(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 November 2006 (23.11.2006)

PCT

(10) International Publication Number
WO 2006/123251 A2

(51) International Patent Classification:
A61M 5/46 (2006.01) *A61M 5/32* (2006.01)

(21) International Application Number:
PCT/IB2006/001709

(22) International Filing Date: 20 April 2006 (20.04.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
05.03963 20 April 2005 (20.04.2005) FR

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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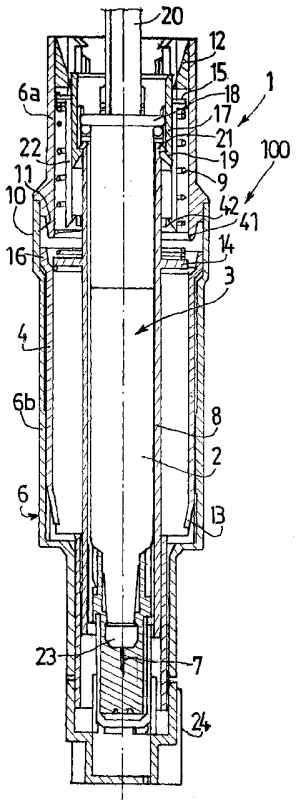
(54) Title: INJECTION ASSISTANCE DEVICE FOR CONTROL OF NEEDLE INSERTION DEPTH



(57) Abstract: The invention relates to an injection assistance device (1) for an injection device (3) for administering via injection a product (25) into an injection site (25), comprising a body (2) a needle (7) a piston plunger (26), comprising at least -grasping means (6) receiving the body (2), and being arranged in such a way as to allow the axial mobility of said body (2) relative to said grasping means (6) from an initial position to an insertion position, -first retaining means (14, 16) of said body (2) in its initial position, -first deactivating means (11, 16) arranged in such a way as to deactivate said first retaining means (14, 16; 29, 36) and allow the movement of said body (2) to its insertion position, characterized in that it further comprises: -actuating means (4), for causing the deactivation of the first retaining means (14, 16), and -first coupling means (20) for causing translation of said piston plunger (26) and performing injection of said product (25).

WO 2006/123251 A2

Published:

— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Injection assistance device for control of needle insertion depth

The present invention relates to an injection assistance device for an injection device, in the administration of a product via injection, and to an injection set provided with the said assistance device, these devices allowing a product to be injected into an injection site.

In this application, the distal end of a component or of a device is to be understood as meaning the end furthest from the user's hand and the proximal end is to be understood as meaning the end closest to the user's hand. Likewise, in this application, the "distal direction" is to be understood as meaning the direction of injection, and the "proximal direction" is to be understood as meaning the opposite direction to the direction of injection.

In order to administer a product, for example a medicinal product, to a body, particularly the human body, there are various possible routes depending on the place in the body at which the said product is to be injected: thus, the product may be injected intravenously, intramuscularly, subcutaneously, into a joint, or else intradermally. In many of these latter cases, and, particularly when injecting subcutaneously, the depth to which the needle is inserted and therefore at which the product is injected is particularly significant. Thus, it is possible to observe an adverse immunological reaction if, for example, a product that should have been injected into the subcutaneous tissues is finally injected into the intradermal tissues.

The operation of injecting a product using a syringe is therefore particularly delicate. The patient may make an unforeseen movement or alternatively the person administering the injection might make a wrong move. Thus, errors in the depth to which the needle is inserted are particularly difficult to avoid and discrepancies of less than one millimetre may, themselves alone, lead to errors in injection depth that may have dramatic consequences.

Likewise, once the needle has been inserted, it is important to guarantee that the insertion depth is maintained throughout the injecting of the product so as to guarantee the correct injection depth during the whole injection.

As far as subcutaneous injection is concerned, there are various injection techniques currently used. Some users prefer to pinch the skin before inserting the needles, others prefer not to, and still others angle the syringe before inserting it into the skin, it being possible for this angle to vary from one

user to another. The result of all this is that the depth to which the needle is inserted and therefore at which the product is injected may itself also vary from an injection to another, with the unpleasant consequences mentioned above.

Furthermore, in this kind of operation, it is also important to avoid any needlestick injury due to the exposed needle, whether this being before or after injection. It is also important that the protection system of the needle be not triggered before the end of injection.

In addition, to limit the apprehension felt by the patient, particularly in the case of injections administered by the patient himself, it is desirable for the administration device not to look like a conventional syringe and/or for the needle not to be visible or to be visible only a little prior to insertion.

Finally, administering a product using traditional injection devices generally entails at least two manual steps. For example, in the case of syringes, one manual step is to hold the body of the syringe in order to insert the needle into the injection site, another step consists in pressing on the piston rod in order to administer the injection, the progression from one step to the other generally entailing moving the fingers with respect to the syringe.

Moreover, it is important that the user be able to adjust the dose to be injected before proceeding with any injection step and/or to perform a vein test to prevent injection in the vein.

There therefore remains a need for an administration via injection assistance device and for an injection set which are made safe, that is to say which make it possible to insure a predetermined insertion depth, to limit the impact of undesired movements of the patient and/or of the user in order to prevent a variation in the depth to which the needle is inserted when administering the injection so as to avoid unintentionally injecting the said product at an inadequate depth, to limit the number of manipulations to be carried out by the user, to limit the risk of needlestick injury both to the patient and to the person administering the injection, to limit the apprehension felt by the patient and to make the giving of the administration via injection easier and to allow the dose adjustment of the product to be injected.

There also remains a need for such an administration via injection assistance device and an injection set that allow the user to be certain of causing the needle to penetrate the injection site to a predetermined insertion depth and, in addition, guarantee that the injection of the product is administered at a corresponding predetermined depth.

The present invention remedies these needs by proposing an injection assistance device for an injection device for administering via injection a product into an injection site, this injection device comprising at least :

- one hollow body intended to receive a product that is to be injected, and provided at its distal end with at least one hollow injection needle intended to penetrate the injection site,

- one piston plunger housed in said body, said piston plunger being able to be moved in axial translation with respect to said body, in order to push said product towards said distal end of said body and thus realize injection,

- grasping means intended to receive, at least partially, said body, and being arranged in such a way as to allow the axial mobility of said body relative to said grasping means from an initial position, in which said needle is not exposed over the totality of its insertion length, to an insertion position, distally spaced relative to said initial position, in which said needle is exposed by a predetermined insertion length L, said grasping means being coupled to at least first elastic return means aiming at moving said body at least from its initial position to its insertion position,

- first retaining means of said body in its initial position,

- first deactivating means arranged in such a way as to deactivate said first retaining means and allow the movement of said body to its insertion position,

characterized in that it further comprises at least:

- actuating means provided with a bearing surface intended to bear on said injection site, said actuating means being able to, under the action of a distal force exerted on said grasping means, move relative to said grasping means from at least a rest position to a bearing position, proximally spaced relative to said rest position, and cause, during this movement, via the first deactivation means, the deactivation of the first retaining means, and

- first coupling means, designed to be coupled to said piston plunger and to be manually operated so as to cause said axial translation of said piston plunger in said body and thereby perform the injection of said product.

The injection assistance device according to the invention allows the administration of the product via injection in a minimum number of actions, particularly disposing with the manual step of inserting the needle into the injection site described above. Thus, the administration of the product is made

easier, the step of inserting the needle in particular being done automatically, without the user having to complete any other operation than apply and press the assistance device on the injection site.

The assistance device according to the invention further makes it possible to control and maintain the insertion depth of the needle in the injection site during the injection, and then to avoid any risk of error of administration depth of the product. Moreover, because the automatic triggering of the insertion step is not dependent on any coupling means with the piston plunger, like for example a plunger rod which movement would trigger the automatic insertion, the user may move the piston plunger before or during the injection without any consequences on the triggering of said insertion step. This assistance device therefore makes it possible to purge the injection device before use, to complete a vein test, or to inject only a part of the product contained in the body of the injection device or to adjust the dose before injection.

Moreover, in the injection assistance device of the invention, the final protection means can be automatically triggered by withdrawal of said injection assistance device from the patient skin, preferably at the end of injection.

In an embodiment of the invention, the injection assistance device is arranged in such a way that, in the insertion position, said grasping means are separated from said body, or from an element coupled to said body at least in said insertion position, by a gap that allows the said grasping means to move with respect to said body, when distal pressure exerted on said grasping means is released.

In an embodiment of the invention, the injection assistance device is arranged in such a way that, in the insertion position, said grasping means are separated from said body, or from an element coupled to said body at least in said insertion position, by a space that allows the said grasping means to move with respect to said body, when distal pressure exerted on said grasping means is increased.

In an embodiment of the invention, the injection assistance device further comprises at least:

- protection means intended to receive, at least partially, said body, and being arranged in such a way as to allow the axial mobility of said body relative to said protection means at least from an injection position, in which

said needle is exposed, and a protection position, in which said protection means covers at least partially said needle,

- said protection means being coupled to second elastic return means aiming at moving said protection means from said injection position to said protection position,

- second retaining means of said protection means in its injection position,

- second deactivating means arranged in such a way as to be able to deactivate said second retaining means and authorize the movement of said protection means from its injection position to its protection position.

Preferably, said second deactivating means are designed to deactivate said second retaining means under release of said distal force exerted on said grasping means against the injection site.

In an embodiment of the invention, said second deactivating means are designed to deactivate said second retaining means under additional distal pressure applied on the plunger rod at the end of the injection.

In an embodiment of the invention, the injection assistance device further comprises first arresting means designed to prevent the translation of said body in the proximal direction within said grasping means, when said body is in its insertion or protection positions.

Preferably, said first arresting means comprises at least one flexible projection located on said grasping means or linked to said body, said flexible projection allowing, by its deformation, the passage in the distal direction of said body from its initial position of said body to its insertion position and preventing its return in the proximal direction when said body is in the insertion position.

In an embodiment of the invention, the injection assistance device further comprises at least one ring receiving at least partially the proximal region of said body, said ring being coupled to said body and being movable with respect to said grasping means, at least one of said ring and grasping means comprising said flexible projection.

In an embodiment of the invention, said second retaining means are being formed partly on said ring and partly on said protection means, and said second deactivating means are being formed partly on said ring and partly on said grasping means.

In an embodiment of the invention, said second retaining means are being formed partly on said ring and partly on said protection means, and said second deactivating means are being formed partly on said ring and partly on said first coupling means.

Preferably, said second retaining means comprise at least one flexible teeth, formed on said ring or protection means, and at least one stop, formed respectively on said protection means or ring, said flexible teeth being engaged in said stop in the injection position of said protection means.

