United States Patent [19]

Kessel

[11] **3,766,918**

[45] **Oct. 23, 1973**

[54] **SELF-ASPIRATING HYPODERMIC AMPULE**

[76] Inventor: **John D. Kessel,** 458 Arneil Rd., Camarillo, Calif.

[22] Filed: **Sept. 7, 1971**

[21] Appl. No.: **177,984**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 848,052, Aug. 6, 1969, abandoned.

[52] **U.S. Cl.** ..... **128/218 P,** 128/276, 222/386.5, 128/272

[51] **Int. Cl.** **A61m 5/22,** A61m 1/00

[58] **Field of Search** ..... 128/218 P, 215, 218 R, 128/218 D, 218 DA, 272, 234, 235, 219, 218 M; 92/243–245; 215/52; 222/386, 386.5

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Assistant Examiner—J. C. McGowan
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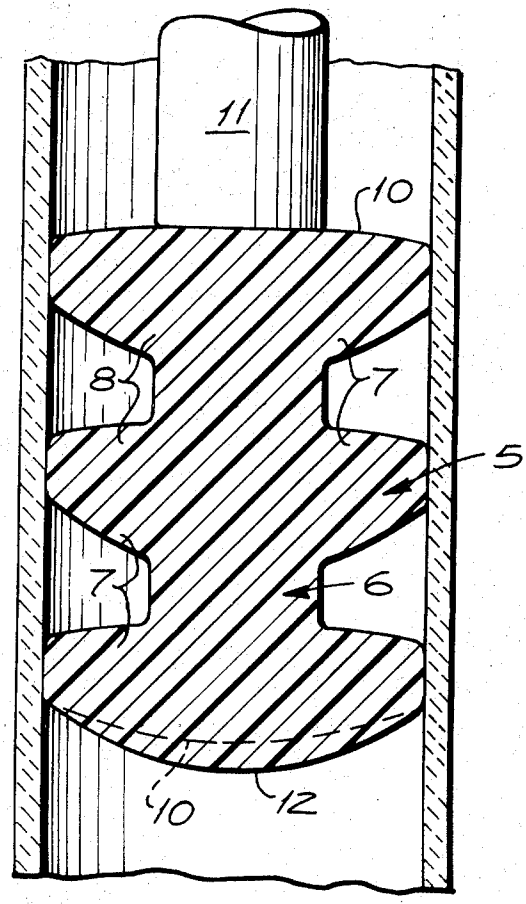
[57] **ABSTRACT**

A self-aspirating hypodermic ampule which incorporates a piston capable of limited resilient movement when a force is manually applied to effect a hypodermic injection so that, when the force is subsequently released, the piston retracts sufficiently to cause a back flow or aspirating flow through the needle into the ampule for blood detection; the piston including radial flanges the axial sides of which converge to permit resiliant distortion and axial displacement of the central portion of the piston before sliding movement of the piston relative to the surrounding walls of the ampule; the piston also being arranged for insertion in the ampule, either end forward and its ends being shaped to minimize gas entrapment thereby maximizing the effect of its aspirating movement.

7 Claims, 9 Drawing Figures



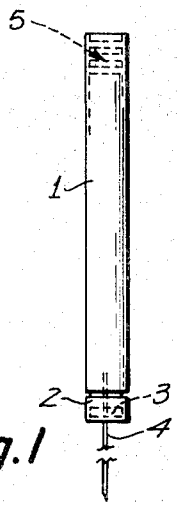


Fig. 1

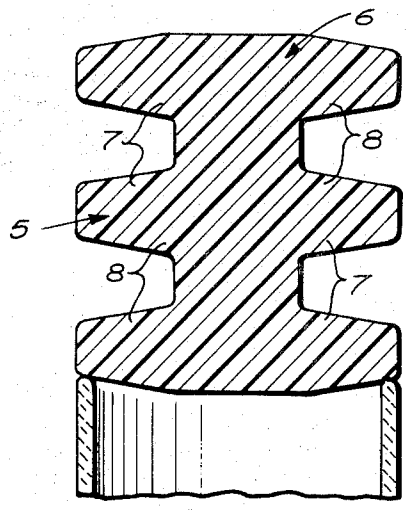


Fig. 2

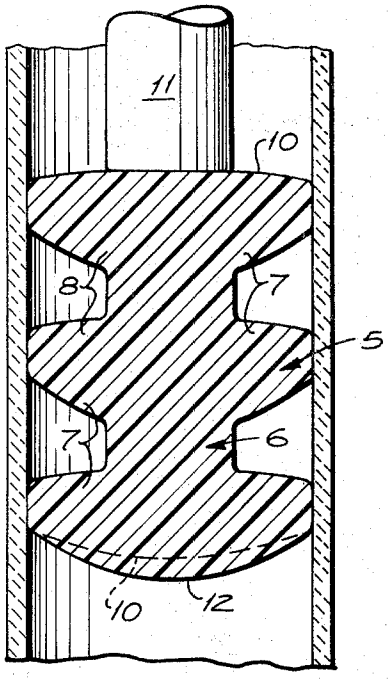


Fig. 4

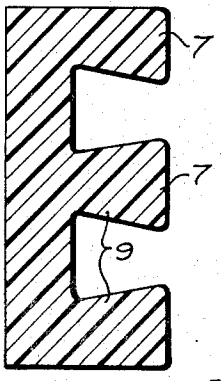


Fig. 7

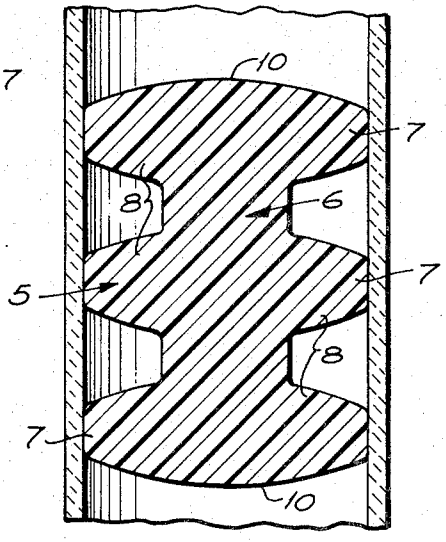


Fig. 3

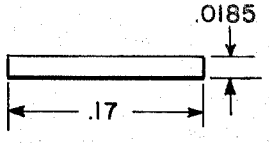


Fig. 5

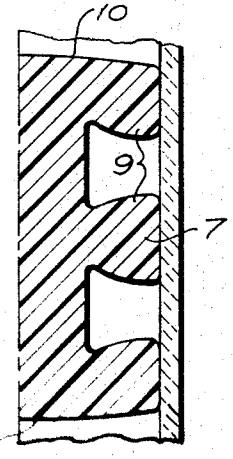


Fig. 8

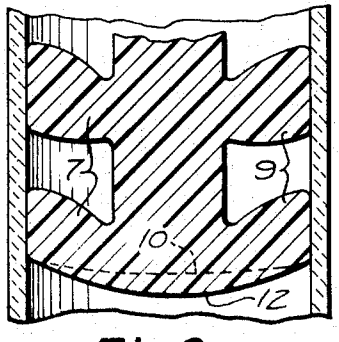


Fig. 9

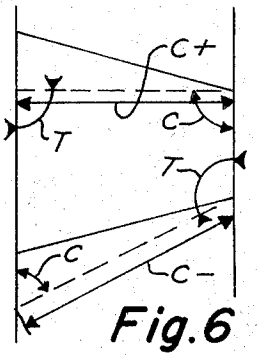


Fig. 6

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SELF-ASPIRATING HYPODERMIC AMPULE

This application is a continuation-in-part of my previous application, Ser. No. 848,052 filed Aug. 6, 1969 entitled: SELF-ASPIRATING PISTON FOR AMPULES AND HYPODERMIC SYRINGES, and now abandoned.

BACKGROUND OF THE INVENTION

The desirability of providing an aspirating action in a hypodermic syringe has long been recognized, as by doing so, one can detect if the needle is properly positioned in the tissue, rather than penetrating a blood vessel. This is particularly true when giving local anesthetic injections prior to surgery. Should the medicine enter the blood stream, it is carried away from the intended site and distributes the effect. It is common practice to withdraw the piston manually to aspirate the body fluid for detection of blood, before completing the injection. However, this requires considerable skill and an extremely steady hand, otherwise, the injection may be quite painful. Also, in order to effect manual aspiration the piston must be capable of being mechanically attached to the plunger of the syringe.

Attempts have been made to produce a piston having an automatic aspirating effect; one example is disclosed in U.S. Pat. No. 3,045,674. The piston here illustrated requires mechanical connection to the plunger rod. The existence of this connection materially interferes with self-aspirating action; that is, the amount of resiliant deformation is so limited that the aspirating action is minimal. Also, in order to effect mechanical connection, end cavities are required which tend to entrap gas. Presence of gas, whether it be an inert gas such as nitrogen, entrapped during the initial filling of an ampule, or air which enters during preparation of the syringe prior to injection provides a compressible bubble which subtracts from the self-aspirating action.

SUMMARY OF THE INVENTION

The present invention is directed to a self-aspirating hypodermic ampule and is summarized in the following objects:

First, to provide a self-aspirating hypodermic ampule which incorporates a piston having a relatively small central core portion surrounded by flanges of relatively substantial radial proportions, the axial ends of the flanges having axially converging surfaces, whereby the core is supported for resiliant movement.

Second, to provide a self-aspirating piston as indicated in the previous object wherein its ends are arranged to minimize gas entrapment.

Third, to provide a piston as indicated in the preceding objects wherein either end may be inserted first into the ampule and wherein either end is engageable by conventional hypodermic syringe push rods.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view of the self-aspirating hypodermic ampule indicating essentially diagrammatically a hypodermic needle inserted therein, remaining parts of the hypodermic syringe being omitted.

FIG. 2 is an enlarged sectional view of the self-aspirating piston in its normal state before insertion into the ampule, the ampule being indicated fragmentarily for comparison.

FIG. 3 is another enlarged dissectional view of the piston shown radially compressed within the ampule but otherwise in its normal condition, the ampule being shown fragmentarily.

FIG. 4 is an enlarged dissectional view similar to FIG. 3 but showing the piston elastically deformed by a syringe plunger, the plunger being indicated fragmentarily.

FIG. 5 is a diagrammatical view of a cylinder representing the volume of liquid which is displaced by elastic deformation of the piston.

FIG. 6 is a diagrammatical view representing one of the piston flanges in section to illustrate the restoring forces involved when the piston flange is elastically deformed.

FIG. 7 is an enlarged sectional view showing one half of a modified form of the piston in its free condition.

FIG. 8 is an enlarged sectional view showing one half of the modified piston as it appears under radial compression, but otherwise undestorted as it appears within an ampule, the ampule being shown fragmentarily.

FIG. 9 is a fragmentary sectional view of the modified piston and ampule with the piston shown in its resiliently distorted position.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The self-aspirating hypodermic ampule includes an ampule cylinder 1 having a cap 2 at one end which secures a penetrable sealing disk 3 through which a syringe needle 4 may be inserted, the needle forming a part of the syringe structure in which the ampule is placed.

The ampule cylinder receives a piston 5 formed of an elastomeric material of which a number are commercially available. For example, natural or synthetic rubber may be used or plastic materials having elastomeric properties, are suitable. An example is a butadiene-styrene copolymer of the type marketed by Shell Chemical Co., under the Trademark "KRAYTON."

