

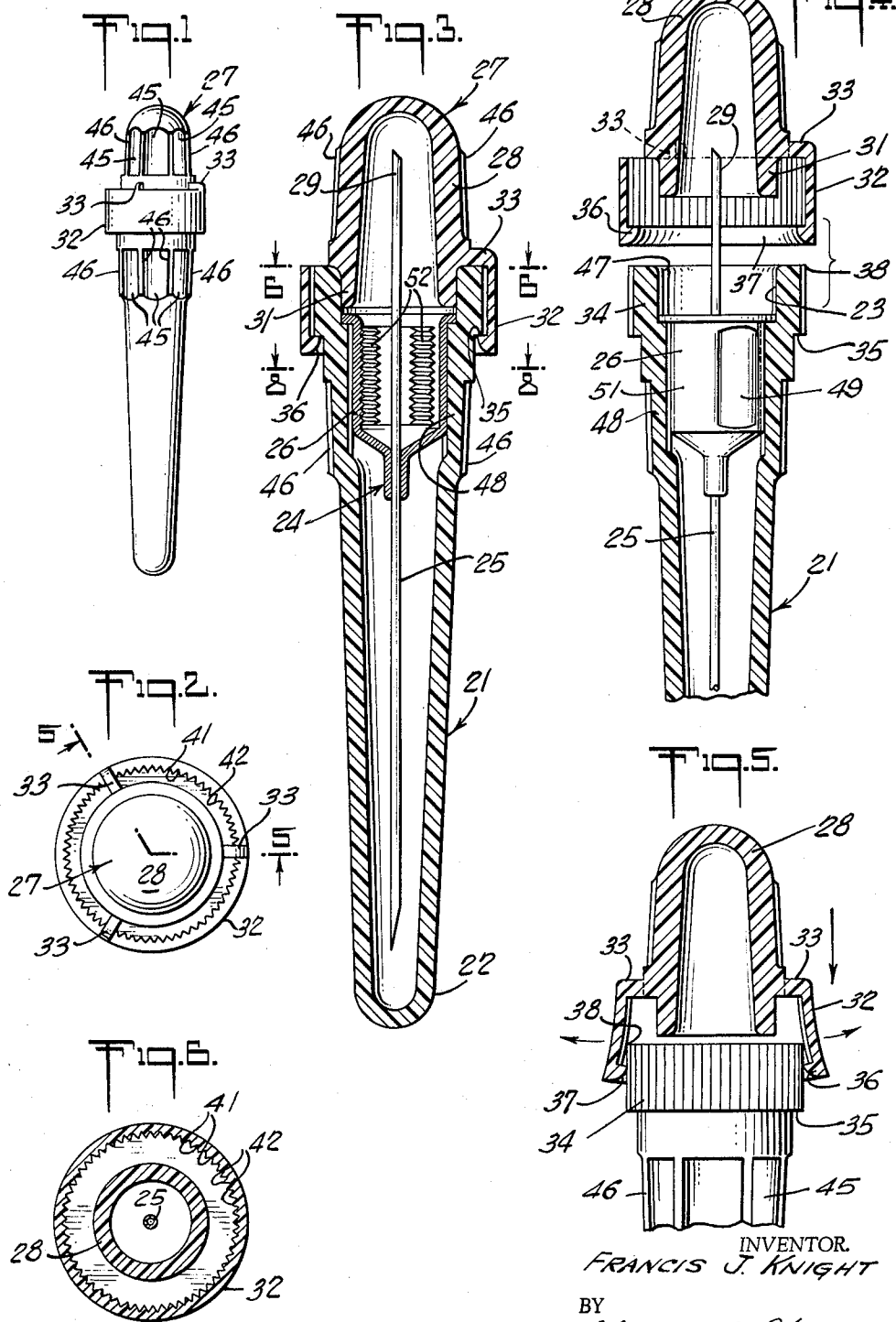
April 12, 1966

F. J. KNIGHT
STERILE CONTAINER

3,245,567

Filed Aug. 27, 1962

2 Sheets-Sheet 1



INVENTOR.
FRANCIS J. KNIGHT

BY
Charles C. Harris
ATTORNEY

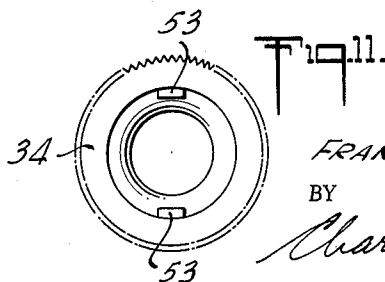
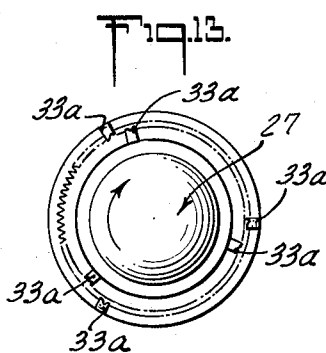
