Sept. 3, 1963 S. D. GOLDBERG 3,102,539

DISPOSABLE CARTRIDGE TYPE HYPODERMIC SYRINGE DEVICES

Filed Nov. 23, 1960

FIG. 1

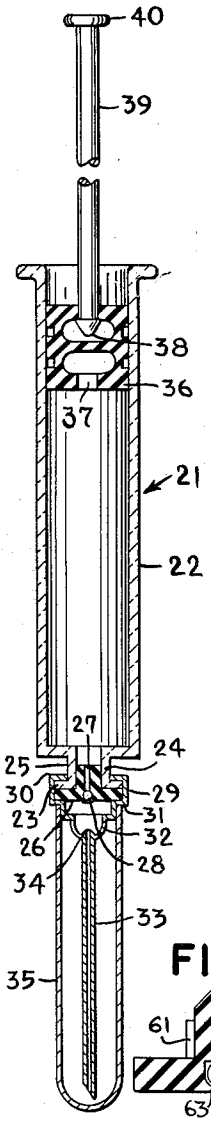


FIG. 2

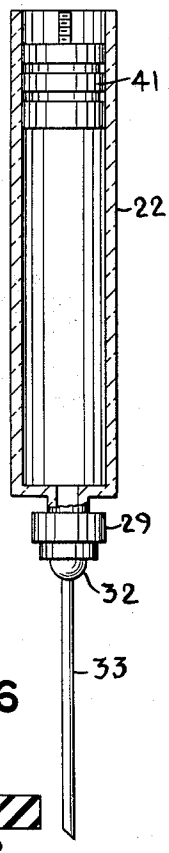


FIG. 3

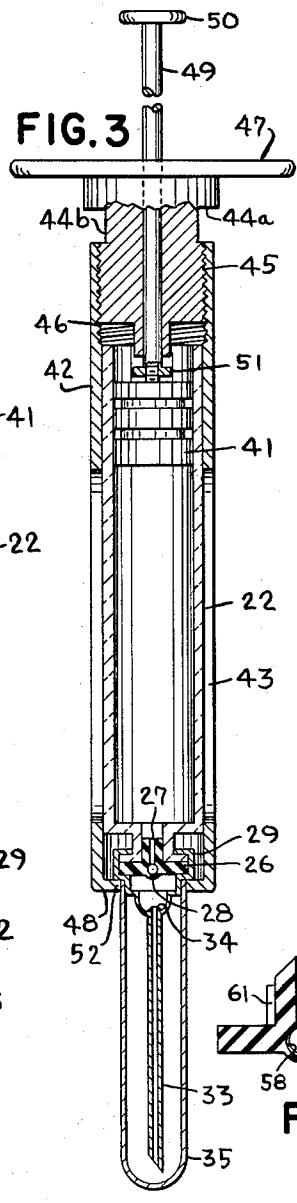


FIG. 4

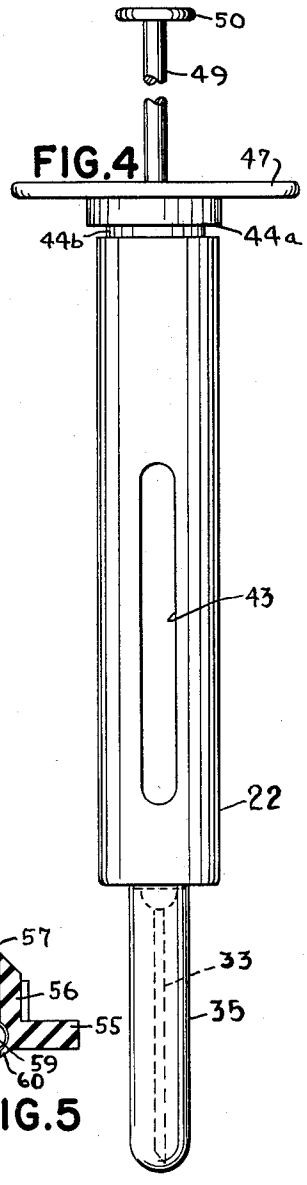
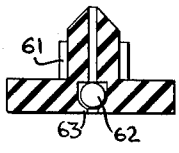


FIG. 5

FIG. 6



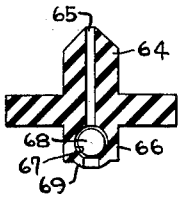


FIG. 7

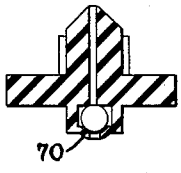


FIG. 8

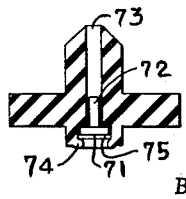


FIG. 9

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DISPOSABLE CARTRIDGE TYPE HYPODERMIC SYRINGE DEVICES

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The present invention relates to hypodermic syringes of the type used in parenteral administration of medicaments and the like agents in the diagnosis, therapy, and prophylaxis of diseases of the human or animal organism.

More particularly, the invention is concerned with hypodermic syringes of the type comprising disposable, single dose cartridges or ampules containing the liquid to be parenterally administered, closed at one end by a temporary closure sealing the ampulse to prevent premature discharge of the contents thereof, through the needle, and closed at the other end by a plunger or piston that seals the ampule permanently and is adapted to move axially within the ampule to expel the liquid contained therein.

Single dose cartridges for use in hypodermic syringes frequently involve a separation of the needle from the solution or similar contents of the cartridge until the hypodermic syringe is to be readied for immediate use. Usually, this separation of the cannula from the liquid in the ampule is accomplished by the interposition, between the captive terminal portion of the needle and the solution, of a partition, frequently in the nature of some sort of diaphragm made of a material and with a wall thickness such that it is susceptible of being ruptured or pierced, on application of a force tending to either move the cartridge on to the needle, or else compel the needle to move toward the solution contained in the cartridge. In either instance, the relative displacement of the liquid containing portion of the ampule and the captive terminal portion of the cannula result first in contact of the diaphragm or other partition with the pointed end of the needle and on continuation of the relative displacement, in the penetration and rupture of the partition by the needle which now extends into the solution or other liquid contained in the ampule.

Parenteral administration of liquids by means of a hypodermic syringe may be classified into two categories: the administration of liquids intravenously and administration of liquids subcutaneously but not intravenously. In the first category the liquids administered are those that may be introduced directly into the blood stream without untoward effects; whereas in the second category the liquids administered are those that must not be introduced directly into the blood stream, either because they would produce acute or even fatal toxic effects or because they would be so rapidly excreted that the desired therapeutic levels could not be obtained for any appreciable period.

For example, local anesthetics are administered subcutaneously, but never intravenously, because venously their dissemination through the blood stream would be so rapid as to preclude local development of adequate concentration to effect anesthesia, and, moreover, the venous toxicity of these substances is appreciable.

When using a hypodermic syringe for administering liquids intended for absorption from subcutaneous tissues, it is customary for the technician to insert the hypodermic needle in the selected place on the skin and then, to assure that the needle is not in a vein, to retract the plunger slightly before beginning forward movement of the plunger to effect administration of the liquid. If the needle is in a vein, blood will be drawn within the ampule, thus warning the technician that administration should not be continued without readjusting the position of the needle. The technician then withdraws the needle and inserts it

in another place in the skin and repeats the operation above mentioned to assure that intravenous administration of the material will not take place. When a suitable place has been found, the contents of the ampule are expelled through the needle into the tissue by forcing the plunger axially forward within the ampule toward the partial closure end thereof.

Although the art is replete with attempts at improving this type of disposable, single dose cartridge, none of the devices proposed thus far have given complete satisfaction from a mechanical point of view, and mechanical failures of one kind or another have been excessive, particularly considering the delicate nature of this field where nothing short of a thoroughly positive, safe and reliable performance of the instrument can be tolerated.

In the first place, devices of this kind suffered from the inherent deficiency that in requiring rupture of a diaphragm or similar partition by the sharp edges of a hollow, tubular metallic needle which cut into the material of the diaphragm like a knife, at least some of the material thus cut out was bound to be forced into the open mouth of the needle, under the impact of the solution advancing into the needle under a very material pressure, with the result that clogging of the needle could occur, but far more often, particles of the material were passed along with the solution to enter into the organism of the patient. The entry of such foregin matter as the particles of a ruptured diaphragm, of course, tends to defeat the primary objectives of this class of instruments where the preservation of sterility, purity, and effective exclusion of all extraneous matter is of the most vital importance.

In the second place, the slight retraction of the plunger, customarily resorted to by the technician prior to administration of the liquid, created a problem which so far did not meet with a satisfactory solution regardless of the type of temporary closure employed.

It is a major object of the present invention to eliminate the drawbacks of the disposable single dose cartridges of the prior art, and to provide a device having thoroughly improved characteristics.

More particularly, it is an object of this invention to provide a disposable cartridge wherein the needle is effectively separated from the liquid contents of the ampule until the cartridge is used for purposes of injection, yet the removal of such separation, and the establishment of contact between the medicament and the needle, is effected without any relative displacement of the cartridge and the needle whereby to eliminate the mechanical failures frequently attendant on such displacement.

It is another object of this invention to provide a disposable, single dose cartridge involving effective separation of the liquid contents of the ampule from the needle up to the time of actual injection, but requiring no rupture of any wall or other separating element tending to introduce foreign particles into the needle, into the medicament, and ultimately, into the organism.

It is a further object of this invention to provide a disposable, single dose cartridge facilitating a slight retraction of the piston to assure that the needle is not in a vein prior to subcutaneous administration of a drug or the like.

It is still another important object of this invention to provide a disposable, single dose hypodermic syringe incorporating a self-contained cartridge and needle unit.

It is a still further object of the invention to provide a hypodermic syringe accommodating the disposable cartridge, needle and temporary closure assembly, wherein the piston mount can be displaced over a predetermined distance.

Among ancillary objects of this invention are enhanced simplicity, and consequently, an improved economy of

manufacture of disposable cartridges, obtained along with the elimination of the prior art drawbacks enumerated above.

Other objects, and the manner in which the same are attained, will become apparent as this specification proceeds.

Regarded in certain of its broader aspects, the invention comprises a disposable cartridge incorporating a seal-controlled closure and a seal disposal chamber therefor, interposed below the liquid contents of the ampule and a needle mounted in fixed position at the bottom of said chamber with its captive terminal portion adequately spaced from the closure to avoid any mutual contact of the needle and the closure, the closure being made of an elastomer, such as rubber and the like, the closure having a center bore and incorporating a seal such as a sphere, bead or ball disposed in a cavity in said center bore and effectively closing the same, until, under the influence of the very material pressure exerted on the liquid contents of the ampule by the actuation of the piston normally depressed for injection purposes, the bead, ball or other seal element is ejected into the free space inside the seal disposal chamber, whereupon the center bore in the closure is free to serve as a passage for the solution in the ampule on its way to the needle and hence into the organism. The captive top end of the needle is provided to project into the free space inside the cup-shaped bottom portion of the seal disposal chamber to prevent the ejectable seal member from becoming located in front of the mouth of the said needle. Preferably also the bottom opening of the seal controlled closure is provided with an annular downwardly projecting portion designed to prevent the seal member from ever re-entering the seat portion in the closure under the influence of suction attendant on retraction of the piston. Manifestly, opening of the ejectable seal controlled passage involves none of the risks of clogging and contamination encountered on rupture of a diaphragm by the needle, nor any danger of mechanical failure because of the absence of any relative displacement of the cartridge and the needle.

Suitable materials for use in making ejectable seal controlled closures according to this invention include soft natural and synthetic elastomers, of which rubber chiefly is preferred, and the removable seal elements may be beads, balls, disks, etc., made of metal, plastics, or the like. The closure may be provided in the form of a disk with a perforation in the center and an enlarged portion therein to serve as seat for the removable seal member; it may be a disk with a central extension at the bottom wherein the seal seat and seal are disposed; it may include a disk portion with a stem upwardly extending into the center bore in the closure; whatever particular seal structure is adopted, the closure usually is provided in the form of a mushroom-shaped structure wherein from the top of the disk, a tubular guide portion extends into the bore at the bottom of the tubular cartridge.

The invention also contemplates a hypodermic syringe accommodating the disposable cartridge, needle and interposed ejectable seal controlled closure and seal disposal chamber, and including a piston mount displaceable over a predetermined distance so that on insertion of the assembly in the syringe, when the piston mount is screwed into the top of the tubular cartridge holder, the piston is displaced over just that predetermined distance which will suffice to eject the seal member from its seat in the closure so as to open the passage therethrough without effecting, pending a further downward stroke of the piston, any substantial passage of liquid into and through the needle.

In order to facilitate a more complete understanding of these and other facets of the present invention, reference is made to the accompanying drawing wherein several embodiments of the invention are illustrated, by way of example rather than with any limitative intent.

In the drawings:

FIG. 1 is a sectional view of a disposable hypodermic syringe assembly including a cartridge comprising an ejectable seal controlled closure and an ejectable seal disposal chamber therefor, according to the present invention;

FIG. 2 is a sectional view of essential parts of a modification showing a disposable cartridge, needle and interposed ejectable seal controlled closure and ejectable seal disposal chamber assembly particularly adapted for insertion in a hypodermic syringe;

FIG. 3 is a sectional view of a hypodermic syringe accommodating the disposable cartridge, needle and interposed ejectable seal controlled closure and ejectable seal disposal chamber assembly shown in FIG. 2, and incorporating a piston mount displaceable over a predetermined distance;

FIG. 4 is a side view of the hypodermic syringe shown in FIG. 3;

FIG. 5 is a diagrammatic sectional showing a closure forming part of a disposable cartridge according to the invention, the closure having a central bore, including an enlarged space serving as the seat of an ejectable seal;

FIG. 6 is a similar showing of a modification of the ejectable seal controlled closure of FIG. 5;

FIG. 7 is a similar view of a closure including a central bottom extension;

FIG. 8 is a similar showing of a modification of the ejectable seal controlled closure of FIG. 7;

FIG. 9 is a similar sectional view of a closure according to the invention provided with a disk-shaped ejectable seal including a stem extending into the center bore.

Referring now to the drawings, wherein like elements are indicated by identical reference numerals, and first to FIG. 1, this illustrates a preferred embodiment of the invention involving a complete cartridge, ejectable seal controlled closure and hypodermic needle assembly. The medicament-carrying cartridge **21** is seen to comprise an essentially straight, tubular body portion **22** of substantially uniform bore, open at one end and terminating at its opposite end **23**, in a partially constricted tubular portion **24**, having a diameter considerably smaller than that of the tubular body portion **22** and provided, on its outer surface with an annular groove **25**. A closure **26** is positioned against the end portion **24**, substantially as shown. This closure **26** is formed of a resilient, liquid impervious, elastomer material such as natural or synthetic rubber, synthetic rubber-like material, or composite laminated material comprising the foregoing, capable of being sterilized and substantially inert toward, and insoluble in, liquids, solvents and medicaments normally parenterally administered by injection, and comprises a bore **27**, and an ejectable seal member **28** seated in the closure so as to close the bore **27** until it is ejected from the closure and into the seal disposal chamber **32**, by the material pressure brought to bear on the liquid by the descent of the piston **35** in the tubular body portion **22** of the cartridge **21**.

A substantially tubular closure collar element **29**, turned in at its ends, is disposed around the end portion **23** of the cartridge and has a top part **30** turned in so as to be sealed in and engaged with the annular groove **25**, while a bottom part **31** is similarly turned in at its ends to support, in its central region, the substantially tubular ejectable seal disposal chamber **32** in the bottom of which the hypodermic needle **33** is mounted; the captive end **34** projects slightly into the seal disposal chamber **32** to prevent the seal member **28** from taking up a position blocking the entrance into the needle.

Manifestly, these parts are held together firmly and permanently providing a liquid-tight closure across the mouth of the cartridge unless and until the application of compressive forces ejects the ejectable seal member **28** and thus, opens the passage **27**. An elongated needle cover or sheath **35** made of rubber, plastic, or similar material is slipped over the seal disposal chamber and

needle mount 32 to provide an airtight seal for the sterile needle until it is used.

In order to bring the compressive forces into play, an essentially cylindrical piston 36 is provided which on its circumference, is provided with a plurality of annular grooves formed at spaced intervals and serving to facilitate fluid-tight sealing of the ampule. While this piston, on principle, could be of any conventional type, it may be provided, advantageously, of the improved type disclosed and claimed in my copending application for U.S. Letters Patent, Serial No. 776,014, filed November 24, 1958, now Patent No. 3,045,674, which is distinguished by the disposition of identical top and bottom openings 37 either one of which is susceptible of being engaged by the head 38 mounted on the syringe plunger rod 39. Piston actuating means 40 are mounted on the plunger rod 39 and will serve in the depression of the piston 36 when the syringe is used in the parenteral administration of a medicament or similar agent contained therein. A finger grip provided in the form of a flared end portion integral with said body, serves to further assist in a firm hold on, and safe operation of, the syringe.

The preferred embodiment of the invention according to FIG. 1 thus will be understood to be in the nature of a self-contained disposable single dosage syringe which incorporates a perfectly fluid-tight seal effective from the time of manufacture and introduction of the medicament, through the periods of shipment and storage, to the very instant of actual administration when the exertion of pressure on the piston, and the consequent exertion of pressure, transmitted by the liquid in the cartridge, on the ejectable seal controlled closure, will eject the seal member and open the passage therein, so the liquid will pass through this passage and enter the needle disposed underneath the same, for injection into the organism, all dangers of mechanical failure, clogging, contamination or discoloration being effectively eliminated.

Referring now to FIG. 2, this illustrates a disposable, single dosage cartridge according to the invention which is designed for introduction and use in hypodermic syringes as shown in FIGS. 3 and 4, rather than as a self-contained unit assembly as illustrated in FIG. 1.

The disposable cartridge of FIG. 2 distinguishes from the self-contained unit of FIG. 1 by the elimination of the plunger rod 39, the piston actuating means 40, and the finger grip, the functions of these elements being taken over by corresponding members associated with the hypodermic syringes of FIGS. 3 or 4. Also, FIG. 2 shows a different type of piston 41 including an externally threaded stem and designed to be engaged by a correspondingly threaded head on a plunger shaft, as more fully described below.

Referring now to FIGS. 3 and 4, these illustrate cartridge type hypodermic syringes corresponding, to a certain extent, to the devices covered by my United States Patent 2,753,867, distinguishing, however, therefrom, in such respects as will be fully outlined below. These syringes essentially comprise three associated and coacting elements; a barrel, a plug engaging the barrel end, and a plunger assembly mounted in said plug. The barrel 42 is substantially tubular and provided with one or more longitudinally extending inspection openings or slots 43. The plug 44 has an opening extending axially through it, and is comprised of a cylindrical top portion 44*a* having substantially the same diameter as the barrel, and an elongate, also essentially cylindrical bottom portion 44*b* having a materially smaller diameter and provided, in its center, with external threading 45, engaging with mating threading 46, in the interior end portion of the barrel 42 when the plug is positioned therein substantially as shown. It will be observed that the plug 44 is provided with a pair of integrally formed, oppositely radially extended lugs 47, together constituting the finger grip of the syringe, and serving also to facilitate rotating the plug relative to the syringe barrel, whereby the plug may be advanced toward or retracted from the bottom 48 of the barrel 42.

The syringe plunger assembly serving as the piston actuating means, comprises a shaft 49 slideably received in the axially extending opening formed in the plug 44, terminating at one end in a head 50, shaped to fit the syringe user's hand and to constitute the hand grip of the syringe, and, at the opposite end, terminating in a head 51 which is provided with internal threading to engage the externally threaded stem of the piston 41.

In FIG. 3, the bottom 48 comprises a circular, centrically disposed opening 52 of a diameter substantially smaller than that of the portion 24, at the bottom of the tubular body 22 of the cartridge shown in FIG. 1. If a cartridge according to FIG. 2 is inserted in the barrel 42 of the hypodermic syringe of FIG. 3, it will be understood that the ejectable seal disposal chamber and needle mount member 32, the needle 33, and the cover or sheath 35 engaging member 32 so as to protect said needle, will pass through the opening 52 in the barrel bottom 48, the remainder of the cartridge remaining disposed inside the barrel as the bottom 48 will abut against the collar portion 31 and restrain the cartridge from passing through the aperture 52.

In the operation of the embodiment of the invention illustrated in FIG. 3, the head 51 is caused to engage the piston 41 before the plug 44 has been screwed into the threaded end portion of the barrel 42. When the plug 44 is screwed into the barrel, it causes the piston 41 to descend, and the resulting downward displacement of piston 41 is sufficient to eject the ejectable seal member so as to open the passage toward the needle without, however, actually commencing the injection. Once it has been ascertained by slight retraction of the piston, that the needle is not in a vein, the liquid may be administered by downward displacement of the shaft 49.

It will be appreciated that in the embodiment of the invention according to FIGS. 3 and 4 the disposable cartridge inserted in the barrel is firmly secured therein, and this applies to cartridges according to FIG. 2, of varying length. It will be understood further that regardless of the particular type or size of cartridge employed, the disposable cartridge-needle units, when inserted in the devices of FIGS. 3 and 4, will operate on the same principle as the complete disposable syringe assembly of FIG. 1, by relying on the ejectable seal controlled closure 26 for maintaining a perfect seal for the cartridge content until the piston is caused to descend so as to eject the bead, ball or similar seal member 28 into the free space of the seal disposal chamber, and in so doing, open the passage 27 and allow the liquid to pass through this passage and into the needle, without incurring any of the drawbacks of contamination, or mechanical failure so frequently observed with prior art devices.

Referring now to FIGS. 5, 6, 7, 8, and 9, it will be understood that these figures illustrate various forms of ejectable seal controlled closures which can be used to advantage in disposable, single does cartridges or syringes according to the invention.

FIG. 5 shows an ejectable seal controlled closure of generally disk-like configuration which may be molded from rubber or some similar elastomer and which comprises a flat outer portion 55, a tubular guide portion 56, a central bore 57 and an enlargement 58 therein which serves as the seat for a bead-like seal member 59, retained in its seat until material pressure ejects it downwardly. At the bottom, the seal retaining chamber 58 preferably is surrounded by an annular downwardly extending projection 60 provided at spaced intervals with several slots, said projection offering no resistance to the seal member 59 when it is ejected from the chamber 58, but impeding any chance of a re-entry of the seal member 59 into the chamber 58 when the piston is retracted to test the proper location of the needle and the suction resulting from such retraction may cause the seal member 59 to be attracted into the proximity of the bottom

opening of the bore **57**. Preferably, the outer surface of the tubular portion **56** is provided, at spaced intervals, with axially extending ridges **61** which define air-vents extending therebetween.

FIG. 6 shows a similar closure wherein the seal member **62** instead of being seated in a portion conforming to its shape, is retained by an annular portion **63** partly closing the enlarged seal portion but having increased resiliency to facilitate ejection of the seal member under substantial pressure.

FIG. 7 illustrates a closure of generally disk-like configuration which comprises a tubular guide portion **64**, a central bore **65**, a tubular downward extension **66**, and provided in such extension, an enlargement **67** serving as the seat for a bead-like seal member **68**. An annular downward projection **69** may be provided on the portion **66**, for the purpose described with reference to FIG. 5.

