

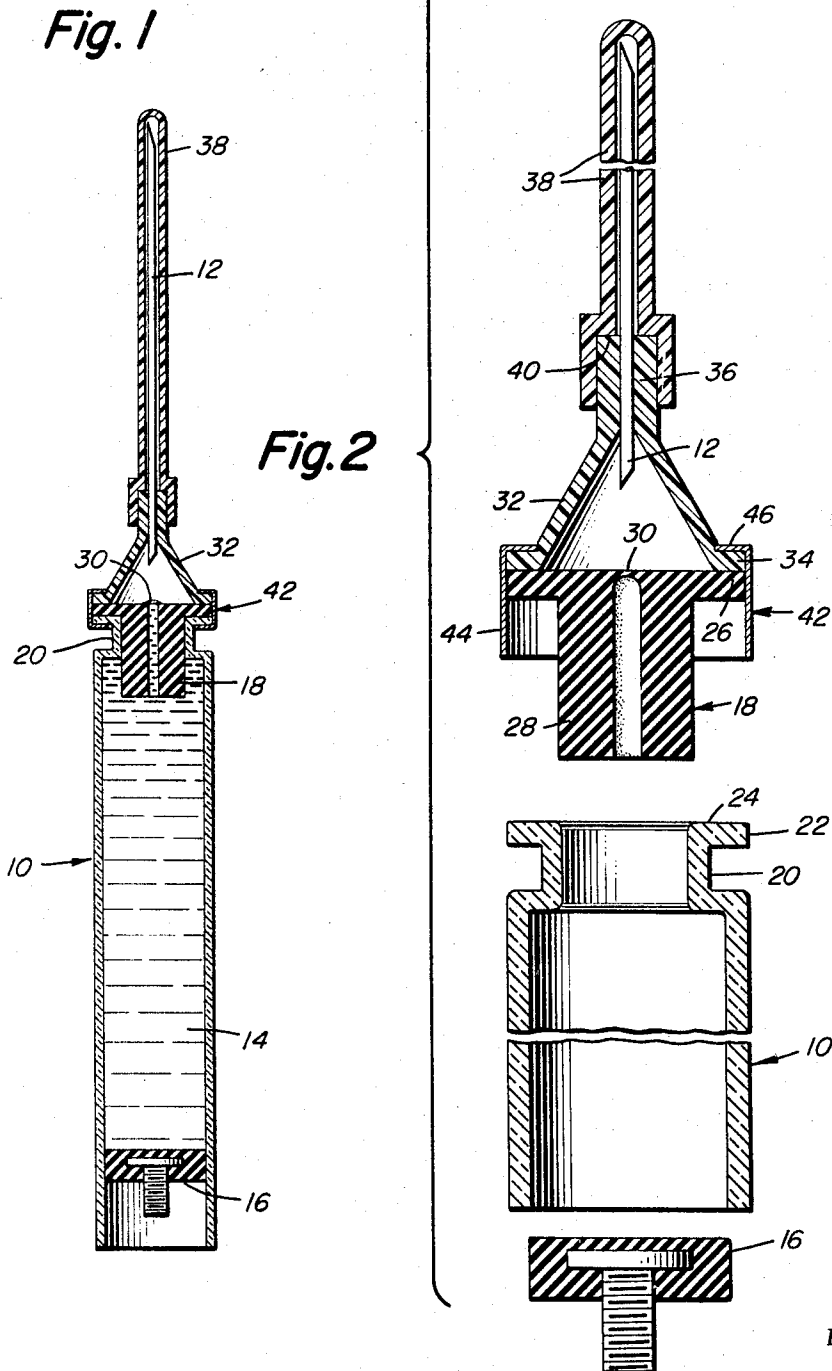
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CARTRIDGE WITH BURSTABLE SEAL

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CARTRIDGE WITH BURSTABLE SEAL

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9 Claims. (Cl. 128—218)

ABSTRACT OF THE DISCLOSURE

A hypodermic cartridge consisting of a vial with fluid therein has a plunger at one end of the vial and a stopper at the other end, said stopper in part having a distendable diaphragm. Held to the vial at the stopper end is a conical transparent shield supporting a hollow needle, the inner end of which extends into the shield. Upon plunger operation the fluid will distend the diaphragm which will burst allowing fluid to flow to and through the needle. Also, a needle guard closely surrounds the needle.

