

[54] **REEL-LABEL FOR SMALL DIAMETER SUTURES**

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[52] U.S. Cl..... **206/63.3, 206/227, 206/388**

[51] Int. Cl... **A61I 17/02, B65d 73/00, B65h 55/00**

[58] Field of Search..... **206/63.3, 227, 388**

[56] **References Cited**

UNITED STATES PATENTS

1,171,194	2/1916	Hammond-Knowlton	206/388
2,949,181	8/1960	Buccino	206/63.3

3,043,067	7/1962	Rynkiewicz et al.....	53/27
3,136,418	6/1964	Stacy et al.	206/63.3
3,357,550	12/1967	Holmes et al.	206/63.3
3,728,839	4/1973	Glick	206/63.3 X

FOREIGN PATENTS OR APPLICATIONS

1,409,244	7/1965	France	206/63.3
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Primary Examiner—Leonard Summer

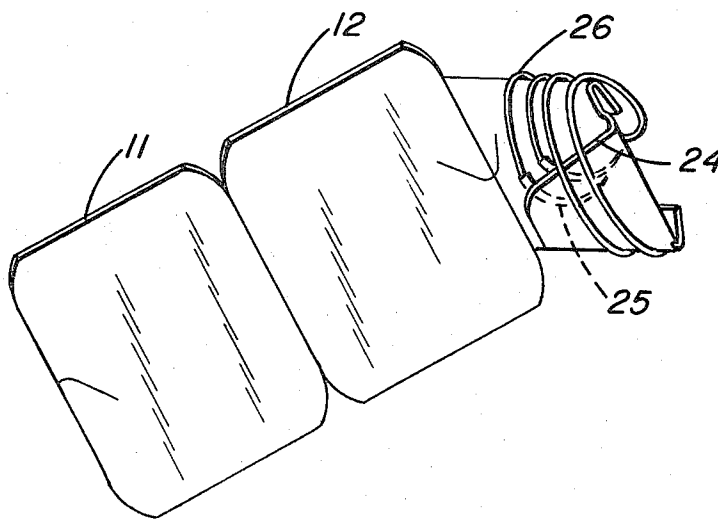
Attorney, Agent, or Firm—Samuel Branch Walker

[57]

ABSTRACT

Very fine surgical sutures having needles thereon are wound from the needled end on a printed reel-label which is cut from a single piece of label stock in such fashion that the very fine sutures are wound over folded edges rather than cut edges to protect them from being frayed by the cut edges of the label stock. The suture on the reel-label is stored in a protective envelope, preferably in a strippable outer envelope.

