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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 August 2016 (25.08.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/133752 A1

(51) International Patent Classification:
A61M 25/01 (2006.01) *A61M 25/06* (2006.01)

(21) International Application Number:
PCT/US2016/017282

(22) International Filing Date:
10 February 2016 (10.02.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
14/624,818 18 February 2015 (18.02.2015) US

(72) Inventor; and
(71) Applicant : **KIEV, Jon** [US/US]; 1145 Museum Boulevard, Vernon Hills, Illinois 60061 (US).

(72) Inventor: **PLISHKA, Michael**; 37801 N. Douglas Lane, Lake Villa, Illinois 60046 (US).

(74) Agent: **LINDERMAN, Evan**; 116 Mulberry Road, Deerfield, Illinois 60015 (US).

(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, BN, 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, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU,

[Continued on next page]

(54) Title: DEVICE AND METHOD FOR ACCESS TO INTERIOR BODY REGIONS

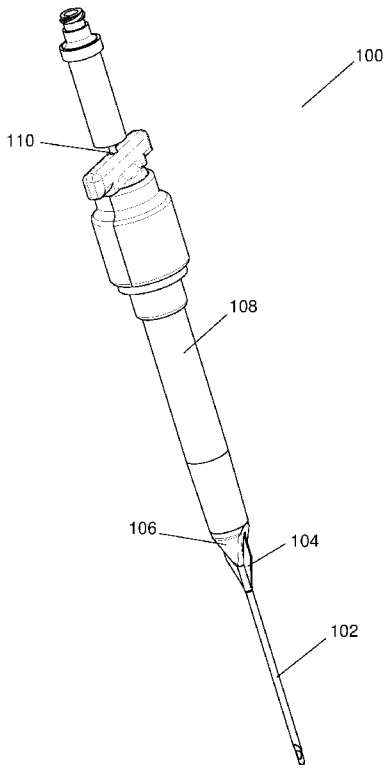

FIG. 1

(57) Abstract: A device and method is provided to gain access to interior body regions. The system includes a safety needle assembly, a blade assembly, an obturator assembly, and a dilator assembly. The safety needle assembly accesses an interior body region, after which the blade assembly expands the pathway created by the safety needle assembly. The obturator then further expands the pathway and delivers the dilator assembly to the desired location. The safety needle assembly, obturator assembly, and blade assembly are removed, leaving the dilator assembly in place for future procedures.

WO 2016/133752 A1

LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

Published:

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR U.S. LETTERS PATENT

Title:

Device and method for access to interior body regions

Inventor:

Jon Kiev, MD

TECHNICAL FIELD

[0001] The present invention relates to devices and methods to access interior body regions. More particularly, it relates to devices and methods used to create space to insert a tube into a patient.

BACKGROUND

[0002] Embodiments of the invention relate to devices to create access to interior body regions and methods of using the devices.

[0003] There are many instances in which a practitioner must access the chest, abdomen, or pelvis, and insert a drainage tube, or chest tube. Examples of these instances include: collapsed lung, lung infection, bleeding in the chest cavity, fluid or air buildup due to other medical conditions or trauma, and prior surgery.

[0004] The traditional way of inserting a chest tube begins with the practitioner prepping the side of the body for the chest tube by sterilizing the area. Using a scalpel, the practitioner then makes a small incision (skin nick), between the ribs closest to the desired location in the chest. Then, using a combination of blunt dissection and surgical clamps, the practitioner will slowly open the space and extend it into the chest cavity. Once the practitioner confirms she has reached the desired space, the chest tube is inserted and sutured in place to prevent slippage.

[0005] Critics claim that the traditional method of chest tube insertion is barbaric and does not take advantage of advances in technology that can make the insertion process safer and more effective. Some companies have designed devices, called trocars, to facilitate safer and easier chest tube placement without using multiple, separate components.

[0006] Many groups of trocars include a combination of a safety needle, an obturator and a dilator. The doctor advances the device against the skin and interior body regions using the safety needle. As the doctor advances the device through the body, the obturator expands the pathway created by the safety needle. When the device reaches the desired area, the practitioner removes the safety needle and the obturator from the dilator, leaving the dilator in place. The practitioner then pushes the chest tube through the dilator and removes the dilator, leaving the chest tube in the desired location.

[0007] Problems arise with these types of trocars, however, because the obturator does not actually work very well in expanding the pathway created by the relatively small safety

needle. The skin provides a tough membrane that resists expansion, and additional skin nicks (using a separate scalpel) are required around the safety needle to allow the obturator to properly expand the skin layer and continue to penetrate deeper into the body.

[0008] To address this issue, other groups of trocars employ a retractable blade instead of a safety needle. The blade is used to create a larger skin nick and advance through other tissues as needed until reaching the desired location. The obturator easily expands the pathway as it passes through the skin layer while the practitioner advances the device, and then the blade is retracted and the blade/obturator combination is removed, leaving the dilator in place for the chest tube.

[0009] While these groups of trocars address the issue of requiring an additional scalpel to allow the obturator to expand the skin layer, they do not include the safety needle that prevents the doctor from progressing too quickly or too far and causing harm to the patient. Without the safety needle as part of the system, the patient is at a greater risk of complications.

[0010] What is needed in the market is an all-in-one trocar device that provides the ability to create a skin nick and maintain safety as the device is inserted deeper into the body, while quickly accessing the desired location for chest tube placement.

BRIEF SUMMARY OF THE INVENTION

[0011] Benefits achieved in accordance with principles of the disclosed invention include a device that provides access to interior body regions.

[0012] Some aspects of the present invention relate to a safety needle assembly, a blade assembly, an obturator assembly, and a dilator assembly. The safety needle assembly, blade assembly, obturator assembly, and dilator assembly are assembled to create an access device.

[0013] In some aspects of the present invention, the blade assembly includes multiple blades, while in other aspects of the present invention, the blade assembly includes a single blade.

[0014] In other aspects of the present invention, the safety needle assembly includes a hub through which fluid may be drawn in order to confirm the device has reached the proper location within the body.

[0015] In further aspects of the present invention, the blade assembly and safety needle assembly are longitudinally coaxial, while in still further aspects of the present invention, the blade assembly and safety needle assembly are not longitudinally coaxial.

[0016] Yet other aspects of the present invention relate to a method of accessing interior body regions in which the safety needle assembly is advanced through skin and into interior body regions to create a pathway. The blades of the blade assembly are deployed and the blade assembly is advanced into the skin to create a skin nick, after which the blades are retracted. The access device is then advanced into the tissue, and the obturator assembly increases the diameter of the pathway created by the safety needle. After the access device is in the proper location, the safety needle assembly, blade assembly, and obturator assembly are removed from the dilator assembly, leaving the dilator assembly in the body to provide a conduit through which other devices may be inserted.

BRIEF SUMMARY OF THE DRAWINGS

[0017] The accompanying drawings, which are incorporated in and form a part of the specification, illustrate example embodiments and, together with the description, serve to explain the principles of the invention. In the drawings:

[0018] FIG. 1 illustrates an insertion device according to aspects of the present invention;

[0019] FIG. 2 illustrates a safety needle according to aspects of the present invention;

[0020] FIG. 3 illustrates a blade assembly according to aspects of the present invention;

[0021] FIG. 4 illustrates an obturator assembly according to aspects of the present invention;

[0022] FIGs. 5A-B illustrate an alternate embodiment of a blade assembly and an obturator assembly according to aspects of the present invention;

[0023] FIG. 6 illustrates a first step in inserting the insertion device according to aspects of the present invention;

[0024] FIG. 7 illustrates a second step in inserting the insertion device according to aspects of the present invention; and

[0025] FIG. 8 illustrates a final step in inserting the insertion device according to aspects of the present invention.

