Jan. 31, 1967 P. E. REGAN, JR 3,301,392

NESTED PACKAGE

Filed Nov. 24, 1965

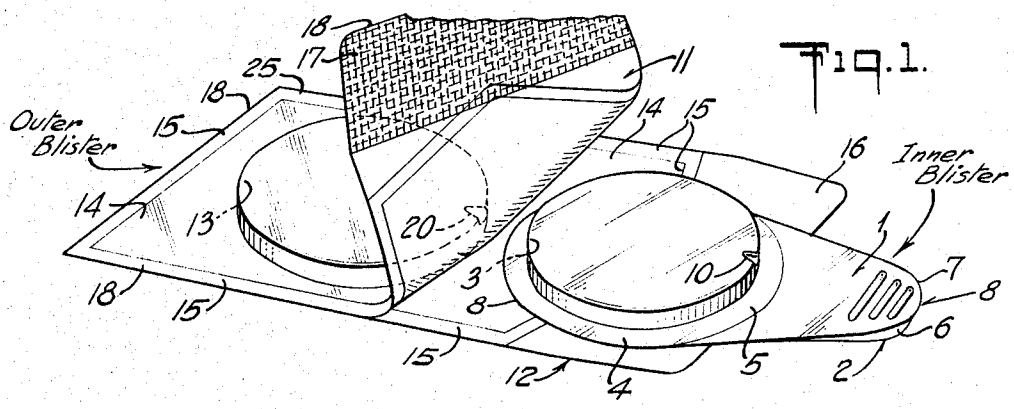


Fig. 1.

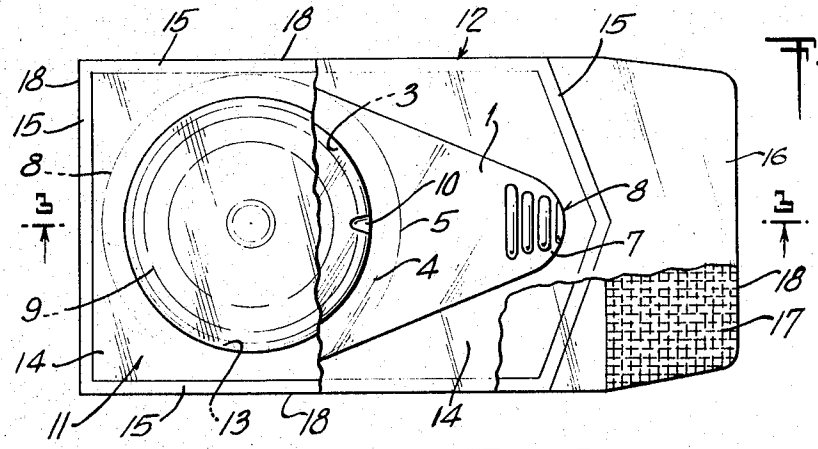


Fig. 2.

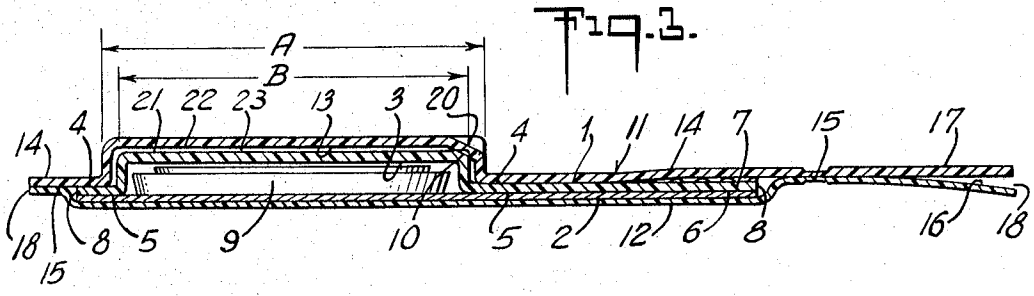


Fig. 3.

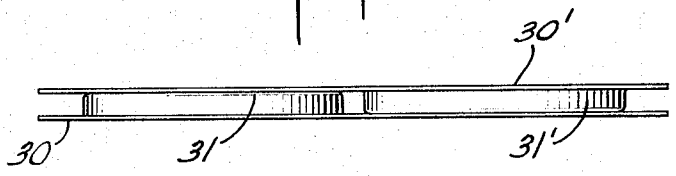


Fig. 4.

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United States Patent Office 3,301,392 Patented Jan. 31, 1967

3,301,392

NESTED PACKAGE

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Filed Nov. 24, 1965, Ser. No. 509,486
7 Claims. (Cl. 206—56)

This invention relates to sterile surgical packages and, more particularly, to sterile surgical blister packages.

Surgical packages must be permeable to sterilizing vapors and gases and yet must remain bacteria impervious up until the moment the sterile surgical product is used. Although the various package members must be securely sealed together so as to provide a package impervious to bacteria, the package must be subject to swift opening and to the sterile removal of the sterile surgical product under what usually amounts to emergency conditions. The surgical packages should have a degree of rigidity so as to protect the surgical product during handling and storage; however, the construction of the package should also be such that an adequate hospital or office supply of the packaged product occupies a minimum of storage space.

Not only must the surgical product be sterile but, in addition, it is desirably enclosed in a container which is sterile. This is conveniently accomplished by enclosing an inner container in which the sterile surgical product is enclosed in a bacteria impervious outer container. Thus, when it is necessary to use the product, the outer container may be stripped open by the circulating nurse and the sterile inner container removed by the sterile nurse and placed in the surgical area without contaminating the surgical area. This outer container, of course, is also desirably easily openable and is preferably transparent so that both the sterile surgical product and any message present on the inner container is visible, thus permitting visual confirmation by the surgeon of the presence of the proper surgical implements.

It is extremely important that both the inner container and the outer container remain structurally independent despite their cooperation. Thus, when the inner container is removed from the outer container, the integrity of the sterile inner container is not affected. For this reason when the sterile inner container in which the sterile surgical product is enclosed is positioned within the members which when sealed together will form the outer container, it must be assured that the sterile inner container will be in and will remain in a definite predetermined position so that there is no chance of it becoming sealed to the package members forming the outer container.

According to this invention, a sterile surgical package is provided in which the sterile surgical product is enclosed in an inner blister container and the inner blister container is, in turn, enclosed within an outer blister container. Both the inner container and the outer container comprise a molded sheet which is shaped to form a receiving chamber and a flat rim surrounding the receiving chamber, and a cover sheet which is sealed to the molded sheet around the flat rim. The surgical product is received by the chamber of the molded sheet of the inner container, and the inner cover sheet is sealed to the inner molded sheet in an area around its rim to complete the inner container. The peripheral dimensions of the chamber of the outer container are slightly greater than the peripheral dimensions of the chamber of the inner container. Thus, when the chamber of the completed inner container is received by the chamber in the molded sheet of the outer container, the flat rim of the inner container is oriented in a definite predetermined position with respect to the flat rim of the molded sheet of the outer container. When the outer cover sheet is sealed to the outer molded

sheet in an area around its rim beyond the rim of the inner container to complete the outer container and thus complete the sterile surgical package, it is assured that the inner container will not, as a result of being out of position, become sealed to the members forming the outer container.

In the completed package, the rim of the inner container is unbonded to, but clamped between, the molded sheet and the cover sheet of the outer container by virtue of which the peripheral surfaces of the inner chamber are situated in a definite position with respect to the peripheral surfaces of the outer chamber. The above described nesting of the chambers and the clamping of the rim of the inner container combine to essentially entirely restrict the movement of the inner container within the outer container.

At the time of the forming of the package, a permanent gap of predetermined magnitude can be provided between the peripheral surfaces of the outer chamber and the peripheral surfaces of the inner chamber. As a result of the space between the surfaces of the inner chamber and outer chamber, the outer molded sheet and the inner molded sheet provide the package with two separate and independent barriers which protect the sterile product from crushing and other forces applied to the package from its molded side. Since the molded side of the package preferably is transparent, it is usually this side which is exposed when the package is placed on a stand or table prior to use.

Since the rim of the inner container is clamped within the rim of the outer container, the outer container utilizes a smaller receiving chamber than would be possible if the entire inner container were received within the chamber of the outer container. Thus, the design of the containers is such that they may be stored in large numbers while using a minimum amount of storage space.

In addition to the above mentioned advantages, the containers may be made transparent so that the sterile surgical product may be seen through the walls of the package. Despite the cooperation between the inner container and outer container to restrain the inner container in a definite position within the outer container, the inner container remains structurally independent of the outer container and both containers may be made easily openable by providing a stripping tab at the periphery of the rim of the inner container and at the periphery of the rim of the outer container.

The inventive concept and the advantages resulting therefrom can be best understood by reference to the attached drawings and following description. In the drawings,

FIG. 1 is an exploded view in perspective of the package of this invention,

FIG. 2 is a plan view of a sterile surgical package of this invention,

FIG. 3 is a cross sectional view of the package of FIG. 2 taken along line 3—3,

FIG. 4 is a schematic representation of the packing together of two packages of this invention.

Referring now to the figures, there is shown a sterile surgical package comprising a hermetically sealed outer container, a hermetically sealed inner container situated within the outer container and a sterile surgical product enclosed in the sterile inner container. The sterile inner container comprises a relatively rigid bacteria impervious preferably transparent molded inner product receiving sheet **1** and a bacteria impervious inner cover sheet **2**. The outer container similarly comprises a relatively rigid bacteria impervious preferably transparent molded outer receiving sheet **11** and a bacteria impervious outer cover sheet **12**. The inner cover sheet is preferably opaque so

as to permit a message to be printed thereon while the outer cover sheet is preferably transparent to permit reading of the message.

The molded inner product receiving sheet 1 is shaped to form an inner chamber 3, which entirely receives the sterile surgical product 9, and a flat peripheral rim 4 surrounding the inner chamber. While the inner chamber will usually conform substantially to the shape of the product, this is not essential to the inventive concept. The inner cover sheet 2 overlaps the inner chamber 3 and overlaps the peripheral rim 4 of the molded inner product receiving sheet around its entire perimeter. In the preferred embodiment illustrated, the inner cover sheet is the same shape and size as the molded inner product receiving sheet; however, the invention is not limited to this embodiment. The inner cover sheet may be any shape or size as long as it overlaps at least a portion of the flat peripheral rim 4 of the inner product receiving sheet 1 around its entire perimeter and as long as it is not of such greater size than the inner product receiving sheet as to interfere with the nesting of the inner container within the outer container and the sealing of the members of the outer container hereinafter more fully described. It is preferably relatively flexible so that opening of the container by peeling is facilitated.

The inner cover sheet 2 is sealed to the peripheral rim 4 of the inner product receiving sheet in a continuous area 5 around its entire perimeter. In the preferred embodiment illustrated, the inner cover sheet is free of any seal with the inner product receiving sheet in an unbonded area 6 at the periphery of the inner cover sheet so as to form an inner stripping tab 7. Thus by grasping the tab and the cover sheet, the inner container may be opened easily by stripping and the sterile product extracted. Any number of other varieties of stripping tabs can be formed, as for example, by extending the inner cover sheet beyond the peripheral rim of the inner receiving sheet and sealing the inner cover sheet to the peripheral rim of the inner receiving sheet in all areas where they overlap or, if it is desired, no stripping tab need be provided at all.

The package members will usually be thermoplastic and for this reason and because a better hermetic seal can usually be obtained through heat sealing than through pressure sensitive adhesive sealing, the package members are preferably sealed together by heat sealing. Pressure sensitive adhesive bonding can be used, however, without departing from the inventive concept.

Referring now to the outer container, the molded outer receiving sheet 11 is shaped to form an outer chamber 13 and a flat rim 14 surrounding the outer chamber. The peripheral dimension A of the outer chamber 13 is slightly greater than the peripheral dimension B of the inner chamber 3 so that the inner chamber can nest within the outer chamber. As a result of the nesting configuration, the flat rim 4 of the inner container is oriented in a definite position with respect to the flat rim 14 of the molded sheet of the outer container. The outer edges 18 of the rim 14 of the outer container lie substantially beyond the outer edges 8 of the peripheral rim 4 of the inner container and overlap the peripheral rim 4 of the inner container around its entire perimeter. The outer cover sheet 12 overlaps the outer chamber 13 and overlaps the rim 14 of the outer container around its entire perimeter. Although in the preferred embodiment illustrated, the outer cover sheet and the outer receiving sheet are the same size and shape, the outer cover sheet may be any size and shape as long as it overlaps the inner container and a portion of the peripheral rim 14 of the outer receiving sheet beyond the outer edges 8 of the inner container around its entire perimeter. The outer cover sheet 12 is sealed to the rim of the outer receiving sheet in a continuous area 15 beyond the outer edges 8 of the inner container and surrounding the inner container. This sealed area 15 must lie entirely beyond the outer edges 8 of said inner container so that the rim of the inner container is unbonded to the outer container. Again the cover sheet is preferably relatively flexible to faciliate opening of the outer container.

By virtue of the rim of the inner container being situated in a definite position with respect to the rim of the outer container it is assured that when the outer cover sheet is sealed to the outer molded sheet, the rim of the inner container will not interfere with the sealing of or become sealed to the outer container. In the special case of the circular chamber illustrated, an inner notch 10 and an outer notch 20 may suitably be provided to prevent the rotating of the inner container within the outer container.

Although the rim of the inner container is not bonded to the outer container, it is preferably, as illustrated in the drawings, clamped between the molded sheet and cover sheet of the outer container. By virtue of the clamping of the inner peripheral rim within the outer peripheral rim, the outer top peripheral surface 21 of the inner chamber is situated in a definite position with respect to the inner top peripheral surface 22 of the outer chamber. This clamping, combined with the nesting of the inner chamber within the outer chamber, serves to restrain essentially all movement of the inner container within the outer container. By virtue of the space 23 between the peripheral surfaces of the outer chamber and inner chamber, which may be any predetermined space, any minor crushing of the molded side of the outer container does not affect the inner chamber. Thus, the inner molded sheet presents a second independent barrier which protects the sterile product from crushing and other forces applied to the package from its molded side. If the outer container is damaged during handling, an undamaged inner container may still be available for placing in the operative area.

The outer cover sheet is free of any seal with the outer receiving sheet in an unbonded area 16 at the periphery of the outer cover sheet so as to form outer stripping tab 17. Although in the preferred embodiment illustrated an outer stripping tab is so formed, packages of this invention can also be formed which do not have such an outer stripping tab or have tabs of various configurations.

Since the rim of the inner container is clamped within the rim of the outer container rather than the inner container being entirely received by the chamber of the outer container, a number of the packages can be stored in a minimum of space. FIG. 4 is a schematic representation of two packages of this invention positioned for bulk packaging. A portion of the peripheral rim 30, 30' of each package overlaps the chamber 31, 31' of a second package thus forming a compact unit.

The containers thus formed are bacteria impervious. They may be made transparent so that the sterile surgical product may be seen through the walls of the package and are relatively rigid so as to protect the surgical product during transportation and storage. The particular design of the container is such that it may be stored in large numbers without using a substantial amount of storage space. The two containers are structurally independent of each other. The outer container can be easily and independently stripped open to extract the inner container and the inner container can be easily and independently stripped open to extract the sterile surgical product.

While the particular package illustrated and above described is substantially rectangular in shape, the packages of this invention can be square, circular, triangular or any other shape which may be desired for a given surgical product. The chambers of each container can be of any shape or size as long as the above discussed relationship between them is fulfilled.

A wide variety of materials may be used to form the packages of this invention. The materials chosen for each of the members of each of the containers need only be bacteria impervious, sterilizable, and mutually heat sealable. The materials are also, of course, chosen with a

view toward the desired transparency and flexibility or rigidity of each of the package members.

Almost any of the conventional unsupported thermoplastic films can be used to form packages according to this invention. As previously discussed, it is desirable that each of the individual containers be easily openable by peeling so that the inner container may be quickly removed from within the outer container and so that the sterile surgical product may be rapidly extracted from the inner container. Therefore, in the preferred embodiments of this invention the materials to be used for mutually bonded members are made of either the same thermoplastic material or materials belonging to the same group of thermoplastic materials. Therefore, the molded sheet and the corresponding cover sheet usually differ only in thickness or weight. Since only the surfaces of the sheets which form the sealed interface need have matched thermoplastic properties to provide easy peelability, the package members may be in the form of single films, coated films or film laminates.

Of the many acceptable materials, polyvinyl chloride acetate butyrate, cellulose propionate, cellulose acetate, polycarbonate, polyethylene and polypropylene are among the best. Polyvinyl chloride and acetate butyrate have been found to be especially suitable for the packages of this invention. Sheets of the latter substances are easily moldable and thermoplastic seals formed between two sheets of one of these materials are strong, yet easily peelable. The materials are stable to heat, ethylene oxide, or cobalt sterilization. They are transparent and various degrees of rigidity or flexibility may be provided by varying the film thicknesses; for example, a 10 mil thick polyvinyl chloride film may be chosen for one of the relatively rigid molded receiving sheets while a 3 mil thick laminate consisting of a polyvinyl chloride heat sealable coating on a substrate such as aluminum foil or transparent thermoplastic sheet could be used to provide a relatively flexible cover sheet.

The packages of this invention may be produced by conventional thermoplastic sealing and molding techniques, the temperture and pressure conditions of which are well known in the art. The package members may be molded, where necessary, by conventional molding methods and the members then aligned in the proper relation with respect to each other and sealed together.

Although several specific embodiments of the invention have been illustrated and described, the same should not be interpreted as limiting the invention. The invention should be limited only by the following claims.

What is claimed is:

1. A sterile surgical package which comprises a hermetically sealed outer container, a hermetically sealed sterile inner container situated within said outer container, and a sterile surgical product enclosed in said sterile inner container, said sterile inner container comprising a relatively rigid bacteria impervious molded inner product receiving sheet and a bacteria impervious inner cover sheet, and said outer container comprising a relatively rigid bacteria impervious molded outer receiving sheet and a bacteria impervious outer cover sheet, said molded inner product receiving sheet being shaped to form an inner chamber which entirely receives said sterile surgical product and a flat peripheral rim surrounding said inner chamber, and said inner cover sheet overlapping said inner chamber and said peripheral rim of said inner container around its entire perimeter and being sealed to said rim in a continuous area around its entire perimeter, said molded outer receiving sheet being shaped to form an outer chamber and a flat rim surrounding said outer chamber, the peripheral dimensions of said outer chamber being slightly greater than the peripheral dimensions of said inner chamber and said inner chamber nesting within said outer chamber so as to orient the peripheral rim of the inner container in a definite position with respect to the peripheral rim of the outer container, the outer edges of the rim of said outer container lying substantially beyond the outer edges of the peripheral rim of said inner container and overlapping the peripheral rim of said inner container around its entire perimeter, the outer cover sheet overlapping the outer chamber and rim of the outer container around its entire perimeter and being sealed to said rim in a continuous area only beyond the periphery of said inner container and surrounding said inner container, whereby a package is provided wherein the peripheral rim of the inner container is situated in a definite position with respect to the peripheral rim of said outer container by virtue of the nesting of said inner chamber and said outer chamber and wherein the peripheral rim of said inner container is nested between the moldable receiving sheet and the outer cover sheet of said outer container inward of the area in which the outer receiving sheet is sealed to the outer cover sheet.

2. The sterile surgical package of claim 1 in which each of said inner and outer chambers is substantially circular in shape with respect to the plane of the rim surrounding the chamber and in which each chamber presents a stop adapted to cooperate with the stop of the other to facilitate registration of the chambers and retain them in position with respect to one another.

3. The sterile surgical package of claim 1 in which said inner cover sheet is free of any seal with said inner receiving sheet in an area at the periphery of said inner cover sheet so as to form an inner stripping tab and in which said outer cover sheet is free of any seal with said outer receiving sheet in an area at the periphery of said outer cover sheet so as to form an outer stripping tab, whereby a package is provided wherein the outer container can be easily and independently stripped open to extract said inner container and the inner container can be easily and independently stripped open to extract said sterile surgical product.

4. The sterile surgical package of claim 1 in which the molded inner product receiving sheet and the molded outer receiving sheet are transparent.

5. A sterile surgical package according to claim 1 in which said inner chamber substantially conforms to the shape of said sterile surgical product.

6. The sterile surgical package of claim 1 in which the flat peripheral rim of the inner container is clamped between the outer receiving sheet and the outer cover sheet inward of the area in which the outer receiving sheet is sealed to the outer cover sheet so as to orient the peripheral surfaces of the inner chamber in a definite position with respect to the peripheral surfaces of the outer chamber, whereby a package is provided wherein the inner container is situated in a definite position within said outer container.

7. The sterile surgical package of claim 6 in which the outer chamber is appreciably deeper than the inner chamber thereby defining a gap in depth between the molded chamber portions of the inner container and the outer container, whereby a package is provided which possesses two separate and independent barriers which protect the sterile product from crushing and other forces applied to the package from its molded side.

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