Jan. 30, 1968 N. L. HOBBS 3,366,113

TAMPER-PROOF HYPODERMIC-SYRINGE CARTRIDGE UNIT AND METHOD OF MAKING

Filed Sept. 14, 1964

FIG.1.

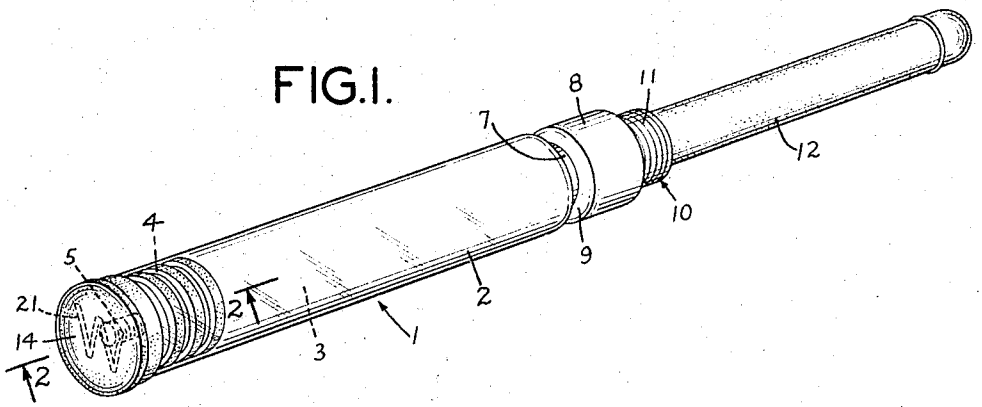
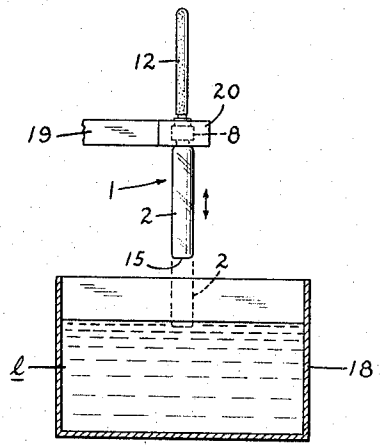



FIG.3.



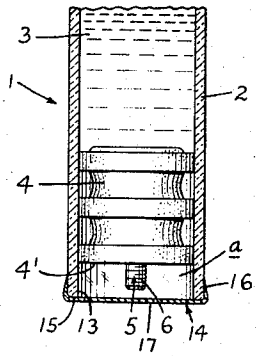




FIG.2.

INVENTOR
NORMAN L. HOBBS
BY
Andrew Kafes
ATTORNEY

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# TAMPER-PROOF HYPODERMIC-SYRINGE CARTRIDGE UNIT AND METHOD OF MAKING

Norman L. Hobbs, Rosemont, Pa., assignor to American Home Products Corporation, New York, N.Y., a corporation of Delaware

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## ABSTRACT OF THE DISCLOSURE

A disposable cartridge unit, to be used as or with a hypodermic syringe, is provided with a seal comprising a thin layer of flexible plastic material adhering to the otherwise open end of the barrel of the unit, to render the latter tamper-proof. The thin layer may be applied by a dipping process. Optionally, the exposed surface of the plastic layer is provided with a fluorescent dye imprint.

This invention relates generally to sealed containers for materials, and more particularly, to a tamper-proof cartridge unit for use as, or with, a hypodermic syringe.

Disposable cartridge units as, or for use with, hypodermic syringes for injecting medicaments of various kinds, have found widespread acceptance in the medical and related professions due to the obvious advantages inherent therein, particularly with respect to assurance of sterility, uniform dosage, economy, quick availability, ease of use, and the like. A disposable cartridge unit of the general type to which the present invention pertains is described and claimed in U.S.P. 2,671,449, which discloses an embodiment usable per se as a hypodermic syringe. U.S.P. 2,671,450 discloses another embodiment of said type, which, in this case, is adapted for use in a syringe device. Both types are presently available commercially under the "Tubex" trademark of Wyeth Laboratories, Inc.

