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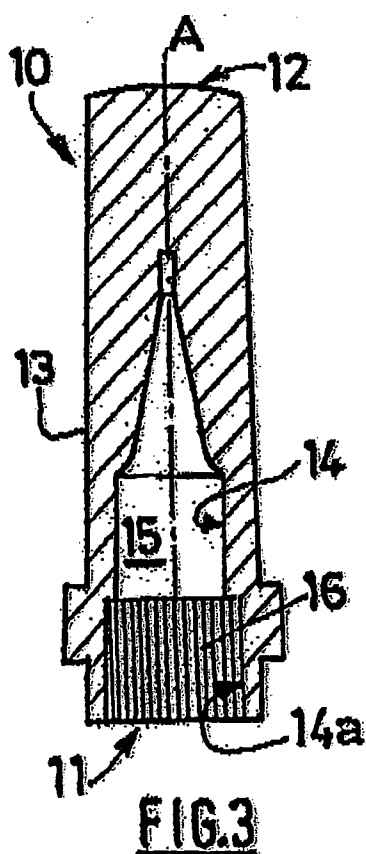
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(54) Title: NEEDLE SHIELD WITH SPECIFIC ROUGHNESS



(57) Abstract: The present application relates to a shield (10) for the distal extremity of an administration device (3) comprising a hub (2) on which said shield (10) is to be removably engaged, said shield (10) having a wall (13) the internal face (14) of which defining an interior cavity (15) for receiving the extremity of the administration device (3), at least a portion (14a) of said internal face (14) being intended to be in contact with said hub (2) when said shield (10) is engaged on the extremity of said administration device (3), whereby said portion (14a) has, distributed over a major portion of said portion (14a), a surface feature (16, 17) that defines the amount of contact between said portion (14a) and said hub (2).

WO 2009/016428 A1

Needle shield with specific roughness

The present invention relates to a shield for covering the distal extremity of an administration device at least prior to use of the administration
5 device.

In this application, the term distal means the part furthest from the user's hand, and the term proximal means the part closest to the user's hand. Likewise, in this application, the term "distal direction" means the direction of administration, i.e., towards the patient, and the term "proximal direction"
10 means direction opposite to the direction of administration, i.e., away from the patient.

Administration devices are commonly used in several technical fields such as, for example, the medical field, to administer to a patient, for example a medical product, either by spraying for spraying devices or by
15 injection for injection devices. To do so, the distal extremity of the administration device can be provided with a staked needle or nozzle or a luer connection allowing provision of an assembly such as a nozzle assembly or a needle assembly.

In the present application, by "staked needle" one means a
20 needle fixed on the tip of the injection device by gluing or by any other suitable method such as for example shrinking of the tip of the syringe surrounding the needle after heating.

In the medical field, injection devices, such as syringes provided with needles, either staked needles or needle assemblies on luer syringes, are
25 usually provided to the end-users with needle shields: indeed, needles must remain sterilized until use and need to be protected from possible contamination from the environment. Moreover, in the case of injection devices with needle, the end user must also be protected from accidental needle-stick injuries. Moreover, in the case of prefilled syringes, needle shields ensure
30 tightness and avoid the loss of content during storage.

Similarly, injection device such as syringe with no needle, provided with luer or with nozzle or with luer lock fitting, are usually provided to the end-users with a tip cap protecting the extremity of the luer or of the nozzle from possible contamination from the environment.

The present invention applies to both needle shields and tip caps. In this application, unless it is otherwise specified, the term "shield" is used indifferently for "needle shield" or for "tip cap".

These shields, or at least part of these shields, are usually made of an elastic material, such as a thermoplastic elastomer, such as rubber, and are secured on the distal extremity of the administration device for instance on assembly lines of industrial pharmaceutical companies. In this view, the distal extremity of the administration device usually comprises a hub to which the needle may be secured by gluing for example and upon which the shield is removably engaged by friction, for example.

One of the problems encountered with the automatic assembling of needle shields on the distal extremity of an administration device in assembly lines is that the needle shield is not always adequately put on the extremity of the administration device. In particular, it can happen that the needle shield is not directed along the longitudinal axis of the administration device at the time it is fit on the extremity of said device. The result is that the longitudinal axis of the needle shield is not confounded with the longitudinal axis of the administration device, the needle shield is inclined with respect with the extremity of the administration device. As the shield is usually made of rubber, which is quite a sticky material under normal use conditions, the shield happens to stuck on the hub of the administration device in an inappropriate position. Furthermore, it may be difficult to remove it at the time of use of the administration device.

Another problem caused by the fact that the shields are badly positioned is that it becomes difficult to position them in the nests of a handling tray, in particular with automatic means of assembly lines : this may cause breakage and emergency stop of the manufacturing lines.

Moreover, in the case where the administration device comprises a staked needle, the tip of the needle may penetrate the elastic material forming the shield: this phenomenon is very problematic for the subsequent use of the needle which may be contaminated by particles coming from said elastomeric material. Furthermore, the tip of the needle may transfix the wall of the shield, which would cause evident tightness and sterility issues. Lastly, the needle itself can be damaged, as it can be bended due to the bad positioning of the shield. Figures 1a to 1d illustrate the problem of the prior art described hereinabove. On these figures is shown the step of securing a needle shield 1

of the prior art on the hub 2 of the distal extremity of an administration device such as syringe 3 according to an automatic industrial process like those taking place in assembly lines of pharmaceutical companies for example.

On figure 1a is shown the beginning of the operation of securing the needle shield 1 on the hub 2. As appears on this figure, the needle shield 1 is made of a wall 4 defining a cavity 5. On figure 1a, the cavity 5 of the needle shield 1 is approached from the needle 6 fixed at the distal extremity of the syringe 3. As can be seen from figure 1a, during the approach of the needle shield 1 toward the needle 6, the longitudinal axis A of the needle shield 1 is not parallel to the longitudinal axis B of the syringe 3. On figure 1b is shown the step of positioning the needle shield 1 on the extremity of the syringe 3, thanks to vibrating means. After this step, the respective longitudinal axis A and B of the needle shield and of the administration device should be parallel, but due to the stickiness of the elastomer, the needle shield 1 remains held in an inappropriate position, in which the respective longitudinal axis A and B of the needle shield 1 and of the administration device 3 are not parallel. In consequence, the tip 7 of the needle 6 enters in contact with the elastomeric wall 4 of the needle shield 1. As shown on figure 1c, a distal force, represented as arrow F on figure 1c, is then applied on the needle shield 1 in order to fit it on the extremity of the administration device. On figure 1c, under the action of the distal force exerted on the needle shield 1, the respective axis of the needle shield 1 and of the administration device 3 are now parallel but this causes the needle 6 to bend. On figure 1d, is shown the assembly once the distal force exerted on the needle shield 1 is released. The return force of the needle 6 brings the longitudinal axis of the needle back substantially in the direction of the longitudinal axis of the syringe 3 but this action forces the needle shield 1 to become inclined with respect to the longitudinal axis of the syringe 3.

As appears clearly from figure 1d, the elastomeric wall 4 of the needle shield 1 is stuck against the hub 2, in an incorrect position. Such a phenomenon makes it difficult to remove the needle shield at the time of use of the syringe. Moreover, as is clear from figure 1d, the tip 7 of the needle 6 has penetrated the elastomeric wall 4 of the needle shield. The tip 7 of the needle 6 may be contaminated by elastomeric particles from the wall 4.

There is therefore a need for a shield for covering the extremity of an administration device, said shield allowing a correct fitting of the shield on the hub of the extremity of the administration device, especially by industrial

automatic means such as those used in assembly lines. Such a shield should also be easily removable from the hub on which it is secured when it is decided to use the administration device, keeping good sterility and tightness properties when said shield is in place.

- 5 The present invention meets this need by providing a shield having a specific internal face allowing for a better fitting of the shield on the extremity of the administration device.

10 A first aspect of the invention is a shield for covering at least part of the distal extremity of an administration device, said distal extremity of said administration device comprising a hub on which said shield is intended to be removably secured, said shield having an open proximal end, a closed distal end and a longitudinal wall extending from said proximal end to said distal end, the internal face of said longitudinal wall defining an interior cavity for receiving at least part of the extremity of the administration device, at least a portion of
15 said internal face of said longitudinal wall being intended to be in contact with said hub when said shield is secured on the extremity of said administration device, characterized in that said portion has, distributed over a major portion of said portion, a surface feature that defines the amount of contact between said portion and said hub.

- 20 In an embodiment, said surface feature of said portion is generally longitudinal.

25 The shield of the invention is easily fit on the extremity of an administration device. In particular, it is possible to fit the shield of the invention on the extremity of an administration device in such a way that the respective longitudinal axis A and B of the shield and of the administration device are parallel. The shield of the invention does not get stuck on the hub of the administration device on which it is secured. In case the administration device comprises a needle, an advantage of the shield of the invention is that, because the needle shield is easily and correctly fit on the administration
30 device, said needle does not enter in contact with the wall of the shield.

Moreover, the shield of the invention is easily removable from the extremity of the administration device when one wants to use said administration device. In particular, the pull out force necessary to remove the shield from the administration device is reduced with the shield of the invention.

In the present invention, said surface feature has a mean radial roughness of more than 2 μm , preferably more than 5 μm , more preferably more than 10 μm .

In the present application, the mean radial roughness is measured according the following method : roughness measurements done in triplicate are performed by using a profiler Wyko NT 1100 (Veeco Instruments Inc. Tucson USA) on scans 370 μm x 240 μm with a VSI mode (Vertical Scanning Interferometry). The calibration of the apparatus is performed following the procedure WI 7.6-20 using measuring instruments traceable to the National Institute of Standards and Technology (NIST).

In an embodiment of the invention, said mean radial roughness is less than 100 μm , preferably less than 50 μm , more preferably less than 30 μm .

In an embodiment of the invention, said mean radial roughness is about 25 μm .

For example, said surface feature defines a contact ratio between said portion of said internal face and said hub of less than 90% when said shield is secured on said hub, preferably less than 80%. Preferably, said contact ratio is more than 10%, preferably more than 20%. In an embodiment of the invention, said portion of said internal face is provided with microreliefs defining a said radial roughness.

Said microreliefs may be selected among grooves, ridges, bulges and their combinations.

In the case where the shield is a moulded part, such a rough surface may be obtained by a modification of the core pin on the moulds : this modification may be obtained by any machining technique. In another embodiment of the invention, the portion of said internal face of said longitudinal wall may have undergone a surface treatment in order to render it rough.

Preferably, the micro-reliefs of said internal face are distributed regularly or randomly along a circumference of said portion of said internal face. The mean radial roughness of said portion, such as the micro-reliefs mentioned above, define a contact ratio between said portion of said internal face and said hub of less than 90% when said shield is secured on said hub : in particular, thanks to the roughness of said portion, a certain percentage, for example 10% of the surface of said portion is not in contact with the hub when the shield is secured on the hub. This allows air to flow between said portion

and said hub, which reduces the sticky effect of the elastomer when positioning and fitting the shield on said hub or when removing said shield.

Moreover, the roughness of the portion, such as the micro-reliefs mentioned above, may guide the shield on the hub when the shield is put in place on the hub, facilitating thereby the correct fitting of the shield on said hub.

The contact ratio between said portion of said internal face and said hub is preferably not less than 10%, otherwise the shield may not be well secured on the administration device and some pop off effect may take place, for instance during the sterilization of the administration device after the shield has been secured on it, where a little increase of the internal pressure of the administration device may eject the shield from it.

In an embodiment of the invention, the value of said mean radial roughness varies from the proximal end to the distal end of said portion.

For example, said mean radial roughness may be greater in the region of the proximal end of said portion than in the region of the distal end of said portion.

In an embodiment of the invention, said microreliefs are under the form of a plurality of grooves that are parallel to the longitudinal axis A of said shield.

In another embodiment of the invention, said microreliefs are under the form of a plurality of grooves that are inclined with respect to the longitudinal axis A of said shield.

Another aspect of the invention is a method for protecting the distal extremity of an administration device, characterized in it comprises the step of securing a shield as described above on to the distal extremity of said administration device.

Preferably, said securing step is completed on an assembly line by automatic means.

Other advantages of the present invention will now be specified with the aid of the description which follows and of the attached drawings in which:

- Figures 1a to 1d show the steps of assembling a shield of the prior art on the extremity of an administration device,
- Figure 2 is a cross section view of a shield according to the invention,

- Figure 3 is a cross section view of a second embodiment of a shield of the invention,

- Figure 4 is a cross section view of a third embodiment of a shield of the invention.

5 On figure 2 is shown a shield 10 of the invention. The shield 10 is intended to cover the distal extremity of an administration device such as a syringe 3 (partially shown on figure 2). Alternatively, the administration device may be a needle assembly. The distal extremity of the syringe 3 is provided with a hub 2 on which is fixed a needle 6. The shield 10 has an open proximal end 11, a closed distal end 12 and a wall 13 extending from the proximal end 11 to the closed distal end 12. The internal face 14 of the wall 13 defines a cavity 15 for receiving part of the distal extremity of the syringe 3. A portion 14a of the internal face 14 is intended to be in contact with the hub 2 of the distal extremity of the syringe 3 when the shield 10 is secured on the distal extremity of the syringe in order to protect said distal extremity, for example during transport of the administration device before use.

 On figure 2, the portion 14a of the internal face 14 of the wall 13 has a mean radial roughness of more than 2 μm and preferably less than 100 μm . Said mean radial roughness defines a contact ratio between the portion 14a and the hub 2 of less than 90% and more than 10% when the shield is secured on the hub 2. For example, said roughness is about 25 μm measured as described above.

 Such a mean radial roughness may be obtained by modifying with machine technique the core pin of the moulds used for moulding the shield.

25 Preferably, the wall 13 is made of an elastomeric material such as rubber.

 On figure 3 is shown another embodiment of the shield of figure 1 in which the portion 14a of the internal face 14 of the wall 13 is provided with a plurality of grooves 16. The references designating the same elements as in figure 2 have been maintained. The grooves 16 are regularly distributed along the circumference of the portion 14a and they are parallel to the longitudinal axis A of the shield 10. They allow the air to flow during the assembly of the shield on the hub 2. The sticky surface of the shield is smaller, so the assembly is facilitated and it is easy to have the respective longitudinal axis A and B (see figure 2) of both the shield 10 and the administration device 3 to remain confounded. The shield 10 of the invention is therefore perfectly and correctly

secured on the extremity of the administration device 3. Because of the grooves created by the specific roughness of the portion 14a of the internal face 14 of the wall 13, it is then easier to remove the shield 10 from the extremity of the administration device 3 at the time of use of the administration
5 device 3.

On figure 4 is shown another embodiment of the shield 10 of the invention in which the portion 14a is provided with a plurality of inclined grooves 17. The grooves 17 are randomly distributed on the surface of said portion 14a. The grooves 17 cover at least 10% of the surface of the portion 14a. The
10 references designating the same elements as in figures 2 and 3 have been maintained. The grooves 17 are inclined with respect to the longitudinal axis A of the shield 10.

According to the process of the invention, it is possible to assemble the shield 10 of the invention on the extremity of an administration device in a very simple and efficient way. Because of the specific nature of the portion 14a of the internal face 14 of the wall of the shield of the invention, the shield 10 is guided in the direction of the longitudinal axis of the administration device. In particular, when the portion 14a is provided with grooves (16; 17), the fitting of the shield 10 on the hub 2 is correct and the respective longitudinal axis of the
15 shield 10 on one hand and of the administration device 3 on the other hand remain confounded. The shield 10 of the invention is allowed to be secured on an administration device 3 with automatic means such as robots in industrial processes using assembly lines.

The shield 10 of the invention is also easy to remove at the time of use because of the air flow authorized by the micro-reliefs, such as grooves, ridges or bulges, created by the specific surface of the portion 14a of the shield 10 intended to be in contact with the hub 2 of the administration device 3 when the shield 10 is secured on said administration device 3.
25

According to a variant of the invention, the grooves may be provided only on a limited surface of said portion 14a, closest to the proximal end of said portion 14a.
30

According to another variant of the invention, the grooves may be provided with a variable radial roughness, for instance with a greater mean radial roughness close to the proximal end of the portion 14a.

35 The invention has been described with grooves ensuring the contact ratio less than 90% between the portion 14a and the hub 2. The

invention also applies to other geometries for the portion 14a, as for example ridges, bulges, or any other geometry.

CLAIMS

1. A shield (10) for covering at least part of the distal extremity of an administration device (3), said distal extremity of said administration device (3) comprising a hub (2) on which said shield (10) is intended to be removably engaged, said shield (10) having an open proximal end (11), a closed distal end (12) and a longitudinal wall (13) extending from said proximal end (11) to said distal end (12), the internal face (14) of said longitudinal wall (13) defining an interior cavity (15) for receiving at least part of the extremity of the administration device (3), at least a portion (14a) of said internal face (14) of said longitudinal wall (13) being intended to be in contact with said hub (2) when said shield (10) is secured on the extremity of said administration device (3), characterized in that said portion (14a) has, distributed over a major portion of said portion (14a), a surface feature (16, 17) that defines the amount of contact between said portion (14a) and said hub (2).

2. A shield (10) according to claim 1, characterized in that said surface feature (16) of said portion (14a) is generally longitudinal.

3. A shield (10) according to claim 1 or 2, characterized in that said surface feature has a mean radial roughness of more than 2 μm , preferably more than 5 μm , and more preferably more than 10 μm .

4. A shield (10) according to one of claims 1 to 3, characterized in that said surface feature has a mean radial roughness of less than 100 μm , preferably less than 50 μm , more preferably less than 30 μm .

5. A shield (10) according to one of claims 1 to 4, characterized in that said mean radial roughness is about 25 μm .

6. A shield (10) according to one of claims 1 to 5, characterized in that said surface feature defines a contact ratio between said portion (14a) of said internal face (14) and said hub (2) of less than 90% when said shield (10) is secured on said hub (2), preferably less than 80%.

7. A shield (10) according to the preceding claim, characterized in that said contact ratio is more than 10%, preferably more than 20%.

8. A shield (10) according to one of the preceding claims, characterized in that said portion (14a) of said internal face (14) is provided with microreliefs (16; 17) defining said radial roughness.

9. A shield (10) according to the preceding claims, characterized in that said microreliefs are selected among grooves, ridges, bulges and their combinations.

5 10. A shield (10) according to claims 8 or 9, characterized in that said microreliefs are distributed regularly or randomly along a circumference of said portion (14a) of said internal face (14).

11. A shield (10) according to one of claims 8 to 10, characterized in that said microreliefs are under the form of a plurality of grooves (16) that are parallel to the longitudinal axis (A) of said shield (10).

10 12. A shield (10) according to one of claims 8 to 10, characterized in that said microreliefs are under the form of a plurality of grooves (17) that are inclined with respect to the longitudinal axis (A) of said shield (10).

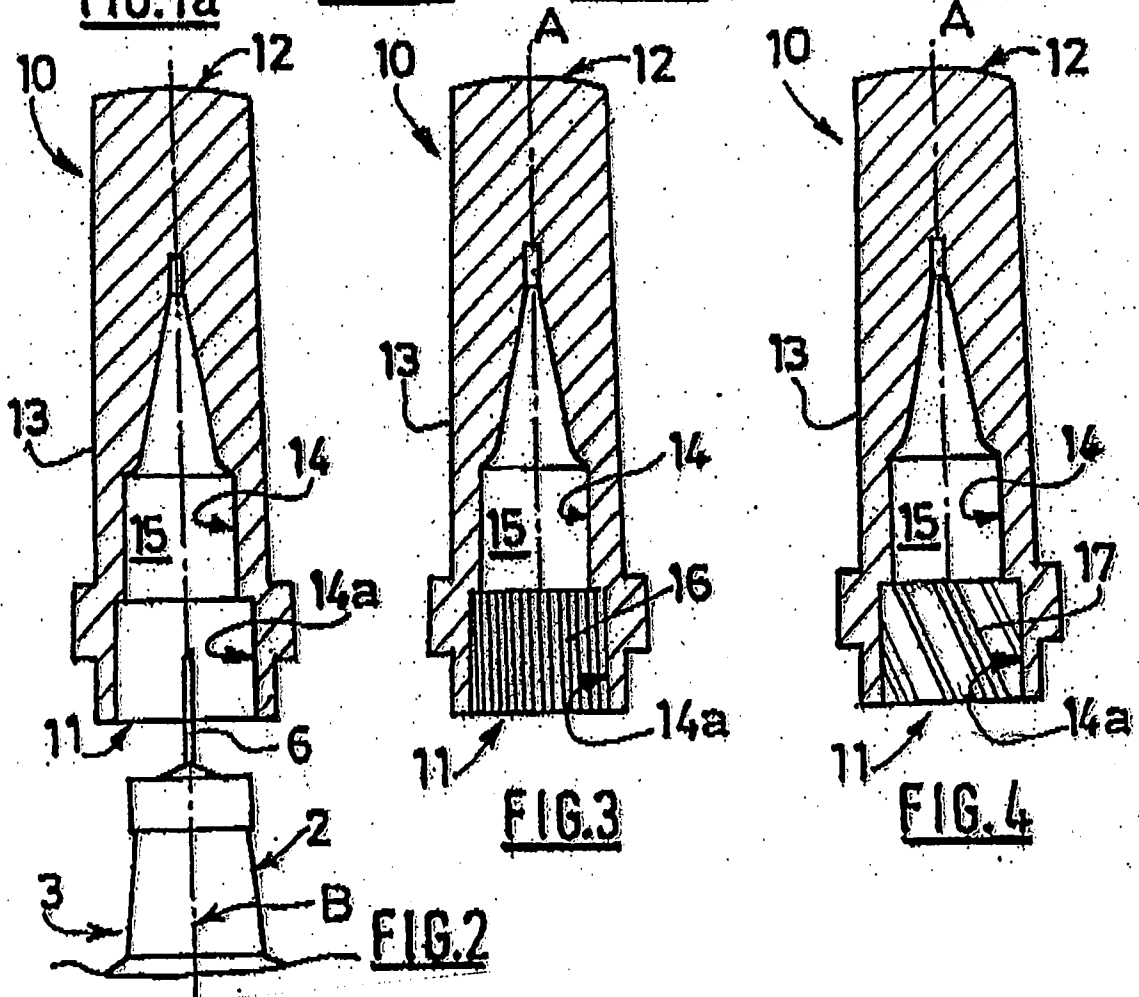
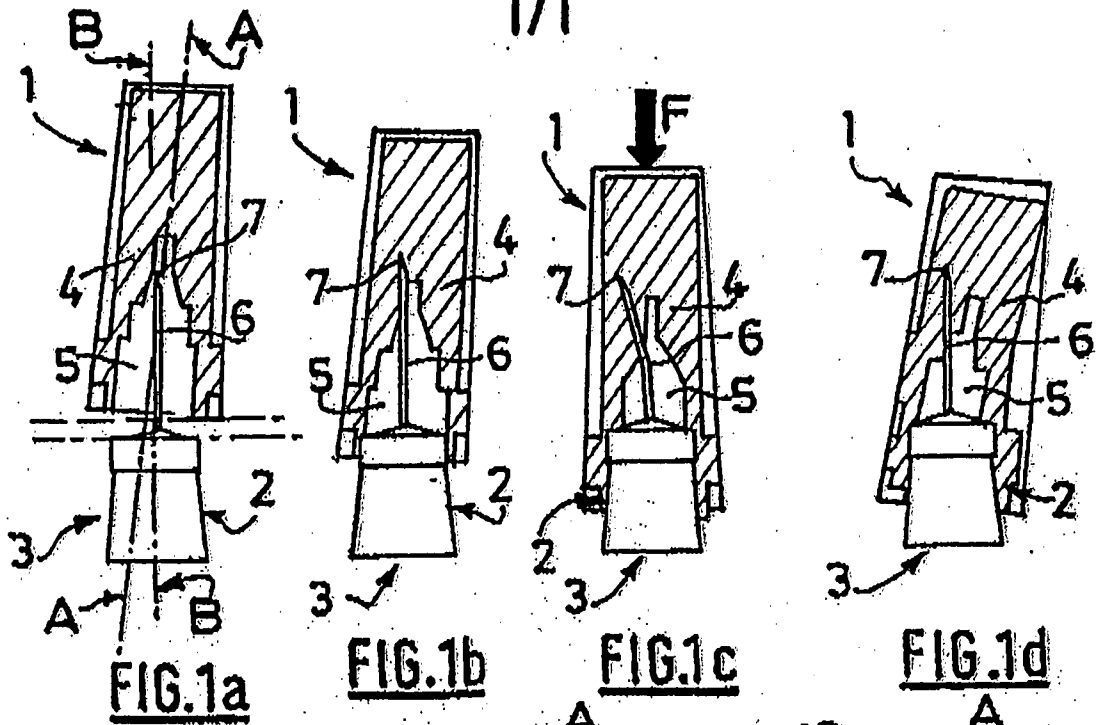
13. A shield (10) according to one of claims 1 to 12, characterized in that the value of said mean radial roughness varies from the proximal end to
15 the distal end of said portion (14a).

14. A shield (10) according to the preceding claim, characterized in that said mean radial roughness is greater in the region of the proximal end of said portion (14a) than in the region of the distal end of said portion (14a).

20 15. Method for protecting the distal extremity of an administration device (3), characterized in that it comprises the step of securing a shield (10) according to one of claims 1 to 13, on to the distal extremity of said administration device (3).

16. Method according to claim 15, characterized in that the securing step is completed on an assembly line by automatic means.

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INTERNATIONAL SEARCH REPORT

International application No

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A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/32

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	EP 0 976 415 A (BECTON DICKINSON CO [US]) 2 February 2000 (2000-02-02) figures	1-16
X	US 4 240 425 A (AKHAVI DAVID S [US]) 23 December 1980 (1980-12-23) figures 1-3	1-16
X	EP 0 240 787 A (WIMMER PHARMA GUMMI GMBH [DE]) 14 October 1987 (1987-10-14) figures 1,2,4-7	1-16
X	US 3 381 813 A (GEORGE COANDA ET AL) 7 May 1968 (1968-05-07) figures 1,2,5,6	1-16

☐

Further documents are listed in the continuation of Box C.

☒

See patent family annex.

* Special categories of cited documents :

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- *P* document published prior to the international filing date but later than the priority date claimed

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- *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.
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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2007/003214

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0976415	A	02-02-2000	DE 69925205 D1	16-06-2005
			DE 69925205 T2	09-03-2006
			JP 2000051354 A	22-02-2000
			US 2001044608 A1	22-11-2001
US 4240425	A	23-12-1980	NONE	
EP 0240787	A	14-10-1987	CA 1270168 A1	12-06-1990
			US 4735311 A	05-04-1988
US 3381813	A	07-05-1968	NONE	