

## Brady

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- [54] PACKAGE FOR STERILIZED PRODUCTS**

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229/51 AS. 229/66

- [51] Int. Cl. ....B65d 33/16, A61b 19/02

- [58] **Field of Search**.....229/62, 66, 51 AS, 487;  
206/63.2 R, 63.3 R, DIG. 29, DIG. 34

- [56]
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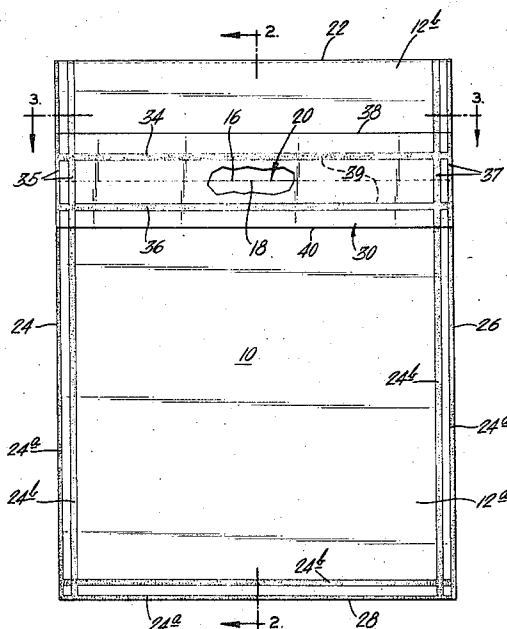
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[57] **ABSTRACT**

A package for sterilized products comprising a container made of a plastic material, means defining an access opening through which the products may be withdrawn, and a tear strip of an opaque porous material sealed over said access opening in a seal area about the periphery of said access opening, said seal area being transparent to provide indicia of an integral seal.

## 7 Claims, 9 Drawing Figures





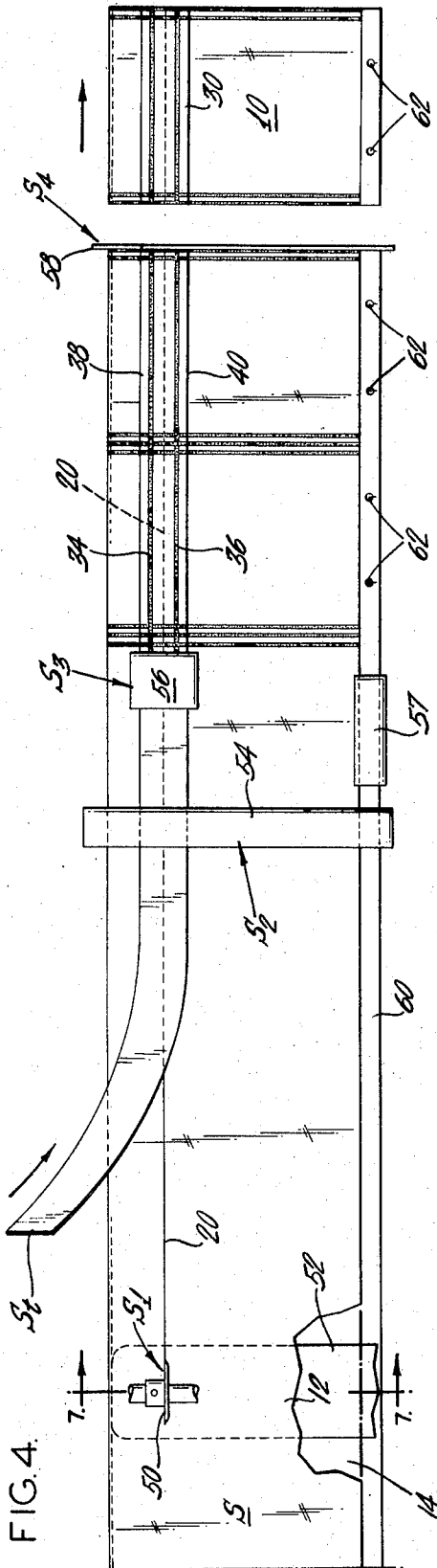


FIG. 4.

FIG. 6.

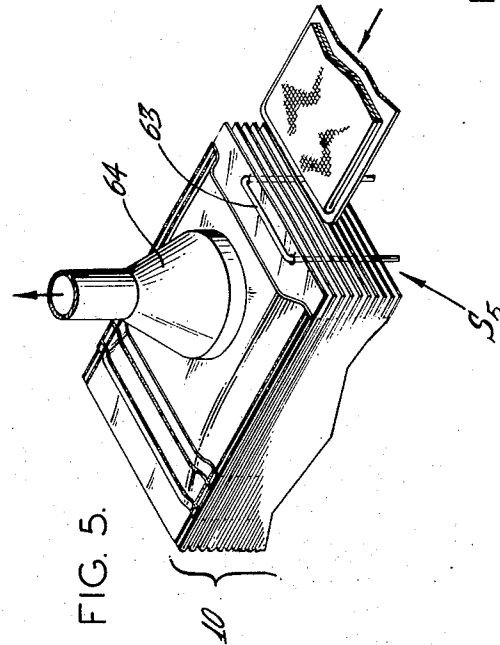
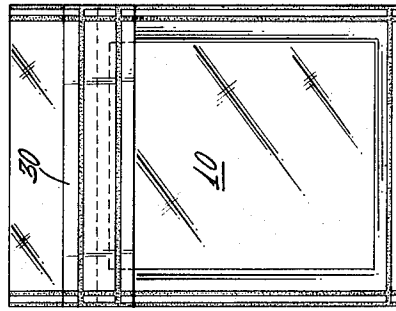


FIG. 5.

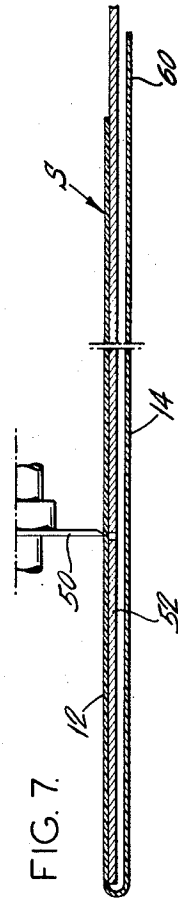


FIG. 7.

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**PACKAGE FOR STERILIZED PRODUCTS**

The present invention relates to improvements in packages for sterilized products, for example hospital supplies and a novel method of making the same.

There are various types of packages for sterile products such as hospital supplies, the most common being in the form of a plastic or porous paper bag having an access opening therein which is normally sealed by a tear strip made of paper adhered over the access opening. There are several disadvantages or drawbacks in this type of package. For example, in cases where the tear strip is glued over the access opening, there is a tendency to fragment the tear strip when removing it to withdraw the contents of the package. This presents the danger of contaminating the sterile product of the package. Furthermore, in none of these packages is there any visual indicia means whereby the user is absolutely certain that the contents of the package have been maintained in a sterile condition prior to use.

The package of the present invention overcomes these objections and drawbacks and comprises broadly a pair of front and rear panels, preferably made of a transparent plastic material such as polyethylene, which are sealed about their peripheral edges to define a pocket for the contents. One of the panels has an access opening which is normally sealed by a tear strip made of an opaque porous material, preferably a spun fiber product which is porous to permit sterilization by ethylene oxide. An important feature of the present invention is the provision of visual indicia means whereby the manufacturer may at a glance be assured that the package has an integral seal primarily in the area surrounding the access opening. An integral seal is one which is strong enough to resist rupture as a result of variations in internal pressure in the package which may occur during manufacture, loading, shipping, storage, or normal handling. More specifically, this indicia means is in the form of a transparent sealing band which results when the tear strip is secured over the access opening by impulse sealing. By this arrangement, if the peripheral band around the access opening is transparent, then this is notice that the seal is integral. Additionally, the sealing band is spaced inwardly from at least one side edge of the tear strip to define a tab which can be gripped by the user to remove the tear strip to expose the access opening without contacting the sterile zone in the vicinity of the access opening.

The package may comprise separate front and rear panels. In this event, the filled package of the present invention includes a double seal arrangement at the open edges of the overlying panels which is also for the purpose of insuring sterility of the contents. This double seal zone or band may also be transparent by employing the impulse sealing method.

The package design of the present invention is relatively simple and is economical to manufacture. Further, the process of packaging the products including sterilization thereof also lends itself to high production techniques.

These and other objects of the present invention and the various features and details of the construction thereof are hereinafter more fully set forth with reference to the accompanying drawings, wherein:

FIG. 1 is a plan view of a package for sterilized products in accordance with the present invention;

FIGS. 2 and 3 are enlarged sectional views taken on lines 2—2 and 3—3 of FIG. 1;

FIG. 4 is a schematic illustration of a method for making a package in accordance with the present invention;

FIG. 5 is a plan view showing a means for loading the contents in the package;

FIG. 6 is a similar view showing the encapsulated product with the package sealed;

FIG. 7 is a view taken on line 7—7 of FIG. 4;

FIG. 8 is a perspective view showing the partial removal of the tear strip; and

FIG. 9 is a perspective view showing the package with the tear strip removed and the product being removed from the package.

Referring now to the drawings and particularly FIG. 1 thereof, there is shown a package for sterile products in accordance with the present invention which is generally designated by the numeral 10. The package comprises front and rear panels 12 and 14 respectively which, in the illustrated embodiment are of generally rectangular shape and are made of a flexible resilient material. The material may be a transparent plastic material such as polyethylene and of a sufficient thickness, for example about 3 mils, to provide sufficient strength and durability so that it does not readily rupture in normal use or handling. As illustrated, the front panel has a lower section 12a and an upper section 12b, the adjacent confronting edges 16 and 18 of which define an access opening 20, through which the contents may be withdrawn. In the present instance, the upper section 12b of the front panel 12 is formed integrally with the rear panel 14 along an upper transverse fold line 22.

The front and rear panels are in opposed confronting relation and are joined along their opposed side edges 24 and 26 and along the bottom edge 28. The panels are sealed along these edges by conventional means, that is application of heat and pressure. However, in the particular construction illustrated, the panels are joined along the side and bottom edges by double spaced apart seals 24a, 24b. In a package of this type it is essential that the contents of the package be maintained in a sterile condition prior to use and the double seal insures against the possibility of any breakage of the seal, for example during manufacture, the sterilization process, or normal handling during shipping and subsequent handling in the hospital.

The package further includes a tear strip 30 which overlies the access opening 20 and as illustrated is of generally rectangular shape and of a width substantially equal to the width of the package. The tear strip 30 is preferably made of a permeable opaque material to facilitate sterilization of the product after packaging of the product by treatment with a sterilizing medium such as ethylene oxide. A suitable material for the tear strip 30 is a spun polyolefin manufactured by DuPont Company under the trade name Tivek. The tear strip 30 is secured to the front panel of the package over the access opening 20 along the opposed side edges by a double seal which as described hereafter is performed during the sealing of the side edges of the front and rear panels. Additionally, the tear strip is detachably sealed to the front panel in two parallel areas 34 and 36 on opposite sides of the access opening 20 and spaced inwardly from the opposed parallel side edges of the tear strip. By this arrangement, the upper and lower tabs 38 and 40 are formed to facilitate removal of the tear strip by the user as explained in more detail hereafter.

An important feature of the present invention is the provision of means for visually determining whether the seal around the access opening 20 in the package is intact at the time the user desires to withdraw the contents of the package thereby insuring its sterility. To this end the parallel transverse seal areas 34 and 36 as well as the longitudinal seal areas 35 and 37 at opposite ends of the tear strip 30 are transparent. This is accomplished during the sealing operation of the tear strip 30 over the access opening 20 by means of an impulse sealing unit wherein the application of heat and pressure are controlled in a predetermined manner. Additionally, the face of the tear strip 30 confronting the front panel is coated, for example, with wax which in combination with the sealing method produces the transparent seal areas around the periphery of the access opening 20. By this construction there is an integral seal around the access opening, one which resists rupture during normal processing and handling. It is noted that in the drawings the transparent bands or seal areas are shown as stipled zones or areas for purposes of illustration.

It is noted that the seal areas 34 and 36 are in the present instance equi-spaced on opposite sides of the access opening 20 to define therebetween a sterile zone 39. This provides a measure of safety in insuring that the user does not contact unsterile portions of the package during removal of the product after the tear strip 30 has been removed. [See FIG. 9].

There is illustrated schematically in FIG. 4 a method and system for making the packages or containers of the present invention. As illustrated therein, a single sheet S of the plastic material for the package, such as polyethylene, is overlapped and fed in a continuous manner along a support surface where at a first station  $s_1$ , cutting means in the form of, for example a rotary blade 50, slits the front panel 12 of the overlapped sheet to form the access opening 20 for the package. A suitable back up anvil 52 is provided at this station to preclude cutting the back panel 14 of the package. Thereafter, the tear strip material  $S_t$  is fed in a continuous manner so that it overlies the access opening 20. It is noted that the coated face of the tear strip material is fed from its supply source so that it confronts the front panel in the manner illustrated. The sheet material S and the tear strip material  $S_t$  may be in roll form at a stationary supply station [Not shown].

Suitable sealing means 54 at a first sealing station  $S_2$  is provided to form a triple seal at predetermined spaced intervals and this sealing means may be of the conventional impulse type wherein the triple seal areas are provided by localized application of heat and pressure. It is noted that by conventional means the linear feed speed of sheet material S may be synchronized with the sealing means 54 to seal at predetermined spaced locations depending on the desired width of the package. Thereafter, the sheet material passes through a second sealing station  $S_3$  where an impulse sealing unit 56 effects the transverse seal areas 34 and 36 of the tear strip 30 over the access opening 20 in the front face of the package. The sealing unit 56 is oriented and arranged to effect the seal areas to define the opposed tear tab portions 38 and 40 of the tear strip and also in a manner to effect the transparent sealing of the tear strip in the zones 34 and 36. This is an important aspect of the present invention whereby visual inspection of

the sealed package permits the manufacturer to determine that the package is effectively sealed around the periphery of the access opening. The sheet assembly then passes through a cutoff station  $S_4$  wherein a suitable cutoff blade 58 severs the sheet material approximately at the center of the central side seal area so that the package at this stage has the double seal on opposing side edges. In the present instance the sheet material S is overlapped in a manner so that the rear panel 14 extends beyond the lower edge of the front panel 12 to provide a flap 60 having a pair of holes 62 therein to facilitate loading of the packages at the loading station  $S_5$ . A conventional hole punching apparatus 57 is provided to puncture the flap 60 to form the holes 62. It is noted that the sealing stations  $S_2$  and  $S_3$  may be reversed so that the tear strip is sealed to the front panel prior to formation of the side seals.

The packages in this form are then accumulated and moved to the loading station  $S_5$ . In the present instance, a plurality of packages are mounted on a wicket 63 in the manner illustrated in FIG. 5 and suitable means is provided for displacing the front and rear panels to facilitate insertion of the contents of the package in the manner illustrated. This means may comprise a suction cup arrangement 64 or, in lieu of the suction cup arrangement, a system of air nozzles directed into the interior of the package to effect the same result.

After the top package at the loading station  $S_5$  is filled, the filled package is simply pulled from the wicket 63 and then transferred to a final sealing station wherein flap 60 is double sealed and trimmed.

The filled packages may then be placed in shipping cartons or the like and these cartons in turn are treated in a suitable manner with a sterilizing medium, for example, ethyleneoxide.

As noted above, the package may be effectively used for various hospital products where the sterility of the contents must be maintained prior to use. The package of the present invention serves this purpose in an extremely effective manner. Additionally, the arrangement of the tear strip permits the package to be opened very simply without the danger of contaminating the contents by, for example the user's hand contacting unsterile portions of the package. For example, when it is desired to remove the contents of the package, the doctor's aide, for example a nurse, simply rips the tear tab portion of the tear strip and peels the tear strip back to expose the access opening in the manner shown in FIG. 8. The aide then folds back the upper portion of the package to widen the access opening and permit, for example, the sterile nurse to withdraw the contents of the package in the manner shown in FIG. 9. It is noted that with the package of the present invention there is a sterile zone on either side of the access opening to preclude the possibility of the nurse's gloved hand contacting unsterile portions of the package.

In some applications, it may be desirable to make the tear strip 30 a laminated strip comprising a coated thin layer of the Tivek which is adhered to and confronts the front panel of the package and an outer facing of paper. The paper facing would minimize the risk of sparking which is present in the use of the Tivek and would also be more readily adapted to imprinting where it is desired to mark the tear strip with identification indicia.

I claim:

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1. A package for a sterilized product comprising a container made of a plastic material, said container consisting of overlying front and rear panels, the front panel having upper and lower sections adjacent confronting edges of which define an access opening, said front and rear panels being joined along their open edges, an opaque tear strip over said access opening, said tear strip made of spun bond polyolefin having a heat seal waxlike coating on one face thereof confronting said front panel, said tear strip being sealed over said access opening in a predetermined controlled manner so that the seal area about the periphery of said access opening is transparent through said tear strip to provide visual indicia means of an integral seal.

2. A package as claimed in claim 1 wherein the upper section of the front panel is formed integrally with the rear panel along an upper transverse fold line.

3. A package as claimed in claim 1 wherein the front and rear panels are joined by means of a double seal arrangement.

4. A package as claimed in claim 1 wherein the front and rear panels are generally rectangular and said rear panel has a flap extension with openings therein to facilitate loading on a wicket where the packages may be filled.

5. A package as claimed in claim 1 wherein the seal areas extending the length of said access opening are spaced therefrom to define a sterile zone.

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6. A package as claimed in claim 1 wherein the seal areas extending lengthwise of said access opening are spaced inwardly from the opposed edges of said tear strip to define tabs facilitating removal of said tear strip.

7. A package for a sterilized product comprising a container made of a plastic material, said container consisting of overlying front and rear panels, the front panel having upper and lower sections adjacent confronting edges of which define an access opening, said front and rear panels being joined along their open edges, an opaque tear strip over said access opening, said tear strip made of spun bond polyolefin having a heat seal waxlike coating on one face thereof confronting said front panel, said tear strip being sealed over said access opening in a predetermined controlled manner so that the seal area about the periphery of said access opening is transparent through said tear strip to provide visual indicia means of an integral seal, the seal areas extending the length of said access opening being spaced therefrom to define a sterile zone and said product being disposed in the lower portion of said package with the upper edge generally aligned with the access opening whereby upon removal of said tear strip the upper section of said package may be folded to expose the product through said access opening thereby providing a sterile field for delivery of the product.

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