United States Patent [19]

Beroff et al.

[11] **3,799,169**

[45] **Mar. 26, 1974**

[54] **LATERAL RELEASE SUTURE**

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

[22] Filed: **May 11, 1972**

[21] Appl. No.: **252,176**

[52] **U.S. Cl.** **128/339**, 163/1

[51] **Int. Cl.** **A61b 17/06**

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

[56] **References Cited**

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Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Robert W. Kell

[57] **ABSTRACT**

A surgical needle is manufactured with an open channel at the blunt end thereof sized to receive a suture. The suture is bonded to the channel with an adhesive that prevents "pull-out" of the suture as it passes through tissue. After suturing, the surgeon may easily remove the needle from the suture by turning the needle so that the channel is at an angle of about 90° to the direction of the suture and peeling the suture out of the channel.

41 Claims, 14 Drawing Figures

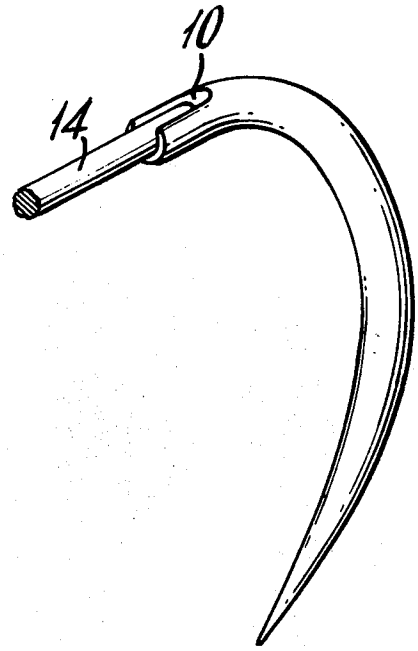


Fig. 1.

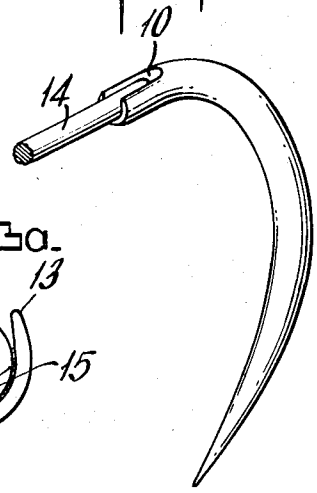


Fig. 2.

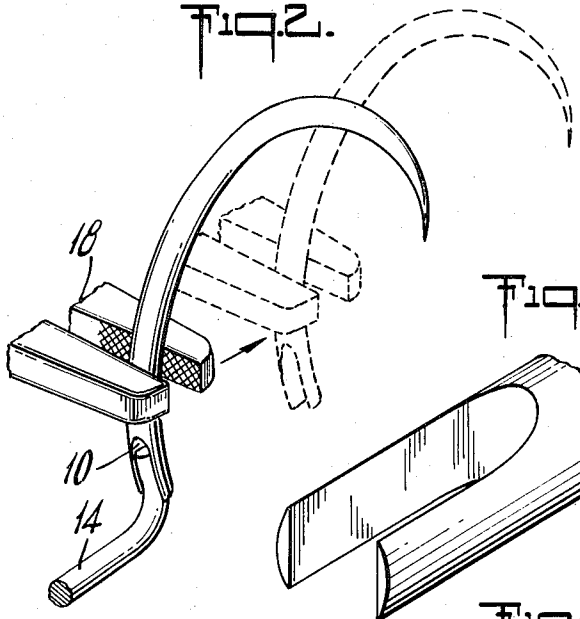


Fig. 3a.

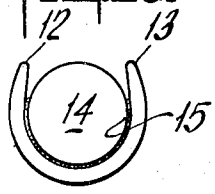


Fig. 9.

Fig. 3.

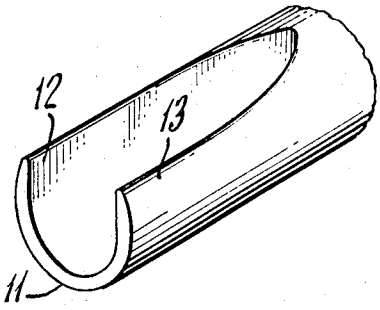


Fig. 9a.

