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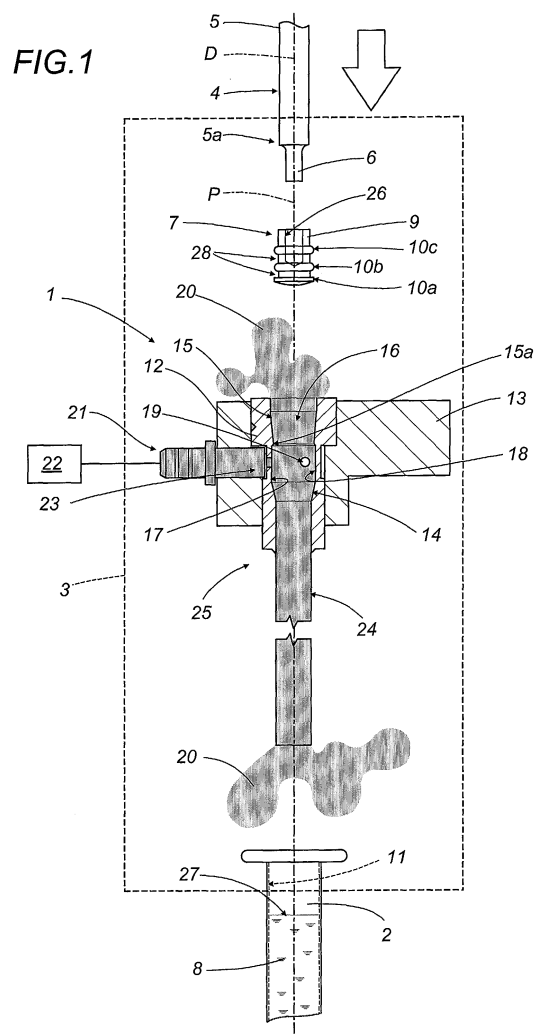
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(54) **Disposable syringe conditioning apparatus and related conditioning method**

(57) The apparatus (1) for conditioning disposable syringes (2) comprises a lower truncated cone shaped first portion (14), an upper truncated cone shaped second portion (15), a central cylindrical third portion (17) and a cylindrical guide tube (24), all extending along a path (P) followed by a stopper (7) moving towards a syringe (2) under the driving action of a plunger. The cylindrical third portion (17) has a plurality of outlet openings (19) for an inert gas (20) supplied by a pressurised source (22).



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Description

[0001] The present invention relates to an apparatus for conditioning disposable syringes.

[0002] In particular, the present invention relates to a device for inserting the stopper into a syringe that has already been filled with a liquid product, normally a medicine or a pharmaceutical.

[0003] In the liquid pharmaceutical packaging sector, it is known that containers such as ampoules, phials and syringes are filled in a substantially inert environment. This is because many medicinal substances tend to deteriorate in contact with air.

[0004] To avoid contact with air, the filling area is supplied with an inert gas such as nitrogen or carbon dioxide.

[0005] In the present specification, the term "inert gas" means any gas that does not chemically react with the liquid substance contained in the syringe.

[0006] Creating an inert environment is relatively simple for ampoules and phials which are filled using a cannula with a double lining, that is to say, having an inner duct for dosing the liquid product and an outer annular duct for discharging the inert gas. The inert gas discharged through the outer duct maintains the required inert environment during liquid filling operations and during subsequent sealing (of ampoules) and capping (of phials).

[0007] In the case of disposable syringes, on the other hand, the maintenance of a suitable inert environment during filling and subsequent insertion of the stopper presents several problems. In particular, it is extremely difficult to keep the required quantity of inert gas in contact with the surface of the liquid inside the syringe.

[0008] In other words, the insertion of the stopper creates a movement of air which "blows" the inert gas away from the surface of the liquid.

[0009] The aim of the present invention is to overcome the above mentioned drawbacks through an apparatus that creates an effective inert environment and that is, at the same time, functional, practical and economical to make.

[0010] The present invention accordingly provides a disposable syringe conditioning apparatus comprising, within a defined working area, means for guiding and positioning a stopper inside a syringe, which is partly filled with a liquid substance, means for emitting an inert gas around the defined working area, the apparatus being characterised in that the emitting means comprise at least one outlet opening for introducing the inert gas into the guide and positioning means.

[0011] The present invention also relates to a disposable syringe conditioning method.

[0012] The present invention accordingly provides a disposable syringe conditioning method comprising the steps of placing a stopper inside respective guide and positioning means, pushing the stopper along a defined feed path through the guide and positioning means, in-

serting the stopper into the syringe, and introducing inert gas in the proximity of the syringe, the method being characterised in that the step of introducing the inert gas comprises the emission of the inert gas directly into the guide and positioning means.

