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Walldorf

[11] **3,924,630**

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[54] **MANUFACTURE OF CONTROLLED RELEASE FLUID SWELLABLE SUTURES**

[75] Inventor: **Diann J. Walldorf,** East Windsor, N.J.

[73] Assignee: **Ethicon, Inc.,** Somerville, N.J.

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[52] **U.S. Cl.** **128/339;** 128/335.5; 163/5; 273/102

[51] **Int. Cl.²** **A61B 17/06**

[58] **Field of Search** 128/335.5, 339; 163/1, 163/5; 223/102

[56] **References Cited**

UNITED STATES PATENTS

1,665,216	4/1928	Morton et al.	128/339
2,620,028	12/1952	Kohut	163/5
3,799,169	3/1974	Beroff et al.	128/339
3,875,946	4/1975	Duncan	128/339

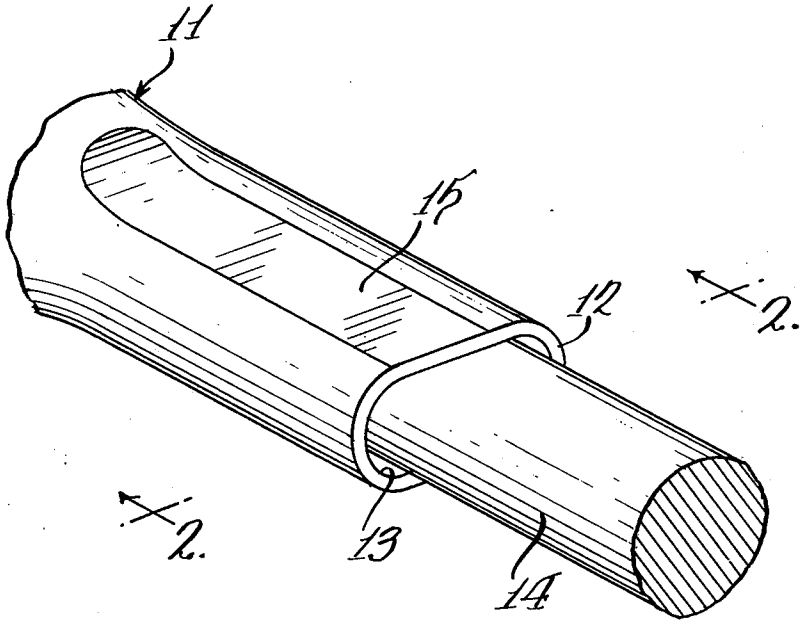
Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] **ABSTRACT**

A system is provided for preserving controlled-release properties in a needle-suture combination in which a fluid-swellable suture is held by swaging in a recess in the blunt end of a needle. A controlled excess cross-sectional area is provided within the swaged portion of the needle recess to permit swelling of the suture end without excessive change in pressure in the areas where the suture end is pressed by the swaged inner walls of the recess.

