

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2007275351 B2**

(54) Title
Surgical instruments

(51) International Patent Classification(s)
A61B 17/04 (2006.01)

(21) Application No: **2007275351**

(22) Date of Filing: **2007.07.17**

(87) WIPO No: **WO08/011417**

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/832,253	2006.07.20	US
60/832,035	2006.07.20	US
60/832,289	2006.07.20	US

(43) Publication Date: **2008.01.24**

(44) Accepted Journal Date: **2013.10.24**

(71) Applicant(s)
Lee Kaplan

(72) Inventor(s)
Kaplan, Lee D.

(74) Agent / Attorney
Spruson & Ferguson, L 35 St Martins Tower 31 Market St, Sydney, NSW, 2000

(56) Related Art
US 6527794
US 5957953
US 5720765
US 2004/0098050

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 January 2008 (24.01.2008)

PCT

(10) International Publication Number
WO 2008/011417 A3

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

(21) International Application Number:
PCT/US2007/073697

(22) International Filing Date: 17 July 2007 (17.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/832,035 20 July 2006 (20.07.2006) US
60/832,253 20 July 2006 (20.07.2006) US
60/832,289 20 July 2006 (20.07.2006) US

(71) Applicant and

(72) Inventor: **KAPLAN, Lee D.** [US/US]; 9417 Hill Creek Drive, Madison, Wisconsin 53593 (US).

(74) Agents: **HUNTER, Paul S.** et al.; Foley & Lardner LLP, 150 East Gilman Street, Post Office Box 1497, Madison, Wisconsin 53701-1497 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

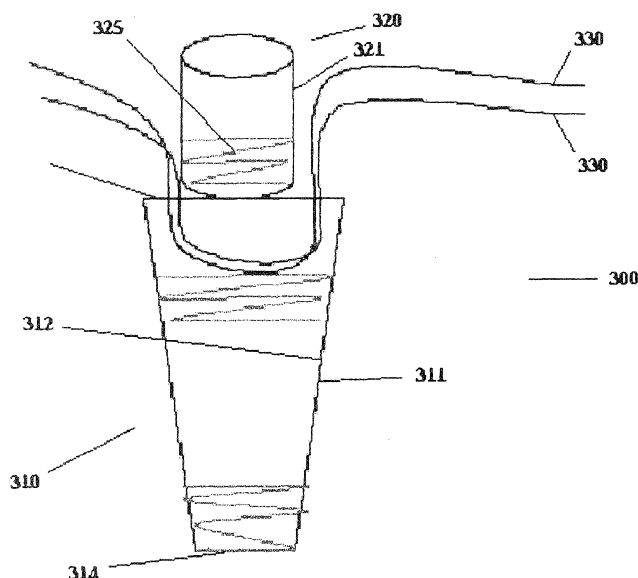
Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
20 November 2008

(54) Title: SURGICAL INSTRUMENTS

FIG. 3



(57) Abstract: A surgical instrument having an anchor and a plug is capable of anchoring a suture. The anchor has a wall that has an outer surface having threads and an inner surface, and a first end, and a second end. The plug has a first end, a second end, and an outer wall. The surgical instrument may be used during surgical procedures and can be used in the re-tensioning of a suture.



WO 2008/011417 A3

SURGICAL INSTRUMENTS

FIELD

[0001] The present disclosure generally related to surgical instruments. More specifically, the disclosure relates to a suture anchor.

BACKGROUND

[0002] Suture anchors are well known in the art. Suture anchors are typically used to anchor soft tissues such as tendons, and the like, to bone using a suture. The suture anchor is typically secured in a bone and sutures, previously having been inserted into tissue, are then threaded through the suture anchor to tension the tissue and hold it in place. The tissue is tensioned to the bone via the suture attached to the anchor.

[0003] Typically, the suture is threaded through a small hole, or series of holes in the anchor and some suture anchors come pre-loaded with the sutures. The suture can then be knotted to prevent release of the suture from the suture anchor. However, the need for knotting can increase surgical time and provide a weak point for suture breakage, hence a need exists for a suture anchor that is fast to use, readily allows for re-tensioning of a suture, and does not introduce knotting weakness to the suture.

[0004] Surgical cannulas are used to enter areas within the body such as the shoulder, knee, or abdomen. The cannula provides a means for passing surgical instruments into and out of a subject. Cannulas are also used as a channel to introduce surgical implements such as surgical instruments, suture anchors, or sutures. Such surgical cannulas typically have a single chamber that is conducive to instruments or items touching and either cross-contaminating one another or disturbing the function of each other. Such surgical cannulas are also subject to the cannula readily pulling out of the subject or falling into a subject and requiring re-insertion or extraction. A need exists for cannulas that resist the tendency to push out of a subject, or fall into a subject. Also multi-chambered cannulas are desired.

