

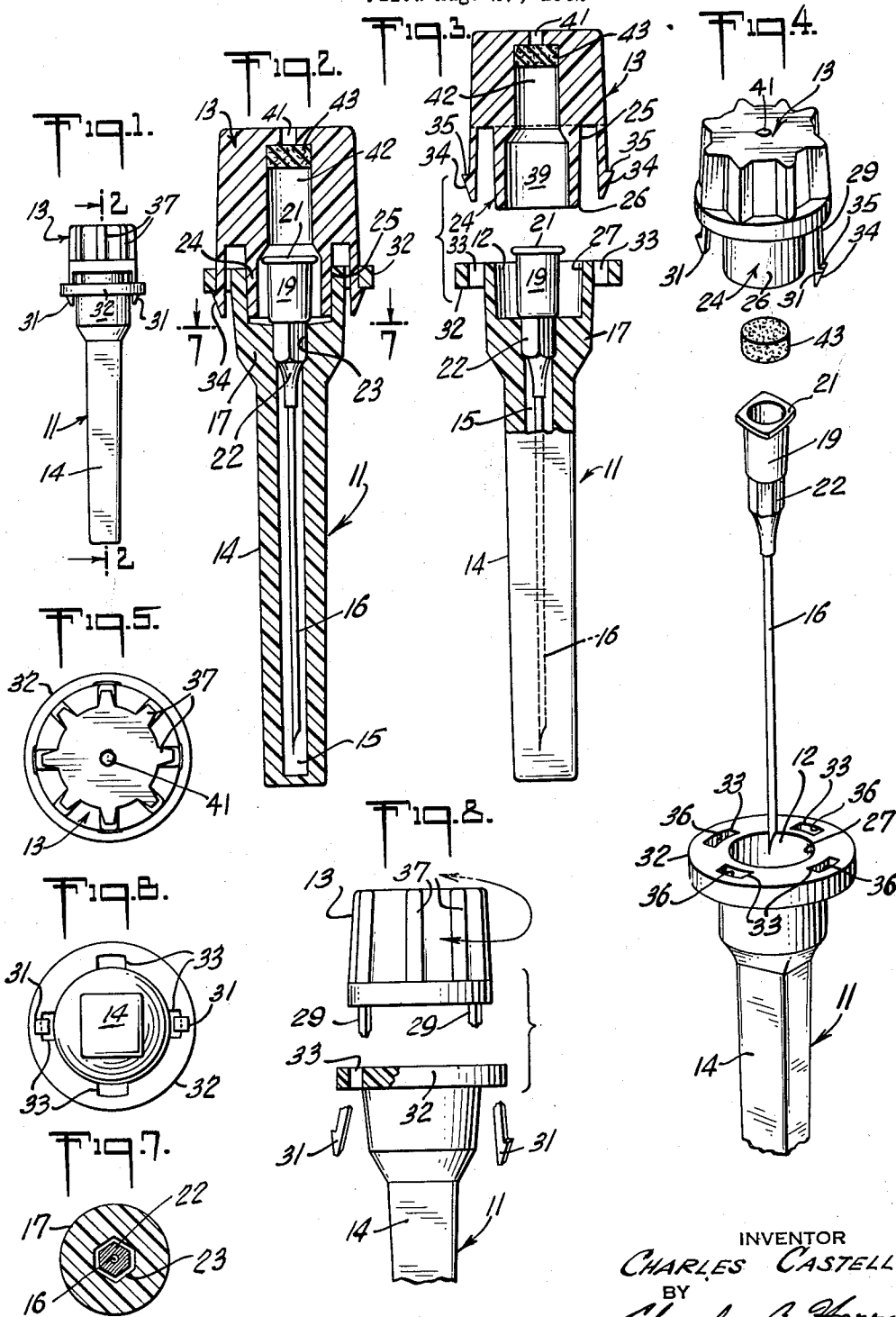
Sept. 22, 1964

C. CASTELLI

3,149,717

CONTAINER FOR HYPODERMIC NEEDLE

Filed Aug. 27, 1962



INVENTOR
CHARLES CASTELLI
BY
Charles A. Harris
ATTORNEY

1

3,149,717

CONTAINER FOR HYPODERMIC NEEDLE

Charles Castelli, New Brunswick, N.J., assignor to Johnson & Johnson, a corporation of New Jersey
Filed Aug. 27, 1962, Ser. No. 219,492
6 Claims. (Cl. 206—43)

The present invention relates to containers for hypodermic syringe needle units of the type which comprises a needle secured to a hub and which, in turn, is adapted to be fitted on one end of a hypodermic syringe.

