COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952

DECLARATION IN SUPPORT OF CONVENTION OR NON-CONVENTION APPLICATION FOR A PATENT

Insert title of invention.

In support of the Application made for a patent for an invention entitled : "APPARATUS FOR CONTACTING MATERIAL SUCH AS A DRUG WITH A FLUID"

Insert full name(s) and address(es) of Declarant(s) being the applicant(s) or person(s) authorized to sign on behalf of an applicant company.

I / We

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Cross out whichever of paragraphs 1(a) or 1(b) does not apply.

1(a) relates to application made by individual(s).

1(b) relates to application made by company; insert name of applicant company.

do solemnly and sincerely declare as follows :-

1. (a) I am / We are ~~the applicant for the patent~~

or (b) I am authorized by DRG (UK) LIMITED
1 Redcliffe Street,
Bristol,BS99 7QY,
United Kingdom.
the applicant..... for the patent to make this declaration on its / their behalf.

Cross out whichever of paragraphs 2(a) or 2(b) does not apply.

2(a) relates to application made by inventor(s)

2(b) relates to application made by company(s) or person(s) who are not inventor(s); insert full name(s) and address(es) of inventors.

2. (a) I am / We are ~~the actual inventor of the invention~~

or (b)

DAVID SCARROW
6 Monmouth Paddock
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Bath, Avon,
United Kingdom

is / are the actual inventor..... of the invention and the facts upon which the applicant..... is / are entitled to make the application are as follows :-

State manner in which applicant(s) derive title from inventor(s)

by virtue of an assignment in respect of the invention from the said actual inventor to the applicant

Cross out paragraphs 3 and 4 for non-convention applications. For convention applications insert basic country(s) followed by date(s) and basic applicant(s).

3. The basic application.s..... as defined by Section 141 of the Act ~~was~~ / were made

in Great Britain ..... on the 2 April 1987

by DRG (UK) LIMITED.....

in Great Britain ..... on the 12 February 1988

by DRG (UK) LIMITED .....

in ..... on the .....

by.....

4. The basic application.s..... referred to in paragraph 3 of this Declaration ~~was~~ / were the first application...S..... made in a Convention country in respect of the invention the subject of the application.

Insert place and date of signature.

Declared at BRISTOL this 4th day of OCTOBER 1989

Signature of Declarant(s) (no attestation required).

For DRG (UK) LIMITED

.....SECRETARY

Note: Initial all alterations.

DAVIES & COLLISON, MELBOURNE and CANBERRA.

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APPARATUS FOR CONTACTING MATERIAL SUCH AS A DRUG WITH A FLUID

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(56) Prior Art Documents
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US 4606734
EP 117489

(57) Claim

1. Apparatus for use in establishing flow communication between the interior of a vial and the interior of a container, said apparatus comprising cup means for receiving a dispensing end portion of the vial, and a retainer means for retaining the vial with its end portion inserted in the cup means; said cup means having a mouth portion through which said end portion of the vial is insertable, a base portion opposed to said mouth portion, and conduit means communicating the interior of the cup means with the exterior, said conduit means being communicable with a container to establish said flow communication, and comprising a tubular spike projecting into the cup means from said base portion so as to confront said end portion of the vial; so that the vial is urgeable axially within the cup means against the

.../2

spike whereby the interior of the vial is communicable with the interior of the container via said conduit means; and wherein said cup means and retainer means have complementary engagement formations; such that the retainer means is engageable with the cup means, said engagement formations comprising locking means engageable to lock the retainer means to the cup means; said cup means and retainer means being initially separate or separable to allow insertion of a vial, and then lockable by engagement of the locking means so that the vial is trapped therein.

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International Bureau

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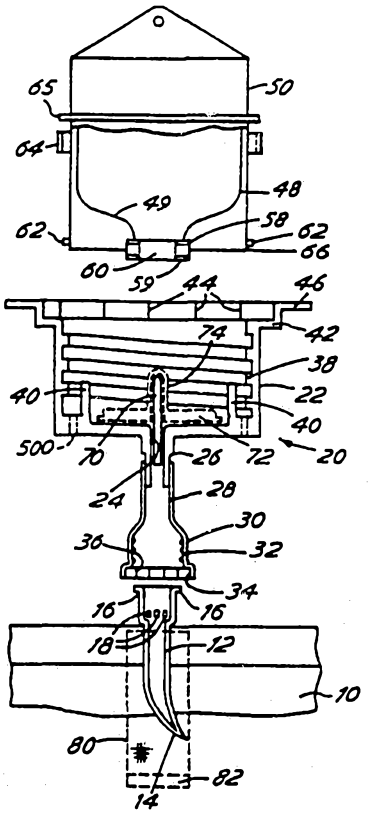
(57) Abstract

A drug delivery system for enabling liquid in a container (10) to contact the contents of a vial (48) employs a cup (22) having a mouth through which a vial (48) is insertable head down. A conduit (70, 26, 12) extends from the cup (22) interior to the container (10) interior, possibly via a non-release coupling (16, 18, 34, 36). A retainer (50) is non-releasably engageable (64, 44) with the cup (22) to trap a vial (48) therein and urge it against the conduit (70). The retainer (50) and cup (22) may engage threadedly (62, 38), with a ratchet (64, 44) preventing disengagement.



APPARATUS FOR CONTACTING MATERIAL SUCH AS A DRUG WITH A FLUID

Background of the Invention

The present invention relates to apparatus for contacting material such as a drug with a fluid. It particularly relates to apparatus by means of which material can be contacted with a fluid in a closed system.

PCT Specification WO 85/03432 discloses a closed drug delivery system comprising a flexible container of fluid, a cup permanently coupled to the container, and a standard glass drug vial within the cup, which is permanently closed by a cap. The cap is deformable to urge the vial downwardly, whereby a spike at the end of a conduit leading into the container is urged into the vial. Thus liquid from the container can contact material in the vial.

