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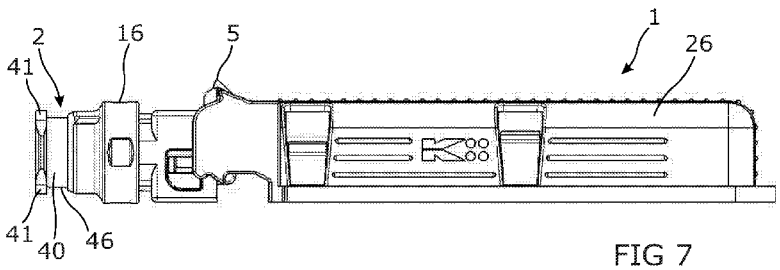

FIG 7

(57) Abstract: A needlestick prevention device (1, 100) for an injection needle carried by a needle- bearing member (2, 102) of a syringe (102) is formed as a one-piece moulding and comprises a first part (3, 103) adapted to be attached to the needle-bearing member (2, 1) and a second part (4,104) providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use. The device is adapted to adopt a first position in which the needle is protected for transport of the device prior to use, a second position in which the needle is exposed for filling of the syringe and injection, a third position in which the needle is protected after filling of the syringe but before injection and a fourth position in which the needle is locked in the device following injection.In one embodiment the shield (104) has a transport recess(124) and a locking recess (125) connected by a gate device (126) at least at the base of the needle(130), the arrangement being such that in the third position the needle (130) is in the transport recess (124) and is able to move into the second position, and in the fourth position the needle moves through the gate device (126) into the locking recess (125), with the gate device (126) preventing movement out of the fourth position.

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NEEDLESTICK PREVENTION DEVICE

This invention relates to a needlestick prevention device for use with injection devices such as syringes.

A needlestick injury generally occurs in a medical environment, and particularly during use of a syringe or other injection device, when the user accidentally sticks the needle into himself or herself, or indeed another person. Such needlestick injuries are a major cause of spreading infections and disease, and are painful and possibly incapacitating, so it is important to prevent them.

There are various known ways of trying to prevent needlestick injuries. An injection needle is commonly supplied with a protective cap, which is removed for use, and is then disposed of, as it is not recommended that the cap is replaced over the needle. Indeed, it is thought that replacement of the cap has been the cause of a significant number of needlestick injuries.

The needle itself may be mounted on a cylindrical collar at the distal end of a syringe barrel. Alternatively, it may be mounted on a separate hub, which is then attached to the syringe barrel. The connection between the hub and the syringe barrel is typically by means of a luer connection, comprising a conical male portion on the barrel and a complementary female portion on the hub. The conical taper is a standard 6°. The connection may be a luer slip type, which is a simple friction fit, or a luer lock type, where the male portion is surrounded by an internally threaded collar, and the hub has external radial lugs to engage in the screw thread. The hub is then, in effect, screwed onto the collar. A further alternative is for the radial lugs to engage behind an undercut on the collar at the distal end of the syringe. The hub is then a push fit on the syringe, being retained by the lugs behind the undercut.

One way of preventing needlestick injuries is to provide a safety shield, mounted on the needle-bearing member, that is, the syringe or the hub, to provide protection for the needle once the disposable cap is removed. The shield pivots away from the needle for use, and is then pivoted back and locked in a position where the needle is shielded. Such an arrangement adds to the complexity and cost of the item, as it requires an extra part.

Another proposal is to mould a safety shield in one piece with the needle and hub. A protective strip ensures the needle is not exposed before use, the strip being removed for use. Again, the shield pivots away from the needle for use, and is pivoted back and locked in a position where the needle is shielded. This arrangement may be difficult to mould, and is not suitable for syringes having an integrated needle.

It has also been proposed to replace the disposable cap with a safety shield. In this case it is of course essential that the safety shield is not removable in the same way as the disposable cap. It is relatively easy to provide a connection between the injection device and the safety shield which prevents removal but this may result in the shield not being orientable on the device. This has the disadvantage that the user normally requires the needle to be in a "bevel up" orientation for injection, but without the shield being a hindrance. If the shield is not rotatable on the device the orientation of the shield and needle cannot be guaranteed, and if it is freely rotatable it may naturally rotate to a position in which it is in the way.

The majority of needlestick injuries are caused after injection has taken place. Typically, the injection device is filled by the user and the injection given immediately. Increasingly however, injections are made up of several different medications, and the injection device is then filled in one location, such as a pharmacy, and then transported to the recipient for injection. To remove the risk of needlestick injury, this requires the needle to be covered again in a transport position, but not to be locked, so that it can be uncovered for injection. It is important that the transport position is clearly distinguishable from the locked position, and that the safety shield cannot move accidentally into the use position or the locked position during transport.

According to a first aspect of the invention, a needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe is formed as a one-piece moulding and comprises a first part adapted to be attached to the needle-bearing member and a second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the device being adapted to adopt a first position in which the needle is protected for transport of the device prior to use, a second position in which the needle is exposed for filling of the syringe and

injection, a third position in which the needle is protected after filling of the syringe but before injection and a fourth position in which the needle is locked in the device following injection.

This arrangement provides a defined transport position, and a construction for the fourth position in which the needle is locked. Preferably the first and second parts are able to adopt three stable positions, to define the four positions of the device. In a first stable position the needle is accommodated in the second part, and the relative positions of the first and second parts is maintained. This is the initial position, in which the device is assembled with the needle-bearing member, and in which it can be transported prior to use. If the needle-bearing member is a hub, the hub and device are attached to the syringe with the device in this initial position. In a second stable position the retaining means is disengaged and the second part is pivoted away from the first part to expose the needle. This is the operative position, in which a syringe can be filled and an injection given. If the injection is not to be given immediately, the second part can be moved back into the first stable position, and maintained there with the needle covered. In this position the syringe can be carried safely if necessary, so that it is in a temporary transport position. Then the second part can be moved into the operative position again when the injection is to be given. Following injection, the device is placed in a third stable position, in which the second part is moved back, through the first stable position, such that a permanent locking arrangement is actuated. This is the locked position, in which the needle is once more shielded to prevent needlestick injuries. The second part may be movable between the operative and transport positions as required.

In one embodiment, the shield has a transport recess and a locking recess connected by a gate device at least at the base of the needle, the arrangement being such that in the third position the needle is in the transport recess and is able to move into the second position, and in the fourth position the needle moves through the gate device into the locking recess, with the gate device preventing movement out of the fourth position.

This arrangement provides a clearly defined transport position, and a simple and safe construction for the fourth position in which the needle is locked. The locking recess contains the needle securely, and as it is retained by engagement with the gate device

at the base of the needle, it is virtually impossible to remove the needle from the locking recess without significant damage. This provides the desired protection against needlestick injuries.

The first and second parts of the device are preferably connected by a living hinge. The hinge provides the force to move the second part between the first and second positions, and between the second and third positions, once movement is initiated by the user. Further manual force is required to move the second part into the fourth position. The hinge also retains the second part in the first and third positions. This provides a particularly simple construction, as no further means are required to retain the second part in the various positions.

Conveniently the first and third positions are the same, so that the needle is initially in the transport recess. The second part is then movable between the second and third positions as required.

Conveniently, the gate device is provided for the whole length of the needle. The gate device preferably comprises a projection formed in the second part to define a partition between the transport recess and a locking recess and a curved or labyrinthine path connecting the transport recess and the locking recess. When the needle is moved into the third position from the second position, it is retained in the transport recess by the projection, but can follow the labyrinthine path into the locking recess when the further manual force is applied. Once in the locking recess, the base of the needle does not have sufficient flexibility to return along the labyrinthine path round the projection.

The second part preferably has an extension leading from the transport recess in a direction away from the locking recess to shield the needle when it is in the first and third positions. The extension may be a funnel to guide the needle into the transport recess.

The second part may be shaped in any suitable way for grasping by the user to initiate movement between the first and second and second and third positions. It may also be grasped or used to apply the manual force to move the second part into the locked position. The second part may have an enlarged portion on the side opposite the

transport recess. The enlarged portion may accommodate the locking recess. Alternatively the second part may have an extension of reduced width on the side opposite the transport recess. Each of the enlarged portion and the extension may be formed with external ribs extending axially, for ease of use. Further alternatives are a finger plate provided on the second part and used to apply the manual force, or a nib or extension at the axial end of the second part.

In another embodiment the first and second parts of the device are preferably connected by a living hinge, and a retaining means. In the first position the needle is accommodated in the second part, and the retaining means is engaged to maintain the relative positions of the first and second parts. In the second position the retaining means is disengaged and the second part is pivoted away from the first part, with the assistance of the hinge, to expose the needle. The second part can be moved back into the first position, and maintained there by the retaining means with the needle covered, to be in the third, transport position. Then the second part can be moved into the operative position again when the injection is to be given. Following injection, the second part is moved back, through the first position such that the retaining means engages in a position where a permanent locking arrangement is actuated.

The retaining means may comprise a pair of detents on one of the first and second parts, adapted to engage in a recess on the other part respectively in the third and fourth positions. Alternatively the retaining means may comprise a co-operating pin and hole arrangement, with a pin being provided on one of the first and second parts, and a hole on the other part, in which the pin engages in the fourth position.

Conveniently the device is closed initially by a removable strip extending along the open face of the second part. The strip may be flexible, such as a foil, or a rigid plastics part. The strip is sealingly attached to the second part. The second part may have a flat flange to which the strip is sealingly attached. The first part may also have a flat face to which the proximal end of the strip is sealed. Alternatively the strip may have a releasable sealing engagement with the second part. The strip conveniently has a free end which can be grasped by the user for removal. Release of the strip may also start the movement of the second part into the operative position. This movement is assisted by the hinge once the second part has moved through a predetermined angle.

The hinge also acts to assist the return movement of the second part to the first position. Further manual force may be required to move the second part into the locked position. The second part may also include a secondary locking mechanism for the needle in the locked position. The secondary locking mechanism may comprise at least a pair of opposing hooks, arranged such that the needle can pass over them in one direction, but not return.

According to a second aspect of the invention a needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe is formed as a one-piece moulding and comprises a first part adapted to be attached to the needle-bearing member and a second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the device being adapted to adopt at least an open position in which the needle is exposed for filling of the syringe and injection and a locked position in which the needle is locked in the device following injection, the shield having a gate device at least at the base of the needle leading to a locking recess, the arrangement being such that in the locked position the needle has moved through the gate device into the locking recess, and the gate device prevents movement of the needle out of the locked position.

The locking recess contains the needle securely, and as it is retained by engagement with the gate device at the base of the needle, it is virtually impossible to remove the needle from the locking recess without significant damage. This provides the desired protection against needlestick injuries.

Conveniently, the gate device is provided for substantially the whole length of the needle. The gate device preferably comprises a projection formed in the second part to define a curved or labyrinthine path to the locking recess. When the needle is moved into the locked position, it follows the labyrinthine path and is retained in the locking recess by the projection. Once in the locking recess, the base of the needle does not have sufficient flexibility to return along the labyrinthine path round the projection.

The third and fourth aspects of the invention address the use of a needlestick prevention device as a replacement for a disposable cap.

According to a third aspect of the invention, a needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe is formed as a one-piece moulding and comprises a first part adapted to be attached to the needle-bearing member and second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the first part being attached to the needle-bearing member by attachment means providing for the rotation of the needlestick prevention device relative to the needle-bearing member through an angle of at least 90° and less than 180° in each direction, but preventing removal of the device.

This arrangement ensures that the device cannot be removed from the needle-bearing member but can be oriented such that it is not in the way of an injection being given, with the needle in the bevel up position.

Preferably the first part is not freely rotatable on the needle-bearing member. Instead the engagement between them is arranged to allow rotation when a torque is applied manually, and for the members to remain in their relative position when the torque is removed. This arrangement may be provided by a frictional engagement between the first part and the needle-bearing member.

Conveniently, the attachment means comprises a projection on one of the needle-bearing member and the needlestick prevention device, and a groove on the other. Preferably, the projection is provided on the needlestick prevention device, and the groove on the needle-bearing member. The projection is arranged with an inclined face allowing the needlestick prevention device to be assembled onto the needle-bearing member, and an abutment face engaging with the groove to resist separation of the device and the needle-bearing member.

The groove conveniently extends round two separate arcs of the circumference of the needle-bearing member, the adjacent ends of the arcs being separated by any desired distance. The needlestick prevention device is formed with a pair of projections, diametrically opposed, with each projection accommodated in a respective arc of the groove.

According to a fourth aspect of the invention, a needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe is formed as a one-piece moulding and comprises a first part adapted to be attached to a cylindrical or conical portion of the needle-bearing member and second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the engagement between the first part and the needle-bearing member being arranged with an increased coefficient of friction to resist axial separation of the needlestick prevention device and the needle-bearing member, and an orientation arrangement to define the relative circumferential positions of the needlestick prevention device and the needle-bearing member.

Arranging the engagement with an increased coefficient of friction increases the axial force required to remove the device, which means that it cannot be pulled off like a standard disposable cap. Further, it is simple to make as a one-piece moulding, and easy to assemble, so reducing the cost. The orientation arrangement means that the device can adopt the required orientation relative to the needle for injection.

Conveniently the first part of the device has a substantially cylindrical collar engaging over the cylindrical or conical portion of the needle-bearing member. The collar may have at least one axial split extending from its free end. The split or splits provide radial resilience for the collar, to ensure ease of demoulding and assembly onto the needle-bearing member.

Preferably the internal surface of the collar is not smooth, but at least a part is arranged with an increased coefficient of friction to increase the friction between the first part and the needle-bearing member. This ensures that the device engages with either a cylindrical or a conical portion with sufficient force to resist axial separation. The increase in friction coefficient may be provided by a defined pattern of roughening or the like, or a random arrangement. For example, a defined pattern of circumferential ridges may be moulded in, or a random arrangement may be provided by a suitable post-moulding treatment of a smooth moulded surface. In either case it has been found that there is less resistance to relative rotation of the first part and the needle-bearing member than to axial separation, so that the device can be removed by a screwing motion, if necessary. The axial extent of the area of increased friction coefficient is preferably limited, and does not extend over the whole length of

engagement between the parts. The attachment may also require a projection to be provided on the needlestick prevention device, and a groove on the needle-bearing member.

