

April 9, 1968

J. M. GRANOWITZ ET AL
PACKAGE FOR SURGICAL SUTURES

3,376,973

Filed July 15, 1966

2 Sheets-Sheet 1

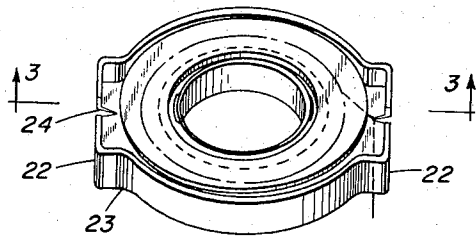


FIG - 1

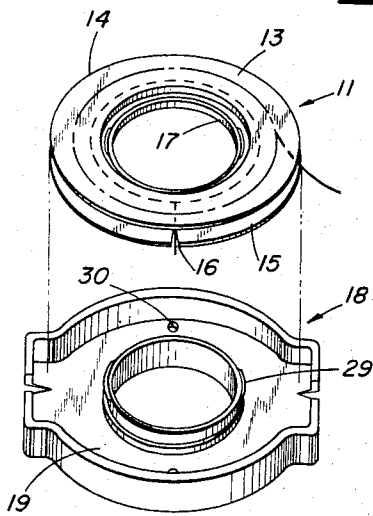


FIG - 2

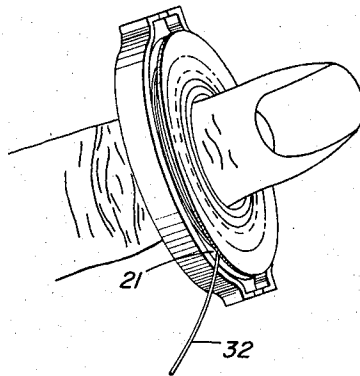


FIG - 4

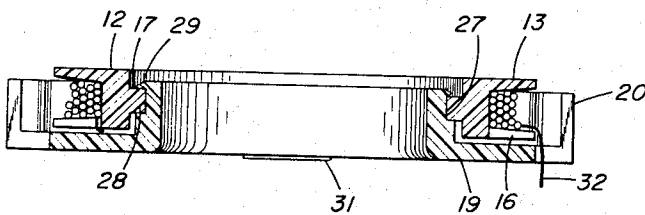


FIG - 3

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2 Sheets-Sheet 2

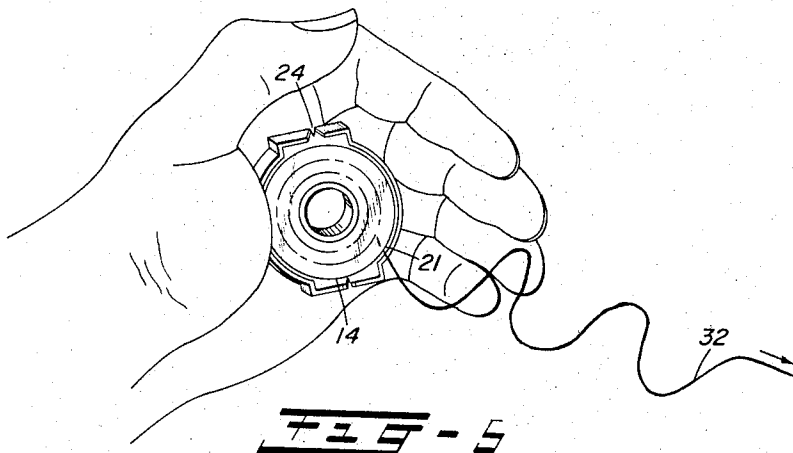


FIG. 5

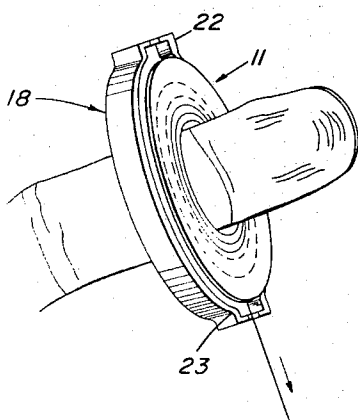


FIG. 6

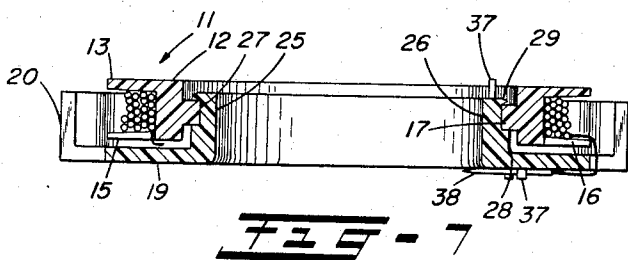


FIG. 7

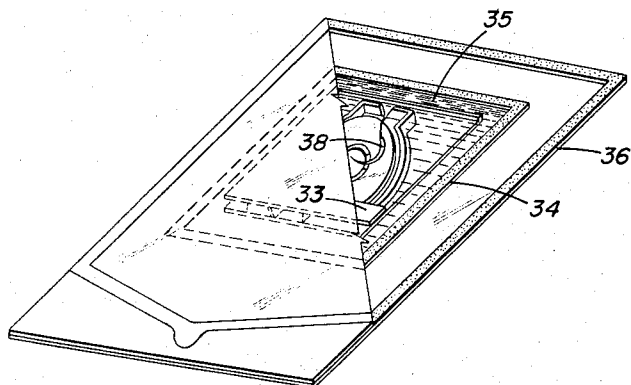


FIG. 8

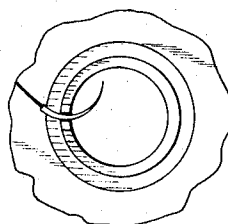


FIG. 9

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3,376,973

PACKAGE FOR SURGICAL SUTURES

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10 Claims. (Cl. 206-63.3)

ABSTRACT OF THE DISCLOSURE

A surgical suture or ligature is stored under sterile conditions until time of use on a thin, flat reel which reel is rotably mounted on a hollow axle of such size as to fit over the finger of the surgeon, with the external surface of the axle being the bearing for the reel, with the reel being held between a support flange and a retaining lip; and with a generally flat, round case attached to the axle and surrounding the reel. Wings on the case have suture holding notches so that the case can be held either on a finger or in the flat of the hand, and the suture may be dispensed either axially, through the notch, or radially. The entire assembly is packed in a double strippable envelope, and may have a conditioning fluid present.

This invention relates to a holder and dispensing package for surgical sutures, in which a hollow shaft mounted reel holds a surgical suture, mounted in a protective case, which permits dispensing of the suture axially, radially, or through a feed slot, and which case has wings to prevent slippage when held in the fingers, and a hollow axle, large enough to slip over the end of a finger of the user's hand.