This system has some disadvantages. It is a sealed unit, including the container of fluid and the vial of drug. Thus every possible combination of fluid and drug must be manufactured and stocked. A manufacturer who produces containers of fluid may not wish to involve himself with the cup portions and vials of drugs and in any case it would be desirable for the same containers to be usable in other manners.

It is desirable to sterilise the filled fluid container using steam, but steam sterilisation of the cup assembly can lead to problems. It is thus necessary to steam-sterilise only the filled container portion. This is

then placed in a room with the remaining components, and they are all subjected to sterilisation using a sterilising gas. The unit is then assembled within the sterilising room. Not only is this double sterilisation inconvenient, but the usual sterilising gas, ethylene oxide, may become absorbed by or dissolved in plastics components. It may leak into the fluid. Even if this does not happen, it is necessary to leave the units in ventilated storage for some time so that gas that has been taken up or adsorbed can escape. Conventionally, medical articles are over-wrapped prior to sterilisation, but in this case only the container portion can be over-wrapped. Thus the cup portion may be contaminated during the steam sterilisation process and in subsequent handling.

The manufacture of a cup with a lid such that it can be used for pressing down a vial is relatively difficult and therefore expensive; and the operation of using the lid to press down a vial is not easy.

A given cup is only suitable for a single size and shape of vial.

The present invention enables one to ameliorate one or more of the above drawbacks.

Summary of the Invention

In one aspect the invention provides apparatus for use in establishing flow communication between the interior of a vial and the interior of a container, said apparatus comprising cup means for receiving a dispensing end portion

of the vial, and a retainer means for retaining the vial with its end portion inserted in the cup means; said cup means having a mouth portion through which said end portion of the vial is insertable, a base portion opposed to said mouth portion, and conduit means communicating the interior of the cup means with the exterior, said conduit means being communicable with a container to establish said flow communication, and comprising a tubular spike projecting into the cup means from said base portion so as to confront said end portion of the vial; so that the vial is urgeable axially within the cup means against the spike whereby the interior of the vial is communicable with the interior of the container via said conduit means; and wherein said cup means and retainer means have complementary engagement formations; such that the retainer means is engageable with the cup means, said engagement formations comprising locking means engageable to lock the retainer means to the cup means; said cup means and retainer means being initially separate or separable to allow insertion of a vial, and then lockable by engagement of the locking means so that the vial is trapped therein.

Preferably, the retainer means is adapted to be urgeable against a vial inserted in the cup means to urge the vial against the spike, and the engagement formations are such that the retainer means is displaceable axially relative to the cup means during engagement; the locking means being arranged so that the operation of engaging them so that the vial is retained non-removably brings the vial interior into flow communication with the conduit means.

The complementary engagement formations can take various forms. A simple arrangement is for the retaining means (which may constitute a lid for the cup means and cup means) to have respective ones of a ratchet and detent means, arranged to be mutually engageable but not disengageable. Alternatively there may be complementary ribs that can be pushed past one another in one sense but not withdrawn.

The engagement means may employ a thread within the cup. The lid may then have an external thread or thread portions (e.g. lugs, e.g. as in a Luer lock). Alternatively or additionally, the locking means may comprise engagement means provided by the cup

means for irreversibly engaging a vial.

Thus a large number of fluid/drug combinations are available from a moderate number of vials of different drugs and containers of different fluids. Once a vial has been brought into communication with the fluid, the assembly is locked together, so that the vial cannot be removed, which would allow adulteration of the contents of the container. More importantly, it would bring a risk of contamination.

Cup means may be permanently connected to a container. However, it is also possible for a container to have connecting means for coupling with complementary means associated with the cup. These may comprise a thread and a Luer lock. Preferably there are means for rendering their engagement irreversible, e.g. a ratchet arrangement similar to that described above. Storage of fluid containers can be more efficient when they are not coupled to the cups. A further way of permitting this is for the cup to have an external tubular spike portion so that it can be brought into communication with a container by pushing a spike through a rubber septum or the like provided by the container. Of course, unless means are provided for preventing withdrawal, this brings the risk associated with removable vials.

Spacers may be provided so that different types of vial can be used with the same cup. For example, the cup may have a cup-shaped lid into which vials can be fitted,

with the interposition of spacer means as required.

In different aspects the invention provides and makes possible an assembly comprising a cup and a container, coupled or couplable together; a cup adapted to be coupled to a container; and

a method of contacting a material such as a drug with a fluid.

Brief Description of the Drawings

Fig. 1 is a schematic sectional view of apparatus embodying the invention;

Fig. 2 is a detail of a modified embodiment;

Fig. 3 is a detail of a modified conduit;

Fig. 4 is a plan view of a first type of spacer member;

Fig. 5 is a view of an assembly for providing a second type of spacer member;

Fig. 6 is a view of the second type of spacer member;

Fig. 7 is a sectional view of a diaphragm assembly;

Fig. 8 shows a further form of cup assembly;

Fig. 9 A,B,C and D show alternative housings;

Fig. 10 shows a further embodiment of the invention;

Fig. 11 shows details of a still further embodiment of the invention; and

Fig. 12 is a schematic sectional view showing an aperture with controlled porosity.

Description of the Preferred Embodiments

A sterile fluid container 10 has a conduit 12 extend-

ing from the interior to the exterior. At the interior, it is closed by a breakable seal 14. At the outer end, it has the external formations 16 of a Luer lock. A little way beneath these, there are some detents 18, which are small flexible vanes.