12 Claims, 3 Drawing Figures



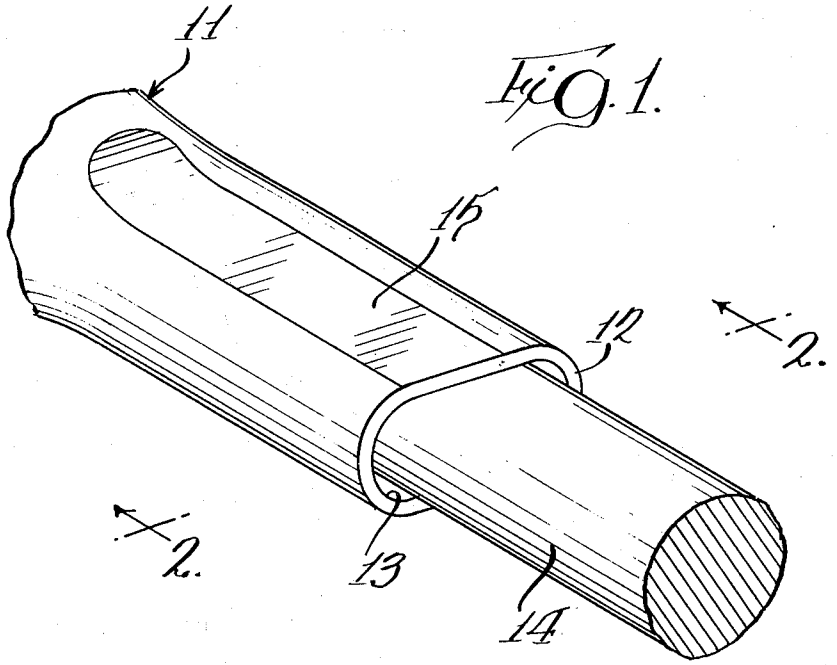


Fig. 1.

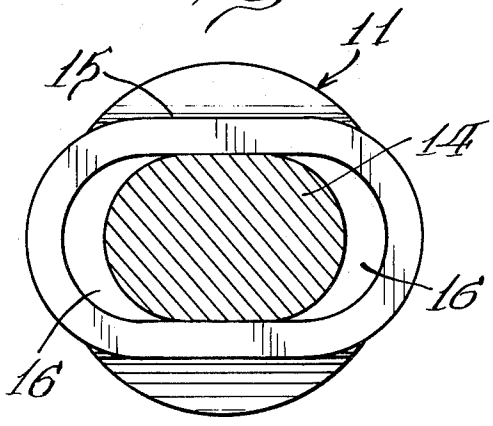


Fig. 2.

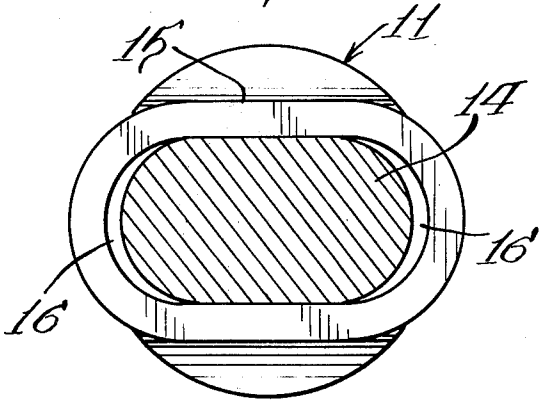


Fig. 3.

MANUFACTURE OF CONTROLLED RELEASE FLUID SWELLABLE SUTURES

BACKGROUND OF THE INVENTION

This invention relates to needle-suture combinations and particularly to a combination of a surgical needle with a fluid swellable suture in which the force necessary to separate the needle from the suture remains within an acceptable range regardless of the moisture content of the suture.

In many surgical procedures, surgeons use a technique which employs a non-needled suture and an eyed needle. The needle is threaded by the nurse and the surgeon takes one pass through the tissue using a needleholder. He slips the needle off the suture, returns the needle to the nurse, and is ready for another threaded needle from the nurse. An assistant follows behind and ties the suture.

Surgeons find that this technique is more simple than using a needled item and cutting the suture with a scissors after each pass. However, the time required for threading results in a significant waste of expensive operating room time.

The security of attachment of eyeless needles to absorbable surgical sutures or to non-absorbable surgical sutures is prescribed in the U.S. Pharmacopoeia, Vol. XVIII at Page 944 (also see U.S. Pharmacopoeia, Vol. XVII, Page 919). It has been the practice of suture manufacturers in the United States and abroad to securely attach the suture to the needle by swaging or with an adhesive so that the minimum pull-out standard recited in the U.S. Pharmacopoeia is met or exceeded.

To avoid the problems discussed above it has been found useful to use needle-suture combinations in which the needle and the suture are readily separable from each other by a sharp tug. Several methods have been devised for preparing needle-suture combinations in which the pull-out values, or the force required for separating the needle from the suture by a straight pull, is within a controlled range.