The piston includes a cylindrical core 6 having a diameter approximately one half the diameter of the piston; radiating from the core is a series of integral axially spaced flanges 7. Three flanges are preferred, although two or more than three flanges may be used if desired.

Referring to the embodiment shown in FIGS. 2, 3 and 4, the flanges have radially outwardly converging axial surfaces 8. That is, the flange surfaces in a normal state define cones. Alternatively, as shown in FIGS. 7, 8 and 9, the flanges may have radially inwardly converging axial surfaces 9. In either case the flanges are essentially trapezoidal in radial cross-section.

The piston 5 is slightly larger in its normal diameter than the inside diameter of the ampule cylinder 1. As a consequence, when the piston 5 is forced into the ampule cylinder the flanges 7 are radially compressed causing their surfaces 8 or 9 to assume a slightly convexed configuration. Also, when either embodiment is encased in the ampule cylinder its ends are essentially convexed as indicated by 10.

When the embodiment of the piston shown in FIGS. 2, 3 and 4 is in its normal state within the ampule cylinder, the flanges are essentially symmetrical as indicated in FIG. 3. If an axial force is applied to one end of the piston, for example by a syringe plunger 11, the frictional contact of the radial ends of the flanges against the walls of the ampule cylinder, permits the core of the piston to be forced axially a limited distance without sliding movement between the flanges and the surface

of the ampule cylinder. This produces a resiliant distortion in each of the flanges as indicated in FIG. **4.** As a result the end of the piston exposed to the liquid contained in the ampule produces an extended contour **12.** The difference in the normal contour **10** and the extended contour **12** is utilized to produce an aspirating effect. More specifically, movement of the end of the piston from the contour **10** to the contour **12** causes a displacement of liquid from the ampule which is injected through the syringe needle into a patient. When the distorting pressure is removed by relaxing the force on the syringe plunger **11,** the piston returns from the condition represented in FIG. **4** to the condition represented in FIG. **3,** but also indicated by broken lines in FIG. **4,** producing an aspirating or suction effect which withdraws a corresponding portion of fluid from the patient into the ampule. If the syringe tip has entered a blood vessel, a small quantity of blood will be drawn into the ampule where it can be observed. If the liquid contained in the ampule is a local anesthetic it is undesirable to direct it into the blood stream, thus if blood is observed the hypodermic needle is relocated by thrusting it past the blood vessel whereupon a second test may be made if needed.

While desireability of causing the piston to perform an automatic aspirating operation, in order to detect blood in the ampule, is recognized, the amount of resilient movement to accomplish this operation has been so slight that the test often fails. This may be due to several reasons:

1. The existence of a small bubble of gas in the liquid may result in mere compression of the gas bubble.
2. Unless the displacement exceeds the volume represented by the bore of the hypodermic needle, a blood sample will not be received.

By arranging the flanges so that their axial surfaces converge in a radially outward or a radially inward direction and providing a relatively small core, it has been found that the effective resiliant displacement of the piston may represent as much as five or more times the volume of the hypodermic needle, thus assuring that an adequate sample of blood resulting from return or aspirating movement of the piston is obtained.

By way of example: Assuming an ampule having an inside diameter of 0.250 inches, and assuming a resiliant axial piston displacement of 0.0185 inches, the cylindrical equivalent as shown in FIG. **5** of the volume of the crescent shaped displacement shown in FIG. **4** is approximately 0.0185 inches × 0.170 inches or 0.004 cubic inches. Assuming a hypodermic needle to have an inside diameter of 0.010 inches and a length of one inch, the displaced volume is approximately five times the needle bore volume, an ample ratio to accomplish aspiration.

The trapezoidal configuration of the flanges plays an important part in producing the desired aspirating movement of the piston; thus, referring to FIG. **6,** the solid outline represents diagrammatically, a radial section of flange. If the flange is deflected resiliantly without movement of its surface in contact with the ampule, the flange will assume the position indicated by broken lines. Applying the diagram to the embodiment shown in FIGS. **2,3** and **4,** radial compression increases as indicated by the line C+ at the upper portion of the figure and decreases as indicated by the line C− at the lower portion of the figure. Also, at the corners of the figure a restoring compression force C and a restoring tension force T occurs. If the axial surfaces were parallel the radial compression throughout the flange would decrease with axial displacement of the core. It is believed that the increased radial compression C+ enables the core to move a greater distance relative to the walls of the ampule than would otherwise be the case and that this force coupled with the angular restoring forces C and T at the corners of the flange insure an adequate aspirating effect.

A similar effect is attainable with the embodiment shown in FIG. **7, 8** and **9.** That is, FIG. **6** is applicable at least to the central and top flanges if the drawing be inverted.

While particular embodiments of this invention have been shown and described, it is not intended to limit the same to the details of the constructions set forth, but instead, the invention embraces such changes, modifications and equivalents of the various parts and their relationships as come within the purview of the appended claims.

I claim

1. A self-aspirating hypodermic ampule comprising:
a. an ampule cylinder;
b. a piston formed of resilient material including:
a central elongated imperforate core occupying approximately half the internal diameter of the ampule cylinder;
a series of annular flanges integrally connected to the core, each flange having an axial length approximating its radial dimension and each said annular flange having an outer diameter normally larger than the internal diameter of the ampule cylinder, whereby the flanges are under radial compression when the piston is received therein;
said flanges, when subjected to a first axial force insufficient to effect sliding movement of the piston in the ampule cylinder, being caused to undergo resilient distortion to displace an initial quantity of fluid from the ampule cylinder, and, upon release of said force, to restore to their normal configuration thereby to aspirate the previously discharged quantity of fluid.

2. A self-aspirating piston, as defined in claim **1,** wherein:
a. the surfaces of the flanges are essentially trapezoidal in radial section.

3. A self-aspirating piston, as defined in claim **2,** wherein:
a. the radially inner peripheries of the flanges have a lesser axial extent than their radially outer peripheries.

4. A self-aspirating piston, as defined in claim **2,** wherein:
a. the radially inner peripheries of the flanges have a greater axial extent than their radially outer peripheries.

5. A self-aspirating piston, as defined in claim **2,** wherein:
a. the core is solid from end to end, and on radial compression, the piston ends assume a convex contour; one end, on application of an axial force thereon, tending to flatten, causing the opposite end to increase its convex contour to effect liquid displacement.

6. A self-aspirating piston, as defined in claim **2,** wherein:

a. the surfaces of the flanges define converging essentially conical surfaces;

b. and on application of said first axial force to effect displacement of liquid from the ampule cylinder, one surface of at least a selected flange becomes increasingly conical and its corresponding side is subject to decreasing radial compression; whereas, the opposite surface of said flange becomes less conical and its corresponding side is subject to increasing radial compression; thereby providing a restoring force acting axially on the piston to effect an aspirating movement of the piston.

7. A self-aspirating hypodermic ampule, comprising:

a. an ampule cylinder having a discharge end for a liquid initially contained therein;

b. a piston formed of resilient material received in the ampule cylinder and capping the liquid contained therein; the piston having a central core occupying approximately half the internal diameter of said cylinder and presenting essentially flat end surfaces, and a series of annular flanges integral with the core and having a normal outer diameter greater than the ampule cylinder, whereby when the plunger is inserted in the ampule cylinder, the flanges are radially compressed;

c. each flange having an axial length and radial depth which are approximately equal;

d. and a plunger accessible from the end of the ampule cylinder and having an essentially flat end surface for end contact with the piston core to force liquid from the ampule cylinder upon movement of the piston therein;

e. the plunger being responsive to a limited axial force to effect resilient distortion of the flanges prior to displacement of the flanges along the ampule cylinder to force an initial quantity of fluid from the ampule cylinder, and upon release of such limited force, to resume their normal configuration thereby to aspirate the previously discharged quantity of fluid.

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