The conduit 12 may be provided with a filter to trap any debris produced by breaking the seal. As shown in Figs. 1 and 2, this may comprise a filter sheath 80 about the end portion of the conduit 12. This may be provided by a flat tube of filter material, e.g. nylon mesh, sealed at its lower end region 82. The upper end region of the sheath may be sealed into the container 10 by the sealing step that forms the upper seal 74 of the container.

Fig. 3 shows an alternative form of conduit 12'. This has an internal breakable barrier 14' of known type (employing axial vanes 17). Downstream of this, a widened portion 79 of the conduit houses a porous disc filter 80'. Alternatively the filter 80' can be housed in a separate tube portion which is attached to the end of the conduit.

A cup assembly 20 includes a plastics cup member 22. In the base thereof there is a central opening 24, which extends outwardly through a spigot portion 26. A short conduit 28 is sealed to this, and terminates in a socket portion 30 having an internal thread 32 for engaging the Luer lock formations 16. The socket portion 30 has an enlarged mouth portion 34 within which there are ratchet teeth. The arrangement is such that the socket portion 30

and conduit 12 can be screwed together. Finally the detents 18 engage the ratchet teeth 36, which prevent unscrewing.

Fig. 2 shows a variant in which the cup assembly 20 is permanently connected to the fluid container 10. In effect, the spigot portion 26 has been extended and made integral with the conduit 12 that is sealed into the container 10.

The cup member 22 has an internal thread 38. A short cylindrical wall 40 extends axially from the base, a short distance radially within the thread 38. The upper mouth region of the cup 22 has an enlarged mouth portion 42, which is formed with ratchet teeth 44. Finally, there is a peripheral flange 46.

A vial 48 is housed within a housing 50. As shown, the vial 48 fits snugly within the housing 50, abutting the end thereof such that the mouth of the vial 48 projects slightly beyond the housing 50. To enable the same housing 50 to be used with differently dimensioned vials, spacers may be employed. Fig. 4 shows a spacer 52 which is an annulus 54 with five equispaced ribs 56 dimensioned to contact the inner wall of the housing 50. For use with a short vial 48, the spacer may itself be cup-shaped to take up the excessive length.

We have found that glass vials of the same nominal size actually vary quite widely, so there is a risk that an over-sized vial will not fit into an annular spacer 52.

Figs. 5 and 6 show a spacer assembly having a wide tolerance. An injection-moulded plastics blank 90 has three rectangular panels 91 hinged together in a row by thinned regions 92. Each panel has a transverse slot 93. A disc 94 with an annular rib 95 is connected to one panel 91 by a nib 96. For use, the disc 94 is snapped off and the array of panels is folded to define approximately a trigonal prism, within which a vial may be housed. Depending on the length of the vial, the disc 94 may be omitted or mounted in the slots 93 to provide an end wall. The effective depth of the vial housing is variable by orienting the disc with the rib projecting upwardly or downwardly. Of course, a plurality of sets of slots 93 may be provided.

The vial 48 is of conventional type, having a neck 49 leading to a mouth with an annular rim. The mouth is closed by a cap 58 with an aluminium collar 59 engaged over the rim, and a penetrable rubber septum 60.

The housing 50 has lugs 62 adjacent its open lower end. These are threadedly engageable with the thread 38 within the cup member 22. At an intermediate region, the housing 50 has tangentially projecting external vanes 64. Just above them, there may be an annular flange 65. Thus, when the housing 50 is screwed into the cup member 22, this is initially reversible. However, towards the end of its travel, the vanes 64 engage the ratchet 44, and the engagement becomes irreversible. The engagement becomes

still more firm and positive because a mouth region 66 of the housing becomes engaged between the outer wall of the cup 22 and the cylindrical wall 40. If the flange 65 is present, it covers the ratchet means 44,64 thus making it still more difficult for someone to force disengagement.

The cup member contains a tubular spike 70 which passes sealingly through the aperture 24. This is dimensioned so that, when a housing 50 containing a vial 48 is screwed into the cup member 22, the spike 70 is driven through the rubber septum 60 into the interior of the vial 48. This does not occur until the vanes 64 engage the ratchet 44. There may be a rubber gasket 72 on the base of the cup, against which the vial is sealingly and resiliently urged. A sheath portion 74 may initially cover the spike 70, and be ruptured by the vial.

Thus, in use, an appropriate vial and an appropriate receptacle 10 of fluid are selected. The rubber septum 60 of the vial is swabbed with a sterilising fluid. The cup assembly 20 is secured irreversibly to the container 10. The vial is engaged in the housing 50, using a spacer if necessary. The housing 50 is then screwed down into the cup member 22, so that the spike 70 is urged into the vial. Then, the sealed end 14 of the conduit 12 can be snapped off. Now, the interior of the receptacle 10 and the interior of the vial 48 are in flow communication. This has been achieved under normal aseptic handling conditions, and the arrangement is tamper-proof. Fluid can be pumped

from the receptacle 10 into the vial 48 and back again by squeezing the receptacle 10, in generally known fashion.

Particulate contamination produced by breaking the seal (14 or 14') or particulate material from the cup member 22, e.g. undissolved drug particles, will be filtered out by the filter (80 or 80').

Instead of (or in addition to) the provision of spacers, a range of different housings may be provided. Thus Figs. 9 A-D show housings 190 formed in two parts: a standard lower portion 192, providing the ratchet vanes 64 and the screw lugs 62; and an upper portion 194 which provides the base 196 and a suspension loop 198. A flange 65 can be provided at the zone of connection. The different upper portions 194 are adapted to different lengths and diameters of vials.

The cup assembly may be sealed for storage under sterile conditions. Thus there may be a peelable diaphragm across the cup mouth, and a similar or different seal across the lower mouth 34.

