

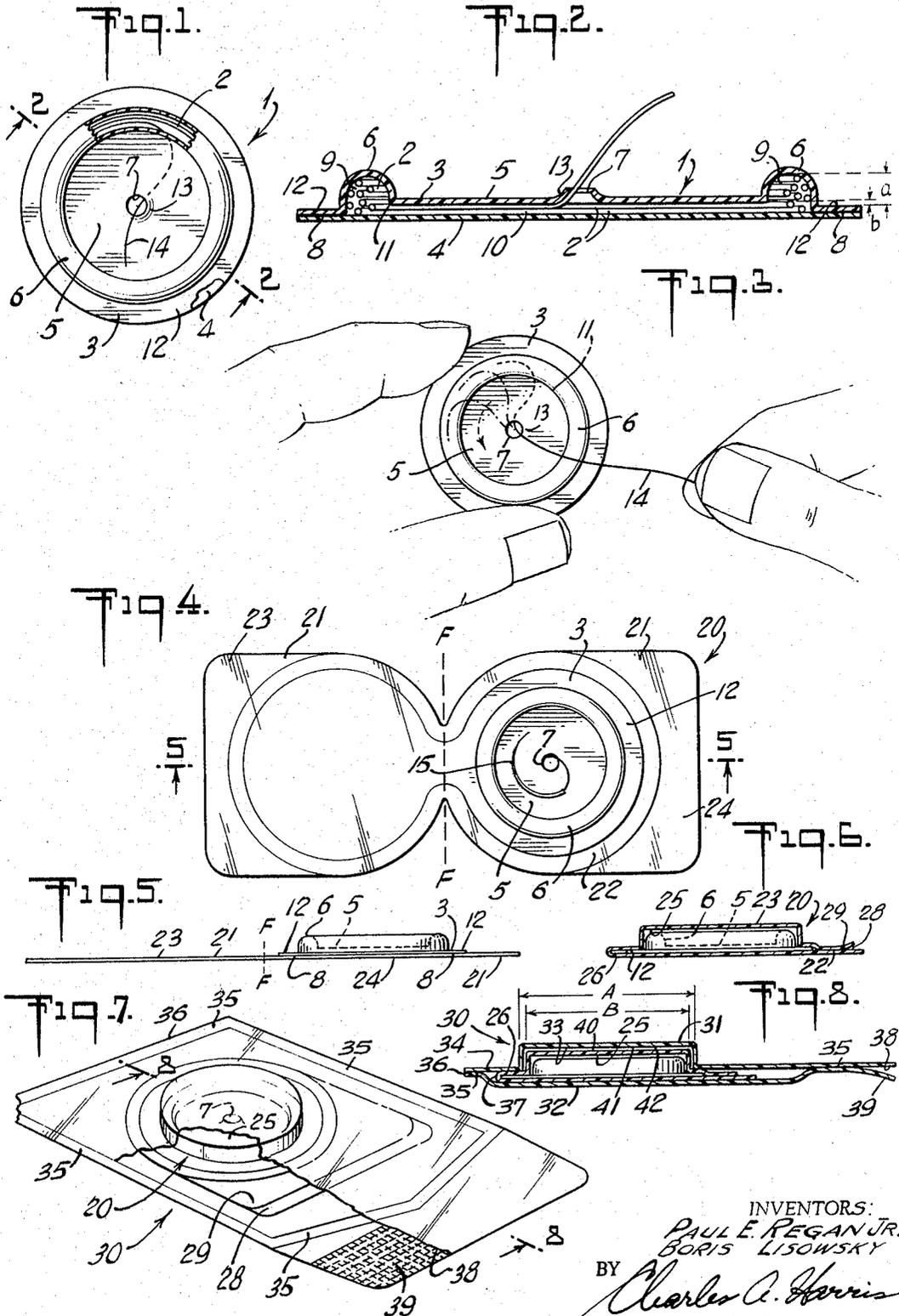
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SUTURE PACKAGE

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**SUTURE PACKAGE**

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This invention relates to packages for surgical sutures and, more particularly, to such packages wherein the suture is dispensed directly from the package.

Where the term "suture" or "sutures" is used in this application, it shall mean surgical strands used for suturing, ligating, and the like and shall include such strands commonly called either sutures or ligatures.

Suture packages have been proposed which include a small relatively flat dispensing unit enclosing the suture in coiled form and having a central access aperture through which one end of the suture extends for dispensing the suture from the unit. However, when the suture is dispensed in this manner by drawing it through the aperture, the innermost convolutions of the suture coil tend to tighten and form kinks which make it difficult at times to draw the suture from the package and, under certain conditions, result in pinching or otherwise damaging the suture. In some cases, the suture convolutions may become entangled before they are removed from the package because they are not retained properly in coiled form in the unit.

According to this invention, a novel suture package is provided comprising a disk-shaped container which in turn comprises a top wall and a bottom wall together defining an annular compartment of substantial diameter and a shallow centrally located disk-shaped passage in communication with the annular compartment all around the inner border of the compartment, the annular compartment being substantially greater in depth than the disk-shaped passage, the walls being joined to one another only outwardly of the compartment and one of the top and bottom walls defining a centrally located suture dispensing aperture. The disk-shaped container additionally comprises a coiled suture located in the annular compartment with one end of the suture extending from the coil through the disk-shaped passage and thence outwardly of the container through the dispensing aperture. The passage is sufficiently shallow to minimize tightening of the suture coil convolutions when the suture is progressively removed from the package by drawing it through the dispensing aperture by exerting a force on the end passing through the aperture and is sufficiently deep to allow any coil convolution which does tighten when the force is exerted thereon to snap back to its original position in the annular compartment when the force is released therefrom.

In a second embodiment of the invention the suture package comprises a disk-shaped top wall defining a centrally located suture dispensing aperture; a bottom sheet comprising a base portion joined to the top wall adjacent the periphery of the top wall and together with the top wall defining a circular suture compartment, the base portion extending beyond the top wall all around the periphery of the top wall, and the bottom sheet additionally comprising a cover portion foldably connected to the base portion at one side of the package and folded down over the top wall to overlie the base portion and sandwich the top wall between the base and the cover portions of the bottom sheet; and a coiled suture located in the compartment with one end of the suture extending from the coil through the aperture, the cover portion of the bottom sheet being continuously joined to the base portion all around the periphery of the top wall to pro-

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vide a sealed chamber for the top wall and the suture in the compartment.

The invention and its advantages may be more clearly understood by reference to the following description and the attached drawings, wherein,

FIG. 1 is a top view of a surgical package according to this invention;

FIG. 2 is a cross-section of the surgical package of FIG. 1 taken along line 2-2 thereof;

FIG. 3 illustrates a surgeon removing a portion of the suture from the package of FIGS. 1 and 2 by pulling on the end of the suture and further illustrates the manner in which the coiled suture unwinds;

FIG. 4 is a plan view of a second package according to this invention which has been opened to provide access to the suture;

FIG. 5 is a cross-sectional view of the package of FIG. 4 taken along line 5-5 thereof;

FIG. 6 is a cross-sectional view of the package illustrated in FIGS. 4 and 5 in its sealed condition;

FIG. 7 is a view in perspective of a surgical package comprising the package of FIG. 6 as an inner container enclosed within an outer container;

FIG. 8 is a cross-sectional view of the package of FIG. 7 taken along line 8-8 thereof.

Referring now to FIGS. 1 and 2 there is illustrated a coiled suture 2 enclosed in the disk-shaped container 1. The disk-shaped container comprises a top wall 3 and a bottom wall 4. The top wall is shaped to form a flat section 5 and a raised annular chamber 6 surrounding the flat section 5. The flat section 5 of the top wall 3 defines a centrally located suture dispensing aperture 7. The bottom wall 4 overlies the inner surface of the flat section 5 and of the raised annular chamber 6 of the top wall 3 and is joined to the top wall 3 only in an area 8 outward of the raised annular chamber. The top wall and the bottom wall cooperate to define an annular compartment 9 of substantial diameter which contains the coiled suture 2. The flat section 5 of the top wall 3 and the bottom wall 4 cooperate to define a shallow centrally located disk-shaped passage 10 in communication with the annular compartment 9 all around its inner border. The annular compartment 9 has a depth "a" substantially, i.e., several times, greater than the depth "b" of the centrally located passage. One end 14 of the suture extends from the coil through the disk-shaped passage and thence outwardly of the container through the aperture 7.