[0013] The technical characteristics of the invention, with reference to the above aims, are clearly described in the claims below and its advantages are apparent from the detailed description which follows, with reference to the accompanying drawings which illustrate a preferred embodiment of the invention provided merely by way of example without restricting the scope of the inventive concept, and in which:

- Figure 1 is a schematic side elevation view, with some parts in cross section and others cut away for clarity, of the disposable syringe conditioning apparatus according to the present invention in a first step of its process cycle;
- Figures 2 to 7 are schematic side elevation views, scaled down compared to Figure 1, showing six successive steps in the operation of the apparatus of Figure 1;
- Figure 8 is a schematic detail view, with some parts in cross section, showing a part of the apparatus illustrated in the other figures.

[0014] With reference to the accompanying drawings, the numeral 1 denotes a portion of an apparatus for conditioning disposable syringes 2.

[0015] The portion 1 forms a defined working area 3 of the conditioning apparatus.

[0016] The apparatus 1 comprises a plunger 4 having a shaft 5 and, at the latter's lower end 5a, a tip 6 which engages with a stopper 7 designed to be inserted into the syringe 2, the latter being prefilled with a defined quantity of a liquid substance 8.

[0017] The stopper 7 comprises a cylindrical body 9 and three elastic annular elements 10a, 10b, 10c, respectively, lower, central and upper elements, which are designed to come into sealed contact with an inside surface 11 of the syringe 2.

[0018] The plunger 4 is reciprocatingly mobile in a straight direction D and is driven by customary drive means, for example, pneumatic or hydraulic, which are not illustrated.

[0019] As it moves in the direction D, the plunger 4 engages with a bush 12 in such a way as to feed the stopper 7 along a defined feed path P that substantially coincides with the direction D.

[0020] The bush 12 is mounted in a supporting block 13 and comprises a lower truncated cone shaped first portion 14 and an upper truncated cone shaped second portion 15.

[0021] The truncated cone shaped first and second portions 14, 15 together constitute a section 16 for elastically deforming the elastic annular elements 10a, 10b, 10c.

[0022] The truncated cone shaped first and second portions 14 and 15 have between them an interposed central cylindrical third portion 17 forming an annular band 18 whose centre is located on the feed path P of the stopper 7.

[0023] At equal angular intervals around the annular band 18 there is a plurality of outlet openings 19 for discharging an inert gas 20 into the bush 12.

[0024] The outlet openings 19 are connected, through a pneumatic conduit 21, to a source of the inert gas 20 under pressure, schematically represented as a block 22 in the drawings.

[0025] The outlet openings 19, the pneumatic conduit 21 and the source 22 together constitute for the apparatus 1, means 23 for emitting the inert gas 20.

[0026] The portion 1 also comprises a cylindrical tube 24 for guiding the stopper 7 and connected to the bush 12 at the lower end of the truncated cone shaped first portion 14. The outside diameter of the cylindrical guide tube 24 is smaller than the inside diameter of the syringe 2.

[0027] The plunger 4, the bush 12 and the cylindrical tube 24 together constitute means 25 for guiding and positioning the stopper 7 in the syringe 2.

[0028] As illustrated in more detail in Figure 8, the narrower end 15a of the truncated cone shaped second portion 15 has a rounded edge 15b that joins the second portion 15 to the cylindrical third portion 17 in such a way as not to damage the stopper 7 as the latter passes through the portions 15, 17.

[0029] Similarly, the outlet openings 19 also have rounded edges 19a that do not damage the stopper 7 as it is pushed along the feed path P.

[0030] With reference to use, the operation of the disposable syringe conditioning apparatus 1 is illustrated in a succession of operating steps in Figures 1 to 7.

[0031] As shown in Figure 1, the syringe 2, after being filled to a defined level with the liquid substance 8 at a customary dosing station which is not illustrated, is positioned under the mounting block 13 in a first, lowered position. Above the mounting block 13, the plunger 4 is at its raised end position. The stopper 7 is schematically represented as being suspended at an intermediate position between the plunger 4 and the mounting block 13 and is held in this position by customary supporting means which are not illustrated. Inert gas 20 is injected into the bush 12 through the pneumatic conduit 21 and outlet openings 19. The inert gas 20 spreads into the guide and positioning means 25 both above and below the outlet openings 19.

[0032] With reference to Figure 2, the plunger 4 is lowered in the straight direction D by the aforementioned drive means (not illustrated) until its tip 6 engages with a cavity 26 formed in the cylindrical body 9 of the stopper 7.