A conventional peelable diaphragm across the cup mouth may give rise to problems, e.g. if paper tear brings a risk of particulate contamination of the cup interior. Thus we may employ a diaphragm assembly 160 which provides a clean tear. A suitable assembly is shown in Fig. 7. It may be injection moulded from pvc optionally blended with a nitrile rubber. An annular outer portion 161 may be welded to the flange 46 to close the open mouth of the cup member

22. The illustrated assembly 160 has a circular disc having a central depressed portion 162 and an outer flange 164. In an intermediate region the flange 164 has an annular "thinned" region 166 which forms a tear line. A finger pull tab 168 may be formed on the flange inwardly of the thinned region 166. In use, this is pulled to tear away the assembly within the thinned region 166, leaving a cleanly exposed cup member 22. It has been found that, during autoclaving, the external pressure may force the central portion 162 down into the cup so far that it may be damaged by the spike 70. It may be shaped to minimise this risk, e.g. being connected to the flange 164 via an annulus that extends upwardly from the flange 164. Alternatively or additionally, the diaphragm may have a porous region for preventing the formation of large pressure differences across it. This may be provided as shown in Fig. 12. An aperture 400 is provided in the central portion 162. A filter membrane 402 is laid over it, and a plastics annular washer 404 is placed on the membrane. The washer may have a flat flange portion 408 with a raised rib 406 surrounding the aperture. The flange portion 408 of the washer is sealed to the central portion 162 of the diaphragm through the membrane 402 by a suitable technique, e.g. RF, heat or ultrasonic welding, depending on the materials involved. The filter membrane 402 is selected to provide sufficient porosity while still serving as a barrier to microorganisms. For example it may be a filter medium of nylon-6,6 (e.g. as

available under the trademarks Ultipor and Posidyne from Pall Process Filtration Ltd.), e.g. with a pore size of 2μm.

Fig. 8 shows a modified cup assembly 20', differing from that shown in Fig. 1 in that the spigot portion 26' terminates in a conduit portion 98 carrying a tubular spike 99. Thus the cup assembly 20' (when containing a vial) can be coupled to a fluid container (shown schematically at 10') by pushing the spike through an administration port 12' (generally having a penetrable septum 14') of the container.

Fig. 10 shows another embodiment. The cup assembly 120 includes a plastics cup member 122 of smaller axial extent. Its central opening 124, spigot portions 126 etc. may be as previously described, and are open to similar modifications.

Again there is an inner cylindrical wall 140, but this is of smaller diameter and has, in its upper region, an inwardly projecting detent bead 141. This is so dimensioned (and positioned relative to the spike 170) that when a vial 48 (as shown in Fig. 1) is pushed on, as the spike 170 is forced through the septum 60, the cap 58 is forced past the detent bead 141. This bead is shaped so that the inward passage of the cap 58 is relatively easy, but it is then trapped. (This can be enhanced if the cap 58 is given a complementary shape.) It may not then be essential to use a housing 150, so that the form of the cup

assembly could be simplified. However for greater security, use of a housing is still recommended. This example shows a different form of engagement: the inner cylindrical face of the cup member 122 has ribs 138 of sawtooth section, and the housing 150 has a complementary rib 162.

Thus the housing can be pushed into the cup member 122, and its rib 162 clips behind one or more ribs 138 of the cup member 122 and is, for practical purposes, unreleasable. This is achieved more simply than in the Fig. 1 embodiment which requires not only threaded engagement means 62,38 but also the relatively elaborate ratchet means 64,44. Of course, this form of detent means is not restricted to this embodiment. Ribs (162 and/or 138) could be replaced by projections.

Fig. 11 shows fluid container 210 and cup assembly 220 of a further embodiment of the invention. The container 210 has a conduit 212 extending into its interior. Initially the exterior of the conduit 212 opens in an expansion chamber 300. This is provided by an end portion 302 of the container delimited by a tear line 304 so it can be torn away to expose the end of the conduit 212. An insert 306 of polycarbonate plastics material projects from the inner end of the conduit 212. It is initially just a push-fit within the conduit, its degree of insertion delimited by a flange 307, but becomes bonded during heat sterilisation. The insert 306 provides (from the outer

end) an internally threaded portion 308, a location taper 310 (of standard Luer type), and a breakable barrier 217 which closes the conduit 212. A lower conduit portion 312 is pushed over the projecting lower part of the insert 306 to retain the broken off part of the barrier 217 when it is snapped. The lower conduit portion 312 may have apertures to facilitate flow once the barrier 217 is broken.

The cup assembly 220 comprises a cup member 222 (possibly of K resin) which may be generally as any previously described. Its base has a central spigot 226. This has an external thread 314 complementary to the threaded portion 308 of the insert in the container 210. (They may be two-stage threads to give rapid engagement.) An end portion 316 of the spigot 226 has an external taper complementary to the location taper 310. The spigot 226 may initially be protected by a disposable cover 318.

For use, the conduit 212 and spigot 226 are exposed by removal of the expansion chamber 300 and cover 318. The spigot 226 is screwed into the insert within the conduit until the tapered portions 310,316 engage. Locking means prevent disengagement. Thus there may be ratchet teeth 320 within an outer portion of the conduit for irreversible engagement with tangentially projecting vanes 322 on an upper portion of the spigot 226.

Apparatus embodying the invention is also useful in the field of blood products. Thus we may provide an unfilled fluid container 10 coupled with a cup assembly

(e.g. 20), with a housing (e.g. 50) inserted partially (and therefore removably) into the cup member; the whole assembly being sealed in a pouch and sterilised, suitably by gamma irradiation or steam sterilisation. Use of steam sterilisation under pressure may tend to cause the housing 50 to become deformed. This can be avoided by providing the housing 50 or cup member 22 with controlled gas permeability. In one form, the housing 50 is provided with a porous region as described above with reference to Fig. 12 for the cup diaphragm 160. Such a filter membrane 402 allows steam to gain access to the interior of the housing, even if its open end is closed by insertion into the cup member 22. For use it is removed from the pouch and the container is filled with (e.g.) blood plasma. The housing is removed to enable a vial of medicament to be selected, inserted, and brought into contact with the plasma by means of the assembly.

In an alternative form, one or more apertures 500 (Fig. 1) are provided in the base of the cup member 22, in the region between the side wall of the cup and the inner cylindrical wall 40. Thus, when a housing 50 is inserted partially into the cup member 22, gases (e.g. air and steam) can pass into and out of the interior of the cup assembly 20 via the apertures 500. When a housing 50 (containing a vial 48) is moved into its final, operable position (from which it cannot be withdrawn), the apertures 500 are closed by the leading edge of the housing 50.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. Apparatus for use in establishing flow communication between the interior of a vial and the interior of a container, said apparatus comprising cup means for receiving a dispensing end portion of the vial, and a retainer means for retaining the vial with its end portion inserted in the cup means; said cup means having a mouth portion through which said end portion of the vial is insertable, a base portion opposed to said mouth portion, and conduit means communicating the interior of the cup means with the exterior, said conduit means being communicable with a container to establish said flow communication, and comprising a tubular spike projecting into the cup means from said base portion so as to confront said end portion of the vial; so that the vial is urgeable axially within the cup means against the spike whereby the interior of the vial is communicable with the interior of the container via said conduit means; and wherein said cup means and retainer means have complementary engagement formations; such that the retainer means is engageable with the cup means, said engagement formations comprising locking means engageable to lock the retainer means to the cup means; said cup means and retainer means being initially separate or separable to allow insertion of a vial, and then lockable

by engagement of the locking means so that the vial is trapped therein.

2. Apparatus according to claim 1 wherein the retainer means is adapted to be urgeable against a vial inserted in the cup means to urge the vial against the spike, and the engagement formations are such that the retainer means is displaceable axially relative to the cup means during engagement; the locking means being arranged so that the operation of engaging them so that the vial is retained non-removably brings the vial interior into flow communication with the conduit means.

3. Apparatus according to claim 1 or 2 wherein said complementary engagement formations comprise threaded engagement means and ratchet means such that threaded engagement is permitted but threaded disengagement is restrained.

4. Apparatus according to claim 1 or 2 wherein said complementary engagement means comprise annular ribs of sawtooth cross section on one member and at least one complementary rib or projection on the other.

5. Apparatus according to any preceding claim wherein said retainer means comprises a cylindrical sleeve for embracing the vial and said cup means includes an annular cup wall and a coaxial internal annular wall; the arrangement being such that the retainer means is displaceable to a configuration in which its sleeve

projects snugly between the annular cup wall and the coaxial internal annular wall.

6. Apparatus according to claim 5 wherein said internal annular wall has an inwardly projecting detent bead dimensioned and positioned so that when the vial having a cap is urged axially within the cup means the cap is forced past the detent bead which thereafter resists its withdrawal.

7. Apparatus according to claim 5 or 6 including a plurality of retainer means selectively engageable with the cup means, and providing cylindrical sleeves adapted to embrace vials of respective different dimensions.

8. Apparatus according to any preceding claim further including at least one spacer dimensioned to fit snugly within the cup means and adapted to hold the vial which would otherwise be a loose fit within the cup means.

9. Apparatus according to any preceding claim wherein said conduit means has an exterior end portion adapted to be coupled to second conduit means associated with a container with whose interior communication is to be established.

10. Apparatus according to any preceding claim including a diaphragm by which the mouth portion of the cup means is closed, said diaphragm having a portion adapted to be removed to permit engagement of said

retainer means and the vial.

11. Apparatus according to any preceding claim wherein said conduit means terminates exteriorly of the cup means in a tubular spike.

12. A drug delivery system comprising apparatus according to any preceding claim and a container for a liquid; said conduit means being in communication or communicable with the interior of the container.

13. A drug delivery system according to claim 12 wherein the conduit means comprises a first conduit means communicating with the interior of the cup means and a second conduit means communicating with the interior of the container; said first and second conduit means having complementary formations whereby they are couplable together; said complementary formations being adapted to permit coupling and to restrain uncoupling.

14. A drug delivery system according to claim 12 or 13 wherein the container has a conduit portion for said flow communication; said container conduit portion having frangible means that prevent said flow communication until broken.

15. A drug delivery system according to claim 14 including a particulate material retaining member arranged to trap particulate material generated by breaking said frangible means.

Dated this 7th day of January, 1992

DRG FLEXPAK LIMITED

By its Patent Attorneys

Davies Collison Cave

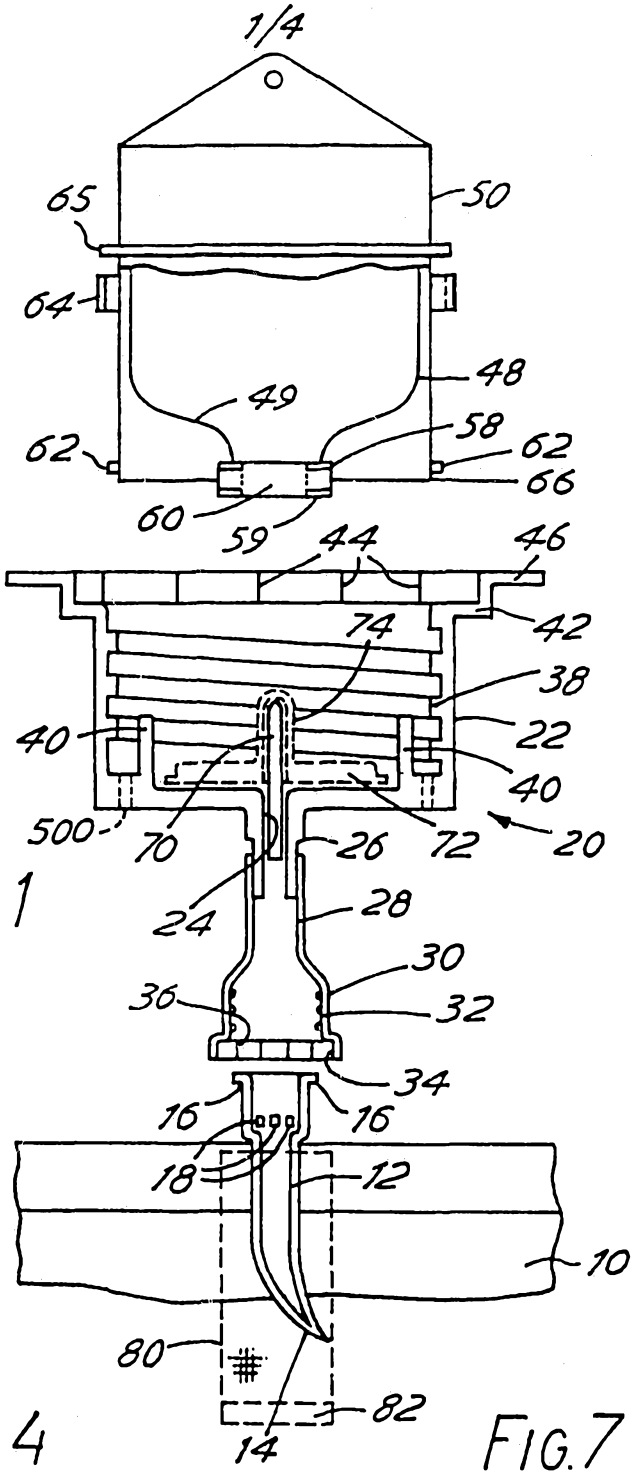


FIG. 1

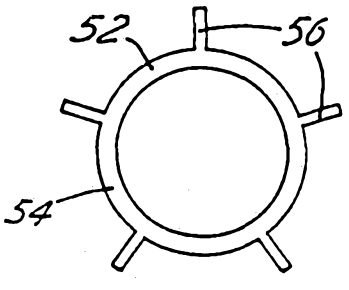


FIG. 4

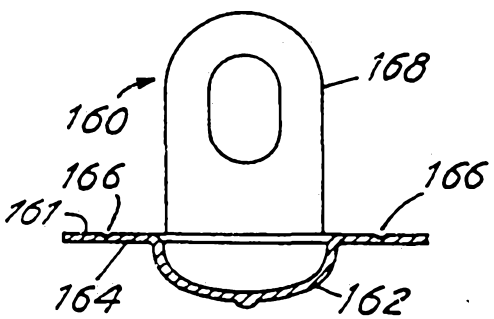


FIG. 7

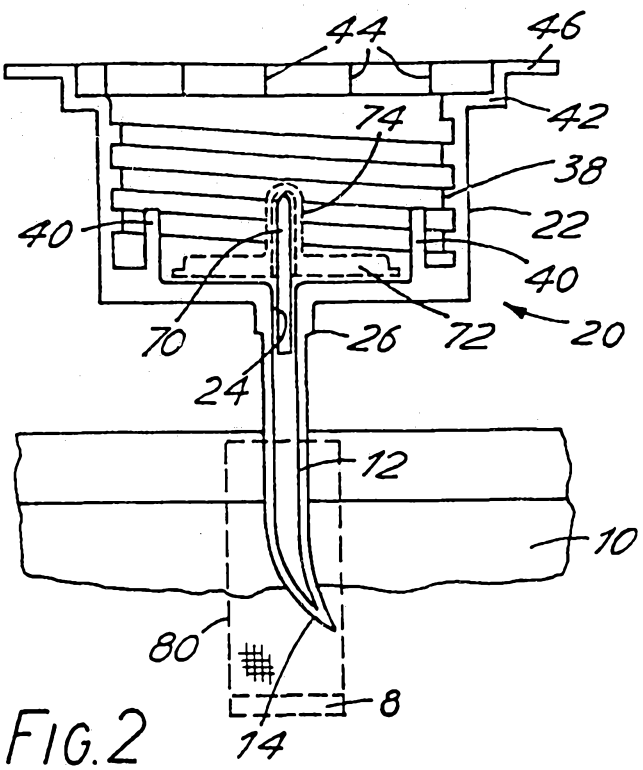


FIG. 2

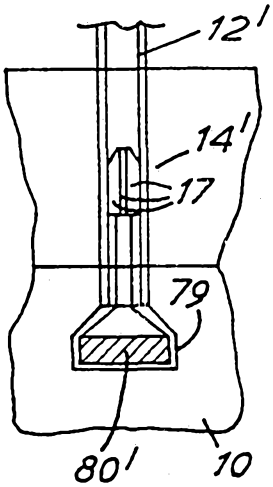


FIG. 3

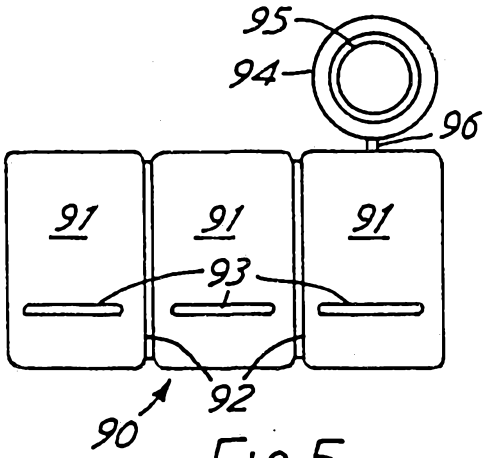


FIG. 5

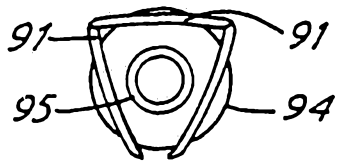


FIG. 6

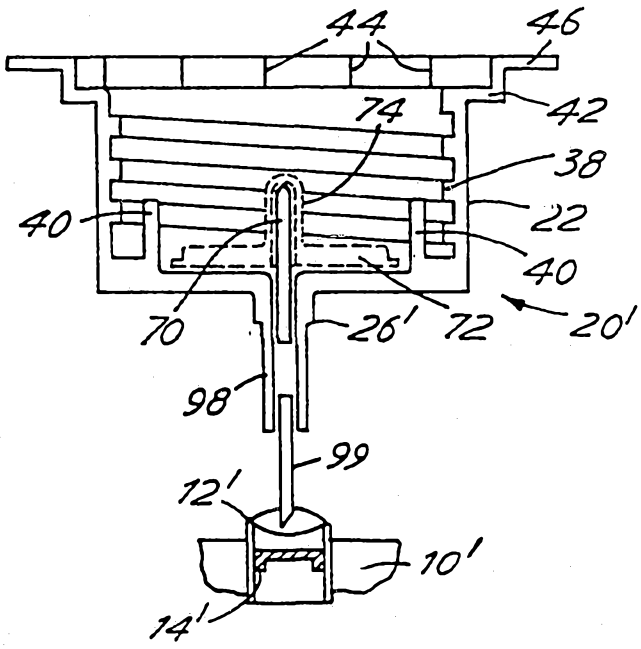


FIG. 8

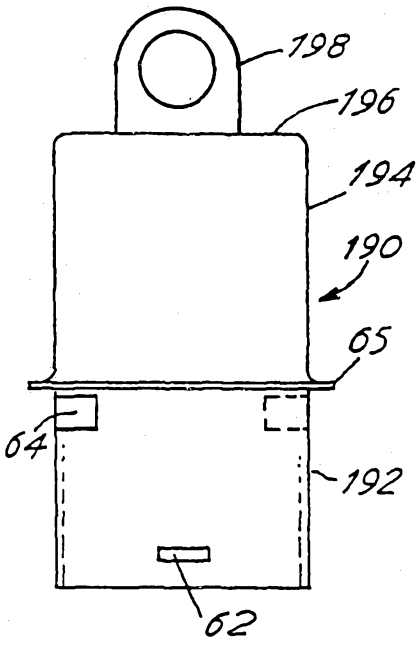


FIG. 9A

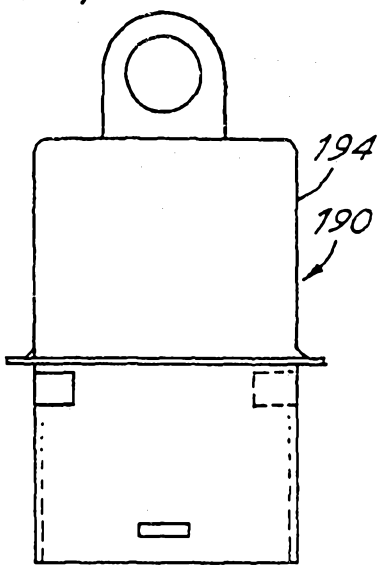


FIG 9B

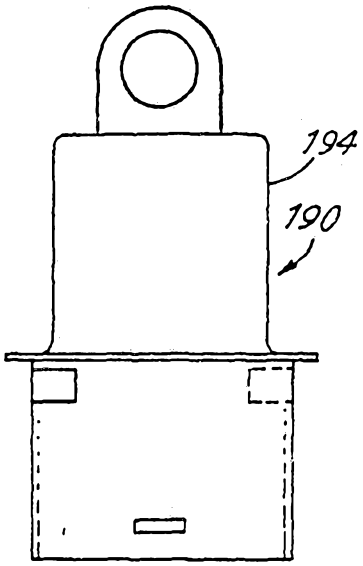


FIG. 9C

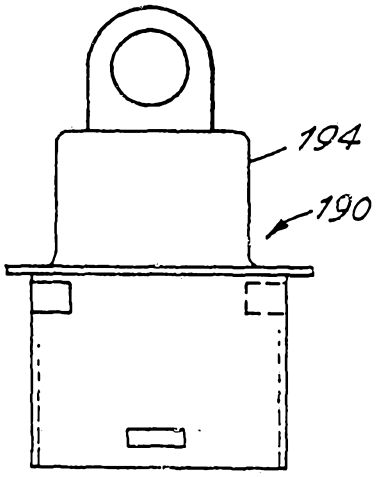


FIG. 9D

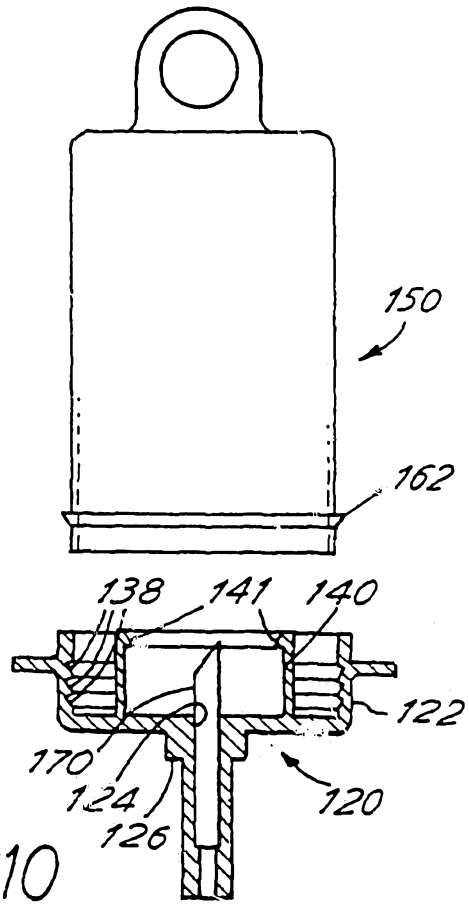


FIG. 10

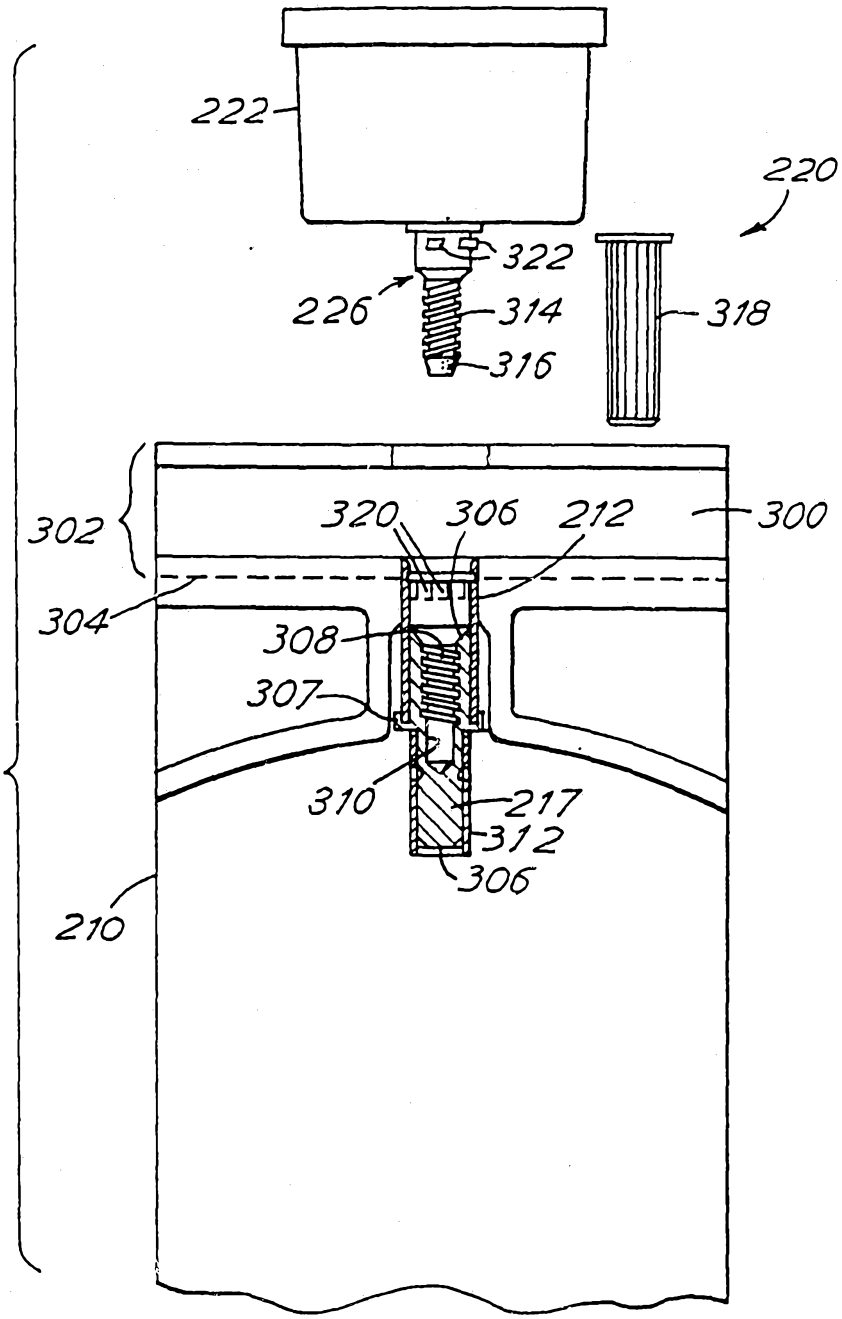

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FIG.11

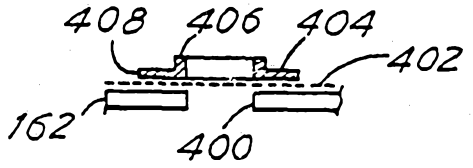
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FIG.12

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 88/00256

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

IPC[4]: A 61 J 1/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 J

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	WO, A, 85/03432 (TRAVENOL EUROPEAN RESEARCH AND DEVELOPMENT CENTRE), 15 August 1985, see the whole document cited in the application	1
A	US, A, 4606734 (ABBOTT LABORATORIES) 19 August 1986, see the whole document	1
A	EP, A, 0117489 (ABBOTT LABORATORIES) 5 September 1984, see the whole document	1

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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
14th June 1988	08 JUL 1988
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	P.C.G. VAN DER PUTTEN

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8800256 SA 21500

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 29/06/88
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
WO-A- 8503432	15-08-85	AU-A- 3933085	27-08-85
		EP-A- 0172836	05-03-86
		US-A- 4583971	22-04-86
		JP-T- 61501129	12-06-86
		CA-A- 1234369	22-03-88
US-A- 4606734	19-08-86	None	
EP-A- 0117489	05-09-84	AU-A- 2442184	06-09-84
		JP-A- 59209535	28-11-84
		US-A- 4614267	30-09-86
		CA-A- 1230084	08-12-87