



- (51) International Patent Classification:  
*A61M 1/04* (2006.01)      *A61B 17/34* (2006.01)
- (21) International Application Number:  
PCT/AU2017/051286
- (22) International Filing Date:  
22 November 2017 (22.11.2017)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
2016904770      22 November 2016 (22.11.2016) AU
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- (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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,

(54) Title: SURGICAL SYSTEM AND METHOD OF USE

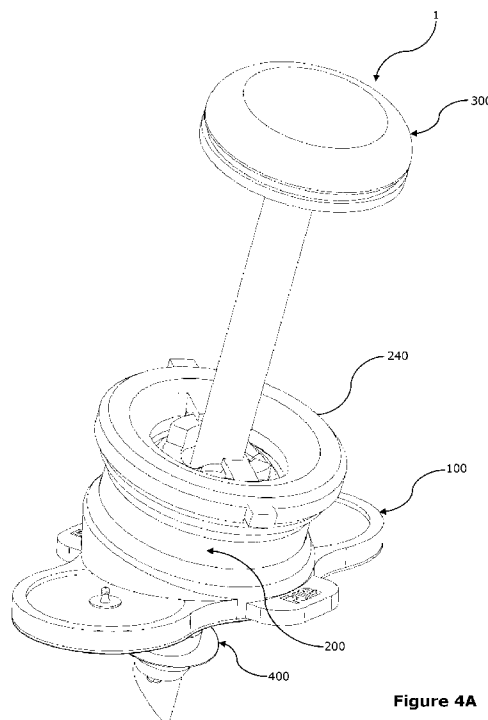


Figure 4A

(57) Abstract: A surgical system for use in establishing and maintaining an opening to an anatomical space of a body, the system comprising an obturator assembly having a cutting portion at a distal end and a cannula, the cannula being detachably coupled to the cutting portion and deployable into the anatomical space of a patient, the cannula comprises a locking portion, and a lengthwise extendable body; a valve assembly comprising a passage for receiving the cannula, a first end for coupling to a fluid extraction device and a second end for placement external and adjacent the anatomical space; a base comprising a plate for placement on a patient external and adjacent the anatomical space, the plate has an aperture configured for receiving the obturator assembly and coupling means located about the aperture for coupling with the valve assembly; and wherein, in use, the locking portion of the cannula is configured to be retained in the valve assembly with the extendable body extended into the anatomical space to facilitate a path for fluid extraction, and



KR, KW, 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, 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).

**Published:**

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

### **Surgical system and method of use**

The entire content of Australian Provisional Patent Application No. 2016904770 as originally filed is incorporated herein by reference.

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#### Field of the invention

The invention relates to a surgical system and method for establishing and maintaining a percutaneous cannula into an anatomical space such as a body cavity to permit controlled passage of fluid, and more particularly to a pleural decompression system and method for  
10 use in the treatment of simple and tension pneumothorax.

#### Background of the invention

Tension pneumothorax (TP) is a life-threatening condition occurring in 1-3% of major trauma patients who have sustained penetrating or blunt chest trauma including blast  
15 injury. It is associated with hypoxia in 50% of spontaneously breathing trauma patients and respiratory arrest in 9.3% of the patients. TP has been identified as the cause of death in 3-4% of fatally wounded combat casualties and is responsible for 33% of preventable deaths on the battlefield.

20 Decompressing the pleural space and venting air or blood is the definitive emergency intervention for tension pneumothorax and failure to decompress a tension pneumothorax is a well-recognized cause of avoidable, early trauma death. Needle Thoracostomy (NT) is a technique currently recommended as the emergency intervention for achieving rapid pleural decompression. The conventional NT method involves the use of a decompression  
25 needle (see Figure 1) for piercing through the chest of a patient to access and extract fluid build-up in the pleural space (see Figure 2).

However, the conventional NT method has a high risk of failure attributable to several factors including improper needle placement and inappropriate catheter length. It is  
30 understood that deficient needle length for effective pleural decompression may relate to increased anterior Chest Wall Thickness (CWT) of military personnel. Potential solutions

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thus far have been two-fold; using a longer catheter and considering other sites of access. However inter-population difference in CWT means that the "one-length NT fits all" approach is flawed and the variable length approach is logistically complicated for a field operator to determine and deploy under stress.

5

The applicant has determined that it would be advantageous to provide an improved, easy to use surgical system and method that is suitable for use in the treatment of simple and tension pneumothorax despite inter-population differences in CWT. The present invention seeks to at least in part alleviate the problems identified above.

10

#### Summary of the invention

According to an aspect of the present invention, there is provided a surgical system for use in establishing and maintaining an opening to an anatomical space of a body, the system comprising: an obturator assembly having a cutting portion at a distal end and a cannula, 15 the cannula being detachably coupled to the cutting portion and deployable into the anatomical space of a patient, the cannula comprises a locking portion, and a lengthwise extendable body; a valve assembly comprising a passage for receiving the cannula, a first end for coupling to a fluid extraction device and a second end for placement external and adjacent the anatomical space; a base comprising a plate for placement on a patient 20 external and adjacent the anatomical space, the plate has an aperture configured for receiving the obturator assembly and coupling means located about the aperture for coupling with the valve assembly; and wherein, in use, the locking portion of the cannula is configured to be retained in the valve assembly with the extendable body extended into the anatomical space to facilitate a path for fluid extraction, and wherein the cannula 25 comprises means for retaining the cannula in its extended state.

According to another aspect of the present invention, there is provided a pleural decompression system for use in the treatment of simple and/or tension pneumothorax, the system comprising: an obturator assembly having a cutting portion at a distal end and a 30 cannula, the cannula being detachably coupled to the cutting portion and deployable into a pleural space of a patient, the cannula comprises a locking portion, and a lengthwise

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extendable body; a valve assembly comprising a passage for receiving the cannula, a first end for coupling to a fluid extraction device and a second end for placement above an intercostal space; a base comprising a plate for placement on a patient above an intercostal space, the plate has an aperture configured for receiving the obturator assembly and  
5 coupling means located about the aperture for coupling with the valve assembly; and wherein, in use, the locking portion of the cannula is configured to be retained in the valve assembly with the extendable body extended into the chest wall of the patient to facilitate a path for pleural fluid extraction, and wherein the cannula comprises means for retaining the cannula in its extended state.

10

According to another aspect of the invention, the surgical system is provided for use in the treatment of simple and/or tension pneumothorax.

Preferably, the cannula is configured to have a minimum length of about 4 cm and a  
15 maximum length of about 9 cm.

Preferably, a coiled spring is mounted around the cannula body to provide a bias around the body to move towards an extended configuration.

20 Preferably, the means for retaining the cannula in its extended state comprises an anchoring portion located at a distal end of the cannula. Preferably, the anchoring portion is in the form of a helical flange. Preferably, the helical flange is operable between an anchoring configuration in which the flange is collapsed in the longitudinal direction, and an extraction configuration in which the flange is extended in the longitudinal direction.

25

Alternatively, the cannula comprises two or more telescopic sections extendable from the cannula body. Preferably, the means for retaining the cannula in its extended state comprises locking means for locking each telescopic section in its extended state when the cannula is in an extended state.

30

Preferably, the coupling means is configured to receive the valve assembly at an angle

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inclined to an axis perpendicular to the plane of the plate.

Preferably, an underside of the plate is provided with adhesive means for securing the plate to the patient. Preferably, the adhesive means is foam-backed adhesive.

5

Preferably, the system further comprises an indicator extending from the plate for assisting a user with placement of the plate above the intercostal space.

10 Preferably, the system further comprises side portions extending in opposite directions from the plate for stabilising the plate from movement when applied to the torso.

Preferably, the system further comprises an electrode embedded in the plate configured for outputting cardiac spatial data to an external monitoring device.

15 Preferably, the valve assembly comprises a one-way efflux valve.

Preferably, the first end of the valve is configured to receive a cap for coupling with a fluid extracting device.

20 Preferably, the obturator assembly comprises a hollow stem and the cutting portion being located at the distal end of the stem.

25 Preferably, the obturator assembly further comprises a spring-loaded inner stylet housed within the stem and movable relative to the stem, the stylet having a handle located at a proximate end and a blunt portion located at a distal end of the stem, wherein the obturator assembly is configured to operate between a retracted cutting configuration in which the blunt portion of the stylet is received within the stem to expose the cutting portion and an extended configuration in which the blunt portion extends past the cutting portion.

30 Preferably, the obturator assembly is configured with locking means to hold the stem and stylet in the cutting and extended configurations.

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Preferably, the locking means comprises one or more complementary protrusion and aperture formations on the stem and the stylet.

5 Preferably, the obturator assembly transforms from the cutting configuration to the extended configuration by a user pushing the stylet handle such that the blunt portion extends past the cutting portion and the locking means engages the stylet in the extended configuration.

10 Preferably, the cutting portion comprises a cutting blade having a chamfered tip.

According to another aspect of the invention, there is provided a method of establishing and maintaining an opening to an anatomical space of a body, the method comprising the steps of: affixing a base comprising a plate on a patient external and adjacent the  
15 anatomical space of the patient, the plate having an aperture configured for receiving an obturator assembly and coupling means located about the aperture for coupling with a valve assembly; coupling the valve assembly to the base, the valve assembly comprising a passage for receiving the cannula and an open end for coupling to a fluid extraction device; cutting through muscular tissues into the anatomical space with a cutting portion of the  
20 obturator assembly by inserting the obturator assembly through the valve assembly passage and the plate aperture, and pushing a handle of the obturator assembly so that the cutting portion cuts through the tissues, a blunt portion of the obturator assembly automatically extends past the cutting portion with a loss of cutting pressure and locks the blunt portion relative to the cutting portion to prevent visceral organ injury; deploying a cannula into the  
25 anatomical space from the obturator assembly by securing a locking portion of the cannula to the valve assembly and removing the obturator assembly, the cannula further comprises a lengthwise extendable body extendable into an anatomical part of the patient to facilitate a path for fluid extraction into the valve assembly, the cannula having means for retaining the cannula in its extended state in use; extracting fluid from the anatomical space by  
30 coupling the fluid extraction device to the valve assembly.

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According to another aspect of the invention, there is provided a method of extracting fluid from a pleural cavity of a patient using a pleural decompression system in the treatment of simple and/or tension pneumothorax, the method comprising the steps of: affixing a base comprising a plate on a patient above an intercostal space of the pleural cavity, the plate  
5 having an aperture configured for receiving an obturator assembly and coupling means located about the aperture for coupling with a valve assembly; coupling the valve assembly to the base, the valve assembly comprising a passage for receiving the cannula and an open end for coupling to a fluid extraction device; cutting through muscular tissues into the pleural cavity with a cutting portion of the obturator assembly by inserting the obturator  
10 assembly through the valve assembly passage and the plate aperture, and pushing a handle of the obturator assembly so that the cutting portion cuts through the tissues, a blunt portion of the obturator assembly automatically extends past the cutting portion with a loss of cutting pressure and locks the blunt portion relative to the cutting portion to prevent visceral organ injury; deploying a cannula into the pleural cavity from the obturator  
15 assembly by securing a locking portion of the cannula to the valve assembly and removing the obturator assembly, the cannula further comprises a lengthwise extendable body extendable into the chest wall of the patient to facilitate a path for pleural fluid extraction into the valve assembly, the cannula having means for retaining the cannula in its extended state in use; extracting fluid from the pleural cavity by coupling the fluid extraction device  
20 to the valve assembly.

Preferably, the cannula is configured to have a minimum length of about 4 cm and a maximum length of about 9 cm.

25 Preferably, a coiled spring is mounted around the cannula body to provide a bias around the body to move towards an extended configuration.

Preferably, the cannula comprises two or more telescopic sections extendable from the cannula body.

30

Preferably, the method further comprises the step of: locating a mid-point of an upper arm



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of a supine-positioned patient between the olecranon and the acromion when the elbow of the patient is flexed to 90 degrees with the patient's forearm in a mid prone position; projecting a line, perpendicular to the upper arm, from the mid-point of the upper arm across to the torso of the patient; and marking the area of contact between the projecting  
5 line and the torso as a safe zone for performing pleural decompression.

According to another aspect of the invention, there is provided a base which, in use, receives an obturator assembly for establishing and maintaining an opening to an anatomical space of a body, the base comprising a plate for placement on a patient external  
10 and adjacent the anatomical space, the plate having an aperture configured to receive the obturator assembly.

According to another aspect of the invention, there is provided a base which, in use, receives an obturator assembly for the treatment of simple and/or tension pneumothorax,  
15 comprising a plate for placement on a patient above an intercostal space, the plate having an aperture configured to receive the obturator assembly.

Preferably, an underside of the plate is provided with adhesive means for securing the plate to the patient. Preferably, the adhesive means is foam-backed adhesive.  
20

Preferably, the base further comprises an indicator extending from the plate for assisting a user with placement of the plate external and adjacent or above the anatomical or intercostal space.

25 Preferably, the plate further comprises coupling means located about the aperture for receiving a valve assembly operable to seal the aperture in use.

Preferably, the coupling means is configured to receive the valve assembly at an angle oblique to an axis perpendicular to the plane of the plate.  
30

Preferably, the base further comprises side portions extending in opposite directions from

the plate for stabilising the plate from movement when applied to the torso.

Preferably, the base further comprises an electrode embedded in the plate configured for outputting cardiac spatial data to an external monitoring device.

- 5 Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.
- 10 Throughout this specification and the claims which follow, unless the context requires otherwise, the term "fluid" would be understood to include gaseous fluids such as air as well as liquid fluids such as blood and other bodily fluids.

#### Brief description of the drawings

- 15 Further aspects of the present invention and further embodiments of the aspects described in the preceding paragraphs will become apparent from the following description. The invention will now be described, by way of example only, with reference to the accompanying drawings, in which:
- Figure 1 is a photograph showing conventional Needle Thoracostomy (NT) device;
- 20 Figure 2 is a photograph showing a field use of a conventional NT device for treating tension pneumothorax;
- Figures 3A to 3D are photographs showing the positioning of a patient for locating a pleural cavity in accordance with an embodiment of the invention;
- Figure 4A is a rendered view showing an assembled surgical pleural decompression system in accordance with an embodiment of the invention;
- 25 Figure 4B is a rendered partial exploded view showing the system of Figure 4A;
- Figure 4C is a rendered side view showing the system of Figure 4A;
- Figure 4D is a rendered perspective view showing another assembled surgical pleural decompression system in accordance with an embodiment of the invention;
- 30 Figure 4E is a rendered perspective view showing another assembled surgical pleural decompression system in accordance with an embodiment of the invention;

Figure 5A and 5B are rendered perspective views showing bases without sealed caps in accordance with embodiments of the invention;

Figure 6A and 6B are rendered perspective views showing bases with sealed caps in accordance with embodiments of the invention;

5 Figure 7A is a rendered side view showing the base of Figure 5A;

Figure 7B is a rendered bottom perspective view showing the base of Figure 5B;

Figure 8 is a rendered perspective view showing a valve assembly in accordance with an embodiment of the invention;

10 Figures 9A and 9B are rendered top perspective views showing different configurations of a valve locking tab in accordance with an embodiment of the invention;

Figure 10A and 10B are rendered partial sectional plan views showing the valve assembly with docking locks in accordance with an embodiment of the invention;

15 Figure 11 is a rendered partial sectional side view showing the valve assembly of Figure 8;

Figure 12 is a rendered partial sectional side view showing the efflux valve of the valve assembly of Figure 8;

Figure 13A and 13B are rendered perspective sectional views showing the efflux valve of the valve assembly of Figure 8;

20 Figure 14 is a rendered perspective sectional view showing a valve assembly in accordance with another embodiment of the invention;

Figure 15 is a rendered perspective sectional view showing an assembled valve assembly coupled to a base in accordance with another embodiment of the invention;

25 Figure 16 is a rendered perspective sectional view showing a valve assembly having a valve seal in accordance with another embodiment of the invention;

Figure 17 is a rendered perspective sectional view showing an assembled valve assembly having a valve seal coupled to a base in accordance with another embodiment of the invention;

30 Figure 18 is a rendered perspective view showing an obturator assembly in accordance with an embodiment of the invention;

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Figure 19 is a rendered perspective view showing an obturator assembly in accordance with another embodiment of the invention;

5 Figure 20 is a rendered side view of the obturator assembly of Figure 18 showing an inner stylet in a retracted configuration in accordance with an embodiment of the invention;

Figure 21 is a rendered side view of the obturator assembly of Figure 18 showing the inner stylet in a transition between the retracted configuration and an extended configuration in accordance with an embodiment of the invention;

10 Figure 22 is a rendered side view of the obturator assembly of Figure 18 showing the inner stylet in a fully extended configuration in accordance with an embodiment of the invention;

Figures 23A and 23B are rendered close up perspective views showing the handle of the obturator assembly of Figure 19;

15 Figure 24 is a rendered close up perspective view of a cutting portion of the obturator assembly of Figure 19 showing a cannula release mechanism in accordance with an embodiment of the invention;

Figure 25 is a rendered close up perspective view showing the cannula release mechanism of Figure 24;

20 Figure 26 is a rendered close-up side view showing a cannula mounted proximate the cutting portion of the obturator assembly in accordance with an embodiment of the invention;

Figure 27 is a series of close up schematic sectional side views showing an inner stylet in a retracted configuration and a fully extended configuration in accordance with an embodiment of the invention;

25 Figure 28 is a rendered perspective view showing a cannula in accordance with an embodiment of the present invention;

Figure 29 is a rendered front view showing the cannula of Figure 28 in a retracted configuration in accordance with an embodiment of the invention;

30 Figure 30 is a rendered front view showing the cannula of Figure 28 in an extended configuration in accordance with an embodiment of the invention;

Figure 31 is a rendered perspective view showing a cannula in accordance with

another embodiment of the present invention;

Figure 32 is a rendered close up front view of the cannula of Figure 31 showing an enlarged helical flange;

5 Figure 33 is a rendered close up front view of a cannula showing a helical flange in accordance with another embodiment of the present invention;

Figures 34A to 34G are schematic illustrations showing the steps of deploying a surgical pleural decompression system according to an embodiment of the invention;

10 Figure 35 is a schematic illustration showing a base according to an embodiment of the invention for deployment external and adjacent a patient's trachea;

Figure 36 is a schematic illustration showing a valve assembly according to another embodiment of the invention coupled to the base of Figure 35;

15 Figure 37 is a schematic illustration showing a ventilation port according to another embodiment of the invention coupled to a valve assembly and a base deployed external and adjacent a patient's trachea;

Figures 38A to 38E are schematic illustrations showing the steps of deploying a surgical system according to another embodiment of the invention for use in cricothyroidotomy;

20 Figures 39A to 39E are schematic illustrations showing the steps of deploying a surgical system according to a preferred embodiment of the invention for use in cricothyroidotomy;

Figures 40A to 40E are schematic illustrations showing the steps of deploying a surgical system according to a preferred embodiment of the invention for use in treating obstructed urethra;

25 Figure 41 is a perspective schematic illustration showing a surgical system according to an embodiment of the invention for use in treating obstructed urethra;

Figure 42 is a rendered perspective view showing a valve assembly in accordance with another embodiment of the invention;

Figure 43 is a rendered side view of the valve assembly of Figure 42;

30 Figure 44 is a rendered sectional top view of the valve assembly of Figure 42 showing locking members in a closed state;

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Figure 45 is a rendered sectional top view of the valve assembly of Figure 42 showing locking members in an opened state;  
Figure 46 is a rendered perspective view of a locking member of Figure 42;  
Figure 47 is a rendered perspective view of a telescopic cannula in accordance with an embodiment of the invention showing the cannula in a retracted condition;  
5 Figure 48 is a rendered perspective view of the telescopic cannula of Figure 47 showing the cannula in a partially extended state;  
Figure 49 is a rendered perspective view of the telescopic cannula of Figure 47 showing the cannula in a fully extended state;  
10 Figure 50 is a rendered perspective view showing an obturator assembly in accordance with another embodiment of the invention;  
Figure 51 show a series of rendered side views of the obturator assembly of Figure 50 in use with a telescopic cannula; and  
Figures 52A to 52G are schematic illustrations showing the steps of deploying a  
15 surgical pleural decompression system according to another embodiment of the invention.

#### Detailed description

20 Figures 1 and 2 show a conventional Needle Thoracostomy (NT) device and its use in the field for treating tension pneumothorax. It can be seen that the conventional NT device comprises a fixed-length needle and catheter which is administered directly over a patient above an intercostal space for relieving pleural fluid for treating tension pneumothorax.

Preferred embodiments of the present invention seek to provide easy to use surgical pleural  
25 decompression devices and systems for the treatment of simple and tension pneumothorax despite inter-population differences in chest wall thickness. Also described herein, with reference to Figures 3A to 3D, is a new method of effectively locating the pleural cavity of a patient. Conventional methods for locating the pleural cavity involve identifying the fifth intercostal space by locating proxy markers such as nipple. However inherent  
30 variability of the nipple's position on a chest wall renders this an unreliable marker. It is understood that correctly locating the appropriate intercostal space on a patient's torso can

be a challenging task with 40% of medical practitioners unsuccessful in a stress-free environment. This failure rate is estimated to be even higher for combat medics working under pressure as they must also deal with obstructing articles such as body armour and clothing articles on the patient.

5

Figures 3A to 3D illustrate a new method, deemed as the mid-arm point method, of locating a safe zone for administering pleural decompression of a pleural cavity between the fourth to sixth intercostal spaces. It has been found during a study that researchers using the method were able to locate the safe zone 100% of the time. The method involves the following steps. First, the patient is positioned supine with the elbow flexed 90 degrees and forearm mid prone. Second, locate the mid-arm point of an upper arm between the olecranon and the acromion. Third, project a line, perpendicular to the upper arm, from the mid-arm point towards the torso of the patient with a tape ruler. Finally, mark the area of contact between the projecting line and the torso as a safe zone for administering pleural decompression. This new method of locating the safe zone is not only suitable for administering pleural decompression according to embodiments of the present invention, it is equally suitable for use with conventional NT devices for performing pleural decompression.

Referring now to Figures 4A to 4E, preferred embodiments of a surgical pleural decompression system 1 includes a base 100 mountable external and adjacent or above an intercostal space of a patient, a valve assembly 200 attachable to the base 100, the base 100 and the valve assembly 200 defines a guided passage for receiving an obturator assembly 300 configured to reach a pleural cavity by cutting through the chest wall tissues of the patient, and a cannula 400 detachably coupled to the obturator assembly 300 which is deployed as the obturator assembly 300 cuts through to the pleural cavity and creates a path for fluid extraction between the pleural cavity and the valve assembly 200. Each of the components will now be described in detail and methods of using the system will also be provided.

30

Figures 5A to 7B show various embodiments and views of the base 100 for mounting

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above the intercostal space of the patient. The base 100 guides a user in locating the appropriate intercostal space with labelled indicators 108, and mounting the base 100 on the patient effectively marks the identified intercostal space. The base 100 also provides structural support for the pleural decompression assembly 1, and assists with guiding the  
5 insertion of the obturator assembly 300. With reference to Figures 5A, 6A and 7A, the base 100 comprises a plate 102 for mounting on the patient. In some configurations, the plate can be of a resilient material or a plastically deformable material to conform to the body contours of the patient. The plate 102 has an aperture 104 sized for receiving the obturator assembly 300 and the cannula 400. It is to be understood that the aperture 104  
10 can also be sized for receiving conventional obturators, catheters and/or needles according to the NT method. An underside of the plate 102 is provided with adhesives 106, such as foamed adhesives, for securing the plate 102 to the patient after a protective layer 107 is removed prior to use. One would appreciate that any suitable adhesive for mounting the plate 102 to the patient can be used. The base 100 has one or more indicators in the form  
15 of rib alignment labels 108 to assist with positioning the aperture 104 of the base 100 for receiving the obturator assembly 300 between ribs of the patient. The rib alignment labels 108 can extend in opposite directions of the base 100 as shown in the Figures.

The base 100 is provided with a docking or coupling means 110 in the form of a threaded  
20 rim located about the aperture 104 for receiving the valve assembly 200. The rim is supported above a wall 111 of varying height such that a plane of the rim 110 is inclined relative to an axis perpendicular to the plane of the plate 102 as shown in the Figures. It is to be appreciated that while a thread rim is described for coupling with the valve assembly 200, any other suitable docking or coupling means 110 can be used, with non-limiting  
25 examples including interference fit coupling and interlocking clips for "push and click" coupling. In one configuration, the aperture 104 is also similarly angled so that obturator access occurs at an appropriate angle of entry between rib interspaces. The inclined angle of the rim 110 and/or the aperture 104 facilitates access of the pleural cavity while reducing the likelihood of damage to the intercostal neuromuscular bundle.

30

Side portions 120 may be provided extending in opposite directions from the plate 102 for



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stabilising the plate 102 from movement when applied to the torso of the patient. In one configuration, the side portions 120 and the plate 102 form a dumbbell shape for increased surface area of contact so as to prevent lateral displacement when the base 100 is mounted to the patient. The base 100 can also be provided with one or more electrodes 122  
5 embedded in the plate 102 and/or the side portions 120 for outputting data such as information relating to cardiac spatial data to an external monitoring device (not shown). With reference to Figure 5A, the electrodes 122 positioned as shown and mounted to the patient in accordance to the mid-arm point method for locating the intercostal space advantageously provides spatial cardiac monitoring in three orthogonal directions.

10

The base 100 can also be provided with an aperture cap 112 for sealing the space between the aperture 104, the wall 111 and the rim 110 as shown in Figure 6A. The cap 112 can be vacuum fitted to create a sterile environment below the sealed space and to help ensure that asepsis is maintained after mounting the base 100 to the patient. In some embodiments,  
15 the cap is made from tin foil. The aperture cap 112 may also act as a cognitive aid to promote aseptic technique by an operator as the cap 112 will need to be removed or penetrated for access to the valve assembly 200 and the obturator assembly 300. Figures 5B, 6B and 7B show another embodiment the base 100. The aperture 104 can be further provided with a housing 116 enclosing the aperture 104 to define a passage 117 as shown  
20 in Figure 5B for smooth obturator access and withdrawal. The housing 116 may also be provided with O-ring 118 for sealing with the valve assembly 200. The housing 116 also promotes asepsis by preventing environmental contamination to the space between the aperture 104, the wall 111 and the rim 110. Ventral arrow markers 114 can be provided on the aperture cap 112 and/or on the aperture valve 116 to indicate the correct orientation of  
25 the base 100 for mounting on the patient.

While the base 100 is described to be used with the pleural decompression system 1, it is to be understood that the base 100 is equally suitable for use as a standalone device for marking the intercostal position on the patient and providing stabilising structure suitable  
30 for use with conventional pleural decompression techniques as the aperture 104 can be configured and sized to receive conventional obturators, catheters, needles and NT tools.

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Figures 8 to 17 show various embodiments and views of the valve assembly 200. The valve assembly 200 comprises a valve housing 202 having a first end 203 configured for use as an access port for receiving the obturator assembly 300 and for coupling to a fluid  
5 extraction device (not shown) once the cannula 400 has been deployed, a second end 204 configured for coupling to the base 100 and placement external and above or adjacent the intercostal space, and a passage through a valve 220 for receiving the obturator assembly 300 and the cannula 400. In one configuration the housing 202 made from a transparent material so that the contents of the valve assembly 200 and any fluid extracted from the  
10 pleural cavity into the valve assembly 200 can be easily inspected by a user. The second end 204 of the valve assembly 300 is provided with one or more docking tabs 206 for coupling to the docking rim 110 of the base 100. In one configuration, docking the valve assembly 200 is performed by pushing and clicking the docking tabs 206 within complementary recesses of the docking rim 110. The valve assembly 200 can be  
15 subsequently removed from the base 100 by rotating the valve assembly 200 with respect to the base 100 so that the docking tabs 206 moves through the threaded rim 110 and becomes uncoupled.

At or about the second end 204 of the valve assembly 200, there is provided inside the  
20 housing 202 a spring-loaded locking mechanism 210 for locking a corresponding locking portion 412, or a groove, of the cannula 400 by way of a 'push and click' action. The locking mechanism 210 comprises three centrally directed concave shaped locking members which forms an aperture corresponding to the shape of and dimension of the locking portion 412 of the cannula 400. Each of the locking members 212 are biased at  
25 one end with a leaf spring 214 to coerce the locking members 212 towards the middle to form the locking aperture as shown in Figures 10B and 15. The locking members 212 can be pushed apart with force against the leaf springs 214, for example during the insertion of the obturator assembly 300, to temporarily allow passage of the cannula body 420 with larger diameters as shown in Figures 10A and 15.

30

The valve housing 202 is provided with the valve 220 having a central passage 221 to

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control fluid flow from the pleural cavity of the patient. The valve 220 has a port door 222 for sealing an opening of the passage at a distal end of the valve 220; a flow indicator 224 in the form of a ring surrounding the valve 220 to indicate the presence of any fluid, such as gas or pleural fluids, extracted from the pleural cavity into the valve 220; a valve spring  
5 226 to bias the flow indicator 224 in a direction towards the distal end of the valve 220; a O-ring 228 for sealing the connection between the valve 220 and the valve housing 202. In some embodiments, the port door 222 is in the form of a cork held by way of a hinge as shown in Figure 14, and can be opened by way of inserting the obturator assembly 300 and the cannula 400 as shown in Figure 15. In another embodiment, as seen in Figure 13A and  
10 13B, the valve 220 is provided with a flex valve 223A at the bottom of the valve 220 and valve flaps 223B around the perimeter of the valve 220 configured to allow one-way movement of fluids from the patient's body to the valve housing 202 in use. In one configuration, the valve 220 is a one-way efflux valve. For efflux valve configurations, the valve can be configured with an operator adjustable valve lock to prevent efflux if  
15 required.

The first end of the valve 203 is provided with a coupler 230 in the form of a locking ring for coupling with a sealing cap 240 which can be connected to external fluid extraction devices (not shown) such as a fluid collection bag. In the configuration as shown in Figure  
20 4B, the cap 240 is coupled to the valve assembly 200 by way of pushing and clicking the cap 240 on to the locking ring coupler 230. Figure 14 shows another embodiment of the sealing cap 240 which greater surface area of the valve assembly 200 is covered by the sealing cap 240.

25 Figure 16 and 17 show an alternative embodiment of the valve assembly 200. The valve assembly 200 can be provided with a removable or penetrable sealing cap 232 which can be pierced by the obturator assembly 300. The sealing cap 232 keeps the valve assembly 200 sterile prior to use. The sealing cap 232 can further be provided with alignment indicator 234 to indicate the directional orientation of the valve assembly 200 for use with  
30 respect to the base 100 and the patient. In some configurations, the valve housing 202 is provided with one or more couplers 250, 252 for coupling with the docking or coupling

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mechanism 110 of the base 100 as shown in Figures 16 and 17.

Figures 42 to 46 show another embodiment of the valve assembly 200. The valve assembly 200 may also be provided with an elastic member 215 in the form of an O-ring or expandable/collapsible band, which is configured to surround and apply a spring bias against the locking members 212A, urging the members 212A together in a closed state, as shown in Figure 44. This provides the effect of allowing multiple locking members 212A to move between the closed state in which the locking members 212A substantially extend toward one another and an open state in which the locking members 212A are pushed back against the elastic member 215. The elastic member 215 advantageously exerts substantially an evenly spread amount of force on each of the locking members 212A, which allows a smoother passage of a cannula 400 through the valve assembly 200. Additionally, the lock members 212A may be configured with a chamfer 212B or a tapered portion as shown in Figure 46 which interfaces with a cannula 400 to help push the locking members 212A apart as the cannula 400 slides through the opening or valve passage 221 of the valve assembly 200 between the locking members 212A. The lock members 212A may also be configured with side protrusions 212C in the form of tabs which are configured to be received within a corresponding slot or channel of the valve assembly 200 to restrict movement of the locking members 212A on a single plane (i.e. to prevent up/down movement of the locking members 212A). As described previously, the locking members 212A are configured to be moveable between an open state in which the locking members 212A are forced away from each other to allow the body of a cannula 400 to pass through, and a biased close state in which the locking members 212A are urged toward each other and form seals against a corresponding groove portion 412 of a cannula to lock the cannula in place; preventing it from being removed independently to the valve assembly 200.