DETAILED DESCRIPTION

[0026] **FIG. 1** illustrates an insertion device according to aspects of the present invention.

[0027] As shown in the figure, insertion device **100** includes safety needle **102**, blade assembly **104**, obturator assembly **106**, dilator assembly **108**, and handle hole **110**.

[0028] Specific aspects of safety needle **102**, blade assembly **104**, obturator assembly **106**, and dilator assembly **108** will be further described with reference to **FIGs. 2**, **3**, **4**, and **8**, respectively.

[0029] In general, insertion device **100** is assembled by inserting safety needle assembly **102** through handle hole **110** and into blade assembly **104** until safety needle assembly **102** is distal to the distal end of blade assembly **104**. Then, the combination of safety needle assembly **102** and blade assembly **104** is inserted through obturator assembly **106**. Then, obturator assembly **106**, blade assembly **104**, and safety needle assembly **102** are connected to dilator assembly **108**. A more detailed description of the assembly and operation of insertion device **100** will be further described with reference to **FIGs. 2-8**.

[0030] **FIG. 2** illustrates a safety needle according to aspects of the present invention.

[0031] As shown in the figure, safety needle **102** includes cannula **202**, cannula tip **204**, stylet **206**, stylet port **208**, stylet tip **214**, housing **210**, hub **212**, and connection means **216**.

[0032] Cannula **202** is preferably constructed from a generally rigid material, such as metal or plastic, but other rigid materials may be considered. It may be extruded, welded, molded, or manufactured by any other method that would result in a generally rigid material. Cannula **202** is connected to hub **210** such that there is no relative movement between hub **210** and cannula **202**. The connection may be via any mechanical means (a non-limiting example of which includes overmolding), adhesive means (a non-limiting example of which includes UV adhesive), or any other means that would create a bond between housing **210** and cannula **202** to prevent relative motion between the two components.

[0033] Cannula tip **204** is designed to penetrate through tissue, and therefore it is relatively sharp. Cannula tip **204** may be manufactured by any known means to create a beveled tip, a conical tip, a crown tip, or any other geometry that is known in the art to provide a tip sharp enough to penetrate tissue.

[0034] Stylet **206** is preferably constructed from a generally rigid material, such as metal or plastic, but other rigid materials may be considered. It may be extruded, welded, molded, or

manufactured by any other method that would result in a generally rigid material. Stylet **206** is connected to housing **210** such that there may be relative motion between the two components. The outer diameter of stylet **206** is smaller than the inner diameter of cannula **202**, and stylet **206** is slidably positioned inside of cannula **202**.

[0035] Referring now to **FIG. 6**, housing **210** is a generally rigid component that is either machined or molded out of plastic. Housing **210** is connected to cannula **202** and to hub **212**. The center of housing **210** is open to accommodate spring **610** and allow spring **610** to be compressed and uncompressed during use.

[0036] Stylet **206** is connected to spring **610** via any mechanical, chemical or adhesive means that would create a bond between the two components. In an alternate embodiment, stylet **206** and spring **610** may both be connected to an intermediate part, such that stylet **206** and spring **610** are effectively bonded together. Spring **610** is connected to housing **210** and hub **212** via any mechanical, chemical or adhesive means that would create bond between the two components. In yet another alternate embodiment, spring **610** may freely float in between stylet **206** and hub **212** such that no bond between components is required.

[0037] Referring back to **FIG. 2**, stylet tip **214** is designed to avoid penetrating through tissue, and therefore it is relatively blunt and closed at the distal end. Stylet tip **214** may be manufactured by any known means to create a curved tip, a bullet tip, a flat tip, or any other geometry that is known in the art to create a closed distal tip that will avoid penetrating tissue.

[0038] Stylet port **208** is an open section in stylet **206** that is proximal to stylet tip **214** and distal to cannula tip **204** when spring **610** is uncompressed. Stylet port **208** may be manufactured by traditional grinding or machining techniques or by more advanced techniques, including electric discharge machining (EDM), chemical etching, or laser machining.

[0039] Referring back to **FIG. 6**, hub **212** is a generally rigid component that is either machined or molded out of plastic. Hub **212** is connected to spring **206** and to housing **210**. Hub **212** includes connection means **216** such that hub **212** may be connected to an external source for fluid drainage or administration.

[0040] Referring back to **FIG. 2**, connection means **216** is shown as a threaded connection, however any suitable connection means (a non-limiting example of which includes a snap fit) that provide for connection of a fluid drainage or administration device is acceptable.

[0041] Referring to **FIGs. 2** and **6**, in operation, a user grasps hub **210** or another component that may be coupled to hub **210** and advances safety needle assembly **102** toward a patient's skin. The first component of safety needle assembly **102** that contacts the skin is stylet tip **214**. As the user continues to push safety needle assembly **102** into the skin, the blunt stylet tip **214** transfers the pushing force through stylet **206**, compresses spring **610**, causes cannula **202** to move relative to stylet **206**, and allows cannula tip **204** to move toward the skin.

[0042] When the pushing force is sufficient enough, cannula tip **204** will contact the skin and the sharp tip will penetrate the skin and soft tissues underneath the skin. When cannula tip **204** reaches an area of little or no resistance, spring **610** will uncompress, allowing stylet **206** to move forward again such that stylet tip **214** is distal to cannula tip **204**, and stylet port **208** is exposed to the area. Areas of little or no resistance include fluid (or air) filled spaces such as the plerua, lungs, or any other fluid filled space the user desires to reach.

[0043] To confirm that safety needle assembly **102** is in the correct location, the user may connect a fluid drainage device to connection means **216** and use the fluid drainage device to pull fluid or air from the area as means of confirmation. Fluid drainage devices that may be used include syringes, suction canisters, wall suction, and any other means that may operate to pull fluid from the patient to confirm appropriate placement of safety needle assembly **102**.

[0044] **FIG. 3** illustrates a blade assembly according to aspects of the present invention.

[0045] As shown in the figure, blade assembly **104** includes shaft **302**, distal tip **304**, blades **306** and **308**, handle **310**, follower shaft **312**, and follower **314**.

[0046] Shaft **302** is a rigid tube and is preferably made of metal, however any other rigid material would suffice. Shaft **302** is connected to follower shaft **314** such that there is no relative motion between the two components. The connection may be made via mechanical, adhesive, or chemical means. Shaft **302** is also connected to blades **306** and **308**. The connection is preferably a welded connection, however other connection means may be employed. For example, shaft **302** may contain one or more slots at its distal end and blades **306** and **308** may contain one or more matching slots such that blades **306** and **308** may be

assembled on to shaft **302** by sliding slotted sections of blades **306** and **308** on to the corresponding slots at the distal end of shaft **302**.