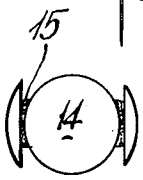


Fig. 4.

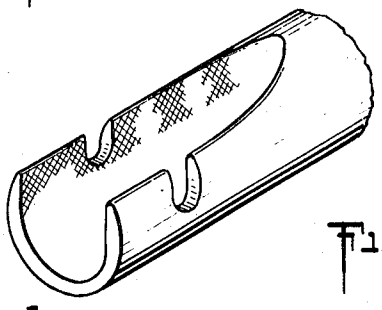


Fig. 6.

Fig. 5.

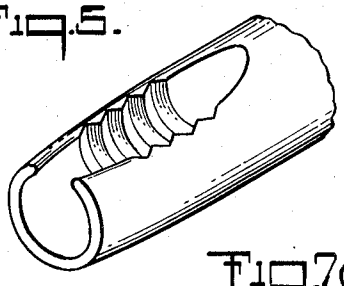
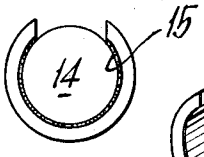


Fig. 6a.



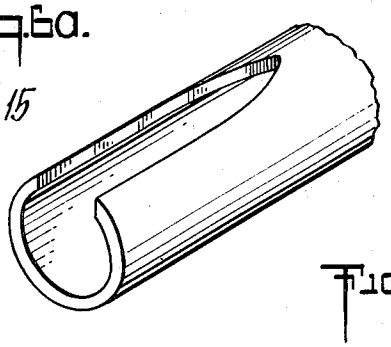


Fig. 8.

Fig. 7a.

Fig. 7.

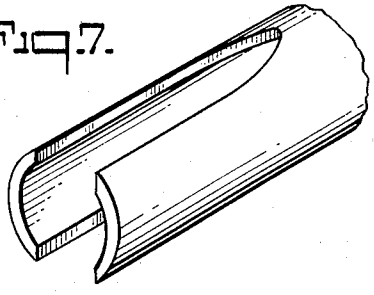
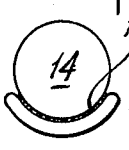
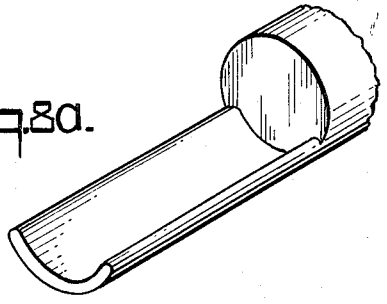


Fig. 8a.





LATERAL RELEASE SUTURE

BACKGROUND OF THE INVENTION

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 snaps the needle off the suture, places the needle on the table and is ready for another threaded needle from the nurse. An assistant follows behind and knots 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.

There is a need for a suture-needle combination that has the convenience of the needle being preattached to the suture and yet permits separation of the suture without the necessity of cutting with a scissors.

One approach to this problem is described in copending application Ser. No. 258,159, filed May 31, 1972 (ETH-362). This approach involves swaging the suture to the needle in a modified manner so that the suture-needle bond is weaker than normal. The philosophy is that the bond will be secure enough to withstand the forces experienced passing through tissue. However, when the passage is complete, the surgeon must merely pull on the needle sharply and it will separate from the suture.

This approach has one drawback, which is the necessity of working between very narrow limits. In any manufacturing procedure, a certain amount of variability is inescapable. Therefore, precise limits must be established so that no bond will be too strong or too weak. The importance of precise control is magnified by the fact that the controlled release of a needle from its attached suture cannot be 100 percent quality controlled because each test must be a destructive test.

In accordance with the present invention, any deficiencies of the swaging method referred to above may be eliminated by utilizing an open channel at the blunt end of the surgical needle. The bottom and two sides of this channel define a space slightly larger than the diameter of the suture to be attached so that the suture may be placed within the channel and bonded to the needle with an adhesive. The bond between the needle and the attached suture, along the length of the open channel, is sufficient to prevent "pull-out" of the suture as the surgeon passes the needle through tissue. Yet, the needle can be easily removed from the suture at any time by simply turning it so that the channel is at an angle of about 90° to the direction of the suture and pulling the needle in a direction opposite to the channel opening.

It is an object of the present invention, therefore, to make available to the surgeon a needle-suture combination useful in suturing, and characterized by a needle-suture attachment that will permit facile removal of the needle from the suture without cutting the suture with a scissors.

Another object of this invention is to provide the surgeon with a needle-suture combination that will reduce the time that the surgical patient must spend in the operating room.

Yet, another object of the invention is to provide a lateral release needle-suture combination that may be pull tested without destruction. Other objects and many of the attendant advantages of the present invention will become more readily apparent upon consideration of the following detailed specification in light of the accompanying drawings wherein:

FIG. **1** is a perspective view of a curved surgical needle-suture combination illustrating the invention;

FIG. **2** is a perspective view of the needle-suture combination of FIG. **1** illustrating the method of separating the suture from the needle;

FIG. **3** is an enlarged perspective view of the blunt end of a needle, illustrating one aspect of the present invention;

FIG. **3***a* is an end view of the needle of FIG. **3** showing the suture in place;

FIG. **4** illustrates a modification of the open channel shown in FIG. **3**;

FIG. **5** illustrates another modification of the open channel shown in FIG. **3**;

FIG. **6** illustrates yet another modification of the open channel shown in FIG. **3**;

FIG. **6***a* is an end view of the needle illustrated in FIG. **6**;

FIG. **7** illustrates still another modification of the needle shown in FIG. **3**;

FIG. **7***a* is an end view of the needle illustrated in FIG. **7** showing the suture in place;

FIG. **8** illustrates another modification of the needle shown in FIG. **3**;

FIG. **8***a* is an end view of the needle illustrated in FIG. **8** showing the suture in place;

FIG. **9** illustrates another modification of the needle shown in FIG. **3**; and

FIG. **9***a* is an end view of the needle illustrated in FIG. **9** showing the suture in place.

Referring now to FIG. **1**, there is shown a half-circle surgical needle having an open channel **10** at the blunt end thereof. As best shown in FIG. **3** and **3***a*, the channel **10** has a bottom **11** and two sides **12** and **13** which define a space slightly larger than the diameter of a suture **14** to be attached. The suture **14** is bonded to the bottom of the needle with an adhesive composition **15**.

FIG. **2** shows the method of removing the needle from the suture in accordance with the present invention. The surgeon, using a technique similar to that used with an eyed needle, makes a single pass through the tissue using a needleholder **18**. He then turns the needleholder as shown in FIG. **2** so that the open channel **10** of the needle is at an angle to the direction of the suture and moves the needle-holder firmly in the direction shown by the arrow, removing the suture from the needle. The actual force required to separate the needle from the suture will vary with the size of the suture, the size of the needle channel and the nature and extent of the bond between the suture and the needle as well as the direction in which the force is applied. Thus, separation will occur at measured forces between 4 and 14 ounces.

It is an important aspect of the present invention that the straight pull-out force, i.e., the force required to separate the needle from the suture while in the position illustrated by FIG. **1** may be about 10 or more times the force required when the relative position of the needle and suture are changed as shown in FIG. **2**.

It will be obvious to those skilled in the art that the size, shape, and position of the needle channel may be varied without diminishing the effectiveness of the invention described. The surgeon, during normal sewing, exerts a substantially longitudinal pull on the needle barrel. If his wrist mistakenly deviates, it is more likely to supinate than pronate. Such a motion could actuate the lateral release unintentionally. For this reason, it is preferred that the channel be placed on the outside of the needle, as shown in FIGS. **1** and **2.** Wrist pronation would then be required for release which is not likely to happen unintentionally. It will be understood, however, that the channel **10** may be on the concave side of the needle instead of opening on the convex side as illustrated in the drawings. In addition, the opening may be on either side of the needle, i.e., in a circular needle at an angle of 90° to the plane of the circle. Thus, placing the channel in either the proximal or distal surface (as held in the needleholder in relation to the surgeon's body) may be done to accommodate the preference of right-handed or left-handed surgeons. A forward or backward pull would separate the needle from the suture. Modifications of the size and shape of the needle channel and the positioning of the suture within the needle channel are illustrated in FIGS. **4** through **9***a*.

With reference to FIG. **4,** there is shown a notched channel which decreases the bonding surface and permits separation of the needle from its attached suture at a lower force.

FIG. **5** illustrates a serrated channel the width of which decreases in the direction of the end of the needle. This construction affects the straight pull-out value of the needle-suture combination as the needle is passed through tissue during a surgical procedure.

In FIG. **6,** the open channel **10** has been narrowed to increase the force that is required to separate needle and suture.

The needle of FIG. **7** is so constructed that the force to obtain separation of the needle from its suture may be applied in either of two diametrically opposite directions.

FIG. **8** illustrates a structure that may be used in combination with a strong adhesive should the surgeon desire a needle that may be removed with less concern about the direction in which the force is applied.

The needle of FIG. **9** is similar in its construction to that of FIG. **7** being formed with a slot to permit facile separation in either of two directions. Any conventional metal customarily employed in the manufacture of needles, such as carbon steel, has application to the present invention. Particularly preferred is stainless steel.

The suture **14** in accordance with the present invention may be absorbable, i.e., catgut, extruded collagen, a braided polyhydroxyacetic ester, a synthetic copolymer of L(-) lactide and glycolide; or non-absorbable, i.e., silk, nylon, polypropylene, cotton, linen, or DACRON.

The adhesive that is used to bond the suture **14** to the needle channel in accordance with the present invention may be any non-toxic adhesive composition, either organic, inorganic or a hybrid. Suitable organic materials are such natural products as starch, dextrins, asphalt, animal and vegetable proteins, natural rubber, shellac; semisynthetic products such as cellulose nitrate and the other cellulosics, polyamides derived from dimer acids, castor-oil based polyurethanes; such well-known synthetic resins as vinyl-type addition polymers, both resins and elastomers: polyvinyl acetate, polyvinyl alcohol, acrylics, unsaturated polyesters, butadiene/acrylonitrile, butadiene/styrene, neoprene, butyl rubber, polyisobutylene; and polymers formed by condensation and other step-wise mechanisms, i.e., epoxies, polyurethanes, polysulfide rubbers, and the reaction products of formaldehyde with phenol, resorcinol, urea, and melamine. Particularly preferred as bonding compositions are the epoxide resins. The following examples will serve to illustrate the invention.

EXAMPLE I

Keith needles (diameter 0.034 inches) having the structure shown in FIGS. **3** and **3***a* are attached to Size 2/0 black braided silk using an epoxy resin as the bonding agent. The length of the needle channel is 0.244 inches.

The epoxy resin employed is a mixture of 93 parts by weight of a bis-phenol-epichlorohydride resin having an equivalent weight per epoxide group of 185–200 and 7 parts by weight of a low boiling monoepoxide having an equivalent weight per epoxy unit of 130–140. This product is sold under the tradename EPOWELD 7310 by the H. B. Hardman Company, 600 Courtland Street, Belleville, N.J.

The curing agent for this epoxy resin is a polyamido polyamine having a viscosity at 75°C. using a 1 spindle (Brookfield Viscometer) at 5 r.p.m. of 700 to 900 cps. The curing agent may also be obtained from said H. B. Hardman Company under the tradename EPOCURE S-6.

The bonding composition is prepared by mixing 2 parts by weight of the epoxide resin (EPOWELED 7310) with 1 part by weight of the curing agent (EPOCURE S-6) and 0.4 parts by weight of 1,1,1-trichloroethylene. Sufficient bonding agent is applied to the bottom **11** and sides **12** and **13** of the needle channel to coat these surfaces and the silk suture is pressed into place so that the end of the suture abutts the end of the needle channel. The epoxide bonding composition is cured with the suture in place by heating the needle and suture for 15 minutes in a circulating air oven at 105–120°C. Pull test results on the needle-suture combination so manufactured are summarized in Table 1.

