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STERILE SURGICAL PACKAGING

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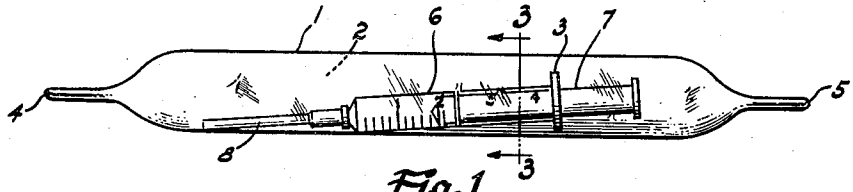

Fig. 1

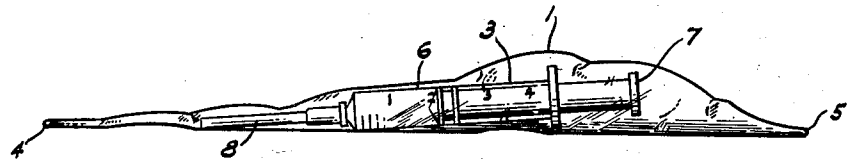

Fig. 2

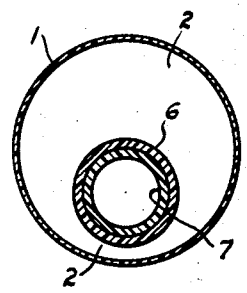

Fig. 3

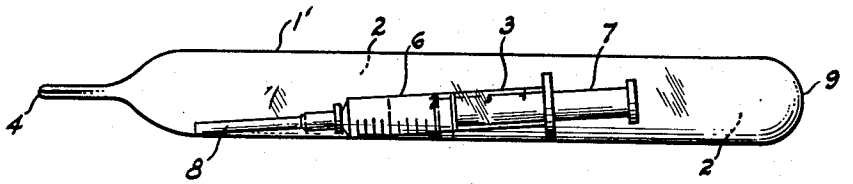

Fig. 4

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STERILE SURGICAL PACKAGING

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1 Claim. (Cl. 206—63.2)

This invention relates to a new article of manufacture, more particularly to a sterilized package containing a sterile surgical appurtenance such as an appliance, surgical instrument, hypodermic needle, hypodermic syringe, and the like.

The use of presterilized packaged hypodermic assemblies and other surgical appurtenances has become a widely accepted procedure by the medical and dental profession.

An advantage of presterilized surgical appurtenances is their availability for prompt and safe usage.

Another advantage is the assurance the user has that the contents have been properly sterilized and are pyrogen free. In the office of the ordinary physician, sterilization facilities may be limited and full sterilization equipment is not always present. On the other hand, the manufacturer or packager is fully equipped not only for complete sterilization but for the necessary and proper testing of the unit to insure safety.

At present, disposable syringes and the various surgical appurtenances are packaged and sealed—sterile and pyrogen free at the packaging plant.

That does not mean the package remains so indefinitely. Somewhere on the package is printed the warning that guarantees this sterility only "while the package is perfectly sealed and not pierced or broken in any way prior to time of use."

Since with time and handling much can happen to such a package, another warning says, "Do not use if package is pierced or broken in any way."

Unfortunately, the tiny holes or cracks which may form and do form in the protective plastic or paper container are generally not easily visible or detectable. It might take high magnification to show them up. As soon as the package is no longer strictly airtight, however, contamination begins, with no means for determining this state of affairs.

As a result, the present "sterilized, pyrogen-free surgical package" is not always absolutely safe.

An object of the present invention is to provide a sterilized package of surgical appurtenances with simple means for detecting if a break has occurred in the package, whereby it no longer would be certain that the contents are still sterilized.

A further object is to provide means to indicate those "contaminated" packages so that they may be discarded before harmful use, or they may be re-packaged and resterilized if the contents so lend themselves.

These and other objects are obtained by inflating the package with a sterile atmosphere, such as an inert gas, nitrogen being a suitable example, to a pressure of from one-half to several ounces per square inch, depending upon the size of the package and the thickness of its walls.

Should the package wall become perforated, the gaseous contents, which are under pressure, commence to escape with subsequent deflation of the package resulting. A package not substantially firmly inflated with gas serves as an indication to the user that the outer container is not intact and resterilization or discarding of the instrument or appliance is in order.

With these objects in mind, reference is had to the attached sheet of drawings showing one practical embodiment of the invention, in which:

FIG. 1 is a side elevational view of a hypodermic syringe and needle assembly, packaged and inflated in accordance with the present invention.

FIG. 2 is a similar elevational view of a hypodermic syringe and needle assembly that had been packaged in accordance with the present invention but which had failed and become deflated.

FIG. 3 is an enlarged sectional view taken along the line 3—3 in FIG. 1.

FIG. 4 is an elevational view of a modified container.

In the drawings, like characters of reference are employed to denote like parts throughout the several figures.

Referring specifically to the drawings, the numeral 1 designates a plastic container enveloping an exemplary appliance or instrument comprising a hypodermic syringe 3. In FIG. 1, it can be seen that the plastic tubular container 1 is inflated with a suitable gas 2, which preferably is inert, and is sealed at the opposite ends 4 and 5. The exemplary syringe packaged within container 1 comprises a needle protected by a suitable sheath 8, the barrel 6, and the piston or plunger 7.

Any pliable synthetic resin or sheet material which is impermeable to or unaffected by gas used for inflation can serve as a container. For example, if a gas such as nitrogen or air is the inflation means, the polyester film "Mylar," a trade name of the DuPont Company, comprising the condensation product from reaction between ethylene glycol and terephathalic acid, may be used. Its permeability to gases is extremely low. It does not become brittle at temperatures as low as —60° C. and the Mylar package readily can be heat sealed with the use of benzyl alcohol.

Where it is desired to give the package an unusually long shelf life, the Mylar can be coated with Saran—which is the trade name of Dow Chemical Company for vinylidene chloride-vinyl chloride copolymer. Polyethylene coated Saran or polyethylene coated Mylar may also be employed. When Saran coated Mylar is used, the package may be sealed by an electronic heat sealer.

Suggested for use as packaging sheet material, also, is transparent Scotchpack film, a trade name of the Minnesota Mining and Manufacturing Co. for non-plasticized regenerated cellulosic film. Scotchpack will not dry out, has a tensile strength ranging up to 10,000 p.s.i., has a burst strength from 32 to 50 p.s.i., and remains flexible at the extreme temperatures of from —70° F. to 240° F. It also has a wide heat-sealable temperature range and a long shelf life, with the thickness of the film determining the length of such life. It is available in thickness from 2 mils to 4.5 mils, the 3 mil heat-sealable film having been found to give highly satisfactory shelf life.

The foregoing are given as suitable examples. Any other appropriate film can be used that meets the requirements of being readily sealable against the escape of gas under reasonable pressure having a reasonable bursting strength, and remaining airtight over a required period of time.

While the amount of gas employed may vary from ½ oz. of pressure to several ounces or more, depending upon the size of the package and thickness of the walls, the inflated package will show signs of collapse as soon as the wall membrane is perforated or broken as is shown in exemplary manner in FIG. 2. In such figure, the collapsed container 1 has draped itself relative to the syringe 3 since there is no internal gas pressure, and it is quite apparent that the package, therefore, has been punctured. This is a signal that the enclosed instrument no longer may be sterile. When a sealed inflated container is squeezed even lightly, one can immediately feel the compression and thus be made aware that the con-

tainer is intact and the syringe or other enclosed instrument is safely sterile for use.

FIG. 3 is a cross sectional view illustrating the manner in which the inflated envelope completely surrounds the barrel 6 of the syringe, as seen on the line 3—3 of FIG. 1.

In FIG. 4, another embodiment of tubular envelope is shown which has only one end 4 to be sealed. The container 1' is shaped like a cylindrical bag or container having an integrally molded or formed bottom 9.

The actual sterilization of the appurtenance or instrument to be packaged may take place either before or after packaging and this has a bearing upon the method of sterilization to be employed. One or more of many well known means and agents may be used for this purpose, such as live steam applied at least twice in 24 hr. intervals at 100° C. for 30 minutes; autoclaving for 30 minutes at 15 lbs. pressure at 121° C.; subjecting to dry heat for an hour at a temperature equivalent to boiling; or chemical immersion in any liquid sterilizing agent, such as Zephiran Chloride (1–500 solution), which is a brand of Zenzalkonium Chloride; an ethyl alcohol-formaldehyde liquid agent; or a gas atmosphere, such as ethylene oxide. All chemical immersion and subjection to gas atmosphere will occur prior to sealing the package.

The foregoing means are illustrative of a few of the numerous methods that may be employed for sterilization of the packaged product. It is understood, however, that the nature of the appurtenance to be sterilized will determine the most ideal method of sterilization for it, and that the nature of the packaging material will suggest the best means for sterilization when packaged contents are to be sterilized, after sealing of the package.

While I have described my invention in accordance with desirable embodiments, it is obvious that many changes and modifications may be made without departing from the spirit of the invention as defined in the following claim.

I claim:

A package comprising a sealed container formed from gas impermeable flexible sheet material, a sterilized surgical appurtenance enclosed within the container, said container being substantially fully inflated by sterile gas sealed therein under positive pressure against any escape and being non-reactive with said sheet material or appurtenance sealed therein, a major portion of the walls of said inflated container being distended out of contact with said surgical appurtenance, whereby the sterile or non-sterile condition of the surgical appurtenance will become readily apparent by merely grasping the package to determine positive inflation thereof.

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