United States Patent

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[54] **SUTURE PACKAGING**
1 Claim, 5 Drawing Figs.

[52] **U.S. Cl.** ..... **206/63.3,** 206/46 ST, 206/56 AA, 206/63.2 R, 206/78 B
[51] **Int. Cl.** **A61i 17/02**
[50] **Field of Search** ..... 206/43, 46 PV, 46 SG, 46 ST, 56 A, 56 AA, 56 AB, 63.2, 63.3, 45.34, 78 B

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ABSTRACT: A package for sutures which are contained under conditions of complete sterilization is disclosed with a method for in-line sterilization packaging of the objects on mass production basis. The package includes a hermetically sealed inner packet in which the suture material is received and which has at least initially, a sterilizing gas confined therein, the inner packet in turn being received in an outer packet of the same general construction as the inner packet and which also is hermetically sealed and initially has a sterilizing gas confined therein. The package is made by filling the inner packet blister with the suture material, then tacking a lid onto the blister and confining the inner packet in a vacuum chamber to remove air from the inner packet. Sterilizing gas is then admitted to the chamber for killing any bacteria on the suture material. The lid is then sealed to an associated blister while still in the chamber so that a quantity of the sterilizing gas is captured within the sealed inner packet. The sealed inner packet is then removed from the vacuum chamber and placed in an outer packet blister and a closure lid tacked in place on the blister. The outer packet is then subjected to the same sterilization and packaging procedures as the inner packet.