In an embodiment of the invention, said second deactivation means comprise at least a second angled abutting surface on said grasping means, said second angled abutting surface cooperating with said flexible teeth, when distal force exerted on said grasping means is released and spring pushes the ring distally, so as to allow deformation of said flexible teeth and disengage said flexible teeth from said stop, thereby freeing said protection means.

In an embodiment of the invention, said second deactivation means comprise at least a second angled abutting surface on said first coupling means, said second angled abutting surface cooperating with said flexible teeth, when distal force exerted on said first coupling means is increased, so as to allow deformation of said flexible teeth and disengage said flexible teeth from said stop, thereby freeing said protection means.

In an embodiment of the invention, said protection means being coupled to said body at least from the initial position to the insertion position of said body, said first retaining means are formed partly on said protection means and partly on said actuating means, and said first deactivating means are formed partly on said grasping means and partly on said actuating means.

In an embodiment of the invention, said first retaining means are formed partly by said grasping means and by said ring, and said first deactivating means are formed partly by said actuating means and by said grasping means or ring.

In an embodiment of the invention, said first retaining means comprise at least a flexible leg and a radial rim, said flexible leg being engaged in said radial rim in the initial position of said body, and

- said first deactivating means comprise at least a first angled abutting surface formed on said grasping means, said first angled abutting surface cooperating with said flexible leg when distal force is exerted on said grasping means, so as to allow the deformation of said flexible leg and the

disengagement of said flexible leg from said radial rim, thereby freeing said body and realizing insertion.

In an embodiment of the invention, said flexible leg is formed on said actuating means or on said protection means and radial rim is formed respectively on said protection means or on said actuating means.

In an embodiment of the invention, the injection assistance device comprises an inner sleeve designed to receive said body, said inner sleeve being movable in regards to said actuating means, said flexible leg being formed on said actuating means or on said inner sleeve and radial rim being formed respectively on said inner sleeve or on said actuating means.

In an embodiment of the invention, said grasping means is elongated in the distal direction, so as to cover said protection means, at least in the initial and insertion positions.

In an embodiment of the invention, the injection assistance device further comprises at least:

- locking means of said second deactivating means, arranged in such a way as to prevent the triggering of said second deactivating means in the injection position, at least part of said locking means being movable within said actuating means from a locked position to an unlocked position,
- releasing means arranged in such a way as to release said locking means under the effect of a manual force exerted on said first coupling means at the end of injection,
- third elastic return means aiming at moving part of said locking means from its locked position to its unlocked position.

In an embodiment of the invention, the injection assistance device further comprises :

- at least one ring receiving at least partially the proximal region of said body, said ring being coupled to said body and being movable with respect to said grasping means,
- at least one annular rim coupled to said ring at least from the initial position to the insertion position of said body,
- said actuating means and said protection means being confounded as a single sleeve said first retaining means are formed partly on said grasping means and partly by said annular rim, and said first deactivating means are formed partly on said sleeve and partly on said grasping means.

In an embodiment of the invention, said first retaining means are under the form of at least one flexible leg formed on said grasping means and said annular rim, said flexible leg being engaged in said annular rim in the initial position of said body, and

- said first deactivating means are under the form of a projection formed at the distal end of said sleeve, said projection cooperating with said flexible leg when distal force is exerted on said grasping means, so as to allow the deformation of said flexible leg and the disengagement of said flexible leg from said annular rim, thereby freeing said ring coupled to said body and realizing insertion.

In an embodiment of the invention, said locking means are formed partly on said ring and partly by said annular rim, and said releasing means are formed partly on said ring and partly on said first coupling means.

In an embodiment of the invention, said locking means is under the form of said annular rim and at least one flexible skirt formed on said ring, said flexible skirt being engaged in said annular rim in the injection position, and said releasing means is under the form of a distal skirt formed on said first coupling means, said distal skirt cooperating with said flexible skirt under the action of a distal force exerted on said first coupling means at the end of injection, so as to deform said flexible skirt and disengage said flexible skirt from said annular rim and thereby unlock said second deactivating means and authorize their further triggering by release of said distal force exerted on said grasping means.

In an embodiment of the invention, the injection assistance device further comprises :

- second coupling means being designed for coupling said first coupling means to said ring at least from said end of injection position to said protection position,

- at least one gasket, said gasket being coupled to said first coupling means from said end of injection position to said protection position,

- said second retaining means being formed partly by said gasket and partly on said grasping means,

- said second deactivating means being formed partly on said first coupling means and partly on said grasping means.

In an embodiment of the invention, said second retaining means are under the form of said gasket and of a flexible teeth formed at the proximal

end of said grasping means, said gasket being engaged in said flexible teeth in said end of injection position,

- said second deactivating means comprise a bevel formed on said first coupling means, said bevel cooperating with said flexible teeth, under release of said distal force exerted on said grasping means, so as to deform said flexible teeth and disengage said gasket from said flexible teeth, thereby releasing said second retaining means and allowing said protection means to move in its protection position.

In an embodiment of the invention, said first elastic return means and said second elastic return means are under the form of a single helicoïdal spring.

In an embodiment of the invention, said first elastic return means, said second elastic return means and said third elastic return means are under the form of a single helicoïdal spring.

In an embodiment of the invention, the injection assistance device further comprises second arresting means designed for at least limiting the translation of said protection means with respect to said body, in the protection position.

The present invention also relates to an injection set for injecting a product into an injection site, the said injection set comprising at least:

- an injection device comprising at least:

- a hollow body intended to receive a product that is to be injected, the said body being equipped with a hollow injection needle intended, during a first phase known as the insertion phase, to penetrate an injection site and, during a second phase known as the injection phase, to channel the said product from the said body towards the said injection site,

- at least one piston plunger housed in a more or less sealed manner in the said body and intended to be moved in the distal direction by movement means in the said injection phase during which it drives the said product through the said needle,

characterized in that it comprises at least an injection assistance device for assisting with the injection device as described hereinabove.

In one embodiment of the invention, the injection set is in the form of a kit that can be assembled prior to use.

The advantages and different embodiments of the invention will appear more clearly from the description that follows and from the accompanying drawings in which :

- figures 1 to 6 are side cross section views of an injection assistance device according to the invention in the following respective positions: before use, before insertion, before insertion with the deactivation of the first retaining means, 1 in the insertion position, in the insertion position with the deactivation of the second retaining means, in the protection position,

- figures 7 to 9 are a cross section views of a variant of an injection assistance device of the invention in the following respective positions: before use, in the insertion position, in the insertion position showing the release of the locking means, in the insertion position at the moment of the deactivation of the second retaining means,

- figure 11 is a cross section view of figure 10 along line AA,

- figure 12 is a cross section view of the injection assistance device of figure 7 in the protection position.

In reference to figures 1 to 6, is represented an injection assistance device 1 according to the invention, intended to be used with an injection device 3 for administering via injection a product 25 into an injection site 27. The injection device 3 comprises a hollow body 2 for receiving the product 25 to be injected. The body 2 is provided at its tip 23 with an injection needle 7 intended to penetrate the injection site 27 as shown on figure 4.

A piston plunger 26, as shown on figure 2, is housed in the body 2, said piston plunger 26 being able to be moved, by a plunger rod 20, in the example shown, in axial translation with respect to said body 2, in order to push said product 25 towards the distal end of said body 2 and therefore realize injection, as shown on figures 4 and 5.

The injection assistance device 1 of figures 1 to 6 comprises grasping means, under the form of an outer sleeve 6 in the example shown, which receives the body 2. In the example shown on figures 1 to 6, the outer sleeve 6 is made of two parts, a proximal part 6a and a distal part 6b but alternatively said outer sleeve 6 could be one single integral part. Said body 2 is axially movable relative to said outer sleeve 6 from an initial position, in which the needle 7 is not exposed over the totality of its length, as shown on figures 1-3, to an insertion position, distally spaced relative to said initial

position, in which said needle 7 is exposed by a predetermined insertion length L, as shown on figure 4.

The outer sleeve 6 comprises, more or less in its middle region on the example shown, a portion of larger diameter 10 defining an inner recess 11, first angled abutting surfaces 41 and second angled abutting surfaces 42. Said outer sleeve 6 further comprises at least two flexible projections 12 defined on the inner wall of its proximal end.

The injection assistance device 1 of figures 1 to 6 further comprises actuating means, represented by an intermediate sleeve 4 in the example shown. Said intermediate sleeve 4 is received within said outer sleeve 6 and comprises a bearing surface 5 at its distal end, said bearing surface 5 being intended to bear on the injection site 27 as shown on figure 3. Said intermediate sleeve 4 is able to move relative to said outer sleeve 6 from a rest position, shown on figure 2 to a bearing position, as shown on figure 3.

The intermediate sleeve 4 is provided at its distal end with at least two flexible legs 13 and at its proximal end with at least two other flexible legs 16, which, in the initial position, bear on the inner wall of said outer sleeve 6 and, in the rest position, cooperate with said first angled abutting surfaces 41. The function of these legs will be explained hereinbelow.

The injection assistance device 1 of figures 1 to 6 further comprises an inner sleeve 8 received within said intermediate sleeve 4. Said inner sleeve 8 is able to move axially relative to said body 2 from an injection position, in which the needle 7 is exposed, as shown on figure 4, to a protection position, in which said inner sleeve 8 covers said needle 7, as shown on figure 6.

In the insertion and injection positions shown on figures 1 to 5, said inner sleeve 8 is coupled to said body 2 by means of a ring 17 in which a proximal flange 18 of said body 2 is clipped. The ring 17 comprises, at its distal end, at least two flexible teeth 19 which are engaged in at least two corresponding stops 21 formed at the proximal end of said inner sleeve 8, from the initial position to the insertion position, as shown on figures 1 to 4. In the initial position as shown on figure 1, said flexible teeth 19 bear radially on an inner longitudinal wall 22 formed on the outer sleeve 6. In the rest position flexible teeth 19 are designed to cooperate with said second angled abutting surfaces 42 as explained hereinbelow.

The inner sleeve 8 comprises a radial rim 14 formed on its outer surface. As shown on figure 1, an helicoïdal spring 9 is placed between the

outer sleeve 6 and the inner sleeve 8 : in the initial position, as shown on figure 1, said spring 9 is under tension, its proximal end bearing on a radial stop 15 formed on the inner wall of the proximal part 6a of said outer sleeve 6 and its distal end bearing on said radial rim 14 of the inner sleeve 8.

The injection operation will now be explained in reference to figures 1 to 6.

