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(54) Title: A NON-REUSABLE INTRA-OSSEOUS ACCESS DEVICE AND METHOD THEREOF

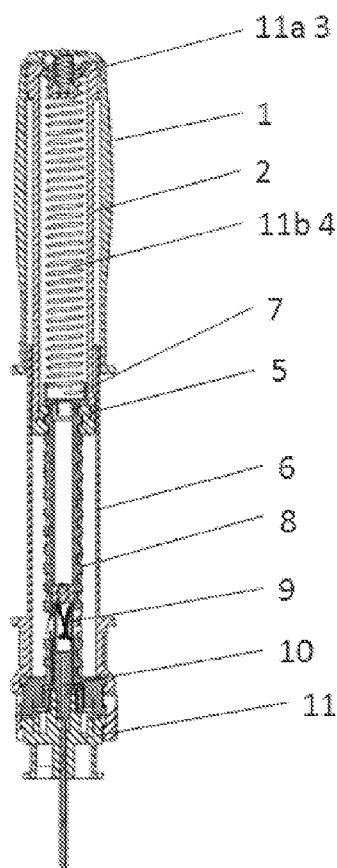


FIGURE 1

(57) Abstract: Disclosed is a non-reusable intra-osseous access device and method thereof. The non-reusable intra-osseous access device which can be easily rendered non-reusable after establishing the access into the marrow region includes the automatic locking of driver unit 5 after removal of needle and trocar assembly from the driver unit. Further, the non-reusable intra-osseous access device also includes the non-loading of the trocar and or needle hub and or trocar with needle hub.





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A NON-REUSABLE INTRA-OSSEOUS ACCESS DEVICE
AND METHOD THEREOF

TECHNICAL FIELD

The present subject matter described herein, in general relates to apparatus and methods to accessing bone marrow at various target areas including, but not limited to, a patient's proximal tibia, and more particularly, to an intra-osseous access device and bone marrow aspiration device, which can get the access to the bone through hard cortical region, and which can be easily rendered non-reusable after establishing the access into the marrow region.

BACKGROUND

Rapid vascular access is critical in resuscitation of patients during clinical emergency. Even though peripheral intravenous (IV) access is a preferred, many a times it is difficult to access these veins. This usually happens in patients of cardiac arrest, trauma, profound blood loss, severe dehydration and burn injury especially in the pre-hospital setting. Failure rates of peripheral IV access in these emergency conditions have been reported in 10-40% cases. Precious time is lost to access these collapsed peripheral veins in this golden period of patient care. This delay leads to substantial morbidity and mortality.

Intraosseous (IO) access is an alternative to difficult IV access under these clinical situations. IO access allows infusion of fluids directly into the intra-medullary space of the long bones. This space, where the IO needle gets inserted is highly vascular and provides a direct conduit to the systemic circulation. These intra-medullary venous channels are supported by bony matrix, keeping it open even in the presence of shock.

Intra-osseous infusion has long been the standard of care in pediatric emergencies when rapid IV access is not possible. The U.S. military used the hand driven IO needles for infusions extensively and successfully during World War II. However, such IO needles were cumbersome, difficult to use, and often had to be manually driven into a bone.

Drugs administered intra-osseously enter a patient's blood circulation system as rapidly as they do when given intravenously. In essence, bone marrow may function as a large non-collapsible vein.

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Traditionally, the bone marrow aspiration process may be conducted out by inserting the needle through the skin into the bone and a syringe is used to draw out the bone marrow. Conventional devices for achieving bone marrow aspiration include a needle with a trocar that is put in the bone either manually or through springs. The impact of the needle may result in bone fracture and pain to the patient. Further, in conventional devices, while
5 accessing the bone marrow due to lack of controlled movement of the needle involves a risk of either needle overshoot or undershoot through cortical layers of the bone. This is mainly because of uncertainty or blindness associated with the procedure, as the operator is not aware of the position of the needle.

Further, in the conventional devices used for bone marrow aspiration, the needle
10 bends or breaks due to the force applied particularly in adult patients who have hard, calcified cortical layer of bone. Also the operators tend to use the same needle for multiple aspirations, thereby leading to infections.

In resource constrained settings, it is important to have a device which is ready to use
15 with no preparation required on-site. Also, such device once used, should not be re-usable to prevent infections. The available devices are reusable and need sterilization prior to use which is a great drawback in resource-constrained setting.

The process of sterilization prior to use is a time consuming process and many times
20 even after the sterilization there is a risk of contamination and possibility of spreading infection by the re-use of the device.

With reference to the above mentioned drawbacks there is need for a non-reusable
intra-osseous access device and bone marrow aspiration device, which can get the access to the bone through hard cortical region, and which can be easily rendered non-reusable after
establishing the access into the marrow region.

SUMMARY

This summary is provided to introduce concepts related a non-reusable intra-osseous
access device and method thereof. This summary is not intended to identify essential features

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of the subject matter nor is it intended for use in determining or limiting the scope of the subject matter.

In one implementation, a non-reusable intra-osseous access device which can be easily rendered non-reusable after establishing the access into the marrow region includes the automatic locking of driver unit after removal of needle and trocar assembly from the driver unit is disclosed.

In one implementation, non-reusable intra-osseous access device which can be easily rendered non-reusable after establishing the access into the marrow region includes the non-loading of the trocar and or needle hub and or trocar with needle hub is disclosed.

Accordingly in one implementation, a non-reusable intra-osseous access device is disclosed. The non-reusable intra-osseous access device comprises of a multi-splined axial shaft 8 engaged with the multi-spiral nut 5, assembly of trocar holder 10 and needle hub 11 engaged at one end of the multi-spiral axial shaft 8 and drive handle 1 coupled to the multi-spiral nut 5 through the inner barrel 2. A multi-spiral axial shaft 8 has a hollow axial cavity 8g and radial opening 8a on shaft surface 8.

In one implementation, a non-reusable Intraosseous (IO) device is disclosed. The device comprises of a handle capable of being displaced by applying force, the handle comprising a spring-clutch and an inner barrel; a multi-splined axial shaft engaged with the multi-spiral nut and is capable of being rotated, the multi-splined axial shaft comprising an axial hollow cavity and at least one opening; a needle hub comprising at least one needle; and when the handle is displaced axially down, it compresses the spring-clutch and engages with inner barrel, thereby enabling the multi-spiral nut to move axially down, and rotating the multi-splined shaft, thereafter transferring the rotational motion and axial thrust to the trocar holder and the needle hub, and enabling access through an injection site by rotational piercing action. The device further comprises of an automatic locking mechanism, operating after enabling access through the injection site, comprising: at least one expandable element, a trocar holder comprising a trocar and a trocar holder shaft, wherein the trocar holder is inside the multi-splined shaft with a trocar holder shaft inside the axial hollow cavity, and the expandable element is configured to protrudes outside the opening preventing axial up-down

motion of the multi-spiral nut along the multi-splined shaft rendering the non-reusable Intraosseous (IO) device non-reusable.

In one implementation, a non-reusable Intraosseous (IO) device is disclosed. The device comprises of the automatic locking mechanism, operating after enabling access
5 through the injection site, wherein the trocar holder and needle hub are configured to be dismantled thereby leading to prevention of the rotation of the multi-splined shaft and making the device non-reusable, by breaking the tearable pouch causing the liquid adhesive within the tear-able pouch to ooze out of the opening, wherein one end of the tear-able pouch is attached to one end of the trocar holder shaft.

10 In one implementation, a non-reusable Intraosseous (IO) device is disclosed. the device comprises of a handle capable of being displaced by applying force, the handle comprising a spring-clutch and an inner barrel; a multi-splined axial shaft capable of being rotated, the multi-splined axial shaft comprising a tear able pouch filled with adhesive material in a axial hollow cavity and at least one opening; a locking mechanism comprising
15 at least one expandable element, a trocar holder comprising a trocar and a trocar holder shaft; and a needle hub comprising at least one needle. The trocar holder is inside the multi-splined shaft with a trocar holder shaft inside the axial hollow cavity to block the opening, preventing the expandable element to protrude outside the multi-splined shaft through opening; and when the handle is displaced axially down, it compresses the spring-clutch and engages with
20 inner barrel, thereby enabling the multi-spiral nut to move axially down, and rotating the multi-splined shaft, thereafter transferring the rotational motion and axial thrust to the trocar holder and the needle hub, and enabling access through an injection site by rotational piercing action.

In one implementation, a method for using a non-reusable Intraosseous device having
25 a handle capable of being displaced by applying force, the handle comprising a spring-clutch and an inner barrel; multi-splined axial shaft capable of being rotated, the multi-splined axial shaft comprising a tear able pouch filled with adhesive material in a axial hollow cavity and at least one opening; a locking mechanism comprising at least one expandable element, a trocar holder comprising a trocar and a trocar holder shaft; and a needle hub comprising at

least one needle is disclosed. The method comprises of: targeting the non-reusable Intraosseous device on the injection site; placing the non-reusable Intraosseous device on the injection site; and applying pressure/force on the non-reusable Intraosseous device to insert the needle by rotational drilling into the injection site thereby establishing access into the injection site.

In one implementation, if the excess force is applied on the handle, it does not get transmitted to trocar and needle holder assembly due to slippage of the trocar holder and needle hub with reference to multi-splined shaft, preventing the damage to the piercing site.

Conventional needles used in accessing bone marrow at various target areas have a single point diamond tip used for piercing. In the present the non-reusable Intraosseous (IO) device, comprises a multiple (at least two) cutting edges along the periphery with flutes of the drilling tip for smooth removal of the hard cortical layer by shearing of hard cortical layer radially. This ensures smooth insertion through the bone as compared to axial piercing action or insertion by diamond tip with rotation allowing bone chips if any to be displaced out radially.

These and other features, aspects, and advantages of the present subject matter will be better understood with reference to the following description and appended claims. This summary is provided to introduce a selection of concepts in a simplified form. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

The detailed description is described with reference to the accompanying figures. In the figures, the left-most digit(s) of a reference number identifies the figure in which the reference number first appears. The same numbers are used throughout the drawings to refer like features and components.

Figure 1 illustrates a non-reusable IO device is shown, in accordance with an embodiment of the present subject matter.

Figure 2 illustrates a top portion comprising handle, inner barrel; spring-clutch and spring lead screw is shown, in accordance with an embodiment of the present subject matter.

Figure 3 illustrates an inner barrel is shown, in accordance with an embodiment of the present subject matter.

5 Figure 4 illustrates multi-splined shaft is shown, in accordance with an embodiment of the present subject matter.

Figure 5 illustrates a 9 locking Element Configuration-1, Configuration-2, and Configuration-3 is shown, in accordance with an embodiment of the present subject matter.

10 Figure 6 illustrates a trocar holder is shown, in accordance with an embodiment of the present subject matter.

Figure 7 illustrates other parts of the overall process is shown, in accordance with an embodiment of the present subject matter.

Figure 8 illustrates a needle hub is shown, in accordance with an embodiment of the present subject matter.

15 Figure 9 illustrates a multi segment lead screw is shown, in accordance with an embodiment of the present subject matter.

Figure 10 illustrates a stiff protrusion: when trocar is not in place is shown, in accordance with an embodiment of the present subject matter.

20 Figure 11 illustrates a tear able pouch filled with adhesive material is shown, in accordance with an embodiment of the present subject matter.

Figure 12 illustrates an external cutting edge on needle outer surface is shown, in accordance with an embodiment of the present subject matter.

Figure 13 illustrates a non-reusable IO device with and without breakable sheath, in accordance with an embodiment of the present subject matter.

25 Figure 14 illustrates a diamond tip trocar tip as used in conventional device, and a multiple cutting edges at the tip with flute tip in accordance with an embodiment of the present subject matter.

Figure **15 (a) and (b)** illustrates a locking element 9, positioned inside the multi splined shaft 8 and a locking element 9, positioned removed from the multi splined shaft 8, in accordance with an embodiment of the present subject matter.

5 DETAILED DESCRIPTION OF THE PRESENT INVENTION

Preferred embodiments of the present disclosure will be described herein below with reference to the accompanying drawings. In the following description, well-known functions or constructions are not described in detail to avoid obscuring the present disclosure in unnecessary detail.

10 The terms and words used in the following description are not limited to the bibliographical meanings, but, are merely used by the inventor to enable a clear and consistent understanding of the invention. Accordingly, it should be apparent to those skilled in the art that the following description of exemplary embodiments of the present invention are provided for illustration purpose only and not for the purpose of limiting the invention.

15 It is to be understood that the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

By the term “substantially” it is meant that the recited characteristic, parameter, or value need not be achieved exactly, but that deviations or variations, including for example, tolerances, measurement error, measurement accuracy limitations and other factors known to
20 those of skill in the art, may occur in amounts that do not preclude the effect the characteristic was intended to provide.

The various components are used in the present invention; the components with the numbering mentioned in the accompanying figures are listed below:

1. Handle	2. Inner barrel 2a – Clutch surface 2b – spring seating	3. Spring-clutch
4. Spring-lead screw	5. Multi-spiral nut	6. Protection cover
7. Spring seating Cap	8. Multi-splined shaft 8a – Opening 8b – seating for trocar + needle assembly 8c - seating	9. Locking cylinder 9b1 – locking holder 9a1 – expandable element 9a2 – expandable element 9b2 – locking holder

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	8d multi spline 8e - Stiff protrusion 8f – tear able pouch filled with adhesive material 8g - axial hollow cavity	9c2 – spring 9a3 - expandable element 9b3 - Spring eyelet 9c3 - Locking arm with bend end
10. Trocar Holder 10a – trocar 10/ 10b – trocar holder 10c – hollow cavity 10d - locking surface 10e - trocar holder shaft	11. Needle Hub 11a - Needle 11/ 11b - Needle Hub 11b1 - locking surface / grove 11c - Hub inlet	12. Other Parts 12a – cylindrical wrap 12b - engaging protrusion 12c – tear grip

In one implementation, a non-reusable intra-osseous access device is disclosed. The intra-osseous access device comprises of a multi-splined axial shaft **8** engaged with the multi-spiral nut **5**, assembly of trocar holder **10** and needle hub **11/11b** engaged at one end of the multi-spiral axial shaft **8** and drive handle **1** coupled to the multi-spiral nut **5** through the inner barrel **2**. A multi-spiral axial shaft **8** has a hollow axial cavity **8g** and radial opening **8a** on shaft surface **8**.

The handle **1** and inner barrel **2** are coupled with spring and clutch surfaces. When the handle **1** is pressed down, it compresses the spring clutch **3** and engages with inner barrel **2**. When handle **1** is pressed down, the multi-spiral nut **5** moves axially down, this rotates the multi-splined shaft **8**. The multi-splined shaft may be covered using a protection cover **6** which is further engaged with the handle **1** at one end and the assembly of trocar holder **10** at other end.

The spring **4**, between spring seating cap **7** and inner barrel **2** gets compressed during downward motion of the handle **1** and released during upward motion of the handle **1**.

Trocar holder **10** and needle hub **11b** are engaged at distal end of multi-spiral shaft **8**. The assembly of trocar holder **10** and needle hub **11b** may be engaged with multi-splined shaft through locking cylinder **12**. The rotational motion and axial thrust of the multi-spiral shaft **8** is transferred to the Trocar holder **10** and needle hub for gaining the access through hard cortical layer of the bone by rotational piercing action.

In one implementation, the locking element **9** seats inside the multi-splined shaft **8**. The locking element has expandable element **9a1**. In assembled condition, expandable

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element **9a1** is locked inside the hollow cavity **10c** of trocar holder **10**. The trocar holder **10** is seating inside the multi-splined shaft **8** with trocar holder shaft **10e** inside the axial hollow cavity **8g** such that the opening **8a** is blocked, preventing expandable element **9a1** to protrude outside the multi-splined shaft **8** through opening **8a**.

5 Post insertion of the hard cortical layer of the bone by the device, the trocar holder **10** and needle hub **11b** are dismantled from the rest of the device. This leads to unlocking of the expandable element **9a1** from the hollow cavity **10c**. The expandable element **9a1** protrudes outside the opening **8a** preventing axial up-down motion of the multi-spiral nut **5** along the multi-splined shaft **8**. This leads to prevention of rotation of the multi-splined shaft **8**
10 rendering the device non-reusable post insertion and dismantling of the trocar holder **10** and needle hub **11b** from the rest of the device.

 In one implementation, the locking element **9** seats inside the multi-splined shaft **8**. The locking element has expandable element **9a2**. In assembled condition, expandable element **9a1** is locked inside the hollow cavity **10c** of trocar holder **10**. The trocar holder **10** is
15 seating inside the multi-splined shaft **8** with trocar holder shaft **10e** inside the axial hollow cavity **8g** such that the opening **8a** is blocked, preventing expandable element **9a2** to protrude outside the multi-splined shaft **8** through opening **8a**.

 Post insertion of the hard cortical layer of the bone by the device, the trocar holder **10** and needle hub **11b** are dismantled from the rest of the device. This leads to unlocking of the
20 expandable element **9a2** from the hollow cavity **10c**. The spring **9c2** presses the expandable element **9a2** which leads to the expandable element **9a2** protrude outside the opening **8a** preventing axial up-down motion of the multi-spiral nut **5** along the multi-splined shaft **8**. This leads to prevention of rotation of the multi-splined shaft **8** rendering the device non-reusable post insertion and dismantling of the trocar holder **10** and needle hub **11b** from the
25 rest of the device.

 In one implementation, the locking element **9** seats inside the multi-splined shaft **8**. The locking element has expandable element **9a3**. In assembled condition, expandable element **9a3** is locked inside the hollow cavity **10c** of trocar holder **10**. The trocar holder **10** is seating inside the multi-splined shaft **8** with trocar holder shaft **10e** inside the axial hollow

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cavity **8g** such that the opening **8a** is blocked, preventing expandable element **9a3** to protrude outside the multi-splined shaft **8** through opening **8a**.

Post insertion of the hard cortical layer of the bone by the device, the trocar holder **10** and needle hub **11b** are dismantled from the rest of the device. This leads to unlocking of the expandable element **9a3** from the hollow cavity **10c**. The spring eyelet **9b3** presses the expandable element **9a3** which leads to the expandable element **9a3** protrude outside the opening **8a** preventing axial up-down motion of the multi-spiral nut **5** along the multi-splined shaft **8**. This leads to prevention of rotation of the multi-splined shaft **8** rendering the device non-reusable post insertion and dismantling of the trocar holder **10** and needle hub **11b** from the rest of the device.

In one implementation, a tear-able pouch filled with liquid adhesive **8f** is fixed within the hollow cavity **8g** such that it is positioned close to the opening **8a** and one end is adhering to the inner cavity **8g** of multi-spline shaft **8**. The other end of the tear-able pouch **8f** is attached to the distal end of the trocar holder shaft **10e**.

Post insertion of the hard cortical layer of the bone by the device, the trocar holder **10** and needle hub **11b** are dismantled from the rest of the device. This leads to breaking of the tear-able pouch **8f**. The liquid adhesive within the pouch oozes out of the opening **8a**.

In one case, upon solidification of the adhesive on splined surface **8d** prevents axial up-down motion of the multi-spiral nut **5** along the multi-splined shaft **8**. This leads to prevention of rotation of the multi-splined shaft **8** rendering the device non-reusable post insertion and dismantling of the trocar holder **10** and needle hub **11b** from the rest of the device.

In another case, the multi-spiral nut **5** gets adhered to multi-splined shaft **8** upon solidification of the adhesive on splined surface **8d** prevents axial up-down motion of the multi-spiral nut **5** along the multi-splined shaft **8**. This leads to prevention of rotation of the multi-splined shaft **8** rendering the device non-reusable post insertion and dismantling of the trocar holder **10** and needle hub **11b** from the rest of the device.

In one implementation, the multi-splined shaft **8** is multi segmented with at least one independent segment (example **8d2** in between **8d1** and **8d3**). The multiple segments are held

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together to form a single shaft **8** by the trocar holder shaft **10e** during assembled condition of the device. Trocar holder shaft **10e** had a section with at least one flat surface so that there is no relative rotation and axial movement of segments (example **8d1**, **8d2** and **8d3**). Hence in assembled condition, the multi-spiral nut **5** moves up-down along the multi-splined shaft **8**,
5 leads to transfer of rotational motion to of the trocar holder **10** and needle hub **11b** during insertion.

Post insertion of the hard cortical layer of the bone by the device, the trocar holder **10** and needle hub **11** are dismantled from the rest of the device. This leads to removal of the trocar holder shaft **10e** leading to disintegration of the multi-splined shaft **8** into its segments.
10 This prevents any rotation of one of the segment (example **8d1**, **8d2** and **8d3**) to the trocar holder **10** and needle hub **11b** for subsequent insertion.

Also, the multiple segments of the multi-splined shaft **8** prevents insertion of the trocar holder shaft **10e** into the axial hollow cavity **8g** rendering the IO device non-reusable
15 for subsequent insertion.

In one implementation, the multi-splined shaft **8** at one distal end has a stiff protrusions **8e** which normally prevents the trocar holder **10** to be seated in assemble condition. The assembly between multi-splined shaft**8** and trocar holder **10** is pre-fitted.

Post insertion of the hard cortical layer of the bone by the device, the trocar holder **10**
20 and needle hub **11b** are dismantled from the rest of the device. This leads to the return of the stiff protrusions **8e** to their original position shrinking the opening. This prevents re-insertion of the trocar holder **10** and needle hub **11b** back into the device rendering the device non-reusable once it is used.

In one implementation, to facilitate the insertion through the rotational action of the
25 trocar hub and needle holder assembly, the needle has external cutting edges along the spirals of external surface.

In one implementation, multi segment lead screw: e.g., **8d1**, **8d2**, **8d3**, when trocar shaft is inserted inside, it becomes single unified shaft. Hence rotation due to nut movement is transferred to trocar with needle assembly. When the trocar is taken out of lead screw, it

becomes three piece / multi piece. Hence the rotation induced due to up-down motion of lead screw is not imparted to the trocar needle assembly. This makes the device non-reusable.

In one implementation, (as shown in figure 10), the trocar with needle assembly is pre-fitted into this lead screw seating. When the trocar is removed from the lead screw, 8e
5 protrude out making the inlet smaller and prevent trocar with needle to insert back. This makes the device non reusable.

In one implementation, when trocar shaft is pulled out, the pouch 8f breaks, the adhesive oozes out on the splined surfaces. The splined surface with adhesive prevent nut to move up and down. In another embodiment, the nut gets stuck with the splined shaft.

10 Referring to figure 1 illustrates a non-reusable IO device, in accordance with an embodiment of the present subject matter.

Referring to figure 2 illustrates a top portion comprising handle, inner barrel; spring-clutch and spring lead screw, in accordance with an embodiment of the present subject matter.

15 Referring to figure 3 illustrates a 2-inner barrel, in accordance with an embodiment of the present subject matter. In one implementation, as shown in figure 3, the inner barrel 2 comprises of a clutch surface 2a and a spring seating 2b. The operation of working of the inner barrel 2 in conjugation with the other components of the device is as explained above.

Referring to figure 4 illustrates multi-splined shaft 8, in accordance with an
20 embodiment of the present subject matter. In one implementation, as shown in figure 4, the multi-splined shaft 8 comprises of the opening 8a, a seating for trocar + needle assembly 8b, a seating 8c, a multi spline 8d, the stiff protrusion 8e, the tear able pouch filled with adhesive material 8f, and the axial hollow cavity 8g. The operation of working of the multi-splined shaft 8 in conjugation with the other components of the device is as explained above.

25 Referring to figure 5 illustrates a 9 locking Element Configuration-1, Configuration-2, and Configuration-3 in accordance with an embodiment of the present subject matter.

Referring to figure 6 illustrates a trocar holder, in accordance with an embodiment of the present subject matter. In one implementation, as shown in figure 6, the trocar holder 10/10b, comprises of the trocar 10a, a hollow cavity 10c, a locking surface 10d, and a trocar

holder shaft 10e. The operation of working of the trocar holder 10/10b in conjugation with the other components of the device is as explained above.

Referring to figure 7 illustrates other parts of the overall process, in accordance with an embodiment of the present subject matter. In one implementation, as shown in figure 7 the other parts 12 comprises a cylindrical wrap 12a, an engaging protrusion 12b, and a tear grip 12c. In one implementation the engaging protrusions engages at one end with the multi-splined shaft 8, at other end with other end it engages with trocar 10 and needle hub 11. This enables transmission of rotational motion and axial motion from multi-splined shaft to the trocar and needle hub assembly. The lockable cylinder can break or allow slipping of the trocar and needle hub assembly with respect to the multi-splined shaft 8 and hence prevents excessive force being transferred to the trocar and needle hub assembly hence preventing any damage. Post insertion, the tear grip 12c is pulled to tear-off to dis-engage the trocar and needle holder assembly from the driver unit by tearing the lockable cylinder.

Referring to figure 8 illustrate a needle hub is shown, in accordance with an embodiment of the present subject matter. In one implementation, as shown in figure 8 the needle hub 11/11b comprises of a needle 11a, a locking surface/groove 11b, and a hub inlet 11c. The operation of working of the needle hub in conjugation with the other components of the device is as explained above.

Referring to figure 9 illustrate a multi segment lead screw is shown, in accordance with an embodiment of the present subject matter.

Referring to figure 10 illustrates a stiff protrusion: when trocar is not in place, in accordance with an embodiment of the present subject matter.

Referring to figure 11 illustrates a tear able pouch filled with adhesive material, in accordance with an embodiment of the present subject matter.

Referring to figure 12 illustrates an external cutting edge on needle outer surface, in accordance with an embodiment of the present subject matter. In one implementation, as shown in figure 12, the external radial grooves on the needle external surface with multiple protrusions are provided so as to facilitate the insertions of the needle into the bone. This

may be either in conjunction with trocar with either single point diamond cut or multiple cutting trocar tip will be used in device.

Referring to figure 13 illustrates a non-reusable IO device with and without breakable sheath, in accordance with an embodiment of the present subject matter.

5 In one implementation, in assembled condition, the spring loaded device handle is held in collapsed position by breakable sheath. The user may have to tear the breakable sheath when handle gets released back. This makes device ready for insertion. In one example, the breakable sheath is cylindrical envelop and thinned axial groves. When the Holder is pulled axially down, it breaks opens and the handle springs back to un-collapsed
10 position. The breakable sheath may not be re-assembled again and needs to be disposed off.

Referring to figure 14 illustrates a diamond tip trocar tip as used in conventional device, and a multiple cutting edges at the tip with flute tip in accordance with an embodiment of the present subject matter.

Referring to figure 15 (a) and (b) illustrates a locking element 9, positioned inside the
15 multi splined shaft 8 and a locking element 9, positioned removed from the multi splined shaft 8, in accordance with an embodiment of the present subject matter.

In one implementation, as shown in figure 15 (a), the locking element 9 is positioned inside the multi-splined shaft 8. The trocar holder 10, as shown, is assembled into multi splined shaft8. The expandable element 9a3, as shown, is locked inside hollow cavity 10c of
20 trocar holder shaft 10e.

In one implementation, as shown in figure 15 (b), when the trocar holder 10 is removed from the multi-splined shaft 8, the expandable element 9a3 is released from the trocar holder shaft 10e and springs back to protrudes out of opening 8a of the multi-spiral shaft 8. The expandable element 9a3 further prevents the axial motion of the multi spiral nut
25 5. This leads to the locking of the driver unit.

The important features of the present invention are as stated below:

1. The non-reusable intra-osseous access device which can be easily rendered non-reusable after establishing the access into the marrow region includes the automatic

locking of driver unit after removal of needle and trocar assembly from the driver unit. The locking of driver unit prevents transmission of rotation and axial motion and/or thrust from the handle to the needle and/or trocar assembly necessary for subsequent insertion.

- 5 2. The non-reusable intra-osseous access device which can be easily rendered non-reusable after establishing the access into the marrow region includes the non-loading of the trocar and or needle hub and/or trocar with needle hub necessary for subsequent insertion.
- 10 3. The lead screw used in the invention is a multi-segmented screw. In assemble condition, the multi-segmented lead screw acts as a single element and transmits the rotational and axial motion and/or trust necessary for insertion. Upon disengagement of the needle and/or trocar the lead screw gets disintegrated into multiple segments. This leads to non-transmission of prevents transmission of rotation and axial motion and/or thrust from the handle to the needle and/or trocar assembly necessary for subsequent insertion.
- 15 4. During the process when needle and trocar are removed, the present device gets locked, and no other/ new trocar and / or needle can be reloaded in the device. This feature of the invention makes it non-reusable.
- 20 5. The re-usable feature of the invention avoids the risk of contamination and possibility of spreading infection by the re-use of device.
- 25 6. For ease of insertion, there are external cutting edges on the needle, which ensures that the cutting remains of the bone/flesh are radially pushed out of the insertion site.
7. If excessive pressure is applied on the handle, the trocar holder and needle hub assembly slips with respect to the multi-splined shaft because of locking cylinder, preventing transmission of excess forces to trocar holder and needle hub leading to prevention of damage to the insertion site.

Accordingly, in one implementation, a non-reusable Intraosseous (IO) device is disclosed. The device comprises of a handle capable of being displaced by applying force, the handle comprising a spring-clutch and an inner barrel; a multi-splined axial shaft capable

of being rotated. The multi-splined axial shaft comprising a tear able pouch filled with adhesive material in an axial hollow cavity and at least one opening. The locking mechanism may include at least one expandable element. The trocar holder may include a trocar and a trocar holder shaft. The needle hub may include at least one needle. In one implementation, the trocar holder is inside the multi-splined shaft with a trocar holder shaft inside the axial hollow cavity to block the opening, preventing the expandable element to protrude outside the multi-splined shaft through opening. When the handle is displaced axially down, it compresses the spring-clutch and engages with inner barrel, thereby enabling the multi-spiral nut to move axially down, and rotating the multi-splined shaft, thereafter transferring the rotational motion and axial thrust to the trocar holder and the needle hub, and enabling access through an injection site by rotational piercing action.

In one implementation, a method for using a non-reusable Intraosseous device having a handle capable of being displaced by applying force, the handle comprising a spring-clutch and an inner barrel; multi-splined axial shaft capable of being rotated, the multi-splined axial shaft comprising a tear able pouch filled with adhesive material in a axial hollow cavity and at least one opening; a locking mechanism comprising at least one expandable element, a trocar holder comprising a trocar and a trocar holder shaft; and a needle hub comprising at least one needle is disclosed. The method comprises of: targeting the non-reusable Intraosseous device on the injection site; placing and holding the non-reusable Intraosseous device on the injection site; and applying pressure on the non-reusable Intraosseous device to insert the needle into the injection site thereby establishing access into the injection site. The needle is inserted by a rotational drilling motion.

In one implementation of the present invention, after the method is performed, trocar and needle hub assembly is dismantled from the driver unit post insertion, thereby removing the trocar from the needle hub.

In one implementation of the present invention, the bone marrow is aspirated through the needle hub by engaging the syringe (needle) with needle hub.

In one implementation of the present invention, the fluids are infused through the needle hub into intraosseous space.

In one implementation, the device comprises a spring type lead screw, at least one nut with multiple spirals (multi-spiral nut), a spring seating cap, and other parts, wherein the handle is coupled to the multi-spiral nut through the inner barrel, and the multi-splined axial shaft is engaged with the multi-spiral nut at one end, and the trocar holder and the needle hub at other end.

In one implementation, the spring type lead screw is present between spring seating cap and the inner barrel, wherein the spring is configured to get compressed during downward displacement of the handle and released during upward displacement of the handle.

In one implementation, during assembled condition the expandable element is locked inside a hollow cavity of the trocar holder.

In one implementation, the trocar holder and needle hub are configured to be dismantled thereby leading to prevention of the rotation of the multi-splined shaft and making the device non-reusable, by at least one of: breaking the tear-able pouch causing the liquid adhesive within the tear-able pouch to ooze out of the opening, wherein one end of the tear-able pouch is attached to one end of the trocar holder shaft; or unlocking of the expandable element from the hollow cavity which enables the expandable element to protrude outside the opening and preventing axial up-down motion of the multi-spiral nut along the multi-splined shaft; or any combination thereof.

In one implementation, the multi-splined shaft is multi segmented with at least one independent segment, and multiple segments are held together to form the multi-splined shaft by the trocar holder shaft during assembled condition.

In one implementation, the trocar holder shaft comprises of a section with at least one flat surface so as to restrict relative rotation and axial movement of the multi-splined shaft, hence, during assembled condition, the multi-spiral nut moves up-down along the multi-splined shaft, thereby leads to transfer of rotational motion to the trocar holder and needle hub during insertion in the injection site.

In one implementation, during dismantling, the trocar holder shaft's removal leads to disintegration of the multi-splined shaft into multiple segments, thereby preventing any rotation of one of the segment to the trocar holder and needle hub for subsequent insertion.

5 In one implementation, the multi-splined shaft at one end comprises of a stiff protrusions configured to prevent the trocar holder to be seated in assemble condition.

In one implementation, the needle comprises of external cutting edges along the spirals of external surface configured to facilitate the insertion through the rotational action of the trocar hub and needle holder.

10 In one implementation, the spring type lead screw is a multi segment lead screw and configured to become a single unified shaft upon insertion of the trocar shaft in injection site.

In one implementation, when the trocar is removed from the lead screw, the trocar is configured to protrude out making the inlet smaller and thereby prevents trocar with needle to insert back.

15 In one implementation, the device comprises of a breakable sheath for holding the handle in collapsed position, wherein the breakable sheath comprises of a holder-to tear the sheath, at least one thinned axial groove, and a cylindrical envelop.

In one implementation, the trocar is a diamond tip trocar with single pointed tip.

20 In one implementation, the trocar tip comprises of (at least two) cutting edges along the periphery of the drilling tip with flutes to smooth removal of the hard cortical layer by shearing of hard cortical layer radially. This ensures smooth insertion through the bone as compared to axial piercing action or insertion by diamond tip with rotation.

25 The above specification and examples provide a complete description of the structure and use of exemplary embodiments. Although certain embodiments have been described above with a certain degree of particularity, or with reference to one or more individual embodiments, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention. As such, the various illustrative embodiments of the present devices are not intended to be limited to the particular forms disclosed. Rather, they include all modifications and alternatives falling within the

scope of the claims, and embodiments other than the one shown may include some or all of the features of the depicted embodiment. For example, components may be combined as a unitary structure, and/or connections may be substituted (e.g., threads may be substituted with press-fittings or welds). Further, where appropriate, aspects of any of the examples
5 described above may be combined with aspects of any of the other examples described to form further examples having comparable or different properties and addressing the same or different problems. Similarly, it will be understood that the benefits and advantages described above may relate to one embodiment or may relate to several embodiments.

Although the present disclosure and its advantages have been described in detail, it
10 should be understood that various changes, substitutions and alternations can be made herein without departing from the scope of the disclosure as defined by the following claims.

CLAIMS

1. A non-reusable Intraosseous (IO) device comprising:

a handle capable of being displaced by applying force, the handle comprising a
5 spring-clutch and an inner barrel;

a multi-splined axial shaft engaged with the multi-spiral nut and is capable of being
rotated, the multi-splined axial shaft comprising an axial hollow cavity and at least one
opening;

a needle hub comprising at least one needle; and

10 when the handle is displaced axially down, it compresses the spring-clutch and
engages with inner barrel, thereby enabling the multi-spiral nut to move axially down, and
rotating the multi-splined shaft, thereafter transferring the rotational motion and axial thrust
to the trocar holder and the needle hub, and enabling access through an injection site by
rotational piercing action;

15 **CHARACTERIZED IN THAT**

an automatic locking mechanism, operating after enabling access through the
injection site, comprising:

at least one expandable element, a trocar holder comprising a trocar and a trocar
holder shaft, wherein the trocar holder is inside the multi-splined shaft with a trocar holder
20 shaft inside the axial hollow cavity and during assembled condition the expandable element
is locked inside a hollow cavity of the trocar holder, wherein

the expandable element is configured to protrude outside the opening preventing axial
up-down motion of the multi-spiral nut along the multi-splined shaft rendering the non-
reusable Intraosseous (IO) device non-reusable; and

25 at least one spring or at least one spring eyelet configured to press the expandable
element to protrude outside the opening preventing axial up-down motion of the multi-spiral
nut along the multi-splined shaft rendering the non-reusable Intraosseous (IO) device non-
reusable post insertion.

21

2. The non-reusable Intraosseous device as claimed in claim 1, wherein the trocar holder and/or the needle hub are configured to be dismantled after enabling access through the injection site.

3. The non-reusable Intraosseous device as claimed in claim 1 comprises a spring type
5 lead screw, a spring seating cap, and other parts, wherein the handle is coupled to the multi-spiral nut through the inner barrel, and the multi-splined axial shaft is engaged with the multi-spiral nut at one end, and the trocar holder, and the needle hub at other end wherein the trocar holder is configured to snap on the spring type lead screw, wherein

the multi-splined shaft is multi segmented with at least one independent segment, and
10 multiple segments are held together to form the multi-splined shaft by the trocar holder shaft during assembled condition;

the spring type lead screw is present between spring seating cap and the inner barrel, wherein the spring is configured to get compressed during downward displacement of the handle and released during upward displacement of the handle;

15 the multi-splined shaft at one end comprises a stiff protrusions configured to prevent the trocar holder to reload back into the driver unit rendering the device/trocar and needle hub non-reusable preventing reuse; and

the other parts 12 comprises a cylindrical wrap 12a, an engaging protrusion 12b, and a tear grip 12c.

20

4. The non-reusable Intraosseous device as claimed in claim 1, wherein, the trocar holder shaft comprises a section with at least one flat surface so as to restrict relative rotation and axial movement of the multi-splined shaft, hence, during assembled condition, the multi-spiral nut moves up-down along the multi-splined shaft, thereby leads to transfer of rotational
25 motion to the trocar holder and needle hub during insertion in the injection site.

5. The non-reusable Intraosseous device as claimed in claim 1, wherein, during dismantling, the trocar holder shafts removal leads to disintegration of the multi-splined shaft

into multiple segments, thereby preventing any rotation of one of the segment to the trocar holder and needle hub for subsequent insertion.

6. The non-reusable Intraosseous device as claimed in claim 1, wherein the needle
5 comprises external cutting edges along the spirals of external surface configured to facilitate the insertion through the rotational action of the trocar hub and needle holder.

7. The non-reusable Intraosseous device as claimed in claim 1, wherein when the trocar
is removed from the lead screw, the trocar is configured to protrude out making the inlet
10 smaller and thereby prevents trocar with needle to insert back rendering the device/trocar and needle hub non-reusable preventing further reuse.

8. The non-reusable Intraosseous device as claimed in claim 1, comprises a breakable
sheath for holding the handle in collapsed position, wherein the breakable sheath comprises a
15 holder-to tear the sheath, at least one thinned axial groove, and a cylindrical envelop.

9. The non-reusable Intraosseous device as claimed in claim 1, wherein, the needle tip
comprises at least two external cutting grooves along the external periphery of the tip with
flutes spiraling upward enabling smooth removal of a hard layer at the injection site by
20 shearing of the hard layer radially, so as to ensure smooth insertion into the injection site.

10. The non-reusable Intraosseous device as claimed in claim 1, wherein the trocar tip
comprises at least two cutting edges along the periphery of the drilling tip with flutes
enabling smooth removal of a hard layer at the injection site by shearing of the hard layer
25 radially, so as to ensure smooth insertion into the injection site.

11. The non-reusable Intraosseous device as claimed in claim 1, wherein when the trocar
is removed from the lead screw, the trocar is configured to protrude out making the inlet
smaller and thereby prevents trocar with needle to insert back.

12. A non-reusable Intraosseous (IO) device comprising:

a handle capable of being displaced by applying force, the handle comprising a spring-clutch and an inner barrel;

5 a multi-splined axial shaft engaged with the multi-spiral nut and is capable of being rotated, the multi-splined axial shaft comprising a tearable pouch filled with adhesive material in an axial hollow cavity and at least one opening;

a needle hub comprising at least one needle; and

10 when the handle is displaced axially down, it compresses the spring-clutch and engages with inner barrel, thereby enabling the multi-spiral nut to move axially down, and rotating the multi-splined shaft, thereafter transferring the rotational motion and axial thrust to the trocar holder and the needle hub, and enabling access through an injection site by rotational piercing action;

CHARACTERIZED IN THAT

15 an automatic locking mechanism, operating after enabling access through the injection site, wherein the trocar holder and needle hub are configured to be dismantled thereby leading to prevention of the rotation of the multi-splined shaft and making the device non-reusable, by breaking the tearable pouch causing the liquid adhesive within the tear-able pouch to ooze out of the opening, wherein one end of the tear-able pouch is attached to one
20 end of the trocar holder shaft.

13. The non-reusable Intraosseous device as claimed in claim 11, wherein the trocar holder and/or the needle hub are configured to be dismantled after enabling access through the injection site.

25

14. The non-reusable Intraosseous device as claimed in claim 11, wherein, the trocar holder shaft comprises a section with at least one flat surface so as to restrict relative rotation and axial movement of the multi-splined shaft, hence, during assembled condition, the multi-

spiral nut moves up-down along the multi-splined shaft, thereby leads to transfer of rotational motion to the trocar holder and needle hub during insertion in the injection site.

15. The non-reusable Intraosseous device as claimed in claim 11, wherein, during
5 dismantling, the trocar holder shafts removal leads to disintegration of the multi-splined shaft into multiple segments, thereby preventing any rotation of one of the segment to the trocar holder and needle hub for subsequent insertion.

16. The non-reusable Intraosseous device as claimed in claim 11, wherein the needle
10 comprises external cutting edges along the spirals of external surface configured to facilitate the insertion through the rotational action of the trocar hub and needle holder.

17. The non-reusable Intraosseous device as claimed in claim 11, wherein when the
trocar is removed from the lead screw, the trocar is configured to protrude out making the
15 inlet smaller and thereby prevents trocar with needle to insert back rendering the device/trocar and needle hub non-reusable preventing further reuse.

18. The non-reusable Intraosseous device as claimed in claim 11, comprises a breakable
sheath for holding the handle in collapsed position, wherein the breakable sheath comprises a
20 holder-to tear the sheath, at least one thinned axial groove, and a cylindrical envelop.

19. The non-reusable Intraosseous device as claimed in claim 11, wherein, the needle tip
comprises at least two external cutting grooves along the external periphery of the tip with
flutes spiraling upward enabling smooth removal of a hard layer at the injection site by
25 shearing of the hard layer radially, so as to ensure smooth insertion into the injection site.

20. The non-reusable Intraosseous device as claimed in claim 11, wherein when the
trocar is removed from the lead screw, the trocar is configured to protrude out making the
inlet smaller and thereby prevents trocar with needle to insert back.

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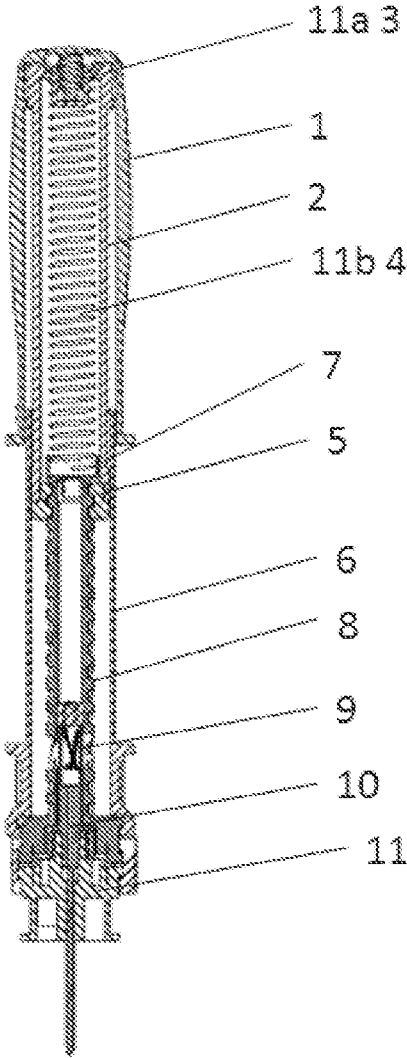


FIGURE 1

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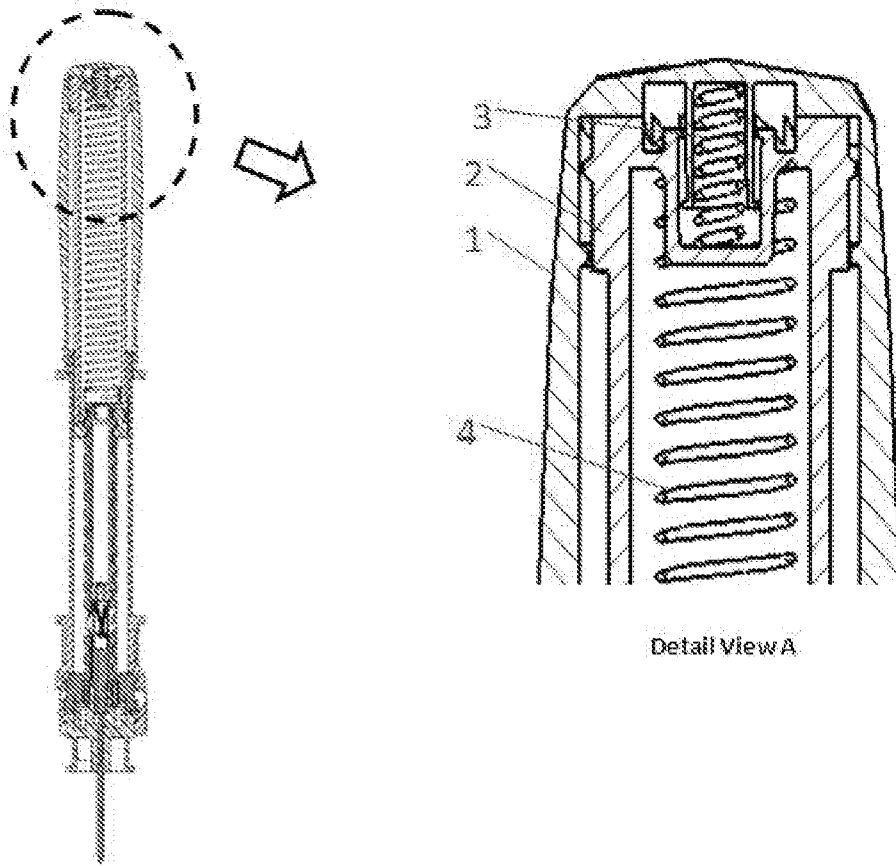
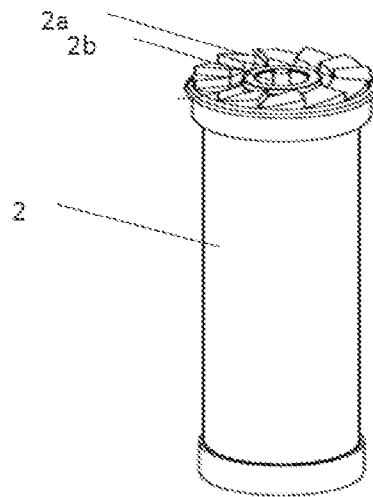


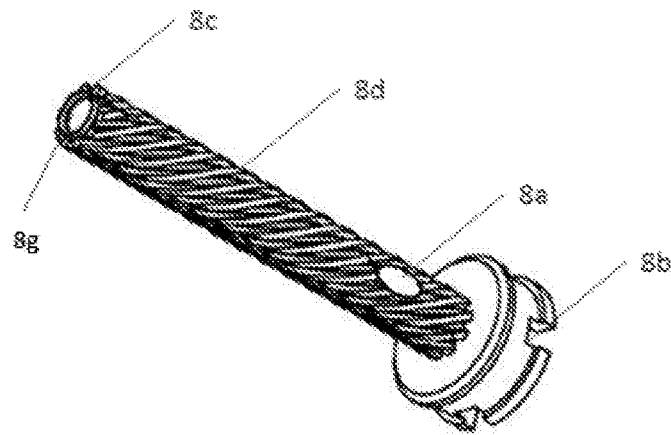
FIGURE 2



2-Inner Barrel

FIGURE 3

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8- Multi-splined shaft

FIGURE 4

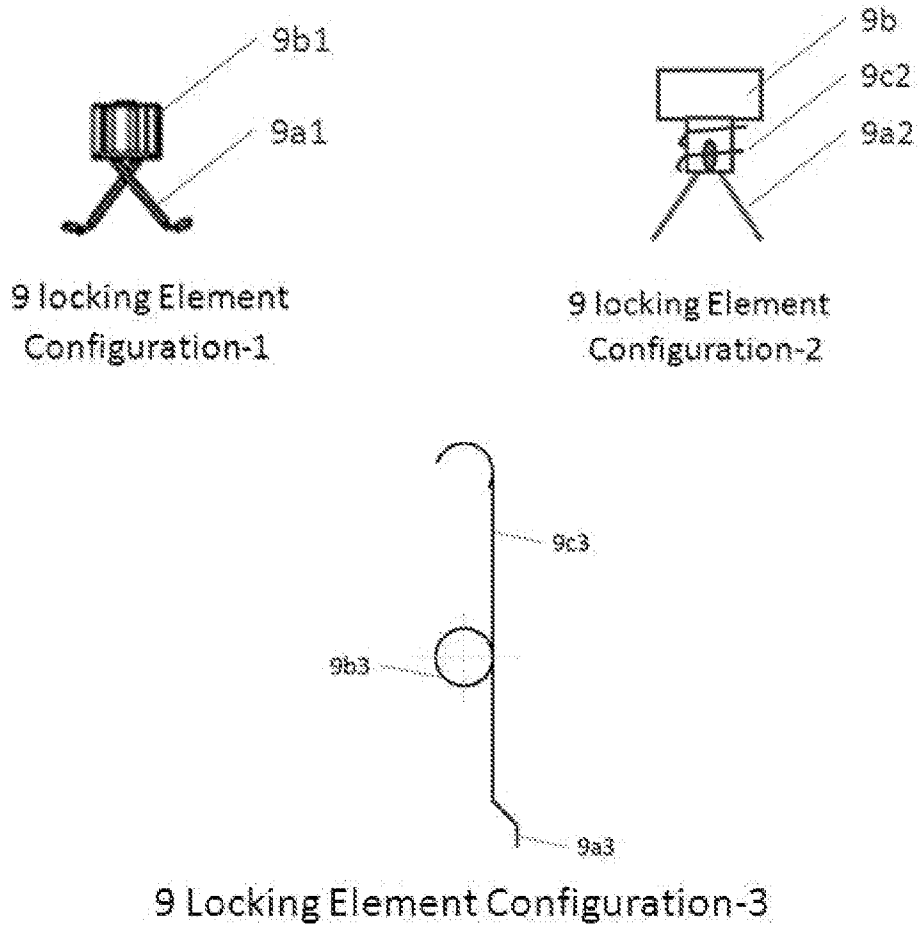


FIGURE 5

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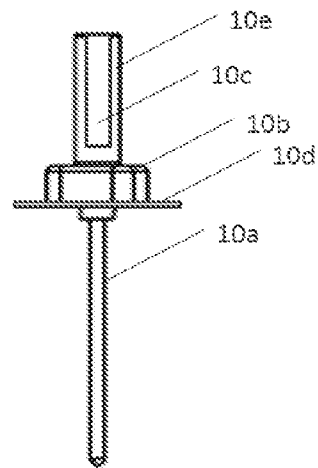


FIGURE 6

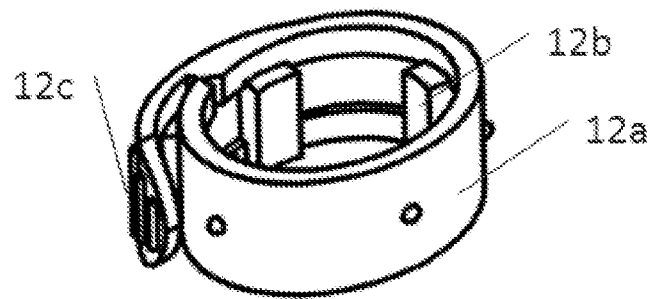


FIGURE 7

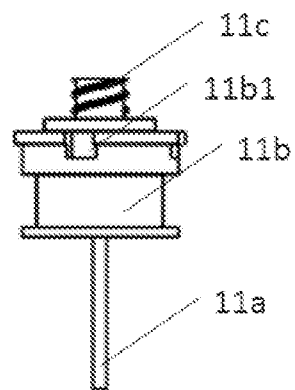


FIGURE 8

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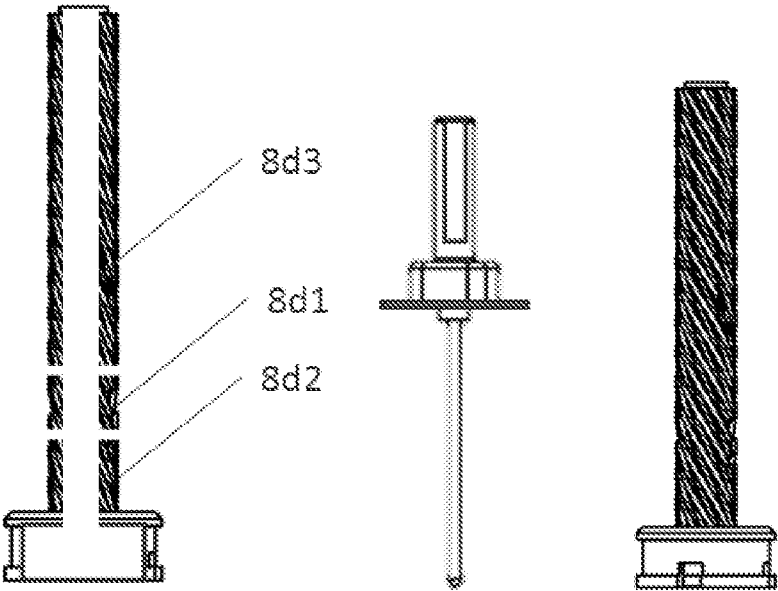


FIGURE 9

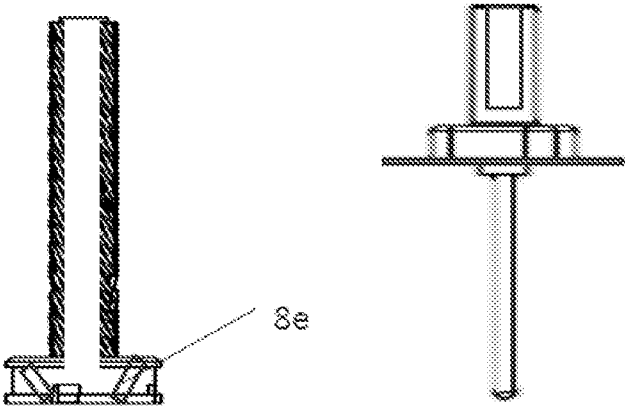


FIGURE 10

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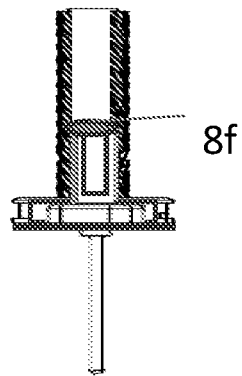


