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(54) Title: SAFETY AND FILLING SYSTEM FOR RETRACTABLE NEEDLES SYRINGES

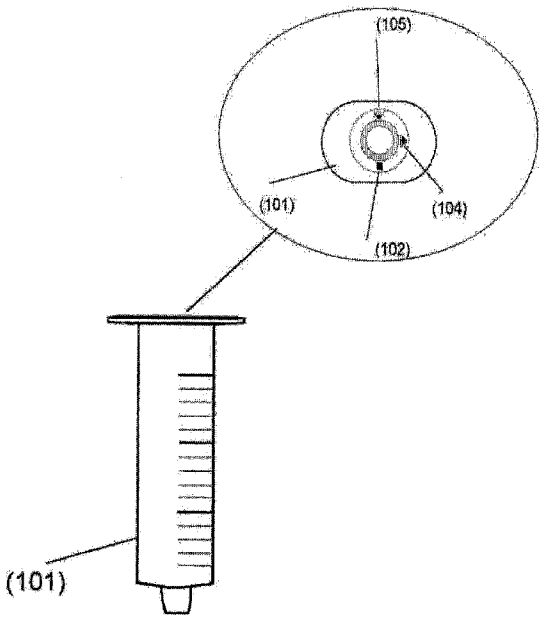

FIG.1

(57) Abstract: The present invention relates to an innovative system which definitively prevents the re-use of syringes with retractable needles, allowing at the same time to fill the tank by means of a mechanical system installed inside the piston. The operation that aims at preventing the re-use of the device takes place through a mechanical system that prevents the return of the piston towards the initial position of aspiration and restricts, therefore, its action in a single direction and prevents the return of the plunger to the initial position of injection and therefore restricts its action in a single direction. Moreover a rotating mechanical transition system prevents the re-positioning of the piston in the previously used position. The filling of the container, instead, takes place through the use of a system via a flexible cannula placed inside the piston.

[Continued on next page]

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SAFETY AND FILLING SYSTEM FOR RETRACTABLE NEEDLES SYRINGES

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The present invention relates to an innovative system which definitively prevents the re-use of syringes with retractable needles, allowing at the same time to fill the tank by means of a mechanical system installed inside the piston.

Healthcare professionals, such as nurses, doctors, veterinary surgeons, dentists, as well as waste disposal workers, are subjected daily to the risk of accidental punctures from inoculation systems previously used for medical therapies or else, which have come into direct contact with biological fluids of living beings potentially carrying transmissible infectious diseases.

Accidental punctures caused by previously used inoculation systems represent the most frequent and dangerous mode of exposure to communicable diseases. In fact, there are over forty transmissible pathogens, through blood or biological fluids, following an accidental puncture. Among them: the human immunodeficiency virus (HIV), the hepatitis B virus (HBV) and the hepatitis C virus (HCV). The problems

connected to the management of biological risk by public and private health systems entail very high and unsustainable costs both from the economic and psychological point of view by those people who suffer the physical injury of an accidental puncture.

But the containers for the introduction or extraction by non-natural way of medicinal substances must not only guarantee the safety from the risk of accidental punctures, but also the impossibility of reuse.

In fact, it is a general custom, especially in countries with a lower economic profile, to re-use containers for the reintroduction of pharmacological substances after the administration of vaccines or other medicines.

On the market there are different types of retractable needle syringes, some also subject to special patent, whose security systems can be bypassed, as often happens, by not completing the piston stroke inside the container, thus allowing the reuse of the device.

It should also be highlighted the use cases of containers of medicinal substances, in vaccination campaigns and for the administration of antithrombotic

drugs, where the containers themselves are supplied to health facilities pre-filled with the drugs.

The filling of the drugs is carried out by the pharmaceutical companies to which the containers are supplied completely disassembled. Thereafter, the pharmaceutical companies assemble them at different stages following the filling with the drug.

This approach, by significantly increasing operators' manipulation, increases the risk of contamination in the numerous preparation phases.

Although attempts have been made to limit these problems in all ways, some of which are also present in a number of patents, including EP2445554B1, US3998224A, US4252118A, US4391273A, US4687467A, US5062833A, US5205825A as well as the RU2236873 and WO1998001174A1 patents, they can in no way completely inhibit the syringes from reuse as well as cannot offer a simple and effective way of filling the siringe without using the needle.

The aforementioned criticalities are overcome by the present invention which allows the introduction and extraction of substances from the human or animal body preventing the re-use of the device by a practically inviolably means and also specifies a

separate way for filling the container with ready to use medicines.

