

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
14 May 2010 (14.05.2010)

(10) International Publication Number
WO 2010/052517 A1

(51) International Patent Classification:
A61M 5/34 (2006.01)

(21) International Application Number:
PCT/IB2008/003703

(22) International Filing Date:
6 November 2008 (06.11.2008)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant (for all designated States except US): **BEC-
TON DICKINSON FRANCE** [FR/FR]; Rue Aristide
Bergès, F-38800 Le Pont-de-Claix (FR).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **VERNIZEAU,
Michel** [FR/FR]; 279 Avenue Victor Hugo, F-26000 Va-
lence (FR).

(74) Agent: **CABINET GERMAIN & MAUREAU**; BP
6153, F-69466 Lyon Cedex 06 (FR).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ,
CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ,
EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO,
NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG,
SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA,
UG, US, UZ, VC, VN, 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, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: IMPROVED DRUG CONTAINER

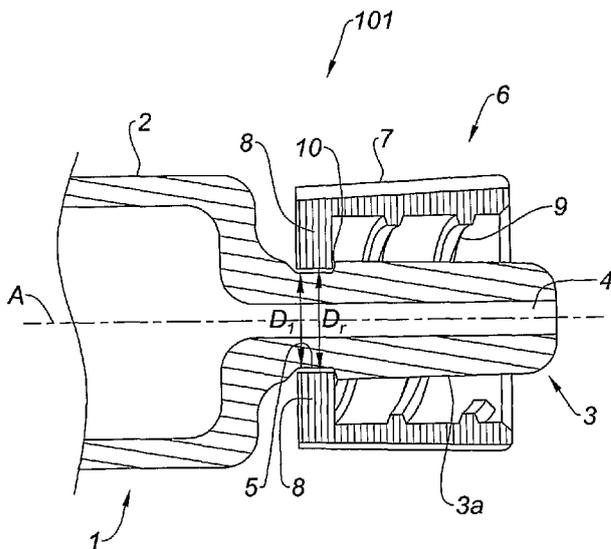


Fig. 7

(57) Abstract: The invention relates to an assembly (101) comprising : an injection device (1) comprising a container (2) for a product, said container (2) comprising a distal tip (3) having a longitudinal axis A, said distal tip (3) encompassing a channel (4) aligned with said longitudinal axis A and providing a passageway for the transfer of said product, an adaptor (6) comprising a ring (7) provided with at least one inner projection (8), said distal tip (3) being provided on its outer surface (3a) with a shoulder (10) being capable of preventing distal movement of said adaptor (6) with respect to said distal tip (3), characterized in that said distal tip (3) is provided on its outer surface (3a) with at least one annular gap (5), proximally spaced with respect to said shoulder (10), said at least one annular gap (5) being capable of cooperating with said at least one projection (8) so as to allow said adaptor (6) to rotate freely with respect to said distal tip (3) around said longitudinal axis A.

WO 2010/052517 A1

Improved drug container

The present invention relates to an assembly comprising an injection device and an adaptor, such as a Luer lock adaptor, allowing a safe
5 connection of the adaptor on the injection device, in view of further connecting a connector element, such as an IV (Intra Venous) connector, to said injection device.

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
10 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.

Various medical devices are known for transferring and/or storing
15 medical fluids, such as syringes, perfusion and transfusion devices and connectors. It is essential that these various medical devices can be assembled together correctly and securely.

A conventional injection device usually comprises a hollow body forming a container for a medical product : the distal end of the body forming
20 the container usually comprises a tip in which an axial passageway is arranged through which the said product is ejected from the container.

The handling of liquid products, in particular for a parenteral administration to a patient which is carried out via a perfusion device, as often
25 in hospitals or in emergency situations, implies, in a general manner, the use of connectors. Such connectors make it possible to seal assemblies of medical devices and provide protection against the contamination of the medical liquid products that they contain.

The connectors, like for example IV connectors, are usually connected to the injection device by means of intermediate elements such as
30 adaptors. Usually, these adaptors are first mounted on the distal tip of the injection device : the connector, such as an IV connector, is then mounted on the free end of the adaptor, for example by screwing. In such a step, the adaptors are friction forced on the distal tip and are supposed to remain immobile, thanks to friction forces, with respect to the distal tip while the
35 connector is screwed on the adaptor. Usually, a shoulder is present on the distal tip to prevent the adaptor to slide distally with respect to the distal tip.

An assembly of the prior art is shown on figures 1 and 2.

On these figures is shown an assembly 200 of the prior art comprising a distal tip 201 of a container 202 having a longitudinal axis A0 and an adaptor 203. The distal tip 201 comprises on its outer surface 204 a shoulder 205. The adaptor 203 comprises a ring 206 and an annular ridge 207 defining a diameter D0 in a rest position of said adaptor 203, as shown on figure 1. The annular ridge 207 of the adaptor 203 is radially expandable upon forces exerted on its inner wall. The adaptor 203 is intended to be friction forced on the distal tip 201 as shown on figure 2. Thanks to its capability to deform, the annular ridge 207 overcomes the shoulder 205 and gets stuck between said shoulder 205 and the distal wall of the container 202. As appears clearly from figure 2, in this position, the adaptor 203 is still in a stressed position of its annular ridge 207 and is supposed to be immobile with respect to the distal tip 201 thanks to friction forces present between the annular ridge 207 and the outer surface 204 of the distal tip 201. Moreover, the adaptor 203 is prevented from sliding distally with respect to the distal tip thanks to the shoulder 205.

However, problems have been reported concerning the use of some adaptors with various injection devices : for example, the adaptor 203 does not remain immobile with respect to the distal tip 201. In particular, it may happen in cases that the adaptor 203 remains immobile and it also may happen in other cases that the friction forces are not important enough to prevent the adaptor 203 to rotate, although with friction, with respect to the distal tip 201 when the user tries to screw a connector on to the adaptor 203: it is therefore impossible for the user to determine whether the connector is well fitted in the adaptor or not and, as a consequence, whether the connector is well connected to the distal tip of the injection device. An incorrect connection between the injection device and the connector may cause leaks of product and therefore incorrect doses administered to the patient.

There is therefore a need for an assembly that would allow the reproducible connection between said injection device and an adaptor, so that the user knows when the connector is correctly connected to the injection device via the adaptor.

One aspect of the present invention is an assembly comprising:
an injection device comprising a container for a product, said container comprising a distal tip having a longitudinal axis A, said distal tip

encompassing a channel aligned with said longitudinal axis A and providing a passageway for the transfer of said product,

an adaptor comprising a ring provided with at least one inner projection, said adaptor being intended to be fitted on said distal tip,

5 said distal tip being provided on its outer surface with a shoulder being capable of cooperating with said at least one inner projection when said adaptor is fitted on said distal tip, so as to prevent distal movement of said adaptor with respect to said distal tip,

10 characterized in that said distal tip is further provided on its outer surface with at least one annular gap, proximally spaced with respect to said shoulder, said at least one annular gap being capable of cooperating with said at least one inner projection so as to allow said adaptor to rotate freely with respect to said distal tip around said longitudinal axis A.

15 In the present application, by "rotate freely" or "free to rotate" is meant that the adaptor rotates with respect to the distal tip with minimal friction between the two surfaces which are in contact, ie the surface of the adaptor which is in contact with the surface of the distal tip : in particular, the friction force between the two surfaces in contact is less than 2 N.cm, measured with a classical torquemeter. The resistance between the two surfaces is very low and
20 the adaptor can rotate very easily with respect to the distal tip.

Because the adaptor is allowed to rotate freely with respect to the distal tip of the injection device but is prevented from moving distally with respect to said distal tip, then the user can simply screw the connector to the adaptor by grasping in his fingers the adaptor on one hand, and the connector
25 on the other hand. The user does not need to bother anymore about the firmness of the friction connection of the adaptor to the injection device like in the prior art.

In the assembly of the invention, during the time the adaptor is being slid on the distal tip of the injection device, before the inner projection of
30 the adaptor reaches the annular gap so as to cooperate therewith, the adaptor and the distal tip are in high friction contact. Once said adaptor is fitted on said distal tip so that said annular gap and said inner projection cooperate together, said adaptor is no more maintained coupled to the distal tip by friction forces. It is maintained coupled to the distal tip by means of said inner projection being
35 engaged in said annular gap, said adaptor being able to rotate freely with

respect to the distal tip but being prevented from moving distally with respect to said distal tip.

In an embodiment of the invention, said ring is radially and outwardly expandable from a rest position, in which said one inner projection defines a first internal diameter D_r of said ring, and a stressed position, in which said one inner projection defines a second internal diameter D_s of said ring, said second internal diameter being greater than said first internal diameter, said ring being in its rest position when said at least one annular gap cooperates with said at least one inner projection, so as to allow said adaptor to rotate freely with respect to said distal tip.

In an embodiment of the invention, said annular gap has a diameter D_1 , D_1 being strictly less than D_r . There are therefore only minimal friction forces between the inner projection of the adaptor and the annular gap. In particular, said friction force is less than 2 N.cm. The ring is therefore not in high friction contact with the distal tip. This allows the adaptor to rotate freely around the longitudinal axis A with respect to the distal tip. Moreover, because of the shoulder, the adaptor is prevented from moving distally with respect to the distal tip.

In an embodiment of the invention, said shoulder has a diameter D_2 , D_2 being strictly more than D_r .

The adaptor is therefore being prevented from moving distally with respect to the distal tip.

For example, if D_r is 4.30 mm, than D_1 may be 4.25 mm and D_2 may be 4.40 mm. In such a case, D_s may be up to 4.40 mm. The ring is therefore allowed to rotate freely with respect to the distal tip while being prevented from moving distally with respect to the distal tip.

The invention and the advantages that arise therefrom will clearly emerge from the detailed description that is given below with reference to the appended drawings in which:

- Figures 1 and 2 are partial cross section views of an assembly of the prior art respectively before mounting the adaptor on the injection device and once the adaptor is mounted on the distal tip of the injection device,

- Figures 3 and 4 are perspective view of an assembly of the invention respectively before mounting the adaptor on the injection device and once the adaptor is mounted on the distal tip of the injection device,

- Figure 5 is a cross section view of the assembly of figures 3 and 4 before mounting the adaptor on the distal tip,

- Figure 6 is a cross section view of the assembly of figure 5 during the step of mounting the adaptor on the distal tip, the adaptor being in its stressed condition,

- Figure 7 is a cross section view of the assembly of figure 5 once the adaptor is fitted on the distal tip.

With reference to figure 3 is shown an assembly 101 of the invention comprising an injection device 1 comprising a container 2 comprising a distal tip 3 having a longitudinal axis A. The container 2 and the distal tip 3 are made of one single element. The container 2 has a tubular shape and defines a reservoir for a product, for example a medical fluid. The container 2 and the distal tip 3 are preferably made of glass material. The container 2 may be sealed at its proximal end by a piston (not shown). The distal tip 3 encompasses a channel 4 aligned with the longitudinal axis A and providing a passageway for the transfer of the product, either from the container 2 to a connector (not shown) such as an IV connector, or from a vial to the container 2. On the example shown, the outer surface 3a of the distal tip 3 has a slightly tapered shape and it is provided in its proximal region with an annular gap 5.

With reference to figure 5, the annular gap 5 defines at its distal end a shoulder 10. The annular gap 5 is therefore proximally spaced with respect to said shoulder 10.

On figure 3 is also shown an adaptor 6 comprising a ring 7. On the example shown the ring 7 is provided in its proximal region with an inner projection under the form of a discontinuous annular bulge 8 extending radially inwardly. In an example not shown, the inner projection may be a continuous bulge. On the example shown, the inner wall of the ring 7 is provided with an internal thread 9 distally spaced from the discontinuous annular bulge 8.

As will appear later in the following description, in a first step, the adaptor 6 is fitted on the distal tip 3, and then, in a second step, the adaptor 6 is intended to be screwed on a connector (not shown), such as an IV connector, in order to connect safely the injection device 1 to the said connector so as to realize the transfer of the product from the injection device to the connector or vice-versa. The said connector is provided with an external thread intended to cooperate with the internal thread 9 of the adaptor in order to screw the adaptor on the connector.

With reference to figures 5 and 6, the adaptor 6 is generally made in a material flexible enough to allow said adaptor 6 to adopt a rest position, shown on figure 5, in which the discontinuous bulge 8 defines a first internal diameter D_r , and a stressed position, shown on figure 6, in which the discontinuous bulge 8 defines a second internal diameter D_s , D_s being greater than D_r . The ring 7 is therefore radially expandable upon a stress exerted on the inner wall of the bulge 8 in the outward and radial direction. As shown on figure 6, such a stress is exerted on the bulge 8 by the outer surface 3a of the distal tip 3 when the adaptor 6 is friction forced on the distal tip 3 during the step of mounting the adaptor 6 on the distal tip 3. For example, the ring 7 is made of plastic material.

The operation of mounting and fitting an adaptor 6 on an injection device 1 of the assembly 101 of the invention in view of further safely connecting a connector on said injection device will now be described with reference to figures 5 to 7.

The user is provided with an injection device 1 and an adaptor 6 as shown on figures 3 and 5. The adaptor 6 is in its rest position as shown on figure 5. The user grasps the injection device 1 with one hand and the adaptor 6 with the other hand. He forces the proximal end of the ring 7 on the distal end of the distal tip 3. Since the diameter of the outer surface 3a of the distal tip 3 is greater than the diameter D_r of the adaptor 6 in its rest position, the outer surface 3a of the distal tip 3 exerts a radial and outward force on the discontinuous bulge 8 of the adaptor 6, and the ring 7 deforms and expands radially, as shown on figure 6. In this stressed position of the adaptor 6, the discontinuous bulge 8 defines an internal diameter D_s greater than D_r and the adaptor 6 and the outer surface 3a of the distal tip 3 are in high friction contact.

The user continues to push the adaptor 6 in direction of the container 2 of the injection device 1 until the discontinuous bulge 8 reaches the annular gap 5 in which it becomes engaged, as shown on figure 7. Since the diameter D_1 of the annular gap 5 is less than the diameter D_r defined by the discontinuous bulge 8, the adaptor 6 comes back to its rest position : in particular, the diameter D_1 of the annular gap 5 is sufficiently less than D_r so that the discontinuous bulge 8 is no more in high friction contact with the outer surface of the annular gap 5 : as a consequence, the adaptor 6 is only in minimal friction contact with the outer surface 3a of the distal tip 3, as shown on figure 7. In particular, the friction force between the adaptor 6 and the outer

surface of the annular gap 5 is less than 2 N.cm. Thus, when it is fitted on the distal tip 3 as shown on figure 7, the adaptor 6 is free to rotate with respect to the distal tip 3 around the longitudinal axis A. Moreover, because of the shoulder 10, the adaptor 6 is prevented from moving distally with respect to the distal tip 3.

For example, the diameter $D1$ of the annular gap 5 is 4.25 mm, and the internal diameter Dr of the ring 7 defined by the discontinuous bulge 8 is 4.30 mm. The ring 7, and therefore the adaptor 6, is therefore allowed to rotate freely with respect to the distal tip 3 while being prevented from moving distally with respect to the distal tip 3. The diameter $D2$ of the shoulder may then be 4.40 mm and Ds may be up to 4.40 mm.

As a consequence, when the user wishes to proceed to the further step of connecting to the adaptor 6 a connector, such as an IV connector, he just has to grasp the adaptor 6 fitted on the distal tip 3 as shown on figure 7 in one hand and then to screw the connector on to the internal thread 9 of the adaptor, without bothering as to whether the adaptor 6 is immobile with respect to the distal tip 3 or not. When the external thread of the connector (not shown) is firmly screwed on the internal thread 9 of the adaptor 6, then the user knows that the injection device 1 and the connector are tightly connected without any risk of leakage of the product to be transferred from one piece to the other.

The assembly of the invention therefore allows connecting safely an injection device to a connector without having to check the tightness of the fixation between the injection device and the intermediate element formed by the adaptor.

The assembly of the invention renders the connection of an injection device to a connector, such as an IV connector, particularly simple, safe and reproducible.

CLAIMS

1. Assembly (101) comprising :

an injection device (1) comprising a container (2) for a product, said
5 container (2) comprising a distal tip (3) having a longitudinal axis A, said distal
tip (3) encompassing a channel (4) aligned with said longitudinal axis A and
providing a passageway for the transfer of said product,

an adaptor (6) comprising a ring (7) provided with at least one
inner projection (8), said adaptor being intended to be fitted on said distal tip
10 (3),

said distal tip (3) being provided on its outer surface (3a) with a
shoulder (10) being capable of cooperating with said at least one inner
projection when said adaptor is fitted on said distal tip (3), so as to prevent
distal movement of said adaptor (6) with respect to said distal tip (3),

15 characterized in that said distal tip (3) is further provided on its
outer surface (3a) with at least one annular gap (5), proximally spaced with
respect to said shoulder (10), said at least one annular gap (5) being capable of
cooperating with said at least one inner projection (8) so as to allow said
adaptor (6) to rotate freely with respect to said distal tip (3) around said
20 longitudinal axis A.

2. Assembly (101) according to claims 1, characterized in that
said ring (7) is radially and outwardly expandable from a rest position, in which
said one inner projection (8) defines a first internal diameter D_r of said ring (7),
and a stressed position, in which said one inner projection (8) defines a second
25 internal diameter D_s of said ring (7), said second internal diameter being
greater than said first internal diameter, said ring (7) being in its rest position
when said at least one annular gap (5) cooperates with said at least one inner
projection (8), so as to allow said adaptor (6) to rotate freely with respect to
said distal tip (3).

30 3. Assembly (101) according to claim 1 or 2, characterized in
that said annular gap (5) has a diameter D_1 , D_1 being strictly less than D_r .

4. Assembly (101) according to claim 3, characterized in that
said shoulder has a diameter D_2 , D_2 being strictly more than D_r .

1 / 4

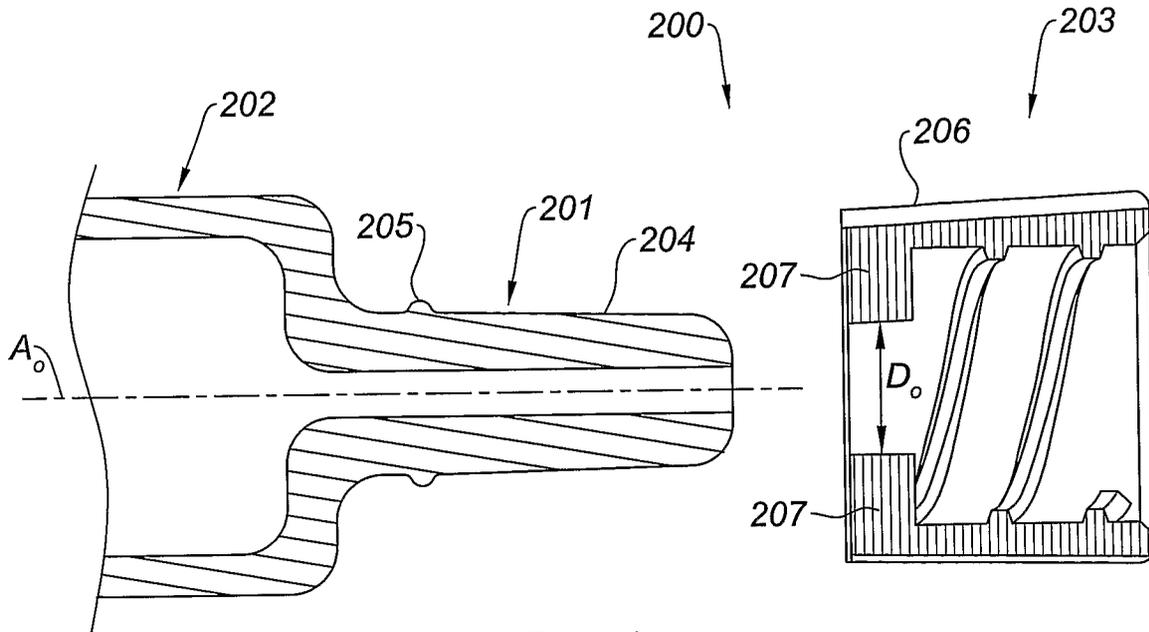


Fig. 1

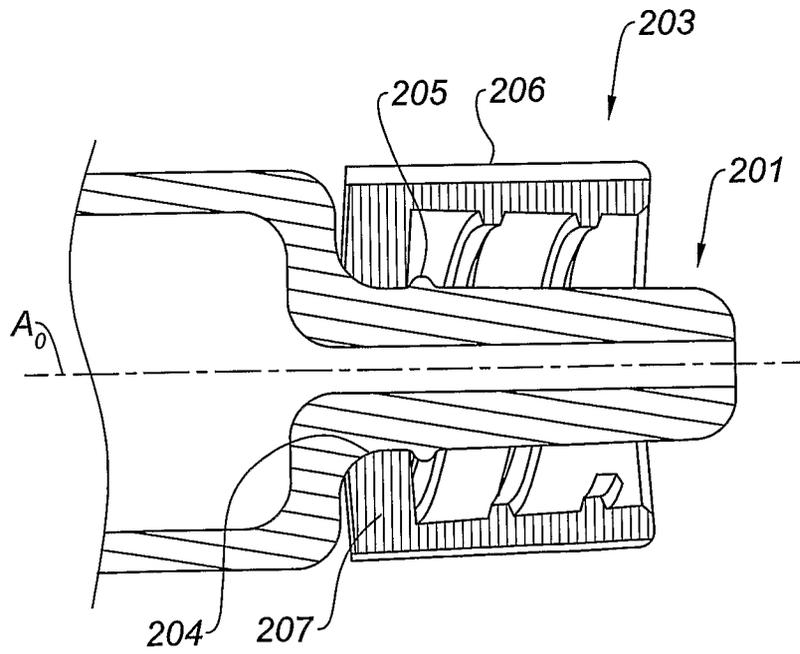
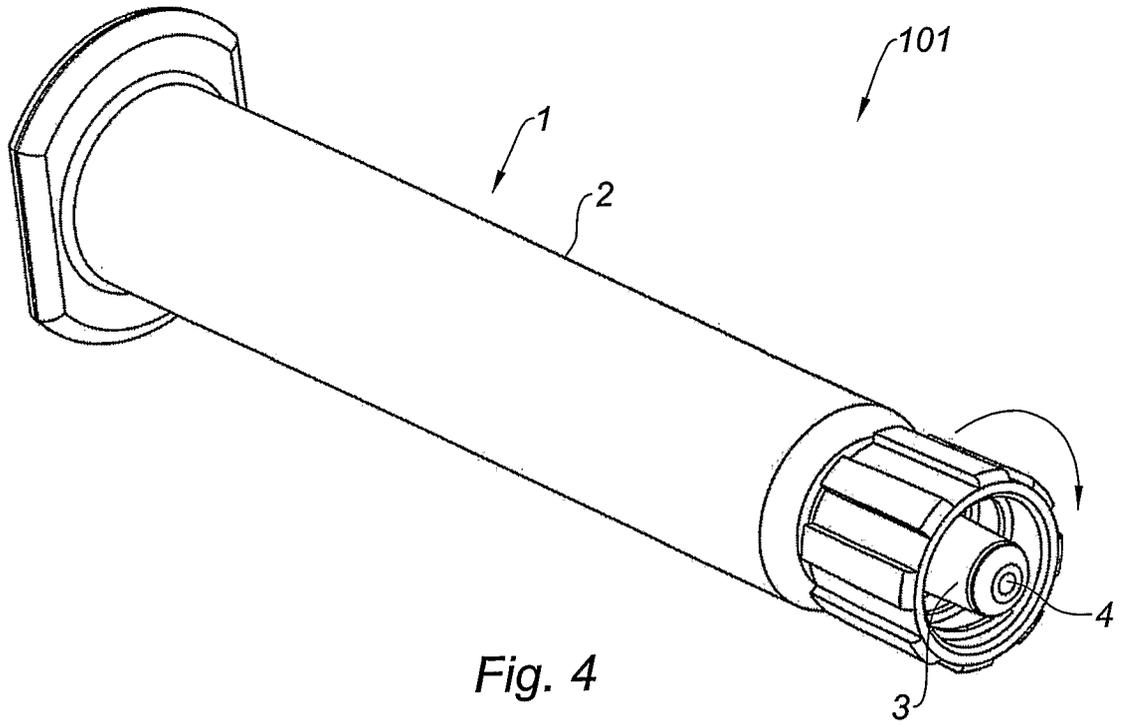
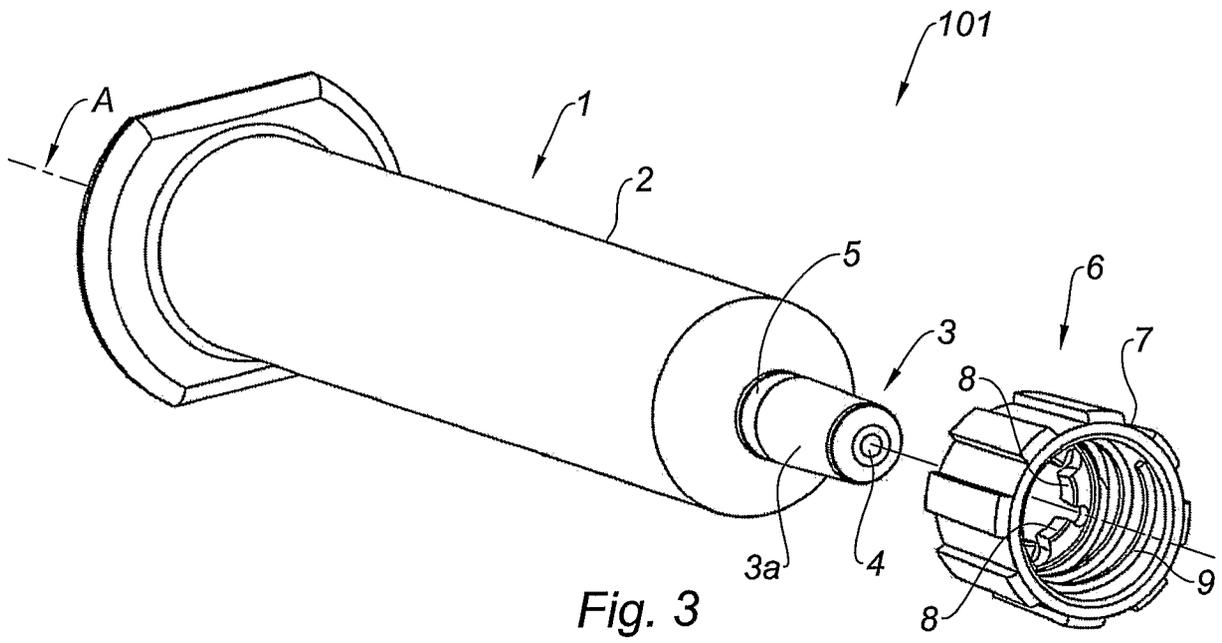


Fig. 2



3 / 4

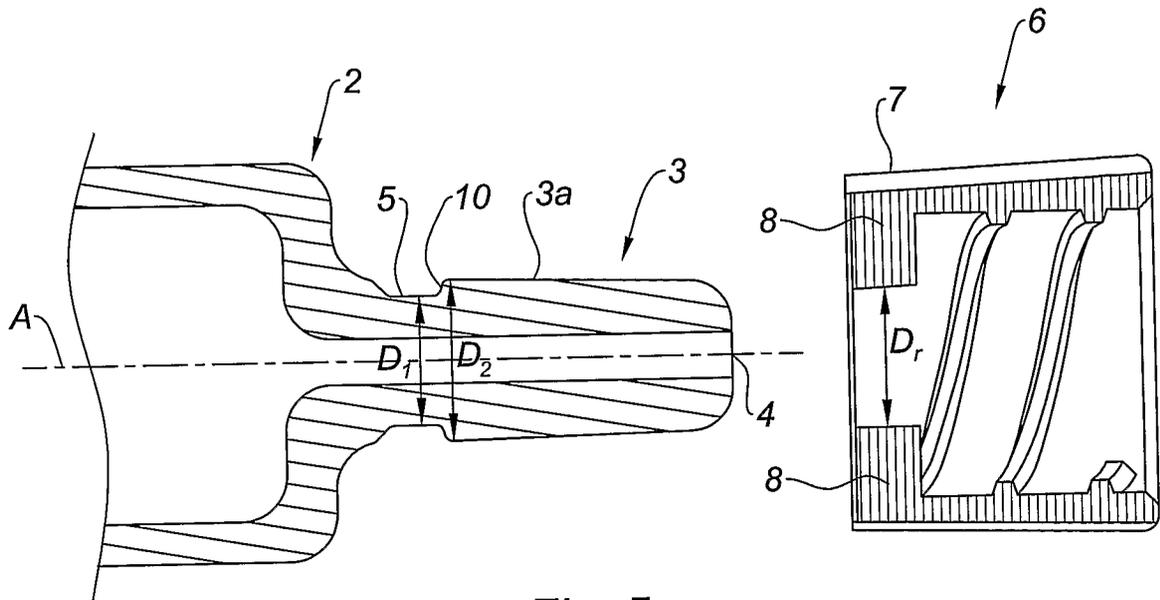


Fig. 5

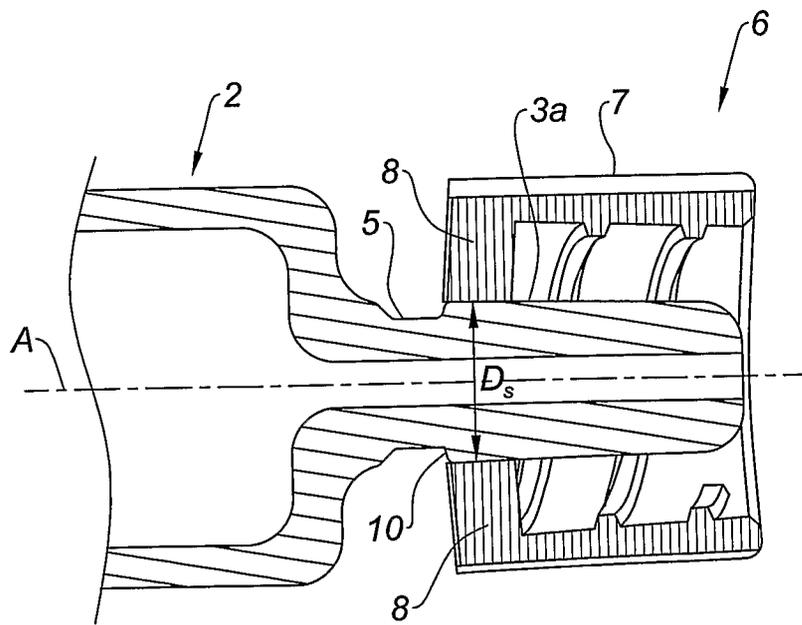


Fig. 6

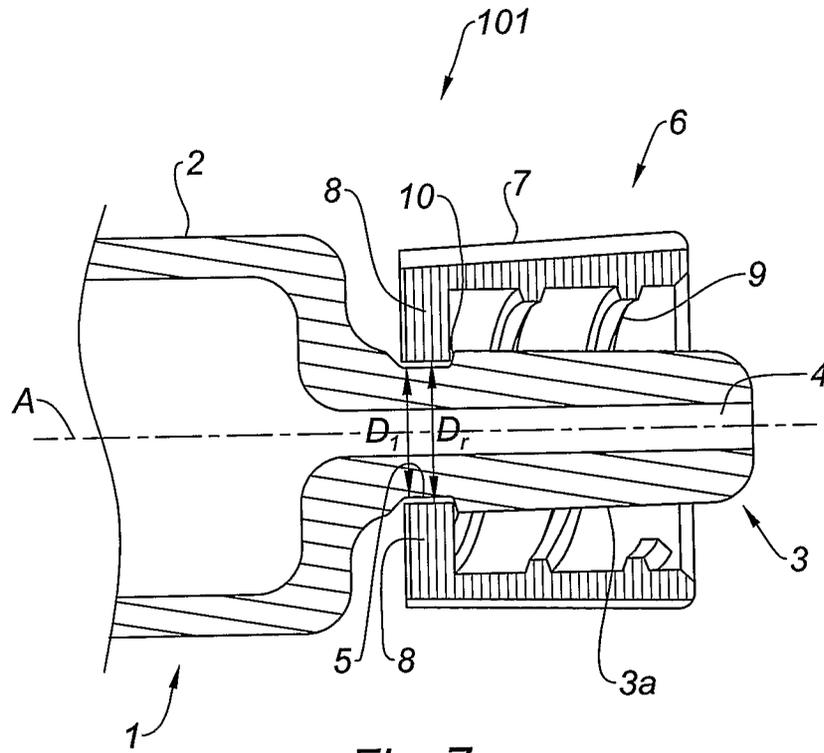


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2008/003703

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/34

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/45985 A (BECTON DICKINSON CO [US]; PORFANO DONALD [US]; KROPATSCH JAMES [US]; G) 16 September 1999 (1999-09-16) abstract figures 2,3 page 13, paragraph 1 - page 14, paragraph 1	1-4
X	WO 2004/012797 A (SCHERING AG [DE]; KUMASHIRO TOSHIO [JP]; KONNO YASUHIKO [JP]; SEGAWA H) 12 February 2004 (2004-02-12) abstract	1-4

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

7 July 2009

Date of mailing of the international search report

14/07/2009

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Guidoin, M

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2008/003703

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 707 859 A (SCHOTT GLASWERKE [DE]; ZEISS STIFTUNG [DE] SCHOTT GLAS [DE]; ZEISS STI) 24 April 1996 (1996-04-24) abstract figure 1a column 6, line 44 - column 8, line 4 -----	1-4
X	FR 2 809 316 A (BECTON DICKINSON FRANCE [FR]) 30 November 2001 (2001-11-30) the whole document -----	1-4
A	US 3 491 757 A (ARCE RAUL OLVERA) 27 January 1970 (1970-01-27) the whole document -----	1-4

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2008/003703

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9945985	A	16-09-1999	AU 3001299 A	27-09-1999
			AU 3001399 A	27-09-1999
			DE 69914725 D1	18-03-2004
			DE 69914725 T2	02-12-2004
			EP 1061974 A1	27-12-2000
			EP 1061975 A1	27-12-2000
			JP 2002505980 T	26-02-2002
			JP 4216467 B2	28-01-2009
			JP 2002505921 T	26-02-2002
			WO 9945984 A1	16-09-1999
WO 2004012797	A	12-02-2004	AU 2003243998 A1	23-02-2004
EP 0707859	A	24-04-1996	DE 4434644 A1	04-04-1996
			JP 3294077 B2	17-06-2002
			JP 8107921 A	30-04-1996
FR 2809316	A	30-11-2001	AU 6402101 A	11-12-2001
			DE 60109598 D1	28-04-2005
			DE 60109598 T2	09-02-2006
			EP 1284766 A1	26-02-2003
			WO 0191839 A1	06-12-2001
			JP 2004513675 T	13-05-2004
			US 2003163093 A1	28-08-2003
US 3491757	A	27-01-1970	NONE	