One approach to this problem is described in copending and co-assigned application Ser. No. 409,974, filed Oct. 26, 1973, now abandoned. This approach involves inserting into a drilled hole in the blunt end of the needle one end of the suture which has been sized with a resin and is smaller in diameter than the remainder of the suture and then swaging the needle at its blunt end to provide a controlled degree of compression to the end of the suture within the hole. This approach is particularly directed to needle-suture combinations wherein the suture is of large size, i.e., size 4-0 and larger (diameter greater than 7.0 mils), and produces average pull-out values of 3 to 26 ounces, indicating that it takes a straight pull of a magnitude within that range to separate the needle from the suture. The disclosure of application Ser. No. 409,974 is hereby incorporated herein by reference.

Another approach to the problem is described in copending and co-assigned application Ser. No. 446,174, filed by Robert Barclay Duncan on Feb. 27, 1974, now U.S. Pat. No. 3,875,946. In this approach sufficient tension is applied to the suture in a swaged needle-suture combination to move the suture relative to the needle recess and the tension is released when the force drops to the range desired for the pull-out value, the range varying for different sizes of suture. This approach is applicable to a broad range of suture sizes, including sizes as small as 8-0. The disclosure of application Ser. No. 446,174 is hereby incorporated herein by reference.

The methods described above assure pull-out values within a desirable range at the time of manufacture in needle-suture combinations of various kinds employing various kinds of suture materials. With suture materials that are relatively stable dimensionally under storage conditions, the suture will retain a pull-out value within the desirable range until the time of use in the operating room.

With certain fluid swellable sutures, however, particularly collagenous sutures whether natural collagen strands, called "gut", or extruded collagen, there is considerable variation in the volume of the suture with varying moisture content therein and therefore a needle-suture combination may have substantially different pull-out values at different moisture contents. The problem is particularly acute with respect to needle-suture combinations utilizing collagenous sutures which are packages and stored in hermetically sealed envelopes containing a tubing fluid (e.g., 90% volume isopropyl alcohol in water) to maintain the suture in a pliable state. If the needle-suture combination is manufactured to have a suitable pull-out value when the collagenous material is in dry state, it will have too high a pull-out value after the collagenous material has soaked in the aqueous alcohol and absorbed water therefrom to expand within the swaged junction. Conversely, if the needle-suture combination is manufactured to have a suitable pull-out value when the collagenous material is swelled with water, it will have too low a pull-out value and may not hold together at all if it is allowed to stand after removal from the aqueous alcohol and the collagenous material starts to dry out.

SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided in a needle-suture combination comprising a needle with a sharp end and a blunt end and a fluid-swellable suture inserted at one end into a recess in said blunt end and held therein by swaging, the improvement which comprises dimensioning said recess to provide in the swaged portion of said recess a cross-sectional area equivalent to from about 150% to about 250% of the cross-sectional area of the suture end therein when said suture is in a non-swollen state.

In a preferred embodiment, the recess is a drilled hole or preclosed channel and the needle-suture combination is made in a controlled manner with a dry collagenous suture to provide, while the collagenous material is still dry, a pull-out value within a desired range and preferably from about 3 ounces to about 26 ounces. For the sake of convenience, the remainder of this specification is directed to collagenous fibers which are water-swellable and represent the suture material of greatest interest with respect to this invention. It is understood however, that any suture material subject to swelling in fluid media is inclined within the scope of this invention.

One method of producing needle-suture combinations with controlled pull-out values utilizes swaging to a controlled degree of compression on the suture and is described in the above-cited application Ser. No. 409,974.

Another method utilizes partial withdrawal of the suture from the swaged portion until the force required for continuing the withdrawal drops to a desired value.

This method is described in the above-cited application Ser. No. 446,174.

It is to be understood that the method of this invention reduces, rather than eliminates, changes in pull-out values for collagenous sutures with change in moisture content, but that some change in pull-out values is still to be expected with variations in moisture content. Increasing moisture content and consequent swelling of the collagenous material may produce either higher or lower pull-out values depending on whether there is a predominance of factors tending to increase pull-out values or a predominance of factors tending to decrease pull-out values.

As the moisture content of the collagenous material increases and the suture swells in a cross-sectional area, there will be an increase in the area of tight engagement between the suture surface and the inner surface of the hole in the needle and there will also be some increase in the pressure at these surfaces despite the provision for expansion space, as provided in this invention. Both of these factors tend to increase the pull-out values.

On the other hand, the collagenous material in a swollen state is weaker and more easily deformed than collagenous material in a dry state; and this factor tends to decrease the pull-out values.

The net change in pull-out values of the needle-suture combinations of this invention upon the swelling of the collagenous material is dependent upon the amount of space allowed within the suture hole for the collagenous suture to swell into and the degree of swelling.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will become more readily apparent upon consideration of the following detailed description when taken in connection with the accompanying drawings wherein:

FIG. **1** is an enlarged fragmentary perspective view of the needle-suture combination of the invention at the juncture of the needle and the suture;

FIG. **2** is a further enlarged cross-sectional view at plane **2—2** of FIG. **1,** showing the needle-suture combination of this invention at the time of manufacture; and

FIG. **3** is a cross-sectional view similar to FIG. **2** but after the collagenous suture has swelled.

DETAILED DESCRIPTION

As may be seen in FIG. **1,** needle **11** has a blunt end **12** containing hole **13** into which one end of suture **14** is inserted, after which flat swaging produces flattened portions **15** of the needle which causes deformation of the portion of the suture within the hole as shown in FIG. **2.**

FIG. **2** shows that spaces **16** of controlled size are present within flattened hole **13** at opposite sides of suture **14.** In accordance with this invention, the total area within the flattened portion of hole **13,** including the cross-sectional area of the dry suture **14** at that point and the cross-sectional area of both spaces **16** is from about 150% to about 250% of the cross-sectional area of suture **14** at that point.

Upon the moistening of the collagenous suture, it expands in width and occupies at least a portion of spaces **16,** as shown in FIG. **3** and, to the extent that spaces **16** are available to take up the swelled volume of the suture, added pressure between the suture tip and the inner surfaces of the wall that would otherwise be produced by the swelling, is held to a minimum.

EXAMPLES 1 to 7

A series of natural gut sutures, ranging in size from 3-0 to 2 (diameters 0.011 inch to 0.023 inch) were inserted in a dry state into holes of various sizes in a series of needles and pull-out values were determined in both the dry and wet states. The holes were flattened circles shaped as shown in FIGS. **2** and **3** and the cross-sectional areas were calculated on the assumption that the flattened circle was made up of two semicircles of diameter equivalent to the flattened height of the hole with a rectangle between them having a width (flat width) equal to the distance between the centers of the semicircles. The results were as shown in TABLE I.

TABLE I

SUTURE SIZE	2	3–0	3–0	3–0	2–0	2–0	0
Suture Diam., Dry-Inches	.023	.011	.011	.011	.014	.014	.017
-mm.	.584	.279	.279	.279	.356	.356	.432
Suture Area, Dry-Sq.In.	.000415	.000095	.000095	.000095	.000154	.000154	.000227
-Sq. mm.	.268	.061	.061	.061	.099	.099	.146
Needle Dia-meter-Inches	.050	0.39	.039	.050	.050	.050	.050
-mm.	1.270	.990	.990	1.270	1.270	1.270	1.270
Hole Diameter -Inches	.025	.016	.019	.025	.025	.022	.029
-mm.	.635	.406	.483	.635	.635	.559	.737
Wall Thickness -Inches	.025	.023	.020	.025	.025	.028	.021
-mm.	.635	.584	.508	.635	.635	.711	.533
Flat Dimension -Inches	.045	.033	.030	.034	.034	.040	.036
-mm.	1.143	.838	.762	.864	.864	1.016	.914
Final Area Height-In.	.020	.010	.010	.009	.009	.012	.015
-mm.	.507	.254	.254	.229	.229	.305	.381
Flat Width -In.	.008	.009	.014	.025	0.25	.016	.022
-mm.	.203	.229	.356	.635	.635	.406	.559
Final							

TABLE I-continued

SUTURE SIZE	2	3-0	3-0	3-0	2-0	2-0	0
Hole Area -Sq.In.	.000474	.000168	.000218	.000289	.000289	.000305	.000507
-Sq.mm.	.306	.108	.141	.186	.186	.197	.327
X-Sectional Area-Ratio -%*	114	177	231	305	188	199	224
Average Pull-Out, Dry-Oz.	15	16	13	12	22	14	19
Average Pull-Out, Soaked Oz.	29	11	10	3	18	9	14

*The X-sectional area ratio is the final hole area divided by the dry suture area and multiplied by 100.

