United States Patent

[11] 3,545,608

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[54] **SUTURE PACKAGE**
10 Claims, 14 Drawing Figs.

[52] **U.S. Cl.** **206/63.3**
[51] **Int. Cl.** **A61l 17/02**
[50] **Field of Search** ..... 206/63.3, 78(B), 59(A), 59(B), 52(W), 56(A2)

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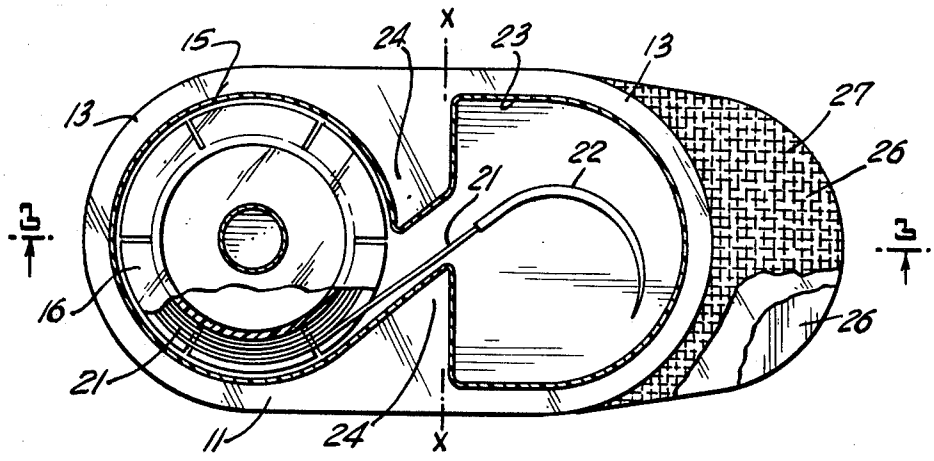
Primary Examiner—Joseph R. Leclair
Attorney—Alexander T. Kardos and Charles A. Harris

ABSTRACT: A sterile surgical suture package comprising an elongated suture or sutures wound upon one or more flat cylindrical reels enclosed within a correspondingly flat permanently formed compartment having fixed axial and radial dimensions greater than those of said reel, and means for retaining the reel enclosed in said package after it is partially opened while allowing the reel to rotate freely therein for dispensing the suture therefrom. The reel may be mounted on an axle integral with the package for this purpose. A transverse stop also is provided to minimize the possibility of exposing the reel when the package is to be opened by stripping and to provide a fold line to position the package for dispensing after it has been opened. A special thin flat reel construction for sutures also is disclosed.



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SHEET 1 OF 4

Fig. 1.

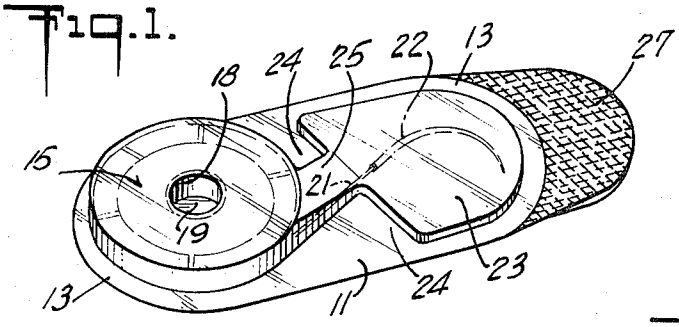

Fig. 2.

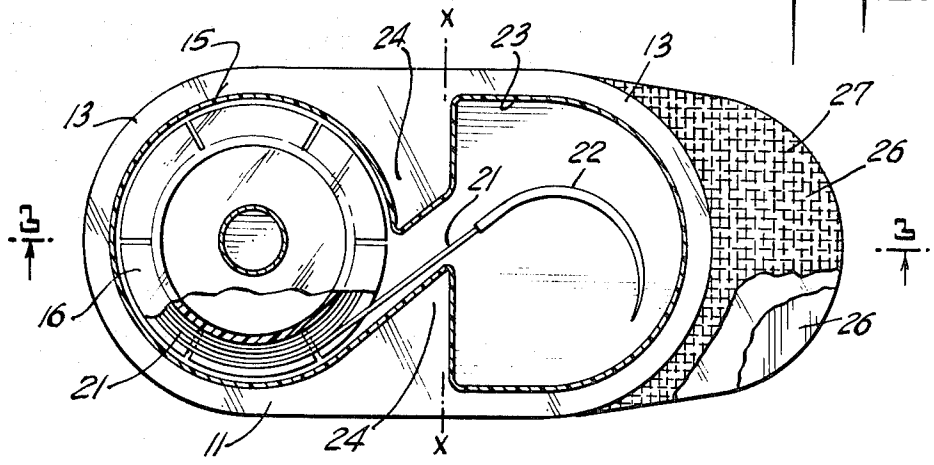

Fig. 3.

