United States Patent

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[73] Assignee **R. P. Scherer Corporation**
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[54] **PLASTIC AMPOULE FOR USE WITH HYPODERMIC INJECTOR**
6 Claims, 11 Drawing Figs.

[52] **U.S. Cl.** **128/173**
[51] **Int. Cl.** **A61m 5/28**
[50] **Field of Search** ..... 128/173(H), 218, 272; 206/43, 63.2; 222/327, 490, 541

[56] **References Cited**

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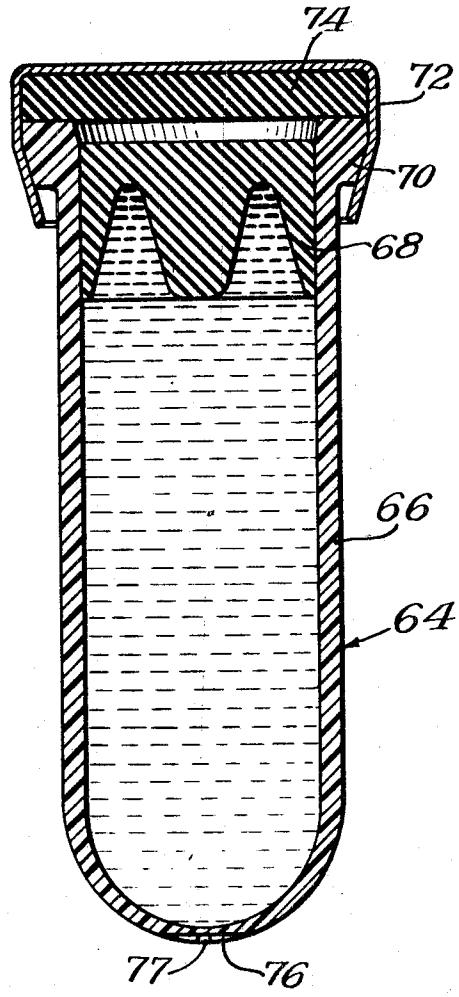
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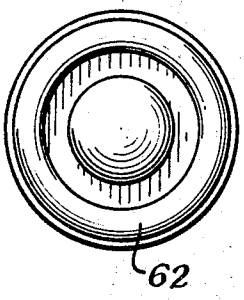
ABSTRACT: An ampoule for a hypodermic jet injector. The end of the ampoule, through which medicament passes, is constructed of a resilient material. Crosscuts are scribed in the resilient end so that a plunger driving a plug into the opposite end of the ampoule forces medicament through the crosscut end by bursting it along lines coincident with the cuts.



Patented Nov. 17, 1970 3,540,444

FIG. 1.

FIG. 2.



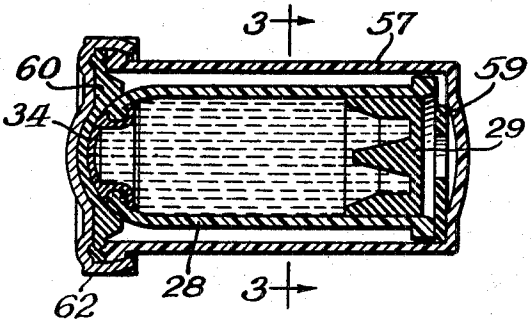


FIG. 3.

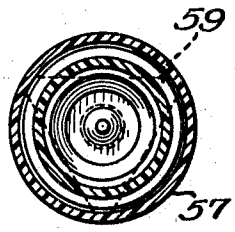


FIG. 4.

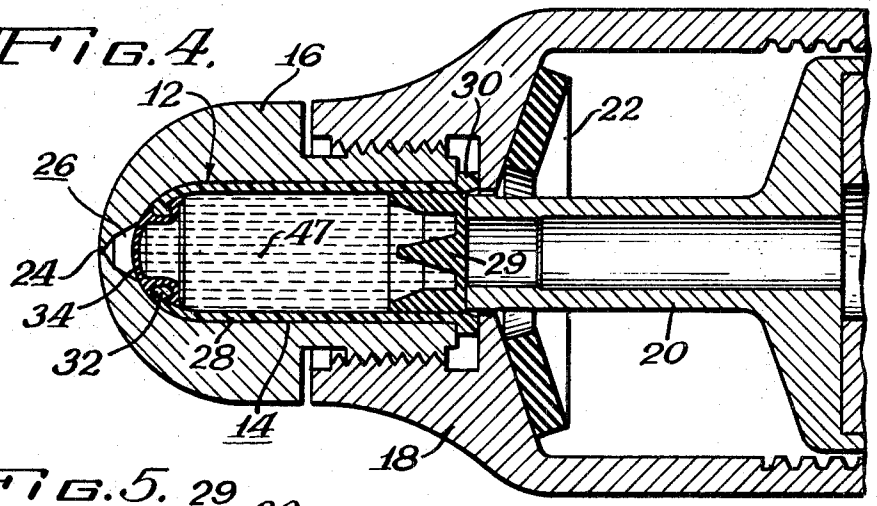


FIG. 5.

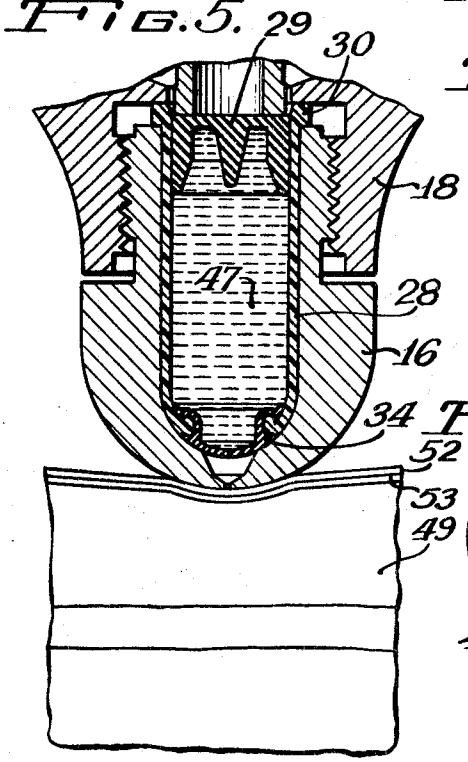


FIG. 6.

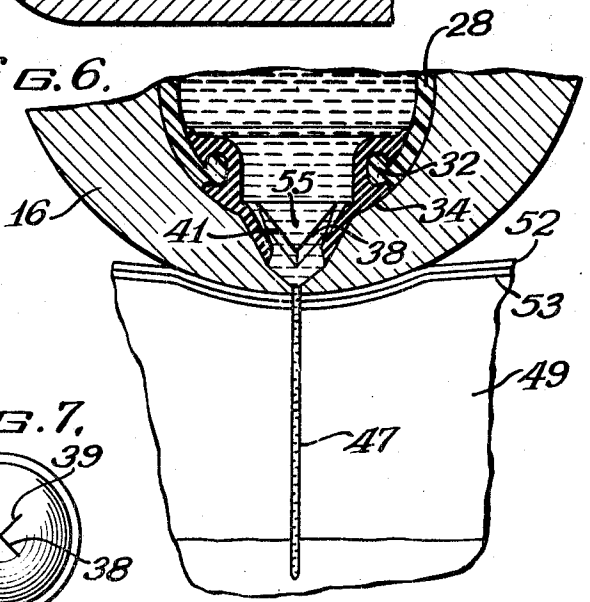
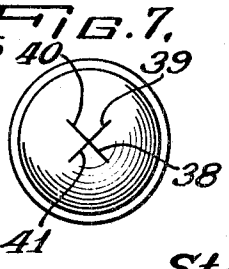


FIG. 7.



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FIG. 8.

