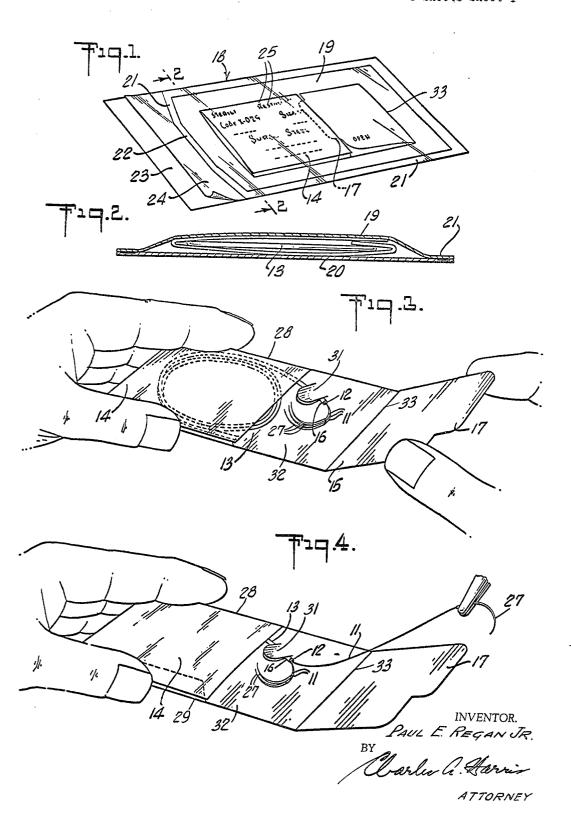
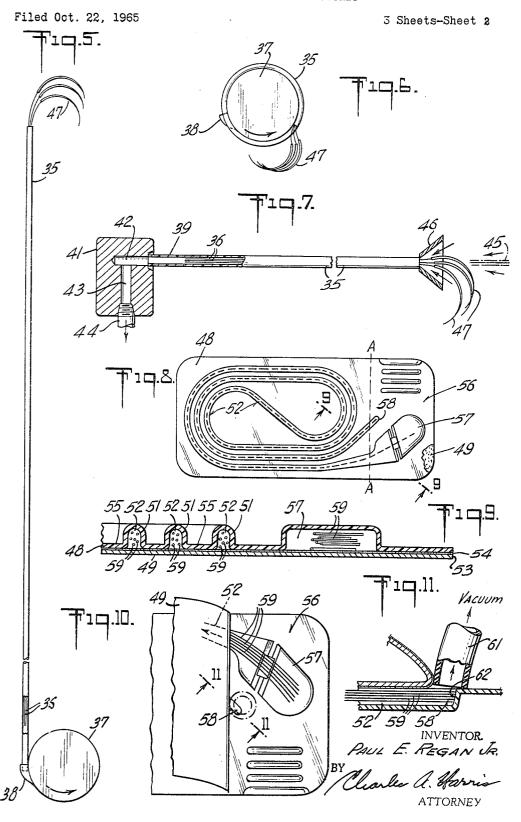
# METHOD OF PACKAGING SUTURES

Filed Oct. 22, 1965

3 Sheets-Sheet 1



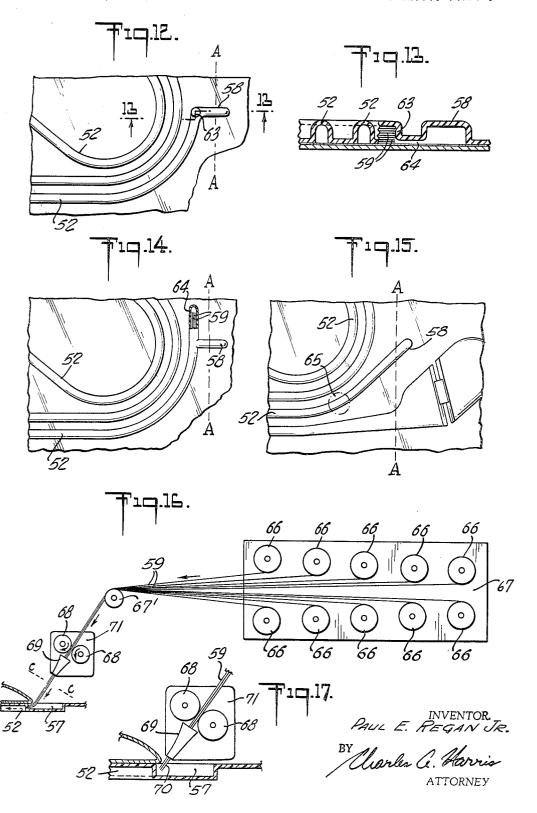
METHOD OF PACKAGING SUTURES



# METHOD OF PACKAGING SUTURES

Filed Oct. 22, 1965

3 Sheets-Sheet 3



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3,490,192
METHOD OF PACKAGING SUTURES
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Continuation-in-part of application Ser. No. 416,368,
Dec. 7, 1964. This application Oct. 22, 1965, Ser.
No. 502,101

Int. Cl. B65b 25/00, 35/48

U.S. Cl. 53-21

14 Claims

## ABSTRACT OF THE DISCLOSURE

A method of packaging surgical sutures is provided wherein individual or plural sutures are fed endwise into a curved, convoluted passageway in a portion of the package, as by drawing a vacuum stream through said passageway and entraining the sutures in said vacuum stream.