FIGURE 11

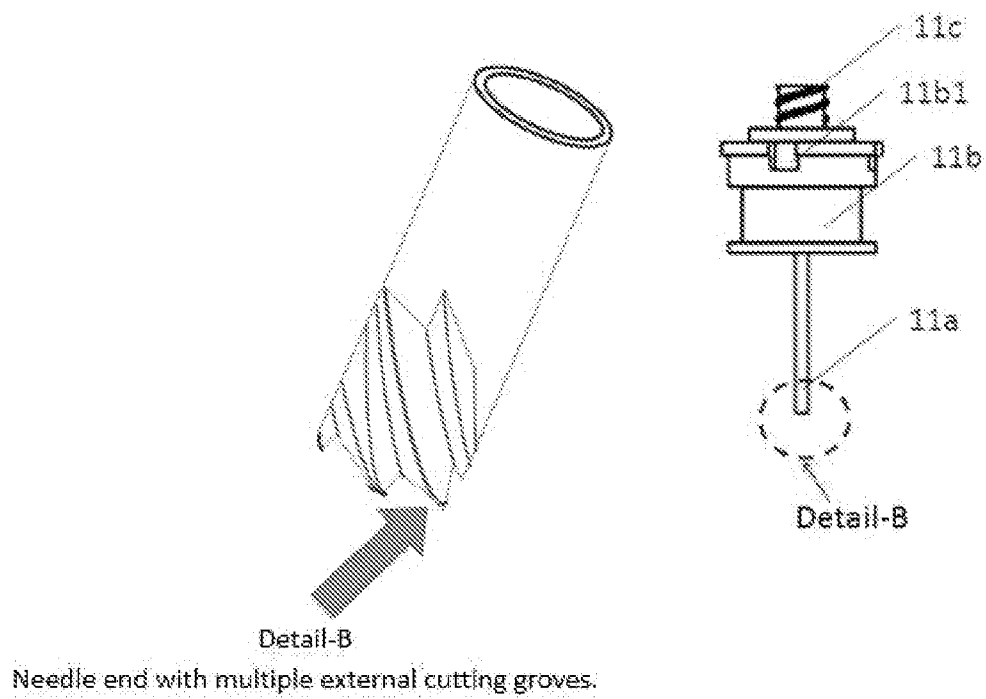


FIGURE 12

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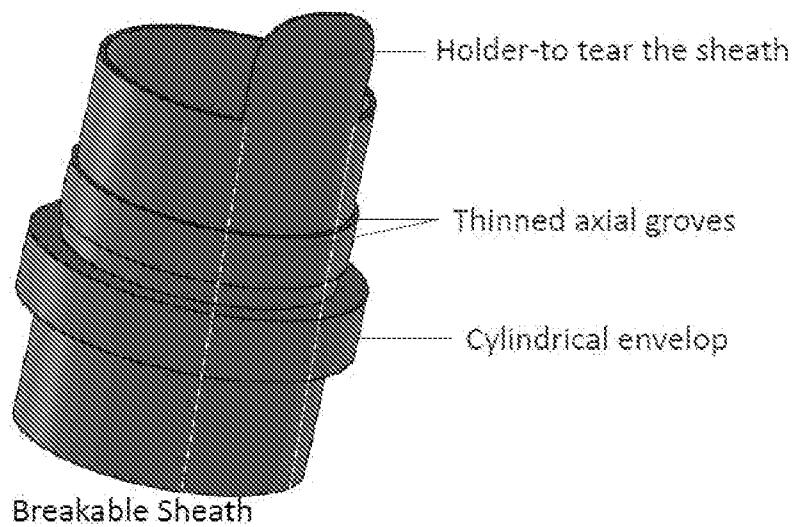
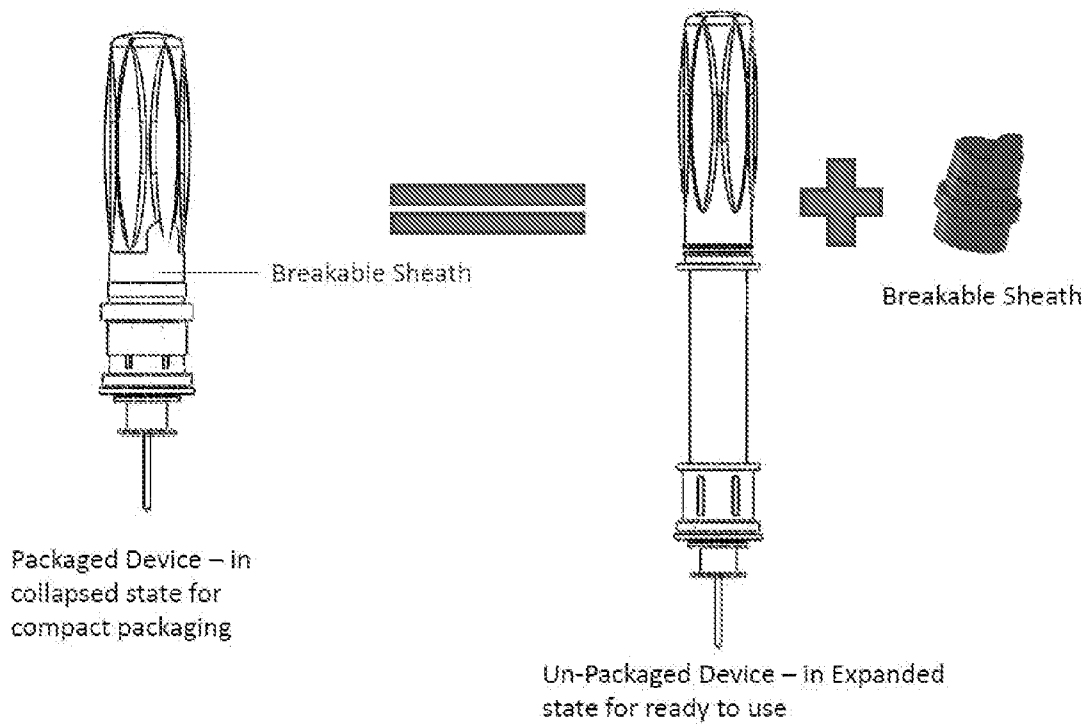


FIGURE 13

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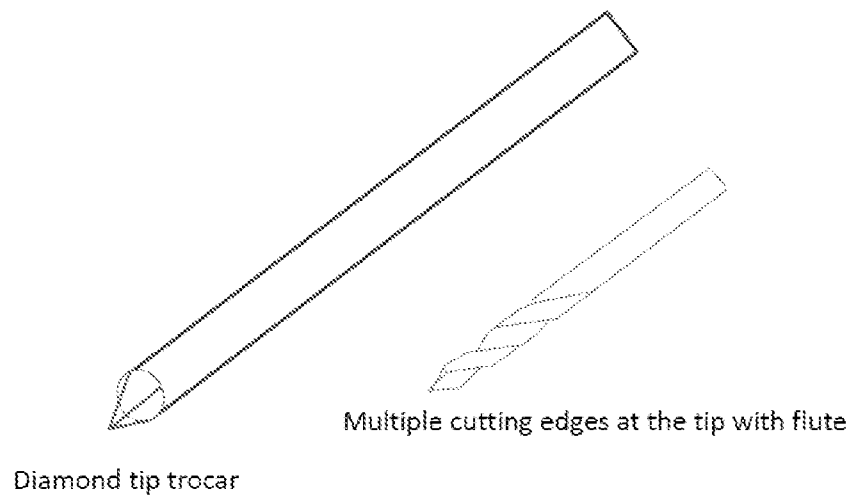


FIGURE 14

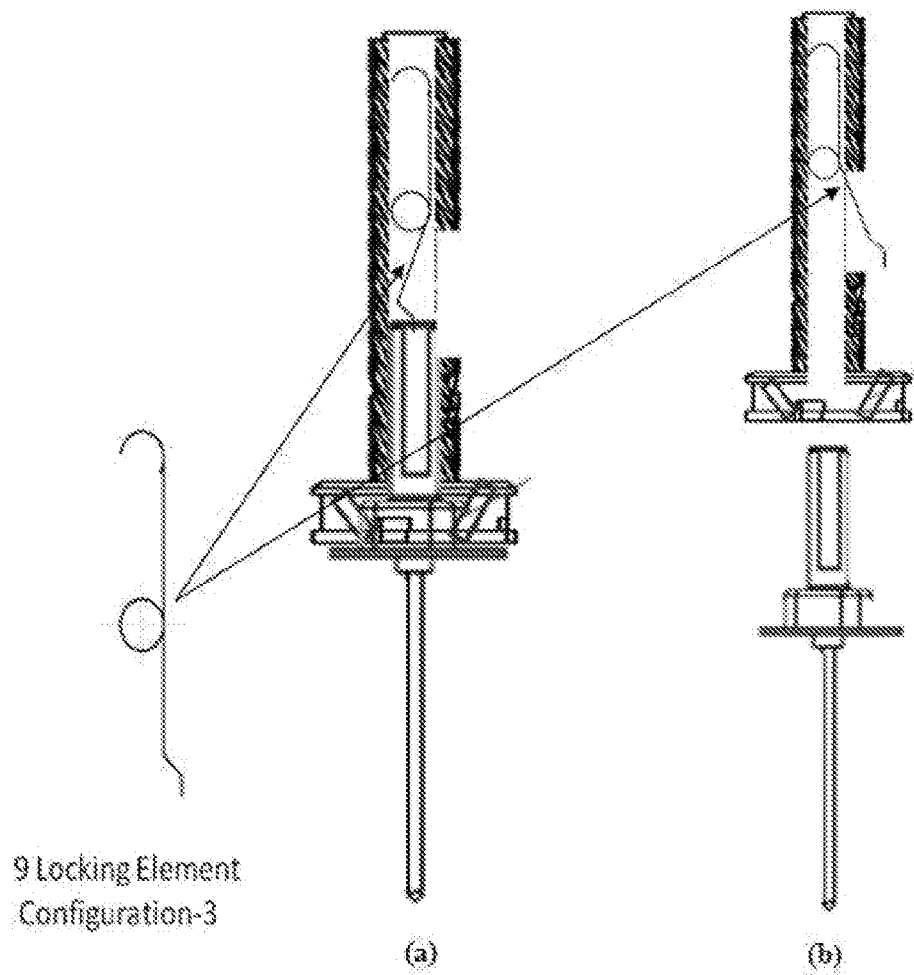


FIGURE 15

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2014/067140

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/00 (2015.01)

CPC - A61B 17/00 (2015.04)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61B 10/02, 17/00; A61M 5/00, 5/32 (2015.01)

CPC - A61B 10/02, 17/00; A61M 5/00, 5/32 (2015.04) (keyword delimited)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/564; 604/110, 195, 232, 263, 264

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

Orbit, Google Patent, Google Scholar

search terms used: intraosseous device, IO, clutch, needle, needle hub, lock, spiral nut, screw, expand

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2011/070593 A1 (SECRETARY, DEPARTMENT OF BIOTECHNOLOGY et al) 16 June 2011 (16.06.2011) entire document	1-20
A	US 5,195,985 A (HALL) 23 March 1993 (23.03.1993) entire document	1-20
A	WO 2005/046769 A2 (VIDACARE CORPORATION) 26 May 2005 (26.05.2005) entire document	1-20

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

29 April 2015

Date of mailing of the international search report

02 JUN 2015

Name and mailing address of the ISA/US

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