Taylor

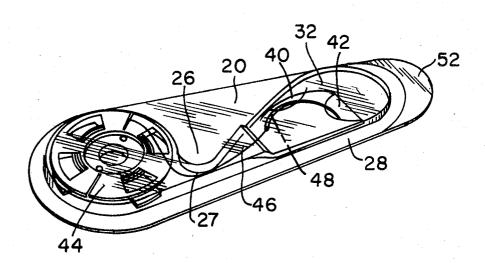
[54]		DISPENSER PACKAGE AND OF MAKING
[75]	Inventor:	Stanley E. Taylor, Chesterton, England
[73]	Assignee:	Cenco Medical Health Supply Corporation, Chicago, Ill.
[22]	Filed:	Sept. 23, 1971
[21]	Appl. No.	: 183,115
[52] [51] [58]	Int. Cl	
[56]		References Cited
	UNI	FED STATES PATENTS
3,545 3,487 3,613 3,338 3,648	,917 1/19 ,879 10/19 ,401 8/19	70 Shave et al. 206/63.3 71 Kemble 206/63.3 67 Regan, Jr. 206/63.3

Primary Examiner—William T. Dixson, Jr. Attorney—Robert E. Wagner

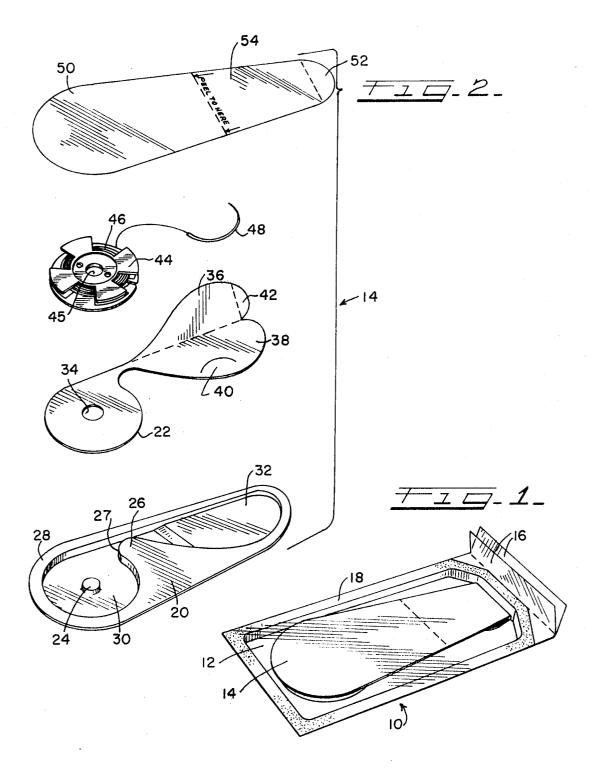
[57] **ABSTRACT**A suture dispenser package for directly dispensing ster-

ile sutures including a molded in depth tray having a circular cavity for receiving a reel means on which an elongated suture is wound, a cavity for receiving a clip means retaining the unwound end of the elongated suture or a needle attached to it, and a narrow passageway between the two cavities which acts to straighten the suture as it is pulled through it. A lid means which is sealable about the periphery of the tray encloses and maintains the suture containing reel and the clip means within their cavities in the tray forming a primary suture pack which may be further enclosed by a secondary package. A method of making a sterile suture dispenser package including, winding an elongated suture about a suture reel, placing the unwound end or suture needle of the suture in a clip means and positioning the reel and clip means in cavities formed in a molded in depth tray, sterilizing the tray and its contents, and sealing a lid to a flange disposed about the upper periphery of the tray, enclosing the tray and its contents. This entire primary suture pack is then enclosed by and sealed within a secondary suture package and externally sterilized through the permeable material forming the secondary suture package.

