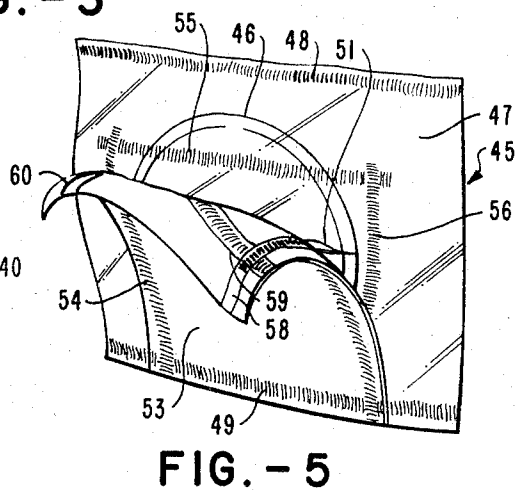
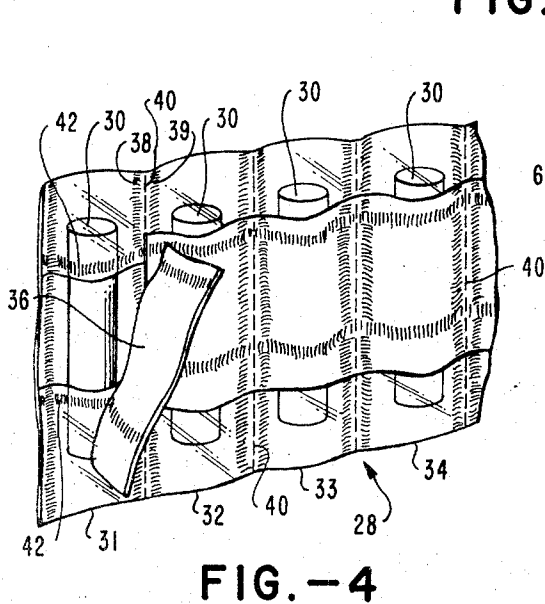
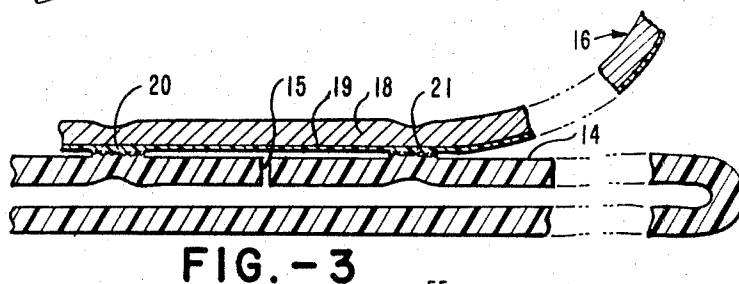
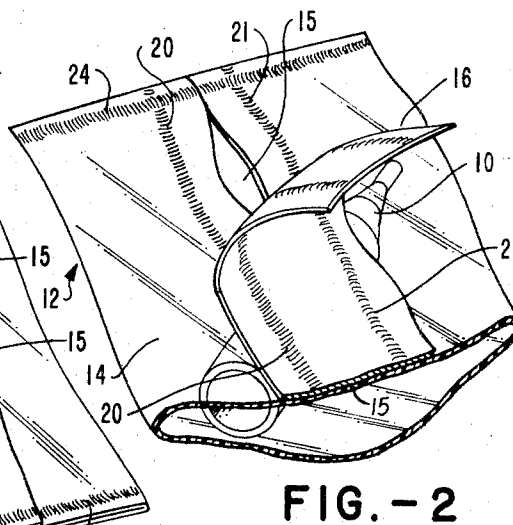
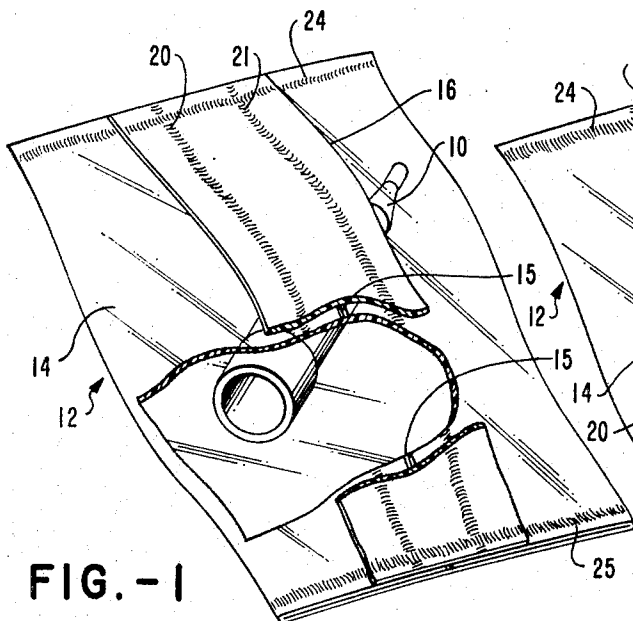


