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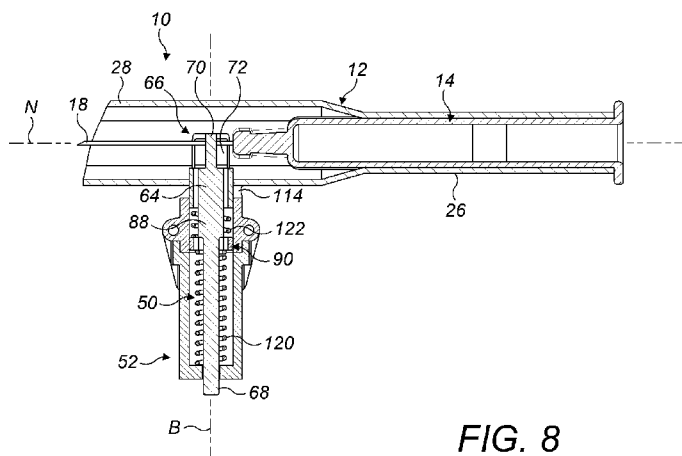


FIG. 8

(57) Abstract: A needle bending assembly (10) for bending a hypodermic needle (18) in a medical device comprises a holder (12) for holding the needle (18) in position along a needle axis (N) and a bending member (50) that is axially movable along a bending axis (B) from an initial state in which the bending member (50) is spaced from the needle axis (N) into a cooperating state in which the bending member (50) is positioned for engagement with the needle (18). The bending axis (B) is non-parallel to the needle axis (N), and the bending member (50) is turnable about the bending axis (B) to apply a bending force to the needle (18) when the bending member (50) is in the cooperating state.

APPARATUS FOR NEEDLE HANDLING

5 The present invention relates to apparatus for needle handling. In particular, but not exclusively, the invention relates to devices for automatically bending a hypodermic needle.

Certain medicaments are most effectively delivered subcutaneously by injection or infusion. Such medicaments are often made available in pre-filled containers or syringes. One common type of pre-filled syringe is available under the registered trade mark Hypak (Becton Dickinson, New Jersey, USA), and includes a tubular glass barrel
10 with a staked hypodermic needle at its distal end, a needle shield to shroud the needle, and a stopper slidably received in the barrel.

Pre-filled syringes of this type can be convenient and cost-effective and are available in standardised sizes. For these reasons, pre-filled syringes are increasingly used in medicament delivery devices, such as auto-injectors, from which the medicament can
15 be injected safely and easily, even in a non-clinical environment.

One characteristic of most known pre-filled syringes is that the needle is axially aligned with the barrel. However, for certain medical device applications, such as in patch pumps, it would be preferable if the needle could be disposed at an angle to the barrel in use. It would therefore be desirable to provide an apparatus for automatically
20 bending a hypodermic needle in a safe and straightforward manner.

From a first aspect of the present invention, there is provided a needle bending assembly for bending a hypodermic needle in a medical device, comprising a holder for holding the needle in position along a needle axis, and a bending member that is axially movable along a bending axis from an initial state in which the bending member
25 is spaced from the needle axis into a cooperating state in which the bending member is positioned for engagement with the needle. The bending axis is non-parallel to the needle axis. The bending member is turnable about the bending axis to apply a bending force to the needle when the bending member is in the cooperating state.

By providing a bending member that is first movable along a bending axis to cooperate
30 with the needle and then turnable about that axis to apply a bending force to the needle, the assembly of the invention is simple, reliable and has a low part count.

Accordingly, the assembly is suitable for use in non-clinical environments by untrained users. For ease of operation, the assembly may be arranged such that turning movement of the bending member occurs automatically when the bending member is in the cooperating state.

- 5 The bending member may comprise a needle engagement formation having a bending surface for applying the bending force to the needle upon turning movement of the bending member. The bending surface may be spaced from and parallel to the bending axis such that, when the bending member is in the cooperating state, the needle axis extends between the bending axis and the bending surface. In one
10 example, the needle engagement formation comprises a bending arm, and the bending surface is provided on the bending arm.

The assembly may also comprise a forming surface arranged such that the needle conforms to or bends around the forming surface when the bending force is applied. The forming surface may be positioned such that, when the bending member is in the
15 cooperating state, the needle axis extends between the forming surface and the bending surface. The forming surface may be cylindrical or part-cylindrical. By providing a forming surface, the shape of the resulting bend in the needle, characterised for example by the radius of curvature of the bend, can be controlled, thus ensuring that fluid flow through the needle is maintained.

- 20 Conveniently, the forming surface is disposed on the bending member. For example, the bending member may comprise a former arranged coaxially with the bending axis, and the forming surface may comprise a surface of the former.

The engagement formation may include a slot arranged to receive the needle when the bending member moves into the cooperating state. The slot may be defined
25 between the forming surface and the bending surface. Means for guiding the needle into the slot may be provided, to allow for variations in the needle position due to manufacturing tolerances and other factors. For example, an end portion of the bending surface and/or an end portion of the forming surface may be shaped to guide the needle into the slot as the bending member moves into the cooperating state. For
30 instance, the end portion of the bending surface and/or the end portion of the forming surface may be bevelled or ramped.

A needle shield for shielding the needle may be provided to shield the needle before use. Movement of the bending member from the initial state to the cooperating state may be triggered by removal of the needle shield. For example, the assembly may comprise a removable deshielder arranged to remove the needle shield from the
5 needle. In this case, movement of the bending member from the initial state to the cooperating state may be triggered by removal of the deshielder from the assembly. With these arrangements, only one user operation is required to remove the needle shield from the needle and to move the bending member into the cooperating state. If the assembly is also arranged such that turning movement of the bending member
10 occurs automatically once the bending member reaches the cooperating state, the needle can be deshielded and bent ready for use with a single user operation.

The bending member may be biased against the needle shield or the deshielder when the bending member is in its initial state. The bending member may then move into the cooperating state under the influence of the bias upon removal of the needle shield.
15 When present, the deshielder may be removable from the holder body by applying a force to the deshielder along the needle axis. The holder body may comprise a sleeve part for receiving the deshielder. The deshielder may include arms for gripping the needle shield.

The assembly may comprise drive means for driving axial movement of the bending
20 member from the initial state to the cooperating state and/or for driving turning movement of the bending member to apply the bending force to the needle. In this way, some or all of the movement of the bending member required to bend the needle can take place without user intervention.

The drive means may include one or more drive springs. For example, the drive
25 means may comprise a drive spring arranged to apply a torque to the bending member to drive the turning movement of the bending member. In this case, the assembly may comprise a retainer for retaining a first end of the drive spring in a fixed angular position with respect to the bending axis, and a second end of the drive spring may be coupled to the bending member.

30 In one embodiment, the drive spring also applies an axial force to the bending member to drive the axial movement of the bending member. Thus, in this embodiment, axial and turning movement of the bending member can be driven by a single drive spring.

In another embodiment, the drive means comprises a second drive spring arranged to apply an axial force to the bending member to drive the axial movement of the bending member. If present, the retainer may be arranged for joint axial movement with the bending member, and the second drive spring may act upon the retainer to apply the axial force to the bending member. A guide arrangement may be provided for guiding axial movement of the retainer along the bending axis and for preventing turning movement of the retainer about the bending axis.

In a further arrangement, the drive means may comprise a drive spring arranged to apply an axial force to the bending member to drive the axial movement of the bending member, and the assembly may further comprise cam means for turning the bending member under the influence of the axial force. In this case, movement of the bending member can be driven by a single compression spring.

The drive means may comprise one or more cam arrangements arranged to apply an axial force and/or a turning force to the bending member to drive the axial and/or turning movement of the bending member, respectively. For example, when the assembly includes a deshielder, the drive means may comprise a cam arrangement having a cam element associated with the deshielder and arranged to cooperate with the bending member to drive axial movement of the bending member upon removal of the deshielder. Alternatively, or in addition, the drive means may include a cam arrangement comprising a helical ramp member and a follower arranged to cooperate upon axial movement of the bending member to drive turning movement of the bending member.

The assembly may comprise guide means for preventing turning movement of the bending member about the bending axis until the bending member has reached the cooperating state and/or for guiding turning movement of the bending member once the bending member has reached the cooperating state. For example, the guide means may comprise a guide track and a guide element for cooperation with the guide track. The guide track may include a first portion that extends parallel to the bending axis for guiding axial movement of the bending member and a second portion that extends circumferentially with respect to the bending axis for guiding turning movement of the bending member.

The guide element may project radially from the bending member, and the guide track may be in a fixed position with respect to the bending axis. For example, the bending

member may be housed in a housing, and the guide track may be a slot, channel, groove or other suitable formation in or on the housing.

5 The guide means may comprise a cam surface arranged to apply a turning force to the bending member upon continued axial movement of the bending member when the bending member has reached the cooperating state. In this way, the turning movement of the bending member can be driven or assisted by cooperation between the cam surface and the bending member.

10 When an axially-movable retainer is provided, the guide means may also guide the axial movement of the retainer whilst preventing turning movement of the retainer about the bending axis. For example, when the guide means comprises a guide track, the retainer may be provided with radially-projecting guide elements for cooperation with the guide track.

15 The assembly may comprise a housing for retaining the bending member. The bending member may comprise a shaft, and the shaft may be supported by the housing to align the shaft with the bending axis. For example, the housing may be provided with an aperture for slidably receiving the shaft. Conveniently, when the assembly includes a retainer that is fixed in position with respect to the bending axis, the retainer may form part of the housing.

20 The needle may be attached or attachable to a medicament container, such as a syringe barrel or a cartridge, and the holder may comprise a carrier for receiving the container. For example, the needle and the medicament container may form part of a pre-filled syringe.

25 The holder may comprise an aperture through which the needle is extendable after application of the bending force. The bending member may be turnable about the bending axis through any desired angle, so that the needle is bent by an optimum amount for a particular application. For example, the bending member may be turnable through between approximately 45° and approximately 110°. Preferably, the bending member is turnable through an angle of at least 90°. In one example, the bending member is turnable about the bending axis through at least 95°.

In a second aspect, the present invention extends to a medical device comprising a needle bending assembly according to the first aspect of the invention. The medical device may for example comprise a patch pump.

5 Preferred and/or optional features of each aspect of the invention may be used, alone or in appropriate combination, in the other aspects of the invention also.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which like reference numerals are used for like features, and in which:

10 Figure 1 is a perspective view of a needle bending assembly according to the present invention;

Figure 2 is a perspective view showing part of the needle bending assembly of Figure 1 with some parts omitted for clarity;

Figure 3 is a top view of the needle bending assembly of Figure 1;

Figure 4 is a sectional plan view of the needle bending assembly of Figure 1;

15 Figure 5 shows perspective views of a needle bending member, spring retainer and drive spring components of the needle bending assembly of Figure 1;

Figure 6 is a side view of the needle bending member and spring retainer components of the needle bending assembly of Figure 1;

20 Figure 7 is a schematic illustration of part of the needle bending assembly of Figure 1 in a sequence of operational states, in which Figure 7(a) shows the assembly in a starting state, Figure 7(b) shows the assembly in an intermediate state and Figure 7(c) shows the assembly in a final state;

Figure 8 is a sectional plan view of the needle bending assembly of Figure 1 in the intermediate state;

25 Figure 9 is a sectional plan view of the needle bending assembly of Figure 1 in the final state;

Figure 10 is a perspective view of the needle bending assembly of Figure 1 in the final state; and

Figure 11 shows sectional plan views of another needle bending assembly according to the present invention, in which Figure 11(a) shows the assembly in a starting state, Figure 11(b) shows the assembly in an intermediate state and Figure 11(c) shows the assembly in a final state.

5 Figures 1 to 4 show a needle bending assembly 10 according to a first embodiment of the invention. The assembly 10 is suitable for use in and may form part of a medical device, such as a patch pump. The assembly 10 comprises an elongate, generally tubular holder body 12 for receiving a pre-filled syringe 14 (shown most clearly in Figure 4). The syringe 14 comprises a tubular barrel 16 for containing a liquid
10 medicament. At a first, distal end of the syringe 14, a hypodermic needle 18 is staked in a reduced-diameter neck 20 of the barrel 16. An opposite, proximal end of the barrel 16 is open to receive a plunger (not shown) of the device, and a stopper 22 is provided in the barrel 16 to contain the medicament. Initially, the needle 18 is shrouded and sealed by a needle cap or shield 24, shown most clearly in Figure 4, which is push-
15 fitted onto the neck 20 of the syringe barrel 16. The needle shield 24 may include an elastomeric inner part supported by a rigid outer part, as is known in the art as a rigid needle shield. The syringe 14 may be of a type generally known in the art.

The holder body 12 includes a tubular carrier part 26 that is sized to accommodate the barrel 16 of the syringe 14. A coaxial sleeve part 28 of the holder body 12 extends
20 distally from the carrier part 26. The sleeve part 28 is generally of a larger diameter than the carrier part 26, and is flattened on its upper and lower sides to form an upper side face 30 (shown in Figures 1 to 3) and a lower side face (not visible). An elongate aperture 32 is provided on the upper side face 30 of the sleeve part 28 to accommodate the needle 18 after the bending operation has been performed, as will
25 be described below.

The end of the syringe barrel 16 opposite the needle 18 is provided with a flange 34 that abuts the proximal end of the carrier part 16 to locate the syringe 14 in the holder body 12. When the syringe 14 is in position in the holder body 12, with the barrel 16 guided by the carrier part 26 and the flange 34 against the proximal end of the carrier
30 part 34, the needle 18 is aligned along a needle axis N. The barrel 16 extends into the sleeve part 28 of the holder body 12 so that the neck 20 of the syringe 14, the needle 18 and the needle shield 24 are accommodated in the sleeve part 28.

A needle removal component or deshielder 36 is received in the distal end of the sleeve part 28 of the holder body 12. The deshielder 36 comprises a disc-shaped base 38 and a pair of parallel arms 40 that extend proximally from the base 38 along opposite sides of the needle shield 24 to embrace the needle shield 24 therebetween.

- 5 As shown in Figure 4, the proximal ends of the arms 40 are provided with clips or barbs 42 that engage the proximal end of the needle shield 24. The distal end of the deshielder 36, including the base 38, protrudes from the open distal end of the sleeve part 28 of the holder body 12, so that the deshielder 36 can be gripped by a user and pulled distally to detach the needle shield 24 from the syringe 14 and to remove the
10 needle shield 24 from the holder body 12.

- A needle bending member 50 is mounted laterally with respect to the holder body 12. The bending member 50 is retained by a housing 52 and is guided for axial movement in the housing 52 along an axis B, referred to hereafter as the bending axis. Viewed from the top of the device, the bending axis B lies at right angles to the needle axis N,
15 although the bending axis B does not intersect the needle axis N.

- The housing 52 is formed in part by a generally tubular, laterally-extending boss 54 of the holder body 12, and in part by a cup-shaped cap 56 that mates with the boss 54. In the illustrated example, the cap 56 is secured to the boss 54 by way of a connecting piece 58 (not shown in Figures 2 to 4) having a pair of pins (not shown) that pass
20 through corresponding holes in a pair of outwardly-extending lugs 60 provided on the boss 54 and in a pair of forwardly-extending arms 62 provided on the cap 56, although it will be appreciated that the cap 56 could be attached to the boss 54 by any other suitable means. Figure 2 shows the assembly 10 with the cap 56 and the connecting piece 58 omitted for clarity.

- 25 Referring additionally to Figures 5 and 6, the bending member 50 is elongate and includes a generally cylindrical head part 64 at its forward end (closest to the needle axis A in the assembly). The forward end of the head part 64 is shaped to provide a needle engaging formation 66, and an opposite rear end of the head part 64 is attached to a shaft 68.

- 30 The needle engaging formation 66 includes a generally cylindrical, rod-like arbor or former 70 that extends from the forward end of the head part 64 along the bending axis B, and a bending arm 72 that extends from the forward end of the head part 64 parallel to the former 70 and offset from the bending axis B. The outer surface of the

bending arm 72 is part-cylindrical and continuous with the outer surface of the head part 64, whilst the inner surface 74 of the bending arm 72, closest to the former 70, comprises a flat surface, referred to hereafter as a bending surface.

As seen most clearly in Figure 6, the former 70 and the bending surface 74 of the bending arm 72 are spaced apart to define a slot 76 therebetween. The slot 76 has an open end at the forward end of the bending member 50. As will be explained in more detail below, in use of the assembly, the bending member 50 moves into a cooperating position with respect to the needle 18 in which the needle 18 is received in the slot 76. To guide the needle 18 into the slot 76, the bending surface 74 of the bending arm 72 is chamfered or bevelled to form an inclined ramp 78 adjacent to the open end of the slot 76. The side of the former 70 that faces the bending arm 72 is similarly chamfered or bevelled at its forward end to form a corresponding inclined ramp 80 adjacent to the open end of the slot 76.

Referring again to Figures 5 and 6, the head part 64 is provided with a pair of guide pins 82, 84. The guide pins 82, 84 project radially outwards from the cylindrical outside surface of the head part 64 and are disposed diametrically opposite one another. The head part 64 is also provided with four spring locating holes 86 (shown most clearly in Figure 5) that are angularly spaced from one another and extend through the head part 64 parallel to the bending axis B.

The shaft 68 of the bending member 50 comprises an elongate rod that extends along the bending axis B from the rear end of the head part 64. The shaft 68 has an enlarged diameter portion adjacent to the head part that forms a collar 88.

A disc-shaped spring retainer 90 is slidably mounted on the shaft 68 of the bending member 50. As shown most clearly in Figure 5, the spring retainer 90 has a central bore 92 for receiving the shaft 68, and two oppositely-facing, radially projecting guide pins 94, 96 that project from its outer rim. The spring retainer 90 is also provided with four angularly-spaced spring locating holes 98 that extend through the spring retainer 90, parallel to the bending axis B.

Referring again to Figure 4, the housing 52 provides a generally cylindrical chamber or bore 100 for receiving the bending member 50 and the spring retainer 90. The outer diameters of the head part 64 of the bending member 50 and the spring retainer 90 are sized to be a sliding fit within the bore 100. The bore 100 is closed by a rear end face

102 of the cap 56, which is provided with an aperture 104 to receive the shaft 68 of the bending member 50. The length of the shaft 68 is such that part of the shaft 68 extends out of the housing 52. In this way, the bending member 50 is supported and guided for axial movement by the housing 52.

- 5 Referring to Figures 2 and 3, the housing 52 includes a pair of guide tracks 110, in the form of slots that extend through the wall of the housing 52. Each guide track 110 is generally L-shaped and comprises a rear portion 112 that extends parallel to the bending axis B, and a forward portion 114 that extends part-way around the circumference of the housing 52. The rear and forward portions 112, 114 of each guide
- 10 track 110 are connected by a respective curved intermediate portion 116. Only one guide track 110 can be seen in Figures 2 and 3, while in Figure 1 parts of both guide tracks 110 are visible. The guide tracks 110 are arranged on opposite sides of the housing 52, on the upper side and the lower side of the assembly 10, and the forward portion 114 of each guide track 110 extends around the housing 52 in the same sense
- 15 (clockwise when viewed from the rear end of the housing 52, in this example).

As seen most clearly in Figures 2 and 3, the rear portion 112 of each guide track 110 extends part-way along the cap 56 of the housing 52, towards the rear end 102 of the cap 56. The remainder of the rear portion 112 of each guide track 110, together with the intermediate and forward portions 116, 114, are formed in the boss 54 of the

20 holder body 12, so that the forward portion 114 of each track 110 lies adjacent to the sleeve part 28 of the holder body 12.

When the bending member 50 and the spring retainer 90 are in position in the housing 52, the uppermost guide pin 82 of the head part 64 of the bending member 50 and the uppermost guide pin 94 of the spring retainer 90 are both engaged with the guide track

25 110 on the upper side of the assembly 10. Similarly, the lower guide pins 84, 96 of the head part 64 and the spring retainer 90 are both engaged with the guide track 110 on the lower side of the assembly (not visible in Figures 1 to 4). In this way, the guide tracks 110 serve to control turning movement of the bending member 50 and the spring retainer 90 about the bending axis B, as will be explained in more detail below.

30 In this embodiment, two drive springs are provided to drive movement of the bending member 50 in use of the assembly 10. A first drive spring 120, in the form of a compression spring, drives axial movement of the bending member 50 along the bending axis B, and a second drive spring 122, in the form of a torsion spring, drives

turning movement of the bending member 50 about the bending axis B. Both drive springs 120, 122 are housed in the bore 100 of the housing 52 and are disposed around the shaft 68 of the bending member 50. The compression spring 120 acts between the rear end 102 of the cap 56 and the rear face of the spring retainer 90, and therefore urges the spring retainer 90 against the collar 88 of the shaft 68.

The torsion spring 122 is terminated at each end with a leg 124 that extends parallel to the bending axis B. The leg 124 at the rear end of the torsion spring 122 extends through one of the locating holes 98 in the spring retainer 90. The leg 124 at the forward end of the torsion spring 122 extends through one of the locating holes 86 in the head part 64 of the bending member 50. The torsion spring 122 is under torsional load when the device is assembled, so that the torsion spring 122 applies a torque between the spring retainer 90 and the bending member 50. It will be appreciated that although only one of the four locating holes 86, 98 in both the head part 64 of the bending member 50 and in the spring retainer 90 are actually used to couple the torsion spring 122 to those components, the provision of the extra holes can reduce the number of alignment steps required during assembly of the device. In a variant (not shown), the locating holes are in the form of annular slots to aid alignment.

Figures 1 to 4 show the assembly 10 in a starting configuration, in which the syringe 14 is in place in the holder body 12 and the deshielder 36 is fitted over the needle shield 24. As shown most clearly in Figure 4, axial movement of the bending member 50 towards the needle axis N is blocked by one of the arms 40 of the deshielder 35. Thus, in the starting configuration, the bending member 50 is held in an initial state in which the bending member 50 is spaced away from the needle axis N so that the needle engaging formation 66 does not cooperate with the needle 18. Said another way, the needle engaging formation 66 does not overlap with the needle axis N in the initial state of the bending member 50.

Figure 7 is a schematic illustration showing the positions of the head part 64 of the bending member 50 and the spring retainer 90 with respect to the guide tracks 110 in the housing 52. When the bending member 50 is in the initial state, as shown in Figure 7(a), the uppermost guide pins 82, 94 of both the head part 64 of the bending member 50 and the spring retainer 90 are located in the axially-extending rear portion 112 of the guide track 110 in the upper side of the assembly 10. Although not visible in Figure 7(a), the lowermost guide pins 64, 96 are likewise located in the rear portion 112 of the

lower side guide track 110. Accordingly, in this initial state, neither the bending member 50 nor the spring retainer 90 can turn about the bending axis B.

To operate the needle bending assembly 10, the user pulls the deshielder 36 away from the holder body 12. Once the deshielder 36 and the needle shield 24 have been removed from the holder body 12, the bending member 50 is free to move into the sleeve part 28 of the holder body 12 under the influence of the compression spring 120. The compression spring 120 pushes the spring retainer 90 against the collar 88 of the bending member shaft 68, so that the spring retainer 90 and the bending member 50 move together towards the needle axis N to bring the needle engaging formation 66 into an overlapping position with respect to the needle axis N. Thus removal of the deshielder 36 causes the bending member 50 to move into a cooperating state in which the bending member 50 is positioned for engagement with the needle 18.

The bending member 50 is oriented such that, as the bending member 50 begins to overlap the needle axis N, the needle 18 is received in the slot 76 of the needle engaging formation 66. The inclined ramps 78, 80 on the bending arm 72 and the former 70 together serve to guide the needle 18 into the slot 76, to compensate for any misalignment between the needle 18 and the slot 76 for example due to manufacturing tolerances in the assembly or the syringe. During a first stage of axial movement of the bending member 50, turning movement of the bending member 50 is still not possible, because each guide peg 82, 84 on the head part 64 of the bending member 50 is still guided by the rear, linear portion 112 of the respective guide track 110.

Figures 7(b) and 8 show the assembly 10 in an intermediate position during the axial movement of the bending member 50, in which the guide pins 82, 84 on the head part 64 of the bending member 50 have reached the forward ends of the rear portion 112 of the respective guide tracks 110 (not shown in Figure 8).

Upon further axial movement of the bending member 50 from the intermediate position shown in Figures 7(b) and 8, the guide pins 82, 84 on the head part 64 of the bending member 50 move into the intermediate portions 116 of the respective guide tracks 110. Turning movement of the bending member 50 can now take place as the guide pins 82, 84 move through the intermediate portions 116 of the respective guide tracks 110 and into the circumferentially-extending forward portions 114.

The turning movement of the bending member 50 is driven by the action of the torsion spring 122. The guide pins 82, 84 on the spring retainer 90 remain in the rear, linear portions 112 of the guide tracks 110 over the whole range of movement of the bending member 50, so that the rear end of the torsion spring 122 cannot turn with respect to the housing 52. In addition, during the initial part of the turning movement, the curved intermediate portions 116 of the guide tracks 110 act as cams that apply an additional turning force to the bending member 50, by way of the guide pins 82, 84, as the compression spring 120 continues to drive axial movement of the bending member 50. During this initial part of the turning movement, the bending member 50 advances further into the sleeve part 28 of the holder body 12, so that the needle engaging formation 66 slides further over the needle 18 while the initial bending movement takes place.

Once the guide pins 82, 84 of the head part 64 of the bending member 50 reach the forward portions 114 of the guide tracks 110, no further axial movement of the bending member 50 can take place. The torsion spring 122 alone drives further turning movement of the bending member 50 until the guide pins 82, 84 reach the forward ends of the respective guide tracks 110.

The turning movement of the bending member 50 causes the bending arm 72 to apply a bending force to the needle 18. The bending force causes the needle 18 to bend against the cylindrical former 70. In this way, the needle 18 conforms to the shape of a part-cylindrical section of the surface of the former 70, creating a smooth bend in the needle 18 that does not substantially restrict fluid flow through the needle. As the needle 18 bends, it emerges from the upper side face 30 of the holder body 12 through the aperture 32. Figures 7(c), 9 and 10 show the assembly 10 in its final position, with the guide pins 82, 84 on the head part 64 of the bending member 50 at the ends of the forward portions 114 of the respective guide tracks 110 (as can be seen most clearly in Figure 7(c), and with the bent needle 18 projecting through the aperture 32 (see Figure 10).

The radius of curvature of the needle 18 is determined by the radius of the former 70, and the angle through which the needle 18 is bent is determined by the angle through which the bending member 50 turns. It will be appreciated that the needle 18 will tend to bend through a slightly smaller angle than the turning angle of the bending member 50 as a result of component clearances, manufacturing tolerances and elastic

deformation of the components. In the illustrated example, the forward portions 114 of the guide tracks 110 are dimensioned so that the bending member 50 turns through an angle of approximately 95 degrees in total, which results in the needle 18 bending through an angle of approximately 90 degrees. For some applications, a bending angle of less than or more than 90 degrees may be appropriate.

The above-described assembly therefore allows the needle 18 to be bent automatically upon removal of the needle shield 24 from the syringe 14, with no further user interaction necessary. With the assembly 10 in its final position as shown in Figure 10, the needle 18 can be inserted into a patient's skin, with the upper side face 30 of the holder body 12 being parallel to the skin. The bending member 50 remains in engagement with the needle 18 during insertion of the needle 18 and subsequent delivery of medicament from the syringe 14, thereby supporting the needle 18.

Figure 11 illustrates a needle bending assembly 210 according to another embodiment of the invention. The assembly 210 of Figure 11 is identical to the assembly 10 of Figures 1 to 10 in most respects, and only the differences will be described.

In the Figure 11 assembly 210, a single drive spring 320 is provided to drive movement of the bending member 50 instead of separate compression and torsion springs. The single drive spring 320 acts both in compression and torsion, and in this example comprises an open-coil helical spring terminating at each end with a leg 324 that extends parallel to the bending axis, in the same way as the legs 124 of the torsion spring 122 of the assembly 10 of Figures 1 to 10. In the Figure 11 assembly 210, however, a moveable spring retainer is not present, and instead the rear end 302 of the housing 52 of the bending member acts as the spring retainer, with four locating holes 298 arranged around the central aperture 104. The leg 324 at the rear end of the drive spring 320 extends through one of these locating holes 298, and the leg 324 at the forward end of the drive spring 320 extends through one of the locating holes 86 in the head part 64 of the bending member 50. During installation in the housing 52, the drive spring 320 is compressed and twisted so that the drive spring 320 applies both an axial force and a torque to the bending member 50.

Figure 11(a) shows the assembly 210 with the bending member 50 in its initial state, in which the deshielder 36 blocks axial movement of the bending member 50. Upon removal of the deshielder 36 and the needle shield 24, the bending member 50 can move axially into its cooperating state, with the needle 18 received in the slot 76 in the

needle engaging formation 66. Axial movement of the bending member 50 is driven by relaxation of the compression in the drive spring 320, but turning movement of the bending member 50 is prevented by engagement of the guide pins 82, 84 on the head part 64 of the bending member 50 with the axially-extending rear portions 112 of the guide tracks 110 (not visible in Figure 11, but as described above with reference to Figure 7(a)).

Figure 11(b) shows the assembly 210 when the guide pins 82, 84 have reached the forward ends of the rear portions 112 of the guide tracks 110. Upon further axial movement of the bending member 50, the guide pins 82, 84 move into the intermediate portions 116 of the guide tracks 110 (as described above with reference to Figure 7(b)) and turning movement of the bending member 50 begins, so as to apply a bending force to the needle 18. The initial turning movement is driven by the torsional and axial forces applied by the drive spring 320, with the intermediate portions 116 of the guide tracks 110 acting as cams as described above with reference to the first embodiment.

Once the guide pins 82, 84 reach the forward portions 114 of the guide tracks 110, axial movement of the bending member 50 stops and the remaining turning movement is driven by the torque applied by the drive spring 320 alone. Figure 11(c) shows the final configuration of the assembly 210, with the needle 18 bent through the desired angle.

The use of separate compression and torsion springs in accordance with the assembly of Figures 1 to 10 may be preferred when a high needle bending force is required. However, when a lower needle bending force is sufficient, the use of an assembly with a single drive spring (and therefore fewer components), as shown in Figure 11, may be preferred.

It will be appreciated that other arrangements for driving the axial and turning movement of the bending member are possible. For example, in a variant (not illustrated) of the Figure 11 assembly, the single drive spring is a simple compression spring, and the guide tracks are modified so that axial movement of the bending member continues throughout the turning movement of the bending member. In this way, turning movement of the bending member is driven solely by the cam action between the guide tracks and the guide pins of the head part of the bending member,

and no torsional force is provided by the drive spring. In this variant, it is not necessary to provide spring locating holes in the spring retainer or in the bending element.

In another unillustrated example, which is a variant of the assembly shown in Figures 1 to 10, the guide tracks in the housing have no intermediate portion, and instead the axially-extending rear portion of each guide track directly meets the circumferentially-extending forward portion. In this case, the compression spring drives only the axial movement of the bending member, and the turning movement of the bending member is driven only by the torsion spring. With such an arrangement, the bending member does not move axially during bending of the needle, thus avoiding lateral loads on the needle during bending.

Instead of a compression spring, a tension spring may be used to drive the axial movement of the bending member. For example, a first end of the tension spring may be attached to the holder body or to the housing adjacent to the holder body, and a second end of the tension spring may be attached to a suitable spring retaining formation associated with the bending member and remote from the needle engagement formation to bias the bending member in the forward direction. A single drive spring that acts in both tension and torsion could also be used to drive both the axial and turning movement of the bending member by appropriate modification of the assembly shown in Figure 11.

Many alternative mechanisms for driving and guiding movement of the bending member are possible. For example, instead of one or more helical drive springs, other spring types or alternative energy storage means could be used. Part or all of the movement of the bending member could be manually driven, for example by direct manipulation of the shaft of the bending member, or indirectly through a suitable mechanism.

Instead of or in addition to drive springs, movement of the bending member could be driven by one or more cam-type arrangements that operate upon relative displacement of the components of the assembly.

For example, the deshielder may be associated with a cam element that is arranged to cooperate with the bending member, such that movement of the deshielder along the needle axis during removal drives axial movement of the bending member along the bending axis. For instance, in a variant of the assembly shown in Figures 1 to 10, the

compression spring is omitted and a cam element attached to the deshielder extends adjacent to or into the housing to cooperate with the guide pins of the spring retainer to drive the axial movement of the bending member. When the guide pins of the head portion of the bending member reach the circumferentially-extending portions of the guide track, turning movement of the bending member is driven by the torsion spring.

In another variant, the torsion spring of the assembly of Figures 1 to 10 is omitted, and the turning movement of the bending member is driven by a cam arrangement. For example, a cam element comprising one or more helical ramp formations may be provided on the forward side of the spring retainer to cooperate with respective followers that extend rearwardly from the rear side of the head portion of the bending member. In this case, axial movement of the bending member presses the spring retainer towards the head portion of the bending member and cooperation of the cam element and the follower causes a torque to act between the spring retainer and the bending member. When the guide pins of the bending member reach the circumferentially-extending portions of the guide tracks, the torque drives the turning movement of the bending member. In one convenient arrangement, the helical ramp formations and the followers each take the form of helical teeth that project towards one another from the spring retainer and the bending member respectively, such that the teeth inter-engage when the spring retainer moves in the forward direction.

In a further variant, both the axial movement and the turning movement of the bending member are driven by respective cam arrangements. In this case, no drive springs are necessary, although it will be appreciated that the annular retainer component, described above as a spring retainer, may still be provided to form part of one or more cam arrangements. It is also conceivable that a combination of one or more drive springs and one or more cam arrangements could be used in combination to drive the axial and/or turning movements of the bending member. In such cases, the forces provided by a drive spring and a cam arrangement may act simultaneously or sequentially (in any order) to cause the desired movement of the bending member.

In the illustrated examples, the bending member is held in its initial state by the deshielder. In other examples, a retaining means such as a clip may be provided to hold the bending member in the initial state. The retaining means may be releasable to allow the bending member to move from its initial state into its cooperating state. Release of the retaining means could be automatic upon removal of the needle shield,

or could require an extra action on the part of the user. It is also conceivable that axial movement of the bending member could be triggered automatically upon removal of the needle shield to engage the bending member with the needle, whilst the turning movement to bend the needle could be triggered separately. In another arrangement, the bending member could be held in its initial state by the needle shield, in which case the desheilder could be omitted and the needle shield could be directly accessible by the user for removal.

The holder body and the housing may be formed in a different way to the illustrated examples. For instance, the holder body and the housing may form part of a clam-shell or other arrangement. The assembly may include a casing, and the holder body and/or the housing may be integrally formed with the casing or supported by the casing. It will be appreciated that the guide tracks or other guide means can be provided in or disposed on any convenient part or parts of the holder body, the housing, and/or other components of the assembly.

The assembly can be arranged to produce substantially any desired needle shape and angle through appropriate design of the needle engagement formation of the bending member and the guide tracks and other parameters, such as the orientation of the bending axis with respect to the needle axis. It is also conceivable that the needle bending angle could be adjustable. For example, the amount of turning movement could be selectable during manufacture of the assembly or adjustable prior to use of the assembly.

The needle bending assembly of the present invention is particularly suitable for use in a patch pump or other medical device, although other applications are also possible. The above-described examples show the assembly in use with a pre-filled syringe having a permanently attached needle, but the assembly could equally be used with other arrangements, such as a medicament container with a separate, attachable needle. The assembly can also be used to bend a needle that is not attached to a medicament container or syringe.

The above-described arrangements are examples only and many further variants and modifications are possible without departing from the scope of the invention as defined in the appended claims.

CLAIMS

1. A needle bending assembly (10; 210) for bending a hypodermic needle (18) in a medical device, comprising:

5 a holder (12) for holding the needle (18) in position along a needle axis (N);
and

a bending member (50) that is axially movable along a bending axis (B) from an initial state in which the bending member (50) is spaced from the needle axis (N) into a cooperating state in which the bending member (50) is positioned for engagement with the needle (18), the bending axis (B) being
10 non-parallel to the needle axis (N);

wherein the bending member (50) is turnable about the bending axis (B) to apply a bending force to the needle (18) when the bending member (50) is in the cooperating state.
- 15 2. A needle bending assembly according to Claim 1, arranged such that turning movement of the bending member (50) occurs automatically when the bending member (50) is in the cooperating state.
3. A needle bending assembly according to Claim 1 or Claim 2, wherein the bending member (50) comprises a needle engaging formation (66) having a bending surface (74) for applying the bending force to the needle (18) upon
20 turning movement of the bending member (50).
4. A needle bending assembly according to Claim 3, wherein the bending surface (74) is spaced from and parallel to the bending axis (B) such that, when the bending member (50) is in the cooperating state, the needle axis (N) extends between the bending axis (B) and the bending surface (74).
- 25 5. A needle bending assembly according to Claim 3 or Claim 4, wherein the needle engaging formation (66) comprises a bending arm (72), and wherein the bending surface (74) is provided on the bending arm (72).
6. A needle bending assembly according to any of Claims 3 to 5, further comprising a forming surface (70) arranged such that the needle (18) conforms
30 to the forming surface (70) when the bending force is applied.

7. A needle bending assembly according to Claim 6, wherein the forming surface (70) is positioned such that, when the bending member (50) is in the cooperating state, the needle axis (N) extends between the forming surface (70) and the bending surface (74).
- 5 8. A needle bending assembly according to Claim 6 or Claim 7, wherein the forming surface (70) is cylindrical or part-cylindrical.
9. A needle bending assembly according to any of Claims 6 to 8, wherein the forming surface (70) is disposed on the bending member (50).
- 10 10. A needle bending assembly according to Claim 9, wherein the bending member (50) comprises a former (70) arranged coaxially with the bending axis (B), and wherein the forming surface comprises a surface of the former (70).
11. A needle bending assembly according to Claim 9 or Claim 10, comprising a slot (76) arranged to receive the needle (18) when the bending member (50) moves into the cooperating state, the slot (76) being defined between the forming surface (70) and the bending surface (74).
- 15 12. A needle bending assembly according to Claim 11, wherein an end portion (78) of the bending surface (74) and/or an end portion (80) of the forming surface (70) are shaped to guide the needle (18) into the slot (76) as the bending member (50) moves into the cooperating state.
- 20 13. A needle bending assembly according to any preceding claim, further comprising a needle shield (24), and wherein movement of the bending member (50) from the initial state to the cooperating state is triggered by removal of the needle shield (24) from the assembly (10).
- 25 14. A needle bending assembly according to Claim 13, further comprising a removable deshielder (36) arranged to remove the needle shield (24) from the needle (18), wherein movement of the bending member (50) from the initial state to the cooperating state is triggered by removal of the deshielder (36) from the assembly (10).
- 30 15. A needle bending assembly according to Claim 14, wherein the bending member (50) is biased against the deshielder (36) when the bending member

(50) is in its initial state, and wherein the bending member (50) moves into the cooperating state under the influence of the bias upon removal of the deshielder (36).

- 5 16. A needle bending assembly according to Claim 14 or Claim 15, wherein the holder (12) comprises a sleeve part (28) for receiving the deshielder (36).
- 10 17. A needle bending assembly according to any preceding claim, comprising drive means (120, 122; 320) for driving axial movement of the bending member (50) from the initial state to the cooperating state and/or for driving turning movement of the bending member (50) to apply the bending force to the needle (18).
- 15 18. A needle bending assembly according to Claim 17, wherein the drive means comprises a drive spring (122; 320) arranged to apply a torque to the bending member (50) to drive the turning movement of the bending member (50).
19. A needle bending assembly according to Claim 18, comprising a retainer (90; 302) for retaining a first end of the drive spring (122; 320) in a fixed angular position with respect to the bending axis (B), wherein a second end of the drive spring (122; 320) is coupled to the bending member (50).
- 20 20. A needle bending assembly according to any of Claims 17 to 19, wherein the drive means comprises a second drive spring (120) arranged to apply an axial force to the bending member (50) to drive the axial movement of the bending member (50).
- 25 21. A needle bending assembly according to Claim 20 when dependent on Claim 19, wherein the retainer (90) is arranged for joint axial movement with the bending member (50), and wherein the second drive spring (120) acts upon the retainer (90) to apply the axial force to the bending member (50).
22. A needle bending assembly according to Claim 21, comprising a guide arrangement (94, 96, 110) for guiding axial movement of the spring retainer (90) along the bending axis (B) and for preventing turning movement of the retainer (90) about the bending axis (B).

23. A needle bending assembly according to Claim 18 or Claim 19, wherein the drive spring (320) is further arranged to apply an axial force to the bending member (50) to drive the axial movement of the bending member (50).
- 5 24. A needle bending assembly according to Claim 17, wherein the drive means comprises a drive spring arranged apply an axial force to the bending member (50) to drive the axial movement of the bending member (50), and wherein the assembly further comprises cam means for turning the bending member (50) under the influence of the axial force.
- 10 25. A needle bending assembly according to any preceding claim, comprising guide means (84, 86, 110) for preventing tuning movement of the bending member (50) about the bending axis (B) until the bending member (50) has reached the cooperating state and for guiding turning movement of the bending member (50) once the bending member (50) has reached the cooperating state.
- 15 26. A needle bending assembly according to Claim 25, wherein the guide means comprises a guide track (110) and a guide element (84, 86) for cooperation with the guide track (110).
- 20 27. A needle bending assembly according to Claim 26, wherein the guide track (110) comprises a first portion (112) that extends parallel to the bending axis (B) for guiding axial movement of the bending member (50) and a second portion (114) that extends circumferentially with respect to the bending axis (B) for guiding turning movement of the bending member (50).
- 25 28. A needle bending assembly according to Claim 26 or Claim 27, wherein the guide element (84, 86) projects radially from the bending member (50), and wherein the guide track (110) is in a fixed position with respect to the bending axis (B).
- 30 29. A needle bending assembly according to any of Claims 25 to 28, wherein the guide means comprises a cam surface (116) arranged to apply a turning force to the bending member (50) upon continued axial movement of the bending member (50) when the bending member (50) has reached the cooperating state.

30. A needle bending assembly according to any preceding claim, comprising a housing (52) for retaining the bending member (50).
31. A needle bending assembly according to Claim 30, wherein the bending member (50) comprises a shaft (68), and wherein the shaft (68) is supported by the housing (52) to align the shaft (68) with the bending axis (B).
32. A needle bending assembly according to any preceding claim, wherein the needle (18) is attached or attachable to a medicament container (16), and wherein the holder (12) comprises a carrier (26) for receiving the container (16).
33. A needle bending assembly according to Claim 32, wherein the needle (18) and the medicament container (16) are part of a pre-filled syringe (14).
34. A needle bending assembly according to any preceding claim, wherein the holder (12) comprises an aperture (32) through which the needle (18) is extendable after application of the bending force.
35. A needle bending assembly according to any preceding claim, wherein the bending member (50) is turnable about the bending axis (B) through at least 90°.
36. A medical device comprising a needle bending assembly (10; 210) according to any preceding claim.
37. A medical device according to Claim 36, comprising a patch pump.

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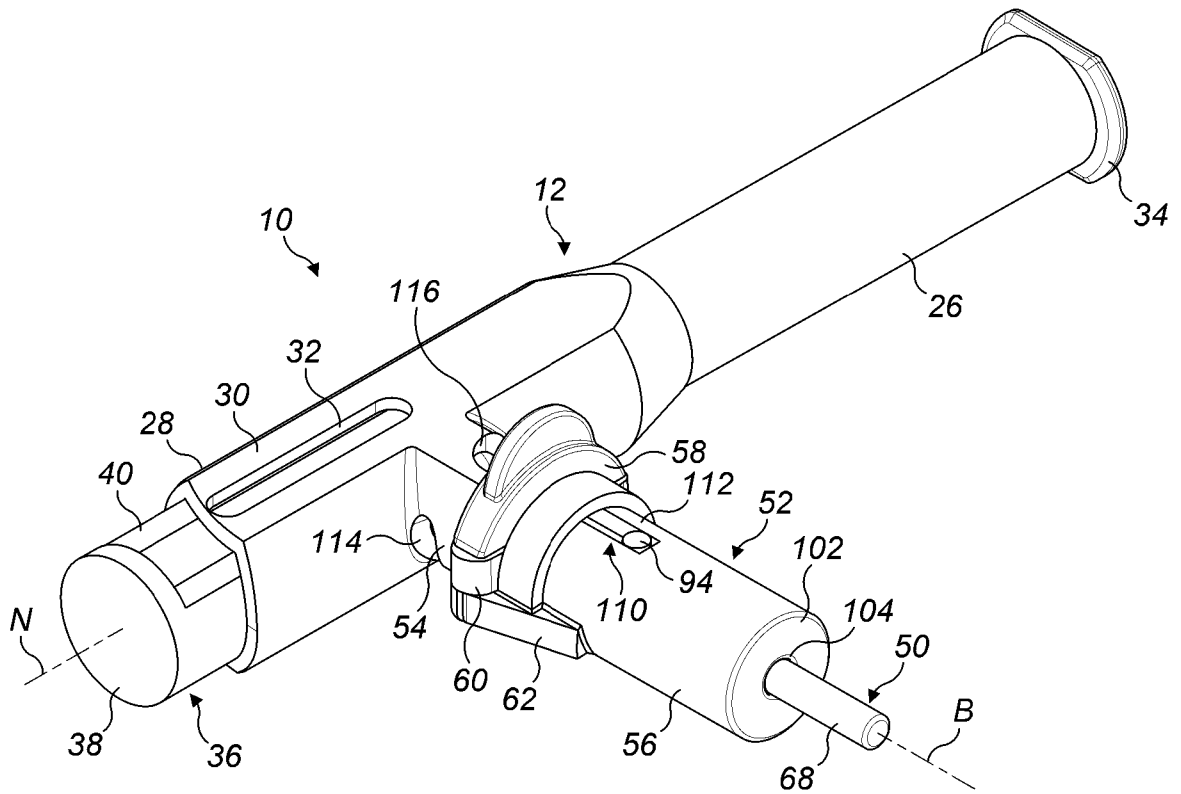


FIG. 1

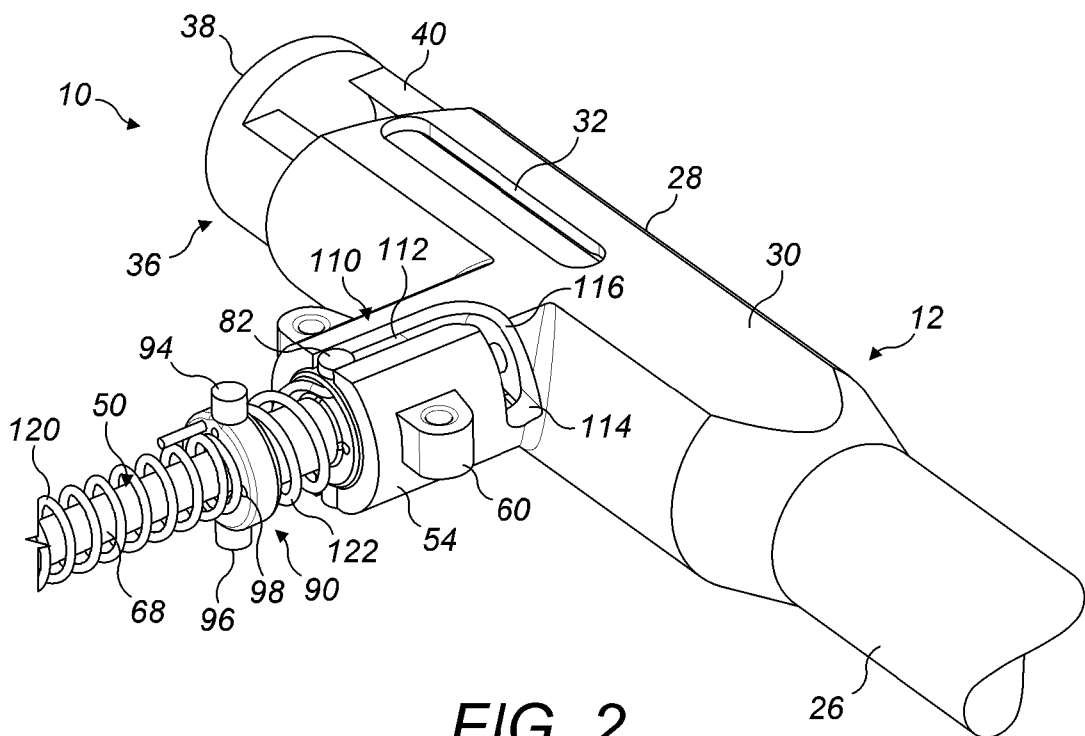
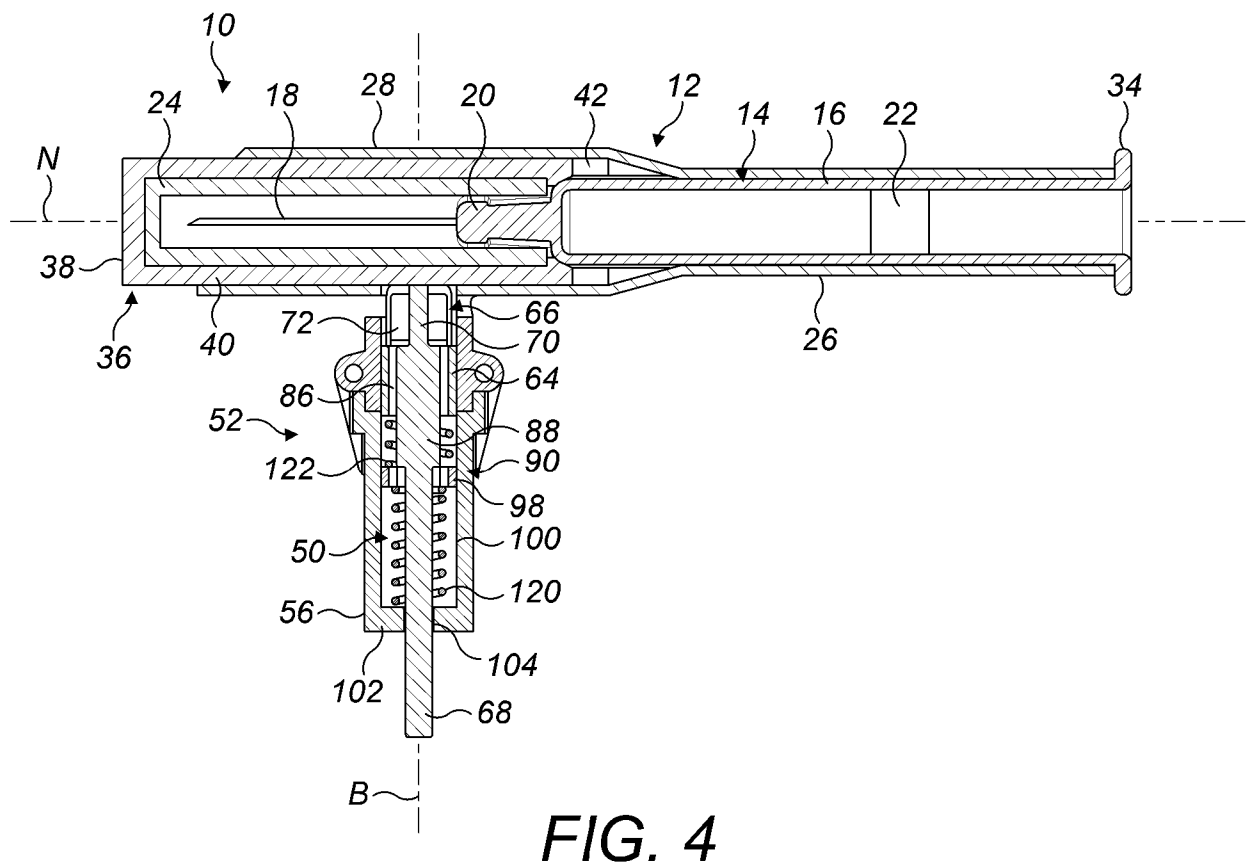
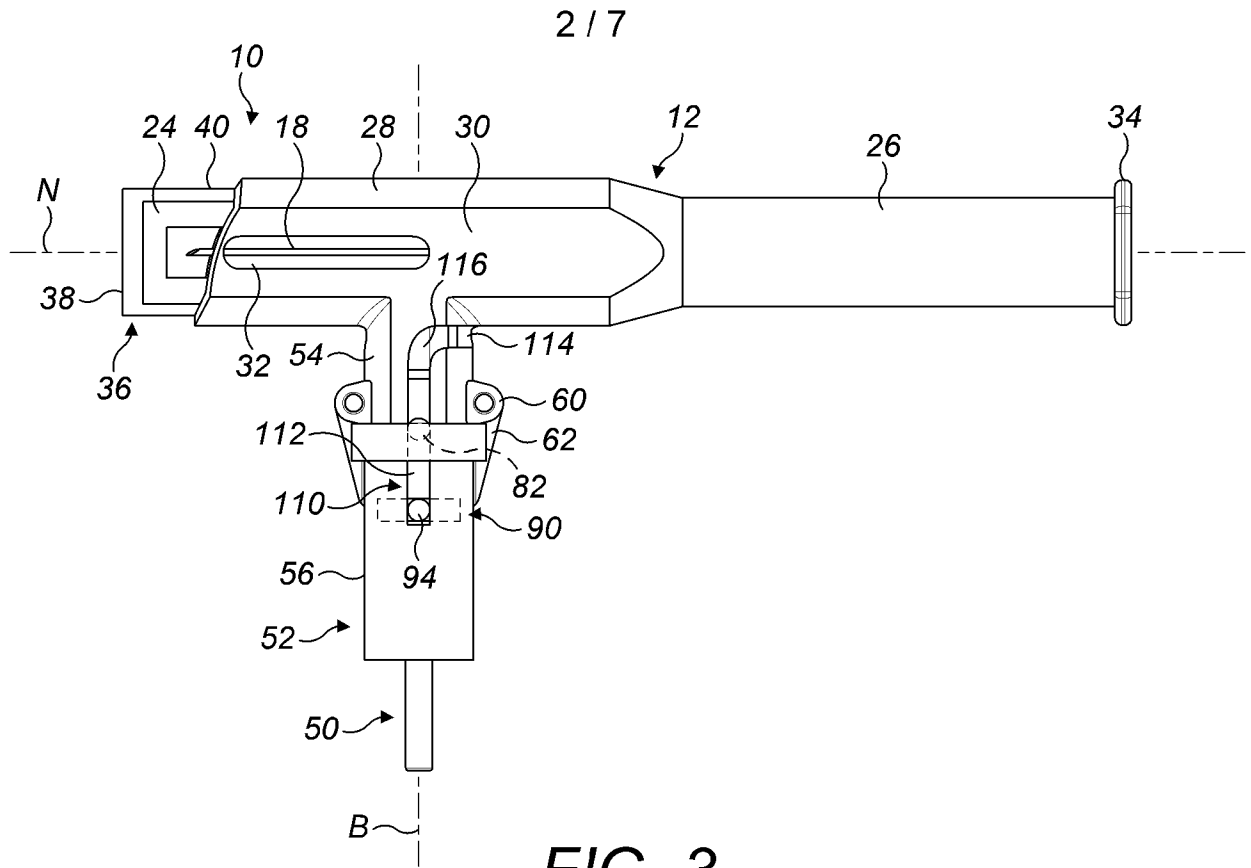


FIG. 2



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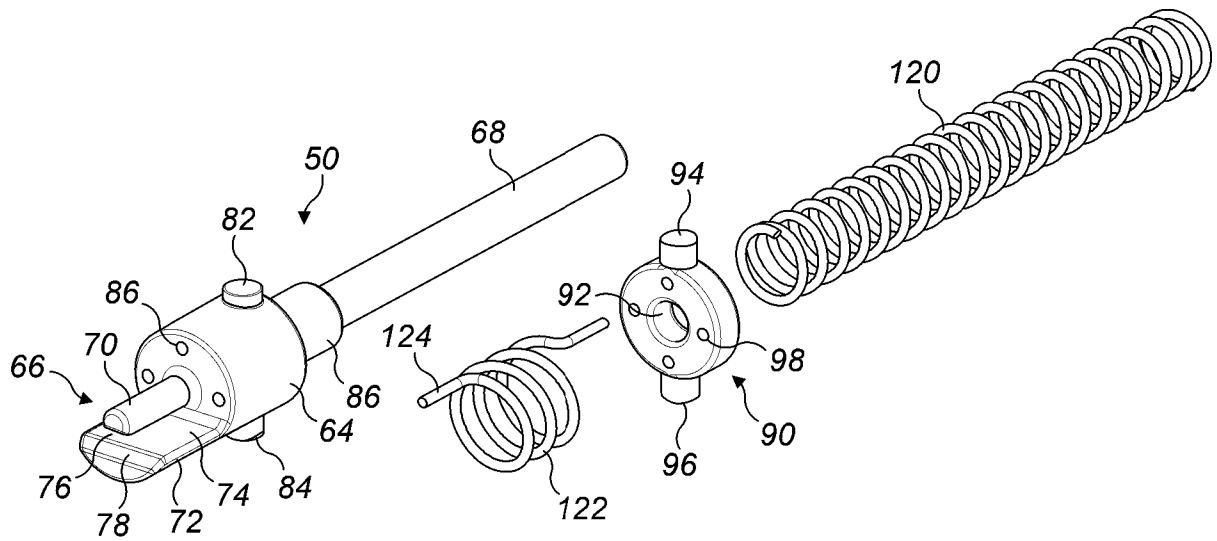


FIG. 5

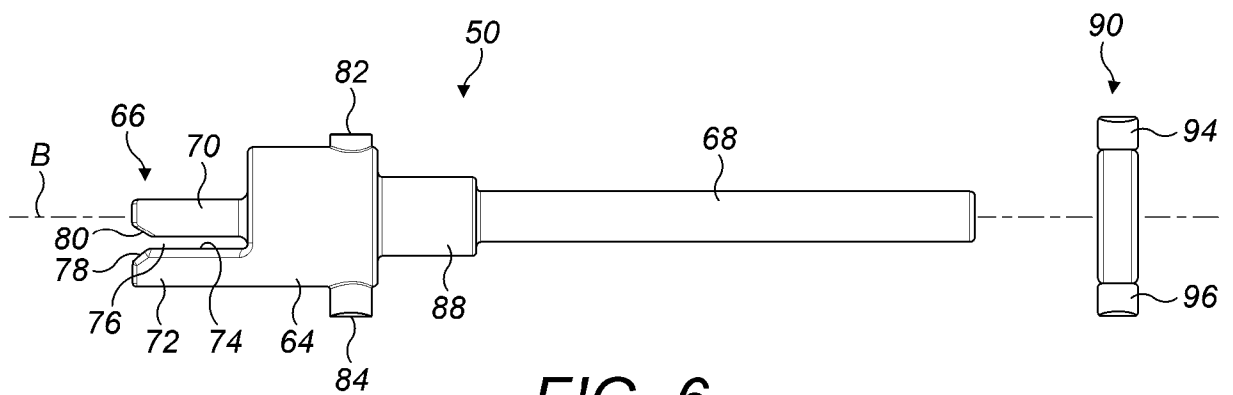


FIG. 6

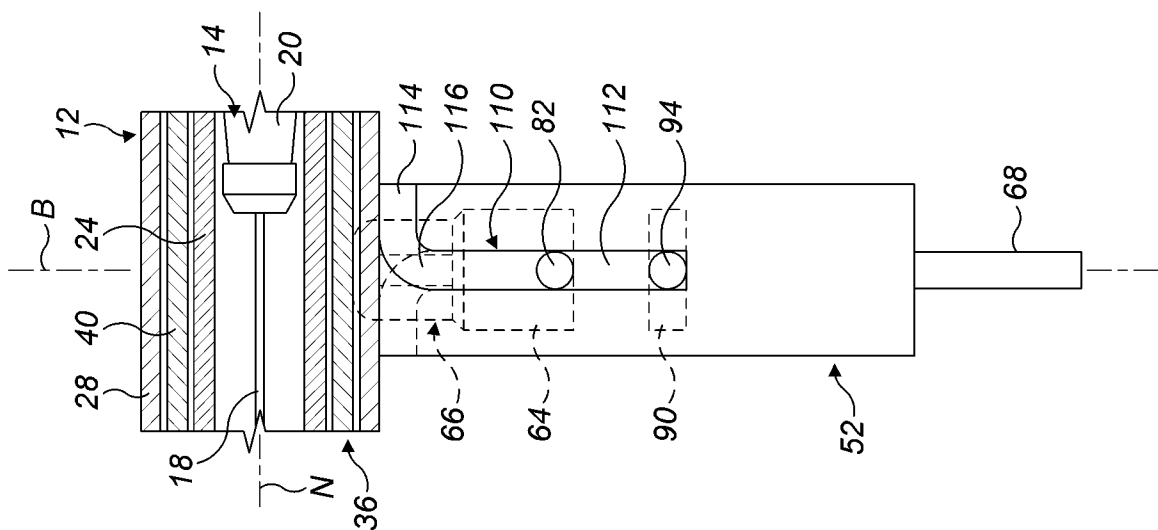


FIG. 7(a)

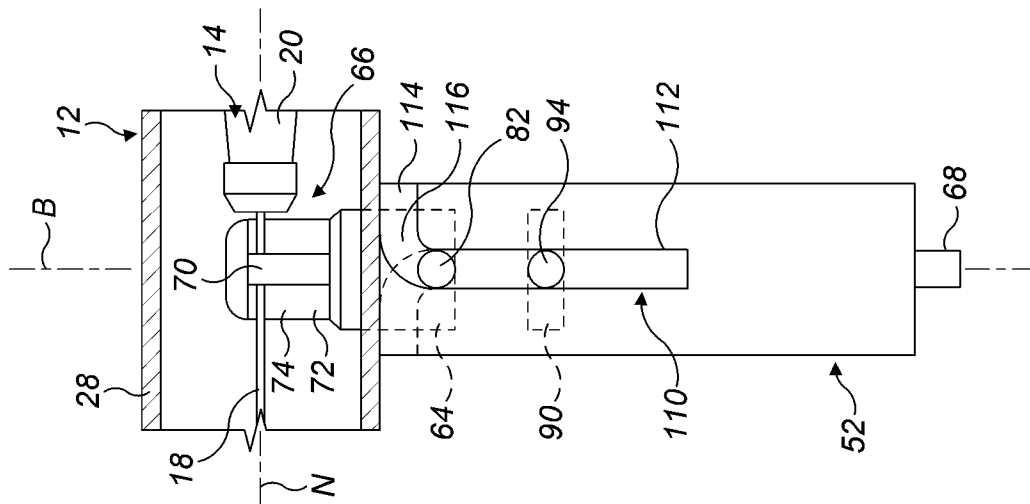


FIG. 7(b)

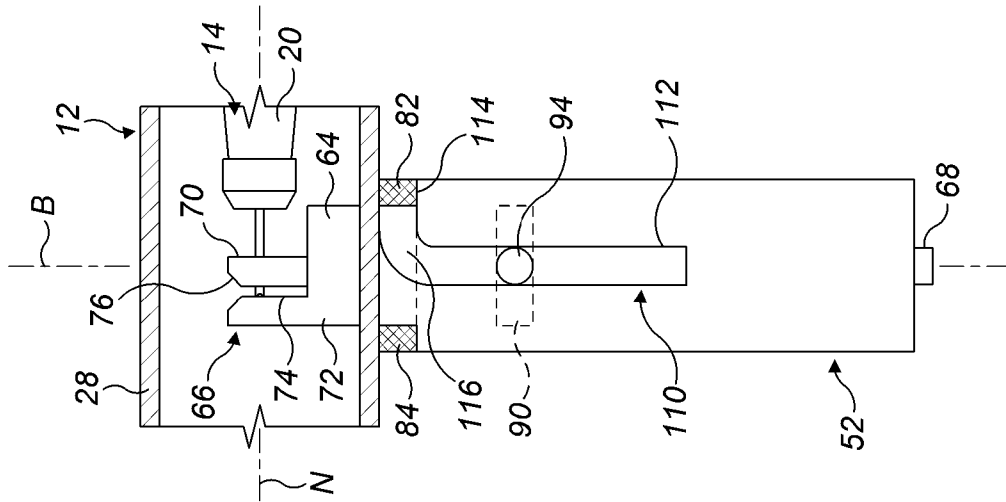
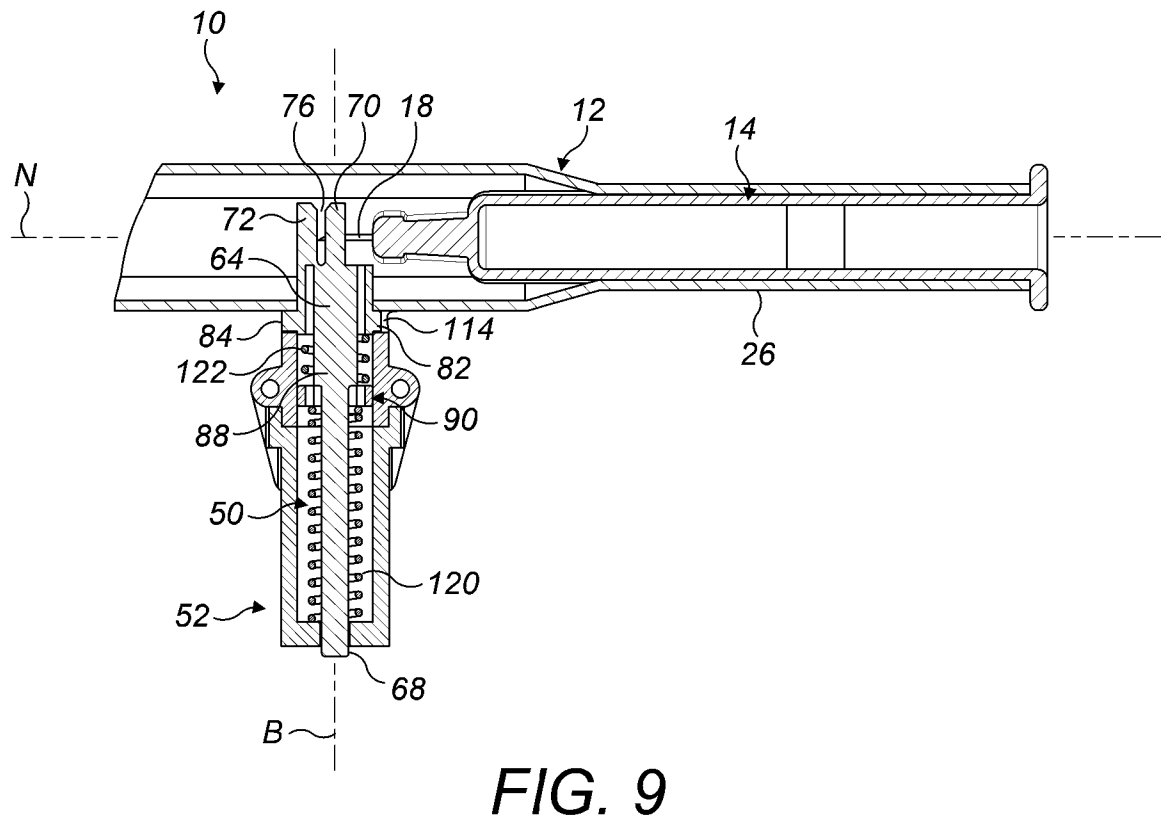
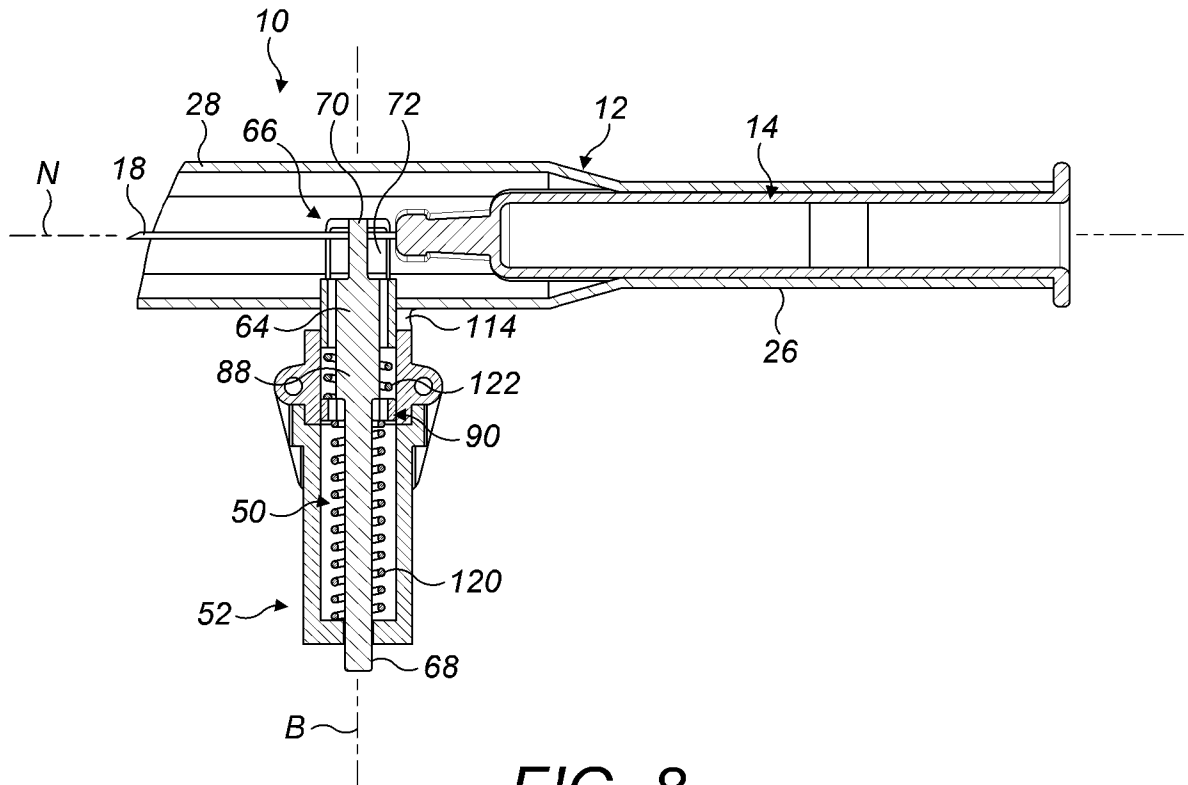


FIG. 7(c)

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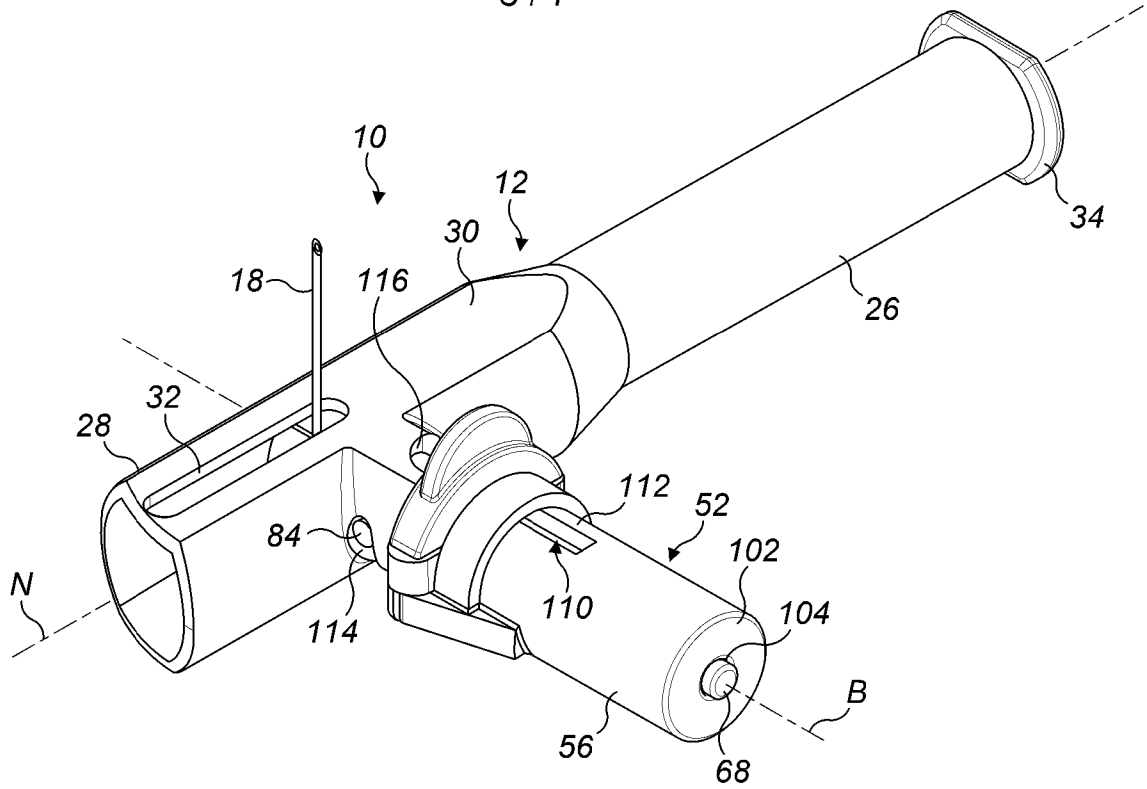


FIG. 10

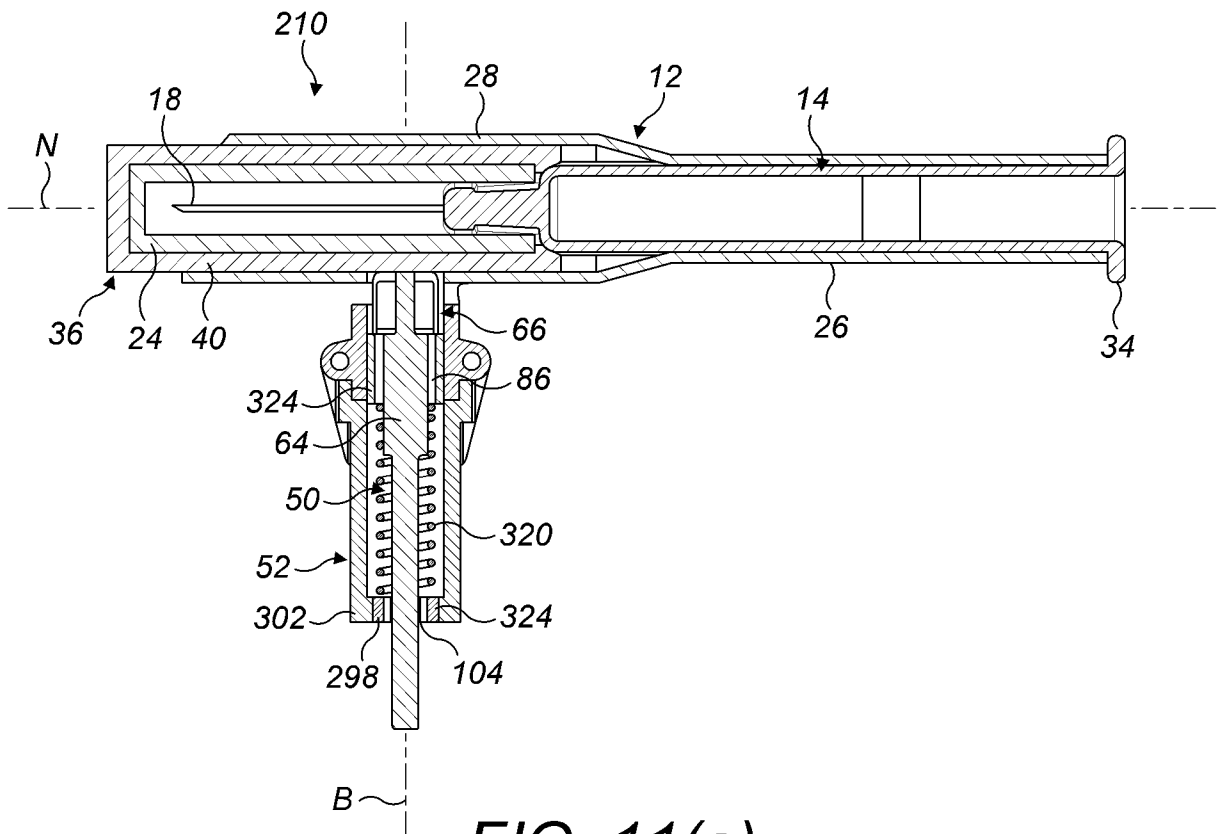


FIG. 11(a)

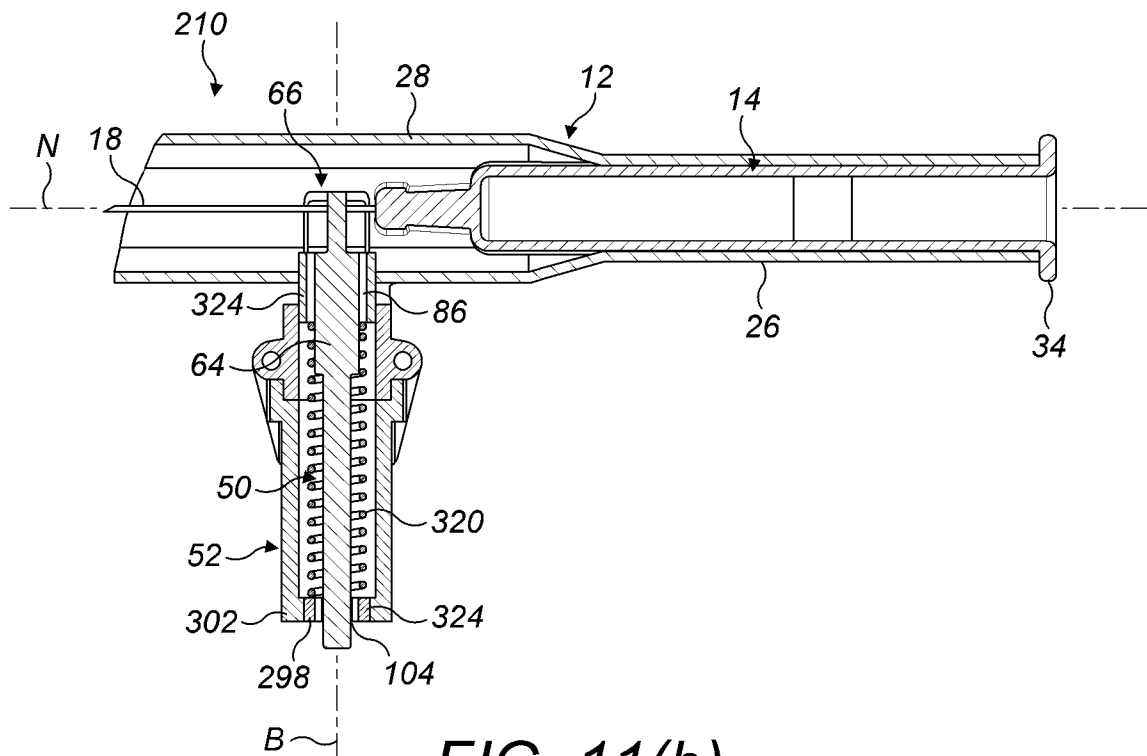


FIG. 11(b)

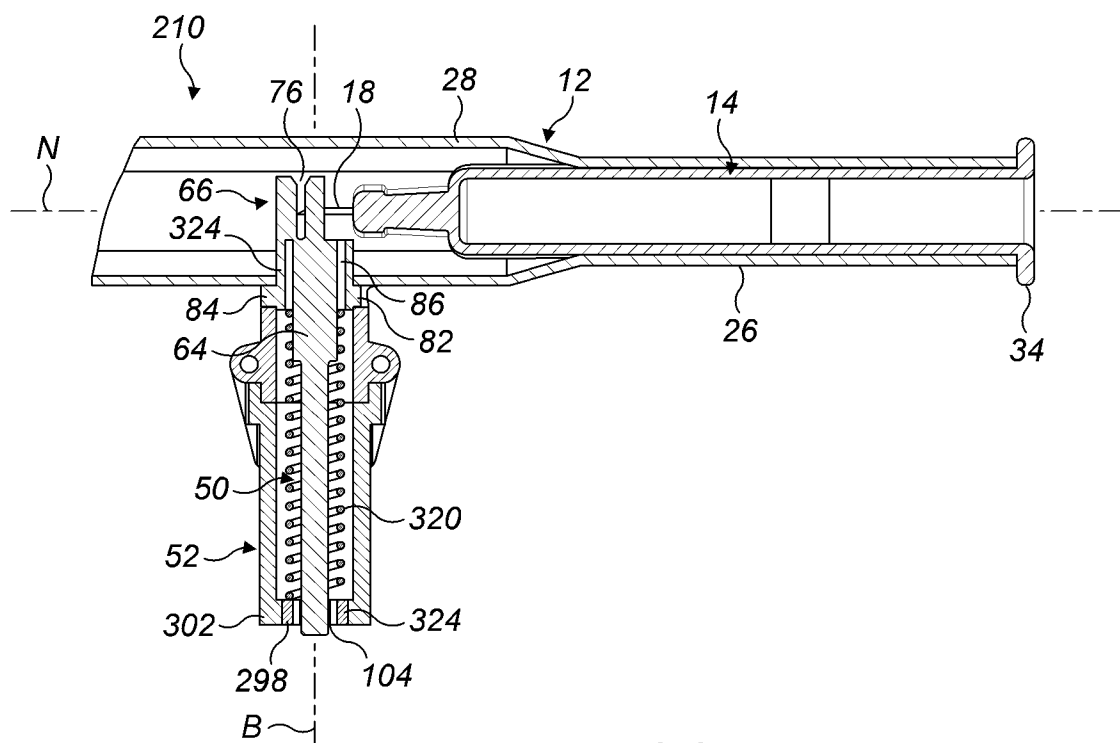


FIG. 11(c)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2017/050417

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/158 A61M5/32 B21F1/00 B21G1/08
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 B21F B21G

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.
A	US 5 201 210 A (STEIN III WILLIAM [US]) 13 April 1993 (1993-04-13) the whole document -----	1-37
A	CN 202 960 707 U (LIU JIEFENG) 5 June 2013 (2013-06-05) the whole document -----	1-37
A	US 5 816 095 A (NORDELL II BENJAMIN T [US] ET AL) 6 October 1998 (1998-10-06) the whole document -----	1-37
A	US 2014/196517 A1 (PETERSON ERIC [US]) 17 July 2014 (2014-07-17) the whole document -----	1-37
	----- -/-	



Further documents are listed in the continuation of Box C.



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Date of the actual completion of the international search

8 May 2017

Date of mailing of the international search report

15/05/2017

Name and mailing address of the ISA/

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Neiller, Frédéric

INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2017/050417

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

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