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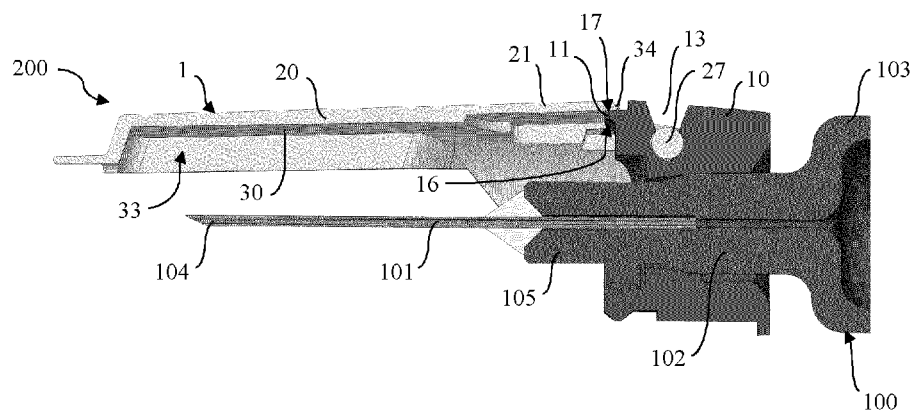


FIGURE 3A

(57) Abstract: The invention relates to a safety device (1) for preventing needle stick injury with a needle (101) extending from a distal tip (102) of a medical injection device (100), comprising: - a ring (10) configured to be attached to the distal tip (102) of the medical injection device and comprising a first hinge portion, and - a protective shield (20) comprising a second hinge portion pivotally coupled to the first hinge portion, the protective shield being configured to adopt successively a storage position wherein the protective shield (20) covers the needle tip, a retracted position wherein the protective shield (20) uncovers the needle tip and a safety position wherein the protective shield (20) covers the needle tip, wherein the ring (10) comprises a lug (11), said lug extending distally and comprising a radially inward side (16) and a radially outward side (17) opposite to the radially inward side relative to the axis of the ring, the protective shield comprises at least one proximal locking member (21, 35); in the safety position, the protective shield (20) is locked on the ring (10) by engagement of the locking member (21, 35) with the lug (11), the locking member (21, 35) is configured to - engage the lug (11) when the protective shield transitions from the retracted position to the safety position, so that said locking member (21, 35) passes from the radially outward side (17) of the lug to the radially inward side (16) of the lug, and - remain engaged with the lug (11) for maintaining the protective shield (20) in the safety position.

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SAFETY DEVICE FOR PREVENTING NEEDLE STICK INJURY WITH A NEEDLE OF A MEDICAL INJECTION DEVICE

5 TECHNICAL FIELD OF THE INVENTION

The invention relates to a safety device for preventing needle stick injury with a needle of a medical injection device. The invention also relates to a safety assembly comprising the safety device and a medical injection device.

10 TECHNICAL BACKGROUND

Medical devices provided with sharp pointed needles are of daily practice among the medical community in order to perform injections or to take samples into or from muscles, veins or arteries. They can be injection devices such as syringes, pen-injectors, catheters or blood collection devices. Sharp pointed needles present an inherent risk of needle stick
15 injury for the medical staff and the patients and are thus usually provided with a needle cap covering the needle before use. This cap not only preserves the needle from contamination but also from undesired contacts or punctures that could occur during transport and delivery by the medical staff. Such a cap needs to be removed immediately before use of the medical device.

20 Replacing the needle cap onto the needle after use is strictly prohibited as it is regarded as a major cause of accident and contamination for the medical staff. Indeed, the whole medical device or at least the used needle should be disposed of after use in an appropriate needle collector. However, a risk of needle stick injury still exists as the medical staff handles the bare, contaminated needles before disposal.

25 Safety devices have thus been designed to prevent needle stick injury with the needle of such medical devices after use i.e. between the end of the injection or collection and the proper disposal of the device. Usually, such safety systems are designed to be locked automatically or manually on at least the needle tip when the medical act is finished. Examples of such safety devices are given in EP0702973 and CA3046821.

30 Nevertheless, many of these safety systems require a triggering step in order to expose the needle tip before use, which slows down the pace of the medical act and decreases the safety level of the medical device. In addition, the majority of such safety systems increase the overall size of the device leading to difficult handling but also to storage concerns particularly for prefilled syringes. Finally, most of these systems do not
35 achieve a complete exposure of the needle tip and impede the medical act by preventing direct view and access to the needle tip.

Additionally, prefillable syringes are transported in sterile packaging after manufacturing in order to be filled by the pharmaceutical companies with a pharmaceutical

product before the final delivery to the medical staff. The sterile packaging is adapted to the length and diameter of the syringe closed with a usual needle cap and may not accept oversized safety devices as currently available

5 **BRIEF DESCRIPTION OF THE INVENTION**

The invention aims to provide a safety device that overcomes the drawbacks detailed previously.

To this end, one object of the invention is a safety device which prevents the user, the patient, or any person around the device, from coming into contact with the needle of the
10 medical injection before and after use of the device, that is, before and after the injection has been performed.

In that way, the needle, especially the needle tip, is not physically accessible, and the risk of accidental pricks or wounds generally caused by contact of the needle with a person close to the device is nullified.

15 The invention aims also to provide a safety device that is readily usable, which presents a simplified structure compared to the known devices, and a size suitable for the transport in sterile packaging.

To this end, one object of the invention is a safety device for preventing needle stick injury with a needle extending from a distal tip of a medical injection device, comprising:

20 - a ring configured to be attached to the distal tip of the medical injection device and comprising a first hinge portion, and

- a protective shield comprising a second hinge portion pivotally coupled to the first hinge portion, the protective shield being configured to adopt successively a storage position wherein the protective shield covers the needle tip, a retracted position wherein the
25 protective shield uncovers the needle tip and a safety position wherein the protective shield covers the needle tip,

wherein

the ring comprises a lug, said lug extending distally and comprising a radially inward side and a radially outward side opposite to the radially inward side relative to the axis of
30 the ring,

the protective shield comprises at least one proximal locking member,

in the safety position, the protective shield is locked on the ring by engagement of the locking member with the lug,

the locking member is configured to:

35 - engage the lug when the protective shield transitions from the retracted position to the safety position, so that said locking member passes from the radially outward side of the lug to the radially inward side of the lug, and

- remain engaged with the lug for maintaining the protective shield in the safety position.

The invention also relates to a safety device for preventing needle stick injury with a needle extending from a distal tip of a medical injection device, comprising:

- 5 - a ring configured to be attached to the distal tip of the medical injection device and comprising a first hinge portion, and

- 10 - a protective shield comprising a second hinge portion pivotally coupled to the first hinge portion, the protective shield being configured to adopt successively a storage position wherein the protective shield covers the needle tip, a retracted position wherein the protective shield uncovers the needle tip and a safety position wherein the protective shield covers the needle tip,

wherein

- 15 the ring comprises a lug, said lug extending distally and comprising a radially inward side and a radially outward side opposite to the radially inward side relative to the axis of the ring,

the protective shield comprises at least one proximal locking member,

in the safety position, the protective shield is locked on the ring by engagement of the locking member with the lug,

- 20 the first and second hinge portions being configured so that at least a part of said first and/or second hinge portions is subject to flexural deformation by engagement of the locking member with the lug during transition from the retracted position to the safety position and subject to buckling deformation in the safety position to impede disengagement of the locking member from the lug.

- 25 The safety device of the invention allows the user to carry out the injection of a pharmaceutical composition to a patient or himself, while preventing any person in the vicinity of the device, in particular the patient and himself, to contact the needle of the medical injection device off injection, thereby avoiding injuries and making said injection device safe. Indeed, in both storage position and safety position, the protective shield covers at least the tip of the needle, thereby preventing any contact between the needle tip and any person around the medical injection device.

- 30 In the safety position, the protective shield is locked on the ring, which prevents said protective shield from moving back to the storage position or the retracted position, thereby further securing the device.

- 35 In the retracted position, the protective shield uncovers the needle tip, thereby allowing the needle to be positioned into the skin of the patient and the injection to be carried out.

According to other optional features of the safety device:

- the locking member comprises a single flexible tab configured to deflect radially outwardly from a body of the protective shield when said protective shield transitions from the retracted position to the safety position;
- the locking member comprises two flexible tabs separated by a slot, configured to deflect radially outwardly from a body of the protective shield when said protective shield transitions from the retracted position to the safety position;
- each flexible tab comprises a free end separated from the body of the protective shield by a respective groove opposite the slot;
- the flexible tab extends axially and proximally from the body of the protective shield;
- the flexible tab protrudes proximally from the lug when the protective shield is in the storage position and/or in the safety position;
- the flexible tab extends toward the second hinge portion.
- the flexible tab comprises an inner surface provided with a rib, and the ring comprises a protrusion provided with a cam member said protrusion extending radially from the ring and comprising a distal side and a proximal side located proximally relative to the distal side,
the flexible tab is configured to deform in flexion by engagement of the rib with the cam member when the protective shield transitions from the storage position to the retracted position, so that the rib passes from the distal side of the lug to the proximal side of the lug, and
the rib is configured to remain engaged with the cam member for maintaining the protective shield in the retracted position;
- the flexible tab comprises an inner surface provided with a rib, and the ring comprises a protrusion provided with a cam member said protrusion extending radially from the ring and comprising a distal side and a proximal side located proximally relative to the distal side,
the flexible tab and the protrusion being configured so that the flexible tab is subject to flexural deformation by engagement of the rib with the cam member during transition from the storage position to the retracted position, and subject to friction with the cam member by frictional engagement of the rib with said cam member in the retracted position to maintain the protective shield in the retracted position;
- the rib and the cam member are configured to maintain the protective shield at an angle superior or equal to 80° relative to an axis of the ring when said protective shield is in the retracted position;
- the first hinge portion comprises a groove defining a pivot axis of the protective shield, and the protective shield comprises an axle clipped into the groove;

- the first hinge portion comprises two colinear pins defining a pivot axis of the protective shield, and the protective shield comprises two proximal legs provided with an opening, each pin engaging a respective opening;
- 5 - the protective shield comprises at least a hook configured to engage the needle so as to lock the needle relative to the protective shield when said protective shield is in the safety position;
- the safety device further comprises a protective cap configured to be mounted onto the distal tip of the medical injection device to cover at least the needle tip, wherein the protective shield is interlocked with the protective cap when said protective shield is in the storage position.
- 10

Another object of the invention is a safety assembly comprising:

- a medical injection device comprising a barrel, a distal tip extending distally from the barrel, and a needle mounted into the distal tip, and
- 15 - a safety device as described previously, wherein the ring is around the distal tip of the medical injection device.

According to a preferred embodiment, the rib and the cam member are configured so that, when the protective shield is in the retracted position, the distal end of the protective shield does not protrude from the needle tip.

