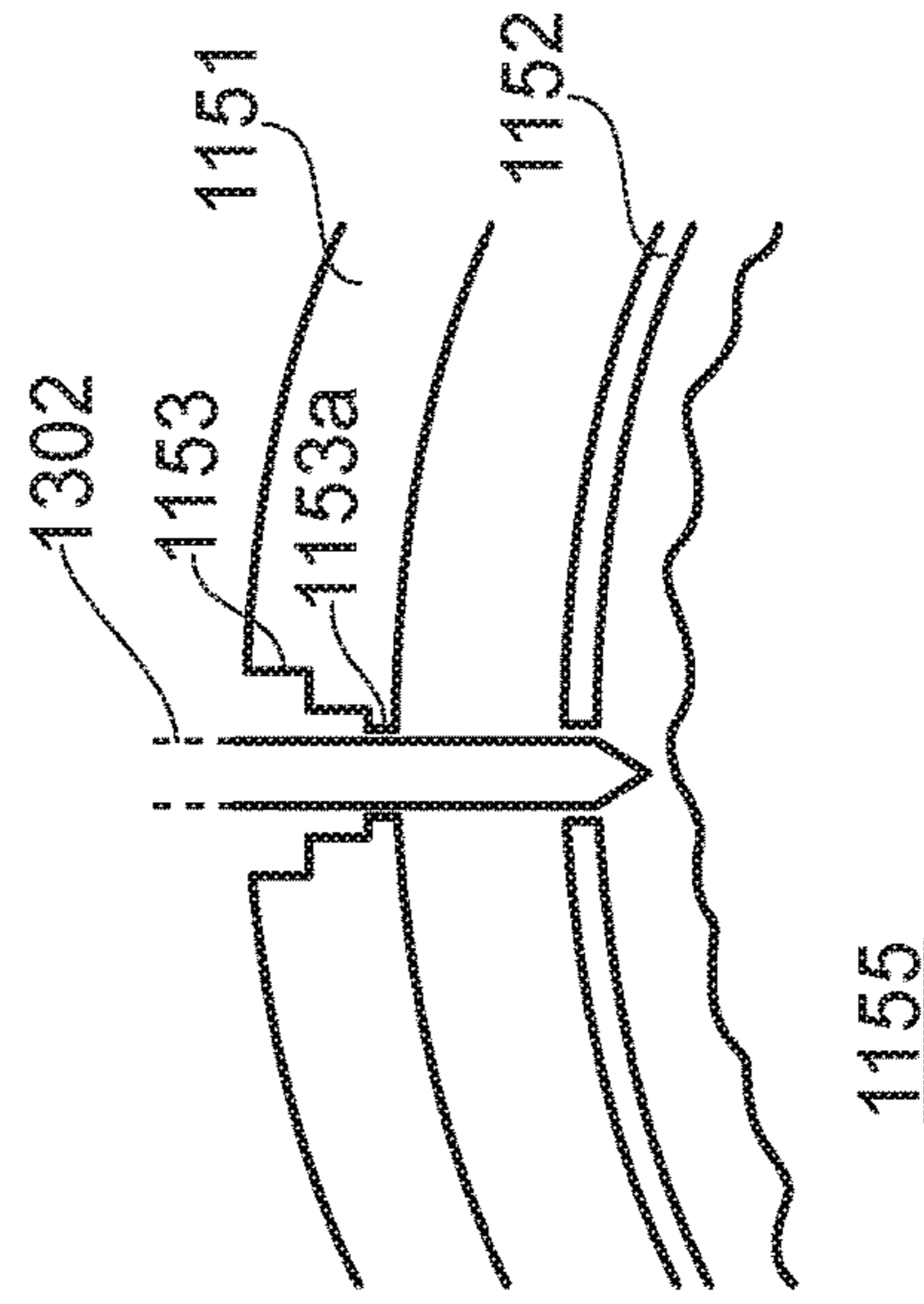


FIG. 14D

CRANIAL DRILL SYSTEM

[0001] This application is a Continuation of application Ser. No. 14/403,862, filed Nov. 25, 2014, which is a national stage of PCT/GB2013/051451, filed May 31, 2013, which claims priority to GB 1209772.1, filed Jun. 1, 2012. The entire contents of the prior applications are hereby incorporated by reference herein in their entirety.