7 Claims, 5 Drawing Figures

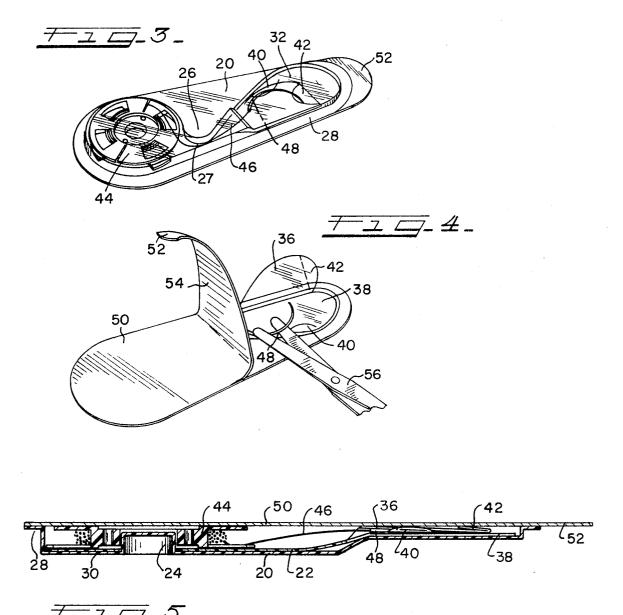


SHEET 1 OF 2



INVENTOR
STANLEY E. TAYLOR
Robert E. Wagner

SHEET 2 OF 2



STANLEY E. TAYLOR

BY Robert E. Wagner

ATT'Y

SUTURE DISPENSER PACKAGE AND METHOD OF **MAKING**

BACKGROUND OF THE INVENTION

This invention relates to suture dispensers, and in 5 particular, to a suture dispenser package for directly dispensing sterile sutures for use in medical and surgical procedures and to a method of making such a pack-

The use of sutures is necessary in almost every area 10 of medical and surgical practice. As the techniques and procedures used in these various areas requiring sutures have become more sophisticated and timewise more efficient, the demand for a type of suture which is readily available in a sterile condition has greatly in- 15 creased.

In order to meet this demand, sutures have been made available over the past few years in small, often hand-held packages which are constructed of disposable materials and which are formed in such a manner 20 that they contain the sutures in ready to use sterile condition. These suture packages are illustrated by U. S. Pat. Nos. 3,338,401 and 3,280,971 issued to P. E. Regan, Jr. All of these new suture packages have attempted to provide a readily accessible suture while 25 maintaining the paramount requirement of complete sterility of the suture at all times. They have also recognized the need for packaging the sutures in a condition which will allow them to be used at a date several months subsequent to their manufacture without their 30 ble before opening. It is apparent that it would be a disbecoming brittle and flaking or breaking during use.

The patents of Regan teach the packaging of sutures within a coiled, sterilized sleeve enclosable within an outer pack ('971) or in a channel having a plurality of convolutions, molded from the suture package itself, 35 receiving a plurality of of elongated sutures and allowing for the introduction of a liquid to surround the sutures within the pack to prevent brittleness and dryness while permitting easy access to one end of the suture through a peelable lid on the pack. ('401)

Despite the advances in suture packaging art illustrated by these patents and by the commercially available types of suture dispenser packs, there remain several significant problems in the development of adequate suture packaging. Considering that sutures are so universally required in medical and surgical work and that the ability to have immediate access to completely sterile non-brittle sutures with a minimum of handling, time consuming package opening operations or inadvertent spillage of liquid is absolutely essential, these problems are extremely important. Among the major problems which have not been solved by the presently available types of suture packs is the coil set taken by sutures from their configuration during storage, no matter what suture winding system is used. This type of set is not only a hindrance to tight stitching and rapid and easy workability of the suture, but also requires that the user manually straighten the sterile suture after extraction from the card or other receptacle containing the suture. Such manual straightening is bothersome, difficult, and increases the chances of contamination of the suture before use.

A further problem is that once the actual suture is obtained from the protective sterile packaging, the operator is often left with various pieces of superfluous packaging which not only have a nuisance value, but also pose a sterility hazard. For example, there may be a

torn off end of a primary package, a cardboard retainer or sleeve for the suture, winding holders, caps, spilled solution from the package, or fiber particles which flake out because of the dryness of the package.

A third problem has been that, with available suture packages, the user has a number of manipulations to perform in order to open the protective or secondary and primary packages before the suture is available for use. Each of these manipulations presents an additional sterility hazard as well as being wasteful of valuable time. Some of the manipulations the user must go through after opening the outer pack and depositing the primary pack on a sterile field area; (1) opening the primary package, (2) withdrawing the suture from the primary package enclosed or held by a card reel, plastic holder or winding stem, (3) opening the card reel and-/or holder while using a clamp to hold the needle, (4) extracting a suture from the card reel and/or holder, and, (5) straightening the suture after removal by tugging at both ends. Again, all of the above manipulations must be completed under sterile conditions.

