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- (71) Applicant: CURAX, LLC [US/US]; 9967 Lin Ferry Road, St. Louis, MO 63123 (US).
- (72) Inventors (for US only): RILEY, A., Jamie; 12430 Tesson Ferry, St. Louis, MO 63128 (US). SCHMIDT, Gary, J.; 65 Turf Court, St. Louis, MO 63119 (US). PARANJPE, Amod, P.; 300 Femme Osage Valley, Augusta, MO 63368 (US).
- (74) Agent: RUSCHE, Frederick, H.; Husch Blackwell Llp, 190 Carondelet Plaza, Suite 600, St. Louis, MO 63103 (US).
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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, KM, 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, 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.

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(54) Title: SUTURE DELIVERY SYSTEM

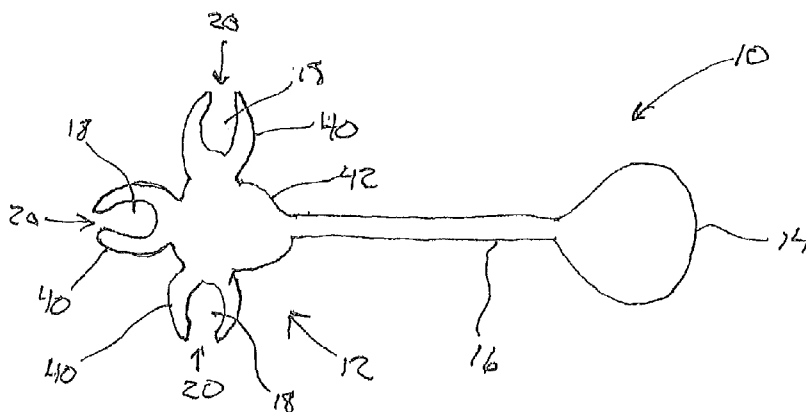


Fig. 5

(57) Abstract: A suture delivery system includes a distal portion having a central opening therein and one or more flanges surrounding said central opening; a body portion connected with said distal portion; and at least one suture strand and needle combination removably connected with at least one of said distal portion and said body portion, wherein a first portion of said suture strand engages said flanges of said distal portion and said body portion stores a second portion of said suture strand and said needle.



## SUTURE DELIVERY SYSTEM

### CROSS REFERENCES

**[0001]** This application claims priority to US Provisional Patent Application No. 61/539,774, filed September 27, 2011.

5

### TECHNICAL FIELD OF THE INVENTION

**[0002]** The present invention relates generally to surgical tools and, more particularly, to a device for enhancing the process of reconnecting soft tissue with underlying bone structures.

### 10 BACKGROUND OF THE INVENTION

**[0003]** Staples and orthopedic washers have been used for many years to surgical attach soft tissues to underlying bone structures. Prior art staples are metallic “U”-shaped structures wherein the legs of the staple are driven into the underlying bone structure to sandwich the soft tissue between a web that connects the legs of the staple and the underlying bone.

15 Examples of such staples are described in U.S. Patent Nos. 4,592,346 and 4,793,335.

**[0004]** Prior art orthopedic washers are typically round or oval in shape with an open center and provided with multiple sharp pins as well as blunt posts on the underside of the washer. The washer is secured to the bone by a screw. Similarly to the prior art staples described above, the soft tissue that is to be secured is sandwiched between the washer and the  
20 underlying bone. The washer is held in place by the screw and sharp pins, while the blunt posts

ensure that sufficient space is maintained between the washer and the bone to avoid damaging the soft tissue being secured.

**[0005]** In each case, these prior art devices are intended to ensure proper contact between the bone and soft tissue, with some degree of compression being exerted, to facilitate reconnection of the soft tissue to the bone. In the case of each type of device, the device is also used as an anchor for sutures that are used to further secure a larger area of soft tissue. These devices are used, for example, to reinforce fracture sites, to reduce potential space between the bone and overlying soft tissue, and to promote vascularity to the periosteal surface.

**[0006]** However, these prior art devices suffer from several drawbacks. First, the nature of these devices requires that they be constructed of a metallic or hard plastic material. Further, the device remains in the body following the subject procedure. Thus, the use of these prior art devices involves the introduction and continued presence – coupled with the possible need for subsequent removal – of an additional foreign body in the patient. This creates a possible additional avenue for infection at the surgical site. Further, it subjects these devices to significant regulation, which in turn increases the cost of producing the devices.

**[0007]** Therefore, it would be advantageous to provide a device that facilitates anchoring of sutures for securing soft tissue to underlying bone structures yet is removable prior to suturing.

## SUMMARY OF THE INVENTION

[0008] One aspect of the invention generally pertains to a suture delivery system that provides quick and accurate placement and secure and repeatable anchoring of one or more sutures at a fixation site.

5 [0009] Another aspect of the invention generally pertains to a suture delivery system that is removable prior to suturing and capable of using low cost, disposable materials in its construction.

[0010] In accordance with the above aspects of the invention, there is provided a suture delivery system that includes a distal portion having a central opening; a body portion; and at  
10 least one suture strand and needle combination removably connected with at least one of the distal, or body portions.

[0011] These aspects are merely illustrative of the innumerable aspects associated with the present invention and should not be deemed as limiting in any manner. These and other aspects, features and advantages of the present invention will become apparent from the  
15 following detailed description when taken in conjunction with the referenced drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Reference is now made more particularly to the drawings, which illustrate the best presently known mode of carrying out the invention and wherein similar reference characters  
20 indicate the same parts throughout the views.

[0013] Fig. 1 is a top view of a suture delivery system according to an embodiment of the present invention.

[0014] Fig. 2 is a side view of the suture delivery system of Fig. 1.

[0015] Fig. 3 is a bottom view of the suture delivery system of Fig. 1.

5 [0016] Fig. 4 is a top view of a suture delivery system according to another embodiment.

[0017] Fig. 5 is a top view of a suture delivery system according to yet another embodiment.

[0018] Fig. 6 is a side view of another embodiment of a suture delivery system.

10 [0019] Fig. 7 is a perspective view of the embodiment of Fig. 6 in which the two halves of the device are separated from one another.

[0020] Fig. 8 is a perspective view of the two halves of the device of Figs. 6 and 7 from the opposite direction of Fig. 7.

## 15 DETAILED DESCRIPTION

[0021] In the following detailed description numerous specific details are set forth in order to provide a thorough understanding of the invention. However, it will be understood by those skilled in the art that the present invention may be practiced without these specific details. For example, the invention is not limited in scope to the particular type of industry application depicted in the figures. In other instances, well-known methods, procedures, and components  
20 have not been described in detail so as not to obscure the present invention.

[0022] Figs. 1 – 3 illustrate a suture delivery system according to an embodiment of the present invention. The system includes a base 10. In the illustrated embodiment, the base 10 is provided with a roughly hourglass shape composed of a distal 12 portion and a body portion that is formed by a proximal 14 portion and an extended handle portion 16. Distal portion 12, alternately referenced as a suture loop snare, is advantageously provided with a central opening 18, which accommodates a surgical screw as described in more detail below. Distal portion 12 is also provided with a break or slot 20 in one side, preferably the side opposite of the connection between the distal portion 12 and the handle 16, to facilitate removal of the base 10 from the surgical screw after implantation of the screw in the underlying bone. Thus, the distal portion 12 will have what may be considered to be “C” shape.

[0023] The underside, or middle, of the distal portion 12 is provided with one or more slots or flanges 22 to capture a portion of several suture strands 24 that are advantageously packaged with the base 10 to form the system. The flanges 22 of the distal portion 12 route the suture strands 24 around the central opening 18 of the distal portion so that they do not interfere with the initial insertion of a surgical screw through the central opening 18. However, the flanges 22 do position the suture strands immediately adjacent to the edges of the central opening 18 to encourage capture of the suture strands by the surgical screw. This arrangement results in a portion of the suture strands being wrapped around the surgical screw to form an extremely solid base connection for the suture strands 24. It should be noted that the suture strands 24 are preferably arranged such that the middle section of each suture strand 24 is positioned in the flanges 22 of the distal portion 12.

[0024] The underside of the handle 16 portion of the base 10 is also provided with slots or flanges 26 to capture the bulk of the suture strands 24 packaged with the system. Alternately, the handle portion 16 may be composed of a pair of horizontal surfaces with the suture strands sandwiched therebetween. In yet another embodiment, the handle portion 16 is formed into a tube through which the suture strands 24 are threaded in preparation for delivery. In essence, the underside of the handle 16 serves as the primary storage area for the suture strands 24. The flanges 26 of the handle open toward the bottom to allow the suture strands to be released from the handle after placement of the base 10 and implantation of the surgical screw.

[0025] In a similar manner, the underside of the proximal portion 14 is provided with slots or flanges 28 to capture needles 30 that are pre-threaded onto the suture strands 24. Thus, after implantation of the surgical screw, and the resultant fixation of the suture strands 24 at the implantation site, needles are immediately available to the surgeon to begin suturing.

[0026] As alluded to above, the base 10 serves primarily as an advantageous initial delivery system to ensure quick and accurate placement and, significantly, secure and repeatable anchoring of the suture strands 24 by the surgical screw. Once the surgical screw has been inserted through the central opening 18 of the distal portion 12 and then secured into the underlying bone, which, again, involves capture of the middle portion of the suture strands 24 to anchor those strands, the base 10 is removed by simply passing the surgical screw through the slot 20 of the distal portion 12 and pulling the base 10 away from the suture strands 24 and needles 30. This leaves the site completely unobstructed with the suture strands 24 and needles

30 perfectly positioned for subsequent suturing. Furthermore, the suture strands 24 are securely anchored by the surgical screw.

[0027] An additional advantage of the described system is that the base 10 can be constructed of low cost, flexible plastic material or reinforced paper. The base 10 is intended to be a single use, disposable unit.

[0028] While the illustrated embodiment has been described in connection with the use of a surgical screw, the system may be utilized with essentially any known surgical hardware, including staples or rivets, in the same manner as described above.

[0029] A further advantage of the described system is that the base 10 may also be used for the application of bone wax to the fixation point. Bone wax may be applied to the underside of the distal portion 12 surrounding the central opening 18 during manufacture of system and prior to packaging.

[0030] Figs. 4 and 5 illustrate additional embodiments of a suture delivery system. The primary difference between the versions in these figures and the embodiments described above resides in the use of multiple suture snares in the distal portion 12 of these embodiments. More particularly, Fig. 4 illustrates a version utilizing two snares 40. As with the previously described embodiment, each snare 40 is generally C-shaped with a break or slot 20 in one side, preferably the side opposite of the connection between the snare 40 and a connecting portion 42 that connects the snares 40 with the handle portion 16, to facilitate removal of the base 10 from the surgical screw after implantation of the screw in the underlying bone. The underside, or middle, of each snare 40 is provided with one or more slots or flanges 22 to capture a portion of the



suture strands 24. This embodiment is particularly useful for forming a suture bridge that is anchored to the surgical screw.

**[0031]** Fig. 5 illustrates a version utilizing three snares 40. As with the previously described embodiment, each snare 40 is generally C-shaped with a break or slot 20 in one side, preferably the side opposite of the connection between the snare 40 and a connecting portion 42 that connects the snares 40 with the handle portion 16, to facilitate removal of the base 10 from the surgical screw after implantation of the screw in the underlying bone. The underside, or middle, of each snare 40 is provided with one or more slots or flanges 22 to capture a portion of the suture strands 24. The embodiment of Fig. 5 is particularly useful for forming an enhanced tangential anchor site or for enhanced radial pull of soft tissue to the anchor site(s).

**[0032]** The remaining portions of the embodiments of Figs. 4 and 5 are essentially the same as the previously described embodiments.

**[0033]** Figs. 6-8 illustrate another embodiment utilizing a slightly different shape. In this embodiment, the base 110 also has a distal portion 112 and a body portion 114. Advantageously, the base 110, which may be molded from a plastic or other suitable material, is composed of two, separable halves, creating a “clam-shell” type package. Figs. 7 and 8 show the two halves of the base 110 separated from one another so that the interior of the base 110 can be seen. As discussed in more detail below, the two halves of the base 110 are separated from one another after the surgical screw has been inserted through the distal portion 112 and implanted in order to access the suture material and remove the base 110 from the surgical site.

[0034] The distal portion 112 is generally cylindrically shaped with an open vertical interior space 118 with openings at its top and bottom. This arrangement allows a surgical screw to be inserted through the central opening 118 of the distal portion 112 for implantation. The top end of the distal portion 112 is provided with a series of slots 122. These slots 122 perform the same function as the slots/flanges 22 in the above described embodiments. In particular, they serve to capture a portion of several suture strands that are packaged with the base 110. The slots 122 route the suture strands around the central opening of the distal portion 112 so that they do not interfere with the initial insertion of the surgical screw but are positioned immediately adjacent to the central opening to encourage the screw to capture the suture strands. Again, this results in a portion of the suture strands being wrapped around the surgical screw to form an extremely solid base connection for the suture strands.

[0035] The interior of the body portion 114 of the base 110 provides a suitable space to house the bulk of the suture strands for the system. The interior of the body portion 114 is provided with a pair of posts 126 in one half of the body portion 114 and a corresponding pair of mating bosses 128 in the other half of the body portion. When the two halves of the base 110 are pressed together, the posts 126 fit into the bosses 127 in a press fit or snap fit manner to secure the two halves together. Advantageously, the posts 126 and bosses 128 provide a structure around which the suture strands may be wrapped to minimize tangling of the suture strand within the body portion 114.

[0036] The body portion 114 is also provided with a port 150 that allows the interior of the body portion to be filled with a fluid material. This is advantageous as surgeons frequently

soak sutures in various materials, for example, antibiotics or bone growth stimulants, prior to use. The open interior space of the body portion 114 with the port provides a means to pre-soak the suture. In a preferred embodiment, the port is provided with a resealable closure. The resealable closure may simply be a rubber seal through which a syringe needle may be inserted.

5 In an alternate embodiment, a proprietary needle lock is incorporated into the port to allow for a measure of control over what substances may be injected into the body portion 114

[0037] The body portion 114 is also provided with a leader tube 125 that communicates with the interior of the body portion 114 and extends horizontally from the body portion 114 toward the top end of the distal portion 112. The leader tube 125 is provided with a  
10 distal orifice 129 at its distal end. During assembly of the system, the suture strands are routed from the interior of the body portion 114, through the leader tube 125, and to the slots 122 of the distal portion 112.

