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(54) Title: SURGICAL CANNULA

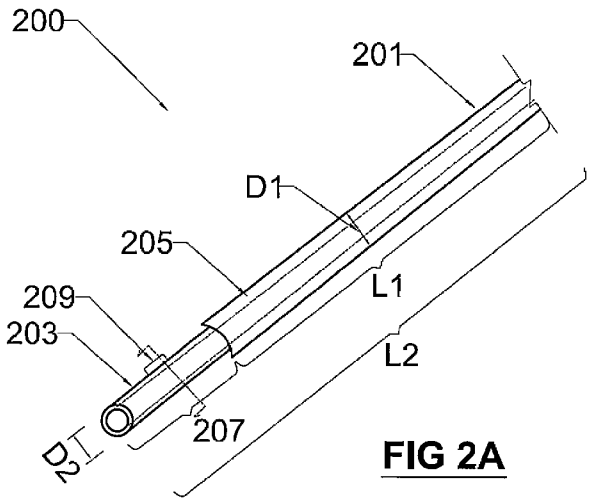

FIG 2A

(57) Abstract: A probe (200, 300, 400) includes a cannula (201, 301, 401), a tube (203, 403) and a detector (209, 340, 430). The tube (203, 403) may be disposed in the cannula (201, 301, 401) and define a second passage (213, 404) to guide a surgical tool into a patient's brain. A first passage (205, 405) may be between the tube (203, 403) and the cannula (201, 301, 401). The detector (209, 340, 430) may be disposed on the tube (203, 403) and configured to collect information associated with brain tissues of the patient. The detector (209, 340, 430) may be electrically connected to a power source through a wire disposed in the first passage (205, 405).

SURGICAL CANNULA

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CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present disclosure claims the benefit of priority of the following commonly-owned, presently-pending provisional application: application serial no. 62221031, filed September 20, 2015, entitled "METHOD OF DESIGNING SENSORS ON CATHETER." The disclosure of the provisional application is hereby incorporated by reference in its entirety, including any appendices or attachments thereof, for all purposes.

FIELD OF THE DISCLOSURE

[0002] The present disclosure generally relates to intraoperative tracking approaches, and more particularly to a surgical cannula with intraoperative tracking capabilities.

BACKGROUND

[0003] Common brain diseases, such as brain tumors, Parkinson's disease, and epilepsy, not only adversely affect the patients' quality of life but sometimes can also directly contribute to the patients' death. Invasive surgical procedures are usually performed after conservative treatments, such as medication or physical therapy that fails to relieve the patients' symptoms.

[0004] Generally, a physician may reach a targeted surgical site to perform treatments along a surgical pathway. The surgical pathway may be determined based on certain pre-operative data. However, the pre-operative data may not accurately reflect the patients' intraoperative status. Such a determined surgical pathway often leads to further complications or an increased mortality rate.

SUMMARY

[0005] In accordance with some embodiments of the present disclosure, a probe comprises a cannula, a tube, and a detector. The tube may be disposed in the cannula and define a passage to guide a surgical tool into a patient's brain. The first passage may be between the tube and the cannula. The detector may be disposed on the tube and configured to

collect information associated with brain tissues of the patient. The detector may also be electrically connected to a power source through a wire disposed in the first passage.

[0006] In accordance with some other embodiments of the present disclosure, a probe assembly comprises a probe and a cannula. The probe may be configured to detect blood flow information of brain tissues along a surgical path in a patient's brain. The cannula may be configured to sleeve the probe. In addition, the probe and the cannula may be configured to couple at an entry point of the surgical path and to decouple at a destination point of the surgical path.

[0007] In accordance with yet some other embodiments of the present disclosure, a probe comprises a cannula, a tube, and a detector. The tube may be disposed in the cannula. The first passage may be between the tube and the cannula. The detector may include a rigid layer and a flexible circuit layer. The rigid layer may be coupled to a first side of the tube. The flexible circuit layer may be disposed on a second side of the tube.

[0008] The foregoing summary is illustrative only and is not intended to be in any way limiting. In addition to the illustrative aspects, embodiments, and features described above, further aspects, embodiments, and features will become apparent by reference to the drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Fig. 1 illustrates an example ultrasonic detector;

Fig. 2A illustrates an example probe;

Fig. 2B illustrates a cross sectional view of an example probe;

Fig. 3A illustrates an example probe assembly;

Fig. 3B illustrates an example couple mechanism;

Fig. 3C illustrates a cross sectional view of an example probe assembly;

Fig. 4A illustrates an example probe; and

Fig. 4B illustrates a cross sectional view of an example probe; all arranged in accordance with some embodiments of the present disclosure.

DETAILED DESCRIPTION

[0010] In the following detailed description, reference is made to the accompanying drawings, which form a part hereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, drawings, and claims are not meant to be limiting. Other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the subject matter presented here. It will be readily understood that the aspects of the present disclosure, as generally described herein, and illustrated in the Figures, can be arranged, substituted, combined, and designed in a wide variety of different configurations, all of which are explicitly contemplated herein.

[0011] This disclosure is drawn, *inter alia*, to a surgical cannula with the intraoperative tracking ability. The surgical cannula may be configured to collect information associated with tissues around the surgical cannula during the surgery.

[0012] In a surgery, a cannula may be used to generate a pathway to a targeted surgical site in the patient to remove from or deliver fluid/medicine to the patient. In some embodiments, a detector is disposed on the cannula. The detector is configured to collect information associated with tissues around the surgical cannula. According to the collected information, some high risk areas (e.g., main blood vessels, tumors, etc.) may be identified when the surgical cannula approaches those high risk areas. The physician may take actions to bypass the high risk areas to decrease the chance of causing unintended injuries to the patient.

[0013] In some embodiments, various detectors may be used in conjunction with the surgical cannula. For example, an optical sensor may be attached at a front edge of the surgical cannula. The optical sensor is configured to transmit light beams and collect the reflected/refracted light beams. Images may be generated based on the reflected/refracted light beams so that a physician may be aware of the tissues surrounding the optical sensor.

