Dec. 23, 1969 R. C. VANDERBECK 3,485,239

SELF-CONTAINED STERILE SYRINGE

Filed Nov. 2, 1967

FIG. 1

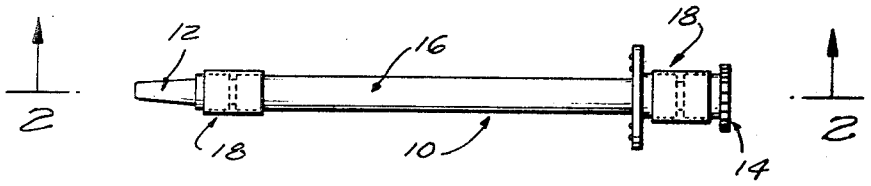


FIG. 2

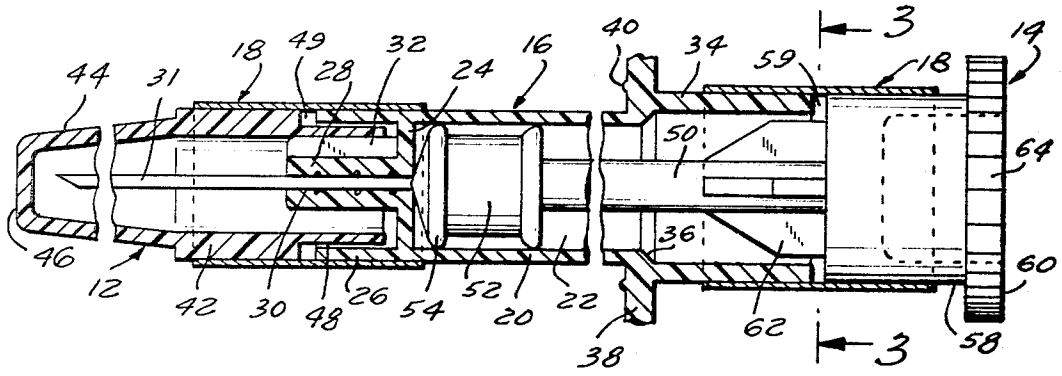


FIG. 4

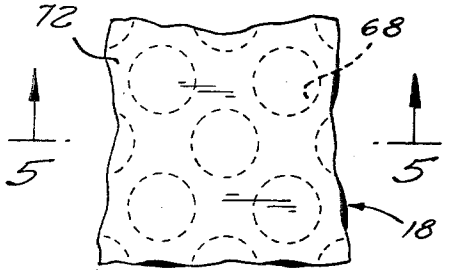
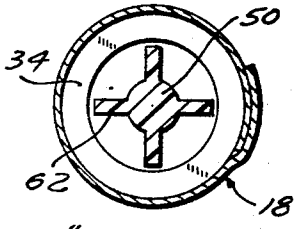


FIG. 3



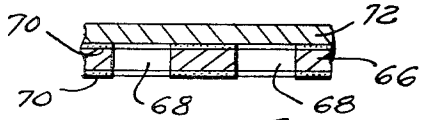
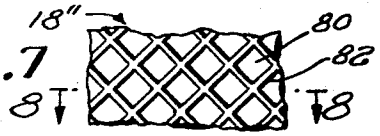


FIG. 5

FIG. 7



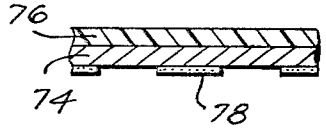
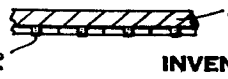


FIG. 6

FIG. 8



INVENTOR
RUSSELL C. VANDERBECK
BY
Kane, Dalsimer, Kane, Sullivan & Smith
ATTORNEYS

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SELF-CONTAINED STERILE SYRINGE

Russell C. Vanderbeck, Saddle River, N.J., assignor to Becton, Dickinson and Company, Rutherford, N.J., a corporation of New Jersey

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U.S. Cl. 128—218 11 Claims

ABSTRACT OF THE DISCLOSURE

A hypodermic syringe of a self-contained one-piece type including a plunger, cap and barrel combination. A pressure or heat sensitive sterile sealing band, permeable to the passage of the gases of sterilization, applied to the cap and plunger thereby securing the same to the barrel so that the inner syringe structure may be sterilized and maintained sterile without additional packaging.