While the foregoing and other advantages of the aforesaid disposable cartridges have unquestionably established them as standard commodities in this field, they have been found to have a single disadvantage which, as far as is known, has not yet been obviated to a desirable degree.

The single disadvantage referred to above resides in that the cartridge units, as presently conventionally provided, permit the possible removal, surreptitious adulteration, and/or contamination of the medicaments contained therein, by unauthorized persons. Thus, it is known that unauthorized removal of the liquid medicament from these now conventional cartridge units may be accomplished with the use of a very thin hypodermic needle for penetration of the piston or plunger in the open end of the barrel of the cartridge unit or by insertion of the needle between the plunger and the inner wall of said barrel. In some instances, access to the contents of the cartridge units may be achieved by the removal of the plunger from the barrel, withdrawal of some or all of the medicament contained therein, and ultimate replacement of the plunger.

The foregoing possibilities provide a very serious problem, particularly where the liquid contained in the cartridge unit comprises a narcotic. Thus, it is not uncommon for unauthorized persons, including addicts, to take great pains to remove all or some of the contents of a cartridge unit containing a narcotic and then to refill the same with another liquid, for example, water or saline solution, thereby to avoid easy detection of their activity. This is of potentially serious consequence, both to the patient, who may receive an ineffective or even contaminated injection, and to those whose addiction to a particular narcotic may be nurtured.



The above-described general problem has been recognized for some time by those skilled in the art, and various attempts have been made to solve said problem successfully. For example, as early as in U.S.P 1,782,938, which issued Nov. 25, 1930, it was suggested to seal both ends of a hypodermic syringe unit with a wax, primarily, however, for purposes of sterility. The wax was intended to be removed by application of heat at the time of use. Apart from the problem engendered by the necessity for heating such units when they are to be used, the expedient employed permits a comparatively easy method for unauthorized removal of the wax to provide access to the medicament therein, followed by replacement of the wax after tampering. Alternatively, it is possible to bore through the wax with a hot hypodermic needle, and on past plunger and into the medicament for withdrawing the same, and then refill the small hole made by the needle, simply by heating the wax and/or adding some thereto.

More recently, in U.S.P. 3,126,004, which issued Mar. 24, 1964, there is disclosed a hypodermic syringe cartridge unit provided with an antipilfering piston. In accordance with said patent, a thin film of sealing wax, or other similar material, covers the exposed face of the piston in the barrel of the cartridge unit and extends to, and is sealed onto, the inner wall of said barrel itself. It is specified in this patent that the sealing wax is of a character which is brittle at normal temperatures although viscous at higher temperatures. As envisioned by the patentee, any reciprocation of the piston relative to the wall of the barrel will result in crumbling or fracture of the sealing wax or similar material and thus provide a visible indication of any previous manipulation of the piston. Additionally, the exposed end face of the wax may have impressed therein an intricate pattern design, whereby such tampering with the wax seal as results in fracturing thereof will become readily apparent.

Since the film disclosed in the latter patent is brittle, it is likely to be broken by jarring or other occurrences than tampering with the piston. Hence, breaking of the film is not a positive indication of whether the seal has been tampered with, or the film has been broken inadvertently during handling, shipping, or the like. Moreover, the film is meltable, which permits removal thereof by heating, tampering with the piston to remove part or all of the medicament in the cartridge, and then replacement of the wax.

In the event the film has a design imprinted thereon, the wax may be penetrated without removal or breakage by means of a warmed needle through the film and then the piston to permit withdrawal of medicament from the cartridge unit, as referred to hereinabove with respect to U.S.P. 1,782,938. Similarly, the aperture may be closed by manipulation of the warmed needle, with addition of a small amount of wax, if necessary. To overcome this possibility, the patentee suggests, in one modification, the inclusion of a liquid dye between the face of the piston and the wax layer. Alternatively, it is suggested by the patentee that the wax may abut the face of the piston as in the first two embodiments, but in this case is impregnated with a heat-sensitive colour-changing dye. Since the wax has to be molten at the time of application to the face of the piston, this involves problems of selection and control of the temperatures at which the wax melts to assure that the colour-changing temperature of the dye is higher, as recognized by the patentee. Moreover, there is an inherent disadvantage in the application of the film on the piston face and the adjacent interior wall of the cartridge unit. It is not readily apparent how this may be accomplished with localization of the wax on

the piston face without fouling of the threaded stud on the exposed side of the piston to which the pushrod is attachable when the cartridge unit is to be used. Additionally, the wax is very apt to interfere with the aspirating stroke of the piston and also to result in soiling of the walls of the cartridge unit at that time with danger of contamination of the medicament when the piston is so reciprocated.

With the disadvantages of the cartridge units presently available in mind, including those units having the previously suggested, but insufficient, means intended to render them tamper-proof; it is a primary object of this invention to provide a cartridge unit having effective tamper-proof means associated therewith.

It is another object to provide a cartridge unit which, when opened for use, may no longer be closed by secure replacement of the sealing means, thereby to indicate to the user whether the cartridge unit has previously been tampered with, regardless of the fact that the full contents thereof may at least appear to be present.

Another object of the invention is to provide such a cartridge unit that also has means to indicate whether the seal of the unit has been tampered with even though it has not been completely broken.

Another object is to assure that after authorised breakage of the seal, the material thereof does not interfere at all with either the aspirating or injection stroke of the piston, or result in contamination of the medicament contained in the unit.

It is yet another object of the invention to provide a seal which avoids fouling of the threaded stud on the piston in the cartridge unit without engendering any complications with respect to application of the seal.

It is yet another object of the invention to provide a cartridge unit of the type described which permits transportation and storage of the unit with inadvertent breakage of the seal kept to a minimum.

Another object of the invention is to provide sealing means for said units, which sealing means are easily applied in a practical and economical manner suitable for use in mass production methods.

The foregoing and other objects and additions of the present invention will become apparent as a result of an understanding thereof upon references to the description that follows.

Generally, the tamper-proof, sterile disposable cartridge unit to be used as or with a hypodermic syringe, in accordance with the present invention, comprises: a glass barrel adapted to contain a liquid medicament, a plunger mounted in one end of said barrel, and a seal for said one end of said barrel; said seal comprising a thin layer of flexible plastic material adhering to the exterior surface of said barrel in the region of said open end thereof and extending transversely of said open end thereof and spaced from said plunger; said plastic material having an adhesive affinity for glass and a tensile strength which permits flexing without breakage. In a preferred embodiment of the invention, the web of plastic material forming the closure for the open end of the cartridge unit as provided with a fluorescent dye imprint.

In the forming of the sealed cartridge units of the invention, the cartridge body may be provided with a needle and a piston and filled with liquid medicament in the manner and sequence as heretofore for the particular unit to which the present invention is to be applied. Thereafter, the unit is merely dipped substantially vertically, with the open end of the cartridge disposed downwardly into a pool of suitable plastic material which preferably is a laquer. The dipping is preferably limited to just the region closely adjacent to the open end of the unit. In accordance with the invention, the piston, which is conventionally in fluid-tight sealing engagement with the interior walls of the cartridge, forms with said walls, to the edge of the open end of the cartridge, the equivalent of an air bell. This air bell prevents the liquid plastic material from entering into the interior of the open end of the cartridge. As a result, only the outside surface of the glass cartridge is wetted by the liquid plastic and, when the cartridge is withdrawn from the pool, a layer of the plastic material adheres to the outside surface of the end of the cartridge and forms a film across the open end thereof which, when withdrawn, dries and solidifies to form the final sealing web. After solidification of the plastic material, the end surface may be imprinted with a fluorescent dye. The flexibility of the material permits such imprint by pressing on of a printing implement without breakage of the web of plastic, which is supported on the open end of the unit only at the circumference thereof.