Another drawback to the present forms of packaging and dispensing is that once the sterile primary pack containing the suture has been opened, the construction of the packages is such that the solution soaking the suture to keept it moist either quickly evaporates or spills. In addition, presently available packages are usually constructed of opaque material or in such a manner or labeled so that neither suture or needle are visitinct advantage to the suture user and other medical personnel to be able to not only distinguish the type of suture being used, but also the position of the holder before opening.

An obvious disadvantage with the Regan patents described above is that having a plurality of sutures in a narrow passageway presents the danger of entangling the sutures or extracting more than one suture when only one is required or desired. Such suture packs, in addition to providing little control over the dispensing of an individual suture, also provide no means by which the suture, stored in coiled position, can be easily straightened. Furthermore, from the manufacturing standpoint, the diposition of a suture or plurality of sutures in narrow passageways may present significant mass production problems.

DESCRIPTION OF THE INVENTION

This sterile suture dispenser package and method of making solves the major problems of presently available suture packages and dispensers by providing a completely sterile pack-age containing a reel held suture which is unwound as desired and straightened as it is unwound. This invention solves the problems described above by a molded in depth tray having a reel containing cavity with a boss or axle extending upward at its center and a suture needle clip containing cavity with a narrow passageway therebetween, which is constructed of a clear, lightweight, easily formed material so that the suture and its orientation are easily visible to the user prior to use. The suture is wound about a conventional suture reel in an easy manufacturing step, leaving one end of the suture unwound for attachment to a suture needle. This needle is then placed in position between a clip means having overlapping tabs retaining the needle between them and having an opposite end of similar configuration to the suture reel with

a hole formed at its center to receive the axle formed in the tray. The reel and the clip means are then inserted into their respective cavities in the formed tray. When nested properly in these cavities, they are sterilized, and then enclosed within the tray by a lidding material which is sealed around the periphery of the side walls of the tray. This lidding material is provided with a tab over extending the end of the tray near the clip means so that the lidding material and tray may be separated for easy access to the suture needle.

This entire primary pack is then placed inside a sleeve or shroud which is sealed around its perimeter. The outside portion of the primary pack is then sterilized through the secondary package by a media which permeates the material forming a secondary package. 15

The unique construction of this package overcomes the problem of the coil set the sutures take from the winding system of the reel because it provides an extraction ramp or shoulder configuration formed in the passageway between the reel containing cavity and the suture needle clip containing cavity. As the suture is unwound from the reel and travels through this passageway, it moves along a convex shoulder which tends to bend the suture in the opposite direction from which it is wound. The user, by placing his thumb on one side of the reel and his finger or fingers on the opposite side, may exert a pressure on the central axis of the reel which will cause the suture to be extracted under tension. This combination of tension and the unique formation of extraction ramp or shoulder cause the suture to be straightened automatically as it is extracted for

The suture dispenser package of this invention also eliminates any superfluous packaging since, once the 35 protective secondary package is removed, the remainder of the pack remains an integral unit. Thus, the user is not left with a tab or a clip which separates from the primary suture package itself. There is only one piece of material to deal with and that contains the suture it-self. When the suture is cimpletely extracted from the package, the entire package may be thrown away. This invention eliminates the nuisance of many disposable pieces and their hazard to sterility.

Moreover, the elimination of excess packaging also 45 tends to eliminate the necessity of excess manipulation in order to arrive at a sterile suture. The operations required by the unique construction of this invention after the secondary package has been opened and the suture primary package disposed on a sterile field are $\,^{50}$ simply; (1) opening the completely sterile primary package by pulling a tab at one end, (2) sliding the suture needle clip means open with a needle clamp, and, (3) pulling on the needle to unwind the desired amount of suture from the reel while exerting a pressure on the center of the reel whenever a braking or tensile force is required. No removal of a suture card or holder or the extra steps of separately opening the needle clamp and straightening the suture are required with the apparatus of this invention.

Furthermore, the construction of this invention is such that the reel containing cavity acts as a container to hold the solution for soaking the suture to prevent dryness. The construction of the narrow passageway between the suture cavity and the clip means cavity as well as the difference in elevation between the two cavities when the suture is held in position, bottom down

for extraction, prevents any unwanted spillage of soaking solution.

Accordingly, it is an object of this invention to provide a suture dispenser package and method of making permitting the direct dispensing of sterile sutures from a sterile package.

It is a further object of this invention to provide a suture dispenser package and method of making such an apparatus allowing the suture user to exert tension on 10 the suture as it is being unwound to control its dispensing.