The user is provided with the assistance injection device 1 of the invention as shown on figure 1. In this position, the needle 7 is preferably covered by a protection cap 24 that the user removes before use. In this initial position, the body 2 is clipped in the ring 17 via its flange 18, said ring 17 being engaged with the inner sleeve 8 by engagement of its flexible teeth 19 in said stops 21 of the inner sleeve 8.

The body 2 is therefore maintained in its initial position by engagement of said radial rim 14 of the inner sleeve 8 with the flexible legs 16 of said intermediate sleeve 4, under the action of said helicoïdal spring 9 which is under tension, said flexible legs 16 bearing radially on the inner wall of said outer sleeve 6.

Once the user has removed the protection cap 24, he can purge the injection device 3 by holding the injection assistance device 1 and pushing distally on the plunger rod 20. Once the purge is done, the user can carry on the distal movement of the plunger rod 20 to adjust the dose to be injected by expelling the product 25 in excess.

In order to perfom the injection, the user grasps the injection assistance device 1 via the outer sleeve 6 and he applies said injection assistance device 1 on the injection site 27 via the bearing surface 5 of said intermediate sleeve 4, as shown on figure 2. In this position, the needle 7 is covered by said intermediate sleeve 4.

As shown on figure 3, the user further exerts a distal force on said outer sleve 6, causing the intermediate sleeve 4 to move proximally relative to said outer sleeve 6, from a rest position, shown on figure 2, to a bearing position, shown on figure 3. This movement causes the distal translation of the recess 11 relative to said intermediate sleeve 4 and the flexible legs 16 are then deformed radially in the outward direction by said angled abutting surfaces 41, thereby freeing the radial rim 14, as shown on figure 3. The radial rim 14 is pushed distally by the spring 9, which tends to come back to its rest position, drawing altogether the inner sleeve 8, the ring 17 and the body 2, until the tip

23 of said body 2 enters in contact with the injection site 27, realizing the insertion of the needle 7 as shown on figure 4. In this insertion position, the needle 7 is inserted in the injection site 27 on a predetermined length L and the insertion depth L is directly linked with the length of the needle 7.

In another first embodiment not shown of the invention, the intermediate sleeve 4 is provided with internal abutments designed to stop the inner sleeve 8 in the insertion position before contact of the tip 23 with the injection site 27. In this case, the insertion depth L is not directly linked with the needle length.

In another second embodiment not shown of the invention, during the injection, the extremity of the inner sleeve 8 is in contact with the injection site 27, allowing a gap between the injection site 27 and the tip 23. In this case, the insertion depth depends on the difference between this gap and the needle 7 length.

According to figure 3, during the distal movement of the inner sleeve 8, the ring 17 and the body 2, the flexible projections 12 have allowed the passage in the distal direction of the ring 17. As shown on figure 4, the return of the ring 17 and by consequence of the body 2 in the proximal direction is now hindered by the distal surfaces of the flexible projections 12 : this allows the user to complete a vein test, that is to say to check whether the needle 7 is in contact with a vein or not, by withdrawing the plunger rod 20 to determine whether some blood is drawn or not, without having to remove the needle 7 from the injection site 27.

The automatic insertion of the needle 7 according to the invention allows a reproductible length of insertion. The handling of the injection assistance device 1 is very simple for the user who does not have to check manually the insertion length.

As can be seen from figure 4, a gap 201 is present between the ring 17 and the second angled abutting surfaces 42. Moreover, the spring 9 is in a partially expanded state.

As seen before, the automatic insertion of the needle 7 according to the invention allows a reproductible insertion length L. The handling of the injection assistance device 1 is very simple for the user who does not have to check manually the insertion length L.

Once the needle 7 is inserted, the combination of the gap 201 (see figure 4) between the ring 17 and the second angled abuting surfaces 42 plus

the remaining possible extension of the spring 9 prevent the needle insertion length L modification, if the user inadvertantly slightly removes the pressure on the outer sleeve 6. This enables to ensure the injection of the product 25 at the right insertion depth L.

On the contrary, if during the injection step, the user increases the distal pressure he exerts on the outer sleeve 6 when applying it on the injection site 27, causing thereby a limited distal movement of said outer sleeve 6, then the spring 9, because it is in a partially expanded state and thanks to the presence of the space 202 (see figure 4) between the radial stop 15 of the outer sleeve 6 and the radial rim 14 of the inner sleeve 8, coupled to the body 2, is allowed to dampen said distal movement by being compressed, thereby maintaining the needle 7 at a constant insertion length, namely its predetermined insertion length L.

The influence of any increase or release of the distal pressure exerted by the user on the outer sleeve 6 during the injection step is therefore neutralized by the presence of the spring 9 in a partially expanded state.

After the needle 7 is inserted, the user proceeds manually with the injection of the product 25 by pushing distally on the plunger rod 20.

According to the injection assistance device 1 shown on figures 1 to 6, in order to adjust the dose of product 25 to be injected, the user may decide to stop the injection at any time without taking any risk of accidental needlestick injury when he removes the injection assistance device 1 from the injection site 27.

Indeed, when the user has decided that enough product 25 is injected, or at the end of injection, as shown on figure 5, the user removes the injection assistance device 1 from the site of injection 27. By this action, the tip 23 of said body 2 is no longer retained by the injection site 27. The body 2, which is coupled to the ring 17 and to the inner sleeve 8 is therefore drawn distally under the action of the spring 9, which tends to come back to its rest position. During this distal translation, the flexible teeth 19 move distally with respect to said inner longitudinal wall 22 of said outer sleeve 6, until they contact the second angled abutting surfaces 42. Then, the flexible teeth 19 are deformed radially in the outward direction by the second angled abutting surfaces 42, as shown on figure 5, and they free said stops 21 in which they were previously engaged.

The inner sleeve 8 is therefore released from said ring 17 and said body 2, and is drawn distally by said spring 9, which tends to come back to its rest position, until said inner sleeve 8 covers the needle 7, thereby realizing the protection of said needle 7, as shown on figure 6.

As described before, with the injection assistance device 1, the user does not have necessarily to inject all the product 25 remaining in the body after the purge to ensure that the needle 7 will be automatically covered by the inner sleeve. Indeed, the triggering of the safety features does not rely on the displacement of the plunger rod 20.

In the protection position, as shown on figure 6, the inner sleeve 8 is prevented from returning back in the proximal direction by means of flexible legs 13 of the intermediate sleeve 4 which are engaged with said radial rim 14, the intermediate sleeve 4 abutting againts the proximal part of the outer sleeve 6.

The injection assistance device 1 is therefore perfectly safe for the user and risks of accidental needlestick injuries are prevented.

In reference to figures 7 to 12, is represented another variant of an injection assistance device 1 according to the invention. The references designating the same elements as in figures 1 to 6 have been maintained. The injection assistance device 1 of figures 7-12 is intended to be used with an injection device 3 for injecting a product 25 into an injection site 27. The injection device 3 comprises a hollow body 2 for receiving the product 25 to be injected. The body 2 is provided at its tip 23 with an injection needle 7 intended to penetrate the injection site 27 as shown on figure 8.

A piston plunger 26 is housed in the body 2, said piston plunger 26 being able to be moved, by a plunger rod 20, in the example shown, in axial translation with respect to said body 2, in order to push said product 25 towards the tip 23 of said body 2 and therefore realize injection, as shown on figures 8 and 9.

The injection assistance device 1 of figures 7 to 12 comprises an outer sleeve 28 which partially receives the body 2. Said body 2 is axially movable relative to said outer sleeve 28 from an initial position, in which the needle 7 is not exposed, as shown on figure 7, to an insertion position, distally spaced relative to said initial position, in which said needle 7 is exposed by a predetermined insertion length L, as shown on figures 8 and 9.

The outer sleeve 28 is formed of a single piece having a proximal region 28a and a distal region 28b. The distal end of said proximal region 28a is provided with at least two flexible legs 29 and the proximal end of said proximal region 28a is provided with at least two flexible teeth 30 shown on figure 11.

The injection assistance device 1 of figures 7 to 12 further comprises an inner sleeve 31, having a proximal region 31a and a distal region 31b of lesser diameter than said proximal region 31a, said proximal region 31a being connected to said distal region 31b by a radial wall 31c. Said proximal region 31a is received partially within said outer sleeve 28 and comprises, at its proximal end, two proximal projections 32. Said inner sleeve 31 comprises a bearing surface 5 at the distal end of its distal region 31b, said bearing surface 5 being intended to bear on the injection site 27 as shown on figures 8 and 9.

Said inner sleeve 31 is able to move relative to said outer sleeve 28 from a rest position, shown on figure 7 to a bearing position, as shown on figure 8.

The inner sleeve 31 is able to move axially relative to said body 2 from an injection position, in which the needle 7 is exposed, as shown on figures 8 to 11, to a protection position, in which said inner sleeve 31 covers said needle 7, as shown on figure 12.

The injection assistance device 1 of figures 7 to 12 further comprises a ring 33 receiving partially the proximal region of said body 2, said ring 33 being coupled to said body 2 by means of two prongs (not shown) that clip a proximal flange 18 of said body 2.

Said ring 33 is provided with a flexible skirt 34 extending in the distal direction and able to be deformed radially, said flexible skirt 34 comprising at its distal end a outer radial rim 35.

Said ring 33 is prolongated toward the distal direction and surrounds the body 2.

The injection assistance device 1 of figures 7 to 12 further comprises an annular rim 36 which is coupled to said ring 33 at least from the initial position to the insertion position by contact on the radial rim 35.

The injection assistance device 1 of figures 7 to 12 also comprises a plunger rod 20, the distal end of which is screwed to said piston plunger 26. The plunger rod 20 is intended to be manually pushed in the distal direction to

cause the axial translation of said piston plunger 26 in said body 2 in the distal direction in order to realize injection.

Said plunger rod 20 comprises at its proximal end a head 37 provided with a distal skirt 38 extending longitudinally in the distal direction, the proximal end of said head 37 being provided with an outer bevel 39.

The injection assistance device 1 of figures 7 to 12 also comprises a gasket 40 which is coupled to said plunger rod 20 from the end of injection position to the protection position, as shown on figures 11 and 12.

An helicoïdal spring 9 is placed between the outer sleeve 28 and the ring 33 : in the initial position, as shown on figure 7, said spring 9 is under tension, its proximal end bearing on the distal surface of said gasket 40 and its distal end bearing on the proximal surface of said annular rim 36.

The injection operation will now be explained in reference to figures 7 to 12.