The present invention relates to the packaging of elongated sutures and the like, most particularly to the packaging of delicate sutures and packaging several sutures in the same container.

This application is a continuation-in-part of my copending United States Letters Patent applications Ser. No. 295,447 filed July 16, 1963, now Patent No. 3,280,971, and Ser. No. 416,368 filed Dec. 7, 1964, now Patent No. 3,338,401.

Heretofore, elongated surgical sutures, i.e., sutures approximately 10 to 20 inches long, have been packaged singly or in groups in various manners, both with and without attached needles. Due to their length they normally have been wound in the form of a coil or upon a reel or looped and placed within a sleeve, or wound in 35 some way to reduce the dimension of the package.

Many problems have arisen in the packaging of delicate sutures such as thin stainless steel wire sutures and very small gauge sutures. In the case of sutures of wire and various other materials, kinks and sharp bends 40 have been formed in the suture during packaging and storage. This may render them unsuitable for delicate work and in some cases, due to the formation of weak spots and breaks in the suture, they cannot be used at all.

If the suture is very thin or brittle, it is subject to damage during winding and is not properly protected when the package is opened to remove the suture, particularly when several sutures are placed in the same package. Very fine gauge sutures are very difficult to handle and tend to become disarranged and entangled very easily because of 50 their fineness.

When several sutures have been packaged together it has been necessary to remove the whole group of sutures from the package in order to separate one from the others. In many cases, the sutures have been wound or looped around a reel or wound together in a coil and have become entangled with one another so that the group of sutures must be straightened out before one can be separated. In these cases, it is necessary to rewind or coil the sutures which are not used and secure them together 60 in some way or reinsert them in an envelope, or the like, so that they may be stored and then resterilized before reuse.

According to the present invention, the most delicate sutures may be packaged singly or in combination with several other sutures in such a way that they can be removed easily from the package and will not be kinked or contain any sharp bends or curves. The nature of the package is such that there is no necessity of winding the sutures in the ordinary manner so that the sutures are never exposed to winding stress or the like. Once the

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sutures are packaged they are fully protected against damage and remain protected until each suture is used. Several elongated sutures may be packaged together in the form of a small coil having a maximum overall dimension which is only a minor fraction of the suture length. The sutures may be packaged in groups with or without attached needles and may be removed easily one at a time from the package without disturbing the sutures remaining therein.

According to the present invention, the suture or sutures are packaged in restraining means defining a coiled narrow passageway having a plurality of convolutions which determine the configuration in which the sutures will be coiled. The passageway, which conveniently is molded in a plastic sheet or defined by a small diameter hollow plastic tube, has a smooth inner surface possessing a high degree of lubricity and the suture restraining means is formed of a material capable of being sterilized without deterioration or detracting from the lubricity of said surface. One or more sutures may be placed inside the passageway with their ends protruding from one end thereof. When the passageway contains a plurality of sutures, the sutures are held loosely therein in nonentangling relationship to one another and are adapted to be removed one at a time by drawing them from the passageway by their protruding ends. As indicated above, individual sutures may be removed easily in this fashion without disturbing the other sutures contained in the passageway. The passageway may be coiled in the form of a spiral, a helix, a figure-eight, or any other smooth curved configuration which will allow a plurality of coils to be formed in a reasonably small area.

This invention contemplates novel methods for packaging elongated sutures in the above manner generally in the form of a small coil, the maximum overall dimension of which is only a minor fraction of the suture length. In one form of the invention, the suture is fed progressively into guiding means already defining a narrow passageway curved in the configuration in which it is desired to coil the suture until the suture assumes the desired coiled configuration. In another form of the invention, the suture is first fed into a small diameter relatively straight hollow tube and the tube is then coiled in the configuration in which it is desired to package the suture. In both forms of the invention, the suture preferably is fed lengthwise into the passageway utilizing a gaseous stream such as may be created by applying a vacuum source to the exit end of the passageway. A gaseous stream, alone, may be used for this purpose, or it may be used in conjunction with mechanical feeding techniques. For instance, the suture may be fed into one end of the passageway by a pair of feeding rollers and then drawn in extended form through the passageway by a gaseous stream passing therethrough which cooperates with the feeding rollers. Other means, such as mechanical vibrations may be used to assure that the suture reaches the desired configuration without being impeded by the walls of the passageway. Techniques of this sort may be desirable when a stiff suture is being packaged in a tightly coiled passageway. In all of these techniques, the sutures may be packaged singly or in loosely assembled groups. For instance, a group of twenty (20) elongated sutures arranged in substantially parallel alignment and in nonentangling relation with one another may be fed together into the passageway and coiled in the desired configuration in such a way that the sutures may be removed easily one at a time without disturbing the sutures remaining in the package.