FIELD OF INVENTION

[0002] This invention concerns a cranial drill system and a method of forming an opening in the skull and the brain. The invention has particular application to a cranial drill system for forming an opening in the skull suitable for receiving a cranial port, such as a cranial port connected with a device, such as a guide device, catheter or electrode.

BACKGROUND

[0003] There are many situations where there is a requirement to deliver therapeutic agents to specific targets within the brain parenchyma via implanted catheters. Furthermore, many of these therapeutic agents will cause unwanted side effects if delivered to healthy parts of the brain. Examples of treating abnormalities of brain function include the acute infusion of Gamma-amino-butyric-acid agonists into an epileptic focus or pathway to block transmission, and the chronic delivery of opiates or other analgesics to the periaqueductal grey matter or to thalamic targets for the treatment of intractable pain. Also, cytotoxic agents can be delivered directly into a brain tumour. Intraparenchymal infusion can also be used to deliver therapeutic agents to brain targets that cannot be delivered systemically because they will not cross the blood-brain barrier. For example, the treatment of patients with Parkinson's disease, Alzheimer's disease, head injury, stroke and multiple sclerosis may be carried out by the infusion of neurotrophic factors to protect and repair failing or damaged nerve cells. Neurotrophins may also be infused to support neural grafts transplanted into damaged or malfunctioning areas of the brain in order to restore function.

[0004] It is also known to insert instruments other than catheters, such as electrodes, directly in the brain parenchyma. For example, stimulating and lesioning electrodes are used in a variety of surgical procedures, including deep brain stimulation (DBS) electrodes. A surgeon wishing to stimulate or lesion a particular area of nervous tissue can target the end of an electrode to the target site so that a desired electrical current can be delivered.

[0005] The above described methods rely on targeting the required site as accurately as possible. Slight misplacement of the instrument being inserted may lead to significant morbidity or treatment failure. For example, brain targets for treating functional disorders are usually deeply situated and have small volumes. A desired target for treating Parkinson's disease is situated in the sub-thalamic nucleus and is 3-4 mm in diameter, or an ovoid of 3-4 mm in diameter and 5-6 mm in length. Other targets such as the globus pallidus or targets in the thalamus are usually no more than 1-2 mm larger. For such a small target sub-optimal placement of as little as 1 mm will not only reduce the effectiveness of the treatment, but may also induce unwanted side effects such as weakness, altered sensation, worsened speech and double vision. It is also desirable to minimise trauma in certain regions of the brain; for example, the mesencephalon (which includes the

subthalamic nucleus, the substantia nigra and the pedunculo-pontine nucleus) is a critical region of the brain where it is important to minimise trauma from the passage of an electrode or catheter.

[0006] A variety of stereotactic devices and methods have thus been developed previously in an attempt to allow instruments to be accurately guided towards a target identified by a surgeon (e.g. using x-rays or magnetic resonance imaging) with the minimum of trauma to other regions of the brain. Examples of prior systems are given in EP1509153, U.S. Pat. Nos. 6,609,020 and 6,328,748.

[0007] GB2357700 discloses a guide device comprising a port (head) which is secured in a hole formed in the skull with a tube of the guide device extending into the brain. In order to insert the guide device into the skull a hole is first drilled into the skull under the guidance of a stereotactic frame. Often, the port has a larger diameter than the catheter/electrode/guide tube to be inserted into the brain. Therefore, it is desirable to drill an opening having a stepped form with an enlarged diameter portion for receiving the port. Devices for drilling such a stepped form are known, for example as described in WO2011/110874.

[0008] To insert the guide device to the desired target the dura is perforated. The surgeon may do this with a scalpel or a device such as described in WO2009/047494.

[0009] Use of a scalpel or a spike, such as disclosed in WO2011/110874, to puncture the dura and the later insertion of probes, such as guide rods, guide tubes, catheters, in to the brain, especially through the denser parts of the brain, may result in the brain being displaced from its original position, resulting in the probes missing the target.

