

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
6 February 2003 (06.02.2003)

PCT

(10) International Publication Number  
**WO 03/009892 A1**

(51) International Patent Classification<sup>7</sup>: **A61M 5/50**

(21) International Application Number: PCT/BR02/00093

(22) International Filing Date: 3 July 2002 (03.07.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
MU 8101570-4 25 July 2001 (25.07.2001) BR

(71) Applicant and

(72) Inventor: **ITO, Roberto, Yassuo** [BR/BR]; Rua Benjamin Constant, 435, CEP-87020-060 Maringá, PR (BR).

(74) Agent: **BARBOSA, Gustavo, José, F.**; Momsen, Leonardos & Cia., Rua Teófilo Otoni, 63, 10th floor, CEP-20090-080 Rio de Janeiro, RJ (BR).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

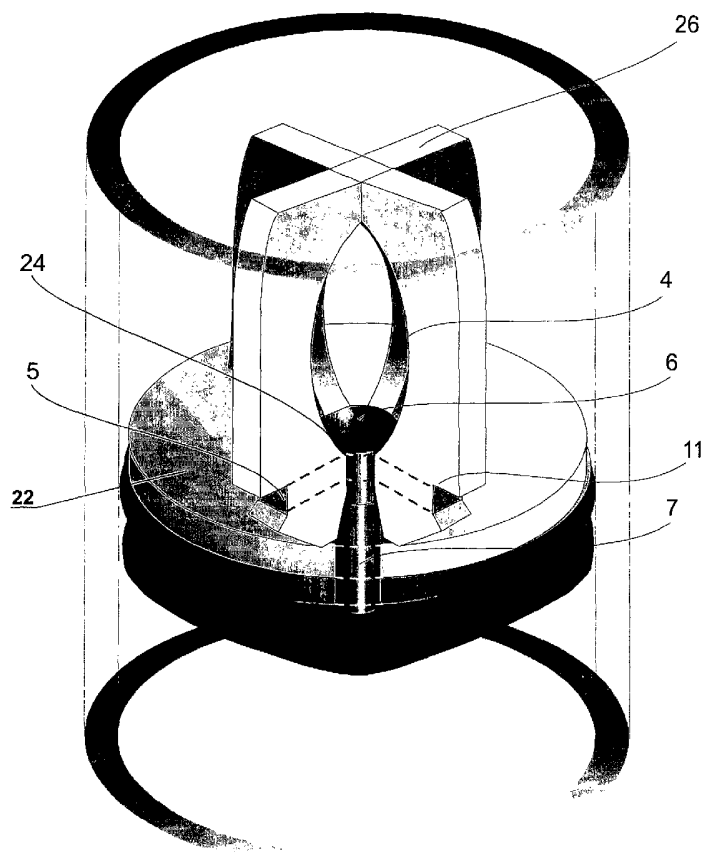
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— with international search report

[Continued on next page]

(54) Title: NON-REUSABLE SYRINGE WITH A PISTON STEM DISENGAGEMENT SYSTEM



(57) Abstract: The invention refers to a self-destructive syringe having a piston stem disengagement system, to provide a device that allows the normal suction of the liquid intended to be injected, in a manner similar to that of disposable syringes commonly used in the market. However, when the course of travel of the piston stem/plunger assembly is reversed in order to inject a liquid, the pressure is transferred to the plunger (22), causing the liquid to also apply a proportional pressure against the plunger, due to the force applied to the piston stem, causing a pressure in the liquid that is greater than the atmospheric pressure, thereupon occurring a deformation of the plunger (22), expelling the supporting pin (6) of the piston stem/plunger assembly, since the pin (6) is displaced, the supporting claws (5) lose their support and the piston stem is detached from the plunger (22) and this latter (plunger) is retained at the bottom of the barrel, rendering impossible a second suction stroke and consequently a reutilization (self-destruction).

WO 03/009892 A1



---

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

## "NON-REUSABLE SYRINGE WITH A PISTON STEM DISENGAGEMENT SYSTEM"

### Field of the Invention

The present invention refers to a self-destructive syringe with a  
5 piston stem disengagement system.

### Background of the Invention

As is widely known, the “disposable syringes” presently existing  
in the market, in spite of the adjective “disposable” being suggestive, are normally  
being reused. There is statistical evidence to the effect that the transmission of  
10 diseases such as HEPATITIS B, HEPATITIS C, AIDS and other highly  
contagious diseases is directly related to the so-called “disposable” syringes.

Although there presently exist in the market several makes and  
models of disposable syringes, there is no model that is actually non-reusable. The  
existing models are designed for the sole purpose of warranting the quality and the  
15 sterility of the product, and do not include any device that renders the same  
actually non-reusable. Therefore, it is extremely important that measures be taken  
towards fighting the diseases transmitted by means of “disposable syringes”, since  
the warnings of “not for multiple use”, “destroy upon using”, etc., printed on the  
packages, are innocuous, and do not warrant the disposal of the product. In  
20 consequence, the final user acquires the product and often reuses the same, thus  
spreading innumerable diseases that might be avoided if the syringes were really  
capable of being disabled for further use.

### Summary of the Invention

Therefore, the present invention is aimed at solving the problems  
25 existing in the prior art, by providing an automatically acting device that renders  
the syringe self-destructive, not capable of being reused after having been used  
once.

Therefore, it is an object of the present invention to provide a  
device that allows the normal suction of the liquid intended to be injected, in a

manner similar to that of the disposable syringes commonly used in the market, further allowing to certify the intravenous or intramuscular injection. However, when the course of travel of the piston stem/plunger assembly is reversed in order to inject a liquid, the pressure is transferred to the plunger, causing the liquid to  
5 also apply a proportional pressure against the plunger, due to the force applied to the piston stem, causing a pressure in the liquid that is greater than the atmospheric pressure, thereupon occurring a deformation of the plunger, expelling the supporting pin of the piston stem/plunger assembly, since the pin is displaced, the supporting claws lose their support and the piston stem is detached from the  
10 plunger and this latter (plunger) is retained at the bottom of the barrel, rendering impossible a second suction stroke and consequently a reutilization (self-destruction).

Therefore, the object of the present invention is to force one sole use of the syringe, since the piston stem detaches itself from the plunger assembly,  
15 thereby rendering impossible a second utilization; the project is intended to warrant the impossibility of reutilization and transmission of diseases.

### The Invention

Therefore, it is an object of the present invention to provide a non-reusable Syringe with a piston stem detachment system, comprising: a syringe  
20 body; and, a piston stem/plunger assembly, to expel the liquid intended to be injected from the inside of the syringe, the said piston stem/plunger assembly comprising a stem having an elongated body that may be engaged in a plunger body, the elongated body being provided at one end thereof, which end shall stay outside of the syringe body, with a pressure element (thumb support); and at the  
25 other end, which other end shall stay inside the syringe body, being provided with a flexible assembly, with claws extending outwardly, that shall engage the plunger body, such claws being designed to enhance the radial flexibility of the lower end, the plunger body being provided with two parallel surfaces hollowed at the central part thereof by central through holes of different diameters, the part of the lower

surface of the plunger body being provided with the hole of lesser diameter being involved by a flexible membrane and the plunger body being further provided with a cross-shaped cut disposed centrally relative to the axis of the through holes, characterized in that: the upper end (the mouth) of the inner wall of the syringe body has a groove wherein there shall be accommodated a guide washer intended to keep the piston stem/plunger assembly centered in relation to the syringe body; the claws of the flexible assembly shall engage in the cross-shaped cut in the plunger body, the claws of the flexible assembly of the piston stem remaining retained in the plunger body by means of the engagement of a supporting pin, which pin has a cylindrical body of lesser diameter, in the through holes of the plunger body, the supporting pin having a length greater than the thickness of the plunger body, the end of its cylindrical body being supported against the internal surface of the flexible membrane that involves the lower part of the plunger body.

In a preferred embodiment, at the lower end, the claws of the flexible assembly are beveled with an angle in excess of 45°.

In another preferred embodiment, the elongated body named the piston stem has a compartment, in the center of the lower end thereof, designed to accommodate the used needle.

In another more preferred embodiment, the guide washer is provided with a cross-shaped central cutout in order to guide the elongated body of the piston stem. Still more preferentially, the body of the guide washer is provided with at least one groove rendering the same frangible.

In another preferred embodiment, the guide washer is welded to the groove in the body of the syringe, by means of laser welding.

In another more preferred embodiment, the elongated body, namely the piston stem, has its length reduced in the longitudinal direction, to an extent enough to create oscillations should there occur an attempt to reuse the syringe without the guide washer.

Also in another more preferred embodiment, the elongated body,

namely the piston stem, detaches from the plunger body.

In another more preferred embodiment, the “head” of the supporting pin is cylindrical or spherical in shape.

In another preferred embodiment, 1 the flexible membrane (rubber) that involves the lower part of the plunger body has its thickness reduced to provide more flexibility thereto.

