Jan. 28, 1969 S. J. SARNOFF 3,424,155

BURSTABLE DIAPHRAGM SEAL

Original Filed April 13, 1965

Fig. 1

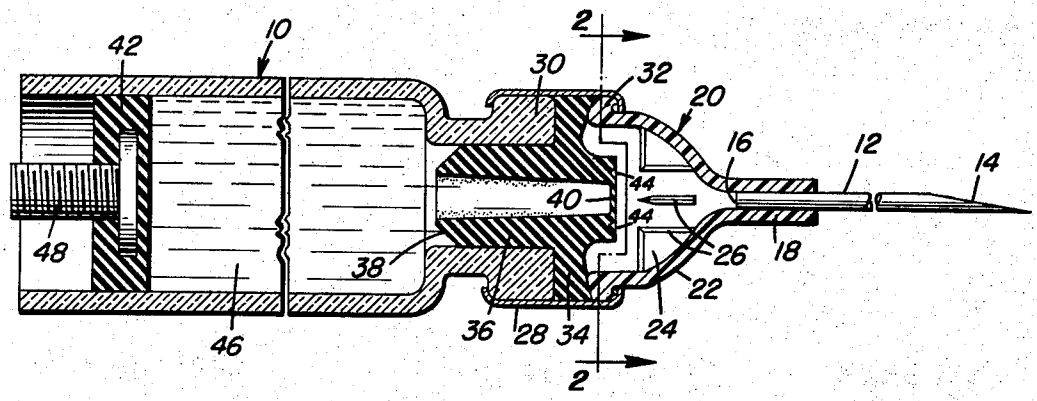


Fig. 2

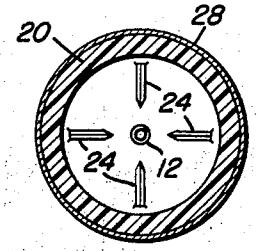


Fig. 3

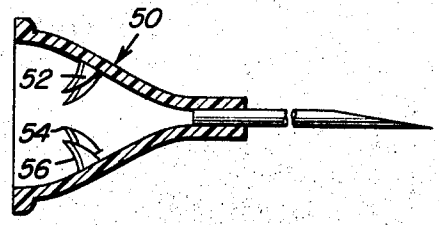


Fig. 4

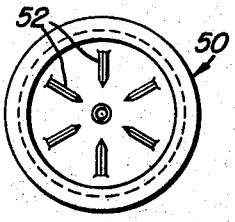
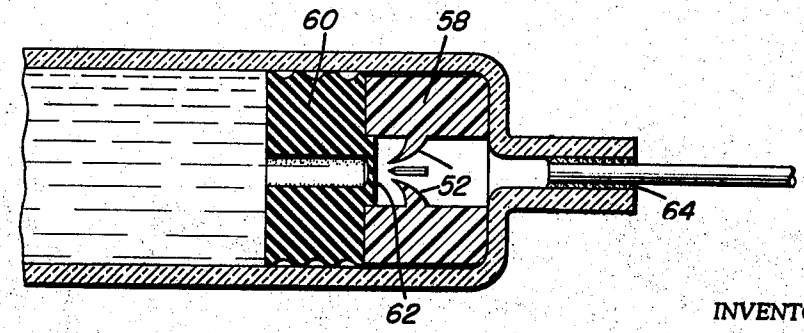


Fig. 5



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BURSTABLE DIAPHRAGM SEAL

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Continuation of application Ser. No. 447,741, Apr. 13, 1965. This application Jan. 24, 1968, Ser. No. 700,299
U.S. Cl. 128—218 9 Claims
Int. Cl. A61m 5/18; A61j 1/06, 1/08

ABSTRACT OF THE DISCLOSURE

A cartridge for a hypodermic syringe is provided at the forward end with a stopper having a diaphragm which when distended into a hollow conical transparent shield will engage projections on the interior of the shield and be burst thereby, if not previously burst.

This application is a continuation of Ser. No. 447,741, filed Apr. 13, 1965, now abandoned.

This invention relates to cartridges such as are utilized in syringes for administering fluid medication to a subject. In particular, the invention relates to a cartridge or syringe wherein the cartridge or syring may contain a medicament which it is desired to maintain normally sealed and away from a cannula carried by the cartridge or the syringe in order to prevent deleterious interaction between the medicament and the cannula or the passage to the cannula.

Where a medicament is contained in the cartridge, it has been known in the prior art, as in Pittinger 1,288,174, Kabnick 1,943,120 or Cohen, et al. 2,847,996, to effect the seal referred to above by means of a membrane which, when it is desired to use the contents of the cartridge, is either pierced by movement of the hypodermic needle relative to the cartridge or by forcing and stretching the membrane into contact with the needle so that the needle may puncture the membrane. It is also known, in the prior art, where a medicament is contained in the cartridge, as in Goold 1,455,047, to effect communication between a fluid container and the needle by bursting a flexible diaphragm, the bursting being effected by reason of fluid pressure applied to the diaphragm to cause it to distend and finally burst because of wall weakness. However, the needle means for puncturing the membrane may cause some of the material of the membrane to enter into the bore of the needle and clog same or be injected into the subject and bursting of the flexible diaphragm merely by ballooning action requires considerable force and accuracy in thinness, formation and quality of the diaphragm and conceivably in the structures adopted by the prior art, where the needle is not utilized to burst the diaphragm, there may be a failure in rupturing action of the diaphragm. In the copending application of Stanley J. Sarnoff, Ser. No. 408,423, filed Nov. 2, 1964, there is disclosed an arrangement wherein the bursting of the membrane or diaphragm is assured by reason of adequate ballooning of the membrane into a confined area between the front stopper of a cartridge and the rear end of the needle or by reason of engagement with a pointed rear end of the needle should, through some malfunction, the diaphragm not burst upon mere expansion into the confined area.

It is an object of this invention to provide means within the cartridge structure whereby the ballooning diaphragm will engage sharp projections or cutting edges other than at the rear end of the needle to effect rupturing of the diaphragm and with little or no chance of any portion of the diaphragm entering the canal of the needle.

More specifically it is an object of this invention to form these projections on the interior of a shield or within the interior wall of a torus inserted within the cartridge.

It is yet another object of this invention to provide means whereby aspiration of fluids into the cartridge may be affected notwithstanding any possibility of occulsion of the opening into the cartridge by reason of valve action of the ruptured diaphragm or membrane.

Still other objects will become apparent after reading the following specification when read in conjunction with the accompanying drawings in which:

FIG. 1 is a longitudinal fragmental section view of a cartridge and needle illustrating an embodiment of the invention;

FIG. 2 is a sectional view on the line 2—2 of FIG. 1 looking in the direction of the arrows;

FIG. 3 is a sectional view of a modified form of shield, showing the needle in fragmental form;

FIG. 4 is a plan view of the shield and needle shown in FIG. 3 looking to the right of the figure, and

FIG. 5 is a view of a modified form of the invention disclosing the use of a fanged insert within the cartridge to effect the bursting of the diaphragm.

Now referring to the drawings in greater detail, there is illustrated in FIG. 1 a cartridge comprising a vial **10** and its associated portions, and a hollow needle **12** and its associated portions. The needle is pointed at its forward end, as indicated at **14**, for body penetration and need not be pointed at the rear end **16**. As illustrated, the needle end **16** is blunt and lies within the neck portion **18** of a needle holder or shield **20** and is fastened thereto in any conventional fashion. The major portion of the holder is bell shaped as indicated at **22** or is otherwise formed with a large chamber within which are located diaphragm rupturing devices **24**. In the form of the invention shown in FIGS. 1 and 2 these devices are projections integral with the hollow bell, made of plastic, rubber or like material. Preferably the holder is made of a transparent plastic material such as nylon so that it may be observed what action occurs within the bell of the holder. The projections **24** illustrated in FIGS. 1 and 2 are formed with bevelled edges forming ridges or knife edges **26**, adapted to cut into an expanding diaphragm, as will be explained.

The needle holder **20** is clamped to the vial in any convenient fashion, as by spinning an aluminum collar **28** over the shoulder of a terminal portion **30** of the vial and over an annular flange **32** integral with the holder. The needle holder is held clamped to the vial with the flange **34** of a stopper **36** between the open mouth of the bell shaped holder and the terminal portion of the vial.

The flange of the stopper is integral with a channeled cylinder **38** fitting tightly in the neck and terminal forward end portion of the vial. The forward end of the channel is sealed off by an expandible diaphragm **40**, sufficiently thin so that when a fluid within the vial is operated on by a piston, a piston **42**, the fluid is forced through the channel in the cylinder **38** against the diaphragm. The diaphragm will therefore balloon out into engagement with the projections within the needle holder. As a result, the projections, particularly because they are provided with the knife edges **26** will penetrate or cut into the diaphragm and cause it to burst. Preferably the diaphragm is made of a resilient material such as rubber so that upon bursting of the balloon the fragments will contract and retract toward the periphery of the stopper, thereby permitting free passage of fluid through the channel and into the needle holder and thence into the body of a patient thru the canal of the needle. To facilitate the formation of the balloon and to confine it to a salient area centrally of the channel in the stopper, the forward face of the stopper is weakened as by providing it with a V-shaped circular groove **44**, the diameter of the groove being inter-

mediate the diameter of the channel within the cylinder and of the cylinder itself.

In use of the cartridge, the vial is filled with a medicament, as a liquid medicament 46, and placed within a cartridge holder, not shown, provided with a plunger rod for coupling with the piston 42, as thru the intermediary of the screw 48 embedded within the piston. The plunger rod is then operated to force the piston 42 toward the forward end of the cartridge. The liquid within the cartridge is forced thru the channel in the stopper 38 and will cause the diaphragm 40 to balloon out into the bell shaped portion 22 of the needle holder 20 until either the diaphragm ruptures because of internal stresses within the diaphragm or until the diaphragm ruptures by reason of engagement of the thinned diaphragm balloon wall with the projections 24. The sharp edges 26 of the projections ensure the rupturing of the balloon. Thus free passage is now afforded for the medicament from the vial and out of the needle. Aspirating can be effected by performing a withdrawing action on the plunger rod immediately after diaphragm rupture and which rupture can be observed thru the transparent holder 20. It should be noted that by reason of the cutting members 24, the back end of the needle need not be sharpened, thus saving expense in the cost of manufacture of the needle, and the positioning of the rear end of the needle is not critical.

In the form of invention disclosed in FIGS. 3 and 4, the holder, here indicated as 50, may be of slightly different configuration. However the interior wall of the holder is provided with inwardly and rearwardly directed fangs or spikes 52 directed toward the stopper with sharp points 54 and preferably with knife edges 56.

In the form of invention disclosed in FIG. 5, the bell shaped structure with its balloon rupturing equipment is replaced by transparent plastic torus 58 positioned in the forward end of the vial. The interior channel wall of the torus is equipped with diaphragm bursting elements as for example the fangs or spikes 52 previously described in detail. In the modification shown in FIG. 5, it is not necessary to provide the balloon delineating V-grooves, as grooves 44 in FIG. 1, since a translatable channeled stopper 60 is provided with a reduced-in-diameter portion 62 defining the diaphragm fitting without restraint against translation within the channel of the torus. The torus can be loose within the vial or be frictionally held there within or be adhered thereto by the use of suitable adhesives. The needle may be bonded to the vial as by the use of epoxy resin, indicated at 64.

The advantages of the form of invention disclosed in FIG. 5 over the other forms is that should, through some unexpected reason, the shreds of the balloon, after bursting and retraction of parts, form a self-closing valve on aspirating movement of the plunger rod, the stopper 60 with its now quasi-healed diaphragm will be drawn to the rear end of the cartridge creating an evacuated space in front of the stopper conducive to aspirating body fluids into the forward end of the vial.

In all the modifications disclosed herein, it is obvious that bursting of the diaphragm occurs without any engagement of the balloon with the rear end of the needle, and therefore without the possibility of balloon fragments entering or clogging the canal in the needle by reason of balloon wall engagement therewith. Furthermore with all modifications, the vial need not contain medicament but merely a gaseous fluid to be expelled prior to use of the syringe, for subsequent aspirating use of the diaphragm.

In all forms of the invention, the assembly of parts of the cartridge may be effected under sterile conditions.

What is claimed is:

1. In a cartridge with attached needle the combination of a vial, a stopper at the forward end of the vial, a piston at the rear end of said vial, a fluid confined within the vial between the stopper and piston, said stopper having a thin elastic imperforate membrane adapted to be ballooned on application of pressure to the fluid, an internally conical hollow shield beyond the stopper, a hollow needle attached to the shield and the shield being fixed to the vial and having its hollow portion beyond the stopper to provide a hollow space between the stopper and the needle and at least one projection located on the interior conical wall on the hollow shield between the stopper and the needle, said projection being normally out of contact with the membrane and extending in a direction to be engaged by the membrane whereby as said membrane balloons, it contacts said projection and is burst thereby.

2. The structure of claim 1 wherein the stopper is provided with a flange clamped in between the forward end of the vial and the shield.

3. The structure of claim 1 wherein the stopper is weakened to define the area of ballooning of said membrane.

4. The structure of claim 1 wherein the projection is provided with knife edges.

5. The structure of claim 1 wherein the rear end of the needle is blunt.

6. The structure of claim 1 wherein the shield has a reduced-in-diameter portion and the rear end of the needle terminates in said portion.

7. A cartridge and attached needle comprising a vial, a stopper at the forward end of the vial, a piston at the rear end of the vial, a medication confined within the vial between the stopper and the piston, a hollow, conical shield, a hollow needle supported by said shield and communicating with the interior of the shield, means clamping the vial, stopper and shield together with said stopper positioned intermediate said vial and shield and with the hollow cone of the shield positioned beyond the stopper, said stopper having a thin elastic imperforate membrane adapted to rupture on distension thereof due to application of pressure to the medication within the vial and the forcing of the medication within the vial against the membrane, and at least one projection on the inner wall of the shield of a length insufficient to engage the membrane in its normal undistended condition, said projection lying in the path of extension of the membrane to be engaged by the membrane to burst the same.

8. A device as set forth in claim 1 in which the shield is transparent.

9. A device as set forth in claim 7 in which the shield is transparent.

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