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S. J. SCHUSTER
 READILY OPENED PACKAGE FOR STORING ITEMS
 IN BACTERIA-FREE CONDITION
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READILY OPENED PACKAGE FOR STORING ITEMS IN BACTERIA-FREE CONDITION

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5 Claims

ABSTRACT OF THE DISCLOSURE

A package for sterilized items, such as disposable hospital supplies, is provided by a plastic bag that is sealed except for an access opening. The access opening is itself covered by a facing paper or paper-like tear strip which is united to the bag along joinder lines extending about the entire periphery of the access opening. At least one portion of the strip protrudes beyond the joinder lines to provide an edge that may be manually gripped for removal of the strip. The tear strip may be sufficiently strong relative to the joinder lines for the entire strip to be separated from the package in a single motion. The tear strip is impermeable to bacteria but permeable to ethylene oxide gas, widely used as a sterilizing agent for medical and surgical items. After loading and sealing, the package may then be sterilized by ethylene oxide passing through the tear strip, the gas thereafter readily being purged from the package under vacuum. Subsequently the contents of the package remain bacteria-free until the package is opened.

Description of the prior art

This invention relates to improved packaging techniques and more particularly to packages which permit the storage and ready utilization of bacteria-free implements.

Substantial need exists for improved techniques for the sterilization and bacteria-free packaging of medical and surgical implements. There is an increasing tendency to make and use individual disposable items, separately packaged, but there can be no compromise with the degree of sterilization demanded. The use of standard heat sterilization techniques is both time consuming and expensive, and the increasing tendency has been to adopt an active sterilant such as ethylene oxide. Ethylene oxide is a highly active gas that ensures rapid and complete destruction of bacteria. Retention of any ethylene oxide is, however, undesirable because of the adverse effects on all living organisms if the ethylene oxide is present in residual form during use of the implement.

A number of practices are currently employed in sterilizing with the use of ethylene oxide. The container, generally an impermeable plastic package, and the implement are separately sterilized, then the container is filled and sealed under aseptic conditions. The difficulties and expense involved in this practice are evident, and it is not advantageous for volume production situations. A separate technique involves loading of the package, sterilization and purging through a special wicking member that is permeable to the ethylene oxide but not to bacteria. The wicking member is a small fibrous cylinder sealed into a corner of the package. Several days of purging are generally required to ensure that the interior of the package is free of ethylene oxide, and a package of this form is relatively difficult to seal completely and to open.

The primary requirement for all such packages is, of course, that they retain the contents in sterile condition until use. At least three additional requirements may, however, be noted, particularly for disposable items. The

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cost of the packaging technique employed is a primary factor, and this cost must be viewed in terms of the total expenditure involved in the package itself, as well as the costs of the loading, sealing and sterilizing operations.

Where the medical or surgical items are of a disposable character, the contribution of package cost to total cost must be as low as possible, preferably a very small fraction of the unit cost.