The injection assistance device 1 of the invention is provided to the user in its initial position shown on figure 7. In this initial position, the body 2 is clipped in the ring 33 via its flange 18. Said body 2 is therefore maintained in its initial position by the fact that said ring 33 is engaged with the outer sleeve 28 by cooperation of said flexible skirt 34, said annular rim 36, said flexible leg 29 and said spring 9.

As appears from figure 7, in the initial position, the needle 7 is covered by said inner sleeve 31, in particular by said distal region 31b of said inner sleve 31.

The user grasps the injection assistance device 1 by the outer sleeve 28, for example by its distal region 28b, and he applies said injection assistance device 1 on the injection site 27 via the bearing surface 5 of said inner sleeve 31.

As shown on figure 8, the user further exerts a distal force on said outer sleve 28, causing the inner sleeve 31 to move proximally relative to said outer sleeve 28, from a rest position, shown on figure 7, to a bearing position, shown on figure 8. This movement causes the distal translation of the flexible legs 29 which come in contact with said proximal projections 32 of said inner sleeve 31. The flexible legs 29 are therefore caused to deform radially in the outward direction, as shown on figure 8, thereby freeing the annular rim 36. The annular rim 36 is pushed distally by the spring 9, which tends to come back to its rest position, drawing with him the ring 33 and the body 2, until the tip 23

of said body 2 enters in contact with the injection site 27, realizing the insertion of the needle 7 as shown on figure 8. In this insertion position, the needle 7 is inserted in the patient on a predetermined insertion length L.

In another first embodiment of the invention not shown, the inner sleeve 31 is provided with internal abutments designed to stop the ring 33 in the insertion position before contact of the tip 23 with the injection site 27. In this case, the insertion depth L is not directly linked with the length of the needle 7.

In another second embodiment not shown of the invention, during the injection, the extremity of the inner sleeve 8 is in contact with the injection site 27, allowing a gap between the injection site 27 and the tip 23. In this case, the insertion depth L depends on the difference between this gap and the needle 7 length.

As seen before, the automatic insertion of the needle 7 according to the invention allows a reproductible insertion length L. The handling of the injection assistance device 1 is very simple for the user who does not have to check manually the insertion length L.

Once the needle 7 is inserted, the combination of the gap 201 between the outer sleeve 28 and the inner sleeve 31 plus the remaining possible extension of the spring 9 prevent the needle insertion length L modification, if the user inadvertantly slightly removes the pressure on the outer sleeve 28. This enables to ensure the injection of the product 25 at the right insertion depth L.

On the contrary, if during the injection step, the user increases the distal pressure he exerts on the outer sleeve 28 when applying it on the injection site 27, causing thereby a limited distal movement of said outer sleeve 28, then the spring 9, because it is in a partially expanded state and thanks to the presence of the space 202 between the flexible legs 29 and the inner sleeve 31, is allowed to dampen said distal movement by being compressed, thereby maintaining the needle 7 at a constant insertion length, namely its predetermined insertion length L.

The influence of any increase or release of the distal pressure exerted by the user on the outer sleeve 28 during injection is therefore neutralized by the presence of the spring 9 in a partially expanded state.

Once the needle 7 is inserted, the user proceeds manually with the injection of the product 25 by pushing distally on the plunger rod 20. As

appears from figure 8, the flexible skirt 34 of the ring 33 is engaged with said annular rim 36 during the totality of the injection operation : in this way, even if the user decides to remove the injection assistance device 1 from the injection site 27 before the end of injection, that is to say before said piston plunger 26 has finished its course at the distal end of said body 2, then, the inner sleeve 31 remains in its injection position and does not cover the needle 7, thus allowing the user to carry on the injection if desired.

At the end of injection, as shown on figure 9, when the piston plunger 26 comes in contact with the distal end of said body 2, the distal force exerted by the user on the plunger rod 20 causes the distal skirt 38 to come into contact with said flexible skirt 34 of said ring 33 and to deform radially in the inward direction said flexible skirt 34, thereby freeing said annular rim 36.

The annular rim 36 is pushed distally by the spring 9, which tends to come back to its rest position, until it is stopped by the proximal surface of the radial wall 31c connecting said proximal region 31a to said distal region 31b of said inner sleeve 31.

The user then maintains the outer sleeve 28 while continuing to apply a distal force on said plunger rod 20 as shown on figures 10 and 11. By this action, the bevels 39 of said plunger rod 20 come into contact with the flexible teeth 30 formed at the proximal end of said outer sleeve 28 and cause the radial deformation of said teeth in the outward direction, thereby freeing said gasket 40.

The user then removes the injection assistance device 1 from the injection site 27, as shown on figure 12. Said spring 9 then tends to come back to its rest position and pushes proximally on said gasket 40. Said gasket 40 pushes proximally on the head 37 of said plunger rod 20 which therefore draws said body 2 in the proximal direction, until said needle 7 is completely withdrawn within said inner sleeve 31 as shown on figure 12.

The injection assistance device 1 of the invention allows the administration of the product 25 via injection in a very safe way. Moreover, it makes it possible to control and maintain the insertion depth of the needle 7 in the injection site 27 during the injection.

In addition, the injection sets and the injection assistance devices according to the invention enable the user to adjust the dose to be injected before proceeding with any injection step and/or to perform a vein test to prevent injection in the vein.

Furthermore, with the first embodiment of the invention described, the injection sets and the injection assistance devices enable the user to not inject all the product 25 contained in the barrel before withdrawing the injection assistance device 1 from the injection site 27 and, despite the fact that the plunger rod 20 is not at the end of its course in the body 2, allow automatic triggering of the safety by said withdrawal.

CLAIMS

1. Injection assistance device (1) for an injection device (3) for administering via injection a product (25) into an injection site (27), this injection device (3) comprising at least:

- one hollow body (2) intended to receive a product (25) that is to be injected, and provided at its distal end (23) with at least one hollow injection needle (7) intended to penetrate the injection site (27),

- one piston plunger (26) housed in said body (2), said piston plunger (26) being able to be moved in axial translation with respect to said body (2), in order to push said product (25) towards said distal end (23) of said body (2) and thus realize injection,

- grasping means (6; 28) intended to receive, at least partially, said body (2), and being arranged in such a way as to allow the axial mobility of said body (2) relative to said grasping means (6; 28) at least from an initial position, in which said needle (7) is not exposed over the totality of its insertion length, to an insertion position, distally spaced relative to said initial position, in which said needle (7) is exposed by a predetermined insertion length L, said grasping means (6; 28) being coupled to at least first elastic return means (9) aiming at moving said body (2) at least from its initial position to its insertion position,

- first retaining means (14, 16; 29, 36) of said body (2) in its initial position,

- first deactivating means (11, 16; 29, 32) arranged in such a way as to deactivate said first retaining means (14, 16; 29, 36) and allow the movement of said body (2) to its insertion position,

characterized in that it further comprises at least:

- actuating means (4; 31) provided with a bearing surface (5) intended to bear on said injection site (27), said actuating means (4; 31) being able to, under the action of a distal force exerted on said grasping means (6; 28), move relative to said grasping means (6; 28) from at least a rest position to a bearing position, proximally spaced relative to said rest position, and cause, during this movement, via the first deactivation means (11, 16; 29, 32), the deactivation of the first retaining means (14, 16; 29, 36), and

- first coupling means (20), designed to be coupled to said piston plunger (26) and to be manually operated so as to cause said axial translation

of said piston plunger (26) in said body (2) and thereby perform the injection of said product (25).

2. Injection assistance device (1) according to claim 1, characterized in that it is arranged in such a way that, in the insertion position, said grasping means (6; 28) are separated from said body (2), or from an element (31) coupled to said body (2) at least in said insertion position, by a gap (201) that allows the said grasping means (6; 28) to move with respect to said body (2), when distal pressure exerted on said grasping means (6; 28) is released.

3. Injection assistance device (1) according to claim 2, characterized in that it is arranged in such a way that, in the insertion position, said grasping means (6; 28) are separated from said body (2) or from an element (31) coupled to said body (2) at least in said insertion position, by a space (202) that allows the said grasping means (6; 28) to move with respect to said body (2), when distal pressure exerted on said grasping means (6; 28) is increased.

4. Injection assistance device (1) according to any of the preceding claims, characterized in that it further comprises at least:

- protection means (8; 31) intended to receive, at least partially, said body (2), and being arranged in such a way as to allow the axial mobility of said body (2) relative to said protection means (8; 31) at least from an injection position, in which said needle (7) is exposed, and a protection position, in which said protection means (8; 31) covers at least partially said needle (7),
- said protection means (8; 31) being coupled to second elastic return means (9) aiming at moving said protection means (8; 31) from said injection position to said protection position,
- second retaining means (19, 21; 30, 40) of said protection means in its injection position,
- second deactivating means (19, 22; 30, 39) arranged in such a way as to be able to deactivate said second retaining means (19, 21; 30, 40) and authorize the movement of said protection means (8; 31) from its injection position to its protection position.

5. Injection assistance device (1) according to claim 4 characterized in that said second deactivating means (19, 22; 30, 39) are designed to deactivate said second retaining means (19, 21; 30, 40) under release of said

distal force exerted on said grasping means (6; 28) against the injection site (27).

6. Injection assistance device (1) according to claim 4 characterized in that said second deactivating means (19, 22; 30, 39) are designed to deactivate said second retaining means (19, 21; 30, 40) under additional distal pressure applied on the plunger rod (26) at the end of the injection.

7. Injection assistance device (1) according to claim 1, characterized in that it further comprises first arresting means (12) designed to prevent the translation of said body (2) in the proximal direction within said grasping means (6), when said body (2) is in its insertion or protection positions.

8. Injection assistance device (1) according to the preceding claim, characterized in that said first arresting means comprises at least one flexible projection (12) located on said grasping means (6) or linked to said body (2), said flexible projection (12) allowing, by its deformation, the passage in the distal direction of said body (2) from its initial position of said body (2) to its insertion position and preventing its return in the proximal direction when said body (2) is in the insertion position.

9. Injection assistance device (1) according to the preceding claim, characterized in that it further comprises at least one ring (17) receiving at least partially the proximal region of said body (2), said ring (17) being coupled to said body (2) and being movable with respect to said grasping means (6), at least one of said ring (17) and grasping means (6) comprising said flexible projection (12).

10. Injection assistance device (1) according to claim 8 characterized in that

- said second retaining means (19, 21) are being formed partly on said ring (17) and partly on said protection means (8), and
- said second deactivating means (19, 22) are being formed partly on said ring (17) and partly on said grasping means (6).

11. Injection assistance device (1) according to claim 8 characterized in that :

- said second retaining means (19, 21) are being formed partly on said ring (17) and partly on said protection means (8), and
- said second deactivating means (19, 22) are being formed partly on said ring (17) and partly on said first coupling means (20).