[0014] In some embodiments, an ultrasonic detector may be coupled with the surgical cannula. The ultrasonic detector is configured to generate ultrasonic waves and collect the echoes of the ultrasonic waves. The collected echoes can then be evaluated to determine attributes of the tissues surrounding the surgical cannula. Fig. 1 illustrates an example ultrasonic detector 100 in accordance with some embodiments of the present disclosure. The ultrasonic detector 100 includes a foil layer 101, a matching layer 103, a piezoelectric material array 105, a flexible circuit layer 107 and a backing layer 109.

[0015] The matching layer 103 is configured to match the acoustic impedance between the piezoelectric material array 105 and the detected target. The matching layer 103 may include multiple layers. Some example materials of the matching layer 103 include, but not limited to, glue, glass, and etc. The piezoelectric material array 105 includes a set of piezoelectric elements 105(1), 105(2), ...105(n). The piezoelectric elements are connected to the flexible circuit layer 107. The backing layer 109 is configured to avoid reflection of acoustic energy. Some example materials of the backing layer 109 include, but not limited to, tungsten and its oxides, cerium and its oxides, epoxy, and a combination of any two materials set forth above.

[0016] In some embodiments, the thickness of the foil layer 101 may be about 5 micrometers to about 15 micrometers. The thickness of the matching layer 103 may be about 50 micrometers to about 150 micrometers. The thickness of the piezoelectric material array 105 may be about 50 micrometers to about 150 micrometers. The thickness of the backing layer 109 may be about 400 micrometers to about 800 micrometers.

[0017] Fig. 2A is an example probe 200 in accordance with some embodiments of the present disclosure. The probe 200 includes a cannula 201, a tube 203, and a detector 209 coupled to the tube 203. In some embodiments, the cannula 201 has a first diameter D1 and a first length L1. The tube 203 has a second diameter D2 and a second length L2. The first diameter D1 is greater than the second diameter D2 so that the cannula 201 sleeves the tube 203. The cannula 201 and the tube 203 may be coaxial or non-coaxial. The second length L2 is greater than the first length L1 so that a portion 207 of the tube 203 may be exposed from the cannula 201. In some embodiments, detector 209 may be disposed adjacent to a distal end (e.g., the portion 207) of the tube 203, so that the detector 209 is not blocked by the cannula 201.

[0018] The cannula 201 may be used to deliver fluids or medicine to a targeted surgical site of a patient. The cannula 201 may be made of stainless steel, Teflon, fused silica glass, or other feasible biocompatible materials.

[0019] In some embodiments, the tube 203 is rigid to provide mechanical support for the cannula 201. The tube 203 is made of one or more biocompatible materials. Some example materials of the tube 203 include, but not limited to, stainless steel, aluminium, and glass-filed thermoplastic resin, and etc. In some embodiments, the tube 203 may include an outer periphery and an inner periphery. The inner periphery may define a hollow space. The outer periphery may sleeve the inner periphery. Tube 203 may have an outer polygonal periphery and an inner polygonal periphery, an outer cylindrical periphery and an inner cylindrical periphery, an outer polygonal periphery and an inner cylindrical periphery, or an outer cylindrical periphery and an inner polygonal periphery.

[0020] The detector 209 may be any technical feasible detector. In some embodiments, the detector 209 may be the ultrasonic detector 100 described above. Fig. 2B illustrates a cross sectional view of the detector 209 coupled to the tube 203 of the probe 200. The detector 209 may include a set of detector members 209(1), 209(2), ...209(n), and a flexible circuit layer 211 is electrically coupled to the detector members. A length of any one of the set of detector members may be 0.05mm, 0.10mm, 0.15mm, 0.20mm, 0.25mm, 0.30mm, or any value between the values set forth above. The detector members may be arranged in an array, for example, a two-dimensional matrix array or a first-dimensional linear array. The flexible circuit layer 211 may be wrapped around tube 203 and so as the detector members.

[0021] The flexible circuit layer 211 may include multiple layers. In some embodiments, the flexible circuit layer 211 includes alternating polyimide and metal trace layers. The electrical signals of the detector members may be routed through the metal trace layers to a pad connector disposed at the bottom of the flexible circuit layer 211 and eventually transmitted through other wires to a processor configured to process the electrical signals.

[0022] In conjunction with Fig. 2A, a first passage 205 may be defined between the cannula 201 and the tube 203. The flexible circuit layer 211 may be disposed in the first passage 205 to provide power from a power source to the detector 209. The flexible circuit layer 211 may also be configured to transmit data and/or control signals between the detector 209

and a processor configured to interpret the information collected by the detector 209. Referring back to Fig. 2B, the tube 203 may define a second passage 213. The second passage 213 may be used as a surgical tool passage so that the surgical tool may reach a targeted surgical site through the second passage 213. The second passage 213 may be also used to transmit one or more fluids during the surgery.

[0023] When the probe 200 is used in a surgery, such as a brain surgery, the physician may first drill a hole on a patient's skull and then insert the probe 200 into the patient's skull via the hole. The detector 209 continues to collect information associated with the tissues surrounding the distal end (e.g., the portion 207) of the probe 200 where the detector 209 is attached. According to the collected information, the physician may avoid passing through some high risk areas of the patient's brain before reaching a targeted surgical site. When the physician determines that the targeted surgical site is reached based on pre-operative data and information collected by the detector 209, a surgical tool may be inserted into the second passage 213 of the probe 200 to reach the targeted surgical site to perform the surgery. The detector 209 may continue to collect information after the surgical tool reaches the targeted surgical site so that the physician has access to the most recent information relating to the site during the surgery.

[0024] Fig. 3A illustrates an example probe assembly 300 in accordance with some embodiments of the present disclosure. The probe assembly 300 includes a cannula 301 and a probe 303. In some embodiments, the cannula 301 has a diameter D3 and a length L3. The probe 303 has a diameter D4 and a length L4. The diameter D3 is greater than the diameter D4 so that the cannula 301 sleeves the probe 303. The cannula 301 and the probe 303 may be coaxial or non-coaxial. The length L4 is greater than the length L3 so that a portion 309 of the probe 303 is exposed from the cannula 301 when the cannula 301 sleeves the probe 303. The portion 309 may be about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, about 10%, about 11%, about 12%, about 13%, about 14%, about 15%, or any value between any two values set forth above, of the length L4. The probe 303 includes a detector, which will further describe below, embedded in the probe 303 at the portion 309.