OBJECT OF THE INVENTION

[0004a] It is the object of the present invention to substantially overcome or at least ameliorate one or more of the above disadvantages.

SUMMARY OF THE INVENTION

[0005] In a first aspect, a surgical instrument is provided comprising a surgical instrument comprising:

- an anchor comprising

- a wall comprising

- an outer surface;

- an inner surface;

- a first end; and

- a second end; and

- a plug comprising a first end, a second end, and an outer wall;

wherein:

- the anchor and the plug form a knotless suture anchor configured to:

- anchor an unknotted suture between the plug and the inner surface of the wall;

- provide for tensioning and re-tensioning of the unknotted suture after securing of the anchor within a bone, wherein the retensioning comprises loosening the plug and adjusting a length of the unknotted suture.

[0006] In one embodiment, the outer wall of the plug comprises threads capable of engaging the inner surface of the anchor via a friction fit. In another embodiment, the inner surface comprises threads. In another embodiment, the outer wall of the plug and the inner wall of the anchor each have threads capable of engaging each other in a screw-like fashion to secure the plug in the anchor.

[0007] In another embodiment, the plug is made of a compressible material. For example, the compressible material may be a polymer such as high density polyethylene, polyurethane, silicones, or a mixture thereof.

[0008] In some embodiments, the first end of the plug has the same diameter as the second end of the plug. In other embodiments, the first end of the plug has a larger diameter than the second end of the plug, such that the plug forms conical shape similar to that of the profile of a funnel.

[0009] In another aspect, a method of using a suture anchor is provided comprising: securing the anchor into a bone, draping an unknotted suture through an interior of the anchor and touching the inner surface; and inserting the plug in the anchor to secure and tension the suture. In some embodiments, the securing is via screwing or cementing of the anchor in the bone. Other embodiments, further comprise removing the plug; re-tensioning the suture; and replacing the plug in the anchor.

[0010] PARAGRAPH LEFT INTENTIONALLY BLANK

[0011] PARAGRAPH LEFT INTENTIONALLY BLANK

[0012] PARAGRAPH LEFT INTENTIONALLY BLANK

[0013] PARAGRAPH LEFT INTENTIONALLY BLANK

[0014] PARAGRAPH LEFT INTENTIONALLY BLANK

BRIEF DESCRIPTION OF THE DRAWINGS

[0014a] A preferred embodiment of the present invention will now be described, by way of an example only, with reference to the accompanying drawings wherein:

[0015] FIG. 1 is a side view of a suture passer without a suture.

[0016] FIG. 2 is a side view of a suture passer having a suture threaded through the suture passer.

[0017] FIG. 3 is a side view of a suture anchor showing the plug and the nest with a sutures passing through, prior to insertion of the plug into the nest.

[0018] FIG. 4 is a top view of a suture anchor showing the plug and the nest with a sutures passing through, prior to insertion of the plug into the nest.

[0019] FIG. 5 is an illustration of a humerus with a hole bored through a portion for the passage of a suture to secure a rotator cuff bed.

[0020] FIG. 6 is an illustration of a humerus with a hole bored through a portion for the passage of a suture to secure a rotator cuff bed.

[0021] FIG. 7 is an illustration of a humerus with a hole bored through a portion for the passage of a suture to secure a rotator cuff bed and a suture anchor secured in the humerus.

[0022] FIG. 8 is an illustration of a humerus with a hole bored through a portion for the passage of a suture to secure a rotator cuff bed and a suture anchor secured in the humerus with the suture beginning to be tensioned.

[0023] FIG. 9 is a side view of a cannula.