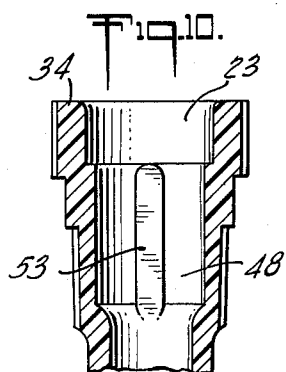
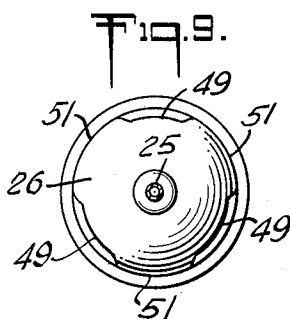
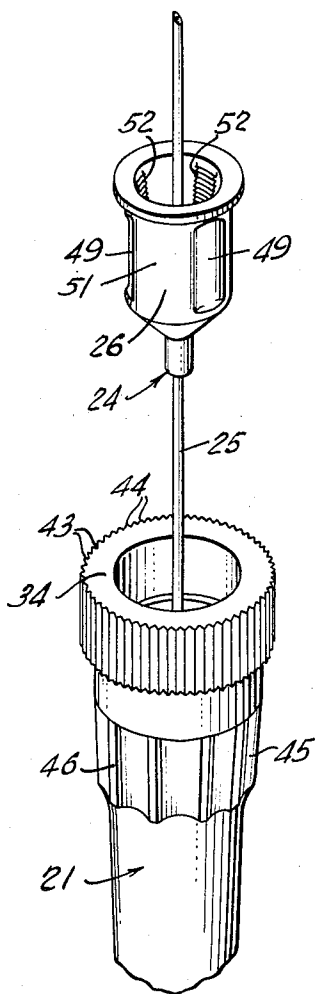
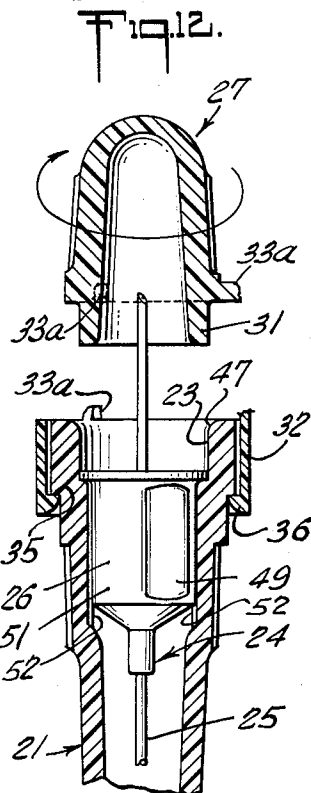
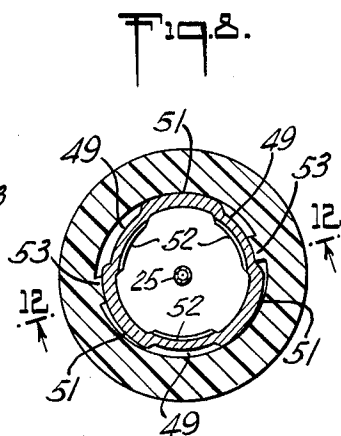
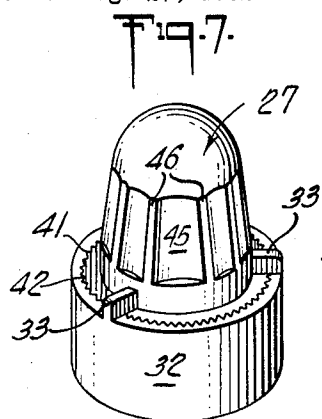
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2 Sheets-Sheet 2



INVENTOR.
FRANCIS J. KNIGHT
BY
Charles A. Harris
ATTORNEY

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3,245,567

STERILE CONTAINER

Francis Joseph Knight, New Brunswick, N.J., assignor to
Johnson & Johnson, a corporation of New Jersey
Filed Aug. 27, 1962, Ser. No. 219,435
4 Claims. (Cl. 215-42)

The present invention relates to sterile containers for hypodermic syringe needle units and the like, more particularly to such containers which are tamper-proof and made up of two basic halves, or parts, which are locked together by mechanical means so that the container can only be opened by breaking a structural element of one of the parts.

In the copending application of Charles Castelli, Serial No. 219,492, filed August 27, 1962, a container of this type is disclosed and claimed. The container of that application comprises a shell having an open end for receiving a needle unit and a cap for closing the open end of the shell. Locking means presented by the cap are adapted to engage cooperating means on the shell as the cap is placed in position on the shell in such a way that the cap is locked on the shell against axial or radial movement with respect thereto. The locking means is connected to the cap by a plurality of thin ribs and the ribs are adapted to break when the cap is twisted with respect to the shell thereby allowing the cap to be removed from the shell. Thus, since access to the contents of the container can be obtained only by breaking the ribs, a clear indication is provided as to whether or not the container has been opened or tampered with.

In the embodiment disclosed in the above-cited Castelli application, the locking means connected to the ribs comprise wedge shaped detents and the cooperating means presented by the shell is in the form of a radially extending flange having slots through which the detents are passed to engage the flange. This means that the detents must be registered with the slots in the flange in order to assemble the cap on the shell.

The present invention contemplates a tamper-proof sterile container of this general type wherein the locking means on the cap need not be registered with the cooperating means presented by the shell and, in fact, is adapted to be placed in full engagement with the shell merely by pressing the cap and the shell together regardless of their angular disposition with respect to one another.

According to the instant invention, a locking ring is connected to a plurality of thin ribs spaced circumferentially about a closure portion of the cap, and a holding rim is presented by the shell for engaging the locking ring when the cap is in position on the shell. The inner diameter of the locking ring is less than the outer diameter of the holding rim and the locking ring is prevented from rotating with respect to the holding rim when in position thereon by the engagement occurring between the inside surface of the locking ring and the outside surface of the holding rim due to the differences between their respective inner and outer diameters. Preferably, the inner surface of the locking ring presents a multiplicity of grooves and teeth running in a generally axial direction and the outer surface of the holding rim presents a corresponding number of alternating grooves and teeth running in the same direction. In this case, the inner

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diameter of the locking ring and the outer diameter of the holding rim is measured across the tips of their respective teeth and the teeth of the ring are adapted to mesh with the grooves of the rim and vice versa so that the locking ring and the holding rim are mechanically engaged with one another in such a way as to prevent relative rotative movement between them when the ring is in position on the rim.

In addition, the locking ring presents a flange portion extending radially inwardly beyond said holding rim from the leading end of the locking ring when the cap is in position on the shell. The locking ring is formed of a resilient material and either the locking ring or the holding rim presents an inclined annular surface for creating a nonreversible cam action between the leading end of the locking ring and the holding rim for radially displacing the locking ring outwardly with respect to the holding rim to allow the flange portion and the remainder of the locking ring to fit over the rim and snap in position thereon after the flange portion passes completely over the rim.

Thus, the locking ring is prevented from rotating with respect to the holding rim by the engagement occurring between the inside surface of the ring and the outside surface of the rim and the ring is prevented from moving axially away from the shell by the flange portion of the ring snapped over the holding rim. Therefore, the cap can only be removed from the shell by twisting the cap with respect to the shell with sufficient force to break the ribs connecting the locking ring to the remainder of the cap. When this is done, a positive indication, in the form of the broken ribs, is provided that the container either has been opened or tampered with.

During the time the cap is in position on the shell, a positive fit is maintained between the closure portion of the cap and a corresponding portion of the bore of the shell. The outer diameter of the closure portion is greater than the inner diameter of the said corresponding portion of the bore of the shell and the closure portion or the bore of the shell presents an inclined annular surface for creating a cam action for radially displacing the closure portion with respect to said bore to allow the closure portion to move inside of and provided a resilient fit with the corresponding portion of the bore. Thus, the closure portion of the cap exerts an outward radial force on the bore portion of the shell and the locking ring exerts an inward radial force on the rim of the shell which surrounds the bore. This, in effect, squeezes the mouth portion of the shell between the closure portion and the locking ring of the cap and assures a positive hermetic seal between the closure portion and the bore of the shell as well as positive mechanical engagement between the locking ring and the rim of the shell.

Other and further advantages of this 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 sterile container for a needle unit, according to one embodiment of the invention;

FIG. 2 is an enlarged top plan view of the container of FIG. 1;

FIG. 3 is enlarged view partly in section and partly in elevation of the container of FIG. 1 showing its contents;

FIG. 4 is an enlarged partial view partly in section and partly in elevation similar to FIG. 3, but showing the cap approaching the sleeve just prior to assembly of the cap on the sleeve;

FIG. 5 is another enlarged partial view partly in section and partly in elevation, taken along the line 5—5 of FIG. 2, showing the parts of the container of FIG. 4 as the locking ring is being displaced outwardly during its motion over the holding rim presented by the sleeve;

FIG. 6 is an enlarged view partly in section and partly in plan taken along the line 6—6 of FIG. 3 with the contents of the container omitted for the sake of clarity;

FIG. 7 is an enlarged exploded view in perspective showing the various parts of the container of the embodiment of FIG. 1;

FIG. 8 is an enlarged sectional view taken along the line 8—8 of FIG. 3;

FIG. 9 is an enlarged bottom plan view of the hub of the needle unit of this embodiment;

FIG. 10 is an enlarged view partly in section and partly in elevation of the open end of the shell of the container of this embodiment with the needle unit removed for the sake of clarity;

FIG. 11 is a top plan view of the shell of FIG. 10;

FIG. 12 is an enlarged view partly in section and partly in elevation illustrating the twisting of the cap with respect to the shell to break the ribs attaching the body of the cap to the shell through the locking ring on the cap;

FIG. 13 is an enlarged top plan view of the container of FIG. 12 illustrating the breaking of the ribs.

Referring to the drawings, there is shown a sterile container according to one embodiment of this invention which comprises an elongated hollow shell 21 having a closed front end 22 and a normally open rear end defining a bore 23 of circular cross section. The bore 23 is adapted to receive a sterile unit, such as a sterile needle unit 24 comprising a hypodermic needle 25 and its hub 26, and hold it firmly in position. A cap 27 is provided for closing the open end of the shell and fitting tightly therewith to provide a hermetic seal which assures that the needle unit is completely sealed inside the container and protected against contamination. The cap 27 also is hollow and comprises a hollow body portion 28 for receiving the rear end 29 of the needle (if a double ended needle is involved), a closure portion 31 adapted to fit tightly in the bore 23 of the shell 21 and a locking ring 32 surrounding the closure portion and concentric therewith. The locking ring 32 is connected to the closure portion 28 and the remainder of the cap by a plurality of thin ribs 33, three to be exact, spaced circumferentially about the closure portion by approximately 120° from one another. The ribs 33 extend radially from the closure portion 31 to the locking ring 32 of the cap and it is preferred that their axial dimension be considerably greater than their circumferential dimension so that they possess a tall rectangular cross section. The reason for this will appear more clearly hereinafter.

The shell 21 comprises a holding rim 34 surrounding and substantially concentric with the bore 23 of the shell at the mouth of the shell. The holding rim 34 extends from the top of the shell to an annular shoulder 35 spaced from the top of the shell.

The inner diameter of the locking ring 32 is less than the outside diameter of the holding rim 34 and the locking ring presents an annular flange portion 36 at its leading end which extends radially inwardly beyond the holding rim 34 when the cap 27 is in position on the shell 21 so that the flange portion 36 of the locking ring is positioned just below the shoulder 35 at the lower end of the rim.

The flange portion 36 of the locking ring 32 presents an inclined annular surface 37 for contacting the leading peripheral edge 38 of the holding rim on the shell and causing the flange portion 36 and the remainder of the

locking ring 32 to be displaced outwardly with respect to the rim 34 so that the ring can pass over the rim as the cap is being positioned on the shell. The inclined annular surface 37 is curved in cross section, as shown in FIGS. 3, 4, 5, and 12. However, it could be flat if it is inclined at the proper angle to distend, or displace outwardly, the locking ring to allow it to pass over the rim.

Once the locking ring 32 is in position on the holding rim 34, the ring and the rim are prevented from rotating with respect to one another by the engagement occurring between the inside of the ring and the outside of the rim due to the differences between their respective inner and outer diameters, and the locking ring is prevented from moving axially away from the shell by the flange portion 36 snapped over the shoulder 35 presented at the lower end of the holding rim. Thus, the cam action provided by the inclined annular inner surface 37 of the flange portion 36 on the ring 32 is nonreversible since the ring 32 will not distend if an attempt is made to pull the cap 27 away from the shell 21. The inner surface of the locking ring 32 presents a multiplicity of alternating grooves 41 and teeth 42 running in a generally axial direction and the outer surface of the holding rim 34 presents a corresponding number of alternating grooves 43 and teeth 44, running in the same direction. The inside diameter of the locking ring and the outside diameter of the holding rim are measured across the tips of their respective teeth and the teeth of the rim are adapted to mesh with the grooves of the rim and vice versa, whereby the locking ring 32 and the holding rim 34 are mechanically engaged in such a way as to prevent relative rotative movement between them when the ring is in position on the rim.

Thus, to remove the cap 27 from the shell 21, it is necessary to break the ribs 33 connecting the locking ring 32 to the remainder of the cap. This is accomplished by twisting the cap with respect to the shell as illustrated most clearly in FIGS. 12 and 13. To facilitate this, the ribs 33 have a thin cross section in a circumferential direction, as mentioned hereinbefore and as shown most clearly in FIGS. 2 and 6. However, they are relatively high, or thick, in an axial direction to give them sufficient strength to retain their integrity during assembly of the cap on the shell, as shown most clearly in FIGS. 3-5. Alternating flutes 45 and ridges 46 are provided on the outside of the body of the cap 27 and on the outside of the shell 21 below the holding rim 34 for gripping the cap and the shell to allow them to be held during twisting for the purpose of breaking the ribs. Once the ribs 33 are broken, the remainder of the cap 27 may be removed from the shell to provide access to the contents of the container. Broken rib portions 33a remain attached to the locking ring and the remainder of the cap and provide clear evidence that the container either has been opened or tampered with, thereby providing a tamperproof container.

A relatively large number of the alternating grooves 41 and 43 and teeth 42 and 44 are provided on the inner surface of the locking ring 32 and the outer surface of the holding rim 34, respectively, so that, as the ring snaps on the rim after the ring has been distended to allow it to move over the rim, the tips of the teeth 42 on the ring automatically enter corresponding grooves 43 on the rim to locate the cap radially with respect to the shell. Thus, there is no problem of registering the cap radially with respect to the shell. It is only necessary to move the cap 27 toward the shell 21 as shown in FIG. 4 and press it over the shell so that the ring 32 distends, as shown in FIG. 5, and allows the cap to snap into position once the flange portion 36 of the ring passes the shoulder 35 on the rim 34 of the shell. However, once the ring 32 is snapped into position on the rim 34 of the shell, it is impossible to rotate the ring with respect to the shell since it is in positive mechanical engagement therewith through the corresponding alter-

nating grooves and teeth on the mating surfaces of the ring and the rim.

When the cap 27 is in position on the shell 21, the mouth portion of the shell 21 which presents the bore 23, on the inside, and the rim 34, on the outside, is squeezed between the closure portion 31 and the locking ring 32 of the cap, since the outside diameter of the closure portion 31 is greater than the inside diameter of the corresponding portion of the bore 23 of the shell and, as previously mentioned, the ring 32 must be distended to fit over the rim 34 of the shell. An inclined annular surface 47 of curved cross section is presented at the mouth of the bore 23 of the shell for radially displacing the closure portion 31 with respect to the bore 23 to allow the closure portion to move inside of and provide a resilient fit with the corresponding portion of the bore. As a result, when the cap 27 is in position on the shell 21, the closure portion 31 exerts an outward radial force on the bore 23 of the shell and the locking ring 32 exerts an inward radial force on the rim 34 of the shell, thereby assuring, both a positive hermetic seal between the closure portion and the bore of the shell, and positive mechanical engagement between the locking ring and the rim of the shell.

In the embodiment of the invention shown in the drawings, the shell 21 of the container is adapted to be utilized as a wrench for applying the needle unit 24 to a hypodermic syringe, not shown, after the cap 27 has been removed from the shell. A sleeve portion 48 of the shell, located just below the open bore 23 thereof, is provided for holding and engaging the hub 26 of the needle unit for this purpose. Both the hub 26 and the sleeve portion 48 of the shell possess corresponding noncircular cross sections, shown most clearly in FIG. 8, to prevent relative rotative movement of the hub 26 with respect to the sleeve portion 48 of the shell when the needle unit is in position therein. The hub 26 comprises alternating flutes 49 and lands 51, i.e., three flutes and three lands, for this purpose. Threads 52 are provided on the inside surfaces of the flutes 49 for engaging corresponding threads, not shown, at the front end of a hypodermic needle. The inner surface of the sleeve portion 48 of the shell includes a pair of inwardly projecting, axially extending, rectangular teeth 53 for engaging the hub 26 and holding it against rotation with respect to the shell 21. The rectangular teeth 53 are located diametrically opposite one another on centers angularly spaced approximately 180° from one another. The alternating flutes 49 and lands 51 each subtend, or extend over, approximately 60° arcs at the outside surface of the hub and the lands are located diametrically opposite the flutes. The teeth 53 are appreciably narrower than the lands and the diametric distance between the teeth is less than the outer diameter of the hub measured over the lands. Because of this arrangement of the flutes 49 and the lands 51 on the hub and the size and location of the flat teeth 53 extending from the inside surface of the sleeve portion, it is not necessary to register the hub 26 angularly with respect to the shell 21 when the needle unit is positioned therein. The needle unit 24 need only be inserted in the shell 21 and it will automatically position itself in the sleeve portion 48 thereof, as illustrated in FIG. 8, in such a way that one of the flat teeth 53 bears against a flute 49 and the other bears against the opposite land 51 of the hub of the needle unit. Since the tooth 53 located in the flute 49 cannot move angularly beyond the edge of the flute, relative rotation of the needle unit with respect to the shell is prevented. The sleeve portion 48 of the shell must be sufficiently flexible and resilient to allow one tooth 53 to fit in the flute 49 and the other to press against the opposite land 51 since the teeth are distorted from their normal positions when in these locations.

It will be apparent that both the cap 27 and the shell

21 of the container of this invention should be formed from a relatively resilient yet tough and impermeable material. It is preferred that both the shell and the cap be molded from a resilient plastic material such as polyethylene. The cap should be molded from a material which has the necessary physical properties to give the ribs 33 sufficient strength during assembly of the cap on the shell and sufficient rigidity or brittleness to facilitate breaking the ribs when the cap is twisted with respect to the shell to open the container. Therefore, for some designs, it may be advantageous to mold the cap from a material such as polystyrene.

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 sterile container comprising a shell for holding a sterile unit and having a normally open end defining a bore of circular cross-section for insertion of the sterile unit in the shell and removal of the unit therefrom; and a press-on cap adapted to close the open end of the shell and provide a hermetic seal therewith, said cap comprising a closure portion adapted to fit tightly in said bore, a plurality of thin ribs spaced circumferentially about said closure portion and connected at one end to said closure portion, a locking ring connected to the opposite ends of said ribs, and a holding rim presented by said shell for engaging said locking ring when said cap is in position on the shell, the normal inner diameter of said locking ring being less than the outer diameter of said holding rim and said locking ring presenting a flange portion extending radially inwardly beyond said holding rim when the cap is in position on the shell, said locking ring being formed of resilient material and one of said locking ring and said holding rim presenting an inclined annular surface for creating a nonreversible cam action for radially displacing said locking ring outwardly with respect to said holding rim to allow the flange portion and the remainder of the locking ring to fit over said rim and snap in position thereon, the locking ring being prevented from rotating with respect to the holding rim by the engagement occurring between the inside surface of the locking ring and the outside surface of the holding rim due to the differences between their respective inner and outer diameters and the locking ring being prevented from moving axially away from the shell by the flange portion snapped over the holding rim, said ribs being adapted to break when the closure portion of the cap is rotated by hand with respect to the shell, thereby allowing the closure portion of the cap to be removed from the shell and at the same time indicating that the container has been opened.

2. A sterile container according to claim 1, wherein the inner surface of the locking ring presents a multiplicity of grooves and teeth running in a generally axial direction and the said outer surface of the holding rim presents a corresponding number of grooves and teeth running in the same direction, the said inner diameter of the locking ring and the said outer diameter of the holding rim being measured across the tips of their respective teeth and the teeth of the ring being adapted to mesh with the grooves of the rim and vice versa, whereby the locking ring and the holding rim are mechanically engaged in such a way as to prevent relative rotative movement between them when the ring is in position on the rim.

3. A sterile container according to claim 3 wherein the outer diameter of said closure portion is slightly greater than the inner diameter of a corresponding portion of said bore and one of said closure portion and said bore presents an inclined annular surface for creat-

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ing a cam action for radially displacing said closure portion with respect to said bore and allowing the closure portion to move inside of and provide a resilient fit with the corresponding portion of said bore.

4. A sterile container according to claim 3, wherein the mouth portion of the shell presenting the bore on the inside and the rim on the outside is squeezed between the closure portion and the locking ring of the cap, thereby assuring a positive hermetic seal between the closure portion and the bore and positive mechanical engagement between the locking ring on the cap and the rim on the shell.

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THERON E. CONDON, *Primary Examiner.*

EARLE J. DRUMMOND, *Examiner.*