Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2734538 C 2016/08/02

(11)(21) **2 734 538**

(12) **BREVET CANADIEN
CANADIAN PATENT**

(13) **C**

(86) **Date de dépôt PCT/PCT Filing Date:** 2009/09/29
(87) **Date publication PCT/PCT Publication Date:** 2010/04/01
(45) **Date de délivrance/Issue Date:** 2016/08/02
(85) **Entrée phase nationale/National Entry:** 2011/02/17
(86) **N° demande PCT/PCT Application No.:** US 2009/058792
(87) **N° publication PCT/PCT Publication No.:** 2010/037099
(30) **Priorité/Priority:** 2008/09/29 (US61/101,061)

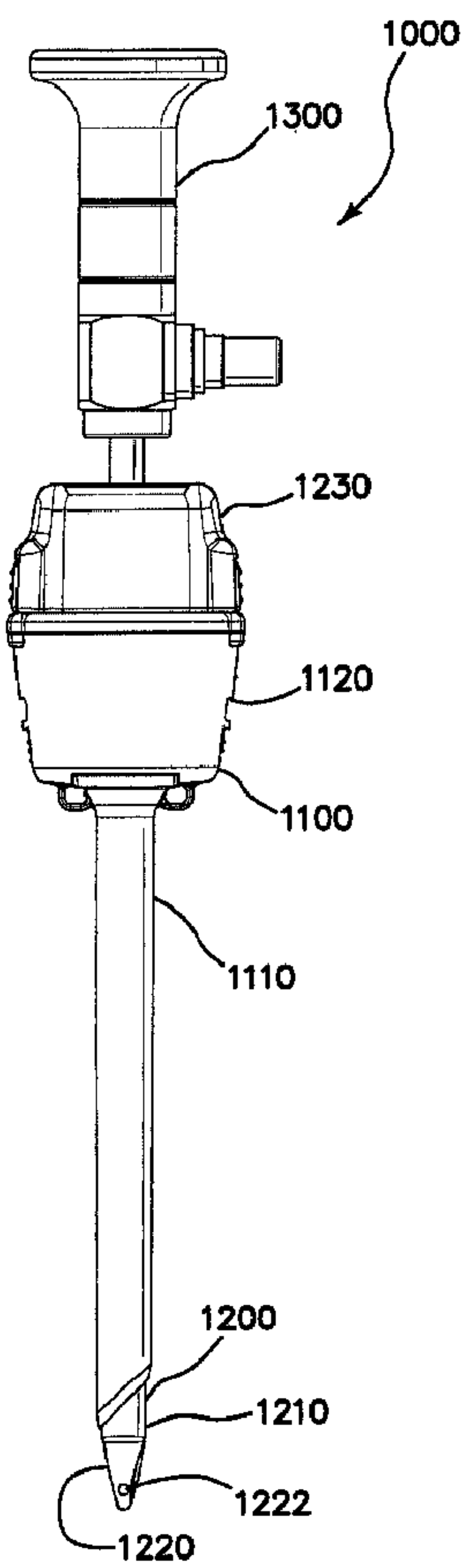
(51) **Cl.Int./Int.Cl.** ***A61B 17/34*** (2006.01)

(72) **Inventeurs/Inventors:**
KAHLE, HENRY, US;
STROKOSZ, ARKADIUSZ, US;
TAYLOR, SCOTT V., US

(73) **Propriétaire/Owner:**
APPLIED MEDICAL RESOURCES CORPORATION, US

(74) **Agent:** BORDEN LADNER GERVAIS LLP

(54) **Titre : SYSTEME DE TROCART DE PREMIERE ENTREE**
(54) **Title: FIRST-ENTRY TROCAR SYSTEM**



(57) **Abrégé/Abstract:**
A surgical access system comprises a trocar, an insufflating optical obturator slidably insertable into the trocar, and a laparoscope slidably insertable into the obturator. A distal end of the obturator comprises a tip, at least a portion of which comprises a wall with a

(57) **Abrégé(suite)/Abstract(continued):**
generally uniform thickness comprising a transparent material. At least one vent hole disposed at the obturator tip is fluidly connected to a gas flow channel defined by an interior surface of the obturator and the laparoscope, which is fluidly connected to an insufflation gas inlet dis-posed at a proximal end of the trocar. Improved optical characteristics of the trocar system permit precise and accurate visual placement thereof into a body cavity. Accordingly the ac-cess system is suitable as a first entry surgical access system. Embodiments of the trocar access are also useful for drug delivery, and/or for fluid and/or tissue aspiration.

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
1 April 2010 (01.04.2010)

PCT

(10) International Publication Number
WO 2010/037099 A1

(51) International Patent Classification:
A61B 17/34 (2006.01)

(21) International Application Number:
PCT/US2009/058792

(22) International Filing Date:
29 September 2009 (29.09.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/101,061 29 September 2008 (29.09.2008) US

(71) Applicant *(for all designated States except US)*: **APPLIED MEDICAL RESOURCES CORPORATION** [US/US]; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

(72) Inventors; and
(71) Applicants *(for all designated States except US)*: **STROKOSZ, Arkadiusz** [US/US]; 24682 Evening Star Drive, Dana Point, CA 92629 (US). **TAYLOR, Scott, V.** [US/US]; 27851 Encanto, Mission Viejo, CA 92692 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **KAHLE, Henry** [US/US]; 25 Wrangler Court, Trabuco Canyon, CA 92679 (US).

(74) Agent: **HO, Pui, Tong**; 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688 (US).

[Continued on next page]

(54) Title: FIRST-ENTRY TROCAR SYSTEM

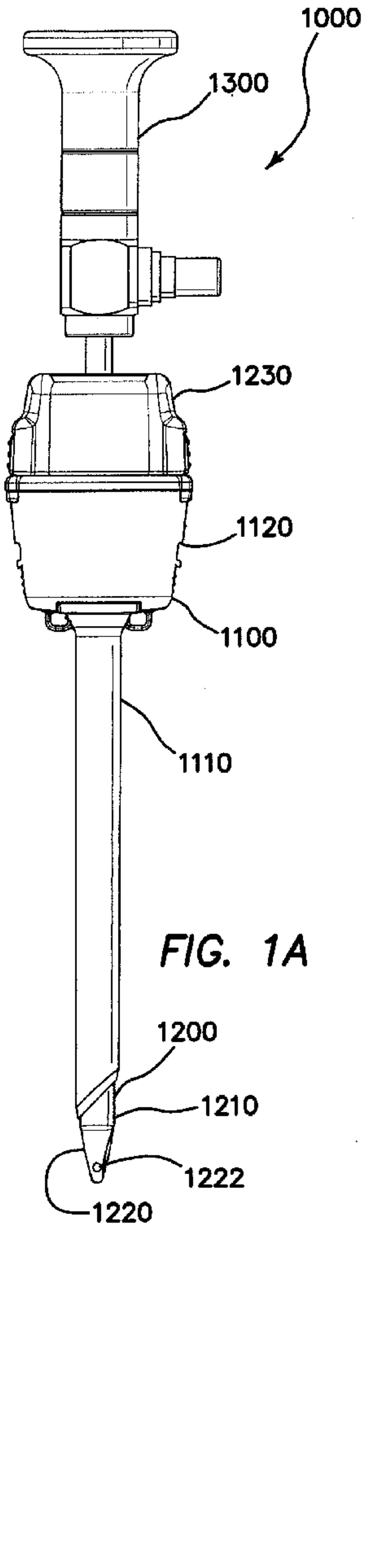


FIG. 1A

(57) Abstract: A surgical access system comprises a trocar, an insufflating optical obturator slidably insertable into the trocar, and a laparoscope slidably insertable into the obturator. A distal end of the obturator comprises a tip, at least a portion of which comprises a wall with a generally uniform thickness comprising a transparent material. At least one vent hole disposed at the obturator tip is fluidly connected to a gas flow channel defined by an interior surface of the obturator and the laparoscope, which is fluidly connected to an insufflation gas inlet disposed at a proximal end of the trocar. Improved optical characteristics of the trocar system permit precise and accurate visual placement thereof into a body cavity. Accordingly the access system is suitable as a first entry surgical access system. Embodiments of the trocar access are also useful for drug delivery, and/or for fluid and/or tissue aspiration.

WO 2010/037099 A1

WO 2010/037099 A1

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

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

Published:

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

FIRST-ENTRY TROCAR SYSTEM

BACKGROUND

Technical Field

This disclosure is generally directed to surgical access devices, and more particularly, to a first-entry surgical access system.

Description of the Related Art

Trocars are used for instrument access to body cavities in minimally invasive surgery, for example, laparoscopic surgery. In laparoscopic surgery of the organs of the abdomen, the abdomen is typically inflated or insufflated with an insufflation gas, for example, carbon dioxide, which lifts the abdominal wall away from the internal organs, thereby facilitating access to the organs, a condition referred to as pneumoperitoneum. Inserting trocars into an abdomen under pneumoperitoneum is relatively easy. Because the abdominal wall is distended away from the internal organs by the pressure of the insufflation gas, inadvertent damage to the organs during insertion is reduced. Before pneumoperitoneum is established, however, the abdominal wall through which the trocar is to be inserted contacts the internal organs directly. Consequently, inserting the first trocar, referred to as first entry, carries an increased risk of damaging the internal organs directly beneath the entry point.

SUMMARY OF THE INVENTION

A surgical access system comprises a trocar, an insufflating optical obturator slidably insertable into the trocar, and a laparoscope slidably insertable into the obturator. A distal end of the obturator comprises a tip, at least a portion of which comprises a wall with a generally uniform thickness comprising a transparent material. At least one vent hole disposed at the obturator tip is fluidly connected to a gas flow channel defined by an interior surface of the obturator and the laparoscope, which is fluidly connected to an insufflation gas inlet disposed at a proximal end of the trocar. Improved optical characteristics of the trocar system permit precise and accurate visual placement thereof into a body cavity. Accordingly the access system is suitable as a first entry surgical access system. Embodiments of the trocar access are also useful for drug delivery, and/or for fluid and/or tissue aspiration.

Some embodiments provide a bladeless trocar that permits visualization of body tissue fibers as they are being separated, thereby permitting a controlled traversal across a body wall. Some embodiments provide a bladeless trocar that accommodates a conventional laparoscope. Some embodiments provide a trocar that enables insufflation of a body cavity and contemporaneous visualization thereof through the distal tip of the obturator.

[0001] Some embodiments provide a surgical access system comprising: a tubular trocar comprising a longitudinal axis, a proximal end, a distal end, an elongate cannula, and a seal assembly disposed at a proximal end of the cannula; an insufflating obturator slidably insertable into the trocar, the obturator comprising a longitudinal axis, a proximal end, a distal end, a tubular shaft, a tip disposed at the distal end of the shaft, at least one vent hole disposed on the tip, and a handle disposed at the proximal end of the shaft; and a fluid inlet disposed at a proximal end of the access system. At least a portion of the obturator tip comprises a wall comprises a transparent material with a substantially uniform thickness, the obturator slidably receives a laparoscope into the obturator shaft, and an interior surface of the obturator shaft and tip, and an outer surface of an inserted laparoscope together define a insufflation gas flow channel fluidly connecting the at least one vent hole to the fluid inlet.