It is also an object of this invention to provide a suture dispenser package which will straighten the suture as it is dispensed from the sterile package.

It is a still further object of this invention to provide a suture dispenser package and method of making allowing retention of the soaking solution within the sterile suture package and eliminating spillage.

It is another object of this invention to provide a suture dispenser package and method of making which will eliminate the superfluous pieces of packing material previously necessary in packaging sterile sutures for direct dispensation.

It is one more object of this invention to provide a su-25 ture dispenser package and method of making for direct dispensing of sterile sutures which eliminates the excessive manipulation necessary to gain access to the suture.

It is still another object of this invention to provide a suture dispenser package and method of making permitting observation of the suture contained therein before and during use.

It is an additional object of this invention to provide a suture dispenser package having a means for holding a suture needle in fixed position after the top of the sterile suture package is removed.

It is also an object of this invention to provide a suture dispenser package and method of making using a secondary package to contain the primary suture pack and maintain its sterility prior to use.

It is further object of this invention to provide a sterile suture dispenser package which may be sterilized inside and out.

These and other important objects of the invention will become apparent from the following description taken in conjunction with the drawings illustrating a preferred embodiment wherein:

FIG. 1 is a perspective view of a complete sterile suture dispenser package;

FIG. 2 is an exploded view of the primary suture containing and dispensing pack shown in FIG. 1;

FIG. 3 is a bottom perspective view of the primary suture package shown in FIG. 2 as assembled;

FIG. 4 is a top perspective view of the primary suture dispenser pack having the portion of lidding material covering the suture needle clip means peeled back, the clip means opened and a needle forceps removing the suture needle; and,

FIG. 5 is an enlarged cross sectional side view of the primary sterile suture dispenser pack of this invention.

Referring now to the drawings and more particularly FIG. 1, the sterile suture dispenser package of this invention is shown at 10.

This suture dispenser 10 includes a secondary package 12, which completely encloses and enshrouds the primary suture pack 14. This secondary suture package 12 is constructed of a foil-paper-adhesive base which is

covered by a transparent film cover. The base and cover are scaled about a peripheral scal area 18 by the chevron type scal shown to define the secondary package 12, and thereby enclose primary suture pack 14. The secondary package 12 is opened by pulling the secondary pack peel tabs 16 in opposite directions thereby peeling the transparent film cover from the foil-paperadhesive base.

The elements of the primary suture pack 14 are shown more clearly in an exploded view in FIG. 2. 10 These include a suture containing means or molded in depth tray 20 which functions as a base for the primary suture pack 14. This suture containing means 20 includes an upwardly protruding axle or boss 24 molded in its bottom which is disposed at the center of a suture reel cavity 30. The suture containing means 20 also includes, at its opposite end, and molded to a lesser depth than the suture reel cavity 30, a clip means cavity 32. Between the reel cavity 24 and the clip means cavity 32, is disposed an extraction ramp means or shoulder 26 which, with the side wall of the molded in depth tray 20, defines a suture passageway 27 between cavities 24 and 32.

Insertable within the suture containing means 20 is a 25 before it is used. suture retention clip means 22 which includes a portion having a configuration similar to that of the suture reel cavity 30 with an opening 34 at its center for insertion over the axle or boss 24 of the reel cavity 30. The suture retention clip means 22 has, at its opposite end, a 30 clip means top flap 36 and a clip means bottom flap 38 which are hingedly attached so that the top flap 36 may be swung downwardly over bottom flap 38 and inserted under a flap securing or tab means 40 to maintain top flap 36 adjacent bottom flap 38 to retain suture needle 35 48 between flaps 36 and 38. This portion of suture retention clip means 22 is likewise disposed within suture containing means 20 in the clip means cavity 32, the bottom flap 38 being adjacent to the inside floor of suture containing means 20. This portion of clip means 40 22 is also provided with a perforated opening pull tab 42 which enables the user to raise top flap 36 to gain access to the suture needle 48.

Reel means 44 may be a conventional spool-type reel having a boss aperature 45 disposed through its center 45 which may be inserted over the axle or boss 24 in suture reel cavity 30 of suture containing means 20, for rotation therearound, after a length of elongated suture 46 is wound on it, as shown in FIG. 2. Normally the suture 46 will not be completely wound about reel 44, but will have one free end on which is disposed a suture needle 48.