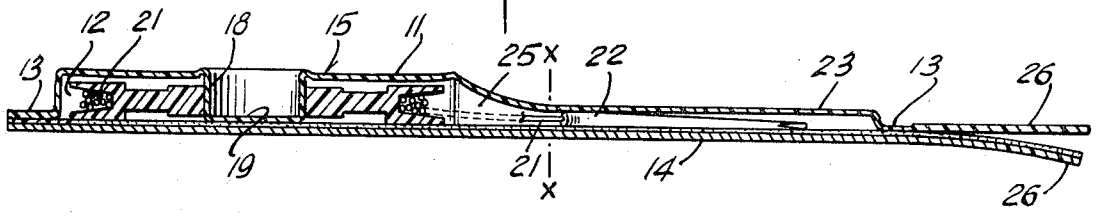

Fig. 4.

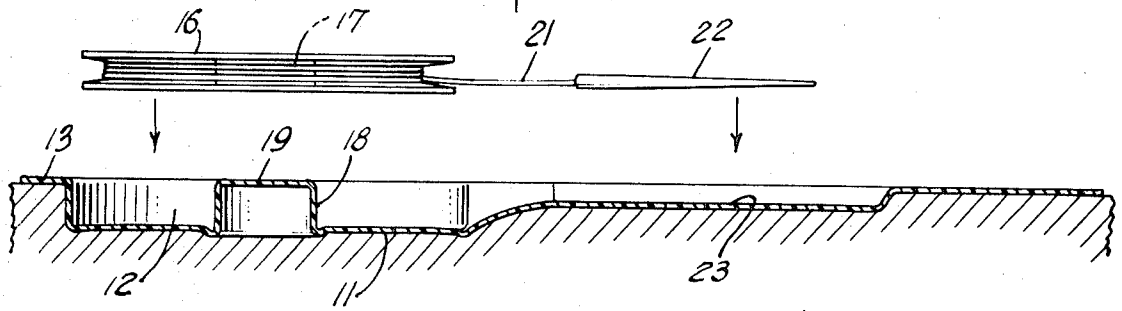

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Fig. 5.

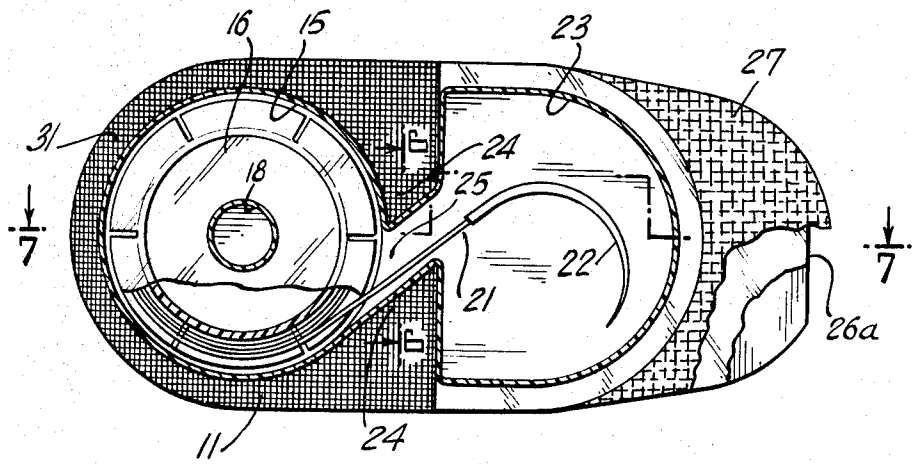

Fig. 6.

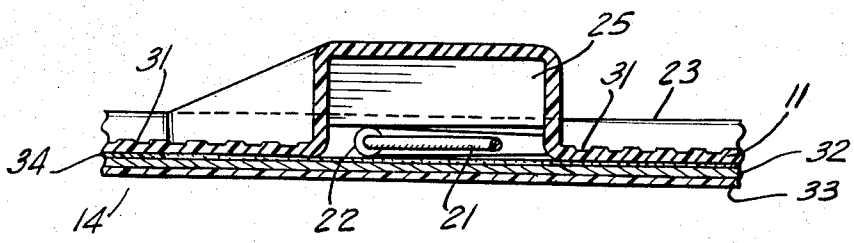

Fig. 7.

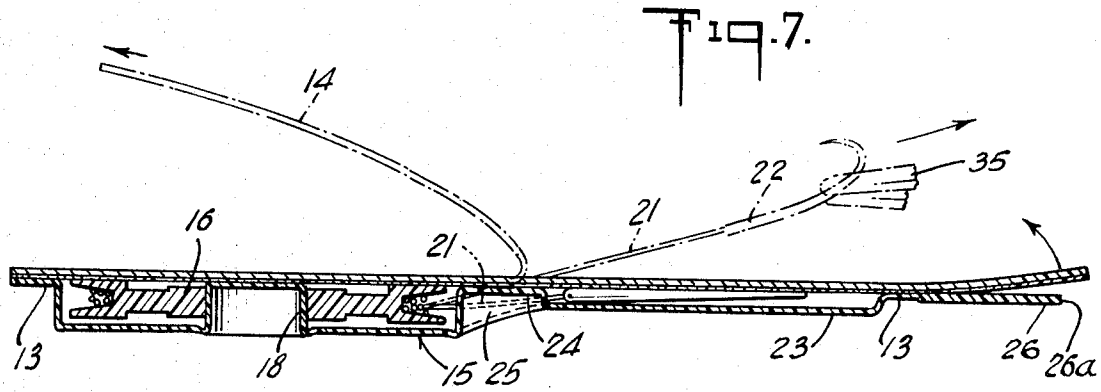

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Fig. 8.