In some embodiments, the seal assembly comprises a septum seal and a duckbill valve.

In some embodiments, the fluid inlet is disposed on the proximal end of the trocar.

In some embodiments, the obturator tip is bladeless. In some embodiments, the wall of the obturator tip is not greater than about 0.65 mm thick. In some embodiments, the obturator tip has a substantially uniform wall thickness. In some embodiments, the obturator shaft and tip are unitary. In some embodiments, the obturator tip comprises at least one of polymer, polycarbonate, polysulfone, PEEK, polyether block amide (PEBAX®), polyester, copolyester, and acrylic.

In some embodiments, the obturator tip comprises a single vent hole. In some embodiments, the at least one vent hole is at least one of circular, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron shaped, triangular, rectangular, rhomboid, and polygonal.

Some embodiments further comprise a depth indicator on the obturator tip. In some embodiments, the depth indicator comprises at least one of indicia disposed in a bore of the at least one vent hole, and indicia disposed proximate to the at least one vent hole.

In some embodiments, the obturator further comprises at least one laparoscope stop disposed on at least one of the interior surface of the obturator tip and the interior surface of the obturator shaft. In some embodiments, the interior surface of the obturator tip comprises a non-circular transverse cross section.

In some embodiments, the obturator accommodates laparoscopes with varying diameters. In some embodiments, the obturator tip accommodates a distal end of the laparoscope.

In some embodiments, at least one opening perforates the obturator shaft.

In some embodiments, a cross-sectional area of the insufflation gas flow channel is at least about 1.6 mm^2. In some embodiments, a flow rate through the access system is at least about 3.5 L/min at an insufflator setting of about 1.6–2 KPa.

Some embodiments further comprise a laparoscope.

Some embodiments further comprise at least one of a gas flow indicator, an audible gas flow indicator, and a visual gas flow indicator.

Some embodiments provide a method for accessing a targeted body region, the method comprising: inserting a laparoscope into the surgical access system, wherein the obturator is inserted into the trocar; contacting the obturator tip with a body wall; advancing access system through the body wall; observing a position of the obturator tip through the laparoscope; and terminating advancement of the trocar system when the obturator tip is observed to reach a targeted body region.

In some embodiments, the targeted body region is a body cavity.

In some embodiments, observing the position of the obturator tip comprises observing the position of the at least one vent hole.

Some embodiments further comprise coupling the gas inlet of the surgical access system to a source of insufflation gas. Some embodiments further comprise at least one of delivering a medicament through the at least one vent hole to the targeted body region; delivering a fluid; aspirating a fluid; and withdrawing tissue.

Some embodiments further comprise removing the obturator from the trocar.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1A** is a front view and FIG. **1B** is a side view of an embodiment of a surgical access system comprising a trocar, an insufflating optical obturator, and a laparoscope. FIG. **1C** is a front cross-sectional view and FIG. **1D** is a side cross-sectional view a distal end of the insufflating optical obturator illustrated in FIGS. **1A** and **1B** with a laparoscope inserted therein. FIG. **1E** is a top view of a transverse cross section of a tip of the insufflating optical obturator illustrated in FIGS. **1A–1D**.

FIG. **2A** is a side cross-sectional view and FIG. **2B** is a front cross-sectional view of a distal end of another embodiment of an insufflating optical obturator with a laparoscope inserted therein. FIG. **2C** is a top view of a transverse cross-section of a tip of the insufflating optical obturator and laparoscope illustrated in FIGS. **2A** and **2B**.

FIG **3A** is a longitudinal cross-section of another embodiment of an insufflating optical obturator. FIG. **3B** is a detailed cross section of a handle of the insufflating optical obturator illustrated in FIG. **3A**.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

FIGS. **1A** and **1B** are front and side views of an embodiment of a surgical access or trocar system **1000**, which is suitable, for example, as a first entry trocar system. The illustrated embodiment is suitable, for example, as a 5-mm trocar system, as well as for trocar systems of other sizes. The illustrated access system **1000** comprises a trocar **1100**, an obturator **1200**, and a laparoscope **1300**.

The trocar **1100** comprises a longitudinal axis, a proximal end, and a distal end. The proximal end is disposed proximal to a user, for example, a surgeon, during use. Conversely, the distal end is disposed away from the user during use. The obturator **1100** comprises a tubular cannula **1110** and a trocar seal assembly **1120** disposed at the proximal end of the cannula **1110**. In the illustrated embodiment, the seal assembly **1120** comprises a fluid inlet comprising a Luer fitting **1122** and a stopcock **1124**. In other embodiments, the fluid inlet has a different configuration and/or is disposed on another component, for example, on the obturator **1100**.

In the illustrated embodiment, the obturator **1200** is an insufflating optical obturator, as will be described in greater detail below. The obturator **1200** comprises a longitudinal axis, a proximal end, and a distal end. The obturator **1200** comprises an elongate shaft **1210**, which is dimensioned for slidable insertion into and removal from the tubular cannula **1110** of the trocar, a tip **1220** disposed at the distal end of the shaft **1210**, and a handle **1230** disposed at the proximal end of the shaft **1210**. In some embodiments, the obturator tip **1220** is a bladeless tip. In other embodiments, the tip **1220** has another configuration useful for traversing and/or penetrating body tissue, for example, a sharp tip, a pointed tip, a pyramidal tip, a bladed tip, a conical tip, and/or a tip comprising one or more sharp edges or sharpened edges. In other embodiments, the tip **1220** is a radiused blunt tip, which is advantageous for traversing an existing body orifice, and/or relatively soft or fatty tissue.

The trocar **1100** and obturator **1200** independently comprise any suitable material. Those skilled in the art will understand that different components of the trocar **1100** and/or obturator **1200** comprise different materials in some embodiments. Suitable materials include, for example, at least one of a polymer, metal, ceramic, and the like. Suitable polymers include engineering polymers, polycarbonate, polysulfone, PEEK, polyether block amide (PEBAX®), polyester, copolyester, acrylic, and the like. Some embodiments of the trocar **1100** and/or obturator **1100** further comprise a composite, for example, a fiber-reinforced polymer. In some embodiments, a stronger material permits reducing a wall thickness of a component without reducing the strength thereof. For example, some embodiments of a metal or composite obturator shaft **1210** are thinner than a corresponding polymer version, thereby increasing the diameter of a lumen thereof without increasing the outer diameter. As discussed in detail below, increasing lumen diameter improves gas flow through the device.

For example, in some embodiments, obturator shaft **1210** comprises a metal tube, for example, a stainless steel tube, with a polycarbonate tip **1220** insert molded onto the tube. In some embodiments, the metal tube has a wall thickness as thin as about 0.003" (about 0.076 mm). An metal obturator shaft **1210** with an inside diameter of about 0.235" (about 6 mm) and an outside diameter of about 0.241" (about 6 mm) provides an acceptable insufflation gas flow rate. The relationship between gas flow rate and component dimensions and configurations is discussed in detail below.

Embodiments of the cannula **1110** typically comprise a rigid material. Some embodiments of the obturator shaft **1210** comprise a rigid material and/or a flexible material because the obturator shaft **1210** is largely supported by the cannula **1110** during use in some embodiments.

The laparoscope **1300** comprises a proximal end and a distal end **1304** (FIGS. **1C** and **1D**). The laparoscope **1300** is of any suitable type, for example, comprising an eyepiece at a proximal end and an objective at a distal end thereof. The distal end **1304** of the laparoscope **1300** is dimensioned for slidable insertion into and removal from the obturator shaft **1210**.

FIG. **1C** is a front cross-sectional view and FIG. **1D** is a side cross-sectional view of the distal end of the insufflating obturator **1200** with a laparoscope **1300** inserted therein. The illustrated embodiment depicts a bladeless obturator **1200** suitable for visualization and insufflation therewith. The device include a pair of vent holes **1222** at the distal tip **1220** of the bladeless obturator, through which an insufflating gas, such as carbon dioxide, flows into a body cavity, as discussed in greater detail below. Other embodiments comprise more or fewer vent holes **1222**. For example, some embodiments of the tip **1220** of the obturator comprise a single vent hole **1222**. In the illustrated embodiment, the vent holes **1222** are generally circular. In other embodiments, the vent holes **1222** have another shape, for example, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron-shaped, triangular, rectangular, rhomboid, polygonal, and the like. In some embodiments, at least one vent hole **1222** has a different shape from another vent hole **1222**.

In some embodiments, the obturator **1200** is an optical obturator in which at least a portion of a distal end of the tip **1220** of the bladeless obturator comprises a generally transparent or translucent material, through which tissue is visualized during the insertion of the obturator **1200** through a body wall. Embodiments of the bladeless obturator **1200** are dimensioned and configured to receive therein any suitable laparoscope **1300**, which typically includes an imaging element and fiber optic light fibers (not illustrated). The illustrated embodiment of the tip **1220** comprises at least one laparoscope stop **1224**, which assists in positioning the laparoscope **1300** within the obturator **1200**. In other embodiments one or more laparoscope stops are disposed within the obturator shaft **1210** and/or at the intersection of the shaft **1210** and tip **1220**. Other embodiments do not comprise a laparoscope stop.

The illustrated embodiment of the bladeless optical insufflating obturator **1200** includes a tip **1220** configuration comprising one or more features that enhance the visualization and clarity through the tip of the obturator. The illustrated transparent tip **1220** of the obturator through which tissue is observed comprises a wall **1225**, at least a portion of which has a substantially uniform thickness. The uniform wall thickness reduces distortion of an image observed through the obturator tip **1220**. In some embodiments, the entire obturator tip **1220** comprises a substantially uniform wall thickness. Embodiments of bladeless optical obturators comprising non-uniform wall thicknesses typically exhibit less clear imaging through the obturator tip because the varying wall thickness distorts the image transmitted therethrough, for example, in bladeless optical obturators comprising a generally circular inner contour and a generally rectangular outer contour.

FIG. **1E** is a top view of a transverse cross section of the obturator tip **1220** illustrated in FIGS. **1A–1D**. In the illustrated embodiment, an inner contour **1226** of the obturator tip **1220** has a generally rectangular transverse cross section, which substantially matches an outer contour **1228** of the obturator tip, which also has a generally rectangular transverse cross section. In other embodiments, the inner and outer transverse cross-sectional contours **1226** and **1228** of the obturator tip **1220** have another shape, for example, generally elliptical, hexagonal, S-shaped, or another suitable shape. In some embodiments, a portion of an interior surface the tip **1220** at which the distal end laparoscope **1300** contacts has a contour different from a shape or contour of the distal end of the laparoscope. For example, in embodiments in which the distal end of the laparoscope **1300** is circular, the portion of the tip **1220** at which the distal end of the laparoscope **1300** contacts is not circular, thereby defining a gas flow channel therebetween, as discussed in greater detail below.