As used herein the term sutures includes ligatures. Ligatures technically are used without a needle for tying, whereas sutures are used with a needle for penetration of tissues as well as tying. The same material can be used for both purposes and frequently parts of the same strand are actually used as both a suture and a ligature depending upon the requirements of the surgeon at a particular time during a surgical procedure.

When used with needles, the needles are conveniently of the eyeless type that are permanently attached to the end of the sutures and designed for but a single use.

The sutures may be of collagen, either natural catgut or regenerated collagen. Such sutures are usually packed in a conditioning liquid such as a mixture of one or more alcohols in water so that the collagen will have a preferred flexibility and are designated as absorbable sutures. Sutures of natural or synthetic fibers may also be packed on the present holder. Such sutures are usually packed dry and may be of such classical materials as silk, usually with a silicone or wax coating, or of cotton or linen, or of one of the newer synthetic materials such as nylon, polyester, isotactic polypropylene, or linear polyethylene, metal wire, such as stainless steel, either insulated or bare, or the suture may be of such other composition as preferred by the surgeon for the surgical procedure in progress.

Typical of packages meeting with commercial acceptance today is that shown in U.S. Patent 2,949,181, G. S. Buccino, "Suture Package and Process of Making Same," Aug. 16, 1960, which shows a double envelope, the outer of which at least is strippable, with the suture dry or wet packed in the sealed inner envelope. The suture is shown as folded in a label.

With the adoption of flat packages the small reels used with glass tubes are becoming obsolete, as it is desired that the sutures, particularly when of gut or monofilament synthetic materials, have comparatively large radii of curvature. By avoiding sharp bends, the sutures as re-

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moved from the package tend to be straighter and freer from kinks. Much work has been done in attempting to package surgical sutures in the most convenient manner practical.