The central passage 10 is sufficiently shallow that the inner wall 11 of the annular compartment 9 prevents most, if not all, of the suture coil convolutions from tightening when the surgeon pulls on the end 14 of the suture as shown in FIG. 3. In general, the coil remains stationary as it is unwound, as indicated by the phantom lines in FIG. 3, and thus there is no kinking or pinching of the suture or entanglement of the coil convolutions one with another. If occasionally one of the coil convolutions tightens, the centrally located passage is sufficiently deep that the resilient suture will spring back to its original position in the annular compartment when the user releases the force of the end 14 of the suture. In the preferred embodiment of the invention, the depth of the centrally located passage is from about 1.5 to about 3 and preferably about 2.5 times the diameter of the suture.

The coiled suture 2 is contained in the annular compartment 9 substantially outward of the suture dispensing aperture 7. By virtue of this construction, even the inner convolutions of the coil have a diameter which approaches the outer diameter of the package and thus sutures of substantial length may be contained in the package without having any coil convolutions of small diameter which would often tend to kink if the suture

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were progressively removed by pulling on the end of the same. In the preferred embodiment of the invention, the diameter of the annular compartment should be greater than about 1 inch.

In the embodiments of the invention illustrated, the disk-shaped container is substantially circular in shape. However, the invention is not restricted to a package of this shape, but may be of any shape, such as an ellipse or the like, as long as a coiled suture may be contained therein without severely bending or pinching the suture. The thin centrally located passage, although preferably flat, need not be flat or of uniform thickness.

In the embodiment illustrated in FIGS. 1 through 3, the top wall is additionally shaped to form a flat peripheral annular rim 12 surrounding the annular chamber. The bottom wall overlies at least a portion of the annular peripheral rim 12 around its entire perimeter and is heat sealed to the top wall only in a circumferential area 8 around the peripheral annular rim 12. However, the top wall may be joined to the bottom wall in any manner as long as it is joined only outward of the annular compartment and, thus, the peripheral rim may be eliminated without affecting the inventive concept. The top wall may be joined at the bottom wall at a plurality of discreet areas or in a continuous area around the entire perimeter.

When, as shown in FIG. 3, the suture is progressively removed by pulling on the end 14 projecting through the aperture 7 in a direction essentially perpendicular to the plane of the suture coil, the tendency of the suture to kink is further minimized because there is a smaller force acting to pull the various coil convolutions inward. Therefore, the top wall 3, the wall which defines the dispensing aperture 7, is suitably additionally shaped to form an upward extending lip 13 surrounding the aperture 7. By virtue of this lip 13, it is assured that the end of the suture projecting outward through the aperture which is pulled to dispense the strand will be disposed at a substantial angle to the plane of the coil.

Referring now to FIGS. 4 through 6, there is illustrated an embodiment of this invention in which the top wall and the coiled suture are sandwiched between two portions of the bottom wall which form a bacteria impervious envelope around the same. In this package, 20, the materials used for the bottom wall are bacteria impervious and flexible. The base portion 24 of the bottom wall 21 extends beyond the periphery of the top wall 3 around the entire periphery of the top wall and is foldably connected to a cover portion 23 of the top wall along line F. The cover portion 23 is folded down over the top wall to overlie the base portion 24 of the bottom wall 21 and form chamber 25. The cover portion and the base portion of the bottom wall are continuously joined in an area 22 all around the periphery of the top wall.

Overlying edge portions, 38 and 39, of the cover portion and base portion of the bottom wall may be left unsealed to each other to form stripping flaps. When it is desired to open the package, the surgeon may pull these flaps in opposite directions to open the package and provide access to the end of the suture projecting through the dispensing aperture.

This embodiment of the invention is particularly suitable for packaging ligatures. As illustrated in FIG. 4, a curved needle 15 conveniently fits within the flat centrally located portion 5 and is held within chamber 25 by the cover portion 23 of the bottom wall. Such a package is useful for office procedures where it is not necessary that the outer surfaces of the package be sterile but only that the suture be sterile and aseptically removable.

When it is desirable that the outer surfaces of the package held by the surgeon also be sterile, the package 20 illustrated in FIG. 6 is suitably enclosed in an outer wrap and acts as an inner container. Such a package, 30, is illustrated in FIGS. 7 and 8.

The outer container comprises a top wall 31 and a

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bottom wall 32. The top wall 31 is shaped to form an outer chamber 33 and an outer flat rim 34 surrounding the outer chamber 33. The peripheral dimension A of the outer chamber 33 is slightly greater than the peripheral dimension B of the chamber 25 of the inner container or disk-shaped container 20 so that the chamber of the inner container nests within the chamber of the top wall 31 of the outer container. By virtue of the nesting, the flat peripheral rim 26 of the inner container is oriented in a definite position with respect to the flat rim 34 of the outer container. The outer edge 36 of the rim 34 of the outer container lies substantially beyond the outer edge 37 of the peripheral rim 26 of the inner container. The outer bottom wall 32 overlaps the chamber 33 and the rim 34 of the outer container around its entire perimeter. The outer bottom wall 32 is sealed to the rim of the outer top wall in a continuous area 35 beyond the outer edges 37 of the inner container and surrounding the inner container. This sealed area lies entirely beyond the outer edges 37 of the inner container so that the rim 26 of the inner container is unbonded to the outer container.

By virtue of the rim 26 of the inner container being situated in a definite position with respect to the rim 34 of the outer container it is assured that when the outer bottom wall 32 is sealed to the outer top wall 31, the rim 26 of the inner container will not interfere with the sealing of or become sealed to the outer container. Thus, it is assured that the inner container and outer container will retain structural integrity so that the surgeon may strip open the outer container to extract the inner container and can strip open the inner container to reach the outward projecting end of the suture.

In order to assist the stripping open of the outer container, the outer bottom wall 32 is free of any seal with the outer top wall 31 in an area 38 at the periphery of the outer bottom wall 32 so as to form outer stripping tab 39.

Although the rim of the inner container is not bonded to the outer container, it should be, as illustrated in the drawings, clamped between the top wall 31 and bottom wall 32 of the outer container. By virtue of the clamping of the inner peripheral rim 26 within the outer peripheral rim 34, the outer top peripheral surface 40 of the chamber 25 of the inner container is situated in a definite position with respect to the inner top peripheral surface 41 of the chamber 33 of the outer container. This clamping, combined with the nesting of the inner chamber 25 within the outer chamber 33, serves to restrain essentially all movement of the inner container within the outer container. By virtue of the gap 42 between the peripheral surfaces of the outer chamber and inner chamber, which may be any predetermined space, any minor crushing of the top wall 31 of the outer container does not affect the inner container. Thus, the cover portion 23 of the inner bottom wall 21 presents a second independent barrier which protects the suture or needle from crushing and other forces applied to the package from its top side. If the outer container is damaged during handling, an undamaged inner container may still be available for placing in the operative area.

The packages of this invention may be made of any of the many suitable materials such as paper, thermoplastic film, or molded plastic. The materials are, of course, chosen with a view toward the desired transparency, rigidity, or bacteria imperviousness of each package member. Thermoplastic materials are particularly suitable since they can be easily sealed together by the application of heat and pressure.

The packages of this invention may be produced by conventional thermoplastic sealing and molding techniques, the temperatures 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 described, the invention should not be construed to be limited thereto but is only limited by the claims.

What is claimed is:

1. A suture package comprising a disk-shaped container which in turn comprises a top wall and a bottom wall together defining an annular compartment of substantial diameter and a shallow centrally located disk-shaped passage in communication with said annular compartment all around the inner border of said compartment, said annular compartment being several times greater in depth than said disk-shaped passage, said walls being joined to one another only outwardly of said compartment and one of said top and bottom walls defining a centrally located suture dispensing aperture, said disk-shaped container additionally comprising a coiled suture located in said annular compartment with one end of the suture extending from said coil through said disk-shaped passage and thence outwardly of the container through said aperture for dispensing the suture from the package, said passage being sufficiently shallow to minimize tightening of the suture coil convolutions when the suture is progressively removed from the package by drawing it through the dispensing aperture by exerting a force on the end passing through the aperture and sufficiently deep to allow any suture coil convolution which does tighten when said force is exerted thereon to snap back to its original position in the annular compartment when the force is released therefrom.

2. A suture package according to claim 1, wherein the depth of the disk-shaped central passage is between about 1.5 and about 2.5 times the diameter of said suture.

3. A suture package according to claim 1, wherein the top wall is molded to form a raised annular chamber and a flat section surrounded by said chamber, and said dispensing aperture is centrally located in the flat section of said top wall.

4. A suture package according to claim 3, wherein said bottom wall is a relatively thin flat sheet continuously heat sealed to said molded sheet all around said annular chamber.

5. A suture package according to claim 3 wherein said top wall is additionally molded to form an outward extending lip surrounding the suture dispensing aperture to insure that the suture when progressively dispensed for use will be removed at a substantial angle to the plane of the coil.

6. A suture package according to claim 3 wherein the top wall comprises a flat peripheral annular rim surrounding said annular chamber and said bottom wall is sealed to said annular rim.

7. A suture package according to claim 6 additionally comprising an outer container, said outer container comprising an outer top wall and an outer bottom wall, said outer top wall being shaped to form an outer chamber and an outer flat rim surrounding said outer chamber, the peripheral dimension of the outer chamber being slightly greater than the peripheral dimension of the chamber of the disk-shaped container so that the chamber of the disk-shaped container nests within the outer chamber, by virtue of which the flat rim of the disk-shaped container is oriented in a definite position with respect to the flat rim of the outer container, the outer edge of the peripheral rim of the outer container lying substantially beyond the outer edge of the peripheral rim and the periphery of the bottom wall of the disk-shaped container, said outer bottom wall overlying the outer chamber and the rim of the outer container around its entire perimeter and being sealed to the rim of said outer top wall in a continuous area beyond the outer edges of the disk-shaped container and surrounding the disk-shaped container.

8. A suture package of claim 7 in which the rim of the disk-shaped container is clamped between the top wall and bottom wall of the outer container and in which the outer chamber is appreciably deeper than the chamber of the disk-shaped container thereby defining a gap in depth between the chamber of the disk-shaped container and the chamber of the outer container, whereby a package is provided in which essentially all movement of the disk-shaped container within the outer container is restrained and in which two separate and independent barriers are provided to protect the suture from crushing forces applied to the package from the top side.

9. A suture package comprising a disk-shaped top wall defining a centrally located suture dispensing aperture; a bottom sheet comprising a base portion joined to said top wall adjacent the periphery of said top wall and together with said top wall defining a circular suture compartment, said base portion extending beyond the top wall all around the periphery of said top wall and said bottom sheet comprising a cover portion foldably connected to said base portion at one side of the package, said cover portion being folded down over said top wall to overlie said base portion and sandwich the top wall between the base and the cover portions of said sheet; and a coiled suture located in said compartment with one end of the suture extending from said coil through said aperture, the cover portion being continuously joined to the base portion of said sheet all around the periphery of said top wall to provide a sealed enclosure for the top wall and the suture in said compartment.

10. A suture package according to claim 9, wherein the cover portion is strippably sealed to the base portion of said sheet and overlying edge portions of said cover and base portions are unsealed to one another to provide stripping flaps for opening said package, whereby the stripping flaps may be pulled in opposite directions to open said package and provide access to the suture end extending through said dispensing aperture.

11. A suture package according to claim 9 wherein said top wall is molded to define a raised annular chamber and a flat section surrounded by said chamber, and said dispensing aperture is centrally located in said flat section, said molded top wall together with the base portion of said bottom sheet defining an annular compartment wherein said suture coil normally is retained and a centrally located shallow disk-shaped passage in communication with said compartment all around the inner border of said compartment, the suture end extending through said aperture passing from said coil to said aperture through said passage.

12. A suture package according to claim 11 wherein the depth of the disk-shaped central passage is between about 1.5 and about 2.5 times the diameter of said suture, and said annular compartment is substantially greater in depth than said disk-shaped passage.

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