Typically, the hubs of such units are adapted to be screwed, or otherwise turned, into grooves or other portions of the front end of the syringe. The syringe normally is especially adapted to receive the unit. The container may be divided into two main components, i.e., a holder, or shell, having an open bore at one end for receiving and holding a needle unit, and a cap for closing the open end of the shell. The hub may be provided with a portion of non-circular cross section adapted to slide axially into a corresponding portion of non-circular cross section in the shell, so that the shell may be used as a wrench to apply the hub to a syringe through the open end of the shell.

The present invention contemplates a needle container of this general type, wherein the cap comprises a closure portion adapted to fit tightly into, or plug, the open bore of the hub to provide a hermetic seal therewith so that the interior of the container and its contents may be maintained sterile. The leading end of the closure portion extends well into the container bore and is maintained sterile as long as the container remains closed with the closure portion of the cap in position in the shell. Thus, when the closure portion and the remainder of the cap is removed from the shell, the adjacent portions thereof which might come into contact with the hub or the inner end of the needle, if a double ended needle is employed, are sterile and therefore can not contaminate the hub or the needle by contact therewith during removal of the cap from the container.

A further feature of this invention is the provision of mechanical means for locking the cap in position on the shell and providing a tamper-proof device which indicates when the container is open. Locking means is provided on the cap which is adapted to enter into engagement with cooperating means on the shell as the cap is moved axially, with respect to the needle unit, into position to seal off the open end of the shell. A non-reversible cam action occurs between the locking means and the cooperating portions of the shell as the cap is moved into position on the shell so that the cap may not be removed from the shell by reversing the movement of the cap with respect to the shell. More specifically, the cap has locking portions which are adapted to spring into locking engagement with portions of the shell when the cap is moved axially into position on the shell, but which can not spring out of engagement with the shell if an attempt is made to remove the cap axially from the shell. The locking portions of the cap are attached to the cap by a plurality of thin frangible extensions which may be broken by twisting the cap with respect to the shell. Once the extensions are broken, the locking means are separated from the cap thereby allowing removal of the cap from the shell and permitting access to the needle unit contained therein. Since the container can only be opened by breaking the extensions, a positive indication is provided when a given container has been opened or tampered with.

To allow sterilization of the inside of the container and its contents with a sterilizing gas or fluid such as ethylene oxide or steam, a hollow sterilizing passage is provided in the cap connecting the bore of the shell with the out-

2

side atmosphere. Blocking means, preferably in the form of fluid-flow-permitting filtering means, is provided in the passage for preventing movement of bacteria into the container but permitting movement of sterilizing fluid through the passage and into the bore.

Other and further advantages of the invention will be apparent from the following description and claims taken together with the drawings wherein:

FIG. 1 is a view in elevation of a needle container according to one embodiment of this invention;

FIG. 2 is an enlarged view partly in section and partly in elevation taken along the line 2—2 of FIG. 1;

FIG. 3 is a view similar to that of FIG. 2 showing the cap as it approaches the shell prior to assembly of the cap and the shell;

FIG. 4 is an exploded view showing the various parts of the needle container of the preceding figures, including the needle unit;

FIG. 5 is a top plan view of the needle container of the preceding figures at the same enlargement as FIG. 2;

FIG. 6 is a bottom plan view of the needle container of the preceding figures;

FIG. 7 is a sectional view taken along the line 7—7 of FIG. 2;

FIG. 8 is a view partly in section and partly in elevation and showing the removal of the cap from the shell after the cap has been twisted, or rotated with respect to the shell, to break the locking ribs.

Referring to the drawings, there is shown a needle container according to one embodiment of this invention, which comprises an elongated holder, or shell, 11 having an open bore 12 at one end, and a cap 13 for closing the open end of the shell. The shell 11 has an elongated front portion 14 defining a hollow chamber 15 for receiving the needle, or cannula, 16 of a hypodermic syringe needle unit; and a widened rear portion 17 defining the open bore 12 for receiving the hub end of the needle unit. The needle hub normally comprises a base portion 19 having a flange 21 for fitting with a hypodermic syringe, not shown, and a front portion 22 of noncircular, in this case hexagonal, cross-section. A corresponding portion 23 of hexagonal cross-section is provided at the top of the hollow chamber 15 of smaller cross-section just where it joins the larger bore 12 in the shell, as shown most clearly in FIG. 7. Thus, once the needle unit is inserted in the shell it may be removed axially, or longitudinally, therefrom but can not be rotated with respect thereto since the fit between the corresponding hexagonal portions of the hub and the shell prevents this.

The cap comprises a hollow closure portion 24 having a plugging section 25 which is adapted to fit into the hollow bore 12 of the shell and form a hermetic seal therewith. The outside surface of the closure portion 24 is substantially cylindrical but tapered slightly outwardly away from the center line of the container from the front to the rear of the closure portion. The outside diameter of the front end 26 of the closure portion is slightly less than the inside diameter of the mouth 27 of the bore in the shell, whereas the diameter of the plugging section 25 of the closure portion, which is spaced from the end of the closure portion, is slightly greater than that of the mouth 27 of the bore. Thus, when the closure portion is inserted fully in the bore, the plugging section is distorted slightly to press firmly against the inside of the bore 12 at the mouth 27 of the bore to provide a hermetic seal therewith along a circular line spaced substantially from the inside end 26 of the closure portion. This assures that the end and side surface portions of the closure portion, itself, are maintained sealed off and sterile inside the container as long as the cap remains in position on the shell.

3

As shown most clearly in FIGS. 2, 3, 4, and 6, a pair of thin frangible extensions 29 spaced approximately 180° from one another about the axis of the container depend from the cap 13 toward the shell 11. Each of the extensions 29 is connected at one end to the cap 13 and is integral therewith. The extensions 29 define detents 31 at their lower ends for engaging the shell and the shell 11 presents a radially extending peripheral flange 32 which defines a set of four slots 33 spaced approximately 90° from one another for cooperating with the detents 31 for holding the cap in position on the shell. The flange 32 is connected to, and integral with, the rear end 17 of the shell 11. The detents 31 have an external inclined face 34 which terminates in locking means in the form of a locking ridge 35 and the diametrical distance across opposite locking ridges 35 is substantially greater than diametrical distance between the outside surfaces 36 of the corresponding cooperating slots in the flange. However, the diametrical distance between the front ends of opposite inclined surfaces 34 of the detents 31 is less than the distance between the outside surfaces 36 of the corresponding slots. Thus, when the two detents 31 are registered with a corresponding pair of slots 33 the cap 13 may be pressed into contact with the shell 11 in such a way that the closure portion 24 fits into the bore 12 of the shell and the inclined surfaces 34 of the detents 31 provide a cam action with the outside surfaces 36 of the slots 33 which deflects the detents radially inwardly toward the center line of the container to allow them to pass through the slots. The extensions 29 are sufficiently resilient to allow the detents to be deflected in this manner and to cause them to spring back to their normal position wherein the ends of the inclined surfaces hook under the peripheral flange 32 of the shell. Thus, once the cap 13 is in position on the shell 11, it can not be removed therefrom without breaking something, since the detents 31 prevent axial movement of the cap away from the shell as well as radial movement with respect thereto. However, if the extensions 29 are broken the cap 13 is no longer mechanically connected to the shell 11 and may be removed therefrom for access to the contents of the container.

The extensions 29 are constructed in such a way that when the cap 13 is twisted, or rotated, with respect to the shell 11 the extensions will break when only a moderate force is used to twist the cap. The elongated front portion 14 of the shell has an outer surface which is square in cross section, as shown most clearly in FIG. 6, to enable the shell to be gripped easily when the cap is twisted with respect thereto. A series of flutes 37 is provided around the cap to facilitate gripping the cap for the same purpose. The result of twisting the cap 13 with respect to the shell 11 is shown graphically in FIG. 8. It is clear from this figure that the broken portions of the extensions 29 which remain attached to the cap 13 and the absence of the detents 31 provide a positive indication that the container either has been opened or tampered with, and thereby provide a tamper-proof feature which insures the sterility of the contents of the container.

In the embodiment shown in the drawings, a pair of extensions 29 and corresponding detents 31 spaced approximately 180° from one another about the center line of the container are provided; and a set of four (4) slots 33 spaced approximately 90° from one another about the center line of the container are located in the flange 32 of the shell for engaging the extensions. Obviously only two of the slots 33 spaced 180° from one another can cooperate with the two extensions 29 for any one position of the cap 13 on the shell 11. However, four slots 33 are provided in the flange 32 to make it easier to register the extensions 29 of the cap with respect to the slots of the shell.

The cap 13 defines a hollow passage communicating with the bore 12 of the shell and with the atmosphere

4

surrounding the container when the closure portion 24 of the cap is in position in the bore 12 of the shell. The hollow passage comprises a broadened lower section 39 for receiving the base portion 19 of the needle hub when the cap is in position on the shell; a small diameter opening 41 in the top surface of the cap; and an intermediate portion 42 of somewhat larger diameter than the opening 41 connecting the opening 41 to the broadened section 39 of the passage. Fluid-flow-permitting filtering means in the form of a flat cylindrical filter 43 is positioned in the top of the intermediate portion 42 of the passage in such a way that a fluid entering the container from the outside atmosphere through the opening 41 at the top of the cap must pass through the filter. The filter 43 may comprise a disc of sterile cotton fibers, or the like, but in any case it is constructed so that it prevents the movement of bacteria from the outside atmosphere to the interior of the container while permitting a sterilizing fluid, such as ethylene oxide gas or steam, to pass there-through.