TABLE 1

PULL TEST RESULTS

Destructive Straight Pull	Non-Destructive Straight Pull	Destructive Side Pull
3 lb. 8 oz.		4 ounces
3 lb. 8 oz.		
1 lb. 12 oz.		
	>2 lbs.	10 ounces
	>2 lbs.	4 ounces
3 lb. 8 oz.		
	>2 lbs.	4 ounces
3 lb. 8 oz.		
		6 ounces
	>2 lbs.	6 ounces
3.2 lb. (Average)		5.7 oz. = 0.36 lb. (Average)

Ratio of Straight Pull to Side Pull: 3.2/.36=9:1

EXAMPLE II

Keith needles (diameter 0.034 inches) having the structure shown in FIGS. **3** and **3***a* and a needle channel 0.244 inches in length are attached to Size 2/0 black

braided silk as described in Example I above. Pull tests on the needle-suture combination so manufactured are summarized in Table 2.

TABLE 2

FULL TEST RESULTS

Destructive Straight Pull	Non-Destructive Straight Pull	Destructive Side Pull
	>2 lb.	0.38 lb.
5 lb.		
3 lb.		
	>2 lb.	0.13 lb.
	>2 lb.	0.19 lb.
4.5 lb.		
	>2 lb.	0.38 lb.
	>2 lb.	<0.38 lb.
	>2 lb.	<0.38 lb.
	>2 lb.	<0.38 lb.
5 lb.		
4 lb.		
	>2 lb.	<.38 lb.
3 lb.		
4.1 (Average)		0.33 lb. (Average)

Ratio of Straight Pull to Side Pull: 4.1:.33=12.42

EXAMPLE III

Example II above was repeated using a larger amount of epoxy resin adhesive to increase the suture bonding area. Pull tests on the needle-suture combination so manufactured are summarized in Table 3.

TABLE 3

PULL TEST RESULTS

Destructive Straight Pull	Non-Destructive Straight Pull	Destructive Side Pull
suture broke at 5		
	4.5 lb.	1.00 lb.
suture broke at 5		
		0.63 lb.
suture broke at 5½		
	>5½ lb.	0.88 lb.
	>4 lb.	0.75 lb.
		0.75 lb.
suture broke at 5½		
	>5½ lb.	0.75 lb.
suture broke at 5½	>5½ lb.	0.75 lb.
>5.3 lb. (Average)		0.79 lb. (Average)

Ratio of Straight Pull to Side Pull: >5.30:0.79=6.71

EXAMPLE IV

Curved taper point needles (diameter 0.026 inches) having the structure shown in FIGS. **3** and **3***a* and a needle channel 0.187 inches in length are attached to Size 3/0 black braided silk as described in Example I above. Pull out tests on the needle-suture combination so manufactured are summarized in Table 4.

TABLE 4

PULL TEST RESULTS

Destructive Straight Pull	Non-Destructive Straight Pull	Destructive Side Pull
1.0 lb.		
	>1 lb.	0.38 lb.
3.0 lb.		
	>1 lb.	0.50 lb.
	>1 lb.	0.56 lb.
3.0 lb. suture broke		<0.25 lb.
1.5 lb.		
2.13 lb. (Average)		0.42 lb. (Average)

Ratio of Straight Pull to Side Pull: 2.13:0.42=5.07

EXAMPLE V

Curved tapered needles (diameter 0.039 inches) having the structure shown in FIGS. **3** and **3***a* and a needle channel 0.239 inches in length are attached to Size 2/0 cotton thread as described in Example I above. An excess of epoxy resin was employed in an amount such that when the suture was in place the resin was forced upwardly to the top of the needle channel. After curing, longitudinal cuts were made with a razor blade parallel to the channel of the needle to facilitate lateral removal of the cotton suture. Pull tests on the needle-suture combination so manufactured are summarized in Table 5.

TABLE 5

PULL TEST RESULTS

Destructive Straight Pull	Non-Destructive Straight Pull	Destructive Side Pull
2 lb.		
	>2 lb.	0.50 lb.
3 lb.		
	>2 lb.	0.31 lb.
	>2 lb.	0.31 lb.
2 lb.		
0.8 lb.		
1 lb.		
1.3 lb.		
	>2 lb.	0.50 lb.
1.68 lb. (Average)		0.41 lb. (Average)

Ratio of Straight Pull to Side Pull: 1.68:0.41=4.10

EXAMPLE VI

Keith needles (diameter 0.034 inches) having the structure shown in FIGS. **3** and **3***a* and a needle channel 0.246 inches in length are attached to Size 1 black braided silk as described in Example I above. Pull tests on the needle-suture combination so manufactured are summarized in Table 6.