[0010] Furthermore, during formation of the openings in the skull and in the dura using these separate instruments, the openings may not be correctly located relative to each other. This is even the case if a stereotactic frame is used for positioning the instruments during formation of the openings as play in the stereotactic frame can result in errors in positioning. This may hinder insertion of an implantable instrument, such as a catheter with integrated port.

SUMMARY OF INVENTION

[0011] According to a first aspect of the invention there is provided a cranial drill system comprising one or more surgical drill elements for drilling into the brain.

[0012] Drilling out an opening in the brain may reduce the extent to which the brain is pushed away during penetration of the dura and during later insertion of probes, such as guide rods, guide tubes, catheters, electrodes etc, in to the brain. This may result in more accurate placement of the probes/implantable instruments.

[0013] The system may comprise first and second drill elements arranged to cooperate together to define a relative position of openings formed using the first and second drill elements. The openings may include an opening in the skull and an opening in the brain. The drill elements may be arranged such that the openings are formed substantially concentric to each other.

[0014] The cranial drilling system may comprise a first drilling element for drilling into the brain and a second drilling element for drilling into the skull, the second drilling element having at least a portion with a diameter greater than a diameter of the first drill element. In this way, the drilling

system can be used both for drilling an opening into the brain and for drilling an opening into the skull for holding an implantable instrument.

[0015] The first drill element and second drill element may be connected or connectable such that drilling with one of the first and second drilling elements is guided by its connection to the other of the second and first drilling elements. Such an arrangement may aid the correct location of the opening in the skull relative to the opening in the brain.

[0016] The first drill element may extend from a distal end of the second drill element such that the first drill element has to be drilled into the skull before the second drill element can be drilled in to the skull. In such an arrangement, the second drilling element can be guided into position relative to an opening formed using the first drilling element by its connection with the first drilling element. Drilling using both the first and second elements may be achieved through rotation of a common shaft and in a continuous process and in this sense comprises a “single step” process. In this way, the opening into the brain and the larger diameter opening in the skull can be drilled without having to remove/detach one of the drill elements from the skull/brain. Drilling multiple features in a continuous manner may reduce leakage of cerebrospinal fluid (CSF) due to the accelerated nature of creating the features.

[0017] The first drill element and the second drill element may be connected such that a length that the first drill element extends from the distal end of the second drill element can be varied. In this way, the system can be adapted for the specified target.

[0018] The first drill element may be connected or connectable to the second drill element such that drilling into the brain with the first drill element is guided by its connection with the second drill element. To achieve this, the second drill element may have a passageway therethrough for receiving the first drill element, the first drill element movable in the passageway from a retracted position, in which the first drill element does not project from a distal end of the second drill element, and an extended position, in which the first drill element does extend from a distal end of the second drill element. In such an arrangement, the first drilling element can be guided into position relative to an opening formed using the second drilling element by its connection with the second drilling element. Such an arrangement may allow the release of cerebrospinal fluid (CSF) from penetrating the dura to be delayed until after the larger diameter opening has been formed in the skull using the second drill element.

[0019] The second drilling element for drilling into the skull may comprise a profile that forms an opening in the skull having a narrower diameter portion and a wider diameter portion,

[0020] The first drilling element may be arranged to be a close fit in the narrower diameter portion of the opening. In one embodiment, the second drilling element comprises a pilot drill element that extends from a distal end of the second drill element, the first drill element arranged to be a close fit in a pilot hole formed using the pilot drill element. In this way, drilling with the first drill element can be guided by fitting the first drill element in the pilot hole.

[0021] The second drill element may comprise a profile to form an opening in the skull with one, two or more stepped transitions between the narrower and wider diameter por-

tions. In this way, the opening can support a correspondingly shaped part of an implantable instrument, such as a port of a catheter or guide tube.

[0022] The second drilling element may comprise a guide, which, during drilling with the second element, can extend into and is a close fit in an opening formed by the first drilling element.

[0023] The cranial drill system may comprise a mount for connecting the first and/or second drill elements to a coordinate positioning apparatus, such as a stereotactic frame and/or robot.