[0025] In some embodiments, the cannula 301 is configured to couple with the probe 303 before the probe assembly 300 reaches a surgical targeted site. The detector embedded in

the probe 303 may collect information associated with tissues surrounding the probe assembly 300. The physician may choose an appropriate path to reach the surgical targeted site based on, in part, the information collected by the detector. After the probe assembly 300 reaches the surgical targeted site, the cannula 301 may be fixed to patient's bone (e.g., skull) so that the position and orientation of the probe assembly 300 is also fixed. After the cannula 301 is fixed, the probe 303 is configured to decouple from the cannula 301 and removed from the patient. A surgical tool may be inserted to the cannula 301 to reach the surgical targeted site after probe 303 is removed.

[0026] In some embodiments, a distal handle portion 311 of the cannula 301 is configured to couple with a proximal handle portion 313 of the probe 303. The cannula 301 and the probe 303 may be locked with any technical feasible fasteners. For illustration only, Fig. 3B illustrates an example couple mechanism 310 configured to couple the cannula 301 and the probe 303 in accordance with some embodiments of the present disclosure. The couple mechanism 310 includes, but not limited to, a bearing 312, a hook 322, teeth 324, a protrusion 326, and teeth 328. The cannula 301 and the probe 303 are configured to rotate with each other with the bearing 312. Along the rotation and in response to the teeth 324 and the teeth 328 match with each other, the hook 322 is locked to the protrusion 326 as well so that the cannula 301 and the probe 303 are coupled together.

[0027] Fig. 3C illustrates an example cross sectional view 330 of the probe assembly 300 in accordance with some embodiments of the present disclosure. The cross section view 330 illustrates a detector 340 embedded in the probe 303. In some embodiments, the detector 340 may be the ultrasonic detector 100 described above. The detector 340 may be a layered structure. For example, the detector 340 may include a matching layer 341, a piezoelectric material array or a capacitive micromachined layer 343, a backing layer 345, and a flexible circuit layer 347. In some embodiments, the detector 340 has a width W1 which is about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, about 100%, or any value between any two values set forth above, of the diameter D4 of probe 303. In some embodiments, the detector 340 has a length about 1%, about 2%, about 3%, about 4%, about 5%, about 6%, about 7%, about 8%, about 9%, about 10%, about 11%, about 12%, about 13%, about 14%, about 15%, or any value between any two values set forth above, of the length L4 of probe 303.

[0028] Fig. 4A illustrates an example probe 400 in accordance with some embodiments of the present disclosure. The probe 400 includes a cannula 401, a tube 403, a tip 407, and a detector 430 attached on the tube 403. In some embodiments, the cannula 401 has a diameter D5 and the tube 403 has a diameter D6. The diameter D5 is greater than the diameter D6 so that the cannula 401 sleeves the tube 403. The cannula 401 and the tube 403 may be coaxial or non-coaxial. The cannula 401 includes a window. In some embodiments, the detector 430 is disposed under the window so that the detection capability of the detector 430 may pass through the window and not be shielded by the cannula 401. The tip 407 may be soft and have a dome shape to reduce tissue damages when the probe 400 is inserted to patient's body.

[0029] In some embodiments, the cannula 401 and the tube 403 define a first passage 405. The detector 430 may receive power transmitted through a cable disposed in the first passage 405. The information collected by the detector 430 may be transmitted to a processor through the first passage 405 for further processing.

[0030] In some embodiments, the tube 403 may be similar to the tube 203 set forth above. The tube 403 may define a second passage 404 for a surgical tool to pass through. In some embodiments, the tip 407 defines a third passage 411 corresponding to the second passage 404 so that the surgical tool can pass through the tip 407 as well.

[0031] The detector 430 may be any technical feasible detector. In some embodiments, the detector 430 may be the ultrasonic detector 100 described above. Fig. 4B illustrates a cross sectional view 420 of the detector 430 attached on the tube 403 of the probe 400. The detector 430 may include a matching and a piezoelectric material array layer 431, a backing layer 432, and a flexible circuit layer 433. In some embodiments, the layers 431 and 432 may be rigid and coupled to a first side (e.g., upper side) of the tube 403. The flexible circuit layer 433 is flexible and disposed on a second side (e.g., right side) of the tube 403.

[0032] For some detectors, such as an ultrasonic detector, the backing layer 432 may reach a specific thickness so that the detector 430 may obtain meaningful information. Therefore, in some embodiments, the backing layer 432 may be shaped so that the side of the backing layer 432 configured to be in contact with tube 403 is complementary with the shape of the tube 403. With such design, the thickness of backing layer 432 may be varied according to

the shape of the tube 403 as illustrated in Fig. 4B. Among the varied thickness distributions, some thickness distribution may reach or beyond the specific of thickness so that the detector 430 may function properly.

[0033] When the probe 400 is used in a surgery, for example deep brain stimulation, the physician first drills a hole on patient's skull and inserts the probe 400 into patient's brain. The size of the probe 400 is critical for such high precision surgery. In some embodiments, the diameter D5 of the cannula 401 of the probe 400 is not greater than 5mm. The diameter D5 may be about 1mm, about 2mm, about 3mm, about 4mm, and any value between any two values set forth above. The diameter D6 of the tube 403 of the probe 400 may not be greater than 3mm. For example, the diameter D6 may be about 0.5mm, about 1.0mm, about 1.5mm, about 2.0mm, about 2.5mm, and any value between any two values set forth above.

[0034] In the surgery, the detector 430 continues to collect information associated with tissues around the distal end of the probe 400 where the detector 430 is embedded. According to the collected information, the physician may avoid to pass through some high risk areas of the patient's brain before reaching a targeted surgical site (e.g., substantia nigra) to block nerve signals generated from the targeted surgical site. When the physician determines that the targeted surgical site is reached based on pre-operative data and information collected by the detector 430, a surgical tool may be inserted into the second passage 404 and the third passage 411 of the probe 400 to reach the targeted surgical site to perform the surgery. In some embodiments, the surgical tool may implant an electrode in the brain nuclei, for example subthalamus nucleus, globus pallidus internal segment and/or ventro-intermediate nucleus. The detector 430 may continue to collect information after the surgical tool reaches the targeted surgical site so that the physician may receive latest information during the surgery.

[0035] While the forgoing is directed to embodiments of the present disclosure, other and further embodiments of the disclosure may be devised without departing from the basic scope thereof, and the scope thereof is determined by the claim that follow.

We Claim:

1. A probe, comprising:

a cannula;

a tube disposed in the cannula and defining a passage to guide a surgical tool into a patient's brain;

a first passage between the tube and the cannula; and

a detector disposed on the tube and configured to collect information associated with brain tissues of the patient, wherein the detector is electrically connected to a power source through a wire disposed in the first passage.

2. The probe of claim 1, wherein the tube and the cannula are substantially coaxial.

3. The probe of claim 1, wherein the tube is rigid and configured to support the cannula.

4. The probe of claim 1, wherein a first edge of the tube is exposed from the cannula.

5. The probe of claim 3, wherein the detector is disposed on the first edge of the tube.

6. The probe of claim 1, wherein the detector comprises a set of detector members coupled by a flexible circuit layer disposed around the tube.

7. The probe of claim 5, wherein a detector element of the set of detector elements has a length with a range from about 0.1mm to 0.2mm.

8. A probe assembly, comprising:

a probe configured to detect blood flow information of brain tissues along a surgical path in a patient's brain; and

a cannula configured to sleeve the probe, wherein the probe and the cannula are configured to couple at an entry point of the surgical path and to decouple at a destination point of the surgical path.

9. The probe assembly of claim 8, wherein the cannula is locked to the skull in response to the probe assembly having reached the destination point.

10. The probe assembly of claim 9, wherein the probe is removed from the cannula and a surgical instrument is inserted to the destination point through the cannula.

11. The probe assembly of claim 8, wherein the cannula is shorter than the probe so that a first portion of the probe is exposed from the cannula.

12. The probe assembly of claim 11, wherein an ultrasonic detector is embedded in the first portion of the probe, and a length of the first portion is about 1% to about 9% of a length of the probe.

13. The probe assembly of claim 12, wherein the ultrasonic detector has a width of about 60% to about 85% of a diameter of the probe.

14. A probe, comprising:

a cannula;

a tube disposed in the cannula;

a first passage between the tube and the cannula; and

a detector comprising a rigid layer and a flexible circuit layer, wherein the rigid layer is coupled to a first side of the tube and the flexible circuit layer is disposed on a second side of the tube.

15. The probe of claim 14, wherein the cannula comprises a diameter not greater than 5mm and the tube comprises a diameter not greater than 3mm.

16. The probe of claim 14, wherein the tube defines a second passage configured to guide a surgical instrument to implant an electrode to a patient's subthalamus nucleus, globus pallidus internal segment, ventro-intermediate nucleus or a comgination thereof.

17. The probe of claim 14, wherein the detector is an ultrasound detector and the rigid layer comprises a backing layer with a shape complementary with the tube.

18. The probe of claim 17, wherein the backing layer comprises a thickness greater than 0.6mm.

19. The probe of claim 14, wherein the tube is disposed away from the axis of the cannula.

20. The probe of claim 14, further comprising a dome tip disposed at one end of the cannula, wherein the dome tip defines a third passage corresponding to the third passage.

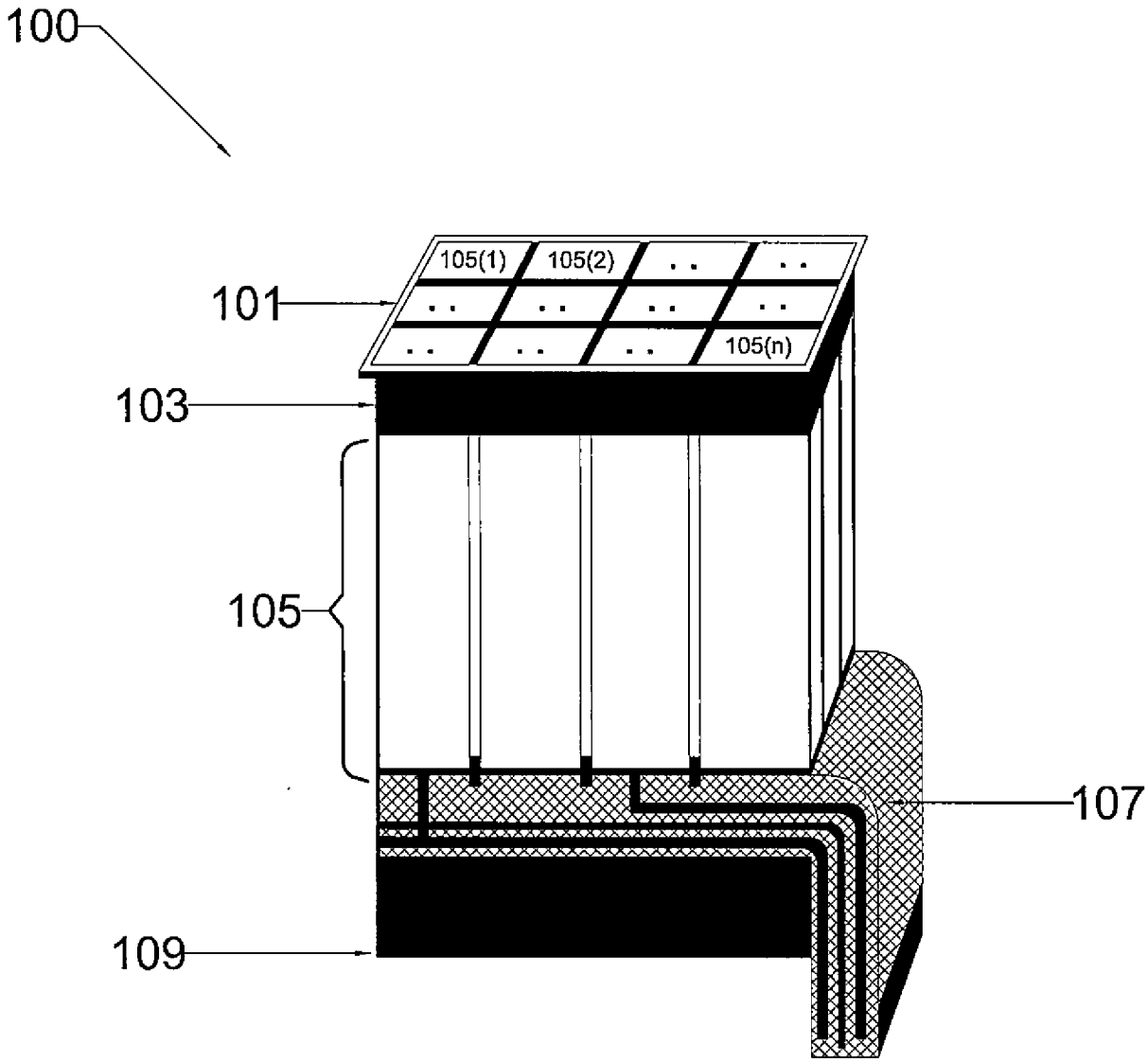

FIG 1

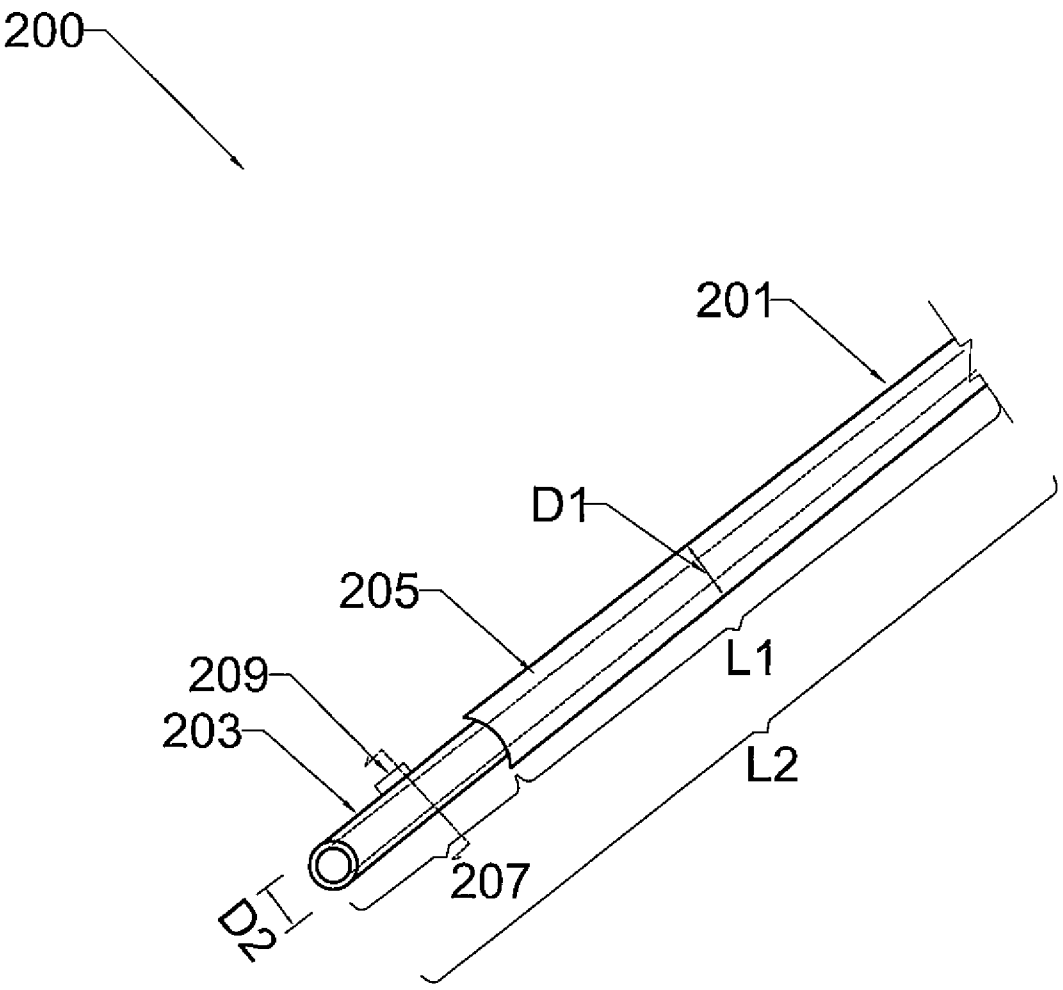

FIG 2A

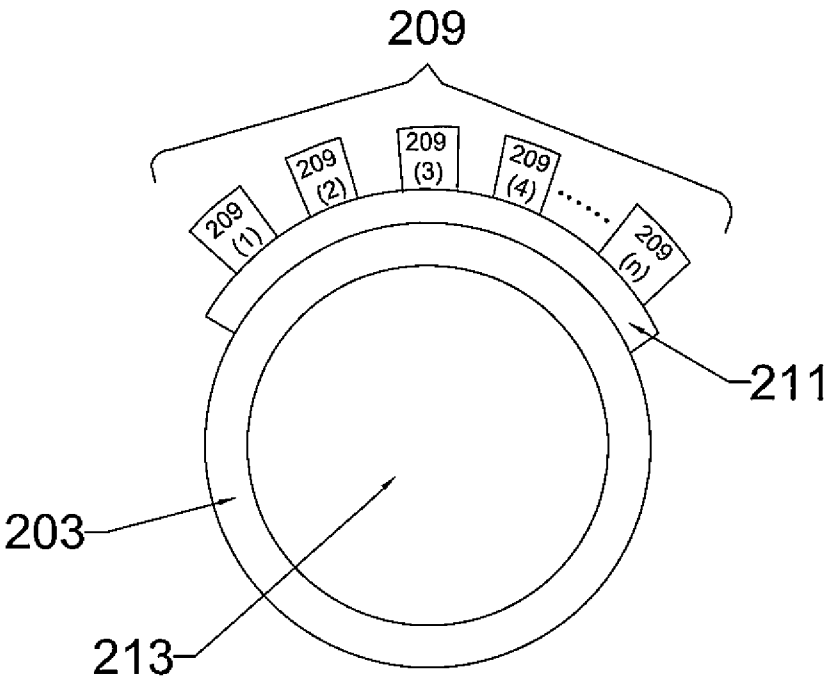

FIG 2B

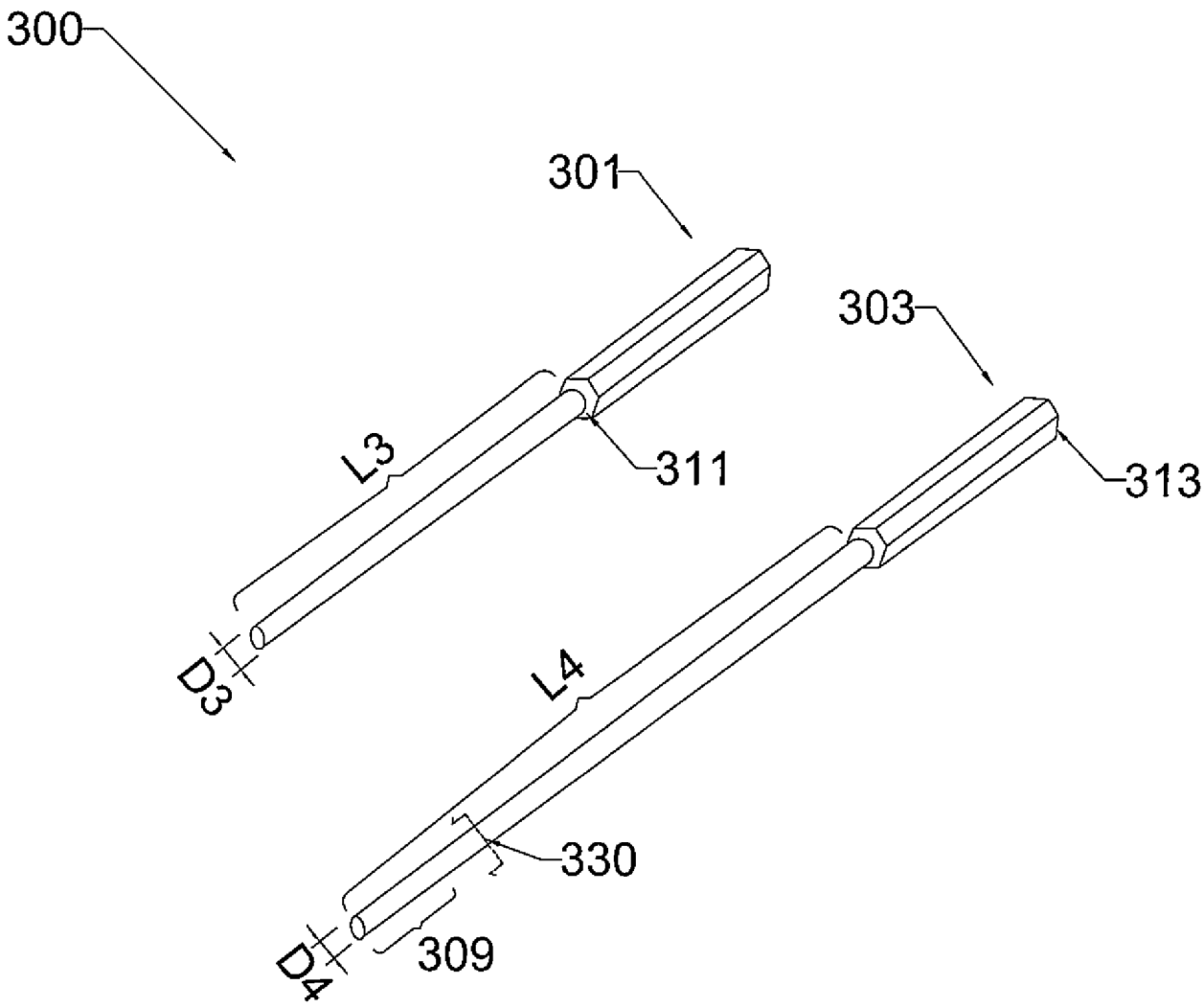

FIG 3A

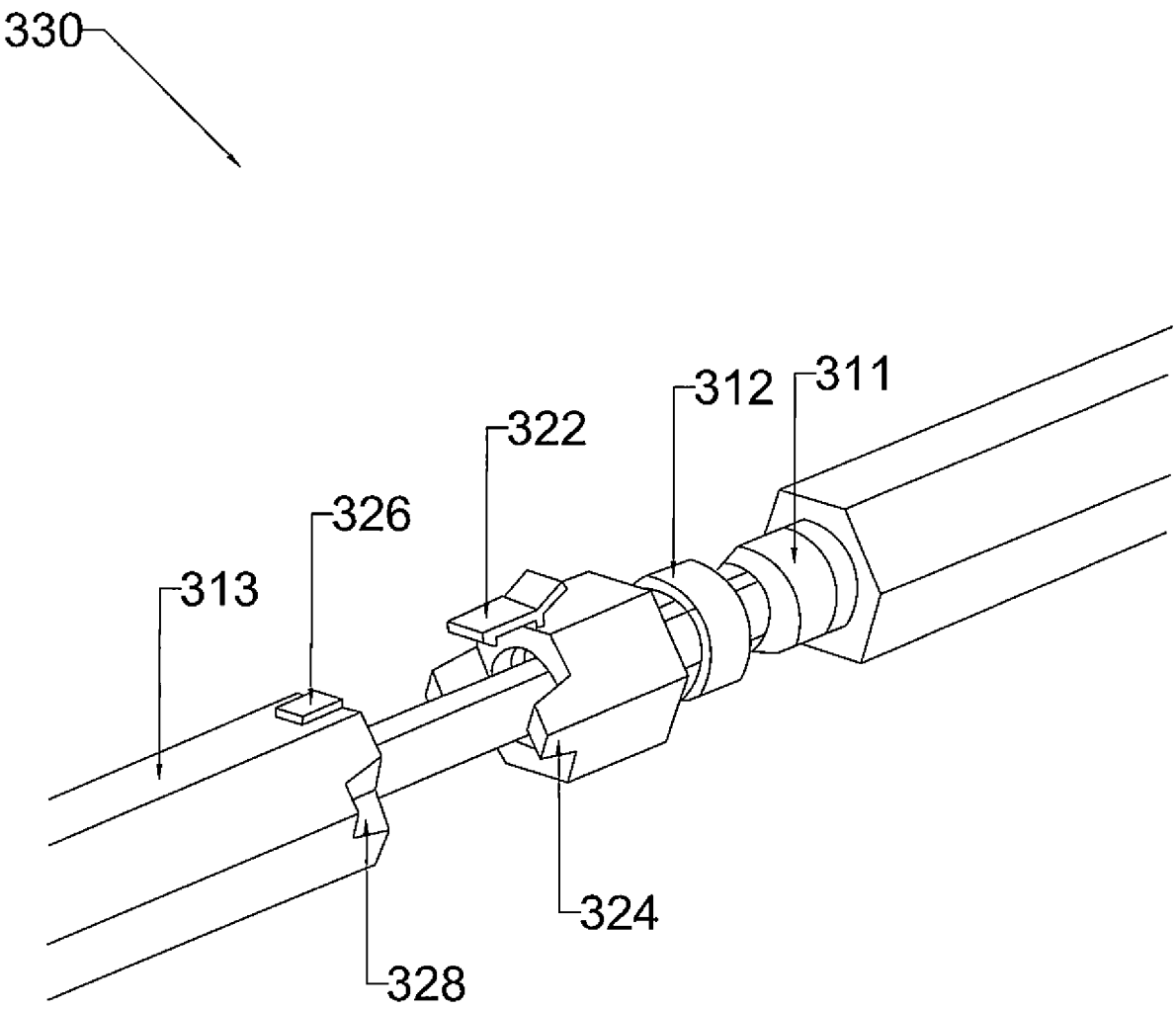

FIG 3B

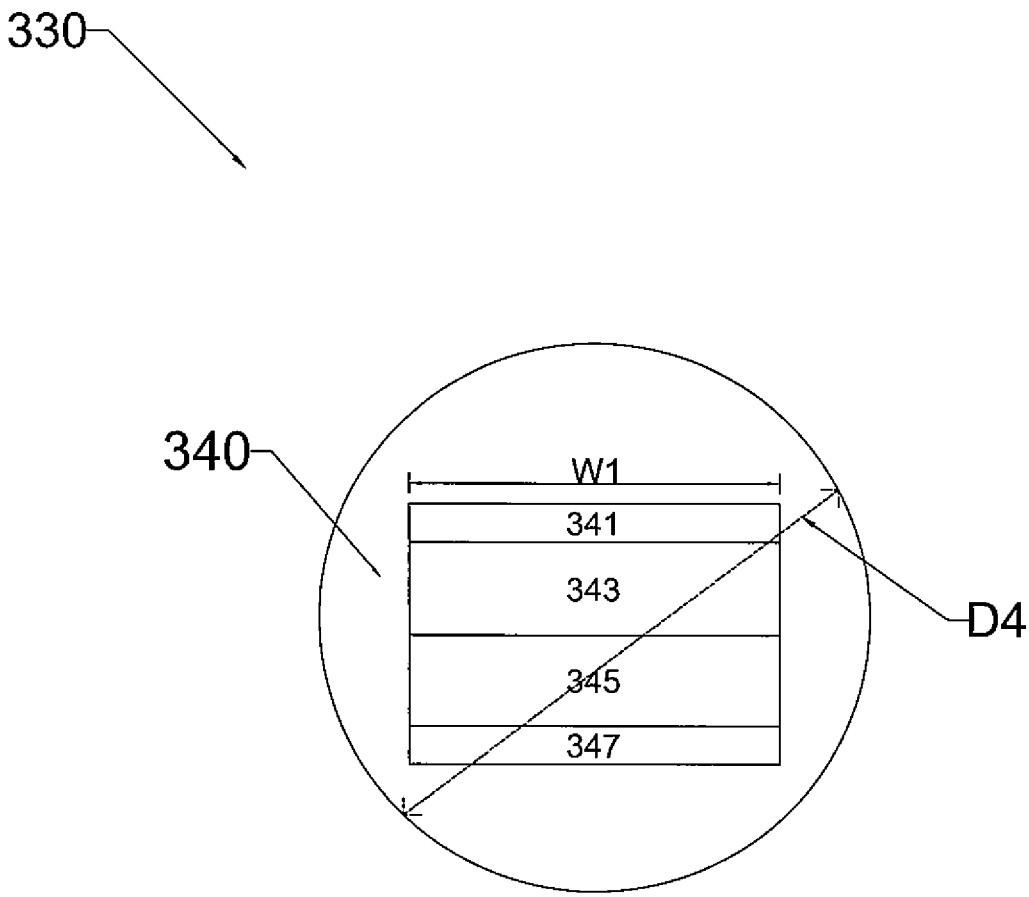

FIG 3C

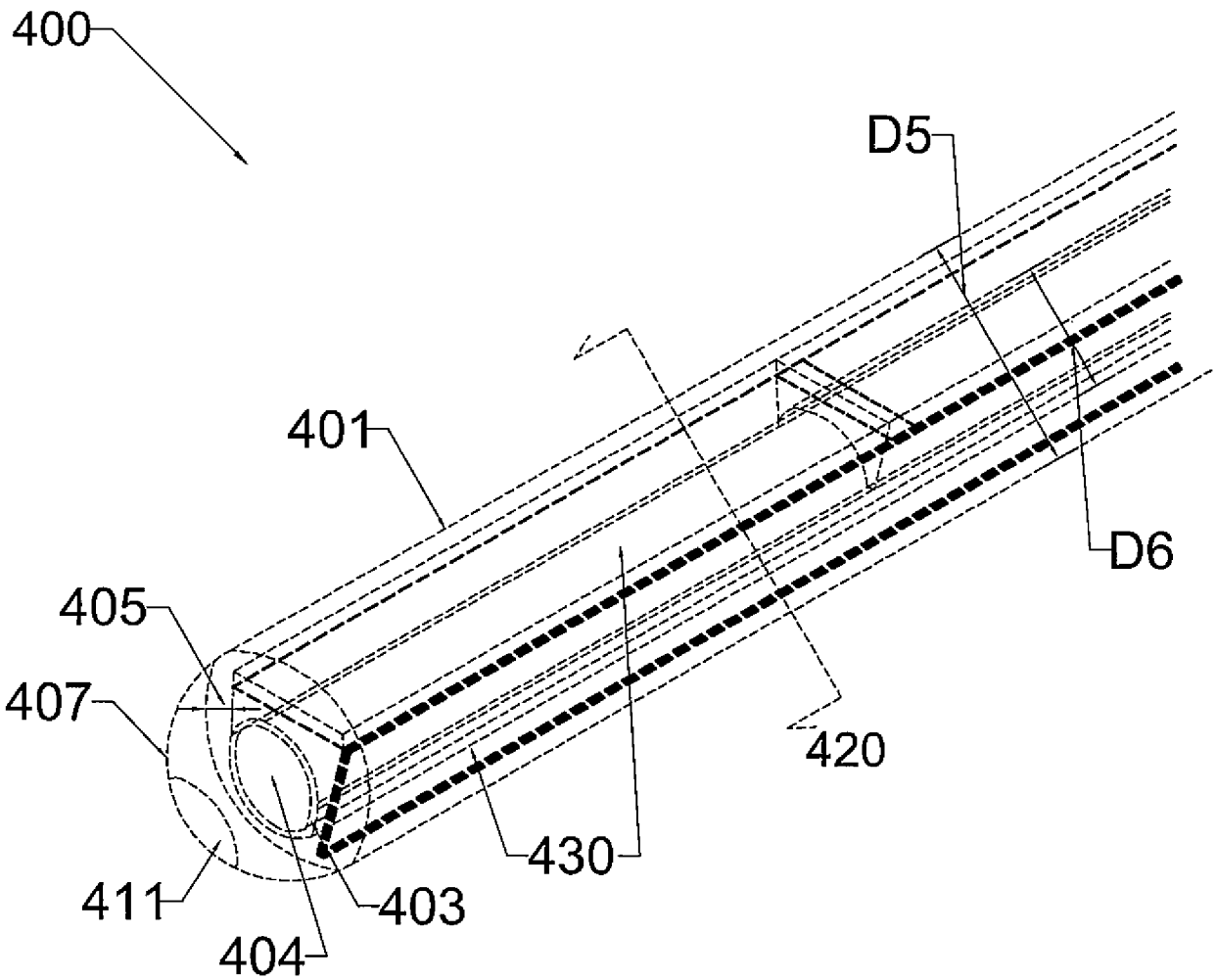

FIG 4A

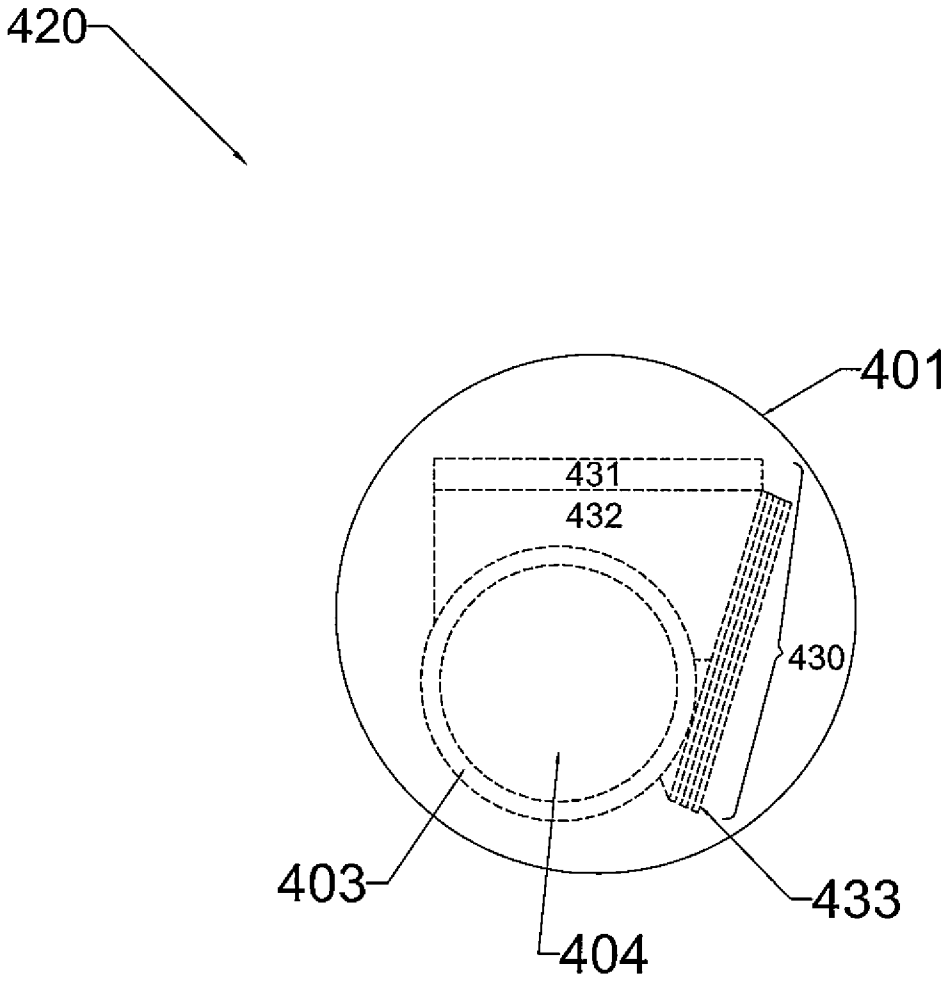

FIG 4B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2016/099233