The final element in the primary suture pack 14 is the tray lidding material or lid means 50 which is sealed about a suture tray sealing flange 28 disposed at the uppermost portion of the walls of the molded in depth tray 20. This lid means 50 acts to completely cover the interior portion of the suture tray 20 and maintain in position within the tray 20 the suture retention clip means 22 and the reel means 44 containing the elongated suture 46 and attached suture needle 48. The lid means 50 is preferrably provided with a peelable portion 54 which may be unsealed and peeled back to afford access to the suture needle 48 held by the top flap 36 and the bottom flap 38 of the clip means 22 in clip means cavity 32. The peel portion 54 is easily pulled back, as shown in FIG. 4, by a lid means peel tab 52.

FIG. 3 illustrates the primary suture pack 14 of this invention in its assembled condition with the lid means 50 sealed in place over the suture tray 20. The molded in depth tray 20 is fabricated of a transparent material such as polyvinyl chloride to permit the suture user to determine the disposition of the suture needle 48, and the type of suture 46 before opening, and the amount of suture 46 remaining during actual use of the suture pack 14. Such visibility also prevents accidental spillage of suture moisturizing fluid because the user is able to determine in what portion of the package the fluid resides.

FIG. 3 also illustrates the configuration of the extraction ramp means or shoulder 26 and the suture passageway 27. The suture 46, as it is unwound or extracted from the reel 44, is pulled through the passageway 27 and across the surface of shoulder 26 before exiting through clip means cavity 32, in such a manner that it is given a reverse bend from that it acquired on the suture reel 44. This reverse bend, plus the tension exerted on the suture needle 48 and suture 46, and the braking pressure applied to suture reel 44 through the primary package 14 causes the suture 46 to be automatically straightened, eliminating coil set, as it is unwound and before it is used.

In the manufacture of the sterile suture dispensing package 10, the suture containing means or tray 20 is initially molded in depth in the general configuration shown in FIG. 2. As mentioned, this tray 20 will have, subsequent to the molding process, a reel cavity 20 and a clip means cavity 32. Though the bottoms of both cavities will be substantially flat, the bottom of the clip means cavity 32 will be elevated somewhat above the suture reel cavity bottom to prevent passage of moisturizing fluid or tubing solution from one cavity to the other during use, and thereby eliminate accidental spillage of the fluid. The suture reel cavity 30 will also have an upwardly protruding boss 24, acting as an axle for reel means 44 to rotate about, molded in its bottom substantially at the center of the cavity 30. The two cavities 30 and 32 are separated by the extraction ramp means or shoulder 26 which partially forms the suture passageway 27 between the cavities.

An elongated suture 46 of any type desired is then wound onto the suture reel 44, a needle 48 being attached, if desired, to the remaining free end of the suture 46. The suture needle 48 is then placed in the needle retention portion of the suture retention clip means 22 between the top flap 36 and bottom flap 38. The top flap 36 is then moved downward over the needle 48 and inserted under flap securing or tab means 40, thereby maintaining needle 48 and suture 46 in a fixed position with respect to the clip means 22.

The sub-assembly of the suture containing reel 44 and attached clip means 22 is then inserted into the tray 20 so that the boss opening 34 of the clip means 22 and the axle opening 45 of the reel means 44 are inserted over the boss 24 molded in the tray 20. When the passageway portion of the clip means 22 and the needle retention portion of this clip means are also in their respective positions within the tray 20, a predetermined amount of tubing solution is applied to the tray to help maintain the proper moisture of the wound suture 46. Likewise, a suitable amount of 100 percent liquid ethylene oxide solution may be applied at the same time as the tubing solution to sterilize the suture 46 and entire contents of the tray 20. Although this method of

moisturization and sterilization is preferred, it is obvious that other methods could be successfully used.

The final step is preparing the primary pack 14 shown in FIG. 2 is heat sealing the tray lid means 50 in proper position onto the tray 20 about the suture tray sealing flange 28. This pre-sterilized lidding means 50, when sealed, encloses a suture pack which is completely sterile on its interior.

The assembled primary pack 14 is then enclosed by the secondary package 12 shown in FIG. 1, and the sec- 10 molding process, to form a multi-cavity unit, such as ondary package 12 sealed about its periphery 18. The secondary package 12 is preferrably fabricated of permeable material to permit sterilization of the exterior of the primary pack and the interior of the secondary 100 percent liquid ethylene oxide is preferred for this sterilization, sterilization could also be accomplished before the sealing of either the primary 14 and secondary 12 packages through the non-opening ends of both packs.