[0024] The first drill element may have a length sufficient to extend into the pia mater of the brain. The first drill element may have a length of greater than 10 mm. In this way, the drill element may have sufficient length to reach targets in the brain. The drill element may comprise a twist drill, which may comprise two flutes.

[0025] A point angle of a tip of the first drill element may be less than 90°, less than 80°, less than 70° and preferably about 60°. It is believed that a sharp tip will aid penetration of the skull and dura reducing the chances of deflection of the drill element from the skull and dura surfaces and reducing deflections of the brain.

[0026] The drill element may be made of a bio-inert material, such as stainless steel or titanium.

[0027] According to a second aspect of the invention there is provided a kit including a cranial drill system according to the first aspect of the invention and an implantable instrument for locating within an opening in a skull formed using the cranial drill system, the second drill element arranged to form an opening having a profile corresponding to a profile of the implantable instrument.

[0028] According to a third aspect of the invention there is provided neurosurgical apparatus comprising a coordinate positioning apparatus for positioning surgical instruments relative to the skull and a cranial drill system according to the first aspect of the invention.

[0029] The coordinate positioning apparatus may be a stereotactic frame or a robot.

[0030] According to a fourth aspect of the invention there is provided a method of surgery comprising drilling into a patient's brain.

[0031] The method may comprise imaging the patient, identifying targets from the image and drilling into the brain based upon the identified targets.

[0032] The method may comprise drilling an opening into the skull using a cranial drill element and, with the cranial drill element remaining in the skull, drilling into the brain using a further drill element, the further drill element connected with the cranial drill element to constrain positioning of the further drill element relative to the cranial drill element.

[0033] The method may comprise using a cranial drill element to drill a pilot hole and an opening with a greater diameter than the pilot hole in the skull and then using a further drill element to drill into the brain, the further drill element inserted through the pilot hole. The method may comprise, before drilling into the brain, puncturing the dura with a spike through the pilot hole.

[0034] According to a fifth aspect of the invention there is provided a cranial drilling system comprising a surgical drill element for drilling into the skull, the surgical drill element comprising a profile that forms an opening in the skull having a narrower diameter portion and a wider diameter

portion, and an element for penetrating the dura, the element arranged to be a close fit, such as an interference fit, in the narrower diameter portion of the opening. The element may be a further drill element or a spike having a substantially smooth outer surface, without flutes of a drill. In one embodiment, the drilling system comprises a spike for puncturing the dura and a further drill element for drilling into the brain.

[0035] According to a sixth aspect of the invention there is provided a cranial drill system comprising a guiding element to be located in a hole formed through the skull and a piercing element for piercing the dura, the guiding element having a passageway or channel therein for receiving the piercing element such that the piercing element is movable relative to the guide element to pierce the dura.

[0036] In this way, the guide element through its interface with the skull provides a means for positioning the piercing element relative to the hole formed in the skull such that the dura can be pierced at a desired location relative to the hole in the skull.

[0037] The guiding element may comprise a drill element for drilling the hole through the skull. Accordingly, the drill is first used to form the hole through the skull and is then used as a guide for guiding the piercing element used to pierce the dura.

[0038] Alternatively, the guide element may be a separate element to a drill element used to form the hole. In such an embodiment, the drill element used to drill the hole in the skull is removed from the hole and the separate guide element inserted into the hole and located through its engagement with the hole. To achieve the desired location, the drill element may comprise a profile that forms an opening in the skull having a narrower diameter portion and a wider diameter portion and the guide element may comprise a profile corresponding to the profile of the drill element.

[0039] The piercing element may be movable in the passageway or channel from a retracted position in which the piercing element does not project from a distal end of the guide element and an extended position in which the piercing element does extend from a distal end of the guide element. The piercing element may be held within the guide element during location of the guide element in the skull or may be insertable into the passageway or channel after the guide element has been located in the skull. For example, the passageway or channel may extend through the guide element such that the piercing element can be inserted into a proximal end portion of the guide element and moved through the passageway or channel to project from the distal end of the guide element.

[0040] The piercing element may be a spike having a substantially smooth outer surface. Alternatively, the piercing element may be a drill element.

DESCRIPTION OF THE DRAWINGS

[0041] FIG. 1 shows a cranial drill system according to a first embodiment of the invention;

[0042] FIGS. 2A to 2D shows schematically a method of neurosurgery using the cranial drill system shown in FIG. 1;

[0043] FIG. 3 shows a cranial drill system according to a second embodiment of the invention;

[0044] FIGS. 4A to 4D shows schematically a method of neurosurgery using the cranial drill system shown in FIG. 3;

[0045] FIG. 5 shows a cranial drill system according to a third embodiment of the invention;

[0046] FIGS. 6A to 6D shows schematically a method of neurosurgery using the cranial drill system shown in FIG. 5;

[0047] FIG. 7 shows a cranial drill system according to a fourth embodiment of the invention;

[0048] FIGS. 8A to 8D shows schematically a method of neurosurgery using the cranial drill system shown in FIG. 7;

[0049] FIG. 9 is a schematic view of a cranial drill system according to the invention attached to a stereotactic frame;

[0050] FIG. 10 is a cross-sectional view of an instrument implanted into the brain;

[0051] FIG. 11 shows a cranial drill system according to a further embodiment of the invention;

[0052] FIGS. 12A to 12D shows schematically a method of neurosurgery using the cranial drill system shown in FIG. 11;

[0053] FIG. 13 shows a cranial drill system according to yet another embodiment of the invention; and

[0054] FIGS. 14A to 14D shows schematically a method of neurosurgery using the cranial drill system shown in FIG. 13;

DESCRIPTION OF EMBODIMENTS

[0055] Referring to FIG. 1, a cranial drill system 100 (200, 300, 400, 1200 and 1300 in other embodiments) is shown comprising a first drill element 102 for drilling into the brain and a second drilling element 104 (204, 304, 404, 1204 and 1304 in other embodiments) for drilling into the skull.

[0056] The second drill element 104 has a stepped profile with a first, distal portion 106 (206, 306, 406, 1206 and 1306 in other embodiments) having a narrower diameter than a second, proximal portion 108 (208, 308, 408, 1208 and 1308 in other embodiments). The second portion 108 also has a diameter greater than a diameter of the first drill element 102. The stepped profile of the second drill element 104 matches that of an implantable instrument to be implanted, such as a port and a catheter to be inserted in the brain.

[0057] The drill elements 102 and 104 are connected aligned along a common axis to a common shaft 110 (210, 310, 410, 1210 and 1310 in other embodiments), which has a mount, in this embodiment a screw thread 111 (311, 411 and 1311 in other embodiments), for attaching the drill system 100 to a surgical drill (501 in FIG. 9). Typically, this is achieved by attaching the drill system 100 to a rod 505 that is carried by a stereoguide frame 502 through which drive from the surgical drill 501 can be transmitted. However, the drill system 100 may also be attached to a robot end effector, which, as well as positioning the drill system, may provide rotation for drilling.

[0058] In this embodiment, the first drill element 102 extends into a passageway (not shown) through the second drill element 104 and shaft 110 and is fixed in place by a grub screw 112 (212 and 1212 in other embodiments). However, it will be understood that other fixing devices could be used to secure the first drill element 102 in place. Releasing the first drill element 102 from the grub screw 112 allows the length that the first drill element 102 extends from a distal end of the second drill element 104 to be varied as appropriate for the intended target in the brain.

[0059] An interface 114 (214, 314, 414, 1214 and 1314 in other embodiments) between the second drill element 104 and the shaft 110 provides an abutment that, in use, can be

engaged with the surface of the skull to limit the depth to which the drilling system is inserted into the brain.

[0060] The first drill element **102** is a twist drill of stainless steel having a point angle at a tip **116** (**216**, **316**, **416**, **1216** and **1316** in other embodiments) of about 60°. In this embodiment, a single flute **118** (**218**, **318**, **418**, **1218** and **1318** in other embodiments) is shown. However, it will be understood that the twist drill may comprise multiple flutes, such as two flutes.

[0061] The second drill element **104** also comprises one or more flutes **120** (**220**, **320**, **420**, **1220** and **1320** in other embodiments) for cutting into the skull.

[0062] In use, first a target that is to be treated is identified in the brain. This may be achieved by imaging the brain, such as with a CT scan, and identifying from the images **503** a location in the brain to be treated. Based on a measured distance to the target site from a location identified on the skull through which the drill system is to be inserted, a length of the first drill element **102** is set. Referring now to FIGS. **2A** to **2D**, the drill system **100** allows drilling of the opening through the skull and into the brain in a continuous (one-step) process. Firstly an opening **150** is drilled into the skull **151** (**1151** in other embodiments) using the first drill element **102** positioned as desired using the stereotactic frame **502** or robot. As the drill system is gradually inserted into the head of the patient, the first drill element **102** contacts the dura **152**. At first the dura may be slightly deflected as shown in FIG. **2B** by the first drill element **102** but the sharp 60° tip **116** soon penetrates the dura. As insertion of the drill system continues with the first drill element **102** entering the brain **155**, the second drill element **104** is guided into contact with the skull by virtue of its connection to the first drill element **102** to begin drilling an opening having a larger diameter than that drilled in the skull by the first drill element **102**. This is shown in FIG. **2C**. Drilling is continued until the abutment **114** engages with the surface of the skull. At this point the first drill element **102** should have reached the intended location in the brain **155** based on its set length and the measurements from the images.

[0063] The drilling system **100** is removed and a catheter **600** (shown in FIG. **10**) or other implantable instrument can be inserted onto the opening **154** in the brain **155** for delivering the treatment, such as a drug or electronic stimulus. The instrument may comprise a port **601** or plug at its proximal end having a profile corresponding to the opening **153** (**1153** in other embodiments) formed using the second drill element **104**. This port or plug is inserted into the opening **153** on insertion of the instrument into the brain.

[0064] Referring now to FIG. **3**, a cranial drilling system **200** according to another embodiment of the invention comprises a first drill element **202** for drilling into the brain and a second drilling element **204** for drilling into the skull. The two drilling elements are similar to the drilling elements described with reference to FIG. **1** and like reference numerals but in the series **200** have been used to refer to corresponding parts.

[0065] In this embodiment, the first drilling element **202** can be inserted from the rear of the body **210** through a passageway **221** and pushed through the passageway so as the tip **216** projects from the distal end of drilling element **204**. A stop **222** is provided on a shaft of the first drilling element **202** to contact a proximal end of the body **210**, limiting the length of the first drilling element **202** that can

project from the distal end of the second drilling element **204**. A position of the stop **222** on the first drilling element **202** can be adjusted by loosening grub screw **212** and sliding the stop along the first drilling element **202**. Separate mounts **211a** and **211b** (**1211a** and **1211b** in other embodiments) are provided on each of the body **210** and the first drilling element **202** for connecting each to a drill.

[0066] Now referring to FIGS. **4A** to **4D**, in use, a target is identified from images **503** and the stop **222** moved to a position on the first drilling element **202** such that, when fully inserted into the body **210**, the first drilling element projects a desired distance into the brain **155**. An opening **153** is then drilled into the skull **151** using the second drilling element (FIGS. **4A** and **4B**). The first drilling element **102** is connected to the drill and inserted into the passageway **221** so as to project from the second drilling element **204**, which remains attached to the skull **151**. The first drilling element **202** is used to puncture the dura **152** and drill into the brain **155** (FIGS. **14C** and **4D**), its position guided by the passageway **221** through the second drilling element **204**. Drilling continues until stop **222** engages to proximal end of the body **210**.

[0067] Once the opening **154** into the brain **155** has been formed an instrument, such as catheter **600**, is implanted into the opening **154**.

[0068] In the embodiment shown in FIG. **5**, the drilling system **300** comprises a first drill element **302** for drilling into the brain and a second drilling element **304** for drilling into the skull. The two drilling elements **302**, **304** are similar to the drilling elements described with reference to FIGS. **1** and **3** and like reference numerals but in the series **300** have been used to refer to corresponding parts. However, unlike the previous embodiments, the drilling system comprises two instruments that are to be used without a physical connection/engagement.

[0069] The first drilling element **302** comprises a distal end having one or more flutes **318** for drilling an opening into the brain **155** and, at a proximal end, scale **322** (**1322** in other embodiments) for measuring the depth that the drill **302** has been inserted into the brain.

[0070] The second drilling element **304** comprises at its distal end a pilot drill **324** having a diameter substantially the same as the first drilling element **302**.

[0071] In use, the second drilling element is first used to drill an opening **153** into the skull **151**. This opening **153** includes a pilot hole **153a** (**1153a** in other embodiments) for guiding later insertion of the first drilling element **302**. Once opening **153** has been drilled, the second drilling element is removed and the first drilling element **302** inserted into the opening **153**. Contact of the first drilling element **302** with side walls of opening **153a** guides the first drilling element **302** to the desired location for penetrating the dura **152** and entering the brain **155**. The surgeon can identify whether the target has been reached from the measurement scale **322** on the first drilling element **302**.

[0072] A further embodiment shown in FIG. **7** shows a cranial drilling system **400** comprising a first drill element **402** for drilling into the brain and a second drilling element **404** for drilling into the skull. The two drilling elements **402**, **404** are similar to the drilling elements described with reference to FIGS. **1**, **3** and **5** and like reference numerals but in the series **400** have been used to refer to corresponding parts. Like the embodiment shown in FIG. **5**, the drilling

system comprises two instruments that are to be used without a physical connection/engagement.

[0073] The first drilling element **402** comprises a distal end having one or more flutes **418** for drilling an opening into the brain **155** and, at a proximal end, scale **422** for measuring the depth that the drill **402** has been inserted into the brain.

[0074] The second drilling element **404** comprises at its distal end a guide **426** having a diameter substantially the same as the first drilling element **402**.

[0075] In use, the first drilling element **402** is first used to drill an opening into the skull **151**, to puncture the dura **152** and drill an opening **154** into the brain. The surgeon can identify whether the target has been reached from the measurement scale **422** on the first drilling element **402**. The first drilling element **402** is then removed and guide **426** of the second drilling element **404** is inserted into the opening in the skull to locate the second drilling element **404** relative to the opening **154**. The second drilling element **404** is then used to drill profiled opening **153**, insertion of the drilling element **404** guided by contact of the guide **426** with the side walls of the opening formed previously with the first guide element **402**.

[0076] FIG. 9 shows a typical set-up a neurological apparatus comprising a stereotactic frame **502** used to position a cranial drilling system **500** on a patient's skull **504**. A drill **501** is shown connected to the drilling system **500**. The drilling system **500** may be any one of the systems described above with reference to FIGS. 1 to 8D.

[0077] FIG. 10 shows an implantable instrument, in this instance a catheter **600** inserted through a guide tube **602** into the opening formed using the cranial drill system. The catheter **600** can then be used to deliver a drug to a target area **604**. The stepped profile formed in the skull by the second drilling element receives the port **601**, which has a corresponding profile.

[0078] A further embodiment of the invention is shown in FIGS. 11 and 12A to 12D. This embodiment is similar to the embodiment shown in FIG. 3 and like reference numerals but in the series **1000** have been used for corresponding features. This embodiment differs from the embodiment shown in FIG. 3 in that the first drilling element **202** has been replaced with a spike **1202** for penetrating the dura **1152**. The spike **1202** comprises a smooth shaft **1218** without flutes of a drill element and a point **1216**. In use, a hole is drilled into the skull using drill element **1204** and then the passageway **1221** is used as a guide to guide the spike **1202** to the desired location above the dura **1152**. The spike **1202** is then inserted further to pierce the dura, as shown in FIG. 12D. The spike **1202** may be removed before it enters the brain **1155**, penetration of the brain achieved using other instruments.