According to the preferred embodiment of this invention, a gaseous stream is passed through guiding means already curved in the configuration in which it is desired

to coil the suture and one end of a group of sutures is entrained in the stream. The sutures then are drawn lengthwise in a group into the desired configuration in the guiding means. As indicated above, the guiding means preferably defines a coiled narrow passageway in which the suture is to be deposited. In this case, the suture, or sutures, is introduced endwise into one end of the passageway to initiate the feeding.

Various means may be utilized for depositing the suture in the guiding means once the desired configuration is 10 reached. For instance, if a vacuum is used for this purpose, the application of vacuum may be timed so that the vacuum source is shut off when the suture has reached the desired configuration. Similarly, other feeding means, whether used independently or in conjunction with vacuum 15 or the like, may be timed to stop feeding when the suture has reached the desired configuration. In one embodiment of this invention, a group of sutures is positively fed endwise by mechanical means such as a pair of feed rollers into one end of the coiled passageway and a vacuum 20 broken away to foreshorten the view. source is applied to the other end of the coiled passageway in such a way that it draws the group of sutures into the desired configuration in the passageway in conjunction with the mechanical means. This allows for positive control and positioning of the sutures in the passageway since the mechanical means may be timed to assure that an exact length of suture is fed into the passageway. When a gaseous stream, alone, is utilized for this purpose, the sutures may be separated from the stream and deposited in the passageway by removing the stream from the pas- 30 sageway at a substantial angle to the axis of the suture when the suture is in the desired configuration in the package. Similarly, forward lengthwise motion of the suture may be mechanically blocked to position the suture when it reaches the desired configuration, providing that 35 sufficient frictional drag is exerted on the suture by the guiding means to prevent the suture from buckling and jamming in the guiding means when its forward motion is blocked. In any case, the gaseous stream may be timed to shut off when the suture has reached the desired posi- 40 tion, or it may be shut off by means responsive to the positioning of the suture in the desired configuration in the guiding means.

In the form of the invention wherein the suture is first inserted into a small diameter relatively straight hollow tube, the tube preferably is wound or coiled about a mandrel having an outer surface curved in a configuration which is at least as tight as that of the desired configuration of the suture coil, yet sufficiently gradual to prevent the tube from collapsing as it is wound about the mandrel. The coiled tube containing the suture is then removed from the mandrel and held in coiled form by retaining means. The coiling of the hollow tube in this manner is accomplished without imparting the coiling or winding forces to the sutures themselves and without collapsing the tube or damaging it in any way which would impede easy removal of sutures from the coiled tube.

În all of the above techniques, the elongated suture initially may be integral with a suture supply of greater length and that portion of the suture which is to be packaged may be severed from the supply after the suture is inserted in the guiding means. In this case, the forward lengthwise motion of the suture through the guiding means may be terminated by limiting further forward movement of the suture material from the suture supply. Severance 65 of the suture from the supply may be effected by a timed cutting device or a cutting device responsive to positioning of the suture in the package.

Other and further advantages of this invention will be apparent from the following description and claims, taken 70 together with the drawings wherein:

FIG. 1 is a view in perspective of a suture package containing sutures coiled according to one embodiment of this invention wherein a strippable outer envelope is

FIG. 2 is a view partly in section and partly in elevation taken along the line 2-2 of FIG. 1.

FIG. 3 is an enlarged view in perspective of a sleeve of the embodiment of FIG. 1 with the flap open to expose the needles attached to the sutures.

FIG. 4 is an enlarged view in perspective similar to FIG. 3 and showing one of the sutures being drawn from the tube by the needle attached to its end.

FIG. 5 is a partially broken schematic elevational view showing the hollow restraining tube of FIG. 1 after the sutures have been inserted in position therein while the tube is still straight, and with one end of the tube held in position on a cylindrical mandrel about which the tube is to be wound.

FIG. 6 is a view similar to FIG. 5 showing the tube after it has been wound on the mandrel.

FIG. 7 is a somewhat enlarged schematic elevational view showing the sutures being drawn by vacuum into the straight tube of FIG. 5, and with the tube partially

FIG. 8 is the top plan view of a package having a molded coiled passageway in which sutures are adapted to be coiled in accordance with this invention.

FIG. 9 is an enlarged view partly in section and partly in elevation taken along the line 9-9 of FIG. 8.

FIG. 10 is an enlarged plan view of one end of the package of FIG. 8 before it has been completely sealed and with the package inverted to better illustrate the loading of sutures therein by vacuum.

FIG. 11 is a more greatly enlarged view partly in section and partly in elevation taken along the line 11—11 of FIG. 10 to illustrate the application of vacuum to one end of the coiled passageway for loading the sutures.

FIG. 12 is a somewhat schematic enlarged plan view of a portion of the package of FIG. 8 modified to illustrate means for coiling the sutures according to a somewhat different embodiment of this invention.

FIG. 13 is a further enlarged view partly in section and partly in elevation taken along the line 13-13 of FIG. 12.

FIG. 14 is a view similar to FIG. 12 showing still a different modification to the package of FIG. 8.

FIG. 15 is a similarly enlarged view of one end portion of the package of FIG. 8 illustrating the coiling of sutures according to another embodiment of this invention.

FIG. 16 is a schematic view partly in section and partly in elevation of apparatus for coiling sutures in a passageway, according to a further embodiment of the method of this invention.

FIG. 17 is an enlarged view of a portion of the apparatus of FIG. 16 showing the sutures as they are being positioned for insertion into the passageway.

Referring to the drawings, there is shown a package wherein a plurality of thin stainless steel wire sutures 11, i.e., three, are coiled according to this invention in a narrow passageway 12 defined by a coiled hollow restraining tube 13, which in turn is inserted inside a holding sleeve 14 formed from relatively stiff sterilizable sheet material such as virgin paperboard approximately 0.01 inch thick. The exterior of the sleeve 14 perferably is treated so that it is water and blood-stain resistant. A two-way foldable flap 15 is provided at one end of the sleeve, and one end 16 of the restraining tube, hereinafter sometimes referred to as the leading end, is adapted to protrude from the sleeve when the flap 15 is folded in its open position, as shown in FIG. 3. The flap 15 is adapted to be folded closed with an end portion 17 thereof inserted in the sleeve to cover the leading end 16 of the tube and the sutures extending therefrom, as shown in FIG. 1. The sleeve 14, with the restrainting tube 13 and sutures contained in the passageway 12 therein, is adapted to be packaged by the manufacturer inside a sealed strippable envelope 18, as shown in FIGS. 1 and 2. The strippable en-75 velope comprises a transparent top sheet 19 and a bottom

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sheet 20 sealed together along their edges to provide a hermetically sealed sterilizable enclosure for the sleeve 14 and its contents. The sheets 19 and 20 are sealed to one another along a strip 21 which forms a shallow peak 22 at one end of the package and the peak is spaced somewhat from the adjacent ends of the sheets to provide stripping flaps 23 and 24 for opening the package. The flaps 23 and 24 are pulled apart to separate the sheets and break the seal when it is desired to remove the sleeve 14 from the envelope. Printing 25 may be applied to one side of the sleeve to identify its contents and the sleeve is inserted so that it may be read through the transparent side of the envelope 18.

The suture restraining tube 13 is in the form of a coil which is both spiral and helical and comprises about two and one-half convolutions. The tube 13, itself, is a small diameter plastic tube of a material such as polypropylene. The inner surface 26 of the passageway 12 and of the tube, itself, is smooth and possesses a high degree of lubricity and the tube is capable of being sterilized by irradiation or by heating to a temperature of at least about 250° F. in the presence of live steam without deterioration or detraction from the lubricity of the inner surface 26. Generally speaking, the inner diameter of the tube 13 is such that, while the tube is narrow enough to provide a definite path for the sutures and means for restraining them in a definite curved configuration, the tube is large enough so that a plurality of sutures contained therein will be held loosely in said passageway 12 in non-entangling relationship with one another.

In one package of this invention, the restraining tube 13 initially is straight and formed of polypropylene tubing having an outer diameter of about 0.064 inch and an inner diameter of about 0.034 inch. The suture or sutures 11, depending upon whether one or several sutures are to be placed in the same package, are inserted or drawn into the straight tubing until the tubing is fully loaded. If the sutures are relatively stiff they may be inserted directly into the tubing. However, if they are at all flimsy, it is preferred that they be drawn by vacuum into the tubing. Vacuum also is preferred since any suture may be loaded in this manner. After the sutures are loaded, the tubing is coiled in the configuration in which it is desired to coil the suture. The coiling of the tube 13 and sutures 11 is accomplished by contacting the tubing only, without 45 touching any of the sutures. In an alternate technique, the coil may be formed first, or the tubing may be coiled in the desired shape, and the suture or sutures may be drawn by vacuum, or in some cases inserted, into the passageway 12 defined by the coil which is already curved in the configuration in which it is desired to coil the suture.

The sutures 11 are drawn into the tube in such a way that the sutures themselves protrude slightly from the leading end 16 of the coil and individual curved needles 27 are attached to each of the sutures 11 at about the same distance beyond the end 16 of the tube 13. The sutures 11 my be removed easily one at a time from the tube 13 without disturbing the other sutures contained therein merely by gripping one of the needles 27 and drawing it 60 away from the tube, as shown in FIG. 4.

The tubing is somewhat flexible and, when coiled, tends to assume a coiled configuration of larger dimension than the sleeve 14. Thus, when the coiled tube 13 containing the sutures 11 is inserted in the sleeve 14, it presses against the inside of the sleeve adjacent the top and bottom edges 28 and 29 thereof to hold the coil in position in the sleeve. The coiled tube 13 is placed in the sleeve 14 so that the leading end 16 of the coil, i.e., the one from which the sutures 11 extend, protrudes from the main 70 part of the sleeve, as shown most clearly in FIGS. 3-5. The leading end 16 of the coiled tube 13 is held in position by placing it under a tab 31 which is struck from an end portion 32 of the sleeve. The coiled tube is firmly held by the sleeve and the tab so that a suture may be with- 75 into the narrow passageway defined by the tube. When

drawn easily from the tube without disturbing the position of the tube in the sleeve. As indicated hereinbefore, a flap 15 is provided at that end of the sleeve to cover the leading end 16 of the coiled tube and the sutures 11 and needles 27 protruding therefrom. The flap 15 folds along a fold line 33 for folding the flap 15 closed and inserting its end portion 17 in the sleeve and for opening the flap 15 to expose the sutures 11.

Referring in particular to FIGS. 5 and 6, there is illustrated a method of coiling an elongated normally straight restraining tube 35 having sutures 36 inserted therein in the configuration in which it is desired to coil the sutures. As described above, the sutures 36 are first inserted in the tube 35 by means, such as an air stream drawn by a vacuum source, until they extend substantially throughout the length of the tube. Then, one end of the tube 35 is fixed in position on a cylindrical mandrel 37 having an outer surface curved in a configuration which is at least as tight as that of the desired suture coil, and a diameter which is only a minor fraction of the length of the tube. As shown in FIG. 5, a flange or clamp 38 extending from the surface of the mandrel 37 and having an opening adapted to receive one end of the tube may be used for this purpose. Once the end of the tube 35 is fixed in the clamp 38, the yet uncoiled portion of the tube is held and the mandrel 37 is rotated to cause the tube to become coiled around the outer surface of the mandrel, as shown in FIG. 6. The restraining tube 35 is flexible and generally is capable of being coiled until the suture has reached its desired coiled configuration, without collapsing or pinching the sutures 36. In addition, the curvature of the outer surface of the cylindrical mandrel 37 is sufficiently gradual that the tube 35 may be coiled tightly about the mandrel, as shown in FIG. 6, without collapsing. When the tube 35 has ben wound fully on the mandrel, it may be removed by sliding it axially off one end of the mandrel, and the tube holding clamp 38 may be slotted on one side for this purpose. Since the tube 35 containing the sutures will tend to straighten out once it is removed from the mandrel, it must be held in the desired coiled configuration by means such as the sleeve 14 described hereinbefore. When the sutures are coiled by coiling a tube in this manner, the coiling forces are applied only to the tube and not transmitted to the sutures contained therein. Thus, the sutures may be coiled without danger of transmitting the coiling forces to the sutures or damaging them in any way.

The sutures 36 may be inserted in the restraining tube 35 by mechanical means, or entirely by vacuum as illustrated in FIG. 7. In fact, the vacuum inserting technique illustrated in FIG. 7 may be used to insert the sutures in almost any kind of a narrow restraining package and is the preferred method of inserting sutures in a passageway which already is coiled. Referring to FIG. 7, a gaseous stream is passed through the restraining tube 35 by applying a vacuum source to the far end 39 of the tube, i.e., that opposite to the end which the sutures enter through. FIG. 7 illustrates a vacuum fitting 41 having two passageways 42 and 43 connected to one another at right angles. One passageway 42 is recessed to receive the far end of the tube and the other 43 is threaded to receive a hose 44 connected to a vacuum source, not shown. When the tube 35 is positioned in the fitting 41, as shown in FIG. 7, and a vacuum is applied thereto through the fitting, a gaseous stream is caused to flow through the tube as indicated by the arrows. The leading end of a group 45 of say three sutures, illustrated by the dotted lines to the right of FIG. 7, is introduced endwise and entrained in the gaseous stream in such a way that the sutures are drawn in a group lengthwise through the tube until they are in position therein. A funnel 46 may be positioned at the entrance end of the tube 35 to assure that the sutures are properly led

the sutures to be loaded have needles 47 attached to their trailing ends, the funnel 46 preferably is split to allow it to be removed easily after the sutures are loaded. There are various ways of controlling the deposition of the sutures in the tube by such a gaseous stream. Some of these will be illustrated specifically hereinafter. Suffice it to say that the application of the vacuum to the fitting may be timed to shut off when the sutures have reached the desired point, the trailing ends of the sutures may be held so that they cannot pass into the tube, or other 10 means may be utilized to achieve the same result. Similarly, as indicated hereinbefore, vacuum techniques may be utilized to load sutures into a passageway which already is coiled in the desired configuration, although somewhat more sophisticated techniques may be desirable 15 for this purpose. Various approaches particularly adapted for loading sutures in coiled passageways will now be described.

