

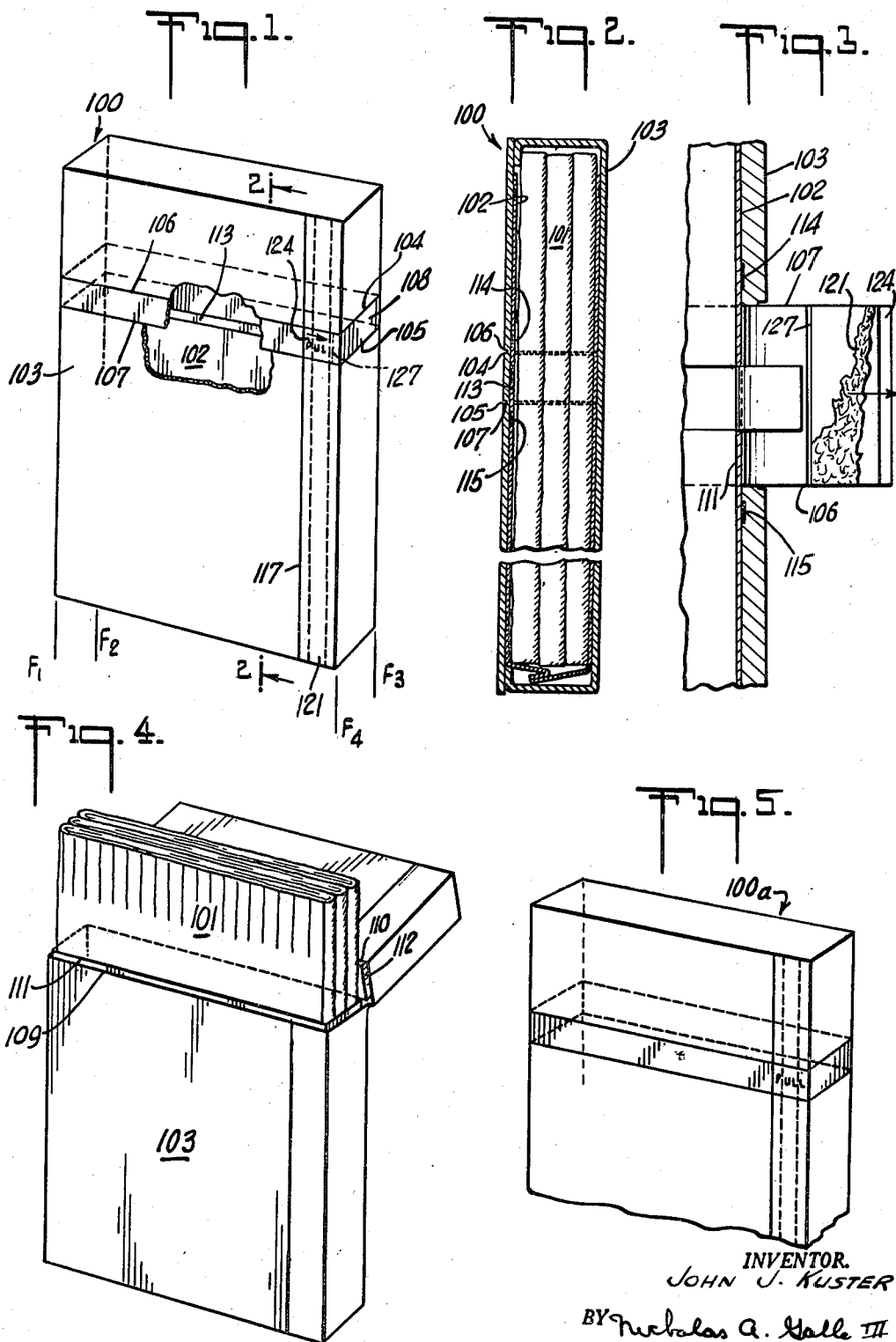
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J. J. KUSTER

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SURGICAL PACKAGE

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SURGICAL PACKAGE

John J. Kuster, Kendall Park, N.J., assignor to Johnson & Johnson, a corporation of New Jersey

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1 Claim

ABSTRACT OF THE DISCLOSURE

Sterile packages are disclosed in which the outer wrapper has an integral tear strip which when removed provides an opening for access to the sterile product, the tear strip being so positioned and of such a shape that when it is removed, the outward facing surfaces of the outer wrapper adjacent the access opening are sterile surfaces.

This application is a division of my copending application Ser. No. 621,578, filed Mar. 8, 1967 now abandoned.

Articles and devices which are used in surgical, obstetrical, and many other medical procedures must be enclosed in a bacteria impervious sterilized package so that they remain free of bacteria until they are used. Surgical packages are therefore conventionally made of materials which are generally impervious to bacteria with at least a portion being pervious to gases so that the package may be sterilized with the article as an integral part of the same.

These packages must also be designed so that they may be opened rapidly without affecting the sterility of the article contained therein and so that the articles may be removed from the package according to approved sterile techniques.

Various means are provided for opening sterile surgical packages. When the package is in the form of a bag or the like, one of the most common opening means is a colored marker at an end or corner of the package indicating an area which may be torn or otherwise severed from the package to provide direct access to the article without affecting its sterility. Once the walls of the package have thus been severed, the sterile article is removed with the aid of forceps or the like.

A second means commonly provided to facilitate the opening of sterile surgical packages is a tear string inserted within a portion of the package wall and projecting outward from the same through a small hole which is carefully sealed around the string to prevent bacteria from entering the package. To open the package, the string is pulled generally parallel to the surface of the package wall to rupture the package wall. Again the sterile article is removed through the article access area defined by the severed edges of the package wall.

A third technique used to facilitate the opening of surgical packages is to form a portion of the package by sealing two materials together which, while they form a strong seal, are readily peelable. When the walls of the package are peeled apart and at least on wall bent back, access to the sterile article is provided and the same can be removed from the package.

No matter which of these techniques is used, when the package walls are severed to provide an article access opening, the outward facing surface areas of the package

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lying immediately adjacent the article access opening are nonsterile surfaces. Thus, in removing the sterile article through the opening, care must be taken so that the article does not touch the edges of the article access opening. If the sterile article touches these edge surfaces, the article is considered contaminated and must be discarded.

It has now been found that surprising and significant advantages may be obtained and the above outlined problems eliminated by incorporating integral tear strips in the package in a manner so that when the strip is removed to provide an article access opening, the outward facing package surface adjacent the article access opening are sterile surfaces.

Two specific embodiments of the invention are of particular interest. One embodiment is a sterile surgical package having a bacteria impervious paperboard panel and an integral removable tear strip in the paperboard panel, the tear strip including an integral tab and being set off by a pair of spaced, preferably parallel, weakened areas or score lines cut into the exterior surface of the paperboard panel, at least one weakened area in the form of a score line preferably generally parallel with and between the aforesaid pair of weakened areas being cut into the interior surface of the paperboard portion of the package, the score lines cut into the exterior surface of the paperboard panel and the score line cut into the interior surface of the paperboard panel cooperating to form a cleavage plane within the thickness of the panel between each exterior score line and an interior score line. When the paperboard panel is severed by the removal of the integral tear strip, the portion of the paperboard panel lying between the exterior score lines and an interior score line or lines delaminates along the cleavage plane to thus form an exterior facing sterile surface bordered outwardly by the exterior score lines and inwardly by an interior score line. Thus, when an article is removed from the package through the article access opening defined by the ruptured panel walls, the article is not contaminated if it touches the exterior surfaces surrounding the article access opening since the same are sterile.

In a second embodiment of the invention, which is the subject of this application, there is contemplated a sterile surgical package having a bacteria impervious paperboard panel and an article access opening defined by an integral tear strip in the paperboard panel, the tear strip including an integral tab and being set off by at least a pair of spaced preferably generally parallel weakened lines cut into the paperboard panel, a sheet of relatively thin and flexible material underlying the paperboard panel in the area of the tear strip and being sealed both to the tear strip inward of its edges and to the paperboard panel outward of the tear strip. When the package is opened by removing the tear strip, the portion of the inner sheet sealed to the tear strip will also be torn away to leave a portion of the sheet projecting inward of the severed edges of the paperboard panel to thus form a sterile exterior facing surface around the edges of the article access opening.

In order to form an integral removable tear strip in a package, it is necessary to provide an extending tab at one end of the strip. However, it is quite important that a surgical package be completely sealed and therefore it is necessary to seal the extending tab of the integral tear strip to some underlying package panel. In the case

of a package which is not adapted to surgical uses, it is not necessary to seal the tab to the underlying package panel, and therefore the same may be easily removed in the usual fashion. However, when the under surface of the tab is sealed to the underlying panel and it is attempted to remove the tear strip by using the tab, the adhesive or other bond between the tab and the underlying panel is stronger than the bond between various layers of the easily delaminatable paperboard panel, and thus the portion of the paperboard panel within the tear strip tends to delaminate along some intermediate plane usually near the inner surface. Therefore due to this delamination within the tear strip, it may be impossible to remove the tear strip to open the package. The tear strip may also internally delaminate haphazardly in such a fashion that it is severed somewhere along its length. This type of tear strip failure is quite unsatisfactory in a sterile surgical package since the same must be easily and assuredly openable at the critical moment when the article contained therein is required in the operating room without endangering the sterility of the product.

In packages not intended for medical use where a bacteria impervious package with an integral tear strip is required, the same has usually been made of metal or some other substance resistant to delamination and the tab portion soldered or welded to the underlying structure. However, packages made from metal or the like are not usually satisfactory for medical use because of the impossibility of passing sterilizing gases therethrough, more difficult sterilizing techniques being required.

In the preferred embodiments of packages of this invention, this problem is eliminated by a score line cut into the interior surface of the tear strip inward of the seal and transversely of the tear strip. Thus, if the tab delaminates along a plane within the tear strip, the transverse score line will terminate the same.

The invention may be more clearly understood by reference to the appended drawings which are described in detail below.

