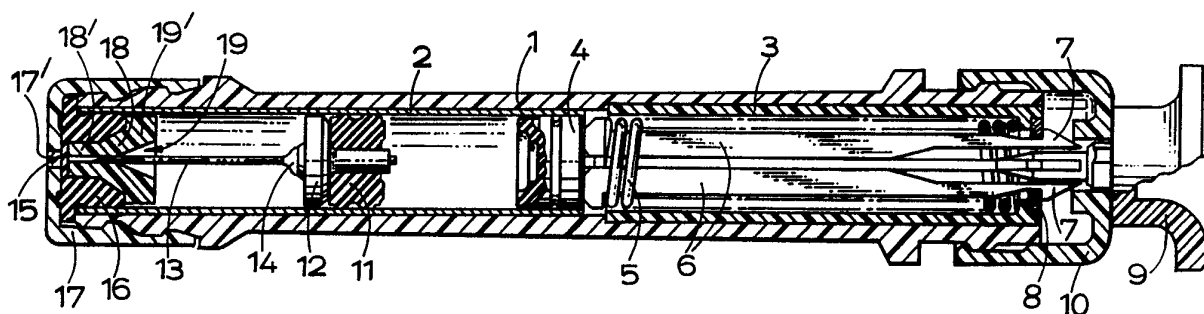




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61M 5/20, 5/28</p>	<p>A1</p>	<p>(11) International Publication Number: WO 92/12745 (43) International Publication Date: 6 August 1992 (06.08.92)</p>
<p>(21) International Application Number: PCT/GB92/00081 (22) International Filing Date: 14 January 1992 (14.01.92) (30) Priority data: 9100819.3 15 January 1991 (15.01.91) GB (71) Applicant (for all designated States except US): MEDI-MECH INTERNATIONAL LIMITED [GB/GB]; 34-35 Riverside, Sir Thomas Longley Road, Frindsbury, Rochester, Kent ME2 4DP (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): WILMOT, John, Glyndwr [GB/GB]; 44 Rectory Lane North, Laybourne, Nr. West Malling, Kent ME19 5RA (GB). (74) Agent: BARKER, BRETTELL & DUNCAN; 138 Hagley Road, Edgbaston, Birmingham B16 9PW (GB).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB, GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent), US. Published With international search report.</p>

(54) Title: SUBCUTANEOUS INJECTOR



(57) Abstract

A disposable, automatic, injector is disclosed which allows self-administration of a medicament to be injected subcutaneously. The injector comprises a barrel (1) with an inner chamber bounded by a liner (2). A first piston (4) and a second piston (11) are provided which may slide within the chamber with a fluid-tight seal with the liner (2). The second piston (11) carries an injection needle (13). A drive means, comprising a compression spring (5) and a releasable retaining collet (6), is provided to act on the first piston (4) to drive it towards the second piston (11). In operation, the drive means urges the first piston towards the second (11). The injection fluid, initially stored between the first and second pistons is incompressible and causes the second piston (11) to move until the needle (13) projects from the end of the barrel (1). When the needle (13) is fully extended the second piston (11) stops but the first piston (4) continues to move so causing injection fluid to be forced out through the needle (13).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	RU	Russian Federation
CG	Congo	KP	Democratic People's Republic of Korea	SD	Sudan
CH	Switzerland	KR	Republic of Korea	SE	Sweden
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
DE	Germany	MC	Monaco	TG	Togo
DK	Denmark			US	United States of America

SUBCUTANEOUS INJECTOR

5 This invention relates to a subcutaneous injector of the disposable automatic or 'one-shot' kind, that is to say, designed to discharge its contents into the user's body automatically and then to be thrown away. Such injectors are of great benefit in epidemics, and in third-world countries, and under battle conditions.

10 There have been many proposals for injectors involving a needle initially sealed within the body of the injector and acted on by a powerful spring released by an action on the part of the user, or by the act of placing the injector against the user's body
15 (after release of a safety catch or pin), and the spring simultaneously acts on a piston to discharge the medicament or other contents through the needle.

20 Generally speaking these have involved a separate casing and spring mechanism into which is inserted a sealed ampoule or cartridge containing the medicament as well as the needle. After use the cartridge is thrown away and the injector is filled with a fresh cartridge, the spring being first re-compressed.
25 Examples of such devices as shown in U. S. Patent Specification Nos. 2 832 339, 2 866 458 and 3 136 313. However fully disposable injectors or syringes are also known, i.e. ones in which the entire device is thrown away after use, and in these there is no separate
30 cartridge. An example of a non-automatic injector of such a construction is shown in U. S. Patent Specification No. 4 059 109.

35 In the design of a disposable syringe or injector there are certain essential requirements, the most important being that of sterility and another important

one is shelf life, i.e. a guarantee that there will be no corrosion, contamination, leakage or loss of sterility over a long period of storage. In the known disposable syringes and in the known disposable cartridges this is achieved by ensuring that the needle is in a wholly sterile environment, isolated from the atmosphere, right up to the moment of use. Generally speaking the needle is contained within a sheath and it penetrates the wall of this sheath as it advances under the force, direct or indirect, of the spring.

In some arrangements, e.g. that shown in U.S. Patent Specification No. 3 882 863, the needle is immersed in the medicament itself within the sheath, which in this case forms part of a cartridge. In others there is a piston carrying the needle, the medicament being behind the piston and the needle being in air, but still cut off from atmosphere.

In most of the known arrangements the injection of the medicament starts as soon as the needle penetrates the seal at the end of the sheath or the end of the barrel of the injector. Thus, from the moment the needle enters the user's body medicament is being dispensed. This is generally undesirable as what is really wanted is that the medicament should all, or substantially all, be placed below the skin.

The aim of the present invention is to overcome this problem and achieve a still further improvement in simplicity and reliability in a disposable syringe or injector.

According to the present invention there is provided a subcutaneous injector comprising;
a barrel having a chamber therein;

a first and second piston within the barrel each arranged to be slidable within the chamber the second piston carrying or being associated with an injection needle projecting away from the first piston;

5 a stop to restrain travel of the second piston towards an end of the barrel;

a releasable drive means; and

10 injection fluid substantially wholly contained in the portion of the chamber between the first and second pistons;

wherein upon its release the drive means urges the first piston towards the second piston so as to first cause the fluid contained therebetween to urge the second piston to move towards the end of the barrel, causing the injection needle to project therefrom, movement of the second piston eventually being restrained by the stop, further movement of the first piston then causing the injection fluid to be urged out through the injection needle.

20

According to another aspect of the invention we propose that a disposable subcutaneous injector comprises a first piston acted on by a spring held back until use by a safety catch, a second piston carrying the needle sealed to it, the medicament being contained substantially wholly in the space in the barrel defined between the two pistons, and the needle projecting in air, not in medicament, from the second piston towards the end of the barrel where there are both a penetrable diaphragm seal and also a tubular seal or guide which is already entered by the tip of the needle in its rest position.

35 When the safety catch (which can be of a known kind, such as that shown in our own European Patent Specification No. 0 361 668) is released, the spring

acts on the first piston to advance it and this in its
turn, acting through the trapped virtually
incompressible body of medicament, advances the second
piston, pushing the needle through the seal and into
5 the patient. Little or no medicament passes through
the needle at this stage, but when the second piston
reaches the end of its travel up against the end of the
barrel, the first piston continues to advance under the
action of the spring and dispenses the medicament into
10 the patient through the needle.

It is a very important feature of the invention
that during the initial advance of the needle the
tubular seal through which the needle passes acts as a
15 venting valve, opening away from the needle as the air
in the progressively decreasing space between the
second piston and the end of the barrel becomes
compressed. In the absence of this venting seal that
air would be trapped and would offer significant
20 resistance to the advance of the second piston.

The action is at first sight similar to that of
the injector disclosed in U.S. Patent Specification No.
3 882 863. However, it is important to note that in
25 that known arrangement the medicament and the needle
are contained in a separate disposable cartridge, the
needle being immersed in the medicament, and as the
whole cartridge advances under the action of the spring
the air in the space between the front end of the
30 cartridge and the end of the barrel can escape easily
around the substantial clearance present between the
outside of the cartridge and the inside of the barrel;
the venting problem only arises in a disposable
injector with an air-immersed needle.

35

One or more air escape channels may be provided from a region adjacent a seal in front of the needle to facilitate the escape of air. The body may have a front wall provided with an enlarged recess or aperture in the region where the needle is to pass through. The air escape channels may extend from the enlarged recess and may be formed in the internal walls of a separate end cap member attached to the body.

Alternatively or additionally air escape channels may be provided in a needle guide or a sealing bush surrounding the needle guide.

Embodiments of subcutaneous injectors according to the invention will now be described by way of example only with reference to the accompanying drawings of which:-

Figure 1 is a longitudinal cross-section through a first automatic injector;

Figure 2 is a longitudinal cross-section through a second automatic injector; and

Figures 3 to 6 are longitudinal sections of the front ends of other, modified, injectors.

The injector of Figure 1 comprises a body 1 of injection-moulded polystyrene containing a barrel liner 2 of F.E.P. 160 and a spring casing 3 of polystyrene. Sliding within the barrel liner 2 is a first piston 4 of rubber acted on by a stainless-steel coil compression spring 5. In the initial condition of the injector the spring is held in the compressed position, as shown in the drawing, by a collet 6 made in two halves having at their tail ends detent teeth 7

engaging a latch ring 8 seated in the end of the spring casing 3. A safety pin 9 of moulded nylon normally keeps the teeth 7 apart but when it is withdrawn they can be urged together to release the collet 6 by a short movement of an end cap 10.