Some of the efforts are described in patents.

French Patent 1,195,425, "Packing Device for Filiform Items, Particularly Surgical Sutures," May 19, 1959, shows a flat annular reel which fits on a cylindrical, radially-slotted boss, which extends from a circular supporting disc on one side of the reel. A shoulder holds the reel on the boss, and the slots permit sufficient flexibility for ease of assembly. The reel and disc are of thermoset or thermoplastic material. The outside of the disc has an annular peripheral shield to protect the edge of the reel, and has an aperture to dispense the free end of the ligature. Both the reel and the supporting disc have other apertures for passage of suture treating fluids.

Suture reels are disclosed in U.S. Patent 2,376,151, J. D. Karle "Suture Spool for Surgical Stitching Instruments," May 15, 1945. Such reels have parallel flanges having openings in the flanges to permit circulation of sterilizing fluids, and reduce weight. The starting end of the suture is held by apertures in the hub or flanges.

Tracers for X-rays are disclosed in U.S. Patent 3,185,299, R. L. Trainer, "Radiopaque Suture Package," May 25, 1965. Many different systems are used in articles used in an operating room to insure that the articles can be located by X-ray, if inadvertently left in an incision.

Reels on spindles holding sutures, which are immersed in an antiseptic fluid, are shown in U.S. Patent 728,444, H. L. Cox "Aseptic Ligature-Receptacle," May 19, 1903.

An single hub-mounted reel in a flat package for dispensing a line is shown in U.S. Patent 1,908,278, K. B. Angell, "Package for Fish Lines and the Like," May 9, 1933.

A free running reel, and a round dispenser with a peripheral dispensing orifice and a radially tabbed reel is shown in U.S. Patent 2,938,624, L. V. E. Runkel et al., "Dispenser for Surgical Ligatures," May 31, 1960.

A one piece reel bent from a metal disc, with internal tongues bent outward to form a reel, mounted in an annular container with a dispensing opening, having a drag brake, is shown in U.S. Patent 2,585,327 A. C. Johnson et al., "Dispensing Reel for Fishing Leaders and the Like," Feb. 12, 1952.

It has now been found that a single combination suture holder and dispenser is adaptable for dispensing axially, radially, or through a feed slot. Such holder and dispenser consists of a reel rotatable in a suture case as shown on the attached drawings which are representative of modifications of the present invention in which:

FIG. 1 is a pictorial view of the assembled reel, case, and suture.

FIG. 2 is a separated view showing the assembly of the reel to the case.

FIG. 3 is a sectional view on a diameter 3-3 of FIG. 1 showing the assembled suture, reel, and case.

FIG. 4 is a pictorial view showing the case slipped on the user's finger with the suture being dispensed radially.

FIG. 5 is a view showing the case being held in the user's fingers, with the wings preventing slippage and axial dispensing of the suture.

FIG. 6 is a view showing the suture being fed through a slot in the case.

FIG. 7 shows the case in section with a needle holder on the back of the case.

FIG. 8 is a holder with a needle holder holding the needle across the hollow axle of the case.

FIG. 9 shows the assembled reel case and suture in an inner transparent plastic envelope in a tubing fluid sealed in an outer strippable transparent envelope.

The reel **11** itself consists of a reel hub **12** which is essentially a hollow cylinder like the rim on a fly wheel. On each side of the hub is a reel flange. The top reel flange **13** is a flat angular disc having a smooth periphery **14**. The bottom reel flange **15** at the other side of the reel hub is of essentially the same size but has at least one starting end holding slot **16**. This slot preferably extends to about the bottom of the flange and is used to hold the starting end of the suture as it is wrapped about the reel. The slot has such size as to engage and hold the sutures to be wound on the reel. Usually, a single slot of about 0.005 to 0.010 inch width at the bottom will hold the starting end of any suture in common use. It is frequently convenient, but not necessary, to have two such starting end holder slots because it is more convenient to mold symmetrical reels. The flanges may have openings in the flanges of the type shown by U.S. Patent 2,376,151, supra, to reduce the weight, and permit ready access of treating fluids to the sutures. For simplicity in molding, such conventional openings are usually not used and, hence, not shown.

