

[54] **BURSTABLE SEAMED HYPODERMIC APPLICATORS**

[76] Inventor: **Bela G. Szabo**, 5138 Delford St., Pittsburgh, Pa. 15207

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[21] Appl. No.: **94,381**

[52] U.S. Cl.**128/216, 128/232, 128/221**

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

[58] Field of Search.....**128/216, 231, 232, 128/239, 272, 224, 234, 235, 221, DIG. 5; 206/47 A, 56 AA; 222/92, 94, 106, 107, 207, 211, 215, 213, 494**

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Primary Examiner—Richard A. Gaudet
Assistant Examiner—J. C. McGowan
Attorney—Samuel Lebowitz

[57] **ABSTRACT**

Single-use hypodermic applicators are formed of single or multiple chambers containing liquid medicaments of all types. These low-cost applicators are formed from synthetic plastic tubing in flattened form with a sterile hollow needle sealed therein and projecting from the front end of the applicator body with the inner end of the needle enlarged and sealed within a chamber formed in tubing forwardly of the medicament chamber. A normally heat-sealed seam between chambers is adapted to be ruptured by finger pressure imposed on the outer walls of the medicament chamber to force the medicament from the latter into the forward chamber and through the hollow needle for ejection through the pointed end thereof when the same is inserted into a receiving body. The applicator body is formed with one, two or more medicament chambers separated by burstable seams extending in straight lines transversely of the longitudinal axis of the tubing and provided with critically dimensioned and oriented weakenings so that finger pressure applied selectively to these chambers will control the dosage of medicament forced forwardly towards the enlarged end of the hypodermic needle. The needles are designed to be packaged compactly and dispensed conveniently for use in large or limited number. Also, the only two components of the applicators, namely, the needles and the plastic medicament containers, may be salvaged and processed for re-use.

9 Claims, 21 Drawing Figures

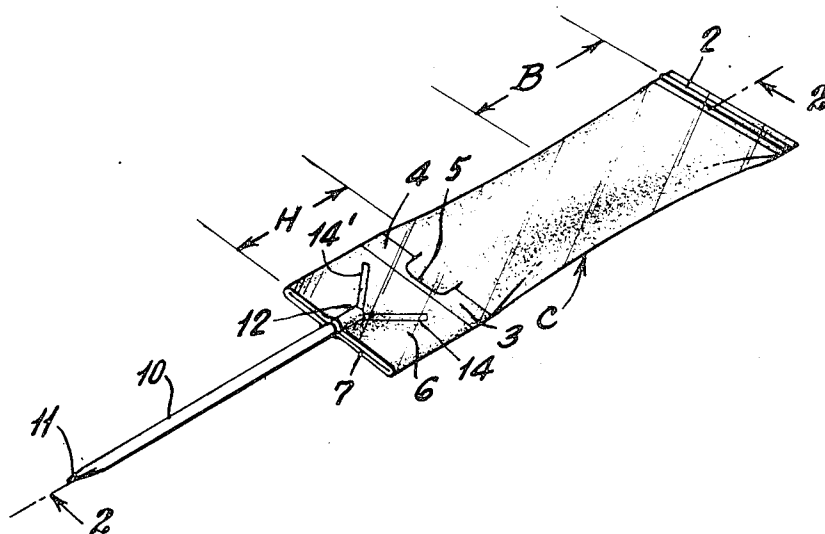


Fig. 1.

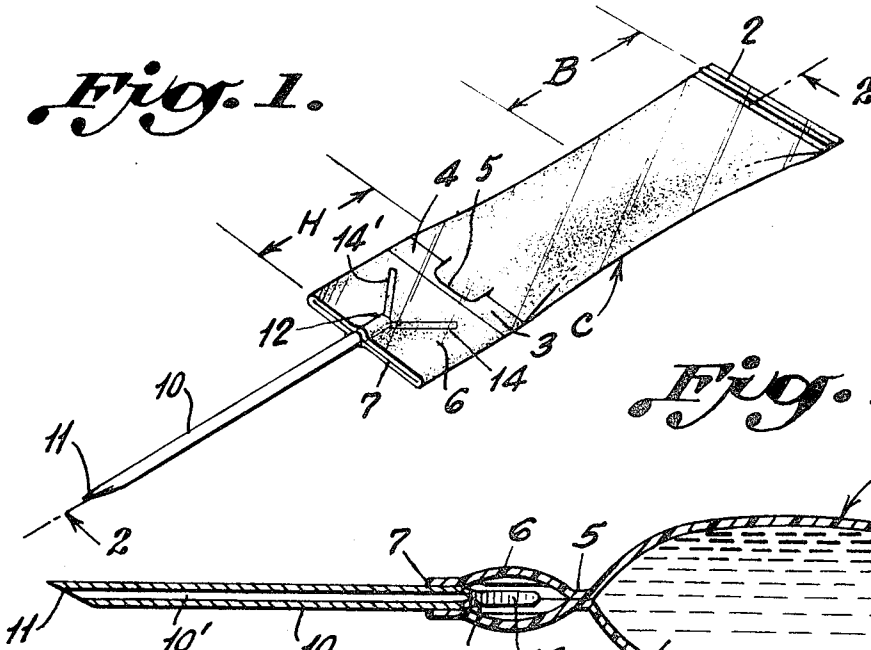


Fig. 2.

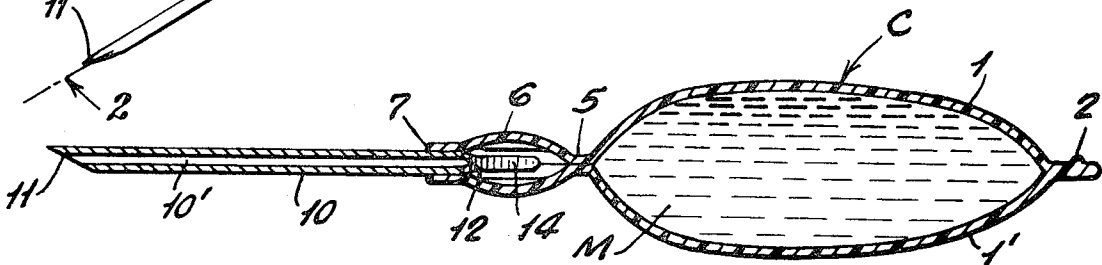


Fig. 3.

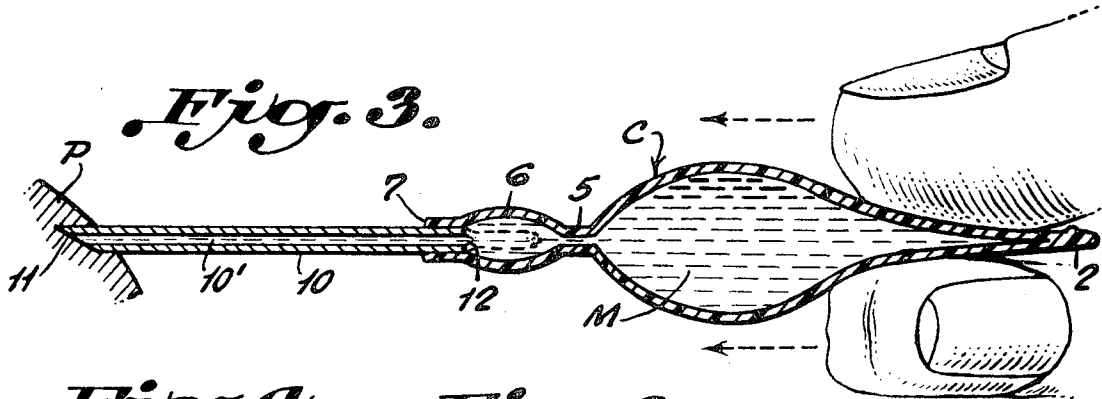


Fig. 4.



Fig. 6.

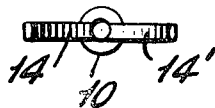


Fig. 5.

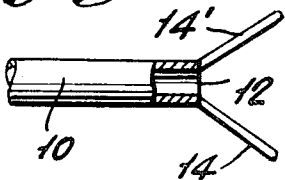
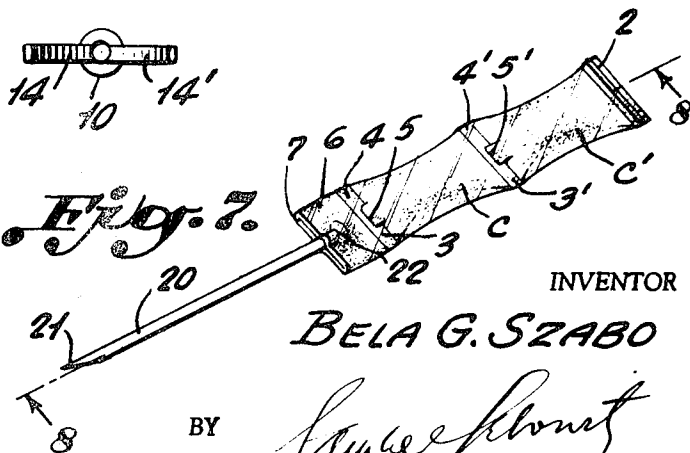


Fig. 7.



INVENTOR

BELA G. SZABO

BY

Samuel Shonoff

ATTORNEY

Fig. 8.

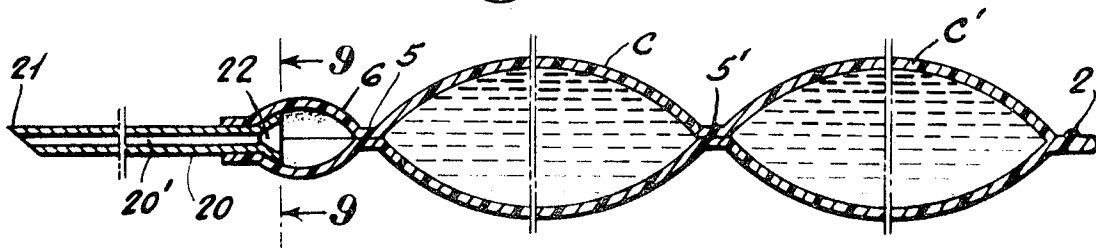


Fig. 9.

