Aug. 19, 1958 M. J. COHEN ET AL 2,847,996

HYPODERMIC SYRINGE

Filed Aug. 13, 1953 2 Sheets-Sheet 1

Fig. 1.

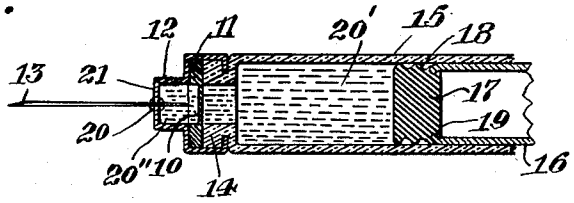

Fig. 2.

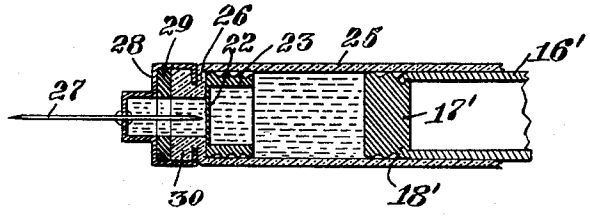

Fig. 3.

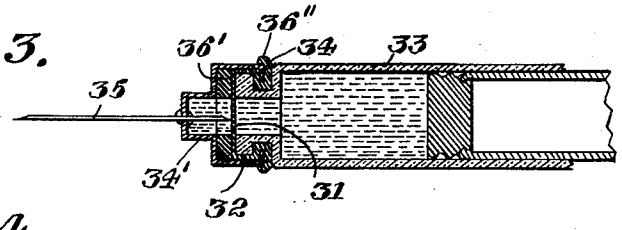

Fig. 4.

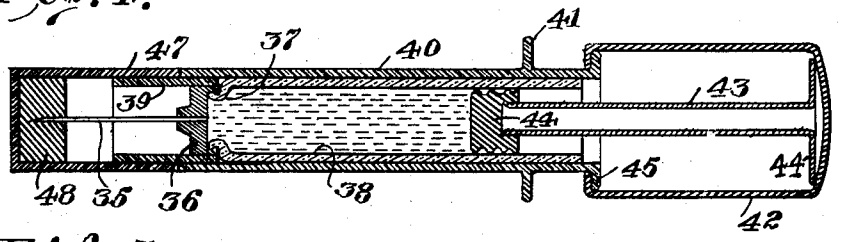

Fig. 5.

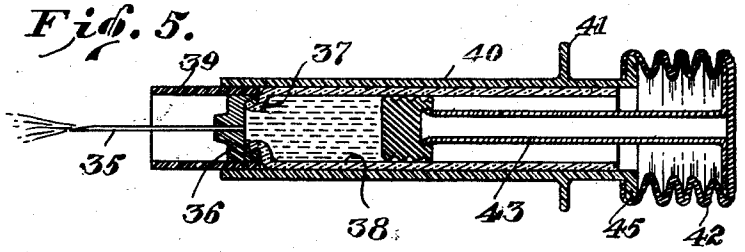

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Fig. 6.

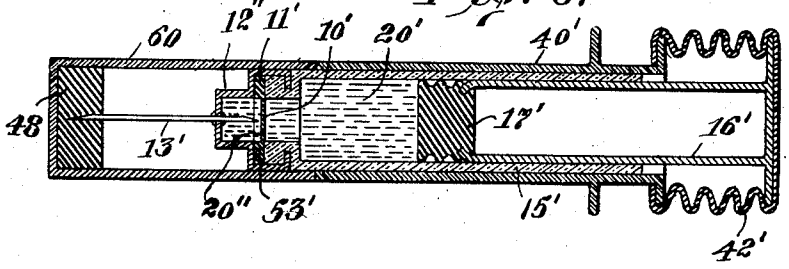


Fig. 7.