Interiorly of the hub is a bearing ring **17**. This bearing ring has a smaller diameter than the hole in the hub, is concentric therewith, permits more convenient placement on an axle and reduces friction. Preferably, the bearing ring is only slightly smaller than the hub to permit as large an axle as feasible to be used.

The case **18** has a flat bottom **19**. Surrounding the bottom is a protective rim **20**. Conveniently, but not necessarily, this rim is a thin upstanding edge at right angles to the bottom of the case and has a height just slightly less than the thickness of the reel and is spaced slightly from the reel so as to leave a slot **21** for radial dispensing of the suture as shown in FIG. 4. The case has two wings **22**. These wings extend in opposing directions on a diameter of the bottom of the case and are preferably of such width that the wings may be readily held in the palm of the hand to prevent the case from turning or sliding while in the fingers of the user. Conveniently, the width of the wings is about the same as the bearing ring diameter of the reel, about $\frac{3}{4}$ inch. In appearance the wings can be considered as a rectangle superimposed on the round bottom of the case with the intersections rounded to avoid sharp corners. The radius **23** between the round bottom of the case and the wings may be of any size convenient in molding, as sharp edges introduce complications in molding design.

Each wing has a free end holding slot **24**, only one of which is used at one time. This slot extends through the protective rim part way into the wing. Preferably, the bottom of the slot is about at the top of the reel flange. The slot is V-shaped and of such size that the end of the suture may be placed in the slot, preferably without undue crushing of the suture. It is found that because of the offset angle of feed onto the slot from the reel, the width of the slot can be slightly greater than the diameter of the suture at its narrowest portion with a rounded bottom and no sharp edges, thus permitting the suture to be dispensed through the slot as shown in FIG. 6 with no risk of damage to the suture from the edges of the slot. Dispensing in this fashion is somewhat like the thread take-off from a bobbin on a sewing machine. The take-off may be radially or the suture may be drawn out of the slot in a direction below the bottom of the case.

Centrally of the case is a hollow axle **25**. This hollow axle is rounded into the bottom of the case and, preferably, has an inside diameter **26** of such size as to fit and be retained on the end of the finger of the user as shown in FIG. 4. When so retained, the using surgeon can hold and control the suture dispenser with one finger of one hand, thus permitting more effective control of the suture. The outside diameter of the hollow axle forms the bearing surface **27** for the bearing ring **17**. A reel support flange **28** is concentric and integral with the axle and extends upward from the bottom of the case to cooperate

with the bearing ring **17** and hold the bottom flange of the reel out of contact with the bottom of the case. This leaves a small clearance for the end of the suture held in the starting end holding slot **16** and reduces friction between the reel and the case by keeping them out of contact except on the bearing ring. Conveniently, the bearing ring extends 360° around the hollow axle. There may be gaps in the flange but such gaps introduce complexities of molding with no commensurate advantages.

At the top of the hollow axle is at least one, and preferably two, reel retaining lips **29** as shown in FIG. 2. These lips can extend from around 20° to 90°, preferably around 60°, and are slightly rounded at the bottom and tapered at the top. The flexibility of the material from which the case is made is such that the reel may be assembled by slipping over the lips, and yet the lips are large enough so that the reel cannot become accidentally disengaged, although it may be pulled off with finger pressure. The lip may extend all the way around the axle, but two shorter lips permit easier assembly and give adequate retention.

Optionally and usually desirably, the bottom of the case has apertures **30** through the bottom of the case to permit liquid to readily flow in and out of the bottom of the case. The bottom of the case may have a trademark and suture size designation **31** molded therein.

In use as shown in FIG. 9, a suture **32** is wound about the reel by placing the starting end in the starting end holding slot **20** and winding up until all but the free end is around the reel, snapping the reel over the lips on the hollow axle and placing the free end in the free end holding slot **24**. A label **33** is placed about the reel, aiding in holding the free end of the suture and identifying as to size, type, origin, lot number, needle type, etc. The holder and dispenser, with the label wrapped about it is then inserted in an inner envelope **34**. The inner envelope may have a tubing fluid, such as a mixture of alcohol and water for conditioning the suture, if of gut, or the inside may be dry for sutures such as silk which are normally dispensed dry. The sealed inner envelope is enclosed in a strippable outer envelope **36**. Such package may be of the type shown in Buccino supra.

Sterilization may be accomplished in accordance with conventional procedures, such as by radiation with gamma rays, heat, or gaseous sterilant added either with the tubing fluid or separately into the inner envelope, the intra envelope space or both.

Where the suture is to be sold with the needle attached, it is convenient to have needle holding arms **37** on either the bottom of the case as shown in FIG. 7 or on the hollow axle as shown in FIG. 8, or both. One or more sets of small parallel arms having notched opposing faces engage and hold the needle **38** either adjacent to the bottom of the case or extending over the hollow axle. It is convenient to have the needle extend over the hollow axle so that the needle is exposed for easy gripping by needle forceps and the needle is protected from accidental contact.

The holder and dispenser are conveniently molded of a somewhat flexible plastic. Linear polyethylene or isotactic polypropylene is preferred. The reel or the case or both may have an X-ray opaque pigment incorporated therein, and the reel or the case or both may be color coded. By analogy to the color coding or resistors in electronic apparatus, a color can be selected for the case or reel which designates the suture size and the other may be color coded to designate the suture type. Other coloring modifications may be used for aesthetic or selective purposes.

The flanges of the reel, and the rim on the case are conveniently slightly tapered, to give a slight draft to permit easier mold release in forming. Such slight taper has no effect on utility. Similarly all edges should be slightly rounded to prevent a sharp corner, or molding flash which could nick the suture.

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Instead of needle holding arms, the case or reel or both may be molded using a magnetic iron filler, which is magnetized to hold the needles during storage. This may be a slug, or a ring of solid metal, or a finely divided metal used as a plastic pigment. The iron used in tape for tape recorders is satisfactory. Such metal also gives contrast for detection by X-ray, or magnetic detectors, should the dispenser be accidentally left in an incision.

The above descriptions are by way of illustration and show certain preferred embodiments. The scope of the invention is set forth in the appended claims.

We claim:

1. A suture holder and dispenser comprising:
 - (A) a flat generally round case,
 - (1) two opposed wings thereon, of such size as to minimize slippage and rolling when held in the fingers,
 - (2) a protective rim around the outer periphery of the case,
 - (3) a suture holding notch in at least one of said swings of such size as to retain without crushing a suture end,
 - (4) a hollow axle centrally of the case, of such internal size as to fit and be retained on the end of the finger of the user, and having an external cylindrical bearing surface, a reel support flange on the case side of the bearing surface and offset from the case a distance sufficient to prevent an axle mounted reel from dragging on the case, and near the free end of the hollow axle at least one reel retaining lip of a size to permit assembly by forcing a reel thereover, but preventing accidental disengagement of the reel and case during use, and
 - (B) a suture holding reel rotatably mounted on said axle, said reel having
 - (1) a reel hub,
 - (2) a reel flange on each side of said hub and in cooperation with each other and said hub forming a suture holding groove, and
 - (3) a bearing ring interior of the hub, rotatably mounted with respect to the hollow axle, and rotatable smoothly and readily on said axle.
2. The suture holder and dispenser of claim 1 in which the reel flange on the case side has at least one suture end holding slot therein.
3. The holder and dispenser of claim 2 in which the case has apertures for the flow of suture treating fluids,

4. The holder and dispenser of claim 1 in which the wings are of a width of about equal to the diameter of the axle, and have ends parallel to each other and an axis of symmetry of the case, and are spaced outward of tangency to the reel.

5. The holder and dispenser of claim 1 in which at least one of the said case and said holder are of colored plastic with a color corresponding to an informational code on suture size and type.

6. The holder and dispenser of claim 1 in which the case has integrally molded at least one pair of opposed suture needle holding arms, of a size and spacing adapted to hold a suture needle therebetween, and parallel to the case.

7. A suture package comprising the holder and dispenser of claim 1, and having a suture wound about the reel.

8. The package of claim 7 in which the suture is an absorbable suture, and in combination therewith an inner envelope, tubing fluid, and an outer strippable envelope, and the holder with suture thereon is sterilely stored in said tubing fluid sealed in said inner envelope, which in turn is sterilely sealed, dry, in said strippable outer envelope.

9. The package of claim 8 in which both envelopes are transparent.

10. The package of claim 7 in which the case has integrally molded at least one pair of opposed suture needle holding arms; of a size and spacing adapted to hold a suture needle therebetween and parallel to the case, a suture needle on said suture, and held between said arms and parallel to the case.

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