TABLE 6

PULL TEST RESULTS

Destructive Straight Pull	Non-Destructive Straight Pull	Destructive Side Pull
	>4 lb.	1.00 lb.
	>4 lb.	0.50 lb.
8 lb.		
	>4 lb.	0.75 lb.
	>5 lb.	0.81 lb.
	>5 lb.	0.75 lb.
	>5 lb.	0.63 lb.
6.5 lb.		
8.5 lb.		
9.5 lb.		
		0.75 lb.
		0.63 lb.
	>6 lb.	1.06 lb.
8.13 lb. (Average)		0.76 lb. (Average)

Ratio of Straight Pull to Side Pull: 8.13:0.76=10.70

As many apparently widely different embodiments of this invention may be made without departing from the spirit and scope thereof. It is to be understood that the invention is not limited to the specific embodiments thereof except as defined in the following claims.

What is claimed is:

1. A controlled release needle-suture combination comprising a surgical needle having an open channel at the blunt end thereof, the bottom and two sides of which define a space sized to receive a suture; and a surgical suture one end of which is received within said channel and bonded thereto with an adhesive composition to prevent movement of the suture toward the point of the needle; said adhesive composition providing a means whereby a force of from about 3 ounces to about 26 ounces will separate the needle from the suture when the needle is turned so that the channel is at an angle of about 90° to the longitudinal axis of the suture and said force is applied in a direction opposite to the channel opening.

2. The needle-suture combination of claim **1**, wherein the suture is bonded to the bottom of the channel.

3. The needle-suture combination of claim 1, wherein the suture is bonded to the bottom and at least one side of the channel.

4. The suture combination of claim 1, wherein the suture is bonded to the bottom and both sides of the channel.

5. The needle-suture combination of claim 1, wherein the sides of the channel terminate at the surface of the suture.

6. The suture-needle combination of claim 1, wherein at least one side of the channel is notched.

7. The needle-suture combination of claim 1, wherein the width of the channel varies along its length.

8. The needle-suture combination of claim 1, wherein the interior surface of said channel is serrated.

9. The needle-suture combination of claim 1, wherein the width of the channel opening is no smaller than the diameter of the needle.

10. The needle-suture combination of claim 1, wherein at least one side of the channel is less than one-half the diameter of the suture.

11. The needle-suture combination of claim 1, wherein each side of the channel is less than one-half of the diameter of the suture.