Referring in particular to FIGS. 8-11 of the drawings, there is shown a package suitable for coiling sutures in 20 accordance with this invention which comprises a laminate of a first molded sheet 48 and a second covering sheet 49. The molded sheet 48 defines a narrow coiled channel 51 having a plurality of convolutions with the channel being U-shaped in cross section and open to 25 one side of the molded sheet, i.e., the top of the U faces this side of the sheet. The cover sheet 49 is sealed to the molded sheet 48 continuously along both longitudinal edges of the channel to close the channel and form a closed coiled passageway 52 having a plurality of con- 30 volutions corresponding to those of the channel 51. In the construction shown, the cover sheet 49 comprises a barrier layer 53 and a heat sealable layer 54 which is firmly attached to the barrier layer and capable of forming a strong permanent seal with the material of 35 the molded sheet 48.

The molded sheet 48 preferably is formed from a transparent plastic material which is capable of being molded by a vacuum technique, blow molded, or the like, to provide a sharply defined relatively rigid structure such 40 as shown in section in FIG. 9. In this construction, the bottom of the channel is depressed below the normal plane of the sheet, assuming that the bottom of the U-shaped channel is down in FIGS. 8, 10 and 11; and the convolutions of the channel are separated by narrow 45 portions 55 of the molded sheet which remain in the original plane of the sheet. In this embodiment, the channel 51 (and the resulting passageway 52) is molded in the form of a modified figure eight comprising three smoothly curved convolutions, more specifically in the 50 form of six approximately straight legs connected by smoothly curved loops. Both ends of the channel 51 and the passageway 52 formed by laminating the cover sheet with the molded sheet extend beyond the convolutions at one end of the package into a loading and dispensing section 56 of the package. One end of the passageway 52 terminates in a somewhat rectangular and oval-shaped access chamber 57 which also is molded in the first sheet 48 to approximately the same depth as the channel 51; and the other end of the channel terminates in 60 the first sheet to form a small vacuum well 58. The portions of the first or moldable sheet 48 surrounding the access chamber 57 and the vacuum well 58 also remain in the original plane of the moldable sheet.

Referring again to FIGS. 8-11, the cover sheet 49 65 first is sealed to the molded sheet 48 up to the line A-A to form the suture passageway 52. This leaves the molded sheet 48 and the cover sheet 49 unsealed to one another to form the loading and dispensing section 56 in the area between the line A-A and the adjacent end of the 70 package. Then, as illustrated in FIGS. 10 and 11, the sutures 59 to be placed or loaded in the package, which conveniently may be in the form of a loosely assembled bundle of a multiplicity of sutures (a typical package

inserted endwise through the access chamber 57 into the passageway 52 connected thereto. At this time the cover sheet 49 may be folded back out of the way about the line A-A, roughly as shown in FIGS. 3 and 4. A suitable vacuum is applied to the opposite end of the passageway 52 through the vacuum well 58 by placing a flexible hose 61 connected to a suitable vacuum source, not shown, over the vacuum well 58, roughly as shown in FIG. 5. This will draw the whole bundle of sutures 59 rapidly into the passageway 52 and completely through the convolutions thereof until they reach the vacuum well. Assuming that the length of the passageway 52 is designed to accommodate the lengths of the sutures 59 loaded, this will result in the suture bundle assuming the position, roughly as shown in FIGS. 8, 10 and 11 with the trailing ends of the sutures extending into the access chamber 57 where they are easily accessible once the access chamber is opened. Then, the access chamber 57 and the vacuum well 58 are sealed off to completely enclose the sutures 59 by folding the unsealed portion of the cover sheet 49 down flat over the molded sheet 48 in the loading and dispensing section 56 of the package. and sealing it tightly to the molded sheet.

In the embodiment of FIGS. 8-11, the vacuum well 58 is formed by terminating the coiled passageway 52 in the molded sheet as described above, and is represented by that portion of the coiled passageway located in the loading and dispensing section 56 outside the line A—A. As shown in FIG. 11, the well 58 terminates in a shoulder 62 which extends at approximately right angles to the axis of the sutures 59 at the end of the passageway. As explained hereinbefore, the vacuum hose 61 is placed over the exposed portion of the vacuum well 58 in such a way that the vacuum is drawn from the top of the well and a gaseous stream (normally of air passing through the passageway) is drawn from the well 58 at a substantial angle, i.e., approximately 90 degrees to the axis of the sutures 59 lying in the passageway 52. The coiled configuration of the passageway 52 inside the line A—A exerts frictional drag on the suture or sutures 59 being drawn into the passageway 52 so that under normal conditions the sutures are maintained in extended form in the passageway. Thus, when the ends of the sutures 59 reach the well 58, they will strike the shoulder 62 at the end of the passageway and tend to remain in this position in contact with the shoulder as the gaseous stream passes over them up through the hose 61. When the sutures 59 are positioned in the coiled passageway 52 in this manner without shutting off the gaseous stream, the application of vacuum must be carefully controlled to assure that the sutures will not be drawn into the hose.

FIG. 12 illustrates a somewhat different embodiment of the invention wherein the end of the passageway 52 is modified so that the vacuum well 58 is formed by bending the coiled passageway 52 at approximately right angles to the axis of its curved configuration. Thus, the well 58, represented by the end of the passageway passing beyond the line A-A, extends at a substantial angle to the adjoining portion of the passageway. The passageway at the bend just described will act as an obstruction which tends to retard further forward movement of the sutures into the vacuum well 58, itself. In addition, in the embodiment illustrated in FIG. 13, the passageway is restricted at the bend by a shoulder 63 which is formed by depressing the passageway. This shoulder 63 extends downwardly from the top of the passageway through a major portion of the height of the passageway and leaves only a narrow orifice 64 at the bottom of the passageway through which the gaseous stream passes into the vacuum well 58. As shown in FIG. 13, the sutures 59 being drawn through the passageway strike this shoulder 63 and tend to block the orifice may include 17 silk sutures, each 18 inches long), are 75 64 below the shoulder, so that once they have reached

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this position in the passageway 52 further forward lengthwise motion of the sutures is blocked or prevented. Blocking means of this type may be used effectively in accordance with this invention to separate the sutures from the gaseous stream while the gaseous stream is still being drawn through the passageway by vacuum as described in connection with the embodiment of FIGS. 8-11

FIG. 14 illustrates a somewhat different embodiment of this invention wherein the vacuum well 58 is in the form of a small channel extending at right angles to the axis of the sutures 59 in the passageway (as in FIG. 12), but the passageway containing the sutures extends for a short distance beyond the point where the vacuum well 58 is connected to the passageway, and then terminates 15 in a straight end portion 64 in the molded sheet. In this embodiment, the momentum of the sutures 59 carries them lengthwise into the straight portion 64 of the passageway until they strike the end of the passageway even though the air stream is separated from the sutures as it passes into the angularly disposed vacuum well 58. Again, the sutures 59 may be separated from the gaseous stream in this manner before the gaseous stream is shut off by other means.

As indicated hereinbefore, in all of the above embodiments the gaseous stream may be applied by means, such as a vacuum source, which is timed to shut off when the sutures have reached the desired configuration in the passageway; in which case, the sutures are deposited in the passageway by shutting off the gaseous stream at a given point in their travel. Another way of accomplishing this is to shut off the gaseous stream by means responsive to the positioning of the sutures in the desired configuration in the passageway or other guiding means. Such a technique is illustrated in FIG. 15 wherein an 35 electric eye 65 is positioned over the end of the passageway 52 to the left of the line A-A in FIG. 15. Here the stream is shut off when the electric eye 65 is activated by the sutures passing through the passageway underneath the eye. While an electric eye has been illustrated, it will be apparent that other sensing means may be used for this purpose.

FIGS. 16 and 17 illustrate another embodiment of this invention wherein mechanical means are used in conjunction with a gaseous stream to positively position the sutures in the passageway or guiding means. These figures illustrate a group of ten sutures 59 being positioned in the coiled passageway 52 of a package according to FIGS. 8-11, wherein a gaseous stream is caused to pass through the passageway by a vacuum source applied to the vacuum well at the end of the passageway through a vacuum hose or a similar device, not shown. FIGS. 16 and 17 show only a portion of the package of FIGS. 8-11 as a view in section through the access chamber 57 into which the surtures are inserted. The ten sutures 59 are drawn from a suture supply, of greater length than the sutures to be deposited in the passageway 52, which is in the form of ten suture spools 66 suitably mounted for rotation on a support 67 which allows the spools 66 to be replaced easily when the supply has been exhausted. The sutures 59 are drawn together from the spools 66 over a guide roller 67' and then between a pair of feed rollers 68 which are urged towards one another and driven to rotate at the same linear speed. The feed rollers 68 are mounted in such a way as to hold the sutures 59 firmly between them at all times and feed the group of sutures positively forward endwise without slippage into a funnel 69 which is adapted to facilitate inserting the ends 70 of the sutures in the passageway 52 through the access chamber 57. The feed rollers 68 and the funnel 69 are mounted together on a head 71 which is adapted to be moved into a first position, shown in FIG. 17, wherein the suture ends 70 passing through the funnel 69 are inserted through the access chamber 57 to a point adjacent the mouth of the coiled passageway 52. When the head 10

71 is in this position, the vacuum source is operated to draw a gaseous stream through the passageway 52 and then the feed rollers 68 are operated to feed the sutures 59 in parallel alignment with one another in the form of a loosely assembled bundle into the mouth of the passageway 52. As the sutures are fed in this manner into the mouth of the passageway, they are entrained in the gaseous stream and drawn lengthwise with the stream into the passageway. The rotation of the feed rollers 68 is designed to stop when a given length of the sutures 59 has been fed into the passageway 52. Thus, the length of sutures fed into the passageway is positively controlled by the feed rollers 68 although they are drawn into position in the desired coiled configuration in the passageway by the gaseous stream. Then, the gaseous stream is shut off by conventional means, not shown, responsive to or correlated with the cessation of feeding by the rollers 68. After the gaseous stream is shut off, the head 71 supporting the feed rollers 68 and the funnel 69 is raised to the position illustrated in FIG. 16, with the result that the trailing ends of the sutures are withdrawn slightly from the passageway as shown. At this point, a cutting device, not shown, in the form of a knife, or the like, is operated to sever the sutures along the line C—C and separate them from the suture supply. The severed trailing ends of the sutures 59 then drop into the access chamber 57 and the filled packages are removed for sealing.

The above mentioned methods of feeding sutures into passageways which already are coiled in the desired configuration, are particularly adapted for feeding flexible suture materials. In this connection, when the term "suture" or "sutures" is used in this application it means surgical strands used for suturing, ligating, and the like, and includes such strands commonly called either sutures or ligatures. These sutures may be of various materials including gut, silk, cotton, wire and any other material suitable for this purpose. It may be advantageous for feeding relatively stiff sutures of materials such as heavy gut and wire to utilize other means to facilitate the loading of the sutures in coiled passageways. For instance, a pulsating gaseous stream derived from a pulsating vacuum source may be used to impart greater force to the sutures during loading. Similarly, mechanical vibrations may be used for this purpose. Although the gaseous stream has been described hereinbefore as eminating from a vacuum source, means such as air jets may be used either alone in some circumstances, or in conjunction with a vacuum source to carry the sutures into the passageway. In fact, air jets may be used in conjunction with both a vacuum source and mechanical feeding means, i.e., in conjunction with the embodiment of FIG. 17, particularly when it is desired to feed relatively stiff sutures into a coiled passageway.

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, applications, modifications, and extensions of the basic principles involved may be made without departing from its spirit or scope.

What is claimed is:

- 1. The method of packaging elongated surgical sutures in the form of a small coil, the maximum overall dimension of said coil being only a minor fraction of the suture length, which comprises progressively feeding a suture into guiding means defining a narrow passageway curved in a plurality of convolutions, and positively guiding the suture progressively along the length of each convolution against displacement radially inwardly or outwardly of the respective convolutions, the end of the suture being introduced endwise into one end of the said passageway to initiate said feeding.
- 2. The method of packaging sutures according to claim 1, wherein a gaseous stream is passed through said passageway and the suture is entrained in said gaseous stream to feed it into the desired configuration in the passageway.

3. The method of packaging sutures according to claim 2, wherein the gaseous stream is created by applying a vacuum source at one end of the passageway.

4. The method of packaging sutures according to claim 1, wherein a group of sutures in parallel alignment and loosely assembled relation with one another are fed to-

gether into said passageway.

5. The method of packaging surgical sutures in coiled form which comprises passing a gaseous stream through guiding means curved in the configuration in which it is desired to coil the suture, entraining one end of an elongated suture in said gaseous stream and drawing said suture lengthwise with the stream into a position in said guiding means wherein it assumes the desired configuration, and depositing the suture in the desired configuration in said guiding means.

6. The method of packaging sutures according to claim 5, which comprises removing the gaseous stream from said guiding means at a substantial angle to the axis of the suture when the suture is in the desired configuration, thereby separating the suture from said stream.

7. The method of packaging sutures according to claim 5, wherein the guiding means exerts frictional drag on said suture as the suture is moved into position therein and the forward lengthwise motion of said suture is 25 blocked when the suture reaches the desired configuration.

8. The method of packaging sutures according to claim 7, wherein the guiding mean is in the form of a coiled narrow passageway having a plurality of convolutions.

9. The method of packaging sutures according to claim 5, wherein the suture is deposited in the desired configuration in the guiding means by shutting off the gaseous stream when the suture has reached the desired position therein.

10. The method of packaging surgical sutures according to claim 9, wherein the gaseous stream is shut off by means responsive to the positioning of the suture in the desired configuration in said guiding means.

11. The method of packaging sutures according to claim 5, wherein a plurality of elongated sutures in parallel alignment and loosely assembled relation with one another are simultaneously drawn in a group by said gaseous stream into position in said guiding means.

12. The method of packaging sutures according to claim 5, wherein the forward lengthwise motion of the suture into said guiding means is terminated by holding the trailing end of the suture outside the guiding means.

13. The method of packaging sutures according to claim 12, wherein the suture initially is integral with a suture supply of greater length and the forward lengthwise motion of said suture is terminated by means limiting further forward movement of the suture material from said supply.

14. A method of packaging sutures according to claim 13, wherein the gaseous stream is shut off after the forward motion of the suture has been terminated and the suture in position in the guiding means is then severed from the supply.

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U.S. Cl. X.R.

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# UNITED STATES PATENT OFFICE CERTIFICATE OF CORRECTION

Patent No. 3,490,192	Dated January 20, 1970
Inventor(s) Paul E. Regan, Jr.	
It is certified that error appears and that said Letters Patent are hereby	
Column 1, lines 5 and 6, Ser. is left out.	No. 295,447, filed July 16, 1963
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Attest:

Edward M. Fletcher, Jr. Attesting Officer WILLIAM E. SCHUYLER, R. Commissioner of Patents