BACKGROUND OF THE INVENTION

In the medical field, as evidenced by the prior art, hypodermic syringes and related structures, for example, needle assemblies, scalpel blades, etc., have been and are presently sterilized while within a package to obviate handling of sterile components and maintained in the sterile condition by the agency of the same external packaging structure. Thus, the implement is first packaged, sterilized and stored until used by a physician or nurse.

Generally the packages are composed either wholly or partially of transparent plastic sheet material which is securely sealed and after sealing being capable of being sterilized by gas. The sealing structure provides ready accessibility to the package interior for removal, without unnecessary handling and consequent contamination of parts, when desired for use. Sterile packaging of this type is discussed, for example, in United States Patent No. 3,036,700, issued on May 29, 1962 and assigned to the assignee of the present invention.

While this type of packaging of hypodermic syringes under sterile conditions is recognized and the widely accepted mode of operation within the medical field the present invention provides, by means of a self contained sterile hypodermic unit, an improvement over heretofore known methods of sterile packaging.

BRIEF SUMMARY OF THE INVENTION

Thus, the present invention seeks to provide an improvement over conventional packaging techniques and particularly relates to a self contained sterile disposable hypodermic syringe having, without the benefit of an external package, a sterile fluid path for gas sterilization.

In broad terms the invention is directed to a sterile disposable self contained syringe assembly. The assembly includes an elongated barrel which provides part of the final package and which is adapted to support at one end a needle cannula unit, a cap receivable over the needle cannula support end, a plunger-piston member received within the other barrel end for reciprocable movement and closing said other end, both the cap and plunger-piston member forming a substantially smooth extension of the barrel, and an adhesive gas permeable wrap received on the smooth surfaces and at the junctures between parts thereby to secure the assemblage and allow for as well as maintain sterilization of components.

It is therefore an object of the present invention to provide a hypodermic syringe unit in the form of a self contained sterile assembly, thereby to obviate the heretofore required external packaging.

Other objects and advantages of the present invention will readily come to mind as the following description to be read in conjunction with the several figures is developed.

BRIEF DESCRIPTION OF THE FIGURES

The accompanying drawing illustrates and forms a part of the present invention. By this drawing

FIGURE 1 is a side view of the assembled self-contained syringe;

FIGURE 2 is a broken apart cross-sectional view of the syringe as seen along the line **2—2** in FIG. 1;

FIGURE 3 is a view in cross-section as seen along the line **3—3** in FIG. 2;

FIGURE 4 is a greatly enlarged plan view of one form of a pressure sensitive sterile gas permeable sealing band;

FIGURE 5 is a cross-sectional view of the band as seen along the line **5—5** in FIG. 4;

FIGURE 6 is a cross-sectional view, similar to the showing of FIG. 5, of a second form of band;

FIGURE 7 is a greatly enlarged plan view of yet another or heat sensitive form of gas permeable sealing band; and

FIGURE 8 is a cross-sectional view of the band as seen along the line **8—8** in FIG. 7.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The self-contained syringe of the present invention, shown in FIG. 1, is generally denoted by the numeral **10**. The syringe, which is to be more particularly described with reference to the remaining figures, includes a cap **12** and a plunger **14** both of which are sealably connected to a barrel **16** by means of a gas permeable paper wrap **18**.

The syringe is considered to be of the disposable type anad, as such may be formed of a plastic material, such as, for example, polyethylene or polypropylene, to name a few. These materials, in addition to other plastics have been recognized as being suitable for the manufacture of disposable type syringe parts.