The use of the sterile suture dispensing apparatus 10 of this invention is both simple and easy to accomplish. Since the secondary package 12 is constructed of a foilpaper-adhesive base and a transparent film cover, the type and length of the suture 46 can easily be deter- 25 mined by reading the identifying copy on the lidding material 50 of the primary suture pack 14 which is visible through the transparent cover of the secondary pack 12. When the proper suture has been selected, the secondary pack peel tabs 16 are pulled apart in oppo-30 site directions to expose the primary pack 14. This package, which is sterile on its outer surface, is then removed from the secondary package 12 and the type and position of the suture 46 contained in the primary package 14 can again be checked by viewing the posi- 35 tion of the suture 46 and needle 48 and the color of the color coded suture reel 44 through the transparent bottom of the suture tray 20.

When the suture 46 is to be used, the lid means peel tab 52, shown in FIG. 2, a portion of the lidding material 50 which extends beyond the flange 28 of the tray 20 and is not sealed thereto, is grasped and pulled backwardly along the lid means peel portion 54 to the line indicated in FIG. 2.

As shown in FIG. 4, this action exposes the free or 45 needle containing end of the suture 46 which has been retained by the clip means 22. The needle 48 is easily accessible by grasping the perforated opening pull tab 42 with a needle clamp or forceps 56 as shown in FIG. 4, and pulling in an upwardly and outwardly direction to move the top flap 36 away from the bottom flap 38 and expose the needle 48. The forceps 56 may be then used to grasp and extract the needle 48 and attached suture 46 from the package. By positioning the thumb and index finger of one hand on opposite sides of the package 14 over the central axis of the reel means 44, the user may control the speed at which the suture 46 is extracted from the primary pack 14. In addition, such a braking action on the reel means 44 will provide sufficient tension on the suture to straighten it as it passes through the passageway 27 and over the shoulder 26 formed in the tray 20.

In FIG. 5 is shown a cross-sectional view of the primary pack 14 as completely assembled. This view gives a more detailed view of the suture 46 wound about the reel 44 and also shows the relationship of the tray 20, the clip means 22 and the reel 44.

The suture reel 44 may be formed of any suitable material which is light in weight, subject to sterilization and easily formed, such as plastic which has been used and found acceptable in injection molding of these reels. Such material should also be adaptable to color coding.

The suture tray 20 may be formed of any suitable material which is again light in weight, transparent, durable and easily molded, preferrably by an injection plastic.

The tray lid material 50 may be formed of any suitable material which is easily sealable to a plastic type material impervious to microorganisms and opaque on pack after sealing of the secondary package 12. While 15 at least its outer surface so that coding, artwork, and suture information may be printed on this surface. Such a surface will thereby permit identification of the manufacturer up to the point of use of the suture, a practice which is not possible with the suture dispensers now available. The material used should be easily peelable and sealable with respect to the suture tray but have suitable sealing capability for the retention of the alcohol base tubing solution.

> The clip means 22 may be formed of lightweight, pliable material which is also transparent and easily cut or shaped to fit within the molded suture tray, such as plastic.

The secondary package may be formed from a suitable material which is permeable for purposes of sterilization but which will prevent the entry of microorganisms and the escape of tubing solution from within, and is preferrably formed of a foil-paper-adhesive base and a transparent film cover which may be heat sealed together about their periphery by a chevron type seal to form a package. Alternatively, the secondary package could consist of a formed pouch which would require only an end sealing after filling.

While the invention has been described in relation to a preferred embodiment, it will be apparent to those skilled in the art that the structural details of the apparatus and sequential steps in its method of making are capable of wide variation without departing from the principles of the invention.

I claim:

1. In a suture dispenser package particularly adapted for the direct dispensing of sterile sutures, and including suture containing means, reel means having an elongated suture wound thereabout and disposed for rotation within said suture containing means to allow said suture to be unwound and dispensed therefrom, extraction ramp means formed in said suture containing means to assist in straightening said suture as said suture is unwound from said reel means, and lid means formed to cover said suture containing means in sealed relationship thereto to form a sterile primary suture pack, a portion of said lid means being removable from said suture containing means at any desired time to permit access to an unwound end of said suture, a remaining portion of said lid means maintaining said reel means within said suture containing means during rotation of said reel means to dispense said suture, the improvement comprising, clip means disposed in said suture containing means to retain, in a fixed position for easy access prior to the dispensing of said suture, the unwound end of said suture, said clip means having a retention portion having a top flap and a bottom flap hingedly mounted thereon, said top flap being position15

able adjacent a portion of said bottom flap by insertion under tab means disposed on said bottom flap, said top flap and said bottom flap when so disposed retaining the unwound end of said suture in fixed position between them prior to use, said clip means also having a 5 mounting portion disposed adjacent said reel means effective to maintain said clip means properly positioned within said suture containing means.