#### Description of the Invention in Relation to the Drawings

In order to allow a better understanding of the present invention, the same shall now be described in illustrative details based on the attached drawings, wherein:

Figure 1 is a side sectional view of the cylinder commonly used in the market, with an inner groove 1 in the mouth thereof for pressure fitting thereunto of the guide washer used in the detachment device of the syringe according to the present invention;

Figure 2 illustrates a type of needle that is commonly used in syringes used for injections;

Figure 3 is an exploded view of the piston stem of the detachment device of the present invention, wherein are shown the elongated body 3 (piston stem), provided with a compartment intended to accommodate the needle upon the use thereof at an end 2, which will stay outside of the syringe body, with an element for applying pressure (thumb support), and which, at the other end, will stay inside the body of the syringe, with a radial flexible assembly 4 having terminations with four claws directed outwardly 5 where each end 27 is beveled with an angle in excess of 45°;

Figure 3 illustrates a side view of the sheathing/sealing guide washer 21 used to guide the piston stem within the body of the syringe;

Figure 3B is a side view illustration of the supporting pin having the head of greater diameter 6 and the body of lesser diameter 7;

Figure 3C is a side view in cross section of the plunger body 22,

wherein there may be noted the two through holes 8 and 9, of different diameters, for engagement of the supporting pin 6 shown in Figure 3B, there being noticeable that the through hole 9 of the lower surface is the one of lesser diameter;

Figure 3D is an illustration of a flexible membrane 10, preferentially made of rubber, used to cover the lower part of the plunger body 22 illustrated in Figure 3C;

Figures 4 and 4A are side views illustrating the engagement of the tip 27 beveled with an angle greater than  $45^\circ$ , of the outwardly directed claws 5, of the flexible assembly 4, in the plunger body 22;

Figure 5 illustrates the flexible membrane 10 in the plunger body 22 in a representation showing a plunger body-flexible membrane assembly in its normal form;

Figure 5A illustrates the deformity of the flexible membrane of the plunger body-flexible membrane 25 assembly;

Figure 6 is a top view illustrating the plunger body 22 wherein there may be noted the cross-shaped cutout disposed centrally;

Figure 6A is a side cross-sectional view, taken along the plane A-A' shown in Figure 6, of the plunger body 22 with details of the two holes 8 and 9 for engagement of the supporting pin 6, there being noticeable that the head of pin 6 will fit within the hole 8 and the body 7, of lesser diameter, of the pin, will pass through the hole 9;

Figure 7 is a side cross-sectional view of the flexible membrane 10, preferably made of rubber, that covers the plunger body 22, with the rubber thickness having been reduced to provide greater flexibility;

Figure 8 is a perspective view illustrating two types of supporting pins (spherical head 6A) detailing the cylindrical bodies of greater diameter 6 and detailing the cylindrical body of lesser diameter 7, for fitting into the holes 8 and 9 of the plunger body 22;

Figures 9 to 13 illustrate in combination an exploded perspective

view of the device according to the invention, where Figure 9 illustrates a perspective view of the assembly 26 showing the claws assembly with the correct positioning of the supporting pin between the claws; Figure 10 is a perspective view illustrating the cross-shaped cutout 12 of the guide washer 21; Figure 11 is a perspective view illustrating the cross-shaped cutout 11 of the plunger body 22; Figure 12 illustrates the flexible membrane that covers the plunger body 22; and Figure 13 illustrates the opening (mouth) of the syringe body whereby the whole assembly shall be inserted;

Figure 14 is a perspective view illustrating the detachment mechanism entirely assembled and inserted in the syringe body, there being noticeable the engagement of the outwardly directed claws 5 of the flexible assembly 4 to the end of the piston stem in the cutouts 11 of the plunger body 22 covered by the flexible membrane 10, showing the details of the engagement of the supporting pin 6 and of the cylindrical body 7 thereof in the holes of the plunger body 22 to secure the four outwardly directed claws;

Figures 15, 15A and 15B depict the shielding guide washer 21 in a side view, in a top view, and in perspective, showing an embodiment wherein several grooves 13 are provided along the body of the washer in order to render the same frangible;

Figure 16 is a top view illustrating the mouth of the syringe cylinder or barrel and the laser welding 14 of the guide washer thereto;

Figure 16A is a cross-sectional view, along the plan A-A' of Figure 16, of the syringe barrel detailing the engagement of the guide washer 21 in the internal wall of the mouth of barrel 1, and further depicting the laser welding 14 of the guide washer to the syringe body;

Figure 17 is a top view illustration of the piston stem, with the hole 2 for insertion of the used needle, thus avoiding accidents that might happen to the user or to third parties while handling the disposed syringes;

Figure 17A is a cross-sectional view, along the plan A-A' of



Figure 17, of the piston stem detailing the compartment for the used needle 2 and the end of the piston stem in projection to enable radial flexibility 4 with tips 27 in outwardly directed claws that are beveled to an angle in excess of 45°;

Figure 17B is a bottom view illustrating the flexible assembly 4  
5 for better understanding of the radial flexibility thereof;

Figure 18 depicts a syringe according to the invention, assembled in the final form that the consumers acquire in points of sale, ready to be used, whereof the piston stem is guided by the guide washer 21;

Figure 18A illustrates the suction of a liquid of any kind whereby  
10 the piston stem is guided by the guide washer 21, pulled outwards together with the assembly comprised by the plunger and the flexible membrane 10, the process occurring in the same manner that it occurs in the case of a common syringe;

Figures 18B and 18C depict the syringe when the pressure is reversed, that is, when the user applies pressure upon the piston stem to expel the  
15 liquid, the energy is proportionally transmitted to the liquid, causing therein a pressure that is greater than the atmospheric pressure, such pressure deforms the flexible membrane 10 of the plunger body 22, such deformation expelling automatically the pin 6 from the flexible assembly at the end of the piston stem 4 of the plunger body-flexible membrane assembly illustrated with reference 25;

Figure 18D illustrates the disengagement of the piston stem, once  
20 that the supporting pin 6 has been expelled, the flexible assembly 4 of the piston stem loses its support and renders a recharging stroke impossible, since the piston stem is disconnected from the plunger body-flexible membrane assembly 25, thereby rendering the syringe unusable;

Figures 19 and 19A depict the piston stem totally uncoupled from  
25 the cylinder or barrel, however the plunger body-flexible membrane assembly 25 shall be retained at the bottom of the barrel, the piston stem serving thereafter as an element intended to accommodate, within its compartment, the used needle 2;

Figure 20 depicts the syringe without the shielding guide washer,

rendering impossible to reuse the syringe;

Figure 21 depicts the syringe being used without the guide washer. If the washer is withdrawn in order to reutilize the syringe, since the guide washer self-destructs by shattering, the syringe becomes unusable due to the fact that without the presence of the guide washer, the stem loses its centering alignment 17 and in consequence the plunger is no longer perpendicular to the wall of the barrel 18 and during the suction 16 the vacuum will suck in air;

Figures 21A and 21B illustrate an injection operation without the guide washer, where the pressure of the liquid is greater than the atmospheric pressure causing the reflux 19;

Figures 22 to 27 illustrate, in the form of a flow diagram, the assembly line in the manufacturing plant where the device according to the invention is mounted in the syringe body, there being shown the insertion of the guide washer 21 along the piston stem; the assembly of the plunger body-flexible membrane assembly 25; the fitting of the piston stem to the plunger body-flexible membrane assembly 25; the insertion of the supporting pin 6; the piston stem/plunger body/rubber membrane assembly inserted into the syringe body and the pressure fitting of the guide washer 21; and the sealing by laser welding 14 of the guide washer 21 to the syringe body;

Figure 28 shows the device adapted for insulin and tuberculin syringes with the syringe in the assembled state;

Figure 29 shows a side view of the device that constitutes the object of the present invention;

Figure 29A is a front view of the device with a detail of the engagement of the hooks 5 directed outwardly;

Figure 29B depicts the assembly upon rupture thereof;

Figure 30 shows the supporting pin where the same will be manufactured using steel and plastic, the needle being made of steel with the cylindrical or flattened head 30 being made of a plastic material, similar to tailor

cushion pins as existing in the market; and,

Figure 31 is a perspective view of the ruptured assembly, also taking into account that the pin may be made of steel or another metal in accordance with medical and hospital standards.

CLAIMS

1. A non-reusable syringe with a piston stem detachment system, comprising: a syringe body; and, a piston stem/plunger assembly, to expel the liquid intended to be injected from the inside of the syringe, the said piston stem/plunger assembly comprising a stem having an elongated body (3) that may be engaged in a plunger body (22), the elongated body (3) being provided at one end thereof, which end shall stay outside of the syringe body, with a pressure element (thumb support); and at the other end, which other end shall stay inside the syringe body, being provided with a flexible assembly (4), with claws extending outwardly (5), that shall engage the plunger body (22), such claws (5) being designed to enhance the radial flexibility of the lower end, the plunger body (22) being provided with two parallel surfaces hollowed at the central part thereof by central through holes (8, 9) of different diameters, the part of the lower surface of the plunger body (22) being provided with the hole (9) of lesser diameter being involved by a flexible membrane (10) and the plunger body (22) being further provided with a cross-shaped cutout (11) disposed centrally relative to the axis of the through holes (8, 9), characterized in that: the upper end (the mouth) of the inner wall of the syringe body has a groove (1) wherein there shall be accommodated a guide washer (21) intended to keep the piston stem/plunger assembly centered in relation to the syringe body; the claws (5) of the flexible assembly (4) shall engage in the cross-shaped cut (11) in the plunger body (22), the claws (5) of the flexible assembly (4) of the piston stem remaining retained in the plunger body (22) by means of the engagement of a supporting pin (6), which pin has a cylindrical body (7) of lesser diameter, in the through holes (8, 9) of the plunger body (22), the supporting pin (6) having a length greater than the thickness of the plunger body (22), the end of its cylindrical body (7) being supported against the internal surface of the flexible membrane (10) that involves the lower part of the plunger body (22).

2. A syringe, according to claim 1, characterized in that at the

lower end (27), the claws (5) of the flexible assembly (4) are beveled to an angle greater than 45°.

3. A syringe, according to any one of claims 1 or 2, characterized in that the elongated body named the piston stem has a compartment (2) at the center of the outer end, such compartment (2) being designed to accommodate the  
5 needle upon the use thereof.

4. A syringe, according to any one of claims 1 to 3, characterized in that the guide washer (21) is provided with a central cutout (12) in the shape of a cross for guiding the elongated body (3) of the stem.

10 5. A syringe, according to claim 4, characterized in that the body of the guide washer (21) is provided with at least one groove (13) rendering the same frangible.

6. A syringe, according to any one of claims 1 to 5, characterized in that the guide washer (21) is welded at the groove (1) of the syringe body, by  
15 laser welding (14).

7. A syringe, according to any one of claims 1 or 2, characterized in that the elongated body, named the stem, has its length reduced longitudinally to an extent enough to create oscillations in case of an eventual reutilization of the syringe without the guide washer (21).

20 8. A syringe, according to any one of claims 1 or 2, characterized in that the elongated body, named the stem, is disconnected from the plunger body (22).

9. A syringe, according to claim 1, characterized in that the supporting pin (6) has a cylindrical or spherical "head" shape.

25 10. A syringe, according to claim 1, characterized in that the flexible membrane (rubber) which involves the lower part of the plunger body (22) has its thickness reduced to create more flexibility.

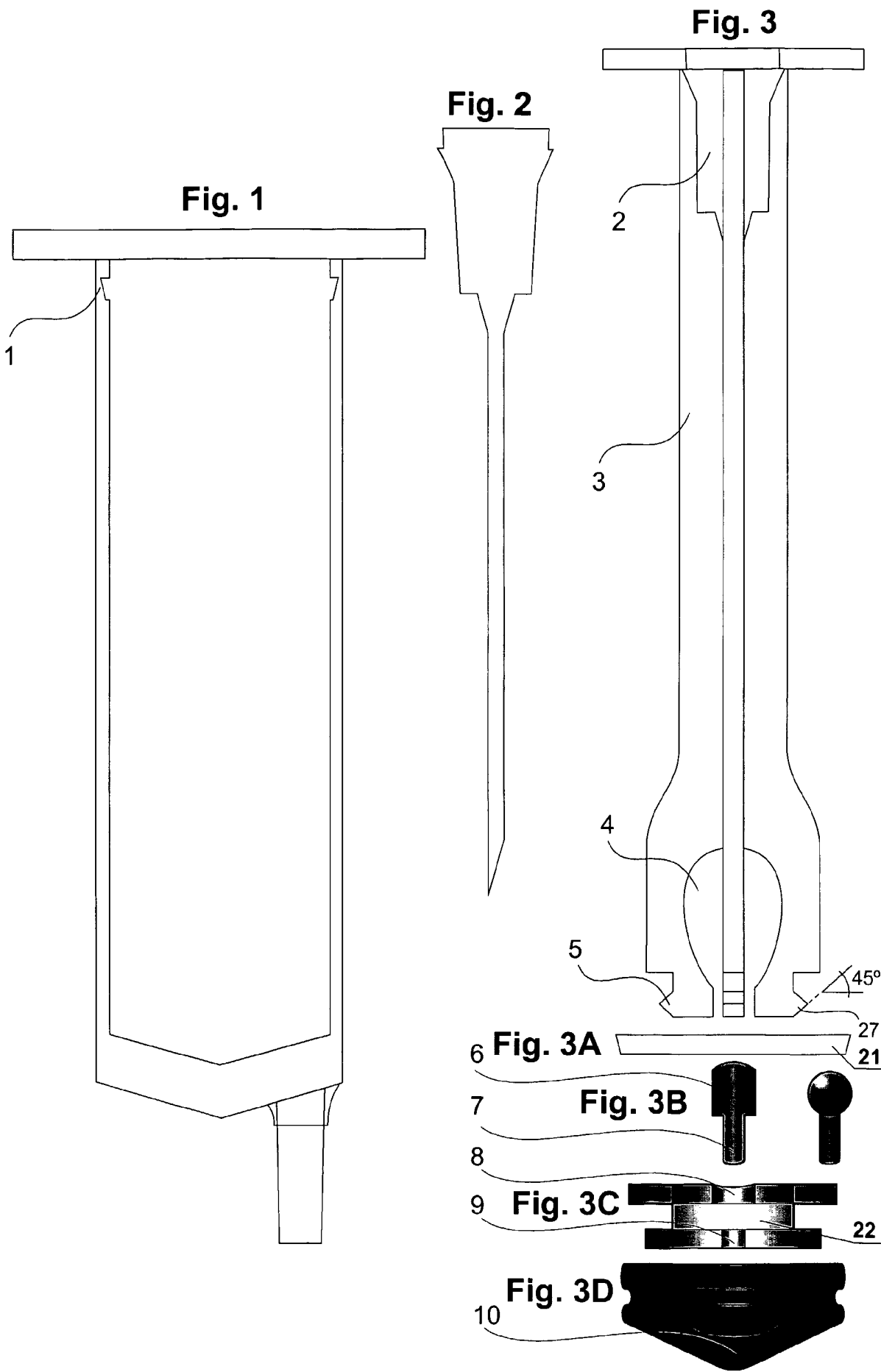


Fig. 4

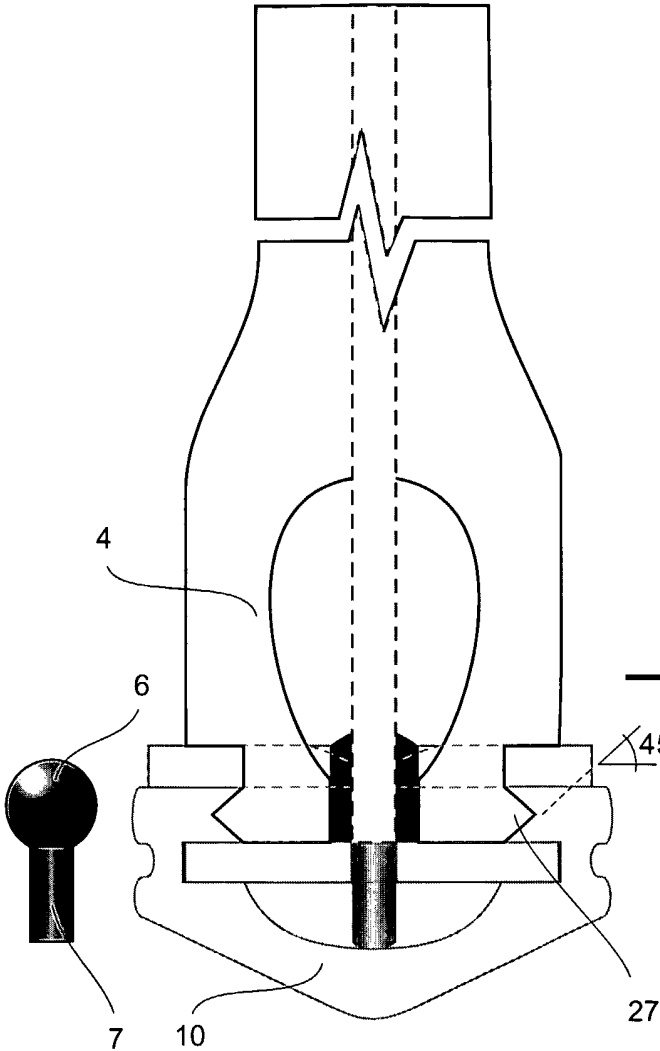


Fig. 4A

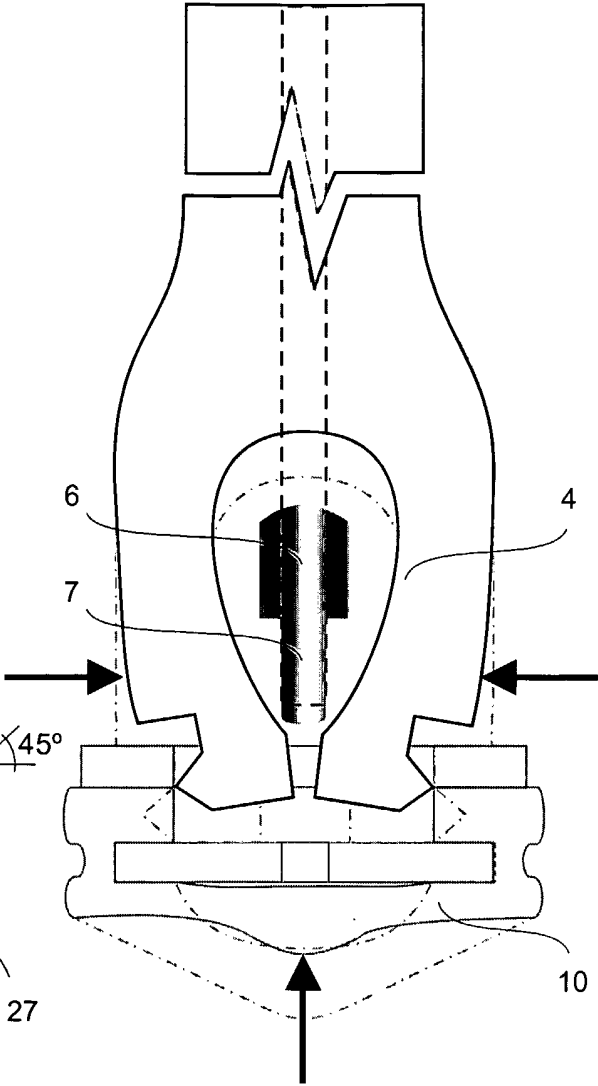


Fig. 5

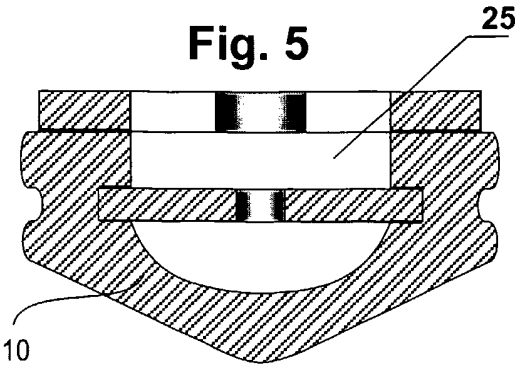


Fig. 5A

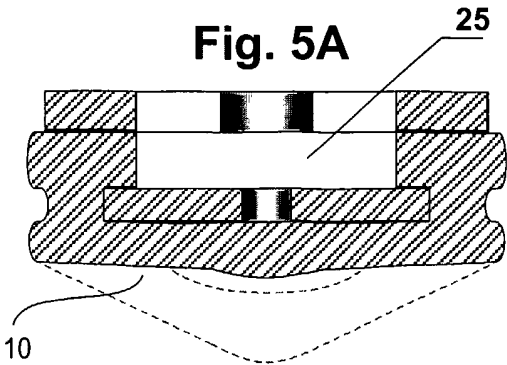


Fig. 6

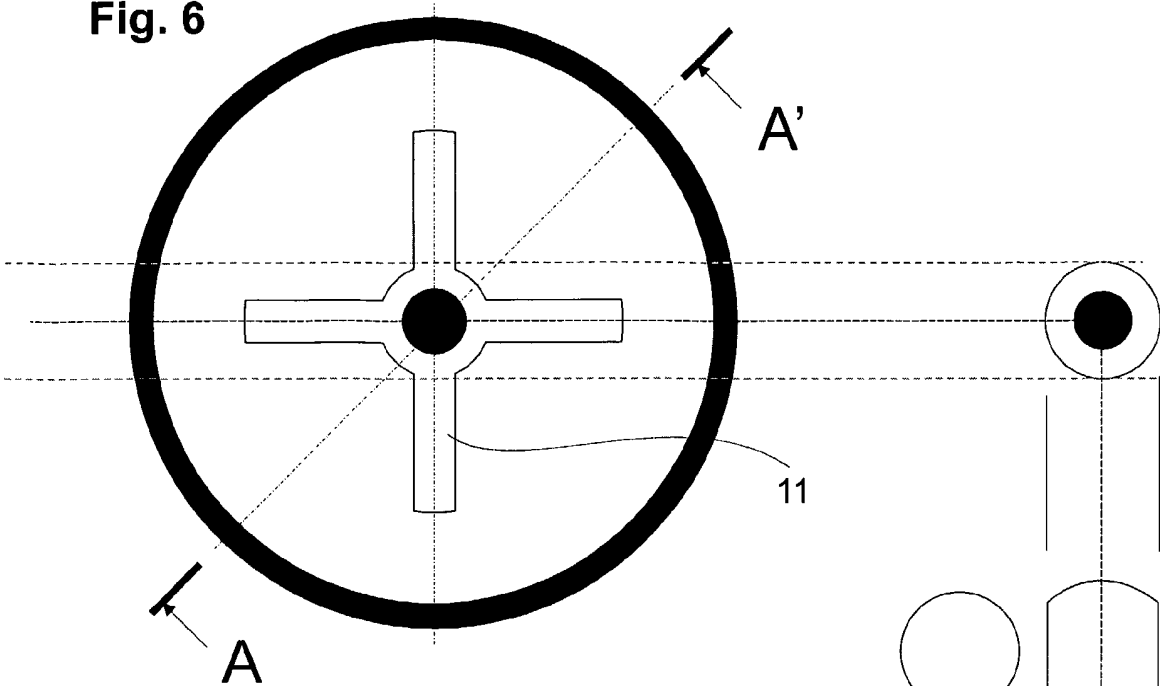


Fig. 6A

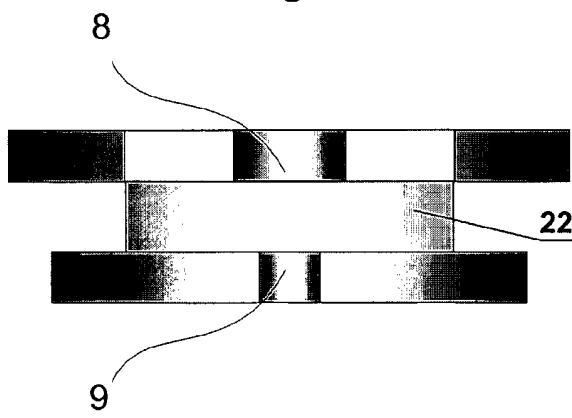


Fig. 7

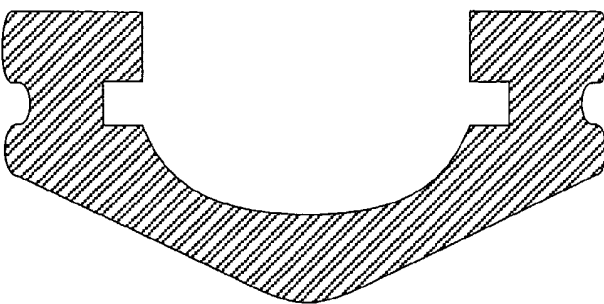
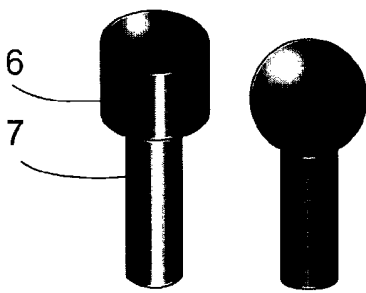


Fig. 8





4/12

Fig. 9

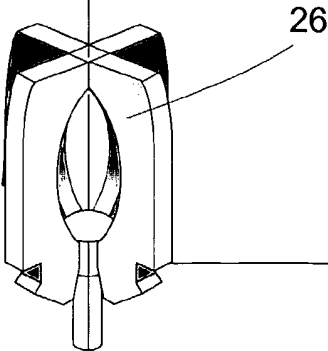


Fig. 8

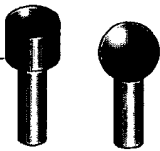


Fig. 10

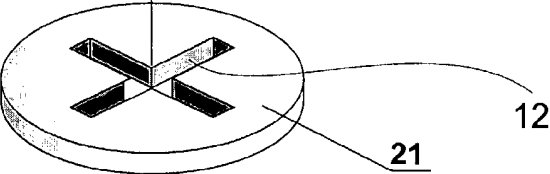


Fig. 11

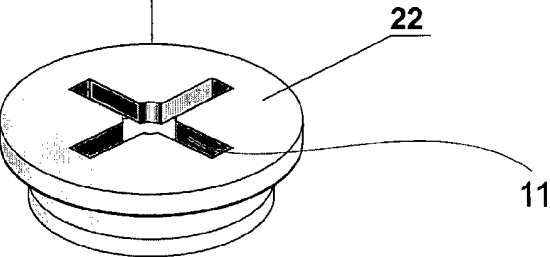


Fig. 12

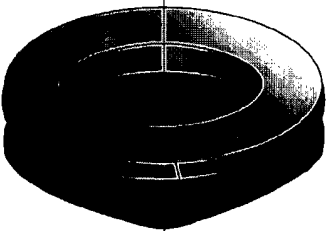


Fig.13

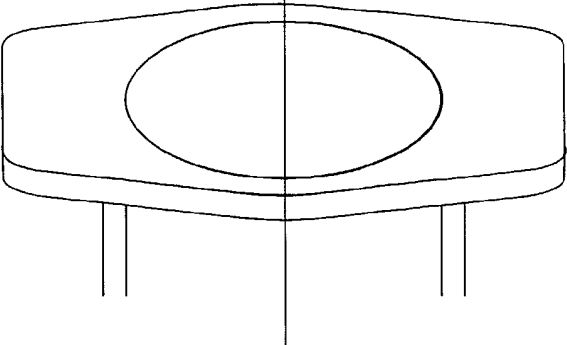
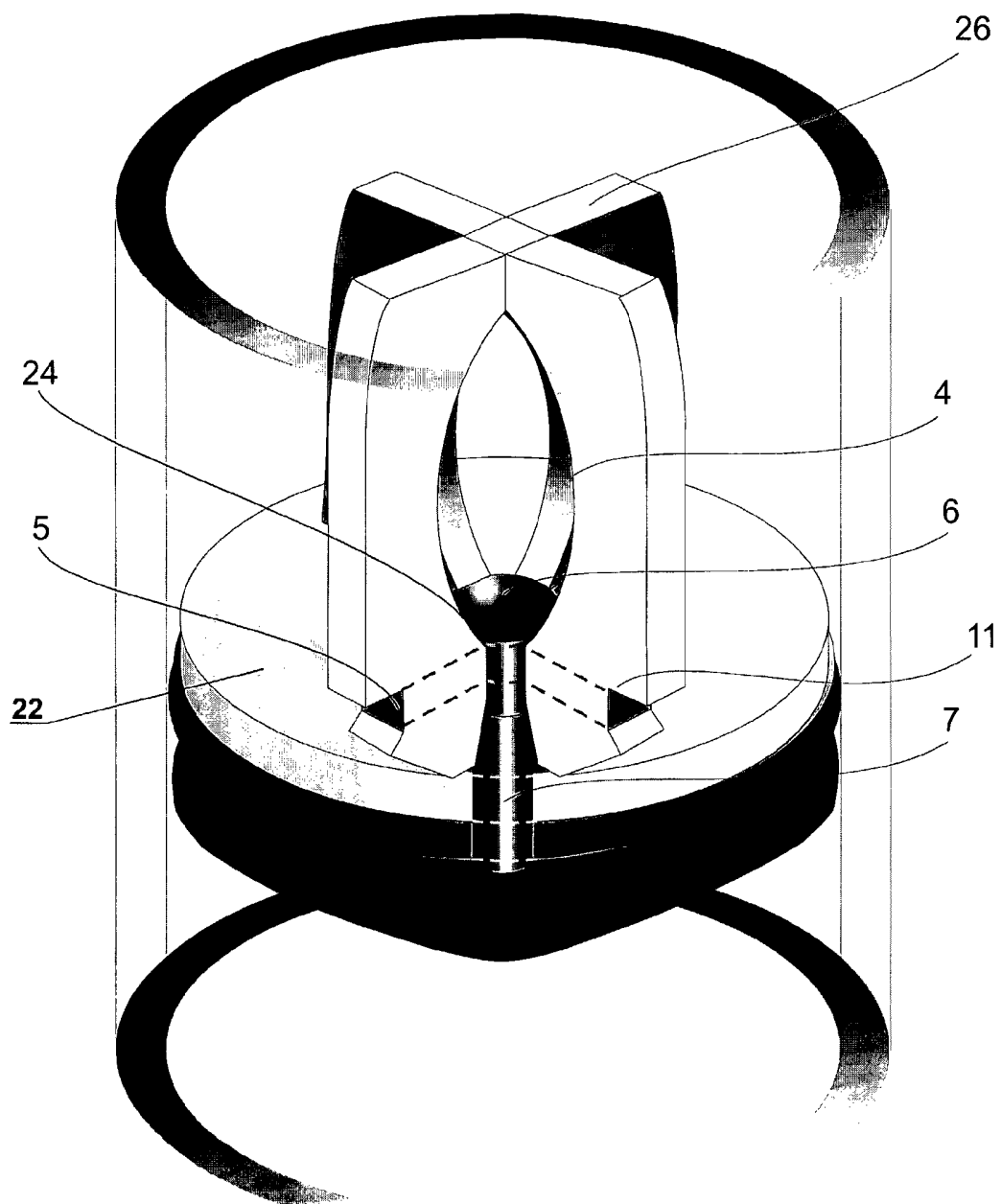


Fig. 14



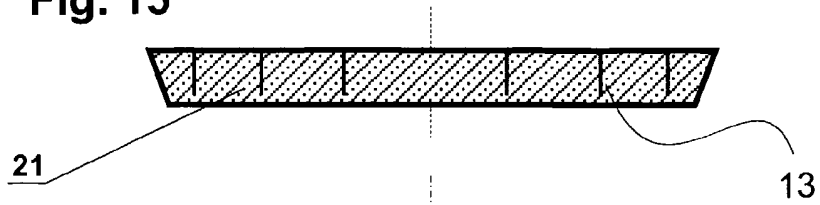
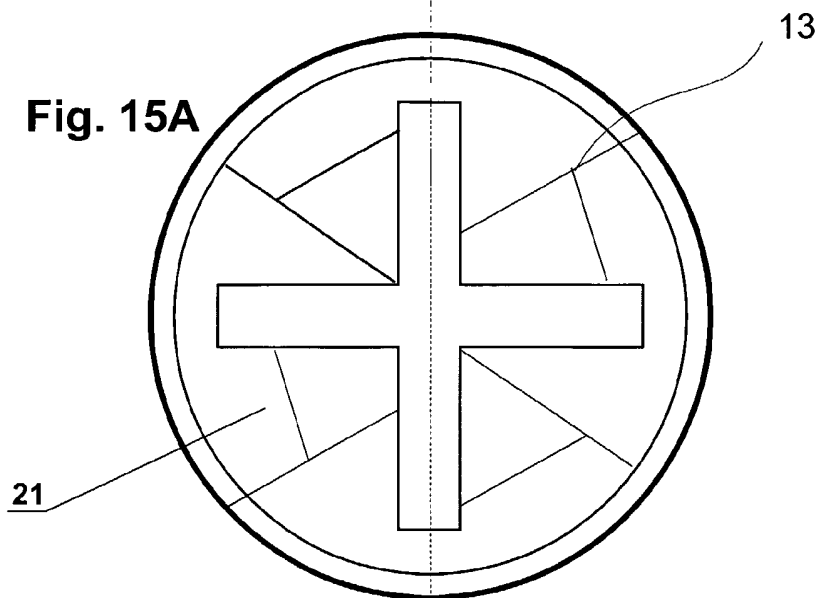
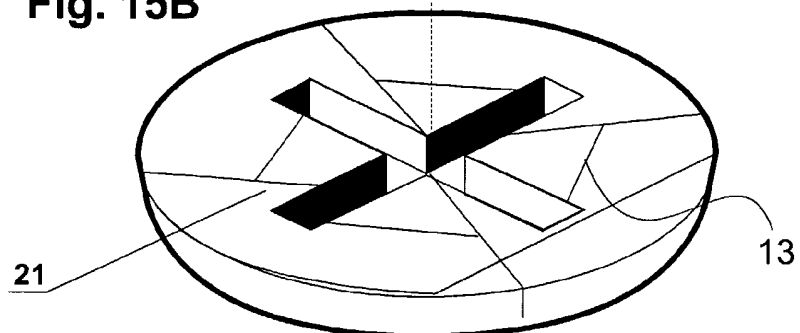
**Fig. 15****Fig. 15A****Fig. 15B**

Fig. 16

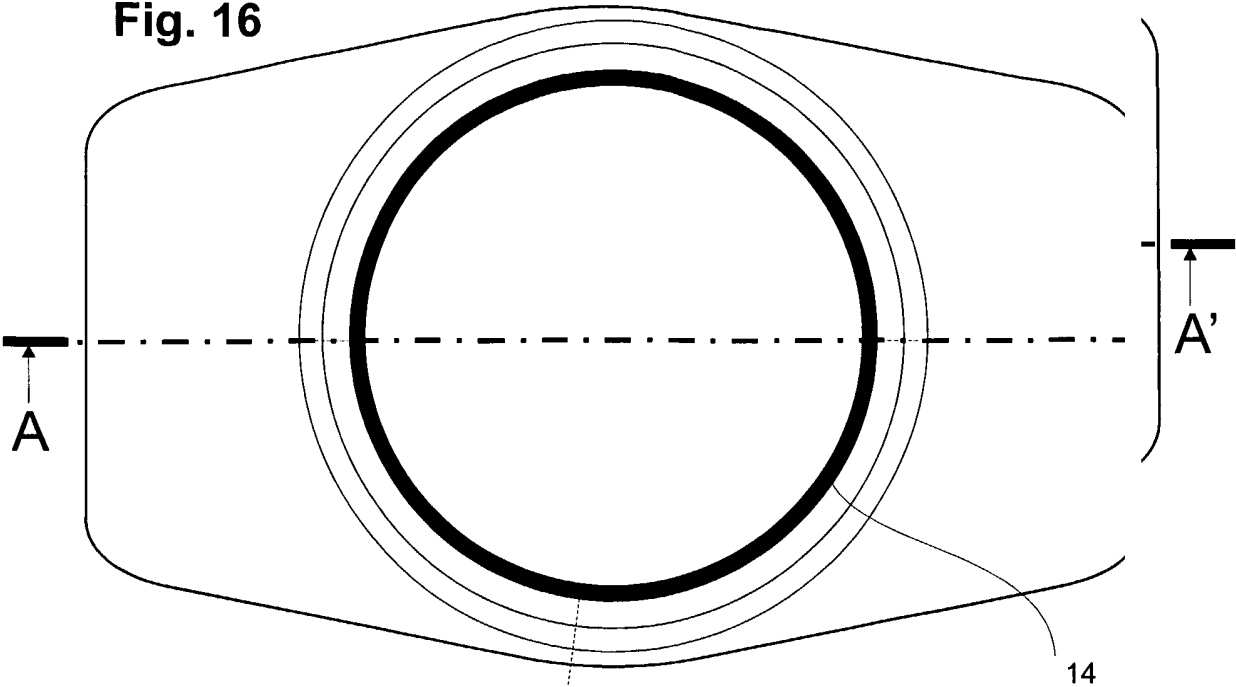


Fig. 16A

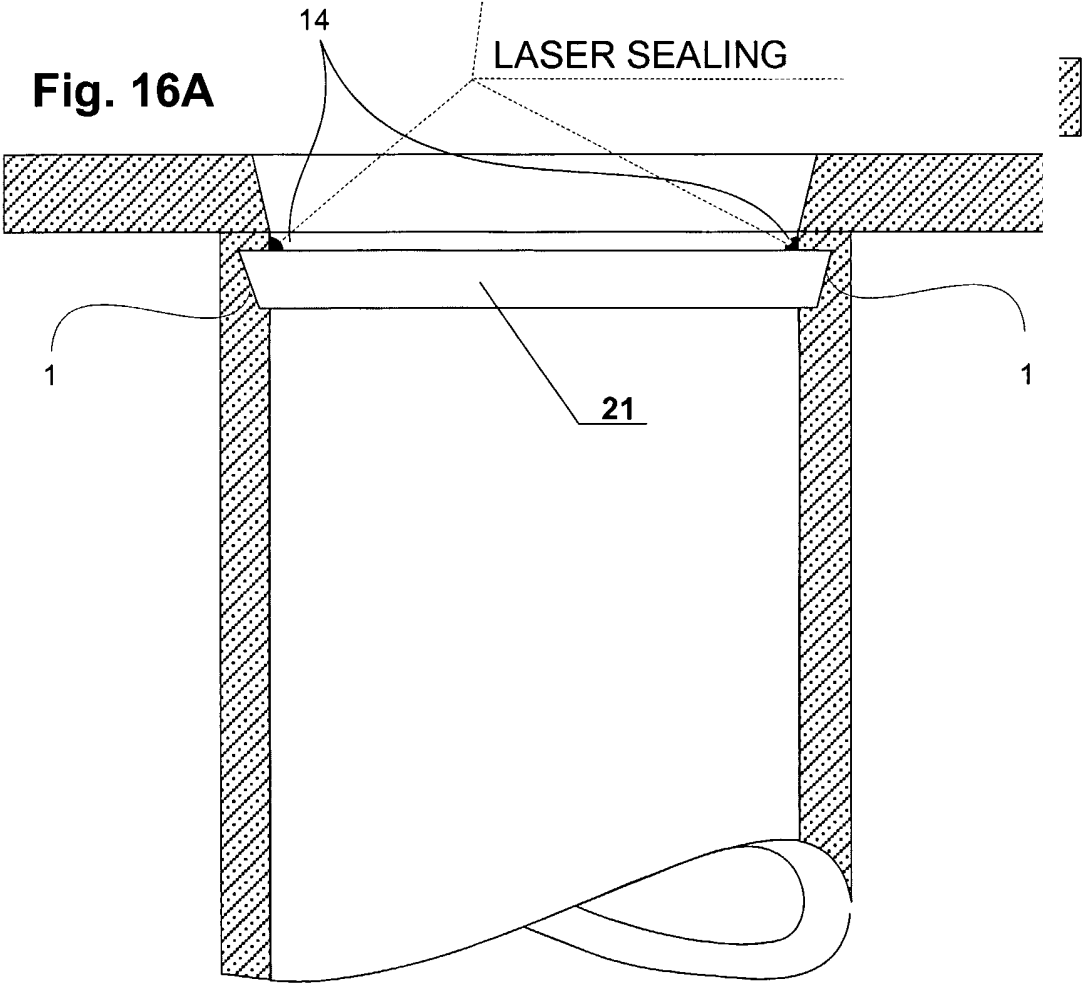


Fig. 17

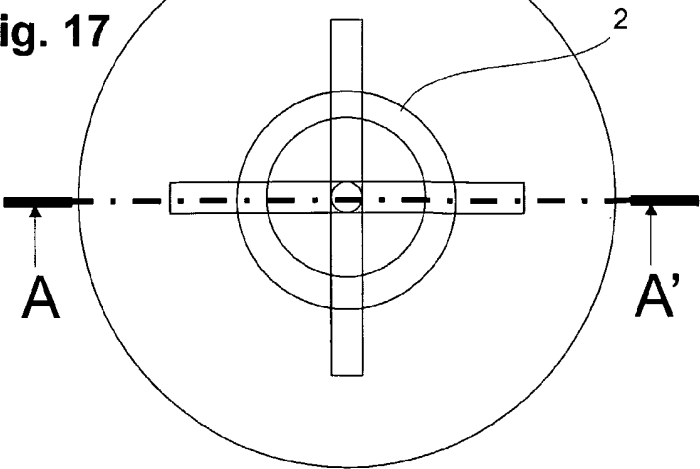


Fig. 17A

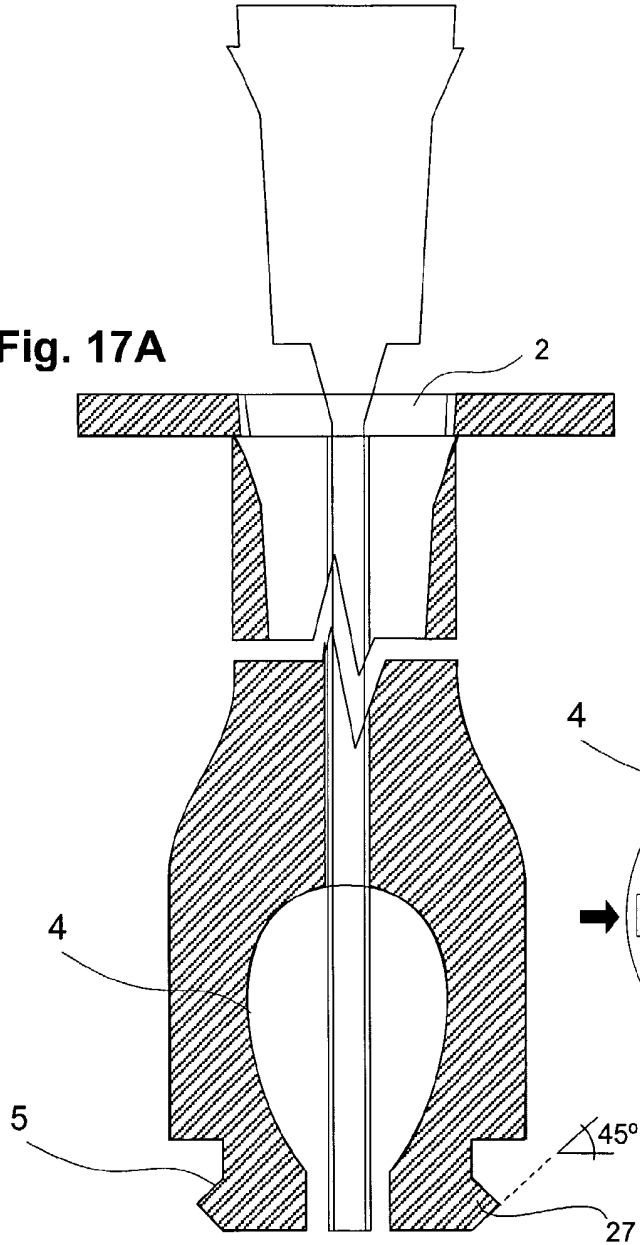
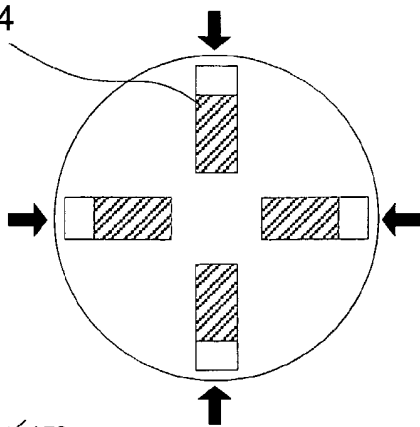
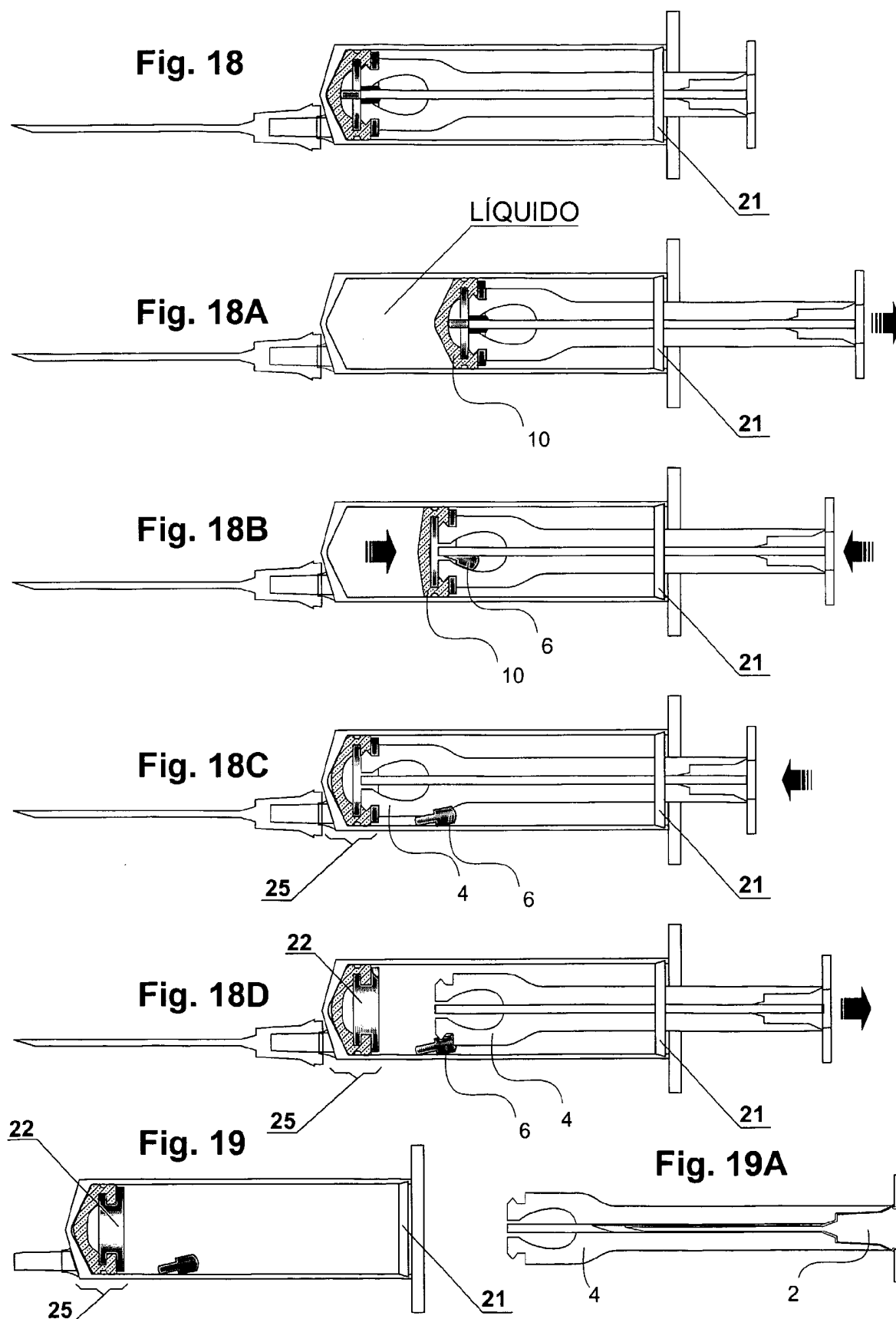
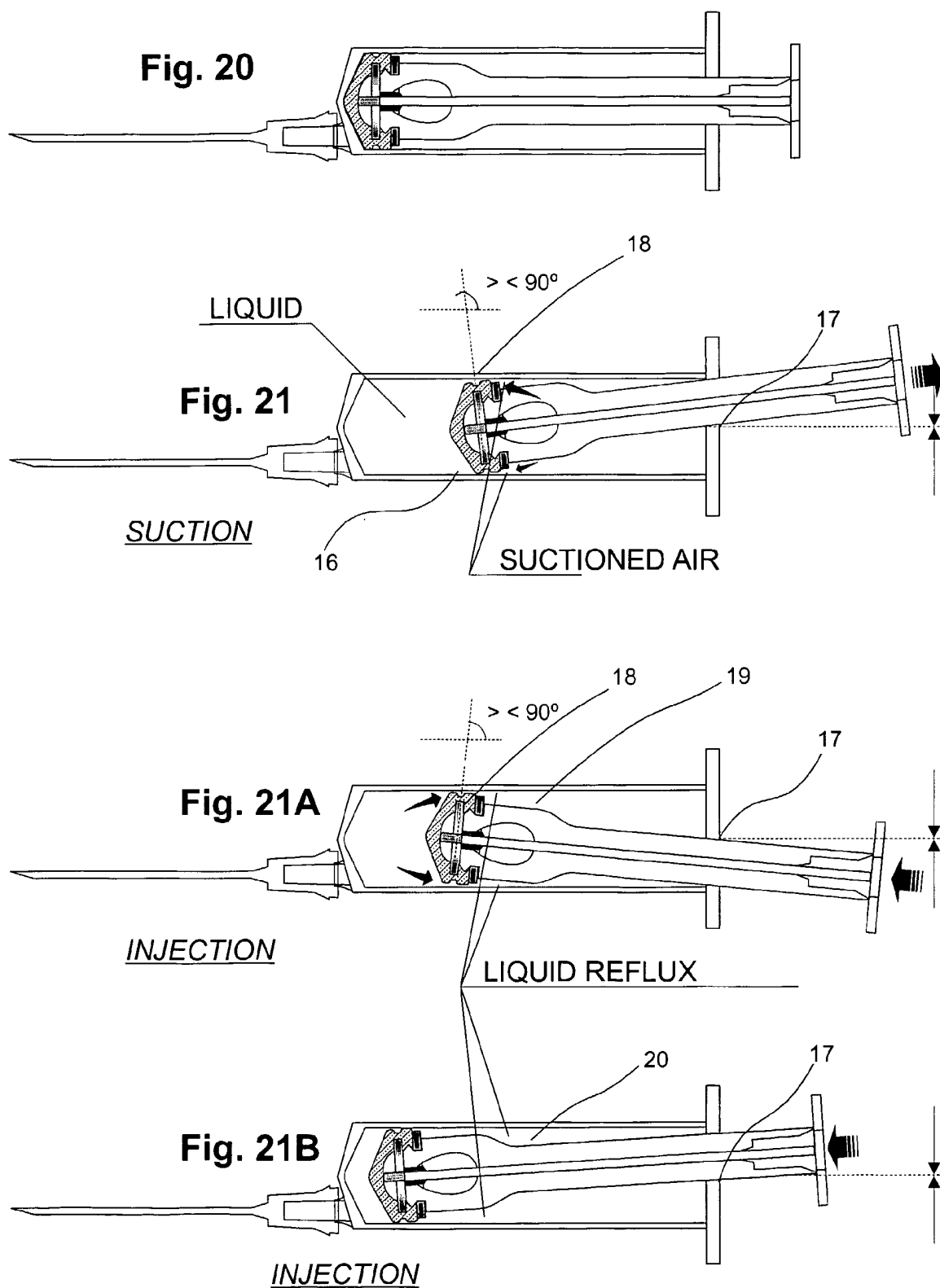
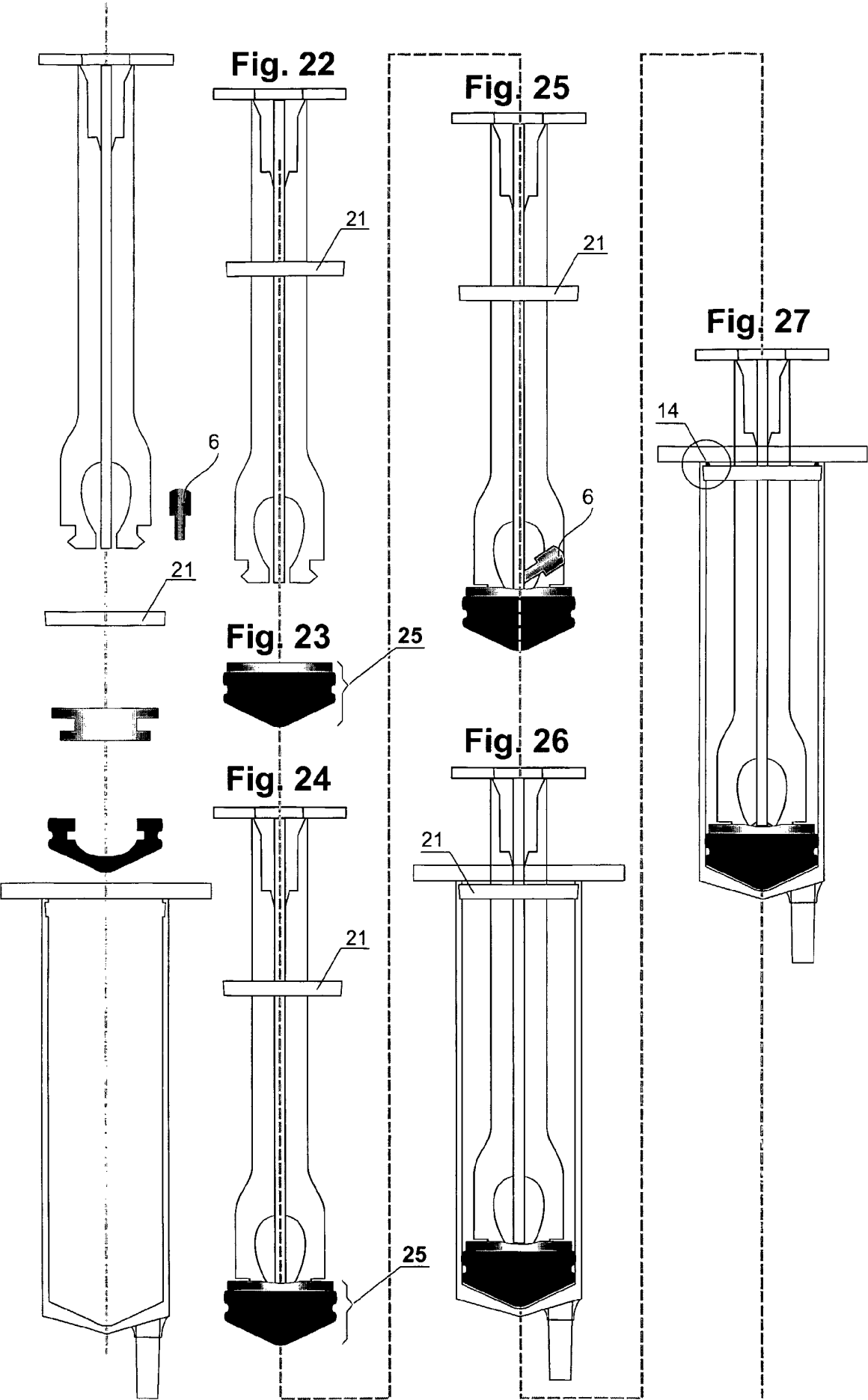