12. The needle-suture combination of claim 1, wherein both sides of the channel are removed.

13. The needle-suture combination of claim 1, wherein the bottom of the channel is removed.

14. The needle-suture combination of claim 1, wherein the suture is a silk suture.

15. The needle-suture combination of claim 1, wherein the suture is a catgut suture.

16. The needle-suture combination of claim 1, wherein the suture is an absorbable collagen suture.

17. The needle-suture combination of claim 1, wherein the suture is an absorbable polyester suture.

18. The needle-suture combination of claim 1, wherein the suture is a polyglycolic acid suture.

19. The needle-suture combination of claim 1, wherein the suture is a poly L(-) lactide copolymer suture.

20. The needle-suture combination of claim 1, wherein the suture is a linen suture.

21. The needle-suture combination of claim 1, wherein the suture is a non-absorbable polyester suture.

22. The needle-suture combination of claim 1, wherein the suture is a polytetrafluoroethylene coated suture.

23. The needle-suture combination of claim 1, wherein the suture is a steel suture.

24. The needle-suture combination of claim 1, wherein the suture is an iodized catgut suture.

25. The needle-suture combination of claim 1, wherein the suture is a silicone-coated suture.

26. The needle-suture combination of claim 1, wherein the suture is a nylon suture.

27. The needle-suture combination of claim 1, wherein the suture is a cotton suture.

28. The needle-suture combination of claim 1, wherein the suture is a polypropylene suture.

29. The needle-suture combination of claim 1, wherein the suture is a braided silk suture.

30. The needle-suture combination of claim 1, wherein the adhesive composition is an epoxy resin.

31. A controlled release needle-suture combination comprising a surgical needle having a longitudinal slot at the blunt end thereof, the two sides of which define a space sized to receive a suture; and a surgical suture, one end of which is received within the slot and bonded thereto with an adhesive composition; said adhesive composition providing a means whereby a force of from about 3 ounces to about 26 ounces will separate the needle from the suture when the needle is turned so that the slot is at an angle of about 90° to the longitudinal axis of the suture and said force is applied in a direction opposite to the opening in the slot.

32. The needle-suture combination of claim 31, wherein the adhesive composition is an epoxy resin.

33. A controlled release needle-suture combination comprising a curved surgical needle having convex and concave surfaces, pointed at one end and having an open channel at the blunt end thereof, the bottom and two sides of which define a space sized to receive a suture; and a surgical suture one end of which is received within the channel and bonded thereto with an adhesive composition to prevent movement of the suture toward the point of the needle; said adhesive composition providing a means whereby a force of from about 3 ounces to about 26 ounces will separate the needle from the suture when the needle is turned so that the channel is at an angle of 90° to the longitudinal axis of the suture and said force is applied in a direction opposite to the channel opening.

34. The needle-suture combination of claim 33, wherein the suture is bonded to the bottom of the channel.

35. The needle-suture combination of claim 33, wherein the adhesive composition is an epoxy resin.

36. A controlled release needle-suture combination comprising a curved surgical needle having convex and concave surfaces and pointed at one end, the other end of which has a channel opening on the concave surface, the bottom and two sides of said channel defining a space sized to receive a suture; and a surgical suture one end of which is received within the channel and bonded thereto with an adhesive composition to prevent movement of the suture toward the point of the needle; said adhesive composition providing a means whereby a force of from about 3 ounces to about 26 ounces will separate the needle from the suture when the needle is turned so that the opening of the channel is at an angle of about 90° to the longitudinal axis of the suture and said force is applied in a direction opposite to the channel opening.

37. The needle-suture combination of claim 36, wherein the adhesive composition is an epoxy resin.

38. A controlled release needle-suture combination comprising a curved surgical needle having convex and concave surfaces and pointed at one end, the other end of which has a channel opening on the convex surface; the bottom and two sides of said channel defining a space sized to receive a suture; and a surgical suture, one end of which is adhesive within the channel and bonded thereto with an adhwsive composition to prevent movement of the suture toward the point of the needle; said adhesive composition providing a means whereby a force of about 3 ounces to about 26 ounces will separate the needle from the suture when the needle is turned so that the opening of the channel is at an angle of about 90° to the longitudinal axis of the suture and said force is applied in a direction opposite to the channel opening.

39. The needle-suture combination of claim **38**, wherein the adhesive composition is an epoxy resin.

40. A controlled release needle-suture combination comprising a curved surgical needle having convex and concave surfaces, pointed at one end and having at the blunt end thereof, a longitudinal slot the two sides of which define a space sized to receive a suture; and a surgical suture one end of which is received within the slot and bonded to the sides thereof with an adhesive composition; said adhesive composition providing a means whereby a force of about 3 ounces to about 26 ounces will separate the needle from the suture when the needle is turned so that the opening of the slot is at an angle of about 90° to the longitudinal axis of the suture and said force is applied in a direction opposite to the opening in the slot.

41. The needle-suture combination of claim **40**, wherein the adhesive composition is an epoxy resin.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,799,169 Dated March 26,1974

Inventor(s) Howard Beroff and Robert G. Ferguson

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

In Column 4, line 29, "using a 1 spindle" should read --- using a #1 spindle ---.

In Column 4, line 35, "EPOWELED" should read --- EPOWELD ---.

In Column 5, Heading in Table 11, "FULL" should read --- PULL ---.

In Column 8, line 58, "adhesive" should read --- received ---.

In Column 8, line 59, "adhwsive" should read --- adhesive ---.

Signed and sealed this 17th day of September 1974.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents