

(19) World Intellectual Property
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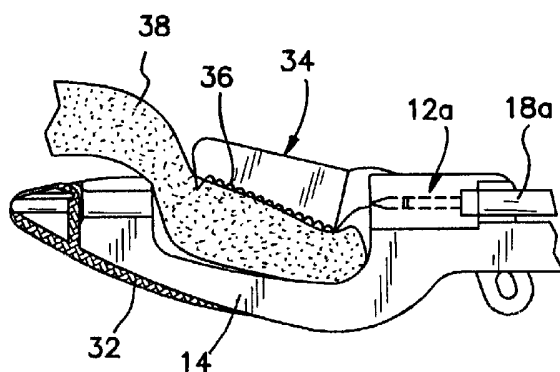
(43) International Publication Date
8 January 2004 (08.01.2004)

PCT

(10) International Publication Number
WO 2004/002324 A1

- (51) International Patent Classification⁷: **A61B 17/04**
- (21) International Application Number:
PCT/US2003/018540
- (22) International Filing Date: 12 June 2003 (12.06.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/391,767 26 June 2002 (26.06.2002) US
10/308,732 3 December 2002 (03.12.2002) US
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- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD,
SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ,
VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: SUTURE CAPTURE DEVICE



(57) Abstract: A suturing instrument (10) for placing mattress stitches in soft tissue, such as a rotator cuff, includes an elongate shaft with both a stationary jaw (14) and a movable jaw (34) disposed at the distal end thereof. The shaft is coupled to a handle grip at the proximal end, which configured to manipulate the jaws into open and closed positions. The jaws are configured to allow for atraumatic grasping of soft tissues (38). The stationary jaw may include a molded tip that holds and positions opposite ends of a single strand of suture material (30). The serrated (36) upper jaw is configured to grasp and immobilize the tissue to be sutured. Hooked needles (20a, 20b) are movably positioned to pierce the grasped and immobilized tissues, and to engage and retrieve the opposite ends of the single strand of suture material (30). The handle is released to open the moveable jaw, whereupon the instrument may be withdrawn, trailing the suture, and leaving a mattress stitch in the grasped tissue.

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SUTURE CAPTURE DEVICE

This application claims the benefit under 35 U.S.C. 119(e) of the filing date of Provisional U.S. Application Serial No. 60/391,676, entitled *Suture Capture Device*, and filed on June 26, 2002, which application is expressly incorporated herein by reference.

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Background of the Invention

The present invention relates to a method and apparatus for placing sutures in soft tissue, and more particularly to methods and devices for arthroscopic repair of a torn rotator cuff.

Suturing of body tissues is a time consuming aspect of most surgical
10 procedures. Many surgical procedures are currently being performed where it is necessary to make a large opening to expose the area of, for instance, the human body that requires surgical repair. There are instruments that are becoming increasingly available that allow the viewing of certain areas of the body through a small puncture wound without exposing the entire body cavity. These
15 viewing instruments, called "endoscopes", can be used in conjunction with specialized surgical instrumentation to detect, diagnose, and repair areas of the body that were previously only able to be repaired using traditional "open" surgery. In the past, there have been many attempts to simplify the task of driving a needle carrying suture through body tissues to approximate, ligate and
20 fixate them. Many prior disclosures, such as described in U.S. Patent No. 919,138 to Drake et al, employ a hollow needle driven through the tissue with the suture material passing through the hollow center lumen. The needle is withdrawn, leaving the suture material in place, and the suture is tied, completing the approximation. A limitation of these types of devices is that
25 they are particularly adapted for use in open surgical procedures where there is

ample room for the surgeon to manipulate the instrument.

Others have attempted to devise suturing instruments that resemble traditional forceps, such as U.S. Patent No. 3,946,740 to Bassett. These devices pinch tissue between opposing jaws and pass a needle from one jaw through the
5 tissue to the other jaw. Graspers then pull the needle and suture material through the tissue. A limitation of these designs is that they also are adapted primarily for open surgery, in that they require exposure of the tissues to be sutured in order that the tissue may be grasped or pinched between the jaws of the instrument. This is a severe limitation in the case of endoscopic surgery.

10 The term "endosurgery" means "endoscopic surgery", or surgery performed using an endoscope. In conjunction with a video monitor, the endoscope permits the surgeon to remotely visualize the operative site. Operations using an endoscope are significantly less invasive when compared to traditional open surgery. Patients usually return home the next day, or in some
15 cases, the same day of the endosurgical procedure. This is in contrast to standard open surgical procedures where a large incision divides the muscle layers and allows the surgeon to directly visualize the operative site. Patients may stay in the hospital for 5 to 6 days or longer following open surgery. In addition, after endosurgical procedures, patients return to work within a few
20 days versus the traditional 3 to 4 weeks recuperative period at home following open surgery.

Access to the operative site using endosurgical or minimally invasive techniques is accomplished by inserting small tubes, known as trocars, into a body cavity. These trocars have a diameter of, for example, between 3mm and
25 30mm and a length of about 150mm (6 inches). There have been attempts to devise instruments and methods for suturing within a body cavity through these trocar tubes.

Such an instrument is disclosed by U.S. Patent No. 4,621,640 to

Mulhollan et al. Mulhollan et al. describe an instrument that may be used to hold and drive a needle, but make no provision for retrieval of the needle from the body cavity, nor the completion of the suture by tying. The instrument disclosed by Mulhollan et al. is limited, in that the arc through which the needle
5 must be driven is perpendicular to the axis of the device.

Another such instrument, intended for endoscopic use, is described in U.S. Patent No. 4,935,027 to Yoon. This instrument uses oppositional hollow needles or tracks pushed through the tissue and adapted to create a tract through which the suture material is pushed. It is not clear how these curved tracks
10 would be adapted to both be able to pierce the tissue planes illustrated, parallel to the tips of the tracks, and be curved toward each other to form the hollow tract.

Yet another instrument and method is shown by Caspari in U. S. Patent Nos. 4,923,461 issued May 8, 1990 and 4,957,498 issued September 18, 1990.
15 The Caspari patents disclose an endoscopic instrument suitable for use through a trocar that resembles the Yoon approach, but with a single hollow needle on one of a set of oppositional jaws. The jaws simultaneously close, grasping the tissue. The jaw opposite the hollow needle has a window through which the hollow needle passes as the jaws close, freeing the lumen of the hollow needle
20 from the tissue. Much like Yoon, a suture or suture snare is pushed down through the lumen and retrieved from the suture site, the jaws released, and the suture pulled back out through the trocar. This device may be used to place simple stitches in tissues that have been mobilized and have an edge accessible to the jaws. A limitation of the device is the manipulation that must be done
25 with the snare if a suture other than a monofilament is used.

Another instrument specifically adapted for the orthopedic surgeon for the repair of a torn anterior cruciate ligament or for meniscal repair is disclosed in U.S. Patent No. 4,836,205 to Barrett. Barrett combines in a single instrument

the functions of grasping the tissue to be sutured and the passing of the needles through that tissue. It is to be understood that this instrument is designed for use specifically under endoscopic view, and through trocars as previously described. A fairly generic endoscopic grasper is disclosed that has been adapted to allow for a hollow lumen from the handle of the grasper down to the distal tip of the grasper jaws. An elongate needle of 8 to 10 inches in length may be passed through this hollow lumen. The needle, being significantly longer than the grasper, is introduced through the handle of the grasper, and may be driven through the tissue being held in the grasping jaws of the device.

5

10 The needle is then retrieved from the tissue via a trocar port placed substantially opposite the port through which the grasper is introduced. If a mattress stitch is desired, two needles attached to opposite ends of a suture are both passed through the tissue and retrieved. A limitation of this device is that there must be both visual and physical access to both sides of the tissue flap to be sutured.

15 This requires trocars to be placed opposite each other and roughly on a line intercepting the tissue. This is a severe limitation in the instance of shoulder repair, and specifically in repair of the rotator cuff.

Yet another instrument adapted for use in endoscopic procedures is described by Garman et al in U.S. Patent No. 5,499,991. This instrument has an elongated housing provided with a needle tip and a lateral opening near the sharpened needle tip. A suture engaging hook, typically formed from wire, is extendable through the lateral opening and away from the axis of the elongated housing by virtue of being predisposed to bend away from the axis in order to snare the suture. The hook is situated at the distal end of an elongated flexible support which is pre-formed in order to enable the hook to be laterally displaced from the axis of the needle tip when the support is moved distally relative to the lateral opening. When a suture is engaged by the hook, the hook is retracted proximally in order to place and hold the suture adjacent the lateral opening.

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The instrument is somewhat limited in the case of rotator cuff repair in that an additional instrument would need to be introduced into the joint to immobilize the tissues sufficiently to allow the needle tip to penetrate the tissues to be sutured. Also, no provision is made for capturing the two ends of a suture to
5 place a mattress stitch, save repeating the prior steps.

A similar instrument is disclosed in U.S. Patent Nos. 5,312,422 and 5,474,565 issued to Trott. These patents also describe a needle structure adapted for penetration of soft tissues and suture retrieval. A substantially flat suturing needle with a hook feature is illustrated which can engage a suture to
10 an outer housing, thereby presenting a relatively smooth surface at the distal end of the needle to minimize tissue trauma. The limitations mentioned above are evident here as well. The requirement for additional instrumentation to immobilize the tissues, and the lack of provision for a mattress stitch are paramount.

15 There have been other attempts to improve the methods of tissue repair. These include the development of staplers and anchoring devices. In response to some of the aforementioned problems in placing sutures in tissues endoscopically, manufacturers have developed tissue staplers. These devices utilize stainless steel or titanium staples that are constructed much like the staples used to hold
20 papers together. The major disadvantage of these kinds of staplers is that they leave metal in the body. For some tissues this is not a problem, however in some procedures, metal staples left within the tissues can be a major hindrance to the healing process. Orthopedic surgeons have begun to explore alternatives to the traditional open approach for the many indications requiring
25 reconstruction of some aspect of the shoulder. As they did in adopting minimally invasive approaches to knee repair and re-construction, the use of either an endoscope or a "mini-open" approach is gaining in popularity with surgeons, patients and third party payers.

It is an increasingly common problem for tendons and other soft, connective tissues to tear or to detach from associated bone. One such type of tear or detachment is a "rotator cuff" tear, causing pain and loss of ability to elevate and externally rotate the arm. Complete separation can occur if the shoulder is
5 subjected to gross trauma, but typically, the tear begins as a small lesion, especially in older patients.

Less invasive arthroscopic techniques are beginning to be developed in an effort to address the shortcomings of open surgical repair. Working through small trocar portals that minimize disruption of the deltoid muscle, a few
10 surgeons have been able to reattach the rotator cuff using various bone anchor and suture configurations. The rotator cuff is sutured intracorporeally using instruments and techniques such as the Caspari punch previously described. This creates a simple stitch instead of the more desirable mattress or Mason-Allen stitch. Rather than thread the suture through trans-osseous tunnels which
15 are difficult or impossible to create arthroscopically using current techniques, an anchor is driven into bone at a location appropriate for repair. The repair is completed by tying the cuff down against bone using the anchor and suture.

Early results of less invasive techniques are encouraging, with a substantial reduction in both patient recovery time and discomfort. However, as
20 mentioned, this approach places only one loop of suture in the cuff for each anchor, reducing the fundamental strength of the repair. The knots in the tendon can be bulky and create a painful impingement of the tendon on the bone. This is because the knots end up on top of the cuff, in the sub-acromial space, and have the opportunity to rub on the acromion as the arm is raised. Because non-
25 absorbable suture materials are used for these types of repairs, the suture and associated knots are not absorbed into the body, and hence provide a constant, painful reminder of their presence.

None of the prior art devices are adaptable to effect the placement of a mattress

stitch in grasped tissues, nor are they adaptable to place sutures precisely and controllably while making provision for needle retrieval when using endoscopic techniques. None of the prior art devices make it possible to place a mattress stitch into, for example, the supraspinatus tendon utilizing an endoscopic approach.

5 What is needed, therefore, is a family of novel suturing devices that overcome the above described disadvantages of prior known devices in a simple and economical manner. The devices should be capable of arthroscopically creating a mattress stitch in a tendon to increase the soft tissue pullout strength of the repaired tendon.

10

Summary of the Invention

Accordingly, the inventors have developed a new and novel approach to securing a mattress stitch in a tissue flap. An instrument that combines the function of both grasping the tissue and passing sutures through the tissue to form a mattress stitch is herein described. The instrument includes a pair of
15 grasping jaws that oppose each other along a line substantially perpendicular to the long axis of the instrument. The distal end of the instrument incorporates the fixed jaw, and proximal to that jaw is a moveable jaw that is controlled by the user via a lever on the handgrip.

In a preferred method of the present invention the instrument is inserted
20 through a portal known as a trocar cannula. The portal is created by first making an incision in the skin, and then inserting a cannula through the incision to the repair site. The distal end of the instrument is inserted through the cannula under direct visualization from a second trocar cannula that has been previously inserted. The visualization is accomplished via an endoscope, of a
25 type well known in the art. The instrument is inserted until the jaws reach, for example, torn rotator cuff tissue. In operation, the distal end of the grasper

aspect of the instrument is positioned at the repair site underneath the tissue to be grasped. The moveable jaw pivots toward the stationary jaw by squeezing the handle lever. The handle lever moves inward by pivoting about a pivot pin. Once the appropriate section of tissue is isolated and grasped by the jaws, the
5 lever may be locked in its closed position using a latch mechanism.

Once the surgeon is satisfied with the placement of the grasper on the grasped tissue, the surgeon can then deploy the suture needles to create a mattress stitch in the tissues, for example, the above-mentioned torn rotator cuff. In operation, the suture needles may be advanced through the grasped tissues by
10 pulling on a second lever. The lever is directly connected to the needles via a connecting rod, and the lever is pulled against the force of a return spring. In turn, the connecting rod pushes a needle carriage, with suture needles held in the carriage. The needle carriage resides behind the proximal moveable jaw of the instrument, and, at the urging of the lever via the connecting rod, is able to
15 move distally with the needles passing around the moveable jaw. As the carriage moves distally, the tips of the suture needles begin to clear the distal edge of apertures created in a more proximal portion of the stationary jaw, and begin to penetrate through the top of the grasped tissue and advance distally towards the more distal portion of the stationary jaw.

20 The stationary distal jaw incorporates two apertures that are adapted to receive the ends of the suture. Secondary open channels perpendicular to the suture apertures are configured with a specific geometry designed to direct the suture needles across the apertures containing the ends of the sutures. As the suture needles approach the end of their stroke, the distal ends of the needles
25 have passed completely through the grasped tissues and begin to enter the secondary open channels in the stationary distal jaw.

At this point, any pull force being applied by the grasper on the grasped tissues is relaxed. Once the tissue is in a relaxed state, the jaws of the grasper

are then opened. The handle lever is unlocked from the locking mechanism and returns to an open position due to the pull force exerted on it by means of a return spring. As the return spring pulls on the lever, it pivots about a pin.

To complete the pull out of the suture needles, it is necessary to pull on
5 the grasper, and to remove it from the repair site. The instrument can be retracted back through the portal via the trocar cannula. As the instrument is removed from the suture site, the free ends of the suture are retrieved as well. This causes the suture to pass through the tissues at the puncture sites. As the suture is pulled through, the loop end of the suture is pulled snug against the
10 underside of the tissues to form what is referred to as a mattress stitch. This process may be repeated as necessary, depending on the number sutures required for the particular procedure being undertaken.

Now it may be seen by those skilled in the art, that the combination of grasping tissues to be sutured and precisely placing a mattress stitch in the
15 grasped tissues, while working through a trocar port, effects a significant advance in the art. Advantages of the present invention thus include providing an endoscopic instrument adapted for the grasping of tissues and creating a mattress stitch within those tissues, as well as the provision of a suturing instrument that allows for the reloading of additional sutures for placement of
20 subsequent stitches. Additionally, the inventive system is advantageous in that it provides for direct capture of the suture material.

More particularly, there is provided in one preferred embodiment of the present invention a suturing device, comprising a distal portion which is engaged with a length of suture, as well as a needle which is axially movable distally and
25 proximally. A soft tissue receiving portion, preferably comprising a clamp having first and second jaws, wherein one of the first and second jaws is movable relative to the other to grasp soft tissue therein, is disposed proximally of the distal portion. A ramp portion for moving the needle radially inwardly and outwardly as the needle

moves axially over the ramp portion is also provided.

In a preferred embodiment, the distal portion for retaining the suture comprises a suture cartridge with a molded tip, having grooves for accommodating the suture. The ramp portion comprises a radially outwardly sloping entrance ramp
5 for moving the needle radially outwardly as the needle moves axially in a distal direction, as well as a radially inwardly sloping retraction ramp for moving the needle radially inwardly as the needle moves axially in a proximal direction. The needle comprises a distal point, a proximal shaft, and a hook defining a suture holding area.

10 The hook portion of the needle is uniquely designed to provide a positive tactile indication as to when the suture has been capture within the suture holding area. This design includes a terminus of the hook, which is cantilevered proximally from a distal end of the needle. A bump on the needle in a location opposed to the hook terminus is provided, so that the hook terminus and the bump together provide
15 a tactile sensation to a user when suture passes thereover into the suture holding area.

In preferred embodiments, a second needle, as well as a second ramp portion, is provided, so that a mattress stitch may be created. A sheath, which is slidable relative to the needle, is provided for selectively covering each needle,
20 particularly when the needle is being retracted proximally through the soft tissue, to prevent unnecessary damage thereto.

In another aspect of the invention, there is provided a needle for a suturing device, which comprises a distal point, a proximal shaft, and a hook defining a suture holding area. As noted above, the needle preferably further comprises a
25 terminus of the hook, which is cantilevered proximally from a distal end of the needle, as well as a bump on the needle in a location opposed to the hook terminus.

In still another aspect of the invention, there is described a method of suturing soft tissue using a suturing device, which comprises steps of retaining a

portion of soft tissue to be sutured, and moving a needle having a hook which defines a suture holding area distally, so that the hook is disposed in a location past the portion of soft tissue and past a length of suture which is retained on a distal portion of the suturing device. Then, the needle is moved proximally in order to
5 capture the suture so that it is retained in the suture holding area. Once the suture is captured, the needle is moved a further distance proximally, so that the needle draws the suture through the portion of soft tissue, thereby suturing the soft tissue. Preferably, when the needle is moved distally, it is also moved radially outwardly in order to avoid contacting, and possibly damaging, the length of suture.
10 Additionally, when the needle is moved proximally, it is also moved radially inwardly in order to ensure proper capture of the suture. In preferred methods, it is further desirable to cover the needle with a sheath prior to retracting the needle proximally through the soft tissue.

The invention, together with additional features and advantages thereof,
15 may best be understood by reference to the following description taken in conjunction with the accompanying illustrative drawing.

Brief Description of the Drawings

Figs. 1A through 1E are detail plan views of the distal end of an instrument constructed in accordance with the principles of the present invention, illustrating
20 the general structure and operation of the instrument;

Figs. 2A through 2E are detail side views of the distal end of the instrument of Figs. 1A through 1E, which again illustrate the general structure and operation of the present invention;

25 Figs. 3A through 3E are cross sectional plan views of the distal end of the

instrument of Figs. 1A through 1E, showing the relationship between the body structure and the needle geometry;

Fig. 4 is a detailed view of a needle of the present invention;

Fig. 5 is a detailed view of the needle of FIG. 4 with an associated sleeve;

5 Fig. 6 is a detailed view of an alternative embodiment of a needle of the present invention;

Fig. 7 is a detailed view of another alternative embodiment of a needle of the present invention;

10 Fig. 8 is a detailed view of still another alternative embodiment of a needle of the present invention; and

Fig. 9 is a perspective view of the needle of Fig. 4.

Description of the Preferred Embodiment

15 The present invention relates to a method and apparatus for the arthroscopic repair of torn tissue and bone at a surgical repair site using an inventive device which is a combination tissue grasper and suture placement device. Although the present invention is described primarily in conjunction with the repair of a torn rotator cuff, the apparatus and method could also be used in arthroscopic repair at other sites, such as the knee, elbow, hip surgery, and for other surgical techniques
20 for securing suture in the soft tissues of the body.

A description of the basic functional elements of suture capture and

retrieval, in accordance with the principles of the invention, follows.

Referring to Figs. 1A through 1E, there may be seen a plan view of the distal end of a suturing device 10 that includes a pair of needles 12a and 12b, a lower jaw 14, and a suture cartridge 16. The needles 12a, 12b further include
5 sliding tubes or sheaths 18a and 18b, needle shafts 20a and 20b, needle points 22a and 22b, and hooks 24a and 24b. The suture cartridge 16 comprises a molded tip 26 with grooves 28a and 28b, into which the two ends 30a and 30b of a length of suture are threaded.

Referring to Fig. 1B, the needles 12a, 12b are advanced distally toward the
10 suture cartridge 16 in preparation for capture and retrieval of the two ends 30a, 30b of the length of suture. It is to be understood that the entire length of the suture which includes the two ends 30a, 30b is not seen in this illustration. The loop of suture between the two ends 30a, 30b trails beneath the distal end of the suturing device 10 and is thus not visible. It will be described more fully later how the
15 capture of the two ends of a suture can be used to create what is known in the art as a mattress stitch.

Referring now to Fig. 1C, it may be seen that the needles 12a, 12b are further advanced distally toward the suture cartridge 16 and past the two ends 30a, 30b of the suture, placing the hooks 24a, 24b in position past the two suture ends
20 30a, 30b in preparation for capture. As it may be seen in Fig. 1D, as the needles 12a, 12b are retracted proximally, the hooks 24a, 24b engage the two suture ends 30a, 30b and capture them for retrieval. As the needles 12a, 12b are further retracted proximally as shown in Fig. 1E, the sliding tubes 18a, 18b, held stationary by frictional forces exerted by tissue (not shown), cover the hooks 24a, 24b and
25 assist in the engagement of the two ends 30a, 30b.

Having understood the basic structure and nature of the suture retrieval mechanism, a more complete disclosure of how this mechanism may be used to place a stitch, and more specifically, a mattress stitch, in soft tissues will now be

described. Referring now to Figs. 2A through 2E, there may be seen detail side views of the same suturing device 10 as described in Figs 1E through 1E. The inventive device 10 includes the suture ends 30a, 30b of a single strand of suture 32, and an upper jaw 34, which includes teeth 36. Referring now to Fig 2B, soft tissue 5 38 is introduced into the space between the upper jaw 34 and the lower jaw 14. By means of a mechanism not discussed or shown herein, but of a type well known to those skilled in the art, the upper jaw 34 is pivoted about an axis, causing it to clamp or grasp the soft tissue 38 and immobilize it between the teeth 36 of the upper jaw 34 and the lower jaw 14. Referring now to Fig. 2C, it may be seen that the needles 10 12 have been advanced distally through the soft tissue 38 and in engagement with the suture cartridge 16 with the needle points 22a, 22b advancing beyond the suture ends 30a, 30b.

It is to be understood that in this view, only one needle 12a of the two needles 12a 12b may be visualized, but that a concomitant needle 12b is penetrating 15 the tissue along a substantially parallel path, as previously illustrated in Fig. 1C. The relative position of the needles 12a, 12b in Figs. 1C and 2C is substantially the same. As seen in Fig. 2D, the needles 12a, 12b are retracted proximally, trailing the suture 32 by virtue of having captured the suture ends 30. In this way, the suture 32 is placed through the soft tissue. Referring to Fig. 2E, it may be seen that the upper 20 jaw 34 has been pivoted away from the soft tissue 38, allowing the suturing device 10 to be retracted away from the soft tissue 38, pulling the suture 32 completely through the soft tissue 38. The result of this action is the placement of a mattress stitch in the grasped tissues in a manner similar to that previously described.

As will now be shown, there are certain characteristics, geometries and 25 interfaces between parts that combine to optimize the performance of the suture capture mechanism. Repeatable capture of the suture material, as well as minimizing damage to the suture ends are objects of the present invention. By referring to Figs. 3A through 3E, the specific methods and devices that facilitate

suture capture in accordance with the principles of the invention will be described.

Figs. 3A through 3E depict cross sections taken along the lines 3-3 in Fig. 2A. Referring now to Fig. 3A, there is seen the suture device 10 which includes the needles 12a, 12b, lower jaw 14, suture cartridge 16, and suture ends 30a, 30b. The upper jaw 34 and the soft tissue 38 have not been shown in these figures for clarity. It is possible to now see entrance ramps 40a, 40b and retraction ramps 42a, 42b that are in the path of the needles 12a, 12b. By referring to Fig. 3B, it may be seen that as the needles 12a, 12b move distally in the direction of the suture cartridge 16, the tips of the needles 12a, 12b engage the entrance ramps 40a, 40b. The engagement with the entrance ramps 40a, 40b deflects the needles 12a, 12b such that the needle points 22a, 22b are directed over and away from the suture ends 30a, 30b, preventing the needle points 22a, 22b from piercing or otherwise damaging the suture ends 30a, 30b. Further distal movement of the needles 12a, 12b, as shown in Fig. 3C, allows the hooks 24a, 24b to be disposed distally of the suture ends 30a, 30b and in position to capture the suture upon retraction. It is to be noted that, at this juncture, the sliding tubes 18a, 18b have entered the area of the entrance ramps 40a, 40b, and have begun to ride up the entrance ramps 40a, 40b, thus further deflecting the needles 12a, 12b.

Referring now to Fig 3D, it may be appreciated that as the needles 12a, 12b are retracted proximally, the needle hooks 24a, 24b ride down the retraction ramps 42a, 42b and under the suture ends 30a, 30b, thereby capturing the suture ends 30a, 30b in the hooks 24a,b, and allowing the suture ends 30a, 30b to be peeled away from the suture cartridge 16 and retracted proximally. It may also be appreciated that as the needle shafts 20a, 20b retract, the sliding tubes 18a, 18b remain motionless in the soft tissue (not shown), allowing the sliding tubes to cover the gap made by the hooks 24a, 24b and allowing smooth passage through the tissue. This retraction may be appreciated by comparing the position of the sliding tubes 18a, 18b relative to the hooks 24a, 24b in Figs 3D and 3E. Once the sliding tubes 18a,

18b have covered the gap, they retract along with the needle shafts 20a, 20b back through the soft tissue 38.

A more complete and detailed description of the construction and operation of the needles may be understood by referring to Figs. 4, 5 and 9, where there may be seen, in isolation, a needle 112 constructed in accordance with the principles of the present invention, wherein like elements to those described in prior embodiments bear like reference numerals, preceded by the numeral 1. It is intended that the needles described in connection with these figures may be utilized in the embodiments shown in Figs. 1-3. The needle 112 thus includes a needle shaft 10 120, and a flattened distal portion 154. The flattened distal portion 154 of the needle 112 includes a hook 124, comprising a bump 158, a hook terminus 160, a hook entrance 162, a suture holding area 164, and a needle point 122. The specific geometry of the needle 112 that is described herein is to be understood as being representative of a family of configurations that embody the design parameters that are now to be described. For instance, the needle point 122 shown herein is a 15 beveled cutting point, but may be, for example, a conical or trocar point. Further, the position of the bump 158 may be on the opposite side of the hook entrance 162. These, and other nuances will be discussed in more detail further below.

When the needle 112 has been introduced through soft tissue (not shown) and has been driven past the suture to be captured as previously illustrated in Figs. 20 1C, 2C, and 3C and has begun to be retracted back through the soft tissue, the hook terminus 160 rides along one of the retraction ramps 42a, 42b and underneath one of the ends 30a, 30b of the suture, thus forcing the suture through the hook entrance 162 and past the bump 158 into the suture holding area 164. The hook terminus 25 160, being cantilevered, has some flexibility, and opens slightly as the suture passes the bump 158, creating a subtle tactile sensation as the suture seats in the suture holding area 164. The suture holding area 164 is sized so that its cross sectional area is slightly smaller than the cross sectional area of the suture it is designed to

capture, thus creating some compression of the captured suture by virtue of the spring loading provided by the above described deformation of the hook terminus 160.

It is important to understand that this particular configuration of needle 112, and indeed all of the needles described in connection with the present invention, are configured to capture a section of suture substantially near one of the ends of the suture. As such, and because the needle is not capturing the suture near the center of the strand of suture where the drag on both legs of the suture as it is retracted through the tissue would be equalized, it is important to prevent the suture from migrating in or through the suture holding area 164. It is also important to secure the suture in the needle while the instrument is being withdrawn, to form and complete, for example, a mattress stitch. Therefore, the combination of deformation, tactile sensation, and compression conspires to hold the suture securely.

Another aspect of the present invention that is to be understood is the mechanism described to effect smooth passage of the needle hook with captured suture back through the soft tissue as the needles are retracted. To that end, Fig. 5 illustrates the needle 112 together with a sliding tube 118, which includes an inner lumen 170, and a lumen opening 172. The sliding tube 118 is dimensioned so that the needle shaft 120 may slide freely through the inner lumen 170, but does not allow sufficient clearance between the inner lumen 170 and the needle shaft 120 to permit tissue to enter the lumen opening 172. As the needle 112 is retracted through the tissue as previously described, the sliding tube 118 remains motionless, closing the opening formed by the hook terminus 160 and the suture holding area 164. The lumen opening 170 ultimately bottoms out against needle shoulders 174a, 174b, and assists in pinching and holding any suture that may be captured in the needle hook 64.

An alternative needle embodiment is illustrated in Fig. 6, wherein like

elements to those of the embodiment of Figs. 4 and 5 are denoted by like reference numerals, except that they are increased by 100. In this embodiment, there may be found a needle 212 that has features similar to that of the needle 112 described above. In this embodiment, a barb 276 is included as part of the suture holding area
5 264, and is configured to penetrate the suture weave and assist in immobilizing the suture.

Figs. 7 and 8 illustrate additional embodiments of the needle, and as above, like elements are denoted by like reference numerals, except in the case of Fig. 7, the labels are increased by 100 respective to Fig. 6, and in Fig. 8, increased by 200
10 respective to Fig. 6.

Accordingly, in Fig. 7 there may be seen a needle 312 that includes a needle shaft 320, and a flattened distal portion 354. The flattened distal portion 354 of the needle 312 includes a hook 324, comprising a bump 358, a hook terminus 360, a hook entrance 362, a suture holding area 364, and a needle point 322. The needle
15 312 is illustrated along with a sliding tube 318 which includes an inner lumen 370, and a lumen opening 372. It is important to note from this illustration that the sliding tube 318 may bottom out on the end of the hook 324 as opposed to covering it as previously described. Also, the bump 358 is shown here on the opposite side of the hook entrance 362.

Referring now to Fig. 8, there may be seen a needle 412 that includes a needle shaft 420, and a flattened distal portion 454. The flattened distal portion 454 of the needle 412 includes a hook 424, comprising a bump 458, a hook terminus 460, a hook entrance 462, a suture holding area 464, and a needle point 422. This embodiment is provided to illustrate that the suture holding area 464 may take on a
25 shape different from that previously disclosed.

To those skilled in the art, the use of a beveled point needle may seem to solve some of the aforementioned problems of spearing the suture by creating a needle that, by virtue of its completely beveled nature, is able to smoothly move

over the suture material without snagging. However, it must be noted that a beveled needle, when forced through soft tissue, has a pronounced tendency to wander, and targeting of the needle in order to place it in an advantageous position for the retrieval of the suture material is quite challenging. In fact, this wandering tendency
5 in the direction of the bevel is uncontrollable to the degree that repeatable suture capture is not possible.

Another way of ensuring that the needle point does not spear the suture is to have the needle diameter be more than twice the suture diameter, so that the pointed face that interfaces with the suture puts the needle point above the profile of the suture
10 diameter. This, however is a limitation, in that the hole left by the needle as it penetrates the soft tissues is considerably larger than the suture material left in its place.

Although an apparatus for the placement of mattress stitches has been disclosed here, instruments for other stitches, for example, a simple stitch, require
15 only a single needle. Such instruments comprising only a single needle, or, in other instances, perhaps more than two needles, are within the scope of the present invention.

The apparatus and method of the present invention may be embodied in other specific forms without departing from its spirit or essential characteristics.
20 The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A suturing device, comprising:
a distal portion which is engaged with a length of suture;
a needle which is axially movable distally and proximally;
a soft tissue receiving portion disposed proximally of said distal
5 portion; and
a ramp portion for moving said needle radially inwardly and outwardly as the needle moves axially over said ramp portion.
2. The suturing device as recited in Claim 1, wherein said soft tissue receiving portion comprises a clamping mechanism.
3. The suturing device as recited in Claim 2, wherein said clamping mechanism comprises a first jaw and a second jaw, wherein one of said jaws is movable relative to the other of said jaws to grasp soft tissue therein.
4. The suturing device as recited in Claim 1, wherein said distal portion comprises a suture cartridge.
5. The suturing device as recited in Claim 4, wherein said suture cartridge comprises a molded tip having a groove for accommodating said suture therein.

6. The suturing device as recited in Claim 1, wherein said ramp portion comprises a radially outwardly sloping entrance ramp for moving said needle radially outwardly as the needle moves axially in a distal direction.

7. The suturing device as recited in Claim 6, wherein said ramp portion further comprises a radially inwardly sloping retraction ramp for moving said needle radially inwardly as the needle moves axially in a proximal direction.

8. The suturing device as recited in Claim 1, wherein said needle comprises a distal point, a proximal shaft, and a hook defining a suture holding area.

9. The suturing device as recited in Claim 8, and further comprising a terminus of said hook, said hook terminus being cantilevered proximally from a distal end of said needle.

10. The suturing device as recited in Claim 9, and further comprising a bump on said needle in a location opposed to said hook terminus.

11. The suturing device as recited in Claim 10, wherein said hook terminus and said bump together provide a tactile sensation to a user when suture passes thereover into said suture holding area.

12. The suturing device as recited in Claim 1, and further comprising a second needle.

13. The suturing device as recited in Claim 1, and further comprising a sleeve for selectively covering said needle.

14. A needle for a suturing device, comprising:
a distal point;
a proximal shaft; and
a hook defining a suture holding area.

15. The needle as recited in Claim 14, and further comprising a terminus of said hook, said hook terminus being cantilevered proximally from a distal end of said needle.

16. The needle as recited in Claim 15, and further comprising a bump on said needle in a location opposed to said hook terminus.

17. A method of suturing soft tissue using a suturing device, said method comprising:

retaining a portion of soft tissue to be sutured;

moving a needle having a hook which defines a suture holding
5 area distally, so that said hook is disposed in a location past said portion of soft

tissue and past a length of suture which is retained on a distal portion of said suturing device;

moving said needle proximally and capturing said suture so that it is retained in said suture holding area; and

10 moving said needle a further distance proximally, so that said needle draws said suture through said portion of soft tissue, thereby suturing said soft tissue.

18. The method as recited in Claim 17, wherein when said needle is moved distally, it is also moved radially outwardly in order to avoid contacting said length of suture.

19. The method as recited in Claim 17, wherein when said needle is moved proximally, it is also moved radially inwardly in order to ensure proper capture of said suture.

20. The method as recited in Claim 17, and further comprising a step of covering said needle with a sheath prior to retracting the needle proximally through said soft tissue.

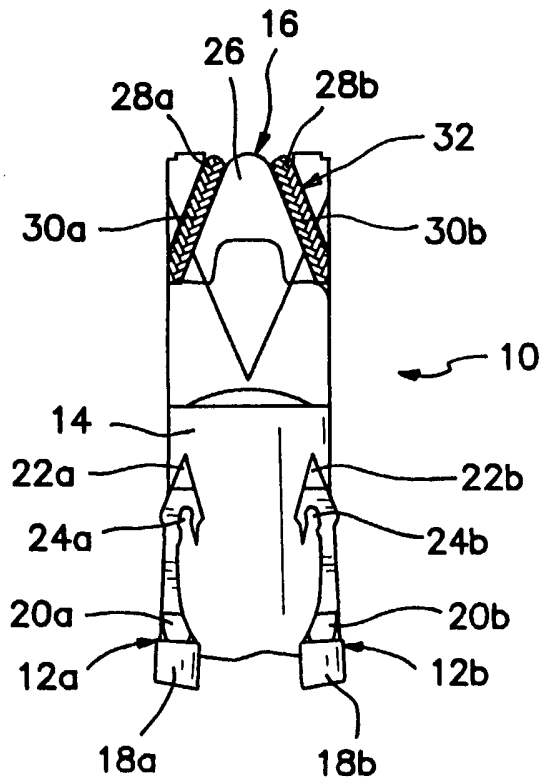


FIG. 1A

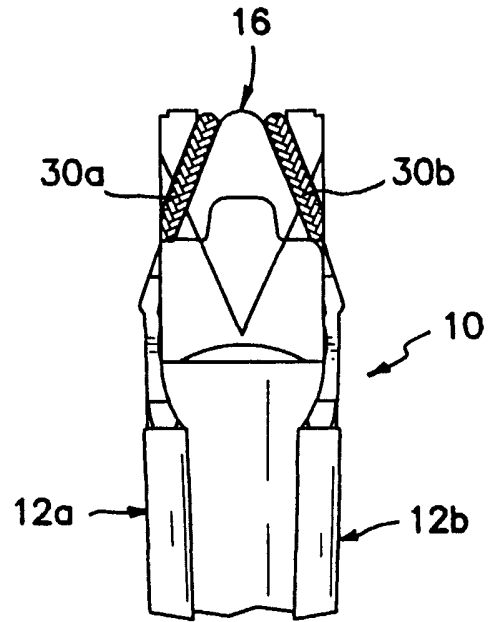


FIG. 1B

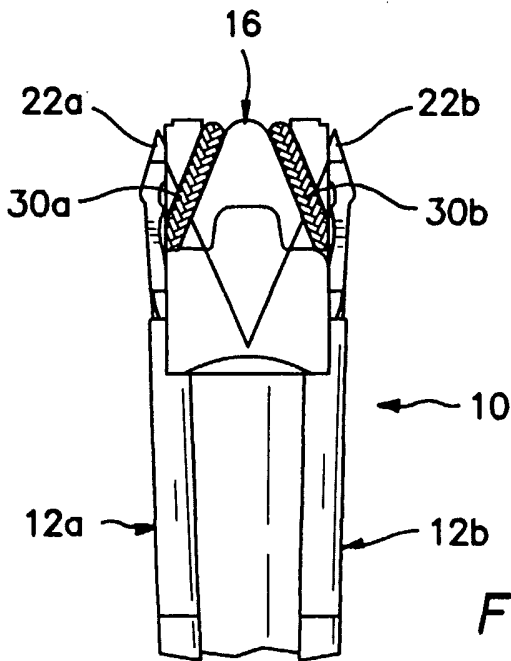


FIG. 1C

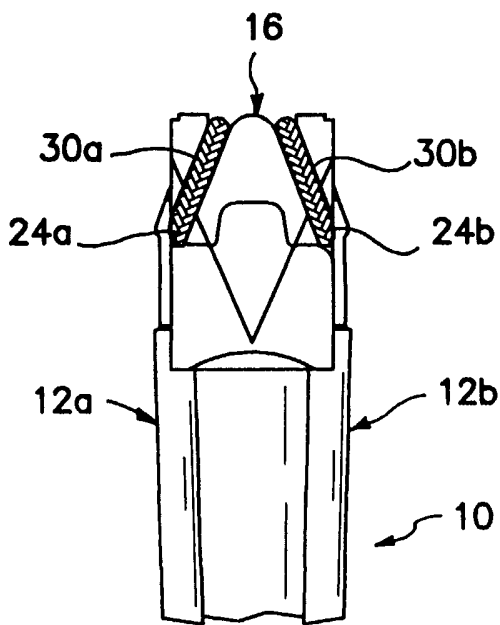


FIG. 1D

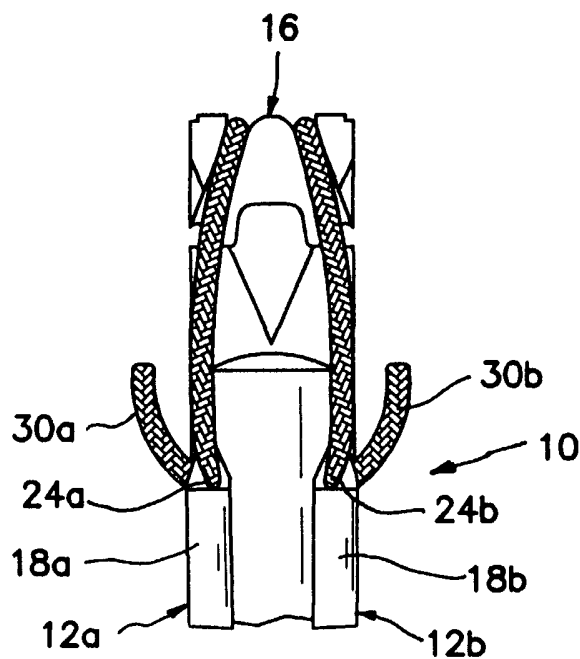


FIG. 1E

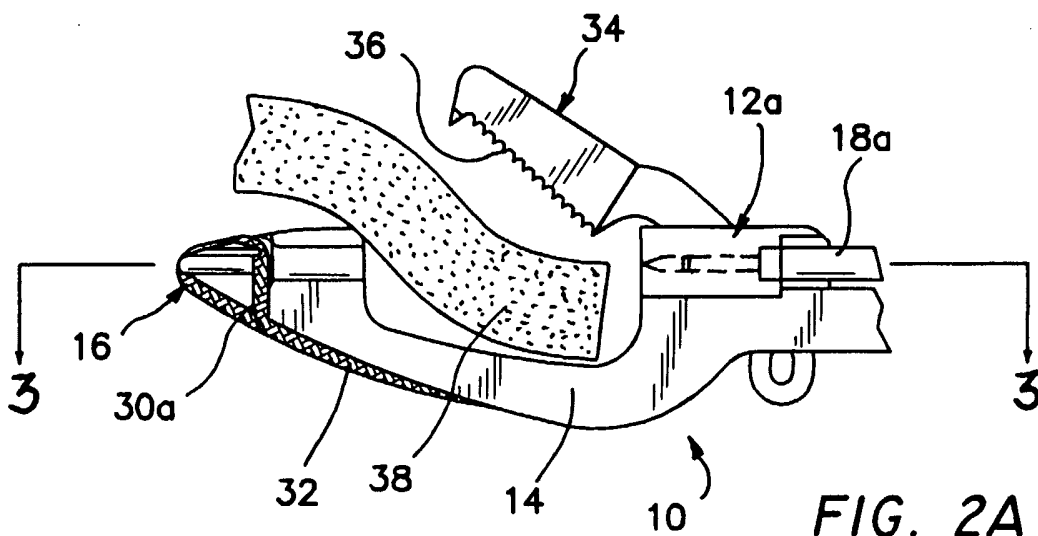


FIG. 2A

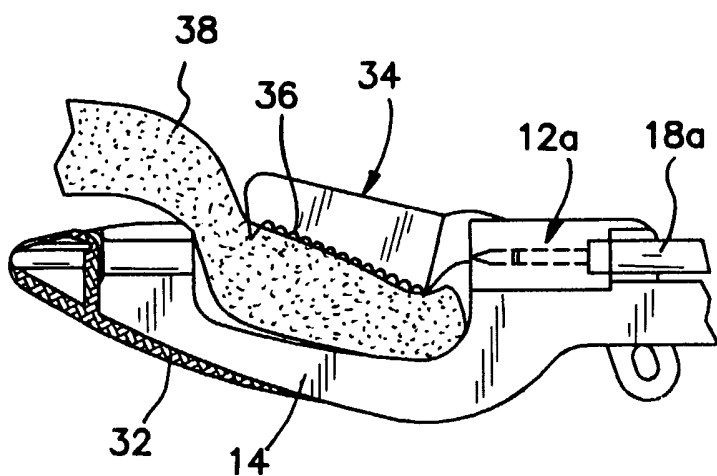


FIG. 2B

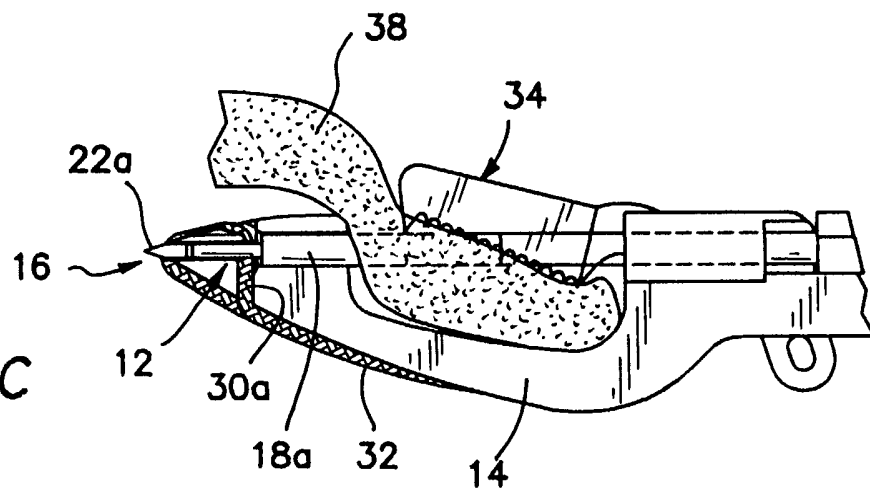


FIG. 2C

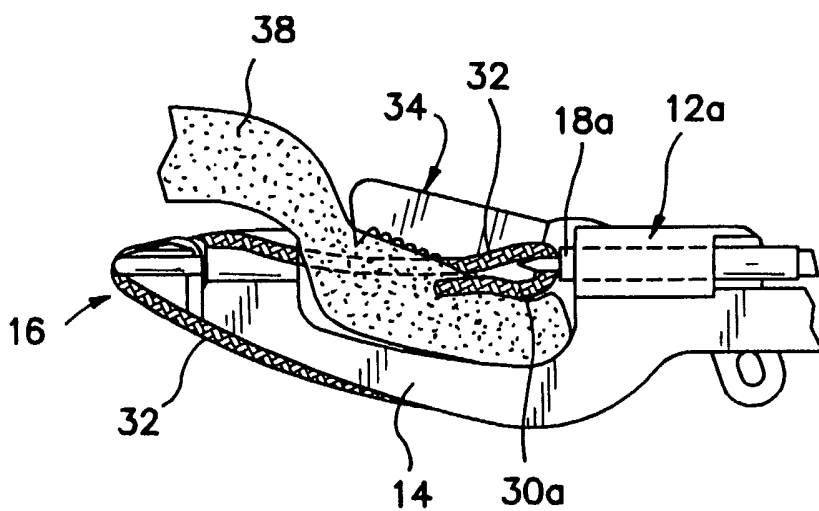


FIG. 2D

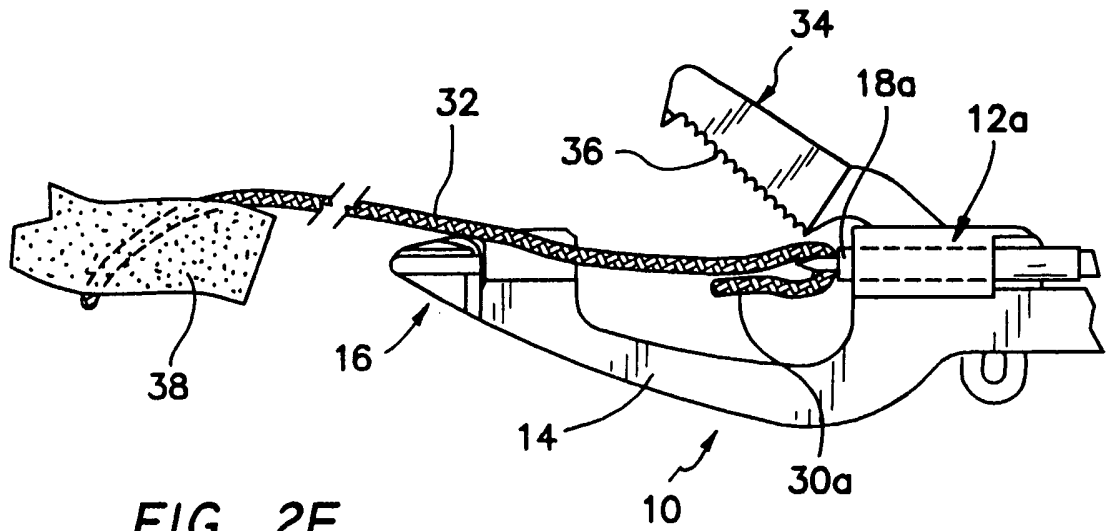


FIG. 2E

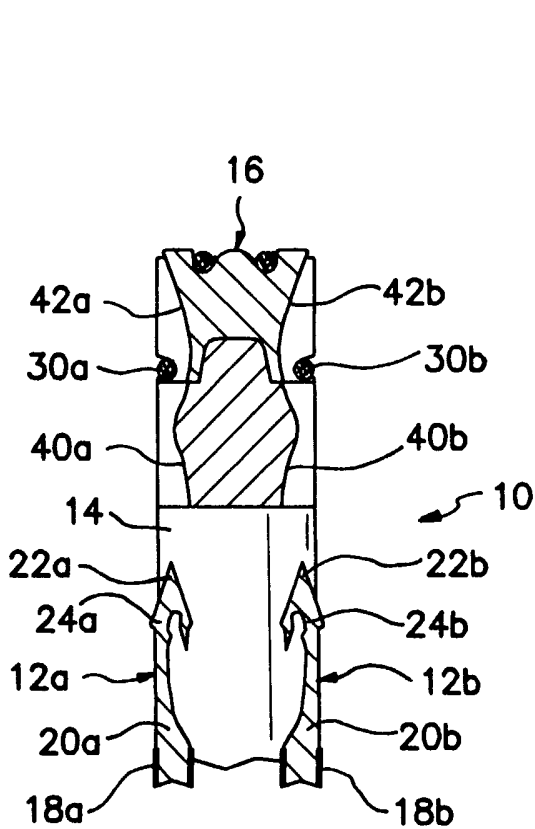


FIG. 3A

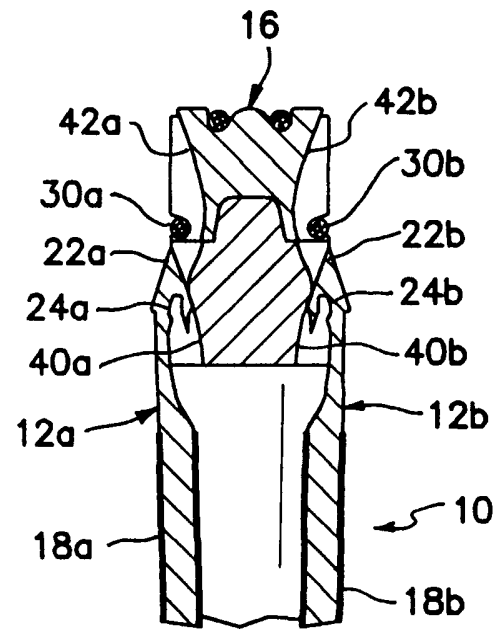


FIG. 3B

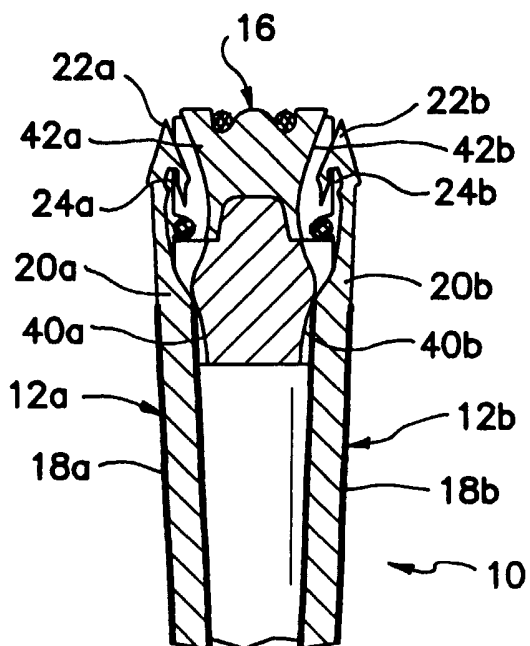


FIG. 3C

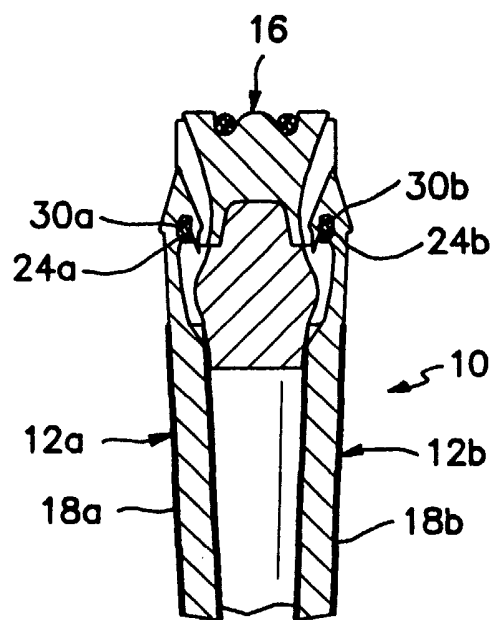


FIG. 3D

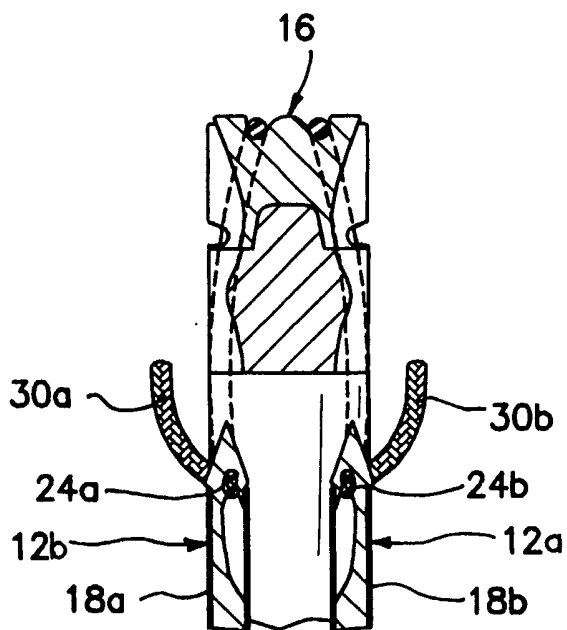
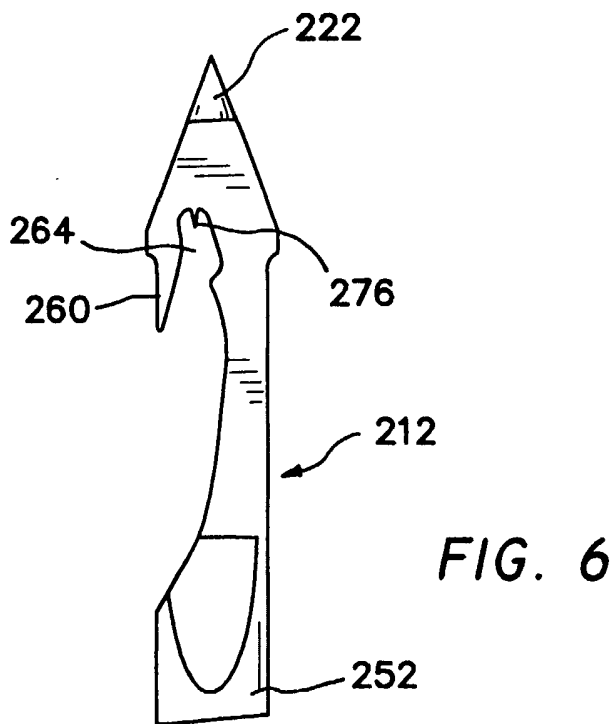
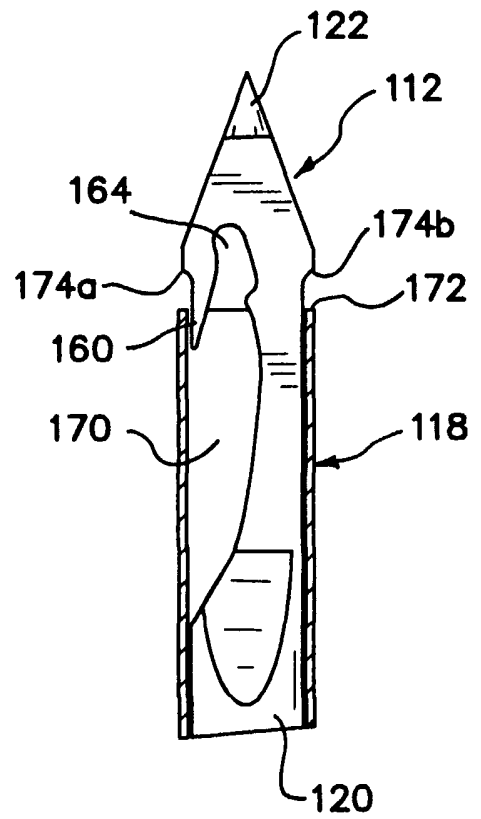
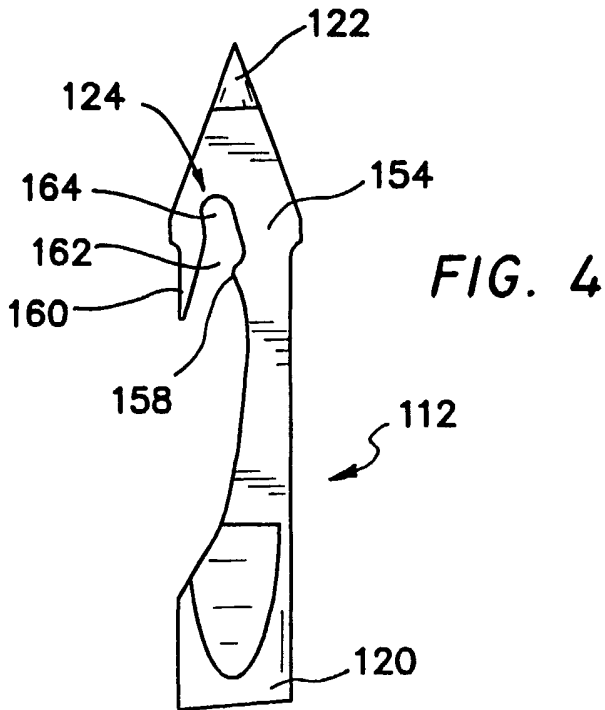


FIG. 3E



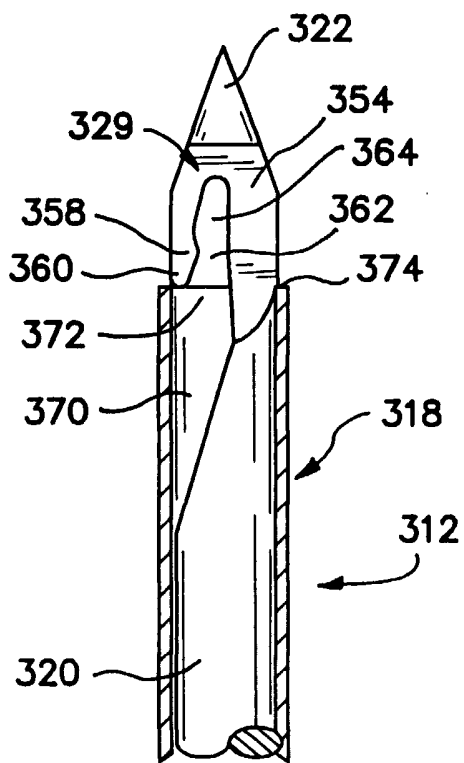


FIG. 7

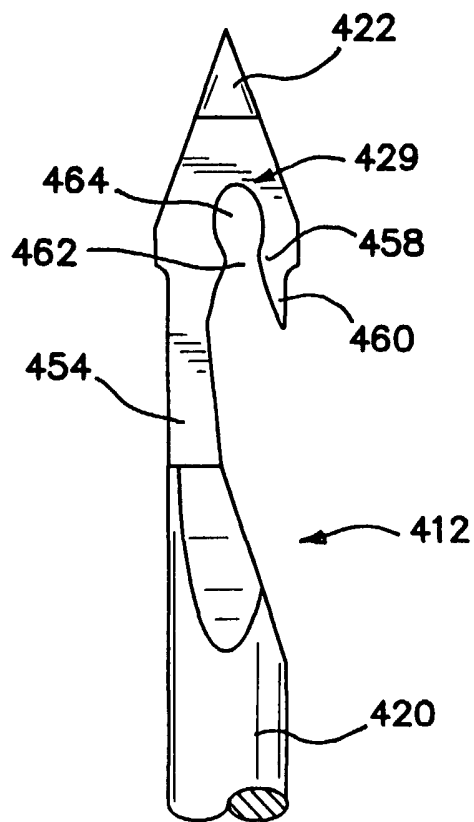


FIG. 8

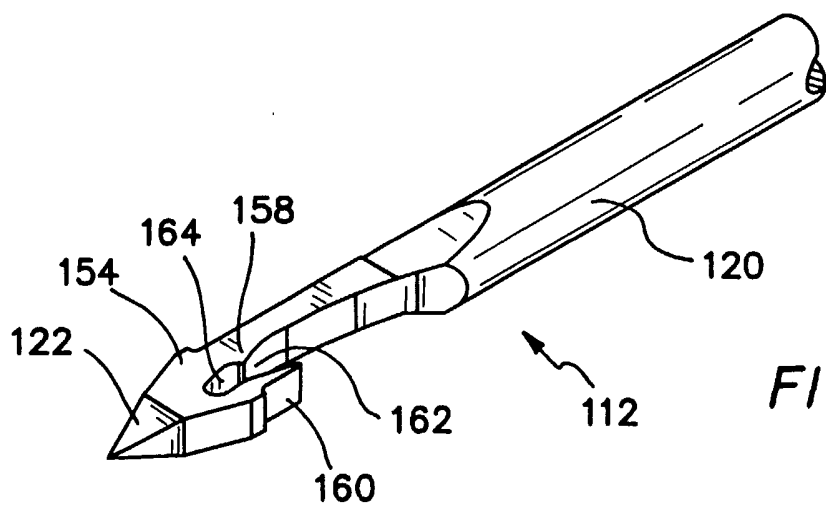


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/18540

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/04
 US CL : 606/144

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)
 U.S. : 606/144

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)
 EAST , 606/144, 213 and search terms: suture passer, suture, needle

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,117,144 (NOBLES et al) 12 September 2000 (12.09.2000), columns 19-23.	1, 4, 6-10 and 12-19
A,P	US 6,551,330 B1 (BAIN et al) 22 April 2003 (22.04.2003), see entire document.	1-20
A	US 5, 474,565 A (TROTT) 12 December 1995 (12.12.1995), see col. 2, lines 11-42.	1-20

Further documents are listed in the continuation of Box C.

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	"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
"E" earlier application or patent published on or after the international filing date	"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
"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)	"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
"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	"&"	document member of the same patent family

Date of the actual completion of the international search

06 October 2003 (06.10.2003)

Date of mailing of the international search report

15 OCT 2003

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