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(71) Applicant(s)
Triage Medical, Inc.

(72) Inventor(s)
Cachia, Victor V.;Von Hoffman, Gerard;Culbert, Brad S.

(74) Agent / Attorney
Wallington-Dummer, Suite 904 Level 9 37 Bligh Street, Sydney, NSW, 2000

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ABSTRACT

A bone fixation device, comprising: an elongate body, having a proximal end and a distal end; a helical anchor on the distal end; the helical anchor fixed by rotation in a distal bone portion a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body, wherein the proximal anchor is movable without rotation in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body.

DISTAL BONE ANCHORS FOR BONE FIXATION WITH SECONDARY COMPRESSION

Background of the Invention

Field of the Invention

[0001] The present invention relates to internal bone fracture fixation devices. In one application, the present invention relates to bone fracture fixation devices and methods adapted for fixation, among other fractures, of femoral neck and other proximal femoral fractures.

Description of the Related Art

[0002] The femur, otherwise known as the thigh bone, generally comprises an elongate shaft extending from the hip to the knee. The proximal end of the shaft includes a head, a neck, a greater trochanter and a lesser trochanter. The head of the femur fits into the acetabular cup of the hip bone to form a ball and socket joint at the hip. The distal end of the femur includes a medial condyle and a lateral condyle. The condyles engage an upper end of the tibia to form the knee joint. Overall, the femur is the longest and strongest bone in the skeleton. However, portions of the femur are extremely susceptible to fracturing.

[0003] Pertrochanteric fractures among geriatric patients are the most frequent in connection with those of the region of the neck of the bone. The advanced age and the pathologies which are encountered in these patients make a timely stabilization of skeletal injuries necessary in order to reduce to a minimum the bed confinement and the rehabilitation times. Preferably, devices and procedures are utilized which minimize complications brought about by the so-called immobilization syndrome, which may be lethal for patients in delicate metabolical circumstances. It is also preferable to reduce to a minimum blood losses related to surgical intervention. At the same time, the syntheses means utilized must be stable in order to allow the patient to very timely assume a seated position and, two or three days following the intervention, to reassume an erect posture with progressive bearing of weight.

[0004] Internal fixation of femoral fractures in general is one of the most common orthopedic surgical procedures. Fractures of the femur occur in both the proximal portion of the femur and the distal portion of the femur. Fractures of the proximal portion

of the femur (hip fractures) are generally classified as femoral neck fractures (capital or sub-capital), intertrochanteric fractures and subtrochanteric fractures. Fractures of the distal portion of the femur (knee fractures) are referred to as supracondylar fractures. Supracondylar fractures generally extend vertically between the condyles at the lower end of the femur to separate the distal portion of the femur into two main bone fragments. A fracture line may be further comminuted to create a plurality of smaller bone fragments. Fractures of the femur which extend into the neck of the bone are generally more difficult to treat than fractures restricted to the shaft of the femur.

[0005] Operative treatment of the fractures requires that the fractures be internally fixed and possibly compressed. Fractures of the neck, head or trochanters of the femur have been treated with a variety of compression screw assemblies which include generally a compression plate having a barrel member, a lag screw and a compressing screw. The compression plate is secured to the exterior of the femur and the barrel member is inserted into a predrilled hole in the direction of the femoral head. The lag screw which has a threaded end and a smooth portion is inserted through the barrel member so that it extends across the break and into the femoral head. The threaded portion engages the femoral head. The compressing screw connects the lag screw to the plate. By adjusting the tension of the compressing screw the compression (reduction) of the fracture can be adjusted.

[0006] A variety of elongated implants (nail, screw, pin, etc.) have been developed, which are adapted to be positioned along the longitudinal axis of the femoral neck with a leading (distal) end portion in the femoral head so as to stabilize a fracture of the femoral neck. The elongated implant may be implanted by itself or connected to another implant such as a side plate or intramedullary rod. The leading end portion of the implant typically includes means to positively grip the femoral head bone (external threads, expanding arms, etc.), but the inclusion of such gripping means can introduce several significant problems. First, implants with sharp edges on the leading end portion, such as the externally threaded implants, exhibit a tendency to migrate proximally towards the hip joint weight bearing surface after implantation. This can occur when the proximal cortical bone has insufficient integrity to resist distal movement of the screw head. Such proximal migration under physiological loading, which is also referred to as femoral head cut-out, can lead to significant damage to the adjacent hip joint. Also, the externally threaded

implants can generate large stress concentrations in the bone during implantation which can lead to stripping of the threads formed in the bone and thus a weakened grip. The movable arms of known expanding arm devices are usually free at one end and attached at the other end to the main body of the leading end portion of the implant. As a result, all fatigue loading is concentrated at the attached ends of the arms and undesirably large bending moments are realized at the points of attachment. In addition, conventional threaded implants generally exhibit insufficient holding power under tension, such that the threads can be stripped out of the femoral head either by overtightening during the implantation procedure or during post operative loading by the patient's weight.

Thus, notwithstanding the variety of efforts in the prior art, there remains a need for an orthopedic fixation device with improved locking force such as within the femoral head in a femoral neck application, which resists migration and rotation, and which can be easily and rapidly deployed within the bone

Summary of the Invention

There is provided in accordance with one aspect of the present invention, a method of securing a first bone fragment to a second bone fragment. The method comprises the steps of drilling a bore through the first bone fragment in the direction of the second bone fragment, and advancing through the bore a fixation device comprising a first portion and a second portion that are coupled to each other. A distal anchor of the fixation device is rotated to secure the fixation device to the second fragment, and the proximal anchor is axially advanced to engage the first fragment and provide compression across the fracture

In one application of the method, the second bone fragment comprises the head of a femur. Alternatively, the second bone fragment comprises a tibia, a fibula, a femur, a humurus, a radius, or an ulna. The first bone fragment may comprise a condyle

The method may additionally comprise the step of uncoupling the first portion from the second portion.

In accordance with another aspect of the present invention, there is provided a femoral neck fracture fixation device. The device comprises an elongate body, having a proximal end and a distal end and a helical anchor on the distal end. A first retention structure is provided on the body, proximal to the anchor. A proximal anchor is moveably carried by the body. The proximal anchor is movable in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body. In one embodiment, the helical anchor is wrapped about a central core or axial lumen. An outer edge of the helical anchor defines an outer boundary and the central core or axial lumen defines a minor diameter.

In accordance with a further aspect of the present invention, there is provided a bone fracture fixation device. The device comprises an elongate body having a proximal end and a distal end. A cancellous bone anchor is on the distal end. A proximal anchor is axially movably carried on the body. Complimentary surface structures are provided between the body and the proximal anchor that permit advancing the proximal anchor in the distal direction to provide compression across a fracture but that resist axial proximal movement of the proximal anchor. In one embodiment, the cancellous bone anchor comprises a helical flange wrapped about a central core or axial lumen and an outer edge of the helical anchor defines an outer boundary and the central core or axial lumen defines a minor diameter.

In accordance with another aspect of the present invention, there is provided a method of treating a femoral fracture. The method comprises the steps of drilling at least one and preferably two or three bores distally into the femur in the direction of a fracture, and advancing into each bore a fixation device that comprises a body having a first portion that forms a distal bone anchor and a second portion that forms a proximal end

A proximal component is rotated to engage the distal anchor with the bone distal to the fracture, and a proximal anchor is advanced distally along the fixation device to compress the fracture.

In accordance with another aspect of the invention a bone fracture fixation device comprises an elongate body having a proximal end and a distal end. The body also includes a helical anchor on the distal end. A first retention structure is on the body located proximal to the anchor. A proximal. anchor is moveably carried by the body and has a tubular housing. The tubular housing has at least one barb extending radially outwardly from the tubular housing and defining an engagement surface that lies within a plane that is transverse to a longitudinal axis of the tubular housing. The proximal anchor is movable in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body.

In accordance with yet another aspect of the present invention, there is provided a femoral neck fracture fixation device. The device comprises an elongated body, having a proximal end and a distal end and comprising a first portion and a second portion detachably coupled to each other at a junction. The first portion includes an anti-rotational structure. A helical distal anchor is provided on the distal end. A first retention structure is provided on the body, proximal to the distal anchor, and a proximal anchor surface is moveably carried by the body. The proximal anchor includes a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion

The proximal anchor surface is moveable in the distal direction with respect to the body.

The retention structure resists proximal movement of the proximal anchor surface with respect to the body, and the anti-rotational structure prevents rotational movement of the first portion with respect to the proximal anchor.

In one embodiment, the first retention structure comprises a series of ridges or grooves. A second retention structure is preferably provided on the interior of the tubular sleeve for cooperating with the first retention structure on the body.

In accordance with a further aspect of the present invention, there is provided a bone fracture fixation device. The fixation device comprises an elongate body having a proximal end and a distal end and comprising a first portion and a second portion that are detachably coupled to each other at a junction. A cancellous bone anchor and/or a cortical bone anchor is carried by the distal end. A proximal anchor is axially moveably carried on the body and includes a tubular portion that extends distally past the junction.

Complementary surface structures are provided in between the first portion of the body and the proximal anchor to permit advancing the proximal anchor in the distal direction to tighten the fixation device but resist axial proximal movement of the proximal anchor and to prevent rotational movement between the first portion and the proximal anchor.

Preferably, the drilling step comprises drilling the bore along an axis which extends into the femoral neck and in the direction of the head of the femur. In one embodiment, the advancing a proximal anchor step comprises axially advancing the proximal anchor without rotating the proximal anchor with respect to the fixation device.

The femoral fracture may be a femoral neck fracture (e. g., capital or subcapital), an intertrochanteric fracture or a subtrochanteric fracture.

Further features and advantages of the present invention will become apparent to those of skill in the art in view of the detailed description of preferred embodiments which follows. when considered together with the attached drawings and claims.

In another broad form of the invention, there is provided a bone fixation device, comprising: an elongate body, having a proximal end and a distal end: a helical anchor on the distal end; the helical anchor fixed by

rotation in a distal bone portion; a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body. wherein the proximal anchor is movable without rotation in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body.

Preferably, the first retention structure comprises an annular structure.

Preferably, the first retention structure comprises a flange.

Preferably, the first retention structure comprises a thread.

Preferably. the proximal anchor is carried by a tubular sleeve

Preferably, the bone fixation device further comprises a second retention structure on the interior of the tubular sleeve for cooperating with the first retention structure on the body.

Preferably, the bone fixation device further comprises a transverse flange extending radially outwardly from the tubular sleeve.

Preferably the flange is angularly moveable with respect to a longitudinal axis of the tubular sleeve.

Preferably, the flange is fixed at a non normal angle with respect to a longitudinal axis of the tubular sleeve.

Preferably the proximal anchor further comprises a rotational coupling on the elongate body

Preferably, the helical anchor comprises a helical flange having a minor diameter and having an outer boundary defined by an outer edge.

Preferably. the helical flange is wrapped about a central core.

Preferably, the outer boundary and the minor diameter are generally cylindrical.

Preferably, the helical flange is wrapped about an axial lumen.

Preferably, the outer boundary and the minor diameter have a generally cylindrical shape.

Preferably, the helical flanges comprises at least a first flange and a second flange spirally wrapped about the axial lumen.

Preferably, the first and second flange include sharpened tips.

Preferably, minor diameter tapers in a distal direction

Preferably, at a distal end of the distal anchor the minor diameter is approximately equal to zero.

Preferably, the outer boundary also tapers in a distal direction.

Preferably, the minor diameter is approximately equal to zero.

Preferably, the helical flange has a generally V-shaped cross-section.

Preferably, the helical flange has a generally rectangular cross-section.

Preferably, the bone fixation device comprises a tubular housing comprising at least one barb that extends radially outwardly from the tubular housing and defines an engagement surface that lies within a plan that is traverse to a longitudinal axis of the tubular housing.

Preferably, the proximal anchor includes a flange, which defines a bone contacting surface that generally faces the engagement surface.

Preferably, the elongate body comprises a first portion and a second portion that are detachably coupled to each other at a junction.

Preferably, the bone fixation device comprises further comprises an anti-rotational structure on the first portion of the body, the anti-rotational structure preventing rotational movement of the first portion of the body with respect to the proximal anchor.

Preferably, the proximal anchor comprises a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion.

Preferably, the retention structure comprises a series of ridges or grooves.

Preferably, the proximal anchor further comprises a second retention structure on the interior of the tubular sleeve for cooperating with the retention structure on the body.

Preferably, the second retention structure comprises a transverse flange extending radially outwardly from the tubular sleeve

Preferably, the flange is angularly moveable with respect to a longitudinal axis of the tubular sleeve.

Preferably the bone fixation device further comprises a rotational coupling on the second portion of the body.

Preferably the bone fixation device further comprises a rotational coupling on the proximal anchor

Preferably, the bone fixation device further comprises a first threaded portion on a proximal portion of the first portion and a second threaded portion on a distal portion of the second portion, the first threaded portion and the second threaded portion configured to detachably couple the first and second portions to each other at a junction.

Preferably, the proximal anchor further comprises an elongate body having a proximal end and a distal end a cancellous bone anchor on the distal end; the bone anchor fixed by rotation in a distal bone portion; a proximal anchor axially movably carried on the body; and complimentary surface structures in between the body and the proximal anchor that permit advancing the proximal anchor without rotation in the distal direction to tighten the fixation device but that resist axial proximal movement of the proximal anchor.

Preferably, the cancellous bone comprises a helical flange wrapped about a central core or axial lumen, an outer edge of the helical anchor defining an outer boundary and the central core or axial lumen defining a minor diameter

Preferably, the minor diameter is approximately equal to zero.

Preferably in the helical flange comprises at least a first flange and a second flange.

Preferably, the proximal anchor comprises a tubular housing, which includes at least one barb extending radially outwardly from the tubular housing and defines an engagement surface that lies within a plane that is transverse to a longitudinal axis of the tubular housing.

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Preferably, the proximal anchor includes a flange, which defines a bone contacting surface that generally faces the engagement surface.

Preferably, the elongate body comprises a first portion and a second portion that are detachably coupled to each other at a junction.

Preferably, the bone fixation device further comprises an anti-rotational structure on the first portion of the body, the anti-rotational structure preventing rotational movement of the first portion of the body with respect to the proximal anchor

Preferably, the proximal anchor comprises a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion.

Preferably, the complimentary surface structures comprise a first retention structure on the first portion comprising a series of ridges or grooves.

Preferably, the complimentary surface structures further comprise a second retention structure on the interior of the tubular sleeve for cooperating with the first retention structure on the body.

Preferably, the second retention structure comprises a transverse flange extending radially outwardly from the tubular sleeve.

Preferably, the bone fixation device further comprises a rotational coupling on the second portion of the first portion

Preferably, the bone fixation device further comprises a rotational coupling on the proximal anchor

Preferably, the bone fixation device further comprises a first threaded portion on a proximal portion of the first portion and a second threaded portion on a distal portion of the second portion, the first threaded portion and the second threaded portion configured to detachably couple the first and second portions to each other at a junction

In a further broad form of the invention, there is provided a bone fixation device, comprising: an elongate body, having a proximal end and a distal end; a helical anchor on the distal end; the helical anchor fixed by rotation in a distal bone portion; a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body, wherein the proximal anchor is movable without totation in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body; and wherein said elongate body comprises a first portion and a second portion that are detachably coupled to each other at a junction.

Preferably, the bone fixation device further comprises an anti-rotational structure on the first portion of the body, the anti-rotational structure preventing rotational movement of the first portion of the body with respect to the proximal anchor.

Preferably, the proximal anchor comprises a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion.

In a further broad form of the invention there is provided a bone fixation device, comprising: an elongate body, having a proximal end and a distal end; a helical anchor on the distal end; the helical anchor fixed by rotation in a distal bone portion; a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body, wherein the proximal anchor is movable without rotation in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body; and wherein a second retention structure comprises a transverse flange extending radially outwardly from a tubular sleeve

Preferably, the flange is angularly moveable with respect to a longitudinal axis of the tubular sleeve.

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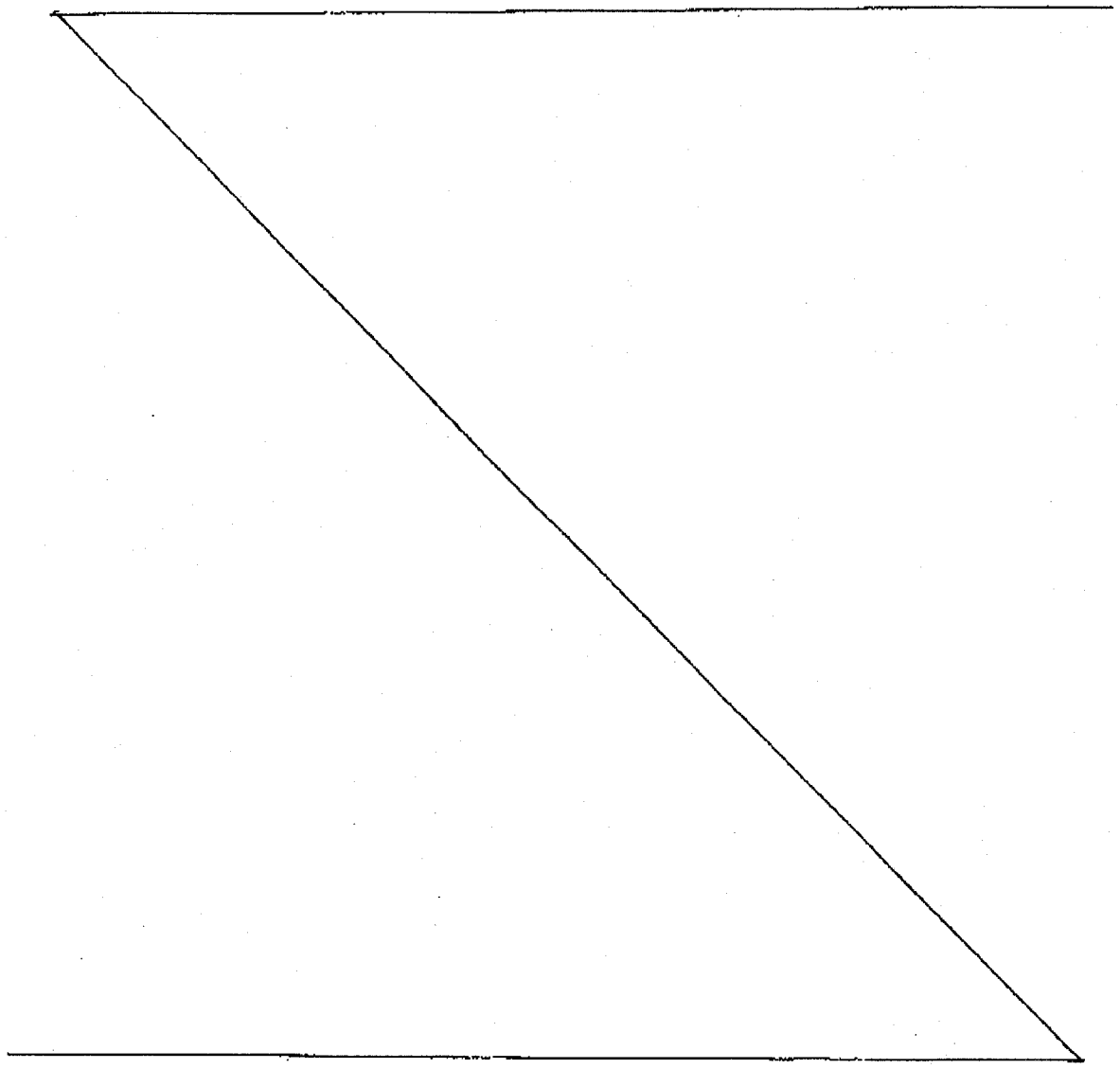
In still a further broad form of the invention, there is provided a method of bone fixation by means of a bone fixation device comprising an elongate body having a distal bone anchor; the distal bone anchor fixed without rotation in a distal bone portion; the device further including a proximal anchor provided with a first retention structure; the method including the steps of:

(a) rotationally inserting the distal bone anchor into cancellous bone of a first bone portion,
(b) advancing a proximal anchor without rotation axially along the body to seat a flange of the proximal anchor against an outer surface of a second bone portion so as to permit compression across the first and second bone portions,

and wherein the retention structure resists proximal movement of the proximal anchor with respect to the elongate body

Preferably, the first and second bone portions are adjacent vertebral bodies



[0019] Further features and advantages of the present invention will become apparent to those of skill in the art in view of the detailed description of preferred embodiments which follows, when considered together with the attached drawings and claims.

Brief Description of the Drawings

[0020] Figure 1 is a posterior elevational posterior cross section through the proximal portion of the femur, having two femoral neck fracture fixation devices positioned therein.

[0021] Figure 2 is a posterior cross section as in Figure 1, with a modified fixation device positioned therein.

[0022] Figure 3A is a side elevational cross section of a fixation device similar to that of Figure 1.

[0023] Figure 3B is a side elevational cross section of a fixation device similar to that of Figure 2.

[0024] Figure 3C is a side elevational view of a double helix distal anchor.

[0025] Figure 3D is a side elevational view of a "V" thread distal anchor.

[0026] Figure 3E is a side elevational view of a buttress thread distal anchor

[0027] Figure 3F is a side elevational view of a triple helix distal anchor.

[0028] Figure 3G is a side elevational view of a split triple helix distal anchor.

[0029] Figure 3H is a side elevational view of a tapered transition thread distal anchor.

[0030] Figure 3I is a side elevational view of a tapered thread distal anchor.

[0031] Figure 4A is a front elevational perspective view of a modified fixation device of the present invention.

[0032] Figure 4B is a front elevational perspective view of a further modification to the fixation device of the present invention.

[0033] Figure 5 is an axial cross sectional view through a distal end of a fixation device of the present invention.

[0034] Figure 6 is a posterior cross section as in Figures 1, with a fixation device and integral proximal plate anchor positioned therein.

[0035] Figure 6A is a cross sectional schematic view of a combination proximal anchor and plate in accordance with the present invention.

[0036] Figure 7A is a posterior cross section as in Figures 1, with a plate and fixation device positioned therein.

[0037] Figure 7B is a cross section through a proximal portion of the femur, illustrating the use of a fixation device in combination with a plate.