The various parts of the container of this invention may be formed from any suitable material. Preferably, however, the cap 13 is formed from a plastic such as polystyrene which is sufficiently brittle to allow the frangible extensions 29 to be broken easily when the cap is twisted with respect to the shell 11 to open the container. The shell 11 preferably is formed from a material such as polyethylene or polypropylene, which is sufficiently tough to provide the desired mechanical protection, and sufficiently resilient and impermeable to allow the parts to fit together and provide a hermetically sealed container which completely shields its sterile contents from contamination. The thickness of the extensions 29, where they are to be broken for opening the container, must be chosen to suit the type of material of which they are made so that they are neither too fragile nor too strong to accomplish their desired function.

Having now described the invention in specific detail and exemplified the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art that innumerable variations, applications, modifications, and extensions of the basic principles involved may be made without departing from its spirit or scope.

The invention claimed is:

1. A needle unit package comprising a shell holding a needle unit therein and having a normally open end defining a bore of circular cross-section for insertion of the needle unit in the shell and removal of the unit therefrom; and a cap closing the open end of the shell and providing a hermetic seal therewith and a sterile enclosure for the needle unit, said cap comprising a closure portion fitting tightly in said bore, a plurality of frangible extensions spaced circumferentially about said closure portion and connected at one end to said closure portion, locking means formed at the opposite ends of said extensions, and cooperating means formed on said shell and engaging said locking means axially for preventing axial movement of the cap away from the shell and engaging said locking means laterally for preventing rotative movement of the cap with respect to the shell, said frangible extensions being adapted to break when the closure portion of said cap is rotated by hand with respect to said shell, thereby allowing the closure portion of the cap to be removed from the shell and at the same time indicating that the package has been opened, said closure portion comprising a hollow plugging section having a normal outer diameter slightly greater than a corresponding portion of said bore and being inserted tightly into said corresponding bore portion to provide a hermetic seal between the cap and the shell along a circular line spaced substantially from the inside end of said closure portion, the hollow plugging section being open at the bottom and the outer end of said needle unit being positioned within said plugging section when the cap is locked in position on said shell, whereby the end and side surface portions of said closure portion inside of said circular line

5

are maintained sterile as long as the cap is in position on the shell and said sterile surface portions protect the needle unit from contamination on removal of the cap from the shell.

2. A needle unit package according to claim 1 wherein portions of said locking means are displaceable radially with respect to the shell to enter into engagement with said cooperating means, and corresponding surfaces of said locking means and said cooperating means are shaped to provide a nonreversible cam action for radially displacing said locking means during assembly of the cap on the shell.

3. A needle unit package according to claim 2, wherein the locking means are in the form of wedge-shaped detents and said cooperating means comprises radially extending flange portions defining openings for receiving said detents.

4. A needle unit package according to claim 1, wherein the cap defines a hollow passage communicating with said bore and with the atmosphere surrounding the package when the closure portion is in position in the bore, and which further comprises blocking means associated with said passage for preventing the movement of bacteria but permitting the movement of sterilizing fluid through the passage and into said bore.

5. A needle container according to claim 4, wherein said blocking means comprises fluid-flow-permitting filtering means.

6. A needle unit package according to claim 1, wherein the shell defines a wrench portion of noncircular cross-section adapted to receive a needle unit having a corre-

6

sponding noncircular cross section and the needle unit may be moved axially but not rotated with respect to the shell when the noncircular cross section of the needle unit is in position in the wrench portion of the shell, whereby the shell may be used as a wrench in applying the needle unit to a syringe after the cap is removed from the package.

References Cited in the file of this patent

UNITED STATES PATENTS

695,759	McNish	Mar. 18, 1902
2,092,547	Allenbaugh	Sept. 7, 1937
2,122,294	Regan	June 28, 1938
2,162,712	Hamberger	June 20, 1939
2,162,754	Schauer	June 20, 1939
2,690,947	Roehrl	Oct. 5, 1954
2,695,723	Waterman	Nov. 30, 1954
2,744,650	Woessner	May 8, 1956
2,899,097	Haskins	Aug. 11, 1959
2,929,510	Penn	Mar. 22, 1960
2,953,243	Roehr	Sept. 20, 1960
3,021,942	Hamilton	Feb. 20, 1962
3,025,989	Williams	Mar. 20, 1962
3,028,992	Bucher et al.	Apr. 10, 1962
3,071,800	Patriquin	Jan. 8, 1963

FOREIGN PATENTS

216,920	Austria	Aug. 25, 1961
397,792	Great Britain	Aug. 31, 1933
1,008,136	France	Feb. 13, 1952