Referring to Figures 18 to 27, the obturator assembly 300 comprises a hollow stem 330 having a cutting portion 324 at a distal end. The cutting portion 324 is provided with a cutting blade 332 for piercing through body tissues to reach the pleural cavity. The cutting blade 332 can be shaped as a chamfered blade as shown in Figures 20 to 22. It can be said

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that the chamfered cutting blade has a conical tip. The obturator assembly 300 further comprises an inner stylet 320 housed within the hollow stem 330, the stylet 320 being configured to be movable relative to the stem 330. The stylet 320 is connected at a proximate end to a handle 310 by way of a spring-loaded coupler, so that when actuated, the handle 310 can move relative to the stylet 330. The stylet 320 is connected to a blunt portion 323 located at a distal end of the stylet 320, the blunt portion 323 comprises a blunt member 329. An intermediate portion 321A, 321B connects the stylet 320 to the blunt portion 323. The blunt portion 323 comprises an extendable shaft housed telescopically within a housing tube 321B of the intermediate portion. A biasing means in the form of a spring 322 is arranged between the stylet 320 and the blunt portion 323 such that the blunt portion 323 is biased to move away from the stylet 320 and extend outwards past the cutting portion 324 of the hollow stem 330 as shown in Figures 20 to 22 and 27.

The relative positions of the blunt portion 323 and the cutting portion 324 of the hollow stem 330 can be locked by way of complementary protrusion and aperture formations. In one configuration as shown in Figures 20 to 22, the blunt portion 323 is configured with one or more protrusions 326 and the cutting portion 324 of the stem 330 is configured with apertures 334 spaced along the longitudinal axis of stem 330. As the blunt portion 323 is moved downward (toward the distal end of the stem 330) by force transmitted through the handle 310, the protrusion 326 of the blunt portion 323 engages with complementary shaped apertures 334 to lock the blunt portion 323 in place by friction. It is to be appreciated that the obturator assembly 300 can be actuated by pushing the handle 310 so that the obturator assembly 300 transforms from a retracted cutting configuration in which the blunt portion 323 is retracted and locked wholly within the stem 330, to an extended configuration in which the blunt portion 323 is locked in an extended position past the cutting portion 324 of the stem 330.

As shown in Figures 23 and 24, the handle 310 is coupled to the stylet 320 by way of a spring 328 connection. The spring 328 biases the handle 310 back towards its original position when force no longer applies on the handle 310. Furthermore, pushing the handle 310 has the effect of unlocking the blunt portion 323 of stylet 320 from its first locked

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position as shown in Figure 21. Alignment indicators 312 can be provided to the handle 310 to assist with alignment of the obturator assembly 300 to the valve assembly 200 prior to insertion. In some configurations, the handle 310 is provided with rubber material for ease of handling and gripping by the operator.

5

The cannula 400 is detachably coupled to the cutting portion 324 of the hollow stem 330 for deploying into the pleural space of the patient as the cutting portion 324 pierces through the chest tissues at the intercostal space. The cannula 400 is sized and dimensioned to be received externally on the cutting portion 324 with a flush fitting to reduce unwanted movement of the cannula 400 prior to and during insertion into the pleural cavity of the patient and for ease of coupling with the obturator assembly 300 as described below. Referring to Figures 24 to 26, the cannula 400 is mounted at the cutting portion 324 and held in place by coupling mechanism 336, 337 in the form of a protruding rim or ridge 336 around the perimeter of the cutting portion 324 and a protrusion 337 configured such that the cannula can be detached from the cutting portion 324 by withdrawing the obturator assembly 300 relative to the cannula 400. At least one protrusion 335 in the form of a ridge located adjacent and/or perpendicular to the cutting blade 332 may be provided to serve the function of a blunt dissector to assist with blunt separation of longitudinal muscle fibres as the obturator assembly 300 cuts through the chest wall tissues, whereby, a clean passage of the obturator assembly 300 is provided. In one configuration, two protrusions 335 are provided perpendicular to the cutting blade 332.

The cannula 400, once deployed, establishes a connection between the pleural space of the patient and the valve assembly 200, and can be used as an access port for insertion of an intercostal catheter or video endoscope after removal of the obturator assembly 300, with the resulting ability to control intra-pleural pressure via air insufflation or venting via the valve and to allow targeted examination and evacuation of the pleural cavity under direct vision, i.e. pleuroscopy/thoracoscopy.

30 Referring to Figures 28 to 30, the cannula is a tube having a proximate end 410 and a distal end 430 for establishing a path between a pleural cavity and the valve assembly 200 for

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pleural fluid extraction in use. The cannula comprises a locking portion 412, an anchoring portion 440 and a lengthwise extendable body 420 extending therebetween. The distal end 430 of the cannula 400 is provided with a tapered head, tapering from a reduced diameter to a larger diameter of the cannula body 420. This feature allows the cannula to engage and open the locking mechanism 210 of the valve assembly 200 as the cannula passes through the valve assembly 200. The locking portion 412 is sized and dimensioned to be received and held by the locking mechanism 210 with the larger diameter of the proximate end 410 abutting against the top of the locking members 212 as shown in Figure 15. The anchoring portion 440 can be configured to be in the form of a helical or spiral flange/screw for anchoring the cannula 400 in the chest wall as shown in Figures 34D to 34F. The anchoring portion 440 is made from a resilient material such as rubber/silicone so that it can fit through the valve passage 221 and locking mechanism 210 of the valve assembly 200 and the aperture 104 of the base 100, but also retain its flanged shape for anchoring in the chest wall once the cannula enters the thoracic cavity. In embodiments where the anchoring portion 440 is a helical flange, the flange would be operable between an anchoring configuration in which the flange is collapsed in the longitudinal direction, and an extraction configuration in which the flange is extended in the longitudinal direction. In one configuration, the anchoring portion 440 is made from a sterile inert rubber material. The anchoring portion 440 which is part of the cannula assembly (Figure 31) can be removed by rotating counter-clockwise (unscrewing) and pulling the cannula (attached to the valve assembly 200) from its anchored position in the chest wall. Figures 31 to 33 show different embodiments of the anchoring portion 440, including an anchoring portion 440 having an elongated helical flange and an anchoring portion 440 with a disc-like configuration.

25

The cannula body 420 is extendable lengthwise along its longitudinal length as shown in Figures 29 and 30. In one embodiment, a coiled spring 422 is mounted around the cannula body 420 to provide a bias around the body to move towards an extended configuration. The cannula 400 is thus advantageously configured to have a minimum length of about 4 cm and a maximum length of about 8.5 cm. In another embodiment, the cannula 400 is configured to have a minimum length of about 4 cm and a maximum length of about 9 cm.

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This feature allows the pleural decompression system 1 to establish a path between the pleural cavity and the valve assembly 200 for pleural fluid extraction despite inter-population differences in chest wall thickness. While the extendable body is described to be configured with a coiled spring 422, other suitable configurations may also be used, with non-limiting examples including telescopically walled cannula bodies. It is to be appreciated that owing to the extendable nature of the cannula body 420, the cannula 400 can be configured with a number of different minimum and maximum lengths without departing from the spirit of the invention.

10 In another embodiment, the cannula 400 can be configured with a telescopic body 420A as seen in Figures 47 to 49. The telescopic body 420A may be configured to house a number of sections or stages 421 such that the body 420A is configurable between a retracted, compact, state as seen in Figure 46 in which all the telescopic sections 421 are retracted within the body 420A, a partially extended state in which one or some of the sections 421 are extended longitudinally from the body 420A as seen in Figure 48, and a fully extended state in which all sections 421 are extended from the body 420A as seen in Figure 49. The top of the cannula 400 may likewise be provided with a groove 412 for coupling with the locking members 212 of the valve assembly 200. In one embodiment, the cannula may also be provided with a tapered portion 413 to allow smooth locking transition between the cannula 400 and the valve assembly 200. The bottom-most cannula section 421 can also be provided with one or more pairs of apertures, also known as "Murphy Eyes" to function as side fluid vents to allow air/fluid to escape. The bottom-most cannula section 421 is also configured to be extended first by an obturator assembly 300 when in use and is accordingly provided with a seat or step 421B for catching on to the protruding ridge 336 of the obturator assembly 300. Each cannula section 421 is further configured such that each section 421, once extended to its full individual sectional length, is locked in place to prevent self-collapse post insertion. In one configuration, the top of each section 421 is provided with a groove portion 424 which locks with a bottom wall of the telescopic body 421A. Radio opaque markings may be provided at the bottom tip of the cannula 400 to help operators determine the extent in which the cannula 400 has been inserted into the body cavity.



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Referring to Figures 50 and 51, the process by which the cannula 400 with a telescopic body 420A is deployed by an obturator assembly 300 is illustrated. Firstly, cannula is inserted at the bottom end of the obturator assembly 300 and inserted through the valve assembly 200 and base 100. The cannula 400, together with the obturator assembly 300, passes through the valve assembly 200 and the cannula locks to the valve assembly 200 when the locking members 212 are coupled to the groove 412 of the cannula 400. The protruding ridge 336 of the obturator assembly 300 pushes against the seat 421B of the bottom-most cannula section 421 such that the cannula section 421 extends outwardly when the obturator assembly 300 is inserted/pushed further through the valve assembly 200 and the base 100. The telescopic body 420A can be fully extended in this manner as the obturator is pushed through the valve assembly 200. The cannula 400 with the telescopic body 420A will remain extended when the obturator assembly 300 is subsequently removed from the valve assembly 200. It is to be understood that while a three-staged telescopic cannula is shown in the Figures, preferred embodiments of the invention may have any suitable number of telescopic sections/stages.

Referring specifically to Figures 24 and 26, the protruding ridge 336 of the cutting portion 324 and/or the edges of the cannula anchoring portion 440 may be provide with radioactive strips or markers (see highlighted portions) to help the medical operator locate the relative positions the obturator assembly 300 and the cannula 400 with an x-ray device or similar during use.

Referring to Figures 34A to 34G, and 52A to 52G, a method of using the pleural decompression system 1 as described above for the treatment of tension pneumothorax is also provided. The method generally includes the following steps to be performed on the patient by a medical practitioner either in a clinical or hospital setting or during field use. The appropriate intercostal space should be identified using the mid-arm point method as described previously to locate a safe zone for performing pleural decompression on the patient. The base 100 is affixed on a patient above or adjacent the intercostal space of the pleural cavity by removing the protective peel 107 and mounting the adhesive 106 to the

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patient, while observing positional alignment using the rib alignment indicator 108 and orientation indicator 114, if available. Optionally, cardiac monitoring devices may be attached to the electrodes 122 to retrieve physical data from the patient. Remove the aperture cap 112 of the base 100 to expose the aperture 104, if available. Coupling the  
5 valve assembly 200 to the base 100 by pushing and clicking the valve assembly 200 into position, observing the alignment indicators if available.

Cutting through muscular tissues of the chest into the thoracic and pleural cavities with the cutting portion 324 of the obturator assembly 300 by inserting the obturator assembly 300  
10 through the passage 221 of the valve assembly 200 and the plate aperture 104 (while observing any alignment indicators where available), and pushing the handle 310 of the obturator assembly 300 so that the cutting portion 324 cuts through the tissues 20. The blunt portion 323 of the obturator assembly 300 automatically extends past the cutting portion 324 through the pleural cavity to abut a lung portion with a loss of cutting pressure  
15 and locks the blunt portion 323 in the extended configuration relative to the cutting portion 324 to prevent visceral organ injury. The cannula 400 is then deployed into the pleural cavity 30 of the patient from the obturator assembly 300 by securing the locking portion 412 of the cannula 400 to the locking mechanism 210 of the valve assembly 200. It is to be appreciated that this step is done automatically by pushing the obturator assembly 300  
20 through the valve assembly 200, as the cannula 400 is moving through the valve assembly 200. The anchoring portion 430 of the cannula 400 is pushed through the tissues along with the cutting portion 324 of the obturator assembly 300 and anchors to the chest wall 20 as shown in Figure 34D. For cannula 400 with a telescopic body 420A, different telescopic sections 421 will extend from the cannula 400 through to the pleural cavity 30  
25 with the bottom-most section 421 being extended by the insertion movement of the obturator assembly 300 first. Each telescopic section 421 stays extended and cannot be compressed as it is locked to the previous telescopic section 421 or telescopic body 420A as the obturator assembly 300 is removed. It is to be understood that due to self-locking configurations of the telescopic sections 421, an anchoring flange may not be required for  
30 use with the telescopic cannula.

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Once the incision is complete, the obturator assembly 300 is removed by withdrawing the obturator assembly 300 from the valve assembly 200. Withdrawing the obturator assembly 300 automatically detaches the cannula 400 from the cutting portion 324 so that the lengthwise extendable cannula body 420 and distal portion 430 remains inside the chest  
5 tissues as shown in Figure 34E, thereby facilitating a path for pleural fluid extraction into the valve assembly 200. An external fluid extracting device can then be attached to the valve assembly 200 to extract fluid from the pleural cavity. The transparent housing 202 of the valve assembly 200 allows the medical practitioner to readily see the properties of the fluid being extracted. The flow indicator 224 is also useful in helping the practitioner  
10 determine the presence of extracted gas in the valve assembly 200.

Although the steps described above are provided in a specific order, it can be performed in any variation of this order and additional steps may be executed between the steps described above.

15

While the surgical system 1 has been described to be used deployed above or adjacent the intercostal space for pleural decompression in the treatment of simple and tension pneumothorax, it is to be understood that substantially the same surgical system 1 is also suitable, with little or no modifications required, for use in other surgical applications to  
20 establishing and maintaining a percutaneous cannula to an anatomical space (for example a body cavity) to permit controlled passage of fluids between the anatomical space and the valve and the external environment, with non-limiting examples including:

- access to the trachea via cricothyroid membrane or sternal notch (for the treatment of emergency cricothyroidotomy, that is for emergency access to a patient's trachea  
25 to ventilate the lungs in the event of inability in accessing the trachea through the mouth or nasal passages);
- suprapubic access to the bladder in patients in acute urinary retention (for the treatment of an obstructed urethra); and
- access to the peritoneum via the abdominal wall and access to the extradural space  
30 via the cranium.

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Referring to Figures 35 to 39, the surgical system 1 can be substantially applied for accessing the trachea 510. In use, the base 100 is placed externally above or adjacent the cricothyroid membrane 500 located between the cricoid cartilage 512 and the thyroid cartilage 504 and deployed substantially as previously described. A suitable strap 130 is attached to the base 100 and looped around the neck of the patient to further secure the base in base. In one embodiment, the strap 130 is fed through apertures of the side portions 120 and tightened with a suitable buckle device. The valve assembly 200 is then coupled to the base 100 as previously described. A ventilator connector or port 260 is provided to be secured to the valve assembly 200 (for example with the coupler 230) for connection with a ventilator. This allows the patient to breathe while the surgical system 1 is deployed. In another embodiment, the valve assembly 200 is provided with a side access connector or port 250 for connection with a ventilator (not shown). The connector or port may be 15 mm in diameter. The obturator assembly 300 and the cannula 400 are then deployed substantially as previously described to provide access to the trachea 510 of the patient, with the anchoring portion 440 of the cannula 400 anchored to an anatomical part in the form of the cricothyroid membrane 500. The obturator assembly 300 can be removed substantially as previously described to leave the cannula 400 providing a conduit between the trachea 510 and the valve assembly 200. The valve assembly 200 and the cannula 400 can be subsequently removed substantially as previously described, by rotating the valve anti-clockwise and pulling the units out from the base 100.

Referring to Figures 40 to 41, the surgical system 1 can be substantially applied for access to the bladder 600 of a patient for the treatment of an obstructed urethra. In use, a medical practitioner would deploy the base 100 externally above or adjacent a pubic symphysis area of the patient (see Figures 40A to 40E). The valve assembly 200 can then be coupled and the obturator assembly 300 and cannula 400 deployed substantially as previously described, with the anchoring portion 440 of the cannula 400 anchored to an anatomical part in the form of the upper wall of the bladder 600. A catheter can then be fed through the module into the bladder.

30

Preliminary experimentation results are provided below:

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Experimentations have been conducted on the background that Tension Pneumothorax (tPTX) remains a serious and life threatening condition if left untreated. An investigation into the concerns associated with tPTX treatment and current challenges from utilising  
5 conventional techniques highlight the importance of developing alternative methods. The existing practices may be appealing in its simplicity and time to perform, yet they continued to be scrutinised for their failure rates and limited set of replicable data in support of their effectiveness. Consequently, an error-free device that can simultaneously address and correct the main issues regarding device placement, cannula length and  
10 obturator length, will form the basis for a breakthrough in treating thoracic trauma.

Tests have been conducted in relation to developing an experimental swine model of tPTX to allow SaPD pilot-testing and validation, testing in-vitro prototype SaPD devices against the conventional needle thoracostomy for pleural decompression and to standardize the  
15 insertion technique; and lastly, to verify any modifications required prior to in-vivo deployment where a reduction in the complications associated with pleural decompression is improved along with improved outcomes.

In conclusion, the SaPD device presents a valuable and effective treatment for the pre-hospital  
20 and clinical treatment of tPTX. This concept aimed to target the multiple aspects leading to the failure of pleural decompression. The cannula does not only contain the capacity to withstands the release of high pressured air, but is also rigid enough to prevent kinking without causing injury, an aspect identified to be lacking in current therapies. Furthermore, the obturator component involving the deployment of the blunt tip was created to reduce the risks associated with blind  
25 insertion of tPTX treatments. With the growing numbers of trauma incidences each year, the appreciation for a device that can fit all patient body types will immensely benefit the trauma management of tPTX.

It will be understood that the invention disclosed and defined in this specification extends  
30 to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

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In the description and drawings of this embodiment, same reference numerals are used as have been used in respect of the first embodiment, to denote and refer to corresponding features.

5

While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example only, and not by way of limitation. It will be apparent to a person skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the  
10 invention. Thus, the present invention should not be limited by any of the above described exemplary embodiments.

## THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A surgical system for use in establishing and maintaining an opening to an anatomical space of a body, the system comprising:
  - 5 an obturator assembly having a cutting portion at a distal end and a cannula, the cannula being detachably coupled to the cutting portion and deployable into the anatomical space of a patient, the cannula comprises a locking portion, and a lengthwise extendable body;
    - 10 a valve assembly comprising a passage for receiving the cannula, a first end for coupling to a fluid extraction device and a second end for placement external and adjacent the anatomical space;
    - a base comprising a plate for placement on a patient external and adjacent the anatomical space, the plate has an aperture configured for receiving the obturator assembly and coupling means located about the aperture for coupling with the valve assembly; and
    - 15 wherein, in use, the locking portion of the cannula is configured to be retained in the valve assembly with the extendable body extended into the anatomical space to facilitate a path for fluid extraction, and wherein the cannula comprises means for retaining the cannula in its extended state.
  
- 20 2. A pleural decompression system for use in the treatment of simple and/or tension pneumothorax, the system comprising:
  - an obturator assembly having a cutting portion at a distal end and a cannula, the cannula being detachably coupled to the cutting portion and deployable into a pleural space of a patient, the cannula comprises a locking portion, and a lengthwise extendable body;
  - 25 a valve assembly comprising a passage for receiving the cannula, a first end for coupling to a fluid extraction device and a second end for placement above an intercostal space;
  - a base comprising a plate for placement on a patient above an intercostal space, the plate has an aperture configured for receiving the obturator assembly and coupling means
  - 30 located about the aperture for coupling with the valve assembly; and
  - wherein, in use, the locking portion of the cannula is configured to be retained in

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the valve assembly with the extendable body extended into the chest wall of the patient to facilitate a path for pleural fluid extraction, and wherein the cannula comprises means for retaining the cannula in its extended state.

- 5 3. A system according to either claim 1 or claim 2, wherein the cannula is configured to have a minimum length of about 4 cm and a maximum length of about 9 cm.
4. A system according to any one of the preceding claims, wherein a coiled spring is mounted around the cannula body to provide a bias around the body to move towards an  
10 extended configuration.
5. A system according to claim 4, wherein the means for retaining the cannula in its extended state comprises an anchoring portion located at a distal end of the cannula.
- 15 6. A system according to claim 5, wherein the anchoring portion is in the form of a helical flange.
7. A system according to claim 6, wherein the helical flange is operable between an anchoring configuration in which the flange is collapsed in the longitudinal direction, and  
20 an extraction configuration in which the flange is extended in the longitudinal direction.
8. A system according to any one of claims 1 to 3, wherein the cannula comprises two or more telescopic sections extendable from the cannula body.
- 25 9. A system according to claim 8, wherein the means for retaining the cannula in its extended state comprises locking means for locking each telescopic section in its extended state when the cannula is in its extended state.
- 30 10. A system according to any one of the preceding claims, wherein the coupling means is configured to receive the valve assembly at an angle inclined to an axis perpendicular to the plane of the plate.



11. A system according to any one of the preceding claims, wherein an underside of the plate is provided with adhesive means for securing the plate to the patient.
- 5 12. A system according to claim 8, wherein the adhesive means is foam-backed adhesive.
13. A system according to any one of the preceding claims, further comprising an indicator extending from the plate for assisting a user with placement of the plate above the  
10 anatomical or intercostal space.
14. A system according to any one of the preceding claims, further comprising side portions extending in opposite directions from the plate for stabilising the plate from movement when secured to the patient.
- 15
15. A system according to any one of claims 12 to 14, further comprising an electrode embedded in the plate configured for outputting physiological data to an external monitoring device.
- 20 16. A system according to any one of the preceding claims, wherein the valve assembly comprises a one-way efflux valve.
17. A system according to any one of the preceding claims, wherein the first end of the valve is configured to receive a cap for coupling with a fluid extracting device.
- 25
18. A system according to any one of the preceding claims, wherein the obturator assembly comprises a hollow stem and the cutting portion being located at the distal end of the stem.
- 30 19. A system according to claim 18, wherein the obturator assembly further comprises a spring-loaded inner stylet housed within the stem and movable relative to the stem, the

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5 stylet having a handle located at a proximate end and a blunt portion located at a distal end of the stem, wherein the obturator assembly is configured to operate between a retracted cutting configuration in which the blunt portion of the stylet is received within the stem to expose the cutting portion and an extended configuration in which the blunt portion extends past the cutting portion.

20. A system according to claim 19, wherein the obturator assembly is configured with locking means to hold the stem and stylet in the cutting and extended configurations.

10 21. A system according to claim 20, wherein the locking means comprises one or more complementary protrusion and aperture formations on the stem and the stylet.

15 22. A system according to either claim 19 or claim 20, wherein the obturator assembly transforms from the cutting configuration to the extended configuration by a user pushing the stylet handle such that the blunt portion extends past the cutting portion and the locking means engages the stylet in the extended configuration.

23. A system according to any one of the preceding claims, wherein the cutting portion comprises a cutting blade having a chamfered tip.

20

24. A method of establishing and maintaining an opening to an anatomical space of a body, the method comprising the steps of:

25 affixing a base comprising a plate on a patient external and adjacent the anatomical space of the patient, the plate having an aperture configured for receiving an obturator assembly and coupling means located about the aperture for coupling with a valve assembly;

coupling the valve assembly to the base, the valve assembly comprising a passage for receiving the cannula and an open end for coupling to a fluid extraction device;

30 cutting through muscular tissues into the anatomical space with a cutting portion of the obturator assembly by inserting the obturator assembly through the valve assembly passage and the plate aperture, and pushing a handle of the obturator assembly so that the

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cutting portion cuts through the tissues, a blunt portion of the obturator assembly automatically extends past the cutting portion with a loss of cutting pressure and locks the blunt portion relative to the cutting portion to prevent visceral organ injury;

5 deploying a cannula into the anatomical space from the obturator assembly by securing a locking portion of the cannula to the valve assembly and removing the obturator assembly, the cannula further comprises a lengthwise extendable body extendable into an anatomical part of the patient to facilitate a path for fluid extraction into the valve assembly, the cannula having means for retaining the cannula in its extended state in use;

10 extracting fluid from the anatomical space by coupling the fluid extraction device to the valve assembly.

25. A method of extracting fluid from a pleural cavity of a patient using a pleural decompression system in the treatment of simple and/or tension pneumothorax, the method comprising the steps of:

15 affixing a base comprising a plate on a patient above an intercostal space of the pleural cavity, the plate having an aperture configured for receiving an obturator assembly and coupling means located about the aperture for coupling with a valve assembly;

coupling the valve assembly to the base, the valve assembly comprising a passage for receiving the cannula and an open end for coupling to a fluid extraction device;

20 cutting through muscular tissues into the pleural cavity with a cutting portion of the obturator assembly by inserting the obturator assembly through the valve assembly passage and the plate aperture, and pushing a handle of the obturator assembly so that the cutting portion cuts through the tissues, a blunt portion of the obturator assembly automatically extends past the cutting portion with a loss of cutting pressure and locks the blunt portion relative to the cutting portion to prevent visceral organ injury;

25 deploying a cannula into the pleural cavity from the obturator assembly by securing a locking portion of the cannula to the valve assembly and removing the obturator assembly, the cannula further comprises a lengthwise extendable body extendable into the chest wall of the patient to facilitate a path for pleural fluid extraction into the valve assembly, the cannula having means for retaining the cannula in an extended state, in use;

30 extracting fluid from the pleural cavity by coupling the fluid extraction device to

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the valve assembly.

26. A method according to claim 25, further comprising the step of:

5 locating a mid-point of an upper arm of a supine-positioned patient between the olecranon and the acromion when the elbow of the patient is flexed to 90 degrees with the patient's forearm in a mid prone position;

projecting a line, perpendicular to the upper arm, from the mid-point of the upper arm across to the torso of the patient; and

10 marking the area of contact between the projecting line and the torso as a safe zone for performing pleural decompression procedures.

27. A method according to any one of claims 24 to 26, wherein the cannula is configured to have a minimum length of about 4 cm and a maximum length of about 9 cm.

15 28. A method according to any one of claims 24 to 27, wherein a coiled spring is mounted around the cannula body to provide a bias around the body to move towards an extended configuration.

29. A system according to any one of claims 24 to 27, wherein the cannula comprises 20 two or more telescopic sections extendable from the cannula body.

30. A base which, in use, receives an obturator assembly for establishing and maintaining an opening to an anatomical space of a body, the base comprising a plate for placement on a patient external and adjacent the anatomical space, the plate having an 25 aperture configured to receive the obturator assembly.

31. A base which, in use, receives an obturator assembly for the treatment of simple and/or tension pneumothorax, comprising a plate for placement on a patient above an intercostal space, the plate having an aperture configured to receive the obturator 30 assembly.

- 35 -

32. A base according to either claim 30 or claim 31, wherein an underside of the plate is provided with adhesive means for securing the plate to the patient.

33. A base according to claim 32, wherein the adhesive means is foam-backed  
5 adhesive.

34. A base according to any one of claims 30 to 33, further comprising an indicator extending from the plate for assisting a user with placement of the plate external and adjacent or above the anatomical or intercostal space.

10

35. A base according to any one of claims 30 to 34, wherein the plate further comprises coupling means located about the aperture for receiving a valve assembly operable to seal the aperture in use.

15 36. A base according to claim 35, wherein the coupling means is configured to receive the valve assembly at an angle inclined to an axis perpendicular to the plane of the plate.

37. A base according to any one of claims 30 to 36, further comprising side portions extending in opposite directions from the plate for stabilising the plate from movement  
20 when applied to the patient.

38. A base according to any one of claims 30 to 37, further comprising an electrode embedded in the plate configured for outputting physiological data to an external monitoring device.

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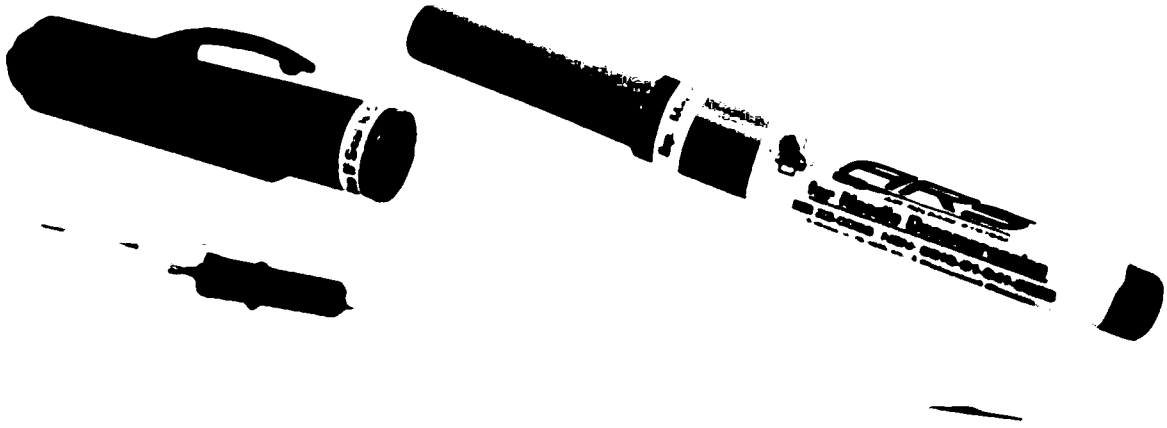


Figure 1



Figure 2

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**Figure 3A**



**Figure 3B**

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**Figure 3C**



**Figure 3D**



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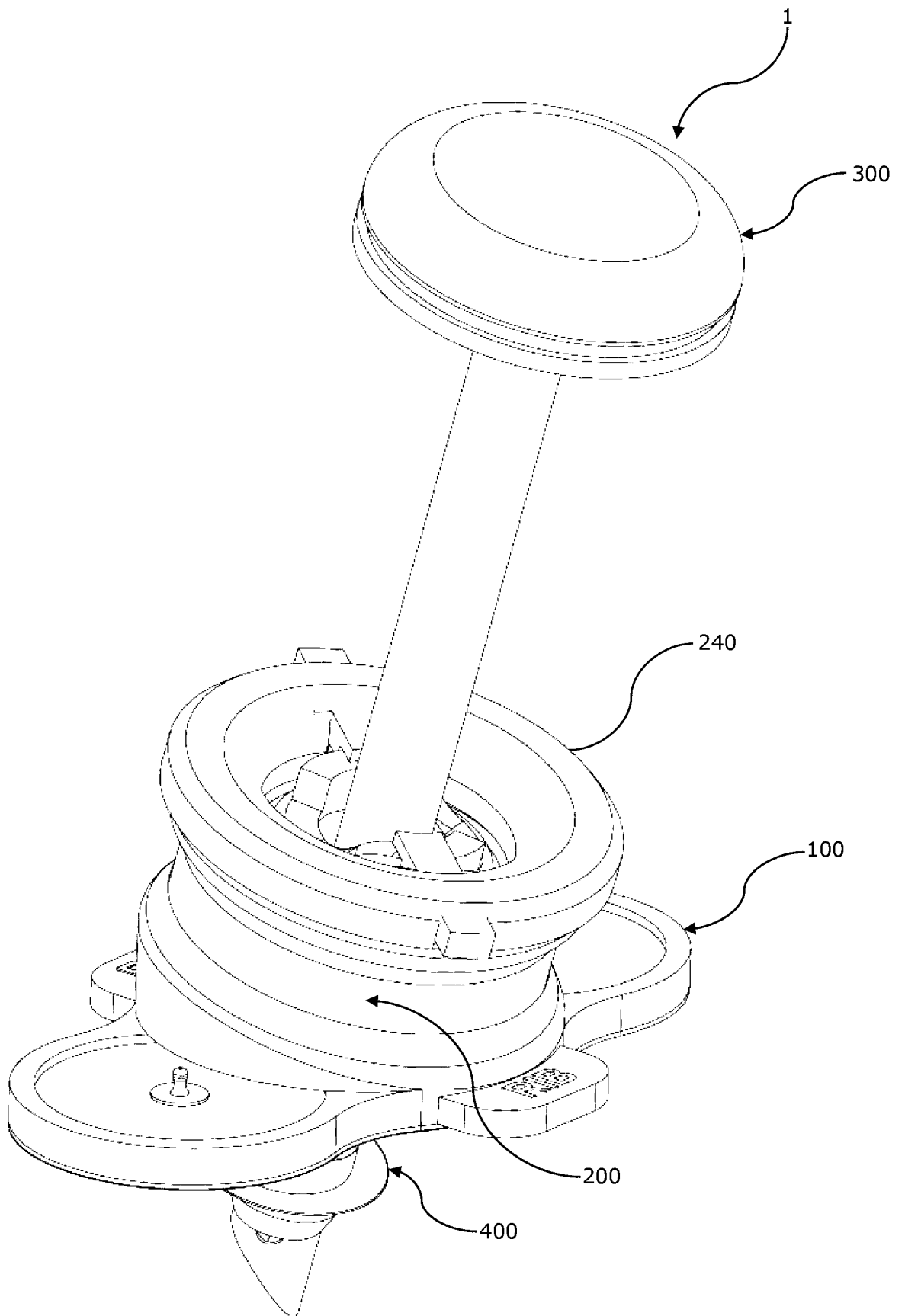