2. The improvement set forth in claim 1 wherein the unwound end of said suture retained by said retention 10 portion of said clip means is attached to a suture needle, said suture needle being similarly retained between said top flap and said bottom flap of said retention portion of said clip means in position for gripping by a nee-

dle clamp prior to use.

3. The improvement set forth in claim 1 wherein the said suture containing means includes a tray formed in depth having a flange disposed about its periphery to provide a sealing area for sealing said lid means thereto, said tray having a reel containing cavity 20 formed in the configuration of said reel means and including an upwardly projecting axle means disposed at its center, said axle means receiving said mounting portion of said clip means thereover, said reel containing cavity receiving said reel means over said axle means 25 for rotation therearound, said tray also having a clip means containing cavity receiving said retention portion of said clip means therein, said reel containing cavity and said clip means containing cavity having extraction ramp means disposed between them including a 30 convex shoulder defining one wall of a passageway open at its opposite ends to said reel containing cavity and said clip means containing cavity, respectively, and being effective to bend said suture being extracted from said reel containing cavity in the reverse direction 35 of its winding as it travels along the passageway toward said clip means containing cavity.

4. The improvement set forth in claim 1 wherein said primary suture pack is completely enshrouded and enclosed within a secondary package means, said second- 40 ary package means being constructed of a transparent, permeable material allowing inspection and steriliza-

tion of said primary package therethrough.

5. A process for manufacturing a suture dispenser package particularly adapted for the direct dispensing 45 of sterile sutures characterized by the steps of:

winding an elongated suture about a suture reel means leaving one end of said suture unwound;

positioning clip means having a retention portion wound end of said suture and a suture needle attached thereto in such a manner that said unwound end and said needle are received between said top flap and said bottom flap of said retention portion of said clip means, said top flap then being moved 55 adjacent said bottom flap to retain said suture and said needle therebetween;

forming suture containing means for receiving said reel means containing said suture in position for rotation therein, and for supporting said clip means, and having extraction ramp means disposed therein to assist in straightening said suture as it is unwound from said reel means;

inserting said clip means retaining the unwound end of said suture and attached needle and said reel means containing said suture into said suture containing means, said retention portion of said clip means being disposed on the opposite side of said extraction ramp means from said reel means, said suture being directed across said extraction ramp means from said reel means to said retention portion of said clip means during dispensing;

applying tubing solution to soak said suture contained on said reel means, and retained in said clip

sterilizing said reel means, said suture, said clip means and said suture containing means;

sealing a lid means about the periphery of said suture containing means thereby enclosing said reel means, said suture, said clip means, and said extracting ramp means to form a primary suture pack:

enshrouding said primary suture pack within a secondary package means having at least a portion

thereof formed of permeable material;

sealing said secondary package means to thereby enclose said primary suture pack; and,

sterilizing the exterior of said primary suture pack and the interior of said secondary package means by sterilization means permeating said secondary package means.

6. The process of claim 5 wherein said suture containing means includes a multi-cavity tray formed in depth having a flange disposed about its periphery to provide a sealing area for sealing said lid means thereto, said tray having a reel containing cavity formed therein in the configuration of said reel means including an upwardly projecting axle means formed at its center, said axle means receiving a mounting portion of said clip means thereover, said reel containing cavity receiving said reel means over said axle means for rotation therearound; said tray also having a clip means containing cavity formed therein receiving said retention portion of said clip means therein said extraction ramp means being formed in said tray between said reel containing cavity and said clip means containing cavity and including a convex shoulder defining one wall of a with a top flap and a bottom flap adjacent the un- 50 passageway therebetween upon which said suture is moved as it is unwound from said reel means and extracted from said reel containing cavity in such a manner that said suture is bent in the reverse direction of its winding to straighten it for use.

7. The process of claim 5 wherein said sterilization means used to sterilize both said primary suture pack and said secondary package means includes one hun-

dred percent ethylene oxide gas.