As may be seen from the foregoing data when the cross-sectional area in the swaged portion of the needle recess is only slightly larger than the cross-sectional area of the sutures in a dry state (e.g., in the size 2 suture in the first column where the former is only 114% of the latter) the pull-out values for the wet sutures are much higher than those for the dry sutures. Conversely, when the cross-sectional area in the swaged portion of the needle recess is far greater than the cross-sectional area of the sutures in a dry state (e.g., at 305% as in the 3-0 suture in the fourth column) the pull-out values for the wet sutures are much lower than the pull-out values for the dry sutures. In the remaining examples in which the cross-sectional area in the swaged portion of the recess is between about 150% and about 250% of the cross-sectional area of the sutures in a dry state, the pull-out values of the dry sutures and of the wet sutures are of about the same order of magnitude.

The invention has been described with respect to preferred embodiments but other embodiments and modifications will be apparent to those skilled in the art.

What is claimed:

1. In a needle-suture combination comprising a needle with a sharp end and a blunt end and a fluid-swellable suture inserted at one end into a recess in said blunt end and held therein by swaging, the improvement comprising the dimensioning and configuration of said recess, said recess being provided within the swaged portion thereof with a cross-sectional area equivalent to from about 150% to about 250% of the cross-sectional area of the suture end therein when said suture is in a non-swollen state so that a suture pull-out value of from about 3 to 26 ounces is obtained.

2. A needle-suture combination of claim **1** wherein said suture comprises a water-swellable collagen selected from the group consisting of natural collagen and extruded collagen.

3. A needle-suture combination of claim **2** wherein said combinations are hermetically sealed in a package containing an aqueous alcohol solution.

4. A needle-suture combination of claim **3** wherein said solution comprises about 90% by volume of isopropyl alcohol and about 10% by volume of water.

5. A needle-suture combination of claim **2** wherein the diameter of the dry suture is from about 0.2 to about 0.6 millimeters.

6. A needle-suture combination of claim **1** wherein the suture pull-out value is from about 3 ounces to about 26 ounces when the suture is in a non-swollen state.

7. A needle-suture combination of claim **1** wherein the suture pull-out value is from about 3 ounces to about 26 ounces when the suture is in a swollen state.

8. A needle-suture combination of claim **1** wherein said suture end is compressed within said swaged recess to from about 64% to about 91% of its original dry state diameter.

9. The needle-suture combination of claim **1** wherein said recess is a drilled hole or a closed channel.

10. In a method for making a needle-suture combination in which a needle having a sharp end and a blunt end is attached at its blunt end to a suture comprising a fluid swellable material by the insertion of one tip of said suture into a recess in said blunt end followed by the swaging of said blunt end and the distortion of said recess to bring at least a portion of the inner surface of said recess into tight engagement with said suture tip, the improvement comprising dimensioning said recess to provide after swaging a cross-sectional area in the swaged portion thereof equivalent to from about 150% to about 250% of the cross-sectional area of said suture tip when said suture is in a dry state.

11. A method of claim **10** wherein said swaging is flat swaging.

12. A method of claim **10** wherein said suture comprises a collagenous material.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 3,924,630

DATED : December 9, 1975

INVENTOR(S) : Walldorf, Diann J.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Column 1, Line 44, the word "Oct. 26, 1973, now abandoned" should read --- " Oct. 26, 1973" ---.

In Column 2, Line 59, the word "inclined" should read --- "included" ---.

In Table I in the Column Identified as 3-0)first occurance 0.39) should read --- ".039" ---.

In Table I in the Column Identified as 2-0 (first occurance 0.25) should read --- ".025" ---.

Signed and Sealed this

twenty-second Day of *June 1976*

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks