(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 March 2014 (20.03.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/043610 A1

(51) International Patent Classification:
A61B 17/06 (2006.01) *A61B 17/04* (2006.01)

(21) International Application Number:
PCT/US2013/059907

(22) International Filing Date:
16 September 2013 (16.09.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
13/621,625 17 September 2012 (17.09.2012) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

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(54) Title: BARBED SUTURES HAVING CONTOURED BARBS THAT FACILITATE PASSAGE THROUGH TISSUE AND INCREASE HOLDING STRENGTH

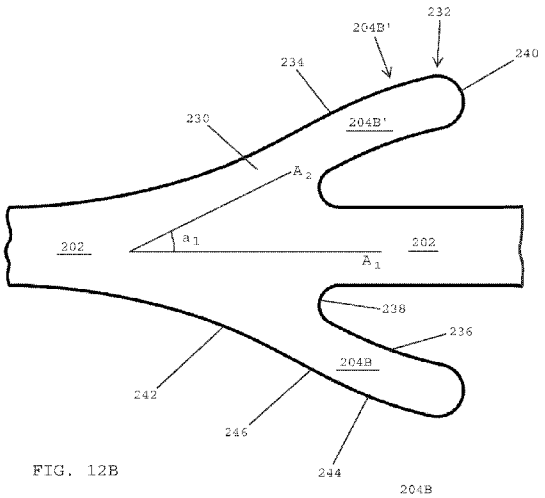


FIG. 12B

(57) Abstract: A wound closure device (200) includes a filamentary element (202) having a proximal end (206) and a distal end (210), and a plurality of barbs (204) extending outwardly from the filamentary element. Each barb has a base (230) connected with the filamentary element, a tip (232) spaced from the base, and an outer edge (234) that extends between the base and the tip. The outer edge includes a first section (242) having a concave surface that extends between the base and a transition point (246) of the barb and a second section (244) having a convex surface that extends between the transition point of the barb and the tip of the barb. The outer edge transforms from the concave surface of the first section to the convex curve of the second section at the transition point of the barb. The tip of the barb has a convexly curved surface facing the distal end of the filamentary element. The unique dual radius shape of the outer edge of the barbs and the tips of the barbs minimizes resistance when the filamentary element is pulled in a first direction through tissue and maximizes resistance to movement when the filamentary element is pulled in an opposite, second direction through tissue for holding the wound closure device stationary.

WO 2014/043610 A1

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

BARBED SUTURES HAVING CONTOURED BARBS THAT FACILITATE PASSAGE THROUGH TISSUE AND INCREASE HOLDING STRENGTH

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of commonly assigned U.S. Patent Appln. Ser. No. 13/248,542, filed September 29, 2011, the disclosure of which is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention generally relates to the field of medical devices, and more particularly relates to barbed sutures having barbs that are specifically designed to facilitate passage through tissue when pulled in a first direction and that exhibit maximum holding strength when pulled in an opposite, second direction.

Description of the Related Art

[0003] Many wounds and surgical incisions are closed using surgical sutures or other forms of surgical closure devices. One type of surgical suture, commonly referred to a barbed suture, is well known and has recently gained attention for use in various medical applications. Typically, barbed sutures are constructed with a series of "barbs" or "protrusions" (used interchangeably herein) that extend outwardly from a central core or filament of the suture. The barbs function to increase the holding strength of the suture and/or eliminate the need for knot tying. The size and shape of the barbs have practical limitations in a surgical setting, and cannot simply be increased in size wherever increased holding strength is desired.

[0004] Some conventional sutures and barbed sutures have been known to include anchors, tabs or the like on the distal end of the suture to provide a "stop" at the distal end that increases the holding strength of the suture and that eliminates the need to tie knots to secure the suture. Conventional thinking dictates that the larger the surface area of the stop in a direction perpendicular to the direction of insertion of the suture, the more holding strength that will be achieved. Again, there are practical limitations on size, however, because large masses may be intolerable in surgical procedures and/or palpable and therefore undesirable. Further,

with T-shaped stops, the perpendicular portion is structurally weak when a bending moment is applied as it would be when pulling on the suture to approximate a wound.

[0005] In view of the above-identified deficiencies, there remains a need for surgical sutures having enhanced holding strength without significantly increasing the insertion force, stiffness of the suture, or palpability of the device. There also remains a need for surgical sutures having barbs that are designed to allow the suture to pass easily through tissue when the suture is pulled in a first direction, but that exhibit maximum holding strength for holding the suture in place when the suture is pulled in an opposite, second direction.

SUMMARY OF THE INVENTION

[0006] The present invention provides a wound closure device including a filamentary element having a proximal end and a distal end, a stop element coupled to the distal end of the filamentary element and having a leading edge area defined by thickness and a width, and a total surface area. The leading edge area faces substantially perpendicular to a longitudinal axis of the filamentary element, and the ratio of the leading edge area to the total surface area is less than 10%. According to one embodiment, the ratio is less than 5%.

[0007] According to various embodiments, the width of the stop element may be greater than 70 mils, the length of the stop element may be greater than 70 mils, and/or the maximum thickness of said stop element may be between 6 and 25 mils.

[0008] According to one embodiment, the thickness of the stop element varies, and/or a minimum thickness of the stop element may be between 4 and 12 mils. According to yet another embodiment, the leading edge thickness includes a maximum thickness at a center and/or at first and/or second outer edges, and a minimum thickness at a location between the center and the first outer edge and between the center and the second outer edge.

[0009] In yet another embodiment, the wound closure device further includes a plurality of projections extending outwardly from the filamentary element along at least a portion of its length. The plurality of projections may extend outwardly from said filamentary element by approximately 6-25 mils.

[0010] The device may be made of a polymeric, metallic or ceramic material that are absorbable or non-absorbable. In yet another embodiment, the device is made of a polymer material selected from the group consisting of absorbable and non-absorbable homopolymers, random copolymers, block copolymers or blends made from polydioxanone, polyglactin, polyglycolic acid, copolymers of glycolide, lactide, and/or caprolactone, polyoxaesters, poliglecaprone, polypropylene, polyethylene, polyvinylidene fluoride (PVDF), hexafluoropropylene, copolymers of vinylidene fluoride and hexafluoropropylene, polyesters, polyethylene terephthalate, polybutylene terephthalate, glycol-modified polyethylene terephthalate, polytetrafluoroethylene, fluoropolymers, thermoplastic elastomers, ionomers, copolymers of ethylene and methacrylic acid, polyamides, polytetramethylene oxide, polystyrene, polybutadiene, polybutylene, etc. including combinations and/or copolymers of absorbable and non-absorbable materials.

[0011] According to yet another embodiment, a ratio of the length to maximum thickness of the stop element is greater than 4.

[0012] In yet another embodiment, the maximum thickness of the stop is approximately 8-25 mils, the width of the stop is approximately 70-120 mils, and the length of the stop is approximately 39-200 mils.

[0013] The present invention also provides a wound closure device including a filamentary element extending along a longitudinal axis between a proximal end and a distal end, and a stop element coupled to the distal end of the filamentary element and that has a length extending substantially parallel to the longitudinal axis of the filamentary element, a width extending substantially perpendicular to said longitudinal axis, and a maximum thickness. The ratio of the length to the maximum thickness of the stop element is at least 4.

[0014] In alternate embodiments, the maximum thickness of the stop element is between 8 and 25 mils, the length of the stop element is greater than 39 mils, and/or the width of the stop element is between 70 and 120 mils.

[0015] In yet another embodiment, the wound closure device further includes a plurality of projections extending outwardly from the filamentary element along at least a portion of its length.

[0016] In yet another embodiment, the thickness of the stop element varies, and in another particular embodiment, the leading edge thickness includes a maximum thickness at a center and/or at first and/or second outer edges, and a minimum thickness at a location between the center and the first outer edge and between the center and the second outer edge.

[0017] Also provided is a wound closure device including a filamentary element extending along a longitudinal axis between a proximal end and a distal end, and a stop element coupled to the distal end of the filamentary element. The stop element has a length extending substantially parallel to the longitudinal axis of the filamentary element, a width extending substantially perpendicular to the longitudinal axis, and a maximum thickness, and for any given maximum thickness of the stop element, the ratio of the length to the width of the stop element is at least 1.

[0018] In a further embodiment, the ratio of the length to the width of the stop element is at least 1.5.

[0019] In one embodiment, a wound closure device preferably includes a filamentary element having a proximal end and a distal end, and a plurality of barbs extending outwardly from the filamentary element. Each barb desirably has a base connected with the filamentary element, a tip spaced from the base, and an outer edge that extends between the base and the tip.

[0020] In one embodiment, the outer edge desirably includes a first section having a concave surface that extends between the base and a transition point of the barb and a second section having a convex surface that extends between the transition point of the barb and the tip of the barb. The outer edge preferably transforms from the concave surface of the first section to the convex curve of the second section at the transition point of the barb. In one embodiment, the concave surface of the first section of the barb has a radius of about 0.075-0.25 inches, and the convex surface of the second section of the barb has a radius of about 0.05-0.1 inches.

[0021] In one embodiment, at least one barb has a tip having a convexly curved surface facing the distal end of the filamentary element. The convexly curved outer surface desirably

extends between the outer and inner edges of the barb and has a radius of about 0.003-0.006 inches.

[0022] In one embodiment, the filamentary element has a length and the barbs are evenly spaced along the length of the filamentary element. In one embodiment, the tips of the evenly spaced barbs define a tip-to-tip pitch of about 0.03-0.09 inches.

[0023] In one embodiment, the barbs include pairs of barbs evenly spaced along the length of the filamentary element. The barbs in each pair are desirably aligned with one another along the length of the filamentary element. In one embodiment, the barbs in each pair project away from one another and are disposed on opposite, lateral sides of the filamentary element. In one embodiment, the tips of the barbs in each pair define a lateral tip-to-tip distance of about 0.025-0.1 inches.

[0024] In one embodiment, each barb has the outer edge facing away from the filamentary element and an inner edge spaced from and facing the filamentary element. In one embodiment, at least one barb has an inner edge that extends between the barb base and the barb tip. In one embodiment, the barb includes an interior concave surface extending between the inner edge of the barb and the filamentary element having a radius of about 0.002-0.006 inches.

[0025] In one embodiment, at least one of the barbs extends along a longitudinal axis that defines an acute angle with the longitudinal axis of the filamentary element of about 5-60°.

[0026] In one embodiment, the bases of the barbs are thicker than the tips of the barbs. In one embodiment, the barbs taper inwardly between the base and the tip at an angle of about 1-20°.

[0027] In one embodiment, the wound closure device includes a stop element connected with the distal end of the filamentary element. The stop element has a total surface area and a leading edge area defined by a thickness and a width, whereby the leading edge area extends substantially perpendicular to the longitudinal axis of the filamentary element. In one embodiment, the ratio of the leading edge area to the total surface area is less than 10%.

[0028] In one embodiment, a wound closure device includes a filamentary element having a proximal end, a distal end, and a longitudinal axis extending between the proximal and distal ends, and a plurality of barbs extending outwardly from the filamentary element. In one embodiment, each barb has a base connected with the filamentary element, a tip spaced from the base, and an outer edge that extends between the base and the tip. The outer edge of the barb preferably includes a first section having a concave surface with a radius of about 0.075-0.25 inches that extends between the base and a transition point of the barb and a second section having a convex surface with a radius of about 0.05-0.1 inches that extends between the transition point of the barb and the tip of the barb. The barb tip desirably has a convex surface facing the distal end of the filamentary element having a radius of about 0.003-0.006 inches.

[0029] In one embodiment, the barbs are evenly spaced along the length of the filamentary element and define a longitudinal tip-to-tip pitch of about 0.03-0.09 inches. The plurality of barbs preferably includes pairs of barbs that are aligned with one another and evenly spaced along the length of the filamentary element. The barbs in each of the pairs preferably project away from one another and are disposed on opposite sides of the filamentary element, whereby the tips of the barbs in each pair define a lateral tip-to-tip distance of about 0.025-0.1 inches.

[0030] These and other objects, features and advantages of the present invention will be apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] FIG. 1 shows a wound closure device including an insertion needle and a stop element, in accordance with one embodiment of the present invention.

[0032] FIG. 2 is an enlarged view of the distal end of the wound closure device and the stop element of FIG. 1.

[0033] FIG. 3 is a top view of the stop element of the wound closure device of FIGS. 1 and 2.

[0034] FIG. 4 is a side view of the stop element of the wound closure device of FIGS. 1-3.

[0035] FIG 5 is a cross-sectional view of the stop element of the wound closure device of FIG. 3 taken along line FIG. 5-FIG. 5 thereof.

[0036] FIG. 6 is a graph illustrating the holding strength of fixation tabs of equal leading edge maximum thickness and width, but with varying length.

[0037] FIG. 7 is a graph illustrating elongation of a fixation tab as a function of length to width ratio for a given maximum thickness.

[0038] FIG. 8 is a graph illustrating a load-extension curve for a fixation tab length to width ratio of 0.5.

[0039] FIG. 9 is a graph illustrating a load-extension curve for a fixation tab length to width ratio of 2.

[0040] FIG. 10 illustrates a wound closure device including a filamentary element having barbs, an insertion needle connected with a leading end of the filamentary element, and a stop element connected with a trailing end of the filamentary element, in accordance one embodiment of the present invention.

[0041] FIG. 11 shows a perspective view of a section of the filamentary element having barbs shown in FIG. 10.

[0042] FIG. 12A shows a left side view of the section of the filamentary element having barbs shown in FIG. 11.

[0043] FIG. 12B shows a magnified view of the section of the filamentary element having barbs shown in FIG. 12A.

[0044] FIG. 13 shows a top plan view of the section of the filamentary element having barbs shown in FIG. 12B.

[0045] FIG. 14 shows a cross-section view of the filamentary element having barbs taken along line FIG. 14-FIG. 14 of FIG. 12B.

DETAILED DESCRIPTION

[0046] FIG. 1 illustrates an exemplary embodiment of a wound closure device 100 according to the present invention. Referring to FIGS. 1 and 2, the wound closure device 100 includes a filamentary element 102 comprised of any suitable surgical suture material (i.e., absorbable and non-absorbable polymeric materials, metallic, or ceramic materials) that preferably includes a plurality of barbs 104 that extend outwardly therefrom. The suture may be formed by any suitable method, but preferably is compound profile punched from preformed material in a manner described in more detail in U.S. Patent Publication No. 2007/0257395, which is incorporated herein by reference in its entirety. Referring to FIG. 1, the proximal end 106 of the wound closure device may include a needle or other insertion device 108. Referring to FIGS. 1-5, in one embodiment, the distal end 110 of the wound closure device includes a fixation tab or stop element 112 or the like. The stop element 112 has a leading edge 114 defined by a leading edge thickness t (FIG. 5) and a leading edge width w (FIGS. 3 and 5). The stop element 112 also has a length l (FIG. 3). As indicated previously, known T-shaped configurations have relatively weak stiffness when a bending moment is applied, such as when tension is applied to the suture to approximate a wound. The graph depicted in Fig. 6 more clearly illustrates the advantage of the present invention over a T-shaped end configuration. Fixation tabs of equal leading edge maximum thickness (t) and width (w) (leading edge area), but varying length (l) were made and the holding strength tested. The holding strength was tested by passing the barbed suture through a porcine abdominal wall fascia sample and pulling against the fixation tab until failure occurred either by the stop breaking in some fashion, the stop pulling through the tissue, or a combination of both. The maximum load prior to failure was recorded and illustrated in FIG. 6.

[0047] As shown in the FIG. 6 graph, the holding strength decreases as the geometry becomes more like a T-shaped member, or in other words, as the ratio of length to leading edge area or length to maximum thickness decreases. The holding strength can be increased by increasing the thickness or width of the stop, but as indicated previously, there are practical and clinical limitations on the size and mass that can be implanted.

[0048] In addition to the length to maximum thickness or leading edge area ratio, the length l to width w ratio is also a significant consideration for any given maximum thickness. Surprisingly and counter-intuitively, a ratio of at least 1:1 provides much increased holding

strength. FIG. 7 illustrates the elongation of the fixation stop or tab as a function of the length to width ratio for a given maximum thickness. As shown, the percentage of elongation (or more simply the amount of deformation) required to reach catastrophic failure increases with increasing length to width ratio.

[0049] In addition to raw elongation percentages, the actual amount of energy required for the failure of the device increases with increasing length to width ratios. This is illustrated by FIGS. 8 and 9, in which the area under the load-extension curve is a measure of the strain energy until catastrophic failure. As the length to width ratio increases, the amount of strain energy required to reach catastrophic failure significantly increases. FIG. 8 illustrates a load-extension curve for a fixation tab having a length to width ratio of 0.5:1. As illustrated, the device reaches a peak load then decreases dramatically with sudden failure. Figure 94 illustrates a load-extension curve for a fixation tab having a length to width ratio of 2:1. As illustrated, the curve has a second peak, and much greater extension before catastrophic failure occurs. In other words, the strain energy significantly increases as the length to width ratio increases from 0.5 to 2.

[0050] Referring to FIGS. 3-5, the leading edge 114 of the stop element 112 has relatively little surface area in contact with tissue when the suture is under tension, but its ratio of length l to maximum thickness t is very large. Thus, the actual area in contact with tissue (i.e., the area of the leading edge area 114) in the direction of load is very small relative to the overall dimensions of the stop element 112. This relatively long length, but minimal thickness allows the stop to be placed in the wound in a relatively flat position, which minimizes palpability and allows the opposing sides of the tissue to neatly cover the stop. Since the stop lies nicely in the tissue, it can be placed at the apex of the wound, lateral to one side of the wound etc, without impeding the surgeon's individual closure technique.

[0051] In a preferred embodiment, the leading edge 114 relative to the total surface area of the stop 112 (sum of surface area of all sides) is small, preferably less than 10% and more preferably less than 5%. This is counterintuitive, as conventional thinking dictates that in order to increase holding strength and/or minimize failure, one must increase or maximize the surface area under load in order to spread out the load and decrease the load per unit area. The

relatively long length l, but minimal thickness t results in clinical advantages, including flat positioning that minimizes palpability, and versatile positioning as mentioned above.

[0052] According to one preferred embodiment, shown in detail in the cross-sectional view of FIG. 5, the leading edge 114 of the stop element 112 is preferably not rectangular, but rather has a thickness that varies across its width. In one embodiment, the stop element 112 has a maximum thickness t at its outer edges 120 and center 122, and a minimum thickness t_2 at points between the center and outer edges. In this embodiment, the filamentary element 102 has a filament width f of approximately 5-25 mils, and the barbs 104 extend outwardly therefrom by a distance d (FIG. 2) of approximately 6-25 mils. Referring to FIG. 3, the stop 112 has a length l of at least 39 mils, preferably 100 to 200 mils, and a width of greater than 70 mils, more preferably greater than 90 mils, and most preferably greater than 95 mils. Further, referring to FIGS. 3-5, the maximum thickness t is greater than 6 mils, and preferably between 10 and 25 mils, and the minimum thickness t_2 is less than 15 mils, but preferably between approximately 5 and 9 mils. In one embodiment, the length to maximum thickness ratio is preferably greater than 4, and the length to minimum thickness is preferably greater than 9. In one embodiment, the length to width ratio is preferably greater than 1, and more preferably greater than 1.5.

[0053] Referring to FIG. 10, in one embodiment, a wound closure device 200 preferably includes a filamentary element 202 having barbs 204 that extend outwardly therefrom. The filamentary element 202 desirably includes a proximal end 206, an insertion needle 208 connected with the proximal end 206 of the filamentary element 202, a distal end 210 of the filamentary element 202 that is remote from the proximal end 206 of the filamentary element 202, and a stop 212 connected with the distal end 210 of the filamentary element 202. The stop element 212 has a leading edge 214 having a leading edge thickness (not shown) and a leading edge width W'. The stop element 212 also has a length L'.

[0054] Referring to FIG. 11, in one embodiment, the filamentary element 202 has a plurality of barbs 204 extending outwardly from the filamentary element. Referring to FIGS. 12A and 12B, in one embodiment, the barbs 204 of the filamentary element 202 are evenly spaced from one another along the length of the filamentary element 202 (i.e., along the longitudinal axis A_1). In one embodiment, the filamentary element 202 has the longitudinal axis A_1 and the barbs 204 extend along an axis A_2 that defines an angle α_1 with the longitudinal axis A_1. In one

embodiment, the angle α_1 is about 5-60°, and more preferably about 10-49°. The exact size of the angle α_1 is desirably selected to control the flexibility of the barbs 204 during tissue passage and also establish the barb holding strength after the wound closure device 200 has been implanted in tissue.

[0055] In one embodiment, the barbs are aligned in pairs that extend away from one another on opposite sides of the filamentary element 202. FIG. 12A shows three different pairs of barbs that are aligned with one another along the length of the filamentary element 202 including a first pair of barbs 204A, 204A', a second pair of barbs 204B, 204B', and a third pair of barbs 204C, 204C'. Only three pairs of barbs are shown in FIG. 12A because only a small section of the filamentary element 202 is illustrated. In other embodiments, however, a filamentary element 202 may include 50, 100, 150 or more pairs of barbs that are aligned with one another along the length of the filamentary element and that extend away from one another on opposite sides of the filamentary element. In one embodiment, at least some of the barbs extending from opposite sides of the filamentary element are staggered relative to one another.

[0056] Referring to FIGS. 12A and 12B, in one embodiment, each barb 204 includes a base 230 that is connected with the filamentary element 202, a tip 232 that is spaced from the base 230, an outer edge 234 that extends between the base 230 and the tip 232, and an inner edge 236 that extends betweens the base 230 and the tip 232. The outer edge 234 of the barb 204 preferably faces away from the filamentary element 202 and the inner edge 236 of the barb preferably faces toward the filamentary element 202. Each barb 204 also desirably includes an interior curved surface 238 that extends between the inner edge 236 of the barb 204 and the filamentary element 202.

[0057] Referring to FIG. 12A, in one embodiment, the distance between tips 232 of adjacent barbs 204 that are spaced from one another along the longitudinal axis A_1 of the filamentary element 202 defines a barb pitch D_1 of about 0.03-0.09 inches, and more preferably about 0.075 inches. In one embodiment, the barb pitch D_1 is consistent for all of the barbs so that the barbs are evenly spaced from one another along the length of the filamentary element. The barb pitch D_1 between the adjacent tips 232 is selected to control passage of the filamentary element 202 through tissue and improves the holding strength of the wound closure device 200. If the barb pitch D_1 between adjacent barb tips is too great (i.e., over 0.09 inches), then the holding

strength of the wound closure device decreases. If the barb pitch D_1 between adjacent barb tips is too small (i.e., less than about 0.03 inches), then the force required to pass the wound closure device 200 through tissue increases to undesirable levels.

[0058] Referring to FIG. 12A, in one embodiment, the lateral tip-to-tip distance D_2 between the barbs of a pair of barbs (e.g. barbs 204C and 204C') is about 0.025-0.1 inches, and more preferably about 0.03-0.06 inches. The lateral tip-to-tip distance D_2 preferably controls passage of the wound closure device 200 through tissue and enhances holding strength of the wound closure device. If the lateral tip-to-tip distance D_2 is too small (i.e., less than 0.025 inches), then the holding strength of the wound closure device 200 decreases to undesirable levels. If the lateral tip-to-tip distance D_2 is too large (greater than 0.1 inches), then the force required to pass the wound closure device 200 through tissue increases to undesirable levels.

[0059] Referring to FIGS. 12A and 12B, in one embodiment, the tips 232 of the barbs 204 define a convex radial surface 240 having a radius of about 0.003-0.006 inches, and more preferably about 0.004 inches. For each barb, the convex radial surface 240 of the tip 232 desirably helps control the flexibility of the barb 204 during tissue passage and helps dictate the moment arm for the barb 204, thereby minimizing the likelihood of the barb bending backwards once implanted in tissue.

[0060] Referring to FIG. 12B, in one embodiment, the outer edge 234 of each barb 204 includes a first section 242 defining a concave surface and a second section 244 defining a convex surface. The first section 242 with the concave surface extends between the base 230 and a transition point 246 of the barb 204. The second section 244 with the convex surface extends between the transition point 246 of the barb 204 and the tip 232 of the barb 204. In one embodiment, the concave surface of the first section 242 has a radius of about 0.075-0.25 inches, and more preferably about 0.09-0.2 inches. The concave surface of the first section 242 preferably controls the flexibility of the barb 204 and passage of the wound closure device through tissue. The concave surface of the first section 242 defines the moment arm for the barb 204, which desirably minimizes the likelihood of the barb 204 bending backwards once implanted in tissue.

[0061] In one embodiment, the convex surface of the second section 244 of the barb has a radius of about 0.05-0.1 inches, and more preferably about 0.07 inches. The convex surface of the second section 244 preferably defines the moment arm of the barb, helps control the flexibility of the barb, and facilitates passage of the barb and the wound closure device 200 through tissue.

[0062] Referring to FIG. 12B, in one embodiment, one or more of the barbs 204 have a unique shape that desirably enables the barbs to more readily collapse inwardly toward the filamentary element 202 when the barbed suture is pulled through tissue in a first direction designated DIR #1, thereby minimizing the amount of force required to pull the barbed suture through tissue in the first direction DIR #1. In particular, the first section 242 of the outer edge of the barb 204 having a concave shape minimizes the profile of the barb relative to the tissue, which minimizes the amount of force required to pull the barbed suture through the tissue in the first direction DIR #1. In addition, the convex curve of the second section 244 of the barb, located between the transition point 246 of the barb and the tip 232 of the barb, minimizes the resistance level of the barb to inward flexing when the suture is pulled in the first direction DIR #1 so that the resistance level is significantly less than the level that would exist if second section 244 were a straight or concave surface. Thus, the unique shape of the outer edge 234 of each barb 204, having a first section 242 with a concave surface and a second section 244 with a convex surface minimizes the level of resistance provided by the barbed suture as the suture in pulled through tissue in the first direction DIR #1 and enables the barbs to more easily collapse inwardly toward the filamentary element 203. In one embodiment, the location of the transition point may be moved and the radii varied to change the moment arm of the barbs, which will change the ease of passage in the first direction and also change the resistance to movement in the second direction.

[0063] In one embodiment, a barbed suture includes one or more barbs 204 having a unique shape that desirably enables the barbs to more readily resist being bent toward the proximal end of the filamentary element 202 (backward bending) when the barbed suture is pulled through tissue in a second direction designated DIR #2, thereby maximizing the amount of force required to pull the barbed suture through tissue in the second direction DIR #2. In one embodiment, the concave surface of the first section 242 of the barb, located on the outer edge 234 of the barb 204, enables the barb to more easily flex away (i.e., bend backward) from the

filamentary element 202 when the suture is pulled in the second direction DIR #2, thereby increasing the lateral tip-to-tip distance D_2 (FIG. 12A) between the respective tips 232 of the paired barbs 204B, 204B', which increases the resistance to movement of the suture in the second direction DIR #2. In addition, the convexly curved surface 240 at the tip 232 of the barb 204 provides more surface area at the tip for contacting the surrounding tissue when the barbed suture is pulled in the direction DIR #2, for further resisting movement of the barbed suture in the second direction DIR #2. Providing a tip 232 with a convex surface 240 provides more surface area for engaging tissue, and provides a dramatic improvement over tips having acutely angled surfaces that have less surface area for engaging tissue. In one embodiment, providing tips 232 having convex surfaces 240 minimizes the chance of the barbs causing tissue damage because the tips do not have sharp edges.

[0064] In one embodiment, the interior concave surface 238 of the barb 204 has a radius of about 0.002-0.006 inches, and more preferably about 0.003 inches. The selected radius of the interior concave surface 238 preferably helps control flexibility of the barb during tissue passage and helps dictate the moment arm of the barb for preventing the barbs from bending backwards once implanted.

[0065] Referring to FIGS. 13 and 14, in one embodiment, the filamentary element 202 of the wound closure device 200 has a greater thickness T_3 than the thickness T_4 of the tips 232 of the barbs 204. As a result, the wound closure device 200 is preferably thinner at the tips 232 of the barbs 204 than at the center of the filamentary element 202. As a result, the barbs 204 taper inwardly from the thickness T_3 of the center of the filamentary element 202 to the tips 232 by an angle α_2 of about 1-20°, and more preferably about 2-10°. The taper of the barbs between the filamentary element 202 and the tip 232 helps control the flexibility of the barbs 204 during tissue passage and also helps dictate the holding strength of the barbs once the wound closure device 200 has been implanted in tissue.

[0066] While the foregoing is directed to embodiments of the present invention, other and further embodiments of the invention may be devised without departing from the basic scope thereof. As such, it is to be understood that the invention is not limited to the precise embodiments disclosed herein, that various other changes and modifications may be effected

herein by one skilled in the art without departing from the scope or spirit of the invention, and that the scope of the present invention is to be limited only as set forth in the appended claims.

What is claimed is:

1. A wound closure device comprising:

a filamentary element having a proximal end and a distal end; and

a plurality of barbs extending outwardly from said filamentary element, each said barb having a base connected with said filamentary element, a tip spaced from said base, and an outer edge that extends between said base and said tip, wherein said outer edge includes a first section having a concave surface that extends between said base and a transition point of said barb and a second section having a convex surface that extends between said transition point of said barb and said tip of said barb.

2. The wound closure device as claimed in claim 1, wherein said concave surface of said first section of said barb has a radius of about 0.075-0.25 inches, and said convex surface of said second section of said barb has a radius of about 0.05-0.1 inches.

3. The wound closure device as claimed in claim 1, wherein said outer edge transforms from said concave surface of said first section to said convex curve of said second section at said transition point of said barb.

4. The wound closure device as claimed in claim 1, wherein said tip of said barb has a convexly curved surface facing the distal end of said filamentary element.

5. The wound closure device as claimed in claim 1, wherein said filamentary element has a length and said barbs are evenly spaced along the length of said filamentary element.

6. The wound closure device as claimed in claim 5, wherein said tips of said evenly spaced barbs define a tip-to-tip pitch of about 0.03-0.09 inches.

7. The wound closure device as claimed in claim 5, wherein said plurality of barbs includes pairs of barbs evenly spaced along the length of said filamentary element, and wherein said barbs in each said pair are aligned with one another.

8. The wound closure device as claimed in claim 7, wherein said barbs in each said pair project away from one another and are disposed on opposite sides of said filamentary element.

9. The wound closure device as claimed in claim 8, wherein said tips of said barbs in each said pair define a lateral tip-to-tip distance of about 0.025-0.1 inches.

10. The wound closure device as claimed in claim 1, wherein each said barb has said outer edge facing away from said filamentary element and an inner edge spaced from and facing said filamentary element, and wherein each said tip has a convexly curved outer surface extending between said outer and inner edges having a radius of about 0.003-0.006 inches.

11. The wound closure device as claimed in claim 10, wherein said inner edge said barb extends between said barb base and said barb tip, and wherein said barb includes an interior concave surface extending between said inner edge of said barb and said filamentary element having a radius of about 0.002-0.006 inches.

12. The wound closure device as claimed in claim 1, wherein at least one of said barbs extends along a longitudinal axis that defines an acute angle with the longitudinal axis of said filamentary element of about 5-60°.

13. The wound closure device as claimed in claim 1, wherein said bases of said barbs are thicker than said tips of said barbs, and wherein each said barb tapers inwardly between said base and said tip at an angle of about 1-20°.

14. The wound closure device as claimed in claim 1, further comprising a stop element connected with the distal end of said filamentary element, said stop element having a total surface area, and a leading edge area defined by a thickness and a width, the leading edge area extending substantially perpendicular to the longitudinal axis of said filamentary element, wherein the ratio of the leading edge area to the total surface area is less than 10%.

15. A wound closure device comprising:

a filamentary element having a proximal end, a distal end, and a longitudinal axis extending between the proximal and distal ends; and

a plurality of barbs extending outwardly from said filamentary element, each said barb having a base connected with said filamentary element, a tip spaced from said base, and an outer edge that extends between said base and said tip, wherein said outer edge includes a first section having a concave surface having a radius of about 0.075-0.25 inches that extends between said base and a transition point of said barb and a second section having a convex surface having a radius of about 0.05-0.1 inches that extends between said transition point of said barb and said tip of said barb, and wherein said tip has a convex surface facing the distal end of said filamentary element having a radius of about 0.003-0.006 inches.

16. The wound closure device as claimed in claim 15, wherein said barbs are evenly spaced along the length of said filamentary element and define a longitudinal tip-to-tip pitch of about 0.03-0.09 inches, and wherein said plurality of barbs includes pairs of barbs that are aligned with one another and evenly spaced along the length of said filamentary element, said barbs in each said pair projecting away from one another and being disposed on opposite sides of said filamentary element, and wherein said tips of said barbs in each said pair define a lateral tip-to-tip distance of about 0.025-0.1 inches.

17. The wound closure device as claimed in claim 15, further comprising a stop element connected with the distal end of said filamentary element, said stop element having a total surface area, and a leading edge area defined by a thickness and a width, the leading edge area extending substantially perpendicular to the longitudinal axis of said filamentary element, wherein the ratio of the leading edge area to the total surface area is less than 10%.

18. The wound closure device as claimed in claim 17, wherein the ratio of the leading edge area of said stop element to the total surface area of said stop element is less than 5%.

19. The wound closure device as claimed in claim 18, wherein the width of said stop element is greater than 70 mils, the length of said stop element is greater than 70 mills, the minimum thickness of said stop element is about 4-12 mils, and the maximum thickness of said stop element is about 6-25 mils.

20. A wound closure device comprising:

a filamentary element having a proximal end and a distal end; and

a plurality of barbs extending outwardly from said filamentary element, each said barb having a base connected with said filamentary element, a tip spaced from said base, an outer edge that faces away from said filamentary element and extends between said base and said tip, and an inner edge that faces toward said filamentary element and extends between said base and said tip, wherein said outer edge has a dual radius curve including a first concave surface that extends between said base and a transition point of said barb and a second convex surface that extends between said transition point of said barb and said tip of said barb, and wherein said tip has a convex surface facing the distal end of said filamentary element.

FIG. 1

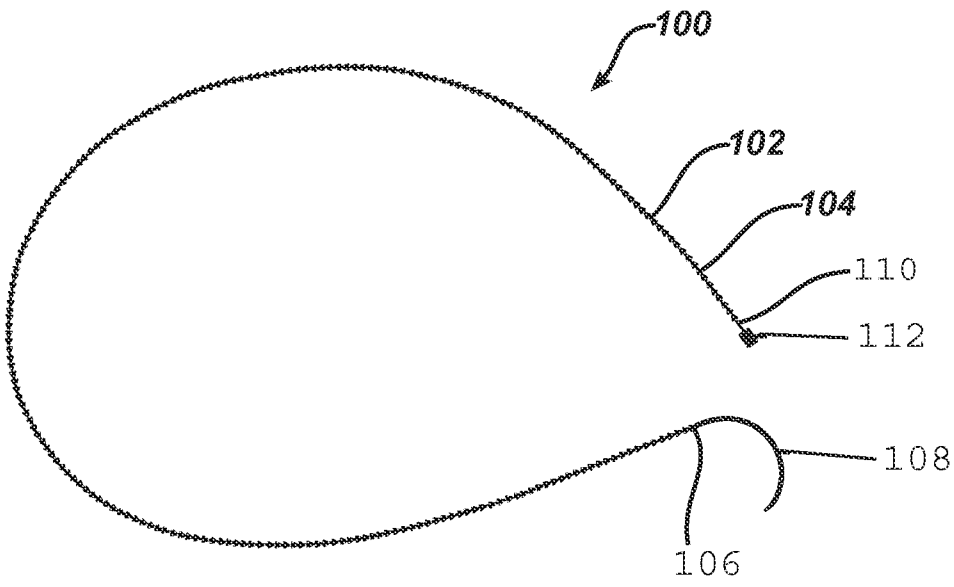


FIG. 2

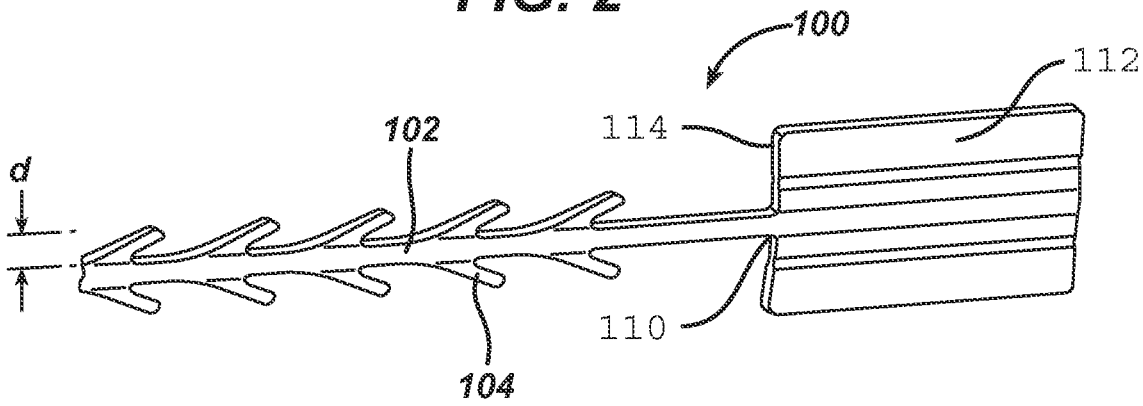


FIG. 3

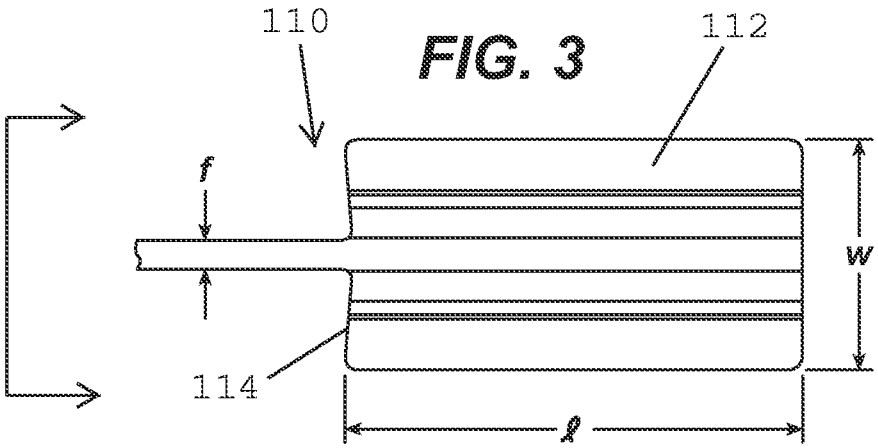


FIG. 4

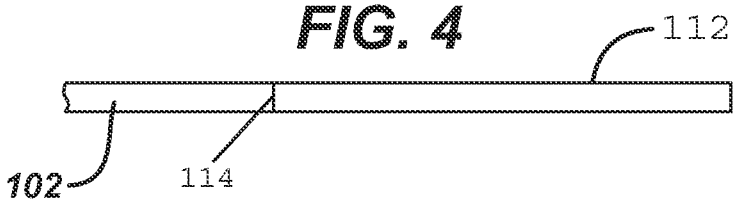


FIG. 5

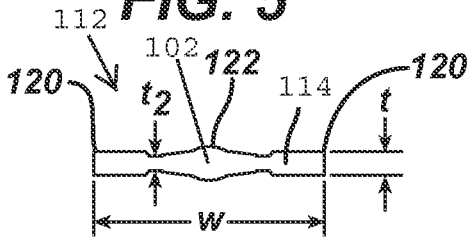


FIG. 6

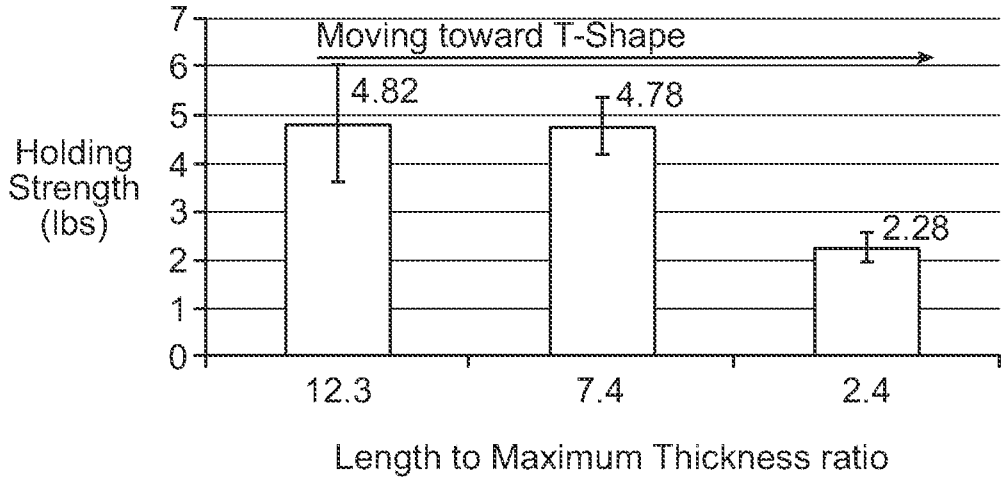

Holding Strength (lbs)
7
6
5
4
3
2
1
0
Moving toward T-Shape
4.82
4.78
2.28
12.3
7.4
2.4
Length to Maximum Thickness ratio

FIG. 7

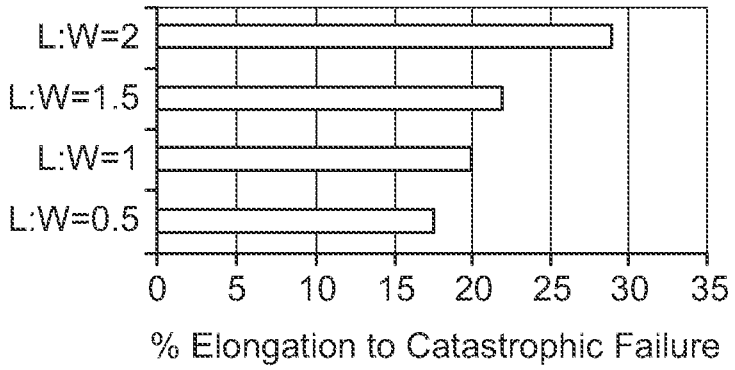

L:W=2
L:W=1.5
L:W=1
L:W=0.5
0
5
10
15
20
25
30
35
% Elongation to Catastrophic Failure

FIG. 8

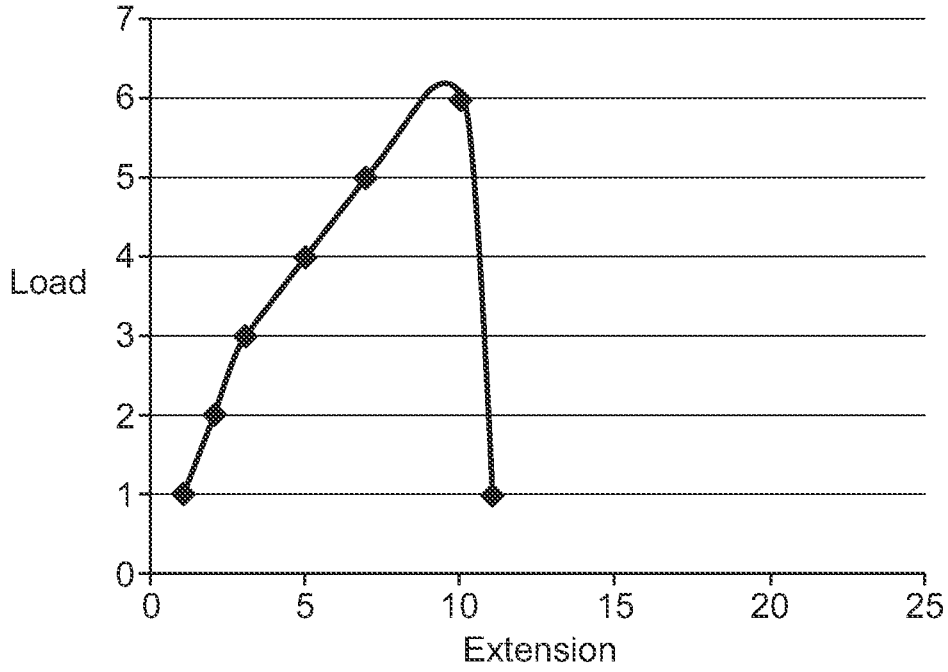
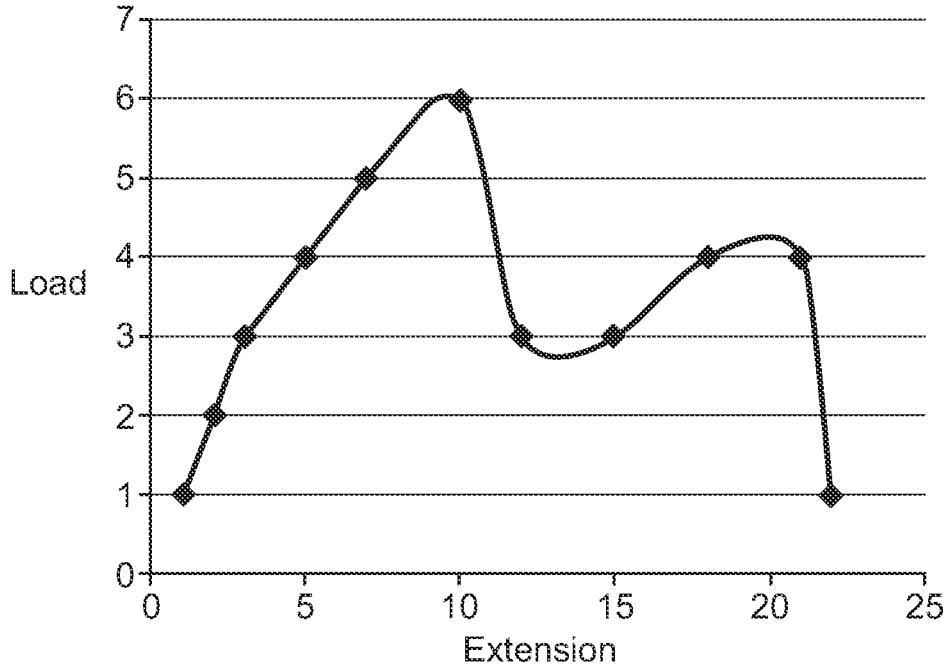

Load
0
1
2
3
4
5
6
7
0
5
10
15
20
25
Extension

FIG. 9


Load
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25
Extension

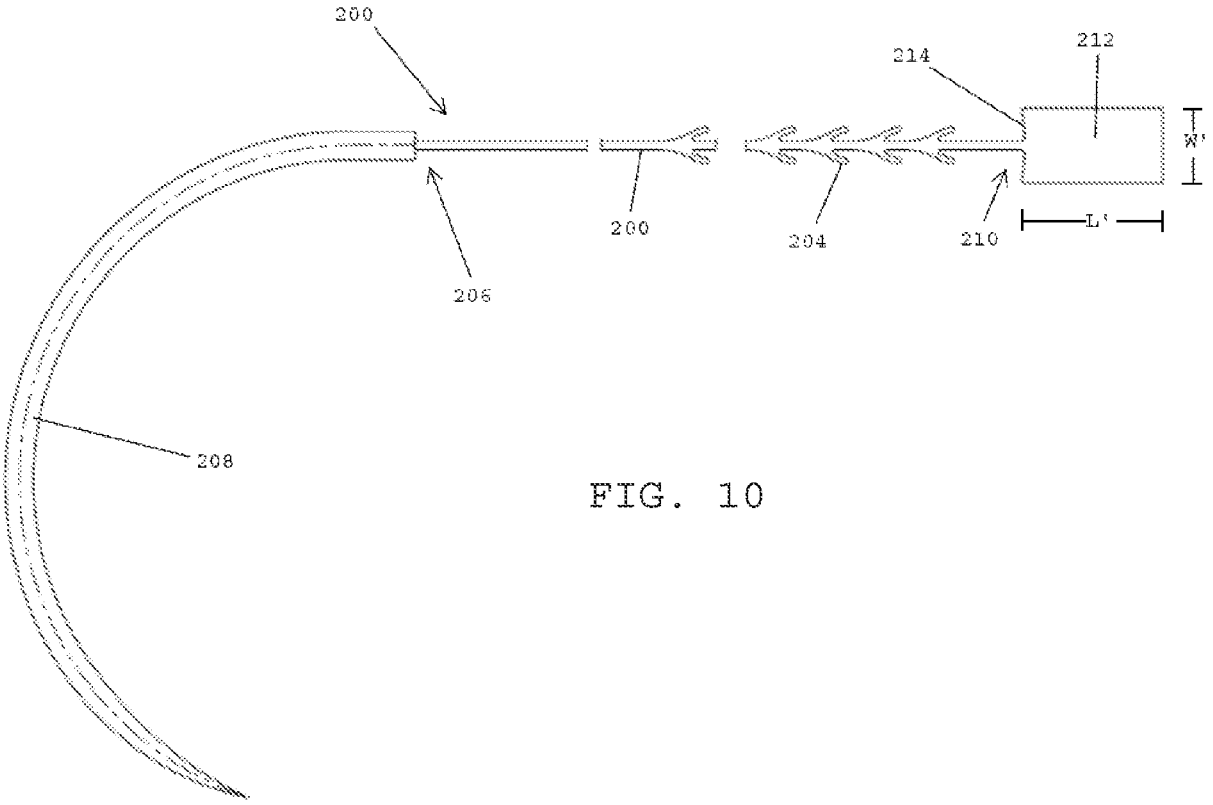


FIG. 10

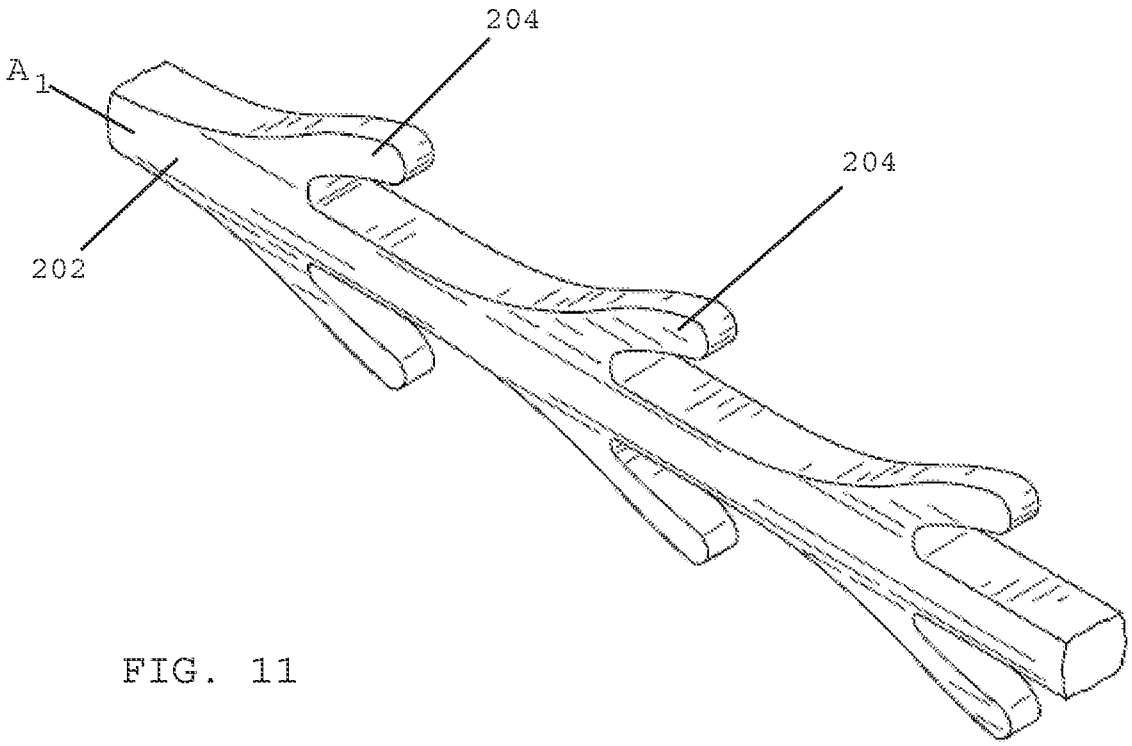


FIG. 11

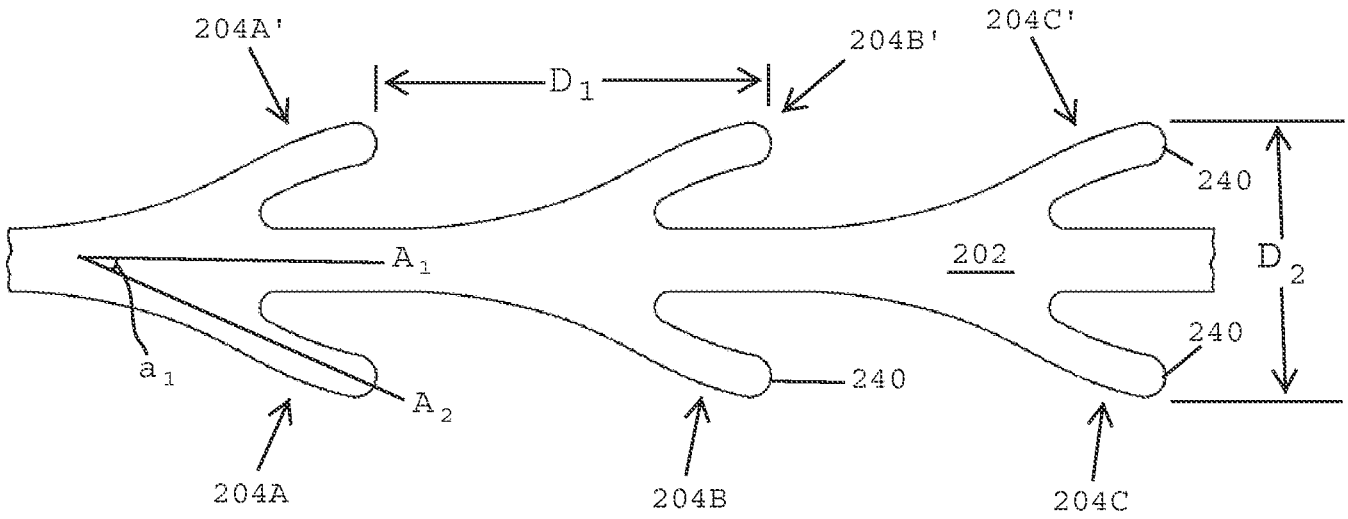


FIG. 12A

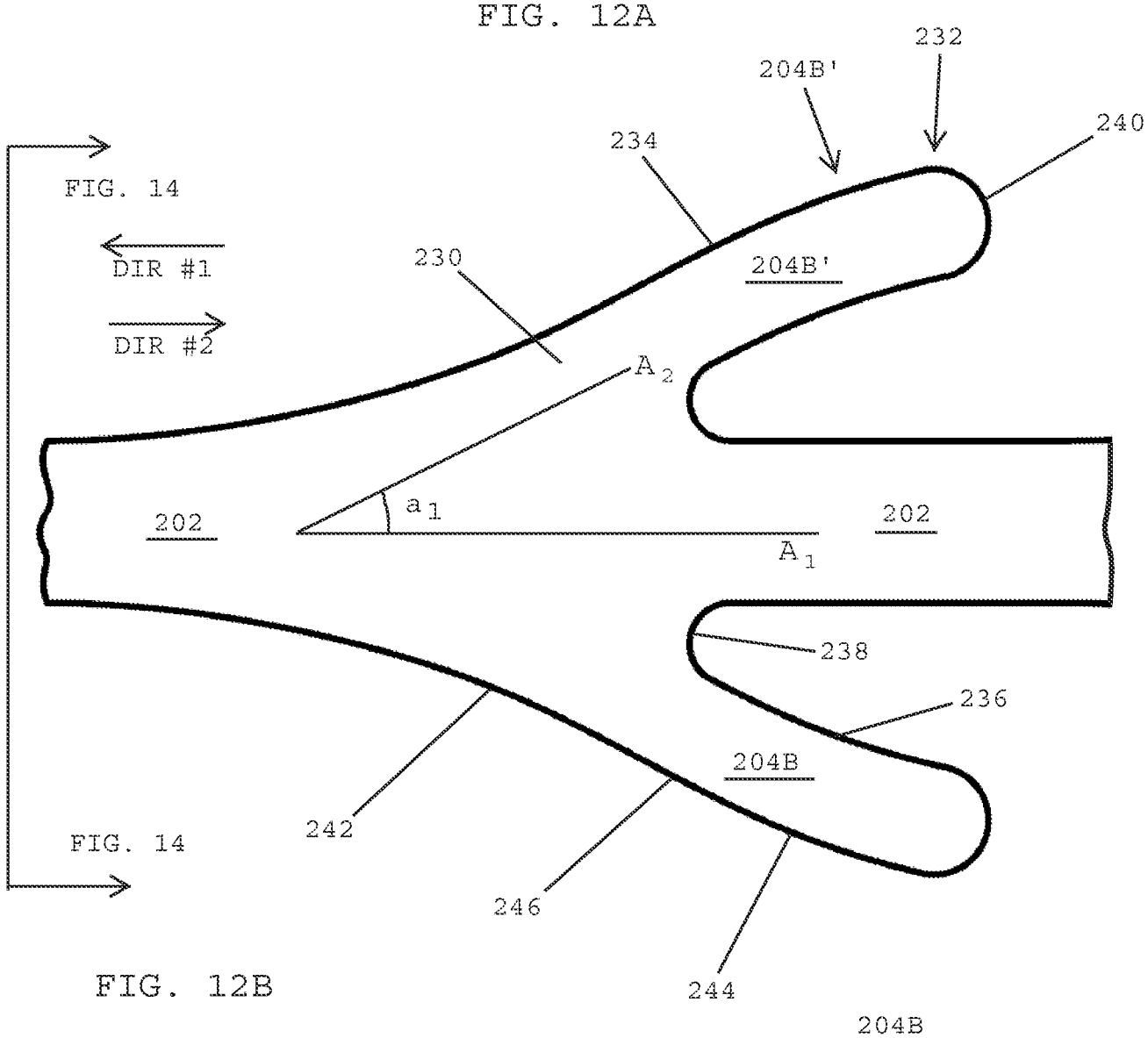


FIG. 12B

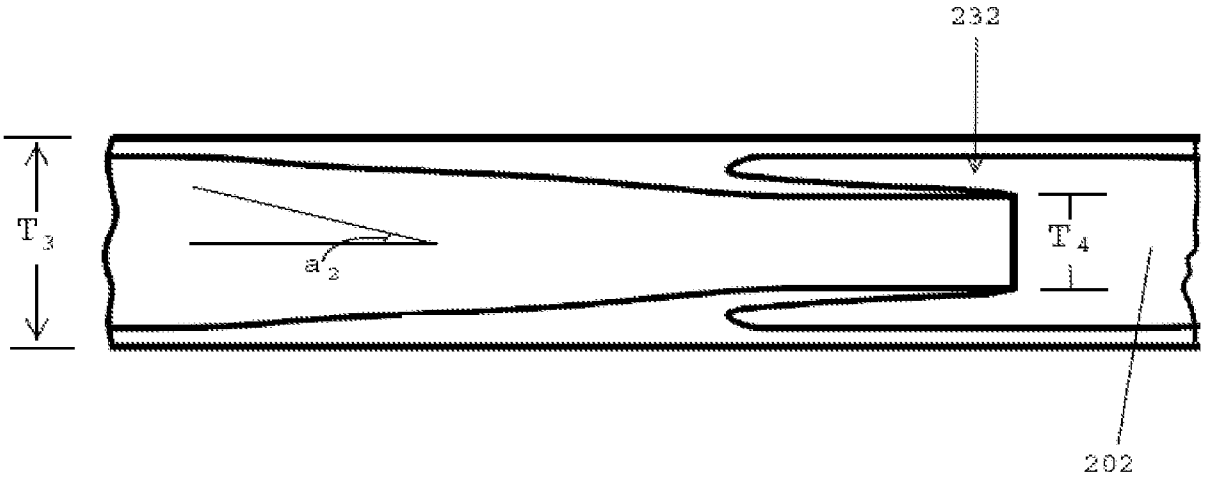
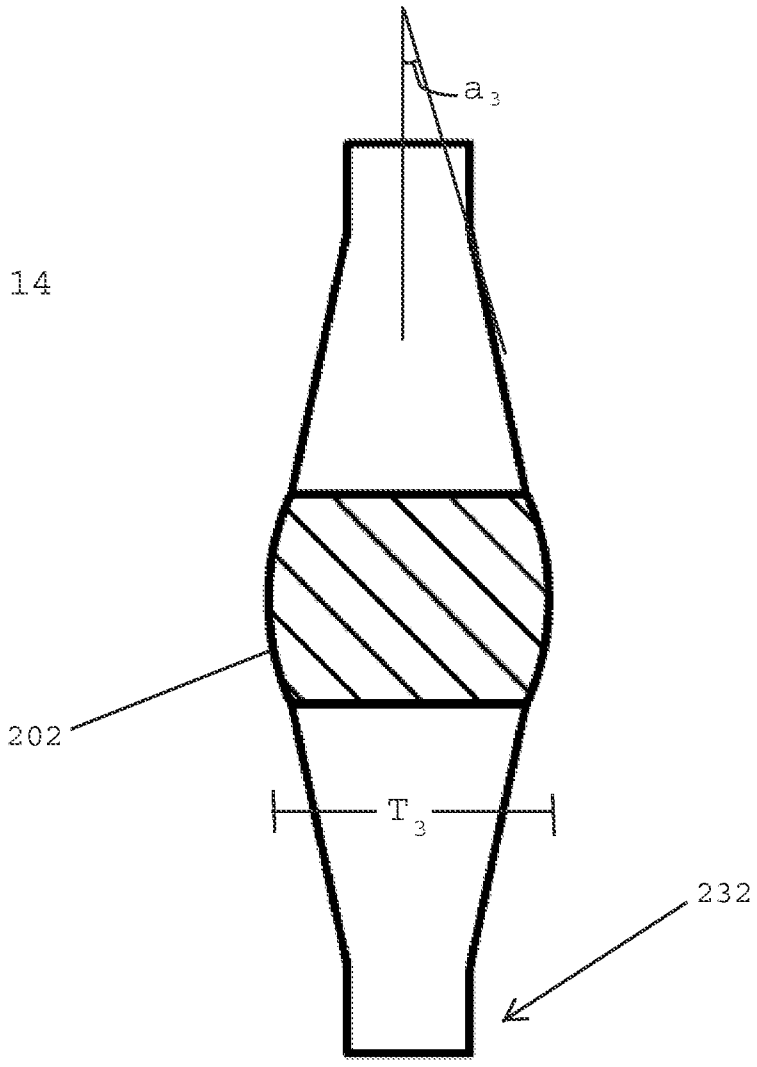


FIG. 13

FIG. 14



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/059907

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/06
ADD. A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/281357 A1 (SUNG AN-MIN JASON [US] ET AL) 13 November 2008 (2008-11-13) paragraphs [0057] - [0059]; figures 4-6	1-14
X	US 2008/312688 A1 (NAWROCKI JESSE G [US] ET AL) 18 December 2008 (2008-12-18) paragraphs [0024] - [0026]; figures 2,6	1-14
X	WO 2009/020795 A1 (ETHICON INC [US]; YUAN JIE JENNY [US]; CROMBIE JOHN S [US]) 12 February 2009 (2009-02-12) figures 2a,6	1-14
X	US 2010/211098 A1 (HADBA AHMAD ROBERT [US] ET AL) 19 August 2010 (2010-08-19) paragraphs [0028] - [0030], [0038], [0039]; figures 1,7,8,	1-3,5-9, 12-14

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 November 2013	21/01/2014

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Maier, Christian

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/059907

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	WO 2013/048947 A1 (ETHICON INC [US]; NAWROCKI JESSE G [US]; LINDH DAVID C SR [US]; PERKIN) 4 April 2013 (2013-04-04) the whole document -----	1-14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/059907

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14

A wound closure device comprising a filamentary element having a proximal end and a distal end, and a plurality of barbs extending outwardly from said filamentary element, each of said barbs having a base connected with said filamentary element, a tip spaced from said base, and an outer edge that extends between said base and said tip, wherein said outer edge includes a first section having a concave surface that extends between said base and a transition point of said barb and a second section having a convex surface that extends between said transition point of said barb and said tip of said barb, so that the insertion force required to pass the wound closure device through tissue is reduced.

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2. claims: 15-20

A wound closure device comprising a filamentary element having a proximal end, a distal end, and a plurality of barbs extending outwardly from said filamentary element, each said barb having a base connected with said filamentary element, a tip spaced from said base, and an outer edge that extends between said base and said tip, and wherein said tip has a convex surface facing the distal end of said filamentary element, so that the holding strength of the wound closure device within tissue is increased.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/059907

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008281357 A1	13-11-2008	CA 2687065 A1	20-11-2008
		EP 2142105 A1	13-01-2010
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WO 2013048947 A1	04-04-2013	US 2013085525 A1	04-04-2013
		WO 2013048947 A1	04-04-2013

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 104640508 A
(43)申请公布日 2015.05.20

(21)申请号 201380048320.8
(22)申请日 2013.09.16
(30)优先权数据
13/621625 2012.09.17 US
(85)PCT国际申请进入国家阶段日
2015.03.17
(86)PCT国际申请的申请数据
PCT/US2013/059907 2013.09.16
(87)PCT国际申请的公布数据
WO2014/043610 EN 2014.03.20
(71)申请人 伊西康公司
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(72)发明人 J.G. 纳罗基 J.T. 佩金斯
D.C. 老林德
(74)专利代理机构 中国专利代理(香港)有限公司 72001
代理人 李强 胡斌
(51)Int.Cl.
A61B 17/06(2006.01)
A61B 17/04(2006.01)

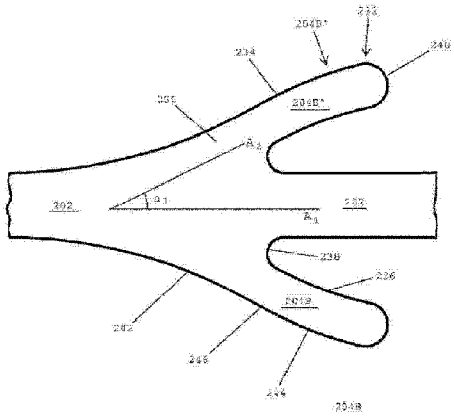
权利要求书2页 说明书8页 附图6页

(54)发明名称

具有有利于穿过组织并且增加保持强度的成轮廓倒钩的带倒钩缝合线

(57)摘要

本发明公开一种伤口闭合装置(200),其包括具有近侧端部(206)和远侧端部(210)的丝状元件(202)以及从丝状元件向外延伸的多个倒钩(204)。每个倒钩具有与丝状元件连接的基部(230)、与基部间隔的顶端(232)以及在基部和顶端之间延伸的外边缘(234)。外边缘包括第一部分(242)和第二部分(244),所述第一部分(242)具有在基部和倒钩的过渡点(246)之间延伸的凹形表面,所述第二部分(244)具有在倒钩的过渡点和倒钩的顶端之间延伸的凸形表面。外边缘在倒钩的过渡点处从第一部分的凹形表面转变至第二部分的凸形曲面。倒钩的顶端具有面向丝状元件的远侧端部的凸形弯曲表面。倒钩的外边缘的独特双半径形状以及倒钩的顶端在沿第一方向牵拉丝状元件穿过组织时最小化阻力,并且在沿相反的第二方向牵拉丝状元件穿过组织时最大化移动的阻力,以便使伤口闭合装置保持固定。



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1. 一种伤口闭合装置，包括：

丝状元件，所述丝状元件具有近侧端部和远侧端部；和

多个倒钩，所述多个倒钩从所述丝状元件向外延伸，每个所述倒钩具有与所述丝状元件连接的基部、与所述基部间隔的顶端以及在所述基部和所述顶端之间延伸的外边缘，其中所述外边缘包括第一部分和第二部分，所述第一部分具有在所述基部和所述倒钩的过渡点之间延伸的凹形表面，所述第二部分具有在所述倒钩的所述过渡点和所述倒钩的所述顶端之间延伸的凸形表面。

2. 根据权利要求 1 所述的伤口闭合装置，其中所述倒钩的所述第一部分的所述凹形表面具有约 0.075-0.25 英寸的半径，并且所述倒钩的所述第二部分的所述凸形表面具有约 0.05-0.1 英寸的半径。

3. 根据权利要求 1 所述的伤口闭合装置，其中所述外边缘在所述倒钩的所述过渡点处从所述第一部分的所述凹形表面转变至所述第二部分的所述凸形曲面。

4. 根据权利要求 1 所述的伤口闭合装置，其中所述倒钩的所述顶端具有面向所述丝状元件的远侧端部的凸形弯曲表面。

5. 根据权利要求 1 所述的伤口闭合装置，其中所述丝状元件具有长度，并且所述倒钩沿所述丝状元件的长度均匀间隔。

6. 根据权利要求 5 所述的伤口闭合装置，其中所述均匀间隔的倒钩的所述顶端限定约 0.03-0.09 英寸的顶端至顶端节距。

7. 根据权利要求 5 所述的伤口闭合装置，其中所述多个倒钩包括沿所述丝状元件的长度均匀间隔的成对的倒钩，并且其中每个所述对中的所述倒钩彼此对准。

8. 根据权利要求 7 所述的伤口闭合装置，其中每个所述对中的所述倒钩远离彼此突出，并且设置在所述丝状元件的相对的侧上。

9. 根据权利要求 8 所述的伤口闭合装置，其中每个所述对中的所述倒钩的所述顶端限定约 0.025-0.1 英寸的顶端至顶端横向距离。

10. 根据权利要求 1 所述的伤口闭合装置，其中每个所述倒钩具有背离所述丝状元件的所述外边缘和与所述丝状元件间隔且面向所述丝状元件的内边缘，并且其中每个所述顶端具有在所述外边缘和内边缘之间延伸的凸形弯曲外表面，所述凸形弯曲外表面具有约 0.003-0.006 英寸的半径。

11. 根据权利要求 10 所述的伤口闭合装置，其中所述倒钩的所述内边缘在所述倒钩基部和所述倒钩顶端之间延伸，并且其中所述倒钩包括在所述倒钩的所述内边缘和所述丝状元件之间延伸的内部凹形表面，所述内部凹形表面具有约 0.002-0.006 英寸的半径。

12. 根据权利要求 1 所述的伤口闭合装置，其中所述倒钩中的至少一个沿纵向轴线延伸，所述纵向轴线与所述丝状元件的纵向轴线一起限定约 5-60° 的锐角。

13. 根据权利要求 1 所述的伤口闭合装置，其中所述倒钩的所述基部比所述倒钩的所述顶端厚，并且其中每个所述倒钩在所述基部和所述顶端之间以约 1-20° 的角度向内渐缩。

14. 根据权利要求 1 所述的伤口闭合装置，还包括与所述丝状元件的远侧端部连接的止挡元件，所述止挡元件具有总表面积以及由厚度和宽度限定的前缘面积，所述前缘面积基本上垂直于所述丝状元件的纵向轴线延伸，其中所述前缘面积与所述总表面积的比率小

于 10％。

15. 一种伤口闭合装置，包括：

丝状元件，所述丝状元件具有近侧端部、远侧端部以及在所述近侧端部和远侧端部之间延伸的纵向轴线；和

多个倒钩，所述多个倒钩从所述丝状元件向外延伸，每个所述倒钩具有与所述丝状元件连接的基部、与所述基部间隔的顶端以及在所述基部和所述顶端之间延伸的外边缘，其中所述外边缘包括第一部分和第二部分，所述第一部分具有在所述基部和所述倒钩的过渡点之间延伸的凹形表面，所述凹形表面具有约 0.075-0.25 英寸的半径，所述第二部分具有在所述倒钩的所述过渡点和所述倒钩的所述顶端之间延伸的凸形表面，所述凸形表面具有约 0.05-0.1 英寸的半径，并且其中所述顶端具有面向所述丝状元件的远侧端部的凸形表面，所述凸形表面具有约 0.003-0.006 英寸的半径。

16. 根据权利要求 15 所述的伤口闭合装置，其中所述倒钩沿所述丝状元件的长度均匀间隔并且限定约 0.03-0.09 英寸的顶端至顶端纵向节距，并且其中所述多个倒钩包括彼此对准并且沿所述丝状元件的长度均匀间隔的成对的倒钩，每个所述对中的所述倒钩远离彼此突出，并且设置在所述丝状元件的相对的侧上，并且其中每个所述对中的所述倒钩的所述顶端限定约 0.025-0.1 英寸的顶端至顶端横向距离。

17. 根据权利要求 15 所述的伤口闭合装置，还包括与所述丝状元件的远侧端部连接的止挡元件，所述止挡元件具有总表面积以及由厚度和宽度限定的前缘面积，所述前缘面积基本上垂直于所述丝状元件的纵向轴线延伸，其中所述前缘面积与所述总表面积的比率小于 10％。

18. 根据权利要求 17 所述的伤口闭合装置，其中所述止挡元件的前缘面积与所述止挡元件的总表面积的比率小于 5％。

19. 根据权利要求 18 所述的伤口闭合装置，其中所述止挡元件的宽度大于 70 密耳，所述止挡元件的长度大于 70 密耳，所述止挡元件的最小厚度为约 4-12 密耳，并且所述止挡元件的最大厚度为约 6-25 密耳。

20. 一种伤口闭合装置，包括：

丝状元件，所述丝状元件具有近侧端部和远侧端部；和

多个倒钩，所述多个倒钩从所述丝状元件向外延伸，每个所述倒钩具有与所述丝状元件连接的基部、与所述基部间隔的顶端、背离所述丝状元件并在所述基部和所述顶端之间延伸的外边缘以及面向所述丝状元件并在所述基部和所述顶端之间延伸的内边缘，其中所述外边缘具有双半径曲面，所述双半径曲面包括在所述基部和所述倒钩的过渡点之间延伸的第一凹形表面以及在所述倒钩的所述过渡点和所述倒钩的所述顶端之间延伸的第二凸形表面，并且其中所述顶端具有面向所述丝状元件的远侧端部的凸形表面。

具有有利于穿过组织并且增加保持强度的成轮廓倒钩的带倒钩缝合线

[0001] 相关申请的交叉引用

[0002] 本申请为 2011 年 9 月 29 日提交的共同转让的美国专利申请序列号 13/248,542 的部分继续申请，其公开内容以引用的方式并入本文。

背景技术

技术领域

[0003]

[0004] 本发明整体涉及医疗装置的领域，并且更具体地涉及具有倒钩的带倒钩缝合线，所述倒钩具体地设计成当沿第一方向被牵拉时有利于穿过组织，并且当沿相反的第二方向被牵拉时表现出极大保持强度。

[0005] 相关领域的说明

[0006] 许多伤口和外科切口是使用外科缝合线或其它形式的外科闭合装置来闭合的。常常被称为带倒钩缝合线的一种类型的外科缝合线为熟知的，并且近来因在各种医疗应用中的使用而引起注意。通常，带倒钩缝合线被构造为具有从缝合线的中心芯或长丝向外延伸的一系列“倒钩”或“突起”（在本文中互换使用）。倒钩用于增加缝合线的保持强度和 / 或消除对打结的需要。倒钩的尺寸和形状在外科定形中具有实际限制，并且不能在需要增大的保持强度的任何地方只是简单地增大尺寸。

[0007] 一些常规的缝合线和带倒钩缝合线已知在缝合线的远侧端部上包括锚定件、突片等，以在远侧端部处提供增加缝合线的保持强度并且消除对打结以固定缝合线的需要的“止挡件”。常规思维表明：止挡件的沿垂直于缝合线插入方向的方向的表面积越大，所获得的保持强度将越大。然而，因为大块体在外科手术中可能是无法忍受的和 / 或可触知的并且因此是不期望的，所以在尺寸上同样存在实际限制。另外，在具有 T 形止挡件的情况下，当施加弯矩时，垂直部分在结构上是脆弱的，如当牵拉缝合线以逼近伤口时的情况。

[0008] 根据以上所识别的缺陷，依然需要具有增强的保持强度而不显著增加缝合线的插入力、刚度或装置的可触知性的外科缝合线。还需要具有倒钩的外科缝合线，该倒钩被设计成当沿第一方向牵拉缝合线时允许缝合线容易穿过组织，但当沿相反的第二方向牵拉缝合线时，倒钩表现出用于将缝合线保持在适当的位置的极大保持强度。

发明内容

[0009] 本发明提供伤口闭合装置，该伤口闭合装置包括：丝状元件，该丝状元件具有近侧端部和远侧端部；止挡元件，该止挡元件联接到丝状元件的远侧端部并具有总表面积以及由厚度和宽度限定的前缘面积。前缘面积面向基本上垂直于丝状元件的纵向轴线的方向，并且前缘面积与总表面积的比率小于 10%。根据一个实施例，该比率小于 5%。

[0010] 根据各种实施例，止挡元件的宽度可大于 70 密耳，止挡元件的长度可大于 70 密

耳，和 / 或所述止挡元件的最大厚度可在 6 和 25 密耳之间。

[0011] 根据一个实施例，止挡元件的厚度可变化，和 / 或止挡元件的最小厚度可在 4 和 12 密耳之间。根据另一个实施例，前缘厚度在中心处和 / 或第一外边缘处和 / 或第二外边缘处包括最大厚度，并且在中心与第一外边缘之间以及在中心与第二外边缘之间的位置处包括最小厚度。

[0012] 在另一个实施例中，伤口闭合装置还包括多个突出，该多个突出沿丝状元件的长度的至少一部分从丝状元件向外延伸。多个突出可从所述丝状元件向外延伸大约 6-25 密耳。

[0013] 该装置可由可吸收的或不可吸收的聚合物材料、金属材料或陶瓷材料制成。在另一个实施例中，该装置由聚合物材料制成，该聚合物材料选自由下列项制成的可吸收的和不可吸收的均聚物、无规共聚物、嵌段共聚物或共混物：聚二氧杂环己酮、丙交酯乙交酯共聚物 (polyglactin)、聚乙醇酸；乙交酯、丙交酯、和 / 或己内酯的共聚物；聚含氧酸酯、聚卡普隆、聚丙烯、聚乙烯、聚偏二氟乙烯 (PVDF)、六氟丙烯；偏二氟乙烯和六氟丙烯的共聚物；聚酯、聚对苯二甲酸乙二酯、聚对苯二甲酸丁二醇酯、二醇改性的聚对苯二甲酸乙二酯、聚四氟乙烯、含氟聚合物、热塑性弹性体、离聚物；乙烯和甲基丙烯酸的共聚物；聚酰胺、聚环氧丁烷、聚苯乙烯、聚丁二烯、聚丁烯等，包括可吸收的和不可吸收的材料的组合物和 / 或共聚物。

[0014] 根据另一个实施例，止挡元件的长度与最大厚度的比率大于 4。

[0015] 在另一个实施例中，止挡件的最大厚度为大约 8-25 密耳，止挡件的宽度为大约 70-120 密耳，并且止挡件的长度为大约 39-200 密耳。

[0016] 本发明还提供伤口闭合装置，该伤口闭合装置包括：丝状元件，该丝状元件沿纵向轴线在近侧端部和远侧端部之间延伸；和止挡元件，该止挡元件联接到丝状元件的远侧端部并具有基本上平行于丝状元件的纵向轴线延伸的长度、基本上垂直于所述纵向轴线延伸的宽度以及最大厚度。止挡元件的长度与最大厚度的比率为至少 4。

[0017] 在另选的实施例中，止挡元件的最大厚度在 8 和 25 密耳之间，止挡元件的长度大于 39 密耳，和 / 或止挡元件的宽度在 70 和 120 密耳之间。

[0018] 在另一个实施例中，伤口闭合装置还包括多个突出，该多个突出沿丝状元件的长度的至少一部分从丝状元件向外延伸。

[0019] 在另一个实施例中，止挡元件的厚度可变化，并且在另一个具体实施例中，前缘厚度包括在中心处和 / 或第一外边缘处和 / 或第二外边缘处包括最大厚度，并且在中心与第一外边缘之间以及在中心与第二外边缘之间的位置处包括最小厚度。

[0020] 还提供伤口闭合装置，该伤口闭合装置包括：丝状元件，该丝状元件沿纵向轴线在近侧端部和远侧端部之间延伸；和止挡元件，该止挡元件联接到丝状元件的远侧端部。止挡元件具有基本上平行于丝状元件的纵向轴线延伸的长度、基本上垂直于纵向轴线延伸的宽度和最大厚度，并且对于止挡元件的任何给定最大厚度，止挡元件的长度与宽度的比率为至少 1。

[0021] 在另一个实施例中，止挡元件的长度与宽度的比率为至少 1.5。

[0022] 在一个实施例中，伤口闭合装置优选地包括：丝状元件，该丝状元件具有近侧端部和远侧端部；和多个倒钩，该多个倒钩从丝状元件向外延伸。每个倒钩有利地具有与丝状元

件连接的基部、与基部间隔的顶端以及在基部和顶端之间延伸的外边缘。

[0023] 在一个实施例中，外边缘有利地包括第一部分和第二部分，所述第一部分具有在基部和倒钩的过渡点之间延伸的凹形表面，所述第二部分具有在倒钩的过渡点和倒钩的顶端之间延伸的凸形表面。外边缘优选地在倒钩的过渡点处从第一部分的凹形表面转变至第二部分的凸形曲面。在一个实施例中，倒钩的第一部分的凹形表面具有约 0.075-0.25 英寸的半径，并且倒钩的第二部分的凸形表面具有约 0.05-0.1 英寸的半径。

[0024] 在一个实施例中，至少一个倒钩具有顶端，该顶端具有面向丝状元件的远侧端部的凸形弯曲表面。凸形弯曲外表面有利地在倒钩的外边缘和内边缘之间延伸并具有约 0.003-0.006 英寸的半径。

[0025] 在一个实施例中，丝状元件具有长度，并且倒钩沿丝状元件的长度均匀间隔。在一个实施例中，均匀间隔的倒钩的顶端限定约 0.03-0.09 英寸的顶端至顶端节距。

[0026] 在一个实施例中，倒钩包括沿丝状元件的长度均匀间隔的多对倒钩。每对中的倒钩有利地沿丝状元件的长度彼此对准。在一个实施例中，每对中的倒钩远离彼此突出，并设置在丝状元件的相对侧上。在一个实施例中，每对中的倒钩的顶端限定约 0.025-0.1 英寸的顶端至顶端横向距离。

[0027] 在一个实施例中，每个倒钩具有背离丝状元件的外边缘以及与丝状元件间隔且面向丝状元件的内边缘。在一个实施例中，至少一个倒钩具有在倒钩基部和倒钩顶端之间延伸的内边缘。在一个实施例中，倒钩包括在倒钩的内边缘和丝状元件之间延伸的内部凹形表面，该内部凹形表面具有约 0.002-0.006 英寸的半径。

[0028] 在一个实施例中，倒钩中的至少一个沿纵向轴线延伸，该纵向轴线与丝状元件的纵向轴线一起限定约 5-60° 的锐角。

[0029] 在一个实施例中，倒钩的基部比倒钩的顶端厚。在一个实施例中，倒钩在基部和顶端之间以约 1-20° 的角度向内渐缩。

[0030] 在一个实施例中，伤口闭合装置包括与丝状元件的远侧端部连接的止挡元件。止挡元件具有总表面积和前缘面积，该前缘面积由厚度和宽度限定，由此前缘面积基本上垂直于丝状元件的纵向轴线延伸。在一个实施例中，前缘面积与总表面积的比率小于 10％。

[0031] 在一个实施例中，伤口闭合装置包括：丝状元件，该丝状元件具有近侧端部、远侧端部以及在近侧端部和远侧端部之间延伸的纵向轴线；和多个倒钩，该多个倒钩从丝状元件向外延伸。在一个实施例中，每个倒钩具有与丝状元件连接的基部、与基部间隔的顶端以及在基部和顶端之间延伸的外边缘。倒钩的外边缘优选地包括第一部分和第二部分，所述第一部分具有在基部和倒钩的过渡点之间延伸的凹形表面，所述凹形表面具有约 0.075-0.25 英寸的半径；第二部分具有在倒钩的过渡点和倒钩的顶端之间延伸的凸形表面，所述凸形表面具有约 0.05-0.1 英寸的半径。倒钩顶端有利地具有面向丝状元件的远侧端部的凸形表面，该凸形表面具有约 0.003-0.006 英寸的半径。

[0032] 在一个实施例中，倒钩沿丝状元件的长度均匀间隔并限定约 0.03-0.09 的顶端至顶端纵向节距。多个倒钩优选地包括彼此对准且沿丝状元件的长度均匀间隔的多对倒钩。每对中的倒钩优选地远离彼此突出，并设置在丝状元件的相对侧上，由此每对中的倒钩的顶端限定约 0.025-0.1 英寸的顶端至顶端横向距离。

[0033] 本发明的这些目标和其它目标、特征和优点可通过结合附图阅读以下对示例性实

施例的详细描述而显而易见。

附图说明

[0034] 图 1 示出根据本发明的一个实施例的包括插入针和止挡元件的伤口闭合装置。

[0035] 图 2 为图 1 的伤口闭合装置的远侧端部和止挡元件的放大视图。

[0036] 图 3 为图 1 和图 2 的伤口闭合装置的止挡元件的顶视图。

[0037] 图 4 为图 1-3 的伤口闭合装置的止挡元件的侧视图。

[0038] 图 5 为沿图 5- 图 5 的线截取的图 3 的伤口闭合装置的止挡元件的剖面图。

[0039] 图 6 为示出具有相等前缘最大厚度和宽度但具有变化长度的固定突片的保持强度的图。

[0040] 图 7 为示出给定最大厚度情况下的固定突片的伸长作为长宽比的函数的图。

[0041] 图 8 为示出固定突片长宽比为 0.5 情况下的负载 - 延伸曲线的图。

[0042] 图 9 为示出固定突片长宽比为 2 情况下的负载 - 延伸曲线的图。

[0043] 图 10 示出根据本发明的一个实施例的伤口闭合装置，该伤口闭合装置包括具有倒钩的丝状元件、与丝状元件的前端连接的插入针以及与丝状元件的后端连接的止挡元件。

[0044] 图 11 示出图 10 中所示的具有倒钩的丝状元件的一部分的透视图。

[0045] 图 12A 示出图 11 中所示的具有倒钩的丝状元件的一部分的左侧视图。

[0046] 图 12B 示出图 12A 中所示的具有倒钩的丝状元件的一部分的放大图。

[0047] 图 13 示出图 12B 中所示的具有倒钩的丝状元件的一部分的顶部平面图。

[0048] 图 14 示出图 12B 的沿图 14- 图 14 的线截取的具有倒钩的丝状元件的剖面图。

具体实施方式

[0049] 图 1 示出了根据本发明的伤口闭合装置 100 的示例性实施例。参考图 1 和图 2，伤口闭合装置 100 包括包含任何合适的外科缝合线材料（即可吸收的或不可吸收的聚合物材料、金属或陶瓷材料）的丝状元件 102，该丝状元件优选地包括从其向外延伸的多个倒钩 104。缝合线可通过任何合适的方法形成，但优选地是由预成形材料以全文以引用方式并入本文的美国专利公布 2007/0257395 中更详细描述的方式冲切而成的复合轮廓。参考图 1，伤口闭合装置的近侧端部 106 可包括针或其它插入装置 108。参考图 1-5，在一个实施例中，伤口闭合装置的远侧端部 110 包括固定突片或止挡元件 112 等。止挡元件 112 具有由前缘厚度 t（图 5）和前缘宽度 w（图 3 和图 5）限定的前缘 114。止挡元件 112 还具有长度 l（图 3）。如先前所指出的那样，当施加弯矩时，诸如当将张力施加至缝合线以逼近伤口时，已知的 T 形构型具有相对弱的刚度。图 6 中描绘的图更清楚地示出本发明相比 T 形端部构型的优点。制造具有相等前缘最大厚度 (t) 和宽度 (w)（前缘面积）但具有变化长度 (l) 的固定突片，并且测试保持强度。通过以下方式来测试保持强度：使带倒钩缝合线穿过猪的腹壁筋膜样本，并且牵拉固定突片直到由于止挡件以某种方式破裂、止挡件牵拉穿过组织或两者的组合而失效。图 6 中记录并且示出失效之前的最大负载。

[0050] 如图 6 图表中所示，当几何形状变得更类似 T 形构件时，或换句话讲，当长度与前缘面积的比率或长度与最大厚度的比率减小时，保持强度减小。保持强度可通过增加止挡

件的厚度或宽度来增大，但如先前所指出的那样，关于可植入的尺寸和质量存在实际和临床限制。

[0051] 除长度与最大厚度或前缘面积的比率之外，在任何给定最大厚度情况下，长度 l 与宽度 w 的比率也是重要考虑因素。出人意料地并且反直觉地，至少 1:1 的比率提供增大许多的保持强度。图 7 示出给定最大厚度情况下的固定止挡件或突片的伸长作为长宽比的函数。如图所示，达到严重失效所需的伸长百分比（或更简单地，变形量）随长宽比的增大而增大。

[0052] 除原始伸长百分比之外，装置失效所需的实际能量的量随长宽比的增大而增大。这由图 8 和图 9 示出，其中在负载 - 延伸曲线以下的面积是直到严重失效的应变能量的量度。随着长宽比增大，达到严重失效所需的应变能量的量显著增大。图 8 示出具有 0.5:1 的长宽比的固定突片的负载 - 延伸曲线。如图所示，装置达到峰值负载随后因突然失效而显著减小。图 94 示出具有 2:1 的长宽比的固定突片的负载 - 延伸曲线。如图所示，曲线在严重失效发生之前具有第二峰值和大得多的延伸。换句话讲，随着长宽比从 0.5 增大至 2，应变能量显著增大。

[0053] 参考图 3-5，当缝合线处于张力下时，止挡元件 112 的前缘 114 具有与组织接触的相对小的表面积，但它的长度 l 与最大厚度 t 的比率非常大。因此，沿负载的方向与组织接触的实际面积（即前缘面积 114 的面积）相对于止挡元件 112 的总尺寸非常小。这种相对长的长度但极小厚度允许止挡件在伤口中放置在相对平坦的位置，这最小化可触知性并且允许组织的相对侧整齐地覆盖止挡件。因为止挡件恰好地位于组织中，止挡件可被放置在伤口的顶点、伤口的一侧的侧面等处，而不妨碍外科医生的单独闭合技术。

[0054] 在优选的实施例中，前缘 114 相对于止挡件 112 的总表面积（所有侧面的表面积的和）较小，优选地小于 10％还更优选地小于 5％。这是反直觉的，因为常规思维表明：为了增大保持强度和 / 或最小化失效，人们必须增大或最大化承受负载的表面积，以便使负载扩展开并减小每单位面积的负载。相对长的长度 l 但极小厚度 t 产生临床优点，包括如上所述的最小化可触知性的平坦定位以及万向定位。

[0055] 根据在图 5 的剖面图中详细示出的一个优选实施例，止挡元件 112 的前缘 114 优选地不是矩形，而是具有在其宽度上变化的厚度。在一个实施例中，止挡元件 112 在其外边缘 120 和中心 122 处具有最大厚度 t，并且在位于中心和外边缘之间的点处具有最小厚度 t_2。在该实施例中，丝状元件 102 具有大约 5-25 密耳的长丝宽度 f，并且倒钩 104 从丝状元件 102 向外延伸大约 6-25 密耳的距离 d（图 2）。参考图 3，止挡件 112 具有至少 39 密耳、优选地 100 至 200 密耳的长度 l，以及大于 70 密耳、更优选地大于 90 密耳并且最优选地大于 95 密耳的宽度。另外，参考图 3-5，最大厚度 t 大于 6 密耳并且优选地在 10 和 25 密耳之间，并且最小厚度 t_2 小于 15 密耳，但优选地在大约 5 和 9 密耳之间。在一个实施例中，长度与最大厚度的比率优选地大于 4，并且长度与最小厚度的比率优选地大于 9。在一个实施例中，长宽比优选地大于 1，还更优选地大于 1.5。

[0056] 参考图 10，在一个实施例中，伤口闭合装置 200 优选地包括丝状元件 202，该丝状元件具有从其向外延伸的倒钩 204。丝状元件 202 有利地包括近侧端部 206、与丝状元件 202 的近侧端部 206 连接的插入针 208、远离丝状元件 202 的近侧端部 206 的丝状元件 202 的远侧端部 210、以及与丝状元件 202 的远侧端部 210 连接的止挡件 212。止挡元件 212 具

有前缘 214，该前缘具有前缘厚度（未示出）和前缘宽度 W'。止挡元件 212 还具有长度 L'。

[0057] 参考图 11，在一个实施例中，丝状元件 202 具有从丝状元件向外延伸的多个倒钩 204。参考图 12A 和图 12B，在一个实施例中，丝状元件 202 的倒钩 204 沿丝状元件 202 的长度（即沿纵向轴线 A_1）彼此均匀间隔。在一个实施例中，丝状元件 202 具有纵向轴线 A_1，并且倒钩 204 沿与纵向轴线 A_1 限定角度 α_1 的轴线 A_2 延伸。在一个实施例中，角度 α_1 为约 5-60°，还更优选地为约 10-49°。有利地选择角度 α_1 的准确尺寸，以控制倒钩 204 在穿过组织期间的柔韧性，并且还在伤口闭合装置 200 已被植入组织中之后建立倒钩保持强度。

[0058] 在一个实施例中，倒钩成对对准，成对倒钩在丝状元件 202 的相对侧上远离彼此延伸。图 12A 示出沿丝状元件 202 的长度彼此对准的不同的三对倒钩，包括第一对倒钩 204A、204A'、第二对倒钩 204B、204B' 和第三对倒钩 204C、204C'。因为仅示出丝状元件 202 的一小部分，图 12A 中仅示出三对倒钩。然而在其它实施例中，丝状元件 202 可包括沿丝状元件的长度彼此对准并且在丝状元件的相对侧上远离彼此延伸的 50 对、100 对、150 对或更多对倒钩。在一个实施例中，从丝状元件的相对侧延伸的倒钩中的至少一些相对彼此交错。

[0059] 参考图 12A 和图 12B，在一个实施例中，每个倒钩 204 包括与丝状元件 202 连接的基部 230、与基部 230 间隔的顶端 232、在基部 230 和顶端 232 之间延伸的外边缘 234、以及在基部 230 和顶端 232 之间延伸的内边缘 236。倒钩 204 的外边缘 234 优选地背离丝状元件 202，并且倒钩的内边缘 236 优选地面向丝状元件 202。每个倒钩 204 还有利地包括在倒钩 204 的内边缘 236 和丝状元件 202 之间延伸的内弯曲表面 238。

[0060] 参考图 12A，在一个实施例中，沿丝状元件 202 的纵向轴线 A_1 彼此间隔的相邻倒钩 204 的顶端 232 之间的距离限定约 0.03-0.09 英寸，还更优选地约 0.075 英寸的倒钩节距 D_1。在一个实施例中，对于所有倒钩，倒钩节距 D_1 是一致的，使得倒钩沿丝状元件的长度彼此均匀间隔。选择相邻顶端 232 之间的倒钩节距 D_1，以控制丝状元件 202 穿过组织并且提高伤口闭合装置 200 的保持强度。如果相邻倒钩顶端之间的倒钩节距 D_1 太大（即超过 0.09 英寸），那么伤口闭合装置的保持强度减小。如果相邻倒钩顶端的之间的倒钩节距 D_1 太小（即小于约 0.03 英寸），那么使伤口闭合装置 200 穿过组织所需的力增大至不期望的水平。

[0061] 参考图 12A，在一个实施例中，一对倒钩（例如，倒钩 204C 和 204C'）的倒钩之间的顶端至顶端横向距离 D_2 为约 0.025-0.1 英寸，还更优选地约 0.03-0.06 英寸。顶端至顶端横向距离 D_2 优选地控制伤口闭合装置 200 穿过组织，并且增强伤口闭合装置的保持强度。如果顶端至顶端横向距离 D_2 太小（即小于 0.025 英寸），那么伤口闭合装置 200 的保持强度减小至不期望的水平。如果顶端至顶端横向距离 D_2 太大（大于 0.1 英寸），那么使伤口闭合装置 200 穿过组织所需的力增大至不期望的水平。

[0062] 参考图 12A 和图 12B，在一个实施例中，倒钩 204 的顶端 232 限定具有约 0.003-0.006 英寸，还更优选地约 0.004 英寸的半径的凸形径向表面 240。针对每个倒钩，顶端 232 的凸形径向表面 240 有利地帮助控制倒钩 204 在穿过组织期间的柔韧性，并且帮助决定倒钩 204 的力矩臂，从而最小化倒钩一旦被植入组织中就向后弯曲的可能性。

[0063] 参考图 12B，在一个实施例中，每个倒钩 204 的外边缘 234 包括限定凹形表面的第一部分 242 以及限定凸形表面的第二部分 244。具有凹形表面的第一部分 242 在基部 230

和倒钩 204 的过渡点 246 之间延伸。具有凸形表面的第二部分 244 在倒钩 204 的过渡点 246 和倒钩 204 的顶端 232 之间延伸。在一个实施例中，第一部分 242 的凹形表面具有约 0.075-0.25 英寸，还更优选地约 0.09-0.2 英寸的半径。第一部分 242 的凹形表面优选地控制倒钩 204 的柔韧性并且控制伤口闭合装置穿过组织性。第一部分 242 的凹形表面限定倒钩 204 的力矩臂，这有利地最小化倒钩 204 一旦被植入组织中就向后弯曲的可能性。

[0064] 在一个实施例中，倒钩的第二部分 244 的凸形表面具有约 0.05-0.1 英寸，还更优选地约 0.07 英寸的半径。第二部分 244 的凸形表面优选地限定倒钩的力矩臂，帮助控制倒钩的柔韧性，并且促进倒钩和伤口闭合装置 200 穿过组织。

[0065] 参考图 12B，在一个实施例中，倒钩 204 中的一个或多个具有独特形状，当沿指定为 DIR#1 的第一方向牵拉带倒钩缝合线穿过组织时，该独特形状有利地使倒钩能够更易于向内朝丝状元件 202 塌缩，从而最小化沿第一方向 DIR#1 牵拉带倒钩缝合线穿过组织所需的力的量。具体地，倒钩 204 的外边缘的具有凹形形状的第一部分 242 最小化倒钩相对于组织的轮廓，从而最小化沿第一方向 DIR#1 牵拉带倒钩缝合线穿过组织所需的力的量。此外，当沿第一方向 DIR#1 牵拉缝合线时，倒钩的位于倒钩的过渡点 246 和倒钩的顶端 232 之间的第二部分 244 的凸形曲面最小化倒钩向内挠曲的阻力水平，使得阻力水平显著小于在第二部分 244 为直表面或凹形表面情况下将存在的水平。因此，具有包括凹形表面的第一部分 242 以及包括凸形表面的第二部分 244 的每个倒钩的外边缘 234 的独特形状最小化当沿第一方向 DIR#1 牵拉缝合线穿过组织时由带倒钩缝合线提供的阻力水平，并且使倒钩能够更容易地向内朝丝状元件 203 塌缩。在一个实施例中，可移动过渡点的位置并且半径变化以改变倒钩的力矩臂，这将改变沿第一方向穿过的容易度并且还改变沿第二方向移动的阻力。

[0066] 在一个实施例中，带倒钩缝合线包括具有独特形状的一个或多个倒钩 204，当沿指定为 DIR#2 的第二方向牵拉带倒钩缝合线穿过组织时，该独特形状有利地使倒钩能够更容易抵抗朝丝状元件 202 的近侧端部弯曲（向后弯曲），从而最大化沿第二方向 DIR#2 牵拉带倒钩缝合线穿过组织所需的力的量。在一个实施例中，当沿第二方向 DIR#2 牵拉缝合线时，倒钩的位于倒钩 204 的外边缘 234 上的第一部分 242 的凹形表面使倒钩能够更容易地远离丝状元件 202 挠曲（即向后弯曲），从而增加成对倒钩 204B、204B' 的相应顶端 232 之间的顶端至顶端横向距离 D_2（图 12A），这增加缝合线沿第二方向 DIR#2 移动的阻力。此外，倒钩 204 的顶端 232 处的凸形弯曲表面 240 在顶端处提供用于在沿方向 DIR#2 牵拉带倒钩缝合线时接触周围组织的更大表面积，以便进一步抵抗带倒钩缝合线沿第二方向 DIR#2 移动。提供具有凸形表面 240 的顶端 232 提供用于接合组织的更大表面积，并且提供优于具有成锐角表面的顶端的显著改善，该成锐角表面具有用于接合组织的更小表面积。在一个实施例中，提供具有凸形表面 240 的顶端 232 因顶端不具有锋利边缘而最小化倒钩导致组织损坏的可能性。

[0067] 在一个实施例中，倒钩 204 的内部凹形表面 238 具有约 0.002-0.006 英寸，还更优选地约 0.003 英寸的半径。所选择的内部凹形表面 238 的半径优选地帮助控制倒钩在穿过组织期间的柔韧性，并且帮助决定倒钩的用于预防倒钩一旦被植入就向后弯曲的力矩臂。

[0068] 参考图 13 和图 14，在一个实施例中，伤口闭合装置 200 的丝状元件 202 所具有的厚度 T_3 大于倒钩 204 的顶端 232 的厚度 T_4。因此，伤口闭合装置 200 优选地在倒钩 204 的

顶端 232 处比在丝状元件 202 的中心处更薄。因此，倒钩 204 从丝状元件 202 的中心的厚度 T_3 向内朝顶端 232 渐缩约 1-20°，还更优选地约 2-10° 的角度 α_2。倒钩在丝状元件 202 和顶端 232 之间的渐缩有助于控制倒钩 204 在穿过组织期间的柔韧性，并且还有助于决定一旦伤口闭合装置 200 已被植入组织中时倒钩的保持强度。

[0069] 虽然上文涉及本发明的实施例，但在不脱离本发明基本范围的情况下，也可以设计出本发明的其它实施例和更多实施例。因此，应当理解，本发明不限于本文所公开的精确实施例，在不背离本发明的范围或精神的情况下，本领域的技术人员在此可实现各种其它改变和修改，并且本发明的范围仅限制为如所附权利要求中所陈述。

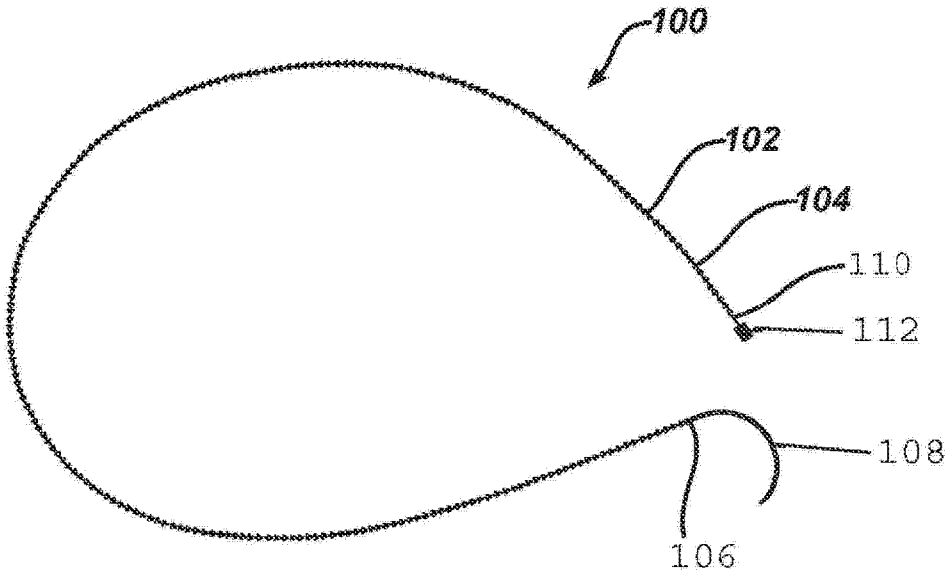

100
102
104
110
112
108
106

图 1

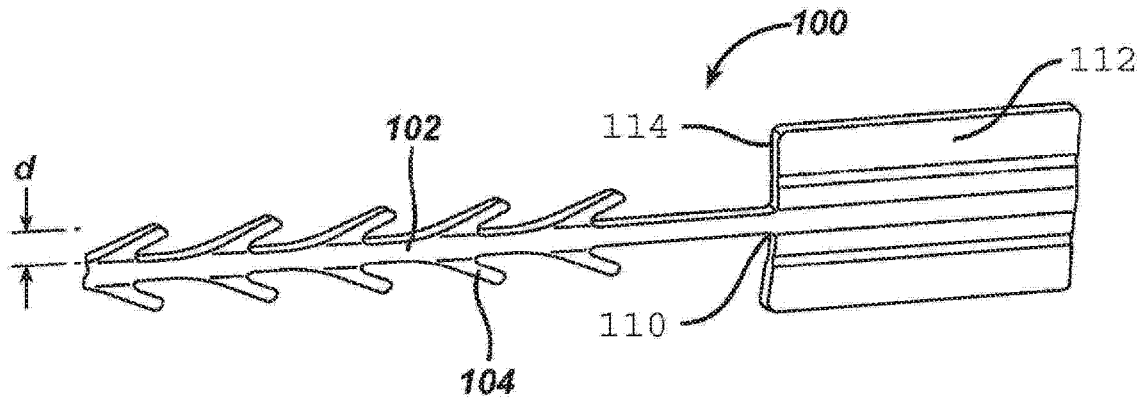

100
112
102
114
d
110
104

图 2

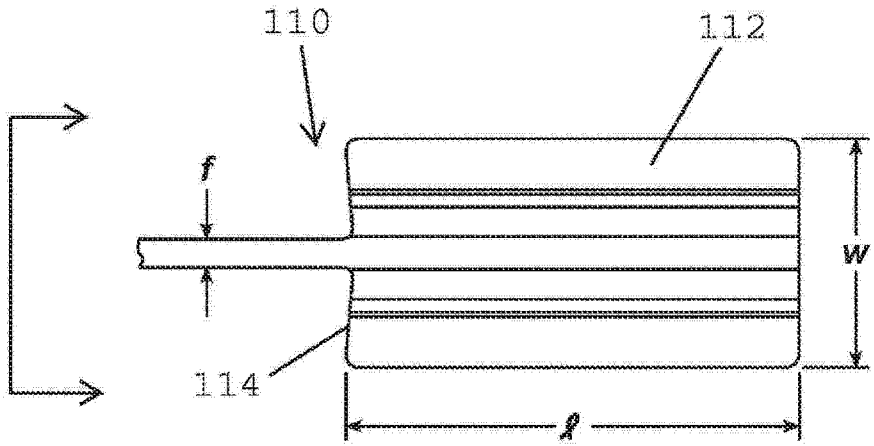

110
112
f
w
114
ℓ

图 3

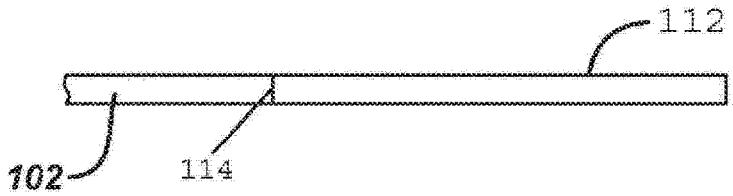

112
102
114

图 4

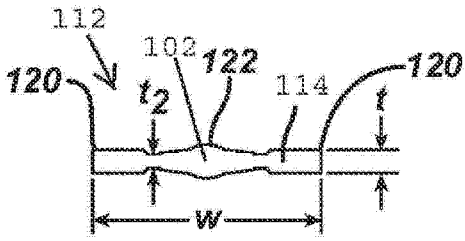

112
102
122
120
114
120
t2
t
w

图 5

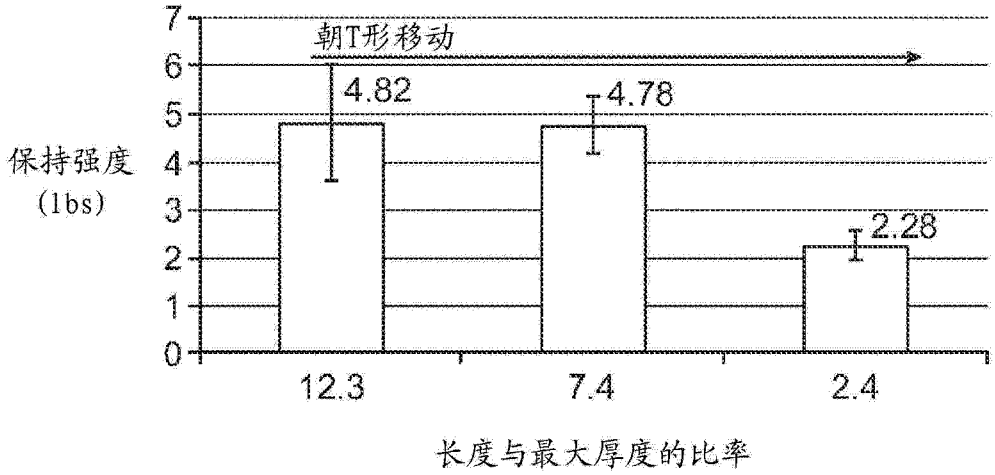

朝T形移动
保持强度
(lbs)
4.82
4.78
2.28
12.3
7.4
2.4
长度与最大厚度的比率

图 6

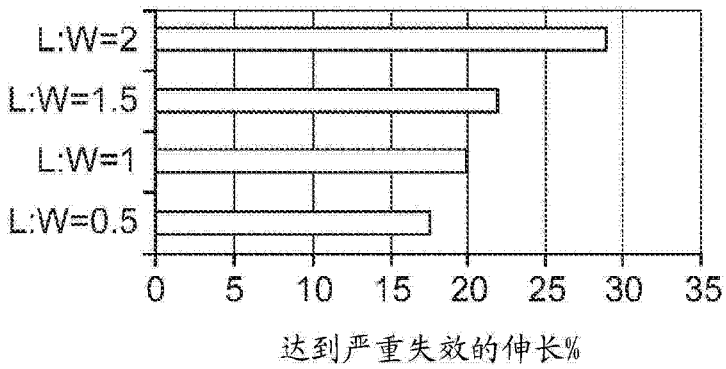

L:W=2
L:W=1.5
L:W=1
L:W=0.5
0
5
10
15
20
25
30
35
达到严重失效的伸长%

图 7

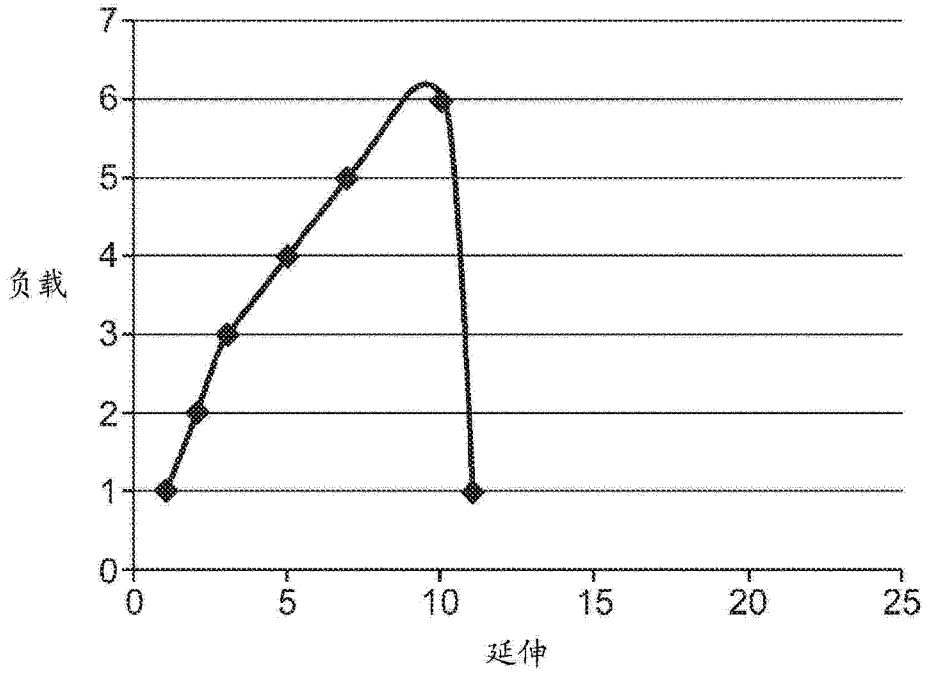


图 8

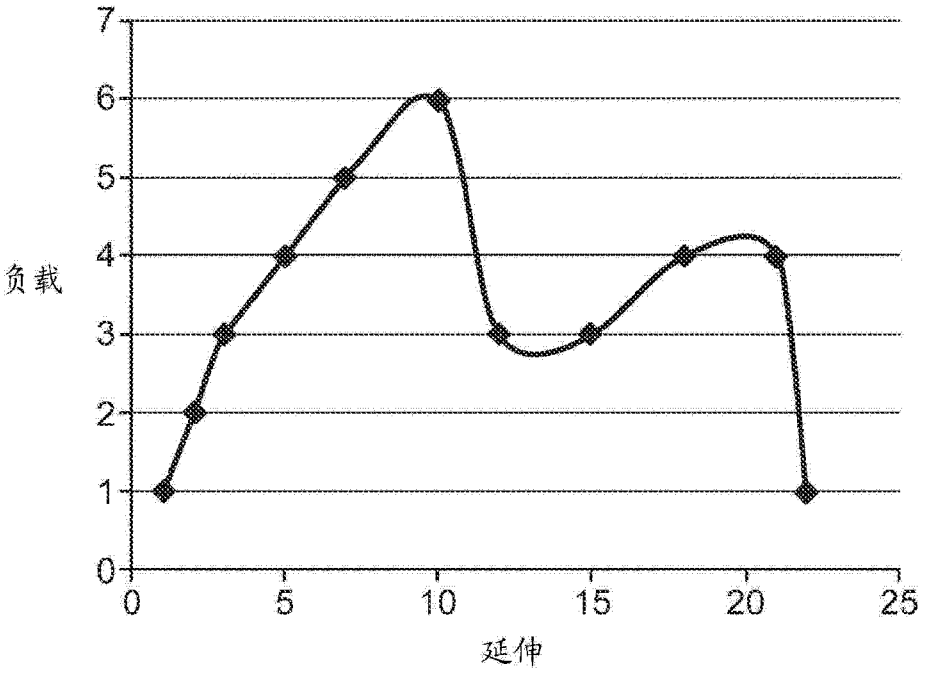


图 9

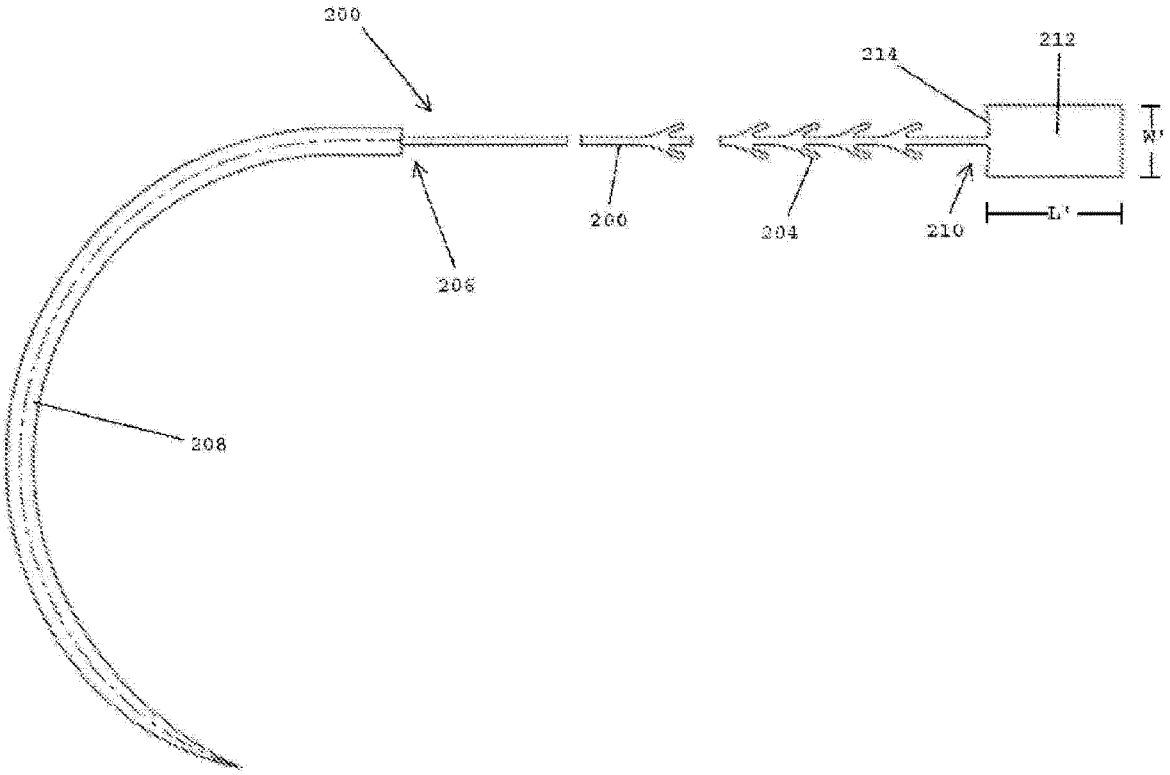


图 10

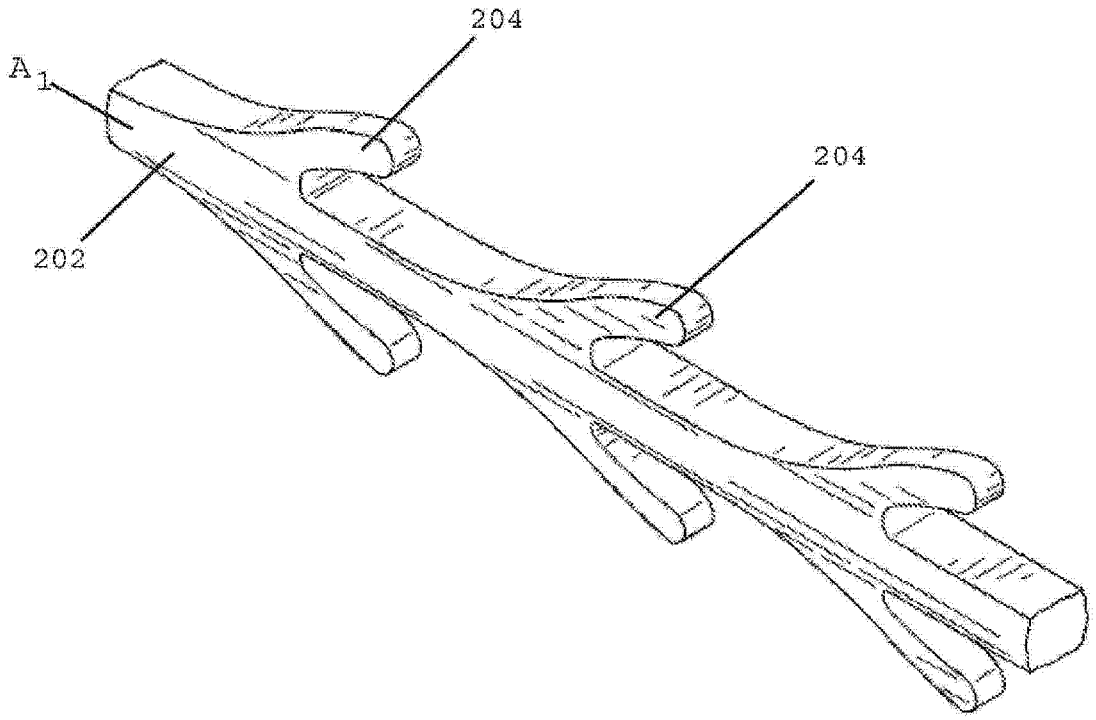


图 11

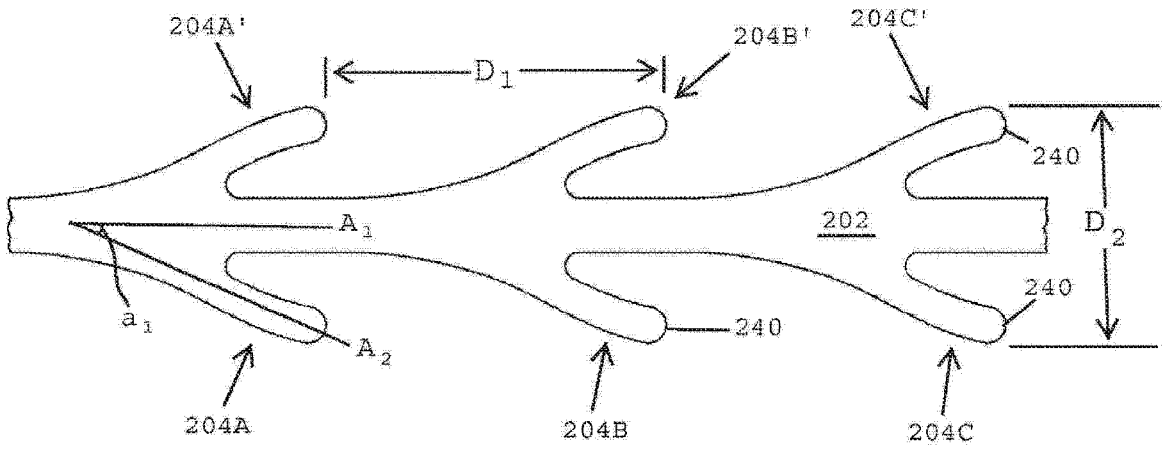

204A'
D1
204B'
204C'
240
A1
202
D2
240
a1
A2
240
204A
204B
204C

图 12A

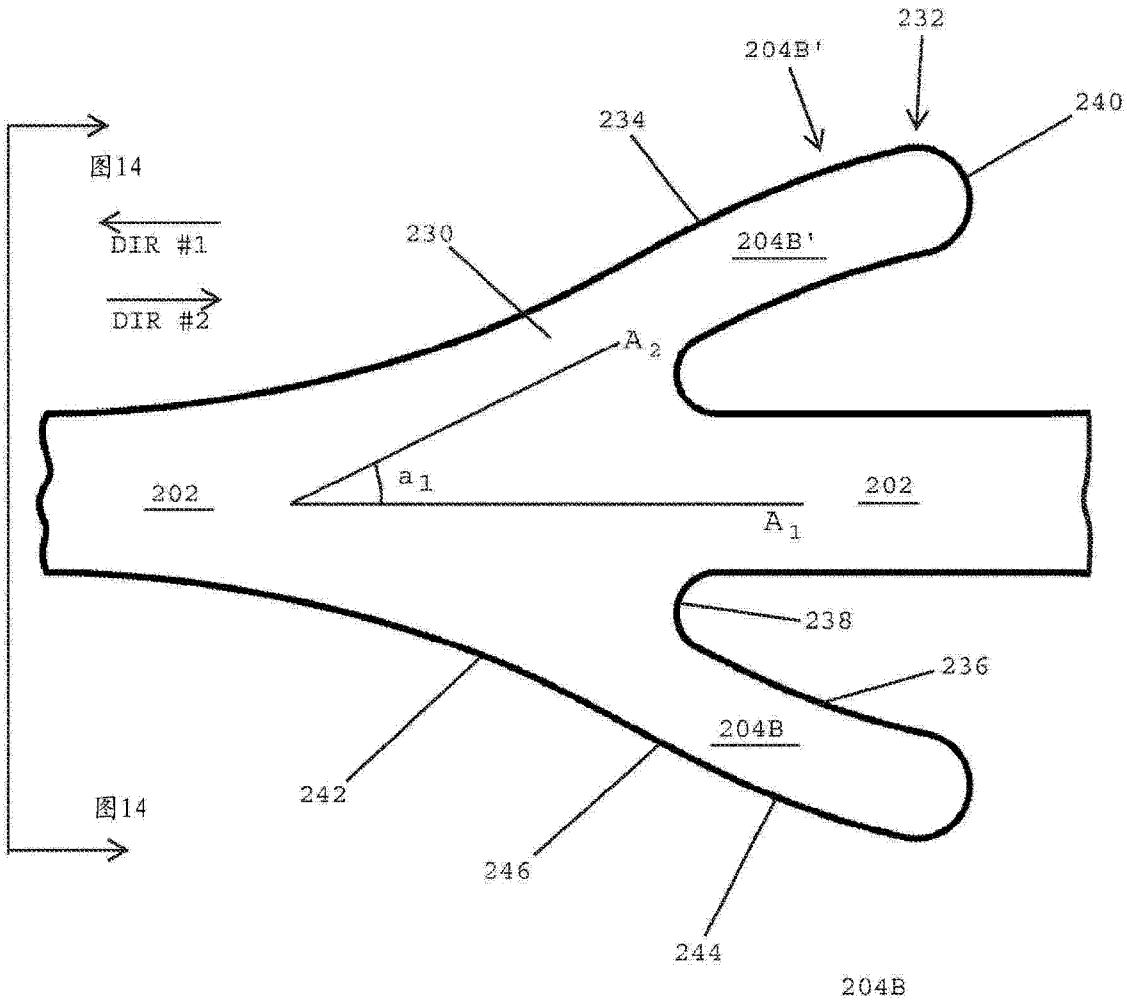

232
204B'
240
234
图14
DIR #1
230
204B'
DIR #2
A2
202
a1
202
A1
238
236
204B
242
246
244
图14
204B

图 12B

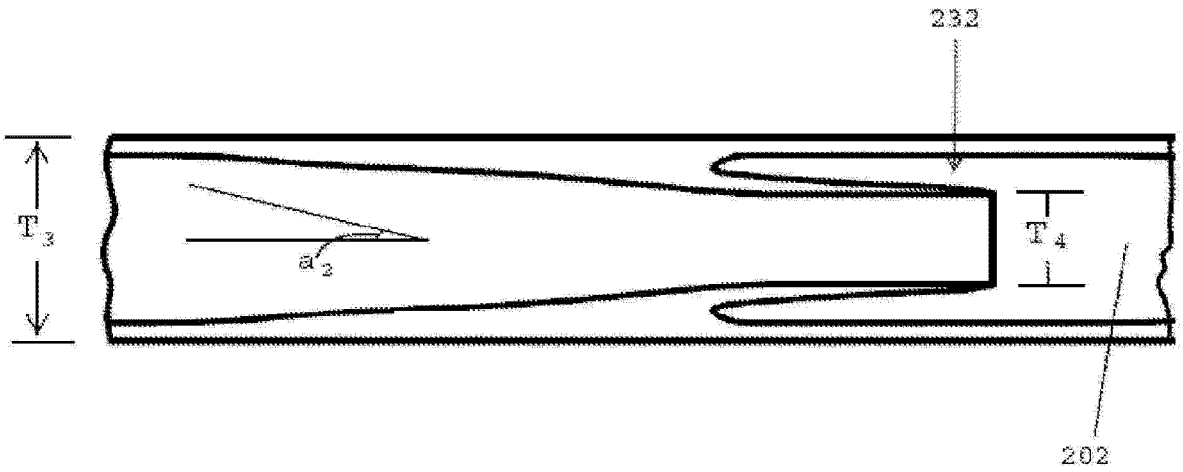


图 13

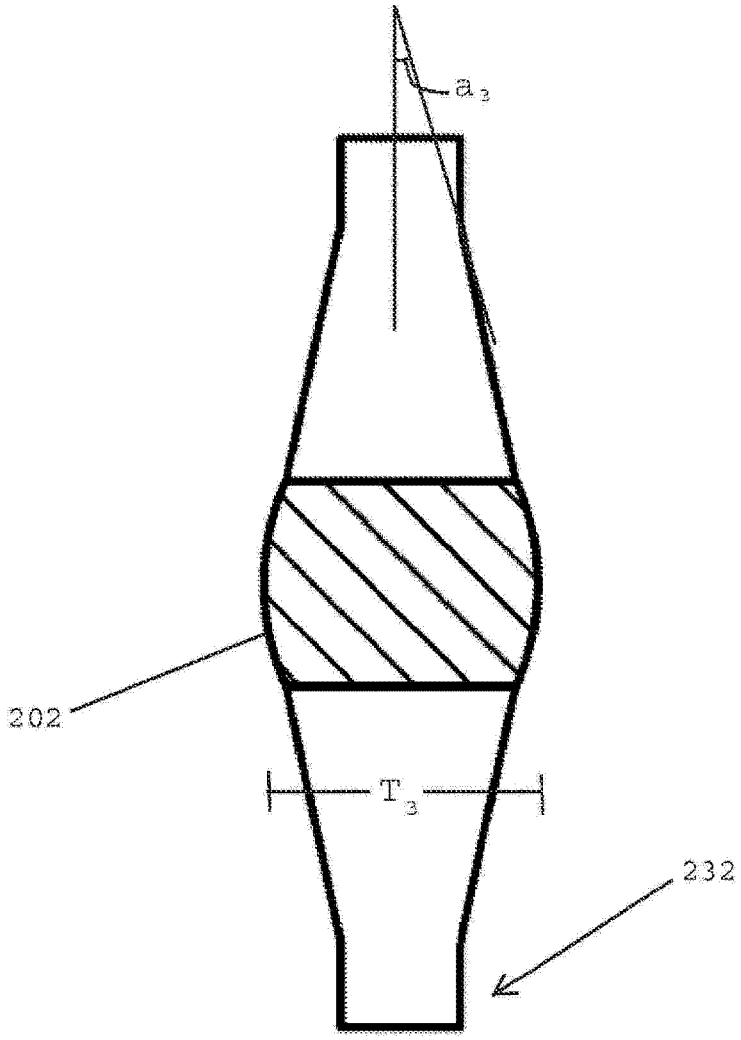


图 14