- 20 In this application, the “distal direction” is to be understood as meaning the direction of injection, with respect to the medical container the safety device of the invention is to be mounted onto. The distal direction corresponds to the travel direction of a plunger positioned at least partially inside the barrel of the injection device during the injection, the pharmaceutical composition contained initially in the barrel being expelled from said barrel.
- 25 Terms related to the distal direction, such as “distal”, or “distally” also relate to the direction of injection. The “proximal direction” is to be understood as meaning the opposite direction to said direction of injection. Terms related to the proximal direction, such as “proximal”, or “proximally” also relate to the opposite direction to the direction of injection. A first element of the safety device or the safety assembly that is located further on the plunger path than
- 30 a second element is thus distal or located distally relative to said second element. On the contrary, a first element of the safety device or the safety assembly that is located closer on the plunger path than a second element is thus proximal or located proximally relative to said second element.

- 35 In the present text, the “injection process” correspond to the use of the medical injection device for performing the injection of a composition contained therein, from the handling by the user of the stored injection device previously filled with the composition to be injected, to the disposal of the empty medical injection device after the injection has been performed. Such injection process comprises especially the steps of handling the stored

medical injection device, positioning the medical injection device in the vicinity of the skin of the patient, pricking the skin of the patient, injecting the composition, removing the needle from the skin of the patient, and disposing of the needle.

5 BRIEF DESCRIPTION OF THE DRAWINGS

Further features and advantages of the invention will become apparent from the detailed description to follow, with reference to the appended drawings, in which:

figure 1 is a general perspective view of the ring according to a first embodiment of the safety device;

10 figure 2 is a general perspective view of the protective shield according to the first embodiment;

figure 3A is a side sectional view of a safety device centered onto the distal tip of the medical injection device, wherein the ring is attached to the distal tip and the protective shield, which is pivotably mounted onto the ring, is in the storage position;

15 figure 3B is a side sectional view of a safety device of figure 3A, wherein the protective shield is in the safety position;

figure 3C is a side sectional view of a safety device of figure 3A, wherein the protective shield is in the retracted position;

20 figure 4 is a general perspective view of the protective shield according to a second embodiment of the safety device;

figure 5A is a side sectional view of a safety device centered onto the distal tip of the medical injection device, wherein the ring is attached to the distal tip and the protective shield, which is pivotably mounted onto the ring, is in the storage position;

25 figure 5B is a side sectional view of a safety device of figure 5A, wherein the protective shield is in the safety position;

figure 5C is a side sectional view of a safety device of figure 5A, wherein the protective shield is in the retracted position;

figure 6 is a general perspective view of the protective shield according to another embodiment of the second embodiment;

30 figure 7 is a general view of the safety device of the second embodiment, provided with a protective cap;

figure 8 is a general perspective view of the ring according to a third embodiment;

figure 9 is a general perspective view of the protective shield according to the third embodiment;

35 figure 10 is a general view of the safety device comprising the protective shield of figure 9 pivotably mounted onto the ring of figure 8;

figure 11A is a side sectional view of the safety device, wherein the protective shield is in the storage position;

figure 11B illustrates the transition of the protective shield from the storage position to the retracted position;

figure 11C illustrates the frictional engagement of the flexible tab of the protective shield with the cam member of the ring, when said protective shield is in the retracted position;

figure 12A is a side sectional view of the safety device, wherein the protective shield is in the storage position;

figure 12B illustrates the transition of the protective shield from the storage position to the safety position;

figure 12C illustrates the buckling deformation of the flexible tab of the protective shield when said protective shield is in the safety position;

figure 13 is a general perspective view of the safety device of the third embodiment, provided with a protective cap;

figure 14 is a general perspective view of the ring according to a fourth embodiment of the safety device;

figure 15 is a general perspective view of the protective shield according to the third embodiment;

figure 16 is a general view of the safety device comprising the protective shield of figure 15 pivotably mounted onto the ring of figure 14;

figure 17A is a side sectional view of the safety device, wherein the protective shield is in the storage position;

figure 17B is a perspective view of the safety device, wherein the protective shield is in the retracted position;

figure 17C is a side sectional view of the safety device, wherein the protective shield is in the safety position;

figure 18 is a general view of the safety device of the fourth embodiment, provided with a protective cap.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The invention relates to a safety device for preventing a user, especially a healthcare professional, from pricking himself or any person around, such as a patient to be treated, with the needle of a medical injection device, such as a syringe or the like, after injection.

The safety device 1 comprises a ring 10 which is configured to be attached to the distal tip 102 of the barrel 103 of the medical injection device 100. The barrel is a container for a medical composition to be injected to the patient. The safety device further comprises a protective shield 20 pivotably coupled to the ring. The composition is a fluid, and may be a liquid such as a pharmaceutical drug, a vaccine, etc. When attached together, the safety device 1 and the medical injection device 100 form a safety assembly 200.

The protective shield 20 is configured to act as a physical barrier which, depending on the step of the injection process, to prevent the user and any person around from contacting the needle 101, especially the needle tip 104, thereby preventing potential pricking injuries.

5 A first embodiment of the safety device 1 according to the invention is illustrated in figure 3A, wherein said safety device comprises the ring 10 illustrated in figure 1 and the protective shield 20 illustrated in figure 2.

In reference to figure 1, the ring 10 has a substantially cylindrical shape, and extends about an axis. In the present text, the term "axially" refers to said ring axis or to an axis parallel to said ring axis. The ring is configured to be attached onto a barrel distal tip.
10 Alternatively, the ring could be integrated to the distal tip of a plastic barrel.

The body of the ring 10 is pierced by a through hole 15 that extends substantially centrally relative to the body. The through hole 15 is adapted to accommodate the distal tip 102 of the medical injection device, as visible in figure 3A. When inserted into the hole 15 of the ring, an end portion 105 of the distal tip 102 protrudes from the ring 10, and the needle
15 101 protrudes from said end portion of the distal tip.

The ring 10 comprises a first hinge portion, and a lug 11 which protrudes from the outer surface of the ring body. In this embodiment, the lug 11 extends axially. More precisely, in this embodiment, the lug 11 protrudes distally from the ring body.

According to the first embodiment, the first hinge portion comprises a groove 13
20 formed in the outer surface of the ring 10. The groove defines a pivot axis about which the protective shield is pivotable.

As particularly visible in figure 3A, the lug is located distally relative to the groove. Moreover, the lug extends perpendicularly to the axis of the groove.

The ring is preferably made of any rigid polymer adapted to medical use, such as high-
25 density polyethylene (PE), polypropylene (PP), polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polyoxymethylene (POM), polystyrene (PS), polybutylene terephthalate (PBT), polyamide (PA), and their combinations.

The protective shield is preferably made of any rigid polymer adapted to medical use, such as high-density polyethylene (PE), polypropylene (PP), polycarbonate (PC),
30 acrylonitrile butadiene styrene (ABS), polyoxymethylene (POM), polystyrene (PS), polybutylene terephthalate (PBT), polyamide (PA), and their combinations.

In reference to figure 2, the protective shield 20 comprises a proximal portion 31 and a distal arm 32 that extends distally from the proximal portion. The proximal portion 31 may comprise two proximal legs 28 which face each other, and which rejoin at the distal
35 projection. Each of the proximal legs is provided with a cam surface 37.

The distal projection 32 may comprise a notch 33 configured to accommodate at least the tip 104 of the needle of the medical injection device in a safety position, when the safety device 1 is mounted onto the distal tip 102 of said medical injection device. The safety

position will be defined in the following of the text. The notch 33 extends along the distal projection 32, parallel to the needle accommodated therein.

The distal projection 32 comprises an inner surface 30.

5 The distal projection 32 may be provided with one or several hook(s) configured to engage the needle 101, so as to lock the protective shield 20 relative to the needle. The hook(s) may be provided in the inner surface 30 of the distal projection 32. When the distal projection 32 is provided with a notch 33, the hook(s) may extend from the inner surface of the notch.

10 The protective shield 20 comprises a second hinge portion that is configured to be pivotally coupled to the first hinge portion of the ring 10.

According to the first embodiment, the second hinge portion comprises an axle 27 which extends between the two proximal legs 28 of the proximal portion, thereby joining said proximal legs. The axle 27 is adapted to be clipped into the groove 13 of the ring while being pivotable relative to the ring. The axle 27 and the groove 13 thereby form a hinge
15 wherein the protective shield 20 is pivotably movable relative to the ring 10 around the pivot axis.

The protective shield further comprises a locking member that is configured to engage the lug of the ring.

20 According to the first embodiment, the locking member comprises a single flexible tab 21 that is adapted to deform to pass from a radially outward side 17 of the lug to a radially inward side 16 of the lug opposite the radially outward side relative to the lug, in a substantially radial direction.

25 According to this embodiment, the flexible tab extends in the proximal direction, and is separated from the two proximal legs 28 by two respective slots 36 that delimit the flexible tab.

The flexible tab 21 preferably extends from the join of the two proximal legs 28, between said proximal legs, toward the axle 27. The flexible tab 21 preferably extends proximally from the distal projection 32 toward the axle 27.

30 The safety device 1 may further comprise a protective cap 50 configured to be mounted onto the distal tip 102 of the medical injection device to cover at least the needle tip 104.

The safety device may further comprise a sealing cap (not represented), made in elastomeric material, configured to accommodate the distal tip 102 of the medical injection device and the needle tip 104. The sealing cap is enclosed in the protective cap.

35 Embodiments of the protective cap and the sealing cap are described in the document US 2018/0140780.

An embodiment of the protective cap 50 is illustrated in figure 7.

The protective cap 50 comprises a tubular body 51 that defines an inner cavity, a distal radial opening 52 and preferably a top proximal extension contiguous to the distal radial opening 52. The protective cap further comprises a bottom proximal extension, parallel to the top proximal extension when present, provided with two curved cuts 53 and two engaging pegs 54.

The protective cap 50 may be made in the same material as the ring 10. It can be either opaque or transparent.

The protective cap 50 is designed to be complementary and interlocked with the protective shield 20 and the ring 10 when the protective shield is in the storage position. In particular, the protective shield 20 and the protective cap 50 are dimensioned and interlocked such that the two curved cuts 53 of the protective cap 50 accommodate the cam surfaces 37 of the proximal legs 28 while the two engaging pegs 54 of the protective cap 50 engage the cam surfaces 37.

The protective cap 50, the protective shield 20, and optionally the ring 10 and/or the sealing cap, are thus totally interlocked in an example of a safety device 1 according to the present invention. Such a safety device 1 can be provided as a pre-assembled sub-unit for a straightforward mounting on the distal tip 102 of the injection device 100. The mounting step may be done as a single step by application of a fitting force directed axially toward the tip 102 of the injection device 100 for arrangement of the safety device 1 onto said tip 102.

The safety device is preferably configured so that removal of the protective cap causes the protective shield to pivot about its axis of rotation, corresponding to the axis of the hinge, in a direction opposite to the needle, i.e. towards the proximal direction.