FIG. 8 illustrates a modification of the closure of FIG. 7 comprising an annular portion **70** of increased resiliency similar to portion **63** of FIG. 6.

FIG. 9 shows a closure generally corresponding to that of FIG. 8, wherein however, the ball- or bead-like seal member is replaced by a disk type seal, including a disk portion **71** and a stem **72** which extends into the bore **73**. An annular portion **74** partly restricts the bottom opening of the enlarged portion **75** until, under the influence of substantial pressure, the seal member **71/72** is ejected from its seat in portion **75** so that the passage **73** is opened.

I wish it to be understood that I do not desire to be limited to the construction, design, and operation of devices according to the invention as shown and described, as modifications within the scope of the following claims and involving no departure from the spirit of the invention nor any sacrifice of the advantages thereof, may occur to workers in this field.

Having thus described the subject matter of this invention, what it is desired to secure by Letters Patent of the United States of America is:

1. A disposable, single dose cartridge for use in parenteral administration of medicaments and the like, and particularly adapted to facilitate aspiration prior to injection to assure that the needle is not in a vein, comprising in combination, a tubular ampule portion, a piston arranged for longitudinal displacement in said ampule portion, a temporary closure mounted in the bottom of said ampule portion, said temporary closure including a disk portion made of an elastomer, a center bore traversing said disk portion and an enlarged cavity disposed substantially at the end of said center bore, an ejectable seal member disposed in said cavity, a part in said elastic disk portion normally retaining said seal member in said cavity whereby to close said center bore, said part including means for releasing this seal member under the influence of pressure exerted on said piston so as to eject said seal member and open said center bore, and for restraining said seal member following its ejection from blocking access to said cavity under the influence of suction caused by retraction of said piston, and a combined needle mount and seal disposal member including a cup-shaped portion, mounted on the bottom of said tubular ampule portion so as to surround and extend underneath said temporary closure, a needle mounted on said needle mount member and opening into said cup-shaped portion, and means for preventing the ejected seal

member from blocking the opening of said needle in said cup-shaped portion.

2. A disposable, single dose cartridge according to claim 1, wherein the seal member releasing and restraining means comprises an annular downwardly projecting portion surrounding the bottom opening of the center bore underneath the seal member retaining cavity.

3. A disposable, single dose cartridge according to claim 1, wherein the means for preventing the ejected seal member from blocking the opening of the needle is a captive end portion of said needle arranged to project above the bottom of said cup-shaped portion.

4. A disposable, single dose cartridge according to claim 1, wherein the bottom of the tubular ampule portion has a center passage, and the elastic disk portion of the temporary closure has a stem extending into said center passage, the center bore in said disk portion extending through said stem.

5. A disposable, single dose cartridge according to claim 1, wherein the cavity enlarging the center bore in said disk portion is disposed within the confines of the disk portion itself.

6. A disposable, single dose cartridge according to claim 1, wherein the disk portion is provided in the center, with a downward extension, and the cavity enlarging the center bore in said disk portion, is disposed in said extension.

7. A disposable, single dose cartridge according to claim 1, wherein the ejectable seal member is a substantially spherical body.

8. A disposable single dose cartridge according to claim 1, wherein the ejectable seal member is a substantially disk shaped body.

9. In combination with a disposable, single dose cartridge according to claim 1, a hypodermic syringe device including a barrel, a bottom opening in said barrel, a piston actuating means, a guide for said piston actuating means mounted for longitudinal displacement in said barrel, and means for advancing said guide, following insertion of the cartridge into the barrel and engagement of said piston actuating means with said piston, into said barrel over a predetermined distance whereby to cause displacement of said piston sufficient to eject said seal member, but insufficient to effect any substantial passage of the liquid content of the ampule into and through the needle.

10. The hypodermic syringe device according to claim 9, wherein the means for advancing the guide in the barrel comprise a screw-threaded portion in the barrel, a matching screw-threaded portion on the guide, and wherein the top of the tubular cartridge inserted in the barrel serves as an abutment for the guide adapted to arrest the displacement thereof.

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