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Published:

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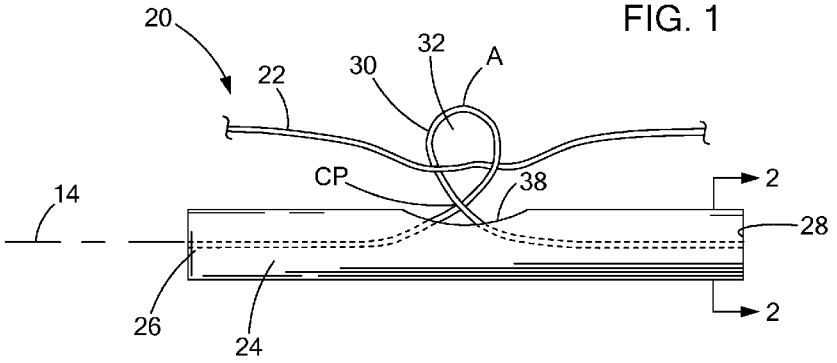
(54) **Title**: TISSUE ANCHORS FOR PURSE-STRING CLOSURE OF PERFORATIONS

FIG. 1



(57) **Abstract**: Medical devices for attaching suture to tissue and that provides reliable and complete closure of perforations and increases the versatility of the device for various other procedures. Embodiments of the medicals devices include a tissue anchor (20) having a crossbar (24) with opposing ends (26,28) and structure (30) for slidably receiving a suture (22).

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TISSUE ANCHORS FOR PURSE-STRING CLOSURE OF PERFORATIONS

FIELD

[0001] The present invention relates generally to tissue anchors for connecting a suture to tissue, such are for using tissue anchors and suture to close perforations in tissue.

BACKGROUND

[0002] Perforations in bodily walls may be naturally occurring, or formed intentionally or unintentionally. In order to permanently close these perforations and allow the tissue to properly heal, numerous medical devices and methods have been developed employing sutures, adhesives, clips, staples and the like. One class of such devices is commonly referred to as tissue anchors (T-anchors) or visceral anchors. An exemplary tissue anchor is disclosed in U.S. Pat. No. 5,123,914, the entire contents of which are incorporated by reference herein. Such tissue anchors have been very successful in medical procedures requiring tissue wall mobilization or wall apposition.

[0003] Tissue anchors have also been successfully used in closing perforations, but are not without their drawbacks. For example, when a series of anchors are placed around a perforation, all of the individual sutures connected to the anchors must be collected and connected together. It can often be difficult to properly tension each of the individual sutures to ensure proper approximation of the tissue around the perforation and complete closure thereof. This is especially critical within the gastrointestinal tract, where the travel of bacteria laden fluids outside of the tract may cause unwanted and sometimes deadly infection.

BRIEF SUMMARY

[0004] The present invention provides medical devices for attaching suture to tissue and that provides reliable and complete closure of perforations and increases the versatility of the device for various other procedures. One embodiment of a tissue anchor for connecting a suture to tissue, constructed in accordance with the teachings of the present invention, generally comprises a crossbar and a strand. The crossbar has first and second opposing ends and defines a longitudinal axis. The crossbar is defined by a tubular wall having an aperture between the first and second ends. The strand has first and second opposing ends connected to the first and second opposing ends of the crossbar, respectively. The strand makes a revolution to define a loop. The strand and its loop project through the aperture and away from the longitudinal axis. The loop is sized to slidably receive the suture therethrough.

[0005] According to more detailed aspects of this embodiment of the tissue anchor, the strand has a diameter less than about 50% of a diameter of the crossbar. The strand preferably has a diameter in the range of about 0.2 mm to about 0.35 mm, while the crossbar has a diameter in the range of about 0.5 mm to about 1.1 mm. The loop has an apex located about 0.35 mm or greater away from the crossbar. The loop defines a cross-point where the ends of the strand cross each other, and the cross-point is preferably positioned radially outside the outer surface of the crossbar. The strand is flexible, and the aperture is sized to permit the loop to travel longitudinally along the strand. The aperture preferably extends a longitudinal distance in the range of about 0.4 mm to about 3.0 mm, while the

crossbar typically has a length in the range of about 3.0 mm to about 10.0 mm. The strand may be a metal wire, and is preferably coated with a low-friction material.