DESCRIPTION

[0024] In one aspect, an instrument comprising a suture passer **100** is described. As shown in FIGS. 1 and 2, the suture passer **100** comprises a body **110** having a tunnel **115**, an articulating arm **120**, **190** connected to the body **110** proximally to a first end of the body **110**, and a fore end **130** distal to the first end of the body **110**. In some embodiments, the suture passer **100**, further comprises suture channels **184**, **185** through which sutures are threaded to load the suture passer **100**. In some embodiments, the suture passer **100** is an arthroscopic instrument. The suture passer **100** may be used to grasp tissue and pass a sliding, locking suture in a single grasp of the tissue. The suture passer **100** grasps tissue **180** between the body **110** and the articulating arm **120**. The suture passer **100** then passes a suture loop **140** through the tissue **180**. This may be done by loading the suture **140** in a U fashion. A needle passes through the tunnel **115** then penetrates the tissue **180** passing

through the suture loop **140**. A second needle or a pass of the same needle passes through a channel within articulating arm **120** and is directed through the suture loop **140** and capturing the other end of the suture. This pulls one end of the suture back in a retrograde fashion through the first loop **140** creating a locking stitch. The suture has one end outside the body **110** and the other end loaded on the other side of the suture passer **100**. This allows for it to be passed through the suture loop **140**, ultimately forming a locking stitch. One end of the suture is passed below the tissue **180** and one end is passed above the tissue **180**. When the bottom suture is pulled longitudinally it pulls the suture loop **140** down perpendicular to the tissue **180** resulting in bringing it downward. When the top suture is pulled it brings the tissue **180** laterally or in line with the sutures. In one embodiment, the articulating arm **120** is connected to the body **110** by a joint or a hinge, such that the articulating arm **120** may move relative to the body **110** in a tweezer-like fashion.

[0025] In other embodiments, the suture passer **100** will grasp tissue, thus allowing for a loop of a single suture (or multiple sutures) to be placed from an inferior aspect of the tissue to a superior aspect of the tissue. A needle or grasping agent will then reach through this loop and pull the other end of the suture back through this suture loop. This will create a locking stitch with one end on the superior and one end on the inferior aspect of the tissue. This is accomplished by a needle driving the loop of suture through the tissue. This needle passes through a channel in the inferior arm of the suture passer. The second needle or grasping agent penetration runs parallel to the first but on the other side of the tissue. This needle may have passage through the superior arm of the suture passer. This allows it to be on the other side of the tissue as the first arm or inferior arm and on the same side as the suture loop. Thus, going through the loop and pulling back the other end of suture. The result is a locking stitch with suture limbs on both sides of the tissue.

[0026] While conventional suture anchors known to those of skill in the art may be used to secure sutures required for tissue repair using the suture passer **100** described above, in another aspect, a suture anchor **300** comprising an anchor **310**, and a plug **320** is described herein and is illustrated in FIGS. 3-8. Such suture anchors **300** may be used with the suture passers **100**, described above, or the suture anchors **300** may be used in any suturing application known to those of skill in the art.

[0027] Suture anchors **300** embodied herein, allow for one or more points of fixation of a tissue to be anchored by a single anchor position. As described below, the suture anchors embodied herein are capable allowing the tensioning of a tissue with a suture to be adjustable and re-tensionable.

[0028] Referring to FIGS. 3-8, the anchor **310** comprises a wall having an outer surface **311**, an inner surface **312**, that may or may not have threads to secure the plug **320**, a first end **313**, and a second end **314**. In the either case of the inner surface **312**, having or not having threads, it is a friction fit between the plug **320** and the inner surface **312** that secures the plug **320** into the suture anchor **300**. In some cases, a diameter of the first end **313** is larger than a diameter of the second end **314**, while in other embodiments, the first end **313** and the second end **314** have the same diameter. The plug **320** comprises an outer wall **321** having threads **325** such that when a suture(s) **330** is draped into the anchor **310** and the plug **320** is inserted into the anchor **310**, the plug **320** secures the suture(s) **330** via a friction fit between the plug **320** and the inner surface **312** of the wall **311**. FIGS. 5-8 further illustrate the suture anchor **300** secured in a humerus **510** and with sutures **530** anchored in the suture anchor **300**.

[0029] Anchor **310** may be secured in any bone via a screw mechanism on the outer surface **311** of the wall, or via a cementing of the anchor **310** to the bone, as is known to those of skill in the art. The anchor **310** may also have a means for driving the screw mechanism into bone. For example, the anchor **310** may have a hex-head, slot, Phillips-type head, or other shaped head that may be mated to a driver for screwing the anchor **310** into bone. Cementing of the anchor **310** to the bone may be accomplished using a variety of bone cements known to those of skill in the art. For example, curable polymers such as polymethylmethacrylate may be used.

[0030] Such suture anchors **300** allow for tightening, adjustment, or re-tensioning of a suture by loosening and/or removal of the plug **320** from anchor **310**, adjusting or re-tensioning of the suture, and tightening and/or re-insertion of the plug **320** into the anchor **310**. Such suture anchors **300** also allow for securing of the suture without the tying of knots or replacement of sutures when re-tensioning is required. Suture anchors **300** may be used for the fixation of soft tissue to bone, or of bone to bone.