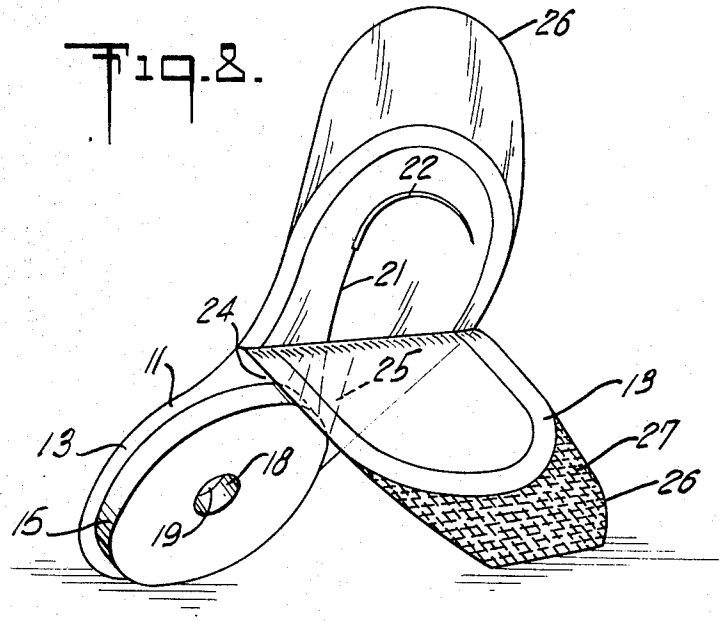

Fig. 9.

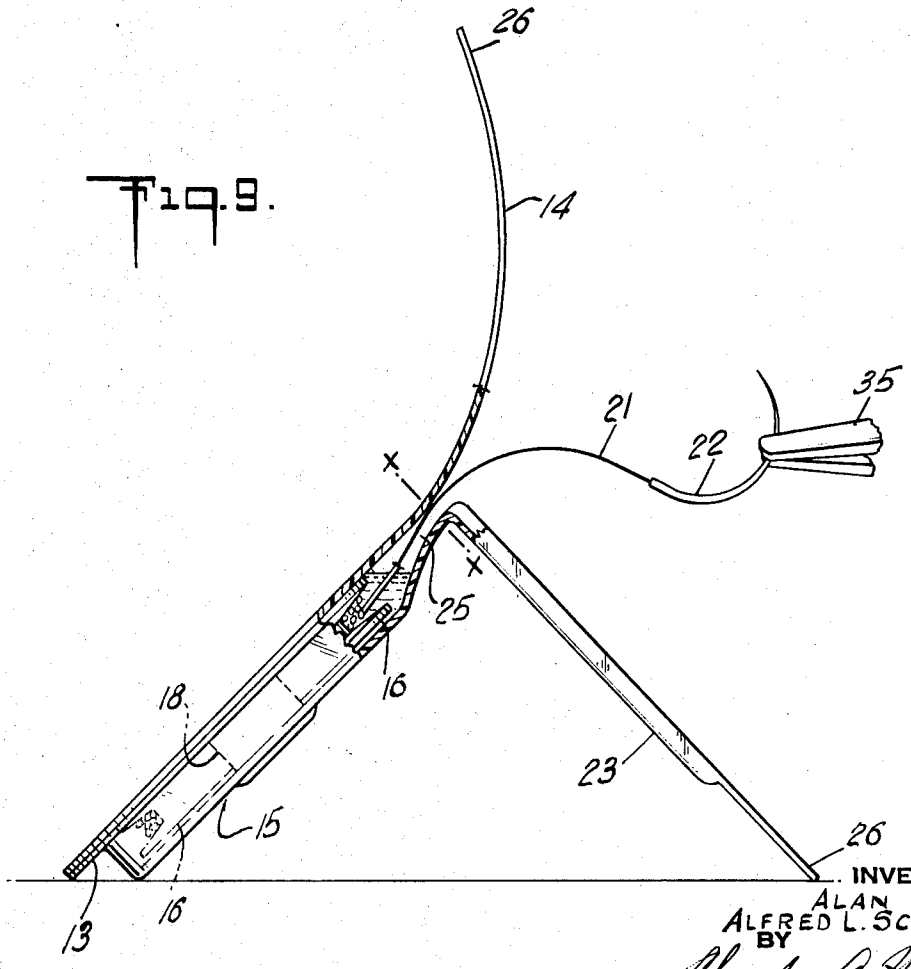

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Fig. 10.