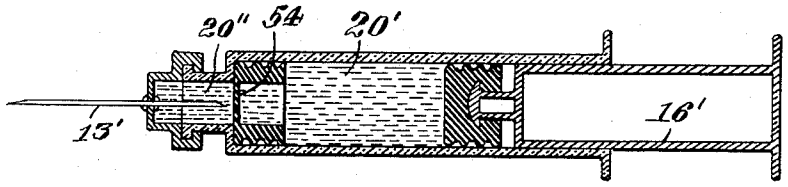


Fig. 8.

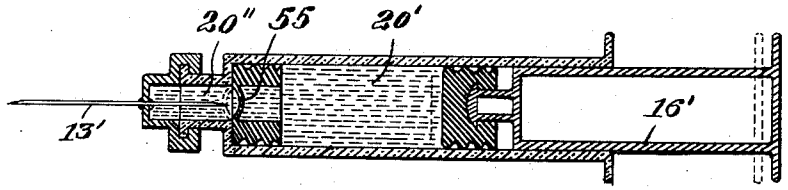


Fig. 9.

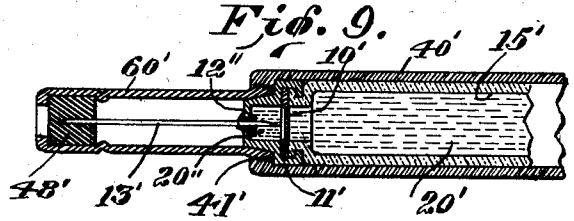
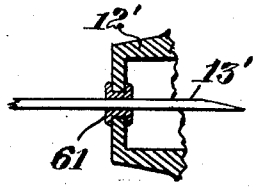


Fig. 10.



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2,847,996

HYPODERMIC SYRINGE

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Application August 13, 1953, Serial No. 374,012

13 Claims. (Cl. 128—218)

Our invention relates primarily to hypodermic syringes, though the means herein disclosed may be useful in other relations. In such syringes it is often desired to preserve different substances that are to be mingled at a future time, or which are to be used in immediate succession, while maintaining those substances unaltered by oxidation or by admixture of such agents as moisture, air, gas and the like. Such substances will ordinarily be liquids or fluent solids such as powdered material or ointment, but the invention is not restricted to separate preservation of any particular substances, nor to preservation of multiple substances in a syringe, as it may be used for protection in unaltered condition of a single substance in a syringe or other container.

The basic objective of this invention is the separation, within a hypodermic syringe, of two substances which it is desirable to keep from contact with each other until the syringe is ready to be used. The invention accomplishes this separation by interposing between two spaces containing the incompatible substances a thin elastic membrane of rubber or other substance having similar characteristics of elasticity.

Another object is to provide improved means to insure sterility of all parts of a syringe up to the actual injection of a medicament by the same.

Still another object is to provide an improved means of aspirating when an opaque liquid is the fluid to be injected.

Other objects and advantages of the invention will appear from the following description and the annexed drawings, which are made a part of this application and in which similar characters of reference indicate similar parts.

Referring now to the drawings,

Fig. 1 is a longitudinal section of one form of the invention, with parts omitted.

Fig. 2, a similar view of another form of the invention,

Fig. 3, a similar view of another form,

Fig. 4, a longitudinal section of a syringe of still different form,

Fig. 5, a view similar to Fig. 4, with the parts in a different position,

Fig. 6, a view similar to Fig. 1 but including added means for insuring that the syringe shall be sterile up to the time of injection thereby,

Figs. 7 and 8, longitudinal sections of a syringe providing improved means for aspirating in connection with the use of opaque medicaments, and

Fig. 9, a modification with parts omitted, and

Fig. 10, an enlarged view of the needle mounting.