Figure 4A

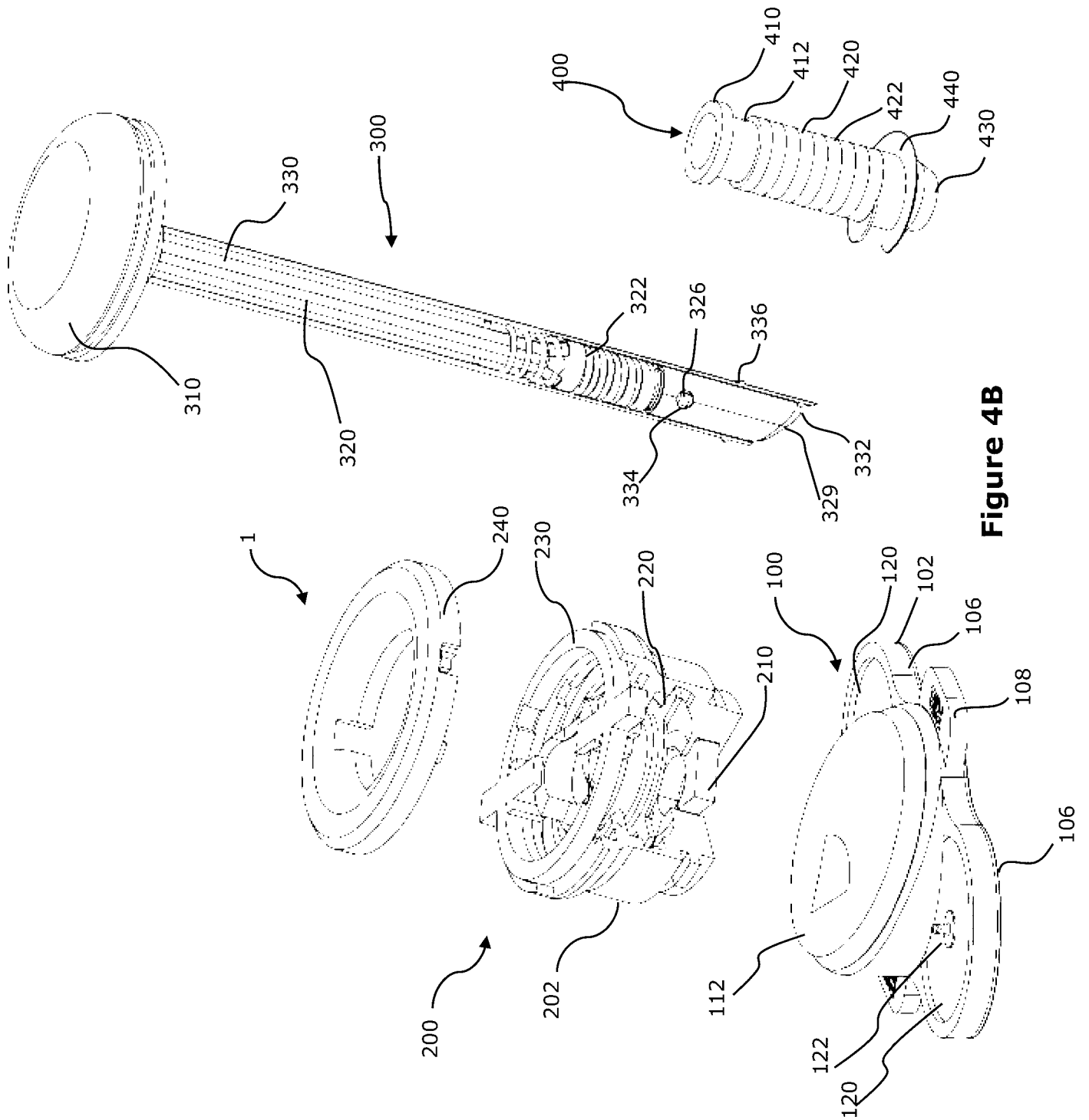


Figure 4B

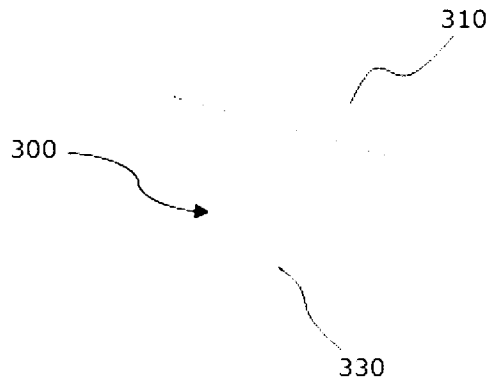


Figure 4C

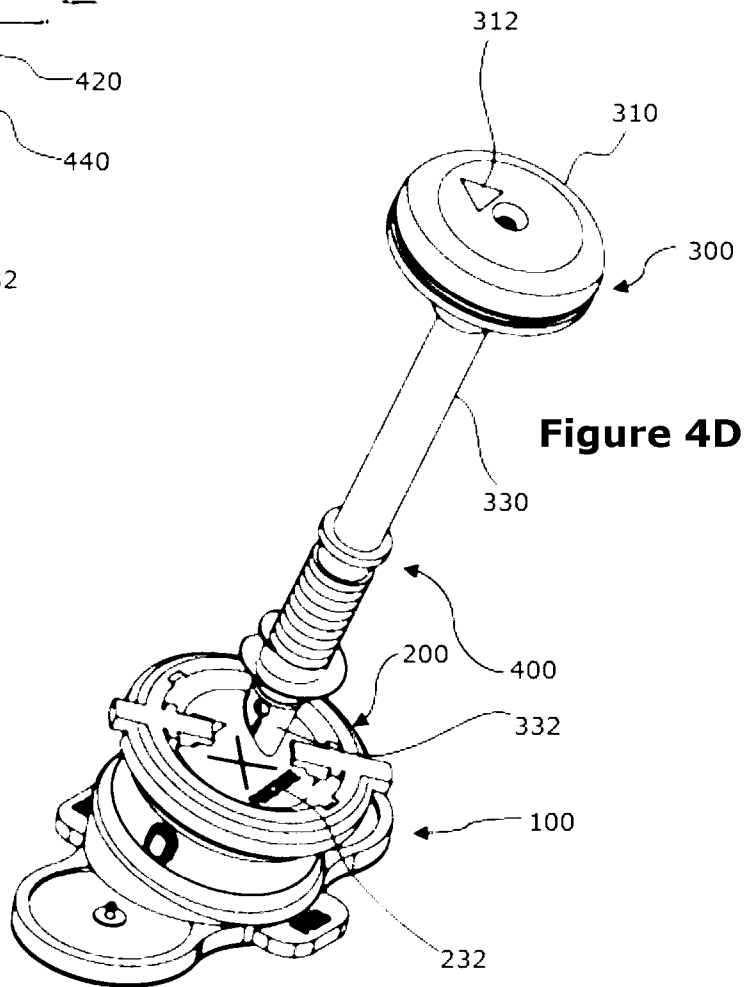
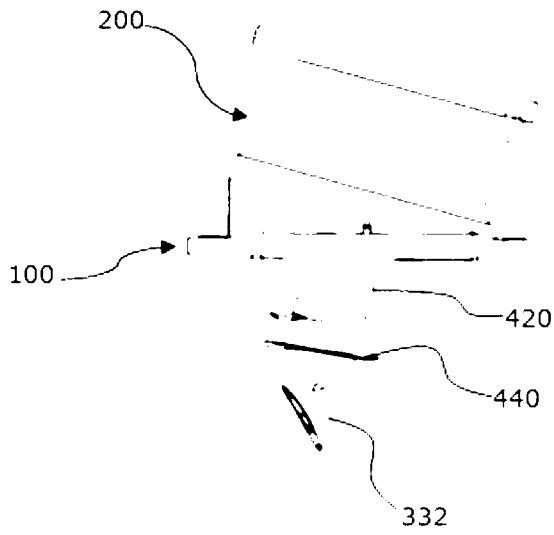


Figure 4D

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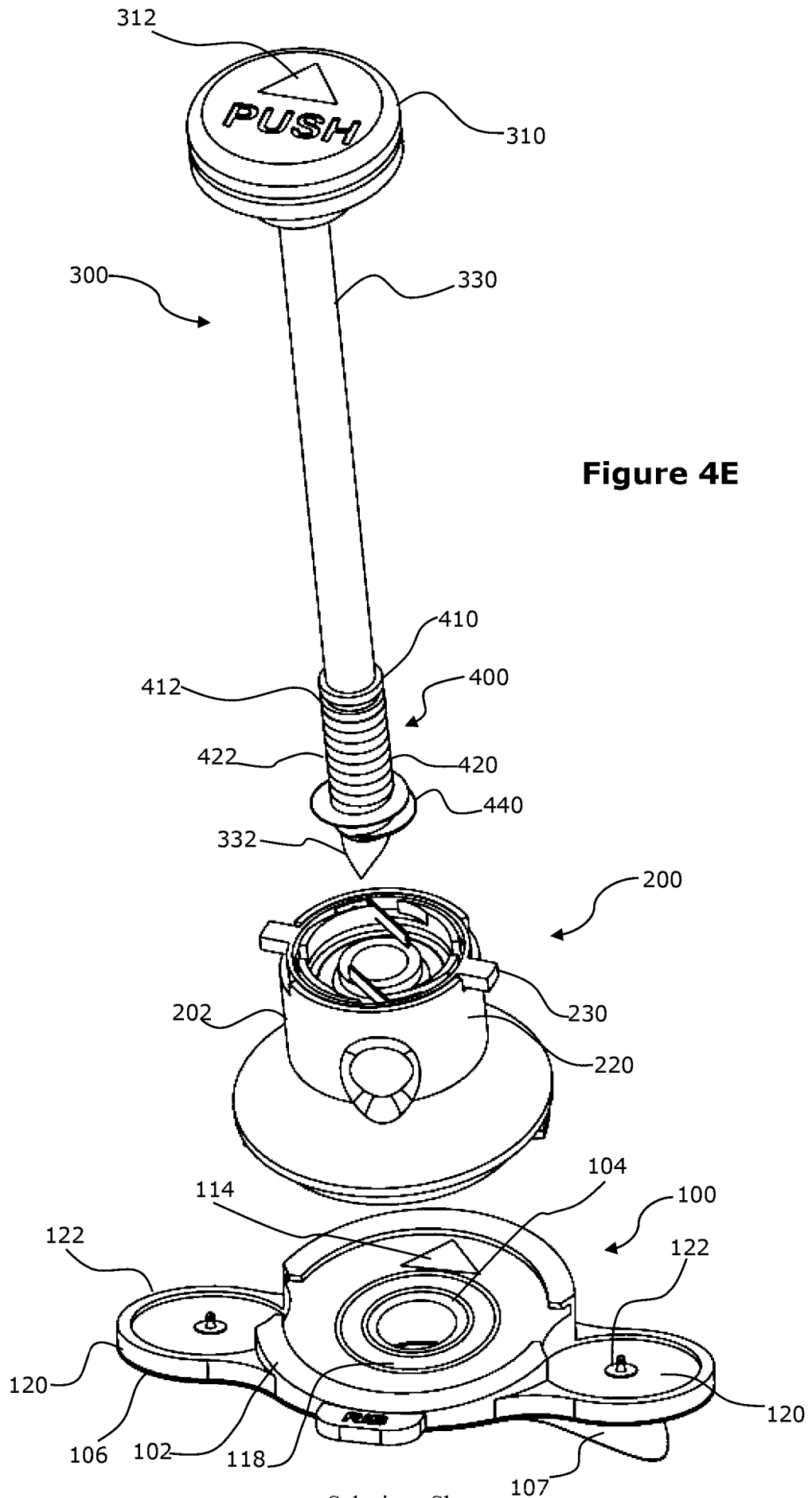


Figure 4E

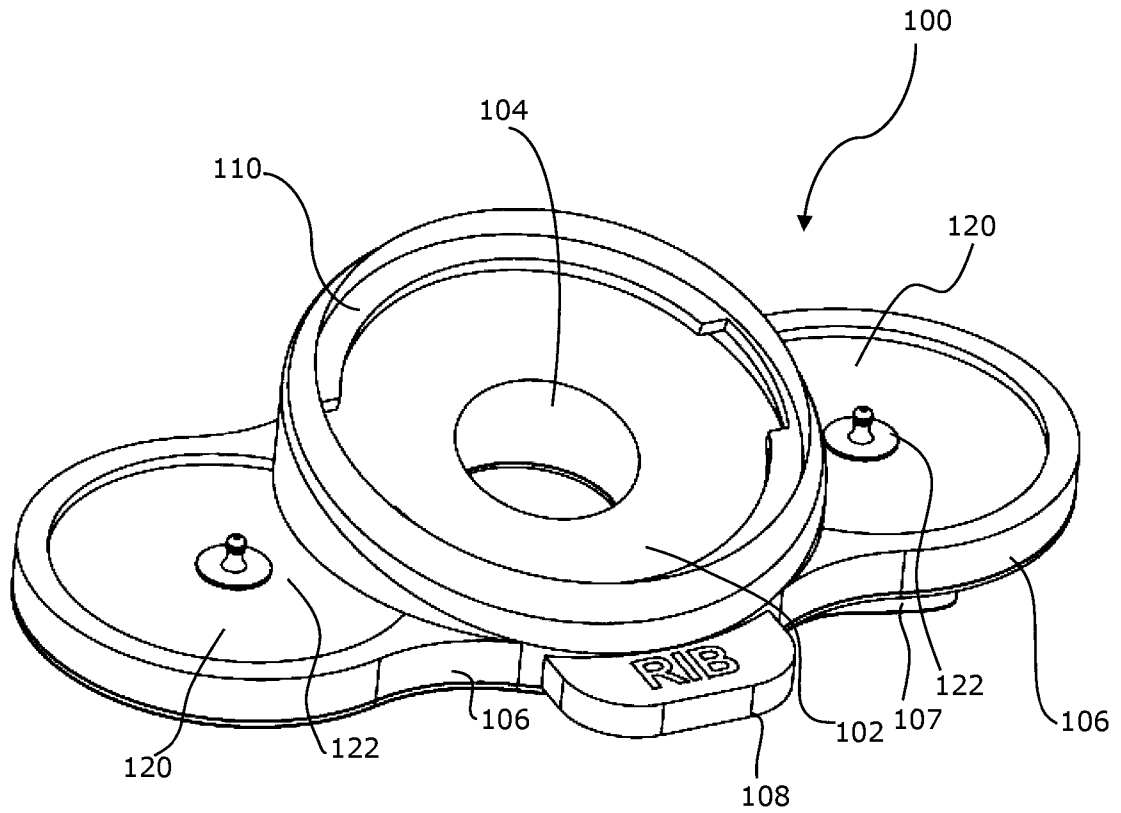


Figure 5A

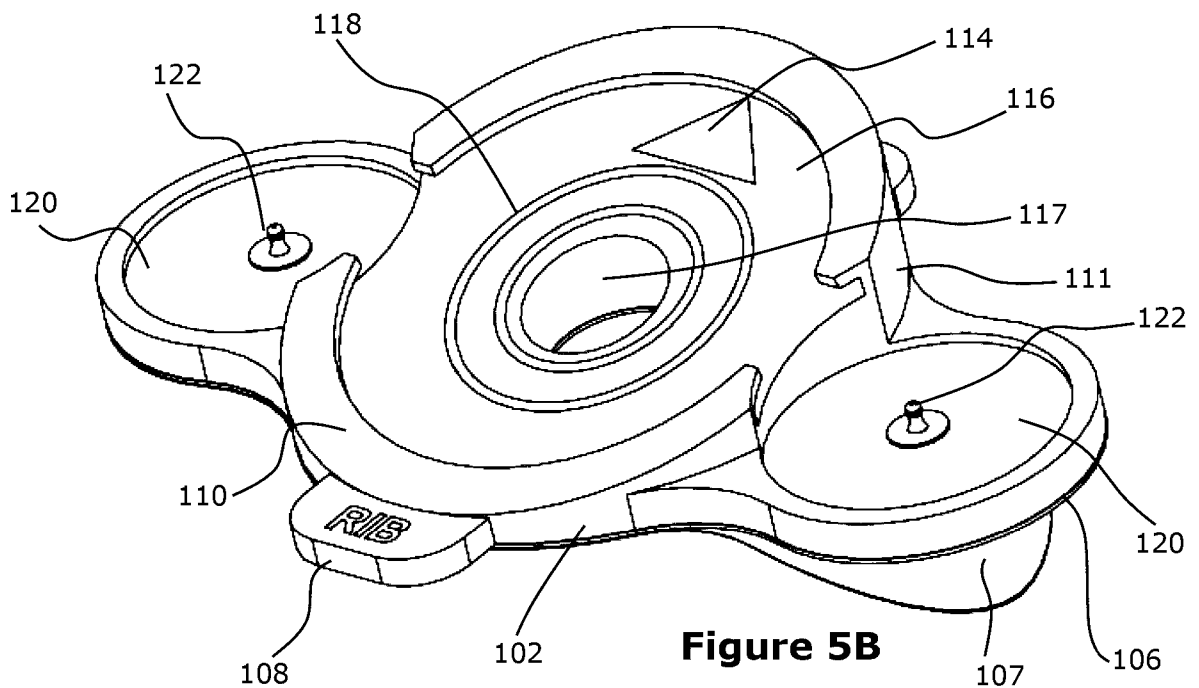


Figure 5B

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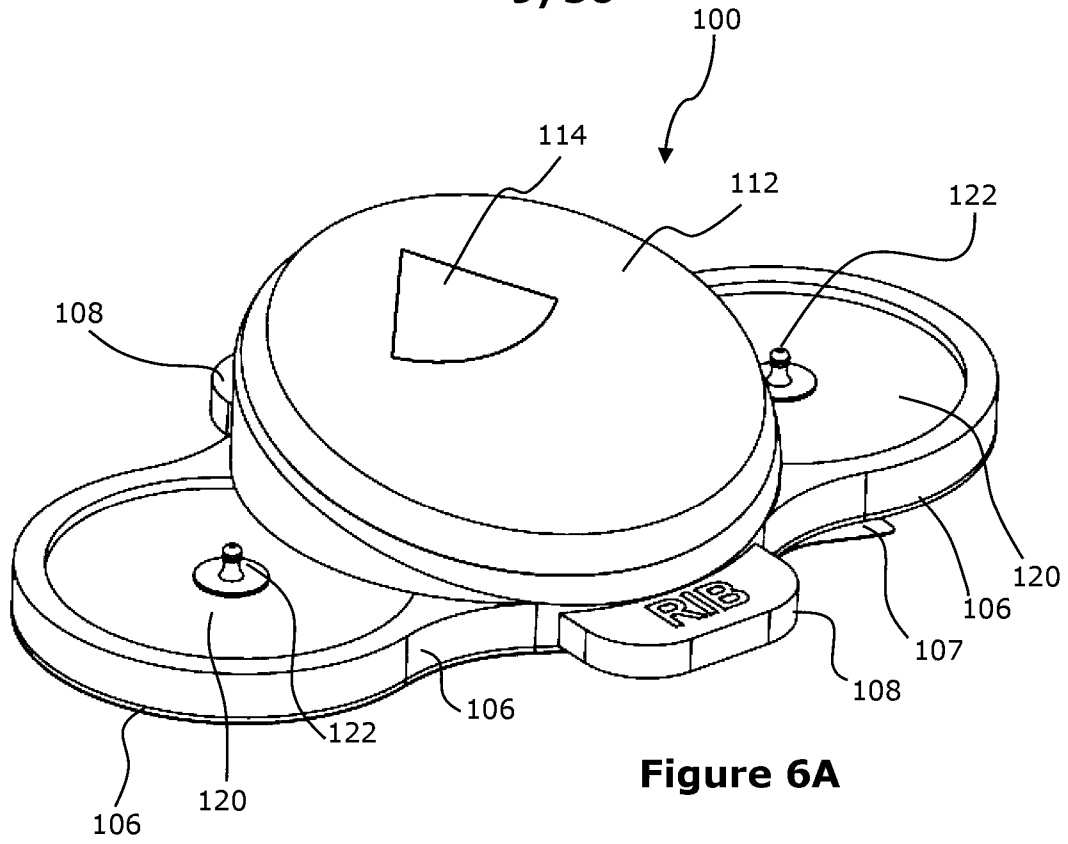