[0038] The interior of the body portion 114 is also provided with one or more flanges 128 that capture needles that are pre-threaded onto the suture strands. Again, this provides  
15 immediately available needles to the surgeon and results in a complete suture package.

[0039] This embodiment operates in the same basic manner as the embodiments described above. The base 110 serves primarily as an advantageous initial delivery system to ensure quick and accurate placement and, significantly, secure and repeatable anchoring of the suture strands by the surgical screw. Once the surgical screw has been inserted through the  
20 central opening 118 of the distal portion 112 and then secured into the underlying bone, which, again, involves capture of the middle portion of the suture strands to anchor those strands, the

base 110 is removed by separating the two halves of the base 110 and pulling the base 110 away from the suture strands and needles. This leaves the site completely unobstructed with the suture strands and needles perfectly positioned for subsequent suturing. Furthermore, the suture strands are securely anchored by the surgical screw.

5 [0040] An additional advantage of the described system is that the base 10 can be constructed of low cost, flexible plastic material or reinforced paper. The base 10 is intended to be a single use, disposable unit.

[0041] The preferred embodiments of the invention have been described above to explain the principles of the invention and its practical application to thereby enable others  
10 skilled in the art to utilize the invention in the best mode known to the inventors. However, as various modifications could be made in the constructions and methods herein described and illustrated without departing from the scope of the invention, it is intended that all matter contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the present  
15 invention should not be limited by the above-described exemplary embodiment, but should be defined only in accordance with the following claims appended hereto and their equivalents.

What is claimed is:

1. A suture delivery system, comprising:  
a distal portion having a central opening therein and one or more flanges  
5 surrounding said central opening;  
a body portion connected with said distal portion; and  
at least one suture strand and needle combination removably connected with at  
least one of said distal portion and said body portion, wherein a first portion of said suture  
strand engages said flanges of said distal portion and said body portion stores a second  
10 portion of said suture strand and said needle.
2. The suture delivery system as set forth in claim 1, wherein said distal portion and  
said body portion are divided and comprise two separable parts.
- 15 3. The suture delivery system as set forth in claim 1, wherein said distal portion  
further comprises a flat, annular surface having a slot therein.
4. The suture delivery system as set forth in claim 1, wherein said distal portion  
further comprises a generally cylindrical shape with said central opening passing through said  
20 cylindrical shape and said flanges being adjacent a top end of said cylindrical shape.

5. The suture delivery system as set forth in claim 2, wherein said two separable parts form an interior of said body portion, said interior further comprising at least a first inwardly extending structure operable to retain said second portion of said suture strand and at least a second inwardly extending structure operable to retain said needle.

5

6. The suture delivery system as set forth in claim 2, wherein said two separable parts form an interior of said body portion and said body portion further comprising an elongated tube having first and second orifices at each end thereof, said first orifice of said elongated tube communicating with said interior of said body portion and said second orifice of said elongated tube extending toward said flanges of said distal portion.

10

7. The suture delivery system as set forth in claim 2, wherein said two separable parts form an interior of said body portion, said body portion further defining a port therein operable to allow said interior to be filled with a fluid material.

15

8. The suture delivery system as set forth in claim 7, wherein said port is resealable.

9. The suture delivery system as set forth in claim 1, wherein said body portion further comprises a proximal portion and a handle, said handle connecting said proximal portion with said distal portion.

20

10. The suture delivery system as set forth in claim 1, wherein said distal and body portions are made of reinforced paper material.

11. The suture delivery system as set forth in claim 1, wherein said distal and body  
5 portions are molded.

12. The suture delivery system as set forth in claim 1, wherein said distal and body portions are formed by first and second clam-shell sections.

10 13. A method of delivering a suture to a surgical site, comprising the steps of:  
providing a suture delivery device comprising:

a distal portion having a central opening therein and one or more flanges surrounding said central opening;

a body portion connected with said distal portion; and

15 at least one suture strand and needle combination removably connected  
with at least one of said distal portion and said body portion, wherein a first  
portion of said suture strand engages said flanges of said distal portion and said  
body portion stores a second portion of said suture strand and said needle;  
positioning said suture delivery device at a surgical site;

20 inserting a surgical screw through said central opening of said distal portion such  
that said surgical screw captures said first portion of said suture strand;

implanting said surgical screw into said surgical screw and securing said first portion of said suture strand at said surgical site;

removing said distal portion and said body portion from said surgical screw; and

suturing tissues at said surgical site with said needle and said second portion of

5 said suture strand.