[0033] As shown in Figure 3, the plunger 4, as it moves down along the feed path P, pushes the stopper 7 into the upper truncated cone shaped second portion

15 of the bush 12. Owing to the narrowing cross section of the second portion 15, the stopper 7 is squeezed transversely, that is to say, its elastic annular seal elements 10a, 10b, 10c are deformed in such a way as to allow the stopper 7 to pass through the narrow end 15a of the second portion 15. The contact of at least one of the elastic annular elements 10a, 10b, 10c of the stopper 7 with the tapered inside surface of the truncated cone shaped second portion 15 stops the inert gas 20 from entering the second portion 15 and from spreading into the upper section of the guide means 25. Customary drive means, which are not illustrated, now move the syringe 2 to a raised position in such a way that the stopper 7 guide tube 24 is inside the syringe 2, at a suitable distance from the surface 27 of the liquid substance 8 in the syringe 2. At this position, the inert gas 20 supplied to the lower section of the guide and positioning means 25 spreads over the surface 27 and, thanks to the clearance fit between the guide tube 24 and the inside surface 11 of the syringe 2, the inert gas 20 is free to flow out of the syringe 2. This prevents the pressure of the gas 20 from accumulating and causing turbulence in the liquid substance 8 in the syringe 2 or, worse still, pushing the liquid substance 8 out of the syringe 2 through the needle (not illustrated).

[0034] As shown in Figure 4, the stopper 7, after going through the central cylindrical third portion 17 of the bush 12, is pushed by the plunger 4 into the lower truncated cone shaped first portion 14. The passage of the stopper 7 through the truncated cone shaped first portion 14 causes it to be transversely squeezed for a second time so that it can be inserted into the guide tube 24. The passage also allows the inert gas 20 to escape through aforementioned narrow end 15a of the upper truncated cone shaped second portion 15.

[0035] With reference to Figures 5 and 6, the plunger 4 is lowered by the aforementioned drive means (not illustrated) in such way that it pushes the stopper 7 through the cylindrical guide tube 24 and positions it inside the syringe 2. By this stage, therefore, the stopper 7 has moved into the guide tube 24 to reach its almost final position within the syringe 2. The instant the pushing action of the plunger 4 causes the lowermost portion of the stopper 7 to protrude from the guide tube 24 and to come into contact with the inside surface 11 of the syringe 2, the guide tube 24 and the syringe 2 are moved apart in such a way that the stopper 7 is left in its final, stable position without sliding against the inside surface 11 of the syringe 2.

[0036] More specifically, with reference to Figure 6, the aforementioned drive means (not illustrated) move the syringe 2 back to the lowered position and the plunger 4 withdraws in the straight direction D, as indicated by the arrow F. During the steps of releasing the stopper 7 as just described, there is still a certain quantity of inert gas 20 between the surface 27 of the liquid substance 8 and the stopper 7 itself, and there is also some inert gas 20 inside the annular sections 28 delimited by the

elastic annular seal elements 10a, 10b, 10c.

[0037] In Figure 7, the plunger 4 is completely withdrawn from the guide and positioning means 24 and has returned to the initial retracted position shown in Figure 1, where it remains until another cycle like the one just described is started in order to insert the next stopper 7 into the next syringe 2.

[0038] Advantageously, with reference to the above description, the emission of inert gas 20 at the cylindrical third portion 17 enables the inert gas 20 to accumulate in the annular sections 28 of the stopper 7, these annular sections 28 being axially delimited, as mentioned above, by the elastic annular seal elements 10a, 10b, 10c. Thus, when the stopper 7 is squeezed into the truncated cone shaped first portion 14, a certain amount of inert gas 20 is trapped within the annular sections 28. When the stopper 7 is released in the syringe 2, the inert gas 20 trapped in the annular sections 28 augments the barrier effect created by the inert gas 20 between the surface 27 of the liquid substance 8 and the stopper 7, preventing contact between the liquid substance 8 and the outside atmosphere.

[0039] It will be understood that the invention can be subject to modifications and variations without thereby departing from the scope of the inventive concept. Moreover, all the details of the invention may be substituted by technically equivalent elements.

Claims

1. An apparatus for the conditioning of disposable syringes (2) comprising, within a defined working area (3):

- means (25) for guiding and positioning a stopper (7) in the syringe (2) that is partly filled with a liquid substance (8);
- means (23) for emitting an inert gas (20) around the defined working area (3);

the apparatus being **characterised in that** the emitting means (23) comprise at least one outlet opening (19) through which the inert gas (20) is introduced into the guide and positioning means (25).

2. The apparatus according to claim 1, **characterised in that** the guide and positioning means (25) comprise a plunger (4) designed to push the stopper (7) into the syringe (2), along a defined feed path (P) through the guide and positioning means (25).

3. The apparatus according to claims 1 and 2, where the stopper (7) is substantially cylindrical and has three elastic annular elements (10a, 10b, 10c) designed to engage with an inside surface (11) of the syringe (2), **characterised in that** the means (25) for guiding and positioning the stopper (7) comprise

a section (16) designed to elastically deform at least the elastic annular elements (10a, 10b, 10c) so as to temporarily reduce the transversal dimension of the stopper (7).

4. The apparatus according to claim 3, **characterised in that** the deforming section (16) comprises at least one first portion (14) which is substantially truncated cone shaped and through which the stopper (7) passes.

5. The apparatus according to claim 4, **characterised in that** the deforming section (16) comprises at least one second portion (15), which is substantially truncated cone shaped and through which the stopper (7) passes, and which is located upstream of the first portion (14) relative to the feed path (P).

6. The apparatus according to claim 5, **characterised in that** the outlet opening (19) for the inert gas (20) is located upstream of the truncated cone shaped first portion (14) along the defined feed path (P).

7. The apparatus according to claims 4 and 5, **characterised in that** the outlet opening (19) is located between the truncated cone shaped first portion (14) and the truncated cone shaped second portion ((15).

8. The apparatus according to any of the foregoing claims, **characterised in that** the emitting means (23) comprise a plurality of outlet openings (19) for the inert gas (20), these outlet openings (19) being distributed around an annular band (18) whose axis substantially coincides with the feed path (P).

9. The apparatus according to claim 8, **characterised in that** it comprises a substantially cylindrical third portion (17) located upstream of the truncated cone shaped first portion (14), the cylindrical third portion (17) constituting the annular band (18) around which the outlet openings (19) for the inert gas are distributed.

10. The apparatus according to claim 9, **characterised in that** the substantially cylindrical third portion (17) is located between the truncated cone shaped first portion (14) and the truncated cone shaped second portion (15).

11. The apparatus according to any of the foregoing claims from 2 to 10, **characterised in that** the outlet opening (19) for the inert gas (20) has a rounded edge (19a) so as not to damage the stopper (7) as it is pushed along the feed path (P).

12. A method for the conditioning of disposable syringes (2) comprising the steps of:

- placing a stopper (7) inside respective guide and positioning means (25);
- pushing the stopper (7) along a defined feed path (P) through the guide and positioning means (25); 5
- pushing the stopper (7) into the syringe (2) that is at least partly filled with a liquid substance (8);
- introducing inert gas (20) in the proximity of the syringe (2); 10

the method being **characterised in that** the step of introducing the inert gas (20) comprises the emission of the inert gas (20) directly into the guide and positioning means (25). 15

13. The method according to claim 12, where the stopper (7) is substantially cylindrical and has three elastic annular elements (10a, 10b, 10c) designed to engage with an inside surface (11) of the syringe (2), **characterised in that** the step of pushing the stopper (7) through the guide and positioning means (25) comprises a sub-step of elastically deforming at least the elastic annular elements (10a, 10b, 10c) so as to temporarily reduce their transversal dimensions. 20 25

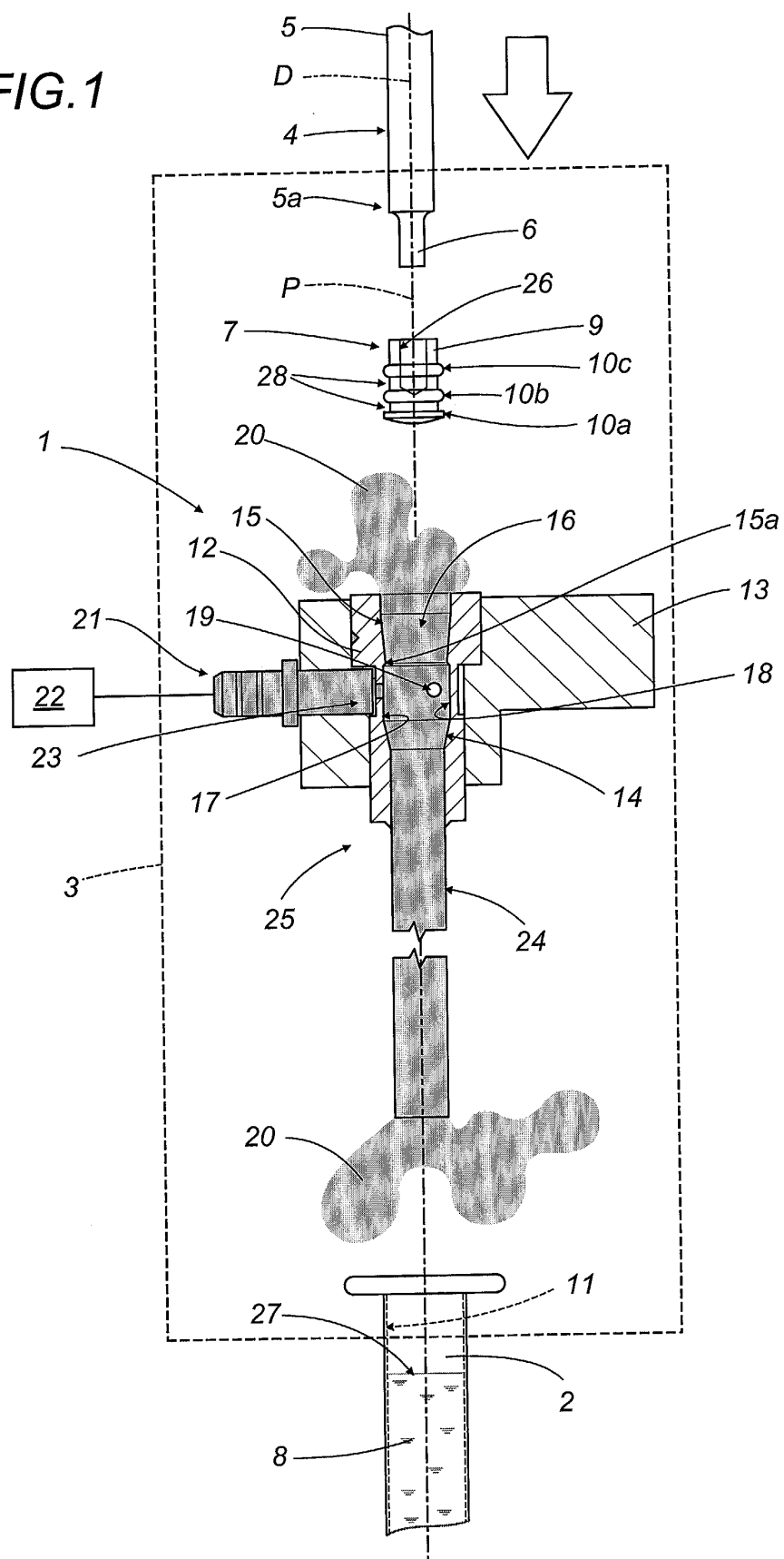
14. The method according to claim 13, **characterised in that** the sub-step of elastically deforming the elastic annular elements (10a, 10b, 10c) is carried out at a defined section (16) of the guide and positioning means (25), the section (16) having at least a truncated cone shaped first portion (14). 30

15. The method according to claim 14, **characterised in that** the emission of inert gas (20) through at least one outlet opening (19) occurs upstream of the truncated cone shaped first portion (14) along the defined feed path (P). 35 40

16. The method according to claims 14 and 15, **characterised in that** the emission of inert gas (20) through at least one outlet opening (19) occurs at a cylindrical third portion (17) of the defined section (16), the third portion (17) being located between the truncated cone shaped first portion (14) and a truncated cone shaped second portion (15) located upstream of the first portion (14). 45 50

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FIG.1



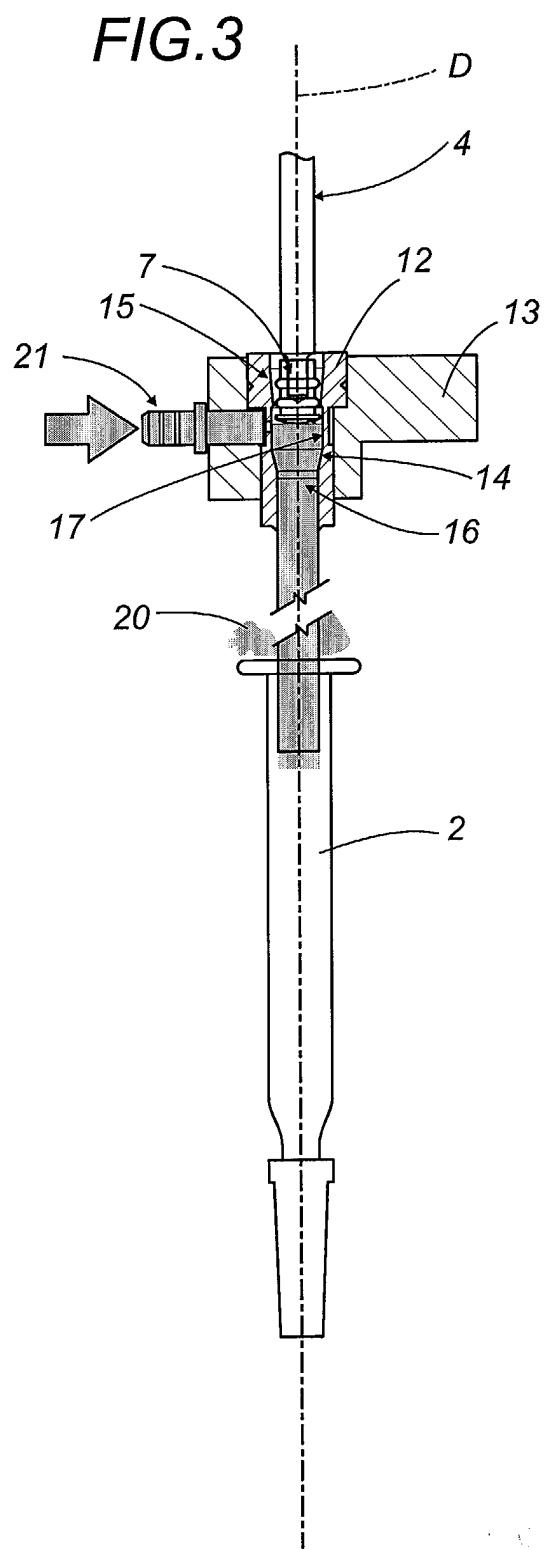
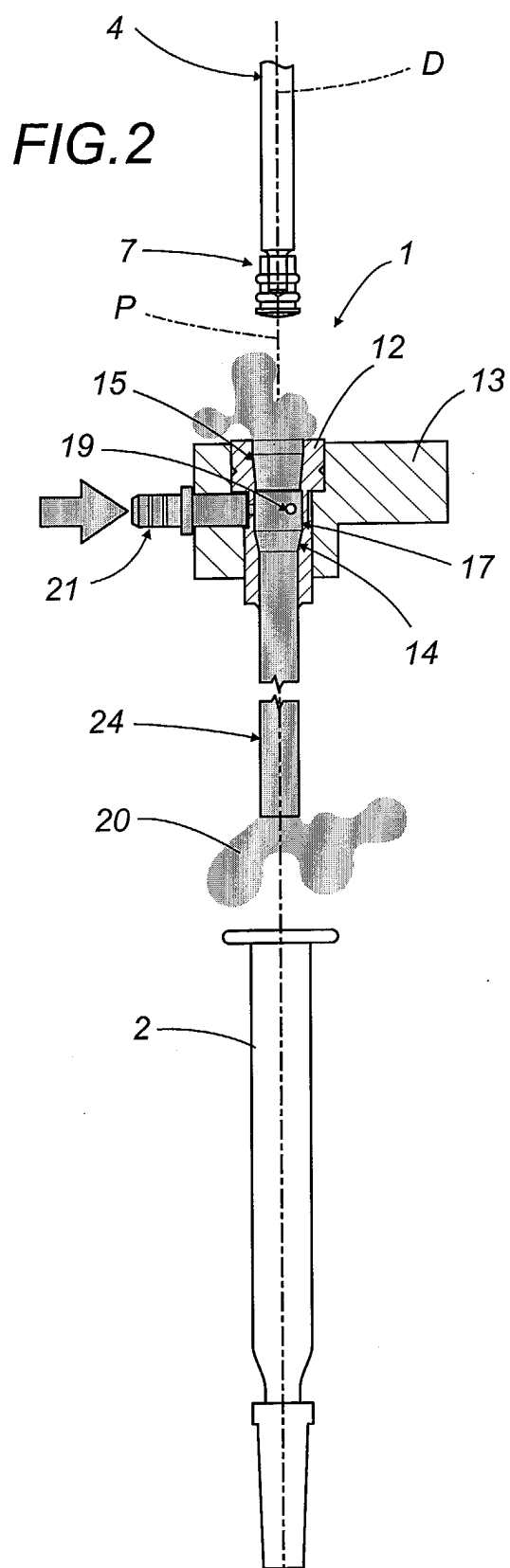