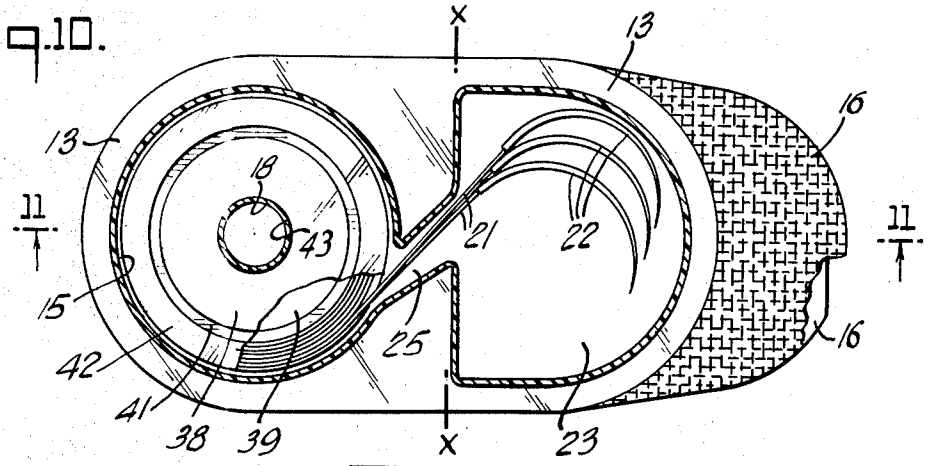
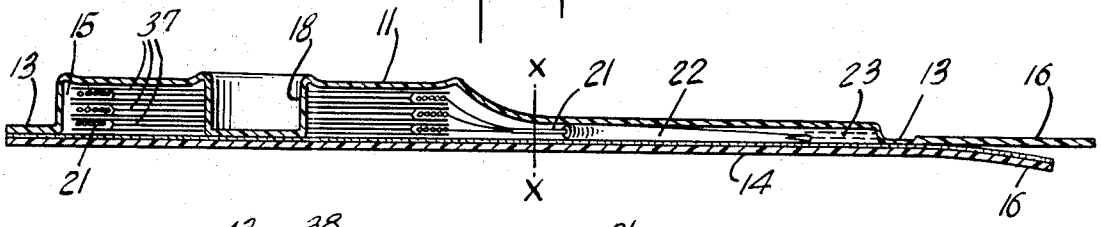


Fig. 11.



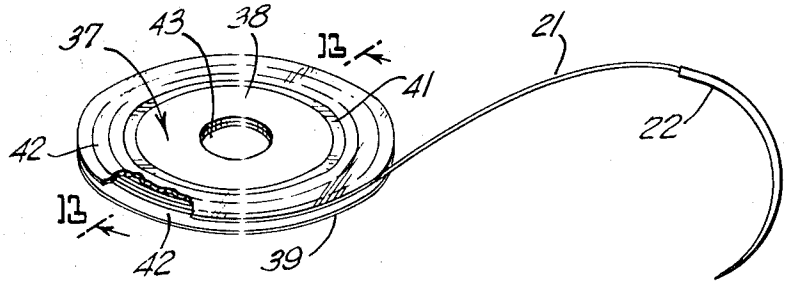
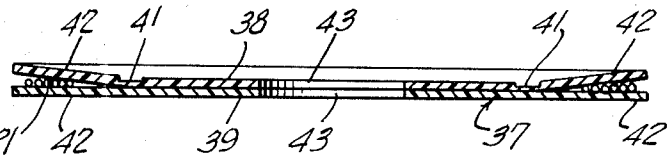


Fig. 12.

Fig. 13.



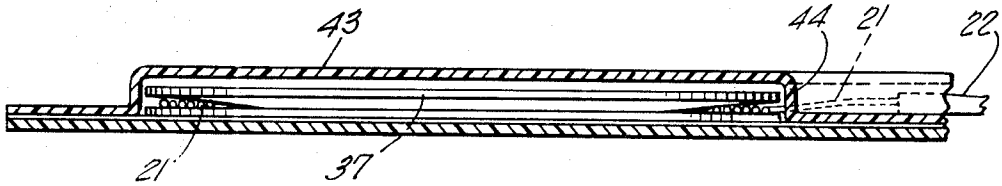


Fig. 14.

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SUTURE PACKAGE

The present invention relates to sterile surgical suture packages wherein the suture is mounted on a cylindrical reel in such a way that the suture normally is free from kinks when unwound from the reel. When the term suture or sutures is used herein it shall mean elongated strands used in surgery for suturing, ligating, or the like and therefore includes such strands normally called ligatures.

Heretofore, surgical sutures have been packaged on reels in sterile enclosures in such a way that the reel may be removed from the package after it is opened to allow the suture to be withdrawn or unwound from the reel. For example, British Pat. No. 1,081,123 published Aug. 31, 1967 shows a fixed, i.e. nonrotatable reel which is adapted to be packaged in this manner. However, since this package does not allow the suture to be unwound by rotating the reel, kinking and twisting of the suture during unwinding is a problem. Furthermore, the suture is fully exposed during the unwinding process and therefore is apt to be contaminated if it is not handled under completely aseptic conditions.

According to the present invention, a package is provided wherein the suture is mounted on a reel which is retained in the package after it is opened in such a way that the reel is completely covered yet adapted to rotate in the package as the suture is withdrawn therefrom. More specifically, the suture is wound on one or more flat cylindrical reels which are enclosed within a permanently formed reel compartment having relatively fixed axial and radial dimensions greater than those of the reel or reels, and the package includes means for retaining the reel in position in the compartment after the package is opened while allowing it to rotate freely therein for dispensing purposes.

The package comprises a molded sheet defining a recess surrounded by an annular sealing flange and a cover sheet sealed to the molded sheet at least through this sealing flange to form a hermetically sealed package. The aforesaid permanently formed compartment is defined by the recess in said molded sheet together with the cover sheet sealed thereto. When the term "annular" is used herein it shall mean generally ring shaped but not necessarily circular and may even include continuous configurations which may be more rectangular than curved. When the term "molded" is used herein to describe a part of the package or reel of this invention it shall mean injection molded, vacuum formed, or otherwise molded, formed or shaped to assume a permanent configuration which it will tend to retain under normal conditions of use.

Preferably, the retaining means for holding the reel rotatably in position in the package is in the form of an axle integral with one or both of the molded sheet or the cover sheet. In this case, the reel includes a hollow central opening and the axle fits into this opening to allow the reel to rotate thereon. Preferably also, the axle is in the form of a hollow boss molded from or in the molded sheet and the boss is sealed to the cover sheet in such a way as to form a fixed annular compartment which accommodates the suture reel which, of course, also is annular. Thus, the reel is adapted to rotate freely in the reel compartment to allow the suture to be unwound therefrom when the free end of the suture is drawn away from the axle. However, the reel retaining means may be an axially extending peripheral wall portion of the compartment itself which is designed to position the reel in the compartment while allowing it to rotate freely.

In the package of this invention, the free end of the suture extends into an access area which is adapted to be exposed when the package is opened. The molded sheet may be further recessed in this area to provide an access compartment for receiving the end of the suture and/or a curved needle attached thereto. Preferably, the cover is firmly sealed to the molded sheet between the reel compartment and the access area to provide a transverse stop for stripping the package open or for folding the molded sheet for positioning it for dispensing as will be described more fully hereinafter. The package includes a passageway connecting the reel compartment with the access area, and the free end of the suture is positioned through the passageway. Preferably, the passageway is disposed at an angle with respect to the reel compartment and the access area in such a way as to facilitate positioning of the needle in a curve reverse to that of the suture wound on the reel. This causes the suture to trail away from the point of the needle after it has been unwound from the reel and thereby facilitates suturing. In the preferred from of this invention, the annular sealing flange extends around both the reel compartment and the access area, and the molded sheet and the cover sheet each extend beyond the sealing flange at the end of the package adjacent to the access area to provide a pair of opposed stripping flaps. In this case, the seal formed between the molded sheet and the cover sheet is adapted to be stripped apart easily by separating the stripping flaps, thereby exposing the access area. However, the transverse stop is adapted to prevent further stripping of the seal without the application of substantially increased stripping forces. This facilitates opening of the package only enough to expose the access area while retaining the reel within its original enclosure or compartment.

The package of this invention is particularly suitable for use with a novel suturing device of this invention which is in the form of a very thin flat cylindrical suture reel which normally consists of two flat discs of resilient plastic or other similar material which are secured to one another by sealing or snapping to form the reel. In a preferred form the discs merely are superimposed radially and adhered to one another, such as by heat-sealing, in a generally annular area adjacent to but spaced radially inwardly from the periphery of the reel. This provides a rim portion of the reel wherein the annular peripheral rim or flange portions of the disc are not adhered to one another, with the result that a surgical suture can be wound upon itself in the form of a spiral between said peripheral flange portions. These flange portions are axially spaced from one another by an amount no greater than about the axial thickness of the spiral to assure that the suture is retained in its spirally wound configuration. In fact, there peripheral rim portions normally are urged toward one another or tend to contact one another, and are displaced from this configuration by the suture wound between them. As a result, at least the innermost convolutions of the suture are gripped firmly between the discs. Preferably, the suture therefor is wound in a spiral of gradually increasing diameter which normally is not greater than one suture diameter in axial thickness. As will be described more fully hereinafter, this type of very flat reel is particularly suited for inclusion in packages of this invention wherein a plurality of reels are included in a single compartment in order to facilitate the dispensing of a plurality of sutures one at a time therefrom.

Other and further advantages of this invention will appear to one skilled in the art from the following description and claims taken together with the drawings wherein:

FIG. 1 is a view in perspective of a suture package according to a preferred embodiment of this invention.

FIG. 2 is a slightly enlarged plan view of the suture package of FIG. 1 partly in section and partly broken away for illustrative purposes.

FIG. 3 is a somewhat more greatly enlarged sectional view taken along the line 3–3 of FIG. 2.

FIG. 4 is an expanded view, partly in section and partly in elevation, of the reel and molded sheet portions of the package of FIG. 3, showing the molded sheet in position in the mold form.

FIG. 5 is a partly sectional and partly broken away plan view similar to that of FIG. 2, showing a package according to a slightly different embodiment of this invention.

FIG. 6 is a greatly enlarged schematic view, partly in section and partly in elevation, taken along the line 6–6 of FIG. 5, and showing the thickness of the cover sheet and the relative parts thereof exaggerated for purposes of illustration.

FIG. 7 is a sectional view similar to FIG. 3 taken along the line 7–7 of FIG. 5, but showing the package inverted to illus-

trate the way in which the cover and molded sheet are stripped apart to expose the access compartment in the package.

FIG. 8 is a view in perspective of the suture package of FIGS. 7—7, illustrating how the package may be opened and positioned for use by folding the molded sheet down about the fold line X–X at the leading edge of the transverse stop.