12. Injection assistance device (1) according to claim 10 or 11, characterized in that said second retaining means comprise at least one flexible teeth (19), formed on said ring (17) or protection means (8), and at least one stop (18), formed respectively on said protection means (8) or ring (17), said flexible teeth (19) being engaged in said stop (18) in the injection position of said protection means (8).

13. Injection assistance device (1) according to claims 10 and 12, characterized in that said second deactivation means (19, 22) comprise at least a second angled abutting surface (41) on said grasping means (6), said second angled abutting surface (41) cooperating with said flexible teeth (19), when distal force exerted on said grasping means (6) is released and spring (9) pushes the ring (17) distally, so as to allow deformation of said flexible teeth (19) and disengage said flexible teeth (19) from said stop (18), thereby freeing said protection means (8).

14. Injection assistance device (1) according to claims 11 and 12, characterized in that said second deactivation means (19, 22) comprise at least a second angled abutting surface (41) on said first coupling means (20), said second angled abutting surface (41) cooperating with said flexible teeth (19), when distal force exerted on said first coupling means (20) is increased, so as to allow deformation of said flexible teeth (19) and disengage said flexible teeth (19) from said stop (18), thereby freeing said protection means (8).

15. Injection assistance device (1) according to any of claims 4 to 14, characterized in that said protection means (8) being coupled to said body (2) at least from the initial position to the insertion position of said body (2), said first retaining means (14, 16) are formed partly on said protection means (8) and partly on said actuating means (4), and said first deactivating means (11, 16) are formed partly on said grasping means (6) and partly on said actuating means (4).

16. Injection assistance device (1) according to any of claims 4 to 14, characterized in that said first retaining means are formed partly by said grasping means (6, 28) and by said ring (17, 33), and said first deactivating means are formed partly by said actuating means (31) and by said grasping means (6, 28) or ring (17, 33).

17. Injection assistance device (1) according to claim 15 or 16, characterized in that said first retaining means comprise at least a flexible leg

(16) and a radial rim (14) , said flexible leg (16) being engaged in said radial rim (14) in the initial position of said body (2), and

- said first deactivating means comprise at least a first angled abutting surface (41) formed on said grasping means (6), said first angled abutting surface (41) cooperating with said flexible leg (16) when distal force is exerted on said grasping means (6), so as to allow the deformation of said flexible leg (16) and the disengagement of said flexible leg (16) from said radial rim (14), thereby freeing said body (2) and realizing insertion.

18. Injection assistance device (1) according to claims 17, characterized in that said flexible leg (16) is formed on said actuating means (4) or on said protection means (8) and radial rim (14) is formed respectively on said protection means (8) or on said actuating means (4).

19. Injection assistance device (1) according to claims 17, characterized in that it comprises an inner sleeve (8) designed to receive said body (2), said inner sleeve (8) being movable in regards to said actuating means (31), said flexible leg (16) being formed on said actuating means (4) or on said inner sleeve (8) and radial rim (14) being formed respectively on said inner sleeve (8) or on said actuating means (4).

20. Injection assistance device (1) according to any of claims 4 to 19, characterized in that said grasping means (6) is elongated in the distal direction, so as to cover said protection means (8), at least in the initial and insertion positions.

21. Injection assistance device (1) according to claim 4, characterized in that it further comprises at least:

- locking means (34, 36) of said second deactivating means (30, 39), arranged in such a way as to prevent the triggering of said second deactivating means (30, 39) in the injection position, at least part of said locking means (36) being movable within said actuating means (31) from a locked position to an unlocked position,

- releasing means (34, 38) arranged in such a way as to release said locking means (34, 36) under the effect of a manual force exerted on said first coupling means (20) at the end of injection,

- third elastic return means (9) aiming at moving part of said locking means (36) from its locked position to its unlocked position.

22. Injection assistance device (1) according to claim 21, characterized in that it further comprises :

- at least one ring (33) receiving at least partially the proximal region of said body (2), said ring (33) being coupled to said body (2) and being movable with respect to said grasping means (28),

- at least one annular rim (36) coupled to said ring (33) at least from the initial position to the insertion position of said body (2),

- said actuating means and said protection means being confounded as a single sleeve (31), said first retaining means are formed partly on said grasping means (28) and partly by said annular rim (36), and said first deactivating means are formed partly on said sleeve (31) and partly on said grasping means (28).

23. Injection assistance device (1) according to the preceding claim, characterized in that said first retaining means are under the form of at least one flexible leg (29) formed on said grasping means (28) and said annular rim (36), said flexible leg (29) being engaged in said annular rim (36) in the initial position of said body (2), and

- said first deactivating means are under the form of a projection (32) formed at the distal end of said sleeve (31), said projection (32) cooperating with said flexible leg (29) when distal force is exerted on said grasping means (28), so as to allow the deformation of said flexible leg (29) and the disengagement of said flexible leg (29) from said annular rim (36), thereby freeing said ring (33) coupled to said body (2) and realizing insertion.

24. Injection assistance device (1) according to the preceding claim, characterized in that,

- said locking means (34, 36) are formed partly on said ring (33) and partly by said annular rim (36), and

- said releasing means (34, 38) are formed partly on said ring (33) and partly on said first coupling means (20).

25. Injection assistance device (1) according to the preceding claim, characterized in that said locking means is under the form of said annular rim (36) and at least one flexible skirt (34) formed on said ring (33), said flexible skirt (34) being engaged in said annular rim (36) in the injection position, and

- said releasing means is under the form of a distal skirt (38) formed on said first coupling means (20), said distal skirt (38) cooperating with said flexible skirt (34) under the action of a distal force exerted on said first coupling means (20) at the end of injection, so as to deform said flexible skirt (34) and

disengage said flexible skirt (34) from said annular rim (36) and thereby unlock said second deactivating means (30, 39) and authorize their further triggering by release of said distal force exerted on said grasping means (28).

26. Injection assistance device (1) according to the preceding claim, characterized in that it further comprises :

- second coupling means being designed for coupling said first coupling means (20) to said ring (33) at least from said end of injection position to said protection position,

- at least one gasket (40), said gasket (40) being coupled to said first coupling means (20) from said end of injection position to said protection position,

- said second retaining means (30, 40) being formed partly by said gasket (40) and partly on said grasping means (28),

- said second deactivating means (30, 39) being formed partly on said first coupling means (20) and partly on said grasping means (28).

27. Injection assistance device (1) according to the preceding claim, characterized in that said second retaining means are under the form of said gasket (40) and of a flexible teeth (30) formed at the proximal end of said grasping means (28), said gasket (40) being engaged in said flexible teeth (30) in said end of injection position,

- said second deactivating means comprise a bevel (39) formed on said first coupling means (20), said bevel (39) cooperating with said flexible teeth (30), under release of said distal force exerted on said grasping means (28), so as to deform said flexible teeth (30) and disengage said gasket (40) from said flexible teeth (30), thereby releasing said second retaining means and allowing said protection means (31) to move in its protection position.

28. Injection assistance device (1) according to any of claims 4 to 28, characterized in that said first elastic return means and said second elastic return means are under the form of a single helicoïdal spring (9).

29. Injection assistance device (1) according to any of claims 21 to 28, characterized in that said first elastic return means, said second elastic return means and said third elastic return means are under the form of a single helicoïdal spring (9).

30. Injection assistance device (1) according to any of claims 4 to 29, characterized in that it further comprises second arresting means (13)

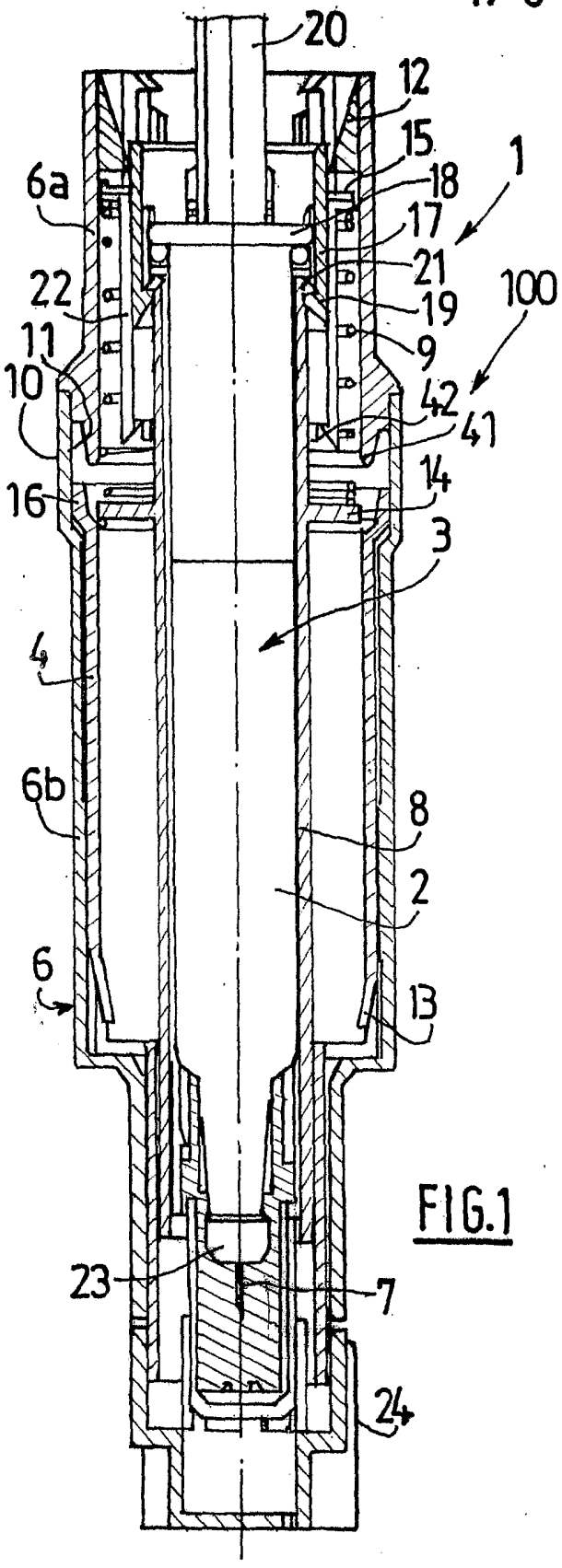
designed for at least limiting the translation of said protection means (8) with respect to said body (2), in the protection position.

