PATENT SPECIFICATION

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COMPLETE SPECIFICATION

DRAWINGS ATTACHED

Improvements relating to Containers for Fluids

We, ALLEN & HANBURYS LIMITED, of Three Colts Lane, Bethnal Green, London, E.2, a British Company, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to containers for fluids, particularly for infusion fluids which are administered parenterally or into body cavities.

For many years, it has been the practice to supply infusion fluids such as blood, physiological saline solution and the like in glass containers. The closure of such containers has been such as to be capable of being pierced by a hollow needle or the like or alternatively the closures have been provided with an orifice designed to accept a needle or the like so that the fluid could without exposure to contamination be infused into a living body. More recently, infusion fluids have been supplied in containers of flexible or semi-rigid plastic material to overcome the disadvantages of glass containers. However, in most cases the plastic container filled with the infusion fluid has been supplied as part of a complete unit which comprises the filled container of fluid, and an "administration set" which may consist of a flexible tube interrupted by a filtering device and drop counting chamber and terminating at the distal end in a needle or similar device for insertion into the vein of a patient. The supply of such complete units has been made necessary by the fact that there have been difficulties in devising a container of plastic material which would satisfactorily provide a means for connection with an administration set as has been possible in the case of glass containers. As it is necessary in many cases to infuse a volume of fluid in excess of that which can be conveniently provided in one container it has been necessary to use an administration set for each unit. This is not only uneconomic in that it has been necessary to use a new administration set for each container used, but it has moreover necessitated the removal of the empty unit from the needle or cannula already in place in the patient or making a new puncture in the vein, both of which procedures are highly undesirable and potentially dangerous owing to the possibility of air embolism. Infusion fluids in containers having separate administration sets are known, but these have the disadvantage that they are designed for use with a single type of administration unit.

The present invention provides a flexible or semi-rigid plastic container for fluids, comprising a closure with a rigid liner fitted inside a neck of the container, the closure being capable of being pierced by a needle or like object while providing a non-leaking attachment with the needle or like object, and a cap which retains the closure in the neck and has an opening through which the needle or like object can be applied to the closure. The container is intended for infusion fluids and permits of the removal of the contained fluid by means of administration sets, for example of the kind commonly used for withdrawal of infusion fluids from glass containers, or from flexible plastic containers. It is to be noted that it is not possible to effect this withdrawal by puncturing the flexible plastic of the container with a needle or the like because the contained fluid leaks from the container around the outer surface of the needle or the like and the weight of the administration set is sufficient to cause the needle to be withdrawn from the container and because of the difficulty in producing a sterile area on the

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surface of the container.

In the accompanying drawings:

Figure 1 is a sectional view of part of a container according to the invention,

Figure 2 is a similar view illustrating a modification, and

Figure 3 is a sectional view illustrating a liner or sleeve for a container neck.

In the embodiment of the present invention illustrated in Figure 1, a flexible or semi-rigid plastic container for infusion fluids is provided with a neck 1 of a similar flexible or semi-rigid plastic material. Inside the neck there is provided a liner 2 in the form of a rigid hollow sleeve which has an out-turned flange 3 which fits over the outer end edge of the neck 1; the rigid sleeve 2, 3 may conveniently be made of a non-toxic rigid plastic material such as nylon or polypropylene. The outer end of the rigid sleeve is closed by a closure 4 in the form of a plug, membrane or disc capable of being pierced by a hollow needle or the like and of re-sealing itself on withdrawal of the hollow needle and of providing a non-leaking attachment with the needle. Such closures may conveniently be made of non-reactive rubber or latex and may include a spigot 5 fitting inside the sleeve 2 and having a flange 6 fitting on the flange 3 of the sleeve 2 in a fluid tight manner and a manner which is proof against the entry of micro-organisms. The closure 4 is retained in the sleeve 2 and the neck 1 of the container by means of a thin cap 7 of metal or other material not deformable by heat at sterilising temperatures, the said cap 7 having an orifice through which a needle or the like may be applied to the closure. The orifice may be covered by a cover capable of easy removal.

Figure 2 illustrates a modification in which the closure 4 is provided with a skirt 8 fitting closely to the neck 1, the cap 7 then having a co-operating skirt 9.

Figure 3 illustrates a modified liner 2 having a transverse septum 10.

WHAT WE CLAIM IS:—

1. A flexible or semi-rigid plastic container for fluids, comprising a closure with a rigid liner fitted inside a neck of the container, the closure being capable of being pierced by a needle or like object while providing a non-leaking attachment with the needle or like object and a cap which retains the closure in the neck and has an opening through which the needle or like object can be applied to the closure.

2. A container as claimed in claim 1 wherein the liner is a sleeve of non-toxic rigid plastic material with an out-turned flange fitting over the outer end edge of the neck, the closure being a plug or disc of non-reactive rubber or latex with a flange fitting on the flange of the sleeve and a spigot fitting inside the sleeve.

3. A container as claimed in claim 2 wherein the sleeve has a transverse septum.

4. A container as claimed in either of claims 2 or 3 wherein the closure has a skirt fitting on the outside of the neck of the container, the cap having a skirt co-operating with the skirt of the closure.

5. A flexible or semi-rigid plastic container for fluids substantially as described with reference to any of the figures of the accompanying drawings.

6. A surgical infusion assembly comprising a container as claimed in any one of the preceding claims and an administration set of a kind known *per se*.

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