Figure 6A

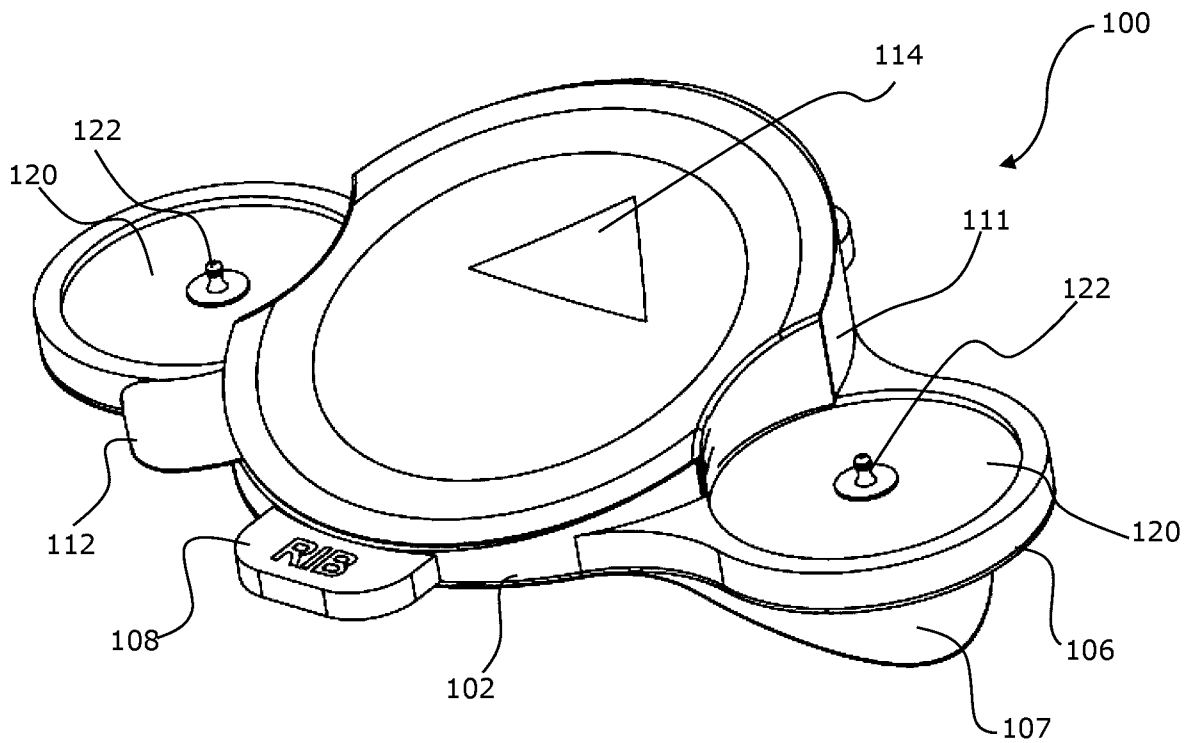


Figure 6B

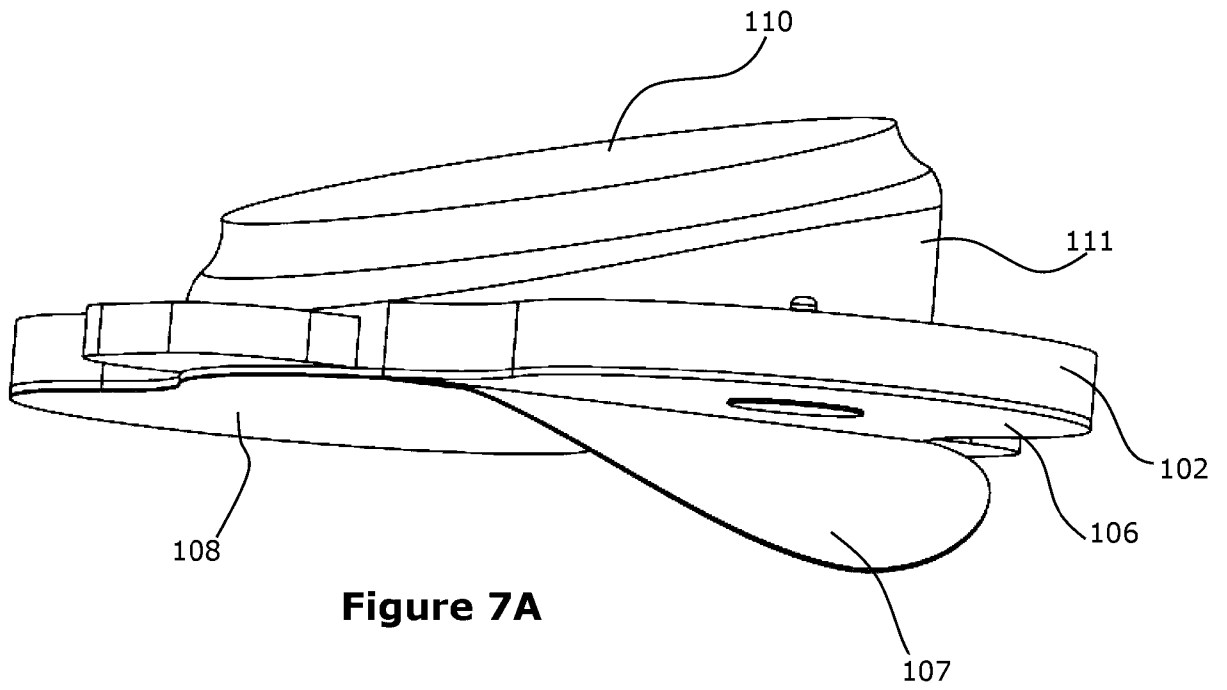


Figure 7A

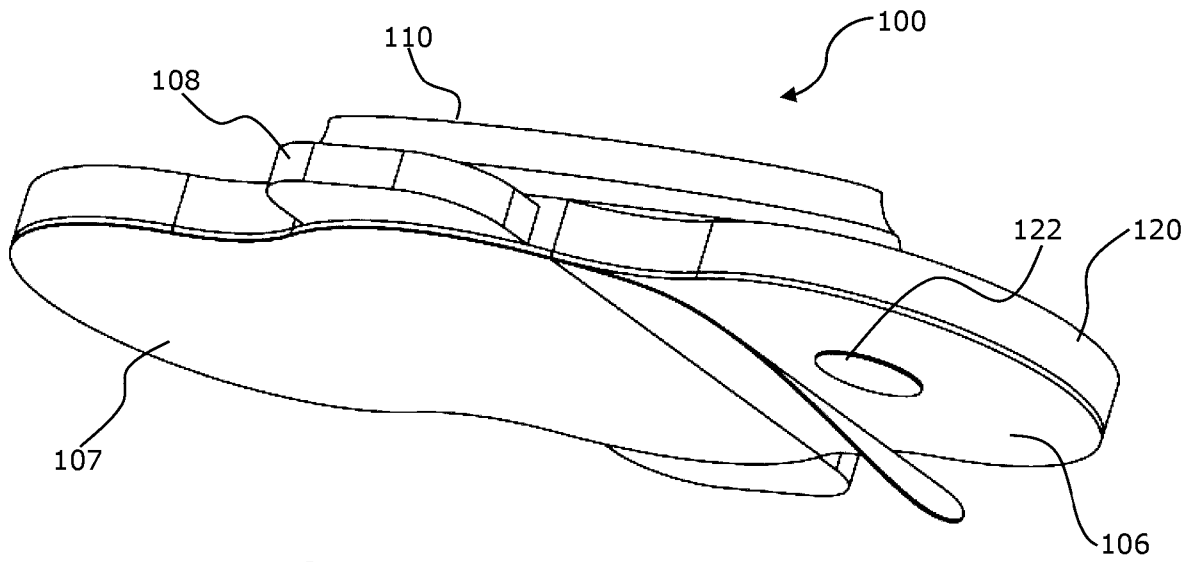


Figure 7B

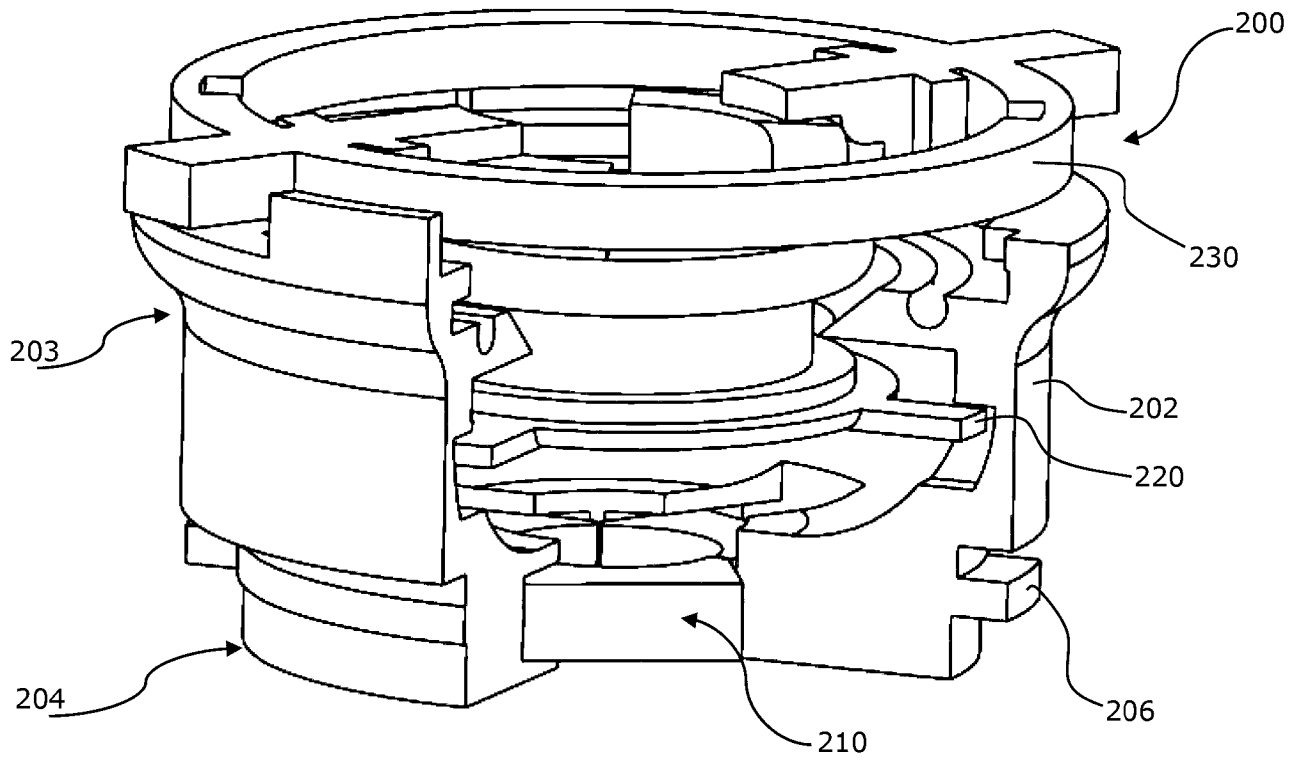


Figure 8



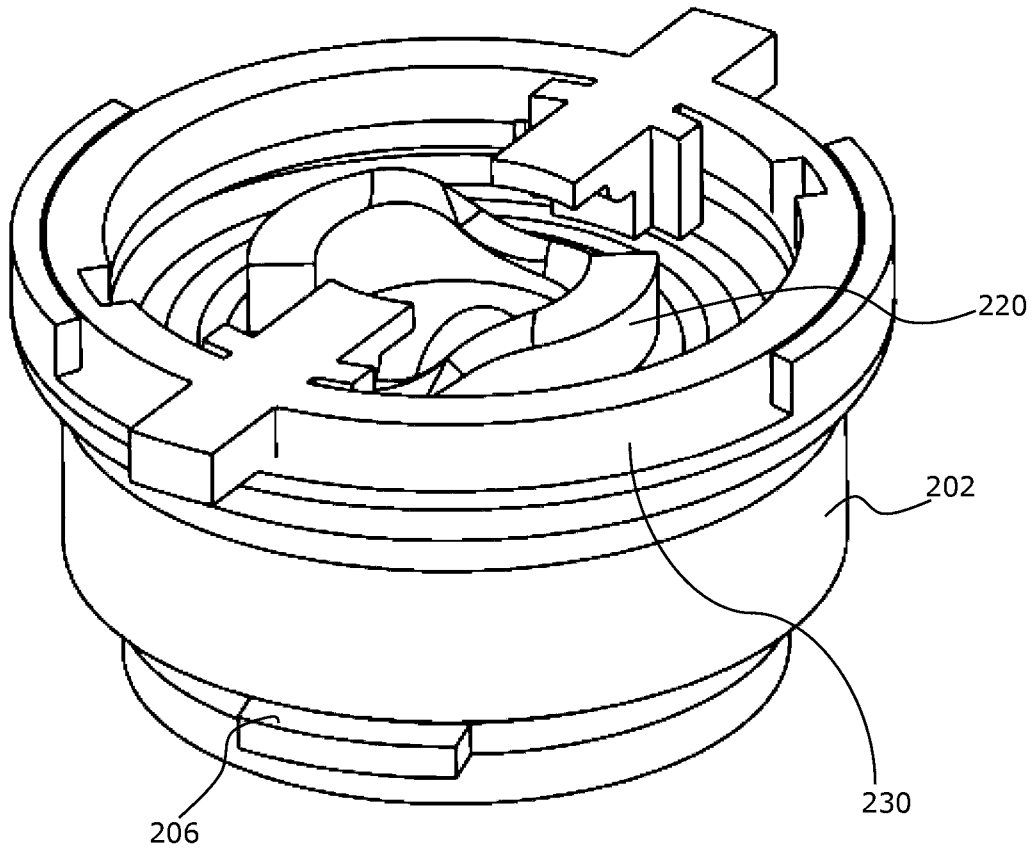


Figure 9A

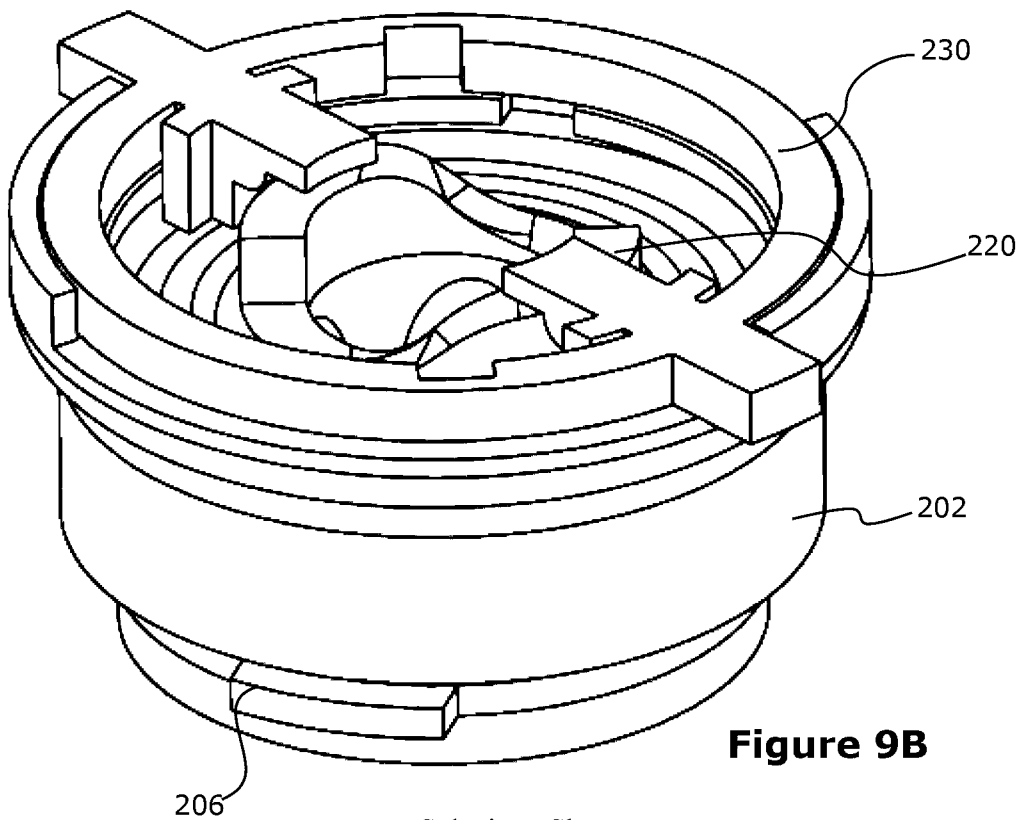


Figure 9B

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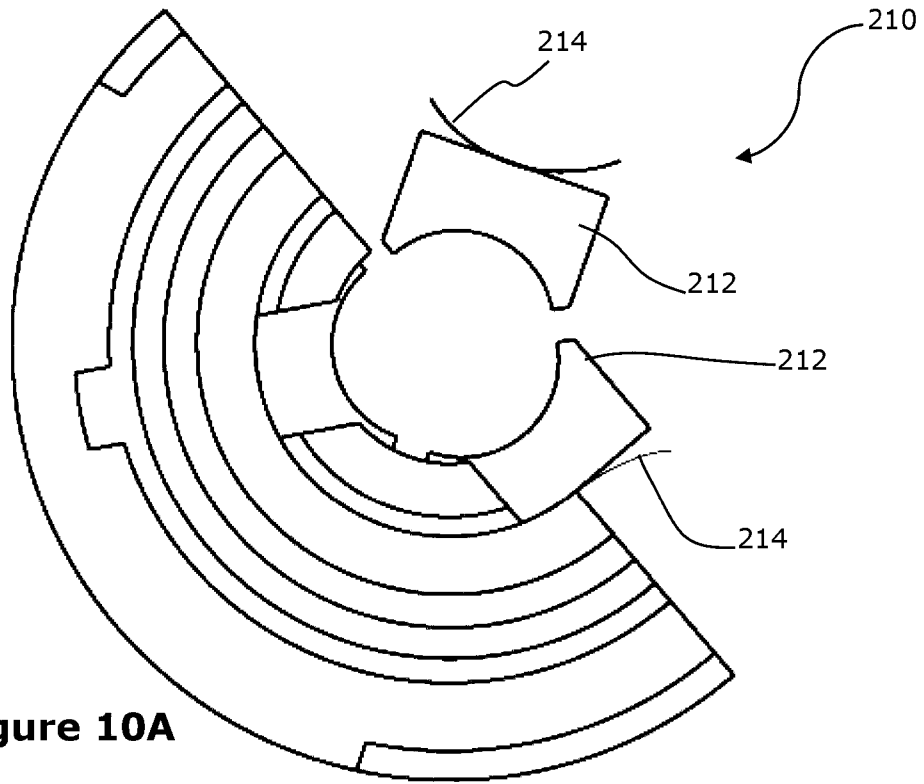


Figure 10A

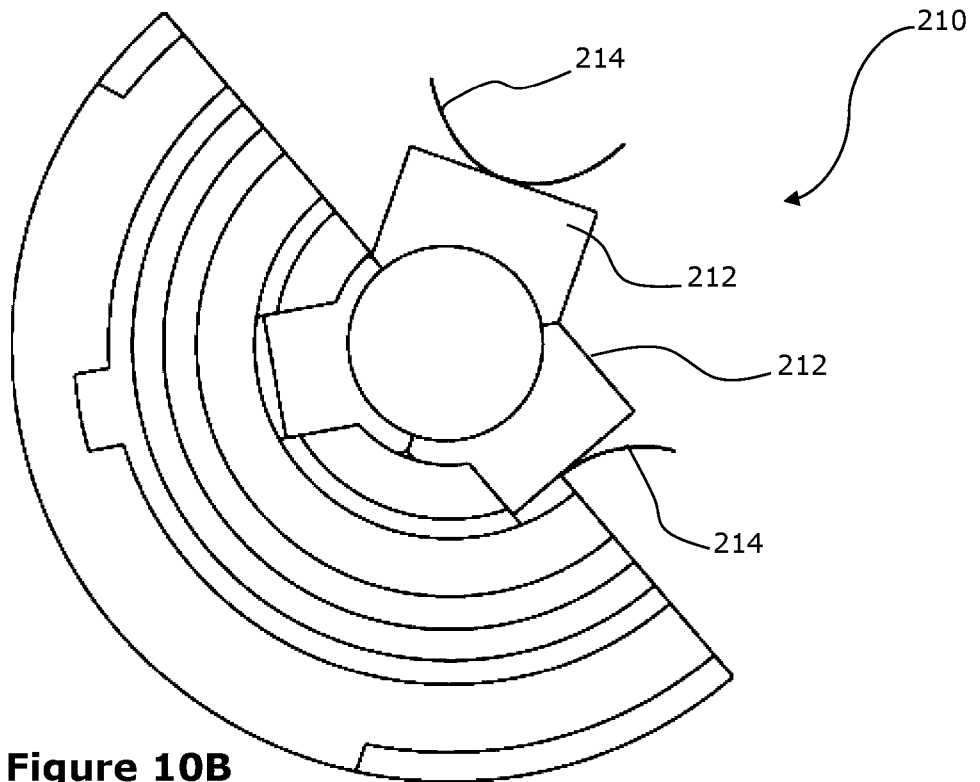


Figure 10B

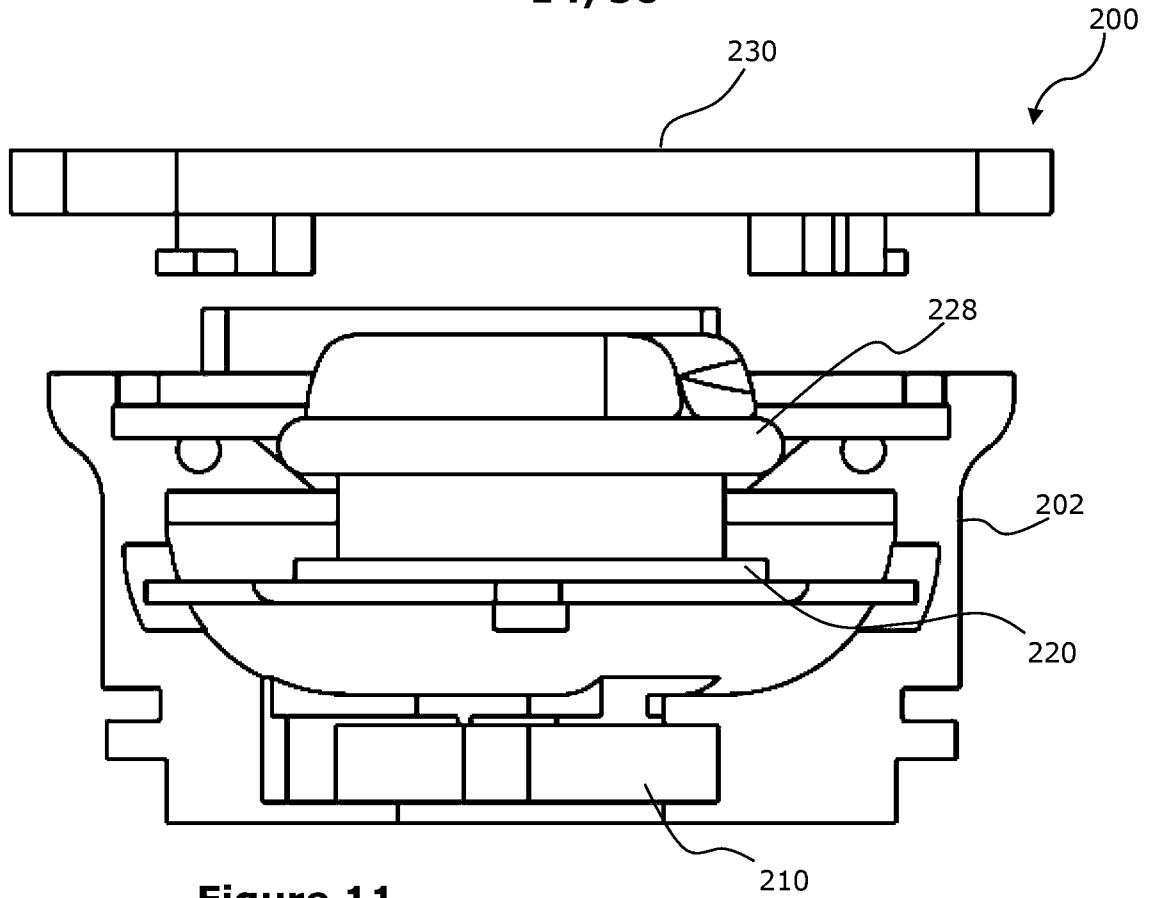


Figure 11

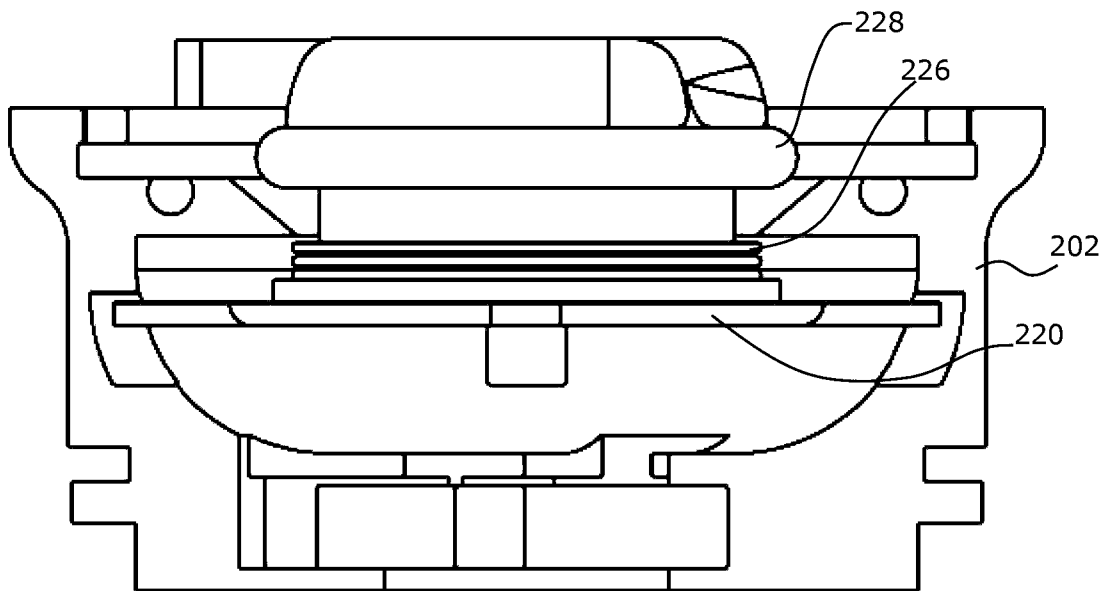
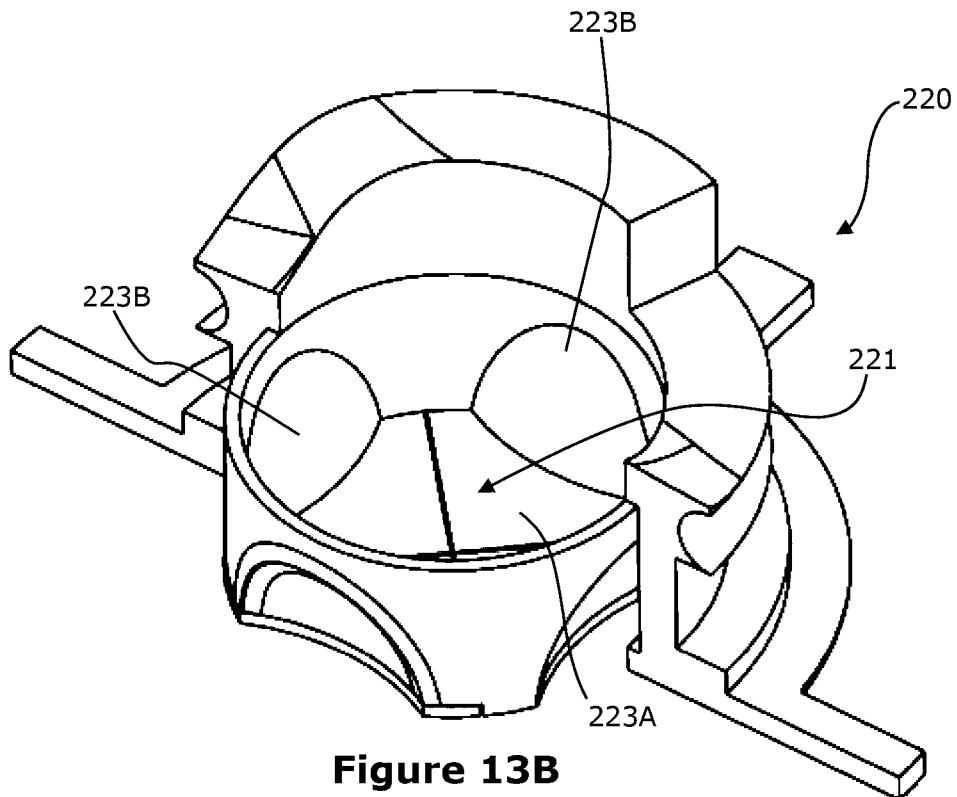
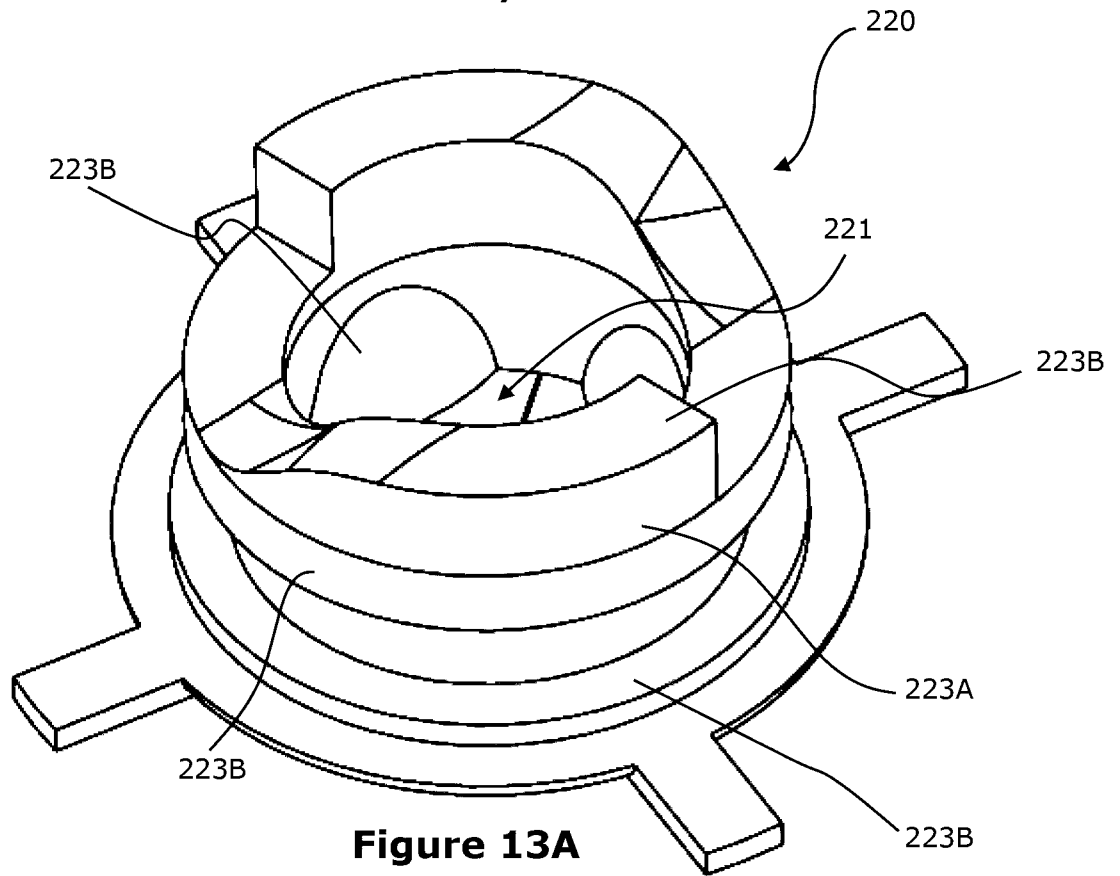


Figure 12

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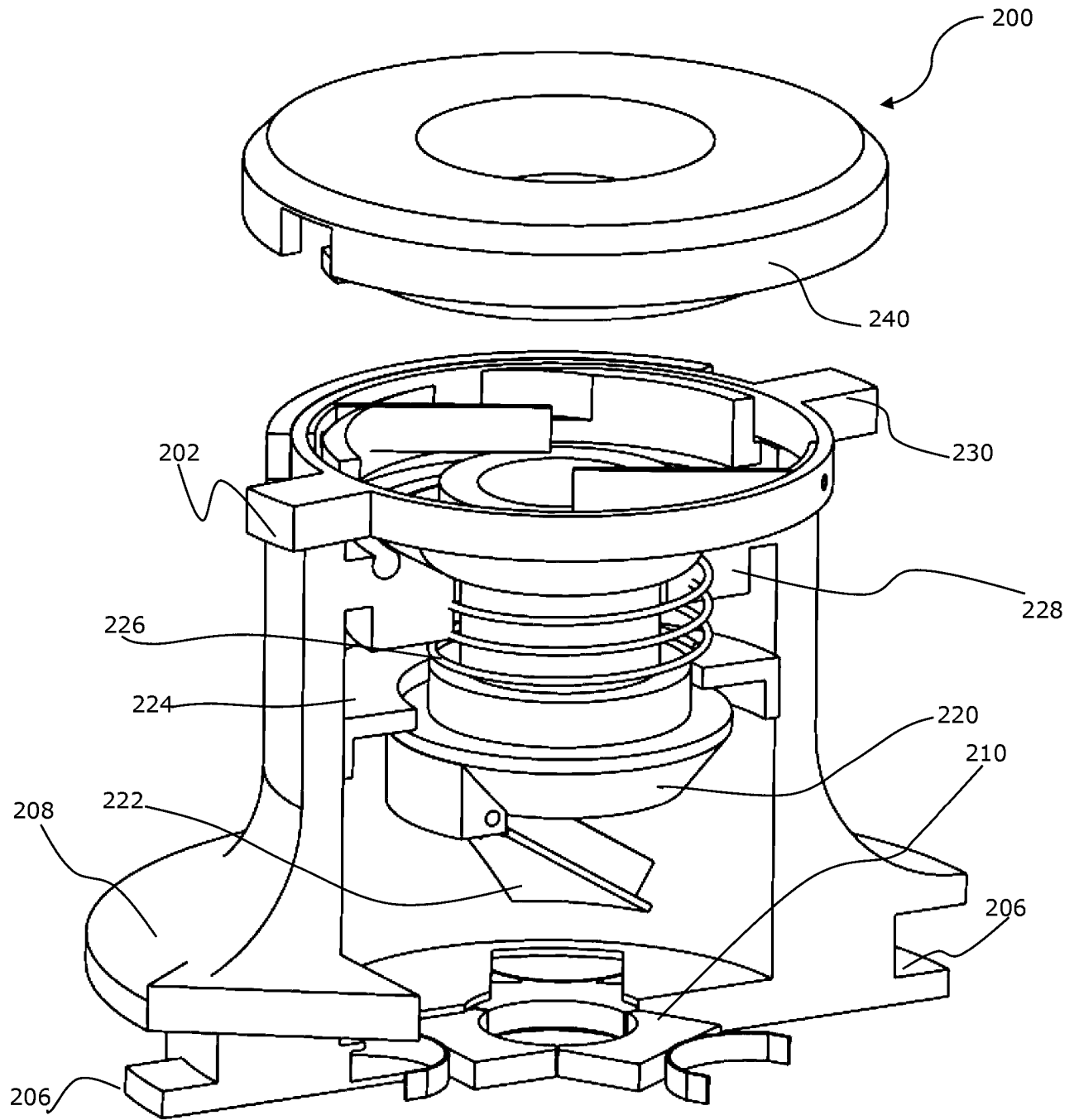
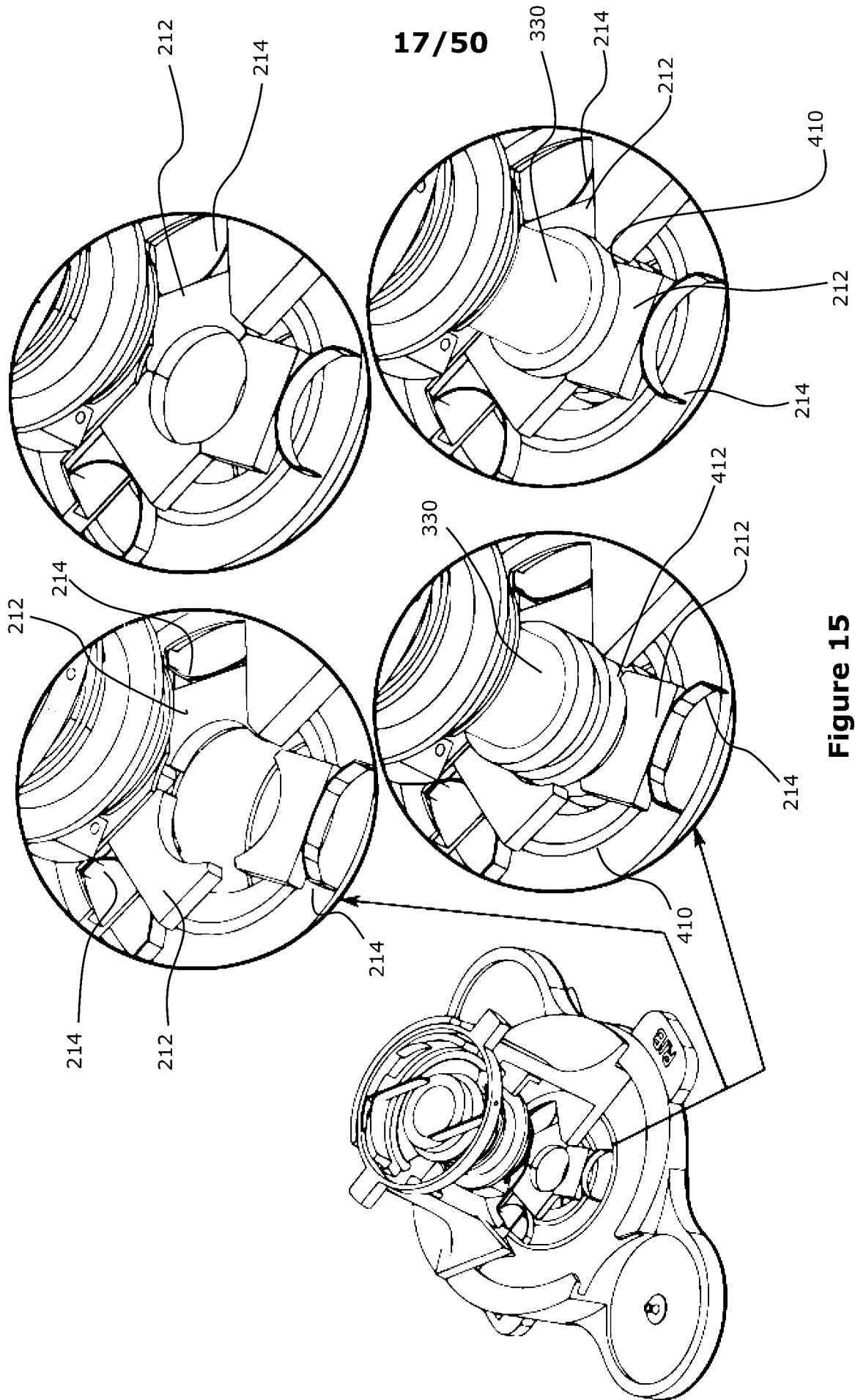
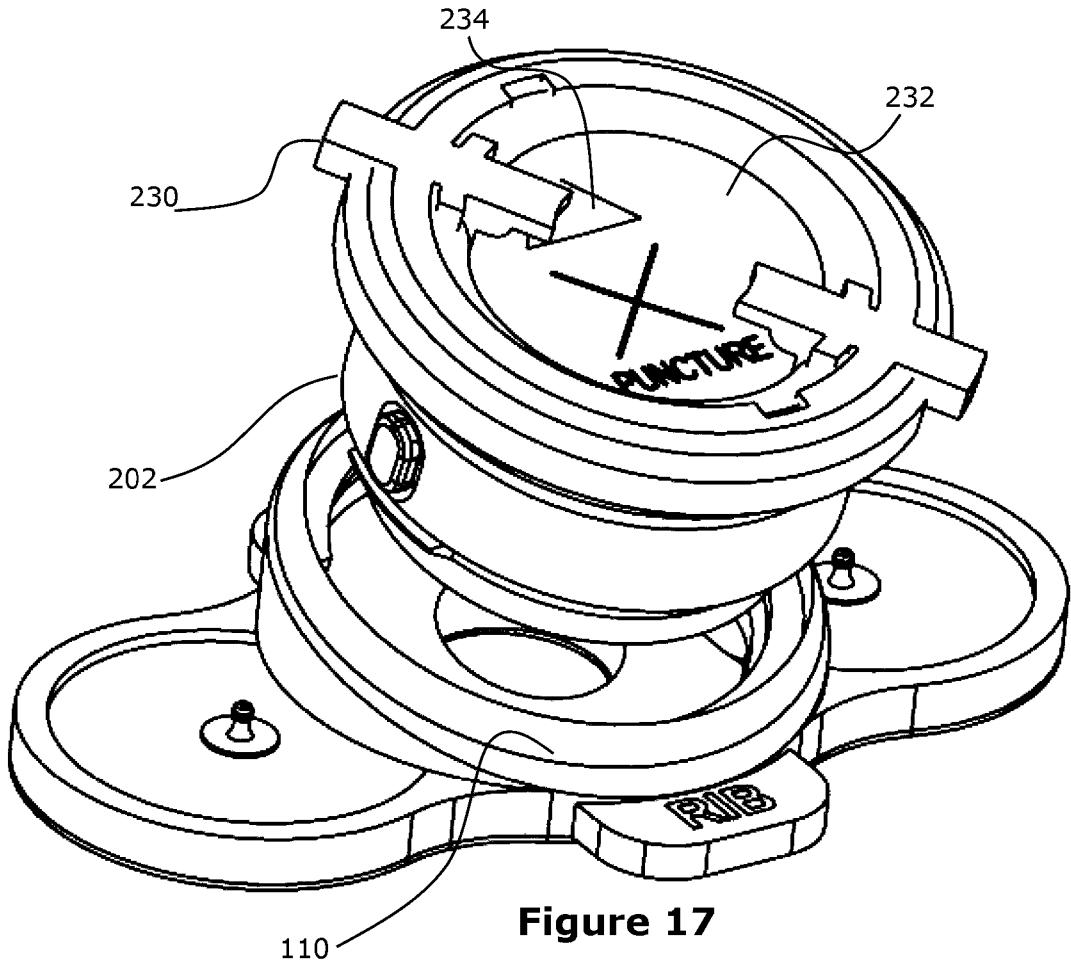
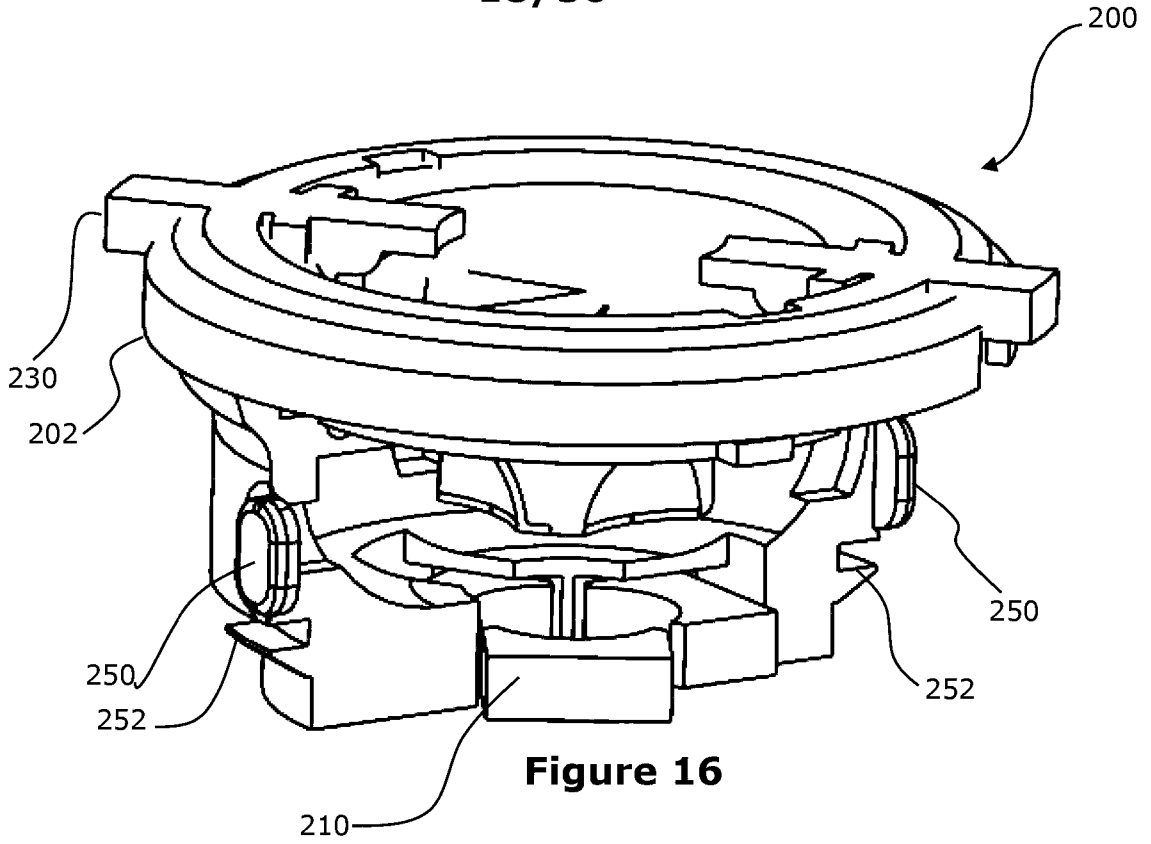