In some embodiments, at least a portion of the wall **1225** of the obturator tip **1220** comprises a thin-wall configuration. The thin-wall configuration enables light to travel through the material with reduced loss in intensity, thereby enhancing the visibility of tissue through the obturator tip **1220** as the obturator is advanced and placed into the targeted body cavity. The thin-wall configuration also reduces distortion of the image viewed through the obturator tip **1220** and maintains the color accuracy of the viewed tissue. Some embodiments of the obturators **1200** have tip wall thicknesses of from about 0.02" (about 0.5 mm) to about 0.025" (about 0.65 mm) for about 5-mm to 12-mm obturators. In some embodiments, the tip wall is thicker, for example, to provide additional strength.

All transparent materials have a light transmittance value of less than 100%. That is, less than 100% of the light incident on the material is transmitted directly through the material. For a given transparent material, as the wall thickness of the material increases, the amount of light that travels through the material decreases. Moreover, because the illuminating light is directed from within the obturator **1200**, the light must travel through the obturator tip **1220** twice, thereby doubling the loss of light due to the transmittance characteristics or absorption of the obturator tip **1220**. Embodiments of an obturator tip **1220** with a reduced wall thickness reduce the loss of light or absorption thereby, thereby improving the image of the tissue through which the obturator **1200** is advanced, and maintaining the color accuracy and fidelity of the observed tissue.

In some embodiments, the obturator shaft **1210** and tip **1220** are injection molded as a unitary or single, integral component, which, in combination with the thin-wall tip **1220**, allows positioning or placing a distal end **1304** of the laparoscope (FIGS. **1C** and **1D**) in close proximity to and/or within the tip **1220** of the obturator. By placing the distal end **1304** of the laparoscope in close proximity to and/or within the tip **1220** of the obturator, an image produced through the laparoscope **1300** is magnified compared with an image produced by a distal end **1304** of the laparoscope **1300** positioned at a greater distance from the obturator tip **1220**. For example, in some embodiments of a 5-mm bladeless optical obturator designed to accommodate laparoscopes with diameters of from about 5 mm to about 5.5 mm, the distal end of the laparoscope is positionable as close as about 0.442" (about 11 mm) from the distal end of the obturator **1200**. Some embodiments of a 12-mm bladeless optical obturator designed to accommodate about 10-mm diameter laparoscopes, permit positioning the distal end of the laparoscope as close as about 0.79" (about 20 mm) from the distal end of the obturator **1200** or less than about 0.83" (about 21 mm) from the distal end of the obturator

1200. In these embodiments, the magnification through the 5-mm optical obturator is greater than that for the 12-mm optical obturator.

The enhanced visibility through the tip **1220** of the obturator also enhances the visibility of the vent holes **1222** in the tip of the obturator. Consequently, in some embodiments, the vent holes **1222** are useful as markers for indicating the penetration depth of the obturator tip **1220**. As the surgeon advances the trocar system **1000** through tissue, the surgeon can view the vent holes **1222** through the laparoscope **1300**, thereby observing when the vent holes **1222** have traversed a body wall, such as the abdominal wall. Once the vent holes **1222** have traversed a body wall and entered a body cavity, the trocar system **1000** need not be advanced further. Accordingly, the enhanced visibility of the obturator tip **1220** permits precise placement of the access system **1000**, and consequently, the trocar **1100** into a body cavity, thereby preventing the trocar **1100** from being advanced too far into the body cavity. Because the surgeon is able to precisely place the trocar system **1000** across a body wall until just the portion of the obturator tip **1200** comprising the vent holes **1222** is positioned within the body cavity, the risk of injury to internal body structures is reduced.

In some embodiments, one or more indicia are provided on at least one vent hole **1222**, thereby increasing the utility, visibility, and/or prominence of the vent holes **1222** as depth indicators. For example, in some embodiments, one or more contrasting and/or fluorescent colors are printed in the vent hole **1222** bores.

In some embodiments, one or more marker bands or indicia are disposed proximate to or near at least one vent hole **1222**, for example, by printing one or more contrasting or fluorescent marker bands. The enhanced visibility through the tip **1220** of the obturator permits using the marker bands for monitoring the penetration depth of the obturator **1200**. For example, in some embodiments, the marker band is highly visible through the laparoscope **1300** as a rectangular band positioned just proximal to the vent holes **1222**. In other embodiments, the marker bands have another shape, for example, dots. As a surgeon advances the access system **1000** through the tissue, the surgeon can view the position of the marker band to determine when the vent holes **1222** have traversed a body wall. The enhanced visualization through the obturator tip **1220** enables precise placement of the trocar **1100** into a body cavity, thereby preventing the trocar **1100** from being advanced too far into the body cavity. Precisely placing the access system **1000** across a body wall until just the portion of the obturator tip **1220** with the vent holes **1222** is in the body cavity reduces the risk of injury to internal body structures.

Referring to FIGS. **1C** and **1D**, some embodiments provide a device comprising an insufflation flow path or channel **1400** defined by an inner wall of the obturator shaft **1210** and the laparoscope **1300**. For example, embodiments of a 5-mm bladeless optical trocar with a 5-mm obturator are dimensioned and configured to accommodate laparoscopes with diameters of from about 5 mm to about 5.5 mm (from about 0.197" to about 0.217") with an insufflation flow channel **1400** extending longitudinally through the inside of the obturator between the outside wall of the laparoscope **1300** and the inside wall of the obturator shaft **1210**. The insufflation flow channel **1400** is dimensioned to accommodate a suitable flow of an insufflating gas, for example, carbon dioxide. In some embodiments, a cross-sectional area of the insufflation flow channel is at least about 0.0025 in^2 (about 1.6 mm^2). In the illustrated embodiment, an inside diameter of the obturator shaft **1210** is larger compared with the inside diameter of the obturator shaft of a typical 5-mm optical obturator. Increasing the inside diameter of the obturator shaft **1210** defines a generally cylindrical flow channel **1400** sufficient for insufflation when either a 5-mm or 5.5-mm laparoscope **1300** is inserted into the obturator **1200**. In the illustrated embodiment, an outer diameter of the obturator shaft **1210** is also increased. To accommodate the slightly larger obturator shaft **1210**, in some embodiments, the inner diameter and outer diameter of the trocar cannula **1110** are also increased compared with typical a 5-mm trocar cannula.

EXAMPLE 1

A polycarbonate insufflating obturator was manufactured in which the inner diameter of the 5-mm insufflating obturator shaft was 0.235" (6 mm), the outer diameter was 0.272" (6.9 mm), and the wall thickness was 0.018" (0.46 mm). The inner diameter of the mating 5-mm cannula was 0.277" (7 mm), the outer diameter was 0.343" (8.7 mm), and the wall thickness of the cannula was 0.033" (0.84 mm). Based on these dimensions, the cross-sectional area of the obturator flow channel with a 5.5 mm laparoscope inserted therein was 0.0064 in^2 (4.1 mm^2), which provides a carbon dioxide flow rate of about 6 L/min at an insufflator pressure setting of about 1.6–2 KPa (about 12–15 Torr).

EXAMPLE 2 (COMPARATIVE EXAMPLE)

For comparison, a polycarbonate 5-mm bladeless optical trocar designed to accommodate 5-mm to 5.5-mm laparoscopes included an obturator with an inner diameter of 0.219" (5.6 mm), an outer diameter of 0.225" (5.7 mm), and a wall thickness of 0.003" (0.076 mm). The mating cannula for this obturator had an inner diameter of 0.227" (5.8 mm), an outer diameter of 0.287" (7.3 mm), and a wall thickness of 0.03" (0.76 mm). For comparison, the cross-sectional area of the obturator flow channel with a 5.5-mm laparoscope inserted in the obturator was 0.00068 in^2 (0.44 mm^2), which provides an insufficient flow of carbon dioxide through the device.

EXAMPLE 3

A 5-mm obturator is molded from polycarbonate with an inside diameter of 0.230" (5.8 mm) and a wall thickness of 0.021" (0.53 mm). The carbon dioxide flow rate through this obturator with a 5.5-mm laparoscope inserted therein is about 3.5 L/minute at an insufflator pressure setting of about 1.6–2 KPa (about 12–15 Torr). The increased wall thickness improves the injection molding process for manufacturing the obturator shaft.

The tip **1220** of a bladeless insufflating obturator is designed to separate and dilate tissue and muscle fibers during traversal of a body wall. Because of the dilating and separating properties of a 5-mm insufflating trocar, increasing the outer diameters of the obturator shaft **1210** and the cannula **1110**, as compared with typically sized 5-mm bladeless trocars, does not adversely affect the insertion force of the trocar in the illustrated embodiment. The wall thickness of the obturator shaft **1210** is also sufficient to permit injection molding the shaft **1210** and tip **1220** as a single piece, thereby reducing the overall device cost and increasing production capacity.

FIG. **2A** is a side cross-sectional view and FIG. **2B** is a front cross-sectional view of a distal end of another embodiment of an insufflating optical obturator **2200** with a laparoscope **2300** inserted therein. FIG. **2C** is a top view of a transverse cross section of a tip **2220** of the insufflating optical obturator **2200** and laparoscope **2300** illustrated in FIGS. **2A** and **2B**. The following description refers to a 12-mm obturator sized to accommodate 10-mm laparoscopes, which defines an insufflation flow channel sufficient for generating pneumoperitoneum. Those skilled in the art will understand that the illustrated embodiment is also scalable to other size trocar systems.

The illustrated 12-mm obturator also accommodates smaller laparoscopes **2300** such as 5-mm and/or 5.5-mm diameter laparoscopes. The tip **2220** of the obturator is configured such that a distal end **2304** a 5-mm to 5.5-mm laparoscope is insertable deep into a tapered portion of the obturator tip **2220**, while still defining an insufflation flow channel **2400** with a sufficient minimum area for a suitable flow of carbon dioxide around the laparoscope **2300**. In the illustrated embodiment, a shorter dimension or width of a generally rectangular internal surface **2226** of the tip of the obturator defines a stop for a 5-mm and/or 5.5-mm laparoscope **2300**. The insufflation flow channel **2400** is defined by the area between the internal longer dimension or internal length of the internal surface **2226** of the tip and the outside wall of the laparoscope **2300**, as best viewed in FIGS. **2A** and **2C**. The insufflation flow channel **2400** is fluidly connected to one or more vent holes **2222** disposed on the tip. The embodiment illustrated in FIG. **2A** also comprises an optional stop **2224** for a 10-mm laparoscope.