FIGURE 1 is a view in perspective of a surgical package of this invention;

FIGURE 2 is a cross section of the package illustrated in FIGURE 1 taken along line 2—2;

FIGURE 3 is an enlarged cross sectional view corresponding to FIGURE 2 of the tear strip area after removal of the tear strip has been initiated;

FIGURE 4 is a view in perspective of the package of FIGURE 1 after the same has been opened;

FIGURE 5 illustrates a modification of the package of FIGURE 1.

Referring to the drawings, the package 100 consists of a bacteria impervious air permeable paperboard blank 103 folded—longitudinally—along four lines F_1 , F_2 , F_3 and F_4 , and the sides of the panel overlapped and sealed together in an area 121, extending the entire length of the package and lying inward of the edge 117 of the panel to define a tab 124. The ends of the blank are folded in conventional fashion and sealed to form a bacteria impervious unit for sterile sheet 101. An integral tear strip 108 is provided in the paperboard panel by virtue of a pair of parallel score lines 104 and 105 cut into the outer surfaces of the panel to a depth nearly equal to the thickness of the same and extending around three sides of the package.

A thin sheet of bacteria impervious paper 102 interlines the paperboard panel and is sealed to the paperboard tear strip 108 in an area 113 lying well inward of the edges 106 and 107 of the tear strip 108. The area 113 of the sheet 102, sealed to the removable strip in the paperboard, thus becomes part of the removable tear strip in the outer wrapper of the package. The paper sheet 102 is also bonded to the paperboard panel 103 along two lines 114 and 115 lying outward of and paralleling score lines 104 and 105.

Thus, as shown in FIGURES 3 and 4, when the time

has come to open the package and the tear strip is removed, the portion 113 of the paper sheet 102, which is sealed to the paperboard tear strip 108, is torn from the remainder of the paper sheet. Portions 111 and 112 of the paper sheet project beyond the edges 109 and 110 of the paperboard panel. Since the outer surfaces of the paper margins 111 and 112 are sterile, the article access opening is bounded by only sterile surfaces. The bond lines between the paper and the paperboard panel lying outward of the tear strip serve to hold the paper margins in position.

When it is attempted to open the package, the thermoplastic bond 121 between the overlapping paperboard panel section in the area of the tear strip 108 is substantially stronger than the internal cohesive strength of the paperboard sheet. Thus, the paperboard panel often begins to delaminate within the tear strip along some plane, near the bonded surface of the same. If this delamination continues, after the tear strip is removed, a thin band of paperboard having a width approximately equal to the distance between the score lines will remain in the article access area. If instead of continuing on a given plane, the delamination proceeds angularly through the longitudinal cross section of the tear strip, the tear strip may break.

Therefore, in the preferred embodiment of the package, a score line 127 disposed transversely of the tear strip 108 inwardly of seal area 121 and extending between longitudinal score lines 106 and 107, is cut into at least one inner surface of the paperboard panel, to about the middle of the panel thickness. Thus, if the tear strip begins to delaminate between the score lines, in the area of the seal, the transverse score line will terminate the delamination.

In the packages of this invention, the so-called score lines need not be in the form of continuous grooves cut into the paperboard panel but may consist of any series of weakened areas along which the panel can be readily and regularly split. The score lines also need not be straight lines but can have any configuration, and co-operating score lines need not be parallel though they must be nonintersecting. Various types of score lines are well known in the art and will not be further described here. The score lines need not be continuous nor extend the entire length of the tear strip.

If a cross score line is used in the packages of this invention, it suitably has a depth which is also about equal to one half of the thickness of the panel and should at least penetrate into the panel $\frac{1}{8}$ or $\frac{1}{4}$ of its thickness. While the cross score line is preferably perpendicular to longitudinal direction of the tear strip, this need not be the case. The cross score line may take many shapes including that of an apex, a semi-circle, or the like. All of the score lines may be cut by means and methods well known in the art.

The paperboard panels themselves are of the type conventionally used in sterile surgical packages, namely, those that have a density which is such as to make the panel pervious to gases but impervious to airborne bacteria. Generally any paperboard sheet having a porosity of from 50 to 200 seconds per 100 cc. of air per square inch measured by TAPPI Standard T460-M49 will be satisfactory.

Although specific embodiments of the invention have been presented, they have only been presented to better describe the inventive concept and should not be construed to limit the invention.

What is claimed is:

1. A sterile surgical package comprising an outer protective wrapper enclosing a sterile article, at least a portion of the outer wrapper comprising a bacteria impervious paperboard panel, said package having an integral removable tear strip,

said tear strip being defined by a pair of spaced score lines cut into the exterior surfaces of the paperboard

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panel, a portion of the paperboard panel lying within the spaced score lines being bonded to an underlying surface, an additional score line being cut into the inner surface of the tear strip of the paperboard panel transversely of the tear strip and inward of said bond,

a thin flexible sheet underlying said paperboard and being bonded to the tear strip only inward of the edges of said tear strip as well as bonded to the paperboard panel outward of the tear strip,

whereby when the tear strip of the paperboard panel is removed, a portion of the thin flexible sheet narrower than the tear strip is also removed and thus the innermost outer facing surfaces of the outer pro-

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tective wrapper adjacent the article access opening will be sterile surfaces.

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MARTHA L. RICE, Primary Examiner

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