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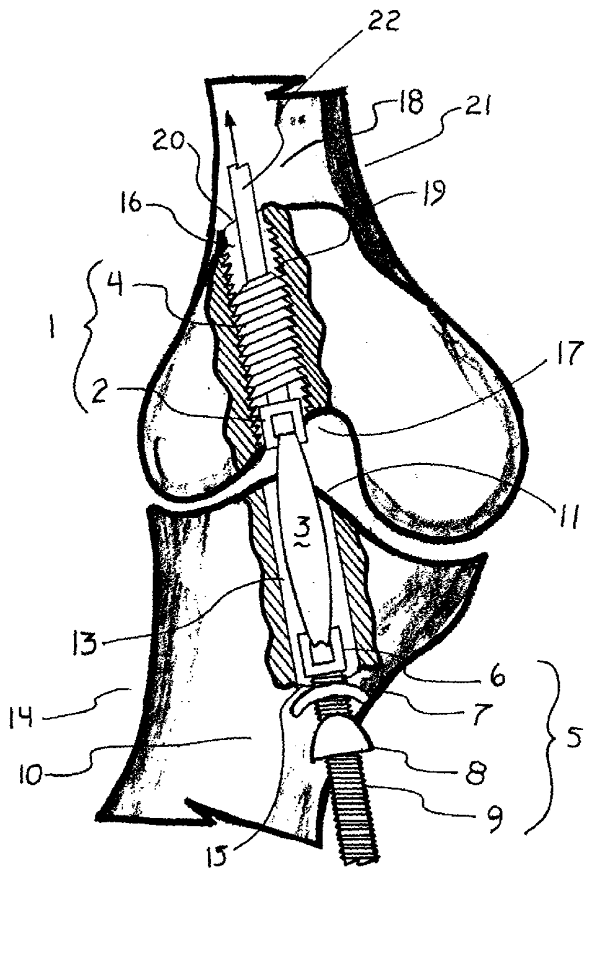
(54) Title: ORTHOPEDIC SWIVEL SCREW



(57) Abstract: An orthopedic swivel screw comprises a threaded shaft and a tissue retainer, which elements are held together by a swivel joint. By virtue of its design, the swivel screw can be installed into a bore in a bone by turning and either pushing or pulling the treaded shaft with a tool. Use of the swivel screw for repair of the ACL, in particular ligament replacement, eliminates or at least minimizes the twisting that typically occurs during conventional ACL repair surgery. In addition, tension of the ligament graft can be precisely adjusted by using the swivel screw in combination with a tension-adjusting device such as a split-nut fastener or a tension bolt. The split-nut is used in combination with any implantable bolt used in orthopedic devices. The split-nut, has two halves, slides down a threaded rod until a rig surrounding the two halves forces them together. The split-nut is then readily threaded tightly onto the threaded rod.

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Orthopedic Swivel Screw

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FIELD OF THE INVENTION

The present invention concerns orthopedic medical devices, in particular, implantable orthopedic devices used to apply tension to biological tissues in a rapid manner or to facilitate orthopedic surgery. The devices of the present include orthopedic swivel screws.

BACKGROUND OF THE INVENTION

The anterior cruciate ligament (ACL) spans the knee joint and attaches to the upper bone, the femur, and the lower bone, the tibia, to maintain smooth movement between their adjacent surfaces as the knee is bent. The ACL is known to tear during sporting accidents, thereby requiring replacement with a graft.

Orthopedic surgeons who conduct ACL repair, which includes replacement, surgery are continuously in search of methods and devices to improve the outcome of the surgery. Two common problems in conventional ACL repair surgery are lack of adjustability of the tension placed upon ligament graft, which results in poor graft performance, and twisting of the ligament graft during installation of orthopedic devices to repair the ACL, which causes the graft to become unduly stressed and thereby more prone to failure.

Conventional surgical techniques for repairing the ACL require drilling a bore through the tibia, spanning the knee joint, into the upper bone, the femur, and passing a ligament or tendon graft up the bore and fastening one end of the graft to the upper bone, the femur, and, attaching the opposite end of the graft to the front surface of the Tibia. Typically, bone screws and bone staples are placed through the end of the ligament graft that protrudes from the bore, fastening it to the Tibia. Such fasteners are almost never removed and replaced during surgery to adjust ligament tension. Hence, if, during surgery, the replacement ligament in perceived to be loose, allowing excessive play between the upper bone, the femur, and the lower bone, the tibia, it is often left this way, leading to discomfort and pain in the knee postoperatively. Moreover, due to the method of installation, conventional devices typically cause the ligament graft to twist and weaken during insertion.

Thus, a need remains for a surgical method and device that overcomes the disadvantages inherent in conventional surgical methods of ACL repair.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages of known related prosthetic devices and thus is generally directed to orthopedic devices that can be used to control the amount of tension on a biological tissue or to facilitate orthopedic surgical procedures. The present invention provides an orthopedic swivel screw system, and method of installation thereof, that is easy to install, minimizes twisting of the ligament graft, and permits precise adjustment of the tension of the ligament graft.

In one aspect, the present invention provides a surgical method for repairing the ACL. The method includes the steps of:

forming an incision through tissue adjacent the knee joint to access a first surface of the upper portion of the tibia;

forming a first bore having a first diameter, wherein the first bore extends along a first direction from the first surface of the tibia through the knee surface of the tibia toward the femur;

forming a second bore having a second smaller diameter, wherein the second bore extends along a second direction from the knee surface of the femur to a second surface of the lower portion of the femur;

tapping the second bore to make it a threaded second bore;

inserting an orthopedic swivel screw, having a ligament graft engaged therewith, through the first bore and into the threaded second bore by way of a tool; wherein the swivel screw is threadably engaged with the threaded second bore; and the ligament graft also has engaged therewith a ligament-tensioning device;

engaging the ligament-tensioning device with the first bore and the first surface of the tibia; and

operating the ligament-tensioning device to adjust the tension of the ligament graft.

Specific embodiments of the invention include those wherein: 1) the ligament-tensioning device is a nut-type fastener having an eyelet engaged with the ligament graft; 2) the knee joint being operated upon is flexed prior to boring the second hole into the femur; 3) the first bore and second bore extend along approximately the same direction when the knee joint is flexed; 4) the tool is used to pull and thread the swivel screw into the second bore; 5) the tool is used to push and thread the swivel screw into the second bore; 6) a second incision is made adjacent the second surface of the femur; 7) the above-described steps are performed with the femur and tibia interchanged such that the first bore is in the femur and the second bore is in the tibia; 8) incisions are closed after complete installation of the device; 9) the swivel screw is initially installed by way of a guide-wire system; and/or 10) the swivel screw is pulled via a marionette-like strings, or guide-wires, and then rotated into the bone.

Another aspect of the invention provides an orthopedic swivel screw having an eyelet-containing member and a threaded shaft rotatably engaged therewith. The swivel screw comprises:

a threaded shaft comprising a swivel joint first-half and tool engaging means adapted to receive a tool that can turn the threaded shaft; and

a tissue retainer comprising a tissue-retaining means and a swivel joint second-half engaged with the swivel joint first-half to form the swivel screw.

Specific embodiments of the swivel screw include those wherein: 1) the tool engaging means is disposed adjacent the swivel joint first-half; 2) the tool engaging means is multi-sided and is adapted to receive a multi-sided tool; 3) the tool engaging means is adapted to receive a tool that turns the shaft while pushing and turning the tool; 4) the tool engaging means is adapted to receive a tool that turns the shaft while pulling and turning the tool; 5) the tool engaging means is a female engaging means adapted to engage with a tool comprising male engaging means; 6) the tool engaging means is male engaging means adapted to engage with a tool comprising female engaging means; 7) the tissue retainer and/or threaded shaft further comprises a tool passageway; 8) the tool engaging means comprises a slotted aperture; 9) one of the swivel joint halves comprises a flanged member and the other swivel joint half comprises a mating receptacle; and/or 10) the tissue-retaining means is an eyelet, clip, post, perforated plate or hook.

Another aspect of the invention provides a system for repairing or reconstructing a ligament in the joint of a human or animal. One embodiment of this aspect provides a system for replacing the torn ACL of a knee comprising:

a swivel screw for installation in a first bone of the knee;

a tension-adjusting device (otherwise referred to as a ligament-tensioning device) for installation in a second bone of the knee; and

a ligament graft engaged with the swivel screw and the tension-adjusting device.

Some embodiments of the system, such as the FAS-TEN-ON™ system available from JUS-TEC, Inc., include those wherein: a) the swivel screw comprises a threaded shaft comprising a tool engaging means and swivel joint first half; and a tissue retainer comprising a swivel joint second half and tissue retaining means engaged with the ligament graft; wherein the swivel joint first and second halves form a swivel joint; b) the swivel joint second half comprises an element selected from the group consisting of an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, cup, partial cup and partial socket; the swivel joint first half comprises an element selected from the group consisting of a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange and hemi-spherical flange; and the tissue retaining means is selected from the group consisting of a bar, ring, arcuate rod, plate, and eyelet; c) the swivel joint first half comprises an element selected from the group consisting of an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, cup, partial cup and partial socket; the swivel joint second half comprises an element selected from the group consisting of a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange and hemi-spherical flange; and the tissue retaining means is selected from the group consisting of a bar, ring, arcuate rod, plate, and eyelet; d) the tension-adjusting device comprises a threaded shaft; a nut threaded onto the threaded shaft; second tissue retaining means disposed at one end of the threaded shaft; and a washer interposed the nut and the tissue retaining means; e) the nut is a split-nut; f) the nut and washer together form a ball and socket joint; g) the ball and socket joint is a flanged ball-and-socket nut assembly comprising an approximately hemispherical convex nut having an internal threaded bore for receiving a threaded shaft; an approximately hemispherical concave socket adapted to receive, mate with and retain the nut, the socket having a first hole or first notch through a portion thereof for receiving a portion of a threaded shaft engaged with the nut, wherein the hole or notch is smaller in size than the nut; and a flange attached to a portion of the periphery of the socket, the flange having a second hole or second notch through a portion thereof, wherein the second hole or second notch is sufficiently large in size to permit passage of the nut into the socket; h) the nut further comprises second tool engaging means adapted to receive a tool that can be used to drive or rotate the nut when engaged with a threaded shaft; i) the second tool engaging means comprises a recess; j) the split-nut comprises two or more nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, and a second annular groove having a second diameter, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut; and a band disposed in either of the first and second grooves to keep the two or more nut sections in assembly; wherein the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove; k) the first groove is disposed adjacent a first end of the nut, and the second groove is disposed between the first groove and a second end of the nut; l) the band of the split-nut is an o-ring or a snap ring; m) a portion of the surface of the band mates with corresponding portions of the peripheral surface of the split-nut; n) the split-nut further comprises a shoulder interposed the first and second grooves; o) each groove of the split-nut further comprises a flange to keep the retainer in its respective groove; p) the split-nut comprises two nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, a second annular groove having a second diameter, a shoulder interposed the first and second grooves, forming a bore and adjoining channel on the surface of a bone wherein the flexible tissue to be anchored was previously attached, wherein the adjoining channel lies in the direction of the length of the flexible tissue;

threading a swivel screw with the bore, wherein the swivel screw comprises a tissue retainer, a threaded shaft having tool engaging means, and a swivel joint formed by the tissue retainer and threaded shaft;

engaging a portion of the flexible tissue to the tissue retainer; and

placing the tissue retainer into the channel;

wherein the steps of threading and engaging can be performed in any order.

Specific embodiments of the above method include ones wherein: 1) the flexible tissue is a muscle, tendon, tissue capsule or ligament; 2) a guide-wire is used to engage the flexible tissue with the tissue retainer; and/or 3) the flexible tissue articulates a joint such as a knee, elbow, shoulder, hip, wrist, or ankle.

Other features, advantages and embodiments of the invention will be apparent to those skilled in the art by the following description, accompanying examples and appended claims.

BRIEF DESCRIPTION OF THE FIGURES

The following drawings are part of the present specification and are included to further demonstrate certain aspects of the invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of the specific embodiments presented herein.

FIG. 1 is a front elevation with a partial sectional view of a human knee joint having a swivel screw device of the invention installed therein.

FIG. 2 is a partial sectional front elevation of a first embodiment of the swivel screw of the invention.

FIGS. 3a and 3b depict sectional end views of the device of FIG. 2 along lines 3a-3a and 3b-3b, respectively.

FIG. 4a is a side elevation of a tool used to install the device of FIG. 3.

FIG. 4b is an end view of the tool of FIG. 4a.

FIG. 5 is a side elevation of a tissue retainer in the device of FIG. 2.

FIG. 6 is a partial sectional front elevation of a second embodiment of the swivel screw of the invention.

FIG. 7 is bottom plan view of the device of FIG. 6.

FIG. 8 is a perspective view of a tool used to install the device of FIG. 6.

FIG. 9 is an exploded perspective view of a third embodiment of the swivel screw of the invention.

FIGS. 10-12 are perspective views of various alternate embodiments of the tissue retainer used in the swivel screw of the invention.

FIG. 13 is an exploded perspective view of a fourth embodiment of the swivel screw of the invention.

FIG. 14 is a partial sectional front elevation of a fifth embodiment of the swivel screw of the invention.

FIG. 15 is a perspective view of a sixth embodiment of the swivel screw of the invention.

FIG. 16 is a partial sectional side elevation of a flanged ball and socket assembly implanted in a bone.

FIG. 17 is a sectional front elevation of the ball of FIG. 16.

FIG. 18 is a perspective view of the flanged washer of FIG. 16.

FIG. 19 is a partial sectional side elevation of the ball and socket assembly of FIG. 16 further including a driving tool and depicting the threaded shaft disposed at different incident angles.

FIG. 20 is a partial sectional side elevation of the ball and socket assembly of FIG. 16 further including a tension measuring means.

FIG. 21 is a sectional side view of a split-nut that can be used in the tension-adjusting device of FIG. 1, wherein the snap ring is not forcing the halves of the split-nut together.

FIG. 22 is a bottom plan view of the split-nut of FIG. 21.

FIG. 23 is a sectional side view of the split-nut of FIG. 21, wherein the snap ring is forcing the halves of the split-nut together.

FIG. 24 is a bottom plan view of the split-nut of FIG. 23.

FIG. 25 is a sectional side view of a snap ring, which is adapted to engage the split-nut of FIG. 21.

FIG. 26 is a partial sectional side view of a joint having a flexible tissue with a swivel screw engaged thereto prior to installation of the swivel screw into a bone.

FIG. 27 is a partial sectional side view of a joint having a flexible tissue with a swivel screw engaged thereto after installation of the swivel screw into the bone.

DETAILED DESCRIPTION OF THE INVENTION

The swivel screw of the invention can be used in various different types of ligament or tendon replacement or repair surgical procedures. Depending upon the ultimate surgical procedure being performed, different swivel screws according to the invention will be preferred. Moreover, the swivel screw and method of installation herein are useful for reparation of injured knees, elbows, shoulders, ankles, wrists or hips and the ligaments and tendons associated with them in humans and animals. In the exemplary embodiments described herein, the swivel screw and an associated ligament graft are used to replace the ACL in a human knee.

FIG. 1 depicts a swivel screw (1) installed in a bore (16) in the femur (21) of a human knee. The swivel screw comprises a threaded shaft (4) and a tissue retainer (2), which in this exemplary embodiment includes an eyelet or other equivalent structure. The tissue retainer has a first end of a ligament graft (3) engaged to it. The second end of the ligament graft is engaged to a tension-adjusting device (5). The tension-adjusting device comprises a second tissue retainer (6), a washer (7), a threaded nut (8), and a threaded shaft (9). The tension-adjusting device is installed in a bore (13) in the tibia (14). Together the swivel screw, ligament graft and tension-adjusting device provide a ligament replacement system.

One method for installing the device of FIG. 1 proceeds as follows. A bore (13) is drilled from an outer surface (10) of the upper portion of the tibia (14) through to the knee-joint surface (11) of the tibia. A bore (16) is then drilled from the knee-joint surface (17) of the femur (21) through to an outer surface (18) of the lower portion of the tibia. The bore (13) generally, but not necessarily, has a larger diameter than the bore (16) such that the swivel screw (1) can be passed through the bore (13) without having to be threaded through it. The bores (13) and (16) are generally alignable, e.g., they may extend along a common linear axis, when the femur and tibia are at a predetermined position with respect to one another such as when the knee is flexed. The bore (16) is then tapped such that the surface of the bore becomes threaded to permit threadable engagement with the threaded shaft (4). The swivel screw (1), by way of a tool or guide-wire, is then passed through the bore (13) and engaged with the bore (16). In the embodiment of FIG. 1, the tool (22) is used to pull and thread the swivel screw (1) into the bore (16). The tissue retainer (2) is engaged with a ligament graft (3), which is engaged with the tension-adjusting device (5). As the swivel screw (1) is worked further into the bore (16), the tension-adjusting device (5) is pulled further into the bore (13). Once the swivel screw is properly positioned, tension is applied onto the graft (3) by adjustment of the relative positions of the washer (7) and nut (8) with respect to the tissue retainer (6). The adjustment is effected by threading the nut (8) closer to the tissue retainer (6). The tension upon the graft is then measured and finally precisely adjusted. Once the proper tension is achieved, the excess length of threaded shaft (9) that extends beyond the nut (8) is removed. Any incisions made in the tissue surrounding the knee are closed to complete the surgical procedure.

Since the tissue retainers (2) and (6) are rotatably engaged with the threaded shaft (4) and nut (8), respectively, twisting of the ligament graft (3) is minimized, with respect to conventional devices, or eliminated.

FIG. 2 depicts a swivel screw (25) comprising a threaded shaft (26) (in section) and a tissue retainer (30). One end of the shaft (26) has a tool receptacle comprising a bore (27) and tool engaging means (28). The other end of the shaft (26) has a swivel joint first half, which comprises a bore having a small diameter first portion (29) and an internal larger diameter second portion (32). The tissue retainer (30) comprises tissue engaging means (31), neck (33) and flange (34). The larger diameter portion (32) of the bore is adapted to receive the flange (34), while the small diameter portion (29) of the bore is adapted to receive the neck (33). When the tissue retainer (30) is engaged with the threaded shaft (26), the tissue retainer will be able to rotate with respect to the threaded shaft.

FIG. 3a depicts a sectional end view along line 3a-3a of the threaded shaft (26), which includes the tool passageway (27) and a notch or groove or channel (38) that extends along the length of the tool passageway and into the tool engaging means (28). FIG. 3b depicts a mid-sectional end view along line 3b-3b of the threaded shaft (26), which also comprises the internal tool engaging means.

FIG. 4a depicts a side elevation of a tool (36) that includes a shaft (35) (which may be a tube or rod) and male engaging means (37). FIG. 4b depicts an end view of the same tool. The male engaging means is adapted to slide within the groove (38) and into the tool engaging means (28) of the threaded shaft (26). When placed in the passageway (27), the male engaging means (37) will engage a surface of the tool engaging means (28). Once the tool (36) is engaged with the threaded shaft, it may be used to turn and push or pull the threaded shaft, thereby threading the swivel screw within a bore in a bone. The tool (36) can comprise one or more male engaging means (37).

FIG. 5 depicts a side elevation of one embodiment of the tissue retainer (30). The tissue engaging means (31) can be thinner, thicker or of the same thickness as the neck (33).

FIG. 6 depicts a partial sectional perspective view of another embodiment of a swivel screw (40) comprising a threaded shaft (41) and tissue retainer (46). This swivel screw is adapted to receive a tool that pushes and turns the swivel screw into a bore in a bone. The threaded shaft comprises a bore having a smaller diameter portion (42) and an internal larger diameter portion (43). This bore is adapted to receive and rotatably engage the flanged tissue retainer (46). The threaded shaft (41) also comprises tool engaging means (44), which is adapted to receive and engage with a multi-sided male driving tool such as an Allen wrench, and an optional guide-wire passageway (45) that extends through to the end (51) of the threaded shaft. The tissue retainer (46) comprises tissue-retaining means (47), a neck (50), a flanged end (48), and a tool passageway (49, 52) extending through the threaded neck, flange and tissue retaining means. The diameter of the tool passageway will be sufficiently large to permit insertion and rotation of a tool without concomitant rotation of the tissue retainer. The diameter of the tool engaging means (44) will be smaller in diameter than the tool passageway.

FIG. 7 depicts a bottom plan view of the swivel screw of FIG. 6. As depicted in FIG. 7, the tool passageway (49), guide-wire passageway (45) and tool engaging means (44) are aligned along a linear axis of the swivel screw (40). As used herein, the term "guide-wire passageway" is taken to mean a small passageway or bore through the swivel screw through which a guide-wire passes to aid during installation of a device according to the invention. The guide-wire passageway permits installation of a guide-wire through the swivel screw so that the screw can slide along the guide-wire until the screw is near the bore, in correct alignment, for installation. The guide-wire passageway and its use are optional. The guide-wire can be a wire, string, strip, strand, thread, braided lace or other equivalent object that is small enough to pass through the bores in the bones and strong enough to aid in installing the swivel screw of the invention. Artisans in the field sometimes refer to these devices as marionette strings. The guide-wire can be made of cotton, silk, suture, polymer, plastic, metal, cotton, wool, natural fiber, synthetic fiber, or a combination thereof. The guide-wire is generally 1/32" to 1/4" or 1/16" to 1/8" in diameter.

FIG. 8 depicts one embodiment of a multi-sided (6-sided) tool (55) comprising a multi-sided shaft (57) and handle (56), which need not be multi-sided. During use, the end of the shaft (57) is passed through the tool passageway (49, 52) and engaged with the tool engaging means (44). By pushing and turning the tool, the threaded shaft but not the tissue retainer turns; thereby permitting installation of the swivel screw into a bore in a bone while minimizing twisting of a ligament graft being implanted. The tool shaft (57) does not injure a ligament shaft engaged with the tissue retaining means (48), since the ligament graft is flexible and easily maneuvered toward one side or the other and out of the way of the tool shaft. The end of the shaft (57) that engages the threaded shaft can be shaped as a standard screw driver, Phillips screw-driver, Allen wrench, square-ended screw driver, star screw driver and other such male driving tools adapted to engage a female receptacle.

FIG. 9 depicts an alternate embodiment of the swivel screw (70) comprising a threaded shaft (71), a neck (79), a beveled or spherical flange (72) and an optional bore (81) extending through the threaded shaft. The swivel joint of the swivel screw (70) is generally of a construction opposite that of the swivel joint of the swivel screw (40), since the threaded shaft (71) comprises the male half (72) of a swivel joint, and the tissue retainer (76) comprises the female half (80) of the swivel joint. The tissue retainer (76) comprises tissue-retaining means (75a), having an optional guide-wire or tool passageway (75b) attached, by way of extended members (73) to a semi-annular ring (77) having an internal shoulder, socket or cup, (82) adapted to engage with and retain the flange, or ball, (72). By semi-annular ring is meant a ring forming less than but at least one-half of a ring. The semi-annular ring (77) forms one-half to three-quarters of a ring, or about two-thirds of a ring. The socket or cup (82) can be partial or complete.

FIG. 10 depicts a tissue retainer (85) comprising a female swivel joint half, or receptacle, (86) defined by a partition (90) and a wall (87) having an inwardly pointing shoulder (89). The partition (90) separates the receptacle (86) from the space provided for the tissue retaining means (84). The partition (90) and the tissue retaining means (84) comprise an optional tool passageway and/or guide-wire passage (88).

FIG. 11 depicts a tissue retainer (91) comprising arcuate tissue retaining means (94), a shouldered semi-annular ring (92) and two extended members (95, 96) that attach the tissue retaining means to the semi-annular ring. As indicated by the arrow (93), the underside of the semi-annular ring is adapted to receive a flange from a threaded shaft. The inside surface of the retaining means (94) defines a tool passageway, which is actually an open area.

FIG. 12 depicts a tissue retainer (100) comprising a ringed tissue retaining means (107) attached to two extended members (104, 105) each having a respective shouldered arcuate member (102, 103, respectively). The arcuate members together define a female swivel joint half and serve to receive a flange or ball from a threaded shaft. By arcuate member is meant a curved member that forms one-fourth to three-eighths of the circumference of a circle or oval. Each arcuate member has an inwardly pointing shoulder that engages a portion of a single male swivel joint half.

FIG. 13 depicts an alternate embodiment of a swivel screw (60) comprising a flanged (62) threaded shaft (61a) and a multi-prong (64) tissue retainer (61b). The tissue retainer comprises two or more shouldered prongs (64) that, together with the partition (65) define a female swivel joint first half (66). The flange (62) is adapted to fit within the female joint first half (66) that is attached to tissue retaining means by way of two extended members (63). This embodiment comprises optional tool passageway (67, 68).

FIG. 14 depicts a swivel screw (110) comprising a threaded shaft (111) and a tissue retainer (115) rotatably engaged therewith by way of a swivel joint. The threaded shaft comprises a female half (112) of a swivel joint, and the tissue retainer comprises the male half (117) of the swivel joint. In this embodiment, the swivel joint is a ball and socket joint. The threaded shaft also comprises a tool passageway (113) and tool engaging means (114). The tissue retainer also comprises tissue-retaining means (116), which is an eyelet, hole or aperture.

FIG. 15 depicts a swivel screw (120) comprising a threaded shaft (121) and tissue retainer (123). The threaded shaft comprises the male portion (122) of a ball and socket joint and tool engaging means (127). On the other hand, the tissue retainer (123) comprises tissue-retaining means (125), a tool passageway (126), and the female portion (124) of a ball and socket joint. It should be noted, embodiments of the swivel screw that employ open receptacles such as (124) and (101) (FIG. 12) do not require additional reinforcement of the female receptacles since the outer surfaces of the receptacles are adjacent the inner surfaces of the respective bores in bones in which they are installed, i.e., the surface of the bore of the bone serves to keep the portions (128) and (129) adjacent and the portions (102) and (103) adjacent during use. The tool passageway (126) is actually an open area defined by the arcuate surface of the tissue retaining means (125).

The swivel screw (120) depicted in FIG. 15 also includes an optional suture (118). The suture is used to tie the engage a biological tissue with the tissue retainer, generally after the swivel screw is in place. For example, the ligament graft, which comprises a loop of ligament tissue, can be fully formed and attached to the tissue retainer prior to insertion of the swivel screw to provide a strong connection between the soft tissue and the bone. Alternatively, the swivel screw is implanted in the bone first, and then the ligament tissue is engaged with the tissue retainer via the suture (118) that passes through the tissue retainer. The latter mode of attachment is generally weaker than the former mode of attachment.

The ball and socket configuration (or universal joint configuration) for the swivel joint permits the threaded screw and tissue retainer to rotate and swing with respect to one another.

The threaded shaft and tissue retainer can be assembled to form a swivel screw according to the invention either before, during or after engagement of a ligament graft with the tissue retainer.

The tissue retaining means can be shaped as desired provided it operates to retain a ligament graft after installation of the swivel screw into a bore in a bone. The tissue retaining means can be shaped as a bar, arcuate rod, ring, circle, oval, square, triangle or other geometric shape. The edges of the tissue retaining means can be beveled to minimize wear of an engaged ligament graft.

The swivel screw and its elements are made of durable materials that retain their physical integrity during use. The material of construction for each element of the swivel screw is independently selected from the group consisting of plastic, metal, alloy, rubber, silicone rubber, dissolvable or degradable plastics (such as poly(galactic acid)), and combinations thereof.

As described herein, the term "ligament graft" refers to fibrous tissue taken from another piece of living tissue, such as strands of muscle tissue, muscle covering or tissue substitute. The ligament is generally made from a biological tissue but can also be made of synthetic materials. The ligament graft is generally a portion of ligament or tendon that has been sutured. This fibrous tissue is generally formed into a continuous loop of tissue by passing it through the tissue retainer and suturing the two ends together. When engaged with the tissue retainer, the location in the graft where the two ends of the tissue meet are generally not directly adjacent the tissue retainer.

To reinforce the ligament graft, the loop can be tensioned and the two strands that are adjacent and parallel are sutured side-by-side. The side-by-side suturing may be done before or after installation onto a tissue retainer; although, it is generally done afterwards.

When a second fastener such as the tissue-tensioning device described below is utilized, the tissue retainer of the second fastener is also generally attached directly to the tissue loop prior to attaching the two ends of tissue together and then suturing the strands side-to-side. This provides a strong continuous loop of tissue that spans between the two tissue retainers.

For the purposes of the present invention, any suitable tension-adjusting device can be used in combination with the swivel screw. Exemplary tension-adjusting devices are depicted in FIGS. 16-25.

Instead of a conventional nut and flat-washer combination, the nut and washer used with the tension-adjusting device can be a ball-and-socket nut assembly. An internally threaded nut has a convex-shaped outer surface. A mating nut retainer has a washer or flange and a concave-shaped socket that is adapted to receive the convex-shaped surface of the nut. When the nut assembly is implanted into a bone, the flange will preferably be disposed on the surface of the bone, the socket will be disposed within a bore in the bone, and the nut will be disposed within the socket. The flange and socket will each have a bore or notch through which a threaded shaft engaged with the nut can pass. A nut assembly of this kind will permit implantation of bolts into bone at many different incident angles, i.e., one single ball-and-socket nut assembly can be used to implant many different types of bolts and many different incident angles relative to the surface of the bone.

FIG. 16 depicts a suitable precision tension-adjusting device (130) implanted within a countersunk bore (131, 132) in a bone (133). The tension-adjusting device comprises a nut (1344), a flanged cup (135), and a threaded shaft (136). The nut (134) is disposed within the flanged cup (137). The socket (138) and the flange (139) each have a bore or notch through which the threaded shaft (136) passes. The nut (134) has been rotated down the shaft until it is in proximity of the cavity (140) within the socket (138). At least a portion of the flange (139) is disposed on the surface (141) of the bone (133). The end of the threaded shaft (136) that is disposed within the bore includes a tissue retainer (142), such as an eyelet, to which a ligament graft (143) is attached.

FIG. 17 depicts a sectional view of the ball-shaped nut (134) comprising a threaded bore (144) and tool-engaging means (145), which is a receptacle for a driving tool. The nut (134) can also be a split-nut as described below.

FIG. 18 depicts the flanged washer (137) having a partial socket or cup (138), a flange (139) attached to the cup, and a notch (135) in the cup to receive a threaded shaft (136). The cup is adapted to receive the ball-shaped nut (134).

FIG. 19 demonstrates that the threaded shaft of the tension-adjusting device (130) can be disposed at different incident angles with respect to the surface of the bone and to the flanged cup (137). The actual incident angle of implantation will depend upon the incident angle at which the bore through the bone is made. This diverse use is due to the swiveling of the nut (134) within the socket (138) and to the notches and/or bores through the flange (139) and socket (138). This construction allows the threaded shaft to rotate and swivel in a variety of angles within the flanged cup to fit a variety of brothels or bores in the bone. The driver or tool (145) is used to rotate the nut (134) in the cup and to drive the nut up and down the shaft (136).

FIG. 20 depicts the nut (134) mating with the socket (138). A tool (145) is used to thread the nut about the threaded shaft (136) and thereby pull the shaft partially out of the bone in the direction of the arrow (A). In so doing, the ligament (143), which is engaged with the eye (142), is tensioned to a precise level. This control of tension averts the problem of arthritic loose knees that result from loose ligament replacements that allow the joint surfaces to slide and rub out.

The tension on the ligament graft is measured by way of a tension gauge (146), which comprises a pressure transducer assembly (166), a rod engaging means (167), a displacement member (168), and tool engaging means (165). The exemplary tension gauge

(146) is operated as follows. The displacement member (168) is threaded into the rod engaging means (167) to abut its end against a surface of the flanged socket (138) thereby displacing the threaded shaft (136) in the direction of the arrow (A) to apply tension to the attached ligament graft. Once the tension gauge displays the desired tension, the nut (134) is tightened down until it assumes the tension load previously carried by the tension gauge. By threading the nut (134) up and down the threaded shaft (136), the shaft is displaced along the arrow (B) thereby changing the tension indicated on the tension gauge. The tension gauge can have a display (C) directly on the pressure transducer assembly (166) or on a connected remote display (168).

A technique for implantation of the swivel screw and tension-adjusting device into a knee generally proceeds as follows. A drill is used to make a bore through each the tibia and the femur. The bore generally passes through the point of attachment of the original ligament that has been torn. The ligament graft is passed through the eyelets of the swivel screw and the tension-adjusting device and sutured onto itself to form a continuous loop. The swivel screw is then passed through the tibia and threaded into the femur with a driving tool. A flanged cup is then put around the threaded shaft of the tension-adjusting device and between the nut and its respective bone surface. The nut is then rotated until it is disposed within the flanged cup. The tension on the ligament is measured and adjusted by threading the nut as needed, and the threaded shaft of the tension-adjusting device is cut to size.

Instead of a conventional nut, a split-nut, or speed-nut, can be used for the tension-adjusting device. The split-nut is designed to speed the threading process for the surgeon by circumventing the need to thread the nut down the entire length of the screw. The split-nut comprises sections that can slide on a threaded shaft until the sections of the nut are compressed by ring. Once the sections are compressed together, the split-nut behaves as a conventional nut and can only be threaded up and down the threaded shaft. When the split-nut is rotated while compressed against the bone surface, it causes a threaded rod to move in or out of a bore in the bone, and thereby apply compression to the bone pieces or apply tension to a the ligament graft. The split-nut fastener comprises two or more nut portions and one or more ring portions surrounding the assembled nut portions. The split-nut is particularly useful when used in combination with long, or one-size-fits-all, threaded shafts or screws.

FIGS. 21-22 depict a snap ring split-nut assembly (150) in an expanded or spaced-apart relation. The split-nut comprises two or more portions (151, 152) which are held spaced from one another by the snap ring, or ring or band, (153). The split-nut has at least two grooves: an upper groove (155) and a lower groove (154), which is narrower in diameter than the upper groove. In order to maintain the portions (151, 152) proximal but spaced, the snap ring (153) is initially located at a lower groove (154). In the open position, the split-nut assembly can be slid down a threaded shaft of the proper diameter thereby avoiding having to be threaded down the shaft. Upon moving the ring to the upper groove (155), the portions (151, 152) are forced together to the closed position to form a nut having a threaded bore (156) which can be threaded about a threaded shaft but which cannot be slid up the shaft.

In order to facilitate threading the closed split-nut on the threaded shaft, a driving tool as depicted in FIG. 20 can be used. The driving tool will engage tool engaging means (157), a slot, or receptacle, on the nut (150). For this reason, the split-nut assembly (150) will generally comprise an engagement means (157), which is adapted to engage the driving tool.

Any threaded shaft can be used in the swivel screw and tissue-tensioning device. The threads on the threaded shaft can be any known threads used in orthopedic devices. Generally, machine, wood, fine metal or buttress threads can be used. Buttress threads generally have a long slope on one side and a short slope on the other. When a split-nut (150) is in the expanded position, the buttress threads on the inside of the nut contact those of the threaded shaft. As the split-nut is slid down the length of the shaft, the sections (151, 152) are pushed outwardly. The short slope of the thread prevents the split-nut from moving backward up the length of the shaft.

When the split-nut is in the closed position (FIGS. 23-24), it can move up or down the length of the shaft only by rotation about the shaft and not by sliding on the shaft. This construction allows the split-nut to rapidly slide to a general position on a rod and then, have its snap ring moved into the compression groove, causing the nut sections to compress a threaded shaft or rod.

FIG. 25 depicts a ring (153) having a slanted or sloped inner surface that is adapted to mate with the surface of the grooves (154, 155). In addition, the grooves are separated by a circumferential shoulder (160) that aids in keeping the band in either the upper or lower groove as needed. Each groove also preferably has an outer flanged portion (161, 162), which also aids in keeping the band seated in a desired groove without sliding off of the split-nut.

The swivel screw can be used to attach other types of soft tissue to bone. For instance, when a uterus rips loose from its moorings, it is typically attached to a vertebral body via a solid anchor or screw-like device. In such surgery, the anchor, with sutures trailing its eye, is attached to the bone and the suture is used to attach the soft tissue to the eye, and abut against the bone surface. Accordingly, a swivel screw provided with a suture that passes through the tissue retainer may be used for anchoring a uterus. Alternatively, some of the tissue of the uterus can be passed through the tissue retainer of the swivel screw and sutured into a strong loop. Following this, the swivel bolt would be inserted into the bone, via rotation, without twisting the soft tissue attached to it.

The swivel screw can be used to attach virtually any soft tissue to bone, or cartilage, and hold it against the bone until it heals and adheres to the bone, with greater strength than traditional suture and anchor combinations. For example, muscle that has ripped free from its attachment to the bone can be reattached to the bone, or, for paralytics, muscle can be cut free from its mooring to a bone and transferred and attached to another location. In these cases, the fibrous end of the muscle, the tendon, is passed through the tissue retainer and sutured into a strong loop of tissue by way of a suture, such as that of FIG. 15. After attachment of the tissue, the swivel screw is installed into the bone via rotation without twisting the attached tissue.

“Soft tissue”, “biological tissue” or “tissue” as used herein generally refers to any tissue in the body that requires attachment to a bone, e.g., ligament that has avulsed from its bone.

Where the ligament has ripped in the middle, it is usually not possible to simply take the end of the ripped ligament and reattach it to the bone. In this case, as noted above, the fibrous portion of the muscle is harvested from the body and sutured into a continuous loop, reinforced via side-to-side sutures and then attached to the bone via the swivel screw.

FIG. 26 depicts a swivel screw (170) being used to reattach a flexible tissue (178) that has become detached from its mooring on the surface of a first bone (179) in a joint (180). The tendon (178) is engaged with the tissue retainer (181) of the swivel screw (170) at one end and is attached to the second bone (184) at the other end. A bore (185) and adjoining channel (186) are formed on the surface of the first (179) bone at approximately the location where the flexible tissue (178) to be anchored was previously attached. Generally, the adjoining channel lies in the direction of the length of the flexible tissue, i.e., in the direction of the second bone or joint. As depicted in FIG. 27, the swivel screw is placed in the bore (185), and the tissue retainer (181) having its tendon attached thereto is placed into the channel (186). The swivel screw can be threaded into the bore either before or after the tendon is engaged with the tissue retainer. Optionally, a guide-wire (not shown) can be used to engage the tendon with tissue retainer. The joint can be a knee, elbow, shoulder, hip, wrist, or ankle.

The above is a detailed description of particular embodiments of the invention. It is recognized that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. Those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed herein and still obtain a like or similar result without departing from the spirit and scope of the invention. All of the embodiments disclosed and claimed herein can be made and executed without undue experimentation in light of the present disclosure.

CLAIMS

I claim:

1. A swivel screw comprising:
a threaded shaft comprising a tool engaging means and swivel joint first half; and
a tissue retainer comprising a swivel joint second half and tissue retaining means;
wherein the swivel joint first and second halves form a swivel joint.

2. The swivel screw of claim 1, wherein the swivel joint first half has a male configuration and the swivel joint second half has a female configuration.

3. The swivel screw of claim 2, wherein the joint first and second halves together form a swivel joint comprising a flange and mating receptacle joint, a ball and socket joint or a universal joint.

4. The swivel screw of claim 2, wherein the swivel joint first half comprises a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange or hemi-spherical flange.

5. The swivel screw of claim 2 or 4, wherein the swivel joint second half comprises an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, or partial socket.

6. The swivel screw of claim 5, wherein the tissue retaining means comprises a bar, ring, arcuate rod, plate, eyelet, annular ring, or hole.

7. The swivel screw of claim 2, wherein the tool engaging means is disposed adjacent the swivel joint first half.

8. The swivel screw of claim 7, wherein the tool engaging means is a female receptacle for receiving a male driving tool.

9. The swivel screw of claim 8, wherein the male driving tool is a standard screw driver, Phillips screw driver, star screw driver, square ended screw driver, multi-sided tool, or Allen wrench.

10. The swivel screw of claim 2, wherein the threaded shaft further comprises a tool passageway and the tool engaging means is disposed within the threaded shaft.

11. The swivel screw of claim 10, wherein the tool passageway comprises a channel, and the tool engaging means comprises a recess having a radius larger than the radius of the tool passageway.

12. The swivel screw of claim 11, wherein the tool passageway and tool engaging means are together adapted to receive a male driving tool that can turn the threaded shaft while pulling the threaded shaft.

13. The swivel screw of claim 1, wherein the swivel joint first half has a female configuration and the swivel joint second half has a male configuration.

14. The swivel screw of claim 13, wherein the joint first and second halves together form a swivel joint comprising a flange and mating receptacle joint, a ball and socket joint or a universal joint.

15. The swivel screw of claim 13, wherein the swivel joint second half comprises a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange or hemi-spherical flange.

16. The swivel screw of claim 13 or 15, wherein the swivel joint first half comprises an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, or partial socket.

17. The swivel screw of claim 16, wherein the tissue retaining means comprises a bar, ring, arcuate rod, plate, eyelet, annular ring, or hole.

18. The swivel screw of claim 13, wherein the tool engaging means is disposed adjacent the swivel joint first half.

19. The swivel screw of claim 18, wherein the tool engaging means is a female receptacle for a male driving tool.

20. The swivel screw of claim 19, wherein the male driving tool is a standard screw driver, Phillips screw driver, star screw driver, square ended screw driver, multi-sided tool, or Allen wrench.

21. The swivel screw of claim 13, wherein the threaded shaft further comprises a tool passageway and the tool engaging means is disposed within the threaded shaft.

22. The swivel screw of claim 21, wherein the tool passageway comprises a channel, and the tool engaging means comprises a recess having a radius larger than the radius of the tool passageway.

23. The swivel screw of claim 22, wherein the tool passageway and tool engaging means are together adapted to receive a male driving tool that can turn the threaded shaft while pulling the threaded shaft.

24. The swivel screw of claim 1, wherein the tissue retaining means comprises an eyelet; the tissue retainer further comprises a tool passageway; and the tool engaging means comprises a female receptacle for receiving a male driving tool.

25. The swivel screw of claim 24, wherein the swivel joint first half comprises a receptacle for a flange; and the swivel joint second half comprises a flange.

26. The swivel screw of claim 25, further comprising a guide-wire passageway.

27. The swivel screw of claim 1, wherein the tissue retaining means comprises an eyelet; the threaded shaft further comprises a tool passageway and tool engaging means, which together are adapted to receive a tool that can turn the threaded shaft while pulling.

28. The swivel screw of claim 27, wherein the swivel joint first half comprises a receptacle for a flange; and the swivel joint second half comprises a flange.

29. The swivel screw of claim 28, further comprising a guide-wire passageway.

30. The swivel screw of claim 1, wherein:

the swivel joint second half comprises an element selected from the group consisting of an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, cup, partial cup and partial socket;

the swivel joint first half comprises an element selected from the group consisting of a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange and hemi-spherical flange; and

the tissue retaining means is selected from the group consisting of a bar, ring, arcuate rod, plate, and eyelet.

31. The swivel screw of claim 1, wherein the swivel joint second half comprises a pair of arcuate members; the swivel joint first half comprises a ball or flange; and the tissue retaining means comprises an arcuate rod or ring.

32. The swivel screw of claim 1, wherein the swivel joint second half comprises a semi-annular ring, the swivel joint first half comprises a ball or flange; and the tissue retaining means comprises an arcuate rod or ring.

33. A method of replacing a ligament in a knee of an animal or human, the method comprising the steps of:

forming a first bore having a first diameter, wherein the first bore extends along a first direction from a first surface of the tibia through the knee surface of the tibia toward the femur;

forming a second bore having a second smaller diameter, wherein the second bore extends along a second direction from the knee surface of the femur to a second surface of the lower portion of the femur;

tapping the second bore to make it a threaded second bore;

inserting an orthopedic swivel screw, having a ligament graft engaged therewith, through the first bore and into the threaded second bore by way of a tool; wherein the swivel screw is threadably engaged with the threaded second bore; and the ligament graft also has engaged therewith a ligament-tensioning device;

engaging the ligament-tensioning device with the first bore and the first surface of the tibia; and

operating the ligament-tensioning device to adjust the tension of the ligament graft.

34. The method of claim 33 further comprising the earlier step of:

forming an incision through tissue adjacent the knee joint to access a first surface of the upper portion of the tibia.

35. The method of claim 34, wherein the knee joint being operated upon is flexed prior to boring the second hole into the femur.

36. The method of claim 35, wherein the first bore and second bore extend along approximately the same linear axis when the knee joint is flexed.

37. The method of claim 34, wherein the tool is used to pull and thread the swivel screw into the second bore.

38. The method of claim 34, wherein the tool is used to push and thread the swivel screw into the second bor.

39. The method of claim 33, wherein the steps are performed with the femur and tibia interchanged such that the first bore is in the femur and the second bore is in the tibia.

40. The method of claim 33, wherein a second incision is made adjacent the second surface of the femur.

41. The method of claim 40, wherein incisions are closed after complete installation of the swivel screw and the ligament-tensioning device.

42. A ligament replacement system for replacing the ACL of a knee, the system comprising:

a swivel screw for installation in a first bone of the knee;

a tension-adjusting device for installation in a second bone of the knee; and

a ligament graft engaged with the swivel screw and the tension-adjusting device.

43. The system of claim 42, wherein the swivel screw comprises:

a threaded shaft comprising a tool engaging means and swivel joint first half; and

a tissue retainer comprising a swivel joint second half and tissue retaining means engaged with the ligament graft;

wherein the swivel joint first and second halves form a swivel joint.

44. The system of claim 43, wherein:

the swivel joint second half comprises an element selected from the group consisting of an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, cup, partial cup and partial socket;

the swivel joint first half comprises an element selected from the group consisting of a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange and hemi-spherical flange; and

the tissue retaining means is selected from the group consisting of a bar, ring, arcuate rod, plate, and eyelet.

45. The system of claim 43, wherein:

the swivel joint first half comprises an element selected from the group consisting of an annular ring, semi-annular ring, pair of arcuate members, multi-pronged receptacle, semi-circular receptacle, socket, cup, partial cup and partial socket;

the swivel joint second half comprises an element selected from the group consisting of a flange, beveled flange, oval-shaped flange, ball, partial ball, circular flange, spherical flange and hemi-spherical flange; and

the tissue retaining means is selected from the group consisting of a bar, ring, arcuate rod, plate, and eyelet.

46. The system of any one of claims 42-45, wherein the tension-adjusting device comprises:

a threaded shaft;

a nut threaded onto the threaded shaft;

second tissue retaining means disposed at one end of the threaded shaft; and

a washer interposed the nut and the tissue retaining means.

47. The system of claim 46, wherein the nut is a split-nut.

48. The system of claim 46, wherein the nut and washer together form a ball and socket joint.

49. The system of claim 46, wherein the ball and socket joint is a flanged ball-and-socket nut assembly comprising:

an approximately hemispherical convex nut having an internal threaded bore for receiving a threaded shaft;

an approximately hemispherical concave socket adapted to receive, mate with and retain the nut, the socket having a first hole or first notch through a portion thereof for receiving a portion of a threaded shaft engaged with the nut, wherein the hole or notch is smaller in size than the nut; and

a flange attached to a portion of the periphery of the socket, the flange having a second hole or second notch through a portion thereof, wherein the second hole or second notch is sufficiently large in size to permit passage of the nut into the socket.

50. The system of claim 49, wherein the nut further comprises second tool engaging means adapted to receive a tool that can be used to drive or rotate the nut when engaged with a threaded shaft.

51. The system of claim 51, wherein the second tool engaging means comprises a recess.

52. The system of claim 47, wherein the split-nut comprises:

two or more nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, and a second annular groove having a second diameter, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut; and

a band disposed in either of the first and second grooves to keep the two or more nut sections in assembly;

wherein the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove.

53. The system of claim 52, wherein the first groove is disposed adjacent a first end of the nut, and the second groove is disposed between the first groove and a second end of the nut.

54. The system of claim 53, wherein the band is an o-ring or a snap ring.

55. The system of claim 54, wherein a portion of the surface of the band mates with corresponding portions of the peripheral surface of the nut.

56. The system of claim 52, wherein the nut further comprises a shoulder interposed the first and second grooves.

57. The system of claim 56, wherein each groove further comprises a flange to keep the retainer in its respective groove.

58. The system of claim 47, wherein the split-nut comprises:

two nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, a second annular groove having a second diameter, a shoulder interposed the first and second grooves, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut;

a snap ring disposed in either of the first and second grooves to keep the two or more nut sections in assembly;

wherein,

the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove; and

a portion of the surface of the snap ring mates with corresponding portions of the peripheral surface of the nut.

59. The method of claim 33 further comprising the step of:

mounting the swivel screw onto a guide-wire prior to inserting the swivel screw.

60. A method of anchoring a flexible tissue comprising the steps of:

forming a bore and adjoining channel on the surface of a bone wherein the flexible tissue to be anchored was previously attached, wherein the adjoining channel lies in the direction of the length of the flexible tissue;

threading a swivel screw with the bore, wherein the swivel screw comprises a tissue retainer, a threaded shaft having tool engaging means, and a swivel joint formed by the tissue retainer and threaded shaft;

engaging a portion of the flexible tissue to the tissue retainer; and

placing the tissue retainer into the channel;

wherein the steps of threading and engaging can be performed in any order.

61. The method of claim 60, wherein the flexible tissue is a muscle, tendon, tissue capsule or ligament.

62. The method of claim 60, wherein a guide-wire is used to engage the flexible tissue with the tissue retainer.

63. The method of claim 60, wherein the flexible tissue articulates a joint.

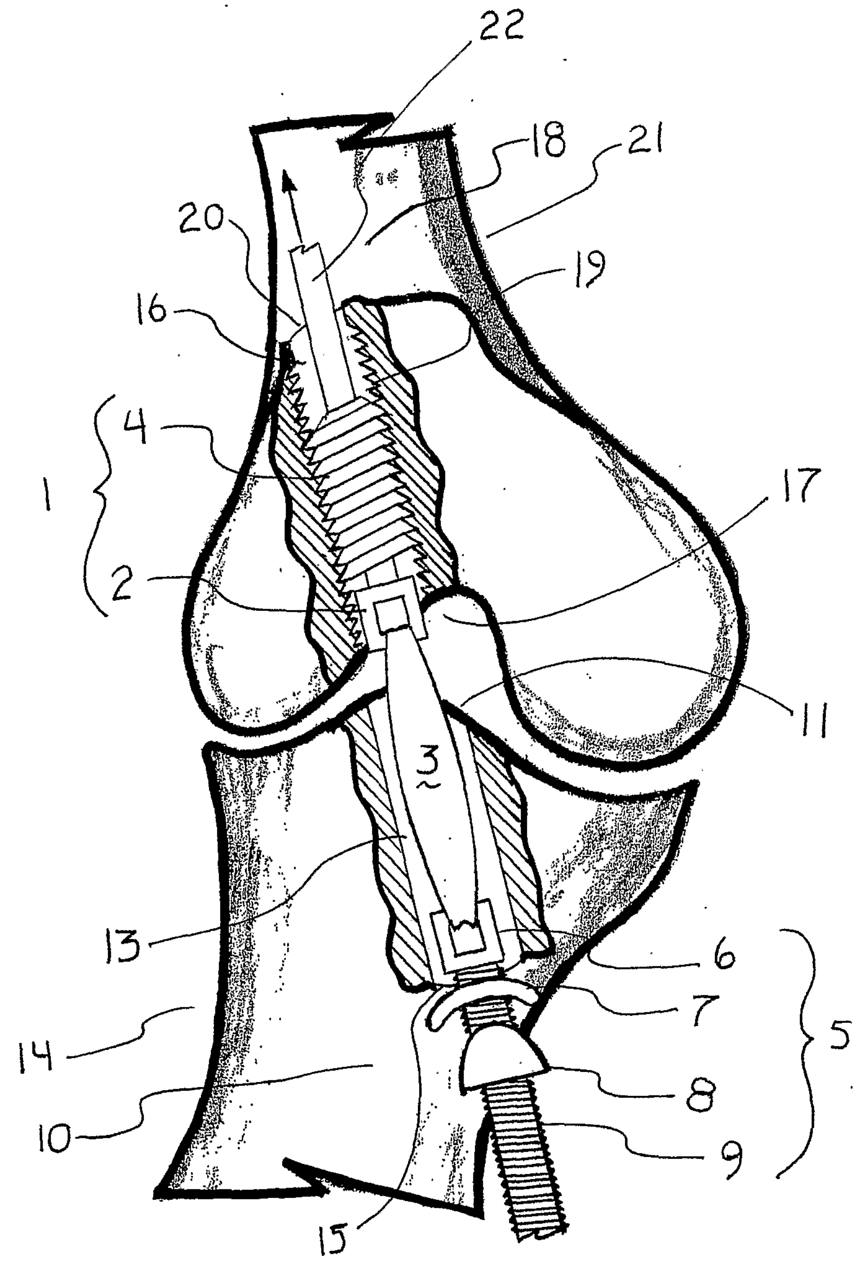


Fig. 1

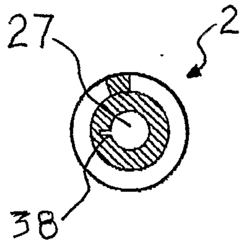


Fig. 3a

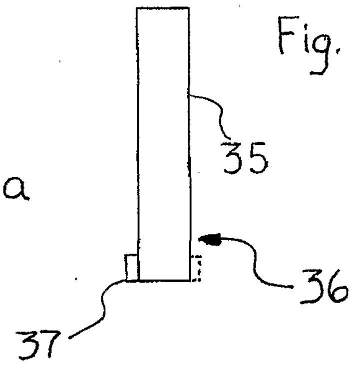


Fig. 4a

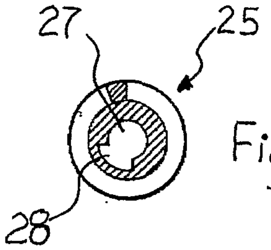


Fig. 3b

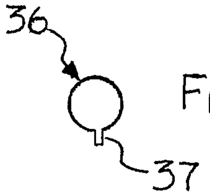
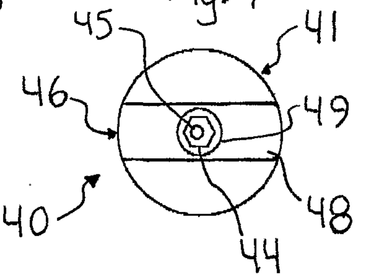


Fig. 4b

Fig. 7


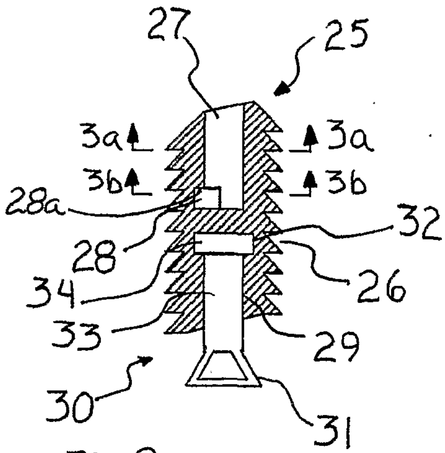


Fig. 2

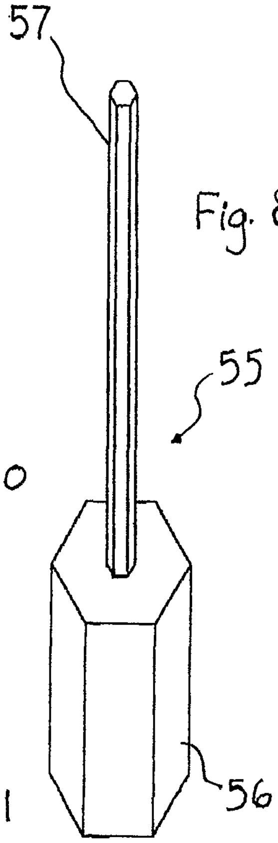


Fig. 8

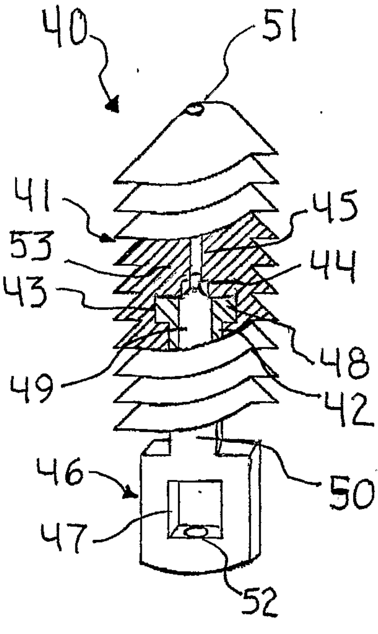


Fig. 6

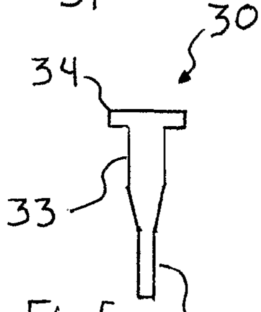


Fig. 5

Fig. 13

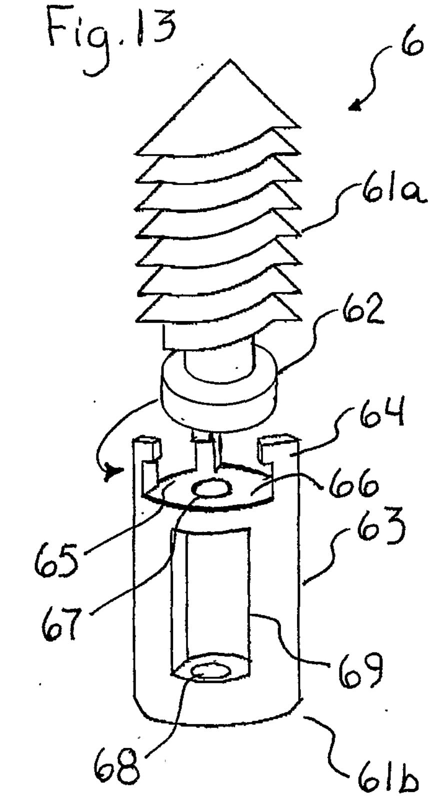
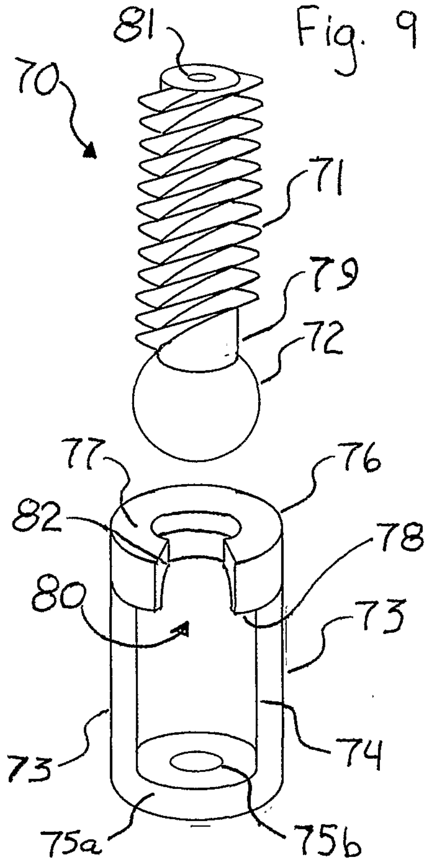


Fig. 9



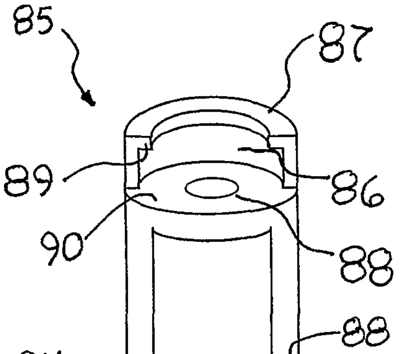


Fig. 10

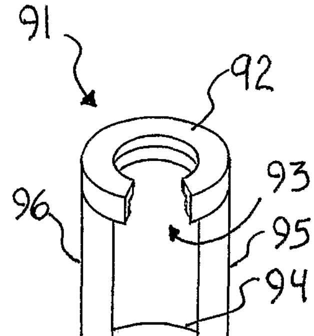


Fig. 11

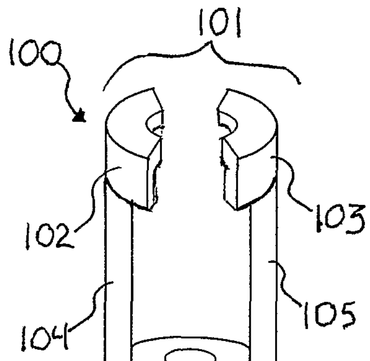


Fig. 12

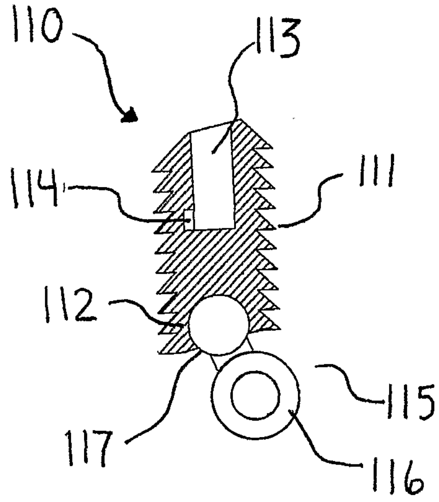

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Fig. 14

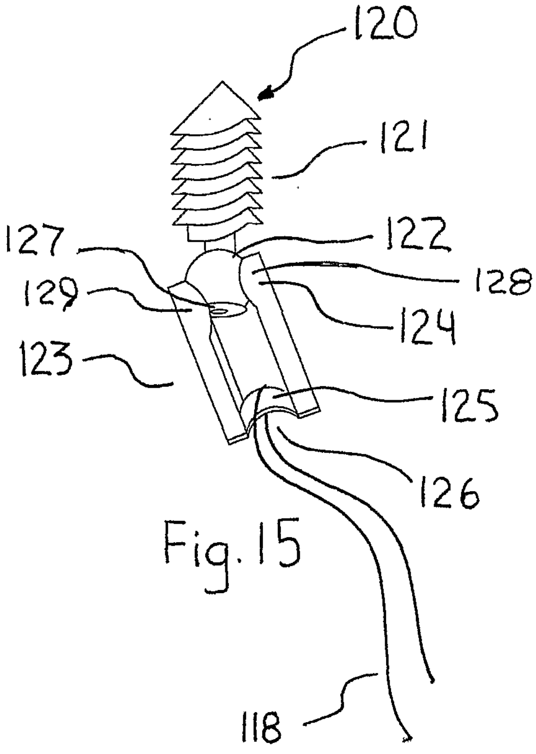
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Fig. 15

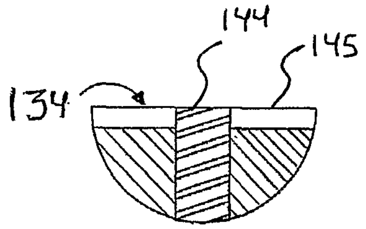

Fig. 17

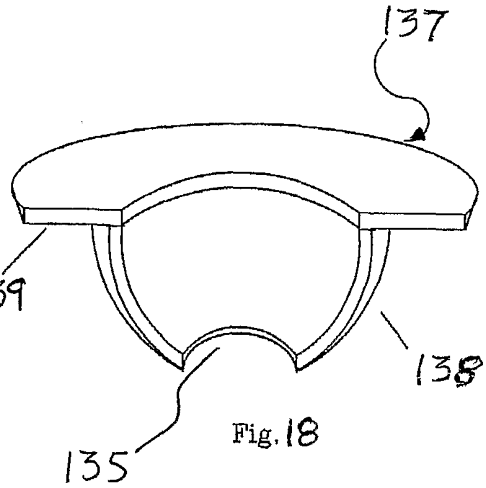

Fig. 18

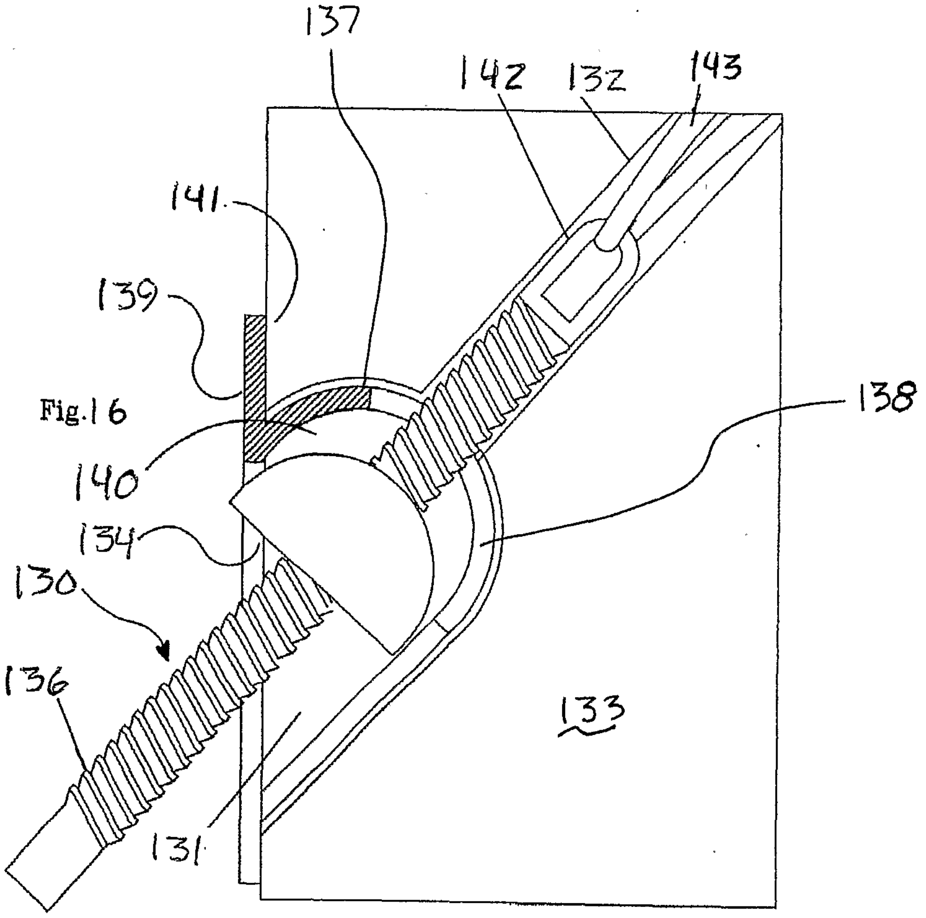

Fig. 16

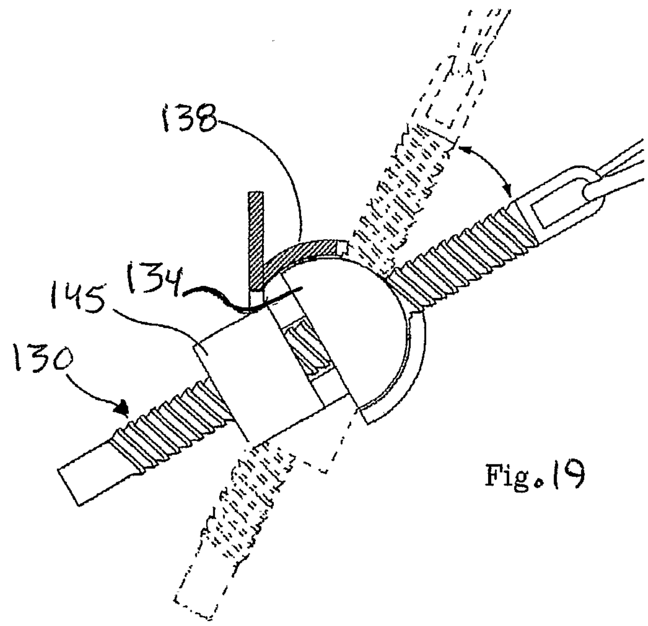
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Fig. 19

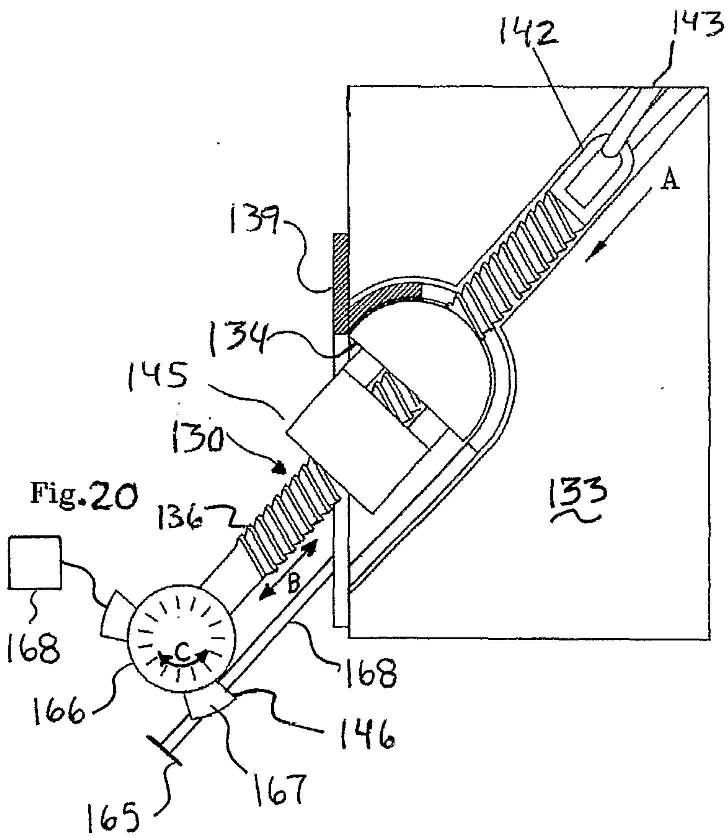
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Fig. 20

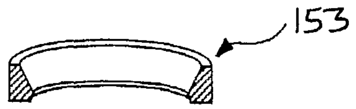

Fig. 25

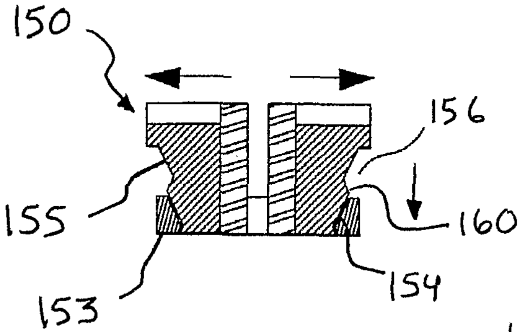

Fig. 21

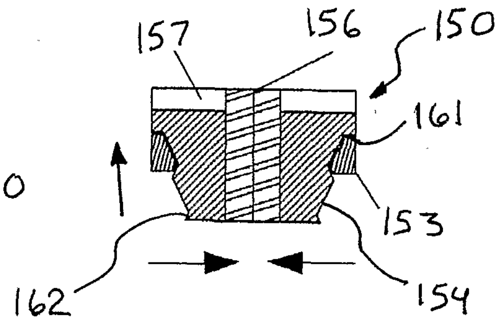

Fig. 23

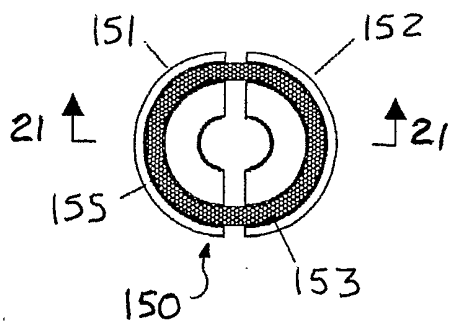

Fig. 22

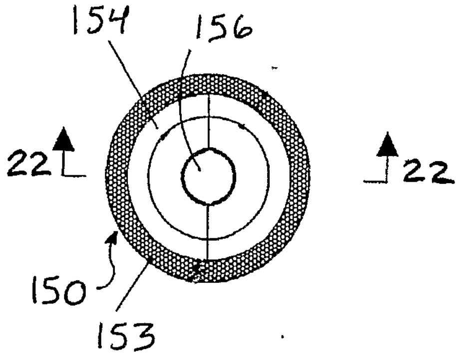

Fig. 24

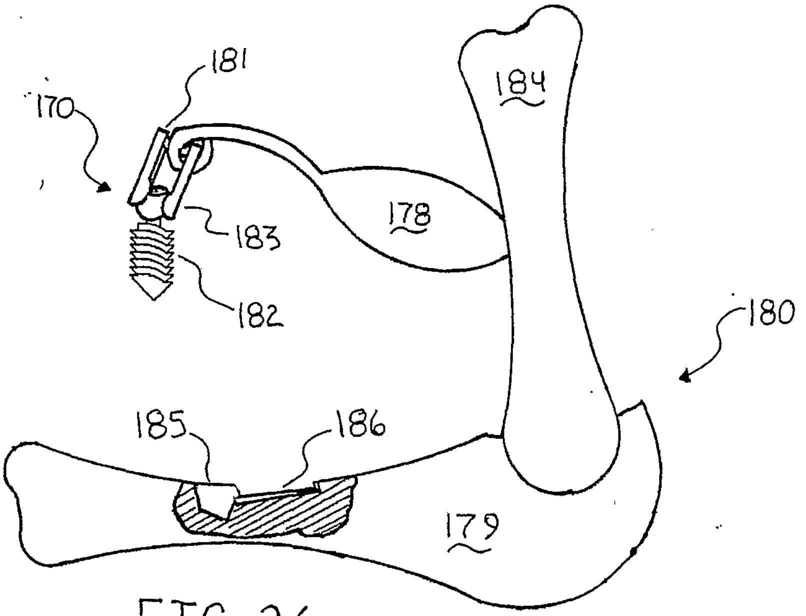
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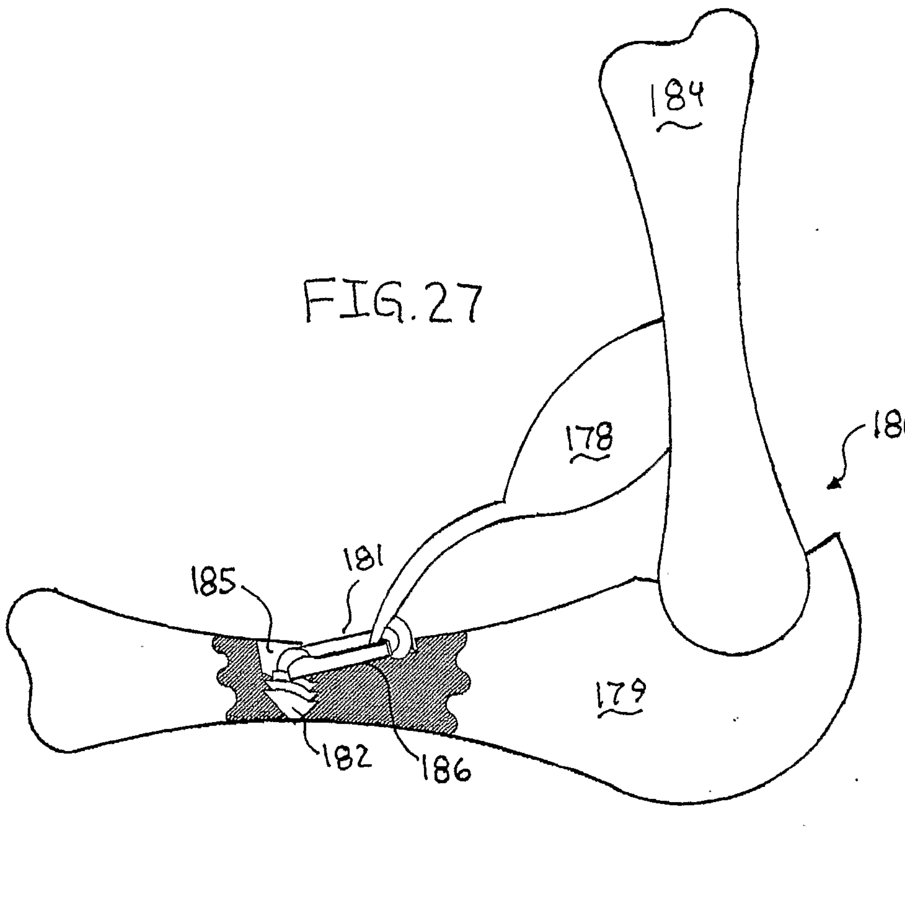
FIG. 26

FIG.27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