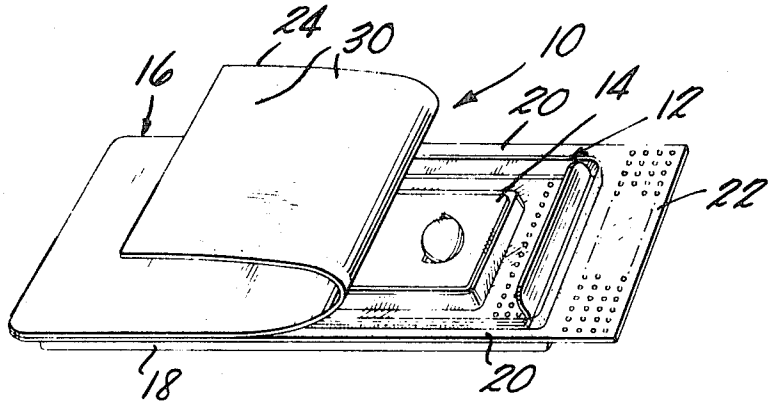


FIG. 1

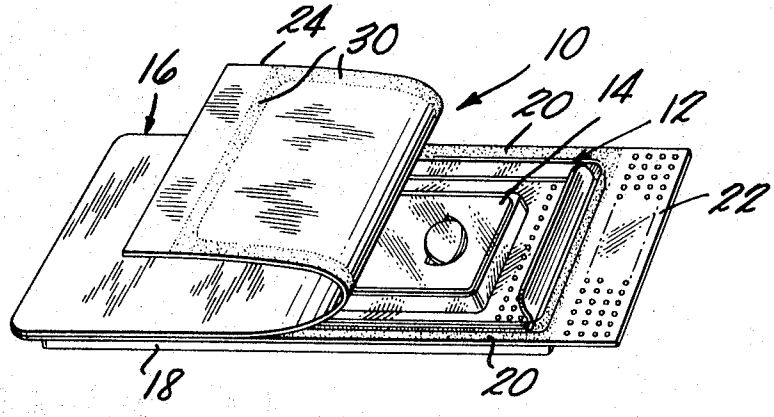


FIG. 2

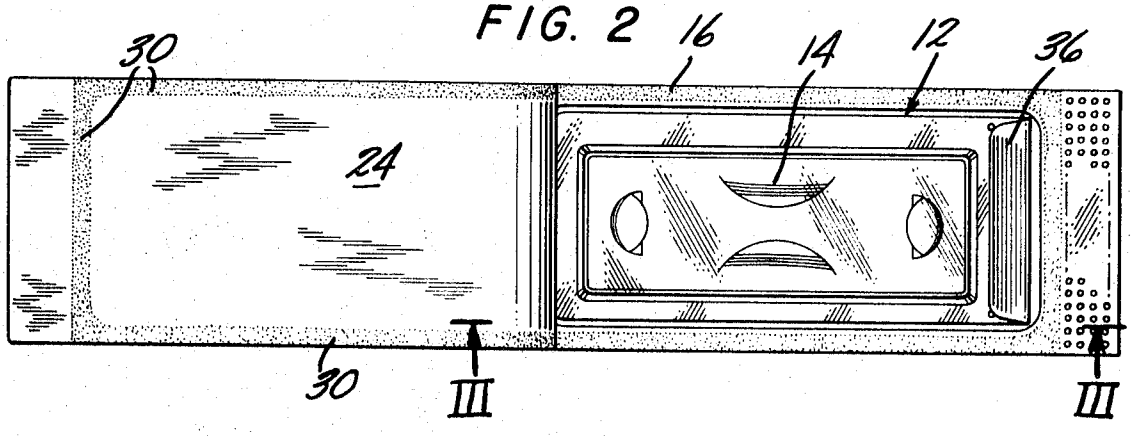


FIG. 3

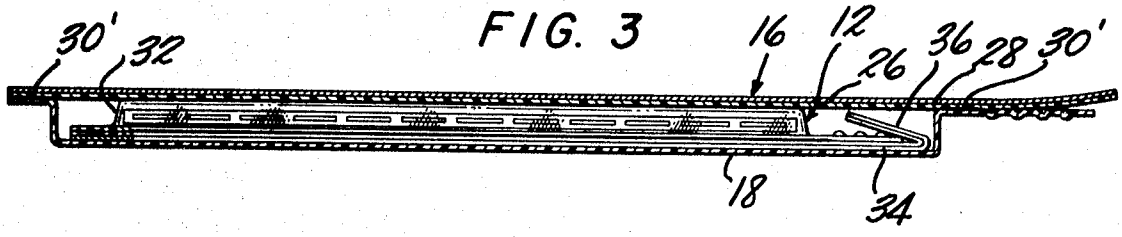
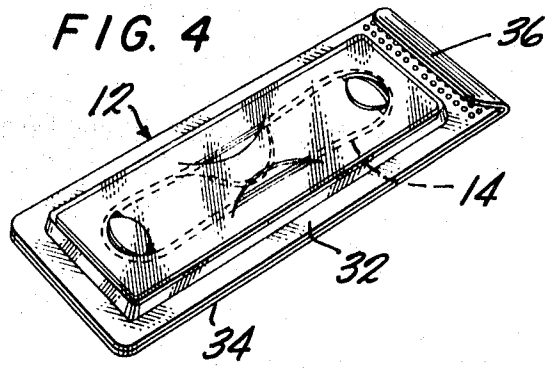


FIG. 4



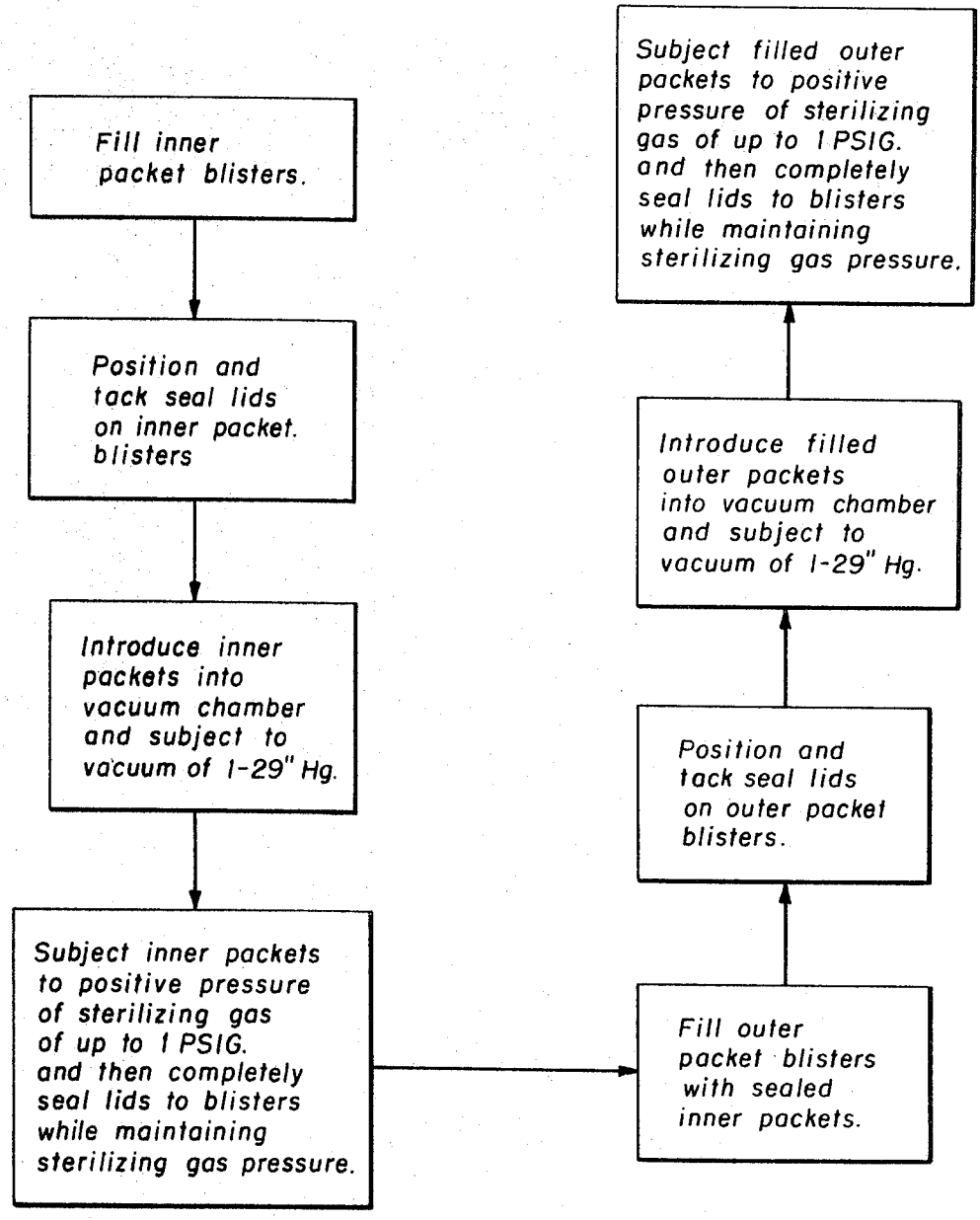

Fill inner packet blisters.
Position and tack seal lids on inner packet. blisters
Introduce inner packets into vacuum chamber and subject to vacuum of 1-29" Hg.
Subject inner packets to positive pressure of sterilizing gas of up to 1 PSIG. and then completely seal lids to blisters while maintaining sterilizing gas pressure.
Fill outer packet blisters with sealed inner packets.
Position and tack seal lids on outer packet blisters.
Introduce filled outer packets into vacuum chamber and subject to vacuum of 1-29" Hg.
Subject filled outer packets to positive pressure of sterilizing gas of up to 1 PSIG. and then completely seal lids to blisters while maintaining sterilizing gas pressure.

FIG. 5

SUTURE PACKAGING

BACKGROUND OF THE INVENTION

It is known to package sterile surgical objects, as for example, suture material in sterilized packages which include an outer sealed package component enclosing a sterile, fully sealed inner package component enclosing a sterile, fully sealed inner package component, the latter in turn containing the surgical object. It is also known to confine in the inner component of a plural component package along with a surgical object, a sterilizing medium or agent such as a tubing solution to effect complete sterilization of the surgical object within the package over a period of time, the tubing solution in some instances remaining in the sealed inner package component until the package is opened preliminary to using the surgical object. Such packages however generally embody features of package construction which make it difficult to confine a sterilizing gas within both the inner and outer package components so that such gas can provide for at least some initial post packaging period, a total package sterilization during post-packaging storage nor do such packages or manufacturing techniques as are known allow for modern in-line sterilization packaging of surgical objects in bulk or continuous mass production basis.

The present invention on the other hand overcomes the above-mentioned shortcomings of prior art surgical object packaging and is characterized by its suitability for high speed, reliable in-line sterilization packaging. In addition to providing a new and improved method of packaging surgical objects, the present invention provides an improved package for sterilized surgical objects.

SUMMARY OF THE INVENTION

In accordance with the present invention an improved package for sterile surgical objects is provided which includes a completely sealed inner packet in which the surgical object is received and an outer packet in which the sealed inner packet is received. The surgical object can be any of a variety of such objects which are required to be rendered and maintained sterile until the time of use by the surgeon, one such object, for example, being suture material. The inner packet providing enclosure structure for the surgical object includes a boxlike bottom or blister having depth, width and length dimensions sufficient to accommodate the surgical object and also having a continuous encircling flange extending outwardly of the blister body to serve as a surface to which a peelably removable lid can be heat sealed to provide a substantially hermetic seal of the inner packet. The inner packet lid preferably comprises a flexible sheet of metallic foil coated on one broad face with a layer of a plastic material adapted to provide means for effecting heat sealing of the lid to the blister. The inner packet lid can be of somewhat greater length than its associated blister to allow for folding of such excess length over and under a projecting end flange portion of the blister, preferably along one transverse edge of the blister and being provided as a tab means for the purpose of readily grasping the inner packet to remove it from the outer packet and also to readily initiate peeling away of the lid to expose the surgical object. The outer packet preferably is of substantially identical construction with the inner packet but is of sufficiently larger dimensions to house or receive the inner packet. The outer packet comprises a boxlike bottom or blister provided with a continuous encircling flange and adapted to receive therein in inverted position, a sealed inner packet. The outer packet also is provided with a lid secured in substantially hermetically heat-sealed condition to the flanges of the outer packet blister. Both the inner and outer packets at least initially have a sterilizing gas confined therein which functions during at least some of the period of post-packaging storage and handling of the package to insure the sterile condition of the surgical object. To open the package, the outer packet lid is peeled off its associated blister to expose the sterile inner packet. The inner packet then can be grasped by the tab means of its lid and removed from outer packet blister whereupon the inner packet lid can be peeled off its associated blister to expose the surgical object for use by the surgeon.

According to the present invention, in-line mass production packaging of surgical objects can be carried out. For this purpose a continuous stock of upright laid inner packet blisters are advanced to a station at which they are each filled with a surgical object, after which lids are positioned on the flanges of the blisters and are tack sealed to such flanges at a number of points only so that fluid access to the inner packet is possible. The filled inner packets are then advanced in succession into a vacuum chamber and subjected to a condition of vacuum so as to withdraw air from the interior of the chamber and inner packet. The vacuum is then broken by admitting sterilizing gas under positive pressure only slightly above atmospheric pressure, the sterilizing gas serving to initiate killing any bacterial agency in or on the surgical object or the interior of the inner packet. The inner packet lid is then completely heat sealed to its associated blister flanges while still in the chamber and while subjected to the presence of the sterilizing gas and with the consequence that a quantity of the sterilizing gas becomes captured within the inner packet. The completely sealed inner packets are then removed from the chamber and advanced to another station whereat they are inserted in inverted position in outer packet blisters. The outer packet lids are then tack-sealed to the associated blisters after which the packages are advanced in succession into a vacuum chamber and exposed to a condition of vacuum. Sterilizing gas is then admitted to the chamber to initiate killing bacterial agency on the exterior of the inner packet and interior of the outer packet following which the outer packet lids are completely sealed to their blisters in the same manner attending sealing of the inner packets.

The invention accordingly comprises the several steps and the relation of one or more of such steps with respect to the others as will be exemplified in the process to be described as well as the features of construction, combination of elements and arrangement of parts exemplified in the construction hereinafter set forth and the scope of the invention will be indicated in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

A fuller understanding of the nature and objects of the invention will be had from the following detailed description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a perspective view of a sterilized suture package constructed in accordance with the principles of the present invention, the peelably removable lid of the outer packet being shown partly removed.

FIG. 2 is a plan view of the suture package shown in FIG. 1, showing the peelably removable lid almost completely stripped off from the outer packet blister.

FIG. 3 is a longitudinal sectional view of the sterilized suture package shown in FIGS. 1 and 2 as taken along the line III—III in FIG. 2, the removable lid of the outer packet being shown in its fully sealed position of closure on its associated blister.

FIG. 4 is a perspective view of the inner packet in which coiled suture material is contained, the inner packet being shown in its sealed condition with the pull tab of the lid with which initiation of peeling of the packet lid is effected being shown folded under a projecting flange portion of its associated blister.

FIG. 5 is a block diagram of the several steps involved in continuous or bulk packaging operations with which suture packages of the present invention can be made.

Throughout the description, like reference numerals are used to denote like parts in the drawing.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides an improved package for sterile surgical objects as well as a method of in-line sterilization of such packages on mass production basis. Although "-sterile surgical objects" will be exemplified herein by way of example as being suture material and the packaging of the same, it will be understood that the present invention has broader application being useful for packaging objects of wide description wherein the basic consideration is establishment and maintenance of a totally sterilized package. In the following description, the construction of the improved package for sterile surgical objects will be discussed first.