The protective shield 20 is configured to adopt different positions with respect to the ring 10, and with respect to the distal tip 102 and the needle 101 of the medical injection device, by pivoting about the pivot axis, depending on the step of the injection process. In particular, the protective shield 20 is configured to adopt successively a storage position wherein the protective shield covers the needle tip 104 without being locked on the lug, a retracted position wherein the protective shield uncovers the needle tip, and a safety position wherein the protective shield covers the needle tip and is locked on the lug.

These positions of the protective shield and the transitions between them will now be described along with the functioning of the safety device, in the following of the present text, in reference to figures 3A, 3B, and 3C.

Figure 3A correspond to the configuration of the safety device 1 before its use. In this configuration, the protective shield is in the storage position wherein it covers the needle tip 104.

In the storage position, the protective shield 20 is interlocked with the protective cap 50 when present, and substantially parallel to the needle 101, which is enclosed in the protective cap 50. Furthermore, the needle tip 104 is embedded in the elastomeric material

of the elastomeric inner cap, thereby avoiding any leakage of the contents of the container of the injection device. The protective cap 50 is useful to protect the needle 101 prior use, for example from shocks, dusts, and contact with any person around or any contaminations. The elastomeric inner cap maintains the sterility and the sealing of the needle.

5 As illustrated in figure 3A, the needle 101 is parallel to the axis of the ring 10. The longitudinal axis of the protective shield 20 is preferably parallel to the axis of the ring. The flexible tab 21 is preferably parallel to the axis of the ring.

The flexible tab 21 is located radially outwardly from the lug 11, relative to the axis of the ring, and may cover the radially outward side 17 of the lug.

10 In order to use the safety assembly 200, the user draws the protective cap 50 in the distal direction. The removal of the protective cap 50 triggers the rotation of the protective shield 20 around the hinge, away from the storage position. The protective shield 20 may further rotate up to the retracted position illustrated in figure 3C. Preferably, the safety device 1 is configured so that removal of the protective cap 50 causes the protective shield
15 20 to pivot about the hinge up to its retracted position.

In more details, as soon as the protective cap 50 moves distally, the engaging pegs 54 of the protective cap 50 push onto the cam surfaces 37 of the protective shield 20, which results into the rotary opening movement of the protective shield 20 towards the barrel 103 of the injection device. The rotary movement of the cam surfaces 37 is optimized by the
20 specific shapes of the curved cuts 53 which allow a smooth and natural movement, similar to the opening of a needle cap that does not have any safety devices.

In the retracted position, the needle tip 104 is uncovered and physically accessible, and the safety assembly is ready for the injection of the composition contained in the medical injection device. The protective shield 20 extends obliquely, or perpendicularly,
25 relative to the axis of the ring 10. The angle between the protective shield 20 and the ring 10 may be adjusted by the user, and may be inferior, equal, or superior to 80°, preferably to 90°. To that end, the movement of the pivot axle 27 in the groove 13 of the ring may be frictional, and the friction may be sufficient to maintain the protective shield 20 in the position the user moved said protective shield into, with no further actuation of said protective shield
30 by the user. Such position may be the retracted position, or any position between the storage position and the retracted position.

As illustrated in figure 3C, the longitudinal axis of the protective shield 20 is oblique or substantially perpendicular to the axis of the ring. The flexible tab 21 is oblique or perpendicular to the axis of the ring.

35 The flexible tab 21 remains located radially outwardly relative to the lug 11, with regard to the axis of the ring, and the proximal end 34 of the flexible tab 21 may face the groove 13 of the ring and the axle 27 accommodated therein.

Once the injection has been performed, the user may pivot the protective shield 20 around the pivot axis, towards the needle 101, into the safety position illustrated in figure 3B. The needle tip 104 is thereby covered by the protective shield 20, and any pricking of the user or any person around by the needle tip is thus prevented.

5 Rotation of the protective shield 20 around the pivot axis causes the flexible tab 21 to engage the lug 11 of the ring. The flexible tab 21 is located radially outwardly from the lug 11, relative to the axis of the ring, and abuts the radially outward side 17 of the lug.

10 The flexible tab 21 is thus subjected to flexural deformation by deflecting radially outwardly from the body 22 of the protective shield. In other terms, the flexible tab lifts slightly.

Further rotation of the protective shield 20 causes the flexible tab 21 to slide on the lug 11 of the ring, until said flexible tab passes the lug, and gets to the other side of the lug 11, called radially inward side 16 of the lug.

15 At the end of the rotating movement, the protective shield 20 is in the safety position, and covers at least the needle tip 104.

As illustrated in figure 3B, the longitudinal axis of the protective shield 20 is oblique relative to the axis of the ring. The flexible tab 21 is oblique relative to the axis of the ring.

The flexible tab 21 is located radially inwardly relative to the lug 11, with regard to the axis of the ring, and the proximal end 34 of the flexible tab 21 faces the lug.

20 The needle may be locked into the protective shield 20 by the hook, and the needle tip 104 is accommodated inside the notch 33, as visible in figure 3B. Therefore, the needle tip 104 is covered and any pricking of a person by the needle is prevented.

25 The protective shield 20 is prevented from moving from the safety position, in particular from moving back to the storage position or the retracted position, by abutment of the proximal end 34 of the flexible tab 21 against the lug 11 which causes said flexible tab 21 to undergo buckling deformation. This buckling deformation impedes disengagement of the flexible tab 21 from the lug 11.

30 As a consequence, the protective shield 20 is secured in the safety position, and the safety device can no longer be used for another injection. Hence, the user may put the whole safety assembly 200 in a bin adapted for this purpose, or may remove the safety device 1 from the medical injection device 100 before putting them into adapted bins, without physically exposing him or any person around to the needle tip. Any risk of needle stick injury is thus prevented.

35 When abutting the needle 101, the protective shield 20 may be further pushed by the user to continue the rotating movement, so that at least the needle tip 104 deforms under the pressure exerted by the user. This position also corresponds to the safety position. As a consequence, the deformed needle tip 104 lies inside the notch 33, parallel to and in

contact with the inner surface 30 of the notch, which further improve the safety by totally covering the needle tip.

A second embodiment of the safety device 1 according to the invention is illustrated in figures 5A, 5B, and 5C, wherein said safety device comprises the ring 10 illustrated in figure 1 and the protective shield 20 illustrated in figure 4.

The ring is the same as that of the first embodiment previously described.

The general structure of the protective shield of the second embodiment is similar to that of the first embodiment described before, and will not be further described. The common features between the first and the second embodiments represented in figures 1, 2, 3A-C and 4, 5A-C are given the same references.

The locking member comprises two flexible tabs 21 separated by a slot 23.

Another embodiment of the protective shield 20 provided with two flexible tabs 21 is illustrated in figure 6, wherein each flexible tab 21 comprises a free end 34 separated from the body 22 of the protective shield by a respective groove 24 opposite the slot 23. The dimensions of the grooves 24 may be adapted to adjust the flexibility and the deformation of each of the flexible tabs.

The functioning of the safety device 1 according to the second embodiment is similar to that of the first embodiment, except that the transition of the protective shield 20 from the retracted position to the safety position causes both flexible tabs 21 to engage the lug 11 of the ring 10. As a result, the two flexible tabs 21 deflect radially outwardly from the body 22 of the protective shield and slightly deviate from each other relative to the slot 23 in-between. This makes the transition between the retracted position and the safety position smoother compared to the first embodiment.

A third embodiment of the safety device 1 according to the invention is illustrated in figures 9, 10A-C, and 11A-C, wherein said safety device comprises the ring 10 illustrated in figure 8 and the protective shield 20 illustrated in figure 9.

The general structures of the ring and protective shield of the third embodiment are similar to that of the first embodiment described before, and will not be further described. The common features between the first and the third embodiments represented in figures 1, 2, 3A-C and 8-10, 11A-C, and 12A-C are given the same references.

According to the third embodiment, the first hinge portion of the ring comprises two colinear pins 14 that define a pivot axis of the protective shield.

The ring 10 comprises a lug 11 which protrudes from the outer surface of the ring, a protrusion 18 provided with a cam member 12, and a groove 13.

The second hinge portion of the protective shield comprises two openings 29, each opening being provided in one of the two proximal legs 28 of the proximal part of the protective shield. Each pin 14 is configured to engage a respective opening 29, thereby

forming a hinge wherein the protective shield 20 is pivotably movable relative to the ring 10 around a pivot axis joining the centers of the pins 14.

The locking member of the protective shield comprises a single flexible tab 21 that is adapted to deform when engaging the lug 11 of the ring 10.

5 The flexible tab 21 comprises an inner surface 25 provided with a rib 26. Said rib is adapted to engage the cam member 12 when the protective shield 20 transitions from the storage position to the retracted position.

The functioning of the safety device according to the third embodiment will now be described, in reference to figures 11A-C and 12A-C.

10 Figure 11A correspond to the configuration of the safety device 1 before its use. In this configuration, the protective shield is in the storage position wherein it covers the needle tip 104.

The needle 101 is parallel to the axis of the ring 10.

15 The longitudinal axis of the protective shield 20 is preferably parallel to the axis of the ring. The flexible tab 21 is preferably parallel to the axis of the ring.

The flexible tab 21 is located radially outwardly from the lug 11, relative to the axis of the ring, and may contact the radially outward side of the lug.

20 In order to use the safety assembly 200, the user draws the protective cap 50 in the distal direction. The removal of the protective cap 50 triggers the rotation of the protective shield 20 around the pivot axis of the hinge, relative to the pins 14 of the ring, away from the storage position (figure 11B). The protective shield 20 may further rotates up to the retracted position illustrated in figure 11C. Preferably, the safety device 1 is configured so that removal of the protective cap 50 causes the protective shield 20 to pivot about the hinge up to its retracted position.

25 Rotation of the protective shield 20 around the pivot axis causes the rib 26 of the flexible tab 21 to engage the cam member 12 of the ring. The flexible tab 21 abuts a distal side 19a of the protrusion 18.

30 The flexible tab 21 is thus subjected to flexural deformation by deflecting radially outwardly from the body 22 of the protective shield, caused by the engagement of the rib 26 with the cam member 12.

In reference to figure 10B, further rotation of the protective shield 20 causes the rib 26 of the flexible tab to slide onto the lug 11 of the ring, and gets to the other side of the lug 11, called proximal side 19b, located distally relative to said proximal side.

35 At the end of the rotating movement, the protective shield 20 is in the retracted position, thereby uncovering the needle tip 104. This situation is illustrated in figure 11C. A proximal portion of the protective shield is accommodated in the groove 13.

The longitudinal axis of the protective shield 20 is oblique or substantially perpendicular to the axis of the ring. The flexible tab 21 is oblique or perpendicular to the axis of the ring.

5 The flexible tab 21 remains located radially outwardly relative to the lug 11, with regard to the axis of the ring, and the proximal end 34 of the flexible tab 21 may face the groove 13 of the ring.