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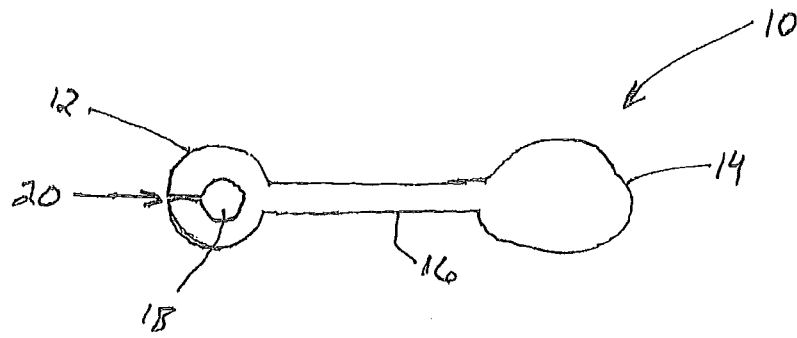


Fig. 1

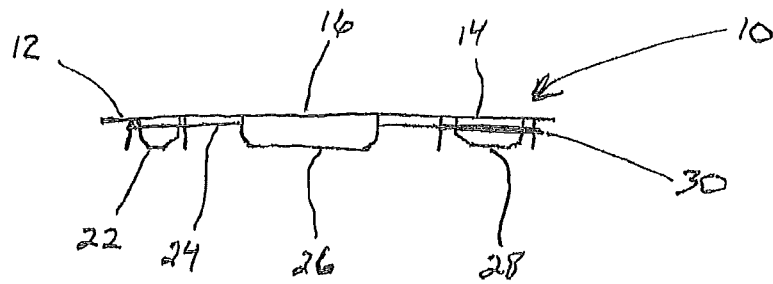


Fig. 2

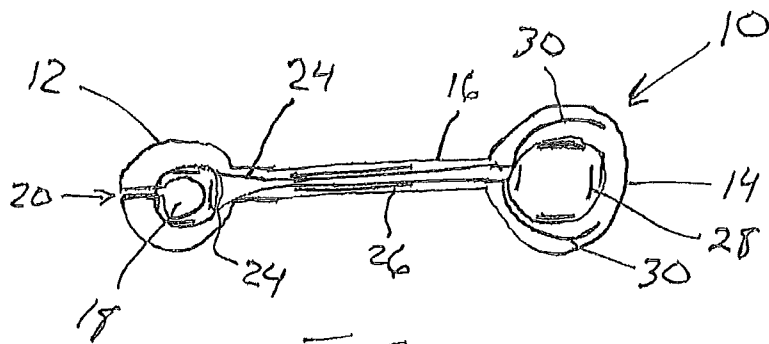


Fig. 3

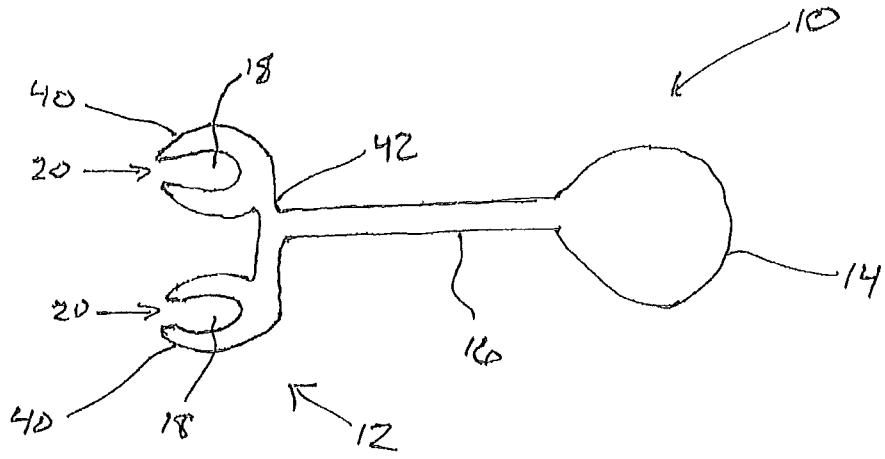


Fig. 4