FIG. 9 is a somewhat enlarged view, partly in longitudinal section and partly in elevation, of the package of FIG. 8 which also illustrates the same dispensing position of the package.

FIG. 10 is a slightly enlarged plan view of a suture package according to a somewhat different embodiment of this invention, partly in section and partly broken away for illustrative purposes.

FIG. 11 is a somewhat more greatly enlarged sectional view taken along the line 11–11 of FIG. 10.

FIG. 12 is a view in perspective of a novel reel embodiment of this invention with a suture wound thereon.

FIG. 13 is an enlarged sectional view taken along the line 13–13 of FIG. 12.

FIG. 14 is a similarly enlarged view, partly in section and partly in elevation, of a portion of a package according to another embodiment of this invention illustrating the reel of FIGS. 12 and 13 in position therein.

Referring to FIGS. 1—4 of the drawings, there is shown a sterile surgical suture package according to a preferred embodiment of this invention which comprises a molded sheet 11 defining an annular recess 12 surrounded by a sealing flange 13 which is in the form of an elongated annulus, and a flat cover sheet 14 heat sealed to the molded sheet 11 through the sealing flange to form a hermetically sealed package which includes a permanently formed reel compartment 15 which possesses an annular shape defined by that of the recess 12. A flat cylindrical suture reel 16 is located within this compartment 15. The reel 16 defines a hollow central opening 17, and the molded sheet presents a cylindrical axle or boss 18 which fits through the opening 17 in the reel and is sealed to the cover sheet 14. The boss 18 is molded directly from the material of the molded sheet 11 and therefore is integral therewith, and possesses a flat tip 19 which is heat sealed to the surface of the cover sheet 14 for this purpose. It will be seen most clearly from FIG. 3, that the dimensions of the compartment both axially and radially of the reel 16 are somewhat greater than those of the reel. Since the reel 16 also is mounted freely on the boss 18 and the structure of the compartment 15 is permanently formed, the reel 16 is free to turn on the boss to allow the suture to be unwound therefrom when the end of the suture is withdrawn from the package as will be described more fully hereinafter.

A surgical suture 21 is wound on the reel 16 in several turns or convolutions and presents a free end which has a conventional curved suturing needle 22 attached thereto. The needle 22 and the free end of the suture 21 extend away from the reel to an access area which also is enclosed within the hermetically sealed portion of the package surrounded by the annular sealing flange 13. The molded sheet 11 is so shaped in this area as to provide a somewhat shallow access compartment 23 for the needle. The cover 14 is similarly heat sealed to the molded sheet 11 between the reel compartment 15 and the access compartment 23 in such a way as to provide a transverse stop 24 which will be described more fully hereinafter. The package includes a passageway 25 connecting the reel compartment with the access compartment and the free end of the suture 21 is threaded through this passageway in the area of the stop 24. The passageway 25 is inclined at an angle with respect to the compartments 15 and 23 in such a way that, when the suture is positioned therein and the curved needle is positioned as shown in the drawings, the curve of the needle is reverse to that of the suture wound on the reel 16. As explained hereinbefore, this causes the suture, after it is unwound from the reel, to trail away from the point of the needle during suturing. The thickness or axial height of the access compartment 23 clearly is low enough to prevent the needle from turning over during handling of the package to interfere with this relationship.

It will be seen from FIG. 4, that the molded sheet 11, which may consist of a sheet of polyvinyl chloride approximately 7—10 mils thick, or thicker, may be shaped by a conventional vacuum-forming technique or the like; and the reel 16 mounting the suture 21 and the needle 22 may be dropped into the recess 12 surrounding the boss 18. Then, the cover sheet 14 may be placed in position and heat sealed to the molded sheet. The molded sheet 11 and the cover sheet 14 each extend beyond the sealing flange 13 at the end of the package adjacent to the access compartment 23 to form a pair of exposed stripping flaps 26. The seal formed between the molded sheet 11 and the cover sheet 14 is adapted to be stripped apart easily merely by pulling the stripping flaps 26 away from one another. The separation of the stripping flaps 26 in this manner proceeds easily until the transverse stop 24 is reached, at which point further stripping is prevented. Thus, the user is able to expose the needle or suture end in the access compartment 23 easily without opening the remainder of the package to expose the reel 16, itself. The stripping flap 26 integral with the molded sheet 11 may be embossed or corrugated as at 27 prior to the time the sheets 11 and 14 are sealed together to facilitate separation and gripping of the stripping flaps 26.

A slightly different embodiment of the package of this invention is illustrated in FIGS. 5, 6 and 7. This package is similar in all respects with that of the foregoing figures with the exception that the heat seal between the cover sheet 14 and the molded sheet 11 includes mechanical embossing 31 in the area of the transverse stop 24, and further that the lowermost stripping flap 26 has been foreshortened to provide a straight edge 26*a* at the end of the flap.

FIG. 6 illustrates the shape of the passageway 25 between the reel compartment 15 and the access compartment 23, as well as a preferred structure for the cover sheet 14. In this form, the cover sheet 14 is a laminate comprising a foil barrier layer 32, an outer protective layer 33 of a polyester film, and an inner heat sealing layer 34 based on a copolymer of vinyl chloride and vinyl acetate coated on the foil at a weight of approximately 5 or 6 pounds per ream. This type of heat sealing layer 34 has been found to form reliable hermetic seals with vinyl chloride sheeting which also are strippable in the manner required by this invention.