Conveniently the outer surface of the collar has a reduced diameter portion allowing it to fit onto a luer lock connection. The outer surface may also have one or more external ribs, corresponding to the lugs on a hub, to engage the screw thread of a luer lock connection.

Standard hubs and syringes have a guide rib to assist with the bevel up orientation of the needle. The first part of the device then conveniently includes a groove for co-operation with the rib.

Further aspects of the invention relate to a combination of a needlestick prevention device and a needle-bearing member.

According to a fifth aspect of the invention, in a combination of a needlestick prevention device and a needle-bearing member, the needle-bearing member has a cylindrical or conical external surface portion with which an internal surface portion of the needlestick prevention device engages, and the needlestick prevention device and needle-bearing member are attached by a projection on one of the needlestick prevention device and needle-bearing member engaging in a groove in the other of the needlestick prevention device and needle-bearing member, the arrangement being such as to allow relative rotation of the needlestick prevention device and needle-bearing member but to prevent separation of the needlestick prevention device and needle-bearing member.

Preferably, the projection is provided on the needlestick prevention device, and the groove on the needle-bearing member. The projection is arranged with an inclined face allowing the needlestick prevention device to be assembled onto the needle-bearing member, and an abutment face engaging with the groove to resist separation of the device and the needle-bearing member.

According to a sixth aspect of the invention, in a combination of a needlestick prevention device and a needle-bearing member, the needle-bearing member has a

cylindrical or conical external surface portion with which an internal surface portion of the needlestick prevention device engages, and at least one of the surfaces has an increased co-efficient of friction such that axial separation of the device and the needle-bearing member is resisted.

Conveniently, only one of the surfaces has the increased co-efficient of friction. It may be either the external surface or the internal surface. It will usually be easier to provide the increased coefficient of friction on the external surface. However, it is equally possible to increase the coefficient of friction on both surfaces.

Preferably the increased coefficient of friction is provided by roughening the surface. The roughening may be a defined pattern or a random arrangement. A defined pattern could consist of circumferential ridges. A random pattern may be produced by a suitable treatment of an initially smooth surface. The increased coefficient of friction may extend across the whole axial length of engagement between the surfaces, or may be limited.

Embodiments of a needlestick prevention device according to the aspects of the invention are illustrated, by way of example only, in the accompanying drawings, in which:-

Figure 1 is a side view of a needlestick prevention device according to the invention;

Figure 2 is similar to Figure 1 but shows the device in an open configuration;

Figure 3 is similar to Figure 2 but shows the device in a locked position;

Figure 4 is an end view of the device of Figure 2;

Figure 5 is a perspective view of the device of Figure 2;

Figure 6 is a detail of the device;

Figure 7 is similar to Figure 1 but shows the device attached to a hub for carrying an injection needle;

Figure 8 is similar to Figure 7 but shows the device in an open configuration;

Figure 9 is a perspective view of part of Figure 7;

Figure 10 is a plan view of the device of Figure 7;

Figure 11 is a perspective view of the device of Figure 7;

Figure 12 is a perspective view of the device of Figure 7 mounted on a syringe barrel;

Figure 13 is a side view of the device of Figure 7 in the locked position;

Figure 14 is a perspective view of the device of Figure 7 in the locked position;

Figure 15 is a perspective view of a further needlestick prevention device according to the invention;

Figure 16 is a side view of the device of Figure 15;

Figure 17 is an end view of the device of Figure 15;

Figure 18 is a cross-section along the line 18-18 of Figure 17;

Figure 19 is a cross-section along the line 19-19 of Figure 16;

Figure 20 is a detail of part of Figure 19;

Figure 21 is a cross-section along the line 21-21 of Figure 16;

Figure 22 is a sectional view of the connection between the device of Figure 15 and a needle hub;

Figure 23 is a perspective view of the device of Figure 15 mounted on a syringe barrel;

Figure 24 shows the device in the operative position on a syringe barrel;

Figure 25 is similar to Figure 24 but shows the device in the locked position;

Figure 26 is similar to Figure 15 but shows a modification;

Figure 27 is an end view of the device of Figure 26;

Figure 28 is a section through a needle hub and the device of Figure 26, showing the connection between them;

Figure 29 is a perspective view of a needle hub;

Figure 30 is similar to Figure 26 but shows a further modification; and

Figure 31 is an end view of the device of Figure 28.

Figures 1 to 6 show a needlestick prevention device 1 for an injection needle carried by a needle-bearing member such as a syringe barrel or a needle hub. Figures 7 to 14 show the device 1 attached to a needle hub 2. The device 1 is intended to replace the standard disposable cap which is typically provided to shield the needle before use, and to provide a safety device which can be used on standard syringes and hubs, as well as being easy and inexpensive to make and assemble.

The device 1 of Figures 1 to 6 is made as a one-piece moulding of a plastics such as polypropylene. It comprises a first part 3 adapted to be attached to a needle-bearing member (not shown in Figures 1 to 6) and a second part 4 providing a shield for the

needle, and pivotally movable relative to the first part 3 to expose the needle for use. The engagement between the first part 3 and the needle-bearing member is arranged so that a force considerably higher than that required to remove a standard needle cap applied solely axially is required to remove the device 1 from the needle-bearing member. The force may for example be 20N or higher.

The first and second parts 3, 4 are connected by a hinge 5 and a retaining means 6. These allow the first and second parts 3, 4 to adopt three stable positions. The first position, shown in Figure 1, is an initial position, following manufacture and assembly. In the initial position a removable foil strip 7 seals the second part 4. The second position, shown in Figure 2, is an open or operative position, in which the needle is exposed for use. The third position, shown in Figure 3, is a locking position, in which the two parts 3, 4 are held firmly, and the needle is trapped in the second part 4.

The first part 3 comprises a portion 8 of substantially rectangular outline and a substantially cylindrical collar 9. The hinge 5 is attached to an edge at one side 10 of the rectangle, while the opposing side 11 is formed with a flat face 12 to which the removable foil strip 7 is sealed initially. The strip 7 has a free end 13 which can be grasped by the user for removal. The remaining pair of sides 14 of the portion 8 are each formed with a part of the retaining means 6. This comprises an open axial recess or slot 15, formed with a slight projection 23 at its opening.

The collar 9 is of stepped outline, having an enlarged central portion 16, and a portion 17 of reduced diameter adjacent the rectangular portion 8 and a free end portion 18 also of reduced diameter. As best seen in Figures 5 and 6, the free end portion 18 and the central portion 16 are formed with a pair of opposed axial slits 19 of a keyhole outline. The external surface of the free end portion 18 is formed with a pair of opposed axially-extending ribs 20. The internal surface is formed with shallow circumferential ridges 21 which increase the coefficient of friction of the internal surface. The ridges 21 can be formed by moulding, because the slits 19 allow expansion of the free end portion 18 for demoulding. The slits 19 also provide the free end portion 18 with radial resilience which assists assembly onto the needle-bearing member.

As best seen in Figures 4 and 6 the first part 3 is provided with an axial groove 22 adapted to co-operate with an axial rib on the needle-bearing member in order to provide a defined position for the device 1 on the needle-bearing member. This is important where it is necessary for the bevel at the free end of the needle to be oriented towards the user when the device 1 is in the operative position. This is commonly called the "bevel up" orientation.

The second part 4 comprises a portion 25 of substantially rectangular outline, and a substantially U-shaped shield member 26. The hinge 5 is attached to one side 27 of the rectangular portion 25. The opposing side 28 has an aperture 29 to allow passage of the needle, and the edge parts 30 of the side 28 are formed with the co-operating part of the retaining means 6. Each edge part 30 has two outwardly-facing detents 31, 32. Each detent 31, 32 is adapted to engage in the corresponding recess 15. If the detent 31 passes the projection 23 and engages in the recess 15 the retaining means 6 holds the parts 3, 4 in the initial position, in which the parts 3,4 are aligned. However, if the second part 4 is pivoted further, the detent 32 passes the projection 23 and enters the recess 15, to place the device in the locking position of Figure 3, where the parts 3, 4 are not aligned. It requires relatively little force to pivot the second part 4 away from the initial position towards the open position, but much more to move it out of the locking position, because the detent 32 projects further than the detent 31. The arrangement of the projections 23, recesses 15 and detents 31, 32 ensure that the initial and locking positions are well defined.

The U-shaped shield member 26 has an open face allowing passage of the needle. It is formed with a lip 35 at its free end and flat faces 36 to allow the strip 7 to be sealed to it. The shield member 26 also has a secondary locking mechanism 37 for the needle, in the form of tongues 38 projecting inwardly from the side wall 39 of the shield member 26. Three tongues 38 are shown in the drawings, two provided on one side of the needle and one on the other. It is essential to have at least two opposing tongues; more may be provided according to the length of the needle. The tongues are of different lengths to ensure that the needle is held securely, whatever its length. It will be appreciated that in the initial position the needle may contact the tongues but is free to move out of the shield member 26. In the locking position the needle contacts and deflects the tongues 38, which then return to their original position and trap the needle in the shield member 26.

As mentioned above, the device 1 is a one-piece plastics moulding, which is therefore simple and inexpensive to make. Once moulded, the removable strip 7 is applied and sealed to it. In an alternative arrangement the strip 7 is replaced by a movable strip attached to the second part. The device 1 may then be assembled with a needle-bearing member. As explained above, this may be a syringe barrel or a needle hub 2.

A syringe barrel with an integrated needle (not shown) usually has a cylindrical collar at the distal end of the barrel, and a cross-shaped projection in which the needle is received and glued. If the syringe barrel does not have an integrated needle it will normally have a hollow conical projection at the distal end of the barrel, to which a needle hub is attached. The hub has an internally tapered surface to fit the conical projection, the connection being known as a luer connection. The standard taper is 6°. The hub may be a push-fit onto the projection and be held by friction, known as a luer slip connection. Alternatively, the conical projection may be surrounded by an internally-threaded collar to provide a luer lock connection. For this, the free end of the hub is provided with radially-extending lugs to engage with the screw threads on the collar, and the hub is attached by rotation.

Figures 7 to 14 show the device 1 of Figures 1 to 6 attached to a hub 2 as the needle-bearing member. Figure 12 shows the hub 2 attached to a syringe by a luer lock connection. For clarity, the needle is shown only in Figures 10, 11 and 14. The device is the same as that of Figures 1 to 6, except that the shield member 26 is provided with four tongues 38 rather than three.

The hub 2 is a standard construction, being a hollow conical member 40. At its proximal larger end the hub has a pair of radially outwardly-extending lugs 41, which are adapted to engage the screw threads of a luer lock connection. The opposing, distal end, has a cylindrical projection 42 into which the needle 43 is inserted, and an axial rib 44 with which the bevel 45 at the tip of the needle 43 is aligned.

The device 1 is assembled with the hub 2 and needle 43 by aligning the axial rib 44 with the groove 22 on the first part 3 of the device 1 and pushing the two together so that the needle 43 enters the shield member 26 and the collar 9 engages over the external taper surface 46 of the hub 2. Because the internal surface of the collar 9 is

cylindrical, the free end portion 18 will expand slightly, and the ridges 21 will engage the external surface 46 to hold the device 1 securely on the hub 2 due to the increased coefficient of friction. The ridges 21 provide a significant resistance to removal of the device 1 using a solely axial force. In fact, a force of at least 30N will need to be used. However, it will be possible to remove the device 1 using rotational as well as axial force, as the resistance to rotational movement will not be as great, due to the circumferential arrangement of the ridges 21. In this position the needle 43 rests on the tongues 38, but is free to move out of the shield member 26, as shown in Figures 10 and 11. If enhancement of the connection is required, it is also possible to increase the coefficient of friction on the external surface 46 of the hub 2, as shown in Figure 9, by forming similar shallow circumferential ridges 48 over a limited axial extent.

Once the device 1 is assembled on the hub 2, the hub 2 can be attached to a syringe barrel with a luer connection. If it is a luer lock connection, as shown in Figure 12, the axial ribs 20, which correspond to the lugs 41 on the hub 2, can enter the screw threads 50 on the internally-threaded collar 51 of the syringe 52. The reduced diameter of the free end portion 18 ensures that the luer lock connection is not inhibited.

When the syringe is to be used, the user removes the strip 7 by grasping the free end 13 and pulling distally. This disengages the retaining means 6 so that the second part 4 pivots away from the first part 3, to expose the needle 43. Once the second part 4 has moved through a given angle the hinge 5, which is a living or spring hinge, assists the movement into the open position of Figure 8. The syringe may then be filled in the usual way.

The injection may be given immediately. However, if this is not possible, the needle 43 may again be shielded by moving the second part 4 back into the initial position. This is a stable intermediate position, so there is no risk of a needlestick injury while the syringe is carried by the user. Then when the injection is to be given the second part 4 can be moved back into the open position.

Because of the alignment of the rib 44 and groove 22, the needle 43 will be in the ‘bevel up’ orientation ready for injection.

After injection the user moves the second part 4 back towards the first part 3. The movement will be assisted by the hinge 5. The user then applies a force to the shield member 26 until it reaches the locking position of Figures 13 and 14. The user will have an audible indication of this as the detent 32 moves past the projection 23 into the recess 15, and will also have a visible indication as the parts 3, 4 are not aligned. In the locking position the needle 43 is moved past the tongues 38, and is trapped by them. The syringe may then be disposed of safely.

If the device 1 is to be used on a syringe with an integrated needle the method of assembly and use are very similar. The difference is that the device 1 is attached to a cylindrical collar on the syringe, rather than the tapered surface 46 of the hub 2. This provides a secure connection, as the free end portion 18 will tend to expand as it is pushed on, and then contract round the syringe collar.

In either case it will be appreciated that in use the user's hand will be proximal of the needle tip or moving away from it, so that safety regulations are complied with.

The embodiment shows the circumferential ridges 21 moulded with the device 1 to provide the increased coefficient of friction. However, the effect can be produced in any other suitable way, for example by post-treatment of a smoothly moulded internal surface of the collar 9 to produce a random or defined pattern to roughen the surface. The same applies to providing the needle-bearing member with an area of increased coefficient of friction.

In a modification (not shown) the retaining means may comprise a co-operating pin and hole arrangement, with a pin being provided on one of the first and second parts, and a hole on the other, in which the pin engages in the locked position.

Figures 15 to 21 show a needlestick prevention device 100 for an injection needle carried by a needle-bearing member such as a syringe barrel or a needle hub. Figures 22 to 25 show the device 100 attached to a needle hub 101 and a syringe 102. The device 100 is intended to replace the standard disposable cap which is typically provided to shield the needle before use, and to provide a safety device which can be

used on syringes and hubs, as well as being easy and inexpensive to make and assemble.

The device 100 is made as a one-piece moulding of a plastics such as polypropylene. It comprises a first part 103 adapted to be attached to a needle-bearing member (not shown in Figures 15 to 21) and a second part 104 providing a shield for the needle, and pivotally movable relative to the first part 103 to expose the needle for use.

The first and second parts 103, 104 are connected by a hinge 105. This allows the first and second parts 103, 104 to adopt three stable positions. The first position is an initial position and a transport position, and can be seen in Figure 23. The second position, shown in Figures 15 and 16, as well as Figure 24, is an open or operative position, in which the needle is exposed for use. The third position, shown in Figure 25, is a locking position, in which the two parts 103, 104 are held firmly, and the needle is trapped in the second part 104.

The first part 103 comprises a cylindrical portion 106 having a free end 107 adapted to be connected to the needle-bearing member 101 or 102. The other axial end 108 has a pair of arms 109 projecting laterally. The outer end 110 of each arm 109 is attached to the second part 104 to form two hinge points, and the arms 109 also carry one end of a hinge spring 111.

The free end 107 terminates in a smaller diameter portion 129 which can be received in a standard attachment of a syringe. The first part 103 has a pair of diametrally opposed axial ribs 112 extending from the end 108 and terminating short of the free end 107. As best seen in Figures 19 and 20, each rib 112 has an internal projection 113, which is used to attach the device 100 to a needle-bearing member, as explained in more detail below with reference to Figure 22. Each projection 113 has a substantially triangular profile, having a face inclined to the axis, and an abutment face 114 perpendicular to the axis.

The second part 104 is a substantially U-shaped shield member. As best seen in Figure 17, the outline is indented at 115 adjacent the open side 116 and the closed part 117 is slightly bulbous. This makes it easy for the user to grasp the second part 104.

At the end of the second part 104 adjacent the first part 103 a pair of arms 118 project laterally, and attach to the respective arms 109 on the first part at the hinge points 120. The arms 118 carry the other end of the hinge spring 111. The free end 121 of the second part 104 is closed at 122.

The open side 116 allows for passage of the needle between the initial position and the open position, and between the open position and the transport position. The open side 116 is formed with a funnel 123 leading to a transport recess 124 which in turn leads to a locking recess 125 through a gate device 126. The transport recess 124 extends along the axis of the device 100 so that it accommodates the needle in the initial and transport positions. The gate device 126 comprises a projection 127 defining a position between the recesses 124 and 125 and a curved or labyrinthine path 128 between them. The projection extends all the way along the axial length of the second part 104, but could be provided only at the end adjacent the first part 103, that is, adjacent the base of the needle.

The device 100 can be manufactured simply by injection moulding.

Once manufactured, the device 100 is assembled to a needle-bearing member such as the needle hub 101 shown in Figure 22. The hub 101 is also typically of polypropylene, and is manufactured by injection moulding.

The needle 130 may be moulded with the hub 101, or assembled afterwards. The hub 101 is of a standard construction, with a conical bore 131 for attachment to a syringe 102, and an out-turned flange 132 at its proximal end. Because the device 100 is replacing the standard disposable cap, it is important that it cannot be removed in the same way as a standard cap. The hub 101 is therefore formed with an external groove 133 made of two arcuate parts 134 extending through about 100°, so that their adjacent ends are separated by an arcuate distance of about 80°. The hub 101 is assembled with the device 100 by introducing the hub 101 into the free end of the first part 103 until the projections 113 each engage in a respective groove part 134. The projections 113 slide along their inclined faces into the groove parts 134, but the abutment faces 114 engage with the groove parts 134 to resist separation of the device 100 and hub 101. However, the device 100 is able to rotate through about 100° in

each direction on the hub 101. The engagement between the first part 103 and the hub 101 has sufficient friction to allow the first part 103 to rotate relative to the hub 101 when a torque is applied manually by the user, but to remain in position when the torque is removed. When the device 100 and the hub 101 are assembled the needle 130 will be accommodated in the transport recess 124, and the device 100 will be maintained in the initial position by the hinge 105.

For use, the assembled device 100 and hub 101 are removed from any packaging and attached to a syringe 102, as shown in Figure 23. The user then moves the second part 104 into the open position of Figure 24, by grasping the bulbous part 117 and applying a manual force in a direction such that the needle 130 starts coming out of the open side 116. The hinge 105 then operates to move the second part 104 pivotally to the open position. The user can then fill the syringe 102 in the usual way.

The injection may be given immediately. However, if this is not possible, the needle 130 may again be shielded by moving the second part 104 back to the transport position. Once again the user needs only to apply a small manual force to start the movement, as the hinge 105 will continue the movement until the needle 130 is in the transport recess 124. There is no risk of a needlestick injury if the syringe is carried by the user as the hinge 105 retains the second part 104 in this stable transport position. When the injection is to be given the second part 104 is again moved into the open position.

Because the device 100 can be rotated in each direction through about 100° on the hub 101, the second part 104 can always be moved out of the user's way when the needle 130 is in the preferred bevel up orientation for injection, and can be maintained in a stable position by the frictional engagement between the first part 103 and the hub 101.

After injection the user again moves the second part 104 back towards the first part 103, with the hinge 105 operative to ensure it reaches the transport position. The user then applies a further force in the same direction to move the needle 130 through the gate device 126 and into the locking recess 125. It will be appreciated that the needle 130 moves round the projection 127 along the path 128 into the locking recess 125. The locked position is shown in Figure 25. The needle 130 is held

securely, particularly by the base of the needle 130, which does not have the flexibility to return along the path 128. It will also be noted that the free end of the needle 130 is distorted by its engagement with the back of the locking recess 125, thus rendering it useless. The syringe 102 can be disposed of safely.

As the needle 10 moves into the transport position it is guided by the funnel 124. If the needle is distorted during injection, for example by hitting a bone accidentally, the funnel 123 will guide it back and may even remove at least some of the distortion, ensuring that it can enter the locking recess 125.

Figures 26 to 28 show a modification of the device of Figures 15 to 35, and corresponding reference numerals have been applied to corresponding parts. Figures 26 to 28 show the second part 104 as a similar external shape with a bulbous closed part 117, which also has external axial ribs 140 for ease of grasping by the user. Figure 26 also shows how the closed end 122 of the second part is formed. The second part 104 has a central aperture 141 surrounded by three flaps 142, whose dimensions are chosen so that in the same plane as the end 122 they will close the central aperture 141. When the device is removed from the mould the flaps 142 will be upstanding as shown, and will be sealed to complete the end 122 as a post-moulding step.

Figures 26 to 28 also show a modification of the gate device 126. It still forms a barrier between the transport and locking recesses 124 and 125, but the sharp corner shown in Figure 21 has been smoothed, so that the path of the needle is eased. The position of the needle in the transport recess (the first and third positions) is also shown. The locking recess 125 is modified with extensions 145 towards the transport recess 124 on each side of the gate device 126. This provides enhanced security, as if the needle in the locked position enters one of these extensions it is much more difficult, if not impossible, for it to return through the gate device 126.

Figures 28 and 29 also show the connection of the device 100 and the hub 101. Figure 29 shows the form of the groove 133. In Figure 29 there is a relatively small distance between the adjacent ends of the groove parts 134, but the radial depth of the groove is increased. Figures 26 to 28 also show a modification of each projection 113. The projections 113 have a greater circumferential extent and also a greater radial depth.

The separation distance between the adjacent ends of the groove parts 134 and the circumferential extent of the projections 113 are chosen to ensure that the device 100 can rotate a sufficient distance to be out of the way when the syringe is being filled and when the injection is given. The rotation should be at least 90°, and will clearly be less than 180°. The amount is preferably about 115°, but could be anywhere in the range - for example, 100°, 110°, 120°, 130°. This modification provides a more secure attachment. In particular, it ensures that the connection will remain secure when the hub 101 is attached to a syringe by a luer lock connection. Otherwise the construction and operation of the embodiments of Figures 26 to 29 is the same as that of Figures 15 to 25.

Figures 30 and 31 show a further modification of the closed part 117 of the second part 104. Otherwise this embodiment is the same as that of Figures 26 to 29, and corresponding reference numerals have been applied to corresponding parts. In Figures 30 and 31, instead of being bulbous the closed part 117 of the second part 104 is provided with an extension 146 of reduced width. The extension 145 also has axial ribs 140. While the enlarged portion of Figures 15 to 29 is easy to grasp for the user, the reduced width extension of Figures 30 and 31 may be preferred in some circumstances. In a further modification (not shown) a finger plate may be provided on the second part 104, for example opposite the open side 116, for grasping by the user in moving the second part 104 to the open position. It would also be possible to provide an axial nib at the free end 121, if preferred. In a further modification (not shown), the gate device 126 may be modified by changing the profile of the projection 127 adjacent the base of the needle to ensure that the needle cannot return from the locked position.

The embodiments described provide a simple construction of needlestick prevention device which is simple to make and to use, while ensuring safe transport.

It will be appreciated that the embodiments described above not only illustrate the first four aspects of the invention, but also illustrate the fifth and sixth aspects of the invention, of a combination of needlestick prevention device and needle-bearing member, where the needle-bearing member has a conical or cylindrical external surface portion with which an internal surface portion of the needlestick prevention device engages, and where the needlestick prevention device and needle-bearing

member are attached by a projection on one of the needlestick prevention device and needle-bearing member engaging in a groove in the other of the needlestick prevention device and needle-bearing member, the arrangement being such as to allow relative rotation of the needlestick prevention device and needle-bearing member but to prevent separation of the device and needle-bearing member, or.at least one of the surfaces has an increased coefficient of friction to resist axial separation of the device and the needle-bearing member. The increased coefficient of friction may be provided on either or both of the device and the needle-bearing member, in the ways described above.

CLAIMS

1. A needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe, in which the device is formed as a one-piece moulding and comprises a first part adapted to be attached to the needle-bearing member and a second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the device being adapted to adopt a first position in which the needle is protected for transport of the device prior to use, a second position in which the needle is exposed for filling of the syringe and injection, a third position in which the needle is protected after filling of the syringe but before injection and a fourth position in which the needle is locked in the device following injection.

2. A needlestick prevention device as claimed in claim 1, in which the first and second parts are able to adopt three stable positions, to define the four positions of the device.

3. A needlestick prevention device as claimed in claim 1 or claim 2, in which the shield has a transport recess and a locking recess connected by a gate device at least at the base of the needle, the arrangement being such that in the third position the needle is in the transport recess and is able to move into the second position, and in the fourth position the needle moves through the gate device into the locking recess, with the gate device preventing movement out of the fourth position.

4. A needlestick prevention device as claimed in any preceding claim, in which the first and second parts of the device are connected by a living hinge, which provides the force to move the second part between the first and second positions, and between the second and third positions, once movement is initiated by the user.

5. A needlestick prevention device as claimed in claim 4, in which the hinge also retains the second part in the first and third positions.

6. A needlestick prevention device as claimed in any of claims 3 to 5, in which the first and third positions are the same, so that the second part is initially in the transport recess.

7. A needlestick prevention device as claimed in any of claims 3 to 6, in which the gate device is provided for substantially the whole length of the needle.

8. A needlestick prevention device as claimed in any of claims 3 to 7, in which the gate device comprises a projection formed in the second part to define a partition between the transport recess and a locking recess and a curved or labyrinthine path connecting the transport recess and the locking recess.

9. A needlestick prevention device as claimed in claim 8, in which the needle is retained in the third position in the transport recess by the projection, but follows the labyrinthine path into the locking recess for the fourth position when a further manual force is applied.

10. A needlestick prevention device as claimed any of claims 3 to 9, in which the second part has an extension leading from the transport recess in a direction away from the locking recess to shield the needle when it is in the first and third positions.

11. A needlestick prevention device as claimed in claim 10, in which the extension is a funnel to guide the needle into the transport recess.

12. A needlestick prevention device as claimed in any preceding claim, in which the second part is shaped for grasping by the user to initiate movement between the first and second and second and third positions and to apply a manual force to move the second part into the locked position.

13. A needlestick prevention device as claimed in claim 12, in which the second part has an enlarged portion on the side opposite the transport recess.

14. A needlestick prevention device as claimed in claim 12, in which the second part has an extension of reduced width on the side opposite the transport recess.

15. A needlestick prevention device as claimed in claim 13 or claim 14, in which the enlarged portion or the extension are formed with external ribs extending axially.

16. A needlestick prevention device as claimed in claim 12, in which a finger plate is provided on the second part.

17. A needlestick prevention device as claimed in claim 1 or claim 2, in which the first and second parts of the device are connected by a living hinge, and a retaining means.

18. A needlestick prevention device as claimed in claim 17, in which in the first position the needle is accommodated in the second part, and the retaining means is engaged to maintain the relative positions of the first and second parts, in the second position the retaining means is disengaged and the second part is pivoted away from the first part, with the assistance of the hinge, to expose the needle, in the third, transport position the second part is moved into the third position, and maintained there by the retaining means with the needle covered and in the fourth position the retaining means engages in a position where a permanent locking arrangement is actuated.

19. A needlestick prevention device as claimed in claim 17 or claim 18, in which the retaining means comprises a pair of detents on one of the first and second parts, each detent being adapted to engage respectively in a recess on the other part in the third and fourth positions.

20. A needlestick prevention device as claimed in claim 17 or claim 18, in which the retaining means comprises a co-operating pin and hole arrangement, with a pin being provided on one of the first and second parts, and a hole on the other part, in which the pin engages in the fourth position.

21. A needlestick prevention device as claimed in any of claims 17 to 20, in which the second part includes a secondary locking mechanism for the needle in the locked position comprising at least a pair of opposing hooks, arranged such that the needle can pass over them in one direction, but not return.

22. A needlestick prevention device as claimed in any preceding claim, in which the device is sealed initially by a strip extending along the open face of the second part.

23. A needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe, in which the device is formed as a one-piece moulding and comprises a first part adapted to be attached to the needle-bearing member and a second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the device being adapted to adopt at least an open position in which the needle is exposed for filling of the syringe and injection and a locked position in which the needle is locked in the device following injection, the shield having a gate device at least at the base of the needle leading to a locking recess, the arrangement being such that in the locked position the needle has moved through the gate device into the locking recess, and the gate device prevents movement of the needle out of the locked position.

24. A needlestick prevention device as claimed in claim 23, in which the gate device is provided for the whole length of the needle.

25. A needlestick prevention device as claimed in claim 23 or claim 24, in which the gate device comprises a projection formed in the second part to define a curved or labyrinthine path to the locking recess.

26. A needlestick prevention device for an injection needle carried by a needle-bearing member of a syringe, in which the device is formed as a one-piece moulding and comprises a first part adapted to be attached to the needle-bearing member and second part providing a shield for the needle and pivotally movable relative to the first part to expose the needle for use, the first part being attached to the needle-bearing member by attachment means providing for the rotation of the needlestick prevention device relative to the needle-bearing member through an angle of at least 90° and less than 180° in each direction, but preventing removal of the device.

27. A needlestick prevention device as claimed in claim 26, in which the attachment means comprises a projection on one of the needle-bearing member and the needlestick prevention device, and a groove on the other.

28. A needlestick prevention device as claimed in claim 27, in which the projection is provided on the needlestick prevention device, and the groove on the needle-bearing member.

29. A needlestick prevention device as claimed in claim 27 or claim 28, in which the groove extends round two separate arcs of the circumference of the needle-bearing member, the adjacent ends of the arcs being separated by any desired distance, and the needlestick prevention device is formed with a pair of projections, diametrically opposed, with each projection accommodated in a respective arc of the groove.

30. A needlestick prevention device as claimed in any of claims 26 to 29, in which the rotation of the needlestick prevention device relative to the needle-bearing member is through an angle of about 110°.

31. A needlestick prevention device as claimed in any of claims 26 to 30, in which the engagement between the first part and the needle-bearing member is arranged to allow rotation when a torque is applied manually, and for the first part and the needle-bearing member to remain in their relative position when the torque is removed.

32. A needlestick prevention device as claimed in claim 31, in which the engagement is a frictional engagement between the first part and the needle-bearing member.

33. A combination of a needlestick prevention device and a needle-bearing member, in which the needle-bearing member has a cylindrical or conical external surface portion with which an internal surface portion of the needlestick prevention device engages, and the needlestick prevention device and needle-bearing member are attached by a projection on one of the needlestick prevention device and needle-bearing member engaging in a groove in the other of the needlestick prevention device and needle-bearing member, the arrangement being such as to allow relative rotation of the needlestick prevention device and needle-bearing member but to prevent separation of the needlestick prevention device and needle-bearing member.

34. A combination as claimed in claim 33, in which the projection is provided on the needlestick prevention device, and the groove on the needle-bearing member.

35. A combination as claimed in claim 33 or claim 34, in which the projection is arranged with an inclined face allowing the needlestick prevention device to be assembled onto the needle-bearing member, and an abutment face engaging with the groove to resist separation of the device and the needle-bearing member.

36. A needlestick prevention device for use in the combination of claim 33.

37. A needle-bearing member for use in the combination of claim 33.

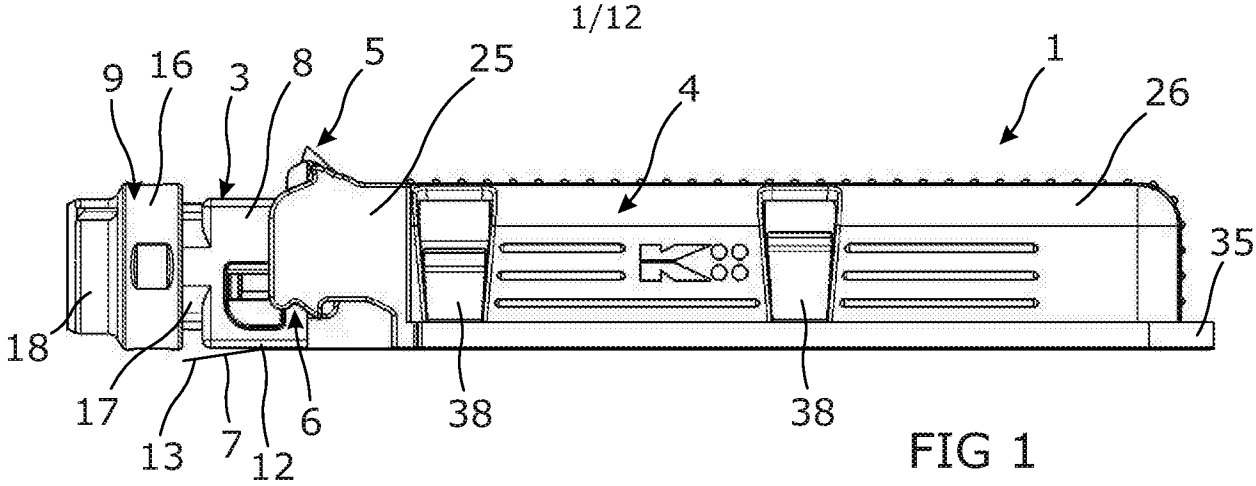

FIG 1

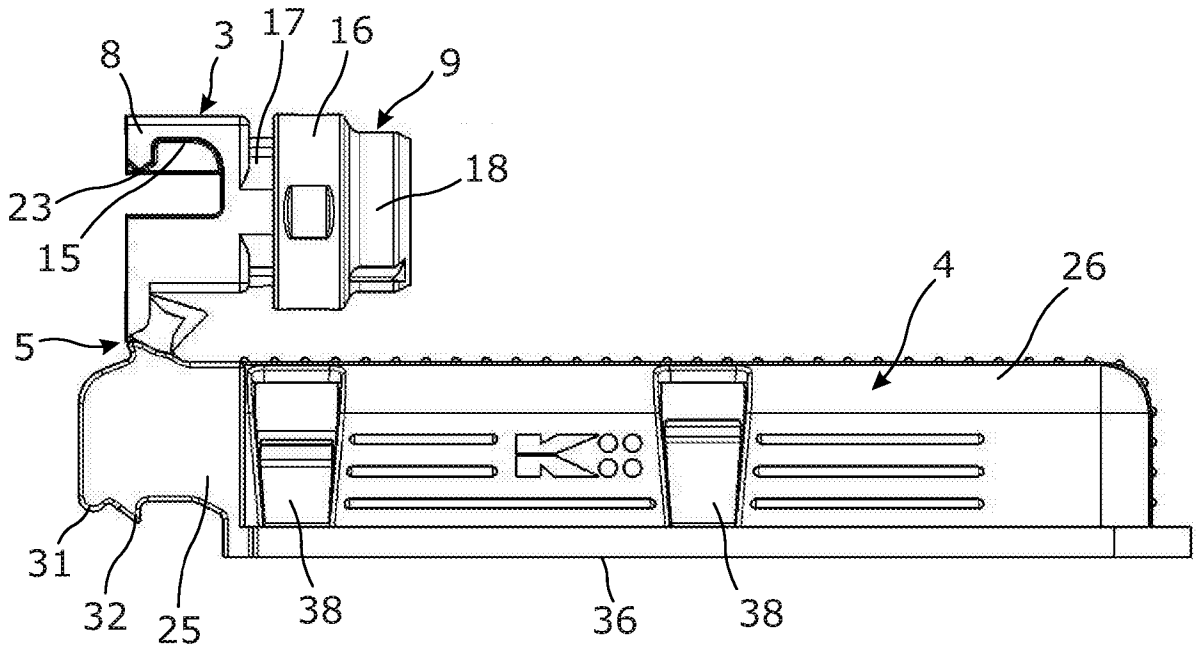

FIG 2

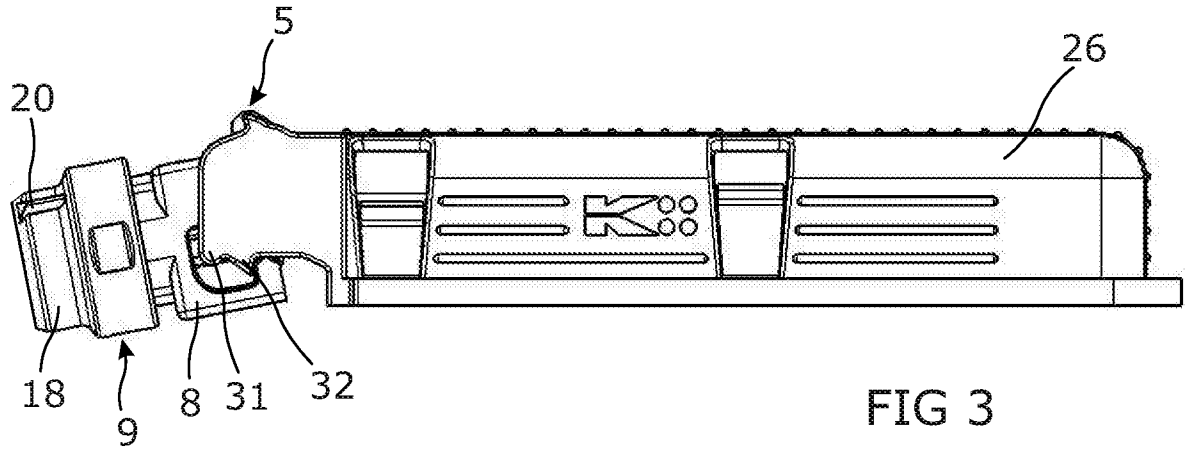

FIG 3

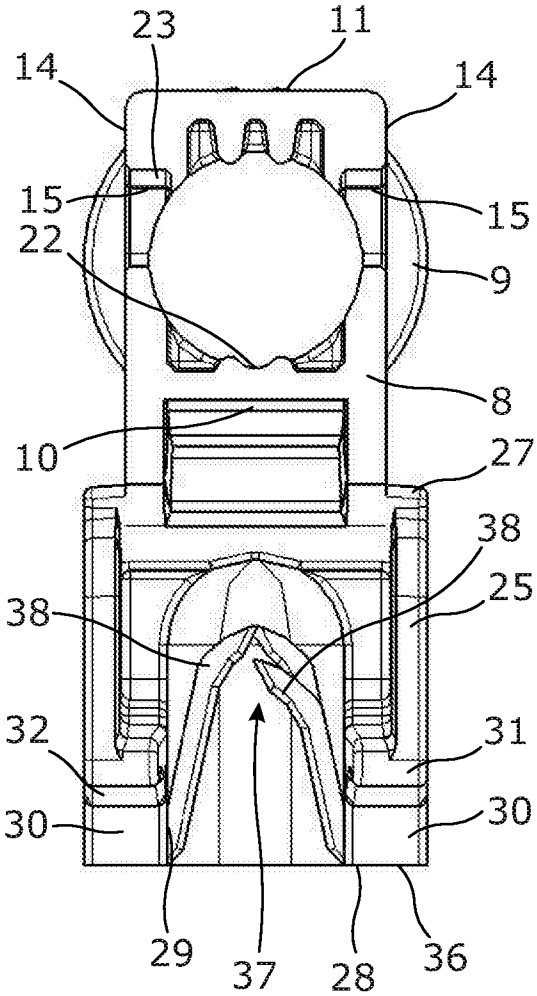

FIG 4

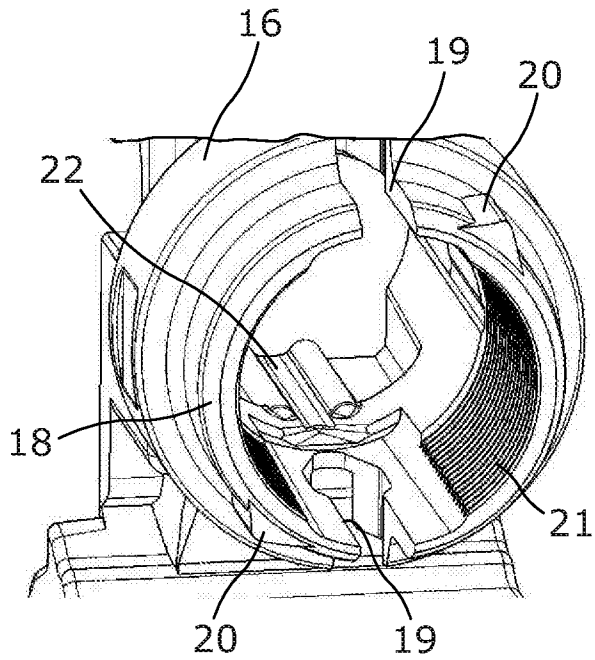

FIG 6

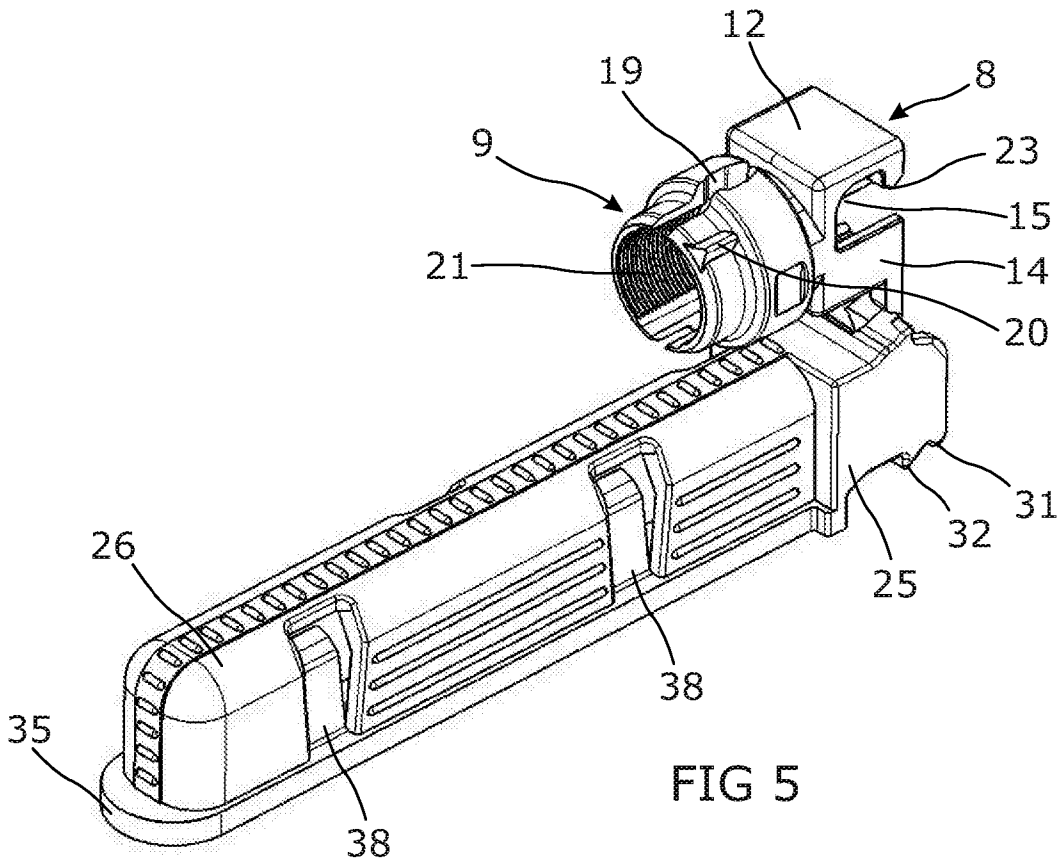

FIG 5

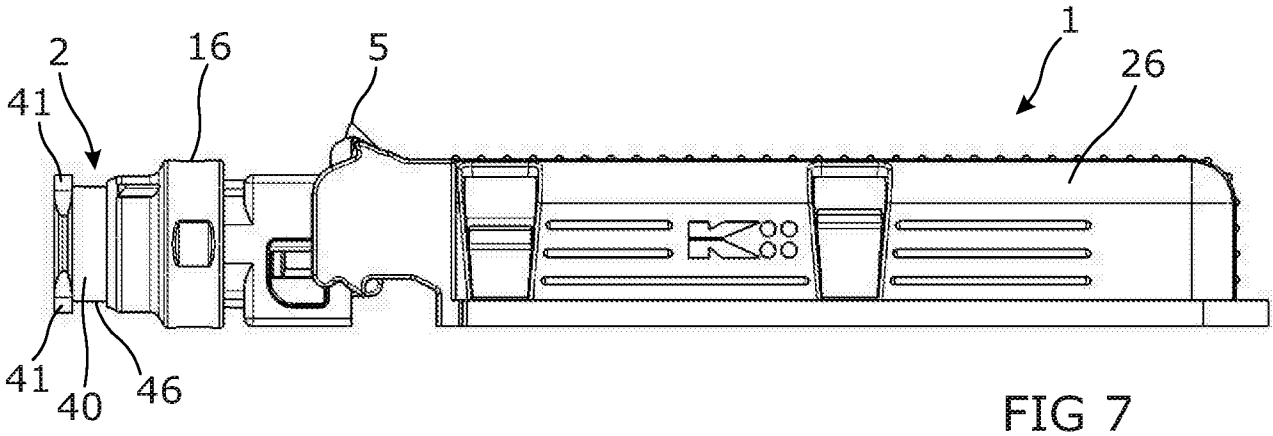

FIG 7

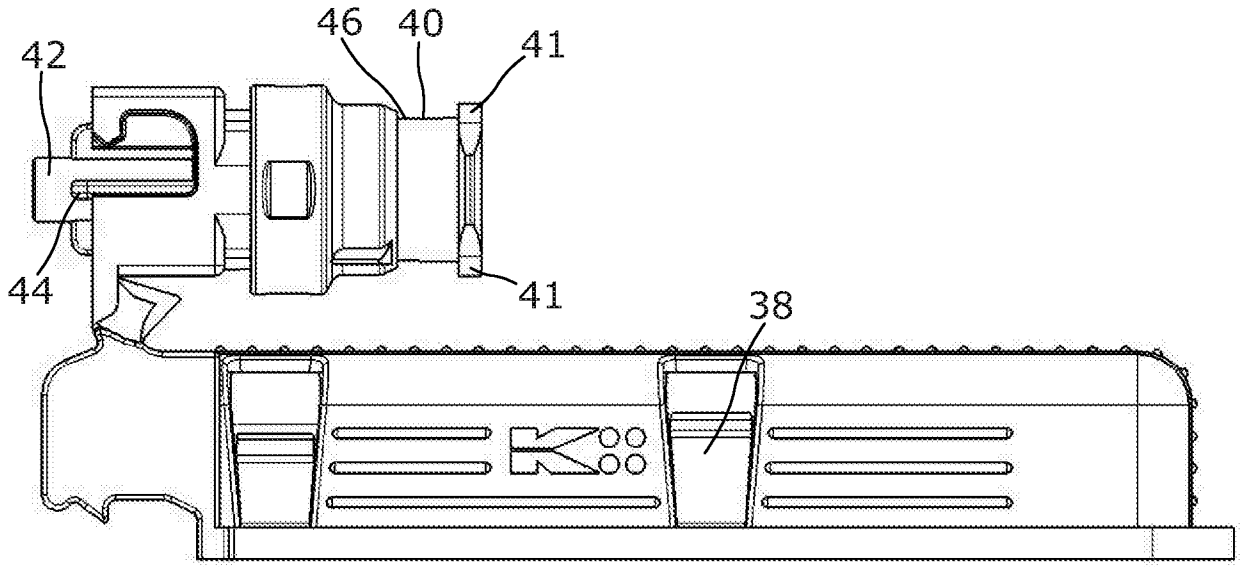

FIG 8

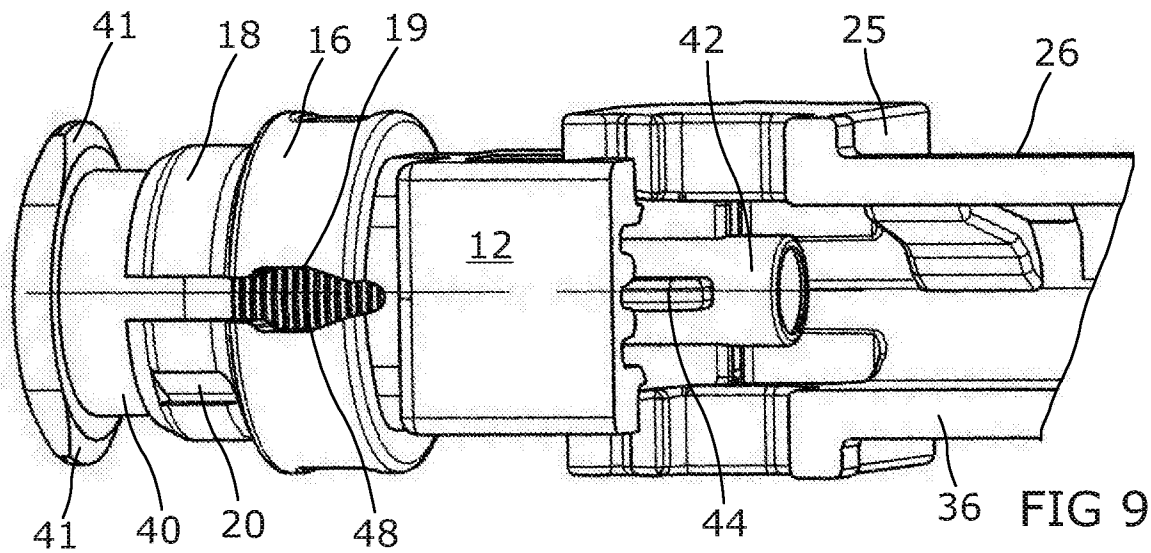

FIG 9

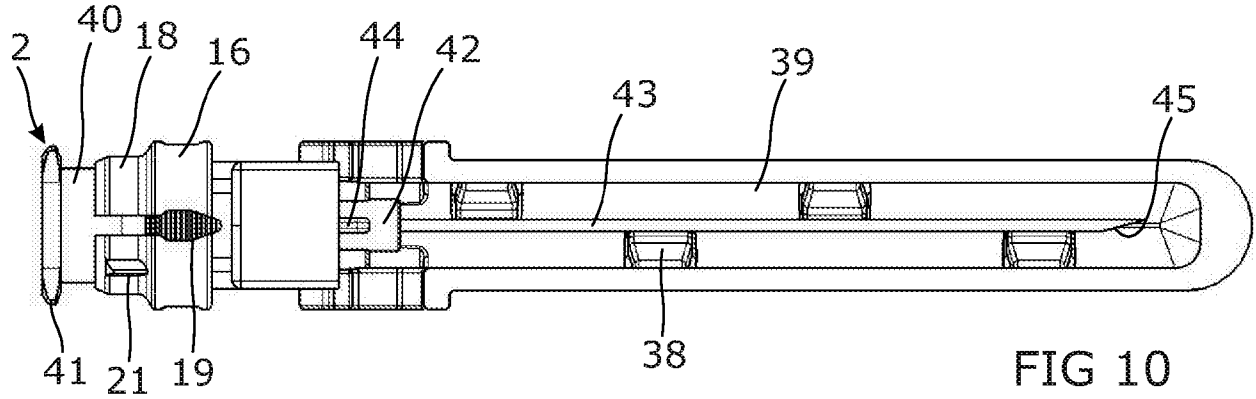

FIG 10

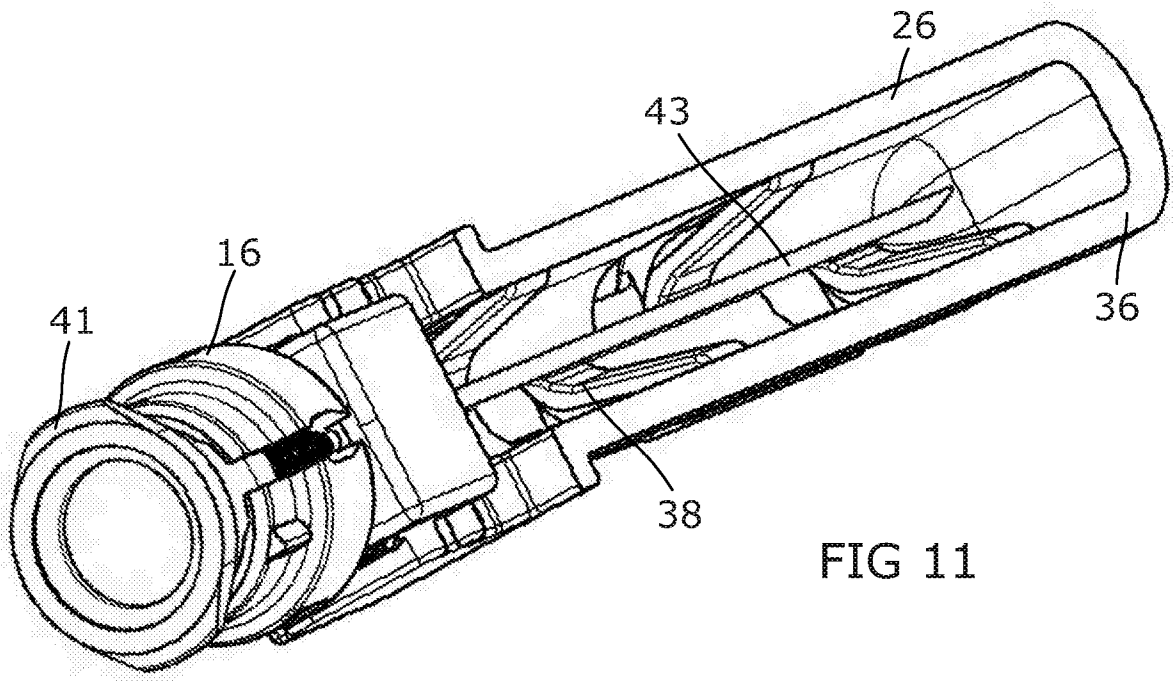

FIG 11

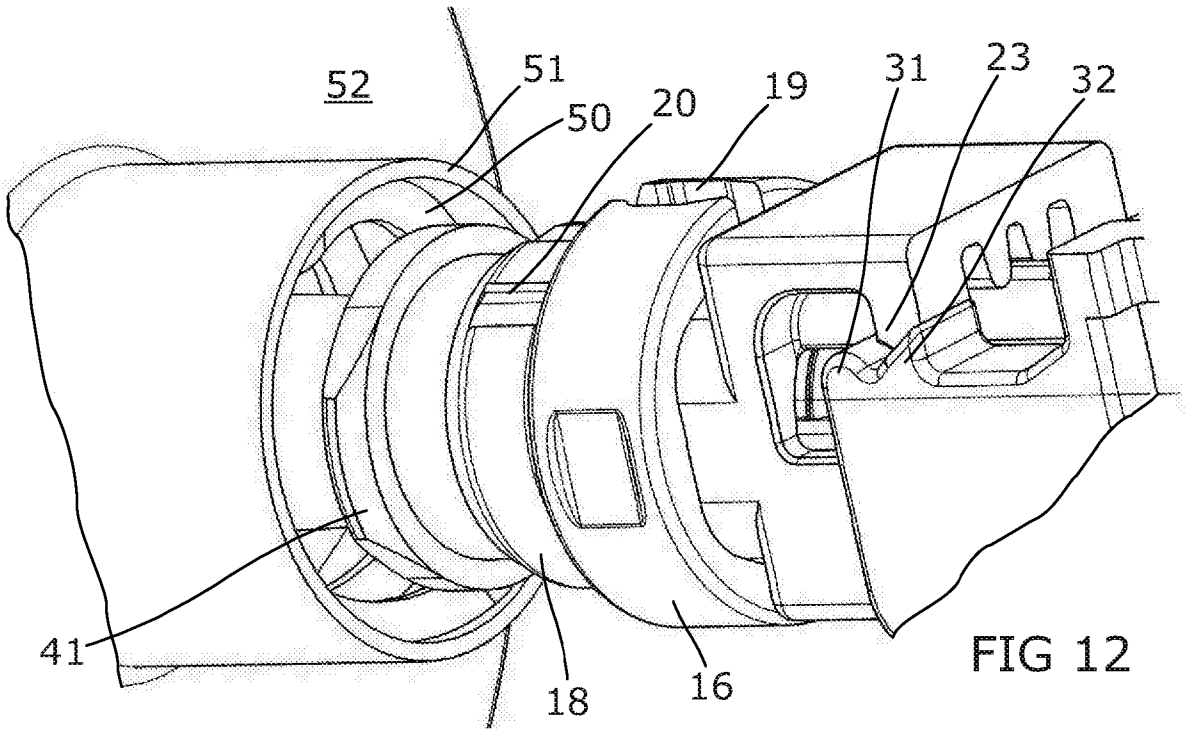

FIG 12

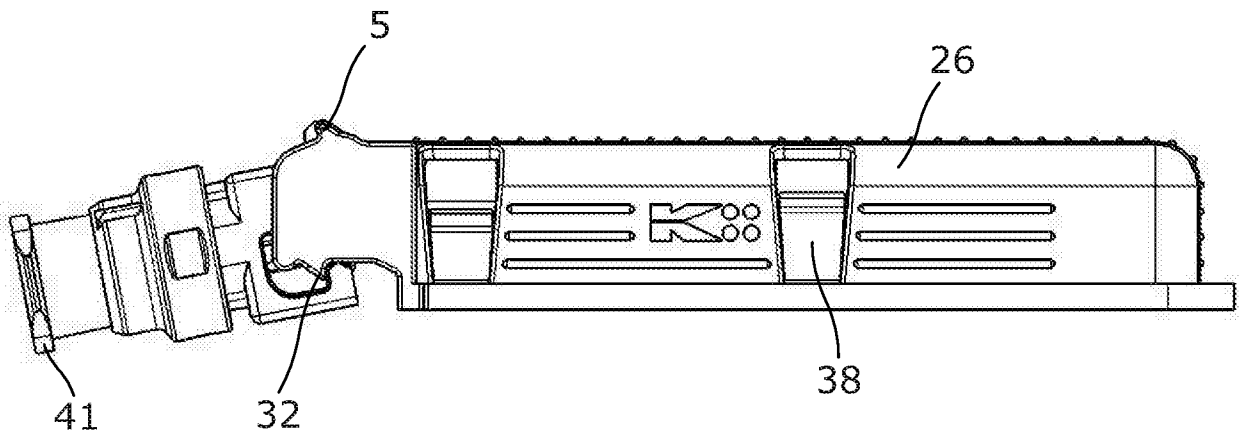

FIG 13

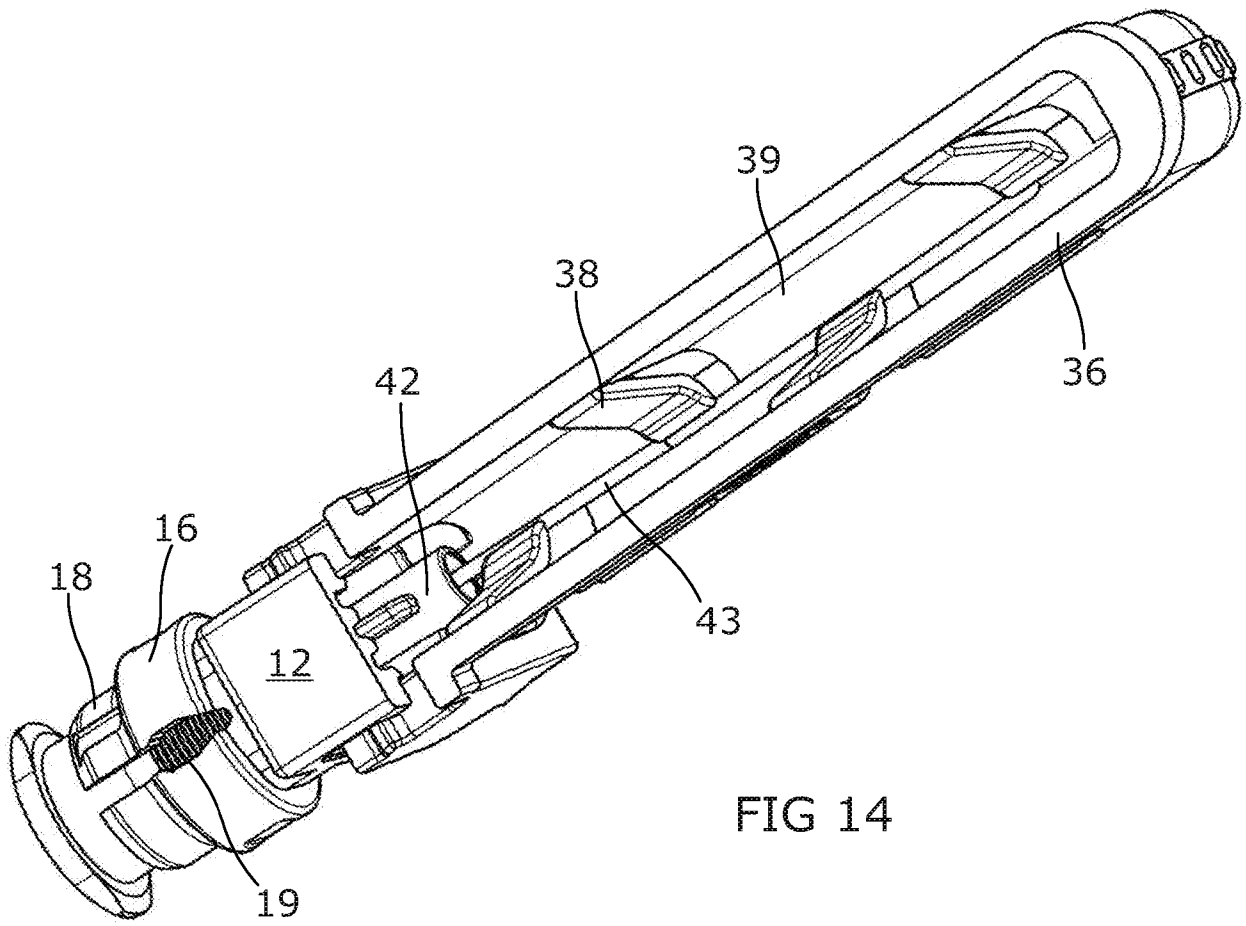

FIG 14

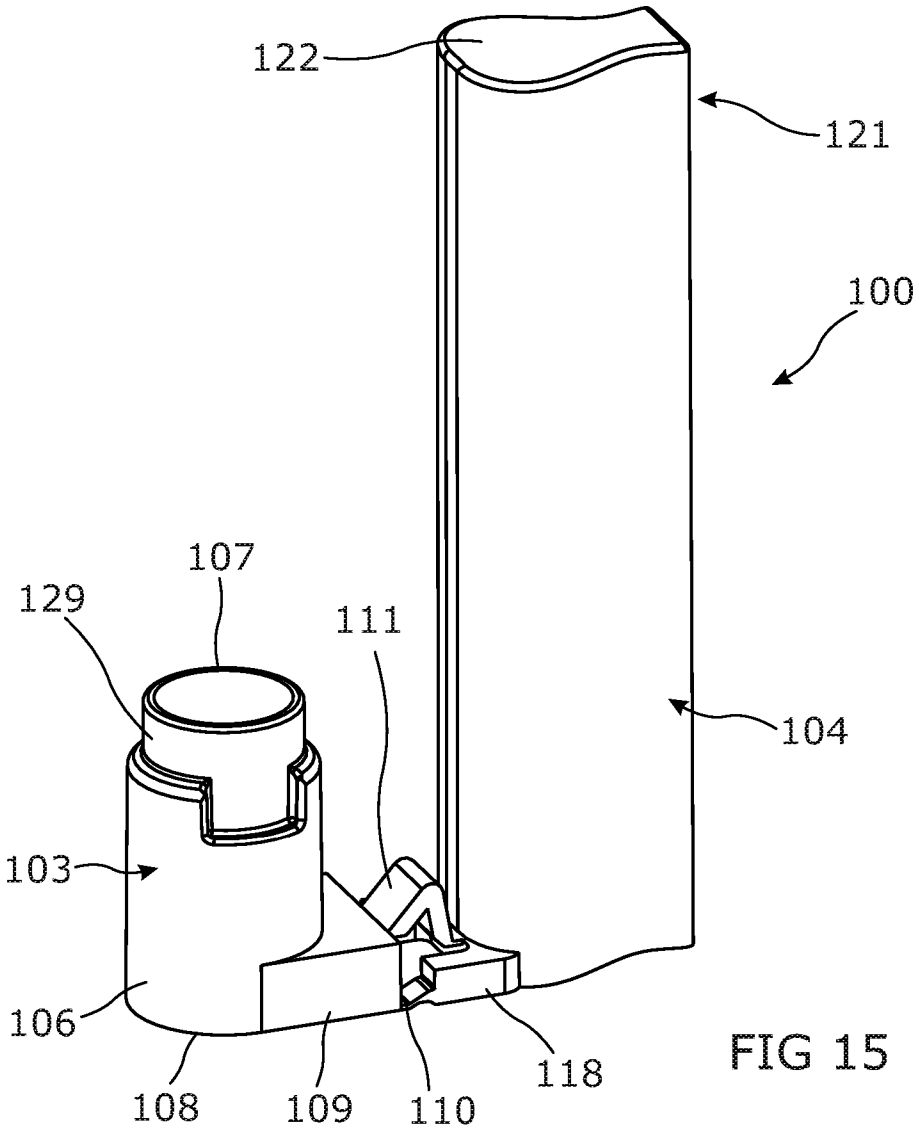
122
121
100
107
129
111
104
103
106
108
109
110
118

FIG 15

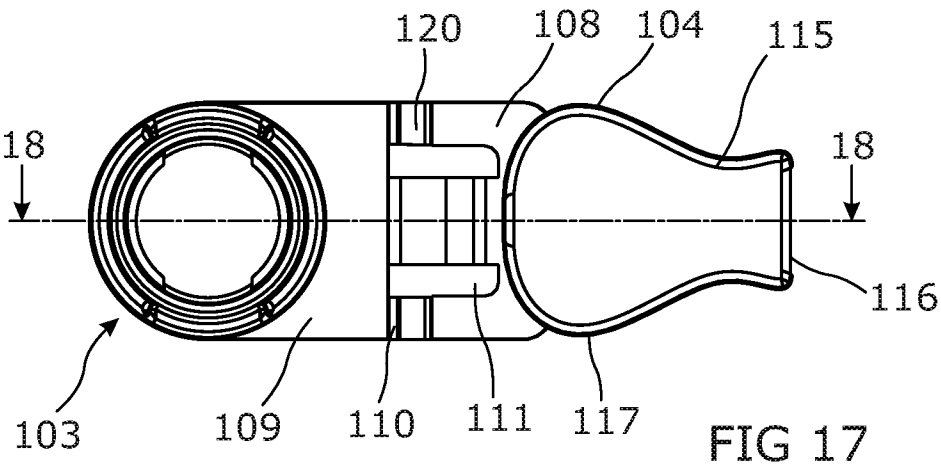
120
108
104
115
18
18
116
103
109
110
111
117

FIG 17

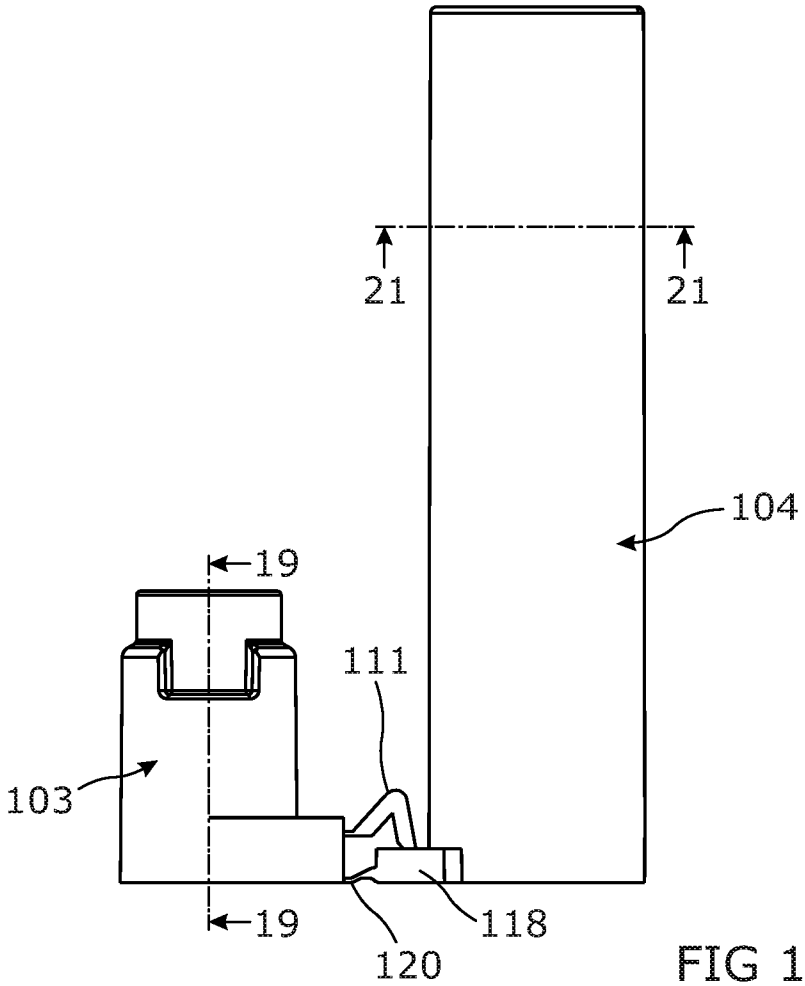

FIG 16

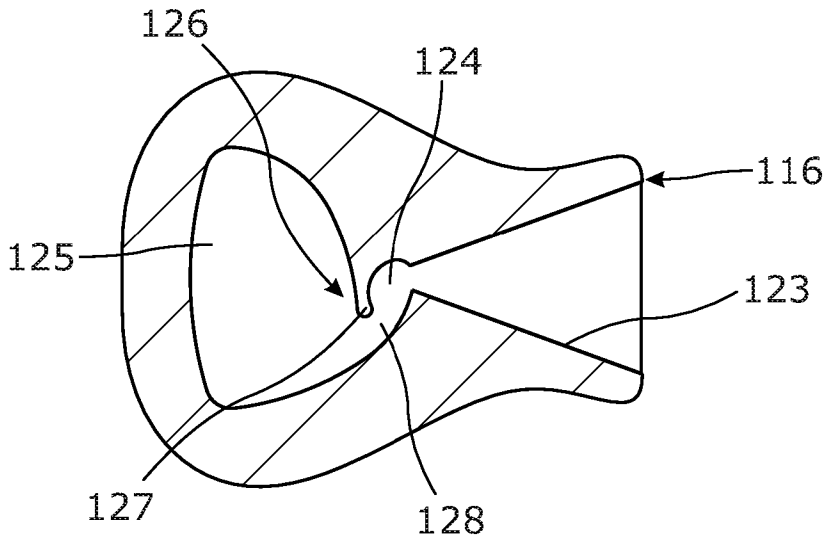

FIG 21

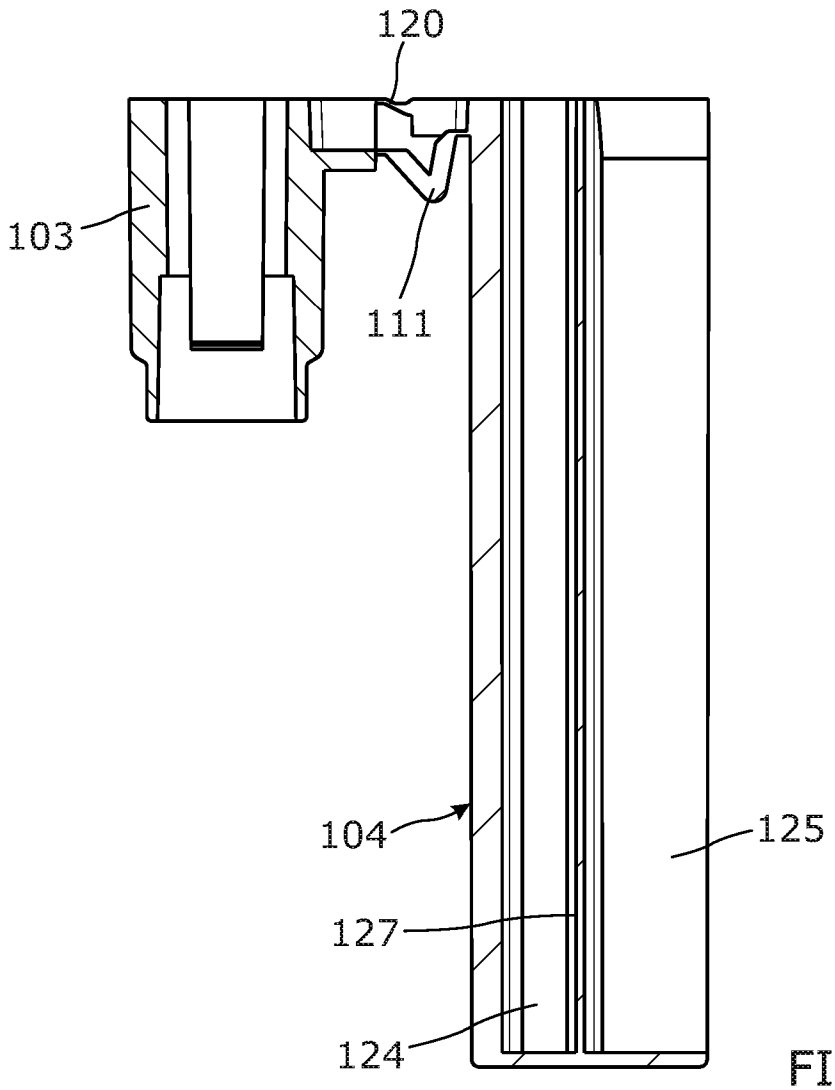

FIG 18

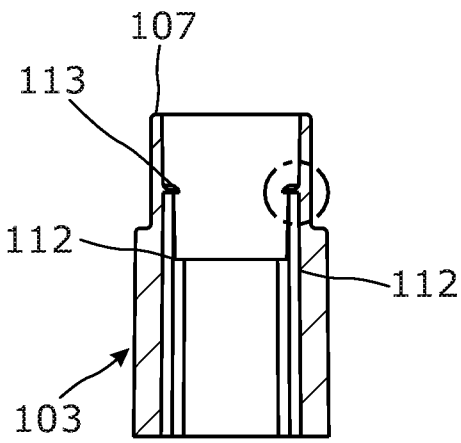

FIG 19

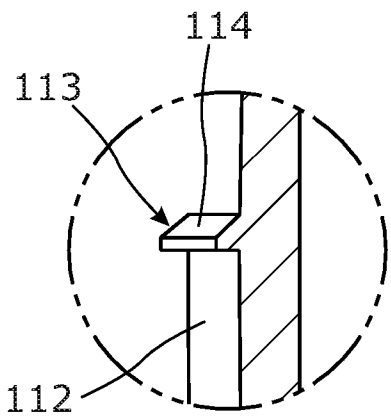

FIG 20

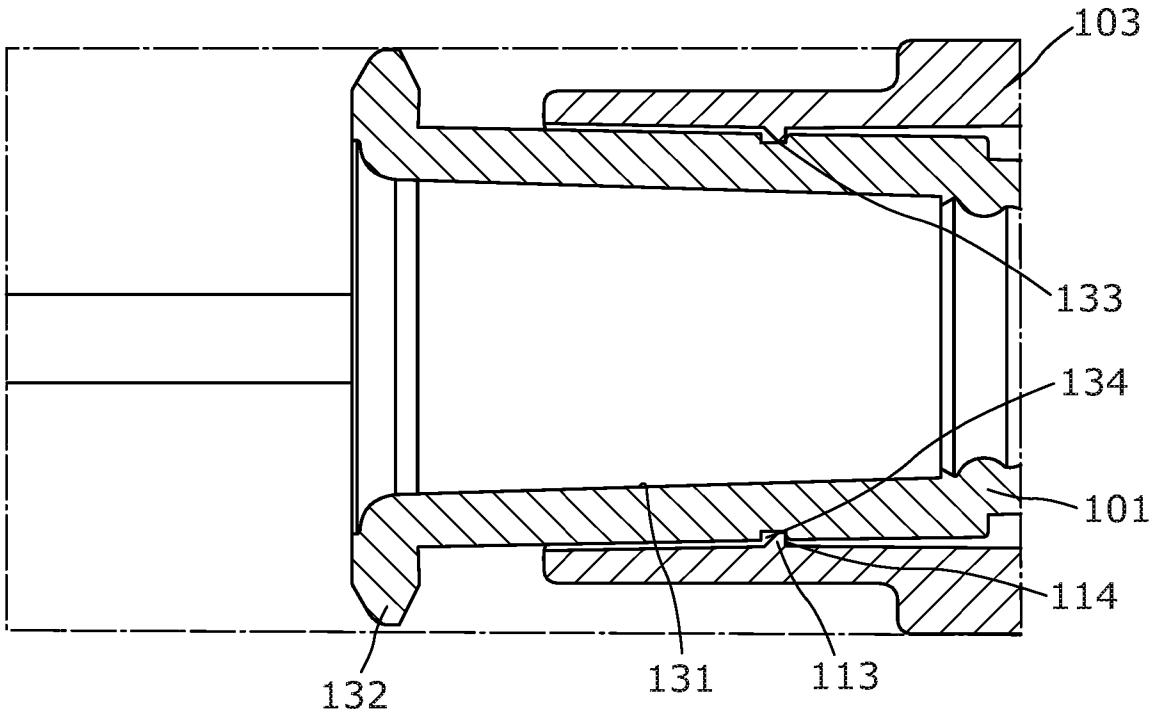

FIG 22

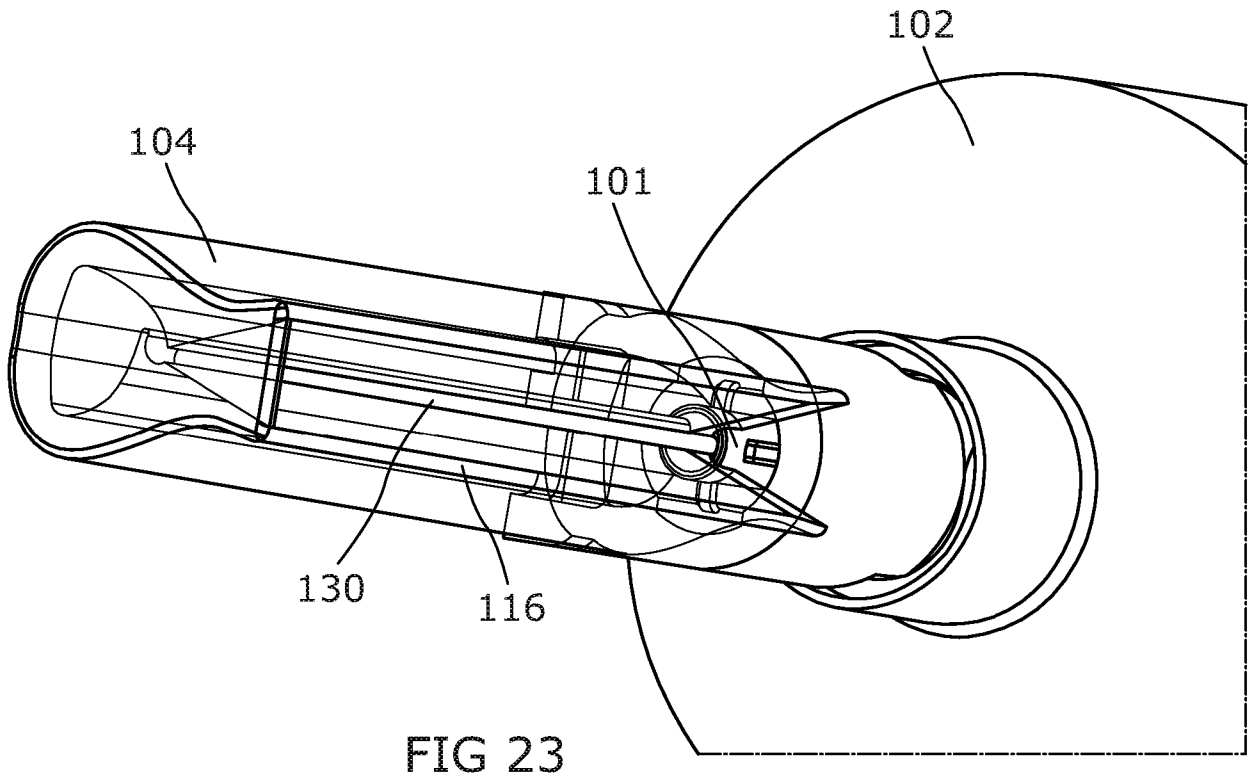

FIG 23

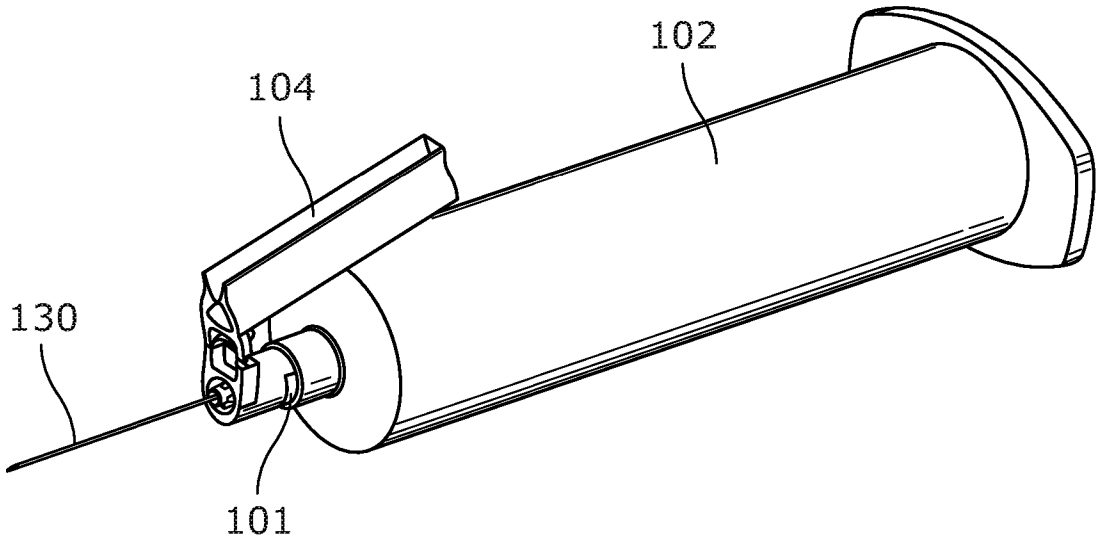

FIG 24

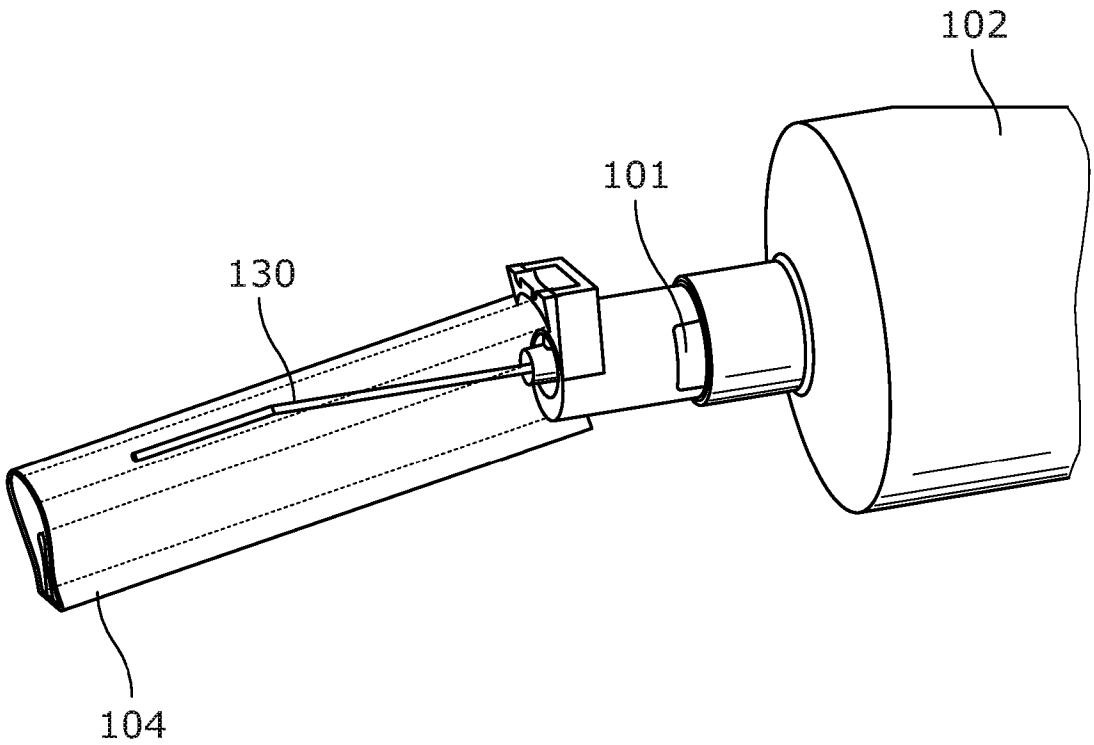

FIG 25

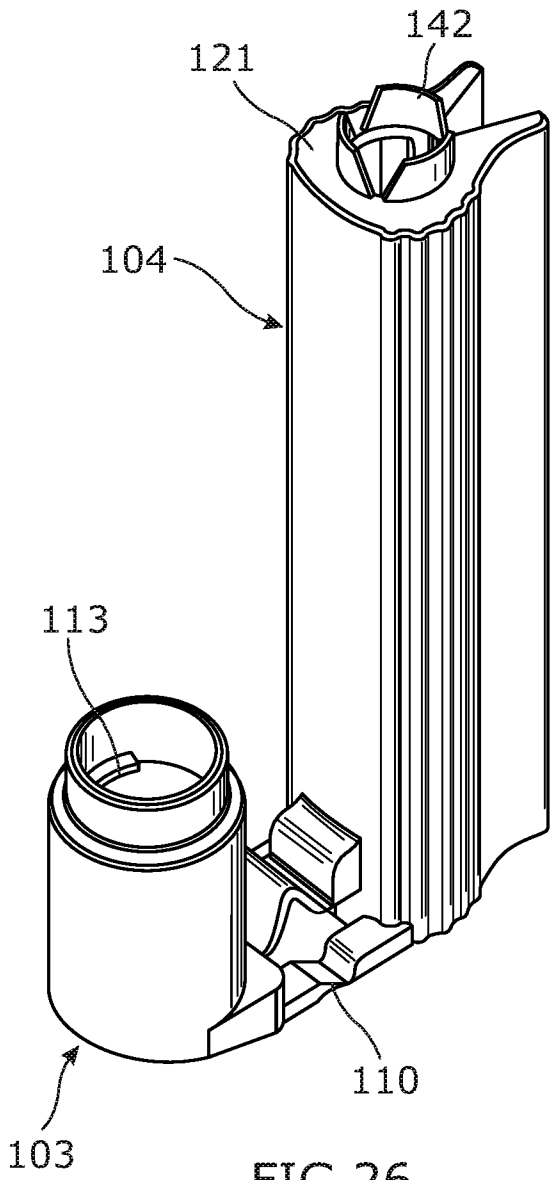

FIG 26

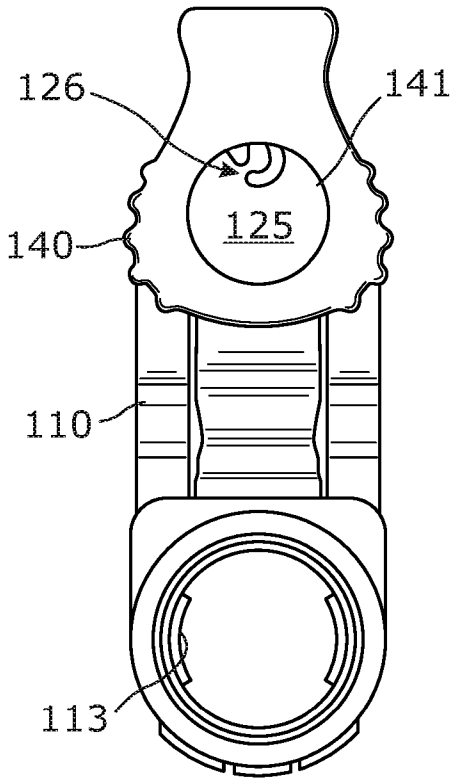

FIG 27

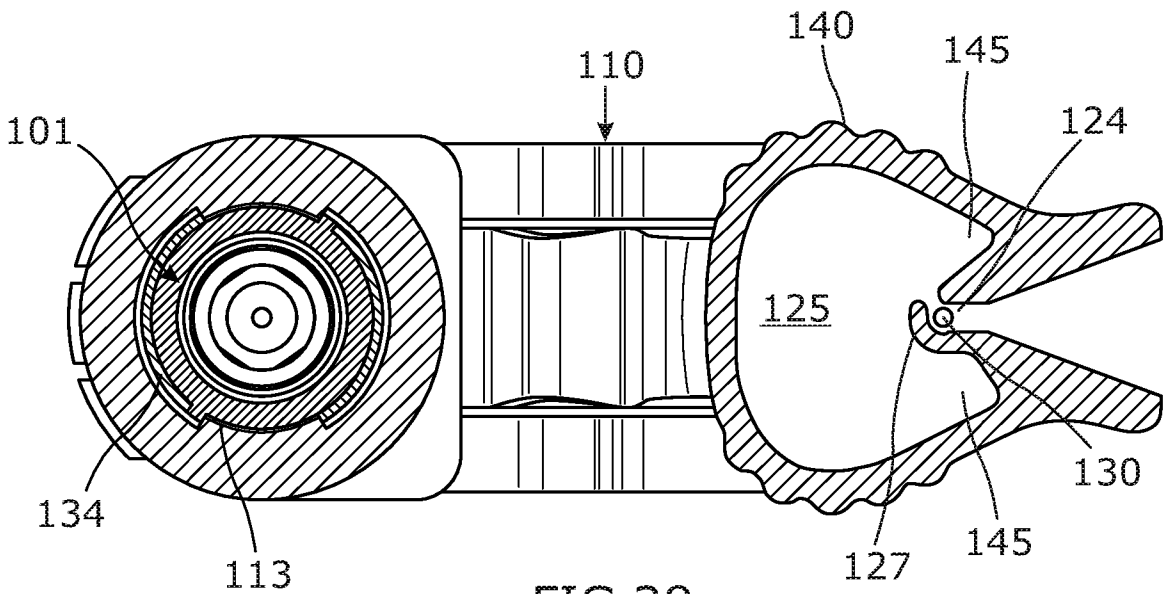

FIG 28

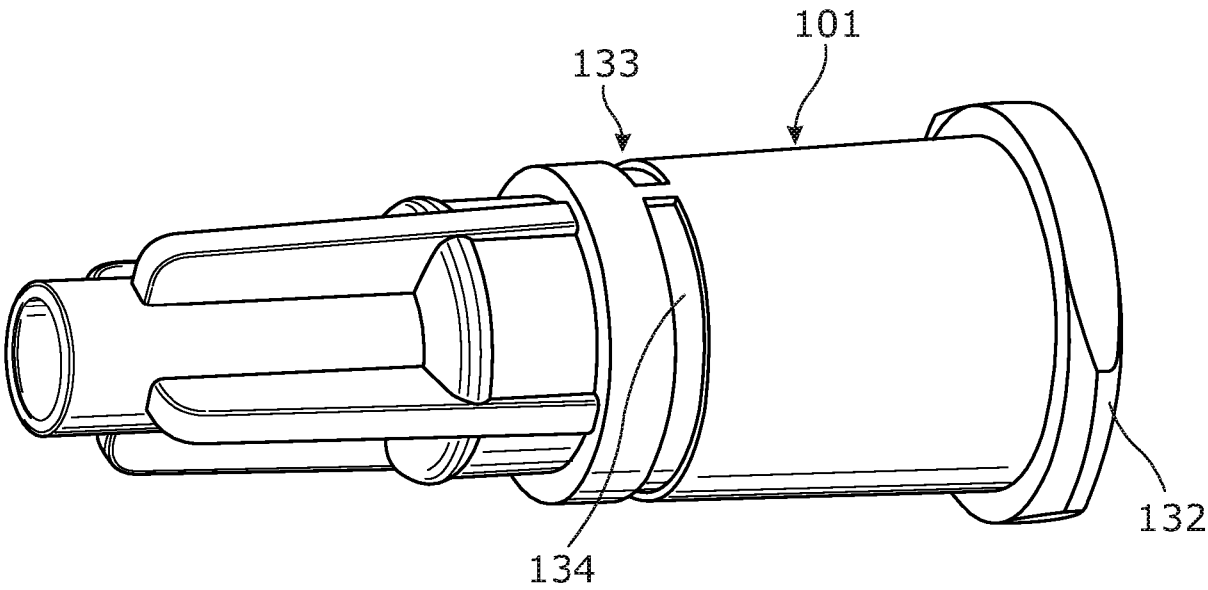

FIG 29

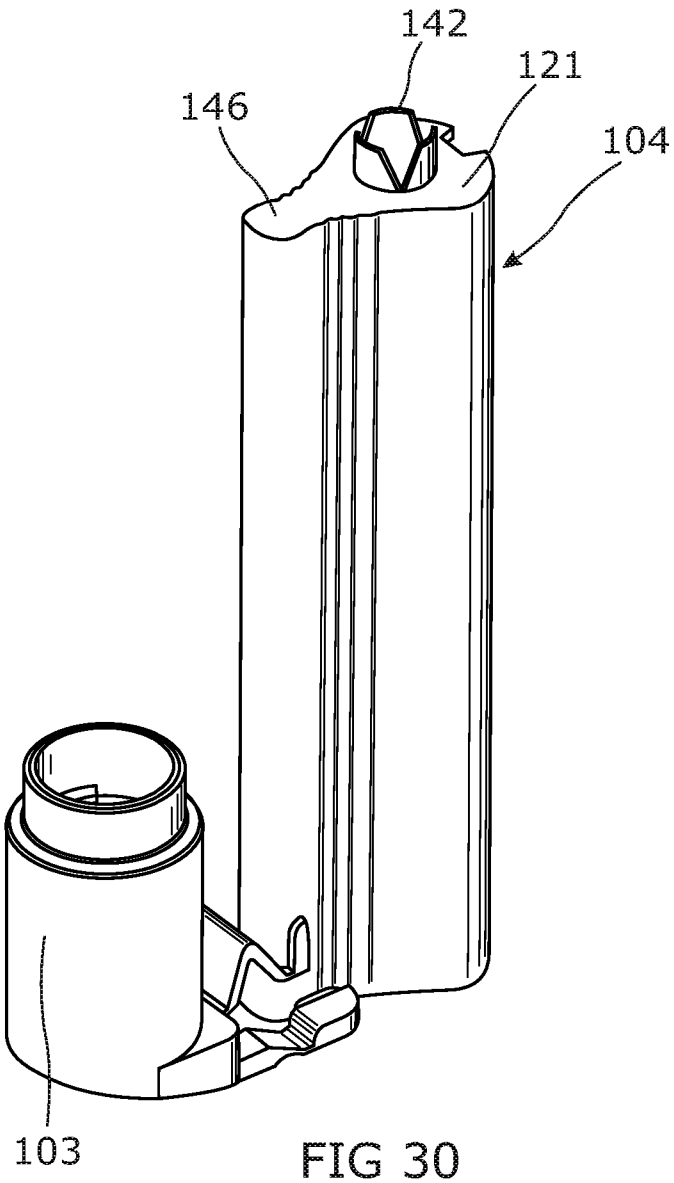

FIG 30

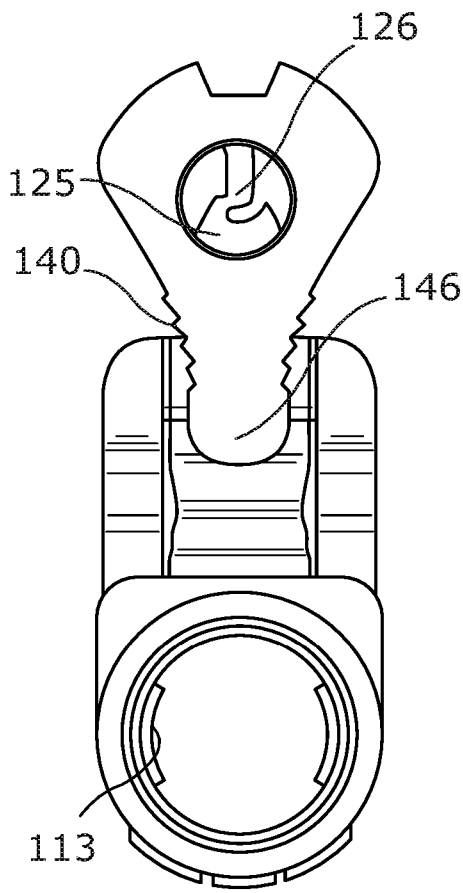

FIG 31