In the drawings, Fig. 1 illustrates a method of separating materials in a syringe by the use of a separator comprising a membrane **10** molded integrally with or otherwise fastened to a thicker ring washer **11** surrounding the membrane. This may be applied in the syringe by placing the washer **11** between two rigid surfaces which are connected with each other under sufficient pressure to compress the ring of the membrane washer and hold it in position. In Fig. 1 the separator is so held in position between the connector cap **12**, to which a double-pointed needle **13** is attached, and the neck **14** of the syringe barrel **15**, one end of the needle projecting into the space in the cap **12**, so as to position its inner point in close proximity to the membrane **10**.

In Fig. 1 a plunger of any conventional or suitable character may be used for acting on the contents of the syringe, but I have here shown a hollow plunger **16**, said plunger having a head **17** of rubber or like material with circumferential corrugations **18** and interposed circumferential grooves, and the head being attached to the tubular plunger by means of an inturned flange **19** on the tube engaged with a groove near the end of the head. In this form of the invention the barrel **15** is preferably made of glass, and the cap **12** is made of aluminum crimped or rolled or other suitable metal to provide an inwardly extending annular flange fitting in a groove in the neck of the barrel **15**. The needle is permanently fixed to the cap by swaging or soldering or by a rivet or other suitable means, as indicated at **20**.

In a preferred method of fixing the needle **13'** to connector cap **12'** the hollow needle is inserted through a hollow rivet **61** (Fig. 10) which in turn is inserted into a hole in the connector cap. Then the rivet is bradded or upset at each end to force it to grip the needle and flow outward over the edges of the hole in the connector cap, thus also gripping the cap as well. This makes a tight joint at both faces of the cap, and insures a solid grip on the needle.

The contents of the barrel may be liquid, as indicated at **20'**, and the cap may contain a different liquid **20''** that reacts with that at **20'** when mixed therewith, but it will be obvious that other materials may be substituted according to need or inclination.

In the use of the syringe of Fig. 1, pressure on the plunger will act on the membrane **10** to flex the same and slight bulging will cause the membrane to contact with the end of the needle which will puncture the membrane and permit the contents of the two compartments to commingle and thereafter to be injected in the usual manner.

In another embodiment of the invention as disclosed in Fig. 2, a membrane **22** is molded integrally with or otherwise fastened across the head of a floating cylindrical piston **23**. In this form the membrane **22** is held in a syringe assembly by inserting the piston into any tubular portion of the syringe, as the barrel **25**, so that the end holding the membrane **22** abuts against a shoulder **26** which holds it in position. The piston **23** is in the barrel **25** of the syringe with the membrane **22** held adjacent to the neck of the syringe, into which projects the needle, which is attached to the neck of the barrel by a cap **28** as in Figure 1 with the inner point of the needle in close proximity to the membrane. A rubber washer **29** is clamped between a shoulder on the cap and the end of the neck **30** of the barrel, the device of Fig. 2 being otherwise as in Fig. 1.

In the use of the device of Fig. 2, the respective compartments in the barrel and the cap may contain different materials which are of such nature that it is desirable to preserve them and yet keep them separate, perhaps for extended periods of time. Since they have contact with such materials as rubber and glass only, this can be done without anything more than placing them in the respective compartments. But, as in the case of the device of Fig. 1, when an injection is required it can be made without any delay except merely to pick up the syringe and insert the needle and press against the plunger **16'**. Then the pressure of the contents of the chamber in the barrel will tend to balloon the membrane **22** out-

ward against the adjacent end of the needle, puncturing the membrane immediately and permitting the mingled contents of the syringe to be injected without anything more. In other words, this device makes possible instantaneous medication by means of uncontaminated materials contained in a disposable syringe that can be discarded at once after use.

In another form of the invention, as shown in Fig. 3, a pre-tensed membrane of rubber or other elastic sheeting is stretched over an opening and fastened tightly in position in its stretched or tensed state.

In this figure a membrane **31** is held in position between the lip **32** of a syringe barrel **33** and the annular inturned flange **34** of a connector cap **34'** to which a double pointed needle **35** is attached. A sheet of elastic material is stretched over the lip **32** of the barrel **33**, and a sealing washer **36'** is placed thereon. A metal connector cap is forced down on the barrel so as to hold the washer **36'** in place, and the free margin of the cap is rolled or crimped into a groove in the neck of the barrel, thereby gripping the lower edge or skirt of the tensed membrane **31** which is held stretched over the lip of the barrel and forcing the margin of the skirt into said groove. After the cap is rolled or crimped on, the skirt of the elastic membrane is cut off a short distance from the lower edge of the metal connector, whereupon that portion of the stretched membrane outside the crimp, being released from tension, will shrink to its normal state, and in doing so will thicken and curl back outside the crimp as at **36''**, which will have a tendency to assist in holding the membrane under tension and in position across the open neck of the barrel.

The inner point of the double pointed needle **35** projects into the space in the connector cap in close proximity to the stretched membrane. If the plunger is operated to force the column of liquid in the barrel against the end of the needle, the elastic sheet will be ruptured and, due to its pre-tensed or stretched condition the membrane will shrink away from the needle, thus making a relatively large hole for passage of fluid and speedy mixture of the contents of both chambers, as well as for passage of liquid to the lumen of the needle.

It is a common element of these three types of membrane seals as illustrated in Figures 1, 2 and 3 that each is held in a position where the pressure from a column of air or liquid, actuated by the plunger when the syringe is used, will stretch and balloon the membrane into an adjacent space into which a needle projects, so that when the membrane, under tension induced by the pressure of the column of liquid or air, strikes the needle, it will be punctured. The elasticity of the membrane will cause the initial perforation made by the needle to be pulled back to a size in the relaxed membrane larger than the size of the initial puncture in the tensed membrane, thereby permitting the substance in each of the previously separated spaces to enter the other space.

The pre-tensed, stretched elastic sheet illustrated in Fig. 3 differs from the membranes of Figs. 1 and 2 in that, because it is stretched when applied, and is held in a stretched state even before it is further stretched by the pressure of the column of liquid or air actuated by the plunger, the hole made by the needle in the membrane will be pulled open to a relatively larger aperture than is the case of the membrane applied without tension. Accordingly, it will permit a freer flow of liquid or other substance between the previously separated spaces with speedier mixing and accelerated reaction between ingredients that are capable of reacting. Moreover, because it is already stretched, assuming membranes of the same initial thickness and composition, the pre-stretched membrane will be more easily ruptured when the syringe is ready for use. In either case, the membrane would be sufficiently thin that the rubber would not re-seal once a puncture is made.

An additional advantage of the tensed sheet membrane is that it may be applied to a succession of syringe assemblies by being fed in a continuous sheet or strip, thereby facilitating multiple assembly by machine methods.

It is an object of this application to describe and claim the basic idea and method of separating incompatible substances in a syringe by dividing the space within the syringe so as to keep apart substances which need to be kept separate until it is desirable that they be mingled. For example, a medicament in solution may, in this manner, be kept sealed from contact with air in the sealing cap and in the lumen of the needle as well as with the metal of the cap and of the needle. Such separation is deemed desirable in order to prevent whatever degree of oxidation or contamination of the medicament might occur as a result of such contact. Or a liquid solvent may be separated, in the manner described, from a medicament in solid or powder form held in the syringe on the opposite side of the sealing membrane until it is desired to mingle the solvent with the solid medicament to make a solution for injection.

It is not intended to limit the claims to the particular application of a membranous seal at or adjacent to the neck of the syringe as shown in the illustrations but to describe and to claim the basic idea and method of separating one part of the syringe from another by the use of membrane seals generally of the kinds described.

Nor is it intended to limit the claims to the puncturing of the membranes by the ballooning action induced by a column of liquid or air actuated by a plunger, as such mode of bringing the puncturing point and the pretensed membrane together for rupturing the latter is illustrative, and not restrictive, of the broader aspects of the invention.

The essential novelty in the membrane washer and the membrane piston is the use of a firm ring around the membrane to facilitate its attachment firmly in position in the syringe.

The essential novelty in the stretched sheet membrane separator is the pre-stretching of the membrane which makes rupture easier when the syringe is used and assures that when the membrane is punctured, the elasticity of the stretched membrane will enlarge the hole sufficiently to permit ready flow of liquids between the previously separated spaces and the syringe assembly.

The illustrative embodiments herein shown and described exemplify suitable modes of stretching the membrane and securing it in position, but such modes are not restrictive of the invention, the essence of this part of the invention being the provisions of a stretched membrane, of material such as rubber, so as to separate the chambers or to isolate materials therein which are to be preserved in contiguity to each other or to other media, and particularly in the case of materials that are incompatible or liable to be damaged by access of foreign materials or influences, such as moisture or heat and the like, and in effect is sealed so as to prevent passage of any fluent material into or out of the syringe.

Another feature that may be advantageously employed in connection with any of the forms of the invention hereinbefore discussed, and also in connection with other syringes, is disclosed in Figures 4, 5, and 6 and consists of a method of packaging a syringe whereby the syringe is enclosed in a casing that is effectively protected against access of any foreign substance.

In Figures 4 and 5 there is shown a syringe having a single-pointed needle **35** mounted in a hub **36** that is shown as having a flange clamped between a reduced neck portion **37** of a barrel **38** and a cylindrical sleeve **39** that is integral with, or secured to, the forward end of a casing member **40** which member has operating means including an annular flange **41** for engagement by the fingers of the user in operation, while the thumb may press upon the outer end of a flexible elastic sleeve **42** that covers the outer enlarged end of a plunger **43**, here shown as tubular in form and as having a head **44**

similar to those above described. The elastic sleeve is held in place on the casing member 40 by engagement over an end flange 45 on member 40. A cap 47 fits on the sleeve 39 and may abut the end of the casing member 40.

A semi-soft mass at 48 serves to seal the needle as in application Serial No. 300,193, filed July 22, 1952, now Patent No. 2,679,246.

The mantle 39 being integral with member 40 or affixed thereto, and the sleeve 42 having been placed on it as shown, and all parts being preferably sterilized at appropriate times during assembly, the sterilized syringe is now slid into the casing until arrested by the abutment of the end of the barrel against the inner end of fixed sleeve 39. The cap 47 is placed on the sleeve 39 and the parts will now have assumed the positions shown in Figure 4, in case that form of syringe is being assembled. Now the sterilized, disposable syringe may be shipped under almost any conditions of climate, and any mode of transportation, without danger of contamination of any part of the syringe or its contents or of damage to the cannula, and the syringe is ready for practically instant use under any conditions of its existence, the only preparation necessary being to remove the cap 47 and to grasp the syringe in obvious manner, and then to insert the needle and press the plunger 43 to inject the contents of the device.

Figure 6 shows another arrangement whereby a device, including a double-pointed hypodermic needle 13' may be sterilized and placed in a protective casing where it will be maintained in sterile condition regardless of the conditions of storage, transportation or handling of the assembled unit, but when an injection is required, all that need be done to operate the syringe is to remove the protective cap 60 and force the plunger 16' toward the needle after inserting the needle in the patient. In this figure, as in Fig. 1, a hollow plunger 16' has an elastic head or piston 17' but the main chamber of the barrel 15' is enclosed in a casing 40' with a protective cap to enclose the operable syringe in sterilized condition. The needle protective cap 60 contains a plug 48, as in application Serial No. 300,193, filed July 22, 1952, which not only serves to protect the needle from damage, and the needle and all portions of the syringe accessible through the lumen from contamination and damage, but also to provide a vacuum block that will hold the piston 17' and the plunger 16' firmly in position until the protective cap is removed, and will retain the liquid in the chamber ahead of the membrane seal 53' within the chamber and the lumen of the needle until the syringe is ready for use. Here also a puncturable membrane 11' is formed so as to close the central aperture in supplemental ring or annulus 53' and is clamped between the end of the barrel and a shoulder of the needle connector cap 12''.

In the testing of hypodermic syringes for use with penicillin in suspension, which is an opaque substance, it has been found that frequently when a syringe containing that substance is aspirated to test whether the needle has struck a vein, the blood drawn from the vein will enter the syringe through the needle into the center of the opaque contents where it is not visible to the user. In at least one known type of syringe, an effort has been made to meet this problem by providing a chamber ahead of the cartridge and having the end plug of the cartridge so designed as to act as a piston in the plastic case of the syringe assembly so that the entire cartridge may be drawn back within the case after the needle is inserted, thereby drawing blood (if a vein or artery has been pierced) in to the air chamber ahead of the cartridge where it will be visible. Although this method may be effective to make visible any blood withdrawn, it would appear to involve the risk that when the cartridge is again depressed so that the needle pierces the end plug of the cartridge to permit the injection of the penicillin, entrapped air from the space ahead of the cartridge may be forced through the needle and into the patient.

A membrane piston 53' (Fig. 6) can be used to deal with this problem (which is peculiar to opaque injectibles) effectively and safely. By filling the needle channel and the space in the connector cap and the neck of the barrel at 20'' ahead of the membrane piston (see Figs. 7 and 8, pistons 54 and 55) with a clear liquid of a character suitable to avoid undesirable reaction with the medicament and any undesirable effect on the patient, all entrapped air is eliminated upon assembly and filling of the syringe. When the needle is inserted the syringe can be aspirated either by drawing back on the plunger shaft or by gently depressing and releasing the plunger shaft a few times. In either case the action will withdraw blood from the patient if a blood vessel has been pierced and the blood will appear in the clear liquid ahead of the membrane piston where it will be plainly visible to the user looking into the liquid 20'' through the transparent neck of the syringe barrel as in Figs. 7 and 8 where the neck and the barrel are transparent.

If aspiration thus discloses that the needle is properly placed, the syringe is operated in the usual fashion to inject the penicillin. The pressure of the column of liquid medicament, actuated by depressing the plunger, will balloon the membrane as in dotted lines in Fig. 8 against the point of the needle projecting into the neck, rupturing it and permitting the medicament to flow through the needle channel. In this process the clear, inert and compatible liquid ahead of the membrane seal will likewise be forced out of the syringe and into the patient. There being no space for air to enter, the risk of injecting a bubble of air into the patient is avoided by this design.

This aspirating function is, of course, peculiar to the membrane piston seal which has visible space ahead of it in the syringe and cannot be performed by either the membrane washer seal or the tensed sheet membrane seal, so long as they are assembled inside a metal connector cap, leaving no space ahead of the seal which is visible to the user of the syringe. But the aspirating function can also be performed by any syringes having devices such as the membrane seal or the pre-tensed membrane herein disclosed, if they are so placed as to provide a visible space ahead of the membrane and providing access of the clear liquid to the needle channel.

The material used in making the different parts may vary but preferably the barrel and mantle 39 are made of glass or other rigid material, hub 36 of hard rubber, head 44 and slevee 42 of soft rubber, the casing members of transparent plastic, and the plunger of aluminum or other metal or hard rubber or a hard plastic. However, we do not limit ourselves to any particular materials.

In Figure 9 there is a modified form similar to Figure 6, but in which the needle protector cap 60' slides onto the tapered end of the connector cap 12'' and has external threads at 41' that screw into internal threads at the outer end of casing member 40'. Upon removal of the needle protector, the solutions in the two chambers that are separated by membrane 10' can be injected as in Figure 6 by merely pressing on the plunger 16' without taking the casing apart or performing any other preliminary operations.

It will be obvious to those skilled in the art that many changes may be made in the means and methods herein disclosed, and therefore we do not limit ourselves to what is shown in the drawings and described in the specification but only as indicated in the appended claims.