FIG. 7 merely illustrates the normal manner of opening this type of package of this invention. Normally, the molded sheet 11 is held downwardly since it actually contains the suture reel 16 and needle 22, and then the stripping flaps 26 are separated in such a way that the cover 14 is pulled back over the access compartment 23 to expose the needle and suture end therein. Further stripping is prevented at the point illustrated by the phantom position of the cover 14 shown in FIG. 7 when the stop 24 is reached. Thus, it is simple for the one opening the package to terminate the stripping at this point and avoid opening any part of the reel compartment 15 or exposing the reel 16 in any way except through the relatively narrow passageway 25 between the two compartments. When stripping has reached this point, the suture 21 may be removed from the package by hand or by gripping the needle 22 with a pair of forceps 35 and pulling the suture away from the package, as shown in phantom at the right of FIG. 7. The reel 16 rotates easily in the compartment 15 to allow the suture to be unwound easily and withdrawn from the package when this is done. One of the advantages of the package of this invention is that, when it has been stripped open to the point illustrated by the phantom portion of FIG. 7, the stripped portion of the cover 14 may be folded down over the reel and the open package may be positioned on a sterile table ready for the desired surgical procedure without the need for exposing the remainder of the suture or any part of the suture reel 16.

FIGS. 8 and 9 show how the package of the foregoing embodiments is particularly adapted to be opened and then positioned in an upright manner for later dispensing of the suture, or sutures 21, contained therein. For this purpose, the leading edge of the transverse stop 24 is adapted to act as a fold line X–X about which the molded sheet 11 may be folded downwardly to assume a position extending at an angle of ap-

proximately 60 or 90°, or the like, to the plane of the reel **16** remaining in the package. When this is done, the opened package may be positioned, or set up easel-fashion, as illustrated in FIGS. **8** and **9** with the folded down flap **26** acting as one leg of the easel and the other end of the package acting as the other leg. The flat edge **26***a* at the end of the folded down flap contacts the table or other surface on which the package is positioned and prevents it from rolling over. In this position, even though the package has been opened and the suture **21** is ready to be dispensed merely by drawing it therefrom, most of the suture remains wound upon the reel which is completely enclosed within the unopened portion of the package. When the suture is absorbable and therefore is packaged with a pliableizing fluid **36**, the suture remaining on the reel **16** stays in contact with the fluid reservoir in the compartment. The easel position of the package, illustrated in FIGS. **8** and **9**, makes it possible to retain the pliableizing fluid in the package for this purpose without danger of spillage. Thus, in the position illustrated in these FIGS. the free end of the suture **21** to which the needle is attached remains protruding from the flaps of the easel like a tongue between two lips and is readily available to be grasped at any time by hand or with forceps **35** and therefore may be removed very easily from the package.

FIGS. **10—13** illustrate another embodiment of this invention which is similar in most respects to those of the foregoing figures but includes a plurality of very flat reels **37**, i.e. three, in accordance with a novel suturing device of this invention. For this reason, the parts of the package will be identified by the same numbers as are used with respect to the foregoing embodiments, except for those referring to the reels **37**, themselves. The flat reels **37** are superimposed axially with respect to one another and positioned over the boss or axle **18** for rotation in the annular compartment **15** surrounding the axle. As described hereinbefore, the compartment has fixed dimensions radially greater than those of said reels and, in this case, axially greater than the total axial dimension of the stack formed by the superimposed reels, as best illustrated in FIG. **11**.

The suturing device of this invention, shown in FIGS. **10—13**, comprises first and second resilient and thermoplastic flat discs **38** and **39** superimposed radially and heat sealed to one another in a generally annular heat seal area **41** adjacent to but spaced radially inwardly of the periphery of the reel **37**. Thus, the annular peripheral rim portions **42** of the two discs are not adhered or sealed to one another outwardly of the annular heat sealed area **41**. Since the discs **38** and **39**, themselves, are initially flat, the rim portions **42** normally would tend to contact one another after the discs are sealed together and, by virtue of their resiliency, would tend to return to this position if forced apart. This construction is utilized to wind a suture **21** on the reel **37** by separating the peripheral rim portions of the reel slightly and then allowing these portions to come toward one another to grip the suture between them, as best illustrated in FIG. **13**. This facilitates winding the suture **21** in the form of a spiral of gradually increasing diameter which normally is not greater than one suture diameter in axial thickness, and assures that at least the innermost convolutions of the suture are firmly held between the discs **38** and **39**. As a result, a very flat suture reel is provided even after the suture is wound thereon. Furthermore, since successive convolutions are wound radially outwardly of one another on the reel, their natural tendency is to unwind in reverse order as the reel is rotated without danger of entaglement between adjacent convolutions. Another important advantage of the foregoing suturing device of this construction is its great simplicity and ease of manufacture. In this connection the central holes **43** in the discs making up the reels **37** may be formed either before or after the discs **38** and **39** are sealed to one another. In fact, they may be formed concurrently with the heat sealing step by a suitable die, not shown, designed for this purpose. Then the three reels **37** may be positioned in the annular compartment **15** one after the other, and the corresponding free ends of the sutures **21** wound on each reel with the needles **22** attached thereto may be laid in the passageway **25** and the access compartment **23**, respectively, prior to sealing the cover sheet **14** in position over the molded sheet **11**, to complete the package, as shown in FIGS. **10** and **11**.

In the embodiment of FIG. **14**, a single flat reel **37** of the type shown in FIGS. **10—13** and described hereinbefore is positioned in a correspondingly flat and permanently formed compartment **43** of a package of this invention. In this package, the centrally located axle of the foregoing embodiments has been eliminated and the axially extending peripheral wall of the compartment **44** at the needle end of the package acts as the retaining means which positions and holds the reel **37** in the compartment after the package is opened while allowing the reel to rotate freely to unwind the suture **21** therefrom when tension is applied to the free end of the suture. As described in connection with the foregoing embodiments, the structure of the compartment **43** is permanently formed and possesses fixed internal axial and radial dimensions greater than those of the reel **37**, thereby assuring that the reel is free to rotate in the compartment and will not become jammed therein. For this purpose, it is preferred that the retaining portion or portions **44** of the peripheral wall of the compartment present axially extending surfaces which the periphery of the reel **37** can slide freely against as the reel rotates to allow the suture to be dispensed. The extreme flatness of this form of package allows it to be packaged in a minimum of space without sacrificing any of the functional advantages of this invention which have been described herein.

Having now described the invention in specific detail and exemplified the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art that innumerable variations, modifications, applications and extensions of the basic principles involved may be made without departing from its spirit or scope. For instance, although only a package which may be opened by stripping has been shown, the package of this invention may be adapted to be opened by tearing through the access area or compartment to expose the needle or suture end, as the case may be. A conventional notch may be included at one edge of the package to initiate tearing for this purpose. Furthermore, the thin flat reel of this invention may be formed by shaping the discs in such a way that they may be snapped together, as indicated hereinbefore, rather than heat sealed or adhered to one another. In fact, it may even be possible to initially form or mold all parts of the thin reel of this embodiment integral with one another without in any way departing from the scope of this invention.

We claim:

1. A sterile surgical suture package which comprises a molded sheet defining a recess at least partially surrounded by a sealing flange, a cover sheet sealed to said molded sheet at least through said sealing flange to form a hermetically sealed package, the recess in said molded sheet and said cover sheet together defining a permanently formed reel compartment, a flat cylindrical suture reel in said compartment, said compartment having relatively fixed dimensions greater than those of said reel both axially and radially of said reel, said reel having a suture wound thereon with its free end extending into an access area adapted to be exposed when said package is opened, and means associated with the compartment for centering the reel in the compartment and for retaining the reel in position in said compartment after the package is opened while allowing the reel to rotate freely to unwind the suture therefrom when tension is applied to the free end of the suture.

2. A sterile suture package according to claim **1**, wherein said centering and retaining means is in the form of an axle integral with at least one of said molded and said cover sheet and located centrally of said compartment, said reel defines a hollow central opening, and said axle fits into said central opening and thereby positions said reel for rotation in said compartment.

3. A sterile suture package according to claim **2**, wherein said axle is in the form of a boss molded from the molded sheet and said boss is sealed to the cover sheet, said compartment

being annular in shape to accommodate the reel which also is annular.

4. A sterile suture package according to claim 1, wherein said centering and retaining means is in the form of an axially extending wall portion of said compartment.

5. A sterile suture package according to claim 1, wherein a plurality of said reels each supporting a separate suture or sutures are superimposed axially with respect to one another in said compartment, and said reels are adapted to rotate independently of one another to facilitate independent dispensing of individual sutures after said package is opened.

6. A sterile suture package according to claim 5, wherein each of said reels is thin and flat and comprises first and second flat annular peripheral flange portions joined to one another adjacent to but spaced from the periphery of the reel to provide a rim portion of the reel wherein the annular flange portions are not secured to one another, and the suture is wound upon itself in the form of a thin spiral between said peripheral flange portions, said flange portions being spaced axially from one another by an amount no greater than about the axial thickness of the spiral, whereby the suture is retained in its spirally wound configuration.

7. A sterile suture package according to claim 1, wherein said cover is firmly sealed to the molded sheet between said compartment and said access area to provide a transverse stripping stop, said package includes a passageway connecting the compartment with the access area and the free end of the suture is positioned through said passageway.

8. A sterile suture package according to claim 7, wherein the annular sealing flange also extends around said access area, and said molded sheet and said cover sheet each extend beyond the sealing flange at the end of the package adjacent to said access area to provide a pair of opposed stripping flaps, the seal formed between the molded sheet and the cover sheet being adapted to be stripped apart easily by the separation of said stripping flaps to expose said access area, and said transverse stripping stop preventing further stripping apart of said seal without the application of substantially increased stripping forces.

9. A sterile suture package according to claim 7, wherein said molded sheet is further recessed to provide an access compartment for receiving the suture and/or needle in said access area.

10. A sterile suture package according to claim 1, wherein said molded sheet is relatively rigid and said cover sheet is flat and relatively flexible, and said sealing flange is in the form of a flat annulus, whereby the axial and radial dimensions of said compartment are determined by the corresponding dimensions of the recess in said molded sheet.