The operation that aims at preventing the re-use of the device takes place through a mechanical system that:

a) once the action of aspiration of the medicinal substance in the device has begun, it prevents the return of the piston towards the initial position of aspiration and restricts, therefore, its action in a single direction;

b) once the injection of the medicinal substance has begun in the device, it prevents the return of the plunger to the initial position of injection and therefore restricts its action in a single direction; as well, a rotating mechanical transition system, placed between the suction and injection operations consisting of a block that guides the piston, prevents the re-positioning of the piston in the previously used position.

The filling of the container, instead, takes place through the use of a system via a flexible cannula placed inside the piston, through which the desired substance is conveyed so that the same is poured inside the container, and thereafter be ready

to be injected.

The present invention will now be described, for illustrative purposes, according to a preferred embodiment thereof, not to be understood in any limiting way, with particular reference to the figures and to the attached drawings, bearing in mind that all the embodiments used, without prejudice to their functionality, may vary in size, numbers and shape without this limiting the present invention:

- **figure 1** shows the container, with emphasis in the box, as a view from above, of the fins and the ratchet;
- **figure 2** shows a section of the container with a fin and the ratchet;
- **figure 3** shows a further view of the container with a fin and the ratchet;
- **figure 4** shows the "U" shaped system of channels on the piston and the rack system;
- **figure 5** shows another view of the "U" shaped system of channels on the piston and of the rack system;
- **figure 6** shows the cavity existing in the piston;
- **figure 7** shows the mechanical system housed

inside the piston;

- **figure 8** shows the details of the mechanical system housed inside the piston;
- **figure 9** shows the details of the mechanical system housed inside the piston when it is compressed.

With reference to the figures as shown, the essential elements of the system are immediately evident, formed by a container (101) equipped, in its apical part, with a tooth (102) and two notched fins (104 and 105) which respectively allow the sliding and locking of a piston (106) whose outer surface is therefore characterized by the presence of a "U" shaped system of channels (107) and a double rack system (108 - 103).

More precisely, inside the container (101) is positioned the tooth (102) which makes the piston slide along the grooved lines (107) therein. The grooved guides (107) sliding along the tooth (102) allow the piston (106) to move first from the bottom upwards to allow the aspiration of the medicinal substances and then, after a rotation, to move from the top bottomwards in order to inject them.

The suction and injection movement of the piston

(106) which becomes irreversible thanks to the locking system made possible by the overlapping of the two notched fins (104 and 105) present in the container (101) and the two rack systems (108 and 103) present on the piston (106) which, by interacting with each other, do not allow the piston (106) to go back.

In this way, once the suction action of the medicinal substance in the device has begun, the overlapping of the rack system (103) with the notched fin (105) prevents the return of the piston (106) towards the initial suction position, allowing it to slide in one direction only. Likewise, once the action of injection of the medicinal substance into the device has begun, the overlapping of the rack system (108) with the notched fin (104) prevents the return of the piston to the initial injection position.

The system described above also avoids, in the case of pre-filled retractable needle devices, the accidental release of medicinal substances.

The Piston (106) also has a special cavity (117) at the base of which there is an interlocking housing (109) which hooks and retracts the needle (114) once the injection phase is ended, and from a pad (110) that guides the suction and injection phase of the

medicinal substances.

Inside the cavity (117) of the piston (106) a mechanical system is installed consisting, in the upper part by a perforated head (111) which allows the entire system to be fastened inside the piston (106), where the perforated head (111) allows the injection of the medicinal substances into the syringe and has at its upper end a valve (112) which prevents the reflux of the medicament present in the container towards the outside.

The perforated head (111) is connected to an accordion cannula (113), made of any biocompatible material, in turn connected, in the lower part, to the interlocking housing (109) which allows the coupling and therefore the retraction of the needle (114), at the end of the injection.

The perforated head (111) and the interlocking housing (109) are connected to each other by a spring (116), which houses the accordion cannula (113) and commands how this extends and retracts during the operations of inoculation and aspiration of the medicinal substances.

The operator or a special machine, through the accordion cannula (113) existing in the piston (106),

after having inserted the latter in the container, can inject the medicinal substance into the container (101) through the perforated head (111), and then close the piston (106) with the protection cap (115).

The present invention has been described in relation to its functionalities for illustrative but not limitative purposes and it is therefore to be understood that variations and / or modifications, also in relation to the shapes, dimensions and measurements of the invention, as well as to the arrangement and materials of the components that compose it can be made without going out of the relative scope of protection.

CLAIMS

1) Safety and filling system for retractable needle syringes, characterized by the presence of a barrel (101) provided, in its internal apical part, with a small tooth (102) and two notched fins (104 and 105) as well as a plunger (106) on whose external surface there is the presence of a system of grooves in the shape of a "U" (107) and a double rack system (108 - 103) while inside it is equipped with a cavity (117) which, in the upper part it has a perforated head (111) on which a valve (112) is positioned and inside which a mechanical system is installed consisting of an interlocking housing (109), a spring (116) and an accordion cannula (113).

2) Safety and filling system for retractable needle syringes, according to the previous claim, wherein the grooved guides (107) present on the external part of the plunger (106), sliding along the tooth (102) present in the inner part of the barrel (101) allow the plunger (106) to move first from bottom to top and then from top to bottom.

3) Safety and filling system for retractable

needle syringes, according to the preceding claims, in which the rack system (103) on the plunger (106) is overlapped on the notched fin (105) present in the barrel (101), thus preventing the return of the plunger (106) towards the initial suction position.

4) Safety and filling system for retractable needle syringes, according to the preceding claims, in which the rack system (108) on the plunger (106) is overlapped on the notched fin (104) present in the barrel (101), thus preventing the return of the plunger (106) towards the initial injection position.

5) Safety and filling system for retractable needle syringes, according to the preceding claims, wherein a mechanical system consisting of a perforated head (111) is installed inside the recess (117) of the plunger (106), and then closed by a valve (112) surmounted by a stopper (115), in which to inject the medicinal substances, connected to an accordion cannula (113), connected in the lower part to the interlocking housing (109) that allows the coupling and then the retraction of the needle (114) at the end of the injection.

6) Safety and filling system for retractable needle syringes, according to claims 1) and 5), in

which the accordion cannula (113) is enclosed inside a spring (116), connected to the perforated head (111) and to the interlocking housing (109), which stretches and retracts during the inoculation and aspiration of the medicinal substances.

