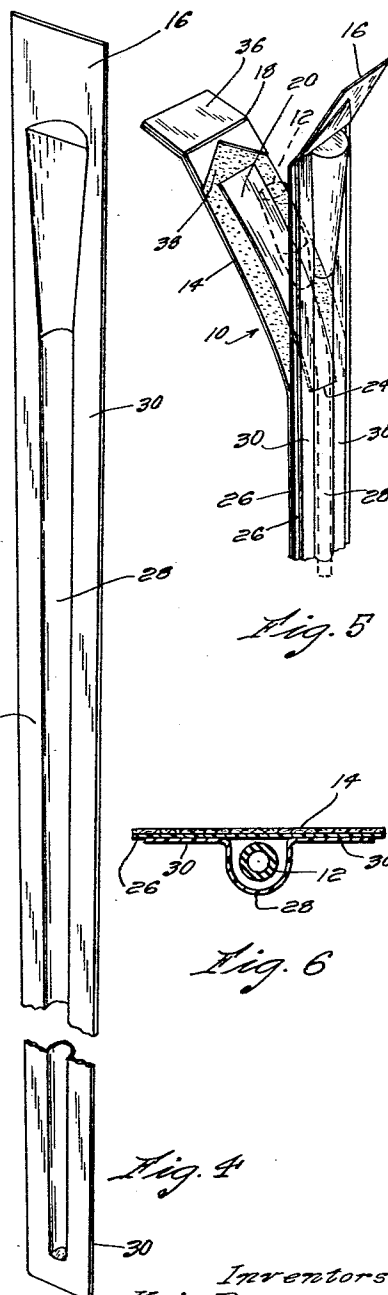
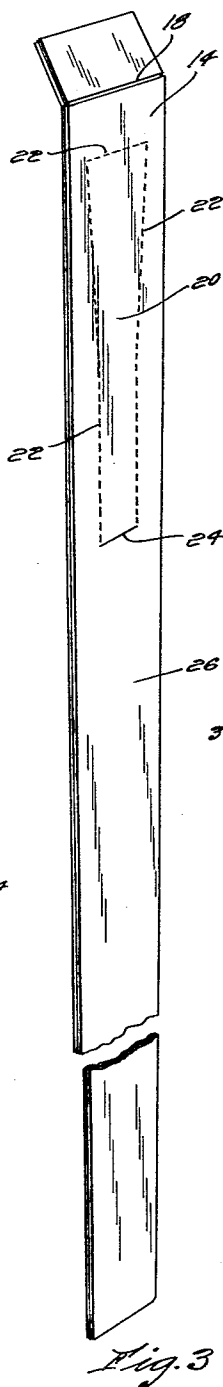
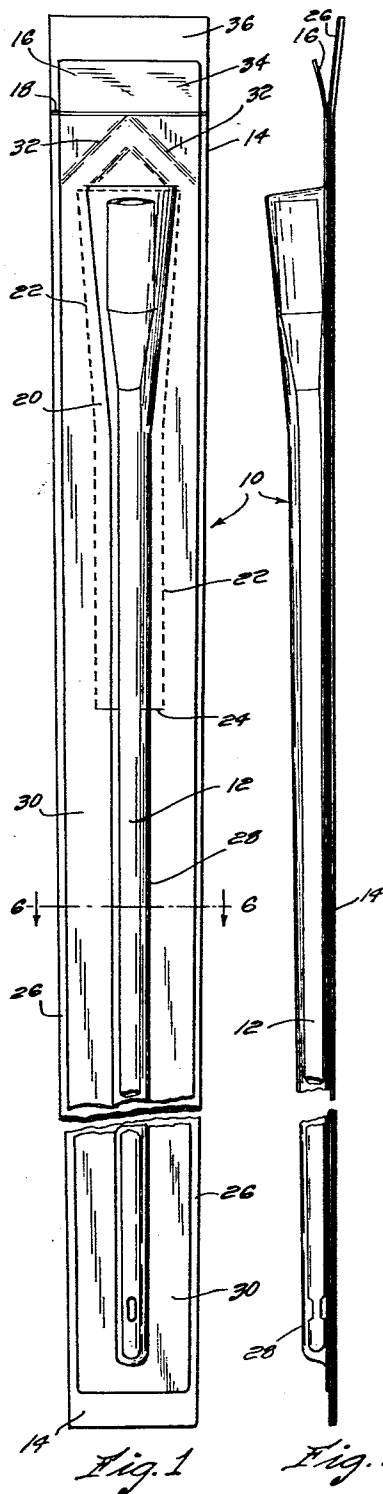


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PACKAGE FOR STERILE ARTICLES

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PACKAGE FOR STERILE ARTICLES

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The present invention relates generally to packaging means for sterile articles and particularly to medical or surgical devices, such as catheters, nipples and the like.

A primary object of the instant invention is the provision of a novel and improved package for surgical or medical devices wherein said devices may be maintained absolutely sterile until the very moment they are to be used.

Another object is the provision of a sterile package for surgical devices wherein the device is visibly displayed.

Another important object of our invention is the provision of a sterile package for surgical devices, which package may be easily opened when it is desired to use the device.

A further object of the present invention is the provision of a sterile package for surgical devices which when opened will not destroy the sterility of the packaged device.

Still another object of our invention is the provision of a sterile package for surgical devices having a novel and improved arrangement whereby when the package is opened the packaged device is exposed for ready grasping without any manipulation of the device itself.

A further object is the provision of a package of the character described which is economically feasible to manufacture in mass quantities, but which nevertheless is highly effective in the accomplishment of its intended functions, and which at the same time provides a package of pleasing appearance and one which effectively displays the contents being packaged.

Other objects, features and advantages of the invention will become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

In the drawings which illustrate the best mode presently contemplated by us for carrying out our invention:

FIG. 1 is a front elevational view of a sterile package constructed in accordance with our invention;

FIG. 2 is a side elevational view thereof;

FIG. 3 is a perspective view of the backing strip which forms a part of our invention;

FIG. 4 is a perspective view of the casing member which forms a part of our invention;

FIG. 5 is a fragmentary perspective view illustrating our package after it has been opened; and

FIG. 6 is a sectional view taken on line 6—6 of FIG. 1.

Although the instant invention will be described in connection with the packaging of a catheter, it will be understood that this invention is equally applicable to the packaging of any surgical or medical device where sterility is of importance.

Referring to the drawings, there is shown generally at 10 an assembled package housing a catheter 12. The package 10 comprises a backing strip 14, preferably constructed of a material having the flexible characteristics of cardboard, and a plastic casing 16.

As indicated above, the backing strip 14 is constructed of cardboard, or any other material having substantially the characteristics thereof, and I have found that bleached Kraft works particularly well, although use of this specific cardboard is not critical. The important thing when choosing the material for backing strip 14 is that the material be capable of controlled delamination or, expressed differently, that it be of a fibrous or laminated construc-

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tion which enables an outer surface of the material to be peeled or pulled away. Even a multilayer plastic construction could conceivably be used if the layers could be pulled apart at their point of lamination. Thus, when reference is hereinafter made to cardboard or a material having substantially the characteristics thereof, it will be understood that a flexible material capable of being delaminated is being defined.

As will be seen most clearly in FIGS. 1 and 3, the backing strip 14 is of elongated rectangular configuration and is provided with a transverse fold line 18 adjacent one extremity thereof, the purpose of which will hereinafter become apparent. The strip 14 is further characterized by a scored area 20 defined by a continuous cut or score 22, the definition of the area 20 being completed by a transverse fold line 24 which interconnects the lower extremities of the score line 22. For reasons hereinafter to become apparent, the scored surface of strip 14 is coated with a suitable plastic as at 26, note FIG. 6. It is important to note that the plastic coating is relatively thin with respect to strip 14, and that the coating 26 covers the entire side of strip 14. It is further important to note that the scoring 22 may be effected either before or after the plastic coating 26 has been applied to the one side of strip 14 and that the cut or score line 22 need be only deep enough to penetrate through the outer surface of strip 14. In practice I have found that a cardboard strip of .020 inch in thickness works satisfactorily, although dimensions are not critical to the success of the instant invention.

As will be seen most clearly from FIGS. 1 and 4, the plastic casing 16 is also of elongated rectangular configuration and specifically comprises an elongated hollowed-out portion 28 which conforms generally in configuration to the outline of catheter 12. Surrounding the hollowed-out portion 28 is a flat, outwardly extending marginal flange 30, it having been found that the hollowed-out portion 28 and marginal flange 30 may be provided as a vacuum-formed cellulose acetate butyrate blister. As will be seen most clearly in FIG. 1, the casing 16 is dimensioned so that both its length and width are slightly less than that of strip 14, although in production manufacture, it may be desirable to peripherally cut the casing and backing strip simultaneously whereupon their marginal edges would be flush.

In assembly and use, the catheter 12 is placed within hollow portion 28 of casing 16, and the casing and enclosed catheter are then positioned against the scored and plastic-coated side of strip 14, as illustrated in FIG. 1. The marginal flange 30 of casing 16 is then bonded or fused to strip 14 by any suitable means, such as the application of heat or pressure or a suitable bonding agent, whereupon casing 16 combines with strip 14 so as to effect an airtight enclosure. It will be understood that the fusing or bonding between casing 16 and strip 14 is facilitated by the presence of the plastic coating 26 on the surface of strip 14, said coating fusing with the cellulose acetate butyrate blister to provide an effective seal. On the other hand, it should be understood that if the casing 16 is made of a plastic that can fuse directly to cardboard, then the presence of the coating 26 would no longer be necessary. It will be understood that this heat seal is possible due to the plastic composition of casing 16 and the plastic coating 26 which is present on the surface of strip 14.

It is important to note that during the heat sealing operation, the uppermost portion of the marginal flange 30 is not sealed to the strip 14, but rather the seal at the upper extremity is defined by the line 32 illustrated in FIG. 1. Once the casing 16 with the enclosed catheter 12 has been sealed to the strip 14, as aforescribed, the entire package and its contents may be sterilized by use of the well-known ethylene oxide method wherein the

ethylene oxide gas is permeated through the completed package to effect sterilization thereof. A package is now provided wherein the catheter 12, or any other surgical device that it may be desirable to package, is completely enclosed and sterilized, but yet is completely visible where the casing 16 comprises a transparent acetate blister, or any other transparent plastic.

When it is desired to remove the catheter 12 from the package 10 for use, it is simply necessary to grasp the upper non-sealed portion 34 of casing 16 and pull or peel the casing 16 apart from strip 14. Initiation of this peeling action is facilitated by the fact that fold line 18 enables the uppermost portion 36 of strip 14 to extend away from the unsealed portion 34 of casing 16, whereupon the parts may be easily grasped. As the casing 16 is pulled apart from the strip 14, the plastic coating 26 and the outermost skin of strip 14 will have a tendency to adhere and stick to the casing. Due, however, to the presence of score line 22, the area of strip 14 defined by said score line, namely, area 20, will simply break away from the surrounding outer surface area of strip 14 and will separate completely from the casing 16, as shown most clearly in FIG. 5. The shaded area 38 in FIG. 5 represents that portion of strip 14 which has been pulled away by casing 16 during the separation of the casing from the strip, and it will be apparent that if the scored area 20 were not provided, the complete surface of strip 14 would pull away and remain adhered to casing 16, whereupon the contents of hollowed out portion 28 would continue to be enclosed and would not be accessible until the thin layer covering same has been punctured. Thus, it is the presence of the score line 22 which enables casing 16 to be pulled apart from strip 14 so that the packaged contents become completely exposed and accessible. The foregoing is true even where the score line is provided before the plastic coating 26 is applied since said coating is structurally weak and will tend to tear adjacent the score line, even though the coating itself is not scored. While perhaps it is easier to score after application of coating 26, it has been found that in some cases the score line might be inadvertently made too deep whereupon air would have a tendency to leak into the package. If, however, coating 26 is applied after the scoring, the coating will function as a protective layer to prevent penetration of air into the package.

It is important to note that as the casing 16 is peeled apart from strip 14, the catheter 12 is not touched in any way by any exposed, non-sterile portions of the package. Quite to the contrary, as will be seen most clearly in FIG. 5, the catheter 12 remains substantially upright between the two pulled-apart portions of casing 16 and strip 14, whereupon the catheter may be easily grasped by forceps or other sterile surgical equipment. Once so grasped, the catheter may be easily pulled out from the package, it being important once again to note that during this operation the catheter is not contacted by any rough or sharp non-sterile edges such as would adversely effect the sterility of the article. It will be understood that the casing 16 and strip 14 are pulled apart until the bottom of score

line 22 is reached, at which point fold line 24 readily enables the strip 14 to pivot or fold away from casing 16, so as to completely expose the catheter 12, as afore-described.

In summarizing, it will be seen that a package is provided wherein a surgical device, such as a catheter, may be enclosed and maintained in complete sterility. In spite of this, the catheter is at all times completely visible due to the transparency of casing 16. When it is desired to use the catheter, the package may be easily opened by peeling the casing 16 away from strip 14, an operation which may be very simply and easily performed by hand, said opening operation resulting in the catheter being completely exposed for removal, without the sterility of the catheter being destroyed. The package is relatively inexpensive and simple to manufacture and assemble, to the extent that it is feasible for disposable use, i.e., once used, the package is discarded.

While there is shown and described herein certain specific structure embodying the invention, it will be manifest to those skilled in the art that various modifications and rearrangements of the parts may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

What is claimed is:

1. A sterile package for surgical devices consisting of a backing strip and a hollow casing having an open side, said casing having a marginal flange adjacent said open side, means securing said flange to one surface of said strip so that said strip and casing cooperate to define an airtight enclosure, said securing means being such that when said casing is peeled away from said strip, the surface of the latter normally pulls away with the casing so as to cover the open side of the casing, and means for automatically preventing said open side from being covered when said casing and strip are peeled apart, said last-mentioned means comprising a score line on said one surface of said strip located within the confines of said enclosure, said score line conforming closely to the periphery of said enclosure and extending for a substantial portion thereof.

2. The sterile package of claim 1 further characterized in that said backing strip is of a material having substantially the characteristics of cardboard, said one surface thereof being coated with plastic, and said casing comprising a cellulose acetate butyrate blister.

3. The sterile package of claim 1 further characterized in that an outer end portion of said flange is not secured to said strip whereby to define a grasping tab for facilitating the peeling of said casing away from said strip.

References Cited in the file of this patent

UNITED STATES PATENTS

2,892,538 Middleton ----- June 30, 1959

FOREIGN PATENTS

1,174,762 France ----- Nov. 10, 1958