A better understanding of the invention will now be had upon reading the description of a specific embodiment of the invention, as an illustration thereof, set forth hereinafter with reference to the drawings wherein:

FIGURE 1 is a perspective view of a preferred embodiment of the novel, sealed, tamper-proof cartridge unit of the invention, the cartridge unit being shown with the imprinted seal intact;

FIGURE 2 is an enlarged fragmentary cross-sectional view of that end of the cartridge unit of FIGURE 1 which bears the seal, the section being taken on line 2—2 of FIGURE 1; and

FIGURE 3 is a schematic representation of a preferred method for applying the seal to the open end of a cartridge unit.

With reference to the presently preferred embodiment of the invention disclosed in the drawings the cartridge unit **1** comprises a barrel **2** of glass containing an ejectable medicament **3** retained therein at one end of the barrel **2** by a slideable rubber plunger **4** moulded with a metal inset or stud **5** provided with a male thread **6**. The opposite end of the barrel **2** is drawn out to a neck portion **7** which is provided at its distal end with a flange (not visible). This end of the barrel may be sealed by a rubber disc or gasket (also not visible) which is pressed firmly against the flange by a ferrule **8**, firmly mounted thereon, thus providing a liquid tight closure at this end of barrel **2**, as plunger **4** provides at the other end thereof. As known in the art, the ferrule may be of metal, as shown, in which case it is held firmly in place by an integrated thin skirt **9** which is rolled or crimped around the flange on barrel **2**. When the ferrule is of plastic material, it may be attached to the barrel by means of an adhesive.

The body of ferrule **8** is provided, at a reduced neck portion **10** thereof, with a male thread **11**, and is further extended in a cylindrical or slightly conical portion (not visible) of still further reduced diameter. Said last-named portion, as appears in FIGURES 1 and 3, is covered by a needle sheath **12**, which is referred to again hereinafter. Ferrule **8** is further provided with a cylindrical bore in which the usual injection needle (not visible) is rigidly mounted with a liquid-tight joint, as by swaging to metal ferrule **8**. The needle may be affixed to the ferrule by means of an adhesive when the ferrule is of plastic. As also disclosed in the aforesaid patents, the proximal end of the needle pierces the gasket so that the needle is in communication with the interior of barrel **2**. Sheath **12**, which also surrounds the needle to complete the unit **1**, is conventionally of a moderate elastic material such as natural rubber, synthetic rubber or other synthetic elastomer.

In accordance with the present invention, the open end **13** of barrel **2**, in which plunger **4** is frictionally maintained, has, as a seal thereover, a web **14** of a resilient flexible plastic material having an adhesive affinity for glass. As appears in FIGURE 2, web **14** abuts the circumferential edge **15** of the open end **13** of barrel **2** to which it is adhered. Web **14** further has its peripheral edge **16** extending along and adhered to the periphery of barrel **2** adjacent to the edge **15** thereof. The major centre por-

tion 17 of web 14 thus extends freely and without further support across the open end 13 of the barrel 2. As appears in FIGURE 1, the exterior surface of web 14 has imprinted thereon, with a fluorescent dye, an identifying and indicating mark or design 21, for a purpose referred to hereinafter.

In the production of the sealed cartridge unit 1 just described above, the unit, in otherwise conventionally finished form; as shown in FIGURE 3, is merely dipped vertically into a pool of lacquer 1 contained in a vat 18, by means of a mounting arm 19 of conventional design, which, as indicated in FIGURE 3 comprises a bifurcated clamping head 20. In accordance with the invention, the dipping is performed in a controlled manner whereby the end of the unit extends beneath the surface of the pool 1 for a limited distance only, as indicated in phantom lines in FIGURE 3. This distance, and vertical direction of dipping, is chosen so that the air pressure built up in the air bell formed by the sealed area *a* defined by the interior surface of the wall of barrel 2, the outwardly directed surface 4' of piston 4, and the surface of pool of lacquer 1, is still sufficient to prevent any substantial amount of lacquer 1 to flow into area *a*. Thus, while lacquer 1 wets the exterior surface of barrel 2 to the extent of the dipping in the pool, no wetting and/or adherence of lacquer occurs with respect to the interior surface of the wall of barrel 2. The ultimate result is that upon lifting of the unit from the pool, a thin film of lacquer adheres to the barrel 2 only at the exterior surface of open end 13 and at circumferential edge 15 with a connecting portion 17, and results in the final sealing web 14 upon drying. After drying operation, the unsupported end web is preferably imprinted with the fluorescent dye by pressing a conventional printing instrument (not shown) thereagainst to provide a mark or insignia. The flexibility of the web permits such imprinting without rupture of the web.

