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Australia

Patents Act 1990

Patent Request: Standard Patent

We, the Applicants/Nominated Persons specified below, request we be granted a patent for the invention disclosed in the accompanying standard complete specification.

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[54] **Invention Title:**
Improved Suture Anchor and Driver Assembly

[72] **Inventors:**
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W. Dwyer

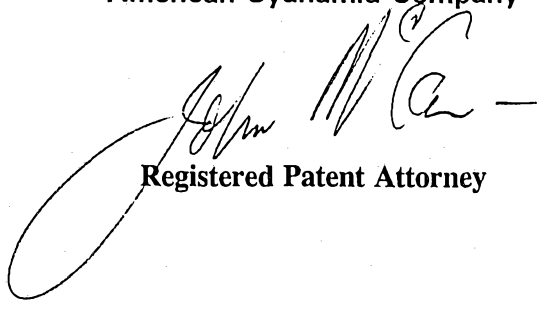
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Basic Convention Application Details

[31]	Application No	[33]	Country	[32]	Date of Application
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	(2) 681,042		US		5 April 1991

Basic Applicants: (1) Jeffrey C. Cerier, Russell F. Warren and Gerard S. Carlozzi
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DATED 25 October, 1994
American Cyanamid Company


Registered Patent Attorney



IRN: 184780

INSTR CODE: 50380

[N:LIBU]10875:KEH

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NOTICE OF ENTITLEMENT

I, Alphonse R. Noë, of American Cyanamid Company

being authorised by the Applicant/Nominated Person in respect of Application
No 80406/91 state the following:-

The Applicant/Nominated Person has entitlement from the actual inventors as
follows:-

The Applicant/Nominated Person is the assignee of the actual inventors.

The Applicant/Nominated Person is the applicant of the applications listed in
the Declaration under Article 8 of the PCT.

The basic applications listed on the Declaration under Article 8 of the PCT
are the first applications made in a Convention country in respect of the
invention.

DATED this 14th

day of October

1994

..... *Alphonse R. Noë*

(Signature)

Alphonse R. Noë
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.....

(Name & Title)

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(12) PATENT ABRIDGMENT (11) Document No. AU-B-80406/91
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 655770

- (54) Title
IMPROVED SUTURE ANCHOR AND DRIVER ASSEMBLY
- International Patent Classification(s)
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- (43) Publication Date : **16.01.92**
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- (56) Prior Art Documents
US 4870957
US 4741330
US 4632100
- (57) Claim

1. A device for anchoring a suture to a bone, said device comprising:
a driver having a handle and an elongated shaft, said shaft having two ends, one of said ends attached to said handle;
an anchor member including an elongated body having a proximal region terminating in a proximal end, and a distal region with a successively narrower cross-section terminating in a distal end to facilitate insertion into a bone;
means, disposed in said proximal region, for releasably engaging the other of said ends of said shaft for insertion of said anchor member into the bone;
at least one non-helical ridge, disposed about the exterior surface of said body proximal to said distal region, for engaging the bone after insertion to resist withdrawal of said anchor; and
means, defined in said elongated body, for receiving a portion of a suture to hold the suture at a selected position in the bone.

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AUSTRALIA

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PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title:

Improved Suture Anchor and Driver Assembly

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

IMPROVED SUTURE ANCHOR AND DRIVER ASSEMBLYCROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of common-owned application Serial No. 552,440, filed on July 13, 1990.

5

TECHNICAL FIELD

A suture anchor for implanting in bone or tissue for surgical use is disclosed. The anchor is securely affixed on the end of a driver device and positioned and installed during surgery.

10

BACKGROUND ART

Anchoring or affixation devices and systems for medical or surgical use are in common use today. The anchors are implanted to aid in holding bone, tissue, ligaments and the like together or in place until healing takes place, or are used temporarily to help perform a procedure necessary for optimum surgical results. When implanted permanently, the anchors can be made from an absorbable material if desired.

20

Bone and suture anchors are used, for example, during orthopedic surgery to hold fractured bones together, affix ligaments to bones and to aid in determining isometric placement of anterior cruciate ligament replacements. Examples of such anchors are shown in U.S. Patent Nos. 4,537,185, 4,632,100, 4,640,271, 4,723,541 and 4,738,255.

25

Some positioning and driver mechanisms and systems are known which are used to accurately position

and install the bone anchors in place. Examples of such mechanisms and systems are disclosed, for example, in U.S. Patent Nos. 3,990,438, 4,537,185, 4,632,100, 4,723,541 and 4,738,255. Two other known systems are
5 the "Statak" mechanism marketed by Zimmer, Inc., Warsaw, Indiana and the "Isotac" mechanism marketed by Acufex Microsurgical, Inc., Norwood, Massachusetts.

It is an object of the present invention to provide an improved bone or suture anchor for surgical
10 use. It is another object of the present invention to provide an improved driver device for a bone or suture anchor.

It is a still further object of the invention to provide a surgical anchor and driver assembly which
15 allows efficient and accurate positioning and placement of a bone or suture anchor during surgery, the anchor being able to be affixed either for permanent or temporary use, and the driver being able to remove the installed anchor if desired.

It is also an object of the invention to provide an anchor and driver assembly in which the bone
20 or suture anchor can be temporary securely affixed to the driver device for installation and removal, and be removed easily from the driver device when desired. It
25 is another object to provide means on the driver device to hold the anchor temporarily in place and prevent it from rotating relative to the driver device.

It is still another object to provide a surgical bone or suture anchor and driver assembly in
30 which sutures holding the anchor in place are recessed or positioned in a way not to obstruct or cause a

problem during positioning, installation and/or removal of the anchor.

Another object of the invention is to provide a guide member for determining and limiting the depth of insertion of the anchor in the bone.

These and other objects are met by the present invention and will become apparent upon review of the following detailed description of the invention, when taken by itself or in view of the drawings.

Disclosure of Invention

According to a first embodiment of this invention there is provided a device for anchoring a suture to a bone, said device comprising:

10 a driver having a handle and an elongated shaft, said shaft having two ends, one of said ends attached to said handle;

an anchor member including an elongated body having a proximal region terminating in a proximal end, and a distal region with a successively narrower cross-section terminating in a distal end to facilitate insertion into a bone;

15 means, disposed in said proximal region, for releasably engaging the other of said ends of said shaft for insertion of said anchor member into the bone;

at least one non-helical ridge, disposed about the exterior surface of said body proximal to said distal region, for engaging the bone after insertion to resist withdrawal of said anchor; and

20 means, defined in said elongated body, for receiving a portion of a suture to hold the suture at a selected position in the bone.

Disclosed herein is a unique and improved anchor, an anchor driver device, and a combined anchor and driver assembly. The anchor is a bone or suture anchor with a rounded, conical or pointed tip and one or more ridges around its circumference which
25 are used to help install (force fit) the anchor into a previously drilled hole in bone or tissue. The ridges act to hold the anchor in position in the hole for its intended use. Preferably, a suture is positioned through a hole in the anchor and extends from the anchor for subsequent use by the surgeon (for example, to hold ligaments, bones or tissue in place, or for use during isometric testing of the positioning for a substitute anterior
30 cruciate ligament).

The anchor is adapted to be securely positioned on the end of a driver device. The driver has a handle and elongated shaft. The anchor snaps or force fits onto the end of the shaft and is keyed against rotation. A guide member can be used to ensure correct depth of placement of the anchor and protect the



5 sutures during use. The suture is affixed to the handle of the driver and grooves or slots are provided along the driver shaft for positioning of the sutures during use of the anchor and driver assembly. By positioning the sutures in the grooves, they are placed out of the way so they cannot interfere with positioning, placement, installation or removal of the anchor.

10 In an alternative embodiment, the anchor is hollow and the driver handle and shaft are cannulated. This allows the sutures to be passed through the anchor and driver and not interfere with the installation or removal procedures.

15 In another alternate embodiment, the driver device is also hollow and the anchor members are sized to fit inside of it. A pusher member is used to push the anchor member out of the driver and insert it into the bone or bone-like structure.

BRIEF DESCRIPTION OF DRAWINGS

20 FIGURE 1 illustrates the unique anchor and driver assembly with the anchor being positioned and held in place on the driver;

FIGURE 2 is a partial exploded view of the anchor and the end of the driver illustrating their features and showing how they are affixed together;

25 FIGURE 3 is a partial exploded view similar to Figure 2 but with the anchor and driver shaft rotated 90° relative to the view shown in Figure 2 and with the suture removed for ease of viewing;

FIGURE 4 is a cross-sectional view of the driver shaft taken along lines 4-4 in Figure 3;

FIGURE 5 is an end plan view of the anchor viewed in the direction of the arrows 5-5 in Figure 3;

5 FIGURE 6 is an end plan view of the driver device viewed in the direction of the arrows 6-6 in Figure 1;

FIGURE 7 is a cross-sectional view of the anchor taken along lines 7-7 in Figure 3;

10 FIGURES 8 and 9 illustrate alternate embodiments of an anchor and driver device;

FIGURES 10, 10A and 11 illustrate the use of the inventive anchor and driver assembly with a depth guide member;

15 FIGURE 12 illustrates the "setting" of the anchor;

FIGURE 13 illustrates the use of the invention to affix soft tissue to a bone;

20 FIGURE 14 illustrates another alternate embodiment of the invention; and

FIGURE 15 depicts still another embodiment of the rod-type anchor.

**BEST MODE FOR CARRYING
OUT THE INVENTION**

5 The features and details of the preferred embodiment of the unique anchor and driver assembly are shown in Figures 1-7. The driver device is generally designated by the reference numeral 10 and the anchor by the reference numeral 16.

10 The driver device has a shaft member 12 attached or connected to a handle member 14. The shaft member and handle member can be separate members securely fastened together or they can be made from a single piece of material. Preferably the handle is a hollow stainless tube member having the shape shown in Figures 1 and 6 and the shaft is a stainless steel rod
15 which is soldered, welded or otherwise affixed in or to the handle.

20 The anchor 16 is situated for installation (and also for removal if that is desired) on end projection 22 of the shaft 12, in a manner to be described in more detail below. A suture 18 is positioned through a hole or opening 24 in the anchor 16 and the two ends 26 and 28 of the suture are securely wrapped or tied around fixation posts 30 and 32, respectively. In order to securely hold the sutures
25 which are wrapped on the posts 30 and 32, O-rings preferably are positioned on the stems of each of the posts. (O-rings 33 are shown in Figure 10.)

30 The positioning of the anchor 16 on end 22 and the affixation of the suture 18 on the fixation posts 30, 32 tightly and securely holds the anchor on the driver for use during surgery. In this manner, the

anchor will not be subject to being dislodged, moved out of position on the shaft or accidentally displaced from the shaft while the driver is being used to position and place the anchor during surgery. This is particularly
5 important when the anchor is being used during arthroscopic knee, shoulder or other joint surgery and it would be harmful for the anchor to become loose in the joint.

The end projection 22 is adapted to fit within
10 a mating recess or socket 34 in the anchor 16 (see Figures 2, 3 and 5). The cross-sectional size and shape of the projection 22 and socket 34 can be of any common geometric shape, but preferably have the same shape and are circular (as shown by Figure 5). If desired, the
15 outside diameter of projection 22 and the inside diameter of socket 34 also can be dimensioned such that the two members have a frictional or slight force fit relationship.

A dowel or pin 36 is positioned in end
20 projection 22 substantially perpendicular to the longitudinal axis of the driver device. The pin 36 projects on both sides of the end 22 forming two "ears" or "tabs".

The rod-type anchor 16 has a pair of slots 38
25 which are formed on opposite sides (180° apart) of the end of the anchor which fits on the driver device. The slots 38 are positioned and dimensioned to snap over and onto the protruding ends of the pin 36 on the driver. The slots 38 have an elongated passageway 40 which is
30 slightly smaller in width than the cross-sectional diameter of the pin 36 and a larger generally circular

end portion 42 which has substantially the same diameter as the pin 36.

5 The pin 36 "keys" the anchor to the shaft and driver so that the anchor cannot be rotated relative to the driver; the pin insures that the anchor can be rotated and maneuvered only with the driver.

10 The dimensioning of the slots 38 relative to the pin 36 also creates a force fit mating relationship and assembly between the anchor and driver device. The anchor 15 has to be forced onto the end 22 of the shaft by forcing the two ends of the pin 36 through the passageways 40 and into the openings 42. The anchor is resilient and "snaps" into place with the openings 42 on the shaft 36. This frictional or force-fit relationship
15 also helps insure that the anchor and driver device will remain together during positioning and installation of the anchor during surgery.

20 The anchor is preferably made from Delrin 150SA material, but it can be made of any other equivalent or compatible plastic or surgical material. It is also possible for some applications for the anchor to be made of a bio-absorbable material, such as polyglycolic acid (PGA) or polylactic acid (PLA).

25 The suture preferably utilized with the present invention is No. USP Size 2 Ticron material made by Davis & Geck Co. It is understood, of course, that any other equivalent suture or other material can be used so long as it satisfies the purposes and objects of the present invention.

The suture 18 can be placed through the hole in the anchor 16 before or after the anchor is positioned on the end of the driver shaft.

5 A pair of elongated slots or grooves 50 are provided on the shaft 12. (The grooves are best shown in Figures 3 and 4). The grooves are positioned 180° apart on the shaft and are of sufficient size and depth to position and retain the suture 18. The grooves 50 are oriented on the driver in axial alignment with the protruding ends of the pin 36 and with the fixation posts 30 and 32. When the anchor 16 is positioned on the driver 10, the suture 18 is tightly pulled into the grooves 50, down the length of the shaft 12 and securely wrapped and affixed around the posts 30 and 32. The ends 26 and 28 of the suture 18 are wound tightly around the fixation posts 30 and 32 which helps to hold the anchor on the driver during use.

20 After the anchor is positioned and installed in place, the ends of the suture are released from the posts 30 and 32 and the driver is pulled from the site. The fixation of the anchor 16 in the bone or tissue must be sufficiently strong and secure to allow the post 36 to be removed from the slots 38. Once the driver device is removed, the anchor 16 and suture 18 attached thereto are positioned in place for subsequent use during surgery. One such use is to fasten the end of a substitute or synthetic ACL ligament. In general, the anchor can be utilized to attach or reattach soft tissue, ligaments and tendons to bone. In these applications, the anchor would remain permanently in place. Another such use is the isometric testing of a proposed position for installation of an ACL replacement. In this application, the anchor and suture

would be removed (and discarded) after the isometric testing was completed. In order to remove the anchor 16, the driver device is again utilized and the installation process reversed.

5 The shape and configuration of the preferred anchor 16 is best shown in Figures 2, 3, 5 and 7. The anchor has a front end or tip 60 which is rounded, conical or pointed for ease of placement and insertion. A sharp pointed anchor would allow it to pierce soft
10 tissue more easily. A plurality of circular ridges 62 extend around the circumference of the anchor and are used to firmly and securely hold the anchor 16 in place in a hole.

15 When the hole for the anchor 16 is drilled or formed in the bone or tissue, the diameter of the drill should be slightly less than the outer diameter of the ridges 62. In this manner, the anchor 16 can be forced into position in the hole and the compression and friction caused by the ridges 62 against the inner walls
20 of the hole will hold it firmly in place.

25 Preferably the outer diameter of the ridges is 0.169 inches and the length of the anchor is 0.410 inches. The socket 34 has a diameter of 0.078 inches and a depth of 0.100 inches. The diameter of the end projection 22 is preferably .076-.077 inches and the length of the pin 36 is 0.097 inches. The passageway of the slots 38 has a width of .025 inches and the pin 36 has a diameter of 0.0313 inches. The overall length of the driver device 10 (handle and shaft) is approximately
30 10 inches. Other sizes and dimensions for the present invention can also be utilized.

Three ridges 62 are shown on the anchor 16 and utilized in the preferred embodiment for sufficient strength of the anchor and to provide the requisite holding force in the bone or tissue. It is understood, of course, that a greater or lesser number of ridges could be provided in accordance with the present invention so long as the objects and purposes of the present invention are obtained.

After the hole in the bone or tissue is formed (by drilling, for example with a K-wire having a diameter of 0.146 inches), the anchor 16 is "snapped" into position on the end 22 of the shaft of the driver and the suture 18 tightly wound on the fixation posts. The anchor and driver assembly is then maneuvered or moved into position by the surgeon (e.g. arthroscopically), and the tip 60 of the anchor positioned at or in the opening of the hole. The anchor 16 is then forced axially into the hole by, for example, the surgeon tapping on the end of the driver with a mallet or the like. It is not necessary to rotate the assembly in order to install it in position.

In order to avoid over-penetration of the anchor 16 into the bone, a guide member 70 is positioned over the shaft 12 of the driver instrument, as shown in Figure 10. The guide member is a hollow cylindrical member, preferably made of plastic, and slips over the driver and anchor assembly after the anchor is positioned on the driver device and the ends of the suture 18 are attached to the fixation posts 30 and 32. Preferably, the guide member 70 is held in place on the driver instrument 10 by a stop or collar member 64 which is soldered to the shaft 12 (see Figure 10A). The guide member 70 has a pair of opposed slots 66 which snap-fit

over pins 68 on the stop member in order to hold it in place. The guide member also protects the sutures during use of the assembly during surgery. A series of guide members of different lengths can be provided in order to provide the insertion depth desired by the surgeon for the anchor. When the anchor is installed in the bone or bone-like structure 72, as shown in Figure 11, the end 74 of the guide member 70 contacts the bone and prevents the anchor from being inserted too far into the bone.

Once the anchor is firmly set in place, the ends 26 and 28 of the suture 18 are removed (unwound) from the fixation posts 30 and 32 and the driver is removed from the surgical site. Since the anchor is retained in the hole with a greater force than that required to snap and unsnap the anchor from the pin 36 on the driver, the driver can be removed easily from the anchor by the surgeon. The two ends of the suture 18 preferably are pulled firmly at an angle to the bone 72 (see Figure 12) to ensure a firm fit and more securely set the anchor in place. The anchor with suture attached is then used for its intended use. One such use is shown in Figure 13 where the suture 18 is tied through a soft tissue (ligament) 76 securely fastening it to the bone 72. In this manner, the ligament is mechanically reattached to the bone and, over time, the two members grow together and become permanently biologically reattached.

If the anchor is to be removed after use, or moved to another position, the installation process is repeated in reverse order, as mentioned earlier.

As an alternate embodiment, as shown in Figures 8 and 9, the driver device 80, consisting of handle 82 and shaft 84, is cannulated and the suture 18 is passed down the length of the driver and affixed on a fixation post 86 positioned adjacent the end 88 of the handle 82. The suture 18 is passed through opening 90 in anchor 92 and out through the open hollow interior 94 of the anchor. With this embodiment, a suture passer can be utilized to thread the suture through the passageway or channel 96 in the driver 80.

Another alternate embodiment is shown in Figure 14. In this embodiment, the driver device 100 is hollow with a central opening 102 through the length of the elongated shaft 104 and handle 106. The anchor member 110 is sized sufficiently small to fit within the opening 102 and has a suture 112 attached to it (in the same manner as suture 18 is attached to anchor 16 as described above). A pusher member 114 consisting of an elongated tubular member 116 and head or handle 118 is inserted in the opening 102 and used to drive the anchor member 110 through and out of the driver device 100 and into the bone or bone-like structure. The suture 112 is threaded through the driver device and pusher member, as shown.

In order to gauge and measure the depth of insertion of the anchor member 110, markings or a scale 120 can be provided on the pusher member. The "hollow tube" driver device is particularly useful for insertion of small anchor member 110, such as on the order of about one-sixteenth of an inch in diameter and three-sixteenths of an inch in length.

Another embodiment of the suture anchor is shown in Figure 15. The anchor 130 has a rod-shaped body 132 with a pair of annular rings 134 and 136 on its outer surface. The front end 138 of the anchor is flat with a 45° chamfer around the edge in order to ease entry of the anchor into the hole in the bone. Chamfer or angled surfaces 140 and 142 are provided on the leading edges of the rings 134 and 136 also in order to ease entry of the anchor into the bone. A hole 144 with opposed slots 146 and 148 are provided for positioning of the suture.

Although particular embodiments of the present invention have been illustrated in the accompanying drawings and described in the foregoing detailed description, it is to be understood that the present invention is not to be limited to just the embodiments disclosed, but that they are capable of numerous rearrangements, modifications and substitutions without departing from the scope of the claims hereafter.

The claims defining the invention are as follows:-

1. A device for anchoring a suture to a bone, said device comprising:
a driver having a handle and an elongated shaft, said shaft having two ends, one of said ends attached to said handle;
- 5 an anchor member including an elongated body having a proximal region terminating in a proximal end, and a distal region with a successively narrower cross-section terminating in a distal end to facilitate insertion into a bone;
means, disposed in said proximal region, for releasably engaging the other of said ends of said shaft for insertion of said anchor member into the bone;
- 10 at least one non-helical ridge, disposed about the exterior surface of said body proximal to said distal region, for engaging the bone after insertion to resist withdrawal of said anchor; and
means, defined in said elongated body, for receiving a portion of a suture to hold the suture at a selected position in the bone.
- 15 2. The device of claim 1, wherein said non-helical ridge is an annular ring having a substantially flat outer surface and having a leading edge with a chamfered surface to ease entry of the anchor member into the bone.
3. The device of claims 1 or 2, wherein said handle includes attachment means for securing another portion of the suture thereto to maintain interconnection between said
20 anchor member and said driver.
4. The device of claim 3, wherein said attachment means includes at least two posts disposed on substantially opposite sides of said handle, each post securing a different portion of the suture to apply tension upon said anchor member.
5. The device of claims 1 or 2, wherein said shaft includes an engagement
25 member having at least one engagement element positioned proximate to the other of said ends of said shaft, and said means for releasably engaging includes a hollow chamber for receipt of said other shaft end in a mating relationship, and at least one slot opening into said chamber for receipt of said engagement element when said anchor member is positioned on said shaft.
- 30 6. The device of claim 5, wherein said shaft includes an engagement member having at least two tab members each of which extends radially outwardly from said shaft in a direction substantially normal to the longitudinal axis of said shaft, and said anchor member includes at least two slots corresponding in position to said tab members.
7. The device of claim 3 further comprising elongated channel means on the
35 exterior surface of said shaft for placement of a portion of the suture extending between said anchor member and said handle.
8. The device of claim 7, wherein said channel means comprises a pair of opposed channels on said shaft.



9. The device of claims 1 or 2, wherein said means for receiving is a passageway in said anchor member passing through opposing walls of said anchor member, said passageway being substantially normal to the longitudinal axis of said anchor member.

10. The device of claim 1 further comprising a guide member for positioning over
5 said shaft and limiting the depth of insertion of said anchor member.

11. The device of claim 10, wherein said guide member comprises a hollow cylinder.

12. The device of claims 1 or 2, wherein said anchor member further includes a pair of opposed positioning slots in said body extending proximally from said means for
10 receiving and into which the suture can lie.

13. A device for anchoring a suture to a bone, substantially as herein described with reference to the accompanying drawings.

Dated 25 October, 1994

American Cyanamid Company

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON



IMPROVED SUTURE ANCHOR AND DRIVER ASSEMBLY

ABSTRACT

An anchor (16) and anchor driver device (10) for securely and accurately positioning and installing a bone suture anchor (16) in place are disclosed. The bone anchor (16) preferably has a rounded or pointed head and one or more ridges (62) around it to help force fit the anchor into a hole and to hold it in place. A suture (18) is positioned through the anchor (16) for subsequent use during the surgical procedure. The driver device (10) has a handle (14) and elongated shaft (12) and is used to position and install the anchor in place. The anchor (16) snap fits onto the end of the shaft (12) over an anti-rotation pin (36) which mates with slots (38) in the anchor. A depth guide (70) can be positioned on the shaft to ensure correct depth of placement. Alternately, the driver shaft (104) is hollow and the anchor (110) is positioned inside it and implanted with a pusher member (114). The ends of the suture (18) can be affixed to the driver handle (14) to assist securing of the anchor (16) to the driver device (10) before and during insertion. Means (50) can be provided on the driver (10) to prevent the suture from interfering with the positioning and installation procedure.

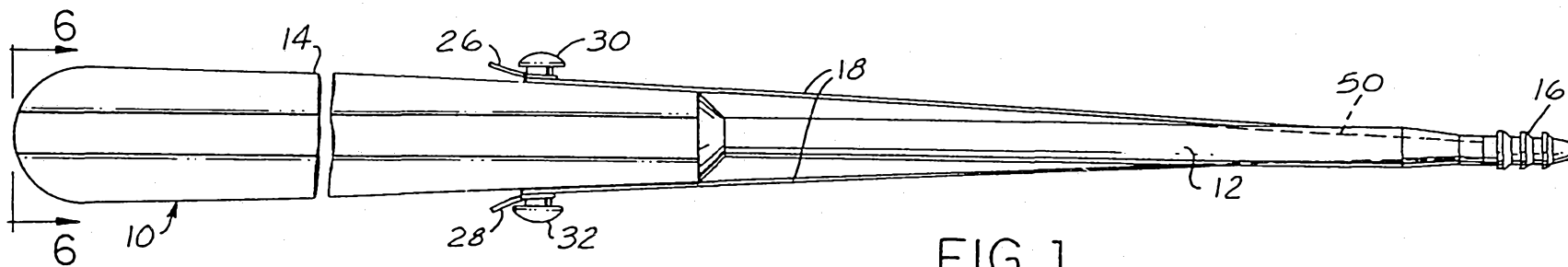


FIG. 1

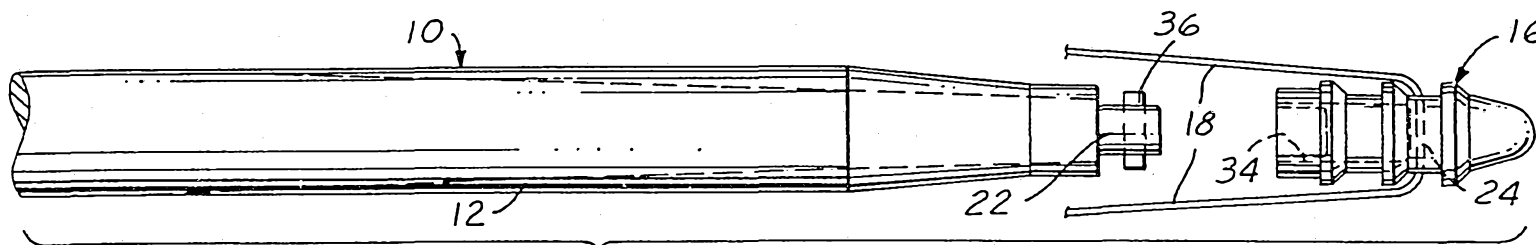


FIG. 2

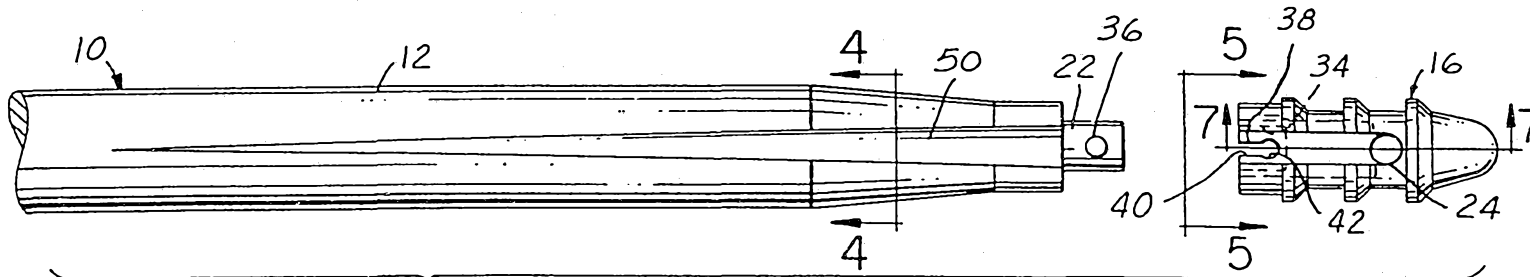


FIG. 3

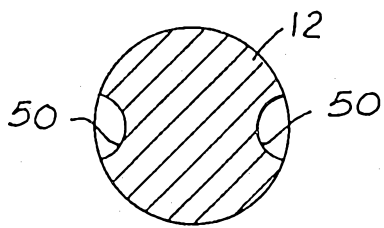


FIG. 4

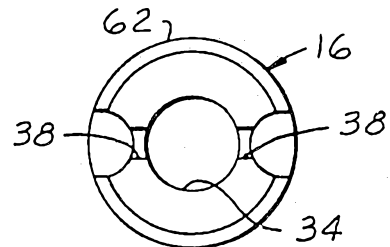


FIG. 5

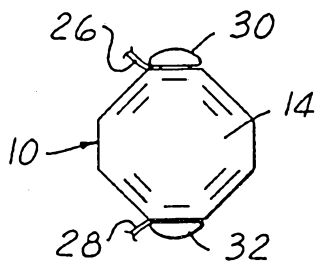


FIG. 6

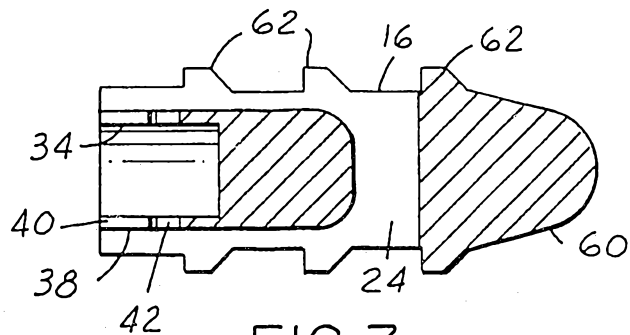


FIG. 7

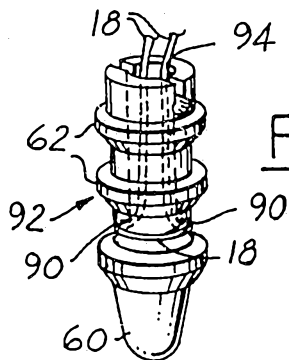


FIG. 8

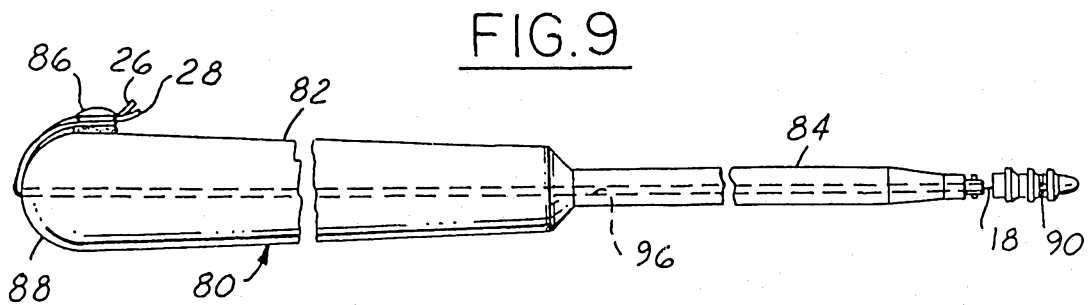
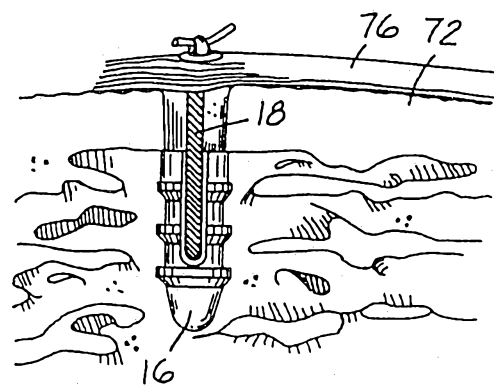
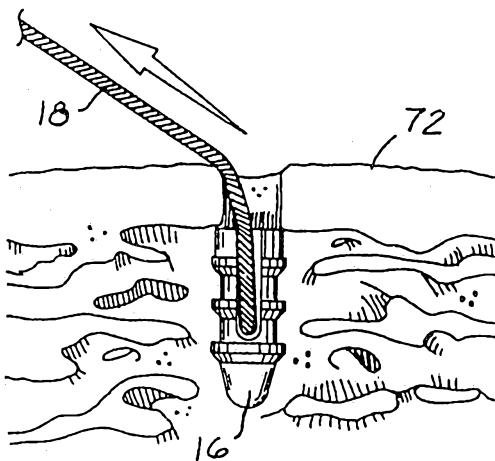
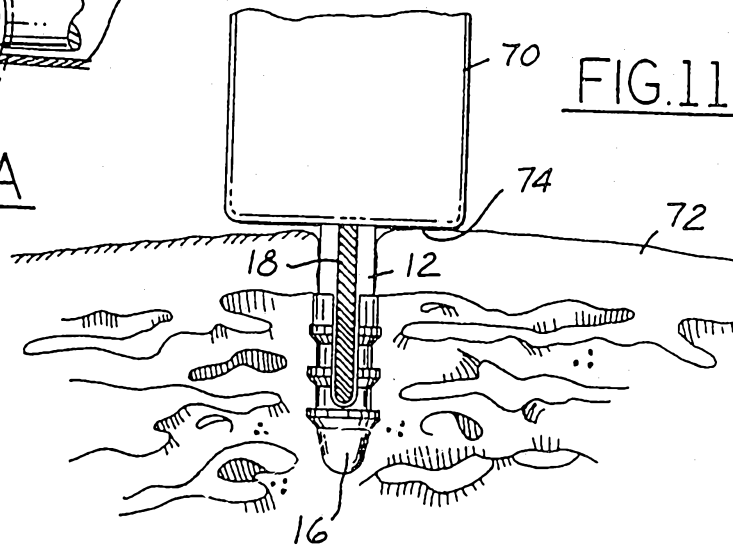
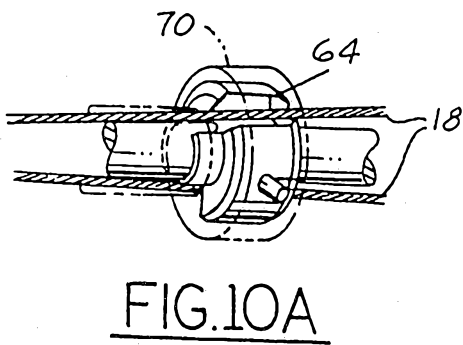
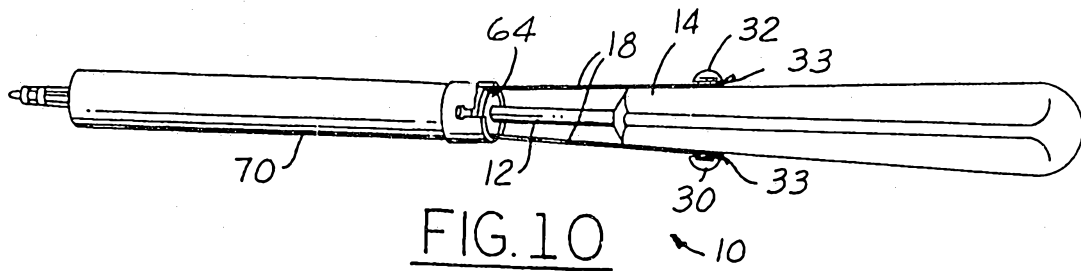


FIG. 9



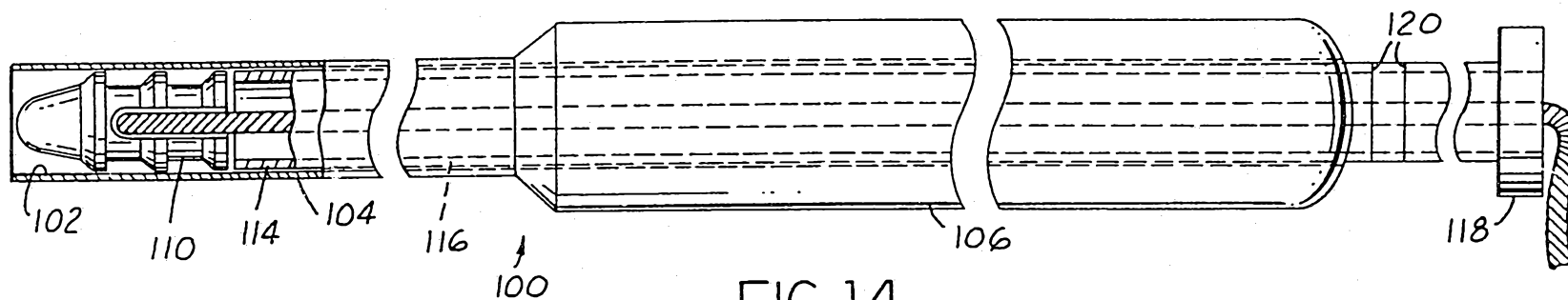


FIG. 14

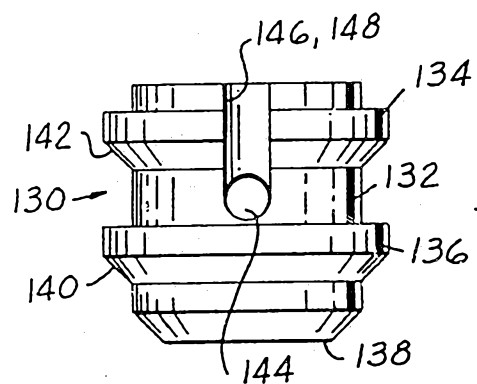


FIG. 15