[0047] Distal tip **304** is at the distal end of shaft **302** and is operable to provide a leading edge for blades **306** and **308**. Distal tip **304** may be produced by any conventional tip grinding or finishing process, and it may be a beveled tip, a conical tip, a crown tip, or any other tip that would provide an appropriate leading edge for blades **306** and **308**.

[0048] Blades **306** and **308** are preferably constructed from metal, more preferably from stainless steel, however any material suitable for medical applications would suffice. Blades **306** and **308** are operable to cut the skin of a patient, and as such are sufficiently sharp to cut skin. The specific shape, grind angles, and tip angles may be of any dimensions such that the effect of cutting skin may be accomplished. Blades **306** and **308** are attached to shaft **302** as previously described.

[0049] Handle **310** includes handle top **320** and cam **316**. Handle **310** is preferably made of plastic via either machining or molding, however any other suitable materials or manufacturing methods may be used. Handle top **320** is designed to be gripped by a user in order to rotate handle **310** relative to follower shaft **312** and follower **314**. Rotating handle top **320** and the motion of follower shaft **312** and follower **314** will be further discussed with reference to operation of blade assembly **104** below. Cam **316** is a slot within handle **310** in which follower **314** travels. Cam **316** may be constructed with any geometry that will provide the desired motion of follower **314**.

[0050] Follower **314** and follower shaft **312** are both preferably made of plastic via either machining or molding, however any other suitable materials or manufacturing methods may be used. In some embodiments, follower **314** and follower shaft **312** may be a single component, however they are shown here as two separate components. Follower **314** and follower shaft **312** are bonded together by any suitable means that will effectively prevent relative motion between the two components. In addition, shaft **302** is bonded to follower **314** and follower shaft **312** to prevent relative motion between the three components.

[0051] In operation, a user will turn handle **310** to effect a linear movement of shaft **302**. The user will grasp handle top **320** with one hand and dilator assembly **108** (not shown) with the other hand. Handle **310** therefore only rotates, and does not move in a linear direction when handle top **320** is turned. **FIG. 3** shows blade assembly **104** with blades **306** and **308**

fully deployed. To retract blades **306** and **308**, the user would turn handle top **320** in the appropriate direction. Turning handle top **320** causes cam **316** to rotate. As cam **316** rotates, follower **314** moves in a linear manner such that follower **314** moves closer to handle top **320**. To deploy blades **306** and **308**, the user would turn handle top **320** in the opposite direction.

[0052] **FIG. 4** illustrates an obturator assembly according to aspects of the present invention.

[0053] As shown in the figure, obturator assembly **106** includes obturator tip **402**, obturator shaft **404**, handle cover **408**, and obturator hub **410**. All components of obturator assembly **106** are preferably made from plastic via either machining or molding processes, however any suitable material or manufacturing method may be used to create the component.

[0054] Obturator tip **402** is operable to enlarge an opening in the skin, and includes blade slot **412**. Blade slot **412** is operable to provide a pathway for blades **306** and **308** to be deployed beyond the distal-most portion of obturator tip **402** and to be fully retracted within obturator tip **402**. Obturator tip **402** is connected to obturator shaft **404** by any suitable means that would prevent relative motion between the two components. In an alternate embodiment, obturator tip **402** and obturator shaft **404** may be a single component.

[0055] Obturator shaft **404** is operable to travel within the enlarged opening created by obturator tip **402**, and includes obturator slot **406**. Obturator slot **406** is present to reduce weight and manufacturing costs. In an alternate embodiment, obturator slot **406** may be omitted entirely such that obturator shaft **404** is a continuous tube with no openings in its diameter.

[0056] Obturator hub **410** is connected to obturator shaft **404** by any means that would create a bond to prevent relative motion between the two components. Obturator hub **410** is operable to constrain the linear motion of follower **314** (not shown), such that blades **306** and **308** can only extend from obturator tip **402** by a defined distance.

[0057] Handle cover **408** is operable to attach to obturator hub **410** and cover cam **316** (not shown) such that a user cannot interfere with the operation of cam **316**. Handle cover **408** may be a single component or multiple components that can be attached together. Additionally, in an alternate embodiment, handle cover **408** and obturator hub **410** may be a single component.

[0058] Returning to **FIG. 1**, and with reference to **FIGs. 2-4**, assembly of insertion device **100** will be described.

[0059] To assemble insertion device **100**, safety needle **102** is inserted through handle hole **110** and extends through the inner diameter of shaft **302** of blade assembly **104**, extending beyond distal tip **304**. The combination of safety needle **102** and blade assembly **104** is inserted through the inner diameter of obturator shaft **404** until obturator hub contacts cam **316** of blade assembly **104**. Handle cover **408** is then installed to cover cam **316**. Finally, the entire assembly is inserted through the inner diameter of dilator assembly **108** to complete the assembly process. There are no connections between dilator assembly **108** and the rest of the components; a simple press-fit interaction serves to keep dilator assembly **108** connected to the rest of the components. In an alternate embodiment, dilator assembly **108** may detachably lock to obturator assembly **106**. Dilator assembly **108** will be further described with reference to **FIGs. 6-8**.

[0060] **FIGs. 5A-B** illustrate an alternate embodiment of a blade assembly and an obturator assembly according to aspects of the present invention.

[0061] As shown in the figures, obturator tip **502** includes cutout **504** to accommodate safety needle **102**. A blade slot similar to blade slot **412** provides space for blade **506** to deploy and retract.

[0062] In this embodiment, blade **506** is a single blade instead of multiple blades as previously described. The single blade may be attached to shaft **302** by any means previously described. If attaching multiple blades to the outer diameter of shaft **302** is difficult to accomplish, this alternate embodiment may be employed, as methods to attach a single blade to a shaft are well known in the art.

[0063] In attaching blade **506** to shaft **302**, a difficulty is encountered as safety needle **102** and blade **506** cannot be longitudinally coaxial with each other as is possible with the multiple blade design. Therefore, it is necessary to create cutout **504** to accommodate safety needle assembly **102**. In this embodiment, blade **506** slides along the outer diameter of safety needle assembly **102**.

[0064] Testing has proven that, even though safety needle **102** is not concentric with respect to the rest of insertion device **100**, the ability of blade **506** to enlarge the pathway created by

safety needle **102** is not impacted, and the performance of insertion device **100** is not diminished.

[0065] In yet another alternate embodiment, and with further reference to **FIGs. 3-4**, it may be desirable to eliminate the need to turn handle **320** to deploy and retract blades **306** and **308**. In such an embodiment, blade assembly **104** may contact a spring that rests on obturator hub **410**. There may be a window in handle cover **408** such that the user's finger could reach blade assembly **104** through the window. Access to blade assembly **104** may also be available via obturator slot **406**. When the user desires to deploy the blades, the user would extend a finger into the window and press down on blade assembly **104**, compressing the spring and exposing the blades. After using the blades, the user would remove his/her finger from blade assembly **104**, which would then automatically retract blades **306** and **308** into obturator assembly **106** as the spring uncompressed.

[0066] **FIG. 6** illustrates a first step in inserting the insertion device according to aspects of the present invention.

[0067] As shown in the figure, system **600** includes skin **602**, soft tissue **604**, and ribs **606** and **608**.

[0068] Prior to inserting device **100** into a patient, a user will palpate the skin to determine the appropriate insertion point between ribs **606** and **608**. Once the desired location is found, the user begins to insert insertion device **100**. While not shown in **FIG. 6**, when first inserting insertion device into the patient, blades **306** and **308** are not deployed and are located within obturator assembly **106** (similar to the device as shown in **FIG. 7**).

