



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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| <p>(51) International Patent Classification ⁷ : A61M 5/24, 5/34</p> | <p>A1</p> | <p>(11) International Publication Number: WO 00/35519</p> <p>(43) International Publication Date: 22 June 2000 (22.06.00)</p> |
| <p>(21) International Application Number: PCT/IB99/01999</p> <p>(22) International Filing Date: 15 December 1999 (15.12.99)</p> <p>(30) Priority Data: TO98A001046 15 December 1998 (15.12.98) IT</p> <p>(71)(72) Applicant and Inventor: BERLOVAN, Achim [IT/IT]; Corso Francia 2, I-10146 Turin (IT).</p> <p>(74) Agent: MICHELI, Bertrand-François; Micheli & Cie, 122, rue de Genève, C.P. 61, CH-1226 Thonex (CH).</p> | <p>(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), 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, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. In English translation (filed in Italian).</i></p> | |
| <p>(54) Title: SYRINGE AND COORDINATED NEEDLE SET FOR INJECTIONS AND MORE SPECIFICALLY FOR ORTHODONTAL ANESTHESIA</p> | | |
| <p>(57) Abstract</p> | | |
| <p>Equipment for injections comprising a syringe and matching needles. The syringe includes a piston, a body with a handle and a means to couple a matching needle. The said needle includes a body having an additional coupling means to the syringe coupling means, in which is fixed a tubular needle. The double ended needle has a main portion for the performance of the injection and a secondary portion to perforate the sealed lid of an ampoule. The body of the needle extends to form a tubular portion to receive an ampoule and the additional coupling means for coupling to the syringe is located at the distal extremity of the needle body. This avoids any possibility of injury of the operator during the coupling of the needle to the syringe, and of needle or syringe contamination during possible temporary removal of the needle from the syringe.</p> | | |

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SYRINGE AND COORDINATED NEEDLE SET FOR INJECTIONS AND
MORE SPECIFICALLY FOR ORTHODONTAL ANESTHESIA

The present invention has as purpose a syringe equipment with matching needles for injections, mainly meant for use in odontological anaesthesia. Given this main application, the following description shall be made regarding the latter, being besides understood that this does not intend having a restrictive nature, because the object is liable of open to various applications.

In odontological anaesthesia practice, the traditional syringes and needles meant for repetitive use after disinfection have for a large part been replaced by matching syringes and needles equipments, where the syringe includes a piston and a body with a handle, a place to receive the appropriate ampoule, said ampoule or phial and a coupling mean for a matching needle, and every needle owns a body forming an additional coupling mean to the coupling mean of the syringe, in which is fixed a needle appropriately said tubular, which comes out from both parts of the body with a main portion meant for the performance of the injection and a secondary portion meant to perforate the sealed lid of the ampoule, the main portion of the tubular needle being protected by a cover and the secondary portion being protected by a cap. The needle with its protection parts is preventively sterilized and meant to be used by only one patient, and is coupled to the syringe through the additional coupling mean of the two parts, after removal of the cap while the cover is subsequently removed at the time of the performance of the injection. In such a way one avoids the necessity of performing the disinfection of the needle while ensuring sterility. Generally the syringe is not subject to disinfection.

However, such a known equipment presents a few disadvantages. During the coupling of the needle with the syringe, the secondary portion of the tubular needle no longer protected by the cover, may enter in contact with the parts of the syringe which are not sterile, or with other objects, and may so be contaminated. During the performance of the injection, the parts of the syringe which extend in the immediate proximity of the main portion of the tubular needle may come in contact with the patient and be contaminated by

him or contaminate him. These disadvantages could of course be avoided by submitting the syringe to disinfection in autoclave but this would be extremely expensive, in particular because of the necessity of having at disposal a great number of syringes for daily use.

Furthermore, as the protection cover of the secondary portion of the tubular needle must be removed before coupling the needle with the syringe, during this operation the protruding point of the tubular needle may injure the operator. If, later, it is necessary to loosen temporarily the needle from the syringe before the end of use of the latter, for example to use on the same patient a new ampoule, the previous one not being sufficient, this operation is difficult for the operator because the body of the needle shows a very small grip surface and the operator's hand must be covered by a glove which reduces the sensitivity and gripping capacity.