Having thus fully described our invention, what we claim is:

1. A hypodermic syringe having a barrel providing a chamber for medicament, a plunger closing one end of the chamber, a hollow cap surrounding the other end of the barrel and providing a second chamber for medica-

ment, a hollow needle mounted on the cap and extending into said chamber and a washer clamped between the end of the barrel and a shoulder on the cap, said washer having a relatively thick outer ring portion and a pretensed membrane extending across the ring abutting said other end of the barrel, said needle having a point located close to said membrane.

2. A device as in claim 1, wherein the membrane is elastic and is sufficiently close to the needle point as to be punctured upon operation of said plunger toward said needle.

3. A hypodermic syringe providing a medicament chamber, a plunger closing one end of said chamber, an annular flange at the opposite end of the chamber, an elastic membrane extending over said flange, a cap covering said membrane and having a marginal portion extending over said flange and clamping the membrane about the same in stretched condition, and a needle mounted on the cap in a position to puncture the membrane when the plunger forces the contents of the chamber against the membrane.

4. A hypodermic syringe comprising a barrel having a chamber for medicament, a plunger slidable in said barrel, a double pointed hollow needle for injecting the contents of said chamber, a thin puncturable membrane closing the end of the chamber next to one point of said needle, a casing in which the barrel fits slidably, external gripping means on the casing, and a flexible cap enclosing the outer end of the plunger and held in engagement with the adjacent end of said casing.

5. A device as in claim 4, including a cap fitting about said barrel and abutting against the needle end of the casing, said cap enclosing said needle.

6. A device as in claim 5, including relatively soft material in the cap in position to occlude the lumen of the needle.

7. A device as in claim 5, said cap being threaded into the needle end of said casing.

8. A hypodermic syringe comprising a barrel having a chamber for opaque medicament, a double-pointed hollow needle, a plunger for ejecting the contents of said chamber through said needle, a second chamber for clear medicament adjacent to said needle and ahead of said chamber for opaque medicament, said second chamber having a transparent wall portion, a thin membrane separating said chambers and secured about its periphery to the barrel, said double-pointed hollow needle projecting into said chamber for clear medicament with the rearward point of the needle in close proximity to the thin membrane separating the two chambers.

9. A hypodermic syringe having a barrel providing a chamber for liquid, a cap at one end of said barrel, a needle projecting from said cap and a rivet mounted in a hole in said cap, said rivet encircling said needle and overlapping the edges of the cap at both ends of the rivet.

10. A hypodermic syringe comprising a barrel having a chamber for medicament, a plunger in said chamber, a hollow needle for injecting the contents of the chamber upon movement of the plunger, a close fitting casing slidable on the barrel, and an operating projection on the casing, a flange at the end of the barrel remote from the needle, a flexible cap fitting over the plunger and secured at its margin to said flange, and a protector cap fitting closely about said barrel and coacting with said casing to maintain the syringe in sterile condition.

11. An assembly of the class described comprising a hypodermic syringe end member having a hole therein, a hypodermic needle passing through said hole in spaced relation to its edges, and a hollow rivet extending through said hole in surrounding relation to said needle, said rivet being upset at both ends and securing said needle fixedly in said hole while forming leak-proof connections between said needle and said rivet and between said rivet and said end member.

12. A hypodermic syringe having a barrel providing a chamber for medicament, a plunger closing one extremity of said chamber, a fixed end closure for the other extremity of said chamber, a thin membrane located intermediate the extremities of said chamber and dividing the latter into aligned compartments, non-compatible medicaments one in each of said compartments, a hollow needle extending through said fixed end closure and having a point located near said membrane in a position to rupture the latter upon initial movement of the plunger toward the same to allow the non-compatible medicaments to commingle, and upon continued movement of the plunger such commingled medicaments are ejected from said compartments.

13. A device as in claim 12 having a cylindrical barrel, a floating piston in said barrel including an annulus with a central cylindrical opening coaxial with said barrel and an elastic membrane closing the end of the opening nearest the needle.

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