1 Claim, 6 Drawing Figures



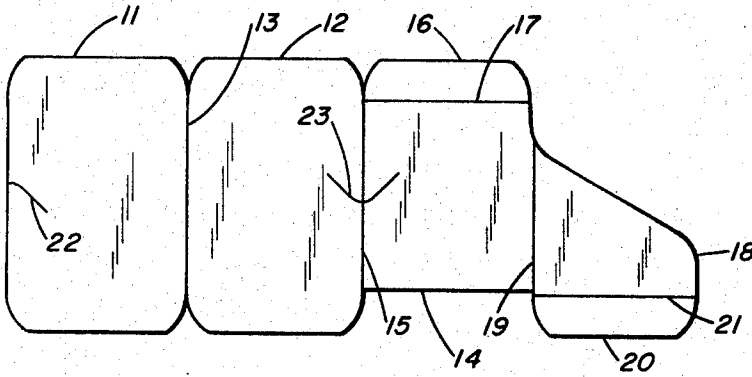


FIG. 1

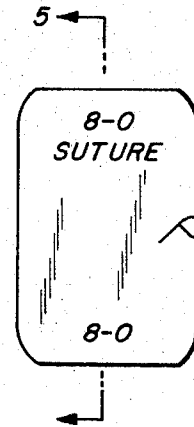


FIG. 4

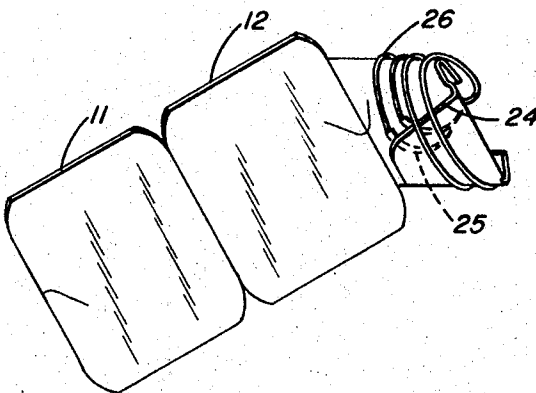


FIG. 2

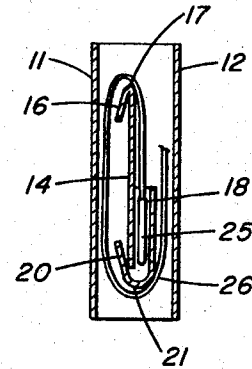


FIG. 5

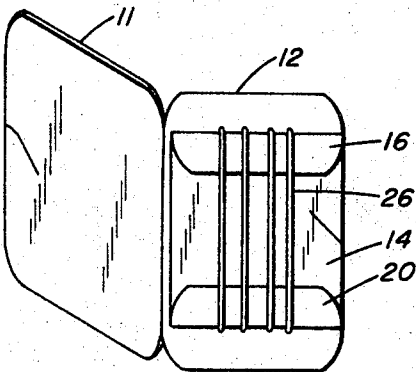


FIG. 3

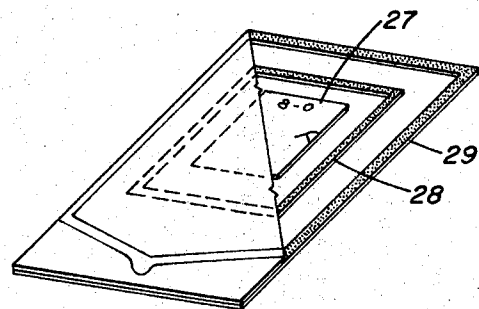


FIG. 6

REEL-LABEL FOR SMALL DIAMETER SUTURES

BACKGROUND OF THE INVENTION

Improved surgical techniques and, particularly, operative techniques under a microscope utilizing very fine structures on, for example, the hand, the eye, or the ear, have increased the demand for finer and finer sutures. In sewing together blood vessels and nerve sheaths of the hand, for example, sutures are desired which are smaller in diameter than a human hair. Sutures of such size are readily scored, abraded, or weakened by contact with the cut edge of a label during packaging.

Reel-labels for sutures have conventionally been used with standard size sutures to protect the suture during storage. Note, for example, U.S. Pat. No. 3,357,550, G. P. Holmes and J. W. Murphy, COMBINATION REEL AND LABEL FOR SURGICAL SUTURES, Dec. 12, 1967. U.S. Pat. No. 3,136,418, Stacy, Flower, and Calabro, shows a multi-panelled reel for surgical sutures.

It is now conventional to package sutures on reels in double, strippable envelope packages of the type disclosed in U.S. Pat. No. 3,043,067, Rynkiewicz and Ayres, SUTURE PACKAGE, July 10, 1962.

From the standpoint of manufacture using common packaging machinery for other packages and having sutures in standard size packages for convenience in storage and inventory control, even the very fine sutures are most conveniently stored in the same size packages and envelopes as bigger sutures.

The requirements of uncompromised sterility are well known in the industry.

SUMMARY OF THE INVENTION

It has now been found that a suture package meeting the requirements of the surgeon is conveniently formed by using the conventional inner envelope inside of a strippable, outer envelope, see Rynkiewicz and Ayres, U.S. Pat. No. 3,043,067, supra, and using a heavy paper reel about which the suture is wound. For very fine sutures, it has been found that the cut edges of a paper reel can score and weaken or cut the suture. The present invention has only folded edges with which the suture comes in abrading contact and, hence, the risk of damaging fine sutures is reduced.

The present standard sizes as set forth in the U.S. PHARMACOPEIA and as follows:

SUTURE SIZES
(U.S. PHARMACOPEIA XVIII)

Suture Size	Maximum Diameter - Inches	
	Absorbable	Non-Absorbable
10/0		0.0010
9/0	0.0015	0.0015
8/0	0.0025	0.0020
7/0	0.0035	0.0030
6/0	0.0050	0.0040

A human hair is approximately 0.003 inch diameter although blonde hair is usually finer than dark and the size of human hair varies between individuals and even on the same individual.

It can be seen that if a suture finer than a human hair is being used, great care in packaging and caring for the suture during manufacture, storage, and serving to the surgeon is required. Usually, sutures of such size are at-

tached to an eyeless needle and are sold in short lengths, frequently with a needle on each end. For example, a standard size package contains a 7-0 chromic gut suture 12 inches long with two $\frac{1}{16}$ inch circle lancet point needles, one on each end. Obviously, the needles are very small and the workmanship of manufacture and handling is very delicate.

The present reel is particularly adapted to sutures of size 6/0 and smaller, although it may, of course, be used with larger sutures if desired.

The reel is formed from sheet label stock, one such being known as 90 pound, sterilizable, offset printing paper. Thinner paper could, of course, be used, but the standard 90 pound paper reduces the manufacturer's inventory problems and gives a reel that is sufficiently stiff to be conveniently handled during manufacture, packaging and storage of the suture and provides a convenient carrier and holder up until the needle is gripped in needle forceps preparatory to surgical use. With the fine sutures for which the present label is particularly adapted, both the needles and the suture could be easily misplaced and lost because of their small size.

The present label can have size and type designations for the suture and needle printed on its external faces and it may be color coded to designate the type of suture and other useful information.

The present reel can best be described in conjunction with drawings which illustrate the same.

THE DRAWINGS

FIG. 1 shows the inside surface of the cut-out label; FIG. 2 shows the label partially folded with a suture wound thereon;

FIG. 3 shows the further folded label with the suture thereon;

FIG. 4 shows the face of the assembled suture and reel showing the engaged holding tongue and holding slit;

FIG. 5 is a cross-section at 5-5 of the suture and reel of FIG. 4;

FIG. 6 shows the completed reel-label in a double, strippable envelope, forming the final package.

Using conventional cutting out and scoring techniques, 90 pound weight basis, sterilizable, offset paper, which accepts both alcohol and water insoluble inks is cut to the configuration shown in FIG. 1. The face panel 11 is a rectangular panel conveniently about $1\frac{1}{4}$ inches by $1\frac{15}{16}$ inches with rounded corners. Three sides of the face panel 11 are free. On the fourth is attached the rear panel 12 along the rear panel fold line 13. The rear panel fold line 13 is a score in which, in accordance with conventional techniques, the paper is crushed to thereby form a weakened zone which folds more readily so that the panels may be folded with respect to each other. Conveniently, but not necessarily, the face panel and rear panel are the same size and shape. On the side of the rear panel 12 away from the face panel, is a reel panel 14. The reel panel is attached on the reel panel fold line 15 and is slightly narrower than the rear panel 12 so that when folded against the rear panel, the rear panel fold line 13 clears the edge of the reel panel. Conveniently, the reel panel may be about one-sixteenth inch narrower than the rear panel.

Conveniently, but not necessarily, the reel panel 14 is about a one-fourth inch shorter at the top and five-sixteenths inch shorter at the bottom than the adjacent rear panel. At the top of the reel panel is a top fold

panel 16 which is attached along the top fold panel fold line 17. Conveniently, but not necessarily, the top fold panel may be the same width as the reel panel and about one-fourth inch high. If it is one-fourth inch high, it brings the top line of the top fold panel into alignment with the top lines of the face panel and rear panel which is convenient in both cut out and assembly but is not essential to the operation of the present reel.

On the opposite side of the reel panel 14, from the rear panel 12, is the pocket panel 18. The pocket panel is attached along the pocket panel fold line 19 to the reel panel. The pocket panel 18 is slightly narrower than the reel panel 14 so that it will fold onto the reel panel conveniently and is skew cut so that the portion attached to the reel panel is markedly longer than the free standing edge. At the bottom of the pocket panel 18 is a bottom fold panel 20 attached to the pocket panel along the bottom fold panel fold line 21. Conveniently, the bottom fold panel fold line is approximately one-sixteenth inch below the level of the bottom of the reel panel 14 for clearance and convenience in folding.

Cut into the free edge of the face panel 11 is a holding tongue 22. The holding tongue is a cut starting at right angles with the free edge of the face panel which is parallel to the rear panel fold line, and extends diagonally. While not necessarily centered thereon, it is convenient that the holding slit be cut so that it starts above the center of the edge and extends below the center of the edge. Conveniently, it is an angle of about 45°. On the rear panel fold line and extending into each of the rear panel and the reel panel is a holding slit 23. The holding slit 23 preferably is formed so that it has a rounded nose crossing the reel panel fold line at approximately 90° and is of such a location that when folded, the holding tongue extends into and laps with the holding slit, cut outs at about 90° to each other.

In assembly, the pocket panel 18 is folded over against the reel panel 14 on the inside surface as shown in FIG. 2. The bottom fold panel is folded both under and around the reel panel 14. The pocket panel 18 forms the face, the reel panel 14 forms the back, the bottom fold panel 20 along the bottom fold panel fold line 21 forms the bottom, and the pocket panel fold line 19 forms the side of a needle pocket 24. Top fold panel 16 is bent back on the top fold panel fold line 17 against the back of the reel panel. Preferably, the top fold panel and the bottom fold panel spring out slightly from the reel panel, that is, they are not sharp creased so as to lie completely flat. This allows a certain resilience, to keep the suture from being wound too tightly.

The surgical needle or needles 25 on the end of a suture 26 are inserted in the needle pocket 24 and the suture is wound about the reel panel 14 and the attached top fold panel 16 and bottom fold panel 20. Because these are resilient and extend slightly away from the reel panel, the suture is neatly held without being stretched by the resilient action of the fold panels. The suture is wrapped with as many turns as its length permits and then the reel panel 14 having the suture wound thereon is folded into the rear panel 12, as shown in FIG. 3. Light friction tends to hold the suture and the needles in position. The face panel 11 is then folded down against the rear panel with the reel panel having the suture thereon in between. The holding tongue 12 is inserted into the holding slit 23 with the resilience of the paper stock holding the assembly closed. As the rear panel and the face panel are closed

together, the top fold panel and the bottom fold panel are pressed against the reel panel, thus, slightly releasing any tension on the suture so that the suture is loosely held without tension during storage. At the time of use, the face panel is lifted, the reel panel is unfolded, and the suture with at least one needle attached is removed from the reel panel.

One or more such reel-label suture assemblies 27 are packaged in an inner envelope 28 which in turn is packaged in an outer strippable envelope 29 as described in more detail in U.S. Pat. No. 2,949,181, Buccino, SUTURE PACKAGE AND PROCESS OF MAKING SAME, Aug. 16, 1960.

The inner envelope and its contents may be bone dry for sutures such as synthetic absorbable sutures of polyglycolic acid, or may be packaged at ambient room conditions such as is usual for linen, cotton, silk, or synthetic nonabsorbable sutures, or may be packaged containing a tubing fluid such as a mixture of water and one or more alcohols as is conventional with collagen sutures.

Conventional sterilizing techniques may be used, depending upon the material being packaged. Sterilization may be accomplished by heat, radiation, ultrasonic energy, or sterilizing gas, or a combination of these. The label stock and envelope construction permits any of these methods to be used, the choice primarily depending upon the qualities of the suture and which type of sterilization is most convenient for a particular suture. Also, the sutures may be pre-sterilized and packaged under sterile conditions.

At the time of use, under operating room procedures the outer strippable envelope 29 is stripped open, releasing the inner envelope 28 which is discharged either directly or by using forceps into the sterile area of an operating room with the inner envelope being opened and the suture on the reel released at the time the surgeon desires to use the suture. The label is unfolded until the needle may be reached, the suture used to pull a needle from the pocket, the needle grasped in the needle forceps, and used by the surgeon.

A further advantage of the present reel is that under emergency conditions, the unwrapping of the reel may be by non-sterile personnel with sterile forceps being used to pick up the suture and needle from the reel panel. Such release without a full scrub procedure may be convenient if a surgeon is to use merely one or two sutures for closing the skin after an accident or minor incision, or more particularly in case of accidents where the first requirement may be to control bleeding in order that the patient may survive to reach an operating room to permit full surgical repair.

Useful information may be printed on the face panel or the rear panel, including instructions on opening, information on the type of suture, and the type of needle, etc.

Usually, a minimum of data should be printed in order that the user may acquire the essential information as to size and type of suture without being confused by extraneous data.

Obviously, the size and proportions of the panels may be varied. It is convenient to have the inner panels slightly smaller so that they will fold conveniently into the larger panels. Similarly, the top fold panels can fold in either direction with resilience and the size and shape of the needle pocket can be varied depending upon the size of the needles being used. The label may

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be slightly larger to permit larger sizes of sutures, but the reel-label is particularly convenient for the very small sizes of sutures which can be damaged by abrasion on the cut edge of a reel as the two folds permit wrapping the suture so that it wrapped only over bent and not cut edges. 5

We claim:

1. A surgical suture package comprising a sealed, sterile envelope having therein in sterile configuration a needled surgical suture on a reel-label, wherein the improvement comprises: 10

a one piece six panel reel-label of stiff sterilizable label stock consisting essentially of

a bottom fold panel,

a pocket panel, 15

a top fold panel,

a reel panel,

a rear panel, and

a face panel,

said bottom fold panel being short and attached to the bottom of said pocket panel, and folded along a score line to enclose the bottom of said reel panel, 20

said pocket panel being smaller than and attached to one side of said reel panel, and folded and held thereagainst by said bottom fold panel to form a needle pocket, 25

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said top fold panel being short and attached to the top of the reel panel, and folded against the reel panel,

said back panel being attached to, larger than, and folded against the reel panel and needle holding pocket,

said face panel being attached to, essentially the same size as, and folded towards the rear panel to enclose therebetween the reel panel, pocket panel, and top and bottom fold panels,

said face panel having a diagonal cut therein to form a holding tongue,

said rear panel having a second diagonal cut therein to form a holding slit,

said holding tongue and holding slit being in interengaging relationship to hold the face panel and rear panel adjacent, and releasably closed, and 15

a surgical suture having a surgical needle attached thereto wound about the reel panel, the top fold panel and bottom fold panel, with the needle enclosed in the pocket formed by the pocket panel, reel panel, and bottom fold panel, thus protecting the suture from the armed edges of the needle, 20

said reel-label being particularly adapted for very fine sutures, by having the suture wrapped over folded rather than cut edges.

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