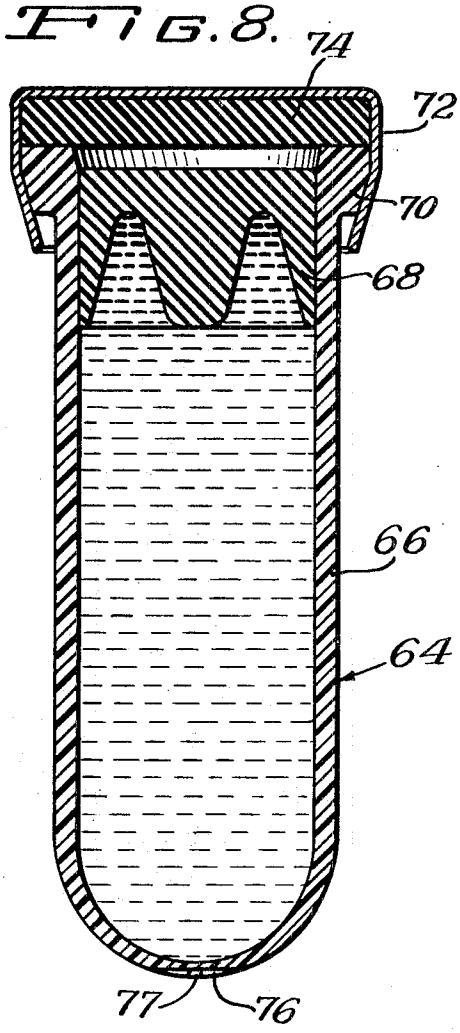


FIG. 10.

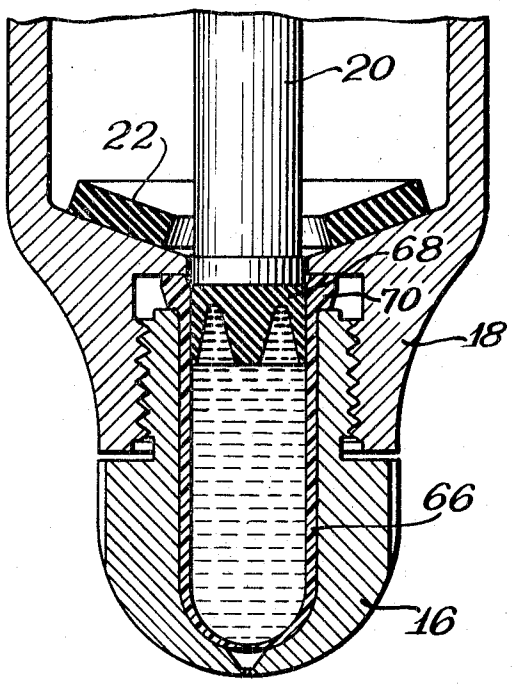


FIG. 9.

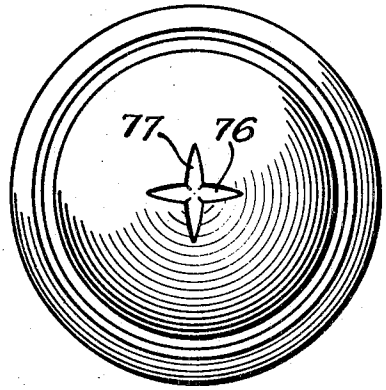
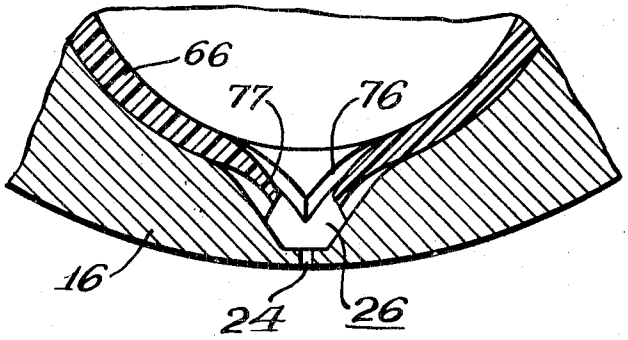


FIG. 11.



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PLASTIC AMPOULE FOR USE WITH HYPODERMIC INJECTOR

BACKGROUND OF THE INVENTION

This invention relates to an improved ampoule for use with a hypodermic jet injector.

There are presently available various types of hypodermic jet injector devices. Typical of those available is the one shown in U.S. Pat. No. 2,754,818 granted to Scherer on July 17, 1956. In a jet injector of the type disclosed by Scherer, an ampoule filled with medicament is positioned in the discharge end of the injector. The ampoule includes a main body section, which is usually formed from a stainless steel material, and a plug which fits in an open end of the ampoule.

The plug is driven by a plunger of the jet injector into the body of the ampoule forcing medicament out through an opening in the opposite end of the ampoule and through the nozzle orifice of the jet injector. Medicament which passes through the nozzle orifice then pierces the skin of the patient and enters the patient. Such a device has been quite favorably received and is especially useful for mass innoculation programs.

A type of ampoule heretofore utilized with a hypodermic jet injector is disclosed in U.S. Pat. No. 2,688,968 granted to Scherer, on Sept. 14, 1954. Such an ampoule includes an opening in one end of the capsule for the passage of medicament and a displaceable driving plug at the opposite end of the ampoule. While these ampoules are very satisfactory, they are not transparent which is a desirable characteristic for ampoules. Moreover ampoules of this construction make direct contact with the patient's skin, the medicament being discharged through the orifice in the ampoule. Thus, protection against slippage of the ampoule by a discharge nozzle attached to the jet injector and especially constructed to prevent slippage is not possible.

SUMMARY OF THE INVENTION

In a principal aspect the present invention comprises an improved ampoule for use with a hypodermic jet injector, the ampoule being comprised of a cylindrically shaped capsule with one open end and a plug which fits into the open end. The opposite end of the capsule is rounded and is made from a flexible material. The rounded end has a pattern of cuts. Thus the pressure created inside the ampoule by forcing a plunger against the plug causes the closed end to burst along seams coincident with the cuts in the closed end. There is also disclosed a method of filling the ampoules with medicament in addition to various embodiments of the invention and packaging means for the improved ampoule.

It is thus an object of the present invention to provide an improved ampoule for use with a hypodermic jet injector unit.

It is a further object of the present invention to provide a rugged yet economical ampoule for use with a hypodermic jet injector unit.

One further object of the present invention is to provide an improved ampoule with a corresponding improved nozzle construction.

These and other objects, advantages and features of the present invention will be more fully understood by reference to the detailed description which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

In the detailed description which follows, reference will be made to the drawings which include the following figures:

FIG. 1 is a side cross-sectional view of a first embodiment of the improved ampoule in a container case;

FIG. 2 is a left-hand end view of the embodiment shown in FIG. 1;

FIG. 3 is a cross-sectional view of the embodiment shown in FIG. 1 taken substantially along the line 3–3 in FIG. 1;

FIG. 4 is a cross-sectional view of the ampoule of FIG. 1 as positioned in a hypodermic jet injector before medicament has been forced therefrom;

FIG. 5 is a cross-sectional view of the ampoule and jet injector illustrated in FIG. 4 positioned in contact with the skin of a patient;

FIG. 6 is a cross-sectional view of the improved ampoule of FIG. 1 following depression of the plunger and plug to force medicament from the ampoule through the jet injector nozzle;

FIG. 7 is an end view of the first embodiment of the ampoule;

FIG. 8 is a cross-sectional view of a second preferred embodiment of the ampoule;

FIG. 9 is an end view of the embodiment shown in FIG. 8;

FIG. 10 is a cross-sectional view of the embodiment shown in FIG. 8 as positioned within a hypodermic jet injector unit; and

FIG. 11 is an enlarged cross-sectional view of the rounded end portion and nozzle orifice of the embodiment illustrated in FIG. 8 during expulsion of medicament from the ampoule.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1 through 7 illustrate a first preferred embodiment of the present invention and FIGS. 8 through 11 illustrate a second preferred embodiment.

Referring now to FIGS. 1 through 7, those of the first preferred embodiment, there is shown in FIG. 4 the front end portion of a typical hypodermic jet injector unit, for example, of the type shown by Scherer in U.S. Pat. No. 2,754,818. The ampoule of the invention, generally shown at 12, is positioned in chamber 14 defined in nozzle 16. The nozzle 16 is threadably attached to body 18 of the hypodermic jet injector unit. Within the body 18 is a plunger 20 which is driven by driving means (not shown). The plunger 20 can thus be moved to the left of its position illustrated in FIG. 4 to cause medicament to be discharged from the ampoule 12 through the end of the nozzle 16. A bumper 22 is provided to engage the plunger 20 at the end of the driving stroke.

The nozzle 16 includes a central orifice 24 leading from the chamber 14 through a flared section 26. The flared section 26 is normally not occupied by medicament or the ampoule 12 but is necessary for proper discharge of the medicament from the ampoule 12 as will be described below.

The ampoule 12 includes a cylindrically shaped body or capsule 28 having an open end to receive a plug or stopper 29. A circumferential flange 30 surrounds the open end of the capsule 28. When the ampoule 12 is inserted into the chamber 14, the flange 30 coacts with the nozzle 16 to precisely position the ampoule 12 at a fixed depth within the chamber 14, to provide a seal between the nozzle 16 and the body 18, and to secure the ampoule 12 in a precise position in relation to the nozzle 16 and the body 18. The capsule 28 includes a circumferential ridge 32 around the inside of the end opposite the flange 30.

The ampoule 12 also includes a closed end section 34 which is preferably rounded and adapted to fit into the end of the capsule 28 opposite plug 29. The closed or rounded end section 34 includes a circumferential groove 36 adapted to mate with the ridge 32 and hold the rounded end section 34 in a snug intimate relation with the capsule 28. The rounded end section 34 is preferably fabricated from a soft, resilient material such as rubber or the like.

As more fully illustrated in FIG. 7 the rounded end portion includes a plurality of cuts 38, 39, 40 and 41 which meet at a common point at the center of the rounded end 34. The cuts pass completely through the rounded end section 34. Thus, when pressure is exerted on a volume of medicament 47 within the ampoule 12, the sections of the rounded end 34, between adjacent cuts, 38 and 39, 39 and 40, 40 and 41, 41 and 38 are forced apart to allow medicament 47 to pass out the rounded end 34.

The stopper or plug 29, as shown in FIG. 4, inserted in the open end of the capsule 28 assures that medicament 47 is maintained within the ampoule 12. During operation of the hypodermic jet injector, the plunger 20 fits against stopper 29

and pushes the stopper 29 into the capsule 28 to drive medicament 47 from the ampoule 12.

Referring now to FIGS. 5 and 6, there is illustrated the sequence of operations during discharge of medicament 47 from the jet injector. In FIG. 5 the nozzle 16 has been positioned against the skin 52 of a patient. Slight pressure is maintained on the nozzle 16 so that part of the nozzle 16 in the region of the orifice 24 causes a slight depression in the layers of skin 52 and 53 and flesh 49.

FIG. 6 illustrates the next step in the sequence of operations. In FIG. 6 the plunger 20 has been depressed to drive the stopper 29 into the capsule 28 thereby causing medicament 47 to be forced through the rounded end section 34 of the ampoule 12 into the flared section 26 of the chamber 14. Medicament then passes out through the orifice 24 of the nozzle 16. A stream of medicament 47 passing through the orifice 24 pierces the layers of skin 52 and 53 and passes into the flesh 49 of the patient.

The rounded end section 34 of the ampoule 12 splits along lines 38 through 41 as set forth above to define four flaps, for example, flap 55 in FIG. 6 between cuts 38 and 41. The flaps, as at 55, fit into the flared section 26 of the chamber 14 without inhibiting the movement of medicament 47 through the orifice 24.

FIGS. 1, 2 and 3 show the ampoule of the invention enclosed in a storage case. The case includes a cylindrically shaped cartridge 57 fabricated from a plastic material and adapted to receive the ampoule through an open end. A triangular-shaped rubber liner or spacer 59 is positioned on the bottom of the cartridge 57. The medicament filled ampoule 12 is inserted into the cylindrical cartridge 57 to rest on the spacer 59. A second rubber liner or spacer 60 fits over the rounded end 34 of the ampoule 12. Liner 60 provides a seal around the open top end of the cartridge 57.

A cap or closure 62 holds the liner 60 in position within the cartridge 57 and provides an airtight seal within the cartridge 57. Thus ampoule 12 is held in a substantially immovable position and is protected against bumping and possible rupture or contamination. The spaces between the ampoule 12 and the interior walls of the cartridge have preferably been purged of air and filled with an inert gas to prevent aging and deterioration of the medicament.

FIGS. 8 through 11 show a second preferred embodiment of the invention. As illustrated in FIG. 10 the second embodiment of an ampoule 64 is adapted to fit into the hypodermic jet injector having the same components as previously described for the first preferred embodiment of an ampoule 12.

FIG. 8 illustrates the second embodiment of the ampoule 64 in a packaged form. The ampoule 64 includes a capsule 66 with a plug or stopper 68 inserted in an open end of capsule 66. The plug 68 is preferably fabricated from a self-healing rubber. The capsule 66 is preferably fabricated from a polycarbonate-type, clear, transparent plastic material, compatible with injectable medicaments. The lower or rounded end portion of the capsule 66 has thinner walls than the main side cylindrical walls of the capsule 66; however, the capsule is a single integral molded piece in contrast to ampoule 12 which includes a separable rounded end 34 and a capsule 28. The thin walls of the rounded end of capsule 66 assures that the rounded end portion of the capsule 66 will be more flexible than the main side walls of capsule 66.