10 The protective shield 20 is prevented from moving from the retracted position, in particular from moving back to the storage position or from moving to the safety position, by frictional engagement of the rib 26 with the cam member 12. In more details, the flexibility of the tab 21 urges said tab towards the cam member 12, which improves the frictional engagement between them.

15 The protective shield 20 is thus secured to the retracted position, unless a determined effort is applied by the user onto the protective shield. Hence, the user has to push the protective shield 20 with a certain effort to overcome the blocking resulting from the frictional engagement for moving the protective shield away from the retracted position, in particular to the safety position. The subsequent injection step thus can be made without the need for the user to handle the protective shield for preventing unexpected tilt of said protective shield during the injection, thereby making the injection safer.

20 The rib 26 and the cam member 12 may be configured to maintain the protective shield 20 at an angle superior or equal to 80° , preferably to 90° , relative to the axis of the ring 10 when said protective shield is in the retracted position. Possible adjustments are for example the dimensions of the rib and the cam member, and the inclination of the rib and the cam member relative to each other. Maintaining the protective shield at an angle superior or equal to 90° allows for completely uncovering the needle, thereby making said 25 needle visible for the user and facilitating the injection.

The rib 26 and the cam member 12 are configured so that, when the protective shield 20 is in the retracted position, the distal end of the protective shield does not protrude from the needle tip 104. In that way, the injection is not disrupted by contact of the protective shield with the skin of the patient.

30 After the injection, the user may rotate the protective shield 20 around the pivot axis of the hinge, towards the needle 101, into the safety position, as illustrated in figures 11A, 11B, and 11C. The needle tip 104 is thereby covered by the protective shield 20, and any pricking of the user or any person around by the needle tip is thus prevented.

35 Rotation of the protective shield 20 around the pivot axis causes the proximal end 34 of the flexible tab 21 to engage the lug 11 of the ring. The flexible tab 21 is located radially outwardly from the lug 11, relative to the axis of the ring, and abuts the radially outward side of the lug.

The flexible tab is thus subjected to flexural deformation by deflecting radially outwardly from the body of the protective shield.

Further rotation of the protective shield 20 causes the flexible tab 21 to slide on the lug 11 of the ring, until said flexible tab 21 passes the lug and gets to the radially inward
5 side of the lug 11.

At the end of the rotating movement, the protective shield 20 is in the safety position, and covers at least the needle tip 104.

As illustrated in figure 12C, the longitudinal axis of the protective shield 20 is oblique relative to the axis of the ring. The flexible tab 21 is oblique relative to the axis of the ring.

10 The flexible tab 21 is located radially inwardly relative to the lug 11, with regard to the axis of the ring, and the proximal end 34 of the flexible tab 21 faces the lug.

The needle may be locked into the protective shield 20 by the hook, and the needle tip 104 may be accommodated inside the notch.

Therefore, the needle tip is covered and any pricking of a person by the needle is
15 prevented.

The protective shield 20 is prevented from moving from the safety position, in particular from moving back to the storage position or the retracted position, by abutment of the proximal end 34 of the flexible tab 21 against the lug 11 which causes said flexible tab to undergo buckling deformation. This buckling deformation impedes disengagement of
20 the flexible tab 21 from the lug 11. As a consequence, the protective shield 20 is secured to the safety position, and the safety device can no longer be used for another injection.

When abutting the needle 101, the protective shield 20 may be further pushed by the user to continue the rotating movement, so that at least the needle tip 104 deforms under the pressure exerted by the user. This position also corresponds to the safety position. As
25 a consequence, the deformed needle tip 104 lies against the protective shield 20, parallel to and in contact with the inner surface 30 of the protective shield 20, which further improve the safety by totally covering the needle tip.

The third embodiment is particularly advantageous, because the flexible tab 21 not only locks the protective shield 20 in the safety position, as in the first and second
30 embodiments, but also maintains the protective shield in the retracted position before the injection.

A fourth embodiment of the safety device 1 according to the invention is illustrated in figures 16, 17A-C, and 18, wherein said safety device comprises the ring 10 illustrated in figure 14 and the protective shield illustrated in figure 15.

35 The general structures of the ring and protective shield of the fourth embodiment are similar to that of the third embodiment described before, and will not be further described. The common features between the first and the third embodiments represented in figures 8-10, 11A-C, 12A-C, and 14-16, 17A-C and 18, are given the same references.

According to the fourth embodiment, the first hinge portion of the ring comprises two colinear pins 14 that define a pivot axis of the protective shield 20.

The ring 10 comprises a lug 11 which protrudes from the outer surface of the ring, and a groove 13.

5 Each pin 14 of the ring is configured to engage a respective opening 29 of the protective shield, thereby forming a hinge wherein the protective shield 20 is pivotably movable relative to the ring 10 around a pivot axis joining the center of the pins 14.

The locking member of the protective shield does not comprise any flexible tab. The engagement of the protective shield with the lug of the ring is achieved via a proximal
10 contacting end 35 of the protective shield from which the proximal legs extends, said proximal contacting end 35 being the locking member.

An advantage of this more rigid design is that the user has a clearer feeling of the locking of the protective shield in the safety position, since the engagement of the locking member with the lug is less smooth than with a flexible leg.

15 The functioning of the safety device according to the fourth embodiment will now be described, in reference to figures 17A, 17B, and 17C.

Figure 17A correspond to the configuration of the safety device 1 before its use. In this configuration, the protective shield is in the storage position wherein it covers the needle tip.

20 The longitudinal axis of the protective shield 20 is preferably parallel to the axis of the ring. The proximal contacting end 35 preferably extends parallel to the axis of the ring.

The proximal contacting end 35 is located radially outwardly from the lug 11, relative to the axis of the ring, and may cover the radially outward side 17 of the lug.

In order to use the safety assembly 200, the user draws the protective cap 50 in the
25 distal direction. The removal of the protective cap 50 triggers the rotation of the protective shield 20 around the pivot axis of the hinge, relative to the pins 14 of the ring, away from the storage position. The protective shield 20 may further rotate up to the retracted position illustrated in figure 17B. Preferably, the safety device 1 is configured so that removal of the protective cap 50 causes the protective shield 20 to pivot about the hinge up to its retracted
30 position.

The proximal contacting end 35 is accommodated in the groove 13.

In the retracted position, the needle tip 104 is uncovered and physically accessible, and the safety assembly is ready for the injection of the composition contained in the medical injection device.

35 The longitudinal axis of the protective shield 20 is oblique or substantially perpendicular to the axis of the ring.

The proximal contacting end 35 remains located radially outwardly relative to the lug 11, with regard to the axis of the ring, and may face the groove 13 of the ring.

After the injection, the user drives the protective shield 20 around the pivot axis of the hinge, towards the needle 101, into the safety position, as illustrated in figures 17C. The needle tip 104 is thereby covered by the protective shield 20, and any pricking of the user or any person around by the needle tip 104 is thus prevented.

5 Rotation of the protective shield 20 around the pivot axis causes the proximal contacting end 35 of the protective shield to engage the lug 11 of the ring 10. The proximal contacting end 35 is located radially outwardly from the lug 11, relative to the axis of the ring, and abuts the radially outward side 17 of the lug. The first and second hinge portions are thus subjected to flexural deformation which allows the rotation of the protective shield
10 20.

Further rotation of the protective shield 20 causes the proximal contacting end 35 to slide on the lug 11 of the ring until said proximal contacting end passes the lug and gets to the radially inward side 16 of the lug 11.

At the end of the rotating movement, the protective shield 20 is in the safety position,
15 and covers at least the needle tip 104.

As illustrated in figure 17C, the longitudinal axis of the protective shield 20 is oblique relative to the axis of the ring. The proximal contacting end 35 is oblique relative to the axis of the ring.

The proximal contacting end 35 is located radially inwardly relative to the lug 11, with
20 regard to the axis of the ring, and the proximal contacting end 35 faces the lug.

The needle may be locked into the protective shield 20 by the hook, and the needle tip 104 may be accommodated inside the notch.

The protective shield 20 is further locked on the needle 101 by the hook, and the needle tip 104 is accommodated inside the notch 33. Therefore, the needle tip is covered
25 and any pricking of a person by the needle is prevented.

The protective shield 20 is prevented from moving from the safety position, in particular from moving back to the storage position or the retracted position, by abutment of the proximal contacting end 35 against the lug 11 which causes the first and second hinge portions to undergo buckling deformation. This buckling deformation impedes
30 disengagement of the proximal contacting end 35 from the lug 11. As a consequence, the protective shield is secured to the safety position, and the safety device can no longer be used for another injection.

When abutting the needle 101, the protective shield 20 may be further pushed by the user to continue the rotating movement, so that at least the needle tip 104 deforms under
35 the pressure exerted by the user. This position also corresponds to the safety position. As a consequence, the deformed needle tip 104 lies against the protective shield 20, parallel to and in contact with the inner surface 30 of the protective shield 20, which further improve the safety by totally covering the needle tip.

In all embodiments, the locking of the protective shield 20 by the locking member 12, 35 takes place in the alignment of said locking member. Therefore, the radial size of the safety assembly does not increase, which does not limit its packaging, for example in nests.

It should be noted that the embodiments described above are not limited to a specific
5 design of the hinge.

Moreover, any embodiment of the first hinge portion may be associated with any embodiment of the second hinge portion, as long as their structure is compatible and the safety device works and achieves the locking of the protective shield in the safety position as described previously. For example, the protective shield of the fourth embodiment,
10 provided with the proximal contacting end 35 (with no flexible tab) may be combined with the axle 27 and groove 13 of the first embodiment.

CLAIMS

1. Safety device (1) for preventing needle stick injury with a needle (101) extending from a distal tip (102) of a medical injection device (100), comprising:

5 - a ring (10) configured to be attached to the distal tip (102) of the medical injection device and comprising a first hinge portion, and

 - a protective shield (20) comprising a second hinge portion pivotally coupled to the first hinge portion, the protective shield being configured to adopt successively a storage position wherein the protective shield (20) covers the needle tip, a retracted position wherein
10 the protective shield (20) uncovers the needle tip and a safety position wherein the protective shield (20) covers the needle tip,

 wherein

 the ring (10) comprises a lug (11), said lug extending distally and comprising a radially inward side (16) and a radially outward side (17) opposite to the radially inward side
15 relative to an axis of the ring,

 the protective shield comprises at least one proximal locking member (21, 35);

 in the safety position, the protective shield (20) is locked on the ring (10) by engagement of the locking member (21, 35) with the lug (11), characterized in that:

 the locking member (21, 35) is a flexible tab; and

20 the locking member (21, 35) is configured to:

 - engage the lug (11) when the protective shield transitions from the retracted position to the safety position, so that said locking member (21, 35) abuts against the radially outward side (17) of the lug and deflects radially outwardly, relative to the axis of the ring, from a body (22) of the protective shield (20) when said
25 protective shield passes from the radially outward side (17) of the lug to the radially inward side (16) of the lug, and

 - remain engaged with the radially inward side (16) of the lug (11) for maintaining the protective shield (20) in the safety position.

30 2. Safety device (1) according to claim 1, wherein the locking member comprises a single flexible tab (21).

 3. Safety device (1) according to claim 1, wherein the locking member comprises two flexible tabs (21) separated by a slot (23).
35

 4. Safety device (1) according to claim 3, wherein each flexible tab (21) comprises a free end (35) separated from the body (22) of the protective shield (20) by a respective groove (24) opposite the slot (23).

5. Safety device (1) according to any of claims 2 to 4, wherein the flexible tab (21) extends axially and proximally from the body (22) of the protective shield (20).

6. Safety device (1) according to claim 5, wherein the flexible tab (21) protrudes proximally from the lug (11) when the protective shield (20) is in the storage position and/or in the safety position.

7. Safety device (1) according to claim 5 or claim 6, wherein the flexible tab extends toward the second hinge portion.

8. Safety device (1) according to any of claims 2 to 7, wherein the flexible tab (21) comprises an inner surface (25) provided with a rib (26), and the ring (10) comprises a protrusion (18) provided with a cam member (12) said protrusion (18) extending radially from the ring (10) and comprising a distal side (19a) and a proximal side (19b) located proximally relative to the distal side,

the flexible tab (21) is configured to deform in flexion by engagement of the rib (26) with the cam member (12) when the protective shield transitions from the storage position to the retracted position, so that the rib (26) passes from the distal side (19a) of the lug to the proximal side (19b) of the lug, and

the rib (26) is configured to remain engaged with the cam member (12) for maintaining the protective shield (20) in the retracted position.

9. Safety device (1) according to claim 8, wherein the rib (26) and the cam member (12) are configured to maintain the protective shield (20) at an angle superior or equal to 80° relative to an axis of the ring (10) when said protective shield (20) is in the retracted position.

10. Safety device (1) according to any of the preceding claims, wherein the first hinge portion comprises a groove (13) defining a pivot axis of the protective shield (20), and the protective shield (20) comprises an axle (27) clipped into the groove (13).

11. Safety device (1) according to any of claims 1 to 9, wherein the first hinge portion comprises two colinear pins (14) defining a pivot axis of the protective shield (20), and the protective shield (20) comprises two proximal legs (28) provided with an opening (29), each pin (14) engaging a respective opening (29).

12. Safety device (1) according to any of the preceding claims, wherein the protective shield (20) comprises at least a hook configured to engage the needle (101) so as to lock the needle relative to the protective shield (20) when said protective shield is in the safety position.

13. Safety device (1) according to any of the preceding claims, further comprising a protective cap (50) configured to be mounted onto the distal tip (102) of the medical injection device to cover at least the needle tip, wherein the protective shield (20) is interlocked with
5 the protective cap (50) when said protective shield is in the storage position.

14. Safety assembly (200) comprising:
- a medical injection device (100) comprising a barrel (103), a distal tip (102) extending distally from the barrel, and a needle (101) mounted into the distal tip, and
10 - the safety device (1) according to any of the preceding claims, wherein the ring (10) is around the distal tip (102) of the medical injection device.

15. Safety assembly (200) according to claim 14 wherein the safety device is as claimed in claim 8, wherein the rib (26) and the cam member (12) are configured so that,
15 when the protective shield (20) is in the retracted position, the distal end of the protective shield does not protrude from the needle tip (104).

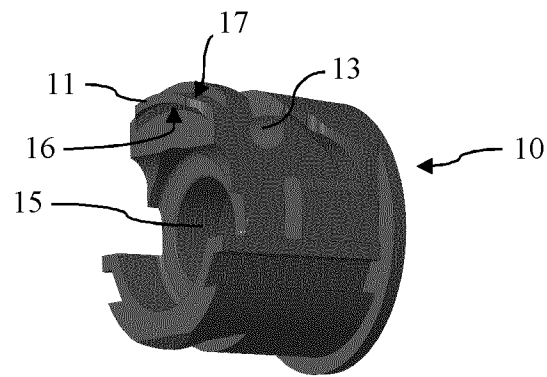


FIGURE 1

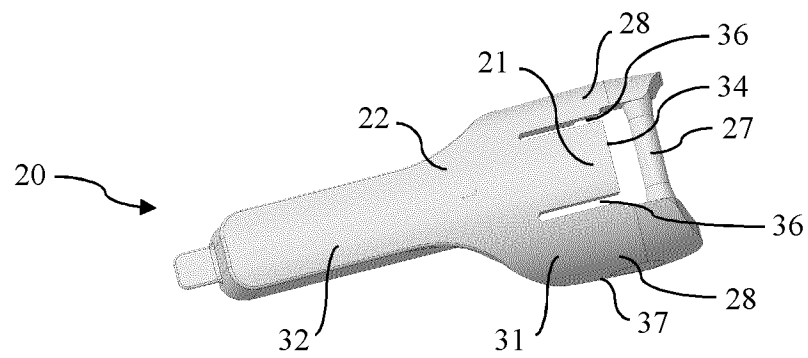


FIGURE 2

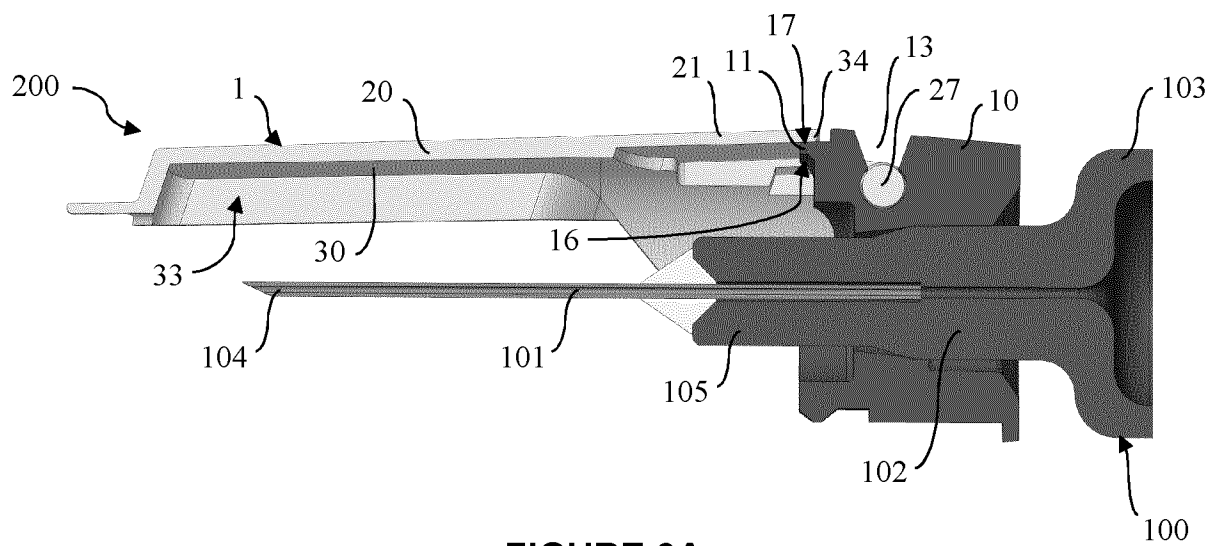


FIGURE 3A

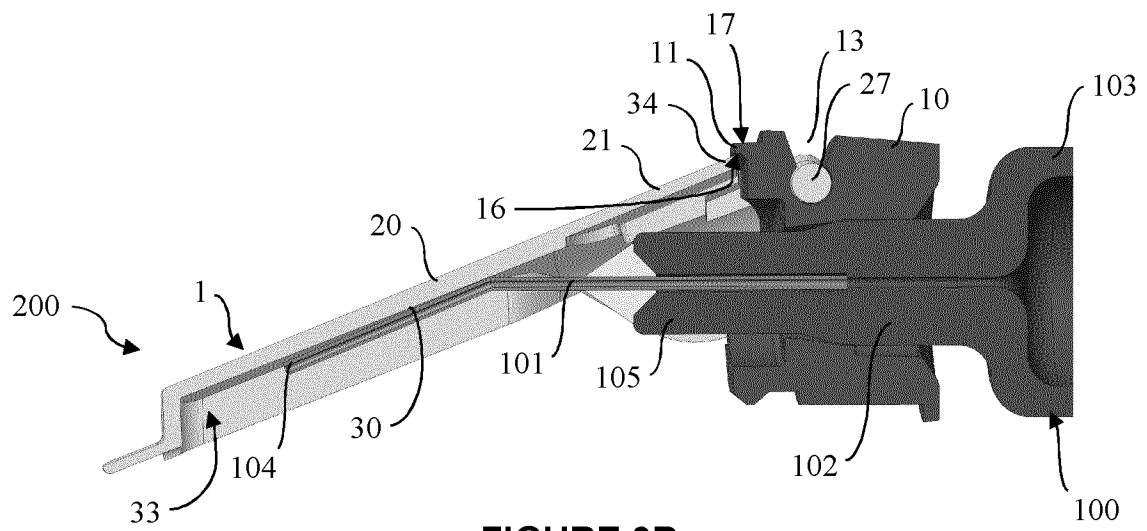


FIGURE 3B

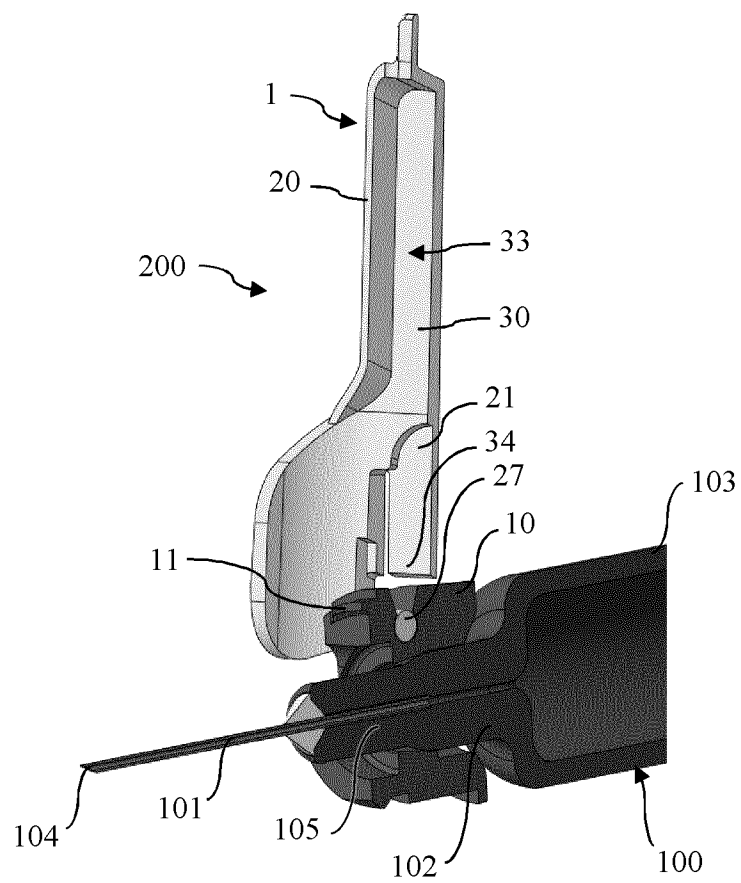


FIGURE 3C

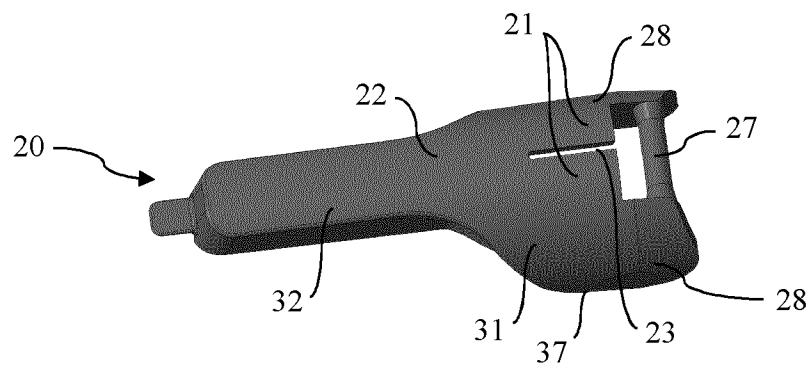


FIGURE 4

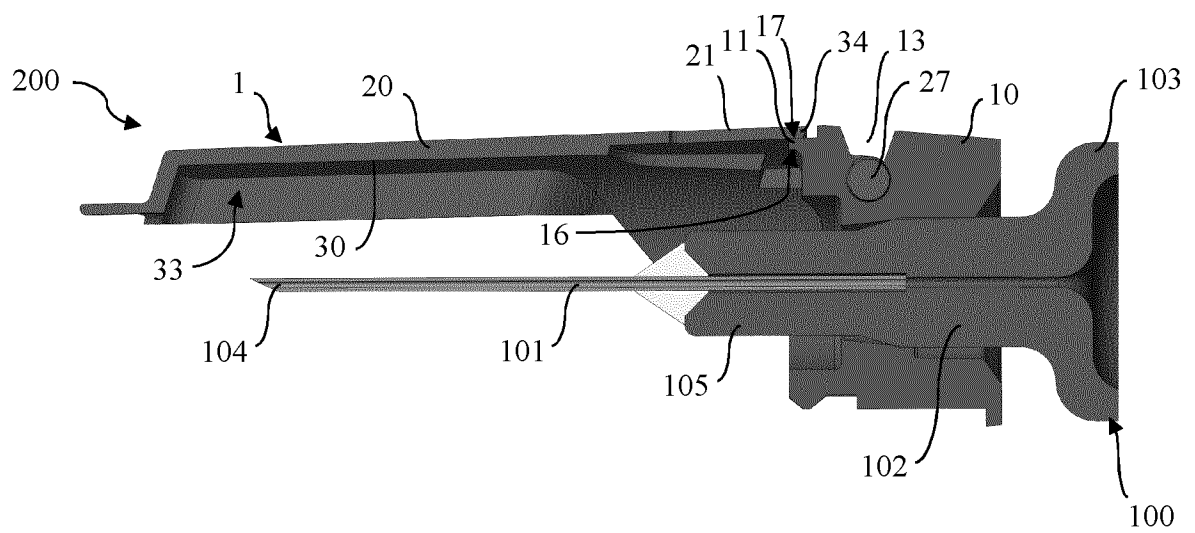


FIGURE 5A

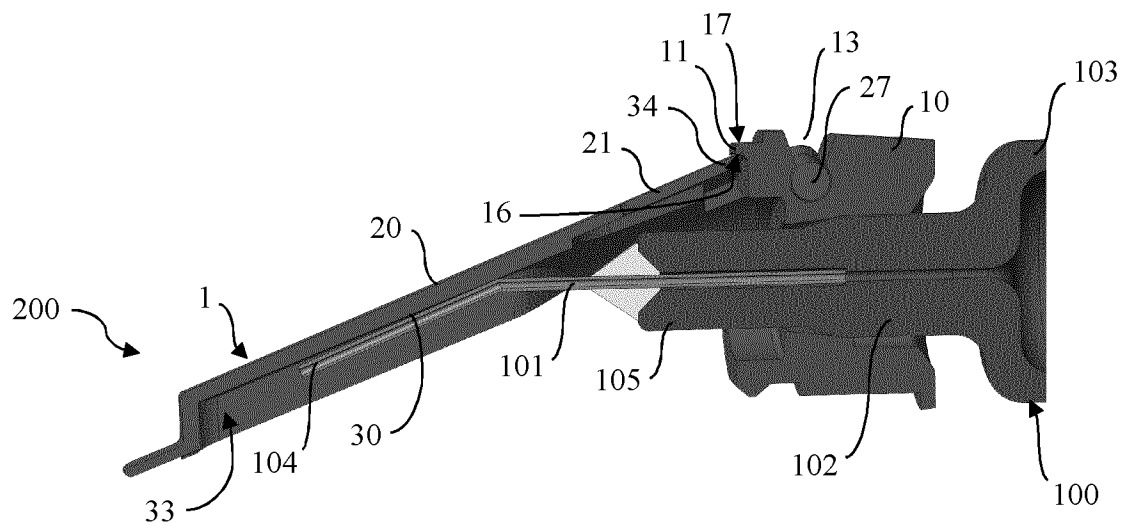


FIGURE 5B

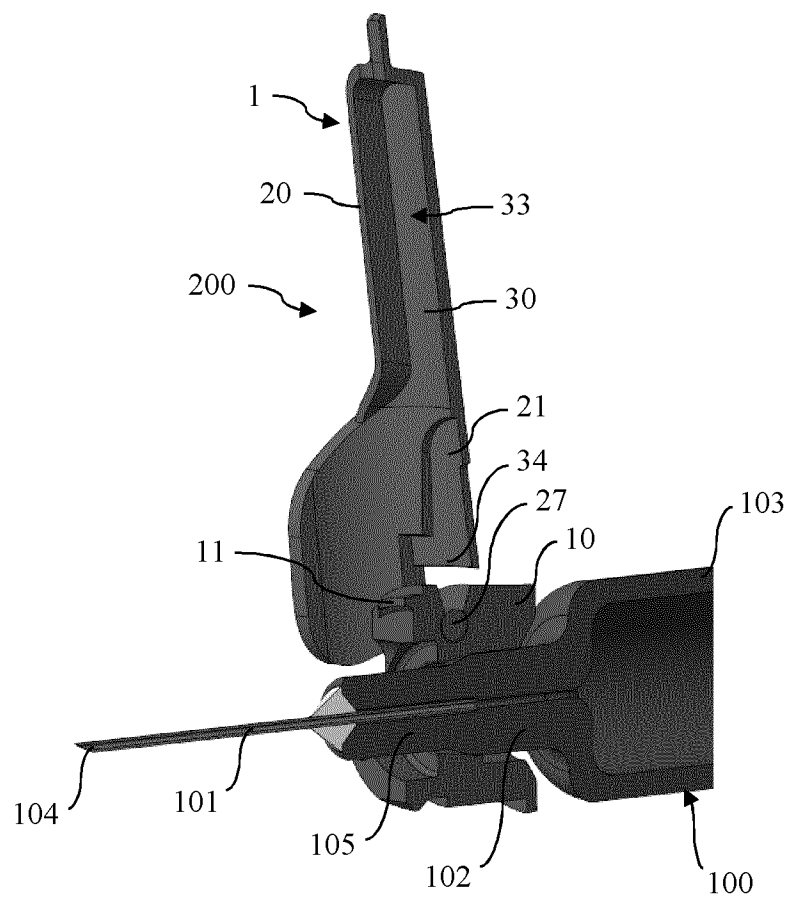


FIGURE 5C

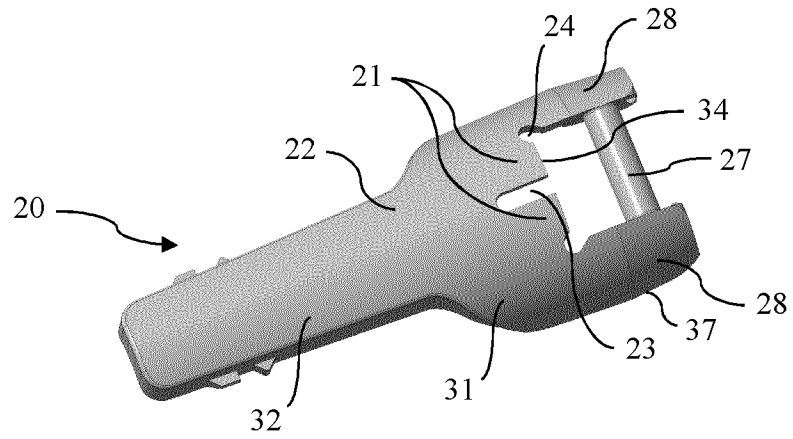


FIGURE 6

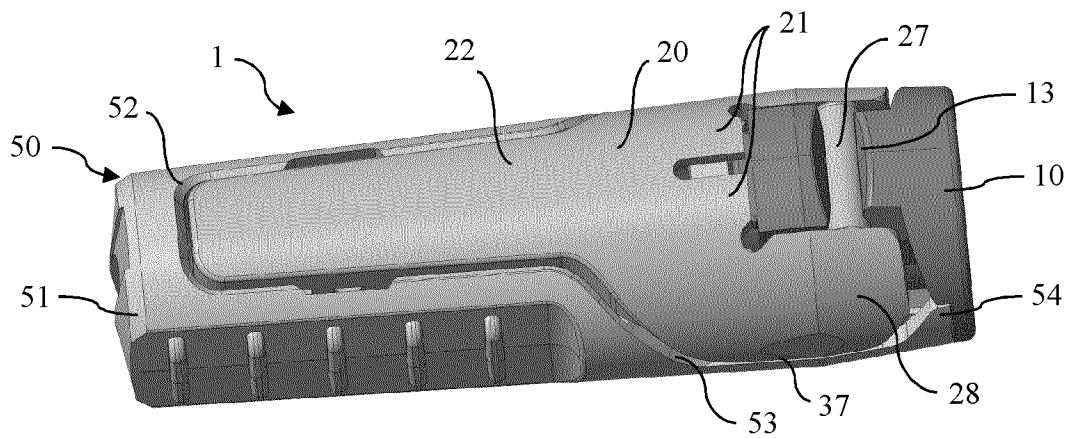


FIGURE 7

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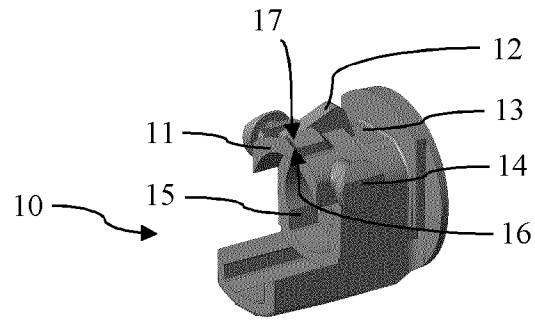


FIGURE 8

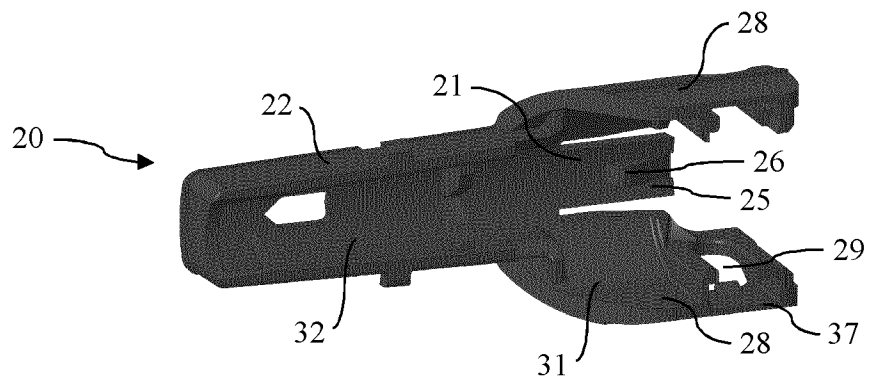


FIGURE 9

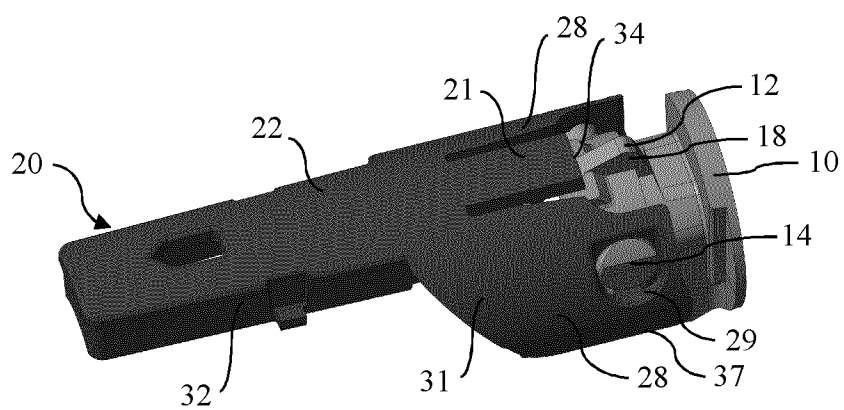


FIGURE 10

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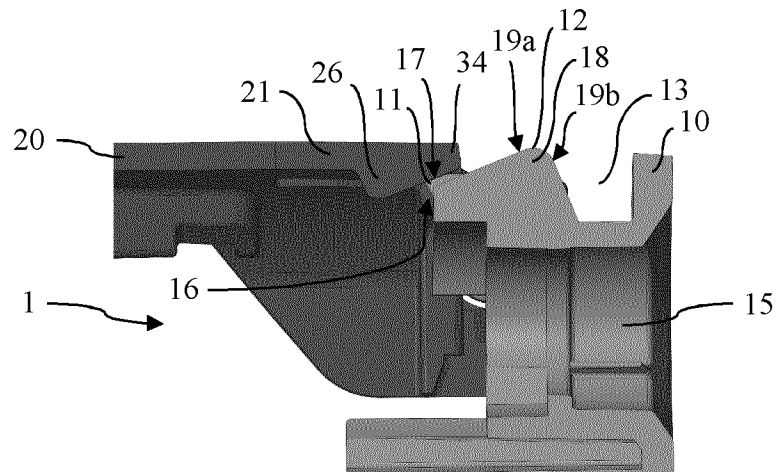


FIGURE 11A

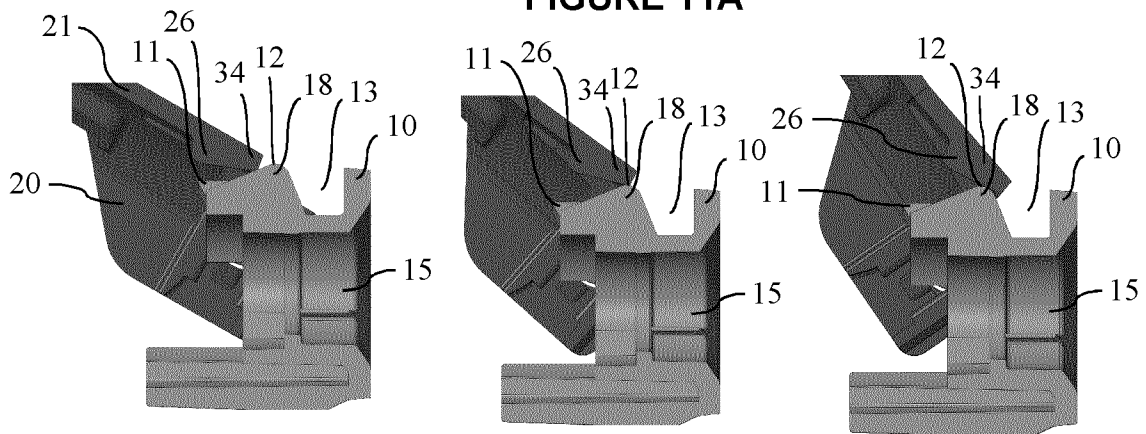


FIGURE 11B

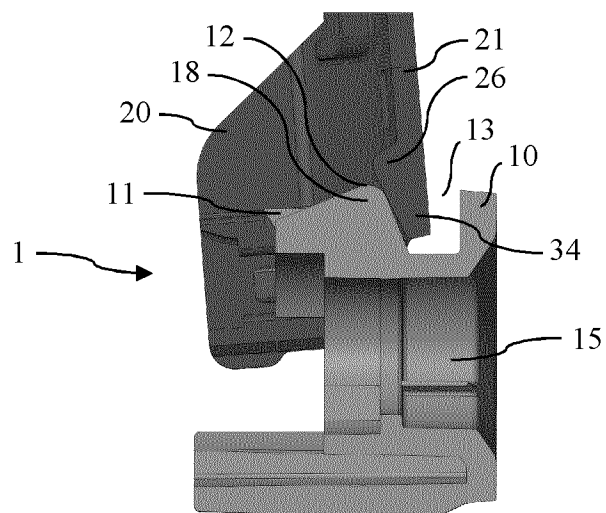


FIGURE 11C

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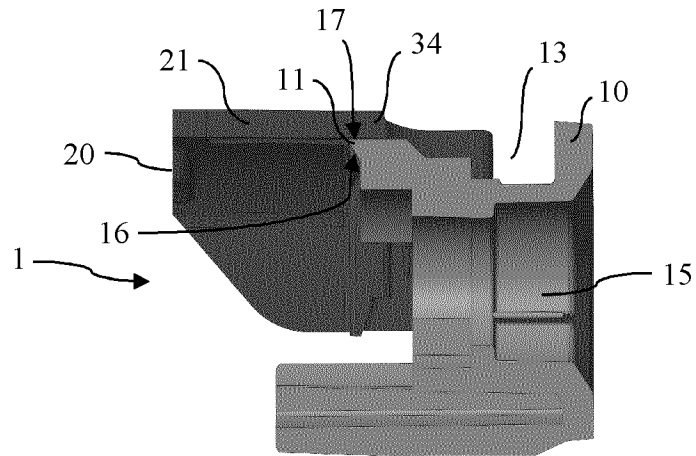


FIGURE 12A

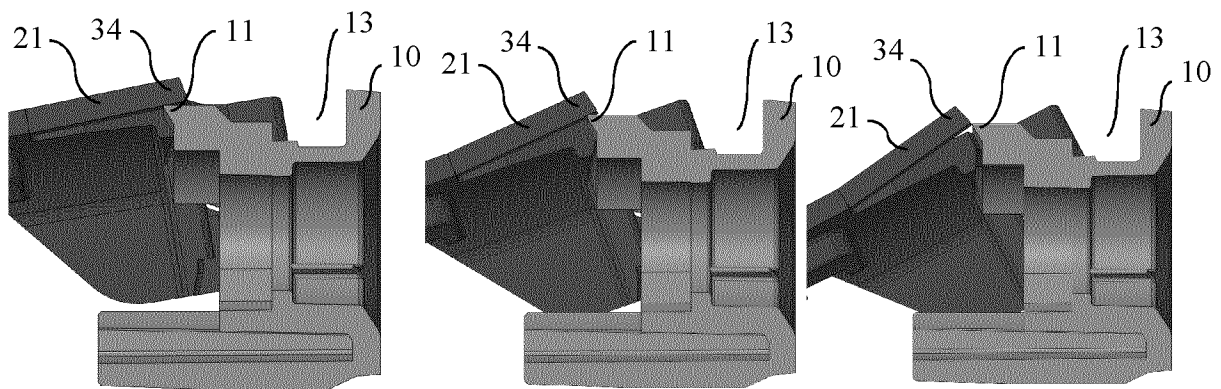


FIGURE 12B

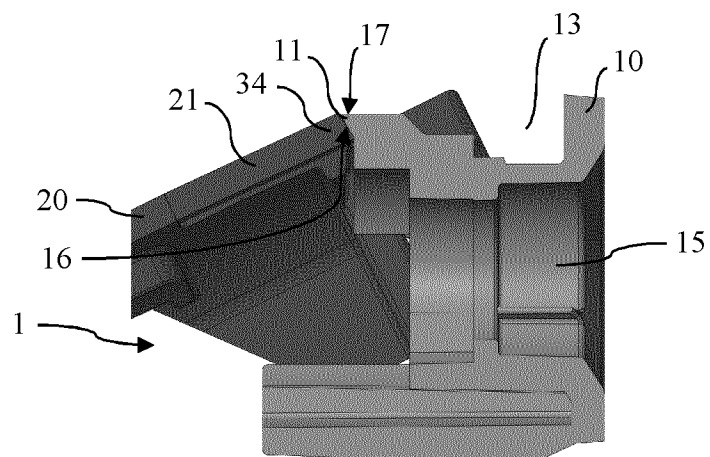


FIGURE 12C

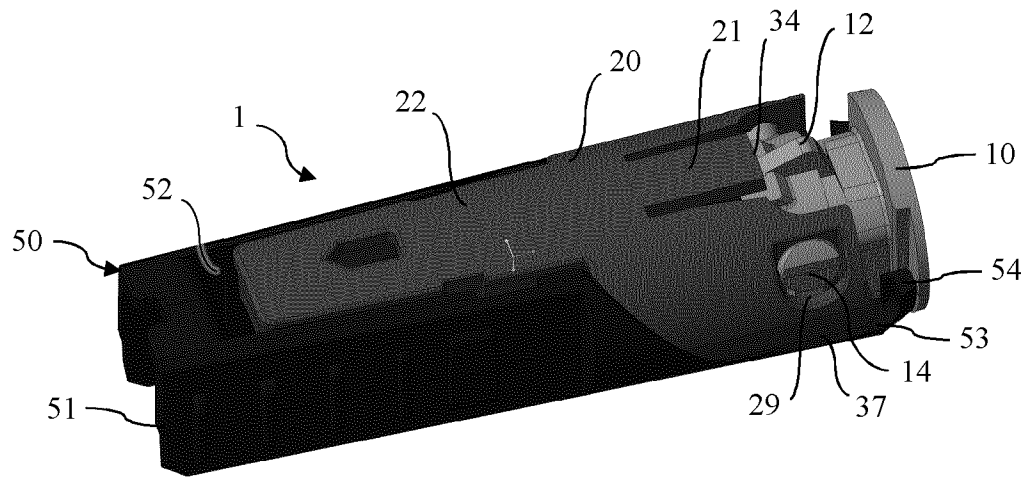


FIGURE 13

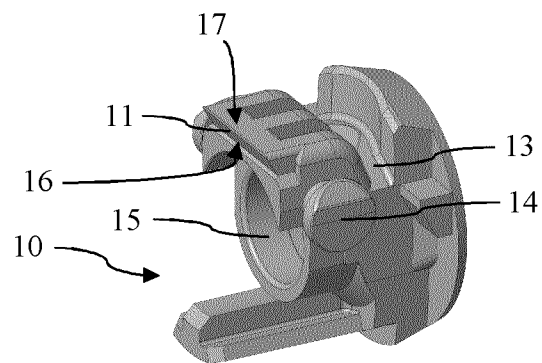


FIGURE 14

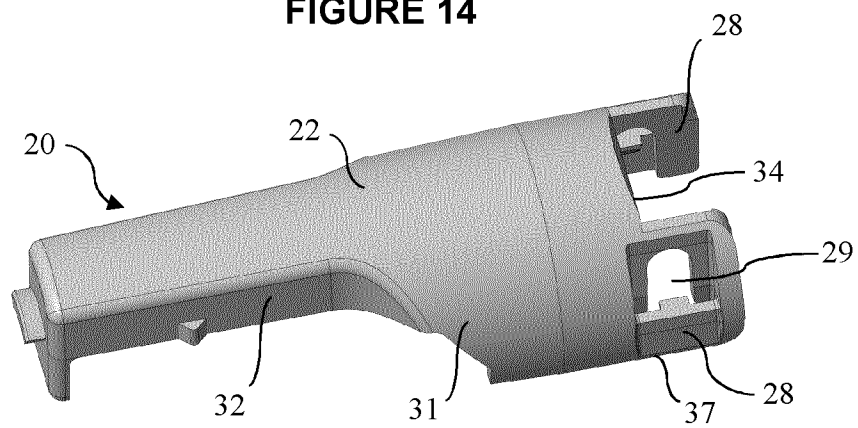


FIGURE 15

10/11

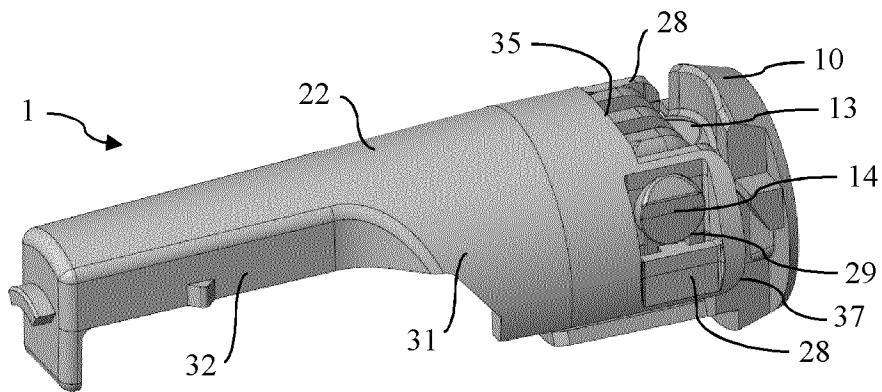


FIGURE 16

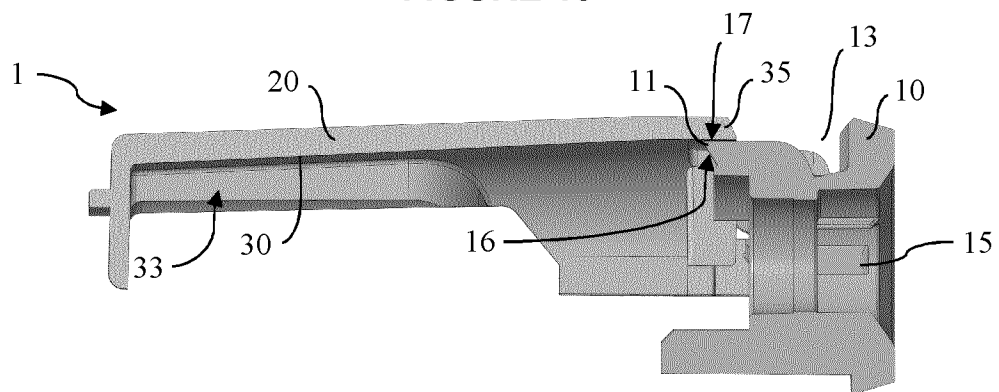


FIGURE 17A

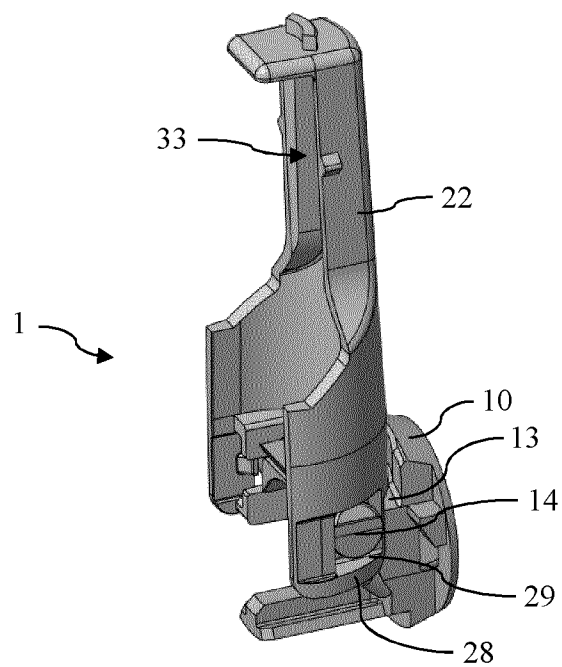


FIGURE 17B

11/11

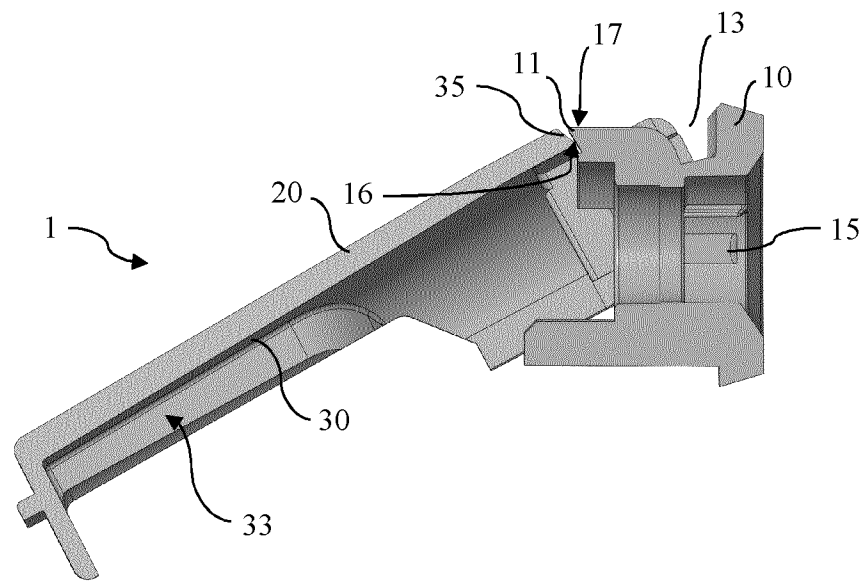


FIGURE 17C

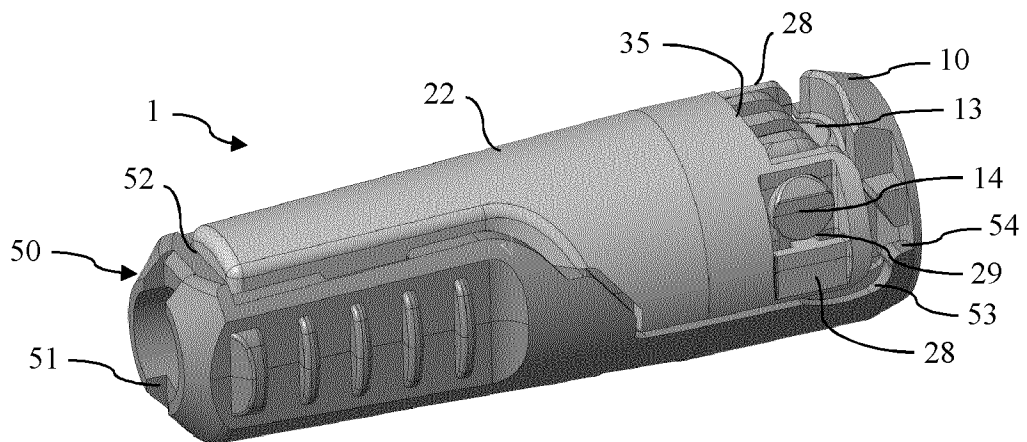


FIGURE 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2020/067181

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/32
ADD.

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)
A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 702 973 B1 (BECTON DICKINSON CO [US]) 17 November 1999 (1999-11-17)	1-12,14, 15
Y	paragraphs [0004], [0013], [0019] - [0020], [0024] figures 12-13, 16-17, 34-35 -----	13
X	CA 3 046 821 A1 (BERPU MEDICAL TECH CO LTD [CN]) 17 May 2018 (2018-05-17) paragraphs [0001], [0006] - [0008] figures 1-9, 13, 20 -----	1-15
X	CN 102 772 840 B (SHANGHAI MENGLI INTERNAT TRADE CO LTD) 29 June 2016 (2016-06-29) abstract paragraphs [0050], [0066] - [0071] figures 1-4, 8 ----- -/-	1-12,14, 15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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INTERNATIONAL SEARCH REPORT

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