[0006] Another embodiment of a tissue anchor for connecting a suture to tissue, constructed in accordance with the teachings of the present invention, generally comprises a crossbar and a strand. The crossbar has first and second opposing ends and defines a longitudinal axis. The cross bar is defined by a tubular wall having first and second apertures between the first and second ends, the first and second apertures being longitudinally spaced apart. A flexible suture has first and second opposing ends connected to the first and second opposing ends of the crossbar, respectively. The suture extends through the first and second apertures and projects away from the crossbar between the first and second apertures to define a loop between the suture and the crossbar.

[0007] Yet another embodiment of a tissue anchor for connecting a suture to tissue, constructed in accordance with the teachings of the present invention, generally comprises a crossbar and a flange. The crossbar has first and second opposing ends and defines a longitudinal axis. The flange is connected to the crossbar between the first and second ends and extends away from the longitudinal axis. The flange has a thickness less than a diameter of the crossbar. The flange defines a hole sized to receive the suture therein. According to more detailed aspects of this embodiment of the tissue anchor, an outer end surface of the flange follows a curved shape. Preferably, the crossbar and flange are unitarily and integrally formed. The crossbar and flange are optionally molded from a resorbable material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] The accompanying drawings incorporated in and forming a part of the specification illustrate several aspects of the present invention, and together with the description serve to explain the principles of the invention. In the drawings:

[0009] FIG. 1 is a front view of one embodiment of a tissue anchor constructed in accordance with the teachings of the present invention;

[0010] FIG. 2 is a cross-sectional view taken about the line 2-2 in FIG. 1;

[0011] FIG. 3 is a front view of another embodiment of a tissue anchor constructed in accordance with the teachings of the present invention;

[0012] FIG. 4 is a front view of yet another embodiment of a tissue anchor constructed in accordance with the teachings of the present invention;

[0013] FIG. 5 is an end view taken of the tissue anchor depicted in FIG. 4;

[0014] FIG. 6 is a plan view schematically depicting a medical device constructed in accordance with the teachings of the present invention;

[0015] FIG. 7 is a cross-sectional view of the medical device depicted in FIG. 6;

[0016] FIG. 8 is a schematic view of the medical device similar to FIG. 6 but showing the medical device closing a perforation; and

[0017] FIG. 9 is a cross-sectional view of the medical device as depicted in FIG. 8.

DETAILED DESCRIPTION OF THE INVENTION

[0018] Turning now to the figures, FIGS. 1-2 depict a tissue anchor 20 constructed in accordance with the teachings of the present invention. The anchor

20 is utilized to connect a suture 22 to tissue, such as for closing a perforation 10 in a bodily wall 12 (see, e.g., FIGS. 6 to 9) or for use in other procedures. The anchor 20 generally includes a crossbar 24 having opposing ends 26 and 28 and defining a longitudinal axis 14. The crossbar 24 is preferably elongated, but may take any form suitable for connecting the suture 22 to the bodily wall 12. A strand 30 is connected to the crossbar 24 and is configured to form a loop 32. As best seen in FIG. 2, the crossbar 24 is constructed of a cannula having a tubular wall 34 defining a lumen 36. An elongated aperture 38 is formed in the tubular wall 34, and the strand 30 passes through the aperture 38. The ends of strand 30 are secured within the lumen 36 of the cannula by welds 44. It will be recognized by those skilled in the art that the strand 30 may be secured to the crossbar 24 using any now known or hereinafter developed attachment means, including mechanical fasteners, adhesives or various welding or soldering techniques. Similarly, the strand 30 may have sufficient rigidity such that its ends do not need to be directly attached to the crossbar, as the formation of loop 32 projecting through the aperture 38 can be enough to retain the strand 30 within the crossbar 24, and/or the ends of the strand 30 may simply be bent or otherwise deformed to keep them within the crossbar 24 and prevent them from passing through the aperture 38.

[0019] The strand 30 is preferably formed from a metal wire, including single filament and multi-filament wires, and wound and braided wires, although the strand 30 can have other constructions such as suture material, plastic strings, rope and the like. As best seen in FIG. 1, the strand 30 is structured to include a revolution thereby defining a loop 32 through which the suture 22 passes. The loop 32 is positioned longitudinally in-line with the elongated aperture 38 so that it projects

through the aperture 38 and away from the longitudinal axis 14. Accordingly, it will be seen that the strand 30 and its loop 32 are flexible and may adjust its shape and orientation based on how the suture 22 is being tensioned. The size of the elongated aperture 38 and the flexibility of the strand 30 allow the loop 32 to travel longitudinally along the length of the strand 30. The loop 32 defines an apex A which is preferably located about 0.35 mm or greater away from the crossbar 24. The loop 32 also defines a cross-point CP where the ends of the strand 30 cross each other. The cross-point CP is preferably positioned radially outside the outer surface of the crossbar 24 including radially outside the side walls of the aperture 38, but also preferably as close to the crossbar 24 as possible. The aperture 38 preferably extends a longitudinal distance in a range of about 0.4 mm to about 3.0 mm, while the crossbar 24 typically has a length in the range of about 3.0 mm to about 10.0 mm. The strand preferably has a diameter less than about 50% of a diameter of the crossbar 24, and most preferably less than about 35%. The strand 30 preferably has a diameter in the range of about 0.20 mm to about 0.35 mm, and most preferably about 0.254 mm. The crossbar 24 preferably has a diameter in the range of about 0.5 mm to about 1.0 mm, and most preferably about 0.8 mm. The strand 30 may be coated with a low-friction material such as known plastic or hydrophilic coatings.

[0020] This construction of the tissue anchor 24 and its loop 32 allows the suture 22 to be tensioned and slid through the loop 32 relative to the crossbar 24 while preventing the suture 22 from engaging the crossbar 24 or the edges defined by the elongated aperture 38. That is, no matter which direction the ends of the suture 22 are pulled or slid relative to the crossbar 24, the wire 30 and its loop 32 will

serve as a barrier between the suture 22 and the canula 24 to prevent any undesired abrasion therebetween. Generally, the strand 30 has a length and the location of the apex A of the loop 32 are such that the loop 32 is sized to project through the tissue in which it is embedded (e.g. it projects from the proximal side of the tissue), allowing reliable tensioning of the suture 22 and preventing abrasion of the tissue.

[0021] Turning now to FIG. 3, another embodiment of a tissue anchor 120 is depicted in accordance with the teachings of the present invention. As in the prior embodiment, the anchor 120 generally includes a crossbar 124 having opposing ends 126 and 128. A strand 130 is connected to the crossbar 124, and in this embodiment, the strand 130 is formed of a flexible suture. The crossbar 24 defines first and second apertures 138, 140 which are longitudinally spaced apart. Moving from left to right in FIG. 3, the strand 130 is attached to the crossbar 124 and passes through the interior of the crossbar 124 and exits radially from the first aperture 138, then extends along the outer periphery of the crossbar 124, and passes back through the second aperture 140 into the interior of the crossbar 124, where it is fixed to the second end 128 thereof. Accordingly, the flexible suture 130 and the crossbar 124 define a loop 132 therebetween which is sized to slidably receive the tying suture 22. The suture 130 has a length, preferably about 10 mm to about 30 mm, such that the distance the suture 130 projects away from the crossbar 124 is variable. The suture 130, when pulled taut, defines an apex that is positioned away from an outer surface of the crossbar about 5 mm. Preferably the suture 130 has a length 18 mm, whereas the crossbar 124 has a length of about 8 mm. The suture 130 may be of a single filament or multi-filament constructions. Through this construction of the suture 130 to form the loop 132, while friction between the anchor

120 and the tying suture 22 is reduced. The loop 132 and with the extra length of the suture 130, the crossbar 124 may be embedded deeper into the tissue.

[0022] Turning now to FIGS. 4 and 5, in yet another embodiment of a tissue anchor 220 has been depicted in accordance with the teachings of the present invention. As with the prior embodiments the anchor 220 generally includes a crossbar 224 having opposing ends 226 and 228. In this embodiment the crossbar 224 is preferably formed of a solid cylinder, and may be a metal bar, plastic molded piece, or any stock materials. The tissue anchor 220 also includes a flange 240 connected to the crossbar 224 and projecting radially away therefrom. The flange 240 preferably has a thickness (best seen in the side view of FIG. 5) that is less than 50% of the diameter of the crossbar 224. The flange 240 defines a hole 242 sized to slidably receive the tying suture 22 therein. Preferably, the crossbar 224 and flange 240 are unitarily and integrally formed, such as in a plastic molding process. Accordingly, the entire tissue anchor 220 may be formed of a single plastic material, and most preferably a resorbable material. This construction of the tissue anchor 220 allows it to be placed in locations where, once the anchor was freed, it would likely not naturally pass through the body. Accordingly, no matter the location the tissue anchors 220, they are still allowed to naturally exit the body.

[0023] As used herein, the term "resorbable" refers to the ability of a material to be absorbed into a tissue and/or body fluid upon contact with the tissue and/or body fluid. A number of resorbable materials are known in the art, and any suitable resorbable material can be used. Examples of suitable types of resorbable materials include resorbable homopolymers, copolymers, or blends of resorbable polymers. Specific examples of suitable resorbable materials include poly-alpha hydroxy acids

such as polylactic acid, polylactide, polyglycolic acid (PGA), or polyglycolide; tri-methlyene carbonate; polycaprolactone; poly-beta hydroxy acids such as polyhydroxybutyrate or polyhydroxyvalerate; or other polymers such as polyphosphazines, polyorgano- phosphazines, polyanhydrides, polyesteramides, poly- orthoesters, polyethylene oxide, polyester-ethers (e.g., poly- dioxanone) or polyamino acids (e.g., poly-L-glutamic acid or poly-L-lysine). There are also a number of naturally derived resorbable polymers that may be suitable, including modified polysaccharides, such as cellulose, chitin, and dextran, and modified proteins, such as fibrin and casein.

[0024] Turning now to FIGS. 6-9, the tissue anchors 20 are preferably deployed as a set of anchors 20a, 20b, 20c, 20d linked together by a single suture 22, all of which collectively forms a medical device 50 for closing the perforation 10 in the bodily wall 12. The suture 22 is slidably connected to each of the tissue anchors 20a, 20b, 20c, and 20d, leaving two free ends 52, 54 of the suture 22 which may be independently tensioned to close the perforation 10. As best seen in FIG. 7, the tissue anchors (20b and 20c depicted) are positioned on a distal side of the bodily wall 12, while the majority of suture 22 is positioned on a proximal side of the bodily wall 12, including the suture ends 52, 54. Accordingly, it will be recognized that the medical device 50 operates in a purse-string fashion to close the perforation 10 in the bodily wall, as will be described in more detail below.

[0025] A method of closing the perforation 10, in accordance with the teachings present invention, includes passing each tissue anchor 20a, 20b, 20c, and 20d through the bodily wall 12 adjacent the periphery of the perforation 10, as shown in FIG. 6. Preferably, the anchors are sequentially positioned around the perforation

10 in a semi-annular or annular shape as shown. The ends 52, 54 of the suture are then tensioned to reduce the distance between the tissue anchors 20a, 20b, 20c, 20d and compress the bodily wall 12 around the perforation 10, as depicted in FIGS. 8 and 9. As best seen in FIG. 9, the ends 52, 54 of the suture 22 are secured to maintain the compression of the bodily wall 10, such as through the use of a suture lock 56. Exemplary suture locks are disclosed in copending U.S. Patent Application Nos. 12/125,525 and 12/191,001, the disclosures of which are incorporated herein by reference in their entirety. It will be recognized that any now known or future developed method for securing the ends 52, 54 of the suture 22 may be employed, such as knotting, tying, clamps, rivets and the like.

[0026] The foregoing description of various embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise embodiments disclosed. Numerous modifications or variations are possible in light of the above teachings. The embodiments discussed were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

CLAIMS

1. A tissue anchor for connecting a suture to tissue, the tissue anchor comprising:

a crossbar having first and second opposing ends and defining a longitudinal axis, the crossbar being defined by a tubular wall having an aperture between the first and second ends; and

a strand having first and second opposing ends connected to the first and second opposing ends of the crossbar, respectively, the strand making a revolution to define a loop, the strand and its loop projecting through the aperture and away from the longitudinal axis, the loop sized to slidably receive the suture therein.

2. The tissue anchor of claim 1, wherein the strand has a diameter less than about 35% of a diameter of the crossbar.

3. The tissue anchor of claim 1, wherein the strand has a diameter in the range of about 0.20 mm to about 0.35 mm.

4. The tissue anchor of claim 1, wherein the crossbar has a diameter in the range of about 0.5 mm to about 1.0 mm.

5. The tissue anchor of claim 1, wherein the loop has an apex located about 0.35 mm away from the crossbar.

6. The tissue anchor of claim 1, wherein the loop defines a cross-point where the ends of the strand cross each other, and wherein the cross-point is positioned radially outside the outer surface of the crossbar.

7. The tissue anchor of claim 1, wherein the strand is flexible, and wherein the aperture is sized to permit the loop to travel longitudinally along the strand.

8. The tissue anchor of claim 1, wherein the aperture extends a longitudinal distance in the range of about 1.0 mm to about 3.0 mm.

9. The tissue anchor of claim 1, wherein the strand is a metal wire.

10. The tissue anchor of claim 1, wherein the strand is coated with a low-friction material.

11. A tissue anchor for connecting a suture to tissue, the tissue anchor comprising:

a crossbar having first and second opposing ends and defining a longitudinal axis, the cross bar being defined by a tubular wall having first and second apertures between the first and second ends, the first and second apertures being longitudinally spaced apart; and

a flexible suture having first and second opposing ends connected to the first and second opposing ends of the crossbar, respectively, the suture extending

through the first and second apertures and projecting away from the crossbar between the first and second apertures to define a loop between the suture and the crossbar, the loop sized to slidably receive the suture therein.

12. The tissue anchor of claim 11, wherein the distance the suture projects away from the crossbar is variable.

13. The tissue anchor of claim 12, wherein the suture, when pulled taught, defines an apex that is positioned away from an outer surface of the crossbar about 5.0 mm.

14. The tissue anchor of claim 11, wherein the strand has a diameter less than about 35% of a diameter of the crossbar.

15. A tissue anchor for connecting a suture to tissue, the tissue anchor comprising:

a crossbar having first and second opposing ends and defining a longitudinal axis; and

a flange connected to the crossbar between the first and second ends and extending away from the longitudinal axis, the flange having a thickness less than a diameter of the crossbar, the flange defining a hole sized to slidably receive the suture therein.

16. The tissue anchor of claim 15, wherein an outer end surface of the flange follows a curved shape.

17. The tissue anchor of claim 15, wherein the crossbar and flange are unitarily and integrally formed.

18. The tissue anchor of claim 15, wherein the crossbar and flange are molded from a resorbable material.

19. The tissue anchor of claim 15, wherein the flange has a thickness less than 50% of a diameter of the crossbar.

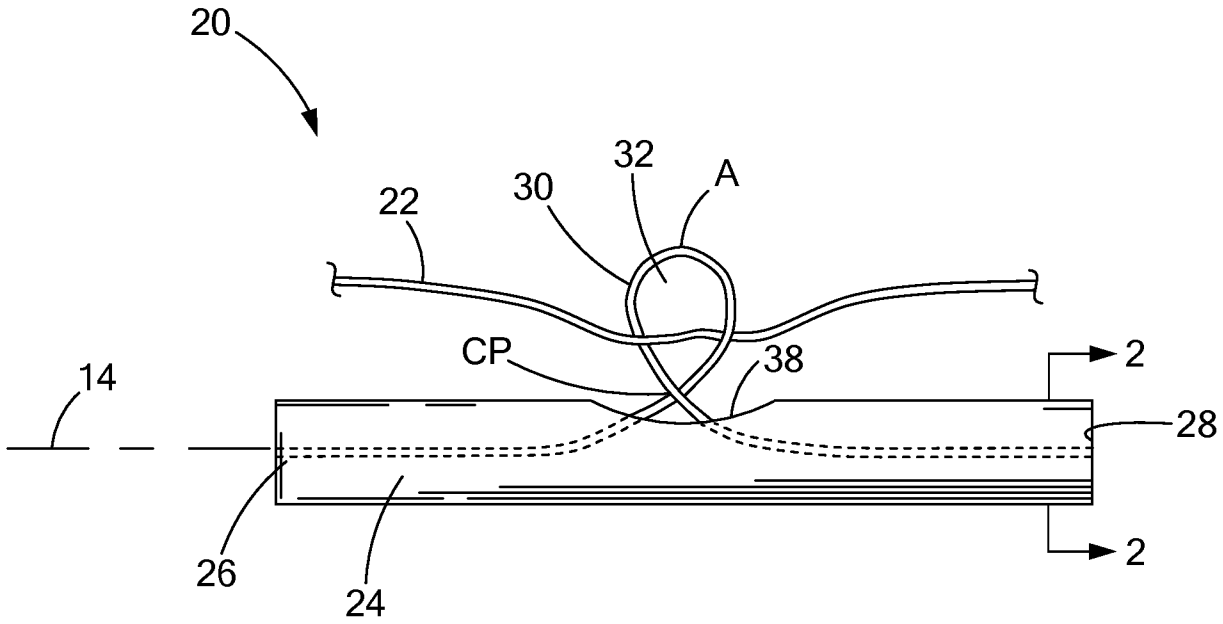

FIG. 1

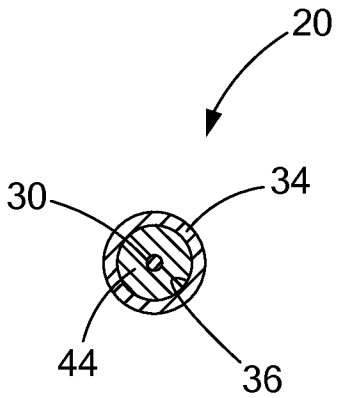

FIG. 2

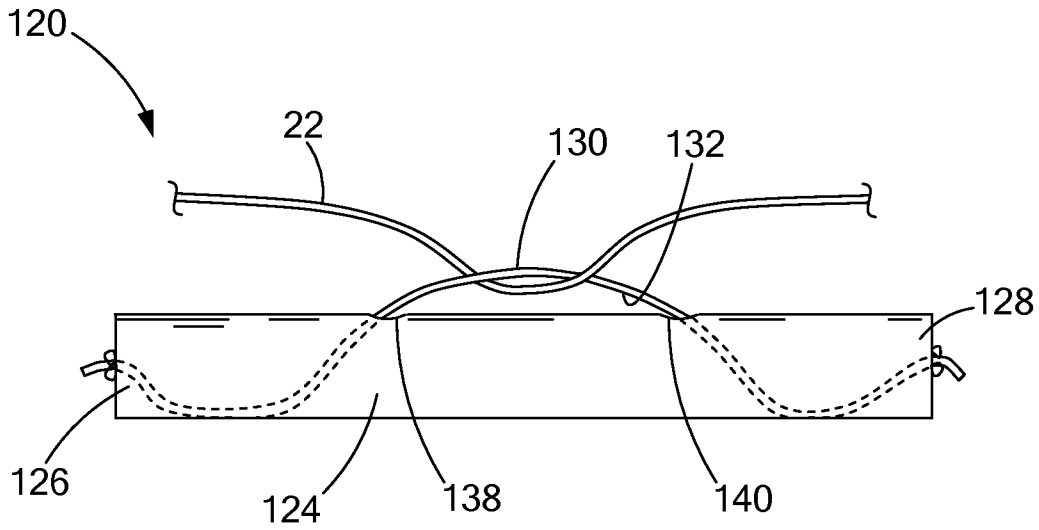

FIG. 3

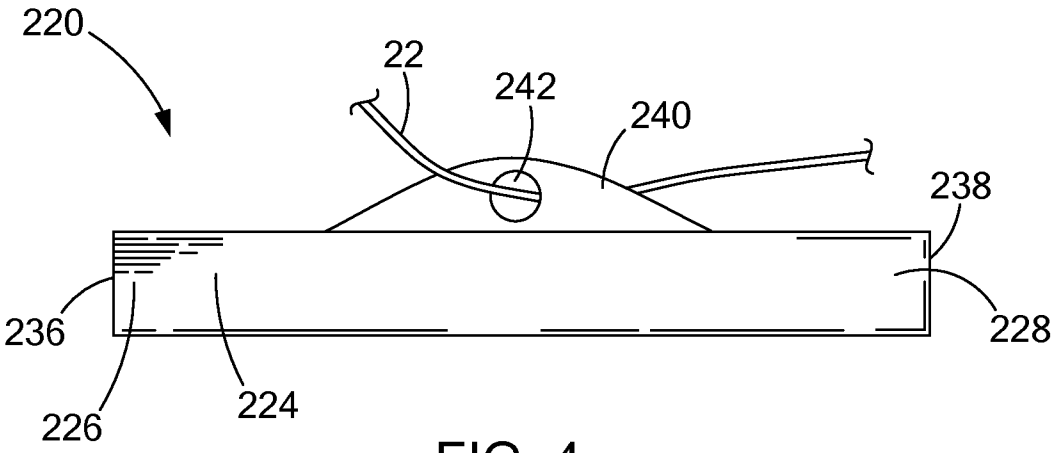

FIG. 4

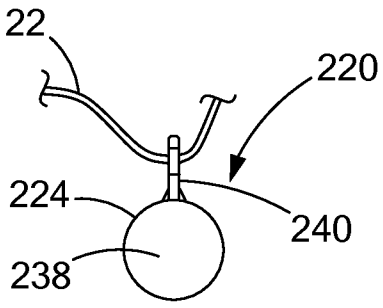

FIG. 5

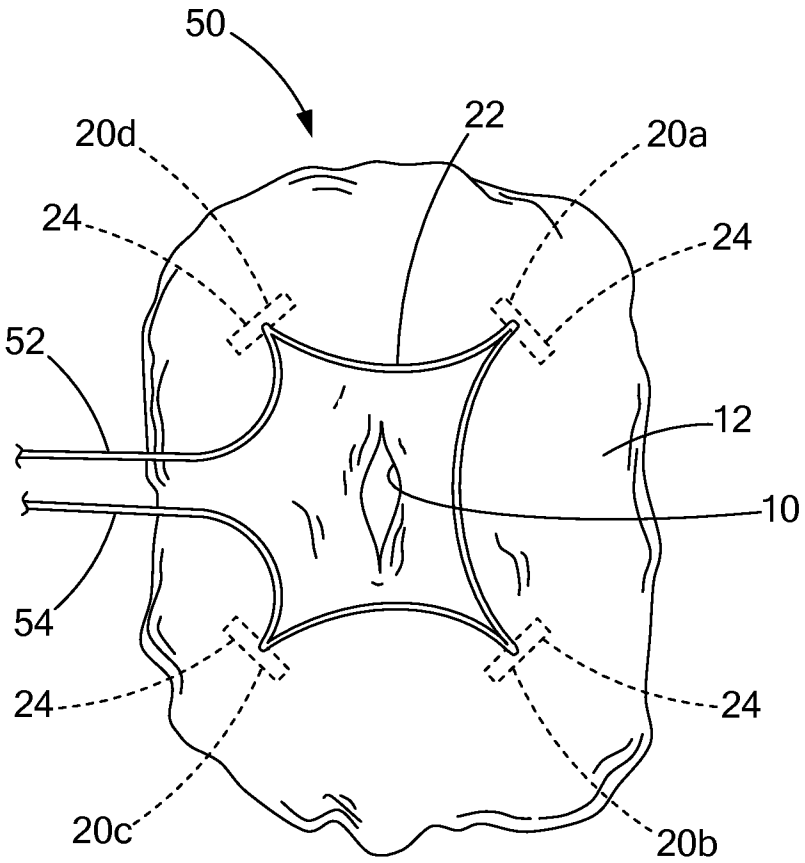

FIG. 6

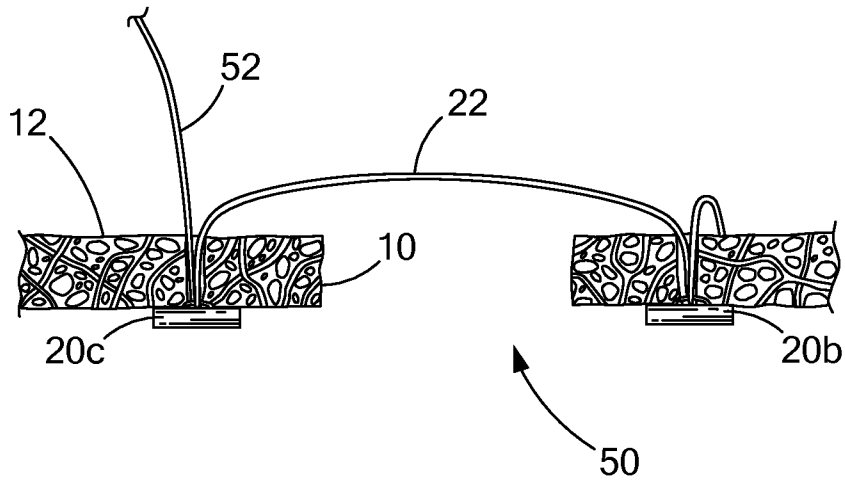

FIG. 7

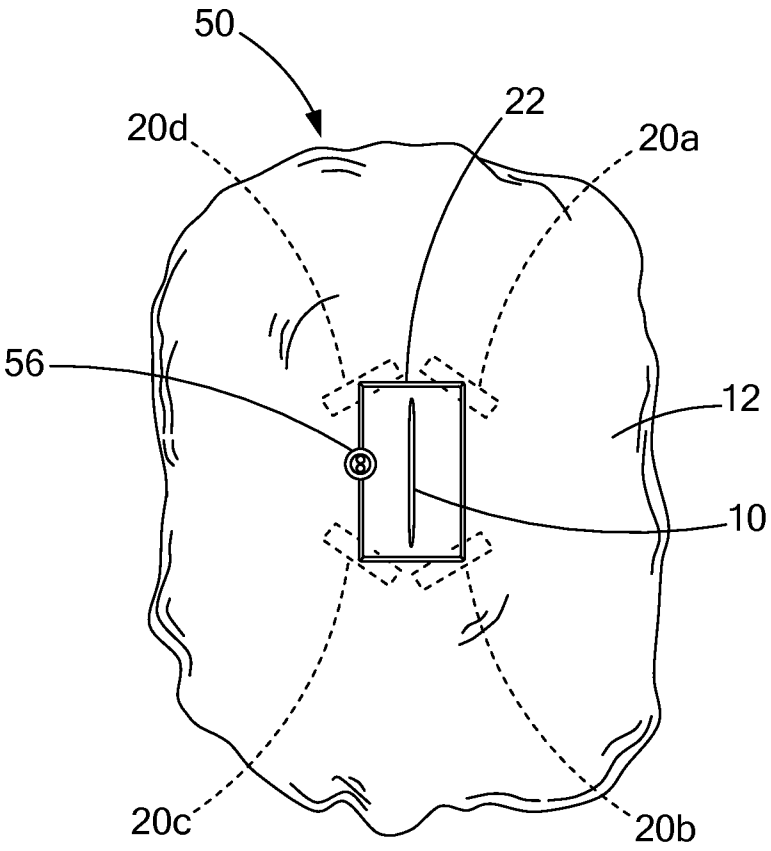

FIG. 8

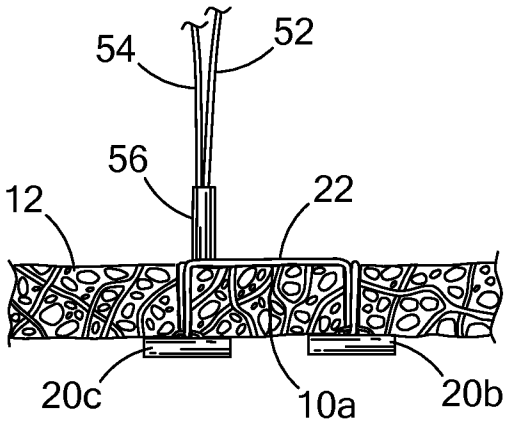

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/066566

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/04
ADD. A61B17/00

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 practical, 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 2004/002734 A1 (FALLIN T WADE [US] ET AL FALLIN T WADE [US] ET AL) 1 January 2004 (2004-01-01) figure 7	1-14
X	WO 01/10312 A1 (INNOVASIVE DEVICES INC [US]) 15 February 2001 (2001-02-15) figures 3a,3b	1-14
X	US 2004/243179 A1 (FOERSTER SETH A [US]) 2 December 2004 (2004-12-02) figures 13A-C,15	1-10
X	WO 2008/109087 A1 (C2M MEDICAL INC [US]; FANTON GARY S [US]; KRUMME JOHN [US]) 12 September 2008 (2008-09-12) figures 24A,24B,25A,25B	1-10

-/--

[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 document but published on or after the international filing date

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"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
26 January 2010	03/05/2010

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/US2009/066566

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/067384 A2 (WILSON COOK MEDICAL INC [US]; SURTI VIHAR C [US]; DESILETS DAVID [US]) 5 June 2008 (2008-06-05) figures 1-3	11-14
X,P	US 2009/024163 A1 (ZEINER MARK S [US] ET AL) 22 January 2009 (2009-01-22) figure 13	1-10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/066566

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 tissue anchor comprising a crossbar defined by a tubular wall having at least one aperture, and a strand making a revolution to define a loop, the strand and its loop projecting through the at least one aperture, so that the loop provides a flexible attachment point for a suture, thereby improving versatility of the anchor.

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2. claims: 15-19

a tissue anchor comprising a crossbar and a flange connected to the crossbar and extending away from the axis of the crossbar, the flange having a hole and a thickness less than a diameter of the crossbar, so that the flange prevents rotational movement about the axis of the crossbar when inserted into tissue, thereby improving anchor fixation.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2009/066566

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