This spring-restraining and release mechanism is known and is substantially the same as that disclosed in our above-mentioned European specification.

10

Also within the barrel liner 2 and spaced about half way along in the initial condition is a second piston 11, also of rubber. Sealed into this piston is a moulded polyethylene needle-mounting 12 carrying the injection needle 13 sealed into it by adhesive 14.

15

In the condition shown, the tip of the needle 13 stops just short of a diaphragm seal 15 formed in a bush 16 which is held in the end of the barrel liner 2 by an end cap 17.

20

The tip of the needle 13 is received in a guide, or seal 18, of HD polyethylene shaped as shown, with its outside fitting into the bush 16 and its inside a good sliding fit on the needle. The guide seal 18 has a cylindrical portion 18' in which the tip of the needle 13 is slidingly and sealingly received, a tapered convergent conical portion 19 which helps to lead the needle into the bore of the guide during assembly of the injector, and an abutment rim flange 19' which abuts the rearmost end of the bush 16 and which serves as a stop for the piston 11 (as will be described later).

25

The space between the pistons contains the medicament and is in communication with the open rear

30

35

end of the needle. The space between the second piston and the end of the body, i.e. the space around the needle, contains air or an inert gas.

5 When the injector is put to use by removing the safety pin 9 and actuating the end cap 10 to release the collet 6, the spring 5 initially advances both pistons together, as the liquid between them is virtually incompressible. The needle 13 advances
10 through the guide 18 and penetrates the seal 15, emerging through the centre of a hole 17' in the end cap 17. The hole 17' is considerably larger in diameter than the needle 13 and the portions of the seal membrane 15 adjacent the hole pierced in it by the
15 needle can open out into the larger hole 17'. The air or gas in the space around the needle is able to force its way between the outside of the needle and the bore of the guide seal 18, and the membrane seal 15, and so does not hold up the advance of the second piston.
20 This is an important feature and it means that the needle is able to advance fully into the patient's body until brought to halt when the mounting 12 comes up against the guide 18, and thereafter medicament is injected by the continued advance of the first piston.
25 Only a negligible quantity, if indeed any at all, is injected during the advance of the needle.

30 The air between the guide seal 18 and the piston 11 may also be able to escape past the outer peripheral edges of the guide seal and the bush 16, and then past the snap fit of the end cap 17 and the forward end of the barrel 1.

35 There is thus provided a disposable injector which is simple to use, low in cost, contains few parts, and keeps the medicament itself and the needle in a wholly

sterile condition up to the moment of use, and at the same time it ensures that during the use substantially the whole of the contents are injected subcutaneously, i.e. only when the needle has achieved the desired penetration.

A second embodiment of the invention is shown in Figure 2. The injector of Figure 2 is in many ways very similar to that of Figure 1 and similar components have been given the same reference numerals. The main differences are discussed below.

The liner 2 is made of glass, instead of plastics, and is shrink wrapped in a PVC sleeve 20. This makes the liner stronger, less fragile, and less likely to notch or scratch. Even if the glass sleeve should fracture the PVC sleeve maintains its structural integrity. The head of the collet 6 (referenced as No. 21) is received in the liner 2 prior to firing of the injector, and engages the inside walls of the liner 2. This ensures accurate alignment of the collet and liner during assembly of the injector and avoids any jarring impact on the liner should the collet hit the rearward end of the liner (which may sometimes occur in the embodiment of Figure 1).

Impact between the collet and the liner is now impossible and this reduces the risk of the glass liner shattering during firing of the injector.

The second piston 11 and the mounting of the needle 13 relative to it are also different. The embodiment of Figure 3 has a similar arrangement and shows the detail more clearly. The needle 13 is a double-ended needle having sharp points at each end and has a needle guide 22 such as a disc (perforated),

cross, or the like swaged to it. The needle guide 22 mainly serves to transmit drive from the piston 11 to the needle 13, but also centres and guides the needle 13. The piston 11 has a stopped central bore 23 at its forward face and a membrane 24 at its rear face. A needle holder, or guide 25, is received in the bore 23 and holds the needle 13 and protects the membrane 24 from the needle. The holder 25 has an annular cylindrical portion closed by an end wall and a divergent tapered conical portion which facilitates the introduction of the needle 13 into the holder 25 during manufacture. The cylindrical portion of the holder 25 defines a central bore 26 in which the needle 13 is a tight sliding and sealing fit.

The end cap 17 has a membrane 27 closing the hole 17', and the guide seal 18 also has a membrane, membrane 28, closing its forward end. In some alternative embodiments the membranes 27 and/or 28 may be omitted.

When the injector is fired forward movement of the first plunger 4 is transferred to the second plunger 11 via the liquid medicament held between them and since the liquid is virtually incompressible serves as a hydraulic lock. The friction fit of the needle 13 in the holder 25 transfers the injection force from the holder to the needle. The needle 13 pierces the three membranes 28, 15, and 27 and continues to move forward until the needle guide 22 hits the abutment flange 19'. Further forward movement of the piston 11 moves the piston 11 relatively towards the needle guide 22 and the rear end of the needle pierces the end wall of the holder 25 and the membrane 24, communicating the needle with the medicament. Further forward movement of the piston 4 expells the medicament

through the needle. It will be appreciated that the medicament does not contact the needle 13 until the injector is fired, and even then the medicament can be dispensed only after substantially all of the air in the injector forward of the piston 11 has been expelled out of the front of the injector. The bush 16 and guide valve 18 of the injector of Figure 2 operate in the same way as those of Figure 1.

It will also be appreciated that the cylindrical seal portion 18' of the guide 18 has a relatively tight sealing fit on the needle 13, but does not seal so tightly that air cannot be forced out of the injector between the cylindrical portion 18 and the needle during firing. In the embodiment of Figures 1 or 2 the cylindrical portion 18' may seal the unactuated injector against the ingress of atmospheric air past the needle, or it may not - the membrane 15 being sufficient.

The way of mounting the needle to the second plunger may be a separate invention.

Figure 3 shows the forward end of another automatic injector which is similar to that of Figure 2 and the same reference numerals have been given to similar components.

The hole 17' in the end cap 17 is blocked by membrane 27, as in Figure 2, but also has rounded or chamfered side walls 30 so as to define a wider recess adjacent the membrane seal 15. This allows the rubber membrane 15 to bellow into the recess and makes it easier to expel the gas from the needle chamber. This prevents the rubber needle guide from gripping to tightly on the needle tube as the tube passes through

and creating too tight a seal. A groove 31 or series of grooves 31 are moulded into the end cap 17 to aid the gas to escape to atmosphere. The groove or grooves 31 extend from the recess along the front and side walls of the end cap 17 and to atmosphere.

Another automatic injector is shown in Figure 4 in which the needle guide 18 is movable relative to the bush 16 during the initial firing of the injector.

10

The bush 16 has a stopped internal bore 40 which communicates with an annular space 41 surrounding the forward end of the bush via a channel 42 in the bush. The channel 42 has an enlarged radially inner end 43. The annular space 41 communicates with atmosphere via the less than airtight attachment of the end cap 17 to the body 1. Air escape grooves, such as groove 31 of the embodiment of Figure 3, may be provided to facilitate the escape of air.

20

The needle guide 18 is initially in the position shown in Figure 4, with its forward membrane seal 28 spaced from the membrane 15 of the bush. The outer surface of the needle guide 18 has a communication groove 44 which is stopped just short of the forward end of the guide 18. It will be noted that the guide 18 is significantly smaller in diameter than the sleeve 2.

30

Prior to firing of the injector the parallel cylindrical sections of the needle guide 18 and bush 16 contact each other so as to form a sterile seal. When the injector is fired the friction of the needle in the needle guide 18 moves the needle guide 18 forward. As the needle pierces the membrane 28 and the membrane 15 the guide 18 is pushed fully into the bore 40. The

35

groove 44 then communicates with end 43 of the channel 42 and air in the needle chamber has an easy escape route past the radially outer edges of the guide 18, through groove 44 and channel 42, and out
5 between the end cap 17 and the body 1. Air can also leave the needle chamber between the needle guide and the needle, via hole or recess 17' (either directly out of the hole 17' after it has been formed by the needle, or out along the interface between the end cap and
10 body).

The embodiment of Figure 5 is similar to that of Figure 4, except that the needle guide 18 has a plurality of external grooves 50 and is fully
15 introduced into the bush 16 during manufacture of the injector. The bush 16 may, or may not, have radial channels akin to channel 42, and the end cap may, or may not, have one or more air escape channels 31.

20 Instead or in addition to being grooved on its external surface the needle guide 18 may be grooved on its internal surface, adjacent the needle 13. Alternatively or additionally the bush 16 may have grooves on its internal surface.

25 The automatic injector of Figure 6 has a bush 16 which has a flexible, weakened, region 60 which in effect serves as a sealing lip. The bush 16 also has a radial passageway or groove 61 in the region of the
30 weakened region 60. The wall of the bush 16 at the weakened region 60 is spaced slightly from the liner 2 at its rearmost end.

35 Prior to use the bush 16 seals around the liner 2 to form a sterile seal. Upon firing of the injector the increase of air pressure in the needle chamber

distorts the bush at the weakened region 60, allowing the air to pass between the region 60 and the liner 2. The air enters air escape groove or grooves 31 in the end cap 17 via the groove 61.

5

A further modification which could be included in any of the embodiments described is that an air escape pathway may be provided in the front (external) face of the end cap 17. This prevents blockage of an air/gas path from the chamber surrounding the needle due to any potential sealing effect between the end cap and the patients' skin. The air escape pathway could comprise one or more grooves or channels, or a textured or roughened surface to the front face of the end cap.

10
15

20

25

30

35

CLAIMS

1. A subcutaneous injector comprising a barrel (1) having a chamber therein; a first and second piston (4,11) within the barrel (1) each arranged to be
5 slidable within the chamber, the second piston (11) carrying or being associated with an injection needle (13) projecting away from the first piston (4); a stop to restrain travel of the second piston (11)
10 towards an end of the barrel; a releasable drive means (5,6,7); and injection fluid substantially wholly contained in the portion of the chamber between the first and second pistons (4,11); wherein upon its release the drive means (5,6,7) urges the first
15 piston (4) towards the second piston (11) so as to cause the fluid contained therebetween to urge the second piston (11) to move towards the end of the barrel (1) thereby causing the injection needle (13) to project from the barrel, movement of the second
20 piston (11) eventually being restrained by the stop, further movement of the first piston then causing the injection fluid to be urged out through the injection needle (13).

25 2. A subcutaneous injector according to claim 1 in which substantially no fluid passes through the injection needle (13) until the movement of the second (11) piston is restrained by the stop.

30 3. A subcutaneous injector according to claim 1 or claim 2 having a seal (15) initially closing the end of the barrel (1), the injection needle (13) piercing the seal (15) as it emerges from the end of the barrel (1).

35 4. A subcutaneous injector according to any preceding claim in which the needle (13) passes through a guide

seal (18), in which it is a close, sealing and sliding fit, the guide (18) being located in and close to the end of the barrel.

5 5. A subcutaneous injector according to claim 4 in which a needle guide (18) has a tubular seal or guide portion (18') which is already entered by the tip of the injection needle (13) when the injector is in its rest configuration.

10

6. A subcutaneous injector according to claim 4 or claim 5 in which the tubular seal portion (18') is surrounded by a bush (16) which restrains at least the major part of the tubular seal portion against movement
15 radially of the needle (13).

7. A subcutaneous injector according to any one of claims 4 to 6 in which the guide seal (18) has a bush abutment means (19') which engage a bush (16) which
20 surrounds at least a cylindrical portion of the guide seal and which restrains forward movement of the guide seal during injection.

8. A subcutaneous injector according to claim 6 or
25 claim 7 in which the bush (16) has a membrane seal (15) initially closing the end of the barrel (1).

9. A subcutaneous injector according to any one of claims 6 to 8 in which the body has a forward end wall and in which the bush (16) abuts against the forward
30 end wall.

10. A subcutaneous injector according to any one of claims 4 to 9 in which the guide seal (18) defines the
35 stop (19') to restrain travel of the second piston (11).

11. A subcutaneous injector according to any one of claims 4 to 10 in which there is sufficient clearance between the needle (13) and the guide (18) to allow air trapped between the guide (18) and the second piston (11) to escape upon release of the drive means (5,6,7).

12. A subcutaneous injector according to any preceding claim in which the drive means (5,6,7) comprises a coil spring (5) held, until its release, in compression.

13. A subcutaneous injector according to any preceding claim in which in its rest configuration the needle (13) projects in air, not medicament, and in which an air release valve is provided forwards of the second piston so as to allow the escape of air during forward movement of the second piston.

14. A subcutaneous injector according to any preceding claim in which there is a liner (2) within the barrel (1) which defines the circumferential boundary of the chamber.

15. A subcutaneous injector according to any preceding claim in which the releasable drive means (5,6,7) is contained within the barrel (1).

16. A subcutaneous injector according to any preceding claim in which the barrel (1) has a front wall provided with a recess or aperture (17') through which the needle (13) extends during injection, the recess or aperture receiving broken or torn portions of a membrane seal (15) after the needle has pierced the seal (15).

17

17. A subcutaneous injector according to claim 16 in which the recess or aperture has an enlarged cross-section at its rearward end.

5 18. A subcutaneous injector according to claim 16 or claim 17 in which the front wall is provided on a separate end cap (17) affixed to a main barrel (1).

10 19. A subcutaneous injector according to any preceding claim in which after the initial stage of actuation of the injector there exists an air escape pathway to atmosphere from a chamber in front of the second piston through the barrel (1), or between a separate end cap and a main barrel component.

15

20. A subcutaneous injector according to claim 19 in which the air escape pathway has a portion extending generally longitudinally rearwardly of the injector.

20 21. A subcutaneous injector substantially as herein described and illustrated with reference to Figure 1, Figure 2, Figure 3, Figure 4, Figure 5, or Figure 6 of the accompanying drawings.

25

30

35

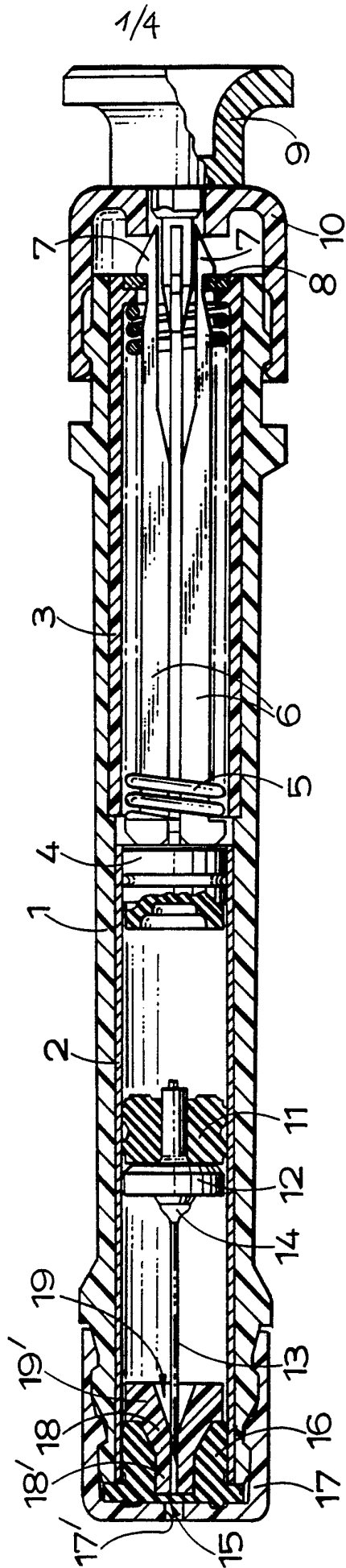


FIG. 1.

2/4

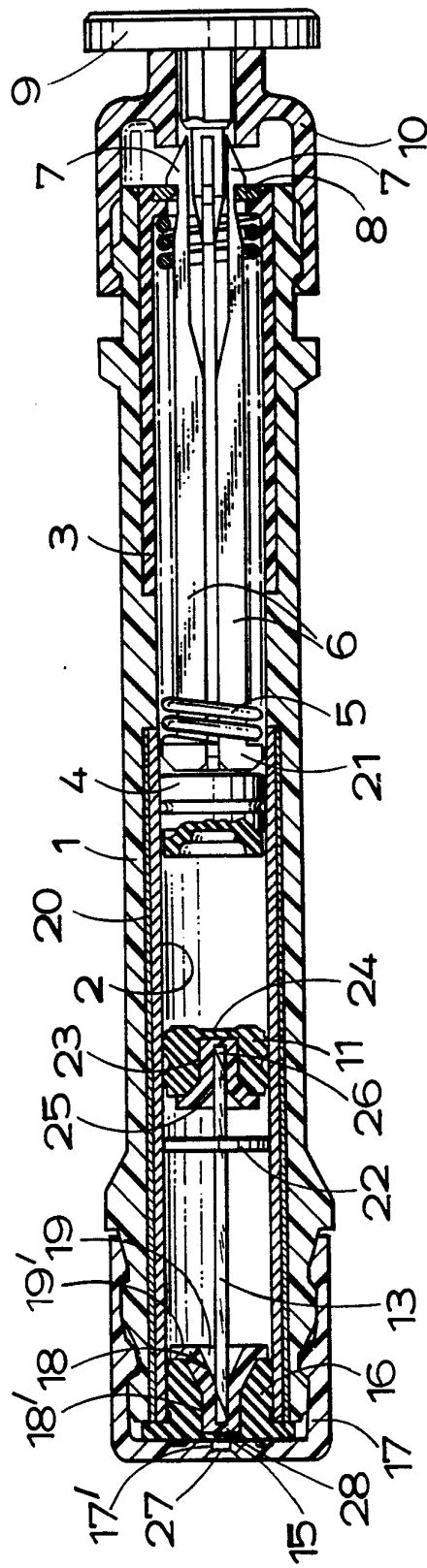


FIG. 2.

3/4

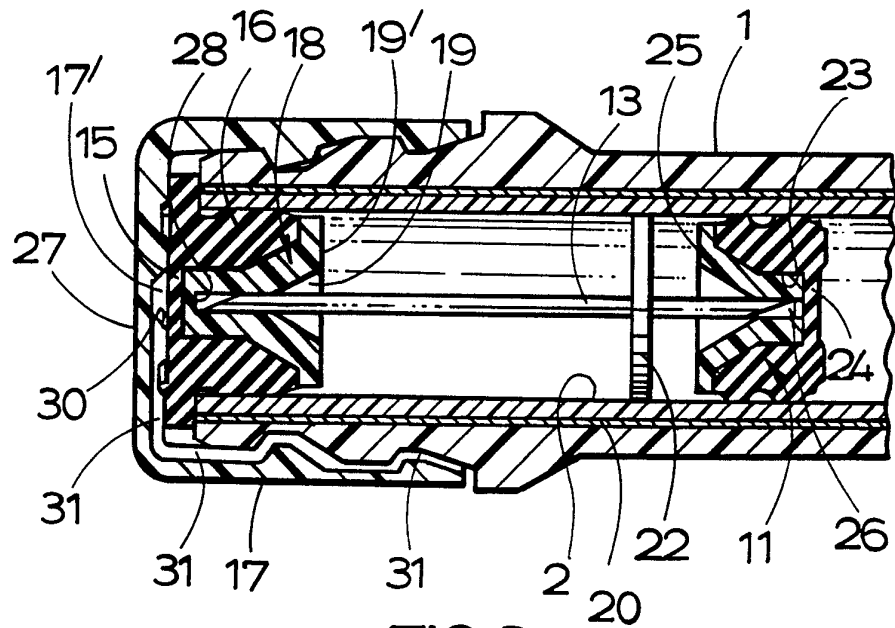


FIG. 3.

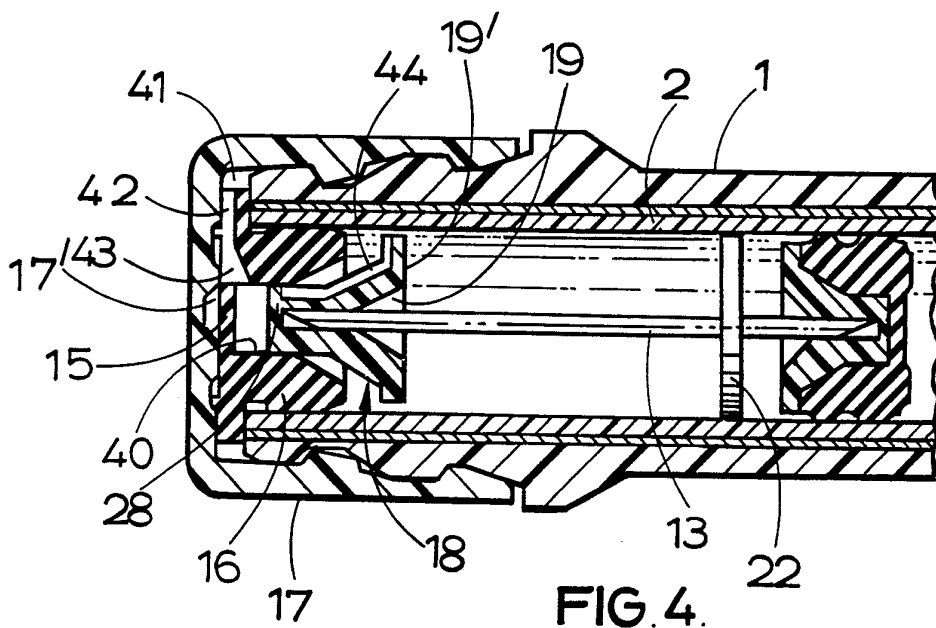
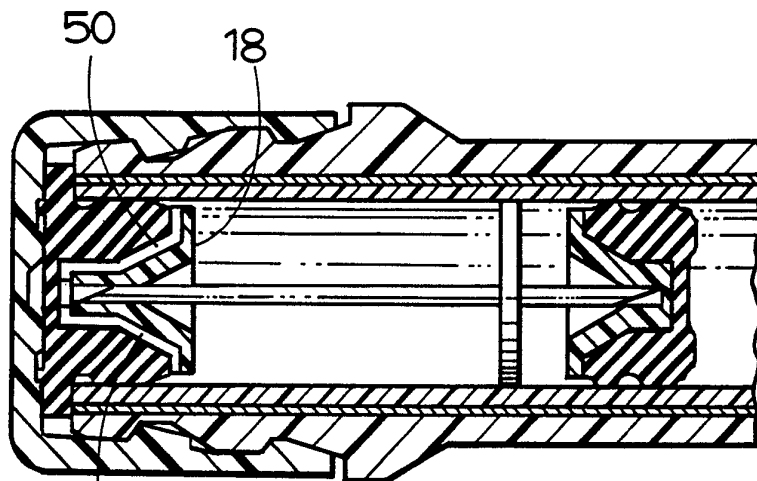
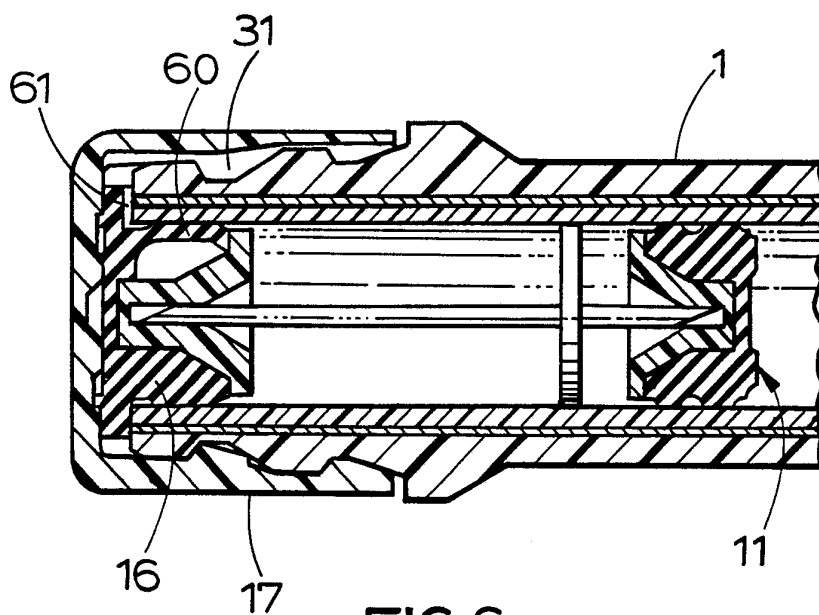


FIG. 4.

4/4



50 18
50
FIG. 5.



61 60 31 1
16 17 11
FIG. 6.

INTERNATIONAL SEARCH REPORT

International Application No **PCT/GB 92/00081**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶				
According to International Patent Classification (IPC) or to both National Classification and IPC Int.C1.5 A 61 M 5/20 A 61 M 5/28				
II. FIELDS SEARCHED				
Minimum Documentation Searched ⁷				
Classification System	Classification Symbols			
Int.C1.5	A 61 M			
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸				
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹				
Category ^o	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³		
X	FR,A,2638091 (POUTRAIT-MORIN) 27 April 1990, see abstract; figures 1,2; page 4, lines 5-34	1-3, 16		
Y	-----	4-10, 12 -15, 17- 19		
Y	EP,A,0361668 (MEDIMECH LIMITED) 4 April 1990, see abstract; figures; column 5, line 58 - column 6, line 11 (cited in the application)	4-10, 12 , 14, 15, 17, 18		
Y	EP,A,0191508 (DUPHAR INTERNATIONAL RESEARCH B.V.) 20 August 1986, see abstract; figures 1-6; page 12, lines 1-19	13, 19		

<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top; padding: 5px;"> ^o Special categories of cited documents :¹⁰ "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 </td> <td style="width: 50%; vertical-align: top; padding: 5px;"> "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 "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. "&" document member of the same patent family </td> </tr> </table>			^o Special categories of cited documents : ¹⁰ "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 "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. "&" document member of the same patent family
^o Special categories of cited documents : ¹⁰ "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 "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. "&" document member of the same patent family			
IV. CERTIFICATION				
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report			
02-03-1992	16. 03. 92			
International Searching Authority	Signature of Authorized Officer			
EUROPEAN PATENT OFFICE	Maria Faria Maria Faria			

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. OBSERVATION WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

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

1. Claim numbers _____ because they relate to subject matter not required to be searched by this Authority, namely: _____

2. Claim numbers 21 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:
 Claims shall not, except where absolutely necessary, rely in respect of the technical features of the invention, on references to the description or drawings. In particular, they shall not rely on such references as: "as described in part... of the description", or "as illustrated in figure... of the drawings." (Rule 6.2(a) - PCT)

3. Claim numbers _____ because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

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 of the International application
2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the International application for which fees were paid, specifically claims: _____
3. 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 claim numbers: _____
4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- The additional search fees were accompanied by applicant's protest.
- No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9200081

SA 55280

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 11/03/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 2638091	27-04-90	None	
EP-A- 0361668	04-04-90	US-A- 5041088	20-08-91
EP-A- 0191508	20-08-86	AU-B- 586851	27-07-89
		AU-A- 5321786	14-08-86
		CA-A- 1245932	06-12-88
		US-A- 4668223	26-05-87