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/34(2006.01)i

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)

A61B

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)

CPRSABS,CNTXT,CNPAT,VEN ultrasound, ultrasonic+, detect+, transducer,trocar, cannula, probe?, flexbile, rigid

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006235455 A1 (OLYMPUS CORP) 19 October 2006 (2006-10-19) description, paragraphs [0017]-[0096] and figures 1-5C	8-13
Y	US 2006235455 A1 (OLYMPUS CORP) 19 October 2006 (2006-10-19) description, paragraphs [0017]-[0096] and figures 1-5C	1-7, 14-20
Y	WO 2015108941 A1 (VOLCANO CORP) 23 July 2015 (2015-07-23) description, pages 11-27 and figures 2A-6C	1-7
Y	WO 2015068080 A1 (KONINKL PHILIPS NV) 14 May 2015 (2015-05-14) description, pages 4-11, figures 1-8	14-20
Y	US 2009030312 A1 (HADJICOSTIS) 29 January 2009 (2009-01-29) description, paragraphs [0031]-[0088] and figures 1-16	14-20
A	CN 101138513 A (TOKYO SHIBAURA ELECTRIC CO ET AL.) 12 March 2008 (2008-03-12) the whole document	1-20

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

☑ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
09 December 2016	**27 December 2016**

Name and mailing address of the ISA/CN	Authorized officer
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Information on patent family members

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