FIG.4

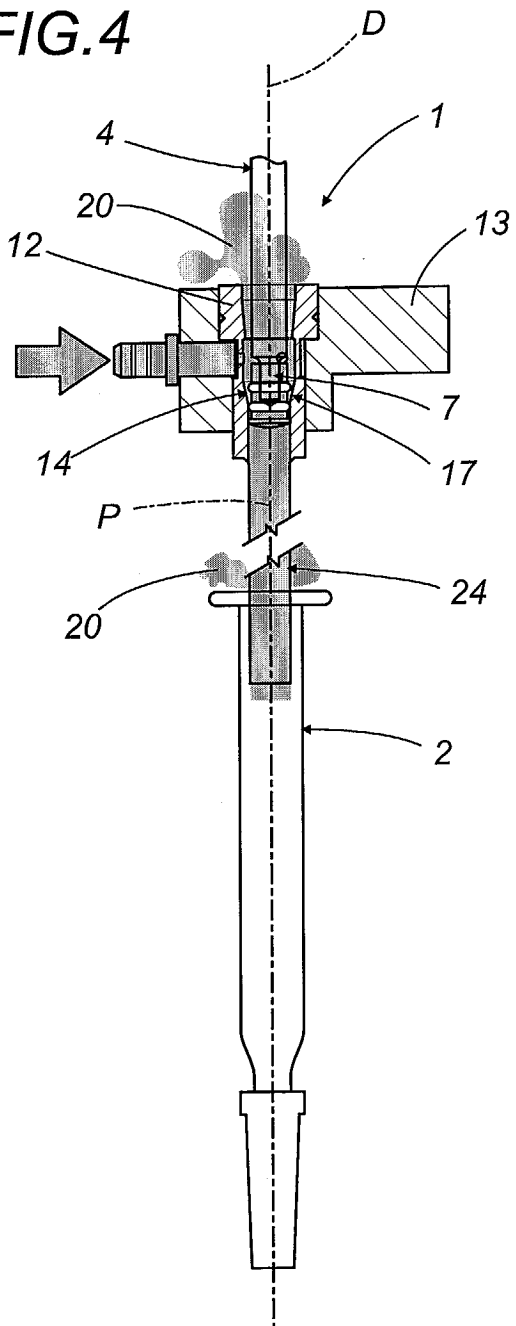


FIG.5

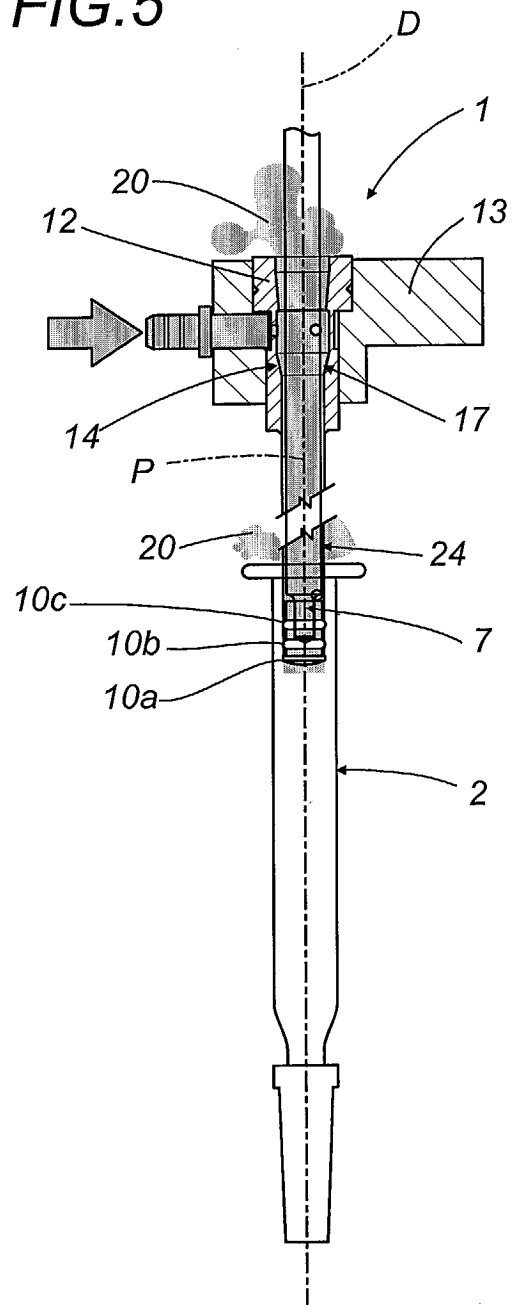


FIG.6

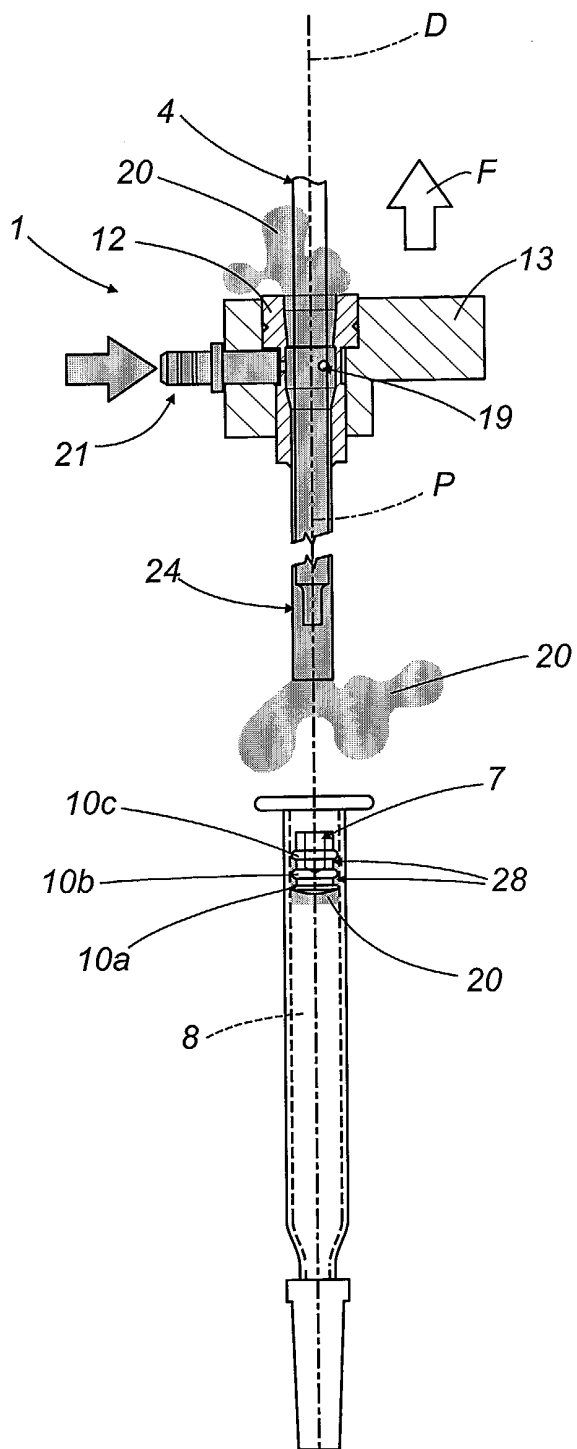


FIG.7

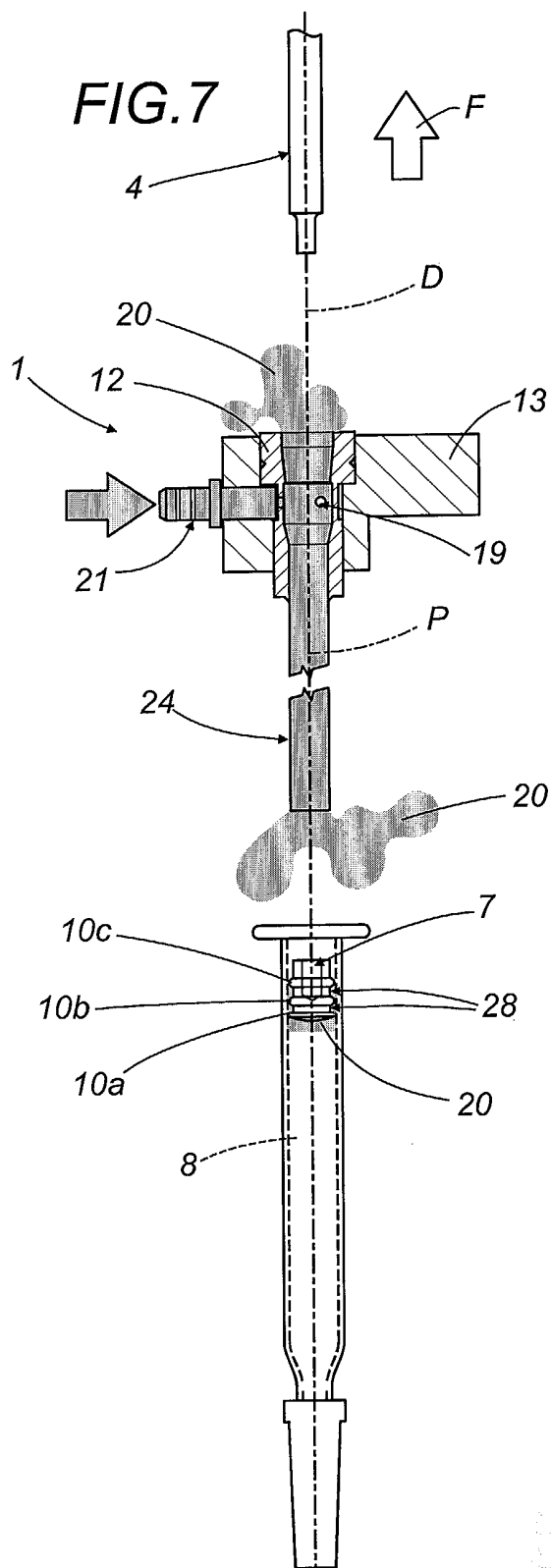
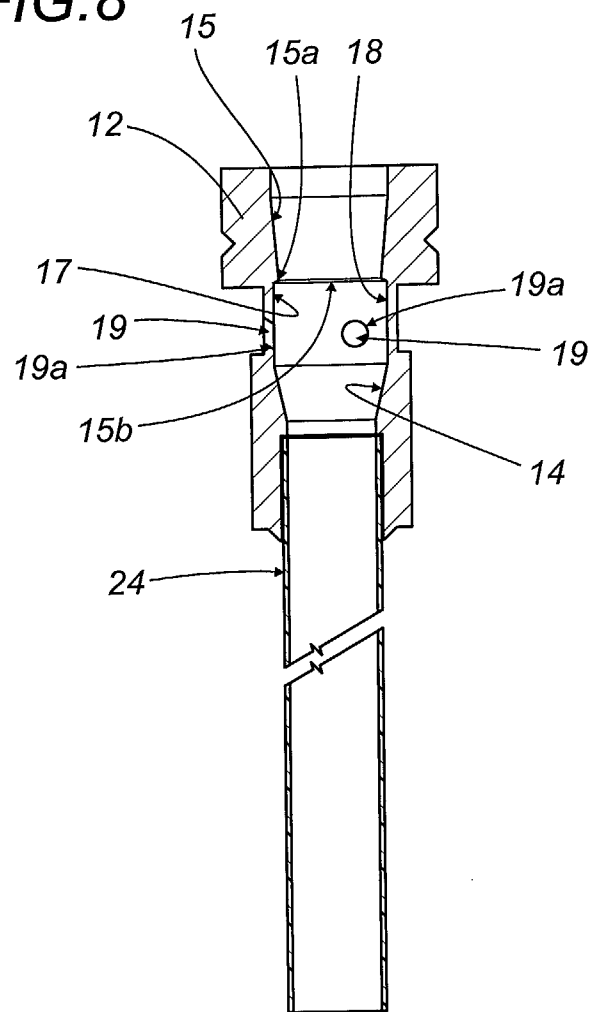


FIG.8





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 03 42 5074

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The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 10 June 2003	Examiner Nielsen, M
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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