Figure 14



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Figure 15



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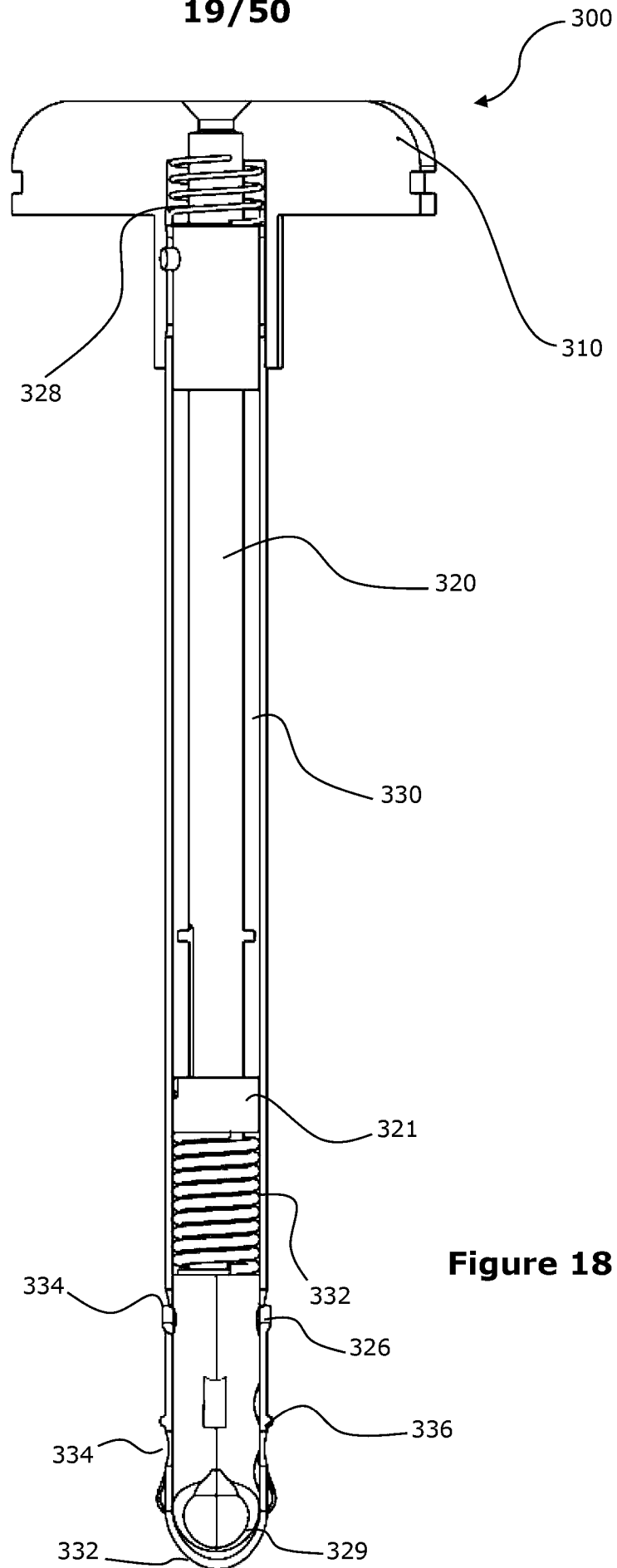


Figure 18



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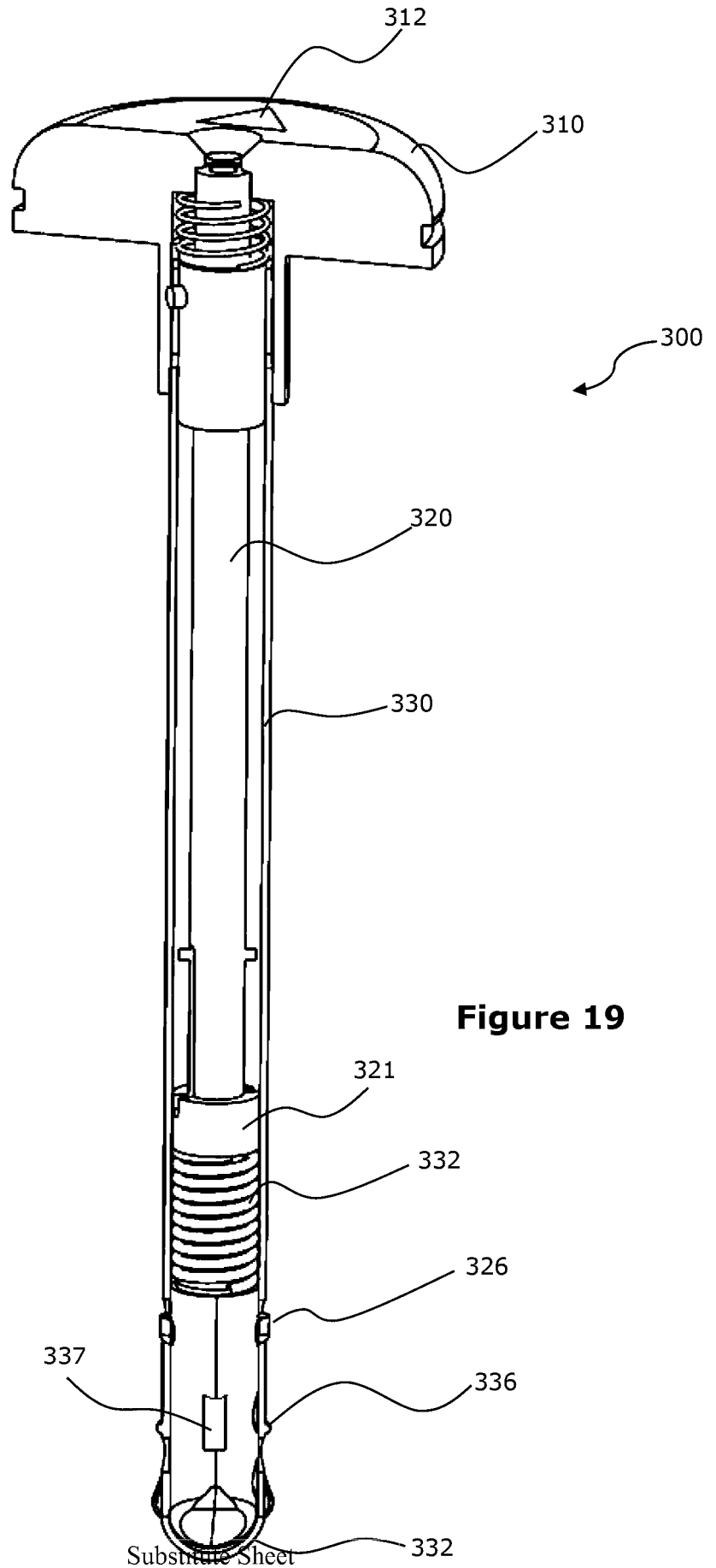


Figure 19

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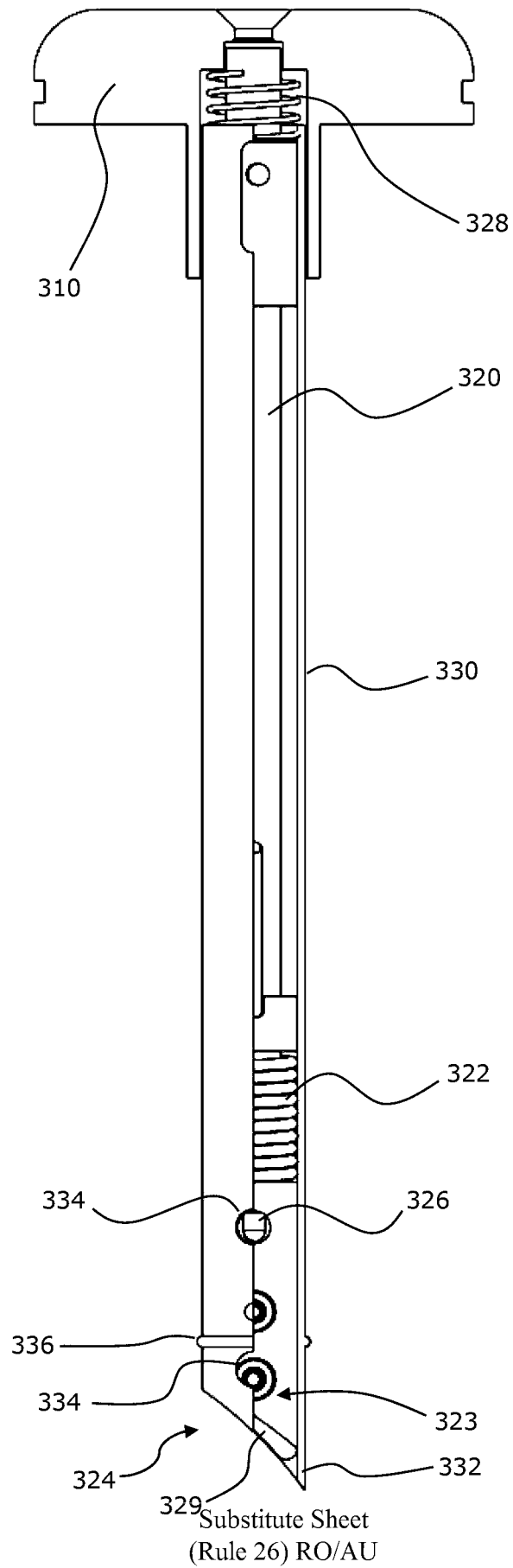


Figure 20

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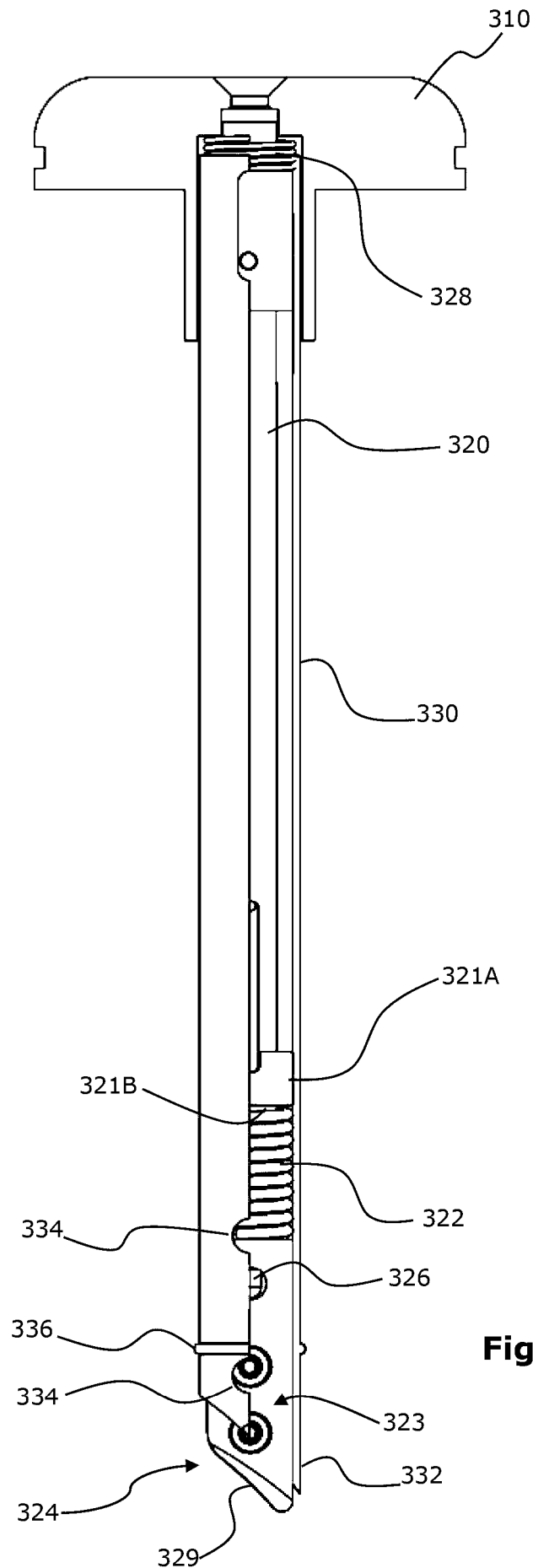


Figure 21

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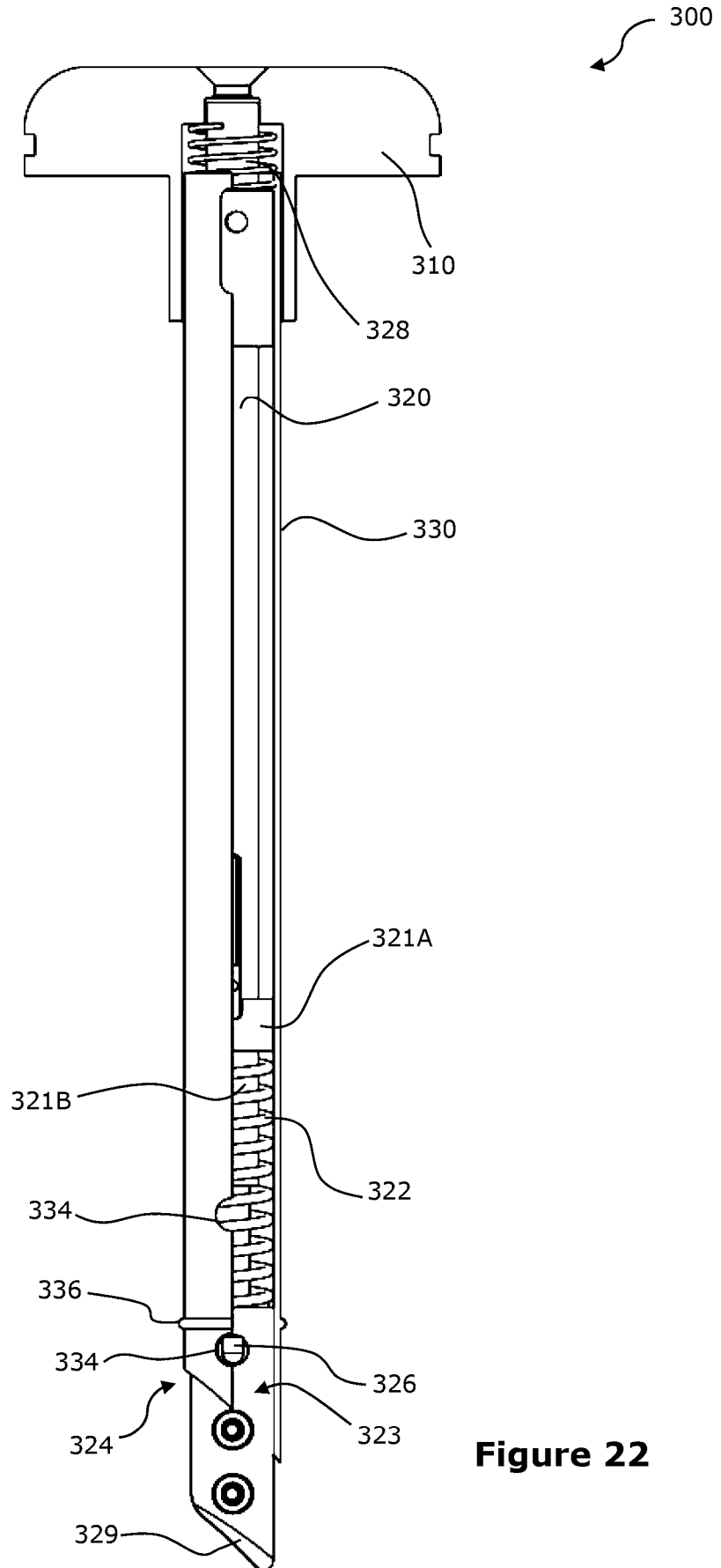
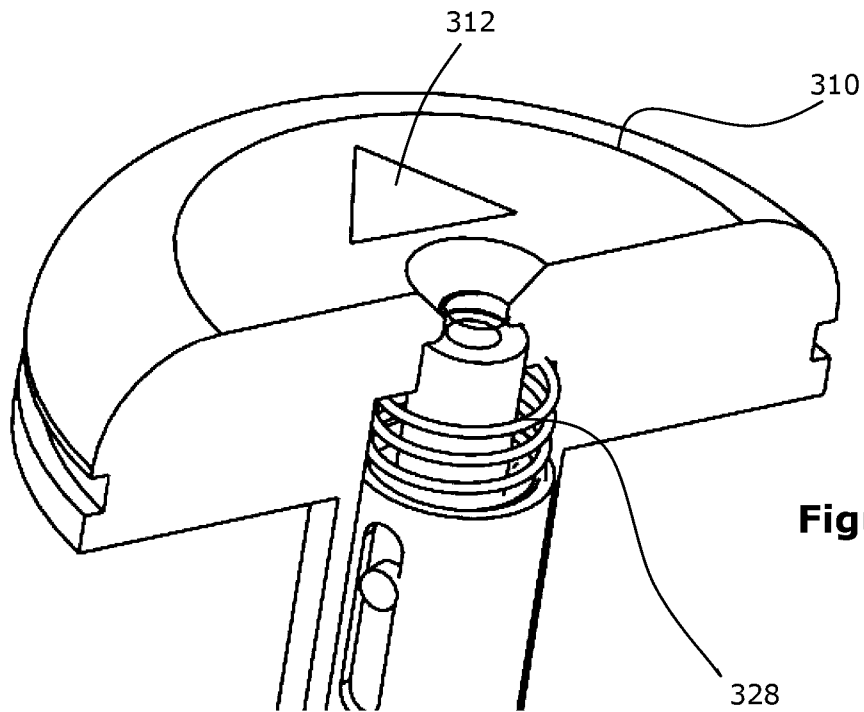
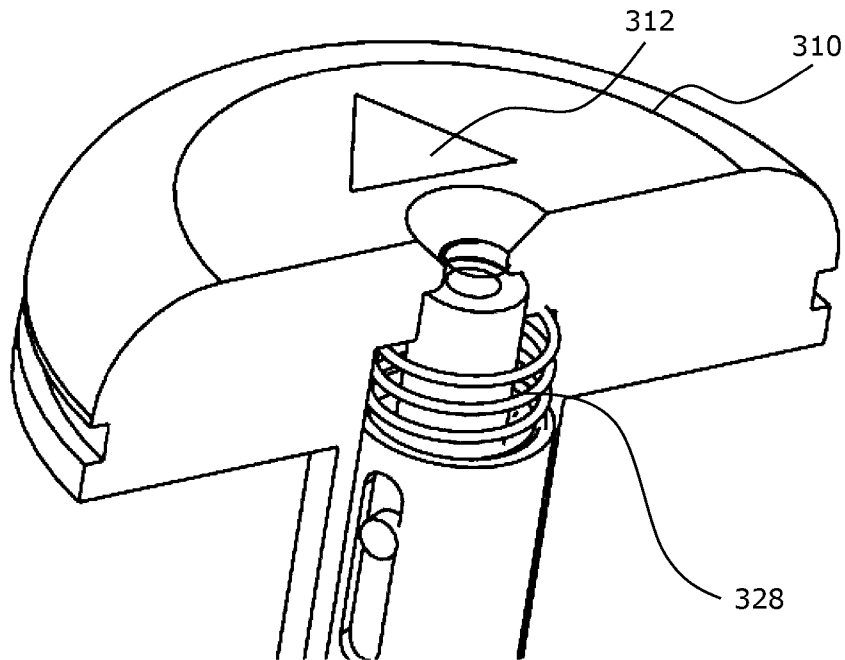


Figure 22



**Figure 23A**



**Figure 23B**

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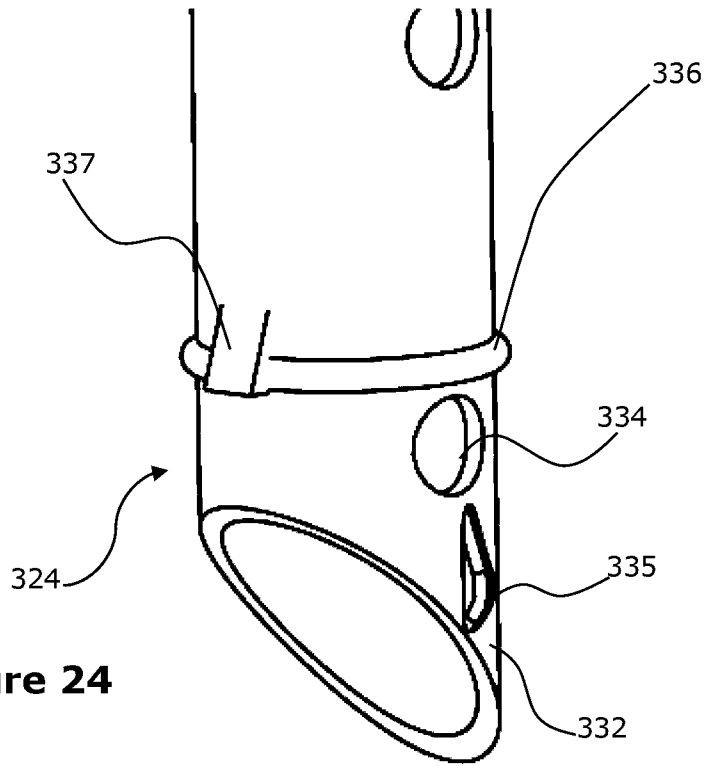


Figure 24

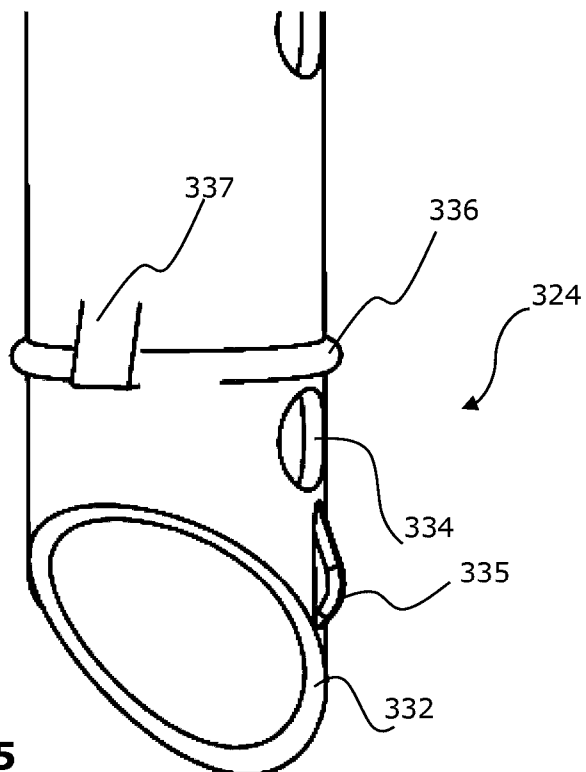


Figure 25

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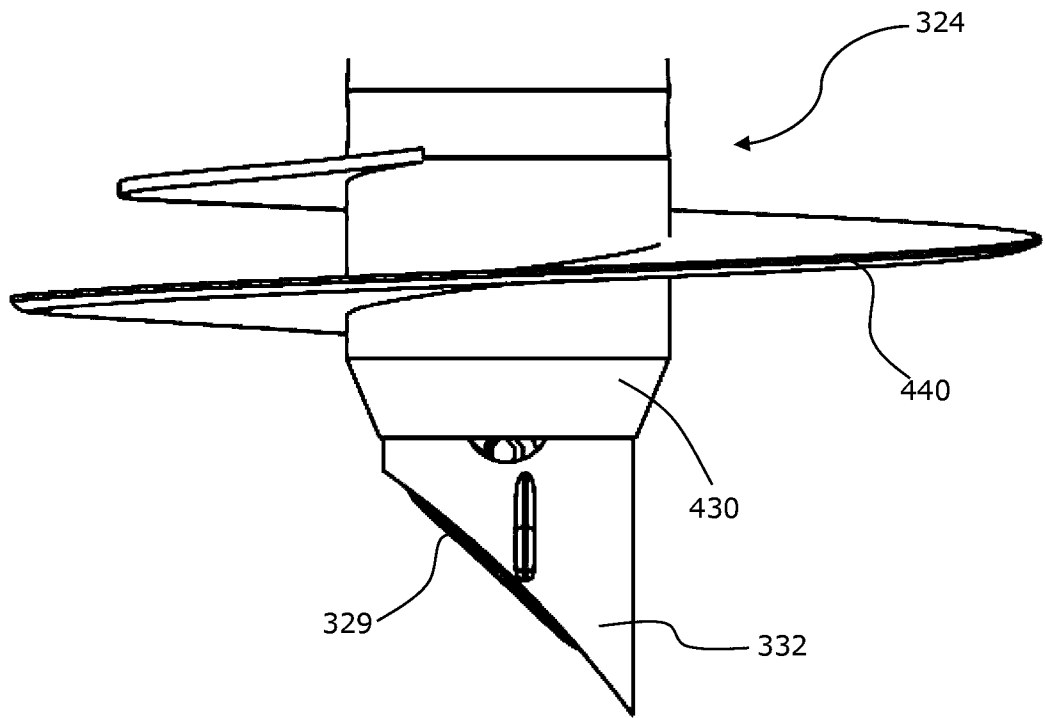


Figure 26

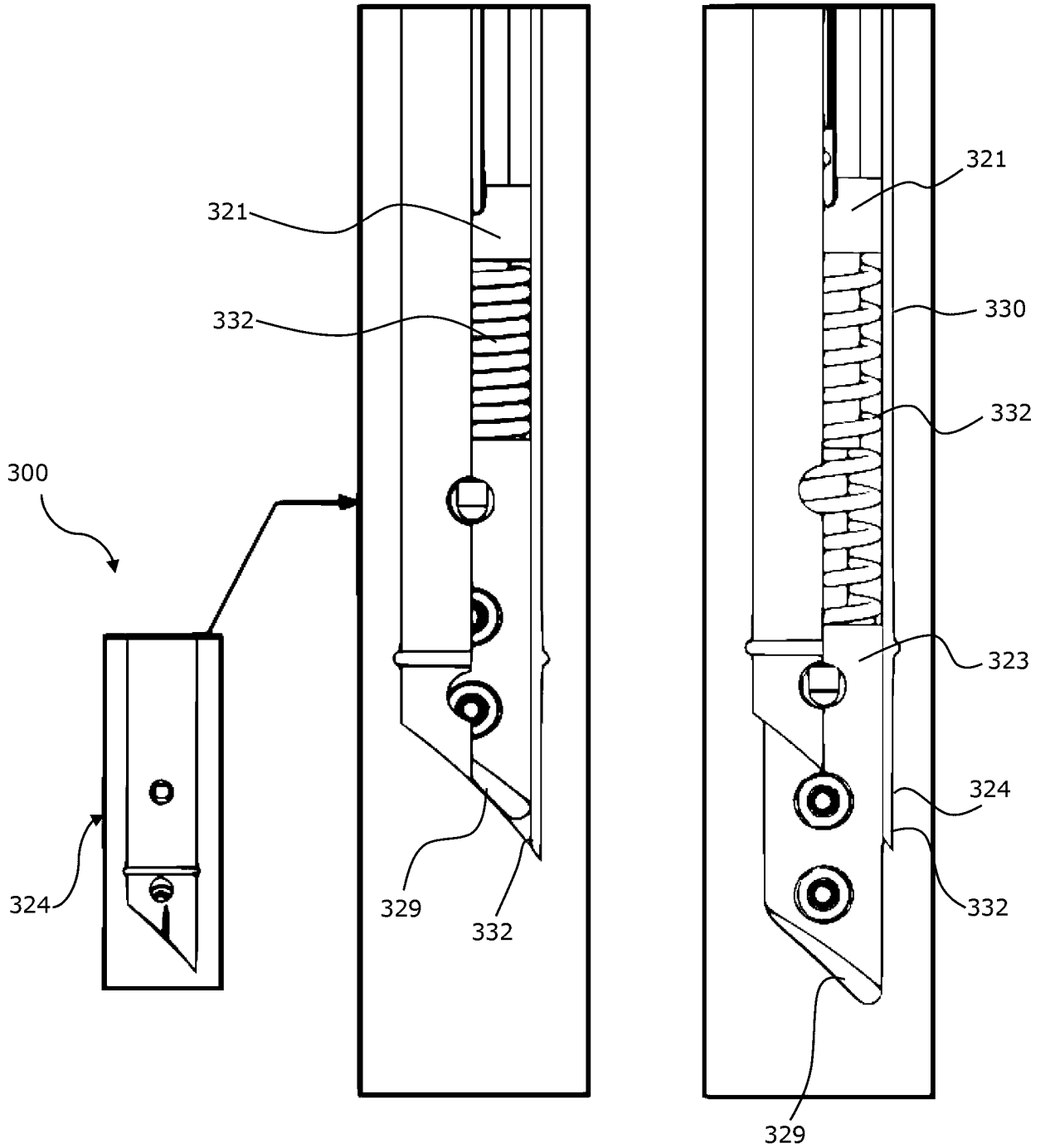


Figure 27



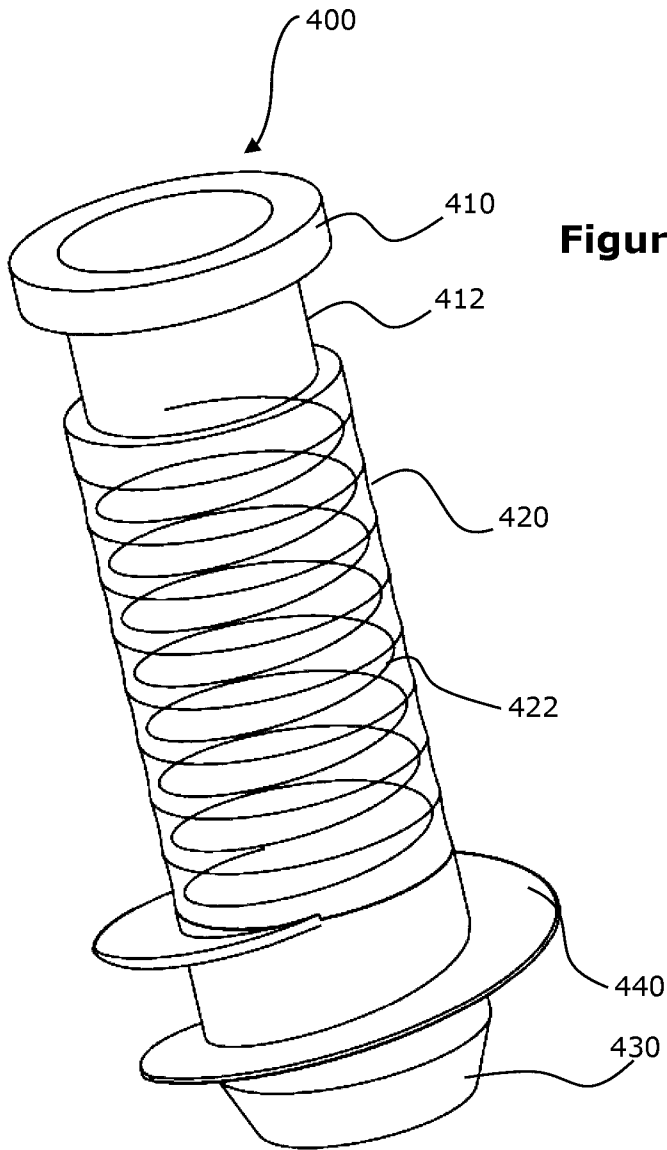


Figure 28

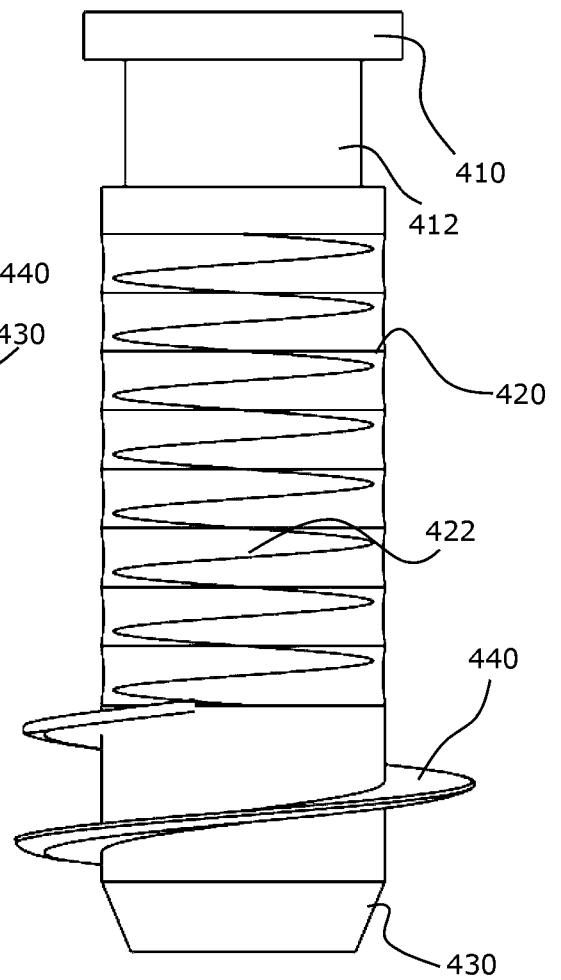


Figure 29

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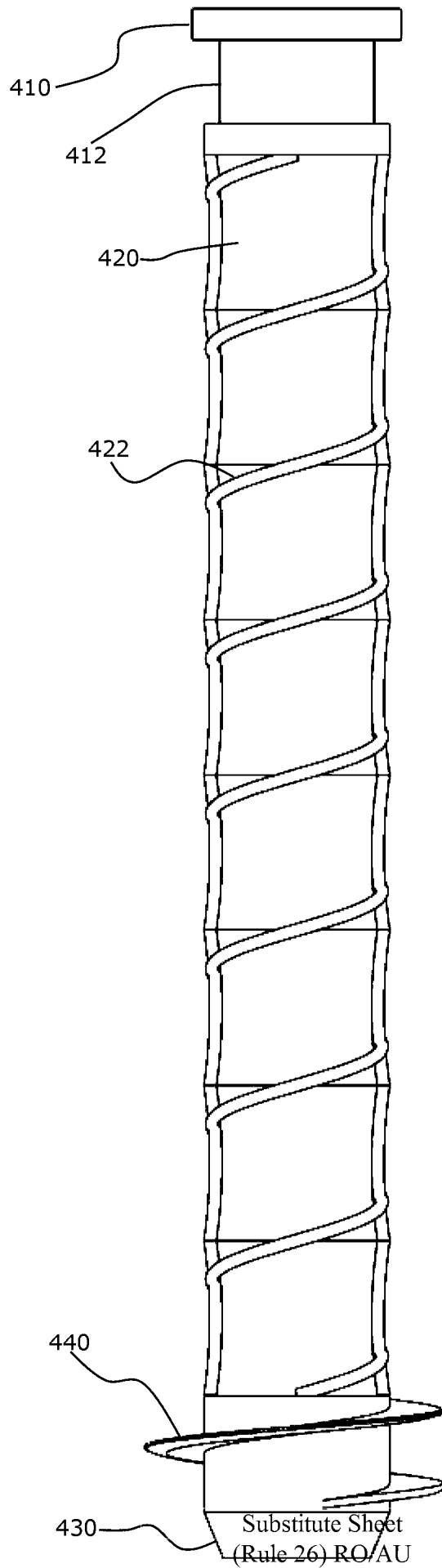


Figure 30

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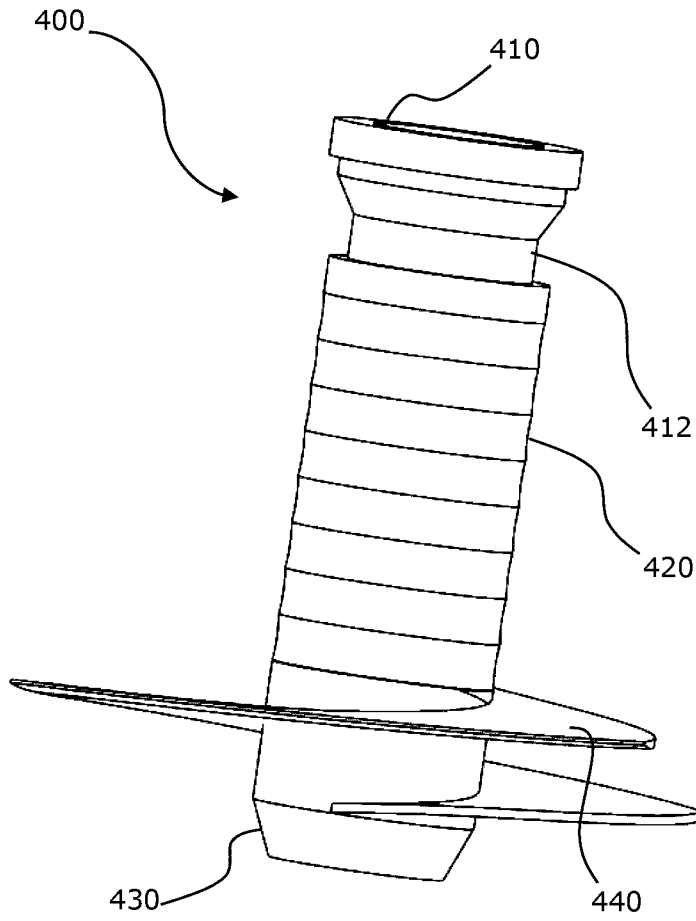


Figure 31

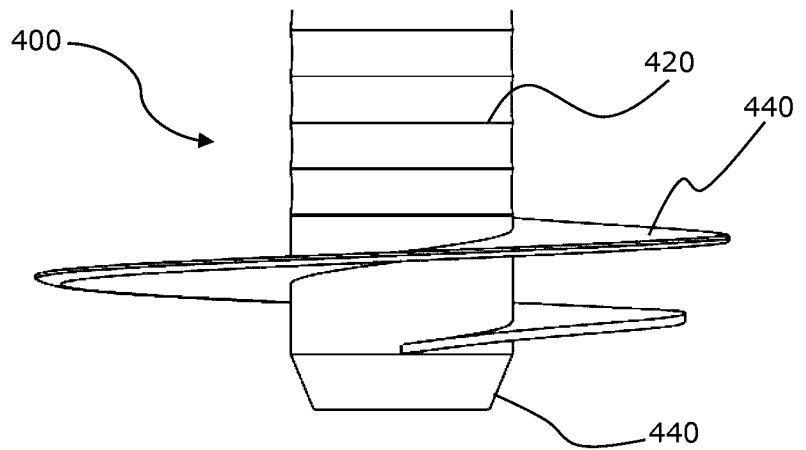


Figure 32

Figure 33

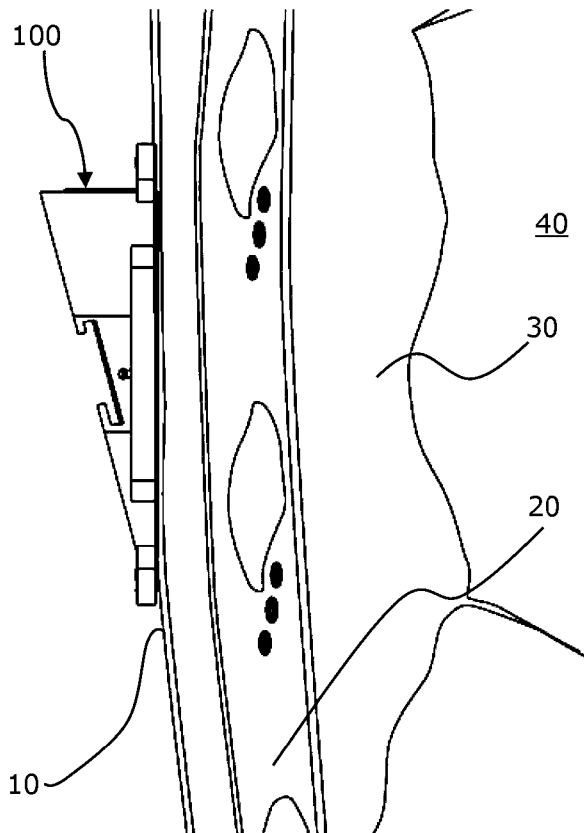
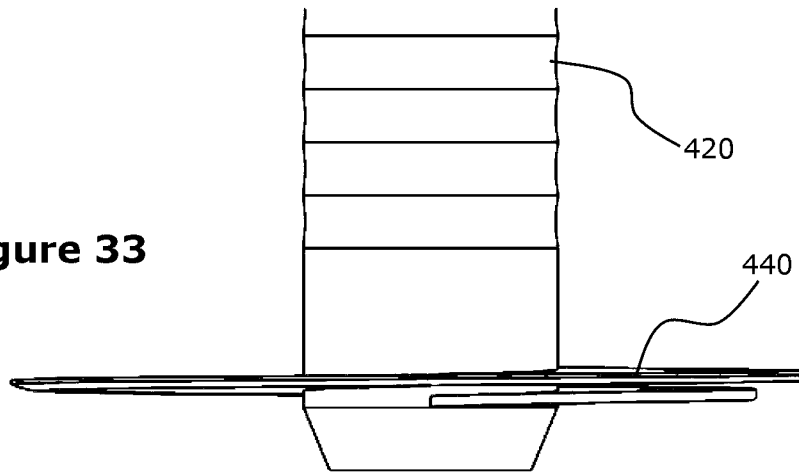


Figure 34A

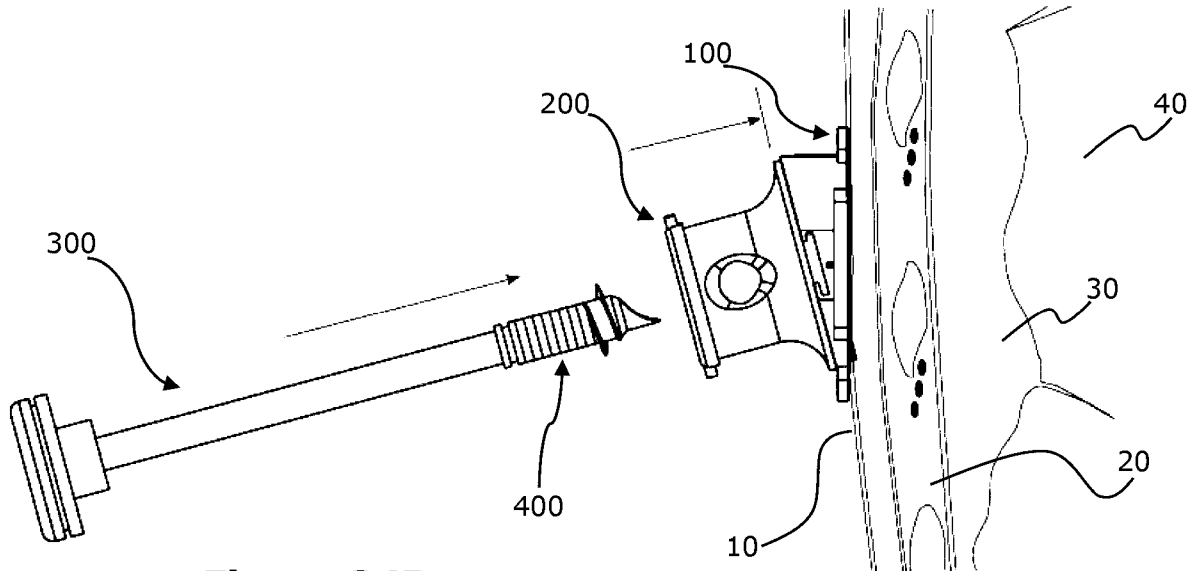


Figure 34B

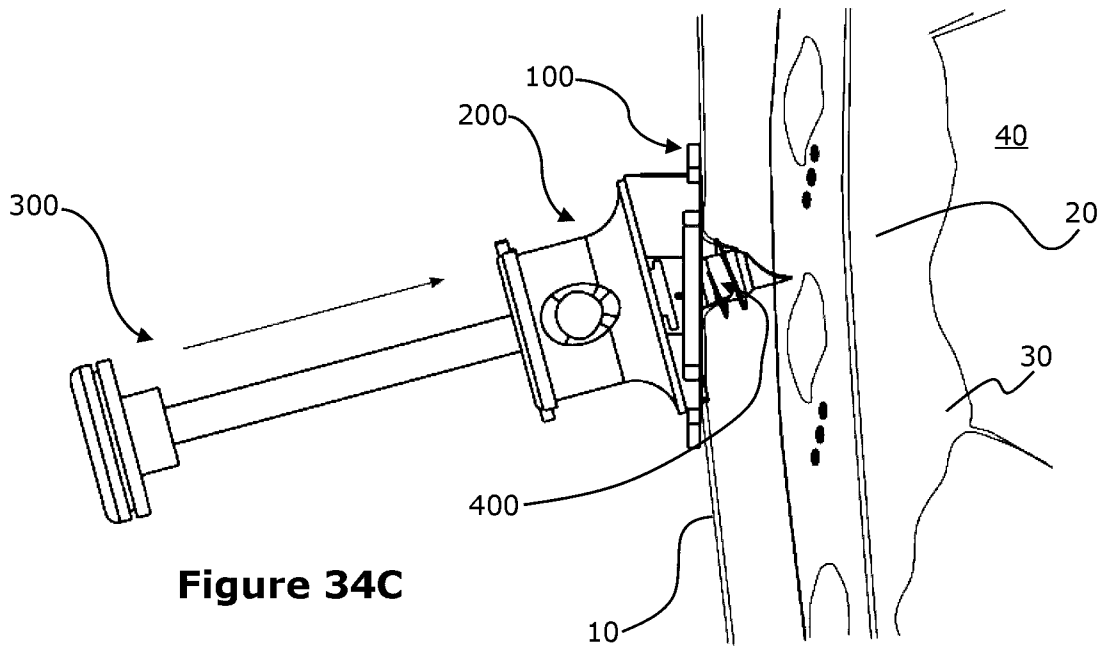
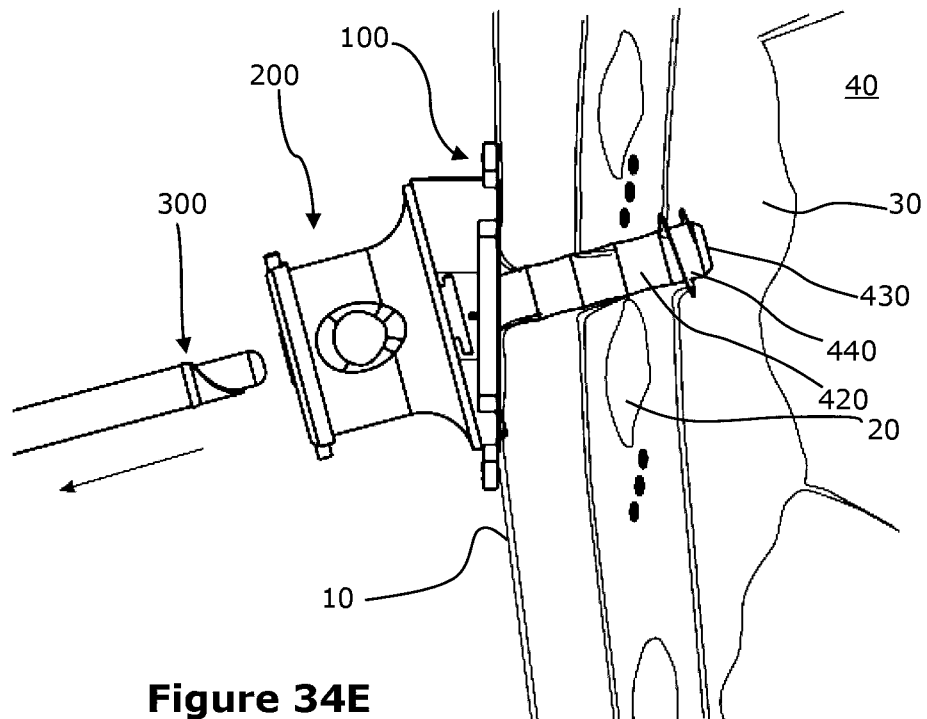
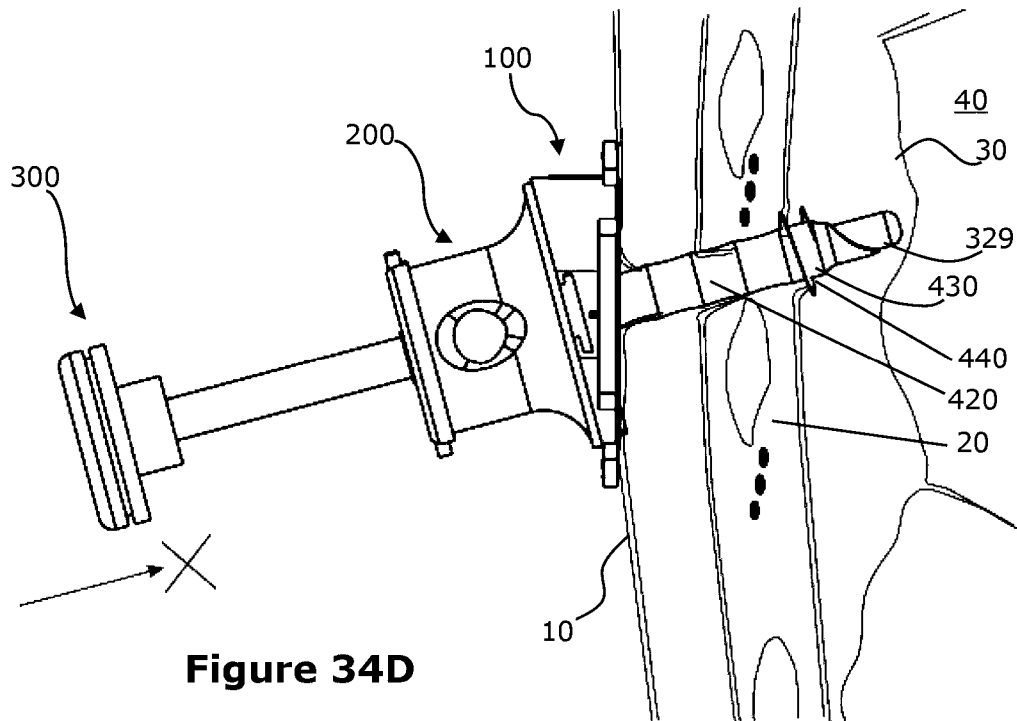


Figure 34C



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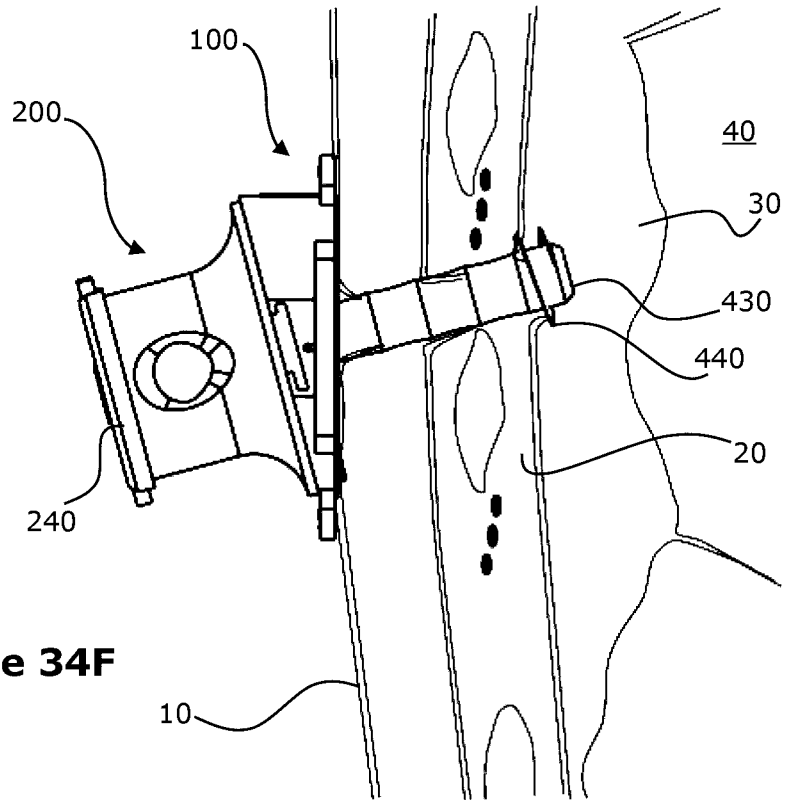


Figure 34F

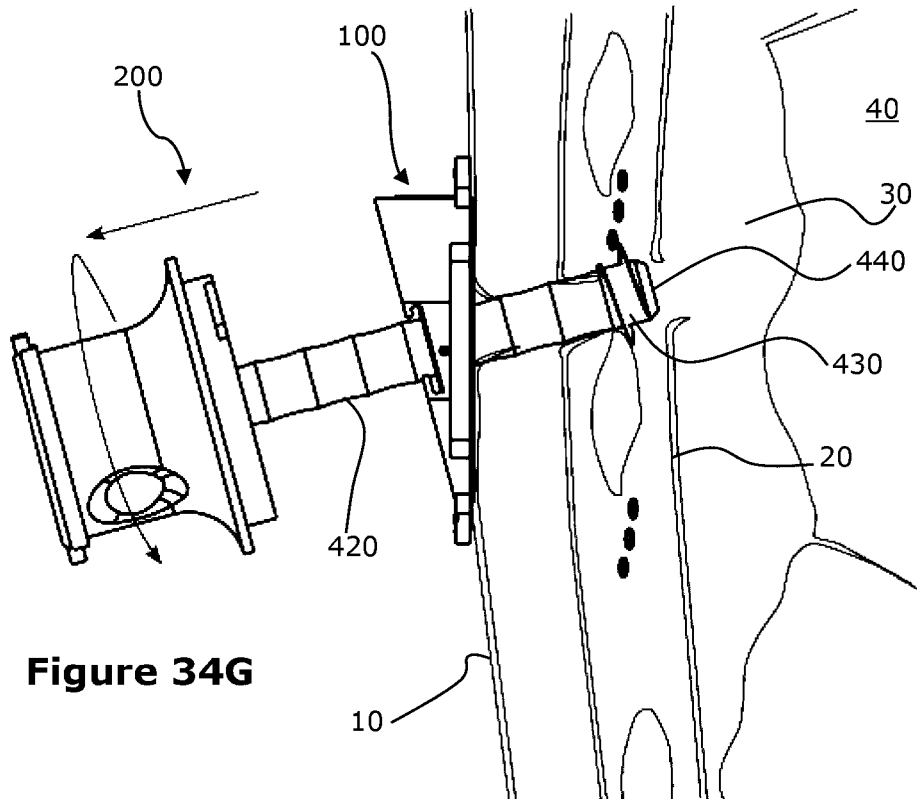


Figure 34G

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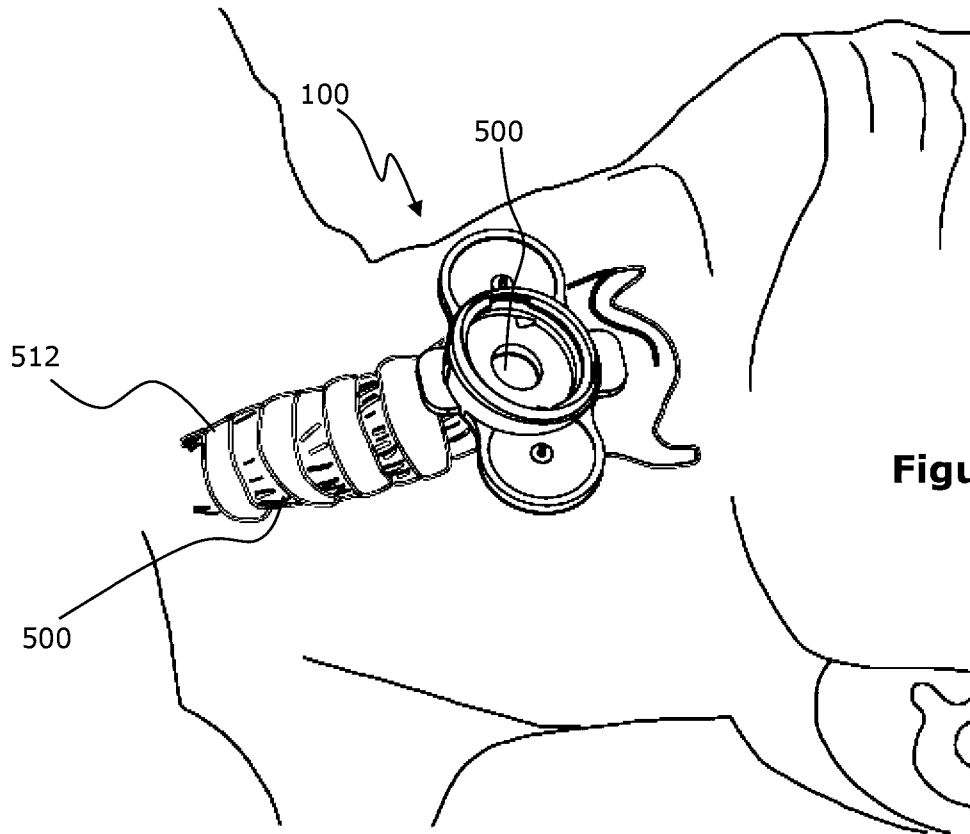


Figure 35

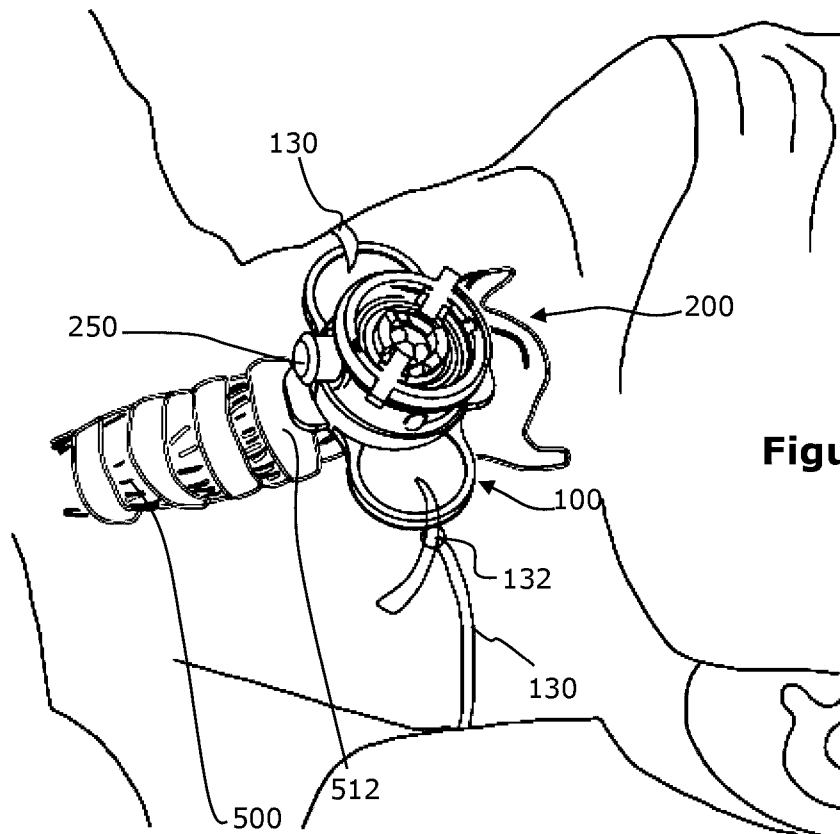


Figure 36



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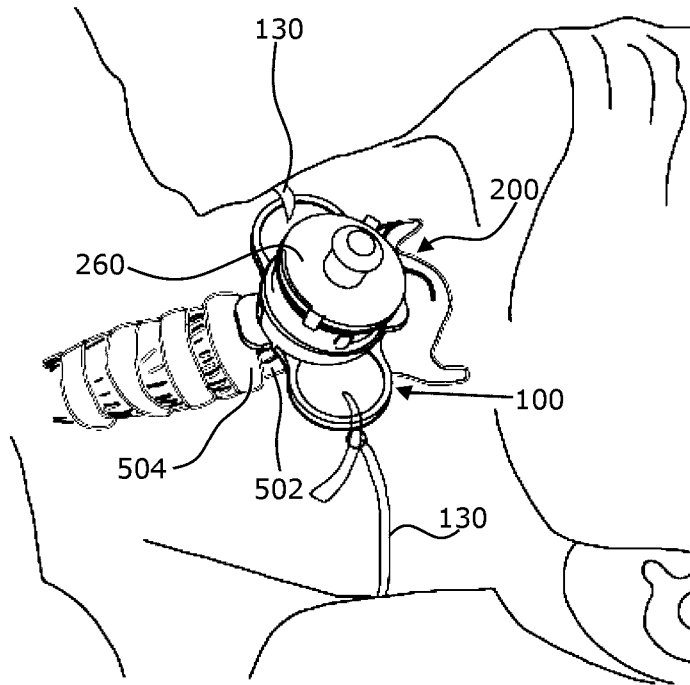


Figure 37

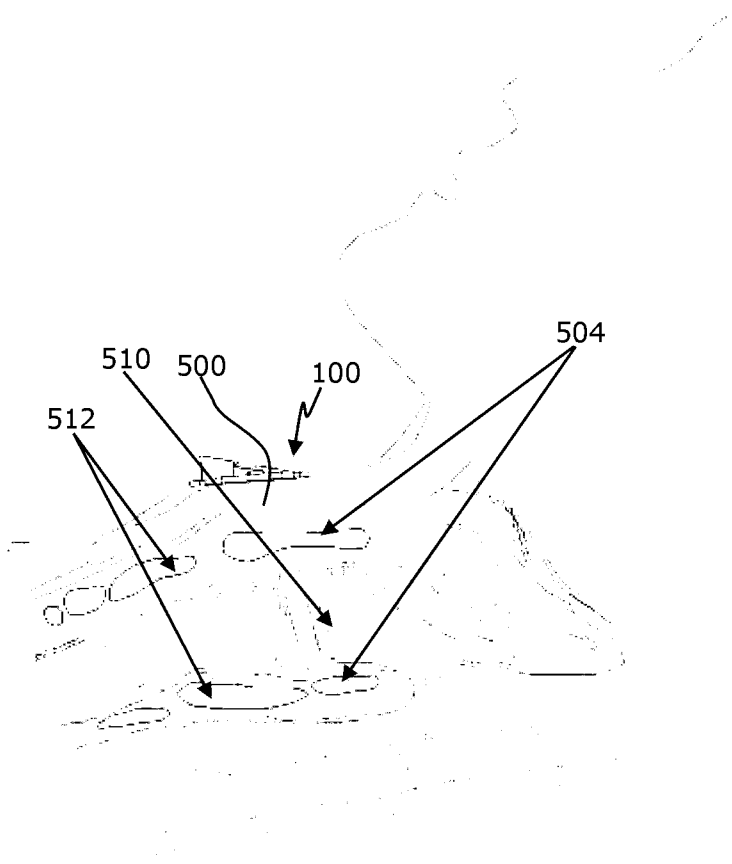


Figure 38A

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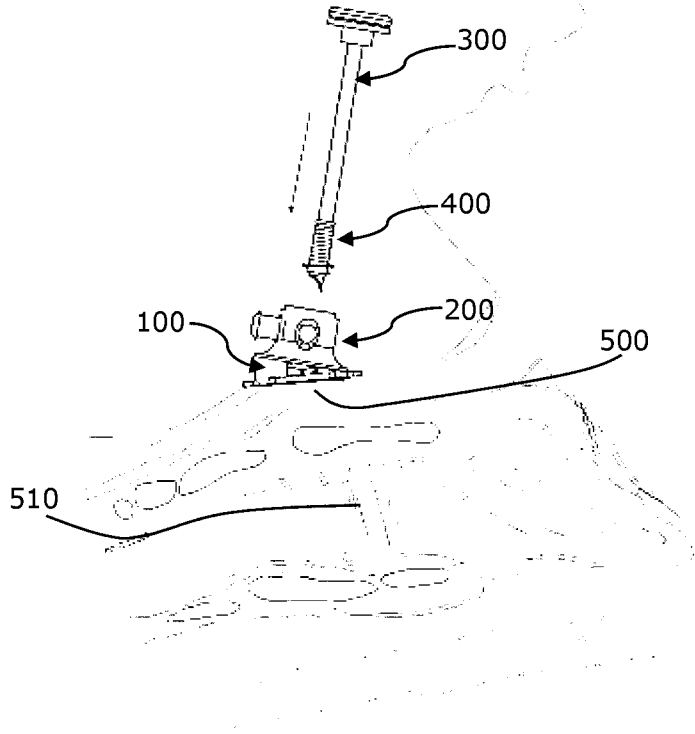


Figure 38B

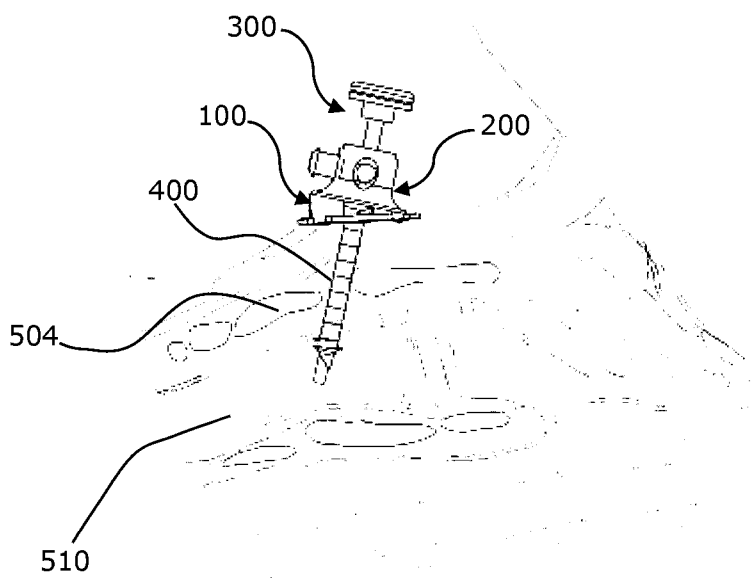


Figure 38C

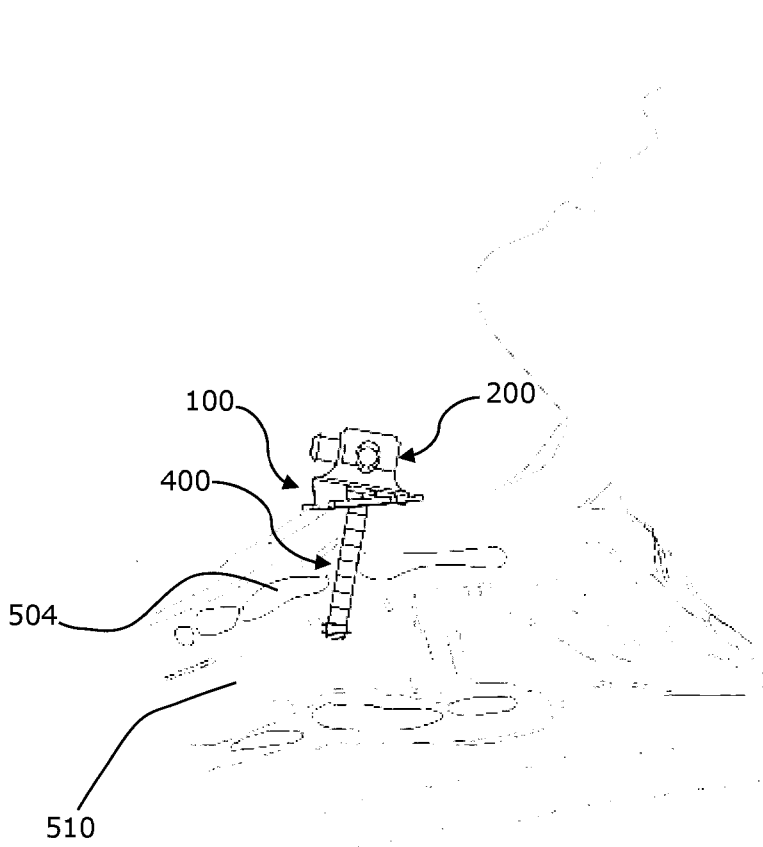


Figure 38D

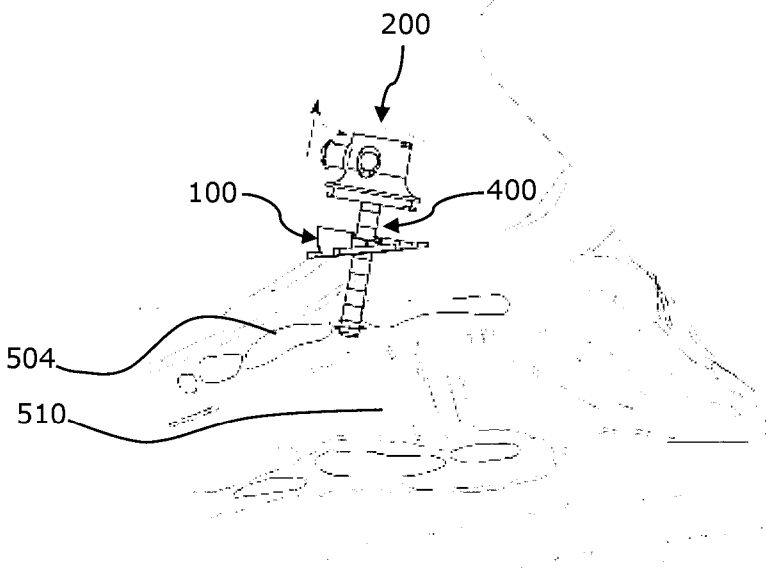


Figure 38E

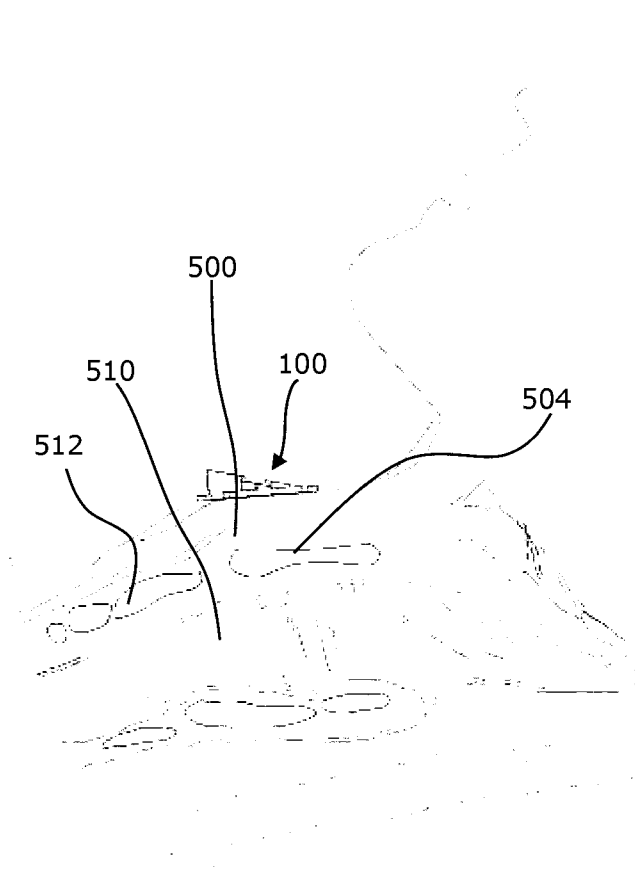


Figure 39A

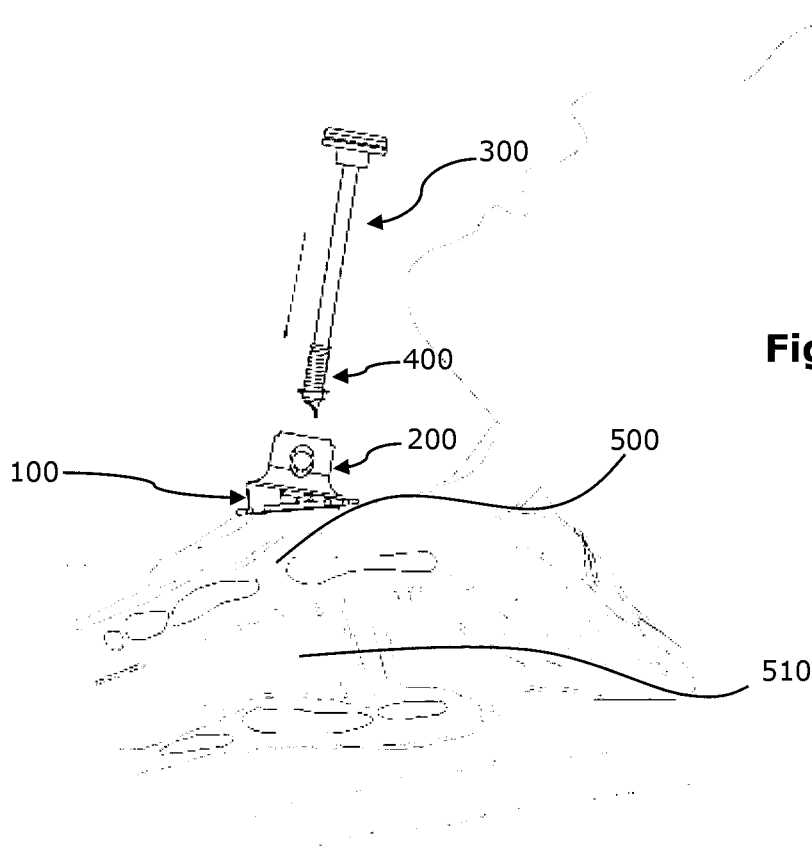


Figure 39B

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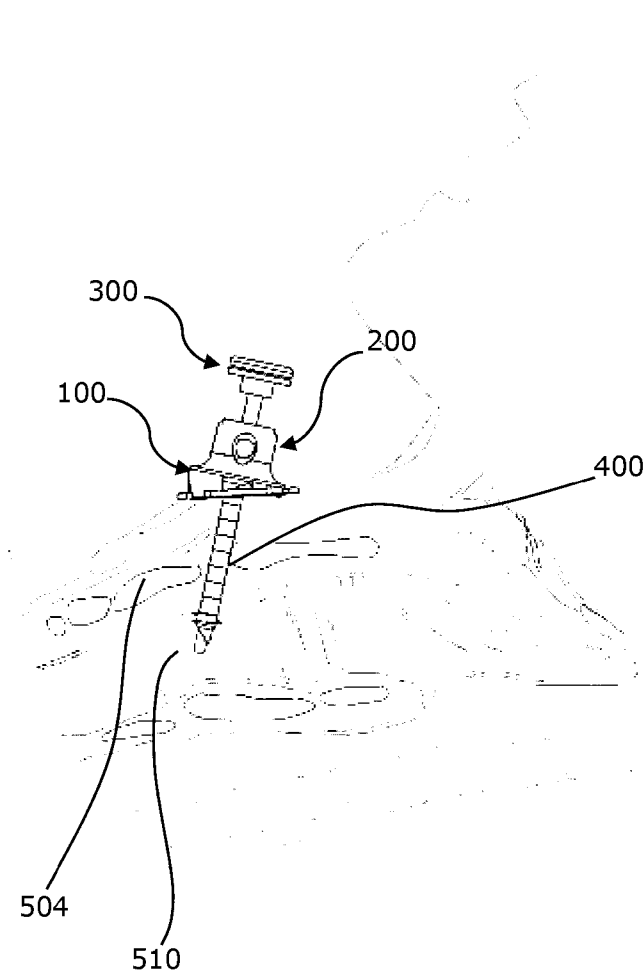


Figure 39C

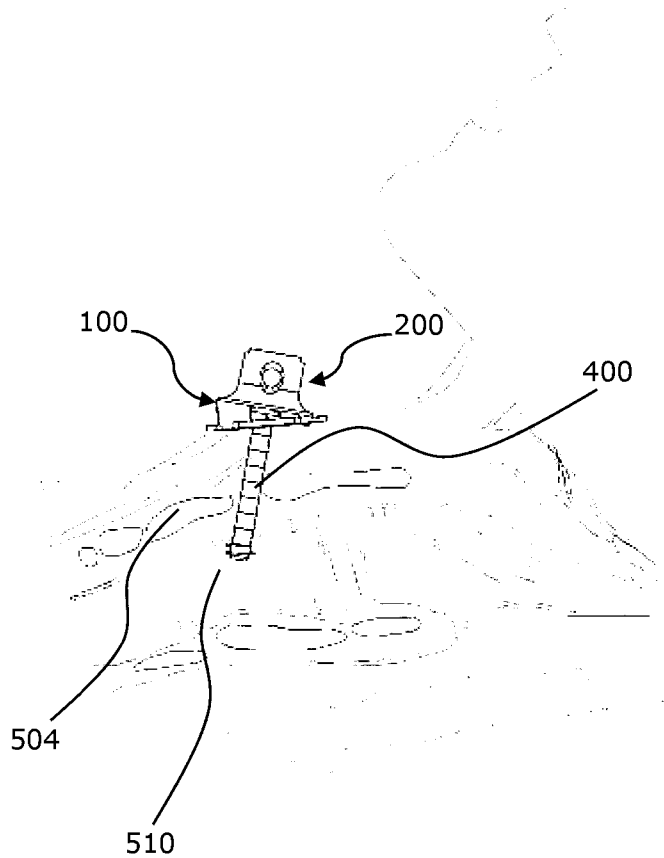


Figure 39D

Figure 39E

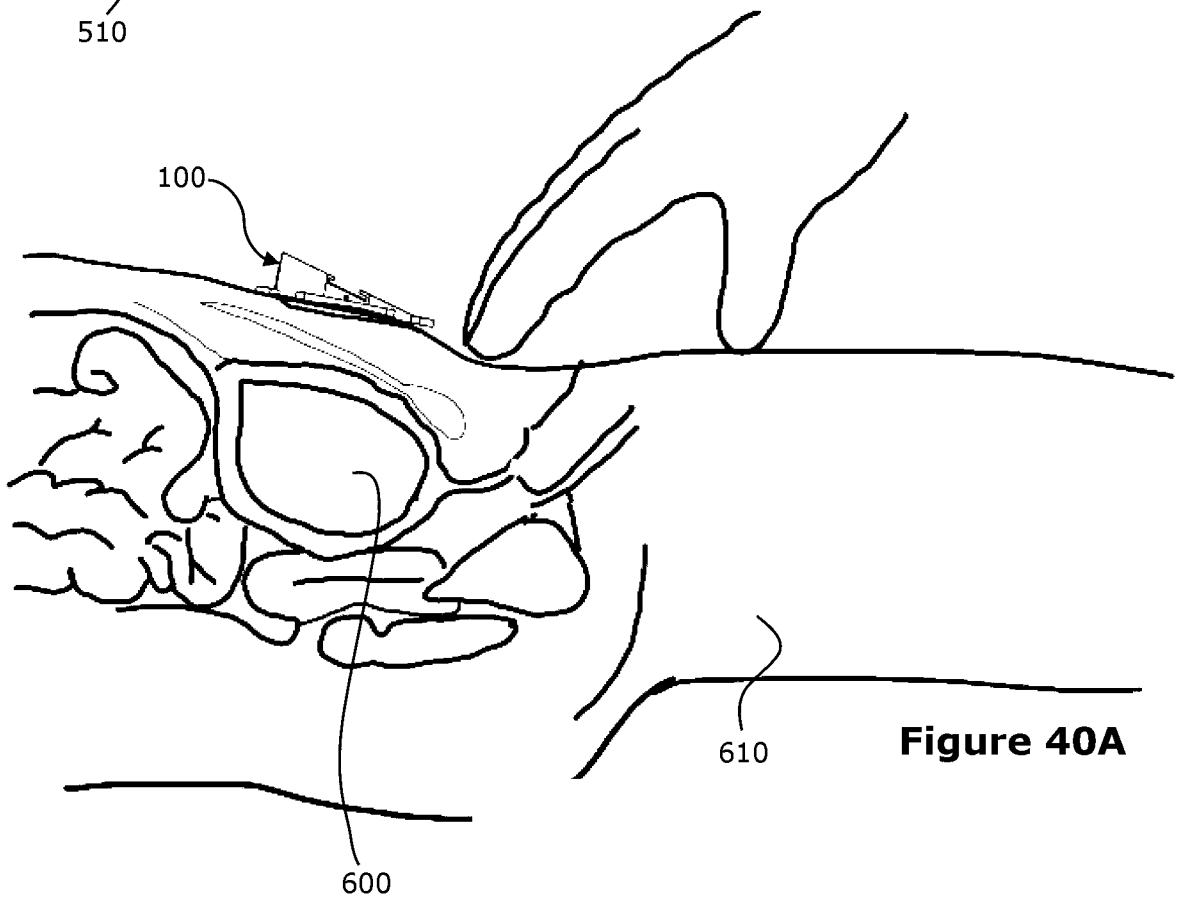
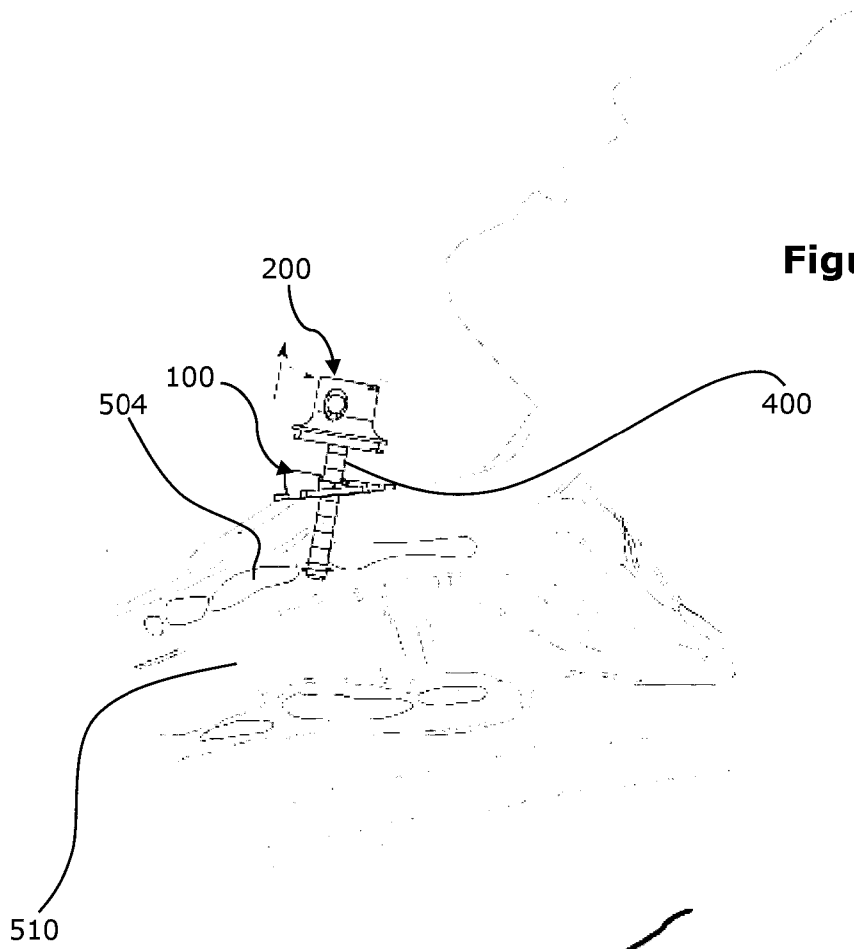


Figure 40A

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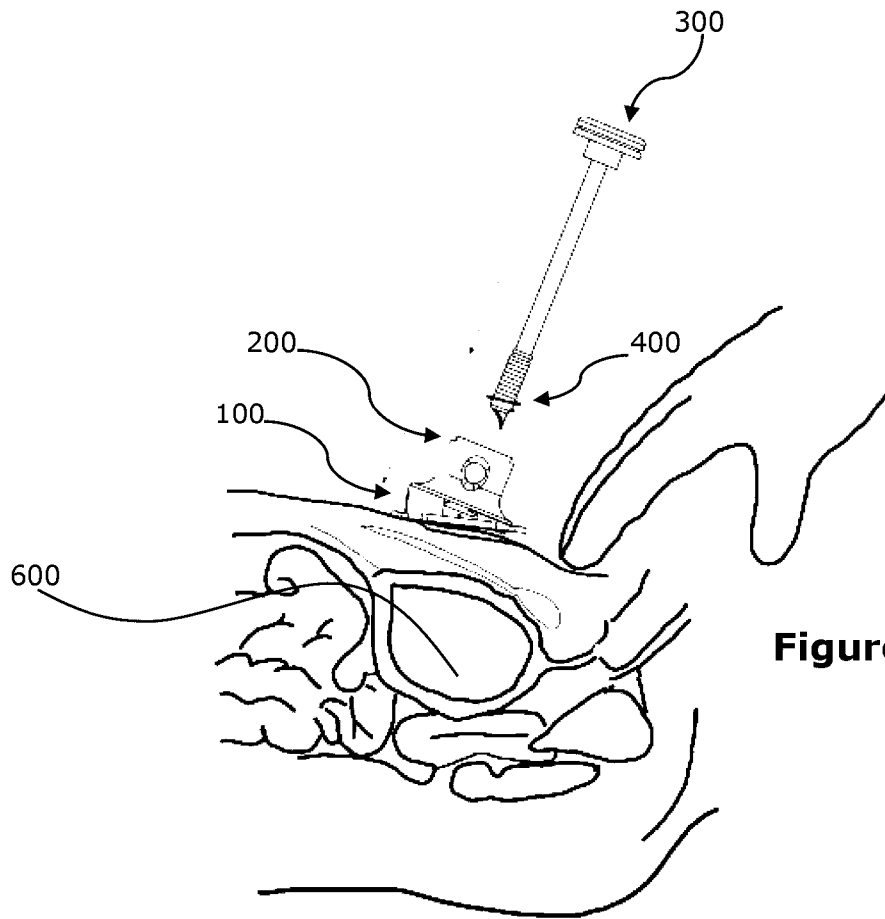


Figure 40B

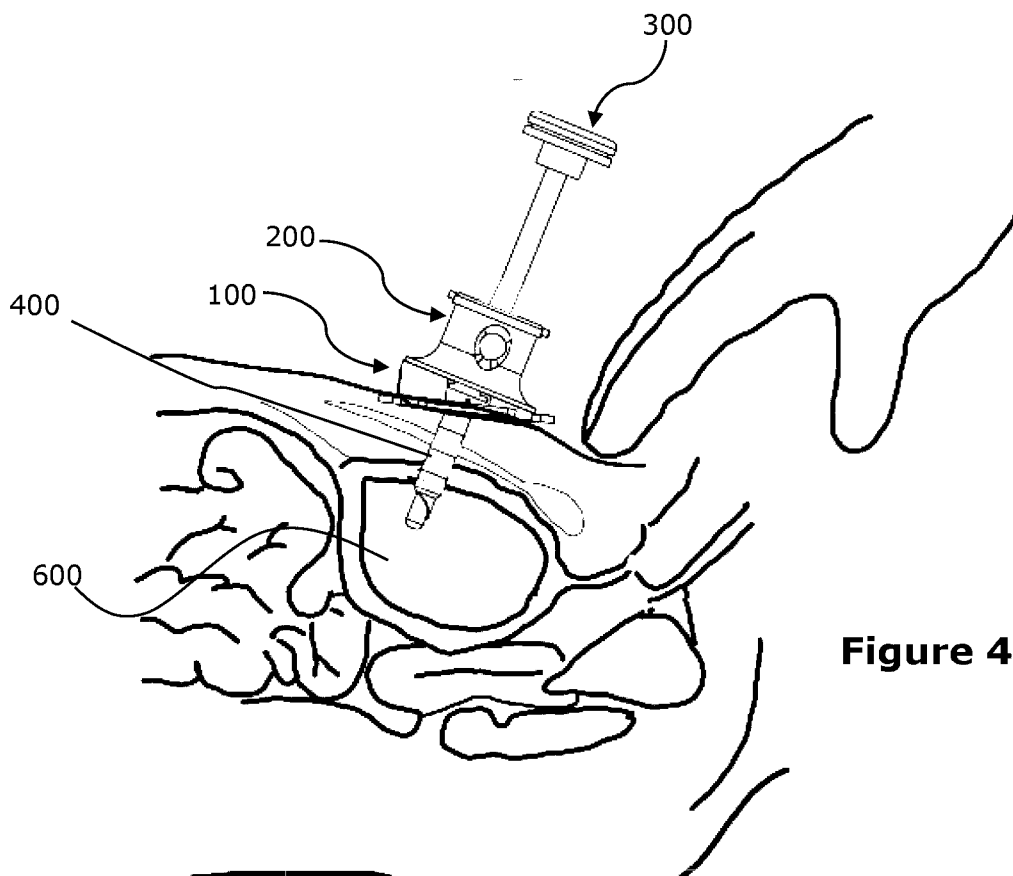


Figure 40C

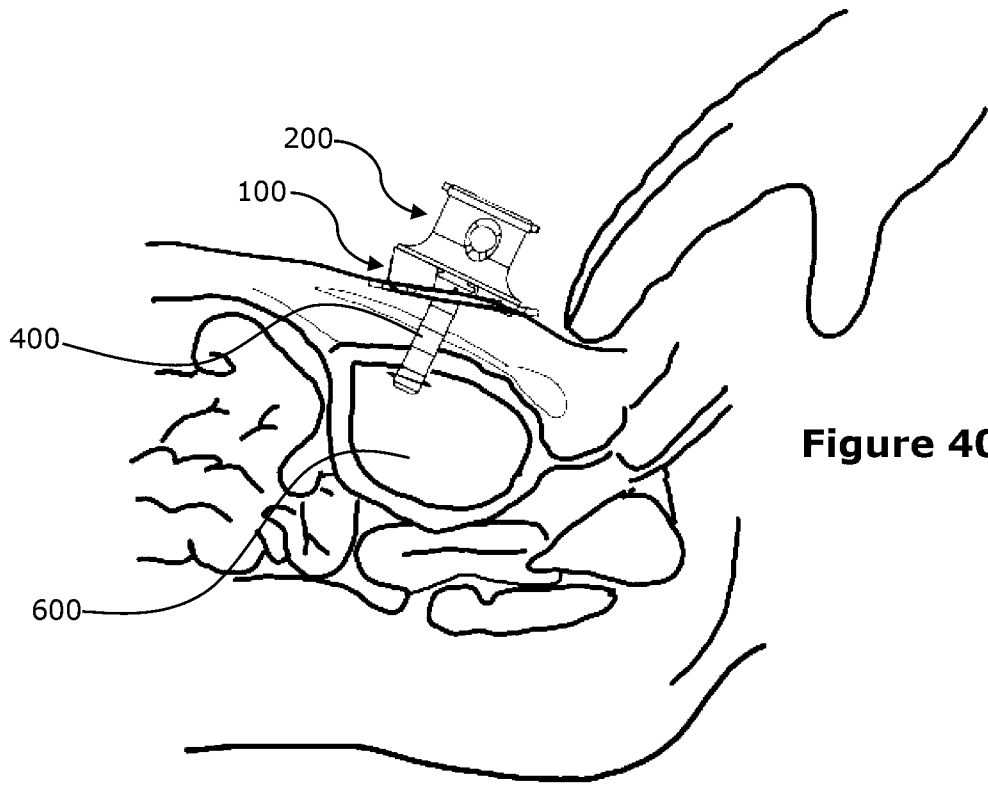


Figure 40D

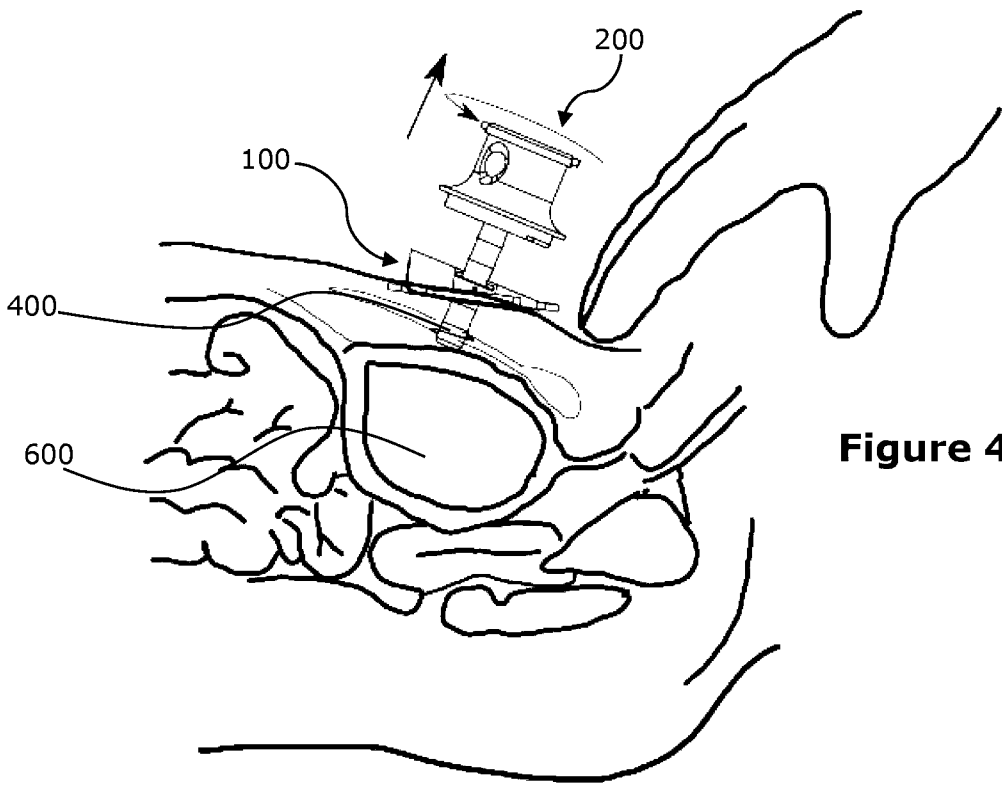


Figure 40E



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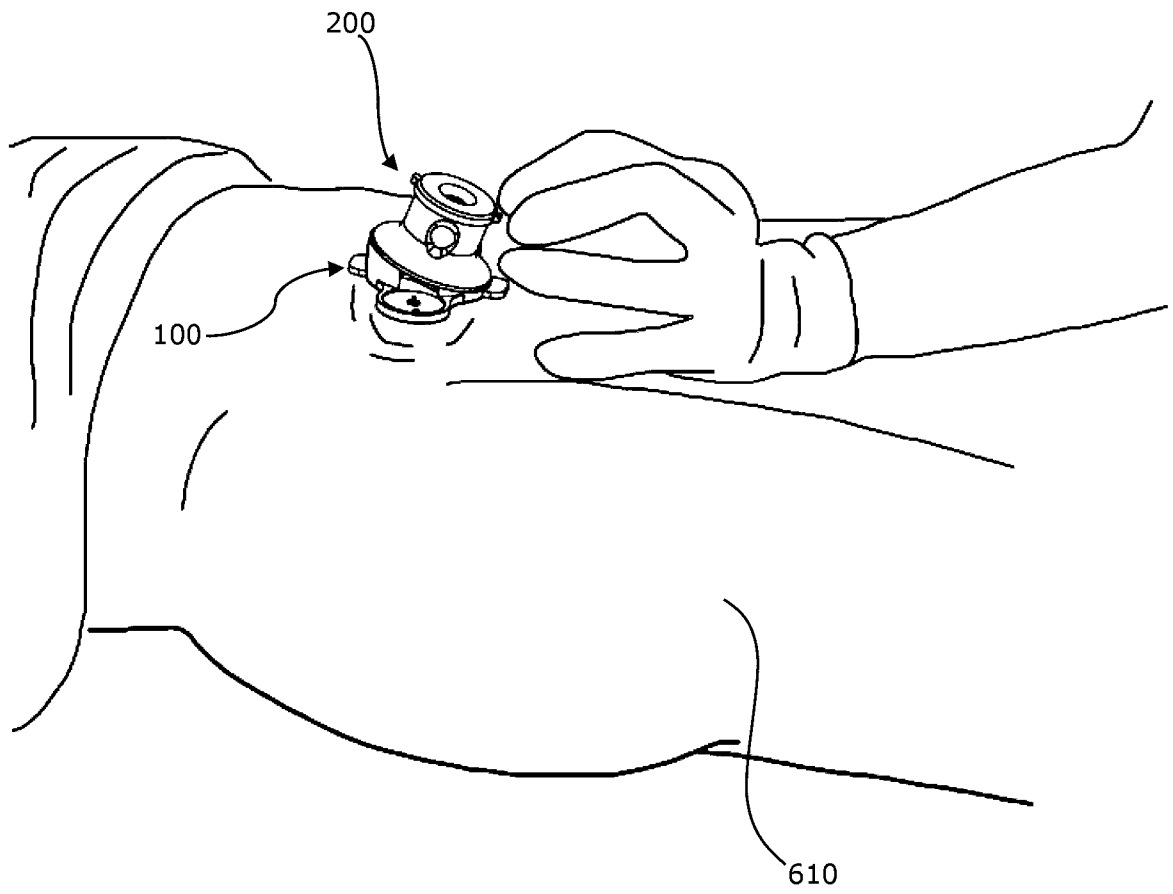
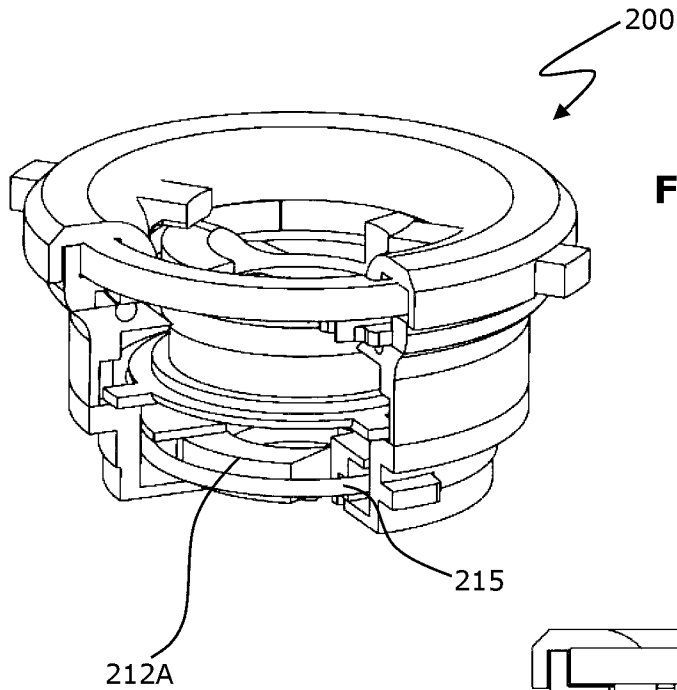
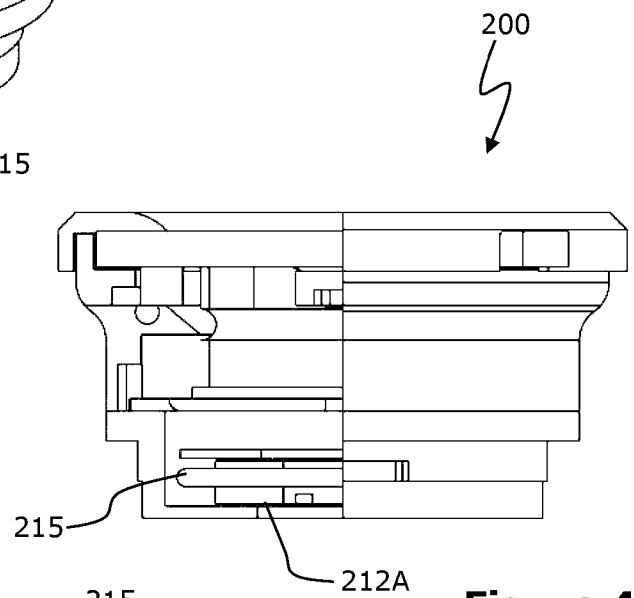


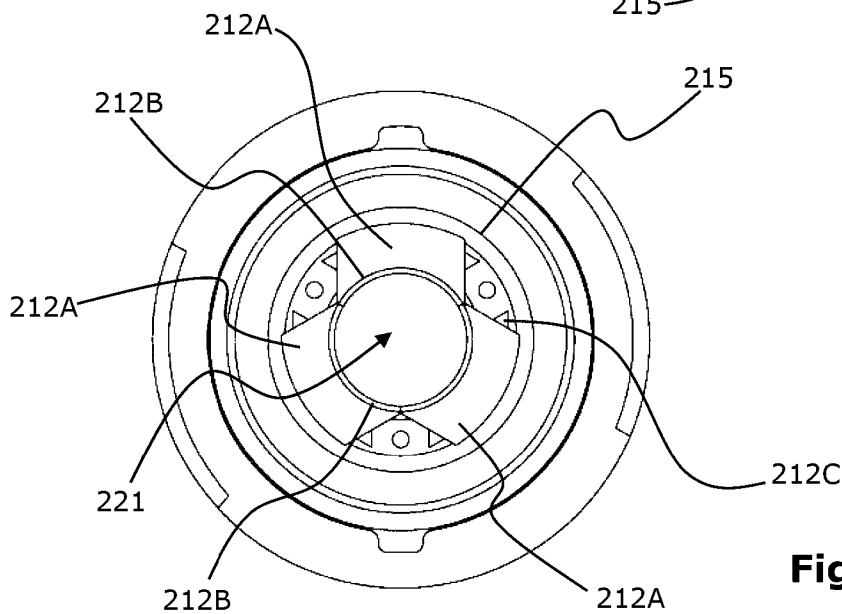
Figure 41



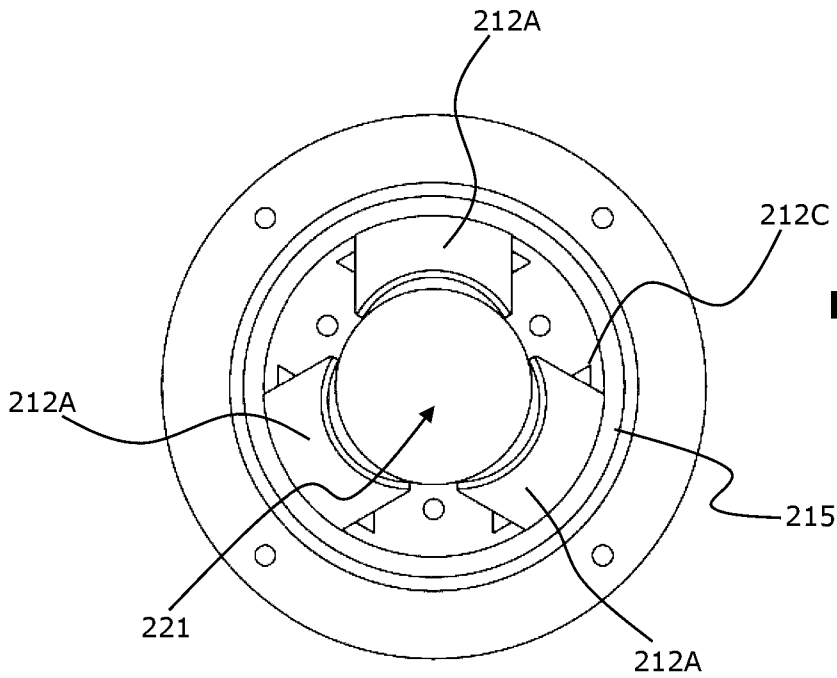
**Figure 42**



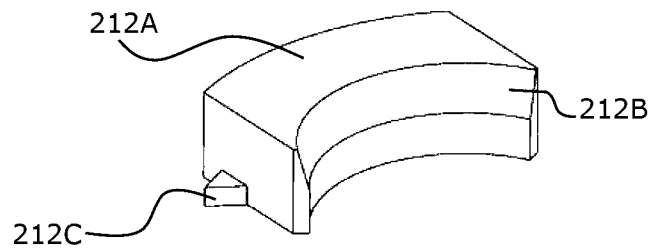
**Figure 43**



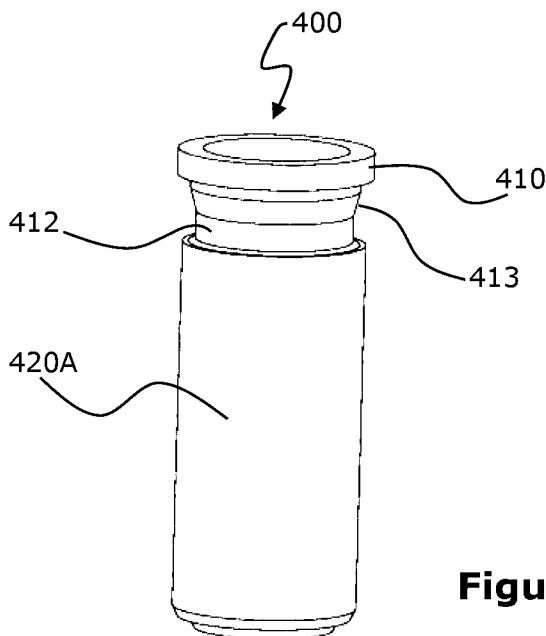
**Figure 44**



**Figure 45**



**Figure 46**



**Figure 47**

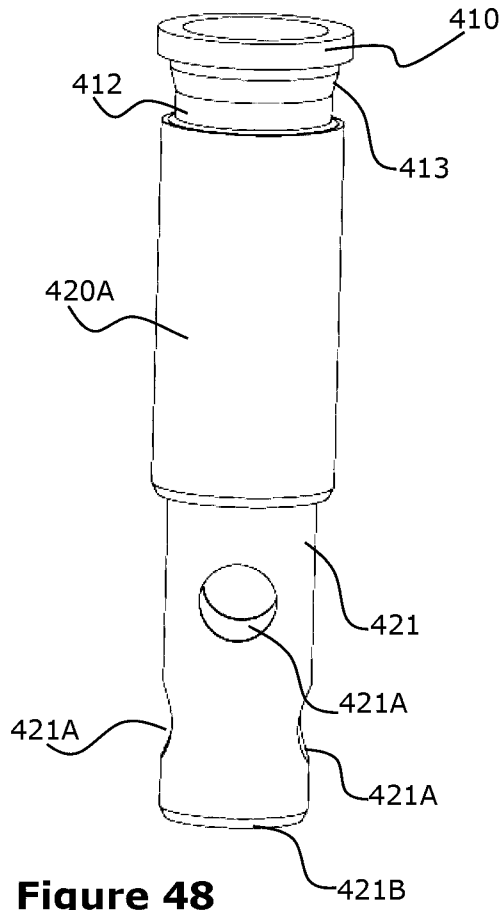


Figure 48

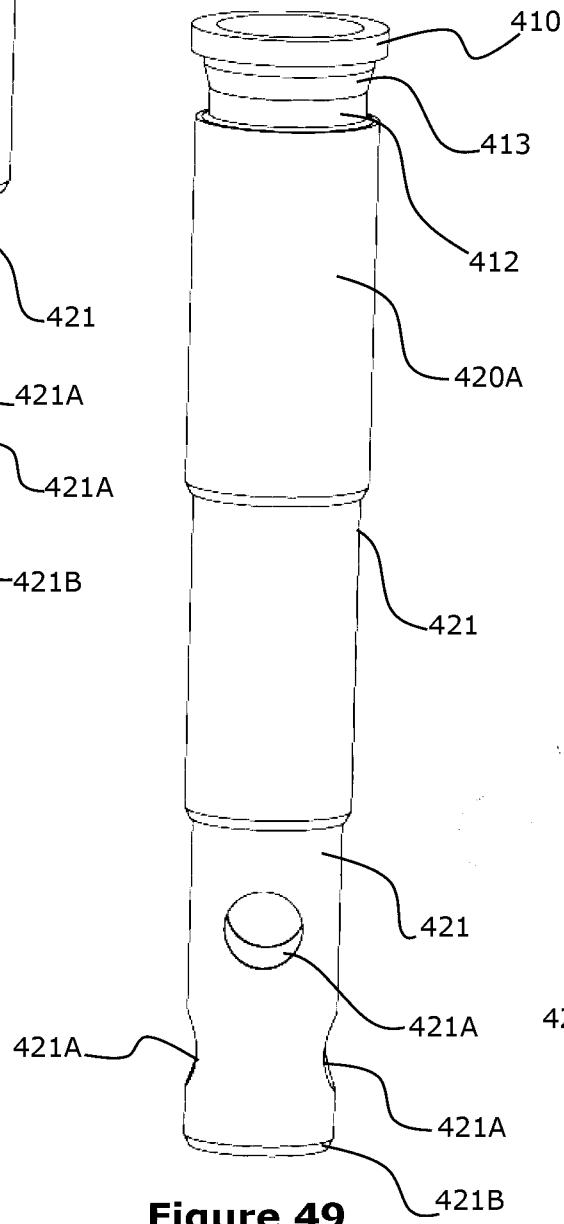


Figure 49

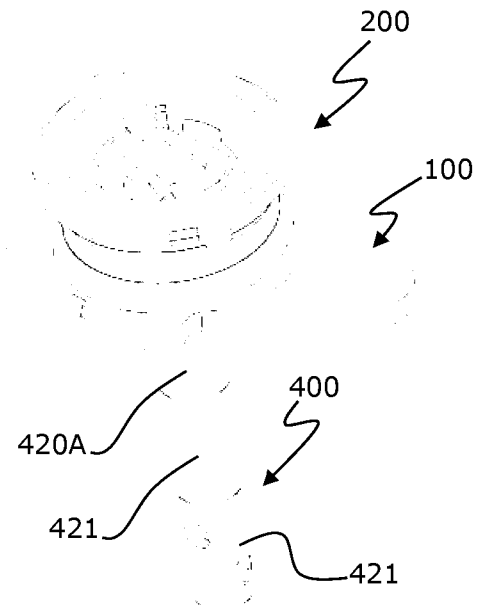
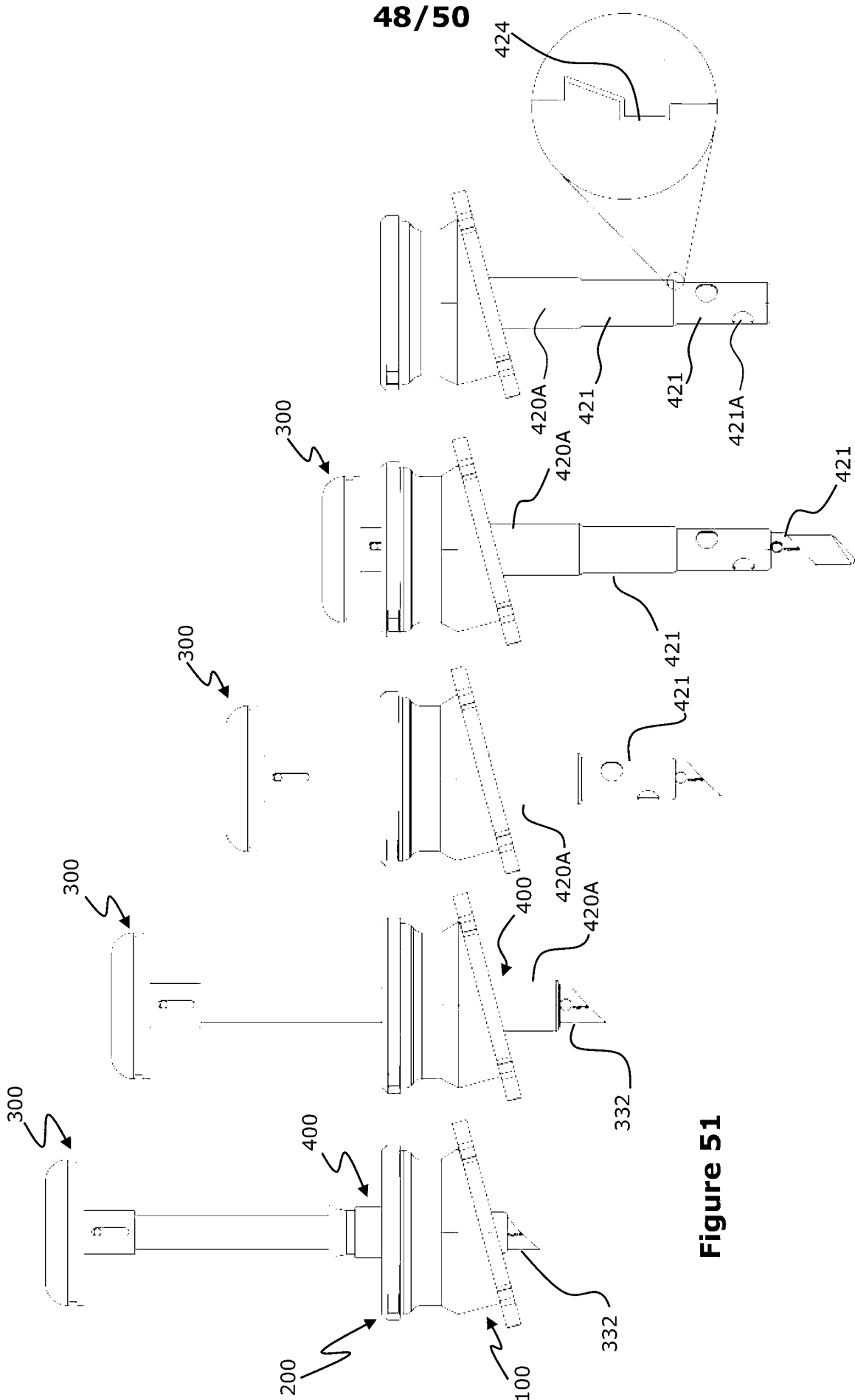


Figure 50



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Figure 51

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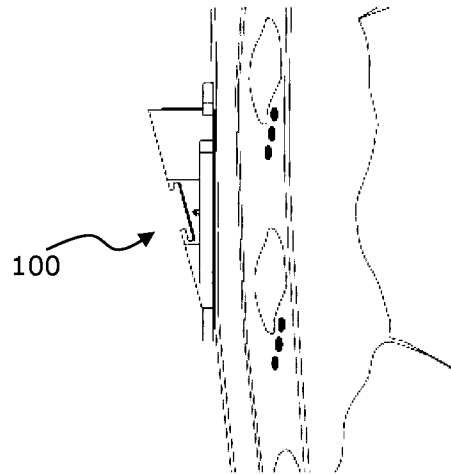


Figure 52A

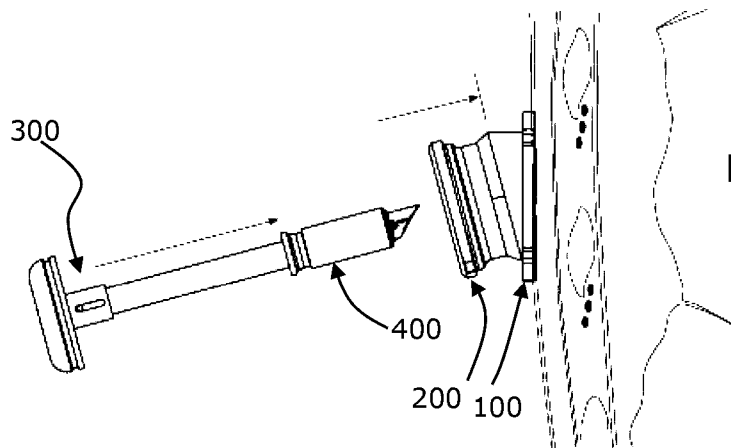


Figure 52B

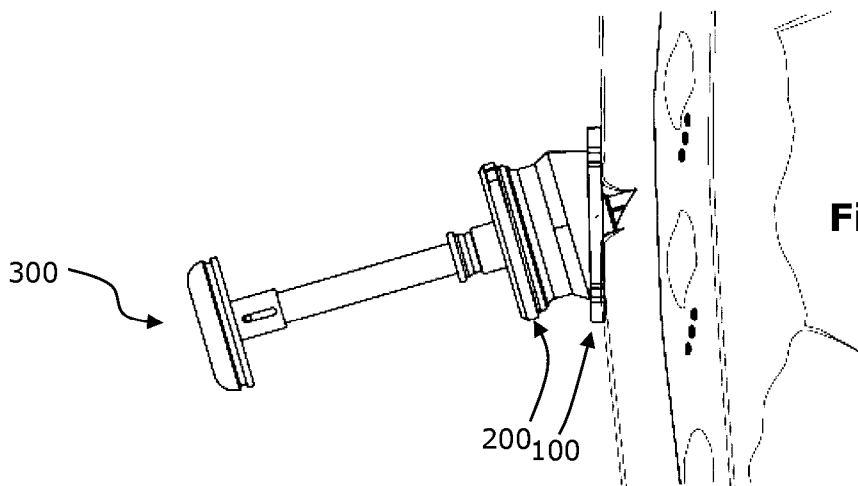


Figure 52C

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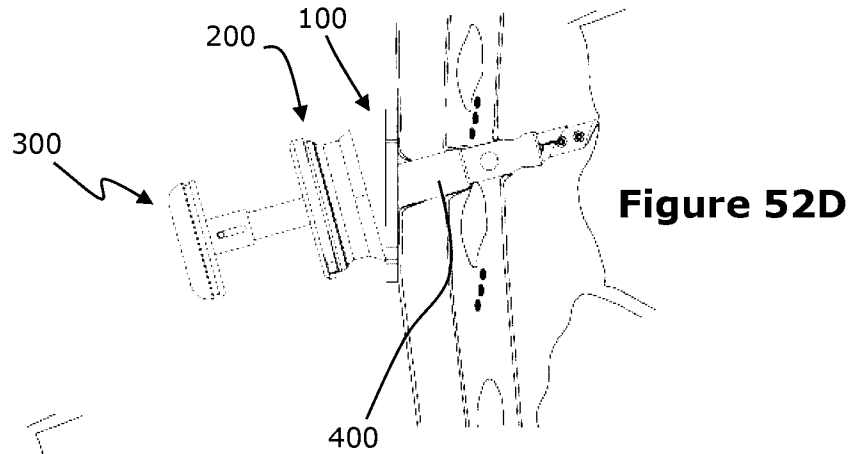


Figure 52D

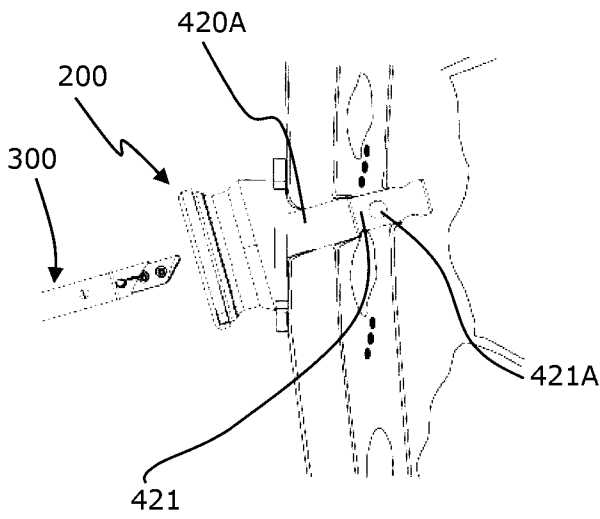


Figure 52E

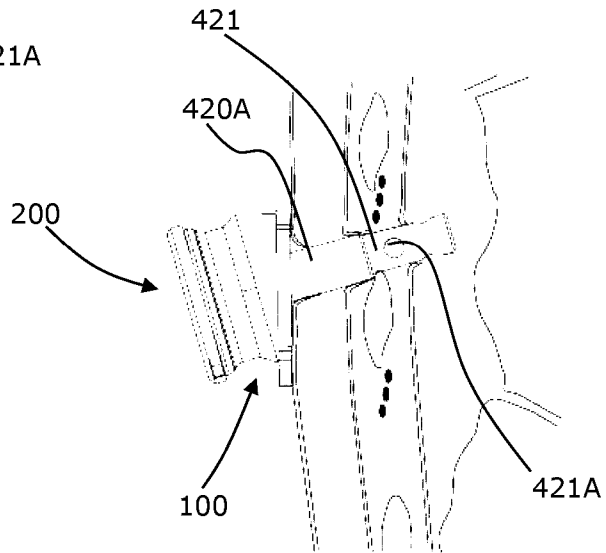


Figure 52F

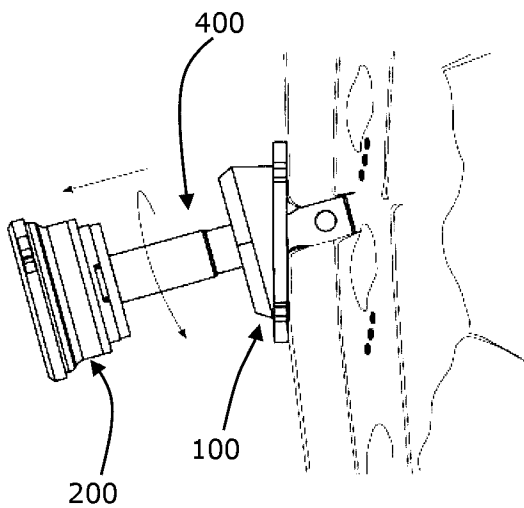


Figure 52G

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2017/051286

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> <b>A61M 1/04 (2006.01) A61B 17/34 (2006.01)</b>		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
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) DATABASES: PATENW, GOOGLE PATENTS and ESPACENET; CPCs/IPC: A61, A61B17/3415, A61B17/3431, A61B17/3496, A61B2017/00809, A61B2017/00991, A61B2017/3427, A61B2017/3443, A61B2017/348/LOW, A61B2017/3492, A61B17/3498, A61B2090/034, A61B2090/08021, A61B2090/0807/LOW, A61M1/00, A61M1/04, A61M2210/101, A61M25/0102, A61M25/0105, A61M2025/0175, A61M27/00, A61M39/0247/LOW, A61M39/24; and keywords: obturator, cut, blade, detachable cannula, locking, pleural decompression, telescopic, one-way valve, fluid extraction, base, plate, and like terms.  Applicant(s)/Inventor(s) name searched in PATENW and internal databases provided by IP Australia.		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier application or patent but published on or after the international filing date	"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
"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)	"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
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
Date of the actual completion of the international search 13 February 2018	Date of mailing of the international search report 13 February 2018	
Name and mailing address of the ISA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Authorised officer  Ezrela Hollis AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61262832869	



<b>INTERNATIONAL SEARCH REPORT</b>		International application No. <b>PCT/AU2017/051286</b>
C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 1204381 B1 (GAYA LIMITED) 23 November 2005 abstract, paragraph [0049], [0050]-[0053], [0060]-[0061], [0072] and [0077], figures 1-2 and 18-19 paragraph [0053], figures 1-2	1-25, 27-29 26, 30-38
A	US 2005/0234390 A1 (BUCKMAN et al.) 20 October 2005 paragraphs [0053], [0069], [0079] and [0085], figure 5A	4, 11-12, 19, 28
A	US 2008/0086075 A1 (ISIK et al.) 10 April 2008 paragraph [0058], figure 11A	14
A	EP 1599143 B1 (SIMPSON et al.) 29 January 2014 whole document	1-29
A	US 2007/0005087 A1 (SMITH et al.) 04 January 2007 paragraph [0040], figures 2-3	30-38
A	US 2010/0324488 A1 (SMITH) 23 December 2010 paragraph [0040], figures 3-5	30-38
A	US 5385552 A (HABER et al.) 31 January 1995 column 7 lines 3-6, figure 1	30-38

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including
2.  Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

**See Supplemental Box for Details**

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
**1-29**

**Remark on Protest**

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

**Supplemental Box****Continuation of: Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-29 are directed to a pleural decompression system for establishing and maintaining an opening to an anatomical space of a body and its method of use. The feature of the locking portion of the cannula being retained in the valve assembly is specific to this group of claims.
- Claims 30-38 are directed to a base receiving an obturator assembly for establishing and maintaining an opening to an anatomical space of a body. The feature of the base comprising a plate having an aperture configured to receive the obturator assembly is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is the base comprising a plate having an aperture configured to receive the obturator assembly.

However this feature does not make a contribution over the prior art because it is disclosed in:

**D1: EP 1204381 B1** (paragraph [0053], figures 1-2): The O rings 905 are construed as the base comprising a plate having an aperture that receives an obturator assembly 703.

**D5: US 2007/0005087 A1** (paragraph [0040], figures 2-3): The housing base 106 is construed as the base comprising a plate having an aperture that receives an obturator assembly 100.

**D6: US 2010/0324488 A1** (paragraph [0040], figures 3-5): The housing base 108 is construed as the base comprising a plate having an aperture that receives an obturator assembly 100.

**D7: US 5385552 A** (column 7 lines 3-6, figure 1): The finger ledge 182 is construed as the base comprising a plate having an aperture that receives an obturator assembly 6.

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a posteriori*.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/AU2017/051286**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

<b>Patent Document/s Cited in Search Report</b>		<b>Patent Family Member/s</b>	
<b>Publication Number</b>	<b>Publication Date</b>	<b>Publication Number</b>	<b>Publication Date</b>
EP 1204381 B1	23 November 2005	EP 1204381 A2	15 May 2002
		EP 1204381 B1	23 Nov 2005
		IE S990659 A2	21 Feb 2001
		WO 0108563 A2	08 Feb 2001
US 2005/0234390 A1	20 October 2005	US 2005234390 A1	20 Oct 2005
		US 7135010 B2	14 Nov 2006
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		AU 2003277157 A1	23 Apr 2004
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EP 1599143 B1	29 January 2014	EP 1599143 A2	30 Nov 2005
		EP 1599143 B1	29 Jan 2014
		AU 2004209999 A1	19 Aug 2004
		AU 2004209999 B2	29 Apr 2010
		AU 2010201427 A1	29 Apr 2010
		AU 2010201427 B2	03 Jun 2010
		CA 2514857 A1	19 Aug 2004
		CN 1756513 A	05 Apr 2006
		CN 1756513 B	24 Nov 2010
		HK 1090271 A1	10 Jun 2011
		US 2005273116 A1	08 Dec 2005
		US 7811293 B2	12 Oct 2010
		US 2007167966 A1	19 Jul 2007
		US 7842058 B2	30 Nov 2010
		WO 2004069035 A2	19 Aug 2004
		WO 2004069498 A2	19 Aug 2004

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

Form PCT/ISA/210 (Family Annex)(July 2009)

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

**PCT/AU2017/051286**

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<b>Patent Document/s Cited in Search Report</b>		<b>Patent Family Member/s</b>	
<b>Publication Number</b>	<b>Publication Date</b>	<b>Publication Number</b>	<b>Publication Date</b>
US 2007/0005087 A1	04 January 2007	US 2007005087 A1	04 Jan 2007
		AU 2006202642 A1	18 Jan 2007
		AU 2006202642 B2	15 Sep 2011
		CA 2550876 A1	30 Dec 2006
		EP 1738700 A1	03 Jan 2007
		JP 2007007395 A	18 Jan 2007
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US 2010/0324488 A1	23 December 2010	US 9320541 B2	26 Apr 2016
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		AU 2008219731 B2	12 Sep 2013
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		EP 2129413 B1	30 Apr 2014
		JP 2010519953 A	10 Jun 2010
		JP 5580054 B2	27 Aug 2014
US 5385552 A	31 January 1995	WO 2008106085 A1	04 Sep 2008
		US 5385552 A	31 Jan 1995

**End of Annex**