[0038] Figure 7C is a cross section as in Figure 7B, illustrating the use of a fixation device of the present invention in combination with an intramedullary nail.

[0039] Figure 8 is a cross sectional view through an angularly adjustable proximal anchor plate.

[0040] Figure 9 is a front perspective view of the proximal anchor plate of Figure 8.

[0041] Figure 10 is an anterior view of the distal tibia and fibula, with fixation devices across lateral and medial malleolar fractures.

[0042] Figure 11 is a side perspective view of another embodiment of a fixation device having certain features and advantages according to the present invention..

[0043] Figure 12 is a side elevational view of the fixation device of Figure 11.

[0044] Figure 13 is a cross-sectional view taken through line 13-13 of Figure 12.

[0045] Figure 13A is an enlarged view of portion 13A of Figure 13.

[0046] Figure 13B is an enlarged view of portion 13B of Figure 13 with the fixation device in a first position.

[0047] Figure 13C is an enlarged view of portion 13C of Figure 13 with the fixation device in a second position.

[0048] Figure 14 is a cross-sectional view taken through line 14-14 of Figure 12.

[0049] Figures 15A-C illustrate a procedure for using of the fixation device of Figure 11 to secure a femoral neck fracture.

Detailed Description of the Preferred Embodiment

[0050] Although the fixation devices of the present invention will be disclosed primarily in the context of fractures of the proximal femur, the methods and structures

disclosed herein are intended for application in any of a wide variety of bones and fractures, as will be apparent to those of skill in the art in view of the disclosure herein. For example, the bone fixation device of the present invention is applicable in a wide variety of fractures and osteotomies in the hand, such as interphalangeal and metacarpophalangeal arthrodesis, transverse phalangeal and metacarpal fracture fixation, spiral phalangeal and metacarpal fracture fixation, oblique phalangeal and metacarpal fracture fixation, intercondylar phalangeal and metacarpal fracture fixation, phalangeal and metacarpal osteotomy fixation as well as others known in the art. A wide variety of phalangeal and metatarsal osteotomies and fractures of the foot may also be stabilized using the bone fixation device of the present invention. These include, among others, distal metaphyseal osteotomies such as those described by Austin and Reverdin-Laird, base wedge osteotomies, oblique diaphyseal, digital arthrodesis as well as a wide variety of others that will be known to those of skill in the art. The bone fixation device may be used with or without plate(s) or washer(s), all of which can be either permanent, absorbable, or combinations.

[0051] Fractures of the fibular and tibial malleoli, pilon fractures and other fractures of the bones of the leg may be fixated and stabilized with the present invention with or without the use of plates, both absorbable or non-absorbing types, and with alternate embodiments of the current invention. Fractures and osteotomies of the mid and hind foot, tarsal arthrodesis and osteotomy, or others as are known to those with skill in the art. One example is the fixation of the medial malleolar avulsion fragment fixation.

[0052] The fixation device of the present invention may also be used to attach tissue or structure to the bone, such as in ligament reattachment and other soft tissue attachment procedures. Plates and washers, with or without tissue spikes for soft tissue attachment, and other implants may also be attached to bone, using either resorbable or nonresorbable fixation devices depending upon the implant and procedure. The fixation device may also be used to attach sutures to the bone, such as in any of a variety of tissue suspension procedures.

[0053] For example, peripheral applications for the fixation devices include utilization of the device for fastening soft tissue such as capsule, tendon or ligament to bone. It may also be used to attach a synthetic material such as marlex mesh, to bone or allograft material such as tensor fascia lata, to bone. In the process of doing so, retention of

the material to bone may be accomplished with the collar as shown, or the pin and or collar may be modified to accept a suture or other material for facilitation of this attachment.

[0054] Specific examples include attachment of the posterior tibial tendon to the navicular bone in the Kidner operation. This application may be accomplished using an appropriately sized implant of the present invention along with a washer with distally extending soft tissue spikes. Navicular-cuneiform arthrodesis may be performed utilizing the device and concurrent attachment of the tendon may be accomplished. Attachment of the tendon may be accomplished in the absence of arthrodesis by altering the placement of the implant in the adjacent bone.

[0055] Ligament or capsule reattachment after rupture, avulsion or detachment, such as in the ankle, shoulder or knee can also be accomplished using the devices disclosed herein.

[0056] The fixation devices can also be used to aid bone fusion between adjacent bones, bone fragments or any of a variety of articulating joints, such as, for example, a first and a second adjacent vertebral bodies of the spine.

[0057] The fixation devices may be used in combination with semi tubular, one-third tubular and dynamic compression plates, both of metallic and absorbable composition, if the collar is modified to match the opening on the plate.

[0058] The cannulated design disclosed below can be fashioned to accept an antibiotic impregnated rod for the slow adsorption of medication locally. This may be beneficial for prophylaxis, especially in open wounds, or when osteomyelitis is present and stabilization of fracture fragments is indicated.

[0059] A kit may be assembled for field use by military or sport medical or paramedical personnel. This kit contains an implanting tool, and a variety of implant device size and types. The kit may include additional components such as sterilization or disinfectant materials, a skin stapler, bandages, gloves, and basic tools for emergent wound and fracture treatment. Antibiotic rods may be included for wound prophylaxis during transport.

[0060] Referring to Figure 1, there is illustrated a posterior side elevational view of the proximal portion of a femur 10, having a two fixation devices 12 positioned therein. The proximal end of the femur 10 comprises a head 14 connected by way of a neck 16 to the long body or shaft 17 of the femur 10. As illustrated in Figure 1, the neck 16 is smaller

in diameter than the head 14. The neck 16 and head 14 also lie on an axis which, on average in humans, crosses the longitudinal axis of the body 17 of the femur 10 at an angle of about 126°. The risk of fracture at the neck 16 is thus elevated, among other things, by the angular departure of the neck 16 from the longitudinal axis of the body 17 of femur 10 and also the reduced diameter of the neck 16 with respect to the head 14.

[0061] The greater trochanter 18 extends outwardly above the junction of the neck 16 and the body 17 of the femur 10. On the medial side of the greater trochanter 18 is the trochanteric fossa 20. This depression accommodates the insertion of the obturator externus muscle. The lesser trochanter 21 is located posteromedially at the junction of the neck 16 and the body 17 of the femur 10. Both the greater trochanter 18 and the lesser trochanter 21 serve for the attachment of muscles. On the posterior surface of the femur 10 at about the same axial level as the lesser trochanter 21 is the gluteal tuberosity 22, for the insertion of the gluteus maximus muscle. Additional details of the femur are well understood in the art and not discussed in further detail herein.

[0062] Figure 1 illustrates a subcapital femoral neck fracture 24. Fractures of the proximal portion of the femur 10 are generally classified as capital or subcapital femoral neck fractures, intertrochanteric fractures and subtrochanteric fractures. All of these fractures will be deemed femoral neck fractures for the purpose of describing the present invention.

[0063] Referring to Figures 1-4, the fixation device 12 comprises a body 28 extending between a proximal end 30 and a distal end 32. The length, diameter and construction materials of the body 28 can be varied, depending upon the intended clinical application. In embodiments optimized for various fractures in an adult human population, the body 28 will generally be within the range of from about 6 mm to about 150 mm in length after sizing, and within the range of from about 2 mm to about 12 mm in maximum diameter. The major diameter of the helical anchor, discussed below, may be within the range of from about 2.0 mm to about 15 mm. In general, the appropriate dimensions of the body 28 will vary, depending upon the specific fracture. In rough terms, for a malleolar fracture, shaft diameters in the range of from about 3 mm to about 4.5 mm may be used, and lengths within the range of from about 20 mm to about 70 mm. For condylar fractures, shaft diameters within the range of from about 3.5 mm to about 8.0 mm may be used with lengths within the range of from about 25 mm to about 70 mm. For colles fractures (distal

radius and ulna), diameters within the range of from about 2.0 mm to about 4.5 mm may be used with any of a variety of lengths within the range of from about 6 mm to about 70 mm.

[0064] In one embodiment, the body 28 comprises titanium. However, as will be described in more detail below, other metals or bioabsorbable or nonabsorbable polymeric materials may be utilized, depending upon the dimensions and desired structural integrity of the finished fixation device 12.

[0065] The distal end 32 of the body 28 is provided with a cancellous bone anchor or distal cortical bone anchor 34. Additional details of the distal bone anchor are described below. In general, in a femoral neck application, distal bone anchor 34 is adapted to be rotationally inserted into the cancellous bone within the head 14 of the femur 10, to retain the fixation device 12 within the femoral head.

[0066] The proximal end 30 of the fixation device is provided with a proximal anchor 36. Proximal anchor 36 is axially distally moveable along the body 28, to permit compression of the fracture 24 as will be apparent from Figure 1 and the description below. As will be explained below, complementary locking structures such as threads or ratchet like structures between the proximal anchor 36 and the body 28 resist proximal movement of the anchor 36 with respect to the body 28 under normal use conditions. The proximal anchor 36 can be axially advanced along the body 28 either with or without rotation, depending upon the complementary locking structures as will be apparent from the disclosure herein.

[0067] In the illustrated embodiment, proximal anchor 36 comprises a housing 38 such as a tubular body, for coaxial movement along the body 28. The housing 38 is provided with one or more surface structures 40 such as radially inwardly projecting teeth or flanges, for cooperating with complementary surface structures 42 on the body 28. The surface structures 40 and complementary surface structures 42 permit distal axial travel of the proximal anchor 36 with respect to the body 28, but resist proximal travel of the proximal anchor 36 with respect to the body 28. Any of a variety of complementary surface structures which permit one way ratchet like movement may be utilized, such as a plurality of annular rings or helical threads, ramped ratchet structures and the like for cooperating with an opposing ramped structure or pawl.

[0068] Retention structures 42 are spaced axially apart along the body 28, between a proximal limit 54 and a distal limit 56. The axial distance between proximal

limit 54 and distal limit 56 is related to the desired axial working range of travel of the proximal anchor 36, and thus the range of functional sizes of the fixation device 12. In one embodiment of the fixation device 12, the retention structure 42 comprise a plurality of threads, adapted to cooperate with the retention structures 40 on the proximal anchor 36, which may be a complementary plurality of threads. In this embodiment, the proximal anchor 36 may be distally advanced along the body 28 by rotation of the proximal anchor 36 with respect to the body 28. Proximal anchor 36 may be advantageously removed from the body 28 by reverse rotation, such as to permit removal of the body 28 from the patient. In this embodiment, a flange 44 is preferably provided with a gripping structure to permit a removal tool to rotate the flange 44 with respect to the body 28. Any of a variety of gripping structures may be provided, such as one or more slots, flats, bores or the like. In one embodiment, the flange 44 is provided with a polygonal, and, in particular, a pentagonal or hexagonal circumference. See, e.g. Figure 4A.

[0069] Figures 4A and 4B additionally illustrate a profile modification that can be made on any of the embodiments discussed herein. Referring to Figure 4A, the retention structures 42 are positioned on a reduced diameter segment 31. The reduced diameter segment 31 is separated from the remainder of the body 28 by an annular shoulder 29. This construction allows the outside diameter of the tubular housing 38 to be approximately the same as the outside diameter of the distal portion of body 28. In this manner, a single diameter bore hole may be formed in the proximal bone segment, to receive both the body 28 and tubular housing 38 with minimal extra tolerance. Alternatively, as illustrated in Figure 4B, the body 28 may have the same diameter throughout its axial length with the retention structures 42 formed thereon. In this embodiment, the outside diameter of proximal housing 38 will be larger than the outside diameter throughout the body 28.

[0070] Thus, the present invention provides a bone fixation device which can provide compression across a fracture throughout a range of motion following the placement of the distal anchor. The distal anchor may be positioned within the cancellous and/or distal cortical bone, and the proximal anchor may be distally advanced throughout a range to provide compression across the fracture without needing to relocate the distal anchor and without needing to initially locate the distal anchor in a precise position with respect to the proximal side of the bone. Providing a working range throughout which tensioning of the proximal anchor is independent from setting the distal anchor allows a

single device to be useful for a wide variety of fractures, as well as eliminates the need for accurate device measurement and accurate placement of the distal anchor. In many applications, the working range is at least about 10% of the overall length of the device, and may be as much as 20% or 30% or more of the overall device length. In the context of a femoral application, working ranges of up to about 10 mm may be provided, since estimates within that range can normally be readily accomplished within the clinical setting. In other applications, such as a metatarsal fracture, a working range in the area of from about 1 mm to about 2 mm may be all that is necessary. The embodiments disclosed herein can be scaled to have a greater or a lesser working range, as will be apparent to those of skill in the art in view of the disclosure herein.

[0071] The proximal anchor 36 includes a flange 44 that seats against the outer surface of the femur or tissue adjacent the femur. The flange 44 is preferably an annular flange, to optimize the footprint or contact surface area between the flange 44 and the femur. Circular or polygonal shaped flanges for use in femoral head fixation will generally have a diameter of at least about 4 mm greater than the adjacent body 28 and often within the range of from about 4 mm to about 20 mm or more greater than the adjacent body 28. In a modified embodiment, the flange 44 can be curved to match the curved shape of the femur and further optimize the footprint or contact surface area between the flange 44 and the femur.

[0072] In the illustrated embodiment, the bone contacting surface 46 of the flange 44 resides in or approximately on a plane which is inclined with respect to the longitudinal axis of the body 28. Any of a variety of angular relationships between the bone contacting surface 46 of the flange 44 and the longitudinal axis of the body 28 and housing 38 may be utilized, depending upon the anticipated entrance angle of the body 28 and associated entrance point surface of the femur 10. In general, the longitudinal axis extending through the head 14 and neck 16 of the human femur is inclined at an angle of approximately 126° from the longitudinal axis of the long body 17 of the femur 10. Angles between the longitudinal axis of body 28 and tissue contacting surface 46 within the range of from about 90° to about 140° will generally be utilized, often within the range of from about 100° to about 120°, for fixed angle fixation devices. Perpendicular flanges (i.e., 90°) are illustrated in Figures 3A and 3B.

[0073] The clinician can be provided an array of proximal anchors 36 of varying angular relationships between the bone contacting surface 46 and the longitudinal axis of the body 28 and housing 38 (e.g., 90°, 100°, 110°, 120°, and 130°). A single body 28 can be associated with the array such as in a single sterile package. The clinician upon identifying the entrance angle of the body 28 and the associated entrance point surface orientation of the femur 10 can choose the anchor 36 from the array with the best fit angular relationship, for use with the body 28.

[0074] In accordance with an optional feature, illustrated in Figures 8 and 9, the flange 44 is angularly adjustable with respect to the longitudinal axis of the body 28. More specifically, in this embodiment, the tubular housing 38 is a separate component from the flange 44. The housing 38 and the flange 44 preferably include corresponding semi-spherical or radiused surfaces 45a, and 45b. The surface 45b surrounds an aperture 49 in the flange 44. This arrangement allows the housing 38 to extend through and pivot with respect to the flange 44. As such, the angular relationship between the bone contacting surface 46 of the flange 44 and the longitudinal axis of the body 28 can vary in response to the entrance angle.

[0075] As an independent feature in Figures 8 and 9, the flange 44 is enlarged and includes one or two or more openings 47 for receiving one or two or more femoral shaft screws (not shown). The flange 44 may be elongated anatomically distally parallel to the axis of the femur, so that it functions simultaneously as a plate, as will be discussed in connection with Figure 6.

[0076] With reference back to Figures 3a and 3b, the proximal end 30 of the body 28 is preferably additionally provided with rotational coupling 48, for allowing the body 28 to be rotationally coupled to a driving device. Any of a variety of driving devices may be utilized, such as electric drills or hand tools which allow the clinician to manually rotate the cancellous bone anchor 34 into the head of the femur. Thus, the rotational coupling 48 may have any of a variety of cross sectional configurations, such as one or more flats or splines.

[0077] In one embodiment, the rotational coupling 48 comprises a proximal projection of the body 28 having a polygonal cross section, such as a hexagonal cross section. The rotational coupling 48 is illustrated as a male component, machined or milled or attached to the proximal end 30 of the body 28. However, the rotational coupling may

also be in the form of a female element, such as a hexagonal or other noncircular cross sectioned lumen extending throughout a proximal portion or the entire length of the body 28. Although illustrated as solid throughout, the body 28 may be cannulated to accommodate installation over a placement wire as is understood in the art. The cross section of the central cannulation can be made non circular, e.g., hexagonal, to accommodate a corresponding male tool for installation or removal of the device regardless of the location of the proximal break point, as will be discussed.

[0078] The body 28 may be provided with at least one and preferably two or three or more break points 50 spaced axially apart along the proximal portion of the body 28. Break points 50 comprise a weakened transverse plane through the body 28, which facilitate severing of the proximal portion of the body 28 following proper tensioning of the proximal anchor 36. Break point 50 may be constructed in any of a variety of ways, such as by machining or milling an annular recess into the exterior wall of the body 28, or created one or more transverse perforations through the body 28 such as by mechanical, laser, or EDM drilling.

[0079] The body 28 may also be provided with at least one and preferably two or three or more graduation markings axially spaced along the proximal portion of the body 28. Such graduation markings can be used to indicate how far the body 28 has been inserted into the bone. Such graduation markings may include indicia indicating the distance (e.g., in millimeters or inches) from the proximal surface of the bone to the distal tip of the distal bone anchor 34.

[0080] In all of the embodiments illustrated herein, the distal anchor 34 comprises a helical locking structure 60 for engaging cancellous and/or distal cortical bone. In the illustrated embodiment, the locking structure 60 comprises a flange that is be wrapped around a central core 62 or an axial lumen, as discussed below. The central core 62 or axial lumen defines a minor diameter of the helical locking structure 60. In a similar manner, the outer edge of the helical flange 60 defines a major diameter or outer boundary of the helical locking structure 60. The flange extends through at least one and generally from about two to about 50 or more full revolutions depending upon the axial length of the distal anchor and intended application. For most femoral neck fixation devices, the flange will generally complete from about 2 to about 20 revolutions. The helical flange 60 is

preferably provided with a pitch and an axial spacing to optimize the retention force within cancellous bone, to optimize compression of the fracture.

[0081] The helical flange 60 of the embodiment illustrated in Figure 1 is shaped generally like a flat blade or radially extended screw thread. However, it should be appreciated that the helical flange 60 can have any of a variety of cross sectional shapes, such as rectangular, triangular or other as deemed desirable for a particular application through routine experimentation in view of the disclosure herein. The ratio of the major diameter to the minor diameter can be optimized with respect to the desired retention force within the cancellous bone and giving due consideration to the structural integrity and strength of the distal anchor 34. Another aspect of the distal anchor 34 that can be optimized is the shape of the major and minor diameters, which in the illustrated embodiment are generally cylindrical with a tapered distal end 32.

[0082] The distal end 32 and/or the outer edges of the helical flange 60 may be atraumatic (e.g., blunt or soft). This inhibits the tendency of the fixation device 12 to migrate anatomically proximally towards the hip joint bearing surface after implantation (i.e., femoral head cut-out). Distal migration is also inhibited by the dimensions and presence of the proximal anchor 36, which has a larger footprint than conventional screws.

[0083] Referring to Figures 2 and 3B, a variation of the distal anchor 34 is illustrated. The distal anchor 34 comprises an elongated helical locking structure 60 that is spirally wrapped about an axial lumen through at least one and preferably from about two to about 20 or more full revolutions. The axial lumen defines a minor diameter that is generally cylindrical. As with the previous embodiment, the elongated body 60 is provided with a pitch and an axial spacing to optimize the retention force within cancellous bone, which optimizes compression of the fracture. The tip 72 of the elongated body 60 may be pointed. Although not illustrated, this variation is particularly suited for a canulated fixation device 12. That is, a design wherein a central lumen extends through the body 28 and the distal anchor 34.

[0084] Figure 5 is an axial cross sectional view through a distal anchor of the type illustrated in Figures 2 and 3B. Figure 5 also illustrates the cross-section of the helical flange which forms the spiral locking structure. The cross-section has a width w, and a height h. Through routine experimentation, the shape, the width w and height h of the elongated body can be varied to optimize the retention force within cancellous bone. When

w is approximately equal to h, the cross section can be circular, square or faceted. In general, w and h are within the range of from about 1 mm to about 8 mm for use in the femoral neck application.

[0085] With reference to Figure 3C, another variation of the distal anchor 34 is illustrated. In this arrangement, the distal anchor 34 forms a double helix comprising two elongated structures 360, 362 spirally wrapped around an axial lumen through at least one and preferably from about 2 to about 20 or more full revolutions. As with the previous embodiments, the shape, the width w and height h of the elongated bodies 360, 362 along with pitch and an axial spacing can be optimized through routine experimentation to optimize the retention force within cancellous bone, which optimizes compression of the fracture. The diameter of the axial lumen can also be optimized. The tip 364 of helical flanges 360, 362 may be tapered or pointed to permit easier insertion through self-tapping and self-drilling. The double helix design may be incorporated into any of the designs disclosed elsewhere herein. In one embodiment for use in the femoral neck, the elongated structures 360, 362 have a generally rectangular cross sectional shape with a height and width within the range of about 1.0 – 4.0 millimeters. In such an embodiment, the major diameter is in the range of about 4.0 –15 millimeters, the minor diameter is in the range of about 2.0 – 8.0 millimeters, and the pitch is in the range of from about 3 to about 12 threads per inch.

[0086] With reference to Figure 3D, yet another variation of the distal anchor 34 is illustrated. In this embodiment, the anchor 34 comprises a helical flange 370 having a generally "V" shaped cross-section. The illustrated flange 370 has sides angled at about 60-degrees, forming two load bearing surfaces 372, 374 and a blunted outer edge 376. The proximally facing surface 372 carries the axial load to resist pullout. In this embodiment of the helical flange 370, the minor diameter is approximately equal to zero. Such an arrangement advantageously leaves more bone in place when the distal anchor 34 is inserted into the distal bone fragment such as a portion of the femur 10. However, it should be appreciated that in a modified arrangement the minor diameter can be increased giving due consideration to the balance between the desired retention force within the cancellous bone and the structural integrity and strength of the distal anchor 34. The angle between the two surfaces 372, 374 along with the pitch and axial spacing of the helical flange 370

are selected to optimize the retention force within cancellous bone, to optimize compression of the fracture.

[0087] Still yet another variation of the distal anchor 34 is illustrated in Figure 3E. In this variation, the distal anchor 34 comprises a helical flange 380 having a buttress thread design. That is, the flange 380 has a generally rectangular cross-section, and extends radially outwardly and in some embodiments is inclined proximally to form a proximally concave spiral. This arrangement enhances the pullout strength of the distal anchor 34 because the bearing surfaces 382, 384 of the flange 380 lie generally perpendicular to the load direction. As with the previous arrangement, the helical flange 380 has a minor diameter that is approximately equal to zero. However, it should be appreciated that in a modified arrangement the minor diameter can be increased minor diameter can increased giving due consideration to the balance between the desired retention force within the cancellous bone and the structural integrity and strength of the distal anchor 34. As with the previous embodiments, the pitch and axial spacing can also be optimized to enhance the retention force within cancellous bone and to optimize compression across the fracture.

[0088] Referring to Figures 3F and 3G, additional variations of distal anchor 34 are illustrated. With initial reference to Figure 3F, the distal anchor 34 comprises at least three helical threads or flanges 390, 392, 394 spirally wrapped around a generally cylindrical central core 395, which in the illustrated arrangement also defines the wall of an axial lumen 397 that can extend through the body 28. The major diameter of the distal anchor 34 is generally cylindrical. The leading tips 396 of the helical flanges 390, 392, 394 may be sharpened so as to aid the screw in being self tapping and/or self drilling. In this arrangement, the helical flanges 390, 392, 394 can be provided with a lower pitch as compared to the arrangement described above. Moreover, as compared to the previous arrangements, this arrangement requires less turns to insert the distal anchor 34 any given axial distance.

[0089] For example, in an embodiment for use in the femoral neck, the pitch of the helical flanges 390, 392, 394 may be within the range of from about 2to about 12 threads per inch. The distal anchor 34 therefore requires fewer turns during insertion to achieve the same axial travel as a single helix thread having a greater pitch. In addition, this arrangement leaves more of the bone intact. In a modified arrangement, the distal anchor can include two or four helical flanges such as flanges 390, 392, 394. The number,

pitch and axial spacing of the helical flanges can be optimized through routine experimentation in light of the disclosure herein. In one dual helical flange embodiment, the minor diameter is about 4.5 millimeters, the major diameter is about 7.0 millimeters and the pitch is about 5.5 threads per inch.

[0090] In Figure 3G, the distal anchor 34 comprises split triple helix distal anchor design that is similar to the arrangement described above. However, in this arrangement, one of the helical flanges is cut through to the axial lumen 397 that is defined by the central core 395. As such, three flanges 400, 402, 403 remain wrapped around the central core 395. As compared to the previous arrangement, this arrangement leaves more bone intact. As with the previous embodiments, the pitch and axial spacing can be optimized through routine experimentation. A split double helix, with two flanges or threads may also be provided.

[0091] Figures 3H and 3I illustrate more variations of the distal anchor 34. In Figure 3H, the distal anchor 34 comprises a generally V-shaped flange 410 that is wrapped around a central core 412 that also defines a central lumen 413, which can extend through the body 28. The major diameter of the V-shaped flange 410 is generally cylindrical. In contrast, the minor diameter of the central core tapers in the distal direction. As such, in the illustrated arrangement, the central core disappears into the generally cylindrical central lumen 413 at a point in between the proximal and distal ends of the threads, and, in the illustrated embodiment, at approximately the longitudinal center 414 of the distal anchor 34. This arrangement strengthens the proximal portion 416 of the distal anchor 34, where stretching and fatigue may be most likely to occur on pullout. It is anticipated that the shape of the flange 410 along with the pitch, axial spacing and the taper of the central core can be optimized through routine experimentation given the disclosure herein.

[0092] In Figure 3I, the distal anchor 34 also comprises a V-shaped helical flange 420 that is wrapped around an axial lumen. In this arrangement, both the major and minor diameters taper from the proximal end 422 of the anchor 34 to the distal end 424. At the distal end 424, the minor diameter is approximately equal to zero. In this arrangement, the distal end 424 of tapered distal anchor 34 can provide for self tapping while the proximal end 422 of the anchor 34 provides for self drilling. As with the previous embodiments, the shape, pitch, axial spacing of the helical flange 430 and the taper of the major and minor diameters can be further optimized through routine experimentation. In a

modified arrangement, the helical flange 430 can be wrapped around a central core that tapers from the proximal end 422 to the distal end 424.

[0093] In any of the embodiments herein, an anti-rotation lock may be provided between the distal anchor and the proximal collar or plate, such as a spline or other interfit structure to prevent relative rotation of the proximal and distal ends of the device following implantation.

[0094] In use, the clinician first identifies a patient having a fracture to be treated, such as a femoral neck fracture, which is fixable by an internal fixation device. The clinician accesses the proximal femur, reduces the fracture if necessary and selects a bone drill and drills a hole 80 in accordance with conventional techniques. In the example of a femoral neck fracture, three holes and fixation devices will often be used as has been discussed. Preferably, the hole 80 has a diameter within the range from about 3 mm to about 8 mm. This diameter may be slightly larger than the diameter of the distal anchor 34. The hole 80 preferably extends up to or slightly beyond the fracture 24.

[0095] A fixation device 12 having an axial length and outside diameter suitable for the hole 80 is selected. The distal end 32 of the fixation device 12 is advanced distally into the hole 80 until the distal anchor 34 reaches the distal end of the hole 80. The proximal anchor 36 may be carried by the fixation device 12 prior to advancing the body 28 into the hole 80, or may be attached following placement of the body 28 within the hole 80. Once the body 28 is in place, the clinician may use any of a variety of driving devices, such as electric drills or hand tools to rotate the cancellous bone anchor 34 into the head of the femur.

[0096] While proximal traction is applied to the proximal end 30 of body 28, such as by conventional hemostats, pliers or a calibrated loading device, the proximal anchor 36 is advanced distally until the anchor 36 fits snugly against the outer surface of the femur or tissue adjacent the femur. Appropriate compression of the fixation device 12 across the fracture is accomplished by tactile feedback or through the use of a calibration device for applying a predetermined load on the implantation device. One advantage of the structure of the present invention is the ability to adjust compression independently of the setting of the distal anchor 34.

[0097] Following appropriate tensioning of the proximal anchor 36, the proximal extension 30 of the body 28 is preferably cut off, snapped off, unscrewed or

otherwise removed. Body 28 may be cut using conventional saws, cutters or bone forceps which are routinely available in the clinical setting. Alternatively, the fixation device can be selected such that it is sized to length upon tensioning, so that no proximal projection remains.

[0098] Following removal of the proximal end 30 of body 28, the access site may be closed and dressed in accordance with conventional wound closure techniques.

[0099] With reference to Figure 2, in one arrangement, the proximal anchor 36 can include one or more barbs 41 extending radially outwardly from the tubular housing 28. The barbs 41 may be radially symmetrically distributed about the longitudinal axis of the tubular housing 38. Each barb 41 is provided with a transverse engagement surface 43, for anchoring the proximal anchor 36 in the bone. The transverse engagement surface 43 may lie on a plane which is transverse to the longitudinal axis of the tubular housing 38 or may be inclined with respect to the longitudinal axis of the tubular housing 38. In either arrangement, the transverse engagement surface 43 generally faces the bone contacting surface 46 of the flange 44. As such, the transverse engagement surface 43 inhibits proximal movement of the proximal anchor 36 with respect to the bone.

[0100] The barbs 41 allow the bone fixation device to capture "secondary compression" of the fracture. As explained above, the bone fixation device can be used to provide an initial compression across the fracture when the proximal anchor 36 is appropriately tensioned. However, as the patient applies weight or stress to the bone post procedure, the fracture typically undergoes secondary compression, which further compresses the fracture. During such secondary compression, the barbs 41 prevent proximal movement of the proximal anchor 36 with respect to the bone. The ratchet-type structures 40, 42 of the proximal anchor 36 and the body 28 allow the proximal anchor 36 to move distally along the body 28. Thus, any slack caused by the secondary compression is taken up by the proximal anchor 36 as the retention structures 40, 42 prevent proximal movement of the proximal anchor 36 with respect to the body 29. This device is therefore self tightening after it has been implanted in the patient.

[0101] Preferably, the clinician will have access to an array of fixation devices 12, having, for example, different diameters, axial lengths and angular relationships. These may be packaged one per package in sterile envelopes or peelable pouches, or in dispensing cartridges which may each hold a plurality of devices 12. Upon encountering a fracture for

which the use of a fixation device is deemed appropriate, the clinician will assess the dimensions and load requirements, and select a fixation device from the array which meets the desired specifications.

[0102] In some types of fractures such as a femoral neck fracture, a clinician may want to introduce two or three or more fixation devices 12 into the femoral head 14 to secure the fracture 24. This may be desirable if the clinician determines that, based upon the nature of the fracture 24, there is a possibility that the head 14 of the femur 10 could rotate about a single fixation device 12. Even minor rotation can inhibit the healing of the fracture. Significant rotation can result in failure of the fixation device or necrosis of the femoral head. Two fixation devices 12 may also be desirable where the direction of the fracture is generally parallel to the axis of implantation as is understood in the art.

[0103] Referring to Figure 6, there is disclosed a variation of the proximal anchor 36 in which the proximal anchor 36 is integrally formed with or attached to a plate. The fixation device 12 in Figure 6 may otherwise be identical to the embodiments previously discussed. The proximal anchor 90 comprises an elongated flange 92, which extends from the housing 93 longitudinally down (anatomically caudad or distally) the body 17 of the femur 10. The elongated flange 92 preferably includes one or more openings 94 for receiving one or more femoral shaft screws 96. The flange 92 may or may not extend above (anatomically proximal to) the housing 93. Elimination of a proximal flange may more easily permit rotational removal of the proximal anchor 36 from the body 28 by reverse rotation in an inclined flange embodiment.

[0104] Referring to Figure 6A, there is illustrated a cross sectional schematic view of an integral proximal anchor 36 and proximal plate. The dimensions and orientation of the proximal anchor 36 may be varied widely, depending upon the intended application. For example, a longitudinal axis of the housing 93 may be inclined or perpendicular with respect to the plane of flange 92. The flange 92 may have any of a variety of dimensions and profiles, depending upon the intended application. Lengths of the plate 92 in the vertical direction as illustrated on Figure 6A, for use in femoral neck fixation fractures, may range from at least about 0.5 inches to about 10 inches or more. The plate 92 may be planar as illustrated, particularly in small plate embodiments, or may be curved or contoured to improve seating of the plate 92 against the adjacent bone. Plate 92 may be provided with

one or more apertures for receiving bone screws or other fixation devices as illustrated in Figures 6 and 7A.

[0105] Referring to Figure 7A, the fixation device 12 is schematically illustrated in combination with a conventional plate 100. The fixation device 12 in Figure 7A may be identical to the embodiments described elsewhere herein. The fixation device 12 is used with an elongated side support or plate 100, which extends longitudinally above and below the hole 80. The elongated side plate 100 includes an opening 102 that preferably has a diameter that is slightly larger than the diameter of the housing 38. The elongated side plate 100 preferably also includes one or more openings 104 for receiving one or more femoral shaft screws 106. Advantageously, the elongated side plate 100 spreads the forces exerted by the flange 44 across a larger area of the femur 17, and affects the distribution of load. In an alternate embodiment, the elongated side plate can 100 include one or more openings above the housing 38 for receiving trochanteric anchor screws (not shown).

[0106] A contoured side plate 100 is illustrated in Figure 7B. The proximal anchor 36 is also formed with a tapered (e.g. conical or concave outwardly) bone or plate contacting surface on flange 44.

[0107] The fixation device 12 of the present invention may also be used in combination with intramedullary nails or rods 101 as schematically illustrated in Figure 7C, as will be understood by those of skill in the art.

[0108] The fixation device 12 of the present invention may be used in any of a wide variety of anatomical settings beside the proximal femur, as has been discussed. For example, lateral and medial malleolar fractures can be readily fixed using the device of the present invention. Referring to Figure 10, there is illustrated an anterior view of the distal fibula 120 and tibia 122. The fibula 120 terminates distally in the lateral malleolus 124, and the tibia 122 terminates distally in the medial malleolus 126.

[0109] A fixation device 12 in accordance with the present invention is illustrated as extending through the lateral malleolus 124 across the lateral malleolar fracture 128 and into the fibula 120. Fixation device 12 includes a distal anchor 34 for fixation within the fibula 120, an elongate body 28 and a proximal anchor 36 as has been discussed.

[0110] Figure 10 also illustrates a fixation device 12 extending through the medial malleolus 126, across a medial malleolar fracture 130, and into the tibia 122.

Although Figure 10 illustrates fixation of both a lateral malleolar fracture 128 and medial malleolar fracture 130, either fracture can occur without the other as is well understood in the art. Installation of the fixation devices across malleolar fractures is accomplished utilizing the same basic steps discussed above in connection with the fixation of femoral neck fractures.

[0111] Figures 11-13 illustrate a modified embodiment of a fixation device 512 having certain features and advantages according to the present invention. As with the previous embodiments, the fixation device 512 comprises a body 28 extending between a proximal end 30 and a distal end 32. The length, diameter and construction materials of the body 28 can be varied, depending upon the intended clinical application. In an embodiments optimized for various fractures in an adult human population, the body 28 will generally be within the range of from about 10 mm to about 150 mm in length after sizing, and within the range of from about 2 mm to about 8 mm in maximum diameter. The major diameter of the helical anchor, discussed below, may be within the range of from about 2.7 mm to about 12 mm. In general, the appropriate dimensions of the body 28 will vary, depending upon the specific fracture. In rough terms, for a malleolar fracture, shaft diameters in the range of from about 3 mm to about 4.5 mm may be used, and lengths within the range of from about 25 mm to about 70 mm. For condylar fractures, shaft diameters within the range of from about 3.5 mm to about 6.5 mm may be used with lengths within the range of from about 25 mm to about 70 mm. For colles fractures (distal radius and ulna), diameters within the range of from about 2.0 mm to about 4.5 mm may be used with any of a variety of lengths within the range of from about 6 mm to about 70 mm.

[0112] Referring to Figures 12, 13, and 13A, the body 28 comprises a first portion 536 and a second portion 538 that are coupled together at a junction 540. In the illustrated embodiment, the first portion 536 carries the distal anchor 34 while the second portion 538 forms the proximal end 30 of the body 28. The first and second portions 536, 538 are preferably detachably coupled to each other at the junction 540. In the illustrated embodiment, the first and second portions 536, 538 are detachably coupled to each other via interlocking threads. Specifically, as best seen in Figure 13A, the body 28 includes an inner surface 541, which defines a central lumen 542 that preferably extends from the proximal end 30 to the distal end 32 throughout the body 28. At the proximal end of the first portion 536, the inner surface 541 includes a first threaded portion 544. The first

threaded portion 544 is configured to mate with a second threaded portion 546, which is located on the outer surface 545 of the second portion 538. The interlocking annular threads of the first and second threaded portions 544, 546 allow the first and second portions 536, 538 to be detachably coupled to each other. In one modified embodiment, the orientation of the first and second threaded portions 544, 546 can be reversed. That is, the first threaded portion 544 can be located on the outer surface of the first portion 536 and the second threaded portion 546 can be located on the inner surface 541 at the distal end of the second portion 538. Any of a variety of other releasable complementary engagement structures may also be used, to allow removal of second portion 538 following implantation, as is discussed below.

[0113] In a modified arrangement, the second portion 538 can comprise any of a variety of tensioning elements for permitting proximal tension to be placed on the distal anchor 34 while the proximal anchor is advanced distally to compress the fracture. For example, any of a variety of tubes or wires can be removably attached to the first portion 536 and extend proximally to the proximal handpiece. In one such arrangement, the first portion 536 can include a releasable connector in the form of a latching element, such as an eye or hook. The second portion 538 can include a complementary releasable connector (e.g., a complementary hook) for engaging the first portion 536. In this manner, the second portion 538 can be detachably coupled to the first portion 536 such proximal traction can be applied to the first portion 536 through the second portion as will be explained below. Alternatively, the second portion 548 may be provided with an eye or hook, or transverse bar, around which or through which a suture or wire may be advanced, both ends of which are retained at the proximal end of the device. Following proximal tension on the tensioning element during the compression step, one end of the suture or wire is released, and the other end may be pulled free of the device. Alternate releasable proximal tensioning structures may be devised by those of skill in the art in view of the disclosure herein.

[0114] As described above, the proximal end 30 of the fixation device is provided with a proximal anchor 36 that is distally moveable along the body 28, to permit compression of the fracture 24 as will be apparent from the description below. As will be explained below, complimentary locking structures such as threads or ratchet like structures between the proximal anchor 36 and the body 28 resist proximal movement of the anchor

36 with respect to the body 28 under normal use conditions. The proximal anchor 36 preferably can be axially advanced along the body 28 without rotation as will be apparent from the disclosure herein.

[0115] In the illustrated embodiment, proximal anchor 36 comprises a housing 552 such as a tubular body, for coaxial movement along the body 28. As best seen in Figures 11 and 13, in a final position, the housing 552 extends distally past the junction 540 between the first portion 536 and the second portion 538. The housing 552 is provided with one or more surface structures 554 such as a radially inwardly projecting flange 556 (see Figures 13B and 13C), for cooperating with complementary surface structures 558 on the first portion 536 of the body 28. In the illustrated embodiment, the complimentary surface structures 558 comprise a series of annular ridges or grooves 560. The surface structures 554 and complementary surface structures 558 permit distal axial travel of the proximal anchor 36 with respect to the body 28, but resist proximal travel of the proximal anchor 36 with respect to the body 28.

[0116] For example, as best seen in Figure 13B, the proximal end of the flange 556 is biased towards the longitudinal axis of the body 28. As such, when the proximal anchor 36 is urged proximally with respect to the body 28, the flange 556 engages the grooves or ridges 560 of the complementary surface structures 558. This prevents proximal movement of the proximal anchor 36 with respect to the body 28. In contrast, as best seen in Figure 13C, when the proximal anchor 36 is moved distally with respect to the body 28, the flange 556 can bend outwardly away from the body 28 and the ridges 560 so as to allow the proximal anchor 36 to move distally. Of course, those of skill in the art will recognize that there are a variety of other complementary surface structures, which permit one way ratchet like movement. For example, a plurality of annular rings or helical threads, ramped ratchet structures and the like for cooperating with an opposing ramped structure or pawl can also be used. In one embodiment, opposing screw threads are dimensioned to function as a ratchet.

[0117] Retention structures 558 are spaced axially apart along the body 28, between a proximal limit 562 and a distal limit 564. The axial distance between proximal limit 562 and distal limit 564 is related to the desired axial working range of the proximal anchor 36, and thus the range of functional sizes of the fixation device 512. Thus, as

described above, the fixation device 512 can provide compression across a fracture throughout a range of motion following the placement of the distal anchor.

[0118] As with the previous embodiments, the proximal anchor 36 includes a flange 44 that seats against the outer surface of the femur or tissue adjacent the femur. In the illustrated embodiment, the flange 44 is an annular flange, to optimize the footprint or contact surface area between the flange 44 and the femur. Circular or polygonal shaped flanges for use in femoral head fixation will generally have a diameter of at least about 4 mm greater than the adjacent body 28 and often within the range of from about 4 mm to about 20 mm or more greater than the adjacent body 28. In the illustrated embodiment, the bone contacting surface 46 of the flange 44 is tapered and generally faces the shaft 17 of the femur 10.

[0119] In a modified embodiment, the housing 552 of the proximal anchor 36 can include one or more one or more barbs that extend radially outwardly from the tubular housing 552. As described above, such barbs provide for self tightening after the device has been implanted in the patient. The barbs may be radially symmetrically distributed about the longitudinal axis of the housing 552. Each barb is provided with a transverse engagement surface, for anchoring the proximal anchor 50 in the bone. The transverse engagement surface may lie on a plane which is transverse to the longitudinal axis of the housing 552 or may be inclined with respect to the longitudinal axis of the tubular housing 552. In either arrangement, the transverse engagement surface generally faces the bone contacting surface 46 of the flange 44. As such, the transverse engagement surface inhibits proximal movement of the proximal anchor with respect to the bone.

[0120] As mentioned above, the clinician can be provided an array of proximal anchors 36 of varying angular relationships between the bone contacting surface 46 and the longitudinal axis of the body 28 and housing 552 (e.g., 90°, 100°, 110°, 120°, and 130°). A single body 28 can be associated with the array such as in a single sterile package. The clinician upon identifying the entrance angle of the body 28 and the associated entrance point surface orientation of the femur 10 can choose the anchor 36 from the array with the best fit angular relationship, for use with the body 28.

[0121] With particular reference to Figures 12 and 13, the proximal end 30 of the body 28 may be provided with a rotational coupling 570, for allowing the second portion 538 of the body 28 to be rotationally coupled to a rotation device. The proximal

end 30 of the body 28 may be desirably rotated to accomplish one or two discrete functions. In one application of the invention, the proximal end 30 is rotated to remove the second portion 538 of the body 28 following tensioning of the device across a fracture or to anchor an attachment to the bone. Rotation of the rotational coupling 570 may also be utilized to rotationally drive the distal anchor into the bone. Any of a variety of rotation devices may be utilized, such as electric drills or hand tools, which allow the clinician to manually rotate the proximal end 30 of the body. Thus, the rotational coupling 570 may have any of a variety of cross sectional configurations, such as one or more flats or splines.

[0122] In one embodiment, the rotational coupling 570 comprises a proximal projection of the body 28 having an axial recess with a polygonal cross section, such as a hexagonal cross section. The rotational coupling 570 is illustrated as a female component, machined or milled or attached to the proximal end 30 of the body 28. However, the rotational coupling may also be in the form of a male element, such as a hexagonal or other noncircular cross sectioned projection.

[0123] In the illustrated embodiment, the body 28 is cannulated to accommodate installation over a placement wire as is understood in the art. The cross section of the illustrated central cannulation is circular but in other embodiments may be non circular, e.g., hexagonal, to accommodate a corresponding male tool for installation or removal of the second portion 538 of the body 28 as will be explained below. In other embodiments, the body 28 may partially or wholly solid.

[0124] As with the previous embodiments, the distal anchor 34 comprises a helical locking structure 60 for engaging cancellous and/or distal cortical bone. In the illustrated embodiment, the locking structure 60 comprises a flange that is wrapped around the axial lumen. The flange extends through at least one and generally from about two to about 50 or more full revolutions depending upon the axial length of the distal anchor and intended application. For most femoral neck fixation devices, the flange will generally complete from about 2 to about 20 revolutions. The helical flange 60 is preferably provided with a pitch and an axial spacing to optimize the retention force within cancellous bone, to optimize compression of the fracture.

[0125] The helical flange 60 of the illustrated embodiment has a generally triangular cross-sectional shape. However, it should be appreciated that the helical flange 72 can have any of a variety of cross sectional shapes, such as rectangular, oval or other as

deemed desirable for a particular application through routine experimentation in view of the disclosure herein. As described above with respect to Figures 3A-3I, the outer edge of the helical flange 60 defines an outer boundary. The ratio of the diameter of the outer boundary to the diameter of the central lumen can be optimized with respect to the desired retention force within the cancellous bone and giving due consideration to the structural integrity and strength of the distal anchor 34. Another aspect of the distal anchor 34 that can be optimized is the shape of the outer boundary and the central core, which in the illustrated embodiment are generally cylindrical.

[0126] The distal end 32 and/or the outer edges of the helical flange 60 may be atraumatic (e.g., blunt or soft). This inhibits the tendency of the fixation device 12 to migrate anatomically proximally towards the hip joint bearing surface after implantation (i.e., femoral head cut-out). Distal migration is also inhibited by the dimensions and presence of the proximal anchor 36, which has a larger footprint than conventional screws.

[0127] A variety of other arrangements for the distal anchor 32 can also be used. For example, the various distal anchors described above be incorporated into the fixation device 512. In particular, the distal anchor may comprise a single helical thread surrounding a central core, much as in a conventional screw, which has been cannulated to facilitate placement over a wire. Alternatively, a double helical thread may be utilized, with the distal end of the first thread rotationally offset from the distal end of the second thread. The use of a double helical thread can enable a greater axial travel for a given degree of rotation and greater retention force than a corresponding single helical thread. Specific distal anchor designs can be optimized for the intended use, taking into account desired performance characteristics, the integrity of the distal bone, and whether the distal anchor is intended to engage exclusively cancellous bone or will also engage cortical bone.

[0128] With particular reference to Figures 11 and 14, the fixation device 512 may include an antirotation lock between the first portion 536 of the body 28 and the proximal collar 36. In the illustrated embodiment, the first portion 536 includes a pair of flat sides 580, which interact with corresponding flat structures 582 in the proximal collar 36. One or three or more axially extending flats may also be used. As such, rotation of the proximal collar 36 is transmitted to the first portion 536 and distal anchor 34 of the body 28. Of course, those of skill in the art will recognize various other types of splines or other

interfit structures can be used to prevent relative rotation of the proximal anchor and the first portion 536 of the body 28.

[0129] To rotate the proximal collar, the flange 44 is preferably provided with a gripping structure to permit an insertion tool to rotate the flange 44. Any of a variety of gripping structures may be provided, such as one or more slots, flats, bores or the like. In one embodiment, the flange 44 is provided with a polygonal, and, in particular, a pentagonal or hexagonal recess 84. See Figure 13.

[0130] In use, the clinician first identifies a patient having a fracture to be treated, such as a femoral neck fracture, which is fixable by an internal fixation device. The clinician accesses the proximal femur, reduces the fracture if necessary and selects a bone drill and drills a hole 80 (see Figure 15A) in accordance with conventional techniques. Frequently, the hole 80 has a diameter within the range from about 3 mm to about 8 mm. This diameter may be slightly larger than the diameter of the distal anchor 34. The hole 80 preferably extends up to or slightly beyond the fracture 24.

[0131] A fixation device 12 having an axial length and outside diameter suitable for the hole 80 is selected. The distal end 32 of the fixation device 12 is advanced distally into the hole 80 until the distal anchor 34 reaches the distal end of the hole 80. The proximal anchor 50 may be carried by the fixation device 12 prior to advancing the body 28 into the hole 80, or may be attached following placement of the body 28 within the hole 80. Once the body 28 and proximal anchor 36 are in place, the clinician may use any of a variety of driving devices, such as electric drills or hand tools to rotate the proximal anchor 36 and thus cancellous bone anchor 34 into the head of the femur.

[0132] Once the anchor 34 is in the desired location, proximal traction is applied to the proximal end 30 of body 28, such as by conventional hemostats, pliers or a calibrated loading device, while distal force is applied to the proximal anchor 36. In this manner, the proximal anchor 36 is advanced distally until the anchor 36 fits snugly against the outer surface of the femur or tissue adjacent the femur and the fracture 24 is completely reduced as shown in Figure 15B. Appropriate tensioning of the fixation device 512 is accomplished by tactile feedback or through the use of a calibration device for applying a predetermined load on the implantation device. One advantage of the structure of the present invention is the ability to adjust compression independently of the setting of the distal anchor 34.

[0133] Following appropriate tensioning of the proximal anchor 36, the second portion 538 of the body 28 is preferably detached from the first portion 536 and removed. See Figure 15C. In the illustrated embodiment, this involves rotating the second portion 538 with respect to the first portion via the coupling 570. In connection with many of the fractures identified previously herein, a single fixation device 512 may be all that is clinically indicated. However, two or three or more fixation devices 512 may be utilized to reduce a single fracture in a similar manner as illustrated in Figure 1, depending upon the location and physical requirements of the fractured portion of the bone. For example, in the case of proximal femoral fractures of the type illustrated herein, typically at least two and preferably three fixation devices 12 will be implanted to span the femoral neck. The use of three fixation devices 512 desirably provides sufficient compression across the fracture, as well as minimizes the risk of rotation of the head of the femur around the axis of a single fixation device 512. The proximal end of the fixation devices may be connected together such as through a three-holed plate or rod, or may be independent of each other.

[0134] Following removal of the second portion 538 of each body 28, the access site may be closed and dressed in accordance with conventional wound closure techniques.

[0135] In a modified arrangement, the second portion 538 may form part of the driving device, which is used to rotate the proximal anchor 36 and thus cancellous bone anchor 34 into the head of the femur. The second portion 538 is used to apply proximal traction so as to compress the fracture. After appropriate tensioning, the second portion 538 can be de-coupled from the first portion 536 and removed with the driving device.

[0136] In the foregoing variation, the second portion 538 may be connected to a rotatable control such as a thumb wheel on the deployment device. A container may be opened at the clinical site exposing the proximal end of the implant, such that the distal end of the second portion 538 may be removably coupled thereto. Proximal retraction of the hand tool will pull the implant out of its packaging. The implant may then be positioned within the aperture in the bone, rotated to set the distal anchor, and the hand piece may be manipulated to place proximal traction on the second portion 538 while simultaneously distally advancing the proximal anchor. Following appropriate tensioning across the fracture, the second portion 38 may be disengaged from the implant, and removed from the patient. In the example of a threaded engagement, the second portion 538 may be disengaged from the implant by rotating a thumb wheel or other rotational control on the

hand piece. In an alternate embodiment, such as where the second portion 538 comprises a pull wire, following appropriate tensioning across the fracture, a first end of the pull wire is released such that the pull wire may be removed from the implant by proximal retraction of the second end which may be attached to the hand piece.

[0137] As mentioned above, the fixation device 512 may also be used in combination with intramedullary nails or rods, as will be understood by those of skill in the art. The fixation device 512 may be used in any of a wide variety of anatomical settings beside the proximal femur, as has been discussed. For example, lateral and medial malleolar fractures can be readily fixed using the device of the present invention. See e.g., Figure 10.

[0138] The fixation devices of the present invention may be made from either conventional bioabsorbable materials or conventional non-absorbable materials, combinations thereof and equivalents thereof. In addition, natural materials such as allografts may be used. Examples of absorbable materials include homopolymers and copolymers of lactide, glycolide, trimethylene carbonate, caprolactone, and p-dioxanone and blends thereof. The following two blends may be useful: 1) the blend of poly(p-dioxanone) and a lactide/glycolide copolymer, as disclosed in U.S. Pat. No. 4,646,741 which is incorporated by reference and (2) the glycolide-rich blend of two or more polymers, one polymer being a high lactide content polymer, and the other being a high glycolide content disclosed in U.S. Pat. No. 4,889,119 which is incorporated by reference.

[0139] A variety of polymers which may be useful for the components of the present invention are identified below. Many of these polymers have been reported to be biodegradable into water-soluble, non-toxic materials which can be eliminated by the body:

Polycaprolactone

Poly (L-lactide)

Poly (DL-lactide)

Polyglycolide

Poly (L-Lactide-co-D, L-Lactide)

70:30 Poly (l-Lactide-co-D, L-Lactide)

95:5 Poly (DL-lactide-co-glycolide)

90:10 Poly (DL-lactide-co-glycolide)

85:15 Poly (DL-lactide-co-glycolide)

75:25 Poly (DL-lactide-co-glycolide)

50:50 Poly (DL-lactide-co-glycolide)

90:10 Poly (DL-lactide-co-caprolactone)

75:25 Poly (DL-lactide-co-caprolactone)

50:50 Poly (DL-lactide-co-caprolactone)

Polydioxanone

Polyesteramides

Copolyoxalates

Polycarbonates

Poly (glutamic-co-leucine)

[0140] The desirability of any one or a blend of these or other polymers can be determined through routine experimentation by one of skill in the art, taking into account the mechanical requirements, preferred manufacturing techniques, and desired reabsorption time. Optimization can be accomplished through routine experimentation in view of the disclosure herein.

[0141] Alternatively, the components can be molded, formed or machined from biocompatible metals such as Nitinol, stainless steel, titanium, and others known in the art. In one embodiment, the components of the bone fixation device are injection-molded from a bioabsorbable material, to eliminate the need for a post-healing removal step. One suitable bioabsorbable material which appears to exhibit sufficient structural integrity for the purpose of the present invention is poly-p-dioxanone, such as that available from the Ethicon Division of Johnson & Johnson. Poly (L-lactide, or co-DL-lactide) or blends of the two may alternatively be used as mentioned above. As used herein, terms such as bioabsorbable, bioresorbable and biodegradable interchangeably refer to materials which will dissipate in situ, following a sufficient bone healing period of time, leaving acceptable byproducts. All or portions of any of the devices herein, as may be appropriate for the particular design, may be made from allograft material, or synthetic bone material as discussed elsewhere herein.

[0142] The bioabsorbable implants of this invention can be manufactured in accordance with any of a variety of techniques known in the art, depending upon the particular polymers used, as well as acceptable manufacturing cost and dimensional tolerances as will be appreciated by those of skill in the art in view of the disclosure herein. For example, any of a variety of bioabsorbable polymers, copolymers or polymer mixtures can be

molded in a single compression molding cycle, or the surface structures can be machined on the surface of the pin or sleeve after the molding cycle. It is also possible to use the techniques of U.S. Pat. No. 4,743,257, the entire disclosure of which is incorporated herein by reference, to mold absorbable fibers and binding polymers together, to create a fiber-reinforced absorbable device.

[0143] An oriented or self-reinforced structure for the device can also be created during extrusion or injection molding of absorbable polymeric melts through a suitable die or into a suitable mold at high speed and pressure. When cooling occurs, the flow orientation of the melt remains in the solid material as an oriented or self-reinforcing structure. The mold can have the form of the finished device component, but it is also possible to manufacture the components of the invention by machining injection-molded or extruded semifinished products. It may be advantageous to make the components from melt-molded, solid state drawn or compressed, bioabsorbable polymeric materials, which are described, e.g., in U.S. Pat. Nos. 4,968,317 and 4,898,186, the entire disclosures of which are incorporated herein by way of this reference.

[0144] Reinforcing fibers suitable for use in the anchor components of the present invention include ceramic fibers, like bioabsorbable hydroxyapatite or bioactive glass fibers. Such bioabsorbable, ceramic fiber reinforced materials are described, e.g., in published European Patent Application No. 0146398 and in WO/96/21628, the entire disclosures of which are incorporated herein by way of this reference.

[0145] As a general feature of the orientation, fiber-reinforcement or self-reinforcement of the components, many of the reinforcing elements are oriented in such a way that they can carry effectively the different external loads (such as tensile, bending and shear loads) that are directed to the anchor as used.

[0146] The oriented and/or reinforced anchor materials for many applications have tensile strengths in the range of about 100-2000 MPa, bending strengths in the range of about 100-600 MPa and shear strengths in the range of about 80-400 MPa, optimized for any particular design and application. Additionally, they are relatively stiff and tough. These mechanical properties may be superior to those of non-reinforced or non-oriented absorbable polymers, which often show strengths between about 40 and 100 MPa and are additionally may be flexible or brittle. See, e.g., S. Vainionpaa, P. Rokkanen and P. Tormnld, "Surgical Applications of Biodegradable Polymers in Human Tissues", Progr.

Polym. Sci., Vol. 14, (1989) at 679-716, the full disclosure of which is incorporated herein by way of this reference.

[0147] The components of the invention (or a bioabsorbable polymeric coating layer on part or all of the component surface), may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like. Such bioactive implants may be desirable because they contribute to the healing of the injury in addition to providing mechanical support.

[0148] In addition, the components may be provided with any of a variety of structural modifications to accomplish various objectives, such as osteoincorporation, or more rapid or uniform absorption into the body. For example, osteoincorporation may be enhanced by providing a micropitted or otherwise textured surface on the anchor components. Alternatively, capillary pathways may be provided throughout the pin and collar, such as by manufacturing the anchor components from an open cell foam material, which produces tortuous pathways through the device. This construction increases the surface area of the device which is exposed to body fluids, thereby generally increasing the absorption rate. Capillary pathways may alternatively be provided by laser drilling or other technique, which will be understood by those of skill in the art in view of the disclosure herein. In general, the extent to which the anchor can be permeated by capillary pathways or open cell foam passageways may be determined by balancing the desired structural integrity of the device with the desired reabsorption time, taking into account the particular strength and absorption characteristics of the desired polymer.

[0149] One open cell bioabsorbable material is described in U.S. Patent No. 6,005,161 as a poly(hydroxy) acid in the form of an interconnecting, open-cell meshwork which duplicates the architecture of human cancellous bone from the iliac crest and possesses physical property (strength) values in excess of those demonstrated by human (mammalian) iliac crest cancellous bone. The gross structure is said to maintain physical property values at least equal to those of human, iliac crest, cancellous bone for a minimum of 90 days following implantation. The disclosure of U.S. Patent No. 6,005,161 is incorporated by reference in its entirety herein.

[0150] The fixation devices may also be made from conventional non-absorbable, biocompatible materials including stainless steel, titanium, alloys thereof, polymers, composites and the like and equivalents thereof. In one embodiment, the distal anchor comprises a metal helix, while the body and the proximal anchor comprise a bioabsorbable material. Alternatively, the distal anchor comprises a bioabsorbable material, and the body and proximal anchor comprise either a bioabsorbable material or a non-absorbable material. As a further alternative, each of the distal anchor and the body comprise a non-absorbable material, connected by an absorbable link. This may be accomplished by providing a concentric fit between the distal anchor and the body, with a transverse absorbable pin extending therethrough. This embodiment will enable removal of the body following dissipation of the pin, while leaving the distal anchor within the bone.

[0151] The components of the invention (or a bioabsorbable polymeric coating layer on part or all of the anchor surface), may contain one or more bioactive substances, such as antibiotics, chemotherapeutic substances, angiogenic growth factors, substances for accelerating the healing of the wound, growth hormones, antithrombogenic agents, bone growth accelerators or agents, and the like. Such bioactive implants may be desirable because they contribute to the healing of the injury in addition to providing mechanical support.

[0152] In addition, the components may be provided with any of a variety of structural modifications to accomplish various objectives, such as osteoincorporation, or more rapid or uniform absorption into the body. For example, osteoincorporation may be enhanced by providing a micropitted or otherwise textured surface on the components. Alternatively, capillary pathways may be provided throughout the body and collar, such as by manufacturing the anchor and body from an open cell foam material, which produces tortuous pathways through the device. This construction increases the surface area of the device which is exposed to body fluids, thereby generally increasing the absorption rate. Capillary pathways may alternatively be provided by laser drilling or other technique, which will be understood by those of skill in the art in view of the disclosure herein. In general, the extent to which the anchor can be permeated by capillary pathways or open cell foam passageways may be determined by balancing the desired structural integrity of the device with the desired reabsorption time, taking into account the particular strength and absorption characteristics of the desired polymer.

[0153] The components of the present invention may be sterilized by any of the well known sterilization techniques, depending on the type of material. Suitable sterilization techniques include heat sterilization, radiation sterilization, such as cobalt 60 irradiation or electron beams, ethylene oxide sterilization, and the like.

[0154] The specific dimensions of any of the bone fixation devices of the present invention can be readily varied depending upon the intended application, as will be apparent to those of skill in the art in view of the disclosure herein. Moreover, although the present invention has been described in terms of certain preferred embodiments, other embodiments of the invention including variations in dimensions, configuration and materials will be apparent to those of skill in the art in view of the disclosure herein. In addition, all features discussed in connection with any one embodiment herein can be readily adapted for use in other embodiments herein. The use of different terms or reference numerals for similar features in different embodiments does not imply differences other than those which may be expressly set forth. Accordingly, the present invention is intended to be described solely by reference to the appended claims, and not limited to the preferred embodiments disclosed herein.

CLAIMS

1. A bone fixation device, comprising: an elongate body, having a proximal end and a distal end: a helical anchor on the distal end; the helical anchor fixed by rotation in a distal bone portion; a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body, wherein the proximal anchor is movable without rotation in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body.

2. A bone fixation device as in Claim 1, wherein the first retention structure comprises an annular structure

3. A bone fixation device as in Claim 1, wherein the first retention structure comprises a flange.

4. A bone fixation device as in Claim 1, wherein the first retention structure comprises a thread.

5. A bone fixation device as in Claim 1, wherein the proximal anchor is carried by a tubular sleeve.

6. A bone fixation device as in Claim 5, further comprising a second retention structure on the interior of the tubular sleeve for cooperating with the first retention structure on the body.

7 A bone fixation device as in Claim 6 further comprising a transverse flange extending radially outwardly from the tubular sleeve.

8. A bone fixation device as in Claim 7, wherein the flange is angularly moveable with respect to a longitudinal axis of the tubular sleeve.

9 A bone fixation device as in Claim 7, wherein the flange is fixed at a non normal angle with respect to a longitudinal axis of the tubular sleeve.

10. A bone fixation device as in Claim 1, further comprising a rotational coupling on the elongate body.

11. A bone fixation device as in Claim 1. wherein the helical anchor comprises a helical flange having a minor diameter and having an outer boundary defined by an outer edge.

12. A bone fixation device as in Claim 11, wherein the helical flange is wrapped about a central core.

13. A bone fixation device as in Claim 12. wherein the outer boundary and the minor diameter are generally cylindrical.

14. A bone fixation device as in Claim 11. wherein the helical flange is wrapped about an axial lumen.

15. A bone fixation device as in Claim 14, wherein the outer boundary and the minor diameter have a generally cylindrical shape.

16. A bone fixation device as in Claim 15, wherein the helical flanges comprises at least a first flange and a second flange spirally wrapped about the axial lumen

17. A bone fixation device as in Claim 16, wherein the first and second flange include sharpened tips.

18. A bone fixation device as in Claim 17, wherein minor diameter tapers in a distal direction.

19. A bone fixation device as in Claim 18, wherein at a distal end of the distal anchor the minor diameter is approximately equal to zero.

20 A bone fixation device as in Claim 18, wherein the outer boundary also tapers in a distal direction.

21 A bone fixation device as in Claim 11, wherein the minor diameter is approximately equal to zero.

22. A bone fixation device as in Claim 11 wherein the helical flange has a generally V-shaped cross-section

23 A bone fixation device as in Claim 21, wherein the helical flange has a generally rectangular cross-section.

24. A bone fixation device as in Claim 1, wherein the proximal anchor comprises a tubular housing comprising at least one barb that extends radially outwardly from the tubular housing and defines an engagement surface that lies within a plan that is traverse to a longitudinal axis of the tubular housing.

25. A bone fixation device as in Claim 24, wherein the proximal anchor includes a flange, which defines a bone contacting surface that generally faces the engagement surface.

26. A bone fixation device as in Claim 1, wherein the elongate body comprises a first portion and a second portion that are detachably coupled to each other at a junction.

27. A bone fixation device as in Claim 26, further comprising an anti-rotational structure on the first portion of the body, the anti-rotational structure preventing rotational movement of the first portion of the body with respect to the proximal anchor

28 A bone fixation device as in Claim 27, wherein the proximal anchor comprises a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion.

29. A bone fixation device as in Claim 28. wherein the retention structure comprises a series of ridges or grooves.

30. A bone fixation device as in Claim 29, further comprising a second retention structure on the interior of the tubular sleeve for cooperating with the retention structure on the body

31 A bone fixation device as in Claim 30, wherein the second retention structure comprises a transverse flange extending radially outwardly from the tubular sleeve

32. A bone fixation device as in Claim 31, wherein the flange is angularly moveable with respect to a longitudinal axis of the tubular sleeve.

33. A bone fixation device as in Claim 28. further comprising a rotational coupling on the second portion of the body.

34. A bone fixation device as in Claim 28. further comprising a rotational coupling on the proximal anchor

35. A bone fixation device as in Claim 28, further comprising a first threaded portion on a proximal portion of the first portion and a second threaded portion on a distal portion of the second portion, the first threaded portion and the second threaded portion configured to detachably couple the first and second portions to each other at a junction.

36. A bone fixation device, comprising: an elongate body having a proximal end and a distal end; a cancellous bone anchor on the distal end; the bone anchor fixed by rotation in a distal bone portion; a proximal anchor axially movably carried on the body; and complimentary surface structures in between the body and the proximal anchor that permit advancing the proximal

anchor without rotation in the distal direction to tighten the fixation device but that resist axial proximal movement of the proximal anchor.

37 A bone fixation device as in Claim 36, wherein the cancellous bone comprises a helical flange wrapped about a central core or axial lumen, an outer edge of the helical anchor defining an outer boundary and the central core or axial lumen defining a minor diameter.

38. A bone fixation device as in Claim 36, wherein the minor diameter is approximately equal to zero

39. A bone fixation device as in Claim 36. wherein the helical flange comprises at least a first flange and a second flange.

40. A bone fixation device as in Claim 36, wherein the proximal anchor comprises a tubular housing, which includes at least one barb extending radially outwardly from the tubular housing and defines an engagement surface that lies within a plane that is transverse to a longitudinal axis of the tubular housing.

41. A bone fixation device as in Claim 40, wherein the proximal anchor includes a flange, which defines a bone contacting surface that generally faces the engagement surface

42. A bone fixation device as in Claim 36, wherein the elongate body comprises a first portion and a second portion that are detachably coupled to each other at a junction.

43. A bone fixation device as in Claim 42, further comprising an anti-rotational structure on the first portion of the body, the anti-rotational structure preventing rotational movement of the first portion of the body with respect to the proximal anchor

44. A bone fixation device as in Claim 43, wherein the proximal anchor comprises a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion.

45. A bone fixation device as in Claim 44, wherein the complimentary surface structures comprise a first retention structure on the first portion comprising a series of ridges or grooves.

46. A bone fixation device as in Claim 45, wherein the complimentary surface structures further comprise a second retention structure on the interior of the tubular sleeve for cooperating with the first retention structure on the body

47. A bone fixation device as in Claim 46, wherein the second retention structure comprises a transverse flange extending radially outwardly from the tubular sleeve.

48. A bone fixation device as in Claim 47, further comprising a rotational coupling on the second portion of the first portion.

49. A bone fixation device as in Claim 47, further comprising a rotational coupling on the proximal anchor.

50. A bone fixation device as in Claim 47, further comprising a first threaded portion on a proximal portion of the first portion and a second threaded portion on a distal portion of the second portion, the first threaded portion and the second threaded portion configured to detachably couple the first and second portions to each other at a junction.

51. A bone fixation device, comprising: an elongate body, having a proximal end and a distal end: a helical anchor on the distal end; the helical anchor fixed by rotation in a distal bone portion; a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body. wherein the proximal anchor is movable without rotation in the

distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body; and wherein said elongate body comprises a first portion and a second portion that are detachably coupled to each other at a junction.

52. A bone fixation device as in Claim 51, further comprising an anti-rotational structure on the first portion of the body, the anti-rotational structure preventing rotational movement of the first portion of the body with respect to the proximal anchor.

53. A bone fixation device as in Claim 52, wherein the proximal anchor comprises a tubular sleeve that in a first position extends distally past the junction between the first portion and the second portion

54. A bone fixation device, comprising: an elongate body, having a proximal end and a distal end; a helical anchor on the distal end; the helical anchor fixed by rotation in a distal bone portion; a first retention structure on the body, proximal to the anchor; and a proximal anchor, moveably carried by the body, wherein the proximal anchor is movable without rotation in the distal direction with respect to the body and the retention structure resists proximal movement of the proximal anchor with respect to the body; and wherein a second retention structure comprises a transverse flange extending radially outwardly from a tubular sleeve.

55. A bone fixation device as in claim 53, wherein the flange is angularly moveable with respect to a longitudinal axis of the tubular sleeve.

56. A method of bone fixation by means of a bone fixation device comprising an elongate body having a distal bone anchor; the distal bone anchor fixed by rotation in a distal bone portion; the device further including a proximal anchor provided with a first retention structure· the method including the steps of:

(a) rotationally inserting the distal bone anchor into cancellous bone of a first bone portion,
(b) advancing a proximal anchor without rotation axially along the body to seat a flange of the proximal anchor against an outer surface of a second bone portion so as to permit compression across the first and second bone portions,

and wherein the retention structure resists proximal movement of the proximal anchor with respect to the elongate body

57 A method as in Claim 56 wherein the first and second bone portions are adjacent vertebral bodies.

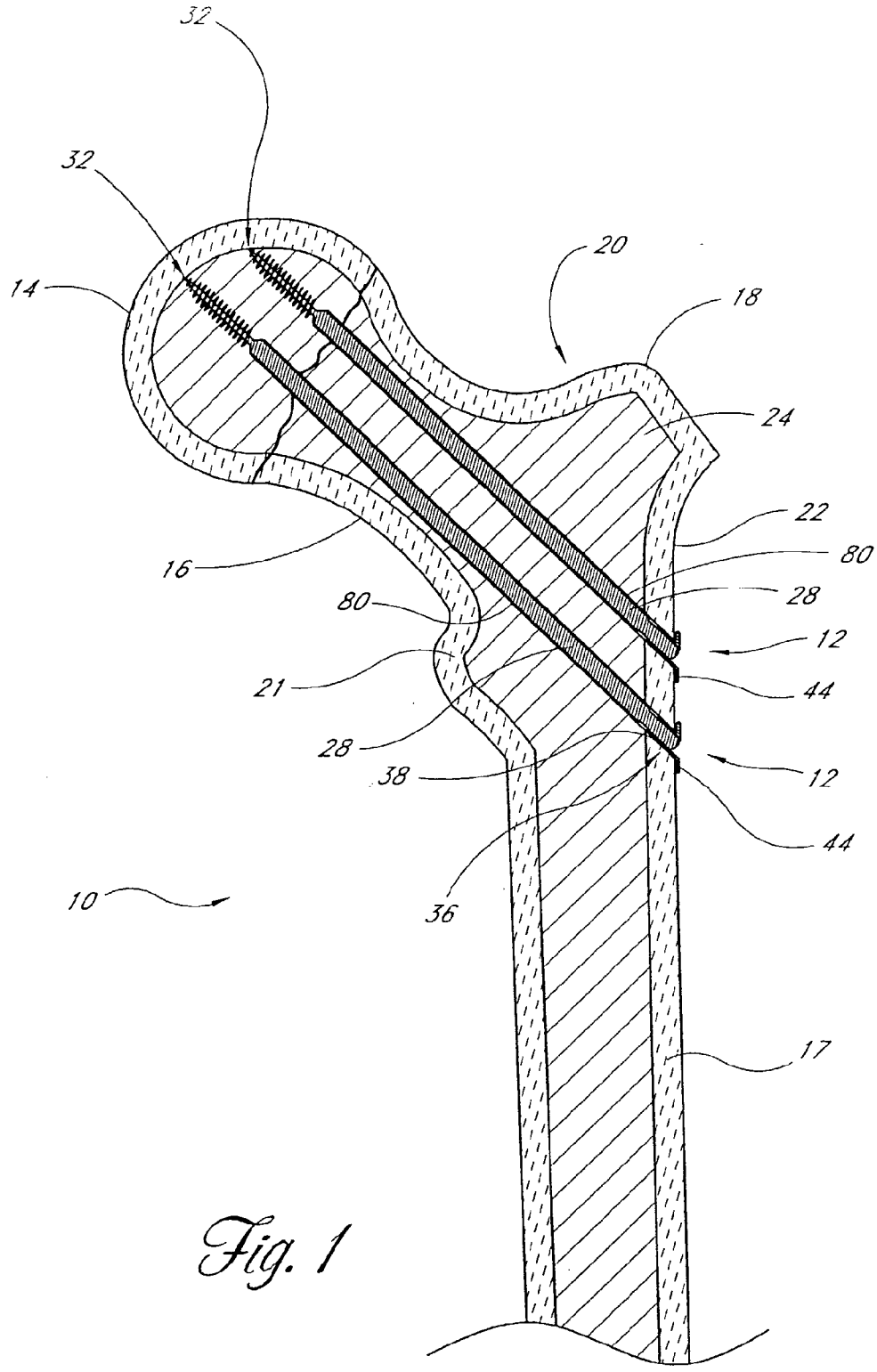


Fig. 1

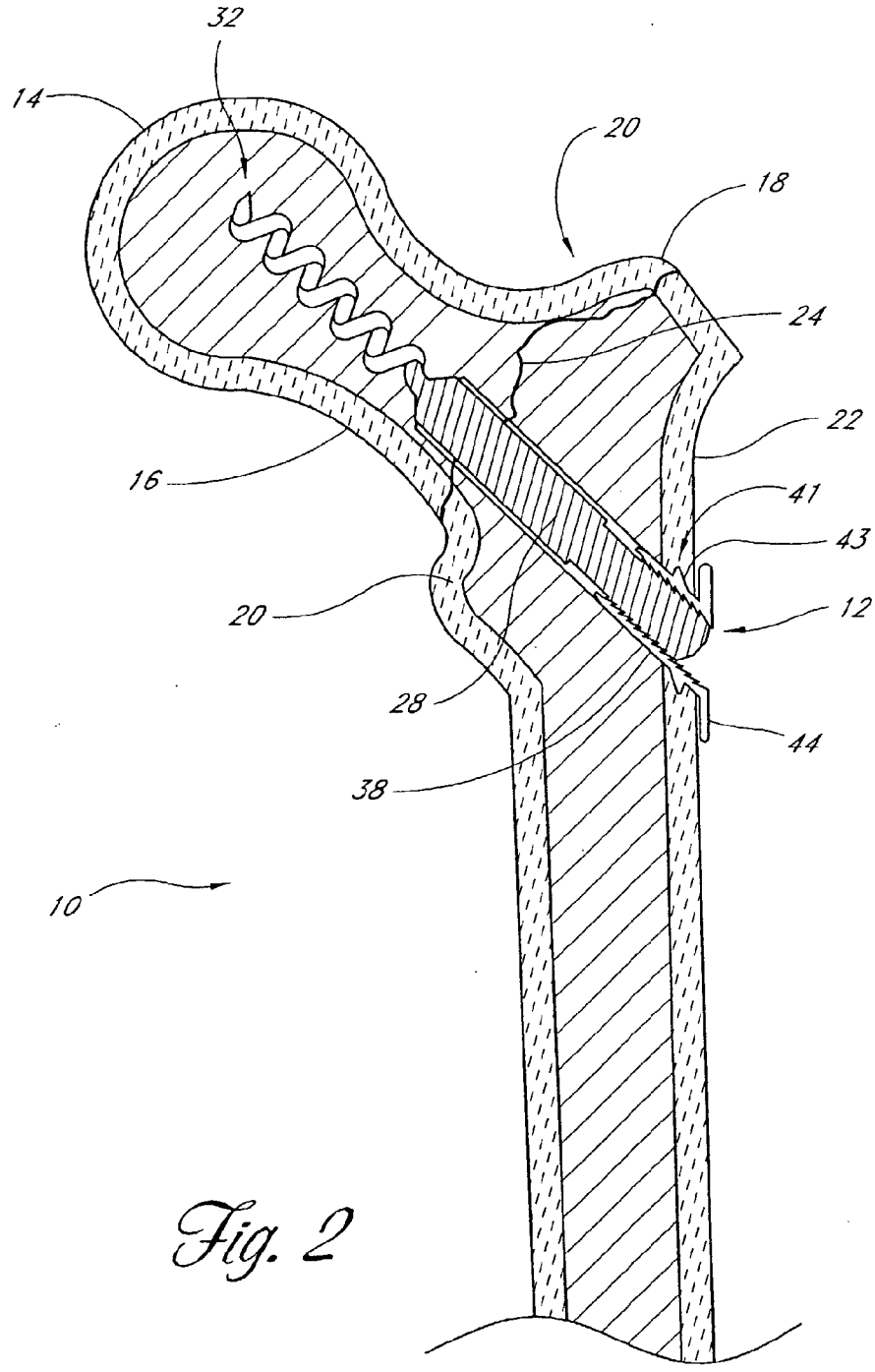


Fig. 2

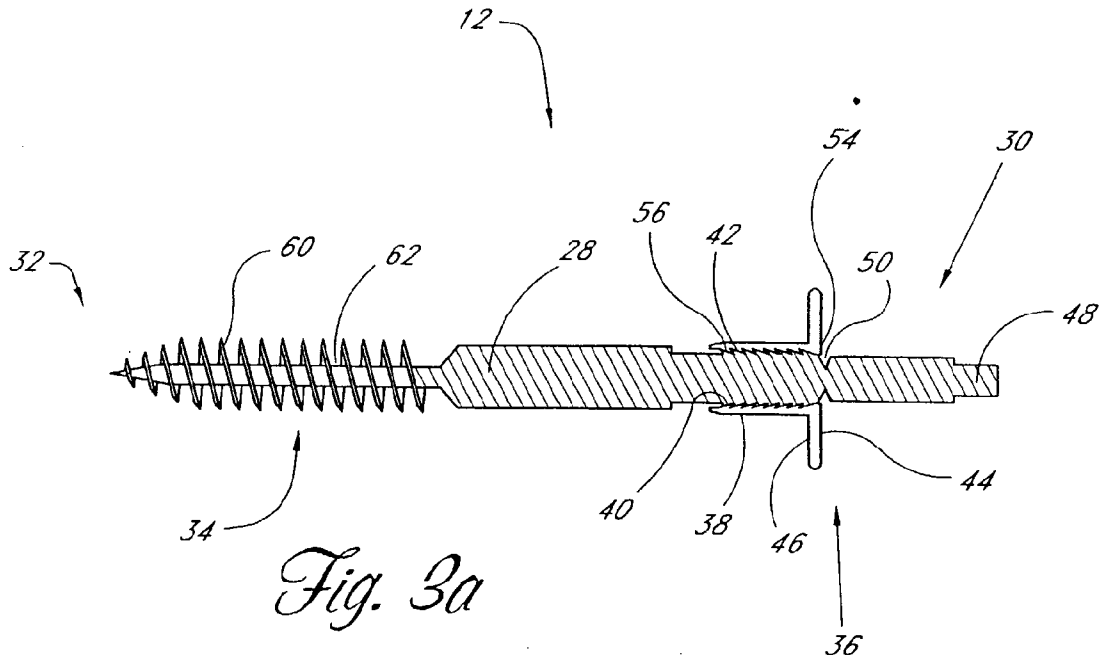

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Fig. 3a

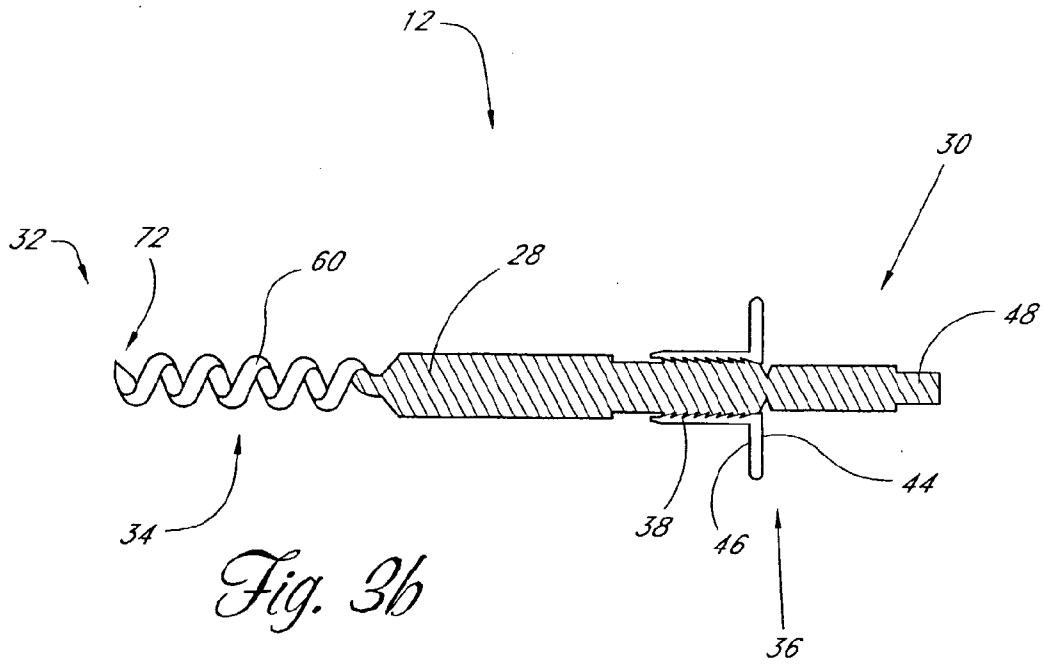
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Fig. 3b

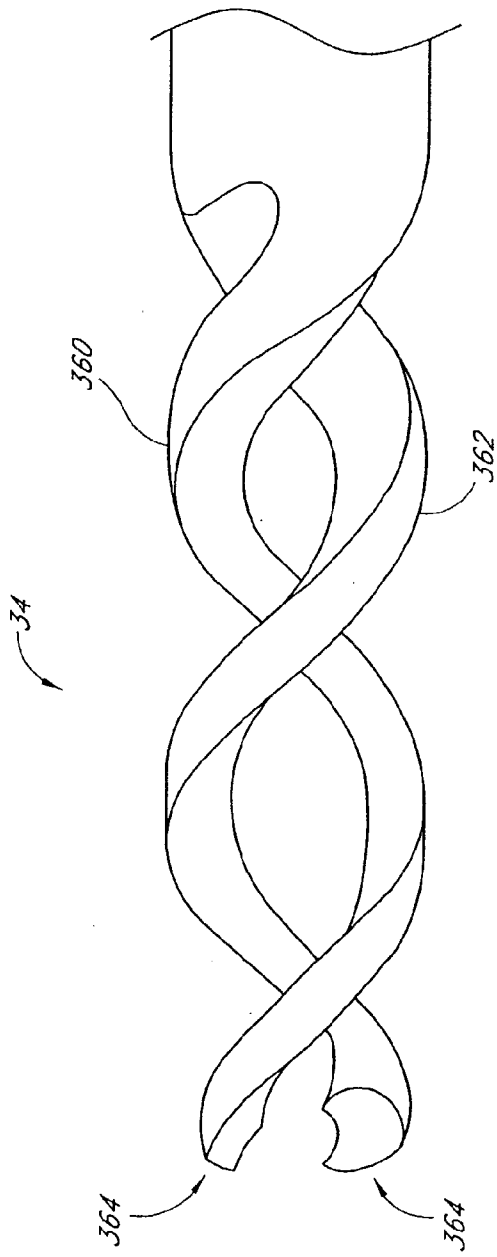


Fig. 3C

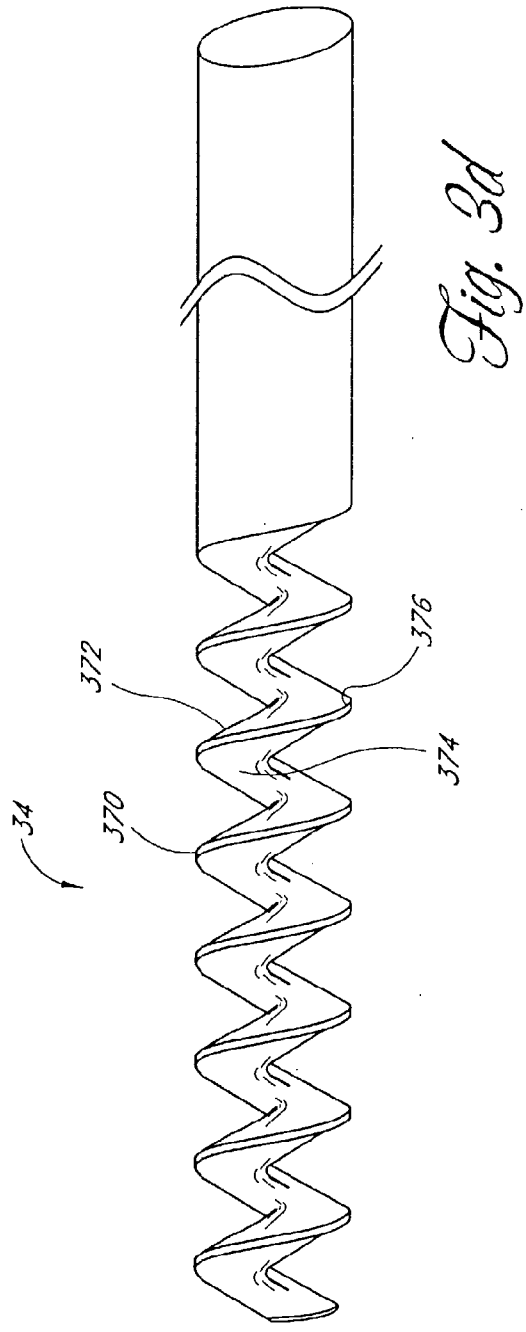
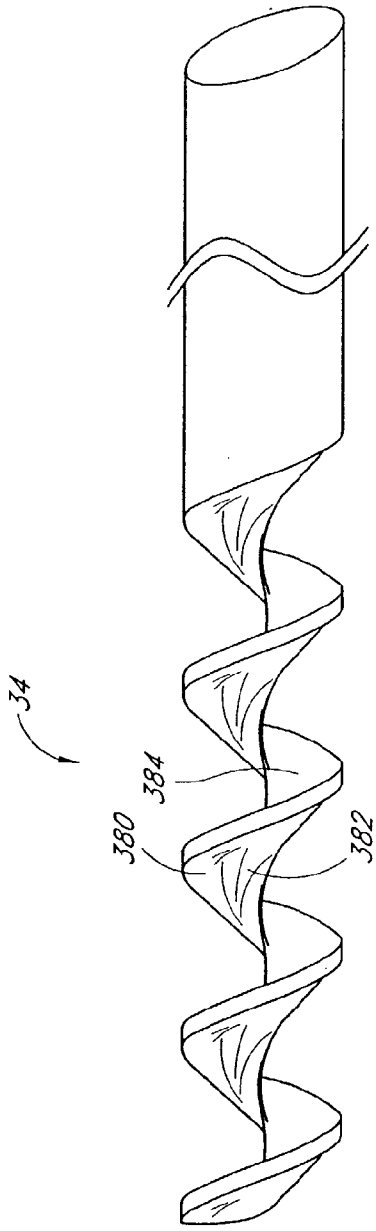


Fig. 3d



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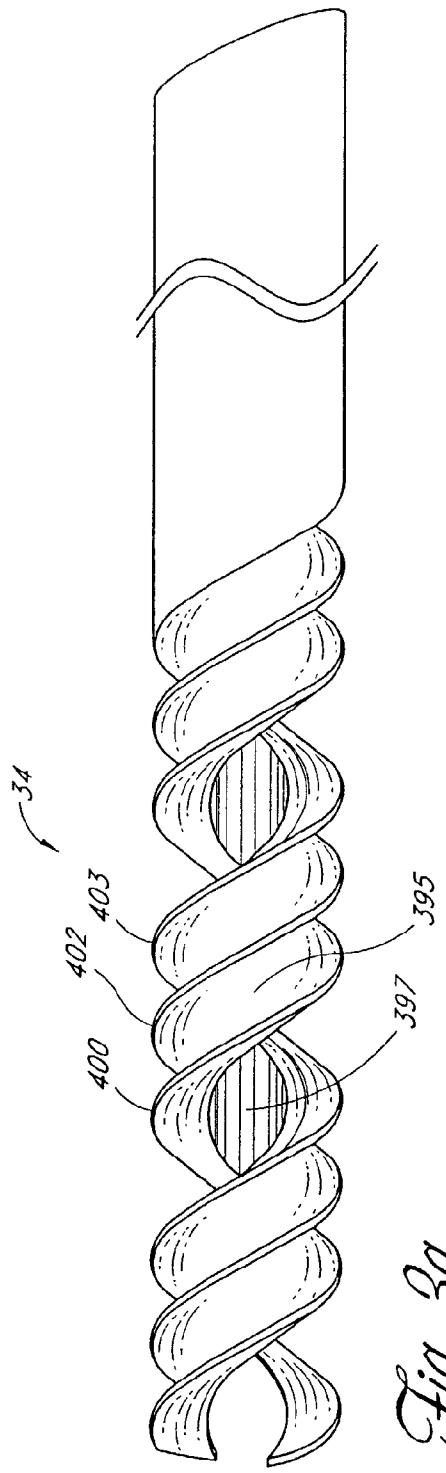
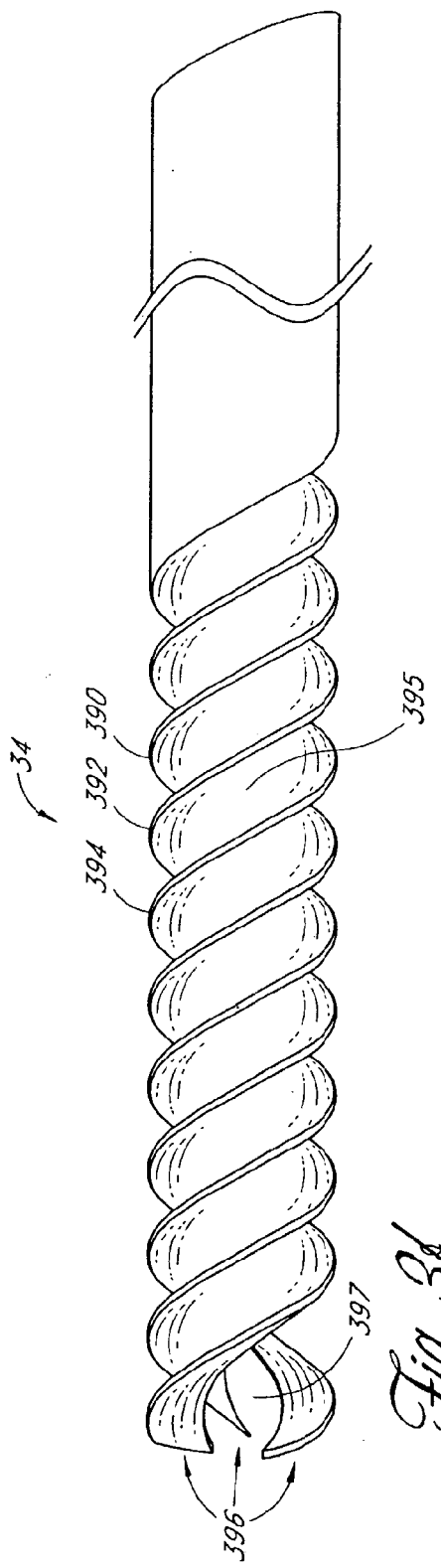


Fig. 3g



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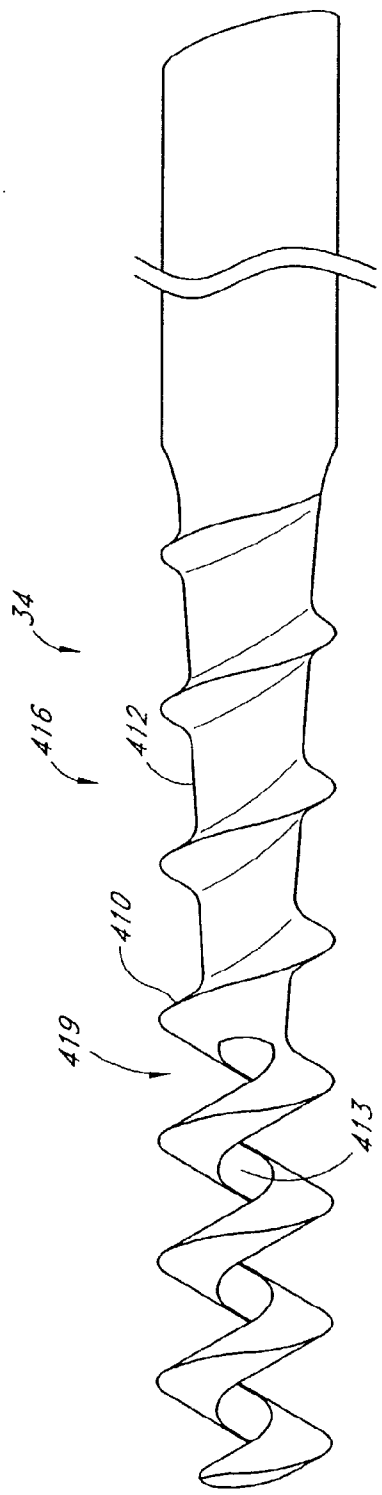

Fig. 3h

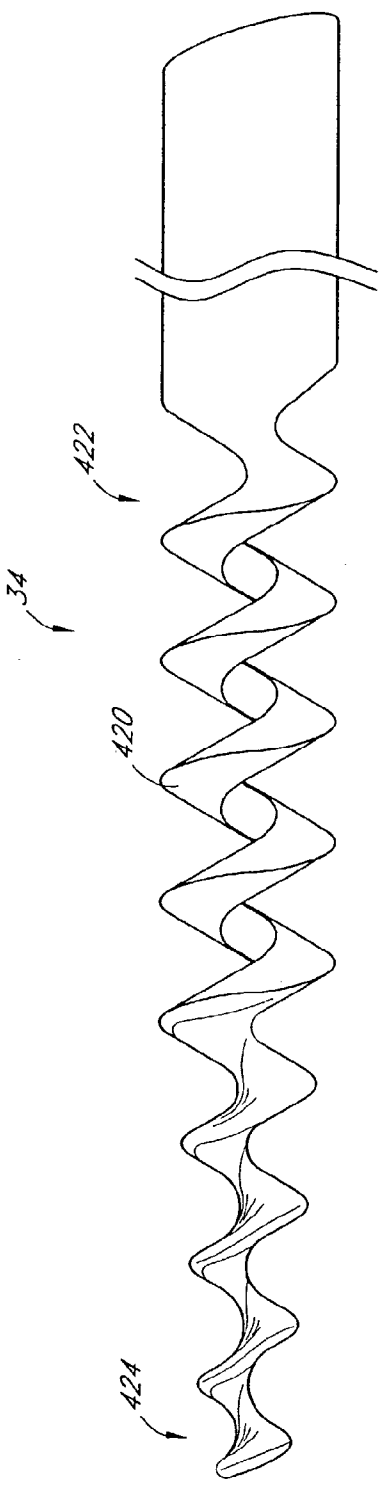

Fig. 3i

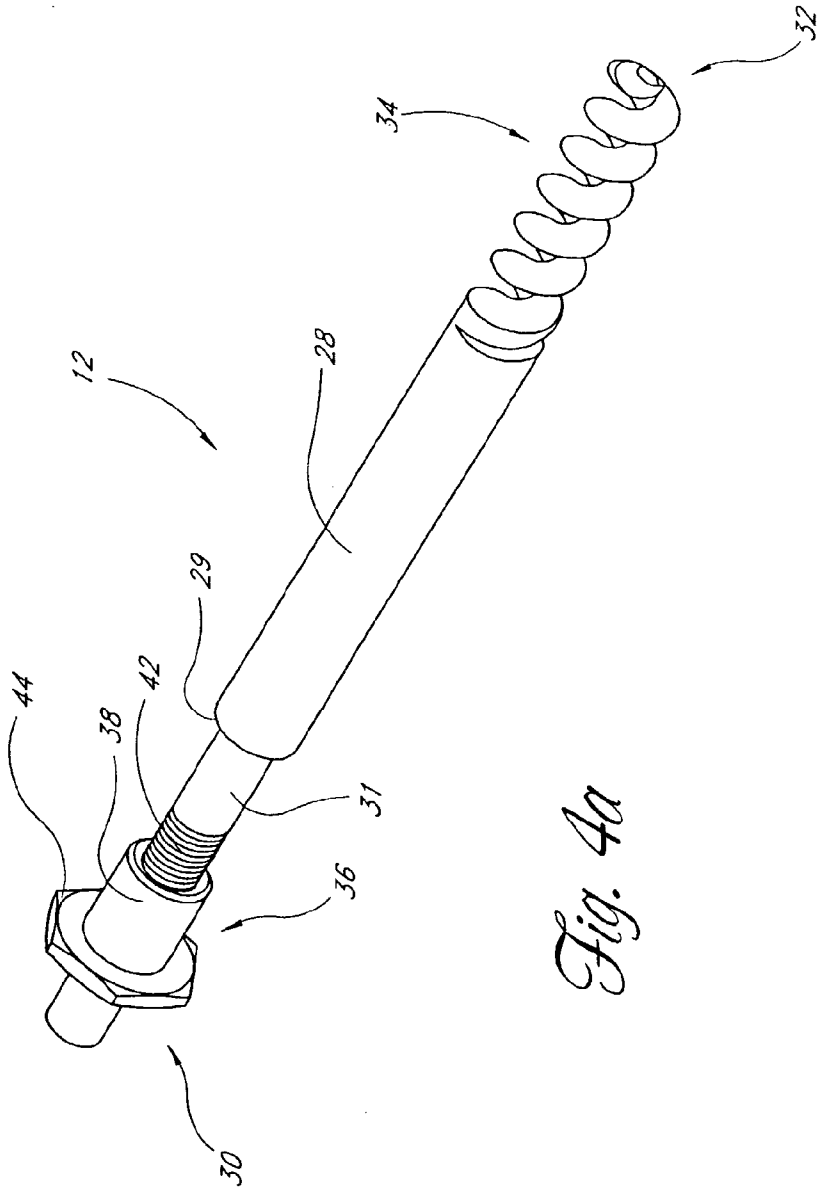

Fig. 4a

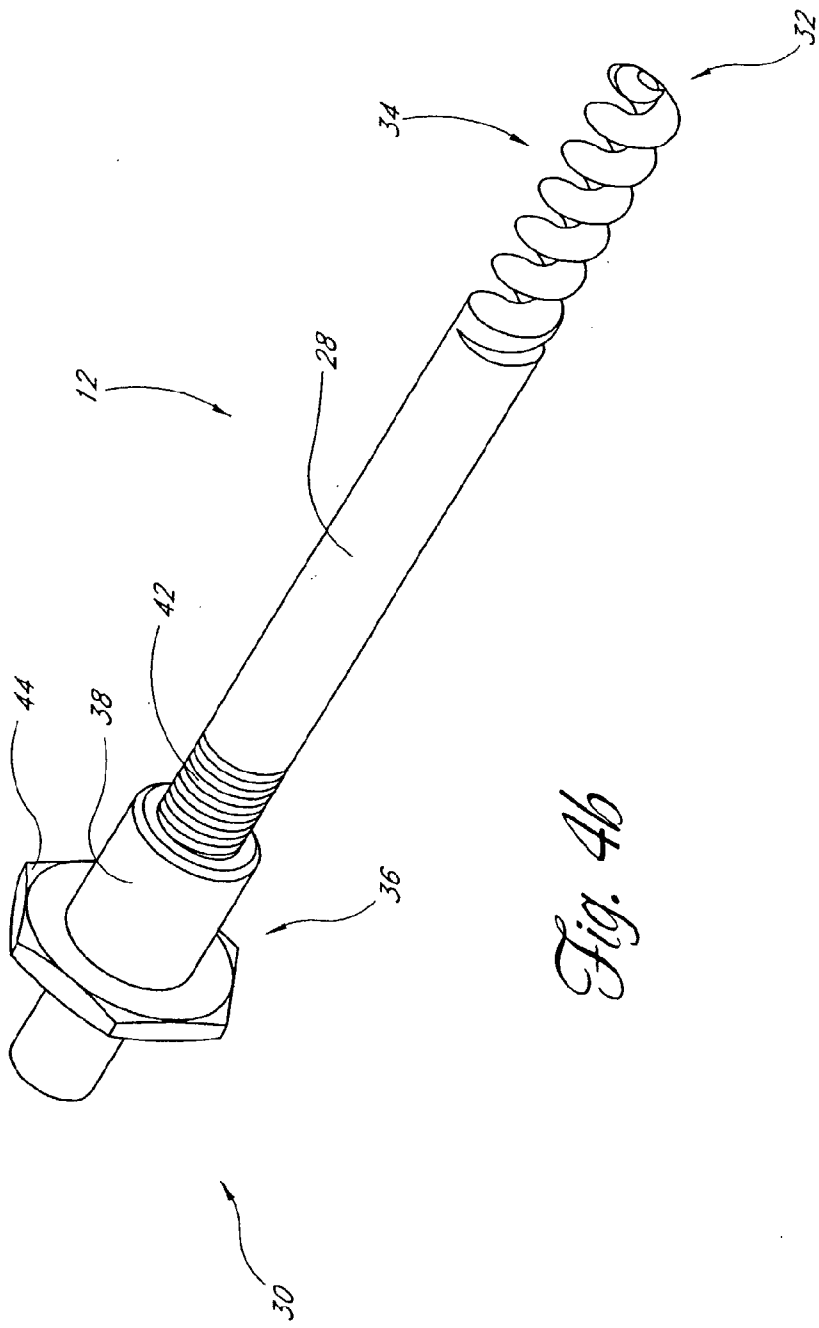

Fig. 4b

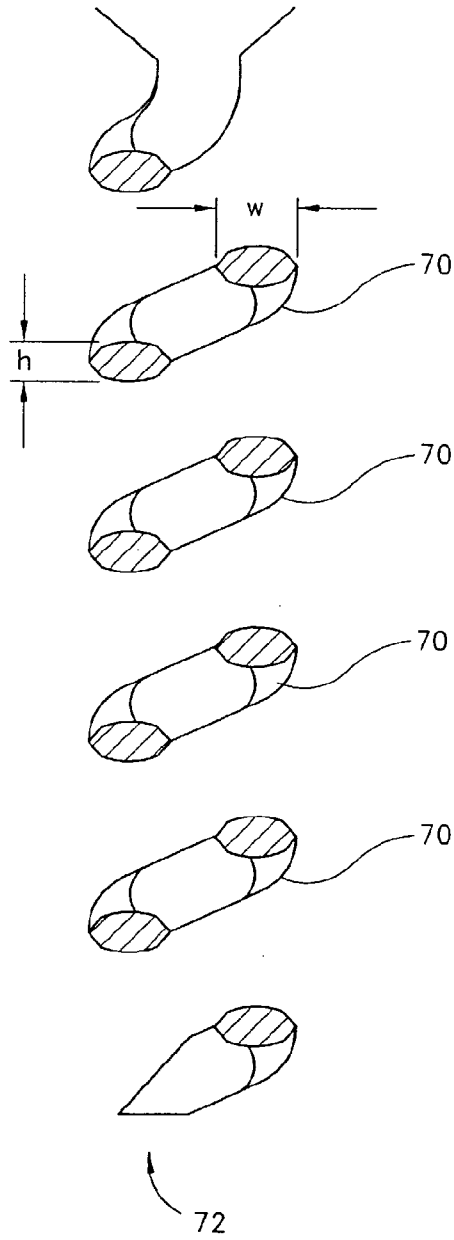

Fig. 5

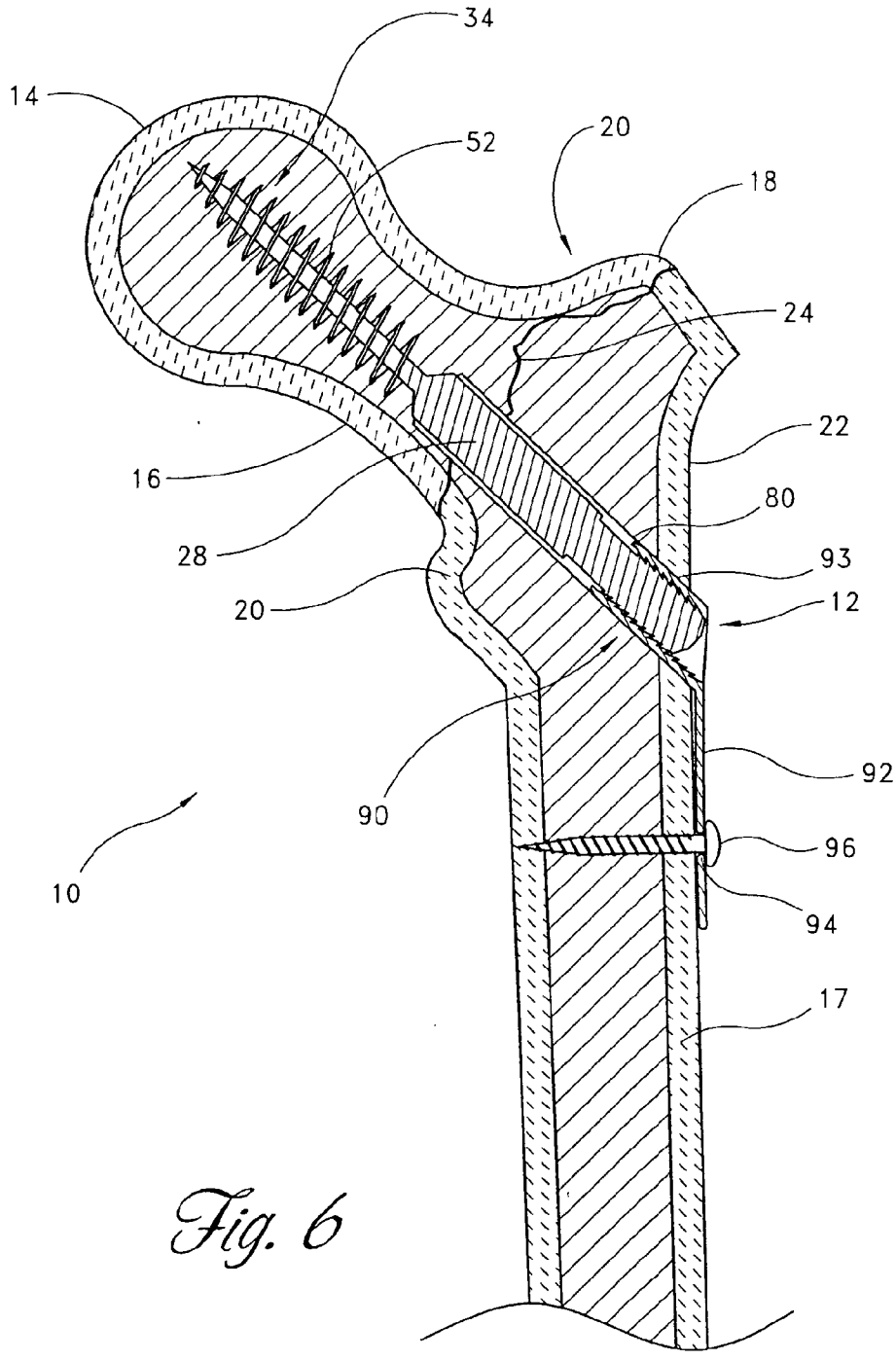

Fig. 6

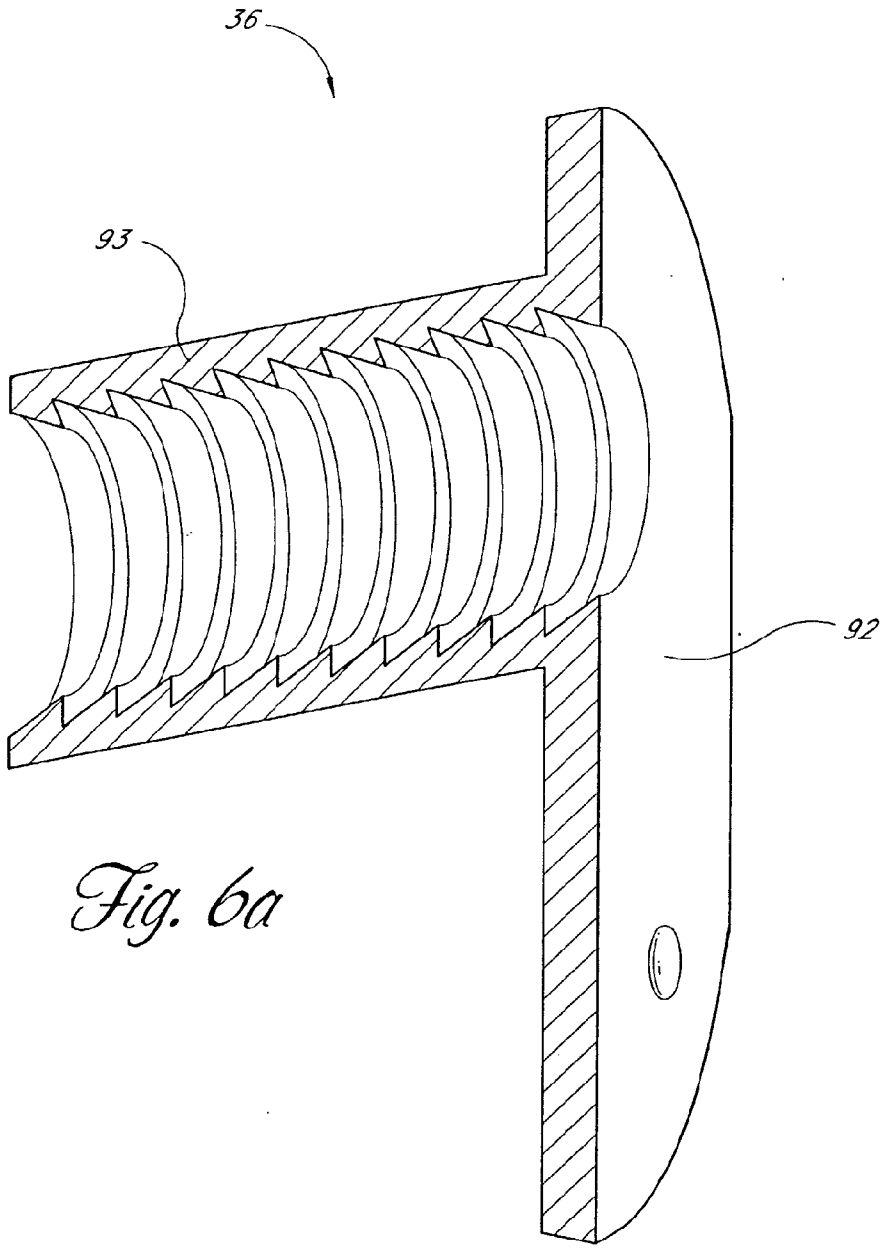

Fig. 6a

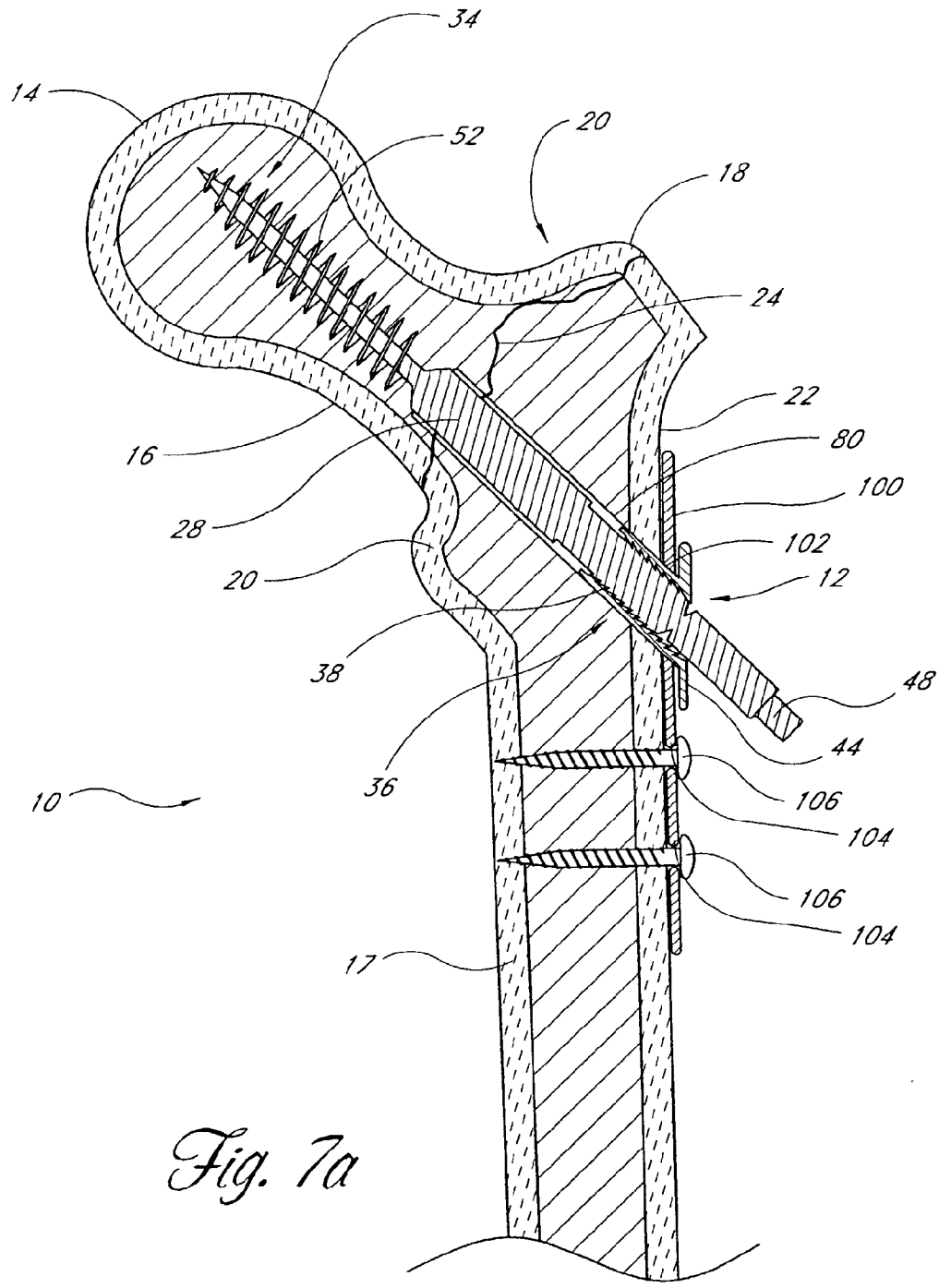
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Fig. 7a

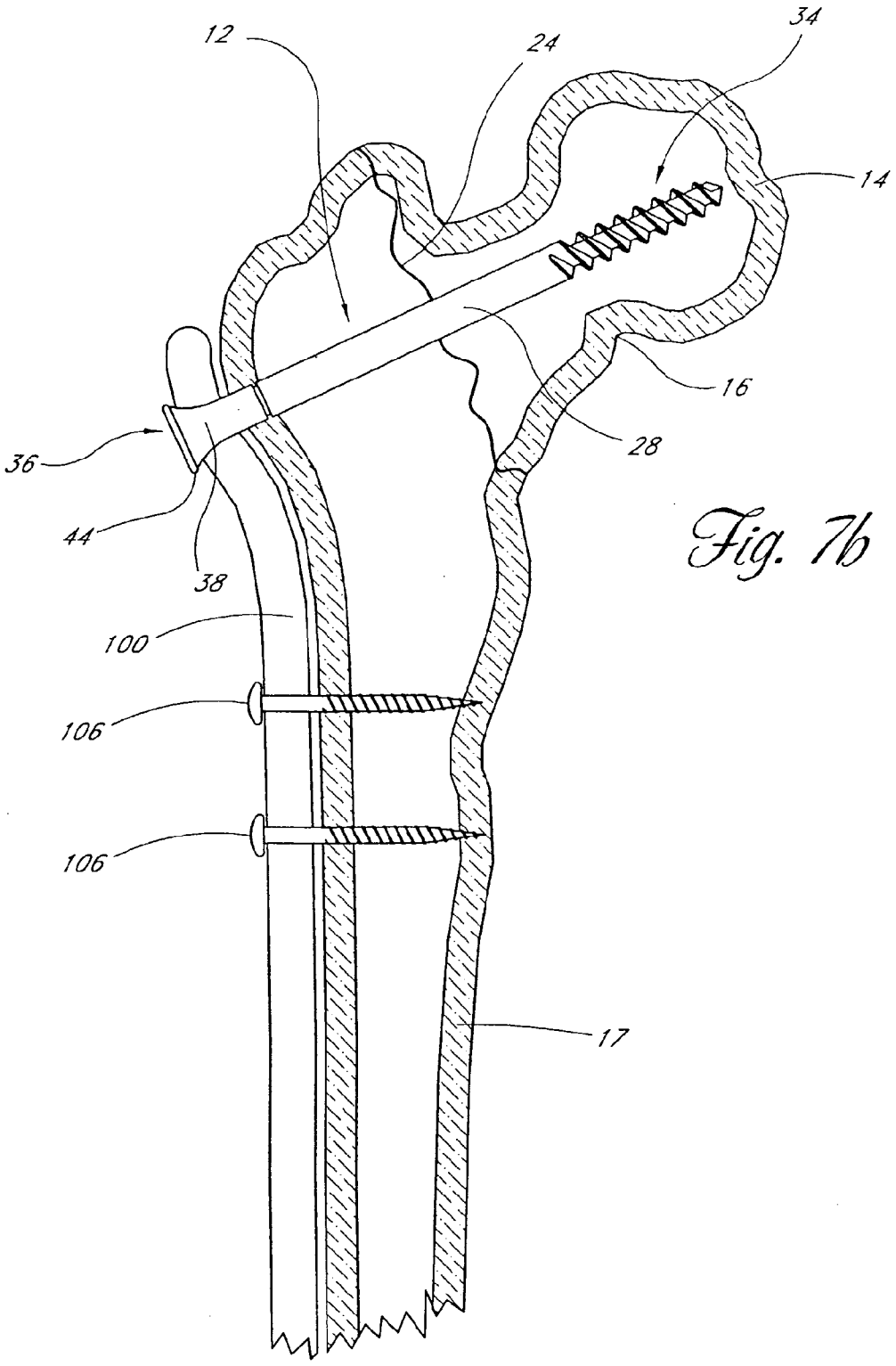


Fig. 7b

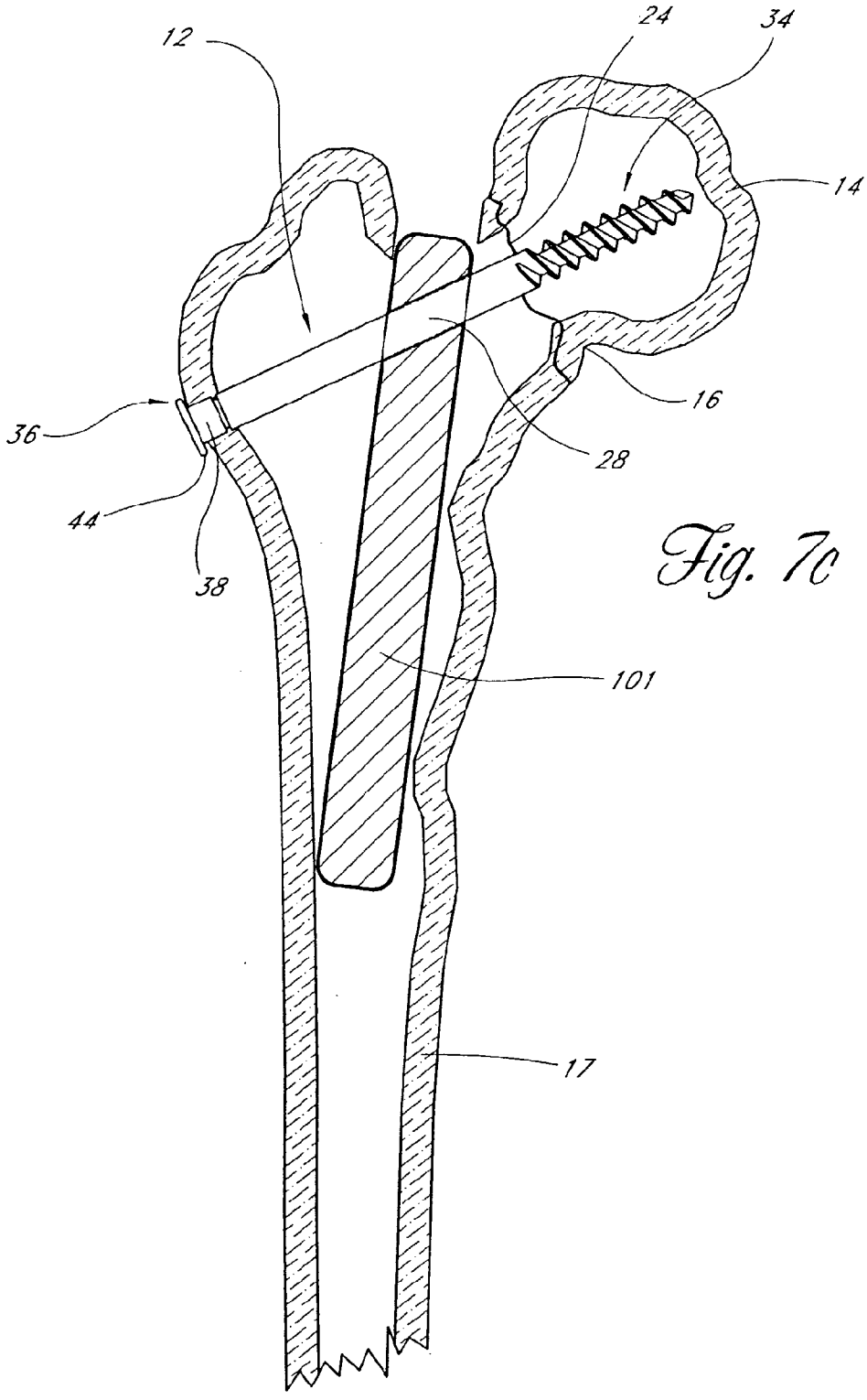


Fig. 7C

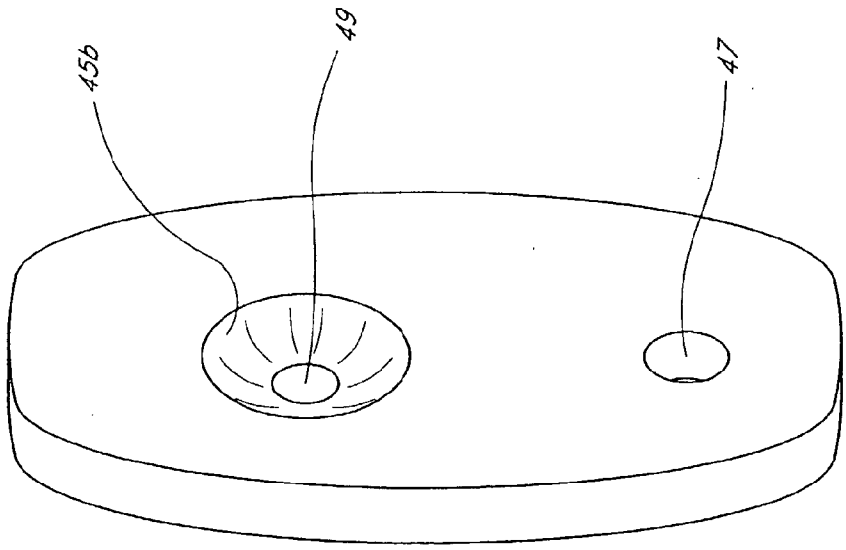


Fig. 9

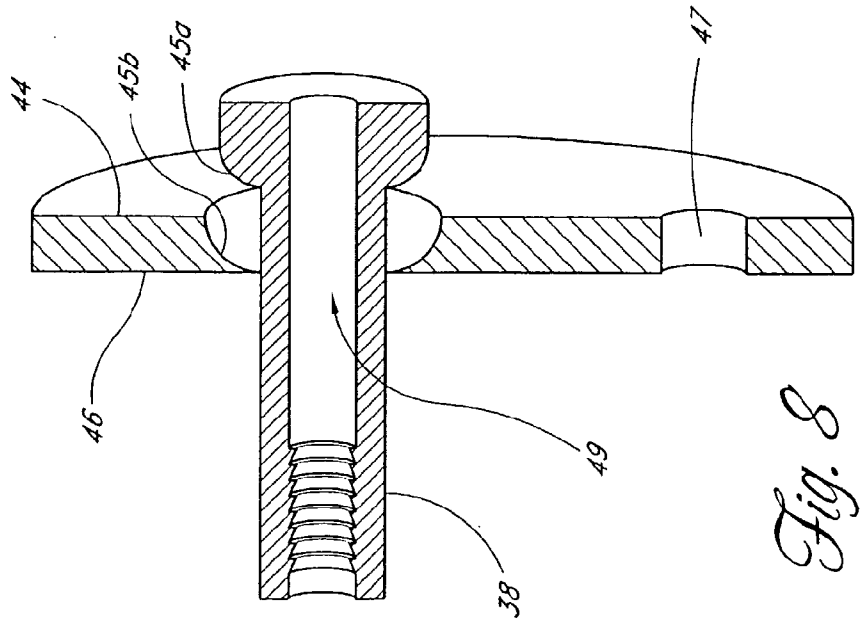
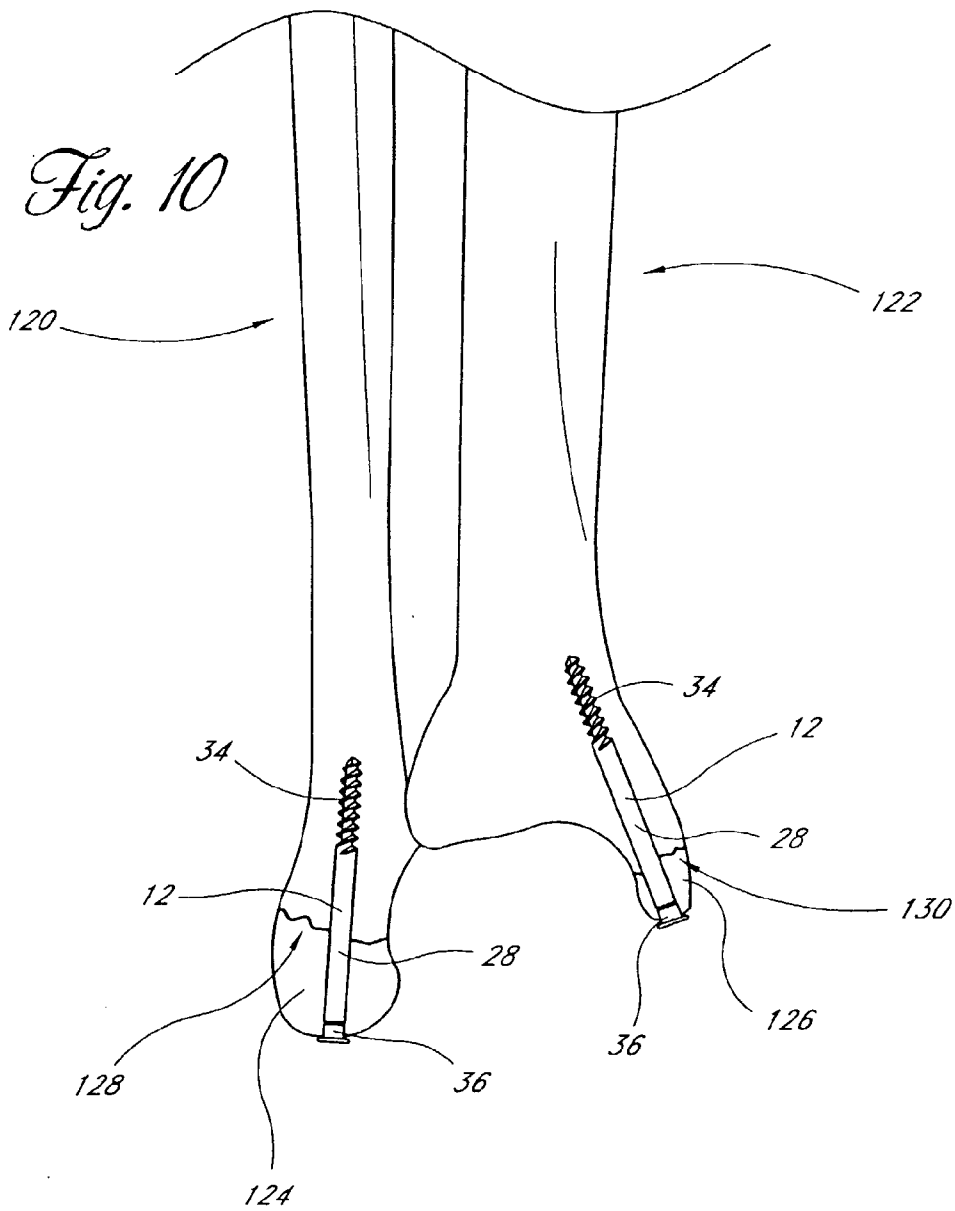


Fig. 8

Fig. 10



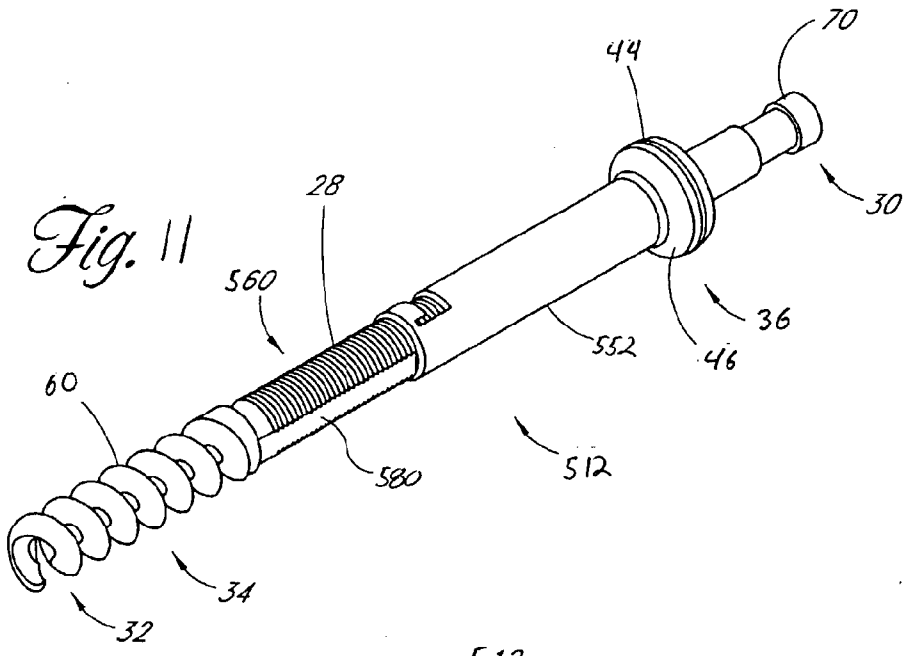


Fig. 11

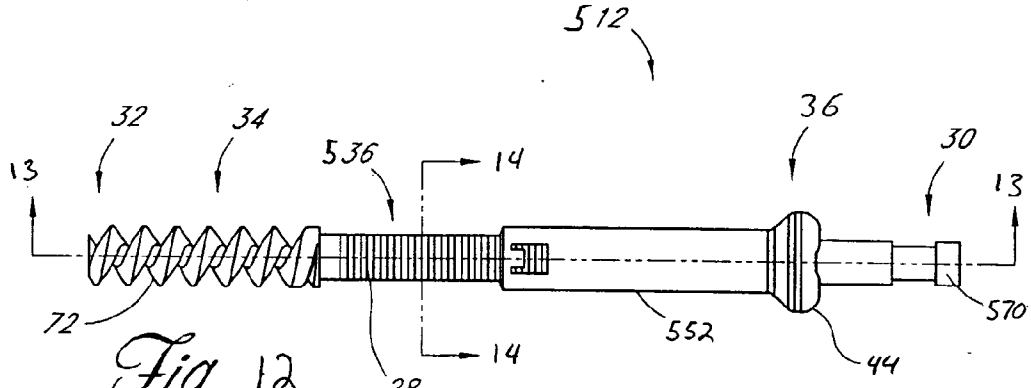


Fig. 12

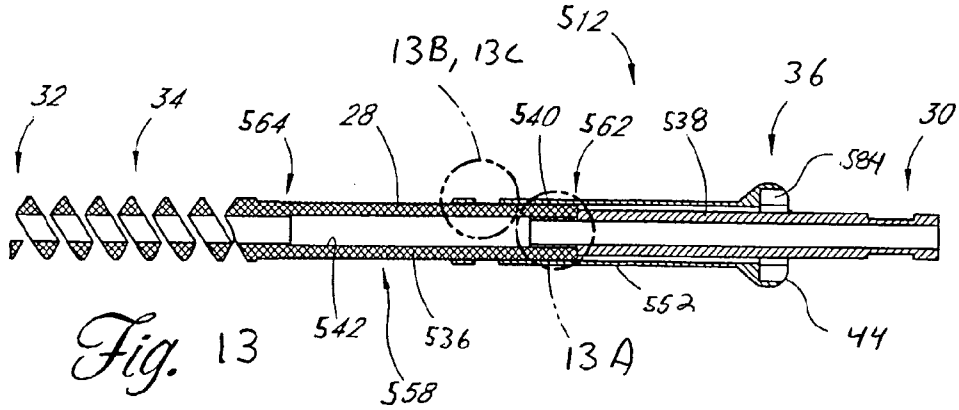


Fig. 13

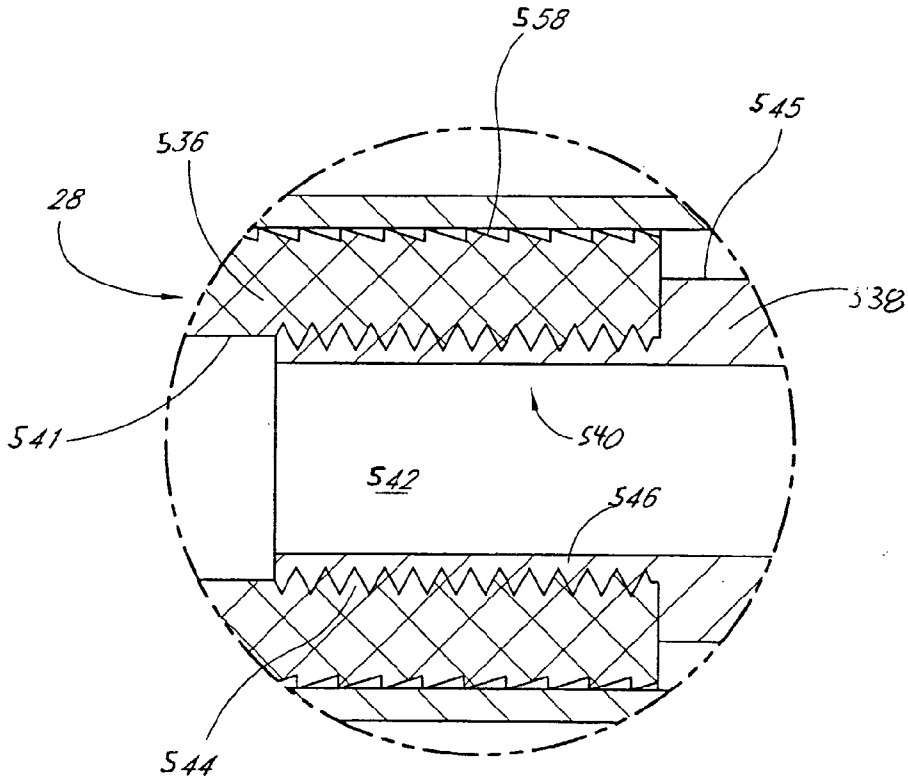


Fig. 13A

Fig. 13B

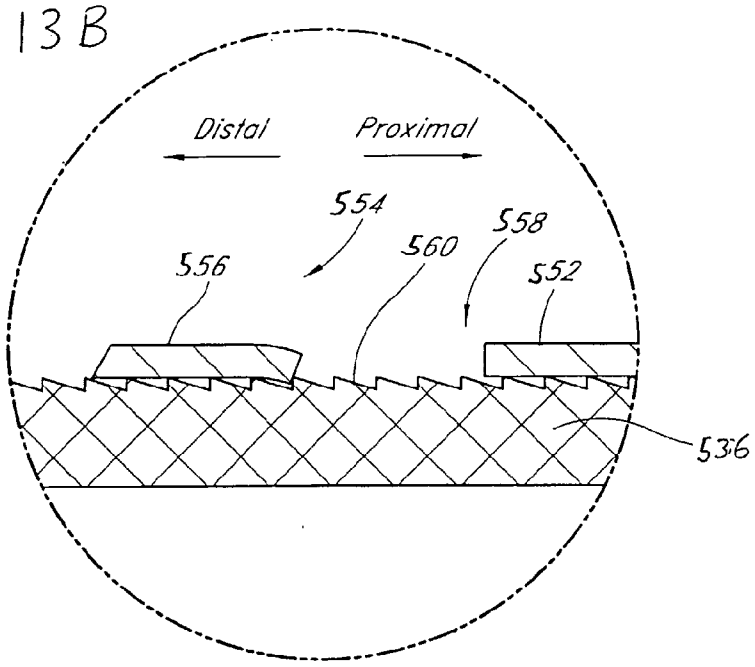
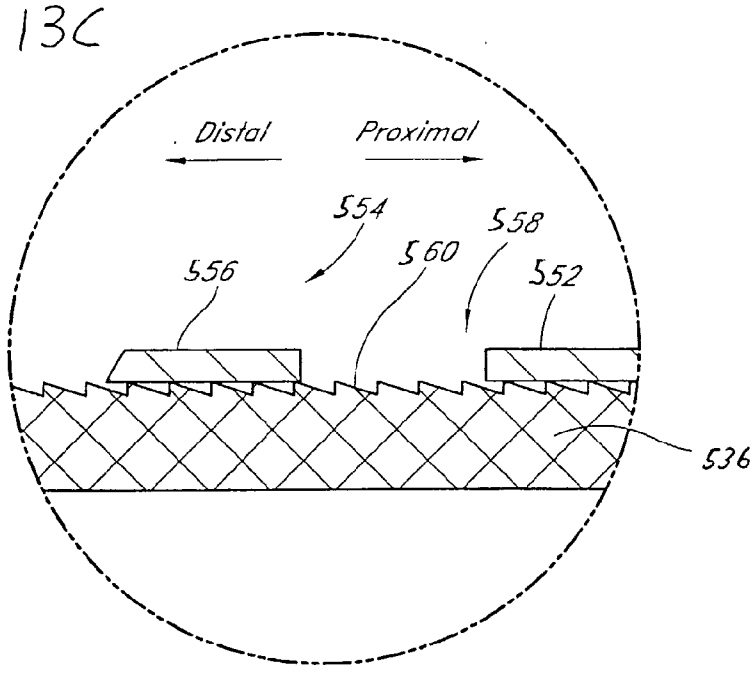


Fig. 13C



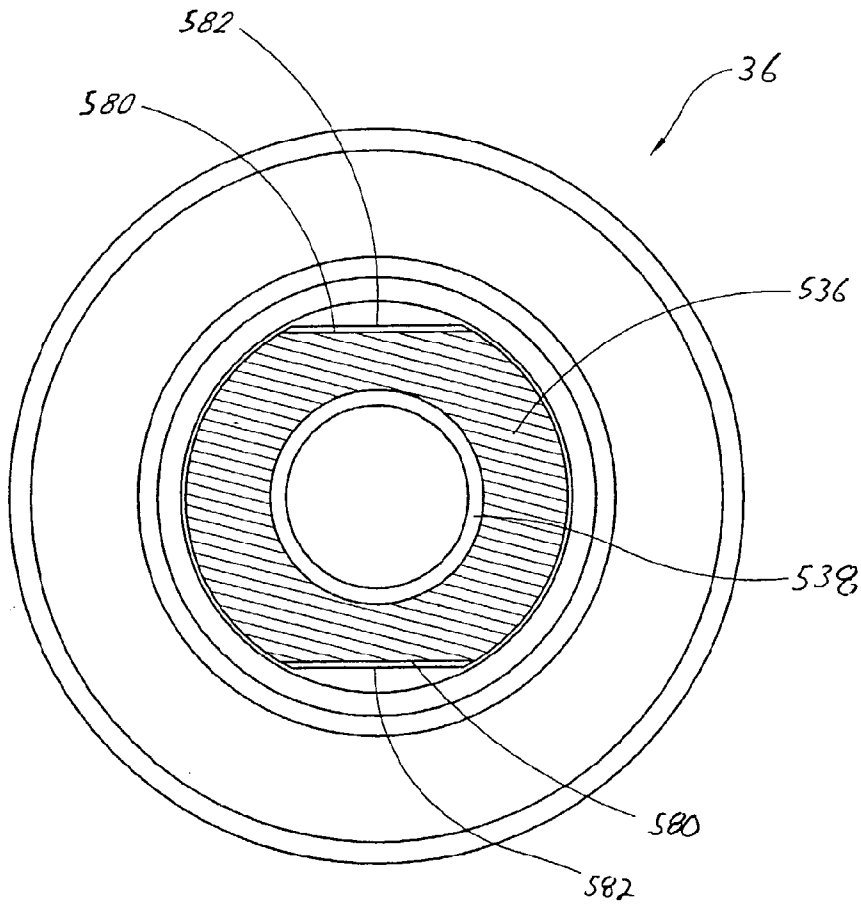


Fig. 14

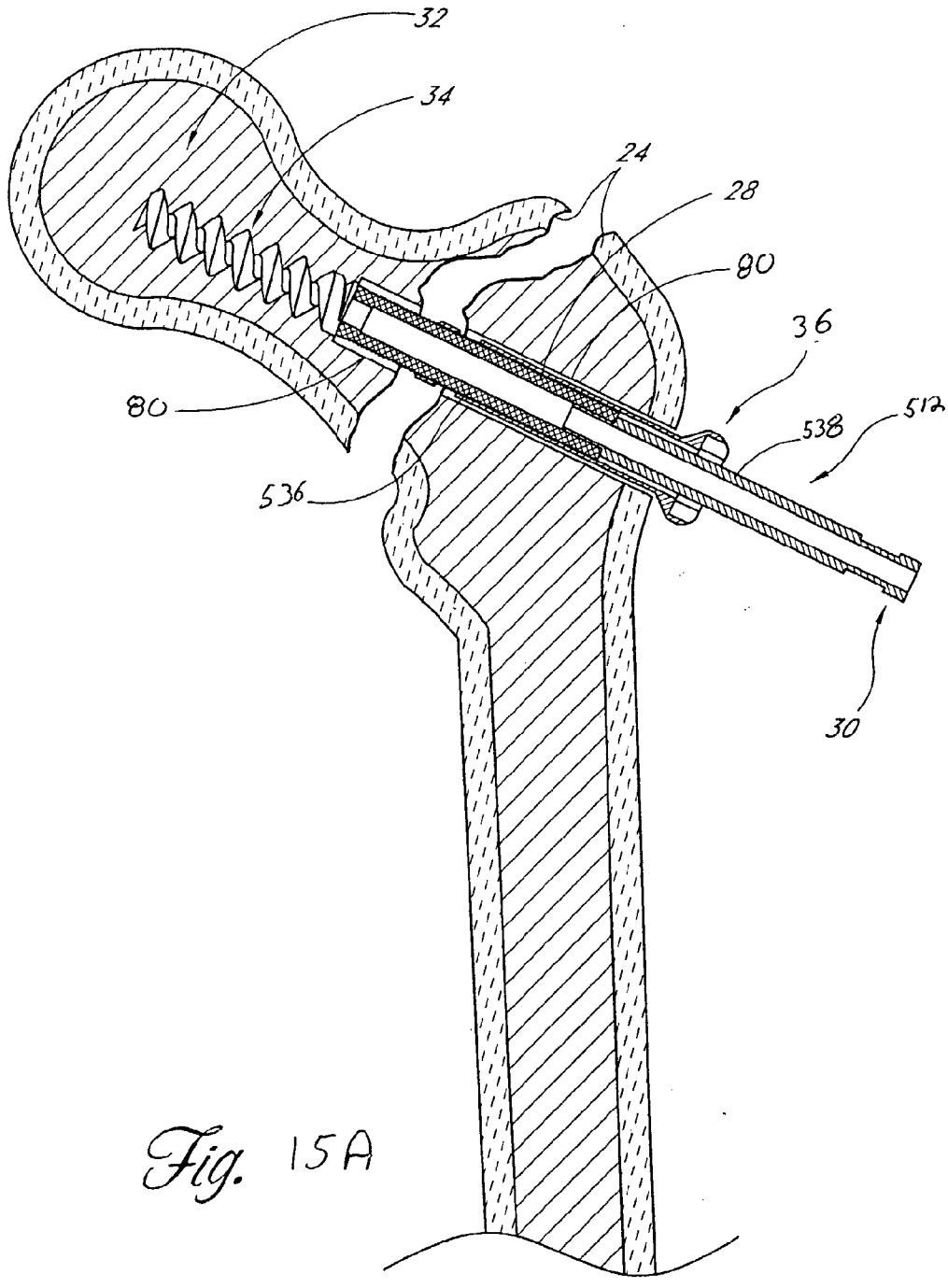


Fig. 15A

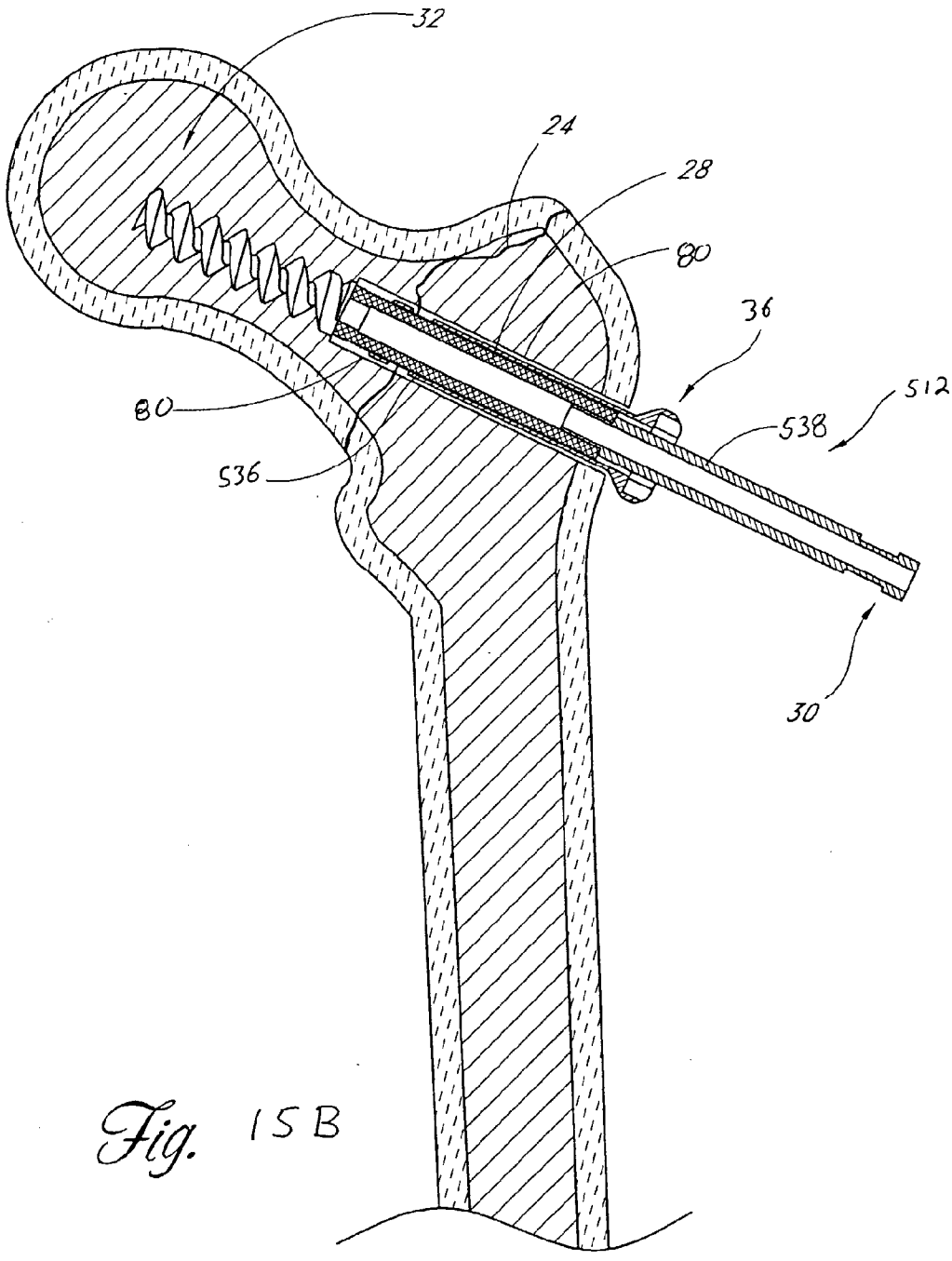


Fig. 15B

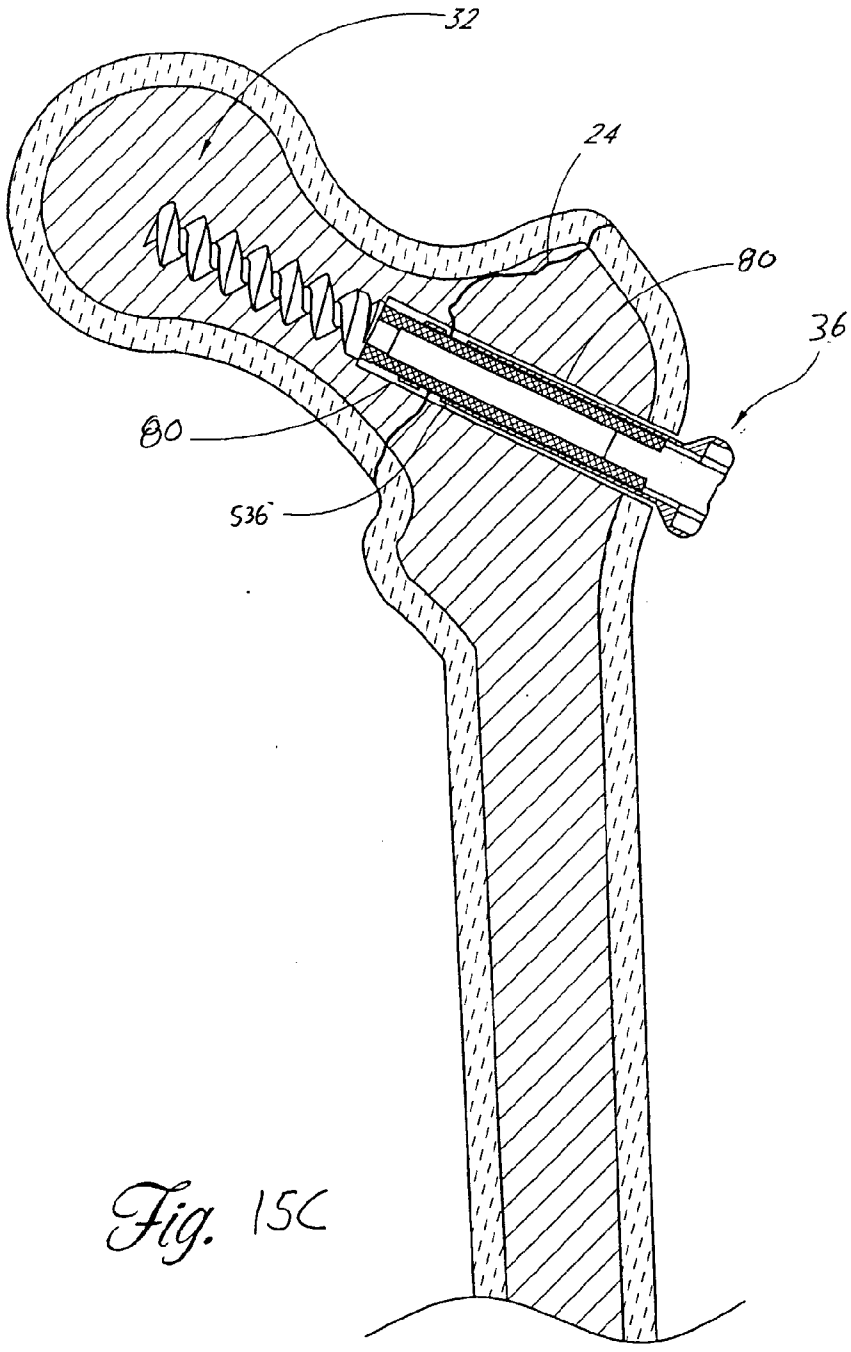


Fig. 15C