This application is a continuation-in-part of the application of Stanley J. Sarnoff, Ser. No. 383,305, filed July 17, 1964, 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 cartridges for use with hypodermic syringes wherein the cartridge may or may not contain a medicament which it is desired to maintain normally sealed and away from a cannula, carried by the cartridge or by the syringe in order to prevent deleterious interaction between the medicament or whatever may be in the cartridge and the cannula.

In this case 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 this seal by means of a thin 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. However, the means for puncturing the membrane may cause some of the material of the membrane to enter into the bore of the needle and clog the same; and bursting of the flexible diaphragm requires considerable force and accuracy in thinness and quality of the diaphragm. Furthermore, the distention of the diaphragm may not, at times, cause rupture thereof.

It is an object of this invention to provide a medicament or blood aspirating device involving a cartridge including a vial, a balloonable stretchable thin membrane and a hollow needle, wherein communication may be established between the interior of the vial and the needle without danger of failure of rupture of the membrane and without danger of the material of the membrane clogging the bore of the needle.

It is a further object in such a device to provide transparent means adjacent to the inlet to the lumen of the needle and extending above and below the inlet to the needle whereby the action of the membrane may be observed as it bursts. In addition, the fluid flow toward the needle, so as to assure the administrator of the medicament that medicament communication with the lumen of the needle has, indeed, been established, can be readily

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observed. These transparent means also permit examination of the fluid withdrawn from a subject, should aspiration be effected, after needle penetration of the subject either preliminary to medication injections into a patient or preliminary to further withdrawal of fluid from the patient, this elimination being effected prior to bursting of the membrane. Still further, the transparent means enables inspection of the membrane subsequent to manufacture and prior to shipping, as after long storage, to insure that the membrane is intact. Also, since the membrane separates the fluid in the vial from metallic parts of the syringe, the cartridge may be filled under non-sterile conditions and then subsequently sterilized.

It is a further object of this invention to provide a cartridge and syringe combination of the type employing a burstable diaphragm wherein the vial of the cartridge is initially devoid of any liquid, except possibly a few drops of a blood anticoagulant, so that initially the syringe may be operated to expel the air or vapor therein while simultaneously bursting the membrane, and subsequently, after needle insertion in a patient, blood or other body fluid may be aspirated into the cartridge for subsequent analysis.

These and other objects will become apparent after a consideration of the following specification when taken in conjunction with the accompanying drawings in which:

FIGURE 1 is a longitudinal sectional view of a cartridge and needle illustrating an embodiment of the invention, and

FIGURE 2 is a sectional fragmentary view of the same elements on an enlarged scale, prior to assembly of the needle and its holder with the vial portion of the cartridge.

Now referring to the drawings in greater detail, there is illustrated a cartridge comprising a vial 10 and its associated portions, and a needle 12 and its associated portions. The needle is pointed at both ends. The vial may have within it a fluid or fluidized medicament 14, the medicament being sealed with the vial by a piston 16 at one end and a stopper 18 at the other end, or it may be empty or provided with a few drops of a blood anticoagulant such as heparin or dicumarol. The piston may be of any conventional type for engagement by a coupling with a plunger, for example, the plunger illustrated in the patent to Sarnoff 2,956,563 or that illustrated in the application of Sarnoff et al. Ser. No. 405,660 filed Oct. 22, 1964 now Patent No. 3,348,545, for Latched Cartridge.

The vial is of transparent rigid material, preferably glass, and is generally cylindrical in form. At the stopper end of the vial, the vial is provided with a neck 20 and a flange 22, the upper surface 24 of which is planar. The stopper 18 is seated on the planar surface and fits snugly into the neck of the vial. The stopper is preferably of a resilient, compressible material such as rubber and includes a flange portion 26 seated on the planar surface 24 of the vial and a tubular plug section 28 snugly engaging the interior wall of the neck of the vial. The tubular portion of the stopper is sealed off by a very thin wall or membrane 30 of the order of .01 inch thick, said wall being integral with the stopper and capable of stretching and thinning out under the influence of pressure applied to the under surface, very much like the walls of an inflatable thin walled rubber balloon.

On the upper surface of the stopper is a preferably conical shield 32 of transparent material as transparent plastic material, the lower end of which is flanged outwardly as indicated at 34, the flanged end being adapted to be firmly clamped to the upper surface of the stopper as will be described.

The upper end of the shield terminates in a cylindrical member 36 by friction or otherwise fixedly holding the hollow needle 12 intermediate of the ends of the needle. The exterior upper portion of the needle is of such a length as may be found desirable for the particular use of the cartridge. However, the end of the needle within the shield extends down into the space within the shield a slight distance, but no more than one-half way to the top of the stopper, for reasons to be explained.

About the needle, to protect the same against physical injury and for maintaining sterility of the needle until actual use, and, where medication is employed, to prevent inadvertent loss of that medicament, is a guard 38, the guard snugly telescoping at its lower end the cylindrical upper end of the shield to prevent entrance of air to within the guard. While guards of the general character herein described are known in the prior art, such as the guard of the patent to Miskel et al. 2,865,372, the association thereof with a burstable membrane and the ratio of bore to needle occupancy to be described was not known prior to this invention. The interior bore of the guard in this invention is small for reasons to be pointed out, the needle in one embodiment filling no less than half the space existing within the guard and in a preferred embodiment filling substantially the entire space within the guard. The guard has a circular shoulder 40 seated against the top surface of the cylindrical portion 36.

A metal double flanged clamping ring 42, as of aluminum, firmly assembles the shield and associated needle, the stopper 18, and the vial into a unitary structure, the clamping action being such that air tight joints are formed between the shield and the stopper, the stopper and the flanged end of the vial and between the aluminum ring and the peripheries of the flanges of the vial and shield.

Preferably, for ease in manufacture of the cartridge and needle, the aluminum ring 42, see FIGURE 2, is initially formed of a ring having a skirt 44 and an inturned flange 46. The flange 46 is pressed into the body of the flange 34 of the shield, frictionally holding the shield and ring together: the ring, additionally, frictionally engages the flange 26 of the stopper forming a unitary sub-assembly of shield with its associated parts and stopper which can be handled without falling apart. When the vial and the just-described sub-assembly are brought together, the lower end of the skirt of the aluminum ring may be spun around the flange 22 of the vial, thus securing the parts together.

After the vial has been filled with medicament, when a medicament is employed, and the piston 16 inserted, the parts are as is shown in FIGURE 1. A slight bulge of the membrane 30 is shown in FIGURE 1 due to the air pressure existing within the vial. The piston is part way in the vial to permit of it being partially withdrawn to effect aspiration.

In the use of the cartridge of this invention, just before insertion of the outer end of the needle into a subject, it is desirable to establish communication between the medicament in the vial and the lumen of the needle. To accomplish this result, the cartridge piston is moved a slight distance into the vial by any appropriate means, as by operating the plunger to which reference has already been made. Thereupon, due to the liquid or gaseous fluid pressure created in the vial, the thin rubber wall 30 or membrane bulges into the space afforded by the interior of the shield, the thin wall distending and becoming thinner and thinner until it ruptures. The conical shape of the shield permits ballooning of the membrane and yet the volume of fluid medicament, when medication is used, which will subsequently fill the space within the shield is kept small.

The parts are so designed that unless some abnormality of manufacture or manipulation of the cartridge exists, the membrane will burst before it contacts the needle. Thereupon, due to its resilience, the membrane shrinks

away from the inner end of the needle allowing free communication between the vial, the shield chamber and the needle. No clogging of the needle with cut-off rubber particles is possible. Since at this time the guard 38 is still in place, air from within the shield is forced up through the lumen of the needle and into the space between the needle and guard. Due to the small available air space within the guard, there is no or very little loss of medicament fluid, when used, by reason of flow thereof into that space. Any excess pressure on the piston merely results in compression of the air in the shield and in the guard. Preparatory to the removal of the guard, pressure on the plunger is released and the back pressure of the air will move the piston back slightly, thus preventing loss of medicament on removal of the guard. After the guard is removed, the outer end of the needle may be inserted into a subject and the plunger then operated to inject any medication in the vial into the subject.

When the cartridge is intended to withdraw fluid samples from a patient, it is initially prepared with the stopper at one end of the vial and the piston close to the other end thereof. However, the vial itself, initially made sterile, is filled with sterile air or with sterile gas and possibly with a small quantity, as a few drops of a blood anticoagulant, for example, heparin sodium oxalate or dicumarol, the amount depending on the anticoagulant used and the volume of the vial. Preliminary to insertion of the needle in the patient, the membrane is burst as heretofore described by pressure applied to the plunger and piston and the piston is moved as far as desired toward the stopper. The gaseous fluid in the vial will be expelled as heretofore described. Any liquid coagulant in the vial will merely wet the walls of the vial and possibly of the shield, the quantity of liquid being much too small to be able to reach the needle or to be expelled there-through. After removal of the guard 38 and insertion of the needle into the patient, the sample of blood or other fluid from the patient may be aspirated into the cartridge, the needle again capped with the guard and the cartridge, properly identified with the patient, shipped or transported to a convenient place for analyses of the vial contents.

Should, by reason of some malfunction, the membrane fail to burst as described above, it will balloon into contact with the pointed inner end of the needle, and be pierced. At this time the wall of the membrane is exceedingly thin and there is no danger of any material of the membrane clogging the lumen of the needle. Due to the distention and bulging of the resilient membrane prior to being pierced, it will quickly shrivel and draw away from the needle, without any part of it entering the needle, again affording unrestricted passage of the medicament into the shield chamber and the lumen of the needle. The needle should project within the shield, but no more than half way down into the cone to permit normal ballooning bursting of the membrane 30 and without needle end contact. The projecting of the needle into the chamber is a safety feature to positively insure membrane rupture.

It should be noted that the manipulator of the cartridge is appraised of rupture of the membrane prior to removal of the guard and penetration of the needle into a patient by reason of the transparency of the shield, through which the condition of the membrane and presence of the medicament from the vial or body fluid from the patient within the shield may be ascertained.

Having thus described the invention, what is claimed is:

1. A cartridge and attached needle comprising:

a vial,

a piston at one end of the vial,

a stopper at the other end of the vial,

a fluid within the vial between the piston and the stopper,

a transparent shield beyond the stopper, the interior of the shield being devoid of fluid,

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a hollow needle supported by said shield and communicating with the interior of the shield, means clamping the vial, stopper and shield together, said transparent shield being hollow beyond the area of the clamping means, and

said stopper having a thin imperforate elastic membrane adapted to rupture on distension thereof due to the piston forcing the fluid against the membrane, said hollow needle having its inner end projecting into the space within the shield for a short distance, the thin membrane being assured of rupture by engagement with the needle should the distended member not be ruptured prior to reaching the needle.

2. The structure of claim 1 combined with a guard embracing the exterior end of the needle and forming an air tight chamber about the needle.

3. The structure of claim 2 wherein the needle occupies approximately one-half the bore space within the guard.

4. A cartridge and attached needle as set forth in claim 1, the means clamping the vial, stopper and shield together in air tight relationship comprising a ring having one flange pressed into the material of the shield and a second flange engaging the flange of the vial.

5. The structure of claim 4 with a guard embracing the exterior end of the needle and forming an air tight chamber above the needle and wherein the needle occu-

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pies no less than one-half of the bore space within the guard.

6. The structure of claim 4 wherein the shield is conical.

5 7. A cartridge and attached needle as set forth in claim 1, wherein the fluid is a gaseous fluid.

8. A cartridge and attached needle as set forth in claim 1, wherein the vial between the piston and the stopper contains a blood anticoagulant and wherein the fluid is gaseous.

10 9. A cartridge and attached needle as set forth in claim 1, wherein the vial between the piston and the stopper contains drops of a blood coagulant and wherein the fluid is gaseous.

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