The barrel **16** is of an elongated cylindrical construction including an outer wall **20** defining an internal chamber **22**. One end of the barrel is open and the other end is provided with an end wall **24**. The end wall **24** is longitudinally spaced from the barrel wall extremity at the closed end thereby to define a skirt portion **26**. A nipple **28** having an internal bore **30** in communication with the barrel bore **22** is integrally or otherwise connected to the end wall **24**. Needle cannula **31** is by any suitable epoxy bonding system secured within the bore. The nipple, as noted in FIG. 2, is supported in a manner so as to be coaxial of the barrel skirt **26** and of an extended longitudinal length. This length is substantially equal to the length of the skirt. To be discussed in more detail below the nipple **28** carries a plurality of radially outwardly directed longitudinal ribs **32**, for example, three ribs spaced at angles of 120°. Each point on the rib surfaces lies within a cylindrical plane which is, also, coaxial of barrel skirt inner surface and radially spaced therefrom.

A collar **34** whose wall thickness is generally similar to the thickness of the barrel wall is integrally or otherwise carried at the open end of the barrel **16**. The inner diameter of the collar is somewhat larger than the inner diameter of the barrel and is connected to the latter by a smooth tapered surface **36**. Ears **38** are carried by the collar portion and by means of a pattern of protuberances **40** providing a somewhat roughened surface on one side of each ear the syringe may be positively grasped during use.

Cap **12**, as seen in FIG. 2, includes a center cylindrical portion **42** having an outer surface diameter which, when the cap is mounted upon the barrel, forms a smooth extension of skirt **26**. Projecting from the central cylindrical portion and extending in opposite directions is a section

44 which tapers to a closed end 46 and a sleeve 48. The sleeve 48 is so dimensioned that its longitudinal length is slightly less than the length of the barrel skirt 26 and its outer diameter is slightly less than the inner diameter of the same. Additionally, the inner diameter of the skirt 48 is slightly less than the diameter of the cylindrical plane defined by the ribs 32. In this manner the sleeve 48, when mounted on the barrel 16, is forced to yield slightly. Due to this slight yielding and the tendency of the sleeve to return to its original shape a relatively tight friction fit is obtained between the cap sleeve and the nipple ribs. Although slightly exaggerated in FIG. 2 an opening 49 remains between the cap cylindrical portion 42 and the skirt 26 when the cap is so received.

Plunger 14 is illustrated in FIG. 2 and includes a piston rod 50 carrying at one end a piston member 52. The piston member 52, formed of an elastomeric material, such as, rubber or polyisoprene, is received on the rod 50 in any suitable manner. Receipt, for example, may be accomplished by providing the piston with an internal socket (not shown) which snap fits over a longtiudinally directed rod projection and bulbous end (not shown).

The piston member is provided with a pair of ribs or rings 54. As shown, the ribs are longitudinally separated by a small distance and as is well known in the art the ribs 54, and necessarily the forward rib, are of a diameter which is slightly in excess of the inner barrel diameter. Thus, a friction fit is obtained between the piston and the wall so that suitable fluids may be either aspirated or expelled. As may be conventional the piston is lubricated by a silicone material.

The piston rod 50 is of an elongated construction thereby to permit reciprocable movement of the piston between the open end of barrel 16 to a substantially abutting relationship at the end wall 24. The rod, so that there is no binding during reciprocal movement of the piston and rod through the barrel bore, is formed so as to provide an annular space between its outer surface and the inner barrel surface.

A head 58 is integrally or otherwise carried by the end of the rod 50 opposed to the piston end. As is apparent in FIG. 2 the outer diameter of the head portion 58 is substantially identical with the outer diameter of collar 34 carried by barrel 16. Thus, when the piston is disposed at the wall end the collar and head define a substantially continuous cylindrical surface, separated by a slight gap 59.

A disc shaped flange 60 projects from head 58 and as may be apparent this surface provides a thumb engaging location upon which pressure may be exerted thereby to expell any fluid from the barrel chamber.

Projecting from the head 58 in the direction of the piston 52 is a second plurality of ribs 62. These ribs may be and are shown as being mounted on the piston rod in quadrature. The ribs are formed so that all points on their outer surface lie in a cylindrical plane having a diameter which is less than the inner diameter of collar 34. The purpose for these ribs is to provide a fluid path along the rod 50 and substantially eliminate any relative movement between the barrel 16 and the rod 50 in directions other than the longitudinal direction.

The thumb engaging portion 60 may be provided with a series of peripheral serrations 64 to aid in gripping during withdrawal of the piston and rod from the barrel and for economy in manufacture and ease in handling the head and thumb engaging portion may be hollow.

FIGS. 4 and 5 show in greatly enlarged form one type of a sterile sealing band 18 which may be used to secure both the cap and plunger members to the barrel thereby to provide an assembled unit that may be sterilized and thereafter maintained in a sterilized condition without the necessary employment of an exterior package. The band of this form is a pressure sensitive band and allows for the entry of sterilizing gases at the respective ends of the syringe. The gases then flow toward central internal syringe locations.

In general terms the first, although not necessarily preferred, band form includes a first paper layer 66 that is provided with an adhesive coating 70 on both sides thereby defining a pressure sensitive paper. The paper may or may not be of porous character to allow for sterilization but irrespective of its inherent porosity, due to the adhesive, the pressure sensitive layer is impermeable to the gases of sterilization. Thus, this layer is die-cut in zones 68. A second layer of web material 72 which is sufficiently porous to allow for sterilization of internal syringe structure, but of close enough texture as to resist the passage of pathogenic organisms therethrough after sterilization procedures and during storage under normal conditions, provides a backing for the pressure sensitive layer. Thus, without causing a break in the plunger in the mounted position on barrel 16 (FIG. 1) the syringe unit may be sterilized.

A second type of pressure sensitive sealing band which may be used in the manner as discussed in relation to the seal of FIGS. 4 and 5 is seen in FIG. 6 and denoted by the numeral 18'. This band is in the form of a permeable paper layer 74, such as the paper web 72, which carries on one side a layer of any suitable thermosetting resin 76, permeable to gases prior to a final cure, and a pattern coated layer 78 of adhesive. A paper of this type is disclosed in Hermanson et al. Patent No. 3,123,210. For further detail reference may be had to the patent. The paper which is formed in this manner is suitably adapted to secure the cap and plunger to the syringe barrel and due to the pattern coating of the adhesive the gases of sterilization are capable of passing from the sterilizing chamber, through both the resinous and paper layers, and into the inner portions of the syringe. Once the syringe has been sterilized the unit may be appropriately heat treated so that the resinous layer 76 is cured thereafter to prevent any communicable fluid flow between the interior of the syringe and the atmosphere.

A third and preferred form of sealing band is denoted by the numeral 18'' in FIG. 7. This band is of the heat sensitive type, a type which is generally recognized as being tamper proof and capable of providing evidence of tampering. The band includes a permeable paper web 80 which is similar to the web material 72 described in relation with FIG. 5. An emulsion 82 is pattern coated on the web. The particular pattern of FIG. 7 is shown for exemplary purposes only but it should be understood that the emulsion is applied in a pattern of some form.

As previously discussed, on assembly of parts, gaps 49 and 59 are provided in communication with the syringe interior. The emulsion, being impermeable to the flow of sterilizing gases, thus eliminates, when adhesively applied to the syringe as in FIG. 1 upon the application of activating heat, any continuous path from the band edges to the juncture of parts. Thus, gas passage is through the permeable paper at each gap 49 and 59. The band form of FIG. 4 likewise eliminates a possible path from the band edge to the juncture.

The method and manner by which the bands 18, 18' and 18'', discussed in relation to FIGS. 4–8, are formed does not fall within the confines of the present invention and therefore will not be discussed at this point. Suffice it to say that those skilled in the paper arts are familiar with both the method and machines by which papers may be pattern coated or continuously coated and die-cut, as discussed above.

Returning to FIGS. 1 and 2, it is seen that both the cap 12 and the plunger 14 are secured to the barrel 16 by an adhesively secured band, either the band 18, 18' or 18'', as discussed. Thus, in the assembled form and without the need for the heretofore necessary external packaging to maintain, under normal storage conditions, sterility the self contained syringe may be sterilized. Conventional treatment methods and apparatus by which the

syringe is subjected to the gases of sterilization, for example, ethylene oxide, which effectively kills or destroys bacteria, viruses, spores, and microorganisms in contact therewith, may be employed.

Thus, among others, the several objects of the invention as specifically aforenoted are achieved and the advantages are apparent. While the invention has been described in its preferred embodiment this description has been for the purpose of illustration not by way of limitation for obviously numerous changes in construction and rearrangement of the parts may be resorted to without a departure from the spirit and scope of the invention as defined by the appended claims.

Having now described the invention, I claim:

1. A sterile disposable self-contained syringe assembly comprising an elongated cylindrical barrel having an end wall, a fluid delivery nipple having a bore for communication with the barrel chamber and being provided with a plurality of radially outwardly directed longitudinal ribs having an overall diameter which is less than the outer diameter of said barrel, said nipple being supported by said end wall so as to extend generally coaxially of the barrel, a cap received on and supported by said nipple ribs for substantially closing said bore to the atmosphere yet removable thereby to allow receipt of a hub and hypodermic cannula, said cap forming generally a smooth extension of said barrel wall, a piston element carried at one end by an elongated piston rod of relatively smaller diameter, said element and rod being disposed within said chamber for reciprocable movement toward and away from said end wall, a head and finger gripping member carried by the other end of said piston rod, said gripping member providing generally a smooth extension of said barrel wall open end and substantially closing the same to the atmosphere when said piston and rod is adjacent said end wall, and a wrapping means adapted to permit the passage of sterilizing gases applied at said barrel ends for securing said gripping member and cap to the barrel thereby to retain all parts assembled and allow for the internal sterilization of the assembled self-contained syringe unit and the maintenance of the same in the sterilized self-contained condition.

2. The assembly of claim 1 wherein said end wall is spaced from the barrel wall extremity thereby to define a barrel skirt and said nipple length is substantially the length of said skirt.

3. The assembly of claim 2 wherein said cap is provided with a skirt that is received within the opening between the barrel skirt and ribs and frictionally retained by the latter, said cap skirt having an outer diametrical and longitudinal dimension thereby to define an open fluid flow path from the atmosphere to the barrel chamber.

4. The assembly of claim 2 wherein the inner cap skirt diameter is less than the rib diameter so that said cap skirt yields upon receipt on said nipple whereby the inherent resiliency of said skirt to return to the initial configuration provides said friction fit.

5. The assembly of claim 1 wherein said wrapping means includes a pressure sensitive band having die-cut zones and a paper backing permeable to the flow of sterilizing gases.

6. The assembly of claim 1 wherein said wrapping means includes a paper permeable to the flow of sterilizing gases having a pressure sensitive adhesive pattern coated on one side and a heat setting resin on the other, said resin, until set by a heating cure, allowing the passage of said gases.

7. The assembly of claim 1 comprising a second plurality of ribs, said ribs being formed on said piston rod and projecting from said head and finger gripping member for stabilization of the rod in said barrel chamber.

8. The assembly of claim 1 comprising a pair of ears projecting from said barrel wall to provide a finger engaging surface during the aspiration and expulsion of fluids.

9. The assembly of claim 1 comprising a needle cannula being received within said nipple bore and retained by an epoxy bonding system.

10. The assembly of claim 1 wherein said wrapping means includes a paper web permeable to the flow of sterilizing gases and an adhesive emulsion carried by one side, said wrapping means being adhesively secured to said barrel ends, cap and gripping member by the application of emulsion activating heat thereby providing a heat sensitive wrap.

11. The assembly of claim 10 wherein said emulsion is pattern coated on said web thereby to eliminate any continuous path from the band edges to the juncture between the barrel, cap and gripping member.

References Cited

UNITED STATES PATENTS

Re. 25,113	1/1962	Wilburn.	
2,490,553	12/1949	Smith	128—220
2,748,768	6/1956	Lipari	128—218
2,854,975	10/1958	Cohen.	
3,036,700	5/1962	Krug	206—43
3,123,210	3/1964	Hermanson et al.	156—309 XR
3,157,277	11/1964	Sorenson	206—63.2
3,203,545	8/1965	Grossman	206—63.2
3,306,291	2/1967	Burke	128—218
3,435,944	4/1969	Ishii	206—43
3,435,948	4/1969	Kaganov et al.	206—63.2 XR

RICHARD A. GAUDET, Primary Examiner

MARTIN F. MAJESTIC, Assistant Examiner

U.S. Cl. X.R.

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