[0031] Suture anchors **300** and plugs **320** may be made from a variety of materials known to those of skill in the art. For example, for the suture anchors **300** the material is typically a rigid material such as a metal, a polymer, or a ceramic. Biocompatible metals include, but are not limited to stainless steel, titanium, tantalum, aluminum, chromium, molybdenum, cobalt, silver, and gold, or alloys of such metals that are known to those of skill in the art. Biocompatible polymers include, but are not limited to, high-density polyethylenes, polyurethanes, or blends of such polymers, as are known to those of skill in the art. Biocompatible polymers also include absorbable materials such as polylactic acid, polyglycolic acid, or mixtures thereof. Biocompatible ceramics include, but are not limited to alumina, silica, silicon carbide, silicon nitride, zirconia, and mixtures of any two or more thereof.

[0032] The plugs **320** may likewise be prepared from similar metals, polymers, and ceramics, however in some embodiments, the plugs **320** are prepared from materials that may be compressed. In such embodiments, the plug material is capable of being compressed from an uncompressed state to a compressed state, prior to or during insertion of the plug **320** into the suture anchor **300**. Such compression allows for the material to recoil from the compressed state to the uncompressed state and thereby increasing the friction fit between the plug **320** and the suture anchor **300**. Such materials that may be compressed include, but are not limited to, polyethylenes, silicones, polyesters, polyurethanes, polylactic acid, polyglycolic acid, or mixtures of any two or more thereof.

[0033] The anchor **300** may be used to secure sutures tensioning tissue without tissue to bone direct contact. Examples of such uses of suture tensioning without tissue to bone contact include, but are not limited to, pelvic surgery, bladder suspension surgery, brow lift or face lift surgery, hand surgery and the like.

[0034] Referring now to FIG. 9, in another aspect, a cannula **900** comprising at least one chamber **910**, **920**, an air passage **930** having a valve **940**, and at least one inflatable donut **950** is described. The cannula **900** has a distal end **970** and a proximal end **980**. The inflatable donut **950** is located at, or near the distal end **970** of the cannula **900**. The cannula may be used in both arthroscopic and endoscopic surgery. The cannula may be used to facilitate the passage of surgical items such as but not limited to instruments, sutures, and

implants, into and out of a subject. The cannula 900 may be at least a single chambered passageway or the cannula 900 may be divided into multiple chambers, such as two chambers 910, 920 as illustrated in FIG. 9, or more than two chambers, depending upon the intended use of the cannula for a given procedure or procedures. In some embodiments, a flexible diaphragm is used to divide cannula 900 into multiple chambers 910, 920. In some such embodiments, the flexible diaphragm extends the entire length of the cannula 900. The donut 950 is an inflatable donut that, when inflated, has a larger diameter than a diameter of the cannula 900. Cannula 900 may also comprise a second donut 960, that may be rigid or inflatable. The second donut 960 may be located at or near the proximal end 980. In one aspect, the cannula 900 is inserted through the skin of a subject and the donut 950 is inflated via the air passage 930. In one embodiment, inflation of donut 950 is via a pump connected to the valve 940, and subsequent filling of the air chamber 930 and donut 950 with air from the pump. In another embodiment, inflation of donut 950 is via insertion of an air-filled syringe through the valve 940, and subsequent filling of the air chamber 930 and donut 950 with air from the syringe. The valve 940 may comprise rubber(s), silicone(s), or other materials known to those of skill in the art to be useful for the insertion and removal of syringes or other devices that may be used for inflation of donut 950. Other methods of inflating the donut 950 will be readily apparent to those of skill in the art. Inflation of donut 950 prevents inadvertent removal of the cannula from the subject during surgical procedures. The presence of inflatable donut 950 allows for less trauma to an insertion point in the skin of a subject by allowing for a cannula 900 of small diameter to be inserted, but then the larger diameter donut 950 prevents removal. In embodiments where the second donut 960 is present, the second donut 960 prevents the inadvertent full insertion of the cannula into a subject beyond the surface of the skin of the subject. As noted above, because the second donut 960 does not pass through the skin of a subject, the second donut may be made of a rigid material or the second donut 960 may be inflatable. The second donut 960 may be integrally formed with cannula 900 or it may be formed separately and attached to cannula 900. In embodiments, where both the first donut 950 and the second donut 960 are inflatable, the donuts 950, 960 may be simultaneously inflatable in a "dumbbell" formation allowing for the inflation both within, via the first donut 950, and external, 960, to the body together.

[0035] Generally, cannulas are used to enter areas within the body such as the shoulder, knee or abdomen. Cannulas are also used as a channel to introduce surgical

implements such as surgical instruments, suture anchors, or sutures. The cannulas embodied herein allow for separate chambers which allow multiple instruments or items to be entered into the joint but partitioned from one another. Another feature is an expandable, inflatable device on the end of the cannula which prevents expulsion of the cannula from the cavity as intracavitary pressure increases. The inflatable device, i.e. inflatable donut, locks the cannula in place.

[0036] In another aspect, methods for using instruments described herein, are provided. For example in some embodiments, methods are disclosed for using the suture passer 100, suture anchor 300, and cannula 900 are described. The embodied methods allow for tissue repair. In some embodiments, the methods provided allow for arthroscopic rotator cuff repair, by attempting to recreate the true native footprint of the rotator cuff of a subject. In some embodiments, such methods comprise preparing the rotator cuff bed, boring a tunnel 510 (FIGS. 5-8), or hole, through a portion of bone such as a humerus 520, passing a suture 530 through the tunnel 510, suturing the tissue using a suture passer 100, and anchoring the sutures 530 in the suture anchor 300, thereby securing the rotator cuff muscles to the bone

[0037] In some embodiments of the methods, the suture passer 100 descends through one chamber 950, 960 of the cannula 900, grasping tissue. The suture passer 100 passes a locking stitch as described above, followed by removal of the suture passer 100, with the sutures remaining in the chamber 950, 960 of the cannula 900. The other chamber 950, 960 of the cannula 900 has a humerus drill inserted. A small hole is bored in a greater tuberosity. One limb of a suture is then passed through the bone. A suture anchor 300 is then placed into the greater tuberosity. Sutures may be placed through the suture anchor 300 either before or after insertion. If not previously completed, the suture anchor 300 is then fixated in the bone. The sutures are then tensioned thus tensioning the tissue. The plug 320 of the suture anchor 300 is then engaged in the anchor 310 and locked into position, thus securing the sutures. This step can be repeated to alter the tension of the sutures and therefore re-tensioning the sutures and tissue.

[0038] For the purposes of this disclosure and unless otherwise specified, “a” or “an” means “one or more.”

[0039] One skilled in the art will readily realize that all ranges discussed can and do necessarily also describe all subranges therein for all purposes, and that all such subranges also form part and parcel of this invention. Any listed range can be easily recognized as sufficiently describing and enabling the same range being broken down into at least equal halves, thirds, quarters, fifths, tenths, etc. As a non-limiting example, each range discussed herein can be readily broken down into a lower third, middle third and upper third, etc.

[0040] While some embodiments have been illustrated and described, it should be understood that changes and modifications can be made therein in accordance with ordinary skill in the art without departing from the scope of the invention.

CLAIMS

1. A surgical instrument comprising:
an anchor comprising
a wall comprising
an outer surface;
an inner surface;
a first end; and
a second end; and
a plug comprising a first end, a second end, and an outer wall;
wherein:
the anchor and the plug form a knotless suture anchor configured to:
anchor an unknotted suture between the plug and the inner surface of the wall;
provide for tensioning and re-tensioning of the unknotted suture after securing of the anchor within a bone, wherein the retensioning comprises loosening the plug and adjusting a length of the unknotted suture.
2. The surgical instrument of Claim 1, wherein the outer wall of the plug comprises threads configured to engage the inner surface of the anchor via a friction fit.
3. The surgical instrument of Claim 1, wherein the inner surface comprises threads.
4. The surgical instrument of Claim 2, wherein the outer wall of the plug and the inner wall of the anchor each have threads configured to engage each other in a screw-like fashion to releasably engage the unknotted suture in the anchor.
5. The surgical instrument of Claim 1, wherein the plug is made of a compressible material.
6. The surgical instrument of Claim 5, wherein the compressible material is a polymer selected from the group consisting of high density polyethylenes, polyurethanes, silicones, blends of any two or more thereof, or copolymers thereof.
7. The surgical instrument of Claim 1, wherein the first end has the same diameter as the second end.

8. The surgical instrument of Claim 1, wherein the first end has a larger diameter than the second end.
9. A method of using the surgical instrument of Claim 1, comprising:
 - securing the anchor into a bone;
 - draping an unknotted suture through an interior of the anchor, the unknotted suture touching the inner surface of the wall of the anchor; and
 - inserting the plug in the anchor to secure and tension the unknotted suture between the plug and the inner surface of the wall.
10. The method of Claim 9, wherein the securing is via screwing or cementing of the anchor in the bone.
11. The method of Claim 9, further comprising:
 - removing the plug;
 - re-tensioning the unknotted suture; and
 - replacing the plug in the anchor.
12. The surgical instrument of Claim 1, wherein the first end is shaped to be mated to a driver that is configured to secure the anchor within a bone.
13. The surgical instrument of Claim 1, wherein the anchor is tapered from the first end of the anchor to the second end of the anchor.
14. The surgical instrument of Claim 1, wherein an interior space of the anchor defined by the wall is conical, the plug is conical, and the plug is configured to nest within the interior space.

Lee D. Kaplan
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

FIG. 1

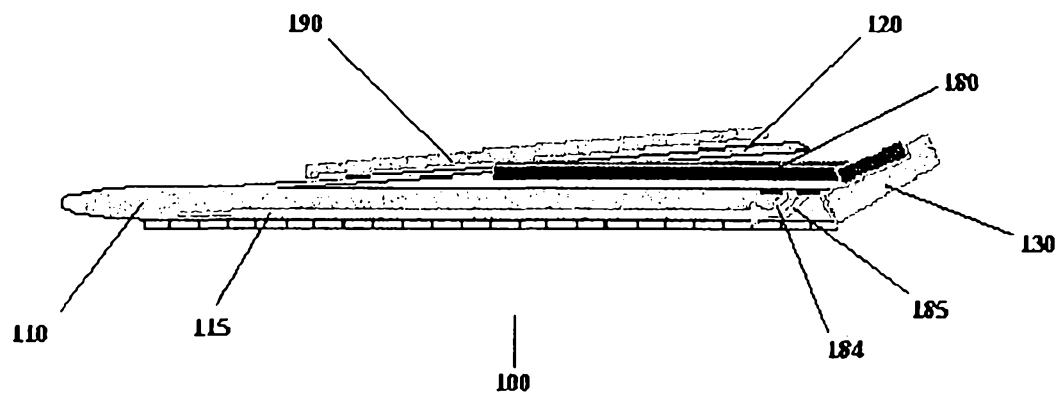
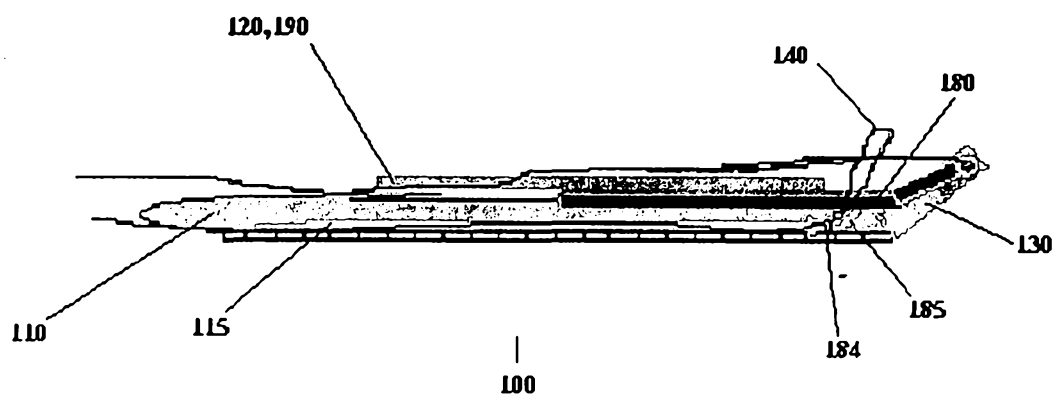


FIG. 2



2/5

FIG. 3

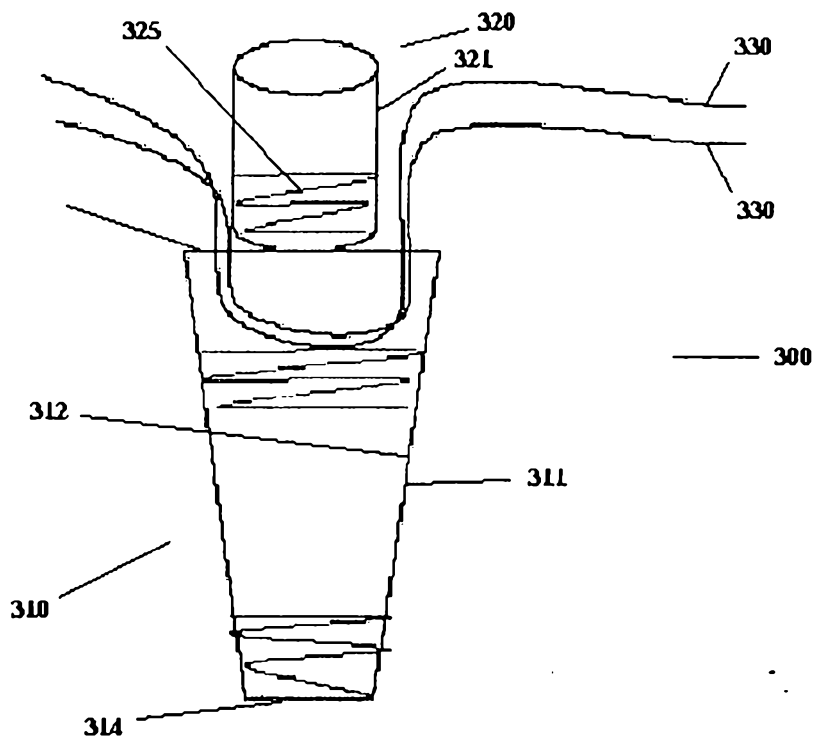


FIG. 4

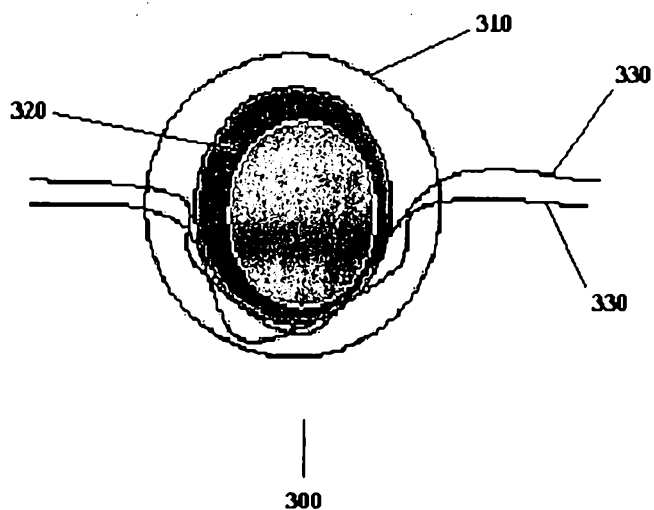


FIG. 5

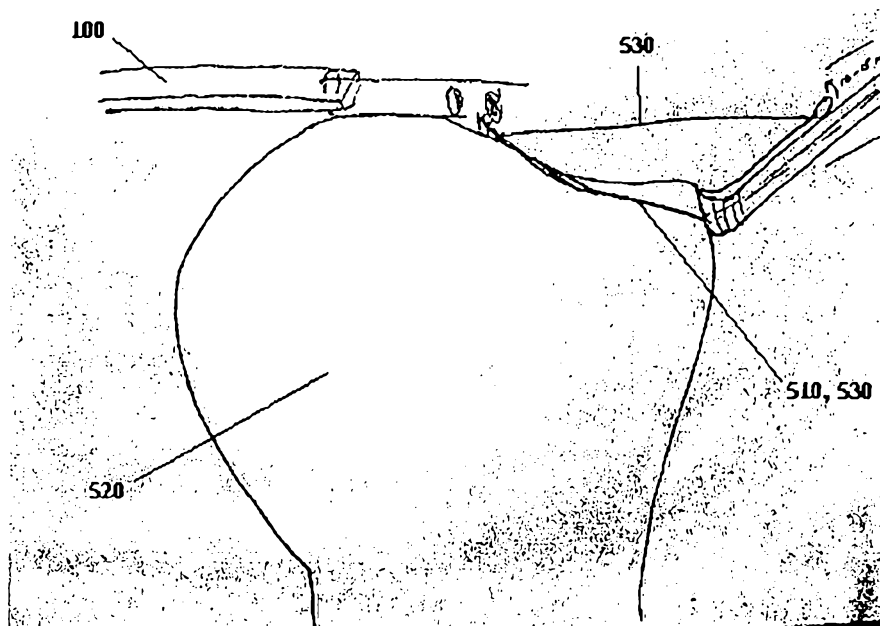


FIG. 6

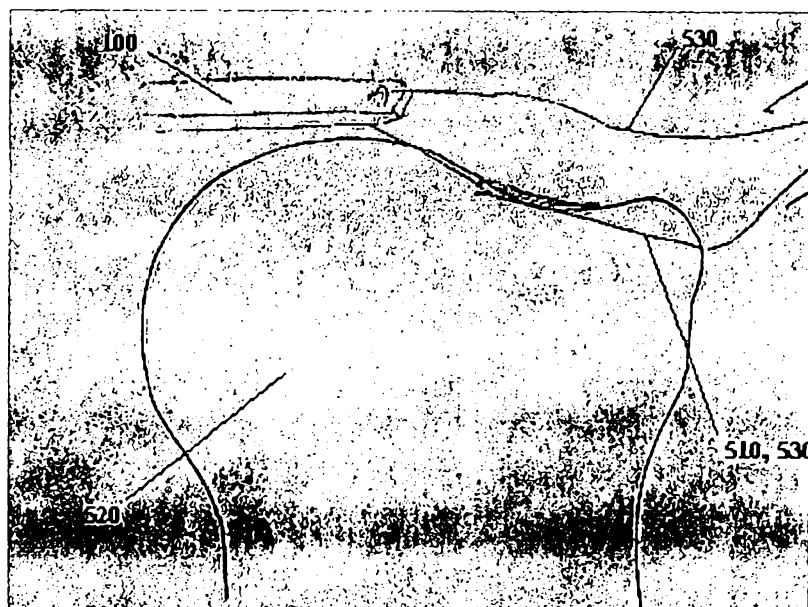


FIG. 7

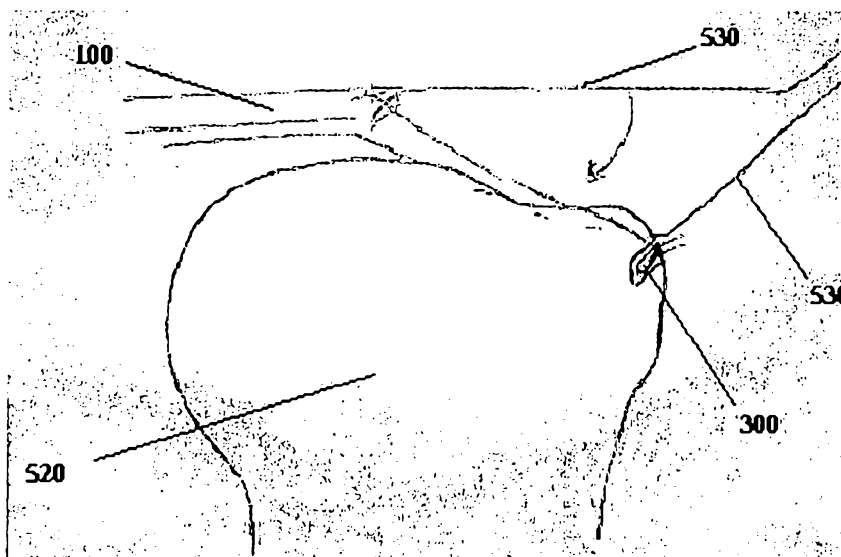


FIG. 8

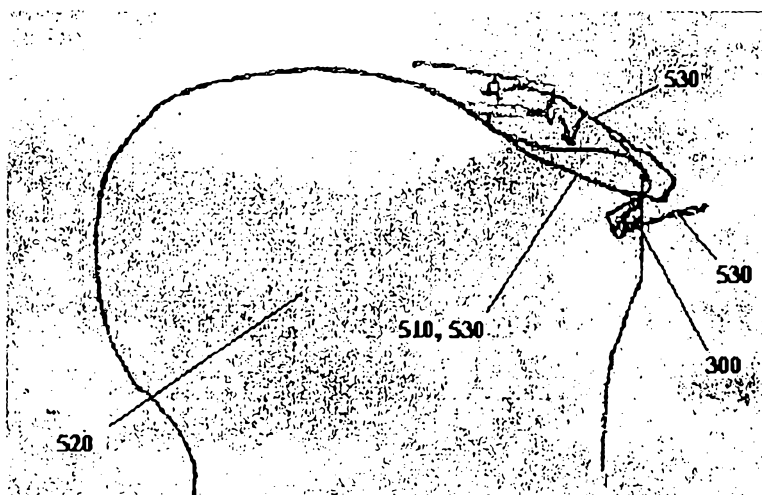


FIG. 9