As can be noted from the accompanying drawings and with particular reference to FIGS. **1** and **3**, the package **10** it will be noted is comprised of two major components, a substantially hermetically sealed inner packet **12** in which is received the surgical object **14**, and a substantially hermetically sealed outer packet **16** in which the inner packet **12** is received. The surgical object **14** is shown by way of example as being a coil of suture material wound on a card support and including the usual suturing needle. The inner packet **12** and outer packet **16** preferably are substantially identical in construction differing essentially only as to size. The outer packet **16** includes a boxlike bottom section or blister **18** which is a shaped, relatively rigidized structure and preferably made from a transparent plastic material and which is provided with outstanding, encircling flanges **20**, the latter being of comparatively greater dimension along one transverse edge as at **22** for a purpose which shall appear. The outer packet **16** also includes a closure member or lid **24** which is generally coextensive with the plan expanse of its associated blister and which is comprised of a layer of metallic foil **26** coated at its underface with a layer of a thermoplastic material **28**, the latter being provided to enable effecting a heat seal of the lid **24** to the flanges of the blister **18**, the heat seal being along a continuous encircling course, the pattern of which may be best seen as denoted by the seal line **30** in FIGS. **1** and **2** and the seal connections **30'** in FIG. **3**. The quality of the heat seal is such as to provide a substantially hermetic seal closure of the outer packet. As used herein, a substantially hermetic seal is intended to mean a condition of seal which substantially retards for a period of time, e.g., 1 week to 10 days, the rate of dissipation of sterilizing gas under pressure from the sealed packets. As can be noted from FIGS. **1–3** an end portion of the lid **24** is not sealed to the blister flange along edge area **22** so that convenient digital access is available for peelably removing the lid from the blister when opening the package.

As was indicated earlier, the outer packet **16** receives the inner packet **12**. The inner packet **12** in turn receives and contains the surgical object **14**. The inner packet **12** as can be noted from FIGS. **3** and **4** and like outer packet **16**, includes a boxlike bottom or blister **32** and a flexible closure lid **34**, the blister **32** being provided with flanges in the same manner as blister **18** to serve as surfaces to which the closure lid **34** can be heat sealed. However, closure lid **34** has a somewhat greater length than blister **32** so that such excess length can be folded around and under one transverse flange of blister **32** to thereby provide tab means **36** for grasping the inner packet **12** when removing it from the outer packet and also for initiating peeling off of the lid **34** from blister **32**. As can be seen in FIG. **3**, the inner packet **12** preferably is received in inverted position in the outer packet **16** so that the lid thereof which can be marked with identifying indicia can be viewed readily.

The package **10** when sealed is completely sterilized and during post packaging storage and handling remains so with respect to the interior of the outer packet and both the exterior and interior of the inner packet. That this condition of sterilization obtains is due, inter alia, to the hermetic seal of each packet and to the presence of sterilizing gas within each packet. While the sterilizing gas is initially confined with each packet at some positive pressure above atmospheric and preferably not greater than 1 p.s.i.g., it will dissipate from the packages at a very slow rate due to the character of the heat seal. Moreover, the character of the heat seal is such as to function as a filter to prevent the incursion of bacterial agency media and hence the package retains its sterile quality although the sterilizing gas may have long been dissipated therefrom. The sterilizing gas can be any known gaseous medium suited for the intended purpose. A mixture of ethylene oxide and inert gas such as carbon dioxide or freon gas in percentages of about 12 percent ethylene oxide and 88 percent inert gas is a particularly effective sterilizing gas.

To open package **10**, the user first peels off lid **24** from outer packet **16** in the manner shown in FIGS. **1** and **2**. The inner packet **12** is then removed from blister **18** by grasping the inner packet **12** at tab means **36**. The inner packet is then opened in the same manner to expose the surgical object **14** which can be removed directly by the surgeon without having been touched by any other person or object which could be a cause of contamination.

Description now will be given of the improved method by which sterile surgical objects can be packaged in an in-line or bulk sterilization process, for which purposes continuing reference is made to FIG. **5**. The present invention as has been stated earlier provides that suture packages can be made most readily on mass production basis. The apparatus with which such packages can be made can be of known construction provided it is capable of performing the functions now to be described. A continuous supply of individual surgical objects are, at an appropriate loading station, laid in inner packet blisters. The inner packet blisters if the operation is to be a bulk sterilization can be formed as a plurality of such blisters, e.g., ten in a sheet. The filled upright arranged inner packet blisters then have their associated closure lids positioned thereon as they advance along the production line and the lids are tack sealed to the blisters. The inner packets are then advanced in successive order or bulk quantity into a suitable conditioning chamber and a vacuum is drawn in the chamber to subject the inner packets to a condition of vacuum as so to withdraw air from both the chamber and the interior of the inner packets. The degree of vacuum can vary from about 1 to about 29 in. Hg., a particularly preferred operating range being 5–29 in. Hg. As soon as the vacuum in the chamber has pulled down to the desired level, it is broken by admitting a flow of sterilizing gas under positive pressure into the chamber. The sterilizing gas can be any one of a number of such sterilizing agents as are known, a particularly suitable gas for this purpose being a mixture of ethylene oxide and an inert gas such as carbon dioxide or freon in proportions of about 12 percent of the former and 88 percent of the latter with the gas pressure being varied depending upon the requirements of the packaging. However, for the package shown in FIGS. **1–4**, a pressure of about 1 p.s.i.g. is particularly suitable. As soon as the sterilizing gas invests the inner packets it immediately initiates killing of any bacterial agency in or on the inner packets and the surgical objects. As soon as the requisite pressure of sterilizing gas is reached within the chamber, the inner packets are then completely sealed by heat sealing the closure lids to the flanges of the associated blisters, such heat sealing being effected within the chamber with the gas pressure being maintained until sealing is completed.

The sealed inner packets are then removed in succession from the chamber and advanced to a station at which they are placed in inverted position in outer packet blisters and whereupon lids are tack sealed to the outer packet blisters, the respective sealed inner packets of course will at this point if they are made in bulk be separated from the base sheet. Similarly if the operation is a bulk one, the individual sealed inner packets may be received in the outer packet blisters while the latter are still joined in bulk from a single formed sheet. The filled but yet unsealed outer packets are then advanced into a chamber and subjected to the vacuum-treating gas exposure and lid sealing in the same manner as applicable to the inner packets. The thus finished package is completely sterilized on the inside of the outer packet and both the inside

and outside of the inner packet. Moreover, both the inner and outer packets are filled with sterilizing gas which is retained for an initial period in the respective packets during post-packaging periods and dissipated only slowly therefrom due to the heat seal connection of the closure lids to the blisters which is effective to substantially retard the rate of gas inflow or outflow from the packets.

It will be thus seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained, and since certain changes can be made in the above construction and different embodiments of the invention could be made without departing from the scope thereof, it is intended that all matter contained in the above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense.

I claim:

1. A package for a sterile surgical object comprising an inner packet including a blister in which the surgical object is received, and a closure lid covering said blister and secured thereto in condition of substantially hermetic heat sealing along a continuous path, and

an outer packet, said outer packet comprising a blister in which the sealed inner packet is received, and a closure lid covering said outer blister and secured thereto in condition of substantially heremetic heat sealing along a continuous path,

said closure lids each comprising a sheet of a foil of a metal including a layer of plastic material covering thereon to permit heat sealing of said lids to said blisters,

the blisters of said inner and outer packets being generally similarly shaped relatively rigidized boxlike transparent structures of thermoplastic material each having a deep main body and encircling flanges outstanding from the main bodies thereof, said flanges providing surfaces to which said closure lids are secured, a length of each closure lid along a portion thereof which is coextensive with an end flange of its associated blister being left unsealed to thereby provide tab means for initiating peelably removing said closure lids from said blisters,

said inner packet being received in inverted position in the blister of said outer packet, the closure lid of said inner packet being of a length in excess of that of its associated blister, such excess length being folded up and over an edge of said blister to provide a grasping tab with which said inner packet can be grasped for removing same from said outer packet,

both said inner and outer packets containing a sterilizing gas mixture of ethylene oxide and an inert gas under positive pressure up to one p.s.i.g.,

the condition of heat sealing with which the closure lids of both said packets are secured to their associated blisters being effective to substantially retard the rate of gas inflow and outflow from said packets, said condition of sealing being further characterized by allowing for readily peelably removing said lids from said blisters.