In the event the unit 1 is dipped other than substantially vertically, the air bell will not be formed in time to prevent interior wetting of the barrel 2. On the other hand, even if the unit is dipped vertically, but the extent of dipping is not limited, the increased hydrostatic pressure in the pool at increased depth proportionately compresses the air in the air bell, whereby flow of liquid thereinto is no longer prevented and the interior wetting occurs accompanied by the undesirable depositing of material within the barrel in the path of the piston and even on the stud to foul the same.

While various suitable lacquers may be used for the above described method for providing a seal for the cartridge unit, preferably, the plastic is a lacquer which at room temperatures has a viscosity of, say, about 380 c.p.s. and, when dried in a film adhered to the glass cartridge units, provides a flexible web of a thickness of from about .004 inch to about .015 inch. Several preferred formulations for such lacquers which must have the requisite glass wetting and adherence, film forming, and ultimate dried web flexibility are given below:

FORMULATION A

| | | |
|---|---|---|
| Pyroxylin | gms | 4.0 |
| Ethyl oxide | cc | 75.0 |
| Alcohol | cc | 25.0 |

to make ca. 100 cc.

FORMULATION B

| | Grams |
|---|---|
| Camphor | 2.0 |
| Castor oil | 2.0 |
| Collodion, q.s. ad | 100.0 |



FORMULATION C

| | Parts |
|---|---|
| Collodion wool | 30 |
| Polyglycol | 4 |
| Butyl acetate | 45 |
| Butyl alcohol | 4 |
| Toluol | 10 |
| Acetone | 6 |
| Castor oil | 1 |
| | 100 |

FORMULATION D

| | Ounces |
|---|---|
| Glycerin | 0.5 |
| Ether | 4.65 |
| ZnO | 15.0 |
| Acetone | 19.0 |
| Amyl acetate | 18.0 |
| Butanol | 22.0 |
| Celluloid | 22.0 |
| Olive oil | 0.5 |
| Ultramarine | 0.15 |
| Lavender oil | 0.20 |

In the use of the cartridge-syringe units, sealed in accordance with the present invention, the user merely inserts the push rod (which may be provided with the unit, as disclosed in U.S.P. 2,671,449 referred to hereinbefore; or by the syringe with which the unit is to be employed, as disclosed in U.S.P. 2,671,450 also referred to hereinbefore), through the free central portion 17 of web 14 and into engagement with the thread 6 on stud 5 of the piston or plunger 4 of the unit and rotated for attachment therewith. Thereafter, the unit may be utilized in the usual manner.

Because of the inherent nature of the lacquers employed in the exercise of the invention, there is no need to peel off any part of the web formed thereby at any time; the penetration with the push-rod as described is sufficient to break the seal. Moreover, because of the location of the web at the extreme end of the barrel, there is no opportunity for the lacquer material thereof to interfere with the reciprocation of the plunger or to soil the walls in which the plunger slides and to risk danger of contamination, as occurs with certain of the prior art sealing arrangements. Because of the flexibility of the lacquer, the portion that remains subsequent to penetration by the push-rod does not interfere in the least with the movement of the latter during the usual aspirating and injecting reciprocation thereof.

On the other hand, in the event an attempt is made by an unauthorized person to insert a needle of small diameter into the cartridge unit to withdraw liquid therefrom by penetration through the side of the piston as referred hereinbefore, an aperture will be left in the web of lacquer. This aperture then functions to alert the authorised user to the possibility of prior pilferage, contamination, or other tampering. In the event the unauthorised person attempts to re-seal the lacquer as by application of additional lacquer in liquid form, the solvent therein will cause the fluorescent dye of the imprint to become spread over the surface of the web. This occurrence can be detected easily upon the routine use of an ultra violet light source, thereby to disclose at once the prior occurrence of this type of tampering.