A second important requirement is that the contents of the package should be readily visible for convenience of storage and use. Another important consideration is the ease with which access may be had to the contents of the package. The typical plastic or other package intended for protection of sterilized items has relatively thick, strong walls in order to guard against accidental puncture or tearing of the package during handling. The same characteristics, however, tend to make the package difficult to open without the use of a cutting tool or scissors and this in turn is undesirable because even if such cutting implements are available substantial time and handling are required. Easy opening of the package and access to the sterilized contents, therefore, represent significant requirements for packages of this type.

The concurrent provision of all of these different characteristics, while retaining the primary characteristic of bacteria-free storage, represents a desirable goal that has not heretofore been achieved by the packaging concepts of the prior art.

Summary of the invention

Packages in accordance with the invention for maintaining items in bacteria-free condition are readily sterilized through the use of an active agent such as ethylene oxide, and readily purged of the sterilizing agent, but nonetheless permit visual inspection of the contents and ready opening. One portion of the package consists of an impermeable transparent plastic container having an access opening while the remainder of the package comprises a strip of a semi-permeable materials, such as paper, that is permeable to ethylene oxide but impermeable to bacteria. The strip is disposed to seal off the access opening while being readily separable from the plastic.

In a specific form of package in accordance with the invention, the transparent part of the package is provided by a rectangular polyethylene sheet having longitudinal edges folded over in abutting facing relation to define a container having an access opening. The sheet is of sufficient thickness and of an appropriate material, such as polyethylene, to be substantially impermeable to ethylene oxide as well as bacteria. The access opening is covered by a paper strip having a polyethylene coating on the side opposing the sheet, and being joined to the sheet along longitudinal heat sealed joinder lines extending parallel to the longitudinal access opening and spaced apart therefrom. The paper strip is of adequate width to extend beyond the joinder lines a sufficient distance to provide manual gripping of the paper edge. A complete seal about the access opening is provided by transverse heat seal joinder lines adjacent each transverse edge of the package. With this construction, individual packages may be repetitively manufactured on conventional packaging equipment, with a relatively low added increment of cost over ordinary packaging systems utilizing tube stock. The medical or surgical item may be inserted manually or by machine into the package, the package may thereafter be completely sealed and subsequently the contents may be completely sterilized by ethylene oxide, with the ethylene oxide thereafter being purged in an extremely short interval.

A feature of the invention is the use of an edge on the tear strip protruding outside the joinder lines. In cooperation with this feature, another advantageous feature is

that the tear strength of the paper strip may be made greater than the separation strength of the joinder lines, so that the entire paper strip may be removed in one single motion, even though the seals have adequate strength for all normal conditions likely to be encountered in loading, storage and use.

Other features of packages in accordance with the invention include the provision of packages that may be fabricated on different types of equipment and the employment of multiple packages that may be individually opened.

Brief description of the drawings

A better understanding of the invention may be had by reference to the following description, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a perspective view, partially broken away, of an improved form of package for sterilized items in accordance with the invention;

FIG. 2 is a perspective fragmentary view of a portion of the package of FIG. 1, showing the package during opening;

FIG. 3 is an enlarged end section view of the package of FIG. 1 showing details of the joinder of the different elements therein;

FIG. 4 is a perspective view, partially broken away, of a different form of package in accordance with the invention, and;

FIG. 5 is a perspective view, partially broken away, of yet another package in accordance with the invention.

Detailed description of the invention

Articles in accordance with the invention, referring now to FIGS. 1 to 3, may be utilized for the ready sterilization, storage and easy removal of a surgical or medical item such as the disposable needle 10. The package is particularly suitable where the item 10 is of a low-cost disposable type, but all the advantages of the invention can be realized regardless of the specific character of the sterilized item to be packaged and subsequently used. As best seen in FIGS. 1 and 2, the principal or container portion of the package 12 comprises a rectangular sheet 14 of transparent material, such as a polyethylene bag approximately two mils thick and substantially impermeable to ethylene oxide. The permeability of polyethylene sheet to this highly active gas used for sterilization purposes increases through thicknesses below about one mil and thereafter increases insignificantly. While a lesser thickness can be used it is generally preferred to have a package body of substantial durability and strength, and which does not rupture or tear in normal use. Other materials than polyethylene may, of course, be used but polyethylene has the added desirable properties of being low in cost, fully transparent and having closely controllable characteristics.

For ready fabrication, the polyethylene sheet 14 is advantageously formed from a single continuous sheet of material, the side edges of which are folded inwardly along longitudinal fold lines. The fold lines then define the edges of the package and the longitudinal edges of the sheet may come into abutting relation to form a longitudinal access opening 15 along the approximate longitudinal center line of the package 12. The folds need not be equal in width and the access opening 15 can be displaced to one side or the other of the center line. Similarly, the access opening 15 can have a greater or lesser width and the edges may even overlap to some extent. Preferably, however, the longitudinal edges come into close relation adjacent a longitudinal central axis for the package 12.

The package 12 itself is completed by a longitudinal semi-permeable tear strip 16 disposed along and in facing relation to the access opening 15 in the package 12. The tear strip 16, as best seen in exaggerated scale in FIG. 3, here comprises a conventional paper backing 18 and a thin polyethylene coating 19, the polyethylene coat-

ing 19 being in facing relation to the folded sheet 14. The polyethylene coating is preferably of the order of one-half mil in thickness, this thickness of material being insufficient to substantially impede the passage of ethylene oxide gas, but nevertheless providing a sufficient thickness to facilitate mechanical joinder between the paper strip 16 and the folded sheet 14. In these views, thicknesses have been greatly exaggerated and relative dimensions have sometimes been distorted for better visualization of the relation of the folded sheet 14 and the strip 16. Paper provides an inexpensive, easily handled semi-permeable membrane for covering the access opening, but depending upon particular needs other materials, both woven and non-woven, may be used that are impermeable to bacteria. These include various paper-like materials such as various glass fiber products and "Tyvac" a spun polyolefin of the Du Pont Company, that are permeable to ethylene oxide but not to bacteria.

As best seen also in FIG. 3, the paper strip 16 is joined to the folded sheet 14, as by longitudinal heat sealed joinder lines 20, 21 spaced transversely apart from the longitudinal access opening 15. The joinders may also be provided by adhesive or other forms of chemical and mechanical bonding. The width of the paper tear strip 16, relative to the longitudinal opening 15, extends sufficiently transversely beyond either or both of the heat sealed joinder lines 20, 21 to provide a manual gripping edge. Although a greater gripping edge may be provided, it is generally sufficient to provide only enough width of material for grasping with the tips of the fingers. Where greater tearing forces are involved more edge may be provided for more secure gripping. The areal dimension of the tear strip 16 is smaller than the corresponding areal dimension of the container defined by the folded sheet 14 to permit ready viewing of the contents and to afford greater protection to the contents.

The transverse end edges of the folded sheet 14 are sealed to each other and to the paper strip by other joinder lines 24, 25 each of which is adjacent a different respective end. These joinder lines 24, 25 are also conveniently provided by heat seals. Thus in this configuration the longitudinal access opening 15 is completely bounded by a continuous seal consisting of heat sealed joinder lines, each of which is impervious to the passage of bacteria. The paper strip 16 may have marginal graphic representations indicating the points at which the strip 16 may be most readily gripped for removal and the preferred direction of removal may also be indicated.

Assuming that the disposable sterilized item 10 is to be inserted manually, the packages 12 may be fabricated individually, as on a standard packaging machine for plastic bags such as a "Simplex" made by the FMC Corporation of San Jose, Calif. In these machines, tube stock may be fed in continuously or in successive steps, transversely heat sealed and cut into separate packages. During assembly, the present package 12 may be made into a composite tube stock equivalent after which the remaining operations of the "Simplex" are unaffected. In manufacturing the composite tube stock, the sheet material may be passed through formers and the edges turned over and flattened to give the folded sheet 14. The paper strip 16 may concurrently be fed along the longitudinal access opening and into contact with the folded sheet 14. The longitudinal joinder lines 20, 21 are continuously added by heated rollers running in contact with the paper strip parallel to the access opening 15, or by an intermittent heat seal mechanism using longitudinal heater bars. If desired, an internal separator mechanism may be positioned along the path of the composite tube stock to act as a backup member for the heat seal elements.

After the composite tube stock is formed in this fashion the transverse heat sealing and cutting operations may take place in conventional fashion, using either roller elements or heat seal bars. If desired, the packages may

be first fabricated with one open end, the disposable item 10 may be inserted, and the open end thereafter sealed manually. If automatic assembly is used, the disposable item 10 may be inserted after formation of the composite tube in any conventional fashion. In either event a fully sealed package is provided on a substantially continuous basis.

Details of the package 12 construction should particularly be noted. The major portion of the package is a container defined by the folded sheet 14 having folded longitudinal edges and joinder lines 24, 25 closing off the transverse edges. This package 12 is substantially rectangular when empty but conforms appropriately to the inserted item 10. The major portion of the package 12 is transparent so that the item may readily be identified, and it has adequate tear strength, elasticity and rigidity to provide protection equivalent to a conventional package. The access opening 15 is small but in practice provides ample passageway for ethylene oxide. As best seen in FIG. 3, the tear strip 16 covering the access opening is united along the longitudinal joinder lines 20, 21 by fusion of the polyethylene coating material 19 to the opposed surface of the sheet 14. The side edges of the paper strip 16 provide gripping extensions as described above, but the tear strength of the paper strip 16 is preferably greater than the separation strength of the longitudinal joinder lines 20, 21, although with some sizes and shapes of package this relationship need not be observed. The paper strip 16 is impermeable to bacteria, and once the contents of the package 12 are sterilized they remain in this condition.

After loading and complete closure of the package 12, therefore, the entire interior of the package 12 and the container item 10 are sterilized by ethylene oxide in a simple and inexpensive operation. Containment of the package 12 within an ethylene oxide atmosphere for a short time (e.g. a few minutes) is sufficient for the gas to completely fill the interior of the package 12, and to ment of the package in an enclosed chamber held at or near vacuum levels for a short time (e.g. a few minutes) is adequate to purge the package 12 of ethylene oxide. Thereafter, the package is ready for storage and use.

In use, a given item 10 is readily identified and when needed is obtained through the access opening 15 simply by removal of the paper tear strip 16 in a single motion. This construction is such that the package 12 may be held at one end in one hand or the item 10 may be held through the package as the tear strip 16 is torn off. The essentially maximum length of the access opening 15 enables the implement 10 to be extracted in a single motion reducing handling to virtually the absolute minimum.

While it is preferred for most applications to have a paper strip 16 of adequate strength to ensure separation along the longitudinal joinder lines 20, 21 the primary consideration is only that the access opening 15 should be opened for withdrawal of the item 10. Therefore, shredding or imperfect separation of the paper strip 16 is seldom a major problem.

A number of alternatives will suggest themselves to those skilled in the art. The longitudinal joinder lines may not only be provided by different types of bonds but may have different strengths, so that removal of the paper strip might be from one side only. Similarly a gripping edge need be provided only on one side of the access opening. While the use of a plastic coated paper is preferable for most applications, a suitable seal can also be provided by uniting the paper directly to the plastic material. As seen in FIG. 3, distortion of the sheet material resulting from the heating action provides a welding effect due to the rise of the temperature of the plastic to a level at which it is in a readily deformed and semi-fluid condition. Under these conditions the application of pressure results in a uniform and airtight bond and seal. For many applications, however, other sealing techniques can be utilized, such as radio frequency (RF) sealing.

It should be noted that in FIGS. 1 and 3 the overlay of the paper strip on the plastic results in a greater thickness in the overlay region than the thickness adjacent the longitudinal edges of the package. A conventional bar type of heat sealer set to deliver an adequate amount of heat to the overlay regions might create undesirable seal openings due to excessive heating in the end regions. Therefore, it may be preferable to utilize a differentially heated sealer having a central section at a higher temperature than the outer sections. The package may be made in the manner of a continuous tube, as described, or in the form of a conventional wrap system.

A different construction in accordance with the invention is shown in FIG. 4, in which application of the principles of the invention is made to a multiple package 28 for separately storing a number of individual disposable medical or surgical items 30. In this type of construction, separate compartments, e.g., 31, 32, 33 and 34 are formed in a composite tube having a single paper tear strip 36. Each compartment is separated from the adjacent compartments by transverse heat seal joinder lines. For easy separation of the separate compartments, pairs of joinder lines 38, 39 are used together with intermediate perforation lines 40. The access opening is relatively wide, in this example, and the paper tear strip 36 has only a single gripping edge. Here an adhesive bond 42 about the periphery of the access opening for each individual compartment 31-34 provides the desired seal between the semi-permeable strip 36 and the plastic to which it is joined. Thus the compartments 31-34 may be divided into separate packages, if desired, or opened separately or together although the contents are readily sterilized simultaneously.

In another type of construction, as shown in FIG. 5, a different configuration of package 45 is provided to permit storage and access of an item 46 in a different fashion. This type of package is particularly amenable to storage in side-by-side or stacked relation. A plastic tube 47 has transversely heat sealed ends 48, 49 and a slit access opening 51. The access opening 51 is covered by a paper tear strip 53 and a peripheral seal about the opening is provided by heat seal joinder lines 54, 55, 56 defining an encompassing rectangle together with one of the edge seals 49. At one end of the package 45 the paper strip 53 is not joined to the adjacent transverse edge 48 so as to provide a gripping edge. In this construction plastic coating strips 53, 59, 60 are applied on the paper tear strip 53 only along the seal lines.

With the product of FIG. 5, the package 45 may be handled from one end, here assumed to be the top, by tearing down on the tear strip 53 while holding the upper end of the package 45. The horizontal access opening 51 is immediately exposed to permit removal of the disposable item 46.

What is claimed is:

1. A package for storing items in bacteria-free condition, comprising:

a transparent polyethylene sheet of a thickness sufficient to be substantially impermeable to sterilizing gas and bacteria, said sheet having longitudinal and transverse edges, said sheet being folded along longitudinal fold lines, said longitudinal edges being disposed in close approximation defining a longitudinally extending slit access opening; and a longitudinally extending strip, permeable to said sterilizing gas but impermeable to said bacteria, extending the length of said package and closing said longitudinal access opening, said strip being secured by a longitudinally extending continuous pressure heat seal line on each side of said opening, the width of said strip being substantially less than the overall transverse width of the package between said fold lines whereby stored items are easily visible through either face of said package and one transverse edge of said sheet having a transverse pressure heat sealed joinder line

to close the end and further uniting the strip to said sheet along said transverse edge.

2. The invention as set forth in claim 1 above wherein the strip is paper and the tear strength of the paper relative to the strength of the heat longitudinal heat seal joiner lines is sufficient so that the paper strip is substantially completely separable from said polyethylene sheet so as to provide substantially complete access to said opening.

3. The package as set forth in claim 1 wherein a plastic coating covers one entire side of the strip but is adequately thin to be substantially permeable to the selected sterilizing gas.

4. The package as set forth in claim 1 wherein said longitudinal edges are overlapped.

5. The package as set forth in claim 1 wherein said

strip includes at least one gripping edge whereby said strip may be easily removed to open said package.

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WILLIAM T. DIXSON, JR., Primary Examiner

U.S. Cl. X.R.

206—56; 229—66

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,472,369

Dated October 14, 1969

Inventor(s) Samuel J. Schuster

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 2, line 12, for "case" read --ease--. Column 4, line 8, for "greately" read --greatly--; line 27, for "manuel" read --manual--. Column 5, line 5, after "tube" insert --stock--; line 9, for "potrion" read --portion--; after line 38 and before line 39, insert --sterilize all accessible surfaces. Thereafter, the place- --; line 67, after "plastic" insert --sheet--. Column 7, line 5, strike out "heat", first occurrence.

SIGNED AND
SEALED

MAY 19 1970

(SEAL)

Attest:

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Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents