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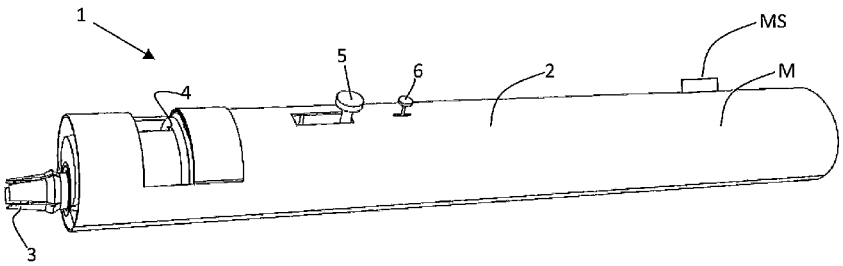

FIG. 1A

(57) Abstract: A dermal punch device for automatically extracting a sample of tissue of a predetermined size and shape from a body comprising a retractable cutter and a sutureless biopsy closure mechanism that includes a wound closure fastener member adapted to be disposed over a biopsy region after the performance of the biopsy, wherein wound closure fastener member is applied without the need of several instruments to seal the wound. The wound closure fastener member is dispensed by a sutureless biopsy closure dispenser located at the same distal end of the biopsy punch device surrounding the biopsy punch cutter assembly avoiding the need of separates instruments, reducing the wound closing steps and surgical procedure time.

TITLE OF THE INVENTION

BIOPSY AND SUTURELESS DEVICE

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT

N/A

RELATED APPLICATIONS

N/A

BACKGROUND OF THE INVENTION

Field of the Invention

This application relates generally to the field of extracting tissue samples from solid bodies, and more specifically to surgical instruments for extracting a biopsy or sample of tissue while providing a sutureless biopsy wound site closure.

Discussion of the Background

Annually thousands of persons and animals are tested for numerous skin problems such as abnormal skin growths and cancers, as well as skin eruptions. Surgical instruments, such as a dermal punch and others are used to obtain samples of skin lesions for diagnostic purposes. The procedure involves the insertion of a cutting surgical instrument into the patient's skin wherein the cutting surgical instrument comprises a cylindrical blade at the distal end of an inert plastic or metal rod. After abutting the cylindrical blade to the skin the cutting instrument is rotated so as to cut out and remove a plug

of the tissue of interest. The tissue is then submitted to be analyzed by a pathologist in order to obtain a diagnosis.

For example in a skin punch biopsy, the skin surrounding the lesion is pulled taut, and the punch is firmly introduced into the lesion and rotated to obtain the tissue specimen. The punch must go deep enough to include an average of a 6mm depth in order to include the lower dermis and subcutaneous fat. The plug is lifted with forceps or a needle. The specimen is placed in a properly labeled sterile container.

After the removal of the tissue, the traditional dermal punch biopsy usually leaves a circular wound opening which is then normally closed by a suture. Some of the problems associated with this technique include, but are not limited to, the use of multiple instruments in performing the suturing which typically requires at least a needle holder, scissors, suture material and forceps. Other problems are the potential for a needle stick injury and the increased cost of the suture and sterilization of the instruments used. Furthermore, there is also a need for more than one person to perform the procedure, for example a nurse has to prepare a sterile instrument tray, pass the instruments to the surgeon, place a bandage on the wound following the procedure and finally pick up and resterilize the instruments.

There is a need for a device that provides a streamlined procedure which does away with the time consuming pre and post operative phase, reduces the currently needed personnel, and instruments and provides an improved sutureless wound closure at the site of the biopsy wound. It should be relatively inexpensive, easy to apply, efficient and not require subsequent procedures.

SUMMARY OF THE INVENTION

The present disclosure describes a biopsy punch device operated by a single operator, wherein the biopsy punch device comprises a mean to obtain the tissue sample while achieving sutureless closing of the biopsy wound site without a need of other instruments. The biopsy punch device cuts and extracts the tissue without lifting the device from the skin. After the tissue is removed the biopsy punch device achieves sutureless closing of the biopsy wound site without the need for additional instruments such as needles, suture material, forceps and scissors. The suture process is achieved by deploying a fastener member having resilient properties configured for this purpose.

The first embodiment of the biopsy punch device comprises an elongated hollow cylinder with a distal end having an exposed cylindrical cutter which rotates during the incision procedure and is then retracted into the body of the elongated hollow cylinder while the cylindrical cutter assists with the grasping

and removing of the tissue sample and; wherein said cylindrical cutter is coupled to a sutureless fastening mechanism. The sutureless fastening mechanism comprises a sutureless dispenser to dispense a biopsy closure fastener member. The sutureless biopsy closure dispenser releases the biopsy closure fastener member at the wound site which renders the biopsy wound site closed by approximating the opposing edges of the wound. The biopsy closure fastener member comprises a two-pronged fastener having resilient properties, wherein the two-pronged fastener may expand to a distance at least equal to the diameter of the wound created by the cylindrical cutter and then contracts when released therein. The present biopsy punch device eliminates the need for multiple instruments and their handling, sutures and speeds-up the process.

It is another objective to provide a retractable biopsy punch actuated by an electric motor, wherein the biopsy punch cutter comprises a constant and uniform depth to provide a tissue specimen having a uniform thickness for accurate diagnosis.

It is a further objective to provide a biopsy punch cutter blade that is inexpensive to manufacture such that it can be made disposable.

It is a further objective to provide a biopsy punch cutter blade that is configured to assist with the removal of the tissue sample.

Another objective is to provide a method for suturing during the procedure without the need of several instruments.

Another objective is to minimize time and effort during the process of closing the wound site.

The preferred embodiment for a biopsy and sutureless device constructed pursuant to this application, both as to its configuration and its mode of operation will be best understood, and additional objects and advantages thereof will become apparent, by the following detailed description taken in conjunction with the accompanying drawings.

The applicant hereby asserts, that the disclosure of the present application may include more than one invention, and, in the event that there is more than one invention, that these inventions may be patentable and non-obvious one with respect to the other.

Furthermore, the purpose of the accompanying abstract is to enable the U.S. Patent and Trademark Office and the public generally, and especially the scientists, engineers, and practitioners in the art who are not familiar with patent or legal terms or phraseology, to determine quickly from a cursory inspection the nature and essence of the technical disclosure of

the application. The abstract is neither intended to define the disclosure of the application, which is measured by the claims, nor is it intended to be limiting as to the scope of the disclosure in any way.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings which are incorporated herein constitute part of the specifications and illustrate the preferred embodiment of a biopsy and sutureless device constructed pursuant to an example embodiment of the present invention.

FIGS. 1A through 1B are perspective views of an exemplary biopsy punch device in accordance with the principles of the present example embodiment of the present invention.

FIG. 2 is a circuit diagram of the battery, rotation control system and motor.

FIGS. 3A through 3C are views of the three principle stages for the rotation control system in accordance with the principles of the present example embodiment of the present invention.

FIGS. 4A through 4B are several views of an exemplary biopsy punch device without motor and battery connection in accordance with the principles of the present example embodiment of the present invention.

FIGS. 5A through 5C are several views of an exemplary

biopsy punch device inner structure in accordance with the principles of the present example embodiment of the present invention.

FIGS. 6A through 6B are cross-sectional views of an exemplary biopsy punch device inner structure in accordance with the principles of the present example embodiment of the present invention.

FIGS. 7A through 7C are perspective and cross-sectional views of an exemplary biopsy cutter and biopsy cutter shaft assembly in accordance with the principles of the present example embodiment of the present invention.

FIGS. 8A through 8B are perspective and exploded views of an exemplary biopsy cutter shaft and motor shaft assembly in accordance with the principles of the present example embodiment of the present invention.

FIG. 9 is an exploded view of an exemplary biopsy cutter shaft inner surface and motor shaft assembly in accordance with the principles of the present example embodiment of the present invention.

FIG. 10 is an exploded perspective view of an exemplary motor shaft assembly in accordance with the principles of the present example embodiment of the present invention.

FIGS. 11A through 11B are perspective and exploded views of a first exemplary biopsy cutter fixing means in accordance

with the principles of the present example embodiment of the present invention.

FIGS. 12A through 12E are perspective and exploded views of several exemplary biopsy cutters in accordance with the principles of the present example embodiment of the present invention.

FIG. 13 is a view of a second exemplary biopsy cutter fixing mean in accordance with the principles of the present example embodiment of the present invention.

FIG. 14 is a cross-sectional view of a biopsy cutter coupled to the cutter shaft in accordance with the principles of the present example embodiment of the present invention.

FIGS. 15A through 15C are perspective and exploded views of an exemplary bearing shaft, cutter shaft and cutter assembly in accordance with the principles of the present example embodiment of the present invention.

FIG. 16 is a view of an exemplary bearing shaft in accordance with the principles of the present invention.

FIGS. 17A through 17B are several views of an exemplary biopsy closure member path-definer element in accordance with the principles of the present example embodiment of the present invention.

FIGS. 18A through 18C are several views of an exemplary

sutureless mechanism assembly in accordance with the principles of the present example embodiment of the present invention.

FIGS. 19A through 19B are several views of an exemplary sutureless mechanism assembly with alternative elastic member configurations in accordance with the principles of the present example embodiment of the present invention.

FIG. 20 is a cross-sectional view of an exemplary sutureless mechanism actuator in accordance with the principles of the present example embodiment of the present invention.

FIG. 21 is a cross-sectional view of an exemplary sutureless mechanism actuator assembly in accordance with the principles of the present example embodiment of the present invention.

FIG. 22 is a cross-sectional view of an exemplary sutureless mechanism actuator assembly in accordance with the principles of the present example embodiment of the present invention.

FIG. 23 is a front view of an biopsy punch device in accordance with the principles of the present invention.

FIGS. 24A through 24C are several views of an exemplary biopsy closure or sutureless fastener member in accordance with the principles of the present example embodiment of

the present invention.

FIG. 25 shows the loading process for the biopsy closure member in the biopsy punch device in accordance with the principles of the present example embodiment of the present invention.

FIG. 26 shows the biopsy closure member releasing process in accordance with the principles of the present example embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1A shows an exemplary biopsy punch device in accordance with the principles of the present application. The first embodiment for a biopsy punch device **1** constructed in accordance with this application comprises an elongated hollow body housing **2** with a distal end having an exposed cylindrical cutter **3**, a sutureless fastener member **4**, loading shaft **5**, a trigger **6** and a automatic system comprising a motor **M** and a control system **MS**.

The automation system is mechanically coupled to the biopsy punch cutter **3** assembly, wherein the automation system is located at the proximal end of the elongated hollow body **2**. The automation system comprises a power supply or battery **MB** electrically coupled to the motor **M** by means of a rotation control system **MS**, wherein the rotation control system **MS** regulates the behavior of the motor **M**, more particularly the

rotation of the motor shaft **15**, as shown in FIG. 1B, which is mechanically coupled to the biopsy punch cutter **3** assembly.

FIG. 2 represents the circuit diagram for the automation system wherein the power supply **MB**, such as a battery is electrically coupled to the rotation control system **MS** and said control system **MS** comprises at least two outputs connected to the motor **M** for controlling the shaft **15** rotation. The rotation control system **MS** provides at least three different stages. The three different stages are achieved, for example, using a double pole center-off, such as a Center-Off Rocker switch. The switch **S** diverts or regulates the current flowing to the motor, in the three different stages as mentioned. The position of the switch **S** with respect to the internal connection of the rotation control system **MS** inner circuit, as shown in FIG. 3A through FIG. 3C, provide a first stage wherein the current supplied to the motor generates a clock-wise rotation at the rotor of the motor **M**, as shown in FIG. 3A. FIG. 3B shows the second stage wherein no current is supplied to the motor resulting in no rotation at the rotor of the motor **M** and FIG. 3C shows the third stage wherein the current supplied to the motor **M** generates a counter clock-wise rotation or a rotation direction opposed to the first stage rotation at the rotor of the motor **M**. Several rotation control systems **MS** or circuit configurations can be used to control the rotational movement of the motor **M**, which

consequently rotates the cutter **3**. However, since both pieces are mechanically coupled it is important to understand that the selection of the motor **M**, more particularly the rotation direction, speed and torque depends on the application of fuction being curried out wethers incision, pick up of tissue or retraction of the cutter **3** into the body of the elongated hollow cylinder.

FIGS. 4A through 4B are several views of an exemplary biopsy punch device without motor and battery connection in accordance with the principles of the present example embodiment of the present invention, wherein the motor shaft **15** is mechanically coupled to the biopsy punch cutter **3** assembly. An opening is provided at the elongated hollow body housing **2**. The opening serves as an entrance to a chamber **C** created at the front part of the elongated hollow body housing **2** which is closed by means of a sliding cover **2a**. Inside the chamber **C** a sutureless fastener member **4** is located.

FIGS. 5A through 5C are directed to the structure inside the elongated hollow body housing **2** excluding the automation system. The biopsy punch device inner structure comprises a biopsy punch cutter **3** assembly and a sutureless fastener member **4** dispenser assembly, wherein the sutureless fastener member dispenser assembly is mechanically coupled to the biopsy punch cutter **3** assembly and located at the same distal end of the

elongated hollow body housing **2**. However, it is important to understand that in the exemplary embodiment the biosy punch assembly and sutureless fastener member dispenser work independently from each other.

FIGS. 5A through 5C show biopsy punch cutter **3** assembly comprising a cutter **3** and a cutter shaft **11** (not show in FIG. 5A through 5C) surrounded by the sutureless member dispenser assembly comprising a sutureless path-definer body **8** with flanges **8a**, a piston **7**, a sutureless fastener member **4**, loading shaft **5**, a trigger **6**, a resilient elastic member **9** and a stopper **10**.

FIGS. 6A through 6B provides a cross sectional view of the biopsy punch device showing in more detail the biopsy punch device inner structure in combination with the elongated hollow body housing **2**. The biopsy punch cutter **3** assembly comprises a cutter **3**, a bearing **B** and a cutter shaft **11**, wherein the cutter shaft **11** comprises a threaded inner surface **111** coupled to the motor shaft **15** which is explained below in more detail. A bearing shaft **12** with a channel or groove **12a** surrounds the biopsy punch cutter **3** assembly. The bearing shaft **12** is coupled to the sutureless member dispenser assembly wherein the elastic resilient member **9** is located between the piston **7** distal ends and the stopper **10**. The stopper **10** is fixed to the elongated hollow body housing **2**. At the front part of the biopsy punch

device, close to the cutter **3**, a chamber **C** is created between the path-definer body **8** and the elongated hollow body housing **2**. The gap between the path-definer body **8** and the elongated hollow body housing **2** serves as a path for the sutureless fastener member **4**.

FIGS. 7A through 7C shows more detail of the cutter **3** and cutter shaft **11**. FIG. 7A shows the cutter shaft **11** attached to the cutter **3** by attaching means that fixes the cutter **3** in a particular position with respect to the cutter shaft **11**. A bearing **B** is fixed to the cutter shaft **11** at the distal end, wherein the bearing **B**, such as a ball bearing, surrounds the cutter shaft **11** allowing the rotational movement of the cutter shaft **11** and as result the rotational movement of the cutter **3**. The ball bearing **B** as shown in FIG. 7B comprises an inner wall, wherein the inner wall is the cutter shaft **11**, an outer wall **OW** **and** several balls located between the cutter shaft **11** and outer wall **OW**. The bearing **B** comprises at least two bearing protrusions **B1**, wherein each bearing protrusion **B1** extends away from the bearing **B** in order to assist with the linear displacement of the cutter shaft **11**. Further, the cutter shaft **11**, as mentioned above and as shown in FIG. 7C, comprises a threaded inner path **111** forming a helix configuration inner path wherein the motor shaft **15** is mechanically coupled. The motor shaft **15** is intended to through the threaded path **111** exerting a

linear displacement of the cutter shaft **11** until it reaches a particular end. While the motor shaft **15** displaces through the threaded path **111** no rotational movement is transmitted to the cutter shaft **11**, however when the motor shaft **15** reaches one of the ends and if the rotation of the motor shaft **15** keeps in the same direction the result is the transmission of the rotation from the motor shaft **15** toward the cutter shaft **11**. Further, if the rotation of the motor shaft **15** changes directions the result of the change in movement is the linear displacement of the cutter shaft **11** in the direction opposed to the displacement through the treaded path **111**. Eventually the motor shaft **15** reaches the opposed end and the rotational movement is transmitted to the cutter shaft **11** in an opposed direction to the rotation achieve when the opposed end is reached.

FIG 8A through FIG 8B show in more details the shaft cutter **11**, wherein the shaft cutter **11** comprises several projections **11b** at the distal end serving as the attaching means, as previously mentioned. The threaded path **111** comprises a first helical groove **111a** and a second helical groove **111b**. The use of two helical grooves **111a**, **111b** assists with the stability of the cutter shaft **11** displacement and rotation. FIG 9 clearly shows the threaded inner path **111** with the surface first spiral groove **111a** and a second helical groove **111b** wherein the motor shaft **15** travels. The rotational movement of the motor shaft **15** results

in a linear displacement of the cutter shaft **11** as long the motor shaft **15** does not reaches any of the two ends of the threaded inner path **111**. In order to provide the rotational movement of the motor shaft **15** inside the cutter shaft **11** and through the threaded inner path **111** the motor shaft **15** is provided with at least a first extension **15b'** and a second extension **15b"**, both located at the distal end the motor shaft **15**, as showed in FIG 10. The first extension **15b'** and a second extension **15b"** travel along the first spiral groove **111a** and the second spiral groove **111b** respectively. Further the motor shaft **15** comprises a flat surface **15a** from where the first extension **15b'** and a second extension **15b"** extends.

FIG 11A through 14 are directed to the cutter **3**. The cutter **3** comprises at a plurality of blades **3a** made of an inexpensive and durable metal and/or plastic materials such as stainless steel blade, a middle cutter body **3c**, tapered gap **3b**, a cutter base **3d** arranged and fixing means **3e**. The plurality of blades 3a is arranged in a substantially circular contour, wherein each blade **3a** is separated by the tapered gap **3b**. The tapered gap **3b** extends from the blade **3a** through the middle cutter body **3c** until reaching the cutter base **3d** as show in FIG 11B.

The inner surface of the blades **3a** comprises at least one rib **31** which is formed by reducing the inner surface. The reduction of the inner surface is achieved by blades grooves **32**.

The ribs **31** assists with the grasping and removing of the tissue sample, therefore the configuration of the ribs **31** depends on the particular action to be performed by the cutter **3**. For example, it is preferred in to have a cutter **3** with just one rib **31** in order to obtain a tissue example, as show in FIG 13 and FIG 14, because multiple ribs may causes damages to the tissue sample instead of assisting with the grasping of the sample.

Further the middle cutter body **3c** is shaped to comprise an articulate configuration. The articulate configuration connects the blades **3a** and the cutter base **3d.** The articulate configuration serves to promote a distal compression at the tips of the blades **3a** when the articulation **3d** is compressed during the retraction of the cutter **3** inside the hollow body of the cutter shaft **11.**

The tapered gap **3b** allows the compression of the cutter **3** without the deformation of neither the blades **3a** nor the cutter base **3d** while the compressing force is exerted at the middle cutter body **3c.** While applying compressing force to the middle body **3c** the tapered tap or space between the blades **3** is reduced and simultaneously the middle body **3c** articulated section is flattened. The space reduction results in a reduction of diameter at the distal end of the blade **3** and serves as a grasping action which is assisted, as mentioned before, by ribs **31** located at the inner surface of the blade **3a.**

The compressive action or force applied to the middle body **3c** is achieved during the rotation of the motor shaft **15** that results in the linear displacement of the cutter shaft **3**, more particular in the linear displacement of the cutter **3** toward the inner surface of the bearing sleeve **12**.

FIG 15A through 16 are directed to the bearing sleeve **12**. The bearing sleeve **12** comprises a cylindrical elongated hollow body **12** with a set of channels **12a** located at the inner surface of the elongated hollow body **12**. The cutter shaft **11** is mechanically coupled to the bearing sleeve **12** by means of the bearing protrusions **B1**. The bearing sleeve **12** limits the linear movement of the cutter shaft **11** while covers part of the cutter base **3d** and cutter shaft **11**. The channels serves as guides for the bearing protrusion **B1** during the linear displacement of the cutter shaft **11**.

The bearing sleeve **12** further comprises a compressing surface **12b**. In the instant case the compressing surface **12b** is a flat surface, however it can be a tapered zone toward the inner surface of the bearing sleeve **12** in order to provide smooth contact with the middle body **3c**. During the linear displacement of the cutter shaft **11** toward the motor **M** the cutter **3** retracts as result of the mechanical connection with cutter shaft **11**. The articulation of the middle body **3c** comprises an increment in diameter, wherein the middle body **3c**

diameter fluctuates from a diameter smaller than the bearing sleeve **12** to a maximum diameter bigger than the bearing sleeve **12**. During the linear displacement of the cutter shaft **11**, due to rotational motion of the motor shaft **15**, the middle body **3c**, more particularly the area of the middle body **3c** wherein the diameter is bigger than the bearing sleeve **12**, is compressed by the compressing surface **12b**. The compressing action is performed from the middle body 3c closer to the cutter base **3d** toward the blades **3a**. As explained above, the deformation of the blade 3a is avoided by the tapered gap **3b**.

After the cutter **3** incises the patient and removes the tissue example from the patient an open wound is left in front of the biopsy punch device **1**. The biopsy device **1** is equipped with a sutureless system comprising a sutureless member dispenser assembly, as mentioned before. FIG 17 through 21 discloses in detail the sutureless system, more particularly sutureless fastener member **4** dispenser assembly comprising a sutureless path-definer body **8** with flanges **8a**, a piston **7**, a sutureless fastener member **4**, loading shaft **5**, a trigger **6**, a resilient elastic member **9** and a stopper **10**, as mentioned before. FIG 17A and 17B are directed to the sutureless path-definer body **8**. The sutureless path-definer body **8** comprises **a** sutureless path-definer main body **8b**, flanges **8a** and an sutureless path-definer elongated body **8c**. The sutureless

path-definer body **8** is fixed to the housing **2** therefore avoiding rotation of the structure with respect to the housing **2**. The sutureless path-definer main body **8b** and flanges **8a** serves as a path for the sutureless fastener members **4**, wherein said sutureless fastener member **4** is positioned around the sutureless path-definer main body **8b**.

The contour of the sutureless path-definer body **8b** comprises a proximal end **82**, central section **81** and a distal end **83**. The central section **81** comprises an increment in dimensions, more particularly in the circumferential dimensions, wherein the diameter achieves an increment in diameter when compared with the proximal end **82** and a distal end **83**. The proximal end **82** is configured to have a tapered contour which results in a smooth surface with a decreased diameter assisting with the traveling of the sutureless fastener member 4 through the path-definer body 8b until reaching the patient's skin. At the distal end **83** the contour is configured to assists with the fixing of the fastener member **4** during the loading procedure before it is pushed by the piston **7**. The configuration and arrangement of the proximal end **82**, central section **81** and a distal end **83** makes the impact and insertion of the sutureless fastener member **4** in the patient's skin more comfortable since the change in dimension reduce the impact force of the sutureless fastener member **4** and simultaneously assists with the insertion of the

fastener member while traveling through the proximal end **82**. In the instant case the sutureless path-definer body **8** surrounds the biopsy punch cutter assembly.

FIGs 18A through 18C are directed to the assembling between the sutureless path-definer body **8** and the piston **7**. The piston **7** comprises a piston head **7a** and a piston loading body **71**, wherein said piston loading body **71** comprises the loading shaft **5** and a trigger stopper **6a**. The piston loading body **71** surrounds the sutureless path-definer elongated body **8c** and the piston head **7a** further surrounds a portion of the sutureless path-definer body **8b** and the sutureless path-definer elongated body **8c**.

A resilient elastic member **9**, such as a spring, is positioned between the stopper **10** and the piston head **7a**, as previously mentioned. During the sutureless procedure the spring **9** is in a loading position wherein the loading position is defined as a position wherein said spring **9** is compress between the stopper **10** and the piston head **7a**. In order to compress the spring **9** the piston **7** is pushed back by means of the loading shaft **5**. After reaching a pre-determinate compression force at the spring **9** the position is locked by means of a trigger **6** and trigger stopper **6a**. The sutureless fastener member **4** is then located or positioned in front of the piston head when the loading position is achieved. The sutureless fastener member **4**

is designed to travel through the sutureless path-definer body 8b when the trigger **6** is released and as result the decompression of the spring **9** provides enough force pushing sutureless fastener member **4** towards the open wound site.

Several resilient elastic members or different resilient elastic member configuration or means to achieve the pushing action of the piston **7** can be used. FIG 19A through FIG 19B discloses the use of a plurality of spiral springs **9a** to performed the pushing action for the sutureless member **4**.

FIG 20 show in more detail the piston **7**, wherein the piston comprises piston head **7a** and a piston loading body **71**, wherein said piston loading body **71** comprises the loading shaft **5** and a trigger stopper **6a**, as mentioned previously. Further the piston comprises a piston chamber **A** with a piston chamber bottom surface **7b** and a piston contact surface **7c**. The piston contact surface **7c** is designed to be in close contact with the sutureless fastener member **4** during the pushing action. The piston chamber **A** comprises a space with dimensions big enough to receive the sutureless path-definer **8b** main body. FIG 21 provides a cross sectional section of the assembly between the piston **7** and the sutureless path-definer body 8. The chamber **A** length is desired to be equal to or bigger than the sutureless main body **8b** length **X** in such way that the sutureless fastener member **4** travels the sutureless main body **8b** with the piston

contact surface **7c** constantly pushing the sutureless fastener member **4**. However it is important to understand that the current dimension may vary depending of factor such as the elastic properties of the elastic member **9** which result in the decompression force, and the friction of the sutureless fastener member **4** with the sutureless main body **8b**. The contour of sutureless path-definer body **8b**, as mentioned above, assists with the traveling of the sutureless fastener member **4**.

FIG 22 is directed to a cross sectional view of the sutureless member dispenser assembly surrounding the biopsy punch cutter **3** assembly, wherein the contact between the sutureless fastener member **4** is clearly show to be in contact with the piston contact surface **7c**. The device is loaded when the sutureless fastener member **4** is positioned in front of the piston contact surface **7c** while the resilient member **9** is compress and in position to be release by means of the trigger **6**. The chamber length **A**, as explained above, limits the range of motion for the piston **7**.

FIG. 23 is a front view of the exemplary biopsy punch device in accordance with the principles of the present invention wherein the front chamber **C** is created at the front part of the elongated hollow body housing **2** wherein the sutureless fastener member 4 travels path-definer during the decompression action.

FIG 24A through 24C discloses the sutureless fastener member **4**. The sutureless fastener member **4** or biopsy closure fastener member comprises two prongs **4b** connected by a fastener body **4a** serving as a bridge between the prongs. The fastener body **4a** has resilient properties, wherein the two-pronged **4b** fastener may expand to a distance bigger than the diameter of the wound created by the cylindrical cutter, as shown in FIG. 24A. The fastener body material is selected from a group or resilient plastic material, resilient ceramic plastic, resilient metal material or any combination. The resilient material selected has to be a no-toxic resilient material.

The two-pronged fasteners 4b are intended to be inserted at opposite sides of the wound site into the patient's skin. The sutureless fastener member **4** is stretched in order to be inserted into the patient's skin at opposite sides of the wound site. The stretching action is assisted by the path-definer body **8b** which keeps the two-pronged fasteners **4b** separated enough to have a distance bigger than the diameter of the wound created by the cylindrical cutter **3**. After the sutureless fastener member **4** is inserted into the patient's skin the resilient properties of the sutureless fastener member **4** acts on the wound site. Since no rigid body is retraining the fastener member **4** stretched the fastener member **4** returns to its original form consequently making the opposite sides of the wound to come together. The

resilient properties of the sutureless member **4** close the wound without the need of additional instruments.

The two-pronged **4b** comprises a recess **4c**, wherein said recess **4c** assists with the fastener member **4** action of pulling together the opposite sides of the wound site. Therefore the sutureless biopsy closure dispenser releases the biopsy closure member **4** at the wound site which renders the biopsy wound site close by approximating the opposing edges of the wound. In addiction the fastener member 4 may be coated with a medicinal drug or substance, such as an antibacterial.

FIG. 25 is directed to the loading of the sutureless fastener member 4, wherein the sutureless fastener member **4** is positioned inside chamber **C**, as explained before. After the sutureless fastener member **4** is expanded and located around the path-definer main body **8b**, more particularly main body distal end **83**. Further, the opening to access chamber **C** is closed by means of a cover **2a**. At this instant the biopsy device **1** is loaded and ready to remove the tissue sample as explained before. While performing the biopsy the motor is controlled to rotate in a particular direction providing the rotation at the cutter **3** without linear displacement, as explained above. After the incision is performed the motor **M** is controlled to rotate in the opposite direction in such way that the cutter **3** is retracted and the tissue is removed from the patient.

FIG 26 is directed to the process after the cutter **3** is retracted. First the trigger **6** is activated **Z1** in such way that the piston **7** is released and the sutureless fastener member **4** is pushed toward the patient's skin. Second the fastener member **4** is inserted into the patient's skin, more particularly the two prong **4b** parts at opposite side of the wound site as result of the pushing action of the piston **7** as explained above. Further the biopsy devise **1** is remove and the sutureless resilient member **4** compresses the opposite side wound wherein the prongs **4b** are inserted pulling together said opposite sides of the wound site. The wound can be covered with a substance that kills bacteria or slows their growth. Further a bandage may be used to support or hold the fastener member **4** in position.

While the invention has been described as having a preferred design, it is understood that many changes, modifications, variations and other uses and applications of the subject invention will, however, become apparent to those skilled in the art without materially departing from the novel teachings and advantages of this invention after considering this specification together with the accompanying drawings. Accordingly, all such changes, modifications, variations and other uses and applications which do not depart from the spirit and scope of the invention are deemed to be covered by this invention as defined in the following claims and their legal

equivalents. In the claims, means-plus-function clauses, if any, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but also equivalent structures.

All of the patents, patent applications, and publications recited herein, and in the Declaration attached hereto, if any, are hereby incorporated by reference as if set forth in their entirety herein. All, or substantially all, the components disclosed in such patents may be used in the embodiments of the present invention, as well as equivalents thereof. The details in the patents, patent applications, and publications incorporated by reference herein may be considered to be incorporable at applicant's option, into the claims during prosecution as further limitations in the claims to patentable distinguish any amended claims from any applied prior art.

Claims

1. A biopsy punch device comprising;

a housing comprising first end and a second end,

a biopsy punch cutter assembly comprising an elongated hollow body housing with a distal end and a proximal end,

a cutter, wherein said cutter is located at the distal end;

suture-less fastener member;

a suture-less fastener member dispenser assembly for the suture-less fastener member surrounding said biopsy punch cutter assembly comprising

a loading mechanism, and

a trigger; and an actuator assembly comprising an actuator mechanism.

2. A biopsy punch device as in claim 1, wherein said actuator assembly comprises a automatic system comprising a motor, motor shaft and a control system, wherein said motor shaft serves as the actuator mechanism.

3. A biopsy punch device as in claim 2, wherein said automation system is located at the proximal end of the elongated hollow body and; wherein said motor

shaft is mechanically coupled to the biopsy punch cutter assembly.

4. A biopsy punch device as in claim 1, wherein said suture-less fastener member comprises a fastener body a first prongs and second prong, wherein said fastener body comprises a fastener distal end and a fastener proximal end, wherein the first prong extend perpendicular to the fastener body and is located at the fastener distal end and wherein the second prong extend perpendicular to the fastener body and is located at the fastener proximal end.

5. A biopsy punch device as in claim 1, wherein the fastener body in made from material selected from resilient plastic material, resilient ceramic material or resilient metal material.

6. A biopsy punch device as in claim 1, wherein said suture-less fastener member dispenser assembly comprises:

a suture-less path-definer body comprising a suture-less path-definer main body, flanges and a suture-less path-definer elongated body, wherein a chamber is created between suture-less path-definer main body, flanges and said housing,

a piston and a stopper.

7. A biopsy punch device as in claim 6, wherein said housing comprises a opening for accessing the chamber, wherein said suture-less fastener member is inserted.

8. A biopsy punch device as in claim 6, wherein said piston comprises a piston head and a piston loading body, wherein said piston loading body comprises a trigger stopper, wherein said loading shaft is coupled to the piston.

9. A biopsy punch device as in claim 6, wherein said stopper is coupled to the housing, wherein an elastic material is located between the piston head and said stopper.

10. A biopsy punch device as in claim 1, wherein the biopsy punch cutter assembly comprises:

a hollow cutter shaft comprising a cutter shaft distal end, a cutter shaft proximal end and threaded inner surface; wherein the cutter shaft proximal end is coupled to the motor shaft and said cutter shaft distal end is coupled to the cutter; and

a bearing, wherein said bearing surrounds said hollow cutter shaft.

11. A biopsy punch device as in claim 1 comprising a bearing shaft surrounding the biopsy punch cutter

assembly comprising grooves, wherein said groves serves a channels to limit the bearing displacement.

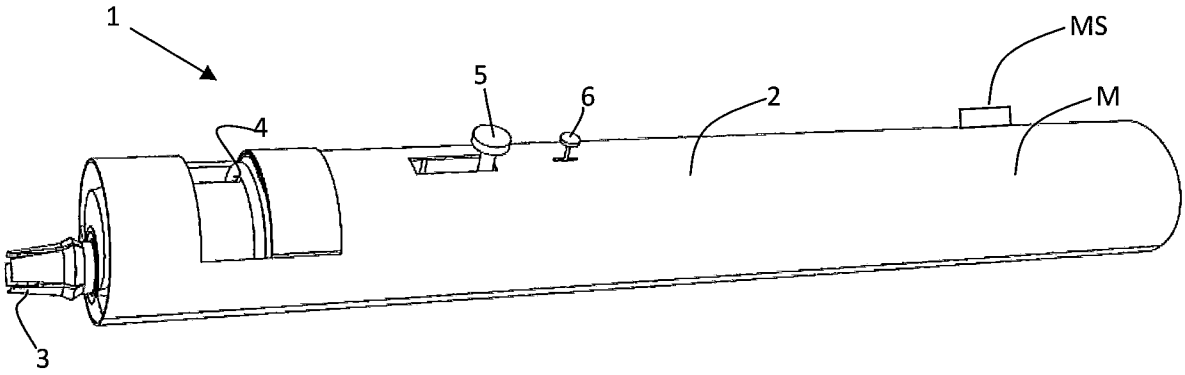

FIG. 1A

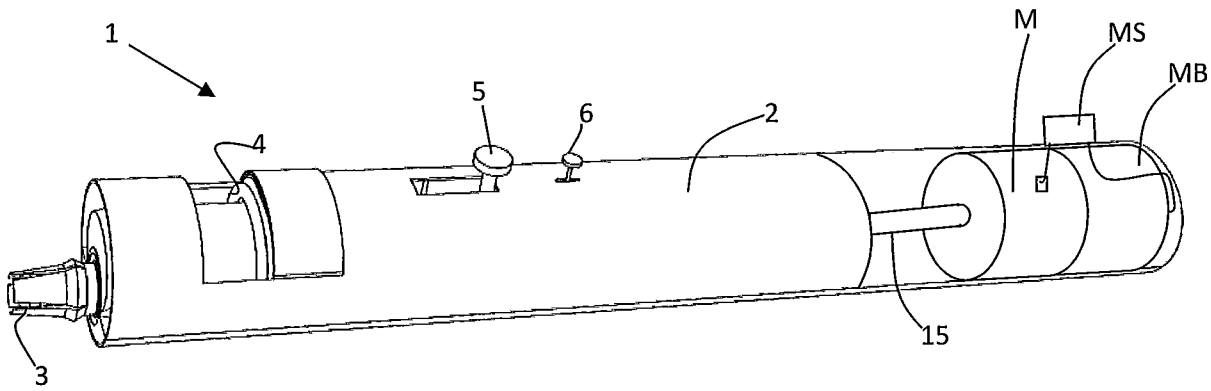

FIG. 1B

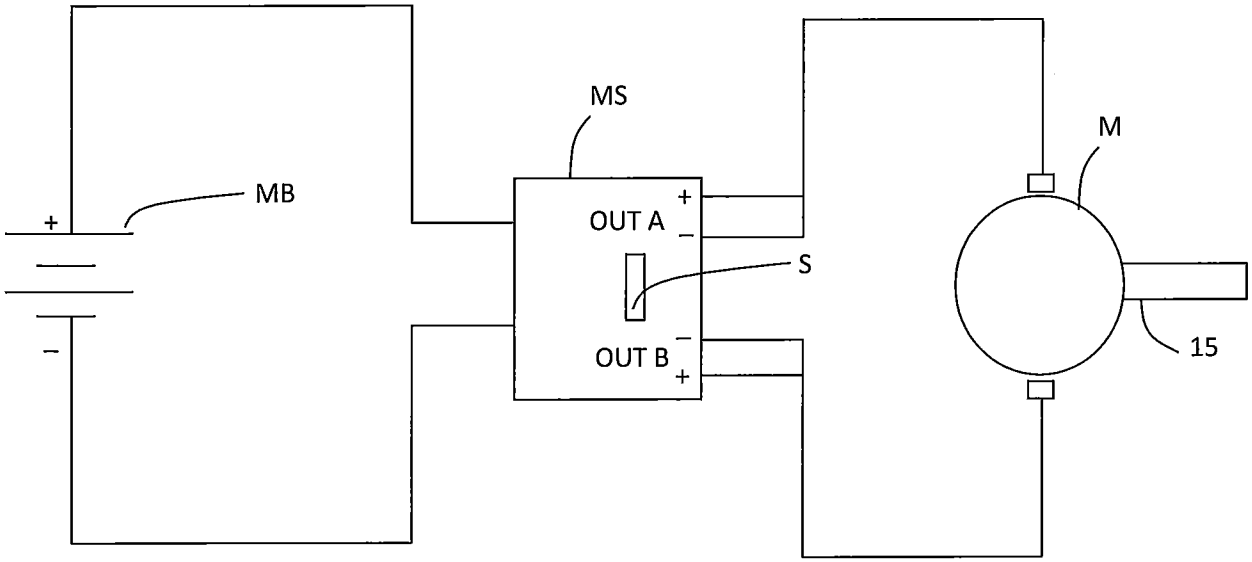

FIG. 2

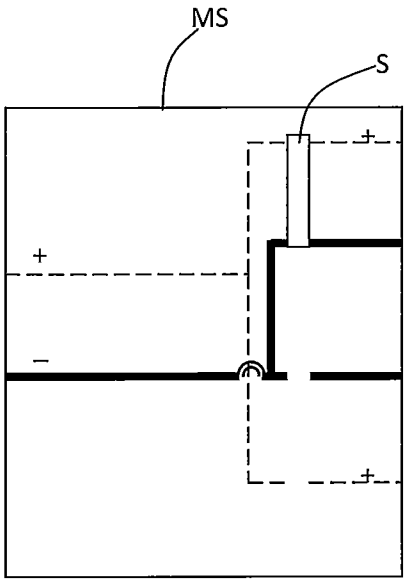

FIG. 3A

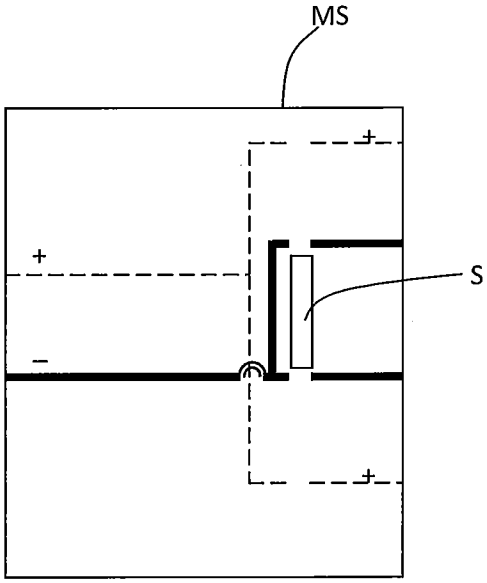

FIG. 3B

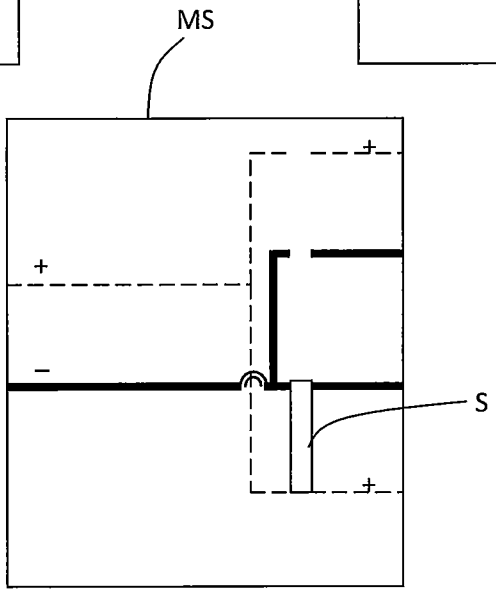

FIG. 3C

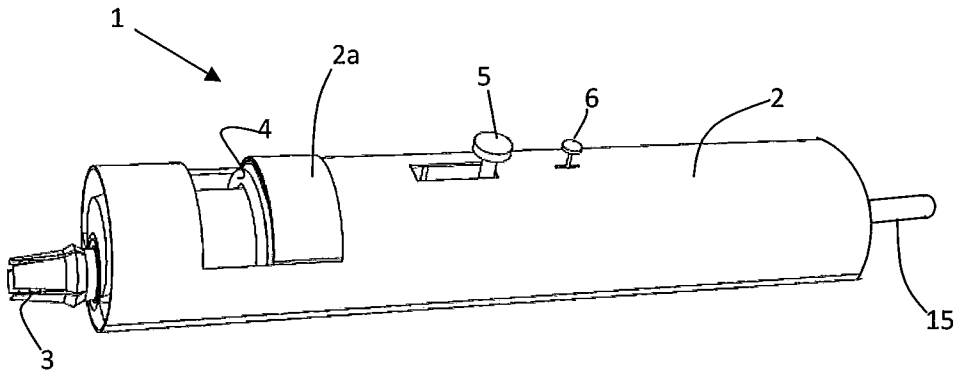

FIG. 4A

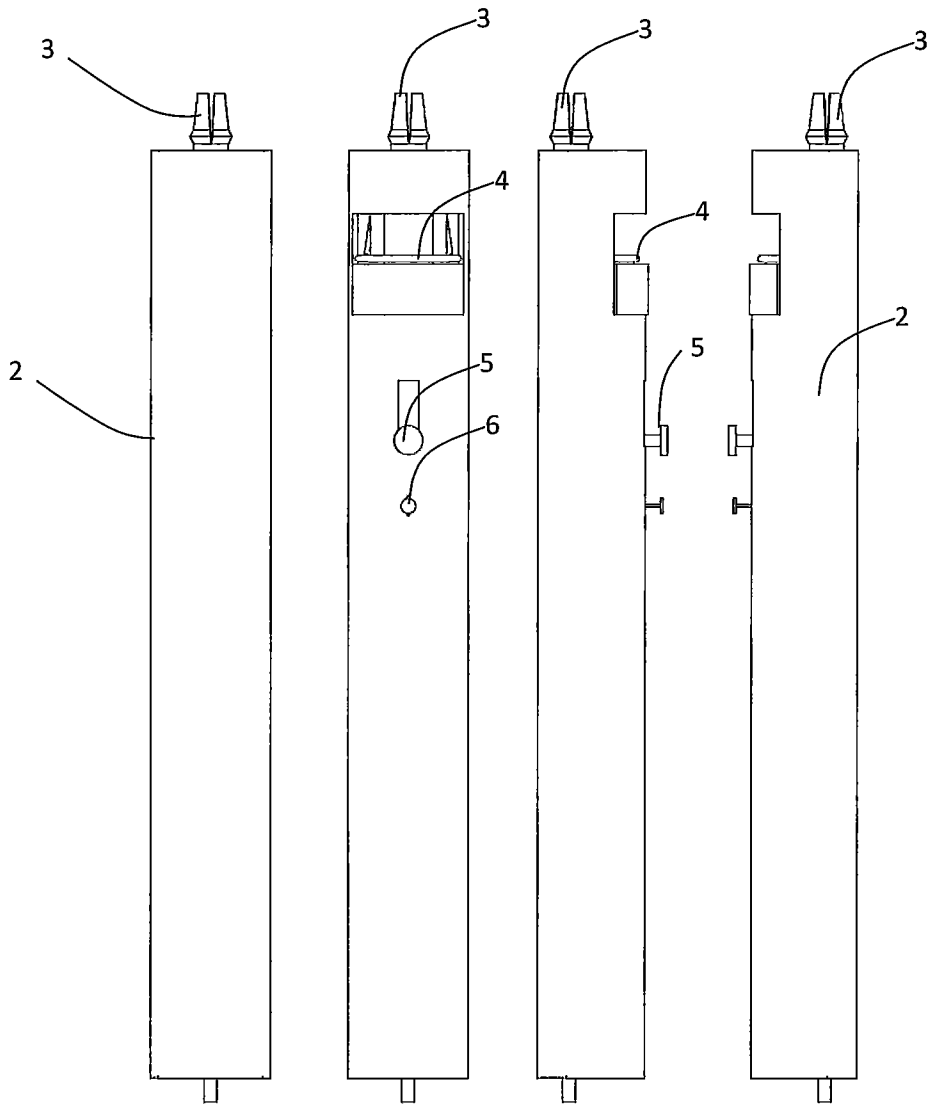

FIG. 4B

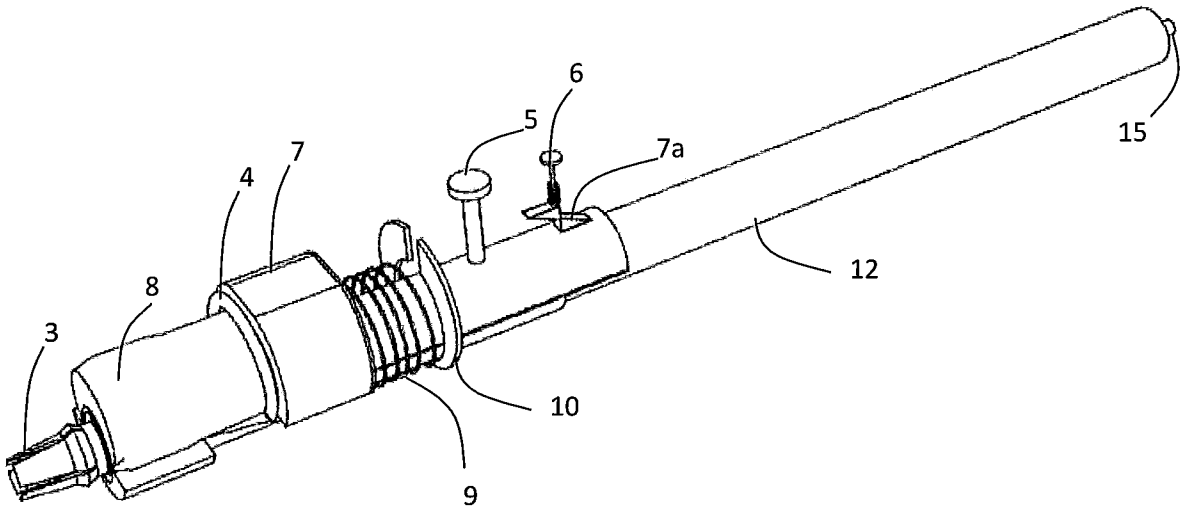

FIG. 5A

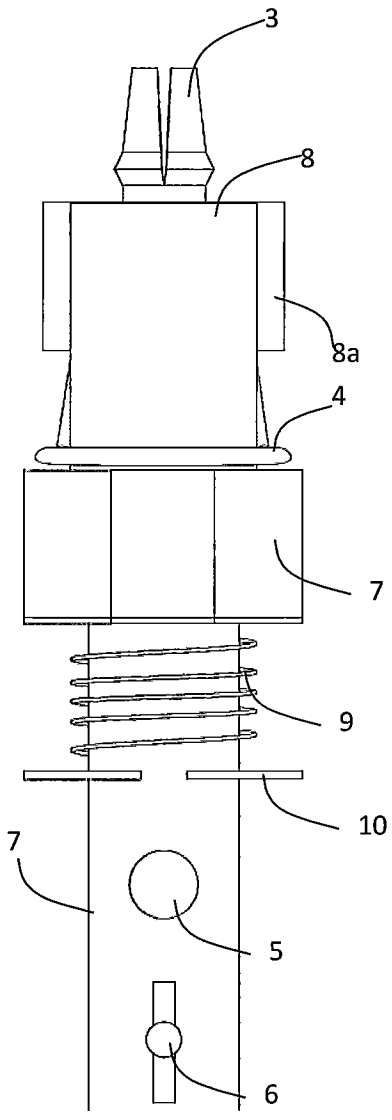

FIG. 5B

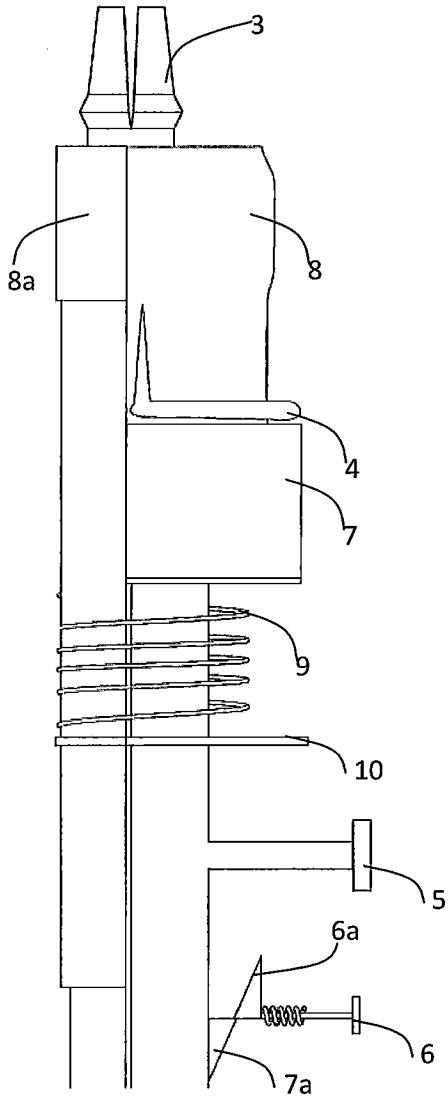

FIG. 5C

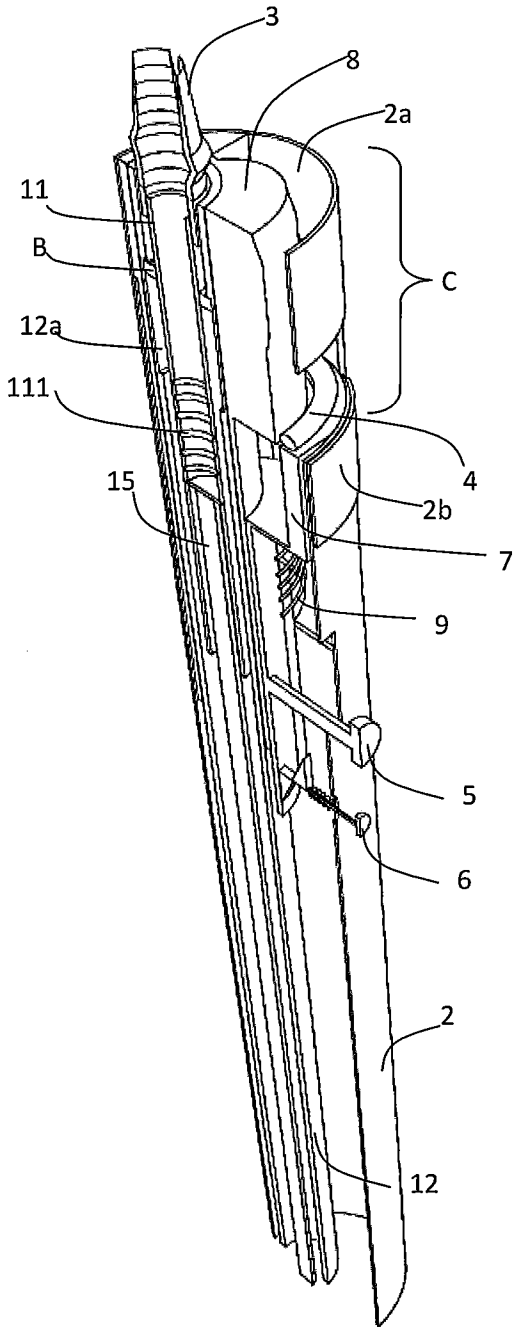
3
8
2a
11
B
C
12a
111
4
15
2b
7
9
5
6
2
12

FIG. 6A

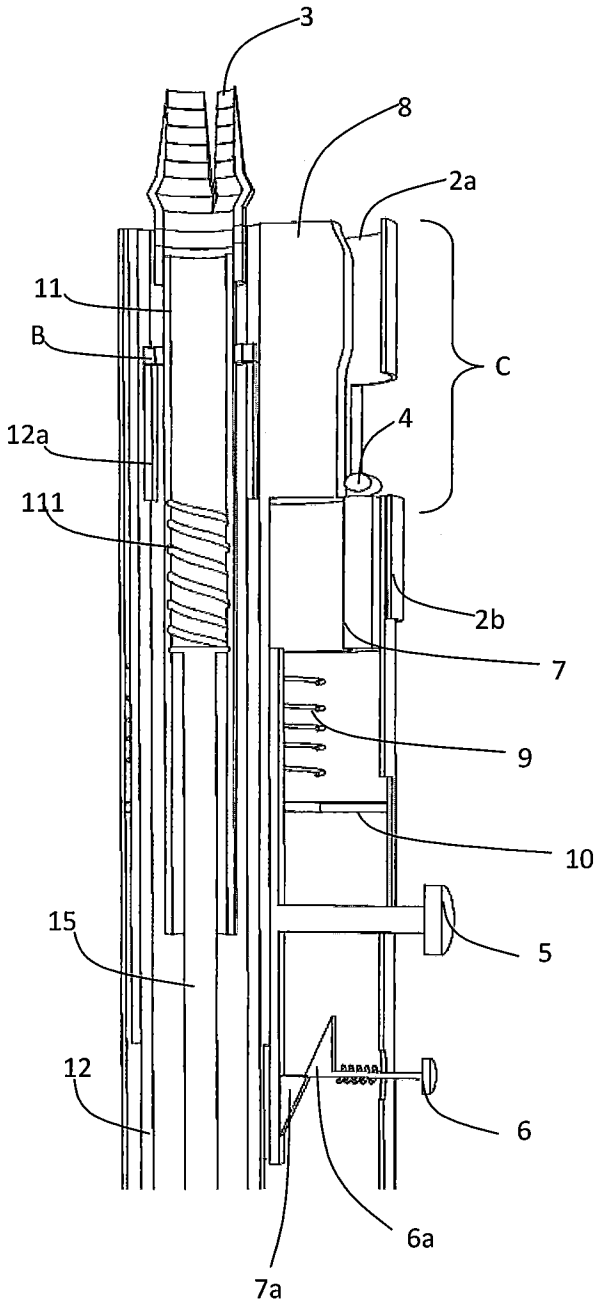
3
8
2a
11
B
C
4
12a
111
2b
7
9
10
15
5
12
6
6a
7a

FIG. 6B

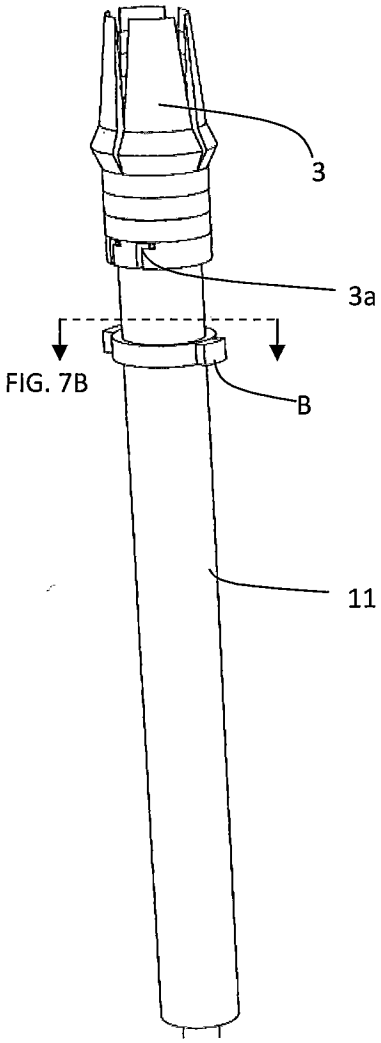

FIG. 7A

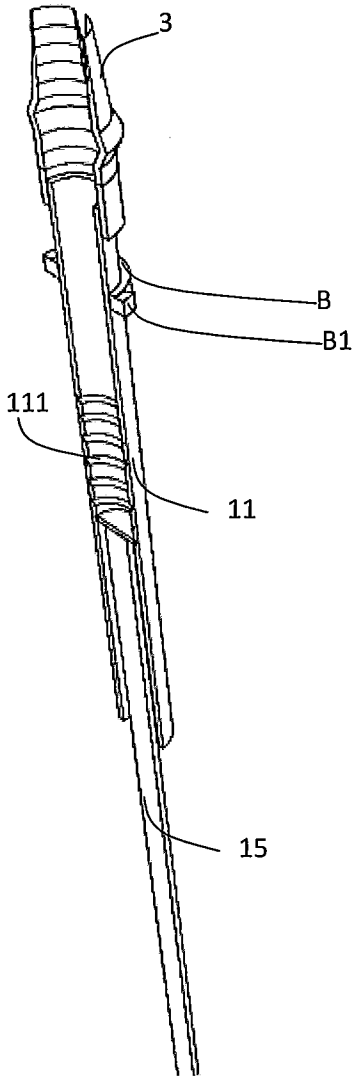

FIG. 7C

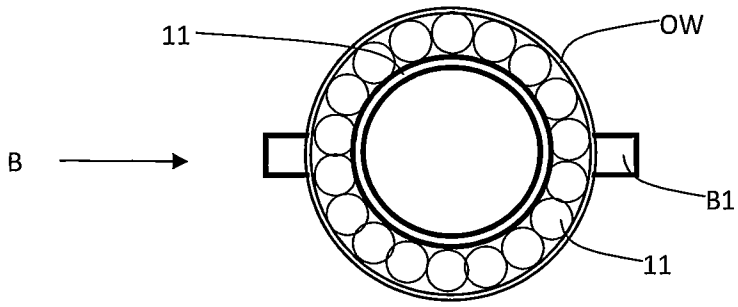

FIG. 7B

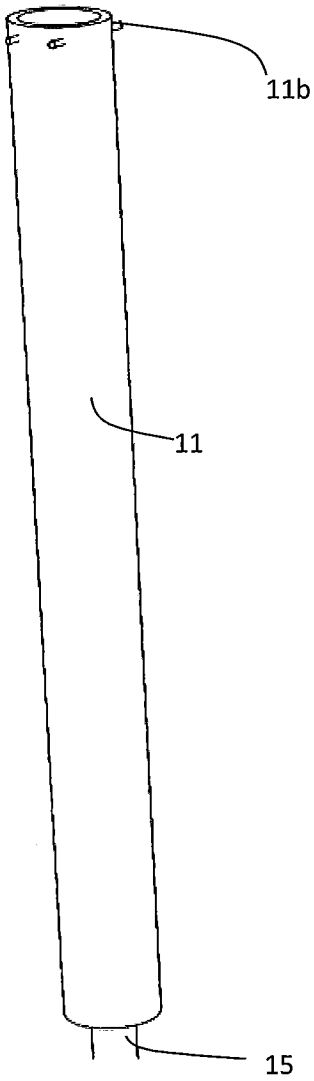

FIG. 8A

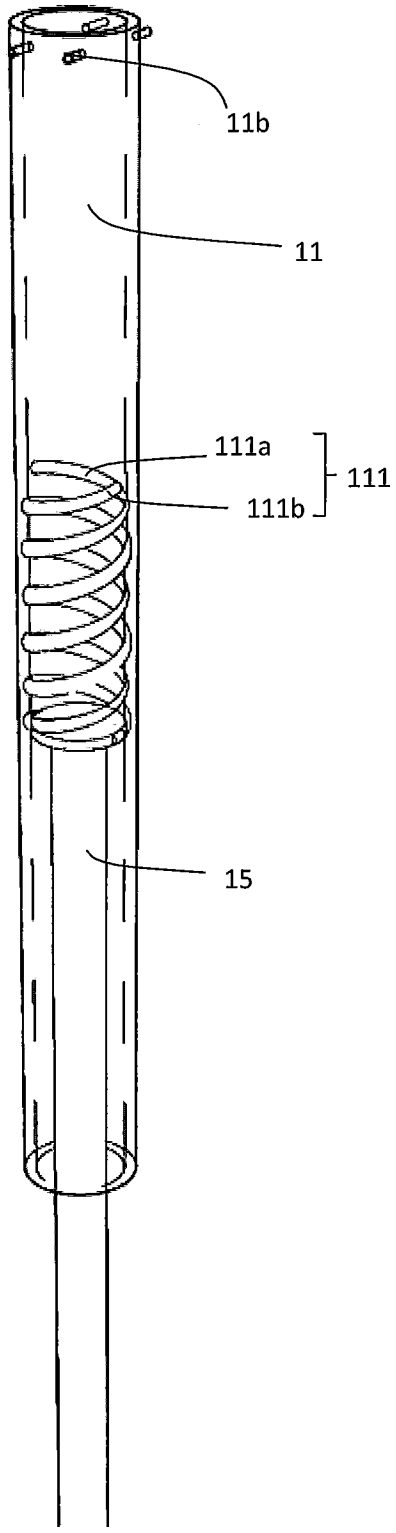

FIG. 8B

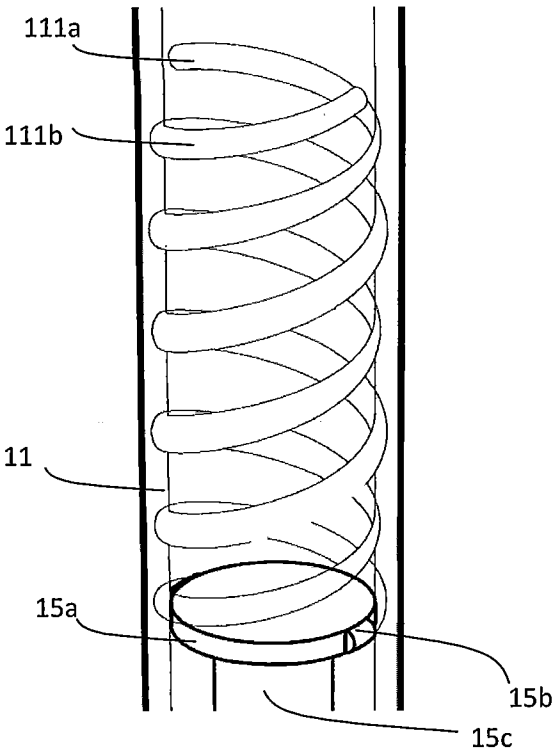

FIG. 9

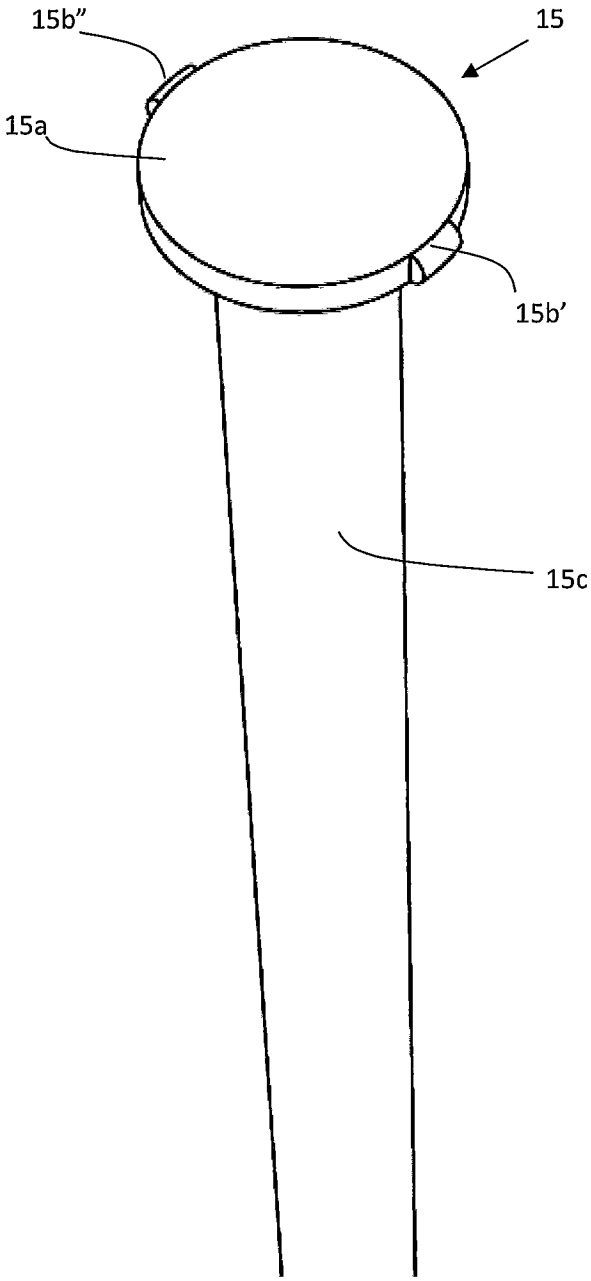

FIG. 10

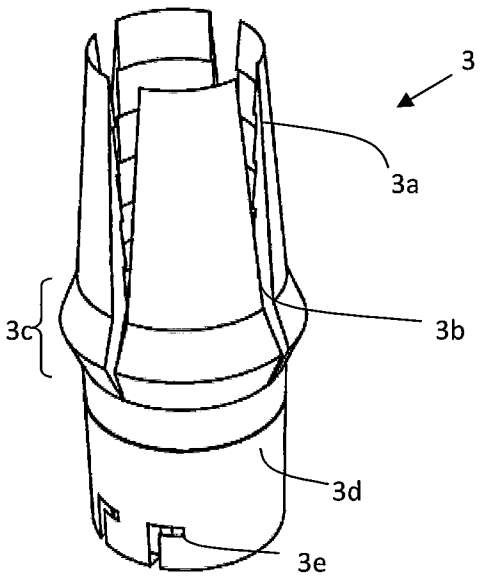

FIG. 11A

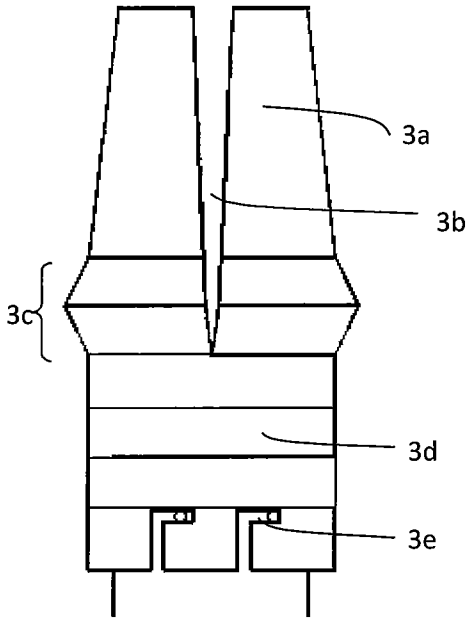

FIG. 11B

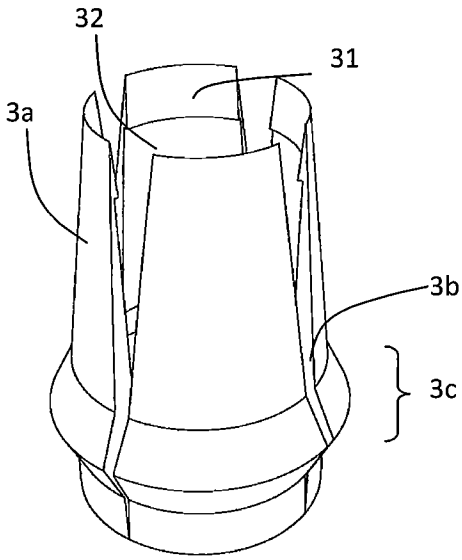

FIG. 12A

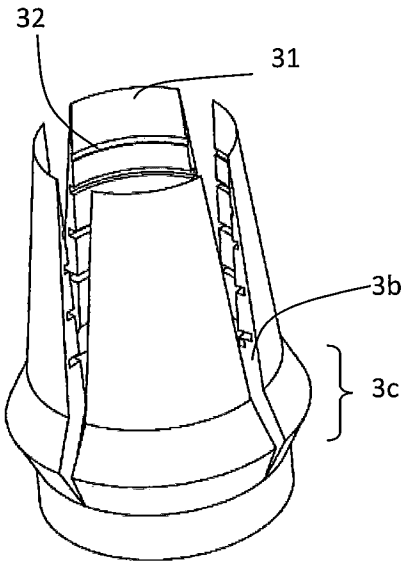

FIG. 12B

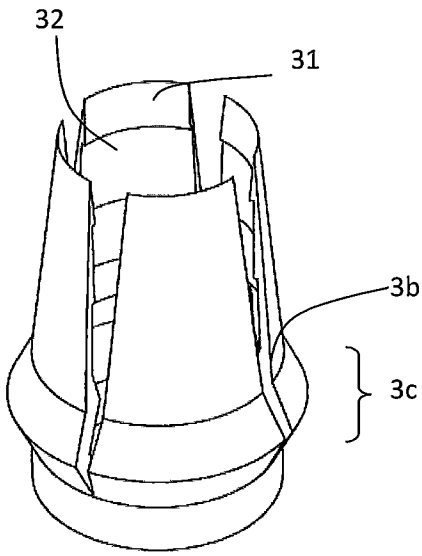

FIG. 12C

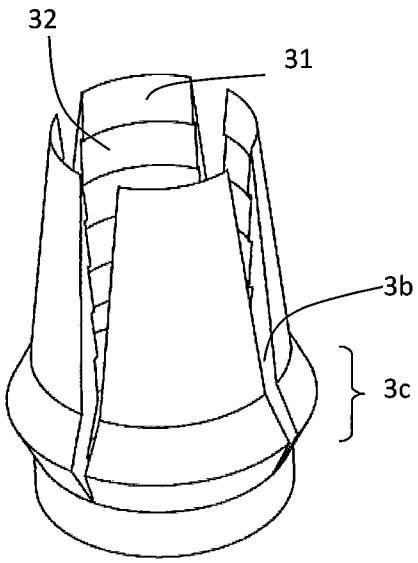

FIG. 12D

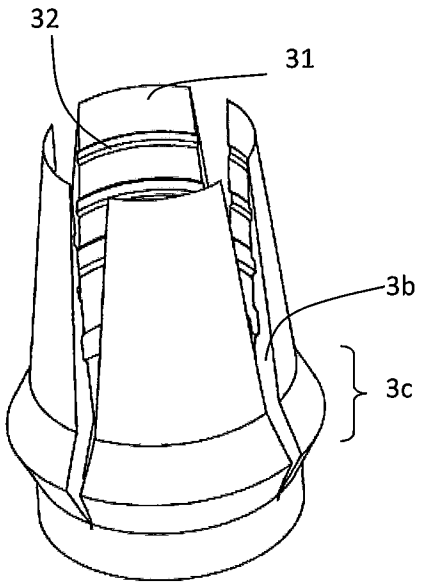

FIG. 12E

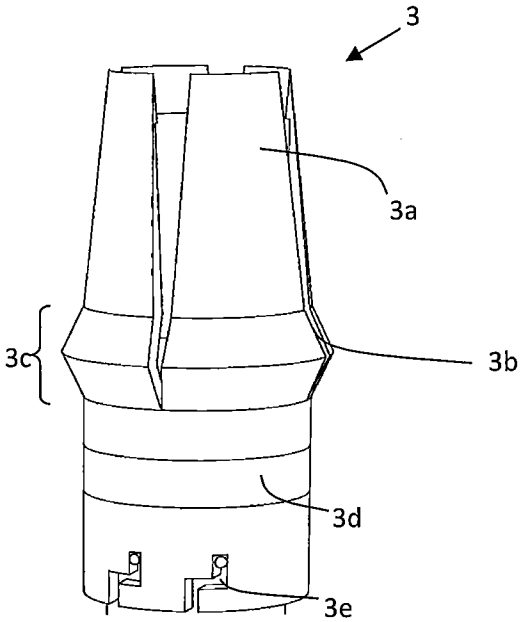

FIG. 13

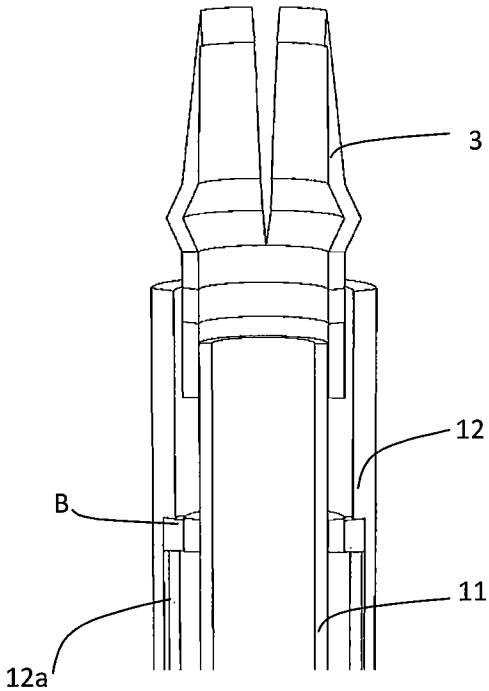

FIG. 14

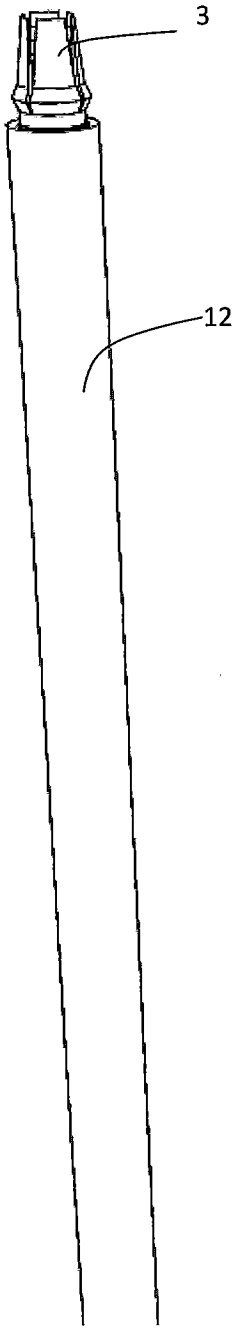

FIG. 15A

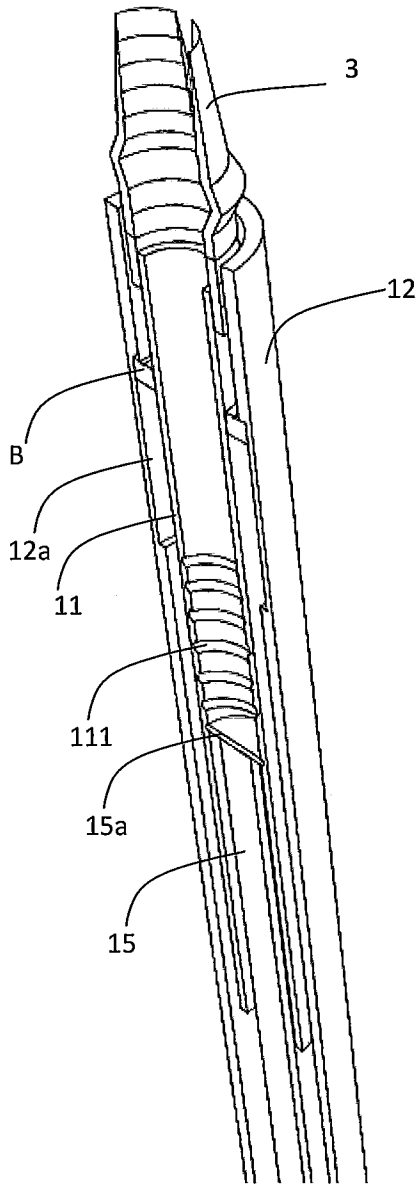

FIG. 15B

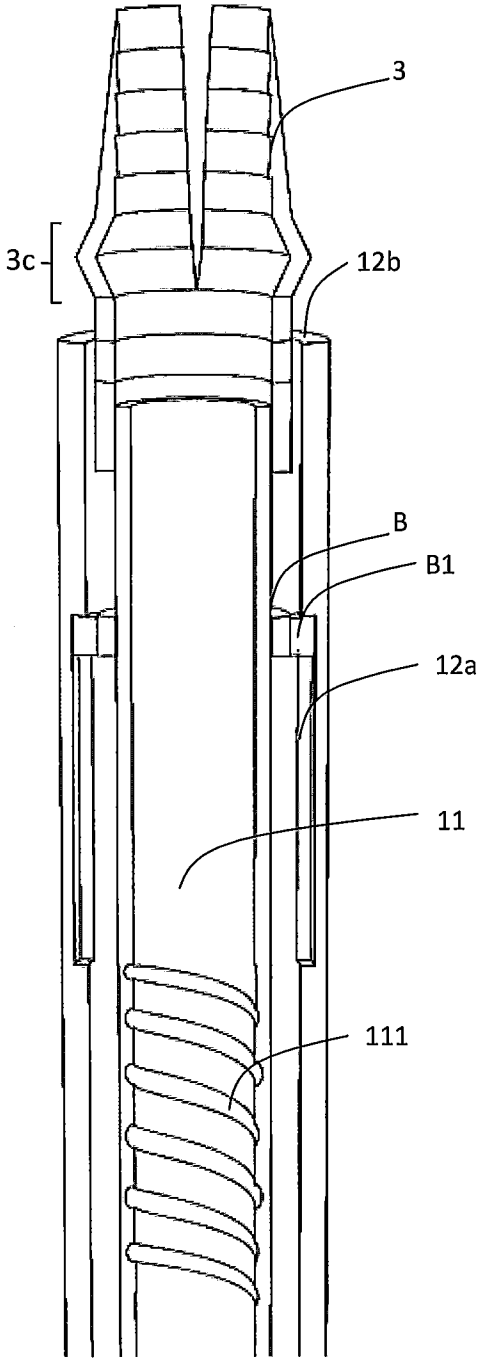

FIG. 15C

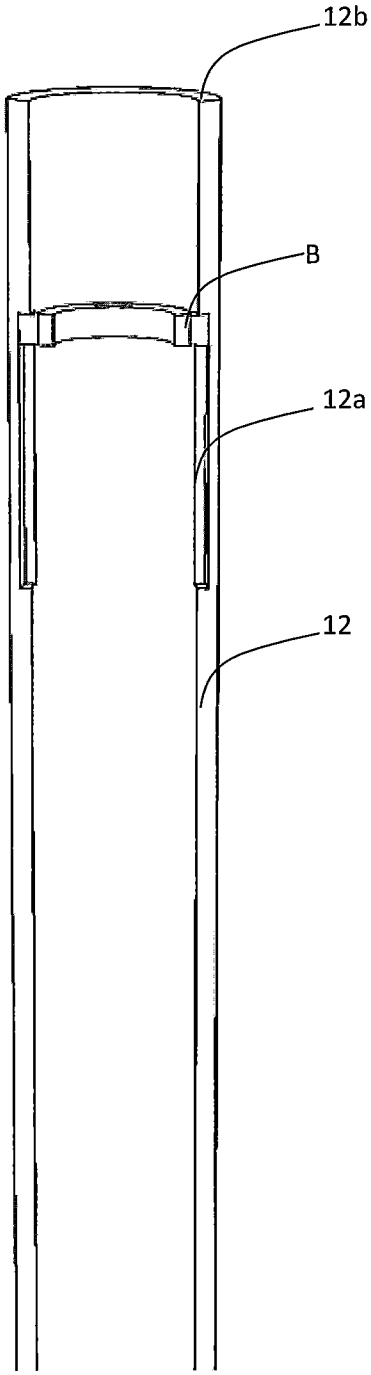

FIG. 16

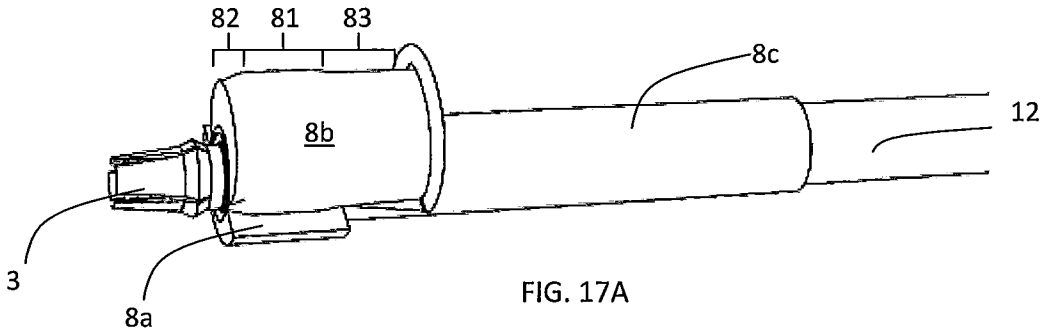

FIG. 17A

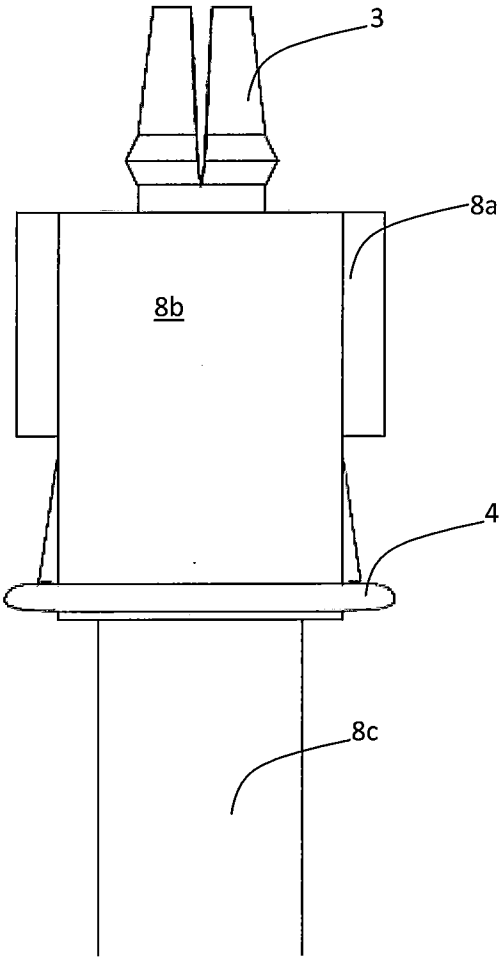

FIG. 17B

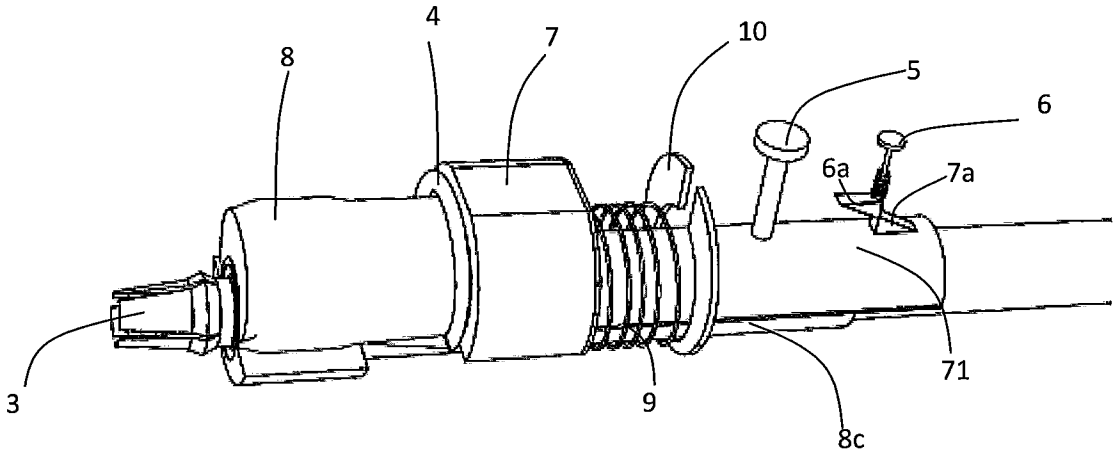

FIG. 18A

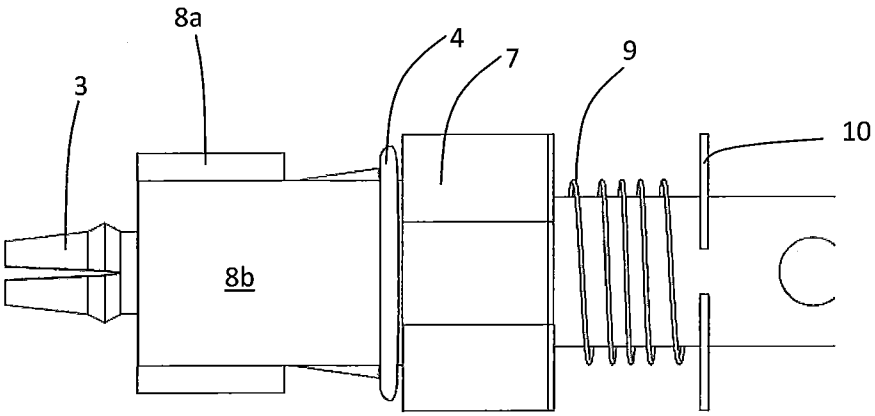

FIG. 18B

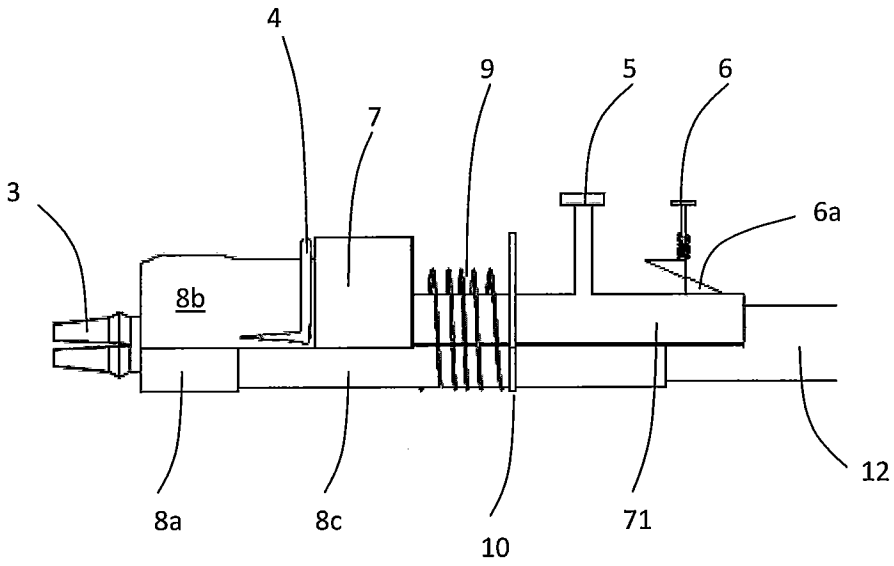

FIG. 18C

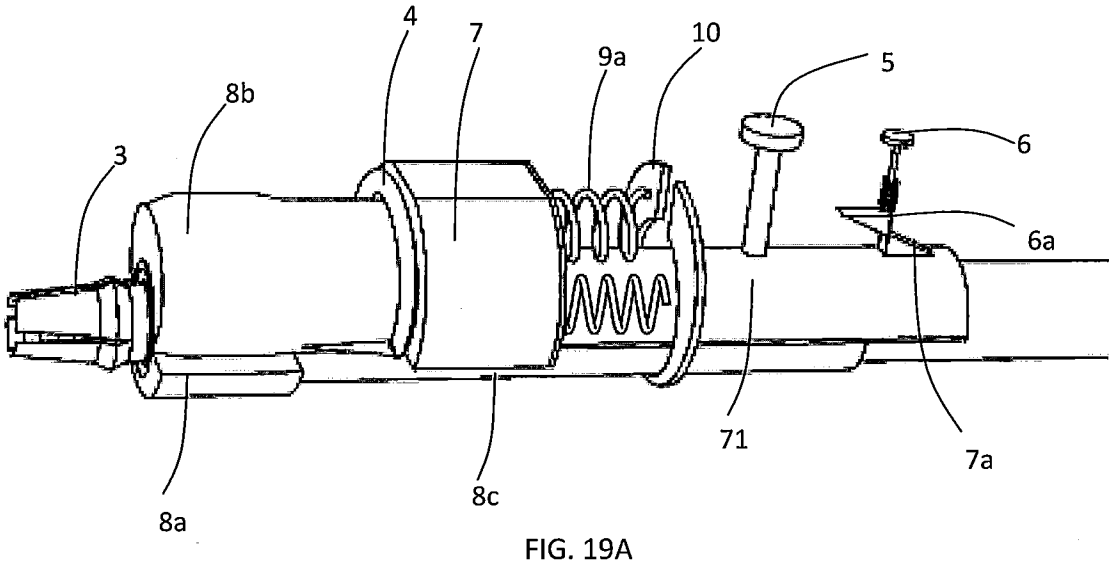

FIG. 19A

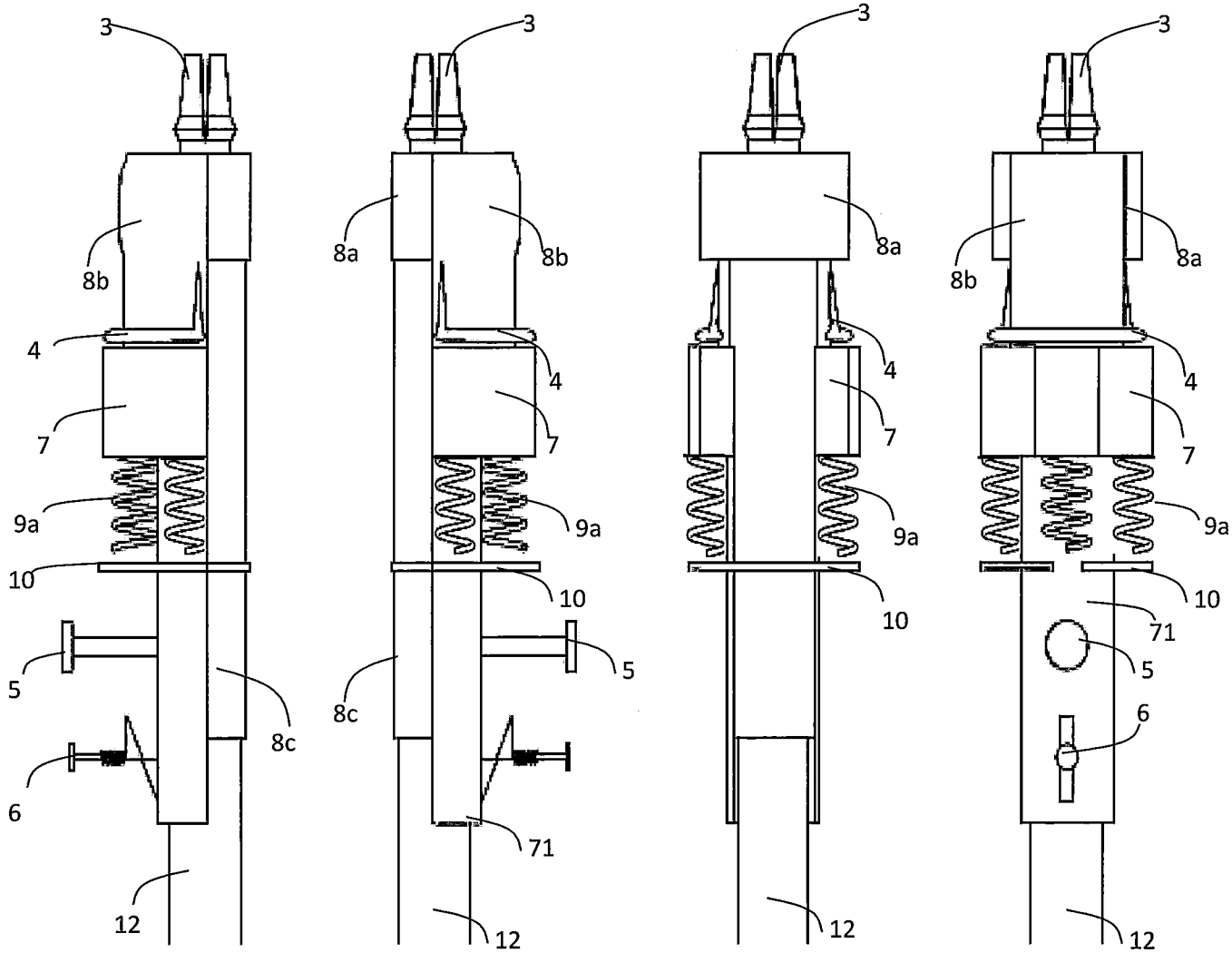

FIG. 19B

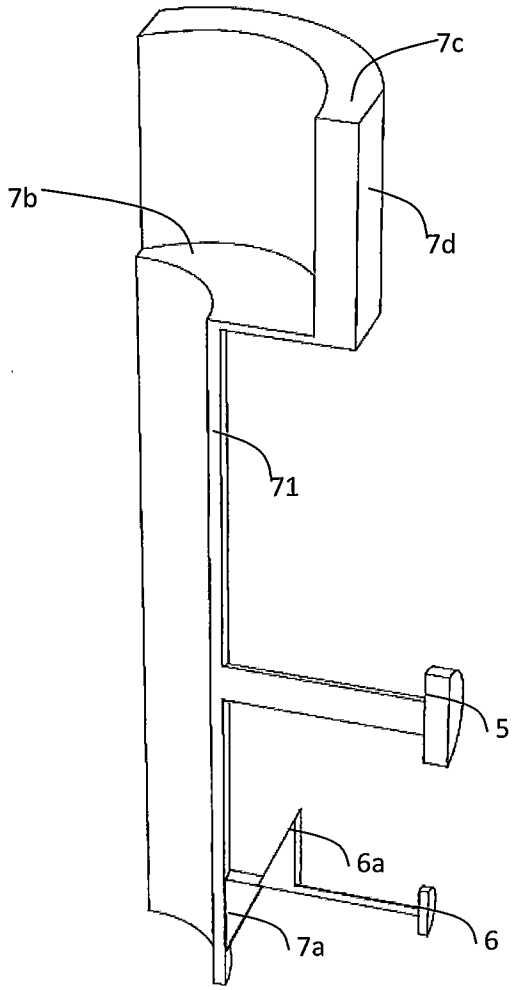

FIG. 20

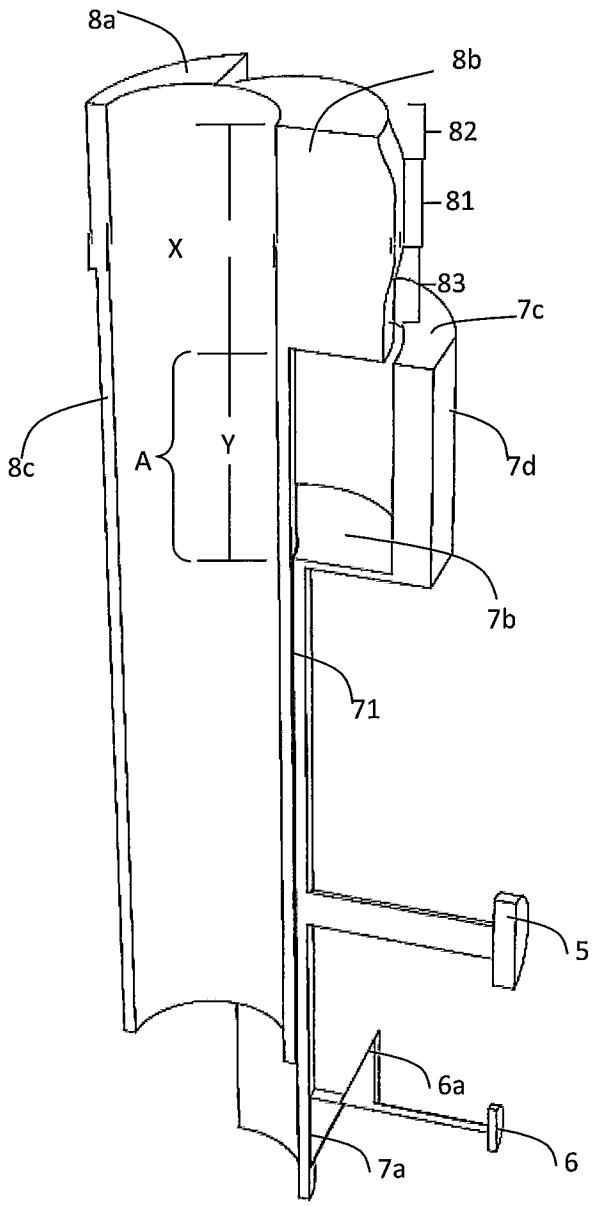

FIG. 21

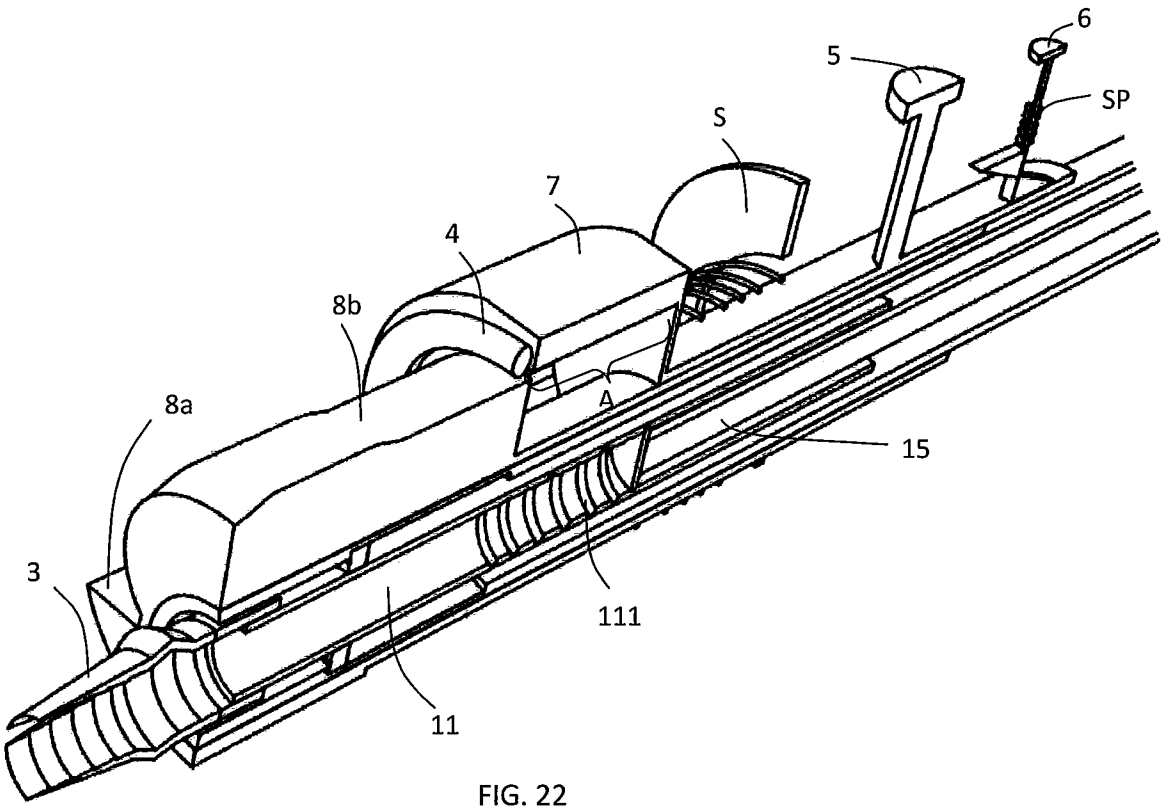

FIG. 22

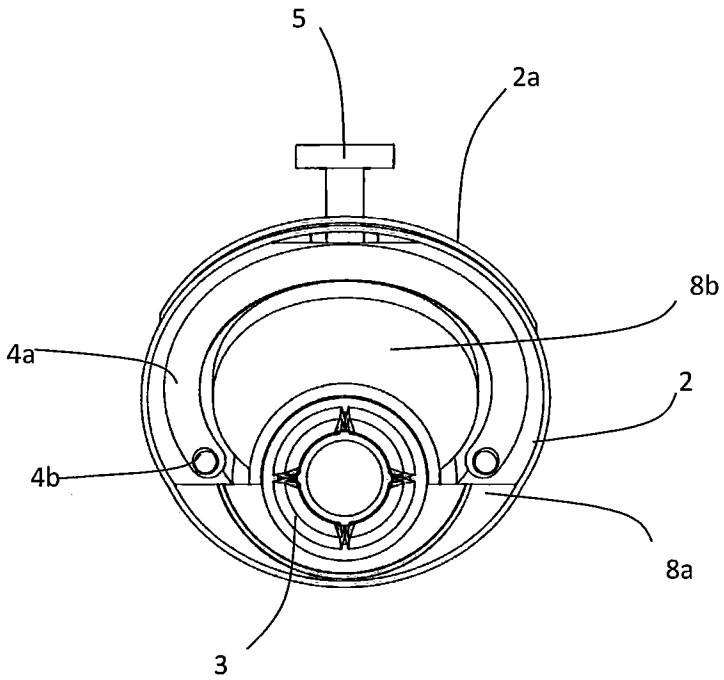

FIG. 23

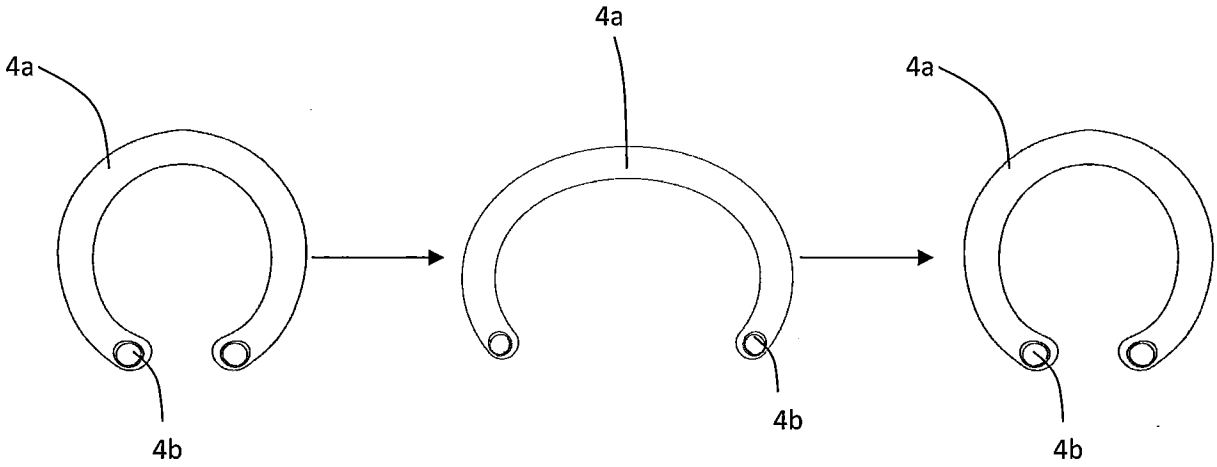

FIG. 24A

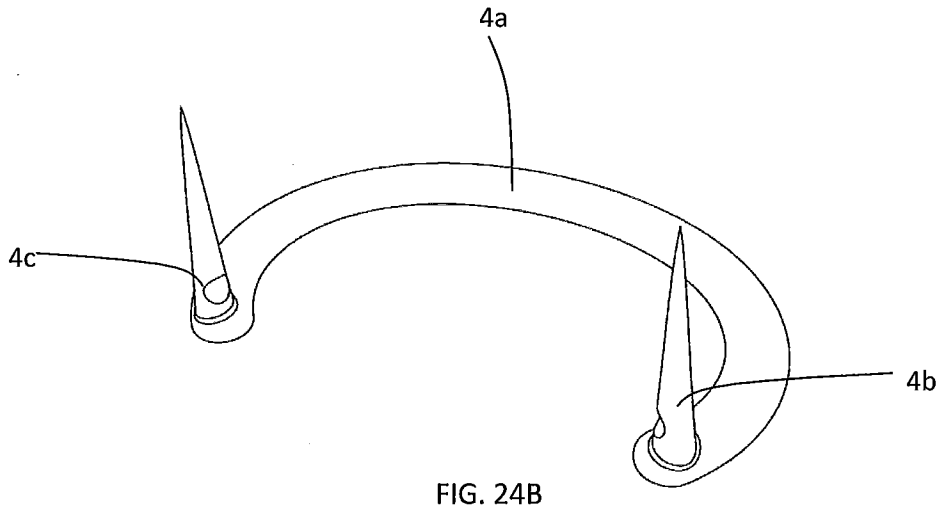

FIG. 24B

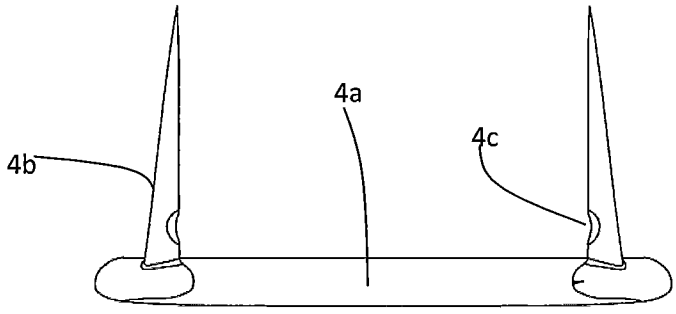

FIG. 24C

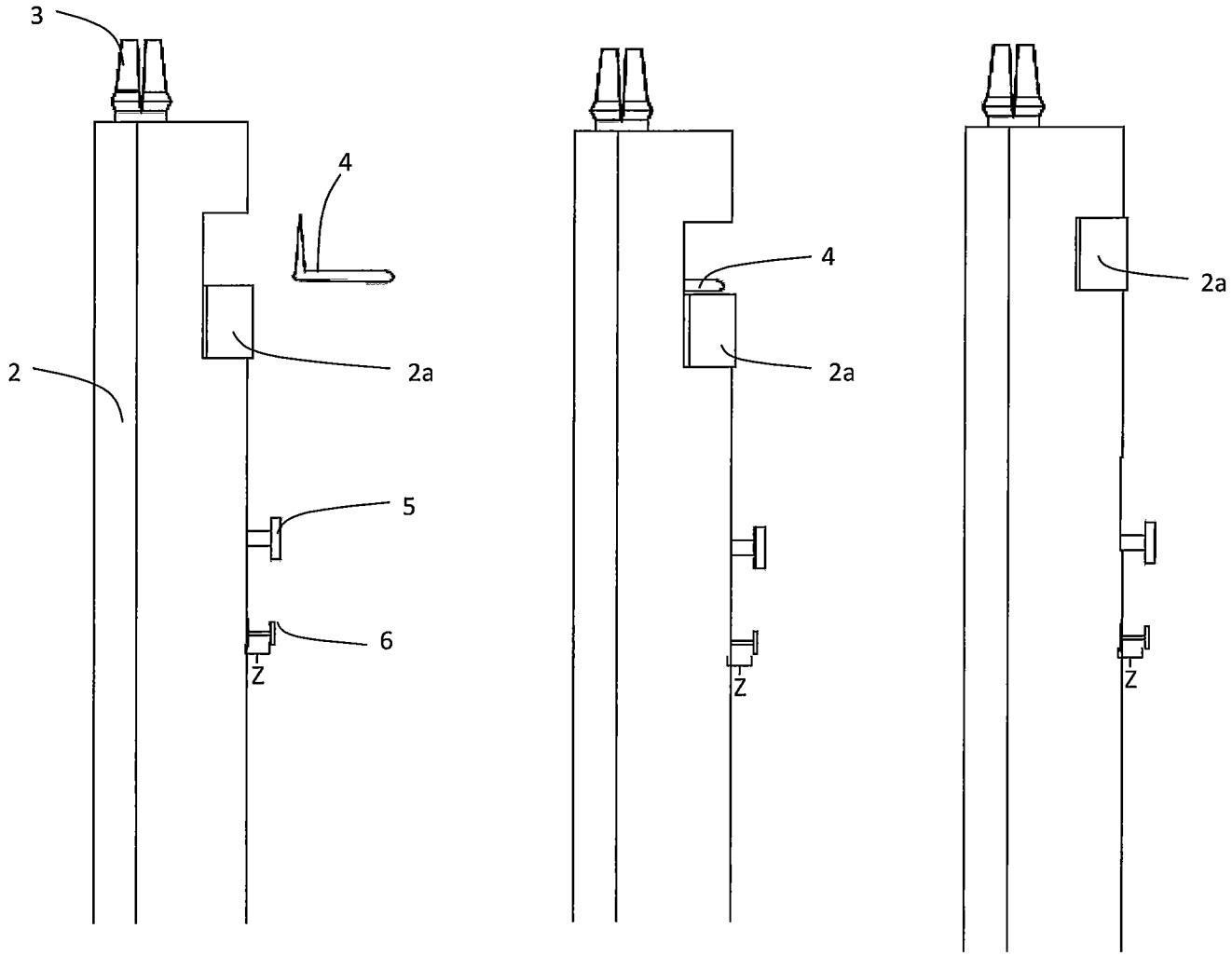

FIG. 25

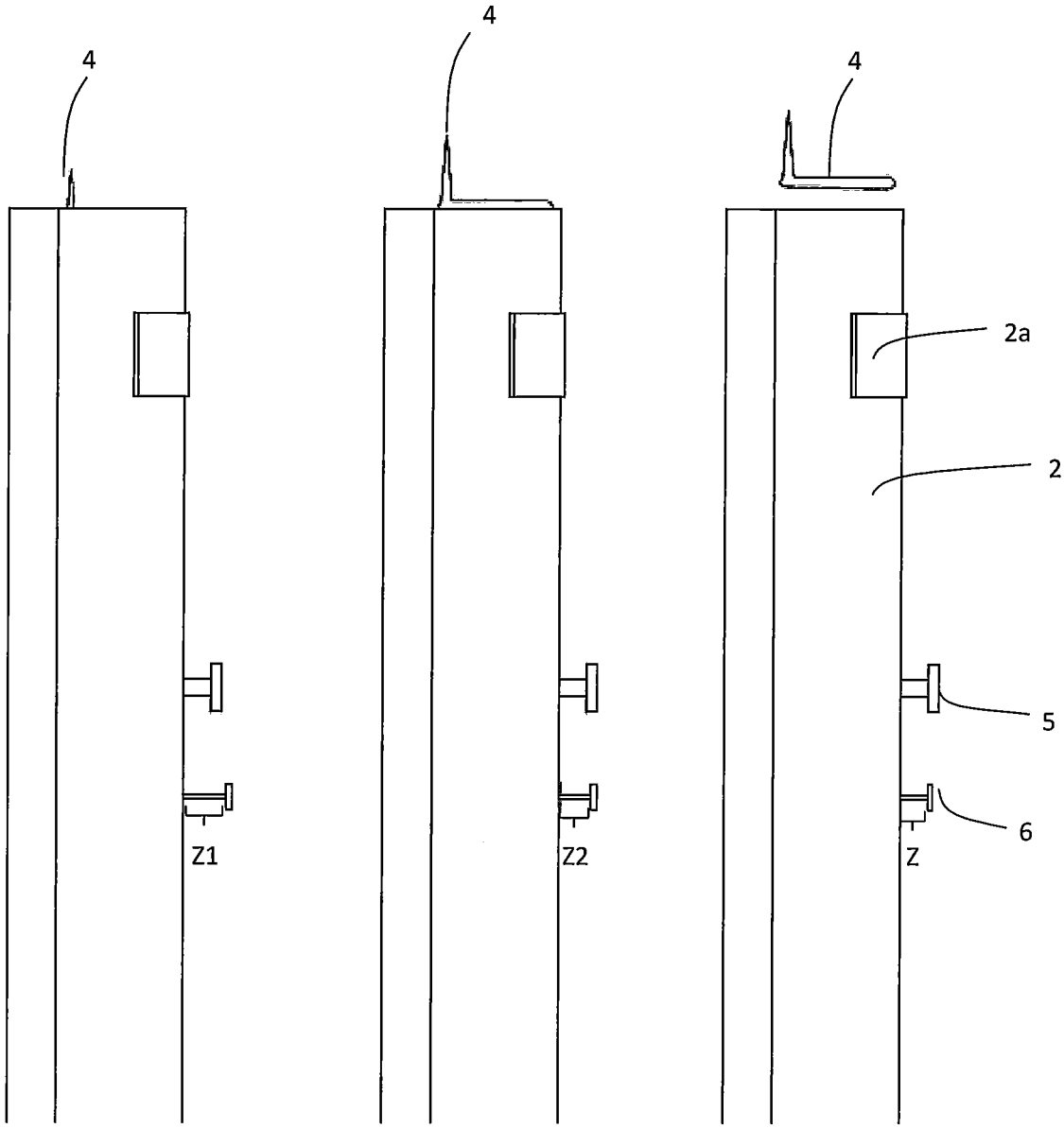

FIG. 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US12/42867

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 10/02**(2006.01)

USPC: 600/567
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : Please See Continuation Sheet

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007/0249960 A1 (WILLIAMSON, IV) 25 October 2007 (25.10.2007), entire document.	1-7, 9-11
Y	US 2007/0232954 A1 (HARRIS et al.) 04 October 2007 (04.10.2007), entire document.	1-7, 9-11
Y	US 2004/0249391 A1 (CUMMINS) 09 December 2004 (09.12.2004), entire document.	4
Y	US 5,312,023 (GREEN et al.) 17 May 1994 (17.05.1994), entire document.	5
Y	US 2002/0065535 AQ (KNEIFEL et al.) 30 May 2002 (30.05.2002), entire document.	6-7, 9
Y	US 4,951,690 A (BAKER) 28 August 1990 (28.08.1990), entire document.	10-11

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
15 August 2012 (15.08.2012)

Date of mailing of the international search report
17 AUG 2012

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Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT	International application No. PCT/US12/42867

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:

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:

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 any 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.:

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.

INTERNATIONAL SEARCH REPORT	International application No. PCT/US12/42867

Continuation of B. FIELDS SEARCHED Item 1:
600/567, 562, 563, 564, 565, 566, 568, 569, 570, 571; 606/167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 184, 185, 213, 215, 216, 217, 218, 219, 220, 221