The goal of the present invention is therefore to give remedy to these disadvantages of the known equipment of matching syringe and needles. More in particular one of the first goals is to preserve in the best way the sterility of the needle, without requiring for this purpose a sterilization of the syringe, providing for means likely to avoid any contact of the secondary portion of the needle with non sterile parts of the syringe or otherwise. Another goal is to avoid any possible contact of the syringe with the patient and therefore any possibility of mutual contamination. Another goal of the invention is to avoid, during the coupling of the needle with the syringe, the presence of any protruding point likely to injure the operator. Is also a goal of the invention to see to it that the body of the needle offers to the operator an extended grip surface to grant an easy handling even from a hand covered by a glove. Finally an extra goal of the invention is to reach the advantages aimed for without excessively aggravating the cost of the equipment.

These goals meet, according to the invention, in an equipment of matching syringe and needles, for injections, including a syringe which includes a piston and a body with a handle and with a coupling mean for a matching needle, the said needle at its turn including a body forming an

additional coupling mean to the coupling mean of the syringe and in which is fixed a needle appropriately said tubular, protruding from both parts of the body with a main portion meant for the performance of the injection and the secondary portion meant to perforate a lid of an ampoule, due to the fact that the body of the needle extends to form a tubular portion likely to receive an ampoule and that because the additional coupling mean to the coupling mean of the syringe is located at the distal extremity of the said body of the needle.

Thanks to these special features, the secondary portion of the tubular needle, meant to perforate a lid of an ampoule, is close to the bottom of the tubular portion of the body of the needle and does not protrude outwards, so that it cannot in any way injure the operator, and it makes contact only with the lid of the ampoule, which of course is sterile, without on the contrary being able to have any contact with parts of the syringe or others. On its side, the body of the syringe lacks the extension usually meant to receive the ampoule, and ends this way at a considerable distance from the main portion of the needle, so that no danger remains that during the performance of the injection parts of the syringe, non sterile, make contact with the patient. Finally, the big extension of the body of the needle, due to the fact that in it (instead than in the syringe) is predisposed the cavity meant to receive the ampoule, offers to the operator a large gripping surface, which ensures an easy handling even from a hand covered by a glove.

Of course, the realization of the tubular extension of the body of the needle, meant to receive the ampoule, involves the use of a larger quantity of material (usually plastic material) for its construction, but the larger inherent cost, furthermore moderate, is compensated at least for a large part by the fact that it is no longer necessary to provide for a protection cap for the secondary portion of the tubular needle. On the other hand, is notably reduced the cost of production of the syringe which body, generally in metal, presents a strongly reduced extension.

These and other special features, goals and advantages of the object of the present invention appear more clearly from the following description of a form of realization, forming a non restrictive example, with reference to the enclosed drawings, in which:

Fig. 1 illustrates a lateral view of a known type of syringe, represented as for comparison.

Fig. 2 illustrates a lateral view of a commercial ampoule, predisposed for use in a syringe according to figure 1

Fig. 3 represents a needle matching the syringe according to figure 1, provided with its protection, before use;

Fig. 4 represents the same needle, as it presents itself after having been deprived from its cap (represented in figure 5) to be coupled with the syringe according to figure 1.

Fig. 6 illustrates a lateral view of a syringe part of the equipment according to the invention.

Fig. 7 illustrates a lateral view of an ampoule fit for use with the equipment according to the invention

Fig. 8 illustrates a lateral view of a needle matching the syringe according to figure 6 as it presents itself before and during its coupling with the syringe.

Fig. 9 and Fig. 10 illustrate the needle according to figure 8 from which the protection cover has been removed and the cover itself.

Fig. 11 illustrates the piston of the syringe according to figure 6, isolated from the body of the syringe.

Fig. 12 is a view of a detail of the piston of the syringe, in a different configuration from that according to figure 11; and

Fig. 13 illustrates a lateral view of the syringe and needle according to the invention, coupled, ready for the performance of the injection after removal of the cover which protects the main portion of the tubular needle.

Referring first to figure 1 to 5, is briefly described, as example, an equipment previously known for injections odontological especially.

The syringe comprises a metallic body 1 which forms a handle comprising a ring 2 and a cam 3 and extends in a tubular part 4 meant to receive a slipped on appropriate ampoule. At the extremity of the tubular part 4 is formed a coupling mean, in particular a bayonet coupling mean 6, for the coupling of a needle matching the syringe. In the body 1 is inserted, sliding, a piston 7 provided with a handle 8 and a head 9, which in certain cases, as in this example, is equipped with an helical system 10.

An ampoule fit to be inserted in the syringe according to figure 1 is represented in figure 2. The latter includes a tube 11 obstructed at one extremity by a stopper 12 forming a sealed lid which can be perforated, and at the opposite extremity by a cylinder 13 sliding inside tube 11. This tube is filled with a liquid which can be injected, as for example an anaesthetic. The ampoule 11-13 is inserted in the cavity of the tubular part 4 of the syringe and the helical system 10 of the syringe (if it is provided for) is screwed in the cylinder 13 of the ampoule.

The needle matching the syringe described presents itself as shown in figure 3, with a body 14 in which is inserted a tubular needle covered with a cover 17 and a cap 18. When cap 18 is removed (figure 5), the needle presents itself as shown in figure 4; the main portion of the tubular needle is still protected and obstructed by the cover 17, while the secondary portion of the tubular needle is slightly protruding with its point 16 out of the body 14 of the needle. This body presents an additional coupling mean to the coupling mean of the syringe and so, in the represented figure, a pivot 15 to introduce in the bayonet slit 6.

When the needle 14-16 is introduced in the syringe 1-10 containing the ampoule 11-13, point 16 of the secondary portion of the tubular needle perforates the sealed lid 12 of the ampoule and places the tubular needle in communication with the inside of the ampoule. At this stage, cover 17 removed, the head 9 of the piston 7 is capable of pushing cylinder 13 to force the liquid contained in the ampoule through the tubular needle, and perform an injection. If the syringe is equipped with the helical system 10, the latter is

screwed in the cylinder 13 of the ampoule and even grants, if required, the exercising of a suction in order to check if the needle has not been introduced in a vein.

As it can be understood, the fact that point 16 of the secondary portion of the tubular needle is protruding out of body 14 of the needle, involves, on the one hand, that during the operations of introducing of the needle in the syringe the operator may be injured by that, and on the other hand that the point itself may come into contact with the extremity of the syringe or with other objects, contaminating itself. Then when the syringe with needle is used, the distance which separates the extremity of the syringe from the main portion of the tubular needle is only represented by a narrow flange of body 14 of the needle, so that the syringe can easily come into contact with the patient. Finally, the exposed surface of body 14 of the needle being extremely reduced, its handling from the gloved hand of the operator is difficult, if the needle has to be detached at the same time as the syringe before the end of its use. Thus outcome the disadvantages exposed here above.

According to the invention, the parts forming the equipment of matching syringe and needle are conceived as it is represented in figures 6 to 10. The syringe according to figure 6 comprises a body, usually in metal, 21, which forms a handle comprising a ring 22 and a cam 23 and extends in a short tubular part 24 at which extremity is formed a coupling mean, for example a bayonet coupling mean 26, for the coupling of a needle matching with the syringe. In body 21 is inserted, sliding, a piston 27 provided with a handle 26.

On its side the needle, illustrated with a removed protection cover in figures 9 and 10, includes a body 34 in which is inserted a needle appropriately said tubular, which protrudes out of it, with a main portion 33, meant to perform an injection, and with a secondary portion 36 meant to perforate the sealed lid 12 of an ampoule 11, which (figure 7) may be identical to the one usually marketed, fit for the known syringes. The particularity of the needle according to the invention consists in the fact that its body 34 extends to form a tubular part 32 predisposed to receive the ampoule 11 and provided

at its extremity with an additional coupling mean to that of the syringe, in this example a couple of pivots 35 fit to be used in the bayonet slit 26 of the syringe. Before and during the coupling operation with the syringe, the main portion 33 of the needle is protected with a cover 37.