[0069] When inserting insertion device **100** into the patient, safety needle **102** is the first component to contact the patient's skin **602**. As described with reference to **FIG. 2**, pushing safety needle **102** against the patient's skin **602** causes stylet **206** to retract, exposing the sharp cannula tip **204** to the skin. As the user continues to push, cannula tip **204** cuts through skin **602** and soft tissue **604**. Soft tissue **604** may include muscle, fat, fascia, or any other soft tissues with which safety needle **102** may come in contact with during the procedure.

[0070] A skilled user can generally tell when the desired location is reached, as a distinct decrease in resistance occurs. The decrease in resistance is an indication that safety needle **102** has reached the desired, fluid-filled location. To confirm that safety needle **102** has reached the desired location, the user will attach a fluid drainage device to hub **212** via

connection means **216**. The user will then attempt to drain fluid from the area. If the desired fluid is drawn from the area, the user may continue with the procedure. If the desired fluid is not drawn from the area, the user may need to continue in attempts to find the desired location.

[0071] Assuming the desired fluid has been located, the user then deploys blades **306** and **308** by turning handle **320** until handle **320** cannot be turned any more, meaning blades **306** and **308** are fully deployed. The user then advances insertion device **100** until blades **306** and **308** enter skin **602** to create a skin nick. If desirable, after creating the skin nick, the user may pull insertion device back such that blades **306** and **308** are not in skin **602**, rotate insertion device **100** 90 degrees, and then advance insertion device again until blades **306** and **308** enter skin **602**. After one or more skin nicks are created, the user turns handle **320** in the opposite direction until it cannot be turned any more, meaning blades **306** and **308** are fully retracted. The user can then further advance insertion device **100**, which is further described with reference to **FIG. 7**.

[0072] In an alternate method, the user may deploy blades **306** and **308** first, create a skin nick, and then retract blades **306** and **308**. The user may then proceed with inserting safety needle **102** into the patient as previously described, or the user may decide to forego using safety needle **102** and instead insert obturator assembly **106**, blade assembly **104**, and dilator assembly **108** into the desired space within the patient.

[0073] FIG. 7 illustrates a second step in inserting the insertion device according to aspects of the present invention.

[0074] As shown in the figure, insertion device **100** is pushed further into the patient. As insertion device **100** advances, obturator tip **402** expands the pathway created by safety needle **102** and the one or more skin nicks. The user holds safety needle **102** with one hand while advancing obturator assembly **106**, blade assembly **104**, and dilator assembly **108**. The distance between housing **210** and handle **320**, noted as "d", will increase as the user continues to advance obturator assembly **106**, blade assembly **104**, and dilator assembly **108**.

[0075] When obturator tip **402** reaches stylet tip **214**, the user may stop advancement. The user may use an appropriate imaging technique to determine when obturator tip **402** reaches stylet tip **214**. In an alternate embodiment, cannula **202** may include an indicator mark, such

that when handle **320** no longer covers the indicator mark, obturator tip **402** has reached stylet tip **214**.

[0076] The user can then remove components to prepare the patient for insertion of a catheter. Safety needle assembly **102**, blade assembly **104**, and obturator assembly **106** may all be removed from dilator assembly **108** at the same time. To remove the components, the user will grip dilator shaft **702** with one hand and handle cover **408** with the other hand. Dilator shaft **702** will be further described with reference to **FIG. 8**. While holding dilator shaft **702** steady, the user will pull back on handle cover **408**. This will serve to detach Safety needle assembly **102**, blade assembly **104**, and obturator assembly **106** from the press-fit connection to dilator assembly **108**. As the user continues to pull back on handle cover **408**, all components will be removed from dilator assembly **108**, leaving dilator assembly **108** in the body.

[0077] **FIG. 8** illustrates a final step in inserting the insertion device according to aspects of the present invention.

[0078] As shown in the figure, dilator assembly **108** is in the patient. Dilator assembly **108** includes dilator shaft **702** and dilator hub **704**. Dilator shaft **702** is preferably made of plastic and may be extruded, molded, or manufactured in any other known way to create the desired geometry. Dilator hub **704** is also preferably made of plastic by any known method to create the desired geometry. Dilator hub **704** and dilator shaft **702** are connected by any known methods that would serve to prevent any relative motion between the two components.

[0079] At this point in the procedure, the user will typically place a catheter through the lumen of dilator shaft **702** to reach the desired location within the body. Essentially, dilator shaft **702** is simply a conduit through which another device (i.e., a catheter) is placed. Once the catheter is placed in the desired location, dilator assembly **108** is removed from the patient. The user then completes the procedure by closing skin **602** around the catheter.

[0080] The foregoing description of various preferred embodiments have been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed, and obviously many modifications and variations are possible in light of the above teaching. The example embodiments, as described above, were chosen and described in order to best explain the principles of the invention and its practical application to thereby enable others skilled in the art to best utilize the invention in

various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims appended hereto.

CLAIMS

What is claimed as new and desired to be protected by Letters Patent of the United States is:

1. An access device comprising:

a safety needle assembly operable to create a pathway through skin and into said interior body regions;

a blade assembly operable to cut tissue to create a skin nick and provide access into interior body regions;

an obturator assembly operable to expand said pathway into said interior body regions; and

a dilator assembly operable to maintain said pathway and provide access to said interior body regions.

2. The device of claim 1, wherein said blade assembly further comprises means to advance a blade into skin to create said skin nick and means to retract said blade after said skin nick is created.

3. The device of claim 2, wherein a sharp point of said blade is not longitudinally coaxial with said safety needle assembly.

4. The device of claim 2, wherein said blade comprises multiple sharp elements arranged around, and longitudinally coaxial with, said safety needle assembly.

5. The device of claim 1, wherein said safety needle assembly further comprises a sharp outer cannula and a blunt inner cannula, and said blunt inner cannula has a closed distal end.

6. The device of claim 5, wherein said blunt inner cannula further comprises side ports operable to contact body fluids within said interior body regions.

7. The device of claim 6, wherein said safety needle assembly further comprises a hub attached to said blunt inner cannula, said hub operable to receive a fluid drainage device such that fluid may be removed from said interior body regions via said side ports of said blunt inner cannula to verify that said safety needle assembly is in the proper location within said interior body regions.

8. The device of claim 1, wherein said obturator assembly further comprises a handle that connects said obturator assembly to said safety needle assembly and said skin nick assembly.

9. The device of claim 1, wherein said dilator assembly further comprises a connector that is releasably attached to said handle of said obturator assembly.

10. A method of accessing interior body regions, comprising:

providing an access device defining:

a safety needle assembly, a retractable and advanceable blade assembly, an obturator assembly, and a dilator assembly, wherein said safety needle assembly, said skin nick assembly, and said obturator assembly are releasably attached to said dilator assembly;

advancing said safety needle assembly through skin and into interior body regions, creating a pathway into said interior body regions;

deploying a blade of said blade assembly;

advancing said blade of said blade assembly, cutting the skin near the outer diameter of said safety needle assembly to create a skin nick;

retracting said blade of said blade assembly;

advancing said blade assembly, said obturator assembly, and said dilator assembly through said skin nick, wherein said advancing comprises pushing said access device such that said obturator assembly increases the diameter of said pathway; and

disconnecting said blade assembly, said safety needle assembly, and said obturator assembly from said dilator assembly, leaving said dilator assembly in the body to provide access to said interior body regions.

11. The method of claim 10, further comprising confirming said safety needle assembly is in the desired location prior to said advancing of said blade assembly.

12. The method of claim 11, wherein said confirming comprises connecting a fluid drainage device to said safety needle assembly, draining fluid from said interior body regions, and using said fluid to determine if said safety needle assembly is in the proper location.

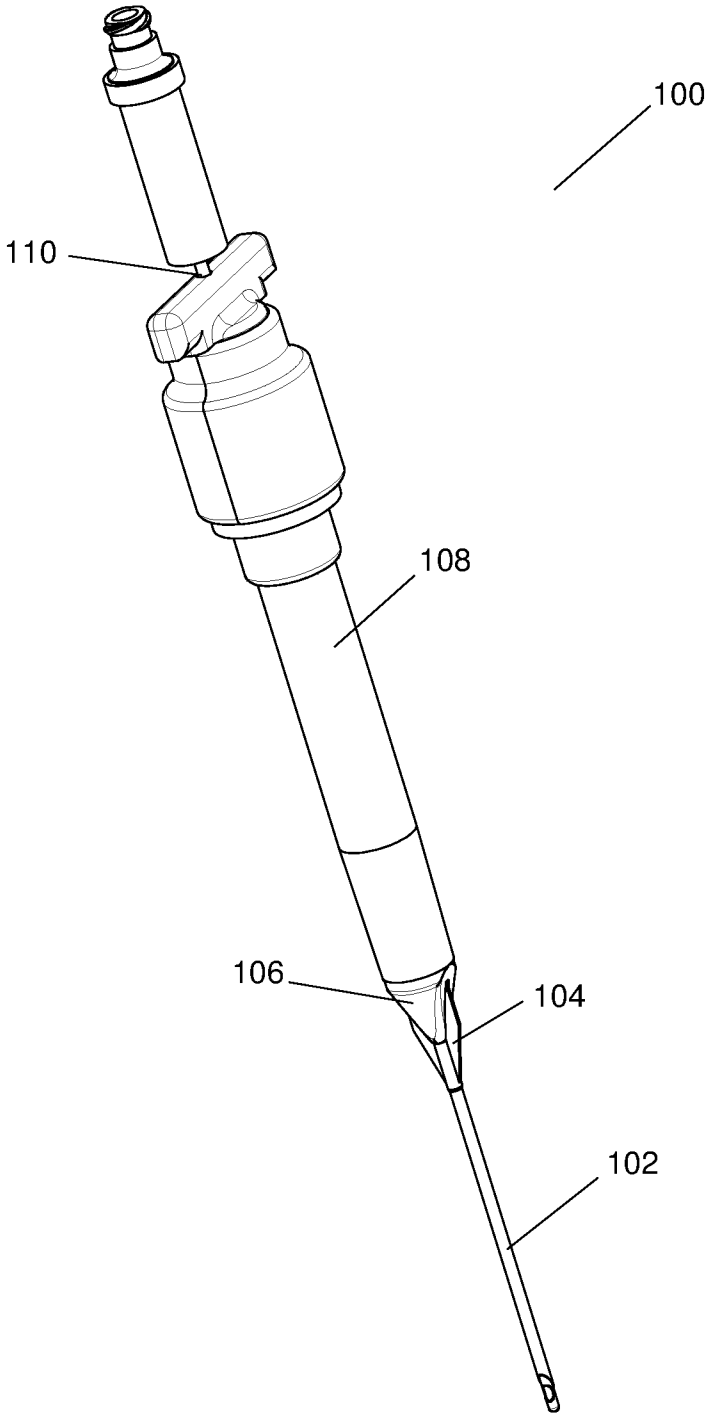

FIG. 1

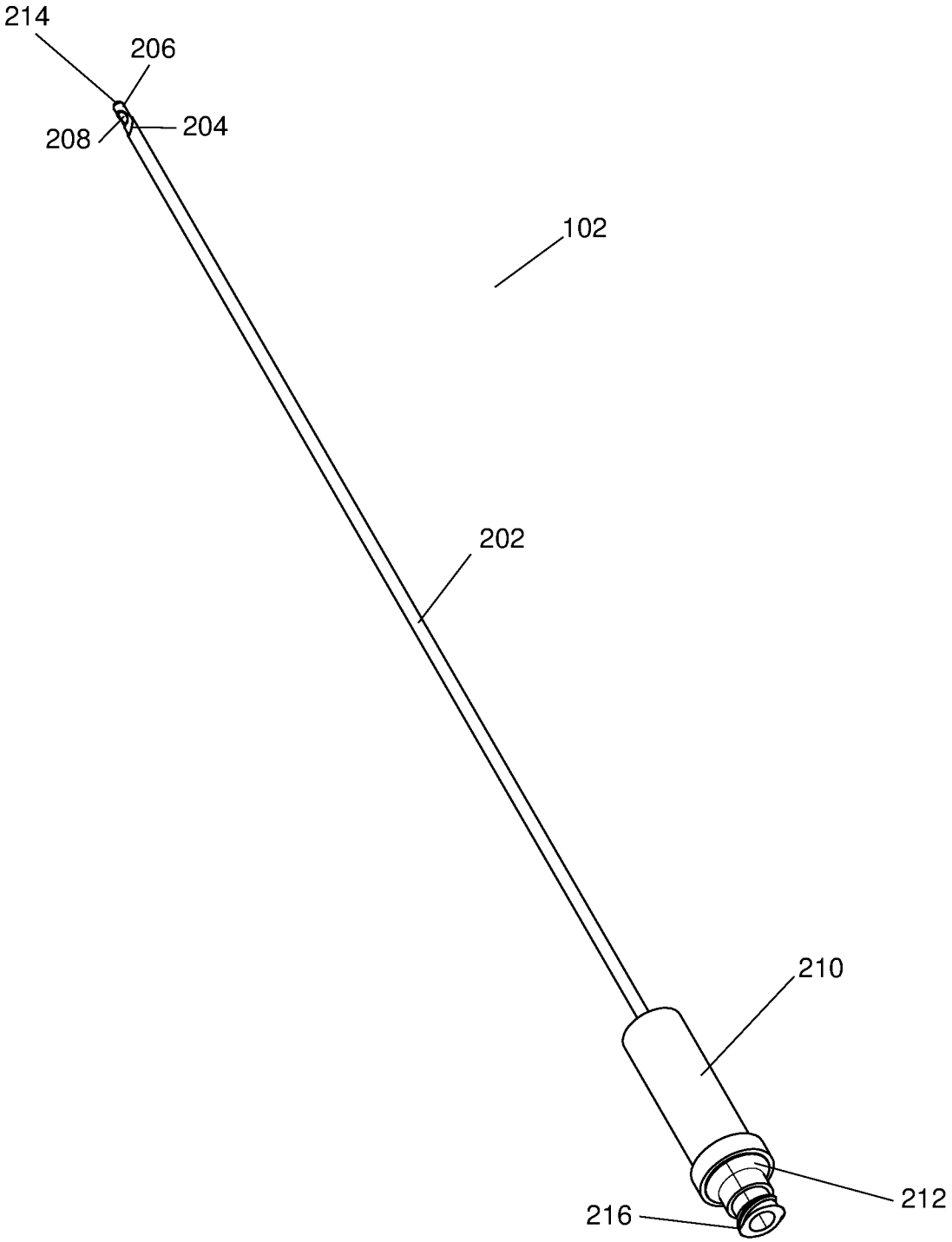

FIG. 2

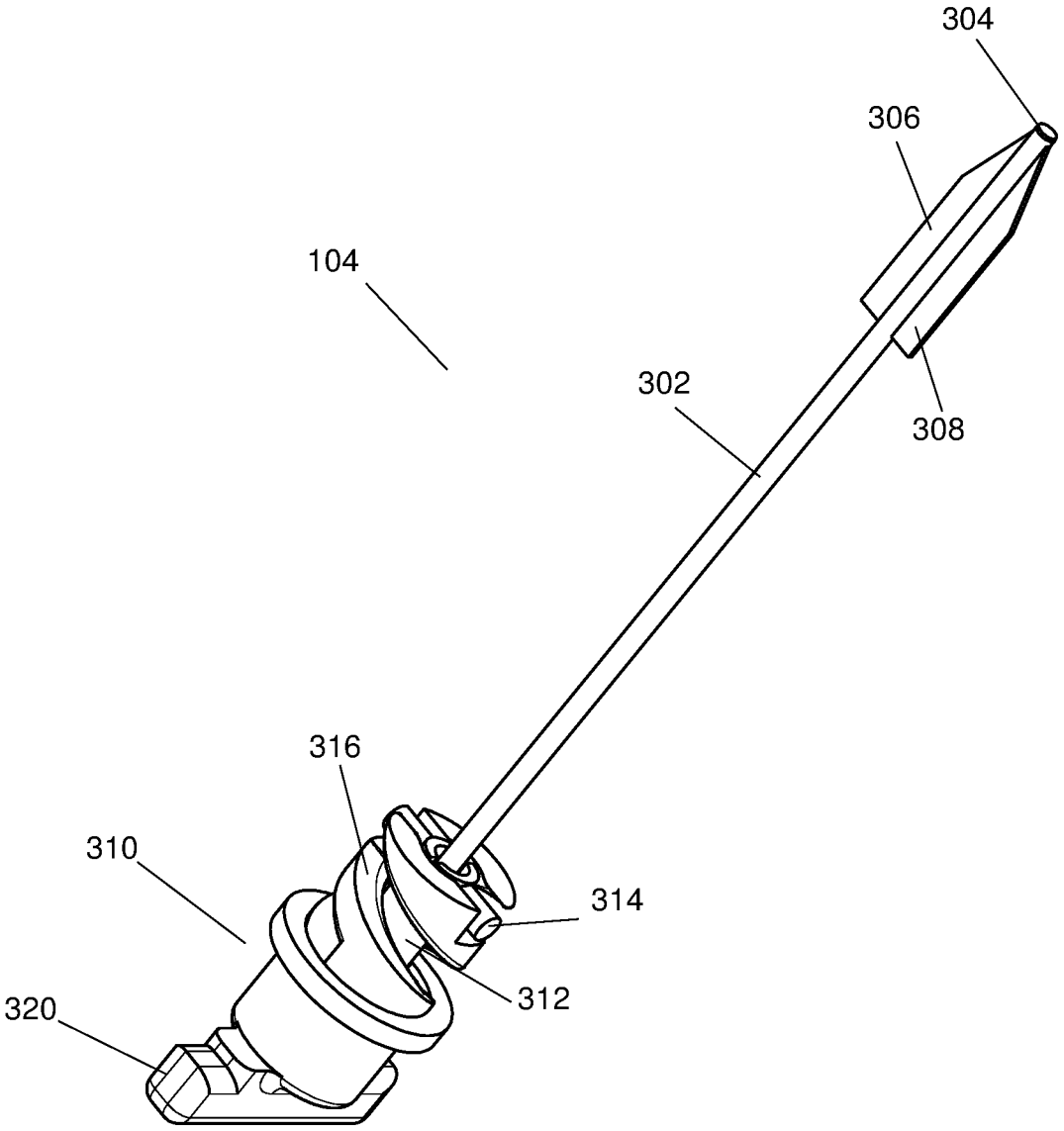

FIG. 3

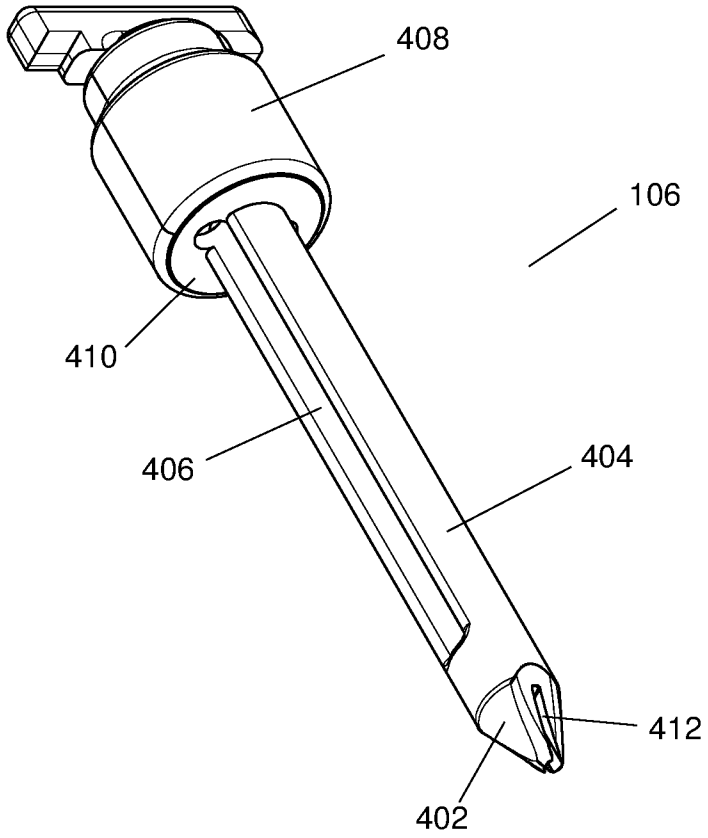

FIG. 4

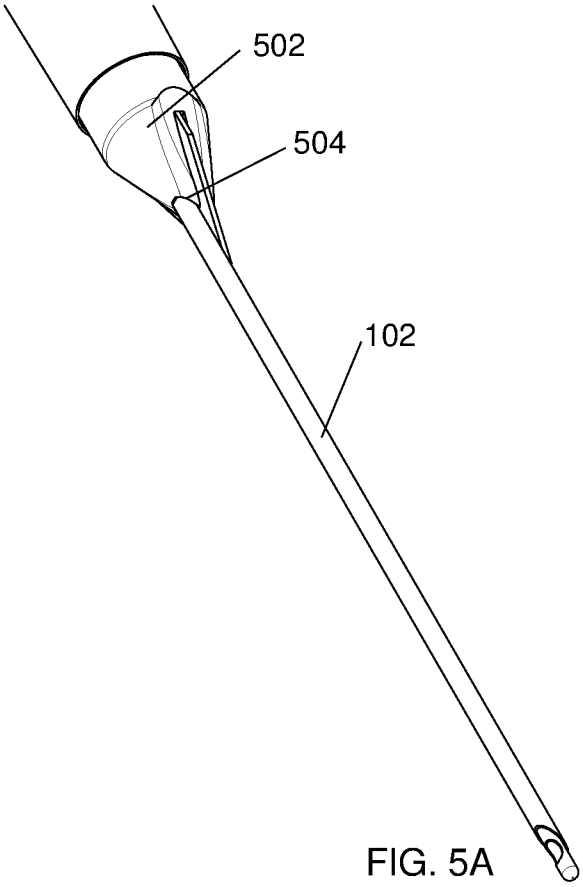

FIG. 5A

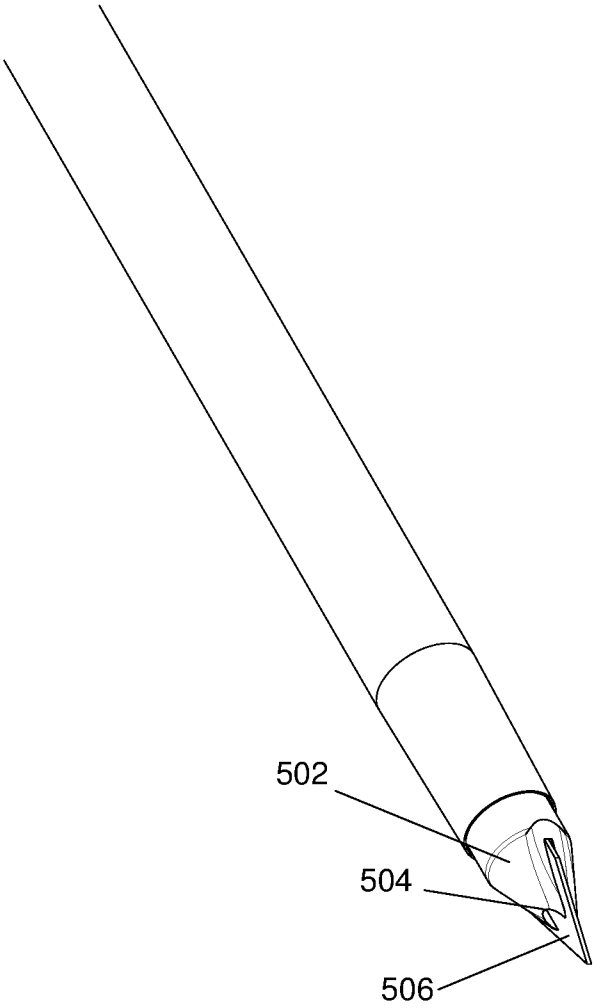

FIG. 5B

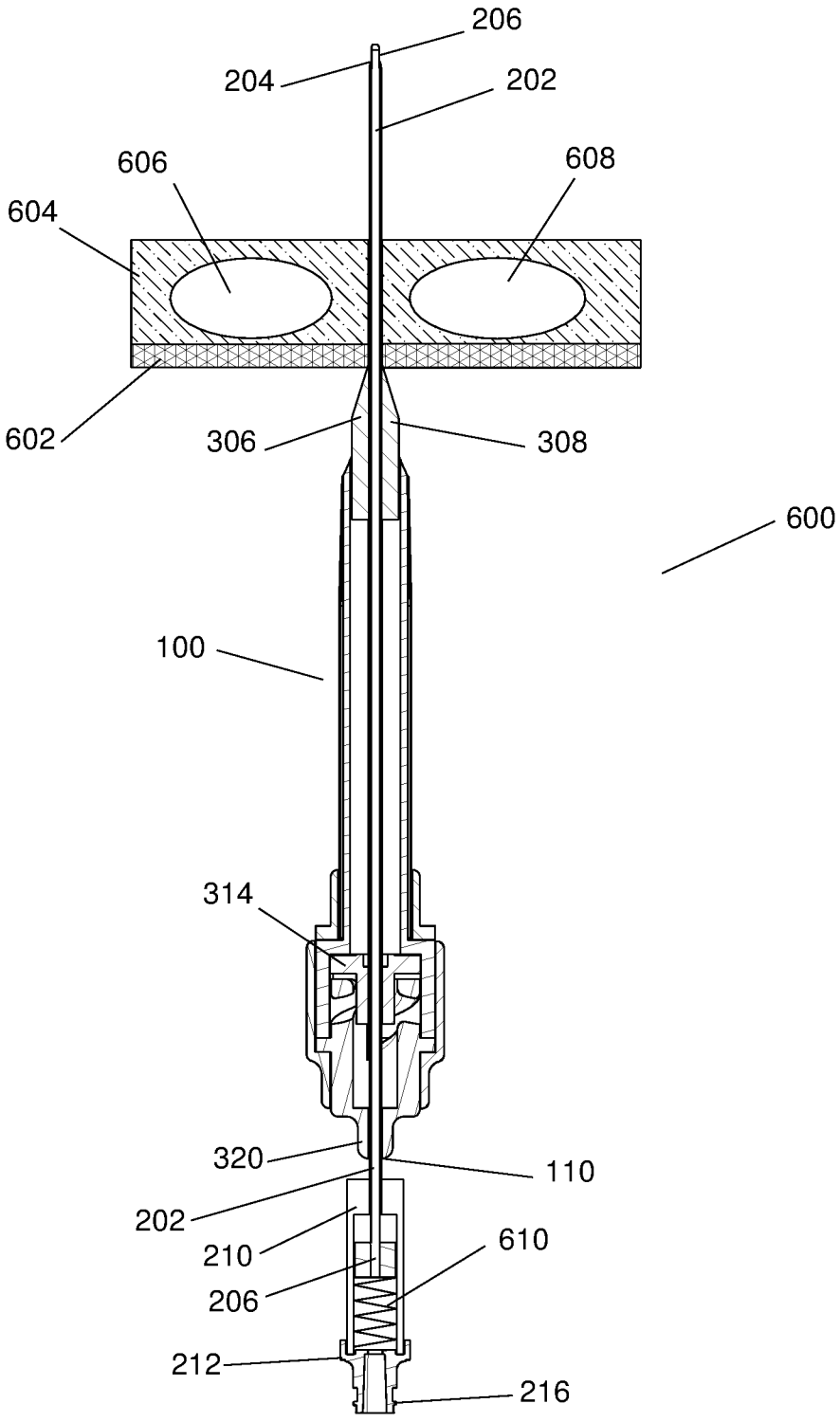
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FIG. 6

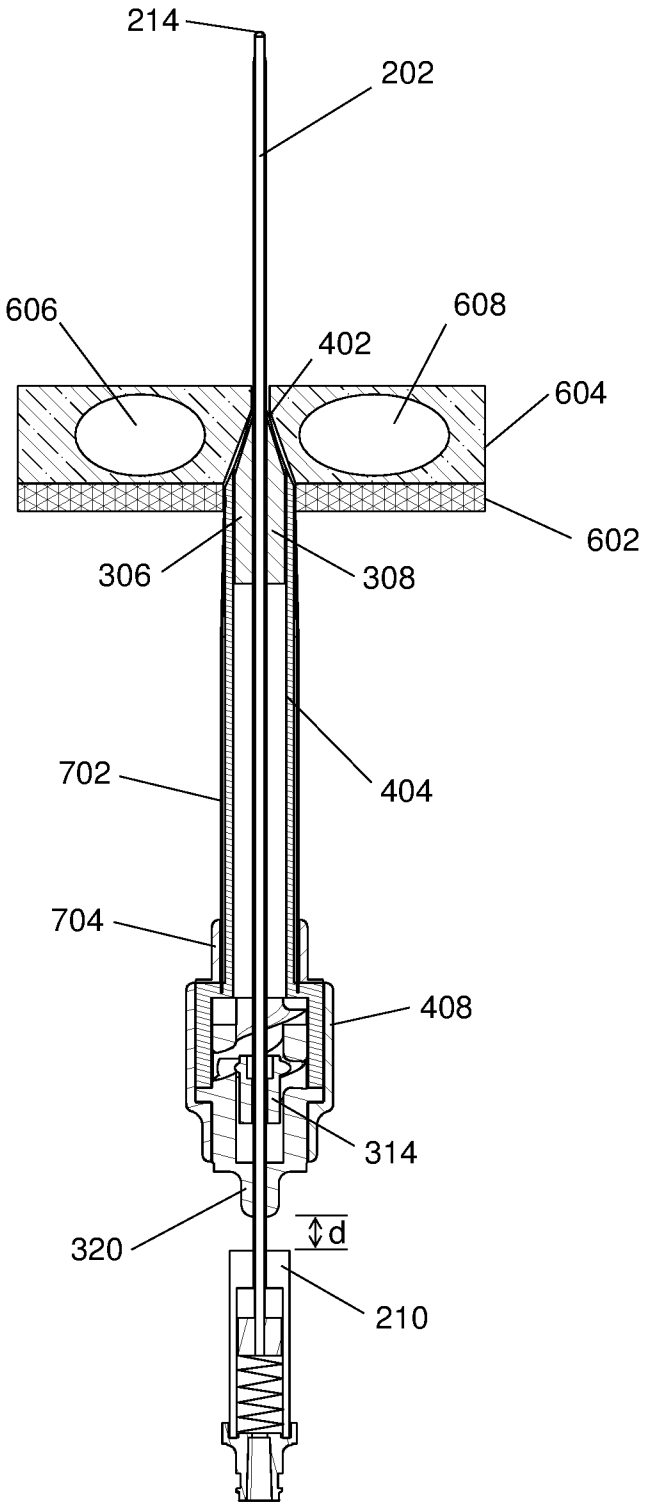

FIG. 7

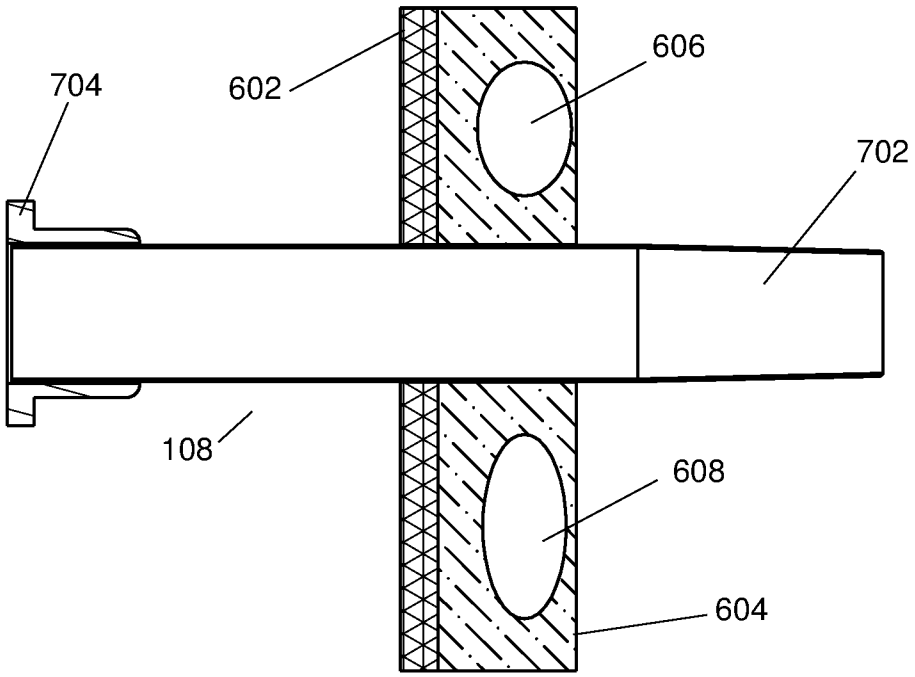

FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US16/17282

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/01, 25/06 (2016.01)
CPC - A61M 25/0068, 25/007, 25/0102, 25/0668
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61M 25/00, 25/01, 25/06 (2016.01)
CPC: A61M 25/0068, 25/007, 25/0102, 25/0668; USPC: 604/117, 161, 170.03; 606/1, 170

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)
PatSeer (US, EP, WO, JP, DE, GB, CN, FR, KR, ES, AU, IN, CA, Other Countries (INPADOC), RU, AT, CH, TH, BR, PH); Google Patents; Google; Google Scholar; EBSCO; PubMed/Medline; Search terms used: skin, transdermal, epidermis, scalpel, blade, "safety needle", obturator, dilator

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y -- A	US 5,693,030 A (LEE, JS et al.) December 2, 1997; abstract; figures 7, 8; column 1, lines 4-17; column 7, lines 51-55; column 8, lines 18-21, 51-55; column 9, lines 6-17, 42-56; column 10, lines 1-9, 66-67; column 11, lines 1-5	1-9 --- 10-12
Y -- A	US 2014/0276532 A1 (SWAN VALLEY MEDICAL INCORPORATED) September 18, 2014; claims 1-3, 12	1-9 --- 10-12
Y	US 2011/0144678 A1 (SLATER, CR) June 16, 2011; paragraphs [0005], [0051]	3
Y	US 2007/0260275 A1 (AHLBERG, RE et al.) November 8, 2007; figures 29-33, 37; paragraph [0066]	4
Y	WO 2014/170338 A1 (VESALIUS MEDICAL TECHNOLOGIES BVBA) October 23, 2014; paragraphs [02], [0048], [0054]; figures 4, 6, 7, 11	5-7
Y	US 2012/0116418 A1 (BELSON, A et al.) May 10, 2012; figures 2A-B, 7A, 7D; paragraph [0028]-[0029], [0033]	8
Y	US 4772266 A (GROSHONG, LRE) September 20, 1988; abstract; figures 1, 2; column 5, lines 50-54; column 6, lines 53-55	9
A	US 2013/0123834 A1 (SWAN VALLEY MEDICAL INCORPORATED) May 16, 2013; paragraphs [0160], [0165]-[0168], [0170]; claim 1	10-12
A	US 2013/0150767 A1 (TSYRULNYKOV, E et al.) June 13, 2013; claim 3	10-12

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

Date of the actual completion of the international search	Date of mailing of the international search report
31 March 2016 (31.03.2016)	22 APR 2016
Name and mailing address of the ISA/ *Mail Stop PCT, Attn: ISA/US, Commissioner for Patents* P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Shane Thomas PCT Helpdesk: 571-272-4300 *PCT OSP:* 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)