[0079] FIG. 13 shows an arrangement similar to FIG. 5 but with the first drilling element **302** replaced with a spike **1302** for penetrating the dura. The spike **1302** is arranged to be a close fit in the pilot hole drilled using the pilot drill **1324**. Such an arrangement may not have some of the benefits derived from drilling into the brain but may benefit from puncturing of the dura with the spike guided by a pilot hole formed in the skull.

[0080] Furthermore, in either of the embodiments shown in FIGS. 11 and 13, a spike for puncturing the dura may be provided in addition to the first drilling element. With such a system, the spike may be a close fit in the pilot hole and

inserted into the pilot hole to puncture the dura. The spike is then removed and the first drill element inserted into the pilot hole to drill into the brain.

[0081] As a modification to the embodiment shown in FIG. 11, a separate guide element for guiding the spike may be provided. In such an embodiment, a drill element is provided for drilling a particular profile in the skull. The separate guide element comprises a portion having a profile corresponding to the profile of the hole formed using the drill element so that it can be located accurately in the hole through engagement with the hole. The spike is then inserted through the guide element to penetrate the dura.

[0082] It will be understood that various modifications and alterations can be made to the described embodiments without departing from the invention as defined herein.

1. A kit comprising:
 - a cranial drill system comprising:
 - at least one surgical drill element configured to drill into a skull and to form an opening in the skull; and
 - the kit further comprising a guide element and a spike for piercing at least one of a dura and a brain, wherein the guide element comprises a through hole configured to guide the spike, the guide element being locatable in the opening through engagement with the opening.
 2. A kit according to claim 1 wherein the spike comprises a stop.
 3. A kit according to claim 2 wherein the stop is configured to contact the guide element to limit the insertion of the spike.
 4. A kit according to claim 3 wherein the stop is configured to contact the guide element remote from part of the guide element configured to engage the opening.
 5. A kit according to claim 3 wherein the stop is adjustable so as to allow adjustment of an insertable length of the spike.
 6. A kit according to claim 1 further comprising a hub being locatable in the opening through engagement with the opening.
 7. A kit according to claim 1 wherein the at least one surgical drill element configured to drill into the skull and to form an opening in the skull is configured such that the opening in the skull has a narrower diameter portion and a wider diameter portion.
 8. A kit according to claim 1 wherein in use, the through hole of the guide element is elongate.
 9. A kit according to claim 1 wherein the guide element is configured such that when located in the opening through engagement with the opening, an amount of the guide element which protrudes outwards from the skull is greater than an amount within the skull and/or engaged with the opening.
 10. A neurological apparatus comprising:
 - a coordinate positioning apparatus configured to position surgical instruments relative to a skull; and
 - a kit according to claim 1.
 11. A kit comprising:
 - a cranial drill system comprising:
 - at least one surgical drill element configured to drill into a skull and to form an opening in the skull, the opening having a narrower diameter portion and a wider diameter portion; and
 - a spike configured to penetrate a dura, the spike dimensioned to be a transition fit in the narrower diameter portion of the opening such that lateral translational movement of a section of the spike is limited when

the section of the spike is located in the narrower diameter portion of the opening; and
an implantable instrument configured to locate within the opening formed using the cranial drill system, the implantable instrument comprising a port,
wherein the cranial drill system is arranged to form the opening having a profile corresponding to a profile of the port.

12. A neurological apparatus comprising:
a coordinate positioning apparatus configured to position surgical instruments relative to a skull; and
a kit according to claim **11**.

13. A kit comprising:
a stepped guide for insertion into a skull and a spike configured to penetrate at least one of a dura and a brain, wherein the stepped guide is configured to guide the spike, the guide element being locatable in an opening in the skull through engagement with the opening.

14. A kit according to claim **13** wherein the spike comprises a stop.

15. A kit according to claim **14** wherein the stop is configured to contact the stepped guide to limit the insertion of the spike.

16. A kit according to claim **14** wherein the stop is adjustable so as to allow adjustment of an insertable length of the spike.

17. A kit according to claim **13** wherein the stepped guide comprises a through hole.

18. A kit according to claim **17** wherein the through hole is elongate.

19. A neurological apparatus comprising:
a coordinate positioning apparatus configured to position surgical instruments relative to a skull; and
a kit according to claim **13**.

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