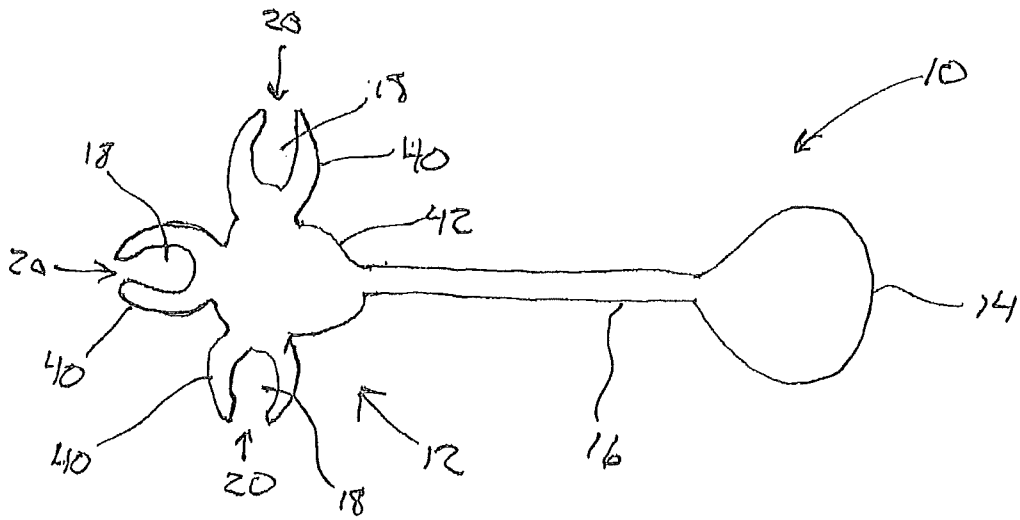


Fig. 5

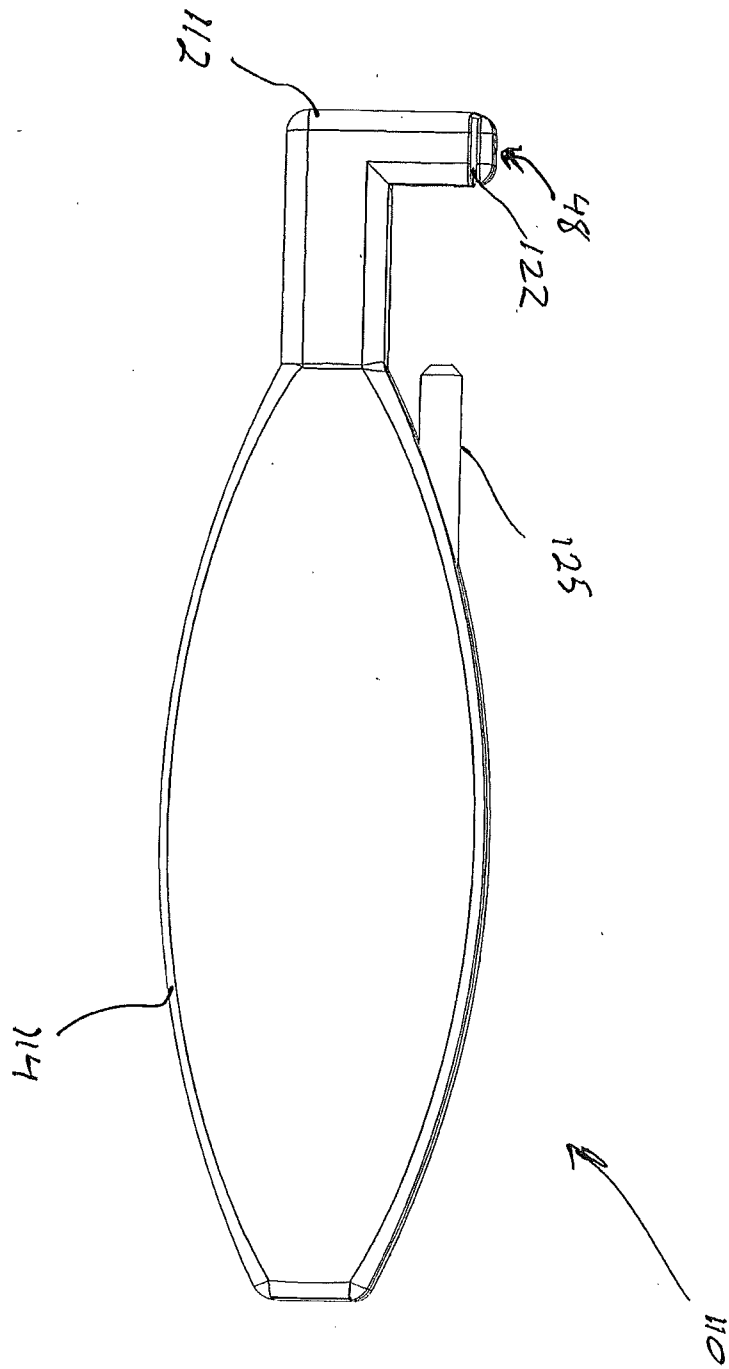
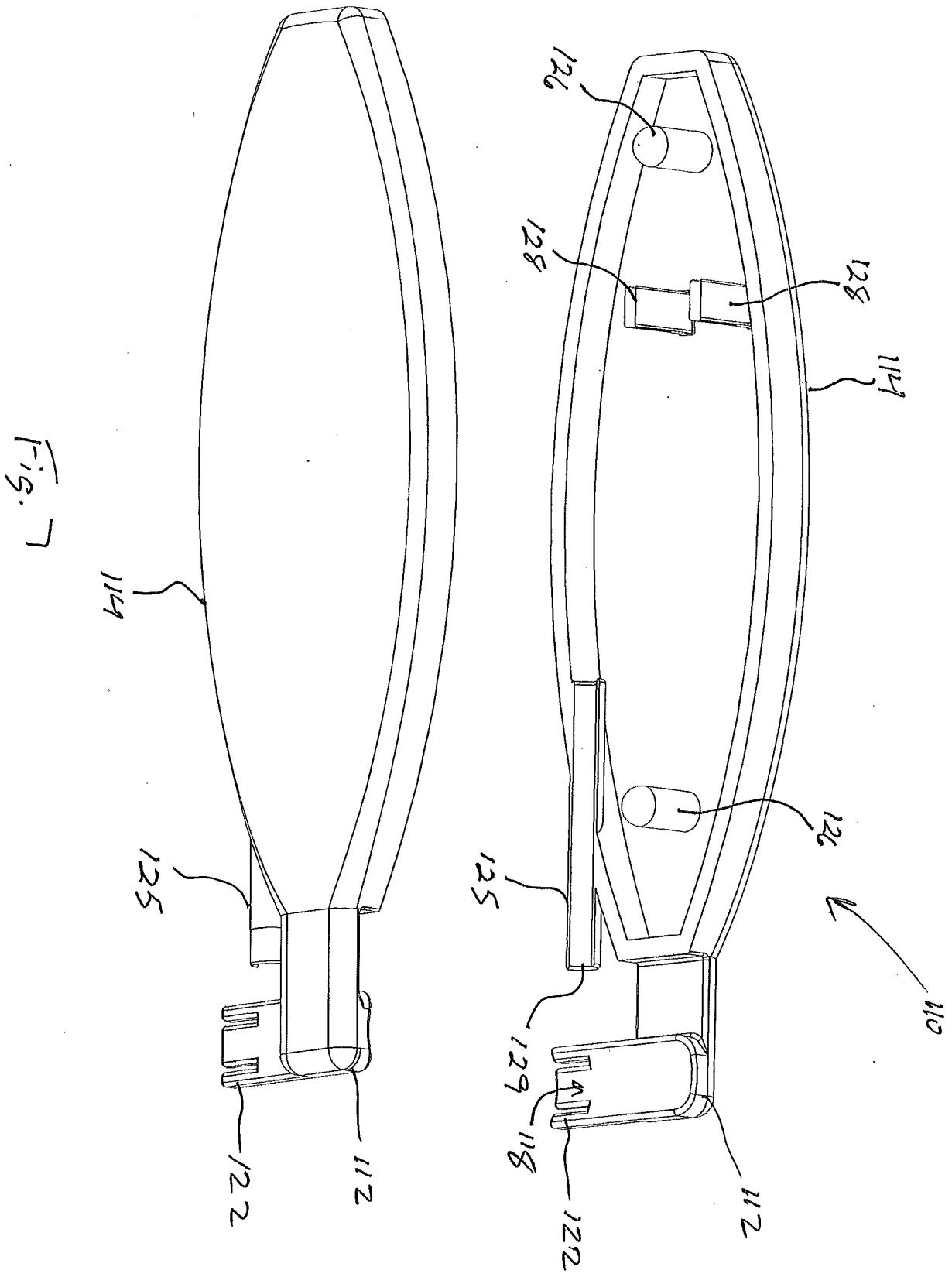


Fig. 6



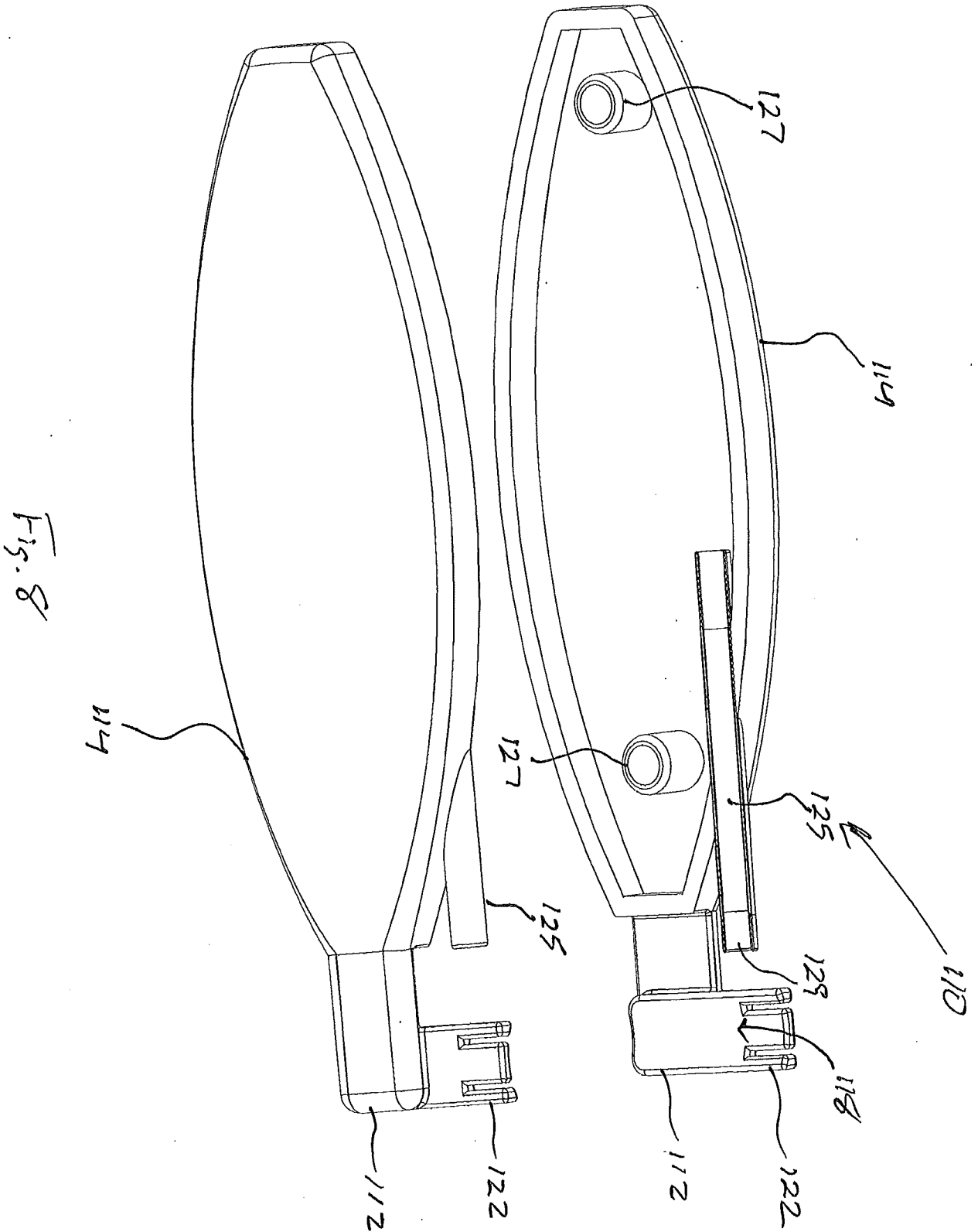


Fig. 8

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/57635

|  |  |                       |
|--|--|-----------------------|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC(8) - A61B 17/04 (2012.01)<br>USPC - 606/144<br>According to International Patent Classification (IPC) or to both national classification and IPC   |  |                       |
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>IPC(8) - A61B 17/04 (2012.01)<br>USPC - 606/144<br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>606/139, 144, 145, 146, 147<br>(Search term limited; see below)<br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>PubWest (PGPB, USPT, EPAB, JPAB); Patbase (All); Google<br>Search Terms: Suture, needle, shape, dumbbell, barbell, opening, aperture, hole, flange, material, paper, cardboard, port  |  |                       |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>  |  |                       |
| Category*  | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
| X  | US 2007/0010832 A1 (MANZO) 11 January 2007 (11.01.2007) Entire document, especially Abstract, para[0052]- para[0055], para[0061]- para[0067], para[0070]- para[0074] and FIGS. 1-4, 6, 14. | 1-9                   |
| X  | US 2011/0046642 A1 (MCCLURG et al.) 24 February 2011 (24.02.2011) Entire document, especially Abstract, para[0035]- para[0040] and FIGS. 1-5.  | 1-2, 11-12            |
| Y  |  | 10                    |
| Y  | US 6,126,666 A (TRAPP et al.) 03 October 2000 (03.10.2000) Abstract, col 4, ln 13-15.  | 10                    |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C.  |  |                       |
| * Special categories of cited documents:<br>"A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"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)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed<br>"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<br>"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<br>"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<br>"&" document member of the same patent family |  |                       |
| Date of the actual completion of the international search<br>30 January 2013 (30.01.2013)  | Date of mailing of the international search report<br><div style="font-size: 24pt; font-weight: bold; text-align: center;">15 FEB 2013</div>   |                       |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201  | Authorized officer:<br><div style="text-align: right;">Lee W. Young</div> PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774  |                       |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/57635

## 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 extra 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 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.:  
1-12

### 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.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/57635

Continuation of Box III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-12, drawn to a system for suture delivery

Group II: Claim 13, drawn to a method of using a system for suture delivery with a surgical screw.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The corresponding special technical feature of the groups comprises a system for suture delivery which is well known in the art (see US 2007/0010832 A1 to Manzo (publication date 11 January 2007), Abstract, para[0052]-[0074] and FIGS. 1-4); more specifically:

Manzo describes a suture delivery system (Abstract), comprising:

a distal portion (104, FIGS. 1-4) having a central opening (unlabeled, FIGS. 1, 4) therein and one or more flanges (162, FIGS. 1-4), surrounding said central opening (Abstract, para[0061]-[0065]);

a body portion (102, FIGS. 1-4) connected with said distal portion (para[0052]); and

at least one suture strand (182) and needle (174) combination removably connected with at least one of said distal portion and said body portion (FIGS. 1-4; para[0067],[0074]), wherein a first portion of said suture strand engages said flanges of said distal portion (FIG. 4) and said body portion stores a second portion of said suture strand and said needle (FIG. 2; para[0065]).

Consequently, pursuant to MPEP 1850 sub III.A. the Groups lack unity because the method and apparatus do not share a corresponding special technical feature. Groups I through II therefore lack unity under PCT Rule 13.