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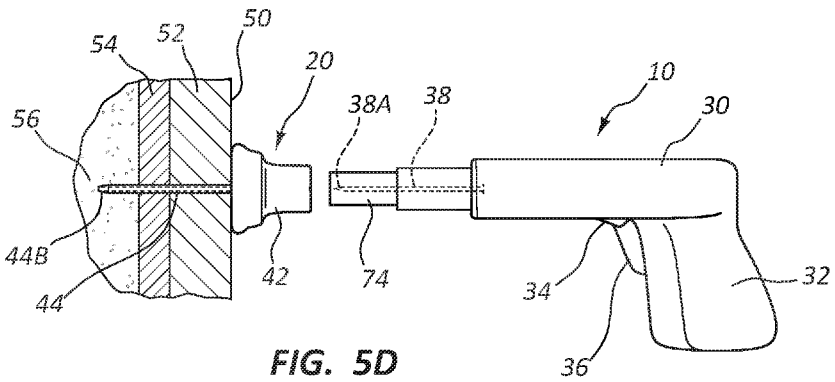


FIG. 5D

(57) Abstract: An access device configured for inserting an intraosseous catheter into an interior portion of a bone is disclosed. In one embodiment, an intraosseous access device is disclosed, comprising a device body, a trocar needle included with the device body, and an intraosseous catheter removably disposed on the trocar needle. The device body is configured to enable a user of the access device to manually insert a distal tip of the trocar needle through a skin surface of a body of a patient to an external surface of a bone of the patient. An advancement mechanism is also disclosed and is configured to selectively and distally advance the trocar needle and intraosseous catheter a predetermined distance into an internal portion of the bone of the patient after the distal tip of the trocar needle has been inserted to the external surface of the bone.

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# INTRAOSSEOUS ACCESS DEVICE

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/413,879, filed October 27, 2016, and entitled "Intraosseous Access Device," which is incorporated herein by reference in its entirety.

## BRIEF SUMMARY

[0002] Briefly summarized, present embodiments are directed to an access device configured for inserting an intraosseous catheter into an interior portion of a bone. Such access is desired in certain situations to enable rapid infusion of medicaments into the interior intraosseous portion of the bone, which medicaments can then be quickly assimilated into the body. In accordance with embodiments to be described, the access devices disclosed herein are capable of inserting the intraosseous catheter a predetermined distance into the bone interior, which enables the user of the device to accurately place the distal tip of the catheter where desired within the intraosseous region, in contrast to known intraosseous devices.

[0003] In one embodiment, an intraosseous access device is disclosed, comprising a device body, a trocar needle included with the device body, and an intraosseous catheter removably disposed on the trocar needle. The device body is configured to enable a user of the access device to manually insert a distal tip of the trocar needle through a skin surface of a body of a patient to an external surface of a bone of the patient. An advancement mechanism is also disclosed and is configured to selectively and distally advance the trocar needle and intraosseous catheter into an internal portion of the bone of the patient after the distal tip of the trocar needle has been inserted to the external surface of the bone.

[0004] In addition to the above, other access device and intraosseous catheter configurations are disclosed.

[0005] These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0006]** A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

**[0007]** FIG. 1 is a side view of an intraosseous access device according to one embodiment;

**[0008]** FIGS. 2A-2D depict various stages of use of an access device such as that shown in FIG. 1;

**[0009]** FIGS. 3A-3D depict various views of an intraosseous catheter according to one embodiment;

**[00010]** FIG. 4 is a cross-sectional side view of an intraosseous catheter according to one embodiment;

**[00011]** FIGS. 5A-5D depict various stages of use of an access device according to one embodiment;

**[00012]** FIG. 6 is a cross-sectional side view of an intraosseous catheter according to one embodiment;

**[00013]** FIG. 7 is a cross sectional side view showing placement of the catheter of FIG. 6;

**[00014]** FIG. 8 is a cross-sectional side view of a portion of the catheter of FIG. 6;

**[00015]** FIGS. 9A and 9B depict various views of the catheter of FIG. 6 and an access device used therewith;

**[00016]** FIG. 10 is a cross-sectional side view of an intraosseous access device according to one embodiment;

**[00017]** FIG. 11 is a cross sectional side view of an intraosseous access device according to one embodiment;

[00018] FIG. 12 is a cross-sectional side view of a intraosseous access device according to one embodiment;

[00019] FIG. 13 is a cross-sectional side view of an intraosseous catheter according to one embodiment; and

[00020] FIG. 14 is a cross-sectional side view of a portion of the catheter of FIG. 13.

## DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

[00021] Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present disclosure, and are neither limiting nor necessarily drawn to scale.

[00022] For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a catheter placed within the body of a patient is considered a distal end of the catheter, while the catheter end remaining outside the body is a proximal end of the catheter. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

[00023] Embodiments of the present disclosure are generally directed to an access device configured for inserting an intraosseous catheter into an interior portion of a bone. Such access is desired in certain situations to enable rapid infusion of medicaments into the interior intraosseous portion of the bone, which medicaments can then be quickly assimilated into the body. In accordance with embodiments to be described, the access devices disclosed herein are capable of inserting the intraosseous catheter a predetermined distance into the bone interior, which enables the user of the device to accurately place the distal tip of the catheter where desired within the intraosseous region, in contrast to known intraosseous devices.

[00024] FIG. 1 depicts various details of an intraosseous access device ("access device"), generally designated at 10, according to one embodiment. The access device 10 is shown with an intraosseous catheter ("catheter") 20, also referred to as an intraosseous cannula, removably included therewith. Though further details will be given below, in the present embodiment the catheter 20 generally includes a hub 42 and an attached cannula 44 that extends between a

proximal end 44A and a distal end 44B. The cannula 44 is slidably received over a trocar needle ("trocar") 38 that distally extends from the access device 10 and terminates at a distal end 38A.

**[00025]** As shown, the access device 10 includes a body 30 extending between a proximal end 30A and a distal end 30B. In the present embodiment, the body 30 is shaped to define a pistol grip suitable for grasping by a user of the access device 10, though many other suitable shapes for the body are possible.

**[00026]** The body 30 houses an advancement mechanism configured to selectively advance the trocar 38 and catheter 20 included therewith in a distal direction during use of the access device 10. In the present embodiment, the advancement mechanism includes an internal spring that is mounted within the body 30 and operably connected to the trocar 38. The spring is selectively releasable by an actuator, such as a release trigger 36, as to advance the trocar 38 distally with respect to the body 30. This enables the trocar 38 and the catheter 20 included therewith to be driven into a bone of the patient, as will be described further below. As illustrated in FIG. 1, a safety switch 34 is also included and configured to prevent inadvertent actuation of the release trigger 36 by the user. In the present embodiment, the safety switch 34 is positioned adjacent the release trigger 36 and must be displaced from its original position, such as by sliding, so as to enable the release trigger to be actuated by a finger of the user, for instance. Of course, other safety switch and release trigger configurations can be employed.

**[00027]** FIGS. 2A-2D depict various stages of use of the access device 10 in inserting the catheter 20 into a bone of a patient, according to one embodiment. For clarity, the hand of the user is omitted from the figures. As shown in FIG. 2A, the user grasps the body 30 of the access device and directs the distal tip 38A of the trocar 38 via manual force through a skin surface 50 and subcutaneous tissue 52 of the patient until the distal tip of the trocar impacts a wall ("bone wall") 54 of the bone. At this point, the safety switch 34 is disengaged by the user and the release trigger 36 is depressed by a finger of the user, which in turn causes the internal spring (or other suitable advancement mechanism) to distally drive the trocar distal tip 38A through the bone wall 54 and into the interior, bone marrow 56, of the bone, as seen in FIG. 2B. This also places the distal tip 44B of the catheter cannula 44 in the bone marrow 56, as desired. Note that the internal spring, as an advancement mechanism, serves as one example of a selective means for advancing the trocar and the catheter. It is appreciated that other

structures and components can be employed to provide the same functionality, in other embodiments, including a drill, a chemical or other charges, controlled explosive charges, etc.

**[00028]** Note that the access device 10 and the advancement mechanism are configured to advance the cannula distal tip 44B a predetermined distance into the bone. In one embodiment, the predetermined distance can vary from about .25 inch to about 1 inch into the bone, though a variety of other possible depths are possible. The variation in predetermined depth may be needed in accessing bones of differing thicknesses. In one embodiment, a depth selector, such as a depth dial, can be included on the access device body 30. With such a depth dial, the user can select the desired depth that the advancement mechanism will advance the distal tip 44B of the cannula 44. The depth dial in such an embodiment can vary the pre-actuation compression of the spring so as to achieve a corresponding advancement of the trocar 38 and catheter 20 according to the depth dial setting. In other embodiments, other controls can be employed to vary actuation of the spring or other advancement mechanism according to predetermined desired depths. In yet another embodiment, the access device 10 can be configured to insert the trocar 38 and catheter 20 to one, pre-set depth.

**[00029]** In FIG. 2C, the trocar 38 is withdrawn from the cannula 44 of the catheter 20 by proximally withdrawing the access device body 30, thus causing separation of the access device 10 from the catheter 20. After withdrawal of the access device 10, the cannula 44 remains in place with its distal tip 44B disposed within the bone marrow 56, as shown. Note that the catheter hub 42 is spaced apart from the skin surface 50 at this point. In FIG. 2D, the catheter 20 is adjusted such that the hub 42 is adjacent the skin surface 50, as explained in further detail below. Also, an extension set 60 is shown operably attached to the hub 42 so as to enable medicaments or other fluids to be infused through the catheter 20 and into the bone marrow 56 via the catheter cannula 44.

**[00030]** FIGS. 3A-3D depict various details of the catheter 20 according to one embodiment, wherein the hub 42 defines a base portion 64 and a connector portion 66 configured to enable the extension set 60 to operably connect with the catheter. The hub 42 includes a lumen 68 that cooperates with the cannula 44 to define a fluid path to allow the passage of fluids through the catheter. As shown, the cannula 44 – which in this embodiment includes a sufficiently rigid material such as stainless steel, PEEK, or other suitable metals/thermoplastics/materials – is slidable with respect to the hub 42 so as to enable the total length of the catheter 20 to be adjusted – a relatively long length for a deep cannula distal tip placement as shown in FIG. 3B,

and a relatively short length for a shallow cannula distal tip placement as shown in FIG. 3C. This in turn enables the hub 42 of the catheter 20 to rest against the skin surface 50, as shown in FIG. 2D, regardless of the depth of the distal tip 44B of the cannula 44. If not adjustable, the catheter may present a situation where the hub 42 is spaced apart from the skin surface 50, similar to what is shown in FIG. 2C.

**[00031]** In greater detail, the variation in extension of the cannula 44 from the hub 42 is made possible by an O-ring 70 that is interposed within the lumen 68 between the base portion 64 of the hub 42 and an outer surface of the cannula 44, which in turn enables the cannula to longitudinally slide within the hub lumen in a fluid-tight arrangement. It is appreciated that the O-ring 70 can be located in other positions within the lumen 68 of the hub 42 and that other fluid sealing modes in addition to an O-ring can be utilized. FIG. 3D, shows that, in the present embodiment, the cannula 44 can be withdrawn into the hub 42 such that it extends past the connector portion 66 of the hub and into the extension set 60, thus enabling further shortening of the overall longitudinal length of the catheter 20.

**[00032]** FIG. 4 depicts the catheter 20 according to another embodiment, wherein the cannula 44 includes a first cannula portion 44A and a second cannula portion 44B that are telescopically mated to one another with two O-rings 70 interposed therebetween and between the first cannula portion and the lumen 68 of the hub base portion 64 as to enable the cannula portions to extend and contract relative to one another and the hub base portion. Such a telescoping configuration can allow for greater variation in total longitudinal length of the catheter 20. Also, as shown, the proximal ends of the first and second cannula portions include radially extending lips that prevent separation of the cannula portions from each and from the hub when the cannula portions are fully extended. Though other gauge sizes are possible, in the present embodiment the first cannula portion 44A is a 15 gauge size while the second cannula portion 44B, which fits inside the first cannula portion, is an 18 gauge size. It is appreciated that one, two, or more telescoping portions can be employed.

**[00033]** FIGS. 5A depict various features and operation of the access device 10 according to one embodiment, wherein the body 30 includes a telescoping portion that initially shields the trocar 38 prior to access device use. During use of the access device 10, and as shown in FIG. 5A, the user grasps the body 30 of the access device and places the distal end 30B thereof against the skin surface 50. The distal tip 38A of the trocar 38 is then inserted via manual pushing through the skin surface 50 and subcutaneous tissue 52 of the patient until the distal

tip of the trocar impacts a wall ("bone wall") 54 of the bone, as shown in FIG. 5B. Note that this action causes the telescoping portion 74 of the access device body 30 to collapse into the more proximal portion of the body so that the trocar 38 can extend from the body. Also, it is appreciated that this action causes the catheter cannula 44, which is disposed about the trocar 38, to be initially retracted at least partially within the catheter hub 42, then extend distally as the trocar extends distally toward the bone wall 54. The configurations of the catheter 20 shown in FIGS. 3A-3D and 4 are examples of suitable catheter configurations that can be utilized with the access device embodiment shown in FIGS. 5A-5D, though other catheter configurations are also possible. As has been discussed, the initial shielding of the trocar 38 by the telescoping portion 74 of the access device body 30 prevents inadvertent contact with the trocar by the user prior to trocar extension from the access device body. In one embodiment, the telescoping portion of the access device body only shields the trocar after use of the access device.

**[00034]** At this point, the safety switch 34 is disengaged by the user and the release trigger 36 is depressed by a finger of the user, which in turn causes the internal spring (or other suitable advancement mechanism) to distally drive the trocar distal tip 38A through the bone wall 54 and into the bone marrow 56 of the bone, as seen in FIG. 5C. This also places the distal tip 44B of the catheter cannula 44 in the bone marrow 56, as desired. Note that, due to the longitudinally extendable nature of the hub 42, the hub rests against the skin surface 50 at the commencement of and throughout the catheter insertion procedure, as seen in FIGS. 5A-5D.

**[00035]** As with the embodiment shown and discussed in connection with FIGS. 2A-2D, the access device 10 and the advancement mechanism are configured to advance the cannula distal tip 44B a predetermined distance into the bone. In this and other embodiments, it is appreciated that the predetermined distance can be varied according to user preference as discussed herein, and that the access device can be configured such that it is capable of advancing the catheter a distance into the bone that is not predetermined before use of the access device.

**[00036]** In FIG. 5D, the trocar 38 is withdrawn from the cannula 44 of the catheter 20 by proximally withdrawing the access device body 30, thus causing separation of the access device 10 from the catheter 20. As the access device body 30 is proximally withdrawn, the telescoping portion 74 distally extends to fully cover and shield the trocar 38 upon its removal from the catheter 20, thus preventing an inadvertent needle stick to the user. In one embodiment, interfering surfaces can be included on both the telescoping portion 74 and the catheter 20 to

assist in the distal extension of the telescoping portion as seen in FIG. 5D. In another embodiment, the telescoping portion 74 can be manually extended by the user.

**[00037]** After withdrawal of the access device 10, the cannula 44 remains in place with its distal tip 44B disposed within the bone marrow 56, as shown. Note that the catheter hub 42 remains in place against the skin surface 50, as desired. The catheter 20 can be dressed, connected to the extension set 60, and otherwise made ready for infusion of fluids into the bone marrow 56 via the catheter cannula 44.

**[00038]** FIGS. 6-8 depict details of an example of a catheter 120 that can be employed with the access device 10 according to one embodiment. As shown, the catheter 120 includes on a proximal end a hub 122 configured to operably connect with an extension set, and on a distal end a rigid cannula portion 124 extending between a proximal end 124A and a distal end 124B. A flexible catheter portion 126 operably connects between the hub 122 and the cannula portion 124 and overlaps the proximal end 124A of the cannula portion in the present embodiment. A lumen 128 that serves as a fluid pathway is defined by the hub 122, cannula portion 124, and the catheter portion 126. The cannula portion 124 includes a sufficiently rigid material to penetrate bone without buckling or collapsing, such as stainless steel, peek, or other suitable material including other metals and thermoplastics. The hub 122 and the catheter portion 126 include suitable thermoplastic or other materials in one embodiment.

**[00039]** FIG. 7 depicts the manner in which the catheter 120 is employed, wherein the cannula portion is shown inserted through the bone wall 54 such that its proximal end 124A resides external to the bone wall and its distal end 124B is disposed in the bone marrow 56. A distal segment of the catheter portion 126 extends between the bone wall 54 and the skin surface 50, while the remainder portion of the catheter resides outside the patient. In the present embodiment, a slidable elbow piece 150 is shown disposed over the catheter tube 126. During use, the elbow piece can be slid along the catheter tube 126 and positioned to help conform the catheter tube to the skin surface 50 at the point of exit from the patient body. The elbow piece can include a 90 degree other angle bend to assist with such conformation of the catheter tube 126.

**[00040]** Also note that, though FIG. 7 shows it extending out through the skin surface 50, the cannula portion 124 in one embodiment can be disposed completely internal to the patient body such that a distal portion of the catheter tube 126 is also disposed beneath the skin surface.

**[00041]** FIG. 8 shows that, in the present embodiment, securement wires 130 attached to the proximal end 124A of the cannula portion 124 extend proximally through the lumen 128 of the catheter portion 126 to the hub 122 where they are secured. The securement wires 130 provide necessary strength to enable the cannula portion 124 to be pulled from the bone wall 54 without separating from the rest of the catheter 120. Note that in one embodiment the securement wires 130 can be integrated into the wall of the catheter portion 126. In another embodiment, one, two, or more securement wires 130 can be included. In yet another embodiment, the securement wires 130 extend out past the proximal end of the hub 122. In another embodiment, the securement wires can take other forms, such as a securement ribbons, for instance. These and other variations are therefore contemplated.

**[00042]** FIG. 9A shows that manner in which the catheter 120 is loaded on the trocar 38 of the access device 10. FIG. 9B shows that the trocar 38 in one embodiment can include a shoulder 134 against which the proximal end 124A abuts when the catheter 120 is disposed on the trocar. This provides the trocar 38 a surface against which to push to advance the catheter 124 through the bone wall 54 and into the bone marrow 56 during use of the access device 30 while still enabling the trocar to readily withdraw from the catheter after catheter placement is complete. Note that the particular location, size, and other configuration of the shoulder can vary from what is shown and described herein.

**[00043]** Fig. 9A further depicts details of an adjustment component configured to adjust the depth to which the advancement mechanism advances the distal tip 38B of the trocar 38 and the catheter 120 (Note that the present discussion regarding the adjustment component can be applied to other embodiments herein). As shown, a spring 140 is included within the access device body 30 and configured as an advancement mechanism to provide a distal advancement force as with other embodiments herein) to the trocar 38 via its proximal end 38A. An adjustment component, here embodied as a rotary adjustment dial 142, is disposed on the surface of the access device body 30 and is movable by a user of the access device to select a predetermined depth to which the distal tip 38B of the trocar 38, and correspondingly, the distal tip 124B of the catheter 120, will be advanced by the spring 140. In the present embodiment, the adjustment dial 142 is operably connected to one or more control arms 144 that are configured to vary the pre-actuation length of the spring 140. This in turn lessens or increases the potential energy stored in the spring 140 prior to actuation, thus providing for relatively more shallow or deep advancement of the trocar 38 and catheter 120 into the bone. In addition

to this, other adjustment components and advancement mechanisms can be employed, in other embodiment.