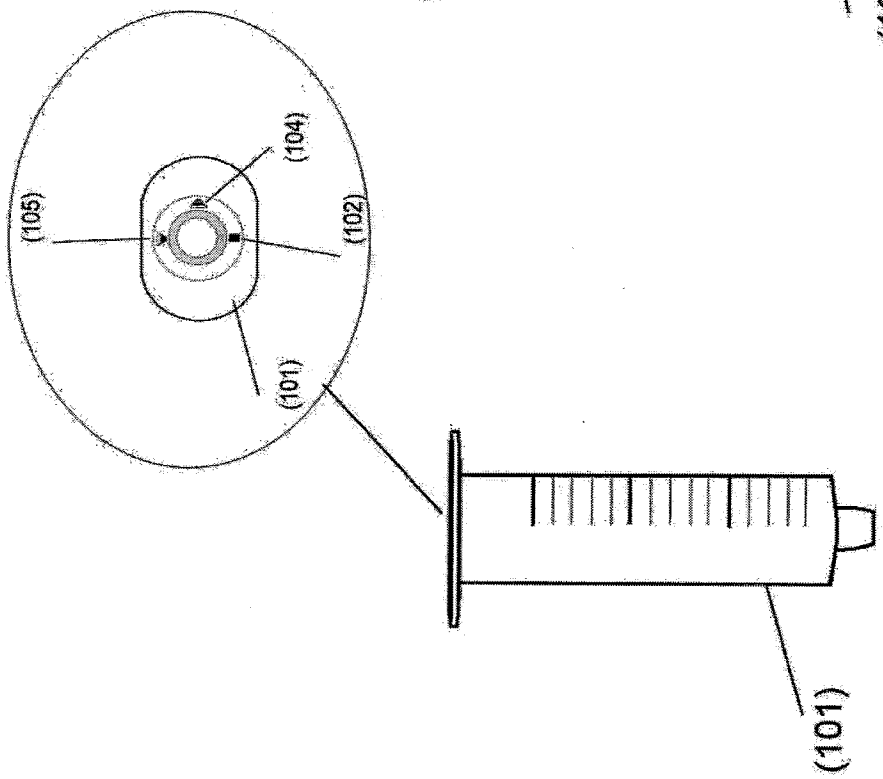


FIG.1

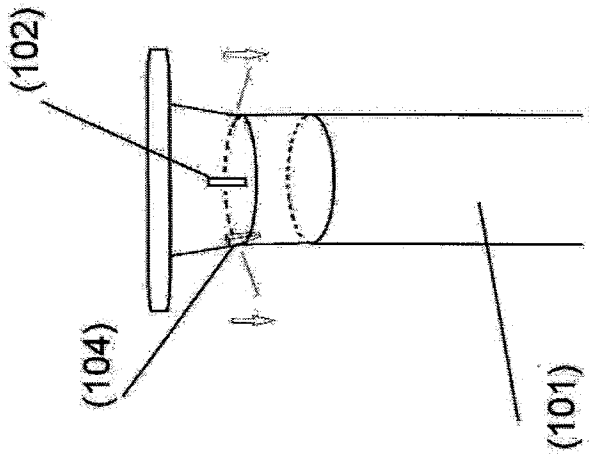


FIG.2

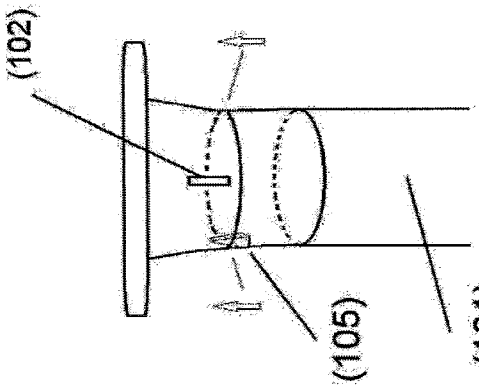


FIG.3

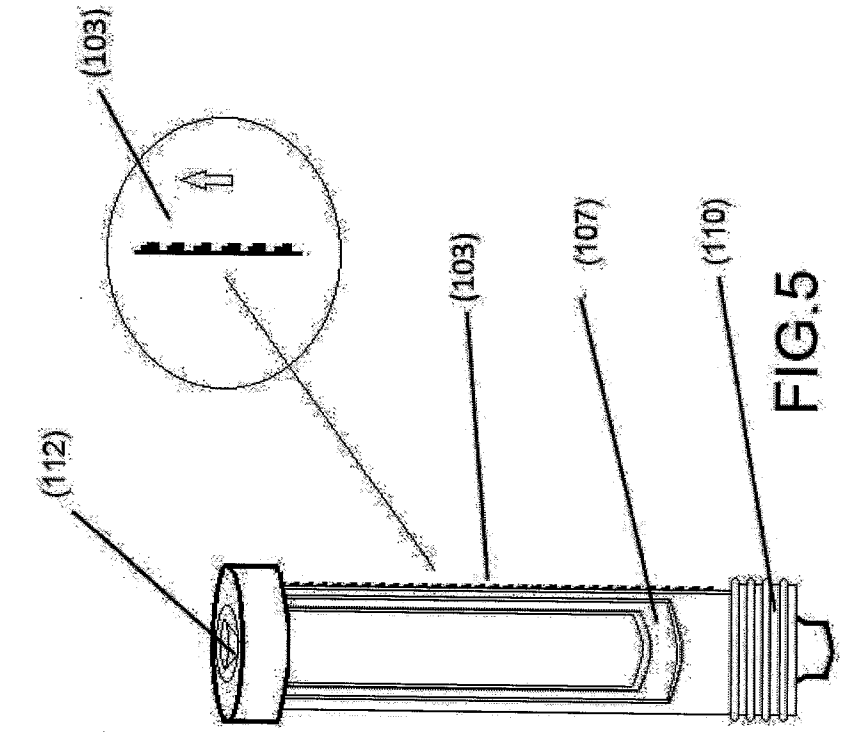


FIG.5

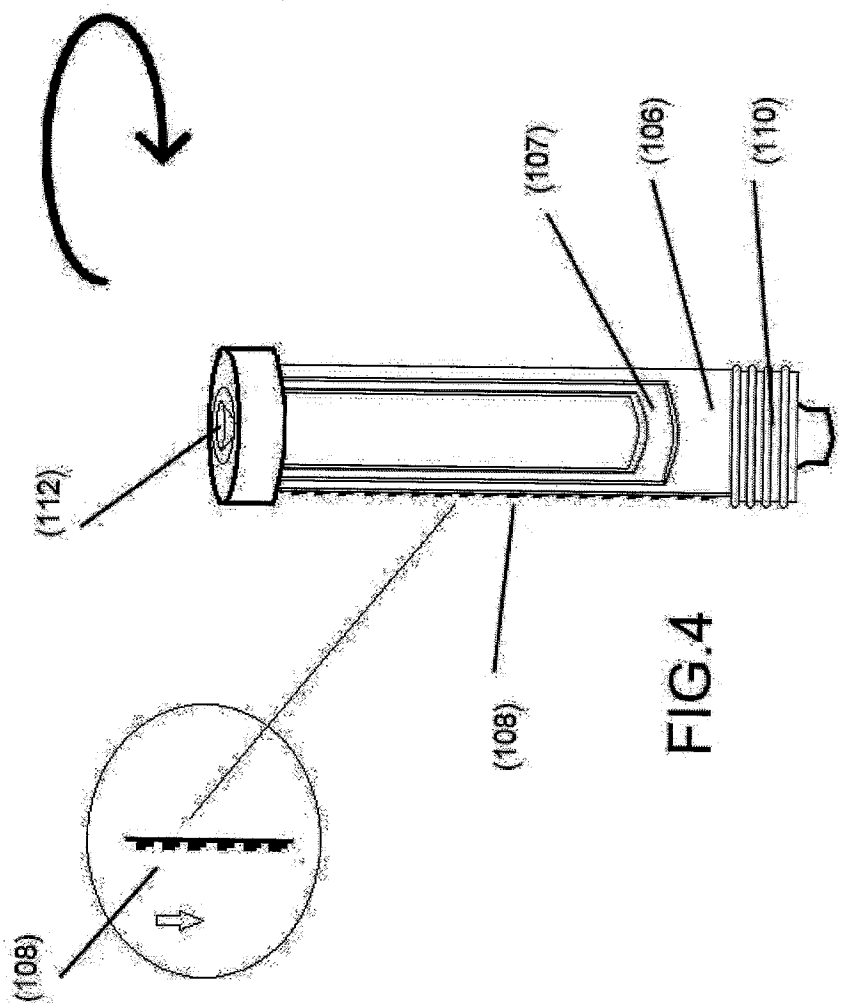


FIG.4

FIG.9

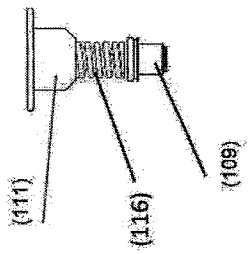


FIG.8

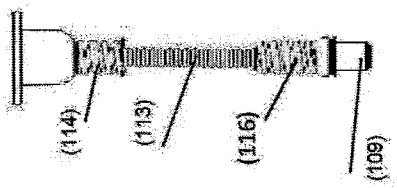


FIG.7

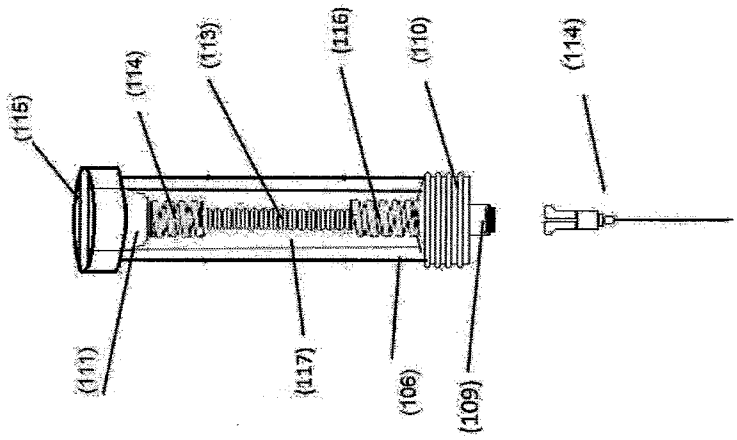
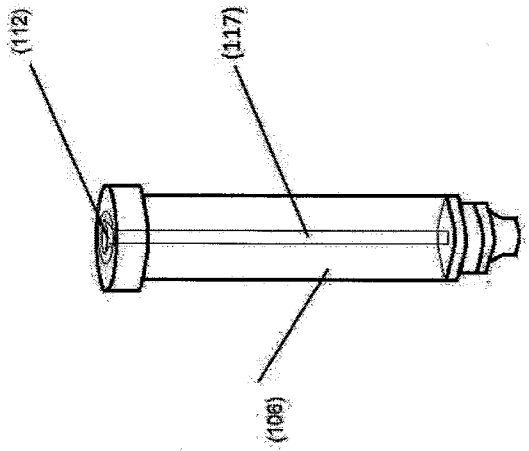


FIG.6



INTERNATIONAL SEARCH REPORT

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PCT/IT2019/050103

A. CLASSIFICATION OF SUBJECT MATTER
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ADD.

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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 6 494 863 B1 (SHAW THOMAS J [US] ET AL) 17 December 2002 (2002-12-17)	1-6
A	US 5 250 030 A (CORSICH CESAR G [AR]) 5 October 1993 (1993-10-05)	1-6
A	US 2012/289899 A1 (WU MING-YUAN [TW]) 15 November 2012 (2012-11-15)	1-6

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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