Fig. 17B



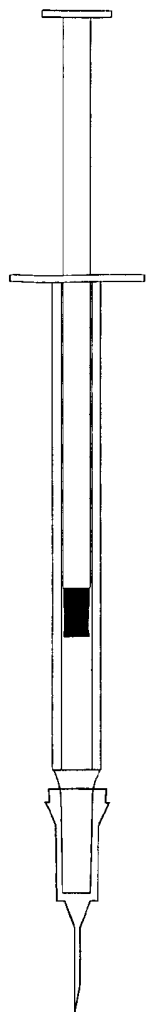




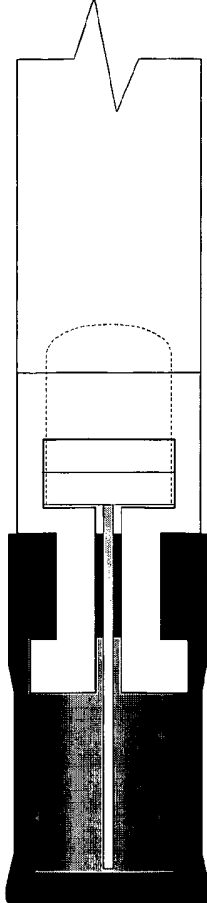




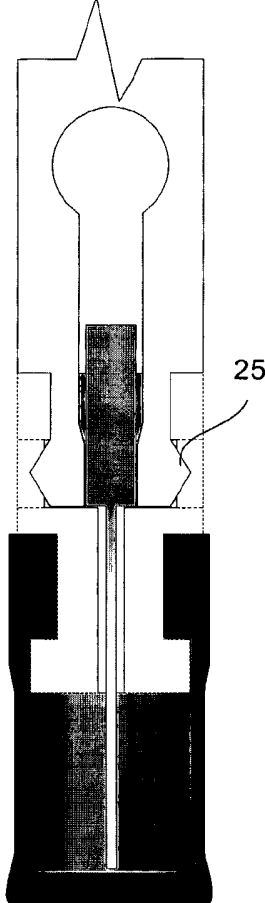
**Fig. 28**



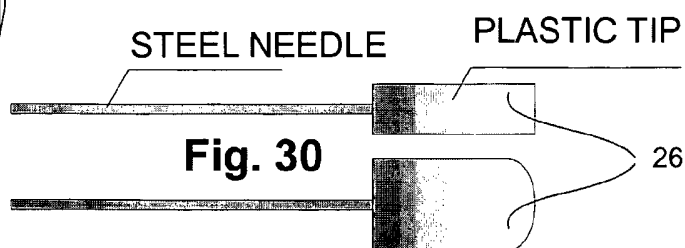
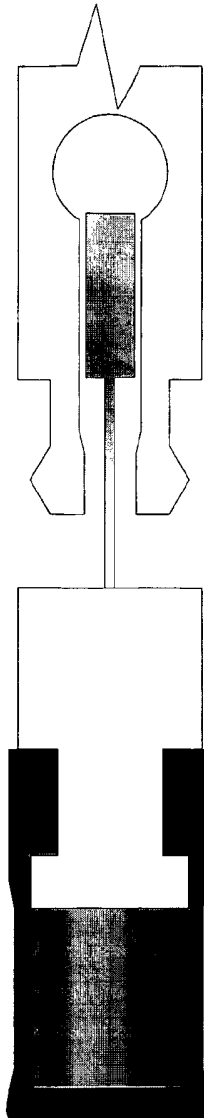
**Fig. 29**



**Fig. 29A**



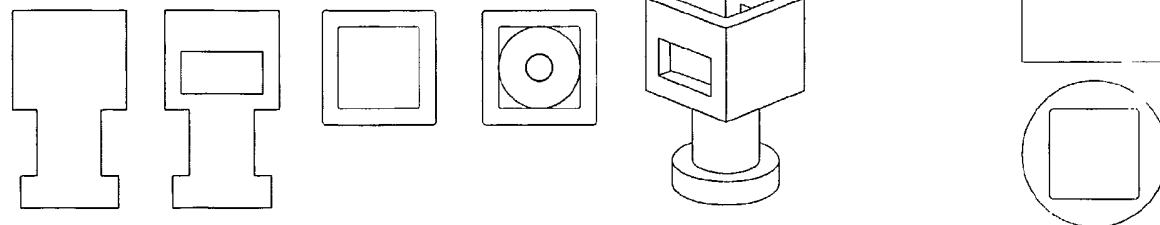
**Fig. 29B**



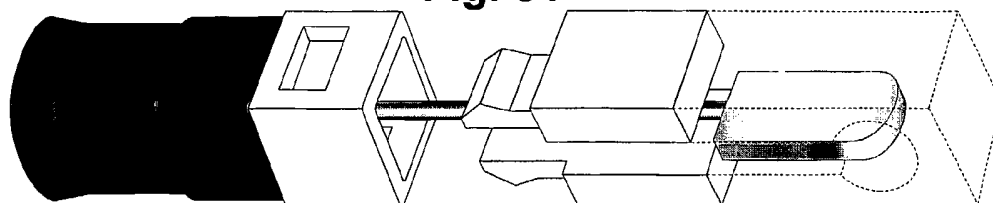
**Fig. 30**

**GUIDE WASHER**

**RUBBER SUPORT**



**Fig. 31**



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/BR 02/00093

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61M5/50

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)

IPC 7 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.
A	US 5 738 655 A (KLOSS JAMES L ET AL) 14 April 1998 (1998-04-14) column 7, line 45 - line 57; figures 1-11 column 8, line 60 - column 9, line 5 -----	1-10
A	US 4 973 309 A (SULTAN JEAN-CLAUDE) 27 November 1990 (1990-11-27) column 2, line 53 - line 61; figures 1-6 column 3, line 32 - column 4, line 2 -----	1-10

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in 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

23 September 2002

Date of mailing of the international search report

24/10/2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Reinbold, S

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/BR 02/00093

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5738655	A	14-04-1998	NONE	
US 4973309	A	27-11-1990	FR 2628635 A1	22-09-1989
			AT 75956 T	15-05-1992
			AU 623126 B2	07-05-1992
			AU 3296089 A	16-10-1989
			DE 68901485 D1	17-06-1992
			EP 0336855 A1	11-10-1989
			WO 8909074 A1	05-10-1989