**[00044]** In light of the above, it is appreciated that the spring 140 serves as one example of a selective means for advancing the trocar and the catheter. Note that the spring 140 is considered selective as it is actuated selectively by the user via a trigger or other suitable component. It is appreciated that other structures and components can be employed to provide the same functionality, in other embodiments.

**[00045]** FIG. 10 depicts details of an intraosseous access device ("access device") 210 according to one embodiment, including an elongate body 230 inside of which is disposed an intraosseous catheter ("catheter") 220, also referred to as an intraosseous cannula. As before, the catheter 220 includes a hub 242 from which distally extends a cannula 244. The catheter 220 in the present embodiment is slidably disposed over a trocar needle ("trocar") 248 and received within a cartridge 246 that itself is disposed within the access device body 230, as shown.

**[00046]** The access device 210 further includes an advancement mechanism configured to selectively advance the trocar 248 and catheter 220 included therewith in a distal direction during use of the access device 210. In the present embodiment, the advancement mechanism includes a first actuator, here implemented as a first trigger 250 configured to selectively activate a first spring 252, and a second actuator, here implemented as a second trigger 260 configured to selectively actuate a second spring 262. The first spring 252 is a relatively low-force spring configured to provide, when actuated by the first trigger 250 (*e.g.*, by manually depressing the first trigger in a distal direction), a force to distally advance the catheter-containing cartridge 246 out a distal end of the access device body 230 a predetermined distance. This action is employed during use of the access device 210 to advance the trocar 248 and catheter 220 through the skin surface and tissue of the patient to the bone wall. Note that in the present embodiment, the distal end of the cartridge 246 rests against the skin surface after actuation of the first trigger 250 to distal advance the catheter 220.

**[00047]** In contrast, the second spring 262 is a relatively high-force spring configured to provide, when actuated by the second trigger 260 (*e.g.*, by manually pulling the second trigger in a proximal direction), a force to distally advance the catheter 220 from the open distal end of the cartridge 246 a further predetermined distance. This action is employed during use of

the access device 210 to advance the distal ends of the trocar 248 and the catheter 220 through the bone wall and into the bone marrow of the patient. The use of the relatively high-force spring 262 is necessary to enable the trocar 248 and catheter 220 to penetrate the relatively stiff and rigid bone wall. Once the distal end of the catheter 220 is in place in the bone marrow of the patient, the trocar can be withdrawn from the patient body by proximally withdrawing the access device body 230 by the user.

**[00048]** It is appreciated that the second spring 262 serves as an example of selective means for advancing the trocar 248 and the catheter 220, and is thus configured to apply the necessary amount of force to cause the above-described penetration of the patient bone wall. The second spring 262 is considered selective as it is actuated by a user via a trigger or other suitable component. It is appreciated that other structures and components can be employed to provide the same functionality, in other embodiments. Note that the first and second springs 252, 262 can be configured to cause penetration of the trocar 248/catheter 220 to different predetermined distances into the bone. In one embodiment, the access device is configured such that the first and second springs cause penetration to a single predetermined depth for each spring. In another embodiment, the access device includes the ability to adjust the force of one or more of the springs to vary the amount of trocar/catheter penetration. These and other modifications are therefore contemplated.

**[00049]** FIG. 11 depicts the access device 210 according to another embodiment, wherein both the first trigger 250 and the second trigger 260 are configured as triggers to be manually pulled in the proximal direction to actuate the first spring 252 and the second spring 262, respectively. Note that FIG. 11 shows the configuration of the access device 210 after actuation of the first spring 252 by manual proximal pulling of the first trigger 250, wherein the catheter 220 is partially extended from an open distal end of the access device body 230, but before actuation of the second spring 262 by manual proximal pulling of the second trigger 260, which causes further distal ejection of the catheter. In one embodiment, it is appreciated that the access device can be configured such that actuation of the first spring, second spring, or both springs can be performed automatically. Also, in one embodiment, the relatively strong second spring can be sized to fit within (such as concentrically, for instance) the relatively weaker first spring. In another embodiment , the first spring is sized to be received within the second spring.

**[00050]** FIG. 12 depicts details of an advancement mechanism according to another embodiment, wherein the access device body 230 defines on an inner surface thereof a plurality

of ratchet teeth 270 that are configured to engage with two radially extending engagement arms 272 that are included on a proximal portion of the cartridge 246 holding the catheter 220. This arrangement enables the cartridge 246 and included catheter 220 to distally advance in a step-wise fashion without having the ability to withdraw back into the access device body 230. Note that the ratchet components can vary in shape, size, position, and other configuration from what is shown and described herein.

**[00051]** FIGS. 13 and 14 depict details of an intraosseous catheter 320 according to one embodiment, including a hub 342 and an elongate cannula 344 distally extending therefrom. The catheter 320 is shown in FIG. 13 in place within a patient, with a distal tip of the cannula 344 extending to the bone marrow 56. A lumen 350 is defined by the catheter 320 to enable infusion of medicaments or other fluids to the bone marrow 56.

**[00052]** FIG. 14 shows that the catheter 320 is adjustable in total length. In light of this, in the present embodiment the hub 342 includes a slide tube defining a cavity 354 and an opening 356 to the cavity. Correspondingly, the cannula 344 is received through the opening 356 and includes on its proximal end a radially extending rim 358 configured to slide proximally/distally within the cavity 354, thus enabling the total longitudinal length to vary according to the position of the rim within the cavity. A seal 360 is placed about the opening 356 to ensure a fluid tight seal between the cannula and the opening. In this way, the catheter 320 can vary in desired length according to bone depth and user preference. If desired, the hub 342 can be adhered to the skin surface 50 after adjustment of the catheter 320 is made to enable the hub to rest against the skin surface.

**[00053]** Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

# CLAIMS

What is claimed is:

1. An intraosseous access device, comprising:

a device body;

a trocar needle included with the device body;

an intraosseous catheter removably disposed on the trocar needle, the device body configured to enable a user of the access device to manually insert a distal tip of the trocar needle through a skin surface of a body of a patient to an external surface of a bone of the patient; and

an advancement mechanism configured to selectively and distally advance the trocar needle and intraosseous catheter into an internal portion of the bone of the patient after the distal tip of the trocar needle has been inserted to the external surface of the bone.

2. The access device as defined in claim 1, wherein the device body includes a pistol grip shape.

3. The access device as defined in claim 1, wherein the advancement mechanism provides a distal advancement force to distally advance the trocar needle and the intraosseous catheter.

4. The access device as defined in claim 3, wherein the advancement mechanism includes a spring, the spring providing the distal advancement force.

5. The access device as defined in claim 3, wherein the distal advancement force is variable in magnitude by a user of the access device.

6. The access device as defined in claim 5, wherein the distal advancement force is user-variable via an adjustment component.

7. The access device as defined in claim 6, wherein the adjustment component includes an adjustment dial mounted on the body of the access device.

8. The access device as defined in claim 7, wherein the advancement mechanism includes a spring and wherein the adjustment component is configured to alter an operable length of the spring prior to distal advancement of the trocar needle and intraosseous catheter.

9. The access device as defined in claim 1, wherein the advancement mechanism is configured to distally advance the trocar needle and the intraosseous catheter a predetermined depth into the internal portion of the bone.

10. The access device as defined in claim 9, wherein the predetermined depth is adjustable via an adjustment component.

11. The access device as defined in claim 1, wherein the advancement mechanism is configured to be actuated by a release trigger.

12. The access device as defined in claim 11, wherein the access device further includes a safety switch, the safety switch configured to prevent inadvertent actuation of the release trigger.

13. The access device as defined in claim 1, wherein the advancement mechanism is configured to distally advance a distal tip of the intraosseous catheter into an intraosseous portion of the bone.

14. The access device as defined in claim 1, wherein the access device is configured for placement of the intraosseous catheter within at least one of a tibia, a sternum, and a humerus bone.

15. The access device as defined in claim 1, wherein the trocar needle extends distally from the device body prior to use of the access device.

16. The access device as defined in claim 1, wherein the advancement mechanism includes at least one of a drill, a chemical-based charge, and a spring.

17. The access device as defined in claim 1, wherein the intraosseous catheter includes a hub, a rigid distal portion, and a flexible catheter portion interposed between the hub and the rigid distal portion, the rigid distal portion configured to be disposed through the external surface of the bone after advancement of the trocar needle and the intraosseous catheter by the advancement mechanism.

18. The access device as defined in claim 1, wherein the intraosseous catheter includes a hub and a cannula, the cannula being slidable with respect to the hub so as to enable a longitudinal length of the intraosseous catheter to be adjusted.

19. A method for inserting an intraosseous catheter into a bone of a patient, the method comprising:

by manual force, inserting a trocar needle of an intraosseous access device through a skin surface of a body of a patient to an external surface of the bone, an intraosseous catheter removably disposed on the trocar needle; and

after inserting the trocar needle to the external surface of the bone and by an advancement mechanism included in the intraosseous access device, advancing the trocar needle into the bone a predetermined distance such that a distal end of the intraosseous catheter is disposed in intraosseous material of the bone.

20. The method for inserting as defined in claim 19, wherein advancing the trocar needle further comprises advancing the trocar needle via a distal advancement force.

21. The method for inserting as defined in claim 20, further comprising advancing the trocar needle via a distal advancement force provided by a spring.

22. The method for inserting as defined in claim 19, wherein the predetermined distance is variable according to adjustment by a user of the intraosseous access device.

23. The method for inserting as defined in claim 19, wherein prior to advancing the trocar needle the method further comprises selecting the predetermined distance for insertion of the trocar needle via an adjustment component.

24. The method for inserting as defined in claim 19, further comprising adjusting a longitudinal length of the intraosseous catheter after the intraosseous catheter is disposed in the intraosseous material of the bone.

25. The method for inserting as defined in claim 24, wherein adjusting the longitudinal length comprises sliding a cannula portion of the intraosseous catheter with respect to a hub portion of the intraosseous catheter.

26. The method for inserting as defined in claim 24, wherein adjusting the longitudinal length comprises sliding a first cannula portion and a second cannula portion with respect to one another and with respect to a hub portion of the intraosseous catheter.

27. An intraosseous access device, comprising:

a device body;

a trocar needle included with the device body, an intraosseous catheter removably disposed on the trocar needle, the device body configured to manually enable a user of the access device to insert a distal tip of the trocar needle through a skin surface of a body of a patient to an external surface of a bone of the patient; and

selective means for advancing the trocar needle and intraosseous catheter into an internal portion of the bone of the patient after the distal tip of the trocar needle has been inserted to the external surface of the bone.

28. The access device as defined in claim 27, wherein the means for advancing is disposed within the device body.

29. The access device as defined in claim 27, wherein the device body includes a telescoping portion that is configured to cover the trocar needle prior to use of the access device.

30. The access device as defined in claim 27, wherein the device body includes a telescoping portion that is configured to cover the trocar needle after the intraosseous catheter has been inserted into the internal portion of the bone and the trocar needle has been removed from the patient.

31. The access device as defined in claim 27, wherein the means for advancing includes a spring configured to impart a distal advancement force to the trocar needle and the intraosseous catheter upon actuation by the user.

32. The access device as defined in claim 27, wherein the means for advancing is configured to be actuated via a release trigger.

33. An intraosseous catheter, comprising:

a hub;

a rigid distal portion; and

a flexible catheter portion interposed between the hub and the rigid distal portion, the rigid distal portion configured to be disposed in a bone wall of a patient wall, a portion of the flexible catheter portion configured to reside external to the patient.

34. The catheter as defined in claim 33, further comprising:

an elbow piece slidably disposed on the flexible catheter portion, the elbow piece configured to bend the flexible catheter portion at a predetermined angle; and

a securement wire proximally extending from the rigid distal portion to the hub, the securement wire configured to enable the rigid distal portion to be pulled and removed from the bone wall of the patient during removal of the catheter from the patient.

35. The catheter as defined in claim 33, wherein the catheter is configured to be inserted into bone wall of the patient by an access device, the access device including a trocar needle that is configured to receive the catheter thereon, the trocar needle including a shoulder portion that is configured to engage with a proximal portion of the rigid distal portion of the catheter and distally advance the catheter.

36. An intraosseous access device, comprising:

a device body;

a trocar needle included with the device body;

an intraosseous catheter removably disposed on the trocar needle;

a first advancement member configured to provide a first distal advancement force sufficient to distally advance a distal tip of the trocar needle and the catheter through a skin surface to an external surface of a bone of a patient; and

a second advancement member configured to provide a second distal advancement force sufficient to distally advance the distal tip of the trocar needle and the catheter through the external surface of the bone after the first advancement member has advanced the distal tip of the trocar and the catheter to the external surface of the bone.

37. The access device as defined in claim 36, wherein the first advancement member is a first spring and wherein the second advancement member is a second spring, the second distal advancement force provided by the second spring being greater in magnitude relative the first distal advancement force provided by the first spring.

38. The access device as defined in claim 37, wherein the first spring is actuated by a first trigger and wherein the second spring is actuated by a second trigger.

39. The access device as defined in claim 38, wherein at least one of the first trigger and the second trigger is actuated via a proximally directed manual force provided by a user.

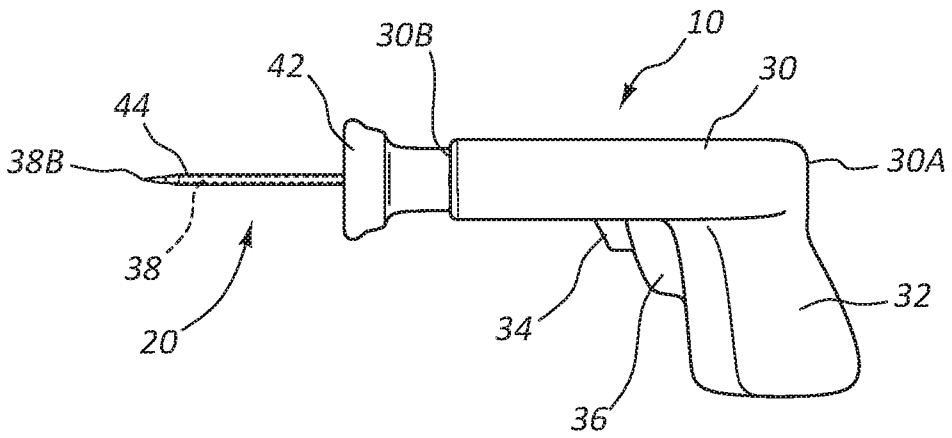


FIG. 1

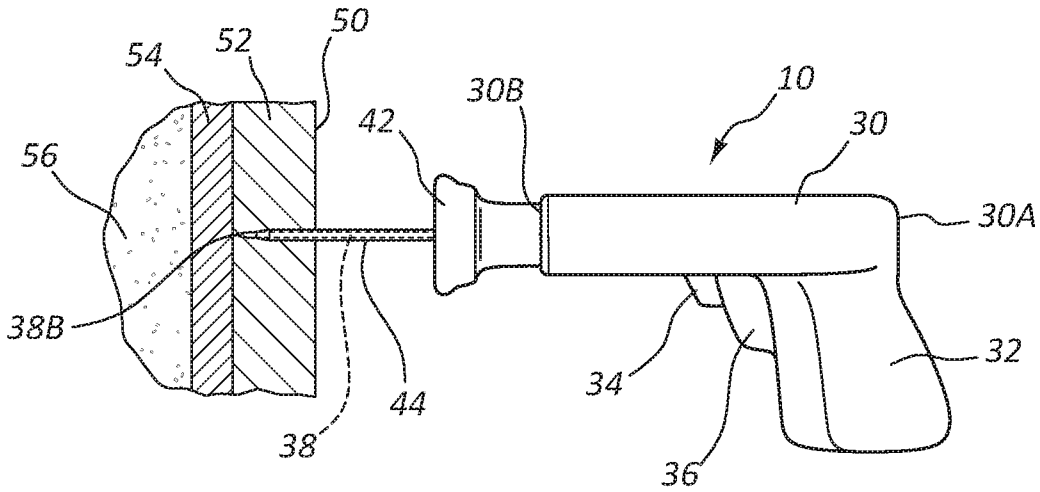


FIG. 2A

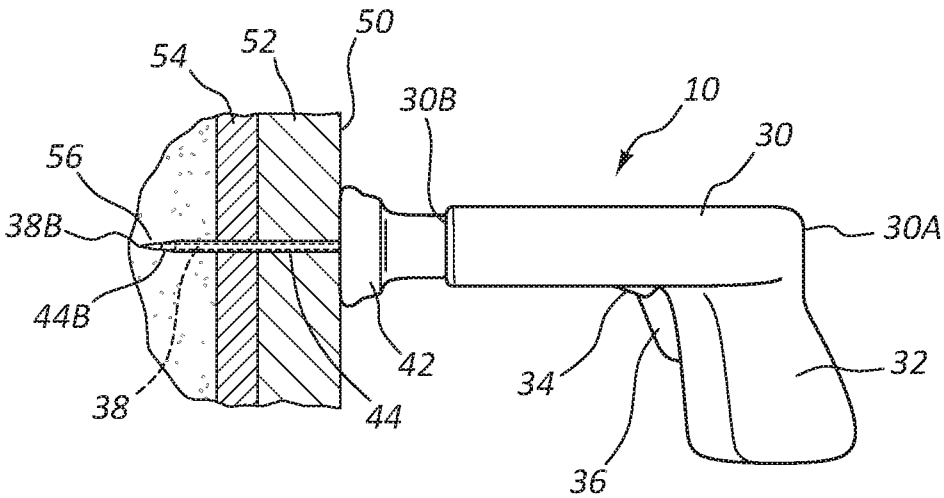


FIG. 2B

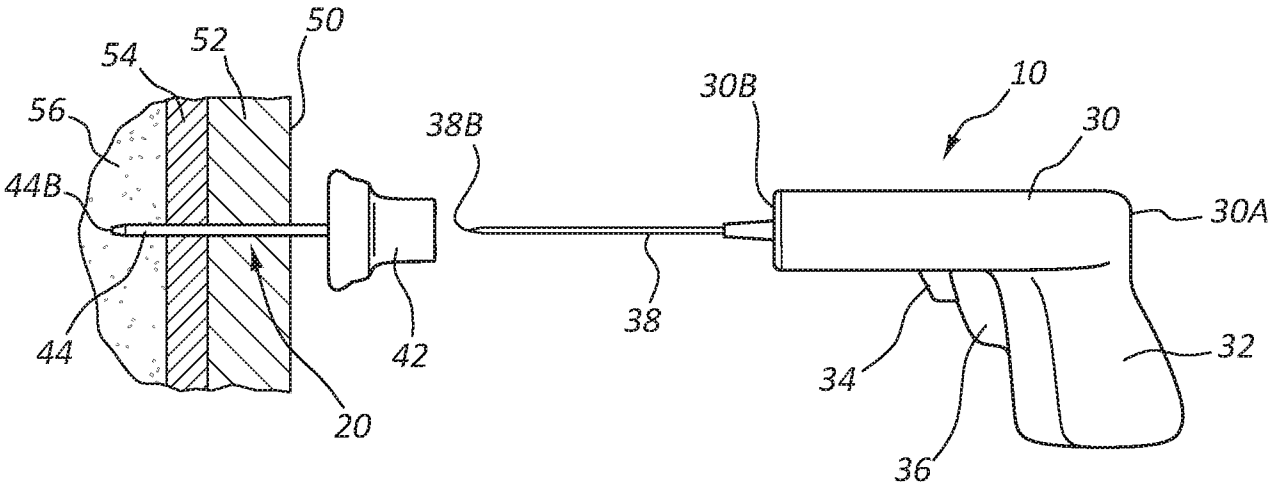
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FIG. 2C

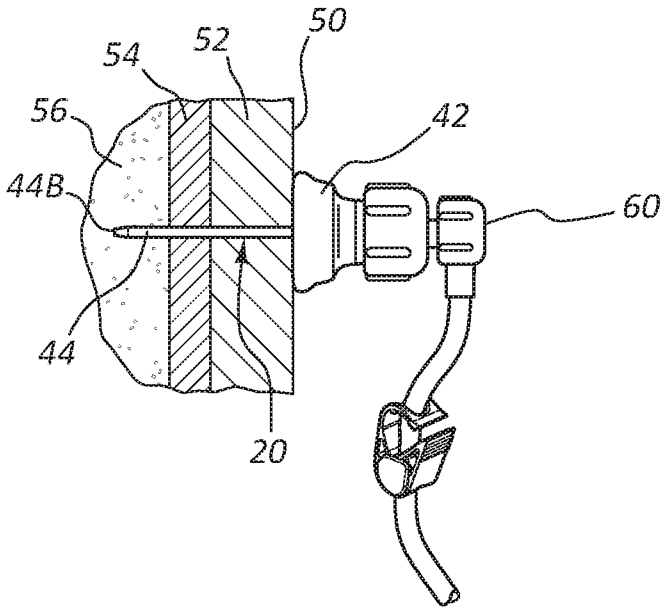
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FIG. 2D

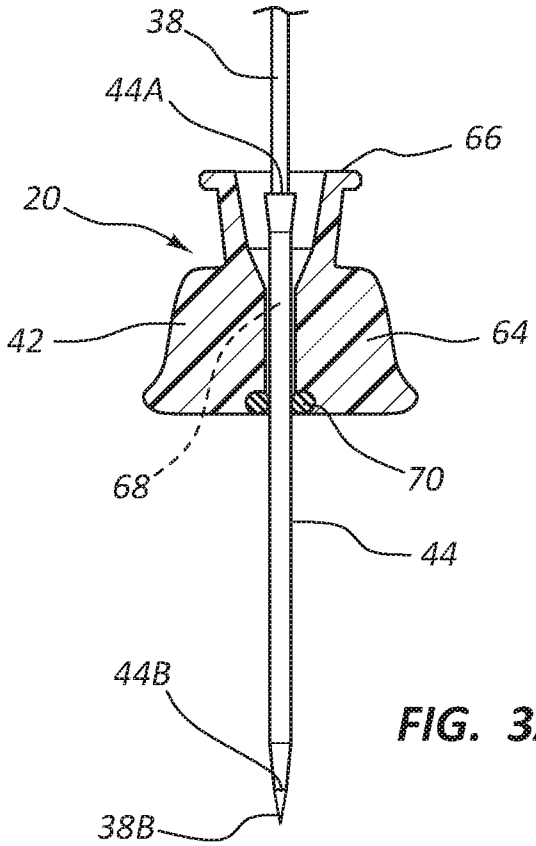


FIG. 3A

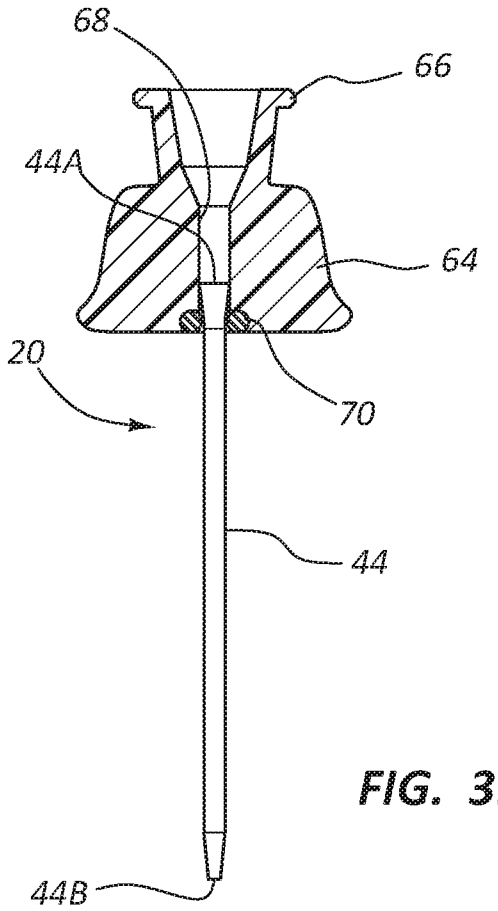


FIG. 3B

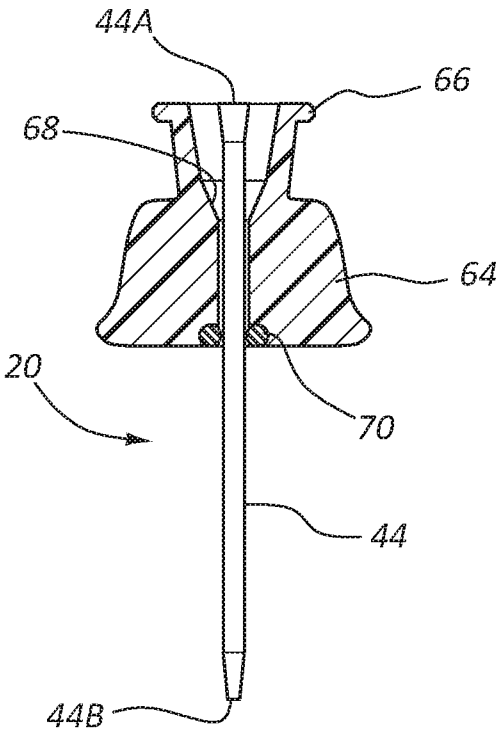


FIG. 3C

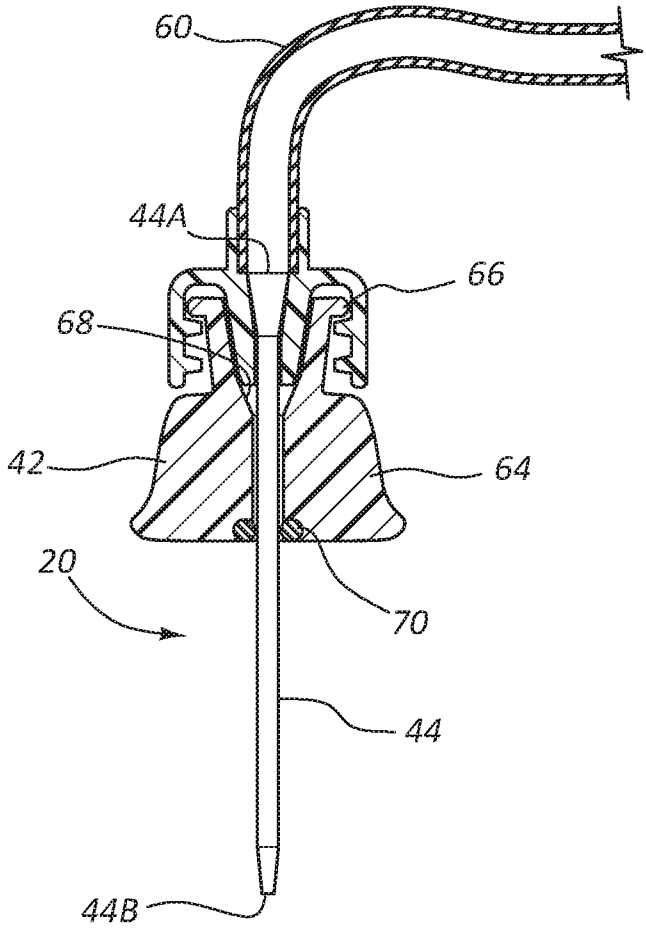


FIG. 3D

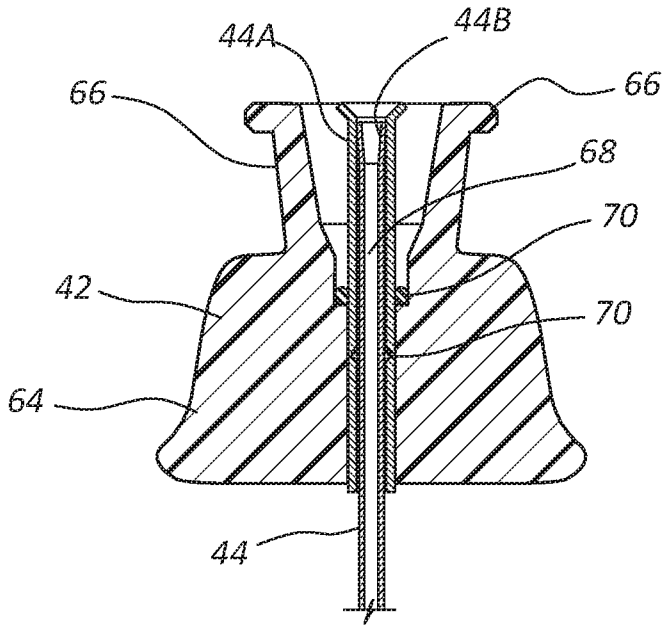


FIG. 4

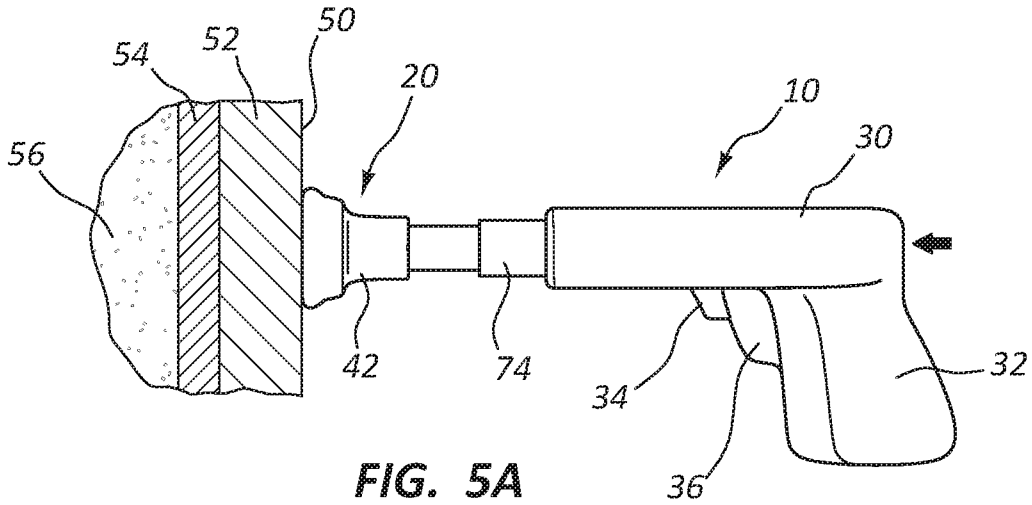


FIG. 5A

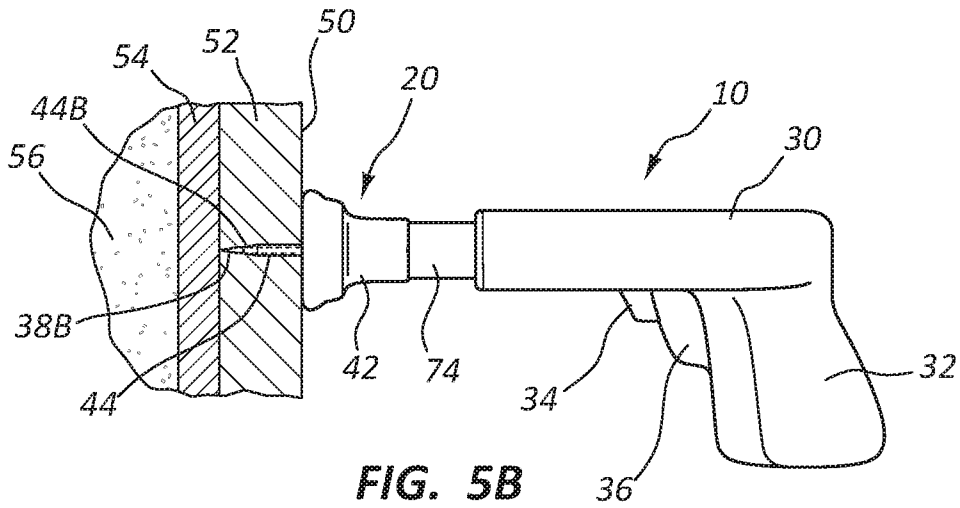


FIG. 5B

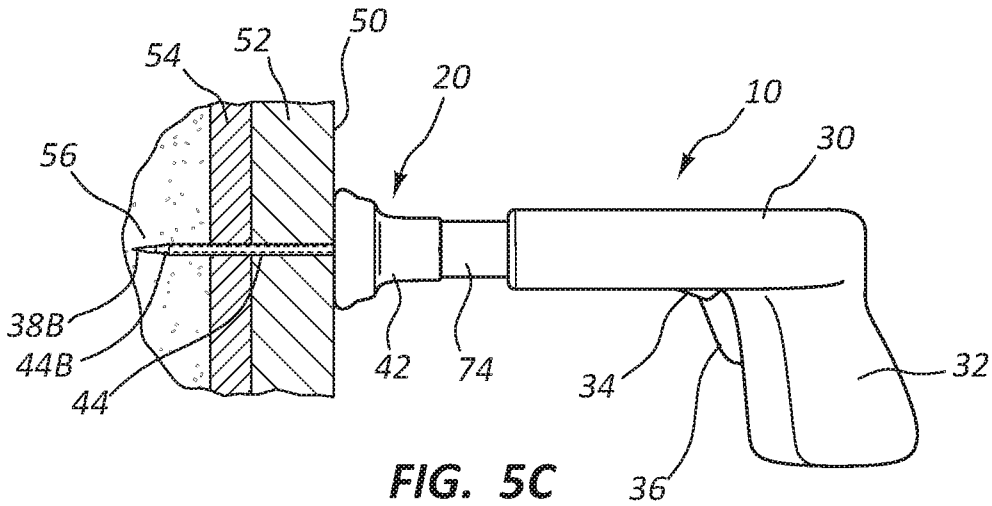


FIG. 5C

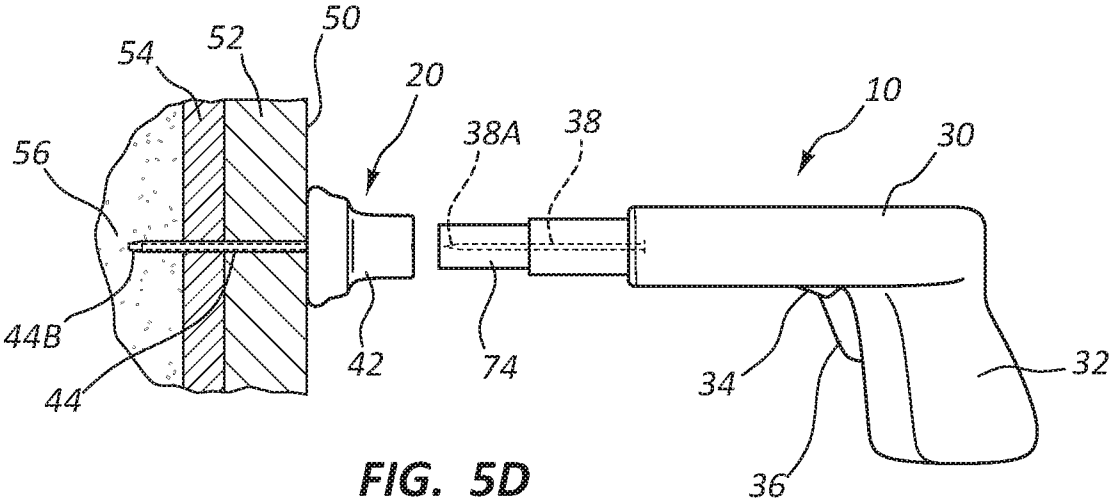


FIG. 5D

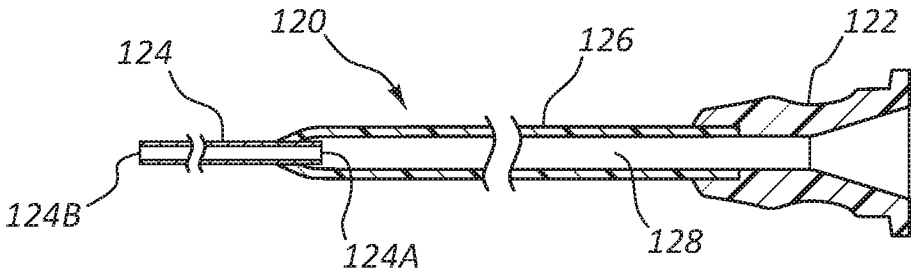


FIG. 6

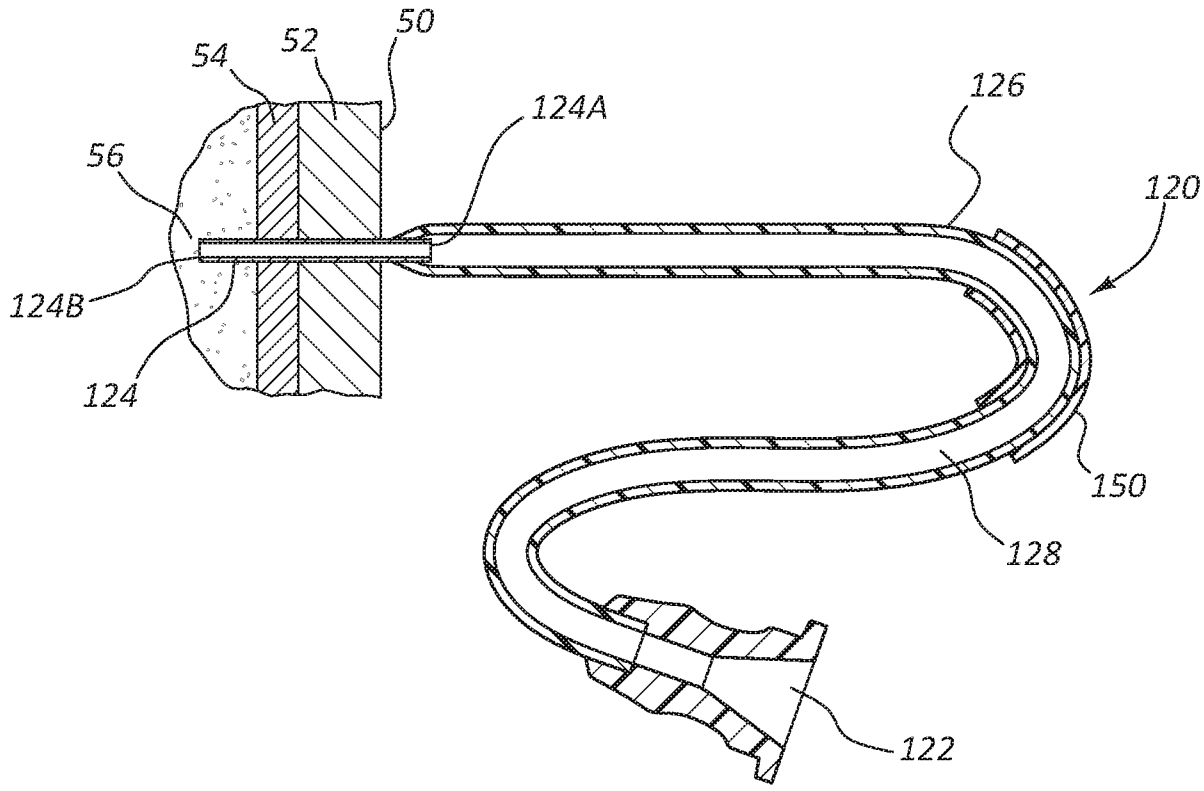


FIG. 7

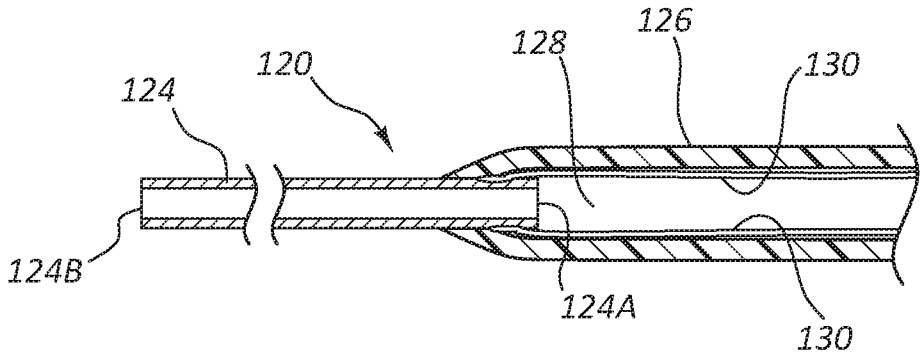


FIG. 8

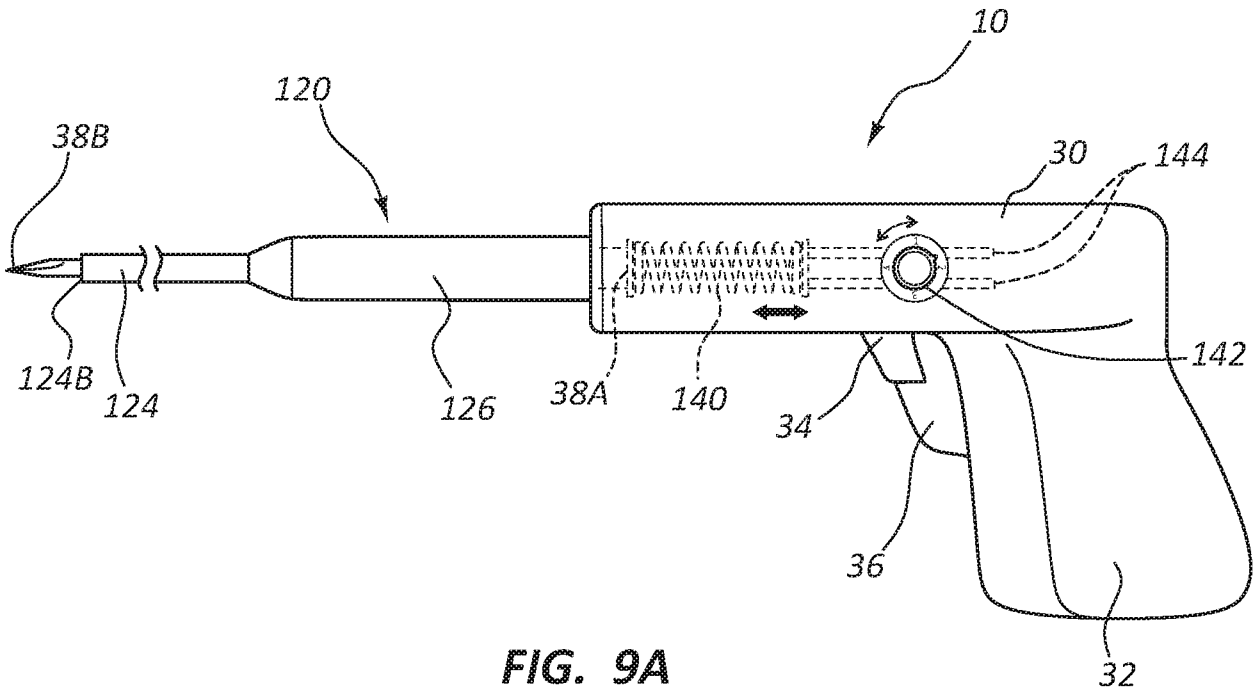


FIG. 9A

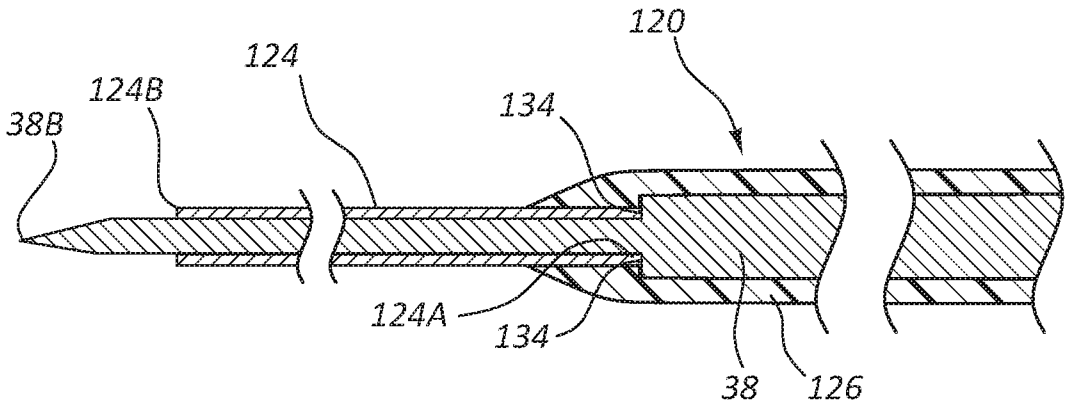


FIG. 9B

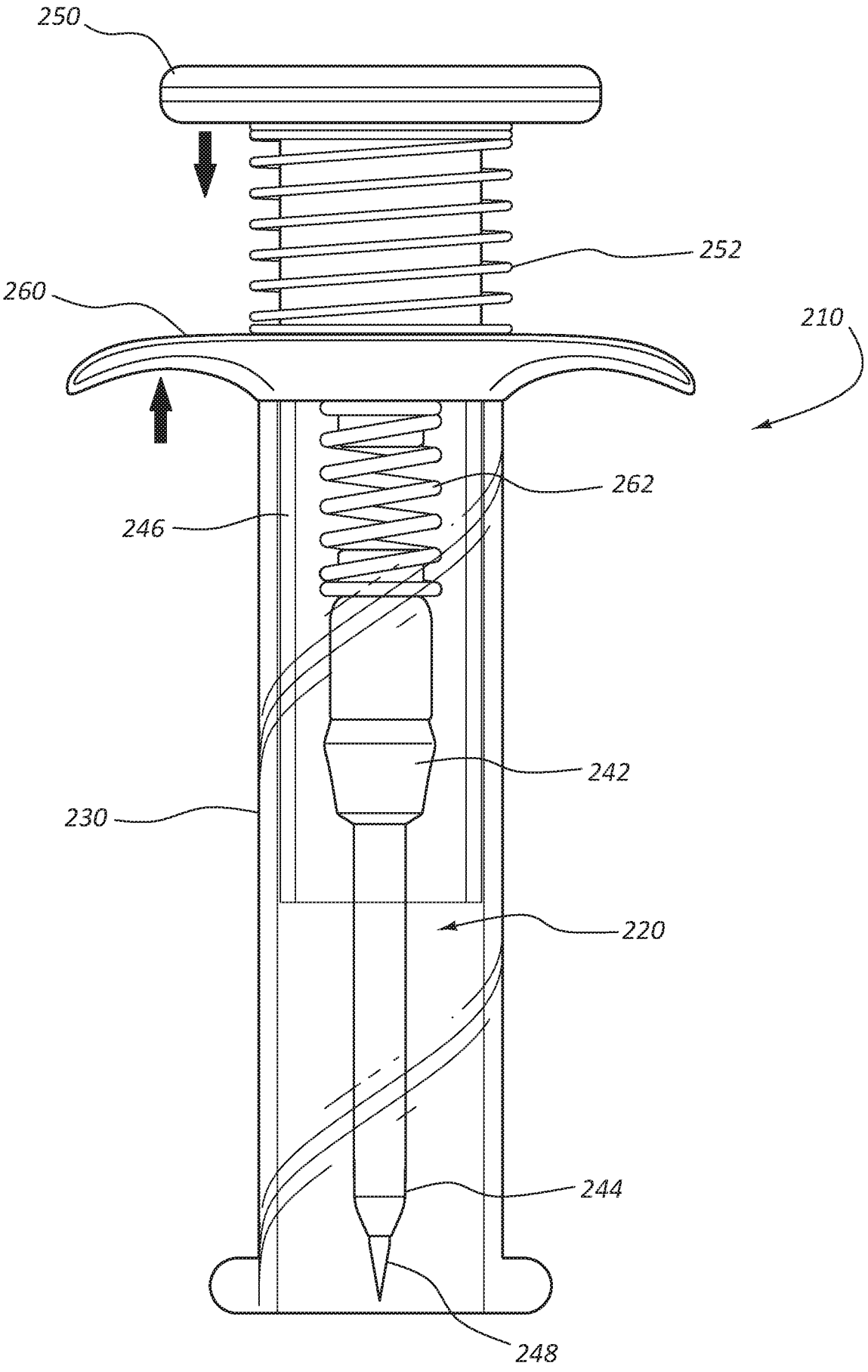


FIG. 10

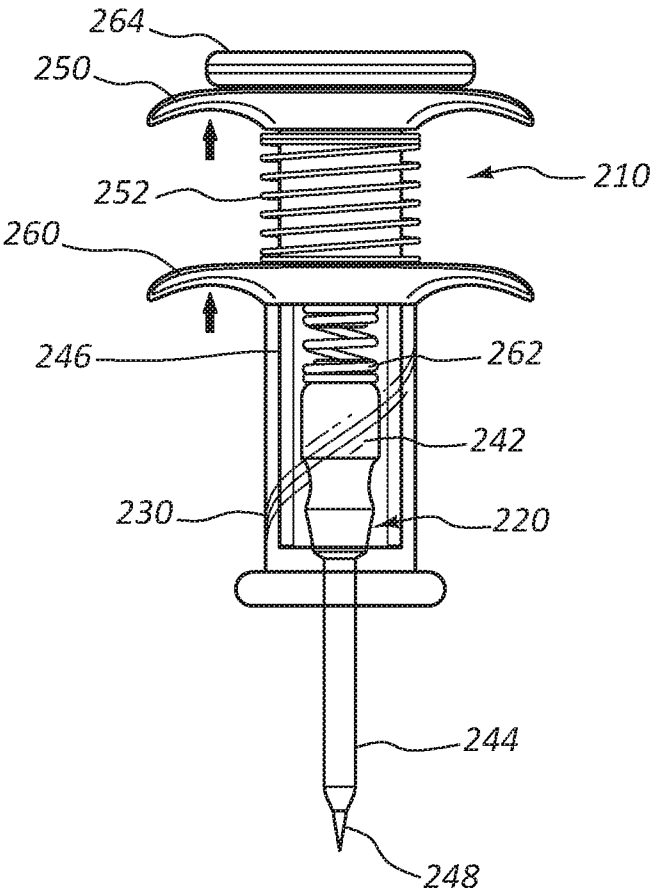
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FIG. 11

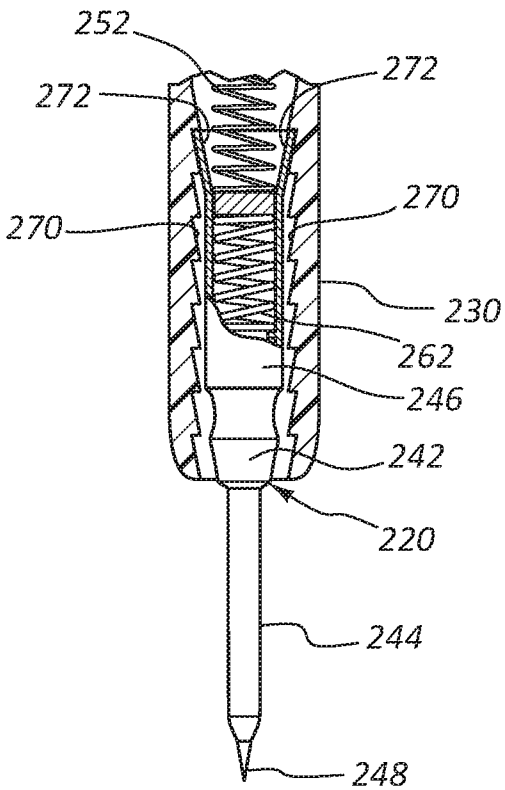
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FIG. 12

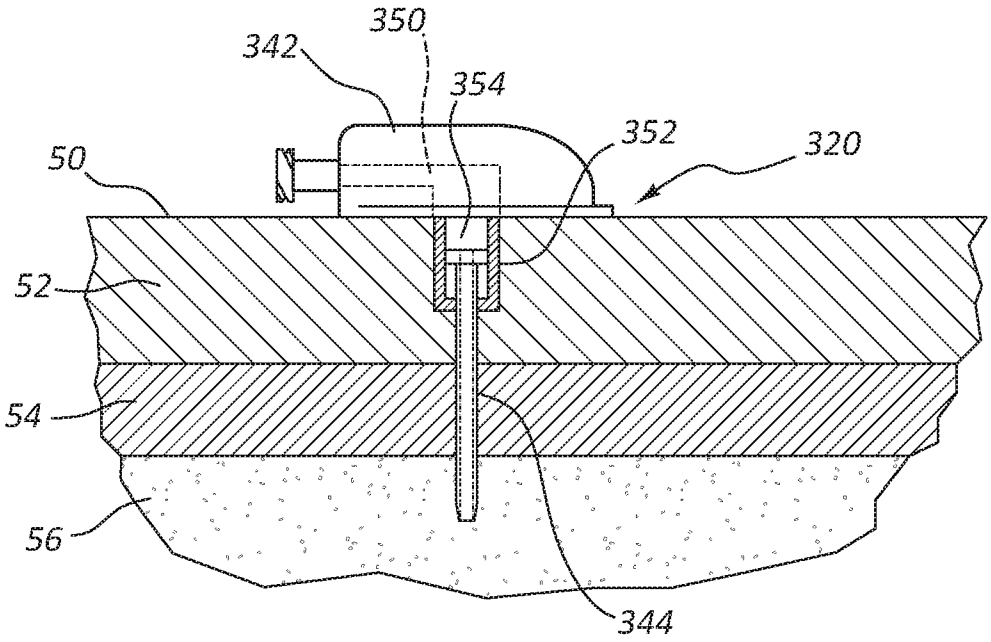
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FIG. 13

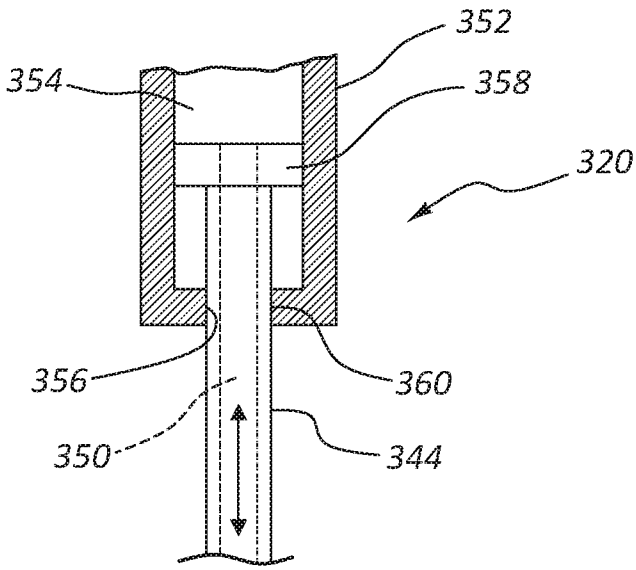
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FIG. 14

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 17/58863

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/34 (2017.01)
CPC - A61B 17/34, 17/3415, 17/3472

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)
See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US 2005/0165403 A1 (MILLER) 28 July 2005 (28.07.2005) see especially para [0009], [0026], [0028], [0029], [0030], [0032], [0033], [0038], [0041], [0042], [0044], [0045], fig 1C, 3A-B, 4 | 1-16, 19-23, 27-28, 31-32<br>---<br>18, 24-26, 36-39 |
| X | US 2004/0220497 A1 (FINDLAY et al) 4 November 2004 (04.11.2004) see especially para [0054], [0055], [0061], [0062], [0074]-[0076], [0079], fig 1 | 17, 33-35 |
| X | US 2010/0312246 A1 (BROWNE et al) 9 December 2010 (09.12.2010) see especially para [0068]-[0070], [0075], [0083], [0084], [0092], [0104], [0105], fig 1, 2A-L | 27, 29-30 |
| Y | EP 0232600 A1 (SHERWOOD MEDICAL COMPANY) 19 August 1987 (19.08.1987) see especially col 6, ln 21-45, col 7, ln 7-30, fig 2 | 18, 24-25 |
| Y | US 2010/0280410 A1 (MOOS et al) 4 November 2010 (04.11.2010) see especially para [0021], [0026], [0027], fig 1-3 | 18, 24, 26 |
| Y | US 2014/0276366 A1 (CORIUM INTERNATIONAL INC) 18 September 2014 (18.09.2014) see especially para [0092]-[0096], [0099], [0100], [0113] | 36-39 |
| A | US 2014/0046327 A1 (TZACHAR et al) 13 February 2014 (13.02.2014) see whole document | 1-39 |
| A | US 2009/0204024 A1 (MILLER) 13 August 2009 (13.08.2009) see whole document | 1-39 |
| A | US 2005/0033235 A1 (FLINT) 10 February 2005 (10.02.2005) see whole document | 1-39 |

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

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

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 14 December 2017 | 29 JAN 2018 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-8300 | Authorized officer:<br>Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

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## INTERNATIONAL SEARCH REPORT

| International application No. |
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| PCT/US 17/58863 |

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| --- | --- | --- |
| A | US 5,591,188 A (WAISMAN) 7 January 1997 (07.01.1997) see whole document | 1-39 |
| A | WO 2015/177612 A1 (SECRETARY, DEPARTMENT OF BIOTECHNOLOGY) 26 November 2015 (26.11.2015) see whole document | 1-39 |