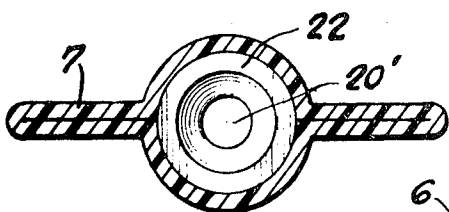


Fig. 10.

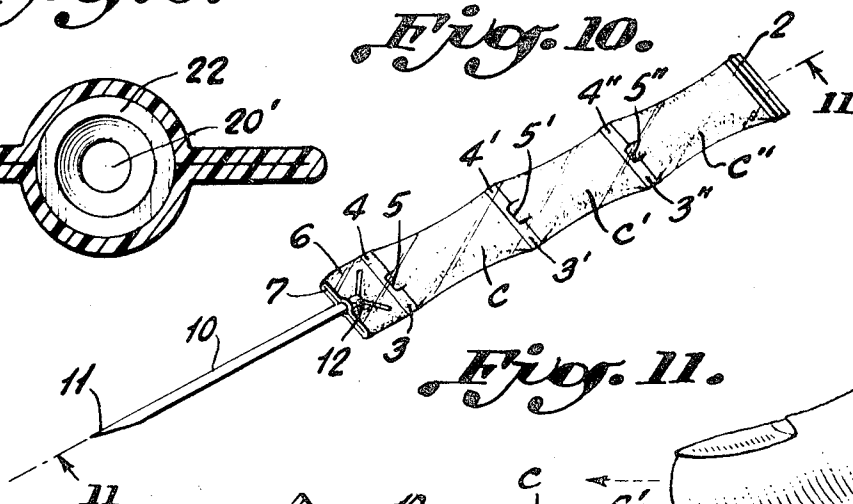


Fig. 11.

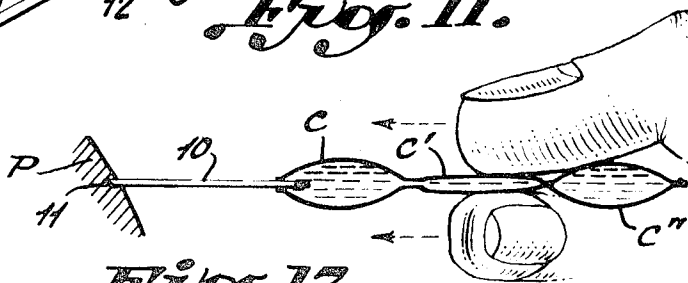


Fig. 14.

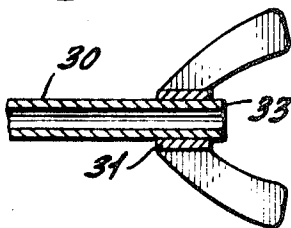


Fig. 17.

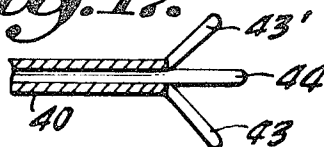


Fig. 15.



Fig. 16.

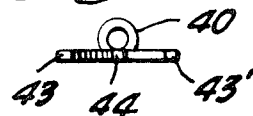


Fig. 12.

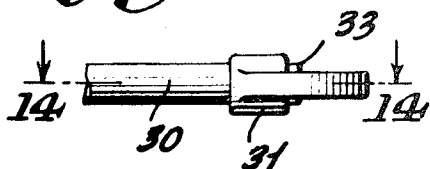
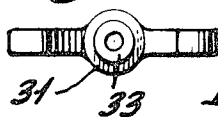


Fig. 13.



INVENTOR

BELA G. SZABO

BY

Samuel K. [Signature]

ATTORNEY

Fig. 18.

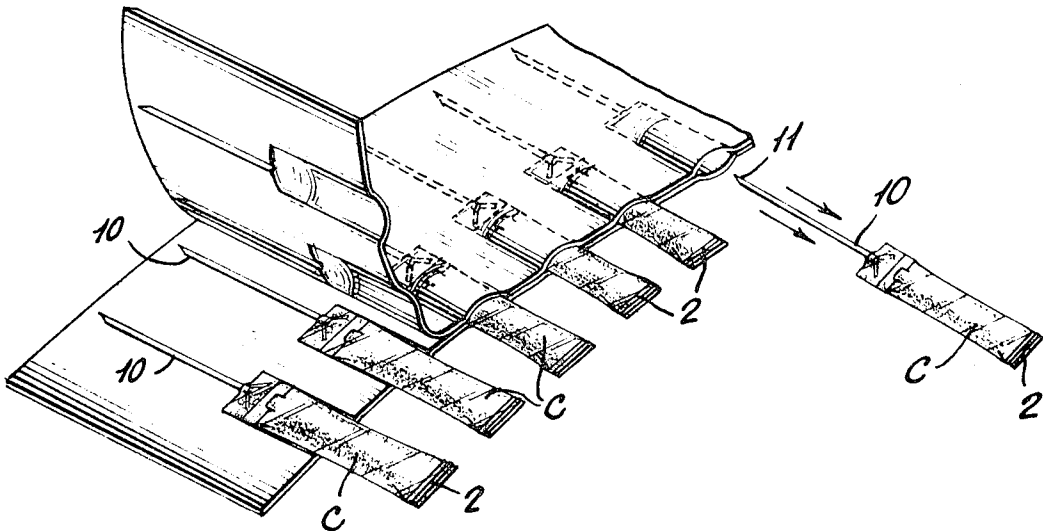


Fig. 19.

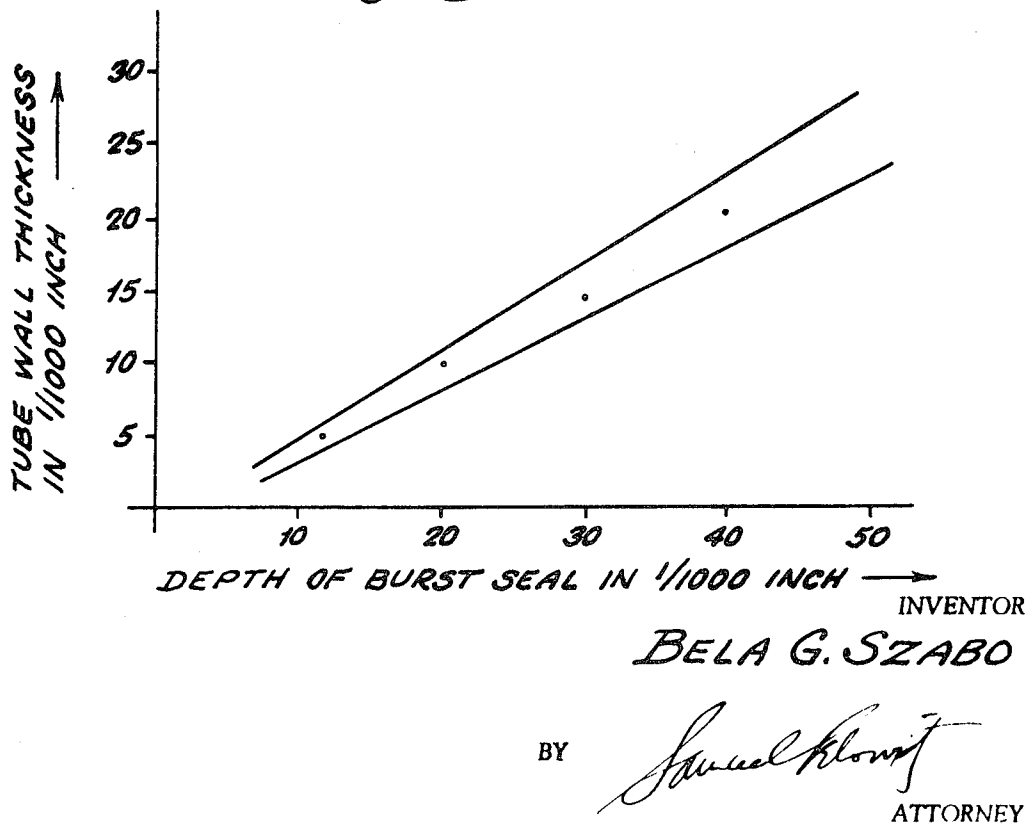


Fig. 20.

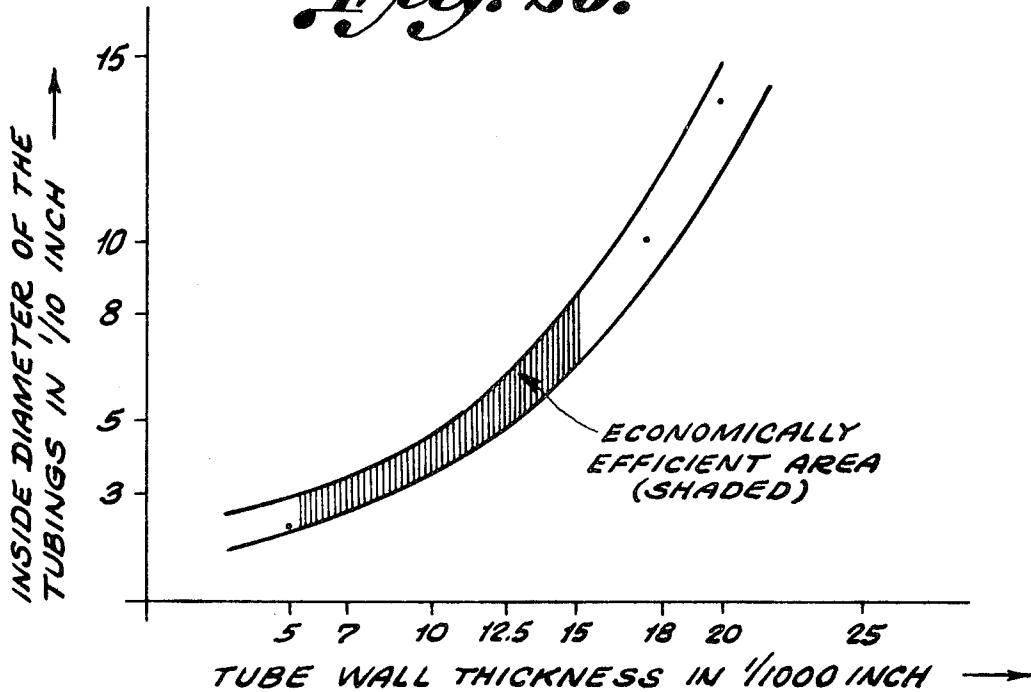
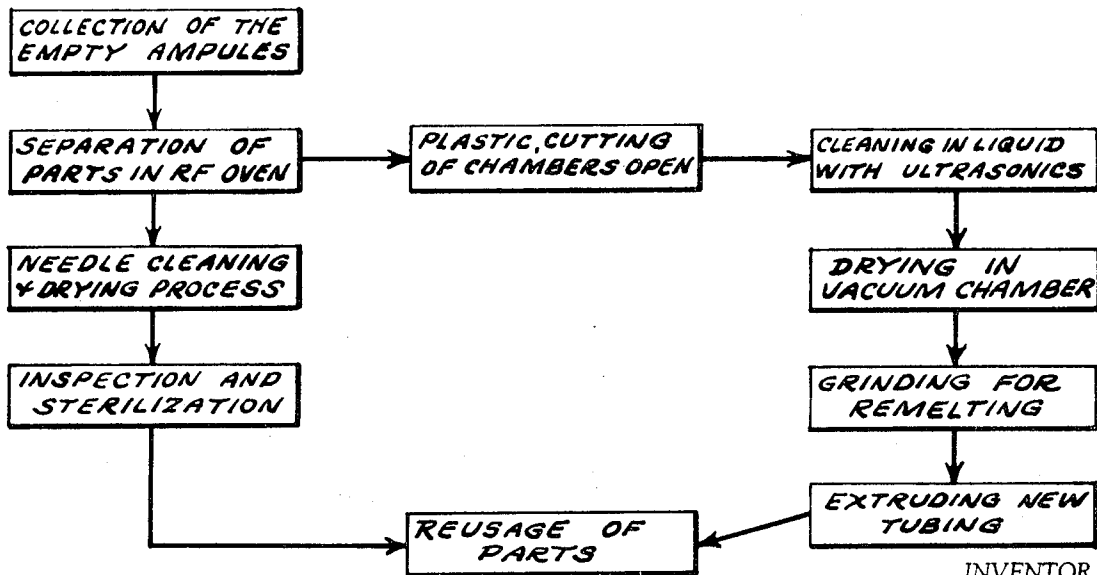


Fig. 21.

PROCESS FOR RAW MATERIAL RECOVERY



INVENTOR

BELA G. SZABO

BY

Richard E. Fleming

ATTORNEY

BURSTABLE SEAMED HYPODERMIC APPLICATORS

This invention relates to single-use hypodermic applicators, and more particularly to two-component hypodermic devices, each consisting of a hollow needle in permanent connection with a tubular flexible plastic container having one or more chambers therein for a liquid medicament, which is adapted to be forced from the container by finger pressure for ejection through the pointed end of the hollow needle.

It is the object of the present invention to provide a low-cost, burstable hypodermic applicator fabricated from flexible synthetic plastic sheet material in flattened tubular form of substantially uniform width, wherein may be effectively sealed the inner end of a hollow needle or cannula in a manner to make possible the accurate and reliable insertion of the hollow needle in a body to be treated and which, at the same time, maintains the liquid medicament in sealed and sterile condition in a separate chamber or compartment until the medicine is forced into the inlet end of the needle. The medicament is injected into the body with ease by the simple application of finger pressure to the outer wall of the medicament chamber, which serves to rupture a burstable seam at the front end of the latter and adjacent to the inlet end of the hollow needle. The continued application of pressure on the outer walls of the chamber forces the medicament from the latter through the hollow passage in the needle.

It is another object of the present invention to provide hypodermic applicators having one or more chambers for containing a medicinal medium, which gives rise to the capability of controlling the amount of medicament which may be selectively discharged through the needle.

It is another object of the invention to provide a single-use hypodermic applicator of low cost which may be used in emergency field applications without need for special training or experience of the administering operators.

The medicinal agents may be of any desired chemical compositions, in dependence upon the special needs to be served thereby. For example, these may be injections to prevent the incidence of all kinds of epidemics such as cholera, influenza, rubella, etc., or these injections may involve medicinal treatments, such as insulin injections to combat diabetes, or antibiotics for the purpose of combating infections. The components of the hypodermic applicators are of low-cost materials, such as synthetic plastic tubing of compositions which are inert to the medicinal compositions encapsulated thereby and hollow needles of stainless steel, which makes possible their rapid and reliable sterilization, decontamination and/or out-gassing before and after their assembly to preserve the hygienic and sterile characteristics thereof.

It is a further object of the invention to provide hypodermic applicators which may be packaged compactly and dispensed conveniently in a manner which does not disturb their sterile condition so that the hypodermic injections may be executed rapidly and effectively either in the field or under cover in buildings such as doctors' offices and hospitals. These applicators present a marked improvement over similar devices known previously, for example such as are disclosed in U.S. Pat.

No. 2,615,446, Oct. 28, 1952, and U.S. Pat. No. 3,192,925, July 6, 1965.

It is another object of the invention to provide single-use hypodermic applicators of simple components which may be salvaged after use and recovered for reuse, to lower the cost of the units and also to reduce the solid waste accumulation which is a growing problem not only in the broad field of ecology, but especially in the field of medicinal and hospital wastes.

Other objects and purposes will appear from the detailed description of the invention following hereinafter, taken in conjunction with the accompanying drawings, wherein

FIG. 1 is a perspective view of a burstable single-chamber hypodermic applicator in accordance with the invention;

FIG. 2 is an enlarged longitudinal sectional view along line 2—2 of FIG. 1;

FIG. 3 is a sectional view similar to FIG. 2, showing the device in operation for hypodermic injection;

FIG. 4 is an enlarged front view of the inner end of the hypodermic needle;

FIG. 5 is a plan view of FIG. 4, with parts broken away, to show clearly the integral divergent retaining arms of the needle;

FIG. 6 is an end view of FIG. 4;

FIG. 7 is a perspective view of a burstable double-chamber hypodermic applicator, constituting another embodiment of the invention;

FIG. 8 is an enlarged longitudinal sectional view along line 8—8 of FIG. 7, with parts cut away, showing a modification of the enlarged inner end of the needle;

FIG. 9 is an enlarged vertical sectional view along line 9—9 of FIG. 8;

FIG. 10 is a perspective view of a burstable triple-chamber hypodermic applicator, constituting another embodiment of the invention;

FIG. 11 is a longitudinal sectional view along line 11—11 of FIG. 10, illustrating diagrammatically the method of executing a hypodermic injection of the contents of only two of the chambers of the applicator;

FIG. 12 is an enlarged front view of another embodiment of the enlarged inner end of the hypodermic needle;

FIG. 13 is an end view of FIG. 12;

FIG. 14 is a horizontal sectional view along line 14—14 of FIG. 12;

FIG. 15 is an enlarged vertical sectional view of another embodiment of the enlarged inner end of the hypodermic needle;

FIG. 16 is an end view of FIG. 15;

FIG. 17 is a horizontal sectional view along line 17—17 of FIG. 15;

FIG. 18 is a perspective view of a packaging and dispensing unit of the hypodermic applicators in accordance with the invention;

FIG. 19 is a graphical representation of the relationship between the wall thickness of the tubing versus the width of the burst seal;

FIG. 20 is a graphical representation of the most economically efficient sizes of medicament chambers, correlating the wall thickness of the flexible tubing with the inner diameter of the latter; and

FIG. 21 is a schematic representation of the process for recovery of the raw materials constituting the hypodermic applicators in accordance with the invention.

In FIGS. 1 to 3 of the drawings is shown a single-use burstable applicator which is composed of a single-chamber containing a predetermined quantity of liquid medicament and which is designed to be ejected through a hollow cannula or needle 10 after the pointed end 11 of the latter is inserted into the body of a human or animal.

The chamber C is formed from a continuous length of flexible plastic tubing in flattened form, which is inert relative to the medicament M confined thereby, and is similar in design and function to the burstable fluid dispensers which are disclosed in my pending application bearing this title, Ser. No. 78,012, filed Oct. 5, 1970. The plastic tubing is preferably of the thermoplastic category known in the trade as the fluorocarbon and vinyl-chloride groups, which are marketed under many different trademarks such as Kel-F, Teflon, Saran, Surlyn, Aclar, etc. Polytrifluoroethylene, which is marketed by the 3M Company under the trademark Kel-F, has especially good properties, although tubing formed of other synthetic resins may also be used.

The plastic tubing is filled with a medicinal composition in a liquid vehicle, and is permanently sealed at the rear end 2 of the unit by the application of the sealing tools to the opposed faces 1,1' of the tubing for a short period of time so that the heat generated by radio-frequency or ultrasonic energy effects a permanent rectilinear seal of the unit at said end. The other end of the unit is sealed by the application of the suitably shaped tools across the entire width of the tubing to provide enlarged sealing areas 3,4 on the opposite sides of a narrowed area 5 at the mid-portion of the burstable seam, which is critically dimensioned to enable the rupture of the seal upon application of a reasonable finger pressure, generally between five to eighteen pounds.

The applicator is provided with a chamber 6 forwardly of the burstable seam between the latter and the front end of the applicator. A hollow needle 10, with a bore 10' extending therethrough, preferably of stainless steel, extends forwardly from the chamber 6. The outer end 11 of the needle is pointed for penetration into the body of a patient P, for either hypodermic, intravenous, intradermal or intramuscular application. The inner end 12 of the needle 10 is sealed within chamber 6 from the forward edge 7 on both sides of the needle and rearwardly thereof for a limited extent. The needle 10 is preferably in alignment with the gate for the medicinal material which is afforded by the area 5 of reduced dimension of the burstable seam. The inner end of the needle is furthermore provided with enlargements which may assume different forms in order to retain the needle within chamber 6 with stability, so that the holding of the applicator in the area H makes possible a reliable penetration of the pointed end of the needle into the body P to the desired extent and in the desired direction. Thereafter, the application of finger pressure to the rear end of the applicator, designated by the portion B, serves to rupture the burstable seam at the front end of the chamber C so that the medicament M passes therefrom into the chamber 6, and the continued pressure and movement of the fingers along the chamber C serves to eject the medicament through the hollow needle, as indicated in FIG. 3.

The enlargement at the inner end of the needle, which is sealed within chamber 6, may assume different forms. As shown in the embodiment illustrated in FIGS.

1 to 6, divergent arms 14,14' integral with the inner end of the needle, extend from diametrically opposite points of the needle in substantially the central flat plane of the tubular applicator body so that there is no tendency for the needle to turn within chamber 6, especially so since the opposite faces 1,1' of the tubular applicator are joined together from the seal 7 at the front edge of the applicator to the divergent arms. Thus, the two components of the hypodermic applicator are integrated effectively in a manner to facilitate the handling thereof for subcutaneous injection without affecting the communication between the gate from the chamber C and the inlet end of the needle 10 at point 12.

An alternative to this "swallow-tail" arrangement, afforded by the divergent arms 14,14', is shown in FIGS. 7 to 9 of the drawings, which embodies a hollow needle 20 having an internal bore 20' with a pointed outer end 21. The inner end of the needle is enlarged into a bell-shaped or conical configuration 22, the outer wall of which is sealed to the inner wall of the chamber 6. The bell-shaped mounting of the needle at the front end of the applicator and the sealing thereof in the forechamber 6 are of sufficient stability to enable a secure grasp of the needle at the base thereof and the penetration thereof into the body P, preparatory to the injection of the medicinal contents therethrough.

In addition, FIG. 7 shows the flexible flat-like tubular plastic body constituted by two chambers C and C' between which is disposed a supplemental burstable seam composed of wide sealing areas 3',4' and the intermediate reduced area 5'. The latter burstable seam is disposed equidistantly between the permanently sealed end 2 and the burstable seam adjoining the chamber 6. Thus, the application of finger pressure at the rear portion of the chamber C', adjacent to the permanently sealed end 2, forces the medicament in chamber C' to rupture the seal 5' to permit the contents of the medicaments in the two chambers to combine, and thereafter the continued finger pressure on the outer wall of the chambers C' and C causes the medicament to burst the seam at 5 for passage of the combined liquids into the inlet end of the hollow needle. If the contents of both chambers are the same, a double injection dosage results.

FIG. 10 illustrates still another embodiment of the invention in which the flat tubular plastic body is subdivided into three chambers C, C' and C'', with two burstable seams 3',4',5' and 3'',4'',5'' disposed equidistantly between the permanently sealed end 2 and the burstable seam 3,4,5 adjoining the chamber 6 housing the inner enlarged end of the needle 10. This arrangement makes possible a selective ejection of the contents of the applicator in varying amounts and, as illustrated in FIG. 11, only two of the dosages in chambers C and C' are employed for ejection. Of course, if the finger pressure were applied to the outermost chamber C'' the entire triple dosage in the three chambers would be ejected.

FIGS. 12 to 14 illustrate another mode of obtaining a swallow-tail enlargement of the inner end of the hollow needle 30. In this arrangement a hub 31, which may be of aluminum, stainless steel, or any other compatible metal, surrounds the outer surface of the needle 30 adjacent to its inlet end 33 and is joined thereto by brazing, soldering or resistance welding.

Another variant of the swallow-tail enlargement and anchoring of the inlet end of the needle is illustrated in

FIGS. 15 to 17. In this embodiment, the end of the needle may be slotted to permit the spreading of three arms. An additional arm 44 extends longitudinally of the needle 40 which supplements the divergent arms 43,43' on opposite sides of the projecting arm 44. This "bird-foot" effect enhances the stability of the seal of the inner end of the needle within chamber 6. In addition, it makes possible a more secure grasp of the front end of the applicator when a hypodermic injection is effected.

In all of the embodiments described above, the hypodermic applicator is conditioned for use by applying finger pressure to the outer walls of the plastic medicament chambers at the portion thereof immediately behind the one or more burstable seams which are desired to be ruptured, and sufficient pressure is applied until the liquid medicament appears at the outlet or pointed end of the hypodermic needle. The front of the applicator is then grasped for penetration into the body to be treated at the proper location and to the proper depth, and following this positioning of the needle, the plastic tubular chambers are compressed to eject the liquid medicament therefrom. In the case of multiple dosage units, it may be necessary to slide the fingers and thumb along the applicator to discharge the liquid medicine completely.

Following the completed injection, the needle is removed and either thrown away, or saved if the salvage or recovery of the components is contemplated.

Of course, the hypodermic applicators may be packaged in many different ways to maintain the same in sterile condition until they are used, for example, in glass or plastic jars, boxes or other receptacles. FIG. 18 illustrates an especially advantageous mode of storage by disposing a series of the applicators between a pair of sheets of paper or plastic which are preferably shaped to conform to the outlines of the applicators so that they securely encase part of the medicament containers as well as the needles projecting therefrom so that the latter may not be contaminated by the surrounding atmosphere. The sheets may be stripped apart to expose the desired number of applicators for utilization. Alternatively, the applicators may be withdrawn from between the sheets, as indicated in the uppermost applicator in FIG. 18. With this mode of withdrawal, the expended applicator may be re-inserted into the space between the sheets for the salvaging operations which are described below.

FIGS. 19 and 20 illustrate graphically desirable dimensions of the burstable applicator which supplement the critical dimensioning of the rectilinear burstable seams which respond to reasonably applied finger pressures and which are oriented in the direction to force the liquid medicament stored within one or more chambers toward the inlet end of the hypodermic needle. The special characteristics of the burstable seams are fully set forth in my above-mentioned application, which range at the reduced midportions from 0.020 to 0.040 inches. In addition, FIG. 19 illustrates optimum relationships between the depth of the burst seal and the tube wall thickness. As the latter increases, the depth of the burst seal should be increased correspondingly.

FIG. 20 portrays desirable relationships of the dimensions of the flexible tubing containing the liquid medicaments. As the dosage chambers become smaller, which require the use of continuous lengths of flexible

tubing of smaller diameters, the wall thickness of the tubing should decrease correspondingly. FIG. 20 indicates that tubing ranging in their inside diameters from approximately 0.2 inch to 0.8 inch should vary in thickness from approximately 0.005 inches to 0.015 inches.

As mentioned above, the provision of hypodermic applicators formed of only two components, which are heat-sealed to confine both the medicament and the metallic needles therein, lend themselves readily to salvaging of the components after the medicines are used up. FIG. 21 portrays schematically the salvaging operations which involve the collection of the empty ampules in large quantities and the heating thereof in an oven energized by radio-frequency energy, which serves to separate the metallic needles from the plastic. The needles are cleaned, dried and sterilized for repeated use. The plastic parts are washed so that all traces of the medicaments are removed therefrom and cleaned with the aid of ultrasonic energy which is followed by drying in a vacuum chamber. The plastic material is then ground for re-melting and is employed for extruding new tubing which may be combined with the metallic needle components and filled with liquid medicaments for repeated use.

If hollow injecting needles are combined with plastic fluid dispensing chambers for purposes other than hypodermic applicators, the contents of the chambers may be varied to attain different effects. Thus, the fluid contents may be selected to generate gas mixtures or combinations of fluent materials which may serve special purposes in the mixing of paints, sealing compositions, etc., which are injected into a space with the aid of a pointed needle.

I claim:

1. A single-use burstable hypodermic applicator comprising

- a. a flexible flat tubular plastic body of chemically inert material having at least two contiguous flattened sealed chambers of the same width, one behind the other along the length of said body with permanently sealed ends at the opposite ends thereof,
- b. a hollow needle of non-corrodible metal having an enlarged flattened end sealed within the forward flattened chamber and laterally extending substantially in the central flat plane of said body with the shank thereof extending from the medial portion of said front sealed end of the body and terminating in a pointed end adapted for hypodermic injection,
- c. a heat-sealed burstable seam at the rear end of said forward chamber to separate said last-mentioned chamber from the chamber rearwardly thereof,
- d. said rearwardly disposed chamber containing a medicament in a liquid vehicle, and
- e. said burstable seam being of uniform thickness but of differential depth in the longitudinal direction to provide a critically dimensioned narrowed area at the medial portion of said seam in alignment with the longitudinal axis of said hollow needle adapted to be forced open by the pressure of the liquid contents of the rearward chamber produced by a predetermined force of finger pressure applied to said rearward chamber, for forcing said liquid contents into the enlarged end of said needle and the ultimate ejection thereof from the pointed end of the needle.

2. A device as set forth in claim 1, wherein the enlarged flattened end of said needle comprises a pair of arms integral with the needle and diverging therefrom towards said burstable seam and disposed substantially in the central flat plane of said tubular body to facilitate manipulation.

3. A device as set forth in claim 1, wherein the enlarged flattened end of said needle comprises a pair of arms integral with the needle and diverging therefrom towards said burstable seam and disposed substantially in the central flat plane of said tubular body, and a third integral arm projecting longitudinally from the end of the needle in the plane of said pair of diverging arms.

4. A device as set forth in claim 1, wherein the enlarged flattened end of said needle comprises a cylindrical hub affixed to the outer surface of said needle adjacent the inner end thereof and a pair of arms integral with said hub and diverging therefrom in substantially the central flat plane of said tubular body.

5. A device as set forth in claim 2, wherein said needle is formed of stainless steel and said hub is of metal affixed to the stainless steel needle through the intermediary of a metal junction.

6. A device as set forth in claim 1, wherein said flexible flat tubular plastic body includes at least two sealed chambers disposed rearwardly of said forward chamber containing the inner end of said hollow needle, with a burstable seam therebetween similar to said burstable seam between the forward chamber and the chamber adjacent thereto.

7. A device as set forth in claim 1, wherein said flexible flat tubular plastic body includes three sealed chambers disposed rearwardly of said forward chamber with two equidistantly spaced burstable seams between the opposite ends thereof, to control selectively the quantity of liquid medicament adapted to be ultimately ejected from the pointed end of the needle.

8. A device as set forth in claim 1, wherein said flexible flat tubular plastic body is of substantially uniform width.

9. A device as set forth in claim 8, wherein said tubular plastic body ranges in internal diameters from 0.2 inches to 0.8 inches and with corresponding variations in wall thickness ranging from 0.005 inches to 0.015 inches.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,736,933 Dated June 5, 1973

Inventor(s) BELA G. SZABO

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In claim 2, column 7, line 6, after "manipulation" insert --thereof--.

In claim 3, column 7, line 8, "flatten" should be --flattened--.

In claim 5, column 7, line 20, "2" should be --4--.

In claim 7, column 8, line 8, "1" should be --6--.

Signed and sealed this 18th day of December 1973.

(SEAL)

Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

RENE D. TEGTMEYER
Acting Commissioner of Patents