The body of this needle may be made in only one piece, or its part 34 in which is inserted in the tubular needle, and the tubular part 32, may be made separately and then connected in any manner whatsoever. This permits for example to use different plastic materials in the manufacturing of these two parts. It is also possible to use the needles 33-34-36 existing on the market, equipped with for example a screw coupling, making the tubular part 32 with an additional coupling to which is connected the needle. This grants further production savings.

This needle may be marketed and kept, as usual, in a sterile pack from which it is taken out at the time of use.

As it can be understood, the secondary portion 36 of the tubular needle, being closed in the tubular part 32, may in no way injure the operator, or come into contact with any non sterile part whatsoever, of the syringe or any other body whatsoever, but only the sealed lid 12 of the ampoule 11. On the other hand, the extremity of the tubular part 24 of the syringe, when the needle is coupled, is, as for the main portion 33 of the needle, at a distance equal to the length of the tubular part 32, that is at the length of the ampoule, and therefore it cannot even by accident come into contact with the patient. Finally, when the needle is coupled with the syringe, its body offers to the operator all the surface of the tubular part 32, and for this reason it can be manipulated with the maximum facility even from a hand having a glove as obstacle. This can easily be understood from the observation of figure 13.

Thus can be overcome the mentioned disadvantages of the known equipment.

Favourably the coupling mean of the syringe, when it is constituted by a bayonet slip, presents a shrink 25 in which pivot 35 of the body of the needle

can be engaged. This provides an additional safety against the decoupling mean by accident of the needle of the syringe.

The piston 27 of the syringe is preferably provided with a tubular head 29, screwed, which, as figure 11 shows, can leave uncovered an helical system 30 meant to be screwed in the cylinder 13 of an ampoule. When the use of this helical system is not planned, the head 29 can be moved by turning it, until the helical system 30 is covered, as figure 12 shows it. The syringe is then more easy to use, not requiring the screwing of the helical system 30 in the cylinder 13 of the ampoule.

It must be understood that the invention is not limited to the described and described as example achieved form. Several modifications are within reach of the specialized technician, for example, for the connection between the syringe and needle a type of coupling mean different from that with a bayonet can be used, and for example a screw. The metal construction of the syringe can be replaced by a construction with synthetic or mixed materials. Even if the use of a commercial ampoule is economically advantageous, it is also possible to produce special ampoules appropriately conceived for the equipment according to the invention. This equipment is particularly fit for use in odontological anaesthesia, but it can find application where ever analogue problems occur.

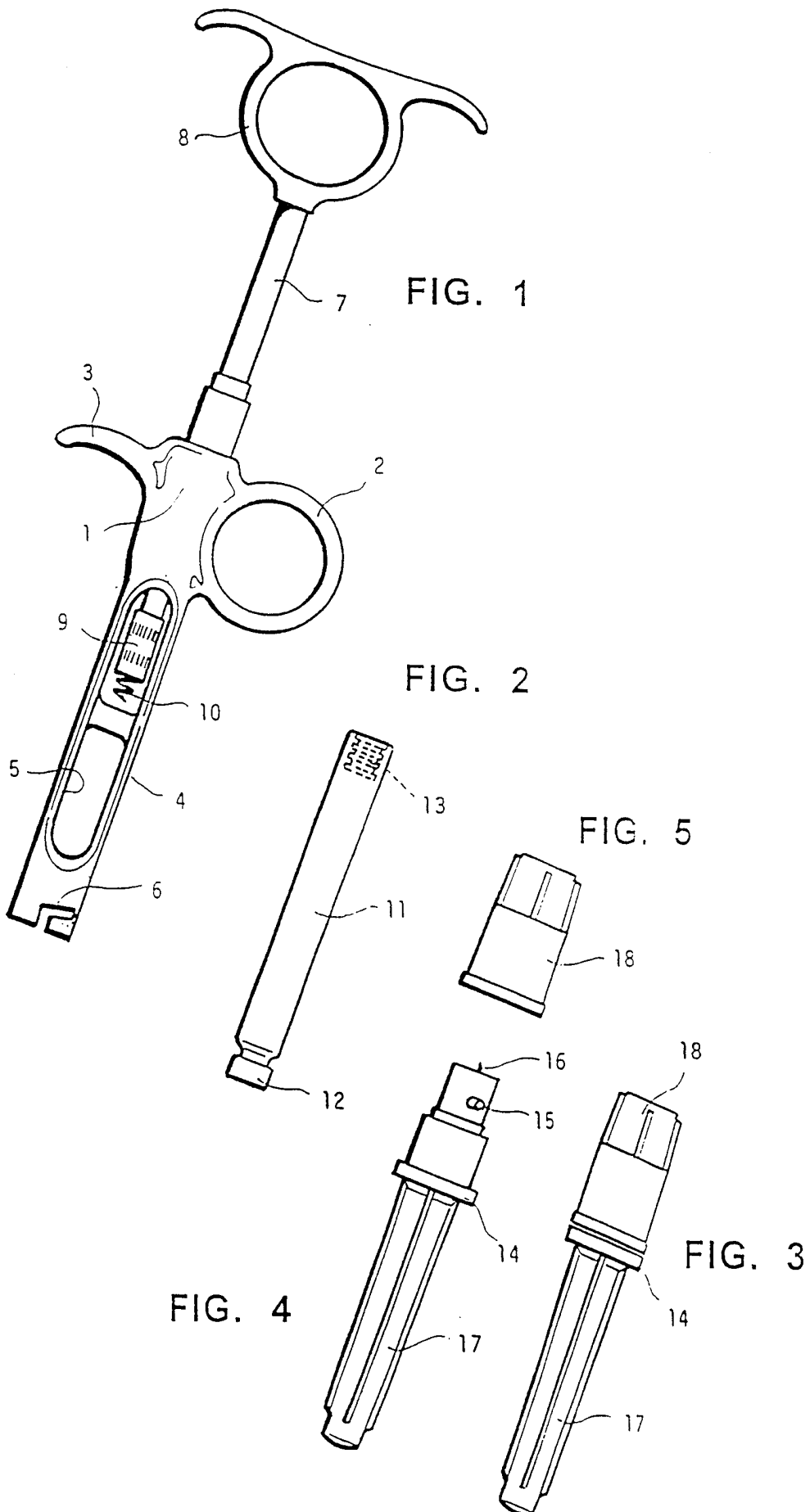
These and other modifications and any replacement with equivalent techniques can be brought to that described and illustrated, without for that departing from the context of the invention and from the reach of the present patent.

CLAIMS

- 1- Equipment of syringe and matching needles, for injections, comprising a syringe which includes a piston and a body with a handle and with a coupling mean for a matching needle, the said needle at its turn including a body forming an additional coupling mean to the coupling mean of the syringe in which is fixed a needle appropriately said, tubular protruding from both parts of the body with a main portion meant for the performance of the injection and a secondary portion meant to perforate the sealed lid of an ampoule, characterised by the fact that the body of the needle extends to form a tubular portion likely to receive an ampoule, and that the said additional coupling mean to the coupling mean of the syringe is located at the distal extremity of the said body of the needle.
- 2- Equipment according to claim 1 characterised by the fact that the said additional coupling means of the syringe and of the needle are of bayonet type.
- 3- Equipment according to claim 2 characterised by the fact that the bayonet coupling mean of the syringe presents a bayonet slip with a safety arrest shrink.
- 4- Needle for an equipment according to claim 1 characterised by the fact that it comprises a body in which is inserted a needle appropriately said tubular, which protrudes from it with a main portion meant to perform an injection and a secondary portion meant to perforate the sealed lid of an ampoule, the body of the needle extending to form a tubular part predisposed to receive an ampoule and provided with close to its extremities with an additional coupling mean to that of the syringe.

- 5- Needle according to claim 4 characterised by the fact that the body holding the tubular needle and the tubular extension of the body are made up of only one piece in plastic material.
- 6- Needle according to claim 4 characterised by the fact that the body holding the tubular needle and the tubular extension of the body are made up of parts separately made in plastic material and mutually connected.
- 7- Needle according to claim 6 characterised by the fact that the body with the tubular needle is of commercial making and the tubular extension is modelled to receive the connection of this body with the tubular needle.
- 8- Needle according to claim 4 characterised by the fact that it is modelled and proportioned in order to be able to receive a commercial ampoule.
- 9- Syringe for an equipment according to claim 1 characterised by the fact that it comprises a metallic body which forms a handle comprising a ring and a cam and extends in a short tubular part at which extremity is formed a bayonet coupling mean for the coupling of a needle matching the syringe, being inserted in the body, sliding, a piston provided with a handle.
- 10-Syringe according to claim 9 characterised by the fact that the said piston presents at its own internal extremity an helical system which can be screwed in the cylinder of an ampoule and a screwed sleeve likely to cover and uncover the said helical system.
- 11-Equipment of syringe and matching needles, for injections, meant for use in odontological anaesthesia and in other applications, characterised by the distinctive features, dispositions and functioning, as they appear in the description set forth here above and in the enclosed drawings or replaced

by their equivalent techniques, taken as a whole, in their various combinations or separately.



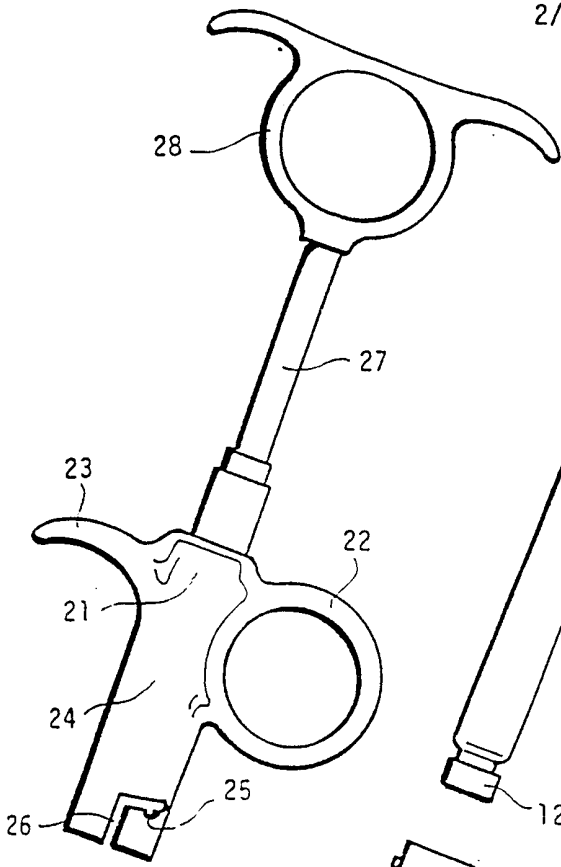


FIG. 6

FIG. 7

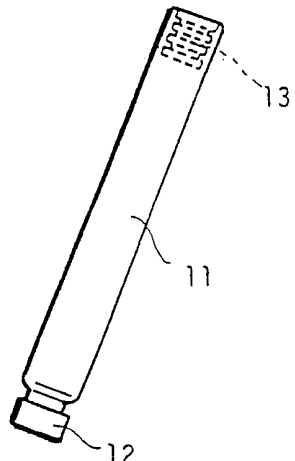


FIG. 9

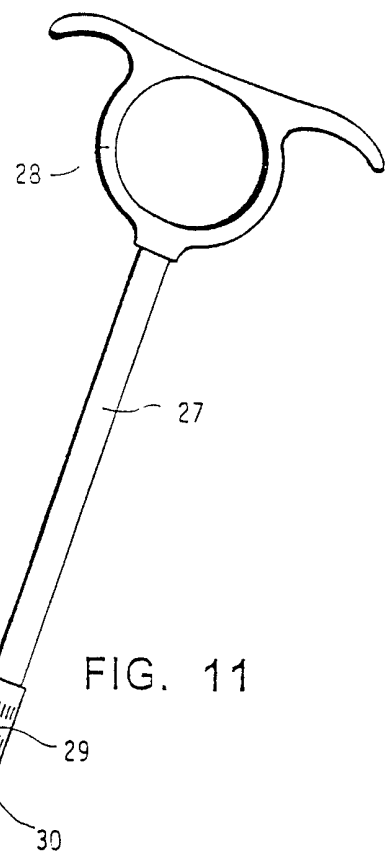


FIG. 11

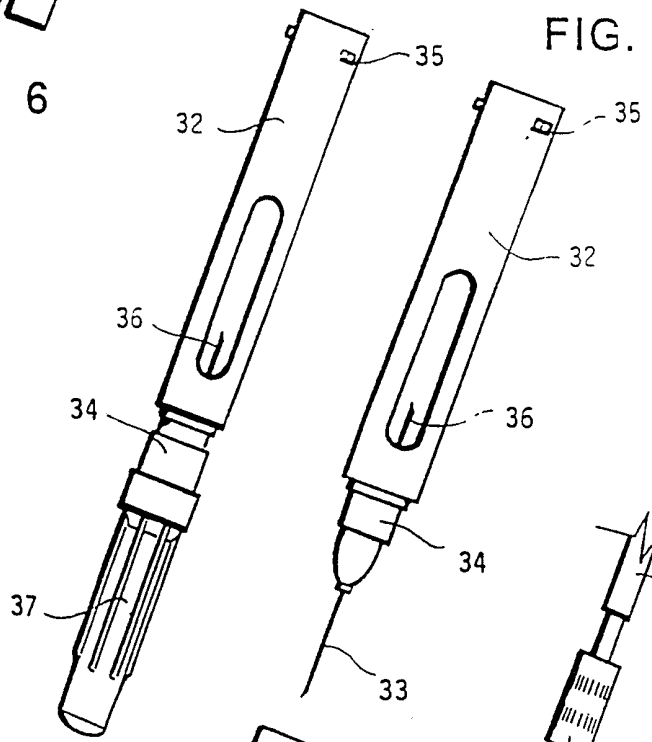


FIG. 8

FIG. 10

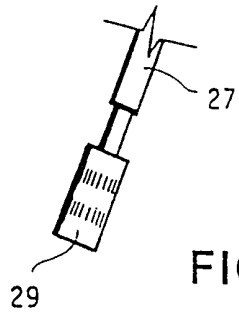
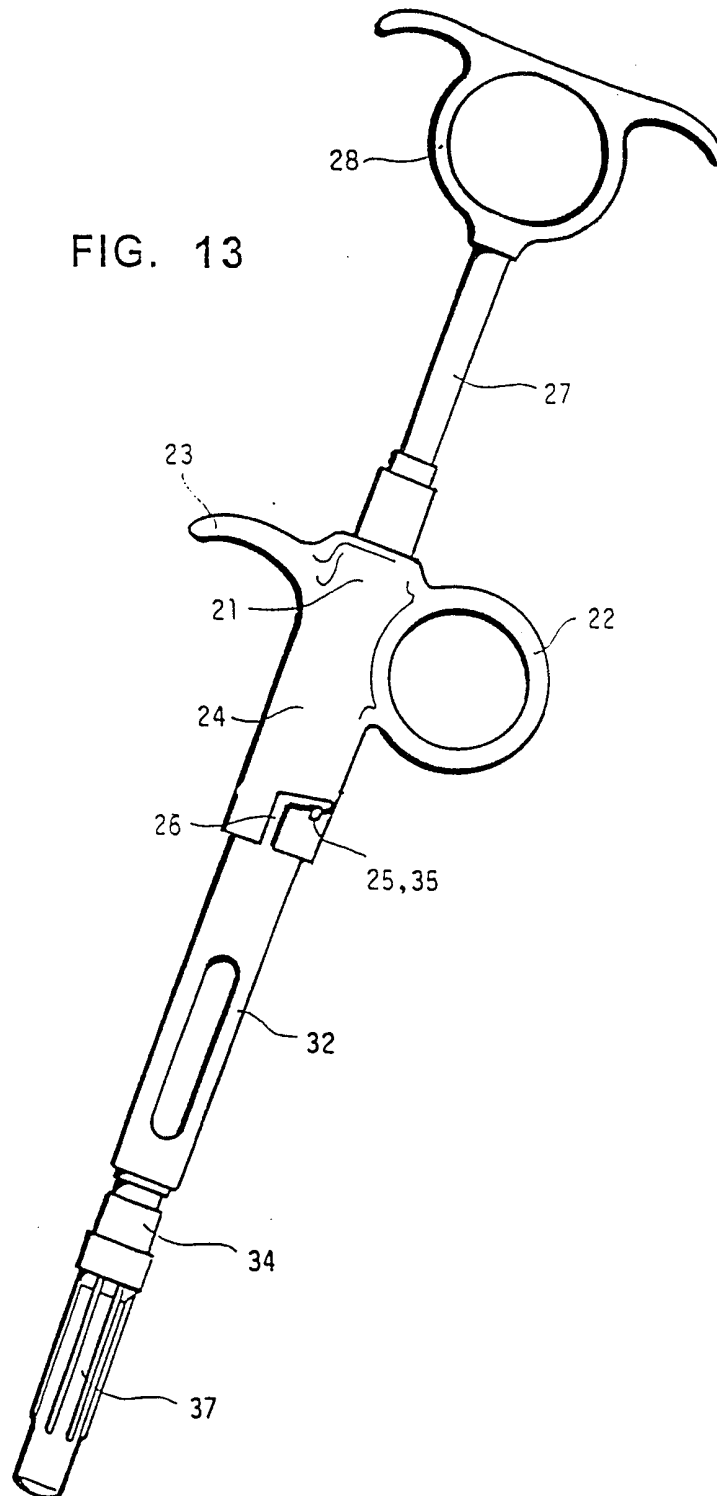


FIG. 12



INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/24 A61M5/34

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| X | WO 93 19795 A (MOLTENI & C ; SEGHI GIOVANNI (IT)) 14 October 1993 (1993-10-14) the whole document | 1-4,6-9 |
| X | US 5 496 286 A (STIEHL MARK A ET AL) 5 March 1996 (1996-03-05) the whole document | 1,4,6-8 |
| A | | 9 |
| X | FR 1 005 300 A (KESSLER) 12 April 1952 (1952-04-12) the whole document | 1-4,8 |
| A | | 9,10 |
| X | FR 1 151 049 A (S.I.T.S.A.) 23 January 1958 (1958-01-23) the whole document | 1,2,4 |
| A | | 9 |
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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
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- "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

27 March 2000

Date of mailing of the international search report

05/04/2000

Name and mailing address of the ISA

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Jameson, P

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 99/01999

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
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| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | US 1 607 271 A (A.E. SMITH) 16 November 1926 (1926-11-16) the whole document | 1 |
| A | AT 32 349 B (KRAUTSCHNEIDER) 26 March 1908 (1908-03-26) the whole document | 1 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB 99/01999

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: **11**
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Claim 11 is not searched because it is characterised by references to the description and drawings, which is contrary to PCT Rule 6.2(a).

3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/IB 99 01999

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 11

Claim 11 is not searched because it is characterised by references to the description and drawings, which is contrary to PCT Rule 6.2(a).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

information on patent family members

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| International Application No PCT/IB 99/01999 |
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| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
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| FR 1151049 A | 23-01-1958 | NONE | |
| US 1607271 A | 16-11-1926 | NONE | |
| AT 32349 B | | NONE | |