It will be apparent that the comparatively simple but novel method of the present invention permits the production of effectively sealed cartridge units in a facile, economical way, which is nevertheless fully effective in providing such units inherently capable of alerting the ultimate user as to whether the units have been tampered with or not.

While a specific embodiment of the invention has been described above, it will be understood that such embodiment is intended to be illustrative only. It is to be further

understood that all modifications of said embodiment, or variations therefrom, which conform to the spirit of invention, as defined in the claims appended hereto, are intended to be included in the scope thereof.

I claim:

1. A method of rendering tamper-proof a cartridge unit having a plunger in the unobstructedly open end thereof, which method comprises: providing a pool of lacquer that has an adherent affinity for glass and which, when dried in a film, forms a flexible web having a thickness of from about .004 inch to about .015 inch; dipping a cartridge unit substantially vertically, with the unobstructedly open end of the barrel thereof downwardly, into the pool a limited distance so that the lacquer wets the exterior surface of the cartridge but is prevented from entering interiorly of the barrel via the open end thereof due to the air entrapped in the open end solely by the interior walls of the barrel, the plunger positioned therein and the surface of the pool of lacquer, lifting the cartridge unit out of the pool, and permitting the lacquer adhered to the exterior surface of the barrel and extending in a film across the open end thereof to dry and form a self-sustaining flexible web thereon.

2. A method of rendering tamper-proof a cartridge unit having a plunger in the open end thereof as defined in claim 1 wherein a fluorescent dye mark is printed on the exposed surface of the self-sustaining flexible web by pressing a printing implement thereagainst.

3. A method of rendering tamper-proof a cartridge unit having a plunger in the open end thereof, as claimed in claim 1, wherein the cartridge is dipped into the pool a limited distance, which is less than the distance from the plunger to the edge of the open end of the barrel.

4. A method of rendering tamper-proof a cartridge unit having a plunger in the open end thereof, as claimed in claim 3 wherein the pool of lacquer has a viscosity of about 380 cps. at 25° C.

5. A method of rendering tamper-proof a cartridge unit having a plunger in the open end thereof, as defined in claim 3, wherein the plunger is provided with a threaded stud adapted for attachment with a push-rod and the cartridge unit is dipped into the pool a limited distance, which is less than the distance from the stud to the edge of the open end of the barrel.

6. A tamper-proof cartridge unit comprising a glass barrel adapted to contain a liquid medicament, means sealing one end of said barrel, the remainder of said barrel being of a cylindrical shape having a substantially uniform cross-section defined by a wall of substantially uniform thickness, said barrel having the other end thereof open and defined by a circumferential edge of cross-sectional and thickness dimensions substantially equal to that of the remainder of said cylindrical barrel and wall thereof respectively, a plunger mounted within said barrel and located inwardly from said open end thereof, a threaded stud mounted on said plunger and directed outwardly so that it is adapted to have attached thereto a threaded push-rod, and a seal for said open end of said barrel, said seal consisting of a thin layer of flexible plastic material having a circumferential portion thereof adhering to the exterior surface of said barrel in the region of said open end thereof and a substantially flat portion thereof extending transversely of said open end and across said circumferential edge and spaced from said plunger, said portion of said thin layer which extends transversely of said open end, having the circumferential region thereof adhered to said circumferential edge of said end and extending substantially in the diametric plane of said circumferential edge and free of attachment to said stud on said plunger, said plastic material having an adhesive affinity for glass, a tensile strength which permits flexing without breaking, and a thickness of from about 0.004" to about 0.015", and a fluorescent dye mark on the exposed surface of said portion of said thin layer of film which extends transversely of said open end of said barrel.

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RICHARD A. GAUDET, *Primary Examiner.*

D. L. BAKER, *Assistant Examiner.*