The capsule 66 also includes a circumferential flange 70 around its molded open end which is utilized in the same manner previously described for the ampoule 12; namely, as a holding and sealing means between the nozzle 12 and the body 18 of the jet injector. The flange 70 for the ampoule 64 also cooperates with a tear-off aluminum closure seal 72 utilized in packaging the ampoule 64 to hold the seal 72 on the capsule 66. A gasket 74 is positioned between the seal 72 and the flange 70 to insure a complete, airtight seal of the packaged ampoule 64.

Referring now to FIGS. 9 and 11 there is shown the end construction of the ampoule 64. Whereas in the first embodiment ampoule 12 cuts were made entirely through the rounded end 34 of the ampoule 12, now diagonal reductions 76 and 77 in the thickness of the wall are formed in the outer surface of the nose of the capsule 66. The diagonal reduction 76 and 77 in the thickness of the capsule wall intersect at substantially right angles. FIG. 8 illustrates a cross-sectional view of the configuration of the reductions 76 and 77 in the thickness of the wall in the nose of the capsule 66.

When the plunger 20 is depressed forcing the stopper 68 to drive medicament 47 from the ampoule 64, the rounded end of the capsule 66 ruptures along the lines defined by the reductions 76 and 77 in thickness of the nose of the capsule 66. This is illustrated in FIG. 11. Medicament 47 thus may pass through the ruptured opening and through the orifice 24 into a patient in the same manner as previously described for the ampoule 12.

As has been illustrated in the first preferred embodiment of the ampoule 12 and the second preferred embodiment of the ampoule 64 there may be a detachable rounded end section or an integral rounded end section, and there may be cuts passing completely through the rounded end section or cuts passing partially through the rounded end section. There has been illustrated only two combinations of these features; namely, an integral rounded end with cuts partially therethrough (ampoule 64) and a detachable rounded end with cuts entirely therethrough (ampoule 12). Other combinations are quite possible and the invention is not limited to those preferred embodiments disclosed herein.

While there has been disclosed preferred embodiments of the ampoule of the present invention, it is to be understood that all those embodiments obvious to persons skilled in the art and all those embodiments which are equivalent to the presently claimed subject matter are to be included within the scope of the appended claims.

I claim:

1. In a hypodermic unit of the type adapted to receive an ampoule in a nozzle compartment and including means to force medicament from one end of said ampoule through a nozzle orifice of said unit and into a patient, an improved, separable ampoule comprising, in combination:

a cylindrically shaped capsule having one open end, one closed end, an inside and an outside, said closed end formed from a flexible, rupturable material and having defined therein a plurality of cuts extending partially through said closed end from the outside thereof such that a pressure differential between the inside and outside of said ampoule causes medicament to pass in the direction of decreasing pressure through an opening in said closed end defined by ruptured of said closed end along said cuts; and

a plug fitted into said open end of said ampoule to thereby define an enclosed chamber within said ampoule for holding medicament, said plug being slidable along the inside of said ampoule to cause pressure differential between the inside and outside of said ampoule.

2. The ampoule of claim 1 wherein there are four of said cuts meeting at a common point on said closed end, any adjacent pair of cuts defining substantially a right angle, said point being positioned on the end of said ampoule such that said point upon insertion into a hypodermic will substantially coincide with said nozzle orifice.

3. The ampoule of claim 1 wherein said cuts meet at a common point and extend entirely through said closed end.

4. The ampoule of claim 1 wherein said cuts meet at a common point to define a pattern of lines along which said closed end will rupture with sufficient pressure differential.

5. The ampoule of claim 1 wherein said closed end is detachable from said ampoule, said ampoule being formed from a semirigid material and said closed end being formed from a pliant, rupturable material.

6. The combination of claim 1 wherein said nozzle compartment of said hypodermic jet injector unit includes a cavity adjacent said closed end, said cavity being connected to said nozzle orifice and providing an area into which portions of said closed end are displaced upon rupture of said closed end due to said pressure differential.