Some embodiments in which distal end of the 5-mm or 5.5 mm laparoscope **2300** and the portion of the inner surface **2226** of the tip that acts as a stop therefor have similar shapes do not provide an insufflation flow channel **2400** with an sufficiently large minimum area to provide a desired insufflation gas flow. For example, inserting a round laparoscope **2300** into an obturator **2200** in which the stop portion of the inner surface **2226** has a circular transverse cross section provides only a small or even no flow channel **2400**, thereby effectively isolating the vent holes **2222** from the lumen of the shaft **2210** and preventing gas flow therethrough.

The illustrated trocar system exhibits improved flexibility, versatility, and/or performance, while reducing cost and inventory requirements. Pairing a 5-mm and/or 5.5-mm laparoscope with a 12-mm obturator improves the flow rate of carbon dioxide through the obturator **2200** with the laparoscope inserted therein compared with the flow rate through the obturator **2200** with a 10-mm laparoscope inserted therein. Also, a hospital or clinic may not have any 10-mm zero-degree laparoscopes readily available, whereas many facilities have 5-mm and/or 5.5-mm zero-degree laparoscopes readily available. Another advantage is that the distal end of a 5-mm or 5.5-mm laparoscope is closer to the distal end of the obturator tip

2200 compared with a 10-mm laparoscope, thereby providing a magnified image. For example, in the illustrated embodiment, the distal end of a 5-mm or 5.5-mm laparoscope is positioned at about 0.430" (about 11 mm) from the distal end of the tip **2200** of the obturator, while the distal end of a 10-mm laparoscope is positioned at about 0.790" (about 20 mm) from the distal end of the tip **3220** of the obturator.

FIG. **3A** is a longitudinal cross-section of another embodiment of an insufflating obturator **3200** and FIG. **3B** is a detailed longitudinal cross section of a proximal end thereof. The insufflating obturator **3200** comprises a shaft **3210**, a tip **3220**, and a handle **3230**. The handle **3230** comprises a funneled entry **3232** disposed at a proximal end thereof. A seal assembly **3240** is disposed distally thereof. Accordingly, the seal assembly **3240** is spaced from and/or recessed from the proximal end of the obturator **3200**, thereby encasing the seal assembly **3240** within the handle **3230**. Thus, in the illustrated embodiment, the seal assembly **3240** is protected from direct user contact and/or manipulation. In some embodiments in which a seal assembly **3240** is disposed at the proximal end of the obturator **3200** and externally accessible, one or more components of the seal assembly **3240** are vulnerable to inadvertent deformation, for example, during placement of the trocar system, which can cause loss of pneumoperitoneum. Furthermore, in some embodiments, the seal assembly **3240** is vulnerable to deliberate and/or inadvertent removal and/or loss. The illustrated seal assembly **3240** seals with instruments of varying diameters as well as providing a zero seal in the absence of an instrument. Again, using a 12-mm obturator as an illustrative example, the seal assembly **3240** seals with any of 5-mm laparoscopes, 5.5-mm laparoscopes, and/or 10-mm laparoscopes, thereby preventing leakage of carbon dioxide from the proximal end of the obturator **3200**.

In the illustrated embodiment of the obturator **3200**, at least one opening **3206** perforates the shaft **3210**, fluidly connecting the interior or lumen with the exterior thereof. When inserted into a suitable trocar, for example, embodiments of the trocar **1110** illustrated in FIGS. **1A** and **1B**, the at least one opening **3206** fluidly connects the interior or lumen of the obturator **3200** to the fluid inlet **1122**, thereby permitting fluid flow from the fluid inlet **1122**, through the openings **3210**, and out the vent holes **3222**. Some embodiments of the obturator **3200** comprise a single opening perforating the shaft. In some embodiments, the opening or openings **3206** independently have another shape, for example, circular, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron-shaped, triangular, rectangular, rhomboid, polygonal, and the like.

Referring to FIG. **3B**, which is a detailed longitudinal cross section of the proximal end of the obturator **3200** illustrated in FIG. **3A**, the illustrated seal assembly **3240** comprises an internal septum seal **3242** and an internal duckbill valve **3244** disposed at the proximal end of the obturator shaft **3210**. The septum seal **3242** prevents carbon dioxide from leaking from the obturator **3200** when a laparoscope **3300** is inserted therein. The duckbill valve **3244** prevents carbon dioxide from leaking in the absence of a laparoscope **3300**, for example, when the laparoscope **3300** is withdrawn from the obturator **3200** or not used at all. The illustrated embodiment also comprises a sleeve **3246** disposed proximally of the septum seal **3242**, which prevents and/or reduces inversion of the septum seal **3242** on withdrawal of the laparoscope **3300** therefrom. The septum seal **3242** and the duckbill valve **3444** are disposed between the obturator shaft **3210** and the obturator handle **3230** in the illustrated embodiment. The obturator handle **3230** comprises a funneled entry **3232** at its proximal end leading into a guide channel **3234**, which guides or directs the laparoscope **3300** into the obturator **3200**. Some embodiments of the obturator handle **3230** comprise a space in the guide channel **3234** sufficient to permit at least some septum seal **3234** inversion during laparoscope **3300** withdrawal without binding the laparoscope **3300**. For example, in some embodiments, the diameter of the cap guide channel **3234** is larger than the diameter of the laparoscope plus the thickness of the inverted septum seal, which is sufficient to prevent binding or lock-up of the laparoscope **3300** during withdrawal from the obturator **3200**.

In some embodiments, at least one of the septum seal **3242** and duckbill valve **3244** is treated by a chlorination process, which reduces friction when inserting, rotating, and/or withdrawing the laparoscope **3300**, which typically has a polished surface that generates high friction with septum seals **3242** and duckbill valves **3244**. In some embodiments, at least one of the septum seal **3242** and duckbill valve **3244** is coated or treated with one or more other anti-friction materials and/or coatings, such as silicone oil, silicone emulsion, parylene, polytetrafluoroethylene (Teflon®), and/or treated by plasma etching.

An embodiment of a method for using the surgical access or trocar system refers to the embodiment **1000** illustrated in FIGS. **1A–1E**, although the method is applicable to any of the embodiments discussed herein. In the method, the bladeless obturator **1200** is first inserted through the trocar seal **1120** and cannula **1110** of the trocar. A laparoscope **1300** is then inserted into the proximal end of the bladeless obturator **1200** and advanced to the stop **1224** or tip **1220** of the obturator. An endoscopic video camera (not illustrated) is attached to the proximal end of the laparoscope **1300** and the access system **1000** is then axially advanced by a surgeon through a body wall. As the surgeon advances the access system **1000** through the body wall, the surgeon visualizes the tissue as it is being separated, for example, using a video monitor connected to the endoscopic video camera. The surgeon can also readily determine when the body wall has been traversed by observing the distal end of the obturator **1200** entering the body cavity. As discussed above, the distal end of the obturator **1200** includes insufflation vent holes **1222** through which an insufflation gas may flow from the obturator **1200** and into a body cavity.

In another embodiment, the optical access system **1000** accesses a targeted body area or region under laparoscopic guidance as discussed above, then is used to administer a medicament under vision. In some embodiments, the medicament is delivered through the stopcock **1124** and Luer fitting **1122**, through the obturator **1200**, and out through the vent holes **1222** disposed at the tip **1220** of the obturator. The term “vent hole” is used here for consistency. Those skilled in the art will understand that in some embodiments, gas need not be delivered through the vent holes. Instead, the vent holes are used for another purpose, for example, for delivering a fluid, aspirating a fluid, withdrawing tissue, and/or as a gauge for placing the device, as discussed above. The trocar **1100**, in this embodiment, is rigid, semi-rigid, or flexible. Some embodiments of the obturator **1200** comprise a single vent hole **1222**. In some embodiments, the vent hole **1222** is disposed at the distal end of the tip **1220**, generally along the longitudinal axis of the obturator **1200**, which permits a more precise delivery of the medicament. The access system **1000** is suitable, for example, for rapidly accessing a trauma site and for rapidly delivering a medicament through the obturator under vision to the trauma site. In some embodiments, the obturator **1200** is usable in this application either with or without a trocar **1100**. In embodiments that do not include a trocar, the obturator **1200** comprises a fluid inlet, for example, a Luer fitting, disposed at or near the proximal end of the obturator **1200**, for example, at the handle **1230**. The fluid inlet is fluidly connected to the vent hole **1222** through the lumen of the obturator shaft **1210**. These embodiments of the trocar system **1100** are also useful for accessing a targeted body area under vision using an inserted laparoscope, then withdrawing a body fluid sample and/or a soft tissue sample through the vent or aspiration hole **1222** of the obturator, for example, for pathology analysis, without a cannula.

In some embodiments, the access system **1000** further comprises an insufflator comprising a gas flow alarm (not illustrated). In some embodiments, a source of insufflation gas, for example, an insufflator, is connected to the Luer fitting **1122**, the stopcock valve **1124** opened, and the insufflation gas flow activated, for example, a carbon dioxide flow. When the tip **1220** of the obturator is placed in tissue such as the abdominal wall, the gas flow is blocked by the tissue, which in turn activates a gas flow obstruction alarm of the insufflator. The gas flow obstruction alarm will continue as the trocar is advanced through the tissue until the vent holes **1222** in the tip of the obturator are positioned within a hollow body cavity, at which point, carbon dioxide automatically starts flowing into the cavity and the gas flow obstruction alarm on the insufflator deactivates, thereby serving as an audible indicator that the distal tip **1222** of the obturator is properly positioned within the body cavity.

Some embodiments of the access system **1000** further comprise an integral audible indicator (not illustrated), which indicates gas flow, for example, carbon dioxide, through the device. The audible indicator produces a sound, for example, a high-pitched tone, for example, by mechanically modulating the gas flow through the device. In some embodiments, the audible indicator is disposed in the trocar **1100**. In some embodiments in which the audible indicator is integral to the trocar seal **1120**, the audible indicator is positioned within and/or integrated with the stopcock Luer fitting **1122**. In other embodiments, the audible indicator is disposed in the obturator **1200**. In yet other embodiments, the audible indicator is a detachable component, for example, disposed between and fluidly connecting the stopcock Luer fitting **1122** and the insufflation tubing.

In some embodiments, the access system **1000** comprising the audible indicator is connected to an insufflator and the carbon dioxide gas flow activated. When the tip **1220** of the obturator is placed in tissue, such as the abdominal wall, the tissue blocks gas flow through the device. As the tip **1220** is advanced though the tissue, the gas flow remains blocked until the vent holes **1222** in the tip of the obturator reach the targeted body cavity. When the vent holes **1222** are positioned within the body cavity, the carbon dioxide automatically starts flowing into the cavity. The gas flow activates the audible indicator, thereby creating a high-pitched tone, which signals that the distal tip **1220** of the obturator is properly positioned within the body cavity.

Some embodiments of the access system **1000** further comprise a visual indicator (not illustrated), for example, a flow sight that indicates carbon dioxide flow through the device. Suitable visual indicators include a flapper, a rotor, and/or an oscillating ball. In some embodiments, the visual indicator is integral to the trocar seal **1120**, for example, positioned within and/or integrated with the stopcock Luer fitting **1122**. In other embodiments, the visual indicator is disposed within the proximal portion of the obturator **1200**. In other embodiments, the visual indicator is a detachable component disposed between the Luer fitting **1122** and the insufflation tubing.

In an embodiment of a method for using the trocar system comprising the integral visual indicator, the trocar system is connected to an insufflator and the carbon dioxide gas flow activated. When the tip **1220** of the obturator is placed in tissue, such as the abdominal wall, the gas flow is blocked. As the tip **1220** is advanced though tissue, the gas flow remains blocked until the vent holes **1222** in the tip of the obturator enter the targeted body cavity. When the vent holes **1222** are positioned within the body cavity, the carbon dioxide automatically flows into the body cavity. The gas flow causes movement of the visual flow indicator, thereby indicating that the distal tip of the obturator is properly positioned within the body cavity.

Some embodiments of the access system **1000** comprise an electronic gas flow indicator. An output of the gas flow indicator is, for example, audible and/or visible.

While certain embodiments have been particularly shown and described with reference to exemplary embodiments thereof, it will be understood by those of ordinary skill in the art that various changes in form and details may be made therein without departing from the scope thereof as defined by the following claims.

CLAIMS:

1. A surgical access system comprising:

a tubular trocar comprising a longitudinal axis, a proximal end, a distal end, an elongate cannula, and a seal assembly disposed at a proximal end of the cannula;

an insufflating obturator slidably insertable into the trocar, the obturator comprising a longitudinal axis, a proximal end, a distal end, a tubular shaft, a tip disposed at the distal end of the shaft, at least one vent hole disposed on the tip, and a handle disposed at the proximal end of the shaft; and

a fluid inlet disposed at a proximal end of the access system,

wherein

at least a portion of the obturator tip comprises a wall comprises a transparent material with a substantially uniform thickness and thin-wall configuration to reduce the distortion of an image observed through the obturator tip,

the obturator slidably receives a laparoscope into the obturator shaft, and an interior surface of the obturator shaft and tip, and

an outer surface of an inserted laparoscope together define a insufflation gas flow channel fluidly connecting the at least one vent hole to the fluid inlet.

2. The surgical access system of claim 1, wherein the seal assembly comprises a septum seal and a duckbill valve.

3. The surgical access system of claim 1, wherein the fluid inlet is disposed on the proximal end of the trocar.

4. The surgical access system of claim 1, wherein the obturator tip is bladeless.

5. The surgical access system of claim 1, wherein the wall of the obturator tip is not greater than about 0.65 mm thick.

6. The surgical access system of claim 1, wherein the obturator shaft and tip are unitary.

7. The surgical access system of claim 1, wherein the obturator tip comprises at least one of polymer, polycarbonate, polysulfone, PEEK, polyether block amide (PEBAX®), polyester, copolyester, and acrylic.

8. The surgical access system of claim 1, wherein the obturator tip comprises a single vent hole.

9. The surgical access system of claim 1, wherein the at least one vent hole is at least one of circular, oval, elliptical, tear-drop shaped, slot shaped, slit shaped, chevron shaped, triangular, rectangular, rhomboid, and polygonal.

10. The surgical access system of claim 1, further comprising a depth indicator on the obturator tip.

11. The surgical access system of claim 10, wherein the depth indicator comprises at least one of indicia disposed in a bore of the at least one vent hole, and indicia disposed proximate to the at least one vent hole.

12. The surgical access system of claim 1, wherein the obturator further comprises at least one laparoscope stop disposed on at least one of the interior surface of the obturator tip and the interior surface of the obturator shaft.

13. The surgical access system of claim 1, wherein the interior surface of the obturator tip comprises a non-circular transverse cross section.

14. The surgical access system of claim 1, wherein the obturator accommodates laparoscopes with varying diameters.

15. The surgical access system of claim 1, wherein the obturator tip accommodates a distal end of the laparoscope.

16. The surgical access system of claim 1, wherein at least one opening perforates the obturator shaft.

17. The surgical access system of claim 1, wherein a cross-sectional area of the insufflation gas flow channel is at least about 1.6 mm^2.

18. The surgical access system of claim 1, wherein a flow rate through the access system is at least about 3.5 L/min at an insufflator pressure of about 1.6–2 KPa.

19. The surgical access system of claim 1, further comprising a laparoscope.

20. The surgical access system of claim 1, further comprising at least one of a gas flow indicator, an audible gas flow indicator, and a visual gas flow indicator.

21. The surgical access system of claim 1, wherein the interior surface of the tip comprises a non-circular transverse cross-section and the outer surface of an inserted laparoscope abuts the interior surface of the tip to define the insufflation gas flow channel between the interior surface of the tip and the outer surface of the inserted laparoscope.

22. The surgical access system of claim 21, wherein the inserted laparoscope has a non-circular transverse cross-section.

23. The surgical access system of claim 1, wherein the obturator tip includes an outer surface; in transverse cross-section of the obturator tip, the outer surface of the obturator tip matches the interior surface of obturator tip.

24. The surgical access system of claim 1, wherein in transverse cross-section of the tip, the outer surface has a generally rectangular transverse cross-section which substantially matches the interior surface which also has a generally rectangular transverse cross-section.

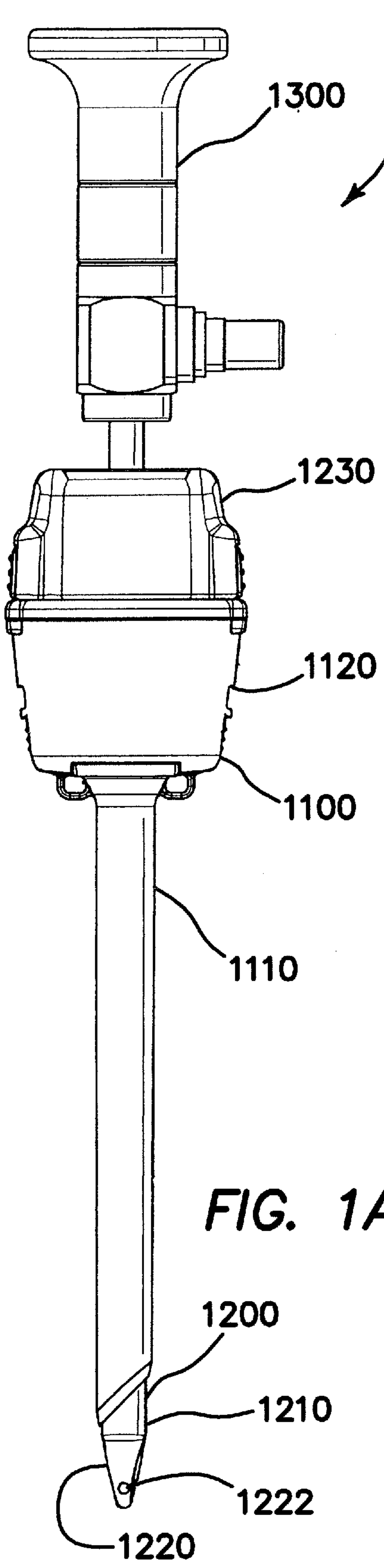

1000
1300
1230
1120
1100
1110
1200
1210
1222
1220

FIG. 1A

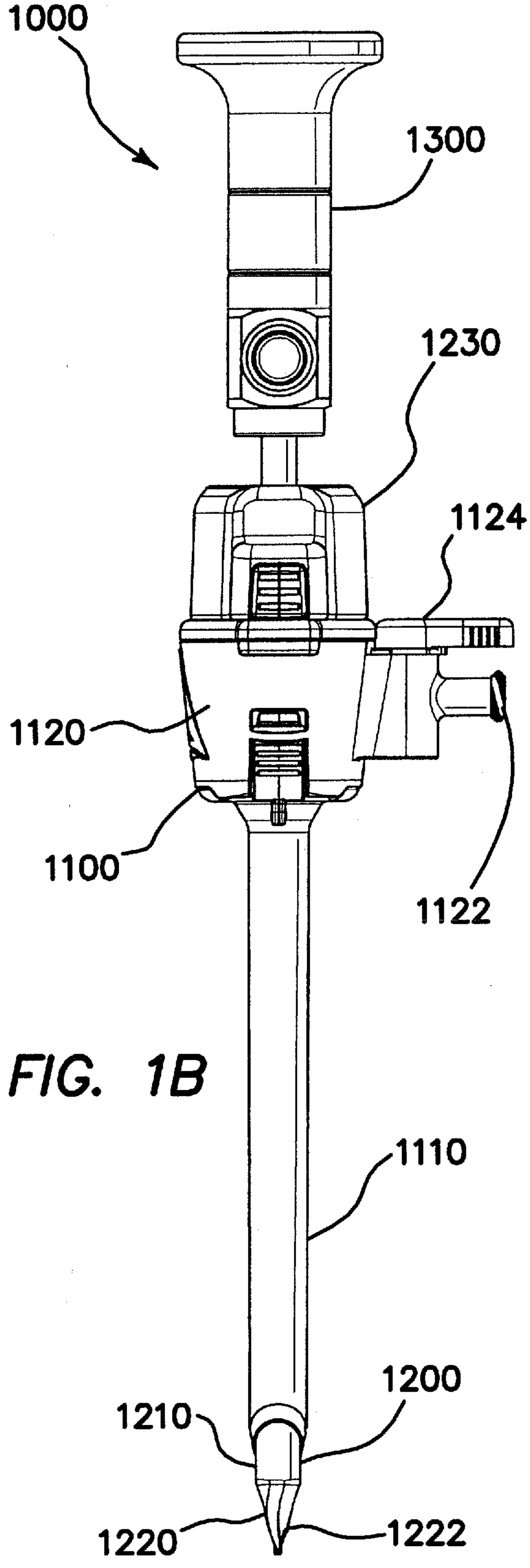

1000
1300
1230
1124
1120
1100
1122
1110
1200
1210
1220
1222

FIG. 1B

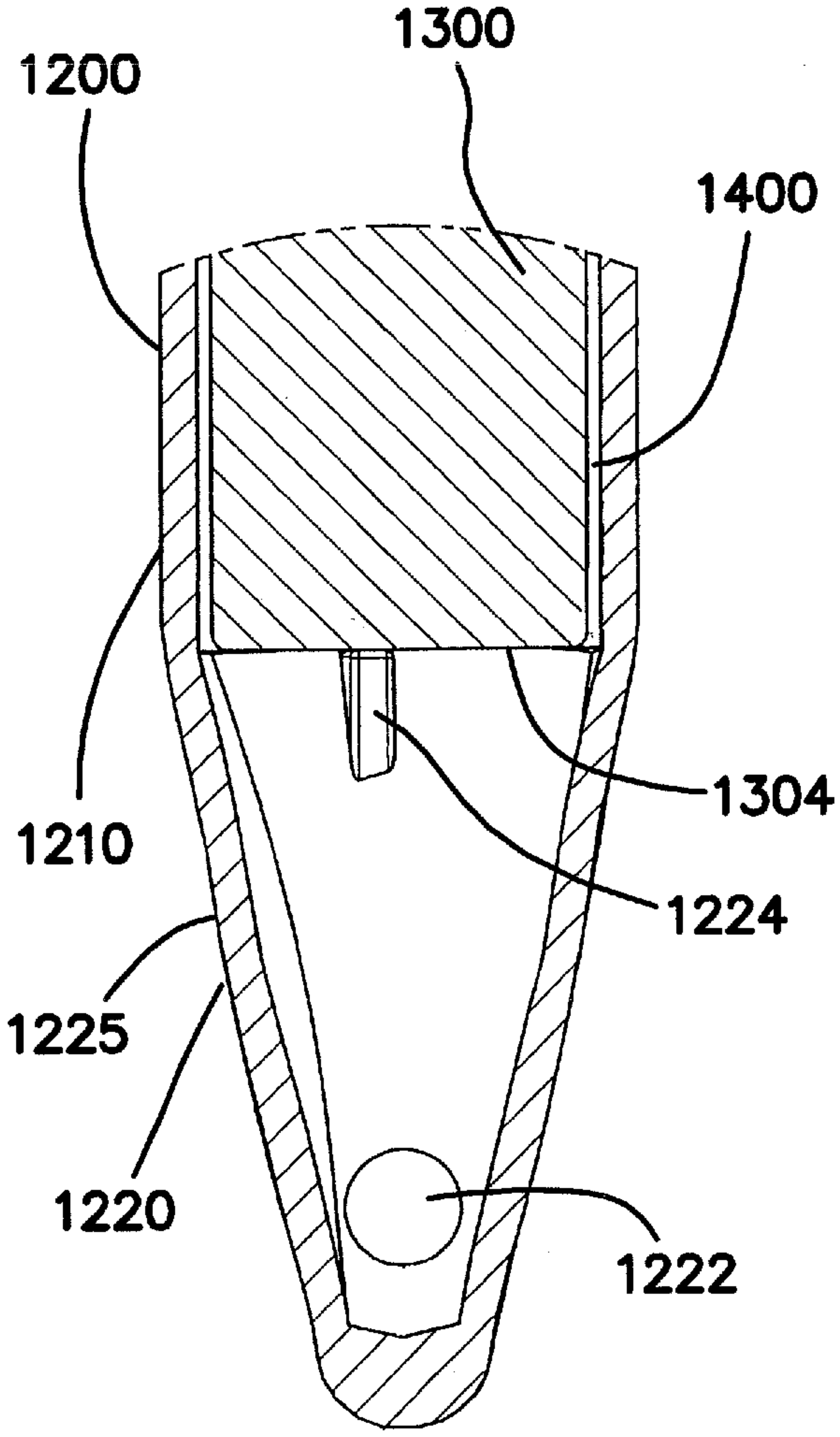

1200
1300
1400
1210
1304
1224
1225
1220
1222

FIG. 1C

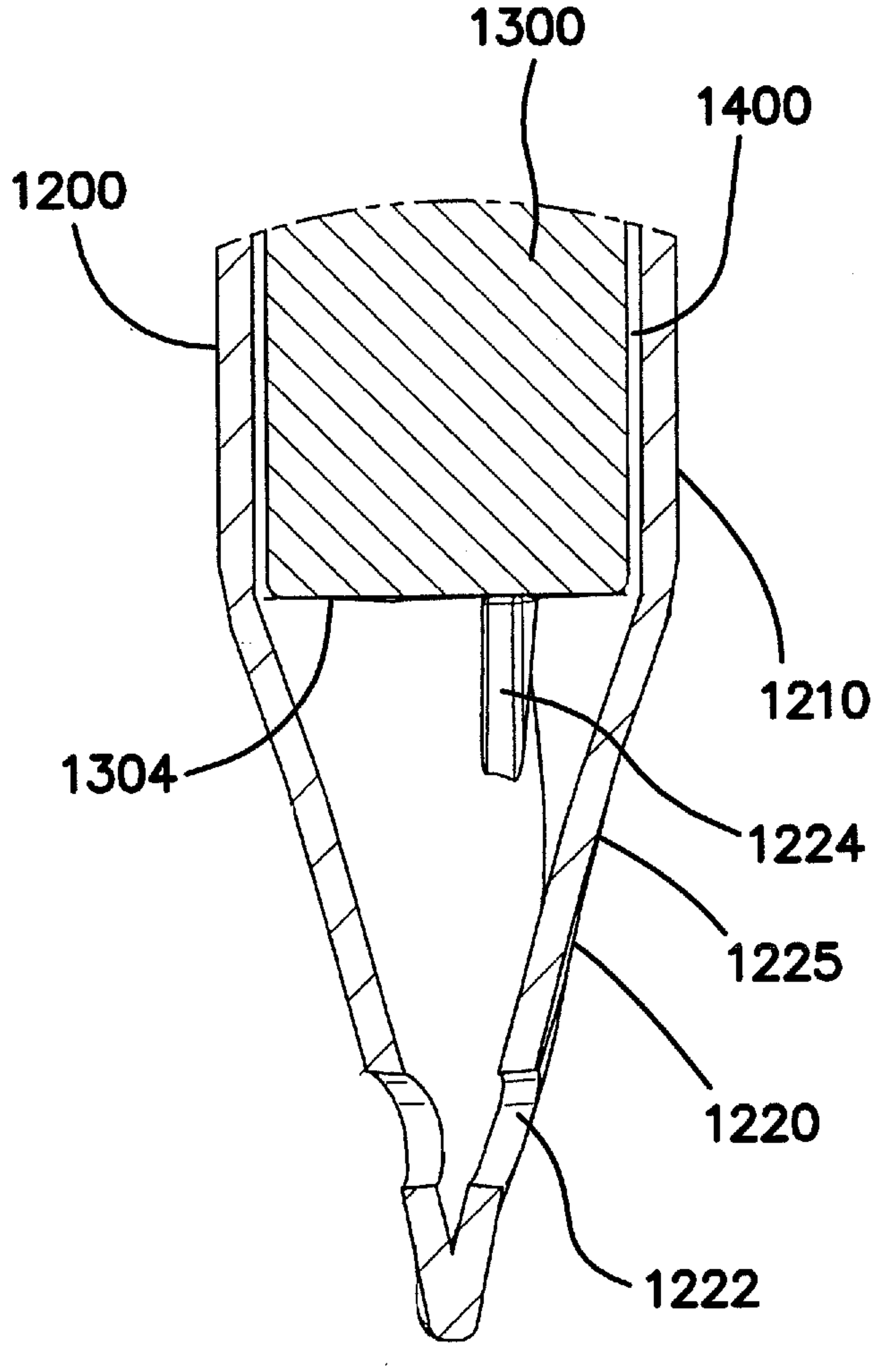

1300
1400
1200
1210
1304
1224
1225
1220
1222

FIG. 1D

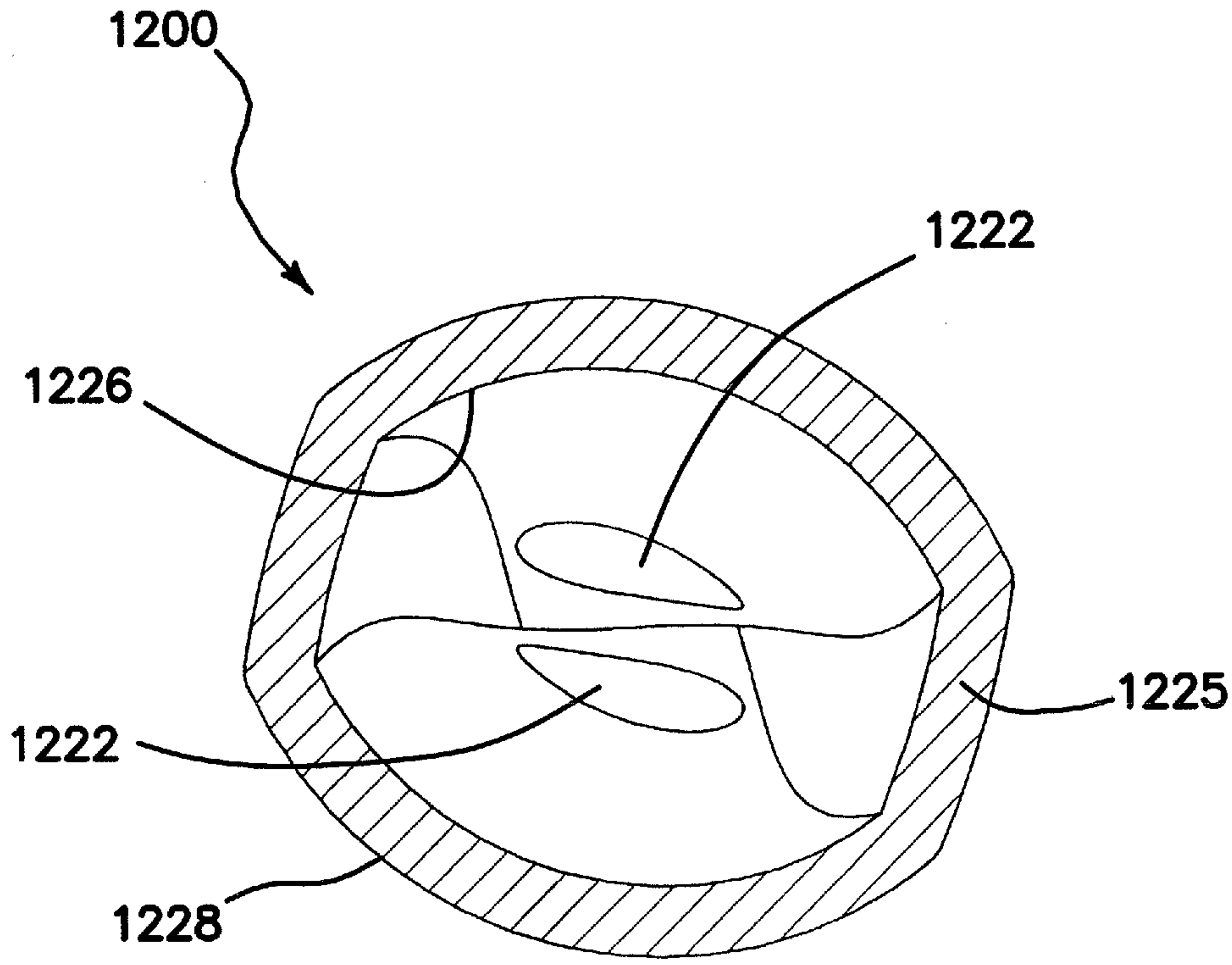


FIG. 1E

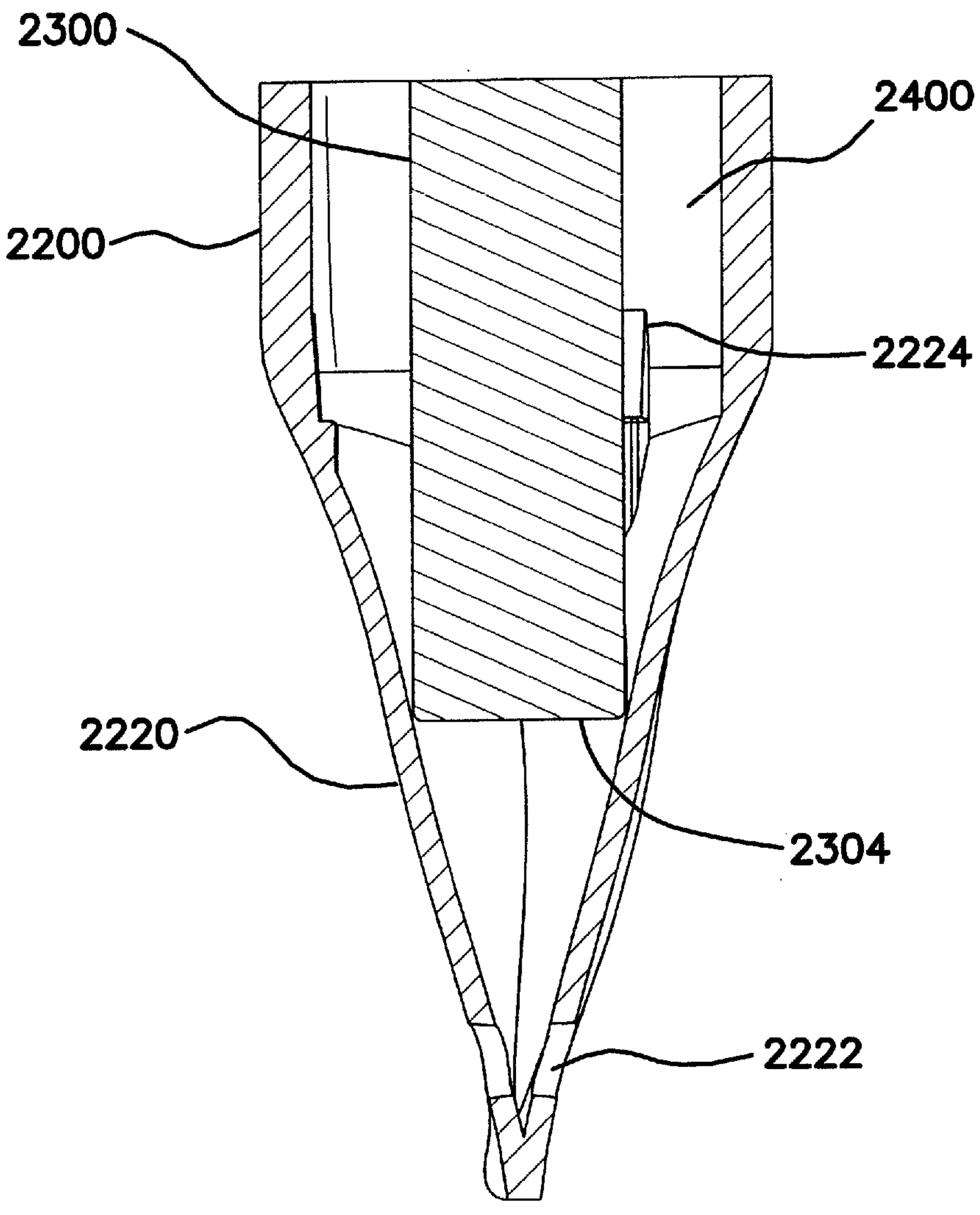


FIG. 2A

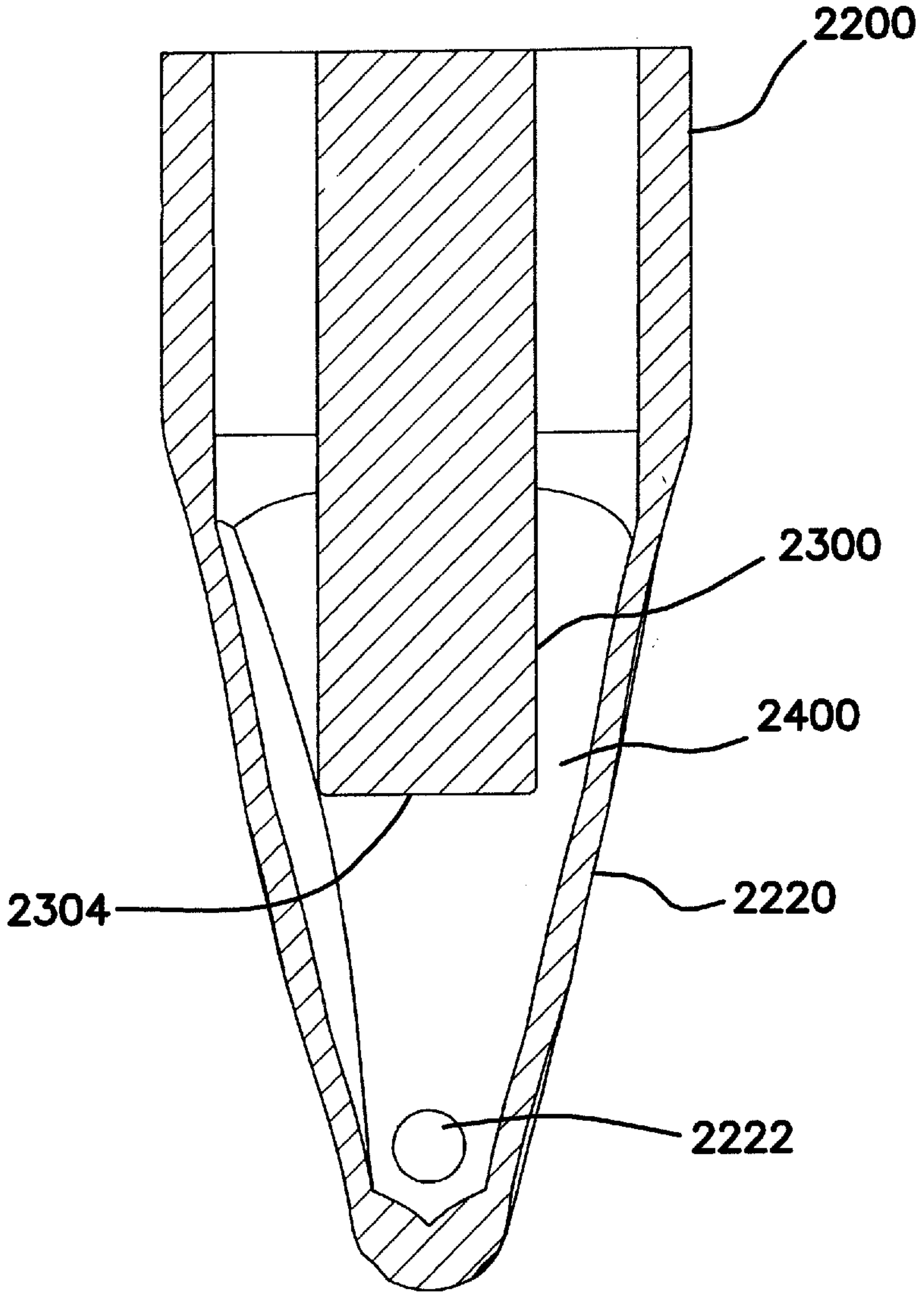


FIG. 2B

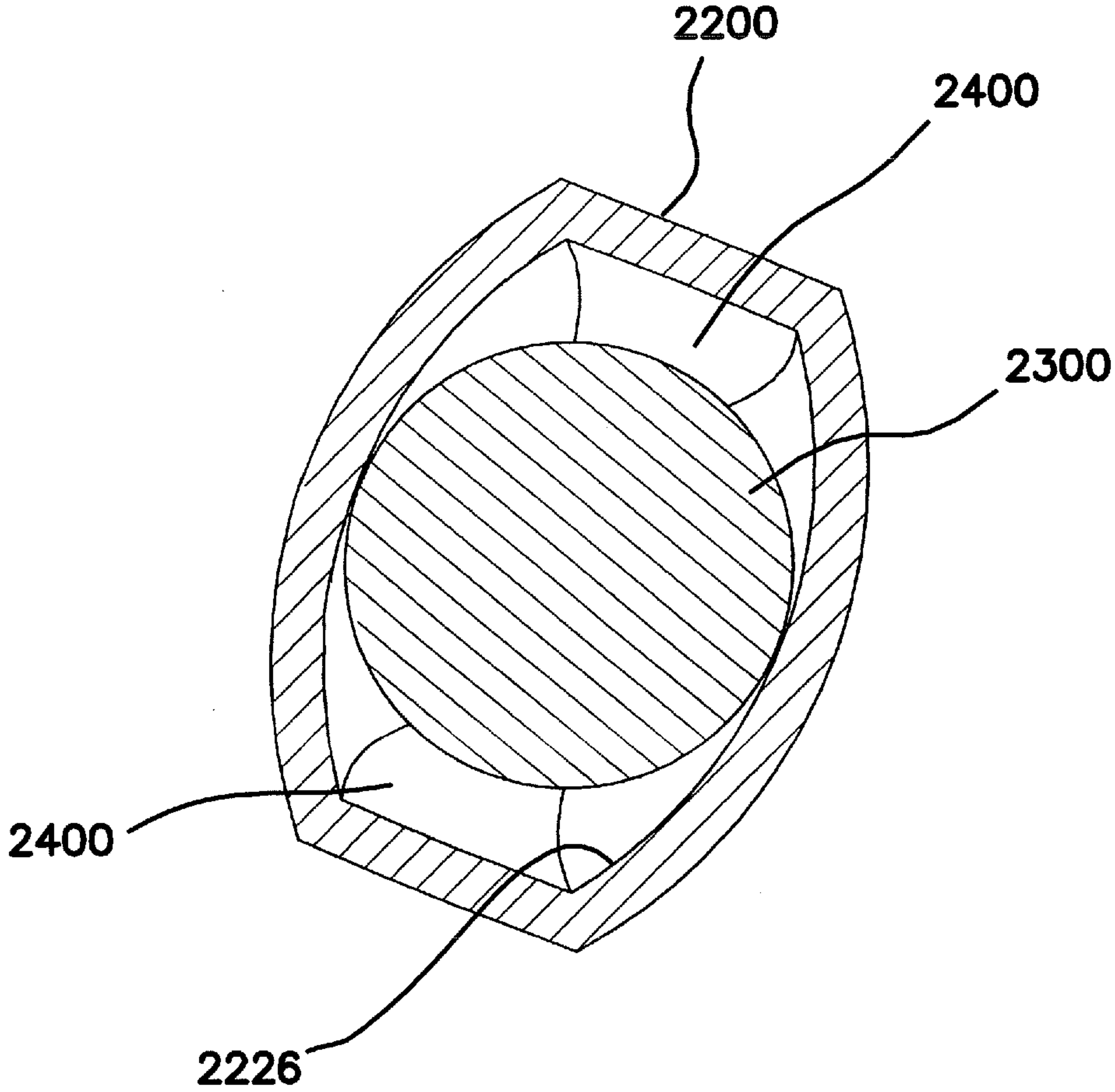


FIG. 2C

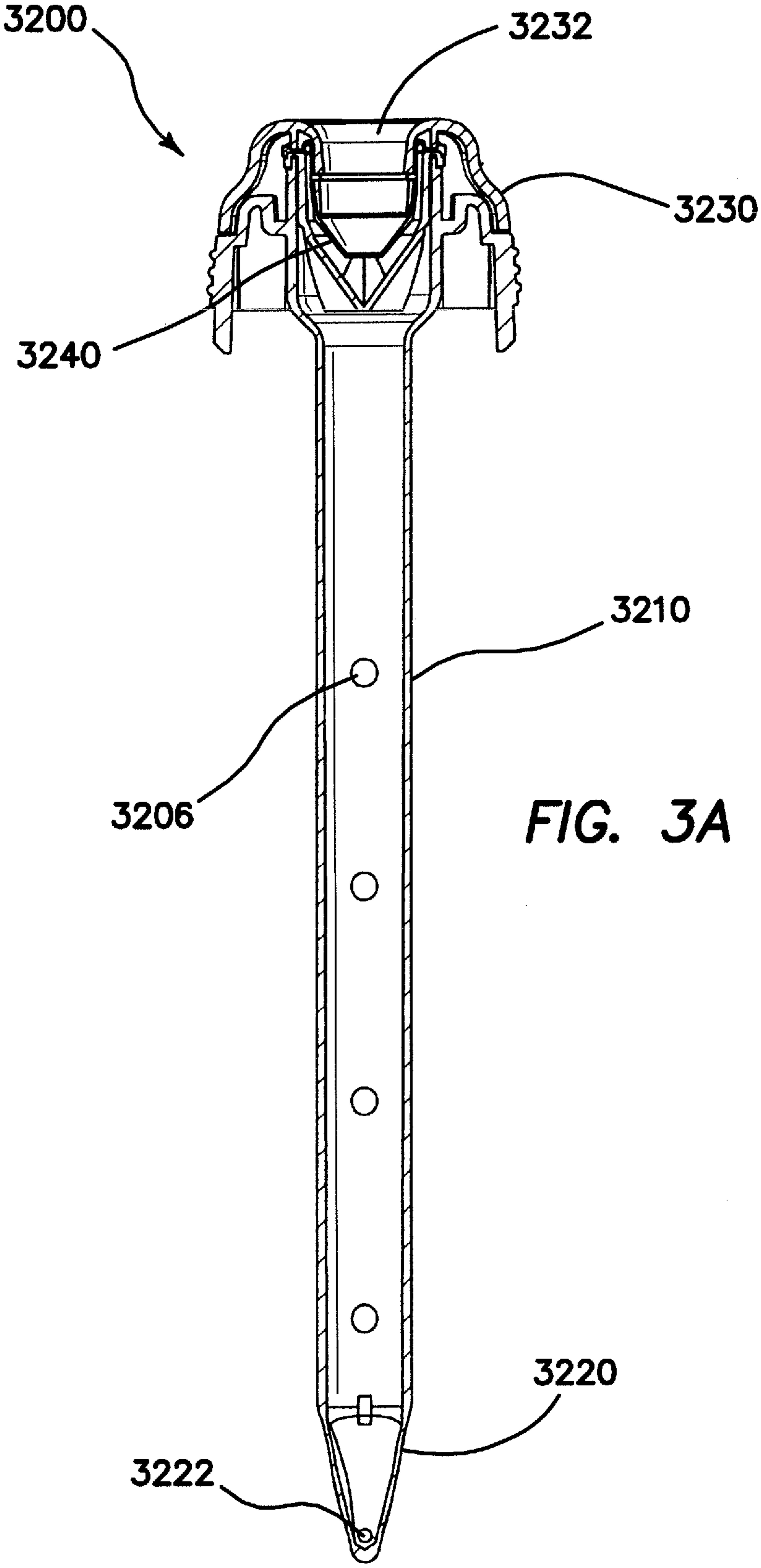


FIG. 3A

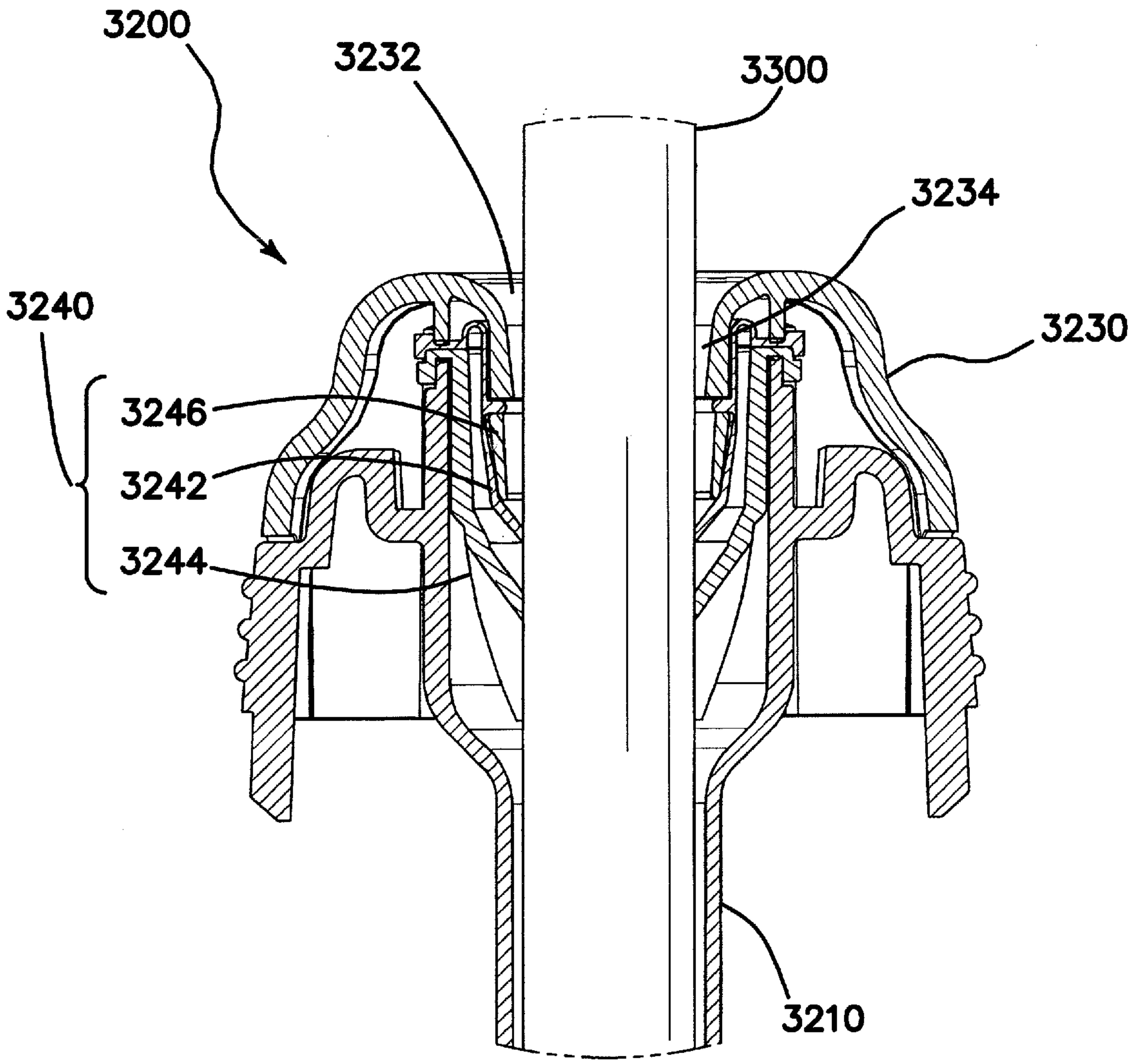
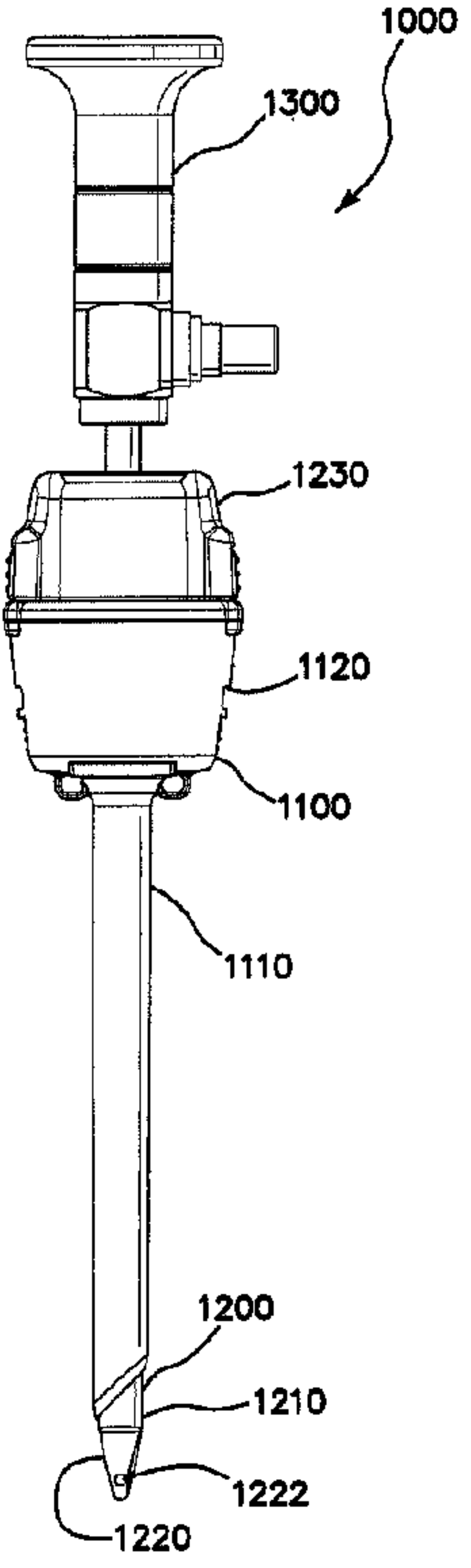


FIG. 3B


1000
1300
1230
1120
1100
1110
1200
1210
1222
1220