31. Injection set (100) for injecting a product (25) into an injection site (27), the said injection set (100) comprising at least an injection device (3) comprising at least:

- a hollow body (2) intended to receive a product (25) that is to be injected, the said body (2) being equipped with a hollow injection needle (7) intended, during a first phase known as the insertion phase, to penetrate an injection site (27) and, during a second phase known as the injection phase, to channel the said product (25) from the said body (2) towards the said injection site (27),
- at least one piston plunger (26) housed in a more or less sealed manner in the said body (2) and intended to be moved in the distal direction by movement means in the said injection phase during which it drives the said product (25) through the said needle (7),

characterized in that it comprises at least an injection assistance device (1) for assisting with the injection device (3) according at least to Claim 1.

32. Injection set (100) according to Claim 31, characterized in that it is in the form of a kit that can be assembled prior to use.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100

FIG.1

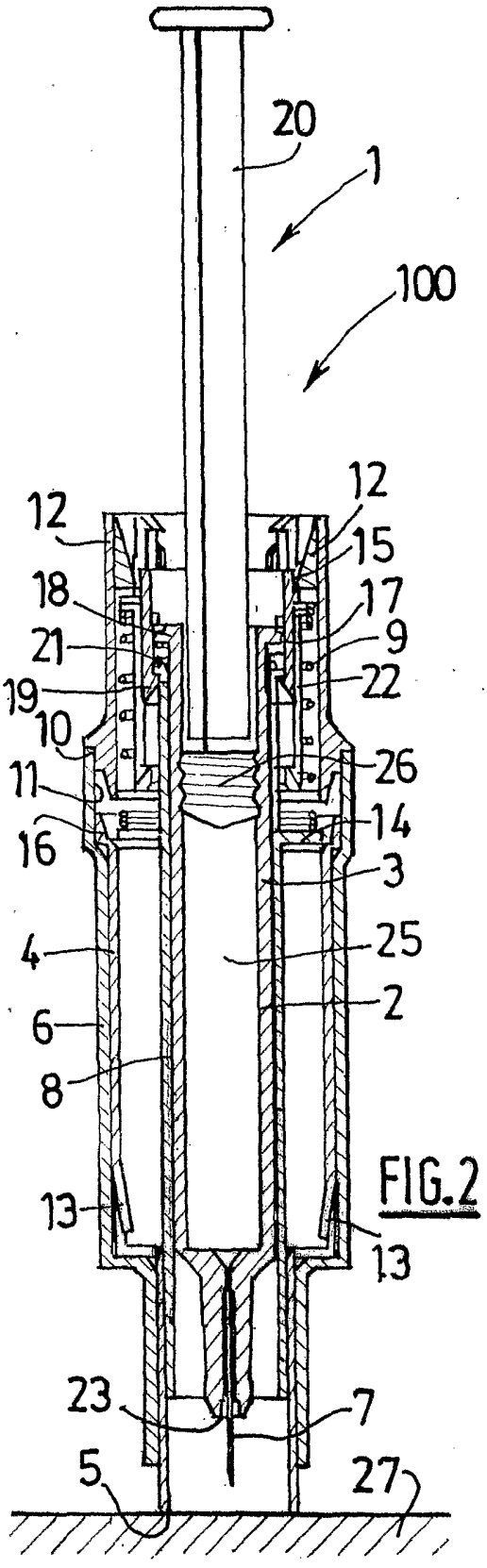
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FIG.2

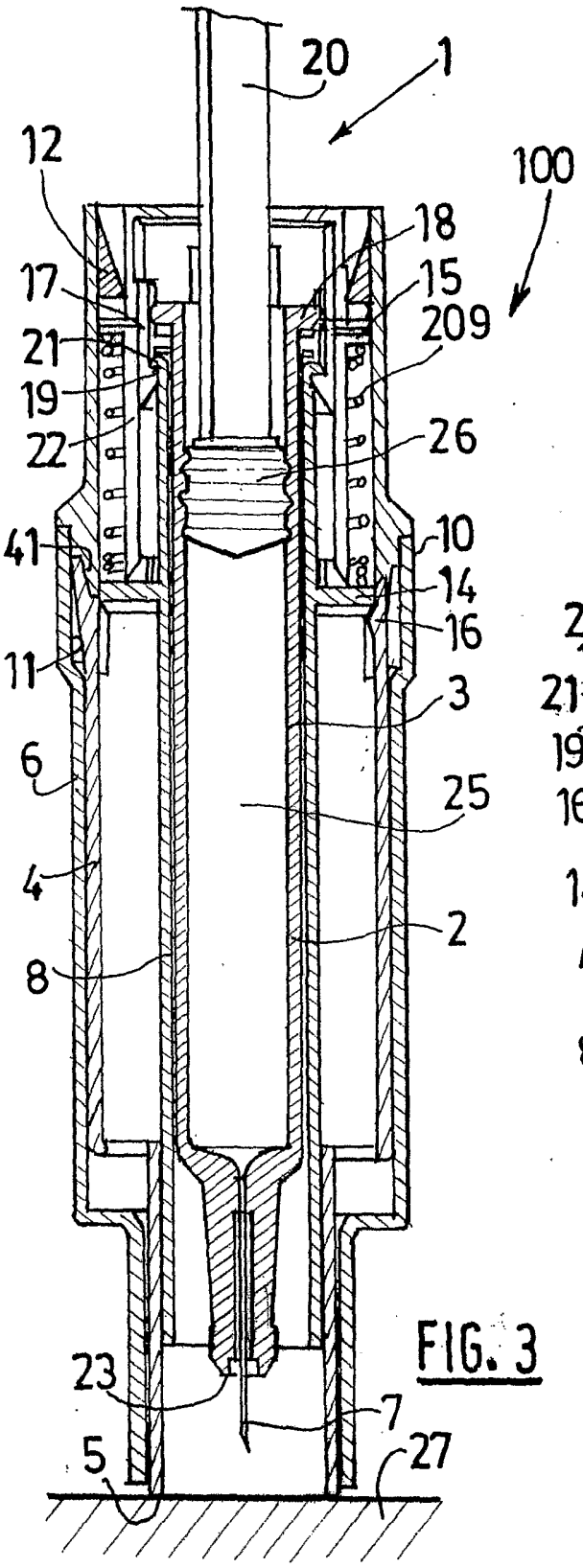
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FIG. 3

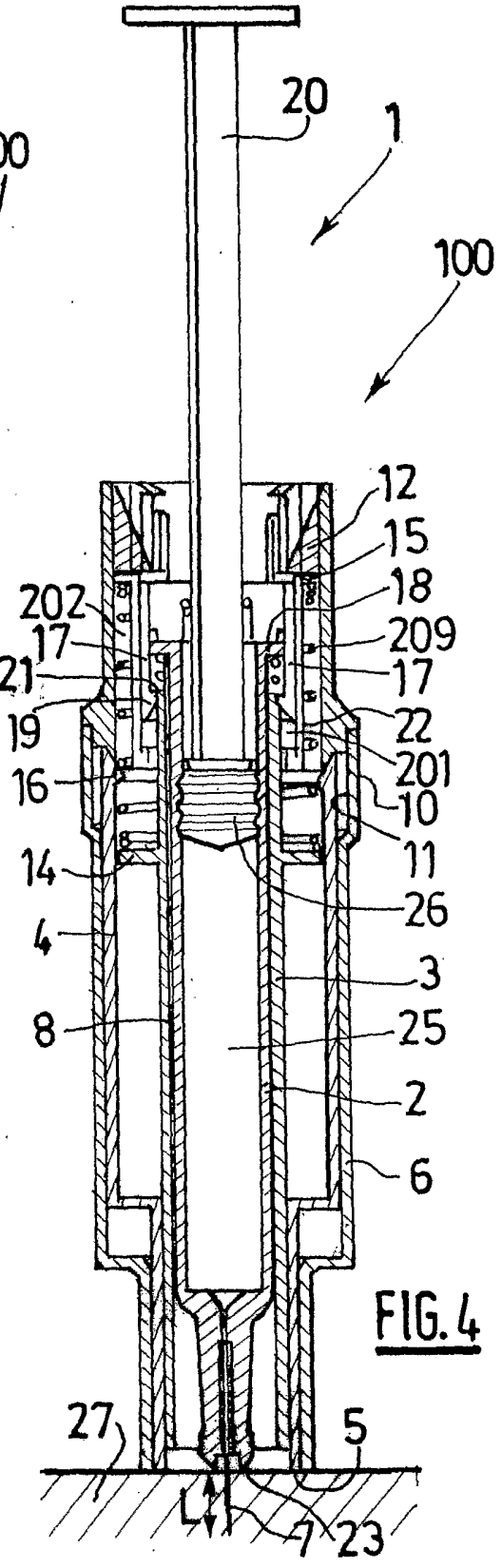
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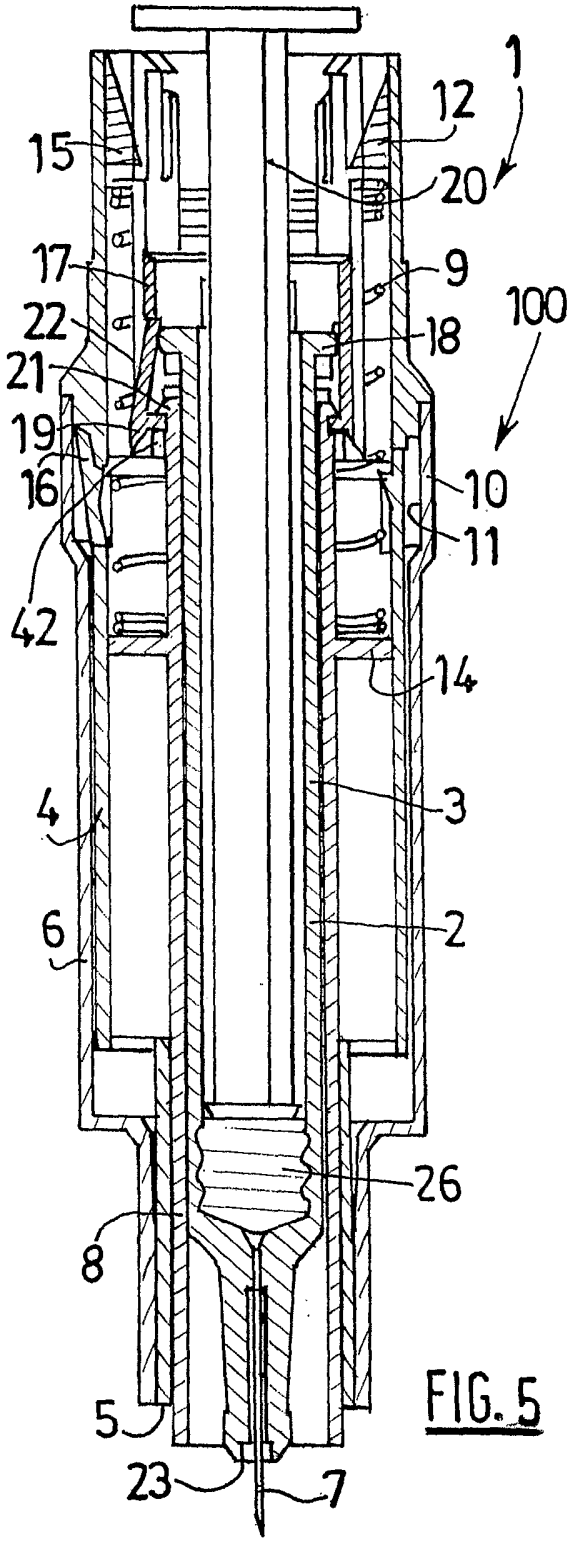
FIG. 4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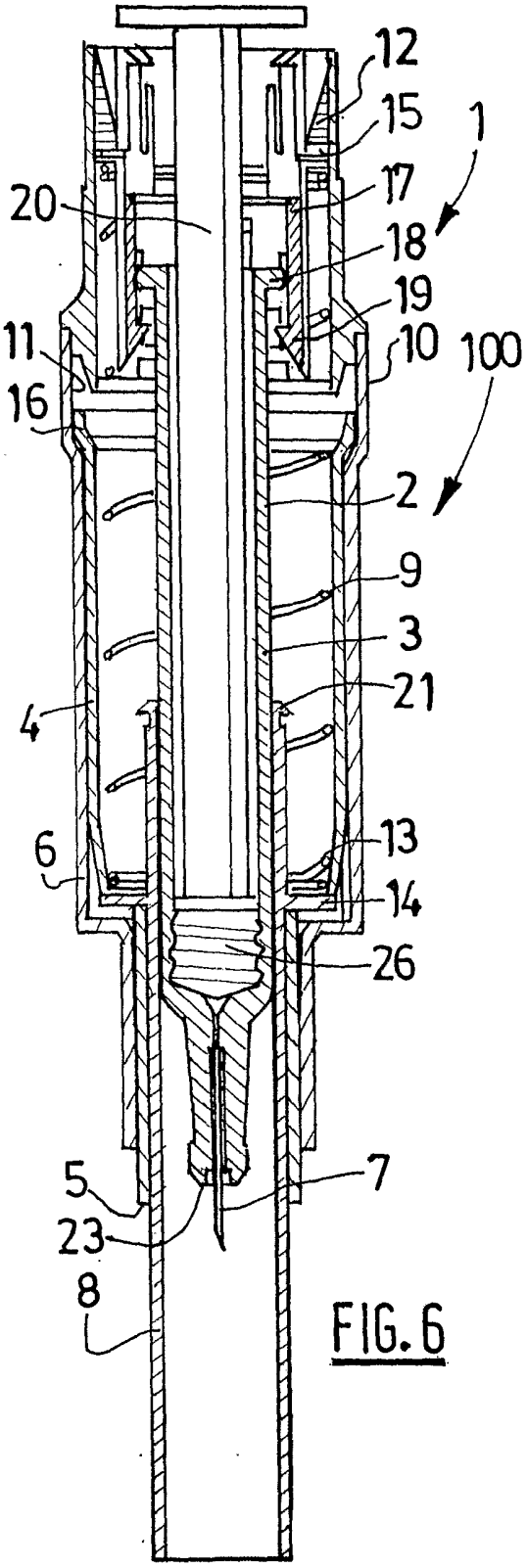
7

FIG. 5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17
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11
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16
2
9
3
4
21
6
13
14
26
5
7
23
8

FIG. 6

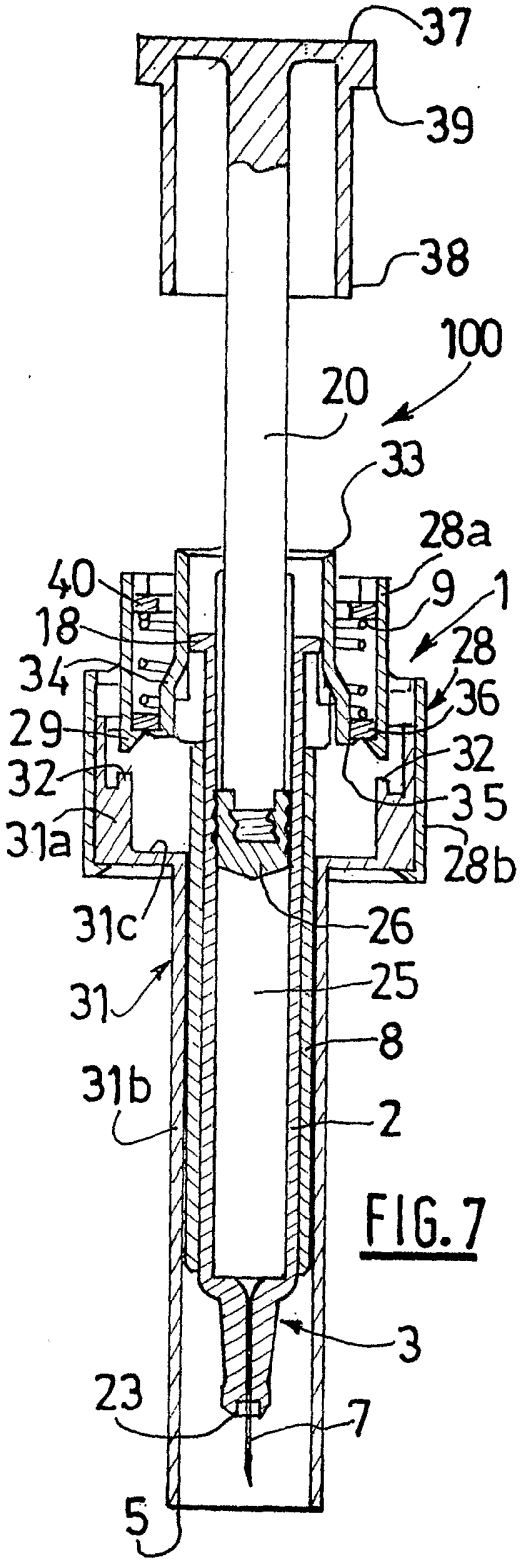
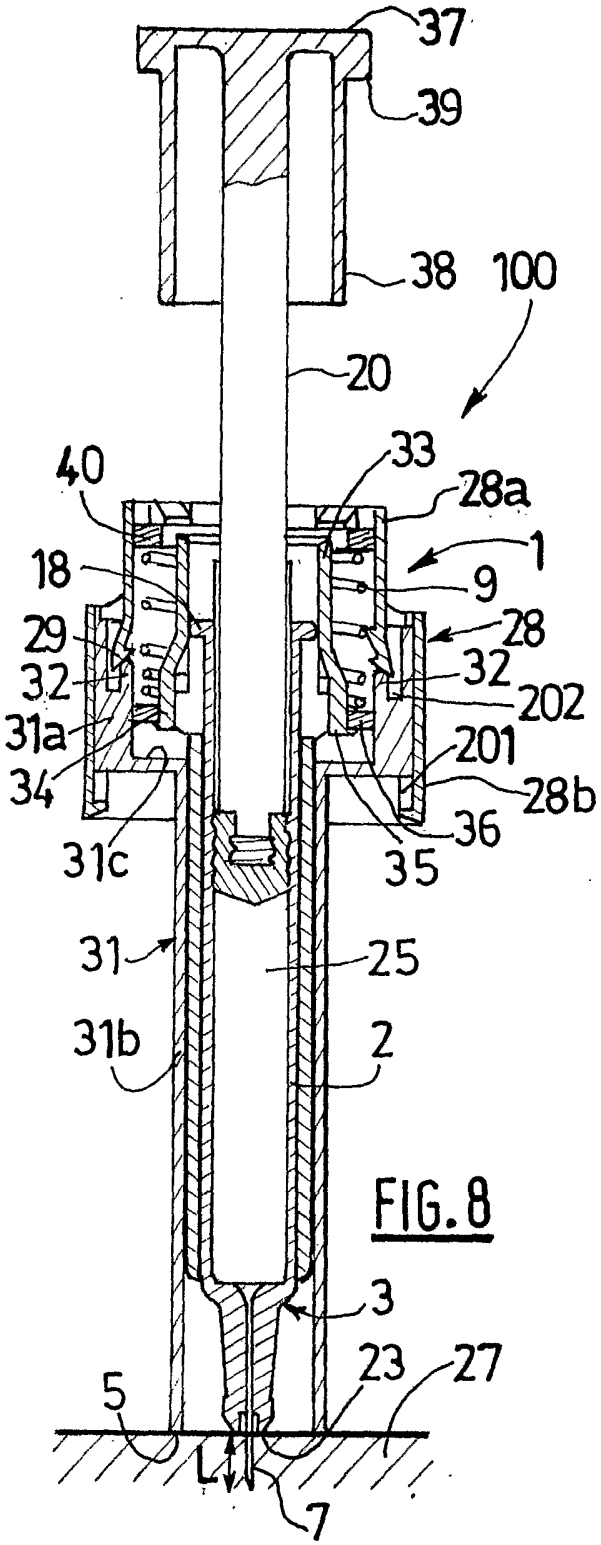

37
39
38
100
20
33
28a
40
9
1
18
28
34
36
29
32
32
31a
35
28b
31c
26
31
25
8
31b
2
3
23
7
5

FIG.7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38
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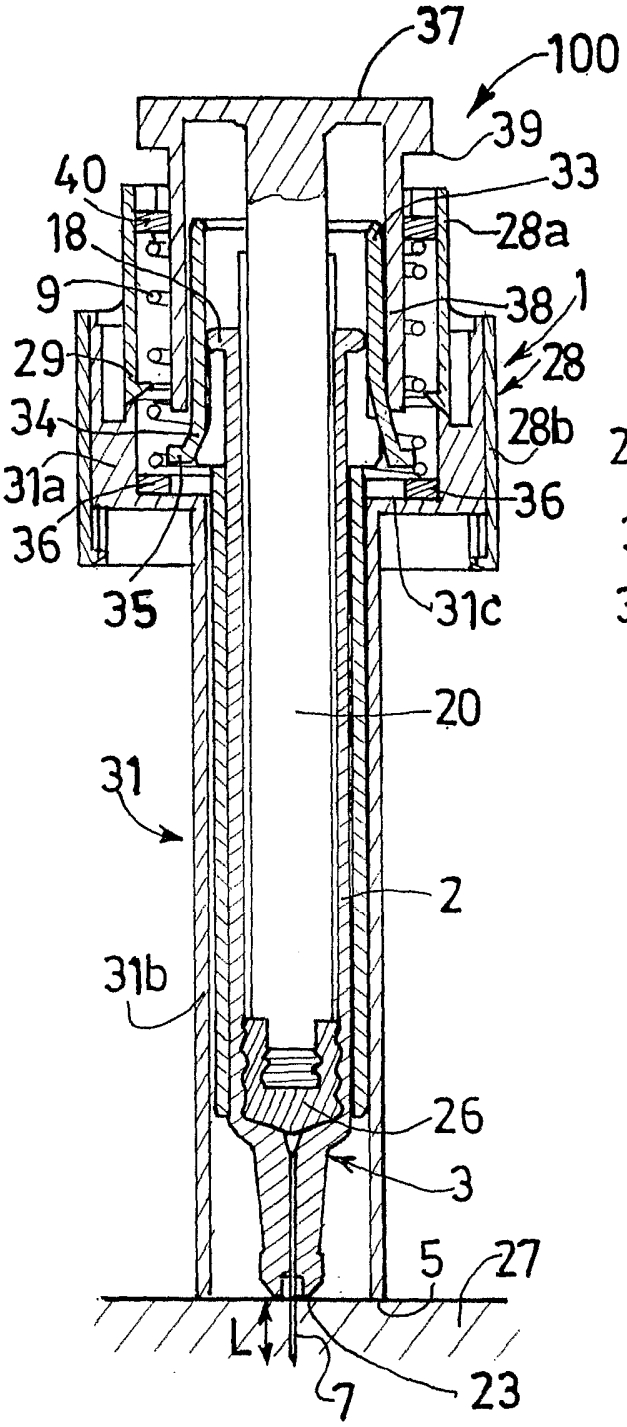
20
40
33
28a
1
18
9
29
28
32
32
202
31a
201
34
28b
36
31c
35
31
25
31b
2
3
23
27
5
L
7

FIG.8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33
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28a
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38
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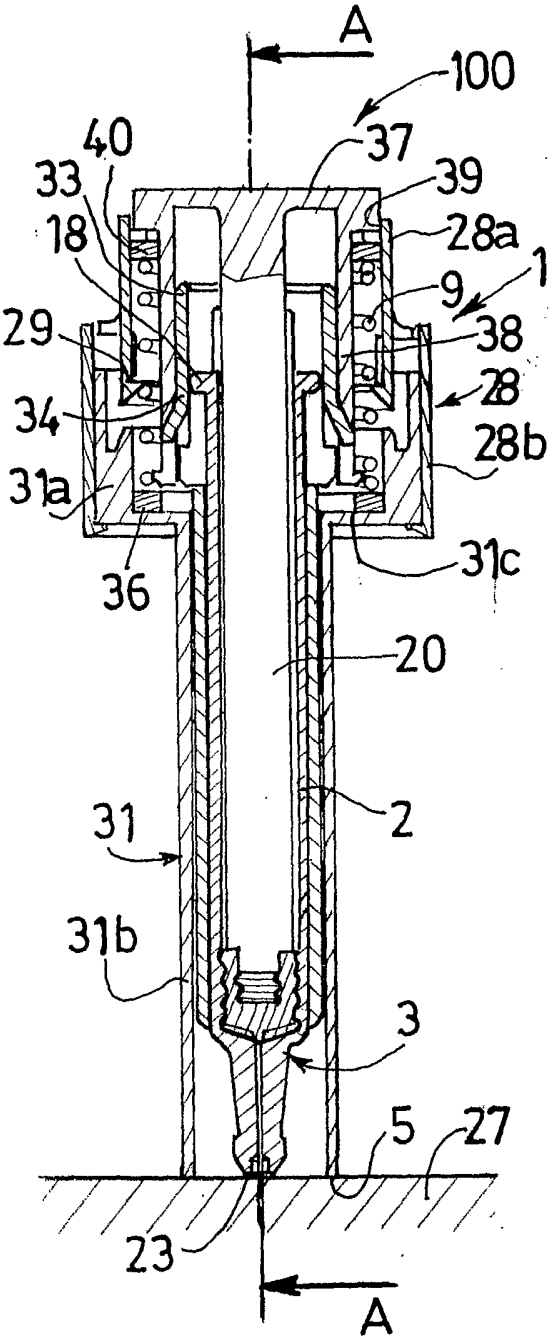
29
28
34
28b
31a
36
36
35
31c
20
31
2
31b
26
3
5
27
L
7
23

FIG.9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39
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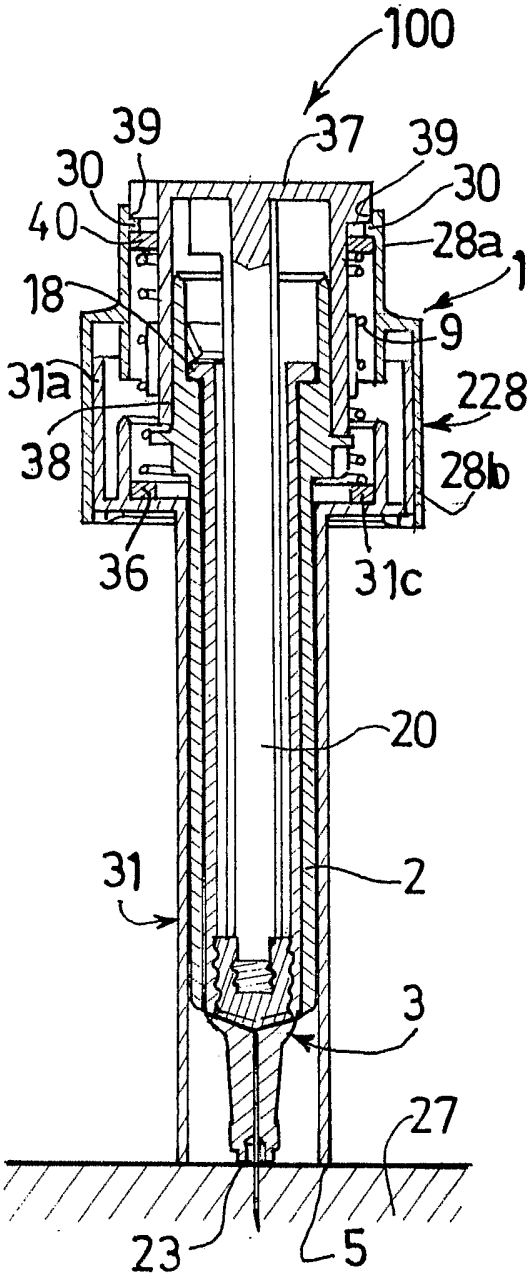
18
28a
1
9
29
38
28
34
28b
31a
36
31c
20
2
31
31b
3
5
27
23
A

FIG.10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39
30
30
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28a
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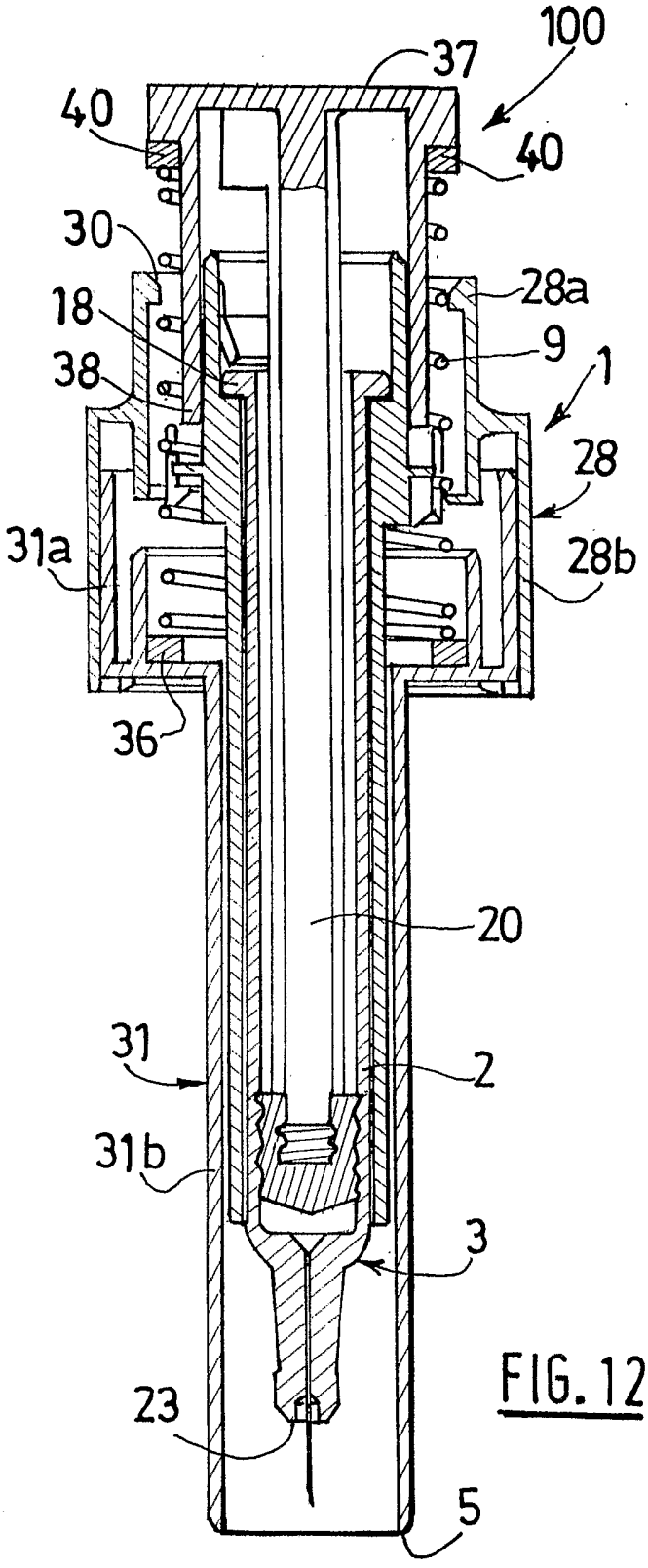
31a
228
38
28b
36
31c
20
31
2
3
27
23
5

FIG.11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40
30
28a
18
9
38
1
28
31a
28b
36
20
31
2
31b
3
23
5

FIG.12